Advanced Manufacturing Technology for Medical Applications

Reverse Engineering, Software Conversion and Rapid Prototyping

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Rapid Prototyping for Medical Applications

Ian Gibson

1.1 Overview

While rapid prototyping (RP) technology has primarily been developed for the manufacturing industry to assist in speeding up the development of new products, its vendors and users were quick to realize the technology was also suitable for applications in the medical field. Doctors and surgeons have always been looking for better ways to describe, understand and diagnose the condition of individual patients. Diagnostic tools have become increasingly more sophisticated and the latest CT, MRI and other medical imaging technology can now present patient data in many ways and with great clarity and accuracy. There are, however, many cases where doctors or surgeons might like to have a physical model in front of them rather than have to look at images on a computer screen. Before RP, such models could only be generic and were not necessarily useful to describe an individual condition. With RP there came a way to create such physically solid models of an individual directly from the 3D data output by the medical imaging system.

RP is an emerging technology. In recent years, a number of books have been written on the subject, either describing the basic technologies from which RP machines have been constructed and/or their applications. Some of the more recently written books have even included medical applications. However, none of these books has described medical applications in any real detail or included a very wide range of applications. This book sets out to address both these points.

RP is becoming used for an increasing number of medical applications as the real benefits become more widely known and appreciated. However, many medical practitioners do not fully understand, or indeed even know about, these applications and this book aims to present these

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to those medical experts. In addition, many engineers familiar with RP would like to understand more completely where these benefits lie so that they can communicate more effectively with medics. While it is well known that RP can be of benefit, the ‘actual’ uses are less clear.

1.2 Workshop on Medical Applications for Reverse Engineering and Rapid Prototyping

The idea for putting together this book came to me when I was on study leave at The National University of Singapore in the second half of 2003. As a long-standing researcher into RP and co-editor of the *Rapid Prototyping Journal*, I have looked for and supported research that broadens the applications for RP. I had previously carried out a number of projects at my home University of Hong Kong, supporting surgeons with models of patient data, and wanted to explore this area during my visit to Singapore. Singapore has long been famous for advanced surgery and had recently gained much publicity and admiration for work on separating conjoined twins. During my stay in Singapore I met with a number of medics and engineers involved in these cases and was interested to see the vital role RP played in the surgical planning. I quickly learned that in fact such operations would not have been carried out had it not been possible to make these models.

Two years previously I had put together a book on research into software systems for RP. The experience of putting together this book was a very profound and fulfilling experience. The approach was to collect together a group of like-minded experts working in the area and run a book workshop. Each expert contributed a chapter to the book and the workshop allowed us all to comment and collectively tune the content. If anyone is thinking of putting together a research book, I can highly recommend this approach. It has many benefits, in addition to the resulting book itself, in terms of establishing professional and personal relationships with experts in similar fields. Having decided that a book should be written on the subject, I did not hesitate to set up a similar event in order to put it together. There were a number of criteria I insisted upon for this event:

- The workshop should have representatives from key commercial organizations involved in making medical models.
- The subjects should include research into a number of key areas: tissue engineering, surgical modelling, implant technology, materials development and different surgical applications.
- There should be input from medical practitioners.
- Representatives should be from around the world.
- There should be a mixture of research and commercial applications.

I then set about finding out who were the experts in the various fields and inviting them to Singapore. As an added incentive to the book workshop, I also organized an open workshop for outside parties in Singapore to learn from these experts. This made it possible for many of these extremely busy individuals to justify attending the event. The resulting workshops were eventually held at The National University of Singapore from 3 to 5 December 2003.

I was delighted by the response and enthusiasm of the workshop participants who have all gone on to supply chapters for this book. I hope you agree that we were able to meet all my criteria and that the collective expertise of these authors represents a significant proportion of the worldwide expertise in this field. I will allow the authors to present themselves in whatever way they wish, but it can be seen that we have representatives from three of the top (in fact probably the top three) companies that fabricate medical models. We also have two of the top research groups into tissue engineering using RP and representatives from a number of important emerging research groups in Asia, Europe and the United States. Applications described include dentistry, neurosurgery, implant design and development, maxillofacial surgery, orthopaedics and separation of conjoined twins.

I hope you agree with me that this book is indeed a mine of information on research and applications of RP for medical applications, and I also hope you gain much support for your own research and application.

1.3 Purpose of This Chapter (Overview)

Most of the chapters of this book cover the use of advanced manufacturing technology for medical applications. Most of the chapters make the assumption that the reader already knows much about the technology used. For many readers we anticipate that this will indeed be the case. However, there will be a number of readers, particularly those with a medical background, who know little or nothing about this technology. This introductory chapter will therefore aim to assist the reader in understanding the basics of RP technology. Where other technologies are involved, for example in reverse engineering and software systems, the authors of the relevant chapters have taken efforts to ensure that technology and terminologies are explained in a clear and concise manner. However, nearly all the chapters include reference to RP technologies of different kinds, and so it is worthwhile devoting some time and effort to explaining these technologies in this single introductory chapter, rather than have the authors repeat themselves too often. This also permits the authors to concentrate on the more important aspects of their work rather than wasting pages to explain basic terms to the reader.

This chapter therefore aims to describe a number of key rapid prototyping technologies. There are many RP technologies commercially available, and it is not within the scope of such a short chapter to describe them all, or in great detail. If readers require more detail, they are advised to refer to one of the numerous excellent books that are dedicated to describing these technologies. A bibliography of the more popular of these books can be found at the end of this chapter. This chapter sets out, if you will pardon the pun, to cover the bare bones of the subject. It also focuses on those technologies that are best suited to medical applications rather than listing all the ever increasing number of available technologies. However, before listing the different machines that are capable of making physical models from medical data, it is necessary to explain the basic principles of RP.

1.4 Background on Rapid Prototyping

Rapid prototyping is a term used to represent a range of technologies that can fabricate 3D objects in a single stage, directly from their CAD descriptions. There are a number of other terms associated with RP that can be used to describe the technology:

- Freeform fabrication. This emphasizes the fact that RP is largely ‘geometrically independent’ in that any increase in the complexity of form does not necessarily make it more difficult to build.
- Automated fabrication. This links RP with other, similar technologies such as NC machining to emphasize the fact that parts are largely produced without human intervention. Since RP

replaces traditional modelmaking skills, this can be considered a huge advantage in terms of increased manufacturing speed, throughput and reduced demand on skilled labour.
- Layer-based additive manufacture. RP simplifies the complex 3D fabrication process by reducing it to a series of finite-thickness 2D forms or layers and adding them together.

The RP term itself has been the subject of much discussion and controversy. RP is also used to describe processes in the software, business and electronics sectors. The general definition relates to being able to create objects, models or systems in a speedy manner so that further development is subsequently streamlined. RP is therefore a relatively ambiguous term that is also linked to rapid product development. However, RP was the first term used to popularize this technology and as such it has stuck.

The final definition of layer-based manufacture is the key to how RP really works. Models are created by bonding layers of material together. If the layers are sufficiently thin, then the models will closely approximate the original intended design. Most RP processes use layer thicknesses of the order of 0.1 mm, and this seems to be sufficient to suit many applications. RP is therefore becoming a well-accepted technology in the manufacturing sector, with many different industries (e.g. kitchenware, electronics, toymaking, jewellery, automotive and aerospace, etc.) making use of its capabilities. The term ‘additive’ manufacture also distinguishes RP from NC machining, which uses a stock material and removes, or subtracts, material to reveal the final shape. With RP you start with just a substrate and add material in layers until the part is completed.

People familiar with medical imaging systems should understand quite easily how the basic concept of RP works. CT and MRI imaging systems both work in a similar manner. 3D images of patient data are constructed by combining 2D slices taken from the sensor systems and interpolating between them. Generally, the slice separation is quite large and coarse in comparison with RP machines, although improved sensors and techniques are enabling models of increasing accuracy to be created. Thus, essentially, the two processes are very similar. CT and MRI combine software slices to create a 3D model, and RP takes a 3D model and reproduces it in a physical form by combining layers together. It is perhaps this synergy between the two types of system that encourages many of us to explore the use of RP for making medical models. The medical imaging systems are capable of creating virtual models, but many medical applications can further benefit from having physical models made from these data. Doctors and surgeons, as we will come to realize through the chapters of this book, are highly physical and therefore tactile people. Being able to feel a representation of the patient data in their hands can go a very long way to solving problems concerning their treatment.

There are many different ways in which the part layers can be made, and consequently there are numerous different RP machines and manufacturers. This chapter will go on to discuss some of the more popular and relevant machines that are suitable to medical applications. However, it should also be noted that RP technology has many limitations, and it is appropriate at this stage to list the most common:

- Layer thickness. A 0.1 mm layer thickness is still too thick for many applications (although probably not a concern for many medical models). The best layer thickness commonly available is around 0.02 mm, but users must be made aware that reduction in layer thickness means more expensive machines and a slower build process. All RP parts exhibit a characteristic 'stair step' texture, most evident on sloping surfaces, and therefore manual surface finishing is required for many models.

- Part accuracy. In addition to layer thickness, there are a number of other accuracy issues that affect the building of parts. In particular, one can expect an RP machine to have a minimum wall thickness for shell-type parts. Normally this will be a few tens of millimetres. Repeatability of RP processes is generally good (of the order of a few microns), but part shrinkage due to material and process constraints can lead to tolerances in the few tenths of a millimetre range.
- Part size. Geometrical independence is not strictly true in that models are restricted by the working envelope of the machine. Many RP machines are of the order of 300 mm^3. This means that a model of a full human skull would be difficult to make in many machines and that many medical applications may require construction of parts in sections or to scale.
- Materials. Much of the part fabrication process in RP is dependent on the ability to combine layers together. This forces severe constraints on the materials suitable for a particular process. The majority of RP processes build models from polymeric materials since this represents satisfactory material properties without the need to resort to very high temperatures and/or forces.
- Part strength. Since parts are built in layers, which are then bonded together in some way, it is likely that these bonded regions represent weaknesses in the overall structure. Even within the material range of a particular process, it is commonly found that the mechanical strength of parts made is slightly inferior to that of parts made with the same material in other manufacturing processes.
- Speed. RP is not as 'rapid' as many people realize and would like. Parts generally take from a matter of hours to perhaps a couple of days to fabricate, depending on the chosen process and size of part. While this is a significant improvement on conventional model-making approaches (with the addition of improved accuracy, material properties, etc.), there is always a demand for further increase in speed. A surgeon working on an emergency case may not be able to wait for models to be made in this time frame.
- Cost. Of course, the capacity to create models quickly, accurately and reliably using RP technology must come at a price. RP technology is still something of a novelty and machines are generally put together as small-volume production. Many of the higher-end machines are over US$200 000. Having said that, the prices of all machines are steadily coming down, and smaller machines that are focused more at the concept modelling sector, generally with limited properties, are approaching a cost similar to many high-end computer products (i.e. around US$30 000). Many applications for medical models can be addressed using these lower-cost machines.

This means that, as researchers and developers, we have plenty of work to keep us busy. For example, systems are being developed that can make parts with micron-scale layer thicknesses. Other machines are focusing on producing parts with a wider variety of materials, namely biomaterials and metals. Ink-jet printing technology is widely used in more recent RP machines, with the major benefits of controllable precision and increased speed of build. Add to this research the incremental improvements in existing technology and system integration and you have a huge amount of potential for achieving the ultimate goal of rapid manufacture.

Medical applications may be classified in terms of demand for high speed, low cost and integration with medical procedures. Accuracy is generally a low-priority issue in comparison with most engineering applications. Material properties have very special requirements related to biocompatibility and approval from medical authorities for use in operating theatres, etc.

1.5 Stereolithography and Other Resin-type Systems

The first ever commercial RP systems were resin-based systems commonly called stereolithography or SLA. The resin is a liquid photosensitive polymer that cures or hardens when exposed to ultraviolet radiation. The UV light comes from a laser, which is controlled to scan across the surface according to the cross-section of the part that corresponds to the layer. The laser penetrates into the resin for a short distance that corresponds to the layer thickness. The first layer is bonded to a platform, which is placed just below the surface of the resin container. The platform lowers by one layer thickness and the scanning is performed for the next layer. This process continues until the part has been completed.

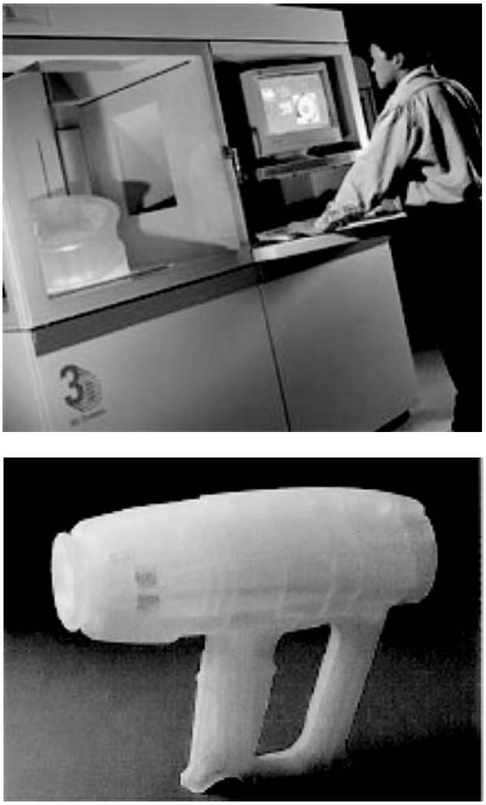

Figure 1.1 Stereolithography equipment with a typical component (courtesy of 3D Systems)

Since the surrounding uncured resin is still in liquid form, any overhanging features of the part must be supported during the build process to prevent them from collapsing under their own weight. Since the part is being built layer by layer, some regions may also be initially detached from the remainder of the part. These detached regions must also be supported to prevent them from floating away on the top of the resin. Parts must therefore be built with additional support structures. These must be removed from the part once the build process has been completed.

The accuracy of this process is generally considered to be among the best of all RP technologies, and SLA resins are generally transparent or translucent, which is a very useful characteristic as far as medical applications are concerned. Being able to look into the resin and see internal features, essentially making the bone appear transparent, can provide a surgeon with much insight into the patient's condition. One particular resin developed specifically for medical applications makes it possible selectively to colour regions within the part by overexposing these regions to UV light. Once completed, parts can be 'fixed' by applying a lacquer that is clear in visible light but blocks out UV. Since the remainder of the SLA part is transparent, the coloured regions can be used to highlight features within the part. For example, the vascular structure can be highlighted in this way and the surgeon can plan the surgical procedure such that blood vessels can be avoided.

SLA is quite an expensive technology, but there are now a number of other resin-based systems at much cheaper prices. However, the original SLA technology from 3D Systems is still widely considered to be the best example of this kind of technology.

1.6 Fused Deposition Modelling and Selective Laser Sintering

There are many ways to distinguish the different RP technologies. Most references would not choose to collect together the selective laser sintering (SLS) process with the fused deposition modelling (FDM) process. However, in relation to medical purposes, applications can be quite similar.

These technologies use heat to melt the base material from which the respective RP parts are fabricated. In FDM the material is melted inside a feed chamber from which it is extruded. In SLS the material is fed in a powder form and a laser is used for selective melting of the layer cross-section. Both processes therefore result in parts that are relatively strong and heat resistant when compared with most of the other RP processes. Such parts are often referred to as having 'functional' properties that can be used for actual applications or at least for testing purposes.

Since FDM parts are produced using a material that is extruded onto a substrate platform, they require support structures for overhanging features in much the same way as SLA parts do. These supports must be removed from the actual part in the finishing operation, and there are currently two different techniques in use. One method uses a material with slightly different mechanical properties to form the support structures. This material breaks away quite easily from the part material when the part is completed. The second approach uses a material that is water soluble. After a short time in warm water, the part material remains. This process can be accelerated using ultrasonic agitation of the water. This second process leaves a cleaner interface region where it used to join with the part, and supports can also be removed from difficult-to-access regions within the parts. The first process, however, can still be useful,

Figure 1.2 Maxum machine, along with a spine model made using FDM (courtesy of Stratasys)

particularly for certain medical applications. Since the support material is extruded from a separate chamber, this material can be chosen to have a different colour. The model can be segmented in such a way as to require building using part material in some regions and support material in another. It is not essential that all the support material be removed, and so the segmented regions can be used to represent different features. For example, one material can be used to represent healthy bone while the other material can be used to represent cancerous material. While these materials are not transparent in the way SLA resins are, there is the advantage that each material can be chosen to have a colour from a range of choices. Since there are only two extrusion chambers in FDM, this is the maximum number of colours that can be feasibly chosen.

Since the SLS process produces parts from a powder substrate, selectively melting the material according to the corresponding cross-section, the major advantage is that supports do not have to be generated. The unmelted powder that surrounds the part is constrained within a build chamber which ultimately provides a natural support for the part during fabrication. This cleans away from the part very easily, reducing the post-processing time as well as the software set-up of the part (since no support data need be generated). Control of the temperature during the SLS process is very critical, and parts exhibit a powdery texture that is also slightly porous (for functional parts around 80%, which also roughly corresponds to the expected tensile strength of a part). The major advantage of this process is its versatility. Parts are generally more accurate than FDM parts, with strength properties acceptable for functional purposes (like cutting and screw fixation) when using a nylon-based material. The same process can also make parts suitable for investment casting applications using a styrene-based material. Change the material again and metal parts can be made with the addition of a furnace infiltration process. These parts are a blend of bronze and steel that is acceptable for short-run injection-moulding tooling applications. The investment casting process may be useful for making parts for medical applications since the metal can be chosen to be biocompatible.

Of course, with the added versatility of the SLS process comes added cost. The baseline FDM machine is considerably lower in price than the SLS machine. The other major difference between the two machines is the time to build. FDM machines are considerably slower than,

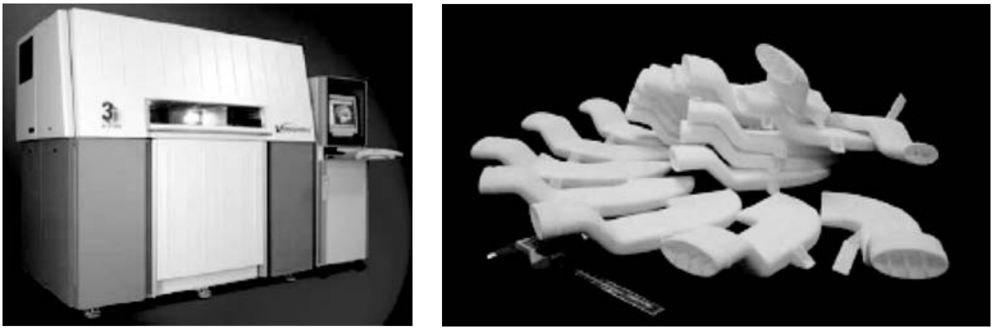

Figure 1.3 Selective laser sintering equipment and sample parts made from nylon powder (courtesy of 3D Systems)

in fact, most other RP processes. While SLS machines have a lengthy warm-up time, it is possible to build parts in batches, which means time per part can be quite low.

1.7 Droplet/Binder Systems

More recent systems have taken advantage of ink-jet or other forms of droplet deposition system to make RP parts. Droplet systems are very controllable, deposit materials in very small quantities and can be constructed in arrays and are therefore very suitable for forming the basis of a deposition system. There are two main ways in which droplet deposition is used: drop-on-powder and drop-on-drop.

Drop-on-powder systems use the ink-jet system to deposit a binder that glues powder particles together. The form of this technology developed for RP has its base in an MIT patent named 3D printing. MIT licensed this technology to a number of companies, the most widely known being ZCorp, which makes a range of high-speed, low-cost machines. Although parts from these machines exhibit relatively poor mechanical properties, they can be strengthened. The ink-jet binder printers can also deposit materials of different colours, thus making them useful for fabricating multicolour parts. These parts are opaque like the FDM process, but the multiple colours may benefit a number of applications where effective communication of ideas is required. Another licensee of the basic 3D printing process is Therics Inc. who have used the process to create controlled drug delivery devices and who are also investigating tissue engineering applications.

Drop-on-drop systems deposit the material in a liquid form, which then solidifies immediately after. This can be achieved with the base material in molten form, using cooling to solidify it, or using a photocuring process similar to SLA. In the latter process a strong curing light is used to solidify the material after it comes from the print nozzle. There are a number of machines using this approach to make parts. Since the machines use mass-produced printing technology, the cost can be kept quite low without compromise to accuracy. These machines are therefore generally low cost and fast acting (although there are some exceptions, particularly regarding speed of build).

Figure 1.4 ZCorp Z406 machine along with some parts made using the colour cabability (courtesy ZCorporation)

Parts that come off these machines are generally weaker than SLA, FDM or SLS parts. There is also a limitation in the range of materials available and therefore the corresponding applications. These machines are often referred to as ‘concept modellers’, their application being well suited to the early stages of product development. For medical applications one might see these machines being used as communication aids where a doctor can illustrate a proposed procedure to a patient with the help of a model of the patient data.

1.8 Related Technology: Microsystems and Direct Metal Systems

As already discussed, there are specific limitations for most RP technologies – those of accuracy and material properties. In general, most RP technologies work on the submillimetre scale, with most machines operating around 100 μm and the most accurate going down to around 25 μm resolution. Similarly, most RP models are made from polymer materials that have limited strength and thermal resistance when compared with metals, for instance. These limitations are a consequence of the layer-based approach and in particular how the layers are combined together. The high temperatures and forces that may be required to combine stronger materials together may also result in expensive technology and energy wastage. Similarly, if machines are built to fabricate parts in the low-micron or submicron scales, machines would require very expensive positioning and control.

Since many existing medical applications do not appear to require high accuracy at present, there are no chapters on this subject in this book. However, there may be some need for such technologies in the future, particularly where there may be a requirement for complex heterogeneous structures. When reading in this book about tissue engineering, I hope you will appreciate the complexity of tissue structures and that they have complex microstructures that may benefit from the developments in micro-RP. Therefore, it is important to note that this technology does exist and a number of systems are under development for manufacturing complex geometry using layer thicknesses of 5 μm or less.

There is a chapter in this book on direct metal fabrication. There is a definite and immediate need for the fabrication of custom artificial implants. While this may be achieved in the longer term by tissue engineering, this technology has many problems to overcome. Direct metal fabrication using RP techniques is also a technology that is still in its infancy, but there are