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THE USE OF ADDITIVE MANUFACTURING IN THE CUSTOM DESIGN OF ORTHOPEDIC IMPLANTS

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ABSTRACT

This Licentiate thesis is devoted to studying the use of additive manufacturing (AM) within orthopedic implant manufacturing, especially for the customization of implants. Over slightly more than a decade, AM methods, yielding 100% dense metal parts have been developed; this new method of layer-wise manufacturing has made it possible to create geometries that were difficult or even impossible before today. In addition to the freedom of geometry, the advantages of using AM for these applications are: the possibility to create desirable surfaces, shortening the surgery time and lowering the manufacturing cost. AM parts are directly manufactured from 3D computer models and it is possible to use a computed tomography (CT) scan as the basis for modelling an implant. The method hence has great potential for customizing of medical implants.

The thesis is based on two different cases of practical use of the AM method, electron beam melting (EBM), for implant manufacturing. One case is built on a comparison between EBM and conventional machining for manufacturing patient-specific hip stems and, the other investigates the potential of implementing digital design and EBM for manufacturing of fixation plates within trauma orthopedics. Both had the purpose of identifying the potential and obstacles posed by the use of AM within these applications. The studies have been carried out in cooperation with orthopedic surgeons, researchers within orthopedics and developers of patient specific orthopedic implants, to get insight in their work and to be able to focus the research on applications where the EBM technology can contribute to new functionality or more effective manufacturing.

The AM has proven to be useful both in the manufacturing of hip stems and the customized plates used in trauma surgery. By using EBM-manufacturing, for the customization of hip stems, file-preparation time is saved and material wastage is considerably lowered (papers I and II). Paper II shows that it is a challenge to solve some critical design issues concerning the EBM-manufactured surface, but if this can be done the cost can be lowered by about 30% through using EBM instead of conventional machining (papers I and II).

A contribution to the development of a routine for the customization of trauma plates for complex fractures was made (paper III). The routine has to be streamlined, especially as regards the modelling, the post processing and the sharing of digital information to be implementable within the orthopedic departments at routine services. But for special clinics, institutes or universities, that have the necessary competence, the routine can be implemented as it is today.

The possibility to create open-celled net structures is an advantage of AM, and has proven to be desirable for customizing the flexibility of the implants. It can contribute to longer lifetime in hip arthroplasty and better healing in plating cases.

Keywords: Additive manufacturing (AM), electron beam melting (EBM), total hip replacement (THR), orthopedic implants, digital design, computer aided design (CAD), bone plates.

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Practical work and experiments have constituted a large part of this work. Thanks to Andrei Koptioug, Lars-Erik Rännar and Slavko Dejanovic for the help in the Additive Manufacturing Laboratory, and to Caisa Wessberg and Isak Elfström at ARCAM AB for giving good support. I'm also thankful, for Torbjörn Carlsberg's help in performing material tests.

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And finally, I want to thank my beloved family; my husband Mattias, my son Hampus and my daughter Alva. Thanks for always supporting me and bringing lots of joy into this journey.

LIST OF PAPERS

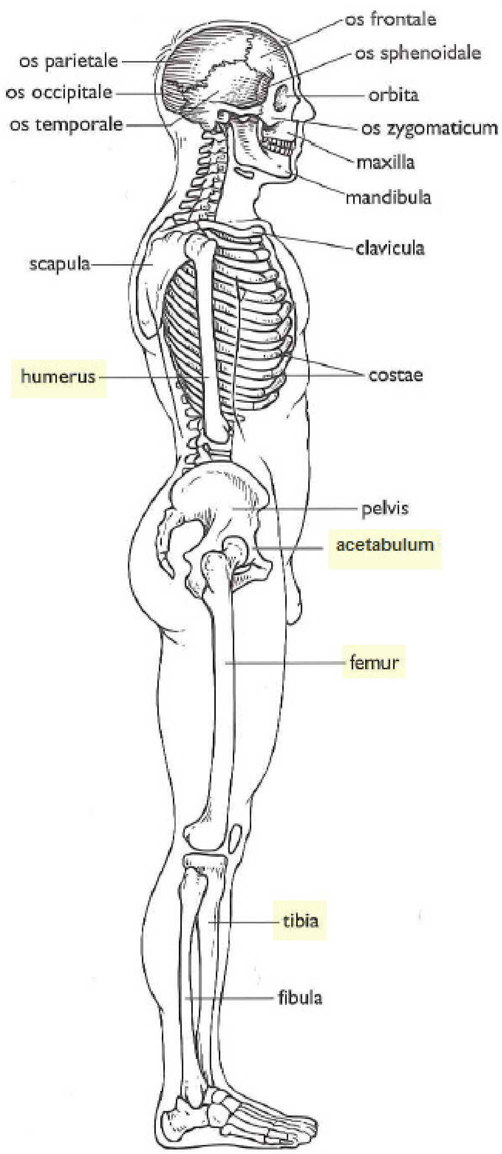
This thesis is mainly based on the following three papers, herein referred to by their Roman numerals:

Paper I	*"Application of electron beam melting to titanium hip stem implants"* M Cronskär, L-E Rännar, A Koptioug, M Bäckström. Proceedings of the 19th International DAAAM Symposium, Vienna, Austria, 2008, pp 1559-1560.
Paper II	*"Production of customized hip stem prostheses-* *A comparison between machining and additive manufacturing"* M Cronskär, L-E Rännar, M Bäckström. Submitted to: Journal of Materials Processing Technology
Paper III	*"Implementation of digital design and solid free form fabrication for customization of implants within orthopedic trauma"* M Cronskär, L-E Rännar, M Bäckström. Accepted for publication in: Journal of Medical and Biological engineering

ABBREVIATIONS AND TERMINOLOGY

AM	*Additive manufacturing*
CAD	*Computer aided design*
CAM	*Computer aided manufacturing*
CNC	*Computer numerical control*
CT	*Computed tomography*
DCP	*Dynamic compression plate*
DICOM	*Digital imaging and communications in medicine*
EBM	*Electron beam melting*
ELI	*Extra low interstitials*
FFF	*Free form fabrication*
MRI	*Magnetic resonance imaging*
RM	*Rapid manufacturing*
RP	*Rapid prototyping*
SFF	*Solid free form fabrication*
STL	*Stereolitography*
THA	*Total hip arthroplasty*

<u>Acetabulum</u>
The cavity in the hip joint
<u>Aseptic loosening</u>
Loosening due to bone resorption at the bone-prostheses interface
<u>Craniofacial / maxillofacial surgery</u>
Surgery of the skull and facial structures
<u>Interfragmentary movement</u>
Small movement between bone fractions, in a fixated fracture
<u>Osseointegration</u>
Direct attachment of bone tissue to an implant
<u>Osteoarthritis</u>
A progressive, degenerative joint disease
<u>Osteoporotic bone</u>
Porous, fragile bone, decreased in bone mass
<u>Polymethylmetacrylate</u>
A thermoplastic, used as a grout to affix implants



The skeleton seen from the side [1].

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1. BACKGROUND

Additive manufacturing (AM) of fully dense metal parts, referred to as direct metal AM, has a history of slightly more than a decade. This new way of manufacturing is forcing researchers and product developers to think in new ways. Building up the geometry by adding material layer by layer makes it is possible to create geometries that have been difficult or even impossible until now [2], see Fig.1.

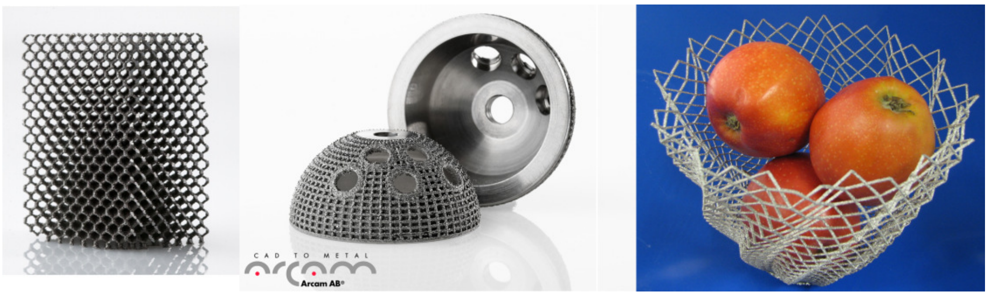

Figure 1. *Examples of parts manufactured by the AM method electron beam melting (EBM); Left, open-celled net structure, middle, acetabular cups (both courtesy of ARCAM), right, specially designed fruit bowl (by the Additive Manufacturing Group, Östersund).*

When starting these licentiate studies, the research team had experience of using additive manufacturing to create plastic models of biological structures used for preoperative planning. Discussions about using AM for implant manufacturing were initiated with the orthopedic department at Östersund hospital. The literature also showed that the medical industry is an interesting application area for AM technology.

Problems within replacement surgeries, i.e. total hip replacement, are that the implants seldom last in the body for the whole life time of young patients and although the implant improves the mobility of the patient significantly, it is not possible to live a physically active life. Both in replacement surgeries and other types of surgery the implant sometimes have to be customized, or could be more functional if they were adapted to each case and patient, but manufacturing of customized implants is time consuming and expensive (papers II and III). The question is whether and how, we can use the advantages of layer-wise manufacturing to solve issues like this? Hence, the purpose of this thesis has been;

To find applications within the medical implant area where EBM technology can contribute to new functionality or more effective manufacturing.

In order to reach that goal, the *contribution and new opportunities* when using EBM in different applications, and the *obstacles* to be solved before implementation is possible, had to be identified.

To find suitable applications, contact with medical professionals was important and the scope of the research had to be kept broad from the beginning. Hence, the study is built on a broad literature survey and hands-on performance in two case studies, in cooperation with medical expertise and expertise in the development of medical implants. In this way, the AM potential areas could be investigated and, at the same time, knowledge of the whole process and insight into the work of the orthopedic surgeon was achieved.

The literature showed that one application area where this technology is widely used and has been successful is within the craniofacial area. Examples are presented in [3, 4]. It is also used for serial production of acetabular cups, by the company Adler Ortho, to achieve a specially designed surface for osseointegration (bone ingrowths) that is created directly in the manufacturing process. Studies devoted to investigating the AM's usefulness in several different medical applications, like artificial joints, in dentistry applications and for tissue engineering, are also reported [5-8]. The literature study led to the application areas of hip implants and plates for the fixation of complex trauma fractures. In the big and successful hip implant industry, there is great potential for creating new desirable designs which have been difficult to manufacture until now. Both in the literature and the contact with orthopedics, customized hip-stems were of high interest [9, 10]. The reason for focusing on plates for trauma fixation was that little was done in this area and it was seen to be an application that had a shorter lead-time to actual implementation, compared to the manufacturing of hip stems.

The rest of chapter 1 is an introduction to the AM and EBM technologies and at the end the included papers are summarized. In chapter 2 the use of AM in orthopedic hip stem and bone plate manufacturing is discussed. Finally, in chapters 3 and 4, conclusions and future developments are presented.

1.1 Additive manufacturing and electron beam melting

AM is a comprehensive term for technologies that produces parts by the successive joining of material layer by layer rather than removing material. It is used to build physical models, prototypes, patterns, tooling components and production parts in different materials. The AM started to develop in the late 1980's with a process called stereolitography. In that process, thin layers of ultraviolet light-sensitive liquid polymer are solidified using a laser. After that many different AM technologies that used different materials followed. In the late 1990's the systems producing metal parts started to emerge. Today there are a number of different direct metal AM processes on the market, most of them using a laser for heat supply, either to heat a metal powder bed layer by layer or using a laser as the heat source combined with a powder deposition head. In the latter case, a 4 or 5 axis motion system is used to position the head. In addition to the laser-based processes there are a few using other approaches to produce metal parts; one of them is the electron beam melting (EBM), which uses an electron beam to melt a metal powder bed layer by layer [2]. See examples of parts manufactured with EBM in Fig. 1.

The EBM technology from the company ARCAM AB has a relatively fast build speed in comparison with competitive methods, and is suitable for the manufacturing of medical implants since the process requires a high vacuum which leads to low gas and moisture contaminants. All AM methods need post processing to some extent to achieve the surface-finish of a machined part, but compared to other AM methods the EBM parts have a relatively coarse surface structure. The material properties of the finished part are comparable with those of conventional manufactured materials [2] and the rough, EBM manufactured surface is promising to be good for bone ingrowth [11]. Murr *et.al*. also showed that EBM manufactured material has a high elongation value compared to the corresponding laser-based method, Solid Laser Melting (SLM), 20% versus 4%, respectively [12].

The EBM process, shown in Fig. 2, uses an electron beam (3) which is formed by electrons emitted from a tungsten filament (1) and accelerated in a high voltage difference in the electron beam gun (2). The beam (3) is focused using two magnetic fields (4, 5) and welds consecutive layers of powder. When one layer is finished a new layer of powder (0.05-0.2 mm) is raked over the build by a movable rake (7) and the powder layer is pre-heated by the beam before it is melted to the geometry from the computer aided design (CAD) file. The powder containers (6) store powder to last for the whole build. The powder bed is kept warm throughout the build to minimize residual stresses and the system is kept at a vacuum of $1x10^{-4}$ mbar. When the build is finished, the part (9) is left in the machine to cool for some hours, depending on the size of the build. Then a special blast chamber is used to remove excess powder, which is later sifted and reused. The material used for medical applications is a Ti-6Al-4V (ELI) powder with a particle size between 45 and 100 microns.

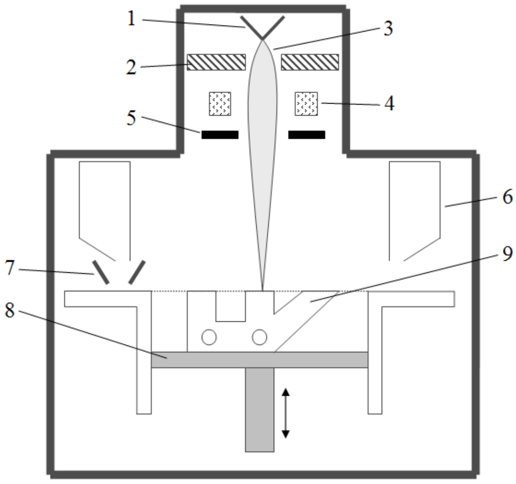

Figure 2. *The EBM process; 1=tungsten filament, 2=beam gun, 3=beam, 4, 5=magnetic fields, 6=powder containers, 7=movable powder rakes, 8=build table, 9=build. [13]*

This metal is biocompatible with extra-low interstitials (ELI) and contains reduced levels of oxygen, nitrogen, carbon and iron. There are many different expressions used to describe this relatively new manufacturing technology, and parts of the technology: FFF (free form fabrication), SFF (solid free form fabrication), RP (rapid prototyping), RM (rapid manufacturing) and ALM (additive layer manufacturing). The consensus standard, recently adopted by the American society for testing and materials (ASTM) is additive manufacturing (AM) and the basic principle of this technology is that the systems use thin, horizontal cross sections from computer aided design (CAD) models, 3D-scanning systems, medical scanners, and video games to directly fabricate parts, by *adding* material, as opposed to subtractive methods.

1.2 Summary of papers

In the first paper, the feasibility of using EBM for the manufacturing of customized hip implants is compared to using conventional machining, by performing a practical study. Gains, obstacles and new opportunities, as results of this replacement, are identified. Such comparisons have not been seen in earlier research. In this study, it was assumed that the surface structure of the medial part of the hip stem (see Fig. 3 and Paper I) could be left without any post processing. The study showed promising results but the results were dependent on how a sufficient surface structure on the medial part was to be obtained, and how it influences the mechanical properties of the implant. Paper II is an expansion of paper I and wider explains the case. The new material in this study concerns the fatigue properties of the EBM manufactured parts and an initial fatigue test, comparing raw test bars with milled test bars, was carried out. AM manufacturing has great opportunities for the manufacturing of customized hip stem implants, but, quite a bit of research and development is needed before implementation is possible.

An application that was likely to have a shorter lead-time to implementation was the customized plates for fixation of complex fractures within trauma surgery. Paper III is devoted to investigate the use of digital design and EBM manufacturing in this application. A practical case was performed to identify the gains, obstacles and new opportunities and to find out whether the plate can be designed and manufactured within the time limit present in trauma cases. Similar studies are found in the literature but none that look at implementation within trauma surgery, with associated time frame, have been found by the author.

The study is based on two single cases. To confirm that the results can be achieved on a regular and predictable basis, further quantitative studies are needed.

2. ADDITIVE MANUFACTURING RELATED TO SOME ORTHOPEDIC IMPLANTS

Orthopedic implants are man-made, medical devices, manufactured from biocompatible materials for implantation in a living biological structure. Their purposes may be to replace a missing structure or to give support to a damaged structure. The most common way of fabricating metallic implants is CAD-driven machining from wrought or cast bar stock.

2.1 Hip stem implants

When the hip joint doesn’t function, due to disease or fracture, a successful and widely used treatment is total hip arthroplasty (THA), see Fig. 3. In a THA, both the acetabulum and femur are replaced. Because of the high pain and debilitation caused by osteoarthritis, the history of surgical experimentation is long, with the insertion of various materials into the joint or cutting away various parts. In the beginning of the 1900’s century new approaches emerged in inserting artificial parts, but it was not until the 1960’s THA was introduced on a large scale.

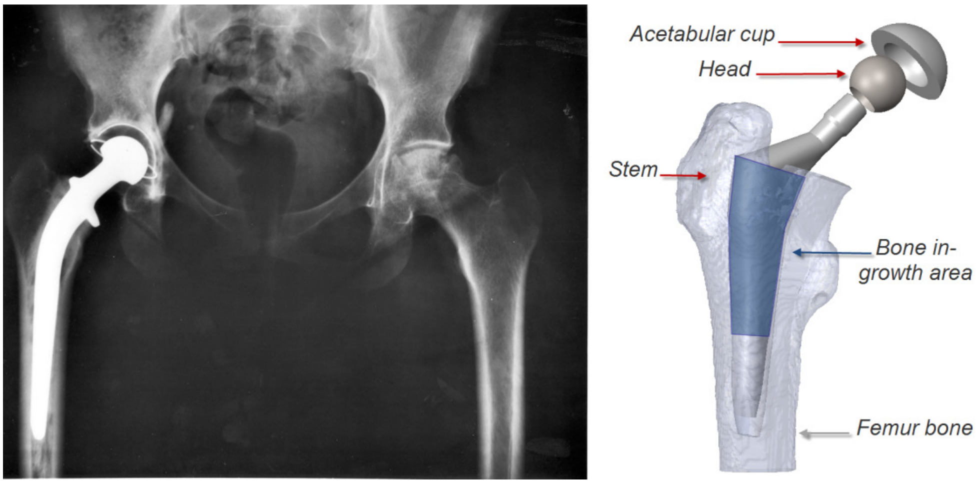

Figure 3. *Left: Total hip replacement (THR). (Courtesy of National Institute of Health, U.S.). Right: The different parts of a THR, in which the medial area for bone ingrowth is shaded in blue.*

John Charnley, together with his technical assistant, Harry Craven, demonstrated the use of a high density polyethylene (HDPE) socket (cup), promoting low friction between the implant components. The whole concept was composed of: a stainless steel femoral prosthesis with small diameter head, the HDPE socket, and acrylic cement to fix them. Long term stability was realized and the total hip replacement is still today based on Charnely's design, Fig. 4 and [14]. There are two techniques to fixate the stem into the femur currently used in THA: cemented fixation where a polymethylmetacrylate (PMM) mixture is used as a grout between the bone and the implant, and cementless fixation, which relies upon bone ingrowths into the implant [15]. There are different opinions in the research community about which one of the methods is to prefer. Recent research show that the two methods are comparable with some exceptions [16].

Figure 4. *Charnely's THA [17].*

THA is a successful orthopedic operation, with good survival within a 10-year period [18], but still there are problems, especially for younger, more active patients, whom are supposed to have the implant for a long time [19]. Often patients have to wait to get an implant, even though they need one, because the surgeons know that it doesn't last for the patient's lifetime and revision surgeries are often more complicated than primary surgery. Most people can only go through 1-3 revision surgeries [11].

The most common reason for revision surgery is asceptic loosening. Mechanical failure, such as fatigue fractions, is rare. Asceptic loosening is caused by both mechanical and biological factors and usually occurs several years after implantation. An important biological factor is the biological response to wear particles, and this is counteracted by reducing the friction coefficient of the materials. Mechanical factors include micro motion between the implant and bone, and a phenomenon called stress shielding [20]. Stress shielding is caused by the unnaturally high stiffness of the implant compared to the bone material as explained in Paper II. In brief, the stiff implant bears too big a share of the load and the surrounding bone tissue, which is a living material, adapts to the low stress level and resorbs [21]. Ways to counteract aseptic loosening due to mechanical factors are: achieving a firm primary stability and lowering the stiffness of the implant while keeping its strength. By creating surface structures to contribute to good bone ingrowth, and open celled net structures (Fig. 1, left), designed to achieve higher flexibility, EBM manufacturing can contribute to solving these issues, as described in Paper II.

2.2 Bone plates for trauma surgery

Plates are devices which are fastened to fractured bone to provide fixation. The plates are divided into groups by their function. A description of some of these groups will follow below.

One group of plates is called *protection or neutralization plates* and the purpose with those is to protect lag screw fixation. The lag screws are used to hold bone fragments in place (Fig. 5, right). *Buttress plates* on the other hand have the functionality of preventing axial deformity by shear or bending and are firmly anchored in the main fragment but not necessarily to the fragment it is supporting (Fig. 5, middle). A lag screw cannot be used to stabilize transverse or short oblique fractures, in these cases a *compression plate* is used to bring stabilization and compression to the fracture. The compression is obtained, either by screwing in the DCP (dynamic compression plate) holes or using a tension device when fixating the plate. The DCP holes are formed like an inclined cylinder and that way force the plate to compress the fracture as the screw goes in. Finally, there are the *bridging plates* (Fig. 5, left), which are firmly fastened in healthy bone, on each side of a badly comminuted segment of bone, to maintain length and alignment. The union then depends on formation of callus rather than primary bone union [22].

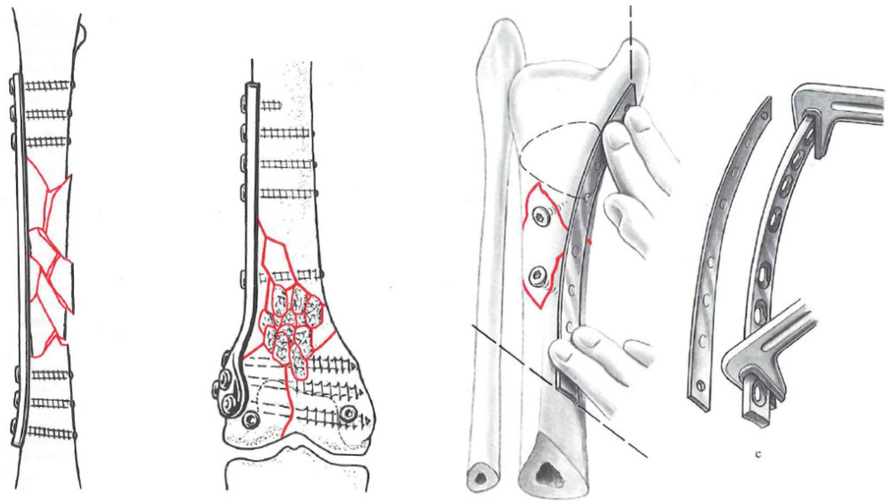

Figure 5. *Examples of bone plates; left, a bridging plate, middle, a buttress plate, right, a combination of a bent and twisted plate and two lag screws [22].*

Bone anatomy is extremely complex in some areas, such as the pelvis around the acetabulum or the distal humerus. In some cases the plate has to be bent in two directions and twisted, hence different amounts of surgery time are needed to shape the plate to fit the fracture [22]. This is one issue that can be solved by using individually adapted plates, manufactured with AM as described in Paper III. Another advantage is the possibility to pre-plan screw locations for optimal attachment, and to design a plate that is optimized not only in shape, but in mechanical properties. The flexibility can, for example, be modified to promote healing as discussed in Paper III. In [23] it is shown that the size of the fracture gap and interfragmentary movement have a great impact on the bending stiffness of healed bones.

By shaping the plate to the exact geometry and digitally pre planning the screws, it is possible to get a better attachment of plates in osteoporotic cases, and one also has a good foundation to be able to accomplish low invasive surgery, which gives small scars, a shorter open wound time and shorter recovery time.

2.3 Design procedure for patient-specific implants using AM

The design procedure from computed tomography (CT) scan to final implant is described, below, with an example of a fracture in the distal tibia, Fig. 6.

The purpose of acquiring a 3D CT scan is to produce a volumetric data set of the fractured bone or part of the skeleton that needs an implant. Two different medical imaging techniques are magnetic resonance imaging (MRI) and CT. MRI provides better images for soft tissues and CT shows greater contrast between bones and soft tissue, and is therefore the method of choice in these applications. A CT is built up of a large series of 2D slices of data to represent the 3D geometry and each CT image is written as an individual file within a directory structure. The format of the images follows the medical industry standard, called DICOM (digital imaging and communications in medicine). The design procedure starts with removing the unwanted structures (skin, fat, muscles) from the CT data, using a threshold segmentation technique, where pixels are distinguished within an image by their grey-scale value. In CT the pixel values, also known as Hounsfield units, range from -1024 to +3072. Bone, is represented by the CT number range from approximately +100 to +2000, where the highest number indicates the densest bone. After bone segmentation, the part of the skeleton is mathematically modeled into a 3D model, where the surface contours of the geometry are described by small, triangular surface elements. The full data set is known as a stereolitography (STL) file. This format is commonly used in AM, as it is easily transferrable between many software packages [24].

Depending on the type of implant to be manufactured, the STL-file of the bone model can be used as it is, or should be modified in some way. In this case, the fracture needed to be reduced (moving the fractions to their correct positions) to form the base for modeling the final implant. Different software packages can be used for this purpose as explained in Paper III. The reduced bone model is later used as a base for orientation of the screws and modeling of the implant. When the final design of the plate is obtained, the STL-file of the plate is prepared for manufacturing and sent to the AM-machine, as described in section 1.1. Preferably, several different implants, or other parts are made in the same build (Fig. 6) since the build time is primarily affected by the height of the build. Finally the parts are post processed to meet the demands of the specific implant.

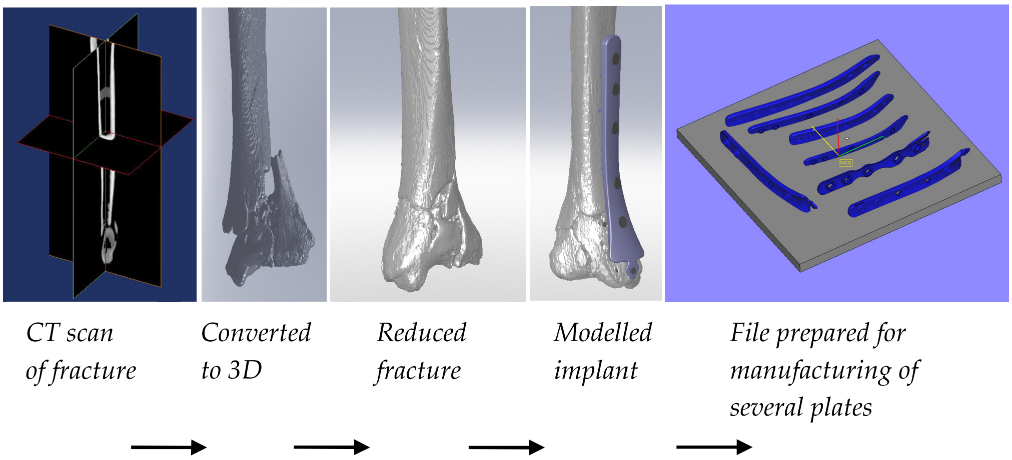

Figure 6. *Digital design of a fixation plate, using a CT scan of the fracture, as the base for modeling.*

3. CONCLUSIONS

As stated in the background chapter, the aim of the study was *"to find applications within the medical implant area, where EBM technology can contribute to new functionality or more effective manufacturing"*.

The study has shown that AM, particularly EBM, has great potential both in the manufacturing of hip stems and customized plates used in trauma surgery.

A contribution has been made (Paper III) to the development of a routine for the design and manufacturing of patient-specific plates, used to fixate complex fractures. The study showed that it is possible to produce plates, with trauma-specific geometry, within the time limit associated with these types of fractures. There is still some development to be done before routine services can benefit from the technology, but in special clinics, institutes or universities, that have competence in all the different areas, the routine can be implemented as it is today, see more in Paper III.

- For digital design and EBM-manufacturing, to be implementable within routine services, the routine from CT to final implant has to be streamlined and the technology has to be more adapted to this area of use. Improvement primarily has to be done in the modeling, post processing and digital data communication between surgeon and engineer (Table 1).

EBM manufacturing is feasible and can lower the manufacturing cost by about 30 %, (compared to conventional machining), for the manufacture of custom-designed hip stem implants, due to savings in material consumption and file preparation time. This result is based on the assumption that the surface for bone ingrowth can be left intact or with little post-processing, more about this in papers I and II.

- The greatest obstacle is achieving a surface structure which is sufficient both for bone in growth and mechanical properties (Table 1).

There is a great interest within implant surgery to be able to design implants with a low young's modulus and high strength, both to reduce the stress shielding effect in hip stems and to increase the flexibility of bone plates to obtain better healing.

Table 1. *Gains and obstacles for implementation of AM*

	Gains	*Obstacles*	*What to do?*
Replacement of conventional machining to EBM for production of patient-specific hip stems	Reduced material consumption Reduced file preparation time Possibilities to reduce stress shielding	The surface of medial part has to be suitable for bone ingrowths and mechanical properties To ensure mechanical properties	Optimizing surface for this application More fatigue tests and develop a method for mechanical properties control Choosing optimal post processing methods
Additive manufacturing (AM) and digitalization for individual adaption of plates within trauma surgery	Shorten surgery time (no need for reshaping) Placement of screws in optimal position and angle. Effective pre planning in accordance with the hardware	To keep down time and cost How to perform the cooperation between engineer and orthopedist To ensure mechanical properties	Develop reliable/fast modeling -method Choosing post processing methods Develop a pre plan/design outline software for the orthopedist Develop method for mechanical properties control

4. FUTURE DEVELOPMENTS

If a metal structure can be produced using EBM technology, with enough strength and elastic properties close to those of bone, this will open a new field within the implant industry. The problem associated with stress shielding has been present for a long time and there have been many different attempts to design stems with higher flexibility. EBM technology has great potential in this area, since the method is capable of producing different porous net structures and the material produced by EBM has a high elasticity compared to wrought material, cast material and material manufactured with the corresponding laser based AM method SLM [12].

Developing hip stems for better long term attachment, leads directly to better life quality for young THA patients, since they don't have to wait for so long to get the necessary implant and can be more active after surgery. Furthermore, economic savings and higher patient safety is gained by less revision surgeries. Future work will have a focus in this area. It is also important to continue work on making the technology possible to implement within routine services. Two principal points in that work are, to streamline the routine and hence lower the cost, and to continue the development of the cooperation between surgeons and engineers, to make the technology more user-friendly (table 1).

Further work will be aimed at developing a metal structure that can be manufactured with EBM technology; one which has flexibility closer to the bone properties and at the same time has adequate mechanical strength and fatigue properties. This work will be performed using finite element modeling (FEM) and practical testing on structures manufactured with the EBM machine. The research team is also focusing on developing surface structure suitable for bone ingrowth, improving methods for post processing, and is continuing the work on the actual implementation of the technology in cooperation with Swedish hospitals.

REFERENCES

[1] M. Budowick, J. G. Bjålie, B. Rolstad and K. C. Toverud, *Anatomisk atlas*. Uppsala: Liber utbildning, Universitetsförlaget, 1993.

[2] T. Wohlers, *Wohlers report 2010*. Fort Collins: Wohlers associates, 2010.

[3] S. Singare, L. Yaxiong, L. Dichen, L. Bingheng, H. Sanhu and L. Gang, "Fabrication of customised maxillo-facial prosthesis using computer-aided design and rapid prototyping techniques," *Rapid prototyping J.,* 12: 206-213, 2006.

[4] P. Dérand and J.M. Hirsch, "Virtual bending of mandibular reconstruction plates using a computer-aided design," *J. Oral. Maxil. Surg.,* 67: 1640-1643, 2009.

[5] Y. He, M. Ye and C. Wang, "A method in the design and fabrication of exact-fit customized implant based on sectional medical images and rapid prototyping technology," *Int. J. Adv. Manuf. Tech.,* 28: 504-508, 2006.

[6] Q. Liu, M. C. Leu and S. M. Schmitt, "Rapid prototyping in dentistry: Technology and application," *Int. J. Adv. Manuf. Tech.,* 29: 317-335, 2006.

[7] I. Gibson, L. K. Cheung, S. P. Chow, W. L. Cheung, S. L. Beh, M. Savalani and S. H. Lee, "The use of rapid prototyping to assist medical applications," *Rapid prototyping J.,* 12: 53-58, 2006.

[8] M. Truscott, "Using rp to promote collaborative design of customised medical implants," *Rapid prototyping J.,* 13: 107-114, 2007.

[9] M. Ruyu, X. Wendong, W. Dongmei, D. Kerong and W. Chengtao, "Design and manufacture of custom hip prostheses based on standard x-ray films," *Int. J. Adv. Manuf. Tech.,* 27: 70-74, 2005.

[10] Y. Jun and K. Choi, "Design of patient-specific hip implants based on the 3d geometry of the human femur," *Adv. Eng. Softw.,* 41: 537-547, 2010.

[11] O. Harrysson and D. Cormier, "Direct fabrication of custom orthopedic implants using electron beam melting technology," in *Advanced manufacturing technology for medical applications*, I. Gibson, (Ed.) Hong Kong: John Wiley & Sons, 191-206, 2006.

[12] L. E. Murr, S. M. Gaytan, S. A. Quinones, M. I. Lopez, A. Rodela, E. Y. Martinez, D. H. Hernandez, E. Martinez, D. A. Ramirez, F. Medina and R. B. Wicker, "Microstructure and mechanical properties of ti-6al-4v for biomedical and related applications involving rapid-layer powder manufacturing," in *Advances in biomedical and biomimetic materials* Hoboken, New Jersey: John Wiley & Sons, 71-82, 2009.

[13] L. E. Rannar, A. Glad and C. G. Gustafson, "Efficient cooling with tool inserts manufactured by electron beam melting," *Rapid prototyping J.,* 13: 128-135, 2007.

[14] J. Anderson, F. Neary and J. V. Pickstone, *Surgeons, manufacturers and patients; a transatlantic history of total hip replacement*. New York: Palgrave Macmillian, 2007.

[15] *Available at: Http://www.Totaljoints.Info/bone_cement, april 2011*

[16] S. Morshed, K. J. Bozic, M. D. Ries, H. Malchau and J. M. Colford, "Comparison of cemented and uncemented fixation in total hip replacement," *acta orthop,* 78: 315-326, 2007.

[17] D. Pate, "Total hip replacement," in *Dynamic Chiropractic*. 8: M. D. Petersen, (Ed.) 1990.

[18] N. A. Athanasou, "The pathology of joint replacement," *Current diagnostic pathology,* 8: 26-32, 2002.

[19] M. G. Joshi, S. G. Advani, F. Miller and M. H. Santare, "Analysis of a femoral hip prosthesis designed to reduce stress shielding," *J. Biomech.,* 33: 1655-1662, 2000.

[20] K.-H. Frosch and K. Stürmer, "Metallic biomaterials in skeletal repair," *European Journal of Trauma,* 32: 149-159, 2006.

[21] D. R. Sumner, T. M. Turner, R. Igloria, R. M. Urban and J. O. Galante, "Functional adaptation and ingrowth of bone vary as a function of hip implant stiffness," *J. Biomech.,* 31: 909-917, 1998.

[22] M. E. Muller, M. Allgöwer, R. Schneider and H. Willenegger, *Manual of internal fixation*. New York: Springer-Verlag, 1995.

[23] L. Claes, P. Augat, G. Suger and H.-J. Wilke, "Influence of size and stability of the osteotomy gap on the success of fracture healing," *J. Orth. Res.,* 15: 577-584, 1997.

[24] B. Bidanda and P. J. Bartolo, *Virtual prototyping & bio manufacturing in medical applications*. New York: Springer, 2008.