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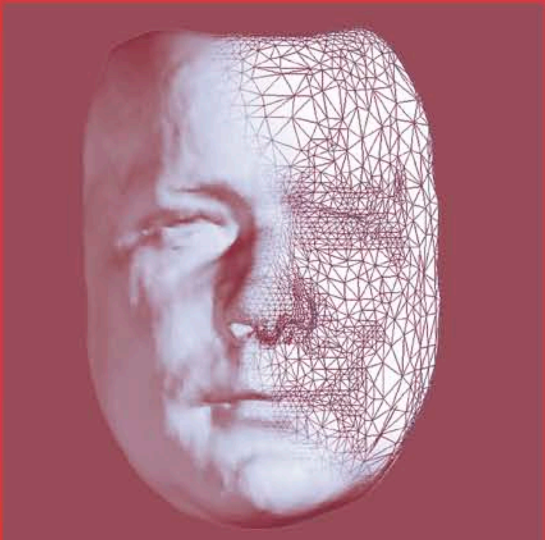
Medical modelling

The application of advanced design and development techniques in medicine

Richard Bibb



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Contents

Preface

The principal aim of this book is to provide a genuinely useful text that can help professionals from a broad range of disciplines to understand how advanced product design and development technologies, techniques and methods can be employed in medicine. The book describes the technologies, methods and potential complexities of these activities as well as suggesting solutions to commonly encountered problems and highlighting potential benefits. This book is based on the collective experience of the Medical Applications Group of the National Centre for Product Design & Development Research (PDR) and their collaborative partners from medicine, academia and industry.

Chapters 1–5 provide an introduction to the various technologies involved, ranging from medical scanning to physical model manufacture. Chapter 6 provides a number of interesting and varied case studies that collectively cover the application of most, if not all, of the technologies introduced in the previous chapters. To ensure that these case studies are relevant and appropriate they have been drawn from work previously published in peer-reviewed journals or conference proceedings with full acknowledgement and permission where appropriate. Many of the images used in this book are taken directly from medical scanning modalities or computer screens and therefore may appear highly pixellated or of poor quality. In most cases, this is a direct reflection of the quality of the data being described and is intentional. Those images that must be seen in colour are additionally reproduced in a colour section.

This text also aims to encourage what is, by its very nature, a multidisciplinary and collaborative field. The case studies selected reflect this by describing a broad range of techniques and applications. Although much work has been done in this area, there is a tendency for people to publish in the journals, language and context of their own professional practice. Whilst this text does not purport to be the most comprehensive review of the work done to date, it is a conscious effort to overcome these professional interfaces and encourage multi-disciplinary collaboration by providing a single source of useful reference material accessible to readers from any relevant background.

Therefore, it is hoped that this book will appeal equally to medical and technical specialities including, for example: Biomedical Engineers, Clinical Engineers, Rehabilitation Engineers, Medical Physicists, Designers, Radiologists, Radiographers, Surgeons, Prosthetists, Orthotists, Orthodontists, Anatomists, Medical Artists and Anthropologists, and perhaps even Archaeologists and Palaeontologists. The text will also provide an excellent resource for postgraduate students, researchers and doctoral candidates working in this rapidly developing, important and exciting area.

Dr Richard Bibb
Cardiff

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This book would not have been possible without the help and support of many people. It is appropriate therefore to offer my thanks to my colleagues at PDR and UWIC for all their assistance. In particular, I would like to thank Professor Robert Brown and Professor Alan Lewis for providing me with the opportunity and support needed to accomplish the research that underpins this book.

As the central theme underpinning this book is multidisciplinary collaboration, it is important to recognise the input of all who have contributed to it. I would like to thank all of my collaborators and co-authors without whom none of the work reported in this book would have been possible. Each case study is fully acknowledged and I would like to thank the various publishers for their kind permission to reproduce our previous papers and articles.

In particular I would like to thank my colleagues, Dominic Eggbeer and Bob Williams from UWIC, Adrian Sugar, Alan Bocca and Peter Evans from Morriston Hospital and Professor Julian Minns for their particular dedication and co-operation. I would also like to thank John Winder for his help with my early drafts.

I would like to thank everyone at Woodhead Publishing for all their help and professional expertise in turning my manuscript into the book you see here.

Finally, I would also like to thank my wife Alison for her patience and proof reading.

1
Introduction

1.1 Background

The purpose of this book is to describe some of the many possibilities, techniques and challenges involved in the field of medical modelling. Medical modelling, sometimes called biomodelling, is the creation of highly accurate physical models of human anatomy directly from medical scan data. The process involves capturing human anatomy data, processing the data to isolate individual tissue or organs, optimising the data for the technology to be used and finally building the model using rapid prototyping (RP) techniques. Rapid prototyping is the general name coined to describe computer-controlled machines that are able to manufacture physical items directly from three-dimensional computer data. Originally, these machines were developed to enable designers and engineers to build models of objects they had designed using computer-aided design software (CAD). These prototypes allowed them to ensure that what they had designed on-screen fitted together with all of the other components of the product being developed. Therefore, the machines were quickly developed to produce models of very high accuracy as rapidly as possible.

In the 1990s, it was realised that RP machines could utilise other types of three-dimensional computer data, such as that obtained from medical scanners. Software was developed to enable the medical scan data to interface with the RP machines and medical modelling began. Since then the field has developed enormously to cover all kinds of applications ranging from forensic science to reconstructive surgery. Early success and clear demonstration of benefits has led to widespread interest in the technologies from many medical specialities. However, with each development more and more clinicians, surgeons, engineers and researchers are realising the potential benefits of RP techniques, which in turn places new challenges on those people whose job it is to build these models.

This book aims to describe the stages required to produce high quality medical models and offer an insight into the techniques and technologies that are commonly used. Chapters 2, 3, 4 and 5 follow the logical sequence of stages in the medical modelling process as shown in Table 1.1. Each chapter describes the technologies and processes used in each stage in general terms for those not familiar with them or new to the field, whilst the following case studies illustrate a number of diverse applications that have been carried out in recent years. Where appropriate, the case studies include cross-references to particular sections of Chapters 2–5 as a reminder, to eliminate repetition or to enable the reader to begin by reading case studies and then find the relevant technical information easily without necessarily having to read the whole book in chapter order.

By its very nature, medical modelling has brought together the fields of engineering and medicine. Consequently, this book aims to satisfy the needs of both fields as they work together on medical modelling. Therefore, whilst it is not possible to cover every medical or technical definition here, this chapter offers a brief introduction to some anatomical terminology for the benefit of engineers new to the field, whilst later chapters and the case studies in particular include additional notes to explain specialist technical or medical terms as and when they occur. Where such an explanation requires a longer or more detailed description an explanatory note may be found in Chapter 8, which also contains glossaries of technical and medical terms and abbreviations. There are also recommendations for further reading at the end of some chapters to enable those with particular interests to develop their knowledge further.

Table 1.1 The stages of the medical modelling process

Step 1 **Medical imaging for rapid prototyping** *Select the optimal modality* *Set appropriate protocols* *Scan the patient*
Step 2 **Export data media and format** *Export the data from the scanner in an appropriate format* *Transfer it to the RP laboratory*
Step 3 **Working with medical scan data** *Isolate data relating to the tissues or organs to be modelled* *Save and transfer the data in the correct format for the RP process to be used*
Step 4 **Physical reproduction – rapid prototyping technologies** *Building the model* *Cleaning, finishing or sterilising as required* *Deliver the model to the clinician*

Whilst this book is essentially technical in nature it is important to consider that it also addresses genuine human needs and consequently there is due consideration for patients and ethics. Therefore, throughout this book, illustrations and case studies have been made anonymous and where necessary permission granted.

1.2 The human form

The human body is the most significant physical form that we possess or encounter. Our physical form is inextricably bound up with our minds and behaviour. It influences but also responds to our lifestyle choices and combined with our character defines us as individuals. Our physical form defines how we appear to others and it affects our perception of ourselves. It displays our health and fitness and even our attractiveness to our loved ones. It enables us to recognise any one individual amongst the six billion fellow humans with which we share the planet.

In addition to its undeniable importance, our physical form is perhaps one of the most complex shapes we encounter in life. Its importance to us makes us sensitive to the tiniest of details and the subtlest of contours. This complexity combined with our sensitivity to the human form has provided perhaps the pre-eminent challenge to artists in our history. Through drawing, painting and sculpture, artists have striven to capture what it is that makes us human and how that is expressed through our physical form and appearance.

In terms of medicine, the human body is both subject and object. The study of the human form is the basis for all medicine as it strives to correct our malfunctions and degradation. It is from these noble aims that we are constantly trying to apply the latest in technology to improve our treatment of all kinds of illness. When such unfortunate things as disease or trauma damage our physical form, it not only physically debilitates us but also affects our psychological health. Therefore, the ability to capture and reproduce human anatomy to the infinite subtlety that we desire is a pursuit that is as important as it is challenging.

The age of computer technology has not necessarily eased this process. The reconstruction and rehabilitation of people can consist of any combination of dressing, rehabilitation, prosthesis and surgery. Skills employed range from the artistry of the prosthetist to the engineering of artificial implants. Until recent times the reconstruction and rehabilitation has relied almost solely on the dexterity and artistry of a small but highly dedicated range of health professionals. However, in this modern age, the pressures on these people grow as survival rates increase and surgical interventions become ever more sophisticated. It is therefore not surprising that medicine looks towards advanced technologies to provide the effort, time and cost savings that have been so successfully achieved in product design and engineering.

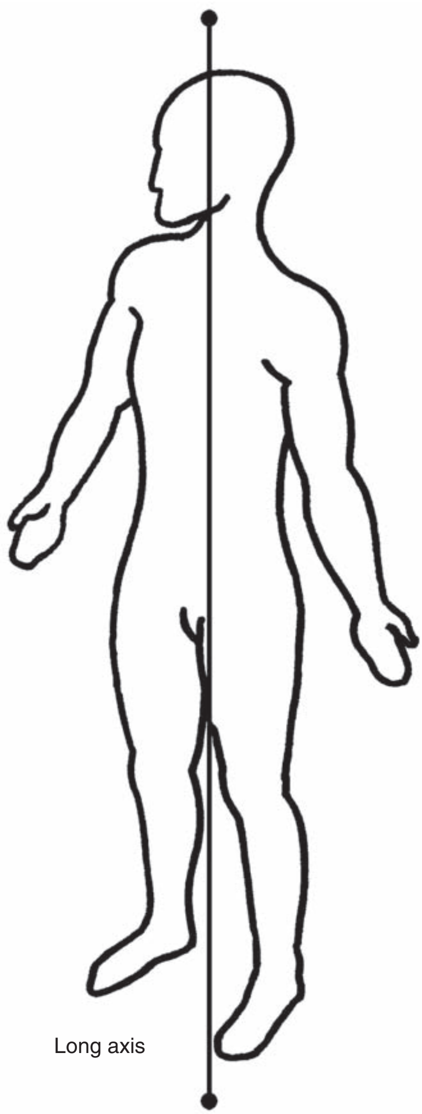
This text aims to describe some of the product design technologies that have been successfully utilised in the field of human reconstruction and rehabilitation and illustrate their application through case studies. As we will discover, there are many benefits to be found from applying modern technologies, yet they are not without their obstacles. The nature of the human form makes the transfer of techniques that are well suited to product design and engineering a particularly challenging yet ultimately rewarding field of work.

1.3 Basic anatomical terminology

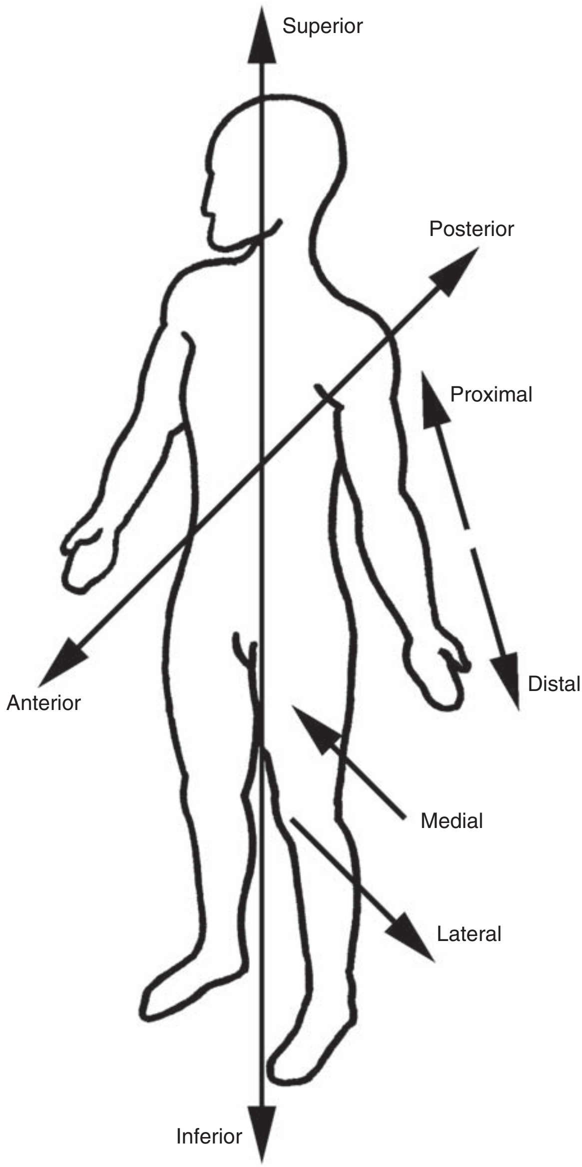
Whilst this book does not intend to be used as a guide to human anatomy, the descriptions of techniques, medical conditions and treatments require the use of accepted anatomical nomenclature. For those readers with medical training this nomenclature will be well known. However, for those from a technical, design or engineering background some basic terminology will prove useful. This section will introduce some basic terms that will enable the reader to proceed with the rest of the text, but further reading on the subject is recommended. There are many excellent texts on anatomy and a selection of titles is provided in the bibliography. Attending a short course in human anatomy and physiology would be highly recommended to any engineer or designer wishing to specialise in clinical or medical applications, and many universities offer such courses.

When referring to human anatomy the relative positions of organs, limbs and features are only useful if the body is in a known pose. Therefore it is standard practice to assume the body is in the 'anatomical position' when describing relative positions of anatomy. The anatomical position is with the body and limbs straight, feet together, head looking forwards, arms at the sides of the torso with the palms facing forward and fingers straight. The principal axis of the human is through the centre of the body running from head to feet; this is referred to as the long axis. This is shown in Fig. 1.1.

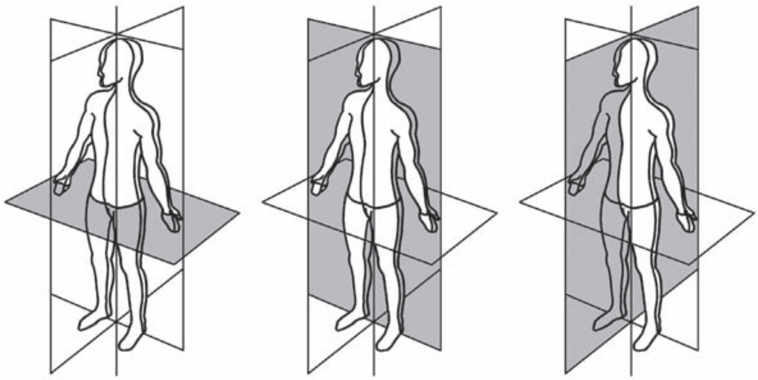
Once the anatomical position is known, perpendicular planes can divide the body. The plane through the body perpendicular to the long axis is known as the axial plane. The planes perpendicular to this are known as the coronal and sagittal. Directions and distances are described as they relate to the centre of the body. Parts nearer to the body are known as proximal and those furthest from the body centre are distal. Parts that are nearer the midline of the body are known as medial and those further from it are described as lateral. These terms are summarised in Table 1.2 and illustrated in Figs. 1.2 and 1.3.



1.1 The anatomical position and the long axis.



1.2 The direction terms used in human anatomy.



1.3 The major reference planes used in human anatomy: axial (left), coronal (middle) and sagittal (right).

Table 1.2 Anatomical directional terms

Term	Definition
Superior	Towards the head (upper)
Inferior	Away from the head (lower)
Anterior	Towards the front of the body
Posterior	Towards the rear of the body
Medial	Nearer to the midline of the body
Lateral	Further from the midline of the body
Contralateral	On the opposite side of the body
Ipsilateral	On the same side of the body
Proximal	Relating to limbs – nearer to the body
Distal	Relating to limbs – further from the body
Superficial	Towards the surface of the body
Deep	Into the body away from the surface

2
Medical imaging for rapid prototyping

2.1 Introduction to medical imaging

In order to manufacture a rapid prototype model of any human anatomy it must first be captured in three dimensions in a manner that allows the computer processes that control the RP process to be used. A number of scanning modalities can be used, ranging from substantial hospital facilities normally found in radiology departments to small hand-held scanners that can be used in the laboratory or clinic.

There are essentially two main categories of scanning modality for human bodies, those that capture data from the whole body both internally and externally and those that capture only external data. Most hospital-based scanners capture data from the whole body both internally and externally. These are normally large, sophisticated medical imaging machines capable of scanning the complete human body. Examples include Computed Tomography (CT), Magnetic Resonance (MR) imaging and positron emission tomography. Each modality uses a different physical effect to generate cross-sectional images through the human body. Typically, the patient is placed lying down on a table that is fed through the scanner whilst the images are taken. The cross-sectional images are arranged in order so that the computer can construct a three-dimensional data set of the patient. Software can then be used to isolate particular organs or tissues. This data can then be used to make an exact replica of the organ using RP techniques. The different physical effects used by each type of scanner result in different types of tissue being imaged. These machines require highly specialised staff to operate and require large capital investment. The use of the two most common modalities in RP will be described in more detail later in this chapter.

The other type of scanning is used to capture only the external surface of a patient. There is a wide range of technologies that can be used for capturing three-dimensional surface data. Three-dimensional surface scanning, sometimes referred to as digitising, has been used in engineering and product design for many years as a method of integrating the surfaces of existing physical objects with computer-aided design (CAD) models. Consequently, this process is often referred to as 'reverse engineering'. There are many types of surface scanner or digitizer available to the engineer or designer. They can be separated into two main categories; 'contact' or 'touch probe digitizers' and non-contact scanners. Touch probe digitizers use a pressure sensitive probe tip and calibrated motion to map out the surface of an object point by point. Depending on the quality of its manufacture, they can be extremely accurate. However, it is also a very slow and laborious process, sometimes taking hours to capture the surface of an object. Whilst this is acceptable when scanning inanimate objects, it is clearly not appropriate to capturing the surface of human anatomy. Therefore, non-contact scanners are typically used when capturing surface data from people. Non-contact scanners utilise light and digital camera technologies to capture many thousands of data points on the surface of an object in a matter of seconds. The fast capture of data and the harmless light used make these types of scanner ideal for capturing human anatomy. These scanners are typically like very large cameras and may be tripod mounted or in some instances even hand held. Despite the variety of surface scanners available on the market, the general principles of their operation and application are the same, and these principles are described later in this chapter.

It is not intended to provide a definitive description of the technology and practice of each scanning modality here but to establish some criteria and guidelines that may be employed to optimise their use in the production of virtual or physical medical models. Many texts are available that describe each modality fully and some are listed in the recommended reading list at the end of this chapter.

2.2 Computed Tomography (CT)

2.2.1 Background

Computed Tomography works by passing focused X-rays through the body and measuring the amount of the X-ray energy absorbed. The amount of X-ray energy absorbed by a known slice thickness is proportional to the density of the body tissue. By taking many such measurements from many angles the tissue densities can be composed as a cross-sectional image using a computer. The computer generates a grey scale image where the tissue density is indicated by shades of grey, ranging from black indicating the density of air to white representing the density of the hardest bone.

As bones are much denser than surrounding soft tissues they show up very clearly in CT images, as can be seen in Fig. 2.1. This makes CT an important imaging modality when investigating skeletal anatomy. Similarly,

2.1 A CT image of the head.

the density difference between soft tissues and air is great allowing, for example, the nasal airways to be clearly seen. However, the density difference between different soft tissue structures is not great and therefore it may be difficult to distinguish between different adjacent organs in a CT image. Artificial contrast agents that absorb X-ray energy may be introduced into the body, which makes some structures stand out more strongly in CT images.

As CT uses ionising radiation in the form of X-rays, it is called a non-invasive modality, but exposure should be minimised, particularly to sensitive organs such the eyes, thyroid and gonads. The X-rays are generated and detected by a rotating circular array through which a moving table can travel. Typically, the patient lies on their back and is passed through the circular aperture in the scanner. The detector array acquires cross sections perpendicular to the long axis of the patient. The images acquired are, therefore, usually termed the axial or transverse images.

The scanner, therefore, performs a spiral around the long axis of the patient. This innovation enables three-dimensional CT scanning to be performed much more rapidly and, consequently, three-dimensional CT scans are frequently referred to as helical CT. In addition, modern CT scanners employ multiple arrays to enhance the rate of data capture and improve three-dimensional volume acquisition.

CT images are generated as a grey scale pixel image, just like a bitmap computer image. If the distance between a series of axial images, called the slice thickness, is known, they can be interpolated from one image to the next to form cuboids, known as voxels. Therefore, a three-dimensional CT scan generates a voxel representation of the human body. Software can be used to re-slice these voxel data sets in axes perpendicular to the long axis enabling different cross-sectional images to be generated from the original axial data. This is typically done in the sagittal and coronal planes; however, images may be generated in any plane.

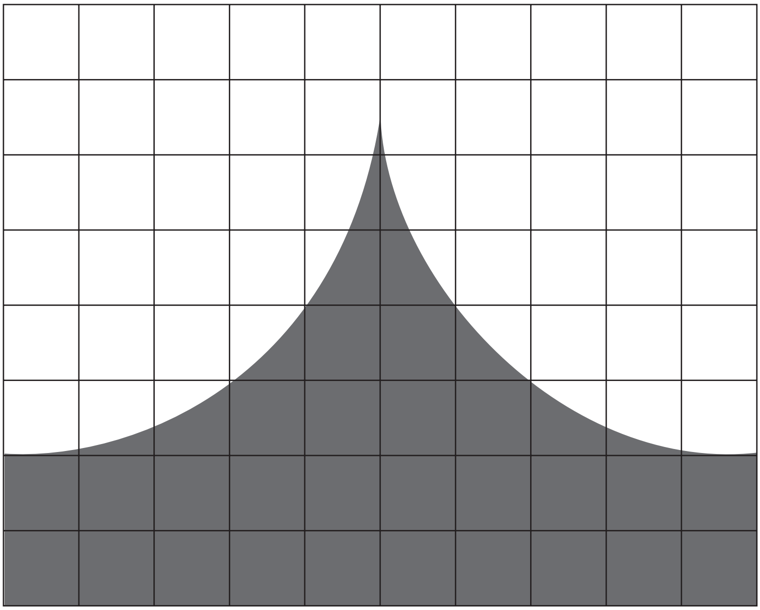
The radiographers who conduct CT scans have specific parameters and settings for different types of scan. These are standardised and referred to as protocols. When embarking on using CT data for medical modelling it may be helpful to discuss it first with the radiographers and they may well develop a protocol specifically for medical modelling. CT scans are time consuming, expensive and potentially harmful so every care must be taken to ensure that the scan is conducted correctly the first and only time.

2.2.2 Partial pixel effect

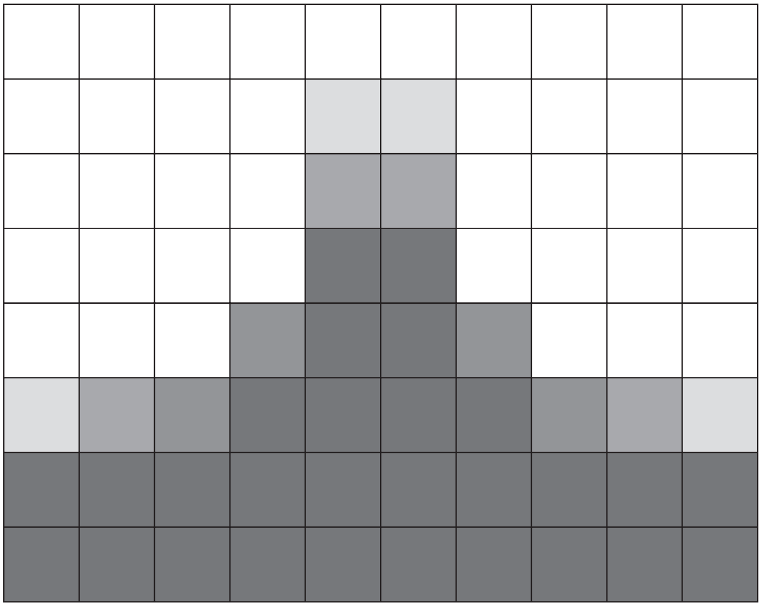
When CT data is captured, the resulting images are divided up into a large number of pixels (typically a 512 × 512 matrix). Each pixel is a shade of grey that relates to the density of the tissue at that location. The resulting images are, therefore, an approximation of the original tissue shapes according to their density. The quality of that approximation is a function of the number and relative size of the pixels as well as other aspects of the CT scanner. The discrete size of the pixels means that edges between different anatomical structures are to some degree affected by this image quality.

The effect can be to ‘blur the edges’ due to the partial pixel effect. If the boundary between two different structures crosses a given pixel, that single pixel cannot represent both densities. Instead that pixel displays an intermediate density which is somewhere between the two. The effect can be illustrated by considering the shape in Fig. 2.2, which consists of two densities, low being grey and high being white. When the CT scan is performed, the cross section is broken down into pixels as shown in Fig. 2.3. In this view, it can be seen that some squares contain both high- and low-density areas. These pixels will, therefore, be shown as an intermediate grey depending on their relative proportions. This leads to the partial pixel effect that can be seen in the tomographic image that results, shown in Fig. 2.4.

2.2 Original object shape.



2.3 The effect of pixel size.



2.4 The resulting tomographic image (blurring of edges).

2.2.3 Anatomical coverage

The coverage of a CT volume is defined in two ways, by the number of axial images taken and the field of view used for those images. In the long axis, it is defined by the table position where the first and last images are acquired. It is clear that the series of axial images must begin and end either side of the anatomy of interest, but it is often important to begin and end the scan some distance either side of the anatomy of interest. When conducting three-dimensional series scans, the data should be continuous. Non-continuous sets of data may be satisfactorily combined in software later, however as the patient has usually shifted position slightly the separate series may not align perfectly.

The area covered by each axial image is referred to as the field of view and is typically square. The axial image consists of a fixed number of pixels, typically 512 × 512. The field of view (FOV) is the physical distance over which the image is taken. Therefore, altering the field of view will alter the pixel size in the axial image. Usually a field of view large enough to capture the whole cross section of the anatomy is used. However, where specific small areas of anatomy are required, the field of view may be reduced to capture only that area. This results in a smaller pixel size, which increases the physical accuracy of the scan. For example, a typical field of view used to CT the head would be 25 cm, resulting in a pixel size of 0.49 mm (assuming a 512 × 512 array), whilst a field of view of 13 cm may be used to capture data relating only to the mouth, which would result in a pixel size of 0.25 mm. Whilst small pixel size is a desirable factor, it is more important that the images cover all of the anatomy of interest plus some margin.

Although exposure to X-rays should be minimised wherever possible, it is more important that the scan covers all of the required anatomy, plus some additional margin. It is better to perform one extensive CT scan than a minimal one that is later found to be inadequate and necessitates subsequent scans. Basic mistakes in capturing the required coverage can be avoided through clear communication between the clinician and radiographer.

2.2.4 Slice thickness

This is the distance between the axial scans taken to form the three-dimensional scan series. In the case of helical CT scanning, the parameter applies to the distance between the images calculated during the scan (distance between cuts). To maximise the data acquired, this distance should be minimised. Some scanners can go as low as 0.5 mm, which gives excellent results, but this must be balanced against increased X-ray dose. Typically, distances of 1–1.5 mm produce acceptable results. A scan distance of 2 mm may be adequate for larger structures such as the long bones or pelvis. A scan distance greater than 2 mm will give poorer results as the scan distance increases.

Collimation is the term used to describe the thickness of the X-ray beam used to take the cross-sectional image. In combination with scan distance, consideration may be given to collimation and overlap. In most circumstances, the scan distance and collimation should be the same. However, using a slice distance that is smaller than the collimation gives an overlap. When scanning for very thin sections of bone that lie in the axial plane, such as the orbital floor or palate, an overlap may give improved results.

Even with a very small scan distance, some detail may be lost where thin sections of bone exist between the scan planes (although this is not true for volumetric acquisition). Typically, these are areas in the skull such as the palate and orbital floors. In addition, very thin sections may prove too delicate to survive the rapid prototyping build process.

2.2.5 Gantry tilt

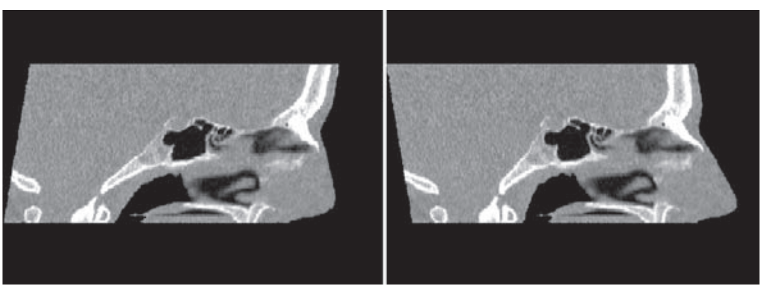
Typically for the purposes of virtual or physical modelling gantry tilt should be avoided as it does not significantly improve the quality of the acquired data and provides an opportunity for error when reading the images. Large gantry tilt angles are clearly apparent on visual inspection and can be corrected. However, small angles may not be easy to check visually and may be compensated for incorrectly. Even the use of automatic import of the medical image standard DICOM (Digital Imaging and Communications in Medicine) is no guarantee as, although the size of gantry tilt angle is included in the format, the *direction* of tilt is not. Failure to compensate for the direction of the tilt correctly will lead to an inaccurate model, wasting time and money and potentially leading to errors in surgery or prosthesis manufacture. This effect is illustrated by the example shown in Fig. 2.5.

2.2.6 Orientation

Anterior-posterior and inferior-superior orientation is usually obvious, but lateral orientation may be ambiguous. This is not a problem with automatically imported data but when manually importing data it is important that the correct lateral orientation can be ascertained. If there is an obvious lateral defect, then a note from the clinician describing it is usually sufficient. Where the lateral orientation cannot be easily determined from the anatomy extra care should be taken to verify the orientation before building a potentially expensive medical model.

2.2.7 Artefacts

This is the general term for signals within an image that do not correspond to anatomy. These may result from patient movement or X-ray scatter. Examples of medical modelling problems that have been encountered because of artefacts are shown in Section 6.2 Implementation case study 2. Scattering is typically caused by dense bones or metal objects such as dental fillings, plates, screws or even shrapnel.



2.5 Incorrect 5° gantry tilt compensation (left) and correct compensation (right).

Movement

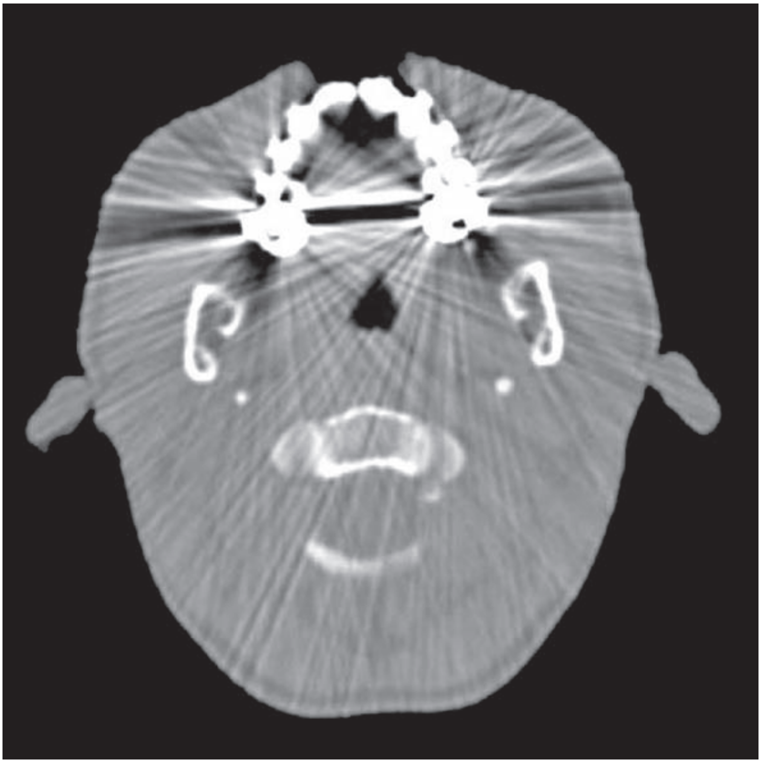
A good quality CT scan depends on the patient remaining perfectly still throughout the acquisition. Movement during the acquisition will lead to distortions in the data (analogous to a blurred photograph). This has become less of a problem as acquisition times have decreased with the advent of helical multi-slice CT. However, it can still present a problem in some cases. For example, involuntary movement of the chest, neck, head or mouth can occur through breathing or swallowing. Movement can be particularly difficult to control when scanning babies, small children and claustrophobic patients, in which case a sedative or even general anaesthetic may be required.

X-ray image scatter by metal implants

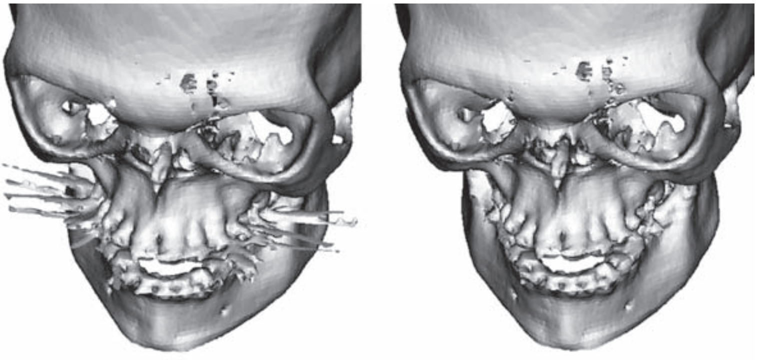
Dense objects such as amalgam or gold fillings, braces, bridges, screws, plates and implants scatter X-rays resulting in a streaked appearance in the scan image. The scatter results in significant image errors where false data appear with corresponding false missing data or shadows. Due to the nature of X-rays, little can be done to eliminate these effects. Fig. 2.6 shows an axial CT image with significant artefact from scatter. Fig. 2.7 (left) shows how the scatter will be demonstrated on a three-dimensional reconstruction of the data, apparent as spikes radiating from the source of the scatter. These effects can be manually edited in software to produce a normal looking model (right). However, this does depend to some degree on the expertise of the operator and consequently the accuracy of the model in the affected areas cannot be guaranteed. In most cases, this does not affect the usefulness of the whole model. As cases showing artefacts usually occur in and around the teeth, a dental cast is typically used in conjunction with the medical model and indeed may be combined with a physical model.

Noise

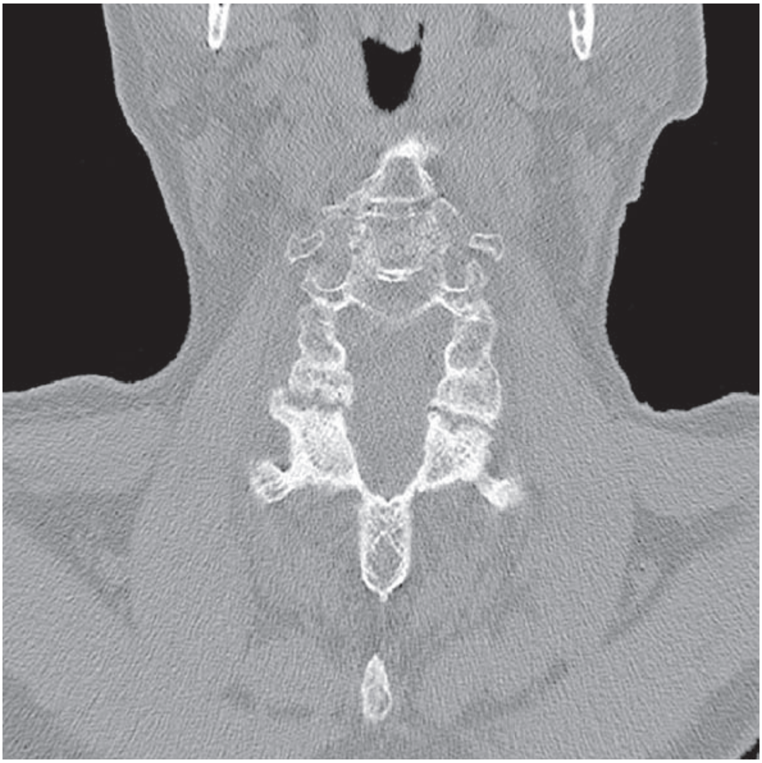
Noise is a fundamental component of a CT image and is especially prevalent in dense tissues. Although these images may be visually acceptable, they are impractical for modelling. Good modelling from CT data depends on identifying a smooth boundary between bone and soft tissue. Noise reduces the boundary, which results in poor three-dimensional reconstructions and consequently poor models. This commonly affects areas through the shoulders and hence vertebrae in the lower neck and upper back (C6 to T4: see explanatory note 8.2.5). A typical example is shown in Fig. 2.8. The effect becomes much more apparent when zooming into image data,



2.6 X-ray scatter artefact in a CT image.



2.7 Three-dimensional reconstruction (left) and edited three-dimensional reconstruction (right).



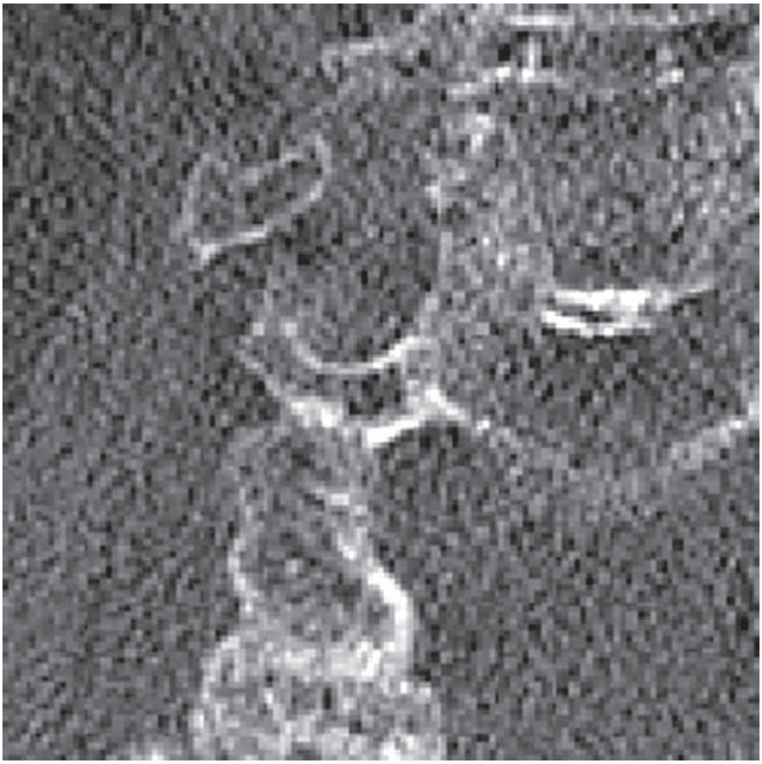
2.8 Noise in CT image.

as can be seen in the close up view of the same data shown in Fig. 2.9. Three-dimensional reconstructions from this data will lead to a poor result as shown in Fig. 2.10. Typically, such reconstructions will appear rough surfaced or porous.

If the effect occurs in only a few images, it may be possible to edit them out to produce a normal looking model. However, this does mean that the accuracy of the model in these areas cannot be guaranteed. If the whole data set is affected, this editing is unfeasible and the resulting model may be too poor to be useful.

2.2.8 Kernels

Modern CT scanning software allows different kernels (digital filters) to be used. These modify the data to give better three-dimensional reconstructions and can help to reduce noise. Typically, the options will range from 'sharp' to 'smooth'. Sharpening filters increase edge sharpness but at a cost



2.9 Close up of noise.

of increasing image noise. Smoothing filters reduce noise content in images but also decrease edge sharpness.

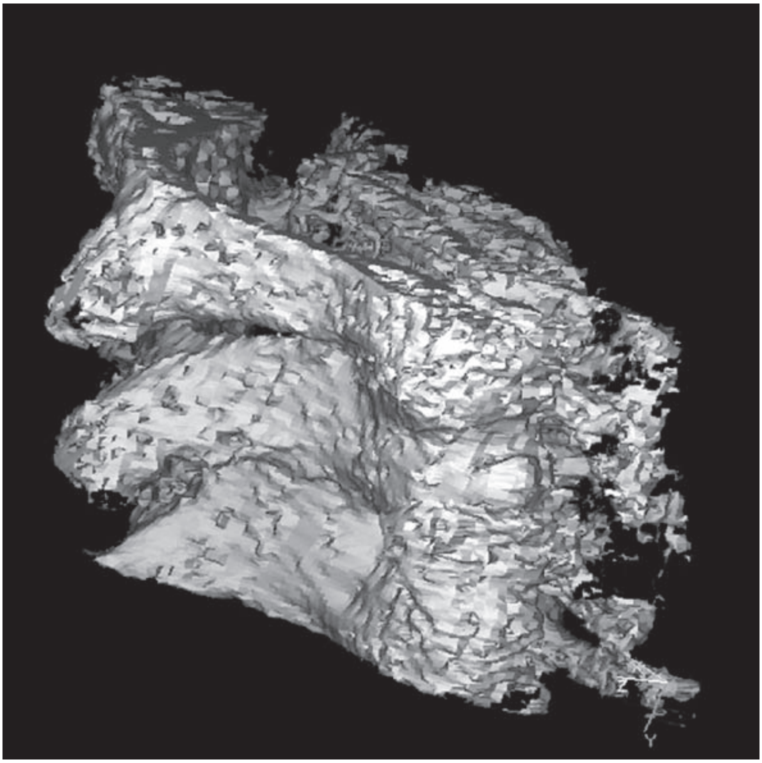
In general, when building medical models, smooth filters tend to give better results and are easier to work with. The effect of sharp versus smooth filtering is illustrated in Figs. 2.11 and 2.12 where the arrow represents a density profile, which is shown as the graph on the right.

Although the smooth image contrast appears poor on screen (Windows computers can only show 256 shades of grey), taking a density profile shows that the actual contrast is good and that the smooth data allows a much lower threshold to be used.

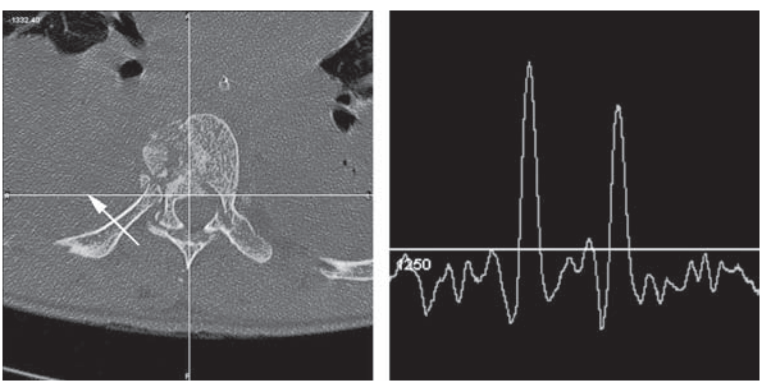
2.3 Magnetic Resonance (MR)

2.3.1 Background

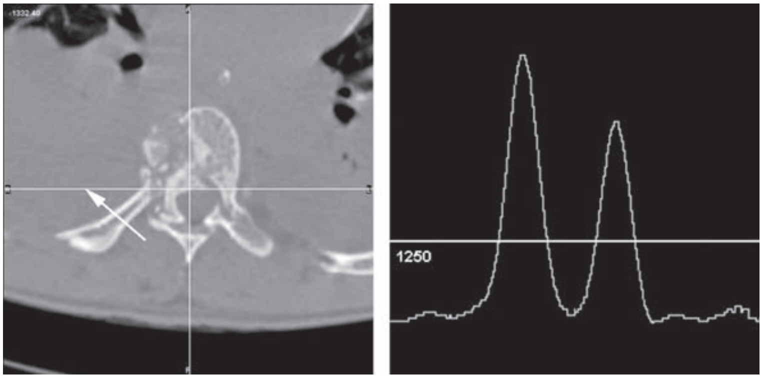
Magnetic Resonance (MR) imaging exploits the phenomenon that all atoms have a magnetic field that can be affected by radio waves. Atoms have a



2.10 Three-dimensional reconstruction of a noisy data set.



2.11 Sharp data.



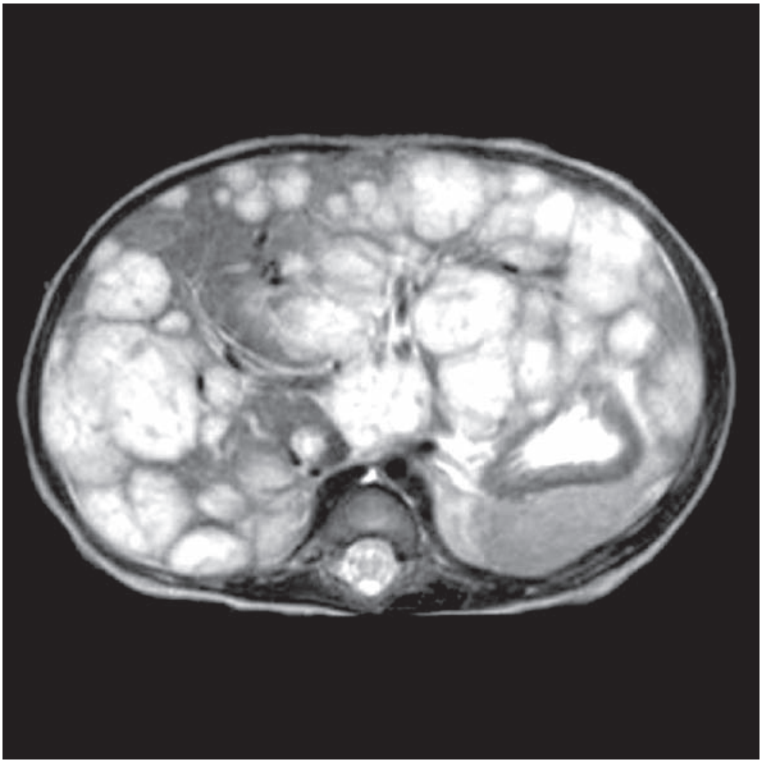
2.12 Smooth data.

natural alignment and MR works by using powerful radio waves to alter this alignment temporarily. When the radio waves are turned off, the atoms return to their natural alignment and release the energy they absorbed as radio waves. To construct an MR image the strength of the radio waves emitted by the atoms is measured at precise locations. By collecting signals from many locations, a cross-sectional image can be created. As in CT scanning the resulting cross-sectional image is a grey scale pixel image, the shade of grey being proportional to the strength of the signal.

As the human body is composed mostly of water, MR scanning targets the hydrogen nuclei present in water molecules. Therefore, locations that have a high water content show up in lighter shades of grey and areas containing little or no water show up darker. For example, air shows up black as will the densest bone, whilst tissues highest in water content, such as fat, will show up white.

As the water content of different soft tissues differs, MR is an excellent modality for investigating the anatomy of soft tissue organs, as can be seen in the typical MR image of the abdomen shown in Fig. 2.13. However, unlike CT, MR is not good for visualising bone. The boundary between air and soft tissue is also good, allowing models to be made of the skin surfaces of patients. Unlike CT, by altering the direction of the radio waves used, MR images can be acquired in cross-sectional slices at any angle. MR also differs from CT scanning in that there are more parameters that can be altered to improve the results for specific tissues. It is, therefore, important that the radiographer knows precisely which tissue type is being targeted before conducting the scans.

Due to the strong magnetic fields encountered during MR, the presence of metal may cause problems. Therefore, jewellery and watches must be removed and patients' notes must be checked to ensure that they do not



2.13 A typical MR image through the abdomen.

have attached or implanted devices that may be adversely affected. As with CT scanning, movement will lead to distorted images, and babies, small children and claustrophobic patients may require sedation or anaesthesia. MR scanners also generate an enormous amount of noise, which even with ear protection is not pleasant for the patient.

Although the MR does not utilise ionising radiation it may present a risk for certain patients. MR scans are time consuming and expensive, so every care must be taken to ensure that the scan is conducted correctly the first and only time. It is also important to consider the dangers that any magnetic metal implants may have before conducting MR scans.

2.3.2 Anatomical coverage

As with any radiographic procedure, basic mistakes can be made through poor communication between the clinician and radiographer. Detail can be lost when the scans do not cover the whole anatomy of interest or do not include sufficient margins surrounding the anatomy of interest. Detail may also be lost by using a field of view that is too small. When conducting three-dimensional series scans, the data should be continuous. Non-continuous sets of data may be satisfactorily combined in software later, however as the patient has usually shifted position slightly and the separate series may not align perfectly.

2.3.3 Missing data

Even with a very small scan distance, some detail may be lost where thin sections of tissue exist between the scan planes. In addition, parts that are very small or connected only by thin sections may not survive the build process.

Due to the time taken to acquire each image, flowing fluids will have moved between the excitation and emission stages of the scan. With multiple images being taken, this may result in the signal being reduced or reinforced. Therefore, blood vessels, for example, may appear too dark or too bright.

2.3.4 Scan distance

This is the distance between the scans taken to form the three-dimensional scan series (unlike CT data capture is not limited to the axial plane), and it may also be referred to as 'pitch' or 'distance between cuts'. To maximise the data available to produce a smooth model this distance should be minimised. Typically, distances of 1–1.5 mm produce good results. A scan distance greater than 2 mm will give increasingly poor results as the scan distance increases. However, taking thinner slices results in less signal strength per pixel being detected by the scanner. Therefore, more echoes are required to boost the signal strength, resulting in significantly longer scan times.

Unlike most CT scanners, the number of pixels used in a cross section is a variable parameter. Typically, the cross section will be broken down in to a relatively small number of larger pixels compared to CT. For example, a typical CT image may be 512 × 512 pixels at a pixel size of 0.5 mm, whereas an MR image may be 256 × 256 pixels at a pixel size of 1 mm. The main reason for this is to maintain signal strength. A larger number of smaller pixels results in less signal strength per pixel. Once again, therefore, more echoes are required to boost the signal strength, increasing scan times.

For three-dimensional modelling, it may be necessary to alter the compromise between scan time and signal strength compared with the protocols normally used for imaging only. MR is often a preferred imaging methodology due to its inherent safety compared to CT. However, the application of MR for three-dimensional modelling should be carefully considered due to the increased scan times. Although MR is safe, the procedure may be uncomfortable and perhaps distressing for the patient, and the added costs and delays incurred by the radiography department should be considered.

2.3.5 Orientation

As with all medical imaging, anterior-posterior and inferior-superior orientation is usually visually obvious but lateral orientation is ambiguous. Usually this is not a problem with automatically imported data but, when manually importing data, it is important that the correct lateral orientation can be ascertained.

2.3.6 Image quality and protocol

MR image data is typically taken to investigate areas of specific illness or locate pathology, such as a tumour. Usually, only as many images as are required to identify the problem are conducted; consequently it is not common practice to undertake three-dimensional MR scans. Conducting a three-dimensional MR scan may take significantly longer than a normal session, and the compromise between scan time and the necessity of the three-dimensional data has to be considered. As conducting MR scans is expensive and a critical resource in most hospitals, increasing the scanning time may cause problems and it increases the inconvenience for the patient. Close collaboration with the radiographer is recommended to ensure that the data are of sufficient quality without creating problems. The configuration of the MR machine may be enhanced by the addition of more coils, which has the effect of increasing the signal strength. Such configurations may be used by specific specialities such as neurosurgery.

Unlike CT images, altering the protocol of an MR scan can dramatically alter the nature of the image. By varying the sequence and timing of excitation and emission of the radio waves, different effects can be achieved. These may serve to improve the image quality for specific tissues or improve contrast between similar adjacent tissues.

2.3.7 Artefacts

This is the general term for corrupted or poor data in MR images. These may result from patient movement or magnetic effects.

Movement

A good quality MR scan depends on the patient remaining perfectly still throughout the acquisition. Movement during the acquisition will lead to distortions in the data (analogous to a blurred photograph). For example, involuntary movement of the chest, neck, head or mouth can occur through breathing or swallowing. When taking multiple scans it may be possible to synchronise the timing of the sequences used with breathing. Movement can be particularly difficult to control when scanning babies, small children and claustrophobic patients, in which case a sedative or even general anaesthetic may be required.

Shadowing by metal implants

Dense metal objects such as amalgam or gold fillings, braces, bridges, screws, plates and implants affect the magnetic field around them leading to the appearance of artefacts in the scan image. The effect is normally apparent as a lack of data shown as dark patches or shadows surrounding the location of the metal object. The extent of this effect depends on the type of metal present.

Noise

Noise occurs in all MR scans and may reduce image quality, but this can be reduced by taking multiple acquisitions. Noise makes the boundaries between adjacent different soft tissues blur. When observing the image, the human eye can account for this and the boundaries appear visible. However, for successful modelling from the data the boundary has to be clear and distinct to a much higher degree than when the images are only used visually.

Taking multiple acquisitions reinforces the signal, improving the quality of the image data; however, this may double or quadruple the time taken to complete a scan session. In practice, a compromise between noise reduction and scan time must be reached with the radiographer.

2.4 Non-contact surface scanning

2.4.1 Background

When attempting to capture human topography, that is the external shape or skin surface, it is frequently more practical and comfortable to use non-contact scanning systems, which typically rely on light-based data acquisition. Non-contact surface scanning uses light-based techniques to calculate the exact position in space of points on the surface of an object. Computer software is then used to create surfaces from these points. These surfaces can then be analysed in their own right or integrated with CAD models.

Unlike CT and MR, these techniques capture only the exterior topography of the patient. This allows models to be made of the skin surfaces of patients. These techniques are not yet considered regular medical imaging modalities, and it is therefore possible that a non-medical scanning facility will have to be used to capture the data. Many product development facilities have access to this kind of equipment, although the nature of the equipment can vary significantly.

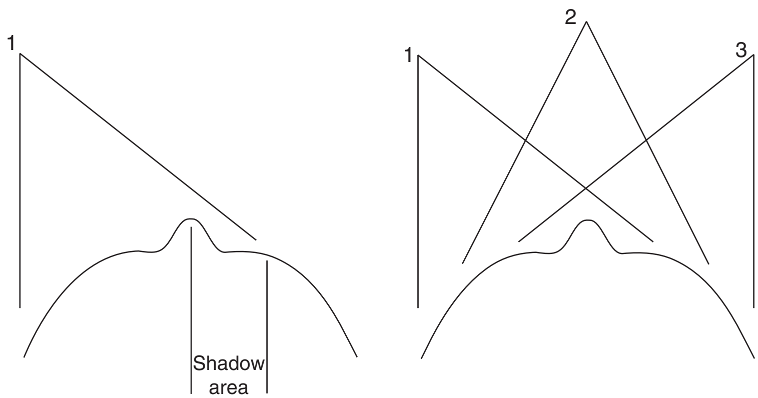
Non-contact surface scanning can be time consuming and potentially expensive but is completely safe. The non-contact nature of the scanning means there is less discomfort for the patient and no distortion of soft tissues caused by the pressure applied when taking casts or impressions. This advantage, in combination with the ability to manipulate data, makes the approach particularly well suited to applications in prosthetic reconstruction and rehabilitation. It is difficult, for example, to take a satisfactory impression of a breast, therefore non-contact scanning may be used in the creation of symmetrical prostheses for mastectomy patients. However, care should be taken when scanning the body surface to ensure it is in the position that relates to the intended use. For example, body parts that are weight bearing will distort according to the position and posture of the patient.

Data manipulation and high accuracy can be a significant aid in prosthesis manufacture, especially for large or complex cases. These techniques may be a valuable aid to shaping and positioning the prosthesis, but the skill and knowledge of the clinicians will always be required to determine the best method of creating, colour matching and attaching the prosthesis to the patient. Case studies illustrating some applications of non-contact scanning are described in Rehabilitation applications in Chapter 6.

2.4.2 Anatomical coverage

Basic mistakes can be made through poor communication between the clinician and technician. Detail can be lost when the scans do not cover the whole region of interest or do not include sufficient margins around the anatomy of interest. Most scanners have a limited field of view and several scans may be required.

In addition, these techniques rely on 'line of sight'. This means that areas that are obscured or at too great an angle to the line of sight will not appear in the scan data. Therefore, several scans may have to be taken from different viewpoints to ensure all of the required details are captured. This can be achieved by moving either the object or the scanner and repeating the process. Depending on the shape of the object, many scans may be necessary. When scanning faces, for example, a single scan will not acquire data where the nose casts a shadow (see Fig. 2.14). However, this is



2.14 Line of sight and viewpoints for scanning the face.

overcome by taking several overlapping scans. The data from each of these scans can then be aligned using software to give a single coherent data set. When conducting a series of scans it is, therefore, important that they overlap so that the individual scans can be put together accurately. Despite using multiple scans, some areas may remain difficult to capture. For example, it is very difficult to capture data from behind the ear and at the nostrils.

2.4.3 Missing data

Because these techniques use light to calculate the points, transparent or highly reflective surfaces can cause problems. Usually human skin performs very well in this respect, but steps may be required to dry particularly greasy or moist skin. These effects may also be overcome somewhat by applying a fine powder, such as talcum powder, that will give the object an opaque matt finish. The eyes may cause problems due to their shiny surface and watering. All optical scanners should be inherently safe; however, care should be taken when scanning the eyes to ensure that bright light or laser light does not directly enter the pupil.

Another inherent problem is caused by hair. Hair does not form a coherent surface and absorbs or randomly scatters the light from the scanner. However, the fine hair present on most body surfaces does not normally affect the captured data, although excessively thick body hair may reduce the quality of the data captured. In most cases, the presence of hair will lead to gaps in the data. Fine or downy body hair often does not cause significant problems, but there may be little that can be done about a full head of hair and it would not be normal to consider shaving the head for such a procedure unless the clinical benefits were overwhelming. When considering scanning the face, gaps are likely to arise from areas of significant facial hair, such as beards and moustaches but may also be encountered around the eyebrows and lashes. These gaps can be clearly seen as black areas in the surface scan data shown in Fig. 2.15.

2.4.4 Movement

As with other scanning modalities, any patient movement during the scan will lead to the capture of poor data. The length of time required varies depending on the exact type and specification of the scanner being used but may range from a fraction of a second to as much as a minute. Consequently, it is important that the subject be scanned in a comfortable and steady posture. This does not normally pose a problem when dealing with co-operative adults and older children, but small children and babies may be difficult to keep still during the scanning. Unlike MR or CT scanning, it is highly unlikely that sedation would be justified for this type of scan.

2.15 Scan data of the face of a male subject.

With most scanning software, if there is sufficient overlap between adjacent scans they can be aligned by the computer. This means the patient does not have to remain perfectly still between successive scans. However, the same body posture or facial expression should be maintained throughout. For the best results, the patient may have to be braced in a comfortable position during each scan. Depending on the scanners being used, it may be simpler to keep the subject still and move the scanner around them. Alternatively, a series of multiple scanners can be positioned around the subject to capture different views simultaneously or in rapid succession.

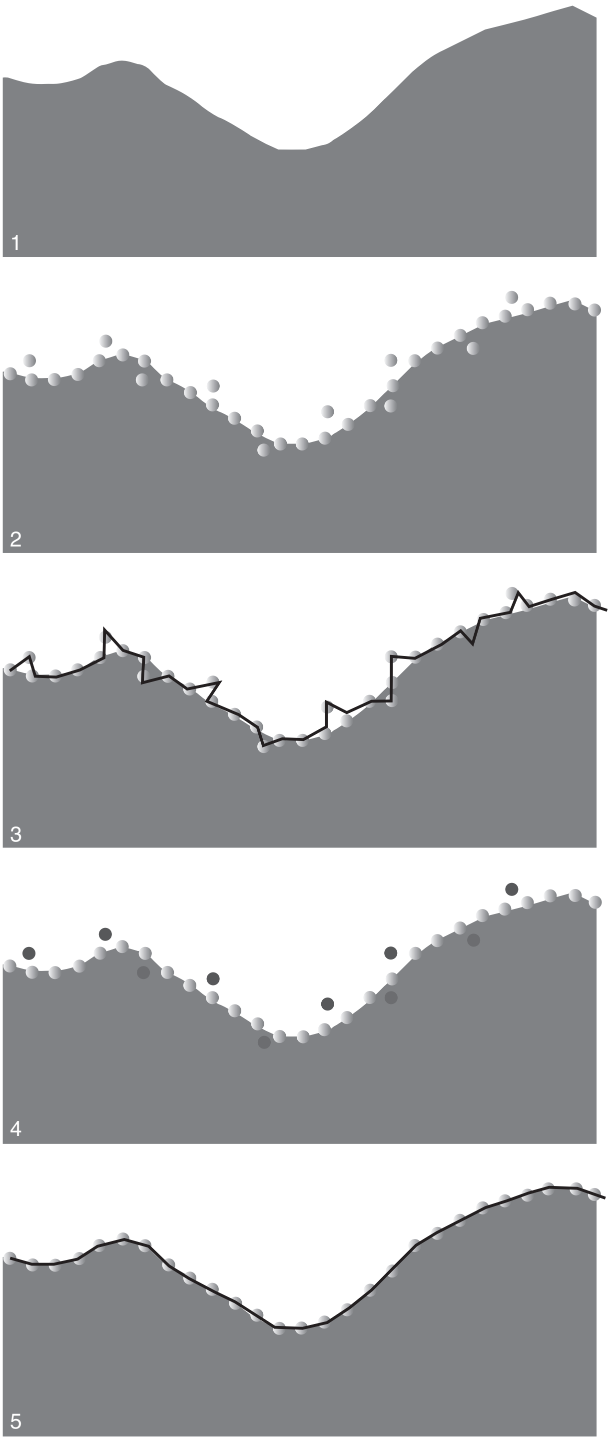
However, despite these steps some movement is likely to be encountered, such as breathing, swallowing and blinking so care should be taken when scanning the face, neck and chest. If the patient is able, a breath-hold may help if the scan time is only a matter of seconds.

2.4.5 Noise

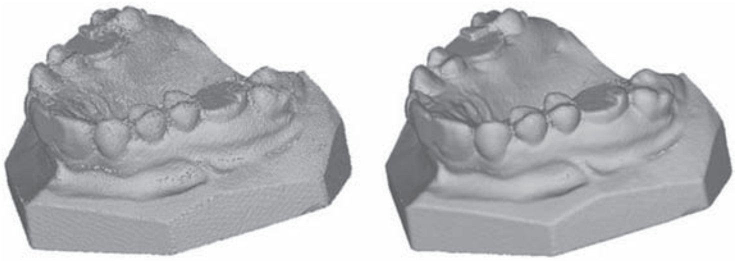
Non-contact scanners capture many thousands of points at a time. The vast majority of these points will fall accurately on the surface of the object being scanned. However, due to tolerances and optical effects some of these points will deviate from the object surface. If enough points deviate from the surface by a sufficient amount, it will affect the quality of the data. These errant points are usually referred to as 'noise' in the data. The amount of noise present in captured data will depend on the type of scanner and the optical properties of the surface being scanned. Smooth, matt surfaces usually produce less noise than reflective or textured surfaces. Although it usually necessary to take multiple overlapping scans to cover the whole surface of an object, large overlapping areas are likely to result in increased levels of noise.

Noise can be reduced by filtering. Filtering selectively removes data points that deviate greatly from the vast majority of neighbouring points. This is illustrated schematically in steps 1–5 in Fig. 2.16: (1) the object surface to be scanned; (2) the scan data points; (3) using all of the data points creates a poor surface; (4) points are selectively filtered according to their deviation from the majority of neighbouring points; (5) deleting filtered points leaves a closer fitting surface to the actual object surface. The magnitude of the deviation can be defined by the user to vary the effect of the filtering. Filtering functions are typically included in the software that is used to operate the scanner.

The effect of noise can be seen in Figure 2.17 (left) showing a three-dimensional polygon model created from optical scan data of a dental cast (in this example the STL file format is used). Noise in the original scan data has resulted in a polygon surface that appears rough and pitted. Post-processing software can be used to improve the quality of the surface



2.16 The effect of filtering to remove noise from optical scan data.



2.17 Scan data showing noise (left) and the same data with noise reduced (right).

model. These functions work by averaging out the angular differences across neighbouring polygons within user-defined tolerances. The effect is to smooth out the surface. When dealing with human anatomy the smooth, curved surfaces typically encountered mean that this approach often leads to a more accurate model despite the additional data operations. Fig. 2.17 (right) shows the same three-dimensional model that has been 'smoothed' to mitigate the effects of noise.

Point cloud data is in itself of little use and it is normally used as the basis for a three-dimensional surface or solid model. This is described in more detail in Chapter 4.

2.5 Recommended reading

Section 6.2 Implementation case study 2 – Medical rapid prototyping technologies: state of the art and current limitations for application in oral and maxillofacial surgery.

Gibbons A J, Duncan C, Nishikawa H, Hockley A D, Dover M S (2003), 'Stereolithographic modelling and radiation dosage', *British Journal of Oral and Maxillofacial Surgery*, **41** (6), 416.

Henwood S (1999), *Clinical CT: Techniques and Practice*, Cambridge, Greenwich Medical Media Ltd, ISBN: 1900151561.

Hofer M (2000), *CT Teaching Manual*, New York, Thieme-Stratton Corp, ISBN: 0865778973.

Kalander W (2000), *Computed Tomography*, Weinheim, Wiley-VCH, ISBN: 3895780812.

Swann S (1996), 'Integration of MRI and stereolithography to build medical models: A case study', *Rapid Prototyping Journal*, **2**, 41–6.

3

Export data format and media

3.1 Medical scan data

Medical scanners such as CT and MR produce pixel-based images in a series of slices whilst non-contact surface scanners produce three-dimensional point clouds. Therefore, the formats used to describe them are completely different and separate software technologies are required to use them.

CT and MR scanners are highly complex pieces of equipment made in low volumes by a small number of high technology firms. The hardware and software interface is usually part of the whole system. Therefore, radiographers are often limited in the output formats that they can deliver. In many cases, the only option available is the archiving system. In some cases, these output formats are also compressed and cannot be read by third party software.

However, this should be less of a problem over the coming years. Many radiology departments are embracing teleradiology and can, therefore, make the image data available over hospital networks. Good third party radiography software should be able to import most of the commonly used proprietary formats. The industry standard is called DICOM and it should be used whenever possible, as almost all software should support it. An example of the practical implications of transferring data from a hospital to a service provider can be found in Section 6.1 Implementation case study 1.

3.1.1 DICOM

DICOM stands for Digital Imaging and Communications in Medicine and is an internationally agreed standard for all medical imaging modalities. The standard was initiated in response to the development of computer-aided imaging in the 1970s by a joint committee from the American College of Radiology (ACR) and the National Electrical Manufacturers Association

(NEMA). They first published an ACR-NEMA standard in 1985 and updated it in 1988. Version 3, which saw the name changed to DICOM, was published in 1993. The standard now covers all kinds of medical images but also includes other data such as patient name, reference number, study number, dates and reports. Since then most manufacturers adhere to the standard and data transfer problems are much less likely to occur than was previously the case.

The DICOM standard enables the transfer of medical images to and from software and scanners from different manufacturers and has aided the development of picture archiving and communication systems (PACS), which can be incorporated with larger medical information or records systems. More information on DICOM can be found at http://medical.nema.org/.

3.1.2 Automatic import

When using medical data manipulation software, such as Mimics (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium) for example, there is usually an automatic import facility. The facility will automatically recognise many manufacturers' formats and will almost certainly recognise data written in the international image standard DICOM. The software will automatically read in the data and convert it into its own format ready for manipulation.

However, depending on the specification of the automatic import software being used, there may be some instances where the user will require some knowledge of the scan parameters in order to complete the import. Usually these factors are not fully described in the DICOM standard. Gantry tilt is one such example. Although DICOM supports the magnitude of gantry tilt, it does not provide the direction. The software will automatically apply a correction, but the user will be required to either confirm or reverse the direction to ensure that the data is correct. The second example is the anatomical orientation of the data set. DICOM will provide left, right and anterior-posterior orientation but may not provide inferior-superior information. The user may be required to select this orientation during import. The inferior-superior orientation is usually anatomically obvious so this rarely creates a problem.

3.1.3 Compression

Image data can be very large and compression is sometimes used, especially for archiving. Data compression may incur a loss of information, called 'lossy' compression, or retain all data but write it in a more efficient manner, called 'lossless' compression. For modelling purposes, compression should be lossless or preferably avoided completely. Any loss of information may reduce the accuracy of models made from the data set. In addition, some compressed formats are unreadable by third party software, rendering the data useless. Compression for medical modelling is not often necessary. In normal circumstances, although the image data may be several hundred megabytes, it can usually be accommodated on a single CD-ROM.

3.1.4 Manual import

When the data is not in a DICOM compatible format or is from a manufacturer that is not directly supported by the software application being used, manual import must be used. Error free manual import of medical scan data will thus require access to *all* of the parameters of the data. Table 3.1 lists the parameters that must be known to import data successfully.

3.2 Point cloud data

The data captured by a non-contact surface scanner is merely a 'point cloud'. This is a collection of thousands of point co-ordinates in three-dimensional space. It is typical to convert this into a more useful format before applying the data to analysis or visualisation. There are a number of formats used for point cloud data and the format will depend on the type of scanner being used.

The simplest forms of export format are polygon meshes, such as the commonly used STL file format (the STL file format is fully described in Section 4.6.2). However, as the export data format used will depend very much on the anticipated use of the data, this area is explored in greater depth in Chapter 4. Some techniques can be applied directly to the point cloud data. These are typically carried out to remove erroneous points or simply reduce the number of them and to decrease noise. This has the effect of cleaning up the data set and reducing the file size.

Table 3.1 Information required for manual data import

Number of images	Integer
File header size	In bytes
Inter image file header size	In bytes
Image size	In pixels e.g. 512 × 512
Slice distance	In millimetres
Field of view or pixel size	In millimetres
Gantry tilt	In degrees
Scan orientation	Left–right or right–left

3.3 Media

In combination with the data format, the output media type is also a part of the whole system. Typically, these are intended for archiving and tend to be high capacity magnetic optical disks (MOD). These are expensive in terms of the disks, hardware and software and are not commonly found in any other fields. It is often prohibitively expensive for service providers to purchase the necessary equipment to read every type of output media. Typically, data on these media is sent to specialists who charge for translation of the data into a readable format and media type. For example, Table 3.2 lists different types of storage media that are used in radiology but not commonly used in other fields. This contributes considerable cost and lead-time to the process of accessing CT data.

However, this problem is rapidly being overcome by advances in computer networks and telecommunications. In addition, there has been widespread adoption of Windows operating systems, PC hardware, compact discs (CD) and digital versatile discs (DVD) as data storage media. With

Table 3.2 Media types used for medical scan data

CD / DVD Recordable (CD-ROM) Re-writable (CD-RW) DVD (R+/–, RW)	PC formatted CDs and DVDs are the preferred media type. They have high capacity; they are secure; they can be read directly by almost any PC; and they are readily available and very cheap.
ZIP / JAZ Iomega ZIP or JAZ disk	PC formatted ZIP and JAZ disks can be read directly by anyone with the appropriate hardware. These disks are not so readily available and relatively expensive.
Floppy disk 3.5″	PC formatted 3.5″ floppy disks can be read directly; however, they are of little use due to their limited capacity. They are readily available and cheap.
MOD / WORM Magnetic optical disk Write once read many 5.25″	Still a commonly used medium in radiography departments. MODs can be translated but may incur additional charge and delay from a service provider to transfer the data to a more convenient format. MODs are not readily available and are expensive.
DAT Digital audio tape 4 mm	DAT is now becoming obsolete in data archiving. However, DAT tapes can be translated but may incur an additional charge and delay from a service provider to transfer the data to a more convenient format.
Magnetic tape	These tapes are no longer in common use and it is unlikely that any service provider will offer a translation service.

teleradiology increasing, many hospitals can now put medical image data onto the hospital local area network. This enables clinicians to remotely access medical image data in their own departments rather than relying on a limited number of films printed in the Radiography Department. Once the data is available over the hospital network it can be burned on convenient and cheap storage media such as CDs.

When dealing with point cloud data, media formats are normally those typically used in the design and engineering community and translation does not pose the problems associated with radiological data.

4
Working with medical scan data

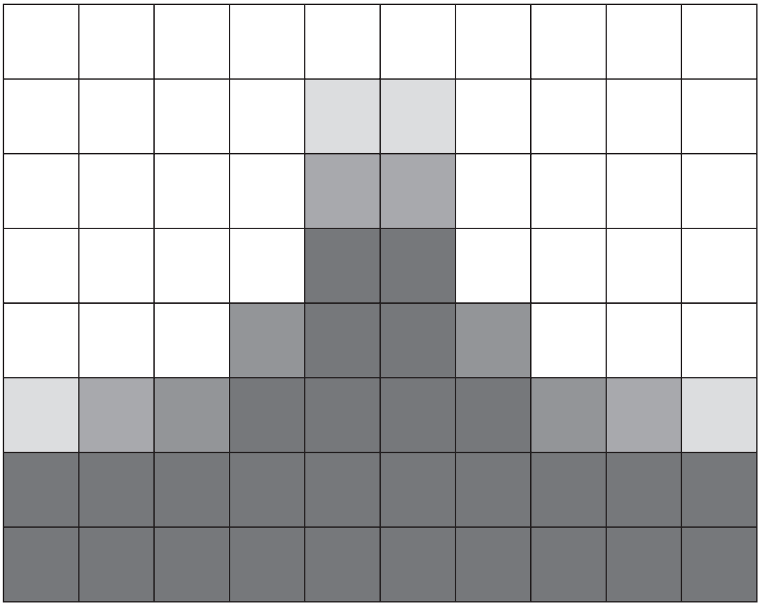
4.1 Pixel data operations

As described in earlier chapters, both CT and MR images are made up of grey scale pixels. In CT, the grey scale is proportional to the X-ray density. In MR, the grey scale will be proportional to the magnetic resonance of the soft tissues. In many cases, it is advisable to work with the original data rather than any three-dimensional reconstruction derived from it. Therefore, CT and MR image data is often manipulated in the pixel format. Much of this data manipulation is similar in concept to popular photo-editing software such as Adobe ® Photoshop ® (Adobe Systems Inc., 345 Park Avenue, San Jose, CA 95110-2704, USA). Many software packages are available that utilise such pixel manipulation to allow specific individual anatomical structures to be isolated from a CT or MR data set and exported in an appropriate format. Many of these packages operate in a similar manner to the software that radiographers routinely use to generate images in radiology departments.

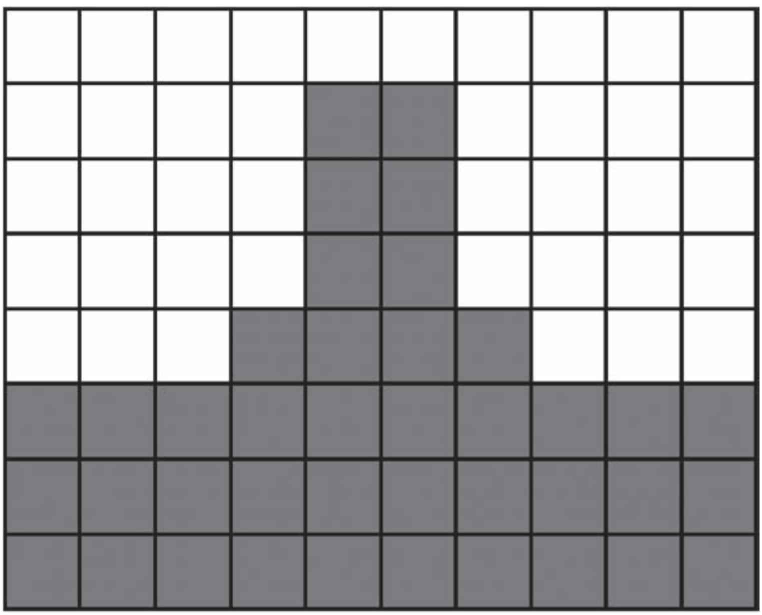
4.1.1 Thresholding

Thresholding is the term used for selecting anatomical structures depending on their density, or grey scale value. By specifying upper and lower density thresholds, tissues of a certain density range can be isolated from surrounding tissues. Due to the partial pixel effect described in Chapter 2, small variations in the thresholds may affect the quality of the anatomical structures isolated. The effect may be to make them slightly larger or smaller as illustrated in Figs. 4.1–4.3. However, thresholding will select all pixels within the specified density range regardless of their relationship to individual anatomical structures. This may be overcome using region growing.

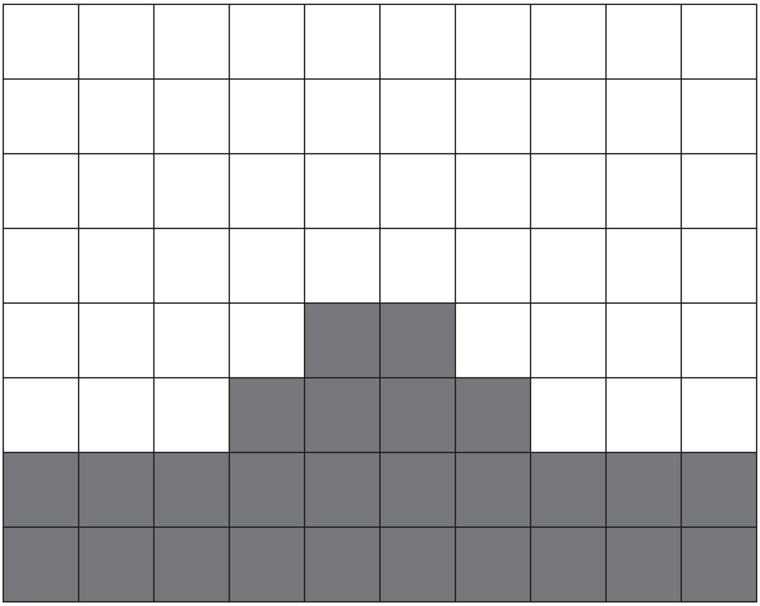
The effect can be clearly seen in the real example shown in Fig. 4.4. In this example, bone is selected by setting a high upper threshold and an appropriate lower threshold, with the resulting region shown in Fig. 4.5.



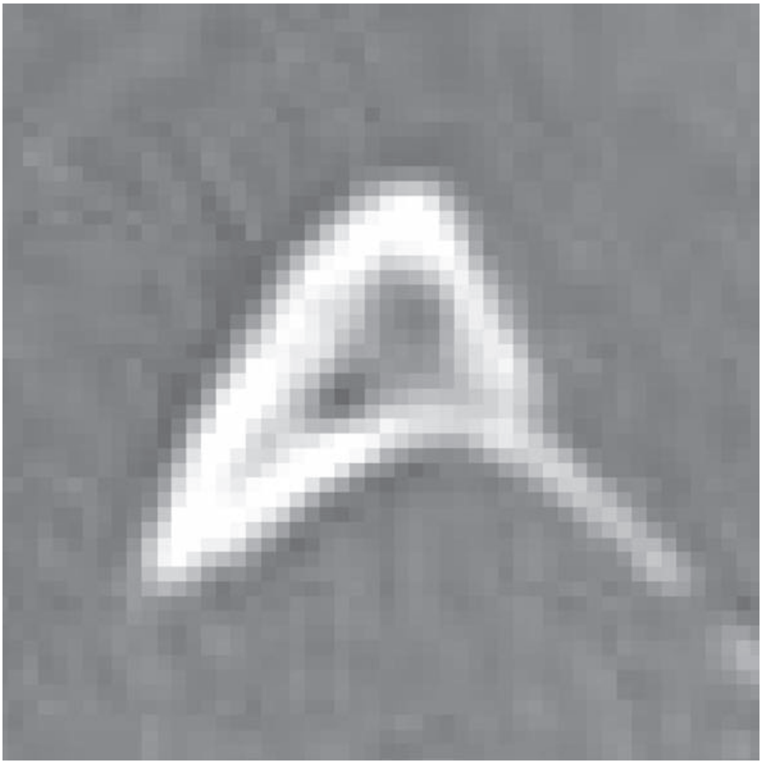
4.1 Original CT image.



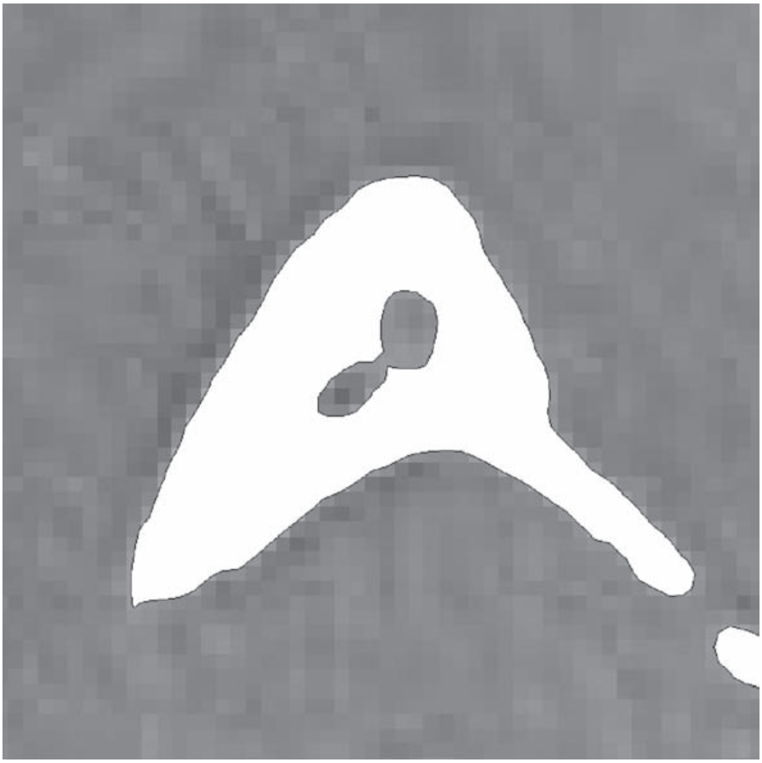
4.2 Effect of a low threshold.



4.3 Effect of a high threshold.



4.4 Original CT image.

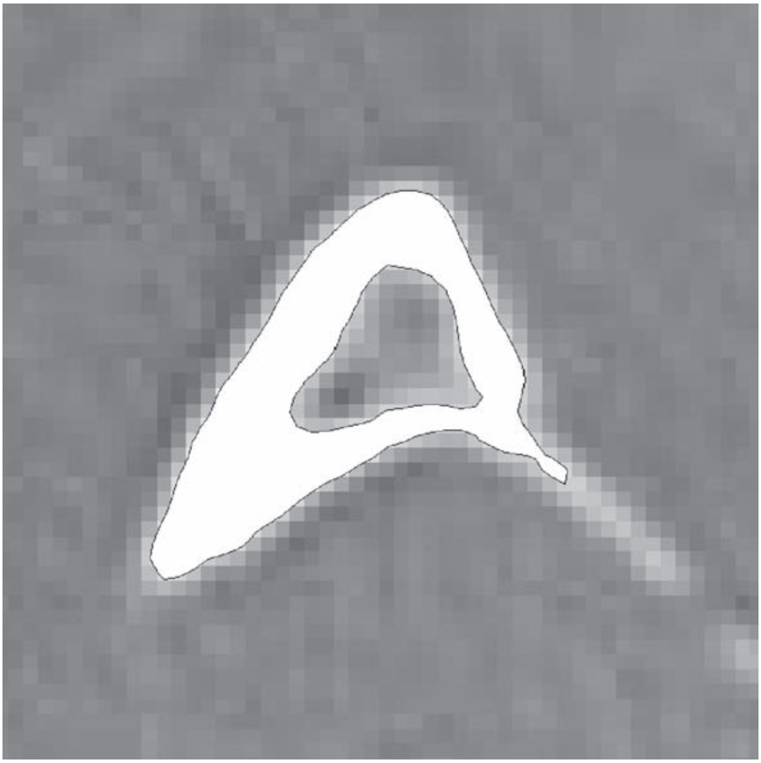


4.5 Region selected using appropriate threshold values.

However, the effects of varying the lower threshold can be seen in Figs. 4.6 and 4.7. Notice that in Fig. 4.6 it is clear that bone is present beyond the boundary of the selected region. However, in Fig. 4.7 we can see that other areas, unconnected to our region of interest, have been selected. It is, therefore, essential that thresholds be accurately selected where accuracy is of high importance. This becomes particularly critical when very thin or narrow objects are of interest as small changes in threshold can result in these areas not appearing in the selected region.

4.1.2 Region growing

In order to select single anatomical structures from all of those present within the specified thresholds, a technique called region growing is typically used. This works by allowing the user to select a single pixel within a region already specified by thresholding. The software then automatically selects every pixel within the specified thresholds that is connected to the



4.6 Region selected using an increased lower threshold value.

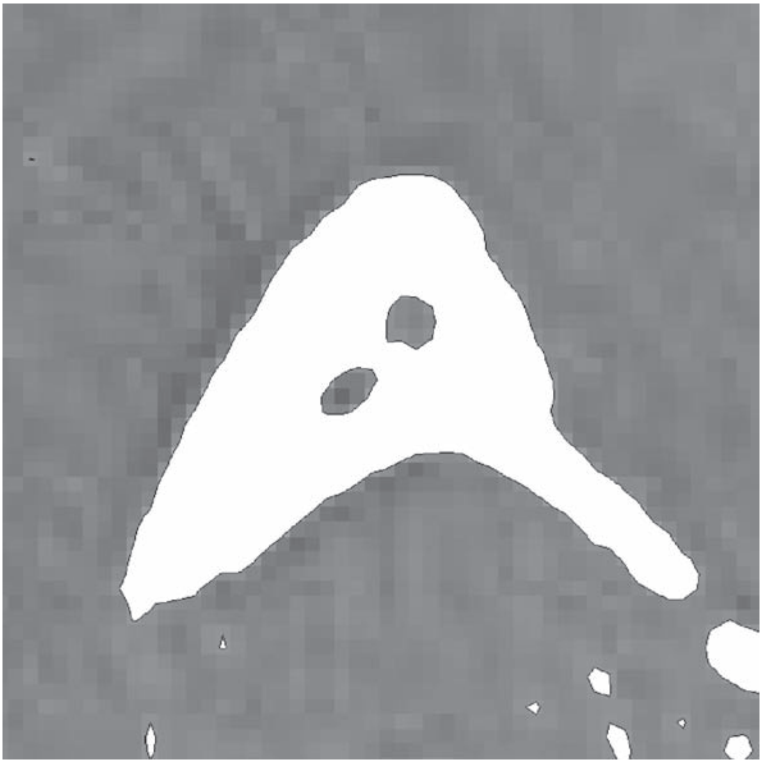
one selected by the user. This results in single anatomical structures being isolated from neighbouring, but unconnected, structures.

However, this is not as simple as it might first appear. It only requires one single pixel (representing perhaps 0.25 mm) to connect two regions for the software to assume that they are the same structure. Therefore, structures that are separate but in close proximity or contact may need to be separated manually before region growing will be successful. This may occur, for example, in joints.

4.1.3 Other techniques

Many other techniques may be available depending on the software being used. Manual techniques can be used and are similar to those found in photo-editing software, such as draw, delete, cavity fill, etc. These allow the user to edit data to remove artefacts or connect neighbouring structures.

Other techniques are sophisticated variations on the thresholding and region growing functions. These may incorporate local variations to

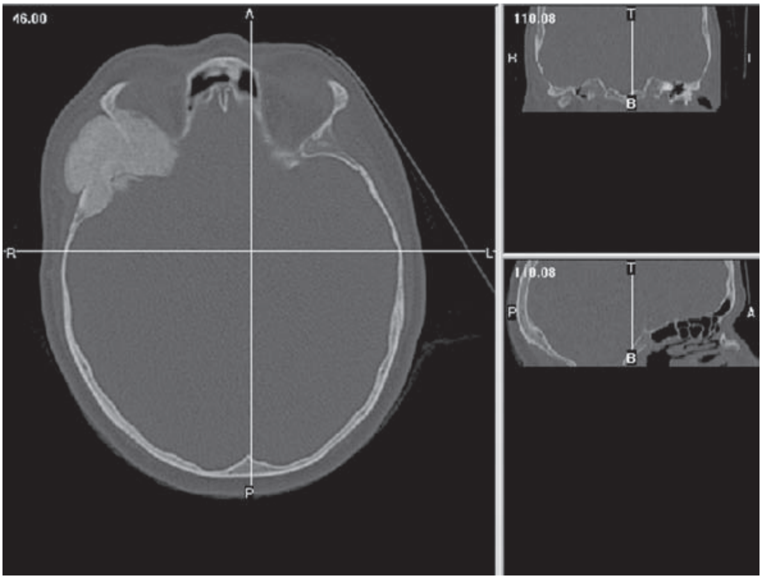


4.7 Region selected using a decreased lower threshold value.

thresholds, or add or remove pixels from selected regions to alter the boundaries. The exact nature of these functions will depend on the software being used; therefore, it is not appropriate to attempt to describe them all here.

4.2 Using CT data – a worked example

To illustrate how such software can be used, let us work through a simple example using the popular software package called Mimics (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium). The first step is to import the data. In most cases, the data will be in a format that is compliant with the internationally recognised DICOM (Digital Imaging and Communications in Medicine) format. If this is the case, the software has an automatic import function. During importing, the software converts the images into a format it recognises as its own and displays the resulting axial images on the screen. The axial images are the original scan images from the CT data. Mimics software also uses the axial pixel data and the slice distance to calculate images in the sagittal and coronal planes as shown in Fig. 4.8.

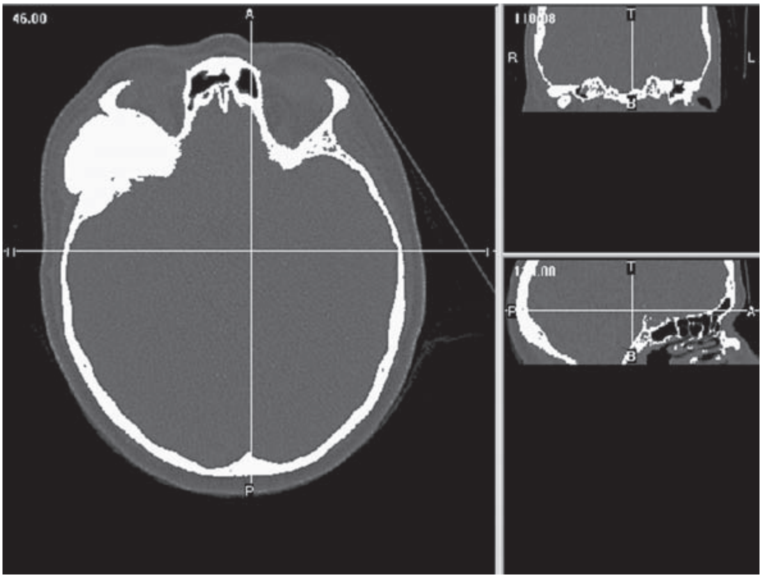


4.8 Thresholding of CT data (see also colour section).

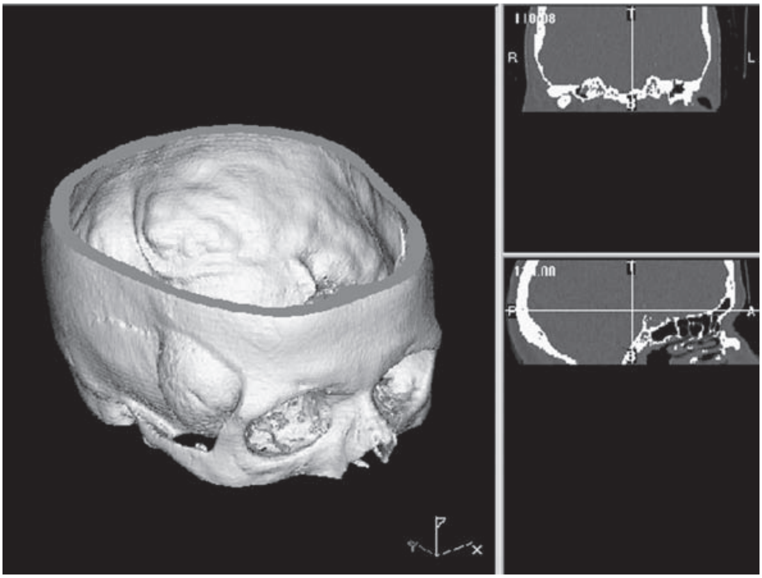
As described earlier, in CT images the grey scale is proportional to the density of the tissue. Therefore, the denser the tissue is, the lighter the shade of grey that corresponds to it will be. Mimics, and software like it, uses these grey scale values to differentiate between different tissue types. By selecting upper and lower grey scale values, specific tissue types can be selected. These levels are typically referred to as thresholds. On importing a new data set, Mimics displays the images using a default threshold for bone, which is shown in green (see Fig. 4.8 in the colour section). Selecting the desired tissue type is accomplished by varying the upper and lower thresholds until the required tissue type is isolated. This process is usually referred to as segmentation.

Once the desired tissue type, in this case bone, has been segmented, it may be necessary to limit the selected data to one particular structure. Region growing allows the user to select a certain pixel within the desired structure and the software then automatically selects all other pixels that are connected to it. As this function operates in all three dimensions, single structures can quickly be segmented from the whole data set. This can be seen in the yellow structure highlighted in Fig. 4.9 (see Fig. 4.9 in the colour section).

The software can also be used to view three-dimensional shaded images of the selected data. The segmented data is then exported in the format used to create the computer files necessary to build the medical model as shown in Fig. 4.10 (see Fig. 4.10 in the colour section).



4.9 Region growing of CT data (see also colour section).



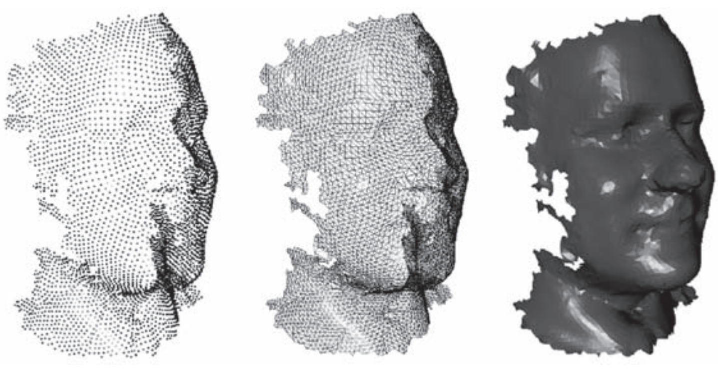
4.10 A three-dimensional shaded image of segmented data (see also colour section).

Scans are usually performed in slices or a spiral form in a plane perpendicular to the long axis of the patient. The interval between the slices may be in the order of a millimetre or two, whereas the models are built in layers between 0.1 and 0.2 mm in thickness. Therefore, additional software is used to interpolate intermediate slices between the scan data slices. Another interpolation is carried out within the plane of the scan to improve resolution. Together, these operations result in the natural and accurate appearance of the model. This interpolated data can then be exported in a number of formats that may be transferred to computer-aided design packages or rapid prototyping preparation software. Some of the different output data formats are described later in this chapter. The same example as shown here is used to enable comparison.

4.3 Point cloud data operations

Non-contact scanning typically produces a large number of points that correspond to three-dimensional co-ordinate points on the surface of the target object. The collection of points taken of an object is usually referred to as a ‘point cloud’. The nature of point cloud data is completely different to the pixel image data we obtain from CT and MR scanning and therefore requires quite different software.

Point clouds in themselves are of little use. They are, therefore, usually converted into three-dimensional surfaces. The simplest method is polygonisation. This involves taking points and using them as vertices for polygon facets. The collection of facets is usually known as a polygon mesh. The simplest form of polygon is the triangle so it is frequently used. The steps from point cloud data to polygon surface are shown in Fig. 4.11. Triangular



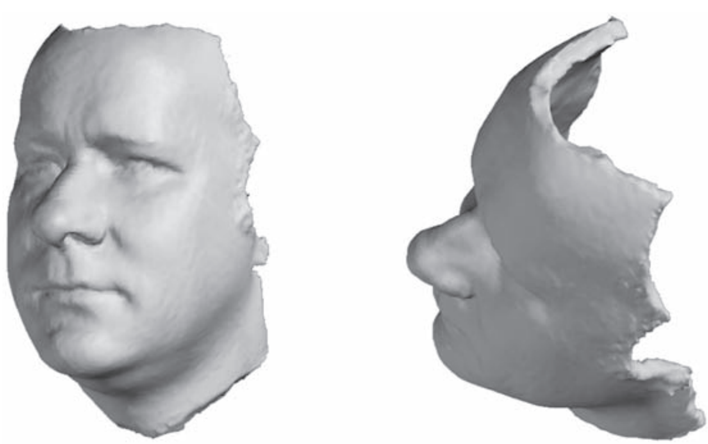
4.11 A triangular polygon mesh created from a point cloud.

faceted meshes can be easily stored in the STL file format. Applying other shapes of polygon mesh, such as square or hexagonal, may be more appropriate, particularly for use in finite element analysis techniques.

Often surface scan data will extend beyond the principal area of interest and unnecessary points should be removed immediately. This reduces the memory requirement for any subsequent operations. Once a surface has been generated from the available points, any gaps will become apparent. At this point patches can be created to fill these gaps to form a single coherent surface.

Surfaces that are more sophisticated can be generated on the point clouds by applying mathematically defined curves to points and creating surfaces from them. This is typically done in reverse engineering, enabling the surface to be taken into traditional engineering CAD systems. This requires a great deal of skill and expensive software and is only necessary when it is desirable to perform precise changes to the surfaces. If the ultimate aim is to produce a physical model by RP techniques then this step is redundant, as the data will only have to be converted into the STL format again.

Whichever route is taken, if a physical model is to be made, the surface has to be turned into a single bound volume. This can be achieved by offsetting the surface and filling the gap, resulting in a model with a definite thickness, as can be seen in Fig. 4.12, which shows two views of a three-dimensional model created from scan data of a face. The oblique view clearly shows the thickness of the model. To reduce file size the rear surface may be simplified as it has no purpose other than to give the model bulk.



4.12 A bound volume STL file created from an offset surface.

4.4 Two-dimensional formats

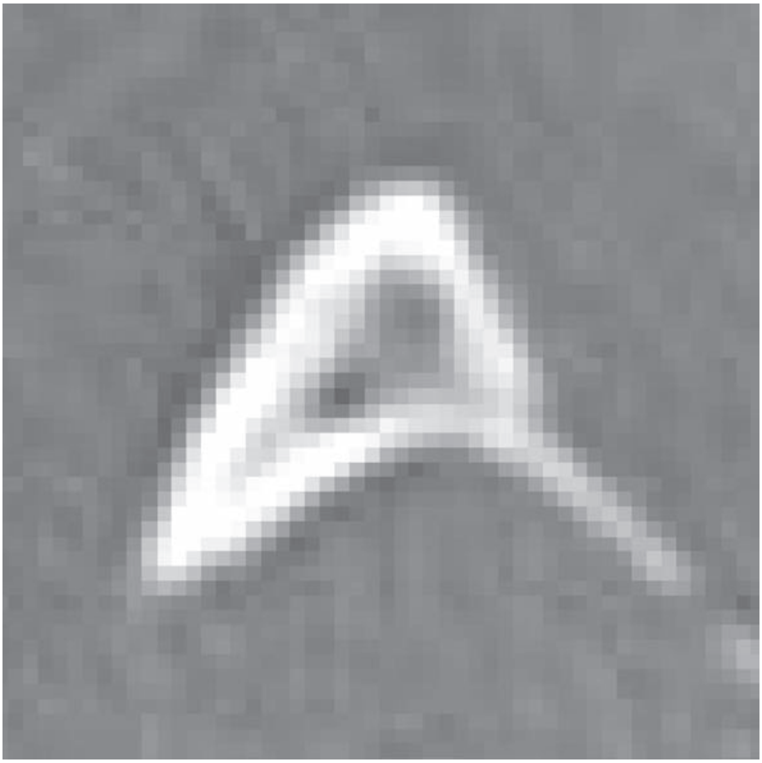
Typically in radiography the output of medical scanning modalities is in the form of two-dimensional images. These images are usually prepared from the scan data by the radiographer according to instructions from doctors and surgeons, and they may be from the slices taken through the body or three-dimensional reconstructions. Often these images are printed on film and treated in much the same way as X-ray films. As medical scan data images are made up of pixels, the images can be exported in familiar computer graphics formats such as bit maps or JPEGs.

4.5 Pseudo three-dimensional formats

Data can be exported in formats that allow three-dimensional operations to be undertaken without being true three-dimensional forms. The objects are defined by a series of two-dimensional contours arranged in increments in the third dimension. These types of file are often referred to as $2^1/_2$D data or 'slice' formats. More typically, however, these formats are used as an intermediate step in creating true three-dimensional CAD representations.

The formats typically are in the form of lines delineating the inner and outer boundaries of structures isolated by thresholding and region growing techniques. The lines are usually smooth curves, or polylines that are derived from the pixel data. This technique results in smooth contours that more closely approximate the original anatomical shape than the pixelated data. For example, if we consider the original CT data shown in Fig. 4.13 we can see that there is a high-density bone structure surrounded by lower density soft tissue. The effect of specifying upper and lower threshold and region growing is shown in Fig. 4.14. The inner and outer boundaries of the selected region are smooth polylines.

The pseudo-three-dimensional effect arises when the two-dimensional polylines are stacked in correct orientation and spacing to provide a layered model, similar in effect to a contour map. Figure 4.15 shows a three-dimensional rendering derived from CT data of the proximal tibia alongside the same data exported in a $2^1/_2$D polyline or 'slice' format. When such formats are used in CAD, it is common to create surfaces between the slices to generate true three-dimensional surfaces. However, when these formats are used to interface directly with rapid prototyping machines, it is common to interpolate intermediate layers between the original slices so that data exists at layer intervals that correspond with the build layer thickness of the machine being used. The formats that follow are essentially the same and appear similar to that shown in Fig. 4.15. The differences between them are concerned with the order and amount of information stored in them.



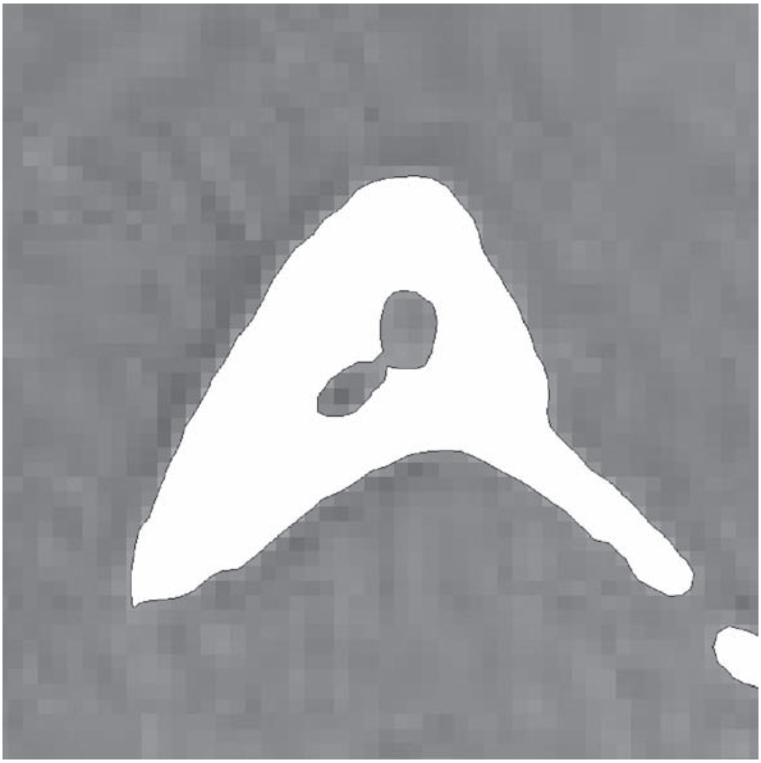
4.13 Original pixelated CT image.

4.5.1 IGES contours

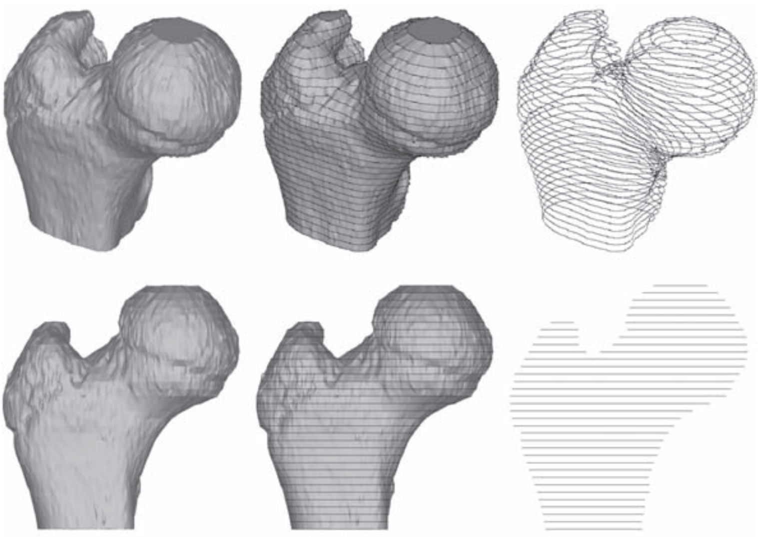
IGES (Initial Graphics Exchange Specification) is an international standard CAD data exchange format that has been used for many years. More information about the standard can be found at http://www.nist.gov/iges/. The standard consists of lists of geometric entities, which can be assigned with size and position properties in three dimensions. When dealing with layer data, two-dimensional contours can be described as simple polylines at increments in the third dimension. These contours can be imported into CAD packages which can then form true three-dimensional surfaces on them. IGES files have the three-letter suffix IGS.

4.5.2 SLC

Derived from the word 'slice', the SLC is a relatively simple file format that describes the perimeter of individual slices through three-dimensional forms. The inner and outer boundaries are expressed as a set of vectors. The format, therefore, is an approximation but, in practice, the vectors can



4.14 Segmented region showing smooth polyline boundaries.



4.15 $2^1/_2$D polyline data (right) compared to 3D rendered model (left). The middle images show how they relate to each other.

be generated with sufficient resolution such that curved surfaces on RP models derived from them appear smooth.

The format was developed by 3D Systems as an alternative input file for their stereolithography technology. If an SLC file can be generated from the original source data, it effectively bypasses the need to create STL files. For a given data set, an SLC file will be much smaller than an STL file of comparable resolution. For example, for the data illustrated in Fig. 4.9 the SLC file would be 28.0 MB, which would compare favourably with the equivalent quality STL file which would be 94.3 MB. Therefore, the SLC provides a highly efficient data transfer format for medical modelling using stereolithography.

4.5.3 CLI

Common Layer Interface is a contour file format that describes cross-sectional slices through an object in much the same way as the SLC file. However, the format is commonly available to many software developers and may be used with a variety of RP technologies. For comparison, the CLI file of the data illustrated in Fig. 4.9 would be 13.8 MB.

4.5.4 SLI

Also derived from the word ‘slice’, the SLI file format is similar to the SLC file format but, rather than being an input file, it is an intermediate file format created during the preparation of stereolithography builds. The file, developed by 3D Systems, not only describes the perimeter of the slices but also includes raster lines that make up the cross-sectional area within the boundary. These raster scan lines are usually referred to as hatches. The file format also includes different types of hatch for up-facing and down-facing layers. This is important in stereolithography because up-facing and down-facing layers are built differently to optimise accuracy. As with the SLC file format, the ability to generate this file format directly from medical scan data provides an efficient data transfer when generating stereolithography files. The extra hatch information contained in the file increases its size in comparison to the SLC. For example, the SLI file of the data illustrated in Fig. 4.9 would be 46.1 MB.

4.6 True three-dimensional formats

4.6.1 Polygon faceted surfaces

Unlike the contour or slice-based formats described above, true three-dimensional data formats generate computer models that have a surface.

If a computer model has a surface it may be rendered and visualised on screen and be manipulated with a higher degree of sophistication than $2^1/_2$D data. However, file sizes are typically higher.

One of the simplest methods of generating a three-dimensional computer model is to create a polygon faceted surface. This is achieved by approximating the original data as a large number of tessellating polygon facets. As the triangle is the simplest polygon, it is frequently exploited in polygon faceted representations. However, other polygons are also used, particularly in finite element analysis (FEA).

4.6.2 STL

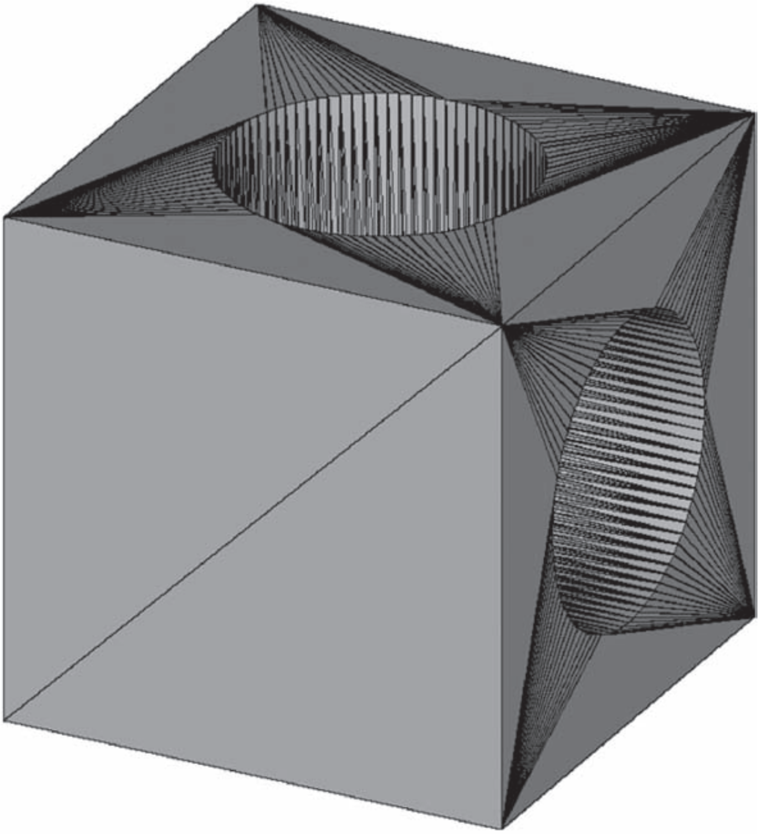
Derived from the word 'stereolithography', the STL file is a simple file format that describes objects as a series of triangular facets that form its surface. For example, if we view a simple object as an STL file we can see the triangles. It can be seen that large flat areas require few facets, whereas curved surfaces require more facets to approximate the original surface closely, see Fig. 4.16. The format was originally developed by 3D Systems to provide a transfer data format from CAD systems to their stereolithography technology, but it has subsequently been adopted as the *de facto* standard in the RP industry.

The STL file simply lists a description of each of the triangular facets, which make up the surface of a three-dimensional model. Figure 4.17 shows the beginning and end of an STL file in text format. The first line describes the direction of the facet normal. This indicates which surface is the outside of the facet. The next three lines give the co-ordinates of the three corners, or vertices, of the facet.

The simplicity of the triangle makes mathematical operations such as scaling, rotation, translation and surface area and volume calculations straightforward. The format also allows the angle of facets to be identified, which is necessary for stereolithography.

STL files can be in binary or text (ASCII) format. Binary format files are much smaller and should be used unless there is a specific reason why the text format is required. STL files can vary in size from around 50K to hundreds of megabytes. Highly complex parts may result in excessively large STL files, which may make data operations and file transfer difficult. Figure 4.18 shows how a large number of facets describe the surface of a complex anatomical shape. However, highly effective compression software is freely available that can reduce an STL file to a small fraction of its normal size to enable easy transfer of files over the Internet or by email.

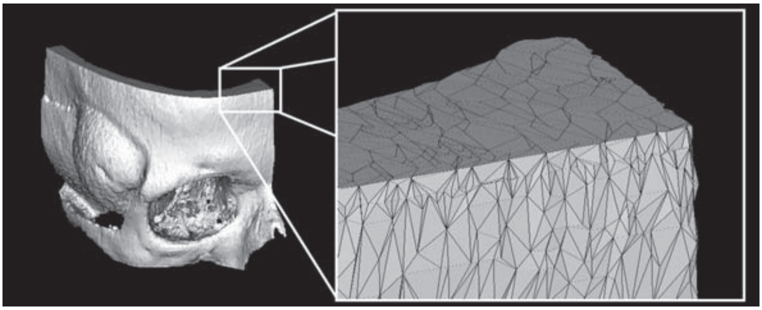
To be used successfully in RP, the STL file must form a single enclosed volume; meaning that it should have no gaps between facets and all the facets should have their normals facing away from the part (i.e. identifying



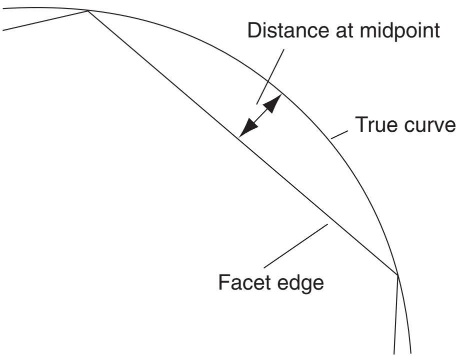
4.16 Cube with circular holes showing the triangular facets.

```
solid FILENAME
  facet normal 1.000000e+00 0.000000e+00 0.000000e+00
    outer loop
      vertex 0.000000e+00 -1.204845e+00 -1.658504e+00
      vertex 0.000000e+00 -1.235913e+00 -3.804270e+00
      vertex 0.000000e+00 -4.000000e+00
    endloop
  endfacet

and so on...

  facet normal 1.000000e+00 0.000000e+00 0.000000e+00
    outer loop
      vertex 1.000000e+00 4.000881e+00 1.221143e-04
      vertex 1.000000e+00 3.535500e+00 3.535500e+00
      vertex 1.000000e+00 3.999953e+00 0.000000e+00
    endloop
  endfacet
endsolid FILENAME
```

4.17 The beginning and end of an STL file in text format.



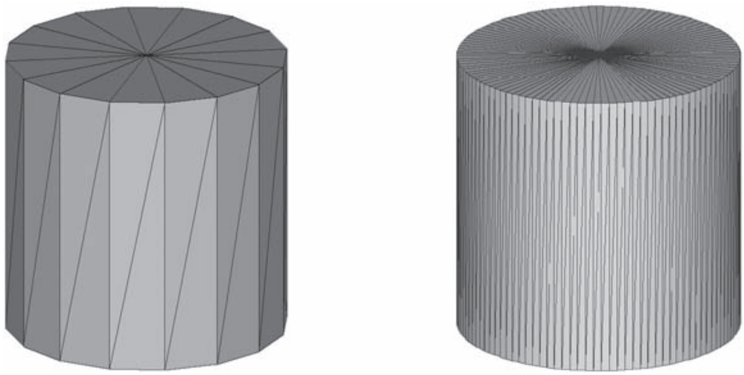
4.18 Close up view showing facets.



4.19 Facet deviation.

which is the inside and outside surface). Usually, small problems with an STL file can be corrected with specialist software or the RP machine preparation software. STL files can be generated from practically all three-dimensional CAD systems. Solid modelling CAD systems rarely have problems creating STL files, but surface modellers can pose problems if the surfaces are not all properly stitched and trimmed.

When exporting an STL file from a CAD system, the user will normally specify a resolution or quality parameter to the STL file. This is normally done by specifying a maximum deviation. The deviation will be the perpendicular distance between a facet and the original CAD data where the facet forms a chord at a curved surface, as shown in Fig. 4.19. In essence, a smaller deviation will give a more accurate representation of the CAD model, but this will result in an STL file with a greater number of smaller facets. The file size depends only upon the number of facets and so a smaller deviation will give rise to a larger file. The effect is illustrated in Fig. 4.20.



4.20 The effect of deviation settings: (left) large deviation = small file and (right) small deviation = large file.

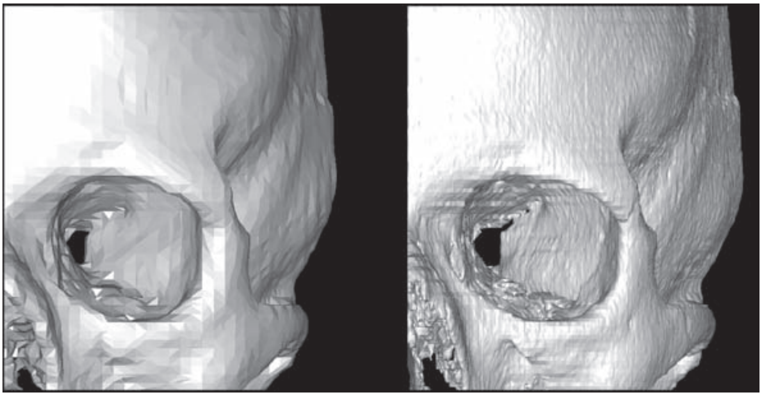
When creating STL files from medical scan data, a similar effect can be achieved. Typically, rather than setting a maximum deviation, the STL file resolution is determined by relating the triangulation to the voxel size of the CT data. If every voxel is triangulated the maximum resolution will be produced; however, the file size will be correspondingly large. By triangulating multiple voxels, a simpler but smaller STL file will be produced. Typically, a compromise is achieved between file size and surface quality. Some software will simplify this by allowing the user to specify low, medium or high quality settings.

For example, for the data previously illustrated in Fig. 4.9, the highest possible resolution settings result in an STL file of over 94 MB. Compare this to the results of the preset software setting that range from 'low' at 4.3 MB, 'medium' at 11.7 MB and 'high' at 34 MB. The two extremes of the effect of these settings can be seen in the close up views of the resulting STL files shown in Fig. 4.21.

STL files can be post-processed in several ways, usually to enable them to be produced by RP methods more efficiently. Many software applications are available that allow STL files to be split into separate parts, or re-oriented in space. In addition, the quality of the STL file can be manipulated somewhat. File size can be reduced by triangle reduction techniques and smoothing algorithms can be applied.

4.6.3 VRML

Early versions of Virtual Reality Modelling Language (VRML) are also triangular faceted surface representations. They are in essence very similar to STL files but are typically created at very small file sizes and are coded



4.21 The effect of STL resolution settings on medical data showing (left) low resolution and (right) the highest possible resolution.

in a more efficient manner to make them suitable for transfer over the Internet.

4.6.4 Finite element meshes

Finite element analysis packages rely on breaking down three-dimensional objects into a large number of small discrete elements. These elements may make up only the surface of the object; for example, the STL file described above may be considered a triangular surface mesh. However, some meshes may break the whole object into discrete three-dimensional elements. These may be tetrahedral, cuboids or other three-dimensionally tessellating polyhedra.

Depending on the software package used, the voxel data of a CT or MR scan may be exported or translated into a solid or surface mesh suitable for use in FEA. There are usually variables to set when conducting the translation that affect the quality of the mesh and the resulting file size. This is similar to specifying the quality versus file size compromise for STL files described previously.

Many FEA packages have their own formats for meshing, and some medical software packages can produce and export the correct format for a given analysis package. However, this may require the purchase of specific translators or additional modules for the software package.

4.6.5 Mathematical curve-based surfaces

Unlike faceted polygon surfaces, curve-based surfaces use complex mathematical routines to produce smooth curves in three-dimensional space.

Some of these routines also operate in three dimensions in order to create complex curved surfaces called 'patches'. An object may require a number of patches to cover the whole object surface. The patches differ according to the complexity of the mathematical curve routine used.

This kind of surface modelling produces highly sophisticated surface models that are typically used in the automotive, motor sports and aerospace industries. Usually, objects are designed using surface modelling packages. However, surface patches are also often used in reverse engineering to create useful CAD geometry from digitised physical objects.

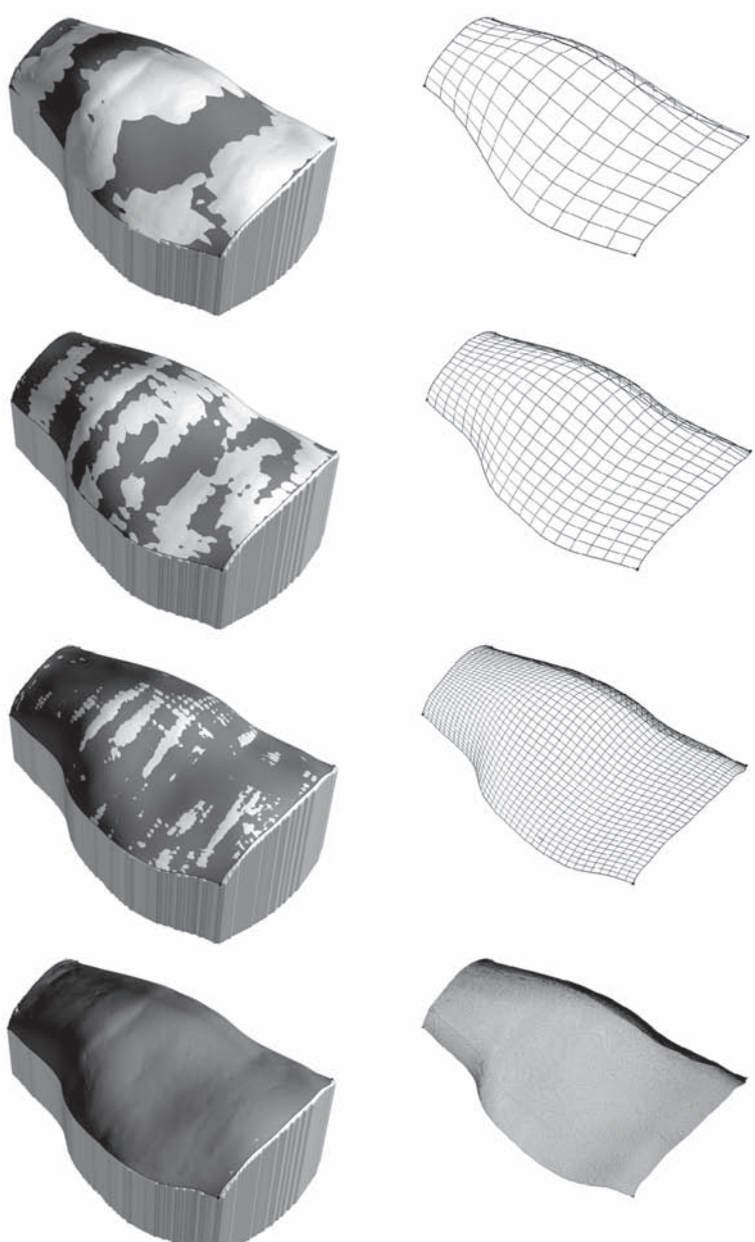
4.6.6 IGES surfaces

As stated before, IGES is an international standard that describes computer-aided design data as mathematically defined geometries positioned in the three-dimensional space (see http://www.nist.gov/iges/). By converting data from the original source through an intermediary three-dimensional format, such as the STL file, some CAD packages may be able to generate IGES curves and surfaces based on the original data. The nature of the surface and the degree to which it accurately reproduces the original anatomy will depend greatly on the data formats and CAD packages used. Some CAD packages also enable the user to create IGES curves and surfaces from point cloud data obtained using touch probe or non-contact surface scanners.

IGES curves and surfaces are mathematically described and are normally relatively smooth and simple surfaces. As such, they are typically used to define the smooth but accurate surfaces of objects in product, aerospace and automotive design. This makes them less well suited to the highly complex surfaces of human anatomy. However, there are many cases where it may prove to be a useful approach, particularly when attempting to integrate human anatomy with the design of products that must accommodate or fit around people.

The curves and surfaces are created by positioning the control points and boundary lines that define the surface patch onto the surface of the source data. The surface patch itself is then mathematically created according to the type of surface the software uses. The most complex type of surface patch is defined by NURBS surfaces (non-uniform rational B-spline). The degree to which this kind of surface patch matches the source data can be controlled by altering the number of control points in the surface. More control points enable the surface patch to be more complex and therefore follow the original data more closely. The number of control points is normally set by the user as a variable when creating the patch.

The effect of altering the number of control points can be seen in Fig. 4.22, which shows an IGES surface patch created from non-contact



4.22 The effect of the number of control points on IGES patch quality, (from top) 6 control points, 10 control points, 20 control points and 100 control points.

scan data of a human hip with control points varying from 6 to 100. The areas of darker grey show where the IGES surface patch closely approximates the scan surface whilst the lighter areas show that the IGES surface patch is below the scanned surface. The IGES surface patch is also shown as a mesh showing the complexity of the surface as the number of control points increases.

Depending on the software being used, the quality of the fit between the IGES surface and the original data can be visually inspected on screen as shown in Fig. 4.22 or numerically quantified. For the surface with only six control points, the average gap between original surface and the IGES patch is 0.818 mm. In comparison, the surface shown with 100 control points is a much closer fit with the average gap almost negligible at 0.00678 mm.

As NURBS surfaces are controlled by mathematical equations, the patches themselves have to obey certain criteria in order for the equations to solve. Failure to obey these constraints will result in no surface patch being generated or a patch that flips, creases or twists. Typically, surfaces that exhibit these faults cannot be physically manufactured or they give rise to other problems.

To create solid models from surface patches, all of the surface area of the object must be covered by NURBS patches. In addition, the patches must meet at common edges and not overlap. These surfaces can then be ‘stitched’ together to form a true three-dimensional solid computer model of the object.

5
Physical reproduction – rapid prototyping technologies

5.1 Background to rapid prototyping

5.1.1 Introduction

Rapid prototyping (RP) is a phrase coined in the 1980s to describe new technologies that produced physical models directly from a three-dimensional computer-aided design of an object. Many other phrases have been used over the years, including solid freeform fabrication, layer additive manufacturing, 3D printing and advanced digital manufacturing. In the late 1990s, the application of these technologies to tooling was investigated, and the phrase 'rapid tooling' was commonly used to cover these direct and indirect processes. More recently, these technologies have been applied to product manufacture as well as prototyping, and the phrase 'rapid manufacturing' is increasingly used to describe this kind of application. Perhaps the most accurate phrase would be 'layer manufacturing' as this covers all of the processes and distinguishes them from previous technologies such as machining. However, despite all of the different applications the phrase RP has been adopted by the industry to cover all these technologies and their applications and it is, therefore, the one used here.

The objects created by RP processes may be used as models, prototypes, patterns, templates, components or even end use products. However, for simplicity, the objects created by the RP processes described in this chapter will be referred to as models, regardless of their eventual use.

5.1.2 A brief history of RP

Processes that build models directly from computer data have come to be generally referred to as RP prototyping techniques. RP systems were originally developed in the 1980s as a method of building exact physical models of products and components designed using computer-aided design. Initial applications concentrated on the automotive and aerospace sectors, as these industries first exploited what were, at the time, expensive CAD/CAM systems. Since then, the incredible progress that has been made in computer processing power and software sophistication has led to the adoption of CAD/CAM in almost all industries. This rapid growth in the application of CAD/CAM systems fuelled the growth in the demand for RP systems. During the 1980s and 1990s the number of RP systems increased dramatically, and a range of material and process approaches were introduced.

Initially, many of these processes were inaccurate and unreliable leading to many promising ideas failing to reach the commercial market. Several processes did secure funding and developed into commercial manufacturing companies producing RP machines for sale across the world. Since then, the established technologies have been developed to produce effective, accurate and reliable machines using a variety of techniques. As with any other emerging industry, there have been some business failures and some consolidation of the market with mergers, acquisitions and licensing agreements.

One of the first casualties from this period was Helisys Inc., manufacturers of the laminated object manufacturing machines. Although initially popular, the machines proved unreliable and sometimes even caught fire. This led to dissatisfied commercial customers and rapidly declining sales that ended the business.

DTM Corp. had been developing selective laser sintering based on technology developed at the University of Austin, Texas since the 1980s and by the mid 1990s had a successful product and good sales. This success was due in part to the fact that the machine used thermoplastic materials and, therefore, produced strong and functional prototypes. However, the company became focused on developing metal materials for use in tooling applications. This technology was costly and somewhat failed to capture the interest of the tooling market, which in the main remained faithful to the increasingly efficient high-speed milling machines. This and protracted legal action against the German RP manufacturer, EOS GmbH, adversely affected the company and it was then acquired by 3D Systems. EOS itself also suffered from the effects of legal action with 3D Systems, which has since been resolved.

This has led to an industry dominated by two large USA-based corporations, 3D Systems and Stratasys. 3D Systems was the first major player in the RP market with stereolithography technology. Good development of the technology and, importantly, the materials led to the highly successful SLA-250 model, which provided the company with an installed customer base and subsequent larger and more efficient machines. Today SLA® (3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA) is still by far the most commonly used RP process. The company has strongly followed a business development strategy, which involved setting up national subsidiaries in many countries, aggressively protecting intellectual property, developing complementary technologies and acquiring competitors. This led the US Justice Department to declare that 3D Systems was effectively in a monopoly situation and they forced the licensing of stereolithography patents to Sony, who had been producing stereolithography machines for the domestic Japanese market for many years. It is yet to be seen what effect this will have on the US RP market.

Meanwhile Stratasys has steadily developed a single technology, fused deposition modelling, to produce a comprehensive and reliable range of machines from the cheapest desktop modelling machines to large capacity functional prototyping machines. Concentration on a single technology and the ability to sell cheaper machines has sustained the company through the economic downturn of recent years.

Recent newcomers to the market include Z-Corp (USA), EnvisionTEC (Germany) and Objet (Israel). Z-Corp produces a range of three-dimensional printing machines using technology licensed from MIT. These machines are fast and cheap to operate. However, the models are comparatively less accurate and physically weaker, although newer materials are being developed to address these issues. The EnvisionTEC machines selectively cure cross sections of photopolymer utilising digital micro-mirror devices to project visible light. The Objet machines aim to deliver the cost efficiencies of printing technology with the functionality and accuracy of stereolithography.

Due to the technology-driven nature of RP companies and their products, the industry is awash with trade names, abbreviations and acronyms for the various processes, software, hardware and materials. Many of these are registered or recognised trademarks and these have been indicated where possible. A glossary of terms can be found in Chapter 8.

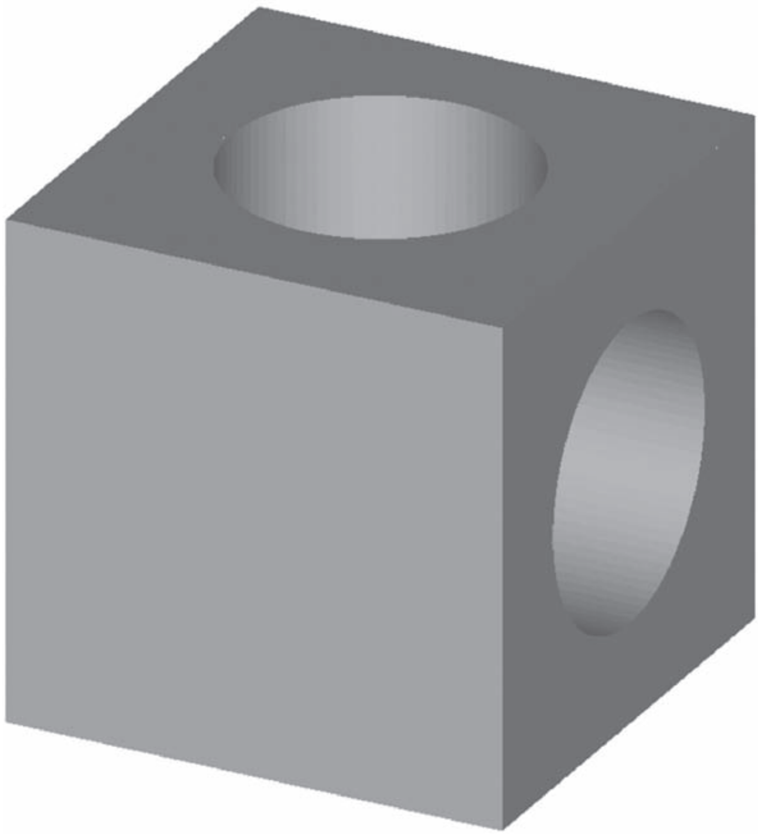
The most common RP processes are described later in this chapter. Each major RP process type is covered in principle and in some detail. Whilst it is not practical to describe every single aspect of every machine available, the sections should provide a good overview of the technologies, their pros and cons and their appropriateness for various medical applications. Further reading and a list of contact details for the major RP manufacturers and material suppliers is provided in Chapter 9.

5.1.3 Layer manufacturing

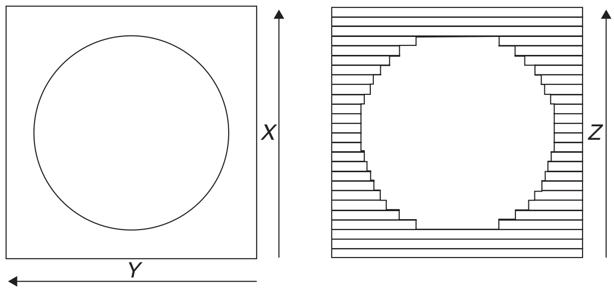
RP systems work by creating models as a series of contours or slices built in sequence, often referred to as layer manufacturing. The different RP systems vary in how they create the layers and in what material. By convention, the axes X and Y represent the plane in which the layers are formed and the Z-axis is the build direction, usually referred to as the height. Consequently, the number of layers required for a given object is a function of the layer thickness and height of the model. The layers are created by some form of precision controlled plotting, scanning or deposition mechanism. The accuracy and resolution in the XY plane is therefore dependent on this mechanism. Most are accurate to fractions of a millimetre, so that any geometry in the XY plane should be faithfully reproduced.

The layer thickness is dictated by the mechanical process that adds the build material and may vary according to the material being used. Layer thickness is usually in the order of 0.05–0.30 mm, although some printing-based technologies offer much thinner layers. This will lead to a stepped effect in geometry perpendicular to the XY plane.

As an example, consider a cube with two perpendicular holes through it, as shown in Fig. 5.1. The hole in the top of the cube, as viewed from above, formed by the scanning mechanism in the XY plane will be formed perfectly (within the capability of the mechanism). However, the hole in the side of the cube, as viewed from the side, formed by the addition of layers



5.1 Cube with circular holes.



5.2 The stepped effect of layer manufacturing.

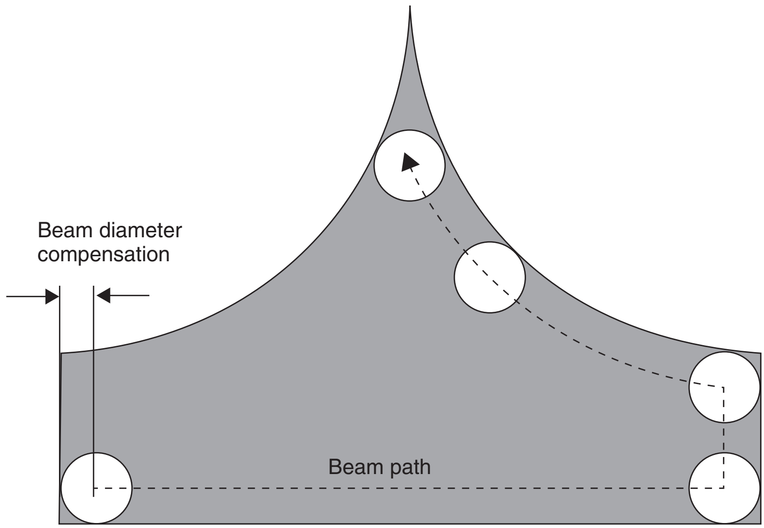
will display a stepped effect (shown in Fig. 5.2). Consequently, when building objects, careful consideration should be given to the orientation so that the optimum features are formed in the XY plane and stepping is avoided. For example, a cylindrical shape should be built upright if the circular section is to be faithfully reproduced.

The extent of the stepping can be diminished by creating thinner layers but, as the overall build time tends to be more dependent on the layer addition process, a larger number of thinner layers leads to longer build times. Therefore, a compromise between surface finish and speed is established for each RP process.

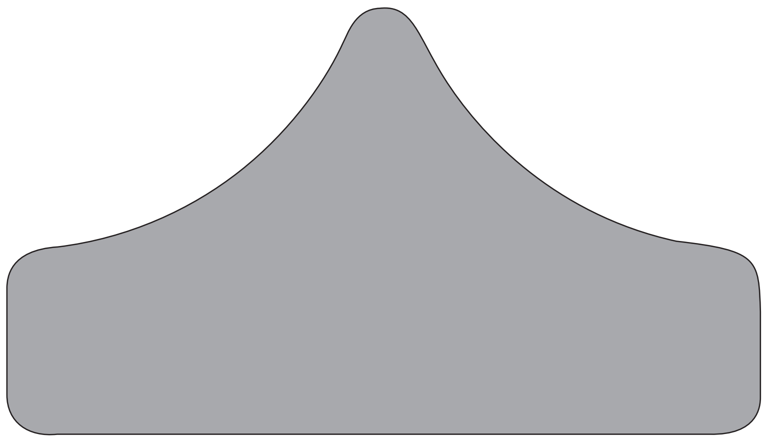
5.1.4 Beam compensation

As RP devices are additive processes, the method used to create the layers has a finite minimum size. In the case of the printing-based technologies, this is usually expressed as the pixel size that the printer is capable of reproducing, which in turn is usually expressed in the same terms as paper printers in dots-per-inch or DPI. However, with laser-based technologies, such as stereolithography and selective laser sintering, the diameter of the laser beam provides the minimum capability. For maximum accuracy, the software that controls this process offsets the path of the laser by half of its diameter so that it draws a path within the boundary of the object. This is illustrated schematically in Fig. 5.3. However, this means that small, thin features below that minimum size cannot be reproduced. A similar effect is shown by fused deposition modelling, where the minimum thickness of the deposited bead of molten plastic is compensated for in the same manner.

In practice the size of offset is very small, typically small fractions of a millimeter; however, the effect should be considered separately to dimensional accuracy. Whilst dimensional accuracy may remain very good, large offset values will have a detrimental effect on the ability of the RP system to reproduce intricate detail, crisp edges and sharp corners, as illustrated in Fig. 5.4.



5.3 Beam compensation.



5.4 The effect of beam compensation.

5.1.5 Data input

All RP systems require a computer model of the object to be built. In all cases, software is used to take a three-dimensional computer model of the object to be built and slice it into a vast number of very thin cross sections. These cross sections are then translated into an appropriate format to direct the layer manufacturing process of the RP system.

As there is a huge variety of CAD programmes available and a number of RP systems, each with different software requirements, industry required a standard translation format that could enable the RP process to build models designed in CAD. Stereolithography was the first RP process to market and employed a mathematically simple approximation of three-dimensional CAD models, called the STL file, which is fully described in Section 4.6.2. The format describes models by closely approximating their shape with a surface made up of a large number of triangular facets. As it was the first convenient transfer format to be offered by CAD software developers, the STL was adopted by other RP manufacturers and has since become a *de facto* standard in the industry. Consequently, despite some shortcomings, all RP machines can use the STL file. However, many other formats are also available, and a description of some of the most common is provided in Chapter 4.

In practice, RP software slices the STL (or equivalent) file into a number of cross sections. The software then creates control files that will instruct the RP machine how to construct each layer and how to deposit subsequent layer material. Depending on the sophistication of the process, there may be a degree of user interaction at this point that can help to optimise the build. The result is one or more files that are transferred to the RP machine itself. Typically, the build file is then checked and the machine prepared for a new build.

Although the models may take many hours to build, the machines typically operate unattended and non-stop. Therefore, a build will frequently be started last thing in the working day and the machine will run overnight, often the model will be completed by the next morning.

All of the systems have some method of supporting the build in progress, and this will require some degree of post-process cleaning and finishing after the model is built. Finishing is usually done by hand to remove residual material, remnants of support structures and the step effect. The level of finishing employed depends on the end use of the model.

RP technologies are constantly being developed and incrementally improved, so the descriptions here are intended to provide an overview of how the technologies work and compare their relative strengths and weaknesses. However, when assessing RP technologies from manufacturers or service providers it is always advisable to obtain the latest specifications. RP manufacturer websites are the best source of such information and the most popular are listed in the bibliography.

5.1.6 Basic principles of medical modelling – orientation

By definition, every medical model is unique and the characteristics of each model need to be considered carefully when selecting and utilising a particular RP system. Compared to engineering products that have been designed for manufacture, models of human anatomy may be much more challenging to prepare for a successful build, even for those experienced in the operation of their RP machines.

The following sections describe some of the most common RP processes and highlight their key technical considerations. However, there are some basic principles that apply to nearly all RP technologies when building medical models. The most important consideration is the orientation of the build. This will have an influence on the surface finish of the model, the time it takes to build, the cost of the model, the amount of support required and the risk of build failure. All of these factors are interdependent, the key to producing a high quality medical model is a thorough understanding of them, correctly identifying the priorities, and reaching a compromise solution that best meets the needs of the clinician. The effect of orientation on these factors is explored below.

Build time and cost

As all RP processes work on a layer-by-layer basis, the builds consisting of two repeated stages; drawing or creating the layer and recoating or depositing material for the next layer. Generally, the material deposition stage takes longer and often poses the greatest risk of build failure. Therefore, orienting a model such that it minimises the number of layers will reduce the build time.

Generally, RP model costs are directly related to the build time. Therefore, the longer the build time the more the model will cost. In many cases, the automatic option is to orient a model for minimum height and therefore minimum cost. However, as described below, this may have an undesirable affect on the quality of the model.

Surface finish, model quality

As described in Section 5.1.3, the layer-by-layer building process results in a stair-step effect on sloping or curved surfaces. Depending on the shape of the object, the orientation may have a great effect on the degree of stair stepping on the model surface. However, the mechanisms that create the layer geometry usually offer better resolution. An example of a model that illustrates the effect of layer thickness in an exaggerated manner can be found in Section 6.2 Implementation case study 2. When considering engineering parts, the most important feature is identified and the build is oriented to provide the optimum surface quality for that feature. However, human anatomy usually possesses curved surfaces in all directions and the optimum orientation may depend on other, more important, factors.

However, there are some obvious examples where orientation makes a considerable difference to surface quality. The long bones of the arms and legs, for example, are essentially cylindrical in form. Orienting a model of a long bone such that it lies flat will minimise build time and cost, but the layers will be readily apparent in the model. Orienting the build in an upright sense will increase build time and cost considerably, but the layered effect would be drastically reduced in comparison, leading to much better model quality. Fig. 5.5 illustrates the effect of stair stepping on a model of a proximal tibia (the relative thickness of the layers has been increased to exaggerate the effect). The upper model was built lying horizontally; whilst this minimised build time, the thickness of the layers has had a negative effect on the reproduction of the contours of the model. The lower model was built upright, and consequently the layer thickness has not had such a detrimental effect, at the cost of increased build time.

Support

All RP processes provide support to the model as it is built. Some processes build supports concurrently with the model whilst others utilise the unused material to support the part as it is built. Usually, parts that are supported by the unused material may be oriented to provide the minimum cost, or

5.5 The stair step effect of build orientation.

to fill the available build volume with the greatest number of parts. However, for those processes that construct supports, their effect on model quality and their subsequent removal should be considered.

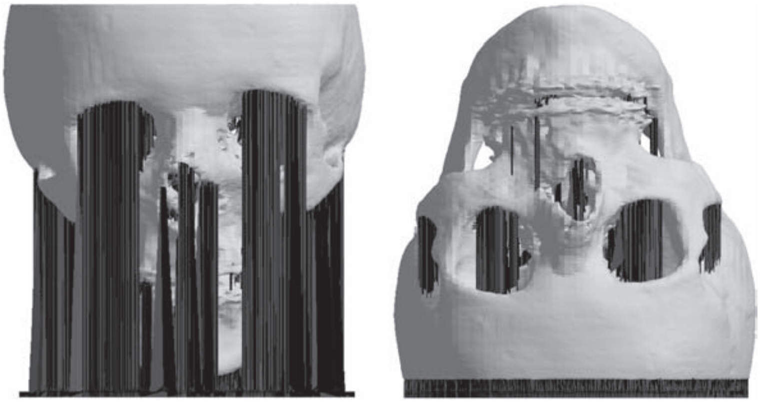
Typically, the more supports that are present the more time will be spent manually removing them, which can add considerably to the overall time to delivery and labour costs. Surface finish and quality will also be affected as most supports leave a witness mark on the surface after their removal. For example, the effect of support removal from stereolithography models is shown in Section 6.2 Implementation case study 2. Another consideration when building medical models is the presence of internal cavities. The skull, for example, contains many such cavities, and supports within them may prove difficult or impossible to remove by hand. Some RP processes utilise soluble supports, which can be removed by immersing the model in a solvent. Whilst this still adds to the overall time to delivery, labour costs are reduced and supports inside cavities are easily removed.

Therefore, it is advantageous to orient a model to minimise the amount of support but not to the degree where the build process is threatened.

Risk of build failure

Whilst RP machines are generally reliable and able to operate for long periods unattended, the build process can be threatened by pushing parameters to their operational limits. As has been stated previously, building models of human anatomy poses challenges to RP due to the highly complex nature of the forms being built. This makes the risk of build failure higher when attempting medical modelling compared to engineering parts. Often the risks to build failure depend very much of the specific RP process being used, but some general principles apply. The overall stability of the model is important in most RP processes. It therefore makes sense to orient the model such that it is most stable, i.e. wider at the bottom than the top. This will almost certainly also directly affect the supports required. Generally, the less support needed the lower the risk of build failure. The principle of stability and the subsequent effect on the supports is shown clearly in the example in Fig. 5.6, where the orientation on the right offers a more stable build and a much-reduced amount of support.

Economic factors are also important. Most RP parameters are set to provide the fastest, and therefore cheapest, build possible. However, setting parameters for speed usually increases risk of build failure. The complex nature of medical modelling means that parameters may have to be altered to lower risk and, consequently, build time and cost may increase compared to an engineering model of similar size.



5.6 The effect of orientation on model support.

Data quality

Whilst the majority of orientation decisions are arrived at by considering the final model's shape and size the computer data used to build it may also have an influence on the choice of build orientation. The choice of data format could limit the options available for orienting the model. For example, if a $2^1/_2$D format is used, such as an SLC file, then the choice of orientation is fixed when the data is created. Usually these formats are created in the same orientation as the original scan data, and this may provide a higher quality data file. The advantages of the data format in terms of quality and efficiency may override the other orientation considerations. The data formats and their various advantages and disadvantages are described in Chapter 4.

5.1.7 Basic principles of medical modelling – sectioning, separating and joining

Prior to preparing an RP build, it is worth considering the nature of the model and its intended use before finalising the data. There are several considerations to address relating to the overall size of the model, whether it is one structure or a number of related structures and whether their positional relationship is important. For these reasons, it may become necessary to section, separate or join different parts to make the model or models required.

Sectioning

Sectioning may be done when selecting the data from the original scan data or could be done by splitting the export data files, such as STL files. The most obvious reason for sectioning a model is to reduce the extent of the model to only those areas that are needed. This reduces build time and cost. However, it may also be used to split very large models into a number of parts that can be accommodated within the build volume of a given RP machine. Sectioning may also be used to gain access to trapped volumes (internal cavities). This may be necessary to remove waste material or supports but may be because the internal anatomy is also of interest to the clinicians.

When sectioning models it may be advisable to incorporate a stepped or keyed section such that the two separate parts are easily located when they are put back together. Many RP software packages provide functions to achieve this. An example is shown in Fig. 5.7 where a long bone has been cut into two pieces. The keyed section helps align to the two pieces when they are joined together.

Separating

As opposed to sectioning models at convenient locations, it may be desirable to separate different adjacent anatomical structures. Often when preparing data from the original scan data, different anatomical structures are sufficiently close to one another that the data becomes a single object. For example, close joints can become closed, effectively creating a single object from two distinct bones. Therefore, it may be desirable to edit the data to separate the different anatomical structures so that they can be built individually. This may be so that the parts can be built separately to save time or cost but may also be because the clinicians wish to be able to articulate the two structures.

Joining

Just as it may be desirable to separate adjacent anatomical structures, the opposite may be true. When building separate anatomical structures, their final use should be considered. If the spatial relationship between the structures is important, for example where bones have been fractured and displaced, then that will have to be created physically in the resultant model.

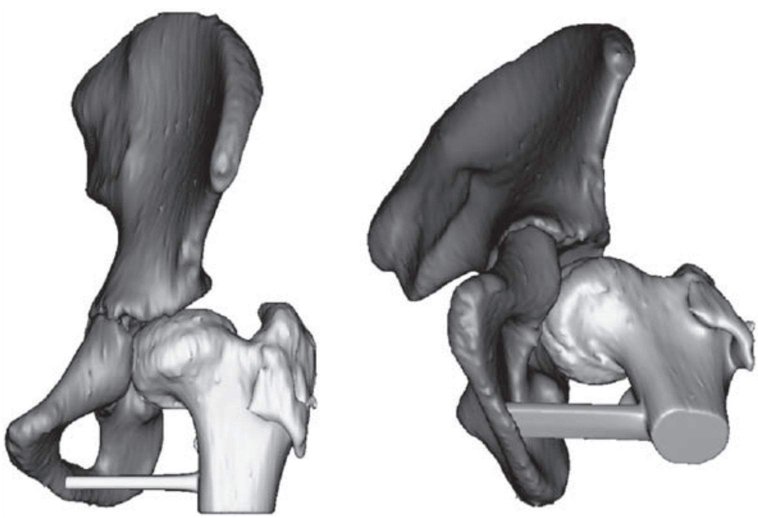
5.7 A long bone model with a keyed section.

In some cases, this may be achieved by leaving supports in place between the different parts. However, supports are not strong enough to achieve this reliably. Instead, it may be necessary to create bridges that join the separate parts together. When creating such bridges, it is important to make them clearly artificial in appearance and locate them away from important areas so that they are not confused with the anatomy. An example of a bridge between two separate bones is shown in Fig. 5.8.

5.1.8 Basic principles of medical modelling – trapped volumes

Compared to engineering parts, the presence of trapped volumes (internal cavities) can pose particular problems in medical modelling. The problem is particularly associated with stereolithography where the effect can lead to build failure, as the resin in the trapped volume does not level correctly (see Section 5.2 for more detail on the trapped volume effect). However, the presence of trapped volumes can cause problems for many RP processes. To produce the unwanted effects of a trapped volume, the cavity does not need to be entirely closed. If the openings to such a cavity are small enough, the effect will be as bad as a fully closed cavity. Examples of cavities are the cranium, the sinuses in the skull and face and the marrow space inside large bones.

The main problem with trapped volumes is removing the waste material and/or supports from within them. Various techniques can be used to



5.8 An example of a bridged model connecting the proximal femur to the pelvis.

address trapped volumes. If the cavities are very small, totally closed and of no interest to the clinician, the data can be edited to fill in the cavity. It may be tempting to leave such cavities in place as they are fully closed; however, this poses risks. If the model is broken, sawn or drilled into at a later date, the unused material may leak out. This could be in the form of loose powder, solvent or liquid resin which may damage the model or prove a nuisance (or, depending on the material being used, even a minor health risk) to the user or patient.

Where cavities are larger or deemed important, artificial openings can be created to enable the waste material to be removed. When creating such openings the location and shape should be chosen to make them obvious so that they are not confused with the anatomy. For example, if holes are made square they are less likely to be confused with naturally occurring holes. Alternatively, as described above, the model can be sectioned into parts that are built separately either to enable access to the cavity or to eliminate it altogether.

5.2 Stereolithography (SL)

5.2.1 Principle

Liquid resin is selectively cured to solid by ultra violet (UV) light accurately positioned by a laser. The laser scans the layers onto the surface of the resin, the first layers being attached to a platform. Successive layers are cured by lowering this platform and applying an exact thickness of liquid resin.

5.2.2 Detail

The Stereolithography Apparatus SLA® was developed and commercialised by 3D Systems Inc. in the 1980s. Models are made by curing a photopolymer liquid resin to solid using a UV laser. Models are built onto a platform that lowers by a layer thickness after each layer is produced. Wait states allow the liquid to flood over the previous layer and level out. Then a recoater blade will pass over the liquid, levelling the resin but also removing any bubbles or debris from the surface. The length of the wait states and speed of the recoater blade will depend on the viscosity of the resin. This method also means that there are problems with building objects with trapped volumes as the liquid in these areas is not in communication with the resin in the vat and does not level out, leading to build failure. In an attempt to remedy this, the recoater blade has a U-section that picks up a small amount of resin with a vacuum and deposits it over the previous layer.

Overhanging or unconnected areas have to be supported. Supports are generated by the build software and built along with the model. When a model is complete, excess resin is washed off using a solvent and the supports removed. The model is then post-cured in a special apparatus by UV fluorescent tubes. All lasers used in stereolithography emit in the UV spectrum and are, therefore, not visible to the naked eye. The laser represents a considerable cost and has a limited life, leading to high running costs. Lasers are replaced on an exchange basis with the manufacturer.

The speed of the machine depends on how much energy the resin requires to initiate polymerisation, as the power of the laser is more or less constant; if more energy is required the laser must travel slower. Material properties and accuracy also depend on the resin characteristics. As the material polymerises, there will be some degree of shrinkage; this can be compensated for in the build parameters but may also lead to other problems, most notably curl. This was especially true early in the development of SL when most systems used acrylate-based resins. These problems were partially eliminated by altering the build style, i.e. the way the laser scans the layers. The development of epoxy-based resins eliminated these problems as it shows very low shrinkage; this gives very accurate models, although it requires more energy to polymerise and therefore builds slower. New materials are becoming available with physical properties more similar to thermoplastics.

Solid resin models proved unusable as sacrificial investment casting patterns, because they swell with heat and crack the ceramic shell. To enable investment casting, quasi-hollow build styles were developed. These produce models as a thin skin with a delicate supporting structure inside. The vent and drain holes are incorporated into the skin allowing the uncured resin to be drained and centrifuged out. These holes are then plugged with wax. The surface area of this type of model is very large, and models will absorb moisture readily so they must be used quickly and stored in dry conditions. When these models are heated, the supporting structure softens so, upon burn out, the models collapse in on themselves and therefore do not crack the investment shell.

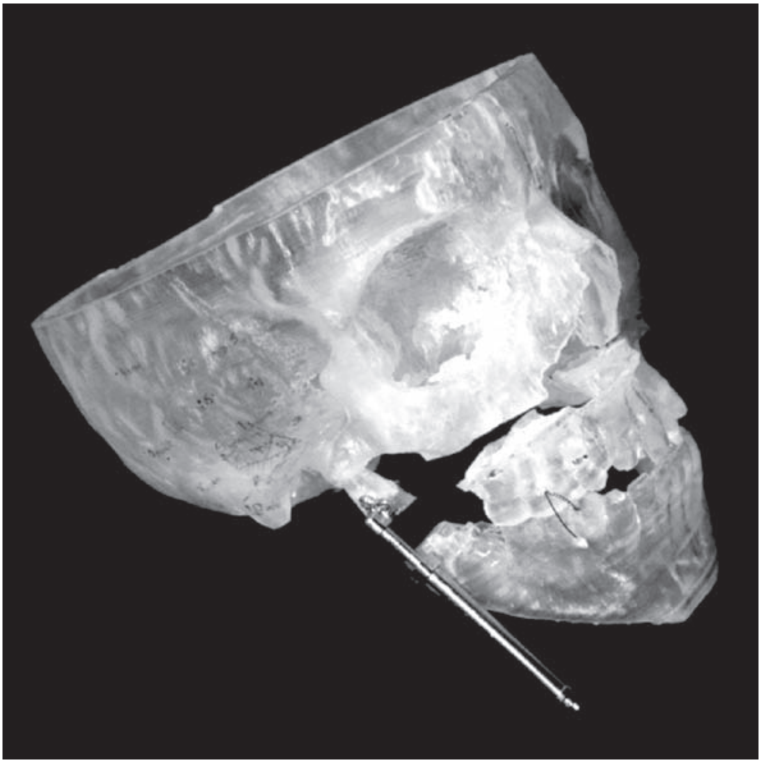
Typical SL medical models are shown in Figs 5.9 and 5.10. In medical modelling terms, SL is in many ways ideal. SL models show good accuracy and surface finish. The transparency of most SL materials enables internal details such as sinuses and nerve canals to be clearly seen. The fact that unused material remains liquid also means that it can be easily removed from internal spaces and voids. This is crucial when considering that the majority of medical modelling is of the human skull, which possesses many such internal features as well as the cranium itself. These advantages can be clearly seen in the examples illustrated here. The solid, fully dense, finished models lend themselves well to cleaning and sterilisation

5.9 SL model of the mandible.

and the development of at least one medical standard material is an advantage.

A range of medical resins are available (RenShape® SL, Huntsman Advanced Materials, Everslaan 45 B-3078 Everberg, Belgium) that have been tested to an internationally recognised standard (USP 23 Class VI). The materials are acrylate-based and hence show some curl characteristics when building square or flat models, but the very nature of anatomical structures normally eliminates this or reduces the effect to the point where it poses no significant problems. The resin has been tested to the standard that shows that it is safe to be exposed to patient fluids, making it suitable for use in the operating theatre as a surgical aid or to make templates and guides.

This resin can also be selectively coloured. A single pass of the laser will solidify the resin, a subsequent high power pass will cause the solidified resin to change colour. This allows internal features to be made visible through the thickness of the model, which can be used to show, for example, the roots of teeth in the jaws bones or tumours, as illustrated in Figs 5.11

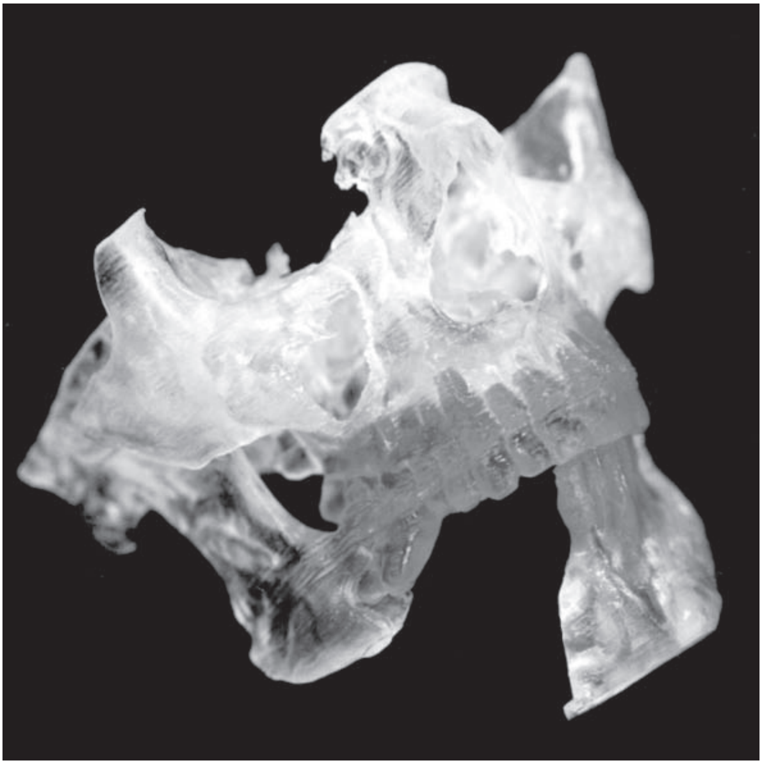


5.10 SL model used for planning maxillofacial surgery.

Table 5.1 Advantages and disadvantages of stereolithography

Advantages	Disadvantages
Well developed, reliable machines and software	High cost of machine and materials
Established sales, support and training	High maintenance costs
High accuracy, good surface finish	Resin handling requirements
Little material waste	'Trapped volumes' problematic
Medical standard material	
Can be sterilised and selectively coloured	
Transparent models	

and 5.12 (see Fig. 5.11 and 5.12 in the colour section). These factors combined with the inherent accuracy of stereolithography make it highly appropriate for medical modelling. The advantages and disadvantages of stereolithography are summarised in Table 5.1.



5.11 Selectively coloured model showing the roots of teeth (see also colour section).

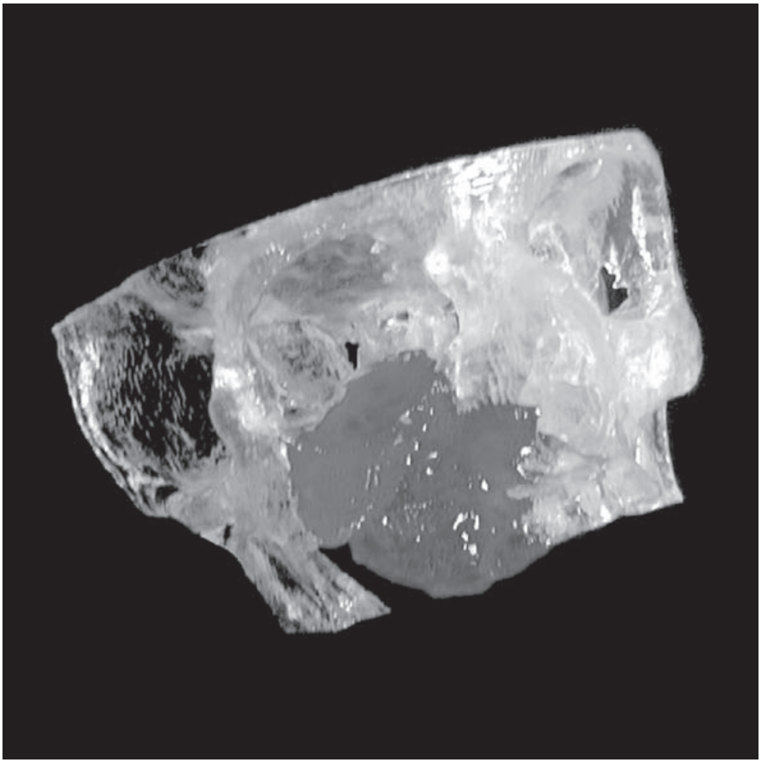
5.3 Digital Light Processing (DLP™)

5.3.1 Principle

Liquid resin is cured to solid by visible light accurately projected as a two-dimensional mask using a digital micro-mirror device (DMD). The cross sections are projected as images by the DMD onto the bottom of a shallow glass vat, curing the layers onto a rising build platform. Successive layers are cured by raising the build platform by an exact layer thickness and allowing resin to flow under the previous layer.

5.3.2 Detail

The German RP company EnvisionTEC GmbH (Elbestrasse 10, D-45768 Marl, Germany) used DLP™ (Texas Instruments DLP Products, 6550 Chase Oaks Blvd, Plano, Texas 75023, USA) as the basis for their



5.12 Selectively coloured model showing a tumour (see also colour section).

Perfactory® machine. Models are built using liquid resin which is cured to solid using visible light. In their Perfactory® machine, models are built onto a platform that rises by a layer thickness after each layer is produced. Raising the build platform allows the liquid to flood into the gap between the transparent base of the vat and the model. The flat, transparent base means that layers are created at the exact layer thickness and are perfectly flat and level. Creating this fixed gap eliminates any of the settling or levelling procedures required in SL, which in turn accelerates the process. This process also means that the layer thickness can be reduced, leading to models built from very thin layers, which improves surface finish. A larger Vanquish machine is also available but builds in the conventional downwards direction.

As the cross section is projected from below in one instant, the exposure time for each layer is fixed regardless of the geometry of any given cross section. This provides rapid and predictable build rates. This method also means that there are no problems when building objects with trapped volumes.

As in SL (but upside-down on the Perfactory®), overhanging or unconnected areas have to be supported. Supports are generated by the build software and built along with the model. When a model is complete, excess resin is washed off, sometimes using a solvent, and the supports are removed. Unlike SL, the models do not require post-curing, although if required this can be achieved without special equipment as the resin will cure in daylight. Also unlike SL, there is no laser, which leads to considerable savings in maintenance and running costs. The projector bulbs will require regular replacement, but the cost of around £300 is negligible compared to the costs of replacing a laser.

The accuracy of the process is a function of the projected image of the cross section. The DMD has a pixel array of 1280×1024 (SXGA), but the image can be scaled using optics. Therefore, the resolution of the model will be defined by the overall size of the build area divided by the number of pixels. Typically, this resolution is in the order of 0.06 mm but may range from 0.15 to 0.032 mm depending on the parameters and optics used.

The materials used are similar to SL resins and produce models that are solid, tough and transparent, although usually orange or red in colour. An example is shown in Fig. 5.13. Materials have been developed and approved for specific medical application in dental technology and hearing aid manufacture. An example of a hearing aid shell manufactured by DLP™ is shown in Fig. 5.14. The advantages and disadvantages of DLP™ are summarised in Table 5.2.

5.4 Fused Deposition Modelling (FDM™)

5.4.1 Principle

Thermoplastic material is fed in filament form to a heated extrusion head. Layers are made by molten material deposited as a fine bead. The build table lowers an exact amount and the next layer is deposited on to the previous layer, bonding due to partial melting.

Table 5.2 Advantages and disadvantages of DLP™

Advantages	Disadvantages
High accuracy, excellent surface finish	Resin handling requirements
Little material waste	Limited material choice
Low maintenance and running costs	Limited build size
Transparent models	

5.13 A Perfactory® model of a mandible.

5.14 A hearing aid shell manufactured using DLP™.

5.4.2 Detail

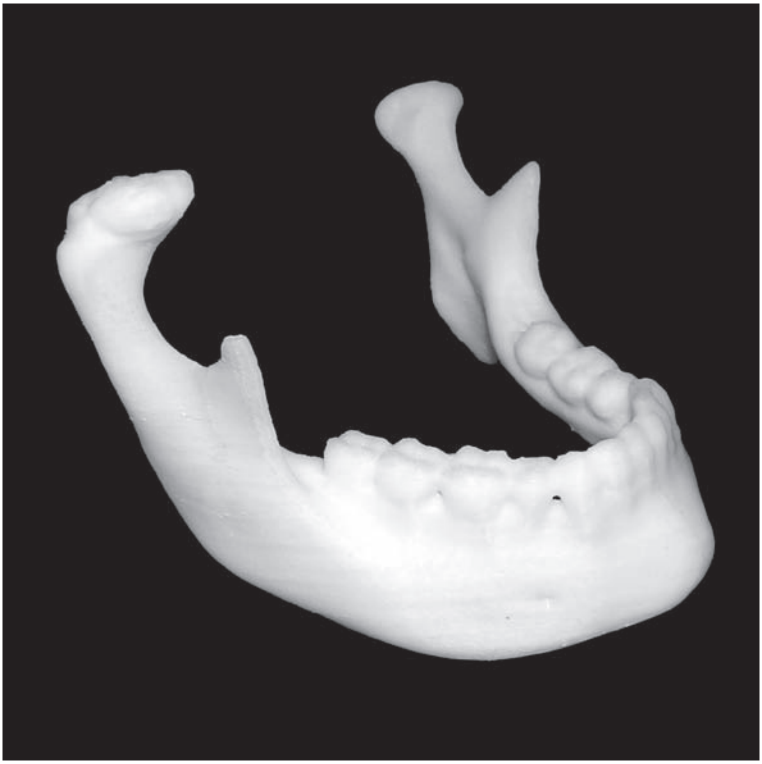
This process was developed in the USA by Stratasys Inc. (14950 Martin Drive, Eden Prairie, MN 55344-2020, USA) and the technology is used in all their machines including the less expensive Dimension branded machines (FDM™ is a Stratasys trademark). Models are made by extruding thermoplastic materials through a heated nozzle. The nozzle moves in the X and Y-axes to produce layers then the build table lowers by a layer thickness and the next layer is produced. Supports for overhangs are built up and are removed when the model is complete. The materials are thermoplastics such as acrylonitrile-butadiene-styrene, nylon, polycarbonate and polyphenylsulphone which are fed in the form of a filament from a spool. The models produced, therefore, can be handled directly and require no special cleaning or curing. The physical properties are close to injection moulded plastic components and so are very strong and durable compared to other RP models. The difficulty of removing the supports has been addressed by the use of a second support material, which does not adhere to the build material, enabling the supports to be more easily removed. On some machines, the support material can be dissolved away in an agitated water bath. This not only reduces labour but also reduces the risk of physical damage to delicate models.

The process also means that the machine is very quiet and clean and is suitable for an office environment. Because the process is relatively simple, there are few moving parts and the machine is, therefore, reliable and comparatively easy to maintain. Surface finish and accuracy are not quite as good as for example SL, but the machines cost less than similar sized SL machines.

As with SL, FDM™ models are hard and completely solid making them suitable for sterilisation for use in theatre. FDM™ models are opaque (usually white) which hides internal details that could be visible in an SL model. A typical FDM™ medical model is shown in Fig. 5.15.

FDM™ is well suited to medical modelling. FDM™ models show reasonable dimensional accuracy and surface finish. The models are particularly tough and can withstand repeated handling, making them ideal for teaching models. The finished models lend themselves well to cleaning and sterilisation and the use of medically acceptable materials is an advantage.

Unlike SL, the unused material is solid and, although it does not adhere to the model, it can be difficult and sometimes impossible to remove from the internal cavities often found in human anatomy. The option of the water-soluble support material has made removing supports from medical models much easier. Stratasys has also recently introduced a material that has been tested to internationally recognised USA standard (USP 23 Class



5.15 FDM™ model of the mandible.

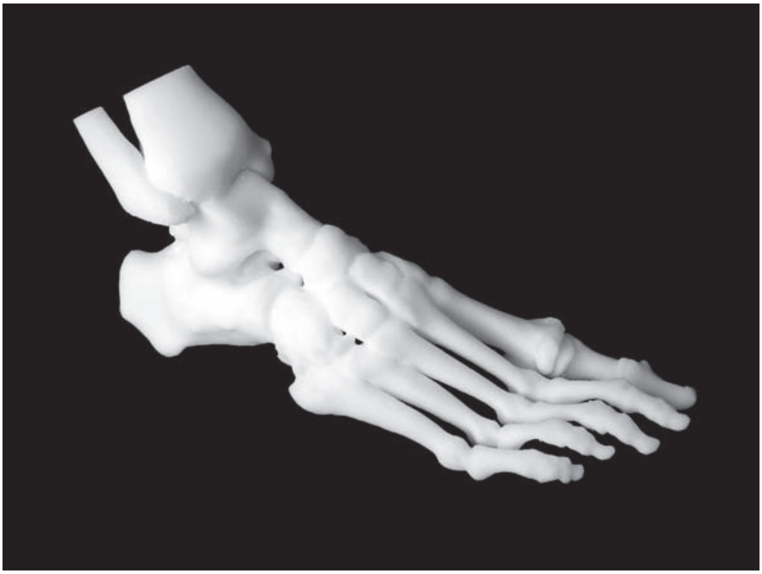
VI) and the European equivalent (ISO 10993). This material, called PC-ISO, is a polycarbonate, which makes it particularly strong compared to most other RP materials.

The fact that the materials are opaque makes the identification of internal voids such as sinuses and nerve canals impossible. However, the white material does tend to represent bones in a familiar manner, and models of long bones and joints can be well modelled. These advantages can be clearly seen in the examples illustrated in Figs 5.16 and 5.17. The advantages and disadvantages of FDM™ are summarised in Table 5.3.

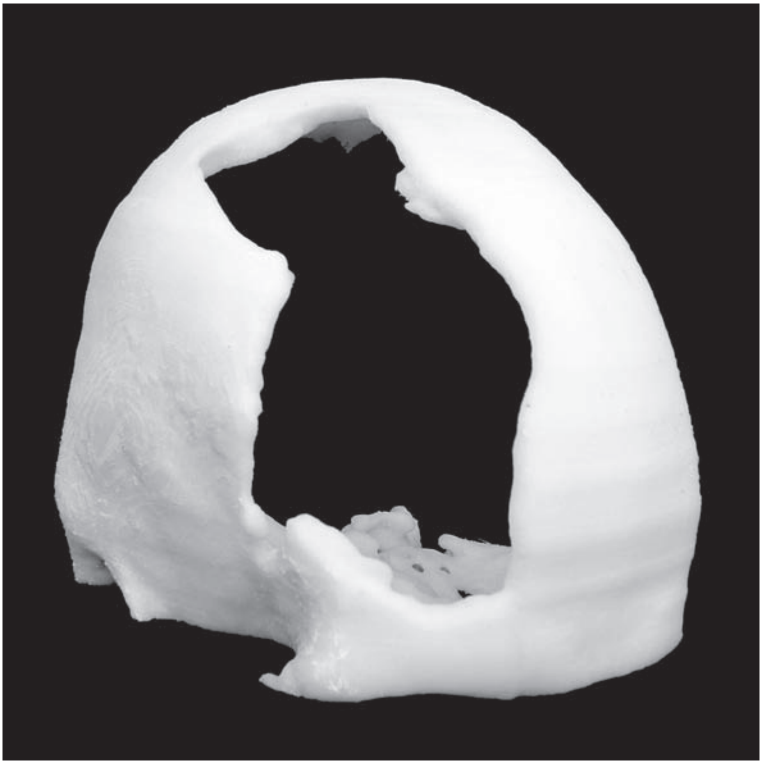
5.5 Selective Laser Sintering (SLS®)

5.5.1 Principle

LS is similar to SL except using powders instead of liquid resins. A powerful laser locally fuses or sinters thin layers of fine particulate material. The build platform is lowered, fresh powder is applied and the next layer



5.16 FDM™ model of a human foot.



5.17 FDM™ model of a partial cranium.

Table 5.3 Advantages and disadvantages of FDM™

Advantages	Disadvantages
Relatively cheap to buy and run	Poorer accuracy and surface finish compared to SL
Reliable	Small features difficult
Clean and safe process	Opaque material
Very strong, tough models	
Medical standard material	
Can be sterilised	

scanned on top of the previous layer. Local melting also forms an interlayer bond.

5.5.2 Detail

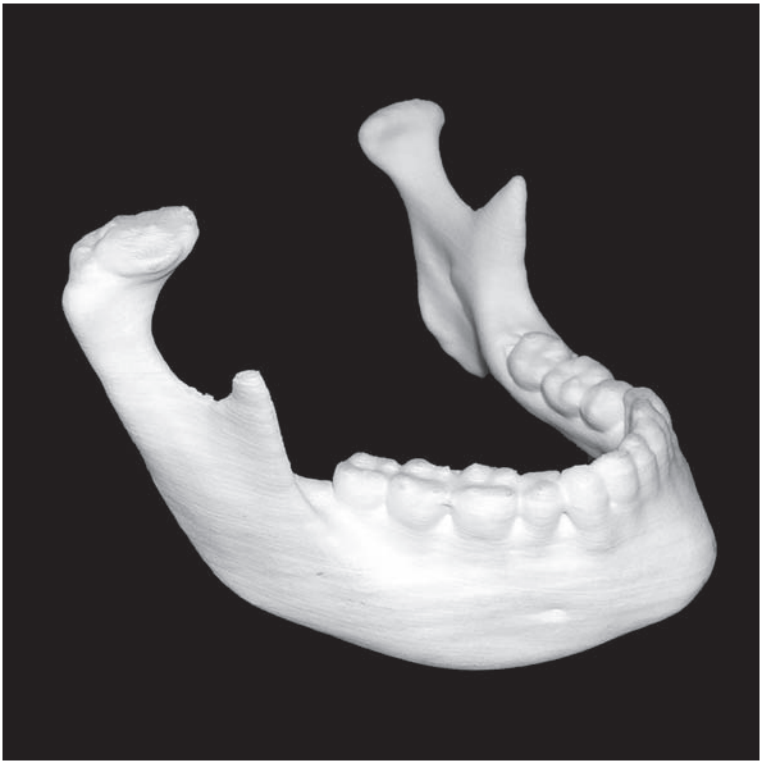
Models are made by selectively sintering thermoplastic powder material using a laser. The materials are heated to near melting point and the laser scans the cross sections, locally heating the powder enough to fuse the particles together. The build platform lowers each layer and fresh powder is spread across the build area by a roller. The inherent dangers of handling fine powders are controlled by purging the build volume with nitrogen gas. Models are supported by the unused powder. Overall, build times are comparatively slow to allow for heat up, around 1.5 hours, and cool down of the powder, around two hours. When completed the model is dug out of the powder and bead blasted to remove any powder adhering to the model's surface. The machines are large and heavy and require water cooling, extraction and nitrogen supply. Consequently, the operating costs are considerable and, therefore, a high throughput is required to justify the purchase of the technology.

Although these machines are produced by two manufacturers, the SLS® abbreviation is a 3D Systems registered trademark. EOS GmbH refers to their machine as a laser sintering machine. LS machines typically use thermoplastic materials. The most commonly used glass-filled nylon material gives relatively low porosity, resulting in strong, robust models compared to SL for example. Surface finish is relatively poor compared to SL as may be expected from a powder. Accuracy is almost as good as SL and comparable with FDM™. Specific materials allow LS models to be used as sacrificial patterns in investment casting. An elastomeric material is also available for prototyping flexible components, and aluminium-filled materials are available for enhanced physical properties. When installed it takes quite a while to set up, the machine parameters, involving a certain amount of trial running. However, once correctly set up, the machines are relatively reliable.

The materials, although reasonably accurate and tough, remain porous. Although the materials themselves pose no inherent medical problems, the porosity makes them particularly difficult to clean and sterilise effectively. Like most RP models, LS models are opaque, which may hide internal details. A typical LS medical model is shown in Fig. 5.18.

Also available is a sand-based material that can be used to make sand moulds and cores for casting metals, allowing components planned for manufacture by sand casting to be prototyped relatively quickly in the production material by the production process. The direct forming of sand moulds and cores could improve prototyping times for complex sand castings.

Some LS machines are capable of producing metal objects using special alloy powders or metal-polymer binder mixes. These materials are not highly functional but are intended to produce mould inserts for injection moulding in small volumes.



5.18 SLS® model of the mandible.

In medical modelling terms, LS models prove useful but perhaps not ideal. LS models offer reasonable accuracy and surface finish and would be comparable to FDM™ models. The strength and toughness of the models is a definite advantage, but the powder nature of the material leads to a rough surface, which can trap dirt and grease in handling. This, together with the porosity of the models, poses some concerns for sterilisation, especially if patient contact is being considered. Unused material remains as loose powder so it can be removed from internal spaces and voids, although this may sometimes be difficult. The advantages and disadvantages of LS are summarised in Table 5.4.

5.5.3 Selective Laser Melting (SLM™) and Direct Metal Laser Sintering (DMLS®)

SLM™, the technology behind the MCP Realizer SLM machine (HEK GmbH, SLM Tech Center Paderborn, Hauptstrasse 35, 33178 Borchen, Germany), and DMLS® (EOS GMBH Electro Optical Systems, Robert-Stirling-Ring 1, D-82152 Krailling/Munich, Germany) are similar in principle to LS except that high power solid-state lasers are used to melt very fine metal powders in inert gas atmospheres. The full melting enables the production of solid, dense metal parts in a single process (i.e. not using binders or post-process furnace operations that have been previously used to make metal parts via LS). A variety of metals can be used, including stainless steels, cobalt-chrome and titanium. These processes are relatively new and, whilst they are not suited to the production of models of human anatomy, their potential for producing custom fitting implants and prostheses is already evident. Fig. 5.19 shows a mandible made using SLM™ whilst Fig. 5.20 shows a partial removable denture framework (described in detail in Section 6.14 Rehabilitation applications case study 7). They also lend themselves well to the manufacture of custom surgical guides, templates and instruments, as described in Section 6.6 Surgical application case study 4. The similar Arcam CAD to Metal® process (Arcam AB (publ.), Krokslätts Fabriker 30, SE-431 37 Mölndal, Sweden) utilises an electron beam to melt

Table 5.4 Advantages and disadvantages of LS

Advantages	Disadvantages
Strong, tough models	High cost of machine and materials
Reasonably accurate	Large machine, nitrogen supply, water cooling
Wide range of materials	Heat up and cool down time
	Poor surface finish
	Materials not suited to sterilisation

5.19 An SLM™ mandible.

5.20 A denture framework made by SLM™.

Table 5.5 Advantages and disadvantages of SLM™ and DMLS®

Advantages	Disadvantages
Very strong, very tough metal parts	Relatively new technology
Accurate	Very high cost of machine and materials
Materials can be sterilised easily (using autoclave)	Inert gas supply required
Wide range of metal materials	

the powder. The advantages and disvantages of SLM™ and DMLS® are summarised in Table 5.5.

5.6 Three-dimensional printing

5.6.1 Principle

Powder material is deposited layer by layer and selectively bonded with adhesive printed onto the powder by heads, similar to those used in inkjet printers.

5.6.2 Detail

This process was originally developed at Massachusetts Institute of Technology and commercialised by the USA-based company Z-Corp. The machines use simple, relatively cheap powder materials such as starch and plaster, which is selectively bound by printing an adhesive. The models have to be removed from the unused powder, which supports the build as it progresses. At this point, the models tend to be delicate and soft and require infiltration of a hardener material such as polyurethane or cyanoacrylate resin. The machines are comparatively inexpensive and the material and running costs are reasonable. The finished models are not as accurate and the surface finish not as good as SL for example, but the advantage is that the machine builds extremely fast compared to other processes. This, combined with low running costs, makes the models comparatively cheap. The finished models remain relatively weak compared to FDM™ or LS models. The machines and materials are safe if slightly messy.

The materials tend to be highly porous and, therefore, not well suited to sterilisation, and no medical grade materials are available. The models are opaque which may hide internal details. A typical Z-Corp medical model is shown in Fig. 5.21. However, machines are available that can produce full colour models. This is achieved by introducing coloured inks into the

5.21 Z-Corp model of the mandible.

Table 5.6 Advantages and disadvantages of three-dimensional printing

Advantages	Disadvantages
Cheaper, small machine	Lower accuracy and surface finish
Very fast build times	Limited application
Easy to use	
Low maintenance and running costs	
Suitable for office environment	
Full colour models possible	

adhesive print head (exactly like an inkjet printer) and using a white powder. Therefore, a wide range of colours is available. This may prove particularly useful in teaching models where different adjacent objects need to be identified. The advantages and disadvantages of three-dimensional printing are summarised in Table 5.6.

5.7 Jetting head technology

5.7.1 Principle

Build material is deposited discretely by jetting heads, similar to those used in inkjet printers. The material is ejected as a liquid, solidifying on contact with solid material or the build platform. The head moves in X and Y-axes to build the layers. The build platform lowers by a layer thickness and material is deposited on to the previous layer.

5.7.2 Detail

There are several companies, such as Objet, Solidscape and 3D Systems, producing small office-based machines that utilise deposition processes similar to those found in inkjet printers. Machines such as the 3D Systems ThermoJet® and those from Solidscape deposit wax-based materials in their liquid state that instantly cool and solidify to produce the model, whilst the 3D Systems InVision™ and those from Objet use photo-polymerising resins that are simultaneously solidified by UV light as they printed. An InVision™ model is shown in Fig. 5.22.

Generally, the machines and materials are clean and safe and do not require extraction or special handling. Most machines build support structures, but the Solidscape and InVision™ machines surround the model with a secondary wax support material that is either melted or dissolved away from the completed model. The Solidscape machine is also unique in employing a milling head to level each layer.

As might be expected from technologies that rely on printing technologies, the resolution of these machines is often quoted in terms of dots per inch (dpi). Some of these machines, such as the ThermoJet® and InVision™ from 3D Systems, are not as accurate as the more expensive systems, such as SL for example, but they are intended more for the concept design stage. A ThermoJet® medical model is shown in Fig. 5.23. Correspondingly, the material strength and surface finish are not as good as SL for example. However, the Objet models are comparable to SL models.

One of the advantages of printing technologies is the ability to produce very thin layers. This reduces the stepping effect, and models are very smooth compared to other layer manufacturing techniques. Layer thicknesses of 0.040 mm are typical but can be as thin as 0.016 mm. This means that models can be made that show excellent surface detail as described in Section 6.17 Research applications case study 3. Another advantage is that each layer is created during a pass of the print head regardless of the geometry of any given cross section, which makes prediction of build times relatively simple and accurate.

5.22 InVision™ model of the mandible.

Unlike the other machines, that use large numbers of print heads to accelerate building speed, the Solidscape machine utilises a single print head. This makes these machines highly accurate, with very thin build layers, and hence models show an excellent surface finish. However, this makes them extremely slow and limited to a very small build envelope. However, they are proving popular with the jewellery trade due to their small size and suitable casting materials.

In medical terms, the wax materials are weak and difficult to sterilise due to their low melting points. The materials are opaque, which may hide internal detail, but the wax materials lend themselves well to casting processes. However, the Solidscape machine is capable of producing very accurate models of extremely small objects. The relative accuracy of the Objet process and the transparency of the materials make them ideal for medical modelling and comparable in most respects to SL models. In addition, an Objet build material has recently been tested to an internationally recognised standard for plastics (USP 23 Class 6) and may, therefore, be sterilised and used in theatre. Recently softer, rubber-like, materials have

5.23 ThermoJet® model of the mandible.

also been developed for the Objet process. The advantages and disadvantages of jetting head technology are summarised in Table 5.7.

5.8 Laminated Object Manufacture (LOM™)

5.8.1 Principle

Inert, flat sheet materials are cut to the profile of a layer. Fresh material is bonded onto the previous layer and the next profile is cut. The layer thickness is dependent on the thickness of the sheet material.

5.8.2 Detail

The LOM™ process was originally developed by Helisys Inc. (Helisys Inc., of Torrance, California, USA ceased trading and was replaced by Cubic Technologies Inc., 1000 E Dominguez St, Carson CA 90746-3608, USA). Helisys machines make models by cutting layers of paper with a laser using

Table 5.7 Advantages and disadvantages of jetting head techology

Advantages	Disadvantages
Cheaper, smaller machines	Low accuracy (ThermoJet®)
Easy to use	Fragile models (ThermoJet®, Solidscape)
Suitable for office environment	Slow build times (Solidscape)
Thin layers	
Fast build times (ThermoJet®, InVision™ SR)	
High accuracy (Solidscape, InVision™ HR)	
Transparent models (Objet)	
Medically appropriate material (Objet)	

an X-Y plotter mechanism. Build time is relatively quick as only the perimeter of the layers is drawn. Builds can be speeded up by cutting more than one layer of paper at a time; the paper is nominally 0.1 mm thick. The paper is adhesive backed and the layers are adhered by a heated roller. The paper is fed from a roll and passes over the build table; unused paper is taken up by another roll. The laser cuts a support wall enclosing the model; material that is outside the model and inside the support wall is cut into squares. The build table lowers, fresh paper is fed over the top of the build and heat bonded, and the next layer is cut and so on. When the model is complete, the block is removed from the table and the support wall is removed. The waste material is broken away to reveal the model. A typical LOM™ medical model is shown in Fig. 5.24.

To obtain a cut that penetrates only one layer of paper requires the speed of travel and laser power to be adjusted manually. Good bonding between layers depends on the compression, temperature and speed of travel of the heated roller, which is again adjusted manually until it is satisfactory. These require regular checking and, generally, the machine needs a lot of maintenance. Extraction of the smoke produced creates a tolerable amount of noise. Although there is a certain amount of waste material, the paper is relatively cheap. Helisys machines are increasingly uncommon and not available in some markets, although many are still in operation around the world.

The Kira system (Kira Europe GmbH, Heinrich-Hertz-Str. 8-10, D-40699 Erkrath, Germany) is similar except that the paper is fed in sheet form by a photocopier mechanism; the adhesive is applied (as toner would be in a photocopier). A hot plate bonds the layers and cutting is by carbide knife using an X-Y plotter mechanism. There may be advantages to this approach compared to the Helisys method. Most notably, less lateral stress is induced on bonding because the hot plate presses evenly downwards as opposed to the roller, which imparts a lateral force as it travels across the model. There

5.24 LOM™ model of the mandible.

is also the cost advantage of standard (photocopier) components and the elimination of lasers. The more recent system offered by 3D Systems and Israeli company, Solidimension Ltd (Sharga Katz Bldg, Be'erot Itzhak 60905, Israel) is aimed at the desktop concept modelling market. The machine uses PVC sheet material supplied on a roll that is precision cut with a blade and bonded with an adhesive.

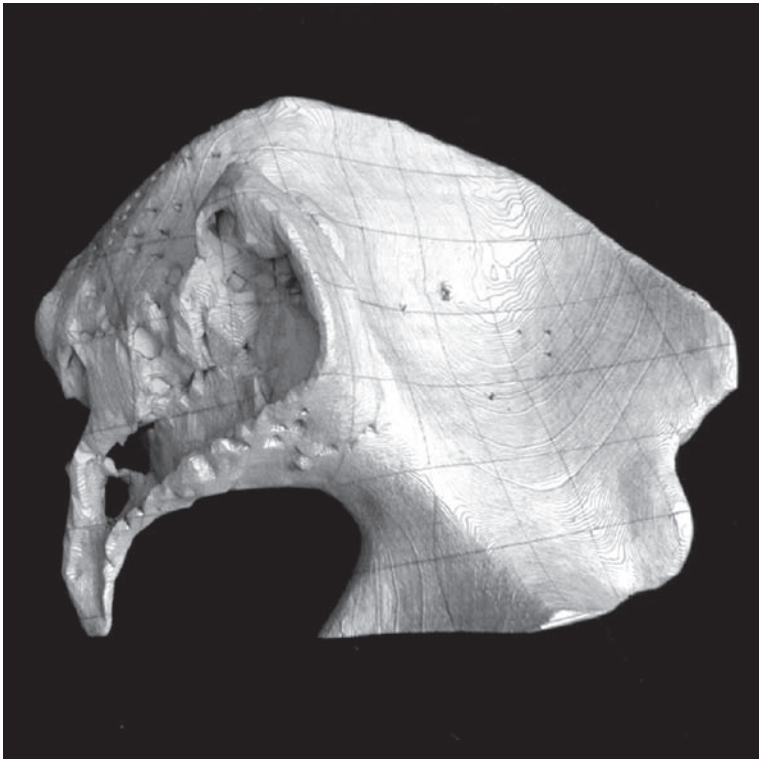
The sheet materials these processes use undergo no state change and therefore shrinkage is not a problem, although the height may alter slightly as built in stresses are relieved. Paper models produced are good for handling and feel similar to wood. The models will burn out of investment casting shells with no problems. These models are very strong in compression and may, therefore, be used as moulds for vacuum forming or light duty pressing.

An inherent problem when breaking models out is that any area of the model that faces upwards or downwards is attached to the waste material. In practice, this is only a problem where the distance between laser cuts is more than around 10 mm. This is partly combated by finer cross-hatching over up-facing areas. It can also be avoided by re-orienting the model. However, this is still a problem over large flat areas or shallow slopes and care must be taken when breaking out the model.

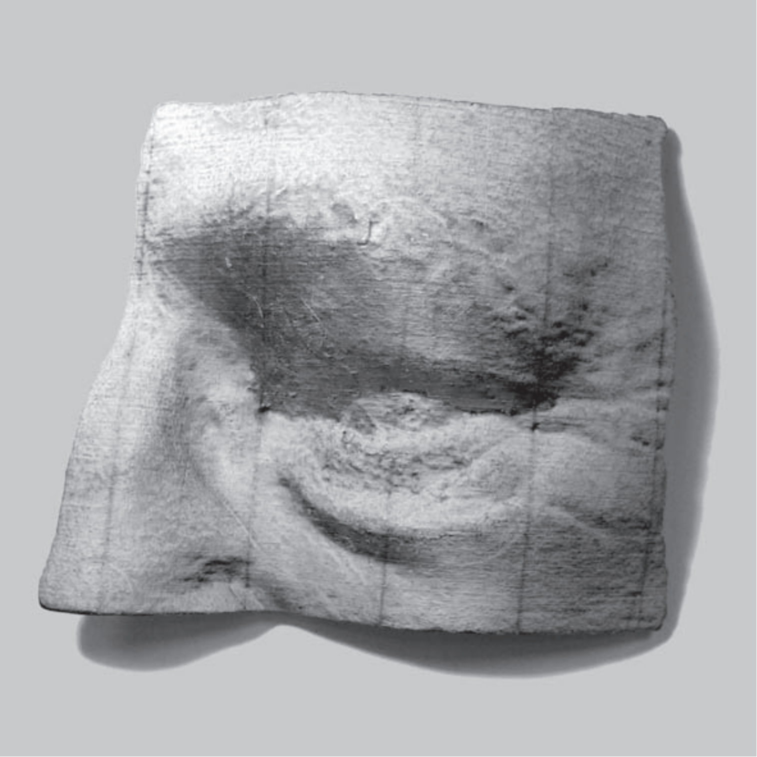
In medical modelling terms, these processes have some uses. They show reasonable accuracy and surface finish. However, the major advantage is the low cost of building very large solid models. This makes the process ideal for producing models of large bones or soft tissues. These advantages can be clearly seen in the examples illustrated in Figs 5.25 and 5.26. The fact that unused material is solid means that it cannot be removed from internal spaces and voids. The advantages and disadvantages of LOM™ are summarised in Table 5.8.

5.9 Computer Numerical Controlled (CNC) machining

Unlike RP techniques, milling has always been of limited use when producing shapes with undercuts, re-entrant features and internal voids. For example, Section 6.2 Implementation case study 2 shows an image of a



5.25 LOM™ model of illium.

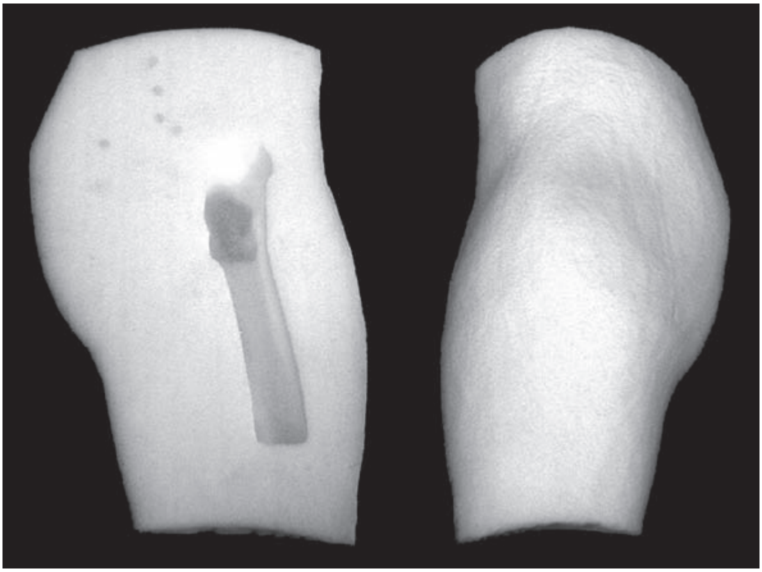


5.26 LOM™ model of a partial face.

Table 5.8 Advantages and disadvantages of LOM™

Advantages	Disadvantages
Relatively cheap machines	Labour-intensive post processing
Cheap materials	High maintenance and set up time
Clean safe materials	Poor for thin walls and small features
Good for large, thick, simple models	Waste material removal

cranial defect and the lack of undercuts and internal shape is readily apparent. Yet, it proves economical and rapid when forming simple, solid shapes and forms. The principal advantages of machining are its availability and versatility. A large number of machines exist from very cheap desktop routers to very large factory-based machine tools. Unlike most RP technologies, machining is not restricted to a limited range of materials. Almost any material can be machined ranging from the hardest metals to soft foams. CNC allows machining to be carried out under computer control



5.27 CNC machined foam model of the soft tissue of the hip.

Table 5.9 Advantages and disadvantages of CNC

Advantages	Disadvantages
Very wide range of machine size and cost	Pre-processing time consuming
Very wide range of materials	Set up time
Clean, safe materials	Clamping the part during cutting
Good for large, thick, simple models	Poor for thin walls and small features
Good accuracy possible	Poor for internal detail, hollow parts or undercuts

based on CAD data. Depending on the machine and material configuration, CNC allows complex forms to be machined rapidly and accurately.

The characteristics of machining make their use in medical modelling particularly suitable to producing larger models of the external anatomical topography. Typical applications may be for moulds and formers or custom fitting supports and wearable devices.

The artificial hip model shown in Fig. 5.27 was made to replicate the human body in impact testing of hip protection devices for the elderly. The model is made of dense, closed-cell foam and shaped using CNC machining to replicate not only the external anatomical topography but also an internal pocket in which an artificial femur can be located. The advantages and disadvantages of CNC are summarised in Table 5.9.

6 Case studies

The following case studies are drawn from the collective experiences of the medical modelling researchers at the National Centre for Product Design and Development Research (PDR) and their various collaborators. The cases were selected for their diversity as well as their technical, clinical and academic merit. To ensure the quality of the case studies included in this book, the majority have been taken from texts that have been previously published in international peer-reviewed journals. However, the texts have been altered to reflect their position in this book and to eliminate repetition, particularly of technical descriptions that appear in the earlier chapters of the book. Therefore, you will find regular references to those previous chapters in these case studies. As some of these case studies were originally written for specialist audiences, the explanation of some technical or medical terms has been inserted to enable the reader from either a medical or technical background to understand the cases described. Where these would prove a distraction, you may be directed to a more substantial explanation in Chapter 8. Other aspects such as trademarks and company names may have been updated to reflect the correct details at the time of writing. Where possible any technology that has been superseded has also been noted.

Appropriate acknowledgement has been given at the beginning of each case study to those that contributed to it and the original source is shown should you wish to locate and read the original version.

The case studies have been grouped into four categories: implementation, surgical applications, rehabilitation and research. The first papers relate to aspects of the general implementation and application of medical modelling, including setting up procedures and problems that may be encountered. The second group consist of papers relating to surgical applications such as reconstructive surgery or joint replacement. The third group of articles broadly relate to rehabilitation. This includes the design and fabrication of prostheses, the production of custom fitting devices or other techniques that may be undertaken by prosthetists in the laboratory. The final group of papers are loosely termed research. This section contains papers on diverse subjects that do not necessarily involve the treatment of an individual patient or are slightly outside the normal practices of medical modelling, such as archaeology.

IMPLEMENTATION

6.1 Implementation case study 1: The development of a collaborative medical modelling service – organisational and technical considerations

6.1.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of the British Association of Oral and Maxillofacial Surgeons.

- Sugar A, Bibb R, Morris C, Parkhouse J, 'The development of a collaborative medical modelling service: organisational and technical considerations', *British Journal of Oral and Maxillofacial Surgery*, 2004, **42** (4), 323–330.

This work has only been possible because of the enthusiasm and hard work of the entire collaborating team from PDR and Morriston Hospital. In particular, the authors gratefully acknowledge the work of Peter Evans and Alan Bocca of the Maxillofacial Unit and Dr E Wyn Jones, Rose Davies and Sian Bowen of the Radiology Department of Morriston Hospital. We are also grateful to our neurosurgical colleague, Tim Buxton, who has supported this project physically and financially since its inception.

6.1.2 Introduction

Medical modelling has been shown to be a valuable aid in the diagnosis of medical conditions, the planning of surgery and production of prostheses **(1, 2)**. RP techniques have shown significant advantages over previous milled models **(3)**. However, the application of the technologies requires close and efficient collaboration between radiographers, surgeons, prosthetists and rapid prototyping service providers. As yet, no optimum method of achieving this has been demonstrated, and the process is often *ad hoc* leading to potential errors and delays. Close co-operation between the Maxillofacial Unit of Morriston Hospital and PDR in several successful cases led to the desire to improve the process in terms of data transfer and clinical decision-making **(4, 5, 6)**. This case study describes the efforts of this hospital and RP service provider to develop an efficient and rapid collaboration that serves the clinical needs of the hospital.

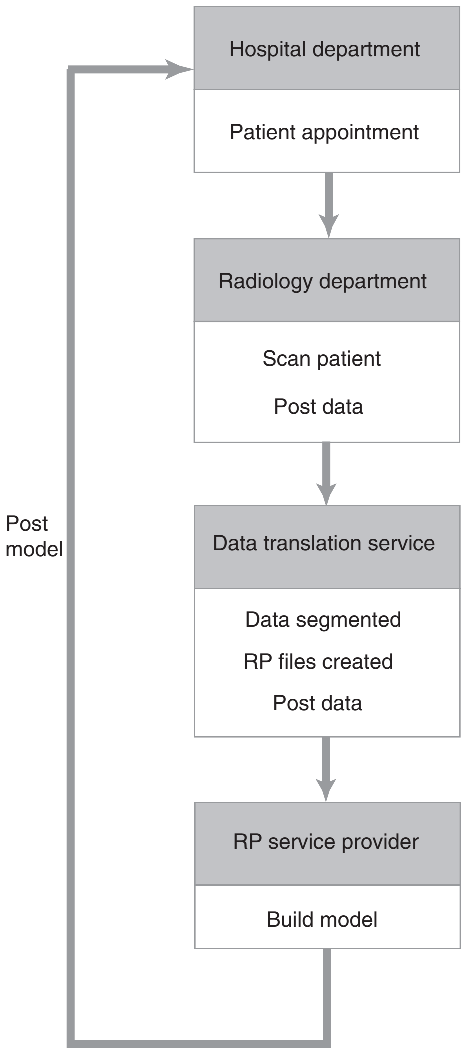
6.1.3 Aims of medical modelling collaboration

For most medical models produced in the UK, the preparation of the RP build files from patient scan data is undertaken by a very small number of specialist suppliers. One of the principal reasons for this is that scan data is only normally available in proprietary formats on archive media, which cannot be read unless the appropriate hardware and software is purchased. This equipment differs for each manufacturer of medical scanner. Additional software is also required to segment the scan data and produce the RP build files. Many RP service providers are, therefore, unwilling to invest the large sums necessary to purchase this expensive software and equipment when the number of models made would make it difficult to recoup the investment.

Therefore, in most cases scan data on archive media (e.g. magnetic optical disk, DAT tape or CD ROM) is posted from the radiology department to the specialist supplier. The supplier translates and segments the data from which the RP build files are created. The transfer of medical scan data is described in Chapter 3. This requires careful communication so that the correct parameters, tissues and extents are used. Once translation is complete, the RP build files are then returned to the RP service provider who builds and delivers the model to the hospital. This procedure, schematically shown in Fig. 6.1 and called the 'Disconnected' Procedure, is time consuming and removes potentially important clinical decision-making opportunities from medical staff.

In an effort to improve this situation, the authors piloted a more collaborative approach. Although the RP generation software needed to be purchased, the use of direct communication eliminated the need to translate data from the archive media saving a considerable amount of time and money. This process involved sharing the necessary procedures between the medical staff and the RP service provider. Effectively, the tasks were accomplished by the most appropriate staff, improving decision-making opportunities whilst reducing cost and turn around time. This approach was further accelerated by the use of electronic communication rather than routine mail.

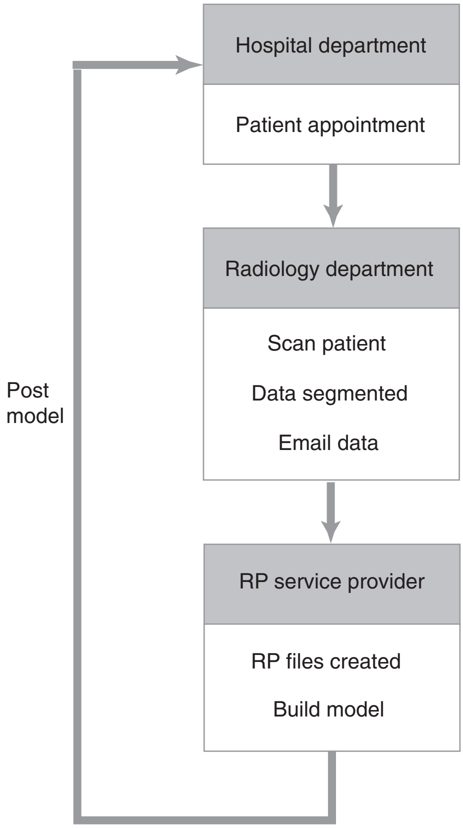
Due to the modular nature of the software used, the initial integrated procedure shown in Fig. 6.2 was first attempted **(7)**. Experienced



6.1 The 'disconnected' procedure.

radiographers in a location accessible to the surgeons conducted the segmentation of the image data within the radiology department. The segmented data was then sent to the RP service provider who used the remaining software modules to prepare and manufacture the models. Once such a route was established, the turn around time from initial scan to finished model was reduced from weeks to days.

This approach had both technical and organisational implications as described in the next section. Such considerations may limit the adoption of what appears at first sight to be the optimal route. The technical issues



6.2 The initial integrated procedure.

may all be overcome given sufficient resources, but organisational conditions will dictate whether such resources are available or appropriate.

6.1.4 Implementation

The software used in this study consists of one module (Mimics, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium) used for the import and segmentation of scan data. A separate module (CT Modeller, CTM) generates the rapid prototyping build files from data exported from Mimics. This allowed the segmentation software (Mimics) to be installed in both the radiology and the clinical departments while the other module (CTM) remained at the RP service provider. The segmentation module was installed on well-specified PCs connected to the hospital network allowing direct access to the scan data. The basic principles of data segmentation are more fully described in Chapter 4.

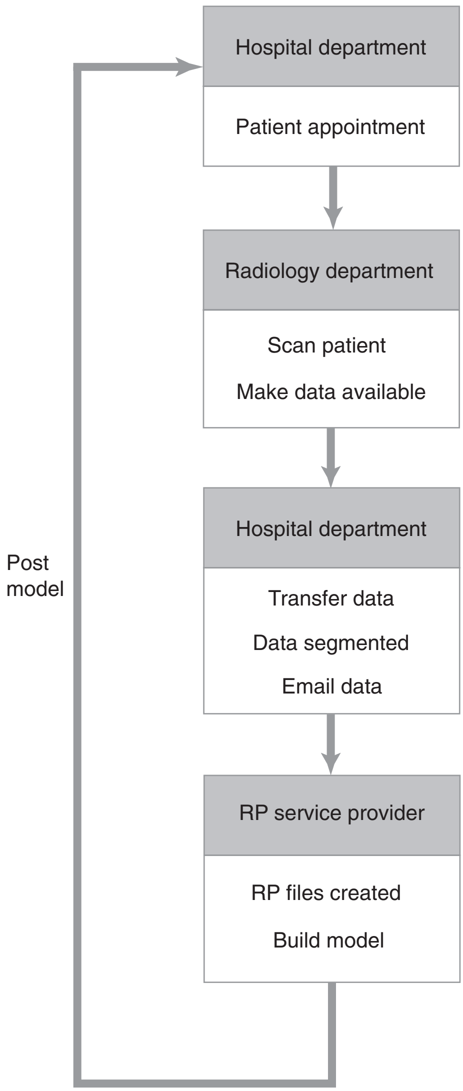
When using this software there is a convenient intermediate step between the different modules. The export file format from Mimics to CT Modeller (called a .3dd file) is highly compressed, typically in the region of 1 MB. Files this small are easily transferred as an attachment to an ordinary email. The use of existing email protocols including the firewalls at the hospital and the service provider eliminated security and network access issues.

After training and some initial trials, it became clear that the file-import, preparation and segmentation was too time consuming to be undertaken by the radiographers. Although highly trained in the operation of the scanner, the radiographers were unfamiliar with other computer formats and network procedures. As the radiology department was already working at capacity, it was felt that this was not the best use of their time. It was originally envisaged that radiographers would be better able to segment the scan data. However, in practice, the simplicity of the software allows accurate segmentation to be accomplished by any adequately trained user and is well within the competence of clinicians. Furthermore, clinicians have a much better idea of what they want to achieve by the segmentation.

It was also felt that the majority of the clinical decision-making should be the responsibility of the clinical department. This would eliminate any potential misunderstandings between medical and technical staff. Therefore, a modified procedure was implemented (Fig. 6.3, the current integrated procedure). This procedure involved the clinical department having the software to enable them to segment the data and email the compressed file format (a three-dimensional image) to the RP service provider.

This method also keeps as much of the workload (and therefore cost) within the clinical department and minimises the workload transferred to radiology. The added benefit of this method is the capability of the clinical department to produce three-dimensional reconstructions on screen. The surgeon can then view and move these images at will rather than relying on a selection of fixed views produced on film by the radiology department. Axial slices can be viewed simultaneously with coronal and sagittal reformats; and the slices can be run through in seconds. Areas of specific interest can be generated in three dimensions and viewed from any angle. The increased access to two-dimensional and three-dimensional data in various forms may also eliminate the need to produce a physical model in many cases, with a potential saving of time and money. The images produced can also be saved on hard disk, printed on plain paper for storage in patients' notes and exported into standard image software and, from there, into slide presentation formats for teaching/lecturing/demonstrations. Hard copy can also be given to patients to help them understand their condition.

When following this procedure, the radiology department obtains the scans in the usual manner and saves the data into a secure directory on a PC hard-wired to the scanner. This PC enables easy storage of data in the



6.3 The current integrated procedure.

radiology department in their preferred format. The PC was connected to the hospital's local Intranet, which makes the data available to the registered user in the Maxillofacial Unit using File Transfer Protocol (FTP) to another PC in the Maxillofacial Unit also connected to the Intranet. Other registered users in other hospital departments can also be included if necessary. The data is then burned in the Maxillofacial Unit onto CD, saved on the PC's hard disk and imported into the specialised imaging software

(Mimics). Image manipulation can then be carried out by clinicians on screen in three dimensions. Sections can be mirror-imaged and manipulated and areas measured without interfering with the schedule of a busy Radiology Department. The file for RP model construction, if required, can then be emailed to the RP provider as an attachment.

Of course, when hospitals change their CT scanners, it is necessary to check that existing procedures still work and that the imaging software (e.g. Mimics) is configured appropriately to receive the new scan format. Current scanners almost invariably now comply with a standard digital format (DICOM) and the importation of such scans into Mimics is in fact made much easier in this format. When Morriston Hospital acquired a new Multislice CT scanner in 2002, all its raw CT data was saved on a server within the hospital Intranet. The Maxillofacial Unit was then given direct access to this server through the Intranet, and CT scans can be picked up directly and saved. This method has effectively replaced the FTP arrangement.

6.1.5 Discussion

Technical issues

The most important technical issues in implementing such a modelling process are:

- the export file format of the scan data;
- the nature of the storage media;
- the electronic transfer of the data.

If the scan data media and/or format are proprietary, the appropriate software and hardware may have to be purchased by the collaborating parties. Many radiology departments are not accustomed to exporting data and may only have such archiving formats available as DAT or optical disk. In addition, some radiology departments are still not networked, although this is likely to change over the next few years as teleradiology becomes more widespread. These data transport issues can be eliminated if the data can be directly transferred across computer networks. Electronic communication can be achieved in a number of ways, and the method chosen should be economic and fast whilst maintaining security.

Problems may be encountered when attempting to transfer very large data sets (a full set of three-dimensional scan data may be 50–300 MB) as network disruptions become more probable during long download times. Such problems may result in corrupted or incomplete data. The use of compression software may help, but the data sets may still be large. However, evidence suggests that data is frequently transferred successfully in this manner. FTP is commonly used for transferring data across local and remote networks. To maintain security FTP sites can be protected with user names and passwords as can access to servers.

Although the National Health Service (NHS) in the UK has a dedicated network (for example, in Wales the local network is called Digital All Wales Network or DAWN) it is, in the short term, unlikely that external RP service providers would be allowed access to such a network. Maintaining security is understandably a high priority for NHS networks. Even if access were allowed, the network capacity is limited when compared to other high-capacity networks, such as the Higher Education service 'JANET' (Joint Academic Network).

If the data files are small enough, they can be sent as an email attachment. In this case, security would be maintained through the email server's existing firewall. However, most email systems would become unsuitable if the file size exceeded 3 MB or the number of files sent per day proves excessive, as most servers set storage limits for users.

An ISDN line could be used, but the security protocols for connecting to NHS networks may still apply in this case. If a PC is connected to a hospital Intranet (and through it to the Internet), connection simultaneously to an ISDN line could breach firewall regulations. The installation of ISDN lines within the hospital is likely to require some form of management approval and agreement concerning which budget will cover the cost of installation, line rental and call charges. However, once in place it should prove a reliable and secure transfer method.

Some consideration will have to be made concerning the amount of traffic the link will be expected to handle. It may well be that in the short term there will be insufficient traffic to warrant the investment in new networks. Alternatively, more commonly used high-capacity storage systems such as CD-R, CD-RW, DAT, ZIP or JAZ drives could be used.

It is worth bearing in mind that the majority of medical models required will be for scheduled elective operations. In such cases, delay in communication of data can be anticipated and planned. However, in the long term, it is hoped that the service may be used to aid in the treatment of trauma victims, in which case speed will be of great importance and a direct link may save crucial hours from the turn around time.

A description of the commonly used formats and some of the issues that may be encountered in the effective transfer of medical scan data can be found in Chapter 3.

Organisational issues

It is self-evident that setting up a successful dedicated medical modelling collaboration between a hospital and an RP service provider requires the full co-operation of the surgical departments, the radiology department, the IT department and the RP service provider. The implications for the various departments will differ depending on which technical solution is adopted. The chosen procedure should reflect the overall needs of the patient whilst taking due account of economic factors. Consequently, the organisational considerations relate to:

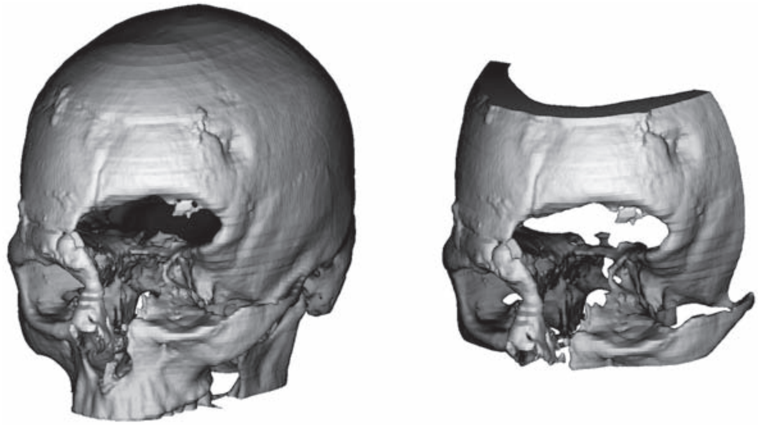
- economics and budgeting;
- staff workload and responsibility.

It is widely acknowledged that hospital departments must operate within strictly controlled budgets. Therefore, it is crucial to obtain the support and commitment of senior hospital management at the outset of a project such as this. The costs involved in setting up the service will have to be met, but there is likely to be pressure within departments to pass on as much of the cost to other sources of funding, thus minimising the impact on departmental budgets.

In terms of workload, it is likely that each of the departments will be running at capacity, which may lead to conflicts between departments when the workload is distributed. Departments will try to resist any increase in their budget requirements or workload. There may be economic reasons for transferring workload from one department to another.

Careful thought will have to be given as to who takes responsibility for the key decisions taken during the medical modelling process. It is likely that clinical departments will want to maintain the maximum amount of responsibility and control whilst minimising workload and expenditure. The only practical method of resolving this difficulty is to try different procedures and determine which one best meets the clinical need. It should then be a matter of using this sound knowledge to apply for the correct budgeting and resources from hospital management.

It is worth emphasising that the use of medical models may drastically reduce theatre time and its associated costs as well as improving the quality and accuracy of surgery. However, cost savings have to be seen in context. For elective cases in the British NHS, the operating time available to surgeons is finite and spare time will be taken up by other cases. Therefore, the principal effect in a public funded healthcare system will be on waiting lists and waiting times for surgery. Quality of patient care and cost-effectiveness of care will improve, but the need for a three-dimensional model will impose an additional charge on tight budgets. Clinical control of the process can, however, enable many of these problems to be minimised. For example, Fig. 6.4 shows a three-dimensional CT reconstruction of a skull with a fronto-zygomatic bone defect (left). A model was required to enable a cranioplasty plate to be constructed and to assist planning for the placement of craniofacial osseointegrated implants. By eliminating



6.4 Whole three-dimensional reconstruction (left) and reduced to the area of interest (right).

unwanted parts of the three-dimensional image, a new three-dimensional image (Fig. 6.4 right) was created by the clinicians and emailed in the form of a .3dd file to the RP provider so that the model constructed could be much smaller and therefore very much cheaper.

6.1.6 Conclusions

The clinical benefits of medical modelling have been documented and this work has demonstrated that a dedicated collaboration between the RP service provider and medical staff can greatly improve speed, efficiency and quality of service. Evidently, careful planning is necessary before embarking upon such collaborations. In particular, close co-operation between the rapid prototyping service provider, the radiology department, information technology departments, surgical teams and hospital management is of the utmost importance. Although it is inevitable that investment will be required, all of the long-term clinical and economic benefits should be clearly indicated to fund managers. Besides the principal goal of creating a medical modelling service, the setting up of convenient data formats and electronic communications can be exploited in many other ways. This can be seen in the number of hospitals embracing tele-radiology, which allows consultants to view medical images from remote locations.

It should be anticipated that existing computer facilities might have to be upgraded with particular attention paid to hardware specification, communication and data transfer issues. In some cases, the scanner may also have to be networked or upgraded to allow the export of image data in a convenient format.

Although it is not in the form originally anticipated, the approach described here enabled a service to be established that provided the desired medical modelling service to the hospital in a fast, efficient and economic manner. The personnel most able to complete each task effectively handle the individual procedures. Data transfer is fast and secure without compromising either party's network security. Importantly, the bulk of the costs and decisions are kept within the surgical department that requires the medical model and that department is thus able to control the process and minimise those costs.

In the near future, it is likely that there will be many other factors driving hospitals to improve their networks and electronic communications. Issues regarding data format compatibility and file transfer will become more apparent and new standards applied to ensure the efficient and secure transfer of all kinds of clinical information. Many of the issues encountered in this collaboration will be overcome by the overriding proliferation of computerised clinical information in all hospitals.

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6.2 Implementation case study 2: Medical rapid prototyping technologies – state of the art and current limitations for application in oral and maxillofacial surgery

6.2.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of the American Association of Oral and Maxillofacial Surgeons.

- Winder RJ, Bibb R, 2005, 'Medical rapid prototyping technologies: state of the art and current limitations for application in oral and maxillofacial surgery', *Journal of Oral and Maxillofacial Surgery*, **63** (7), 1006–1015.

6.2.2 Introduction

Medical rapid prototyping (MRP) is defined as the manufacture of dimensionally accurate physical models of human anatomy derived from medical image data using a variety of rapid prototyping (RP) technologies. It has been applied to a range of medical specialities including oral and maxillofacial surgery **(1, 2, 3, 4, 5, 6, 7)**, dental implantology **(8)**, neurosurgery **(9, 10)** and orthopaedics **(11, 12)**. The source of image data for three-dimensional modelling is principally computed tomography (CT), although magnetic resonance imaging and ultrasound have also been utilised. Medical models have been successfully built of hard tissue such as bone and soft tissues including blood vessels and nasal passages **(13, 14)**. MRP was described originally by Mankowich *et al.* in 1990 **(15)**. The development of the technique has been facilitated by improvements in medical imaging technology, computer hardware, three-dimensional image processing software and the technology transfer of engineering methods into the field of surgical medicine.

The clinical application of medical models has been analysed in a European multi-centre study **(16)**. Results were collated from a questionnaire sent out to partners of the Phidias Network on each institution's use of MRP stereolithography models. The 172 responses indicated the following range of applications:

- to aid production of a surgical implant;
- to improve surgical planning;
- to act as an orienting aid during surgery;
- to enhance diagnostic quality;
- useful in preoperative simulation;

- to achieve patient's agreement prior to surgery;
- to prepare a template for resection.

Further, it was noted that the diagnoses in which a stereolithography (SL) model was employed were as follows: neoplasms (19.2 %), congenital disease (20 %), trauma (15 %), dentofacial anomalies (28.9 %) and others (16.9 %). MRP is also being developed for use in dental implants. Greater accuracy was achieved with the use of rapid prototyped surgical guides for creating osteotomies in the jaw **(17)**, and a CAD/CAM approach to the fabrication of partial dental frameworks has been developed **(18)**.

The creation of medical models requires a number of steps: the acquisition of high quality volumetric (three-dimensional) image data of the anatomy to be modelled; three-dimensional image processing to extract the region of interest from surrounding tissues; mathematical surface modelling of the anatomical surfaces; formatting of data for rapid prototyping (this includes the creation of model support structures which support the model during building and are subsequently manually removed); model building; quality assurance of model quality and dimensional accuracy. These steps require significant expertise and knowledge in medical imaging, three-dimensional medical image processing, computer-assisted design and manufacturing software and engineering processes. The production of reliable, high quality models requires a team of specialists that may include medical imaging specialists, engineers and surgeons.

The purpose of this case study is, firstly, to describe the range of rapid prototyping technologies (including software and hardware) available for MRP, secondly, to compare their relative strengths and weaknesses, and, thirdly, to illustrate the range of pitfalls that we have experienced in the production of human anatomical models. The authors have a combined experience of 17 years working in the field of MRP and have direct experience of the technologies described later. The study begins with a description of three-dimensional image acquisition and processing and computer modelling methods required and common medical rapid prototyping techniques; this is followed by a discussion of model artefacts and manufacturing pitfalls. At present, there is no suitable text describing MRP or its clinical applications; however, there are two useful review papers **(19, 20)**.

6.2.3 Three-dimensional image acquisition and processing for MRP

The modalities and general principles of acquiring medical scan data for RP are described in Chapter 2, but some of the more important observations resulting from a large number of actual cases are discussed here. The volumetric or three-dimensional image data required for MRP models has certain particular requirements. Specialised CT scanning protocols are required to generate a volume of data that is isotropic in nature. This means that the three physical dimensions of the voxels (image volume elements) are equal or nearly equal. This has become achievable with the introduction of multi-slice CT scanners where in-plane pixel size is of the order of 0.5 mm and slice thickness as low as 1.0 mm **(21)**. Data interpolation is often required to convert the image data volume into an isotropic data set for mathematical modelling. Further image processing steps will be required to identify and separate out the anatomy (segmentation) for modelling from surrounding structures. Segmentation may be carried out by image thresholding, manual editing or auto-contouring to extract volumes of interest. Final delineation of the anatomy of interest may require two-dimensional or three-dimensional image editing to remove any unwanted details. A number of software packages are available for data conditioning and image processing for MRP and include Analyze (Analyze Direct Inco, 11425 Strang Line Road, Lenexa, KS 66215, USA, www.AnalyzeDirect.com), Mimics (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium, www.materialise.com), and Biobuild™ (Anatomics Pty Ltd, Suite 4, Level 1, 568 St Kilda Road, Melbourne, VIC, 3004, Australia, www.anatomics.net). There is still a need for seamless and inexpensive software that provides a comprehensive range of data interpretation, image processing and model building techniques to interface with RP technology.

The first models created were of bone that was easily segmented in CT image data. Bone has a CT number range from approximately 200 to 2000. This range is unique to bone within the human body, as it does not numerically overlap with any other tissues. In many circumstances, a simple threshold value was obtained and applied to the data volume. All soft tissues outside the threshold range were deleted leaving only bone structures. Thresholding required the user to determine the CT number value that represented the edge of bone where it interfaced with soft tissue. Note that the choice of threshold may cause loss of information in areas where only thin bone is present.

In many circumstances, the volume of the body scanned is much larger than that actually required for model making. To reduce the model size, and therefore the cost, 3D image editing procedures may be employed. The most useful tool was a mouse-driven 3D volume editor that enabled the operator to delete or cut out sections of the data volume. The editing function deleted sections to the full depth of the data volume along the line of sight of the operator. Image editing reduced the overall model size which also reduced RP build time. Clearer and less complex models may be generated, making structures of interest more clearly visible. Other image processing functions such as smoothing, volume data mirroring, image addition and subtraction should be available for the production of models.

6.2.4 Rapid prototyping technologies

Rapid prototyping (RP) is a generic name given to a range of related technologies that may be used to fabricate physical objects directly from computer-aided design (CAD) data sources. RP enables design and manufacturing of models to be performed much more quickly than conventional manual methods of prototyping. In all aspects of manufacture, the speed of moving from concept to product is an important part of making a product commercially competitive. RP technologies enable an engineer to produce a working prototype of a CAD design for visualisation and testing purposes. There are a number of texts describing the development of rapid prototyping technology and its applications **(22, 23)**. Of the many RP processes that have been applied to medical modelling, the two most extensively employed are stereolithography and fused deposition modelling.

Stereolithography (SL)

The following data provide some technical specifications of a specific type of SL machine that is in common use in medical modelling (3D systems SLA-250/40, 3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA, www.3dsystems.com). However, a full description of the principles of SL is provided in Section 5.2.

- Laser beam diameter = 0.2–0.3 mm.
- Laser scanning speed = 2.54 meters/second.
- Build platform = 250 × 250 × 250 mm.
- Layer build thickness = 0.05–0.2 mm.
- Minimum vertical platform movement = 0.0017 mm.

The above specification indicates the precision of model building that is achievable with SL. The laser focus defines the in-plane resolution whilst the platform vertical increment defines the slice thickness at which the model is built. It should be noted that the imaging modality acquisition parameters are the limiting factors in model accuracy.

Fused Deposition Modelling (FDM™)

The technical specifications of a commonly used FDM™ machine (Stratasys FDM-3000, 14950 Martin Drive, Eden Prairie, MN 55344-2020, USA, www.stratasys.com) used for models in the cases referred to here are as follows. A full description of the working principles of FDM™ is provided in Section 5.4.

- Build envelope 254 × 254 × 254 mm.
- Achievable accuracy of ±0.127 mm.

- Road widths (extruded thermoplastic width) between 0.250 and 0.965 mm.
- Layer thickness (extruded thermoplastic height) from 0.178–0.356 mm.

The above specification indicates the precision of model building that is achievable with FDM™. It can be seen that the results are broadly similar to those achieved by SL. However, SL can achieve thinner layers and more precise control over the laser position compared to the deposition of plastic material in FDM™.

Computerised Numerically Controlled (CNC) milling

Although generally not considered one of the many rapid prototyping technologies, CNC milling can successfully build some medical models **(24)**. This technology was applied in the construction of custom titanium implants for cranioplasty. CNC milling uses a cutting tool, which traverses a block of material removing it on a layer-by-layer basis. Fig. 6.5 shows a model of a skull defect (only half the skull has been created). The complexity of models that can be achieved using CNC milling is limited as it only cuts on one side of the model data. If the model required has any internal features or complex surfaces facing a number of directions, then CNC milling would

6.5 Half skull model created by CNC milling demonstrating a large cranial defect.

not be suitable. An overview of the principal differences between CNC milling and RP is provided in Section 5.9.

Other RP technologies

Selective Laser Sintering (SLS®–3D Systems Inc.) locally heats a thermoplastic powder, which is fused by exposure to an infrared laser in a manner similar to SL. SLS® models do not require support structures and they are therefore cleaned relatively easily, thus saving labour costs. An example of the use of SLS® in medical modelling is described by Berry *et al.* **(25)**. Laminated Object Manufacturing (LOM™) builds models from layers of paper cut using a laser, which are bonded together by heating. Inexpensive sheet materials make LOM™ very cost effective for large volume models. However, the solid nature of the waste material means that it is not suited to models with internal voids or cavities often encountered in human anatomy. The SLS® and LOM™ processes are also described in more detail in Sections 5.5 and 5.8, respectively.

Discussion of MRP technologies

The main factors in choosing which rapid prototyping technology are most appropriate for our clinical applications were as follows:

- dimensional accuracy of the models;
- overall cost of the model;
- availability of technology;
- model building material.

SL models are typically colourless to amber in colour, transparent and of sufficient accuracy to be suitable for MRP work. FDM™ models are typically made of white acrylonitrile-butadiene-styrene (ABS) and are attractive both in terms of appearance and material. It has been pointed out that medical models may be dimensionally accurate to 0.62 mm +/− 0.35 mm **(26)**. It should be noted that the limiting factor in model accuracy is the imaging technique rather than the RP technology employed. In general, CT and MR typically acquire image slices, which have slice thickness of the order of 1.0–3.0 mm, which is much greater than the limiting build resolution of any of the RP technologies.

The potential benefits of exploiting RP techniques in surgical planning have been widely acknowledged and described. The process of producing accurate physical models directly from three-dimensional scan data of an individual patient has proved particularly popular in head and neck reconstruction. In addition, most of the work done to date has concentrated on the use of three-dimensional CT data as this produces excellent images of bone. However, the process is still not conducted in the large volumes associated with industrial rapid prototyping and, as such, practitioners applying these techniques to medicine often confront problems that are not encountered in industry. The small turnover associated with medical modelling also means that many manufacturers and vendors cannot justify investment in specific software, processes and materials for this sector. These characteristics combine to make medical modelling a challenging field of work with many potential pitfalls.

The authors' many years of practical experience in medical modelling has resulted in a knowledge base that has identified the problems that may be encountered, many of which are simple or procedural in nature. This study aims to highlight some of these common problems, the effect they have on the resultant models and suggest methods that can be employed to avoid or minimise their occurrence or impact on the usefulness of the models produced.

6.2.5 Medical rapid prototyped model artefacts

Associated with all medical imaging modalities are unusual or unexpected image appearances referred to as artefacts. Some imaging modalities are prone to geometric distortion like MR **(27)**, and this should be accounted for in soft tissue models manufactured from this source. CT does not suffer from the same distortion as MR and models produced from this source have been proven to be dimensionally accurate **(28)**. In some circumstances artefacts are easily recognisable and taken into account by the viewer, whilst in other circumstances they can be problematic and difficult to explain. Artefacts present in the image data may subsequently be transferred to a medical model. In addition, due to the image processing steps and surface modelling required in the production of medical models there is scope for the appearance of a wide range of artefacts. This section describes and illustrates some of the problems and pitfalls encountered in the production of medical models.

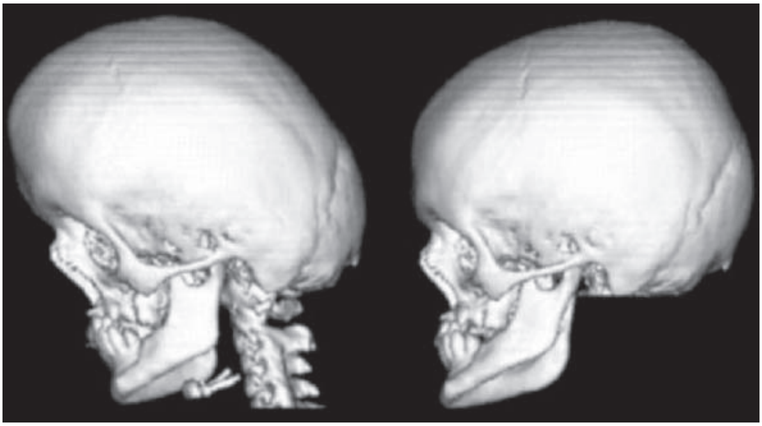
The procedures and potential problems associated with transferring and translating medical scan data are described in Chapters 2 and 3. However, the following observations serve to illustrate particular examples of some of the problems encountered by the authors. An example of some of the practical implications of transferring data from a hospital to an RP service provider is given in Section 6.1 Implementation case study 1.

CT data import errors

CT data consists of a series of pixel images of slices through the human body. When importing data the key characteristics that determine size and scale of the data are the pixel size and the slice thickness. The pixel size is calculated by dividing the field of view by the number of pixels. The field of view is a variable set by the radiographer at the time of scanning. The number of pixels in the X and Y-axis is typically 512×512 or 1024×1024. If there is a numerical error in any of these parameters whilst data is being translated from one data format to another, the model may be inadvertently scaled to an incorrect size. The slice thickness and any inter-slice gap must be known (although the inter-slice gap is not applicable in CT where images are reconstructed contiguously or overlapping). Numerical error in the slice thickness dimension will lead to inadvertent incorrect scaling in the third dimension. This distance is typically in the order of 1.5 mm but may be as small as 0.5 mm or as high as 5 mm. Smaller scan distances result in higher quality of the three-dimensional reconstruction. The use of the internationally recognised DICOM (Digital Image Communications in Medicine, www.acrnema.org) standard for the format of medical images has largely eliminated these errors **(29)**.

CT gantry tilt distortion

A CT scanner typically operates with the X-ray tube and detector gantry perpendicular to the long axis of the patient (Z direction). Therefore, the scan produces the axial images that form the basis of three-dimensional CT scans. However, in some cases the gantry may be inclined at an angle of up to 30º. When a set of two-dimensional slices is combined into an image volume for three-dimensional modelling the gantry angle must be taken into account. With no gantry tilt, the slices are correctly aligned and they will produce an undistorted three-dimensional volume. Slices acquired with a gantry tilt of 15º and converted into a data volume without the gantry tilt being taken into account may have a shear distortion arising from the misalignment of slices. At large angles this is immediately visually apparent and can, therefore, be detected. However, at small angles it may not be so obvious. Building a model with a small, uncorrected gantry tilt angle could be easily done and result in significant geometrical inaccuracies in the resulting model. The use of the image transfer standard, DICOM, automatically provides the scan parameters, including gantry tilt angle. However, the DICOM format does not provide the direction of the angle and it cannot, therefore, be relied on to automatically correct gantry tilt. Therefore, it is advisable to avoid gantry tilt when acquiring a three-dimensional CT image data set, otherwise sophisticated mathematical algorithms are required to successfully correct the data. Fig. 6.6 shows how a distorted 3D CT volume may be corrected using an affine transformation to produce a data set with no distortion.

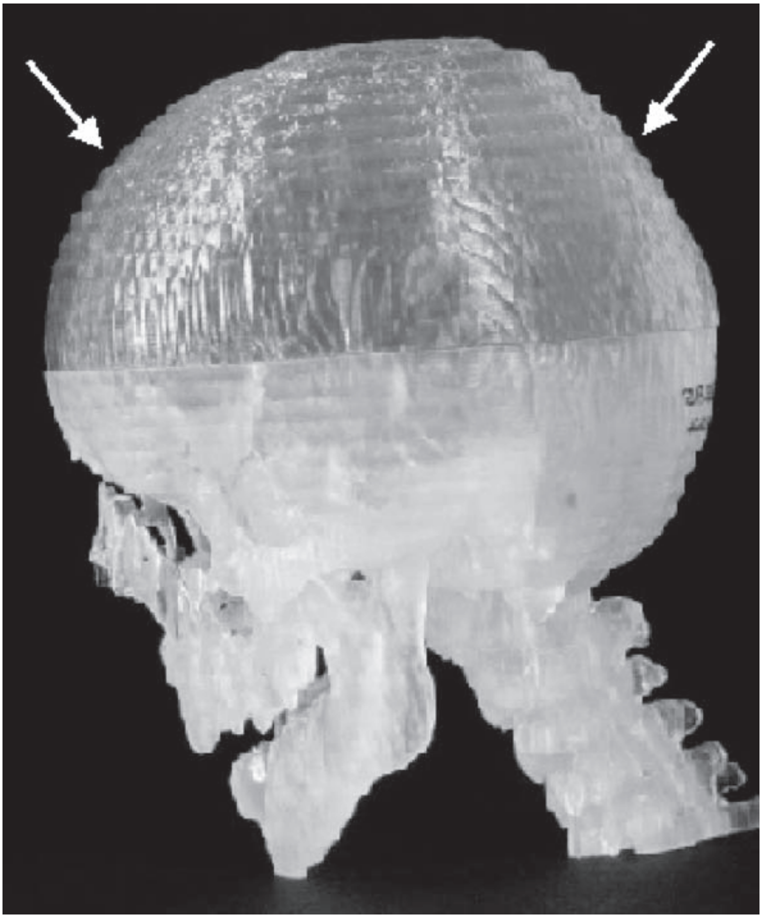


6.6 Effect of gantry tilt on a three-dimensional surface rendered skull (left) and the same after correction (right).

Model stair-step artefact

Two elements contribute to the stepped effect seen in medical models. One contribution is from the discrete layer thickness at which the model is built. This is a characteristic of the particular RP process and material being used. Typically, these range from 0.1–0.3 mm. This effect can be minimised by selecting processes and parameters that minimise the build layer thickness. However, thinner layers result in longer build times and increased costs, and an economic compromise is typically found for each RP process. As the layer thickness is typically an order of magnitude smaller than the scan distance of the CT images, it does not have an overriding effect on the quality of the model.

The second effect arises from the slice thickness of the acquired CT or MR images and any potential gap between them. The stair-step artefact is a common feature on conventional and single slice helical CT scans where the slice thickness is near to an order of magnitude greater than the in-plane pixel size **(30)**. The artefact is manifest as a series of concentric axial rings around the model. The depth and size of these rings depends on the CT imaging protocol, but may be very slight where there is a thin slice used (e.g. 3 mm acquisition with 1 mm reconstruction interval). In thick-slice acquisitions (e.g. >3 mm with similar reconstruction interval to the slice thickness), the stair-step artefact will cause significant distortion to the model. Fig. 6.7 shows a stereolithography model of a full skull. The CT scan was performed on a conventional CT scanner with 5 mm slice thickness and no interpolation of the image data to create thin slices. Note that there was significant stair-step artefact around the top of the skull and on the lower edge of the mandible. The stair-step artefact was most prominent on



6.7 SL model with significant stair-step artefact.

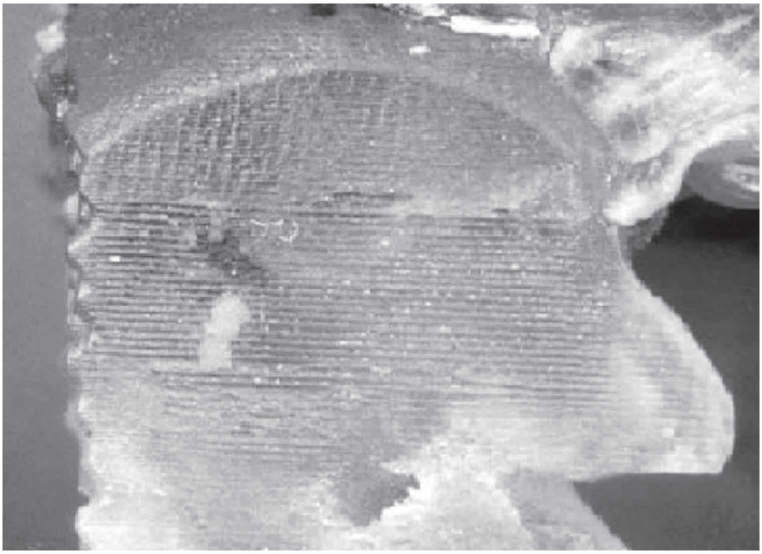
surfaces that were inclined to the data acquisition plane as is the case for 3D surface rendered images. This model was used for surgical planning and reconstruction but was limited in the use for obtaining physical measurements. These effects can be countered to some degree by using interpolation between the original image data slices. Due the natural nature of the cubic curve, the resulting interpolated data results in a good, smooth and natural appearing surface.

Irregular surface due to support structures

Both SL and FDM™ required support structures during the build process. These were subsequently cleaned from the model manually, although they generally left a rough surface. This did not affect the overall accuracy of the model but contributed to a degradation of its aesthetic appearance. Fig. 6.8 shows an SL model where surface roughness was attributed to the support structures. Models were easily cleaned using light abrasive techniques, although this was felt unnecessary as the indentations were of sub-millimetre depth. It is unlikely that these structures would have a detrimental effect in surgical planning or implant design.

Irregular surface due to mathematical modelling

The mathematical modelling of a surface will introduce its own surface effects. The smoothness (governed by the size of the triangle mesh) of the model surface becomes poorer as the surface mesh becomes larger. A larger mesh resulted in a lower number of triangles, reduced computer file size and quicker rendering. A smaller mesh resulted in much better surface representation, much greater computer file size and slower rendering. Fig. 6.9 shows irregular surface structures due to the mathematical modelling process **(31)**. Fig. 6.9 (a) shows a model where the mesh structure is not readily apparent and (b) where the model contours are more clearly observed. In both cases, the surface produced was acceptable for its own clinical application. One could imagine that the mesh resolution used in model (b) would be unacceptable for smaller models where fine detail would be masked.



6.8 Showing surface roughness on an SL model attributed to support structures.

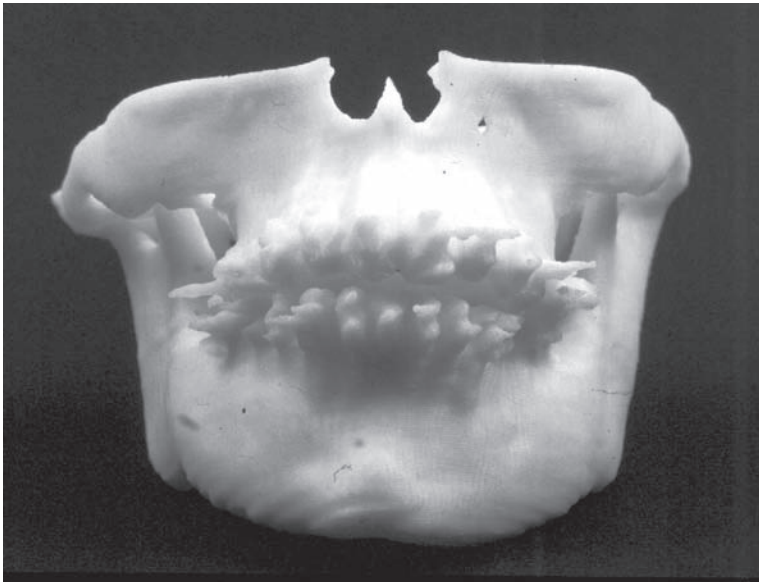
6.9a Smooth surface due to high-resolution meshing algorithm.

6.9b Meshing contours visible due to low-resolution meshing algorithm.

These effects can be avoided by eliminating the creation of a three-dimensional surface mesh and creating the RP build data directly from the CT image data. This essentially creates the $2^1/_2$D layer data for the RP machine from the CT images. Interpolation is used to create accurate intermediate layers between the CT images. This route not only eliminates surface modelling effects but also results in much smaller computer files and faster preparation.

Metal artefact

Metal artefact was present within CT scans of the maxilla and mandible due to the presence of metal within fillings of the teeth or the presence of dental implants. This was manifest as high signal intensities (in the form of scattered rays) around the upper and lower mandible. Fig. 6.10 shows an FDM™ model with significant metal artefact around the teeth. These ray appearances extended from a couple of millimetres to over one centimetre in length. In some circumstances, the artefact may be reduced by software during CT image reconstruction **(32)**. This artefact was plainly visible and added many superfluous structures to the medical models. Although no significant geometric distortion was observed on models, large spikes were visible emanating from around the teeth which distorted the bone in the local area. The artefact may be removed by detailed slice-by-



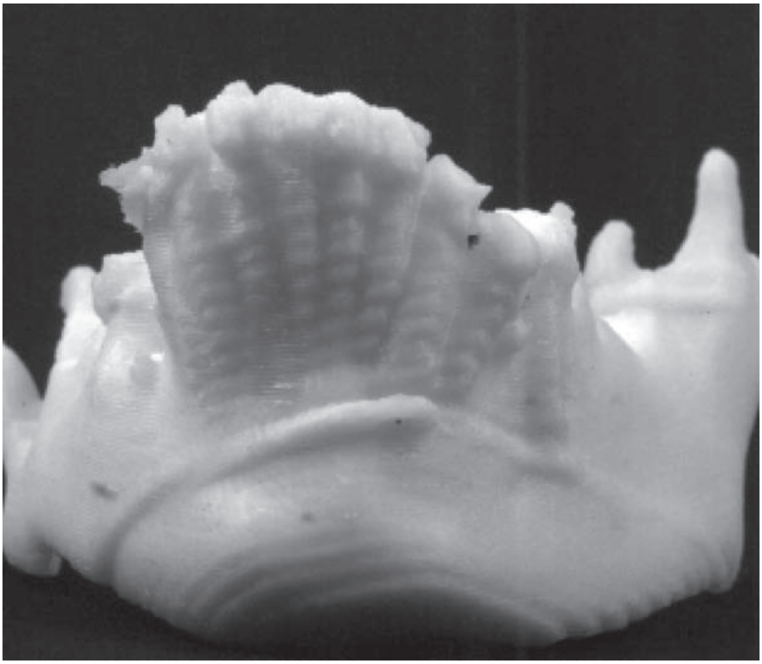
6.10 Metal artefact due to scattering of X-rays from metal within the teeth.

slice editing of the original CT images, to produce a cleaner model. This process is very time consuming and, if not performed with great care, can result in anatomy of interest being removed and the subsequent model becoming unusable.

Movement artefact

CT scanning was prone to movement artefact if a patient was restless. This artefact was readily apparent in a model if the degree of movement was significantly large, i.e. greater than 1 mm. Fig. 6.11 shows a mandible with a distinct artefact present. The patient moved slightly during the acquisition of a couple of images that left a bulge of 4 mm height extending right around the mandible. In addition, present in this model were concentric axial rings of about 3 mm thickness. These corresponded to the common stair-step observed in single slice helical CT scanning. Obviously, the degree of the movement during the scan determines the size of the movement artefact in the model. In the example shown the artefact was felt not to be significant clinically as it did not interfere directly with the placement of a distraction device.

In another example where a model was being used for facial reconstruction, the patient moved whilst the scanner was acquiring data at the region



6.11 Distinct movement artefact on an FDM model of the mandible.

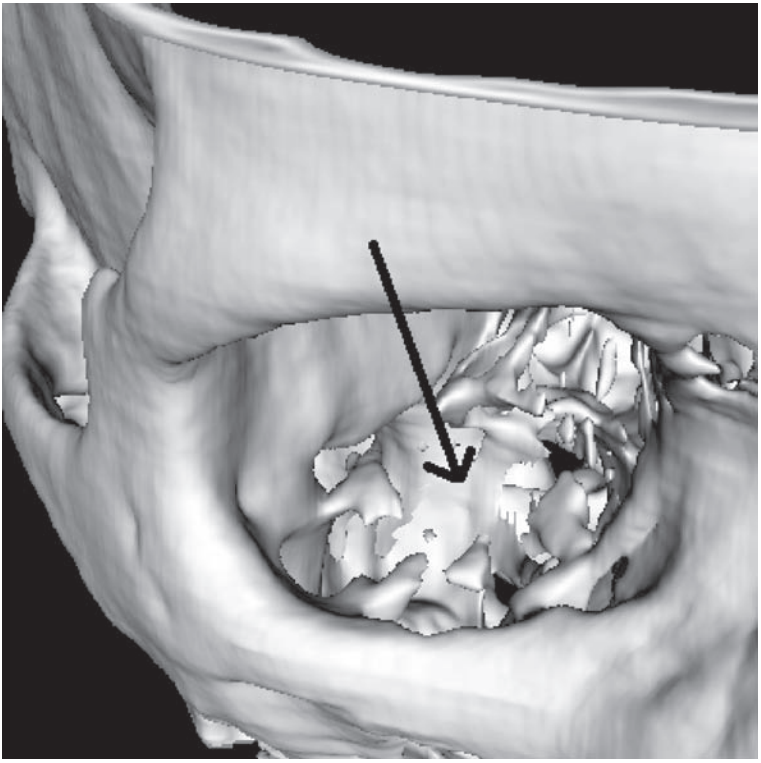
where the surgery was to be performed. The movement artefact resulted in distortion of the model that the surgeon lost confidence in its physical integrity. During the scan, around the supra-orbital ridge, we believe the child rotated its head to look at a parent, which resulted in rotation of this part of the data, which was subsequently transferred to the model. In this case, the patient, a 7-year-old child, had to be rescanned under full general anaesthetic. It was interesting to note that the degree of the artefact was not noted until a physical model was produced. This indicates the need for good quality assurance of the original data set to ensure that a useful model is produced.

Image threshold artefact

One of the simplest and commonest methods of tissue segmentation applied to the skull is CT number thresholding. A CT number range was identified by either region of interest pixel measurements or pixel intensity profiles, which was representative of bone. If the bone was particularly thin or the threshold inappropriately measured, a continuous surface was unachievable. This left the model with a hole where the surface was not closed. In some cases, large areas of bone were removed completely, especially at the back of the orbit and around the cheekbones. Fig. 6.12 illustrates bone deletion by data thresholding in the back of the orbit in this magnified surface shaded image. Anatomical detail is lost as the chosen threshold removed thin bone at the back of the orbit, as indicated by the black arrow. Adjusting the threshold to include bone in this case would have resulted in the inclusion of soft tissue that would have made the image more difficult to interpret. It is useful to specify what is required of a model clearly, so that an appropriate threshold can be chosen to preserve tissue of interest.

6.2.6 Conclusion

Medical rapid prototyping models of human anatomy may be constructed from a number of image data sources and using a range of RP technologies. They are prone to artefacts both from the imaging source, the method of manufacture and from the model cleaning process. It is important to ensure that high quality source data is available to ensure model quality. Clinicians requesting medical models should be aware of their physical accuracy and integrity, which is generally dependent on the original imaging parameters and image processing rather than the method of manufacture, and determine that this is sufficient for its purpose. We have demonstrated a range of model artefact sources ranging from reading computer files to the removal of support structures and suggested ways to avoid or cure them. It is important that the source images be reviewed thoroughly; that robust image



6.12 Removal of bone at the back of the orbit due to inappropriate choice of image threshold.

transfer and image processing procedures are in place; and that the model building material is fit for the purpose for which it was intended. A multi-disciplinary team approach to the manufacture of medical models with rigorous quality assurance is highly recommended.

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SURGICAL APPLICATIONS

6.3 Surgical applications case study 1: Planning osseointegrated implants using computer-aided design and rapid prototyping

6.3.1 Acknowledgements

The work described in this case study was first reported in the references below and is reproduced here in part or in full with the permission of the Institute of Maxillofacial Prosthetists and Technologists and the Council of the Institute of Mechanical Engineers.

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6.3.2 Introduction

In recent years, rapid prototyping (RP) has been used to build highly accurate anatomical models from medical scan data. These models have proved to be a valuable aid in the planning of complex reconstructive surgery, particularly in maxillofacial and craniofacial cases. Typically, RP is used to create accurate models of internal skeletal structures on which operations can be accurately planned and rehearsed **(1, 2, 3, 4)**. Such models have been successfully used for positioning osseointegrated implants. Osseointegrated implants are titanium screws attached directly to a patient's bone structure and passing through the skin to provide a rigid and firm fixture for dentures, hearing aids and prostheses **(5)**. See medical explanatory note 8.2.1 for an explanation of osseointegrated implants. The accuracy of the RP models allows the depth and quality of bone to be assessed, improving the selection of drilling sites before surgery. Although this process has dramatically improved the accuracy and reduced the theatre time of some surgical procedures, it incurs significant time and cost to produce the anatomical model. Whilst it does utilise RP technologies, this current route does not fully exploit the potential advantages of computer-aided design.

To address this issue it was decided to complete as much of the planning as possible in the virtual environment and only use RP to make small templates that would guide the surgeon in theatre. This route would allow the clinicians to conduct all the planning and explore many options without damaging an expensive RP model. To be successful, the approach would have to be simple to conduct and have low investment requirements.

6.3.3 The proposed approach

The approach would use three-dimensional computed tomography (CT) data to create virtual models of the elements necessary to plan the osseointegrated implants required to secure a prosthetic ear. The elements consisted of the soft tissue of the head, a copy of the remaining opposite ear and the bone structure at the implant site. The simple and popular STL **(6)** format was chosen as the three-dimensional representation of the entities. This format ensures easy access to a number of software options at a reasonable cost. In this case, the software package Magics (Materialise NV, Technologielaan 15, 3000, Leuven, Belgium) was chosen. The STL file format is more fully described in Section 4.6.2. The entities were created as STL format files from CT data using one of a number of specialist software packages available for creating STL files from CT data (Mimics, Materialise NV).

The STL manipulation software was used to mirror the copy of the ear and position it in an anatomically and aesthetically appropriate location. The software was then used to create cylinders representing the implants. These cylinders were positioned in the preferred location by the prosthetist observing a lateral view. Then the bone quality at the implant sites could be assessed.

6.3.4 Scanning problems

Misalignment of the patient's head to one side or the other means that the optimum accuracy obtained in the axial plane during scanning is not axial to the patient. This means that entities will not be in alignment with the software co-ordinate system. Although this is not a major issue, it does make control of the angles at which the entities meet more difficult.

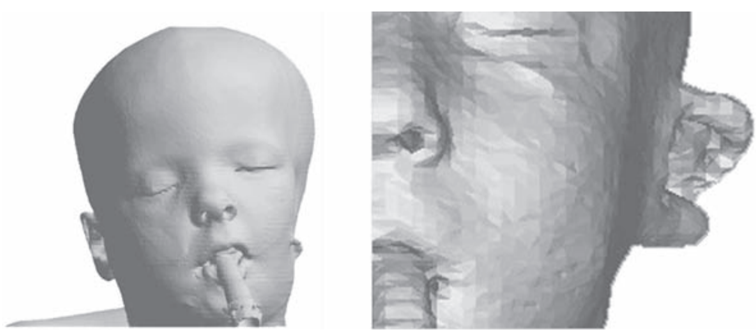
Unintended displacement of the soft tissue during the CT scan results in poor representation of the anatomy. In this example, the ear of one of the patients had become folded over resulting in a deformed anatomical entity (Fig. 6.13). This made positioning the contralateral ear and the implants problematic.

6.3.5 Software problems

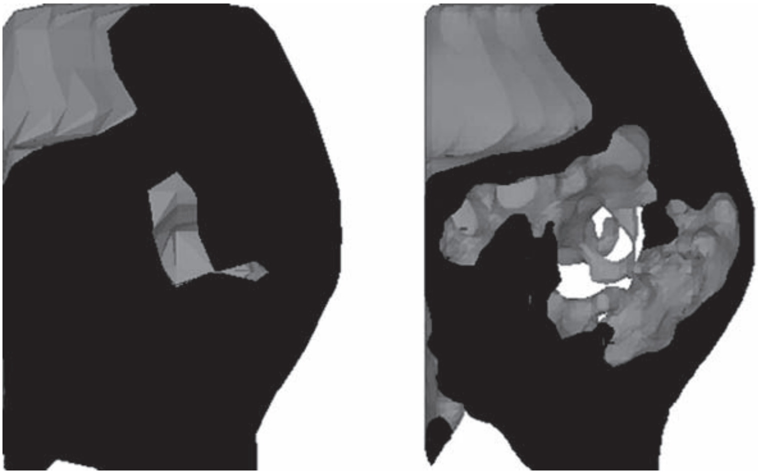
Initially file size was a concern and all of the STL files were produced at a low resolution. This resulted in small STL files that could be handled easily and rapidly by the software. In visual terms, all of the entities appeared to be well represented by the low quality STL files. However, when attempting one of the first cases, it was found that the difference in the representation of internal air cells in the highly pneumatised bone in the mastoid was dramatically altered by the resolution at which the STL file was produced. This led to the mistaken belief that this particular case had adequate bone thickness when in fact the bone was unusually thin (illustrated in Fig. 6.14). From this experience, it was decided to produce only the small amount of bone required for the implants but at the highest possible resolution. This resulted in only one entity having a large file size, which proved to be perfectly within the capabilities of a reasonable specification computer.

6.3.6 An illustrative case study

Three-dimensional CT data was used to create virtual models of the elements necessary to plan the osseointegrated implants required to secure a prosthetic ear. The elements consisted of the soft tissue of the head, a copy of the remaining opposite ear, and the bone structure at the implant site.



6.13 Problems resulting from poor position during CT scanning.



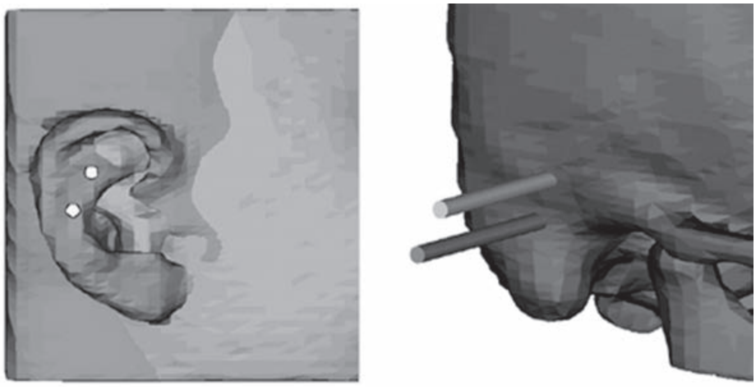
6.14 The effect of file size versus quality (low quality left, high quality right).

6.15 Positioning the contralateral ear.

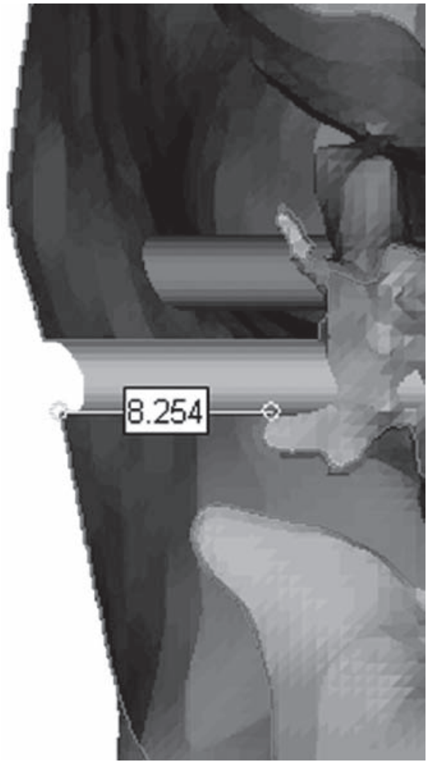
The surgeon and prosthetists then used 3D software to mirror the copy of the ear and position it relative to the head in an anatomically and aesthetically appropriate location (Fig. 6.15).

Cylinders were created to represent the implants. These cylinders were positioned on the ear in the position preferred by the prosthetists observing a lateral view (Fig. 6.16). The soft tissue entities were then removed to see where the implants intersect with the bone as can be seen in the figure. The bone quality at the implant sites was then assessed to check that they would be suitable for implants. Sectioning the virtual model enabled the quality and thickness of the bone to be accurately measured (Fig. 6.17). When the team were satisfied with the implant sites, a block was created that overlapped the implants and the surface of the skull (Fig. 6.18). Then, by using a Boolean operation, the skull and implant cylinders were subtracted from the block to create a template design (Fig. 6.18).

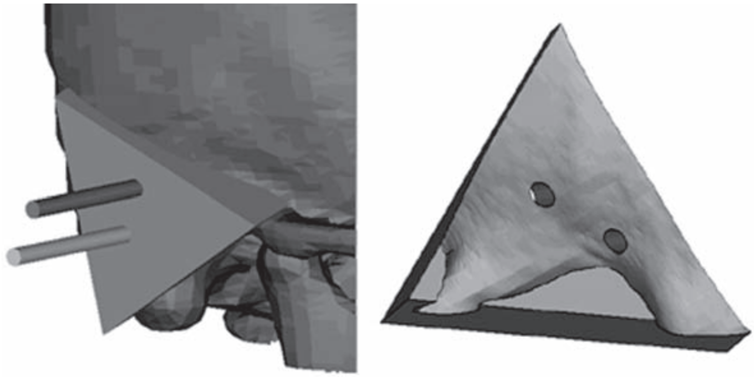
This template, shown in Fig. 6.19, was produced directly in a medically appropriate material by stereolithography **(7, 8)**. See Section 5.2 for a full description of stereolithography. The fact that at the time this was the only RP material that had been tested to a standard recognised by the FDA for



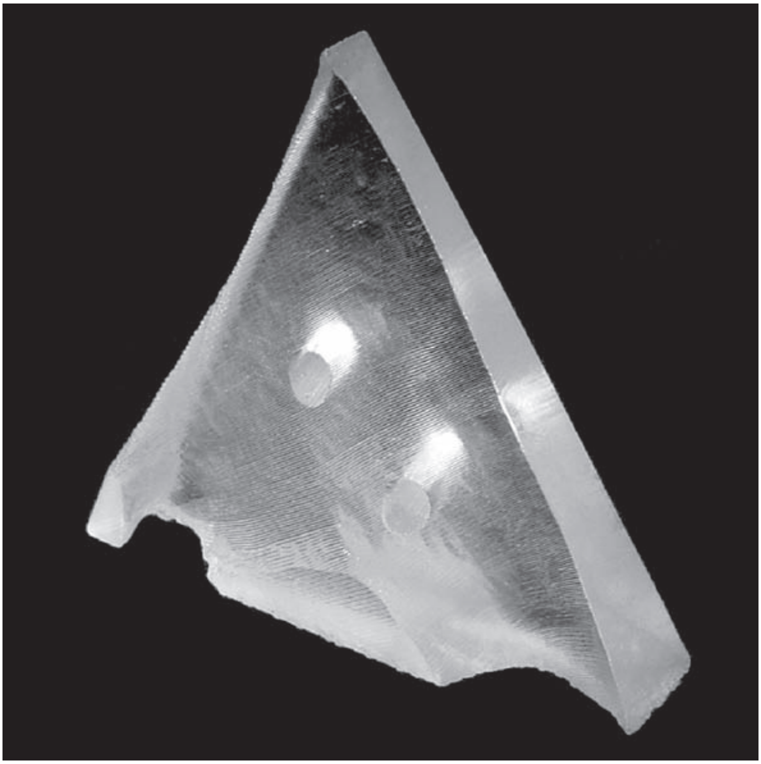
6.16 The implant positions (left) and with soft tissue removed (right).



6.17 Measured section through bone at the implant site.



6.18 The block overlapping the bone surface and implants (left) final template design (right).

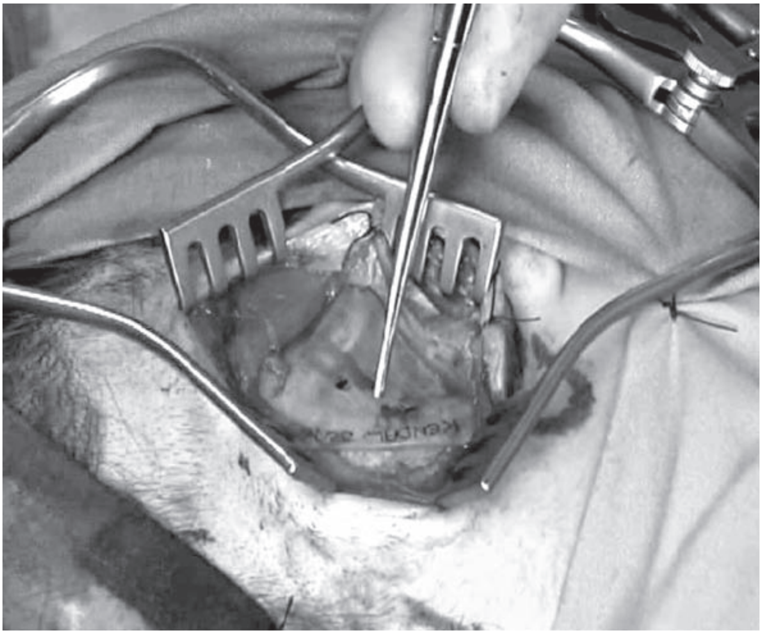


6.19 The final template produced directly using stereolithography.

patient contact in theatre meant that the stereolithography template could be used directly in surgery after sterilisation. Sterilisation presents no practical problems and appropriate methods include ethylene oxide (55 ºC), formaldehyde, low temperature steam (75 ºC) and gamma irradiation. The template locates onto the anatomical features on the surface of the skull at the implant site and indicates the drilling sites to the surgeon. The mastoid and zygomatic process are exploited to provide positive anatomical features so that the template locates accurately and firmly.

6.3.7 Results

In surgery, the template was found to fit very accurately and securely to the area of the skull as shown in Fig. 6.20. The drilling was carried out and the bone thickness and quality was found to be as indicated by the data. The positions indicated by the template were found to be much more accurate than those indicated by marks transferred from the soft tissue with ink and needle, by as much as 5 mm in one case. The team have now successfully carried out many similar cases using this approach with equally positive results and a considerable saving of time and money. If we consider the typical procedure for the traditional method being as follows; carve a planning ear (30 minutes), take impression of defect site (15 minutes),



6.20 The template in position during theatre, located in the centre of the surgical incision.

create template (30 minutes), planning (one hour), marking of template (15 minutes) the total time taken is 2.5 hours. This involves at least one technician, one surgeon and requires a patient appointment which, depending on salaries and overheads, could represent a cost saving of approximately £250.

6.3.8 Benefits and future development

The principal benefits resulting from this approach are reduced cost implications for planning activities. Once the entities are created from the CT data, they can be positioned and repositioned as many times as required. This allows different placement strategies to be performed and evaluated in three dimensions in a matter of minutes and with zero costs implication (other than time).

Once a plan has been agreed between the clinicians, the implant sites themselves can be assessed for bone depth and quality (within the limits of the original CT scan). If they are found to be unsatisfactory, these sites can be altered without incurring cost. When a final solution is achieved, the template model can be made in under two hours and cost dramatically less than even a localised stereolithography model of the bone structure. The CT data used in these cases was taken at 1.5 mm slice distance and proved adequate. However, reducing this slice distance would increase the quality of the three-dimensional entities.

Of course, the purchase and maintenance of the software required for this approach is significant, and it can be anticipated that a high volume of cases would be required to justify this investment in isolation. However, it is the experience of the authors that such software has many useful applications in head and neck reconstruction as well as other medical specialities.

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6.4 Surgical applications case study 2: The use of a reconstructed three-dimensional solid model from CT to aid the surgical management of a total knee arthroplasty

6.4.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of the Institute of Engineering & Physics in Medicine.

- Minns RJ, Bibb R, Banks R, Sutton RA, 2003, 'The use of a reconstructed three-dimensional solid model from CT to aid the surgical management of a total knee arthroplasty: a case study', *Medical Engineering & Physics*, **25** (6), 523–6.

6.4.2 Introduction

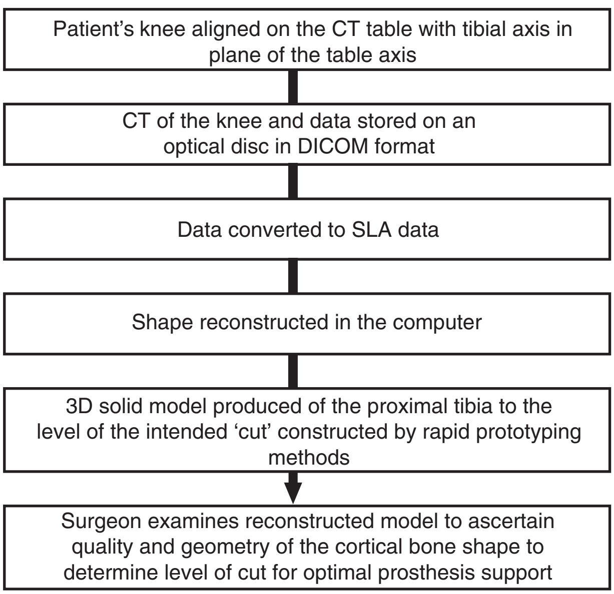
Reconstructing the knee with the aid of a prosthesis in patients with gross degenerative changes and large bone loss presents many challenges to the orthopaedic surgeon; therefore, any aid in the pre-operative planning would enhance the outcome of this form of surgery. Plane radiographs give little insight into the bone geometry in all three dimensions, especially the geometry of the cortex at the potential plane of resection.

The use of three-dimensional reconstructed images from CT for the assessment and planning of complex hip pathologies has been investigated and is reported in the literature **(1, 2, 3, 4, 5)**; it has been shown to be helpful in the planning of surgery. More recently, the production of physical models of the bone-deficient or dysplastic acetabulum using data generated from CT scans has been used in the computer-aided design and manufacture of implants **(6)**. The successful production of custom-made femoral components in total hip replacements has been also been reported **(7, 8, 9)** as well as the use of three-dimensional models in complex cranio-facial surgery. However, their use in the reconstruction of complex bone shapes around the knee has not been reported.

6.4.3 Materials and methods

The patient was a 60 year old lady with a long history of rheumatoid arthritis which first presented at the age of 15 with deformity of the fingers. She had a Benjamin's double osteotomy (see medical explanatory note 8.2.4) of the left knee at 27 because of the potential for subluxation (dislocation of the knee cap), and a synovectomy (surgery to remove inflamed joint tissue) of the right knee at 35. The left knee progressively became more varus (abnormally positioned towards the midline) and unstable and she had presented at the age of 59, wheelchair bound with a grossly unstable and deformed left knee. She was considered for total knee replacement and, due to the gross deformity of the joint, a CT scan was carried out. The scan was carried out in the horizontal plane with her tibial axis aligned at right angles to the scanning plane on the machine's couch with soft firm padding (the tibia is the shin bone). Slices in the horizontal plane at 1.5 mm intervals were taken to 30 mm below the joint line, producing 20 sections. The data was stored onto a magnetic/optical disc in DICOM format for processing and converting into the appropriate file system to produce a 3D model in the computer and consequently a solid model to scale. The whole process to generate the solid model is shown in Fig. 6.21.

The model of the knee was created using stereolithography apparatus (SLA® – 3D Systems Inc., 26081 Avenue Mall, Valencia, CA 91355, USA).



6.21 Work flow.

The SLA® process is described fully in Section 5.2. The preparation from CT data to machine-build files took less than 30 minutes, and the SLA® machine produced the model in less than four hours.

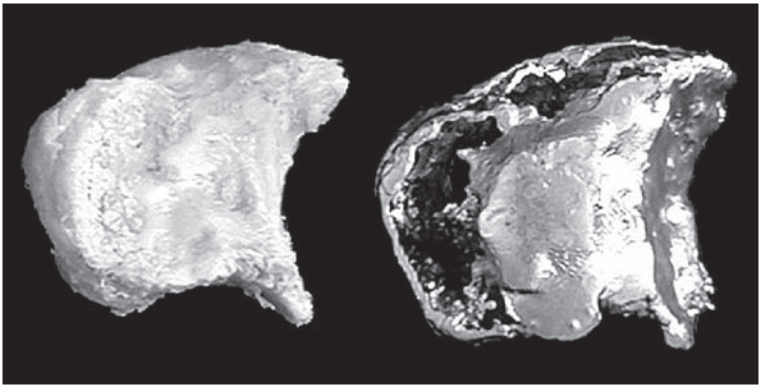
Aligning the tibia during the CT scan was advantageous to the planning of the resection of the proximal tibia in three ways. Firstly, as the optimal surgical cut through the tibia is perpendicular to the tibial axis this aligned approach means that the CT images could be visually inspected as sections through the tibia parallel to the plane of the intended surgical cut.

Secondly, it helps to maintain accuracy when building the physical model. CT data is captured as a series of planar images with a gap between them of typically 1.5 mm, whilst the stereolithography process builds models at a layer thickness of typically 0.15 mm. Therefore, interpolation is used to create intermediate sections between the original images. A cubic interpolation ensured that the intermediate sections were anatomically accurate and natural. These sections then directly drive the rapid prototyping machine that builds the physical model. Aligning the CT images ensures that the layers from which the model is built correspond exactly to the plane of the planned surgical cut. This is a significant aid when viewing the stereolithography model as it ensured that the layers visible in the finished model could be used to guide a perfectly level cut.

Thirdly, this $2^1/_2$D format (called SLC) can be more accurate and less memory intensive than three-dimensional approximation formats such as the commonly used triangular faceted STL file. These formats are described in more detail in Sections 4.5.2 and 4.6.2, respectively.

The initial assessment of the CT sections suggested that the cut should be made 15 mm below the lateral joint line. A solid model of the proximal 15 mm of the tibia was produced showing the cortical bone geometry, in order to assess the size and shape of the supportive bone available after a cut at this level, and compared with the under-surface shape and area of the tibial component. The model suggested that the bone shape and distribution would support a size small Minns™ meniscal bearing tibial component (Corin Group PLC, The Corinium Centre, Cirencester, GL7 1Y5, UK). The thickness of the cut bone removed by the oscillating saw was assumed to be 3 mm.

In theatre, following preparation of the distal femur the tibial cut was made as planned 15 mm below the lateral joint line, orthogonal to a line from the center of the knee to the center of the ankle in the sagittal plane. The CT generated model was seen to accurately represent the clinical findings at the time of surgery, confirmed when the removed bone was compared with the stereolithography model (Fig. 6.22), and a Minns™ meniscal bearing total knee was implanted as planned **(10)**. A pair of 4 mm thick meniscal bearings were found to be most appropriate in this case, and the remainder of the procedure was carried out without incident.



6.22 Resected bone compared to SLA model.

6.4.4 Post-operative management and follow up

Clinically the post-operative period was uneventful; however, a post-operative X-ray the following day revealed a crack fracture of the shaft of the tibia which was thought to have occurred at some point around the operation and was felt to be most probably due to the marked rheumatoid arthritis and disuse as no traumatic event had been noted.

This did alter the normal post-operative regime of early mobilisation and was treated with six weeks in a full leg length splint prior to mobilisation thereafter. The patient went home on the 10^{th} post-operative day mobilising non-weight bearing with a walking frame and using a wheelchair. At six weeks the fracture had united and the patient was allowed to mobilise. At 12 weeks there was a good range of knee movements, the patient walking without support, pain free with much improved gait and delighted with the result.

6.4.5 Discussion

The technique described above provides detailed information of the bone morphology in the region of the intended surgery and facilitated prediction of the level of transection of the deformed tibia at a level best suited to supporting the prosthesis. In addition, it provided a model on which the planned surgery could be carried out, before ever reaching the patient. This degree of pre-operative information is extremely useful and, should there have been insufficient bone at the proposed level of the tibial cut, the size of any required wedge could be accurately predicted.

The fracture of the tibia may have been due to an inability of the bone to resist ordinary pre-operative handling as a result of the patient's long-standing arthritis and subsequent disuse, or possibly due to the inadvertent cortical contact of one of the trephines used to prepare the proximal tibia.

The authors recognise that, although it is still small, there is an increased radiation dose to the patient associated with the use of a CT scan in this technique when compared to the plain radiographs normally used. A scan of the knee, being an extremity, does not put any other radiosensitive structures in the field. Although, in addition to the images produced, there is also the opportunity, as was done in this case, for three-dimensional reconstruction both virtually, and now as a physical model, which can be compared to the proposed prosthesis pre-operatively.

The technique can be used on any tissue that can be clearly distinguished in either CT or MR images. Whilst we do not suggest that this technique is required for any joint replacement which is anything other than 'straightforward', however; this case has demonstrated its value in knee arthroplasty (surgical knee joint repair) in cases with complex anatomy where the bone shape and quality was difficult to predict from plain films. The creation of a three-dimensional model facilitates pre-operative planning in difficult cases and provided valuable information prior to surgery.

6.4.6 References

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6.5 Surgical applications case study 3: The custom-made titanium orbital floor prosthesis in reconstruction of orbital floor fractures

6.5.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of the British Association of Oral and Maxillofacial Surgeons.

- Hughes CW, Page K, Bibb R, Taylor J, Revington P (2003), 'The custom-made titanium orbital floor prosthesis in reconstruction for orbital floor fractures', *British Journal of Oral and Maxillofacial Surgery*, **41** (1), 50–53.

No financial support was given. The National Centre for Product Design & Development Research (PDR) supplied the stereolithography model used in making the prosthesis.

6.5.2 Introduction

Few anatomical sites of such diminutive size have attracted so much variation in treatment as the orbital floor (the bottom of the eye socket) and its related fractures. The range of implant material in reconstruction following blow out fracture of the orbit is extensive and the decision as to which material is used remains debated **(1)**.

Autologous materials (those derived from human tissues) offer clear advantages with cartilage, calvarial bone, antral bone, rib and illium having been described **(1)**. These grafts offer uncertain longevity and result in tissue damage at the donor site. Artificial materials such as Silastic® (Dow Corning Corporation, Auburn Plant, 5300 11 Mile Road, Auburn, MI 48611, USA) have the longest track record, but a well-documented complication rate related in particular to extrusion of the graft **(2)**. Other artificial materials such as polyethylene sheeting (Medpor®, Porex Surgical Products Group USA, Porex Surgical, Inc, 15 Dart Road, Newnan, GA 30265-1017, USA) are reported to give satisfactory results **(3)**, and newer resorbable materials such as polydioxanone are another option **(4)**. The role of bioactive glass is more recently reported, but its use is limited by the size of the defect **(5)**. Titanium is an inert and widely used material **(6, 7)**, but in its pre-formed presentation can be cumbersome for use in the orbital floor and, if it has to be removed, it can present an operative challenge.

Continued development in computer-aided diagnosis and management and construction of stereolithographic models offers unparalleled reproduction of anatomical detail **(8, 9)**. This technology is described in relation to planning in trauma surgery **(10)** and to planning for ablative surgery for malignancies of the head and neck (surgery to remove cancer) **(11, 12)**. Construction of custom-made orbital floor implants is possible **(13, 14)**, although the material of choice is debated.

We describe a simple technique for construction of custom-made titanium orbital floor implants using easily available laboratory techniques combined with stereolithography models. We estimate the implant construction cost at around £300. This is largely accounted for by the cost of producing the model which, depending on the height of orbital contour required on the model, varies between £200 and £300. The making of the implant takes about two hours of a maxillofacial technician's time and the medical grade titanium sheet costs only a few pounds. This compares favourably with some of the newer alloplastic materials. The cost would drop substantially with greater use of the technique and, when reduced operating time is taken into account, the cost comparison is more favourable.

6.5.3 Technique

Imaging

The detail given here is specific to this case; a more general overview of CT scanning is given in Section 2.2. Scanning protocols are observed to minimise the dose of ionising radiation to orbital tissues **(15)**. Maximum detail can be obtained scanning with a 0.5 mm collimation, but the 77 % increase in dosage when compared to using a 1 mm collimation may not be justified. We use a Siemens Somatom Plus-4 Volume Zoom scanner with these settings: 140 kV, 120 mAs, 1 mm collimation, 3.5 feed per rotation, 0.75 rotation time, giving a displayed dose of 45 mGy/100 mAs (Siemens AG, Wittelsbacherplatz 2, D80333, Munich, Germany). Data are reconstructed using 1 mm slices with 0.5 mm increment (50 % overlap) and smooth kernel. Sharp reconstruction kernels normally associated with CT imaging of bony anatomy introduce an artificial enhancement of the edge. If used as part of a three-dimensional volume based on selection of specific Hounsfield values, the enhancement artefact will be included with the bony detail, so degrading the image. The data obtained can be used to construct sharp multi-plane reformats for bony detail and three-dimensional imaging for both hard-copy imaging and for stereo viewing by the surgeons.

Model construction and stereolithography

CT scans are typically taken in the axial plane at intervals exceeding 1 mm. This means that very thin bone lying predominantly in the axial plane may fall between consecutive scans and, therefore, may not be present in the data or three-dimensional model created from it. To overcome this, scans were taken using a smooth kernel at a slice distance of 1 mm but with a 0.5 mm overlap as described above. This improves the resolution of the data in these thin areas. The detail created is exceptionally good. The CT data was then segmented to select the desired tissue type, compact bone, using methods described in Sections 4.1 and 4.2.

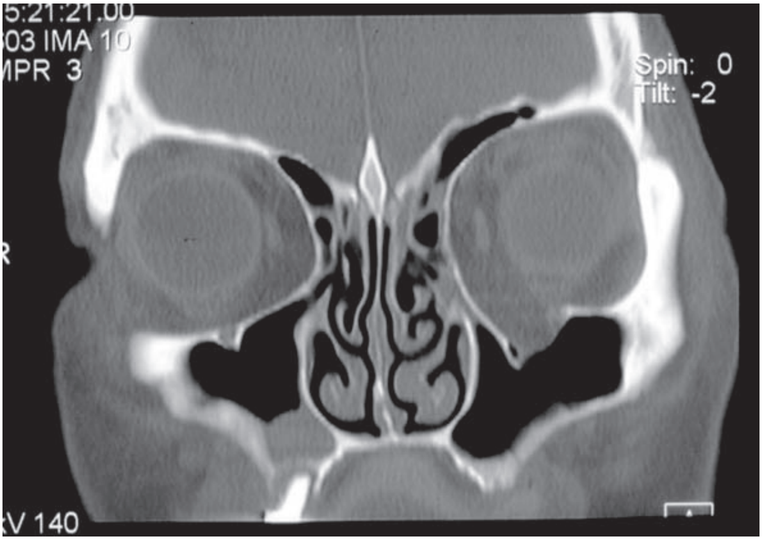
The production of models using stereolithography is described fully in Section 5.2. In this case, to maintain the greatest level of accuracy an epoxy resin was chosen (RenShape® SL5220, Huntsman Advanced Materials, Everslaan 45, B-3078 Everberg, Belgium). This type of resin shows almost no shrinkage during the photo-polymerisation process and can, therefore, produce models with excellent accuracy.

Construction of the prosthesis

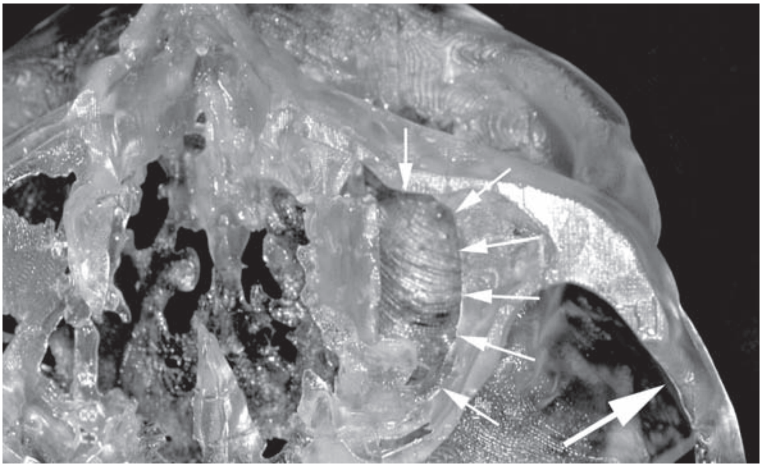
From stereolithography models, the orbital defect is easily seen and assessed. The orbital defect is then filled with wax to reproduce a contour similar to the opposite side and an impression is taken of both orbital cavities using silicone putty impression material. The orbital injury side is then reproduced by pouring a hard plaster/stone model. The defect has been filled and, therefore, appears in its proposed reconstructed form. Using pressure flasks usually used in the construction of dentures, a layer of 0.5 mm medical-grade titanium is swaged onto the stone/plaster model of the orbital floor, producing an exact replica of the proposed orbital floor and rim contour. The titanium sheet may then be trimmed to allow sufficient overlap and the positioning of a flange to fix the screws. The prosthesis is polished and sterilised for use according to local protocols for titanium implants.

6.5.4 Case report

A 54-year-old man sustained a 'blow out' fracture of the left orbital floor and presented with diplopia (double vision) and restriction of upward gaze. Coronal plane CT scanning demonstrated the fracture (Fig. 6.23). A stereolithography model was constructed which shows the trap door of the fractured orbital floor well (Fig. 6.24). The model was then used for

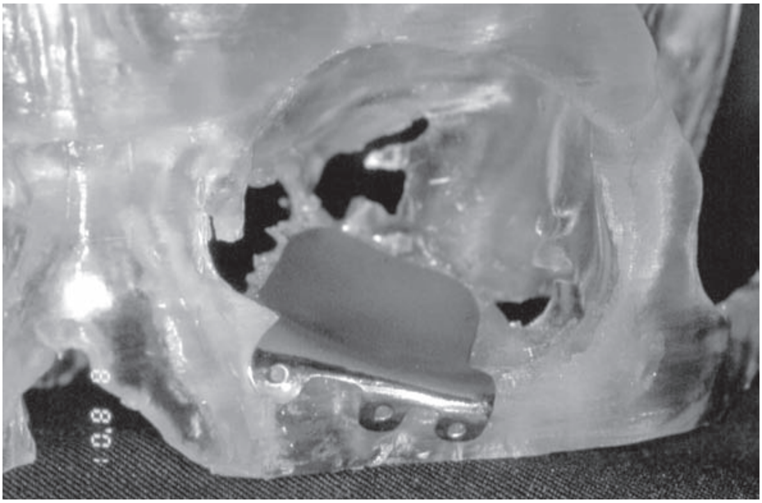


6.23 Coronal CT scan demonstrating classic orbital blow-out fracture.

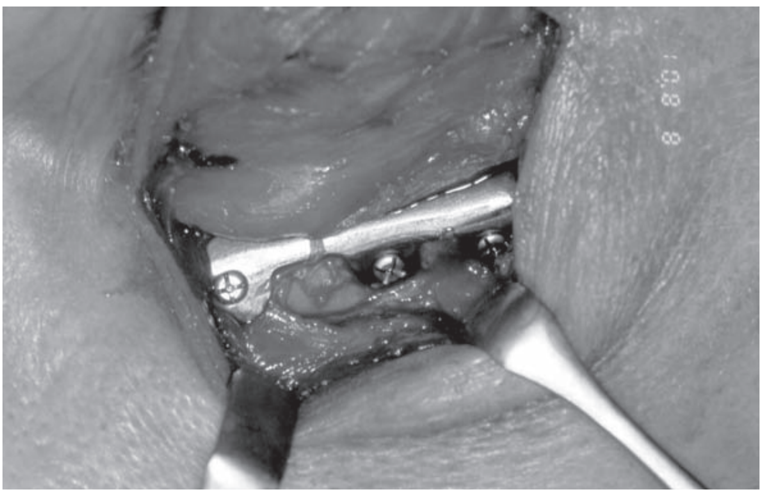


6.24 Stereolithographic model constructed from epoxy resin showing the 'trap door' defect in the left orbital floor, viewed from below as if in the maxillary antrum looking up (lateral margins of the defect indicated with small arrows, under surface of zygomatic arch indicated with single large arrow).

construction of a plaster cast of the orbital defect. A medical-grade titanium prosthesis was constructed from this working cast (Fig. 6.25). The prosthesis was packaged and sterilised by the hospital central sterile supplies department according to standard protocols for titanium medical implants.



6.25 The custom titanium implant is seen on the master model.



6.26 The implant inserted and fixed with 1.3 mm screws – the fit is precise.

The approach to the orbital floor was by a subciliary incision (through the lower eyelid) and the defect was exposed. Herniation and entrapment of the periglobar fat was released and the defect prepared in a standard way (this means that the damaged layer of fat that surrounds the eyeball was repaired and put back in the correct position). The prosthesis fitted perfectly and was stabilised with 1.3 mm titanium screws from a standard plating kit (Fig. 6.26). Forced duction was confirmed as normal (this is a test to check that the eye can rotate upwards freely). Post-operative recovery was uneventful and radiographs revealed the prosthesis to be correctly positioned (Figs. 6.27 and 6.28). At follow-up, complete return to a normal range of ocular movement was found with resolution of the diplopia and no evidence of complications.

6.5.5 Conclusion

We think that this technique has much to offer both for its simplicity and for the reliability of titanium as a prosthetic material. The laboratory

6.27 Plain radiograph in the anterior-posterior plane showing the position of the implant post-operatively.

6.28 Plain radiograph in the lateral plane showing the position of the implant post-operatively.

techniques are simple and readily available in most maxillofacial laboratories. The models require off-site production, but their use is particularly valid in cases where defects may be complicated in three dimensions and where operating time should be reduced to a minimum. The cost of construction of models will drop substantially if numbers increase, and the technique may offer a financially viable alternative to current orbital floor prostheses.

6.5.6 References

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6.6 Surgical applications case study 4: Rapid manufacture of custom fitting surgical guides

6.6.1 Acknowledgements

The work described in this case study was first reported in the reference below.

- Bibb R, Eggbeer D, Bocca A, Sugar A, 2005, 'Rapid design and manufacture of custom fitting stainless steel surgical guides', *Proceedings of the Sixth National Conference on Rapid Design, Prototyping and Manufacture*, pages 65–72, ISBN: 0973778318.

6.6.2 Introduction

Over the last decade rapid prototyping (RP) techniques have been employed widely in maxillofacial surgery. However, this has concentrated on the reproduction of exact physical replicas of patients' skeletal anatomy that surgeons and prosthetists use to help plan reconstructive surgery and prosthetic rehabilitation **(1–12)**.

Developments in this area are moving towards exploiting advanced design and fabrication technologies to design and produce implants, patterns or templates that enable the fabrication of custom fitting prostheses without requiring a model of the anatomy to be made **(13–17)**. However, there is also growing desire from clinicians to conduct more of the surgical planning using three-dimensional computer software. Whilst several approaches have been undertaken in the application of computer-aided surgical planning, the problem of transferring the computer-aided plan from the computer to the operating theatre remains. Two solutions exist to transfer the computer plan to the operating theatre, navigation systems and surgical guides. The use of navigation systems is a specialist field in itself and will not be described here. However, research presented by Poukens, Verdonck and de Cubber in 2005 suggests that navigation and the use of surgical guides are both accurate enough for surgical purposes **(18)**. RP technologies provide a potential method of producing custom fitting surgical guides, depending on the nature of the planning software used. Previous work on the application of RP technologies in the manufacture of surgical guides has concentrated on the production of drilling guides for oral and extra-oral osseointegrated implants **(19–26)**. This case study describes one drilling guide case, but will also report on two cases involving the use of surgical guides for osteotomies (saw cuts through bone), which have not been previously reported.

In order to be appropriate for the manufacture of surgical guides, the RP processes have to be accurate, robust, rigid and able to withstand sterilisation. Due to these requirements, the majority of surgical guides have been produced using stereolithography (SL) and Laser Sintering (LS). SL and LS are described more fully in Sections 5.2 and 5.5, respectively. However, the use of SL in particular has necessitated local reinforcement of the guides using titanium or stainless steel tubes to prevent inadvertent damage from drill bits and the use of low temperature sterilisation methods such formaldehyde or ethylene oxide.

The recent availability of systems capable of directly producing fully dense solid parts in functional metals and alloys has provided an opportunity to develop surgical guides that exploit the advantages of RP whilst addressing the deficiencies of previous SL and LS guides. The ability to produce end use parts in functional materials means that processes such as these may be considered rapid manufacturing (RM) processes. Surgical guides produced directly in hard-wearing, corrosion resistant metals require no local reinforcement, can be autoclaved along with other surgical instruments and are unlikely to be inadvertently damaged during surgery. The use of metals also enables surgical guides to be made much smaller or thinner whilst retaining sufficient rigidity. This benefits surgery as incisions can be made smaller and the surgeon's visibility and access is improved.

6.6.3 Methods

To date three surgical guides have been designed and produced as described here and subsequently used in theatre. The first case was a drilling guide for osseointegrated implants to secure a prosthetic ear. The remaining two cases were for osteotomy cutting guides for the correction of facial deformity. This section describes the general approach to the planning, rapid design and manufacture of surgical guides. The following section describes an individual case where the approach has been successfully employed for an osteotomy.

Step 1: three-dimensional CT scanning

The patients were scanned using three-dimensional computed tomography (CT) to produce three-dimensional computer models of the skull (see Section 2.2). The CT data was exported in DICOM format, which was then imported into medical data transfer software (Mimics, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium, www.materialise.com). This software was used to generate the highest possible quality STL data files of the patient's anatomy using techniques described in Chapter 4. The STL files were then imported into the computer-aided design (CAD) software.

Step 2: Computer-aided surgical planning and design of the surgical guide

The CAD package used in this study (FreeForm®, SensAble Technologies Inc, 15 Constitution Way, Woburn, MA 01801, USA, www.sensable.com) was selected for its capability in the design of complex, arbitrary but well-defined shapes that are required when designing custom appliances and devices that must fit human anatomy. The software has tools analogous to those used in physical sculpting and enables a manner of working that mimics that of the maxillofacial prosthetist working in the laboratory. The software utilises a haptic interface (Phantom® Desktop™ haptic interface; SensAble Technologies Inc.) that incorporates positioning in three-dimensional space and allows rotation and translation in all axes, transferring hand movements into the virtual environment. It also allows the operator to feel the object being worked on in the software. The combination of tools and force feedback sensations mimics working on a physical object and allows shapes to be designed and modified in an arbitrary manner. The software also allows the import of scan data to create reference objects or 'bucks' onto which objects may be designed.

The data of the patients' anatomy was imported into the software. The surgery is then planned and simulated by using the software tools to position prostheses and implants or to cut the skeletal anatomy and move the pieces, as they would be in surgery. When the clinicians were satisfied with the surgical plan the surgical guides were designed to interface with the local anatomy.

In general, the surgical guides were designed by selecting the anatomical surface in the region of the surgery (drilling or osteotomy) and offsetting it to create a structure 1–2 mm thick. The positions of the drilling holes or cuts are then transferred to this piece by repeating the planned surgical procedure through it. Other features may then be added, such as embossed patient names, orientation markers or handles. When the design is completed to the clinicians' satisfaction, the human anatomy data is subtracted from the surgical guide as a Boolean operation. This leaves the surgical guide with the fitting surface as a perfect fit with the anatomical surface. Typically, the curvature and extent of the fitting surface provide accurate location when it is fitted to the patient. The final design is then exported as a high quality STL file for rapid manufacture by Selective Laser Melting (SLM™). SLM™ is described in Section 5.5.3.

Step 3: Rapid manufacture

In order to build surgical guides successfully on the MCP Realizer SLM machine (MCP-HEK GmbH SLM Tech Center Paderbom, Hauptstrasse 35, 33178 Borchen, Germany) adequate supports had to be created using Magics software (Version 9.5, Materialise NV) The purpose of the supports was to provide a firm base for the part to be built onto whilst separating the part from the substrate plate. In addition, the supports conduct heat away from the material as it melts and solidifies during the build process. Inadequate supports result in incomplete parts or heat induced curl, which leads to build failure as the curled part interferes with, or obstructs, the powder recoating mechanism.

Recent developments in support design have resulted in supports that have very small contact points, which has improved the ease with which supports can be removed from parts. However, the parts were all oriented such that the amount of support necessary was minimised and avoided the fitting surface of the guide. This meant that the most important surfaces of the resultant part would not be affected or damaged by the supports or their removal.

The part and its support were 'sliced and hatched' using the SLM™ Realizer software at a layer thickness of 0.050 mm. The material used was

316L stainless steel spherical powder with a maximum particle size of 0.045 mm (particle size range 0.005–0.045 mm) and a mean particle size of approximately 0.025 mm (Sandvik Osprey Ltd, Red Jacket Works, Milland Road, Neath, SA11 1NJ, United Kingdom, www.smt.sandvik.com/osprey). The laser had a maximum scan speed of 300 mm/s and a beam diameter 0.150–0.200 mm.

Step 4: Finishing

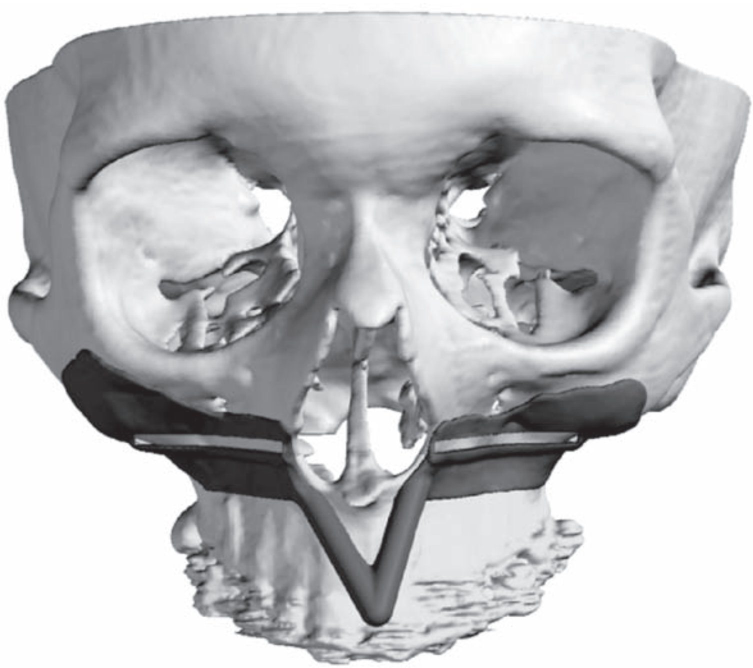
Initially, supporting structures were removed using a Dremel® hand-held power tool (Robert Bosch Tool Corporation, 4915 21st Street, Racine, WI 53406, USA) using a reinforced cutting wheel (Dremel, Reinforced Cutting Disc, Ref. number 426). However, more recently, improved design of the supports has eliminated the need for cutting tools as the supports contact the part at a sharp point that can easily be broken away from it.

The SLM™ parts described here were well formed with little evidence of the stair stepping effect (resulting from the thin layers used) but showed a fine surface roughness. This roughness was easily removed by bead blasting to leave a smooth, matte finish surface. The parts were then sent to the hospital for cleaning and sterilisation by autoclave.

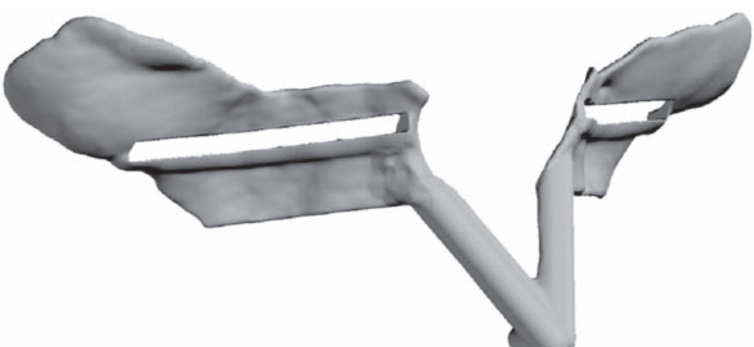
6.6.4 Case study

Although surgical guides have been produced using RP techniques for some years, the application of surgical guides to osteotomies had not been previously attempted. This case was the first attempt at such a guide. The surgery performed in this particular case involved distraction osteogenesis to correct deformity resulting from cleft palate. A description of distraction osteogenesis is given in medical explanatory note 8.2.3. This required a Le Fort 1 osteotomy, which is a cut across the maxilla above the roots of the teeth but under the nose in order to separate and move the upper jaw in relation to the rest of the skull. The maxilla is then gradually moved in relation to the rest of the skull, usually forwards, by mounting it on two devices that use precision screw threads to advance the position by a small increment each day. The small increment causes the bone to grow gradually so that the shape of the face can be altered. When the desired position is reached, the bone is allowed to heal completely to give strong and reshaped skeletal anatomy.

In this case, it was also the intention to include the drilling holes for the distraction devices as well as a slot for the osteotomy. The slot was then made sufficiently wide to allow the saw blade to move freely and to enable sufficient irrigation during the cutting. The lower edge of the slot is made flat and parallel to the direction of the cut in order to provide a reference surface on which the flat saw blade rests. As the cut is in two places on either side of the maxilla, the software design tools are used to join the two parts together into one device, see Figs 6.29 and 6.30. However, it was discovered that at this time there was no way to simulate the bending of the distractor attachment plates using the software. Whilst it was theoretically possible to design and manufacture custom fitting plates and laser weld

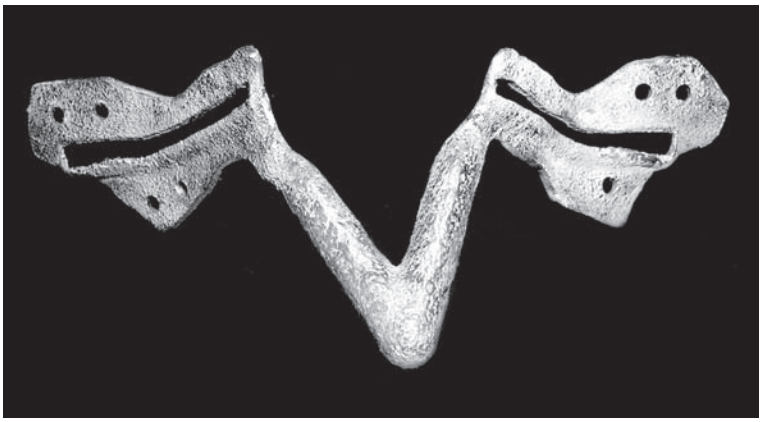


6.29 Patient data and surgical guide design.



6.30 Finished surgical guide design.

6.31 The surgical guide and supports.



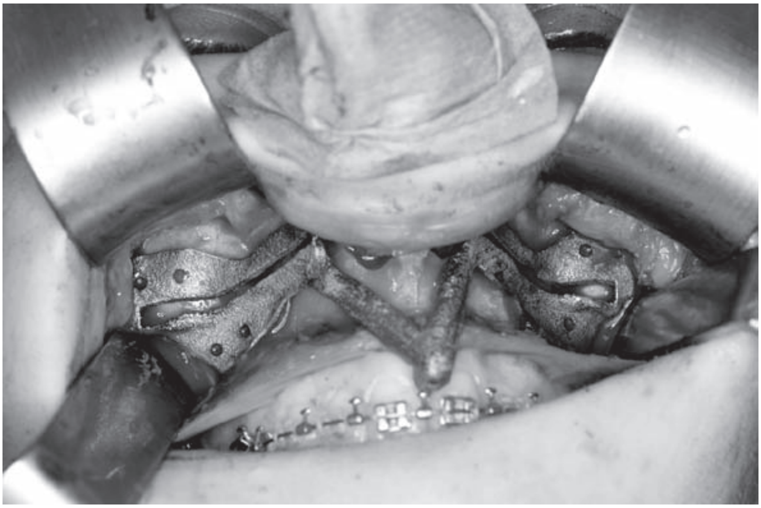
6.32 The finished surgical guide.

them to the distraction devices, the manufacturer of the devices would not allow the modifications.

The guide was 'therefore' finalised, supported and built as described above. The support structure can be seen in Fig. 6.31. The drilling positions for the distraction devices were planned on an SL model of the patient. The SLM™ surgical guide was then fitted to the model and the drilling sites transferred to it. The final guide is shown in Fig. 6.32.

6.6.5 Results

The surgical guides made to date were all assessed by the clinicians before going to surgery and all were deemed satisfactory for surgical use. All of the guides used in theatre so far have displayed good accuracy and fitted the patients' anatomy firmly and securely, as expected. The quality of the surgical guide fit for this particular case was assessed by an experienced maxillofacial prosthetist. This was achieved by fitting it to a SL model of the patient's facial skeletal anatomy where it was found to show excellent fit. Figure 6.33 shows the guide *in situ* in theatre.



6.33 The guide being fitted to the patient during surgery.

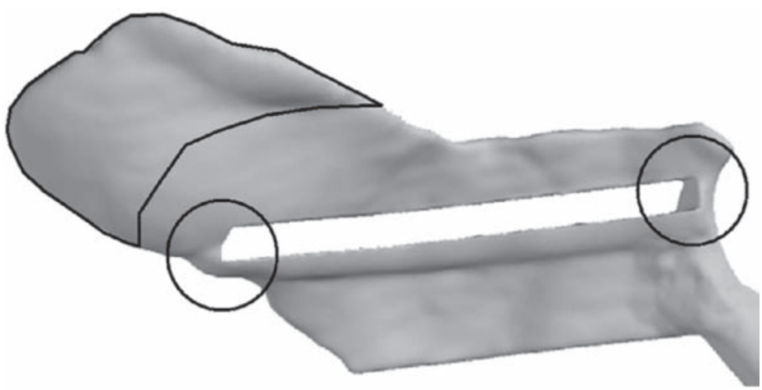
There were no problems experienced with sterilising or using the guides. The guides all resulted in some time saving in theatre, particularly the individual case described here. The surgical outcomes were good and turned out as planned.

6.6.6 Discussion

The surgical guides described here were all deemed successful and contributed to the successful transfer of computer-aided planning to the theatre. The drilling guide was very successful being thinner, more rigid, more hard-wearing and easier to sterilise than previous reported attempts that utilised SLA **(21, 22)**. As can be seen in Fig. 6.34, the incorporation of embossed orientation markers and patient names was also beneficial and could help prevent errors in theatre (the patient name has been deliberately obscured to respect confidentiality).

However, the osteotomy guides proved challenging. There was no previous experience or publications to build on and, given the experimental nature of the two cases undertaken, the results were encouraging. The design of the guides will be significantly better in future cases based on the findings of these cases. The individual case described here illustrates examples of design improvement that resulted from this research. These improvements include the better positioning of handles, smaller extents of the fitting surfaces and avoiding potential weaknesses. For example,

6.34 SLM drilling guide.



6.35 Areas for design improvement.

in the case described here, the thin areas at the ends of the slots proved a potential weakness and the fitting surface was larger than necessary and was reduced by the maxillofacial prosthetist in the laboratory as indicated in Fig. 6.35.

The more fundamental problem of using the approach described here to include the bending and fitting of distractor plates will be addressed in future research by exploring other software applications and techniques.

6.6.7 Conclusions

SLM™ has been shown to be a viable RM method for the direct manufacture of surgical guides for both drilling and cutting. Stainless steel parts produced using the SLM™ process result in surgical guides that are comparable in terms of accuracy, quality of fit and function with previous experience with surgical guides produced using other RP processes yet they display superior rigidity, very good wear resistance and are easy to sterilise.

6.6.8 References

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6.7 Surgical applications case study 5: The use of three-dimensional technology in the multidisciplinary management of facial disproportion

6.7.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of First Numerics Ltd.

- Knox J, Sugar AW, Bibb R, Kau CH, Evans P, Bocca A, Hartles F, 2004 'The use of 3D technology in the multidisciplinary management of facial disproportion' *Proceedings of the 6th International Symposium on Computer Methods in Biomechanics & Biomedical Engineering*, Madrid, Spain, February, (published on CD-ROM by First Numerics Ltd, Cardiff, UK, ISBN: 0954967003).

6.7.2 Introduction

Co-ordinated orthodontic/surgical treatment, which allows the predictable management of dento-facial disproportion, is largely a development of the latter third of the 20th century. Traditionally, the diagnosis, treatment planning and post-operative evaluation of patients requiring such treatment has relied heavily on the use of cephalometric analysis. This has enabled the two-dimensional quantification of dental and skeletal relationships both before and after treatment, with reference to normative data in tabulated or template form **(1, 2, 3)**.

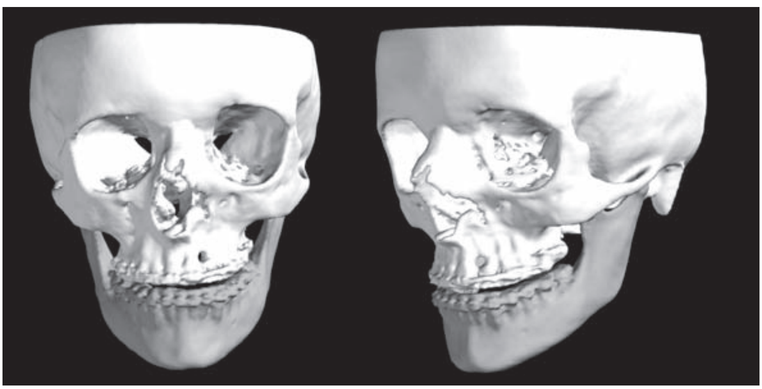
However, the recent development of three-dimensional measuring techniques has allowed a more clinically valid quantification of deformity and assessment of surgical outcomes **(4, 5, 6, 7, 8, 9, 10)**. Computed tomography (CT), magnetic resonance imaging (MRI) and finite element analysis (FEA) have all recently been employed in surgical planning and the visualization of treatment objectives **(11, 12, 13, 14, 15, 16, 17, 18, 19)**. This case study demonstrates the successful use of three-dimensional tomography, surface laser scans and rapid prototyping in the surgical management and post-operative evaluation of a patient presenting with maxillary hypoplasia who underwent surgical maxillary distraction.

6.7.3 Materials and method

Three-dimensional virtual hard tissue images, shown in Fig. 6.36, were constructed using Mimics software (Materialise NV, Technolgielaan 15, 3001 Leuven, Belgium) from 0.5 mm slice CT DICOM data sets. To identify tissue type, upper and lower tissue density thresholds on the CT image were defined and the areas between the slices interpolated to improve resolution. The data was then prepared for medical modelling using stereo-lithography. In addition, STL files were generated so that the same data could be imported into the FreeForm® software (FreeForm, SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA). The preparation of data for file transfer and medical modeling is described in detail in Chapter 4.

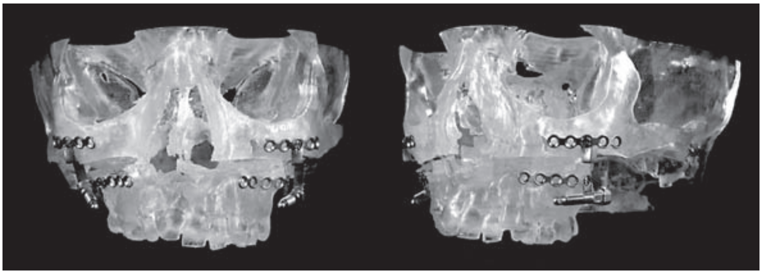
A stereolithography model was then constructed and used to visualize skeletal discrepancy, simulate surgical movements and adapt surgical distractors, as shown in Figs. 6.37 and 6.38. The stereolithography process is described in detail in Section 5.2. The FreeForm® software was used to produce a digital clay model allowing further simulation of surgical movements (see Fig. 6.39).

Three-dimensional facial soft tissue images (see Fig. 6.40) were captured before and after surgery using two high-resolution Konica-Minolta Vivid VI900 3D cameras operating as a stereo-pair (Konica-Minolta Sensing Europe BV, 500 Avebury Boulevard, Milton Keynes, MK9 2BE, UK). The

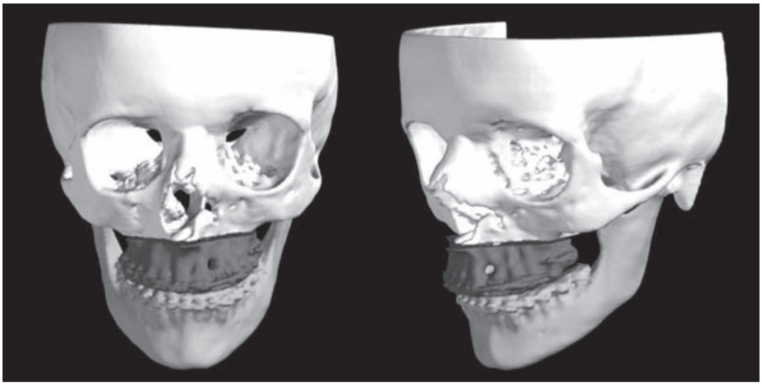


6.36 Virtual hard tissue images.

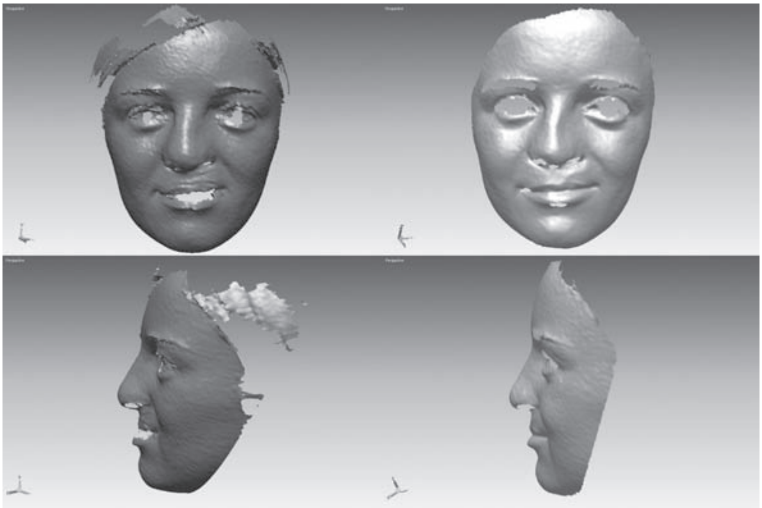
6.37 Stereolithography models.



6.38 Surgical simulation and placement of distractors on stereolithography models.



6.39 Virtual surgical simulations showing maxillary advancement at Le Fort 1 level.



6.40 3D facial images pre-operative (left) and post-operative (right).

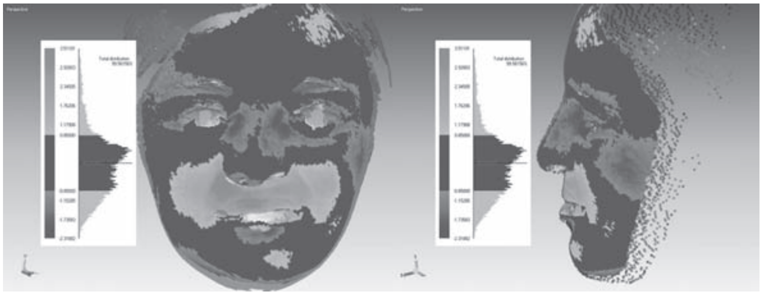
scanners were controlled with Multi-scan software (Cebas Computer GmbH, Lilienthalstrasse 19, 69214 Eppelheim, Germany) and data coordinates were saved in the Minolta Vivid file format (called a .vvd). The scan data was transferred to a reverse modelling software package (Rapidform™ 2004, INUS Technology Inc., SBC, Ludwig-Erhard-Strasse, 30-34, D-65760 Eschborn, Germany) for analysis.

6.7.4 Results

Surgical distraction of the maxilla at Le Fort 1 level was successfully completed (Le Fort 1 is a cut across the maxilla above the roots of the teeth but under the nose in order to separate and move the upper jaw in relation to the rest of the skull). The distractors were activated by 7 mm on right and left sides resulting in an equivalent advancement of the tooth-bearing portion of the maxilla. A description of distraction osteogenesis is given in medical explanatory note 8.2.3. Superimposition of surface scans allowed quantification of soft tissue changes (Fig. 6.41 – see Fig. 6.41 in the colour section). Black areas indicate changes within 0.80 mm or less, which could be attributed to the error of the technique. The blue areas demonstrate negative changes of 0.85–2.30 mm. The red areas demonstrate positive changes of 0.85–3.51 mm.

6.7.5 Discussion

Changes in maxillary prominence and lip relationship can be appreciated by comparison of pre- and post-operative scans in Fig. 6.40. The magnitude



6.41 Merged pre- and post-operative facial scans demonstrating the magnitude of change in soft tissue morphology (see also colour section).

of the soft tissue changes is demonstrated in Fig. 6.41. Here the primary effect of the maxillary distraction at Le Fort 1 level is an advancement of the upper lip and paranasal areas of 1.7–3.5 mm (red areas). The small advancement (pink) demonstrated in the frontal region is an artefact introduced by overlying hair. The small advancement demonstrated in the left chin is probably due to a change in lip relationship and a slight change in facial expression. The blue areas in Fig. 6.41 demonstrate a reduction in lower lip prominence is due to the change in lip relationship caused by the maxillary advancement. The change demonstrated in the sub-mandibular region and upper mid-face is suggested to be due to a reduction in body mass index.

6.7.6 References

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REHABILITATION APPLICATIONS

6.8 Rehabilitation applications case study 1: An investigation of three-dimensional scanning of human body surfaces and its use in the design and manufacture of prostheses

6.8.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of the Council of the Institute of Mechanical Engineers.

- Bibb R, Freeman P, Brown R, Sugar A, Evans P, Bocca A, 2000, 'An investigation of three-dimensional scanning of human body parts and its use in the design and manufacture of prostheses' *Proceeding of the Institute of Mechanical Engineers Part H: Journal of Engineering in Medicine*, **214** (H6), 589–594.

6.8.2 Introduction

Three-dimensional surface scanning, or reverse engineering, has been used in industry for many years as a method of integrating the surfaces of complex forms with computer-generated design data **(1)**. Non-contact scanners operate by using light and camera technology to capture the exact position in space of points on the surface of objects. Computer software is then used to create surfaces from these points. These surfaces can then be analysed in their own right or integrated with computer-aided design (CAD) models. The general principles of non-contact surface scanning are described more fully in Section 2.3. This section includes a description of the potential difficulties that may be encountered when employing the technique and includes suggested methods to overcome them.

The scanner used in the work described in this section was a structured white light system that uses a projected fringe pattern of white light and digital camera technology to capture approximately 140 000 points on the surface of an object (Steinbichler USA, 40 000 Grand River, Suite 101, Novi, MI 48375). Scanners using this type of Moiré fringe pattern have been used in the past in the assessment of spinal deformity **(2)**. In this case, the area to be scanned is distinguished from its surroundings by altering the contrast. For example, a white object may be placed on a dark background and vice versa.

Due to the high accuracy of this type of scanner, nominally accurate to within 0.05 mm, movement of the object was avoided during scanning. Even small movements result in noise and affect the quality of the data captured. In this case, the patient must remain motionless for approximately 40 seconds. Other systems that have been investigated for use in measuring and recording changes in a patient's topography employ multiple cameras and a fast capture time to eliminate the problems associated with motion. However, a smaller number of data points are captured at a slightly lower accuracy **(3)**. Other systems based on scanning have been used to manufacture custom orthotics for podiatric patients **(4, 5)**. At the time of this work, the application of captured surface data in the manufacture of facial prostheses had not been fully investigated.

Whilst prosthetic rehabilitation of the human face offers many potential applications that could exploit this technology, scanning human faces presents particular problems. A primary difficulty is presented by the presence of hair. Hair does not form a coherent surface and the scanner will not pick up data from areas such as the eyebrows and lashes. This problem can be overcome to a certain degree by dusting a fine white powder over the hair. When considering the scanning of faces the area around the eyes may also be particularly difficult. As described above, movement leads to the capture of inaccurate data; to minimise problems caused by blinking during the scan it is more comfortable for the subject to keep their eyes closed. This also alleviates discomfort caused by the bright light emitted by the scanner. If the eye is held open during the scan watering of the eye may cause problems. In addition, the surface of the eyeball is highly reflective making data capture difficult.

Line of sight issues are also encountered when scanning faces. For example, a single scan will not acquire data where the nose casts a shadow. However, this is overcome by taking several overlapping scans as illustrated in Fig. 2.14.

This case study describes how these issues were approached by an investigation into the scanning of human faces and describes the application of these techniques in the manufacture of a facial prosthesis to restore the appearance of a patient recovering from the excision of a rare form of tumour called an olfactory neuroblastoma. Removal of this tumour had necessitated the surgical removal of the patient's left eye.

6.8.3 Methods

Preliminary trial of facial scanning

As a preliminary investigation of the practicality of scanning human faces, a male subject was scanned using the system described above. Initial attempts at scanning the face of the seated subject were poor due to slight involuntary movement of the head despite the subject being seated in a comfortable position. Therefore, additional support was fashioned from a block of polystyrene foam to locate the back of the head and minimise movement. With the subject thus supported in a semi-reclining position, a series of three scans were taken, each from a different viewpoint. Scans were taken from the patient's left side, from directly in front and from the right side. A fourth scan was taken from a central position below the second scan to allow the acquisition of data from the area below the eyebrow ridge. Each scan took approximately 40 seconds, during which the subject remained motionless. The whole process of arranging the subject and taking these four scans took approximately ten minutes.

Once completed, the scans were aligned using the proprietary scanner software. To achieve this alignment, four notable points or landmarks were manually selected in an overlapping area in each of two separate scans. The software then aligns the landmarks and calculates the best fit between the two data sets. Consequent scans were aligned in a similar fashion.

In this experiment, four scans resulted in the capture of accurate data describing the whole face with the exception of areas obscured by hair, such as eyebrows, eyelashes and facial hair. Other areas lacking data not immediately obvious in the figure include areas beyond the line of sight, such as the nostrils. Therefore, it was concluded that the approach could be applied to the scanning of patients provided they could be kept still during the scan.

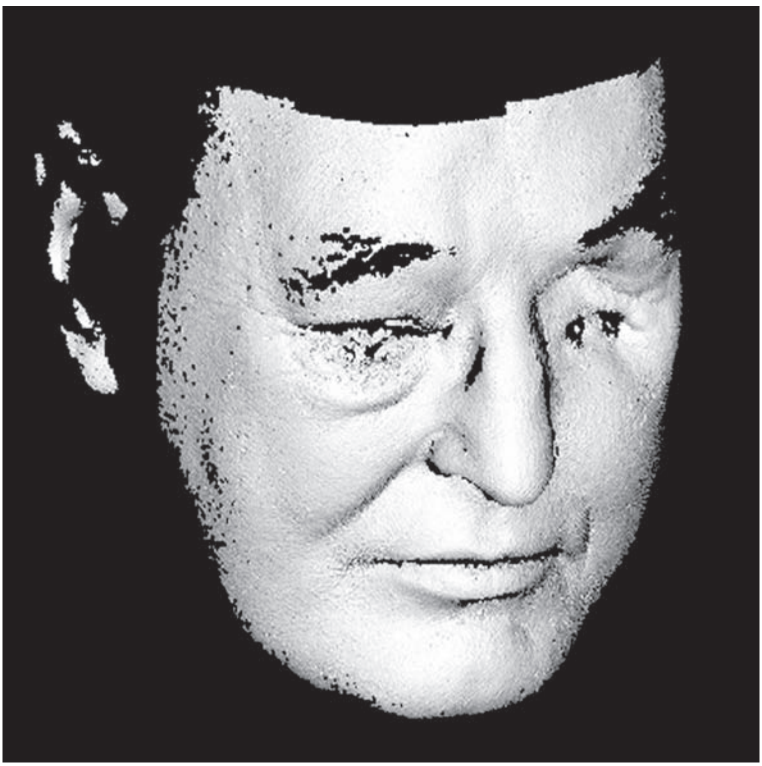
Scanning a surgical subject

In this case, the subject was a patient recovering from reconstructive craniofacial surgery. The surgery required to excise a tumour had necessitated the removal of bone and soft tissue including the left eye. After successful operations to replace the orbital rim, an osseointegrated (bone anchored) prosthetic was planned for the missing eye and surrounding tissue **(6)**. To aid in the construction of this prosthesis, the right (unaffected) side of the patient was scanned and the data used to create a laterally inverted ('mirrored') model that would be used as a guide when creating the prosthesis.

Four scans were taken of the patient's face with the chin supported on a polystyrene block to minimise movement. As the data was intended to aid in the construction of a prosthetic of an open eye, a scan of the open eye was attempted. The scans were taken from angles similar to those described previously; however, care was taken to ensure that the bright light from the scanner did not shine directly into the patient's eye. As before, data was not captured from areas obscured by the eyebrows and lashes. Small unavoidable movements of the eye and eyelids and the reflective nature of the surface of the eye itself affected the accuracy of the captured data. However, as this inaccuracy was extremely small it did not affect the overall quality of the data. The resulting scan data is shown in Fig. 6.42. The whole process of scanning the patient took approximately ten minutes.

The next step required the building of a model of the area around the unaffected eye. To further aid the creation of the prosthesis, the data would be laterally inverted ('mirrored' left to right) before building the model. This model could then be used to guide the production of a prosthetic with good size, fit and aesthetic symmetry.

To create a model from the scan data it was translated into an STL file format **(7)**. This is a triangular faceted surface normally used in rapid



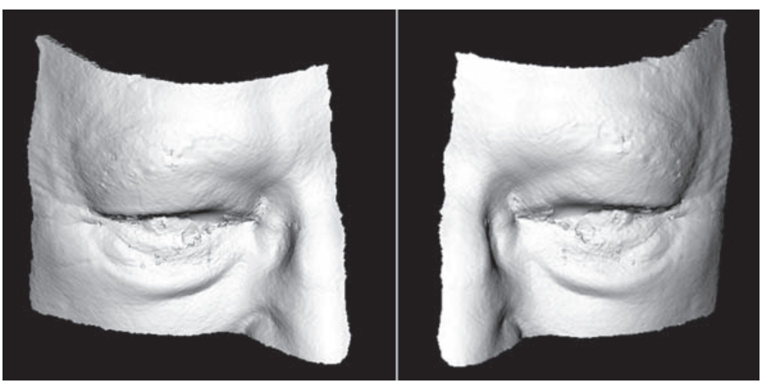
6.42 The aligned scan data.

prototyping systems. The STL file format is more fully described in Section 4.6. However, before the data could be used to produce a model, gaps in the data, such as the area at the eyebrows, were filled. This was achieved by using surface creation software to create a patch that continues the shape of the captured data surface. The patch was created to follow the natural curves of the surrounding data and replicate the surface as well as possible. This required a certain amount of judgement on the part of the operator. However, this case did not present great difficulty in this respect, as the missing areas were relatively small.

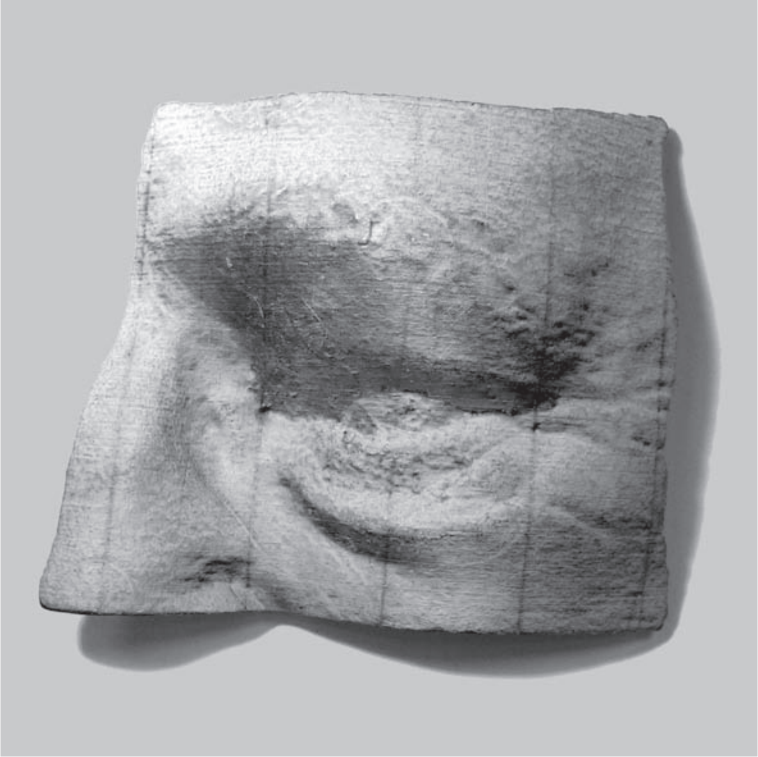
The file size was reduced at this stage by removing unnecessary points. This was achieved without sacrificing accuracy because there were a vast number of points in the captured data coupled with the fact that the accuracy of the scan data is greater than can be achieved by subsequent RP processes. An offset surface was created from the captured data and the gap between them closed to create a finite bound volume. To minimise file size and model cost, only the specific area of interest was selected. The resulting data was stored as an STL file. The STL file size was reduced to 3.6 MB. This was then laterally inverted ('mirrored') as shown in Fig. 6.43. In this case, the process of creating a valid STL file from the scan data took approximately three hours, but this will vary from case to case. The model in this case was produced using Laminated Object Manufacturing (LOM™) – see Section 5.8 **(8)**. The model is shown in Fig. 6.44. The scan data and STL file were archived, in case it is necessary to reproduce the model or for future reference.

Prosthesis manufacture

This case involved the manufacture of an osseointegrated implant retained silicone prosthetic of the left eye (see medical explanatory note 8.2.1 for an



6.43 STL file and 'mirrored' file of the unaffected eye.



6.44 A LOM™ model of the mirrored unaffected eye.

explanation of osseointegrated implants). Previously, two titanium fixtures had been attached to the zygomatic bone (cheekbone) and allowed to integrate to the bone. Six months later, they were exposed and percutaneous titanium abutments attached to them (this means that the abutments passed through the skin to form an anchor for the subsequent prosthesis). The eventual prosthesis would attach to these abutments with magnets. To aid the construction of the prosthesis the LOM™ model was used to cast a wax replica. The prosthetist then removed excess material from the wax until it approximated the required shape. The traditional procedure would have required the prosthetist to carve this piece from wax. This would have taken the prosthetist approximately half a day in this particular case, during which the patient would have been required to sit with the prosthetist for visual reference. Therefore, the use of the model not only saved approximately half a day of work for the prosthetist (from a total of three) but, importantly, also reduced the time required for the patient to attend the clinic.

The aperture for the eye was opened to allow the positioning of the artificial eye. This is considered crucial to the overall success of the prosthesis **(6)**. It was noted that, compared to the traditional methods, the mirrored nature of the model allowed far greater accuracy when locating the artificial eye, especially concerning anterior-posterior positioning. Once the eye position was fixed, the fine details were built up in wax. The areas immediately around the eye were dealt with in particular, as this is where the original scan data, and therefore the LOM model, had lost some detail.

An impression was taken from the patient and used to shape the rear surface of the prosthesis. A small acrylic base plate that would hold the magnets used to locate the prosthesis was also made. When the prosthetist was satisfied with the visual appearance of the fine details and the fit of the prosthesis it was cast in colour-matched silicone in the usual manner.

6.8.4 Results

Accuracy

The accuracy of the scan data is nominally within 0.05 mm. From the data, the theoretical height of the model was 76.76 mm. LOM™ models are nominally accurate to within 0.2 mm. However, when measured, the height of the completed LOM™ model was found to measure 76.7 mm. Therefore, the accuracy of the model can be estimated in the order of ±0.1 mm. As all human faces are somewhat asymmetric and the surface of the skin is pliable, the wax replica was manually manipulated and adjusted to fit the desired area. Therefore, an accuracy of around 0.1 mm is more than adequate for facial prosthesis manufacture. The model also proved to be a good match in terms of reproducing a realistic visual appearance for the prosthesis.

Outcome analysis

The success of this experiment proves the feasibility of three-dimensional scanning of human body surfaces. The ease and relative speed of the scanning allow the complex forms of human features to be permanently captured without hindrance or discomfort to the patient. The accuracy of the data was found more than adequate for prosthesis construction. This method would compare favourably with the current practice of taking impressions, proving to be quicker, more accurate and aiding the reproduction of a realistic visual appearance. In particular, the use of 'mirrored' medical models was felt to be of great help to the prosthetist when positioning artificial eyes in orbital prostheses.

The cost of the scanning equipment is considerable, and it may be difficult for hospitals to justify the initial investment. For this reason, it may prove more feasible for hospitals to use external service providers for the cases where the approach is expected to produce superior results. The cost of the scanning described in this paper would probably amount to several hundred pounds with the LOM™ model costing approximately £120. The costs incurred by this approach should be balanced against the improved results and crucially the time saved over traditional methods. The reduction in time taken allows more patients to be treated, reducing waiting lists (a major goal of the British NHS).

The non-contact nature of the scanning means there is less discomfort for the patient and no distortion of soft tissues caused by the pressure applied when taking impressions. This advantage, in combination with the ability to 'mirror' data, may have many applications in rehabilitation. It is difficult, for example, to take a satisfactory impression of a breast; therefore, a similar technique may be used in the creation of symmetrical prostheses for mastectomy patients. From the results of this case study, it can be concluded that three-dimensional scanning and medical modelling can save a significant amount of time for both the patient and the prosthetist. Lateral inversion and high accuracy can be a significant aid in prosthesis manufacture, especially for large or complex cases. These techniques may be a valuable aid to shaping and positioning the prosthesis, but the skill and knowledge of the clinicians will determine the best method of creating, colour matching and attaching the prosthesis to the patient.

6.8.5 References

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6.9 Rehabilitation applications case study 2: Producing burns therapy conformers using non-contact scanning and rapid prototyping

6.9.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of First Numerics Ltd.

- Bibb R, Bocca A, Hartles F, 2004, 'Producing burns therapy conformers using non-contact scanning and rapid prototyping', *Proceedings of the Sixth International Symposium on Computer Methods in Biomechanics & Biomedical Engineering*, Madrid, Spain, February (Published on CD-ROM by First Numerics Ltd, Cardiff, UK ISBN: 0954967003).

6.9.2 Introduction

This case study describes the use of three-dimensional non-contact scanning, computer-aided design (CAD) software and rapid prototyping (RP) techniques in the production of burns therapy masks, also known as conformers. Such masks are used in the management of hypertrophic scars on the face resulting from burns injuries (see medical explanatory note 8.2.2).

Two case studies were undertaken where non-contact laser scanning techniques were used to capture accurate data of burns patients' faces. The surface data was then manipulated using two different CAD techniques to achieve a reduction in prominence of the scarring. This reduction in height of the scarring on the vacuum-forming mould results in a conforming face-mask that fits the face precisely whilst applying localised pressure to the scars. This pressure on the scars produces the beneficial effect obtained from the use of such masks. Once manipulated to achieve this effect, the data was then used to create vacuum forming moulds via a selection of RP methods.

The effectiveness of the CAD techniques and RP processes for this application are evaluated. The case studies below illustrate the benefits of the approach in comparison to traditional practices whilst indicating operational and technical difficulties that may be encountered. Finally, the cost effectiveness, patient benefits and opportunities for further research are discussed.

Closely fitting masks have been shown to provide a beneficial effect on the reduction of scarring resulting from burns, particularly to the face and neck **(1, 2, 3, 4)**. These masks are typically vacuum-formed from the strong clear plastic material, polyethyleneterephthalate glycol (PETG). Traditionally, the vacuum-forming mould is made from a plaster cast of the patient, which itself is made from an alginate impression. Taking a facial impression is uncomfortable, time consuming for the patient, and it may be particularly disturbing following the physical and psychological trauma of burns.

Published work has indicated that optical scanning and computer-aided manufacturing techniques can be used for various clinical applications **(5, 6, 7)** including the fabrication of burns masks **(8, 9, 10)**. The potential benefit of this approach is the non-contact nature of the data capture, which has been shown to be more accurate, quicker, more comfortable and less distressing for burns patients compared to the traditional impression. The aim of this research was to explore the practical implications of employing such an approach to the treatment of facial burns and to assess various methods of adapting and physically reproducing the data to create a vacuum-forming mould.

6.9.3 Methods

Three-dimensional surface scanning has been used in industry for many years to integrate surfaces of objects with computer-generated designs. Non-contact scanners operate by using structured light or lasers and digital camera technology to capture the exact position in space of a large number of points on the surface of objects. Computer software is then used to create surfaces based on these points. These surfaces can then be analysed or integrated with CAD models. The general principles of non-contact surface scanning are described more fully in Section 2.3.

The optical scanner used in this work uses a laser and digital camera technology to capture the surface of an object (Vivid 900, Konica Minolta Photo Imaging UK Ltd, Rooksley Park, Precedent Drive, Rooksley, Milton Keynes, Buckinghamshire, MK13 8HF, UK). This scanner was selected because the specifications suggested that the accuracy, resolution and range of capture were more than adequate for capturing the human face. It also benefited from ready availability, manufacturer after sales support, comparatively low price and compact size compared to other systems that have been reported, which have been specialised and expensive or locally made prototypes **(9, 10)**.

Although the acquisition time for this type of scanner is only a fraction of a second, movement would still lead to inaccuracy in the captured data. Therefore, the patients remained motionless in a comfortable position during the acquisition. All light-based scanners are limited by line of sight during each acquisition, and this is typically overcome by taking several overlapping scans as illustrated in Fig. 2.14. However, in these cases, a pair of scanners was used to capture both sides of the patient's face. The scanners were positioned low down to ensure data was captured from the areas under the chin and eyebrow ridge **(9)**.

Once the data points are acquired, software is used to create surfaces based on them. The simplest method of creating a surface from point data is polygonisation. Neighbouring data points are joined together to form triangular facets, which form the computerized surface model.

Case study 1

This patient was recovering from burns to the head, neck and arms. Scans were taken as described above, taking approximately five minutes. Eyebrows, eyelashes and blinking affected the accuracy of the data around the eyes but, as the mask is intended to avoid the eyes, this did not present problems.

The point data was then polygonised to create a triangular faceted surface model of the patient's face. This was created in the STL file format (the STL file format is more fully described in Section 4.6), which is commonly used in RP. However, RP requires STL files that represent a single, fully enclosed volume. Therefore, before the data can be used to produce a physical model, gaps in the data have to be filled and the surface needs to be given a thickness to produce a finite bound volume. This was achieved by using CAD software that extruded the perimeter of the captured data surface towards an arbitrary plane to create a solid model as shown in Fig. 6.45 (FreeForm®, SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA). The resulting STL file was thus created in less than five minutes.

In traditional practice, the plaster replica of the patient's face would be ground back in areas of scarring to produce localised pressure on scar sites whilst conforming comfortably to the rest of the face. For this research, the reduction in the height of the scarring was undertaken on the computer before producing the physical RP model. Although software has been reported that has been designed for this purpose, it is not widely available **(9)**. Therefore, this research specifically applied readily available software.

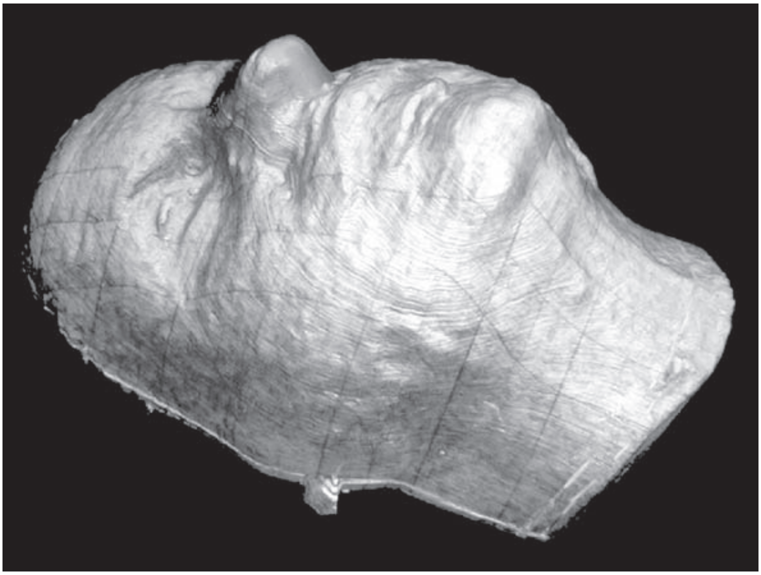
To achieve the desired effect, software that is commonly used to prepare STL files for RP was used (Magics, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium). A 'smoothing' function in this software averages out the STL surface. The effect is to reduce the height of raised features on the surface and produce a simpler, smoother surface. However, the effect is applied to the whole surface of the object.

6.45 Extruded data to form solid computer model.

The second approach utilised CAD software (FreeForm®) that enables the user to conduct virtual sculpture on three-dimensional computer models using a touch-feedback stylus. The software tools mimic those of traditional handcrafting. This makes the software easy to learn and intuitive to use, particularly for prosthetists, and it has been successfully used by the authors in other maxillofacial laboratory applications.

Initially, a smoothing operation was carried out, which produced an effect similar to that obtained using the RP software. Secondly, the smoothing function was used only over areas selected by the user. Finally, a carving tool was used to carve away small areas of scarring locally. The effect is illustrated in an exaggerated manner in Fig. 6.46. In practice, a combination of these functions enabled the prosthetist to rapidly produce a surface that met the needs of the individual case. The data was then cropped so the physical model would form a good vacuum-forming mould. Then Laminated Object Manufacture (LOM™) – see Section 5.8 – was used to produce the vacuum-forming mould shown in Fig. 6.47.

6.46 Smoothing the data (exaggerated for clarity).



6.47 LOM™ vacuum-forming mould.

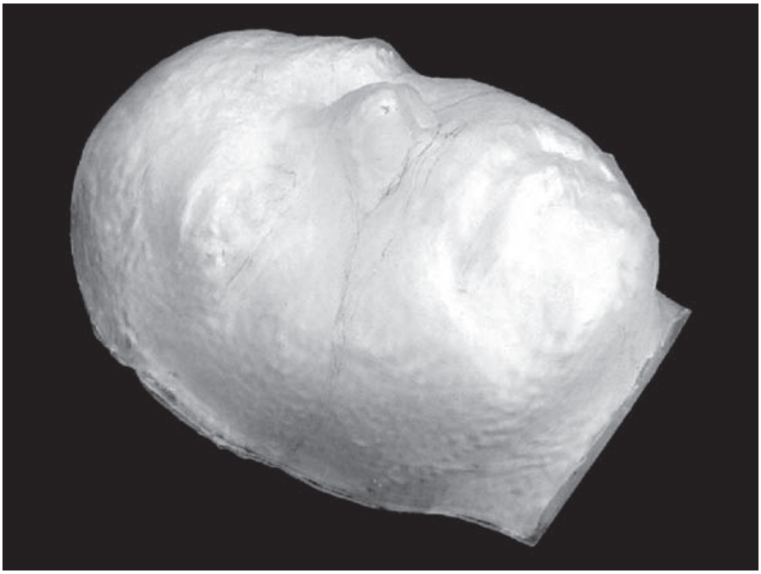
Case study 2

The scan for the second case was carried out as before. In the interests of comparison, a mould was manufactured using stereolithography (SLA®) (3D Systems Inc., 126081 Avenue Hall, Valencia, CA 91355, USA). SL materials and process time are more expensive than LOM™; therefore, to reduce cost, the data was reduced to a thin shell shown in Fig. 6.48. As the glass transition temperature of SL materials may be exceeded during vacuum forming, the shell was filled with plaster as shown in Fig. 6.49. This prevented the SL shell from distorting under the load and heat encountered in vacuum forming.

Experimental moulds

The ThermoJet® (3D Systems Inc.) RP process prints three-dimensional models using a wax material in a layered manner. The layers are very thin, leading to models with excellent surface finish. However, the low melting

6.48 Shelled solid computer model.



6.49 Plaster filled SL mould.

point of the wax precluded its use as a vacuum-forming mould. Instead, reversing the shelling operation used previously resulted in a negative pattern. The intention was to cast a plaster vacuum-forming mould from the wax pattern. However, in practice the pattern was so fragile that it was destroyed during transport to the laboratory.

Other centres have successfully employed Computer Numerically Controlled (CNC) machining in this and similar applications **(8, 9)**. In comparison to RP processes, CNC is a viable option for this application as it is unlikely to encounter undercuts or re-entrant features. To investigate the approach, a trial mould (case 1) was machined from a medium-density board, typically used in industrial model making. Unlike reported techniques that utilise soft foams for ease and speed of machining, this mould proved to be perfectly adequate for direct use as a vacuum-forming mould, requiring no surface treatment or modification **(9)**.

Mask manufacture

The masks were manufactured in the usual manner by vacuum forming sheet PETG over the RP mould. It is common practice to drill holes through moulds to provide even spread of the vacuum. However, holes were not drilled in these cases and the masks were formed perfectly well without them.

6.9.4 Results

Treatment outcome

Both cases responded extremely well to treatment and showed considerable reduction in scarring. The patients' masks fitted well, performed as intended, and proved equally as effective as those produced by traditional methods.

Vacuum moulding

The LOM™ model proved an excellent mould and was unaffected by vacuum forming. The plaster-filled SL mould also proved satisfactory. Both types of mould can be worked with grinding tools should they need to be altered to produce subsequent masks as treatment progresses. However, it was noted that the transparent nature of the SL material combined with the white plaster infill made the surface features difficult to see clearly. The layered surface finish of neither the LOM™ nor SL mould was transferred to the vacuum-formed PETG mask.

Accuracy

The accuracy of the scan data is nominally 0.1 mm. As the skin is somewhat mobile and pliable, the accuracy of the captured data proved to be more than adequate. SL models are typically accurate to within 0.1 mm of the data from which they are built and LOM™ models are nominally accurate to within 0.2 mm. These accuracies proved to be well within the requirements. For this application, relatively inexpensive CNC machines are capable of producing satisfactory moulds.

6.9.5 Discussion

The success of this study illustrates the efficacy of three-dimensional scanning, CAD and RP for this application. The accuracy of the scan data was found more than adequate. The non-contact nature of the scanning imposes less discomfort on patients and eliminates the potential risk of distortion of soft tissues, which may occur when taking impressions. Therefore, the method compares favourably with current practice. In addition, the reduction in anxiety or claustrophobia when taking facial impressions should be seen as an advantage.

Although this research deliberately utilised readily available, manufacturer supported equipment and software, the cost of the scanners, associated software and RP equipment remains considerable, and it may be difficult for hospitals to justify the investment. As with all treatments, the costs must be balanced against the benefits.

6.9.6 Conclusions

As reported by other researchers, the principal benefits observed in this research are increased comfort and speed of the process compared with the traditional impression **(9, 10)**. The scans took no more than a few minutes of the patient's time and presented no discomfort or distress. The time saving also benefits the prosthetist.

The vacuum-forming moulds produced by LOM™ and CNC require no special treatment. The production of the moulds from the scan data presented no inconvenience to the prosthetist and they could be delivered in a matter of days in most circumstances.

6.9.7 References

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6.10 Rehabilitation applications case study 3: An appropriate approach to computer-aided design and manufacture of cranioplasty plates

6.10.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of the Institute of Maxillofacial Prosthetics and Technologists.

- Bibb R, Bocca A, Evans P, 2002, 'An appropriate approach to computer aided design and manufacture of cranioplasty plates', *Journal of Maxillofacial Prosthetics & Technology*, **5** (1), 28–31.

The authors would like to gratefully acknowledge Sarah Orlamuender, Greta Green and James Mason from SensAble Technologies Inc. for their assistance in this project.

6.10.2 Introduction

It has long been recognised in product design and engineering that computer-aided design & manufacture (CAD/CAM) can have significant advantages over traditional techniques, particularly in terms of speed and accuracy. These advantages can be realised at all stages from concept through to mass production.

As these processes have become more widespread in industry attempts have been made to transfer the technology to medical procedures. For example, computer-aided production methods such as rapid prototyping (RP) have been used to build highly accurate anatomical models from medical scan data. These models have proved to be a valuable aid in the production of reconstructive implants such as cranioplasty plates (a cranioplasty plate is an artificial plate that is fitted to the skull to restore the shape of the head and protect the brain). Typically, RP is used to create accurate models of internal skeletal structures, such as skull defects **(1)**. The cranioplasty plate is then handcrafted in wax on the model by the prosthetist **(2, 3, 4)**. Alternatively, the anatomical model can be used to create moulds or formers **(5)**. Although this process has dramatically improved the accuracy of cranioplasty plate manufacture, it incurs significant time and cost to produce the anatomical model. This current route does not fully exploit the potential advantages of an integrated and optimised CAD/CAM process. The major impediment to the application of CAD in prosthetics design is the fact that it requires the integration of existing anatomical forms with the creation of complex, naturally occurring, freeform shapes. Until recently, CAD has been driven and developed specifically to define geometry for engineering processes and consequently the way they operate makes it extremely difficult to integrate human anatomy and create similar forms. In addition, the methods used to define shapes in CAD are based almost entirely on simple mathematical geometry (straight lines, angles, arcs, etc.). Although efforts have been made to investigate the use of CAD in cranioplasty plate design, they have proved time consuming and only served to highlight these limitations **(6)**.

In contrast to engineers, prosthetists have highly developed visual and tactile skills that allow them to handle materials to create accurate freeform shapes. Consequently, there exists a significant barrier to the application of current engineering-based CAD software by experienced prosthetists.

Recent developments in both hardware and software have enabled people with traditional visual and tactile sculpting skills to be able to exploit the potential advantages of CAD. The hardware consists of a three-dimensional stylus developed from research carried out at Massachusetts Institute of Technology. The device gives all six axes of movement via a hand-held stylus, similar to a pen or sculpting tool. Crucially this device not only has six axes of freedom but also incorporates tactile-feedback **(7)**. Thus, when moving the cursor on screen in three dimensions, when the cursor comes to the surface of an object on screen the user feels the contact through the stylus. The resistance can be varied to simulate materials of different hardness and consistency.

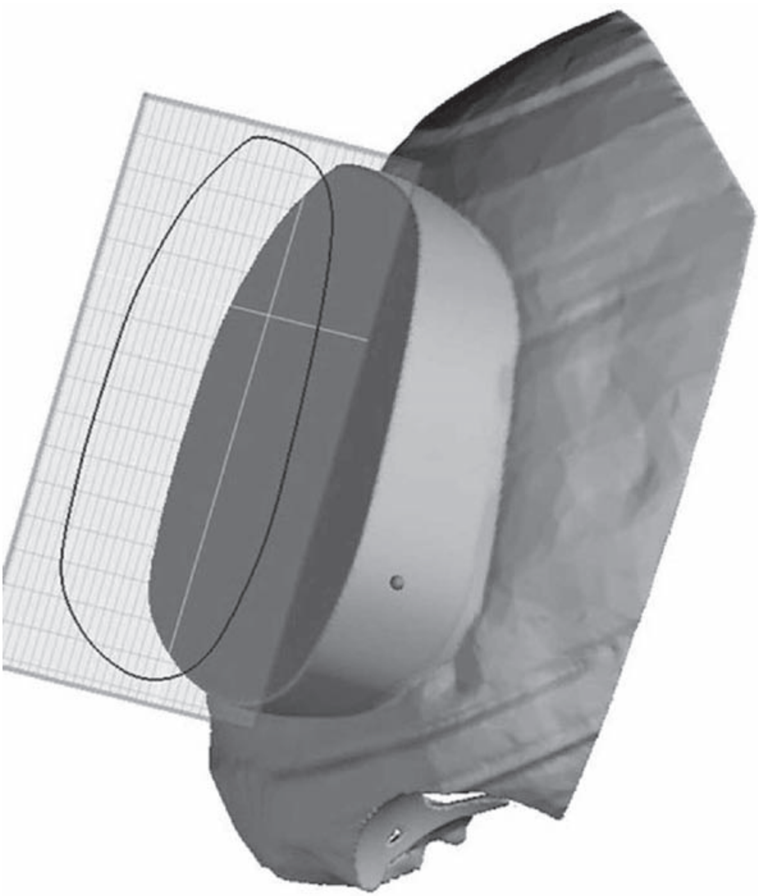
Three-dimensional software, called FreeForm® (SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA), has been developed in tandem with the tactile-feedback stylus. Unlike traditional engineering-based CAD systems, this software has been developed to visualise and manipulate solid, complex, unconstrained three-dimensional shapes and forms. The system utilises a solid three-dimensional voxel representation. In essence, solid objects are made up of thousands of tiny cubes. The user can then free-form these shapes with the stylus. The effect is very much like sculpting clay in a digital environment. The software can impose tools onto the stylus that correspond to traditional sculpting tools. Material can be ground away, drilled, stretched, pushed or added in a manner analogous to sculpting with clay.

Once objects are shaped, they can be integrated into other CAD packages or used directly with computer-controlled prototyping or manufacturing processes. Therefore, the ability to combine the existing visual and dextrous manual skills of the prosthetist with the advantages of CAD/CAM becomes a practical proposition.

6.10.3 An initial case study

To investigate this application, an actual case requiring a cranioplasty plate was attempted. This involved importing a three-dimensional model of the cranial defect. This data was derived from a three-dimensional computed tomography (CT) scan and imported into the software as a 'buck'. This means that the user can feel the surface of the skull but not alter it with any subsequent tools. The next step was to create a piece of 'virtual clay' that could then be worked into the correct shape. In prosthetics terms, it may be more appropriate to refer to this as virtual or digital wax up.

First, a sketch plane is positioned by eye over the defect and a two-dimensional perimeter drawn around it. The planes are then offset either side of the defect and the perimeters joined to form a three-dimensional piece of digital wax approximately the right size, as shown in Fig. 6.50. Material removal tools were then used to 'grind' away material. The tools used are similes of physical sculpting tools such as scrapers, grinding wheels, etc. However, the size and shape of the tools can be arbitrarily altered to suit the job in hand. A wide 'grinding' tool was used to work the surface



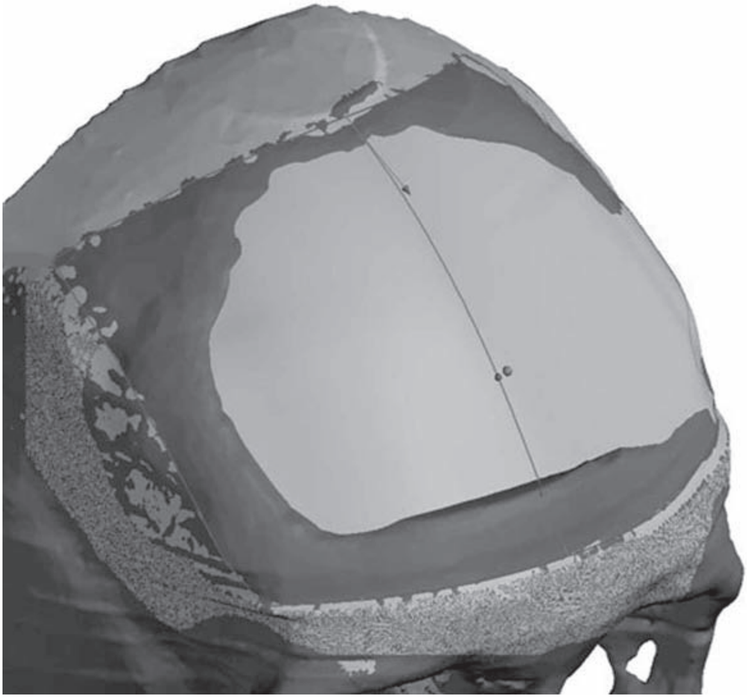
6.50 Extrusion of working material.

back as shown in Fig. 6.51. In addition, the simulated physical properties of the virtual clay can be altered to represent differing hardness and tack strength. When using the system, the user can feel tactile resistance when removing material, and when they reach the surface of the skull resistance is total. Therefore, the approach is a digital equivalent of waxing up on a medical model.

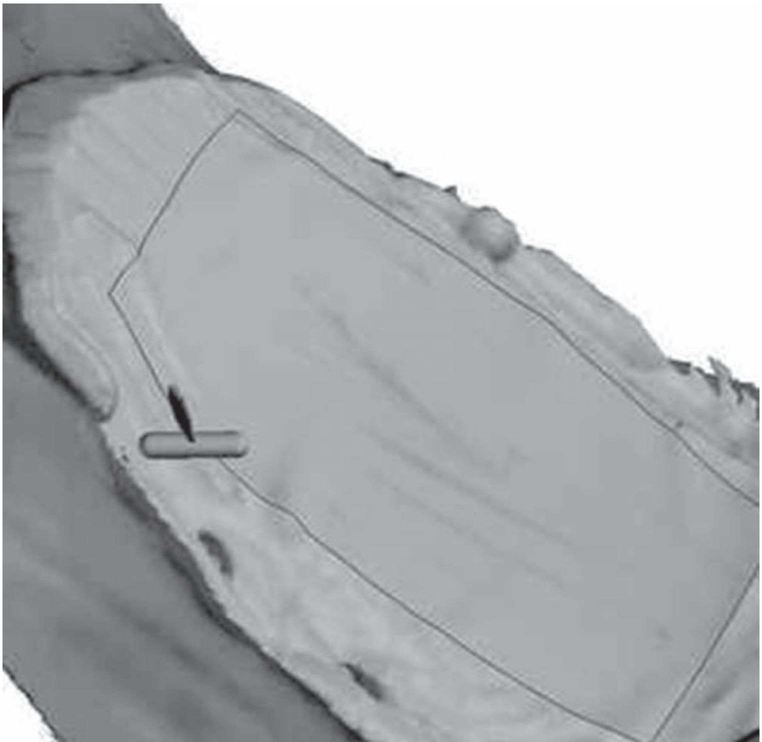
However, operating in the digital domain enables some useful techniques to be exploited. In this case, control curves were created on the surface of the plate. These curves can then be moved using control points on the surface or tangents to the surface. A single control curve applied to the sagittal plane is shown in Fig. 6.52. Many control curves can be added in various planes to achieve a very smooth and well-defined natural curvature that matches the surrounding tissue. In addition, whole areas can be selected by painting on the model with the stylus. Then various operations can be performed on the entire selected area in a single operation. For example, the area could be pulled out to create a bulge or pushed in to create a depression.

The material removal and smoothing process was then repeated for the inner surface illustrated in Fig. 6.53. Then the buck (skull) is subtracted

6.51 Working the material back.



6.52 Controlling curvature.



6.53 Working back the inner surface.

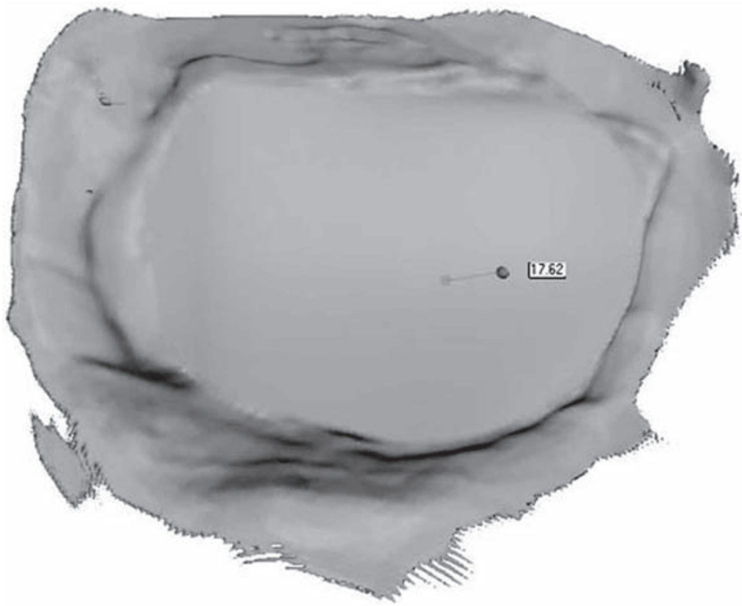
from the wax to leave a freeform shape that would repair the defect as shown in Fig. 6.54. To allow the implant to be inserted from the outside of the skull, the inner edges of the plate were worked back as shown in Fig. 6.55. The final shape can then be accurately fabricated using RP techniques. This can then be used as a pattern from which an implant can be made using an appropriate material.

In this case, a highly accurate stereolithography model was made of both the implant and the defect to test the design for fit and accuracy, see Figs. 6.56 and 6.57. In this case, the fit was excellent and comparable to the results achieved when using stereolithography models and traditional wax up methods. The stereolithography resin used is approved for patient contact under theatre conditions, which will allow the plate to be test fitted to the actual defect at the time of surgery. However, the material is not approved for implantation and so the actual implant used will be cast from the stereolithography master into an approved acrylate.

6.10.4 A second case study

This case followed similar techniques to the initial case yet proved more challenging due to the complex nature of the implant required. The added complexity further illustrated the potential benefits of utilising this approach.

6.54 The result of the Boolean subtraction.

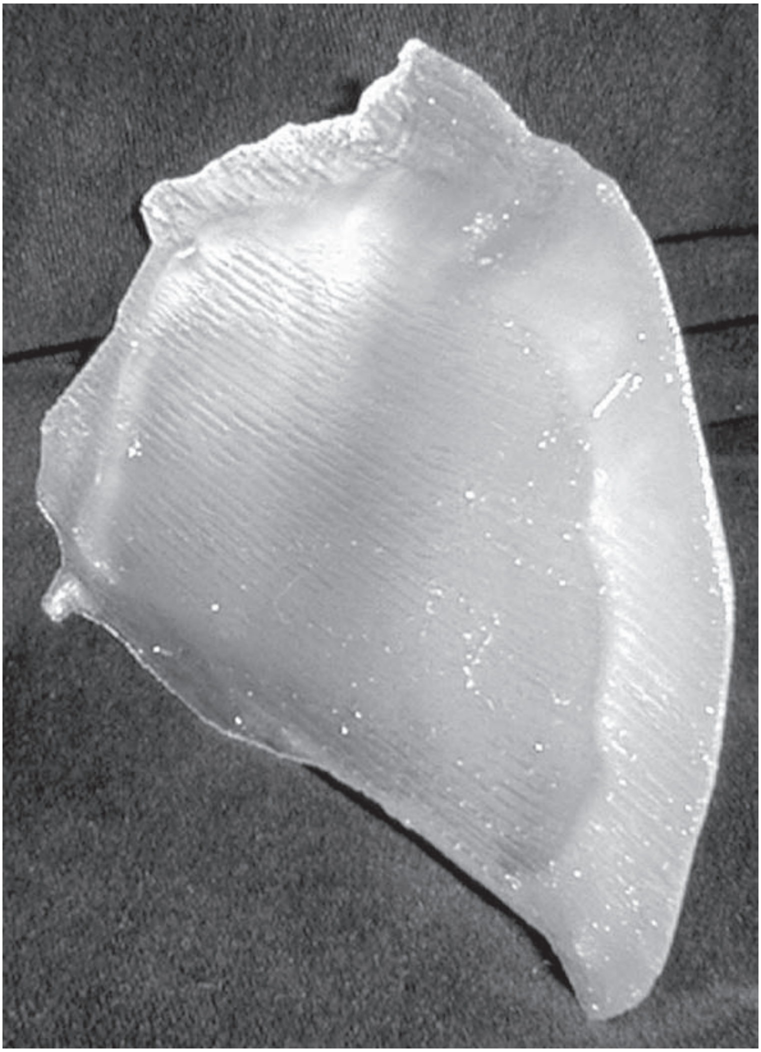


6.55 The final design.

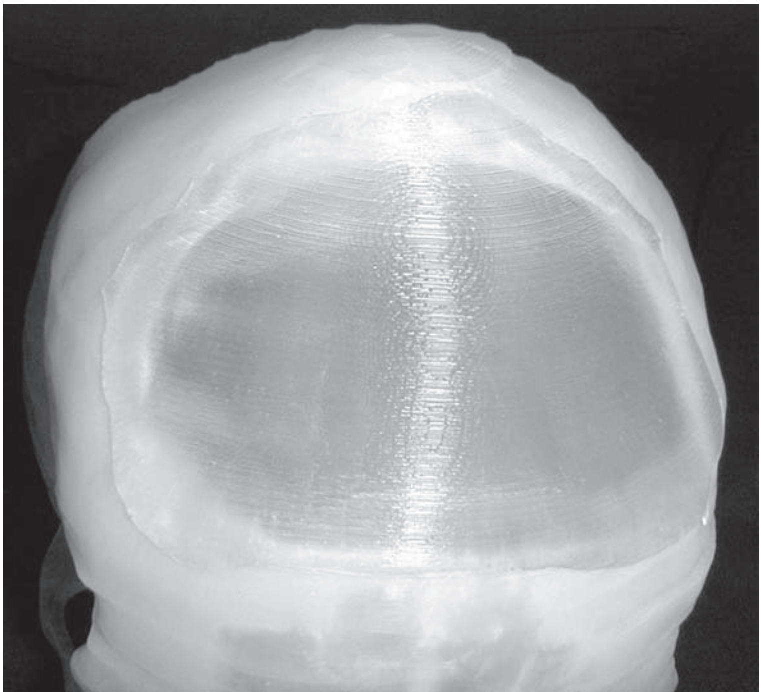
The unaffected side of the patient's skull was copied and laterally inverted to provide a base part from which a well-matched implant could be designed (Fig. 6.58). As in all cases attempted in this manner thus far, the laterally inverted copy does not precisely fit the defect; however, the FreeForm® software enables the form to be modified and adapted to produce a prosthetic design that shows good aesthetic appearance and a precise fit at the margins. The software also enabled the implant design to be produced in a very smooth manner, which will prove suitable for a double processed and polished acrylic implant. As in the previous case, the implant design was manufactured using stereolithography and test fitted to an existing model of the patient defect, as shown in Fig. 6.59.

6.10.5 Future development and benefits

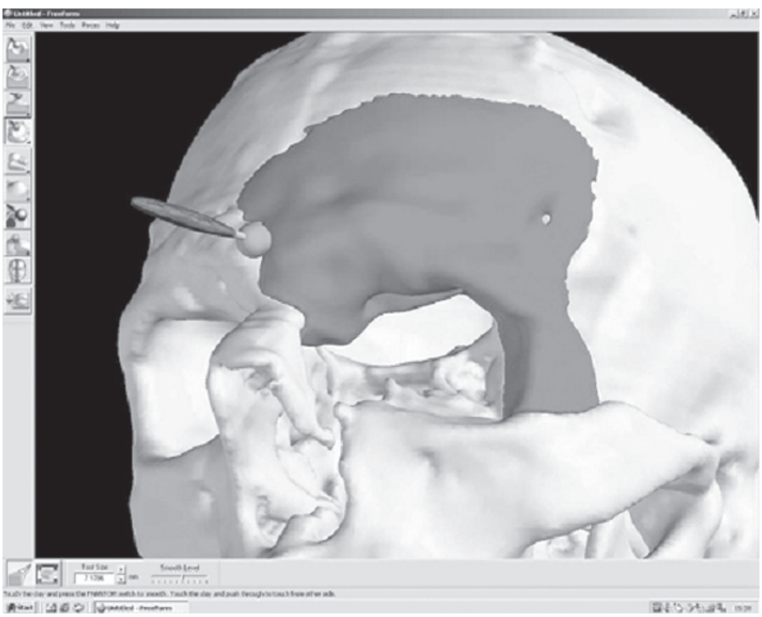
This experiment has proved only that it is feasible to use CAD techniques to design and fabricate implants such as cranioplasty plates. However, the benefits are already apparent. The advantage is that no material is used or wasted in the design and development of the implant. Only when the design is finalised is the implant fabricated. The computer-controlled fabrication methods can be made to compensate automatically for manufacturing characteristics such as shrinkage in the mould. The use of digital media



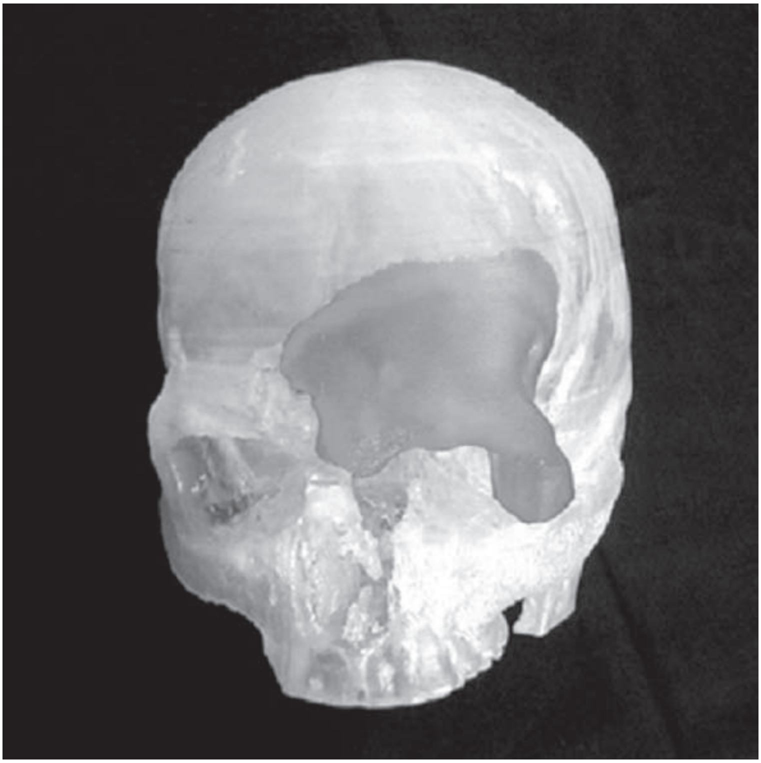
6.56 The SLA model of the plate.



6.57 Checking fit on SLA model of defect.



6.58 Designing a complex implant.



6.59 SLA implant on SLA model of defect.

enables everything to be archived on disk instead of models and casts that require extensive storage space and may suffer damage or degradation over time. The process as a whole is clean and requires minimal floor space, equipment and consumables. The utilisation of the prosthetists' time and skills can be maximised. This combination of advantages could lead to significant improvements in treatment times and cost effectiveness.

The final element in this process will be realised when directly implantable or tissue engineered materials are developed for use with computer-controlled manufacturing using processes such as stereolithography or Envision Technologies Bioplotter (EnvisionTEC GmbH, Elbestrasse 10, D-45768 Marl, Germany). When this is possible, the combination of the prosthetists' skill, the freeform CAD and direct build machine would effectively replace the laboratory. This will reduce the design and fabrication time of typical implants to a matter of hours or even minutes. Although this stage is some years away, the developments will be made and the prosthetics industry will be reaping the advantages currently being enjoyed in product development. An estimate of potential cost and time saving is indicated in Table 6.1.

Table 6.1 Comparison of current technique and potential future technique

Current technique			Future technique		
Three-dimensional CT scan			Three-dimensional CT scan		
Send data to RP service provider	1 day	£5	Derive three-dimensional CAD data	5 minutes	Minimal
Derive three-dimensional CAD data from CT data	5 minutes	Minimal	Import into FreeForm	5 minutes	Minimal
Derive RP files from CAD data	1 hour	£22	Design implant	1 hour	£22
Build RP model of anatomy	1 day	£1000	Direct manufacture of implant	2 hours	£200
Post model to prosthetist	1 day	£18	Sterilise for surgery		
Prosthetist wax up on model					
Create plaster mould	1 day	£250			
Cast implant					
Sterilise for surgery					
Total	4 days	£1295	Total	3 hours	£222

In the near future, this work will continue to develop into the area of external (wearable) facial prosthetics. Non-invasive light-based optical scanning of faces has shown promise in the area but so far been of limited success due to the difficulties in handling point cloud data and converting it quickly and simply into a useable format **(8)**. It is planned that work in facial prosthetics using the proposed approach will follow directly as a natural progression of this study.

6.10.6 References

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6.11 Rehabilitation applications case study 4: The appropriate application of computer-aided design and manufacture techniques in silicone facial prosthetics

6.11.1 Acknowledgements

The work described in this case study was first reported in the references below and is reproduced here in part or in full with the permission of the Council of the Institute of Mechanical Engineers and the Institute of Maxillofacial Prosthetists & Technologists.

- Eggbeer D, Evans P, Bibb R, 2004, 'The appropriate application of computer aided design and manufacture techniques in silicone facial prosthetics', Bocking C E, Rennie A E W, Jacobson D M (eds), *Proceedings of the 5th National Conference on Rapid Design, Prototyping and Manufacture*, 45–52, London, UK, John Wiley and Sons, ISBN: 1860584659.
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6.11.2 Introduction

The design and development of maxillofacial, silicone prostheses is a highly skilled, traditionally craft-based process that seeks to provide patients with an aesthetically pleasing, well-fitted product to camouflage missing tissue. The labour intensive nature of the development process means it can take several days, leading to significant staff costs and considerable patient inconvenience. Thus, an opportunity exists to develop time saving and more efficient methods by exploiting computer-aided design and rapid prototyping (CAD/RP) technologies commonly used in product design and development. Such techniques have been used to produce accurate, physical bone models helping to realise time, cost and accuracy benefits in maxillofacial surgery **(1, 2)**, yet relatively little research has been undertaken in the application of such technologies in soft tissue cases and they remain underdeveloped in clinical use.

Recently, surface anatomy has been captured using methods such as laser, structured white light and computed tomography (CT) scanning, and the data used to digitally plan, design and manufacture prostheses patterns and moulds **(3, 4, 5, 5, 7, 8)**. Whilst these techniques make use of some CAD and RP technologies, more sophisticated prosthesis design has been restricted due to software limitations in representing and modifying complex anatomical forms and its reliance on primarily geometrically defined shapes.

The research reported here aims to bring the time and labour saving benefits that CAD and RP technology have shown in product design and other areas of maxillofacial surgery and apply them to the design of facial, soft tissue prostheses, whilst complementing the needs and existing skills of maxillofacial prosthetists. The FreeForm® Modeling Plus™ CAD package (SenAble Technologies Inc., 15 Constitution Way, Woburn MA, USA) used in this research has tools analogous to handcrafting and offers prosthetists the ability to readily adapt their existing skills and design with more freedom than typical engineering CAD packages. Some medical applications of the software have already been explored, for example in the design of cranioplasty plate patterns **(9)**.

The research will be illustrated though a case study involving the design of a prosthesis required in the rehabilitation of a patient with an ocular defect (the patient had their left eye removed following cancer treatment). The case study also describes the rationale used to select the most appropriate RP process and how the design was manufactured using a wax material that was incorporated into the prosthetist's existing clinical practice.

6.11.3 Materials and methods

Data acquisition

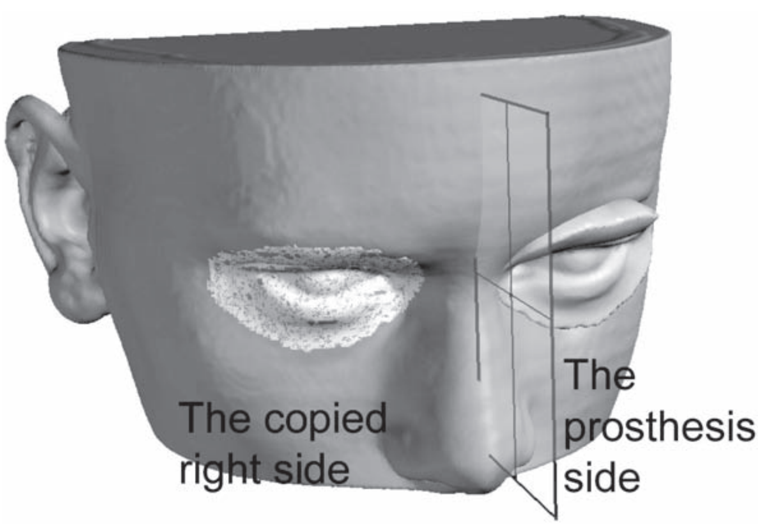
Data from a recent CT scan was imported into Mimics (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium) and the threshold value set to select soft tissue. Extents covering the mid-face were segmented and converted into a high quality STL file that was suitable for importing into FreeForm®. This retained as much detail as possible but, due to the relatively low resolution of CT data, fine detail such as wrinkles and dimples were not visible.

FreeForm® modelling

Within FreeForm®, shapes may be designed and modified arbitrarily by the user with tools analogous to those used in handcrafting. Although the software does not rely as heavily on mathematically defined and constrained geometry as engineering CAD, accurately definable sculpting tools and measuring techniques ensure precision. The computer model of the object being worked is referred to as 'clay' by the software, but may be thought of as a digital version of the wax commonly used when designing a prosthesis pattern. The clay may be handled in a similar way as the physical methods employed in handcrafting. Roughly defined shapes are gradually refined in order to produce the higher levels of detail required in the finishing stages. Shapes can be viewed from any angle, clay added to the model and measurements in any direction established in precise ways. A protective 'mask' or 'buck' setting may also be used to protect a model from inadvertent carving. The user interface with the software is provided by a stylus (PHANTOM® Desktop™ haptic interface, SensAble Technologies Inc.) that incorporates positioning in three-dimensional space and allows rotation in all axes. In essence, the stylus translates hand movement to the virtual sculpting environment. Force feedback sensations (for example, when the virtual tool contacts the model) in relation to the tool position within the sculpting environment are fed through to the user with the result closely mimicking the tactile sensations of handcrafting.

Creation of the basic form

The STL file generated by Mimics was imported into FreeForm® as a protected buck model that could not be accidentally carved. The patient's defect was on their left side, so an area based on the required extents surrounding the unaffected right orbit was first selected. The selected clay was copied and then recreated as a separate model that could be worked on independently from the facial buck model. Fig. 6.60 shows the copied piece being mirrored around the mid-sagittal plane (midline of the body) to form the basis of the prosthesis pattern design. The original right side copied piece was then deleted, leaving the anatomy buck model and prosthesis pattern clay.

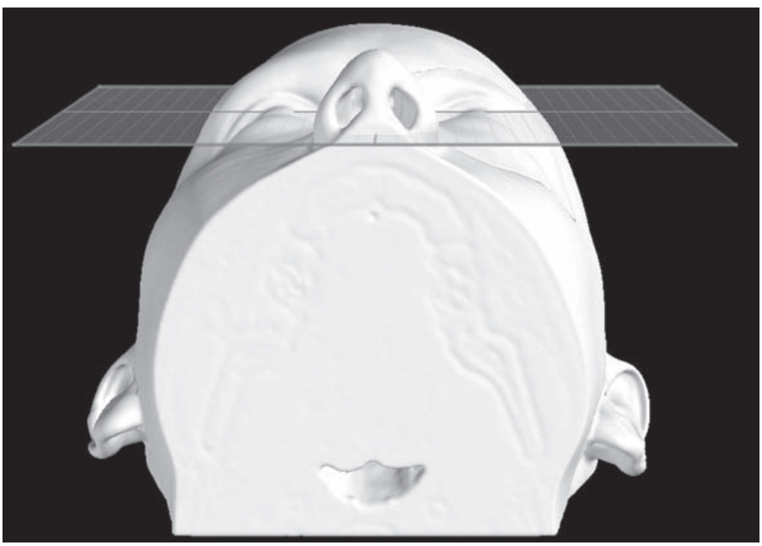


6.60 Mirroring the selected, unaffected area to the affected side.

Establishing the correct depth and location of the eyeball is considered one of the most difficult processes in ocular prostheses design and is vital to achieving a realistic result **(10)**. The tools available within FreeForm® made this significantly simpler and more accurate since the work could be viewed from angles that would be impossible in a clinic situation (Fig. 6.61). The prosthesis was positioned using planes in the three-dimensional environment as guides to locate key anatomical features, such as pupil depth (Fig. 6.61) in relation to each other. Once the pattern was correctly located, discrepancies in the fit between the anatomy and prosthesis became apparent. This was due to significant facial asymmetry caused by reduced growth following radiotherapy treatment on the patient's left orbit.

Design

In order to compensate for the poor fit surrounding the prosthesis pattern, clay was built up until it overlapped fully with the un-editable buck anatomy. It was then combined into the anatomy for shaping and blending to create a seamless edge. A protective mask was 'painted' on to the prosthesis clay where the features were required to match the unaffected side, then 'carve', 'smooth', 'tug' and 'smudge' tools were used to manipulate the clay and feather the fitting edges to the surrounding anatomical contours, recreating a natural appearance. Figure 6.62 shows the aesthetically pleasing result that took less than an hour to achieve.



6.61 Positioning the prosthesis using a guide plane.

6.62 The blended in prosthesis.

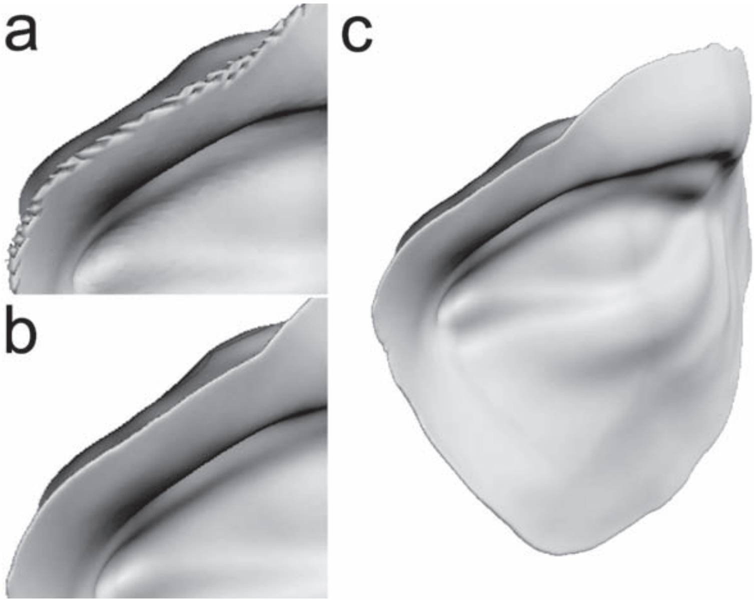
Finishing

The anatomical buck model was then removed, acting as a Boolean cutting tool to leave just the prosthesis pattern. Unwanted clay was also removed from behind the eye with the 'paint on mask' tool used to protect important visible detail from accidental carving.

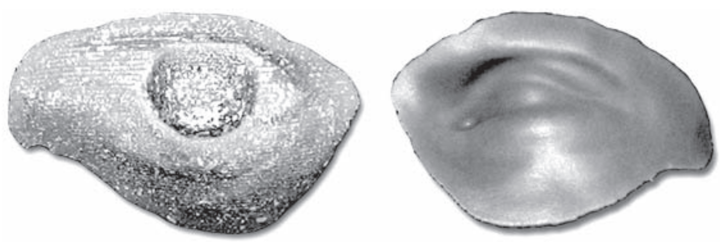
Up until this point, the clay was defined relatively coarsely in order to minimise the use of computer memory. The clay was refined, which had the effect of smoothing edges and refining detail, but also increased the file size. The results can be seen in Figs. 6.63(a–c). The prosthesis pattern was then exported as an STL file for preparation and building.

Manufacture

The pattern was produced using a ThermoJet® printer in the 'TJ88' grade material, (3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA). This process selectively deposits wax layer-by-layer, building the part on a scaffold of supports, and is capable of building thin edges and fine detail. The down-facing surfaces are rougher due to the support structure that attaches the objects to the build platform. The difference between up- and down-facing surfaces is shown in Fig. 6.64. Given that the fitting surface of the prosthesis was likely to require modification, it was decided to orientate it downwards using the preparation software. The entire preparation took approximately 15 minutes.



6.63 The rough (a) and refined edges (b) and the final pattern (c).



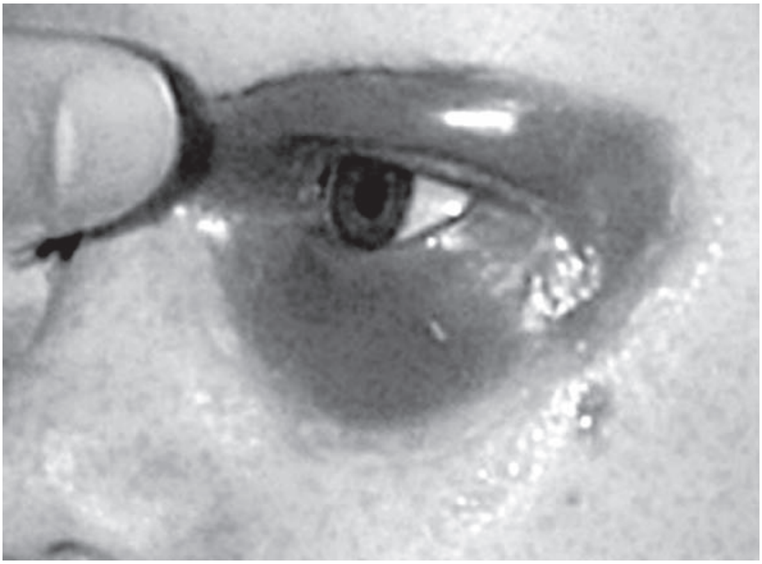
6.64 The down-facing surface on the left, and up-facing on the right.

The ThermoJet® machine took approximately two and a half hours to manufacture one pattern that would cost around £35. Once completed, the pattern was allowed to cool to room temperature before the supports were removed using a scalpel. Great care was taken not to damage the pattern whilst removing the supports, which took around 15 minutes.

Fabrication of the silicone prosthesis

The wax pattern's fitting surface was smoothed by warming it briefly and lightly using a small flame torch. The pattern was then checked for fit on the patient (Fig. 6.65) and the final margins determined. The fit was

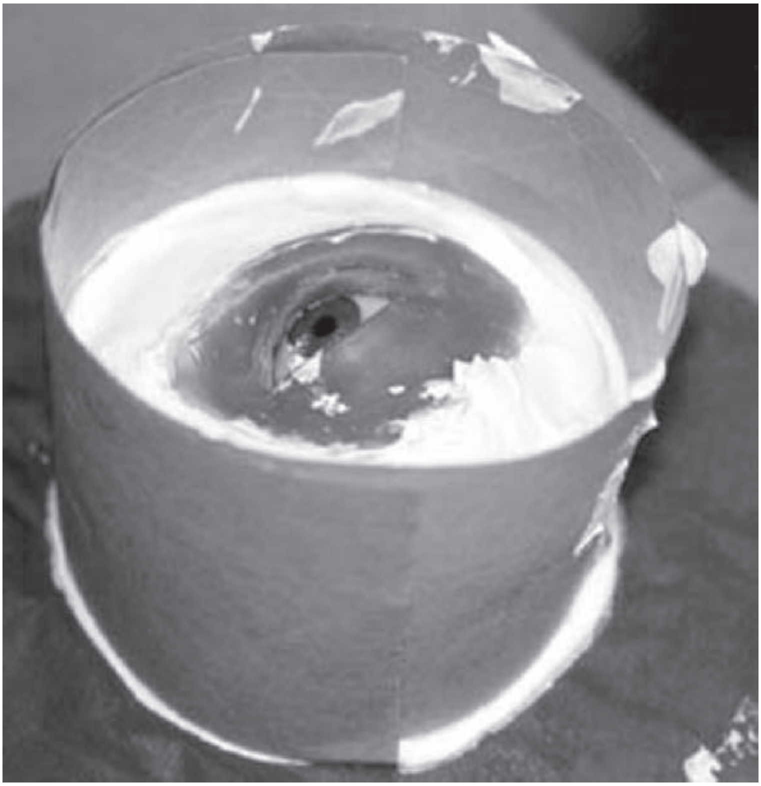
6.65 Checking the pattern fit.



6.66 Final impression taking.

excellent, but it was decided that the patient's natural eyebrows should be visible, so the wax was reduced in that area.

Wax between the eyelids was removed to accommodate the acrylic eye unit and then the fitting surface was smoothed before being coated with a thin layer of impression material. The pattern was then re-located in the orbit to obtain the final fitting surface impression (Fig. 6.66). Finally, the edges were contoured into the surrounding tissue using pink dental wax. A flask-less, two-part plaster mould was created around the wax pattern (Fig. 6.67). The wax pattern was then boiled out.



6.67 The flask-less mould formed around the pattern.

The final prosthesis was completed in silicone, as has become the most commonly used clinical technique **(10)**. The mould surface was first painted with silicone colour matched to the patient's skin (Fig. 6.68) and then packed out to form the body of the prosthesis. The mould was then clamped closed and the silicone cured. Once the main body of the prosthesis was completed, finishing details such as eyelashes and extrinsic colour were added to improve the realism. The result can be seen in Figs. 6.69 (a and b).

6.11.4 Discussion

Design

The ability to work on the prosthesis in conjunction with the patient's anatomy on the computer means that the patient does not have to remain present during much of the design stage. This significantly reduces clinic appointment time and inconvenience to the patient. The ability to view the

6.68 Colouring the mould surface.

6.69 a and b The final prosthetic result.

prosthesis *in situ* on the anatomy from angles not physically possible when observing the patient enables greater accuracy when positioning visually sensitive prostheses, particularly in ocular cases. In addition, the ability to introduce three-dimensional reference planes and markers allows relative positions to be ascertained that would typically prove problematic in the clinic. The FreeForm® CAD environment and user interface proved readily accessible to the prosthetist and exploits their existing visual and tactile skills making the software easy to learn and use.

Manufacture

Various RP technologies have been explored to assist the manufacture of prostheses **(3, 4, 5, 6, 7, 8)**, but ThermoJet® 3D printing was the obvious choice for this application. Parts are produced in a wax material that is directly compatible with those used in a prosthetics laboratory, thus integrating the technology with existing techniques. Previous research has also considered the manufacture of patterns using other methods such as stereolithography (SLA®, 3D Systems Inc.), Fused Deposition Modelling (FDM™, Stratasys Inc., 14950 Martin Drive, Eden Prairie, MN 55344-2020, USA), Laminated Object Manufacture (LOM™, see Section 5.8), Selective Laser Sintering (SLS®, 3D Systems Inc.) and Solid Ground Curing (SGC) **(5, 7)**. Numerically controlled machining and vacuum casting have also been explored **(8)**. The techniques discussed in this previous research all require additional steps in the pattern fabrication process or the extensive use of expensive RP materials and processes since the materials used are not directly compatible with laboratory techniques. Any additional steps in the process add both time and, therefore, cost that direct manufacture in wax eliminates. Mould manufacture is also more complicated (possibly requiring more than two parts to create undercuts in the pattern) and requires more material, thereby increasing build times and costs further **(6)**. Direct mould manufacture also removes the ability to test fit a pattern on the patient and modify the design by creating fine, feathered edges and the best possible fitting surface in order to improve the marginal integrity **(10, 11)**.

Disadvantages of the ThermoJet® technique include the poor quality down-facing surfaces and the delicate nature of the wax parts produced. However, this did not cause a problem in this research. ThermoJet® printing is relatively fast (short preparation and build times: approximately two and a half hours to manufacture a single pattern), clean (safe material, requires no solvents for cleaning), quiet and cheaper than most alternative methods. High levels of surface detail with only a minor stepping effect were also achieved, thereby minimising the need for hand finishing.

6.11.5 Conclusions

Due to the complex production of a facial prosthesis it is difficult to ascertain accurately the time saved by integrating these new methods into the prosthetists' procedures. However, a prosthesis of this nature would normally take around ten hours of patient consultation through the various stages of impression, carving and 'try on'. The same procedure was carried out in four hours with three hours manufacture using reported techniques, a great saving. It is expected that with practice and the establishment of FreeForm® design protocols, the design time could be further reduced.

Although the authors recognise that an experienced prosthetist can hand carve close mirror images of the anatomy, such as an ear, in quite a short time, this technology could really become of benefit when dealing with large orbital cases or those involving multiple facial structures. These not only take a great deal of time to construct but the patients are often too ill to undertake long clinical sessions: so the many benefits of working on a virtual patient may become attractive. This research has shown that the appropriate incorporation of FreeForm® design and ThermoJet® manufacture technique offers time and accuracy benefits that ultimately help to improve patient care. Further research may seek to ensure these technologies become better adapted and more accessible to the field of maxillofacial prosthetics and technology.

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6.12 Rehabilitation applications case study 5: Evaluation of advanced technologies in the design and manufacture of an implant retained facial prosthesis

6.12.1 Acknowledgements

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6.12.2 Introduction

Despite the widespread application of computer-aided design and rapid prototyping (CAD/RP) technologies in the production of medical models to assist maxillofacial surgery, advanced technologies remain under-developed in the design and fabrication of facial prosthetics. Research studies to date have achieved some limited success in the application of CAD/RP technologies, but very few have addressed the whole design and manufacture process or incorporated all of the necessary components **(1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11)**. In particular, the components concerned with retention have been neglected. Given that implant retention is now widely considered state-of-the-art, the incorporation of this into digital facial prosthesis techniques must be addressed. Implant retained prostheses are described in medical explanatory note 8.2.1.

Being able to undertake all of the prosthesis design and construction stages without the patient present has the potential to dramatically reduce clinic time and make the entire process more flexible. Reducing the number of clinic visits and the time involved in them would help to reduce patient inconvenience and improve efficiency and flexibility by allowing the prosthetist to work on any given design at any period.

This case study is based on part of ongoing doctoral research that ultimately aims to identify the target specification requirements for advanced digital technologies that may be used to drive development of advanced technologies such that they will be suitable for the design and manufacture of complex, soft tissue facial prostheses. The study reported here tested the capability of currently available technologies in the design and manufacture of an implant retained prosthesis. Evaluation of the results will clarify the current position and, where they fall short, direct further research that will identify the direction and magnitude of the developments required.

6.12.3 Existing facial prosthetics technique

Facial prosthesis design and construction techniques have changed little in 40 years and are described well in textbooks **(12, 13)** and papers **(14, 15)**. By their nature, prostheses are one-off, patient-specific devices that cannot benefit from batch or mass manufacture. Hand crafting techniques are therefore used to fabricate the prosthesis form and retentive components and, in some cases, join them to pre-fabricated components that enable the prosthesis to be attached to the implants.

Various retention methods may be used to secure a facial prosthesis such as magnets, bar and clip, adhesives or engaging anatomical undercuts. However, in many cases implant-retained prostheses are now considered to be the optimum solution. In implant-retained cases, the prosthesis typically consists of three components; the soft tissue prosthesis itself, a rigid substructure incorporating the retention parts and the corresponding retention parts that remain attached to the patient. The attachment between the two retention components can be by bar and clip or by magnets. Bar and clip gives the highest retention force, and the strength may be altered by crimping the metal clips. Magnets can provide a range or retentive forces (around 500–1000 g) depending on the number and type used. Magnets may either be screwed directly on to the abutments or located on a framework. The prosthesis-mounted components may be bonded directly into the silicone if the prosthesis is small or a substructure is not necessary.

Prosthesis design is typically undertaken by shaping wax on a plaster replica of the patient's anatomy. Realism is predominantly achieved through the prosthetist's ability to interpret the correct location and physically recreate the anatomical shape and detail. Colour matching of the silicone also helps to complete a good blend into the surrounding anatomy.

Although these existing techniques are time consuming, they can be applied to a wide range of situations. Previous studies have shown that to be effective digital technologies must be sympathetically integrated into these existing techniques so that the skills and flexibility of the prosthetist are not hampered **(9, 10, 11)**.

6.12.4 Review of advanced technologies in facial prosthetics

A review of previous research highlights a range of advanced technologies that may be used to design and manufacture a facial prosthesis **(1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11)**.

- **Data capture** Non-contact surface scanning to digitise the surface of the affected anatomy
  Various structured white light scanners, laser scanners, computerised photogrammetry
- **Design** Flexible CAD software
  FreeForm® (SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA); Magics (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium); Rhino Ceros® (Robert McNeel & Associates, 3670 Woodland Park Avenue North, Seattle, WA 98103, USA, www.rhino3d.com)
- **Manufacture** RP processes
  ThermoJet® wax printing (3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA, www.3dsystems.com); SLM™ (MCP-HEK GmbH SLM Tech Centre Paderbom, Hauptstrasse 35, 33178 Borchen, Germany, www.mcp-group.com/index.html); SLA® (3D Systems Inc.), SLS® (3D Systems Inc.) and various CNC machining processes

The review of previous work has shown that these advanced techniques and technologies demonstrate a number of limitations and identified a range of technical challenges. Specifically, there are three notable areas: the capture of data that describes the anatomy and implant abutment features, the design and alignment of the prosthesis components and the manufacture of components in appropriate materials.

Data capture

Although non-contact surface scanning technologies have been used to capture anatomical forms, limitations have also been identified. Areas of hair, undercut surfaces, highly reflective surfaces and patient movement cause poor results **(3, 4, 5, 6)**. Insufficient data resolution and errors in the form of 'noise' also limit the ability of scanning technologies to capture sharp edges and small geometrical features at the scale required **(16)**. The ideal scanning technology must, therefore, be capable of capturing both anatomical surfaces and implant components with sufficient accuracy, resolution and speed to overcome these limitations.

Design

In order to design the various components of the prosthesis such that they accurately fit together using CAD, the operator must be able to import, manipulate, create and align both anatomical and geometric forms.

Engineering CAD software packages typically work with geometric shapes and provide methods of aligning components. However, engineering software is poorly suited to handling complex and individual anatomical forms. CAD software such as FreeForm® provides a more intuitive solution to handling anatomical forms (more akin to a digital sculpting package) yet doesn't provide suitable tools for aligning the various components. A suitable CAD software package must provide tools for precisely aligning geometric shapes as well as the manipulation of complex anatomical forms.

Manufacture

Material requirements for maxillofacial prostheses are varied according to the separate components. For the soft tissue elements that are currently made from colour-matched silicone, no technology exists that is able to build the final prosthesis form directly from CAD data. Therefore, a pattern must be produced instead. The review of previous research and experiments carried out at PDR and Morriston Hospital has shown that producing the pattern in a material compatible with conventional sculpting techniques is highly desirable. Building the pattern in wax allows the prosthetist to easily adjust the pattern using their existing techniques and skills, particularly during test fitting on the patient **(9, 10, 11)**. The substructures need to be accurate and rigid enough to contain the retentive elements and the forces experienced during attachment and removal. The retentive components that remain attached to the patient via the implants must be non-corrosive and un-reactive (similar to jewellery) and also rigid enough to withstand the retentive forces. The materials for all of the components must also not react with each other and resist the effects of being included in the manufacture of the final prosthesis from the pattern, such as mould heating. Finally they must also provide adequate wear resistance, resist permanent distortion and provide adequate retention for the service life of the prosthesis.

6.12.5 Case study 1

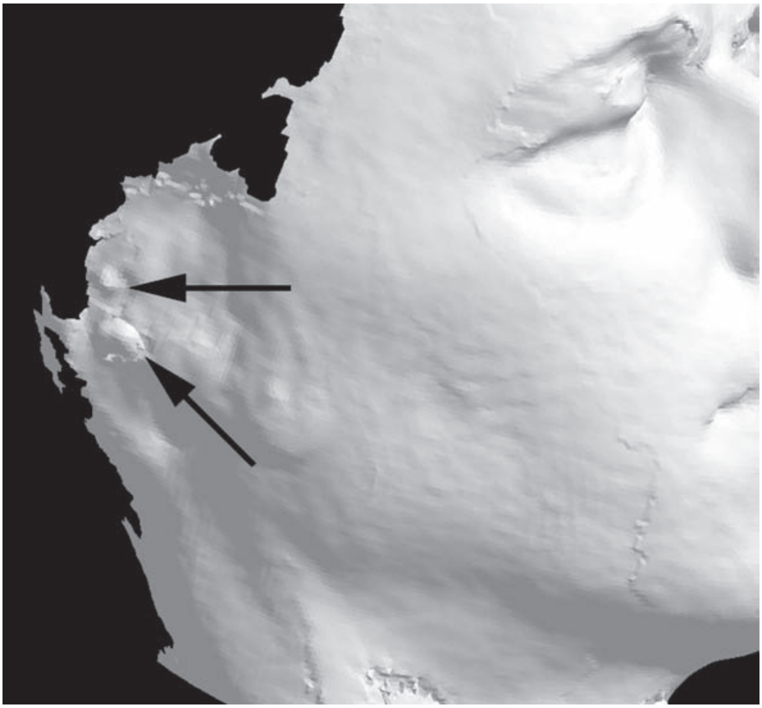
In order to accurately assess the capabilities of current advanced technologies in the design and manufacture of an entire implant-retained prosthesis, an exploratory study was undertaken. The study would not only evaluate the ability of current technologies but measurements and observations made would inform future research. A bar and clip, implant-retained auricular prosthesis case was selected. A three-dimensional computed tomography (CT) scan had already been undertaken and the data used to plan the placement of two implants in a single-stage operation. A healing period of six weeks was allowed before prosthesis construction.

Data capture

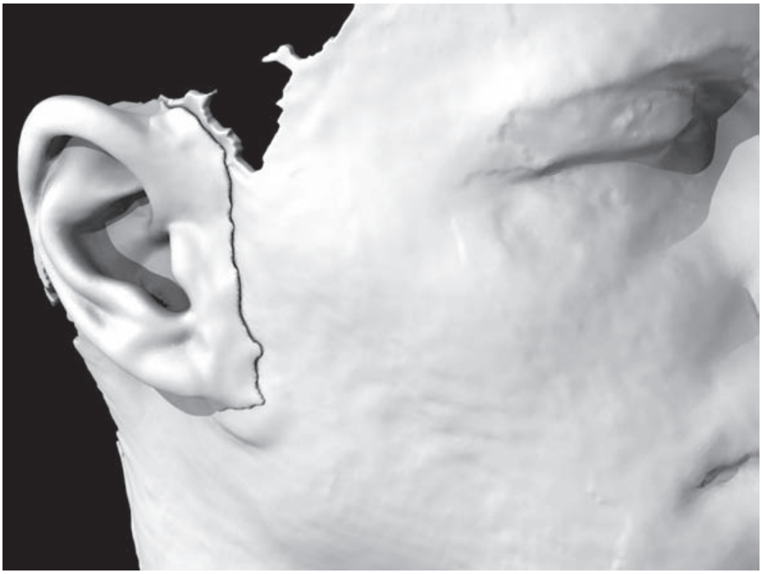
An impression and dental stone replica that recorded the implant abutment locations and the surrounding anatomy was made using conventional methods. In addition, the patient was digitally scanned using a pair of laser scanners (Konica-Minolta Vivid 900 laser scanners, Osaka, Japan) to allow for subsequent digital prosthesis design. Previous work has shown that these scanners had a relatively fast capture time and an accuracy level appropriate to the scanning of faces **(17, 18)**. The actual number of points captured per mm^2 is determined by scanner's field of view. At a distance of 1.35 m, the scanners each captured an area of 445 × 333 mm, resulting in a point density of one point per 0.69 mm^2. A paired set-up was used in order to capture a wider field of view without having to move the patient. In this configuration the scanners are triggered consecutively (simultaneous capture would lead to the scanners interfering with each other). The patient was seated with their head positioned 1.35 m away from the scanners and a 14 mm focal length lens used. Although the specified capture time is 0.6 seconds for each camera, a short pause between scans meant that the patient had to remain motionless and with the same facial expression for approximately eight seconds. The point cloud scan data was aligned and converted to an STL file using Rapidform™ software (INUS Technology Inc., SBC, Ludwig-Erhard-Strasse, 30–34, D-65760, Eschborn, Germany). Shadow areas behind the ears were not captured. However, the three-dimensional CT data that had been acquired for the implant planning was also available to be used as the basis for the prosthesis design.

Design

The scan data was imported into the sculpting CAD package FreeForm® using the 'thickness' option to make a solid model. Whilst the scanners have been shown to be able to capture anatomical detail well, this study demonstrated that the data resolution was insufficient to describe the implant abutments accurately (see Fig. 6.70). However, the data was good enough to allow the abutment locations to be identified, which allowed the overall prosthesis form to be designed around them with sufficient accuracy. The patient's opposite healthy ear was obtained from the CT data, imported into FreeForm® and mirrored to the defect site (see Fig. 6.71). The tools in FreeForm® were then used to blend this ear into the surrounding anatomy and finally subtracted from it to leave an accurate fitting surface using a



6.70 Scan data of the defect site (arrows indicating the implant abutments).



6.71 The mirrored ear positioned at the defect site (before blending).

technique that has also been reported in the digital design of other prostheses **(9, 10, 11)**.

Manufacture

The final design of the prosthesis pattern was physically manufactured using the ThermoJet® printing process in a wax material. The use of wax allowed modifications to include the retentive components to be made using conventional methods. A colour-matched, silicone prosthetic ear was then fabricated for the patient using conventional methods.

Initial findings from Case study 1

This initial trial highlighted the limitations of non-contact scanning to capture anatomy and finely detailed abutments with sufficient resolution.

6.12.6 Case study 2

Data capture

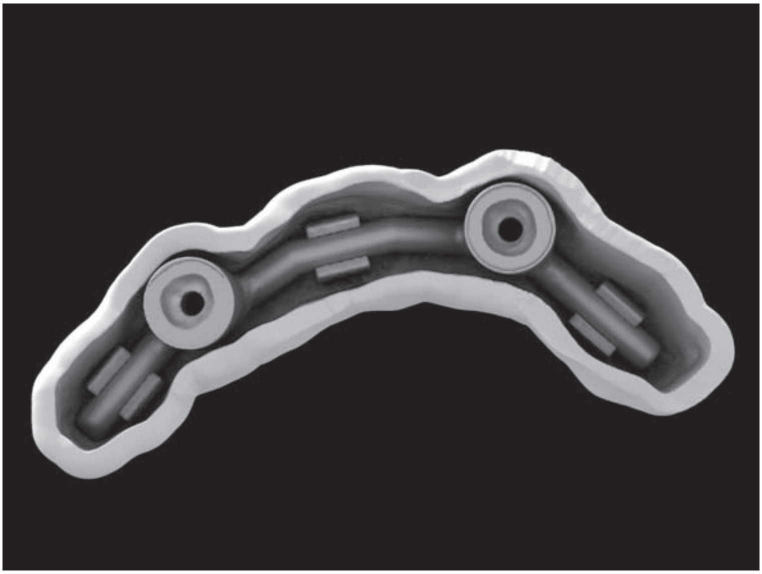
The first case study showed that the data captured was insufficient to be used in the design of the retentive components. Therefore, the same case was repeated using a higher-resolution structured white light scanner (Steinbichler Optotechnik GmbH, Am Bauhof 4, D-83115 Neubeuern, Germany). This type of scanner is typically used for engineering and has a much longer capture time. Therefore, it was used to digitise the dental stone replica of the patient produced using conventional impression methods. This scanner captures approximately nine points per mm^2 (three per mm in the x, y plane) and around 140 000 points per scan over an area of approximately 250 mm × 250 mm and a working range of approximately 180 mm. In order to make the abutment locations easier to scan, magnetic keepers (Technovent Ltd, Headingley House, 39 St Michael Lane, Leeds, LS26 3SR, UK) were screwed on to the abutments to provide a flat surface and the model was coated in a fine matt white powder to reduce reflectivity. A total of six overlapping scans covering the entire model were taken and the data aligned using Polyworks® software (InnovMetric Software Inc., 2014 Jean-Talon North, Suite 310, Quebec, QC Canada, GIN 4N6). STL file data was created from the point cloud information using Spider (Alias-Wavefront Inc., 210 King Street East Toronto, Canada, M5A1J7) and the data imported into Magics. Magics provides alignment and modification tools for STL file data and was used to digitally remove the abutment caps. The flat surfaces of each abutment cap in turn were aligned by selecting a triangle on the top surface and using a Magics function to make it down-facing to the x–y plane. The 'sectioning' and 'cut' tools were then used to remove the exact depth of the cap. This effectively left a perfectly flat surface representing the top surface of the abutments. The modified STL data was then imported into FreeForm®.

Design

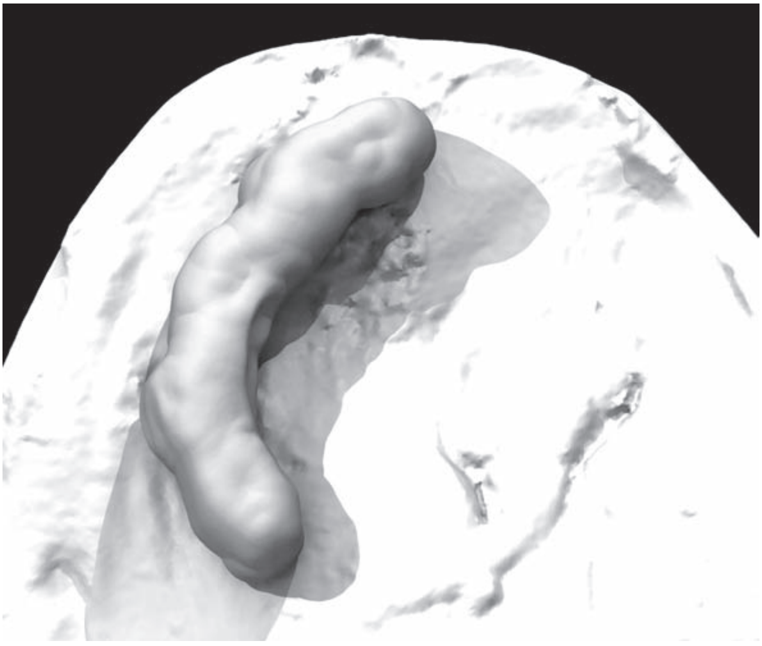
As in the previous study, FreeForm® was used to manually align the ear taken from the CT data to the digital cast based upon the estimated aesthetic requirements and possible substructure location. However, unlike the first case study, the data quality in this case study enabled the design of all of the components to be attempted. Digital versions of the screws used to attach frameworks to the abutments and cylinder components were designed using the drawing and rotation tools in FreeForm®. A circular-section framework linking the two cylinders was created using the 'add clay' tool. As in conventional methods, this followed the thickest section of the ear to ensure that all of the components would fit within the ear profile.

Clip designs were created using the two-dimensional drawing and 'extrude' tools. These were copied three times and manually located along the bar structure at key points of maximum prosthesis thickness. In order to secure the clips into the prosthesis body and to assist application, a substructure shell that would be bonded to the silicone was required. This had to provide enough clearance for the clips to spring open and closed, but provide firm anchorage for bonding to the silicone. Digital 'clay' that enclosed the framework and clips, leaving just their top features as a point of attachment, was built up from the cast model. The 'paint on selection' tool was used to select and copy, then paste the raised section surrounding the framework. The 'create offset piece' tool was then used to create a shell 1.5 mm thick surrounding the clips and bar. Boolean subtraction operations and hand carving were used to finalise the shell before joining it to the clip components. The bar, clip and shell design is shown in Figs 6.72 and 6.73.

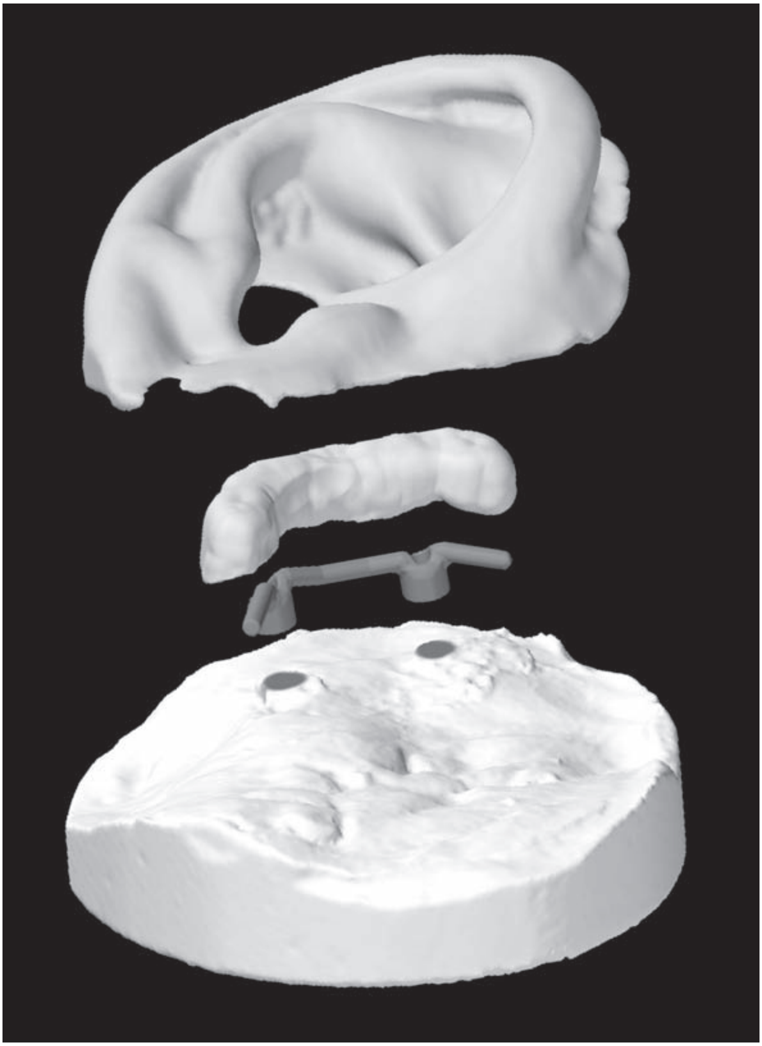
The prosthesis profile was thickened around the clip areas to accommodate the shell component, and a Boolean subtraction operation used to create a fitting recess. The bar design was finalised with Boolean subtraction operations to provide location for the screws, and smoothing operations were applied around the joints with the cylinder features. Hemispherical dimples were also created where cylinders located on the abutments. Fig. 6.74 shows an exploded view of the components in the FreeForm® environment. Each of the components was then exported as high quality STL files ready for RP fabrication (see Section 4.2.6 for more information about the STL file format).



6.72 The bar located in the clips inside the substructure shell (in FreeForm®).



6.73 The located substructure shell (in FreeForm®).



6.74 An exploded view of the components in FreeForm®.

Manufacture

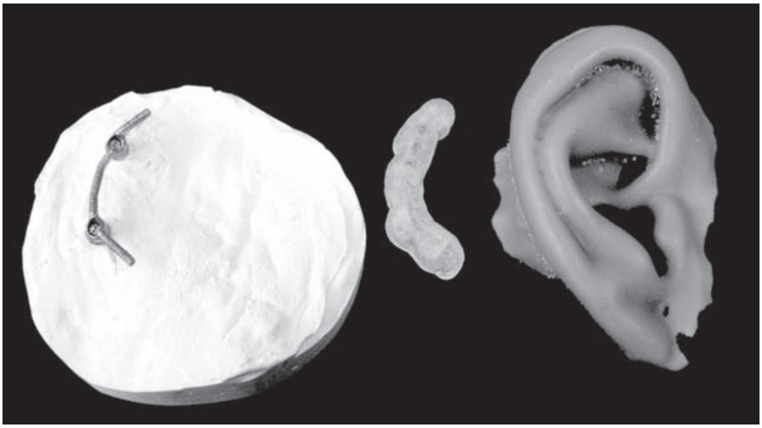
A range of RP technologies were selected to produce the components in the most suitable materials available. Selective Laser Melting (SLM™) was selected to produce the bar component due to its ability to produce parts in corrosion resistant and rigid metals and alloys (see Section 5.5.3, for a description of the SLM™ process). The bar was created using SLM™ in 0.05 mm thick layers using 316L stainless steel. Grit blasting and light polishing was used to remove the rough finish produced by the process.

Stereolithography was used to produce the shell component in DSM Somos 10110-epoxy resin (see Section 5.2 for more information on stereolithography). ThermoJet® wax printing was used to produce the prosthesis pattern (see Section 5.7 for more information on the ThermoJet® process). The physical components are shown in Fig. 6.75.

6.12.7 Results

The parts designed and produced in the second case study did produce a complete prosthesis. However, the fit between the components required a small amount of adjustment. Therefore, although the finished components would not have been suitable for use in an actual prosthesis, it was possible to evaluate them when fitted to the dental stone model.

- **Fit between the implant abutments and the bar** – a passive fit as described by Henry **(19)** was not achieved and, although the bar did screw on to the stone model securely, visible gaps remained. In addition, the surface finish of the SLM bar was slightly pitted when compared to soldered gold bars.
- **Fit between the bar and clips and the substructure** – clip retention was initially good, but repeated application caused the clips to wear. This suggested that the relatively soft epoxy resin is not suitable for use in a clip that undergoes repeated applications.
- **Fit between the substructure and prosthesis pattern** – the fit was tight due to the rough finish left after removing supports from the ThermoJet®



6.75 The manufactured components: SLM™ bar (left), Stereolithography sub-structure (middle) and ThermoJet® pattern (right).

part's down-facing surfaces. This was easily corrected using a heated scalpel, enabling a secure location and close fit.

- **Detail** – the fragile nature of the ThermoJet® wax prevented the pattern's edges from being made any thinner. Thin edges allow the prosthesis margin to blend naturally into the skin when made in silicone. These thin edges were added by the prosthetist using sculpting wax. Heated sculpting metal tools were also used to blend the join between the different waxes and add further anatomical details that helped to achieve a more realistic appearance.

6.12.8 Discussion

This study has highlighted the potential of digital technologies to assist facial prosthesis design, but also demonstrated that there are many limitations that must be addressed to improve their effectiveness. The limitations encountered are discussed in three categories: data capture, design and manufacture.

Data capture

Scanning small detailed abutments proved particularly difficult. The distributed nature of point cloud data captured by optical scanning technologies and the effects of noise meant that, even with a high point density, small features were subject to loss of edge definition. Inadvertent patient movement during data capture exacerbates this problem. With current technologies, a compromise must be made between detail and speed of capture. However, as digital camera technology and computer processor power increases, it can be foreseen that the desired capability to capture rich, high quality data sufficiently quickly to enable the scanning of patients may be achieved in the near future.

Design

This study has shown that digital techniques can be used to design all of the components of a prosthesis. However, as the major aim of embracing digital technologies is the gain in efficiency it is clear that more work is needed to address software capability. This study has shown that, although digital design is possible, it requires the use of multiple software packages to achieve specific tasks. This reduces efficiency, increases costs and also introduces more opportunities for error as data is translated or transferred from one source to another.

Future studies will explore alternative software solutions and identify practical methods of overcoming the issues identified in this research. The authors intend to evaluate other potentially suitable technologies in future studies once an initial specification has been developed.

Manufacture

The technologies used in this study have shown that they are capable of producing a complete prosthesis. However, the processes all require improvement in order to match or improve upon existing techniques. The ThermoJet® wax process produced a good quality pattern in an appropriate and useful material that integrated with existing skills and techniques. However, it requires the ability to generate thinner edges if it is to produce a complete pattern without modification.

The SLM bar was sufficiently strong and rigid enough for the application, and the material should prove corrosion resistant enough for most patients. However, the bar did not fit as precisely as would be expected of a bar made by existing techniques and the surface was slightly pitted. As the overall shape and accuracy appeared adequate, finer control of the process may yield parts with better detail and surface finish.

The stereolithography shell component was accurate and rigid enough for the application. The retention strength of the clips was not very high, although it may have been high enough for the purpose. However, the clips did not withstand repeated use and quickly wore down, severely degrading retention strength. Therefore, the process could prove adequate for the purpose if a harder wearing material was available.

6.12.9 Conclusions

Literature to date and the findings of this study have demonstrated that, whilst advanced technologies enable the digital design and RP fabrication of complete facial prostheses, further work is needed before they produce results comparable to existing techniques. Without a specification against which potential technologies may be measured and towards which they may be developed, quantifying success is based on subjective assessment and expert opinion. The authors intend to use the findings of this study to direct further research aimed at developing a specification that will provide quantifiable and objective measures against which advanced technologies may be assessed.

6.12.10 References

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6.13 Rehabilitation applications case study 6: The computer-aided design and rapid prototyping fabrication of removable partial denture frameworks

6.13.1 Acknowledgements

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6.13.2 Introduction

Computer-aided design, manufacture and rapid prototyping (CAD/CAM/RP) techniques have been extensively employed in the product development sector for many years and have also been extensively used in maxillofacial technology and surgery **(1, 2)**. In addition, CAD/CAM technologies have been introduced into dentistry, particularly to the manufacture of crowns and bridges **(3)**, but there has been little research into the use of such methods in the field of removable partial denture (RPD) framework fabrication. This may in part be attributed to the lack of suitable, dedicated software. Recent pilot studies have showed that CAD/RP methods of designing and producing a sacrificial pattern for the production of metal components of RPD metal frameworks could have promising applications **(4, 5)**. These studies explored the application of computer-aided technologies to the surveying of digital casts and pattern design and the subsequent production of sacrificial patterns using RP technologies.

The potential advantages offered by the introduction of advanced CAD/CAM/RP into the field of RPD framework fabrication include automatic determination of a suggested path of insertion, almost instant elimination of unwanted undercuts (re-entry points) and the equally rapid identification of useful undercuts. At another stage, components of a removable partial denture could be stored in a library and 'dragged and dropped' in place on a scanned and digitally surveyed cast from icons appearing on screen, allowing virtual pattern making to be carried out in a much faster time than is achieved by current techniques. The quality assurance of component design can also be built into the software. Since RP machines build the object directly, scaling factors may also be precisely imposed in order to compensate for shrinkage in casting. In addition to the potential timesavings, the CAD/RP process also delivers inherent repeatability, which may help to eliminate operator variation and improve quality control in the dental laboratory.

The current case study reports on the application of CAD/RP methods to achieve the stages of surveying and design using a software package that provides a virtual sculpting environment, FreeForm® (SensAble Technologies, Inc., 15 Constitution Way, Woburn, MA 01801, USA). It also discusses the application of RP technologies to produce sacrificial patterns for casting the definitive chromium-cobalt framework component. The advantages, limitations and future possibilities of these techniques are concluded.

6.13.3 Materials and methods

Three-dimensional scanning

A three-dimensional scan of a partially dentate patient's dental cast was obtained using a structured white light digitiser (Comet® 250; Steinbichler Optotechnik GmbH, AM Bauhof 4, D-83115 Neubeuern, Germany). This particular type of scanner is used in high-precision engineering applications and has been used in maxillofacial technology **(6)**. Multiple overlapping scans were used to collect point cloud data that was aligned using Polyworks® software (InnovMetric Software Inc., 2014 Jean-Talon Blvd North, Suite

310, Sainte-Foy, Quebec, Canada, G1N 4N6). Spider software (Alias-Wavefront Inc., 210 King Street East, Toronto, Ontario, Canada, M5A 1J7) was used to produce a polygon surface, STL (Manners, C. R., 1993, 'STL File Format' available on request from 3D Systems Inc., 2608, Avenue Hall Valencia, CA 91355, USA) model file that could be imported into FreeForm®.

FreeForm® modelling

FreeForm® is a CAD package with tools analogous to those used in physical sculpting. A haptic interface (PHANTOM® Desktop™ haptic interface; SensAble Technologies Inc.) incorporates positioning in three-dimensional space and allows rotation and translation in all axes, whilst translating hand movements into the virtual environment (Fig. 6.76). It also allows the operator to feel the object being worked on in the software. The combination of tools and force feedback sensations mimic working on a physical object and allow shapes to be designed and modified in an arbitrary manner.

Objects being worked on are referred to as virtual 'clay', which can be rotated and viewed from any angle on the screen. A 'buck' setting prevents a model being unintentionally modified, but allows 'clay' to be added or copied. The STL cast was imported into FreeForm® as a 'buck' model.

Surveying

Surveying is undertaken in dental technology laboratories to identify useful dental features in order for the RPD design to be effectively retained in the oral cavity. The 'parting line' (also known as 'split line') function within FreeForm® was used to delineate up- and down-facing surfaces, thus identifying areas of undercut in a different colour to the 'buck' model. The effect is identical to the physical technique of using dental survey lines to identify and mark the most bulbous areas of teeth with a pencil line (highlighted in Fig. 6.77a). The undercuts were assessed in order to establish the best path of insertion and possible points for active clasp termination and the model was then rotated accordingly. A visual comparison (Figs 6.77a and b) was made between the physically surveyed cast and the same model cast surveyed using the software. Once a suitable angle was chosen, the model was re-exported as an STL file.

Removing unwanted undercuts

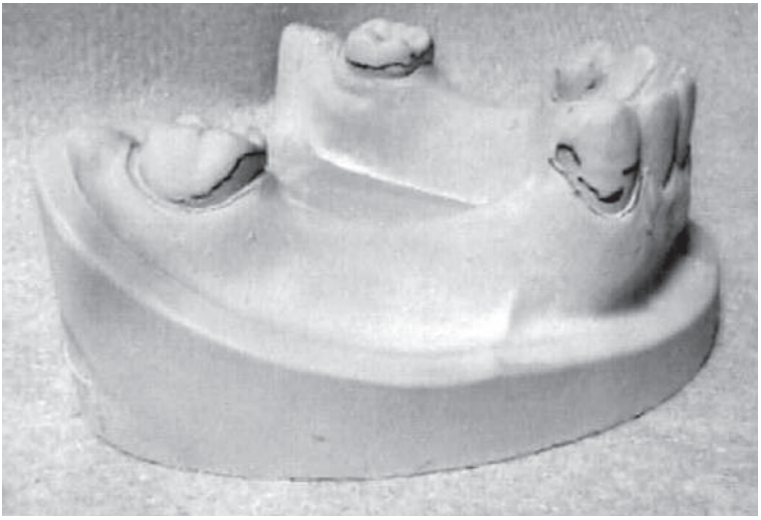
When creating an RPD, most undercuts are removed so that the resulting framework can be inserted and removed in a comfortable manner. The STL

6.76 The PHANTOM® stylus.

file of the rotated cast was imported into FreeForm®, but this time using the 'extrude to plane' option. When the cast was viewed from above, this option took the maximum extents of the profile and extruded them down by a user-defined distance. This effectively removed undercuts and replaced them with vertical surfaces (Figs 6.78a and b).

Identifying useful undercuts

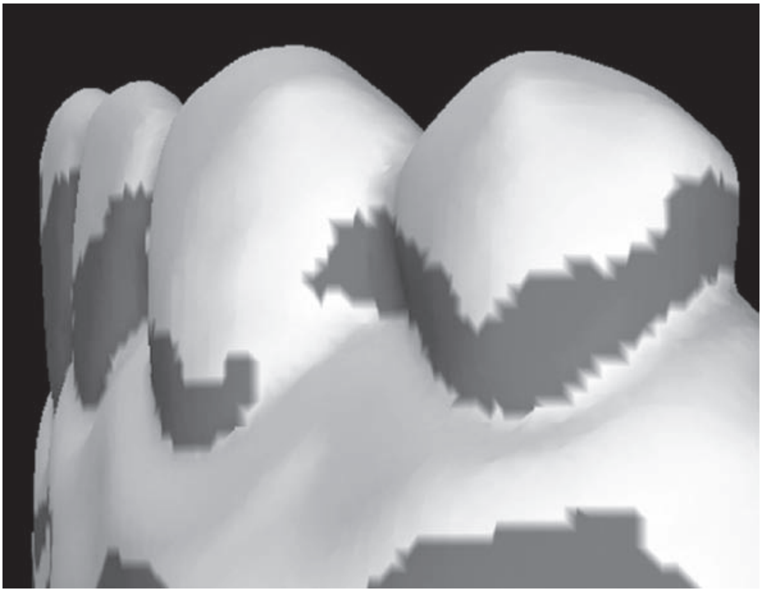
FreeForm®'s 'ruler' tool was used to measure the distance between the original cast model and the version with undercuts removed. The useful



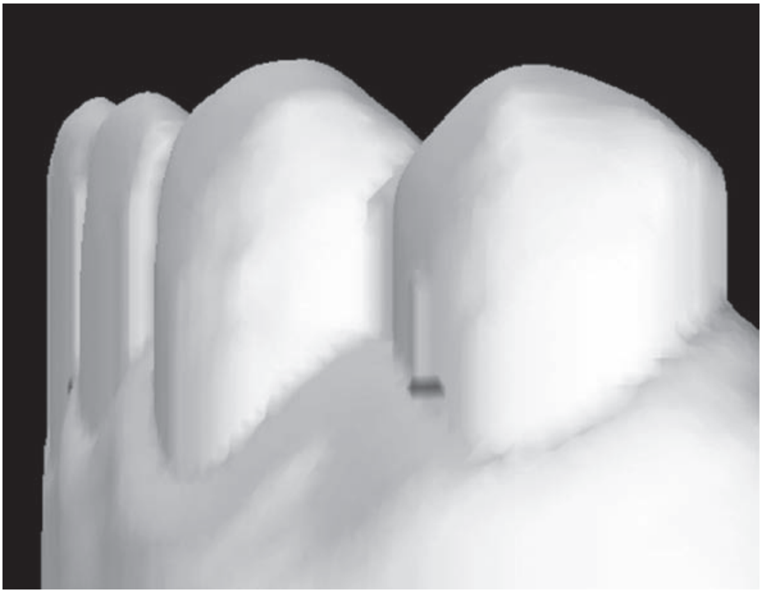
6.77a The physically surveyed cast.

6.77b The digitally surveyed, 'buck' cast – undercuts are shown as dark areas.

undercuts were marked with a line for use in the design stages. RPDs provide firm location on the existing dentition by using flexible clasps. The clasp components of the RPD open on initial contact during insertion and removal, and return to their original position within the undercut on final seating, thus providing secure retention.



6.78a Undercuts are shown as dark areas.



6.78b Undercuts have been removed and replaced by vertical surfaces.

Creation of relief

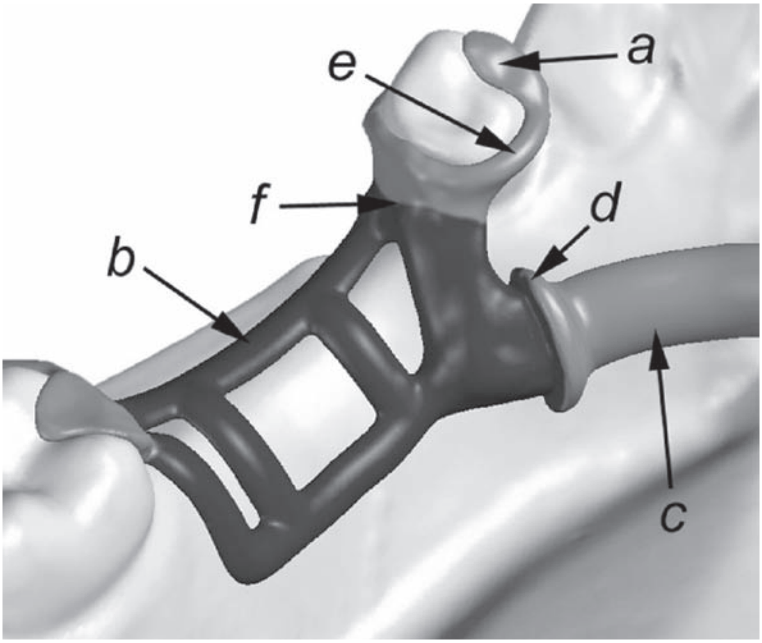
The areas without teeth require a spacer, known as a relief, to prevent the framework resting on the surface of the gums. Relief was created by selecting and copying an area from the cast with undercuts removed, then pasting this as a new piece of clay. This was then offset to the outside by 1 mm. The results of this process are highlighted in Fig. 6.79. The entire modified model was saved as an STL file and then re-imported using the 'buck' setting to avoid unintentional modification during the next stages of RPD design.

Framework design

The RPD design employed in this study was based on recognised dental technology methods emphasising simplicity, aesthetics and patient comfort **(7)**. Some of the key design features outlined in the design stages are labelled in Fig. 6.80.

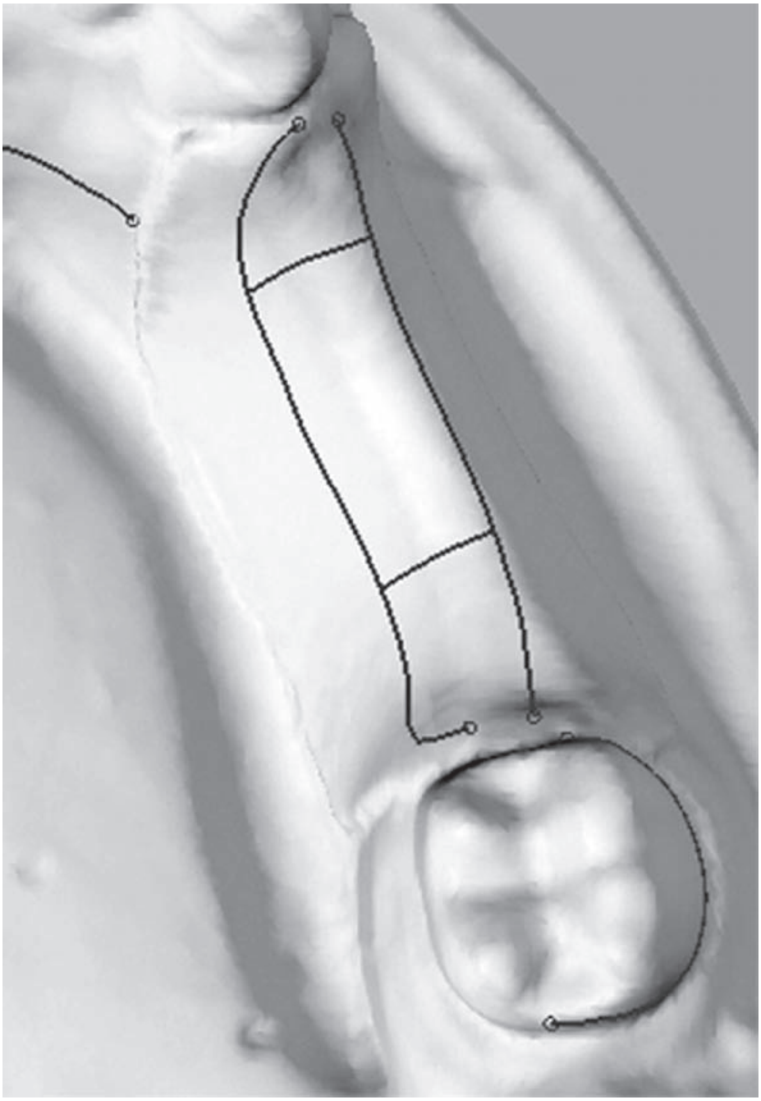
The entire framework was designed on the relieved 'buck' cast with undercuts removed, with the exception of the clasp components. The clasps use the undercuts to function and they were, therefore, designed on the original 'buck' cast. The following techniques were used in the framework design.

6.79 Relieved edentulous areas are shown in the lighter colour on the dark cast.



6.80 a = occlusal rest, b = polymeric retention frame, c = lingual bar, d = acrylic line, e = non-active clasp, f = guide plate.

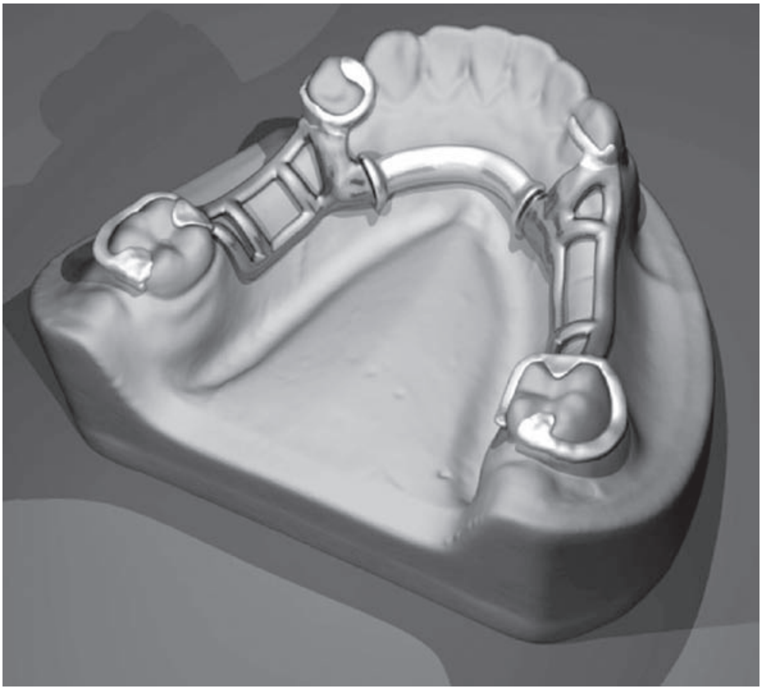
- **Occlusal rests** (a in Fig. 6.80) – a combination of two-dimensional drawing, three-dimensional creation and manipulation tools was used to create pieces of clay that were copied and located where required on the teeth.
- **Polymeric retention framework** (b in Fig. 6.80), **lingual bar** (c in Fig. 6.80), **acrylic line** (d in Fig. 6.80) **and non-active clasps** (e in Fig. 6.80) – the 'draw' tool was used locate curves directly onto the cast surface. These formed the centre of the frameworks profile (Fig. 6.81). The 'groove' tool was used to define and create the exact oval and square sectional dimensions as clay.
- **Guide plates** (f in Fig. 6.80) – Guide plates were created using the same method as relief creation. The 'attract' and 'smudge' tools were also used to build up plate areas and blend them onto the framework sections.
- **Finishing** – 'smooth', 'attract' and 'smudge' tools were used to blend the components together. The 'buck' cast was removed, acting as a Boolean cutting tool to leave just the clay framework.
- **Active clasps** – the clasps were designed in the same manner as the non-flexible parts of the framework, but using the 'buck' cast with



6.81 Construction curves.

undercuts. The construction lines were joined to the termination point previously marked in the undercut measurement stage.

The ‘buck’ cast was removed leaving the clasps. These were joined to the main framework and blended in. Fig. 6.82 shows the final, virtual design. The entire framework was exported as an STL file.



6.82 The complete FreeForm® design.

Pattern manufacture

Four RP methods were compared: stereolithography (SLA®) (3D Systems Inc, 26081 Avenue Hall, Valencia, CA 91355, USA), ThermoJet® (3D Systems Inc.), Solidscape® T66 (Solidscape Inc., 316 Daniel Webster Highway, Merrimack, NH 03054-4115, USA) and Perfactory® (EnvisionTEC GmbH, Elbestrasse 10, D-45768 Marl, Germany). Two stereolithography resins were compared: DSM Somos® 10110 (Waterclear™) (2 Penn's Way, Suite 401, New Castle, DE 19720, USA) and Accura™ Amethyst® (3D Systems Inc.). Both of the SL patterns were an epoxy-based polymer, the ThermoJet® was TJ88 grade wax polymer, the Solidscape® was a soft thermoplastic and Perfactory® an acrylate based polymer. The Waterclear™ and ThermoJet® patterns were manufactured at the National Centre for Product Design and Development Research (PDR) and the others were prepared and built by external suppliers. The Amethyst®, Solidscape® and Perfactory® materials are used by the jewellery industry to produce sacrificial patterns.

6.83 The support structure in 3D Lightyear™.

SLA-250 in Waterclear™ example The STL framework design was prepared using 3D Lightyear™ (3D Systems Inc.) with a 'fine point' support structure (Fig. 6.83). The framework was oriented with the fitting surfaces facing upwards to avoid the rough finish created by the support structures affecting the fit.

Two build styles were compared: standard 0.1000 mm thick layers and high-resolution 0.0625 mm layers. Once completed, the patterns were carefully removed from the machine platform and cleaned in isopropanol. They were then post-cured in UV light to ensure full polymerisation. The other patterns were produced according to the supplier specifications.

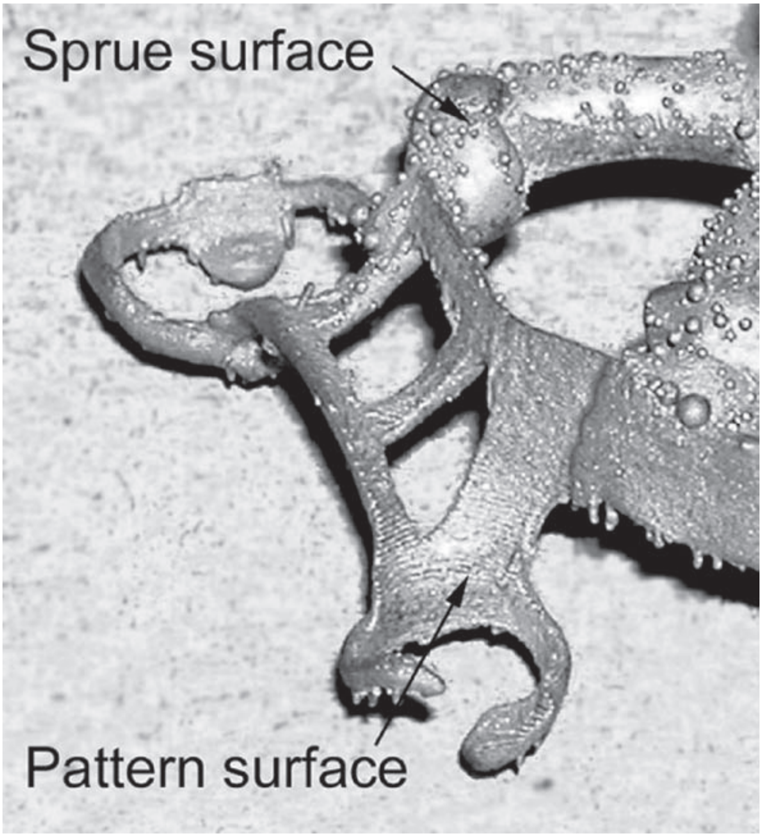
Pattern comparison

Of the four RP processes compared in this study, the SL processes provided the most suitable patterns. The SL patterns were accurate, robust and had an acceptable surface finish, but did require relatively lengthy cleaning and finishing when removing support structures. The Thermojet® build preparation was simpler and faster than SL and both the ThermoJet® and Solidscape® processes produced accurate patterns with a good surface finish that required minimal finishing. These wax patterns were, however, extremely fragile and could not be cast. The Perfactory®-produced pattern showed a very smooth surface finish, but was also extremely flexible and was easily distorted when handled.

Casting

The SL and Perfactory® patterns were cast in chrome cobalt without using a refractory cast. A slow mould heating cycle was used to avoid cracking. Fig. 6.84 shows the unfinished cast from the SL, Amethyst® pattern. This shows that air inclusions from the casting process did not adhere to the pattern surface.

Although casts were obtained from the SL and Perfactory® patterns, it proved difficult to add sprues due to the thin framework sections. In order to improve casting, the design was thickened in FreeForm® and revised SL patterns were produced and cast. This improved the pattern's strength and the casting reliability.



6.84 Surfaces of the unfinished Amethyst® pattern cast.

Finishing

The casts produced from the original, thin Amethyst® and thicker Waterclear™ patterns were polished and test fitted to the original, physical cast. These were all judged satisfactory. Fig. 6.85 shows the finished RPD framework that was cast from the high-resolution Waterclear™, SLA-250 pattern.

6.13.4 Conclusions

The design stages of this technique rely on having an accurate three-dimensional scan of a patient cast and an understanding of both RPD framework design and CAD techniques. This meant that the time taken to produce castable patterns using the technology described is considerable. However, this would be significantly reduced with familiarity and practice.

The most suitable choice of RP process was determined primarily by accuracy and part strength. The ThermoJet® and Solidscape® patterns, although accurate, were too fragile and were, therefore, not suitable for the

6.85 The definitive framework.

tasks associated with spruing and casting. Although the Perfactory® pattern cast well, the accuracy was poor due to distortion inflicted on the flexible pattern during handling. The stiffer patterns produced by SL were easy to handle, accurate and produced satisfactory results. The layer effect exhibited by all RP processes was not evident after finishing and the difference between the high-resolution and standard SLA-250 patterns was negligible.

The techniques undertaken and described above outline a stage in the development of machine-produced RPD frameworks and point to many possible advances that can be achieved in the future. The application of CAD would allow access to new RP technologies that build parts directly in metal alloys, including chromium-cobalt and stainless steel. Sacrificial pattern manufacture and casting may be eliminated altogether. This will be explored in future studies.

The introduction of digital design and RP production into current practices would present a significant change in the field of dentistry and this is unlikely to happen quickly. Studies so far have shown how CAD and RP may be applied and some principles have been developed and established. Possible future benefits and the potential shortfalls have also been discussed.

6.13.5 References

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6.14 Rehabilitation applications case study 7: Rapid manufacture of removable partial denture frameworks

6.14.1 Acknowledgements

The work described in this chapter was first reported in the reference below and is reproduced here in part or in full with the permission of Emerald Group Publishing Limited.

- Bibb R, Eggbeer D, Williams R (2006), 'Rapid Manufacture of Removable Partial Denture Frameworks', *Rapid Prototyping Journal*, **12** (2), 95–9.

6.14.2 Introduction

Over the last decade computer-aided design, computer-aided manufacture and rapid prototyping (CAD/CAM/RP) techniques have been employed in dentistry, but predominantly to the manufacture of crowns and bridges **(1, 2, 3)**. However, there has been little research into the use of such methods in the field of removable partial denture (RPD) framework fabrication. Whilst RP and rapid manufacturing (RM) techniques have proved successful in other dental applications, the lack of suitable design software has restricted their application in producing RPD frameworks. Recent studies have established a valid approach to the computer-aided surveying of digital casts, framework design and the subsequent production of sacrificial patterns using RP technologies **(4, 5, 6, 7)**.

The potential advantages offered by the introduction of CAD in the field of RPD framework design include automatic determination of a suggested path of insertion, instant elimination of unwanted undercuts and the equally rapid identification of useful undercuts, which are all crucial in dental technology. The potential advantages of an RM approach are reduced manufacture time, inherent repeatability and elimination of inter-operator variation.

6.14.3 Methodology

Step 1: three-dimensional scanning

A three-dimensional scan of a partially dentate patient's dental cast was obtained using a structured white light digitiser (Comet® 250; Steinbichler Optotechnik GmbH, AM Bauhof 4, D-83115 Neubeuern, Germany). Multiple overlapping scans were used to collect point cloud data that was aligned using Polyworks® software (InnovMetric Software Inc., 2014

Jean-Talon Blvd North, Suite 310, Sainte-Foy, Quebec, Canada, G1N 4N6). Spider software (Alias-Wavefront Inc., 210 King Street East, Toronto, Ontario, Canada, M5A 1J7) was used to produce a polygon surface in the STL file format **(8)**.

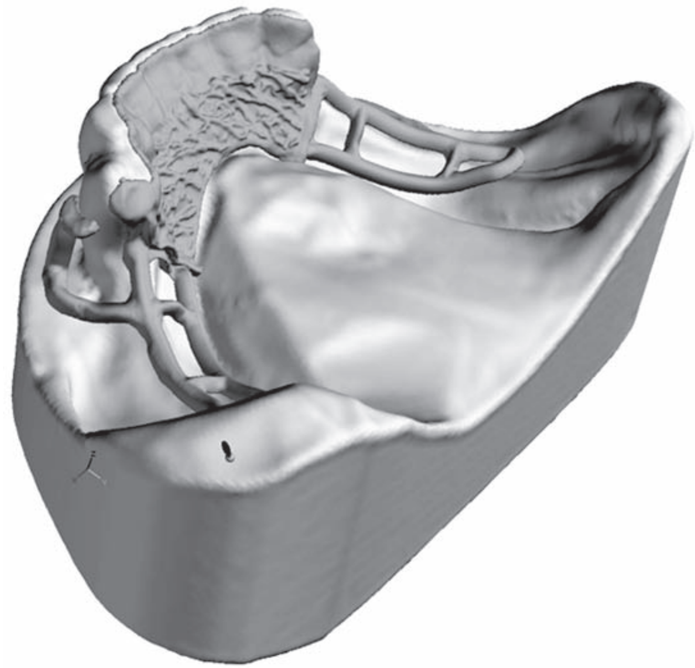
Step 2: design of the RPD framework

The CAD package used in this study, called FreeForm® (SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA), was selected for its capability in the design of complex, arbitrary but well-defined shapes that are required when designing custom appliances and devices that must fit human anatomy. The software has tools analogous to those used in physical sculpting and enables a manner of working that mimics that of the dental technician working in the laboratory. The software utilises a haptic interface (PHANTOM® Desktop™ haptic interface; SensAble Technologies Inc.) that incorporates positioning in three-dimensional space and allows rotation and translation in all axes, transferring hand movements into the virtual environment. It also allows the operator to feel the object being worked on in the software. The combination of tools and force feedback sensations mimic working on a physical object and allow shapes to be designed and modified in a natural manner. The software also allows the import of scan data to create reference objects or 'bucks' onto which fitting objects may be designed. The RPD metal frameworks used in this study were designed according to established principles in dental technology using this CAD software and based on a three-dimensional scan of a patient's cast **(9)**. The computer-aided design of RPD frameworks using this software has been described previously **(5, 6, 7)**. The finished design used in this case is shown in the screen capture shown in Fig. 6.86.

Step 3: rapid manufacture

In a previous study, the application of RP methods was investigated for the production of sacrificial patterns that were used to investment cast RPD frameworks in cobalt-chrome alloy **(7)**. Four RP methods were compared: stereolithography (SLA®) (3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA), ThermoJet® (3D Systems Inc.), Solidscape® T66 (Solidscape Inc., 316 Daniel Webster Highway, Merrimack, NH 03054-4115, USA) and Perfactory® (EnvisionTEC GmbH, Elbestrasse 10, D-45768 Marl, Germany). These various RP processes are described more fully in Chapter 5.

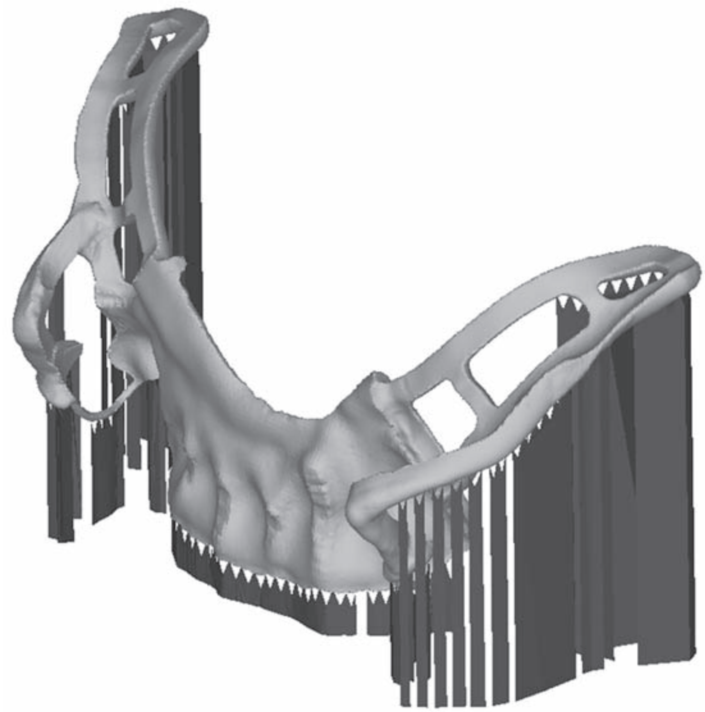
In this study, direct manufacture was attempted with the aim of eliminating the time and material consuming investment-casting process. The development of Selective Laser Melting (SLM™) technology showed potential



6.86 The RPD framework designed in FreeForm® CAD.

application for dental technologies due to the ability to produce complex shaped objects in hard-wearing and corrosion resistant metals and alloys directly from CAD data. SLM™ is described in Section 5.5.3.

In order to build the RPD framework successfully using the SLM™ Realizer machine (MCP-HEK GmbH SLM Tech Centre Paderbom, Hauptstrasse 35, 33178 Borchen, Germany, www.mcp-group.com/index.html), adequate supports had to be created using Magics software (Version 9.5, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium). The purpose of the supports is to provide a firm base for the part to be built onto whilst separating the part from the substrate plate. In addition, the supports conduct heat away from the material as it melts and solidifies during the build process. Inadequate support results in incomplete parts or heat induced curl, which leads to build failure. As the supports need to be removed with tools, the part was oriented such that the supports avoided the fitting surface of the RPD, as shown in Fig. 6.87. This meant that the most important surfaces of the resultant part would not be affected or damaged by the supports or their removal.



6.87 RPD oriented and supported to avoid the fitting surfaces.

First experiment

316L stainless steel was selected for the first experiment for its excellent corrosion resistance making it suitable for dental applications. In addition, the SLM™ machine manufacturers have shown that the material is well suited to processing by SLM™. The part and support files were ‘sliced and hatched’ using the SLM™ Realizer software with a layer thickness of 0.050 mm. The material used was 316L stainless steel spherical powder with a maximum particle size of 0.045 mm (particle size range 0.005–0.045 mm) and a mean particle size of approximately 0.025 mm (Sandvik Osprey Ltd, Red Jacket Works, Milland Road, Neath, SA11 1NJ, United Kingdom). The laser had a maximum scan speed of 300 mm/s and a beam diameter 0.150–0.200 mm. The first two parts attempted were partially successful due to insufficient support and erroneous slice data. These errors resulted in incomplete RPDs. The third attempt was prepared with more support and the data was sliced using different software (VisCAM RP, Marcam Engineering GmbH, Fahrenheitstrasse 1, D-28359 Bremen, Germany). This proved successful and produced a complete stainless steel RPD framework, shown in Fig. 6.88.

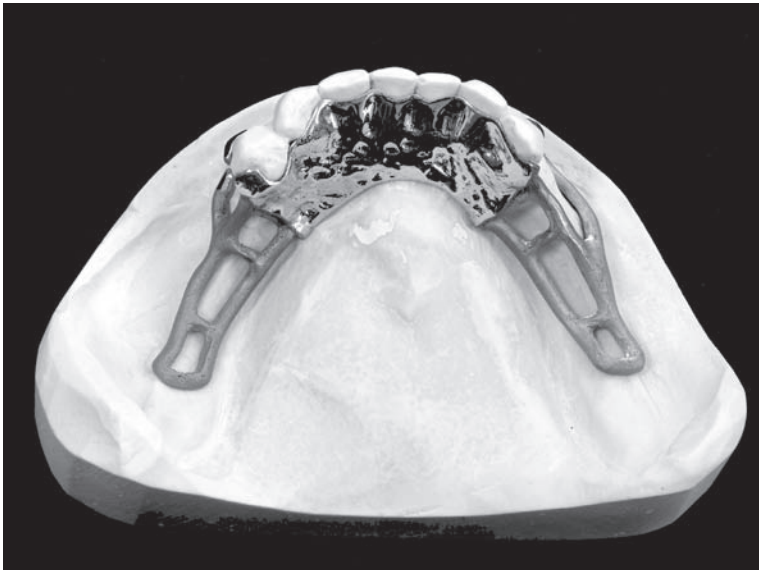
6.88 316L stainless steel RPD framework fitted to patient cast.

Second experiment

The same RPD framework design was manufactured using cobalt-chrome alloy using a layer thickness of 0.075 mm (Sandvik Osprey Ltd). The principal reason for attempting the design in cobalt-chrome was for direct comparison with traditionally made RPD frameworks, which are typically cast from the same material. Like the previous material, the SLM™ machine manufacturers have shown cobalt-chrome to be suitable for processing by SLM™. As before, the laser had a maximum scan speed of 300 mm/s with a beam diameter 0.150–0.200 mm. The material used was cobalt-chrome spherical powder with a maximum particle size of 0.045 mm (particle size range 0.005–0.045 mm) and a mean particle size of approximately 0.030 mm. The part proved successful and produced a complete cobalt-chrome RPD framework, shown in Fig. 6.89.

Step 4: finishing

Supporting structures were removed with a Dremel® hand-held power tool (Robert Bosch Tool Corporation, 4915 21st Street, Racine, WI 53406, USA) using a reinforced cutting wheel (Dremel, Reinforced Cutting Disc,

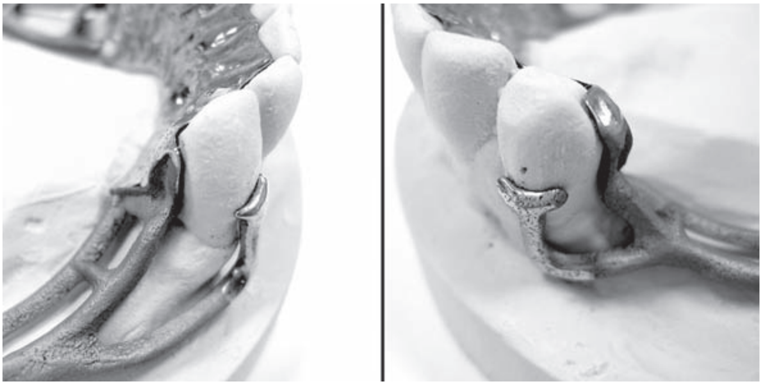


6.89 Cobalt-chrome RPD framework fitted to patient cast.

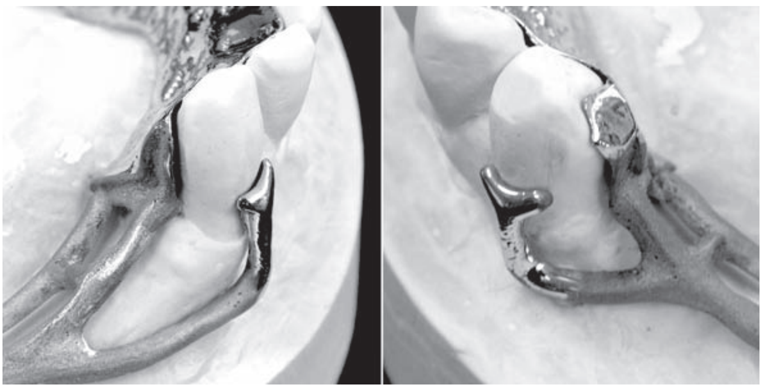
Ref. Number 426). The frameworks in their initial form were well formed but showed a fine surface roughness. This roughness was easily removed by bead blasting. This resulted in a framework that showed similar physical appearance and surface qualities as the investment cast items typically used in dental technology. Therefore, the treatment and finishing of the framework from that point onwards was conducted in the same manner as any other RPD framework, using normal dental laboratory techniques and equipment.

6.14.4 Results

The successful 316L stainless steel RPD framework was assessed for the quality of fit by fitting it to the plaster cast of the patient's oral anatomy. The quality of the fit was assessed according to normal dental practice by an experienced dental technician and found to be excellent. The frameworks showed a quality of fit that was comparable with investment cast frameworks. However, repeated insertion and removal from the patient cast resulted in small but permanent deformation of the clasp components. The clasp components are the functional parts of the framework and are designed to grip the teeth to provide a firm location of the denture (the clasps are the elements shown in the close up photographs in Fig. 6.90). Therefore, the permanent deformation reduces the ability of the framework to grip the teeth and the denture becomes loose. This meant that after



6.90 Close up views of the 316L stainless steel RPD framework fitted to patient cast.



6.91 Close up views of cobalt-chrome RPD framework fitted to patient cast.

several operations the clasps no longer held the framework as securely to the existing teeth as deemed necessary by the dental technician.

The cobalt-chrome RPD framework was complete, polished and finished well with the normal dental technology procedures. The framework proved to be an excellent fit, possessing good clasping when test fitted to the patient's cast (see Fig. 6.91). The framework was test fitted to the patient in the clinic and found to be a precise and comfortable fit with good retention, shown in Fig. 6.92. Therefore, the framework will be fitted with the artificial teeth and given to the patient to use in exactly the same manner as a traditionally manufactured item. Unlike the previous stainless steel framework, the clasping forces did not result in permanent deformation of

6.92 The framework fitted to the patient in clinic.

the clasps, and the framework withstood repeated insertion and removal cycles.

6.14.5 Discussion

Sources of error

Various studies have aimed to assess error in cobalt-chrome partial denture frameworks made using traditional investment casting techniques **(10, 11, 12)**. However, in the absence of an appropriate intra-oral scanning technology, the application of CAD/CAM in dental technology depends on the dental model, which is a plaster cast taken from an impression of the dental anatomy made by a dentist. Clearly, this study cannot address issues relating to the quality of the original dental impression or the casting of the dental model from this impression. In addition, human error in the interpretation of the dentist's instructions or in the dental technician's chosen design for the framework is not addressed. However, the adoption of CAD/CAM/RP technologies may incur several process steps that could contribute to error between the theoretical designs produced using CAD and the final manufactured item. The effect of these processes will be an accumulation of tolerances at each technology stage. However, certain levels of care and skill may still affect the accuracy of these computer-controlled techniques.

Table 6.2 shows the steps in the process investigated here and indicates nominal tolerances associated with the technologies used. The accumulation of tolerances leads to the maximum error that could be expected to result from the technologies alone, assuming no human error is encountered. As human skill level and error cannot be attributed a numerical value

Table 6.2 Process steps and associated tolerances

Process step	Source of error	Tolerance
Impression taking	Human / skill level	No value
Casting study model	Human / skill level	No value
Optical scanning of study model	Scanner	+/–0.050 mm
Creating Polygon computer model from point cloud data	Software setting	+/–0.050 mm
Import into CAD software	Software	0.000 mm
Design in CAD software	Software setting	+/–0.001 mm
Export of CAD data in STL file format	Software setting	+/–0.010 mm
Physical manufacture using SLM™	RP machine	+/–0.100 mm
Removal of RP pattern from machine, cleaning and support removal	Human / skill level	No value
Surface preparation and polishing	Human / skill level	No value
	Total	**+/–0.211 mm**

and might range from zero to complete failure, discussion is not included here. However, as this study aims to investigate the implications of adopting CAD/CAM/RP technologies in dental technology, it is appropriate to attempt to illustrate their potential contribution to error in the final RPD framework. The tolerances used in this table indicate typical or nominal figures, which are quoted by manufacturers or set as parameters in software.

From the processes stated in Table 6.2, it is reasonable to expect a tolerance of approximately 0.2 mm for these parts. It should be noted that cumulative negative and positive tolerances from the various steps might also partially cancel each other, resulting in a lower overall tolerance. The contribution of each individual step would be difficult to demonstrate without a statistically significant number of cases. The closeness of the fit and effective clasping observed when fitting the frameworks to the patient cast, as shown in Figs 6.90 and 6.91, suggest that SLM™ RPD frameworks are in fact within this tolerance.

Error analysis

RPD frameworks are by definition one-off custom-made appliances specifically designed and made to fit a single individual patient. In addition, the anatomically fitting nature of RPD frameworks means that they are complex in form and do not provide convenient datum or reference surfaces. This makes it difficult to achieve an investigation that provides detailed quantitative analysis of error. Therefore, it is not practical to perform the type of repeated statistical analysis that would be commonly encountered in series production or mass manufacture. Instead, it is normal dental practice to assess the accuracy of an RPD by test fitting the device to the patient cast and subsequently, in clinic, to the patient. In this study, the RPD frameworks created were deemed by a qualified and experienced dental technician to be a satisfactory fit and comparable to those produced by expert technicians, see Fig. 6.92. This suggests that the approach and technologies used are fit for purpose in this application although further experiments with a range of patients with differing RPD designs will be required to ensure that this is in fact the general case.

6.14.6 Conclusions

SLM™ has been shown to be a viable RM method for the direct manufacture of RPD metal alloy frameworks. Parts produced using the SLM™ process in conjunction with cobalt-chrome alloy result in RPD frameworks that are comparable in terms of accuracy, quality of fit and function to the existing methods typically used in the dental technology laboratory. The computer-aided design and manufacture approach offers potential advantages in terms of reduced inter-operator variability, repeatability, speed and economy over traditional handcrafting and investment casting techniques.

6.14.7 References

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RESEARCH APPLICATIONS

6.15 Research applications case study 1: Bone structure models using stereolithography

6.15.1 Acknowledgements

The work described in this case study was first reported in the reference below and is reproduced here in part or in full with the permission of MCP UP Ltd.

- Bibb R, Sisias G, 2002, 'Bone structure models using stereolithography: a technical note', *Rapid Prototyping Journal*, **8** (1), 25–29.

6.15.2 Introduction

In order to further the understanding of osteoporosis and its dependence upon the material and structural properties of cancellous bone, many experimental studies continue to be undertaken on natural tissue samples obtained from human subjects and animals. However, a significant difficulty in analysing *in vitro* bone samples is that the structural parameters have to be elucidated by destructive means. In addition, the human *in vitro* samples most readily available tend to be from an elderly population and, therefore, may be of limited structural variation compared to the full population age range. The development of a physical model of cancellous bone whose structure could be controlled would provide significant advantages over the study of *in vitro* samples. This would also enable the relationship between the mechanical integrity and hence fracture risk of cancellous bone and its structural properties to be more exactly defined.

This study describes how these complex three-dimensional structures can be physically reproduced using rapid prototyping (RP) techniques. As the study will show, although use of RP techniques allows the generation of physical objects that would have previously been impossible to manufacture, problems are still encountered. The data, generated from micro-computed tomography, was used to perform finite element analysis (FEA) on the structure of various human and animal bones. The physical models were required to validate the results of the FEA.

The difficulties encountered in creating physical models of these structures arose from the nature of the structure. Not only does the highly complex porous structure result in extremely large computer files but it also presents problems of support during the build process.

6.15.3 Human sample data

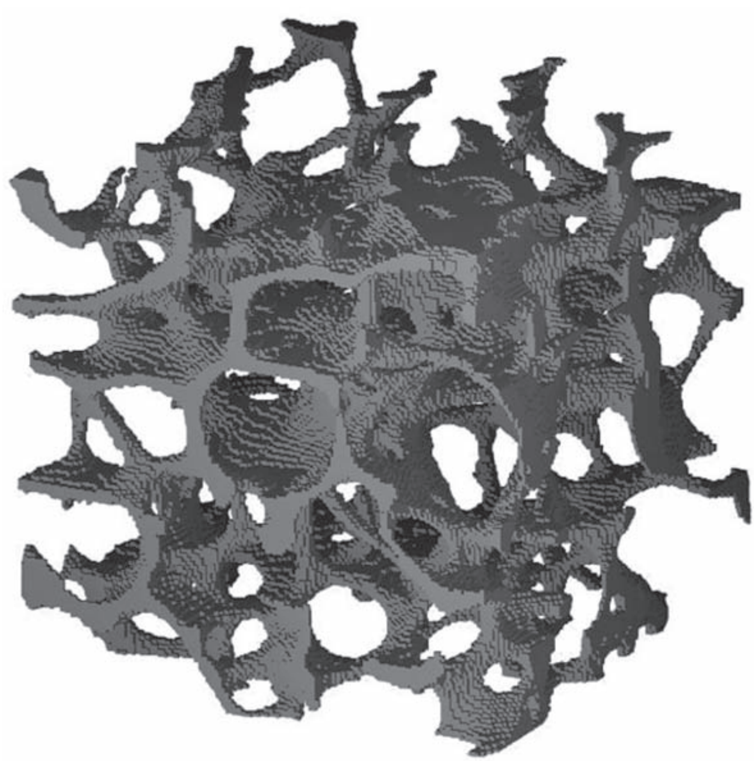
The techniques of serial sectioning and micro-computed tomography (μCT) reconstruction were used to obtain three-dimensional reconstructions of *in vitro* samples of natural cancellous bone tissue. The physical size of each sample is approximately 4 mm × 4 mm × 4 mm and their relative densities are 9–25 %. The models were to be scaled up by an approximate factor of ten and physically produced using RP. The considerable effort that went in to generating the data from which these models would be made is described elsewhere **(1)**.

6.15.4 The use of stereolithography in the study of cancellous bone

For this project, stereolithography (SL) was the preferred method for several essential reasons. Firstly, it is capable of building models at an exact layer thickness of 0.1 mm. This was desirable as the FEA was generated from voxel data with a voxel size of 0.1 mm. Therefore, the SL model would replicate the FEA mesh exactly, i.e. with no smoothing between the layers or within the plane of each slice. Secondly, it is the most accurate method available (except Solidscape machines, but this would have been extremely slow and the models would have proved far too delicate to mechanically test). Thirdly, although Selective Laser Sintering (SLS® – 3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA) and three-dimensional printing had the advantage of not requiring support structures the finished models are not completely dense or sufficiently accurate. Fused Deposition Modelling (FDM™ – Stratasys Inc., 14950 Mantin Drive, Eden Prairie, MN 55344-2020, USA) parts can also show a small degree of porosity and are unable to match the accuracy desired in this case. However, since these models were built, the water-soluble supports that are now available for FDM™ would prove extremely useful for structures such as these. Finally, and most importantly, stereolithography could be used to generate models from slice data rather than triangular faceted data. The intention was to use the SLC file format as it resulted in dramatically smaller files than the same data generated in the STL file format. A general description of all of these RP technologies can be found in Chapter 5. For a general description of the SLC, STL and SLI data formats see Chapter 4.

6.15.5 Single human bone sample (approximately 45 mm cube)

Due to initial problems with the SLC data files the first single model was built from an STL file, see Fig. 6.93. This was attempted to test the general capability of stereolithography to manufacture these forms. Although the STL file was much larger than the equivalent SLC file, as the model was small it was still a feasible option. However, the standard procedures for generating supports were simply not suitable as the software automatically attempts to support all of the down-facing areas of the model. This resulted in over long processing times and a vast number of supports with a correspondingly large support STL file. In addition, the nature of the structure would make it extremely difficult to remove supports from the innermost areas of the model. (Note: This model was constructed before fine-point

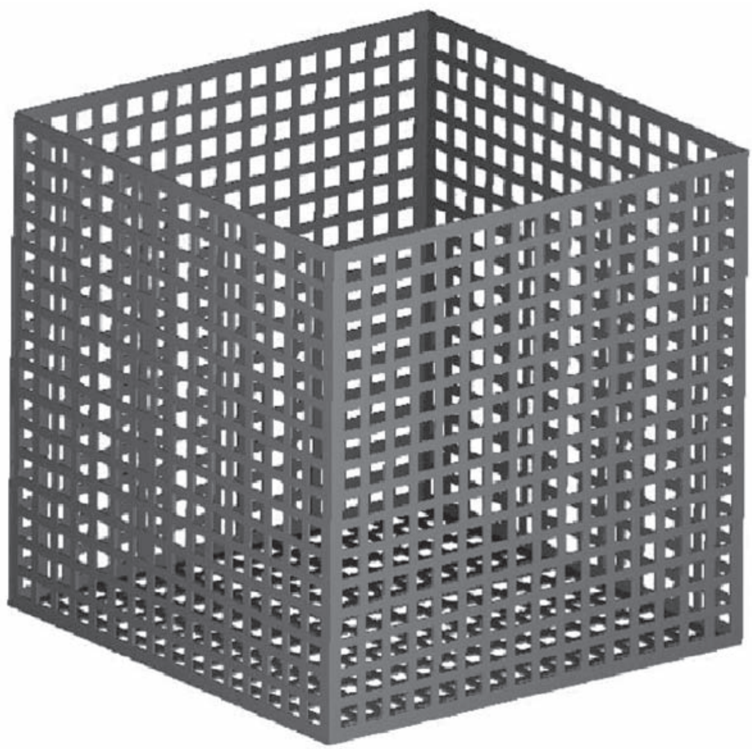


6.93 STL file of the first sample.

supports became available. Although they would have been an improvement in this respect, they would still have resulted in an excessive number of supports with an even larger support STL file.)

To avoid these problems, a novel strategy for producing the necessary support was attempted. The approach was based on two fundamental assumptions. Firstly, as bone is a naturally occurring, load bearing structure it is made up of self-supporting arches. Therefore, the structure should, in theory, support itself except for the sides of the model where the structure has been sliced through. The second assumption was that the open spaces would all be inter-communicating and, therefore, there would be no 'trapped volumes' (a recognised problem in stereolithography).

As automatically generated supports were impractical, a very thin crate was designed using CAD that would support the sides and base of the model yet still allow good draining, see Fig. 6.94. This is necessary to avoid the 'trapped volume' effect that adversely affects the stereolithography process. The crate was then exported as an STL file. Curtain support structures were then automatically generated (using 3D Lightyear™, 3D Systems



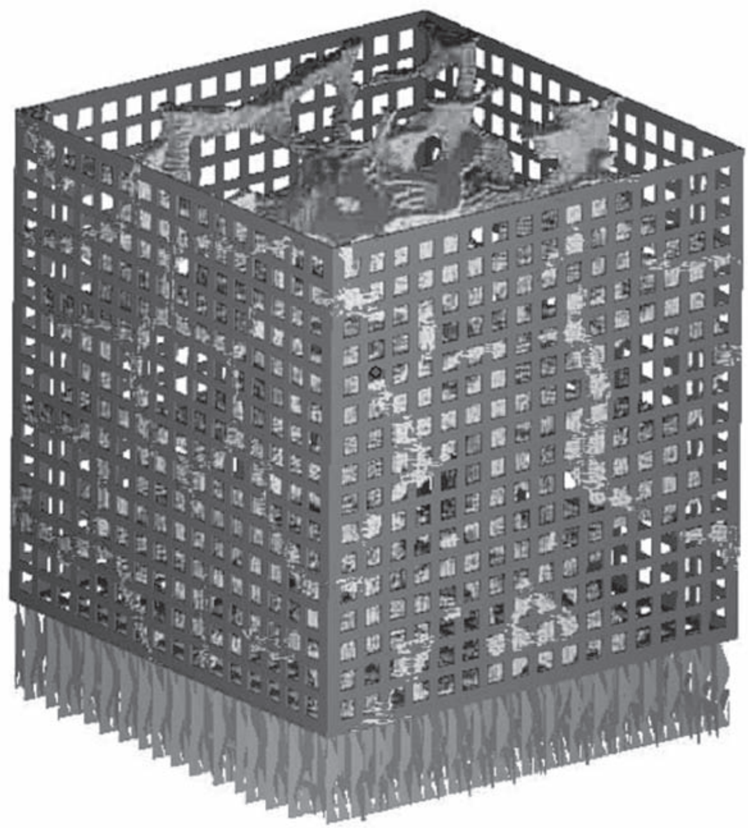
6.94 The crate structure.

Inc.) for the crate only in order to separate the whole build from the platform. This combination can be seen in Fig. 6.95. The objects were then prepared for stereolithography in the usual manner and built on a SLA-250 using SL5220 resin.

The model was built successfully, suggesting that the fundamental assumptions regarding the self-supporting and self-draining nature of the object were indeed sound. The crate structure was carefully broken away along with the supports using a scalpel.

6.15.6 Multiple human samples (approximately 50 mm cube)

For the second batch, five copies each of five types of model were required. The STL approach was not feasible due to the incredibly excessive size of the files. Instead, contour files were generated from the original data in the SLC file format.



6.95 Sample, supports and crate.

However, the problem of how to support the sides and base was encountered again. Although automatic support software is available to generate supports for SLC files, it presented exactly the same problems as the previous attempt. To create minimal supports, a combination of two approaches was used. The first involved the use of C-Sup to generate supports automatically that would separate the bottom of the model from the build platform. These supports were automatically generated to end just above the bottom of the part as it was again assumed that the internal structure of the model would be self-supporting. To support the sides, the crate structure was used again (minus the bottom). Automatic support-generation software was then used to create supports that would separate the crate from the build platform. The STL files of these structures were then converted into the SLC format (using Magics, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium). This resulted in four SLC files that could be prepared for the stereolithography process. These are not shown here, as the files are only contours and therefore cannot be rendered and viewed from an angle.

However, this was not a simple task to achieve. The first problem was encountered when arranging the items in the correct positions for part building due to the use of the SLC format. The SLC file is essentially the contours of the model at the layer thickness intended to build the model. Therefore, it has to be generated in the correct position and orientation relative to the z-axis. Once generated, the files cannot be repositioned or rotated relative to the z-axis. Initially this was overlooked resulting in corrupt SLC files after repositioning. Therefore, the SLC generation code was re-written to create the first contour and 8 mm in z height to allow room for support structures.

The second, more fundamental and difficult, problem was discovered with the software that generated the bone structure SLC files. The SLC files created were invalid and were not recognised by current stereolithography software (3D Lightyear™). However, no error files are generated by 3D Lightyear™ and so it was impossible to ascertain the nature of the problem. When using the obsolete Maestro software (3D Systems Inc.), the SLC files were again found invalid but error message files were generated. Reading these error messages showed that the orientation of the contours was incorrect. Crucially, when attempting to prepare a build using these SLC files Maestro was able to re-orient them, resulting in valid slice files in the SLI format. These error messages also highlighted the fact that the final layer had zero thickness. Although Maestro was unable to correct this error automatically, once it had been discovered it was a relatively simple matter to correct the code.

The reason that the SLC files were invalid in 3D Lightyear™ is that they were generated according to an obsolete specification from 3D Systems.

This means that they are not recognised by current 3D Systems software releases. A similar issue can be found when attempting to use SLI files generated by CTM (a module of Mimics, Materialise NV), which are also not recognised by Lightyear™. This effectively renders the SLI export option of CTM redundant unless the user is prepared to maintain and use Maestro. This is an important point as the ability to move from CT or MR data directly to the SLI format represents by far the most efficient route to a stereolithography build.

Given the fact that Maestro is old software, running on obsolete UNIX hardware, the SLC files took an incredibly long time to prepare (approximately three days). To reduce the file size requirement, four types of model were prepared in a line that would fit across the width of the SLA-250 build platform. Once generated, this vector file was then copied four times at the SLA machine. This method does not increase the size of the vector file but offsets the whole set and repeats it. This enabled us to complete 16 models without creating an unnecessarily large vector file. Even after taking these steps, the vector file was large and the build took approximately 65 hours using SL5220 resin. A second build was implemented along the same lines to produce the remaining models of the 25 required.

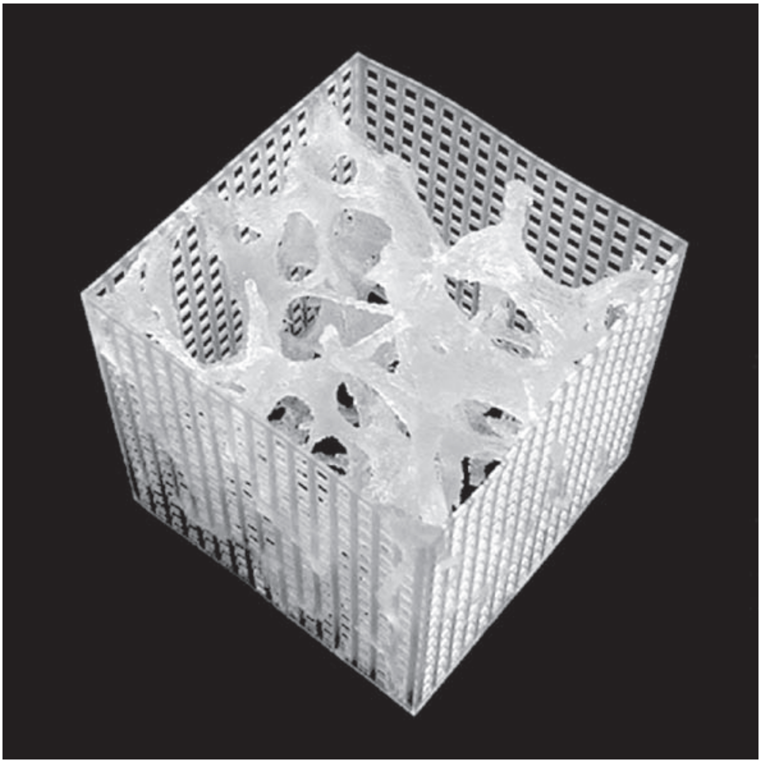
An example of one of the models with its supporting crate is shown in Fig. 6.96. Due to the extremely delicate nature of the models, they were painstakingly hand finished using scalpels to remove the supporting structures without causing damage. This was complicated by the inability to familiarise the technicians with the models because it is not possible generate three-dimensional rendered views of SLC data. One of the finished models is shown in Fig. 6.97.

6.15.7 Conclusion

Issues caused by RP software made these items a particular challenge to the application of stereolithography. The machine operators' complete dependence on the preparation software that is supplied with the machine presents two main reasons behind the difficulties.

Firstly, as RP develops and improves, the software is increasingly designed to automate as many functions as possible. This is intended to improve the ease and speed of use in the commercial environment. However, this increasing level of automation reduces accessibility to variables and parameters, removing many options from the expert user, particularly those in the research community. In this case, typical semi-automated methods for support generation would have proved utterly impractical for the nature of these objects.

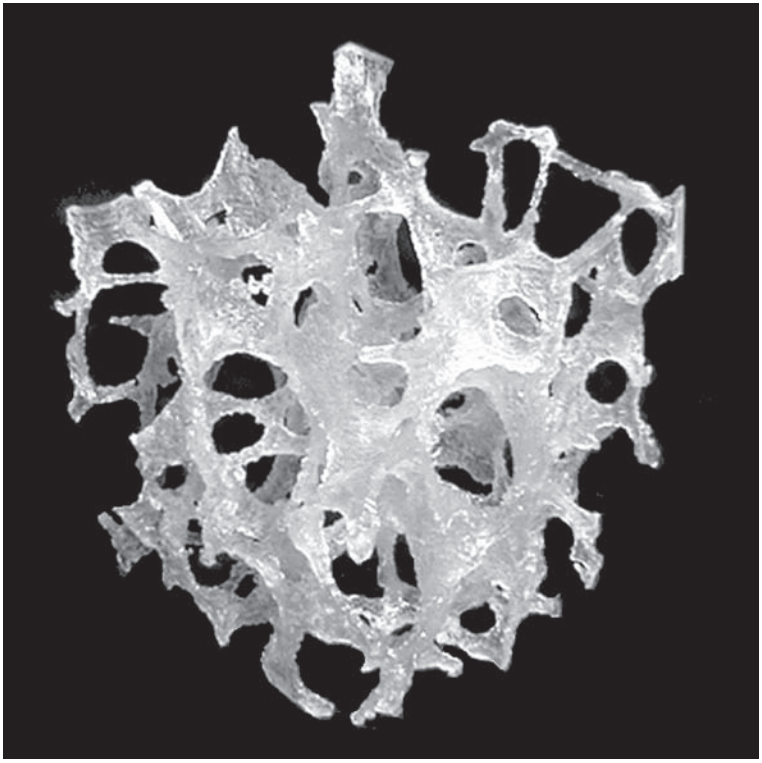
The second issue is the industry's concentration on the STL file format and complete neglect of $2^1/_2$D alternatives. As this case in particular shows,



6.96 Model of one of the samples supported by the crate.

contour-based formats can be dramatically more efficient. However, current stereolithography users have no functions within the preparation software (3D Lightyear™) for the verification, translation and orientation or crucially support generation of contour formats, specifically the SLC. This is despite the fact that the necessary code for each of these functions exists elsewhere (C-Sup, VerSLC).

These problems meant that to successfully build these models necessitated the utilisation and combination of several different pieces of software where appropriate and a thorough understanding of the stereolithography process. Objects that appear unfeasible for the standard practices of STL file and automatic support generation may in fact be perfectly possible if they are considered carefully (there is always more than one way around a problem). For example, these models were made possible because (1) the nature of the objects suggested that they would form self-supporting and self-draining structures in the inner volume and (2) the SLC file format was used.



6.97 Final cleaned model of one of the samples.

As building these models has shown, seemingly obsolete software may still posses a level of accessibility that is extremely useful to the expert user, especially in research. Consequently, for many researchers in this field it is advisable to maintain copies of superseded RP software.

6.15.8 Software

- C-Sup – a module of Mimics Version 7.0, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium, 2001.
- 3D Lightyear™ version 1.1 – Advanced User License, 3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA, 2000.
- VerSLC, 3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA, 1993.
- Maestro version 1.9.1, 3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA, 1996.
- Slicer – a module of Magics version 6.3, Materialise NV, Technologielaan 15, 3001 Leuven, Belgium, 2000.

6.15.9 Reference

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6.16 Research applications case study 2: Producing physical models from CT scans of ancient Egyptian mummies

6.16.1 Acknowledgements

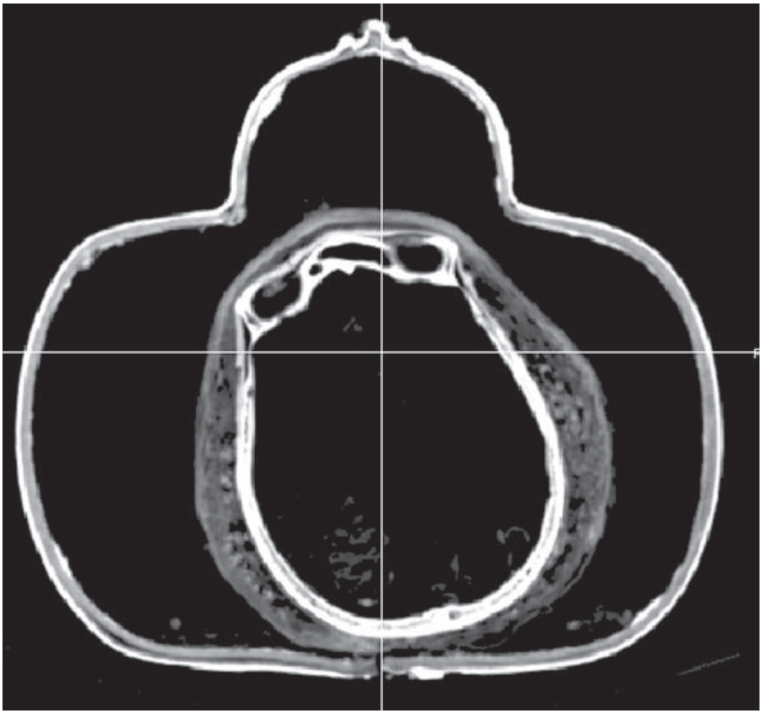
This case study is based on a project conducted in collaboration with Dr John Taylor, Assistant Keeper at the Department of Ancient Egypt & Sudan. The 'Jeni' project was performed on CT data acquired in 1993 by Clive Baldock, Reg Davies, Ajit Sofat, Stephen Hughes and John Taylor (British Museum). The CT data was gratefully obtained from Stephen Hughes via the Internet. The Nespurennub project was conducted on CT scans acquired at the National Hospital for Neurology and Neurosurgery, London. The facial reconstruction work was undertaken by Dr Caroline Wilkinson at the Unit of Art in Medicine, The University of Manchester.

Figure 6.98 is reproduced from Taylor JH, 'Mummy: the inside story', 2004 with the permission of the Trustees of the British Museum and Dr Caroline Wilkinson, University of Manchester.

6.16.2 Introduction

The development of computed tomography (CT) has allowed archaeologists to gain access to the internal details of mummies without destroying the cartonnage cases or disturbing the wrappings and remains. This non-destructive investigation has proved very successful, and several investigations have been conducted in this way at various locations in the world, improving with advances in CT technology **(1–5)**. These scans have given archaeologists and forensic experts many insights into the condition of the remains and provided additional evidence relating to Egyptian funerary practice and the health of the individual. Figure 6.98 shows an axial CT slice of a mummy.

PDR, the Department of Ancient Egypt and Sudan at the British Museum and the Unit of Art in Medicine at Manchester University have formed a long-term relationship exploring the non-invasive investigation and reconstruction of ancient Egyptian mummies. The first of two mummies investigated, called Tjentmutengebtiu ('Jeni' for short), was the subject of X-ray investigation in the 1960s **(6)** and subsequent investigation by CT scan more



6.98 Axial CT image of 'Jeni'.

recently in 1993 **(7)**. The second mummy, called Nesperennub, had also undergone previous X-ray investigation. However, this mummy was recently scanned to capture better data. This CT data, specifically the series of scans of the head, was used in these studies. Both mummies belong to the British Museum.

The aim of this work was to go a step beyond viewing two-dimensional images of the mummies and to use the data to manufacture precise physical replicas of the mummies' skulls. This would allow the skulls to be investigated and handled at will without causing any damage to the original priceless remains. Facial reconstructions could also then be performed on the models. The more recent Nesperennub case was used for investigation into the cause of death, reconstruction of the facial features and other artefacts of interest for a major new exhibition at the British Museum called 'Mummy: the inside story'.

6.16.3 Technology

A range of advanced computer software and rapid prototyping hardware was required to achieve accurate digital and physical models of the two mummies. Mimics software (Materialise NV, Technologielaan 15, 3001 Leuven, Belgium) was instrumental in importing, segmenting, cleaning and outputting the required files in order to produce the three-dimensional model files for visualisation and manufacture. The physical models of the skulls were produced by stereolithography **(8)**. Stereolithography is increasingly used to produce models of patients with many medical conditions and has subsequently been applied to other archaeological and palaeontological remains **(9–11)**. Stereolithography and Laminated Object Manufacture (LOM™ – see Section 5.8) were used to reproduce physical models of some objects that were wrapped up with the mummy.

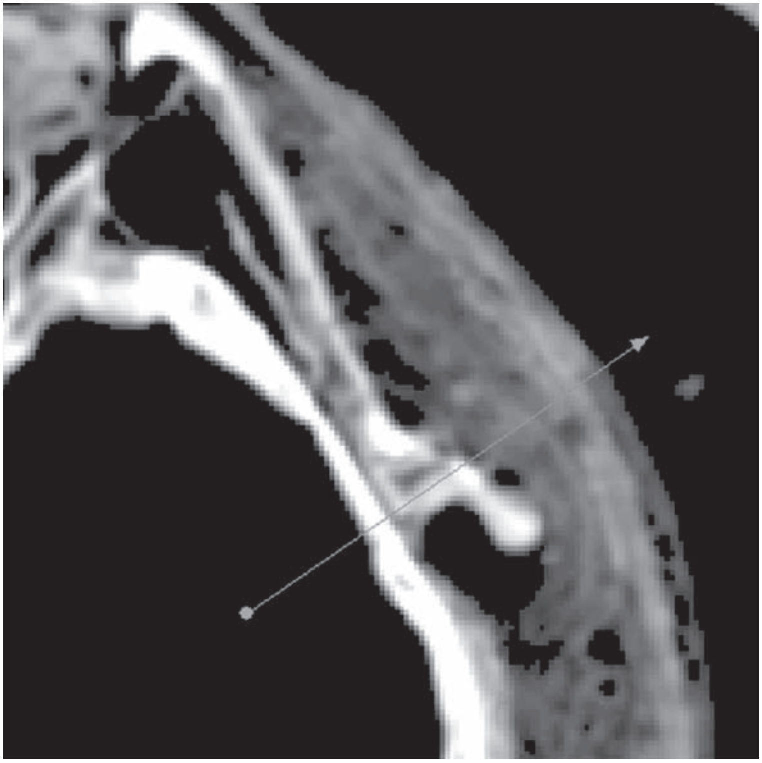
6.16.4 Case study

Mimics software is typically used in medicine to segment CT data to isolate the tissue of interest. Frequently the tissue of interest is bone. This is accomplished by using the 'threshold' functions to select the appropriate limits of density and the numerous editing and segmentation tools to make adjustments to ensure the desired bone structures are isolated.

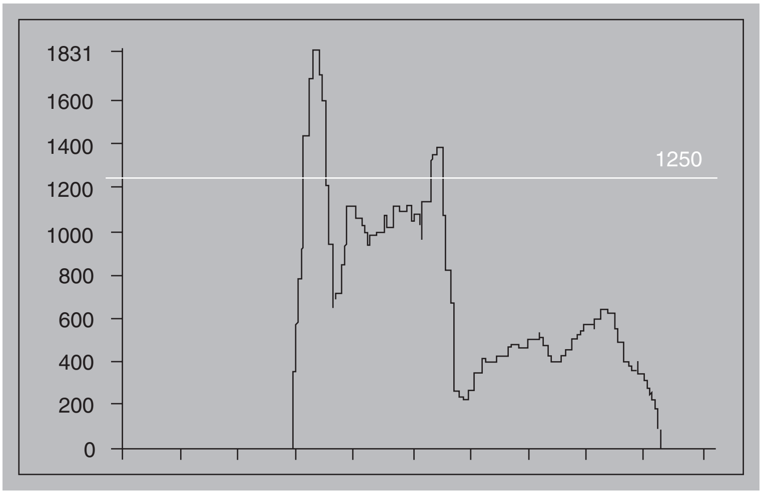
In contrast, when attempting the first case, 'Jeni', a number of challenges made accurate reconstruction of the bony anatomy extremely challenging. In living patients, the difference in density between bone and the adjacent soft tissues is quite marked. This allows the segmentation of bone to be performed relatively easily. However, in these ancient Egyptian mummy cases, all of the soft tissues were completely desiccated by the mummification process. This resulted in the soft tissue remains having an artificially high density compared to the remaining bone (see Figs 6.99 and 6.100).

This effect is confounded by the demineralisation of some bone structures, also resulting from the mummification process. Therefore, performing the segmentation by density-threshold only results in a poor three-dimensional reconstruction. It loses some data from the skull whilst including unwanted elements of desiccated soft tissue. This effect can be seen in the reconstruction on the left of Fig. 6.101.

In previous image reconstructions, higher thresholds had been used to try to eliminate some of the desiccated soft tissue remains. Although this improves matters, it results in the loss of low-density bone structures whilst some soft-tissue structures remain. In addition, the high-density artificial objects also remained present in the eyes, mouth and neck. To produce a model of the skull from this data would have resulted in gaps in the surface of the skull and the absence of some of the more delicate bone structures. For example, gaps could be seen in the temporal bone and zygoma (cheekbones), and the soft tissue of the ears is still present. As facial reconstruction depends on imposing known depths of soft tissue on to the facial bones, these defects would make the whole process more difficult and less reliable.



6.99 Profile through the skull and ear of 'Jeni'.



6.100 Graph of density through the profile.

6.101 3D reconstruction of data segmented by the standard threshold for bone (left) and the manually edited data (right).

To improve the data describing the surface of the facial bones required the extensive use of the manual editing tools in Mimics. Some areas were improved by using the local 'Thresholding tools' within the Edit tools in Mimics. This allowed small areas to be selected according to higher or lower densities without affecting the overall segmentation. However, specific areas have to be edited manually using the Edit tools to delete data relating to soft tissue and draw in data relating to bone. The flexibility of these editing tools combined with good anatomical knowledge resulted in accurate segmentation of the skull. Although this was quite time consuming, the improved results are well worth the effort and would ensure that the subsequent facial reconstruction was carried out on the best model possible.

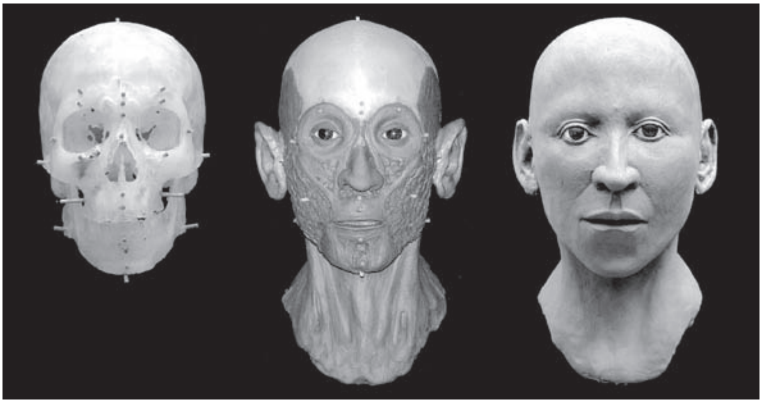
The inner surfaces of the skulls were more easily identified because the brains had been removed as part of the mummification process. However, other areas proved much more difficult to pick out from the surrounding tissue. This was especially the case in the mouth, palate and nasal cavities where desiccated soft tissue remained in place. The nose also posed problems due to the presence of cartilage and the fact that the nasal bones were broken and displaced. Again, this damage resulted from the mummification process.

The three-dimensional reconstruction functions of Mimics were used to assess the quality of the segmentation on screen. Finally, the highest quality three-dimensional reconstructions were created to check the data before building the models. The final reconstruction can bee seen on the right of Fig. 6.101.

Once we were satisfied that we had a good segmentation of the skull, the data was prepared for model building using stereolithography. The RP Slice module of Mimics was used to generate SLC files of the skulls. The RP Slice module was then also used to create the necessary supports, also in the SLC format. This direct interface to a layer format suitable for stereolithography results in smaller file sizes whilst retaining excellent detail and accuracy. In addition, the single support file generated proves simpler to process and subsequently easier to remove from the model when compared with alternative formats. The skull models produced provided Caroline Wilkinson at the Unit of Art in Medicine at Manchester with a sound basis for the facial reconstructions as shown in Figs 6.102 and 6.103 **(12)**.

With the Nesperennub case, the STL+ module of Mimics was also used to export the skull data as an STL file. The availability of a high quality STL file enabled Caroline to attempt a digital facial reconstruction using a sophisticated virtual sculpture system **(13)**.

6.102 ‘Jeni’ stereolithography model.

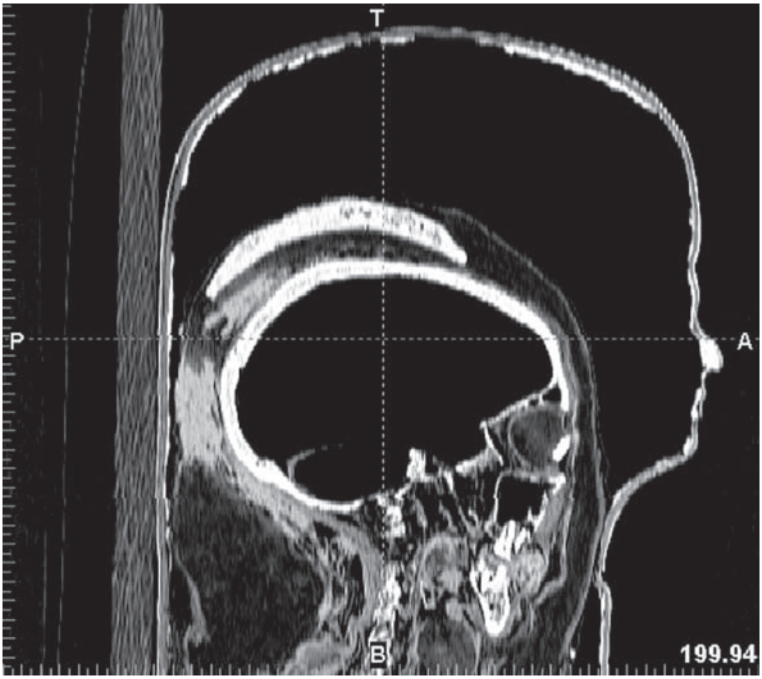


6.103 The stages of facial reconstruction on the Nesperennub stereolithography model.

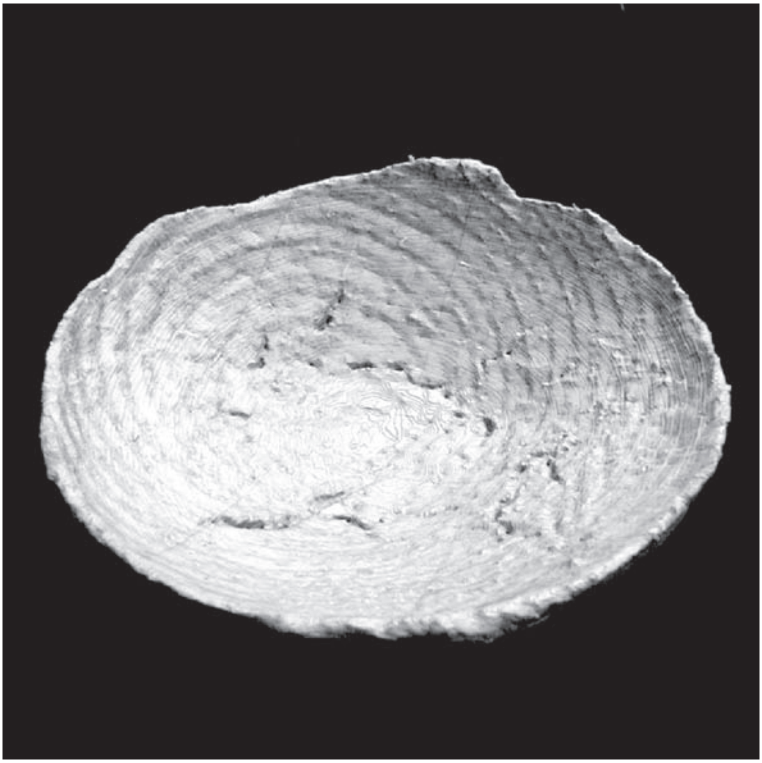
The Nesperennub CT data also showed a number of other articles of interest that had been wrapped up with the mummy. These included objects found in some other mummies of the period, a snake amulet on the forehead and artificial eyes in the sockets. Uniquely Nesperennub also appeared to have a bowl on top of his head (see Fig. 6.104). The British Museum was very keen to have replicas of these objects for use in the exhibition.

Mimics was used to segment the data describing these objects so that they could be made using RP techniques. The artificial eyes and snake amulet appeared to have high densities and were, therefore, relatively easy to threshold and segment from their surroundings. However, the bowl proved more difficult as the density was quite high but similar to bone and in close contact with the head in some areas. Therefore, the bowl was segmented using the same approach used for the skulls. The bowl was of particular interest as it had never been seen in a mummy before and nobody was quite sure what its function was.

The STL+ module of Mimics was used to generate STL files of the objects that were made by RP. The snake amulet and eyes were made using stereolithography and the bowl was made using LOM™ (see Fig. 6.105). The model of the bowl was used to help museum staff to identify the object and speculate as to how it came to be in the mummy's wrappings. Handling and inspecting the bowl led them to the conclusion that it was a simple unfired clay bowl that was probably used to hold the resin used in the mummification process. It had probably become glued to Nesperennub's head by accident during the mummification process and was simply covered up to hide the mistake. The bowl model was also used in a film reconstructing the mummification process, which is shown as part of the exhibition. The amulet, eyes and bowl are now on display in the exhibition.



6.104 A sagittal CT image of Nesperennub.



6.105 The LOM™ model of the bowl.

6.16.5 Conclusions

> 'The exhibition at the British Museum has proved a great success, attracting 388000 visitors. Since the mummy has never been unwrapped, the models of the skull, bowl and amulets are key elements in the display, providing an essential complement to the non-invasive images obtained from CT scans. The models have also been used successfully at the museum in handling sessions for visually impaired visitors.'

Quote by Dr John Taylor, Assistant Keeper at the Department of Ancient Egypt & Sudan, The British Museum.

6.16.6 References

The Nesperennub case was shown in the major exhibition 'Mummy: the inside story' at the British Museum, London and described in the accompanying book of the same name by Dr John Taylor **(14)** and featured in a TV documentary shown in the UK on Channel 5.

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6.17 Research applications case study 3: Recreating skin texture relief using computer-aided design and rapid prototyping

6.17.1 Acknowledgements

The work described in this case study was written by Dominic Eggbeer, Peter Evans and Richard Bibb as part of the long-term collaboration between the National Centre for Product Design & Development Research, University of Wales Institute, Cardiff, UK and the Maxillofacial Unit, Morriston Hospital, Swansea, UK.

6.17.2 Introduction

Maxillofacial prosthetists and technologists (MPTs) seek to meet the needs of patients with various degrees of facial deformity by restoring aesthetic and functional portions of missing tissue using artificial materials. Prosthetic restoration of lost tissue precedes surgical reconstruction and, despite recent advances in surgery, many cases remain where prosthetic rehabilitation is a more appropriate treatment **(1)**. Patients typically suffer from conditions resulting from traumatic injury (such as road traffic accidents), congenital deformity or diseases that cause significant tissue damage such as cancer.

Factors that contribute to the aesthetic success of prostheses include skin colour match, appropriate contours and realistic texture **(2)**. The MPTs who create the prostheses attempt to address these factors, which are conventionally assessed by eye and carved by hand in wax on a plaster replica of the patient's defect. Firstly, the external and fitting surfaces are shaped so that the contours of the prosthesis are established. This is often done with the patient present for test fittings. The detail is gradually refined using sculpting tools to define features, creases, folds and smaller skin details that recreate missing anatomy (perhaps using old photographs as a guide) and that match the topography of the surrounding anatomy.

In order to create a more realistic appearance for the prosthesis skin texture may be added. This can be achieved in a variety of techniques, such as stippling with a stiff brush or taking an impression from orange peel or gauze. Conversely, a flame torch may be used to locally melt or soften the wax in order to selectively smooth areas or decrease the prominence of textures and bumps. When the wax sculpting is complete, a plaster mould is made from it. The mould surface picks up the texture and detail of the wax carving. Once the plaster mould is set, the wax is melted out and the mould is packed with silicone elastomer that has been matched to the patient's skin colour. Other details may be added at this stage such as the use of red rayon fibres that replicate superficial capillaries and veins. The silicone is heated under pressure to produce the final solid but flexible prosthesis. Depending on the complexity and size of the prosthesis, this process may take two to three days.

Improved surgical and medical techniques have led to improved survival rates from accidents and cancer treatments, which has in turn led to an increased workload for MPTs. This has driven growing interest in the application of advanced computer-aided design and manufacturing technologies. Technologies such as computer-aided design (CAD) and rapid prototyping (RP) have shown benefits in reducing time and labour in product design and development, and initial research suggests that similar benefits may be realised in the production of facial prosthetics. However, whilst some RP technologies have been successfully exploited in maxillofacial surgery for many years, their application in facial prosthetics remains relatively unexplored **(3)**. Recent technological advances have increased opportunities for MPTs to benefit from these technologies, and this can be seen in the recent research **(4–12)**. Despite this interest and some promising results, most of this research has focused on the creation of the overall shape of the prosthesis and has not considered the importance of the smaller details that make a prosthesis visually convincing. Given the importance of details such as texture and wrinkles in achieving a natural and realistic result, it was important to explore the problem through the study described here.

This research aimed to identify and assess suitable technologies that may be used to create and produce fine textures and wrinkles that may be conveniently incorporated into prosthesis design and production techniques.

6.17.3 A definition of skin texture

Visible skin texture may be classified according to the orientation and depth of the lines **(13)**. Primary and secondary lines form a pattern on the skin surface and are only noticeable on close observation. They typically form a polygon pattern ranging from 20–200 μm in depth **(14)**. The back of the hand often shows a good example. It has been suggested that the term 'wrinkle' should apply when an extension of the skin perpendicular to the axis of the skin surface change leaves a marked line representing the bottom of the wrinkle **(13)**. Further, an assessment scale that was subsequently used to assess and quantify deep facial wrinkles has been developed by Lemperle *et al.* **(15)**. Wrinkles from various facial locations were subjectively graded from 0–5 by dermatologists. 0 was described as no wrinkles and 5 very deep wrinkles, redundant folds. Following the visual grading, the wrinkles were then measured using profilometry and the results correlated. This produced a graded wrinkle scale table with associated depth of wrinkle values for the various facial locations. Using this scale, a nasolabial wrinkle (side of the nose) with a grading of 1 would correlate to a wrinkle depth of less than 0.2 mm and a grading 5 would be greater than 0.81 mm in depth. This varied with other facial locations with the minimum measured depth being 0.06 mm and maximum 0.94 mm. The proposed margins on the scale ranged from >0.1 mm to <0.81 mm.

6.17.4 Identification of suitable technologies

Specification requirements

Based upon the rating scale developed by Lemperle *et al.* **(15)**, potential digital technologies must be capable of creating and reproducing wrinkle and texture details with a minimum depth of 0.1 mm. The CAD software used must be capable of creating and manipulating complex anatomical forms and the RP process capable of producing parts or patterns to this resolution in a material compatible with current prosthetic methods **(8, 11, 12)**.

Computer representation and manipulation of skin textures

Three-dimensional CAD packages have traditionally been developed for two main markets, engineering design and computer gaming/animation. Engineering CAD has been developed to define exact shapes using mathematical geometry (lines, arcs, circles, squares, etc). Relatively complex surfaces may be generated, for example the surfaces of cars, but the mathematical geometry used is aimed towards smooth flowing surfaces and limits the ability to define the levels of contouring, such as creases, folds and sharp radii required to represent anatomical forms and textures. In fact, in applications such as automotive and aerospace design it is highly desirable to avoid unwanted creases in the surfaces being created. Software aimed towards three-dimensional computer gaming and animation, such as 3dsMax® (Discreet-AutoDesk Inc., 10 Duke Street, Montreal, Quebec, H3C 2L7, Canada) exhibits many of the same limitations as engineering CAD, but typically allows a greater freedom for surface manipulation. As these objects are not actually physically produced, as long as the visual effect on the screen is convincing there is no need to go further in terms of detail. The textures that appear on these animations and games are normally represented by two-dimensional images that are 'wrapped' around the object. This creates an illusion of texture rather than true three-dimensional relief. Therefore, for the purposes of prosthesis manufacture, this wrapped texture cannot be used, because it cannot be physically reproduced using RP techniques.

Recently, methods of true three-dimensional texture creation have been explored **(18)**. The application of textures has been applied in the jewellery industry and software such as ArtCAM™ (Delcam plc, Small Heath Business Park, Birmingham, B10 0HJ, UK) incorporate tools to map three-dimensional textures around a CAD model **(18)**. However, ArtCAM™ and other jewellery design software construct their shapes in the same manner as engineering CAD and are, therefore, not suited to the representation and manipulation of anatomical forms. Recent developments in CAD software have led to design packages that offer a more intuitive and freehand interface to the design process. Software such as ZBrush® (Pixologic Inc., 320 West 31st Street, Los Angeles, CA 90007, USA) and FreeForm® (SensAble Technologies Inc., 15 Constitution Way, Woburn, MA 01801, USA) may provide a CAD environment that is more analogous to sculpting by hand which clearly is more appropriate to the design and manufacture of a facial prosthesis. Both FreeForm® and ZBrush® allow complex three-dimensional forms to be manipulated and given high-resolution textures in a freehand manner. FreeForm® has been shown to be suitable for facial prosthesis design in previous research **(8, 11, 12)**. In addition, the haptic interface between the user and FreeForm® software allows shapes to be manipulated in ways that more closely mimic the hand carving techniques used in conventional prosthesis sculpting. Also, FreeForm® has a number of functions that can create relief on a model surface derived from a two-dimensional image.

RP reproduction of skin textures

RP offers the most suitable solution to the production of a prosthesis or pattern from CAD data **(11, 12)**. Computer numerically controlled (CNC) machining has also been used to create textures **(18)**, but is not as well adapted to create fitting and undercut surfaces and is also limited by suitable material choice (machining of soft flexible materials is difficult). CNC becomes very slow when creating intricate or small scale detail such as textures and requires a cutting tool with a very small diameter. A review of the currently available RP technologies highlights a number of technologies that are capable of creating the level of detail required to reproduce realistic skin textures. A critical parameter in order to achieve the level of detail required is the layer thickness that the RP system uses. To achieve the level of detail identified above, a layer thickness of below 0.1 mm is necessary. Currently available RP technologies that can achieve a layer thickness of below 0.1 mm include:

- ThermoJet® wax printing (3D Systems Inc., 26081 Avenue Hall, Valencia, CA 91355, USA);
- Perfactory® digital light processing (EnvisionTEC GmbH, Elbestrasse 10, D-45768 Marl, Germany);
- Solidscape wax printing (Solidscape Inc., 316 Daniel Webster Highway, Merrimack, NH 03054-4115, USA);
- Objet PolyJet™ modelling (Objet Geometries Ltd, 2 Holzman St, Science Park, PO Box 2496, Rehovot 76124, Israel);
- Stereolithography (SLA®, 3D Systems Inc.).

Of these, only the ThermoJet® and Solidscape printing technologies are capable of producing parts in a material directly compatible with current prosthetic construction techniques. Therefore, it was decided that these would provide the focus of the study. The Solidscape process utilizes a single jetting head to deposit a wax material and another one to deposit a supporting material, which can be dissolved from the finished model using a solvent. This process produces very accurate, high-resolution parts but, due to its single jetting head, is extremely slow. Therefore, the process is highly appropriate for small, intricate items such as jewellery or dentures but proves unnecessarily slow for facial prosthetic work. Like the Solidscape process, the ThermoJet® process deposits a wax material through inkjet-style printing heads, building a solid part layer by layer. The object being built requires supports, which are built concurrently as a lattice, which can be manually removed when the part is completed. The ThermoJet® process uses an array of jetting heads to deposit the material and is, therefore, much faster. The material is also softer than that used by Solidscape, making it more akin to the wax already used by MPTs and, therefore, more appropriate for manipulation using conventional sculpting techniques. Although no accuracy specifications are given for ThermoJet®, it is advertised as having a very high resolution ($300 \times 400 \times 600$ dots per inch in x-, y- and z-axes) and is aimed at producing finely detailed parts (a drop of wax approximately every 0.085 mm by 0.064 mm in layers 0.042 mm thick).

Suitable technologies identified

From the review of currently available technologies and the required parameters stated above, the following technologies were selected. Prosthesis design was to be performed using FreeForm® CAD software, including the addition of texture. The completed prosthesis design would be produced from this design file using the ThermoJet® wax printing process.

6.17.5 Methods

Case studies were conducted that explored utilizing the technologies identified. Firstly, the application of two-dimensional texture maps to create three-dimensional relief on anatomical models was explored using FreeForm® CAD and ThermoJet® RP. This was followed by a series of test pieces designed and manufactured to test the ability of the selected CAD software to create and export texture relief that would provide a range of realistic skin textures and the capability of the RP machine to reproduce these textures to the required accuracy.

Assessment

Subjective analysis of the results was used in this study since the nature of prosthesis production and texture detailing results in complex forms that do not provide convenient datum or reference surfaces from which to measure accuracy. By definition, prostheses are one-off custom-made appliances made to fit individual patients. Therefore, it is not practical to perform the type of repeated statistical analysis that would be commonly encountered in series production or mass manufacture. The aesthetic outcome and accuracy of prostheses is subjectively assessed by the prosthetist and subsequently the patient.

The RP produced patterns were first assessed against the CAD models. Secondly, the level of detail in each of the model sets was assessed by a qualified and experienced prosthetist and the ability of the technologies to create and manufacture realistic and convincing skin textures was commented on.

6.17.6 Case studies

Pilot study 1

An initial pilot study was used to assess the capability of FreeForm® in creating texture relief and ThermoJet® in reproducing the detail. A series of texture images were converted into high contrast black and white images using photographic manipulation software. These images were used to create relief textures on small rectangular samples (20 mm × 10 mm × 5 mm high). A four-sided patch was drawn on the top surface of the blocks and the 'emboss with wrapped image' function used to overlay the texture maps. The scaling tools were used to gauge the approximate depth and density of the required texture relief. The method of creating the textures is described in detail in the experimental section below.

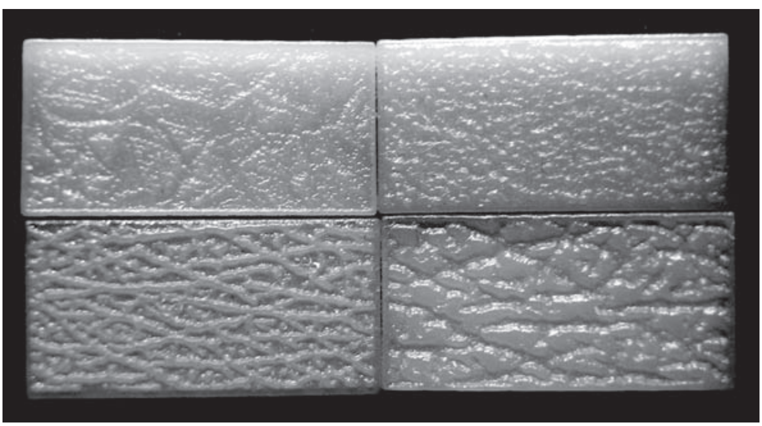
ThermoJet® was used to produce the physical models of the test pieces shown in Fig. 6.106. The details were produced with good visual effect. However, the texture was neither sufficiently detailed nor deep enough to prove conclusive.

Pilot study 2

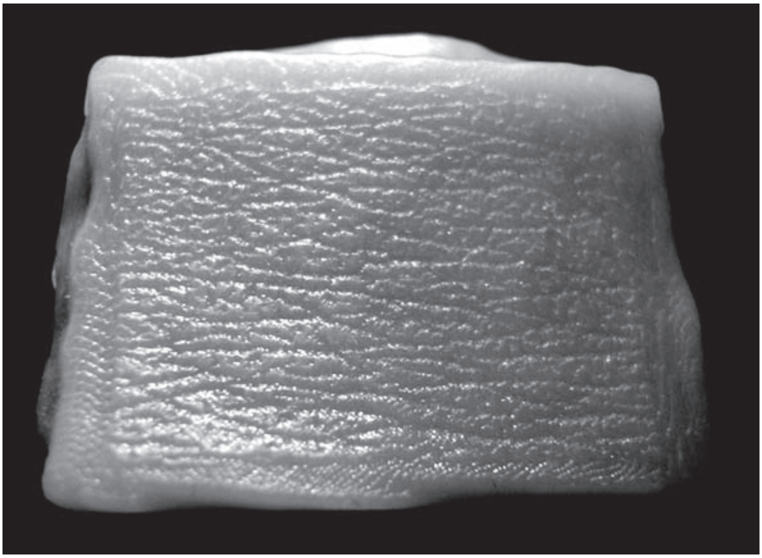
Another slightly larger test piece was created with an image that more closely resembled a detailed skin texture. The texture was created on a segment of anatomical data to assess the effect on a contoured piece rather than the simple flat area of the previous test pieces. The contoured test piece was approximately 27 mm × 21 mm × 10 mm at its highest point. The model was built using the ThermoJet® RP machine, shown in Fig. 6.107. Again, the depth was judged by eye and the resulting pattern suggested that a realistic skin texture could be produced over a contoured surface.

Experimental series

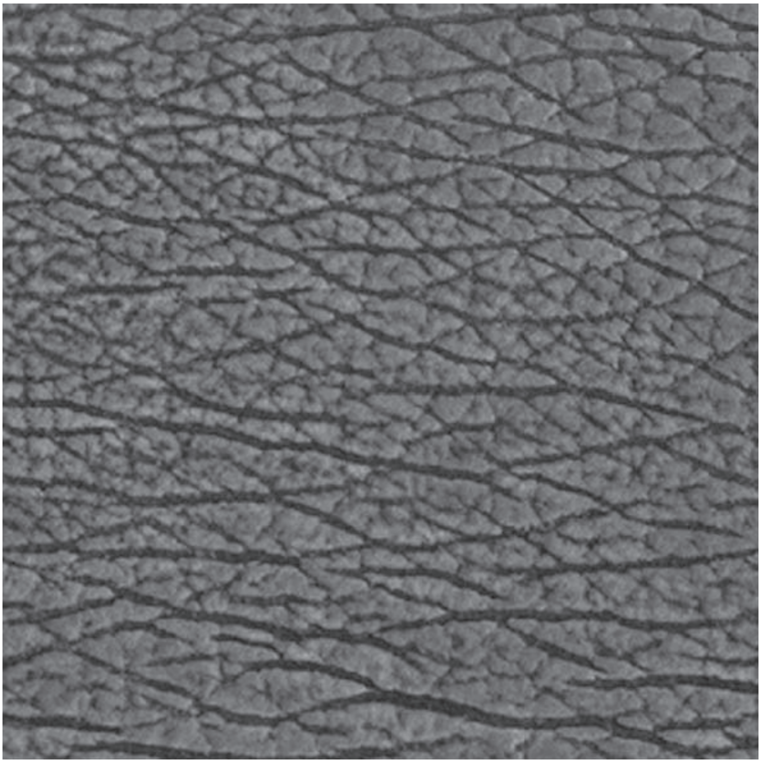
Step 1 – producing the texture image A sample skin texture image was located in the form of a two-dimensional grey scale bitmap, shown in Fig. 6.108. This image was then manipulated to produce a high contrast, black



6.106 Close-up photograph of the four trial pieces.



6.107 A close-up photograph showing the contoured test piece.

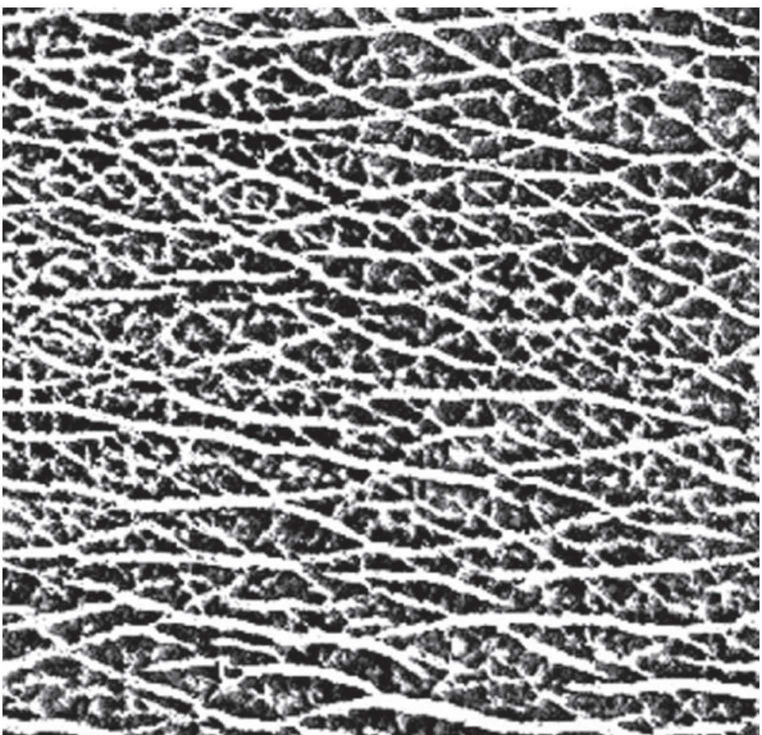


6.108 The skin texture image used in this study.

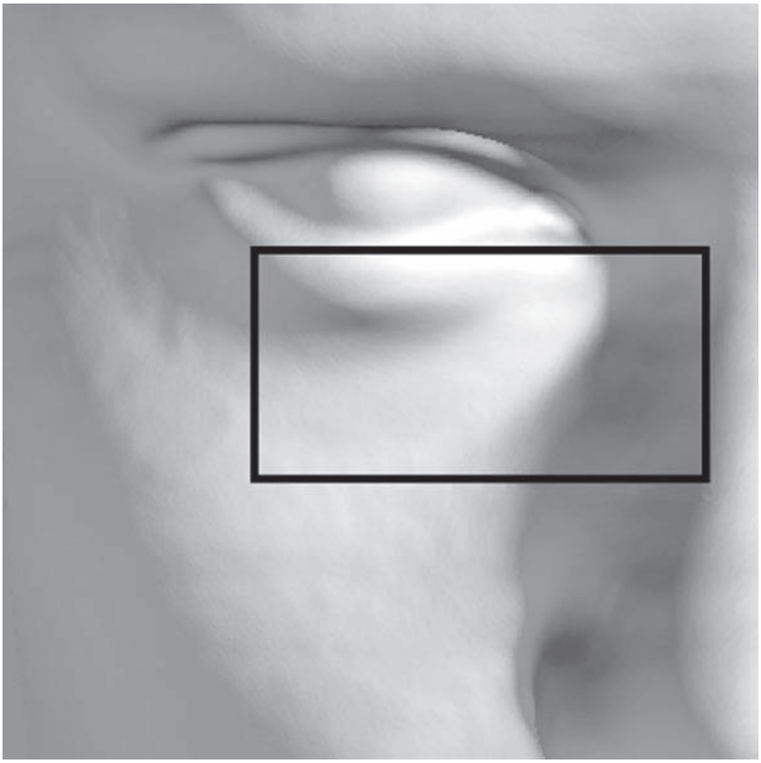
and white image shown in Fig. 6.109 using Photoshop® software (Adobe Systems Inc., 345 Park Avenue, San Jose, CA 95110-2704, USA). Suitable texture images may be obtained from databases, digital macro-photographs or a pad print of skin produced from an impression.

Step 2 – application of textures in CAD To assess the effect of creating textures on anatomical shapes associated with maxillofacial prosthetics, a small section of data was taken from a three-dimensional CAD model of a human face derived from a three-dimensional CT scan. The area was selected to display a variety of compound curved surfaces, whilst the size of the selected area was kept small to minimise build time and cost. The selected region is shown in Fig. 6.110. A series of test pieces based on the selected data were created in FreeForm® with a 0.1 mm edge definition.

A rectangular box was drawn on the contoured surface and the 'emboss with wrapped image' function was used to overlay the sample two-



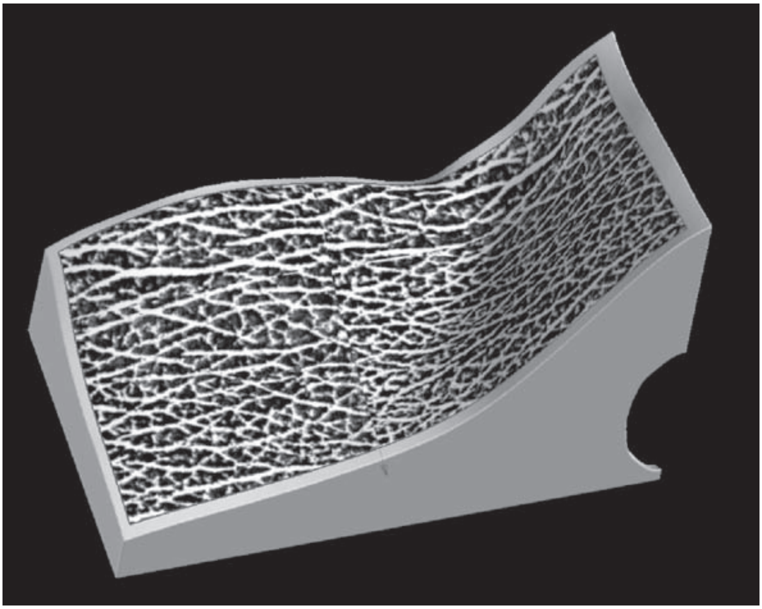
6.109 The manipulated, high contrast version used to create the relief.



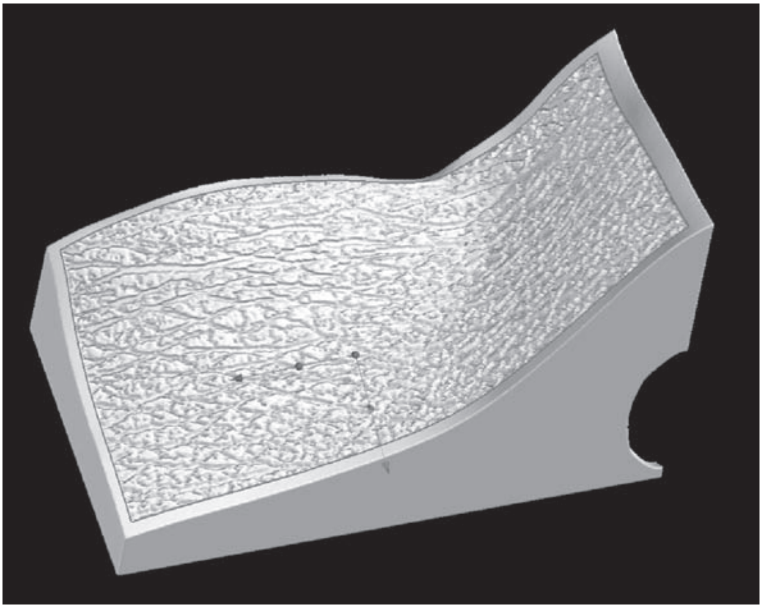
6.110 The selected region of facial anatomy.

dimensional texture image in the box. The 'emboss' function was used to set varying depths of texture relief, at 0.1, 0.15, 0.25, 0.35, 0.5 and 0.8 mm. These depths corresponded to the wrinkle depth scale and associated measurements in various facial areas developed by Lemperle *et al.* **(15)**. The actual emboss depth produced in the model is also influenced by the grey scale values in the image. Black areas are embossed to the full depth selected whilst grey areas will be proportionally embossed to lesser degree. The embossing effect may be previewed as an image (Fig. 6.111) or as the resultant texture relief (Fig. 6.112). The 'ruler' function in FreeForm® was used to ascertain the depth of the textures by measuring the distance from an original smooth copy of the part, to the deepest part of the grooves in the textured part.

Step 3 – RP manufacture The blocks were manufactured using ThermoJet® printing with the contour surface set facing upwards. The test pieces were 18.5 mm × 35 mm × approximately 27 mm high at the tallest point. All six



6.111 Preview of the image for the embossing function.



6.112 The texture relief created by the emboss function.

patterns were built in less than three hours. The results can be seen in Fig. 6.113, with the shallowest relief (0.1 mm) on the left ranging to the deepest relief (0.8 mm) on the right.

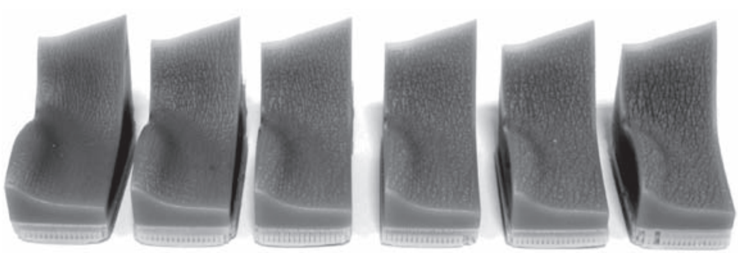
6.17.7 Results

All of the texture depths were visible on the ThermoJet® patterns. This indicated that the process was capable of producing patterns with sufficient detail to describe realistic skin textures. The layer stepping effect commonly exhibited by layer manufacture RP processes was not visible on the surface and did not interfere with the texture pattern. However, textures would not be well defined on down-facing surfaces due to the dense support structure that, when removed, left a rough finish. This may be a problem if the technique was used in the production of complex prosthetic forms where all surfaces are on show such as hands.

6.17.8 Discussion

The tools available in FreeForm® were well adapted to creating accurate texture relief from two-dimensional images. One possible limitation is file size. In order to represent texture faithfully and wrinkle detail at each stage of both methods, large amounts of data are required. A high-resolution model setting that demands a lot of computer processing power must be used in the CAD stage. The output STL (Standard Triangulation Language) file required for the subsequent ThermoJet® production stage must also have good detail definition that translates to a large file size. Whilst more modern, high-specification computers may be able to handle the large file sizes, it may make the process unmanageably slow for others. Further research will be undertaken in order to optimise the file size versus quality settings.

The ThermoJet® process was capable of producing all of the texture samples faithfully and did not exhibit the stair stepping effect that some other RP processes display. This ability, combined with the suitable



6.113 The six ThermoJet® produced skin texture sample patterns.

material properties, demonstrates how the process may be integrated into digital prosthesis design and production techniques that are compatible with conventional handcrafting techniques.

Limitations

This study was unable to quantify the accuracy and resolution of the ThermoJet® produced patterns, although ultimately the visual effect would need to be measured subjectively by a qualified and experienced prosthetist. This study has shown that CAD and RP processes may be used to generate fine texture detailing, but further research is required in order to quantify the resolution and accuracy requirements of these processes. The authors intend to apply profilometry to assess the surface of the RP produced patterns and compare these with the CAD models.

6.17.9 Conclusions

This research has identified methods of capturing, creating and reproducing three-dimensional, skin texture like relief using CAD and RP technologies. Furthermore, it has highlighted how these techniques may be integrated into digital prosthesis design and construction processes. Limitations of current technologies have also been highlighted and the authors intend to refine the techniques and evaluate their effectiveness in suitable patient case studies.

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7
Future developments

7.1 Background

Several areas of development combine the advantages of computer-aided design (CAD), rapid prototyping (RP) and medical applications. Materials development is progressing in RP, and this is opening up new opportunities to use objects made by RP techniques directly in medical treatments or to manufacture medical devices. For example, the direct manufacture of hearing aid shells is currently being developed and marketed by more than one medical device company.

The ability to process fully dense functional metals in RP machines is also of particular interest in the manufacture of custom-designed implants. Machines are already undergoing research in the application of materials such as stainless steel, and the potential to employ titanium is seen by many researchers as an excellent opportunity.

Tissue engineering is a fascinating area of development, and CAD and RP approaches are being actively developed in many research centres to facilitate the direct manufacture of custom fitting tissue scaffolds or even living tissue constructs. The potential to construct living tissue replacements for damaged or missing organs and bones is challenging but may ultimately reduce our dependence on organ donors and save many lives.

As can be seen, by considering the technological development discussed below the future has a great deal of potential for everyone working in this varied and challenging but, ultimately, highly rewarding field.

7.2 Scanning techniques

Computed Tomography (CT) scanning continues to develop although this tends to be incremental. More sensitive detectors are allowing X-ray doses to be lowered whilst capturing more data at smaller pixel sizes. The use of multiple arrays of detectors is drastically reducing scanning times. The improving ability to collimate the X-ray beams is allowing much thinner slices to be taken. In addition, increasing computing power and more sophisticated software are enabling ever-greater resolution and more control over how the images are handled and displayed.

Cone beam CT shows a great deal of potential and could expand the application of three-dimensional CT data and therefore increase the number of sources available for medical modelling. Rather than using rotating collimated X-ray beams and detectors, cone beam scanners use a cone shaped beam of X-rays in conjunction with a single, but large, flat detector to enable the simultaneous capture of many slices of data. This greatly reduces the complexity of the scanner making it a cheaper technology than existing CT scanners. It also results in significantly lower X-ray dosage for the patient. Because they use one large detector, current cone beam scanners are limited in the extent of anatomy that they can capture. Therefore, they are being targeted at specific applications, such as dentistry. The advent of this cheaper and more accessible technology will open up many opportunities for computer-aided design, computer-aided surgical planning and medical modelling.

Magnetic Resonance (MR) imaging has so far been used infrequently for three-dimensional virtual and physical modelling, but the development of more tissue specific protocols is enabling imaging of organs that has previously been difficult to achieve using CT. It is likely that the use of MR for many types of imaging requirement will increase as the speed and sophistication of the scanners improves. As with CT, the development of more sensitive detectors and the use of multiple arrays of detectors will improve speed and resolution. More sophisticated software will be able to better filter out noise and produce sharper, clearer images.

The benefit of using non-ionising radiation will lead to a greater demand for MR compared to CT for some clinical situations that cannot justify the exposure to X-rays. This is likely to lead to a growing application of modelling from MR. The growing interest in modelling soft tissues is also likely to encourage more work with MR data.

Different types of scanner are also likely to show potential in three-dimensional modelling. Positron emission tomography, for example, shows the potential for scanning devices to be pathology targeted rather than anatomy targeted. Such modelling projects may enable better treatment planning or enable computer-aided, computer guided or even robotic surgery.

Improvements in three-dimensional ultrasound scanning may lead to the ability to model from the data, which has until now tended to show too much noise to be of practical use in modelling. However, some modelling work has been done, and the ease of use, compact size and relative safety of ultrasound will encourage the exploitation of the data it can provide in modelling.

7.3 Data fusion

One of the areas currently of great interest is data fusion, which is taking data of the same patient from a number of different imaging modalities and combining them into a single, comprehensive three-dimensional model. So far, work has been done to combine similar image types, such as merging CT and MR images, and to combine different image types, such as 3D CT models with surface models from optical scanners. However, to date much of this work has been research based and more clinically based work needs to be done to validate data fusion so that the effect of the merging of different data types is fully understood. The widespread use of common data formats, such as Digital Imaging and Communications in Medicine (DICOM), will be a key enabling factor in allowing data fusion to be explored.

7.4 Communication

The rapid development of the Internet and the increasing affordability of high-powered PCs have enabled the sharing and rapid transport of medical scan data. Despite the large data files involved, the advent of cheap CD writers and subsequently DVD writers means that even large medical scan data files can be cheaply and safely recorded and mailed. However, issues of confidentiality and patient privacy must equally be incorporated into the handling of all medical information. These issues may place barriers to the full sharing of data despite what may be technically feasible.

7.5 Rapid prototyping

The development of rapid prototyping may seem to have reached a plateau and current developments are often incremental, but, in general terms, RP machines are becoming cheaper, faster and more reliable making them ever more accessible to researchers and engineers working in a variety of applications. However, materials developments are also a major driver in medical applications of RP technologies. More biocompatible materials will be required if much of the potential of RP is to be realised in mainstream medical treatment. The shift in emphasis in much RP research towards rapid manufacture rather than modelling or prototyping will provide a strong driver in this respect. In fact, many medical applications of RP predicted and predated this shift in industrial thinking towards the ability to make end use products using RP technologies. However, it is highly likely that, due to the considerable expense involved in developing and marketing new RP technologies, large, well funded industrial sectors such as aerospace and automotive will lead the way. As in the past, this will lead to developments that require research and ingenuity on the part of engineers and clinicians to adopt, adapt and implement these technologies in ways appropriate to medicine.

7.6 Tissue engineering

The ability to create implants that are entirely compatible with the tissue they are replacing is a major goal for reconstruction and rehabilitation and many research groups are actively pursuing the area to such an extent that it is becoming a field in its own right. However, the majority of approaches to manufacturing tissue-engineered structures depend on computer-controlled techniques, many of which are similar in concept to rapid prototyping. This provides yet another crucial driver in the ability to accurately capture anatomy, design for anatomy and specify multiple materials using computer-aided design techniques. Many of the challenges of tissue engineering will require many years of study from multi-disciplinary teams, which will include not only clinicians and engineers but also biologists and biochemists. Many of the proposed developments also require a shift in scale to the cellular level, which will provide yet more challenges to the engineers attempting to model human tissue.

Glossary of terms and abbreviations

Technical terms and abbreviations

3D Lightyear™	3D Systems SLA preparation software (3D Systems trademark)
3D Printing	RP technology that creates models by selectively adding bind to layers of powder
3D Systems Inc.	USA based company producing a range of RP machines
ADM	advanced digital manufacturing
Arcam	Swedish RP machine manufacturer
Boolean	simple mathematical addition or subtraction of one thing with another according to set theory
CAD/CAE/CAM	computer-aided design/engineering/manufacture
CNC	Computer Numerical Control – of machining centres, lathes and milling machines
digitizing	capturing data points from an object's surface, 3D scanning
DLP™	Digital light processing (Texas Instruments trademark)
EnvisionTEC	German manufacturer of RP machines
EOS GmbH	Electro Optical Systems – a German manufacturer of RP machines
FDM™	Fused Deposition Modelling (Stratasys trademark)
FEA	finite element analysis, computer testing of strength or stiffness
Helisys Inc.	USA based company that produced laminated object manufacture machines
InVision™	three-dimensional printing type RP machine utilising acrylate material (3D Systems trademark)

Kira	Japanese manufacturer of object manufacture machines
LOM™	Laminated Object Manufacture
LS	Laser Sintering
Maestro	obsolete 3D Systems SLA preparation software
Magics	STL manipulation and RP preparation software (Materialise NV)
MCP-HEK	German RP machine manufacturer
Mimics	software for processing medical scan data for RP (Materialise NV)
MJM	Multi Jet Modelling
Objet	Israeli manufacturer of RP machines
Photo-polymerisable	liquid or resin that will solidify (cure) when exposed to certain wavelengths of light
PolyJet™ modelling	multiple jet printing process used on Objet RP machines
QuickCast™	SL build style for sacrificial investment casting patterns (3D Systems trademark)
reverse engineering	to create computer model of an object, by digitizing or scanning it
RP	rapid prototyping – general term for free form build technologies
RP&M	rapid prototyping and manufacturing
RP&T	rapid prototyping and tooling
sintering	fusing a powder, usually by heat
SL	Stereolithography
SLA®	Stereolithography Apparatus (3D Systems registered trademark)
SLC	slice format for three-dimensional computer data
SLI	slice format for three-dimensional computer data
SLM™	Selective Laser Melting (MCP-HEK trademark)
SLS®	Selective Laser Sintering (3D Systems registered trademark)
Solidscape	USA based company producing wax deposition type RP machines
STL	derived from stereolithography – computer file format used by most RP technologies
TCT	time compression techniques (technologies)
ThermoJet™	3D printing type RP machine utilising wax material (3D Systems trademark)
UV	ultra-violet light

vacuum casting	method of producing plastic parts from a silicone mould from a master pattern
Z-Corp	USA based manufacturer of RP machines

Medical terms and abbreviations

alloplastic	artificial material
artefact	something artificial, a distortion that does not reflect normal anatomy or pathology, not usually found in the body, usually used in radiology
arthroplasty	the surgical repair of a joint, usually joint replacement
autologous	derived from an organism's own tissues or DNA
benign	non-cancerous, treatment or removal is curative
collimation	the operation of controlling a beam of radiation
craniofacial	relating to both the face and the head
cranioplasty	plastic surgery of the skull; a surgical correction of a skull defect
Hounsfield number	normalised value of the calculated X-ray absorption coefficient of a pixel in a computed tomogram (after the inventor of CT)
in vitro	in glass, meaning in the laboratory
in vivo	in life, meaning within the body
malignant	said of cancerous tumours, tending to become progressively worse
maxillofacial	pertaining to the jaws and face, particularly with reference to surgery
morphology	the configuration or structure of
occlusion	the relationship between the upper and lower teeth, the bite
osteoporosis	reduction in the amount of bone mass, leading to fractures after minimal trauma
osteotomy	the surgical cutting of a bone
pathology	the branch of medicine concerned with disease, especially its structure and its functional effects on the body
prosthesis	an artificial substitute for a missing body part, used for functional or cosmetic reasons or both
radiography	making film records (radiographs) of internal body structures by passage of X-rays
tibia	bone in the lower leg, the shin bone

valgus — an abnormal position in which part of a limb is twisted outward away from the midline

varus — an abnormal position in which part of a limb is twisted inward toward the midline

Medical explanatory notes

Osseointegrated implants and implant retained prostheses

Osseointegrated implants are titanium screws that are driven into patients' bones to form rigid and permanent fixation points for prostheses. The screw is driven into the bone in carefully selected positions during an operation. The screw is then typically left in place under the skin until the bone has healed and re-grown around the screw. The screw is then exposed through the skin and an abutment added. This abutment then forms the anchor point for the rigid and strong fixation of prostheses, i.e. implant retained prostheses. These types of implants are extensively used in dental restoration and increasingly in facial prosthetics.

For more information see:

- **The Osseointegration Book: From Calvarium to Calcaneus**
  Brånemark P, Chien S, Grondahl H-G, Robinson K
  Quintessence Publishing London
  2006
  ISBN: 0867153474

Hypertrophic scar

A hypertrophic scar is a thick, raised scar resulting from skin injury such as burns. The formation of this kind of scar is not a part of normal wound healing and develops over time. They are more likely to be a problem in patients with a genetic tendency to scarring and in deep wounds that require a long time to heal. In general, they are more likely to form in areas of the body that are subject to significant pressure or movement. Treatment is typically by applied pressure for long periods.

Distraction osteogenesis

Distraction osteogenesis is a method of lengthening bones by cutting through the bone and then controlling a steady gap between the two sections of bone. If the gap is kept small but constant, the bones attempt to grow in order to fill the gap, as they would when healing from a fracture. The gap is typically maintained by mounting the two parts of the bone onto a precision screw mechanism. Adjusting the screw mechanism on a daily basis maintains the required gap. Typically the device is removed after the desired growth has occurred and been allowed to heal fully. The technique can be used in three dimensions to correct any number of skeletal abnormalities and has been used successfully in orthopaedic and maxillofacial surgery.

Benjamin's double osteotomy

Benjamin's double osteotomy was a double transverse cut, one cut through the distal femur and one through the proximal tibia. The rationale was that it would relieve the inter-osseous pressure underneath the subchondral bone, which was thought to accelerate the degeneration of the cartilage and sever the nerve in the subchondral bone plate, which was also thought to contribute to pain relief. A Charnley compression clamp was used to fix the osteotomy. The procedure developed a poor reputation because the condyles and tibial plateaux blood supplies were compromised, and bone necrosis led to above knee amputations in some cases. In addition, a long rehabilitation period was required for a minimal benefit.

Vertebrae

The 33 human vertebrae are named and numbered according to their anatomical position starting at the head and working downwards. They are split into three categories, cervical (neck), thoracic (chest) and lumbar (lower body). The seven cervical vertebrae are therefore referred to as C1 to C7. The 12 thoracic vertebrae are attached to the ribs and referred to as T1 to T12. The lower spine consists of five lumbar vertebrae (L1 to L5), the sacrum and the coccyx. The sacrum is made up of five fused vertebrae and it forms the rear of the pelvic area. The coccyx is made of four fused vertebrae that are an evolutionary remnant of a tail.

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26081 Avenue Hall, Valencia, CA 91355, USA
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2014 Jean Talon North, Suite 310, Sainte Foy, Quebec, Canada, G1N 4N6
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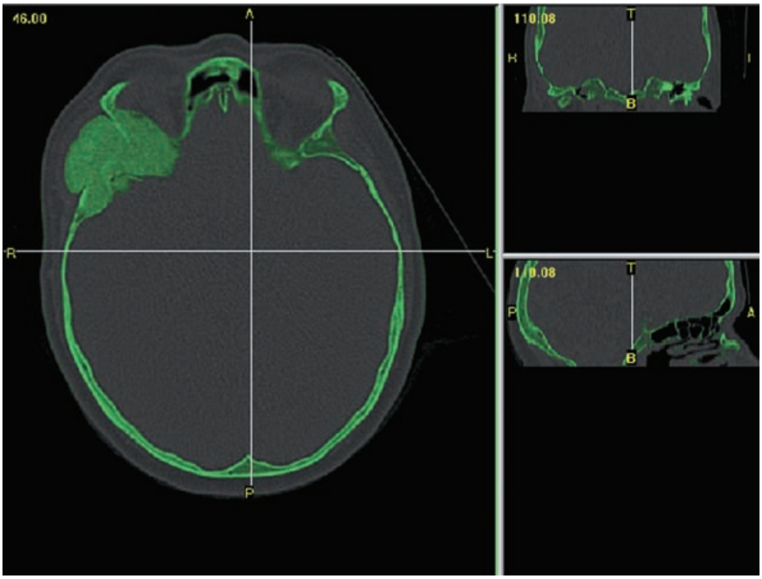
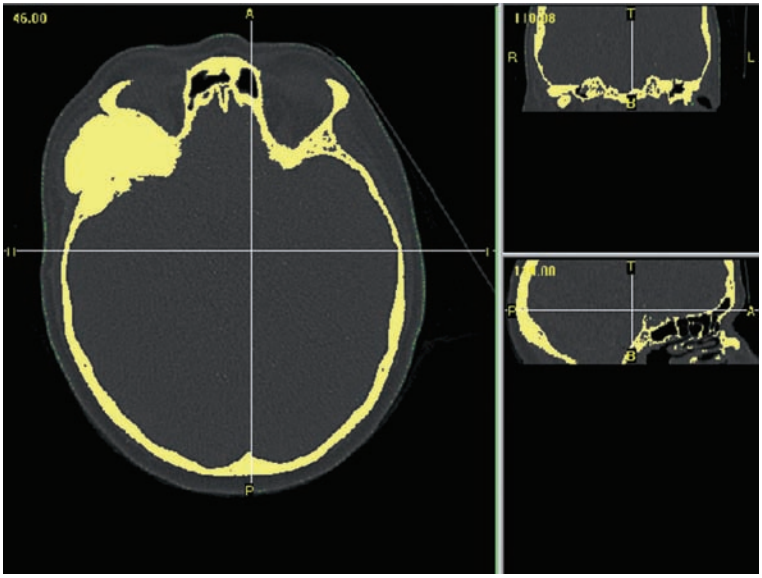
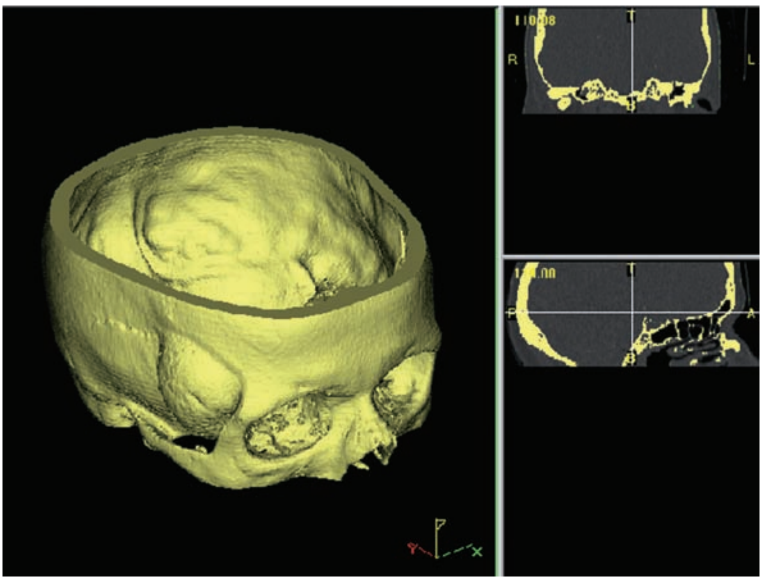


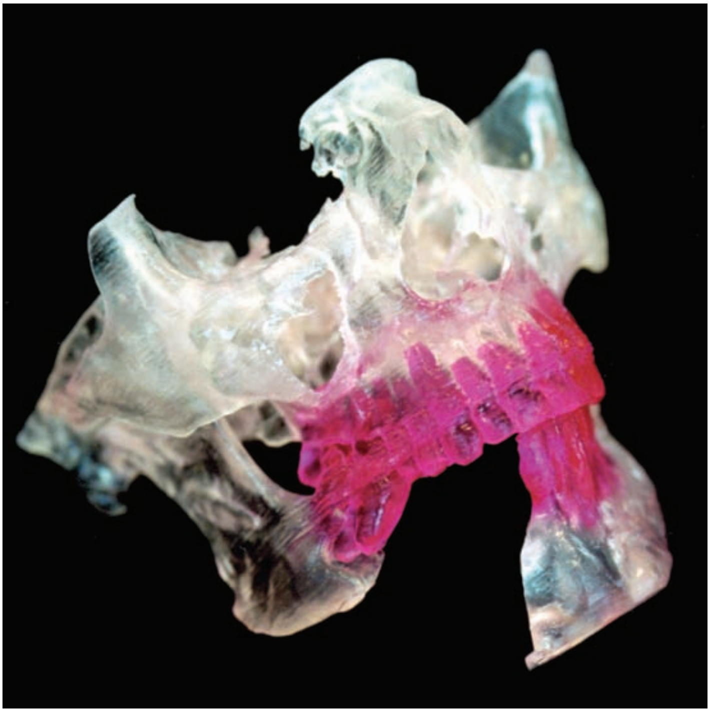
4.8 Thresholding of CT data.



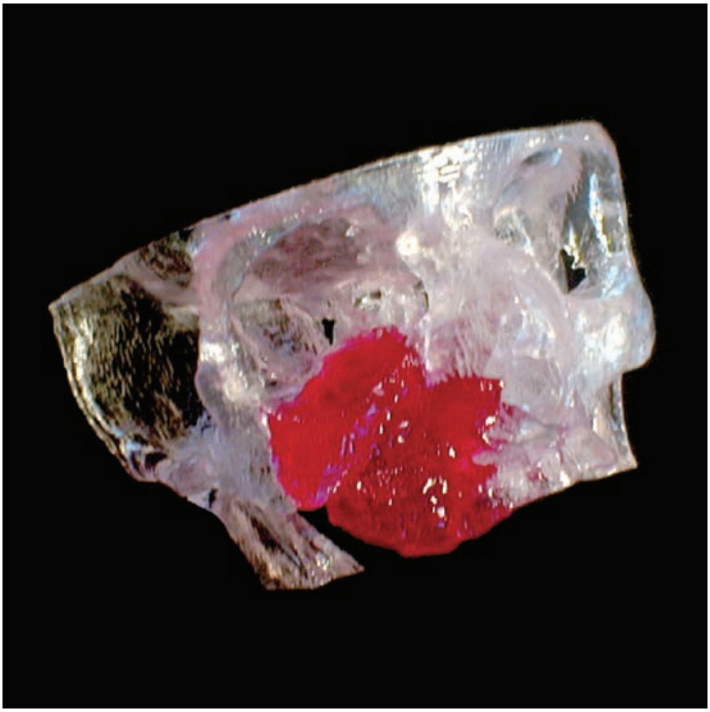
4.9 Region growing of CT data.



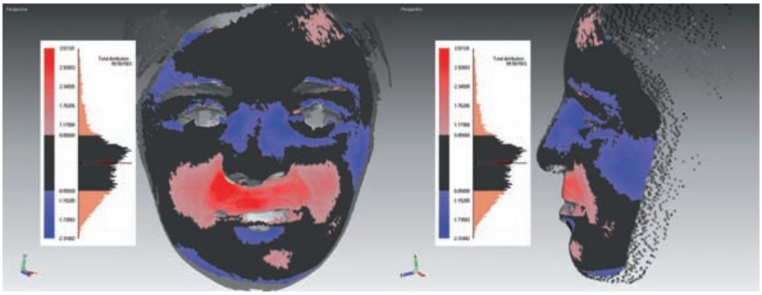
4.10 A three-dimensional shaded image of segmented data.



5.11 Selectively coloured model showing the roots of teeth.



5.12 Selectively coloured model showing a tumour.



6.41 Merged pre- and post-operative facial scans demonstrating the magnitude of change in soft tissue morphology.