White Paper

An Assessment of Objet Geometries' Technologies in the Medical Arena

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ABSTRACT

This paper is an evaluation of how Objet PolyJet™ Technology fits within a medical applications framework. The advantages of using additive fabrication technology in medical applications have long been evident. However, to date the number of machines sold for medical use has been limited. This may change in the future as companies address some of the issues discussed in this paper. In addition, this paper explains how Objet technology is at the forefront of certain medical applications.

INTRODUCTION

Rapid prototyping (RP), now more commonly referred to as layer-based additive fabrication, is in its third decade of commercial technological development. Since its introduction there have been a number of significant changes, including improvements in accuracy and material strength, increases in the range of applications and reductions in the cost of machines and parts. One of the most important recent innovations is the introduction of droplet-based deposition which takes advantage of the expertise generated from the development of ink-jet technology and applies it to different substrates and materials in RP processes. The droplets are extremely small in volume, which allows for a high precision needed for fine detail and in the surface finish of RP parts. In addition, the base material is strong enough for the fine detail to support its own mass.

Objet's PolyJet™ Technology employs print heads similar to those used in high-speed inkjet systems, ejecting photopolymer layer by layer. This process uses different print nozzles to deposit part material along with support material. As mentioned above, the parts can be finely detailed due to the droplet size, allowing for thin layers and walls in any orientation. Support material can be easily removed using water jets. This means the downward-facing surfaces are also very clear, a property lacking in other technologies. Different material properties can be achieved using different photopolymers, and the newer machines now deposit more than one part material to create parts with multiple properties such as two colors or two hardness values.

By using multiple nozzles, it is possible to increase the deposition speed. And by using additional nozzlesmore material can be deposited without compromising accuracy or part quality. Objet's machines, which are in effect 3D printers, have up to eight separate jetting heads, with 96 nozzles each, covering a large printing band in a single pass. This provides important advantages when compared with other RP machines that use fewer nozzles or a single laser spot to scan the surface. Objet 3D printers employ a raster scanning system, which allows for each layer to take approximately the same time to build. This makes build planning very easy to calculate. The alternative system, vector scanning, which, though it may be quicker for building layers that have only small areas, may have highly variable build times per layer. Thus, with vector scanning systems, build times are notoriously difficult to calculate.

In addition, PolyJet Technology has a positive impact on machine cost due to the photopolymer materials used, as curing does not require expensive lasers. Instead, a low-cost UV lamp follows the print head as each layer is deposited. The complex technology is concentrated in the inkjet printer heads that, despite their very precise and sophisticated technology, are a hig- volume product -as similar technology is used in the printing industry. When compared to the printing industry, the RP industry is currently a low volume market, and as a result, cannot dictate the development course of technology.

The technological advantages mentioned above position Objet as a strong competitor in a rapidly growing marketplace. Originally driven by the automotive, aerospace and medical industries, RP has aksi found applications in the design and development of almost every consumer product sector. Increased popularity will bring cost reductions, generating more momentum and further broadening the range of applications.

RP Support for Medical Applications

Almost from the outset, RP models have been used in medical applications. Both RP and Computerized Tomography (CT) developed alongside 3D representation techniques. RP technology is the most effective means of physically realizing models based on While CT data was originally used only for imaging and diagnostic purposes, it soon was commonly used in CAD/CAM systems for model design. Due to the complex, organic nature of the product, RP technology was the most effective means of realizing these models. Medical data generated from patients is unique to the individual. Because of the complexity of CT data, the automated and deskilled form of production provided by RP makes it an excellent choice for generating products based on patient data. RP-based fabrication has been used in the following medical applications:

- Surgical and diagnostic aids
- Prosthetics and medical product development
- Manufacturing
- Tissue Engineering

Surgical and Diagnostic Aids: This was probably the first RP medical application. Surgeons perform much of their work in the operating room using both sight and touch. Consequently, models, which can be seen and touched from any angle, are useful because they help surgeons understand complex surgical procedures. Also, models help improve communications between the surgery team members and between the surgeon and the patient. RP models have been known to reduce surgery time in complex cases by allowing the surgeons to both better plan ahead and to better understand the situation during the procedure. (In such cases, sterilized models are brought into the operating room.)

The model materials resemble bone and respond to cutting in a similar manner. As a result, most models are of bony tissue rather than soft tissue constructs. While CT data provides the source for the majority of medical models, , MRI data can also be used. For example, cases of complex vascular models based on MRI data have been reported. RP models of soft tissue are useful for certain aspects of visualization but little can be learnt from practicing surgery on them.

Models can be multi-colored to highlight important features, such as tumors, cavities, vascular tracks, etc. And, when these features are buried inside bone or other tissue, an opaque material encased in a transparent material can be used.

Prosthetics and Medical Product Development: Initially, CT-generated data were combined with low resolution RP to create models that looked anatomically correct but were not accurate when compared with the actual patient. As the technologies improved, models have become more precise and it is now possible to use these technologies in the fabrication of close-fitting prosthetic devices. CAD software supports this process by providing fixtures for orientation and tooling guidance when screwing into bone. It is quite common for surgeons to use flexible titanium mesh for bone replacement or for joining pieces of broken bone prior to osteointegration. Models can be used as templates for these meshes, allowing the surgeon's technical staff to bend the mesh into the correct shape prior to surgery, so that minimal rework is required during surgery. Alternatively, RP processes can create parts to be used as casting patterns or reference patterns during machining processes.

Many prosthetics are built using components that come in a range of sizes to fit a standard population distribu difficulties. Greater comfort and performance can be achieved when some of the components are customized. For example, in the case of the, While a socket fixturing for a total hip joint replacement built using a standardized process often returns joint functionality to the patient, incorrect fixturing of the socket commonly causes discomfort, requiring extensive physiotherapy. A customized fixture would reduce the discomfort by making it possible to more precisely match the original or preferred geometry and kinematics.tion. This means that a precise fit is often not possible, resulting in the patient experiencing post-operative

Fig 2. Medical models can be used to create prosthetic devices, such as implants precisely fabricated to match a cavity. Engineering features can be easily added, making it possible to correctly fix the implant in place.

Manufacturing: The concept of developing RP into rapid manufacturing (RM) is set to extend the scope of the industry by an order of magnitude. RP technology provides the ability to incorporate custom features into mass-produced products. This form of mass-customization can be applied to consumer products that require anatomical information to perform effectively. The two most well known examples are in-the-ear hearing aids and orthodontic aligners. Both these applications involve taking precise data from an individual and applying this to the design of a manufactured product. Using PR technology may make the production process more expensive but the product will perform more effectively and can, therefore, sell at a premium price.

Tissue Engineering: The ultimate in medical implants would be the fabrication of replacement body parts. This can be feasibly done using RP technology, with the deposited materials being cells, proteins and other materials that assist in the generation of integrated tissue structures. An indirect process would be to create a scaffold from a biocompatible material that represents the shape of the final tissue construct and then add cells at a later juncture. Such processes generally use bioreactors to incubate the cells prior to implantation. While creating soft tissue structures or load-bearing bone is still not technologically possible, some non-load bearing bone constructs have already been commercially proven.

Limitations of RP for Medical Applications

Although medical models are useful aids in solving complex surgical problems, there are numerous deficiencies in the RP technology used to generate the models. This is partly due to the RP equipment having been originally designed for manufactured product development and not specifically to solve medical problems. Subsequent developments in the technology have focused on improvements to help manufacturers rather than surgeons. However, recent improvements are set to open the way to much wider application in the medical industry. Key issues that will make RP technologies more useful in the future include:

Speed: RP models can take a day or even longer to create. Because medical data must be segmented and processed according to anatomical features, data preparation can take longer than the RP building time. This means medical models can be included only in surgical procedures that involve long-term planning and cannot be used as aids in emergency operations. Objet 3D printers have an excellent throughput rate, both in terms of build speed and post-processing requirements. Additional improvements in throughput would allow these machines to be used in outpatient clinics. However, this application is contingent on improvements in the supporting software for 3D model generation.

Cost: Using RP models to solve manufacturing problems can save millions of dollars in high-volume productions. For the medical products mentioned above, machine cost is not as important as some other factors. However, when medical models are used for diagnosis, surgical planning and prosthetic development, the cost-effectiveness is difficult to quantify since the results are shorter planning times and improved quality, effectiveness and efficiency. Consequently, only complex cases can justify the expense of the models.

The lower the machine, materials and operating costs, the more practical RP will be for additional medical applications. Already, Objet machines are priced competitively thanks to the use of inkjet printing technology. There are other RP processes that use less expensive materials. Nevertheless, consumables costs can be reduced with higher volume output.

Accuracy: While many RP processes are undergoing improvements to enable more accurate models, medical applications do not currently require higher accuracy because the data available from 3D imaging systems is considerably less accurate than what the RP machines can produce. However, as CT and MRI technologies become more sophisticated, the requirements for RP technology accuracy will become more challenging.

In manufacturing of medical devices, as opposed to models, the requirements for accuracy are more stringent. However, Objet 3D printers are presently able to meet such requirements and applications for the precise fitting of implants using Objet technology are becoming commonplace.

Materials: Only a few RP materials are classified as safe for transport into the operating room and none are currently safe for insertion inside the body. The machines that provide the most suitable material properties are also the most expensive machines. Powder-based systems are difficult to implement due to contamination issues. These restrictions limit the range of applications for medical models. Despite the stringent requirements, Objet has a range of materials that are clinically approved for these purposes. The accuracy of parts produced using PolyJet process makes it a viable option when more complex process chains are required, for example to manufacture cast metal parts.

Ease of Use: RP machines generally require a degree of technical expertise to achieve good quality models. This is particularly true for the larger, more complex and more versatile machines, which are not particularly well suited for medical laboratory environments. Coupled with the software skills required for data preparation, there is a significant training investment required for any medical establishment wishing to use the technology. This is a problem all RP technologies face due to the complexity of the support software for part preparation and design. As a result, Objet designs machines with simple setup options and easy materials handling and general maintenance.

DISCUSSION AND CONCLUSIONS

It is difficult to say whether a particular RP technology is more or less suited to medical applications because there are numerous ways in which these machines can be applied in this field. Different technologies may find their way into different medical departments based on the specific benefits they provide.

Objet machines certainly seem to be well suited for producing models to be used as communication aids between surgeons, technical staff and patients. These models can also be used as diagnostic aids, to assist in the planning and development of surgical procedures, and for creating surgical tools and prosthetics.

However, for these technologies to be properly accepted in the medical industry, a number of factors must be addressed:

Approvals – While a number of materials have been granted medical approvals (such as Objet's FullCure720) for use in medical applications, questions remain regarding the fabrication technologies and procedures for generating models. The relatively few surgeons using RP processes have achieved excellent results and are able to present numerous successful case studies. Nevertheless, the medical industry is understandably cautious about the introduction of new technologies. Surgeons must employ creative approaches to promote the use of PR processes in surgery including having patients sign waivers, using commercial RP service companies and word of mouth. Additionally, hospitals do not have standard procedures for the purchasing of RP machines in the same way they do for CT machines.

Insurance – Many hospitals treat patients according to their insurance coverage. Insurance companies do not have a protocol for the use of RP in the treatment process. Companies may question the purpose of the RP models, requiring additional paperwork that may deter surgeons.

Engineering Training – Creating RP models requires skills that many surgeons and medical technicians do not possess. While Objet machines do not require significant skills to operate, the preparation of the files and post-processing requirements may require more training.

Location of the Technology – It is possible to locate RP machines in various medical departments. The most likely location would either be in a laboratory where prosthetics are produced or in a specialist medical imaging centre. If placed in a laboratory, the necessary operating skills will be present but the accessibility will be low. If placed in an imaging center, accessibility will be high but the applications of the technology will be limited to visualization rather than fabrication of medical devices.
Fortunately, most hospitals are well equipped with high speed intranets where patient data can be accessed quickly and easily. It is preferable to locate the RP machine in a separate facility closely linked to the patient data network, with the necessary software and skilled technicians for image processing and for model post-processing and associated downstream activities.

Most of the problems mentioned above are procedural rather than technical issues. A concerted effort to convince the medical industry of the value of RP models offer will advance their usage.