INCREMENTAL SHEET FORMING (ISF) IN THE MANUFACTURING OF TITANIUM BASED PLATE IMPLANTS IN THE BIO-MEDICAL SECTOR

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ABSTRACT

Titanium, recognized by its high strength-to-weight ratio, is a material previously disregarded as a result of its high cost and difficult formability. Recent projects undertake the usage and manufacturing of titanium as a replacement material in certain components in the aerospace and mining sectors. The biomedical industry has also shown great favor towards titanium as a result of its corrosive resistance and great biocompatibility with the human body.

Incremental sheet forming (ISF) is a forming method capable of forming intricate, asymmetrical components as a result of highly localized deformations. The ISF process forms the component using stretching and bending while maintaining the material’s crystal structure. The process can be performed using any 3-axis (and higher) Computer Numeric Controlled (CNC) machine, making it highly available and cost effective to the manufacturing industry.

This paper investigates the forming of bio-medical titanium plate implants for minimal invasive surgical procedures. It proposes a customizable process chain capability for the production of patient-specific bio-medical implants using the incremental forming technology.

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1 INTRODUCTION

Osteoarthritis (OA), also known as degenerative joint disease is a progressive disorder of the joints caused by gradual loss of cartilage and resulting in the development of bony spurs and cysts at the margins of the joints. The degradation of the musculoskeletal system, which is mainly caused by joint injury, obesity (leading to musculoskeletal fatigue) and aging can also lead to osteoarthritis. The hands, feet, spine, and large weight-bearing joints, such as the hips and knees are commonly affected [1].

The only medical solution to severe cases of osteoarthritis is the surgical reconstruction or replacement of a malformed or degenerated joint, better known as arthroplasty. Arthroplasty makes use of biomedical implants and replacements to restore functionality of the joints. Biomedical engineering in arthroplasty is an ever increasing field of interest as a result of its innovative improvements to surgical quality.

Certain cases of partial osteoarthritis require less surgical action. Partial knee replacement surgery, also known as unicompartmental (or unicompartmental) knee arthroplasty involves a covering which is placed over the affected area to resurface the affected bone and protect the patient from further degeneration. Advantages of partial replacement include faster recovery time and less post-operative pain. The biomedical implants used for these operations consist of a standardized implant that is fit onto the bone by modifying (cutting away) the outer structure of the bone. The result is known to cause post-operative discomfort among some patients. Figure 1 shows the basic steps in Total Knee Replacement (TKR).

![Figure 1: Implementation Of Standard Size TKR Implants [2]](image)

The problem with these standard designs includes the requirement of the removal of unaffected (healthy) bone matter, leading to induced trauma and pain for patients during the recovery phase of the operations. A preferred alternative to the standard design would be to create a custom implant for every patient, reducing the need to remove parts of unaffected bone matter. The implementation of this proposed method tends toward Minimally Invasive Surgery (MIS). MIS is normally preferred as it reduces the risk of various negative consequences of normal arthroplasty such as nerve or tendon damage during surgery. It could be argued that the proposed method may cause less damage to the fragile tendon, bloodflow and nerve networks of the knee.

Increasing material costs of metal products introduce great interest in more cost efficient forming processes to reduce the loss of redundant blank material. Incremental Sheet Forming (ISF), a relatively new class of forming process, has the potential to meet the need for this more efficient forming process. The ISF process is highly flexible, reduces production cost by up to 90% in comparison to processes such as stamping and can be developed in normal milling machines [3]. The ISF process is a non-patented process, as the existing patents are referred to the designed machines and not the process.

The availability of the ISF process contributes greatly to its attractiveness. ISF can be implemented in any facility that has access to a three- or more-axis CNC machine. The advantage of ISF implemented in CNC machines is that CNC technology has already reached
a mature stage in development, contributing to the accuracy and methodology (such as feed rate or angular velocity of the tool) of the ISF process [4].

The forming of valuable lightweight materials is well covered by ISF processes. A variety of studies contribute to research on the forming of titanium and titanium based alloys as part of ISF of lightweight materials [5]. The ISF process utilizes the functionality of commercial CNC machines, making the process very available to most manufacturing companies. The ISF process offers fast setup times and flexibility of the forming process, especially using five-axis machines [6].

The purpose of this project is to define the process chain for creating a customized biomedical implant as well as documenting the design and development procedure of a titanium based biomedical arthroplasty implant using innovative Incremental Sheet Forming (ISF) techniques. The research results are from both data collection and expert interviews.

2 BACKGROUND LITERATURE

The implementation of incrementally formed bio-medical implants in knee arthroplasty requires sufficient background knowledge of both current surgical procedures and of current ISF research conducted in this field.

2.1 Current Surgical Methodology

Surgeons choose a standard design implant based on the measurement of a patient’s morphological aspects from x-ray images for the traditional surgical implementation of knee replacement surgery. The standard implants require interfering bone structures to be cut away using a series of different bone removal tools so that the implant would fit. Due to the variation in morphological aspects of the human femur, complications can arise as the currently available mass manufactured implants offer limited ranges of geometry [7].

Pain and discomfort experienced by the patient during the post-operative and recovery phases of surgery is probably the one major drawback of currently implemented knee replacement surgery scheme. Traditional surgery causes damage to unaffected cartilage and bone matter as well as ligaments [8]. A high concentration of nerves is disturbed as result of the removal or damage implied to unaffected matter in the joint. The removal of the outer, harder bone surface leads to the increase in pain and discomfort in the post operational phases. The disturbed ligaments contain more than just strands of tensile collagen fibres. Blood vessels as well as nerve endings are integrated into the ligaments of the knee. The nerve endings in the ligaments of the knee are essential to optimal muscle activation and certain reflex actions. Damage of these ligaments, as in cases of total knee arthroplasty where the ACL and PCL are severed, result in the loss of proprioceptive function and reflex triggering of the hamstrings [8].

Most surgical cases of knee replacement occur at a later stage of the human life, typically in between the age of 60 to 80 years as a result of excessive pain due to very severe cases of osteoarthritis [9]. The traditional knee replacement surgery involves an incision of approximately 20.3 cm. MIS techniques typically reduce the incision length to approximately 7.6 cm [10]. This aspect of surgery greatly reduces the damage done to sensitive ligaments, blood veins and nerve endings.

2.2 Current Research On New Surgical Methodologies

Reverse engineering of the human knee is a topic currently being researched. The implementation of reverse engineering enables the creation of implants custom-made for every patient. Mismatched or standard implants seen in Figure 2 require excessive removal of bone matter, and can often cause a severe balancing problem and short-term durability [7]. Studies concerning the morphological analysis of the human knee joint are being performed by Yongtae Jun for the purpose of creating custom-made implant models for TKR applications based on the morphological data of every patient [7].
Current research is also done on the implementation of custom-made implants in the field of unicompartmental knee replacement (UKR) surgery [11]. Van den Heever, et al. implied that UKR surgery shown in figure 3 could improve on current procedures by implementing a series of polynomials and B-splines to describe the geometry of the distal part of the femur. Their library of geometries will be used to design a specific knee implant based on the CT data of the patient's knee a self-organising map (SOM) technique. The implant is produced using rapid manufacturing (RM) techniques [11].

3 APPROACH (PROCESS CHAIN)

The introduction of modern day manufacturing methods with the increased fields of application shifts the limitation of production from the prototype manufacturability to the digital design. The application of reverse engineering (RE) introduces a method of design capable to produce a reliable 3D model of almost any object [12].

This project applies the techniques of reverse engineering to scan the knee joint and design a customised implant. The implant will be manufactured out of titanium using the incremental forming technique. The process chain proposed in Figure 4 seeks to standardize and include all procedures that are followed in the implementation of the new knee arthroplasty process.
Figure 4: The Developed Process Chain For Customised Unicondylar Knee Arthroplasty

The prototype design and manufacture process was designed to follow a process chain parallel to the procedure described above. The consultation phase will be replaced with background studies and the surgery phase will be replaced with a commercial viability study by means of interviews with orthopaedic surgeons.

3.1.1 Obtaining Patient Specific Morphological Data

The design of the implant is only dependent on the quality of information obtained from the object it is based upon. In this case, the accuracy and level of detail of the 3D model of the knee joint. A digital model of the knee joint can be obtained using an actual knee as subject. The joint will be scanned using a CT scanner (also known as a CAT scan). The CT scan will produce DICOM CT images with intersections set to 1mm to obtain higher resolution images.

The obtained DICOM CT images contains a series of 1mm thick slices of the leg as seen from the three traditional views, known as the axial, coronal and sagittal views. The complied set of DICOM CT images can be imported into DICOM processing software such as Mimics Software (Materialise NV, Belgium). Segmentation and region growing methods was performed by implementing various masks on every slice of the DICOM images. The identification of the desired bone matter was conducted by implementation of a suitable threshold value, which can be referred to as “density identification” to implement discernment between bone and other organic material. The processing software recompiles the layers of slices to form a 3D model of the knee. The model is, however only compiled as
a series of identified outer points, creating a “point cloud” model. The converted format of these files are known as *.stl files.

Manual identification is conducted on the point cloud to implement the wireframe model with external planes with the purpose of creating a filled volume of the 3D model. The digital model will be imported to a sampling program such as 3Matic and act as a basis for the surface integration design of the implant, discussed in the following phases of the project.

3.1.2 Implant Design

The design of the implant is conducted using CAD/CAM software such as Delcam PowerSHAPE (Delcam, UT) or AutoCAD Inventor software (Autodesk, Inc., CA). The implant will be designed to fit onto an epicondyle of the distal extremity of the femur, as this is the origin and normal location of a damaged or diseased knee joint [13]. The implant, designed to be custom for each case, will be based upon the form and external condition of the epicondyle of every patient. This will be made possible by the thickening of the planes (generated using manual identification) to align accurately with the patient’s femoral morphology.

The implant will have to fit onto the epicondyle without restricting movement of the joint or inhibiting the working of the nerve or blood supply networks of the joint. Care will therefore be given that the thickness of the implant will not exceed the thickness of the surrounding cartilage. Special attention will be placed upon external factors such as the implementation of the prototype during surgery. The surgical process, classified under Minimal Invasive Surgery (MIS) should cause the least amount of possible damage and discomfort to the patient during and after surgery.

3.1.3 Implant Manufacture

A preliminary prototype was produced to assure important aspects such as manufacturability, accuracy and end product surface quality. The prototype was manufactured by implementing the incremental forming process on 1mm thick AA1200 Aluminium sheets using an OKUMA OSP-U100M 4-axis CNC machine. The final prototype will be manufactured out of 1mm thick Grade 2 Titanium sheets. The forces measured during the manufacturing will be recorded and documented for future research applications.

3.1.4 Surgical Implementation

Various aspects regarding the patient’s anatomic information have to be regarded during the planning of the surgical procedure to implement the prototype. Aspects such as the location of the main ligaments and blood supply network have to be taken into account. One of the most important goals of the surgical implementation planning is to adhere to Minimal Invasive Surgical (MIS) standards. This does not require the sacrifice of the anterior and posterior cruciate ligaments, connecting the femur to the tibia, as conventional surgical methods do. Also the hard cortical bone surface is to be prepared to receive the plate cap. This preparation is limited to a rough smoothing of the surface to remove any protrusions. The cortical bone remains structurally intact which is favoured by MIS goals. A bone growth agent can be introduced to increase adhesion to the cap.

4 RESEARCH INTO THE COMMERCIAL VIABILITY OF THE PRODUCT

The complete concept of the implementation of custom made MIS implants for arthroplasty operations is relatively new to the medical industry. The commercialization of these implants will be researched by means of data gathering through interviews and questionnaires. Interviews will mainly be conducted with experienced orthopaedic surgeons to obtain the best possible feedback.
5 CONCLUSION

Partial joint replacement in the knee, also known as unicompartmental knee arthroplasty is still a very new and concept compared to total knee replacement surgery. The implementation of incremental sheet forming along with the application of customised, patient-specific introduces a new range of patient-specific bio-medical implants. Research and operational improvements concerning unicompartmental knee arthroplasty can be made with the correct application of biomedical engineering (BE). These improvements can be made by the implementation of a customized implant that supports minimally invasive surgery techniques. This document discussed the planned research on the manufacturability and commercial viability of a titanium based biomedical implant using Incremental Sheet Forming (ISF) methods.

6 REFERENCES


