Chapter 15
Medical Applications for Additive Manufacture

15.1 Introduction

Additive Manufacturing is coming into its third decade of commercial technological development. During that period, we have experienced a number of significant changes that has led to improvements in accuracy, better mechanical properties, a broader range of applications and reductions in costs of machines and the parts made by them. Also in previous chapters, we have seen that AM technologies can vary according to the following non-exclusive list of parameters:

Cost: Since some machines employ more expensive technologies, like lasers, they will inevitably cost more than others.
Range of materials: Some machines can only process one or two materials, while others can process more, including composites.
Maintenance: With some machines being more complex than others, the maintenance requirements will differ. Some companies will add cost to their machines to ensure that they are better supported.
Speed: Due to the technologies applied, some machines will build parts faster than others.
Versatility: Some machines have complex setup parameters where part quality can be balanced against other parameters, like build speed. Other machines have fewer setup variations that make them easier to use but perhaps less versatile.
Layer thickness: Some machines have a limitation on the layer thickness due to the material processing parameters. Making these layers thinner would inevitably slow the build speed.
*Accuracy:* Aside from layer thickness, in-plane resolution also has an impact on accuracy. This may particularly affect minimum feature size and wall thickness of a part. For example, laser-based systems have a minimum feature size that is based on the diameter of the laser beam.

Driven by the automotive, aerospace and medical industries, AM has found applications in design and development within almost every consumer product sector imaginable. As AM becomes more popular and as technology costs inevitably decrease, this can only serve to generate more momentum and further broaden the range of applications. This momentum has been added to with the recent addition of commercial AM machines that can directly process metal powders.

This chapter discusses the use of AM for medical applications which has consistently been one of the key industries driving innovation in AM. With aerospace and automotive industries, AM is valued mainly because of the time that can be saved in development of products. With medicine, the benefit is primarily in the ability to include patient-specific data from medical sources so that customized solutions to medical problems can be found.

15.2   The Use of AM to Support Medical Applications

AM models have been used for medical applications almost from the very start, when this technology was first commercialized. AM could not have existed before 3D CAD since the technology is digitally driven. Computerized Tomography (CT) was also a technology that developed alongside 3D representation techniques. Figure 15.1 shows a CT machine, a model directly generated from this machine (shown as cross-sectional slices) and a model with all segments combined into a 3D image. CT is an X-ray based technique that moves the sensors in 3D space relative to the X-ray source so that a correlation can be made between the position and the absorption profile. By combining multiple images in this way, a 3D image can be built up. The level of absorption of the X-rays is dependent on the density of the subject matter, with bone showing up very well because it is much denser than the surrounding soft tissue. What some people don't realize is that soft tissue images can also be created using CT technology. Clinicians use CT technology to create 3D images for viewing the subject from any angle; so as to better understand any
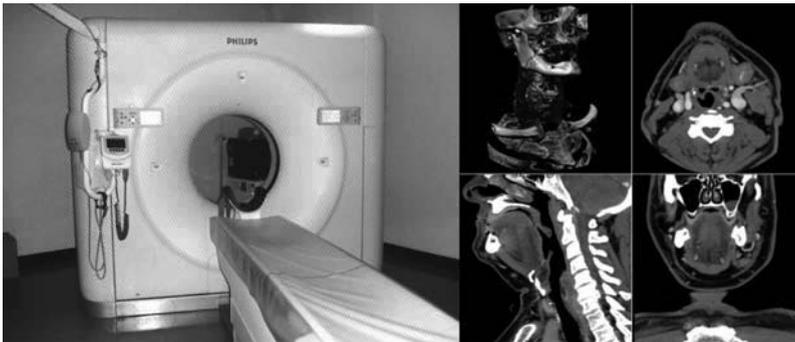
Fig. 15.1 A CT scanner with sliced images and a 3D image created using this technology

associated medical condition. Note that this is one of a number of developing technologies working in the 3D domain, including 3D MRI, 3D Ultrasound, and 3D laser scanning (for external imaging). With this increasing use of 3D medical imaging technology, the need to share and order this data across platforms has led to information exchange standards like DICOM [1], from the National Electrical Manufacturers Association in the US, which allows users to view patient data with a variety of different software and sourced from a variety of different imaging platforms.

While originally used just for imaging and diagnostic purposes, 3D medical imaging data quickly found its way into CAD/CAM systems, with AM technology being the most effective means of realizing these models due to the complex, organic nature of the input forms. Medical data generated from patients is essentially unique to an individual. The automated and de-skilled form of production that AM provides makes it an obvious route for generating products from patient data.

AM-based fabrication contributes significantly to one or more of the following different categories of medical applications:

• Surgical and diagnostic aids
• Prosthetics development
• Manufacturing of medically related products
• Tissue Engineering

We will now go on to discuss how AM is useful to these application areas and some of the issues surrounding their implementation.

15.2.1 Surgical and Diagnostic Aids

The use of AM for diagnostic purpose was probably the first medical application of AM. Surgeons are often considered to be as much artists as they are technically proficient. Since many of their tasks involve working inside human bodies, much of their operating procedure is carried out using the sense of touch almost as much as by vision. As such, models that they can both see from any angle and feel with their hands are very useful to them.

Surgeons work in teams with support from doctors and nurses during operations and from medical technicians prior to those operations. They use models in order to understand the complex surgical procedures for themselves as well as to communicate with others in the team. Complex surgical procedures also require patient understanding and compliance and so the surgeon can use these models to assist in this process too. AM models have been known to help reduce time in surgery for complex cases, both by allowing the surgeons to better plan ahead of time and for them to understand the situation better during the procedure (by having the model on hand to refer to within the operating theater). Machine vendors have, therefore, developed a range of materials that can allow sterilization of parts so that models can be brought inside the operating theater without contamination.

Most applications relate to models made of bony tissue resulting from CT data rather than using soft tissue constructs. MRI data, which is more commonly used for soft tissue imaging, can also be used and cases with complex vascular models have been reported [2]. Bone, however, is more obvious because many of the materials used in AM machines actually resemble bone in some way and can even respond to cutting operations in a similar manner. AM models of soft tissue may be useful for some visualizations, but less can be learned from practising surgery on them since they will not be compliant in the same way. Many models may benefit from having different colors to highlight important features. Such models can display tumors, cavities, vascular tracks, etc. FDM and Objet technology can both be used to represent this kind of part, but probably the most impressive visual models can be made using the colored 3D Printing process from ZCorp. Sometimes, these features may be buried inside bone or other tissue and so having an opaque material encased in a transparent material can also be helpful in these situations. For this, the Stereocol resin that was independently developed for SLA machines [3] or the Connex material from Objet [4] can be used to see inside the part. The Stereocol material no longer appears to be commercially available, however. Some examples of different parts that illustrate this capability can be seen in Fig. 15.2.
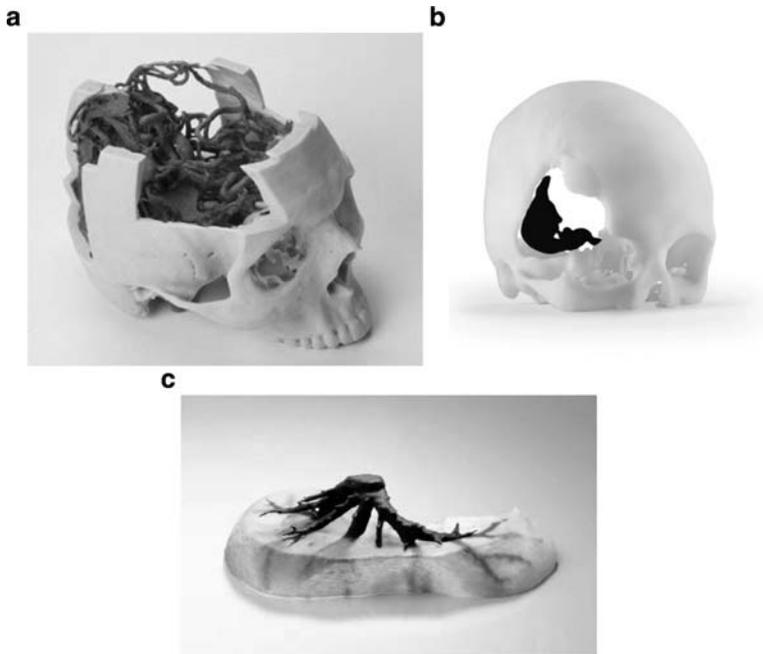

Fig. 15.2 Images of medical parts made using different colored AM systems. (**a**) 3DP used to make a skull with vascular tracks in a darker color. (**b**) A bone tumor highlighted using ABS. (**c**) Objet Connex process showing vascularity inside a human organ

15.2.2 Prosthetics Development

Initially, CT generated 3D models combined with the low resolution of earlier AM technology to create models that may have looked anatomically correct, but that were perhaps not very accurate when compared with the actual patient. As the technology improved in both areas, models have become more precise and it is now possible to use them in combination for fabrication of close-fitting prosthetic devices. Wang [5] states that CT-based measurement can be as close as 0.2 mm from the actual value. While this is subjective, it is clear that resulting models, when built properly, can be sufficiently precise to suit many applications.

Support from CAD software can add to the process of model development by including fixtures for orientation, tooling guidance, and for screwing into bones. For example, it is quite common for surgeons to use flexible titanium mesh as a bone replacement in cancer cases or as a method for joining pieces of broken bone together, prior to osteointegration. While described as flexible, this material still requires tools in order to bend the material. Models can be used as templates for these meshes, allowing the surgeon's technical staff to precisely bend the mesh to shape so that minimal rework is required during surgery. Figure 15.3 shows a maxillofacial model that has been used for this purpose [6].

Alternatively, many AM processes can create parts that can be used as casting patterns or reference patterns for other manufacturing processes. Many prosthetics are comprised of components that have a range of sizes to fit a standard population distribution. However, this means that precise fitting is often not possible and so the patient may still experience some post-operative difficulties. These difficulties can further result in additional requirements for rehabilitation or even corrective surgery, thus adding to the cost of the entire treatment. Greater comfort and performance can be achieved where some of the components are customized, based on actual patient data. An example would be the socket fixation for a total hip joint replacement. While a standardized process will often return joint functionality to the patient, incorrect fixation of the socket commonly results in variable motion that may be a discomfort, painful and require extensive physiotherapy to overcome. Customized fixtures can be made directly in titanium or cobalt–chromium (both
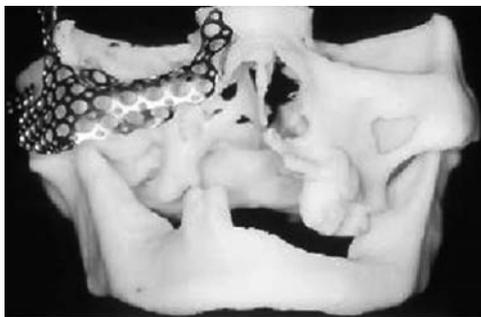
Fig. 15.3 Titanium mesh formed around a maxillofacial model

of which are widely used for implants) using powder bed fusion technology. Such custom devices would reduce the previously mentioned problems by making it possible to more precisely match the original or preferred geometry and kinematics. The use of metal systems provides considerable benefit here. While metal AM systems are not capable of producing the smooth surface finish required for effective joint articulation; the characteristic slight roughness can actually benefit osteointegration when placed inside the bone. Smooth joint articulation can be achieved through extensive polishing and use of coatings. Most metal systems may provide custom shaped implants, but the use of highly focused energy beams will mean that the microstructure will be different and the parts may be more brittle than their equivalent cast or forged components; making brittle fracture from excessive impact loading a distinct possibility.

15.2.3 Manufacturing

There are now examples where customized prosthetics have found their way into mainstream product manufacture. The two examples that are most well known in the industry are in-the-ear hearing aids from companies like Siemens and Phonak and the Invisalign range of orthodontic aligners as developed by Align Technologies. These examples are discussed in detail in Chap. 14. Both of these applications involve taking precise data from an individual and applying this to the basic generic design of a product. The patient data is generated by a medical specialist who is familiar with the procedure and who is able to determine whether the treatment will be beneficial. Specialized software is used that allows the patient data to be manipulated and incorporated into the medical device.

  One key to success for customized prosthetics is the ability to perform the design process quickly and easily. The production process often involves AM plus numerous other conventional manufacturing tasks, and in some cases the parts may even be more expensive to produce; but the product will perform more effectively and can sell at a premium price because it has components which suit a specific user. This added value can make the prosthetic less intrusive and more comfortable for the user. Additionally, the use of a direct digital manufacturing makes it easier for manufacturers and practitioners.

15.2.4 Tissue Engineering and Organ Printing

The ultimate in fabrication of medical implants would be the direct fabrication of replacement body parts. This can feasibly be done using AM technology, where the materials being deposited are living cells, proteins and other materials that assist in the generation of integrated tissue structures. However, although there is a great

deal of active research in this area, practical applications are still quite a long way off. The most likely approach would be to use printing and extrusion-based technology to undertake this deposition process. This is because droplet-based printing technology has the ability to precisely locate very small amounts of liquid material and extrusion-based techniques are well-suited to build soft-tissue scaffolding. However, ensuring that these materials are deposited under environmental conditions conducive to cell growth, differentiation and proliferation is not a trivial task. This methodology could eventually lead to the fabrication of complex, multi-cellular soft tissue structures like livers, kidneys and even hearts.

A slightly more indirect approach that is more appropriate to the regeneration of bony tissue would be to create a scaffold from a biocompatible material that represents the shape of the final tissue construct and then add living cells at a later juncture. Scaffold geometry normally requires a porous structure with pores of a few hundred microns across. This size permits good introduction and ingrowth of cells. A micro-porosity is often also desirable to permit the cells to insert fibrils in order to attach firmly to the scaffold walls. Different materials and methods are currently under investigation, but normally such approaches use bioreactors to incubate the cells prior to implantation. Figure 15.4 shows a scaffold created for producing a mixture of bone and cartilage and then implanted into a rabbit [7]. The scaffold was a mixture of polcaprolactone (PCL) which acts as a matrix material, which is also biodegradable. Mixing Tri-calcium phosphate (TCP) enhances the biocompatibility with bone to encourage bone regeneration and also enhances the compressive modulus of the scaffold. Even with this approach, it is still a challenge to maintain the integrity of the scaffold for sufficient lengths of time for healthy and strong bone to form. While using this approach to create soft tissue structures or load-bearing bone is also some way from reality, some non-load-bearing bone constructs have already been commercially proven [8].
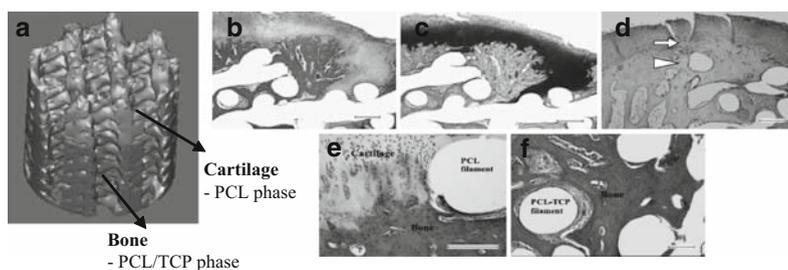
Fig. 15.4 Hybrid scaffolds composed of two phases: (**a**) Polycaprolactone (PCL) layer for cartilage tissue and bottom PCL/TCP (Tri-calcium phosphate) layer for bone. (**b–f**) Implantation in a rabbit for 6 months revealed formation of subchondral bone in the PCL/TCP phase and cartilage-like tissue in PCL phase. Bar is 500 μm in (**b–d**) and 200 μm in (**e**) and (**f**)

15.3   Software Support for Medical Applications

There are a number of software tools available to assist users in preparing medical data for AM applications. Initially, such software concentrated on the translation from medical scanner systems and the creation of the standard STL files. Models made were generally replicas of the medical data. With the advent of the DICOM scanner standard, the translation tools became unnecessary and it became necessary for such systems to add value to the data in some way. The software systems therefore evolved to include features where models could be manipulated and measured and where surgical procedures like jawbone resections could be simulated in order to determine locations for surgical implants. These have further evolved to include software tools for inclusion of CAD data in order to design prosthetic devices or support for specific surgical procedures.

Consider the application illustrated in Fig. 15.5 [9]. In this application, a prosthetic denture set is fixed by drilling precisely into the jawbone so that posts can be placed for anchoring the dentures. A drill guide was developed using AM, positioning the drill holes precisely so that the orthodontist could drill in the correct location and at the correct angle. The software system allows the design of the drill guide to be created, based on the patient data taken from medical scans. AM models can also be used in the development of the prosthetic itself.

Most CAD/CAM/CAE tools are used by engineers and other professionals who generally have good computer skills and an understanding of the basic principles of how such tools are constructed. Clinicians have very different backgrounds and their basic understanding is of biological and chemical sciences with a deep knowledge of human anatomy and biological construction. Computer tools must therefore focus on being able to manipulate the anatomical data without requiring too much knowledge of CAD, graphics or engineering construction. Software support tools for AM-related applications should therefore provide a systematic solution where different aspects of the solution can be dealt with at various stages so that the digital data is maintained and used most effectively, like the application in Fig. 15.5 where software and AM models were used at various stages to evaluate the case and to assist in the surgical procedure.

Tissue engineering is where DDM is heading in the medical arena, leading to direct manufacture of medical replacement parts. Software tools that deal with these applications are likely to be very different from conventional CAD/CAM tools. This is because the data is constructed in a different form. Medical data is

Fig. 15.5 Drill guides developed using AM related software and machines
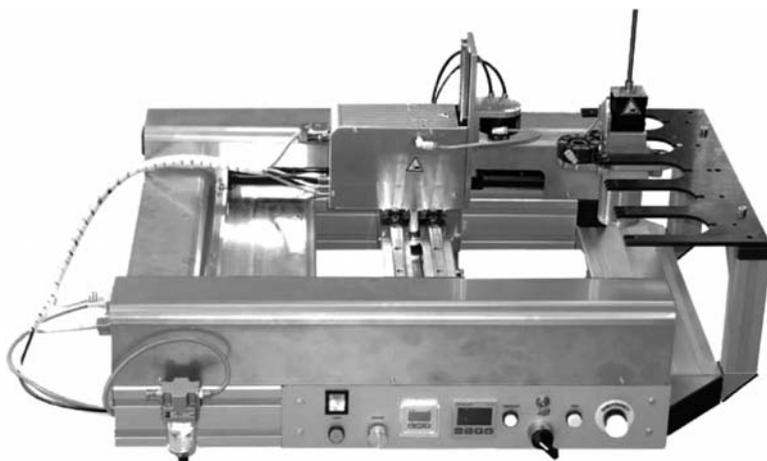
Fig. 15.6 The Envisiontec Bioplotter. Note the interchangeable extrusion head system and the extensive use of stainless steel in the fabrication

almost by definition freeform. If it is to be accurately reproduced, then these models require large data files. In addition, the scaffolds to be created will be highly porous, with the pores in specific locations. STL files are likely to be somewhat useless in these applications, plus if the STL files included the pore architecture they would be inordinately large. Figure 15.4a for example, would normally be made using an extrusion process similar to FDM, where each cross-member of the scaffold would normally correspond to an extrusion road. It would be somewhat pointless for every cross-member to be described using STL, since the slices correspond to the thickness and location of these cross-member features. Most scaffold fabrication systems, like the 3D-Bioplotter from Envisiontec [10], shown in Fig. 15.6, include an operating system that includes a library of scaffold fill geometries that include pore size, layer thickness, etc. rather than STL slicing systems.

15.4 Limitations of AM for Medical Applications

Although there is no doubt that medical models are useful aids to solving complex surgical problems, there are numerous deficiencies in existing AM technologies related to their use to generate medical models. Part of the reason for this is because AM equipment was originally designed to solve problems in the more widespread area of manufactured product development and not specifically to solve medical problems. Development of the technology has therefore focused on improvements to solve the problems of manufacturers rather than those of doctors and surgeons. However, recent and future improvements in AM technology may open the doors to

a much wider range of applications in the medical industry. Key issues that may change these deficiencies in favor of using AM include:

– Speed
– Cost
– Accuracy
– Materials
– Ease of use

By analyzing these issues, we can determine which technologies may be most suitable for medical applications as well as how these technologies may develop in the future to better suit these applications.

15.4.1   Speed

AM models can often take a day or even longer to fabricate. Since medical data needs to be segmented and processed according to anatomical features, the data preparation can in fact take much longer than the AM building time. Furthermore, this process of segmentation requires considerable skill and understanding of anatomy. This means that medical models can effectively only be included in surgical procedures that involve long-term planning and cannot be used, for example, as aids for rapid diagnosis and treatment in emergency operations.

  Many AM machines now have excellent throughput rate, both in terms of build speed and post-processing requirements. A few more iterations towards increasing this throughput could lead to these machines being used in outpatient clinics, at least for more effective diagnosis. However, it must be understood that this use must be in conjunction with improvements in supporting software for 3D model generation that reduces the skill requirements and increases the level of data processing automation. For tissue engineering applications, the time-frames are a lot longer since we must wait for cells to proliferate and combine in the bioreactors. However, the sooner we can get to the stage of seeding scaffolds with cells, the better.

15.4.2   Cost

Using AM models to solve manufacturing problems can help save millions of dollars for high-volume production, even if only a few cents are saved per unit. For the medical product (mass customization) manufacturing applications mentioned earlier, machine cost is not as important as perhaps some other factors. In comparison, the purpose of medical models for diagnosis, surgical planning and prosthetic development is to optimize the surgeon's planning time and to improve quality, effectiveness and efficiency. These issues are more difficult to quantify in

terms of cost, but it is clear that only the more complex cases can easily justify the expense of the models. The lower the machine, materials and operating costs, the more suitable it will be for more medical models. Some machines are very competitively priced due to the use of low-cost, high-volume technologies, like inkjet printing. Some other processes have lower cost materials, but this relates to consumable costs, which can also be reduced with increase of volume output.

15.4.3 Accuracy

Many AM processes are being improved to create more accurate components. However, many medical applications currently do not require higher accuracy because the data from the 3D imaging systems are considerably less accurate than the AM machines they feed into. However, this does not mean that users in the medical field should be complacent. As CT and MRI technologies become more accurate and sophisticated, so the requirements for AM will become more challenging. Indeed some CT machines appear to have very good accuracy when used properly. Also, this generally relates to medical models for communication and planning, but where devices are being manufactured the requirements for accuracy will be more stringent. Applications which require precise fitting of implants are now becoming commonplace.

15.5 Materials

Only a few AM polymer materials are classified as safe for transport into the operating theater and fewer still are capable of being placed inside the body. Those machines that provide the most suitable material properties are generally the most expensive machines. Powder-based systems are also somewhat difficult to implement due to potential contamination issues. This limits the range of applications for medical models. Many AM machine manufacturers now have a range of materials that are clinically approved for use in the operating theater.

Metal systems, on the other hand, are being used regularly to produce implants using a range of technologies, as reported by Wohlers [11]. Of these, it appears that titanium is the preferred material, but Cobalt Chromium and Stainless Steel are both available candidates that have the necessary biocompatibility for certain applications.

15.5.1 Ease of Use

AM machines generally require a degree of technical expertise in order to achieve good quality models. This is particularly true of the larger, more complex and more

versatile machines. However, these larger machines are not particularly well suited to medical laboratory environments. Coupled with the software skills required for data preparation, this implies a significant training investment for any medical establishment wishing to use AM. While software is a problem that all AM technologies face, it doesn't help that the machines themselves often have complex setup options, materials handling, and general maintenance requirements.

15.6   Further Development of Medical AM Applications

It is difficult to say whether a particular AM technology is more or less suited to medical applications. This is because there are numerous ways in which these machines may be applied in this field. One can envisage that different technologies may find their way into different medical departments due the specific benefits they provide. However, the most common commercial machines certainly seem to be well suited to being used as communication aids between surgeons, technical staff and patients. Models can also be suitable for diagnostic aids and can assist in planning, the development of surgical procedures and for creating surgical tools and even the prosthetics themselves. Direct fabrication of implants and prosthetics is however limited to the direct metal AM technologies that can produce parts using FDA (The US Food and Drug Administration) certified materials plus the small number of technologies that are capable of non load-bearing polymer scaffolds.

For more of these technologies to be properly accepted in the medical arena, a number of factors must be addressed by the industry:

– Approvals
– Insurance
– Engineering training
– Location of the technology

15.6.1   *Approvals*

While a number of materials are now accepted by the FDA for use in medical applications, there are still questions regarding the best procedures for generating models. Little is known about the materials and processes outside of the mainstream AM industry. Approval and certification of materials and processes through ASTM will certainly help to pave the way towards FDA approval, but this can be a very long and laborious process.

Those (relatively few) surgeons who are aware of the processes seem to achieve excellent results and are able to present numerous successful case studies. However,

the medical industry is (understandably) very conservative about the introduction of these new technologies. Surgeons who wish to use AM generally have to resort to creative approaches based on trusting patients who sign waivers, the use of commercial AM service companies, and word of mouth promotion. Hospitals and health authorities still do not have procedures for purchase of AM technology in the same way they might purchase a CT machine.

15.6.2   Insurance

Many hospitals around the world treat patients according to their level of insurance coverage. Similar to the aforementioned issue of approvals, insurance companies do not generally have any protocols for coverage using AM as a stage in the treatment process. It may be possible for some schemes to justify AM parts based on the recommendations of a surgeon, but some companies may question the purpose of the models, requiring additional paperwork that may deter some surgeons from adopting that route.

Again, this issue may be solvable through a process of legitimizing the industry. In the past, AM was considered as a technology suitable mainly for prototypes in the early phases of product development. As we move more and more into mainstream manufacturing, the industry and consumers become more demanding. Part of the satisfying of this demand is the certification process. Insurance companies are also more likely to accept these technologies as part of the treatment process if there are effective quality control mechanisms in place. Also, the increasing number of successful applications using metal systems may lead to the polymer-based machines also becoming more acceptable.

15.6.3   Engineering Training

Creating AM models requires skills that many surgeons and technicians will not possess. While many of the newer, low-cost machines do not require significant skill to operate, preparation of the files and some post-processing requirements may require more ability. The most likely skills required for the software-based processing can be found in radiology departments since the operations for preparation of a software model are similar to manipulation and interpretation of CT and MRI models. However, technicians in this area are not used to building and manipulating physical models. These skills can however be found in prosthetics and orthotics departments. It is generally quite unusual to find radiology very closely linked with orthotics and prosthetics. The required skills are, therefore, distributed throughout a typical hospital.

15.6.4 Location of the Technology

AM machines could be located in numerous medical departments. The most likely would be to place them either in a laboratory where prosthetics are produced, or in a specialist medical imaging center. If placed in the laboratories, the manual skills will be present but the accessibility will be low. If placed in imaging centers, the accessibility will be high but the applications will probably be confined to visualization rather than fabrication of medical devices. Fortunately, most hospitals are now well equipped with high speed intranets where patient data can be accessed quickly and easily. A separate facility that links closely to the patient data network and one that has skilled software and modeling technicians for image processing and for model post-processing (and associated downstream activities) may be a preference.

15.6.5 Service Bureaus

It can be seen that most of the hurdles for AM adoption are essentially procedural in nature rather than technical. A concerted effort to convince the medical industry of the value of AM models for general treatment purposes is, therefore, a key advancement that will provide a way forward.

There are small but increasing number of companies developing excellent reputations by specializing in producing models for the medical industry. Companies like Medical Modelling LLC [12] and Anatomics [13] have been in business for a number of years, not just creating models for surgeons but assisting in the development of new medical products. These service bureaus fill the skill gap between the medics and the manufacturers. At the moment, this technology is not well understood in the medical industry and it may be some time before it can be properly assimilated. Eventually, AM technology will become better suited to a wider range of medical applications and at this point, the hospitals and clinics may have their own machines with the in-built skills to use them properly. Furthermore, the large medical product manufacturers will also see the benefits of this technology in product development and DDM. As the technology becomes cheaper, easier to use and better suited to the application, such support companies may no longer be necessary to support the industry. This is something the AM industry has seen in other application sectors. In the meantime, these companies provide a vital role in supporting the industry from both sides.

15.7 Exercises

1. How does Computerized Tomography actually generate 3D images? Draw a sketch to illustrate how it works, based on conventional knowledge of X-ray imaging.

2. What are the benefits of using color in production of medical models? Give several examples where color can be beneficial.
3. Why might extrusion-based technology be particularly useful for bone tissue engineering?
4. What AM materials are already approved for medical applications and for what types of application are they suitable?
5. Consider the manufacture of metal implants using AM technology. Aside from the AM process, what other processing is likely to be needed in order to make a final part that can be implanted inside the body?

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