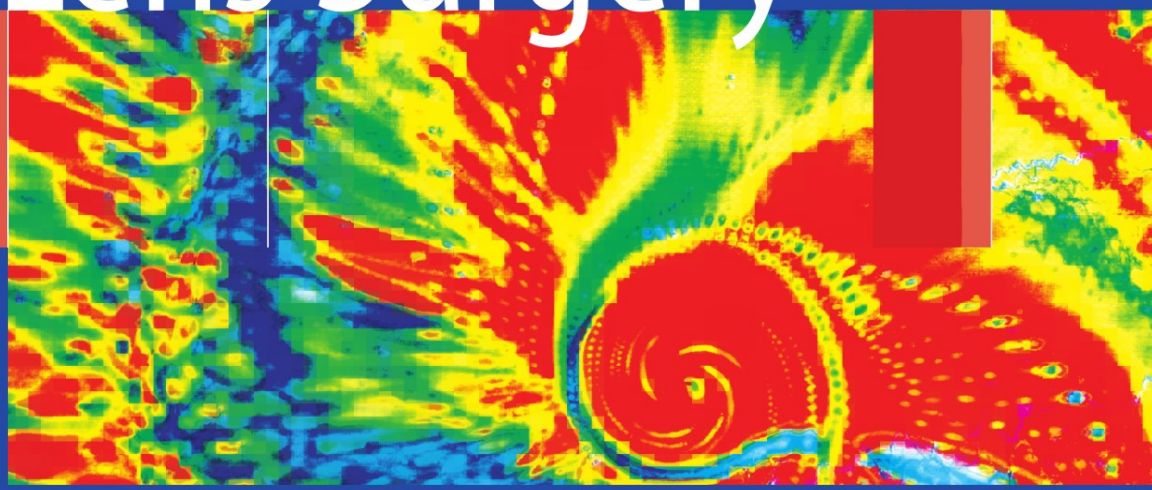
I. Howard Fine
Mark Packer
Richard S. Hoffman *Editors*

Refractive Lens Surgery



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Refractive Lens Surgery
I. H. Fine
M. Packer
R. S. Hoffman (Eds.)

Editors I. Howard Fine
Mark Packer
Richard S. Hoffman

Refractive Lens Surgery

With 170 Figures, Mostly in Colour, and 11 Tables

Springer

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Dedication for Refractive Lens Surgery

The editors respectfully dedicate this book to the many pioneers of refractive surgery who had the courage to operate on healthy eyes in order to enhance the quality of life of their patients. They were right all along and those of us who were doubters have learned that lesson and as a result have enhanced the satisfaction we derive from our own careers.

Preface

The first recorded time a human lens was removed for the purpose of addressing a refractive error was by an ophthalmologist named Fukala in 1890. We do not know what type of criticism he experienced, but we know that today he is a forgotten man in ophthalmology. The introduction of this as a concept in the late 1980s by both Drs. Paul Koch and Robert Osher's manuscripts, resulted in considerable disdain and some condemnation by some of their colleagues and peers. At the time, refractive surgery in the United States was limited to radial keratotomy. With the development of excimer lasers came a very marked change in the attitude of eye surgeons internationally regarding the concept of invading "healthy" tissue for refractive purposes and within a relatively short period of time, LASIK was a firmly established procedure as were other modalities of corneal refractive surgery.

However, we have come to recognize that corneal refractive surgery, and especially LASIK, has limitations. We have also learned much in the recent past about functional vision through the use of contrast sensitivity and an analysis of higher order optical aberrations. We have also learned that the cornea has constant spherical aberration but the lens has changing spherical aberrations. In the young, the human lens compensates for the cornea's positive spherical aberration, but as we age the changing spherical aberration within the lens exacerbates corneal spherical aberration. Because of the changing spherical aberration in the lens, no matter what is done to the cornea as a refractive surgery modality, including the most sophisticated custom corneal shaping, functional vision is going to be degraded by changing spherical aberration in the lens over time. This coupled with the fact that higher myopes and hyperopes, patients with early cataracts, and presbyopes are not necessarily good candidates for LASIK has resulted in a fresh look at lens-based refractive surgery. We have seen recent improvements in phakic IOL technology and utilization and we ourselves have been increasingly motivated to work with lens related refractive surgery modalities.

Our own work with power modulations, the IOL Master, and wavefront technology IOLs has convinced us that lens-related refractive surgery can give superior results. Stephen Klyce, MD, the developer of corneal topography has demonstrated, using topographical and wavefront analysis methods, that IOL intraocular optics are far superior to the optics of the most sophisticated, customized wavefront treated cornea. We have also seen the development of new lens technologies including improved multifocal IOLs, improved accommodative IOLs, light adjustable IOLs, injectable IOLs, and a variety of other investigational IOL technologies that suggest unimaginable possibilities. Our own results with the Array and Crystalens have

been very encouraging as has our work with bimanual micro-incision phacoemulsification, which I believe has allowed us to develop a refractive lens exchange technique that sets a new standard for safety and efficacy. It is our belief that refractive lens exchange is indeed not only the future of refractive surgery, but in many ways the procedure that will become a mainstay of ophthalmology within the coming decades.

A major task for any editor is delegation, and this book represents the ultimate in delegation. My reliance on my two partners is evident throughout the book in the authorship of the chapters we have produced. It is my belief that just as refractive lens exchange represents the future of refractive surgery that my partners, Drs. Richard S. Hoffman and Mark Packer, represent the new generation of leadership in anterior segment ophthalmic surgery.

I. Howard Fine

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1 The Crystalline Lens as a Target for Refractive Surgery

Mark Packer, I. Howard Fine, Richard S. Hoffman

1.1 Introduction

Refractive surgeons have historically offered procedures for clients or patients desiring spectacle and contact lens independence. With the availability of new technology, however, surgeons are now finding a competitive advantage among their increasingly well-educated clientele by offering improved functional vision as well [1]. Measured by techniques such as wavefront aberrometry, contrast sensitivity, night driving simulation, reading speed and quality of life questionnaires, functional vision represents not only the optical and neural capability to see to drive at night or walk safely down a poorly illuminated flight of stairs, but also the ability to read a restaurant menu by candle light or navigate a web page without reliance on glasses. Our goal as refractive surgeons has become crisp, clear and colorful naked vision at all distances under all conditions of luminance and glare, much like the vision enjoyed by young emmetropes.

In large part because of the immense popularity of laser-assisted in-situ keratomileusis (LASIK), refractive surgeons have focused on the cornea as the tissue of choice for refractive correction. Excimer laser ablations, with wavefront guidance or prolate optimization, can achieve excellent results with great accuracy and permanency [2]. However, while the corrected cornea remains stable, the human lens changes. All young candidates for corneal refractive surgery must be advised that they will eventually succumb to presbyopia and the need for reading glasses due to changes occurring primarily in the crystalline lens [3]. In a more subtle but nevertheless significant change, lenticular spherical aberration dramatically reverses from negative to positive as we age and causes substantial loss of image quality [4]. Therefore, any refractive correction of spherical aberration in the cornea will be overwhelmed by aging changes in the lens. Finally, and in ever-increasing numbers, those who have had corneal refractive surgery will require cataract extraction and intraocular lens implantation. So far, the accuracy of intraocular lens power calculation for these patients has remained troubling [5].

Presbyopia, increasing spherical aberration and the development of cataracts represent three factors that should prompt the refractive surgeon to look behind the cornea to the lens. Most commonly, however, the reason to consider refractive lens surgery remains the physical and biological limits of LASIK. In younger patients, with intact accommodation, the insertion of a phakic refractive lens offers a compelling alternative. Beyond the age of 45, any refractive surgical modality that does not address presbyopia offers only half a loaf to the most demanding and wealthiest generation ever to grace this planet, the venerable baby boomers [6].

Science and industry are responding to the demographic changes in society with the development of improved technology for biometry, intraocular lens power calculation and lens extraction, as well as a wide array of in-

novative pseudophakic intraocular lens designs. The goal of *Refractive Lens Surgery* is to provide a snapshot of developments in this rapidly changing field. The time lags inherent in writing, editing and publishing mean that we will inevitably omit nascent yet potentially significant technological advances.

The future of refractive surgery, in our opinion, lies in the lens. Candidates for surgery can enjoy a predictable refractive procedure with rapid recovery that addresses all refractive errors, including presbyopia, and never develop cataracts; surgeons can offer these procedures without the intrusion of third-party payers and re-establish an undisrupted physician–patient relationship; and society as a whole can enjoy the decreased taxation burden from the declining expense of cataract surgery for the growing ranks of baby boomers who opt for refractive lens surgery and ultimately reach the age of government health coverage as pseudophakes. This combination of benefits represents an irresistible driving force that will keep refractive lens procedures at the forefront of ophthalmic medical technology.

References

1. Packer M, Fine IH, Hoffman RS (2003) Functional vision. Int Ophthalmol Clin 43 (2), 1–3
2. Reinstein DZ, Neal DR, Vogelsang H, Schroeder E, Nagy ZZ, Bergt M, Copland J, Topa D (2004) Optimized and wavefront guided corneal refractive surgery using the Carl Zeiss Meditec platform: the WASCA aberrometer, CRS-Master, and MEL80 excimer laser. Ophthalmol Clin North Am 17:191–210, vii
3. Gilmartin B (1995) The aetiology of presbyopia: a summary of the role of lenticular and extralenticular structures. Ophthalmic Physiol Opt 15:431–437
4. Artal P, Guirao A, Berrio E, Piers P, Norrby S (2003) Optical aberrations and the aging eye. Int Ophthalmol Clin 43:63–77
5. Packer M, Brown LK, Fine IH, Hoffman RS (2004) Intraocular lens power calculation after incisional and thermal keratorefractive surgery. J Cataract Refract Surg 30:1430–1434
6. Jeffrey NA (2003) The bionic boomer. Wall Street J Online 22 Aug 2003

2 Refractive Lens Exchange as a Refractive Surgery Modality

Richard S. Hoffman, I. Howard Fine, Mark Packer

CORE MESSAGES

- New multifocal and accommodative lens technology should enhance patient satisfaction.
- Newer lens extraction techniques using microincisions and new phacoemulsification technology will enhance the safety of this procedure.
- Ultimately, refractive lens exchange will be performed through two microincisions as future lens technologies become available.
- Attention to detail with regard to proper patient selection, preoperative measurements, intraoperative technique, and postoperative management has resulted in excellent outcomes and improved patient acceptance of this effective technique.

Advances in small incision surgery have enabled cataract surgery to evolve from a procedure concerned primarily with the safe removal of the cataractous lens to a procedure refined to yield the best possible postoperative refractive result. As the outcomes of cataract surgery have improved, the use of lens surgery as a refractive modality in patients without cataracts has increased in popularity.

Removal of the crystalline lens for refractive purposes or refractive lens exchange (RLE) offers many advantages over corneal refractive surgery. Patients with high degrees of myopia, hyperopia, and astigmatism are poor candidates for excimer laser surgery. In addition, presbyopia can only be addressed currently with monovision or reading glasses. RLE with multifocal or accommodating intraocular lenses (IOLs) in combination with corneal astigmatic procedures could theoretically address all refractive errors including presbyopia, while simultaneously eliminating the need for cataract surgery in the future.

Current attempts to enhance refractive results and improve functional vision with customized corneal ablations with the excimer laser expose another advantage of RLE. The overall spherical aberration of the human eye tends to increase with increasing age [1–4]. This is not the result of significant changes in corneal spherical aberration but rather increasing lenticular spherical aberration [5–7].

This implies that attempts to enhance visual function by addressing higher-order optical aberrations with corneal refractive surgery will be sabotaged at a later date by lenticular changes. Addressing both lower-order and higher-order aberrations with lenticular surgery would theoretically create a more stable ideal optical system that could not be altered by lenticular changes, since the crystalline lens would be removed and exchanged with a stable pseudophakic lens.

The availability of new IOL and lens extraction technology should hopefully allow RLEs to be performed with added safety and increased patient satisfaction.

2.1 Intraocular Lens Technology

2.1.1 Multifocal IOLs

Perhaps the greatest catalyst for the resurgence of RLE has been the development of multifocal lens technology. High hyperopes, presbyopes, and patients with borderline cataracts who have presented for refractive surgery have been ideal candidates for this new technology.

Historically, multifocal IOLs have been developed and investigated for decades. Newer multifocal IOLs are currently under investigation within the USA. The 3M diffractive multifocal IOL (3M, St. Paul, Minnesota), has been acquired, redesigned, and formatted for the three-piece foldable Acrysof acrylic IOL (Alcon Laboratories, Dallas, Texas). Pharmacia previously designed a diffractive multifocal IOL, the CeeOn 811 E (AMO, Groningen, The Netherlands), which has been combined with the wavefront-adjusted optics of the Tecnis Z9000 with the expectation of improved quality of vision [8] in addition to multifocal optics.

The only multifocal IOL currently approved for general use in the USA is the Array (AMO, Advanced Medical Optics; Santa Ana, California). The Array is a zonal progressive IOL with five concentric zones on the anterior surface. Zones 1, 3, and 5 are distance-dominant zones, while zones 2 and 4 are near dominant. The lens has an aspheric design and each zone repeats the entire refractive sequence corresponding to distance, intermediate, and near foci. This results in vision over a range of distances [9].

A small recent study reviewed the clinical results of bilaterally implanted Array multifocal lens implants in RLE patients [10]. A total of 68 eyes were evaluated, comprising 32 bilateral and four unilateral Array implantations. One hundred per cent of patients undergoing bilateral RLE achieved binocular visual acuity of 20/40 and J5 or better, measured 1–3 months postoperatively. Over 90% achieved uncorrected binocular visual acuity of 20/30 and J4 or better, and nearly 60% achieved uncorrected binocular visual acuity of 20/25 and J3 or better. This study included patients with preoperative spherical equivalents between 7 D of myopia and 7 D of hyperopia, with the majority of patients having preoperative spherical equivalents between plano and +2.50. Excellent lens power determinations and refractive results were achieved.

Another recent study by Dick et al. evaluated the safety, efficacy, predictability, stability, complications, and patient satisfaction after bilateral RLE with the Array IOL [11]. In their study, all patients achieved uncorrected binocular visual acuity of 20/30 and J4 or better. High patient satisfaction and no intraoperative or postoperative complications in this group of 25 patients confirmed the excellent results that can be achieved with this procedure.

2.1.2 Accommodative IOLs

The potential for utilizing a monofocal IOL with accommodative ability may allow for RLEs without the potential photic phenome-

na that have been observed with some multifocal IOLs [12–14]. The two accommodative IOLs that have received the most investigation to date are the Model AT-45 crystalens (eyeonics, Aliso Viejo, California) and the 1 CU (HumanOptics, Mannheim, Germany). Both lenses have demonstrated accommodative ability [15, 16], although the degree of accommodative amplitude has been reported as low and variable [17, 18].

As clinical investigators for the US Food and Drug Administration clinical trials of the AT-45 crystalens, we have had experience with the clinical results of the majority of accommodative IOLs implanted within the USA. In our practice, 97 AT-45 IOLs were implanted, with 24 patients implanted bilaterally. All patients had uncorrected distance vision of 20/30 or better and uncorrected near vision of J3 or better. Eighty-three per cent of patients were 20/25 or better at distance and J2 or better at near. And 71% were 20/20 or better at distance and J1 or better at near. These results confirm the potential clinical benefits of accommodative IOL technology for both cataract patients and refractive patients and place accommodative IOLs in a competitive position with multifocal IOL technology.

2.1.3 Future Lens Technology

There are lens technologies under development that may contribute to increased utilization of RLE in the future. One of the most exciting technologies is the light-adjustable lens (LAL) (Calhoun Vision, Pasadena, California). The LAL is designed to allow for postoperative refinements of lens power in situ. The current design of the LAL is a foldable three-piece IOL with a cross-linked silicone polymer matrix and a homogeneously embedded photosensitive macromer. The application of near-ultraviolet light to a portion of the lens optic results in polymerization of the photosensitive macromers and precise changes in lens power through a mechanism of macromer migration into polymerized regions and subsequent changes in lens thickness. Hyperopia, myopia, and astigmatism can be fine-tuned postoperatively and Calhoun Vision is currently working on creating potentially reversible multifocal optics and higher-order aberration corrections. This capability would allow for more accurate postoperative refractive results. In addition, it would enable patients to experience multifocal optics after their lens exchanges and reverse the optics back to a monofocal lens system if multifocality was unacceptable. The ability to correct higher-order aberrations could create higher levels of functional vision that would remain stable with increasing age, since the crystalline lens, with its consistently increasing spherical aberration, would be removed and replaced with a stable pseudophakic LAL [19].

Other new lens technologies are currently being developed that will allow surgeons to perform RLEs by means of a bimanual technique through two microincisions. Medennium (Irvine, California) is developing its Smart Lens – a thermodynamic accommodating IOL. It is a hydrophobic acrylic rod that can be inserted through a 2-mm incision and expands to the dimensions of the natural crystalline lens (9.5 mm × 3.5 mm). A 1-mm version of this lens is also being developed. ThinOptX fresnel lenses (Abingdon, Virginia) will soon be under investigation in the USA and will also be implantable through 1.5-mm incisions. In addition, injectable polymer lenses are being researched by both AMO and Calhoun Vision [20, 21]. If viable, the Calhoun Vision injectable polymer offers the possibility of injecting an LAL through a 1-mm incision that can then be fine-tuned postoperatively to eliminate both lower-order and higher-order optical aberrations.

2.2 Patient Selection

There is obviously a broad range of patients who would be acceptable candidates for RLE. Presbyopic hyperopes are excellent candidates for multifocal lens technology and perhaps the best subjects for a surgeon's initial trial of this lens technology. Relative or absolute contraindications include the presence of ocular pathologies, other than cataracts, that may degrade image formation or may be associated with less than adequate visual function postoperatively despite visual improvement following surgery. Pre-existing ocular pathologies that are frequently looked upon as contraindications include age-related macular degeneration, uncontrolled diabetes or diabetic retinopathy, uncontrolled glaucoma, recurrent inflammatory eye disease, retinal detachment risk, and corneal disease or previous refractive surgery in the form of radial keratotomy, photorefractive keratectomy, or laser-assisted in-situ keratomileusis.

High myopes are also good candidates for RLE with multifocal lens technology; however, the patient's axial length and risk for retinal detachment or other retinal complications should be considered. Although there have been many publications documenting a low rate of complications in highly myopic clear lens extractions [22–27], others have warned of significant long-term risks of retinal complications despite prophylactic treatment [28, 29]. With this in mind, other phakic refractive modalities should be considered in extremely high myopes. If RLE is performed in these patients, extensive informed consent regarding the long-term risks for retinal complications should naturally occur preoperatively.

2.3 Preoperative Measurements

The most important assessment for successful multifocal lens use, other than patient selection, involves precise preoperative measurements of axial length in addition to accurate lens power calculations. Applanation techniques in combination with the Holladay 2 formula can yield accurate and consistent results. The Zeiss IOL Master is a combined biometry instrument for non-contact optical measurements of axial length, corneal curvature, and anterior chamber depth that yields extremely accurate and efficient measurements with minimal patient inconvenience. The axial length measurement is based on an interference-optical method termed partial coherence interferometry, and measurements are claimed to be compatible with acoustic immersion measurements and accurate to within 30 microns.

When determining lens power calculations, the Holladay 2 formula takes into account disparities in anterior segment and axial lengths by adding the white-to-white corneal diameter and lens thickness into the formula. Addition of these variables helps predict the exact position of the IOL in the eye and has improved refractive predictability. The SRK T and the SRK II formulas can be used as a final check in the lens power assessment; and, for eyes with less than 22 mm in axial length, the Hoffer Q formula should be utilized for comparative purposes.

2.4 Surgical Technique

Advances in both lens extraction technique and technology have allowed for safer, more efficient phacoemulsification [30]. One of the newest techniques for cataract surgery that has important implications for RLEs is the use of bimanual microincision phacoemulsification. With the development of new phacoemulsification technology and power modulations [31], we are now able to emulsify and fragment lens material without the generation of significant thermal energy. Thus the removal of the cooling irrigation sleeve and separation of infusion and emulsification/as-

piration through two separate incisions is now a viable alternative to traditional coaxial phacoemulsification. Machines such as the AMO WhiteStar (Santa Ana, CA), Staar Sonic (Monrovia, CA), Alcon NeoSoniX (Fort Worth, TX), and Dodick Nd:YAG Laser Photolysis systems (ARC Laser Corp., Salt Lake City, UT) offer the potential of relatively "cold" lens removal capabilities and the capacity for bimanual cataract surgery [32–38].

Bimanual microincision phacoemulsification offers advantages over current traditional coaxial techniques for both routine cataract extraction and RLEs. The main advantage has been an improvement in control of most of the steps involved in endocapsular surgery. Separation of irrigation from aspiration has allowed for improved followability by avoiding competing currents at the tip of the phaco needle. Perhaps the greatest advantage of the bimanual technique lies in its ability to remove subincisional cortex without difficulty. By switching infusion and aspiration handpieces between the two microincisions, 360° of the capsular fornices are easily reached and cortical clean-up can be performed quickly and safely.

There is the hope that RLEs can be performed more safely using a bimanual technique. By constantly maintaining a pressurized eye with infusion from the second handpiece, intraoperative hypotony and chamber collapse can be avoided [39]. This may ultimately result in a lower incidence of surgically induced posterior vitreous detachments and their associated morbidity, which would be of significant benefit, especially in high myopes.

2.5 Targeting Emmetropia

The most important skill to master in the RLE patient is the ultimate achievement of emmetropia. Emmetropia can be achieved successfully with accurate intraocular lens power calculations and adjunctive modalities for eliminating astigmatism. With the trend towards smaller astigmatically neutral clear corneal incisions, it is now possible to address more accurately pre-existing astigmatism at the time of lens surgery. The popularization of limbal relaxing incisions has added a useful means of reducing up to 3.50 diopters of pre-existing astigmatism by placing paired 600-micron deep incisions at the limbus in the steep meridian.

2.6 Refractive Surprise

On occasion, surgeons may be presented with an unexpected refractive surprise following surgery. When there is a gross error in the lens inserted, the best approach is to perform a lens exchange as soon as possible. When smaller errors are encountered or lens exchange is felt to be unsafe, various adjunctive procedures are available to address these refractive surprises.

Laser-assisted in-situ keratomileusis (LASIK) can be performed to eliminate myopia, hyperopia, or astigmatism following surgery complicated by unexpected refractive results. Another means of reducing 0.5–1.0 D of hyperopia entails rotating the IOL out of the capsular bag and placing it in the ciliary sulcus to increase the functional power of the lens. Another simple intraocular approach to the postoperative refractive surprise involves the use of intraocular lenses placed in the sulcus over the primary IOL in a piggyback fashion. Staar Surgical produces the AQ5010 V foldable silicone IOL, which is useful for sulcus placement as a secondary piggyback lens. The Staar AQ5010 V has an overall length of 14.0 mm and is available in powers between –4.0 to +4.0 diopters in whole diopter powers. In smaller eyes with larger hyperopic postoperative errors, the Staar AQ2010 V is 13.5 mm in overall length and is available in powers between +5.0 to +9.0 diopters in whole diopter steps. This approach is especially useful when expensive

refractive lasers are not available or when corneal surgery is not feasible.

2.7 Photic Phenomena Management

If patients are unduly bothered by photic phenomena such as halos and glare following RLEs with Array multifocal IOLs, these symptoms can be alleviated by various techniques. Weak pilocarpine at a concentration of 1/8% or weaker will constrict the pupil to a diameter that will usually lessen the severity of halos without significantly affecting near visual acuity. Similarly, brimonidine tartrate ophthalmic solution 0.2% has been shown to reduce pupil size under scotopic conditions [40] and can also be administered in an attempt to reduce halo and glare symptoms. Another approach involves the use of overminused spectacles in order to push the secondary focal point behind the retina and thus lessen the effect of image blur from multiple images in front of the retina [41]. Polarized lenses have also been found to be helpful in reducing photic phenomena. Finally, most patients report that halos improve or disappear with the passage of several weeks to months.

2.8 Conclusion

Thanks to the successes of the excimer laser, refractive surgery is increasing in popularity throughout the world. Corneal refractive surgery, however, has its limitations. Patients with severe degrees of myopia and hyperopia are poor candidates for excimer laser surgery, and presbyopes must contend with reading glasses or monovision to address their near visual needs. Ironically, the current trend in refractive surgery towards improving functional vision with customized ablations to address higher-order aberrations may ultimately lead to crystalline lens replacement as the best means of creating a highly efficient emmetropic optical system that will not change as a patient ages.

The rapid recovery and astigmatically neutral incisions currently being used for modern cataract surgery have allowed this procedure to be used with greater predictability for RLE in patients who are otherwise not suffering from visually significant cataracts. Successful integration of RLE into the general ophthalmologist's practice is fairly straightforward, since most surgeons are currently performing small-incision cataract surgery for their cataract patients. Essentially, the same procedure is performed for a RLE, differing only in removal of a relatively clear crystalline lens and simple adjunctive techniques for reducing corneal astigmatism. Although any style of foldable intraocular lens can be used for lens exchanges, multifocal intraocular lenses and eventually accommodative lenses offer the best option for addressing both the elimination of refractive errors and presbyopia.

Refractive lens exchange is not for every patient considering refractive surgery, but does offer substantial benefits, especially in high hyperopes, presbyopes, and patients with borderline or soon to be clinically significant cataracts who are requesting refractive surgery. Advances in both IOL and phacoemulsification technology have added to the safety and efficacy of this procedure and will contribute to its increasing utilization as a viable refractive surgery modality.

References

1. Guirao A, Gonzalez C, Redondo M et al (1999) Average optical performance of the human eye as a function of age in a normal population. Invest Ophthalmol Vis Sci 40:197–202
2. Jenkins TCA (1963) Aberrations of the eye and their effects on vision: 1. Br J Physiol Opt 20: 59–91

3. Calver R, Cox MJ, Elliot DB (1999) Effect of aging on the monochromatic aberrations of the human eye. J Opt Soc Am A 16:2069–2078
4. McLellan JS, Marcos S, Burns SA (2001) Age-related change in monochromatic wave aberrations of the human eye. Invest Ophthalmol Vis Sci 42:1390–1395
5. Guirao A, Redondo M, Artal P (2000) Optical aberrations of the human cornea as a function of age. J Opt Soc Am A 17:1697–1702
6. Artal P, Guirao A, Berrio E, Williams DR (2001) Compensation of corneal aberrations by the internal optics in the human eye. J Vision 1:1–8
7. Artal P, Berrio E, Guirao A, Piers P (2002) Contribution of the cornea and internal surfaces to the change of ocular aberrations with age. J Opt Soc Am A 19:137–143
8. Packer M, Fine IH, Hoffman RS, Piers PA (2002) Prospective randomized trial of an anterior surface modified prolate intraocular lens. J Refract Surg 18:692–696
9. Fine IH (1991) Design and early clinical studies of the AMO Array multifocal IOL. In: Maxwell A, Nordan LT (eds) Current concepts of multifocal intraocular lenses. Slack, Thorofare, NJ, pp 105–115
10. Packer M, Fine IH, Hoffman RS (2002) Refractive lens exchange with the Array multifocal lens. J Cataract Refract Surg 28:421–424
11. Dick HB, Gross S, Tehrani M et al (2002) Refractive lens exchange with an array multifocal intraocular lens. J Refract Surg 18:509–518
12. Dick HB, Krummenauer F, Schwenn O et al (1999) Objective and subjective evaluation of photic phenomena after monofocal and multifocal intraocular lens implantation. Ophthalmology 106:1878–1886
13. Haring G, Dick HB, Krummenauer F et al (2001) Subjective photic phenomena with refractive multifocal and monofocal intraocular lenses. Results of a multicenter questionnaire. J Cataract Refract Surg 27:245–249
14. Gills JP (2001) Subjective photic phenomena with refractive multifocal and monofocal IOLs. Letter to the editor. J Cataract Refract Surg 27:1148
15. Auffarth GU, Schmidbauer J, Becker KA et al (2002) Miyake-Apple video analysis of movement patterns of an accommodative intraocular lens implant. Ophthalmologe 99:811–814
16. Kuchle M, Nguyen NX, Langenbucher A et al (2002) Implantation of a new accommodative posterior chamber intraocular lens. J Refract Surg 18:208–216
17. Langenbucher A, Huber S, Nguyen NX et al (2003) Measurement of accommodation after implantation of an accommodating posterior chamber intraocular lens. J Cataract Refract Surg 29:677–685
18. Dick HB, Kaiser S (2002) Dynamic aberrometry during accommodation of phakic eyes and eyes with potentially accommodative intraocular lenses. Ophthalmologe 99:825–834
19. Hoffman RS, Fine IH, Packer M (2005) Light adjustable lens. In: Agarwal S, Agarwal A, Sachdev MS, Mehta KR, Fine IH, Agarwal A (eds) Phacoemulsification, laser cataract surgery, and foldable IOLs, 3rd edn. Slack, Thorofare, NJ
20. DeGroot JH, van Beijma FJ, Haitjema HJ et al (2001) Injectable intraocular lens material based upon hydrogels. Biomacromolecules 2:628–634
21. Koopmans SA, Terwee T, Barkhof J et al (2003) Polymer refilling of presbyopic human lenses in vitro restores the ability to undergo accommodative changes. Invest Ophthalmol Vis Sci 44:250–257
22. Colin J, Robinet A (1994) Clear lensectomy and implantation of low-power posterior chamber intraocular lens for the correction of high myopia. Ophthalmology 101:107–112
23. Pucci V, Morselli S, Romanelli F et al (2001) Clear lens phacoemulsification for correction of high myopia. J Cataract Refract Surg 27:896–900
24. Jimenez-Alfaro I, Miguelez S, Bueno JL et al (1998) Clear lens extraction and implantation of negative-power posterior chamber intraocular lenses to correct extreme myopia. J Cataract Refract Surg 24:1310–1316
25. Lee KH, Lee JH (1996) Long-term results of clear lens extraction for severe myopia. J Cataract Refract Surg 22:1411–1415
26. Ravalico G, Michieli C, Vattovani O, Tognetto D (2003) Retinal detachment after cataract extraction and refractive lens exchange in highly myopic patients. J Cataract Refract Surg 29:39–44
27. Gabric N, Dekaris I, Karaman Z (2002) Refractive lens exchange for correction of high myopia. Eur J Ophthalmol 12:384–387

28. Rodriguez A, Gutierrez E, Alvira G (1998) Complications of clear lens extraction in axial myopia. Arch Ophthalmol 105:1522–1523
29. Ripandelli G, Billi B, Fedeli R et al (1996) Retinal detachment after clear lens extraction in 41 eyes with axial myopia. Retina 16:3–6
30. Fine IH, Packer M, Hoffman RS (2002) New phacoemulsification technologies. J Cataract Refract Surg 28:1054–1060
31. Fine IH, Packer M, Hoffman RS (2001) The use of power modulations in phacoemulsification: choo choo chop and flip phacoemulsification. J Cataract Refract Surg 27:188–197
32. Soscia W, Howard JG, Olson RJ (2002) Microphacoemulsification with WhiteStar. A wound temperature study. J Cataract Refract Surg 28:1044–1046
33. Hoffman RS, Fine IH, Packer M, Brown LK (2002) Comparison of sonic and ultrasonic phacoemulsification utilizing the Staar Sonic Wave phacoemulsification system. J Cataract Refract Surg 28:1581–1584
34. Alzner E, Grabner G (1999) Dodick laser photolysis: thermal effects. J Cataract Refract Surg 25:800–803
35. Soscia W, Howard JG, Olson RJ (2002) Bimanual phacoemulsification through 2 stab incisions. A wound-temperature study. J Cataract Refract Surg 28:1039–1043
36. Tsuneoka H, Shiba T, Takahashi Y (2002) Ultrasonic phacoemulsification using a 1.4 mm incision: clinical results. J Cataract Refract Surg 28:81–86
37. Agarwal A, Agarwal A, Agarwal S et al (2001) Phakonit: phacoemulsification through a 0.9 mm corneal incision. J Cataract Refract Surg 27:1548–1552
38. Tsuneoka H, Shiba T, Takahashi Y (2001) Feasibility of ultrasound cataract surgery with a 1.4 mm incision. J Cataract Refract Surg 27: 934–940
39. Fine IH, Hoffman RS, Packer M (2005) Optimizing refractive lens exchange with bimanual microincision phacoemulsification. J Cataract Refract Surg 2004; 30:550–554
40. McDonald JE, El-Moatassem Kotb AM, Decker BB (2001) Effect of brimonidine tartrate ophthalmic solution 0.2 % on pupil size in normal eyes under different luminance conditions. J Cataract Refract Surg 27:560–564
41. Hunkeler JD, Coffman TM, Paugh J et al (2002) Characterization of visual phenomena with the Array multifocal intraocular lens. J Cataract Refract Surg 28:1195–1204

3 Biometry for Refractive Lens Surgery

Mark Packer, I. Howard Fine, Richard S. Hoffman

CORE MESSAGES

- Achieving emmetropia in refractive lens surgery depends on accurate biometry and IOL power calculation.
- Immersion ultrasound and partial coherence interferometry demonstrate a very high degree of correlation in determination of axial length.
- In eyes with a history of keratorefractive surgery, keratometry cannot be used to determine the central power of the cornea. Using corneal topography allows accurate determination of corneal power in eyes that have undergone incisional refractive surgery, such as radial keratometry.

Axial length measurement remains an indispensable technique for intraocular lens (IOL) power calculation. Recently, partial coherence interferometry has emerged as a new modality for biometry [1]. Postoperative results achieved with this modality have been considered "analogous" to those achieved with the ultrasound immersion technique [2]. Reportedly "user-friendly" and less dependent on technician expertise than ultrasound methods, non-contact optical biometry is, however, limited by dense media, e.g., posterior subcapsular cataract. A second limitation of the optical method is the lack of a lens thickness measurement, which is a required variable in the Holladay II IOL power calculation software, version 2.30.9705. On the other hand, according to Holladay, the lens thickness can be estimated by the formula 4.0 + (age/100). Also, optical biometry can provide keratometry measurements, obviating the need for a second instrument.

Immersion ultrasound has long been recognized as an accurate method of axial length measurement, generally considered superior to applanation ultrasound techniques [3, 4]. The absence of corneal depression as a confounding factor in measurement reduces the risk of inter-technician variability in technique. In addition to having a short learning curve, immersion ultrasound has no limitations in terms of media density and measurement capability. On the other hand, optical biometry may be superior in eyes with posterior staphyloma because of more precise localization of the fovea.

We have compared axial length measurements obtained by optical biometry using the

IOL Master (Zeiss Humphrey Systems, Jena, Germany) with measurements obtained by immersion ultrasound using the Axis II (Quantel Medical, Clermont-Ferrand, France). We have also examined the postoperative refractions of patients undergoing cataract extraction with posterior chamber IOL implantation to determine the accuracy of the immersion ultrasound technique.

Fifty cataractous eyes underwent preoperative axial length measurement with both the Axis II and the IOL Master. For the Axis II immersion technique the Praeger shell was employed. Patients were placed in a sitting position in an examination room chair with the head reclined gently against the headrest. The average "Total Length" reported by the unit was entered into the Holladay II IOL power calculation formula. For the IOL Master, the selected axial length with the highest signal-to-noise ratio was used as the basis for comparison. The measured axial lengths were plotted and a linear regression trendline fitted to the data. The Pearson correlation coefficient was determined to assess the relationship between the immersion and the optical measurements according to the formula:

$$\rho = 1/(1-n)\ \Sigma\ ((x - \mu)/s)((y - \mu)/s).$$

Keratometry was performed with the IOL Master. The three reported sets of values were compared for consistency and correlated with the axis and magnitude of the eye's preoperative astigmatism. Either an averaged value of three measurements or of the two closest measurements (in case one measurement appeared to be an outlier) was entered into the formula. In selected cases autokeratometry (HARK 599, Zeiss Humphrey Systems, Jena) and/or computerized corneal topography (EyeSys Technologies, Houston) were utilized to delineate better the preoperative keratometry. The corneal white-to-white diameter was determined with the Holladay-Godwin Corneal Gauge.

One surgeon (IHF) performed all surgery. The Holladay II IOL power calculation formula was used to select the intraocular lens for implantation in each case. This program automatically personalized the surgeon's A constant during the course of the study. To provide uniform results, the Collamer IOL (CC4204BF, Staar Surgical, Monrovia, CA) was implanted in all 50 eyes. The surgical technique has been described previously [5]. Briefly, a temporal clear corneal incision is followed by continuous curvilinear capsulorrhexis, cortical cleaving hydrodissection and hydrodelineation, and nuclear disassembly utilizing horizontal chopping with high vacuum and flow but very low levels of ultrasound energy. The intraocular lens is inserted into the capsular bag via an injection device.

All patients underwent autorefractometry (HARK 599, Humphrey Zeiss Systems, Jena) and subjective manifest refraction 2–3 weeks postoperatively. Only eyes obtaining 20/30 or better best-corrected visual acuity were included in the study. The postoperative refraction was then entered into the Holladay IOL Consultant (Holladay Consulting, Inc., Bellaire, TX). Utilizing the Surgical Outcomes Assessment Program (SOAP), the spherical equivalent prediction error was measured and analyzed.

3.1 Axial Length Measurements

The axial length measurements obtained with the Axis II and the IOL Master correlated very highly (Pearson correlation coefficient = 0.996, Fig. 3.1). The mean of the axial lengths measured by immersion was 23.40 (range 21.03–25.42), while the mean of the optically measured axial lengths was 23.41 (range 21.13–25.26). Technicians noted that immersion measurements required 5 minutes, while optical measurements required about 1 minute.

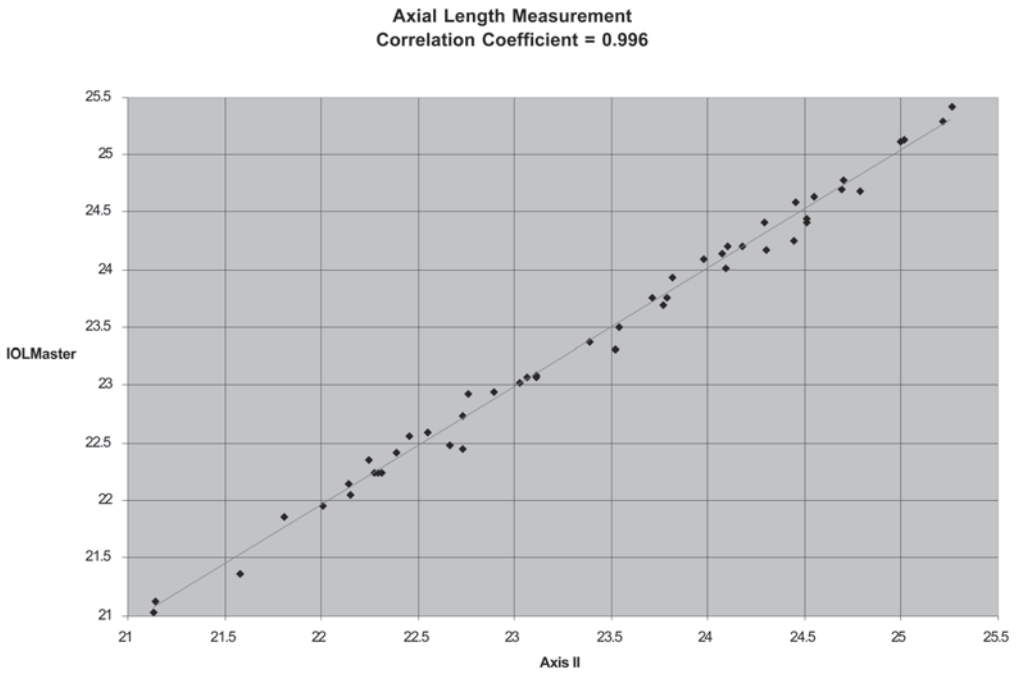


Fig. 3.1. Comparison of axial length measurements with immersion ultrasound (*abscissa*) and optical coherence interferometry (*ordinate*). The linear regression trendline reflects the very high correlation between the two sets of values

3.2 Surgical Outcomes Assessment

The Holladay IOL Consultant report reflects a personalized A constant of 119.365 (ACD 5.512), as compared to the manufacturer's suggested constant of 119.0 (ACD 5.55). The frequency distribution of postoperative spherical equivalent prediction error reveals that 48% of eyes precisely achieved the targeted refraction. The cumulative distribution graph demonstrates that 92% of eyes measured within ±0.5 D of the targeted refraction, and 100% of eyes measured within ±1.00 D of the targeted refraction (Fig. 3.2). The mean absolute error measured 0.215 D, while the mean error of –0.105 reflected the trend toward myopia.

The near-perfect correlation of immersion ultrasound and optical coherence biometry measurement techniques indicates the high level of accuracy of both these methodologies. Our high rate of achieving the targeted refraction by utilizing immersion ultrasound measurements and the Holladay II formula compares favorably with previously reported results. For example, Haigis achieved accurate prediction within ±1.00 D in 85.7% of eyes by utilizing immersion ultrasound [2]. Additionally, Sanders, Retzlaff and Kraff have indicated that achievement of about 90% of eyes within ±1.00 D of the targeted refraction and a mean absolute error of approximately 0.5 D represents an acceptable outcome [6].

Technicians report that the immersion ultrasound method with the Praeger shell is well tolerated by patients and relatively easy to learn. Its applicability to all types of cataracts and its ability to generate a phakic lens thickness represent significant advantages, especially for surgeons who utilize the Holladay II calculation formula.

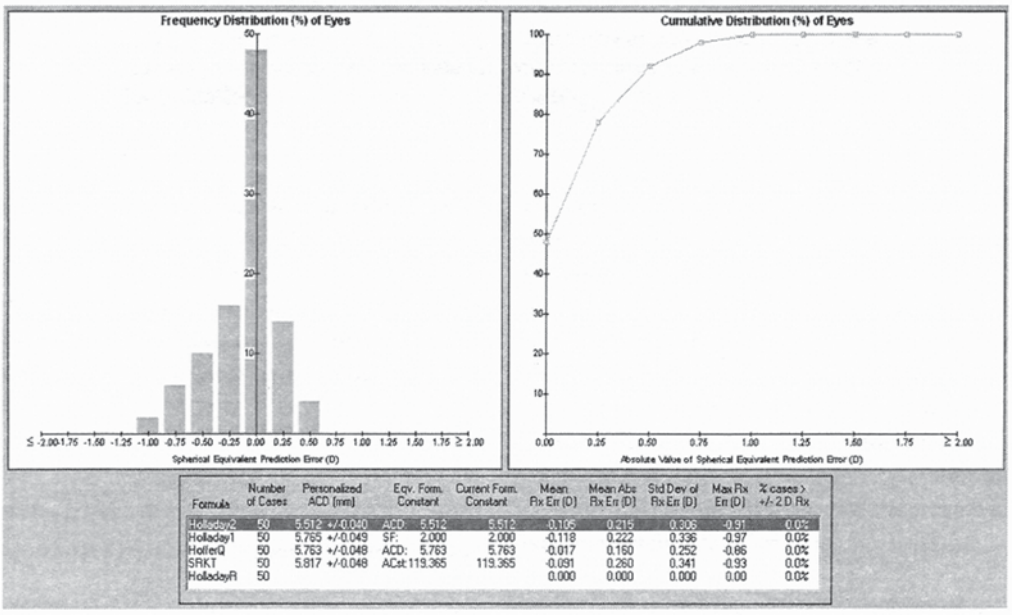


Fig. 3.2. Holladay IOL Consultant Surgical Outcomes Analysis. Introduction

3.3 Keratometry after Keratorefractive Surgery

Intraocular lens power calculations for cataract and refractive lens exchange surgery have become much more precise with the current theoretical generation of formulas and newer biometry devices [7].

However, intraocular lens power calculation remains a challenge in eyes with prior keratorefractive surgery. The difficulty in these cases lies in determining accurately the corneal refractive power [8–10].

In a normal cornea, standard keratometry and computed corneal topography are accurate in measuring four sample points to determine the steepest and flattest meridians of the cornea, thus yielding accurate values for the central corneal power. In irregular corneas, such as those having undergone radial keratotomy (RK), laser thermal keratoplasty (LTK), hexagonal keratotomy (HK), penetrating keratoplasty (PKP), photorefractive keratectomy (PRK) or laser-assisted in-situ keratomileusis (LASIK), the four sample points are not sufficient to provide an accurate estimate of the center corneal refractive power [11].

Traditionally there have been three methods to calculate the corneal refractive in these eyes [12]. These include the historical method, the hard contact lens method, and values derived from standard keratometry or corneal topography. However, the historical method remains limited by its reliance on the availability of refractive data prior to the keratorefractive surgery. On the other hand, the contact lens method is not applicable in patients with significantly reduced visual acuity [13]. Finally, the use of simulated or actual keratometry values almost invariably leads to a hyperopic refractive surprise [14].

It has been suggested that using the average central corneal power rather than topography-derived keratometry may offer improved accuracy in IOL power calculation following corneal refractive surgery [15]. The effective refractive power (Eff RP, Holladay Diagnostic Summary, EyeSys Topographer, Tracey Technologies, Houston, TX) is the re-

fractive power of the corneal surface within the central 3-mm pupil zone, taking into account the Stiles-Crawford effect. This value is commonly known as the spheroequivalent power of the cornea within the 3-mm pupil zone. The Eff RP differs from simulated keratometry values given by topographers. The simulated K-readings that the standard topography map gives are only the points along the 3-mm pupil perimeter, not the entire zone. As with standard keratometry, these two meridians are forced to be 90 degrees apart. The higher the discrepancy between the mean simulated K-readings and the Eff RP, the higher the degree of variability in the results of intraocular lens calculations [3].

Aramberri recently reported the advantages of using a "double K" method in calculating IOL power in post-keratorefractive surgery eyes [16]. Holladay recognized this concept and implemented it in the Holladay IOL Consultant in 1996 [17]. The Holladay 2 IOL power calculation formula (Holladay IOL Consultant, Jack Holladay, Houston, TX) uses the corneal power value in two ways: first, in a vergence formula to calculate the refractive power of the eye, and second, to aid in the determination the effective lens position (ELP). The formula uses a total of seven variables to estimate the ELP, including keratometry, axial length, horizontal white-to-white measurement, anterior chamber depth, phakic lens thickness, patient's age and current refraction.

The Holladay 2 program permits the use of the Eff RP as an alternative to keratometry (Alt K) for the vergence calculation. For the ELP calculation, the program uses either the K-value entered as the Pre-Refractive Surgery K or, if it is unknown, 43.86, the mean of the human population (personal communication, Jack Holladay, February 3, 2004).

We performed a retrospective analysis of all patients in our practice who underwent cataract or refractive lens exchange surgery after incisional or thermal keratorefractive surgery in whom the Eff RP and Holladay II IOL calculation formula were utilized for IOL power determination. Between February 23, 2000 and October 28, 2002, a total of 20 eyes met these criteria. Fourteen eyes had undergone RK, three eyes HK, and three eyes LTK with the Sunrise Sun1000 laser (Sunrise Technologies, Fremont, CA).

Preoperative evaluation included a complete ophthalmic examination. Axial length measurements were performed with the IOL Master (Carl Zeiss Meditec, Dublin, CA). The protocol for axial length measurements with the IOL Master allowed up to 0.15 mm of variation within 10 measurements of one eye and up to 0.20 mm of variation between the two eyes, unless explained by anisometropia. The signal-to-noise ratio was required to read 1.6 or better, and a tall, sharp "Chrysler Building" shaped peak was preferred. If any of these criteria were not met, the measurements were repeated with immersion ultrasonography (Axis II, Quantel Medical, Bozeman, MT).

The corneal white-to-white distance was measured with a Holladay-Godwin gauge in the initial 14 eyes, and with the newly available frame grabber software on the IOL Master in the final six eyes. The phakic lens thickness was estimated as 4 plus the patient's age divided by 100 (e.g., a 67-year-old patient's lens thickness was estimated as 4.67) or determined by immersion ultrasonography. The Holladay II formula was used for all IOL power calculations (Holladay IOL Consultant, Bellaire, TX). "Previous RK" was set to "Yes," and the Eff RP value from the Holladay Diagnostic Summary of the EyeSys Corneal Analysis System was input in the "Alt. K" area. This procedure instructs the formula to use the Eff RP value in place of standard keratometry for the vergence calculation. In no case was the pre-refractive surgery keratometry known, so the formula used 43.86 as the default value to determine the effective lens position. The "Alt. K" radio button was highlighted, and the Eff RP value was printed on the report as a confirmation that the formula had utilized it in the calculation. In every case

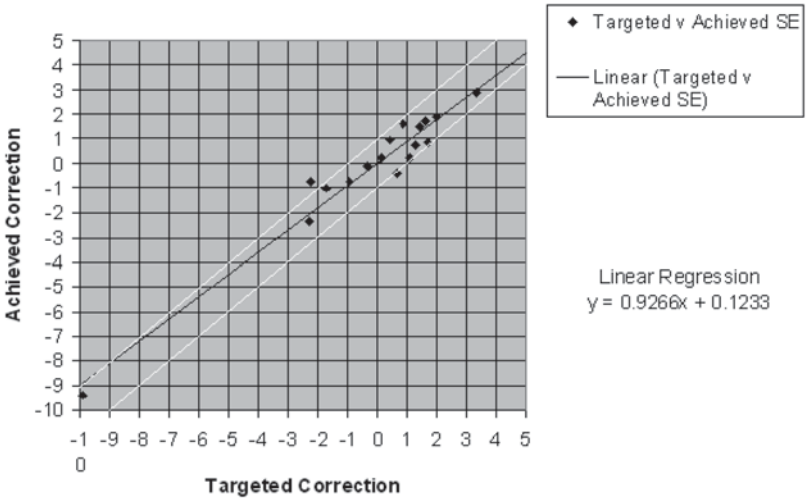


Fig. 3.3. Targeted correction in spherical equivalent (SE), calculated by the Holladay 2 formula compared with the achieved postoperative SE correction. Linear regression analysis ($y = 0.9266x + 0.1233$) demonstrated a slightly hyperopic trend

the targeted postoperative refraction was emmetropia.

Preoperative astigmatism was addressed at the time of cataract or lens exchange surgery by means of limbal relaxing incisions performed with the Force blade (Mastel Precision Surgical Instruments, Rapid City, SD) as described by Gills [18] and Nichamin [19]. In general, with-the-rule corneal astigmatism equal to or greater than 1.00 D and against-the-rule corneal astigmatism equal to or greater than 0.75 D were considered appropriate for correction.

The surgical technique, including clear corneal cataract extraction with topical anesthesia and the use of power modulations in phacoemulsification, has been described previously [20]. Eight eyes of five patients received the Array SA 40 multifocal IOL (AMO, Santa Ana, CA), five eyes of three patients received the AQ2010V (Staar Surgical, Monrovia, CA), both eyes of one patient received the CLRFLXB (AMO, Santa Ana, CA), both eyes of one patient received the SI 40 (AMO, Santa Ana, CA) and one eye of one patient each received the CeeOn Edge 911 A (AMO, Santa Ana, CA), the Tecnis Z9000 (AMO, Santa Ana, CA) and the Collamer CC4204BF (Staar Surgical, Monrovia, CA). The deviation of the achieved postoperative spherical equivalent from the desired postoperative goal for each eye was determined. Each group of keratorefractive patients was also analyzed separately. The differences between the Eff RP value and the corneal refractive power derived from the corneal topographer and autokeratometer were also analyzed. All data were placed in an Excel spreadsheet and statistical analyses were performed.

In the RK group, the number of radial incisions ranged from four to 20, with the majority having eight incisions. Fifty per cent of the RK patients had astigmatic keratotomy performed in addition to RK. For all eyes, the mean duration from intraocular lens surgery to the last postoperative refraction was 6.73 months (range 1–24 months). The RK group had the longest follow up, averaging 9.25 months (range 2.5–24 months).

The mean deviation from the calculated postoperative refractive goal for all patients was 0.13±0.62 D (range –1.49 to 1.03 D). The difference from the postoperative refractive goal for each group of keratorefractive eyes was 0.27±0.51 D for the RK group, –0.07 ±0.44 D for the LTK group and –0.32±1.10 D for the HK group. The targeted versus achieved spherical equivalent correction is shown in Fig. 3.3. A linear regression equation fitted to the data,

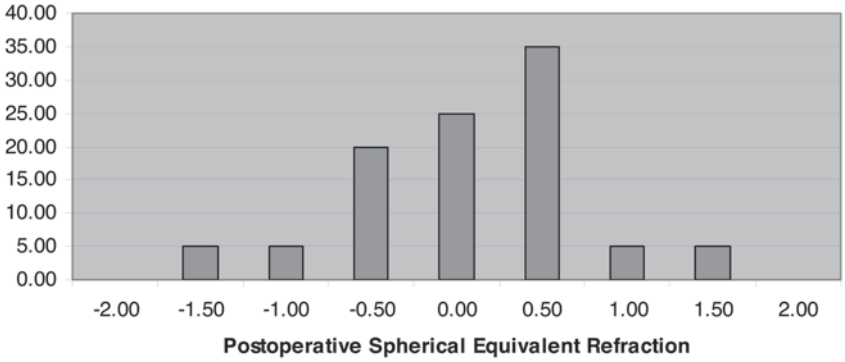
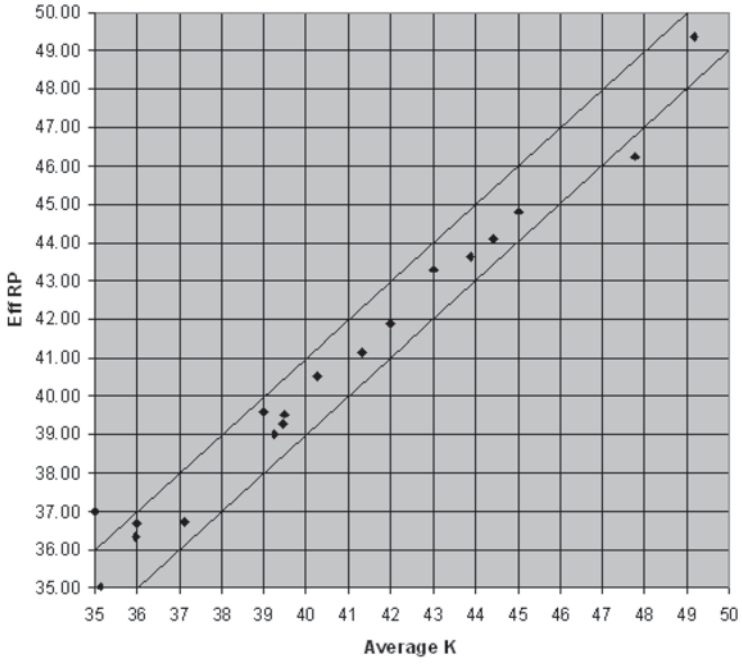


Fig. 3.4. The frequency distribution of eyes (%) determined by the postoperative spherical equivalent refractions

Fig. 3.5. The average keratometry reading (IOL Master) compared with the Eff RP determined by the Holladay Diagnostic Summary. Although the mean difference was small, the range of differences was broad (–1.50 to +2.00). Equivalency lines show the range ±1.0 D



Achieved Correction = 0.9266 (Targeted Correction) + 0.1233 D

demonstrates the slightly hyperopic trend in achieved spherical equivalent correction. All eyes achieved a postoperative refraction within 1.5 D of emmetropia, and 80% were within 0.50 D of emmetropia (Fig. 3.4).

The mean difference between standard automated keratometry readings (IOL Master, Carl Zeiss Meditec, Dublin, CA) and the Eff RP values was 0.01±0.66 D (range –1.5 to 2.00 D). These results are shown in Fig. 3.5. Within the individual groups, the difference was 0.12±0.65 D (range 0.47 to 2.00 D) for the RK eyes, 0.05±0.29 D (range –1.5 to 0.24 D)

for the LTK eyes, and 0.48±0.91 D (range –0.26 to 0.28 D) for the HK group.

The mean difference between standard simulated keratometry readings from topography and Eff RP values was –0.85±0.73 D (range –2.28 to 0.31 D). Within the individual groups, the mean difference was –1.03 ±0.74 D (range –2.28 to –0.19 D) for the RK eyes, –0.01±0.28 D (range –1.08 to –0.5 D) for the LTK group and –0.84±0.30 D (range –0.13 to 0.31 D) for the HK eyes.

Axial lengths in all eyes averaged 24.78±1.54 (22.31–27.96) mm. In the RK group the mean axial length measured 25.38 ±1.40 (23.04–27.96) mm; in the LTK group the mean axial length measured 23.21±1.26 (22.31–24.65) mm; in the HK group the mean axial length measured 23.57±0.43 (23.08–23.82) mm. No significant correlation between axial length and postoperative spherical equivalent was found (Pearson correlation coefficient = 0.08).

The eye with –9.88 D preoperative spherical equivalent refraction deserves a brief comment because of its position as an outlier and the unusual features of the case. This patient presented 22 years after "failed" RK in this eye. She had never proceeded with surgery on the fellow eye. No other history was available.

The fellow unoperated eye had a spherical equivalent of –4.86 D, with keratometry of 42.82 X 44.34 @ 98 and axial length of 25.13. Her preoperative best-corrected acuity in the operated eye was 20/30 with a correction of –10.75+1.75 X 33. Keratometry in the operated eye was 41.31 X 42.67 @ 64, yielding an average K of 41.99. Simulated keratometry was 41.36 X 42.55 @ 70. The calculated Eff RP was 41.90 D, and the axial length was 26.59 mm. Examination revealed moderate nuclear sclerosis. The Holladay II formula predicted a postoperative spherical equivalent refraction of –0.02 D. The eye achieved a final best-corrected visual acuity of 20/20 with a correction of +0.25 +0.75 X 55, indicating a predictive error of 0.64 D.

The determination of IOL power following keratorefractive surgery remains a challenge for the cataract and refractive surgeon. Using a combination of measured and calculated K values with the historical and contact lens methods, as well as a myopic target refraction, Chen and coauthors achieved a postoperative refractive outcome of 29.2% within ±0.50 D of emmetropia in a series of 24 eyes with a history of RK [8]. They suggested that "corneal power values that involve more central regions of the cornea, such as the effective refractive power in the Holladay diagnostic summary of the EyeSys Corneal Analysis System, would be more accurate K-readings in post-RK eyes." Our results would tend to support that conclusion.

Accurate biometry also plays an important role in IOL power determination. The use of partial coherence interferometry (IOL Master, Carl Zeiss Meditec, Dublin, CA) for axial length measurement improves the predictive value of postoperative refraction [21], and it has been shown to be equivalent in accuracy to immersion ultrasound [22].

It is interesting to note the smaller difference between simulated keratometry and the Eff RP in the LTK group as compared to the incisional keratorefractive surgery groups. One possible explanation of this difference is that the LTK corneas had undergone regression from treatment and therefore returned to a less distorted anatomy.

The IOL calculation formula plays a critical role in obtaining improved outcomes. The Holladay II formula is designed to improve determination of the final effective lens position by taking into account disparities in the relative size of the anterior and posterior segments of the eye. To accomplish this goal the formula incorporates the corneal white-to-white measurement and the phakic lens thickness, and uses the keratometry (or Eff RP) values, not only to determine corneal power but also to predict effective lens position. We have found that the use of the Holla-

day II formula has increased the accuracy of our IOL power calculations [23].

Our study has been limited to eyes that have undergone incisional and thermal keratorefractive surgery. Ongoing research will help to determine the most effective methods of calculating IOL power in eyes that have had lamellar keratorefractive surgery such as PRK or LASIK. It appears that further modification is necessary in these situations because of the inaccuracy of the standardized values of index of refraction [24].

We continue to tell our patients as part of the informed consent process that IOL calculations following keratorefractive surgery remain a challenge, and that refractive surprises do occur. We explain that further surgery (e.g., placement of a piggyback IOL) may be necessary in the future to enhance uncorrected visual acuity. We defer any secondary procedures until a full 3 months postoperatively and document refractive stability before proceeding.

References

1. Drexler W, Findl O, Menapace R et al (1998) Partial coherence interferometry: a novel approach to biometry in cataract surgery. Am J Ophthalmol 126:524–534
2. Haigis W, Lege B, Miller N, Schneider B (2000) Comparison of immersion ultrasound biometry and partial coherence interferometry for intraocular lens power calculation according to Haigis. Graefes Arch Clin Exp Ophthalmol 238:765–773
3. Giers U, Epple C (1990) Comparison of A-scan device accuracy. J Cataract Refract Surg 16: 235–242
4. Watson A, Armstrong R (1999) Contact or immersion technique for axial length measurement? Aust NZ J Ophthalmol 27:49–51
5. Fine IH, Packer M, Hoffman RS (2001) Use of power modulations in phacoemulsification. J Cataract Refract Surg 27:188–197
6. Sanders DR, Retzlaff JA, Kraff MC (1995) A-scan biometry and IOL implant power calculations, vol 13. Focal points. American Academy of Ophthalmology, San Francisco, CA
7. Fenzl RE, Gills JP, Cherchio M (1998) Refractive and visual outcome of hyperopic cataract cases operated on before and after implementation of the Holladay II formula. Ophthalmology 105:1759–1764
8. Hoffer KJ (1994) Intraocular lens power calculation in radial keratotomy eyes. Phaco Foldables 7:6
9. Holladay JT (1995) Understanding corneal topography, the Holladay diagnostic summary, user's guide and tutorial. EyeSys Technologies, Houston, TX
10. Celikkol L, Pavlopoulos G, Weinstein B, Celikkol G, Feldman ST (1995) Calculation of intraocular lens power after radial keratotomy with computerized videokeratography. Am J Ophthalmol 120:739–750
11. Speicher L (2001) Intraocular lens calculation status after corneal refractive surgery. Curr Opin Ophthalmol 12:17–29
12. Hamilton DR, Hardten DR (2003) Cataract surgery in patients with prior refractive surgery. Curr Opin Ophthalmol 14:44–53
13. Zeh WG, Koch DD (1999) Comparison of contact lens overrefraction and standard keratometry for measuring corneal curvature in eyes with lenticular opacity. J Cataract Refract Surg 25:898–903
14. Chen L, Mannis MJ, Salz JJ, Garcia-Ferrer FJ, Ge J (2003) Analysis of intraocular lens power calculation in post-radial keratotomy eyes. J Cataract Refract Surg 29:65–70
15. Maeda N, Klyce SD, Smolek MK, McDonald MB (1997) Disparity between keratometry-style readings and corneal power within the pupil after refractive surgery for myopia. Cornea 16: 517–524
16. Aramberri J (2003) Intraocular lens power calculation after corneal refractive surgery: double K method. J Cataract Refract Surg 29:2063–2068
17. Koch DD, Wang L (2003) Calculating IOL power in eyes that have had refractive surgery (editorial). J Cataract Refract Surg 29:2039–2042
18. Gills JP, Gayton JL (1998) Reducing pre-existing astigmatism. In: Gills JP (ed) Cataract surgery: the state of the art. Slack, Thorofare, NJ, pp 53–66
19. Nichamin L (1993) Refining astigmatic keratotomy during cataract surgery. Ocul Surg News April 15

20. Fine IH, Packer M, Hoffman RS (2001) Use of power modulations in phacoemulsification. Choo-choo chop and flip phacoemulsification. J Cataract Refract Surg 27:188–197
21. Rajan MS, Keilhorn I, Bell JA (2002) Partial coherence laser interferometry vs conventional ultrasound biometry in intraocular lens power calculations. Eye 16:552–556
22. Packer M, Fine IH, Hoffman RS, Coffman PG, Brown LK (2002) Immersion A-scan compared with partial coherence interferometry: outcomes analysis. J Cataract Refract Surg 28:239–242
23. Packer M, Fine IH, Hoffman RS (2002) Refractive lens exchange with the array multifocal intraocular lens. J Cataract Refract Surg 28: 421–424
24. Hamed AM, Wang L, Misra M, Koch DD (2002) A comparative analysis of five methods of determining corneal refractive power in eyes that have undergone myopic laser in-situ keratomileusis. Ophthalmology 109:651–658

4 Intraocular Lens Power Calculations: Correction of Defocus

Jack T. Holladay

Financial interest: Dr. Holladay is author of the Holladay formula and provides consultation for A-scan companies that use his formula.

CORE MESSAGES

- The improvements in IOL power calculations over the past 30 years are a result of improving the predictability of the variable effective lens position.
- The intraocular power calculations for clear lensectomy are no different than the calculations when a cataract is present.
- Determining the corneal power in patients who have had prior keratorefractive surgery is difficult and is the determining factor in the accuracy of the predicted refraction following cataract surgery.
- The third-generation IOL calculation formulas (Holladay 1, Hoffer Q and the SRK/T) and the new Holladay 2 are much more accurate than previous formulas, especially in unusual eyes.
- In cases where no power is being removed from the eye, such as secondary implant in aphakia, piggyback IOL in pseudophakia or a minus IOL in the anterior chamber of a phakic patient, the necessary IOL power for a desired postoperative refraction can be calculated from the corneal power and preoperative refraction – the axial length is not necessary.
- In patients with a significant residual refractive error following the primary IOL implant, it is often easier surgically and more predictable optically to leave the primary implant in place and calculate the secondary piggyback IOL power to achieve the desired refraction.

4.1 Introduction

The indications for intraocular lens (IOL) implantation following cataract or clear lensectomy have significantly increased. These expanded indications result in more complicated cases such as patients with a scleral buckle, silicone in the vitreous, previous refractive surgery, piggyback IOLs in nanophthalmos, positive and negative secondary piggyback IOLs and specialty lenses, such as multifocal and toric IOLs. Techniques for determining the proper IOL and power are presented.

Several measurements of the eye are helpful in determining the appropriate IOL power to achieve a desired refraction. These measurements include central corneal refractive power (K-readings), axial length (biometry), horizontal corneal diameter (horizontal white to white), anterior chamber depth, lens thickness, preoperative refraction and age of the patient. The accuracy of predicting the necessary power of an IOL is directly related to the accuracy of these measurements [1, 2].

4.1.1 Theoretical Formulas

Fyodorov first estimated the optical power of an IOL using vergence formulas in 1967 [3]. Between 1972 and 1975, when accurate ultrasonic A-scan units became commercially available, several investigators derived and published the theoretical vergence formula [4–9]. All of these formulas were identical [10], except for the form in which they were written and the choice of various constants such as retinal thickness, optical plane of the cornea, and optical plane of the IOL. These slightly different constants accounted for less than 0.50 diopters in the predicted refraction. The variation in these constants was a result of differences in lens styles, A-scan units, keratometers, and surgical techniques among the investigators.

Although several investigators have presented the theoretical formula in different forms, there are no significant differences except for slight variations in the choice of retinal thickness and corneal index of refraction. There are six variables in the formula: (1) corneal power (K), (2) axial length (AL), (3) IOL power, (4) effective lens position (ELP), (5) desired refraction (DPostRx), and (6) vertex distance (V). Normally, the IOL power is chosen as the dependent variable and solved for using the other five variables, where distances are given in millimeters and refractive powers given in diopters:

$$IOL = \frac{1336}{AL - ELP} - \frac{1336}{\dfrac{1336}{\dfrac{1000}{\dfrac{1000}{DPostRx} - V} + K} - ELP}$$

The only variable that cannot be chosen or measured preoperatively is the ELP. The improvements in IOL power calculations over the past 30 years are a result of improving the predictability of the variable ELP. Figure 4.1 illustrates the physical locations of the variables. The optical values for corneal power (K_{opt}) and axial length (AL_{opt}) must be used in the calculations to be consistent with current ELP values and manufacturers' lens constants.

The term "effective lens position" was recommended by the Food and Drug Administration in 1995 to describe the position of the lens in the eye, since the term anterior chamber depth (ACD) is not anatomically accurate for lenses in the posterior chamber and can lead to confusion for the clinician [11]. The ELP for intraocular lenses before 1980 was a constant of 4 mm for every lens in every patient (first-generation theoretical formula). This value actually worked well in most patients because the majority of lenses implanted were iris clip fixation, in which the principal plane averages approximately 4 mm posterior to the corneal vertex. In 1981, Binkhorst improved the prediction of ELP by

Table 4.1. Clinical conditions demonstrating the independence of the anterior segment and axial length

Anterior segment Size	Axial length		
	Short	Normal	Long
Small	Small eye Nanophthalmos	Microcornea	Microcornea +Axial myopia
Normal	Axial hyperopia	Normal	Axial myopia
Large	Megalocornea Axial hyperopia	Megalocornea	Large eye Buphthalmos +Axial myopia

using a single-variable predictor, the axial length, as a scaling factor for ELP (second-generation theoretical formula) [12]. If the patient's axial length was 10% greater than normal (23.45 mm), he would increase the ELP by 10%. The average value of ELP was increased to 4.5 mm because the preferred location of an implant was in the ciliary sulcus, approximately 0.5 mm deeper than the iris plane. Also, most lenses were convex-plano, similar to the shape of the iris-supported lenses. The average ELP in 1996 has increased to 5.25 mm. This increased distance has occurred primarily for two reasons: the majority of implanted IOLs are biconvex, moving the principal plane of the lens even deeper into the eye, and the desired location for the lens is in the capsular bag, which is 0.25 mm deeper than the ciliary sulcus.

In 1988, we proved [13] that using a two-variable predictor, axial length and keratometry, could significantly improve the prediction of ELP, particularly in unusual eyes (third-generation theoretical formula). The original Holladay 1 formula was based on the geometrical relationships of the anterior segment. Although several investigators have modified the original two-variable Holladay 1 prediction formula, no comprehensive studies have shown any significant improvement using only these two variables.

In 1995, Olsen published a four-variable predictor that used axial length, keratometry, preoperative anterior chamber depth and lens thickness [14]. His results did show improvement over the current two-variable prediction formulas. The explanation is very simple. The more information we have about the anterior segment, the better we can predict the ELP. This explanation is a well-known theorem in prediction theory, where the more variables that can be measured describing an event, the more precisely one can predict the outcome.

In a recent study [15], we discovered that the anterior segment and posterior segment of the human eye are often not proportional in size, causing significant error in the prediction of the ELP in extremely short eyes (<20 mm). We found that, even in eyes shorter than 20 mm, the anterior segment was completely normal in the majority of cases. Because the axial lengths were so short, the two-variable prediction formulas severely underestimated the ELP, explaining part of the large hyperopic prediction errors with current two-variable prediction formulas. After recognizing this problem, we began to take additional measurements on extremely short and extremely long eyes to determine if the prediction of ELP could be improved by knowing more about the anterior segment. Table 4.1 shows the clinical conditions that illustrate the independence of the anterior segment and the axial length.

For 3 years, we gathered data from 35 investigators around the world. Several additional measurements of the eye were taken,

but only seven preoperative variables (axial length, corneal power, horizontal corneal diameter, anterior chamber depth, lens thickness, preoperative refraction and age) were found to be useful for significantly improving the prediction of ELP in eyes ranging from 15 to 35 mm.

The improved prediction of ELP is not totally due to the formula, but is also a function of the technical skills of the surgeons who are consistently implanting the lenses in the capsular bag. A 20-D IOL that is 0.5 mm axially displaced from the predicted ELP will result in an approximately 1.0-D error in the stabilized postoperative refraction. However, when using piggyback lenses totaling 60 D, the same axial displacement of 0.5 mm will cause a 3-D refractive surprise; the error is directly proportional to the implanted lens power. This direct relationship to the lens power is why the problem is much less evident in extremely long eyes, since the implanted IOL is either low plus or minus to achieve emmetropia following cataract extraction.

The Holladay 2 formula provides more predictable results in unusual eyes. Once these additional measurements become routine among clinicians, a new flurry of prediction formulas using seven or more variables will emerge, similar to the activity following our two-variable prediction formula in 1988. The standard of care will reach a new level of prediction accuracy for extremely unusual eyes, just as it has for normal eyes. Calculations on patients with axial lengths between 22 and 25 mm with corneal powers between 42 and 46 D will do well with current third-generation formulas (Holladay, SRK/T [16, 17]). In cases outside this range, the Holladay 2 should be used to assure accuracy.

4.2 Normal Cornea with no Previous Keratorefractive Surgery

4.2.1 Clear Lensectomy for High Myopia and Hyperopia

The intraocular power calculations for clear lensectomy are no different than the calculations when a cataract is present. The patients are usually much younger, however, and the loss of accommodation should be discussed thoroughly. The actual desired postoperative refraction should also be discussed, since a small degree of myopia (–0.50 D) may be desirable to someone with no accommodation to reduce their dependence on spectacles.

This procedure is usually reserved for patients who are outside the range for other forms of refractive surgery. Consequently, the measurements of axial length, keratometry, etc., are usually quite different from those of the typical cataract patient because of the exceptionally large refractive error and younger age of the patient. In most of the cases with high myopia, the axial lengths are extremely long (>26 mm). In cases of high hyperopia, the axial lengths are very short (<21 mm).

In patients with myopia exceeding 20 D, removing the clear lens often results in postoperative refractions near emmetropia with no implant. The exact result depends on the power of the cornea and the axial length. The recommended lens powers usually range from –10 D to +10 D in the majority of these cases. The correct axial length measurement is very difficult to obtain in these cases because of the abnormal anatomy of the posterior pole. Staphylomas are often present in these eyes, and the macula is often not at the location in the posterior pole where the A-scan measures the axial length. In these cases it is recommended that a B-scan be performed to locate the macula (fovea) and recheck the measurement determined by A-scan. I have personally seen 3- to 4-D surpris-

es because the macula was on the edge of the staphyloma, and the A-scan measured to the deepest part of the staphyloma. Such an error results in a hyperopic surprise because the distance to the macula is much shorter than the distance to the center of the staphyloma. The third-generation theoretical formulas yield excellent results if the axial length measurement is accurate and stable.

In patients with hyperopia exceeding +8 D, the axial lengths are often less than 21 mm and require lens powers that exceed the normal range (>34 D). In these cases, piggyback lenses are necessary to achieve emmetropia [15]. The only formula available at this time in these eyes is the Holladay 2. If the required lens power is less than or equal to 34 D, the piggyback lenses are not required and third-generation theoretical formulas may be used.

4.2.2 Piggyback IOLs to Achieve Powers Above 34 D

Patients with axial lengths shorter than 21 mm should be calculated using the Holladay 2 formula. In these cases, the size of the anterior segment has been shown to be unrelated to the axial length [15]. In many of these cases the anterior segment size is normal and only the posterior segment is abnormally short. In a few cases, however, the anterior segment is proportionately small to the axial length (nanophthalmos). The differences in the size of the anterior segment in these cases can cause an average of 5-D hyperopic error with third-generation formulas because they predict the depth of the anterior chamber to be very shallow. Using the newer formula can reduce the prediction error in these eyes to less than 1 D.

Accurate measurements of axial length and corneal power are especially important in these cases because any error is magnified by the extreme dioptric powers of the IOLs. Placement of both lenses in the bag with the haptics aligned is essential. Inadvertently placing one lens in the bag and the other in the sulcus can cause a 4 diopter refractive surprise.

4.3 Patients with Previous Keratorefractive Surgery

4.3.1 Background

The number of patients who have had keratorefractive surgery (radial keratotomy – RK, photorefractive keratectomy – PRK, or laser-assisted in-situ keratomileusis – LASIK) has been steadily increasing over the past 20 years. With the advent of the excimer laser, these numbers are predicted to increase dramatically. Determining their corneal power accurately is difficult and usually is the determining factor in the accuracy of the predicted refraction following cataract surgery. Providing this group of patients the same accuracy with intraocular lens power calculations as we have provided our standard cataract patients presents an especially difficult challenge for the clinician.

4.3.2 Preoperative Evaluation

4.3.2.1 Corneal Evaluation

At present, far more patients have had RK than PRK and LASIK combined. Also, our long-term follow-up of RK patients is much greater. The long-term studies of RK patients reveal that some have hyperopic shifts in their refraction and develop progressive against-the-rule astigmatism [18]. The long-term refractive changes in PRK and LASIK are unknown, except for the regression effect following attempted PRK corrections exceeding 8 diopters. No matter which procedure the patient has had, the stability or instability of the refraction must be determined. This determination includes daily fluctuations

from morning to night as well as long-term changes over the past few years. Each of these factors must be used in determining the desired postoperative target refraction and to prepare the patient for the visual changes and realistic expectations following the procedure.

In all of these cases, biomicrosopy, retinoscopy, corneal topography and endothelial cell counts are recommended. These first three tests are primarily directed at evaluating the amount of irregular astigmatism. This determination is extremely important preoperatively because the irregular astigmatism may be contributing to the reduced vision as well as the cataract. The irregular astigmatism may also be the limiting factor in the patient's vision following cataract surgery. The endothelial cell count is necessary to recognize any patients with low cell counts from the previous surgery who may be at higher risk for corneal decompensation or prolonged visual recovery.

The potential acuity meter (PAM), super pinhole and hard contact lens trial are often helpful as secondary tests in determining the respective contribution to reduced vision by the cataract and the corneal irregular astigmatism. The patient should also be informed that only the glare from the cataract will be eliminated; any glare from the keratorefractive procedure will essentially remain unchanged.

4.3.2.2 Methods of Determining Corneal Power

Accurately determining the central corneal refractive power is the most important and difficult part of the entire intraocular lens calculation process. The explanation is quite simple. Our current instruments for measuring corneal power make too many incorrect assumptions with corneas that have irregular astigmatism. The cornea can no longer be compared to a sphere centrally, the posterior radius of the cornea is no longer 1.2 mm steeper than the anterior corneal radius, etc. Because of these limitations, the calculated method and the trial hard contact lens method are most accurate, followed by corneal topography, automated keratometry and finally manual keratometry.

4.3.2.2.1 Calculation Method

For the calculation method, three parameters must be known: the K-readings and refraction before the keratorefractive procedure and the stabilized refraction after the keratorefractive procedure. It is important that the stabilized postoperative refraction be measured before any myopic shifts from nuclear sclerotic cataracts occur. It is also possible for posterior subcapsular cataracts to cause an apparent myopic shift, similar to capsular opacification, where the patient wants more minus in the refraction to make the letters appear smaller and darker. The concept that we described in 1989 subtracts the change in refraction due to the keratorefractive procedure at the corneal plane from the original K-readings before the procedure to arrive at a calculated postoperative K-reading [19]. This method is usually the most accurate because the preoperative K-readings and refraction are usually accurate to ±0.25 D. An example calculation to illustrate the calculation method is given.

Example:

- Mean preoperative K = 42.50 @ 90° and 41.50 @ 180° = 42.00 D
- Preoperative refraction = −10.00 + 1.00 × 90°, Vertex = 14 mm
- Postoperative refraction = −0.25 + 1.00 × 90°, Vertex = 14 mm

Step 1. Calculate the spheroequivalent refraction for refractions at the corneal plane (SEQ_C) from the spheroequivalent refractions at the spectacle plane (SEQ_S) at a given vertex, where

a. SEQ = Sphere + 0.5 (Cylinder)

b. $$SEQ_C = \frac{1000}{\frac{1000}{SEQ_S} - Vertex(mm)}$$

Calculation for preoperative spheroequivalent refraction at corneal plane

a. $SEQ_R = -10.00 + 0.5 * (1.00) = -9.50$ D

b. $$SEQ_C = \frac{1000}{\frac{1000}{-9.50} - 14} = -8.38\text{D}$$

Calculation for postoperative spheroequivalent refraction at corneal plane

a. $SEQ_R = -0.25 + 0.5 * (1.00) = +0.25$ D

b. $$SEQ_C = \frac{1000}{\frac{1000}{+0.25} - 14} = +0.25\text{D}$$

Step 2. Calculate the change in refraction at the corneal plane.

Change in refraction = preoperative SEQ_C – postoperative SEQ_C

Change in refraction = –8.38 – (+0.025) = –8.68 D

Step 3. Determine calculated postoperative corneal refractive power.

Mean postoperative K = mean preoperative K – change in refraction at corneal plane

Mean postoperative K = 42.00 – 8.68 = 33.32 D

This value is the calculated central power of the cornea following the keratorefractive procedure. For IOL programs requiring two K-readings, this value would be entered twice.

4.3.2.2.2 Trial Hard Contact Lens Method

The trial hard contact lens method requires a plano hard contact lens with a known base curve and a patient whose cataract does not prevent them from being refracted to approximately ±0.50 D. This tolerance usually requires a visual acuity of better than 20/80. The patient's spheroequivalent refraction is determined by normal refraction. The refraction is then repeated with the hard contact lens in place. If the spheroequivalent refraction does not change with the contact lens, the patient's cornea must have the same power as the base curve of the plano contact lens. If the patient has a myopic shift in the refraction with the contact lens, the base curve of the contact lens is stronger than the cornea by the amount of the shift. If there is a hyperopic shift in the refraction with the contact lens, the base curve of the contact lens is weaker than the cornea by the amount of the shift.

Example:

The patient has a current spheroequivalent refraction of +0.25 D. With a plano hard contact lens with a base curve of 35.00 D placed on the cornea, the spherical refraction changes to –2.00 D. Since the patient had a myopic shift with the contact lens, the cornea must be weaker than the base curve of the contact lens by 2.25 D. Therefore, the cornea must be 32.75 D (35.00–2.25), which is slightly different than the value obtained by the calculation method. In equation form, we have

SEQ Refraction without hard contact lens = +0.25 D

Base curve of plano hard contact lens = 35.00 D

SEQ Refraction with hard contact lens = –2.00 D

Change in refraction = –2.00 – (+0.25) = –2.25 D (myopic shift)

Mean corneal power = base curve of plano hard contact lens + change in refraction

Mean corneal power = 35.00 + –2.25

Mean corneal power = 32.75 D

NB: This method is limited by the accuracy of the refractions, which may be limited by the cataract.

4.3.2.2.3 Corneal Topography

Current corneal topography units measure more than 5,000 points over the entire cornea and more than 1,000 points within the central 3 mm. This additional information provides greater accuracy in determining the power of corneas with irregular astigmatism compared to keratometers. The computer in topography units allows the measurement to account for the Stiles-Crawford effect, actual pupil size, etc. These algorithms allow a very accurate determination of the anterior surface of the cornea [20]. They provide no information, however, about the posterior surface of the cornea. In order to determine accurately the total power of the cornea, the power of both surfaces must be known.

In normal corneas that have not undergone keratorefractive surgery, the posterior radius of curvature of the cornea averages 1.2 mm less than the anterior surface. In a person with an anterior corneal radius of 7.5 mm using the Standardized Keratometric Index of Refraction of 1.3375, the corneal power would be 45.00 D. Several studies have shown that this power overestimates the total power of the cornea by approximately 0.56 D. Hence, most IOL calculations today use a net index of refraction of 1.3333 (4/3) and the anterior radius of the cornea to calculate the net power of the cornea. Using this lower value, the total power of a cornea with an anterior radius of 7.5 mm would be 44.44 D. This index of refraction has provided excellent results in normal corneas for IOL calculations.

Following keratorefractive surgery, the assumptions that the central cornea can be approximated by a sphere (no significant irregular astigmatism or asphericity) and that the posterior corneal radius of curvature is 1.2 mm less than the anterior radius are no longer true. Corneal topography instruments can account for the changes in the anterior surface, but are unable to account for any differences in the relationship to the posterior radius of curvature. In RK, the mechanism of having a peripheral bulge and central flattening apparently causes similar changes in both the anterior and posterior radius of curvature so that using the net index of refraction for the cornea (4/3) usually gives fairly accurate results, particularly for optical zones larger than 4–5 mm. In RKs with optical zones of 3 mm or less, the accuracy of the predicted corneal power diminishes. Whether this inaccuracy is due to the additional central irregularity with small optical zones or the difference in the relationship between the front and back radius of the cornea is unknown at this time. Studies measuring the posterior radius of the cornea in these patients will be necessary to answer this question.

In PRK and LASIK, the inaccuracies of these instruments to measure the net corneal power is almost entirely due to the change in the relationship of the radii of the front and back of the cornea, since the irregular astigmatism in the central 3-mm zone is usually minimal. In these two procedures, the anterior surface of the cornea is flattened with little or no effect on the posterior radius. Using a net index of refraction (4/3) will overestimate the power of the cornea by 14% of the change induced by the PRK or LASIK, i.e. if the patient had a 7-D change in the refraction at the corneal plane from a PRK or LASIK with spherical preoperative K-readings of 44 D, the actual power of the cornea is 37 D and the topography units will give 38 D. If a 14-D change in the refraction has occurred at the corneal plane, the topography units will overestimate the power of the cornea by 2 diopters.

In summary, the corneal topography units do not provide accurate central corneal power following PRK, LASIK and in RKs with optical zones of 3 mm or less. In RKs with larger optical zones, the topography units become more reliable. The calculation method and hard contact lens trial are always more reliable.

4.3.2.2.4 Automated Keratometry

Automated keratometers are usually more accurate than manual keratometers in corneas with small optical zone (≤3 mm) RKs because they sample a smaller central area of the cornea (nominally 2.6 mm). In addition, the automated instruments often have additional eccentric fixation targets that provide more information about the paracentral cornea. When a measurement error on an RK cornea is made, the instrument almost always gives a central corneal power that is greater than the true refractive power of the cornea. This error occurs because the samples at 2.6 mm are very close to the paracentral knee of the RK. The smaller the optical zone and the greater the number of the RK incisions, the greater the probability and magnitude of the error. Most of the automated instruments have reliability factors that are given for each measurement, helping the clinician decide on the reliability in the measurement.

Automated keratometry measurements following LASIK or PRK yield accurate measurements of the front radius of the cornea because the transition areas are far outside the 2.6-mm zone that is measured. The measurements are still not accurate, however, because the assumed net index of refraction (4/3) is no longer appropriate for the new relationship of the front and back radius of the cornea after PRK or LASIK, just as with the topographic instruments. The change in central corneal power as measured by the keratometer from PRK or LASIK must be increased by 14% to determine the actual refractive change at the plane of the cornea. Hence, the automated keratometer will overestimate the power of the cornea proportional to the amount of PRK or LASIK performed.

4.3.2.2.5 Manual Keratometry

Manual keratometers are the least accurate in measuring central corneal power following keratorefractive procedures, because the area that they measure is usually larger than automated keratometers at 3.2 mm in diameter. Therefore, measurements in this area are extremely unreliable for RK corneas with optical zones ≤4 mm. The one advantage with the manual keratometer is that the examiner is actually able to see the reflected mires and the amount of irregularity present. Seeing the mires does not help get a better measurement, but does allow the observer to discount the measurement as unreliable.

The manual keratometer has the same problem with PRK and LASIK as topographers and automated keratometers, and is therefore no less accurate. The manual keratometer will overestimate the change in the central refractive power of the cornea by 14% following PRK and LASIK.

4.3.2.3 Choosing the Desired Postoperative Refraction Target

Determining the desired postoperative refractive target is no different than for other patients with cataracts, where the refractive status and the presence of a cataract in the other eye are the major determining factors. A complete discussion of avoiding refractive problems with cataract surgery is beyond the scope of this text, and is thoroughly discussed in the reference given [21]. A short discussion of the major factors will follow.

If the patient has binocular cataracts, the decision is much easier because the refractive status of both eyes can be changed. The most important decision is whether the patient prefers to be myopic and read without glasses, or near emmetropic and drive without glasses. In some cases the surgeon and patient may choose the intermediate distance (–1.00 D) for the best compromise. Targeting for monovision is certainly acceptable, provided the patient has successfully utilized monovision in the past. Trying to produce monovision in a patient who has never expe-

rienced this condition may cause intolerable anisometropia and require further surgery.

Monocular cataracts allow fewer choices for the desired postoperative refraction, because the refractive status of the other eye is fixed. The general rule is that the operative eye must be within 2 D of the non-operative eye in order to avoid intolerable anisometropia. In most cases this means matching the other eye or targeting for up to 2 D nearer emmetropia, i.e. if the non-operative eye is –5.00 D, the target would be –3.00 D for the operative eye. If the patient is successfully wearing a contact lens in the non-operative eye or has already demonstrated his ability to accept monovision, an exception can be made to the general rule. It should always be stressed, however, that should the patient be unable to continue wearing a contact, the necessary glasses for binocular correction may be intolerable and additional refractive surgery may be required.

4.3.2.4 Special Limitations of Intraocular Lens Power Calculation Formulas

As discussed previously, the third-generation formulas (Holladay 1, Hoffer Q and the SRK/T) and the new Holladay 2 are much more accurate than previous formulas the more unusual the eye. Older formulas such as the SRK1, SRK2 and Binkhorst 1 should not be used in these cases. None of these formulas will give the desired result if the central corneal power is measured incorrectly. The resulting errors are almost always in the hyperopic direction following keratorefractive surgery, because the measured corneal powers are usually greater than the true refractive power of the cornea.

To complicate matters further, the newer formulas often use keratometry as one of the predictors to estimate the ELP of the intraocular lens. In patients who have had keratorefractive surgery, the corneal power is usually much flatter than normal and certainly flatter than before the keratorefractive procedure. In short, a patient with a 38-D cornea without keratorefractive surgery would not be expected to be similar to a patient with a 38-D cornea with keratorefractive surgery. Newer IOL calculation programs are now being developed to handle these situations and will improve our predictability in these cases.

4.3.3 Intraoperative Evaluation

4.3.3.1 Intraoperative Visualization and Corneal Protection

Intraoperative visualization is usually more difficult in patients with previous RK than in the normal cataract patient and is somewhat similar to severe arcus senilis or other conditions that cause peripheral corneal haze. The surgeon should be prepared for this additional difficulty by making sure that the patient is lined up to visualize the cataract through the optical zone. This usually means lining the microscope perpendicular to the center of the cornea, so that the surgeon is looking directly through the optical zone at the center of the cataract. When removing the peripheral cortex, the eye can be rotated so that visualization of the periphery is through the central optical zone. It is also prudent to coat the endothelium with viscoelastic to minimize any endothelial cell loss, since the keratorefractive procedure may have caused some prior loss.

4.3.3.2 Intraoperative Autorefractor/ Retinoscopy

Large refractive surprises can be avoided by intraoperative retinoscopy or hand-held autorefractors. These refractions should not be relied upon, however, for fine tuning the intraocular lens power, since there are many factors at surgery that may change in the

postoperative period. Factors such as the pressure from the lid speculum, axial position of the intraocular lens, intraocular pressure, etc. may cause the intraoperative refraction to be different than the final stabilized postoperative refraction. If the intraoperative refraction is within 2 D of the target refraction, no lens exchanges should be considered unless intraoperative keratometry can also be performed.

4.3.4 Postoperative Evaluation

4.3.4.1 Refraction on the First Postoperative Day

On the first postoperative day following cataract surgery, patients who previously have had RK usually have a hyperopic shift, similar to the first postoperative day following their RK. This phenomenon is primarily due to the transient corneal edema that usually exaggerates the RK effect. These patients also exhibit the same daily fluctuations during the early postoperative period after their cataract surgery as they did after the RK. Usually this daily shift is in a myopic direction during the day due to the regression of corneal edema after awakening in the morning [22]. Because the refractive changes are expected and vary significantly among patients, no lens exchange should be contemplated until after the first postoperative week or until after the refraction has stabilized, whichever is longer.

Very few results of cataract surgery following PRK and LASIK are available. In the few cases that have been performed, the hyperopic shift on the first day and daily fluctuations appear to be much less, similar to the early postoperative period following these procedures. In most cases the stability of the cornea makes these cases no different than patients who have not had keratorefractive surgery.

4.3.4.2 Long-term Results

Long-term results of cataract surgery following RK are very good. The long-term hyperopic shifts and development of against-the-rule astigmatism over time following cataract surgery should be the same as in the long-term studies following RK. The problems with glare and starburst patterns are usually minimal because the patients have had to adjust to these unwanted optical images following the initial RK. If the patient's primary complaint before cataract surgery is glare and starbursts, it should be made clear to him that only the glare due to the cataract will be removed by surgery, and the symptoms that are due to the RK will remain unchanged.

Long-term results following PRK and LASIK are non-existent. Since there are no signs of hyperopic drifts or development of against-the-rule astigmatism in the 5-year studies following PRK, one would not expect to see these changes. However, the early studies following RK did not suggest any of these long-term changes either. Only time will tell whether central haze, irregular astigmatism, etc. will be problems that develop in the future.

4.4 Patients with Previous Scleral Buckling and/or Silicone in the Vitreous Cavity

Patients who have undergone scleral buckling usually have an increase in their axial length by an average of 0.8 mm, which usually results in an approximate 2.4 diopter myopic shift. This value may range from 0 to 2.0 mm, depending on the location and tension on the encircling band. If no silicone oil has been placed in the vitreous cavity, measuring the axial length is no different than in patients with high myopia. Choosing the target postoperative refraction is also no different than for the normal patient, although

many of these patients prefer myopia since in many cases this has been the refraction most of their life.

If the patient does have a longer axial length in the eye with the scleral buckle, matching the refraction to the other eye will require a weaker power IOL. Although the patient may experience aniseikonia (image size disparity, larger in the eye with the buckle), he will usually adjust to this difference within 2–3 weeks. If the lens power is chosen to eliminate image size disparity by choosing a stronger lens to make the patient more myopic so that the spectacle has more minus, the image sizes are nearly the same (iseikonia). The problem is that the anisometropia (unequal refractive errors) induces a prism difference that causes diplopia when reading. The patient cannot adjust to the diplopia and either the spectacles must be slabbed off, a contact lens must be worn, a secondary piggyback IOL must be implanted, or a lens exchange must be performed.

If silicone has been placed in the vitreous cavity, the case becomes much more complex. An accurate axial length cannot be measured with silicone in the vitreous cavity. The oil is so dense that the ultrasound echoes rarely come from the retina because they are so attenuated. The measured axial length is far too short, even when the measurement is adjusted for the ultrasound speed in silicone oil. It is recommended that the axial length from the other eye be used in these cases and 0.8 mm added to this length of the cataractous eye if a scleral buckle has been performed. If both eyes have silicone in the vitreous cavity and preoperative axial lengths were not measured, one simply uses a standard lens power, adjusting up or down depending on the patient's most recent refraction before any surgery. Many retina surgeons are now measuring the axial length before using silicone oil to avoid this dilemma.

If the axial length is known in the eye with silicone, the IOL power can be determined in the normal manner, except for adjusting for the index of refraction difference between silicone and vitreous. It is recommended that convexo-plano IOLs be used in these cases to minimize the effect of the silicone reducing the effective power of the back surface of the IOL. When convexo-plano lenses are used, the average additional power required with silicone in the vitreous cavity is approximately 3–5 diopters. If a lens with power on the posterior surface is used, the required power is much greater and ranges from 5 to 10 diopters, depending on the power of the back surface.

An additional benefit of the convexo-plano lens is that it minimizes the change in refraction if the silicone oil is removed. It is best to leave the patient near plano if it is possible that the silicone IOL will be removed, since the shift when the oil is removed will always be in a myopic direction. The formulas for calculating the exact lens power, with an accurate axial length and silicone in the vitreous cavity, are too complex for this discussion, but several computer programs now have the appropriate formulas to perform this calculation exactly. Unfortunately, in many of these cases the best corrected vision is poor, making exact calculations resulting in very little additional benefit to the patient.

4.5 IOL Calculations Using K-readings and Preoperative Refraction

4.5.1 Formula and Rationale for Using Preoperative Refraction vs. Axial Length

In a standard cataract removal with IOL implantation, the preoperative refraction is not very helpful in calculating the power of the implant because the crystalline lens will be removed, so dioptric power is being removed and then replaced. In cases where no power is being removed from the eye, such as secondary implant in aphakia, piggyback IOL in pseudophakia or a minus IOL in the anterior

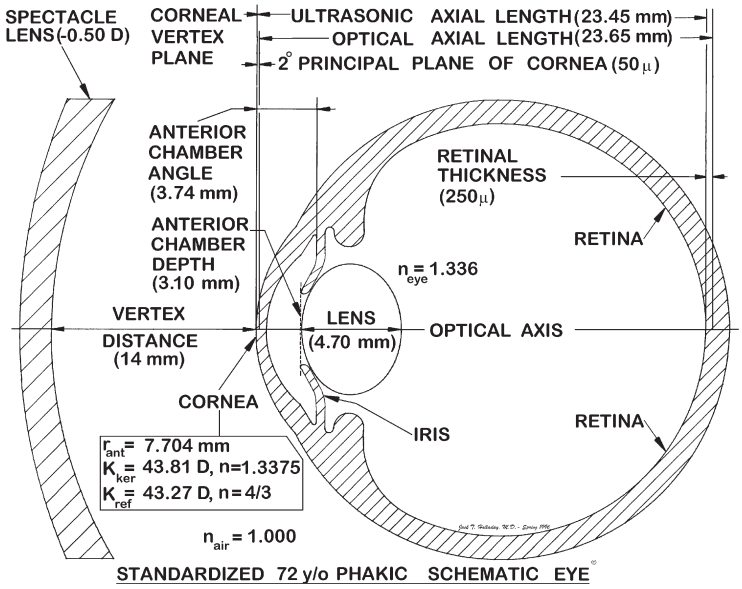


Fig. 4.1. Standardized 72 y/o phakic schematic eye

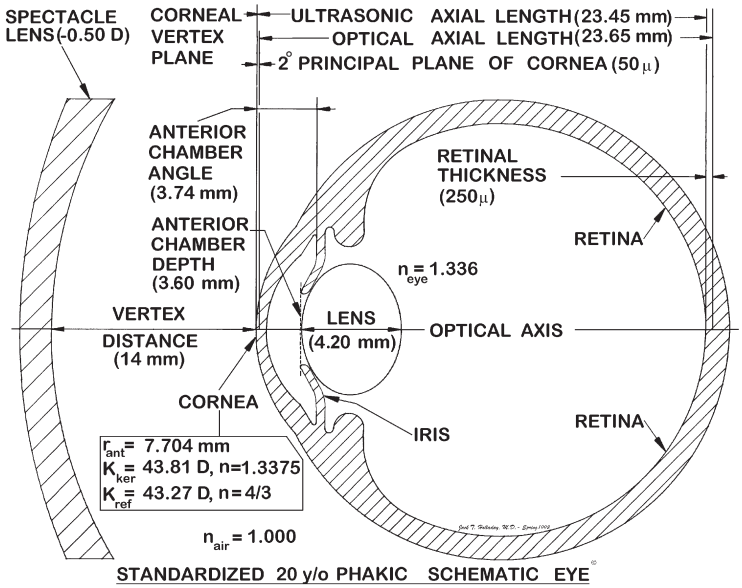


Fig. 4.2. Standardized 20 y/o phakic schematic eye

chamber of a phakic patient, the necessary IOL power for a desired postoperative refraction can be calculated from the corneal power and preoperative refraction – the axial length is not necessary. The formula for calculating the necessary IOL power is given below [23]:

$$IOL = \frac{1336}{\frac{1336}{\frac{1000}{\frac{1000}{PreRx} - V} + K} - ELP} - \frac{1336}{\frac{1336}{\frac{1000}{\frac{1000}{DPostRx} - V} + K} - ELP}$$

where ELP = expected lens position in mm (distance from corneal vertex to principal plane of intraocular lens), IOL = intraocular lens power in diopters, K = net corneal power in diopters, PreRx = preoperative refraction in diopters, DPostRx = desired postoperative refraction in diopters, and V = vertex distance in mm of refractions. The physical location of these variables is identical to those in Fig. 4.1. The standardized 20-year-old phakic schematic eye is shown in Fig. 4.2.

4.5.2 Example Cases Calculating the IOL Power from Preoperative Refraction

As mentioned above, the appropriate cases for using the preoperative refraction and corneal power include: (1) secondary implant in aphakia, (2) secondary piggyback IOL in pseudophakia and (3) a minus anterior chamber IOL in a high myopic phakic patient. In each of these cases, no dioptric power is being removed from the eye, so the problem is simply to find the intraocular lens at a given distance behind the cornea ELP that is equivalent to the spectacle lens at a given vertex distance in front of the cornea. If emmetropia is not desired, an additional term, the desired postoperative refraction (DPostRx), must be included. The formulas for calculating the predicted refraction and the back-calculation of the ELP are given in the reference and will not be repeated here [23].

4.5.2.1 Example: Secondary Implant for Aphakia

The patient is 72 years old and is aphakic in the right eye and pseudophakic in the left eye. The right eye can no longer tolerate an aphakic contact lens. The capsule in the right eye is intact and a posterior chamber intraocular lens is desired. The patient is –0.50 D in the left eye and would like to be the same in the right eye.

Mean keratometric K = 45.00 D

Aphakic refraction =
+12.00 sphere @ vertex of 14 mm

Manufacturer's ACD lens constant = 5.25 mm

Desired postoperative refraction = –0.50 D

Each of the values above can be substituted in the refraction formula above, except for the manufacturer's ACD and the measured K-reading. The labeled values on intraocular lens boxes are primarily for lenses implanted in the bag. Since this lens is intended for the sulcus, 0.25 mm should be subtracted from 5.25 mm to arrive at the equivalent constant for the sulcus. The ELP is therefore 5.00 mm. The K-reading must be converted from the measured keratometric K-reading (n = 1.3375) to the net K-reading (n = 4/3), for the reasons described previously under corneal topography. The conversion is performed by multiplying the measured K-reading by the following fraction:

$$Fraction = \frac{(4/3)-1}{1.3375-1} = \frac{1/3}{0.3375} = 0.98765$$

Mean refractive K =
mean keratometric K * fraction

Mean refractive K =
45.00 * 0.98765 = 44.44 D

Using the mean refractive K, aphakic refraction, vertex distance, ELP for the sulcus and the desired postoperative refraction, the pa-

tient needs a 22.90-D IOL. A 23-D IOL would yield a predicted refraction of –0.57 D [23].

4.5.2.2 Example: Secondary Piggyback IOL for Pseudophakia

In patients with a significant residual refractive error following the primary IOL implant, it is often easier surgically and more predictable optically to leave the primary implant in place and calculate the secondary piggyback IOL power to achieve the desired refraction. This method does not require knowledge of the power of the primary implant, nor the axial length. This method is particularly important in cases where the primary implant is thought to be mislabeled. The formula works for plus or minus lenses, but negative lenses are just becoming available at this time.

The patient is 55 years old and had a refractive surprise after the primary cataract surgery and was left with a +5.00-D spherical refraction in the right eye. There is no cataract in the left eye and he is plano. The surgeon and the patient both desire him to be –0.50 D, which was the target for the primary implant. The refractive surprise is felt to be from a mislabeled intraocular lens that is centered in-the-bag and would be very difficult to remove. The secondary piggyback intraocular lens will be placed in the sulcus. This is very important, since trying to place the second lens in-the-bag several weeks after the primary surgery is very difficult. More importantly, it may displace the primary lens posteriorly, reducing its effective power and leaving the patient with a hyperopic error. Placing the lens in the sulcus minimizes this posterior displacement.

Mean keratometric K = 45.00 D

Pseudophakic refraction =
+5.00 sphere @ vertex of 14 mm

Manufacturer's ACD lens constant =
5.25 mm

Desired postoperative refraction = –0.50 D

Using the same style lens and constant as the previous example and modifying the K-reading to net power, the formula yields a +8.64-D intraocular lens for a –0.50-D target. The nearest available lens is +9.0 D, which would result in –0.76 D. In these cases extreme care should be taken to assure that the two lenses are well centered with respect to one another. Decentration of either lens can result in poor image quality and can be the limiting factor in the patient's vision.

4.5.2.3 Example: Primary Minus Anterior Chamber IOL in a High Myopic Phakic Patient

The calculation of a minus or plus intraocular lens in the anterior chamber (ACL) or posterior chamber (intraocular contact lens – ICL) is no different than the aphakic calculation of an anterior chamber lens in a phakic patient, except the power of the lens is usually negative. Figure 4.3 illustrates the physical locations of these two types of phakic IOLs. In the past these lenses have been reserved for high myopia that could not be corrected by RK or PRK. Since most of these lenses fixate in the anterior chamber angle or front of the crystalline lens, concerns of iritis, glaucoma, cataract and pupillary block have been

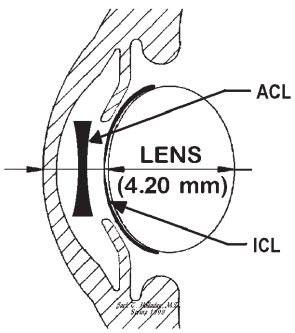


Fig. 4.3. Phakic anterior segment with ACL or ICL

raised. A more thorough discussion of the performance of these lenses follows under the next section on clinical results with phakic IOLs. Nevertheless, several successful cases have been performed with good refractive results. Because successful LASIK procedures have been performed in myopia up to –20.00 D, these lenses may be reserved for myopia exceeding this power in the future. Interestingly, the power of the negative anterior chamber implant is very close to the spectacle refraction for normal vertex distances.

Mean keratometric K = 45.00 D

Phakic refraction =
–20.00 sphere @ vertex of 14 mm

Manufacturer's ACD lens constant =
3.50 mm

Desired postoperative refraction = –0.50 D

Using an ELP of 3.50 and modifying the K-reading to net corneal power yields –18.49 D for a desired refraction of –0.50 D. If a –19.00-D lens is used, the patient would have a predicted postoperative D.

4.6 Clinical Results with Phakic IOLs

We have had the opportunity to evaluate several data sets for both anterior and posterior chamber IOLs. No significant surprises have occurred in the back-calculated constants for the phakic anterior chamber IOLs in that the lens constants are no different than those obtained with secondary anterior chamber implants in aphakia or pseudophakia (Fig. 4.3). The accuracy of the predicted refractions is very similar to that of standard IOL calculations from axial length in that more than 50 % of the cases result in a refraction that is within ±0.50 D. The number of cases with greater than a 2-D prediction error is virtually zero, as with calculations from axial length.

Intraocular contact lenses are different. Unlike anterior chamber phakic IOLs that have primarily biconcave optics, ICLs are meniscus in shape, like contact lenses (Fig. 4.3). The current prediction accuracy of these lenses is less than anterior chamber phakic IOLs. The exact reasons are unknown at this time, but most include parameters such as the meniscus shape, new index of refraction and possible interaction with the power of anterior crystalline lens.

In all of the data sets we have analyzed, the ICLs appear to perform consistently with 10–15 % less effective power than the labeled power, i. e. a lens labeled –20 D performs as if its power were –17 D. Although there are many plausible explanations for this finding, the exact cause is unknown at this time.

Some of the more obvious explanations would include the following. ICLs could have 15 % more power in vitro than in vivo. The most likely cause for this disparity would be a change in power at eye temperature (35 °C) versus room temperature (20 °C). A change in the index of refraction for silicone has been well demonstrated for standard biconvex IOLs [24]. A second possibility would be the change in shape of the lens, due to either temperature or osmotic differences from the test conditions that are used to verify the power of the lens.

An explanation that does not seem plausible is that the "tear meniscus" created between the ICL and the crystalline lens is a positive "meniscus lens", which would cancel some of the negative power of the ICL. Although this statement sounds plausible at first, it is not true. If we look at the surface powers of the ICL and the anterior surface of the crystalline lens when the lens is vaulted, we recognize that the anterior crystalline lens power remains the same no matter what the vaulting of the ICL. It is true that the vaulting should cause an increase in the posterior curvature of the ICL, which would result in more minus power, but the change in the positive front surface should be proportional, and the

net change in the total power should be zero. We know this is true for soft contact lenses where a –4.0-D soft contact lens provides the same –4 D of power on a flat or steep cornea, even though the overall curvature of the lens is different. The reason is that both surfaces change proportionately.

Another possibility is that the axial position of the ICL is much greater than that predicted preoperatively (it must be deeper than predicted to reduce the effective power of the lens). This possibility cannot explain a 15% difference, because the axial position would need to be more than 2 mm deeper to explain a 15% error. Postoperative A-scans and high-resolution B-scans have shown the exact position of the lens to be close to the anatomic anterior chamber depth, proving that the axial position of the lens is not the explanation.

In any case, back-calculated constants for the ICLs, using the phakic IOL formula above, result in lens constant ELPs that are 5.47–13.86 mm, even though the average measured ELP is 3.6 mm. In the data sets that we have analyzed, when the optimized back-calculated ELP is used, the mean absolute error is approximately 0.67 D, indicating that 50% of the cases are within ±0.67 D. This value is higher than the ±0.50 D typically found with standard IOL calculations following cataract surgery. The ICLs should be better than ACLs, since the exact location of the lens can be predicted from the anatomic anterior chamber depth preoperatively. This difference is puzzling, not only because of the better prediction of the ELP, but also because any errors in the measurement of the axial length are irrelevant because it is not used in the phakic IOL formula.

4.7 Bioptics (LASIK and ACL or ICL)

When patients have greater than 20 D of myopia, LASIK and ICLs have been used to achieve these large corrections. Although only a few cases have been performed by a few surgeons, the results have been remarkably good. The surgeon performs the LASIK first, usually treating 10–12 D of myopia, and waits for the final stabilized refraction. Once a postoperative stable refraction is attained, an ICL is performed to correct the residual myopia (e.g. 10–20 D). These patients are especially grateful, since glasses and contact lenses do not provide adequate correction and the significant minification of these corrections causes a significant reduction in preoperative visual acuity. Changing a 30-D myopic patient from spectacles to emmetropia with LASIK and ICL can increase the image size by approximately 60%. This would improve the visual acuity by slightly over two lines due to magnification alone (one line improvement in visual acuity for each 25% increase in magnification).

4.8 Conclusions Regarding Phakic Intraocular Lenses

Phakic IOLs are still in their adolescence. Power labeling issues, temperature-dependent index of refractions, changes in the meniscus shape and actual lens locations are being experimentally evaluated and are similar to the evolution of IOLs used following cataract surgery in the early 1980s. There is no question that our ability to predict the necessary phakic IOL power to correct the ametropia will improve, possibly exceeding the results with standard IOLs because of the more accurate prediction of the lens location axially. Determining the optimal vaulting and overall diameter to minimize crystalline lens contact, posterior iris contact and zonular, ciliary processes or sulcus contact are all being investigated at this time. These refinements are no different than the evolution in location from the iris, to the sulcus and finally the bag for standard IOLs. Because of our improved instrumentation with high-resolution B-scans, confocal microscopes, and ante-

rior segment laser imaging and slit scanning systems, these refinements should and will occur much more rapidly. The use of phakic IOLs will become more widespread as the current problems are solved and will begin to erode the percentage of patients who have LASIK because of the potential for better overall optical performance of the eye.

References

1. Holladay JT, Prager TC, Ruiz RS, Lewis JW (1986) Improving the predictability of intraocular lens calculations. Arch Ophthalmol 104: 539–541
2. Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS (1988) A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg 13:17–24
3. Fedorov SN, Kolinko AI, Kolinko AI (1967) Estimation of optical power of the intraocular lens. Vestnk Oftalmol 80:27–31
4. Fyodorov SN, Galin MA, Linksz A (1975) A calculation of the optical power of intraocular lenses. Invest Ophthalmol 14:625–628
5. Binkhorst CD (1972) Power of the prepupillary pseudophakos. Br J Ophthalmol 56:332–337
6. Colenbrander MC (1973) Calculation of the power of an iris clip lens for distant vision. Br J Ophthalmol 57:735–740
7. Binkhorst RD (1975) The optical design of intraocular lens implants. Ophthalmic Surg 6:17–31
8. Van der Heijde GL (1976) The optical correction of unilateral aphakia. Trans Am Acad Ophthalmol Otolaryngol 81:80–88
9. Thijssen JM (1975) The emmetropic and the iseikonic implant lens: computer calculation of the refractive power and its accuracy. Ophthalmologica 171:467–486
10. Fritz KJ (1981) Intraocular lens power formulas. Am J Ophthalmol 91:414–415
11. Holladay JT (1997) Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. J Cataract Refract Surg 23:1356–1370
12. Binkhorst RD (1981) Intraocular lens power calculation manual. A guide to the author's TI 58/59 IOL power module, 2nd edn. Binkhorst, New York
13. Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS (1988) A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg 14:17–24
14. Olsen T, Corydon L, Gimbel H (1995) Intraocular lens power calculation with an improved anterior chamber depth prediction algorithm. J Cataract Refract Surg 21:313–319
15. Holladay JT, Gills JP, Leidlein J, Cherchio M (1996) Achieving emmetropia in extremely short eyes with two piggyback posterior chamber intraocular lenses. Ophthalmology 103:1118–1123
16. Retzlaff JA, Sanders DR, Kraff MC (1990) Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16:333–340
17. Hoffer KJ (1993) The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cataract Refract Surg 19:700–712
18. Holladay JT, Lynn M, Waring GO, Gemmill M, Keehn GC, Fielding B (1991) The relationship of visual acuity, refractive error and pupil size after radial keratotomy. Arch Ophthalmol 109:70–76
19. Holladay JT (1989) IOL calculations following RK. Refract Corneal Surg J 5:203
20. Lowe RF, Clark BA (1973) Posterior corneal curvature. Br J Ophthalmol 57:464–470
21. Holladay JT, Rubin ML (1988) Avoiding refractive problems in cataract surgery. Surv Ophthalmol 32:357–360
22. Holladay JT (1992) Management of hyperopic shift after RK. Refract Corneal Surg J 8:325
23. Holladay JT (1993) Refractive power calculations for intraocular lenses in the phakic eye. Am J Ophthalmol 116:63–66
24. Holladay JT, van Gent S, Ting AC, Portney V, Willis T (1989) Silicone intraocular lens power versus temperature. Am J Ophthalmol 107: 428–429

5 IOL Calculations Following Keratorefractive Surgery

Douglas D. Koch, Li Wang

CORE MESSAGES

- Various methods have been developed to improve the accuracy of estimation of corneal refractive power and the appropriate use of corneal power in IOL calculation formulas.
- Methods for estimating corneal refractive power can be characterized according to whether or not prior historical data are required.
- Methods requiring prior historical data include the clinical history, adjusted effective refractive power, and Feiz-Mannis methods.
- Methods not requiring prior data include contact lens over-refraction and certain topographic measurements. For corneas that have undergone incisional refractive surgery, these topographic values can be used unmodified. For corneas that have undergone photorefractive keratectomy or laser-assisted in-situ keratomileusis, the modified Maloney method may be an excellent option.

Accurate intraocular lens (IOL) power calculation remains a challenge for lens surgery in eyes that have undergone previous keratorefractive surgery. There are two key issues: (1) The estimation of effective lens position (ELP) by the third- or fourth-generation formulas is not correct when the postoperative corneal power values are used [1, 2]; and (2). In a post-surgical cornea, the standard keratometry or computerized videokeratography (CVK) may not accurately measure the corneal curvature, and the calculation of corneal power from the anterior corneal measurement by using the standard effective refractive index of the cornea (1.3375) is not appropriate in eyes following procedures that remove corneal tissue (e.g., excimer laser photorefractive keratectomy [PRK] or laser-assisted in-situ keratomileusis [LASIK]).

5.1 Incorrect use of IOL Calculation Formulas

Most third- or fourth-generation IOL formulas use corneal power values to predict the ELP [3–5]. Following corneal refractive surgery, corneal power has been altered, so use of this value often leads to inaccurate prediction of ELP. For example, in eyes following myopic

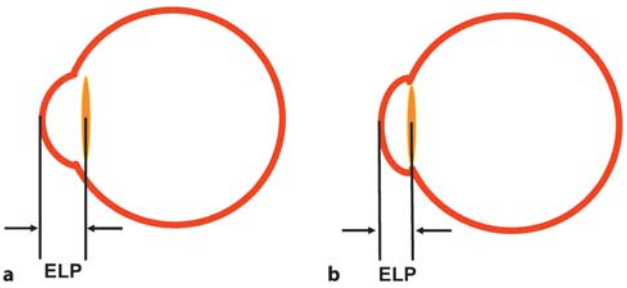


Fig. 5.1. Most third- and fourth-generation IOL formulas predict the effective lens position (ELP) using corneal power (**a**). If the flattened corneal power after myopic surgery is used, the predicted ELP will be anterior and lower IOL power will be predicted, resulting in postoperative hyperopia (**b**)

corneal refractive surgery, the ELP calculated with the flat postoperative corneal power values will be artificially low, thereby estimating that the IOL will sit more anteriorly; this results in implantation of a lower power IOL and a hyperopic postoperative refractive error (Fig. 5.1).

Aramberri [1] proposed a modified IOL formula, called double-K formula, in which the pre-refractive surgery corneal power is used to estimate the ELP and the post-refractive surgery corneal power is used to calculate the IOL power, in contrast with the traditional method in which one corneal power (the so-called single-K formula) is used for both calculations. Holladay had previously recognized this problem when developing the Holladay 2 formula. The magnitude of the error in predicting ELP depends on the IOL formula used, the axial length of the eye, and the amount of refractive correction induced by the refractive surgery. In general, the ELP-related IOL prediction errors are the greatest for the SRK/T formula, followed by Holladay 2, Holladay 1, and Hoffer Q formulas; this error decreases in long eyes and increases with increasing amount of refractive correction [2, 6].

In a previous study, we confirmed the greater accuracy of the double-K versions of three third-generation (SRK/T, Holladay 1 and Hoffer Q) and the Holladay 2 fourth-generation IOL calculation formulas, with decreased chances of hyperopic surprises [7]. Tables for performing double-K adjustments on third-generation formulas have been published [2]. The Holladay 2 permits direct entry of two corneal power values for the double-K calculation. If the corneal power value before refractive surgery is unknown, the "Previous RK, PRK..." box should be checked, which will instruct the formula to use 44 D as the default preoperative corneal value. Another option is to use the Haigis formula, which does not use the corneal power for ELP prediction [8].

5.2 Difficulties in Obtaining Accurate Corneal Refractive Power

Two factors cause the inaccurate estimation of corneal refractive power:

1. Inaccurate measurement of anterior corneal curvature by standard keratometry or CVK. Standard keratometry or simulated keratometry from CVK measures only four paracentral points or small regions. This is insufficient for the post-surgical cornea, which can have wide ranges of curvature even within the central 3-mm region (Fig. 5.2).
2. Inaccurate calculation of corneal refractive power from the anterior corneal curvature by using the standardized value for refractive index of the cornea (1.3375 in most keratometers and CVK devices). Based on the assumption that there is a stable ratio of anterior corneal curvature to posterior corneal curvature, the standardized index of refraction has been used

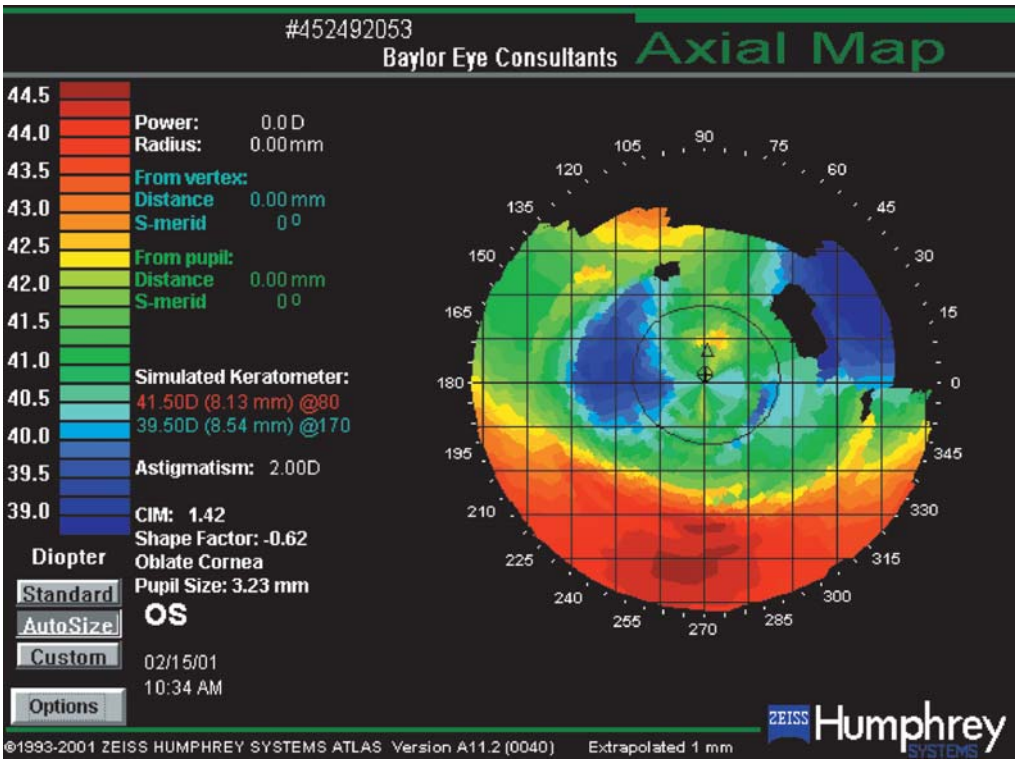


Fig. 5.2. In a post-surgical cornea, wider ranges of curvatures within the central region of the cornea are missed by the four points measured by simulated keratometry

to convert the measurements of anterior radius of curvature to an estimate of the total refractive power of the cornea. However, procedures that remove corneal tissue (e.g., PRK or LASIK) change the relationship between the front and back surfaces of the cornea, invalidating the use of the standardized index of refraction [9].

5.3 Methods to Calculate Corneal Refractive Power

Various methods have been proposed to improve the accuracy of corneal power estimation for IOL calculation in patients who have undergone corneal refractive surgery; these can be categorized according to whether or not they require data acquired before refractive surgery was performed (Table 5.1). These methods are obviously applicable to patients with cataracts and also patients scheduled to undergo refractive lens exchange. One potential advantage of the latter is that a cataract-induced refractive change has not occurred; this might facilitate a more accurate use of the clinical history method (see below).

5.3.1 Methods Requiring Historical Data

5.3.1.1 Clinical History Method

Required data: the keratometry values prior to corneal refractive surgery and the amount of refractive correction induced by the surgery.

Table 5.1. Methods proposed to improve the accuracy of calculating corneal refractive power in eyes following corneal refractive surgery

Historical data required	Methods and calculation
Keratometry values prior to corneal refractive surgery (K_{pre}) and Refractive correction induced by the surgery (RC)	Clinical history method: subtract RC from K_{pre} [10] Feiz-Mannis method[a]: calculate IOL power using K_{pre}, then add RC/0.7 [11]
Refractive correction induced by the surgery (RC)	Adjusted Eff RP: Eff RP–0.15 RC–0.05 (myopia) [9] Eff RP+0.16 RC–0.28 (hyperopia) [14] Adjusted AnnCP[b]: AnnCP+0.19 RC–0.40 (hyperopia) [14] Adjusted keratometry: keratometry–0.24 RC + 0.15 (myopia) [9]
None	Contact lens over-refraction: sum of contact lens base curve, power, and difference between refraction with and without a contact lens Eff RP: obtain from EyeSys device ACP[c]: obtain from TMS system Modified Maloney method: central power × (376/337.5)–6.1 [7] Correcting factors: apply correcting factors based on axial length of eye [21]

[a] Method proposed to improve the accuracy of IOL power estimation.
[b] Annular corneal power: average of curvatures at the center and the 1-, 2- and 3-mm annular zones from the numerical view map of Humphrey.
[c] Average central power within the entrance pupil from the TMS system.

Calculation: subtract the change in manifest refraction at the corneal plane induced by the refractive surgical procedure from the corneal power values obtained prior to refractive surgery.

This method was first proposed by Holladay [10] for the purpose of accurate corneal power estimation in cataract patients with previous corneal refractive surgery. Studies involving small numbers of eyes undergoing cataract surgery suggested that the clinical history method is in general an accurate method for calculating IOL power; however, unacceptably large refractive surprises have still occurred. To maximize its accuracy, the accurate historical data are mandatory, since a 1-D error in these data produce nearly a 1-D error in the postoperative refractive error.

5.3.1.2 Feiz-Mannis Method [11]

Required data: the keratometry values prior to corneal refractive surgery and the amount of correction induced by the surgery.

Calculation: first, one determines the IOL power as if the patient had not undergone corneal refractive surgery. IOL power is calculated using the corneal power values before surgery and the axial length measured just prior to lens extraction. To this value is added the surgically induced change in refractive error divided by 0.7.

This method avoids the problems of inaccurate corneal power measurement/calculation and ELP estimation when the postoperative keratometric values are used. Inconsistent performance of this method has

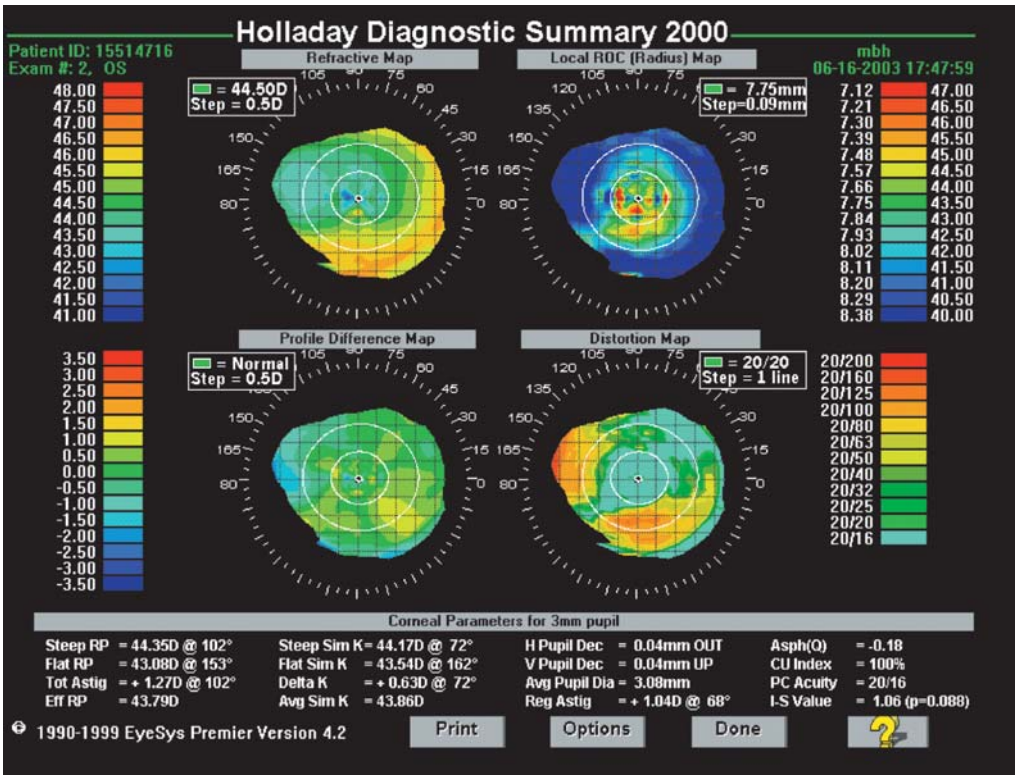


Fig. 5.3. Effective refractive power (Eff RP) displayed on the Holladay Diagnostic Summary of the EyeSys Corneal Analysis System

been reported due to the heavy dependence on reliable historical data and the use of the conversion factor of 0.7 [7, 12].

5.3.1.3 Modifying Values from CVK or Keratometry

Required data: the amount of surgically induced refractive correction (RC).

There are several approaches:

- Adjusted Eff RP: obtain the effective refractive power (Eff RP), which is displayed in the Holladay Diagnostic Summary of the EyeSys Corneal Analysis System (Fig. 5.3); it samples all points within the central 3-mm zone and takes into account the Stiles-Crawford effect [13]. The adjusted Eff RP (Eff RP_{adj}) can be obtained using the following formulas in eyes after myopic LASIK or hyperopic LASIK, respectively [9, 14]:

$$\text{Eff } RP_{adj} = \text{Eff RP} - 0.15\,RC - 0.05 \text{ (myopia)}$$

$$\text{Eff } RP_{adj} = \text{Eff RP} + 0.16\,RC - 0.28 \text{ (hyperopia)}$$

This method is primarily based on the corneal power measured at the time of the lens surgery, and is altered by only 0.15–0.16 D for every diopter of surgically induced refractive change. In 11 eyes of eight patients who had previously undergone myopic LASIK and subsequently phacoemulsification with implantation of the SA60AT IOLs by one surgeon, the variances of IOL power prediction error for Eff RP_{adj} were smaller than

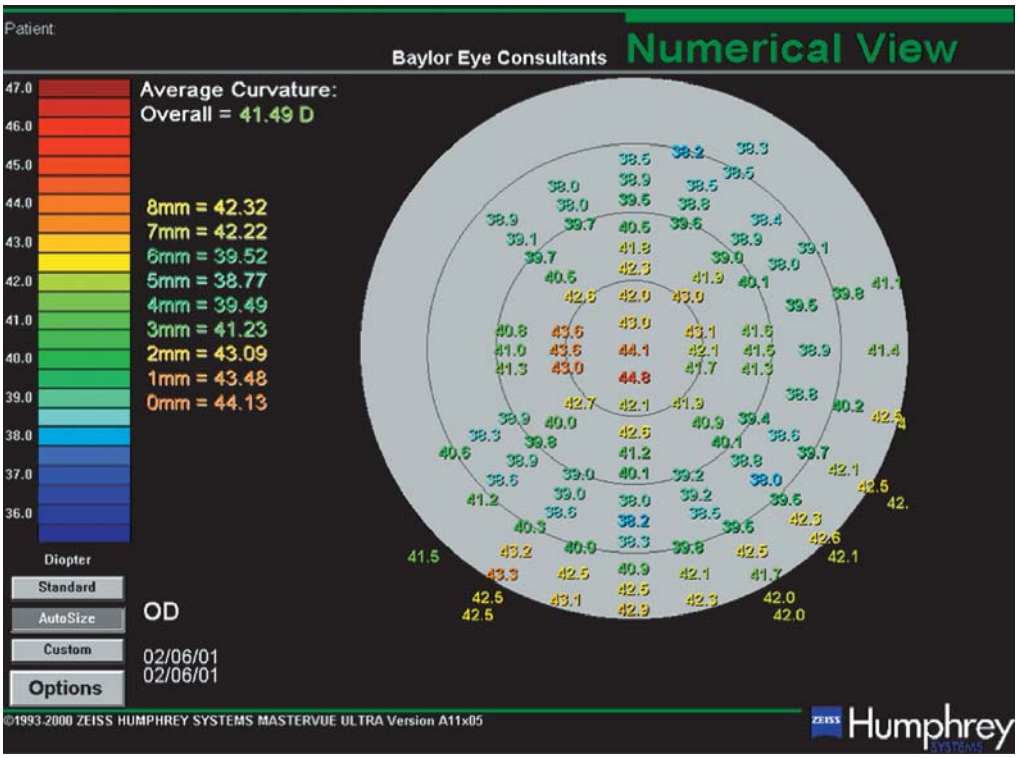


Fig. 5.4. Numerical view map from the Humphrey Atlas device

those for the clinical history method, indicating better prediction performance of the Eff RP_{adj} [7].

- Adjusted annular corneal power: some CVK devices provide values for corneal power at incremental annular zones. Modification of the average of curvatures from certain annular zones may improve the accuracy of corneal power estimation. Using the Humphrey Atlas device, in hyperopic LASIK eyes, the average of curvatures at the center and the 1-, 2- and 3-mm annular zones (AnnCP) from the numerical view map can be modified using the following formula (Fig. 5.4) [14]:

  Adjusted AnnCP =
  AnnCP + 0.19 RC – 0.4 (hyperopia)

  Further studies are needed to validate this method.
- Adjusted keratometry: if there is no CVK available, for myopic LASIK eyes, keratometric values may be used and modified as follows [9]:

  Adjusted keratometry =
  keratometry – 0.24 RC + 0.15 (myopia)

Randleman et al. [12] studied the results of cataract surgery in ten post-LASIK eyes and found that most accurate values were adjusted keratometry values in three of ten eyes, clinical history method also in three of ten eyes, and contact lens method in two of ten eyes.

5.3.2 Methods Requiring no Historical Data

5.3.2.1 Contact Lens Over-refraction

Using this method, the corneal power is calculated as the sum of the contact lens base curve, power, and the difference between manifest refraction with and without a contact lens.

Zeh and Koch evaluated this method in cataract patients who had normal corneas and found acceptable accuracy for eyes with Snellen visual acuity of 20/70 or better [15]. Unfortunately, this method appears to be less accurate in eyes that have undergone corneal refractive surgery. Presumably, this is due to the mismatch between the contact lens and the modified corneal shape. Our experience with this method has been disappointing, and this has been reflected in several other series as well [7, 16–18].

5.3.2.2 Mean Central Corneal Power from CVK

Certain CVK devices provide mean values for central corneal power, such as the Eff RP from the EyeSys device and the average central power within the entrance pupil from the TMS system [19]; these values overcome some of the limitations of using keratometric or simulated keratometric values and can be used in eyes that have undergone incisional keratorefractive surgery. However, they are inaccurate in post-PRK and post-LASIK eyes due to the above-mentioned inaccuracy of using 1.3375 as a standardized value for corneal refractive index [9]. In a recent study, Packer and colleagues [20] evaluated the efficacy of Eff RP in determining the central corneal power in IOL power calculation after incisional and thermal keratorefractive surgery. With the double-K Holladay 2 formula, they found that 80% of the eyes achieved postoperative refraction within ±0.50 D of emmetropia.

5.3.2.3 Modified Maloney Method

Maloney proposed a method of modifying the corneal power at the center of the Humphrey Atlas axial topographic map (Robert K. Maloney, personal communication, October 2002); we have modified it slightly based on our retrospective data [7]:

$$\text{Central power} = [\text{central topographic power} \times (376/337.5)] - 6.1$$

where central topographic power is simply the power with the cursor in the center of the topography map (Fig. 5.5). This method converts the corneal central power obtained from corneal topography back to the anterior corneal power, and then subtracts the posterior corneal power (6.1 D).

In a previous study, based on a retrospective study of 11 eyes that had previously undergone myopic LASIK and subsequently cataract surgery with implantation of the SA60AT IOLs by one surgeon [7], we found that the variances of the IOL prediction error for the Maloney method were significantly smaller than those by the clinical history method, indicating that, with appropriate modification, this method might provide more consistent results. Further studies are needed to validate this modified Maloney method.

5.3.2.4 Adjusting Corneal Power using a Correcting Factor

With assumption of axial myopia in most patients (i.e., amount of refractive correction is correlated to the axial length of eye), correcting factors were proposed to calculate corneal power according to the axial length of the eye [21]. Further studies are required to evaluate the accuracy of this method.

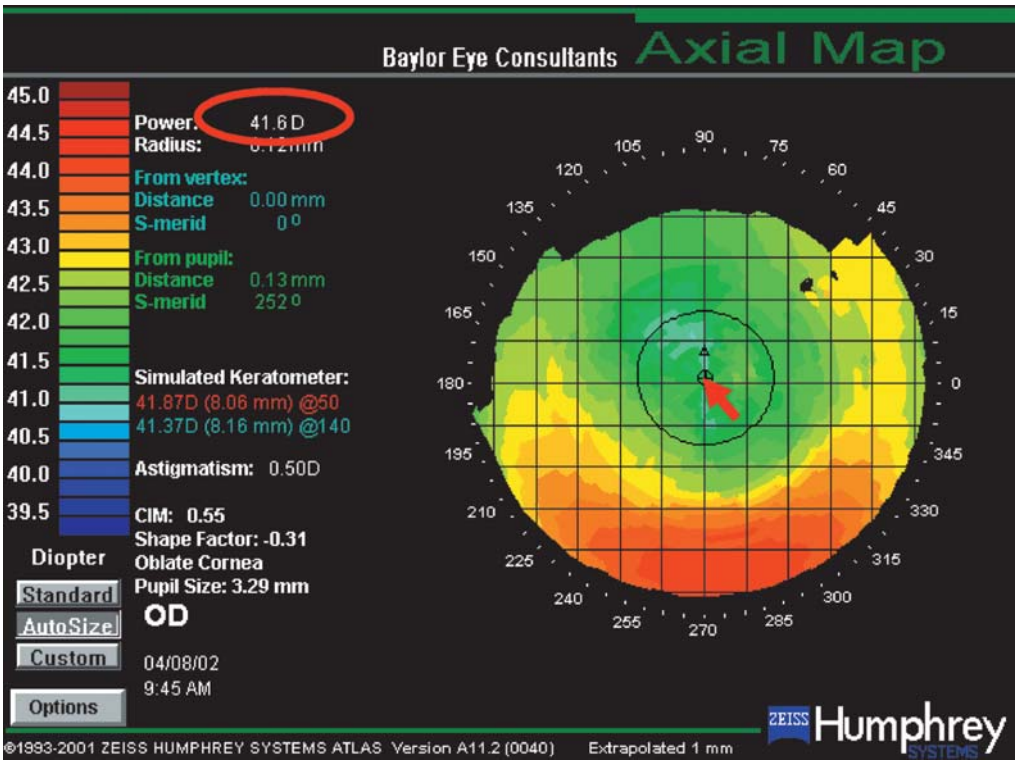


Fig. 5.5. Central topographic power obtained by putting the cursor in the center of the topography map

5.3.2.5 Direct Measurement using Orbscan Topography

Since the Orbscan system measures the anterior corneal surface, posterior corneal surface, and the thickness of the cornea, there is a potential use of the Gaussian optics formula to calculate the corneal refractive power after laser refractive surgery [22, 23]. Unfortunately, this has not proven to be sufficiently accurate. Srivannaboon et al. [22] reported that the standard deviations of differences between changes in refraction and changes in corneal power obtained from the Orbscan total optical power map were high (range: 1.16–1.85 D), with 95% of measurements accurate to within ±2.32 to ±3.7 D. Therefore, the use of Orbscan in this situation is not recommended.

5.4 Conclusion

Because of extremely high patient expectations, accurate IOL power calculation is especially critical in refractive lens exchange. Our current approach for IOL power calculation in these eyes is as follows:

1. Corneal power calculation:
   (a) In eyes that have undergone prior refractive keratotomy, use average central topographic values (e.g., Eff RP from EyeSys).
   (b) In eyes that have undergone PRK or LASIK:
      (i) Measure the central corneal power using the Humphrey device, and calculate the corneal power with the Modified Maloney method.
      (ii) Measure the Eff RP using the EyeSys system, and adjust it according to

the amount of refractive change induced by the surgery. If pre-LASIK/PRK data are available, calculate the corneal power using the clinical history method.

2. IOL power calculation:
   (a) Using the double-K Holladay 2 formula, calculate the IOL power using each of the three corneal powers obtained from the above methods.
   (b) Select the middle or the highest of the three IOL powers for implantation.

Despite our good outcomes to date, refractive surprises may still occur. Patients should be warned of the greater risk of unacceptably high postoperative myopia or hyperopia and the possible need for additional surgery, which could include corneal refractive surgical enhancement, IOL exchange, or piggyback IOL. Further studies are required in this field.

5.5 Case Sample

Pre-LASIK data:
- Pre-LASIK refraction: –8.50 D
- Pre-LASIK mean keratometry: 44.06 D

Post-LASIK data:
- Post-LASIK refraction: –0.50 D
- Eff RP: 38.82 D
- Central topographic power (Humphrey Atlas): 39.00 D
- Axial length: 25.24 mm

Post-cataract surgery data:
- An Alcon SA60AT lens with power of 23.5 D was implanted in this eye, and the spherical equivalent of the manifest refraction after cataract surgery was +0.125 D.

Corneal refractive power estimation:
Clinical history method:
- Pre-LASIK refraction at corneal plane (vertex distance: 12.5 mm):

  (–8.50) / {1–[0.0125*(–8.50)]} = –7.68 D
- Post-LASIK refraction at corneal plane:

  (–0.50) / {1–[0.0125*(–0.50)]} = –0.50 D
- LASIK-induced change in refraction:

  –0.50 – (–7.68) = 7.18 D

  Corneal power = 44.06 – 7.18=36.88 D

Contact lens over-refraction:
- Refraction without contact lens: –0.25 D
- Contact lens base curve: 37.75 D
- Contact lens power: +1.75 D
- Refraction with contact lens: –1.75 D

  Corneal power = 37.75 + 1.75 + [(–1.75) – (–0.25)] = 38.00 D

  Adjusted Eff RP:

  Adjusted Eff RP = 38.82 – 0.15 * 7.18 – 0.05 = 37.69 D

  Modified Maloney method:

  Corneal power = 39.00 * (376/337.5) – 6.1 = 37.35 D

IOL power calculation:
Using the double-K Holladay 2 formula (inserting the pre-LASIK K value into the formula for calculating the ELP), and refractive goal of +0.125 D, the calculated IOL powers for the Alcon SA60AT using different methods were as follows:
- Double-K clinical historical method: 24.42 D
- Double-K contact lens over-refraction: 23.01 D
- Double-K adjusted Eff RP: 23.54 D
- Double-K modified Maloney method: 23.94 D
- Feiz-Mannis method:
  IOL power using pre-LASIK K (aiming at refraction of +0.125 D): 14.55 D
  IOL power achieving refraction of +0.125 D after LASIK:

  14.55 + 7.18/0.7 = 24.81 D

IOL power prediction error using different methods (implanted – predicted):

- Double-K clinical historical method: –0.92 D
- Double-K contact lens over-refraction: 0.49 D
- Double-K adjusted Eff RP: –0.04 D
- Double-K modified Maloney method: –0.44 D
- Feiz-Mannis method: –1.31 D

References

1. Aramberri J (2003) IOL power calculation after corneal refractive surgery: the double-K method. J Cataract Refract Surg 29:2063–2068
2. Koch DD, Wang L (2003) Calculating IOL power in eyes that have undergone refractive surgery. J Cataract Refract Surg 29:2039–2042
3. Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS (1988) A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg 14:17–24
4. Hoffer KJ (1993) The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cataract Refract Surg 19:700–712
5. Retzlaff JA, Sanders DR, Kraff MC (1990) Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16:333–340
6. Koch DD, Wang L, Booth M (2004) IOL calculations after LASIK. In: Probst L (ed) LASIK – advances, controversies and custom, chap 22. Slack, Thorofare, NJ, pp 259–267
7. Wang L, Booth MA, Koch DD (2004) Comparison of intraocular lens power calculation methods in eyes that have undergone laser in-situ keratomileusis. Ophthalmology 111:1825–1831
8. Haigis W, Lege B, Miller N, Schneider B (2000) Comparison of immersion ultrasound biometry and partial coherence interferometry for intraocular lens calculation according to Haigis. Graefes Arch Clin Exp Ophthalmol 238:765–773
9. Hamed AM, Wang L, Misra M, Koch DD (2002) A comparative analysis of five methods of determining corneal refractive power in eyes that have undergone myopic laser in situ keratomileusis. Ophthalmology 109:651–658
10. Holladay JT (1989) Consultations in refractive surgery (letter). Refract Corneal Surg 5:203
11. Feiz V, Mannis MJ, Garcia-Ferrer F, Kandavel G, Darlington JK, Kim E, Caspar J, Wang JL, Wang W (2001) Intraocular lens power calculation after laser in situ keratomileusis for myopia and hyperopia: a standardized approach. Cornea 20:792–797
12. Randleman JB, Loupe DN, Song CD, Waring GO 3rd, Stulting RD (2002) Intraocular lens power calculations after laser in situ keratomileusis. Cornea 21:751–755
13. Holladay JT (1997) Corneal topography using the Holladay diagnostic summary. J Cataract Refract Surg 23:209–221
14. Wang L, Jackson DW, Koch DD (2002) Methods of estimating corneal refractive power after hyperopic laser in situ keratomileusis. J Cataract Refract Surg 28:954–961
15. Zeh WG, Koch DD (1999) Comparison of contact lens overrefraction and standard keratometry for measuring corneal curvature in eyes with lenticular opacity. J Cataract Refract Surg 25:898–903
16. Hoffer KJ (1995) Intraocular lens power calculation for eyes after refractive keratotomy. J Refract Surg 11:490–493
17. Haigis W (2003) Corneal power after refractive surgery for myopia: contact lens method. J Cataract Refract Surg 29:1397–1411
18. Argento C, Cosentino MJ, Badoza D (2003) Intraocular lens power calculation after refractive surgery. J Cataract Refract Surg 29:1346–5131
19. Maeda N, Klyce SD, Smolek MK, McDonald MB (1997) Disparity between keratometry-style readings and corneal power within the pupil after refractive surgery for myopia. Cornea 16:517–524
20. Packer M, Brown LK, Hoffman RS, Fine IH (2004) Intraocular lens power calculation after incisional and thermal keratorefractive surgery. J Cataract Refract Surg 30:1430–1434
21. Rosa N, Capasso L, Romano A (2002) A new method of calculating intraocular lens power after photorefractive keratectomy. J Refract Surg 18:720–724
22. Srivannaboon S, Reinstein DZ, Sutton HF, Holland SP (1999) Accuracy of Orbscan total optical power maps in detecting refractive change after myopic laser in situ keratomileusis. J Cataract Refract Surg 25:1596–1599
23. Sonego-Krone S, Lopez-Moreno G, Beaujon-Balbi OV, Arce CG, Schor P, Campos M (2004) A direct method to measure the power of the central cornea after myopic laser in situ keratomileusis. Arch Ophthalmol 122:159–166

6 Correction of Keratometric Astigmatism: Incisional Surgery

Louis D. Nichamin

CORE MESSAGES

- Options to reduce astigmatism include manipulation of the main incision, supplemental peripheral relaxing incisions, use of a toric IOL or Bioptics.
- Intralimbal relaxing incisions have proven to be a more forgiving approach to reducing astigmatism as compared to more centrally placed corneal relaxing incisions.
- Devising the surgical plan may be the most challenging aspect of limbal relaxing incision surgery, in that one often encounters difficulty obtaining consistent measurements of astigmatism.
- Incisions are usually placed at the start of surgery. A limbal orientation mark should be used to allow recognition of possible cyclotorsion of the eye.
- A keratorefractive enhancement following refractive lens exchange surgery can very effectively reduce residual refractive error.

6.1 Introduction

In recent years, managing pre-existing astigmatism at the time of cataract surgery has become an increasingly important facet of this extraordinary procedure. In the context of refractive lens exchange (RLE) surgery, this aspect of the procedure takes on a requisite and indispensable role. Indeed, the chasm dividing the fields of cataract and refractive surgery is now practically evanescent, and we may currently view lens extraction surgery as an amalgam of each. An increasing proportion of refractive surgical candidates, mostly of presbyopic age, are being treated more propitiously through a lenticular means as opposed to traditional keratorefractive surgery. Experience with corneal-based surgery has proven that levels of astigmatism no greater than 0.75 diopters (D) may leave a patient symptomatic with visual blur, ghosting and halos. In embracing lens exchange surgery, the surgeon should aspire to a level of refractive accuracy that we equate with current keratorefractive surgery. Fortunately, techniques have emerged that afford the refractive lens

surgeon the ability to reduce cylinder error effectively, safely, and reproducibly to acceptable levels of 0.50 D or less.

6.2 Surgical Options

Options to reduce astigmatism include manipulation of the main incision, supplemental peripheral relaxing incisions, use of a toric intraocular lens (IOL) or Bioptics. Limbal relaxing incisions (LRIs) are the most commonly employed approach and have proven to be safe, successful and cost-effective. Lens rotation with toric IOLs remains a consideration with their use. Bioptics with the excimer laser affords exquisite accuracy to reduce residual astigmatism and spherical error.

Several different approaches may be taken to reduce or eliminate pre-existing astigmatism either at the time of, or following lens exchange surgery. Perhaps the simplest method is to manipulate the main surgical incision in order to achieve a particular degree of astigmatic reduction. This is accomplished by centering the incision upon the steep corneal meridian (or positive cylinder axis) and then, by varying its size and design, one may effect a certain amount of wound flattening [1, 2]. This approach, however, presents logistical challenges, including movement around the surgical table, often producing awkward hand positions. In addition, varying surgical instrumentation may be required along with a dynamic mindset. For these reasons, this approach has largely been supplanted by other techniques, most notably through the use of additional relaxing incisions, as described in detail below.

Another viable means to reduce astigmatism is through the use of a toric IOL [3]. This option has the advantage of avoiding additional corneal surgery, at least for modest-to-moderate levels of cylinder, or may be combined quite effectively with additional keratorefractive techniques to reduce high levels of astigmatism [4]. This alternative, although effective, has seen somewhat limited acceptance, at least within the USA. This may be due to Food and Drug Administration (FDA) approval of only one toric implant thus far – a single-piece plate-haptic design comprised of an early-generation silicone elastomer with a relatively low index of refraction – a design that seems to have generated only modest interest at this time.

This particular implant, Staar Surgical's model AA-4203, is available in two toric powers of 2.0 and 3.5 D that will correct 1.4 and 2.3 D, respectively, at the corneal plane. The lens is manufactured in two overall lengths: the TF version, which is 10.8 mm and available in spherical powers of 21.5–28.5 D, and the TL version, which is 11.2 mm in length and runs from 9.5 up to 23.5 D. The most widely encountered problem with this device is postoperative rotation. Euler's theorem reminds us that axis misalignment of 5, 10, and 15 degrees will result in 17, 33, and 59% reduction, respectively, of surgical effect [5]. Reports of significant rotation with this implant vary from 9.2 to 18.9% [3, 6]. Optimal timing for repositioning would appear to be between 1 and 2 weeks postoperatively, just as capsular bag fibrosis is beginning to take place. The use of toric implants will likely increase as newer designs reach the marketplace.

An additional keratorefractive option to reduce astigmatism in association with implant surgery exploits the advanced technology of the excimer laser. This is generally performed subsequent to the lens exchange procedure, similar to its use with myopic phakic implants as first described by Zaldivar, and is now widely referred to as Bioptics [7]. More recently approved modalities such as conductive keratoplasty are now being studied in an off-label fashion to enhance both hyperopic spherical and astigmatic error [8].

6.3 Limbal Relaxing Incisions

Intralimbal relaxing incisions have proven to be a more forgiving approach to reducing astigmatism as compared to more centrally placed corneal relaxing incisions. Advantages include less axis shift, less tendency to induce irregular astigmatism, less discomfort, and they are technically easier to perform. No change in IOL power is needed when these peripheral incisions are used.

The notion of combining astigmatic relaxing incisions with implant surgery dates back to the mid-1980s [9, 10]. Originally, advocates for these corneal incisions generally recommended an optical zone of approximately 7 mm. Although effective, this form of astigmatic keratotomy carried with it some risk, most significantly that of induced irregular astigmatism. In recent years, many authors have recommended shifting these adjunctive incisions out to the peripheral cornea or limbal region [11]. It has been this author's experience that these (intra-) LRIs are a more forgiving approach to astigmatism reduction [12].

Specifically, LRIs are less likely to cause a shift in the resultant cylinder axis. This is presumably due to a reduced need to center the incision precisely upon the steep meridian. Perhaps more importantly, there is less of a tendency to cause irregular flattening, and hence induce irregular astigmatism. Technically, LRIs are less demanding to perform than shorter and more central corneal astigmatic incisions, and patients generally report less discomfort and enjoy a quicker recovery of vision.

An additional advantage gained by moving out toward the limbus concerns the "coupling ratio", which describes the amount of flattening that is induced in the incised meridian relative to the amount of steepening that occurs 90 degrees away. LRIs, in this author's experience, exhibit a very consistent 1:1 ratio and, as such, have no significant effect on the spheroequivalent, thus obviating the need to adjust the IOL power. Admittedly, these more peripheral incisions are less powerful, but are still capable of correcting up to 2.5–3.5 D of astigmatism in the presbyopic-age population – those most likely to be undergoing RLE surgery. In addition, one must keep in mind that the overall goal is to reduce the patient's cylinder, without overcorrecting or shifting the resultant axis.

6.3.1 Incision Decisions

Devising the surgical plan may be the most challenging aspect of LRI surgery, in that one often encounters difficulty obtaining consistent measurements of astigmatism. Historically, standard keratometry has been most widely used, and still, in general, reliably determines the cylinder axis. Refraction may show a different quantity of astigmatism, and a compromise between measurements is often needed. Modern topography is increasingly used to determine both the location and extent of the incisions. When combined with RLE, adjusted blade depth settings are employed based upon pachymetry readings.

The first decision faced by the surgeon is whether to address pre-existing astigmatism at the time of implantation or to defer and treat the cylinder separately. One could argue that for the highest level of accuracy, sufficient time for wound healing should take place and a stable refraction ought to be documented prior to astigmatic correction. Given the widespread use today of foldable implants that permit insertion through unenlarged phacoemulsification incisions, surgeons may reproducibly achieve nearly neutral and stable astigmatic outcomes [13, 14]. Most surgeons therefore favor concomitant treatment, most often with LRIs, and thereby spare both patient and surgeon the requirement of a second procedure.

When devising the surgical plan, most authors would err on leaving a small amount of residual with-the-rule cylinder, knowing

Table 6.1. The Nichamin age- and pach-adjusted (NAPA) nomogram: intralimbal arcuate astigmatic nomogram

"With-the-rule"				
preoperative cylinder (diopters)	Paired incisions in degrees of arc			
	20–30 years	30–40 years	40–50 years	50–60 years
0.75	40	35	35	30
1.00	45	40	40	35
1.25	55	50	45	40
1.50	60	55	50	45
1.75	65	60	55	50
2.00	70	65	60	55
2.25	75	70	65	60
2.50	80	75	70	65
2.75	85	80	75	70
3.00	90	90	85	80
"Against-the-rule"				
Preoperative cylinder (diopters)	Paired incisions in degrees of arc			
	20–30 years	30–40 years	40–50 years	50–60 years
0.75	45	40	40	35
1.00	50	45	45	40
1.25	55	55	50	45
1.50	60	60	55	50
1.75	65	65	60	55
2.00	70	70	65	60
2.25	75	75	70	65
2.50	80	80	75	70
2.75	85	85	80	75
3.00	90	90	85	80

When placing intralimbal relaxing incisions following or concomitant with radial relaxing incisions, total arc length is decreased by 50%.

that most patients will gradually drift toward against-the-rule cylinder over their lifetime. Our preferred nomogram, therefore, differs and is more conservative for the correction of with-the-rule versus against-the-rule cylinder (Table 6.1). Of course, when planning surgery one must also take into consideration the status of the fellow eye, but in the setting of lens exchange surgery, presumably both eyes will be treated for the maximal reduction of pre-existing astigmatic error.

Perhaps the most challenging aspect of astigmatism surgery is in determining the quantity and exact location of the preoperative cylinder to be corrected. Unfortunately, preoperative measurements – keratometry, refraction, and topography – do not always agree. Lenticular astigmatism likely accounts

for some of this disparity; however, our experience supports the notion that traditional measurements of astigmatism using standard keratometry (only two points measured in each meridian at a single paracentral optical zone) may not adequately describe the amount of astigmatism that is present. We do feel that keratometry tends to provide an accurate determination of the axis, but that refraction in many cases yields a more reliable indicator of the quantity of cylinder. Admittedly, this last supposition is debated among different authors.

When confounding measurements do arise, one can compromise and average the disparate readings, or consider deferring the astigmatic surgery until after the implant procedure, at which time more consistent measurements might be obtainable. Corneal topography is particularly helpful when there are such disputes, and is increasingly relied upon as the "tie-breaker" and ultimate determinate of the surgical plan. In addition, topography will not infrequently detect subtle underlying pathology such as irregular astigmatism attributable to anterior basement membrane dystrophy, or keratoconus fruste, which would contraindicate the use of relaxing incisions.

Once the amount of astigmatism to be corrected is determined, a nomogram is consulted to develop the definitive surgical plan. Table 6.1 depicts our nomogram of choice when performing LRIs in conjunction with RLE surgery. One simply aligns the patient's age in one column with the amount of desired cylinder correction in the opposite column. As opposed to our slightly more conservative nomogram, which is used at the time of cataract surgery with typically older patients [15, 16], the NAPA nomogram employs pachymetry readings and adjustable blade settings. This extra detail lends slightly more accurate outcomes, which would seem to be justified when performing RLE surgery. One takes ultrasound pachymetry measurements over the entire extent of the intended incision, just inside of the surgical limbus, and an adjustable micrometer blade is then set at 90% of the thinnest reading obtained. Alternatively, one could utilize an empiric blade depth setting such as 600 microns, as is common practice at the time of cataract surgery, but a modest undercorrection should be expected. Exact results will depend upon the design of the blade and how "aggressively" it cuts; our preference is for high-grade diamond knives that have been specifically designed for this application. Incisions are always placed as opposing pairs to optimize symmetric corneal flattening, and expressed in degrees of arc rather than millimeters, as corneal diameter may significantly impact the relative length of the arcuate incision and its resultant effect (Fig. 6.1).

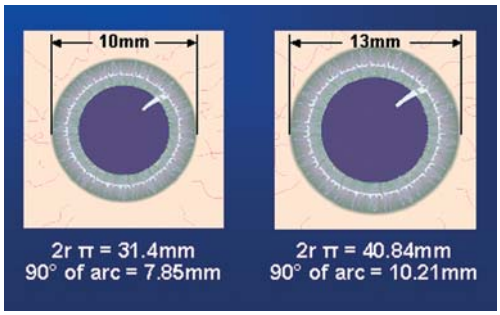


Fig. 6.1. Nomogram design: note relative disparity in incision length between a large and small corneal diameter if measured in millimeters. Degrees of arc lend consistency irrespective of corneal size

This nomogram may be used in conjunction with any modern phacoemulsification incision, but one must know the exact astigmatic effect of the incision, whether it is clear cornea, a scleral tunnel, or even bimanual micro-incisions, and factor this potential variable into the surgical plan. Our preference is always to operate temporally and to utilize a single-plane, paracentesis-like clear corneal phacoemulsification incision, as first advocated by Dr. I. Howard Fine, with either coaxial or bimanual instrumentation. When the final incision size is maintained at or less than

3.2 mm, its negligible astigmatic effect may be ignored. The LRIs are then superimposed where needed, upon the steep corneal meridian.

6.3.2 Surgical Technique

Incisions are usually placed at the start of surgery. A limbal orientation mark should be used to allow recognition of possible cyclotorsion of the eye. Intraoperative keratoscopy further helps to confirm the proper meridian for incision placement. Incisions are placed at the peripheral-most extent of clear corneal tissue. In making the incision, the blade should be kept perpendicular to the corneal surface.

6.3.2.1 When?

Many surgeons prefer to place all astigmatic relaxing incisions at the conclusion of surgery in the event that a complication necessitates a modification to the incision plan. Our preference is to place all incisions at the outset in order to avoid epithelial disruption, with one exception: in the case of high against-the-rule astigmatism wherein the nomogram calls for a temporal arcuate incision of greater than 40 degrees. This temporal arc, when superimposed upon the phacoemulsification incision, in essence, becomes a "deep groove." If its arc length exceeds 40 degrees, one is likely to encounter significant wound gape and edema secondary to intraoperative instrument manipulation. In this situation, the temporal incision is made by first creating a two-plane, grooved phacoemulsification incision (the depth of which is determined by pachymetry as described above), which is later extended to its full arc length, as determined by the nomogram, near the end of the case. I favor lengthening the incision just prior to implant insertion, following instillation of viscoelastic, since the globe will be firm at this point and little additional wound manipulation is expected. The corresponding nasal arc may be extended to its full arc length at the beginning of the case. When the LRI is superimposed upon the phacoemulsification incision, the keratome entry is achieved by pressing the bottom surface of the keratome blade downward upon the outer or posterior edge of the LRI. The keratome is then advanced into the LRI at an iris-parallel plane. This angulation will allow the keratome to enter at mid-stromal depth.

6.3.2.2 Where?

Although still debated, most authors agree that cyclotorsion is possible upon assuming a supine position; therefore, an orientation mark is placed at the 6:00 limbus while the patient is upright. A meridian gauge (Mendez, Nichamin or Dell) may then be aligned to this mark for proper identification of the intended, steep meridian to be incised. We also utilize some type of intraoperative keratoscopy to help confirm the location of the steep meridian. This may be in the form of a simple hand-held device (Maloney or Nichamin) or a more sophisticated lighted device that is mounted to the operating microscope, such as Mastel Precision's Ring of Light. When assessing the corneal mire, the steep meridian over which the incisions are centered corresponds to the shorter axis of the elliptical mire.

The exact placement of the incision should be at the peripheral-most extent of clear corneal tissue, just inside of the true surgical limbus, irrespective of the presence of vessels or pannus. If bleeding is encountered, it may be ignored and will stop spontaneously. Care must be taken not to place the incisions out at the true (gray-to-blue) surgical limbus in that a significant reduction in effect will occur. As noted, our preference is to utilize a diamond blade specifically designed for this technique

Fig. 6.2. Mastel Precision's latest adjustable micrometer and single footplate diamond knife is ideal for LRIs in conjunction with RLE surgery. The blade depth is set at 90% of the thinnest pachymetry reading obtained over the length of the incision

such as that manufactured by Mastel Precision (Fig. 6.2). Similar designs are available from Rhein Medical, Storz, ASICO and other manufacturers. A knife that has a single footplate is preferred in order to improve visualization.

6.3.2.3 How?

First and foremost, accurate centration of incisions over the steep meridian must take place to achieve optimal results. Working off of the pre-placed limbal orientation mark, one of several different degree gauges may be used to mark the steep meridian. The extent of arc to be incised may also be demarcated in several different ways. Various press-on markers are available that will not only

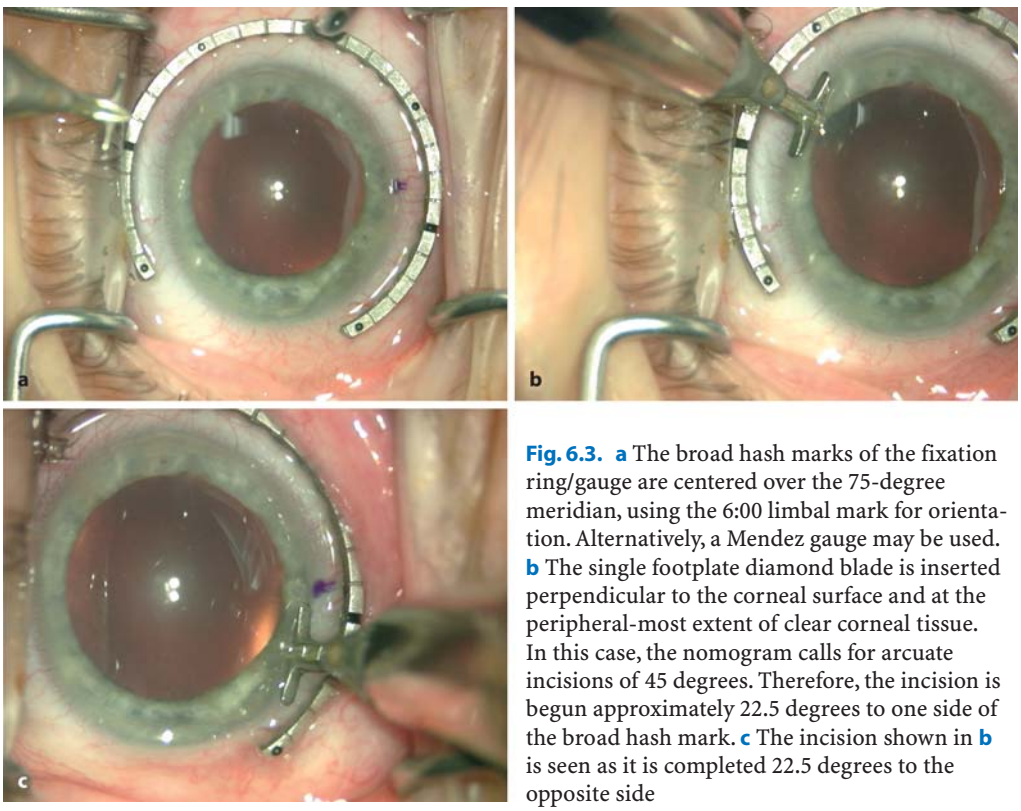


Fig. 6.3. **a** The broad hash marks of the fixation ring/gauge are centered over the 75-degree meridian, using the 6:00 limbal mark for orientation. Alternatively, a Mendez gauge may be used. **b** The single footplate diamond blade is inserted perpendicular to the corneal surface and at the peripheral-most extent of clear corneal tissue. In this case, the nomogram calls for arcuate incisions of 45 degrees. Therefore, the incision is begun approximately 22.5 degrees to one side of the broad hash mark. **c** The incision shown in **b** is seen as it is completed 22.5 degrees to the opposite side

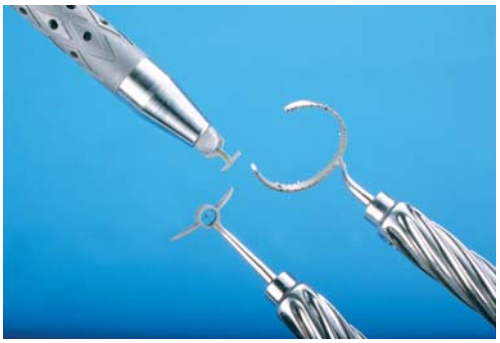


Fig. 6.4. The Nichamin modified Fine-Thornton fixation ring, diamond blade, and two-cut RK marker that can be used to mark and delineate the extent of the relaxing incisions

demonstrate the extent of the incision, but may also serve as a visible guide or stencil for the incision (Rhein Medical, Mastel Precision, ASICO). My preferred method, however, makes use of a specifically modified Fine-Thornton fixation ring that both serves to fixate the globe and allows one to delineate the extent of arc by visually extrapolating from the limbus where the incision is being made to marks upon the adjacent fixation ring (Mastel Precision, Rhein Medical, and Storz) (Fig. 6.3a–c). Each incremental mark on the surface of the ring is 10 degrees apart, and bold hash marks located 180 degrees opposite each other serve to align with the steep meridian. This approach avoids inking and marking of the cornea. If desired, a two-cut RK marker may be used to mark the exact extent of arc to be incised in conjunction with the fixation ring/gauge (Fig. 6.4).

When creating the incision, it is important to maintain a perpendicular relationship between the blade and the surface of the cornea. This will prevent wound gape and lead to a more consistent incision depth. The knife should be held between thumb and index finger, as if one were throwing a dart, thus allowing rotation of the knife handle as it is being advanced, thereby facilitating an arcuate path. A moistened corneal surface will help to prevent epithelial drag and abrasions.

6.3.3 Complications of LRIs

CORE MESSAGES

- Avoid operating on the wrong axis!

Strong consensus exists for the safety and efficacy of LRIs, especially when compared to astigmatic keratotomies placed at a smaller optical zone. Nonetheless, potential for problems will always exist, and several are listed below: infection, weakening of the globe, perforation, decreased corneal sensation, induced irregular astigmatism, misalignment/axis shift, wound gape and discomfort, and operating on the wrong (opposite) axis. Of these, operating on the wrong axis is likely to be the most common error experienced. When this complication is encountered, it typically takes the form of a "90-degree" mistake with the incisions being centered upon the opposite, flat meridian. This, of course, leads to an increase and probable doubling of the patient's pre-existing cylinder. Compulsive attention is needed in this regard, with safety checks such as clear written plans being available within the operating room for reference and, as mentioned, confirmation of the steep meridian through the use of intraoperative keratoscopy. Incisions are centered upon the plus (+) cylinder axis, and opposite the minus (–) cylinder axis.

6.4 Bioptics

A keratorefractive enhancement following RLE surgery can very effectively reduce residual refractive error. Laser-assisted in-situ keratomileusis (LASIK) is most commonly used, but other techniques may be utilized. This possibility should be discussed with the patient prior to RLE surgery.

The term Bioptics, as first coined by Zaldivar, originally referred to the use of LASIK

as an enhancement tool following myopic phakic IOL surgery. It has now come to be more generally applied to any combination of lenticular and keratorefractive surgery. Not long after Zaldivar's first description of this technique, many surgeons began to utilize LASIK to refine the refractive outcome following pseudophakic surgery [17]. Given the exquisite accuracy of excimer technology, the surgeon – through this combined approach – now has the potential essentially to eliminate any or all residual spherical or astigmatic error.

There are, however, logistic, economic and safety issues that arise when considering Bioptics. The most obvious is that a second operation is being performed, and patients should be made aware of this possibility preoperatively. In so doing, the patient's understanding and acceptance of the lack of perfect refractive predictability with RLE should be heightened. In fact, many patients find it reassuring that there are additional ways to refine the refractive result should the RLE not result in the desired outcome. This holds true for surgeon as well.

Typically, there is additional cost associated with Bioptics; however, most practices tend to lower their standard fee for LASIK given the out-of-pocket cost of RLE surgery. All of the attendant risks of excimer surgery must be considered and shared with the patient, but it has been our experience that no additional risk seems to be associated with LASIK when it is performed after IOL surgery. Our initial protocol was similar to that of Zaldivar wherein the LASIK flap was created prior to the implant surgery. The flap was later lifted and ablation performed as necessary. It quickly became evident that many unnecessary flaps were being created in that laser enhancement following RLE was needed in less than 10% of cases. We now perform LASIK (flap and ablation) 6 weeks after RLE surgery, and we have experienced no IOL incision-related complications. The LASIK flap may still be safely cut even if LRIs were incorporated into the RLE operation. Surface ablation or laser epithelial keratomileusis certainly are viable options as well should there be a contraindication for LASIK. One could further argue that this is an ideal setting for wavefront-guided custom ablation since the dynamic crystalline lens has been removed, and the optics and aberrations of the eye should remain stable henceforth.

Conductive keratoplasty (CK) is a contact radio frequency-based technology that is currently FDA-approved for the treatment of low levels of hyperopia (0.75–3.0 D) and for the temporary treatment of presbyopia. CK has been effectively utilized "off-label" to treat residual hyperopia and hyperopic astigmatism following IOL surgery [8]. It is also useful in those patients who initially opt for emmetropia in each eye, but later desire better uncorrected vision in one eye. The simplicity, safety and lower cost of this technology have made CK an important option in our Bioptics protocol.

6.5 Conclusion

Astigmatism management in association with refractive lens surgery plays a vital and requisite role, and may determine its ultimate success. For optimal uncorrected visual function, the surgeon's goal is to reduce pre-existing cylinder to a level of less than 0.75 D. LRIs are a relatively simple, safe and cost-effective way in which this may be achieved. Toric IOLs are another viable option. Manipulation of the implant incision may also reduce pre-existing astigmatism, but is currently a less favored approach. Bioptics, utilizing the excimer laser, is a very accurate way in which both astigmatism and spherical error may be reduced or eliminated following RLE surgery. Low levels of residual hyperopia and hyperopic astigmatism may also be treated through the off-label use of conductive keratoplasty.

References

1. Anonymous (1991) Small incision surgery: wound construction and closure. J Cataract Refract Surg 17 (Suppl):653–748
2. Kohnen T, Koch DD (1996) Methods to control astigmatism in cataract surgery. Curr Opin Ophthalmol 7:75–80
3. Sun XY, Vicary D, Montgomery P et al (2000) Toric intraocular lenses for correcting astigmatism in 130 eyes. Ophthalmology 107:1776–1781
4. Gills JP (2002) Treating astigmatism at the time of cataract surgery. Curr Opin Ophthalmol 13:2–6
5. Abrams D (1970) Ophthalmic optics and refraction. In: Duke-Elder S (ed) System of ophthalmology. Mosby, St Louis, MO, pp 671–674
6. Ruhswurm I, Scholz R, Zehetmayer M et al (2000) Astigmatism correction with a foldable toric intraocular lens in cataract patients. J Cataract Refract Surg 26:1022–1027
7. Zaldivar R, Davidorf JM, Oscerow S et al (1999) Combined posterior chamber phakic intraocular lens and laser in situ keratomileusis: bioptics for extreme myopia. J Refract Surg 15:299–308
8. Nichamin LD (2002) Advanced applications of conductive keratoplasty. Paper presented at the annual meeting of the American Academy of Ophthalmology. Orlando, FL
9. Osher RH (1984) Annual meeting of the American Intraocular Implant Society
10. Maloney WF (1986) Refractive cataract replacement: a comprehensive approach to maximize refractive benefits of cataract extraction. Paper presented at the annual meeting of the American Society of Cataract and Refractive Surgery. Los Angeles, CA
11. Budak D, Friedman NJ, Koch DD (1998) Limbal relaxing incisions with cataract surgery. J Cataract Refract Surg 24:503–508
12. Nichamin LD (2000) Changing approach to astigmatism management during phacoemulsification: peripheral arcuate astigmatic relaxing incisions. Paper presented at the annual meeting of the American Society of Cataract and Refractive Surgery. Boston, MA
13. Lyle QA, Jin G (1996) Prospective evaluation of early visual and refractive effects with small clear corneal incisions. J Cataract Refract Surg 22:1456–1460
14. Masket S, Tennen DG (1996) Astigmatic stabilization of 3.0 mm temporal clear corneal cataract incisions. J Cataract Refract Surg 22:1451–1455
15. Nichamin LD (2004) Astigmatism management at the time of cataract surgery. In: Krachmer JH, Mannis MJ, Holland EJ (eds) Cornea, 2nd edn, chap 165. Mosby, St Louis, MO, pp 7–11
16. Nichamin LD (2003) Management of astigmatism in conjunction with clear corneal phaco surgery. In: Gills JP (ed) Complete surgical guide for correcting astigmatism: an ophthalmic manifesto. Slack, Thorofare, NJ, pp 41–47
17. Nichamin LD (2001) Correspondence: expanding the role of bioptics to the pseudophakic patient. J Cataract Refract Surg 9:1343–1344

7 Correction of Keratometric Astigmatism: Staar Toric IOL Refractive Lens Surgery

Stephen Bylsma

Financial interest: Dr. Bylsma is a consultant to Staar Surgical Company.

CORE MESSAGES

- Clinically significant corneal astigmatism is encountered frequently by the refractive lens surgeon.
- Off-axis rotation of a toric IOL will decrease the desired astigmatic correction in proportion to the magnitude of deviation.
- The Staar toric IOL has been widely studied, with the reports showing a consistent, predictable effect of reduction of preoperative refractive cylinder for the group of eyes studied.

7.1 Introduction

Successful refractive surgery must correct clinically significant preoperative astigmatism to reach the goal of emmetropia [1]. Refractive lens surgery, using either clear lens extraction or cataract surgery, is a unique form of refractive surgery in that one of the two refractive components of the eye that produce astigmatism is completely replaced. In the straightforward case when pre-existing astigmatism is purely lenticular, a spherical intraocular lens (IOL) will restore emmetropia from the aphakic state. However, refractive lens surgeons more commonly encounter patients in whom significant corneal asymmetry is the primary cause for astigmatism. In these cases, a spherical IOL alone will not suffice; alternative or adjunctive treatments are required to reach emmetropia in the presence of significant corneal astigmatism.

Clinically significant corneal astigmatism is encountered frequently by the refractive lens surgeon. Astigmatism has been reported to occur in 14–37% of adults [2–5]. One large study of refractive errors measured a mean refractive cylinder of ≥0.75 D in 37% and ≥1.5 D in 13% of 3,654 individuals between 49 and 97 years old, with an age-dependent increase in the mean refractive cylinder from −0.6 D in those less than 60 years old to −1.2 D for those above 79 years old [5]. The modest difference between the incidences of refractive errors found in other population-based studies is likely due to a difference in the mean age of each study [6].

Corneal astigmatism may be surgically reduced by two differing approaches: optical correction versus tissue (structural) treatment. Optical correction employs an inert, manufactured optic (toric IOL) to correct simultaneously both the spherical and astigmatic refractive error components of the

aphakic state. In contrast, tissue-directed treatments such as astigmatic keratectomy (AK) [7–11], limbal relaxing incisions (LRIs) [12–16], laser-assisted in-situ keratomileusis (LASIK) [17, 18], photorefractive keratectomy (PRK) [19, 20], paired keratotomy incisions [21, 22], and on-axis incisions [23] correct astigmatism by altering the shape of the cornea; the astigmatic treatment is adjunctive to the spherical IOL correction of aphakia. These adjunctive corneal procedures all share the potential for postoperative tissue remodeling, which may lead to a regression and diminution of the treatment efficacy over time. While LASIK and PRK offer quite precise and relatively stable treatment of astigmatism, their cost is prohibitive to many refractive lens surgeons and patients. As a result, LRIs and AK are often used with a spherical IOL, but these may be less predictable, require nomogram adjustments for age- and gender-specific variation between individuals and are known to be less reliable for younger eyes and higher magnitudes of corneal astigmatism [24].

In contrast, optical treatments of corneal astigmatism have the advantages of offering a less invasive, single-step surgery implantation of an inert device of precise refractive power that does not change over time. In addition, higher magnitudes of astigmatism may be treated optically compared to the tissue-limited treatment. For example, various custom toric optics have been successfully used for cases of up to 30 diopters of astigmatism [25–28]. Thus, the significant potential benefits of optical rather than structural correction of astigmatism at the time of lens refractive surgery include simplicity, precision, versatility, and refractive stability.

Despite these advantages, a potential drawback of optical correction is the possibility of the toric IOL deviating from the intended cylinder axis after implantation. Off-axis rotation of a toric IOL will decrease the desired astigmatic correction in proportion to the magnitude of deviation. If the toric IOL is rotated off-axis by 10–20 degrees, the astigmatic correction is decreased by about one-third, and if off by 20–30 degrees, it is decreased by about two-thirds [26, 29]. Beyond 30 degrees of off-axis rotation, astigmatism is no longer corrected and may in fact increase with more severe malpositions. Therefore, a toric IOL must not only be implanted in the proper corneal meridian, but also resist long-term off-axis rotation successfully to treat astigmatism. As we will see, early studies of the toric IOL were characterized by intensive investigations to determine the design that was most rotationally stable and best suited for development into a toric IOL. The result of these early efforts is that the only toric IOL that has reached Food and Drug Administration approval in the USA to date is one of plate-haptic design.

Thus, refractive lens surgeons confronted with an astigmatic patient have a choice to correct astigmatism with tissue treatment versus optical correction. Each modality has its inherent advantages and disadvantages. In this chapter, we will explore the clinical use of the only Food and Drug Administration (FDA)-approved toric IOL available in the USA: the Staar toric IOL (STIOL).

7.2 The Staar Toric IOL

Today, the STIOL is the only pseudophakic IOL available in the USA for the correction of astigmatism. The STIOL is a posterior-chamber foldable IOL made of first-generation silicone that employs a plate-haptic design (Fig. 7.1). The STIOL is available in two models, both with 6.0-mm optics (model AA-4203-TF and model AA-4203-TL; Staar Surgical, Monrovia, CA). The two models differ in their overall length. Model AA-4203-TF, which is now available in a spherical equivalent (SE) power from 21.5 to 28.5 D (no longer to 30.5 D), is 10.8 mm in length, while model AA-4203-TL is available from 9.5 to 23.5 D SE power and is 11.2 mm in overall length. The

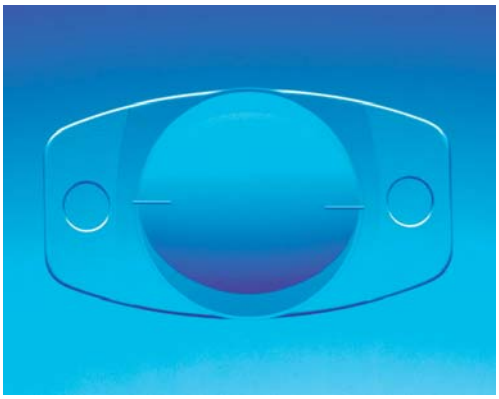


Fig. 7.1. The Staar toric IOL (STIOL). Orientation markings at the optic–haptic junction indicate the axis of toric power as a plus-cylinder lens

longer TL model that is available in the lower diopter range is intended to increase the STIOL stability against off-axis rotation in the larger-sized eyes of myopic patients. The manufacturer's suggested A-constant is 118.5 and anterior chamber depth is 5.26. As with other silicone plate-haptic IOLs from this manufacturer, the STIOL has two 1.5-mm fenestration holes in the haptic to promote fibrosis of the peripheral lens capsule around the IOL as an aid to stabilization after implantation through a 3.0-mm incision using a cartridge and plunger delivery system.

The STIOL is manufactured as a plus-cylinder lens. The axis of the toric power is designated with two small hash-marks at the peripheral optic junction, and during implantation these marks should be aligned as would any plus-cylinder lens along the steep keratometric axis. This IOL is available with a choice of either a +2.0-D toric power or a +3.5-D toric power at each SE for the correction of differing magnitudes of astigmatism. The anterior–posterior orientation of this lens is important; it is packaged with the toric power facing upward. The manufacturer's labeling calls for the anterior, toric surface to be implanted facing the anterior capsule.

7.3 Clinical Studies of STIOL

The optical correction of corneal astigmatism by refractive lens surgeons was pioneered in the early 1990s by Gills, Grabow, Martin, Shepherd, Sanders, Shimizu and others [26, 29, 30]. Initial efforts were directed at determining the best design for the toric IOL to prevent off-axis rotation after implantation. Early evaluations of a toric optic on a three-piece design with polypropene haptics resulted in 20% of cases undergoing late counterclockwise rotation of over 30 degrees [26]. Later studies confirmed that while both loop-haptic and plate-haptic designs showed a similar frequency of early rotation (within 2 weeks postoperatively), only the plate-haptic IOL was significantly more stable thereafter, as 89% of loop-haptics had rotated counterclockwise by 6 months [31]. Further evidence of the stability of this IOL design came later from Hwang, who showed less decentration with the plate-haptic (spherical Staar AA4203) than the three-piece (AMO SI-30) IOL [32].

In 1992, a pilot study demonstrated rotational stability of the spherical plate-haptic IOL (Staar 4203) in 52 eyes [29]. Thereafter, a toric surface was incorporated onto the anterior IOL surface and the overall length was increased to 10.8 mm (Staar 4203 T). Using this IOL platform, in 1994 Grabow reported less than 5% rotation rate of over 30 degrees [33]. Grabow then reported on an early phase I FDA trial in 1997 [34], in which 95% of cases were found to be within 30 degrees of the intended axis, and a mean reduction of 1.25 D of refractive cylinder was achieved.

Together, these early pioneering data suggested that, while occasional rotations could occur in the early postoperative period, the Staar plate-haptic IOL was quite stable against late malposition and the plate-haptic design was an appropriate choice for future toric IOL developments. The STIOL, in one of its two current designs (AA-4203-TF, 10.8 mm

length), underwent full FDA clinical trial, leading to its approval in 1998. Data from the overall FDA study showed 76% of cases within 10 degrees, 88% within 20 degrees, and 95% within 30 degrees of the intended cylindrical axis. The uncorrected visual acuity (UCVA) of eyes with the STIOL was significantly improved compared to those that received the spherical IOL of similar design. Two years later, the FDA went on to designate the STIOL as a "new-technology" IOL due to its demonstrated improvement of UCVA in astigmatic patients when compared to a spherical IOL. Thereafter, the longer TL model was introduced in the lower diopter powers (≤24 D) as a prophylactic against off-axis rotations in these larger myopic eyes. To date, both STIOL models have been widely evaluated [34–41]. These reports are quite consistent in demonstrating a predictable improvement in UCVA with the STIOL, yet they do differ widely in the occurrence of early off-axis rotation.

In 2000, Sun and colleagues [35, 36] retrospectively compared 130 eyes that received the Staar AA-4203-TF to 51 eyes that received a spherical IOL with LRI. The STIOL was found to be superior to LRIs in producing UCVA of ≥20/40 (84% vs. 76%) as well as in reducing refractive cylinder to ≤0.75 D (55% vs. 22%) and to ≤1.25 D (85% vs. 49%). Twelve eyes (9%) underwent STIOL repositioning for off-axis rotation. That same year, Ruhswurm used only the +2.0-D toric power STIOL in 37 eyes with a mean preoperative refractive cylinder of 2.7 D and found 48% to achieve UCVA of 20/40 or better, with a reduction of refractive cylinder to 0.84 D postoperatively [37]. No cases of STIOL rotation greater than 30 degrees were observed, although 19% rotated up to 25 degrees.

One year later, Leyland's group used vector analysis software to calculate the magnitude of expected correction produced by the STIOL in 22 eyes [38]. The group achieved 73% of the planned reduction of astigmatism, including the 18% of cases that experienced off-axis rotation by more than 30 degrees. In a smaller study of four eyes, a digital overlay technique was used to measure precisely the STIOL axis postoperatively; 75% of eyes were determined to be within 5 degrees and clinical slit-lamp estimates of axis were found to be quite precise in all cases [39]. All these reports exclusively studied the shorter TF model, as it was the only design available to the investigators at the time of their studies.

More recent studies include data on the longer TL model. Till reported on 100 eyes and found a magnitude of reduction of 1.62 D for the +2.0-D toric power and 2.86 D for the +3.5-D power in the 89% of eyes that were observed to be within 15 degrees of the intended axis [40]. No difference in rotation rate between STIOL models was observed. In contrast, Chang compared the 50 cases receiving the longer TL model against the 11 receiving the shorter TF model and found a significant difference in rotation rates specifically for the TF group in the lower diopter range [41]. No case of rotation of more than 10 degrees was observed in any of the 50 eyes with the TL or in the five eyes with the higher-power TF. However, three of six eyes with the lower-power TF model required repositioning. This strongly suggests that lengthening the original (short) TF model in the lower power range (≤24 D) may prove to be very beneficial in discouraging early off-axis rotations of the STIOL.

In summary, the STIOL has been widely studied, with the reports showing a consistent, predictable effect of reduction of preoperative refractive cylinder for the group of eyes studied. The variability in the magnitude of correction of the STIOL in these numerous studies is not surprising, as the amount of refractive (spectacle) astigmatism correction of a given IOL varies with the overall refractive error of each patient [42]; myopes will achieve greater spectacle correction of astigmatism than hyperopes due to vertex-distance issues. Regardless, the STIOL has been clearly shown to be highly predictable in the correction of astigmatism at the time of refractive lens surgery.

Another consistent finding of these clinical studies is that, although each group of eyes studied shows good efficacy of mean cylinder reduction by the STIOL, a small percentage of individuals were found to experience an early significant off-axis rotation. The variability in these findings is likely multifactorial. First, earlier studies used the shorter STIOL exclusively (TF model), which is now thought to be of inadequate length for larger eyes [34–39]. Some later reports that included the TL model did not provide diopter-specific data on which TF cases underwent rotation [40]. Change provided the one study that detailed the diopter-specific results of each STIOL model, and the longer TL model in the lower diopter range showed no rotations [41], suggesting that recent design modifications of the STIOL may indeed improve future outcomes. Second, surgical technique varies among surgeons, including the completeness of viscoelastic removal between the STIOL and the posterior capsule. Third, the axis of implantation was marked on the eye preoperatively in the upright position by some investigators, while others used a Mendez gauge at the time of implantation; torsional rotation of the eye that occurs in the recumbent position may have produced mild misalignments in some cases. Next, a few cases of implantation on the improper axis were suspected in some reports, yet these eyes were included in the calculation of overall rate of STIOL malposition. Finally, and most obviously, there is clearly a tendency for the STIOL to rotate spontaneously within the capsule between the time of implantation and the first postoperative day examination.

Regardless of the reasons for variability among rates of off-axis rotation, it is clear that occasional cases of off-axis alignments will be encountered. It is not known why some individuals experience spontaneous rotational malposition of the STIOL in the early postoperative period. Presumably there is a disparity in size between the capsule and the STIOL in some eyes. Larger capsules may be found in myopic eyes as well as in cases of enlarged, hard, and more advanced 4+ nuclei [43, 44]. Other factors, including eye rubbing or digital compression, may play a role in some cases. Fortunately, these same clinical studies that document early malpositions also clearly demonstrate that repositioning of the off-axis STIOL after 1 or 2 weeks uniformly restores the desired effect, and late rotations are very rare.

Other clinical studies have used the STIOL to correct excessive astigmatism with novel procedures. To correct excessive amounts of astigmatism, Gills combined LRIs with the STIOL or used multiple STIOLs in "piggyback" fashion [45–47]. Other suggestions that have not been well studied include placing a multifocal IOL in the sulcus as a piggyback over a bag-fixated toric IOL, or using toric IOLs to create pseudo-accommodation by leaving a residual refractive cylinder to aid in reading.

In summary, these numerous clinical studies have clearly demonstrated the clinical results that can be expected when using the STIOL to produce improved UCVA in astigmatic eyes undergoing lens refractive surgery. We now turn our attention to the specific recommendations with which refractive lens surgeons must be familiar to achieve the best clinical outcomes for their patients.

7.4 Using the STIOL

7.4.1 Preoperative Issues

One of the advantages of using the STIOL for the correction of astigmatism is that refractive lens surgeons must learn few new techniques or procedures. No significant changes to spherical IOL calculations are required, but a few specific steps must be taken to insure a successful outcome when using the STIOL.

The first step is for surgeons to review recent cases and determine the keratometric changes that occur postoperatively in their

K-Astigmatism	Toric Power
<1.4	0
1.4–2.3	+2.0
≥2.4	+3.5

Fig. 7.2. Standard nomogram for choosing STIOL toric power based on the amount of preoperative keratometric astigmatism

hands. While most refractive lens surgeons today use clear cornea incisions of 3.0 mm or less and do not induce significant astigmatism, few, if any, create truly "astigmatically neutral" incisions. Thus, it is important to review the way in which the cornea changes, as it is the goal of STIOL implantation to treat the postoperative, not preoperative keratometry.

The next step is to calculate the STIOL power. The STIOL is available in SE powers from 9.5 to 28.5 D, and each SE power is available in two distinct toric powers (+2.0 and +3.5 D). The surgeon's preferred IOL calculation formula is used in an identical fashion as with spherical IOLs to determine the STIOL SE power. If the SE power is between 21.5 and 23.5 D, a choice of IOL models must be made. Due to the increased rotational stability demonstrated by Chang [41], the longer TL model should be chosen. The unique step required when using the STIOL is to choose either the +2.0-D toric power or the +3.5-D toric power as determined by keratometry. Due to vertex distance issues, a perfectly aligned +2.0-D STIOL is expected to correct 1.4 D of keratometric cylinder, and the +3.5-D STIOL corrects 2.3 D of regular corneal astigmatism. Thus, the manufacturer recommends that the +2.0-D toric power STIOL be used for preoperative keratometric astigmatism between 1.4 and 2.2 D; the +3.5-D toric power is used when the keratometry shows greater than 2.2 D of astigmatism (Fig. 7.2). Therefore, the only difference in choosing the power of the STIOL compared to a spherical IOL is that the toric power must be specified. Adjustments to the calculations are not needed otherwise.

Once the specific STIOL is selected, the intended axis of implantation is then determined and recorded. The STIOL is a plus-cylinder lens, and should be aligned as would any plus-cylinder lens to neutralize the keratometric astigmatism.

Topography is strongly encouraged to verify that the astigmatism is regular and to assist with determination of the steep corneal axis. Irregular corneal astigmatism will not be appropriately corrected by the STIOL. The chosen axis for STIOL alignment must be documented for later use in the operating room unless qualitative keratometry is to be used intraoperatively to align the STIOL.

Finally, on the day of surgery, the eye should be marked with the patient in the upright position to avoid misalignments due to torsional changes that may occur in the recumbent position. Some surgeons allow the preoperative team to do this, while others will not delegate this duty. A marking pen may be used at either the vertical or horizontal meridian for later orientation with a Mendez gauge to insure proper alignment of the STIOL at the time of implantation. Alternatively, qualitative keratometry may be used intraoperatively, in which case this step may be omitted.

7.4.2 Implanting the STIOL

Implanting the STIOL is similar to implanting other plate-haptic IOLs from the same manufacturer. As with all plate-haptic IOLs, the STIOL should not be implanted without an intact capsule and complete continuous curvilinear capsulorrhexis. Current cartridge design allows delivery through a 3.0-mm clear cornea incision. The cartridge tip does not need to enter entirely into the anterior chamber, but does need to enter fully the corneal incision. Retracting the plunger several times as the STIOL is pushed down the cartridge is required to insure no overriding of plunger that could tear the trailing haptic.

The leading haptic is placed into the capsule filled with viscoelastic, and the trailing haptic is placed with a second instrument as with other plate-haptic IOLs.

Once the STIOL is placed fully within the capsule, the STIOL is oriented into the desired axis. Careful removal of viscoelastic from between the posterior capsule and the STIOL is important to help stabilize the implant from early rotation, and this is done prior to final orientation along the desired axis. The axis is determined using the previously placed limbal orientation marks or using qualitative keratometry with projected light. After final irrigation/aspiration of viscoelastic and verification of a water-tight incision, the STIOL orientation is again checked. Some surgeons prefer to leave the eye slightly soft to encourage early contact between the capsule and the STIOL.

7.4.3 Postoperative Management

Management of eyes with the STIOL implanted is similar to spherical IOL cases. If an off-axis rotation of the STIOL is encountered, it is best managed on an individual basis. As clinical studies have shown, off-axis rotations of the STIOL may occur in the very early postoperative period, with later rotations rarely observed. In most cases of mild rotation, the UCVA remains excellent and no intervention is needed. For larger rotations, the patient's tolerance of the malposition should be considered. In refractive lens surgery, where patients have an intense desire for excellent UCVA, even moderate rotations may require repositioning to the desired axis. The best time for repositioning is 2–3 weeks after implantation. If repositioned earlier, capsule fibrosis may not be sufficient to prevent the lens from returning to its original malposition. After 3 weeks, the fibrosis of the capsule intensifies, making repositioning more difficult. After 2–3 months, the capsule assumes the orientation of the long axis of the plate-haptic with significant fibrosis, and repositioning to a new axis is difficult if not impossible. Although some eyes may require Nd:YAG capsulotomy for posterior capsule opacification, there have been no reports of STIOL malposition occurring after laser treatment.

7.5 Improving Outcomes with the STIOL: Author's Observations and Recommendations

Experience with the STIOL over the past 6 years has provided several important insights that have improved the author's clinical outcomes when using the STIOL for refractive lens surgery. Discouraged by the occasional off-axis rotations in the first year after FDA approval, the author considered discontinuing use of the STIOL at the same time that data were becoming available that suggested a novel method to promote stabilization of the STIOL against rotation. As reported previously [48], implanting the STIOL in a "reversed" position, with the toric surface facing the posterior capsule rather than the anterior capsule, appeared to improve but not cure the frequency of off-axis rotations. The rationale for initially implanting the STIOL in this manner, and the findings that resulted, will be briefly reviewed here, with additional insights to follow.

Why was the STIOL ever intentionally implanted in the reversed position? After FDA approval and initial enthusiasm for results obtained with the STIOL, occasional patients were encountered with "borderline" astigmatism. For example, a patient may present with 1.2 D of corneal astigmatism, which is below the manufactured suggested limit of 1.4 D. The STIOL could "flip" the astigmatic axis in such a patient. However, theoretical optics calculate that the toric power of the STIOL would be decreased by 8% if the optic was reversed, as the toric (anterior) surface of the

STIOL in the reversed position would then be closer to the nodal point of the eye and less effective toric power would result without changing the SE. For these borderline patients, the STIOL was intentionally reversed, and the results were startling.

The first observation occurred when the implant was placed into the capsule in the reversed position. Compared with the normal position, the reversed position seemed to resist manipulation when rotating the STIOL into the desired axis. Although this observation was interesting, the significance of it was not immediately realized, and implanting the STIOL in the reversed position was reserved for only those occasional eyes with borderline astigmatism. Later, the first years' data were analyzed and suggested that eyes with the optic reversed showed outstanding outcomes. While the reason for these results may have been multifactorial, the decision was made to implant all STIOLs in the reversed position, and the resulting data further suggested that this technique was useful in reducing the rate of malpositions.

A retrospective analysis was performed on 171 eyes. Postoperative UCVA and residual refractive cylinder were compared between eyes implanted with the STIOL in the standard vs. reversed position. Surprisingly, a statistically significant increase in the percentage of eyes achieving 20/40 or better UCVA was found for the STIOL in the reversed vs. standard position (83% vs. 58% respectively). Also, there was a significantly improved UCVA for the STIOL in the reversed vs. standard position (0.60 ± 0.18 vs. 0.49 ± 0.21). Finally, the reverse-STIOL position group showed a significant increase in the percentage of eyes achieving a residual refractive cylinder ≤0.5 D (56% vs. 34%).

Thus, the STIOL in the reversed position was observed to promote improved UCVA and reduction of refractive cylinder despite an expected 8% reduction of toric power in this position. It is proposed that the STIOL was more stable in this reversed position, and fewer off-axis rotations occurred. The more precise rotational alignment was more important than the very mild reduction of toric power.

These data are not to be interpreted that the "reversed" STIOL provides more toric power. On the contrary, a perfectly aligned STIOL with the toric surface facing the anterior capsule will correct more corneal astigmatism than the same lens in the reversed position. The importance of the reversed position is that it stabilizes the STIOL against rotation. Therefore, for a large group of eyes, more reversed STIOLs will be on-axis, and the mean UCVA will be improved.

Therefore, based on these findings, it is recommended that all eyes be implanted with the optic of the STIOL intentionally reversed, and the toric power is chosen based on the modified "reversed" nomogram (Fig. 7.3). For keratometric asymmetry of 1.2–2.1 D, use the +2.0-D toric power in the reversed position, and for corneal astigmatism above 2.2 D, use the +3.5-D STIOL in the reversed position. Using this nomogram will insure the axis is not overcorrected and, together with other recommendations here, will help to minimize the frequency of off-axis rotations.

In addition to using the reversed nomogram and implanting the STIOL in the reversed position to discourage early malpositions, other observations and recommendations are shared here as the chapter closes.

With regards to preoperative recommendations, aside from using the "reversed" nomogram to choose the toric power of the STIOL, the main problem to avoid is eyes with irregular astigmatism. Obviously, topographical data are required to detect such cases. A prudent protocol is to have all patients with more than 1.25 D of keratometric asymmetry who are scheduling for surgery to undergo topography. Another suggestion specifically for clear lens extraction patients who are expecting excellent UCVA is to inform the patient about the potential need for repositioning. While most patients do not need such

K-Astigmatism	Toric Power
<1.1	0
1.2–2.0	+2.0
≥2.1	+3.5

Fig. 7.3. "Reversed" nomogram for choosing STIOL toric power based on planned reversal of STIOL optic to aid in stabilization against off-axis rotation

intervention, those that do are very accepting of such intervention when they are prepared in advance. If repositioning is performed in the operating room, which is suggested, financial arrangements for such a procedure should likewise be understood in advance. A reasonable approach is to estimate the frequency of returning to the operating room for 100 patients, then calculate the costs for those visits, and incorporate that cost into the overall charge to all patients. If cash-pay patients who require repositioning are charged for the procedure, they feel a "double-whammy" of requiring a second surgery and having to pay for it.

Intraoperative suggestions start with the recommendation of implanting all STIOLs in the reversed position to promote rotational stability. Simply open the package, grasp the STIOL, turn the upward (anterior) surface toward the floor, and load it into the cartridge, thus reversing the optic. The second suggestion is to use endocapsular phacoemulsification techniques rather than flipping techniques. The frequency of STIOL off-axis rotations was found to increase dramatically for cases in which the nucleus was "tire-ironed" into a vertical position and underwent phaco-flip (data not shown). While the reasons for this observation are unknown, it is suspected that increased manipulation of the capsule while prolapsing and emulsifying the nucleus with the flip technique caused some stretching or enlargement of the capsule.

At the time of implantation, it is recommended to avoid a rapid expulsion of the lens; if it "shoots" into the capsular bag, there is a tendency for the STIOL to rotate towards the axis that it was forced into the bag. A gentle "push-pull" retraction of the plunger is useful in delivering the leading haptic slowly into the capsule. Next, the choice of viscoelastics may be important, as pointed out by Chang [41], who recommends avoiding dispersive viscoelastics that coat the IOL such as Viscoat. He achieved good results with sodium hyaluronate 1.0%, while the author generally uses methylcellulose 1% (Occucoat) with good results. As mentioned previously, it is critical to remove the viscoelastic from behind the IOL to prevent early rotations. Next, when moving the STIOL into its final position, it is recommended to rotate both sides of the optic to promote equal forces on all sides of the implant. Finally, it is critical to recheck the STIOL axis at conclusion of the surgery, including after speculum and drape removal.

Postoperative management recommendation includes the use of a shield at bedtime over the operative eye. Patients may place this themselves. There is a suspicion that some off-axis rotations may occur overnight due to external pressure in those eyes without a shield. If repositioning is needed, a sterile field in the operating room is strongly recommended for safety, but some surgeons may intervene at the slit-lamp. Repositioning in the operating room may be performed through a paracentesis with a cystatome on a BSS free-flow line. Gentle rocking on both sides of the optic will free early capsule adhesions, and the STIOL is rotated to the desired axis without the need of a keratome incision or viscoelastic.

In conclusion, this chapter has reviewed the clinical aspects important to understanding the development and use of the STIOL. This lens is quite effective in treating corneal astigmatism at the time of lens refractive surgery, yet occasional patients may require repositioning of the STIOL in the early postoperative period, with resulting excellent UCVA. As improvements in STIOL design continue and as our understanding increases

about the dynamics at work in the eye during the perioperative period, there are high expectations that our refractive lens patients with significant astigmatism will consistently reach emmetropia.

References

1. Fine IH, Hoffman RS (1996) Refractive aspects of cataract surgery. Curr Opin Ophthalmol 7: 21–25
2. Hoffer KJ (1980) Biometry of 7,500 cataractous eyes. Am J Ophthalmol 90:360–368; correction 890
3. Grabow HB (1994) Intraocular correction of refractive errors. In: Kershner RM (ed) Refractive keratotomy for cataract surgery and the correction of astigmatism. Slack, Thorofare, NJ, pp 79–115
4. Bear JC, Richler A (1983) Cylindrical refractive error: a population study in western Newfoundland. Am J Optom Physiol Opt 60:39–45
5. Attebo K, Ivers RQ, Mitchell P (1999) Refractive errors in an older population: the Blue Mountain Eye study. Ophthalmol 106:1066–1072
6. Wang Q, Klein R, Moss SE (1994) Refractive status in the Beaver Dam Eye Study. Invest Ophthalmol Vis Sci 35:4344–4347
7. Maloney WF, Sanders DR, Pearcy DE (1990) Astigmatic keratotomy to correct preexisting astigmatism in cataract patients. J Cataract Refract Surg 16:297–304
8. Osher RH (1992) Transverse astigmatic keratotomy combined with cataract surgery. In: Thompson K, Waring G (eds) Contemporary refractive surgery. Ophthalmology Clinics of North America. Saunders, Philadelphia, pp 717–725
9. Price FW, Grene RB, Marks RG et al (1995) Astigmatism reduction clinical trial: a multicenter prospective evaluation of the predictability of arcuate keratotomy. Arch Ophthalmol 113:277–282
10. Kershner RM (1995) Keratolenticuloplasty: arcuate keratotomy for cataract surgery and astigmatism. J Cataract Refract Surg 21:274–277
11. Buzard KA, Laranjeira E, Fundingsland BR (1996) Clinical results of arcuate incisions to correct astigmatism. J Cataract Refract Surg 22:436–440
12. Troutman RC, Swinger C (1980) Relaxing incision for control of postoperative astigmatism following keratoplasty. Ophthalmology 11: 117–120
13. Gills JP (1997) Optimizing vision with limbal relaxing incisions. Ophthalmol Management 1:2
14. Budak K, Friedman NJ, Kock DD (1998) Limbal relaxing incisions with cataract surgery. J Cataract Refract Surg 24:503–508
15. Muller-Jensen K, Fischer P, Siepe U (1999) Limbal relaxing incisions to correct astigmatism in clear corneal cataract surgery. J Refract Surg 15:586–589
16. Nichamin LD, Wallace RB (2001) Reducing astigmatism. In: Wallace R (ed) Refractive cataract surgery and multifocal IOLs. Slack, Thorofare, pp 167–172
17. Ayala M, Perez-Santonja JJ, Artola A et al (2001) Laser in situ keratomileusis to correct residual myopia after cataract surgery. J Refract Surg 17:12–16
18. Nichamin LD (2003) Bioptics for the pseudophakic patient. In: Gills JP (ed) A complete guide to astigmatism management. Slack, Thorofare
19. McDonnell PJ, Moreira H, Garbus J et al (1991) Photorefractive keratectomy to create toric ablations for correction of astigmatism. Arch Ophthalmol 109:710–713
20. Artola A, Ayala M, Claramonte P et al (1999) Photorefractive keratectomy for residual myopia after cataract surgery. J Cataract Refract Surg 25:1456–1460
21. Shepherd JR (1989) Correction of preexisting astigmatism at the time of small incision cataract surgery. J Cataract Refract Surg 15:55–57
22. Lever J, Dahan E (2000) Opposite clear corneal incisions to correct preexisting astigmatism in cataract surgery. J Cataract Refract Surg 26:803–805
23. Kohnen T, Koch DD (1996) Methods to control astigmatism in cataract surgery. Curr Opin Ophthalmol 7:75–80
24. Budak K, Yilmaz G, Aslan BS, Duman S (2001) Limbal relaxing incisions in congenital astigmatism: 6 month follow-up. J Cataract Refract Surg 27:715–719
25. Frohn A, Dick HB, Thiel HJ (1999) Implantation of a toric poly(methyl methacrylate) intraocular lens to correct high astigmatism. J Cataract Refract Surg 25:1675–1678

26. Shimizu K, Misawa A, Suzuki Y (1994) Toric intraocular lenses: correcting astigmatism while controlling axis shift. J Cataract Refract Surg 20:523–526
27. Schwartz DM, Jethmalani JM, Sandstedt CA, Kornfield JA, Grubbs RH (2001) Post implantation adjustable intraocular lenses. Ophthalmol Clin North Am 14:339–345
28. Tehrani M, Stoffelns B, Dick B (2003) Implantation of a custom intraocular lens with a 30-diopter torus for the correction of high astigmatism after penetrating keratoplasty. J Cataract Refract Surg 29:2444–2447
29. Sanders DR, Grabow HB, Shepherd J (1992) The toric IOL. In: Grills JP, Martin RG, Sanders DR (eds) Sutureless cataract surgery. Slack, Thorofare, NJ, pp 183–197
30. Gills JP, Martin RG, Thornton SP, Sanders DR (eds) (1994) Surgical treatment of astigmatism. Slack, Thorofare, NJ, pp 159–164. Martin RG, Gills JP, Sanders DR (eds) (1993) Foldable intraocular lenses. Slack, Thorofare, NJ, pp 237–250
31. Patel CK, Ormonde S, Rosen PH, Bron AJ (1999) Postoperative intraocular lens rotation: a randomized comparison of plate and loop haptic implants. Ophthalmology 106:2190–2195; discussion 2196
32. Hwang IP, Clinch TE, Moshifar M et al (1998) Decentration of 3 piece versus plate-haptic silicone intraocular lenses. J Cataract Refract Surg 24:1505–1508
33. Grabow HB (1994) Early results with foldable toric IOL implantation. Eur J Implant Refract Surg 6:177–178
34. Grabow HB (1997) Toric intraocular lens report. Ann Ophthalmol 29:161–163
35. Sun XY, Vicary D, Montgomery P, Griffiths M (2000) Toric intraocular lenses for correcting astigmatism in 130 eyes. Ophthalmology 107: 1776–1781
36. Kershner RM (2000) Toric intraocular lenses for correcting astigmatism in 130 eyes (discussion). Ophthalmology 107:1781–1782
37. Rushwurm I, Scholz U, Zehetmayer M, Hanselmeyer G, Vass C, Skorpik C (2000) Astigmatism correction with a foldable toric intraocular lens in cataract patients. J Cataract Refract Surg 26:1022–1027
38. Leyland M, Zinicola E, Bloom P, Lee N (2001) Prospective evaluation of a plate haptic toric intraocular lens. Eye 15:202–205
39. Nguyen TM, Miller KM (2000) Digital overlay technique for documenting toric intraocular lens axis orientation. J Cataract Refract Surg 26:1496–1504
40. Till JS, Yoder PR, Wilcox TK et al (2002) Toric intraocular lens implantation: 100 consecutive cases. J Cataract Refract Surg 28:295–301
41. Chang DF (2003) Early rotational stability of the longer Staar toric intraocular lens: fifty consecutive cases. J Cataract Refract Surg 29: 935–940
42. Novis C (2000) Astigmatism and toric intraocular lenses (review). Curr Opin Ophthalmol 11:47–50
43. Vasavada A, Singh R (1998) Relationship between lens and capsular bag size. J Cataract Refract Surg 24:547–551
44. Vass C, Menapace R, Schmetterer K et al (1999) Prediction of pseudophakic capsular bag diameter based on biometric variables. J Cataract Refract Surg 25:1376–1381
45. Gills J, van der Karr M, Cherchio M (2002) Combined toric intraocular lens implantation and relaxing incisions to reduce high preexisting astigmatism. J Cataract Refract Surg 28: 1585–1588
46. Gills JP (2003) Sutured piggyback toric intraocular lenses to correct high astigmatism. J Cataract Refract Surg 29:402–404
47. Gills JP, van der Karr MA (2002) Correcting high astigmatism with piggy back toric intraocular lens implantation. J Cataract Refract Surg 28:547–549
48. Bylsma S (2004) Toric intraocular lenses. In: Roy FH, Arzabe CW (eds) Master techniques in cataract and refractive surgery. Slack, Thorofare

8 Correction of Keratometric Astigmatism: AcrySof Toric IOL

Stephen S. Lane

CORE MESSAGES

- AcrySof toric IOL clinical results demonstrated improved uncorrected visual acuity, best spectacle-corrected visual acuity, and reduced astigmatic refractive cylinder when compared to AcrySof IOL, monofocal lens.
- AcrySof toric IOL's biomaterial and truncated edged optic design reduce posterior capsule opacification accumulation.
- Implantation utilizing a toric IOL offers greater predictability and reversibility than astigmatic keratotomy.

Astigmatism is caused by refractive aberrations in the cornea or lens that focus light unevenly onto the retina, consequently distorting images. In recent years there has been increasing interest in correcting astigmatism at the time of cataract surgery or clear lens exchange to achieve emmetropia. Cataract surgeons and their patients today hope to achieve 20/20 or better visual acuity and not have to rely on spectacles or contact lenses for the correction of distance vision. Approximately 15–29 % of cataract patients have astigmatism measuring more than 1.50 D of corneal or refractive astigmatism [1, 2]. Pre-existing astigmatism is due to lens or corneal aberrations, while post-surgically-induced astigmatism results from incision wounds made in the course of surgery that affect the cornea.

Historically, alternatives for the correction of astigmatism subsequent to cataract surgery included the utilization of: contact lenses, glasses, or refractive surgery post-cataract surgery. This spectacle dependency following cataract surgery continued until the toric intraocular lens (IOL) was introduced in 1998 [3]. Prior to the development of the toric IOL, two surgical procedures were considered for correcting pre-existing astigmatism: astigmatic keratotomy (incisional limbal or corneal relaxation) and varying the length and location of the cataract incision [4]. More recently, the excimer laser has become another alternative to implantation of a toric IOL for the correction of astigmatism.

The results of astigmatic keratotomy have been relatively unpredictable and may induce undercorrection or overcorrection of astigmatism [5, 6]. In addition, there is a limit to how much cylinder can be corrected by using corneal incisions and/or varying the incision site. A study performed by Gills et al. determined that patients with very high astigma-

tism (>5.00 D) may benefit from the combination of corneal or limbal incisions with toric IOL implants when the amount of cylinder present exceeds the powers available with a toric IOL alone [7]. The high cost of excimer laser correction makes this a less desirable alternative for cylinder correction for many people.

An effective toric IOL must have the capability of improving visual acuity and maintaining rotational stability so as not to diminish the effects of the correction provided by the toric lens.

8.1 AcrySof Toric IOL

Alcon Laboratories Inc. has recently developed an exceptionally stable toric IOL to aid in the correction of astigmatism (Fig. 8.1). The AcrySof toric IOL, model SA60TT, is designed to focus the light, otherwise scattered by corneal and/or lenticular astigmatism, in order to limit image distortion. The AcrySof toric IOL corrects for aphakia as well as preexisting or post-surgically-induced corneal astigmatism. The structure of the AcrySof toric IOL is based on the presently marketed AcrySof single-piece IOL, SA60AT monofocal lens. The toric lens design is comprised of a foldable, single-piece, acrylic polymer, with UV absorber. The AcrySof toric IOL is intended for long-term use and is implanted into the capsular bag following phacoemulsification. Its overall length is 13.0 mm with a 6.0 mm diameter asymmetrical biconvex optic. This IOL easily folds in half and may be inserted through an incision measuring between 3.0 and 3.5 mm using the Monarch II Injector. Larger incision lengths may result in an increase in surgically induced corneal astigmatism. The AcrySof toric IOL examined in a clinical investigation was provided in three cylinder powers at the IOL plane: 1.50 D, 2.25 D, and 3.00 D. Additional power options are intended to be available to the market. The SA60TT covers a spherical range between 16.0 D and 25.0 D in 0.5-D increments.

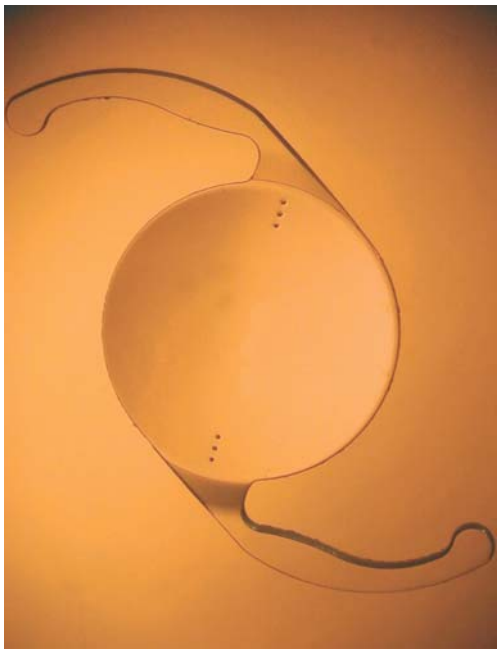


Fig. 8.1. The AcrySof toric IOL: the lens is marked with three alignment dots on each side to delineate the axis of the cylinder to be aligned on the steep meridian. (Courtesy of Alcon Laboratories Inc.)

The AcrySof toric IOL's material and design offer a number of advantages. Posterior capsule opacification (PCO), also known as a secondary cataract that forms over the visual axis, often impairs visual acuity. This complication was reported more frequently with earlier IOL designs. Two major features of the AcrySof toric IOL limit PCO. The first is the AcrySof biomaterial, which adheres to the capsular bag via a single layer of lens epithelial cells. The resulting lack of space through which essential life-sustaining nutrients can pass to and from these cells ultimately leads to their death and subsequently to the direct adherence of the AcrySof material to the capsular bag via common extracellular proteins such as fibronectin and collagen IV. This overall process is sometimes referred to as the "no space, no cells" concept, which creates

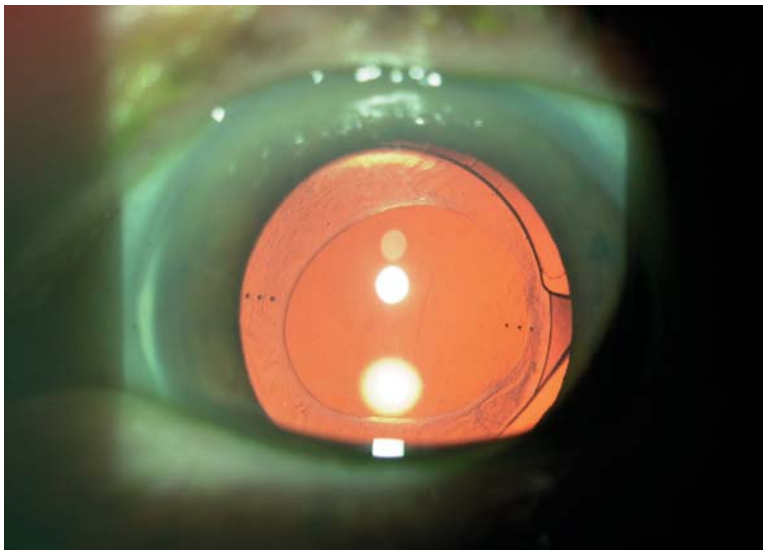


Fig. 8.2. AcrySof toric IOL implanted into the eye. (Courtesy of Stephen Lane, MD)

an unfavorable environment for cell proliferation [8]. In addition to this biomaterial adhesive property being effective at aiding in the reduction of PCO, it may also account for the exceptional rotational stability necessary for a successful toric IOL.

The second feature of the AcrySof toric IOL that increases its ability to maintain a clear posterior capsule and ultimately reduces the need for a Nd:YAG capsulotomy is the design of the posterior optic edge [8, 9]. Nishi et al. demonstrated in an animal study that the sharp-edged optic design of the AcrySof IOL incorporates a PCO-reducing effect [10]. Proven in a separate study, the AcrySof IOL's square truncated optic edge created a barrier to migration of lens epithelial cells, leaving the visual axis clear of PCO [8].

The stable-force haptics are another beneficial design attribute of the AcrySof toric IOL. These haptics are designed for maximum conformance to the capsular bag, offering the greatest possible surface area for adherence between the IOL and the capsular tissue. This in turn leads to greater stability of the IOL, and to a pronounced "shrink-wrap" effect (Fig. 8.2), which takes place during the early postoperative time course. It is this property that is likely responsible for "locking" the lens in place.

In essence, the AcrySof single-piece IOL platform provides the ideal material and design features for a toric IOL. The soft acrylic material allows for small-incision surgery, the natural PCO reduction characteristics allow for fewer postoperative complications, and the adhesion and capsular bag conformance properties allow for highly stable and predictable positioning of the IOL.

8.2 Surgical Procedure

Implantation of the AcrySof toric IOL implantation follows a similar procedure as that of most modern small-incision cataract surgeries, using phacoemulsification and in-the-bag IOL placement. Extra corneal marking steps are included to ensure proper positioning of the toric correction. To account for cyclorotation, the cornea is marked at the 3 and 9 o'clock limbus while the patient is in an upright position. Once the patient is positioned for surgery, a Dell astigmatism marker is used to mark the axis of the steep corneal meridian using the previously placed 3 and 9 o'clock

marks as reference points for the 180-degree meridian. Following phacoemulsification, the IOL is inserted into the capsular bag utilizing a Monarch II injector. Following insertion, the lens begins to unfold naturally within the capsule. The surgeon then carefully aligns axis indication marks on the IOL with the steep meridian of the cornea. Care must be taken to remove the ophthalmic viscosurgical device (OVD) from behind the IOL without disrupting the IOL position. A final positioning step following OVD removal may be necessary to reposition the lens on axis.

One key for a successful surgical outcome is choice of astigmatic power of the IOL and the proper identification of the axis of the steep meridian of the cornea. Both are calculated using software provided by Alcon Laboratories Inc., called the toric IOL calculator. The A-constant and keratometric analysis are entered into the software, and the toric IOL calculator uses this information, along with an assumption of the astigmatic effects of the cataract incision, in order to calculate the appropriate astigmatic power correction and position of the steep axis.

8.3 US Clinical Trial Results

Best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), residual astigmatism, and lens rotation were assessed during a comparative, multi-center, prospective, clinical trial between the AcrySof toric IOL, model SA60TT (SA60T3, SA60T4, SA60T5) and a control IOL, AcrySof single piece, model SA60AT. Approximately 250 subjects were implanted with SA60TT and 250 subjects were implanted with SA60AT. All subjects were followed for 1 year following first eye implantation.

Table 8.1. Visual acuity (BSCVA and UCVA), all subjects. AcrySof toric IOL (SA60TT) compared to AcrySof IOL monofocal (SA60AT)

80–100 day data	SA60TT	SA60AT
BSCVA	$n = 77$	$n = 68$
20/20 or better	76.6% subjects	67.6% subjects
20/25 or better	89.6%	91.2%
20/30 or better	97.4%	95.6%
20/40 or better	100 %	97.1%
Worse than 20/40	0%	3%
UCVA	$n = 74$	$n = 67$
20/20 or better	31.1% subjects	11.9% subjects
20/25 or better	63.5%	26.7%
20/30 or better	83.8%	46.3%
20/40 or better	94.6%	73.1%
Worse than 20/40	5.4 %	26.9%

8.3.1 Visual Acuity Outcomes

At the 80–100 day visit, 100% ($n = 77$) of toric subjects and 97.1% ($n = 68$) of control subjects achieved BSCVA 20/40 or better. In comparing UCVA, 94.6% ($n = 74$) of toric subjects while only 73.1% ($n = 67$) of control subjects achieved 20/40 or better (Table 8.1).

8.3.2 Astigmatic Refractive Cylinder Outcomes

The three toric models, SA60T3, SA60T4 and SA60T5, correct for 1.5 D, 2.25 D and 3.0 D of astigmatism, respectively, at the IOL plane. Collectively, all three toric models are referred to as SA60TT. In order to make direct comparisons, the overall control subject group was divided into three subsets corresponding to these three levels of astigmatism. All three toric models had mean residual cylinders of 0.9 D as compared to the control, all measuring 1.9 D mean residual cylinder.

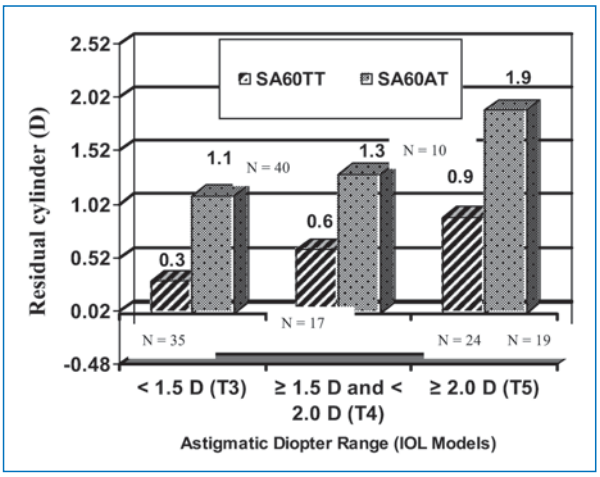


Fig. 8.3. Mean absolute residual cylinder at 80–100 day visit. SA60AT (control) compared to SA60TT (toric)

8.3.3 Rotational Stability Outcomes

At the 80–100 day visit, with 75 toric subjects being evaluated, 82.7% presented with 0–5° rotation from surgical placement, 12.0% with >5–10°, and 5.3% with >10–15°rotation. None of the toric subjects had >15° rotation. Since the AcrySof toric IOL is so similar in mechanical design to the control IOL in this study, and since the absence of axis delineation marks on the control IOL make it difficult to assess rotational position, a direct comparison between the two was not made in the clinical investigation. A comparison can, however, be made between the data gathered for the AcrySof toric IOL in this study and that gathered in a Food and Drug Administration (FDA) clinical trial for a currently marketed, plate-haptic toric IOL. In PMA number P880091/S14, data indicate that 76% of subjects had 10° rotation, 88% had 20° and 95% had 30°, leaving 5% that had >30° rotation [11]. In 1999, Staar Surgical developed a longer toric lens that appears to have greater centration [3].

8.4 Discussion

The greatest concern of implanting currently marketed toric IOL designs is that of rotational stability. The US clinical trial comparing the Alcon AcrySof toric IOL to Alcon's spherical control lens demonstrates the toric IOL's ability to maintain rotational stability, thus assuring accurate correction of corneal astigmatism and improvement of visual acuity.

8.4.1 Importance of Rotational Stability

When a toric lens has rotated more than 10 degrees off axis, only 66% of the effective cylindrical power remains. At 20 degrees of misalignment, only 33% of the effective power remains. At 31 degrees rotation, the refractive cylinder increases above the corneal value, resulting in an increase in astigmatism [12]. When a lens is misaligned by 31 degrees, surgical intervention for repositioning of the lens should be considered. Clearly, axial alignment of a toric IOL is crucial to the degree of effectiveness of astigmatic correction, and placement of the toric IOL at surgery should be performed as accurately as possi-

ble. During the early time-course following implantation, IOLs may rotate within the capsular bag until a bioadhesive bond is formed with the posterior capsule [12]. The AcrySof material allows for this fixation to occur soon after implantation, as its bioadhesive nature facilitates the rapid creation of this connection [9]. In the US clinical trial, with 75 subjects reporting at the 80–100 day visit, the AcrySof toric IOL had over 80% of subjects experiencing less than 5 degrees of rotation from surgical placement and zero who experienced over 15 degrees. These preliminary clinical study results indicate that the AcrySof toric IOL exhibits characteristics that make it an excellent platform for cylindrical correction following phacoemulsification.

FINAL COMMENTS

The AcrySof toric IOL is a biocompatible, single-piece, truncated-edged foldable lens with a UV absorber, fabricated from a naturally bioadhesive soft hydrophobic acrylic elastomer. These inherent attributes provide for an IOL design that not only performs as any modern IOL should, controlling PCO and continuously providing exceptional vision, but also allows for maximal capsular bag conformance while minimizing IOL rotation. All of these are critical for accurate cylindrical correction. Keratometric astigmatic surgery offers less predictable results and may cause over- or undercorrection of astigmatism. Phacoemulsification with the implantation of the AcrySof toric IOL provides an attractive alternative for the cataract patient, which may reduce spectacle dependence. An advantage for patients with astigmatism greater than is correctable with a toric IOL alone is the ability to combine corneal incisions or laser refractive surgery with toric IOL implantation.

The safety and effectiveness of the AcrySof toric IOL are under investigation in a US clinical investigation. Subjects attained improved BSCVA and UCVA and reduced astigmatic refractive cylinder when compared to subjects with equivalent levels of astigmatism who were implanted with a spherical IOL. In addition, the AcrySof toric IOL subjects experienced less postoperative rotation of the IOL than those enrolled in the FDA clinical trials of a currently marketed toric IOL. The introduction of the AcrySof toric IOL into the market will permit ophthalmologists to offer patients another viable option beyond astigmatic keratotomy or excimer laser correction to treat astigmatism.

References

1. Hoffer KJ (1980) Biometry of 7,500 cataractous eyes. Am J Ophthalmol 90:360–368, correction 890
2. Grabow HB (1994) Intraocular correction of refractive errors. In: Kershner RM (ed) Refractive keratotomy for cataract surgery and the correction of astigmatism. Slack, Thorofare, NJ, pp 79–115
3. Chang DF (2003) Early rotational stability of the longer Staar toric intraocular lens in fifty consecutive cases. J Cataract Refract Surg 29: 935–940
4. Troutman RC, Swinger C (2002) Relaxing incision for control of postoperative astigmatism following keratoplasty. Opthalmology 11:117–120
5. Gills JP, Gayton JL (1998) Reducing pre-existing astigmatism. In: Gills JP, Fenzl R, Martin RG (eds) Cataract surgery: the state of the art. Slack, Thorofare, NJ
6. Till JS (2002) toric intraocular lens implantation: 100 consecutive cases. J Cataract Refract Surg 28:295–301
7. Gills JP et al (2002) Combined toric intraocular lens implantation and relaxing incisions to reduce high preexisting astigmatism. J Cataract Refract Surg 28:1585–1588
8. Apple DJ et al (2000) Elimination of cataract blindness: a global perspective entering the new millennium. Surv Ophthalmol 45:S1–S1969
9. Linnola R et al (1999) Intraocular lens bioactivity tested using rabbit corneal tissue cultures. J Cataract Refract Surg 25:1480–1485
10. Nishi O (1999) Posterior capsule opacification, part 1. Experimental investigations. J Cataract Refract Surg 25:106–117
11. Staar Surgical Co. Elastic TM ultraviolet absorbing silicon posterior chamber intraocular lens with toric models AA-4203T and AA-4203TF. PMA No. P880091/S14
12. Vukich JA (2001) Toric intraocular lens. In: Ford JG, Karp CL (eds) Cataract surgery and intraocular lenses: a 21st century perspective. Clinical Education Division of the Foundation of the American Academy of Ophthalmology, Singapore, pp 144–151

9 Wavefront Technology of Spherical Aberration

Mark Packer, I. Howard Fine, Richard S. Hoffman

CORE MESSAGES

- Contrast sensitivity declines with age even in the absence of ocular pathology.
- Wavefront science demonstrates that the youthful crystalline lens compensates for aberrations in the cornea. The aging lens loses its balance with the cornea, as both the magnitude and the sign of its spherical aberration change.
- The Tecnis Z9000 intraocular lens (AMO, Santa Ana, CA) has been designed with a modified prolate anterior surface to compensate for the spherical aberration of the cornea, thus eliminating total ocular spherical aberration.
- Clinical data demonstrate that this modified prolate IOL provides superior functional vision similar to that of younger people and hence improves visual performance when compared with conventional spherical IOLs.
- The integration of wavefront technology and lens-based surgery represents a step toward improving functional vision and quality of life for cataract patients.

9.1 Introduction

The term functional vision describes the impact of sight on quality of life. Recognizing faces and facial expressions, reading the newspaper, driving at night, performing vocational tasks and participating in recreational pursuits all bear a relation to functional vision for ophthalmic patients. Functional vision not only implies the role of sight in safety and accident prevention, but also suggests the importance of high-quality vision in vocations such as astronomy, aeronautics and visual arts.

Visual acuity does not entirely reflect functional vision. As stated in the basic and clinical science course of the American Academy of Ophthalmology, "We know intuitively that given the appropriate set of circumstances each of us with 20/20 vision will func-

tion as a visually handicapped individual. Thus, when a person is driving into the sun at dusk, or dawn, changes in contrast sensitivity and the effect of glare alter detail discrimination" [1].

Multiple scientific studies have demonstrated that contrast sensitivity represents a robust indicator of functional vision [2–10]. The contrast sensitivity function, measured under varying conditions of luminance and glare, establishes the limits of visual perception across the spectrum of spatial frequencies. Contrast sensitivity testing determines the relationship between the optical efficiency of the eye (modulation transfer function) and the minimum retinal threshold for pattern detection (modulation threshold function) [11, 12]. Therefore, contrast sensitivity testing effectively describes the function of the physiologic visual system as a whole.

The correction of spherical and cylindrical refractive errors, whether by spectacles, contact lenses or surgery, represents an integral part of the determination of the intrinsic contrast sensitivity of the visual system. Ametropias produce blur and hinder recognition of objects [13]. Higher-order optical aberrations such as spherical aberration and coma also have an impact on contrast sensitivity and functional vision [14–22]. The total effect of all monochromatic optical aberrations, as measured by wavefront-sensing techniques [23, 24], represents an expression of the optical quality of the eye. High optical quality is necessary for high contrast sensitivity.

In order to test the limits of the visual system beyond the retina, we must first produce an image of the highest possible quality on the retina. The production of this high-quality image remains the goal of lenticular surgery.

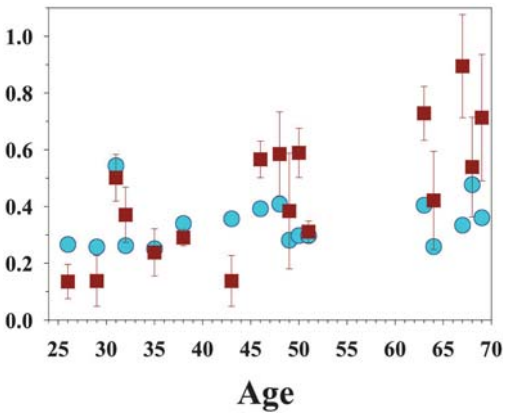


Fig. 9.1. In youth, the total optical aberrations of the eye (*squares*) are less than those of the cornea (*circles*). With age, the total aberrations become greater than those of the cornea. (From [27])

9.2 Contrast Sensitivity and Spherical Aberration

Contrast sensitivity declines with age, even in the absence of ocular pathology such as cataract, glaucoma or macular degeneration [25]. Advances in wavefront science have allowed researchers to show that this decline in visual capability likely involves decreased retinal image quality due to changes in the spherical aberration of the crystalline lens [26]. It has been shown that spherical aberration of the human lens increases with age, while the amount of spherical aberration in the human cornea remains constant or tends to increase only slightly with age (Fig. 9.1) [27]. The youthful lens counteracts much of this defect by inducing negative spherical aberration, whereas the aging lens fails to compensate for aberrations in the cornea [28].

9.3 Conventional Spherical and Modified Prolate IOLs

Conventional spherical intraocular lenses (IOLs) have positive spherical aberration. As a result, contrast sensitivity of pseudophakic patients is no better than that of their age-matched counterparts without cataract [29]. In fact, patients with prior IOL surgery show statistically significant elevation of fourth-order spherical aberration and total wavefront variance for pupil sizes greater than 5 mm, compared to normals [30]. Investigations have been conducted recently to evaluate a complementary IOL that would mimic the youthful crystalline lens by reducing total optical spherical aberration and improve contrast sensitivity levels [31]. The amount of negative spherical aberration incorporated into this new IOL was based on the average positive spherical aberration present in a population of 71 cataract patients (Z [4,0] = 0.27 +/– 0.02 μ). This mean corneal spherical aberration value has since been confirmed by independent investigators, whose study included 228 eyes of 134 subjects (Z [4,0] = 0.28 +/– 0.086 μ) [32].

A unique IOL with a prolate anterior surface has been designed to compensate for the average spherical aberration of the cornea and improve the ocular optical quality of pseudophakic patients. Known as the Tecnis Z9000 IOL (AMO), this lens features a modified prolate surface with negative spherical aberration, thereby approximating the optical system of the youthful eye. As a result, it is hypothesized to produce higher-quality retinal images. The Tecnis Z9000 IOL has a biconvex design, a refractive index of 1.46 and an optic diameter of 6 mm. The lens has a posterior and anterior sharp-edge design. The superior optical performance of the Tecnis Z9000 IOL is maintained as long as the lens is tilted at an angle of less than 70, and decentered less than 0.4 mm, surgical tolerances routinely achieved with continuous curvilinear capsulorrhexis and in-the-bag placement of IOLs [31]. Depth of focus is comparable to a spherical IOL [31].

9.4 Clinical Data Evaluating a Modified Prolate IOL with Negative Spherical Aberration

Clinical data from a range of studies demonstrate that the use of a modified prolate IOL during cataract surgery has the potential to provide superior contrast sensitivity under both mesopic and photopic conditions. Clinical results also confirm the theoretical preclinical calculations that the spherical aberration of the eye after cataract surgery can be eliminated by modifying the anterior surface of the IOL.

The first published clinical data reported results of a prospective randomized trial comparing the contrast sensitivity obtained with the Tecnis Z9000 IOL with that obtained using the AR40e Opti-Edge IOL (AMO), a standard spherical intraocular lens [33]. Assessment of peak mesopic contrast sensitivity showed that the Tecnis IOL provided a 0.27 log unit (77.9%) gain in peak contrast sensitivity at three cycles per degree compared with the control IOL. The authors found no statistically significant difference between the Tecnis Z9000 mesopic contrast sensitivity and the AR40e photopic contrast sensitivity. This remarkable finding implies that patients implanted with a modified prolate IOL see as well in very dim light as those implanted with a spherical IOL see in bright light. Furthermore, a comparison between patients in this study and healthy subjects aged 20–50 years showed that contrast sensitivity was actually better in the Tecnis patients than it was in the 20- to 30-year-old healthy subjects [34].

Results from an expansion of this earlier study show enhanced functional vision with the Tecnis IOL. The lens was associated with statistically significantly better contrast sensitivity vs. the comparator lens, increasing by 23.4–62.6% (0.14–0.24 log unit difference) in photopic conditions and between 38.3 and 74% (0.15–0.27 log unit difference) under mesopic conditions (Fig. 9.2) [35].

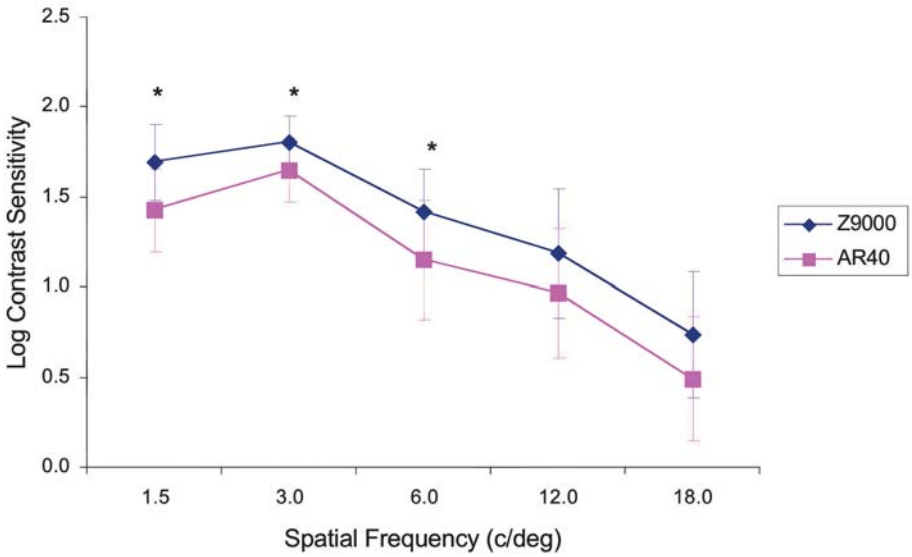


Fig. 9.2. Statistically significant superior contrast sensitivity was found in the eyes implanted with the modified prolate IOL at 1.5, 3.0 and 6.0 cycles per degree. (From [35])

9.5 Corroborating Evidence

In another clinical comparative study, investigators carried out an intraindividual randomized study comparing the Tecnis Z9000 lens with the SI-40 IOL (AMO) in 45 patients with bilateral cataract [36]. Thirty-seven patients were examined at all follow-up visits up to 3 months after surgery. Although the eyes with the Tecnis Z9000 IOL had significantly better best corrected visual acuity after 3 months, the improved quality of vision was more apparent when assessing low-contrast visual acuity and contrast sensitivity. Wavefront measurements revealed no significant spherical aberration in eyes with a Tecnis Z9000 IOL, but significantly positive spherical aberration in eyes with an SI-40 IOL.

Clinical findings of a prospective study comparing the Tecnis IOL with the conventional spherical SA60AT (Alcon) IOL also showed improvements in contrast sensitivity with the Tecnis lens (Fig. 9.3) [37]. Thirty patients with senile cataract but no other eye pathology who were scheduled for sequential bilateral surgery were included in this prospective interindividual comparison. Statistically significant differences in photopic and low-light contrast sensitivity were noted in favor of those eyes implanted with the Tecnis Z9000 foldable lens, generating significantly better functional results than those achieved with a conventional acrylic IOL.

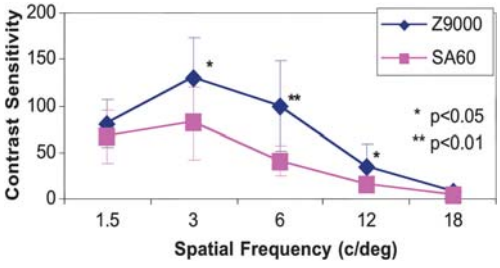


Fig. 9.3. Significant differences in contrast sensitivity under mesopic conditions occurred in this randomized, prospective study. (From [37])

9.6 Retinal Image Contrast and Contrast Sensitivity

Another investigator has described a prospective, randomized study comparing the Tecnis Z9000 modified prolate (aspheric) IOL with conventional spherical silicone and acrylic IOLs in terms of effect on retinal image contrast and functional visual performance [38]. Two hundred and twenty-one eyes of 156 patients were randomly assigned to receive one of each of three intraocular lenses with 6 months of follow-up. Measured parameters included visual acuity, fundus photographic retinal image contrast, and functional acuity contrast testing. The differences in the pre- and postoperative spherical and astigmatic refractive error and preoperative best corrected visual acuity between groups were not statistically significant. In the first postoperative month, uncorrected visual acuity was best in the aspheric group. The aspheric IOL group exhibited up to 47% increase in contrast for photopic, 38% in photopic with glare, 100% in mesopic and 100% in mesopic with glare functional acuity contrast testing. Acrylic IOLs showed no increase in photopic, up to 38% increase in photopic with glare, 50% in mesopic and 50% in mesopic with glare. Spherical silicone IOLs showed no increase in contrast testing when compared to cataract. Digital analysis of retinal imaging demonstrated increased threshold luminance levels in the aspheric group (range 116–208) and a fourfold increase in image contrast compared to the silicone and acrylic groups. The aspheric IOL (Tecnis) provided significant improvement in objective retinal image contrast and in visual performance, as measured by visual acuity and functional acuity contrast testing. This improvement was most pronounced in night vision and night vision with glare contrast testing when compared with conventional spherical silicone and acrylic IOLs.

9.7 Spherical Aberration and Night Driving Simulation Studies

Data from a large prospective, randomized, double-masked multicenter trial involving 77 patients implanted with the Tecnis Z9000 IOL in one eye and the SA60AT IOL in the fellow eye have been submitted to the US Food and Drug Administration. One of the most surprising results of this study was a statistically significant difference in best corrected Early Treatment of Diabetic Retinopathy Study visual acuity favoring eyes implanted with the Tecnis IOL, assessed 90 days postoperatively (0.140 vs. 0.171 logMAR, difference = –0.031, $p = 0.0066$). Using wavefront aberrometry, spherical aberrations were eliminated in eyes implanted with the Tecnis IOL but still observed in control eyes [39].

Double-masked night driving simulator tests were conducted in a sub-population of 29 patients. Using a variety of different targets, such as road signs or pedestrians, under a variety of different conditions, city or rural, improved detection and identification distances for virtually all targets were found for those eyes implanted with the Tecnis IOL. The results show that the Tecnis IOL is superior to the SA60AT in allowing detection of most of the targets under various conditions, with the greatest advantage seen for a hazard target (e.g., pedestrian) under rural (lower light) conditions. This suggests that the Tecnis IOL is superior, especially for low-contrast targets under low illumination [39].

Additionally, evaluation of the effect of glare showed that those eyes with the Tecnis IOL performed as well as control eyes without glare. Also, the driving test performance of patients correlated significantly with their residual spherical aberration. This may suggest that correcting spherical aberration may improve a person's ability to recognize targets earlier while operating under reduced visibility conditions.

9.8 Conclusion

Evidence from several well-conducted, peer-reviewed clinical investigations confirms that correction of spherical aberration using an IOL with a modified anterior surface leads to a significant improvement in quality of vision in pseudophakia, as demonstrated by contrast sensitivity testing and night driving simulation. Clinical data demonstrate that the modified prolate IOL, designed to compensate for the positive spherical aberration of the cornea, provides superior functional vision and hence improved visual performance when compared with conventional spherical IOLs, as measured by sine wave grating contrast sensitivity, wavefront sensing and night driving simulation testing.

Future directions include potential customization of this prolate lens, with a range of spherical powers to suit individual aberration values outside the estimated population average. The development of a prolate multifocal IOL offers further potential in the field of refractive optics. Another exciting technology that will employ wavefront sensing to correct optical aberrations is the light-adjustable lens (Calhoun Vision). This is a silicone IOL with photosensitive material that can be adjusted after implantation to correct myopia, hyperopia, astigmatism and perhaps coma or spherical aberration [40].

References

1. Miller D, Gurland JE, Isbey EK et al (1992) Optics, refraction and contact lenses. In: Wilson FM (chairperson) Basic and clinical science course. American Academy of Ophthalmology, San Francisco, pp 103–104
2. Ginsburg AP (1986) Spatial filtering and visual form perception. In: Boff K (ed) Handbook of perception and human performance. Wiley, New York
3. Owsley C, Sloane M (1987) Contrast sensitivity, acuity, and the perception of "real world" targets. Br J Ophthalmol 71:791–796
4. Decina LE, Staplin L (1993) Retrospective evaluation of alternative vision screening criteria for older and younger drivers. Accid Anal Prev 25:267–275
5. Ginsburg AP, Rosenthal B, Cohen J (1987) The evaluation of reading capability of low vision patients using the Vision Contrast Test System (VCTS). In: Woo GC (ed) Low vision: principles and applications. Springer, Berlin Heidelberg New York
6. Ginsburg AP, Evans DW, Sekule R, Harp SA (1982) Contrast sensitivity predicts pilots' performance in aircraft simulators. Am J Optom Physiol Opt 59:105–109
7. Rubin GS, Bandeen Roche K, Huang GH et al (2001) The association of multiple visual impairments with self-reported visual disability: SEE project. Invest Ophthalmol Vis Sci 42:64–72
8. Lord SR, Menz HB (2000) Visual contributions to postural stability in older adults. Gerontology 46:306–310
9. Owsley C, Stalvey BT, Wells J et al (2001) Visual risk factors for crash involvement in older drivers with cataract. Arch Ophthalmol 119: 881–887
10. Lord SR, Dayhew J (2001) Visual risk factors for falls in older people. J Am Geriatr Soc 49: 676–677
11. Campbell FW, Green DG (1965) Optical and retinal factors affecting visual resolution. J Physiol 181:576–593
12. Schwiegerling J (2000) Theoretical limits to visual performance. Surv Ophthalmol 45:139–146
13. Miller D, Gurland JE, Isbey EK et al (1992) Optics, refraction and contact lenses. In: Wilson FM (chairperson) Basic and clinical science course. American Academy of Ophthalmology, San Francisco, p 106
14. Tang CY, Charman WN (1992) Effects of monochromatic and chromatic oblique aberrations on visual performance during spectacle lens wear. Ophthalmic Physiol Opt 12:340–349
15. Applegate RA, Howland HC, Sharp RP et al (1998) Corneal aberrations and visual performance after radial keratotomy. J Refract Surg 14:397–407
16. Schlote T, Derse M, Wannke B et al (1999) Impairment of mesopic vision following photorefractive keratectomy of myopia. Klin Monatsbl Augenheilkd 214:136–141

17. Seiler T, Kaemmerer M, Mierdel P, Krinke HE (2000) Ocular optical aberrations after photorefractive keratectomy for myopia and myopic astigmatism. Arch Ophthalmol 118:17–21
18. Applegate RA, Hilmantel G, Howland HC et al (2000) Corneal first surface optical aberrations and visual performance. J Refract Surg 16: 507–514
19. McLellan JS, Marcos S, Burns SA (2001) Age-related changes in monochromatic wave aberrations of the human eye. Invest Ophthalmol Vis Sci 42:1390–1395
20. Negishi K, Ohnuma K, Hirayama N, Noda T (2001) Effect of chromatic aberration on contrast sensitivity in pseudophakic eyes. Arch Ophthalmol 119:1154–1158
21. Marcos S (2001) Aberrations and visual performance following standard laser vision correction. J Refract Surg 17:S596–S601
22. Guirao A, Redondo M, Geraghty E, Piers P, Norrby S, Artal P (2002) Corneal optical aberrations and retinal image quality in patients in whom monofocal intraocular lenses were implanted. Arch Ophthalmol 120:1143–1151
23. Liang J, Grimm B, Goelz S, Bille JF (1994) Objective measurement of wave aberrations of the human eye with the use of a Hartmann-Shack wave-front sensor. J Opt Soc Am A 11:1949–1957
24. Mierdel P, Kaemmerer M, Mrochen M et al (2001) Ocular optical aberrometer for clinical use. J Biomed Opt 6:200–204
25. Packer M, Fine IH, Hoffman RS, Ginsburg A, Paggiarino D (2003) Contrast sensitivity in healthy subjects 20 to 69 years old [abstract 53]. Symposium on cataract, IOL and refractive surgery. American Society of Cataract and Refractive Surgery, San Francisco, 12–16 Apr 2003
26. Artal P, Berrio E, Guirao A, Piers P (2002) Contribution of the cornea and internal surfaces to the change of ocular aberrations with age. J Opt Soc Am A 19:137–143
27. Guirao A, Redondo M, Artal P (2000) Optical aberrations of the human cornea as a function of age. J Opt Soc Am A Opt Image Sci Vis 17: 1697–1702
28. Artal P, Guirao A, Berrio E, Williams D (2001) Compensation of corneal aberrations by the internal optics in the human eye. J Vis 1:1–8
29. Nio YK, Jansonius NM, Fidler V, Geraghty E, Norrby S, Kooijman AC (2002) Spherical and irregular aberrations are important for the optimal performance of the human eye. Ophthalmic Physiol Opt 22:103–112
30. Miller JM, Anwaruddin R, Straub J, Schwiegerling J (2002) Higher order aberrations in normal, dilated, intraocular lens, and laser in situ keratomileusis corneas. J Refract Surg 18: S579–S583
31. Holladay JT, Piers PA, Koranyi G, van der Mooren M, Norrby NE (2002) A new intraocular lens design to reduce spherical aberration of pseudophakic eyes. J Refract Surg 18:683–691
32. Wang L, Dai E, Koch DD, Nathoo A (2003) Optical aberrations of the human anterior cornea. J Cataract Refract Surg 29:1514–1521
33. Packer M, Fine IH, Hoffman RS, Piers PA (2002) Prospective randomized trial of an anterior surface modified prolate intraocular lens. J Refract Surg 18:692–696
34. Packer M, Fine IH, Hoffman RS (2003) Functional vision, wavefront sensing, and cataract surgery. Int Ophthalmol Clin 43:79–91
35. Packer M, Fine IH, Hoffman RS, Piers PA (2004) Improved functional vision with a modified prolate intraocular lens. J Cataract Refract Surg 30:986–992
36. Mester U, Dillinger P, Anterist N (2003) Impact of a modified optic design on visual function: clinical comparative study. J Cataract Refract Surg 29:652–660
37. Bellucci R, Morselli S, Piers P. (2004) Comparison of wavefront aberrations and optical quality of eyes implanted with five different intraocular lenses. I Refract Surg 20(4):291–306
38. Kershner RM (2003) Prospective evaluation of aspheric, silicone and acrylic IOLs on visual performance (abstract 801). Symposium on cataract, IOL and refractive surgery. American Society of Cataract and Refractive Surgery, San Francisco, 12–16 Apr 2003
39. Packer M (2003) Evaluation of a modified prolate surface IOL with the WASCA Analyzer. Publication no 000000–1276–350. Carl Zeiss Meditec, Jena, Germany
40. Schwartz D (2003) "Light adjustable IOL." 12th annual ocular surgery news symposium, New York, 20 Sep 2003

10 The Eyeonics Crystalens

Steven J. Dell

CORE MESSAGES

- Early observations with standard plate-haptic intraocular lenses suggested that an accommodating lens could be designed to take advantage of the hydraulic gradient present between the anterior and posterior chambers during ciliary muscle contraction. These observations led to the development of the Eyeonics Crystalens.
- The Eyeonics Crystalens is a modified plate-haptic silicone accommodating intraocular lens designed to flex anteriorly in response to ciliary muscle contraction. As vitreous pressure increases in response to action of the ciliary muscle, the Crystalens moves anteriorly.
- Crystalens FDA clinical trial results demonstrate that near vision through the distance correction is significantly improved over that typically achieved with traditional intraocular lenses. Dysphotopsia has been rare despite the relatively small 4.5-mm optic, and contrast sensitivity results have been comparable to standard intraocular lenses.
- Patient satisfaction with the Crystalens has been very good, with a high percentage of patients achieving spectacle independence for distance, intermediate and near tasks. The accommodative effect persists after YAG capsulotomy, and it has been sustained throughout the duration of clinical experience with the lens.
- Precision biometry and a watertight wound closure are essential to achieve good clinical results with the Crystalens. Corneal astigmatism should be addressed at the time of surgery, typically with limbal relaxing incisions. Cycloplegia is essential in the early postoperative period to ensure correct positioning of the lens.

10.1 The Pursuit of Accommodation

Traditional pseudophakic intraocular lenses (IOLs) have provided excellent levels of uncorrected distance acuity, but have proved ineffective in dealing with the absolute presbyopia accompanying their use. The Eyeonics Crystalens offers the ability to provide accommodation in addition to high-quality uncorrected distance vision, and represents a major advance in lens surgery. The accommodative abilities of the Crystalens have made it a particularly popular choice for patients undergoing refractive lens exchange.

The design of the Crystalens accommodative IOL evolved from a number of observations made by Dr. Stuart Cumming, the inventor of the lens. Cumming noted that some pseudophakes with plate-haptic lenses had relatively good near acuity through the distance correction. Studies by Coleman examining primates found that, with electrical stimulation of the ciliary muscle, pressure within the vitreous cavity increased and pressure within the anterior chamber decreased [1]. Busacca carefully examined the ciliary muscle of an aniridic patient with gonioscopy and noted that during accommodation, the ciliary redistributed its mass and impinged upon the vitreous base [2]. Thornton examined the anterior chamber depth in pseudophakic patients with traditional IOLs and determined that shallowing of the anterior chamber could be observed with accommodation [3]. Cumming reasoned that an IOL could be designed that took advantage of this hydraulic pressure differential during accommodation to shift the position of the optic.

The Eyeonics Crystalens is a modified plate-haptic silicone IOL, designed to move in response to ciliary muscle contraction with accommodation (Fig. 10.1). This movement provides a single point of focus that moves throughout the full range of distance, intermediate and near vision. It is the first accommodative IOL to receive Food and Drug Administration (FDA) approval for use in the USA.

Fig. 10.1. The Eyeonics Crystalens. (Courtesy of Eyeonics)

Fig. 10.2. Crystalens with 4.5-mm optic diameter, and hinges at the plate-optic junction. Polyimide loops terminate from the plates. The material is a third-generation silicone. (Courtesy of Eyeonics)

The Crystalens incorporates a relatively small 4.5-mm optic with hinges at the plate-optic junction. Polyimide loops terminate off the plate haptics and ensure excellent fixation in the capsular bag (Fig. 10.2). The overall length of the lens is 10.5 mm, with a diameter of 11.5 mm from loop tip to loop tip. The lens

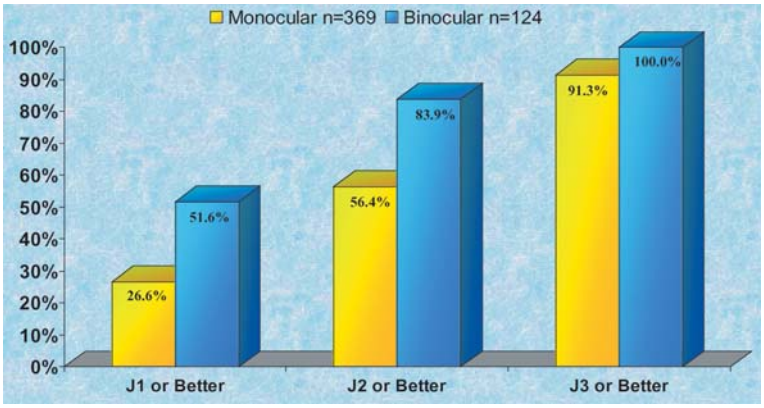


Fig. 10.3. Under binocular conditions, 84% of Crystalens patients in the FDA trial achieved DCNVA of J2 or better

material is a third-generation silicone with an integrated chromophore. The plate-haptic configuration was originally selected for this lens design because of the tendency for plate-haptic IOLs to position themselves very far posteriorly in the capsular bag [4, 5]. This maximum posterior positioning allows for the greatest potential anterior movement upon ciliary body contraction. For an average power IOL, approximately 1 mm of anterior movement is required to achieve 2 diopters of accommodative effect. The relatively small optic was selected as a result of studies by Kammann demonstrating that plate lenses with smaller optics tended to position themselves even further posteriorly than lenses with larger optics, despite the same overall IOL length [4]. While the optic is unusually small, its position near the nodal point of the eye, where light rays cross, theoretically allows the lens to achieve the optical functionality of an implant with a larger optic. The placement of hinges at the optic-plate junctions is designed to maximize anterior movement of the optic.

Thus, the proposed mechanism of action of the Crystalens involves constriction of the ciliary muscle, with redistribution of its mass. This in turn exerts pressure on the vitreous base, which increases pressure in the vitreous cavity and pushes the highly flexible, posteriorly vaulted optic anteriorly. With accommodative effort, transient myopia results, and the patient is able to function well at near.

10.2 FDA Clinical Trial Results

The US FDA clinical trial examined the use of the Crystalens in cataract surgery. The trial was completed in November 2001, with a total of 497 implantations performed. The trial results showed that the Crystalens offered visual performance at distance comparable to any standard IOL, with excellent uncorrected and corrected distance acuities. Accommodative visual performance was measured by testing the near vision through the distance correction. This measurement is referred to as the distance-corrected near visual acuity (DCNVA). Monocular testing of Crystalens patients demonstrated that 91% of eyes were able to achieve DCNVA of J3 or better, and binocular testing showed that 100% of patients achieved DCNVA of J3 or better, with 84% achieving DCNVA of J2 or better (Fig. 10.3). This level of near acuity is significantly better than that typically achieved with standard IOLs [6, 7]. Vision at the intermediate distance was very impressive as well. Testing binocularly through the distance correction, 100% of these patients could see J1 or better at 32 inches, and 98% could see J1+. From a clinical standpoint, these patients were largely spectacle independent, with 74% reporting that they either did not wear spectacles, or wore them almost none of the time (Fig. 10.4).

There was a general tendency for the near performance of these patients to improve with time throughout the first year of clinical study. The reasons for this phenomenon are unknown. It is possible that the ciliary muscle slowly begins to function again after years of disuse. Another possible explanation is that a stiffer posterior capsule more effectively transfers force from the vitreous, allowing more movement of the optic.

Bilateral Implanted Subjects		
Wearing Spectacles	n/n (%)	
I do not wear spectacles	33/128 (25.8%)	73.5%
Almost none of the time	61/128 (47.7%)	
26% to 50% of the time	20/128 (15.6%)	
51% to 75% of the time	8/128 (6.3%)	
76% to 100% of the time	6/128 (4.7%)	
Night Spectacles	n/n (%)	
No	110/128 (84.6%)	
Yes	20/130 (15.4%)	

Fig. 10.4. Spectacle use survey of FDA trial participants showed that 74% either did not wear spectacles, or wore them almost none of the time

The unusually small 4.5-mm optic initially sparked concerns among the clinical investigators that the Crystalens would create dysphotopsia in patients. The results of the trial demonstrated that this is not the case, and Crystalens patients generally report night vision comparable to standard IOLs. In a substudy examining pupil size under 0.04 Lux scotopic conditions, a questionnaire demonstrated minimal glare complaints despite average scotopic pupil sizes of 5.02 mm [8]. Studies of contrast sensitivity comparing the Crystalens to a traditional 6-mm Acrysof IOL have demonstrated comparable contrast sensitivity scores throughout the spatial frequency range [8].

Wavefront analysis has been used to demonstrate a refractive power change in Crystalens patients as they shift their gaze from near to distance fixation [9]. This is probably the most direct evidence of the accommodative abilities of these patients, although such measurements are a challenge to obtain given current wavefront aberrometry technology. Variations in pupil size, convergence during accommodation and lack of an accommodative target are just a few of the

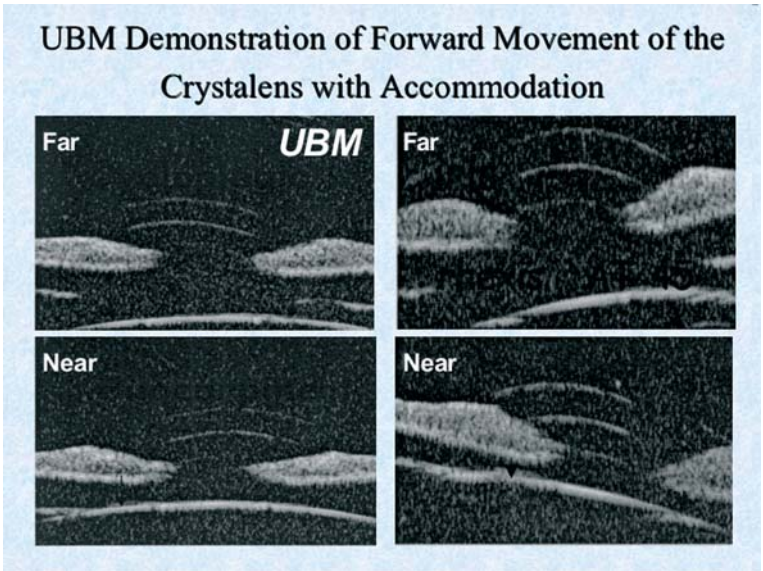


Fig. 10.5. Ultrasound biomicroscopy showing anterior movement of the Crystalens in response to accommodation. (Courtesy of Miguel Angel Zato)

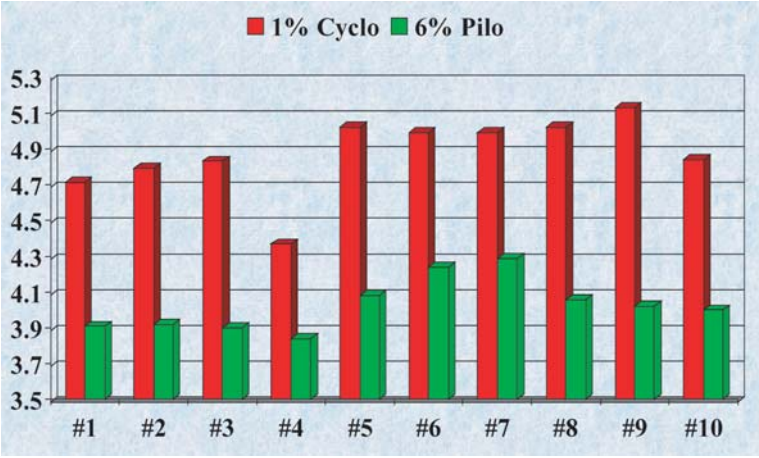


Fig. 10.6. Anterior movement of the Crystalens with pilocarpine as compared to cyclopentolate. The mean movement of 0.84 mm when applied in a weighted fashion to the various IOL powers actually implanted yields a mean monocular accommodative change of +1.79 diopters

challenges associated with obtaining valid power change maps with wavefront aberrometry.

High-resolution ultrasound studies have also been performed, which demonstrate anterior movement of the Crystalens optic upon accommodation (Fig. 10.5). Additionally, in a study using immersion A-scan ultrasonography to examine the anterior chamber depth (ACD) in Crystalens patients upon paralysis of accommodation with a cycloplegic as compared to stimulation of accommodation with a miotic, the ACD decreased significantly [10]. Average forward movement of 0.84 mm was demonstrated in this study, which translated into 1.79 diopters of average monocular accommodation with the Crystalens (Fig. 10.6).

10.3 Clinical Considerations

With an implant available that provides accommodation, what factors influence the decision to use the Crystalens in any given patient? One concern regarding the Crystalens, particularly in young patients, is the possibility that the lens could experience material fatigue, resulting in failure of the hinge over time. The lens has been subjected to biomechanical testing, which simulates the many accommodative cycles likely to occur throughout the lifespan of a patient. In fact, the testing performed subjected the lens to much more vigorous movement than would ever be encountered physiologically. This testing indicates that the lens material will last without deterioration. Unlike acrylic, which has a tendency to crack under repeated stress, the flexibility of silicone is well suited to a moving hinge.

Another consideration relates to the use of the Crystalens in patients with very large pupils. While excellent scotopic results were achieved in the clinical trial, these patients had an average age of approximately 70 years. How will the lens perform in much younger patients with larger pupils? My own clinical impression is that Crystalens patients have no greater incidence of dysphotopsia than those with any other IOL, but I tend to proceed cautiously in patients with very large pupils. As we gain more experience with this lens, we will understand this issue more thoroughly.

Patients with diseased maculae and limited visual potential after lens surgery will probably not obtain sufficient benefit from the Crystalens to justify its use. Similarly, patients in whom the use of a silicone IOL is contraindicated are not candidates. FDA labeling of the Crystalens states that it should not be used in the presence of a posterior cap-

sule tear at the time of cataract surgery. An intact capsulorrhexis is required for placement of the lens. Due to the unpredictable capsular contraction possible in pseudoexfoliation patients, use of the Crystalens is probably not indicated in these cases as well.

Patients should be cautioned to expect halos from pupil dilation in the first week after surgery. During this period of cycloplegia, their near acuity will be quite poor. In fact, data from the clinical trial indicate that near acuity does not begin to improve significantly for several weeks. Patients should also be advised that the accommodative results tend to continue to improve throughout the first postoperative year. Additionally, in the FDA trial, bilateral implantations yielded better results than unilateral implantations.

One critical factor in the success of the Crystalens is its ability to perform well throughout the axial length range. Since the lens relies upon movement of the optic to produce its accommodative power change, one could infer that high-power lenses would perform better than low-power lenses. As an extreme example, an IOL with zero power could be moved an infinite distance with no effect on refractive power. When the accommodative function of the Crystalens was evaluated as a function of IOL power in the range included in the US clinical trial (16.5–27.5 D), the lens performed as well with low-power implantations as with high-power implantations. One possible explanation for this is that, although low-power implantations derive less refractive change for each millimeter of anterior lens motion, the lens–iris diaphragm configuration of these longer eyes allows for a greater anterior excursion of the lens upon ciliary body contraction. It remains to be seen what the lower-power limits will be for Crystalens implantation.

One could imagine a scenario where the IOL power used for any given eye could be artificially increased in a number of ways. Under one such scenario, a bioptics procedure could be performed in which a Crystalens power would be selected that would render the patient iatrogenically highly myopic, but a phakic IOL could be piggybacked in front of the Crystalens to return the patient to emmetropia. This may have the effect of boosting the potential accommodative amplitude to even higher levels.

Preservation of accommodation after YAG capsulotomy is another issue that has been thoroughly examined. Over 50 eyes in the US clinical trial have undergone YAG capsulotomy, and their accommodative abilities have remained undiminished by the YAG capsulotomy. Additionally, when patients who had undergone YAG were compared with those who had not undergone YAG who had clear capsules, there were no differences in accommodative abilities between the two groups. The incidence of YAG capsulotomy may be higher for the Crystalens than for some other intraocular lenses [11, 12]; however, many of these Crystalens patients underwent capsulotomy despite 20/20 best corrected distance vision. The reason for this is that very subtle posterior capsular fibrosis has an effect on near acuity prior to affecting distance acuity. The implication is that such patients would not receive a capsulotomy with a standard intraocular lens. Capsulotomy openings should be kept small, in the order of 3 mm or less, to avoid vitreous herniation around the optic.

Lastly, what assurances do we have that the accommodative effects of the Crystalens will persist? Three-year data are now available on the eyes from the US clinical trial, which show no degradation in accommodative performance over time (Fig. 10.7). Longer follow-up data are available from outside the US, which similarly indicate no degradation of the accommodative effect.

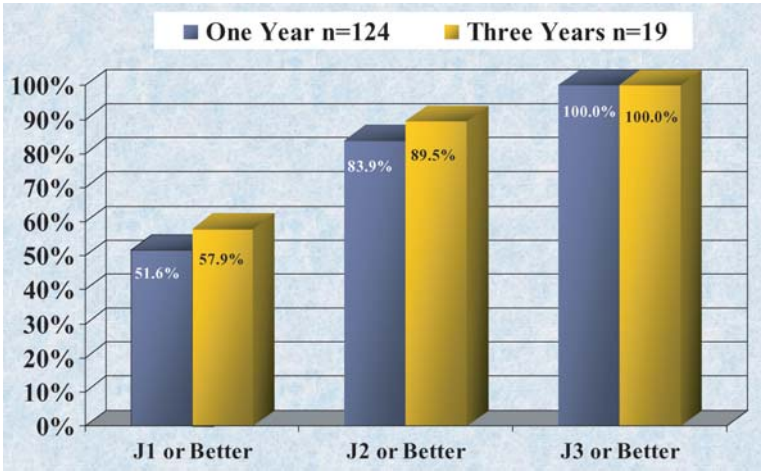


Fig. 10.7. One- and 3-year data from the FDA trial, demonstrating no deterioration of accommodation

10.4 Preoperative Considerations

Clinical success with the Crystalens requires achieving near emmetropia in a high percentage of patients. This is particularly true as many patients receive the lens in the context of refractive lens exchange. Precision biometry is essential to meet this goal. Accurate axial length determinations can be accomplished with immersion A-scan ultrasonography or laser interferometry using the IOL Master (Carl Zeiss Meditec, Jena, Germany); however, contact A-scan ultrasonography should be avoided as it is prone to compression errors with resulting underestimation of true axial length.

In the clinical trial, manual keratometry was used in all patients. The use of a manual keratometer is highly recommended, as automated keratometers lack the accuracy of manual readings. Topographically derived keratometry also lacks the accuracy of manual keratometry, and is therefore not recommended. Surgeons should take care to calibrate their keratometers regularly, as these instruments may periodically drift out of calibration.

Intraocular lens calculations should be performed with a modern IOL software program such as the Holladay II formula (Holladay Consulting, Inc., Bellaire, TX). The surgeon's outcomes should be regularly tracked to monitor refractive accuracy.

For patients with corneal astigmatism, limbal relaxing incisions (LRI) are useful to reduce this component of the patient's refractive error [13, 14]. Eliminating the spherical component of the refractive error without addressing the remaining corneal astigmatism will likely result in an unsatisfactory clinical outcome. LRIs may be performed at the time of Crystalens implantation, or at a later date after the astigmatic effects of the original surgery are known.

Patients seeking refractive lens exchange may have previously undergone keratorefractive surgery in years past. This is an issue of increasing significance. Prior keratorefractive surgery is not a contraindication to surgery with the Crystalens; however, such patients must be cautioned that the accuracy of biometry is reduced, and unexpected refractive errors may result.

10.5 Surgical Considerations

The Crystalens is intended for placement in the capsular bag only, and a relatively small capsulorrhexis is required, typically in the range of 5.5 mm. This ensures that the extremely flexible plate haptics of the Crystal-

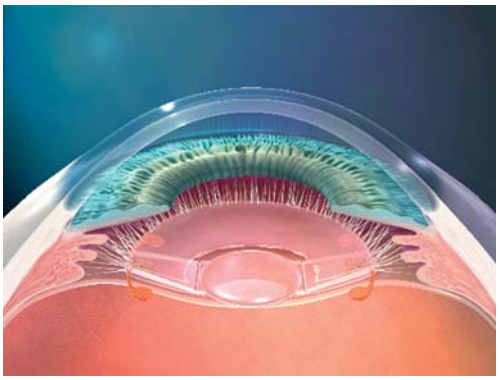


Fig. 10.8. Small capsulorrhexis helps ensure correct posterior vaulting of the Crystalens. A capsulorrhexis that is too large can allow anterior vaulting of the lens, while one that is too small complicates cortical removal and lens implantation, and tends to provoke an intense fibrotic reaction of the capsule

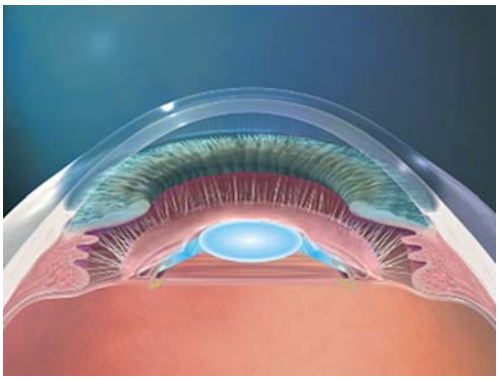


Fig. 10.9. Crystalens that has become stuck in an anteriorly vaulted position due to a wound leak or sudden anterior chamber decompression. Striae are typically visible in the posterior capsule corresponding to the long axis of the lens. Surgical repositioning is required

ens are posteriorly vaulted in the correct position (Fig. 10.8). A capsulorrhexis that is too large can allow anterior vaulting of the lens, while one that is too small can lead to an overly aggressive fibrotic response of the posterior capsule as many more anterior lens epithelial cells are left in place. Very small capsulorrhexes have the added disadvantages of complicating cortical removal and delivery of the trailing plate into the capsular bag. Additionally, a very small capsulorrhexis may dampen accommodative movement of the optic by trapping the Crystalens in a fibrotic cocoon formed by fusion of the anterior and posterior leaves of the capsule. Surprisingly, proper capsulorrhexis sizing has been one of the more challenging aspects of the first few cases of surgeons transitioning to this lens.

In general, the Crystalens provides excellent centration as a result of the polyimide loops at the termination of the plate haptics. Fixation of the polyimide loops occurs relatively early in the postoperative period and exchanging or repositioning the Crystalens can be difficult after approximately 4 weeks. The Crystalens cannot be dialed or rotated in a traditional fashion, as the four polyimide loops engage the peripheral posterior capsule. However, the lens can easily be rotated by centripetally pulling on the optic and allowing it to rotate in short "jumps" with each such maneuver.

A watertight wound closure is essential with the Crystalens, as the implant is susceptible to a unique complication from a leaking wound. Standard IOLs may tolerate a wound leak with only transient shallowing of the anterior chamber, which re-deepens as the wound eventually seals. However, the architecture of the Crystalens creates a different situation. As a result of the extremely flexible plate haptics, a wound leak can allow the Crystalens to vault anteriorly, and the lens can become stuck in this position. This phenomenon requires surgical repositioning of the lens (Fig. 10.9). The Crystalens is designed to be implanted without folding. Typically, the lens can be implanted through an incision of approximately 3.2 mm as it auto-conforms to the incision tunnel architecture. As uniplanar clear corneal incisions are prone to leakage in the early postoperative period, their use is discouraged with the Crystalens [15, 16]. Miotics are not used at the time of surgery.

10.6 Postoperative Considerations

Cycloplegia is essential in the early postoperative period with the Crystalens. Patients are typically placed on cyclopentolate 1%, three times a day for a week after surgery. This ensures that the ciliary muscle is at rest as the Crystalens orients itself in the correct posteriorly vaulted position. Inadequate cycloplegia can allow the lens to shift anteriorly in this critical time period. A classification scheme for anterior vaults has been developed, which differentiates those vaults arising due to inadequate cycloplegia (type 1) from those resulting from wound leaks (type 2) (Figs. 10.10, 10.11).

Contractile forces of the capsule must also be monitored more closely with the Crystalens, as the extremely deformable plate haptics that allow accommodative movement of the optic can also be influenced by fibrotic contraction of the capsule. This can result in changes in the position of the lens within the capsular bag, with induced refractive error. The treatment for this phenomenon is straightforward, and involves a YAG capsulotomy of the fibrotic areas of the posterior capsule. This allows the lens to return to its correct position.

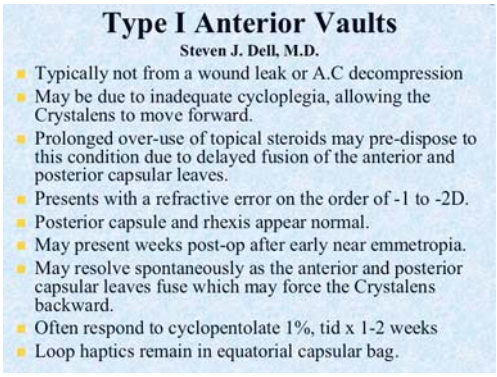


Fig. 10.10. Type I anterior vaults

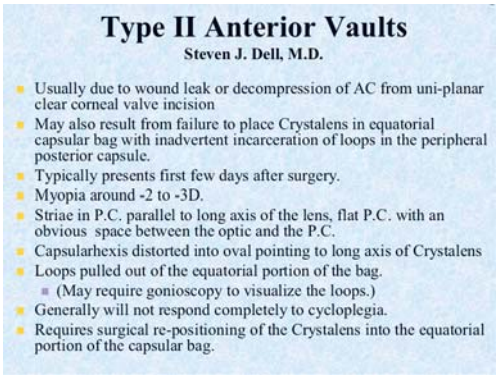


Fig. 10.11. Type II anterior vaults

FINAL COMMENTS

The Crystalens represents a significant advance in intraocular lens technology, and provides surgeons with a novel method of restoring the accommodative abilities of pseudophakic patients. For surgeons willing to invest the time and effort necessary to optimize biometry, surgical technique and postoperative care, the results are very rewarding.

Patients receiving the Crystalens experience a high degree of spectacle independence and patient satisfaction, and they have typically been willing to pay a premium price for the technology. As a refractive surgical device, the lens has proved popular as an attractive alternative to keratorefractive surgery for many presbyopes, especially those with hyperopia. Given the limitations of hyperopic keratorefractive procedures, refractive lens exchange with the Crystalens is a very attractive option for this subset of patients. These hyperopic presbyopes are typically some of the happiest patients to receive accommodative refractive lens exchange. Their preoperative condition renders them unable to function well at any distance, and with the Crystalens, they experience improved functionality at all distances. For myopes, and in particular long axial length myopes, concerns regarding retinal tears after refractive lens exchange will continue to generate controversy. The true incremental risk of refractive lens exchange with modern micro-incisional surgery will be debated for years to come. The Crystalens may offer a theoretic advantage over other lens styles in this group of patients as well. As the Crystalens vaults extremely far posteriorly, it compresses and stabilizes the anterior vitreous face. Many of these patients have shorter vitreous cavity lengths than they did when they were phakic. This stabilization of the anterior vitreous face may offer some protection against vitreoretinal traction in this group of high-risk patients. Only time and careful epidemiological study will resolve this issue.

References

1. Coleman PJ (1986) On the hydraulic suspension theory of accommodation. Trans Am Ophthalmol Soc 84:846–868
2. Busacca A (1955) La physiologie du muscle ciliaire étudiée par la gonioscopie. Ann Ocul 188:1–21
3. Thornton S (1991) Accommodation in pseudophakia. In: Percival SPB (ed) Color atlas of lens implantation. Mosby, St Louis, pp 159–162
4. Kammann J, Cosmar E, Walden K (1998) Vitreous-stabilizing, single-piece, mini-loop, plate-haptic silicone intraocular lens. J Cataract Refract Surg 24:98–106
5. Cumming JS, Ritter JA (1994) The measurement of vitreous cavity length and its comparison pre- and postoperatively. Eur J Implant Refract Surg 6:261–272
6. Steinert R, Aker BL, Trentacost DJ et al (1999) A prospective comparative study of the AMO ARRAY zonal-progressive multifocal silicone intraocular lens and a monofocal intraocular lens. Ophthalmology 106:1243–1255
7. Lindstrom RL (1993) Food and Drug Administration study update. One-year results from 671 patients with the 3 M multifocal intraocular lens. Ophthalmology 100:91–97
8. Dell SJ (2003) C&C vision AT-45 Crystalens. Paper presented at the American Society of Cataract and Refractive Surgery annual meeting; 10–16 Apr 2003, San Francisco, CA
9. Dick HB, Kaiser S (2002) Dynamic aberrometry during accommodation of phakic eyes and eyes with potentially accommodative intraocular lenses. Ophthalmologe 99:825–834

10. Dell SJ (2004) Objective evidence of movement of the Crystalens IOL during accommodation. Paper presented at the American Society of Cataract and Refractive Surgery annual meeting; 1–5 May 2004, San Diego, CA
11. Davison JA (2004) Neodymium:YAG laser posterior capsulotomy after implantation of AcrySof intraocular lenses. J Cataract Refract Surg 30:1492–1500
12. Ando H, Ando N, Oshika T (2003) Cumulative probability of neodymium:YAG laser posterior capsulotomy after phacoemulsification. J Cataract Refract Surg 29:2148–2154
13. Packer M, Fine IH, Hoffman RS (2002) Refractive lens exchange with the array multifocal intraocular lens. J Cataract Refract Surg 28: 421–424
14. Bayramlar Hü, Daglioglu MC, Borazan M (2003) Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery. J Cataract Refract Surg 29:723–728
15. Shingleton BJ, Wadhwani RA, O'Donoghue MW et al (2001) Evaluation of intraocular pressure in the immediate period after phacoemulsification. J Cataract Refract Surg 27: 524–527
16. McDonnell PJ, Taban M, Sarayba M, Rao B, Zhang J, Schiffman R, Chen Z (2003) Dynamic morphology of clear corneal cataract incisions. Ophthalmology 110:2342–2348

11 Presbyopia – Cataract Surgery with Implantation of the Accommodative Posterior Chamber Lens 1CU

Nhung X. Nguyen, Achim Langenbucher, Berthold Seitz, M. Küchle

CORE MESSAGES

- The 1CU (HumanOptics, Erlangen, Germany) is a one-piece hydrophilic acrylic IOL with a spherical optic (diameter 5.5 mm), a total diameter of 9.8 mm, and four specifically designed haptics with transmission elements to allow anterior movement of the lens optic secondary to contraction of the ciliary muscle.
- Patients with 1CU showed a larger accommodative range and better distance-corrected near visual acuity than those in a control group with conventional IOLs.
- Refraction, accommodative range, and lens position all remained stable without signs indicating a systemic trend towards myopia, hypermetropia, posterior chamber IOL dislocation or regression of accommodative properties.
- The incidence and postoperative time point of significant posterior capsular opacification necessitating Nd:YAG capsulotomy in patients with 1CU are equal to those after implantation of hydrophilic acrylic IOLs reported in the literature. After uncomplicated YAG capsulotomy, pseudophakic accommodation capabilities were completely restored.
- Further studies are necessary and are presently being conducted. These include (1) longer follow-up of patients with the 1CU posterior chamber IOL to test long-term stability of posterior chamber IOL position, refraction, and pseudophakic accommodation and (2) a randomized, double-masked, multicenter design to prove definitively the superiority of the 1CU posterior chamber IOL over conventional posterior chamber IOLs.

11.1 Introduction

Presbyopia remains one of the great unsolved challenges in ophthalmology. Ever since von Helmholtz [1], much research has been conducted concerning mechanisms of accommodation, presbyopia and potential solutions [2–8].

Despite excellent restoration of visual acuity and good biocompatibility of presently used posterior chamber intraocular lenses (PCIOL), there is no accommodation in pseudophakic eyes so that patients usually remain presbyopic after cataract surgery. Newer attempts surgically to correct or reduce presbyopia, including scleral expansion surgery, zonal photorefractive keratectomy, or implantation of corneal inlays, so far have achieved no or very limited success in solving the problem [9–11]. Multifocal intraocular lenses (IOLs) allow for improved uncorrected near vision, but at the cost of reduced contrast sensitivity and loss of image quality [12]. This problem has only partly been solved by the introduction of diffractive and bifocal PCIOL [13]. Therefore, in the past few years, there has been increased interest in the development of new IOL devices to achieve active, ciliary muscle-derived accommodation by optic shift principles without reducing image quality. Among these new IOLs, a new accommodative PCIOL (1CU, HumanOptics, Erlangen, Germany) has been designed after principles elaborated by K.D. Hanna. This PCIOL is intended to allow accommodation by anterior movement of the lens optic (optic shift) secondary to contraction of the ciliary muscle.

11.1.1 Definitions

In the literature, various terms such as accommodation, pseudo-accommodation and apparent accommodation are being used interchangeably with regard to pseudophakic eyes. We define pseudophakic accommodation as dynamic change of the refractive state of the pseudophakic eye caused by interactions between the contracting ciliary muscle and the zonules–capsular bag–IOL, resulting in change of refraction at near fixation. Furthermore, we define pseudophakic pseudo-accommodation (apparent accommodation) as static optical properties of the pseudophakic eye independent of the ciliary muscle, resulting in improved uncorrected near vision.

11.1.2 Anatomy and Description of the 1CU Accommodative Intraocular Lens

Several studies using impedance cyclography, ultrasound biomicroscopy and magnetic resonance imaging have shown that the ciliary body retains much of its contractility in older patients [5–7]. Furthermore, modern technology allows refined finite element computer methods to simulate the changes of the ciliary body–zonular–lens apparatus during accommodation. Based on these models, the 1CU PCIOL was developed to allow transmission of the contracting forces of the ciliary body into anterior movement of the lens optic to achieve pseudophakic accommodation. This focus shift principle should allow a defined amount of accommodation, theoretically 1.6–1.9 D per 1-mm anterior movement of the PCIOL optic using the Gullstrand eye.

11.1.3 1CU Posterior Chamber Intraocular Lens

Based on concepts by K.D. Hanna and on finite element computer simulation models, a new acrylic hydrophilic foldable single-piece PCIOL has been designed and manufactured (Type 1CU, HumanOptics AG, Erlangen, Germany). The spherical optic has a diameter of 5.5 mm, with a total diameter of the PCIOL of 9.8 mm (Fig. 11.1). This PCIOL is intended to allow accommodation by anterior movement

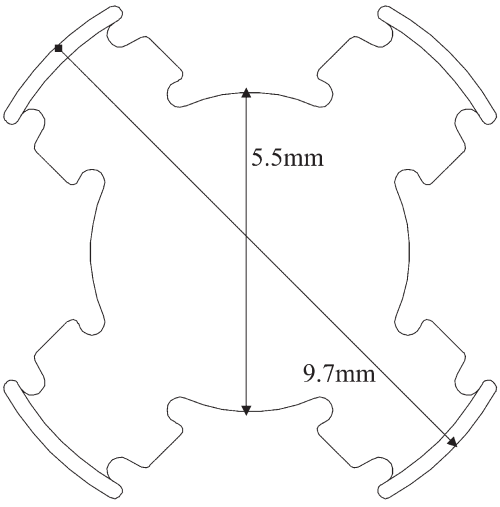


Fig. 11.1. Schematic drawing of the 1CU accommodative intraocular lens

of the optic (focus shift) secondary to contraction of the ciliary muscle. To achieve this aim, the lens haptics are modified with transmission elements at their fusion with the lens optic. In earlier laboratory studies in porcine eyes and human donor eyes not suitable for corneal transplantation, we have refined methods for intraocular implantation of this PCIOL. The 1CU PCIOL is CE-approved.

11.2 Indications and Contraindications

At present, only patients with cataract (i.e. clinically manifest and visually disturbing lens opacities) are candidates for lens exchange with implantation of the 1CU accommodative IOL.

We have carefully observed exclusion criteria, including manifest diabetic retinopathy, previous intraocular surgery, previous severe ocular trauma involving the lens, the zonules or the ciliary body, visible zonulolysis, phacodonesis, pseudoexfoliation syndrome, glaucoma, uveitis, high myopia, and high hypermetropia.

Furthermore, this kind of surgery will not result in satisfying clinical results in patients with severe age-related macular degeneration or marked glaucomatous optic atrophy.

If there are problems during cataract surgery, such as radial tears of the capsulorrhexis, diameter of capsulorrhexis >5.5 mm, zonulolysis, rupture of the posterior capsule, or vitreous loss, the 1CU accommodative IOL should not be implanted and surgery should be converted to implantation of a conventional PCIOL.

11.3 Surgical Techniques and Main Outcome Measures

Generally, any of the modern small-incision phacoemulsification techniques may be used to remove the lens nucleus and lens cortex before the 1CU accommodative IOL is implanted.

11.3.1 Anesthesia

Phacoemulsification and implantation of the 1CU accommodative IOL may be safely performed under local or topical anesthesia. The surgeon may choose the method for cataract surgery with which he is most comfortable. No specific modifications of anesthesia are necessary for implantation of the 1CU accommodative IOL.

11.3.2 Procedure (General)

Phacoemulsification of the lens nucleus and cortical cleaning are not very different from routine cataract surgery. The surgeon may choose the incision and phacoemulsification technique that he routinely uses for cataract surgery. Either a clear cornea or a sclerocorneal incision may be used. If possible, the incision should be placed in the steepest corneal meridian to reduce any pre-existing corneal astigmatism. The capsulorrhexis is of

great importance: it should be small enough (maximum 5.0 mm) to safely and circularly cover the peripheral optic of the IOL (diameter 5.5 mm). In addition, the capsulorrhexis should be round and well centered to allow for the elastic forces of the zonules and lens capsule to be equally distributed. Meticulous removal of all lens cortex and polishing of the posterior lens capsule is important to reduce the risk of capsular fibrosis and posterior capsular opacification. Any of the commercially available viscoelastic agents may be used.

11.3.3 Procedure (Specifics)

Implantation and placement of the 1CU accommodative IOL is the main step of the surgical procedure. It differs in some aspects from implantation of standard IOLs but is relatively easily accomplished. Intraocular lens implantation is best performed with a cartridge and an injector. Folding and implantation with a forceps is also possible but may be associated with an increased risk of damaging the thin and delicate lens haptics. An incision width of 3.2 mm is usually sufficient. The 1CU accommodative IOL is placed into the cartridge with the edges of the haptics pointing upwards/anterior. When folding the lens inside the cartridge, care should be executed to avoid damage to the haptics. After completely filling the anterior chamber and the capsular bag with a viscoelastic agent, the lens is then implanted into the anterior chamber or directly into the capsular bag. If the lens optic is placed in front of the capsular bag, it may be easily pressed down into the capsular bag with a cannula or a spatula. Then the four lens haptics are unfolded inside the capsular bag with a push–pull hook or an iris spatula. The viscoelastic agent should be completely removed also from behind the lens to prevent development of capsular block or capsular distension syndrome, which might theoretically develop otherwise because of the relatively small size of the capsulorrhexis. The lens haptics should be placed at the 12–3–6–9 o'clock positions.

11.3.4 Postoperative Treatment

Postoperative care and medications are similar to those of routine cataract surgery. Postoperative medication usually includes topical antibiotics, topical corticosteroids, and topical short-acting mydriatics such as tropicamide.

Our current postoperative regimen includes combined antibiotic and corticosteroid eye drops (dexamethasone sodium phosphate 0.03% and gentamicin sulfate 0.3%) twice daily and tropicamide 0.5% twice daily. After 5 days, the combined antibiotic/steroidal eye drops are discontinued and changed to prednisone acetate 1% eye drops five times a day for 4 weeks. The tropicamide eye drops are also discontinued after 4 weeks. No atropine is used.

11.3.5 Assessment of Accommodation and Main Outcome Measures

In pseudophakic patients, objective measurement techniques of refraction or accommodation are more difficult to apply due to a significant optical reflex from the anterior as well as from the posterior surface of the artificial lens. As the refractive index of the artificial lens material is significantly higher than that of the crystalline lens, and as the surfaces of the artificial lens are mostly spherical, in contrast to the aspherical crystalline lens where a lot of (higher-order) optical aberrations are present, the Purkinje images III and IV may interfere with the measurements of auto- and videorefractometers. Thus, some of the measurement methods do not yield proper results in pseudophakic patients and should only be used with great care, whereas other methods have to be modified to provide correct results after cataract surgery. Further-

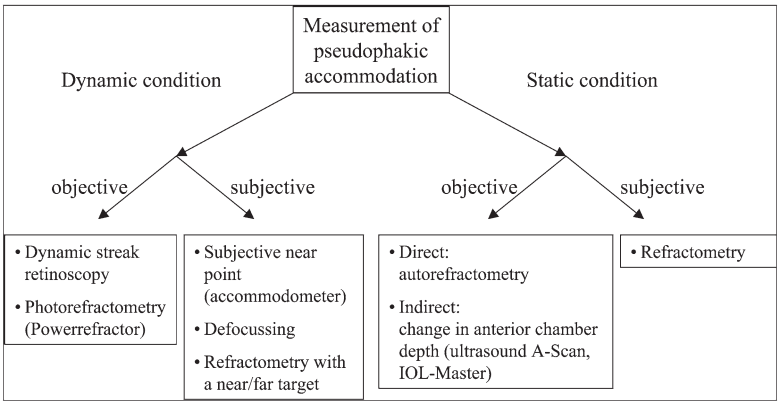


Fig. 11.2. Different principles of measuring accommodation in pseudophakic patients. Classification was done in the dynamic and static condition as well as in objective and subjective measurement methods

more, pupillary constriction induced by accommodation and/or pilocarpine may interfere with correct measurements. Figure 11.2 gives an overview of the different methods used to determine accommodation amplitude.

In addition to the routine early postoperative examinations, all patients underwent detailed examinations at 6 weeks, then every 3 months until 1 year postoperatively, then every 6 months, with the following tests [14]:

- Patients were carefully refracted for distance, the spherical equivalent (SEQ) was calculated in diopters (D) due to form (SEQ = spherical refraction (D) + 0.5*cylindric refraction (D)). Distance visual acuity was determined with best distance correction. Subsequently, near reading vision was determined using the same distance correction and Birkhäuser reading charts (Scalae Typographicae Birkhaeuseri, Birkhäuser Verlag, Basel, Switzerland) at a distance of 35 cm with an illumination of 70 cd/m^2. The reading charts were held by the patients at normal reading position, i.e. angled slightly inferiorly by 20°.
- Accommodation was determined subjectively using the same distance correction. With an accommodometer (Clement Clarke RAE, Frohnhäuser, Unterhaching, Germany), a small reading chart was slowly moved towards the eye from a distance of 1 m (with a spherical reading glass of +2 diopters added to the distance correction) until the patient noted blurring of the optotypes. Reading distance was converted to diopters and corrected for the 2-diopter near addition to get the subjective accommodation or – reconverted to distance – to get the subjective near point.
- Near and distance refractions were determined by streak retinoscopy [13]. All retinoscopy was performed by one skilled examiner who was not informed as to whether the individual patient had received the new PCIOL or a conventional PCIOL. For distance retinoscopy, patients were asked to fixate a visual chart projected at a distance of 5 m. For near retinoscopy, patients were asked to maximally fixate a near chart. Accommodative range was the difference between near and distance refractions.
- Defocusing was performed with a far distance correction for the patient and reading charts at 5 m distance. Visual acuity was measured with defocusing of the patient in steps of 0.5 diopters, starting with +0.5, 0, –0.5, –1.0, ..., –3.0 diopters spherical glasses. As accommodation amplitude we defined the minus lens with which the patient retained visual acuity of 0.4 (20/50).
- Anterior chamber depth indicating the position of the PCIOL was measured with the IOL Master (Zeiss, Jena, Germany) without medical influence of pupil size or the state of the ciliary muscle.

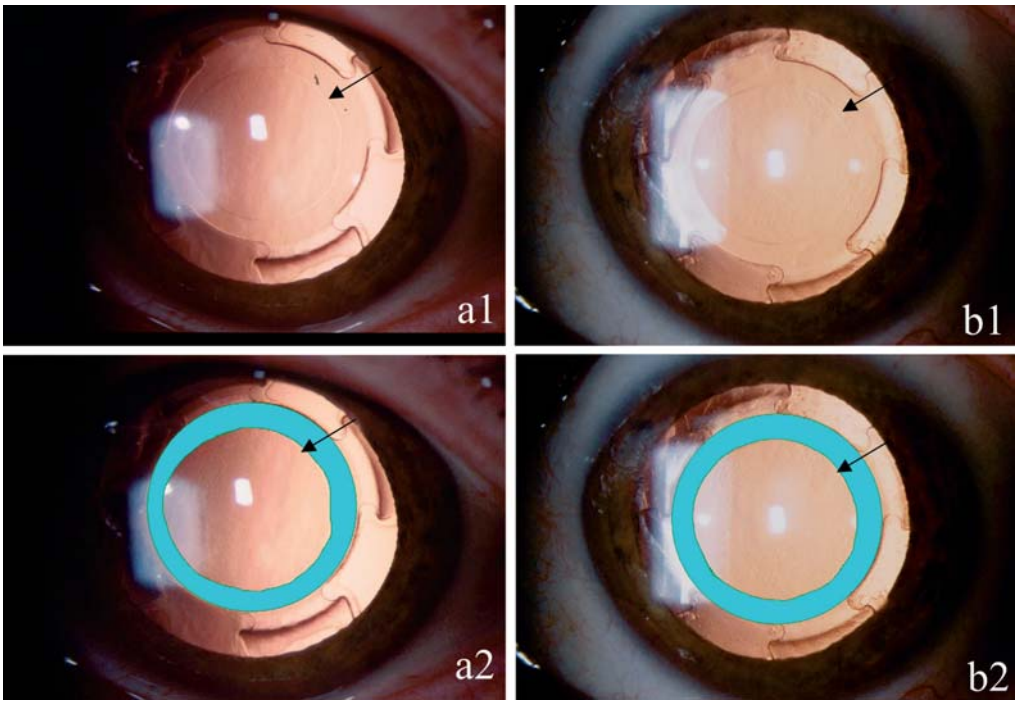


Fig. 11.3. Transillumination photograph of 1CU localized in the capsular bag 1 year (*a1* and *a2*) and 2 years (*b1* and *b2*) after implantation. The *arrow* shows the border of well-centered round capsulorrhexis

11.4 Clinical Outcomes

11.4.1 Safety

The 1CU PCIOL could be inserted without complications in all patients, and the PCIOLs were well centered in the capsular bag at all times (Fig. 11.3). No signs of contraction of the capsular bag or of the anterior lens capsule, nor decentration or dislocation of the 1CU PCIOL was observed in any of the patients during follow-up [15].

None of the patients developed inflammatory fibrin reactions, synechiae or macrophages on the PCIOL optic. Using laser flare photometry, only a minimal and short-lasting alteration of the blood–aqueous barrier was observed [16]. Four weeks postoperatively, aqueous flare was normal in all patients and remained stable below the normal limit for up to 12 months. No signs of persisting inflammation or pigment dispersion were detected. The intraocular pressure remained in the normal range (<20 mmHg) in all patients at all times without antiglaucoma medication.

11.4.2 Accommodation Ability in Comparison with Conventional Intraocular Lenses

To compare the accommodative ability of patients with 1CU PCIOL with that of patients with conventional PICOL, a non-randomized study analyzed the 6-months results of 20 patients with 1CU and 20 age-matched patients with three different PCIOLs (one-piece polymethyl methacrylate lenses in 11 eyes, one-piece hydrophilic acrylic lenses (K3, HumanOptics, Erlangen, Germany) in four eyes, and three-piece hydrophobic acrylic

Table 11.1. Findings in two groups (1CU group and age-matched controls with conventional intraocular lenses) 6 months after implantation of posterior chamber intraocular lens. Indicated are mean, standard deviation, median and range

	1CU group	Control group	Difference between two groups and level of significance
Best corrected distance visual acuity (D)	1.0±0.16 1.0, 0.63–1.25	0.95±0.11 1.0, 0.7–1.0	p=0.13
Near visual acuity with best distance correction (Birkhäuser reading charts in 35 cm)	0.36±0.10 0.4, 0.2–0.6	0.16±0.06 0.2, 0.1–0.3	p<0.001
Accommodative range determined by near point (D)	1.83±0.49 1.85, 1.0–2.7	1.06±0.27 0.9, 0.78–1.35	0.67 p<0.001
Accommodative range determined by defocusing (D)	1.85±0.43 2.0, 1.0–2.5	0.64±0.21 0.5, 0.5–1.0	1.21 p<0.001
Accommodative range determined by streak retinoscopy (D)	0.98±0.55 0.88, –0.13 to +2.0	0.17±0.22 0.25, –0.25 to +0.5	0.81 p<0.001

lenses (Acrysof MA 60 BM, Alcon, Freiburg, Germany) in five eyes).

Mean postoperative best corrected distance visual acuity was 1.0±0.16 in the 1CU group and 0.93±0.11 in the control group, and the difference between the two groups was not statistically significant (p=0.13).

Median near visual acuities determined with best distance correction and Birkhäuser charts at 35 cm were significantly higher (0.4, range 0.2–0.6) in the 1CU group than in the control group (0.2, range 0.1–0.3, p<0.001).

Median subjective near points with best distance correction were 55 cm (range 37–100) in the 1CU group and 86 cm (59–128) in the control group. Mean accommodative ranges as determined by subjective near point were 1.83±0.49 D (range 1.0–2.7) in the 1CU group and 1.16±0.27 D (0.78–1.69) in the control group. Mean accommodative ranges as determined by defocusing were 1.85±0.43 D (1.0–2.5) in the 1CU group and 0.64±0.21 D (0.5–1.0) in the control group. Mean accommodative ranges as determined by retinoscopy were 0.98±0.55 D (0.13 to +2.0) in the 1CU group and 0.17±0.22 D (0.25 to +0.5) in the control group (Table 11.1, Fig. 11.4).

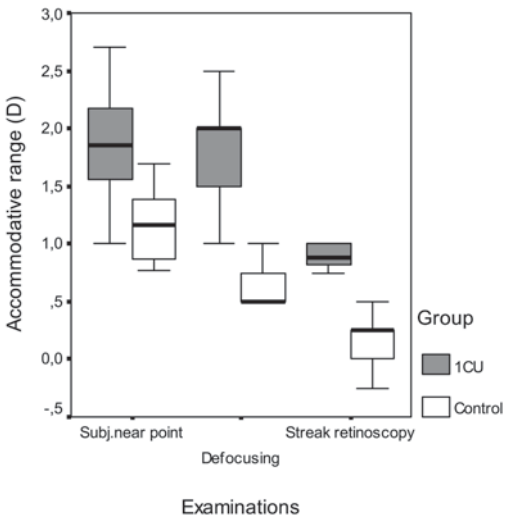


Fig. 11.4. Box plots indicating accommodative range (D) of the two groups (1CU group and age-matched controls with conventional intraocular lenses). The accommodative range was quantified using three different methods: subjective near point, defocusing and streak retinoscopy. The boxes include 50% of measured values (between the 25th and 75th percentiles) and show the position of the median (*horizontal line*). The error bars indicate 1.5 times the interquartile distance from the upper and lower box edges. The difference between the two groups is statistically significant (p=0.001)

Thus, the mean treatment effects (difference between 1CU group members and controls) were 0.67 D (subjective near point), 1.21 D (defocusing), and 0.81 D (retinoscopy). All differences between the 1CU and control groups according to accommodation ability were statistically highly significant ($p<0.001$) (Table 11.1).

A major problem in designing studies to investigate accommodative PCIOLs in patients is to choose adequate methods of quantifying pseudophakic accommodation [12]. In this present study, three methods of more accurately measuring pseudophakic accommodation as the major outcome measure were chosen. Two of these rely on subjective patient information (near point and defocusing), whereas the third method uses more objective retinoscopy with near and distance fixation of the patient. With all three methods, a significantly higher accommodative range in the 1CU group, with differences of mean values of 0.67, 1.21, and 0.81 D between the 1CU group and the control group were found. This, in our opinion, puts the results of our study on a broader and safer base [17].

Even though the amount of additional pseudophakic accommodation that we achieved was relatively limited (depending on the measurement method, an excess of between 0.67 and 1.21 D in comparison with the control group with conventional PCIOL), we have the clinical impression that the degree of additional pseudophakic accommodation is useful for the patients in daily life. This may be explained by the fact that, in addition to the mentioned amount of true pseudophakic accommodation, other mechanisms of pseudo-accommodation, such as increased depth of focus by pupillary constriction, spherical aberration, and multifocality of PCIOL and cornea, may also contribute to or further increase the quality of near vision.

11.4.3 Stability of Refraction, Accommodation, and Lens Position

The design of the 1CU PCIOL includes modification of lens haptics with reduced thickness near the lens optic for higher flexibility to allow reversible anterior movement of the lens optic secondary to contraction of the ciliary muscle. Thus, one could imagine the theoretical potential problem with the 1CU PCIOL in that progressive and/or irreversible anterior movement of the PCIOL optic brought about by shrinkage and contraction of the capsular bag might occur. This problem could consequently result in a myopic shift of refraction and loss of pseudophakic accommodation.

Prospective studies that followed patients with the 1CU PCIOL showed that refraction, anterior chamber depth and accommodative range all remained stable without signs indicating a systemic trend towards myopia, hypermetropia, PCIOL dislocation or regression of accommodative properties [18].

We found a distance refraction (spherical equivalent, mean and standard deviation) of –0.28±0.54 D after 3 months, –0.29±0.52 D after 6 months, and –0.21±0.54 D after 12 months (Table 11.2). Best corrected distance visual acuity was 20/16–20/25 in all patients and remained stable during follow-up. Mean accommodative range determined by near point was 1.93±0.47 after 3 months, 1.85±0.62 after 6 months and 2.02±0.38 D after 12 months (Fig. 11.5). Mean anterior chamber depth (Zeiss IOL Master) without pharmacological induction of ciliary muscle contraction was 4.40±0.44 mm after 3 months, 4.35±0.50 mm after 6 months, and 4.25±0.53 mm after 12 months (Table 11.2). Mean distance-corrected near visual acuity (Birkhäuser charts in 35 cm) was 0.41±0.15 after 3 months, 0.37±0.12 after 6 months, and 0.39±0.11 after 12 months (Table 11.2). None of these comparisons, neither overall nor pairwise, reached statistical significance ($p>0.1$ for all analyses).

Table 11.2. Findings in 30 eyes of 30 patients at different time points following implantation of the 1CU accommodative posterior chamber intraocular lens. Indicated are mean, standard deviation, median and range

	Three months	Six months	Twelve months
Spherical equivalent of distance refraction (D)	–0.28±0.54 –0.25, –1.38 to +0.75	–0.29±0.52 –0.25, –1.38 to +0.5	–0.21±0.54 –0.25, –1.13 to +0.5
Accommodative range determined by near point (D)	1.93±0.47 2.0, 1.0–2.78	1.85±0.62 1.85, 0.5–2.7	2.02±0.38 2.0, 1.32–2.56
Anterior chamber depth (mm)	4.40±0.44 4.47, 3.30–5.21	4.35±0.50 4.45, 3.30–5.23	4.25±0.53 4.30, 3.28–4.97
Near visual acuity with best distance correction (Birkhäuser reading charts in 35 cm) and corresponding Jaeger values	0.41±0.15 0.4, 0.2–0.7 (J3, J10–J1)	0.37±0.12 0.3, 0.2–0.6 (J7, J10–J1)	0.39±0.11 0.4, 0.3–0.6 (J3, J7–J1)

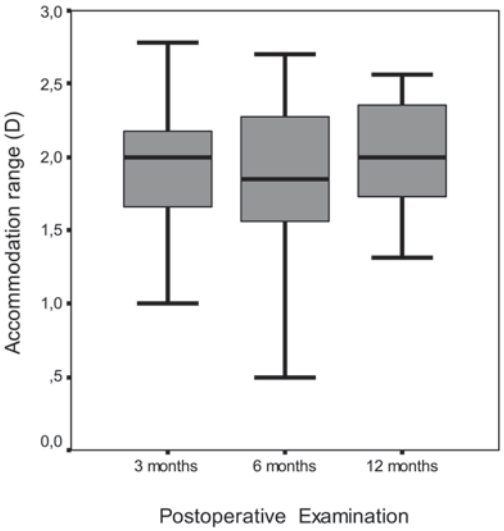


Fig. 11.5. Box plots showing accommodative range (D) determined by near point at different time points after implantation of the new accommodative 1CU posterior chamber intraocular lens in 15 patients. The boxes include 50% of measured values (between the 25th and 75th percentiles) and show the position of the median (*horizontal line*). The error bars indicate 1.5 times the interquartile distance from the upper and lower box edges

Our results indicate that for up to 12 months, the 1CU PCIOL shows no tendency of myopization, anterior movement of the lens optic or loss of distance-corrected near visual acuity. One possible explanation for these encouraging observations may be that we observed very little fibrosis of the capsular bag or the anterior and posterior lens capsule. This may be a result of the design of the 1CU PCIOL and the fact that we carefully performed a well-centered round capsulorrhexis of 5 mm with the remaining anterior lens capsule circumferentially covering the rim of the PCIOL optic. Furthermore, we carefully observed inclusion and exclusion criteria that excluded eyes with potential zonular weakness and tendencies to develop increased fibrosis of the lens capsule, i.e. traumatic changes, pseudoexfoliation, and proliferative diabetic retinopathy.

Based on our findings, we conclude that it is unlikely that problems such as anterior vaulting, anterior movement or dislocation of the 1CU PCIOL will occur after more than 12 months. Nevertheless, we believe that further studies with longer follow-up and a randomized, masked, multicenter design are needed to analyze further the 1CU PCIOL with regard to long-term biocompatibility and accommodative properties.

11.4.4 Accommodation Ability after Nd:YAG Capsulotomy

Posterior capsular opacification (PCO) is the most common complication of cataract surgery, with a reported incidence of 10–50 % [1, 2, 4, 21]. In cases of vision-impairing PCO, Nd:YAG laser capsulotomy is usually performed to improve visual function. The rate, the postoperative time point of PCO necessitating YAG capsulotomy and the accommodation ability after Nd:YAG capsulotomy in patients with 1CU PCIOL were evaluated in a prospective study of 65 patients with a mean postoperative follow-up of 23±10 (median 24, range 4–40) months.

A clinically relevant PCO with significant decrease of visual acuity (0.4±0.2 D) and a need for Nd:YAG capsulotomy was diagnosed in 20 % of all patients with 1CU between 15 and 22 (mean 20±4, median 20) months postoperatively. All patients reported that the first subjective visual impairment noted was a problem with reading. It was not possible to determine the accommodation range immediately before capsulotomy in most of the patients. All capsulotomies performed were uncomplicated. No decentration or dislocation of the 1CU PCIOL was observed in any of the patients during follow-up.

Six weeks after capsulotomy, best corrected distance visual acuity was improved (1.1±0.1). Near visual acuity with best distance correction was 0.4±0.1. Accommodative range determined by near point was 1.9±0.4 D, and by defocusing was 1.7±0.4 D (Fig. 11.6). Six weeks after capsulotomy, none of the measurements of accommodative range were statistically different from the 12-month results before occurrence of PCO (p>0.5) (Table 11.3, Fig. 11.7).

The rate of significant PCO necessitating Nd:YAG capsulotomy in our patients with 1CU was about 20 % during a mean follow-up of 23±10 months, occurring mainly after 15 months postoperatively. The incidence and time point are equal to results after implantation of hydrophilic acrylic IOLs reported in the literature [18–20].

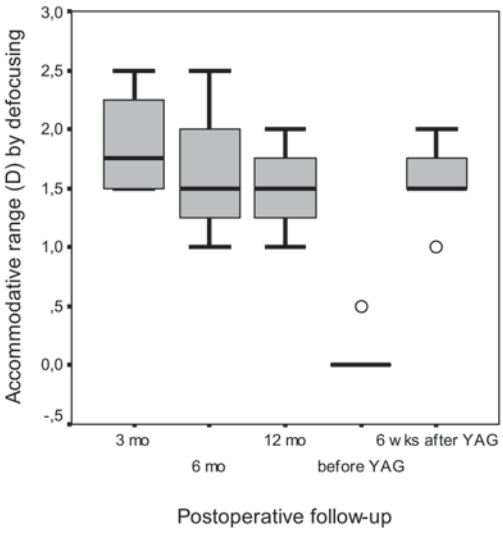


Fig. 11.6. Box plots showing accommodative range (D) determined by defocusing at different time points before and 6 weeks after Nd:YAG capsulotomy in patients after implantation of the new accommodative 1CU posterior chamber intraocular lens. The boxes include 50 % of measured values (between the 25th and 75th percentiles) and show the position of the median (*horizontal line*). The error bars indicate 1.5 times the interquartile distance from the upper and lower box edges. Values more than 1.5 interquartile ranges away from the box are shown as circles

Interestingly, we found that all patients with PCO complained first about their near visual acuity but not about their distance visual acuity, although the distance visual acuity also decreased. A possible explanation for this finding is that PCO may occlude the entire pupillary area when reading as the pupil contracts by accommodation.

The results of the present study showed that 6 weeks after capsulotomy the accommodation ability and visual acuity had improved significantly to the levels before PCO occurred. Our results indicate that Nd:YAG capsulotomy may not affect the accommodation ability of the 1CU.

Table 11.3. Findings in 15 eyes of 15 patients at different time points following implantation of the 1CU accommodative posterior chamber intraocular lens before and 6 weeks after Nd:YAG capsulotomy. Indicated are mean, standard deviation and median

	Three months	Six months	Twelve months	At time point of YAG capsulotomy	Six weeks after YAG capsulotomy
Best corrected distance visual acuity (D)	1.0±0.28 1.0	1.0±0.28 1.0	0.96±0.22 1.0	0.4±0.10 0.4	1.0±0.1 1.0
Near visual acuity with best distance correction (Birkhäuser chart in 35 cm)	0.41±0.15 0.4	0.37±0.12 0.4	0.39±0.11 0.4	0.13±0.14 0.1	0.39±0.08 0.4
Subjective near point (cm)	48±9.4 50	53±8.8 53	53±9.4 52	107±10.6 100	52±7.5 52
Accommodative range (D) determined by near point	1.93±0.47 2.0	1.85±0.62 1.85	2.02±0.38 2.0	0.7±0.3 0.5	1.95±0.6 1.9
Accommodative range (D) determined by defocusing	1.88±0.47 1.75	1.82±0.33 1.5	1.88±0.47 1.75	0.06±0.18 0.0	1.88±0.47 1.75
Anterior chamber depth (mm)	4.4±0.2 4.4	4.3±0.3 4.4	4.2±0.4 4.3	4.3±0.3 4.4	4.4±0.3 4.3

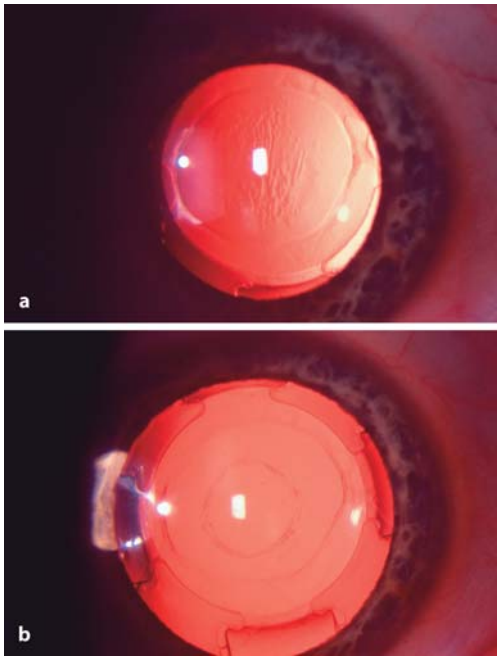


Fig. 11.7. **a** Transillumination photograph of 1CU localized in the capsular bag before Nd:YAG capsulotomy. The best corrected distance visual acuity was 0.5, near visual acuity with best corrected distance correction was less than 0.1; it was not possible to determine the accommodation range. **b** 6 weeks after Nd:YAG capsulotomy. The best corrected distance visual acuity was 1.0, near visual acuity with best corrected distance correction was 0.4, accommodation range determined by near point was 1.7 D, and by defocusing was 1.5 D

FINAL COMMENTS

The 1CU (HumanOptics AG, Erlangen, Germany) is an acrylic hydrophilic foldable single-piece PCIOL with a spherical optic diameter of 5.5 mm and a total diameter of 9.8 mm. This PCIOL is intended to allow accommodation by anterior movement of the optic (focus shift) secondary to contraction of the ciliary muscle. To achieve this, the lens haptics are modified with transmission elements at their fusion with the lens optic. With adequate indication and surgical technique, the 1CU IOL has been safe and effective in our hands.

Even though the amount of additional pseudophakic accommodation that is achieved in patients with accommodative 1CU was relatively limited (depending on the measurement method, an excess of between 0.67 and 1.21 D in comparison with the control group with conventional PCIOL), the degree of additional pseudophakic accommodation is useful for the patients in daily life.

The rate and postoperative time point of significant PCO necessitating Nd:YAG capsulotomy in our patients with 1CU are equal to results after implantation of hydrophilic acrylic IOLs reported in the literature. After uncomplicated capsulotomy, pseudophakic accommodation capabilities were completely restored compared to the results before occurrence of PCO.

One potential drawback of evaluation of pseudophakic accommodation in our patients with 1CU was that objective measurement methods were not used to quantify pseudophakic accommodation at the various time points. However, there is a lack of measurement methods for use in clinical studies that are easily applicable to patients and that allow exact measurements of pseudophakic accommodation. Recent studies have indicated that after application of miotics, measurement of anterior chamber depth in pseudophakic eyes does not always give accurate, valuable and reproducible results. However, the results of our studies obtained by different examination methods (near visual acuity with best corrected distance refraction, subjective near point, defocusing and streak retinoscopy) indicate good visual function and accommodation ability of the accommodative 1CU PCIOL.

Future research should be directed to improving further the optic and accommodative results of this new generation of accommodative PCIOLs.

References

1. Von Helmholtz H (1855) Über die Akkommodation des Auges. Albrecht von Graefes Arch Klin Exp Ophthalmol 1:1–74
2. Rohen J (1969) Akkommodationsapparat. In: Velhagen K (ed) Der Augenarzt, Bd 1. Thieme, Leipzig, pp 51–69
3. Bacskulin A, Gast R, Bergmann U, Guthoff R (1996) Ultraschallbiomikroskopische Darstellung der akkommodativen Konfigurationsänderungen des presbyopen Ziliarkörpers. Ophthalmologe 93:199–203
4. Glasser A, Kaufman PL (1999) The mechanism of accommodation in primates. Ophthalmology 106:863–872
5. Ludwig K, Wegscheider E, Hoops JP, Kampik A (1999) In vivo imaging of the human zonular apparatus with high-resolution ultrasound. Graefe's Arch Clin Exp Ophthalmol 237: 361–371
6. Strenk SA, Semmlow JL, Strenk LM et al (1999) Age-related changes in human ciliary muscle and lens: a magnetic resonance imaging study. Invest Ophthalmol Vis Sci 40:1162–1169
7. Swegmark G (1969) Studies with impedance cyclography on human ocular accommodation at different ages. Acta Ophthalmol 47: 1186–1206
8. Weale R (1989) Presbyopia toward the end of the 20th century. Surv Ophthalmol 34:30

9. Mathews S (1999) Scleral expansion surgery does not restore accommodation in human presbyopia. Ophthalmology 106:873–877
10. Vinciguerra P, Nizzola GM, Bailo G et al (1998) Excimer laser photorefractive keratectomy for presbyopia: 24-month follow-up in three eyes. J Refract Surg 14:31–37
11. Keates RH, Martines E, Tennen DG, Reich C (1995) Small-diameter corneal inlay in presbyopic or pseudophakic patients. J Cataract Refract Surg 21:519–521
12. Allen ED, Burton RL, Webber SK et al (1996) Comparison of a diffractive bifocal and a monofocal intraocular lens. J Cataract Refract Surg 22:446–451
13. Steinert RF, Aker BL, Trentacost DJ et al (1999) A prospective comparative study of the AMO ARRAY zonal-progressive multifocal silicone intraocular lens and a monofocal intraocular lens. Ophthalmology 106:1243–1251
14. Langenbucher A, Huber S, Nguyen XN et al (2002) Measurement of accommodation after implantation of a new accommodative posterior chamber intraocular lens (1CU). J Cataract Refract Surg 18:208–216
15. Küchle M, Nguyen XN, Langenbucher A et al (2002) Implantation of a new accommodative posterior chamber intraocular lens. J Refract Surg 18:208–216
16. Nguyen NX, Langenbucher A, Seitz B et al (2002) Short-term blood-aqueous barrier breakdown after implantation of the 1CU accommodative intraocular posterior chamber intraocular lens. J Cataract Refract Surg 28: 1189–1194
17. Küchle M, Seitz B, Langenbucher A et al (2004) Comparison of six-month results of implantation of the 1CU accommodative intraocular lens with conventional intraocular lenses. Ophthalmology 111:318–324
18. Küchle M, Seitz B, Langenbucher A et al (2003) Stability of refraction, accommodation, and lens position following 1CU accommodative posterior chamber intraocular lens implantation. J Cataract Refract Surg 29:2324–2329
19. Ando H, Ando N, Oshika T (2003) Cumulative probability of neodymium. YAG laser posterior capsulotomy after phacoemulsification. J Cataract Refract Surg 29:2148–2154
20. Apple DJ, Solomon KD, Tetz MR et al (1992) Posterior capsule opacification. Surv Ophthalmol 37:73–116
21. Schaumberg DA, Dana MR, Christen WG et al (1998) A systematic overview of the incidence of posterior capsule opacification. Ophthalmology 105:1212–1221

12 Synchrony IOL

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CORE MESSAGES

- The Synchrony IOL (Visiogen, Irvine, California) is a dual-optic, silicone, single-piece, foldable, accommodating IOL. The IOL features a 5.5-mm high-powered anterior optic connected to a 6.0-mm negative power optic by haptics.
- The mechanism of accommodation potential is based on a lens complex formed by two optics linked by a spring system.
- With accommodative effort, the zonules relax, releasing the tension on the capsular bag, thus allowing release of the strain energy stored in the interoptic articulations and anterior displacement of the anterior optic.
- The Synchrony IOL has been implanted in more than 70 human eyes in different centers around the world. The lens has been safely implanted in the capsular bag after conventional phacoemulsification, with no major complications in the intra- and postoperative period.
- The Synchrony dual-optic system represents a promising surgical option for cataract surgery and may enable an extended accommodative range.

Accommodation in the youthful, phakic human eye is accomplished by contraction of the ciliary body and subsequent release in the resting tension of the zonular fibers by which the crystalline lens is suspended, resulting in increased lens curvature [1–3]. Presbyopia is defined as the progressive loss of accommodation amplitude producing compromised near function, and has been attributed to mechanical changes in the lens and capsule including changes in elastic property [1] and progressive circumferential enlargement of the crystalline lens [2, 3], weakening of the ciliary muscle [4], and loss of zonular and ciliary body effectiveness and elasticity [5, 6]. An excellent review of the variety of proposed mechanisms has been presented by Atchison [7].

12.1 Surgical Restoration of Accommodation

Although the mechanism of presbyopia remains incompletely understood, the weight of current evidence seems to suggest that, although some loss of ciliary body action might contribute to reduced accommodation [8], significant ciliary body function persists into advanced maturity, and that loss of lens and capsule elasticity in concert with changes in the geometry of zonular attachments are probably most culpable in producing the distress of presbyopia [9]. If so, then replacement of the crystalline lens with a lens that responds to ciliary body contraction should restore accommodative function.

Attempts have been made to replace the crystalline lens by refilling the capsular bag with appropriately deformable gels [8, 10, 11]. However, this approach is limited by the intrinsic mechanical instability of such materials that at the moment cannot be expected to retain a specific shape (and thus optical power) over time while sustaining a rapid, constant, and predictable response to equatorial tension as demanded by the dynamics of accommodation.

12.2 Axial Lens Movement

The principle of axial lens movement has been adopted by more recent accommodating intraocular lens (IOL) designs. For example, the AT-45 (CrystaLens, Eyeonics Inc., Aliso Viejo, CA, USA) is a hinged single-optic IOL that is intended to be implanted with posterior vault. Cummings et al. reported the results of early clinical trials with this IOL design, in which varying degrees of near function were described in subjects following implantation [10]. Near function was ascribed to anterior axial displacement of approximately 0.7 mm (Cumming; unpublished data, 1989) and corresponding conjugation power change postulated by the authors to result from increased vitreous pressure. Küchle and co-workers [11] have recently reported clinical results of a more anteriorly positioned posterior chamber lens, the accommodative 1CU (HumanOptics, AG, Erlangen, Germany), also designed to undergo anterior axial displacement with accommodative effort. A mean retinoscopic accommodative range of 1.2 D (SD: 0.4) was achieved in these patients, and pharmacologically induced accommodation by instillation of pilocarpine produced a mean change of 0.63 mm (SD: 0.16) in anterior chamber depth. If these measurements are correct, the amount of excursion generated (usually between 0.4 and 0.7 mm) limits the accommodative range of a single-optic design.

12.3 Dual Optics

Recognizing these limitations, Hara et al. proposed refilling the capsular bag with a rigid shell, described as two lenses 8 mm in diameter connected by a polypropylene coil spring [8]. This design was later replaced by a pair of inflexible polymethylmethacrylate optics, 6 mm in diameter, connected by four peripheral closed polyvinylidene fluoride flexible loops separating the optics by 3.0 mm. The posterior optic was assigned no optical power, and change in the conjugation power of the eye was achieved by anterior and posterior movement of the anterior lens to which was assigned the full optical power of the lens system [12].

Visiogen Inc. (Irvine, California) has developed a dual-optic, silicone, single-piece, foldable, accommodating lens called Synchrony. The IOL features a 5.5-mm high-powered anterior optic connected to a 6.0-mm negative power optic by haptics that have a spring-like action (Fig. 12.1). In order to respond to ciliary body action, energy must be stored and released in the system. The mechanism of action of this lens is based on a lens complex formed by two optics linked by a

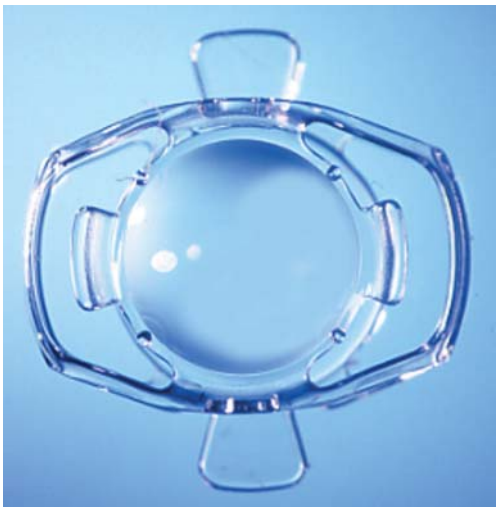


Fig. 12.1. The single-piece silicone lens consisting of an anterior convex and posterior concave optic linked by haptics with spring action

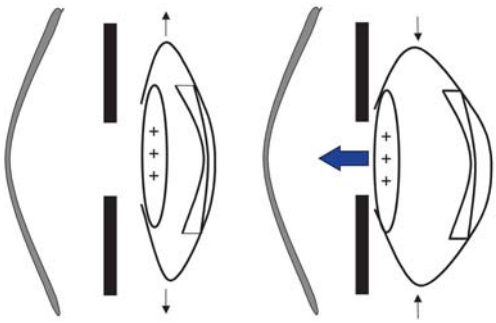


Fig. 12.2. Accommodative function of the dual-optic IOL. At ciliary body rest, the zonules are put on stretch, producing axial shortening of the capsular bag, thus pulling the optics together and loading the haptic springs. With accommodative effort, zonular tension is released, compressive capsular tension on the optics and spring haptics is released and thus the anterior optic moves forward

spring system that, at rest outside of the confines of the capsular bag, produce an outward force separating the axes of the optics by approximately 3.7 mm. When implanted within the capsular bag, bag tension compresses the optics, reducing the interoptic separation – that is, the resting ciliary body maintains zonular tension, which is transmitted to the bag, producing outward circumferential movement of the equator, axial shortening of the capsular bag, and thus compression of the lens complex, resulting in the storage of strain energy in the connecting arms. Elements are incorporated to control minimum separation, thus setting the resting distance refraction at emmetropia. With accommodative effort, the zonules relax, releasing the tension on the capsular bag, thus allowing release of the strain energy stored in the interoptic articulations and anterior displacement of the anterior optic (Fig. 12.2). The posterior element is designed with a significantly larger surface area than anterior, thus reducing the tendency toward posterior axial excursion, and maintaining stability and centration within the capsular bag during the accommodation/non-accommodatio process.

The optical power of the anterior optic is within the range of 30.0–35.0 D, well beyond that required to produce emmetropia, and the posterior optic is assigned a variable diverging power in order to return the eye to emmetropia. The overall length of the device is 9.5 mm and width 9.8 mm. When compressed, the total lens thickness is 2.2 mm. The optical principle behind this lens design relies on axial displacement of the anterior optic. Ray tracing analysis software (ZEMAX, Focus Software Inc, Tucson, AZ, USA) using a theoretical eye model [13] has been used to analyze the expected optical effect of axial movement of this IOL when positioned at the posterior capsule plane.

12.4 Laboratory Results

Ray tracing analysis suggested that anterior movement of the anterior optic of a dual-optic IOL design with a high-power anterior converging lens and a compensatory posterior diverging lens produces significantly greater change in object distance compared

to similar displacement of a single-optic IOL [14]. For example, a 1-mm anterior axial movement of a single-optic 19-D IOL would produce a refractive power change of the eye of approximately 1.2 D. However, for a dual-optic system placed in the same model eye, assuming an anterior +32-D lens separated by 0.5 mm from a posterior –12-D lens, 1-mm forward displacement of the anterior convex lens is calculated to produce a refractive change of approximately 2.2 D. Based on the optical calculations described above, it is evident that a greater change in refractive power per unit axial displacement can be generated by choosing a more powerful anterior lens, but the advantages of increased accommodative range must be weighed against the increased optical sensitivity of the system. The power of the IOL is calculated by means of proprietary algorithms based on axial length, keratometry, anterior chamber depth, and lens thickness. These algorithms have been constantly improved in order to decrease deviation from target refraction.

Studies performed in laboratory settings using rabbit and human cadaver eyes demonstrated that this lens could be implanted without distortion/ovalization of the capsulorhexis and the capsular bag. Folding and implantation into human cadaver eyes via a 4-mm clear cornea wound was confirmed. In one such experiment, a standard phacoemulsification clear corneal incision was created in a cadaver eye. A metal blade was used to create a 4.0-mm groove at the limbus and a shelved 2-mm entry into the anterior chamber was created using a metal 3.2-mm keratome. This opening was then widened to approximately 4.0 mm by side-to-side motion of the keratome, and the dimensions of the opening were confirmed with calipers. Without removal of the crystalline lens, ophthalmic viscosurgical device (OVD) was injected to deepen the anterior chamber. The two optics of the IOL were brought together with lens forceps, the lens was depressed and folded around the forceps into a taco configuration (Fig. 12.3), and then guided through the wound into the anterior chamber. The wound width was then re-measured with calipers, and found to be approximately 4.0 mm. In two subsequent experiments, phacoemulsification was performed on cadaver eyes, and using the procedure described above, the lens unfolded within the capsular bag via a 4-mm clear cornea wound.

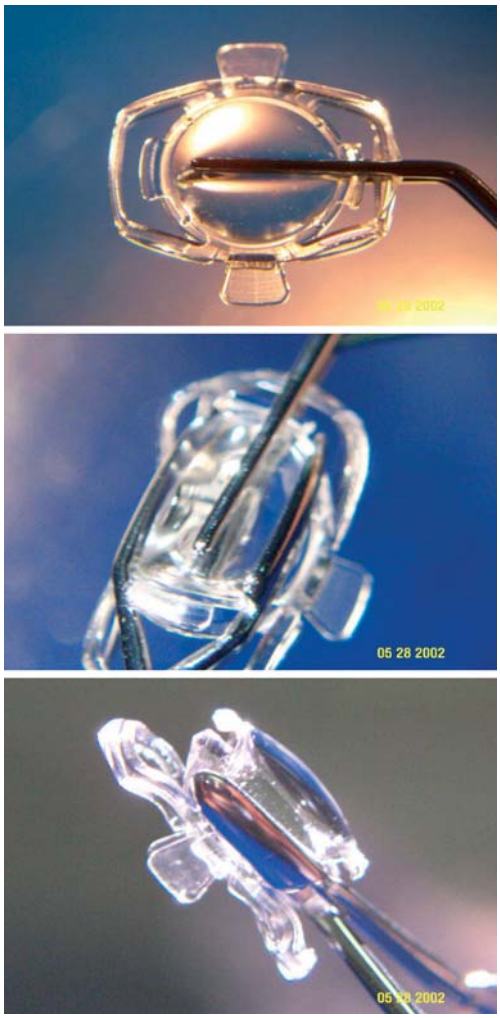


Fig. 12.3. Photographs that demonstrate Synchrony's IOL folding process. The two optics of the IOL are compressed together with lens forceps, and the lens is depressed and folded around the forceps into a taco configuration

12.5 Clinical Results

Clinical trials are being conducted for pseudophakic correction after cataract surgery. By mid-2004, the Synchrony IOL (Fig. 12.4) had been implanted in more than 70 human eyes in different centers around the world (e.g., University of Mainz and University of Heidelberg, Germany). The lens can be safely implanted in the capsular bag after conventional phacoemulsification. Special care was taken to create a "perfectly centered" continuous curvilinear capsulorhexis (CCC), with a size between 4.5 and 5 mm. After complete removal of the lens nucleus and cortical material, careful polishing of the anterior lens capsule was performed in order to diminish lens epithelial cell proliferation over the anterior capsule, thus reducing the incidence of anterior capsule opacification, a theoretically limiting factor for the correct performance of the lens. The capsular bag was filled with OVD, and the IOL was folded with forceps (Fig. 12.3). The incision size was increased to 4.4 mm for easy implantation (some surgeons felt comfortable implanting the lens with a 4.0-mm incision), and the lens was delivered into the capsular bag in a single-step procedure. All the OVD needed to be removed, with special attention to the space behind the posterior optic, and the interface between the two optics. Typically no sutures were required. Ultrasound biomicroscopy showed the optics of the Synchrony IOL 3 months after implantation, their relation to each other inside the capsular bag, as well as to the adjacent intraocular structures (Fig. 12.5 a, b, c).

At the Department of Ophthalmology, Johannes Gutenberg-University, Mainz, Germany, we conducted a prospective clinical study with 15 eyes (12 patients). All surgeries were performed by one surgeon (H.B.D.) with no intraoperative complications. Both optics of the IOL were placed in the capsular bag uneventfully in all cases (Fig. 12.6). With a minimum follow-up of 3 months, no case of intralenticular opacification could be observed. We observed no major complications, sight-threatening complications or explanted IOLs. All patients were very satisfied with the visual functioning and achieved accommodation ranges between 0.5 and 2.5 D. A typical and characteristic defocus curve of an emmetropic eye 6 months after Synchrony IOL implantation is shown in Fig. 12.7. Especially in the bilateral group (three patients), the patients described better daily functioning and reading ability. However, a longer follow-up and a larger series are mandatory to make final conclusions.

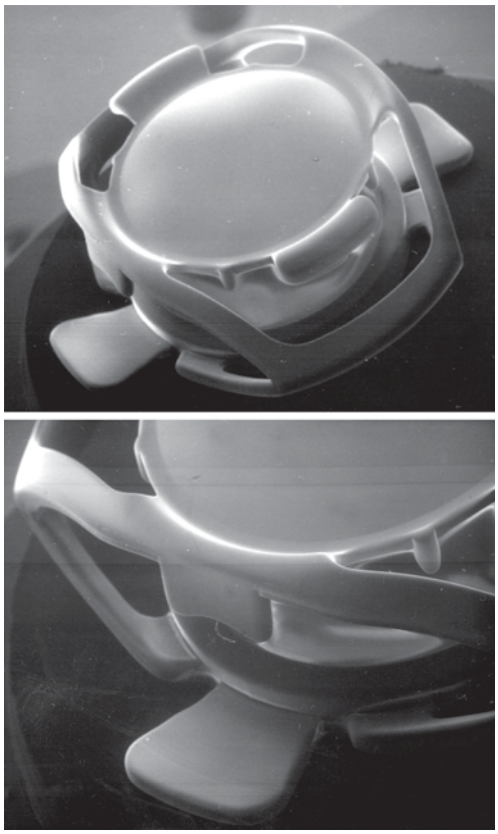
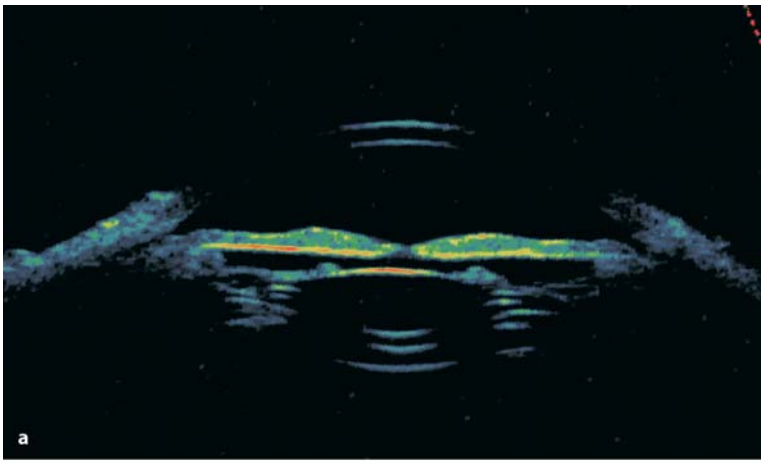
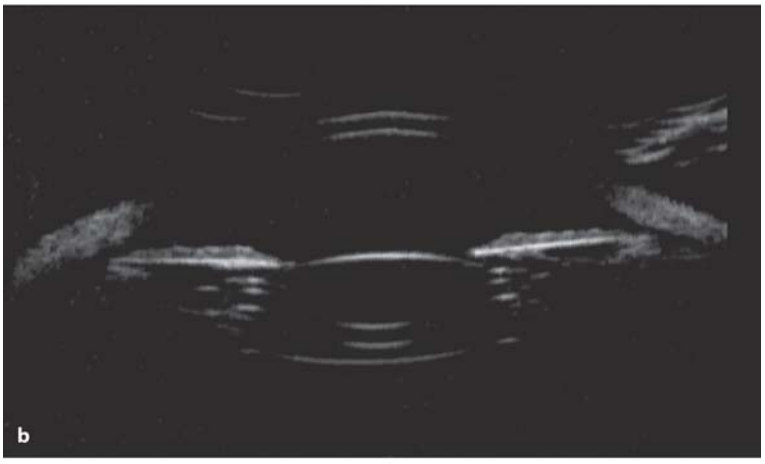


Fig. 12.4. Scanning electron microscopy of the Synchrony IOL. Note the smooth and clean surface conditions of this implant even in critical areas like the optic–haptic junction area. No surface irregularities can be observed





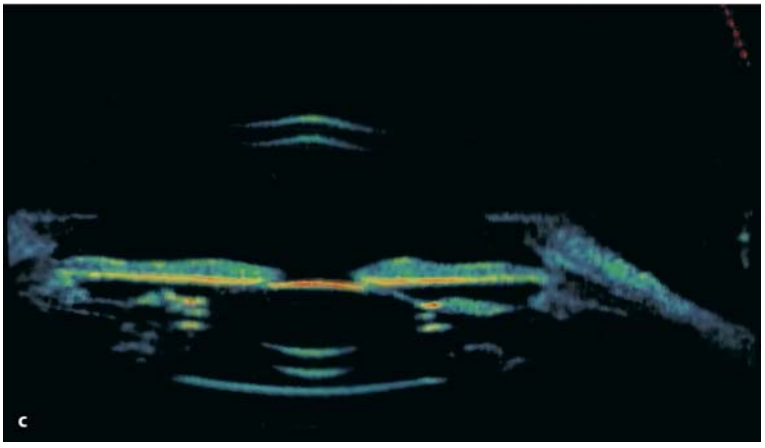


Fig. 12.5 a–c. Ultrasound biomicroscopy of an eye implanted with a Synchrony IOL. Note the relation between the IOL's anterior optic and the iris, ciliary body and zonules. The high-powered biconvex anterior optic is linked to the negative-powered posterior optic by a spring system. The gap between both optics can be appreciated

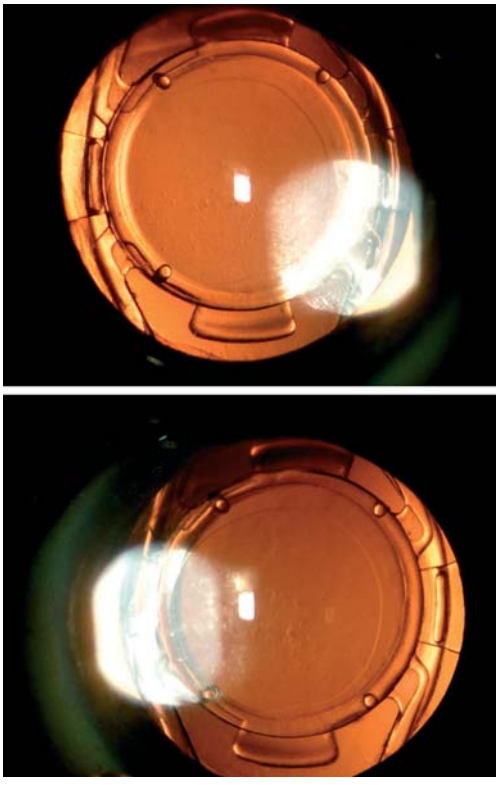


Fig. 12.6. Retroillumination photographs of human eyes implanted with Synchrony IOLs 3 months after surgery. Note that the IOL is well centered, without signs of anterior or posterior capsule opacification

Meanwhile, the company has implemented some IOL design changes, e.g. several small holes are placed in the two optics to maximize the aqueous humor flow between the two optics. Further, special efforts were made to optimize the IOL power calculation program in order to decrease deviations from target refraction.

Following cataract surgery and IOL implantation, options to extend the depth of field allowing distance and near function include monovision (the assignment of one eye to distance activities and the other eye to near), multifocal IOL implantation and, most recently, accommodating IOL implantation. The advantage of multifocal or accommodating IOL implantation over the monovision approach is the potential for binocular function at all distances. Multifocal lenses are designed to produce at least two axially separated focal points that create the functional equivalent of accommodation. The design of such lenses is rendered challenging by the demands of minimizing loss of incident light to higher orders of diffraction, minimizing optical aberration, and balancing the brightness of the focused and unfocused images [12].

Current accommodating intraocular lenses might be expected to provide superior im-

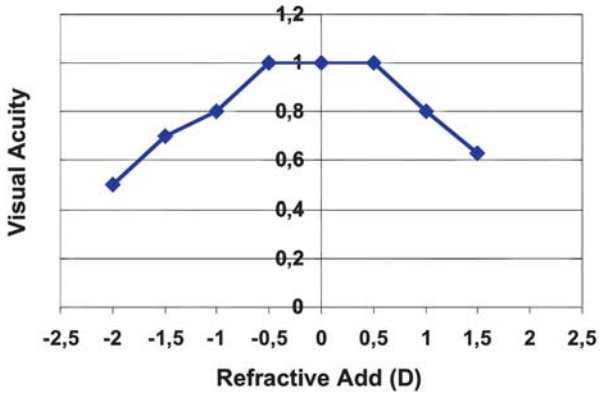


Fig. 12.7. The defocus curve of an eye implanted with a Synchrony IOL, demonstrating a sufficient range of visual functionality

age quality compared to multifocal lenses, since competing retinal images are avoided, but as described above, the accommodative range of a single rigid optic design that depends upon axial displacement of the optic is limited by the range of excursion generated [15, 16]. The Synchrony IOL has the potential to allow the extremes of distance and near focus characteristics of multifocal designs, but additionally offers improved function at intermediate distance, and improved image quality at all object distances.

It is important to emphasize the significance of an intact CCC, and in-the-bag placement of the IOL to achieve pseudo-accommodation. Unfortunately, it is very hard to address the ideal CCC size. A previous report [17] based on HumanOptic's 1CU accommodative IOL found that the ideal CCC size for visual performance was between 4.5 and 5.0 mm. A smaller CCC (more overlapping) can increase the risk of anterior capsule fibrosis, which can lead to phimosis of the CCC opening and, as shown in this study, lower near visual acuities. A larger CCC (very low overlapping), as shown in previous studies, can increase the odds of decentration and formation of posterior capsular opacification [18].

FINAL COMMENTS

The Synchrony IOL is a new alternative in the field of refractive lens exchange for cataract and presbyopic surgery. Refractive lens exchange is increasingly seen as an advantage over cornea-based refractive procedures. The function of the dual optic offers the opportunity to achieve accommodative amplitude of 3–4 D by virtue of its increasing power. This represents a huge technological leap in the advancement of cataract and refractive surgery for the world's aging population. To optimize surgical outcomes with the dual-optic IOL design (as with any other new IOL technology), we emphasize the importance of careful patient selection, an adequate and consistent biometry method for accurate power calculation, and the implementation of a consistent surgical technique: CCC size and shape, complete cortical clean-up, anterior capsule polishing, in-the-bag IOL implantation and rigorous postoperative regimen. Further studies with large numbers and longer follow-up are necessary for final estimation.

References

1. Fisher RF (1973) Presbyopia and the changes with age in the human crystalline lens. J Physiol (Lond) 228:765–779
2. Koretz JF, Handelman GH (1986) Modeling age-related accommodative loss in the human eye. Math Modelling 7:1003–1014
3. Schachar RA (1994) Zonular function: a new model with clinical implications. Ann Ophthalmol 26:36–38
4. Duane A (1925) Are the current theories of accommodation correct? Am J Ophthalmol 8:196–202
5. Tamm E, Lütjen-Drecoll E, Jungkunz E et al (1991) Posterior attachment of ciliary muscle in young, accommodating old, and presbyopic monkeys. Invest Ophthalmol Visual Sci 32: 1678–1692
6. Croft MA, Kaufman PL, Crawford KS et al (1998) Accommodation dynamics in aging rhesus monkeys. Am J Physiol 275 (Regulatory Integrative Comp Physiol 44):R1885–R1897
7. Atchison DA (1995) Accommodation and presbyopia. Ophthal Physiol Opt 15:255–272
8. Hara T, Hara T, Yasuda A et al (1990) Accommodative intraocular lens with spring action, part 1. Design and placement in an excised animal eye. Ophthalmic Surg 21:128–133
9. Gilmartin B (1995) The aetiology of presbyopia: a summary of the role of lenticular and extralenticular structures. Ophthal Physiol Opt 15:431–437
10. Cumming JS, Slade SG, Chayet A, AT-45 Study Group (2001) Clinical evaluation of the model AT-45 silicone accommodating intraocular lens: results of feasibility and the initial phase of a Food and Drug Administration clinical trial. Ophthalmology 108:2005–2009
11. Kuechle M, Nguyen NX, Langenbucher A et al (2002) Implantation of a new accommodating posterior chamber intraocular lens. J Refract Surg 18:208–216
12. Pieh S, Marvan P, Lackner B et al (2002) Quantitative performance of bifocal and multifocal intraocular lenses in a model eye. Point spread function in multifocal intraocular lenses. Arch Ophthalmol 120:23–38
13. El Hage SG, Le Grand Y (1980) Physiological optics, vol 13. Springer series in optical sciences. Springer, Berlin Heidelberg New York, pp 64–66
14. McLeod SD, Portney V, Ting A (2003) A dual optic accommodating foldable intraocular lens. Br J Ophthalmol 87:1083–1085
15. Dick HB, Kaiser S (2002) Dynamic aberrometry during accommodation of phakic eyes and eyes with potentially accommodative intraocular lenses. Ophthalmologe 99:825–834
16. Dick HB (2005) Accommodative intraocular lenses: current status. Curr Opin Ophthalmol 16:8–26
17. Vargas LG, Auffarth GU, Becker KA et al (2004) Performance of the accommodative 1 CU IOL in relation with capsulorhexis size. J Refract Surg (in press)
18. Schmidbauer JM, Vargas LG, Apple DJ et al (2002) Evaluation of neodymium:yttrium-aluminum-garnet capsulotomies in eyes implanted with AcrySof intraocular lenses. Ophthalmology 109:1421–1426

13 Sarfarazi Elliptical Accommodative Intraocular Lens

Faezeh Mona Sarfarazi

CORE MESSAGES

- The elliptical accommodative intraocular lens (EAIOL) is a unique approach that utilizes two optics connected by three haptics. The optical design includes an anterior optic that is biconvex (plus lens) and a posterior optic that is a concave convex (minus lens).
- The haptics are uniquely designed to serve a dual function. First, they are elliptically shaped to conform to the natural shape of the capsule to correctly position and center the optics. Second, the haptics provide the resistance force necessary to separate the two optics.
- This single-piece silicone lens is designed to achieve accommodation through the natural contraction/relaxation of capsule by the ciliary muscle.
- The primary objective of this research was to determine whether the EAIOL could effect significant changes in optical power in the monkey eye.
- Lens design and mold were developed to match the size and characteristics of monkey eyes.
- This lens, when tested in primates, induced 7–8 diopters of accommodation.
- A clinical study in humans began in 2004.

13.1 The Nature of Presbyopia

In the human eye, multifocal vision is provided by the optical system comprised of the cornea and the natural crystalline lens, which in combination form a series of convex–concave lenses. Accommodation of vision at both infinity and near vision of 250 mm is provided by a peripheral muscular body extending about the capsular bag and connected to the equator thereof by the zonula of Zinn. While there are some differences of opinion regarding the exact mechanism, in general, tension and the relaxation of the ciliary muscles cause the capsular bag to lengthen or contract, which varies the focus of the eye.

Presbyopia is characterized as a reduction in both amplitude and speed of accommodation with age. The amplitude of accommodation decreases progressively with age from approximately 14 diopters in a child of 10 years to near zero at age 52. The exact explanation for the physiological phenomena is open to debate. However, it is observed that the curvatures of excised senile lenses are considerably less than those of juvenile ones. Failure could be due to a hardening of the lens material, sclerosis, decrease in the modulus of elasticity, a decrease in the thickness of the capsule or a combination of the above. Regardless of the cause, it is a recognized fact that beginning at about 40–45 years of age, correction for both near and far vision becomes necessary in most humans.

Many methods have been or are being explored to correct presbyopia, including monovision approaches, multifocal lenses, modification of the cornea, injectable intraocular lenses (IOLs) and single-optic IOLs that utilize the optic shift principle. All have experienced some limitation or have not yet provided a consistent solution. While new versions of bifocal contact lenses are constantly being developed, they are still limited in their range of accommodative correction. Monovision approaches with contact lenses seem to be suitable for a limited group of people. Multifocal IOLs suffer from the fact that light is split, thereby reducing contrast sensitivity. Modification of the cornea using lasers, heat or chemicals to create multifocal patterns on the surface is still in an exploratory stage. Scleral expansion techniques have tended to experience regression over time.

Single-optic IOLs utilizing the optic shift principle are limited in the amount of accommodation they can provide. Injectable IOLs, where the capsular bag is filled with a flexible material, is an intriguing approach but appears to be far from developed and is not expected to be feasible for the foreseeable future. For this reason, a great deal of attention is focused on twin-optic IOLs.

13.2 Twin-Optic Accommodative Lens Technology

The idea of using two or more lenses to create accommodation is not new. In 1989, Dr. Tsutomu Hara presented a twin lens system with spring action, which he called the spring IOL. The spring IOL consists of two 6-mm optics held 4.38 mm apart and four flexible loops [2, 3]. Early efforts to implant this lens were unsuccessful.

At approximately the same time, the author filed a patent for an accommodative lens with two optics and a closed haptic, which forms a membrane and connects the two optics to each other (US patent number 5,275,623). While the design most closely resembles the mechanics of a natural lens, the technology does not yet exist that can manufacture this lens.

13.3 The Sarfarazi EAIOL

The elliptical accommodating IOL (EAIOL) is an accommodative lens system with dual optics that employs technologies that are novel in the ophthalmic field [1]. The anterior optic is a biconvex lens of 5.0-mm diameter (Fig. 13.1), the posterior lens is a concave–

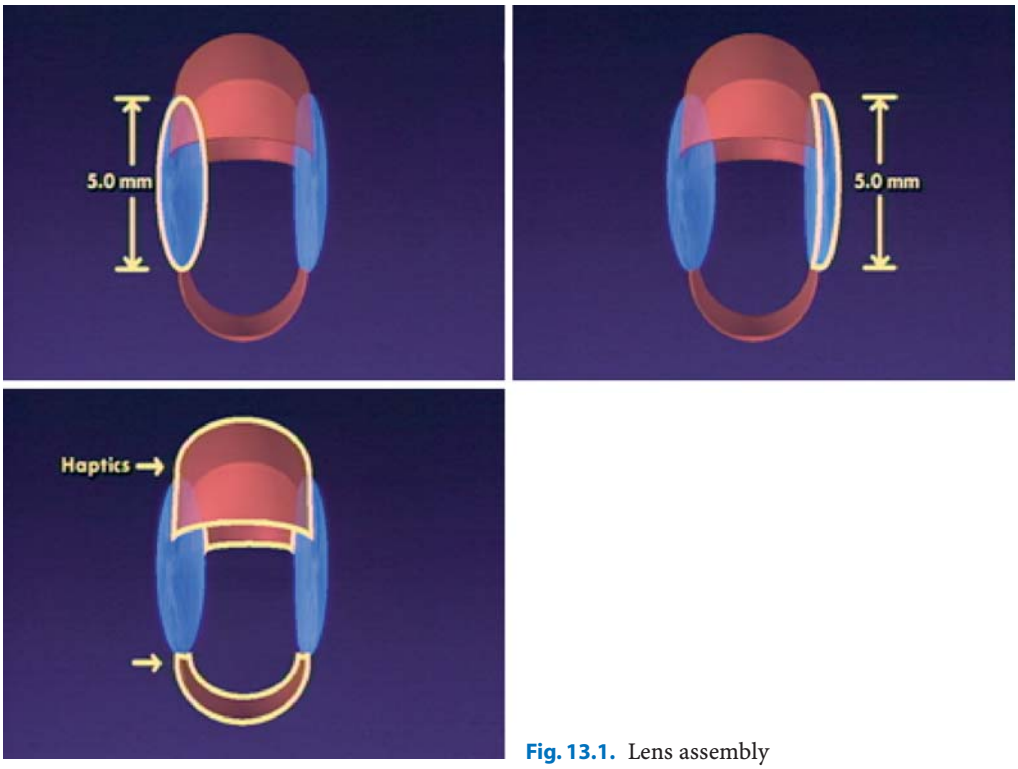


Fig. 13.1. Lens assembly

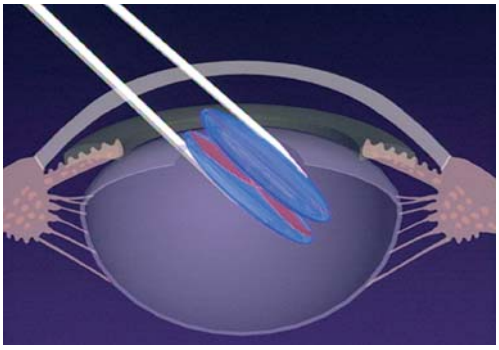


Fig. 13.2. Insertion in the bag

convex lens with negative power and 5.0-mm diameter. The two lenses are connected to each other by three band-like haptics. Each haptic covers a 40-degree angle of the lens periphery, and the angle of separation between them is 80 degrees. A useful property of these optics is that the convex surface of the anterior lens "nests" within the concave surface of the posterior optic, thereby simplifying insertion through the cornea and capsulorrhexis (Fig. 13.2). The overall diameter of the EAIOL lens assembly (including haptics) is 9 mm.

The haptic design is unique in that the haptics serve two critical roles. First, they position and center the EAIOL in the capsule in a fashion similar to that of the haptics for a standard IOL. Second, they provide the spring-like resistance that separates the two optics. It is called an elliptical accommodating IOL because it forms an elliptical shape, which resembles the shape of the natural lens (Fig. 13.3). When inserted in the bag after removal of natural lens material, the EAIOL occupies the entire capsular space. It uses the contraction and relaxation forces of the ciliary muscle against the spring-like tension of the haptics to emulate the accommodation of the natural lens (Fig. 13.4).

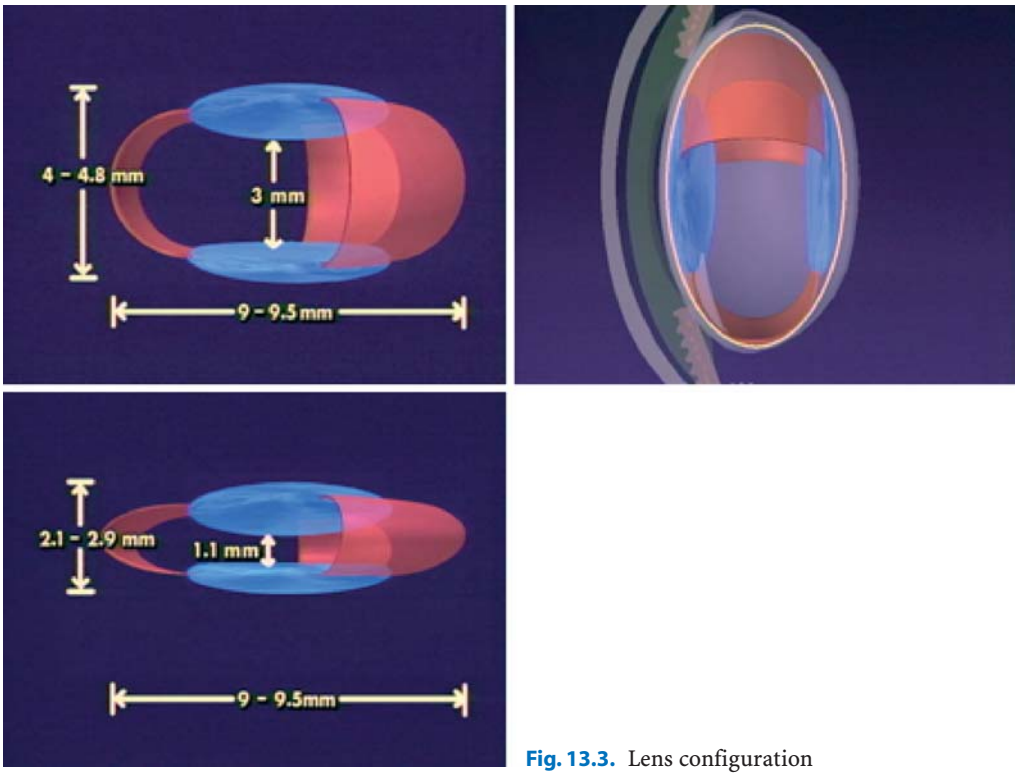


Fig. 13.3. Lens configuration

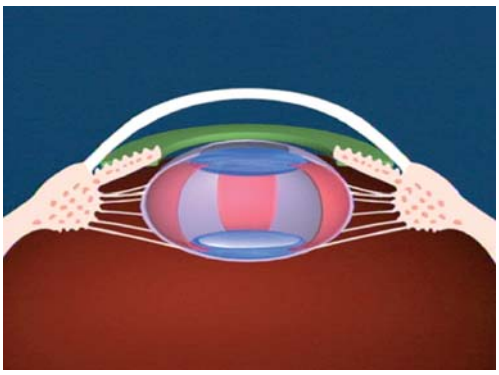


Fig. 13.4. Lens in the bag

13.4 Design Considerations for the EAIOL

The accommodation process in a twin-optic lens depends on increasing and decreasing the lens diameters (i.e., the lens diameter along the optical path). According to Wilson [4], during accommodation the lens diameter of the natural lens is consistently reduced and enlarged during non-accommodation. A finite element analysis for the EAIOL shows similar changes. The diameter of the EAIOL reduces from 9.0 to 8.5 mm during accommodation.

According to Koretz [5], the rate of change per diopter of accommodation is independent of age for the entire adult age range. With increasing accommodation, the lens becomes thicker and the anterior chamber shallower along the polar axis. This increase in sagittal lens thickness is entirely because of an in-

crease in the thickness of the lens nucleus. In the EAIOL, during the accommodation process the lenses move further apart from one another (2.5 mm), decreasing the anterior chamber depth. The amount of distance between two lenses is reduced during the non-accommodative process.

Beauchamp suggested that about 30% of the lens thickening during accommodation is accounted for by posterior lens surface displacement [6]. If the crystalline lens power is calculated on the basis of an equivalent refractive index, changes in the posterior surface of the lens contribute around one-third of the increase in the lens power associated with 8.0 D of ocular accommodation [7, 8]. In the EAIOL, the posterior lens is a negative lens and it sits on the posterior capsule and experiences minimal movement. It could, however, use this posterior vitreous pressure to move forward.

Non-invasive biometry of the anterior structures of the human eye with a dual-beam partial coherence interferometer showed that the forward movement of the anterior pole of the lens measured approximately three times more than the backward movement of the posterior pole during fixation from the far point to the near point [9]. In the EAIOL, the haptics were designed according to this principle. The anterior lens moves forward in the accommodation phase and backward during the non-accommodative process.

Total anterior segment length (defined as the distance between the anterior corneal and posterior lens surfaces), vitreous cavity length (distance between the posterior lens and anterior retinal surfaces), and total globe length were each independent of age. This constellation of findings indicates that the human lens grows throughout adult life, while the globe does not, that thickening of the lens completely accounts for reduction of depth of the anterior chamber with age, and that the posterior surface of the lens remains fixed in position relative to the cornea and retina [10].

As mentioned previously, the EAIOL posterior lens sits on the posterior surface of the capsule and has minimal movement during the accommodation process. Because of the stability of the globe during the aging process, the EAIOL could be a suitable lens for children as well as adults.

13.5 Optical and Mechanical Design

The design of the EAIOL evolved from its original concept through an extensive series of mechanical (Fig. 13.5) and optical (Fig. 13.6) engineering studies. Many variations on the basic system were investigated to determine an acceptable design for the lens that would result in the desired amount of accommodation. The configuration of the Zonula of Zinn was included in these representations to determine their effect as they pull outwardly on the lens.

Among the attributes studied were the shape and stresses that the implant would encounter during use. Color-coded plots were used to represent various magnitudes of deformation. Comparative stress studies at maximum deformation indicated that the lens material would not fail in this application.

Chief among the optical design factors determining the amount of accommodation and visual acuity was the available motion of the anterior lens. A high degree of motion allows for the lowest possible powers on the two lenses. The posterior lens is a negative lens and, in the recommended optical design, the anterior lens moves 1.9 mm to achieve a minimum of 4 diopters of accommodation. Ray aberration diagrams indicated excellent image performance and sufficient power in the lenses for this amount of accommodation. The curves for the candidate designs, distant (infinity) and near vision (250 mm) were evaluated with respect to such variables as: (a) number of powered lenses, (b) use of as-

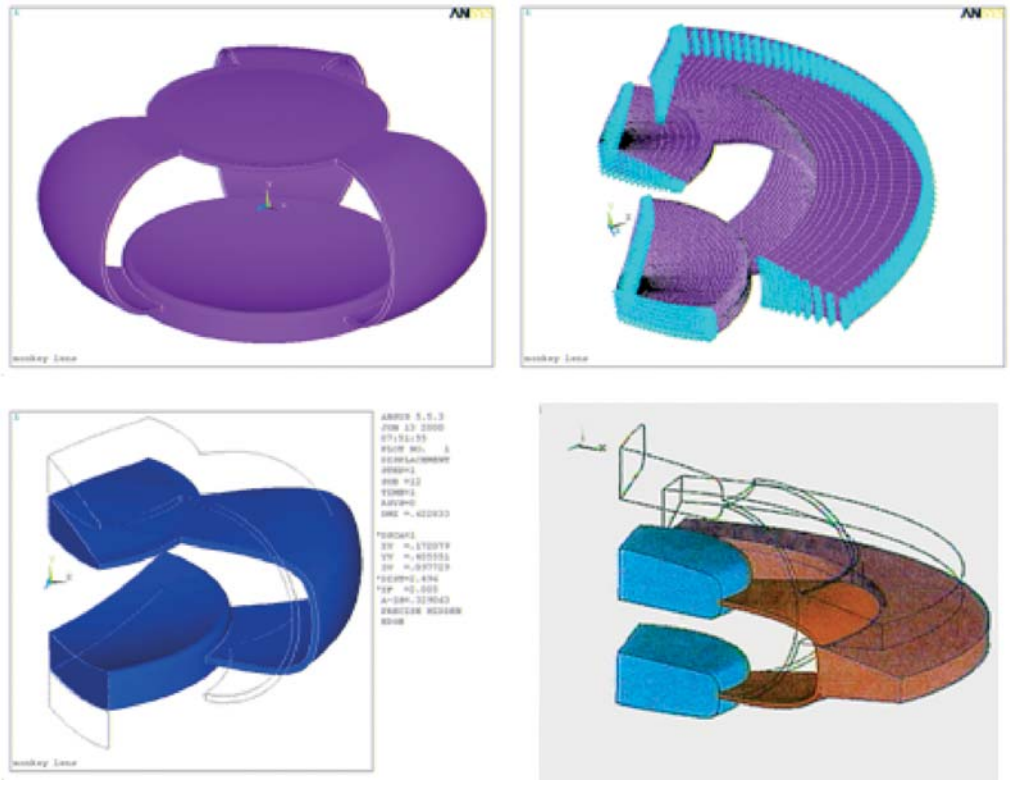


Fig. 13.5. Mechanical design

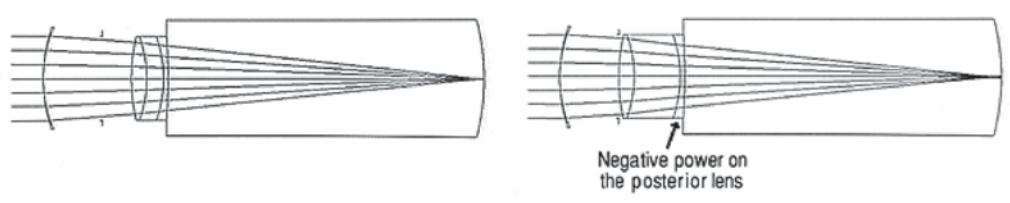


Fig. 13.6. Optical design: *left* unaccommodated; *right* accommodated

pheric surfaces, (c) pupil size, (d) lens placement and dimensions, (e) field of view and (f) wave length. Results were provided on image performance as a function of field position, and there was no difference between these two images. The letter E was clear during the entire accommodation process.

13.6 Prototype Development

Initially, several prototypes from different materials such as PMMA, polypropylene, polyimide acetyl (used in heart valves) and Flexeon materials were made using different techniques such as etching and assembling. The PMMA lenses were used with varying haptic materials and configurations. Although the tests of these designs for mechan-

ical and optical properties were satisfactory, insertion in the eye through a 3-mm corneal incision was difficult and caused permanent deformation and/or shear cracks in the haptics. Implantation of two versions of this unit in human cadaver eyes, using an open sky technique, showed that the EAIOL fitted in the capsular bag and occupied the entire bag space. A Miyake technique examination showed that it centered well. Pushing on the anterior lens transferred the force to the posterior lens and the haptics responded to the pressure.

These initial tests indicated that a PMMA version of the EAIOL would not be suitable for small-incision surgery and that a more flexible material was desirable. As a result, the development effort shifted to developing complete EAIOL designs from silicone and acrylic materials, both of which are already approved for use in human implantation. In both cases, the model analyses indicated that the finished EAIOL units would be more pliable and therefore more suitable for small-incision insertion. This was especially critical for implantation in the smaller eye of a monkey, which was to be the next phase of testing.

13.7 Primate Testing

The goal of the next phase of the program was to design a lens that could be implanted in the eye of a monkey. This work was time consuming and costly due to a lack of information regarding the exact parameters of a monkey eye. Measurements of monkey vision were performed in vivo and in vitro to characterize a monkey's vision and the lens requirements needed for the study. There had previously been no reported research on such parameters at the depth needed for molding and designing the lens. Further, there was no lens available on the market to fit the monkey capsular bag. Previous studies had been focused primarily on the ciliary muscle structure and the nature of accommodation.

Fig. 13.7. Flexible, foldable lens prototype

Fig. 13.8. First phase testing: Miyake technique (Dr. Mamalis, University of Utah)

Once a flexible, foldable lens prototype was developed (Fig. 13.7), the following tests were conducted.

Initial testing of the EAIOL was performed using the Miyake technique in a human cadaver eye. The test indicated that the lens centered well and gave an initial indication that the lens design would function successfully in a monkey eye (Fig. 13.8).

A second phase of testing was further proof of concept work on a monkey eye. Using Dr. Glasser's stretching device to simulate

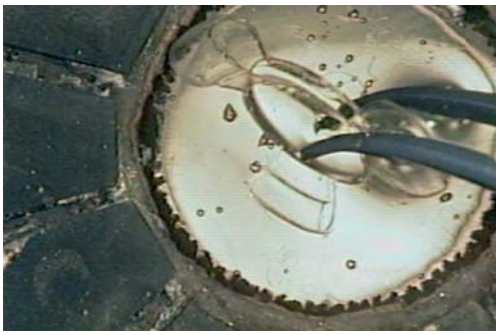


Fig. 13.9. Second phase testing: Dr. Glasser's device, University of Houston

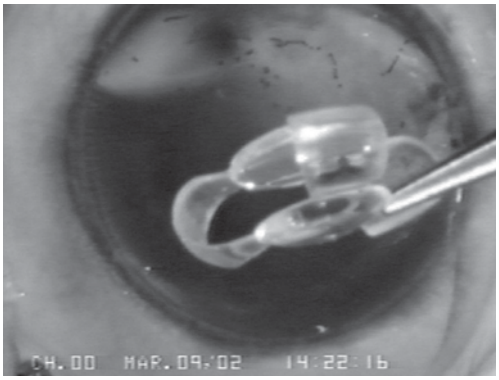


Fig. 13.10. Third phase testing

accommodation caused by the ciliary muscle, the lens performance was demonstrated at various stages of accommodation measuring optical and mechanical properties with ultrasound biomicroscopy (UBM) (Fig. 13.9).

In the third phase of testing, EAIOL lenses were implanted in the eye of several Rhesus monkeys (Fig. 13.10).

The lenses developed for primate testing were one-piece, molded lenses made from a silicone material. The ultimate objective was to determine whether the EAIOL could effect significant changes in optical power in a monkey eye.

During the third phase of testing, the lens was implanted into the eyes of three monkeys. Prior to surgery, the iris was removed to allow for better visualization of the surfaces of the lens. In each case, several tests were performed before and after accommodation, which was induced by a supramaximal dose of carbachol. It was observed that the anterior chamber shallowed and the lens thickened in response to the carbachol before IOL implantation. UBM examinations showed a strong contraction of the ciliary muscle (Fig. 13.11), as did goniovideography images. Baseline refraction was measured with the natural lens in place before and after carbachol injection.

The eye was prepared with the same standard procedures used for implanting conventional IOLs. The diameter of the optic on this lens was 3.7 mm. The corneal incision was approximately 4 mm, and the capsulorrhexis was between 3.5 mm and 3.7 mm. A normal phacoemulsification procedure was performed to remove the natural lens material.

To implant the lens into the capsular bag, the two optics were nested together and inserted through the corneal incision (Figs. 13.12 and 13.13). The haptics easily followed. It is expected that a folder or an injector will be used to implant the lens in the human eye. Repeated procedures on three monkey eyes showed that insertion of the Sarfarazi EAIOL was comparable to that of conventional lens implants with no surgical complications.

The twin-optic lens was easily positioned in the capsule. In all cases, the two optics separated inside the bag, although it required some manipulation due to sticking of the optics to each other. Once the lens was in place, it maintained its position in the capsular bag. No decentration or rotation was observed and the lens remained in place on the optical axis due to its elliptical shape. The remainder of the surgery was routine. For safety, two sutures were used to close the incision in the monkey eye.

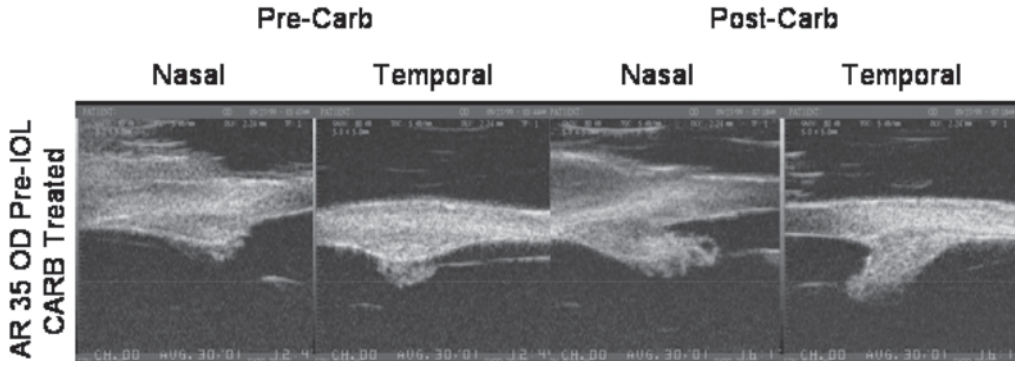


Fig. 13.11. Ultrasound biomicroscopy before and after carbachol (*Carb*)

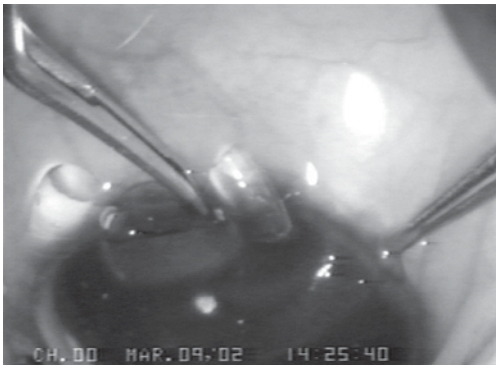


Fig. 13.12. Implantation of lens into capsular bag (1)

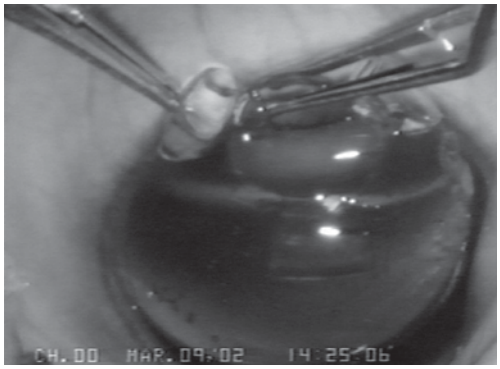


Fig. 13.13. Implantation of lens into capsular bag (2)

13.8 Implantation Results

Several days after IOL insertion, experiments were conducted to determine initial results. The Scheimpflug imaging technique was used in repeated tests to observe the lens in open and closed positions (Figs. 13.14 and 13.15). A slit lamp examination showed the cross-section of the cornea and the two optics in the closed position. After carbachol was added, the two optics separated and a simulated accommodation of 7–8 diopters was measured using a Hartinger coincidence refractometer and retinoscopy. Goniovideography images clearly showed the placement of the haptics adjacent to the zonules in the equator of the capsular bag (Fig. 13.16).

Ultrasound biomicroscopy confirmed that the two optics move properly in relation to the cornea (Fig. 13.17). Again, the haptics were clearly seen close to the equator of the capsule working in conjunction with the zonules and ciliary muscle (Figs. 13.18, 13.19 and 13.20).

Anterior chamber depth was obtained from A-scan, Scheimpflug, and UBM measurements. Anterior chamber depth was decreased due to the forward movement of the anterior optic of the EAIOL in the same manner as with the natural lens (Fig. 13.21). The thickness of the EAIOL (degree of separation of the optics) was increased after carbachol was added according to both A-scan and Scheimpflug measurements.

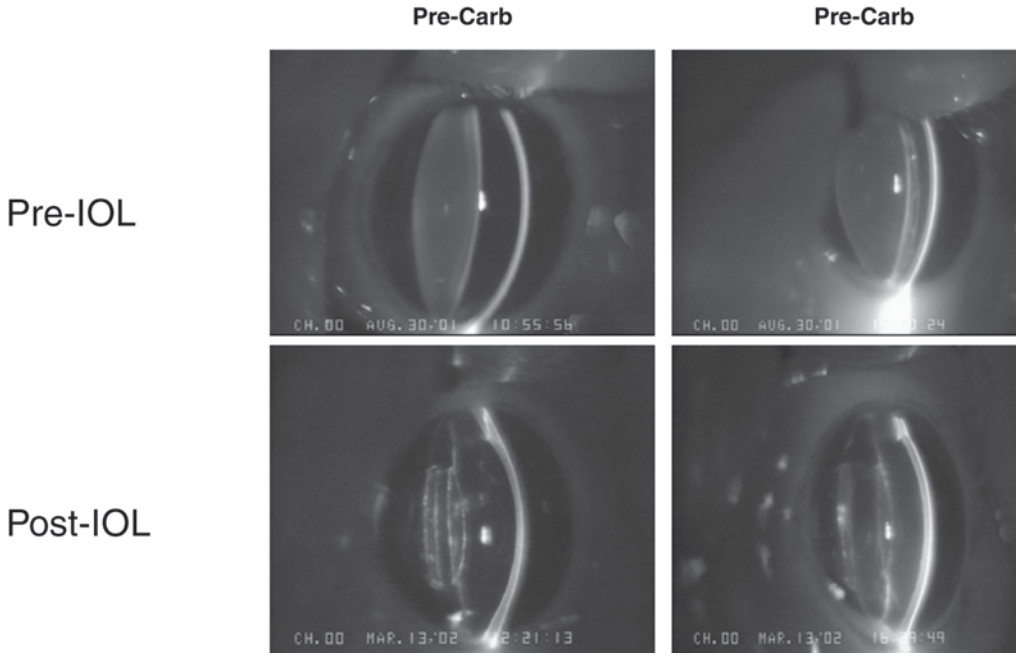


Fig. 13.14. Scheimpflug imaging results (*Carb* carbachol)

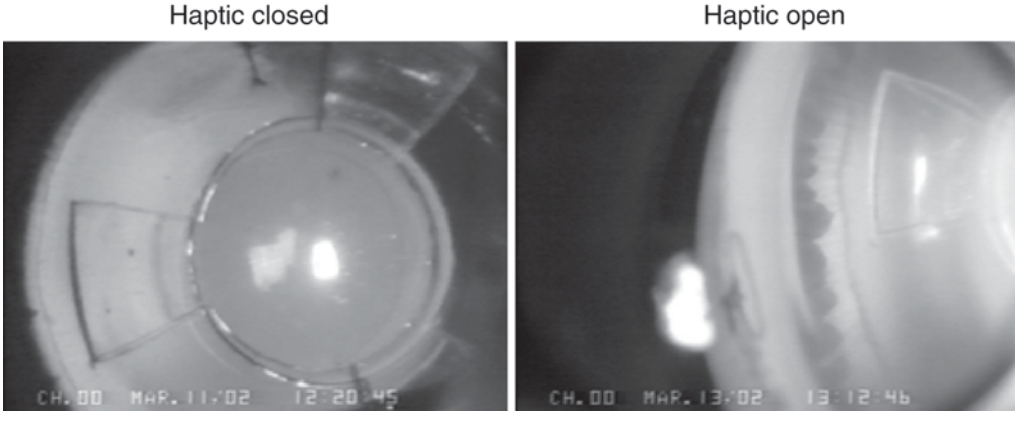


Fig. 13.15. Scheimpflug imaging: left *haptic* closed; right *haptic* open

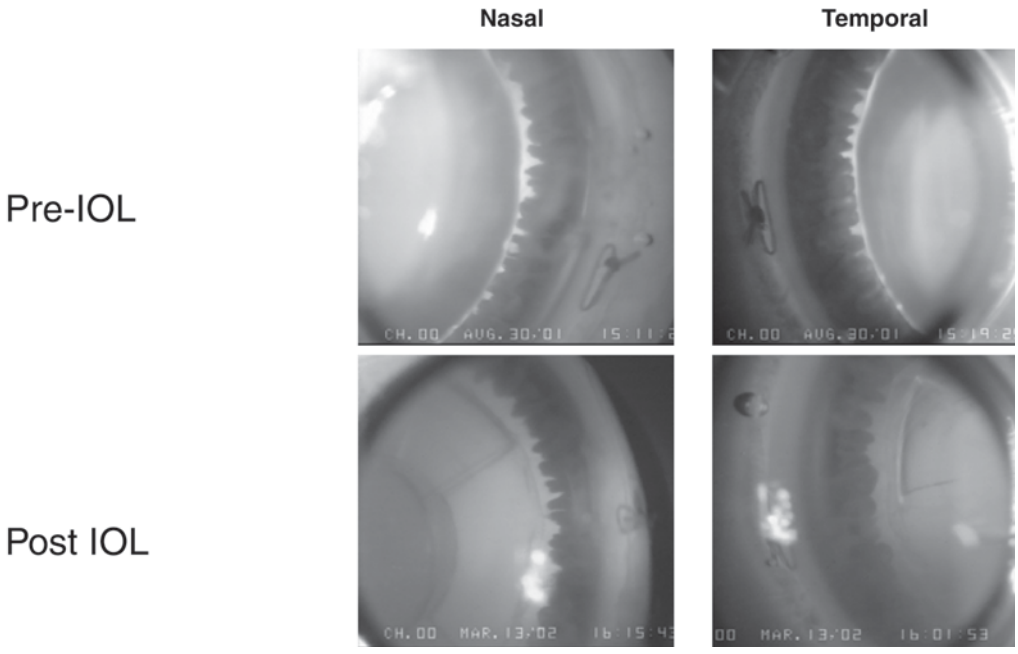


Fig. 13.16. Goniography results after carbachol

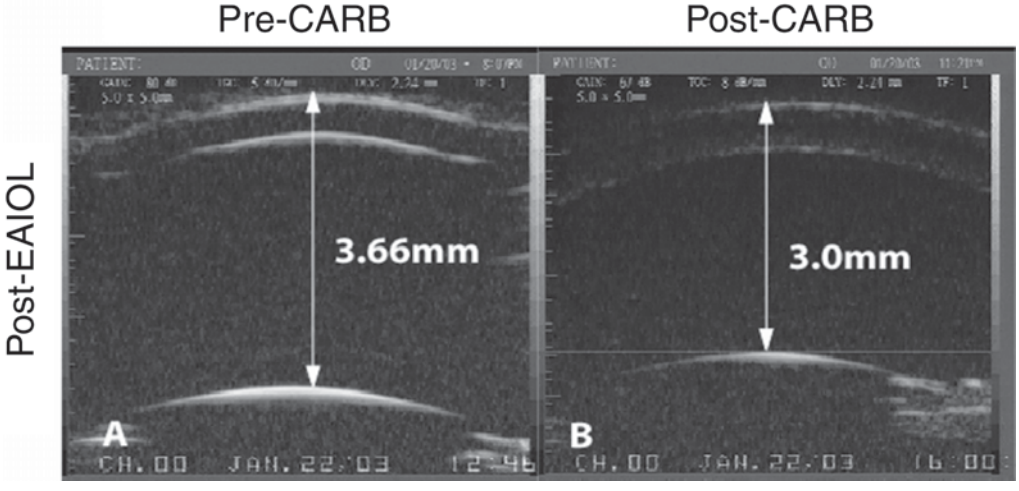


Fig. 13.17. Ultrasound biomicroscopy: movement of optics in relation to cornea (*CARB* carbachol)

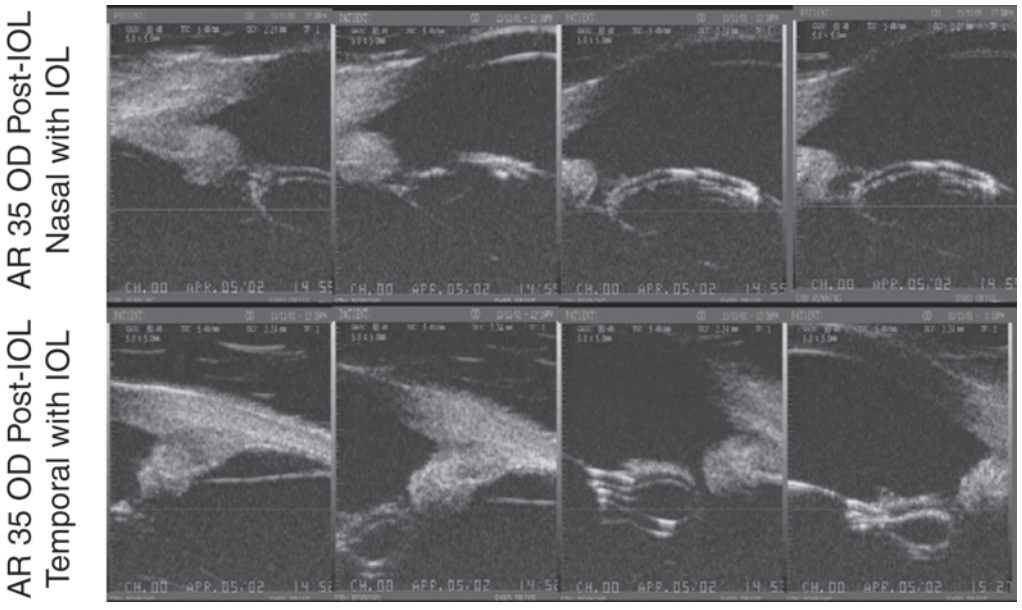


Fig. 13.18. Working of haptics after carbachol (1)

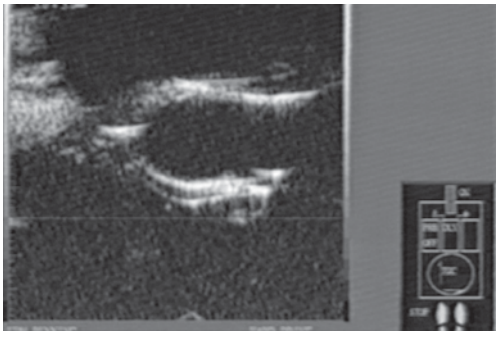


Fig. 13.19. Working of haptics after carbachol (2)

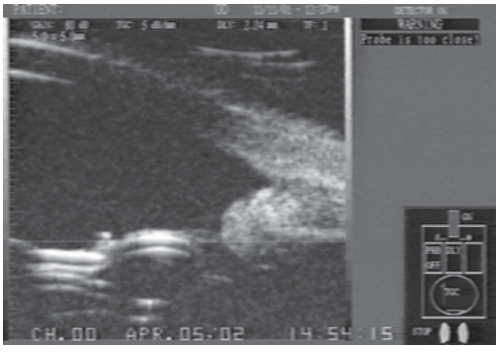


Fig. 13.20. Working of haptics after carbachol (3)

Follow-up testing at 4 and 7 weeks after IOL insertion showed that the separation between the two optics decreased by about 20% after carbachol. However, no decrease in accommodation occurred over time because the lens adapted to the size of the capsular bag. Repeated tests indicated that the monkey eye consistently achieved 7–8 diopters of accommodation (Fig. 13.22).

Two of the monkeys exhibited significant inflammation. However, the prototype lenses were not made under processes normally used for human lenses. Recent electron microscope examinations of the prototype lenses indicate that the polymer contained significant contamination. It is believed that this contamination was the major contributor to the inflammation. This is not expected to be a concern for the lenses being developed for human implantation, which will utilize manufacturing processes currently developed for human IOLs.

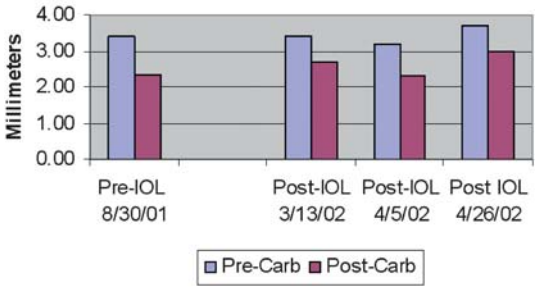


Fig. 13.21. Anterior chamber depth as measured by Scheimpflug imaging (*Carb* carbachol)

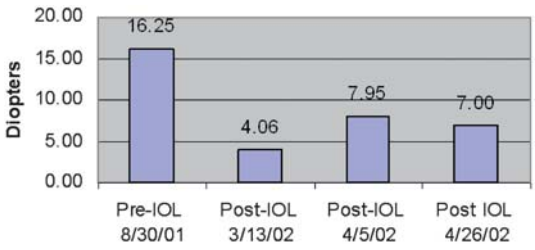


Fig. 13.22. Accommodation measured using refractometer

FINAL COMMENTS

The ability of the Sarfarazi EAIOL to accommodate appears to be primarily due to the shallowing of the anterior chamber and lens thickening as observed in UBM imaging.

These tests indicate that this EAIOL can emulate the performance of the natural lens and can potentially achieve a significant degree of accommodation. The implantation procedures are simple and effective and do not require any unusual equipment or techniques. Observation of the monkey eyes after implantation demonstrated that the use of this lens in place of conventional IOLs is safe and has no adverse reaction on the eye structures involved. No atrophy or changes in the ciliary muscle structure were observed several months after the EAIOL was implanted.

Enrolment of patients for clinical feasibility studies has now been initiated.

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References

1. Masket S (2004) Accommodating IOLs: emerging concepts and designs. Cataract Refract Surg Today 1:32–36
2. Hara T, Hara T, Yasuda A, Yoshiharu Y (1990) Accommodative intraocular lens with spring action, part 1. Ophthalmic Surg 21:128–133
3. Hara T, Hara T, Akihiro Y, Yasuda A, Yoshiharu Y (1992) Accommodative intraocular lens with spring action, part 2. Ophthalmic Surg 23: 632–635
4. Wilson RS (1997) Does the lens diameter increase or decrease during accommodation? Human accommodation studies: a new technique using infrared retro-illumination video photography and pixel unit measurement. Trans Am Ophthalmol Soc 95:261–267
5. Koretz JF, Kaufman PL, Neider MW, Goeckner PA (1989) Accommodation and presbyopia in the human eye – aging of the anterior segment. Vis Res 29:1685–1692
6. Beauchamp R, Mitchell B (1985) Ultrasound measures of vitreous chamber depth during ocular accommodation. Am J Optom Physiol Opt 62:523–532
7. Garner LF, Yap MK (1997) Changes in ocular dimensions and refraction with accommodation. Ophthalmic Physiol Opt 17:12–17
8. Garner LF, Smith G (1997) Changes in equivalent and gradient refractive index of the crystalline lens with accommodation. Optom Vis Sci 74:114–119
9. Drexler W, Baumgartner A, Findl O, Hitzenberger CK, Fercher AF (1997) Biometric investigation of changes in the anterior eye segment during accommodation. Vision Res 37:2789–2800
10. Koretz JF, Cook JF, Kaufman PL (1997) Accommodation and presbyopia in the human eye. Changes in the anterior segment and crystalline lens with focus. Invest Ophthalmol Vis Sci 38:569–578

14 AcrySof ReSTOR Pseudo-accommodative IOL

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None of the authors has a financial interest in any product mentioned in this chapter.

CORE MESSAGES

- The AcrySof ReSTOR IOL (model: SA60D3) is a pseudo-accommodative, apodized diffractive, one-piece, foldable, hydrophobic acrylic, posterior chamber IOL made of the same material as the monofocal AcrySof IOL.
- It has a central 3.6-mm diffractive optic region, with 12 concentric diffractive zones on the anterior surface of the lens, which divide the light into two diffraction orders to create two lens powers. The central 3.6-mm part is surrounded by a region that has no diffractive structure over the remainder of the 6-mm diameter lens. The near correction is calculated at +4.0 D at the lens plane, resulting in approximately 3.2 D at the spectacle plane. This provides 6 D of pseudo-accommodation at the 20/40 level.
- The diffractive structure of AcrySof ReSTOR is apodized. Distinct from other diffractive IOLs, there is a gradual decrease in step heights of the 12 diffractive circular structures, creating a transition of light between the foci and reducing disturbing optic phenomena like glare and halo.
- Current study results demonstrate excellent near visual acuity without compromising distance vision, with approximately 80% of investigated patients not needing spectacles for near, distance, or intermediate vision.

The implantation of intraocular lenses (IOL) into the human eye reached its 50th anniversary in 1999. Despite the major achievements in correction of the distance vision by more accurate IOL formulas and biometry instrumentation, the combined near and distance correction is still not perfectly achieved [1]. Introduction of refractive and diffractive multi- (or bi-) focal IOLs aims to correct both distance and near vision, thus being able to correct ametropia and also address presbyopia [2]. The perfect pseudo-accommodative IOL will not jeopardize quality of vision, e.g. contrast sensitivity or glare disability. The

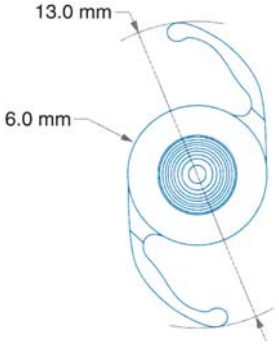
limitations of currently available refractive and some diffractive multifocal optics are related to sub-optimal near correction and possible photic phenomena like glare and halos. PMMA diffractive IOLs provide improved near vision in most cases; however, due to incision requirements, modern state-of-the-art small-incision cataract surgery is not feasible. The currently available apodized ReSTOR pseudo-accommodative lens is a hybrid foldable IOL featuring a central diffractive and a peripheral refractive region that combines the advantages of both optical design principles and provides quality near to distance vision outcomes.

14.1 AcrySof ReSTOR Lens

Multifocal IOLs have been developed and evaluated for decades. In the 1980s the 3M multifocal IOL (3M Corporation; St. Paul, MN, USA) was developed with a diffractive multifocal design. As 3M Vision Care was acquired by Alcon (Alcon Laboratories, Fort Worth, Dallas, TX, USA), the diffractive design was redesigned for the foldable pseudo-accommodative AcrySof ReSTOR IOL by the company.

The AcrySof ReSTOR IOL (model: SA 60D3, Fig. 14.1) is a one-piece, foldable, hydrophobic acrylic, posterior chamber lens with a 6-mm optic (Figs. 14.1 and 14.2) designed for implantation into the capsular bag after phacoemulsification. It is made of the same material as the original AcrySof IOL (Fig. 14.2). The IOL has a central 3.6-mm diffractive structure on the anterior surface of the lens with 12 concentric steps and a surrounding 2.4-mm wide ring with a traditional refractive function. The diffractive region is "apodized": the diffractive steps gradually reduce in size to blend into the refractive periphery, resulting in a smooth transition between the foci, which should reduce optical phenomena like glare and halos. Controlling the diameter of the pseudo-accommodative diffractive optic also reduces the halos as the defocused image size is minimized. As light passes through the diffractive portion of the lens optic, the steps on the anterior surface create light waves that form distinct images, as the waves intersect at different focal points. It should be mentioned that, strictly speaking, the ReSTOR lens is a bifocal IOL, providing simultaneously very good distance and near vision, while at the same time permitting acceptable intermediate vision, yet its hybrid nature makes it a pseudo-accommodative IOL.

The design used in a European multicenter trial of ReSTOR was a three-piece model with a 6-mm optic and two PMMA haptics with a



Model Number:	**SA60D3**
Optic Diameter:	6.0 mm
Optic Type:	Apodized diffractive optic with a central 3.6 mm diffractive pattern
Diffractive Power:	+4.0 diopters of add power at the lens plane for near vision, equal to approximately +3.2 diopters of additional power at the spectacle plane
Haptic Angulation:	0 degree (planar)
Haptic Configuration:	Modified L (STABLEFORCE™)
A-Constant:	118.2
Refractive Index:	1.55
Diopter Range:	+18.0 through +25.0 diopter (0.5 diopter increments)

Fig. 14.1. AcrySof ReSTOR lens design and specifications

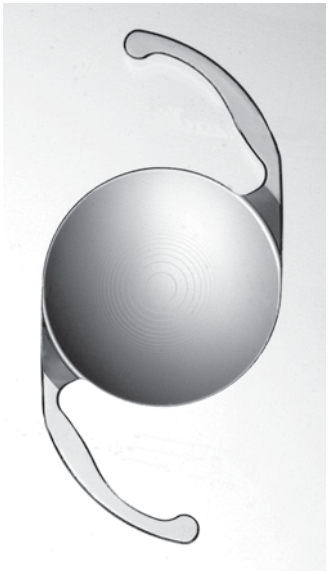


Fig. 14.2. AcrySof ReSTOR in vitro

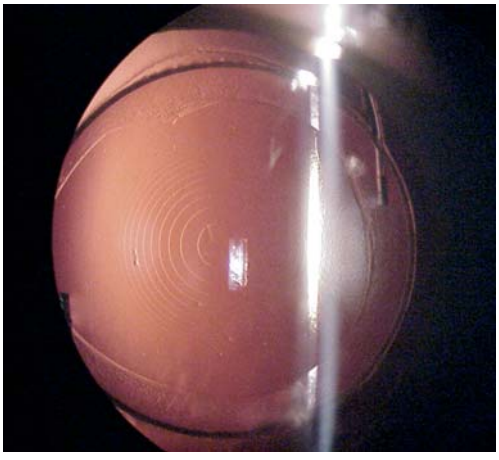


Fig. 14.3. Implanted MA60D3 (investigative lens)

total diameter of 13 mm, 360° sharp edge and 0° haptic angulation (Fig. 14.3, model: MA60D3).

The AcrySof ReSTOR lens is already marketed in Europe, and Food and Drug Administration approval in the USA for a cataract indication is avoilable.

14.2 Preoperative Considerations

Beside routine preoperative ophthalmologic examinations and detailed discussion of the pros and cons of a ReSTOR lens implantation, the following points are worth considering in the preoperative patient selection and preparation of the surgery:

- Currently the ReSTOR IOL is available from 16 to 25 D, thus an early preoperative IOL calculation is necessary to assure that an IOL with the desired power is available. However, the diopter range will be expanded in the future by Alcon.
- Patients with significant pre-existing ocular pathology (e.g. age-related macular degeneration, diabetic maculopathy, etc.) should not be considered for implantation. We also strongly recommend amblyopic eyes not to be considered.
- It is extremely important for patient satisfaction, in refractive lens exchange procedures, to achieve a distance emmetropia of 0 to +0.5 D, thus a meticulous biometry is necessary. If possible, two independent technicians should perform the biometry, as best possible IOL calculations are crucial. Furthermore, the A-constant of the ReSTOR lens (118.2 D for ultrasound measurements and 118.6 for IOL Master) is subject to further evaluation and should be customized by the surgeon to achieve best refractive results.
- Corneal astigmatism greater than 1.5 D is difficult to correct accurately by incisional procedures within the framework of a refractive lens exchange surgery; thus we recommend either not to consider such patients for ReSTOR IOL implantation or to plan for a secondary post-implantation refractive procedure, e.g. laser-assisted in-situ keratomileusis (LASIK), in cases of unsatisfactory visual results. Generally, limiting the amount of preoperative corneal astigmatism to less than 1 D is advised.

- Usually patients seeking refractive lens exchange are younger than cataract surgery patients, potentially having larger pupil sizes. Therefore, measurement of scotopic pupil size is recommended for exclusion of eyes with large pupil sizes, usually greater than 6 mm.
- Bilateral implantation has shown more favorable results than unilateral implantation of pseudo-accommodative IOLs. Therefore, we recommend ReSTOR IOL implantation in both eyes.
- Last but not least, we also caution prospective patients whose primary professional activities center around night driving, before implanting any multifocal IOLs, including the pseudo-accommodative ReSTOR IOL.

14.3 Surgery

The technique of the ReSTOR IOL implantation is similar to that of other foldable IOLs. Either a Monarch II injector or Alcon-approved forceps may be used for implantation. The surgery should be performed in the usual manner, with special attention to the following parameters:

- The incision site may be chosen with special attention to the preoperative axis of astigmatism. Limbal relaxing incisions may be performed for reduction of the amount of astigmatism, if necessary, or, as already mentioned, a secondary post-implantation refractive procedure (LASIK) may be performed.
- We recommend an incision size of 3.6 mm with the Monarch A cartridge for the three-piece ReSTOR IOL and 3.3 mm with the Monarch B cartridge and 3.0 mm with the Monarch C cartridge for the one-piece ReSTOR IOL [3].
- The capsulorrhexis size should be 5.0–5.5 mm, but not too large (<5.5 mm) to avoid a buttonhole effect and posterior capsular opacification.
- Good centration of the ReSTOR lens is crucial since the optical outcome of the surgery may be adversely affected by tilt and decentration.
- The ReSTOR IOL should not be implanted in cases of severe intraoperative complications, when perfect positioning of the IOL is not guaranteed, e.g. severe zonulysis or posterior capsular rupture with vitreous loss.
- If the postoperative refractive results are unsatisfactory for any reason, a keratosurgical refinement procedure, e.g. LASIK, may be considered in selected cases.

14.4 Results

All presented data are related to cataract patients; however, these results are of significant importance in refractive lens exchange, since no other specific data on this topic are currently available. We do, however, expect comparable results in refractive lens exchange.

Six-month results of the AcrySof ReSTOR apodized diffractive IOL (MA60D3, the three-piece IOL version) in a European multicenter clinical trial presented at the 2004 joint meeting of the American Academy of Ophthalmology and the European Society of Ophthalmology in New Orleans, LA, USA indicate excellent near visual acuity with a mean bilateral uncorrected near visual acuity of 0.09 (logMAR) in 118 subjects [4]. The mean bilateral uncorrected distance visual acuity is reported at 0.04 (logMAR), thus no compromise of the distance vision was found. The authors report spectacle independence for distance and near vision in 88.0% and 84.6%, respectively.

Results of the American multicenter AcrySof ReSTOR IOL study, as provided by Alcon, in a population of 566 individuals and a comparison group of 194 patient receiving the AcrySof monofocal IOL are as follows: 88% of patients with the ReSTOR lens achieved a distance visual acuity of 20/25 or

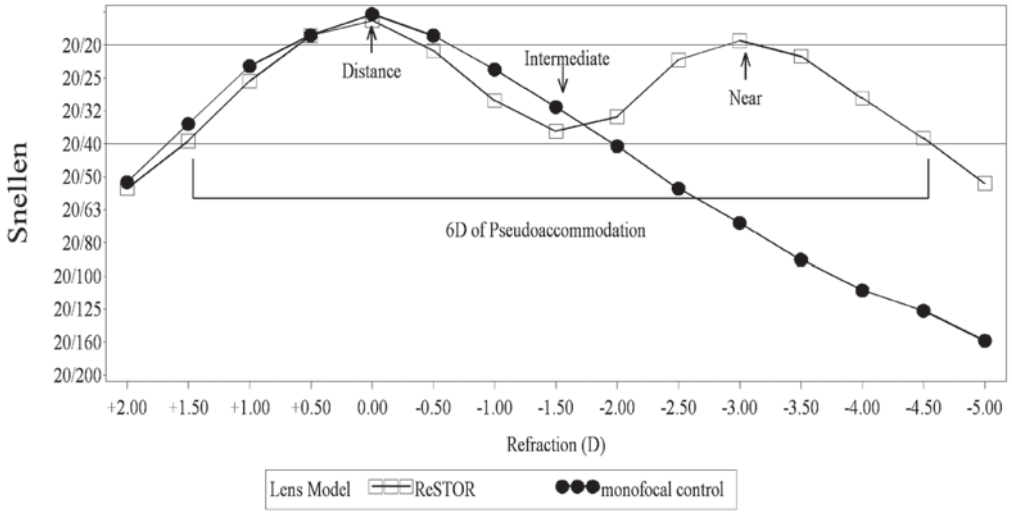


Fig. 14.4. MA60D3 vs. MA60BM. Mean defocus curves by lens model at 6 months postoperatively. Binocular distance-corrected visual acuity (MA60D3 – investigative lens)

better without correction versus 92% of the control monofocal group. For near vision, 74% of patients receiving ReSTOR IOL achieved a near visual acuity of 20/25 (J1) or better without correction following bilateral implantation, versus 14% in the monofocal control group. Eighty per cent of AcrySof ReSTOR patients report never using spectacles for near or distance vision versus 8% of patients who received the monofocal AcrySof lens.

Furthermore, our personal experience indicates the following points:

- Patient satisfaction increases markedly after the implantation of the second eye.
- Patients often need a few weeks to adapt to pseudo-accommodation for near vision.
- Disturbing photic phenomena are reported less frequently with the ReSTOR IOL than with other multifocal IOLs used by us.
- When postoperative glare was noted by a very sensitive patient, the intensity markedly decreased during the first 6 months. This experience should be explained to patients experiencing similar phenomena.
- In addition to perfect near and distance vision, functional intermediate vision is achieved for most patients. This is related to the diffractive IOL design, which emphasizes two foci, approximately 3.2 D apart at the spectacle plane. A US substudy demonstrated that ReSTOR IOL best-case patients (n=34) achieved a mean distance and near visual acuity of 20/20 or better, with a pseudo-accommodative amplitude of +1.50 to –4.50 D of defocus (Fig. 14.4). In this analysis, pseudo-accommodative amplitude was defined as the total range of defocus where the visual acuity was 20/40 or better.
- For those patients experiencing unexpected postoperative myopia or myopic astigmatism (distance refractive errors), distance-correcting spectacles provided emmetropia without affecting the pseudo-accommodative properties of the lens; thus bifocals were not necessary.

In summary, proper selection of patients as mentioned above enhances the success of this pseudo-accommodative lens. In our patients,

more than 80% enjoy independence from spectacles for any distance after bilateral implantation of the AcrySof ReSTOR lens.

14.5 Patient Satisfaction

From our experience with the AcrySof ReSTOR in cataract patients, satisfaction with the postoperative refractive status and quality of vision is very high. The majority of our patients achieve uncorrected distance and near visual acuity values that provide total independence from spectacles. In cases of postoperative distance ametropia, an excellent near visual acuity can be reached through pseudo-accommodation while wearing distance correction. Functional intermediate vision is satisfactory for most patients.

In contradiction to various publications reporting loss in quality of vision expressed as decreased contrast sensitivity or increased glare disability and/or halos with multifocal (diffractive and refractive) IOLs, our experience to date has been very encouraging. Undesired photic phenomena, contrast sensitivity loss, or night-driving difficulties potentially affecting quality of life were reported by only very few patients. The number of those patients appears to be comparable to patients receiving monofocal IOLs following cataract extraction. Furthermore, it seems that the percentage of such patients is significantly lower than in published data of other multifocal IOLs. It should be taken into account that most of our experience is related to cataract patients and there may be some special features in patient satisfaction when using ReSTOR IOLs in refractive lens exchange. In conclusion, this pseudo-accommodative IOL is of great interest to patients seeking presbyopia correction – either following cataract extraction or as a refractive surgical procedure – and to ophthalmic surgeons responding to this increasing need.

14.6 Additional Studies

Currently an international multicenter study for cataract indications is being performed for evaluation of the AcrySof ReSTOR lens; the mid- and long-term results will deliver further insight into the properties of this new IOL technology. Furthermore, the long-term results of the European study will provide additional detailed information. In a phase I clinical trial, as reported by Phillippe Dublineau, MD and Michael Knorz, MD at the 2002 American Society of Cataract and Refractive Surgery meeting, with two groups of 12 patients receiving either ReSTOR MA60D3 or the Array SA40 N lens bilaterally, the distance vision was similar with both IOLs. However, MA60D3 (ReSTOR) demonstrated better near vision when compared to SA40 N without any addition to best distance correction. However, a comparative study of these IOLs with a greater patient population is certainly necessary to deliver definite comparative results.

A comparative aberrometry study between a monofocal (AMO AR40e), an aspherical (AMO Tecnis) and a pseudo-accommodative (Alcon AcrySof ReSTOR MA60D3) lens, performed by Thomas Kasper, MD et al. at the Department of Ophthalmology, Johann Wolfgang Goethe University, Frankfurt am Main, Germany, revealed the following, among other results (personal communications): A diffractive IOL design (ReSTOR) did not influence higher-order aberrations significantly more than a monofocal spherical IOL. However, further investigation appears necessary in this field, too.

14.7 Complications

Surgical complications are expected to be similar for pseudo-accommodative IOLs as for monofocal IOLs, since the lenses are very similar and no modification to the surgical technique is necessary. If the postoperative refractive results are unsatisfactory for any reasons, a keratosurgical refinement procedure, e.g. LASIK or limbal relaxing incisions, may be considered in selected cases.

References

1. Hoffmann RS, Fine IH, Packer M (2003) Refractive lens exchange with a multifocal intraocular lens. Curr Opin Ophthalmol 14:24–30
2. Leyland M, Zinicola E (2003) Multifocal versus monofocal intraocular lenses in cataract surgery. A systemic review. Ophthalmology 110:1789–1798
3. Kohnen T, Kasper T (2005) Incision sizes before and after implantation of 6-mm optic foldable intraocular lenses using Monarch and Unfolder injector systems. Ophthalmology 112:58–66
4. Kohnen T (2004) Results of AcrySof ReSTOR apodized diffractive IOL in a European clinical trial. Joint meeting of the American Academy of Ophthalmology and European Society of Ophthalmology, Oct 2004, New Orleans, LA

15 The Tecnis Multifocal IOL

Mark Packer, I. Howard Fine, Richard S. Hoffman

The youthful, unaberrated human eye has become the standard by which we evaluate the results of cataract and refractive surgery today. Contrast sensitivity testing has confirmed the decline in visual performance with age, and wavefront science has helped explain that this decline occurs because of increasing spherical aberration of the human lens. Since we have learned that the optical wavefront of the cornea remains stable throughout life, the lens has started to come into its own as the primary locus for refractive surgery. At the same time, laboratory studies of accommodation have now confirmed the essentials of Helmholtz's theory and have clarified the pathophysiology of presbyopia. What remains is for optical scientists and materials engineers to design an intraocular lens (IOL) that provides unaberrated optical imagery at all focal distances. This lens must, therefore, compensate for any aberrations inherent in the cornea and either change shape and location or employ multifocal optics.

Accommodative IOLs have now made their debut around the world (CrystaLens, Eyeonics and 1CU, HumanOptics). Clinical results indicate that restoration of accommodation can be achieved with axial movement of the lens optic [1]. However, concerns remain about the impact of long-term capsular fibrosis on the function of these designs. Flexible polymers designed for injection into a nearly intact capsular bag continue to show promise in animal studies [2]. These lens prototypes require extraction of the crystalline lens through a tiny capsulorrhexis and raise concerns about leakage of polymer in the case of YAG capsulotomy following the development of posterior or anterior capsular opacification. A unique approach now in laboratory development involves the utilization of a thermoplastic acrylic gel, which may be shaped into a thin rod and inserted into the capsular bag (SmartLens, Medennium). In the aqueous environment at body temperature it unfolds into a full-size flexible lens that adheres to the capsule and may restore accommodation. Another unique design involves the light-adjustable lens, a macromer matrix that polymerizes under ultraviolet radiation (LAL, Calhoun Vision). An injectable form of this material might enable surgeons to refill the capsular bag with a flexible substance and subsequently adjust the optical configuration to eliminate aberrations.

While these accommodating designs show promise for both restoration of accommodation and elimination of aberrations, multifocal technology also offers an array of potential solutions. Multifocal intraocular lenses allow multiple focal distances independent of ciliary body function and capsular mechanics. Once securely placed in the capsular bag, the function of these lenses will not change or deteriorate. Additionally, multifocal lenses can be designed to take advantage of many innovations in IOL technology, which have

already improved outcomes, including better centration, prevention of posterior capsular opacification and correction of higher-order aberrations.

The fundamental challenge of multifocality remains preservation of optical quality, as measured by modulation transfer function on the bench or contrast sensitivity function in the eye, with simultaneous presentation of objects at two or more focal lengths. Another significant challenge for multifocal technology continues to be the reduction or elimination of unwanted photic phenomena, such as haloes. One question that the designers of multifocal optics must consider is whether two foci, distance and near, adequately address visual needs, or if an intermediate focal length is required. Adding an intermediate distance also adds greater complexity to the manufacture process and may degrade the optical quality of the lens.

We have been able to achieve success with the AMO Array multifocal IOL for both cataract and refractive lens surgery, largely because of careful patient selection [3]. We inform all patients preoperatively about the likelihood of their seeing haloes around lights at night, at least temporarily. If patients demonstrate sincere motivation for spectacle independence and minimal concern about optical side-effects, we consider them good candidates for the Array. These patients can achieve their goals with the Array, and represent some of the happiest people in our practice.

In the near future, the Array will likely become available on an acrylic platform, similar to the AMO AR40e IOL. This new multifocal IOL will incorporate the sharp posterior edge design ("Opti Edge") likely to inhibit migration of lens epithelial cells. Prevention of posterior capsular opacification represents a special benefit to Array patients, as they suffer early deterioration in near vision with minimal peripheral changes in the capsule. AMO also plans to manufacture the silicone Array with a sharp posterior edge (similar to their Clariflex design).

The Array employs a zonal progressive refractive design. Alteration of the surface curvature of the lens increases the effective lens power and recapitulates the entire refractive sequence from distance through intermediate to near in each zone. A different concept of multifocality employs a diffractive design. Diffraction creates multifocality through constructive and destructive interference of incoming rays of light. An earlier multifocal IOL produced by 3M employed a diffractive design. It encountered difficulty in acceptance, not because of its optical design but rather due to poor production quality and the relatively large incision size required for its implantation.

Alcon is currently completing clinical trials of a new diffractive multifocal IOL based on the 6.0-mm foldable three-piece AcrySof acrylic IOL. The diffractive region of this lens is confined to the center, so that the periphery of the lens is identical to a monofocal acrylic IOL. The inspiration behind this approach comes from the realization that during near work the synkinetic reflex of accommodation, convergence and miosis implies a relatively smaller pupil size. Putting multifocal optics beyond the 3-mm zone creates no advantage for the patient and diminishes optical quality. In fact, bench studies performed by Alcon show an advantage in modulation transfer function for this central diffractive design, especially with a small pupil at near and a large pupil at distance (Figs. 15.1 and 15.2).

Recent advances in aspheric monofocal lens design may lend themselves to improvements in multifocal IOLs as well. We now realize that the spherical aberration of a manufactured spherical intraocular lens tends to worsen total optical aberrations. Aberrations cause incoming light that would otherwise be focused to a point to be blurred, which in turn causes a reduction in visual quality. This reduction in quality is more severe under low luminance conditions because spherical aberration increases when the pupil size increases.

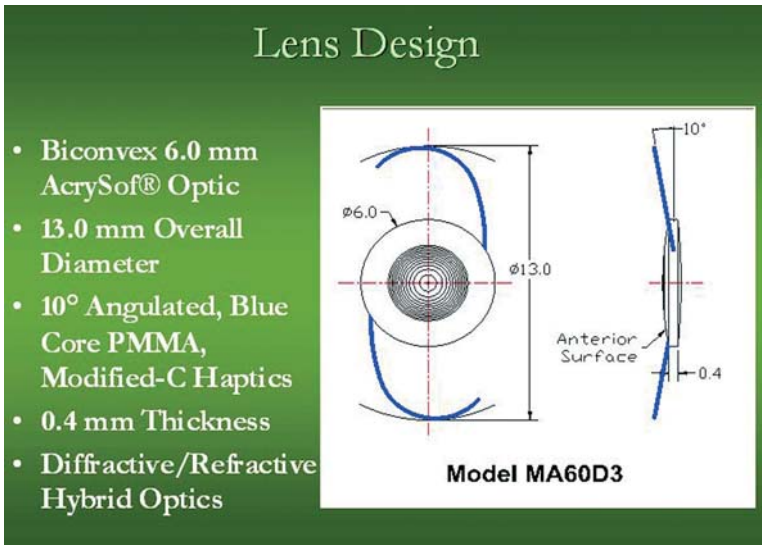


Fig. 15.1. The Alcon AcrySof multifocal IOL

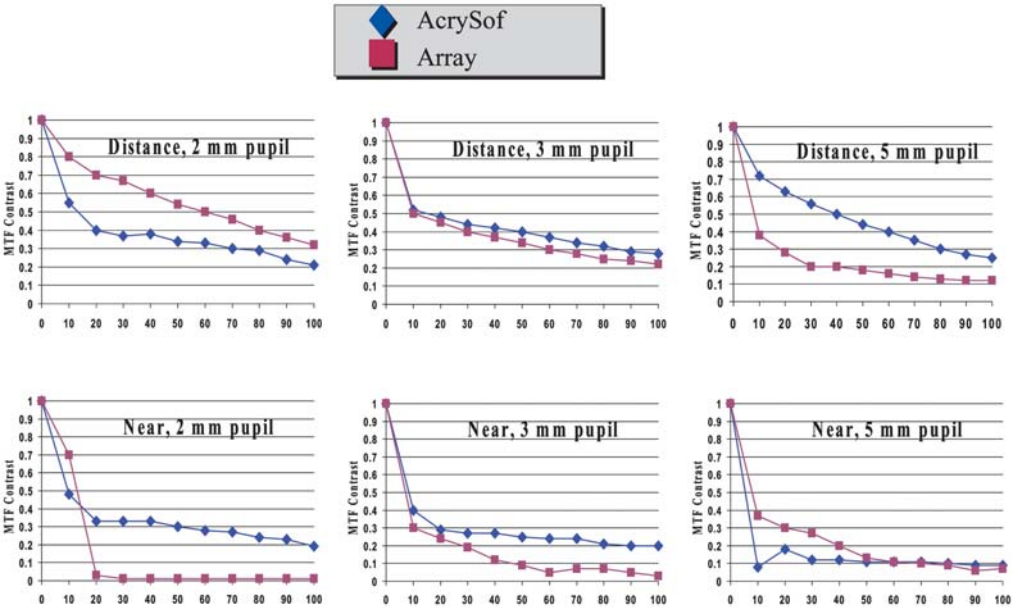


Fig. 15.2. Diffractive vs. zonal refractive optics (AcrySof vs. Array)

The Tecnis Z9000 intraocular lens (AMO, Santa Ana, CA) has been designed with a modified prolate anterior surface to reduce or eliminate the spherical aberration of the eye. The Tecnis Z9000 shares basic design features with the CeeOn Edge 911 (AMO), including a 6-mm biconvex square-edge silicone optic and angulated cap C polyvinylidene fluoride (PVDF) haptics. The essential new feature of the Tecnis IOL, the modified prolate anterior surface, compensates for average corneal spherical aberration and so reduces total aberrations in the eye.

Fig. 15.3. The Tecnis ZM001, CeeOn 911A, Tecnis Z9000, and CeeOn 811E IOLs

Clinical studies show significant improvement in contrast sensitivity and functional vision with the new prolate IOL [4]. AMO plans to unite this foldable prolate design with their diffractive multifocal IOL currently available in Europe (811E) (Fig. 15.3). Improved visual performance and increased independence for patients constitute the fundamental concept behind this marriage of technologies. This new prolate, diffractive, foldable, multifocal IOL has received the CE mark in Europe. Introduction of the IOL in the USA will be substantially later. Food and Drug Administration-monitored clinical trials were expected to begin in the fourth quarter of 2004. Optical bench studies reveal superior modulation transfer function at both distance and near when compared to standard monofocal IOLs with a 5-mm pupil, and equivalence to standard monofocal IOLs with a 4-mm pupil (Fig. 15.4). When compared to the Array multifocal IOL, the Tecnis IOL has better function for a small, 2-mm pupil at near and for a larger, 5-mm pupil at both distance and near (Fig. 15.5). From these studies, it appears that combining diffractive, multifocal optics with an aspheric, prolate design will enhance functional vision for pseudophakic patients.

Multifocal technology has already improved the quality of life for many pseudophakic patients by reducing or eliminating their need for spectacles. We (i.e., those of us over 40) all know that presbyopia can be a particularly maddening process. Giving surgeons the ability to offer correction of presbyopia by means of multifocal pseudo-accommodation will continue to enhance their practices and serve their patients well.

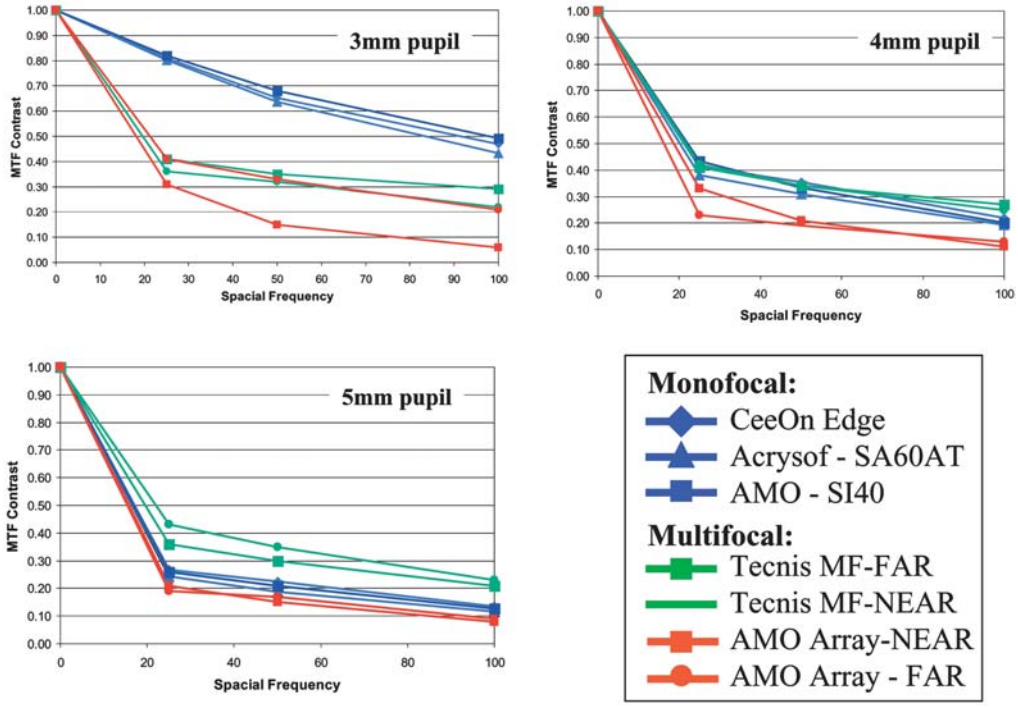


Fig. 15.4. Multifocal vs. monofocal IOLs

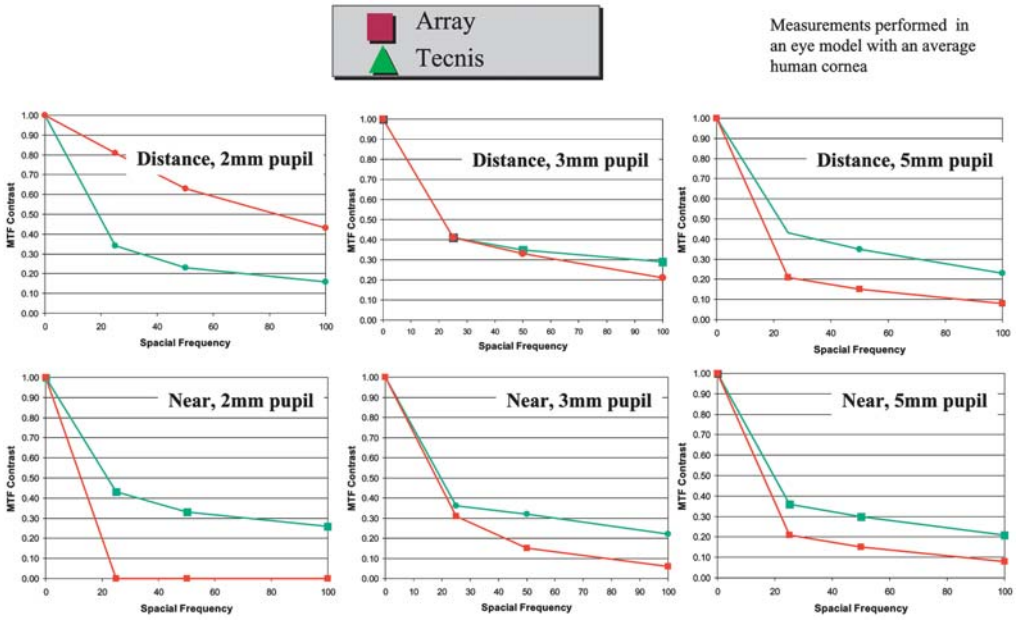


Fig. 15.5. Diffractive vs. zonal refractive optics (Array vs. Tecnis)

References

1. Doane J (2002) C&C CrystaLens AT-45 accommodating intraocular lens. Presented at the XX Congress of the ESCRS, Nice, Sept 2002
2. Nishi O, Nishi K (1998) Accommodation amplitude after lens refilling with injectable silicone by sealing the capsule with a plug in primates. Arch Ophthalmol 116:1358-1361
3. Packer M, Fine IH, Hoffman RS (2002) Refractive lens exchange with the Array multifocal intraocular lens. J Cataract Refract Surg 28: 421–424
4. Packer M, Fine IH, Hoffman RS, Piers PA (2002) Initial clinical experience with an anterior surface modified prolate intraocular lens. J Refract Surg 18:692–696

16 Blue-Light-Filtering Intraocular Lenses

Robert J. Cionni

16.1 Introduction

The normal human crystalline lens filters not only ultraviolet light, but also most of the higher frequency blue wavelength light. However, most current intraocular lenses (IOLs) filter only ultraviolet light and allow all blue wavelength light to pass through to the retina. Over the past few decades, considerable literature has surfaced suggesting that blue light may be one factor in the progression of age-related macular degeneration (AMD) [1]. In recent years, blue-light-filtering IOLs have been released by two IOL manufacturers. In this chapter we will review the motivation for developing blue-filtering IOLs and the relevant clinical studies that establish the safety and efficacy of these IOLs.

16.2 Why Filter Blue Light?

Even at the early age of 4 years, the human crystalline lens prevents ultraviolet and much of the high-energy blue light from reaching the retina (Fig. 16.1). As we age, the normal human crystalline lens yellows further, filtering out even more of the blue wavelength light [2]. In 1978, Mainster [3] demonstrated that pseudophakic eyes were more susceptible to retinal damage from near ultraviolet light sources. Van der Schaft et al. conducted postmortem examinations of 82 randomly selected pseudophakic eyes and found a statistically significant higher prevalence of hard drusen and disciform scars than in age-matched non-pseudophakic controls [4]. Pollack et al. [5] followed 47 patients with bilateral early AMD after they underwent extracapsular cataract extraction and implantation of a UV-blocking IOL in one eye, with the fellow phakic eye as a control for AMD progression. Neovascular AMD developed in nine of the operative versus two of the control eyes, which the authors suggested was linked to the loss of the "yellow barrier" provided by the natural crystalline lens.

Data from the Age-Related Eye Disease Study (AREDS), however, suggest a heightened risk of central geographic retinal atrophy rather than neovascular changes after cataract surgery [6, 7]. There were 342 patients in the AREDS study who were observed to have one or more large drusen or geographic atrophy and who subsequently had cataract surgery. Cox regression analysis was used to compare the time to progression of AMD in this group versus phakic control cases matched for age, sex, years of follow-up, and course of AMD treatment. This analysis showed no increased risk of wet AMD after cataract surgery. However, a slightly increased risk of central geographic atrophy was demonstrated.

The retina appears to be susceptible to chronic repetitive exposure to low-radiance light as well as brief exposure to higher-radiance light [8–11]. Chronic, low-level exposure

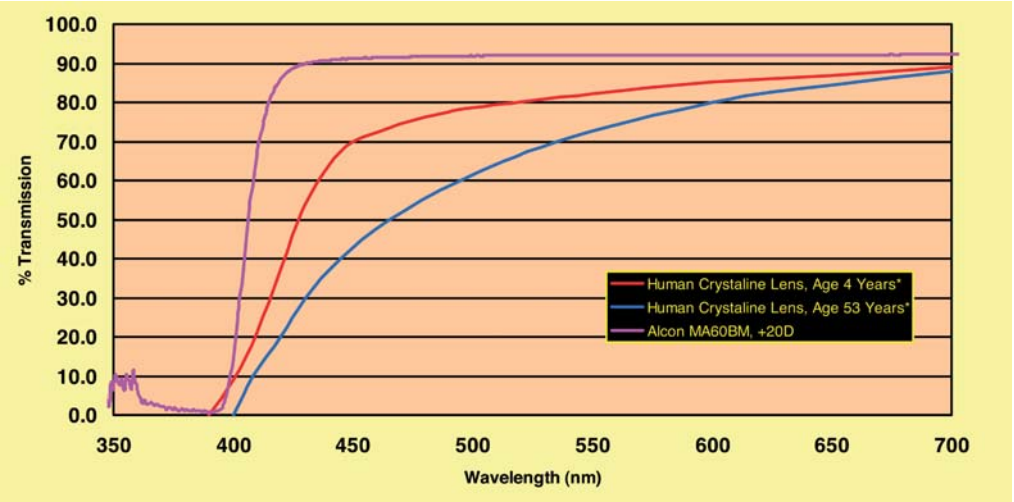


Fig. 16.1. Light transmission spectrum of a 4-year-old and 53-year-old human crystalline lens compared to a 20-diopter colorless UV-blocking IOL [37, 42]

(class 1) injury occurs at the level of the photoreceptors and is caused by the absorption of photons by certain visual pigments with subsequent destabilization of photoreceptor cell membranes. Laboratory work by Sparrow and coworkers has identified the lipofuscin component A2E as a mediator of blue-light damage to the retinal pigment epithelium (RPE) [12–15]; although the retina has inherent protective mechanisms from class 1 photochemical damage, the aging retina is less able to provide sufficient protection [16, 17].

Several epidemiological studies have concluded that cataract surgery or increased exposure of blue-wavelength light may be associated with progression of macular degeneration [18, 19]. Still, other epidemiologic studies have failed to come to this conclusion [20–22]. Similarly, some recent prospective trials have found no progression of diabetic retinopathy after cataract surgery [23, 24], while other studies have reported progression [25]. These conflicting epidemiological results are not unexpected, since both diabetic and age-related macular diseases are complex, multifactorial biologic processes. Certainly, relying on a patient's memory to recall the amount of time spent outdoors or in specific lighting environments over a large portion of their lifetime is likely to introduce error in the data. This is why experimental work in vitro and in animals has been important in understanding the potential hazards of blue light on the retina.

The phenomenon of phototoxicity to the retina has been investigated since the 1960s. But more recently, the effects of blue light on retinal tissues have been studied in more detail [8, 26–30]. Numerous laboratory studies have demonstrated a susceptibility of the RPE to damage when exposed to blue light [12, 31]. One of the explanations as to how blue light can cause RPE damage involves the accumulation of lipofuscin in these cells as we age. A component of lipofuscin is a compound known as A2E, which has an excitation maximum in the blue wavelength region (441 nm). When excited by blue light, A2E generates oxygen-free radicals, which can lead to RPE cell damage and death. At Columbia University, Dr Sparrow exposed cultured human retinal pigment epithelial cells laden with A2E to blue light and observed extensive cell death. She then placed different UV-

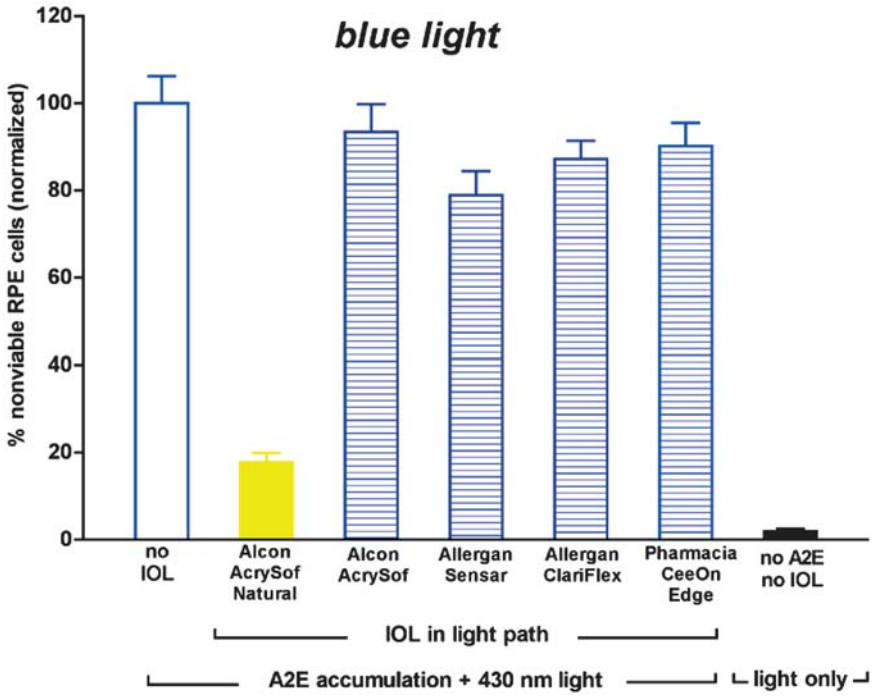


Fig. 16.2. Cultured human RPE cells laden with A2E exposed to blue wavelength light. Cell death is significant when UV-blocking colorless IOLs are placed in the path of the light, yet is markedly reduced when the AcrySof Natural IOL is placed in the light path [32]

blocking IOLs or a blue-light-filtering IOL in the path of the blue light to see if the IOLs provided any protective effect. The results of this study demonstrated that cell death was still extensive with all UV-blocking colorless IOLs, but very significantly diminished with the blue-light-filtering IOL [32] (Fig. 16.2). Although these experiments were laboratory in nature and more concerned with acute light damage rather than chronic long-term exposure, they clearly demonstrated that by filtering blue light with an IOL, A2E-laden RPE cells could survive the phototoxic insult of the blue light.

16.3 IOL Development

As a result of the mounting information on the effects of UV exposure on the retina [1, 33], in the late 1970s and early 1980s IOL manufacturers began to incorporate UV-blocking chromophores in their lenses to protect the retina from potential damage. Still, when the crystalline lens is removed during cataract or refractive lens exchange surgery and replaced with a colorless UV-blocking IOL, the retina is suddenly bathed in much higher levels of blue light than it has ever known and remains exposed to this increased level of potentially damaging light ever after. Yet, until recent years, the IOL-manufacturing community had not provided the option of IOLs that would limit the exposure of the retina to blue light. Since the early 1970s, IOL manufacturers have researched

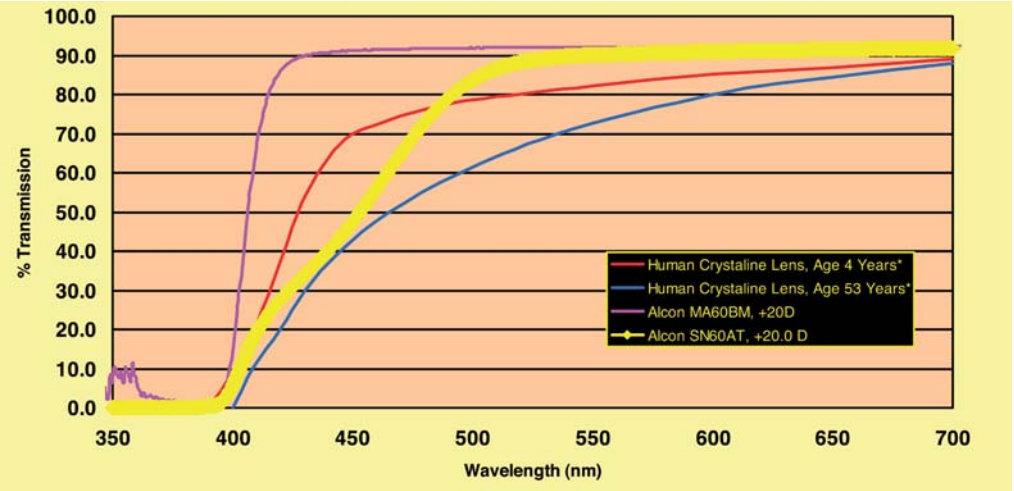


Fig. 16.3. Light transmission spectrum of the AcrySof Natural IOL compared to a 4-year-old and 53-year-old human crystalline lens and a 20-diopter colorless UV-blocking IOL [37, 42]

methods for filtering blue-wavelength light waves in efforts to incorporate blue-light protection into IOLs, although these efforts have not all been documented in the peer-reviewed literature. Recently, two IOL manufacturers have developed stable methods to incorporate blue-light-filtering capabilities into IOLs without leaching or progressive discoloration of the chromophore.

16.4 Hoya IOL

Hoya released PMMA blue-light-filtering IOLs in Japan in 1991 (three-piece model HOYA UVCY) and 1994 (single-piece model HOYA UVCY-1P). Clinical studies of these yellow-tinted IOLs (model UVCY, manufactured by Hoya Corp., Tokyo, and the Meniflex NV type from Menicon Co., Ltd., Nagoya) have been carried out in Japan [16, 17, 34]. One study found that pseudophakic color vision with a yellow-tinted IOL approximated the vision of 20-year-old control subjects in the blue-light range [35]. Another study found some improvement of photopic and mesopic contrast sensitivity, as well as a decrease in the effects of central glare on contrast sensitivity, in pseudophakic eyes with a tinted IOL versus a standard lens with UV-blocker only [36]. Hoya also introduced a foldable acrylic blue-light-filtering IOL with PMMA haptics to some European countries in late 2003.

16.5 AcrySof Natural IOL

In 2002, the AcrySof Natural, a UV- and blue-light-filtering IOL, was approved for use in Europe, followed by approval in the USA in 2003. The IOL is based on Alcon's hydrophobic acrylic IOL, the AcrySof IOL. In addition to containing a UV-blocking agent, the AcrySof Natural IOL incorporates a yellow chromophore cross-linked to the acrylic molecules. Extensive aging studies have been performed on this IOL and have shown that the chromophore will not leach out or discolor [37]. This yellow chromophore allows the IOL not only to block UV light, but selectively to filter varying levels of light in the blue wavelength region as well. Light transmission assessment demonstrates that this IOL approximates the transmission spectrum of the normal human crystalline lens in the blue light spectrum (Fig. 16.3). Therefore, in addi-

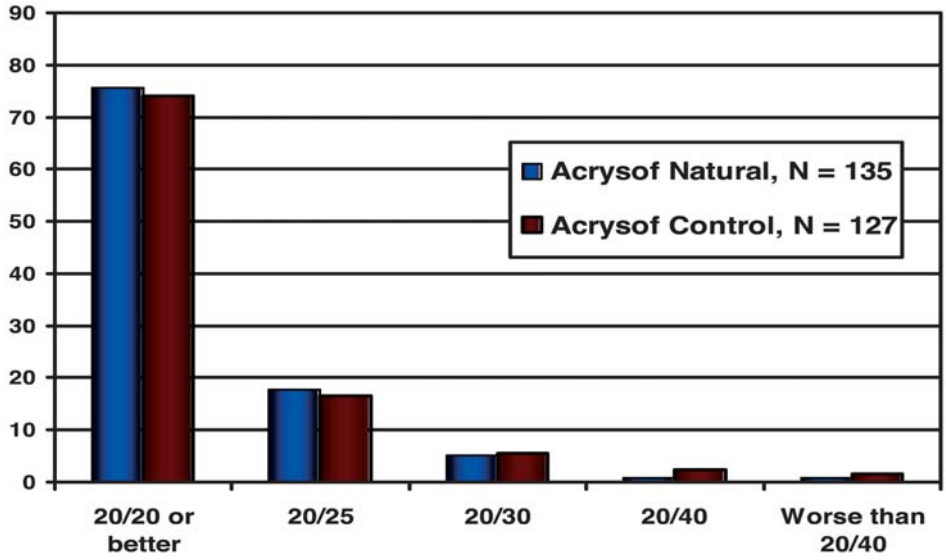


Fig. 16.4. Data from Alcon's FDA study showing no significant difference in best corrected visual acuity between the AcrySof colorless IOL and the AcrySof Natural IOL

tion to benefiting from less exposure of the retina to blue light, color perception should seem more natural to these patients as opposed to the increased blueness, clinically known as cyanopsia, reported by patients who have received colorless UV-blocking IOLs [38].

16.6 FDA Clinical Study

In order to gain approval of the Food and Drug Administration (FDA), a multi-centered, randomized prospective study was conducted in the USA. It involved 300 patients randomized to bilateral implantation of either the AcrySof Natural IOL or the clear AcrySof Single-Piece IOL. One hundred and fifty patients received the AcrySof Natural IOL and 147 patients received the AcrySof Single-Piece IOL as a control. Patients with bilateral age-related cataracts who were willing and able to wait at least 30 days between cataract procedures and had verified normal preoperative color vision were eligible for the study. In all bilateral lens implantation cases, the same model lens was used in each eye. Postoperative parameters measured included visual acuity, photopic and mesopic contrast sensitivity, and color perception using the Farnsworth D-15 test. Results showed that there was no difference between the AcrySof Natural IOL and the clear AcrySof IOL in any of these parameters [39] (Figs. 16.4, 16.5, 16.6 and 16.7). More substantial color perception testing using the Farnsworth–Munsell 100 Hue Test has also demonstrated no difference in color perception between the AcrySof Natural IOL and the clear AcrySof IOL [39].

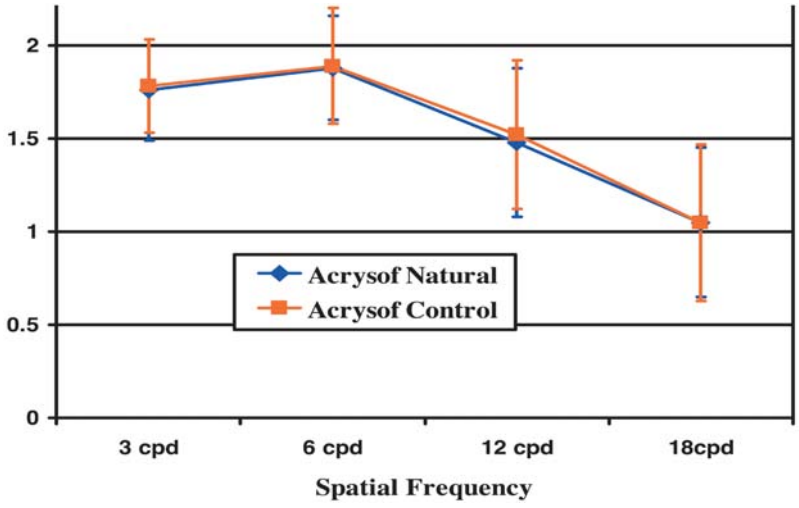


Fig. 16.5. Data from Alcon's FDA study showing no significant difference in photopic contrast sensitivity between the AcrySof colorless IOL and the AcrySof Natural IOL

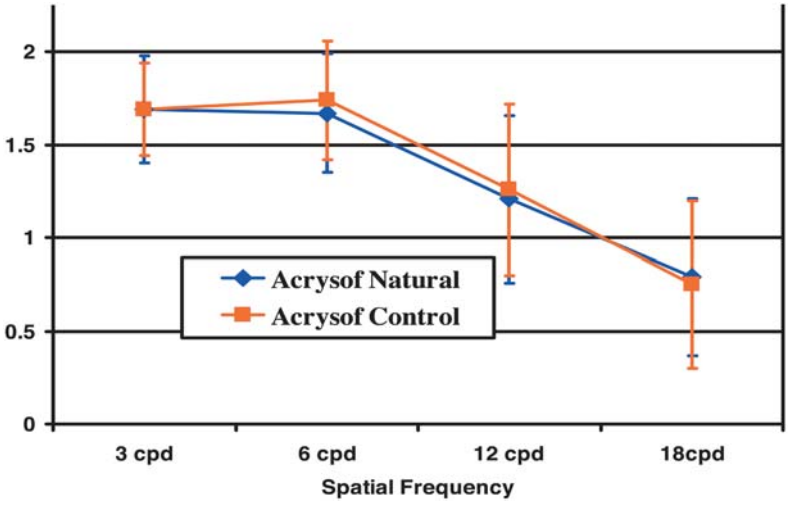


Fig. 16.6. Data from Alcon's FDA study showing no significant difference in mesopic contrast sensitivity between the AcrySof colorless IOL and the AcrySof Natural IOL

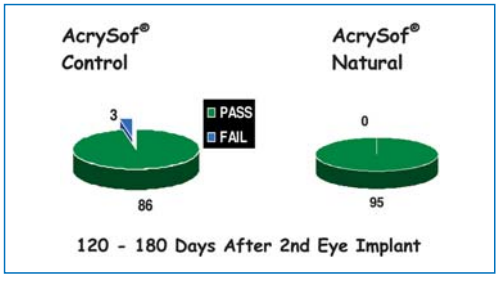


Fig. 16.7. Data from Alcon's FDA study showing no significant difference in color perception using the Farnsworth D-15 test between the AcrySof colorless IOL and the AcrySof Natural IOL

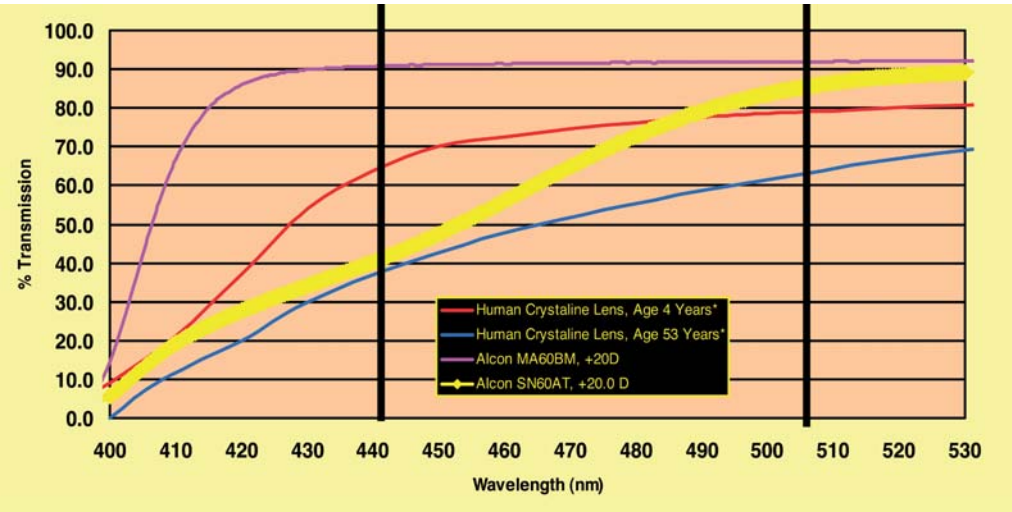


Fig. 16.8. Blue-light transmission spectrum showing low transmission of 441 nm light and high transmission of 507 nm light with the AcrySof Natural IOL

16.7 Blue-Light-Filtering IOLs and Low Light Conditions

Both mesopic vision and scotopic vision refer to vision with low-light conditions. Wyszecki and Stiles point out that mesopic vision begins at approximately 0.001 cd/m^2 and extends up to 5 cd/m^2 for a 3° diameter centrally fixated target; however, the upper range could extend up to 15 cd/m^2 for a 25° diameter target [40]. Nevertheless, 3 cd/m^2 is the most often cited upper limit for mesopic vision. One can liken this to the low light conditions on a cloudless night with a full moon. The contrast sensitivity tests performed under mesopic conditions in the FDA trials demonstrated that the AcrySof Natural IOL does not negatively affect mesopic vision. Scotopic refers to light levels below the mesopic range, which can be likened to a moonless, starry night. Since blue wavelength light is imperative for scotopic vision, some are worried that attenuating blue light will negatively affect scotopic vision. Certainly, if all blue light were blocked, one might expect some decrease in scotopic vision. However, the AcrySof Natural IOL does not block all blue light. Indeed, the most important wavelength for scotopic vision is at and around 507 nm [41]. The AcrySof Natural allows transmission of approximately 85% of light at 507 nm. In comparison, a UV-blocking colorless IOL transmits only 5% more. The normal human crystalline lens at any age transmits significantly less light at and near 507 nm than does the AcrySof Natural IOL and therefore, patients implanted with the AcrySof Natural IOL should have enhanced scotopic vision. It would be counterintuitive to believe that scotopic vision would be diminished instead of enhanced (Fig. 16.8).

16.8 Clinical Experience

Having implanted more than 1,000 AcrySof Natural IOLs over the past year, I have had the opportunity to gain insight into the quality of vision provided by this unique IOL. The IOL behaves identically to the clear AcrySof IOL in all aspects. It also has the advantage of being easier to visualize during folding, loading and implantation due to its yellow coloration. The visual results in my patients have been

excellent without any complaints of color perception or night vision problems. I have implanted this blue-light-filtering IOL in the fellow eye of patients previously implanted with colorless UV-filtering IOLs. When asked to compare the color of a white tissue paper, 70% do not see a difference between the two eyes. Of the 30% that could tell a difference, none perceived the difference before I checked and none felt the difference was bothersome. With more than 1,000,000 AcrySof Natural IOLs implanted worldwide by the time of this writing, there are no confirmed reports of color perception or night vision problems.

16.9 Summary

Given the growing body of evidence implicating blue light as a potential factor in the worsening of AMD and the positive collective clinical experience with this new IOL, the AcrySof Natural has become the lens of choice in cataract surgery patients for many ophthalmologists worldwide. When performing refractive lens exchange, especially in the younger patient, one should ponder the potential consequences of exposing the retina to higher levels of blue light for the rest of that patient's life. I believe that blue-light-filtering IOLs will become the lens of choice for these patients as well.

References

1. Ham WT, Mueller A, Sliney DH (1976) Retinal sensitivity to short wavelength light. Nature 260:153–155
2. Lerman S (1980) Biologic and chemical effects of ultraviolet radiation. In: Radiant energy and the eye. Macmillan, New York, pp 132–133
3. Mainster MA (1978) Spectral transmittance of intraocular lenses and retinal damage from intense light sources. Am J Ophthalmol 85: 167–170
4. Van der Schaft TL, Mooy CM, de Bruijn WC, Mulder PG, Pameyer JH, de Jong PT (1994) Increased prevalence of disciform macular degeneration after cataract extraction with implantation of an intraocular lens. Br J Ophthalmol 78:441–445
5. Pollack A et al (1996) Age-related macular degeneration after extracapsular cataract extraction with intraocular lens implantation. Ophthalmology 103:1546–1554
6. Ferris FL (2002) The new AREDS findings. Paper presented at annual meeting of the American Academy of Ophthalmology, 21 Oct 2002, Orlando, FL
7. Age-Related Eye Disease Study Group (2000) Risk factors associated with age-related macular degeneration. A case-control study in the Age-Related Eye Disease Study: Age-Related Eye Disease Study report number 3. Ophthalmology 107:2224–2232
8. Marshall J (1991) The effects of ultraviolet radiation and blue light on the eye. In: Cronly-Dillon J (ed) Susceptible visual apparatus. Macmillan Reference Ltd, London (Vision and visual dysfunction, vol 16)
9. Marshall J, Mellerio J, Palmer DA (1971) Damage to pigeon retinae by commercial light sources operating at moderate levels. Vision Res 11:1198–1199
10. Sperling HG, Johnson C, Harwerth RS (1980) Differential spectral photic damage to primate cones. Vision Res 20:1117–1125
11. Sykes SM, Robison WG Jr, Waxler M, Kuwabara T (1981) Damage to the monkey retina by broad-spectrum fluorescent light. Invest Ophthalmol Vis Sci 20:425–434
12. Sparrow JR, Cai B (2001) Blue light-induced apoptosis of A2E-containing RPE: involvement of caspase-3 and protection by Bcl-2. Invest Ophthalmol Vis Sci 42:1356–1362
13. Ben-Shabat S, Parish CA, Vollmer HR, Itagaki Y, Fishkin N, Nakanishi K, Sparrow JR (2002) Biosynthetic studies of A2E, a major fluorophore of retinal pigment epithelial lipofuscin. J Biol Chem 277:7183–7190
14. Liu J, Itagaki Y, Ben-Shabat S, Nakanishi K, Sparrow JR (2000) The biosynthesis of A2E, a fluorophore of aging retina, involves the formation of the precursor, A2-PE, in the photoreceptor outer segment membrane. J Biol Chem 275:29354–29360

15. Marshall J, Mellerio J, Palmer DA (1972) Damage to pigeon retinae by moderate illumination from fluorescent lamps. Exp Eye Res 14: 164–169
16. Winkler BS, Boulton ME, Gottsch JD, Sternberg P (1999) Oxidative damage and age-related macular degeneration. Mol Vis 5:32
17. Roberts JE (2001) Ocular phototoxicity. J Photochem Photobiol 64:136–143
18. Taylor HR, West S, Munoz B et al (1992) The long-term effects of visible light on the eye. Arch Ophthalmol 110:99–104
19. Cruickshanks KJ, Klein R, Klein BE, Nondahl DM (2001) Sunlight and the 5-year incidence of early age-related maculopathy: the beaver dam eye study. Arch Ophthalmol 119: 246–250
20. Darzins P, Mitchell P, Heller RF (1997) Sun exposure and age-related macular degeneration. An Australian case-control study. Ophthalmology 104:770–776
21. Delcourt C, Carriere I, Ponton-Sanchez A et al (2001) Light exposure and the risk of age-related macular degeneration: the Pathologies Oculaires Liees a l'Age (POLA) study. Arch Ophthalmol 119:1463–1468
22. McCarty CA, Mukesh BN, Fu CL et al (2001) Risk factors for age-related maculopathy: the Visual Impairment Project. Arch Ophthalmol 119:1455–1462
23. Krepler K, Biowski R, Schrey S et al (2002) Cataract surgery in patients with diabetic retinopathy: visual outcome, progression of diabetic retinopathy, and incidence of diabetic macular oedema. Graefes Arch Clin Exp Ophthalmol 240:735–738
24. Squirrell D, Bhola R, Bush J et al (2002) A prospective, case controlled study of the natural history of diabetic retinopathy and maculopathy after uncomplicated phacoemulsification cataract surgery in patients with type 2 diabetes. Br J Ophthalmol 86:565–571
25. Chung J, Kim MY, Kim HS et al (2002) Effect of cataract surgery on the progression of diabetic retinopathy. J Cataract Refract Surg 28:626–630
26. Mainster MA (1987) Light and macular degeneration: a biophysical and clinical perspective. Eye 1:304–310
27. Nilsson SE, Textorius O, Andersson BE, Swenson B (1989) Clear PMMA versus yellow intraocular lens material. An electrophysiologic study on pigmented rabbits regarding "the blue light hazard". Prog Clin Biol Res 314:539–553
28. Li ZL, Tso MO, Jampol LM, Miller SA, Waxler M (1990) Retinal injury induced by near-ultraviolet radiation in aphakic and pseudophakic monkey eyes. A preliminary report. Retina 10:301–314
29. Rapp LM, Smith SC (1992) Morphologic comparisons between rhodopsin-mediated and short-wavelength classes of retinal light damage. Invest Ophthalmol Vis Sci 33:3367–3377
30. Pang J, Seko Y, Tokoro T, Ichinose S, Yamamoto H (1998) Observation of ultrastructural changes in cultured retinal pigment epithelium following exposure to blue light. Graefe's Arch Clin Exp Ophthalmol 236:696–701
31. Schutt F, Davies S, Kopitz J, Holz FG, Boulton ME (2000) Photodamage to human RPE cells by A2-E, a retinoid component of lipofuscin. Invest Ophthalmol Vis Sci 41:2303–2308
32. Sparrow J, Miller A, Zhou J (2004) Blue light-absorbing intraocular lens and retinal pigment epithelium protection in vitro. J Cataract Refract Surg 30:873–878
33. Noell WK, Walker VS, Kang BS, Berman S (1966) Retinal damage by light in rats. Invest Ophthalmol Vis Sci 5:450–473
34. Miyake K, Ichihashi S, Shibuya Y et al (1999) Blood-retinal barrier and autofluorescence of the posterior polar retina in long-standing pseudophakia. J Cataract Refract Surg 25:891–897
35. Ishida M, Yanashima K, Miwa W et al (1994) Influence of the yellow-tinted intraocular lens on spectral sensitivity (in Japanese). Nippon Ganka Gakkai Zasshi 98:192–196
36. Niwa K, Yoshino Y, Okuyama F, Tokoro T (1996) Effects of tinted intraocular lens on contrast sensitivity. Ophthalmic Physiol Optics 16:297–302
37. Data on file, Alcon Laboratories, Inc., Fort Worth, Texas, USA
38. Yuan Z, Reinach P, Yuan J (2004) Contrast sensitivity and color vision with a yellow intraocular lens. Am J Ophthalmol 138:138–140
39. Cionni R (2005) Blue-light filtering IOLs. Optical downside no. Presented at AAO 2005, New Orleans, USA

40. Wyszecki G, Stiles WS (1982) Color science concepts and methods, quantitative data and formulae, 2nd edn. Wiley, New York
41. Swanson WH, Cohen JM (2003) Color vision. Ophthalmol Clin North Am 16:179–203
42. Lerman S, Borkman R (1976) Spectroscopic evaluation of classification of the normal, aging and cataractous lens. Opthalmol Res 8:335–353 and data on file, Alcon Laboratories, Inc

17 The Light-Adjustable Lens

Richard S. Hoffman, I. Howard Fine, Mark Packer

CORE MESSAGES

- The light-adjustable lens is a foldable three-piece IOL with a cross-linked photosensitive silicone polymer matrix, a homogeneously embedded photosensitive macromer, and a photoinitiator.
- Irradiation of near-ultraviolet light to a portion of the lens optic results in polymerization of the photosensitive macromers within the irradiated region of the silicone matrix and eventual migration of non-polymerized macromers into that region. This results in a change in the radius of the curvature and a change in power.
- Irradiating the central portion of the lens adds power, irradiating the periphery reduces power, and irradiating along a meridian reduces cylindrical power.
- Animal studies have demonstrated precise accuracy of adjustment, and optical bench studies have demonstrated excellent optical quality following adjustment.
- Higher-order corrections are also theoretically possible, allowing for the elimination of both lower-order and higher-order optical aberrations.

Despite the introduction of more accurate intraocular lens (IOL) formulas and biometry instrumentation, cataract and refractive lens surgery have yet to achieve the ophthalmologist's ideal of perfect emmetropia in all cases [1–5]. This limitation stems from occasional inaccuracies in keratometry and axial length measurements, an inability to assess accurately the final position of the pseudophakic implant in a fibrosing capsular bag, and the difficulty of completely eliminating pre-existing astigmatism despite the use of limbal relaxing incisions and toric IOLs [6, 7]. A new lens technology offers the hope of taking ophthalmologists one step closer to achieving emmetropia in all cases and also perhaps to further improving the final result by addressing higher-order aberrations.

17.1 The Ideal Pseudophakic Lens

A pseudophakic lens that could be non-invasively adjusted or fine-tuned following implantation would allow for extreme accuracy in the final refractive outcome. Ideally, this lens would have the ability to be precisely adjusted using a non-toxic external light source and allow for several diopters of myopic, hyperopic, or astigmatic correction should a postoperative refractive surprise occur. Micron-precision adjustment would allow for the possibility of modifying not only the lower-order aberrations of sphere and cylinder but also higher-order optical aberrations such as coma and spherical aberration. The lens should be stable following adjustment and composed of a safe biocompatible material. In addition, a foldable lens that could be inserted through a 2.5–3.0-mm clear corneal incision would insure control of surgically induced astigmatism [8]. Finally, if possible, an injectable flexible polymer design that could be injected through a 1-mm incision would further reduce any surgically induced astigmatism or higher-order corneal aberrations and conceivably, depending on its final elasticity, could return accommodative ability to the lens/ciliary body apparatus.

17.2 Light-Adjustable Lens

This ideal lens technology is no longer science fiction and is currently being developed by Calhoun Vision (Pasadena, CA, USA). It is termed the light-adjustable lens (LAL; Fig. 17.1). The current design of the LAL is a foldable three-piece IOL with a cross-linked photosensitive silicone polymer matrix, a homogeneously embedded photosensitive macromer, and a photoinitiator. The application of near-ultraviolet (UV) light to a portion of the lens optic results in disassociation of the photoinitiator to form reactive radicals that initiate polymerization of the photosensitive macromers within the irradiated region

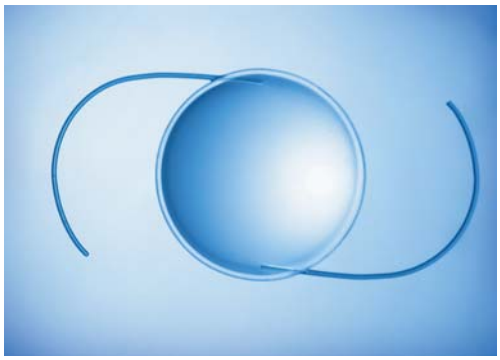


Fig. 17.1. Calhoun Vision's light-adjustable lens (LAL). (Courtesy of Calhoun Vision Inc.)

of the silicone matrix. Polymerization itself does not result in changes in lens power; however, it does create a concentration gradient within the lens, resulting in the migration of non-irradiated macromers into the region that is now devoid of macromer as a result of polymerization. Equilibration from migration of the macromers into the irradiated area causes swelling within that region of the lens with an associated change in the radius of curvature and power. Once the desired power change is achieved, irradiation of the entire lens to polymerize all remaining macromer "locks in" the adjustment so that no further power changes can occur [9].

17.3 Modulating Refractive Power

The treatment of residual postoperative sphere and cylinder aberrations is fairly straightforward. In a patient whose postoperative refraction reveals residual hyperopia, power will need to be added to the LAL in order to achieve emmetropia (Fig. 17.2). Once postoperative refractive stability has been reached (2–4 weeks), irradiation of the central portion of the lens with the light delivery device (Fig. 17.3) polymerizes macromer in this region. Over the next 12–15 h, macromers in the peripheral portion of the lens will diffuse centrally down the concentration gradi-

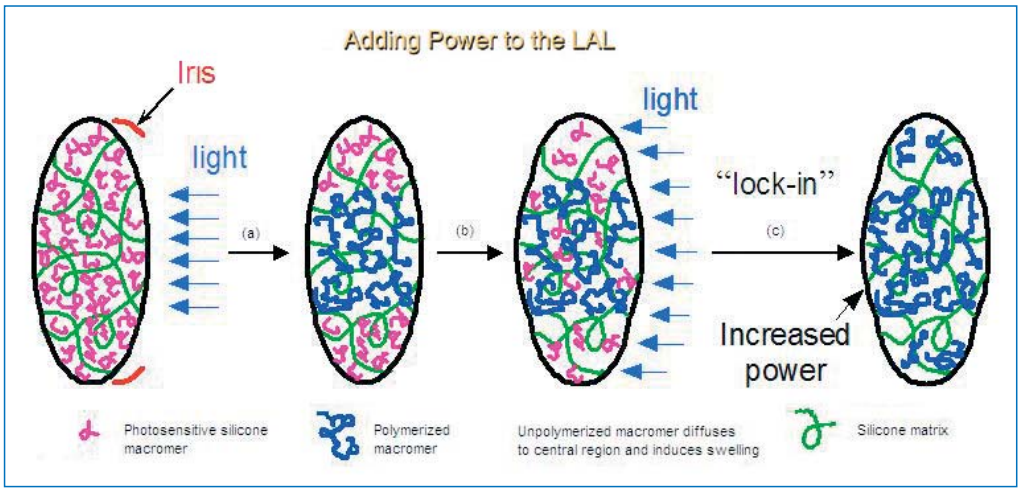
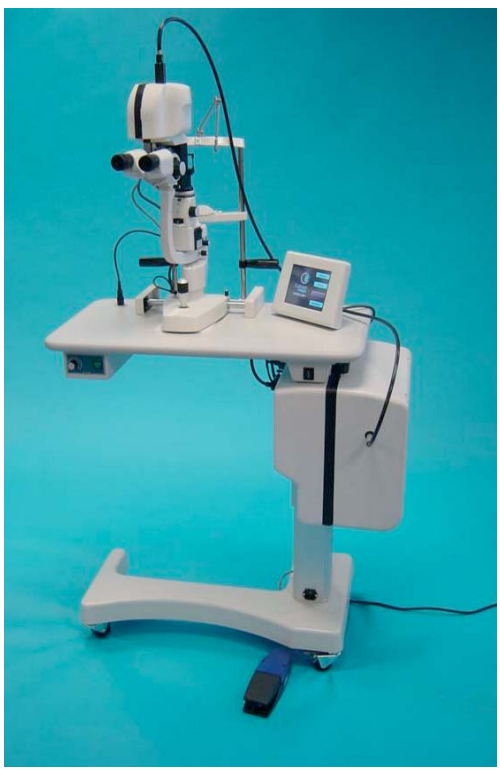


Fig. 17.2 a–c. Cross-sectional schematic illustration of the mechanism for treating hyperopic correction. **a** Selective irradiation of the central portion of the lens polymerizes macromer, creating a chemical gradient between irradiated and non-irradiated regions; **b** in order to re-establish equilibrium, macromer from the peripheral lens diffuses into the central irradiated region leading to swelling of the central zone; **c** irradiation of the entire lens polymerizes the remaining macromer and "locks in" the new lens shape. (Courtesy of Calhoun Vision Inc.)

Fig. 17.3. The light delivery device is mounted onto a conventional slit lamp. The refractive error and desired refractive outcome are entered on the color console and irradiation is activated using either a foot pedal or the joystick. (Courtesy of Calhoun Vision Inc.)



ent in order to achieve concentration equilibrium with the central lens, which has been depleted of macromers due to their poly- merization. This migration results in swelling of the central portion of the lens with an increase in the radius of curvature and an associated increase in the power of the LAL. With variation in the duration and power of light exposure, differing amounts of hyperopia can be corrected. One day or more after this adjustment, the entire lens is treated to lock in the fine adjustment. Since outdoor UV light can affect the LAL, patients wear sunglasses to eliminate UV exposure until the final lock-in is performed. Once final polymerization and lock-in are executed, no further UV protection is necessary.

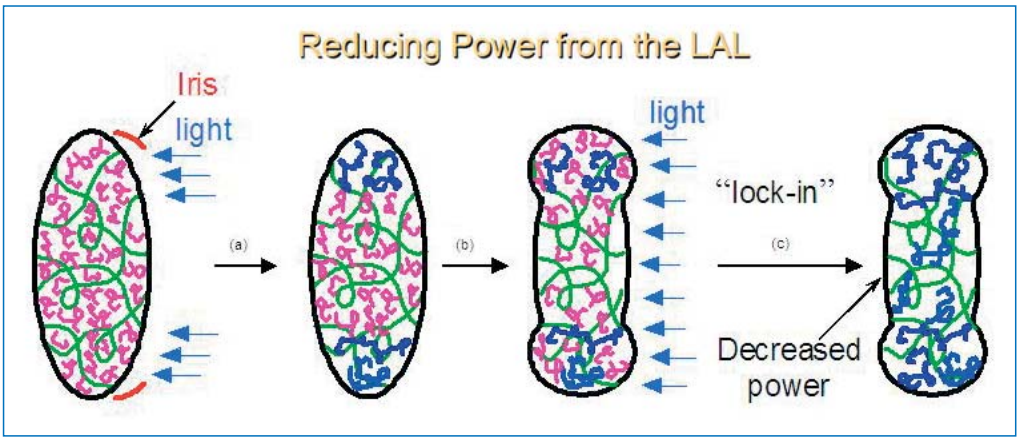


Fig. 17.4 a–c. Cross-sectional schematic illustration of the mechanism for treating myopic correction. **a** Selective irradiation of the peripheral portion of the lens polymerizes macromer, creating a chemical gradient between irradiated and non-irradiated regions; **b** macromer from the central zone diffuses peripherally leading to swelling of the peripheral lens; **c** irradiation of the entire lens polymerizes the remaining macromer and "locks in" the new lens shape with less power. (Courtesy of Calhoun Vision Inc.)

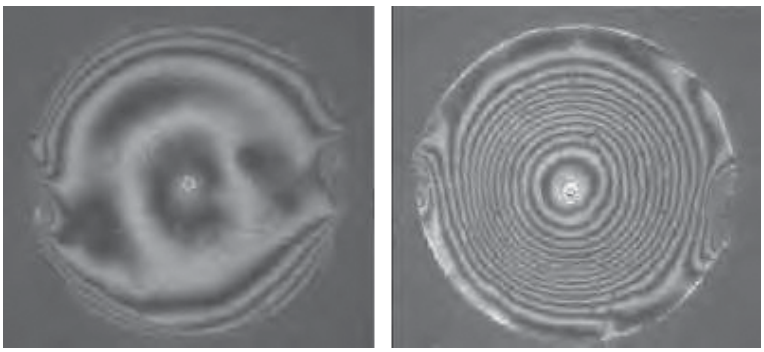


Fig. 17.5. Left: Fizeau interference fringes of a LAL immersed in a water cell maintained at 35°C before irradiation. Right: Fizeau interference fringes of the same lens 24 h after myopic peripheral irradiation. Note, approximately 14 fringes of wavefront curvature added to the lens corresponding to approximately 1.5 D of myopic correction. (Courtesy of Calhoun Vision Inc.)

In a patient with a myopic postoperative result following primary surgery, power will need to be reduced from the LAL in order to achieve emmetropia (Fig. 17.4). In this scenario, irradiation of the peripheral portion of the lens in a doughnut configuration will result in polymerization of macromers in this region with a resultant diffusion of central lens macromers into the peripheral irradiated portion of the lens. This creates swelling of the peripheral annulus of the lens with a concomitant increase in the radius of curvature and a decrease in lens power (Fig. 17.5). Similarly, astigmatism can be treated by irradiating the LAL along the appropriate meridian in order to create a toric change in the radius of curvature of the lens and thus increase power 90° from the treated meridian.

17.4 Animal Studies

Dr. Nick Mamalis, from the Moran Eye Center, University of Utah, has been instrumental in documenting some of the early data regarding the efficacy and accuracy of LAL adjustment in animal studies. In his pilot study, five rabbits underwent cataract surgery and LAL implantation followed by irradiation to correct 0.75 D of hyperopia. Each lens was then explanted and its power change analyzed. The mean power change was extremely close to the target correction at 0.71±0.05 D (Fig. 17.6a). Four additional rabbits underwent LAL implantation and treatment to treat –1.00 D of myopia. Their eyes also demonstrated precise adjustments averaging –1.02±0.09 D of power reduction (Fig. 17.6b).

In addition to these animal tests documenting the accuracy and reproducibility of LAL adjustments, Calhoun Vision has also performed extensive animal testing demonstrating biocompatibility and safety. Toxicology testing has revealed that there is no leaching of the macromers embedded in the cross-linked silicone matrix despite experimental transection of the IOL.

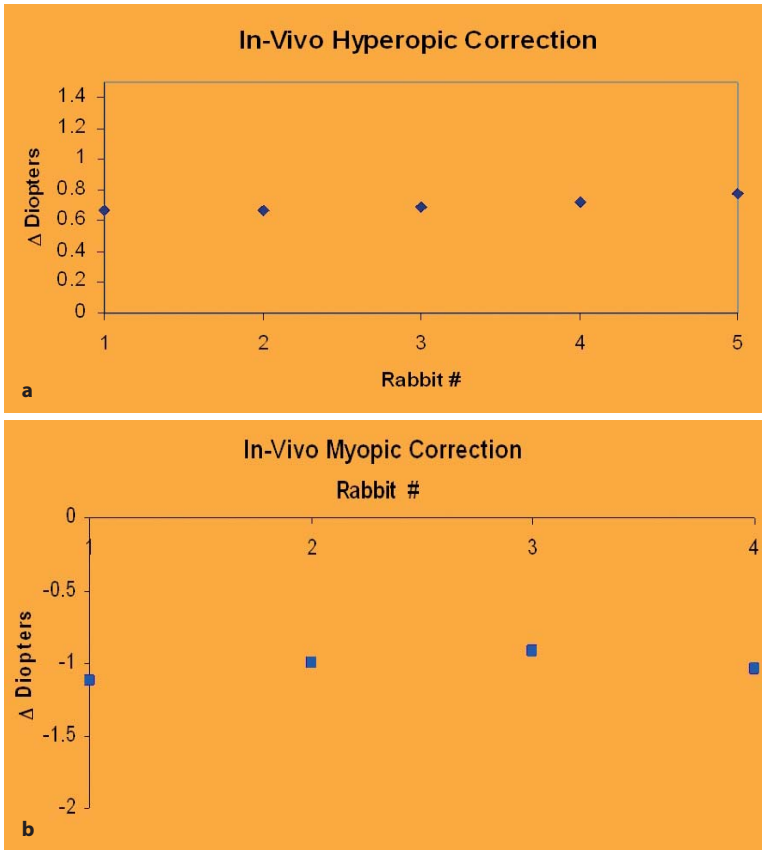


Fig. 17.6. **a** In vivo hyperopic correction in five rabbit eyes. Target correction was 0.75 D and the mean result was 0.71±0.05 D. **b** In vivo myopic correction in four rabbit eyes. Target correction was –1.0 D and the mean result was –1.02±0.09 D. (Courtesy of Dr. Nick Mamalis)

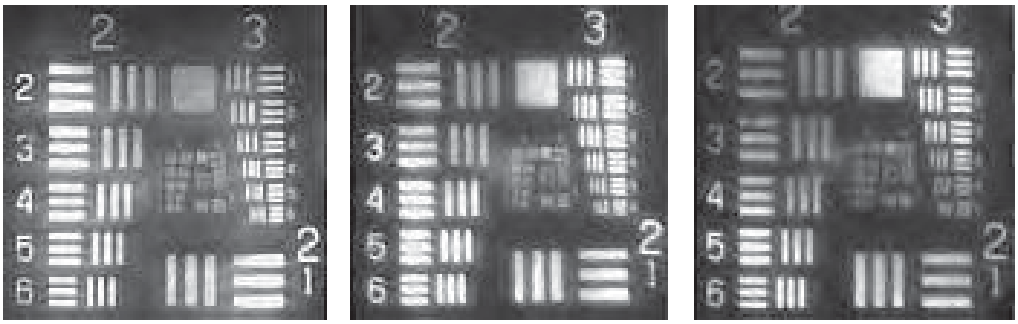


Fig. 17.7 a–c. US Air Force resolution target imaged in air though (**a**) a LAL prior to irradiation, (**b**) a LAL 24 h after –1.58 D of treatment, and (**c**) a 20-D AMO SI40 silicone IOL. (Courtesy of Calhoun Vision Inc.)

17.5 Resolution

Although the ultimate determination of the effect of an IOL on the quality of vision can best be determined by contrast sensitivity testing after human implantation, the resolution efficiency of a lens can be determined using optical bench studies. To monitor the resolution efficiency of the LAL after irradiation, the lens was evaluated on a collimation bench using a standard 1951 US Air Force resolution target. Figure 17.7a demonstrates the quality of the resolution target through the LAL in air before irradiation. Figure 17.7b reveals the imaged target 24 h after treatment of the LAL for –1.58 D of myopia. Figure 17.7c shows the image through a +20-D AMO SI40 IOL for comparison. Inspection of the images reveals that the resolution efficiency of the LAL is not compromised following irradiation [9].

17.6 Refractive Lens Exchange

Perhaps one of the greatest possible uses of a LAL is as a platform for refractive surgery. The concept of exchanging the human crystalline lens with a pseudophakic IOL as a form of refractive surgery is gaining popularity in the ophthalmic community. This stems from several problems inherent in excimer laser corneal refractive surgery, including the limitations of large myopic and hyperopic corrections, the need to address presbyopia, and progressive lenticular changes that will eventually interfere with any optical corrections made in the cornea.

Currently acceptable methods of performing refractive lens exchange incorporate multifocal lenses as a means of maximizing the final refractive result [10]. Multifocal IOLs allow presbyopic patients considering refractive surgery to address their distance refractive error in addition to their near visual needs without resorting to monovision with monofocal lens implants. In patients whose nighttime visual demands preclude the use of multifocal technology, monofocal IOLs can still be used with the understanding that monovision or reading glasses will be necessary to deliver functional vision at all ranges.

The LAL is an ideal implant for refractive lens exchanges, since emmetropia can be fine-tuned following insertion. In addition, Calhoun Vision has demonstrated in vitro an ability to irradiate multifocal optics of any near add onto any portion of the LAL (Fig. 17.8). Theoretically, a patient undergoing a refractive lens exchange could have their lens adjusted for emmetropia and then have multifocality introduced to determine whether they were tolerant to multifocal op-

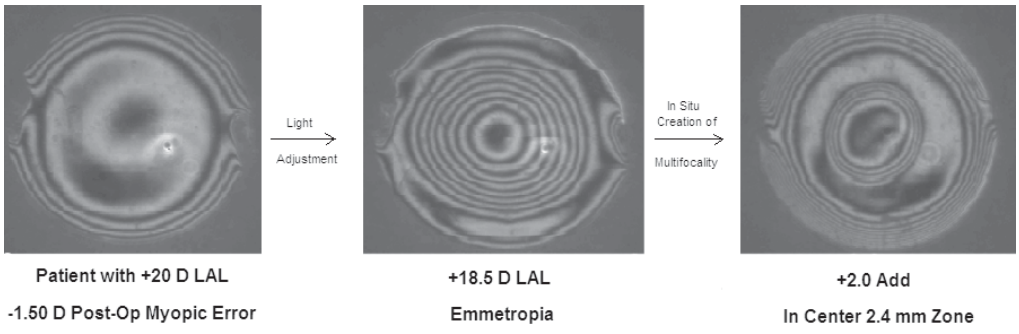


Fig. 17.8. A laser interferogram (*left*) demonstrates a 20-D LAL in vitro. If a –1.50-D postoperative error resulted, the lens could be irradiated to reduce the power and achieve emmetropia (*center*). This could then be followed by creation of a +2.0-D add power in the central zone of the lens (*right*) in order to yield a multifocal optic. (Courtesy of Calhoun Vision Inc.)

tics. If intolerant, the multifocality could be reversed and a trial of monovision could be induced. Once the desired refractive status was achieved, the LAL could then be locked in permanently. This would give patients the option of experimenting with different refractive optics and deciding in situ which was best for them.

To date, the potential drawbacks of refractive lens exchange have included the risk of endophthalmitis, retinal detachment, and the inability to guarantee emmetropia in these highly demanding patients [11, 12]. Hopes of reducing or eliminating the risks of endophthalmitis are now being boosted by the introduction of newer fourth-generation fluoroquinolone antibiotics, while the issue of lens power accuracy can now be potentially solved with the adjustment capabilities of the LAL [13].

Retinal detachment following cataract and refractive lens surgery is more common in high myopes but can occur in any patient. Detachments usually occur secondary to tears from posterior vitreous detachments that develop by removing the space-occupying crystalline lens and replacing it with a thin pseudophakic IOL. Calhoun Vision has researched an injectable silicone polymer with the same light-adjustable properties as the LAL, which offers the possibility of reducing the risk of retinal detachment following lens surgery (Fig. 17.9). By reinflating the capsular bag with an adjustable polymer, vitreous detachment and subsequent retinal detachment risk would theoretically lessen. In addition, an injectable polymer would allow for the possibility of utilizing advanced phacoemulsification techniques through microincisions of 1.0 mm and implanting an adjustable lens material through these same minute incisions.

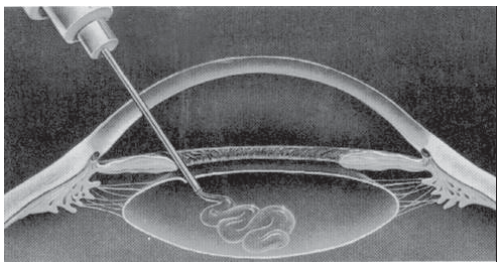


Fig. 17.9. A soft and injectable light-adjustable silicone polymer could be injected into the capsular bag and then irradiated postoperatively to achieve emmetropia. Refilling of the capsular bag would eliminate the creation of potential space behind the capsular bag and theoretically decrease the incidence of vitreous detachment. A soft pliable material could also potentially allow for the return of accommodation. (Courtesy of Calhoun Vision Inc.)

17.7 Higher-Order Aberrations

One of the hottest topics in the field of refractive surgery today is the concept of correcting higher-order aberrations within the eye. The elimination of higher-order optical aberrations would theoretically allow the possibility of achieving vision previously unattainable through glasses, contact lenses, or traditional excimer laser refractive surgery [14].

One of the major limitations of addressing higher-order aberrations with corneal ablations lies in the fact that higher-order aberrations such as spherical aberration tend to remain constant within the cornea throughout life, whereas aberrations in the crystalline lens tend to change as a patient ages [15–17]. Thus, any attempt to perfect the human visual system with wavefront-guided ablations to the cornea will be sabotaged at a later date by increasing positive spherical aberration in the naturally aging crystalline lens. If the higher-order aberrations within the cornea are indeed stable throughout life, a better approach for creating an aberration-free optical system that endures as a patient ages would be the removal of the crystalline lens and replacement with an implant that could be adjusted using wavefront technology to eliminate higher-order optical aberrations within the eye.

Calhoun Vision claims the ability to adjust the LAL with micron precision. If true, wavefront-guided treatments could be irradiated onto the lens, essentially negating any aberrations introduced into the optical system by the cornea. Spherical aberration has been successfully corrected on a LAL (Fig. 17.10) and additional research investigating the treatment of other higher-order aberrations is underway. In collaboration with Carl Zeiss Meditec, Calhoun Vision is developing a digital light delivery device (DLDD) that holds the promise of irradiating precise complex patterns onto the LAL as a means of correcting higher-order aberrations (Fig. 17.11).

The core of the DLDD is a complex digital mirror device composed of a chip containing thousands of tiny aluminized silicone mirrors. The chip can be programmed in such a way that an inverse gray-scale image of a patient's mathematically modeled wavefront pattern can be generated (Fig. 17.12). The gray-scale image is generated by rapid fluctuations of the tiny mirrors within the chip and this image can then be irradiated directly onto the LAL (Fig. 17.13). By creating an inverse or conjugate wavefront pattern, higher-order treatments can be transferred to the LAL, effectively neutralizing the eye's higher-order aberrations. Ultimately, wavefront-guided adjustments to the LAL could result in

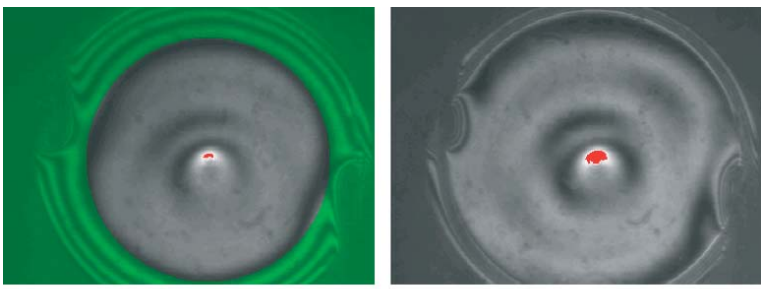


Fig. 17.10. Irradiation of an annular ring at the edges of the LAL corrects spherical aberration. Note that two fringes from the interferometry pattern in the lens periphery are removed, corresponding to 0.5 D of correction. (Courtesy of Calhoun Vision Inc.)

enhanced visual function that remains stable. Since aberrations in the cornea do not change with age and potential progressive crystalline lens aberrations are eliminated with lensectomy, wavefront treatments to the LAL should not change with time and should produce a stable aberration-free optical system throughout the patient's lifetime.

Fig. 17.11. Digital light delivery device (DLDD). (Courtesy of Calhoun Vision Inc.)

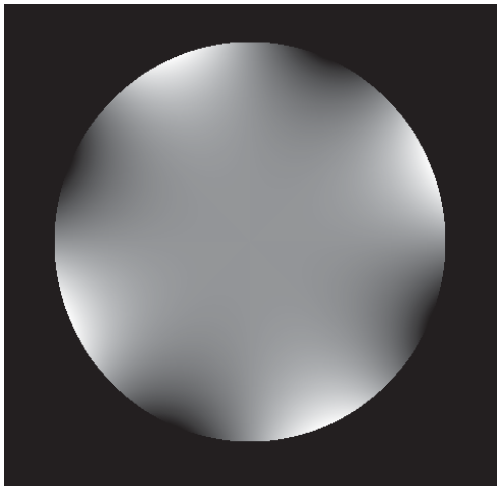
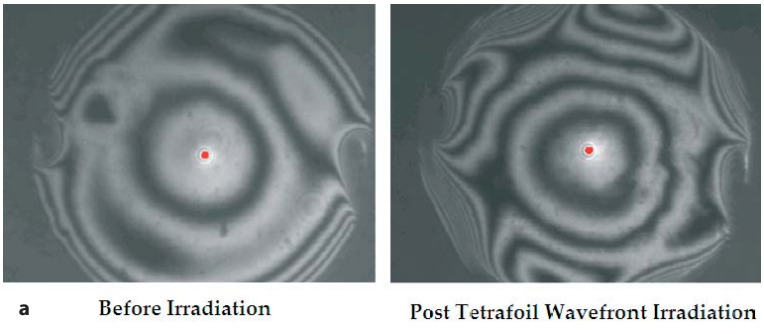


Fig. 17.12. A tetrafoil spatial intensity pattern is represented digitally. This pattern can be directly transferred to a LAL or an inverse pattern could likewise be irradiated to the LAL to correct this aberration. (Courtesy of Calhoun Vision Inc.)



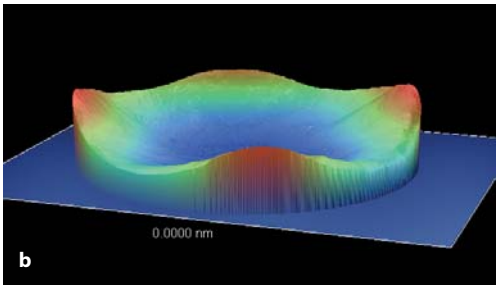


Fig. 17.13. **a** LAL interferometry pattern before and after irradiation with DLDD to create tetrafoil wavefront. **b** Three-dimensional representation of tetrafoil wavefront created in LAL. (Courtesy of Calhoun Vision Inc.)

FINAL COMMENTS

Cataract surgery has come a long way since the time of intracapsular extraction and large-incision extracapsular surgery. Incremental advancements in phacoemulsification technology have allowed ophthalmologists to offer their patients the safest and most rapidly visually rehabilitative cataract surgery ever available. Emphasis now has shifted to improving IOL technology. Research into newer multifocal and accommodative IOLs will be instrumental in allowing ophthalmologists to provide not only state-of-the-art cataract surgery but also to offer refractive lens exchanges to their refractive surgery patients as a means of treating distance-refractive errors and the presbyopic condition.

Current limitations in cataract and refractive lens surgery stem from the inability to guarantee emmetropia in even the most experienced hands. In addition to many other options, the LAL offers an incredible opportunity for ophthalmologists to deliver excellent postoperative visual acuities. IOLs will now have the potential of being fine-tuned following surgery to provide not only emmetropia but also multifocality and higher-order aberration-free corrections if the patient desires. The early reversible nature of the LAL prior to the final "lock in" will allow patients the opportunity to experience monovision, multifocality, and wavefront-guided treatments and then decide whether that refractive status is acceptable.

The LAL is truly one of the great revolutions in modern cataract and lens surgery. Clinical trials in the USA commenced in 2003.

References

1. Brandser R, Haaskjold E, Drolsum L (1997) Accuracy of IOL calculation in cataract surgery. Acta Ophthalmol Scand 75:162–165
2. Drexler W, Findl O, Menapace R et al (1998) Partial coherence interferometry: a novel approach to biometry in cataract surgery. Am J Ophthalmol 126:524–534
3. Giers U, Epple C (1990) Comparison of A-scan device accuracy. J Cataract Refract Surg 16: 235–242
4. Watson A, Armstrong R (1999) Contact or immersion technique for axial length measurements? Aust NZ J Ophthalmol 27:49–51
5. Packer M, Fine IH, Hoffman RS et al (2002) Immersion A-scan compared with partial coherence interferometry. Outcomes Analysis. J Cataract Refract Surg 28:239–242
6. Olsen T (1992) Sources of error in intraocular lens power calculation. J Cataract Refract Surg 18:125–129
7. Pierro L, Modorati G, Brancato R (1991) Clinical variability in keratometry, ultrasound biometry measurements, and emmetropic intraocular-lens power calculation. J Cataract Refract Surg 17:91–94
8. Masket S, Tennen DG (1996) Astigmatic stabilization of 3.0 mm temporal clear corneal cataract incisions. J Cataract Refract Surg 22: 1451–1455
9. Schwiegerling JT, Schwartz DM, Sandstedt CA, Jethmalani J (2002) Light-adjustable intraocular lenses. Review of refractive surgery; Newtown Square, Jobson Publishing, LLC, Feb 2002
10. Packer M, Fine IH, Hoffman RS (2002) Refractive lens exchange with the Array multifocal lens. J Cataract Refract Surg 28:421–424
11. Rodriguez A, Gutierrez E, Alvira G (1987) Complications of clear lens extraction in axial myopia. Arch Ophthalmol 105:1522–1523
12. Ripandelli G, Billi B, Fedeli R, Stirpe M (1996) Retinal detachment after clear lens extraction in 41 eyes with axial myopia. Retina 16:3–6

13. Mather R, Karenchak LM, Romanowski EG et al (2002) Fourth generation fluoroquinolones: new weapons in the arsenal of ophthalmic antibiotics. Am J Ophthalmol 133:463–466
14. Macrae SM, Krueger RR, Applegate RA (2001) Customized corneal ablation. The quest for supervision. Slack, Thorofare, NJ
15. Guirao A, Redondo M, Artal P (2000) Optical aberrations of the human cornea as a function of age. J Opt Soc Am A Opt Image Sci Vis 17:1697–1702
16. Oshika T, Klyce SD, Applegate RA, Howland HC (1999) Changes in corneal wavefront aberrations with aging. Invest Ophthalmol Vis Sci 40:1351–1355
17. Artal P, Berrio E, Guirao A, Piers P (2002) Contribution of the cornea and internal surfaces to the change of ocular aberrations with age. J Opt Soc Am A Opt Image Sci Vis 19:137–143

18 Injectable Polymer

Sverker Norrby

CORE MESSAGES

- The feasibility of achieving accommodation with an injectable polymer has been demonstrated in primates.
- Materials with the required physical, mechanical and biological properties exist.
- Although in some cases eyes are clear after several months, lens epithelial cell proliferation remains an issue.
- Indirect methods indicate that the optical quality is sufficient, but this must be verified by direct measurement.
- Surgical assessment methods that allow surgeons to control the amount of material to inject must be developed.
- Long-term stability regarding lens clarity, refraction and accommodative range must be demonstrated in primates before this technology is a clinical reality.

18.1 Introduction

If you assume Helmholtz' theory of accommodation, it is a natural thought that accommodation could be restored by replacing the stiff presbyopic lens with a material mimicking the young crystalline lens. Such a material must be soft and transparent, and have a refractive index close to that of the natural lens. The material must further be biocompatible, stable over time and safely confined within the capsular bag. There must be a surgical procedure that allows extraction of the crystalline lens while preserving the capsular bag. Following injection into the capsular bag, the bag must be able to mould the material into a lens having the right power and sufficient optical quality.

18.2 The Pioneers

Julius Kessler, a New York ophthalmologist, was the first to attempt refilling the lens capsule following endocapsular lens extraction. In a first paper he describes lens extraction

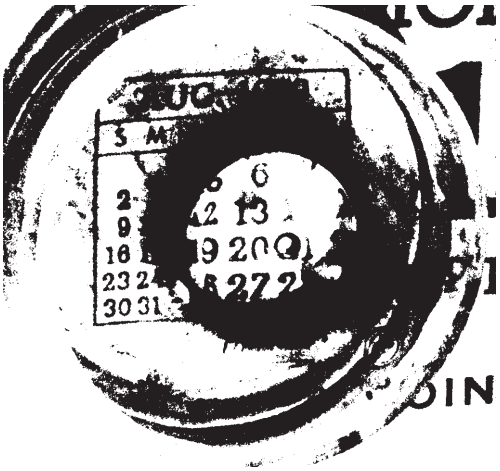


Fig. 18.1. Small calendar viewed through an oil-refilled bovine lens. Note clarity, magnification and date. Reproduced from [1] by courtesy of *Archives of Ophthalmology*

via a pars plana route through a 2-mm scleral incision [1]. This technique was already in use for cases of congenital or juvenile cataracts (Kessler quotes a paper by Blaess from 1938). Kessler used loops of thin wire to cut the nuclevs and ascertains that even hard human nuclei could be cut and extracted in this way. He tried several commercially available filling materials, liquids as well as compounds curing into gels in situ. With liquids, the hole in the bag was sealed with a plug to prevent leakage. The techniques were first developed on bovine cadaver eyes and subsequently applied on living rabbits. The lenses formed by the bag appeared to have good optical quality (Fig. 18.1). In the rabbits the fundus could be clearly seen, even after 6 months, and Kessler noted that there was no regrowth of lens substance, i.e. no capsule opacification. One material used was Silastic, Dow Corning RTV S-5395, a silicone curing at ambient temperature. It has a refractive index of 1.4, which Kessler considered too low, explaining the hyperopia found. He described the lens formed as harder than normal young lens substance. This first attempt in lens refilling was remarkably successful.

In a second paper [2], Kessler modified the surgical technique to an approach via a 2-mm clear cornea incision. The aqueous was first drained, which brought the lens in contact with the cornea. The capsule was then punctured and a spreader, made of thin wire and fixed by a suture to episclera, was used to keep the entrance to the lens open. The lens matter was then aspirated with an 18-gauge blunt cannula. The same size cannula was used to inject Silastic. To avoid synechiae to the capsule wound, the pupil was kept dilated for 2 weeks. The eyes were again noted as hyperopic. There was no capsule opacification for as long as observed, up to 23 months. In eyes implanted with glass lenses, the capsules opacified.

In a third paper [3], Kessler returned to the pars plana route. Some capsules were left empty and some were refilled with Silastic. In the refilled capsules there was no opacification for up to 2 years, while regrowth of lens substance was observed after 2 weeks in the empty capsules.

Agarwal and coworkers [4] can also be considered as pioneers, though they were aware of Kessler's first paper at the time of writing theirs. They also chose the pars plana route in rabbits. They tried several materials, including gelatin, but only silicones were found to be useful. When filling with liquids, Dow Corning Sylgard 184 (a two-component silicone curing into a gel) was used to seal the opening in the capsule. Sylgard 184 was also tried as filling material, but was noted to have less transparency than the liquid silicone oils (Dow Corning of various viscosities). The filled capsules remained free of opacities, though for how long was not clearly stated. The novelty brought by this group was measurement of accommodation. They determined refraction with cycloplegia (atropine) and without cycloplegia by retinoscopy. The difference was calculated as accommodation. Without cycloplegia probably refers to the natural state, without use of any miotic agent; however, this was not clearly stated. In both

states phenyl epinephrine was used to dilate the pupil. Preoperative accommodation ranging from 0.5 to 1.25 diopters was found. Postoperatively it decreased to between 0.25 and 0.75 diopters. It was noted that the retinal reflex was less clear in refilled eyes than in natural eyes, indicating less optical quality, and that the refilled eyes were hyperopic.

In a subsequent paper, Agarwal and coworkers [5] described refilling of lenses in rhesus monkeys. First a cataract was induced by trauma to one eye. When the cataract had developed in this eye, lens extraction followed by lens refilling was performed. Postoperative inflammation was noticed and required about 3 weeks of steroid treatment to clear. Initially refraction by funduscopy could be performed, but the posterior capsule, and later the anterior capsule, gradually opacified. After 28 days the posterior segment was no longer visible. They concluded that primates react more to the surgical trauma than rabbits.

18.3 The Followers

The pioneering work of Kessler went unnoticed: when Parel coined the name Phaco-Ersatz [6] for the procedure of refilling the lens, he was not even aware of Kessler's work. Parel's group studied several aspects of the procedure and a first paper [7] appeared in 1986. On August 19, 1989 they founded the Accommodation Club, which held its 4th meeting on April 30, 2004 at Bascom Palmer Eye Institute, Miami, Florida. After trying many materials, Parel's group also came to the conclusion that a low-temperature curing silicone was the best candidate material. The eyes were entered via a limbal incision and a 1-mm diameter opening was made in the capsule by cautery. The nucleus (of human cadaver eyes) was then extracted by means of ultrasound phacoemulsification using a 0.89-mm tip, followed by aspiration of the cortex through a 20-gauge cannula connected to a 10-cc syringe. The group also performed the procedure in rabbit and cat eyes in vivo. Instead of plugging the hole in the capsule, they used a highly viscous, precured silicone that by cohesion largely stayed in the bag until fully cured after 12 h.

Parel's group then turned to owl monkeys as a model for human accommodation [8]. Using essentially the surgical technique developed earlier, a low-temperature curing silicone was injected into the emptied capsules of seven monkeys. Fundus angiograms taken immediately after surgery (Fig. 18.2) demonstrated good optical quality of eyes with Phaco-Ersatz. However, aqueous flare and gradually increasing capsule opacification later prevented measurement of refraction, hence measurement of accommodation. Instead, anterior chamber depth shallowing in response to pilocarpine was measured by optical pachymetry as an indirect indicator of accommodative response. The accommodative shallowing in operated eyes was about 0.9 mm and constant over a period of 6 months. In the contralateral natural eyes, the shallowing was 0.7 mm. In addition, Scheimpflug photography was used to demonstrate the combined effects of shallowing anterior chamber and increasing anterior lens curvature (Fig. 18.3). Two cases of late leakage of polymer out of the capsule were attributed to capsule shrinkage caused by lens epithelial cell proliferation.

Six old (>17 years) rhesus monkeys were implanted using the same techniques and material and were followed for extended times, in one case 4 years. This animal was almost presbyopic at the time of operation. Decrease of anterior chamber depth in response to pilocarpine was preoperatively 0.2 mm in both eyes and increased to 0.4 mm after 4 months in the operated eye. After 1 year it was 0.9 mm, which was attributed to training effects of the ciliary muscle. The response then declined but remained at 0.5 mm after 4 years. At this time the fellow natural eye showed no response to pilocarpine, indicat-

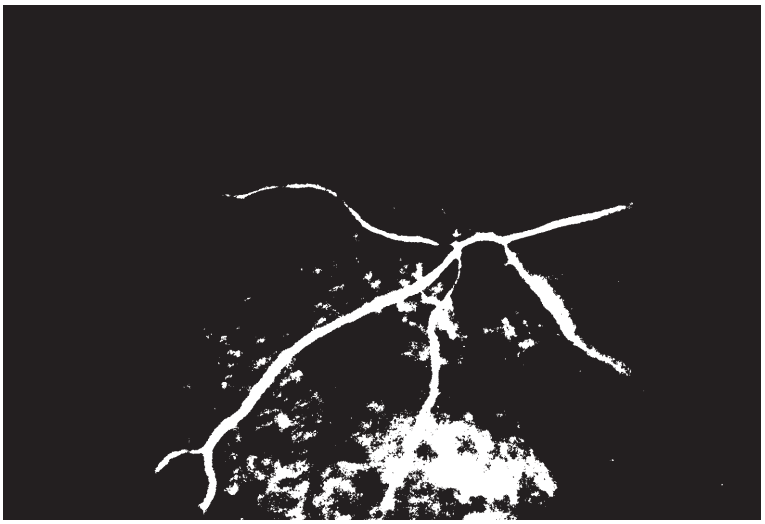


Fig. 18.2. Fundus angiogram of an owl monkey taken immediately after implantation of a silicone polymer lens. Reproduced from [8] by courtesy of *Ophthalmology*

Fig. 18.3. Scheimpflug photography of the anterior segment of an owl monkey with a silicone lens. Photographs in unaccommodated (top) and accommodated (bottom) states are joined at the corneal apex to emphasize the difference in anterior chamber depth. The steeper curvature of the anterior lens surface in the accommodated state is also clearly seen. Reproduced from [8] by courtesy of *Ophthalmology*

ing complete presbyopia. Thus it appeared that accommodation could be restored. However, problems with postoperative inflammatory reaction and capsule opacification due to lens epithelial cell proliferation remained to be resolved.

In 1997, Parel revitalized research on Phaco-Ersatz in cooperation with the Vision Cooperative Research Centre, Sydney, Australia, also involving polymer chemists at the University of Melbourne. They are now working with a photocuring silicone using a minicapsulorrhexis valve to seal the capsule [9].

In the early 1980s, Gindi and coworkers conducted extensive research into endocapsular cataract extraction and lens refilling [10] with surgery on 200 rabbits, five dogs, five baboons and one stumptailed macaque. After experimenting with several materials, they settled for a silicone polymer curing in situ (within about 5 h). The capsulotomy was about 3 mm. To keep the polymer in the capsule during filling and curing, they sutured the corneal wound to allow them to create and maintain anterior chamber pressure by infusion of BSS through a cannula. The rabbits were followed for up to 8 months. Twenty rabbits were implanted with polymer and meas-

ured by autorefraction. Postoperative refraction was in the range +5 to +15 diopters, thus hyperopic. Preoperative refraction was from +2 to +4 diopters. The capsules remained clear up to 2 months postoperatively. The monkeys were all old and received no implant. They were sacrificed directly after surgery. The dogs all had dense senile nuclear cataracts and also received no implant. No further publications on the subject can be found from this group.

Nishi has studied lens refilling extensively. He presented the experimental technique in his first paper [11] (in Japanese) in 1987. He made a smile incision (referred to as a Baïkoff-Hara-Galand incision) in the capsule, through which he extracted the lens by phacoemulsification. He then implanted a lens-shaped balloon, which was subsequently filled with silicone oil. Finally, the capsule incision was closed with sutures. Essentially the same paper also appeared in English [12]. Postoperative refractions from +12 to +20 diopters, thus very hyperopic, were measured by skiascopy. Accommodation up to +1.0 diopter was found, though it is not stated how it was induced. The fundus was clearly visible initially. After about 3 months, visibility was occluded due to anterior capsule opacification. Histological examination indicated that the capsulotomy was closed by a newly formed basal membrane. Applying the technique to human cadaver eyes, capsule suturing failed due to tearing.

Nishi continued his work, together with Hara, Sakka and other coworkers [13, 14]. Hara and coworkers [15] had also experimented with balloons fitted with a filling tube that was cut after polymer injection. They introduced metered control of the amount of polymer injected [14]. Various capsulotomy geometries were tried, among them a circular one created with a 1.3-mm electric microtrephine [16]. Hara and Sakka have subsequently continued to work on refinement of the trephine [17].

Sakka and coworkers [18] implanted balloons filled with silicone fluid in four Japanese monkeys and were able to measure refractive change in response to pilocarpine by autorefractometry. Average response after 60 min was 6.7 diopters in operated eyes and 8.3 diopters in control eyes, which is four times more than Nishi et al. [19] found in the same species. The material used by these Japanese researchers appears to be a two-component low-temperature curing silicone provided by Menicon (a Japanese intraocular lens manufacturer).

Eventually, Nishi abandoned the endocapsular balloon [20] because capsule opacification invariably occurred. Instead he introduced a plug to seal a round capsulotomy [21] (Fig. 18.4). He also studied the effect of degree of filling on accommodative amplitude. The ciliary body with zonules and lens was excised from pig cadaver eyes. The ciliary body was then sutured to a ring device. By changing the diameter of the ring, tension could be applied to the zonular fibers. With this setup, Nishi found maximum accommodative amplitude (6 diopters) when 55% of the original lens volume was replaced by the silicone material. Nishi next took his new approach to rabbits [22]. With the capsules filled to about two-thirds, he found about 1 diopter of accommodation in response to pilocarpine, measured with an autorefractor. With this degree of filling, the eyes were about 19 diopters hyperopic. Unfortunately, the capsules developed opacification. Nd:YAG capsulotomy was performed in two animals. Surprisingly, the filling neither leaked nor bulged out of the YAG capsulotomy.

In primates [23], Nishi's new technique produced accommodation of up to 4.5 diopters, with a mean of 2.3 diopters, compared to 8.0 diopters preoperatively. Thick posterior capsule opacification precluded refractometry after 3 months. Also in this study the capsules were filled to about two-thirds of the original lens volume. Nishi finally concluded that capsule opacification must be prevented to make lens refilling feasible for restoration of accommodation in presbyopic or cataractous human eyes.

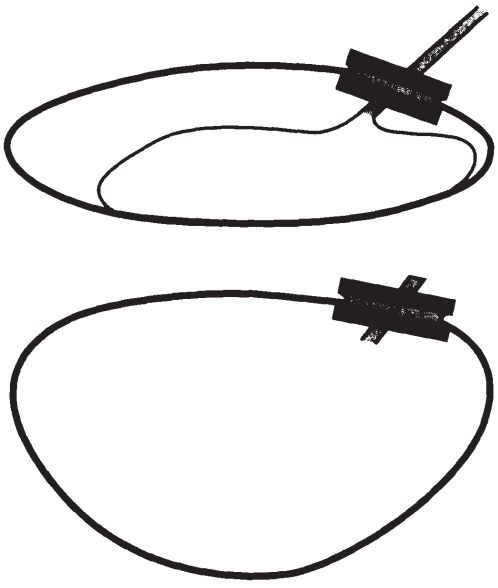


Fig. 18.4. Schematic representation of capsular refilling using a capsular plug to contain the injected silicone in the capsule. Reproduced from [21] by courtesy of *Archives of Ophthalmology*

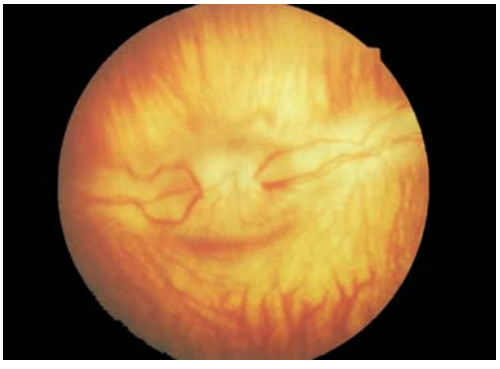


Fig. 18.5. Fundus photograph of a living rabbit eye with an in situ polymerized lens 10 weeks postoperatively. Reproduced from [27] by courtesy of the author

To overcome problems with leakage of injected material during curing, Hettlich [24] studied a photocuring material, which solidified within 20 s. The material was based on acrylates with a photoinitiator working at wavelengths between 400 and 500 nm (blue light). Thus harmful ultraviolet light was avoided. The monomers used were slightly cytotoxic, which turned out to be favorable. The toxicity prevented or reduced lens epithelial cell proliferation, yet there was no damage of other tissue, because the material was confined within the capsule [25]. The optical quality of the refilled eyes allowed sharp fundus photography even 10 weeks after implantation in rabbits (Fig. 18.5). Unfortunately, the material was hard, so no accommodation could be expected. Its refractive index was also much too high (1.532).

Hettlich introduced a bimanual lens emulsification procedure. In this way he could reduce tip dimensions by separating irrigation and aspiration/emulsification. Two stab incisions were made in the capsule and both tips were introduced into the lens, which was then extracted. During filling and curing, the material was prevented from leaking out of the capsule by maintaining pressure in the anterior chamber by means of the irrigation.

Polymerization of monomers is known to create considerable heat (in contrast to curing, which is crosslinking of polymers). Hettlich [26] measured the temperature in cadaver eyes and found it to rise to 45 °C at the posterior capsule shortly after photoinitiation. The temperature rise at the retina was negligible. He also measured the retinal irradiation caused by the light source for curing, and found it to be well below the levels of the operating microscope. It thus appeared that photopolymerization may be safe, but a material that had the right physical properties for lens replacement remained to be found. The work of Hettlich, partly in German, has been summarized in a book [27] in English.

In 1996, Pharmacia arranged the Gullstrand workshop on accommodation (Capri, Italy, August 30–31). Gullstrand's Nobel prize address "How I found the mechanism of intracapsular accommodation" (December 11, 1911) was reprinted for the occasion. (Pharmacia was acquired by Pfizer on April 16, 2003; later, on June 26, 2004, the surgical oph-

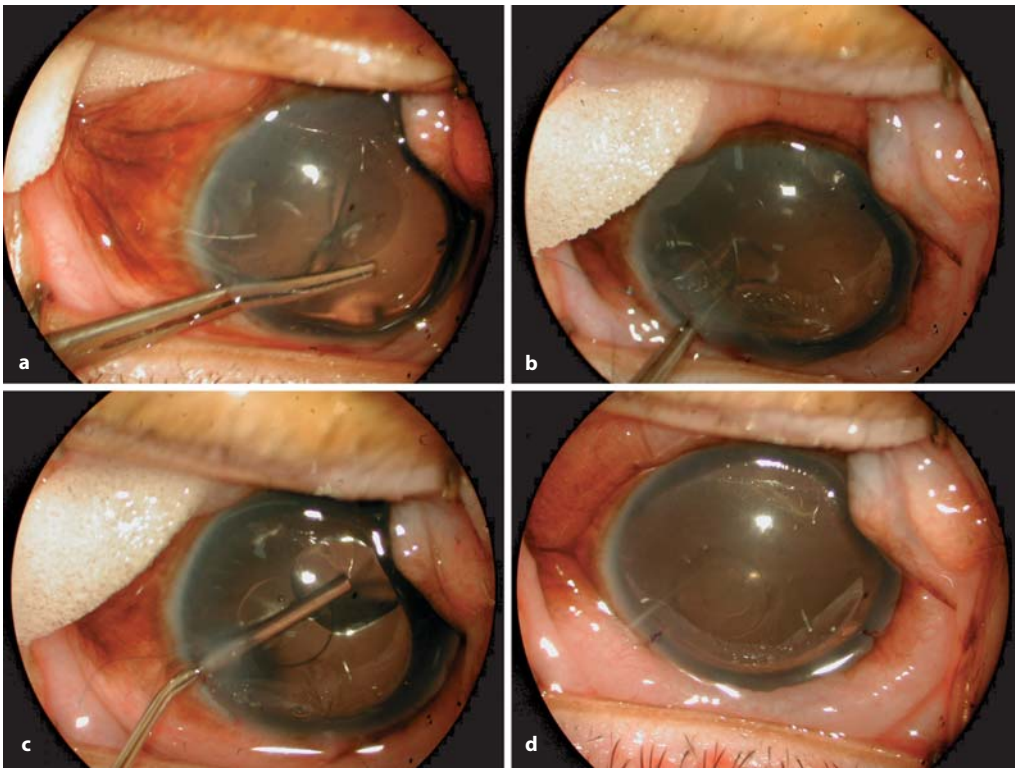


Fig. 18.16 a–d. Surgical technique of lens refilling in a primate. **a** Small peripheral capsulorrhexis. **b** Lens extraction by aspiration. **c** Injection of polymer between capsule and sealing membrane. **d** The lens is curing while the sealing membrane prevents leakage. Printed with permission of Dr Steven Koopmans, who performed the surgery

thalmology business was divested and acquired by Advanced Medical Optics.) The Gullstrand workshop involved several researchers in fields related to accommodation.

A silicone material that can be produced within a wide range of refractive index, while maintaining the desired modulus and density has since been developed at Pharmacia. Using early versions of this material, Koopmans and coworkers [28] compared the accommodative ability of natural and refilled lenses in human cadaver eyes in a stretching apparatus that allowed zonular tension to act on the lens submerged in aqueous. By scanning the lens with a laser beam, power was measured. They used two materials with a refractive index of 1.428. One had a Young's modulus of 3.6 kPa and the other 0.8 kPa. For natural lenses, the difference in accommodative range turned out to decline with age, as expected, and was zero in specimens older than 50 years. In contrast, refilled lenses exhibit accommodation that was independent of specimen age. The two filling materials exhibited the accommodation range expected for an age corresponding with their moduli. A further improved material has subsequently been tested in rabbits and rhesus monkeys. The surgical procedure is shown in Fig. 18.6.

Human-like accommodation can be studied only in primates, and the rhesus monkey is the best established model. To be able to measure accommodation optically, the eyes must remain clear. In our initial experiments,

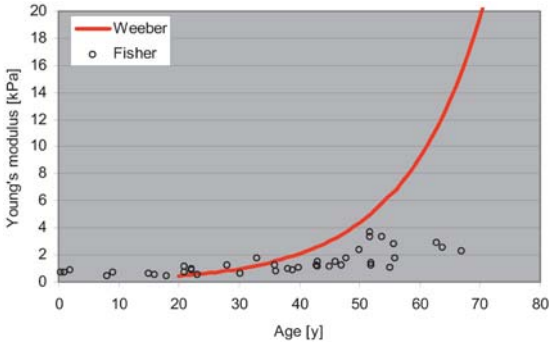


Fig. 18.7. Young's modulus of human lens material at different ages. Data of Weeber et al. [34] compared to those of Fisher [56]. Printed with permission of Henk Weeber, who provided the graph

there was fibrin formation in the anterior chamber in the early postoperative period, later followed by opacification of the capsule due to lens epithelial cell proliferation. Recently, we have managed to control the postoperative inflammation by steroid therapy and prevent capsule opacification by means of a cytotoxic compound. The clear eyes now allow measurement of refraction in accommodated and unaccommodated states using a Hartinger coincidence refractometer. Accommodation is induced by means of a miotic agent (pilocarpine or carbachol). Accommodation of about 3 diopters has been measured up to 6 months postoperatively [29]. This research was carried out in part in collaboration with Dr. Adrian Glasser, Houston, Texas.

18.4 The Materials

The crucial properties for a lens replacement material are refractive index, modulus (softness), and, to a lesser extent, density.

The natural lens has a gradient refractive index. The index is lower at the surface and increases towards the middle. Gullstrand [30] calculated that a homogeneous material replacing the crystalline lens should have an index of 1.413 for the unaccommodated state, and 1.424 for 9.7 diopters of accommodation. In accordance with the Dubbelman eye model [31], the equivalent refractive index for a 35-year-old person is 1.427 in the unaccommodated state and 1.433 for 4 diopters of accommodation. That the equivalent refractive index increases with accommodation is due to the gradient refractive index of the crystalline lens. A homogeneous replacement will therefore produce less accommodation for the same amount of lens curvature change, as pointed out by Ho et al. [32] .

Fisher [33] found the elastic modulus of the human lens to be about 1.5 kPa and to increase slightly with age. More recently, Weeber et al. [34] measured shear compliance (the inverse of modulus) of human crystalline lenses as a function of age. They found lens compliance to decrease (increase in stiffness) by a factor of 1,000 over a lifetime. Figure 18.7 shows the data of these two papers in comparable units. While the results of Weeber et al. explain better why lens stiffness prevents accommodation, they are comparable to those of Fisher for young lenses, which are the target for a lens replacement material.

The density of an artificial lens material should be slightly higher than that of water to avoid flotation, yet not so dense as to cause inertia forces on the zonules when the head is shaken.

18.4.1 Silicones

In the early literature most research groups appear to have used poly(dimethyl siloxane) – common silicone. It has a refractive index of 1.40 and a specific gravity of 0.98. By copolymerizing dimethyl siloxane with diphenyl

siloxane, the refractive index can be increased and at the same time the specific gravity increases well over 1. Such materials are used in high refractive index foldable intraocular lenses (IOLs). In order to counteract excessive increases in specific gravity, a third comonomer can be introduced [35].

Silicone polymers by themselves are liquids. They can be crosslinked into gels. The stiffness of such gels depends on the length of polymer chains between crosslinks.

It appears that the gels used in the published literature have been produced by crosslinking of vinyl-ended polysiloxane with hydrosilyl-type crosslinkers, facilitated by a platinum catalyst. This is a commonplace route to obtain silicone gels at low temperatures within a reasonable amount of time. Using traditional nomenclature, a part A containing polymer and catalyst, and a part B containing polymer and crosslinker are formulated. When the two parts are mixed, the crosslinking reaction commences. A lens replacement material should have a Young's modulus of about 1 kPa. A typical foldable IOL has a modulus about 1,000 times higher, i.e., similar to a presbyopic crystalline lens. How this low modulus is achieved is mostly considered proprietary knowledge.

Alternatively, curing can be initiated by light – photoinitiation. With such a system there is no need to mix components, but the formulation must be protected against light until the right moment. After injection into the bag, crosslinking is started by exposure to light. The initiation requires light of sufficient energy. Ultraviolet is harmful and therefore blue light is preferable. Photoinitiation of silicone curing is known in ophthalmology in conjunction with the light-adjustable lens from Calhoun [36]. Photocuring silicones for lens refilling have been revealed recently by Garamszegi and coworkers [37] and are being investigated by Parel's group [9].

18.4.2 Hydrogels

Hydrogels are another class of potential candidates for a lens replacement material. In contrast to silicones, these polymers contain water. The desired refractive index requires a rather high percentage of polymer. Too much polymer can make the hydrogel too viscous for injection. Therefore polymers with high intrinsic refractive index must be sought.

With hydrogels it is crucial to control the polymer/aqueous interaction. If a polymer that is water soluble is injected into the bag, the hydrogel will expand upon crosslinking. This makes the degree of filling difficult to control and the capsule can even burst. If the polymer is not water soluble, it cannot form an injectable hydrogel. To be useful the polymer must be just on the limit – swell but not dissolve in water. Hydrogels are intuitively attractive, as they are felt to be close to natural materials. In fact, the proteins of the crystalline lens are technically hydrogels.

Kessler [1] tried Damar gum and Agarwal [4] gelatin, in both cases without success.

De Groot and coworkers studied a number [38, 39] of hydrogel systems with the aim of using them as accommodating lens replacements. Poly(ethylene glycol) diacrylate was used to crosslink a copolymer of N-vinylpyrrolidone and vinyl alcohol by photopolymerization, using a phosphine oxide initiator. Lenses were formed in pig cadaver eyes. The lenses formed had the transparency of a 25-year-old human lens. A novel hydrogel based on poly(1-hydroxy-1,3-propandiyl) showed promise in forming a material with low modulus. In a different approach, small particles were crosslinked to form a loosely crosslinked gel [40]. The particles provided refractive index and the loose gel low modulus. The idea of crosslinking particles has been pursued by Pusch [41].

Murthy and Ravi [42] used poly(ethylene glycol)-based hydrogels as mechanical probes to study accommodation. Lenses were formed in porcine cadaver eyes. The softest

material had a Young's modulus of 10 kPa. Though these polymers had 94% optical transmission, they did not have a high enough refractive index to serve as a lens replacement. Ravi [43] has lately presented hydrogels prepared by copolymerization of acrylamide and bisacryloylhistamine. The network forms by disulfide bonds that can be reversibly dissolved and reformed. Material crosslinked in vitro can thus be dissolved and injected to reform in vivo. The refractive index is reported to be up to 1.42 with a modulus of about 0.5 kPa. The material is toxic [44] and further developments will address this issue. Toxicity, if confined to the capsule, could be an advantage in preventing capsule opacification, as observed by Hettlich [26].

18.4.3 Proteins

Since the lens mainly consists of proteins, replacing it with proteins is a natural thought. Kelman [45] patented such a material and an article appeared in *Ocular Surgery News* in 1990. Besides a presentation [46], there is no further account of this material.

18.4.4 Cells

In a series of papers, Gwon studied regrowing lenses in vivo from lens epithelial cells. Her first publication [47] dates back to 1989, but the idea is very old. Gwon cites a paper by Cocteau from 1827. It indeed turned out possible to regrow lenses from lens epithelial cells in lensectomized rabbits. The cells differentiated and gradually formed fibers with eventual loss of nuclei [48]. An image-analysis method to quantify the amount of regrowth [49] was developed. With this method a regrowth of 75% was found [50]. In this study rabbits in which cataract had been induced were used. In later experiments a collagen patch was applied to seal the opening in the capsule. This allowed injection of air and hyaluronic acid to distend the capsule, which facilitated regrowth. Lens thickness increased by 0.3 mm per month and the lenses formed were spherical with normal cortical structure. Unfortunately, in all cases there was nuclear opacity, making the lenses useless as optical elements. In an attempt to avoid the opaque nucleus, Gwon used soft contact lenses as intracapsular scaffolding for the lens cells to grow around. However, this resulted in poor optical clarity posterior to the contact lens [51].

18.5 The Issues

18.5.1 Surgical Technique

Making a peripheral, small capsulotomy – by capsulorrhexis, diathermy or trephination – appears feasible, keeping in mind that most of the work has been done on young animal eyes. Performing a capsulotomy safely and reproducibly in old human capsules is still a challenge. Extracting a hard nucleus through this capsulotomy without tearing the edges is the real challenge. Liquefying the nucleus by means of laser, chemicals or enzymes is a possibility. The Avantix endocapsular vortex emulsification technology [52] may offer an opportunity, when/if it appears on the market.

How can the surgeon know how much to inject? The obvious thought of an online optical measuring system integrated with the operating microscope is not as simple as it may seem. The cornea is being distorted by the operation, resulting in false feedback. One could apply a lens similar to a Goldmann gonioscopy lens (plano power, no mirror) to eliminate the influence of the anterior corneal surface, but the posterior surface must still be estimated. Filling to the same thickness as preoperatively, or filling the preoperatively estimated volume by volumetric injection, assumes that the refilled lens will take the exact form of the crystalline lens,

which may not be the case. Whether the lens should be filled to its preoperative volume remains an open question [21]. Koopmans et al. [53] recently confirmed Nishi's results in porcine cadaver eyes. Going from 50% refilling upwards to 100%, and stretching the ciliary body diameter by 3 mm, they found that the accommodative amplitude decreased from about 8 diopters to about 4 diopters. Nomograms or computer programs need to be developed to estimate the final result from preoperative information in combination with peroperative feedback. A beginning can be made in animal models, but fine tuning requires studies in human eyes.

A fallback procedure also needs to be in place. It must be shown that the surgeon can safely revert to normal IOL implantation, should complications occur.

18.5.2 Capsule Opacification

It is intriguing that Kessler [1] did not observe capsule opacification, whereas later researchers did. He used a commercial polymer for technical applications. Maybe it was toxic enough to kill the lens epithelial cells, without harm to surrounding tissue, because it was confined within the capsule? Agarwal [4] made the same observation in rabbits, whereas there was capsule opacification in monkeys [5]. Later researchers have all observed opacification of the capsule. In our case [29] it seems that opacification can at least be delayed.

A therapy or other treatment to prevent lens epithelial cell proliferation is a must for lens refilling to become an acceptable procedure. This is not only because of opacification, but also because capsule contraction could squeeze out the material and thereby change the power and other optical properties of the lens. YAG capsulotomy is not acceptable for the same reasons.

18.5.3 Optical Performance

Fundus visibility is a good indication of the optical quality of the total optical system of the eye. Fundus photographs can be analyzed to give quality metrics of the optics of the eye [54]. Power measurement with the Hartinger coincidence refractometer offers another indirect quality measure. In this instrument two sets of lines are aligned (Fig. 18.8). The images of these sets have traveled twice through the optics of the eye. Hence their clarity is indicative of the optical quality of the eye.

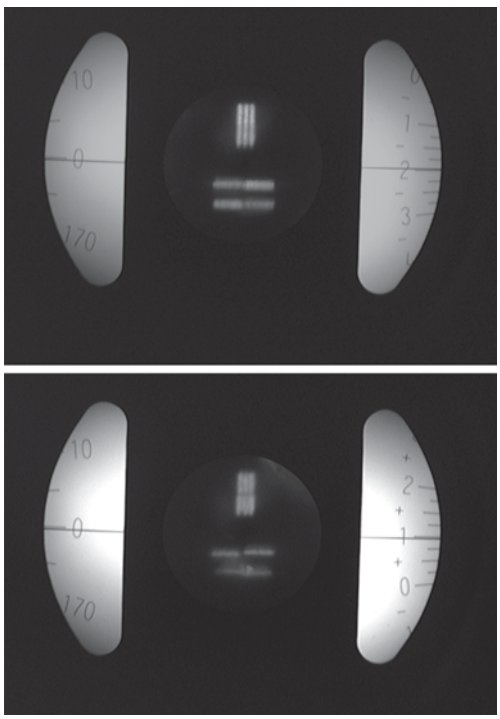


Fig. 18.8. Hartinger coincidence refractometer measurements of monkey eyes in the unaccommodated state. The eye with the natural lens is –2 diopters (myopic) and the one with the refilled lens is +1 diopter. The vertical mires are well resolved in the eye with the natural lens, indicative of the optical quality of a normal eye. The image of the mires in the eye with the refilled lens is more blurred, but still indicative of reasonable optical performance of that eye

Koopmans et al. [28] found positive spherical aberration in refilled human capsules, while natural lenses have negative spherical aberration. If the result is the same in living eyes, the compensatory effect of the lens of the corneal aberrations [55] is lost. It remains to measure living eyes with refilled capsules by wavefront sensing, to see if the aberration pattern is changed. If that is the case, wavefront correction could be achieved by implanting a compensating phakic lens or by corneal reshaping.

It is worth mentioning that a gradient index, like in the crystalline lens, is not required to obtain good optics, as evidenced by the Dubbelman eye model [31], which has a homogenous lens and is practically aberration free.

18.5.4 Long-Term Functionality

Before implantation in humans can commence, the long-term stability of the injected lens must be demonstrated in an animal model. This can be done only in monkeys, because other animals do not have the same accommodation mechanism as humans.

Besides the long-term absence of capsule opacification or other sequelae to lens epithelial cell proliferation, it must be assured that the material itself remains clear in the living environment, that distance refraction remains stable, and that accommodation at a high enough level is maintained. Accommodation should at least correspond with 3 diopters of spectacle power to be useful. Stable accommodation requires that the material does not undergo mechanical or optical changes, and that the accommodative apparatus of the eye remains functional.

References

1. Kessler J (1964) Experiments in refilling the lens. Arch Ophthalmol 71:412–417
2. Kessler J (1966) Refilling the rabbit lens. Further experiments. Arch Ophthalmol 76:596–598
3. Kessler J (1975) Lens refilling and regrowth of lens substance in the rabbit eye. Ann Ophthalmol 7:1059–1062
4. Agarwal LP, Narsimhan EC, Mohan M (1967) Experimental lens refilling. Orient Arch Ophthalmol 5:205–212
5. Agarwal LP, Narsimhan EC, Mohan M (1967) Experimental lens refilling. II. Orient Arch Ophthalmol 5:278–280
6. Parel J-M, Treffers WF, Gelender H, Norton EWD (1981) Phaco-Ersatz: a new approach to cataract surgery. Ophthalmology 88 (Suppl 9): 95
7. Parel J-M, Gelender H, Trefers WF, Norton EWD (1986) Phaco-Ersatz: cataract surgery designed to preserve accommodation. Graefe's Arch Clin Exp Ophthalmol 224:165–173
8. Haefliger E, Parel J-M, Fantes F, Norton EWD, Anderson DR, Forster RK, Hernadez E, Feuer WJ (1987) Accommodation of an endocapsular silicone lens (Phaco-Ersatz) in the nonhuman primate. Ophthalmology 94:471–477
9. Nader N (2004) Accommodating lens refilling procedure may begin clinical trials by 2005. Ocul Surg News 5:1
10. Gindi JJ, Wan WL, Schanzlin DJ (1985) Endocapsular cataract surgery – I. Surgical technique. Cataract 2:6–10
11. Nishi O (1987) Refilling the lens of the rabbit eye after endocapsular cataract surgery. Folia Ophthalmol Jpn 38:1615–1618
12. Nishi O (1989) Refilling the lens of the rabbit eye after intercapsular cataract surgery using an endocapsular balloon and an anterior capsule suturing technique. J Cataract Refract Surg 15:450–454
13. Nishi O, Hara T, Hara T, Hayashi F, Sakka Y, Iwata S (1989) Various kinds of experimental refilling lens with endocapsular balloon. In: Draeger J, Winter R (eds) New microsurgical concepts II. Cornea, posterior segment, external microsurgery. Dev Ophthalmol 18:125–133
14. Nishi O, Hara T, Hara T, Sakka Y, Hayashi F, Nakamae K, Yamada Y (1992) Refilling the lens with an inflatable endocapsular balloon: surgical procedure in animal eyes. Graefe's Arch Clin Exp Ophthalmol 230:47–55

15. Hara T, Sakka Y, Sakanishi K, Yamada Y, Nakamae K, Hayashi F (1994) Complications associated with endocapsular balloon implantation in rabbit eyes. J Cataract Refract Surg 20:507–512
16. Hara T, Hara T (1990) Electric microtrephine for new anterior capsular openings (barbell-like tear-free slit openings). Ophthalmic Surg 21:202–205
17. Hara T, Sakka Y, Hayashi F (2000) Electric double-sleeved vacuuming microtrephine for lens refilling. J Cataract Refract Surg 26:1717–1721
18. Sakka Y, Hara T, Yamada Y, Hara T, Hayashi F (1996) Accommodation in primate eyes after implantation of refilled endocapsular balloon. Am J Ophthalmol 121:210–212
19. Nishi O, Nakai Y, Yamada Y, Mizumoto Y (1993) Amplitudes of accommodation of primate lenses refilled with two types of inflatable endocapsular balloons. Arch Ophthalmol 111:1677–1684
20. Nishi O, Nakai Y, Mizumoto Y, Yamada Y (1997) Capsule opacification after refilling the capsule with an inflatable endocapsular balloon. J Cataract Refract Surg 23:1548–1555
21. Nishi O, Nishi K, Mano C, Ichihara M, Honda T (1997) Controlling the capsular shape in lens refilling. Arch Ophthalmol 115:507–510
22. Nishi O, Nishi K, Mano C, Ichihara M, Honda T (1998) Lens refilling with injectable silicone in rabbit eyes. J Cataract Refract Surg 24:975–982
23. Nishi O, Nishi K (1998) Accommodation amplitude after lens refilling with injectable silicone by sealing the capsule with a plug in primates. Arch Ophthalmol 116:1358–1361
24. Hettlich H-J, Kaden P, Otterbach F, Fritz A, Kreiner CF (1991) Endokapsuläre Polymerisation einer injizierbaren Intraokularlinse – erste In-vitro- und In-vivo-Ergebnisse. In: Schott S (ed) 4. Kongress der Deutschen Gesellschaft für Intraokularlinsen. Springer, Berlin Heidelberg New York
25. Hettlich H-J, Lucke K, Kreiner CF (1992) Light-induced endocapsular polymerization of injectable lens refilling materials. German J Ophthalmol 1:346–349
26. Hettlich H-J, Lucke K, Asiyo-Vogel MN, Schulte M, Vogel A (1994) Lens refilling and endocapsular polymerization of an injectable intraocular lens: in vitro and in vivo study of potential risks and benefits. J Cataract Refract Surg 20:115–123
27. Hettlich H (1996) Accommodative lens refilling. Principles and experiments. Pharmacia and Upjohn Groningen BV, Groningen
28. Koopmans SA, Terwee T, Barkhof J, Haitjema H, Kooijman AC (2003) Polymer refilling of presbyopic human lenses in vitro restores the ability to undergo accommodative changes. Invest Ophthalmol Vis Sci 44:250–257
29. Koopmans SA, Terwee T, Glasser A, Wendt M, Vilupuru A, van Kooten T, Haitjema HJ, Norrby S, Kooijman AC (2005) Accommodative lens refilling in Rhesus monkeys. Submitted to Invest Ophthalmol Vis Sci
30. Gullstrand A (1909) Die Dioptrik des Auges. In: Gullstrand A, von Kries J, Nagel W, von Helmholz H (eds) Handbuch der Physiologischen Optik, vol 1, 3rd edn. Voss, Hamburg
31. Norrby S (2005) The Dubbelman eye model analysed by ray tracing through aspheric surfaces. Ophthalmol Physiol Opt 25:153–161
32. Ho A, Erickson P, Manns F, Pham T, Parel J-M (2001) Theoretical analysis of accommodation amplitude and ametropia correction by varying refractive index in Phaco-Ersatz. Optom Vis Sci 78:405–410
33. Fisher RF (1971) The elastic constants of the human lens. J Physiol 212:147–180
34. Weeber HA, Eckert G, Soergel F, Meyer CH, Pechhold W, van der Heijde RGL (2005) Exp Eye Res 80:425–434
35. Huo PP, Zhou SQ, Liau CJY, Norrby S (2000) Injectable intraocular lens. United States patent US 6,066,172
36. Schwiegerling JT, Schwartz DM, Sandstedt CA, Jethmalani J (2002) Light-adjustable intraocular lenses. Review of refractive surgery. Jobson Publishing, New York
37. Liu Y, Garamszegi L, Hilborn JG, Nguyen TQ, Plummer CJG, Haitjema H, Dillingham KA, Norrby S (2005) Synthesis and characterization of hydroxyhexyl terminated poly(dimethyl-co-diphenyl-co-methyltrifluoropropylsiloxane): Intermediate to injectable intra- ocular lens materials. Submitted to Biomacromolecules
38. De Groot JH, van Beijma FJ, Haitjema HJ, Dillingham KA, Hodd KA, Koopmans SA, Norrby S (2001) Injectable intraocular lens materials based upon hydrogels. Biomacromolecules 2:628–634
39. De Groot JH, Spaans CJ, van Calck RV, van Beijma FJ, Norrby S, Pennings AJ (2003) Hydrogels for an accommodating intraocular lens. An explorative study. Biomacromolecules 4:608–616

40. De Groot JH, Zurutuza A, Moran CR, Graham NB, Hodd KA, Norrby S (2001) Water-soluble microgels made by radical polymerization in solution. Colloid Polymer Sci 279:1219–1224
41. Pusch J (2004) Strategies of preparing transparent latices with application to the synthesis of transparent hydrogels for intraocular lenses. Thesis, Technical University of Eindhoven, Netherlands
42. Murthy KS, Ravi N (2001) Hydrogels as potential probes for investigating the mechanism of lenticular presbyopia. Current Eye Res 22: 384–393
43. Ravi N, Aliyar H, Hamilton P (2004) Novel copolymer compositions with high refractive index and low modulus as lens substitute material. ARVO abstract no 1727
44. Hamilton PD, Aliyar H, Ravi N (2004) Biocompatibility of novel polyacrylamide copolymer suitable for intraocular lenses. ARVO abstract no 1728
45. Kelman CD (1993) Injectable collagen-based compositions for making intraocular lens. International patent WO 93/02639
46. DeVore DP, Kelman CD (1997) Formulation of a collagen-based, injectable IOL. 3rd Accommodation Club meeting, Instituto Barraquer, Barcelona, Spain
47. Gwon A, Enomoto H, Horwitz J, Garner MH (1989) Induction of de novo synthesis of crystalline lenses in aphakic rabbits. Exp Eye Res 49:913
48. Gwon AE, Gruber LJ, Mundwiler KE (1990) A histologic study of lens regeneration in aphakic rabbits. Invest Ophthalmol Vis Sci 31:540–547
49. Gwon AE, Jones RL, Gruber LJ, Mantras C (1992) Lens regeneration in juvenile and adult rabbits measured by image analysis. Invest Opthalmol Vis Sci 33:2279–2283
50. Gwon A, Gruber L, Mantras C, Cunanan C (1993) Lens regeneration in New Zealand albino rabbits after endocapsular cataract extraction. Invest Ophthalmol Vis Sci 34:2124-2129
51. Gwon A, Kuszak J, Lawrence JG (1999) Intralenticular implant study in pigmented rabbits: opacity lensmeter assessment. J Cataract Refract Surg 25:268–277
52. Seibel BS (2002) Endocapsular vortex emulsification technology. Cataract Refract Surg Today
53. Koopmans SA, Terwee T, Haitjema HJ, Deuring H, van Aarle S, Kooijman AC (2004) Relation between injected volume and optical parameters in refilled isolated porcine lenses. Ophthalmic Physiol Opt 24:572–579
54. Kershner RM (2003) Retinal image contrast and functional visual performance with aspheric, silicone, and acrylic intraocular lenses. J Cataract Refract Surg 29:1684–1694
55. Artal P, Guirao A, Berrio E, Williams D. Compensation of corneal aberrations by the internal optics in the human eye. J Vision 1:1–8
56. Fisher RF (1977) The elastic constants of the human lens. J Physiol 212:147–180

19 The Vision Membrane

Lee Nordan, Mike Morris

Refractive surgery creates a dynamic and steady flow of new concepts and products in an attempt to improve results. A major shift in the philosophy of refractive surgery is slowly but steadily emerging as the limitations of keratorefractive surgery become more evident.

Corneal optical aberrations are inherent in the process of changing the shape of the cornea. No amount of "custom cornea" ablation can reduce the significant aberrations caused by the correction of moderate to severe ametropia. In addition, all efforts to correct presbyopia at the surface of the cornea are doomed to failure because the creation of a bifocal cornea creates too much distortion of distance vision. The only possible method of performing aberration-free refractive surgery for all degrees of ametropia is an intraocular lens (IOL)-type device.

At the same time, the advantages of diffractive optics compared to refractive optics for the correction of presbyopia are now well established in pseudophakic bifocal IOL trials in Europe and the USA.

These two items, the limitations of keratorefractive surgery and the advances in diffractive optics, have re-kindled major interest in anterior chamber IOLs as potentially the best method of correcting moderate to severe ametropia, as well as presbyopia. The Vision Membrane employs a radically new approach to the correction of ametropia and presbyopia (Fig. 19.1).

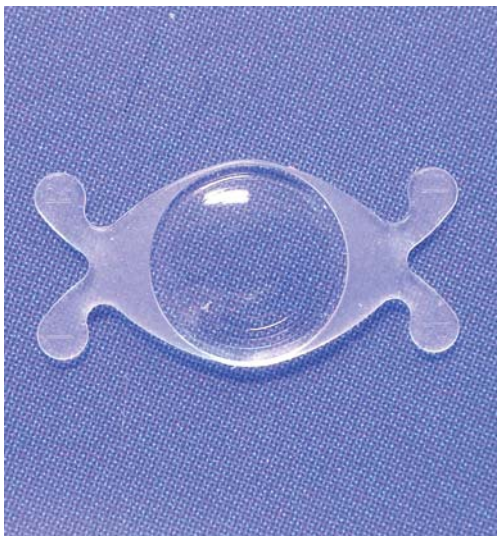


Fig. 19.1. The Vision Membrane is 600 µm thick, possesses a curved optic, employs sophisticated diffractive optics and can be implanted through a 2.60-mm wound

19.1 Historical Development

Refractive surgery has recently enjoyed major popularity as a result of the introduction of the excimer (ultraviolet) laser, which is used in performing laser-assisted in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK). LASIK and PRK are performed on the cornea and generally provide excellent results. However, several factors, such as prolonged healing times, corneal ir-

regular astigmatism, haloes at night and laser expense and maintenance have encouraged the continued development of IOLs for refractive surgery purposes.

A phakic IOL provides better quality of vision than LASIK or PRK, especially as the refractive error increases. Implantation of the Vision Membrane requires only a 3–4 minute surgical procedure using topical anesthetic. Recovery of vision occurs within minutes and is not subject to healing variation. Many cataract surgeons would rather utilize their intraocular surgical skills to perform refractive surgery than perform LASIK.

Up to now, the use of phakic IOLs has been limited for various reasons:

- With anterior chamber IOLs, the thickness of the IOL necessitates a smaller diameter optic in order to eliminate endothelial touch. These small-diameter IOLs cause significant glare because the IOL is centered on the geometric center of the cornea, not on the pupil, which is usually rather displaced from the corneal center. This disparity of centration creates a very small effective optic zone and a large degree of glare as the pupil increases in diameter.
- Iris-fixated IOLs can provide excellent optical results but can be tricky to implant and can be significantly de-centered.
- The true incidence of cataract formation caused by phakic posterior chamber IOLs will be determined in the future.
- Exposure to the risks, imprecise refractive results and inadequate correction of presbyopia associated with the removal of the clear crystalline lens that may still possess 1.00 D of accommodation seems excessive, unwise and clinically lacking to many ophthalmic surgeons.

The Vision Membrane represents the proposition that an ultra-thin, vaulted, angle-fixated device with a 6.00-mm optic will be the simplest and safest IOL to implant and provide the best function. Of course, the quality of results in the marketplace of patient and surgeon opinion will determine the realities of success for all of these products and procedures.

19.2 Description of Vision Membrane

The Vision Membrane is a very thin, vaulted membrane, implanted in the anterior chamber of the eye, which is capable of correcting refractive errors (near sightedness, far sightedness, astigmatism) as well as presbyopia. Depending upon the material, the Vision Membrane ranges from about 450–600 microns in thickness for all refractive powers, compared to approximately 800–1200 microns in thickness for a standard IOL based on refractive optics. The Vision Membrane employs sophisticated modern diffractive optics rather than refractive optics in order to focus incoming light. These dimensions and vaulted shape provide an excellent blend of stability, flexibility and small-incision implantability.

The design of the Vision Membrane provides several major advantages concerning implantation, intraocular safety and improved function, such as:

- The Vision Membrane is very foldable and can be implanted through an incision less than 2.60 mm wide.
- There is greater space between the Vision Membrane and the delicate corneal endothelium as a result of the curved optic.
- The optic can be at least 6.00 mm in diameter in order to eliminate haloes and glare in almost all cases, unlike the 4.50-mm optic of the pioneering Baikoff IOL.
- The quality of the image formed by the diffractive optics is equal to that of an optic employing refractive optics.
- No peripheral iridotomy is necessary, since the Vision Membrane is vaulted and does not create pupillary block.
- The Vision Membrane is angle fixated, allowing for a simpler implantation technique.

- The broad haptic design and the extremely hydrophobic nature of silicone prevent anterior synechiae.
- The extreme flexibility and vault of the Vision Membrane in the anterior chamber allows for one-size-fits-almost-all eyes.

The Vision Membrane is constructed entirely of medical-grade silicone, which has been used as an IOL material for more than 20 years and is approved by the US Food and Drug Administration. Unlike standard IOLs, which use refractive optics, the diffractive optics of the Vision Membrane do not rely significantly on the index of refraction of a given material in order to gain the desired refractive effect.

19.3 Multi-Order Diffractive Optics

The most significant technological advance embodied in the Vision Membrane is the optic, which is based upon the principle of multi-order diffraction (MOD). The MOD principle allows the Vision Membrane to be constant in thinness for all refractive powers and it also eliminates the chromatic aberration, which has made conventional diffractive optics unusable in IOLs in the past.

A conventional diffractive-optic lens utilizes a single diffraction order in which the optical power of the lens is directly proportional to the wavelength of light (Fig. 19.2 a). Therefore, with white-light illumination, every wavelength focuses at a different distance from the lens. This strong wavelength dependence in the optical power produces significant chromatic aberration in the image. For example, if one were to focus the green image onto the retina, the corresponding red and blue images would be significantly out of focus and would produce red and blue haloes around the focused green image. The result with white light is a highly chromatically aberrated image with severe color banding observed around edges of objects; this is, of course, completely unacceptable.

In contrast, the Vision Membrane lens utilizes a sophisticated MOD lens, which is designed to bring multiple wavelengths to a common focus with high efficiency, and is thereby capable of forming sharp, clear images in white light. As illustrated in Fig. 19.2b, with an MOD lens the various diffractive orders bring different wavelengths to the common focal point.

The MOD lens consists of concentric annular Fresnel zones (see Fig. 19.1). The step height at each zone boundary is designed to

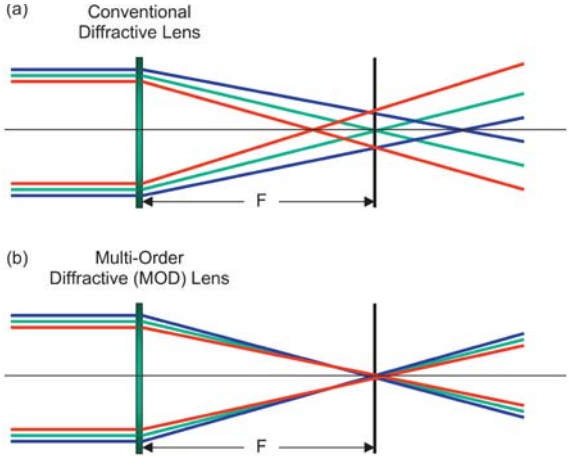


Fig. 19.2. **a** A conventional diffractive lens is highly dispersive and focuses different wavelengths of light to different focal positions. **b** A multi-order diffraction lens brings multiple wavelengths across the visible spectrum to a common focal point, and is thereby capable of forming high-quality images in white light

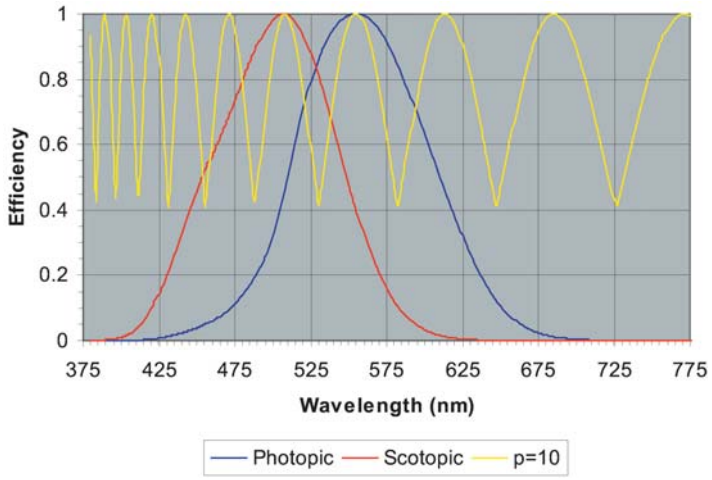


Fig. 19.3. Diffraction efficiency versus wavelength for a p=10 multi-order diffraction lens

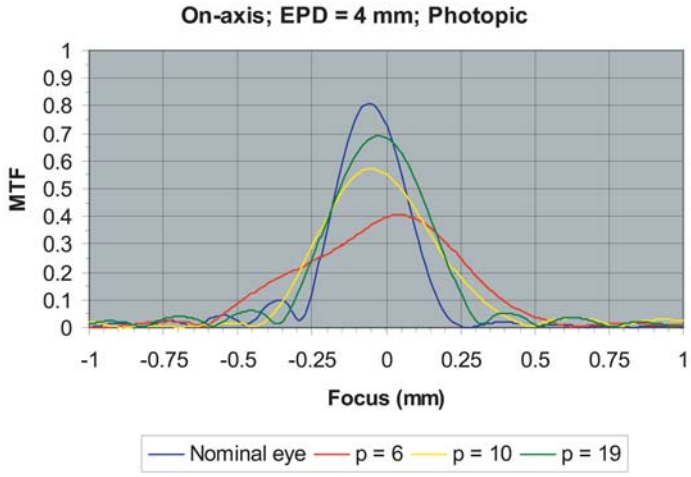


Fig. 19.4. Through-focus, polychromatic modulation transfer function (MTF) at 10 cycles per degree for three different multi-order diffraction lens designs (p=6, 10, and 19), together with an MTF for a nominal eye

produce a phase change of 2p in the emerging wavefront, where p is an integer greater than one. Since the MOD lens is purely diffractive, the optical power of the lens is determined solely by choice of the zone radii, and is independent of lens thickness. Also, because the MOD lens has no refractive power, it is completely insensitive to changes in curvature of the substrate; hence one design is capable of accommodating a wide range of anterior chamber sizes, without introducing an optical power error.

To illustrate its operation, consider the case of an MOD lens operating in the visible wavelength range with p=10. Figure 19.3 illustrates the wavelength dependence of the diffraction efficiency (with material dispersion neglected). Note that several wavelengths within the visible spectrum exhibit 100% diffraction efficiency. As noted above, the principal feature of the MOD lens is that it brings the light associated with each of these high-efficiency wavelengths to a common focal point; hence it is capable of forming high-quality white light images. For reference, the photopic and scotopic visual sensitivity curves are also plotted in Fig. 19.3. Note that with the p=10 design, high diffraction ef-

ficiencies occur near the peak of both visual sensitivity curves.

In Fig. 19.4, we illustrate the on-axis, through-focus, polychromatic modulation transfer function (MTF) at 10 cycles per degree with a 4-mm entrance pupil diameter for three different MOD lens designs (p=6, 10, and 19), together with the MTF for a "nominal eye". Note that both the p=10 and p=19 MOD lens designs yield acceptable values for the in-focus Strehl ratio and also exhibit an extended range of focus compared to a nominal eye. This extended range-of-focus feature is expected to be of particular benefit for the emerging presbyope (typical ages: 40–50 years old).

19.4 Intended Use

There are presently two forms of the Vision Membrane. One is intended for the correction of near sightedness and far sightedness ("single-power Vision Membrane"). The second form is intended for the correction of near sightedness or far sightedness plus presbyopia ("bifocal Vision Membrane"). The range of refractive error covered by the single-power Vision Membrane will be from –1.00 D through –15.00 D in 0.50-D increments for myopia and +1.00 D through +6.00 D for hyperopia in 0.50-D increments.

Patients must be 18 years old or older with a generally stable refraction in order to undergo Vision Membrane implantation. The bifocal Vision Membrane may be used in presbyopes as well as in those patients who have already undergone posterior chamber IOL implantation after cataract extraction and have limited reading vision with this conventional form of IOL.

19.5 Summary

The Vision Membrane is a form of IOL that can correct refractive error and presbyopia. The Vision Membrane's 600-micron thinness and the high-quality optic are achieved by the use of modern diffractive optics as well as medical-grade silicone, which has been used and approved for the construction of IOLs for many years. The Vision Membrane possesses a unique combination of advantages not found in any existing IOL. These advantages consist of simultaneous flexibility, large optic (6.00 mm), correction of presbyopia and refractive error, and increased safety by increasing the clearance between the implant and the delicate structures of the anterior chamber – the iris and the corneal endothelium.

It is likely that refractive surgery in the near future will encompass a tremendous increase in the use of anterior chamber IOLs. The Vision Membrane offers major advantages for the correction of ametropia and presbyopia. LASIK and PRK will remain major factors in the correction of low ametropia and in refining pseudophakic IOL results, such as astigmatism. However, anterior chamber IOL devices such as the Vision Membrane may be expected to attract ocular surgeons with cataract/IOL surgery skills into the refractive surgery arena because refractive surgery results will become more predictable, the incidence of bothersome complications will be greatly reduced and the correction of presbyopia will be possible.

Once again, refractive surgery is continuing to evolve. The factors responsible for evolution as well as a major revolution in refractive surgery are upon us.

20 Bimanual Ultrasound Phacoemulsification

Mark Packer, I. Howard Fine, Richard S. Hoffman

CORE MESSAGES

- Proponents of performing phacoemulsification through two paracentesis-type incisions claim reduction of surgically induced astigmatism, improved chamber stability in every step of the procedure, better followability due to the physical separation of infusion from ultrasound and vacuum, and greater ease of irrigation and aspiration with the elimination of one, hard-to-reach subincisional region.
- The greatest criticism of bimanual phacoemulsification lies in current limitations in IOL technology that could be utilized through these microincisions. At the conclusion of bimanual phacoemulsification, perhaps the greatest disappointment is the need to place a relatively large 2.5-mm incision between the two microincisions in order to implant a foldable IOL.

The promise of bimanual, ultra-small incision cataract surgery and companion intraocular lens (IOL) technology is today becoming a reality, through both laser and new ultrasound power modulations. New instrumentation is available for bimanual surgery, including forceps for construction of the capsulorrhexis, irrigating choppers and bimanual irrigation and aspiration sets. Proponents of performing phacoemulsification through two paracentesis-type incisions claim reduction of surgically induced astigmatism, improved chamber stability in every step of the procedure, better followability due to the physical separation of infusion from ultrasound and vacuum, and greater ease of irrigation and aspiration with the elimination of one, hard-to-reach subincisional region. However, the risk of thermal injury to the cornea from a vibrating bare phacoemulsification needle has posed a challenge to the development of this technique.

In the 1970s, Girard attempted to separate infusion from ultrasound and aspiration, but abandoned the procedure because of thermal injury to the tissue [1, 2]. Shearing and colleagues successfully performed ultrasound phacoemulsification through two 1.0-mm incisions using a modified anterior chamber maintainer and a phacoemulsification tip without the irrigation sleeve [3]. They reported a series of 53 cases and found that phacoemulsification time, overall surgical time, total fluid use and endothelial cell loss were comparable to those measured with their standard phacoemulsification techniques.

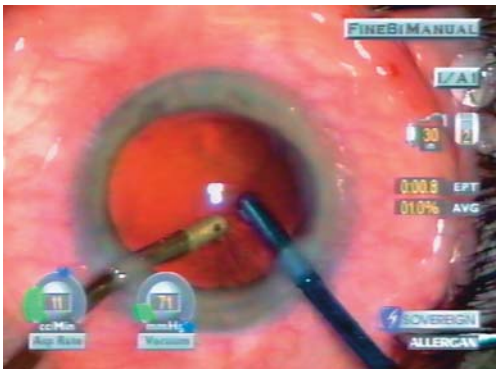


Fig. 20.1. Switching irrigation and aspiration between the hands permits access to all areas of the capsular bag, eliminating one hard-to-reach subincisional area

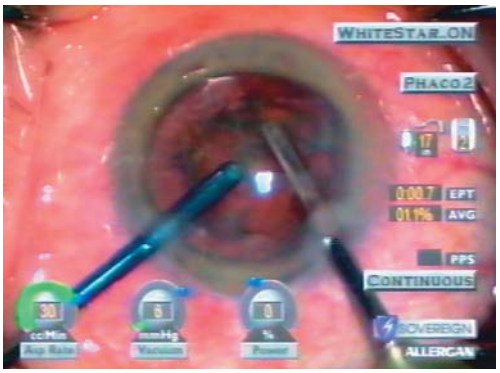


Fig. 20.2. An irrigating chopper in the left hand is used in the same way as a standard chopper

Crozafon described the use of Teflon-coated phacoemulsification tips for bimanual high-frequency pulsed phacoemulsification, and suggested that these tips would reduce friction and therefore allow surgery with a sleeveless needle [4]. Tsuneoka, Shiba and Takahashi determined the feasibility of using a 1.4-mm (19-gauge) incision and a 20-gauge sleeveless ultrasound tip to perform phacoemulsification [5]. They found that outflow around the tip through the incision provided adequate cooling, and performed this procedure in 637 cases with no incidence of wound burn [6]. More recently, they have shown their ability to implant an IOL with a modified injector through a 2.2-mm incision [7]. Additionally, less surgically induced astigmatism developed in the eyes operated with the bimanual technique. Agarwal and colleagues developed a bimanual technique, "Phakonit," using an irrigating chopper and a bare phacoemulsification needle passed through a 0.9-mm clear corneal incision [8–11]. They achieved adequate temperature control through continuous infusion and use of "cooled balanced salt solution" poured over the phacoemulsification needle.

The major advantage of bimanual microincisions has been an improvement in control of most of the steps involved in endocapsular surgery. Since viscoelastics do not leave the eye easily through these small incisions, the anterior chamber is more stable during capsulorrhexis construction and there is much less likelihood for an errant rrhexis to develop. Hydrodelineation and hydrodissection can be performed more efficiently by virtue of a higher level of pressure building in the anterior chamber prior to eventual prolapse of viscoelastic through the microincisions. In addition, separation of irrigation from aspiration allows for improved followability by avoiding competing currents at the tip of the phacoemulsification needle. In some instances, the irrigation flow from the second handpiece can be used as an adjunctive surgical device – flushing nuclear pieces from the angle or loosening epinuclear or cortical material from the capsular bag. Perhaps the greatest advantage of the bimanual technique lies in its ability to remove subincisional cortex without difficulty. By switching infusion and aspiration handpieces between the two microincisions, 360° of the capsular fornices are easily reached and cortical clean-up can be performed quickly and safely (Fig. 20.1) [12].

The same coaxial technique (either chopping or divide-and-conquer) can be performed bimanually, differing only in the need

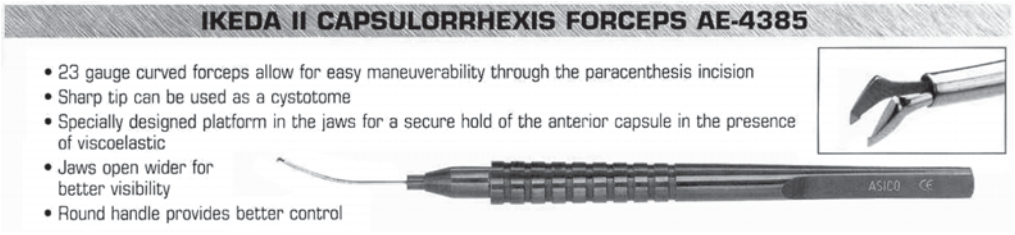


Fig. 20.3. Specially designed capsulorrhexis forceps such as these allow initiation and completion of a continuous tear through an incision of less than 1.3 mm

Fig. 20.4. The irrigating chopper handpiece requires some adjustment on the surgeon's part as it is both heavier and bulkier than a standard chopper

Fig. 20.5. This open-ended vertical irrigating chopper is suitable for denser nuclei

for an irrigating manipulator or chopper (Fig. 20.2). If difficulty arises during the procedure, conversion to a coaxial technique is simple and straightforward – accomplished by the placement of a standard clear corneal incision between the two bimanual incisions.

The disadvantages of bimanual phacoemulsification are real but easy to overcome. Maneuvering through 1.2-mm incisions can be awkward early in the learning curve. Capsulorrhexis construction requires the use of a bent capsulotomy needle or specially fashioned forceps that have been designed to perform through these small incisions (Fig. 20.3). The movement is performed with the fingers, rather than with the wrist. Although more time is required initially, with experience, these maneuvers become routine.

Also, additional equipment is necessary in the form of small incision keratomes, rrhexis forceps, irrigating choppers (Figs. 20.4 and 20.5), and bimanual irrigation/aspiration handpieces (Figs. 20.6 and 20.7). All of the major instrument companies are currently working on irrigating choppers and other microincision adjunctive devices. For the divide-and-conquer surgeon, irrigation can be accomplished with the bimanual irrigation handpiece, which can also function as the second "side-port" instrument, negating the need for an irrigating chopper.

The greatest criticism of bimanual phacoemulsification lies in current limitations in IOL technology that could be utilized

Fig. 20.6. The roughened 0.3-mm aspirator allows removal of cortical material and polishing of the capsule

Fig. 20.7. This blunt, smooth dual-side port irrigator may be used during irrigation/aspiration to safely manipulate cortical or epinuclear material in the capsular bag

through these microincisions. At the conclusion of bimanual phacoemulsification, perhaps the greatest disappointment is the need to place a relatively large 2.5-mm incision between the two microincisions in order to implant a foldable IOL. An analogy to the days when phacoemulsification was performed through 3.0-mm incisions that required widening to 6.0 mm for PMMA IOL implantation is clear. Similarly, we believe the advantages of bimanual phacoemulsification will prompt many surgeons to try this technique, with the hopes that the "holy grail" of microincision lenses will ultimately catch up with technique. Although these lenses are currently not available in the USA, companies are developing lens technologies that will be able to employ these tiny incisions.

Ultimately, it is the surgeons who will dictate how cataract technique will evolve. The hazards of and prolonged recovery from large-incision intra- and extracapsular surgery eventually spurred the development of phacoemulsification. Surgeons who were comfortable with their extracapsular skills disparaged phacoemulsification, until the advantages were too powerful to ignore. Similar inertia has been evident in the transition to foldable IOLs, clear corneal incisions, and topical anesthesia. Yet the use of these practices is increasing yearly. Whether bimanual phacoemulsification becomes the future procedure of choice or just a whim will eventually be decided by its potential advantages over traditional methods and by the collaboration of surgeons and industry to deliver safe and effective technology.

References

1. Girard LJ (1978) Ultrasonic fragmentation for cataract extraction and cataract complications. Adv Ophthalmol 37:127–135
2. Girard LJ (1984) Pars plana lensectomy by ultrasonic fragmentation, part II. Operative and postoperative complications, avoidance or management. Ophthalmic Surg 15:217–220
3. Shearing SP, Relyea RL, Loaiza A, Shearing RL (1985) Routine phacoemulsification through a one-millimeter non-sutured incision. Cataract 2:6–10
4. Crozafon P (1999) The use of minimal stress and the teflon-coated tip for bimanual high frequency pulsed phacoemulsification. Presented at the 14th meeting of the Japanese Society of Cataract and Refractive Surgery, Kyoto, Japan, July 1999

5. Tsuneoka H, Shiba T, Takahashi Y (2001) Feasibility of ultrasound cataract surgery with a 1.4 mm incision. J Cataract Refract Surg 27:934–940
6. Tsuneoka H, Shiba T, Takahashi Y (2002) Ultrasonic phacoemulsification using a 1.4 mm incision: clinical results. J Cataract Refract Surg 28:81–86
7. Tsuneoka H, Hayama A, Takahama M (2003) Ultrasmall-incision bimanual phacoemulsification and AcrySof SA30AL implantation through a 2.2 mm incision. J Cataract Refract Surg 29:1070–1076
8. Agarwal A, Agarwal A, Agarwal S, Narang P, Narang S (2001) Phakonit: phacoemulsification through a 0.9 mm corneal incision. J Cataract Refract Surg 27:1548–1552
9. Pandey SK, Werner L, Agarwal A, Agarwal A, Lal V, Patel N, Hoyos JE, Callahan JS, Callahan JD (2002) Phakonit: cataract removal through a sub-1.0 mm incision and implantation of the ThinOptX rollable intraocular lens. J Cataract Refract Surg 28:1710–1713
10. Agarwal A, Agarwal S, Agarwal A (2003) Phakonit with an AcriTec IOL. J Cataract Refract Surg 29:854–855
11. Agarwal A, Agarwal S, Agarwal A, Lal V, Patel N (2002) Antichamber collapser. J Cataract Refract Surg 28:1085–1086; author reply 1086
12. Hoffman RS, Packer M, Fine IH (2003) Bimanual microphacoemulsification: the next phase? Ophthalmology Times 15:48–50

21 Low-Ultrasound Microincision Cataract Surgery

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CORE MESSAGES

- Microincisional cataract surgery (MICS) utilizing incisions of 1.5 mm or less implies not only a smaller incision size but also a global transformation of the surgical procedure towards minimal aggressiveness.
- MICS surgery using ultrasound or laser offers the advantage of having a superior biological effect on the ocular structures compared to conventional phacoemulsification procedures.
- With the new developing technology of phacoemulsification machines and the power settings, together with adequate instruments, all the cataract grades are amenable to MICS. Refractive lens exchange using MICS has the advantage of preventing induced astigmatism and wound complications.

Microincisional cataract surgery (MICS) and operating through incisions of 1.5 mm or less are no longer new concepts in cataract surgery. Understanding this global concept implies that it is not only about achieving a smaller incision size, but also about making a global transformation of the surgical procedure towards minimal aggressiveness.

The incision size has been an important issue of investigation for many years, starting from reducing the size from 10 mm in intracapsular surgery to 7 mm in extracapsular cases, and finally from 3.4 mm to 2.8 mm using the phacoemulsification technique. The need to reduce the incision size was mainly for the purpose of reducing the induced astigmatism, as modern cataract surgery is also refractive surgery. The other essential factor in the development of a new technique was how we could reduce the amount of energy being liberated inside the eye when using ultrasound emulsification. Until now the amount of energy being liberated or the power used to operate a cataract inside the eye has not been determined. As it is a source of mechanical, wave-shock, constitutional and thermal damage, this energy and power delivered inside the eye has an effect on the ocular structures. The thermal effects of this liberated energy affect all the intraocular structures, endothelial cells, corneal stroma, and incisions.

The main issues and steps involved in the transition from phacoemulsification to MICS may be summarized as follows:

1. *Fluidics optimization*: MICS surgery should be performed in a closed environment. Because the probe fits the incision exactly, fluid outflow through the incision is minimal or absent. Taking into account the closed chamber concept, we need to optimize the probe function and diameter to balance the outflow and inflow that is taking place every second in this new environment [1].
2. *Bimanuality and separation of functions:* The use of both hands simultaneously is another factor that added to the success of MICS surgery. The surgeon should be aware that working with two hands means working with irrigation and aspiration separately. In this way, irrigation and aspiration not only become part of the procedure, but also become instruments in the hands of the surgeon [1].
3. *New microinstruments:* The newly developed microinstruments have been designed to perform their function, while at the same time acting as probes. They do not necessarily need to be similar to the traditional choppers or forceps, which were mostly manufactured or created in the extracapsular era. These new specifically designed instruments, coordinated with the fluidics and combined with the new maneuvers, will improve efficiency compared with normal phacoemulsification that has been performed until now through "small" incisions [1].
4. *Lasers*: Lasers have become a technological possibility in performing cataract surgery. It is true that their capability of handling very hard nuclei is subject to debate. However, the elegance of laser, the very low levels of energy developed inside the eye, and the possibilities of improving the efficiency of this technology in the future makes them attractive for the MICS surgeon.
5. *Ultrasonic probes*: Ultrasonic probes have to be modified in order to be used without sleeve. Taking off the sleeve is not the only way to use the probes in performing microsurgery [2, 3]. These probes should be designed to be used more efficiently, manipulating through microincisions without creating any tension in the elasticity of the corneal tissue. Furthermore, the friction created between the probe and the corneal tissue should be avoided with the special protection and smoothness of the external profile of the probe.
6. *New intraocular lens (IOL) technology:* The technological development that enables operation of cataracts through a 1.5-mm incision should be adequately balanced with the development of IOL technologies capable of performing this surgery with IOL implantation though this microincision. At present, different IOLs of new designs, new biomaterials and new technologies are available for implantation through microincisions. Should we change the material, develop the optic technology, or both?

21.1 MICS Surgical Instruments

Surgical instruments are important for safe and adequate MICS surgery. With a minor movement of the surgeon's fingers, the metal instruments respond more than expected, uniting the fingers and the instruments to achieve excellent manipulation during MICS surgery (Fig. 21.1).

The instruments are finger-friendly and each has its own function. Once the surgeon becomes accustomed to them, they will be a new extension to his or her fingers inside the eye [1].

1. The MICS microblade is a diamond or stainless-steel blade that can create a trapezoidal incision from a 1.2- to 1.4-mm microblade (Katena Inc., Denville, NJ, USA) [1].

Fig. 21.1. MICS surgical instruments

2. The MICS capsulorrhexis forceps (Katena Inc., Denville, NJ, USA) has microtriangular tips that can be used to puncture and grasp the capsule to perform the capsulorrhexis with a single instrument. It can also be used for other intraocular maneuvers such as grasping the iris to perform small iridotomies or to cut pre-existing synechia in the anterior or posterior chambers [1].
3. Alio MICS prechoppers are for bimanual use and, as opposed to the single-handed prechopping technique, can be used for all types of cataracts regardless of the hardness. The tip has a blunted square hook that should be introduced gently underneath the anterior capsular rim, with one instrument opposite the other [1].
4. The MICS hydrodissector or irrigating fingernail (Katena Inc., Denville, NJ, USA) facilitates manipulation of the nucleus fragments, as well as functions as an irrigating instrument. It can also be useful to divide the nuclear fragments further. The forward-directed pointing tip, which has a highly blunt point-like end, is like a fingernail – hence its name. The irrigating fluid exits through a large port (1 mm) directed under the tip. This feature helps to push away the posterior capsule to obtain stable fluidic control in the anterior chamber when combined with the phacoemulsification or MICS aspirating tip. The flow rate or the free irrigation flow of this instrument is 72 cc/min, which is considered the highest flow of any instrument performing the same function in the market. This generates anterior chamber stability regardless of the high vacuum level in MICS [1].
5. The MICS irrigating chopper (Katena Inc., Denville, NJ, USA) was designed to chop medium to hard cataract if prechopping has not been performed. It has a sharp pointed triangular-shaped tip, which is angled downward to "chop" off segments of the nucleus. The irrigating fluid exits through a large port (1 mm) directed under the tip of the instrument [1].
6. The MICS aspiration handpiece (Katena Inc., Denville, NJ, USA) has a bullet-shaped tip designed for easy entry through a paracentesis incision and a 0.3-mm diameter aspirating port close to the tip in the interior part of the curvature. This design works to maintain the fluid balance in the anterior chamber when used with the MICS irrigating fingernail and MICS chopper, and while aspirating the residual cortex [1].
7. The intraocular manipulator (Katena Inc., Denville, NJ, USA) is multifunctional and efficiently helps in iridolenticular synechia dissection, IOL manipulation and other intraocular maneuvers such as vitreous knuckles or stabilization of the IOL. The conical base is the same diameter as the internal MICS incision in order to maintain the stability of the anterior chamber, thus preventing viscoelastic outflow [1].

8. MICS scissors (Katena Inc., Denville, NJ, USA) have a 23-gauge (0.6-mm) shaft, so they fit exactly through a very small paracentesis. They have extremely delicate blunt-tipped blades, which are ideal for cutting synechia and capsular fibrosis and membranes, as well as for performing small iridotomies [1].

21.2 Low-Ultrasound MICS

21.2.1 Mackool Tips

Mackool tips generate less heat at the incision compared to non-Mackool tips. The thickness of the polymer sheathing the tip is only 50–75 microns, which is much less than that of the infusion sleeve; its thermal conductivity is also much less than that of conventional infusion sleeve material. This tubing system also prevents the spraying effect caused by the solution coming out of the irrigating tip, which occurs when power settings higher than 30% are used for MICS.

Most of the tips are three-quarters of an inch long and have a 45° angulation. Soft and moderately hard nuclei up to +2 hardness can be easily emulsified by using low-ultrasound MICS (LUS-MICS); prechopping will shorten the time of surgery and the energy delivered inside the eye. Hard nuclei of grade 3 or over are more amenable to LUS-MICS, which is capable of emulsifying hard nuclei of any density.

21.2.2 Incisions

After the surgical field has been isolated and an adjustable eye speculum (Duckworth & Kent, England) has been inserted, the positive corneal meridian is marked and two trapezoidal incisions of 1.2 mm internally and 1.4 mm externally are performed using the Alio corneal keratome. An external incision of 1.4 mm will be adequate for instrument manipulation. The two incisions are performed in clear cornea 90° apart, at 10 and 2 o'clock, followed by the injection of 1% preservative-free lidocaine diluted 1:1 in balanced salt solution.

21.2.3 Prechopping (Counter Chopping Technique)

After the capsulorrhexis is performed using Alio's capsulorrhexis forceps, the prechopping is performed. This is a bimanual technique, requiring the use of both hands with the same efficiency. This technique allows manual cut and division of the nucleus, without creating any grooves prior to the MICS procedure. In order to protect the endothelium and to perform an adequate counter chopping technique, more dispersive or cohesive viscoelastic material is injected. The technique of counter prechopping could be applied to all surgical grades of cataract density (up to grade +5). A chopper is introduced through one of the two incisions, depending on the surgeon's preference. A nuclear manipulator is introduced through the other incision to decrease the stress on the capsule and zonules being inserted beneath the anterior capsulorrhexis edge. The rounded microball tip of the nuclear manipulator will protect the posterior capsule during the prechopping procedure. The tips of the nuclear manipulator and the chopper should be aligned on the same axis, together with the hardest point of the nucleus along the direction of the lens fibers; appropriate force is then applied between the two instruments. After cracking the nucleus into fragments, the nucleus is rotated and the maneuver is repeated on the other axis to crack the nucleus into four quadrants. Once the fragments have been obtained, the MICS Mackool tip and Alio hydromanipulator fingernail are introduced to manipulate and emulsify the fragments [1].

21.2.4 Low-Ultrasound MICS Surgical Steps

The MICS technique can be performed using either phacoemulsification (LUS-MICS) or a laser (laser-MICS). After termination of prechopping, the Accurus or Infiniti machine is adjusted according to the settings described previously. The LUS-MICS tip and Alio's hydromanipulator fingernail are introduced through the two incisions and an inferior segment is mobilized and brought in contact with the MICS tip, assisted with Alio's hydromanipulator, in order to be emulsified. After the elimination of the first hemi-nucleus, the second prechopped hemi-nucleus is rotated to the distal portion of the bag and Alio's hydromanipulator is used to mobilize the segments, making them easy to emulsify. Using this technique reduces the tendency for the nuclear material to come up into the anterior chamber during the procedure, and maintains its position within the epinuclear cover. Following the emulsification of all the nuclear segments, the epinuclear rim is trimmed in the different quadrants to remove all the cortical material remaining in the capsular bag. An adequate ophthalmic viscosurgical device is injected deep in the capsular bag to reform the bag and prepare it for IOL implantation; this helps to force the Viscoat anteriorly, facilitating its removal to prevent a postoperative rise in intraocular pressure [1].

21.3 MICS versus Phacoemulsification: a Clinical Study

In a prospective, comparative, clinically controlled, masked study of a consecutive series of 100 eyes (50 patients), 50 eyes were operated with the MICS technology and 50 eyes were operated using conventional phacoemulsification. The patients had a mean age of 65.5 (45–86) years. Mean cataract grade was 3.01 with the lens opacities classification system III grading scale [4].

21.3.1 Inclusion Criteria

Patients ranging between 40 and 90 years:
1. Cataract eyes with a grade of 1–4
2. Normal clear corneas
3. Low or a minimal degree of astigmatism
4. Normal anterior segment
5. Normal retina and posterior segment
6. Normal intraocular pressure

Eyes with any ocular pathology were excluded.

21.3.2 Pre- and Postoperative Examinations

All patients had a full ophthalmologic examination, preoperatively, at 1 week, 1 month and 3 months postoperatively:
1. Uncorrected and best corrected visual acuity
2. Anterior and posterior segment examination
3. Intraocular pressure measurement
4. Endothelial cell count using the SP 2000 P TOPCON machine
5. Laser flaremeter using the FC 1000KOWA laser flaremeter
6. Cataract density evaluation

21.3.3 Operative Parameters

Only one memory and prechopping technique was used in both groups:
1. Phacoemulsification parameters:
   (a) Aspiration: 550 cc/min
   (b) Power: 20–30 %
   (c) Flow rate: 20 cc/min
2. MICS operative parameters:
   (a) Aspiration: 550 cc/min
   (b) Power: 20–30 %
   (c) Flow rate: 20 cc/min

The eyes included in the study were divided into the following two groups:

1. Group I: MICS versus regular phacoemulsification (100 eyes) in the following parameters:
   (a) Incision size
   (b) Cataract grade
   (c) Endothelial cell count
   (d) Laser flare
   (e) Pachymetry
   (f) Mean emulsification time
   (g) Mean power
   (h) Mean effective phacoemulsification time
2. Group II: MICS versus regular phacoemulsification (40 eyes of 24 patients) in the following parameters:
   (a) Postoperative astigmatism
   (b) Intraoperative saline consumption

21.3.4 Results of LUS-MICS

Microincision cataract surgery using ultrasound or laser offers the advantage of having a superior biological effect on the ocular structures compared with conventional phacoemulsification procedures. A study of the parameters that control the procedure in both techniques found the following.

Working in a closed compartment while operating through the microincisions is characteristic of MICS surgery. The pressure of the anterior chamber was found to be higher in MICS surgery than in conventional phacoemulsification.

The vacuum used during surgery was found to be higher in MICS surgery, which is essential in performing this type of surgery.

The percentage of phacoemulsification differed according to the machine used. The grades of cataract operated with different machines were compared. A lower percentage of phacoemulsification was performed when using MICS 30- and 300-burst modes (Accurus system), but using the 300-burst mode delivered less power to the ocular tissue when the power was calculated (Fig. 21.2).

Microincision cataract surgery offers the advantage of lowering the percentage of cells loss during the procedure. Comparing the re-

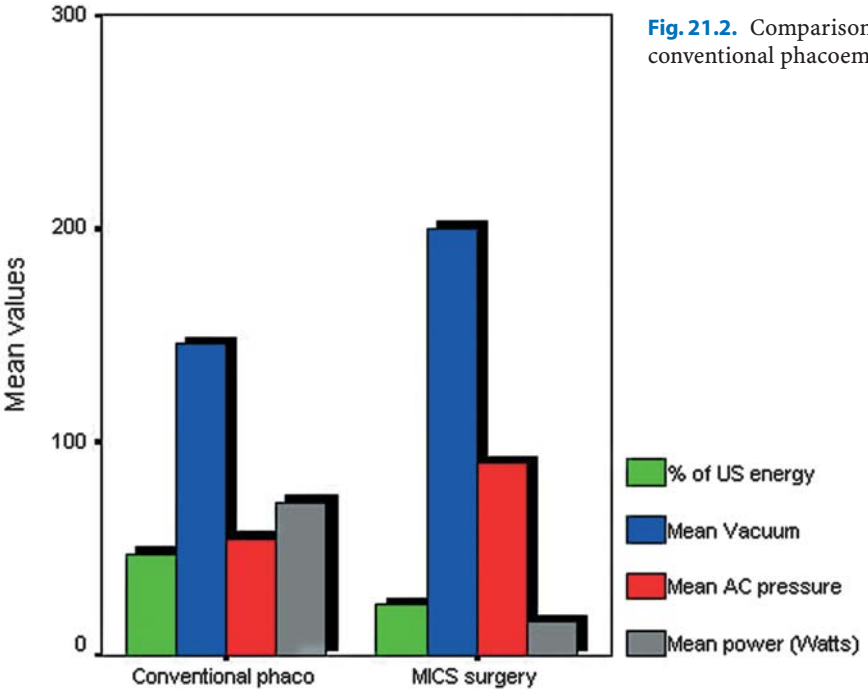

Fig. 21.2. Comparison of MICS with conventional phacoemulsification

Table 21.1. Comparison of flare and inflammatory cell values between MICS and conventional phacoemulsification

		Conventional phaco-emulsification (mean ± SD)		MICS surgery (mean ± SD)	
Preoperative	Flare value	5.8	6.3	3.8	3.3
	Inflammatory cells	0.74	1.5	0.5	0.8
First month	Flare value	9.9	11.1	5.7	3.3
	Inflammatory cells	1.5	1.5	1.3	1.2
Third month	Flare value	5.2	3.5	5.2	2.3
	Inflammatory cells	0.9	1.1	0.6	0.5

Table 21.2. Comparisons between MICS and phacoemulsification

	MICS	Phacoemulsification	*p* value
Mean cataract grade	2.95 (0.99 SD)	3.05 (0.93 SD)	0.745
Mean incision size	1.7 (0.21 SD)	3.3 (0.25 SD)	0.001
Mean endothelial cell loss (%)	11.37 (13.24 SD)	15.65 (19.96 SD)	0.330
Mean flare value	14.51 (17.01 SD)	12.37 (16.79 SD)	0.669
Mean anterior chamber cells	11.2 (11.99 SD)	14.11 (17.59 SD)	0.363
Mean phacoemulsification time	0.38 (0.41 SD)	0.41 (0.44 SD)	0.259
Mean power (%)	5.28 (3.91 SD)	19.2 (10.98 SD)	0.001
Mean effective phacoemulsification time	2.19 (2.77 SD)	9.2 (12.38 SD)	0.001

sults of endothelial cell count pre- and postoperatively, there was no statistically significant difference between the numbers, although the cell loss was reduced in MICS surgery. The flare and inflammatory cells developing after the procedure were also found to be equal and even lower after MICS surgery (Table 21.1).

21.3.4.1 Group I

This group included 100 eyes of 50 patients divided in the following way:

1. Phacoemulsification: 50 eyes
2. MICS: 50 eyes

The means and standard deviations of the cataract grade, incision size, endothelial cell count, flare and cells in the anterior chamber, phacoemulsification time, percentage power and effective phacoemulsification time are shown in Table 21.2.

Table 21.3. Mean changes in pachymetry

	MICS	Phaco-emulsification
Preoperative	549.7 (34.3 SD)	551.7 (33.23 SD)
1 day	599.4 (56.11 SD)	600.6 (71.25 SD)
1 month	552.7 (31.86 SD)	554.8 (33.73 SD)
3 months	554.8 (34.44 SD)	552.3 (34.61 SD)

Table 21.4. Comparison of mean surgical time and saline consumption between the two groups

	MICS	Phacoemulsification	*p* value
Mean surgical time	4.4 (1.67 SD)	3.13 (2.29 SD)	0.121
Mean saline consumption	92.77 (34.52 SD)	113.84 (30.96 SD)	0.198

21.3.4.2 Group II

Twenty eyes (11 patients) operated with MICS were compared to 20 eyes (13 patients) operated with phacoemulsification. The eyes included in this group provided data about astigmatic changes and saline consumption, which were compared between the two techniques.

1. Astigmatic changes: using vector analysis to detect the postoperative changes in astigmatism:
   (a) MICS group:
   (i) Seventeen eyes had a change of ≤0.5 D
   (ii) Three eyes had a change ranging between 1 and 0.5 D
   (b) Phacoemulsification group:
   (i) Four eyes had a change of ≤0.5 D
   (ii) Six eyes had a change ranging between 0.5 and 1.0 D
   (iii) Ten eyes had a change of more than 1 D
2. Saline consumption and pachymetry: the differences between the two groups are illustrated in Tables 21.3 and 21.4.

21.4 Advantages of MICS

Performing small incisions in cataract surgery has a number of theoretical advantages:

1. Fast visual recovery and improved visual outcome
2. Decrease in postoperative astigmatism
3. Reduction in the anatomical healing time
4. Fewer complications
5. IOL insertion through microincisions is now possible
6. Reduction in the operating time

MICS can be performed using laser energy, which is as safe as ultrasound energy. The use of either source of energy permits:

1. Visual acuity improvement on the first postoperative day
2. Reduction of the inflammatory reaction postoperatively
3. Lower percent of in endothelial cell loss

Improving both techniques will open the way to emulsification of all grades of nucleus density; this could be achieved by improving the safety and the fluidity of the low-ultrasound phacoemulsification and laser, with the possibility of obtaining greater aspiration and more vacuum that helps to maintain continuous contact between the crystalline lens to be removed and the laser aperture.

21.5 Conclusions

Microincision cataract surgery today is becoming a popular technique in crystalline lens surgery. With the new developing technology of phacoemulsification machines and power settings, together with adequate instruments, all the cataract grades are amenable to MICS. Refractive lens exchange using the MICS technique has the advantage of preventing induced astigmatism and wound complications.

References

1. Alio JL, Rodriguez-Prats JL, Galal A (2004) Micro-incision cataract surgery. Highlights of Ophthalmology International, Miami, USA
2. Tsuneoka H, Hayama A, Takahama M (2003) Ultrasmall-incision bimanual phacoemulsification and AcrySof SA30AL implantation through a 2.2 mm incision. J Cataract Refract Surg 29:1070–1076
3. Tsuneoka H, Shiba T, Takahashi Y (2002) Ultrasonic phacoemulsification using a 1.4 mm incision: clinical results. J Cataract Refract Surg 28:81–86
4. Chylack LT, Wolfe JK, Singer DM et al (1993) Lens opacities classification system III. Arch Ophthalmol 111:831–833

22 The Infiniti Vision System

Mark Packer, Richard S. Hoffman, I. Howard Fine

CORE MESSAGES

- NeoSoniX technology (Alcon) represents a hybrid modality involving low-frequency oscillatory movement that may be used alone or in combination with standard high-frequency ultrasonic phacoemulsification. Softer grades of nuclear sclerosis may be completely addressed with the low-frequency modality, while denser grades will likely require the addition of ultrasound.
- One of the most recent innovations in phacoemulsification has been the introduction of AquaLase to the Infiniti. Rather than using mechanical ultrasound energy from a vibrating phacoemulsification needle to emulsify lens material, the AquaLase handpiece uses heated pulses of balanced salt solution (57 °C) propelled from the tip at 50 Hz to strain and dissolve the lens for aspiration.

The newest addition to the Alcon line of phacoemulsification machines is the Infiniti Vision System (Alcon Laboratories Inc., Fort Worth, TX). The Infiniti offers three phacoemulsification options including traditional ultrasound, NeoSoniX, and AquaLase (Fig. 22.1). NeoSoniX was originally introduced as an upgrade on the Alcon Legacy and provides the capability of delivering oscillatory sonic as well as axial ultrasonic energy, separately or in combination. The oscillatory motion involves small 2.0° arc excursions at a 100-Hz frequency. The addition of oscillatory movement improves surgeon control and occlusion management by constantly repositioning material on the phacoemulsification tip. It also enhances cutting performance, allowing for lower energy production with a resultant lower risk for thermal injury and improved followability [1].

The Legacy and the Infiniti may be programmed to initiate NeoSoniX at any desired level of ultrasound energy. It appears most efficacious at 50% amplitude with a horizontal chopping technique in the AdvanTec burst mode at 50% power, 45 ml/min linear flow and 450 mmHg vacuum [1]. A 0.9-mm microflare straight ABS tip rapidly impales and holds nuclear material for chopping. During evacuation of nuclear segments, the material flows easily into the tip, with very little tendency for chatter and scatter of nuclear fragments. With refinement of parameters, a 57% reduction in average phacoemulsification power, and an 87% reduction in effective phacoemulsification time have been reported [1].

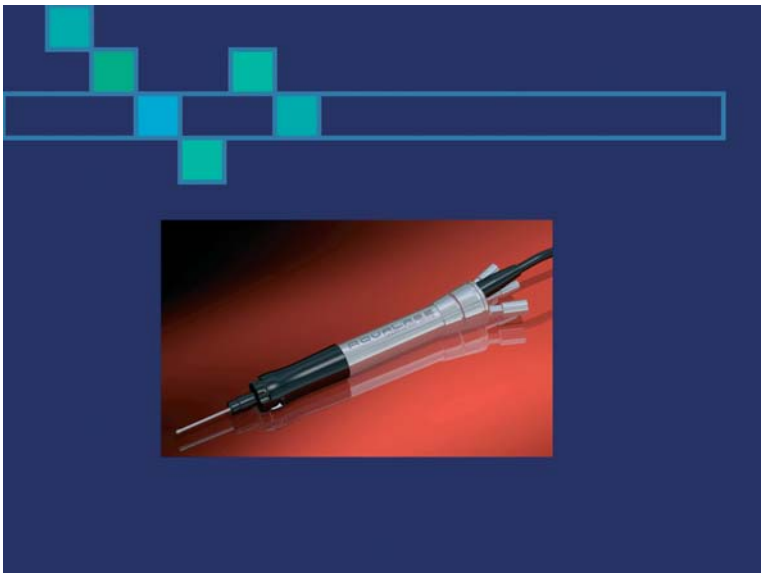

Fig. 22.1. AquaLase phacoemulsification system

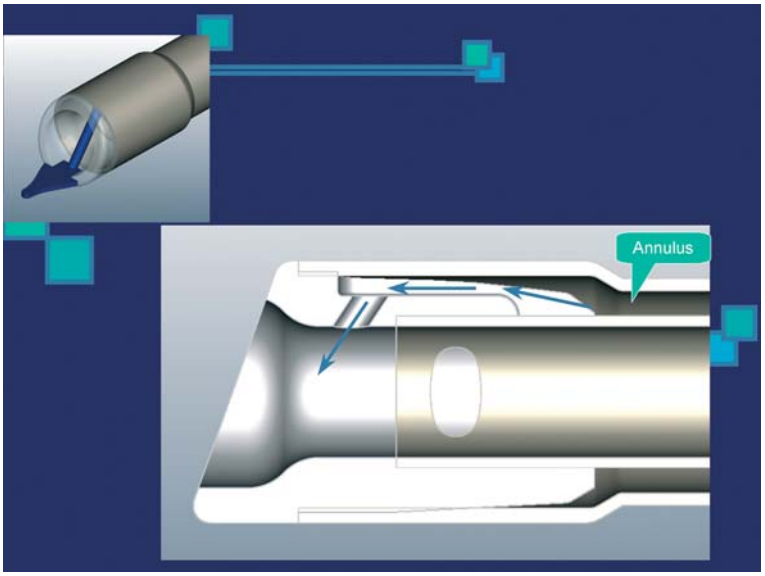

Fig. 22.2. Inside the AquaLase handpiece, 4-microliter fluid pulses are generated as current passes between electrodes. The fluid pulses pass through a channel in the outer sleeve of the tip and then leave through a single small orifice positioned within the lumen of the needle

NeoSoniX has permitted further reduction in the application of ultrasonic energy to the eye when used in conjunction with ultrasound, and allowed non-thermal cataract extraction when used alone. It represents an important new modality in phacoemulsification technology.

One of the most recent innovations in phacoemulsification has been the introduction of AquaLase to the Infiniti. Rather than using mechanical ultrasound energy from a vibrating phacoemulsification needle to emulsify lens material, the AquaLase handpiece uses heated pulses of balanced salt solution (57 °C)

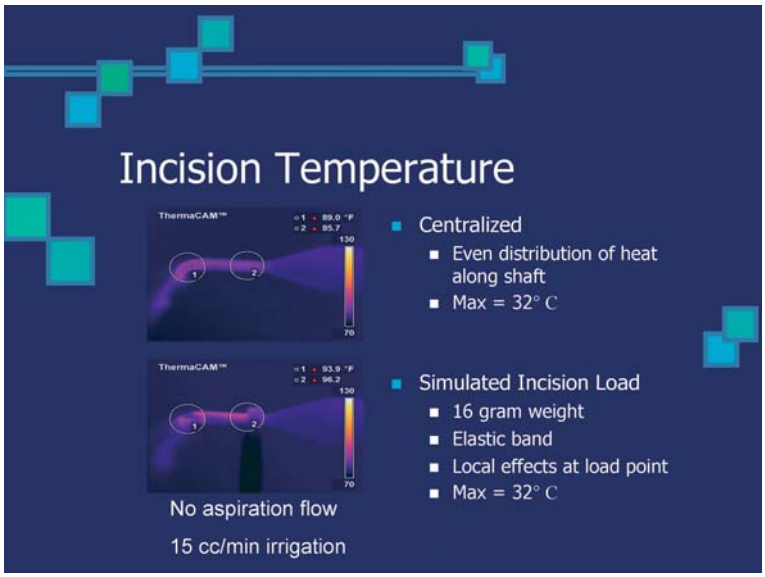

Fig. 22.3. The AquaLase handpiece uses heated pulses of balanced salt solution (57 °C) propelled from the tip at 50 Hz to strain and dissolve the lens for aspiration

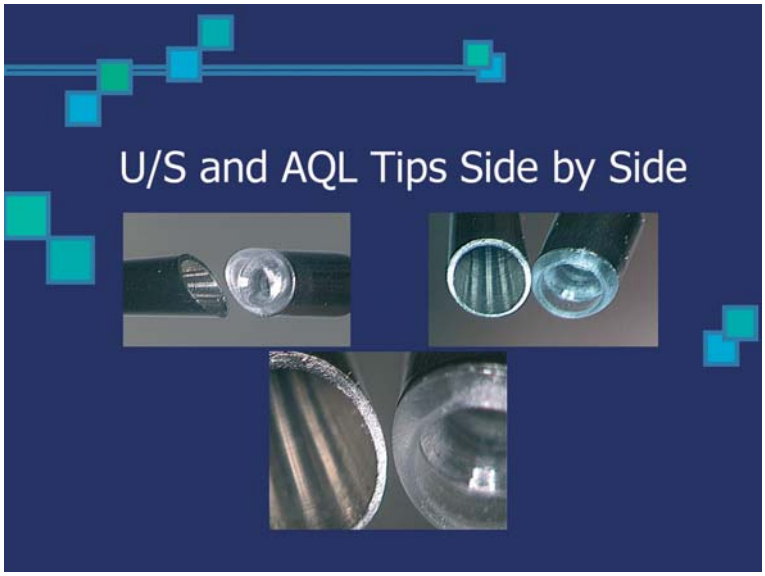

Fig. 22.4. Comparison of ultrasound and AquaLase tips

propelled from the tip at 50 Hz to strain and dissolve the lens for aspiration. Inside the AquaLase handpiece, 4-microliter fluid pulses are generated as current passes between electrodes. The fluid pulses pass through a channel in the outer sleeve of the tip and then leave through a single small orifice positioned within the lumen of the needle (Figs. 22.2, 22.3 and 22.4).

AquaLase offers the advantage of eliminating the risk of incisional burns and potentially reducing the risk for posterior capsule rupture. Another possible advantage of AquaLase would be the reduction of lens epithelial cells

(LECs) through mechanical dislodgment, with a potential resultant lower incidence of posterior capsule opacification [2]. If this becomes a reality, the bimanual microincision approach to cataract extraction may be an ideal technique for AquaLase use, since all portions of the capsule fornices with their populations of LECs could be easily treated with the fluid pulses. Another means of addressing LECs independent of the AquaLase system could entail the use of distilled-deionized water placed within a sealed capsule to lyse these cells [3].

Other features of the Infiniti include improved fluidics aided by an infusion pressure sensor and reduced system compliance by means of a rigid elastomeric membrane within the peristaltic design. Compared with the Alcon Legacy, the Infiniti has demonstrated reduced surge and better vacuum performance with faster dynamic rise times yielding improved accuracy and response.

References

1. Fine IH, Packer M, Hoffman RS (2002) New phacoemulsification technologies. J Cataract Refract Surg 28:1054–1060
2. Mackool RJ, Brint SF (2004) AquaLase: a new technology for cataract extraction. Curr Opin Ophthalmol 15:40–43
3. Crowston JG, Healey PR, Hopley C et al (2004) Water-mediated lysis of lens epithelial cells attached to lens capsule. J Cataract Refract Surg 30:1102–1106

23 The Millennium

Rosa Braga-Mele, Terrence Devine, Mark Packer

CORE MESSAGES

- Refinements in power modulations and control on the Millennium Microsurgical System (Bausch & Lomb, Rochester, NY) with the introduction of phacoburst technology (Bausch & Lomb) have reduced the total amount of ultrasonic energy delivered to the eye during phacoemulsification.
- Bausch & Lomb has developed new custom control software for power modulation, which is now available as an upgrade to the Millennium phacoemulsification machine. The custom control software consists of a new pulse mode, fixed-burst mode and multiple-burst mode.
- The new advanced flow system on the Millennium employs a closed fluid design for maximum patient protection against bacterial infection, minimized transducer volume and rigid pump head tubing for low compliance.

Cataract surgery and phacoemulsification techniques have advanced dramatically over the past 10 years. The initiative has been towards less traumatic surgery by using ultrasound-assisted phacoaspiration instead of vacuum-assisted phacoemulsification. Refinements of power modulations [1] and control have allowed reductions to the total amount of ultrasonic energy delivered into the eye and thus less risk of injury to the corneal endothelium and the incision. Agarwal [2] has reported his success using the Phaconit method of bimanual lens extraction though a 0.9-mm incision with a sleeveless phacoemulsification needle. Recent research on the Sovereign system has shown that microphaco using a bare phacoemulsification needle through a relatively small incision could be conducted using specific parameters on that machine [3].

Even though currently there is not a lens available that will fit through a small stab incision, there are obvious advantages of lens extraction through two smaller incisions [4]. Irrigation though the side-port instrument can assist in moving lens material toward the phacoemulsification needle tip; when irrigation is delivered through the sleeve, the irrigation fluid may potentially create a current, which may push the lens material away from

the needle tip. Separating the irrigation from the aspiration should theoretically direct loose pieces towards the aspiration port. Second, nuclear material can be approached from two different incision sites if needed. Third, subincisional cortex can be removed more easily. Fourth, small stab incisions theoretically allow for a tightly closed and stable anterior chamber, but in microphaco flow is sometimes reduced and chamber stability may be in question.

The feasibility of performing bimanual sleeveless phacoemulsification is dependent on the phacoemulsification needle staying cool during the surgery. With a sleeve in place, a thermal barrier exists consisting of the irrigating fluid surrounded by the Teflon sleeve. With modern high-vacuum phacoemulsification and chopping techniques, the total ultrasound time to perform phacoemulsification is decreasing. Furthermore, adjuvant methods of cooling the wound can be applied, such as using cooled irrigating solution or providing direct and constant irrigation externally to the incision site. This has raised the question of whether a sleeve is absolutely necessary to prevent corneal wound burns. Furthermore, the Bausch & Lomb Millennium Microsurgical System operates at a relatively low ultrasonic frequency of 28.5 kHz. This machine could potentially produce less heat than others operating at higher frequencies since the amount of heat generated is proportional to the operating frequency, although this also depends on other factors such as the ability of the machine to maintain resonant frequency, i.e. continuous autotuning.

Refinements in power modulations and control on the Millennium Microsurgical System (Bausch & Lomb, Rochester, NY) with the introduction of phacoburst technology (Bausch & Lomb) have reduced the total amount of ultrasonic energy delivered to the eye during phacoemulsification. These improvements lower the risk of thermal injury to the cornea and incision site.

23.1 Phacoburst Mode

Phacoburst mode is ideal for phacoemulsification chop techniques because it decreases chatter, essentially creating more effective cutting and better followability. Lens chatter is caused primarily by the fluid wave and the acoustical wave "pushing" the nucleus away from the tip. Cavitation is increased by lower frequencies, i.e. 28.5 kHz produces more cavitation than 40 kHz. During the "off" time (pulse interval), cavitation is decreased, but more importantly so is the fluid wave and acoustical wave. This reduces repulsive forces and allows more time for vacuum-holding force to develop. This reduces chatter. Newer power modulations with the addition of custom control software (Bausch & Lomb) with microburst mode technology, hyperpulse technology, and variable duty cycle capabilities on the Millennium have led to refinements that further lower the total ultrasonic energy delivery into the eye. Duty cycle is the duration or "on time" expressed as a percentage of the total cycle time.

23.2 Pulse Mode

The new expanded pulse mode allows the surgeon to program linear power, pulses per second (pps) between 0 and 120, and a duty cycle between 10 and 90 % of on time.

23.3 Fixed-Burst Mode

Fixed-burst mode also allows for linear power, and the surgeon directly programs the pulse duration (on time) and pulse interval (off time). Duration and interval choices are between 4 and 600 milliseconds (Fig. 23.1).

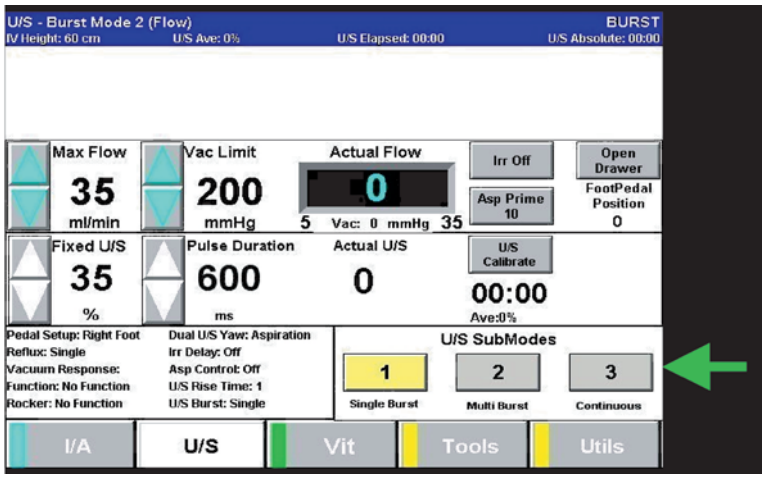

Fig. 23.1. Bausch & Lomb's new custom control software for power modulation consists of a pulse mode, fixed-burst mode and multiple-burst mode

23.4 Multiple-Burst Mode

Multiple-burst mode utilizes fixed power, and the surgeon selects the pulse duration of between 4 and 600 milliseconds. The cycle time then varies from 1,200 milliseconds at the start of foot pedal position 3 and becomes progressively shorter as the pedal is depressed.

When selecting a mode, it is helpful to remember that both pulse and fixed- burst modes allow the surgeon to design a particular pulse cycle pattern that is then locked in as the power is varied with the linear foot pedal. In contrast, multiple-burst mode locks in a particular ultrasonic power and then provides linear control of the interval or off time.

23.5 Vacuum Control

The Millennium is unique in that it allows dual-linear control of vacuum in the Venturi cassette or pump speed with the advanced flow system. This gives the surgeon the ability to control and titrate the amount of vacuum-holding force when the phacoemulsification tip is occluded and the flow rate and "followability" when the phacoemulsification tip is open. These two modalities (burst and dual-linear control) used in unison are ideal for phacoemulsification chop, because they create more effective cutting and better followability. A combination of refined power modulations and enhanced fluidic control aids in the performance of microincisional cataract surgery on any system.

23.6 Feasibility Study

An initial feasibility in vitro study was performed on human cadaver eyes to measure the temperature of the bare phacoemulsification needle within the clear corneal wound using different power modalities on the Millennium [5]. In pulse mode and a non-occluded state at 100% power, the maximum temperature attained was 43.8°C. In the occluded state at 30% power, the maximum temperature was 51.7°C after 70 seconds of occlusion. For phacoburst mode (multiple-burst modality) with a 160-millisecond burst-width interval, the maximum temperature was 41.4°C (non-occluded at 100% power). At 80% power, the maximum temperature was 53.2°C within 60 seconds of full aspiration occlusion with the foot pedal fully depressed. For 80 milliseconds, burst-width interval in both the non-occluded and occluded

states (100% power, foot pedal fully depressed for 3 minutes) showed no significant temperature rise. The maximum temperature was 33.6°C in the non-occluded state and 41.8°C in the occluded state.

In all instances, the corneal wound remained clear. No wound burn or contracture was noted. The results revealed that bare-needle phacoemulsification did not result in clinically significant temperature rises in phacoburst mode using 80-millisecond burst-width intervals of up to 100% power and 160-millisecond burst-width intervals of up to 70% power. The demonstrated temperature rises were under clinically unusual parameters. Phacoemulsification with a sleeveless needle through a small stab incision can be safely performed using conventional phacoburst-mode settings within certain parameters on the Millennium.

23.7 Additional Research

Other recent wound temperature studies have focused on the newer power modulations, including hyperpulse and fixed burst. Settings of 8 pps with a 30% duty cycle; 120 pps with a 50% duty cycle; and fixed burst of 4 milliseconds on, 4 milliseconds off; 6 milliseconds on, 12 milliseconds off; and 6 milliseconds on, 24 milliseconds off, were all tested with a thermocoupler in the wound as described previously. There were no significant temperature rises.

Investigators in a clinical study [6] used a quick-chop technique on cataracts ranging from 2 to 4+ nuclear sclerosis. They performed phacoemulsification using a burst-mode setting of 100-millisecond burst-width intervals with a bare, sleeveless MicroFlow 30° bevel, 20-gauge phacoemulsification needle (Bausch & Lomb, Rochester) through a 1.4-mm incision made with a diamond blade. This wound size allows the 1.1-mm phacoemulsification tip to enter the eye without any strain on the wound, and a small amount of egressing fluid cools the wound without compromising the chamber. The investigators also employed irrigation through a 1.4-mm side-port incision using a 19-gauge irrigating chopper with two side irrigating ports. Using an irrigating chopper with two side irrigating ports rather that one main central port may improve the fluidics within the anterior chamber, thus allowing currents to direct nuclear fragments to the phacoemulsification tip, whereas a direct stream of fluid could repel fragments.

In this study, vacuum levels were set on the Millennium using Venturi mode to vary between 165 and 325 mmHg using dual-linear technology, and the bottle height was set between 115 and 125 cm. The ability to vary the vacuum during bimanual phacoemulsification allows the surgeon the control necessary to titrate the vacuum level according to the fluidics and thereby minimize anterior chamber instability. For instance, one could use high vacuum when the tip is fully occluded and hold is necessary in order to ensure an efficient chop technique. However, once occlusion is broken, the surgeon may lower the vacuum to a level that produces the level of flow and followability desired for efficient removal of the segment. Under the parameters and technique described earlier, phacoemulsification has been performed safely and effectively by means of a bimanual sleeveless method with no trauma or burns to the wounds. Absolute phacoemulsification times ranged from 2 to 4 seconds in these cases, and the average case time from skin to skin was approximately 2 minutes longer than with conventional phacoemulsification techniques. The wounds were clear on the first postoperative day with negligible corneal edema.

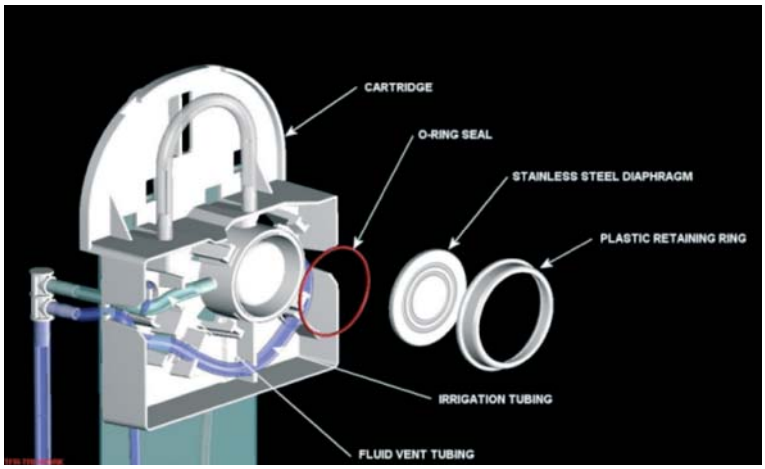

Fig. 23.2. Advanced flow system cartridge

23.8 Advanced Flow System

The new advanced flow system on the Millennium employs a closed fluid design for maximum patient protection against bacterial infection, minimized transducer volume and rigid pump head tubing for low compliance. The tubing features an increased inner diameter for better flow as well as increased wall thickness for improved kink resistance and less compliance of aspiration tube (Fig. 23.2).

23.9 Custom Control Software

Bausch & Lomb has developed new custom control software for power modulation, which is now available as an upgrade to the Millennium phacoemulsification machine (Fig. 23.3). The custom control software consists of a new pulse mode, fixed-burst mode and multiple-burst mode. The software also allows the surgeon to program up to three different power modulations as "sub-modes", which can then be selected during surgery with either the console panel or the foot pedal by moving it inward in yaw while in position 2. To describe these pulse and burst modes, we define the ultrasonic energy "on time" as "duration", "off time" as "interval" and the sum of "on" and "off" as "cycle time". Duty cycle is the duration or "on time" expressed as a percentage of the total cycle time.

The new expanded pulse mode allows the surgeon to program linear power, pulses per second (pps) between 0 and 120, and duty cycle between 10 and 90% of "on" time. Pulse duration can be as low as 4 milliseconds and pulse interval can be as low as 2 milliseconds. The duty cycle setting may be limited by the selection of pulse rate. For example, a pps=100 means the cycle time would be 10 milliseconds. The minimum pulse duration is 4 milliseconds, so the minimum duty cycle would be 40% (not 10%). Below 20 pps, the duty cycle can be as low as 10%.

All three new modes (pulse, fixed burst, and multiple burst) can be programmed with either ultrasound rise time 1 or 2. Rise time 1 is the conventional and familiar "square-wave" pulse, while rise time 2 produces a unique "ramped" power. Rise time 2 is based on an "envelope modulation" or "pulsed pulse". The "envelope" is defined as a series of pulses whose total "on time" equals 250 milliseconds (Figs. 23.4 and 23.5).

Now, with five power modulations (continuous, pulsed, single burst, fixed burst, and multiple burst) and two ultrasonic rise time options, the surgeon is able to "custom de-

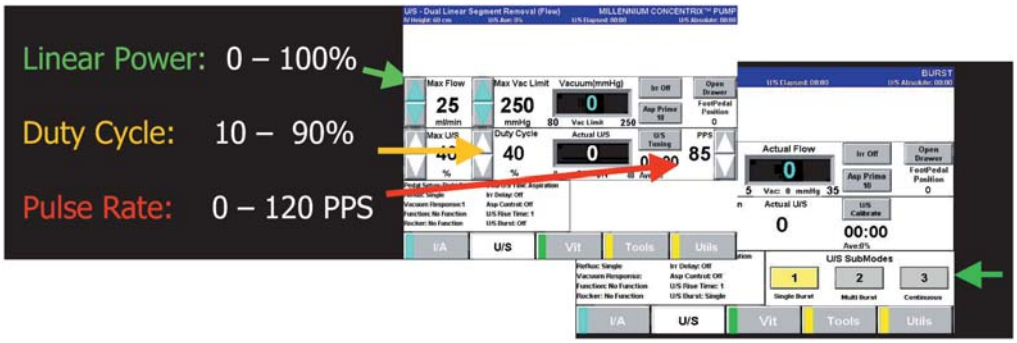

Fig. 23.3. Pulse mode allows the surgeon to program linear power, pulses per second (pps) between 0 and 120, and duty cycle between 10 and 90% of "on" time

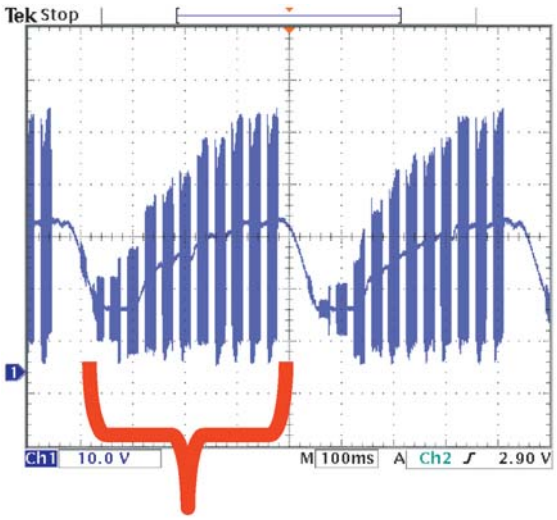

Fig. 23.4. Rise time 2 is based on an "envelope modulation" or "pulsed pulse". The "envelope" is defined as a series of pulses whose total "on time" equals 250 milliseconds

sign" the ultrasound to match any particular technique or type of cataract (Fig. 23.6). But, with almost limitless possibilities, a few guiding principles might be helpful. Our goal is to minimize ultrasonic energy and heat, and to maximize followability and cutting efficiency. To achieve this, we must balance the pulse interval and duration. The interval, or "off" time, allows for cooling and unopposed flow to the tip. The pulse duration produces the mechanical impact, acoustical wave, fluid wave and cavitation, all of which contribute to emulsify the nucleus. Compared to square-wave pulses, rise time 2 not only produces less total energy but its graduated off time improves followability and allows more time to develop vacuum-holding force. During sculpting, however, long intervals or "off times" may result in the needle pushing the nucleus, producing greater stress on the zonules. This becomes more likely with denser cataracts, so for a 3+ to 4+ nucleus the surgeon may want to use either linear power or rise time 1 with very short "off" intervals for sculpting, and then switch to rise time 2 for segment removal. With 1+ to 2+ cataracts, ultrasound rise time 2 would be less likely to pull through the soft eye epinucleus to dam-

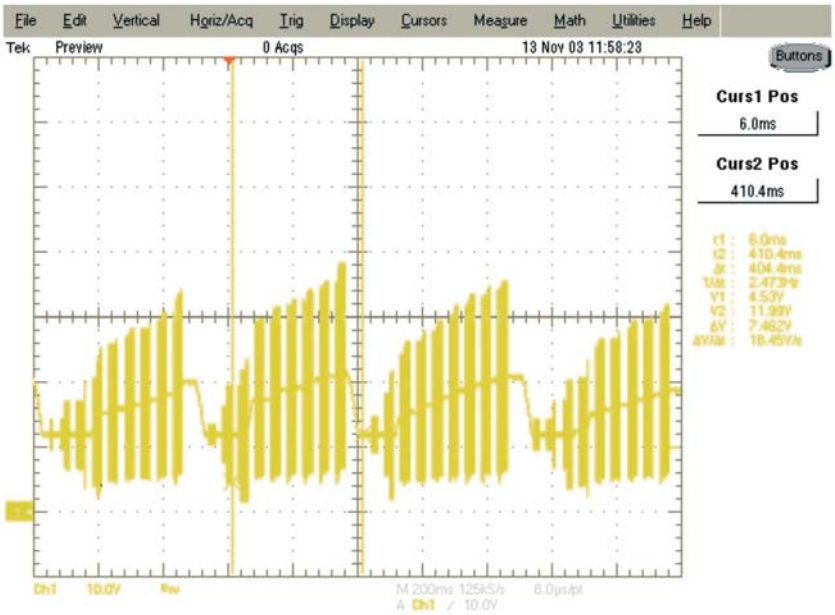

Fig. 23.5. Pulse or burst mode with rise time setting 2

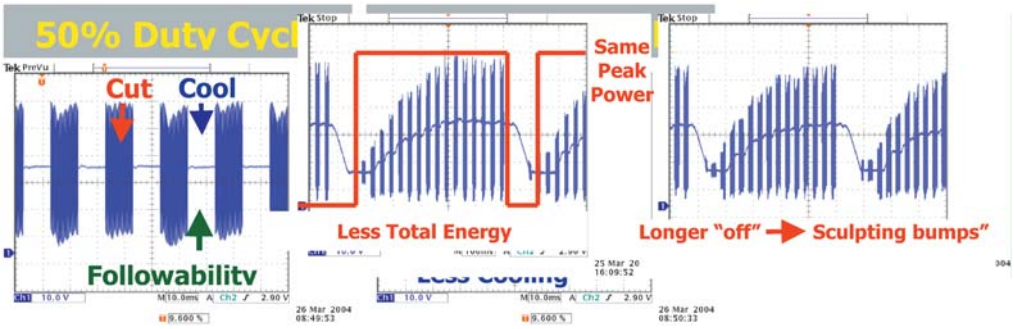

Fig. 23.6. The ultrasound can be "custom designed" to match any particular technique or type of cataract

age the capsule. In selecting a mode, it is helpful to remember that both pulse and fixed burst allow the surgeon to design a particular pulse cycle pattern, which is then "locked in" as the power is varied with the linear foot pedal. In contrast, multiple burst "locks in" a particular ultrasonic power and then provides linear control of the interval or "off time."

23.10 Conclusion

The Millennium gives the surgeon the ability to access and control flow, vacuum, and ultrasound power simultaneously and to the degree that is necessary. It is the ability to deliver short bursts of phacoemulsification power and utilize vacuum as an extractive technique – ultimately decreasing the thermal energy delivery to the eye and speeding visual recovery – that facilitates the use of sleeveless microincisional cataract surgery.

References

1. Fine IH, Packer M, Hoffman R (2001) Use of power modulations in phacoemulsification – choo-choo chop and flip phacoemulsification. J Cataract Refract Surg 27:188–197
2. Agarwal A, Agarwal S, Agarwal A (1999) Phakonit and laser phakonit lens removal through 0.9 mm incision. In: Agarwal A, Agarwal S, Sachdev MS et al (eds) Phacoemulsification, laser cataract surgery and foldable IOLs. Jaypee Brothers, New Delhi
3. Soscia W, Howard J, Olson R (2002) Bimanual phacoemulsification through 2 stab incisions. A wound temperature study. J Cataract Refract Surg 28:1039–1043
4. Tsuneoka H, Shiba T, Takahashi Y (2002) Ultrasonic phacoemulsification using a 1.4 mm incision: clinical results. J Cataract Refract Surg 28:81–86
5. Braga-Mele R, Lui E (2003) Feasibility of sleeveless bimanual phacoemulsification on the Millennium Microsurgical System. J Cataract Refract Surg 29:2199–2203
6. Braga-Mele R (2003) Bimanual sleeveless phaco on the Millennium: wound temperature and clinical studies. Paper presented at the ASCRS/ASOA Symposium; 15 Apr 2003, San Francisco, California

24 The Staar Sonic Wave

Richard S. Hoffman, I. Howard Fine, Mark Packer

CORE MESSAGES

- Sonic technology offers an innovative means of removing cataractous material without the generation of heat or cavitational energy by means of sonic rather than ultrasonic technology.
- Both the Staar SuperVac coiled tubing and the cruise control limit surge flow that occurs during high flow rates, such as those that develop upon loss of occlusion.
- The ability to review surgical parameters on a timeline as the video image is being displayed allows surgeons to analyze unexpected surgical events as they are about to occur in a recorded surgical case. This information can then be used to adjust parameters or surgical technique to avoid these pitfalls in future cases.

The last decade has given rise to some of the most profound advances in both phacoemulsification technique and technology. Techniques for cataract removal have moved from those that use mainly ultrasound energy to emulsify nuclear material for aspiration to those that use greater levels of vacuum and small quantities of energy for lens disassembly and removal. Advances in phacoemulsification technology have taken into account this ongoing change in technique by allowing for greater amounts of vacuum to be utilized. In addition, power modulations have allowed for more efficient utilization of ultrasound energy with greater safety for the delicate intraocular environment [1, 2].

One of the most recent new machines for cataract extraction is the Staar Wave (Fig. 24.1). The Wave was designed as an instrument that combines phacoemulsification technology with new features and a new user interface. Innovations in energy delivery, high-vacuum tubing, and digitally recordable procedures with video overlays make this one of the most technologically advanced and theoretically safest machines available.

Fig. 24.1. The Staar Wave phacoemulsification console

24.1 Conventional Surgical Features

The Wave contains all of the customary surgical modes routinely used to perform cataract surgery, including ultrasound, irrigation/aspiration, vitrectomy, and diathermy. The ultrasound handpiece is a lightweight (2.25 ounces), two-crystal, 40-kHz piezoelectric autotuning handpiece that utilizes a load-compensating ultrasonic driver. The driver senses tip loading 1,000 times a second, allowing for more efficient and precise power adjustments at the tip during phacoemulsification.

One of the unique features of the Wave is its ability to adjust vacuum as a function of ultrasound power. This feature is termed "A/C" (auto-correlation) mode. It enables lens fragments to be engaged at low-vacuum levels in foot position 2. Vacuum levels are proportionally increased with increases in ultrasound power in foot position 3. Proportional increases in vacuum allow for faster aspiration of lens fragments by overcoming the repulsive forces generated by ultrasound energy at the tip. Another unique feature of the Wave is the random pulse mode, which randomly changes the pulse rate. This increases followability by preventing the formation of standing waves in front of the tip.

24.2 New Surgical Features

Although ultrasonic phacoemulsification allows for relatively safe removal of cataractous lenses through astigmatically neutral small incisions, current technology still has its drawbacks. Ultrasonic tips create both heat and cavitational energy. Heating of the tip can create corneal incision burns [3, 4]. When incisional burns develop in clear corneal incisions, there may be a loss of self-sealability, corneal edema, and severe induced astigmatism [5]. Cavitational energy results from pressure waves emanating from the tip in all directions. Although increased cavitational energy can allow for phacoemulsification of dense nuclei, it can also damage the corneal endothelium and produce irreversible corneal edema in compromised corneas with pre-existing endothelial dystrophies. Another aspect of current phacoemulsification tech-

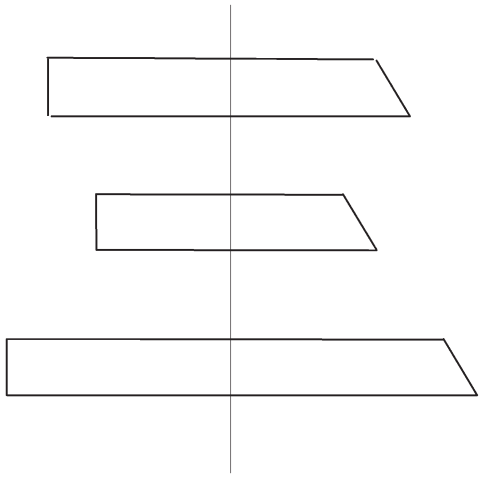

Fig. 24.2. The tip undergoes compression and expansion, continuously changing its dimensional length. Heat is generated due to intermolecular friction

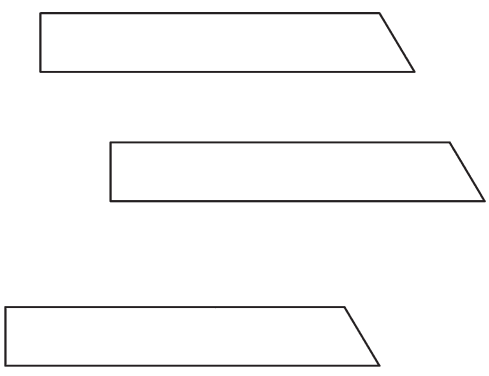

Fig. 24.3. The tip moves back and forth without changing its dimensional length. Heat due to intermolecular friction is eliminated

nology that has received extensive attention for improvement has been the attempt to maximize anterior chamber stability while concurrently yielding larger amounts of vacuum for lens removal. The Wave addresses these concerns of heat generation and chamber stability with the advent of its revolutionary "Sonic" technology and high-resistance "SuperVac" coiled tubing.

Sonic technology offers an innovative means of removing cataractous material without the generation of heat or cavitational energy by means of sonic rather than ultrasonic technology. A conventional phacoemulsification tip moves at ultrasonic frequencies of between 25 and 62 kHz. The 40-kHz tip expands and contracts 40,000 times per second, generating heat due to intermolecular frictional forces at the tip that can be conducted to the surrounding tissues (Fig. 24.2). The amount of heat is directly proportional to the operating frequency. In addition, cavitational effects from the high-frequency ultrasonic waves generate even more heat.

Sonic technology operates at a frequency much lower than ultrasonic frequencies. Its operating frequency is in the sonic rather than the ultrasonic range, between 40 and 400 Hz. This frequency is 1–0.1 % lower than ultrasound, resulting in frictional forces and related temperatures that are proportionally reduced. In contrast to ultrasonic tip motion,

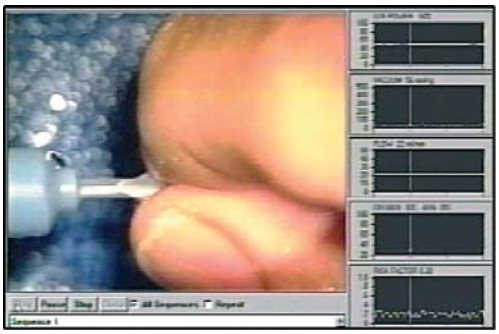

Fig. 24.4. Phacoemulsification tip in sonic mode being grasped with an ungloved hand, demonstrating lack of heat generation

Fig. 24.5. High-magnification view of SuperVac coiled tubing

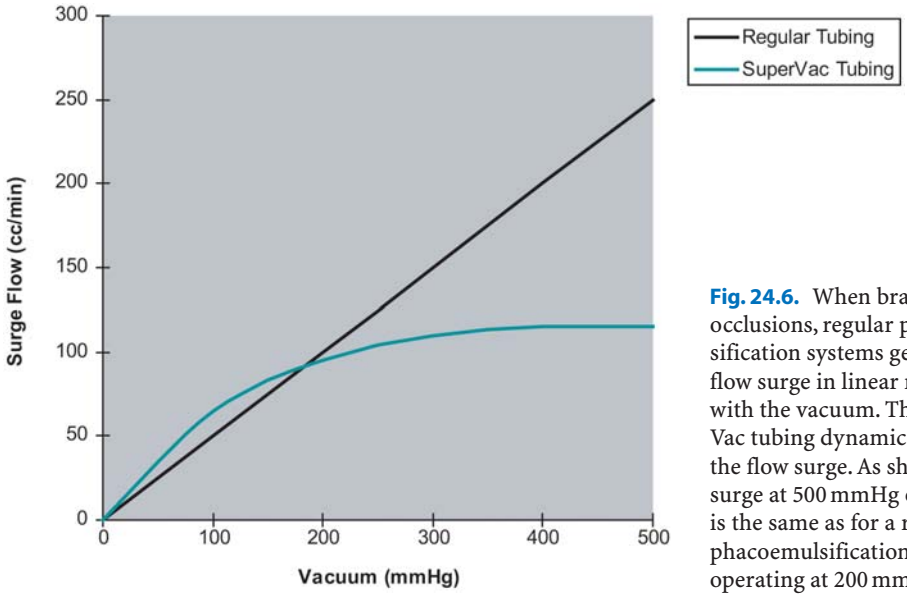

Fig. 24.6. When braking occlusions, regular phacoemulsification systems generate a flow surge in linear relation with the vacuum. The SuperVac tubing dynamically limits the flow surge. As shown, the surge at 500 mmHg or higher is the same as for a regular phacoemulsification system operating at 200 mmHg

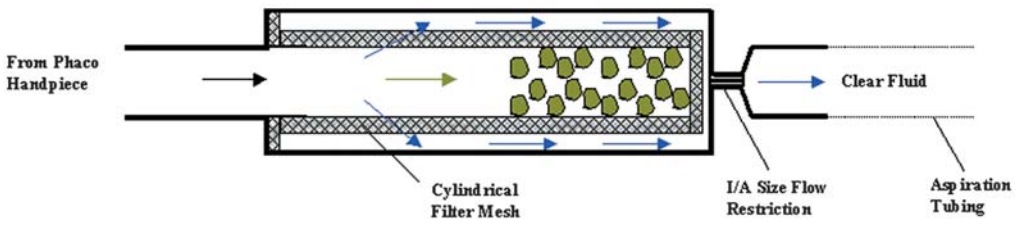

Fig. 24.7. Schematic representation of the Staar cruise control

the sonic tip moves back and forth without changing its dimensional length (Fig. 24.3). The tip of an ultrasonic handpiece can easily exceed 500° Celsius in a few seconds, while the tip of the Wave handpiece in sonic mode barely generates any frictional heat, as intermolecular friction is eliminated (Fig. 24.4). In addition, the sonic tip does not generate cavitational effects and thus true fragmentation, rather than emulsification or vaporization, of the lens material takes place. This adds more precision and predictability in grooving or chopping and less likelihood for corneal endothelial compromise or incisional burns.

The most amazing aspect of the sonic technology is that the same handpiece and tip can be utilized for both sonic and ultrasonic modes. The surgeon can easily alternate between the two modes using a toggle switch on the foot pedal when more or less energy is required. The modes can also be used simultaneously with varying percentages of both sonic and ultrasonic energy. We have found that we can use the same chopping cataract extraction technique [4] in sonic mode as we do in ultrasonic mode, with no discernible difference in efficiency.

The ideal phacoemulsification machine should offer the highest levels of vacuum possible with total anterior chamber stability. The Staar Wave moves one step closer to this ideal with the advent of the SuperVac tubing (Fig. 24.5). SuperVac tubing increases vacuum capability to up to 650 mmHg while significantly increasing chamber stability. The key to chamber maintenance is to achieve a positive fluid balance, which is the difference between infusion flow and aspiration flow. When occlusion is broken, vacuum previously built in the aspiration line generates a high aspiration flow that can be higher than the infusion flow. This results in anterior chamber instability. The coiled SuperVac tubing limits surge flow resulting from occlusion breakage in a dynamic way. The continuous change in direction of flow through the coiled tubing increases resistance through the tubing at high flow rates, such as upon clearance of occlusion of the tip (Fig. 24.6). This effect only takes place at high flow rates (greater than 50 cc/min). The fluid resistance of the SuperVac tubing increases as a function of flow and unoccluded flow is not restricted.

Staar has also recently released its cruise-control device, which has a similar end result of increasing vacuum capability while maintaining anterior chamber stability. The cruise control (Fig. 24.7) is inserted between the phacoemulsification handpiece and the aspiration line. It has a small port at the end attached to the aspiration line to restrict flow when high flow rates are threatened, such as during occlusion breakage. A cylindrical mesh within the cruise-control tubing is designed to capture all lens material before it reaches the restricted port, thus occlusion of the port is prevented. The mesh is designed with enough surface area to guarantee that aspiration fluid will always pass through the device. This device is especially important during bimanual phacoemulsification, as the anterior chambers of eyes undergoing this technique are susceptible to chamber instability if postocclusion surge develops.

24.3 New User Interface

Perhaps the most advanced feature on the Wave is its new user interface. The Wave Powertouch computer interface mounts onto the Staar cart above the phacoemulsification console. The touchscreen technology allows the user to control the surgical settings by touching parameter controls on the screen. The interface utilizes Windows software and is capable of capturing digitally compressed video displaying the image live on the monitor screen. A 6-gigabyte hard disk can store up to 8 hours of video without the need for VHS tapes.

The most useful and educational aspect of the Wave interface is the event list, which displays multiple data graphs to the right of the

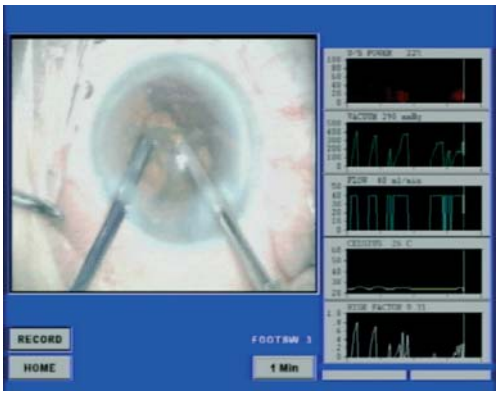

Fig. 24.8. Wave video overlay demonstrating multiple data graphs to the right with power, vacuum, flow, and theoretical tip temperature parameters

surgical video (Fig. 24.8). The event list displays recorded power, vacuum, flow, theoretical tip temperature, and risk factor for incisional burns on a constantly updated timeline. The vertical line in each graph represents the actual time event occurring on the video image. Surgical events to the left of the line represent past events, while data to the right of the line represent future events ready to occur. A CD-Rom recorder can be used to transfer surgical video and data graphs from the hard drive to a writable CD. This allows the surgeon to view each case on any Windows home or office computer or use the images for presentations. The ability to review surgical parameters on a timeline as the video image is being displayed allows surgeons to analyze unexpected surgical events as they are about to occur in a recorded surgical case. This information can then be used to adjust parameters or surgical technique to avoid these pitfalls in future cases. Staar eventually plans to transmit live surgical cases over the internet so that surgeons anywhere in the world can log on and watch a selected surgeon demonstrate his or her technique with real-time surgical parameter display.

24.4 Conclusion

The Staar Wave is one the most advanced phacoemulsification systems available today. The use of sonic rather than ultrasonic energy for the extraction of cataracts represents a major advancement for increasing the safety of cataract surgery. Sonic mode can be used by itself or in combination with ultrasonic energy, allowing for the removal of all lens densities with the least amount of energy delivered into the eye. SuperVac tubing allows higher levels of vacuum to be used for extraction with increased chamber stability by nature of the resistance of this tubing to high flow rates when occlusion is broken. Finally, the addition of advanced video and computer technology for recording and reviewing surgical images and parameters will allow surgeons further to improve their techniques and the techniques of their colleagues through better communication and teaching.

References

1. Fine IH (1998) The choo-choo chop and flip phacoemulsification technique. Operative Techn Cataract Refract Surg 1:61–65
2. Fine IH, Packer M, Hoffman RS (2001) The use of power modulations in phacoemulsification of cataracts: the choo-choo chop and flip phacoemulsification technique. J Cataract Refract Surg 21:188–197
3. Fine IH (1997) Special report to ASCRS members: phacoemulsification incision burns. Letter to American Society of Cataract and Refractive Surgery members
4. Majid MA, Sharma MK, Harding SP (1998) Corneoscleral burn during phacoemulsification surgery. J Cataract Refract Surg 24:1413–1415.
5. Sugar A, Schertzer RM (1999) Clinical course of phacoemulsification wound burns. J Cataract Refract Surg 25:688–692

25 AMO Sovereign with WhiteStar Technology

Richard S. Hoffman, I. Howard Fine, Mark Packer

CORE MESSAGES

- The addition of WhiteStar technology to the Sovereign machine reduces thermal escalation at the wound while maintaining the cutting efficiency seen with continuous-mode ultrasound and improving nuclear fragment followability.
- Markedly reduced thermal energy at the incision site allows for safe bimanual microincision phacoemulsification without the need for a cooling irrigation sleeve.
- The Sovereign Compact maintains many of the desirable features of the Sovereign. The reduced cost of the Sovereign Compact and its easy portability should make it a competitive phacoemulsification unit in today's market.

One of the more advanced and versatile phacoemulsification machines on the market today is the AMO Sovereign (Advanced Medical Optics, Santa Ana, CA). The Sovereign offers all of the traditional features of phacoemulsification machines and has been recently upgraded with the addition of WhiteStar technology. WhiteStar is a new technology in that an ultrapulse mode is able to modulate the delivery of energy by changing both the duration and the frequency of ultrasonic vibrations. Energy is delivered in extremely brief, microsecond bursts, interrupted by rest intervals. The burst length and rest period can be varied independently of each other, yielding numerous modes of varying duty cycles to choose from (Fig. 25.1).

The addition of WhiteStar technology to the Sovereign machine reduces thermal escalation at the wound while maintaining the cutting efficiency seen with continuous-mode ultrasound and improving nuclear fragment followability [1]. Reduced thermal energy results from the ultrashort delivery of energy and the interval rest period. Despite the short bursts of energy, each pulse of WhiteStar ultrasound has been demonstrated to deliver similar cutting ability as that delivered with continuous-mode ultrasound. This has been demonstrated by Dr Mark E. Schafer, wherein the acoustical energy of WhiteStar pulses was transposed into electrical signals using a transducer. Similarly, the acoustical signal of continuous-mode phacoemulsification was

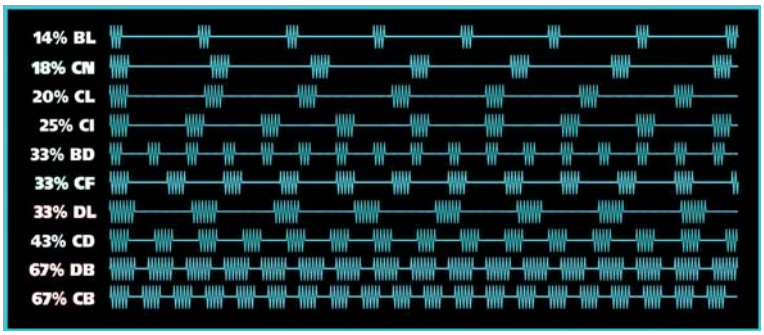

Fig. 25.1. Ten energy-delivery modes available on the Sovereign exhibiting both lower and higher duty cycles (duty cycle = burst time/s). (Photo courtesy of Advanced Medical Optics)

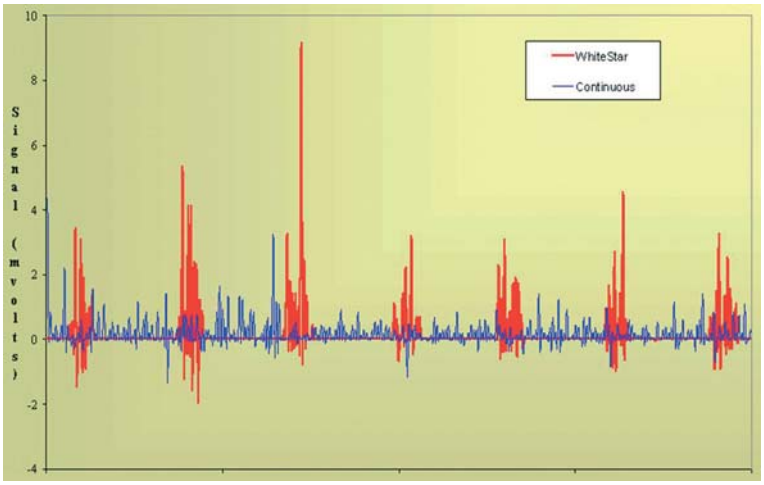

Fig. 25.2. Acoustical energy of WhiteStar pulses (*red*) and continuous ultrasound (*blue*) transposed into electrical signals. Note each WhiteStar pulse delivers more energy than continuous ultrasound. (Photo courtesy of Advanced Medical Optics)

also recorded and compared to WhiteStar pulses. Each pulse of WhiteStar was found to have a larger electrical signal and overall greater amounts of energy delivered despite the rest period following the pulse (Fig. 25.2).

It is postulated that the greater amounts of energy delivered with WhiteStar stem from the type of cavitational energy created. In traditional ultrasound, the vacuum created in front of the phacoemulsification tip by rapid compression and expansion of the tip causes gases in the aqueous to come out of solution. Subsequent rarefaction and compression waves from the phacoemulsification tip will cause these gas bubbles to expand and contract until they eventually implode, releasing intense energy (Fig. 25.3).

Two types of cavitational energy have been proposed to develop – transient and stable cavitation. With transient cavitation there is violent bubble collapse, releasing high pressures and temperatures in a very small region. In order to create transient cavitation, the tip must reach a threshold driving waveform pressure to create gas bubbles of the correct size. This threshold driving waveform pressure is generated with WhiteStar technology.

With stable cavitation, there is a continuous process of small gas bubbles oscillating and collapsing without achieving the full violent collapse that is achieved with transient cavitation. With continuous ultrasound, the very initial delivery of energy is transient cav-

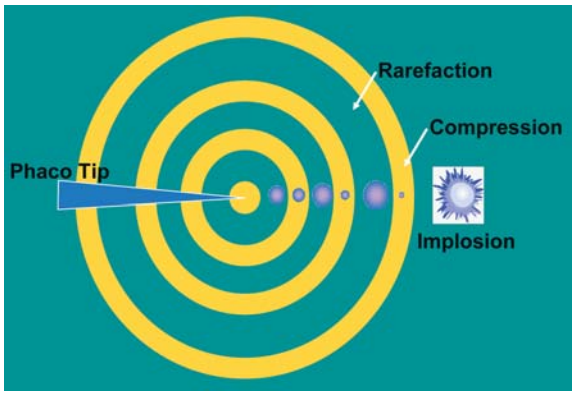

Fig. 25.3. Schematic diagram of cavitational energy creation

Fig. 25.4. Left, AMO Sovereign with WhiteStar technology. Right, AMO Sovereign Compact. (Photos courtesy of Advanced Medical Optics)

itation but the subsequent energy is all stable cavitation, while with WhiteStar, each pulse of ultrasound delivers transient cavitation at the initial pulse with small amounts of stable cavitation in the remainder of the pulse. This results in the improved cutting ability of WhiteStar. Each pulse is more effective at cutting than with continuous mode but less heat is generated.

Studies performed by Donnenfeld et al. have confirmed the reduced likelihood for thermal injury by demonstrating maximum corneal wound temperatures during bimanual microincision phacoemulsification well below the temperature for collagen shrinkage, ranging between 24 and 34° Celsius [2]. Another wound-temperature study in cadaver eyes required 45 seconds of total occlusion of aspiration and irrigation with 100% continuous power using a bimanual technique before serious clinically significant wound temperatures developed [3].

The safety of bimanual microincision phacoemulsification using WhiteStar technology in dense nuclear sclerotic (NS) cataracts was further substantiated by a recent study performed by Olson [4]. In this study, 18 consecutive patients with 3 or 4+ NS cataracts

Fig. 25.5. Sovereign foot pedal demonstrating Variable WhiteStar delivery of four different duty cycles in foot position 3. (Photo courtesy of Advanced Medical Optics)

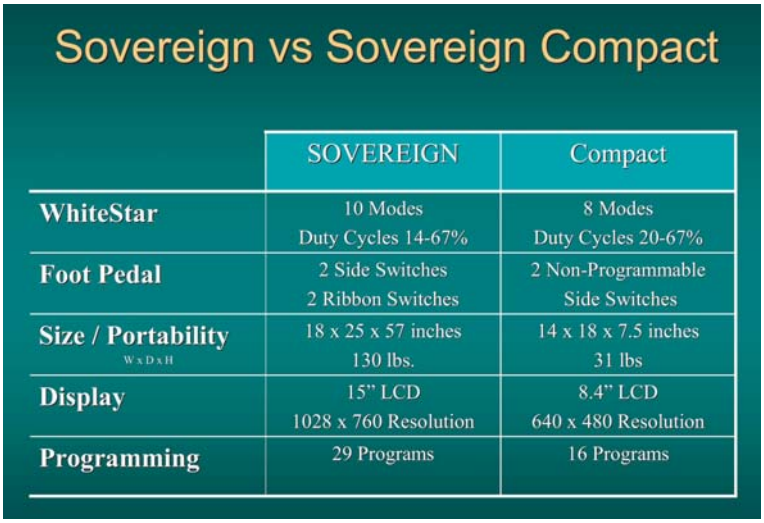

Fig. 25.6. Comparison of features of Sovereign and Sovereign Compact

underwent 21-gauge bimanual phacoemulsification. No complications occurred during the procedure. On the first postoperative day, 72% of patients had no corneal edema and the mean level of anterior chamber inflammation for all patients was quite low. Olson has also performed wound studies of cadaver eyes undergoing phacoemulsification with both the Sovereign with WhiteStar and the Alcon Legacy with AdvanTec, and found less increase in wound temperatures with the Sovereign machine [5].

Another new addition to the Sovereign has been the version 6.0 software delivering Variable WhiteStar (Fig. 25.4). This new software allows surgeons to program up to four different duty cycles that can be delivered with excursions of the foot pedal through position 3 (Fig. 25.5). It also offers additional WhiteStar options including single-burst, multi-burst and burst-continuous modes, as well as continuous and long pulse functions.

AMO is currently producing a slimmed-down version of the Sovereign marketed as

the Sovereign Compact (see Fig. 25.4). The Sovereign Compact offers the same basic fluidics and WhiteStar technology as the Sovereign. It differs in having less programmability of foot-pedal switches, fewer duty-cycle modes, a smaller LCD screen, fewer surgeon memory programs, and perhaps most importantly, 100 lb less weight (31 vs. 130 lb; Fig. 25.6). The reduced cost of the Sovereign Compact and its easy portability should make it a competitive phacoemulsification unit in today's market.

References

1. Olson RJ, Kumar R (2003) WhiteStar technology. Curr Opin Ophthalmol 14:20–23
2. Donnenfeld ED, Olson RJ, Solomon R et al (2003) Efficacy and wound-temperature gradient of WhiteStar phacoemulsification through a 1.2 mm incision. J Cataract Refract Surg 29:1097–1100
3. Soscia W, Howard JG, Olson RJ (2002) Microphacoemulsification with WhiteStar. A wound-temperature study. J Cataract Refract Surg 28:1044–1046
4. Olson RJ (2004) Clinical experience with 21-gauge manual microphacoemulsification using Sovereign WhiteStar technology in eyes with dense cataract. J Cataract Refract Surg 30:168–172
5. Olson RJ, Jin Y, Kefalopoulos P, Brinton J (2004) Legacy AdvanTec and Sovereign WhiteStar: a wound temperature study. J Cataract Refract Surg 30:1109–1113

26 Refractive Lens Exchange in High Myopia: Weighing the Risks

Mark Packer, Richard S. Hoffman, I. Howard Fine

CORE MESSAGES

- Eyes with long axial length and vitreoretinal changes consistent with axial myopia may be at higher risk for retinal detachment following lens extraction and intraocular lens implantation.
- Minimizing risk is critical to the success of refractive lens exchange and refractive surgery in general, since these are entirely elective procedures.
- The published literature supports an acceptable safety profile for refractive lens exchange in high myopia.

Desire for a life free of spectacle and contact lens correction is not limited to low and moderate myopes under the age of 40. The high myope with accommodative reserve may be a good candidate for phakic refractive lens implantation, and the presbyopic hyperope has become well recognized as a candidate for refractive lens exchange with an accommodating or multifocal intraocular lens (IOL) [1]. The myope over the age of 45, however, may be greeted with skepticism. Surgeons worry that presbyopic low myopes will not be satisfied with a simple trade of distance correction for near after bilateral laser-assisted in-situ keratomileusis (LASIK) or a compromise of depth perception with monovision, while a multifocal or accommodating IOL may not offer the same quality of near vision they already have without correction. Refractive lens exchange for moderate to high myopes may raise concerns about significant complications, especially retinal detachment. In particular, eyes with long axial length and vitreoretinal changes consistent with axial myopia may be at higher risk for retinal detachment following lens extraction and IOL implantation. A review of the published literature is helpful in the evaluation of this risk.

In an oft-cited study, Colin and colleagues have reported an incidence of retinal detachment of 8.1% after 7 years in high myopes (>12 D) undergoing refractive lens exchange [2]. Colin's case series includes 49 eyes with a total of four retinal detachments. The first occurred in a male with an axial length of 30 mm and preoperative myopia of −20 D who required preoperative argon laser prophylaxis for peripheral retinal pathology and underwent refractive lens exchange at 30 years of age. His retinal detachment occurred 18 months after his lens surgery. The other three retinal detachments occurred following

YAG laser capsulotomy. These two patients were 8–9 years older than the first, and their eyes were not as extremely myopic, did not have preoperative retinal pathology and suffered retinal detachment 5.5–6 years after lens surgery and 1–2 years after YAG capsulotomy.

A striking feature of Colin's paper is the relationship of YAG capsulotomy to retinal detachment. Ranta and colleagues recently demonstrated that each millimeter increase in axial length increases the risk of retinal detachment after YAG capsulotomy by a factor of 1.5 [3]. Their findings also support the conclusion that about half of retinal detachments that occur after YAG result from new lesions (horseshoe tears), while the other half result from "potentially antecedent small atrophic holes." Unfortunately, preoperative prophylaxis cannot address the former. The statistical methodology of this study represents a good model for further research in that it quantifies risk in terms of axial length rather than diopters of myopia. To our knowledge no one has suggested additional risk for retinal detachment to extremely steep keratometry.

A review of the literature to help determine the actual risk of retinal detachment after lens surgery should be limited as much as possible to current techniques, such as small-incision lens extraction, capsulorrhexis and in-the-bag IOL placement. Sanders has recently pointed out that some of the publications cited in the literature employed techniques no longer representative of the standard of care [4]. For example, Javitt [5] assumed an ultimate rate of retinal detachment of 7.5% based on the earlier work of Barraquer. However, Barraquer's series included 3% intracapsular lens extractions, while only nine of 165 eyes in his series received an IOL [6]. Sanders suggests that the 1,372 subjects of 14 peer-reviewed articles who underwent refractive lens exchange by phacoemulsification with posterior chamber IOL implantation comprise a more pertinent comparison group. Retinal detachments in this group numbered 14, for a cumulative rate of 1%.

A still more recent publication by Fernandez-Vega reports a retrospective case series of 190 eyes of 107 patients with a minimum axial length of 26.00 mm that underwent refractive lens exchange with posterior chamber IOL implantation and had a mean follow-up of 4.78 years (3.1–8.03 years) [7]. The surgical technique involved capsulorrhexis, hydrodissection, phacoemulsification and insertion of a one-piece polymethylmethacrylate (PMMA) IOL through an enlarged 6.5-mm incision with suture closure as needed. The reported YAG capsulotomy rate was 77.89% (148 eyes). Retinal detachment developed in four eyes with a mean axial length of 30.44 mm (29.60–32.30 mm), all of which had undergone YAG capsulotomy. The overall incidence of retinal detachment was 2.1%.

The question arises as to the natural incidence of retinal detachment in high myopia without surgical intervention. An oft-quoted figure is 0.68% per year for myopia greater than –10 D [8]. This rate amounts to 3.25% over the 4.78-year mean follow-up period of the series studied by Fernandez-Vega. Their reported rate of 2.1% for eyes undergoing refractive lens exchange actually compares favorably with the rate for unoperated eyes, as does the cumulative 1% rate quoted by Sanders.

Minimizing risk is critical to the success of refractive lens exchange and refractive surgery in general, since these are entirely elective procedures. Several conclusions emerge from the literature on retinal detachment following refractive lens exchange. First, careful preoperative examination and counseling should precede any decision to operate. Complete funduscopic examination with scleral depression and determination of the state of the vitreous body comprise essential steps in the examination. Referral to a vitreoretinal specialist should be entertained if any doubt emerges about the nature of a lesion or the indication for prophylaxis.

Second, surgical principles should emphasize minimal disturbance of the intraocular environment. Microincision techniques facilitate maintenance of a stable chamber, construction of a round and centered capsulorrhexis, effective cortical cleaving hydrodissection, efficient aspiration of lens material without application of ultrasound energy, and safe bimanual cortical clean-up through two paracentesis-type incisions. A fresh temporal clear corneal incision may be constructed for introduction of the IOL. All incisions should be Seidel negative at the conclusion of the case.

Third, eventual YAG capsulotomy should be avoided if possible. The construction of a capsulorrhexis that completely overlies the edge of the IOL optic, the use of cortical cleaving hydrodissection, meticulous cortical clean-up and the implantation of an IOL with a sharp posterior edge all facilitate maintenance of a clear posterior capsule.

By following these guidelines, we may be able to improve on the outcomes recently reported by Fernandez-Vega. It is equally encouraging that none of the eyes that did experience a retinal detachment in that series lost a line of best corrected visual acuity. Careful patient selection and follow-up will always contribute to improved results. For now, the published literature supports an acceptable safety profile for refractive lens exchange in high myopia. This procedure, with the implantation of an accommodative or multifocal IOL and the use of concomitant limbal relaxing incisions, can also successfully address astigmatism and presbyopia among the highly myopic population.

References

1. Packer M, Fine IH, Hoffman RS (2002) Refractive lens exchange with the Array multifocal lens. J Cataract Refract Surg 28:421-424
2. Colin J, Robinet A, Cochener B (1999) Retinal detachment after clear lens extraction for high myopia. Ophthalmology 106:2281–2285
3. Ranta P, Tommila P, Kivela T (2004) Retinal breaks and detachment after neodymium:YAG laser posterior capsulotomy: five-year incidence in a prospective cohort. J Cataract Refract Surg 30:58–66
4. Sanders DR (2003) Actual and theoretical risks for visual loss following use of the implantable contact lens for moderate to high myopia. J Cataract Refract Surg 29:1323–1332
5. Javitt J (1994) Clear-lens extraction for high myopia. Is this an idea whose time has come? (Editorial) Arch Ophthalmol 112:321–323
6. Barraquer C, Cavelier C, Mejia LF (1994) Incidence of retinal detachment following clear-lens extraction in myopic patients: retrospective analysis. Arch Ophthalmol 112:336–339
7. Fernandez-Vega L, Alfonso JF, Villacampa T (2003) Clear lens extraction for the correction of high myopia. Ophthalmology 110:2349–2354
8. Perkins ES (1979) Morbidity from myopia. Sight Saving Rev 49:11–19

27 Conclusion: The Future of Refractive Lens Surgery

Mark Packer, I. Howard Fine, Richard S. Hoffman

Since the time of Charles Kelman's inspiration in the dentist's chair (while having his teeth ultrasonically cleaned), incremental advances in phacoemulsification and intraocular lens (IOL) technology have produced ever-increasing benefits for patients with cataract. The modern procedure simply was not possible even a few years ago, and until recently prolonged hospital stays were common after cataract surgery. Advances in efficacy and safety have justified the current transition from cataract to refractive lens surgery.

A recent survey of members of the American Society of Cataract and Refractive Surgery has revealed that 40% of respondents performed at least one refractive lens exchange (RLE) per month during 2003, up from 15% in 1999 [1]; 2.4% said they performed six or more RLEs per month in 2003. When asked about their level of interest in new technology, 100% said they were interested in an accommodative IOL.

Our current ability to achieve emmetropia following refractive lens surgery rivals the results of corneal refractive surgery, yet covers a much wider range of refractive errors. While phakic refractive lenses extend the range of correction for younger patients, RLE also offers, with new IOLs, a high probability of achieving functional binocular vision at distance, intermediate and near focal lengths. For these reasons, RLE will become the dominant refractive procedure for patients past the age of presbyopia. With RLE, patients can enjoy a predictable refractive procedure with rapid recovery, which addresses all types of refractive errors, including presbyopia, and never develop cataracts. Surgeons can offer these procedures without the intrusion of their party payers and establish a gratifying and mutually beneficial relationship with their patients. Government programs can enjoy the decreased financial burden from the expense of cataract surgery for the ever-increasing ranks of baby boomers that opt for RLE to address their refractive surgery goals, ultimately reaching the age of coverage as pseudophakes.

The competitive business environment and the wellspring of human ingenuity continue to demonstrate synergy in the improvement of surgical technique and intraocular lens technology. Future advances will continue to benefit our patients and allow even greater success for refractive lens surgery.

Reference

1. Leaming DV (2004) Practice styles and preferences of ASCRS members – 2003 survey. J Cataract Refract Surg 30:892–900

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