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July 25, 2014

Mr. Smith
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Dear Mr. Smith,

Thank you for providing me with the opportunity to research emerging technology for Denver Biomedical Frontiers. Enclosed is my final report, "Recommended Biomaterials and Manufacturing Futures." Within this report you will find my recommendations for biocompatible materials, advanced manufacturing equipment, and techniques for those materials.

If you have further questions or require assistance, please contact me.

Respectfully,

Student

Recommended Biomaterials and Manufacturing Futures

for

Mr. Smith

Denver Biomedical Frontiers, LLC.

Board of Directors

by

Denver Biomedical Frontiers, LLC

Research and Development Department

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example

Abstract

This report provides an analysis and evaluation of the EOS M 290 in relation to Denver BioMedical Frontiers LLC (DBF). Methods of analysis include research of 3D printing, biomedical implants and trends, feasibility, and forecasts for the use of this technology. Results of this research show that direct metal laser sintering (DMLS) has current and future applications in the biomedical field. This report also found that the need for biomedical implants continues to expand. DBF would greatly benefit from the acquisition of an EOS M 290 DMLS printer. Although this report is limited in scope. FDA regulations and approval process of DMLS manufactured implants was not fully reviewed for this paper.

example

Introduction

Titanium is an optimal choice when it comes to biomedical implants. According to Emsley (2001), titanium is corrosion resistant, is biocompatible, and can remain in place for up to 20 years. Titanium implants can be rapidly manufactured with extreme precision via direct metal laser sintering. This report examines the feasibility of bringing DMLS application to the Denver Biomedical Frontiers company.

Background

Denver Biomedical Frontiers is well known for breaking boundaries in the biomed field. DBF has consistently stayed ahead of the curve to provide patients with cutting edge solutions and technologies.

The current process for complex implants is slow and inaccurate. Implants are currently manufactured via lengthy processes. Machining, a process that removes material from a solid block of titanium (or other material), is extremely accurate but cannot create the complex geometries required for most implants. Casting titanium requires the creation of expensive molds, is somewhat inaccurate, and lacks the ability for certain geometries as well. Not only are these processes of fabrication lengthy, but the inaccuracies within these fabrications increase time required for surgical procedures. The EOS M 290s laser is capable of precision down to 100 μm (0.004 in). The M 290 can produce a nearly finished product in a matter of hours or days instead of weeks. Denver Biomedical Frontiers plans to implement the M 290 as the industry standard for patient specific titanium implants.

Methods

Research and evaluation must be completed by Denver Biomedical Frontiers before obtaining new technology. Studies and reports from reliable sources were reviewed to determine the best implant material and the ideal manufacturing technique for that material. Sources were also

reviewed to determine feasibility, current status, and projected usage of this technology.

Results

Best Materials

Only a limited number of materials can be implanted in the human body without the chance for rejection. Biomedical engineering firms have created different forms of biocompatible polymers. This report found that biocompatible polymers have a very promising future but DBF will not implement them yet. Titanium has been established as an excellent biomedical implant material. It is strong, resistant to corrosion, and will not be rejected by the body if implanted. Emsley (2001) found that the material can easily stay in a body for 20 years and that some dental implants were still intact after 30 years. Although the process of DMLS printed implants for patient specific issues is new studies have already been completed on DMLS manufactured implants. Research by F. Mangano, Franco, Macchi, Piattelli and C. Mangano found that 100% of implants (15 patients) in a 1-year study were found to be stable with no signs of infection.

Manufacturing techniques

The current manufacturing processes have many issues. If a surgery is performed and a custom made implant isn't used the surgeon may choose to use an "off the shelf" alternative. These alternatives have a few sizes but rarely fit as needed. If a custom implant is desired it must be manufactured with a lengthy and/or inaccurate process.

In order to increase accuracy a computed tomography (CT) scan or a magnetic resonance imaging (MRI) scan is performed. These scans provide a very high resolution three-dimensional image of the affected area. The scans are then imported into a three dimensional computer aided design (CAD) program. The technician then has the ability to create an implant that will fit perfectly with/into the affected area.

The idea of sintering metal to create an object was patented in 1970 but effective commercial application of DMLS wasn't achieved until 1994 according to Shellabear (2004). Direct metal laser sintering is a relatively simple process to explain although everything about the process is

very complex. A very fine layer of powdered metal ($\sim 20\ \mu\text{m}$) is automatically spread onto the build platform. A very powerful and precise laser then fires at areas determined by the 3D CAD model to sinter the metal. The build platform is then lowered and recoated with the powdered metal. The process continues, layer by layer, until the part is created. Figure 1 provides an illustrated look at the process.

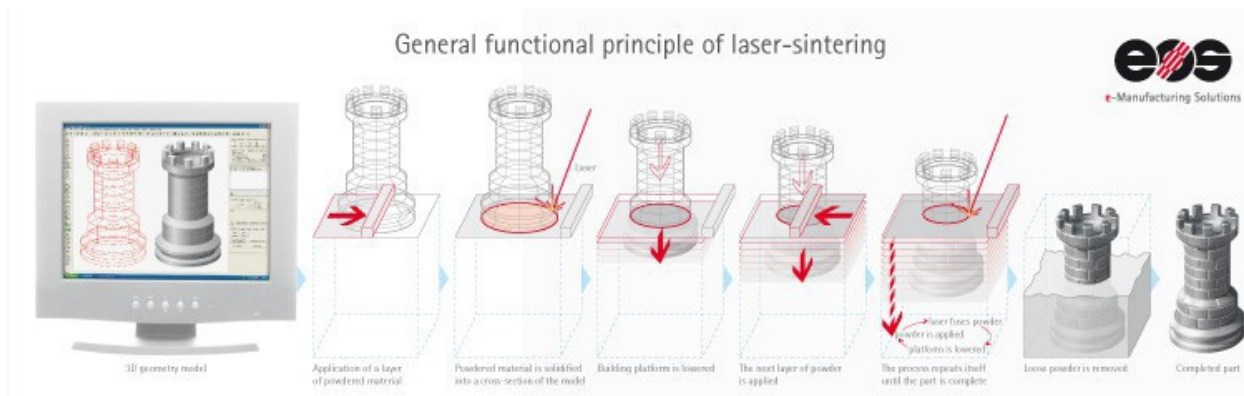


Figure 1: General Functional Principle of Laser-sintering (Source: EOS)

These processes can then be combined to manufacture a patient specific implant. The common workflow to generate this part is illustrated in figure 2. This workflow has already been combined and used successfully. A groundbreaking hip surgery was conducted at the University of Southampton, England, in May of 2014 (University of Southampton, 2014). Figure 3 shows the patients hip pre and post operation. The patient had 6 hip surgeries prior to this surgery, none of which were successful. The new hip implant was a perfect fit for the patient and functioned properly. A Belgian patient lost her jaw to osteomyelitis but doctors successfully replaced her jaw with a titanium jaw created via DMLS (Reuters UK, 2014). The jaw was a perfect fit, the surgery was only a few hours, and the patient was able to leave the hospital that day. With traditional methods this surgery would have taken 20 hours and the patient would have stayed in the hospital for months (Reuters UK, 2014). DMLS continues to grow and expand. CU Denver Anschutz Medical Campus recently acquired the EOS M270 for study and application (CU Connections, 2014).

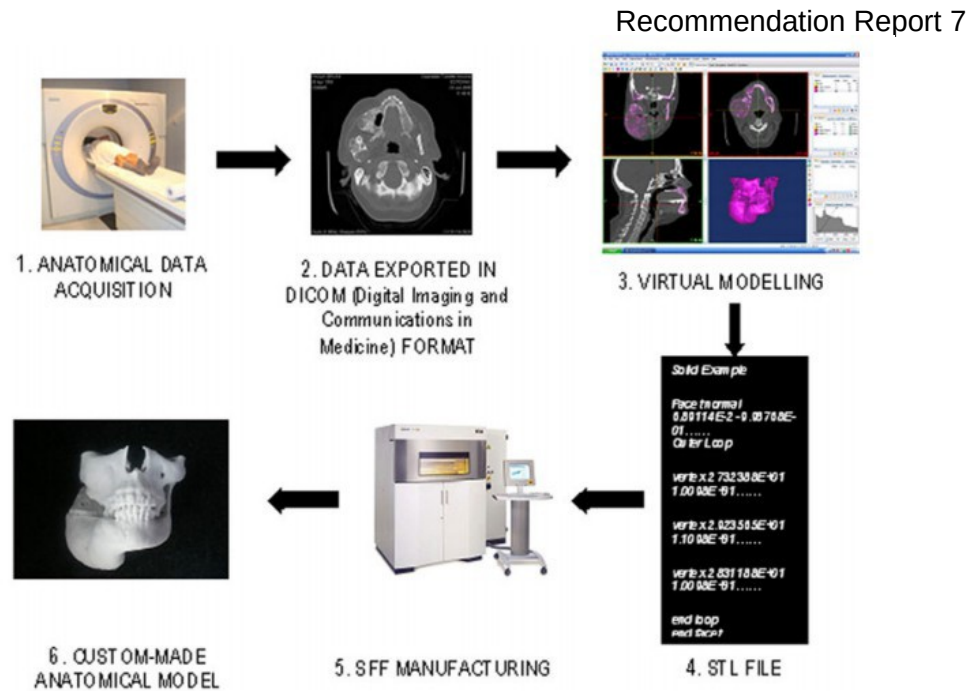


Figure 2: DMLS biomedical implant manufacturing process flow (Source: [Medical & Biological Engineering & Computing](#))

Pre- and postoperative situation

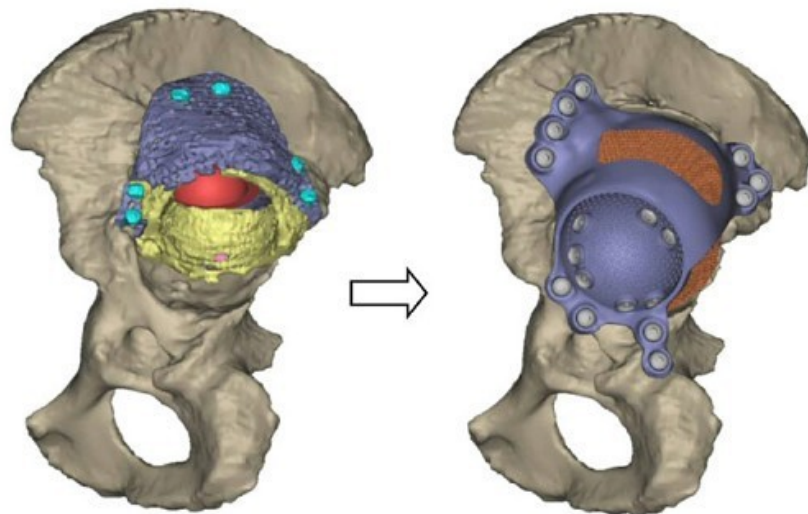


Figure 3: Pre and post operative hip surgery (Source: University of Southampton)

Current and predicted futures

The need to orthopedic implants continues to rise in the United States. The number of total knee replacement (TKR) surgeries has doubled in the U.S (Kurtz et al., 2009) Figure 4 displays the trend of TKR rapidly increasing but also shifting to a younger demographic. Figure 5 displays the increase and forecast for total hip arthroplasty (THA) and total knee arthroplasty (THK). Transparency Market Research (2013) estimates that the 3D printing market for medical applications generated revenues of nearly \$346 million in 2012, and that the number will grow to almost \$1 billion by 2019.

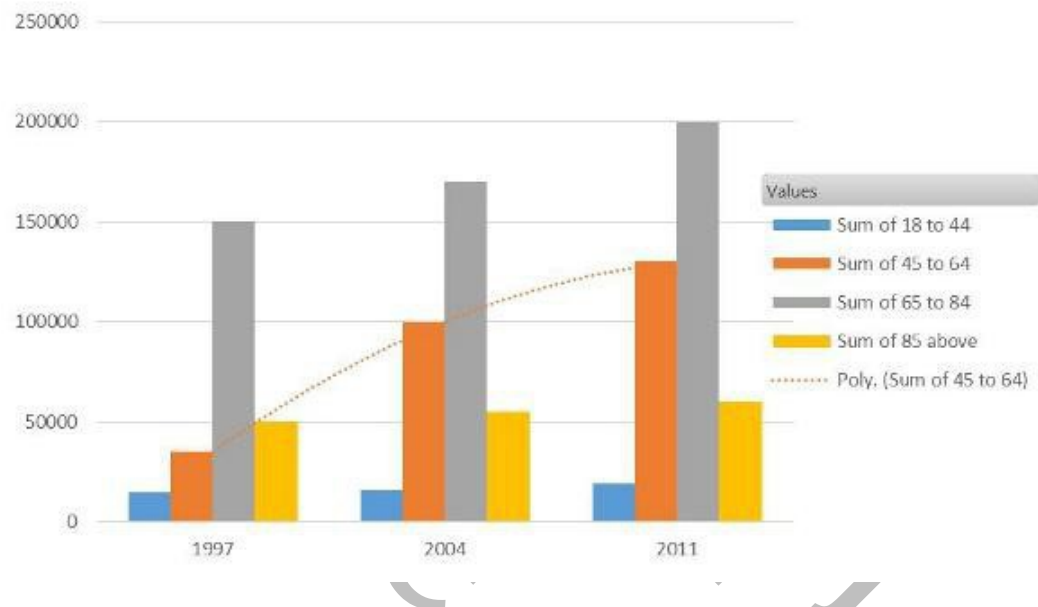


Figure 4: Distribution of adults in need of a knee replacement in the U.S. (Source: Agency of Healthcare Research and Quality)

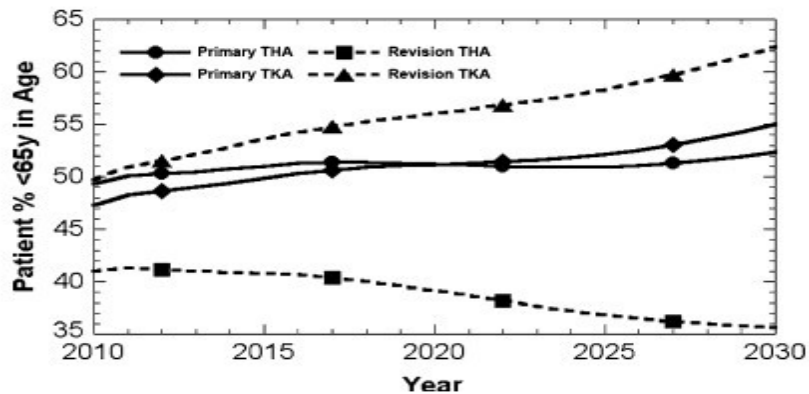


Fig. 1 The projected relative proportion of the younger patient population (< 65 y) for primary and revision total joint replacement between 2010 and 2030 is shown.

Figure 5: The projected relative proportion of the younger patient population (<65 y) for primary and revision total joint replacement between 2010 and 2030 (Source: CORR)

Costs and placement

The price tag on the EOS M 290 fits into our research and development budget. The purchase price for an M 290 is \$700,000. This purchase price includes delivery, installation, training and a one year service contract. Ample room is available in our Dahlia St workshop. No renovations will be required as the workshop is already a sterile environment for medical research. The current electrical system at the Dahlia workshop is already prepared for the needs of the M 290.

Limitations and uncertainties

Full technical data can be found in the appendix under figure 6. The main limitation is that the build volume is limited to 250 mm x 250 mm x 325 mm (9.85 x 9.85 x 12.8in).

Although we already exceed FDA standards in other areas, more research must be conducted

to identify the FDA regulations and requirements. Another study has started to identify these areas but the work accomplished so far is very promising.

Conclusions

The technology and application of DMLS is new and has a promising future. DMLS for biomedical use decreases surgical/recovery time while generating new possibilities for surgery. The need for biomedical implants continues to increase in the United States as does the need for 3D printed implants. DMLS has been proven to be a precise and feasible technology for patient specific titanium implants. DMLS will likely become a more common technique for biomedical manufacturing as technology prices decrease and surgical needs increase.

Recommendations

Denver Biomedical Frontiers would greatly benefit from the purchase of an EOS M 290. The need for this technology and skill set has been established and is predicted to rise. We must take advantage of this technology while it is new and establish ourselves as the absolute standard in the industry.

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Appendix

Technical Data EOS M 290	
Building volume	250 mm x 250 mm x 325 mm (9.85 x 9.85 x 12.8 in)
Laser type	Yb-fibre laser; 400 W
Precision optics	F-theta-lens; high-speed scanner
Scan speed	up to 7.0 m/s (23 ft./sec)
Focus diameter	100 µm (0.004 in)
Power supply	32 A
Power consumption	max. 8.5 kW / typical 3.2 kW
Nitrogen generator	integrated
Compressed air supply	7,000 hPa; 20 m³/h (102 psi; 706 ft³/h)
Dimensions (W x D x H)	
System	2,500 mm x 1,300 mm x 2,190 mm (98.4 x 51.2 x 86.2 in)
Recommended installation space	min. 4,800 mm x 3,600 mm x 2,900 mm (189 x 142 x 114 in)
Weight	approx. 1,250 kg (2,756 lb)
Data preparation	
Software	EOS RP Tools; EOSTATE; EOSPRINT; Materialise Magics RP with SG+ and further modules
CAD interface	STL. Optional: converter for all standard formats
Network	Ethernet

Figure 6: EOS M 290 Technical Data (Source: EOS)