Development of incrementally formed patient-specific titanium knee prosthesis

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December 2012

Synopsis

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. 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 unicondylar (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.

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, can be developed in normal milling machines, and can reduce production cost by up to 90% in comparison to processes such as stamping. 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. 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. The ISF process utilizes the functionality of commercial CNC machines, improving the process availability of many manufacturing companies. The ISF process offers fast setup times and flexibility of the forming process.

The purpose of this project is to define a process chain for creating a customized biomedical implant as well as determining the validity of the process chain by applying each step. The design and development procedure of a titanium based biomedical arthroplasty implant using innovative Incremental Sheet Forming (ISF) techniques will be documented, as well as an investigation of the financial cost and potential gain that this implant can offer.

Opsomming

Osteoartritis is ‘n gewrig siekte wat degeneratiewe newe-effekte behels in die gewrigte. Hierdie siekte lei to die geleidelike verlies van kraakbeen en lei tot die onreelmatige ontwikkeling van abnormale beengroei. Osteoartritis kan ook deur beserings in die gewrig veroorsaak word. Die hande, voete, ruggraat, en enige groter gewigdraende gewrigte, soos die heupe en knieë kan geaffekteer word. Die enigste mediese oplossing tot ernstige gevalle van die siekte is chirurgiese rekonstruksie of vervanging van die gewrig, meer bekend as artroplastie. Artroplastie maak gebruik van biomediese implantate om funksionaliteit van die gewrig te herstel. Biomediese ingenieurswese in artroplastie is ‘n toenemende navorsingsveld as gevolg van die innoverende aspekte om chirurgiese kwaliteit te verhoog.

Sekere gevalle van gedeeltelike osteoartritis vereis veel minder chirurgiese behandeling. Gedeeltelike knie vervanging chirurgie, meer bekend as unikompartementele knie artroplastie, behels ‘n bedekking wat slegs die geaffekteerde been bedek, om die pasiënt van verdere degenerasie te beskerm. Voordele van gedeeltelike vervanging sluit vinniger herstel tyd en minder pyn in. Die biomediese implantate wat gebruik word vir hieride operasies bestaan uit standaard ontwerpe wat aan die been gepas word deur die wysiging (of wegsny) van die buitenste beenstruktuur. Die nagevolg van hierdie chirurgie is lang herstel periodes en kan ongemaklikheid in die knie veroorsaak.

Die probleem met die bogenoemde standaard is dat die prosedure die verweidering van selfs ongeaffekteerde (of gesonde) been in sluit, wat lei tot verdere kniepyn en ongemak vir pasiënte lei tydens die herstelperiode. ‘n Verkiesde alternatief tot die standaard ontwerpe is om ‘n persoonlikke implantaat vir elke pasiënt te skep, en so kan die behoefte om dele van ongeaffekteerde been te behou moontlik wees. Die toepassing van die voorgestelde metode neig na Minimale Skade Chirurgie (MSC). MSC word gewoonlik verkies om die risiko van verskeie negatiewe nagevolge te verminder, en skade aan die tendon, bloed- en senunetwerke van die knie te beperk.

Die toenemende materiaalkoste vand metal produkte lei tot ‘n groot belangstelling in meer koste besparing vormings prosesse, om sodoende die verlies van oortollige materiaalverlies te verminder. Inkrementele Plaat Vervorming (IPV), ‘n relatiewe nuwe klas van vervorming, is ‘n waardige kanidaat om hierdie doel te bereik. Die IPV proses is baie toepaslik, en kan deur die gebruik van Rekenaar Numeriese Kontrole (RNK) masjienerie toegepas word. Verder sal dit vervaardigingskoste kan verlaag met soveel as 90% in vergelyking met ander prosese soos die stempel metode.

Die beskikbaarheid van die IPV proses dra grootliks by tot die proses se aantreklikheid in die industrie. IPV kan geimplementeer word in enige fasiliteit wat toegang tot ‘n drie-as RNK masjien het. Die voordeel van dit is die feit dat RNK masjienerie klaar ontwikkel en volwasse is, wat kan bydra tot goeie akkuraatheid in die vormingsproses. Die vervaardiging van laegewig materiale soos titaan of aluminium is gedokumenteer. ‘n Verskeidenheid van studies dra waarde tot navorsing van die

vormingsproses van titaan as deel hiervan. Die IPV proses bied vinnige opstel tye en goeie buigsaamheid met die vormingsproses, veral met behulp van ‘n vyf-as masjien.

Die doel van hierdie projek is om ‘n proses ketting te ontwerp. Die proses ketting, wat uit vele stappe bestaan, sal die ontwerp en vervaardigingsproses van ‘n persoonlike biomediese knie implantaat bevestig deur middel van die IPV vormings tegniek. Validasie van die proses ketting sal dus plaasvind deur die stappe van die voorgestelde proses ketting uit te voer. ‘n Finale ondersoek sal die finansiele en regalutoriese aspekte van die projek aanspreek.

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1 INTRODUCTION

This thesis forms part of a research area of Industrial Engineering applied in the Incremental Sheet Forming of titanium sheets in the biomedical field, with specific focus paced upon the development and manufacturing of patient-specific knee implants by means of the ISF process. This section will introduce a brief background of this field followed the specific problem statement that initiated this project.

1.1 Background

Knee pain is a constant and growing problem among most of the world's population. A recent study performed by Nguyen et al. concluded that the number of reported cases of knee pain has increased substantially over the past 20 years, where the prevalence of knee pain increased by 65% from 1974 to 1994 mainly as a result of increasing obesity of the population[1].

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[2]. The prevalence of osteoarthritis increases with the age and approaches nearly 99% in patients aged 65 and older[3]. 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 unicondylar (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 using invasive and destructive methods to modify (remove) the external structure of the bone. This method is known to cause post-operative discomfort among some patients.

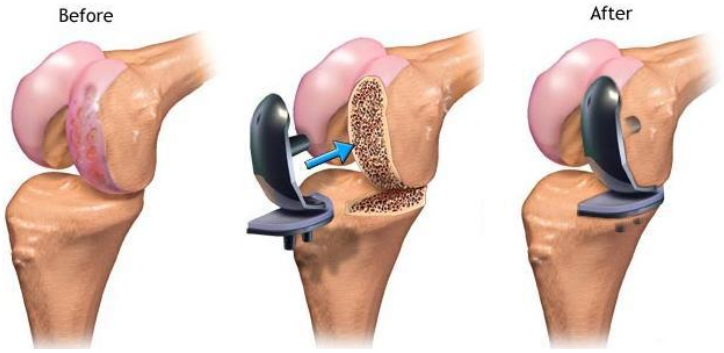


Figure 1: Unicondylar knee arthroplasty using standard designs[4]

The problem with these standard designs includes the requirement of the removal of unaffected 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 method supports 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.

The market potential for biomedical implants in the medical sector

The development of a load bearing implant, especially for human implementation is an extensive and vast project as the incorrect research, design or implementation procedures can lead to injury even to a fatal extent. The product development process therefore needed to be discussed for future implementation. The medical device sector of the healthcare industry will encompass a wide range of technologies. The aspect of research into innovation is crucial as large medical device companies do not typically invest heavily in internal, early stage, research and development, but prefer to enhance their product portfolio by licensing and acquisition of “near market” opportunities[5]. The difficulty of implementing novel biomedical devices into the medical sector can be allocated to its competitiveness, as the key characteristics of the medical device industry are[6]:

- Rapid innovation
- Short product life cycles
- Competitors leap-frogging each other with more advanced, user friendly technology.

The development of novel biomedical implants therefore normally originates from individual clinicians or academics. Growth in the medical devices market is also an ever increasing factor, as the estimated annual growth of the US market is an annual compound rate of 9%. The markets with the fastest growth rate is allocated to Latin America and Asia, with rates as high as 15% per year[7]

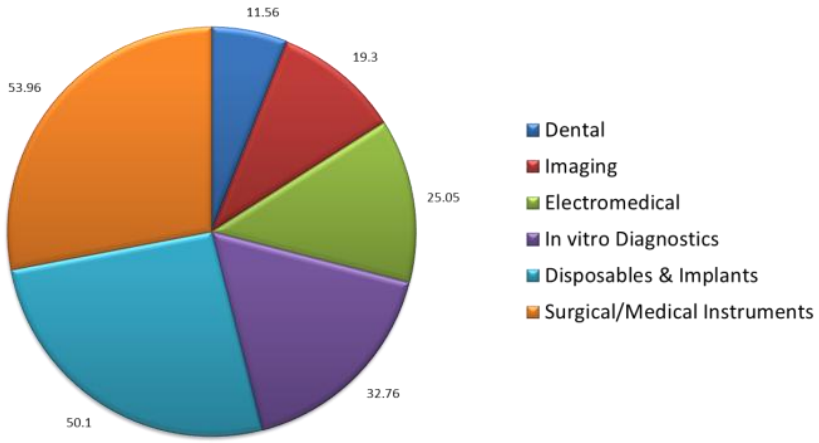


Figure 2: Medical devices sales in € bn in 2001[7]

The innovation of a novel product into a highly competitive sector can prove challenging. The aspect of innovation in product development have been mentioned previously, but the true need of innovation lies in the bridging of the technology and design part of the academics to the external market of the medical sector. In effect, the implementation of an innovation strategy is required for the bridging of this gap in between the academic institutions and the major medical device companies (see Figure 3).

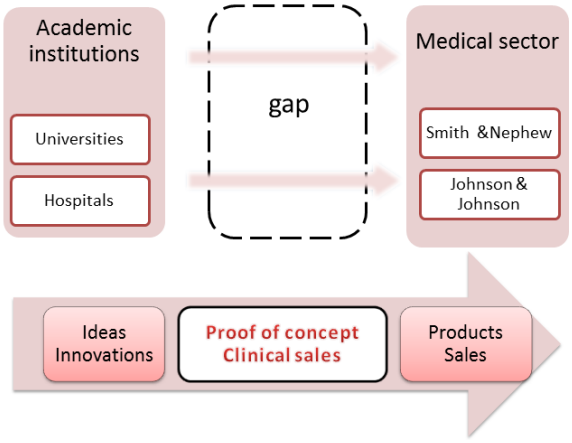


Figure 3: The function of innovation in product development

Incremental Sheet Forming

The ever increasing material costs of metal product processing introduces great interest in more cost efficient forming processes to reduce the loss of unused blank material. A relatively new class of forming processes known as Incremental Sheet Forming (ISF) have been investigated as a result of this need for more efficient forming processes. The ISF process is highly flexible, reduces production cost reduction of up to 90% in comparison to processes such as stamping and can be developed in normal milling machines[8]. 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, as ISF can be implemented in any facility that owns a basic CNC (Computer Numeric Control) machine. The advantage of ISF implemented in CNC machines is that the CNC technology have 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[9]. The forming of valuable lightweight materials is greatly covered by ISF processes. A large variety of studies contribute to the research on the forming of titanium and titanium based alloys as part of ISF of lightweight materials[10]. The ISF process utilises 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 when using five-axis machines[11]. The purpose of this project is to find means of creating a customized biomedical implant as well as document the design and development procedure of a titanium based biomedical arthroplasty implant using innovative Incremental Sheet Forming (ISF) techniques. The research will occur by means of experimentation of the manufacturing process.

1.2 Problem statement

Knee replacement surgery, also known as knee arthroplasty is seen as a solution to osteoarthritis and is considered as one of the most common and successful orthopaedic surgeries[12], but surgical procedure is only seen as a last resort, as a various number of perioperative complications can occur (discussed further in Section 2.2.4). As a result of this sacrificial surgery, some perioperative complications include the removal of the harder, exterior bone matter, as well as the ligaments supporting the knee joint. The ligaments contain blood vessels as well as nerve endings, responsible for optimal muscle activation and certain reflex actions. The consideration of only implementing surgical procedures as a last resort also results in the delay of the disease until it reaches a severe state. The delay of knee arthroplasty is therefore not always medically indicated or preferred by patients. Alternatives to knee arthroplasty exist, such as the use of Hylan G-F 20 (also known as Synvisc), a medical fluid that acts as a lubricant and shock absorber for the joints that is injected directly into the knee joint. The use of Hylan G-F 20 will reduce the pain in the knee but not cure the prevalence of osteoarthritis, resulting only in a delay of the surgical procedure. Recent studies have shown that the use of Hylan G-F 20 will only delay the need for total knee arthroplasty by a median of 2.1 years[13]. Partial knee replacement has been in and out of the medical sector for the past 60 years [14]. The implementation of unicompartmental knee arthroplasty has been renewed as a result of improvements in surgical application and the fitting procedure of the implants. These less invasive surgical techniques have therefore been reconsidered as standard implant designs does not ensure a matching fit to the specific topography of the patient's knee[14].

1.2.1 Research objectives

Partial joint replacement in the knee, also known as unicondylar knee arthroplasty is still a very new concept compared to total knee replacement surgery. Research and operational improvements concerning unicondylar knee arthroplasty can be made with the correct application of biomedical

engineering. These improvements can be made by the implementation of a customized implant that supports minimally invasive surgery (MIS). This project will firstly develop and propose a process chain to enable the obtaining of custom data and the design and manufacture of a patient-specific biomedical implant. The problem statement can thus be formulated into a research question:

Is it possible to produce titanium based knee implants using Single Point Incremental Forming (SPIF) as a forming technique?

The possibility of this proposed device can be allocated in two aspects, firstly the technical possibility, and secondly the commercial possibility. The project assessed various sub questions based on the main research questions:

- Can a valid process chain be developed to produce incrementally formed titanium knee implants?
- How can the produced prototypes be analysed to determine the formability of the ISF process?
- Will the process formability differ when the end-product geometry of aluminium is compared to titanium based prototypes?
- Can the implementation of a custom made backing plate improve process formability of the incremental forming process?
- Is this invention patentable?
- Is the proposed implant commercially viable?

1.3 Roadmap of this document

The introduction to this thesis included a brief background to the thesis as well as a problem statement that identified and discussed room for improvement in the bio-medical sector. Chapter 2 discusses various aspects of the project background by means of a literature review. These aspects include the basic anatomical structure of the human knee joint, followed by the current methodology in knee replacement surgery and conclude with the discussion of the theory, applications and current research on the Incremental Sheet Forming (ISF) process. Chapter 3 implements the application of systems engineering principles to design an empirical study that can be followed to solve the research question in Section 1.2. Chapter 4 proposes the developed and validation of a process chain to manufacture a patient-specific knee implant by means of reverse engineering methodology and the Incremental Forming (IF) process. Chapter 5 inspects the technical feasibility of the project such as experimentation and tests performed on manufactured prototypes while Chapter 6 determines the commercial feasibility of the proposed products by means of Discounted Cash Flow (DCF) methodology and cost comparisons. Chapter 7discusses the results and analysis of the tests performed on the prototypes. Chapter 8, the final chapter, concludes the study by answering the main research question as well as the sub questions. The final chapter proposes a set of recommendations for future studies in this field of research as well.

2 LITERATURE REVIEW

2.1 Medical Background

The area of application is focussed on the biomedical implants of knee replacement surgery. The design and manufacturing of biomedical knee implants requires knowledge of the anatomy and working of the knee. The anatomy of the human knee is therefore studied as part of the literature review to understand the focus areas applicable to the design of a biomedical device. This section is also documented to highlight and identify the functional purpose of the joint tissue in order to understand the function of the knee joint.

2.1.1 Anatomy of the knee

The knee is the largest joint in the human body consisting of an extensive and intricate network of ligaments and muscle tendons[15]. The knee consists out of four different bones:

- The largest bone, known as the femur is part of the thigh and forms two compartments, known as the medial and lateral condyle (see Figure 4).
- The tibia, attached to the femur using ligaments and a capsule and forms part of the shin.
- The fibula, or outer shin bone, is located below and extends parallel with the tibia.
- The patella, also known as the knee cap acts as an extensor mechanism which is connected to the quadriceps (thigh muscles). The patella is able to move along a groove in between the two condyles as the joint flexes and extends[16].

The knee joint can compensate for the different types of movement that occurs to enable normal working of the knee. The knee joint does not only flex and extend, as studies have only recently detected that slight rotational movement occurs as well[2].

The femur, tibia, and fibula are all covered in articular cartilage. The cartilage is extremely hard and smooth to reduce the frictional forces between the interconnecting bones as movement occurs. The socket of the tibia is equipped with the lateral and medial meniscus as well. The menisci absorb shock delivered to the joint to reduce the fatigue placed on the joint during movement[17].

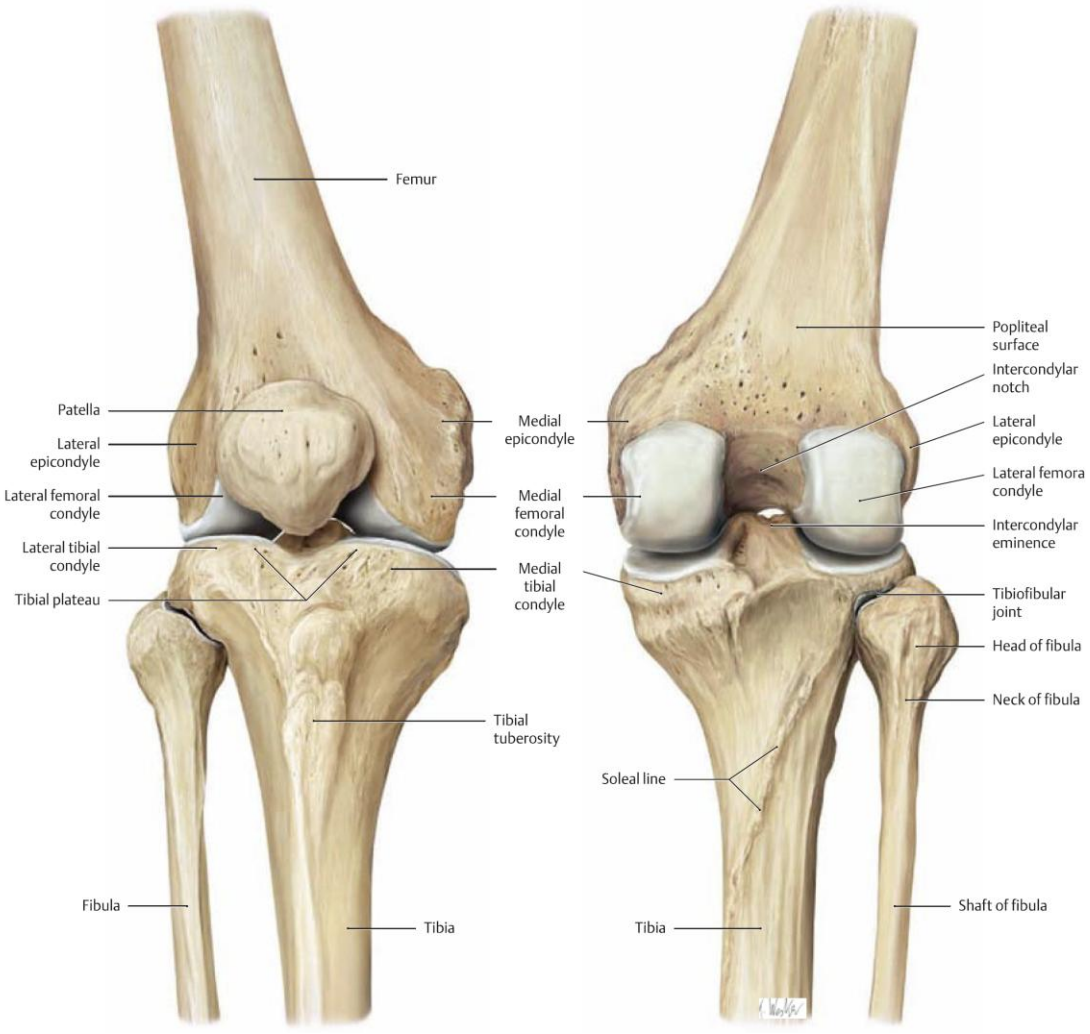


Figure 4: The knee joint: articulating bones[18]

2.1.2 Major ligaments of the knee

The knee joint is covered and integrated with a network of ligaments to enable the joint to operate correctly. The knee ligament network consists of two internal ligaments and four main external ligaments[16]. The two internal ligaments are the Anterior Cruciate Ligament (ACL) and the Posterior Cruciate Ligament (PCL) these ligaments cross each other (resulting in the cruciate reference), connecting the femur to the tibia. The purpose of the ACL and PCL is to offer stability during movement and reduce tension on the external ligaments of the knee joint.

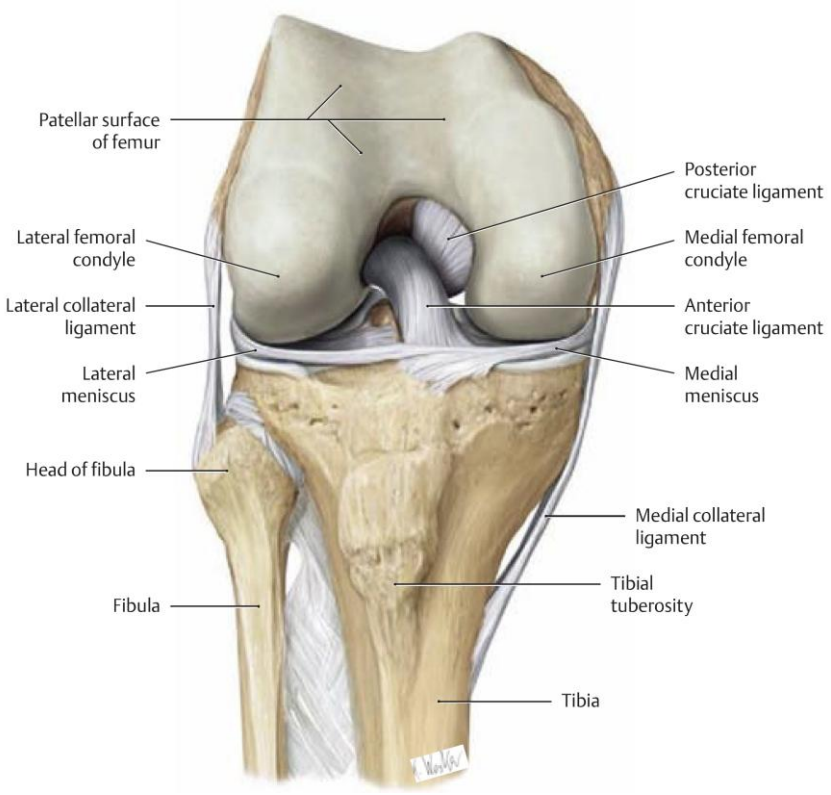


Figure 5: The ligaments of the knee joint[18]

Two additional ligaments are located on each side of the knee joint, known as the medial and lateral collateral ligaments that offers stability and prevents excessive abduction of the knee. The Medial Collateral Ligament (MCL), also referred to as the Tibial Collateral Ligament (TCL) is located on the inner side of the knee joint as the name suggests and connects the femur to the tibia. The Lateral Collateral Ligament (LCL) is situated on the outside of the knee joint and protects the knee from outwards (varus-directed) forcing. This ligament connects the femur to the fibula [16].

2.1.3 Physiology of the knee

Minimal invasive surgery requires the exact knowledge of the anatomy as well as the physiology of the knee. The study of the physiology will indicate all sensitive areas of the joint prone to damage during surgery. These network areas have to be considered in the design process of a device that does the least damage to unaffected tissue such as tendons, nerve networks, and blood flow systems. Focus will therefore be placed on the systems that might be damaged during knee arthroplasty operations.

The major blood vessels around the knee travel with the popliteal nerve along the back of the leg. The popliteal artery and popliteal vein are responsible for most of the blood transfer to the lower leg, as seen in Figure 6. The popliteal artery and vein will not be an issue when considering minimal invasive surgery as incisions will be made at the anterior area the knee [19].

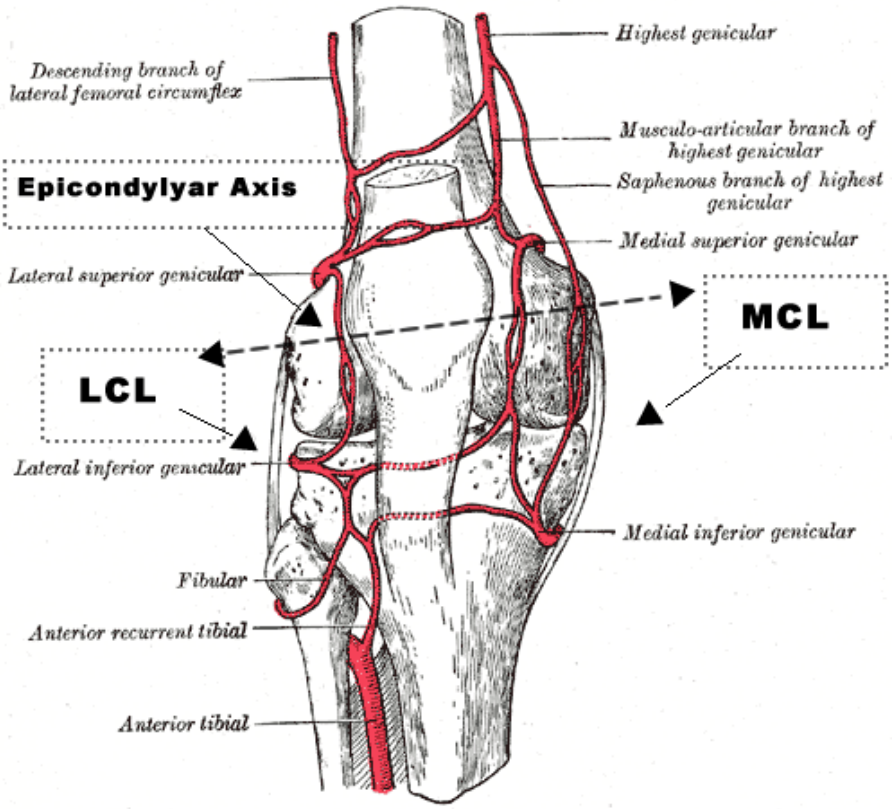


Figure 6: The blood supply system of the knee [20]

2.1.4 The synovial cavities

The synovial cavities are located in all major joints of the human body. These cavities act as reservoirs for synovial fluid. Synovial fluid is crucial to the correct functioning of the knee, as the fluid contains hyaluronic acid (see section 2.2.2). This fluid forms a thin layer on the surface of the cartilage, providing correct function of the knee joint by[21]:

- reducing sliding friction by lubricating the joint.
- absorbing shock, as this is a non-newtonian fluid.
- removing nutrients and waste from the joint's contact area, as the fluid acts as a medium for oxygen.

2.2 Surgical methodology – knee arthroplasty

This section will describe the background and give a comprehensive view of the implementation of knee replacement surgery, also known as knee arthroplasty, with the main focus on the specific designs of the knee implants.

2.2.1 Osteoarthritis

Osteoarthritis is a degenerative bone disease, considered as an active disease process that causes the degradation of cartilage, thickening in the subchondral bone, and the formation of new irregularities of bone matter in the joints. Osteoarthritis is also the most prevalent form of arthritis, and up to a third of older adults (aged 55 years and up) in the general population are affected by this disease [22]. Cases where osteoarthritis in the knee is classified as severe are most commonly treated by means of surgery[13]. Classification of osteoarthritis of the knee is only established in 1957 by J.H. Kellgren and J.S. Lawrence, and is graded by means of radiological assessment in five grades, where Kellgren-Lawrence grade 0 indicates a definite absence of osteoarthritis, and Kellgren-Lawrence grade IV defines end-stage arthritis, or a severely affected knee joint[23].

2.2.2 Conservative treatment to knee pain

This section describes the solutions to knee pain, especially of osteoarthritic nature, that is conservative, referring to treatments or measurements that are less radical. Surgeons and patients alike avoid the surgical solution to knee pain (as a result of age, heart disease, diabetes, pulmonary disease, obesity, or generalized medical debilitation). Surgery, on the other hand can also cause various complications such as infection, pulmonary embolism, thrombosis, hemarthrosis, nerve damage, and vascular injuries, causing a higher reluctance towards conservative treatment of knee pain[13].

Current therapeutic options for osteoarthritis are available as well. Nonpharmacologic techniques such as weight loss, the education of patients, and physical therapy are used to reduce further prevalence of the disease. The most common and relatively new solution to conservative knee treatment is the implementation of intra-articular hyaluronan therapy. This therapy is used when the patient is no longer responsive to nonpharmacologic therapy, and is administered by injecting steroids or hyaluronic acid into the joint[24].

Hylan G-F 20 (also referred to as Synvisc) is a cross-linked hyaluronan derivative approved for the treatment of osteoarthritic knee pain if other conservative methods have failed. According to Adams et al., the synovial fluid in the knee joints in osteoarthritic joints is lower in elasticity and viscosity than that of healthy knees. The reduction in rheological properties of the synovial fluid results in the reduction in concentration of hyaluronan in the synovial fluid[21]. Studies have shown that three injections of hylan G-F 20 given 1 week apart resulted in reduced knee pain for as long as 26 weeks after treatment [24].

2.2.3 Minimally invasive surgery

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 [25].

The traditional knee replacement surgery involves an incision of approximately 20.3 cm. The application of MIS enables the reduction of the incision length to approximately 7.6 cm [26]. This aspect of surgery greatly reduces the damage done to sensitive ligaments, blood veins, and nerve endings.

Further findings have proved that unicondylar knee arthroplasty (UKA) procedures have reduced blood loss to approximately 200ml, avoids the normal tissue sacrifice (such as opposite compartment, patellar bone, and cruciate ligaments), and decreased morbidity as the patellofemoral region is unaffected during UKA. Performing UKA rather than total knee arthroplasty has proven to be more cost effective as it is performed as an outpatient procedure in 80% of all cases[27].

2.2.4 Total knee replacement surgery

The treatment of end stage arthritis of the knee will almost always require total knee replacement surgery, as total knee arthroplasty is seen as a predictable, effective, and durable procedure in long-term follow-up studies[28]. This procedure promises a return to activities of daily living with a reduction in knee pain. According to Boettner, the results of total knee replacement surgery have improved over the past two decades, as the ten year implant survival confidence has reached a 95% level, and 20 year survival rate is rated in between 85%-90%[29].

For the traditional surgical implementation of knee replacement surgery currently implemented today, total knee replacement (TKR) surgery is performed where surgeons choose a standard design implant based on the measurement of a patient's morphological aspects from x-ray images. The standard implants will then be applied to the knees of patients, where interfering bone structures are cut away using a series of different bone removal mechanisms to allow the implant to fit. Complications can however arise due to the variation in morphological aspects of the human femur, as the available implants offer limited ranges of geometry for the mass manufacturing scheme [30].

The current procedure for TKR surgery is summarized by the following steps[30] and is displayed in Figure 7:

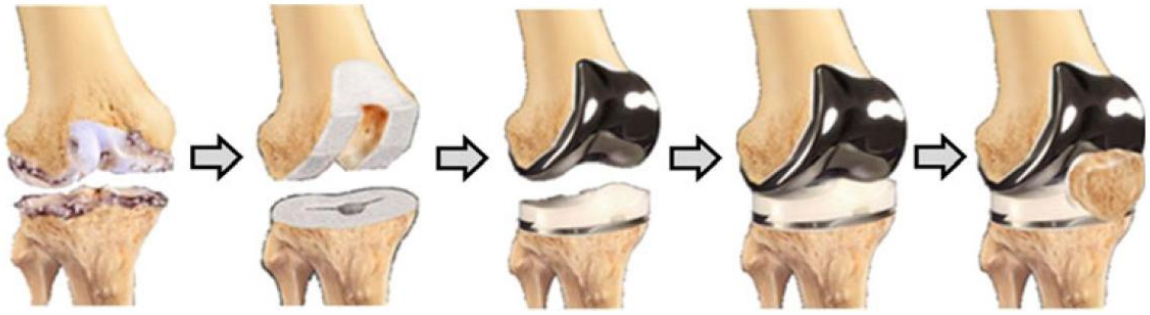


Figure 7: Complete procedure of current TKR surgery [30]

- The surgeon determines a proper implant that is manufactured from standard designs based on measuring the patient's X-ray images.
- The damaged portions of the femur and the tibia are removed using special jigs that allow guidance of the blades to cut bone to allow proper alignment and fixation.
- The bone cement is applied to the implant-bone interface to enable fixation.
- A femoral component is cemented to the distal femur
- The patella is then reconstructed, and a polyethylene patella button is cemented into it.

One of the greatest drawbacks of currently implemented knee replacement surgery is the pain and discomfort experienced by the patient during the post-operational and recovery phases of surgery. Pain and discomfort is experienced as a result of the removal or damage implied to unaffected matter in the joint. Traditional surgery causes damage to unaffected cartilage and bone matter as well as ligaments [16]. The removal of the outer, harder bone surface leads to the increase in pain and discomfort during post operational phases of the surgery.

The aforementioned 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 [16].

Other complications can also arise with the implementation of TKR surgery, as these procedures are considered as more invasive of nature, more damage is done to unaffected organic matter. During the procedure, perioperative arterial complications can also include blood loss, infection, early hemorrhage, wound breakdown and intraoperative fractures[31].

Is it a better option to delay total knee replacement?

The question then remains if it is a better option to delay total knee replacement surgery. Studies have shown that the use of intra-articular hyaluronan treatment can delay surgery. A recent study by Waddell et al. determined if the implementation hylan G-F 20 treatment can delay the need for total knee replacement surgery. A total of 1978 courses of hyaln G-F 20 were given to 1187 knees. The study found that intra-articular hyaluronan treatment delayed the operation by a median of 2.1 years. Once the osteoarthritis is classified as severe or end stage (Kellgren-Lawrence grade IV), the implementation of total knee replacement is inevitable as a result of complete joint degradation. The implementation of this type of therapy using Hylan G-F 20 requires up to 4 courses. With each course consisting out of three weekly injections, the current cost for this procedure can sum up to a total of $ 4,908 (recorded July 2012) to delay an inevitable procedure for an approximate time of 2.1 years.

2.2.5 Partial knee replacement

Partial knee replacement is classified as a variant of knee arthroplasty that does not replace the entire knee, meaning that not all of the femoral condyles, the tibial plateau, and the patella are resurfaced. The most common type of partial knee replacement is unicompartmental knee arthroplasty[14]. The implementation of partial knee replacement has been reviewed continuously since its proposal in the 1950s, and has gained great reluctance as a result of the lack of surgical technique[14].

The application of unicompartmental knee replacement (UKR) has increased dramatically in popularity as a treatment option for isolated medial or lateral cases of osteoarthritis. Some advantages to this procedure include a conservative bone resection, the maintenance of more natural knee kinematics and reflex function with the retention of the cruciate ligaments, better proprioception, an improved range of motion (ROM), predictable pain relief, and faster post operational recovery[28]. The option of partial knee replacement is however limited to only some patients, as the patient selection criteria have to be passed for a patient to be considered as a viable candidates.

Patient selection criteria

Historically, the implementation of partial knee replacement surgery was only recommended for older, lighter, less active patients[28]. The partial knee replacement surgery can only be applied to a small percentage of patients suffering from osteoarthritis. Boettener estimated that in 2008 only 6 - 10% of all patients undergoing knee replacement surgery could be considered as candidates for partial knee replacement for the procedures available during that time[29]. Stuart et al. established several criteria according to different aspects of the patient. Choosing appropriate candidates involves consideration of the following[32]:

- Age – The most suitable candidates for unicondylar arthroplasty are more than sixty years of age, as they have a lower demand for activity.
- Weight – The best candidates cannot be obese (have a BMI higher than 25) or exceed a bodyweight of 82 kilograms.
- Occupational and recreational demands – The correct candidates cannot have a high level of activity requirement, as all joint replacements are at risk for mechanical failure or loosening if they are subjected to heavy cyclical loads.
- Preoperative ROM (or range of motion) - The ideal range of motion requirement for all candidates should at least display a preoperative arc of flexion of 90 degrees.
- Extent of angular deformity – The angular deformity of the knee should be less than 15 degrees, and the deformity must be passively correctable to neutral at operation after the removal of osteophytes.

Survival rate of unicompartmental implants

A recently concluded study by O'Rourke et al. investigated the results of a survival rate analysis of unicompartmental knee implants. The study was conducted over a minimum time period of 21 years. The investigation perceived the patients that had undergone unicompartmental surgery between July 1975 and January 1982, where a total number of 136 knees of 103 patients where partially replaced using surgery. The final follow-up was then conducted, and a Kaplan-Meier survivorship analysis was done with a confidence interval of 95%. The survivorship of the unicompartmental knee implants was 84% after 20 years and 72% after 25 years[28]. A generated Kaplan-Meier survivorship analysis curve is shown in Figure 8:

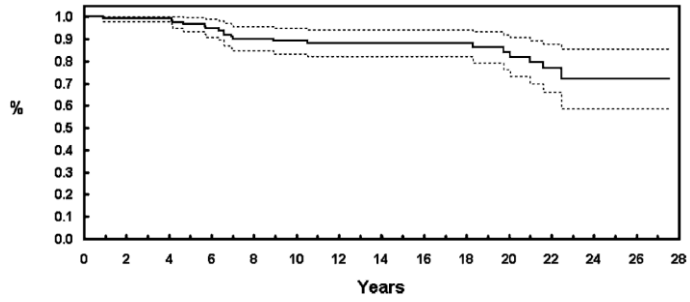


Figure 8: The Kaplan-Meier survivorship analysis curve of UKR implants[28]

2.3 Room for improvement

In a case study review of 40 cases of titanium cranioplasty, most of which reported to be ill-fitting, or aesthetically poor[33]. A new Rapid Prototyping (RP) technique using patient-specific CT (Computerised Tomography)-derived techniques was proposed to improve on the inaccurate designs of the previous standard equipment. A CNC milling machine was used to mill a life-sized replica of the cranial defect, which resulted in an accuracy error of 0.6mm as a result of poor CT resolution (having slices of 3mm thick), but was considered to be quite acceptable. A die was created from this model that consisted out of class 2 dental stone. The biomedical implant was then created by pressing a titanium plate over the die using a hydraulic press. Surgical procedures were conducted and the implant was fastened using screws and flanges. The result of this surgery displayed a great improvement on fitting time and final appearance[34].

A recent study was conducted to determine if the application of RP techniques in the biomedical sector improved on the medical welfare of the patients. A quantitative analysis was performed by D'Urso et. al to determine the true success rate of this application. The trial was based on 45 patients where biomodels had been used for diagnosis and planning prior to craniomaxillofacial surgery. The results showed great improvements in all fields. Accuracy of diagnosis increased from 65.6% from CT imaging alone up to 95.2% with utilization of biomodels. The measurement accuracy error improved from 44% with the CT imaging alone, up to 8% with the utilization of biomodels. Further improvements include reduction in operating times and the use of the models proved to be more cost-effective[35]

2.3.1 Current surgical research conducted

The current surgical methodology researched today includes the application of reverse engineering of the human knee. The implementation of this method will enable the application of creating custom-made implants for every patient, as mismatched implants often cause a severe balancing problem and a short-term durability[30]. 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[30].

Research with regarding the implementation of custom-made implants in the field of UKR surgery is also currently performed[36]. Van den Heever, et al. implied the application of UKR surgery to improve on current procedures regarding knee replacement by implementing a series of polynomials and B-splines to describe the geometry of the distal part of the femur. This 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, however produced using rapid manufacturing (RM) techniques[36].

Figure 9: Patient-specific UKR implant[36]

2.4 Titanium as a metal

The applicability and utilisation of titanium in the manufacturing of titanium based components is limited only by the physical properties of the metal. It is therefore required to understand the physical properties and capabilities of titanium prior to its applications and manufacturing methods.

Table 1: Physical properties of titanium[37]

Property	Value
Atomic number	22
Atomic mass	47.90 $g.mol^{-1}$
Density	4.51 $g.cm^{-3}$ @ 20°C
Melting point	1660 °C
Boiling point	3287 °C
Young's modulus	105 - 120 GPa
Poisson's Ratio	0.37
Ultimate tensile strength	900 MPa
Yield strength	730 MPa

The metal is known for its high strength-to-weight ratio, making it highly applicable for systems in which efficiency is one of the most important aspects such as the automotive and aeronautical industry. The metal is also known for being chemically inert and bio-compatible, improving its attractiveness for applications in biomedical technology such as hip and knee replacements, pace-makers as well as skeletal plates and screws[37].

2.4.1 The biocompatibility of titanium

Biomedical implants need to satisfy the properties of biocompatibility, strength and corrosion resistance; of which titanium is one of the best and most widely used biocompatible metals in the biomedical industry [38]. Medical implants more focussed on arthroplasty and the replacement of weight bearing joints places a higher importance on strength, toughness and torque in mechanical properties, as well as abrasion resistance in the tribology of artificial joints [38]. With significant properties that allow benefits with the use of titanium, surgeons and engineers alike make use of this metal. As titanium is absolutely inert in the human body, compatible with bone growth, strong and flexible, it is considered as the most biocompatible of all metals[39].

Why is titanium biocompatible?

Titanium is identified with its high biocompatibility and corrosive resistance as a result of the oxidization of the external layer upon contact with oxygen. Upon exposure to oxygen, the titanium (Ti) reacts to form a highly stable oxide, Titania (TiO_2), on the surface. TiO_2 can undergo further modifications upon binding various surrounding ions including calcium, phosphate, and hydrogen as a result of its high dielectric constant of 85MHz [40]. Various other properties of titanium are unique to the metal, improving its attractiveness to the biomedical sector. These properties are discussed in Table 2:

Table 2: Titanium's unique properties for biomedical application[39]

Property	Description
Inert to human body fluids	The protective Titania (TiO_2) layer, which forms naturally in the presence of any trace amounts of any form of oxygen, enables the implant to be completely resistant to body environments, under stress, fatigue and in crevice conditions. The film is highly adherent, insoluble and chemically non-transportable, preventing any reaction to human tissue.
Osseointegrates	Titanium, having a high dielectric constant, has the ability to enable the binding to bone and living tissue to the metal. Instances where the metal is used for implants, it will physically bind with the bone matter, improving the long-term survival rate of the implants.
High relative strength	Titanium, being 56% less dense than steel, yet having a 25% higher tensile strength. Titanium has a higher strength-to-weight ratio than any other metal used for biomedical implants. In addition, it's density is very similar to that of bone matter, reducing scatter in medical imaging such as x-ray, MRI and computed tomography images.
Flexible	The modulus of elasticity and coefficient of thermal expansion of titanium nearly match those of bone matter, greatly reducing the risks of implant failure.
Non-magnetic	Titanium is a paramagnetic, non-ferrous metal, and will not be susceptible to outside interference, and will not trigger metal detectors or cause interference with MRI imaging during follow up procedures.
Easily worked	The workability and forming technology of titanium can be performed using conventional metal processing tools and techniques, as it is comparable to stainless steels and Tungsten Inert Gas welding, which can be performed outside of a vacuum.

Metastable β titanium alloys

While current titanium based biomedical applications mostly consist of the more common commercially pure (CP Ti) and alpha-beta titanium alloys, the utilization of newer, more specialised alloys are increasing in the biomedical industry. The past decade has shown a substantial increase in the synthesis of metastable β titanium alloys designed specifically for the biomedical field[37]. While α-β alloys are used for bone plate or support implants, the β-alloy alternative possesses a lower young's modulus (closer to that of bone matter) and enhanced biocompatibility, these alloys are now considered for biomedical applications such including spinal and trauma, where three alloys were developed simultaneously in Japan and the United States, namely $Ti_{29}Nb_{13}Ta_{4.6}Zr$, $Ti_{12}Mo_6Zr_2Fe$ (TMZF), and $Ti_{35}Nb_7Zr_5Ta$ (TiOsteum)[37].

2.4.2 Material properties of CP Titanium Grade 2

Commercial purity titanium has long been used for biomedical applications, such as cardiovascular stents, lead wires, and spinal fixation devices. Titanium based implants cause little concern for adverse interaction between the implant and the human body when the Fe content is kept low[37]. Commercially pure grade 2 titanium is used for these biomedical applications as a result of its good workability as well as full bio-tissue compatibility in comparison to the stronger CP Ti Grade 4 or 5[39].

In an attempt to enhance the mechanical performance of the grade 2 commercially pure titanium, Rack and Qazi reported on a strengthening method in utilising equal channel angular pressing (also known as ECAP). The comparison of commercially pure titanium grade 2 with varying grain structure, in comparison to Ti-6Al-4V ELI is shown in Table 3.

Table 3: Mechanical properties of grade 2 CP Ti in different states[37]

Structure type	Hv, (MPa)	UTS, (MPa)	YS, (MPa)	EL. (%)	RA (%)	Fatigue limit (MPa)
Coarse-grained	1800	460	380	26	60	238
UFG (Equiaxed, submicron-grained)	2700	460	625	14	60	403
UFG (Fibrous w. high dislocation density)	2821	960	725	10	45	434
UFG (subgrained w. internal cells)	2850	1100	915	9	40	500
Ti-6Al-4V ELI (annealed)	-	965	875	10-15	25-47	515

2.4.3 Titanium in the biomedical industry

Titanium as a product is available in commercially pure and alloyed product forms, in both prefabricated components, as well as mill products (such as bar, billet, plate and sheet). The wide range of applicability causes an extensive range of requirements in mechanical properties. The alloying materials favour non-toxic elements including niobium, zirconium, tantalum and molybdenum. The most common titanium alloys are listed below:

Table 4: Titanium alloys for medical use[39]

Commercially pure grades 1-4	The unalloyed titanium strains are the most corrosion resistant. CP Ti Grade 1 is the most formable, while higher grades have progressively greater oxygen contents for higher strength.
Ti-6Al-4V ELI	This α-β alloy is most commonly used for orthopaedic surgery. The ELI grade was developed to improve the fracture toughness and cryogenic ductility. Other uses include spinal fixations, staples and needles.
Ti-6Al-7Nb	This α-β alloy has similar mechanical properties to Ti-6Al-4V, but with improved corrosion resistance.
T-13Nb-13Zr	This near-β alloy has a low modulus of elasticity, and high strength, making it ideal for orthopaedic implants. It is also very formable, and highly corrosion resistant.
Ti-15Mo-3Nb	This is a β alloy having a higher strength and lower modulus of elasticity than Ti-6Al-4V. It offers long term survivability in orthopaedic implants.
Ti-12Mo-6Zr-2Fe	A relatively new alloy, having a low modulus of elasticity, having excellent mechanical properties, corrosion resistance and formability as well as good wear and notch fatigue resistance.

2.5 Incremental Sheet Forming

Incremental Sheet Forming (ISF) is defined as a range forming processes in which a sheet is formed incrementally using localised deformation, without drawing in of material from a surrounding area and using a fully clamped blank, where the final shape is determined by the xyz movement of some tool part without the need for a die[41]. The sheet is traditionally clamped onto a three or five axis CNC machine by means of a simple frame for the duration of the forming procedure. The tool used is continuously moved according to a preprogrammed trajectory, which is usually predefined and automatically generated by a CAD/CAM system. The tool trajectory is initiated at the outer regions of the shape, moving inwards and downwards incrementally [42]. The application of highly localised deformations causes progressive deformations in the workpiece rather than a complete simultaneous deformation. This aspect of Incremental Forming (IF) leads to the increase in material formability when compared to other forming processes such as the traditional stamping process[42].

The IF process focussed on for this application is known as single point incremental forming (variations of incremental forming is later discussed in Section 2.5.3). For this specific application of the forming process, there is no supporting backup die used on the back surface of the sheet. The use of only one point of contact leads to the name Single Point Incremental Forming (SPIF). A representation of the basic components required for the incremental sheet forming process as shown in Figure 10, the basic components[43]:

- Sheet metal blank
- Blank holder
- Backing plate
- A rotating forming tool.

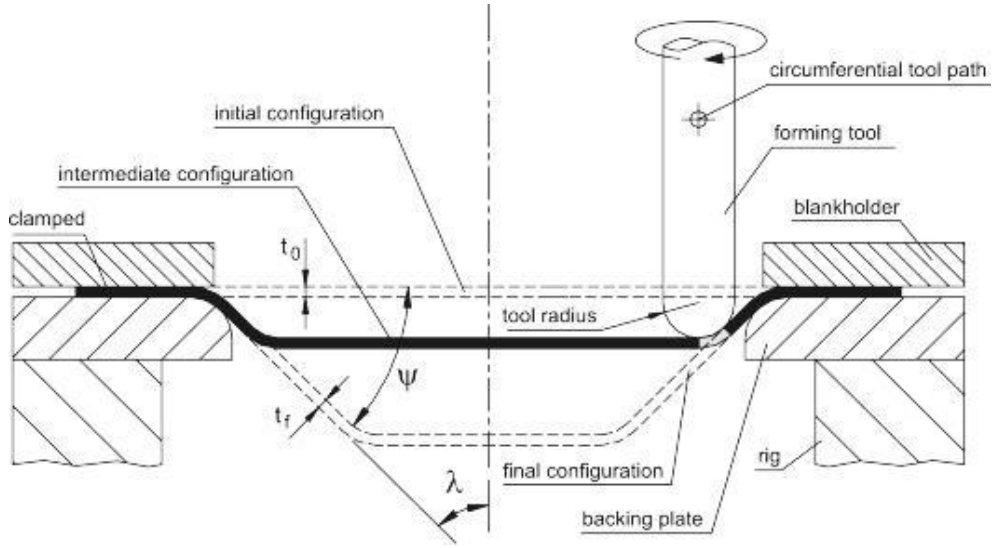


Figure 10: Schematic representation of SPIF[43]

2.5.1 The history of ISF

The early development and definition of ISF failed to completely discern between IF and a process known as spinning. Spinning mainly consists of a workpiece that is deformed into a desired shape by rotating the workpiece using a mandrel and applying spinning tools[41]. The application of true IF involves a stationary, clamped workpiece (also referred to as a blank). The usage of using a stationary blank enables true IF to produce asymmetric forms. An extensive study of Asymmetric Incremental Sheet Forming (AISF) is documented by Jeswiet et al. in 2005[9].

Some of the patents concerning ISF (according to the mentioned definition) prior to the distinction between spinning and IF involve a spinning patent, issued by Leszak in 1967. This process involves the rotation of a blank. The blank is formed using a roller to apply vertical displacement onto an elastic medium. Even this specific patent refers back to earlier patents, where the earliest date back to 1898[41]. The method described above can be classified as one of the earliest forms of IF, as no distinction could be made at that time.

The first form of asymmetric part manufacture was developed in Japan by Iseki et al. that utilises a three dimensional CNC milling machine[44]. The technological maturity and availability of CNC machines was low during the early 1990's, which led to the main cause for slow development of the usage of CNC machines in ISF processes[41]. The development of the ISF process remained slow and unnoticed to the western world up until 1997 where the simplicity of the process became more attractive to an industry where clients required smaller, more diverse product shapes[41].

2.5.2 Classifications of ISF

One of the most advantageous qualities of IF is the ability to create asymmetric forms, as this process application eliminates the need for expensive dedicated dies, greatly reducing the overall production cost of the parts[9]. Although AISF can describe a large spectrum of different forming strategies, it is still defined as [9]:

- a process in which a certain sheet metal blank is formed,
- utilises a solid, small-sized forming tool,
- does not require large, dedicated dies,
- has a forming tool which is in continuous contact with sheet metal,
- has a tool that is operated under control, in a three dimensional space,
- can produce asymmetric sheet metal end products.

Single point vs. Two point incremental forming

The IF process can be classified under two main categories based on the forming strategy chosen. Two point incremental forming (TPIF) was introduced into the industry to meet the need for quick, inexpensive production of low volume asymmetric sheet metal parts. During the TPIF process, the

sheet metal blank is moved along the z-axis as the forming tool pushes in the sheet metal and against an opposing force exerted with a certain offset (created using a die). This process therefore consists of two contact points and is therefore called TPIF[9]. Single point Incremental forming refers to the IF process when only one contact point is used during forming. It is an improved form of the TPIF process, the main improvement being that it does not require a partial or full die for the forming process[9].

2.5.3 The theory of Incremental Sheet Forming

The main theory behind the IF process is focussed around the effects of parameters on the improvement on the formability. Due to a recent increase in the diversification from the manufacturing requirements, large areas of focus on the improvement of IF are allocated towards the improvement of formability. Several studies with emphasis on the assessment and improvement of the formability of sheet metal have been performed. A recent study by Kim and Park was conducted to assess the effect of process parameters, such as tool type, tool size, feed rate, friction on the contact area, and the sheet's plane anisotropy on the formability[45]. The main theory behind IF consist of various modes of deformation as well as the state of stress and strain, the friction in between the tool and sheet, the inclined wall adjacent to the forming tool, and the sheet thinning. Jeswiet et al. discussed the four major parameters of IF[9]:

- The thickness of the sheet.
- The size of the incremental step down.
- The forming speed (rotational and feed rate).
- The radius of the forming tool.

The influence of the sheet thickness and the incremental step size (first two parameters) is commonly explained by means of the sine law. Due to the conservation of volume, the end product wall thickness (t_1) can be predicted by the relationship between the wall angle (α) and the original wall thickness (t_0) by means of the sine law (Equation 1). Matsubara first found that the sine law was able to provide an accurate prediction of end-product wall thickness during IF[46].

$$t_1 = t_0 . \sin(\alpha) \qquad (1)$$

The second parameter, the incremental step size, greatly relates to the formability of the forming process. Although the general opinion concerning formability is that the formability will decrease with an increase in incremental step size, experimental work reported by Ham and Jeswiet indicated that the incremental step size does in fact not have a significant effect on the formability of the sheet.

The speed of the forming tool is known to have a direct influence on the formability of the workpiece. This is as a result of its direct influence on the frictional conditions at the concentration of the strains at the zone of deformation of the workpiece at the point of contact[47].

Studies by Silva et al. proved that the tool diameter directly influences the formability of the workpiece. Experimental results proved improved formability results with the utilisation of smaller tool diameters[43]. By reducing the tool diameter, the contact area can be concentrated at the deformation zone whereas larger tools have a tendency to distribute the strains over a more similar to conventional stamping mechanics. This theory will be discussed further in the review of friction below.

Friction during forming

The forming tool used consists of a body and a hemispherical shaped tooltip, which is used to cause deformations when applied to the material. These deformations can lead to friction in between the workpiece and tooltip at the contact area. Friction can lead to excessive heat exposure causing increased tool wear and surface degradation[9]. A method of reducing friction apart from lubrication application is to increase the rotation speed of the tool. Jeswiet et al. proposed a strategy to obtain minimal friction during the forming process focussed mainly on the concept that the relative motion of the surface of the tool to the surface of the workpiece[9].

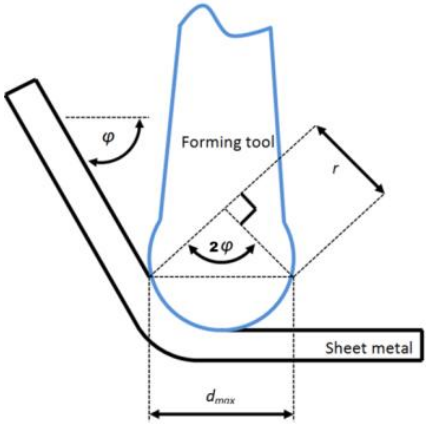


Figure 11: Contact area of the tooltip during incremental forming[9]

Regarding Figure 11, for any draw angle φ, a contact point tangent to the hemisphere will exist having a maximum contact diameter (d_{max}). This requires that the feed rate (or distance travelled along the work piece) to the workpiece be equal to the spindle speed multiplied by the average contact circumference of the tool. The rotational speed ω can be calculated mathematically using the feed rate (f) and the hemispherical tool radius r[9]*:*

$$\omega = \frac{v}{\pi \cdot r\sqrt{\frac{1}{2}(1-\cos 2\phi)}} \qquad (2)$$

2.5.4 Forming strategies of ISF

Current literature on the development of SPIF techniques indicates that the designed toolpath of the process dramatically influences the overall formability, surface quality, end-product accuracy, end thickness and overall forming time [48]. The most popular approach to tool path generation is the

application of a contour toolpath generated using a surface milling module of commercial CAM packages developed for milling[48]. Despite major contributions made by various researchers on the development of IF technology for industrial applications as well as characterization improvement of the forming limits of the process, the mechanics of deformation remains little understood due to the complexity and low predictive ability of the finite element models that have been employed to the study process. The SPIF process, according to Silva et al., is one of the few if not the only metal forming processes in which experimentation proves to be more advantageous over theoretical research. The advantage of experimentation over theory is therefore absolute even for solving the simplest practical problem[43].

Improvement in toolpath generation

The application of conventional toolpath generation, as mentioned in section 2.5.4 above, utilises the strategy of implementing various planar contours with differentiating depth in incremental step sizes. Problems can, however arise, as deformation is biaxial at the starting and end points of each contour, increasing the likelihood of tearing at the start and end points of each contour in comparison to the rest of the toolpath. This phenomenon is seen as stretch marks along the contour of the formed part during inspection[48]. The generated toolpath, according to Malhotra, composed out of a combination of forming, scanning and reforming, making the process iterative and time consuming. These observations lead to the development of a forming strategy capable of producing better end-product quality. The improvements were performed by implementing a constant incremental depth (Δz) to eliminate the occurrence of equibiaxial stretching.

The application of SPIF in the sheet forming industry, although attractive as a result of its flexibility and high degree of formability, is not widely adopted as a result of extended forming time and geometrical accuracy shortages. In an attempt to improve on this technology, the application of 3D spiral toolpaths was implemented, and experiments were conducted by Malotra et.al. to see if the application of helical toolpaths with a continuous federate would improve on process aspects. The results of this were the improvement on geometric accuracy and suface quality of the end product when compared to that generated by commercial CAM packages[48].

2.5.5 Advantages of ISF

The main question concerning the application of incremental sheet forming is why it is preferred to other forming techniques such as stamping or spinning for this application. The application of the incremental sheet forming offers a large amount of advantages:

- The process does not require dies to form the products, eliminating the production costs otherwise used for custom dies.
- Part designs are considered as highly flexible as design sizes can be easily modified using design software.

- The ISF process is one of the easiest rapid prototyping methods of metal products [9].
- The application of minute deformations of incremental nature contributes to increased formability of the material, making it ideal for applications of low formability sheets.
- The process can be performed using conventional CNC milling machines, eliminating large overhead costs.
- The need for specialized tooling is minimised as it only requires a round tipped forming tool.

2.5.6 Disadvantages of ISF

The IF process will require an extended operation time as a result of small incremental deformations and is considered very slow when compared to conventional forming methods such as stamping. Further disadvantages to the IF process are listed:

- In order to be economically viable, the process is limited to small batch sizes (see section 2.5.8).
- For 3-axis CNC applications, the forming of right angles cannot be done in a single step, but requires a multi-step process.
- Springback can occur if the implemented toolpath designs do not compensate for this aspect.

2.5.7 Applications of ISF

The process of incremental sheet forming has been seen as a more cost efficient alternative to more popular conventional sheet pressing processes. The ISF process supports the preference for low-volume, high value applications[11]. The field of application concerning ISF processes is greatly increased as a result of its ability to create asymmetrical parts out of a large variety of metals. Further preference to this process can be accounted to its high flexibility with short set-up times[11]. The ISF process is generally applied to most manufacturing processes that require small to medium size batches as it supports diverse and unique designs as a result of high flexibility. The high end product forming flexibility in the ISF process is much higher than conventional sheet metal stamping processes as reviewed by Malhorta et al. and Jeswiet et al.

Aeronautical applications

One of the most applicable fields of manufacture is in transportation engineering. The manufacture of lightweight components is required for more efficient systems where system mass is a critical factor in design. One of the most applicable fields of lightweight component manufacture is in aeronautical applications[10].

The European Aeronautics Science Network (EASN) reports of current projects undertaken to improve manufacturing processes of Titanium based components. The INMA (Innovative Manufacturing) project focuses on the innovative manufacturing of complex Titanium sheet components to "drastically reduce the current aircraft development costs incurred by the fabrication of complex titanium sheet

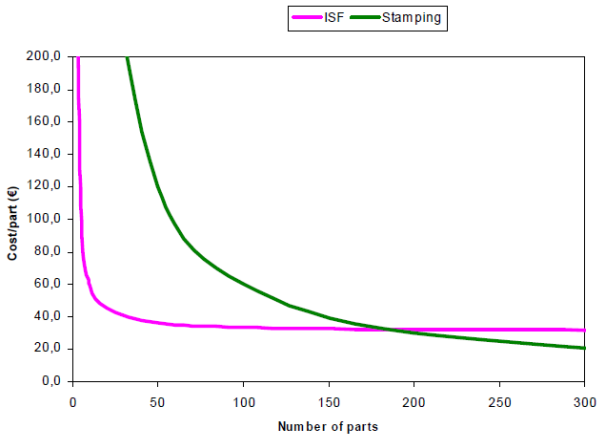
components with minimal environmental impact"[49]. This project implements advances in Asymmetric incremental sheet forming in aeronautical Titanium based components such as pylon fairings, fan blades, exhaust ducts, and air collectors. The application of this method will replace cost intensive forming processes such as deep drawing, hot forming, super plastic forming, and hydroforming. The INMA project also predicts that the application of this process will cause a reduction in costs of dedicated tooling with 80%, a reduction in component lead times by 90% as well as the buy-to-fly ratios that will reduce with 20%[49].

Biomedical applications

The IF process has been considered for biomedical applications. This is especially helpful for biomedical applications as a result of the high degree of customisation requirements when the geometrical uniqueness of human anatomy is considered. Ambrogio et al. revised the application of IF techniques for the manufacturing of high customised medical orthopaedic products[42]. The research conducted by Ambrogio et al. focussed on the sheet profiling of to produce a customised ankle support for a patient. The same process discussed by Ambrogio et al. can be implemented to various biomedical product development applications.

2.5.8 Economic analysis of ISF

Aspects such as the efficiency and cost reduction in the current competitive manufacturing field are regarded as highly important. Reductions in production costs for IF applications are therefore considered. Traditionally, the manufacturing of sheet metal components are performed by implementing dies and punches, resulting that this conventional manufacturing method can only be adequate for mass production[45]. The ISF process was compared to other conventional forming methods such as stamping and deep drawing by Rodriguez in 2006. This study concluded with an economic analysis of the production of designs consisting of various complexities[8]. The cost per part versus number of parts graph for a design of normal complexity is shown in Figure 12:



	ISF	Stamping
Number of parts	Unit cost	Unit cost
1	320,0	6015,1
10	59,6	601,6
20	45,1	300,8
50	36,4	120,4
100	33,5	60,2
200	32,1	30,2
500	31,2	12,1
1000	30,9	6,1

Figure 12: Cost comparison of incremental forming versus stamping[8]

This study indicates the break-even point at approximately 160 units, indicating that the application of IF will be a cheaper solution for a batch size of less than 160 units. A similar study conducted by Jackson [50] included the economic evaluation between negative point IF to processes that requires the fabrication of dies. The economic analysis that indicated the same results, and concluded that IF processes will be a more cost efficient solution for applications of a batch size smaller than 200 units.

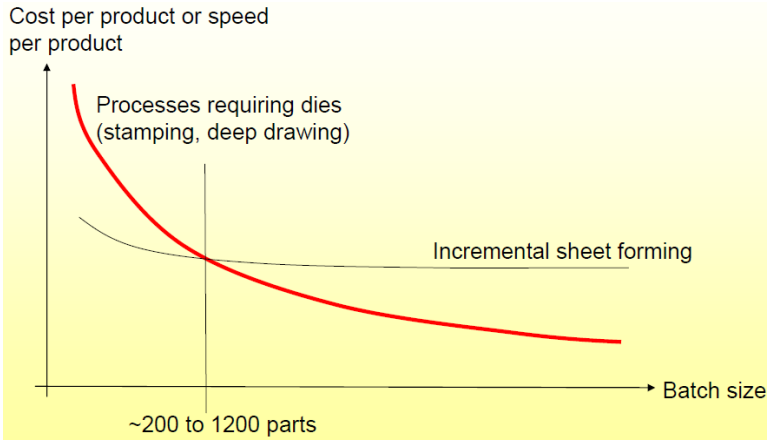


Figure 13: Economical analysis of incremental forming[50]

2.5.9 Advances in incremental forming technology

Improvements from contour milling techniques

Up until 2010 the IF toolpath, which has played a significant role in the end-product geometric accuracy, surface finish, and forming time, was generated purely using commercial CAM packages. The conventional 3D spiral toolpaths implemented was not capable of using specified constraints on both geometric accuracy and maximum scallop heights as inputs to generate a 3D spiral toolpath. The research conducted by Malhotra et al. exploited the similarities between IF and layered manufacturing to develop a methodology for automatic generation of 3D spiral toolpaths for forming asymmetric components. This developed methodology resulted in various improvements in SPIF technology, including[48]

- improved geometrical accuracy,
- reduced forming time, and
- reduced scallop heights, resulting in improved surface finish.

The main focus of the research conducted by Malhotra et al. was the improvement of end-product accuracy. Figure 14 displays the improvements made by the implementation of this developed methodology.

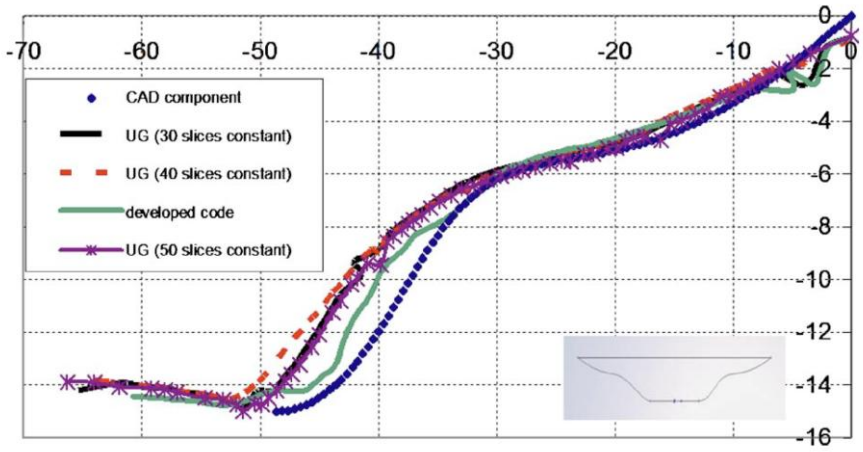


Figure 14: End product accuracy improvements by developing a new toolpath generation strategy[48]

Electric hot ISF

Electric hot incremental forming of metal sheets is a technique first introduced by Fan et al. in 2008 by applying a DC power source to implement an electric heating system during the forming process[51]. Duflou et al. proved that the process formability can be improved by implementing local heating[52]. Figure 15 describes a proposed method of implementing electric hot ISF. A DC power source was used by closing a circuit when connecting a transformer with cables to both the forming tool and the sheet blank to constitute a closed circuit.

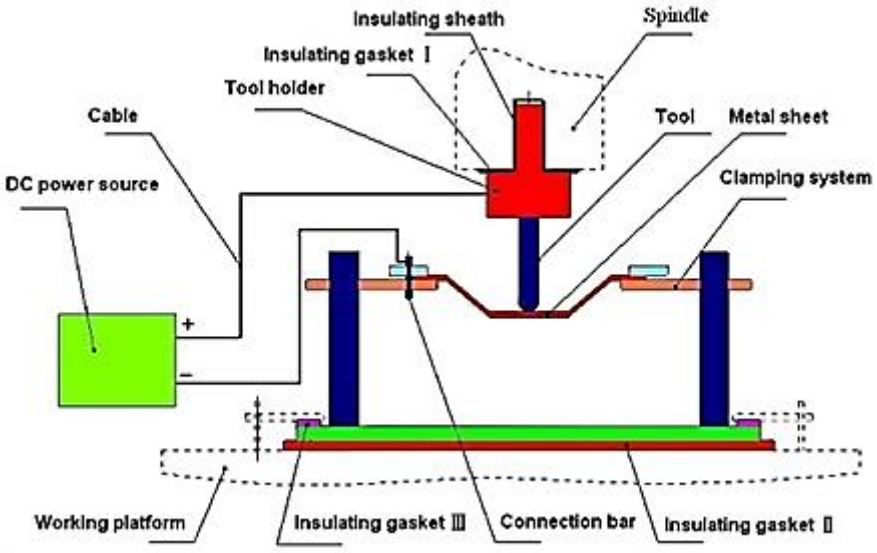


Figure 15: Electric hot ISF[51]

This process is based upon Joule's law. As current flows from the tool to the sheet, the high-current density generates heat. The increase in temperature in the localised zone at the tool-sheet interface increases the ductility of the material, creating an environment for increased formability. The study documented improvements made by the increase in the temperature of the workpiece. A series of Ti-

6Al-4V sheets were used with Mo_2S self-lubricating material. The experimental setup, based upon that described by Figure 15, was used to heat the workpiece to a temperature in between 500-600°C. The resulting formability increase of the process allowed a maximum draw angle of 72°[51].

Laser assisted incremental forming

Accompanied by the improvement of IF technology, the requirement of a die in the forming process can still be required in some applications [9, 46]. Based upon the theory of electric hot incremental forming (as previously discussed), an attempt is made to improve on the formability even more by means of introduction of thermal treatment to the process. The application of a 500W Nd-YAG laser with glass fibre beam delivery system is used as a heating source. The focussing lens is mounted on a 3-axis positioning system that is linked to a controller of a 6-axis robot performing the forming process[52], as seen in Figure 16.

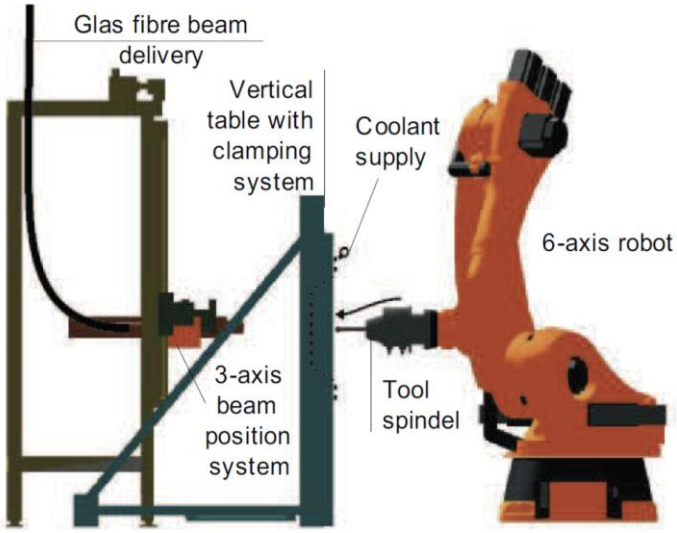


Figure 16: Single point incremental forming with dynamic laser supported heating[52]

The results of the application of laser assisted incremental forming included the reduction of the forming force of up to 50% for Al5282, reduction in plastic deformation and springback, an increase in formability of the working material and a reduction in residual stress [52].

2.6 Five-axis versus three-axis CNC machines

Computer numerical control (CNC) machines refer to the automation of machine tools using pre-programmed commands. CNC machines provide much more flexible and versatile control over machine tools in comparison to manually operated machining tools[53]. The more common, 3-axis CNC machines utilise a ball end tool capable of moving in three directions, or three different degrees of freedom. The more sophisticated model, known as the five-axis CNC machines enables two additional degrees of freedom. This approach enables the use of a more flexible method, as the contact angle between the tool and workpiece. The five-axis CNC machine provides an increase in formability of sheet metal, as less unidirectional strain is applied to the deforming blank[54].

Five-axis machining requires certain motion commands. These commands are generated using a Computer-Aided Manufacturing (CAM) system that is loaded onto the CNC machine that adopts a real time interpolator. The CNC interpolator can convert the cutter path to motion trajectories of the five separate axes in order to communicate their motion in five-axis machining[55]. A large variety of interpolators have been developed for different types of motion trajectories, of which the linear and spline interpolators are most favoured[55].

2.6.1 Advantages of using Five-axis machines

The five-axis machine has the ability to create more intricate shapes, undercuts, and difficult angles. The five-axis machines reduce setup costs and labour time, resulting in a better cost per part[56]. Further advantages of using five-axis machines include:

- Reduction of manual setup positions eliminates the highest cause of alignment error.
- More complex designs possible.
- Easy to maintain close tolerances and repeatability.
- One-time setup reduces overall setup time, labour costs and eliminates repositioning.
- Future production runs have a quick set up time, allowing the company to maintain just-in-time inventories[56].

However, a recent study by Aerens et al. stated that performing the SPIF process on an industrial robot with more than three axes can cause additional part inaccuracies due to the limited stiffness of the hardware set-up, unless the force acting on the forming tool can be predicted and compensated for[57].

2.7 Materials used in ISF processes

In the manufacturing industry, the material properties of some products (such as its tensile modulus) cannot be improved by simply changing the processing method. Improvement of the product's attributes can only be completed by using an alternative material. The ISF processes are based on different design strategies as other manufacturing methods as it prefers low-volume, high-value applications as mentioned in section 2.2. The ISF process will be able to maintain the product's geometry as well as enhance its material properties such as yield strength or density by using special materials. One of the most applicable types of metals used for the ISF process is that of lightweight components[10]. The applicable material alternatives are discussed in this section.

2.7.1 Titanium

Titanium metals are considered as a relatively new material concerning lightweight materials. The main reason for this is that the metal was not completely considered as a result of its high price and large Young's modulus, making it extremely difficult to form. The price of titanium can range between

30-120 times more than the price of steel[10]. The usage of titanium is very popular in the aerospace industry. Titanium is seen as a weight saving alternative in the production of certain aircraft parts, as mentioned in Section 2.2. The main material properties of consideration are its high strength at high temperatures as well as its durability under dynamically changing loads, making it highly applicable for certain aerospace applications such as helicopter rotor heads or turbine components of the Airbus A330/340[10].

Commercially pure titanium consists of hexagonally close-packed (HCP) crystal structures, showing low ductility at room temperature. The difficult formability of titanium can pose to be problematic in applications of the IF process. A study conducted on the formability of incrementally formed parts indicated springback, leading to the emergence of geometric inaccuracies in the consecutive stages of the process [52]. Figure 17 illustrates the difference in programmed toolpath and resulting shape with the unwanted deformation.

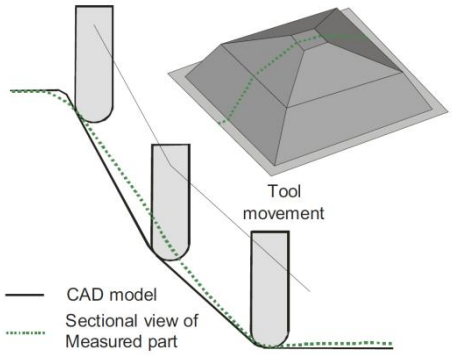


Figure 17: Difference in programmed toolpath and resulting shape[52]

Tool components

A study was conducted by Hussain, et al. to determine the most suitable tool material and surface treatment for the incremental sheet forming of Commercially Pure titanium (CP Ti). The study focused on different tools that performed incremental sheet forming on the same type of CP Ti sheet. The results proved that the usage of either surface-hardened (62-65 HRC) high-speed steel (HSS) or tooling steel does not undergo excessive wear to the finished component. Other materials used such as case hardened $Cr_{12}MoV$ steel had simply worn out instead of deforming the material[58].

Optimum lubrication process of CP Ti forming

Hussain et al. conducted studies to determine the most applicable lubrication method in addition to the studies conducted to determine the optimum tool material. These studies focussed on the viscosity of the lubricant, as preliminary experiments using mineral and machine oils as lubricants simply thinned out under the tool pressure[58]. The study used solid lubricants dispersed (20%) in water, a thick paste of MoS_2 powder in grease and a bonded film of MoS_2 that was sprayed onto the blank. The results shown that the most successful lubrication method used was the application of MoS_2 powder in

grease (4:1 ratio), gently applied to the blank surface. Surface quality tests proved that this method led to the least amount of surface roughness[58].

2.7.2 Magnesium

The application of magnesium alloys in the transportation industry has existed since the early 1950's. The primary use for this alloy was in engine and gearbox casings[10]. Magnesium has a density of only 1.74kg.dm^{-3}, approximately 35% lighter than aluminium. The material does however contain more disadvantages than advantages when seen from a forming perspective, according to Kleiner et al. Magnesium offers low ductility at room temperature, making it more prone to stress cracks, but temperatures higher than 100°C can cause poor creep and corrosion resistance in the material. At temperatures exceeding 225°C, additional sliding planes are activated, increasing the ductility of the material [10]. Forming applications of this material is therefore applicable, but limited to the operating capability of each process.

2.8 The application of titanium

2.8.1 Aerospace applications

Titanium and its alloys can be seen as an excellent candidate for application in the aerospace industry, considering the need for continuous improvement in strength and weight in aircraft components. Current aeronautical research and development projects such as the INMA (Innovative Manufacturing) project of the European Aeronautics Science Network are highly active[49].

The application of titanium in the aerospace industry is described in depth by R.R. Boyer of the Boeing Commercial Airplane Group Seattle. The primary justifications for using such a costly material, according to Boyer, are [59]:

- Reduction in component weight (in comparison to steel).
- Reduction the size requirement of the component (to replace aluminium alloys).
- Better strength at high temperatures (compared to Al, Ni and steel alloys).
- Composite compatibility (to replace Al alloys).

The exceptional strength to weight ratio of titanium can be allocated as the most probable reason for the implementation of titanium in the industry. Titanium can be seen as a well suited alternative to aluminium in situations where operating temperatures exceed 130°C[59]. The Ti-6Al-4V is the most commonly used alloy, where up to 80%-90% of all types of titanium alloys used in airframes it Ti-6Al-4V. Commercial transport aircraft such as the Boeing 757 utilises titanium in all sections of the aircraft such the fuselage, landing gear, nacelles, wings, empennage as well as the Pratt and Whitney 4084 engine[59].

2.8.2 Biomedical industry

The popularity of the use of modern titanium bases alloys and orthopaedic metastable β titanium alloys can be referred back to its light weight, biocompatibility and chemically inert properties, according to Xuanyong et al. The biomedical application of titanium is mainly focussed on arthroplasty, also known as joint replacement. Artificial joints such as the knee or hip joints are the most common areas of arthroplasty surgeries[60]. Titanium can be implemented in cardiac and cardiovascular operations such as artificial heart valves or vascular stents. Additional biomedical uses for titanium exist as bone screws and plates that are used specifically for the support of fractured bones[60], as the ceramic-like surface oxides formed allows the growth of living bone matter[34]

2.8.3 Other applications

Further applications of titanium exist as part of the energy industry to provide cost savings and technology enablement in energy generating structures. The high corrosion resistance of titanium makes is highly applicable for components such as geothermal brine wells, offshore riser taper stress joints and deep water offshore drilling risers[61].

2.9 Conclusion

The literature study conducted was used to provide the reader with background knowledge more in depth than the introduction chapter of this thesis. The section documented various research areas such as the medical background, which involved anatomical information as well as current surgical procedure and research. Further aspects focussed on titanium as a metal and the forming of it by means of Incremental Sheet Forming. This section provides relevant information for the following sections that document the methodology to solving the research question stated in Section 1.2.

3 SYSTEMS ENGINEERING APPLICATION

The application of systems engineering introduces and describes a roadmap that describes the methodology that will be followed to solve the research questions defined in Section 1.2. The study was conducted to solve the research questions. The main steps to solving the research question are based upon the procedure that is discussed in this chapter. A simplified structure is then developed that refers the reasoning behind the study back to the research question. A simple input-output model (see Figure 18) is then assembled.

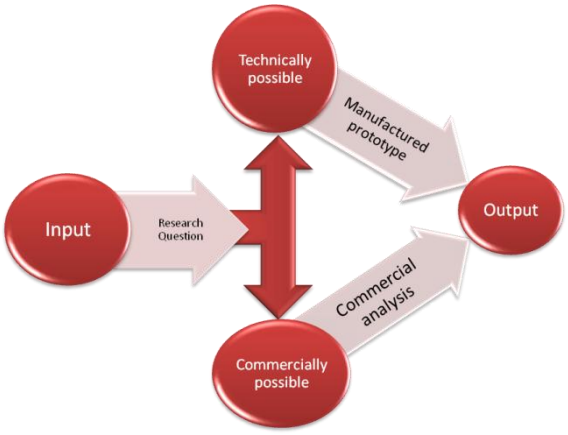


Figure 18: Simplified input-output model of the study design

The input-output model describes the sequence of events that will be followed in the study. The empirical study is therefore planned to provide a solution to the research question as an output.

3.1 Research design

The research design can be initialised once a research problem is compiled. The research design is discussed to clarify the class of research proposed, and to act as blueprint of the research process. The research design is developed based on the research problem stated in Section 1.2. The problem pertaining to human health and welfare is based on one of the ordinary social and physical reality of pragmatic interest. This can be classified as a world 1 problem statement, as part of the three worlds framework first developed in "Understanding social research" [62]. This framework was developed to define and conceptualize the research problem for clearer aspects of logic research [62]. The study is executed in two main segments. The first segment is designed to perform research into the technical possibility of forming physical knee implants. The research into producing a proof of concept will therefore be defined by a empirical study, where primary data is collected. The technical section of the research question can be classified as an evaluative question, based upon an empirical structure. The planned study can therefore be classified as an empirical study. The first segment will be solved by the evaluation of experimental results, leading to the requirement of primary data. The chosen study design path can be seen in Figure 19:

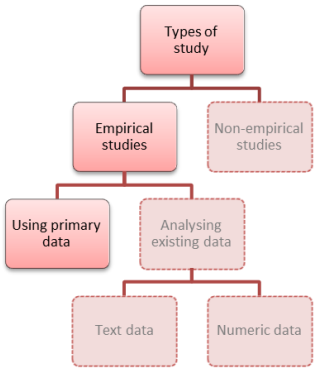


Figure 19: Classifications of study[63]

The experiments are designed to primarily prove that the required prototype design can be manufactured from titanium sheet metal using the incremental sheet forming process. As part of the experimental procedures, preliminary runs will be conducted on aluminium sheets before attempting to form titanium sheets. A series of tests will then be run to obtain the dimensional data of each formed part to be compared and analysed for geometric accuracy analysis.

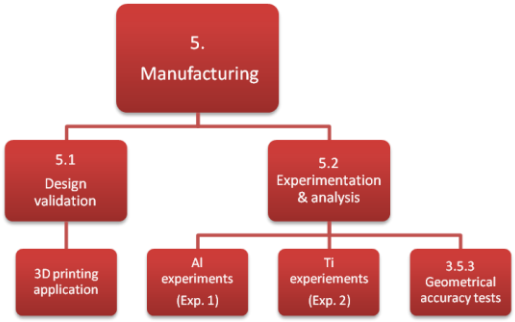


Figure 20: Manufacturing sections of the study

The second segment introduces the commercial research into the economic, regulatory, and risk analysis to determine if this invention can be seen as a commercially viable option in the market place. A process chain will be introduced that describes the steps required to produce a custom made biomedical product. The process chain will focus on the engineering aspect of the process, such as the design and manufacturing. The process chain will then verified by applying various engineering techniques. The application of reverse engineering will enable the acquisition of patient-specific data, the implant design will enable the acquisition of a usable file format, and the manufacturing will then produce a prototype of the bio-medical implant. The empirical study documents the process of patent registration as part of the commercialisation of the invention into the medical sector.

3.1.1 Consideration of alternatives

The nature of this research subject, as discussed earlier, is the gathering of empirical data, with the solution to the research problem reachable by means of various methods. The process of decision-making, although seemingly obvious can provide more insight into the specific consideration and

selection of alternatives. The following figure depicts the different alternatives placed under consideration.

Table 5: Reasoning behind experimental design

Alternative	Answer
Why is experiments conducted with aluminium before it is applied to titanium?	Aluminium is considered as a more ductile material than titanium, improving the formability of the end product to ensure a higher success rate.
Why use titanium rather than aluminium for the final implant prototypes?	Titanium, unlike aluminium is completely bio-compatible to human tissue (refer to Table 2 for more information).
Why is incremental sheet forming used for this application?	• The implants require a high degree of customisation. • Localised deformations maintain the crystal structure that would otherwise be restructured if laser sintering techniques is used. • Low setup times are required for situations where patients are waiting for the manufacturing of implants. • The IF technology is economically more efficient in low volume production applications.

Selection of alternatives

The different alternatives to finding a solution to incrementally forming titanium based bio-medical implants were considered. The chosen alternative for each main category, as well as the motivation to the chosen answer is depicted in Figure 21.

Medical implant	Base Material	Stainless steel **Titanium** Cobalt-chromium Polyurethane	Titanium is known for its bio-compatitbility, and research by Jeswiet et.al proved the viability of incrementally forming titanium parts [61].
	Surface application	**Unicompartmental** Bicompartmental Complete resurfacing	The implant is chosen to be applied to only one condyle of the human femur for simplification purposes. The resurfacing of both condyles will be left for future research
	Fixation of the implant	Cemented Cementless	The implant can be attached to the bone using bone cement, but the possibility of allowing the bone to bond with the titanium surface can be considered as well, as a result of the metal allowing osseointegration
Incremental forming of titanium	Forming tool material	Titanium **K110 tooling steel** HSS	Tooling steel was chosen for this application as it's success have been documented by Hussain et al. [58].
	Forming tooltip diameter	**10mm** 12mm	A tool diameter was chosen to be small enough to reduce forces, but large enough for the tool to allow the experimental data to be compared to previous literature and future research.
	Process improvement	**Formability** Tool survival Surface quality	Focus was placed on the formability of the part, as a better, smoother surface would not necessarily result in better bone growth conditions for osseointegration
	Incremental depth	**0.2mm** 0.5mm 1mm	A more time consuming procedure will minimize risk of workpiece tearing by means of excessive deformation
	Lubricant	Rocol RTD liquid Graphite powder **Molybdenum disulphide powder** Self-lubrication (no lubricant)	The most successful lubricant, according to Hussain et al., was a mixture of MoS2 powder with petroleum jelly [58].

Figure 21: Discussion of alternative selection

4 EXECUTING A PROPOSED 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 of producing a reliable 3D model of almost any object[42]. This project applies the techniques of reverse engineering for the scanning of the knee joint and design of a customised implant. The implant will be manufactured out of titanium using the IF technique. The process chain of the complete procedure is designed to standardize and include all procedures that are followed in the implementation of the knee arthroplasty process. The development of a process for creating a custom made, patient-specific implant for every patient can be obtained by following a sequential set of prescribed developments. The purpose of this study is to propose a certain developed process chain that is capable of defining steps of designing and manufacturing custom-made, minimal invasive knee implants conforming to the topography of the distal condyles of the patient's femur. This process chain will also integrate various aspects of biomedical engineering. Aspects such as traditional diagnosis (based upon experience) will be integrated into the technological aspect of reverse engineering methodology as well as advanced rapid prototyping technology (both based upon current technology), ending once again with the surgeon through surgical implementation. The prototype design and manufacture process will be designed to follow a process chain parallel to the procedure described above. The planned phases will be discussed in the following sections.

4.1.1 Enclosures and segregations

The development of a process chain was designed to include the basic steps of the design and manufacturing of knee arthroplasty plate implants. Still, not all aspects of the complete process chain could be included into the process chain, leaving room for on-going research and improvements during future studies. The scope of this project does not include some aspects of the complete procedure that a patient will undergo. The reasoning behind this is that the process chain presented in this study is to be validated; every step (except for the surgery and follow-up) is performed by the author to prove that the proposed process chain is realistic. The process chain will therefore exclude certain steps of a commercialised product. Certain segregations include the involvement of clinical studies on patients, as well as surgical implementation studies for post-production procedures.

4.1.2 The developed process chain

The proposed process chain that was developed will thus focus on the engineering aspects of the manufacturing of these implants, with the main areas of focus primarily based upon the design and manufacture processes of the implant rather than clinical trials and surgical procedure. The input of clinical specialists such as orthopaedic surgeons is regarded as important, and every step of the process chain will continuously revert back to the specialist to incorporate feedback. The developed process chain is shown in Figure 22:

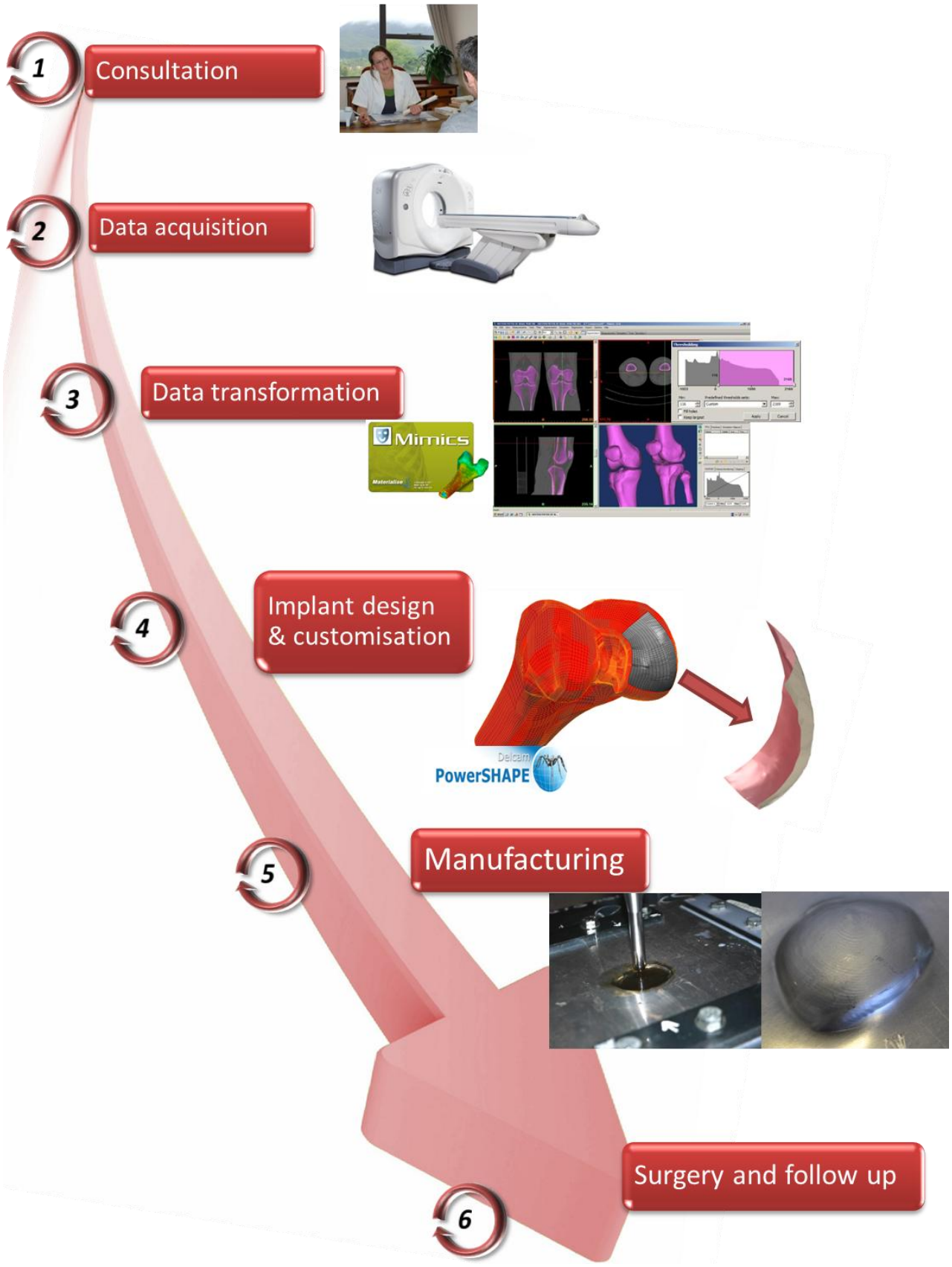


Figure 22: Proposed process chain for the design and manufacture of incrementally formed, patient-specific knee implants

4.2 Data flow cycle

The data flow cycle acts as a representative indication to illustrate the actual manipulation required to achieve a physical prototype of the model. The data undergoes migration from a physical environment to a virtual one, and finally returns to the physical when the implant is produced. The data is primarily obtained from the physical morphology of the patient's femur, where the data can then be processed by implementing reverse engineering techniques. With the availability of the three dimensional solid modelling, the implant model can be designed and the data can be used to produce a physical implant. The data flow model is shown in Figure 23 below:

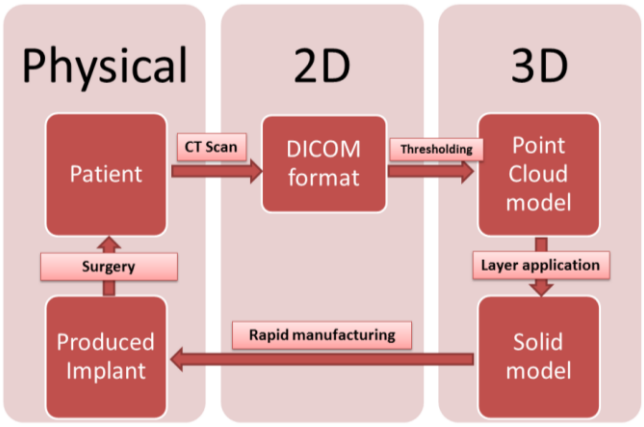


Figure 23: Data flow cycle

4.3 Consultation

Although knee replacement surgery is not the only solution to knee pain, it can be considered as the only long term solution to this problem. The decision to undergo knee replacement surgery is an individualized question, depending on the patient's activity level and functional needs. The possibility that a patient will not be eligible for a partial knee replacement is also quite high, as a recent study by Boettner estimated that only 6- 10% of all candidates are accepted for partial knee replacement surgery [29]. The patient will therefore have to pass the patient selection criteria (as described in Section 2.2.5) to be considered as a valid candidate for partial knee replacement.

4.4 Data acquisition

Assuming that the patient passes the requirements and is considered as a valid candidate, the acquisition of the patient's biometric data can commence. In order to ensure that the implant designed is firstly patient-specific, and secondly accurate, the application of reverse engineering techniques will be required. The data that is to be obtained has to be accurate The data acquisition phase is therefore implemented with the goal on obtaining accurate enough to suffice the requirements of creating a custom knee implant that will fit the specific patient.

Obtain DICOM CT images

The first step of implementing reverse engineering is the scanning of the physical properties and to replicate these properties in a digital environment. The design of the implant is also completely dependent on the quality of information obtained from the object it is based upon, which in this case is the resolution of the 3D model of the knee joint. In the case of the patient adhering to the designed process chain, a CT (also referred to as CAT) scan is used to obtain the relevant unique morphological data of the patient. The resolution of the CT scan can be chosen, where the smallest incremental slice thickness has to be chosen to ensure the best possible resolution of the scan.

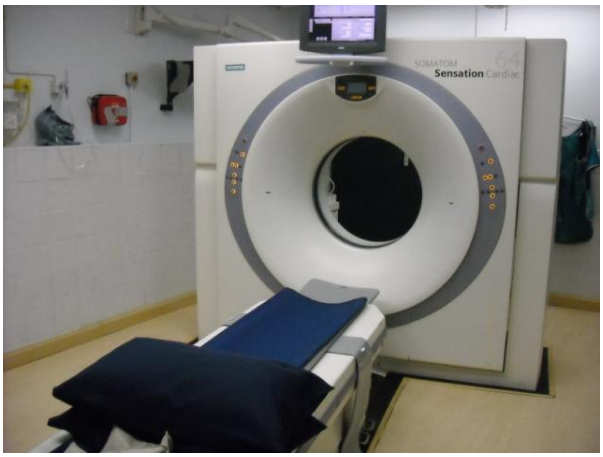


Figure 24: Siemens SOMATOM CT scanner at George Mediclinic

The scanned data of the patient is exported as DICOM CT images. These DICOM (Digital Imaging and Communications in Medicine) images can be described as a series or compilation of 2D scans of the selected part in all three standard planes of view (the sagittal, coronal and transverse planes). Singular images of each scan are shown in each view of Figure 25:

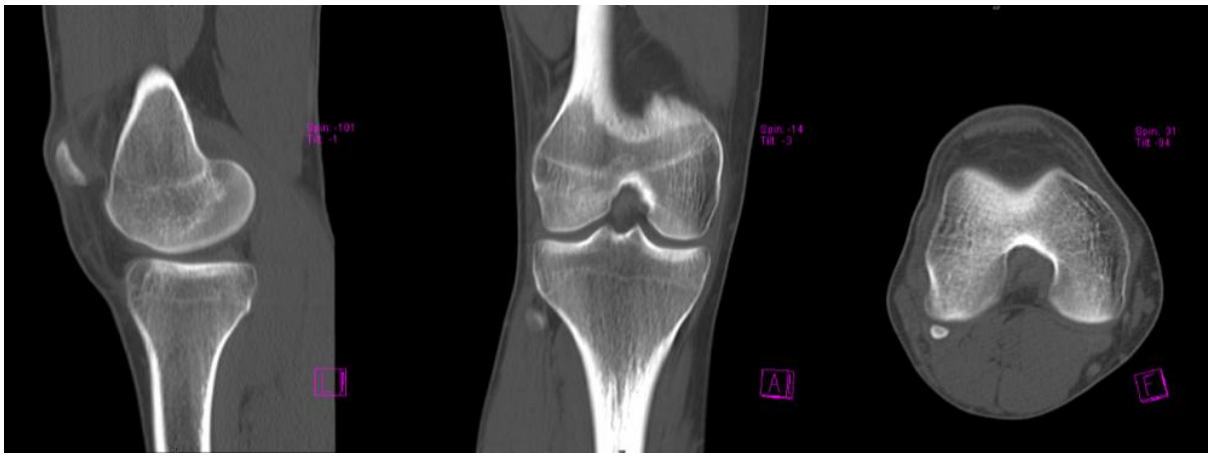


Figure 25: The coronal, sagittal and transverse planes of view

4.5 Data transformation

This section describes the application of Reverse Engineering (RE) techniques used to obtain a usable, 3D CAD (Computer-Aided Design) model from a human subject. The process will follow a series of steps that relates closely to the procedure required for any patient following the proposed process in the medical industry. The data that is now available is only of DICOM format, being compilations of two dimensional scans. By means of the application of reverse engineering methods, an accurate three dimensional model can be obtained by stacking these two dimensional scans together using specialised virtual region growing programs. Manual identification was 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 complied set of DICOM CT images was imported into Mimics Software (Materialise NV, Belgium). Segmentation and region growing methods was performed by implementing various masks on every slice of the DICOM 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 images contained various sets of redundant information.

Thresholding

The thresholding process is the most common known method of image segmentation. In theory, this technique is used to denoise the overall domain where each coefficient is thresholded by comparing against a selected threshold range. If the coefficient is smaller than the threshold, the coefficient is set to zero if it is smaller than the threshold, and is otherwise kept. For this application in reverse engineering, the greyscale DICOM images are segmented by means of thresholding to enable the discernment between different types of organic matter to isolate the bone matter in the scans. 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. As seen in Figure 26, the minimum thresholding value is set to 116 CT Hounsfield unit (HU) and the lower thresholding value is set to the maximum.

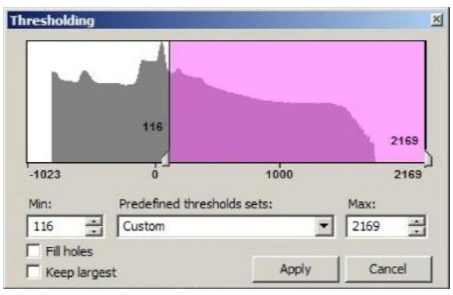


Figure 26: The custom thresholding value

Virtual region growing

The application of thresholding is applied to the DICOM images by means of masks. Various masks are then applied to add or remove certain areas of the main selected base mask created by the thresholding process. A pre-programmed algorithm within the mimics software is then used to grow a three dimensional representation of a selected mask. The growth algorithm is initiated by a user selected starting point, and then includes its growth selection to any connected parts on any adjacent CT images the final mask.

Figure 27 below illustrates the method of virtual region growing in the mimics program. The mask is applied in all three views, where the coloured area is used to identify the mask selection. The bottom right view of the mask is used to show the final 3D geometry of the mask. The virtual growth algorithm was applied to the DICOM data eight times in the scenario shown below (applied once for each individual bone) to grow each femur, patella, tibia and fibula (see Section 2.1.1 for identification of each bone). In the instance of severe osteoarthritis, where the several degradations and even growth spurs can be located in the distal femur, the selective identifications of normal bone matter might be required which can require more time. For the application of the designed implants, and for the acceptance of MIS criteria, cases of severe osteoarthritis will cause the patient to by ineligible for this procedure.

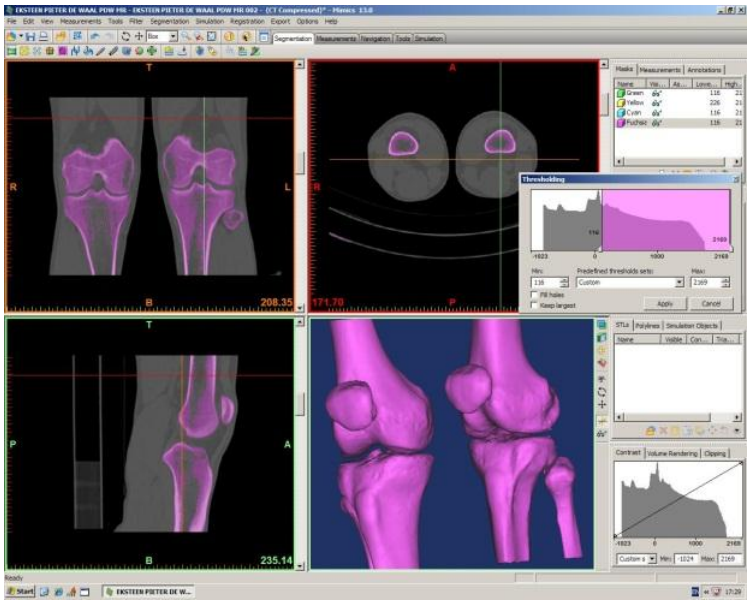


Figure 27: Applying masks to identify bone matter

The mimics software can now export the virtually grown region as a 3D model. The model is, however only compiled as a series of identified point coordinates, creating a “point cloud” model. The converted format of these files are of *.stl (Standard Triangular Language) format. This format can directly be applied to additive manufacturing processes (later described in Section 5.1). This concludes the virtual region growing process, and the patient’s morphological data is now available in 3D format.

4.6 Point cloud surface fitting

The current format of the data (*.stl), although 3D of nature, is only of point cloud nature, these coordinates therefore do not comprise of a solid model, but rather only an array of different coordination points. Manual identification was conducted on the point cloud to implement the data points with external planes with the purpose of creating a filled volume of the 3D model. This procedure was done using CopyCAD (Delcam, Birmingham) software designed specifically for point cloud model handling. The point cloud was imported to the CopyCAD interface and fitted with surfaces using curve parameterisation. Curve parameterisation was performed using an equal number of even breakpoints (5 T breakpoints and 5 U breakpoints) as seen in Figure 28.

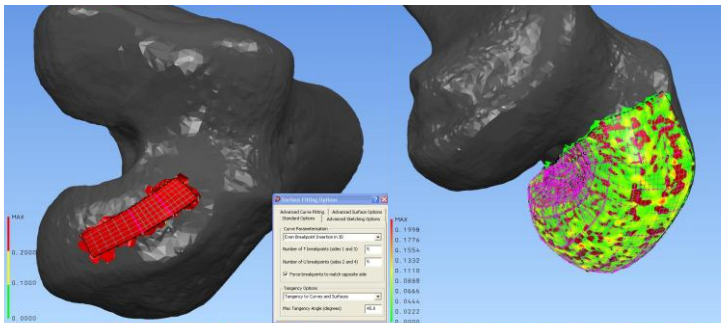


Figure 28: Surface fitting of the point cloud model

Neighbouring surfaces are integrated with each other to combine the model as a whole. The neighbouring surface integrations are fitted with maximum tangency angles of 45° to improve on the surface finish. An example of the surface fitting procedure is shown in Figure 29.

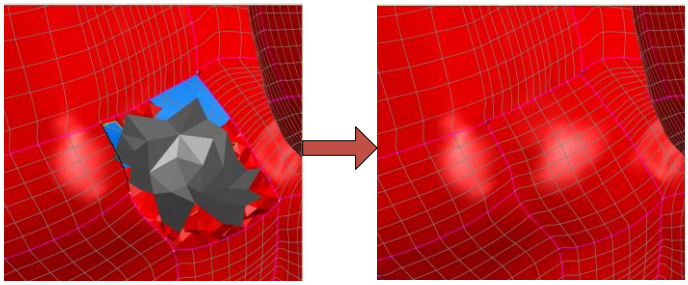


Figure 29: Integration of fitted surfaces

The model has the prerequisite of being watertight before it can be made solid for export into a usable CAD 3D model. The model is therefore first imported into Delcam PowerSHAPE 2011 (Delcam, Birmingham). The model is made watertight with an interference tolerance of 0.019 mm. The final shape can then be exported in IGES (Initial Graphics Exchange Specification) format for implant design in conventional CAD programs.

Author's notes:

The surface fitting procedure of large models can be a lengthy and time consuming project. The PowerSHAPE software was used mainly because Autodesk Inventor 2011 could not import point cloud (.stl) files. The new 2012 release of Inventor is compatible with .stl files; which can reduce the required time and effort for obtaining a watertight model of the patient's femur.

The 3D model, now solid, can be imported into various 3D solid modelling programs such as Autodesk Inventor software (Autodesk, Inc., CA), SolidWorks (Dassault Systems, Vélizy, France) and Pro/ENGINEER (Parametric Technology Corporation, Needham, USA).

4.7 Implant design and customisation

The scenario of the initial phase of osteoarthritis (stage 1 or 2, as stage 0 describes a healthy knee) in a patient was considered, and the implant was therefore designed to fit onto an epicondyle of the distal extremity of the femur, as this is the normal origin and location of a damaged or diseased knee joint[15]. 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. 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.

The design of the implant can be made using most 3D CAD software packages. For this project, the proposed methodology of the design process was recommended using Delcam PowerSHAPE 2011. This was verified by the design of an implant based upon the solid model obtained by means of point cloud surface fitting as described by Section 4.6. The selection of the resurface area can be performed using any CAD programs to obtain the geometrical information of the area that requires resurfacing. As final part of the implant design and customisation, the part is rotated for manufacturing purposes to minimise the angle of attack from the tool, and therefore minimise the forming angle requirement. The surface selection procedure shown is performed using both Delcam PowerSHAPE 2011 (Figure 30) and Autodesk Inventor 2011 (Figure 31).

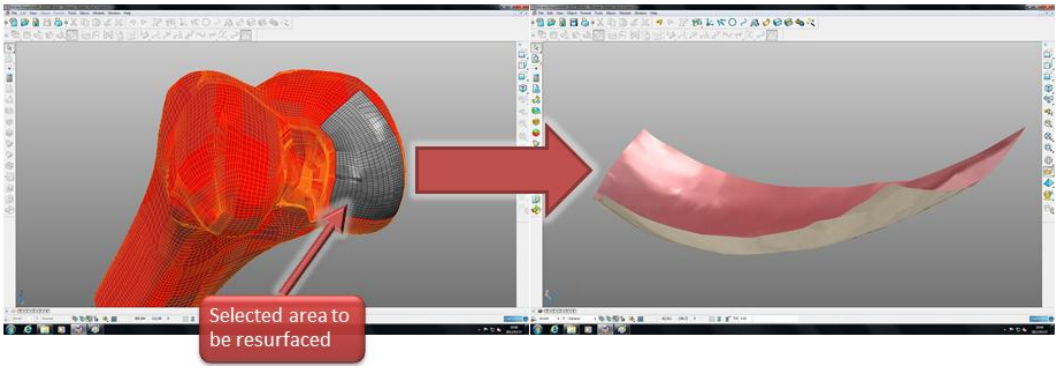


Figure 30: Implant design procedure using Delcam PowerSHAPE 2011

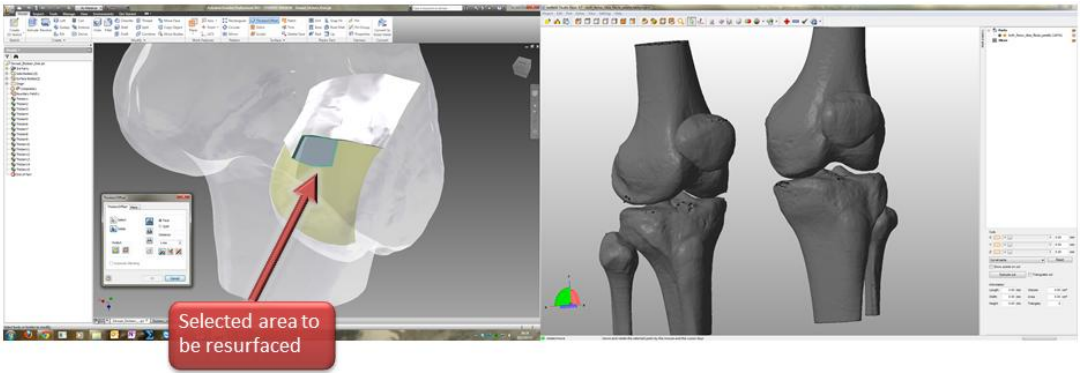


Figure 31: Implant design procedure using Autodesk Inventor 2011

4.8 Implant manufacturing

The implementation of a cost effective manufacturing alternative is introduced in this section. This project introduces an alternative manufacturing method to the production of patient-specific implants; most commonly produced using rapid manufacturing technology such as Direct Metal Laser Sintering and LaserCusing[64]. As previously stated, the biomedical implants were created from titanium based sheets to ensure that the sheets are bio-compatible. The implant is manufactured using a 3-axis CNC machine to perform the ISF process on a sheet of commercially pure, grade 2 titanium. The setup of the components and the procedure followed to produce a proof of concept is documented more extensively in Section 5.2, and the manufactured titanium prototype is shown in Figure 32:

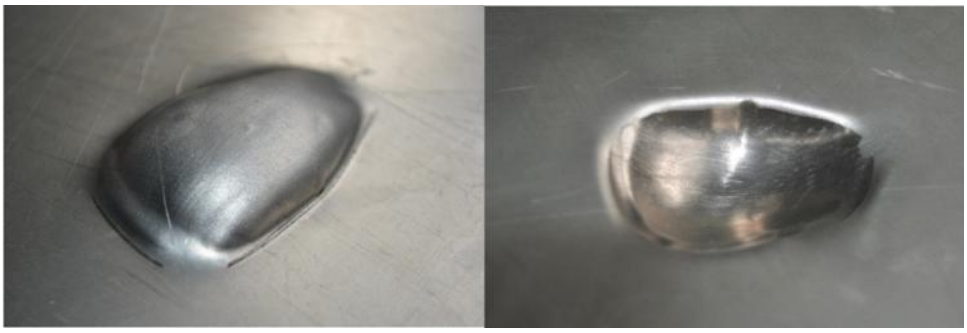


Figure 32: The manufactured titanium prototype

4.9 Surgery and follow up

The final step of the process chain is discussed to revert the flow of information back to the patient by means of surgical implementation of the proposed implant (see Figure 23) and follow up after the surgical procedure. The only aspect researched of this section is the application of 3D printing in surgical preparation (see Section 5.1). Other aspects of this segment are excluded from the engineering aspect of the complete process chain as a medical practitioner is required to complete the procedure.

5 TECHNICAL VIABILITY – PRODUCING A PROOF OF CONCEPT

This section describes the complete manufacturing procedure of a titanium prototype as well as additional aspects of manufacturing. The subsections include the description of the implementation of 3D printing for simulation purposes, the forming process experimentation and testing of the manufactured prototypes.

5.1 3D printing application

A recent study by D'Urso (described in Section 2.3) use of biomodels by means of reverse engineering was used to improve diagnoses accuracy and reduced the measurement inaccuracies, operating times and overall costs of the surgical procedures[35, 34]. A representative model of the femur joint was therefore required for the implementation of an illustrative perspective of the surgical implementation of the prototype. The production of a representative model was required for the testing, representation of surgical implementation as well as fulfilling the purpose of feedback in the representation of the prototype in the biomedical sector. The application of 3D printing in reconstructive surgery is known as each reconstruction is case specific and therefore requires a unique solution. The application of 3D printing is can be utilised for various other applications in the medical sector, such as areas of testing, implementation, demonstration and feedback to the patient.

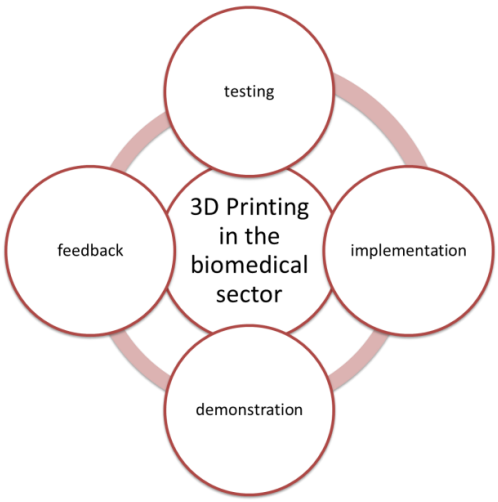


Figure 33: The application of 3D printing in the biomedical sector

Recent studies by Honiball investigated the applicability of 3D printing in reconstructive surgery, as surgeons are currently making use of radiographic imaging to assist in pre-operative planning[65]. The current use of radiographic imaging in for the pre-operational phase of the surgery still only supply the surgeon with a 2D, or at best a 3D virtual representation of the patient's status for the implementation into a physical environment. The limited availability of information therefore initiates a need for a platform providing a more realistic planning tool in preparation of the surgery. The ultimate desired end

result is the solution that can reduce the surgical risk as well as an improvement to offer patients a better chance to full recovery. Figure 34 illustrates the use of 3D printing implemented as part of a surgical planning aid during spinal surgery:

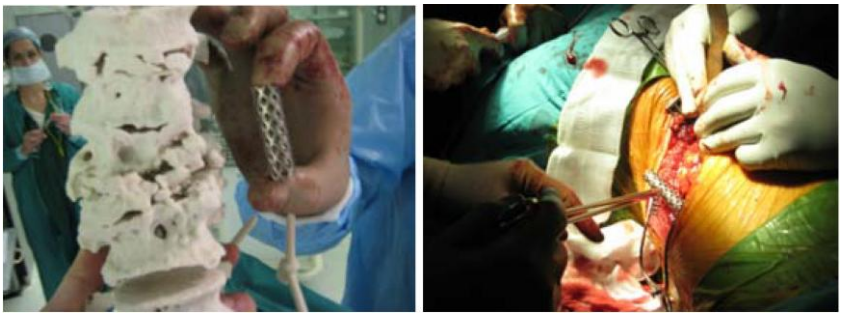


Figure 34: 3D printing as part of pre-operative planning and surgical implementation aid[65]

Model criteria

The model had the requirement of representing a morphologically accurate simulation of an actual human femur. This model production also required a relatively low production cost, as to assist in the low cost model for this process as described by the patient's process chain.

Manufacturing of a physical representative model

The first step of the manufacturing phase is the implementation of reverse engineering methodology as per described in the developed process chain (see Section 3). The digital model of the author's knee was obtained by implementing these steps in the process chain. The 3D point cloud model of the knee (distal femur segment for this instance) was then imported from the medical modelling software to ZPrint software, designed by ZCorp. The point cloud model is then placed into a virtual build volume, as seen in Figure 35:

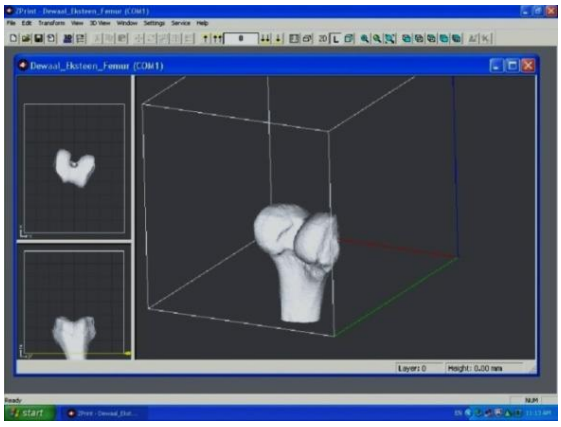


Figure 35: Pre-production simulation in the virtual build volume of ZPrint

The desired part is shown in the program where all sections of the part inside the virtual build volume is shown will be produced by the 3D printer. Several settings were applied to the 3D printer as shown in the 3D printing specifications of Table 6:

Table 6: 3D printing property settings

Property	Setting
3D file import format	.stl
Build material	ZP150 powder
Print layer increments	0.0875mm
Bleed compensation	on

The program is then executed onto the 3D printer's processor, resulting in the 3D representative model. The manufactured model is shown in Figure 36:

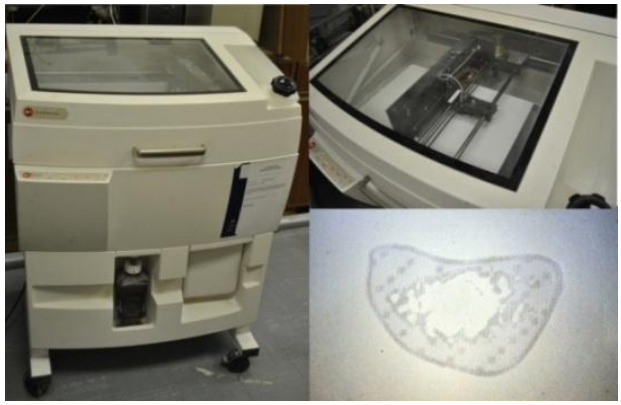


Figure 36: Z Corp 3D printer with sample profile layer

The part is carefully removed from the build volume and cleaned from any excess powder using a brush. The model is then placed in an oven with a temperature of 70°C for 90 minutes to allow the binding material to harden. Epoxy resin was mixed and applied to the model surface and allowed to infiltrate the external surface to increase the overall strength and durability of the part. As soon as the first layer of the resin has infiltrated the surface, a second and third layer is applied. The part was then placed into the oven for three hours at 70°C. The final model with the applied epoxy resin is shown in Figure 37:

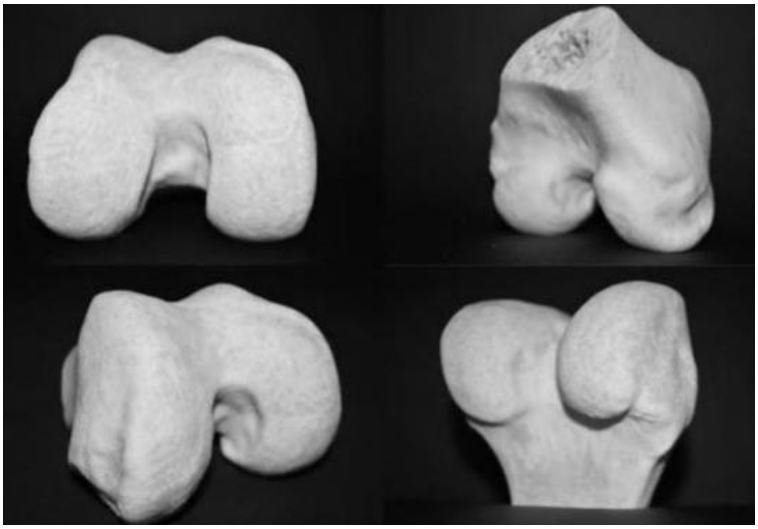


Figure 37: 3D printed model of the author's distal femur

5.2 Proof of concept production experimentation

The applications of a forming method novel to the manufacturing sector of biomedical engineering require incremental steps towards the understanding and correct application of this process. The experimental planning designed steps toward completion, where completion requires a proof of concept of the proposed titanium knee implant. The process parameters (such as the spindle speed, federate etc.) are seen as variables in the manufacturing an application of IF. These parameters all influence the results of the experiments. The acquisition of comparable data does however require coherence of the maximum number of variables possible.

The importance of experimental research on incremental forming processes should not be underestimated. Silva et al. stated that despite major contributions made by various researchers on the development of IF technology for industrial applications as well as characterization improvement of the forming limits of the process, the mechanics of deformation remains little understood due to the complexity and low predictive ability of the finite element models that have been employed to the study process. The SPIF process, according to Silva et al., is one of the few if not the only metal forming processes in which experimentation proves to be more advantageous over theoretical research[43]. The advantage of experimentation over theory is therefore absolute event for solving the simplest practical problem[43]. In addition to this the experiments were required to obtain a physical prototype of the proposed knee implant as part of manufacturing in the data flow cycle.

5.2.1 Experimental objectives

The main objective of the experiments was to:

- Determine if it is possible to form the proposed prototype using the IF process from a 1mm thick CP Ti Grade 2 sheet.
- Obtain a dimensionally accurate prototype of a knee implant.

In order to achieve these objectives, the experiments that are run will be initiated on a basic level before increasing the complexity of the process for the forming of titanium based prototypes. In an attempt to keep the complexity of the process low, the first experiment was designed as a preliminary procedure that focussed on the incremental forming of aluminium sheets. By implementing the experimental procedure on aluminium, a material that is widely used for incremental forming experimentation, a small degree of uncertainty of the IF process can be eliminated. Furthermore, the utilisation of a workpiece material more ductile than titanium will increase the formability of the process and focus can be placed on the programming of the toolpath rather than the formability limitations. The implementation of experimental procedures on aluminium based workpieces will also reduce overall costs (cheaper forming tool, lubricant, and larger incremental changes reduces machine time). The second experiment was designed to apply the knowledge obtained from the first experiment to the forming of titanium based sheets. The second experiment was also performed to achieve the experimental objectives by using titanium based workpieces. In an attempt to enhance simplicity of the

experimental design and results, the number of different runs of each experiment is tagged under different names. The first experiment executed five different runs, and the second experiment executed two runs, each producing a prototype for analysis. Each run from each experiment is therefore tagged: "*Al 1*" to "*Al 5*" represents the five prototypes formed from each run and "*Ti 1*" and "*Ti 2*" represents the two titanium prototypes produced from the second experiment. The reasoning behind the experimental design is displayed in Figure 38:

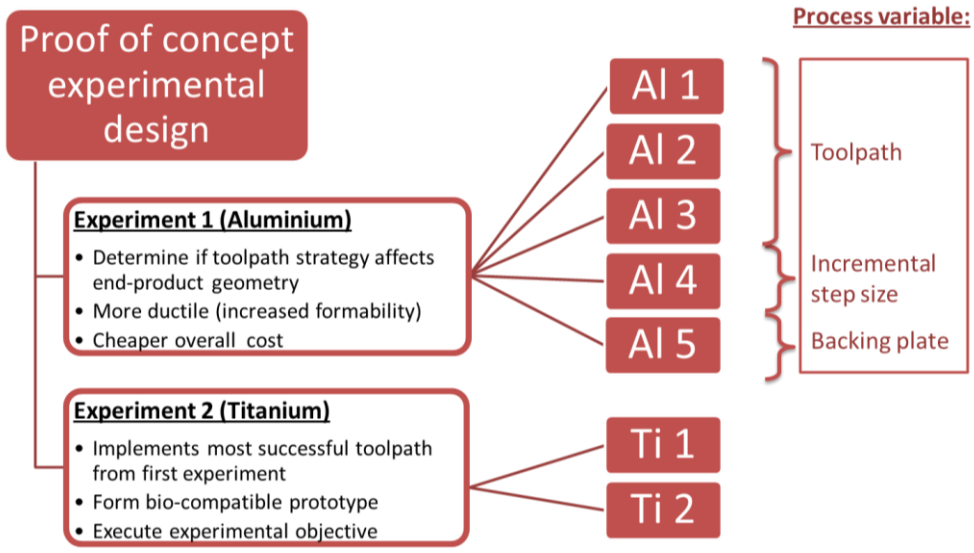


Figure 38: Experimental design and motivation for the experiments

5.3 Experimental setup

The same experimental setup was used for both the aluminium based experiments (*experiment 1*) as well as the titanium based experiments (*experiment 2*). The setup was mainly based upon the CNC table. This section briefly discusses the various elements required for the experiments. As the specific requirement for each element may differ for different forming purposes, the specifications of each element will be discussed more in depth for each experiment.

The 3D model of the prototype

The digital model that the program is based on from prototype design is a unicompartmental knee implant. This was done to ensure that the final titanium based prototype could be compared to the results of the aluminium based experiment (see Figure 66). The design geometry was obtained by implementing reverse engineering methods from the morphological data of the distal femur condyles. The implant design was based on only one of the condyles as this procedure is intended for unicompartmental arthroplasty and is discussed in more depth in 4.7. Design of the implant led to the compilation of a custom created surface in IGES format. This format ensured the compatibility of most CAD/CAM modelling software. The IGES file was created using Delcam PowerSHAPE 2012 (Birmingham, UK) completely replicating the morphology of a condyle of the distal femur.

The external dimensional boundaries of the design were 45.75mm long, 27.756mm wide and 11.98mm deep. This data was used to find out if it will be possible for the forming limitations of this process to reduce the risk of tearing of the sheet as a result of excessive forming angles. The final 3D model of the prototype that the programming and toolpath generation is based on is represented in Figure 39:

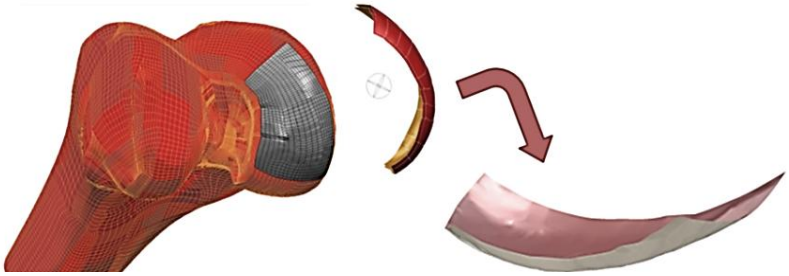


Figure 39: Selection of morphological data to obtain a 3D prototype model

Programming

Programming was required for the implementation of numerical control of the CNC milling machine. The 3D model obtained was rotated to obtain the smallest possible forming angle. This is necessary to improve on success rates and reduce the risk of tearing present in the sheet due to excessive forming angles. After the tool path is selected, the programming phase is used to execute the program by means of the controller on the CNC machine. The final model is implemented in Delcam PowerMILL Pro 2011 (Birmingham, UK) and implemented into an OSP-U100M controller, as seen in Figure 40.

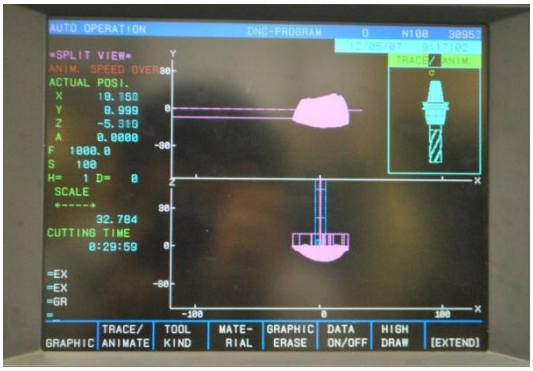


Figure 40: G-code implementation (mid-process)

The CNC Machine

The experiments were performed using an OKUMA MB-56VA 4-axis CNC machine with an OSP-U100M controller. CNC machines are highly available as a result of their large area of application. Although mainly used for milling applications, the CNC machines can also be used to perform incremental forming of sheet metal by using a forming tool rather than a cutting tool.

5.3.1 Case specific variables

As part of the experimental setup for the IF process, the following process components are discussed as well as the components required for the forming of both aluminium and titanium. The process parameters requires consistency and was replicated as much as possible to ensure that the results of the titanium based experiments can be compared to the aluminium based experiment results. Some process parameters could however not be replicated on the forming process on titanium, as properties of titanium differ from aluminium and would result in different end-products. The following components of the experimental setup are classified as process variables that cannot be kept constant for the application of ISF on both aluminium and titanium:

The forming tool

As previously mentioned in the literature review, a forming tool is required for the incremental sheet forming process. The tools were specifically made for the experiments and the main design of these tools consisted of a Ø10mm tooltip supported by a neck that is connected to the main body. The tool was designed with a thick base to support the tooltip for any axial forces exerted by the workpiece. Engineering drawings of the design is shown in Appendix A.

Figure 41: The forming tool installed in the chuck

For the forming of aluminium in the first experiment a mild steel forming tool was used for the forming application. The tool was machined with a Ø10mm spherical tooltip concentric to the shaft of the tool to ensure maximum accuracy during the forming process. The second experiment required a stronger material for the forming of titanium. The tool material was K110 tooling steel obtained form Bohler-Uddeholm (Cape Town, RSA), where after machining was hardened to a hardness of 60-65HRC by means of vacuum hardening. The tool was then finally machined for a second time to ensure concentricity of the tooltip to the body.

The backing plate

The end product accuracy of the IF process can be greatly improved with the application of a backing plate, as the unsupported sections of the sheet are also deformed, causing undesired downwards plastic deformation of the external section of the sheet. The backing plate will therefore provide a stable counteracting support when a downward force is applied to the sheet by the tool to minimise plastic deformations outside of the forming area. Two 250x220x6mm mild steel constructs was manufactured using laser cutting at Fabrinox (Pty) Ltd. (Paarl, RSA). The first backing plate was manufactured with an Ø70mm circle with an internal 3mm radius to allow downward forming of the

plate without shearing. A relatively large area has been given to allow the stretching of materials outside the deformation area. The plastic deformations are therefore limited to this area. The plate used was manufactured to be used for any incremental forming application of a profile that could fit in the Ø70mm circular area.

Author's notes:

Research on the implementation of a profile-specific (custom made) backing plate for the IF process has never been documented. The effect of the application of a profile-specific backing plate is also unknown to the SPIF process. The opening profile of the backing plate is therefore the only section where bending is allowed, but complications can occur if the central opening is too close to the deformation zone, as tearing of the sheets can occur (note results of the first titanium prototype, Ti 1).

A second backing plate was manufactured during the experiments in an attempt to increase the obtained formability of the prototypes. The second backing plate was used for the fifth prototype of the first experiment as well as the complete second experiment (*Al 5*, *Ti 1*, and *Ti 2*). To ensure maximum accuracy and correlation between the toolpath and the opening in the backing plate, scaled profile of the prototype as viewed from the top (in the x-y plane) is cut with a profile offset of 5mm to account for the sheet thickness and tool radius. The custom cavity was machined using two tungsten carbide cutting tools, a ϕ16mm for the main machining and a ϕ6 for pocketing of the profile. The backing plate was specifically manufactured for the forming of this specific profile to ensure minimal elastic springback, as this is a common problem with the incremental forming of metals with high tensile strengths and high strain hardening coefficients such as stainless steel or titanium [9, 42, 66]. The profile as seen in the x-y plane is shown in Figure 42:

Figure 42: The profile cut into the second backing plate

With the great emphasis placed on the complete dimensional correlation between the backing plate and toolpath, the backing plate was welded to the base frame to ensure that no displacement occurs during the run of the experiments.

The lubricant

The forming process, being based on the principle of highly concentrated, localised deformations inadvertently result in high frictional forces on the small contact area. These forces, as discussed by Hussain et al. and Jeswiet et al., can be reduced by applying a rotational force on the tool, or by means of lubrication [9, 58]. A lubricant is therefore applied to the contact area of the tooltip and the

workpiece to reduce contact friction and wear on the tool and sheet. The specific lubricant used for each experiment will also vary according to the workpiece material.

For all applications of aluminium forming, the lubricant used was Rocol RTD liquid, as this is most commonly used for milling applications to improve on tool life. The lubrication can regulate heat away from the contact area, reducing heat damage caused by excessive friction, but act as an indicator if tearing occurs as well (as the fluid will drain out of the cavity of the tear).The lubricant used for titanium applications was placed under consideration of alternatives, as there various lubricant candidates exist. According to experiments conducted by Hussain et al., the use of no lubrication (also referred to as self-lubrication) is not suggested, and a lubricant was therefore required. The best possible candidate suggested by Hussain et al. was the application of molybdenum disulphide (MoS_2) with petroleum jelly[58]. This product (MoS_2) is purchased in powder form and is not suitable for use in tis dry form, as it is not adhesive and will not provide adequate lubrication in this form. In order to create an adhesive substance that will be able the application to the sheet, a mixture of 4 parts MoS_2 to one part petroleum jelly was created. The lubricant mixture was then pasted onto the workpiece, as shown in Figure 43:

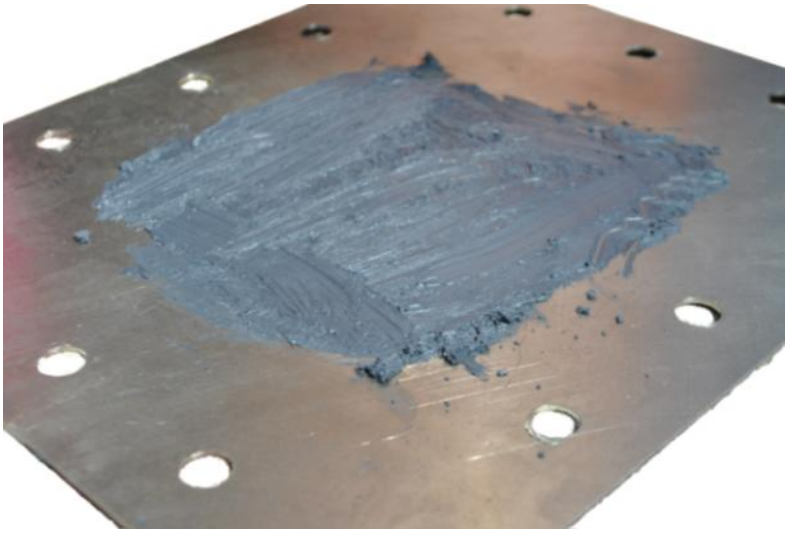


Figure 43: Molybdenum disulphate lubricant

5.4 Assembly and experimental setup summary

The final setup of the experiment involved the sheets clamped together by the endplates using standard M10 bolts. The bolts secure the drilled holes of the sheet metal to anchor the blank sheet during forming, as the downwards force exerted by the tool can cause a drawing effect as a result of biaxial forces. The backing plate holding the sheet metal is then clamped to the table of the CNC machine. The machine is then calibrated to find the zero point to act as datum for the pre-programmed toolpath that will be implemented during the forming process. The component summary for both experiments is indicated in Table 7. A data sheet of the 2mm CP Titanium Grade 2 is displayed in Appendix:

Table 7: Component description for the experiments

		Experiment 1	Experiment 2
Components	**Workpiece material**	Aluminium (AA1200)	Titanium (CP Ti Grade 2)
	CNC Machine	OKUMA MB-56VA 4-axis	OKUMA MB-56VA 4-axis
	Controller	OSP-U100M	OSP-U100M
	Programming	Delcam PowerMILL Pro 2011	Delcam PowerMILL Pro 2011
	Forming tool	ϕ10 Mild steel	ϕ10 K110 tooling steel
	Backing plate	Mild steel	Mild steel
	Lubrication	Rocol RTD liquid	MoS2:petroleum jelly (4:1)

The setup for the workpiece depicts the positioning of the backing plate to ensure support of the part of the sheet where deformation is undesired. The workpiece setup is depicted in Figure 44 and the setup for both experiments is shown in Figure 45.

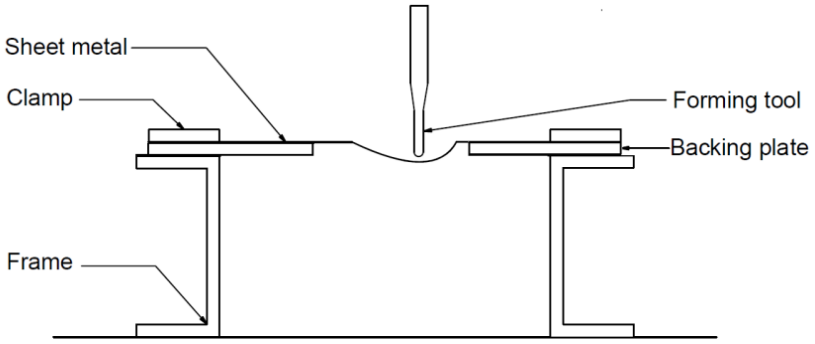


Figure 44: Setup of the workpiece

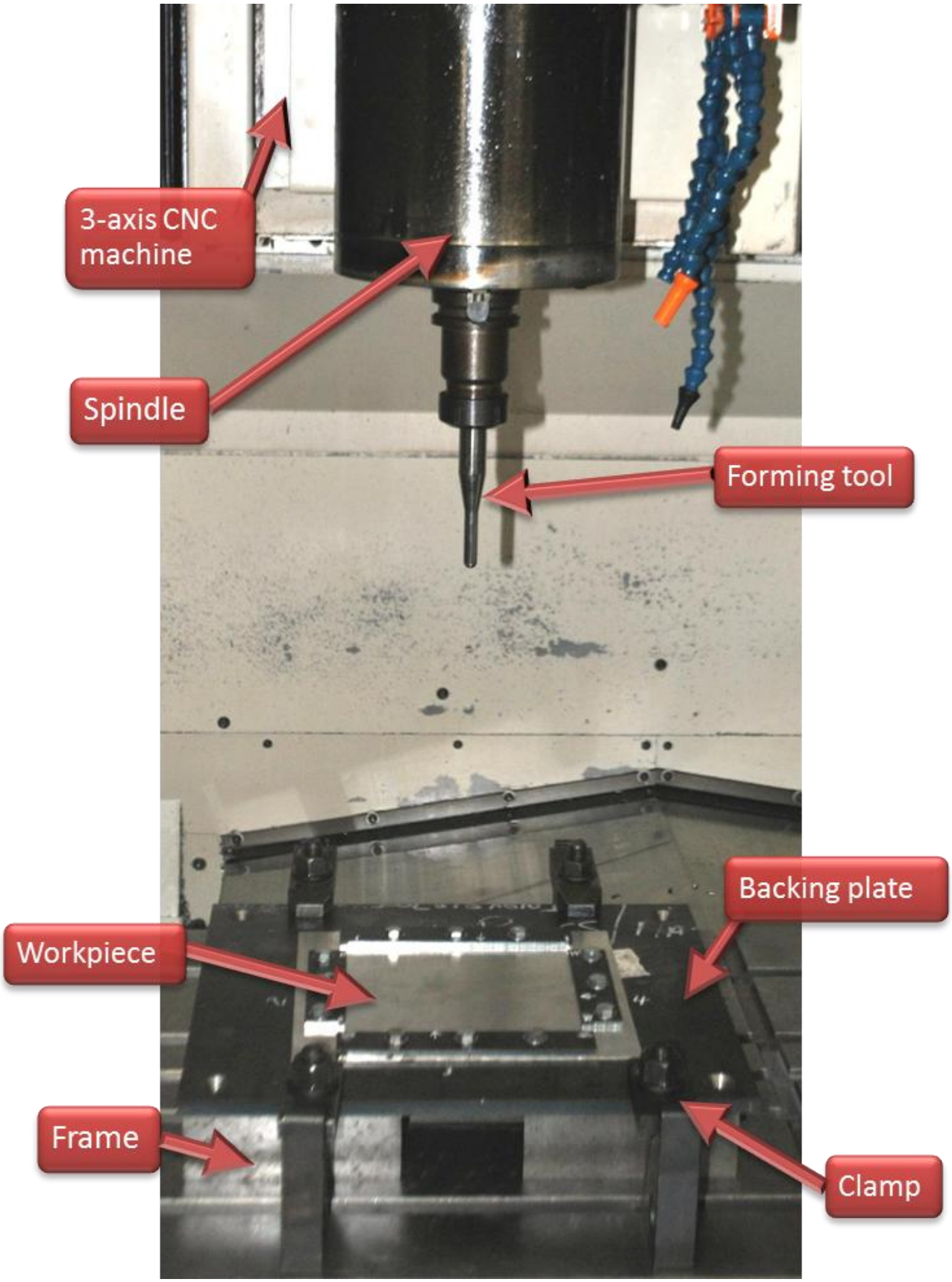


Figure 45: The experimental setup on the CNC machine

5.5 Experiment 1 – Aluminium based experiments

The first experiment was conducted to act as a foundation of the incremental sheet forming process. This experiment focussed on the forming of Aluminium sheets (AA1200H4) as this alloy, consisting of almost 90% Aluminium, was considered as one of the most ductile Aluminium sheets that can be used. With the focus also placed on the reduction of costs, a forming tool manufactured out of mild steel was manufactured at COMAR (Stellenbosch, RSA). The results of this experiment can then be used and compared to the formed titanium sheets of the second experiment.

5.5.1 Experimental planning and setup

The main objective of the first experiment is to promote process development and therefore determine if certain changes in process variables affect the resulting end-product geometry. The first experiment, conducting five runs each produced a prototype (*Al 1 – Al 5*), made changes in three process variables of the SPIF process. This was done to monitor the effect of variable changes on the SPIF process. The variables are listed as

- the toolpath strategy,
- the incremental step size, and
- the backing plate.

The nature of this study, being based upon primary empirical data acquisition, requires the continuous process improvement during the research conducted. Small changes were therefore made to the process parameters to eliminate the different process variables, and the results were documented (see Section 7). The selection of a tool path is considered an important aspect of the forming process, as the implementation of different tool paths will give different end shape geometries and surface qualities. Three different tool paths were chosen to be implemented was the raster finishing cut, the constant z finishing cut and the spiral tool path. The incremental step size for the forming of the fourth prototype (*Al 4*) was doubled to document the effect of a drastic increase in step size to be compared to literature. The final process variable that was monitored was the application of a profile-specific backing plate for the forming of the fifth aluminium prototype (*Al 5*). The experimental summary for the first experiment displaying the process parameters is displayed in Table 8.

Table 8: Experimental parameters of the first experiment

Exp. 1		Process variable changed	Toolpath	Backing plate cavity	Incremental step size (mm)	Tool speed (mm/min)	Machine time
	First run (*Al 1*)	Toolpath	Raster finish	Ø 70mm	1	1000	31 min
	Second run (*Al 2*)	Toolpath, Tool speed	constant z contour cut	Ø 70mm	1	2000	35 min
	Third run (*Al 3*)	Toolpath	Spiral finishing	Ø 70mm	1	2000	34 min
	Fourth run (*Al 4*)	Incremental step size	Spiral finishing	Ø 70mm	2	2000	21 min
	Fifth run (*Al 5*)	Backing plate	Raster finish	Profile-specific	0.6	2000	48 min

5.5.2 Execution of the first experiment

The experiment consisted of five runs, each one done in an attempt to improve the end-product geometry of the previous. The first experiment, consisting of five individual runs was modified by changing some of the process variables such as incremental step size or programmed toolpath. A new blank sheet was used for all experiments, and the same Rocol RTD lubrication liquid was applied for all purposes.

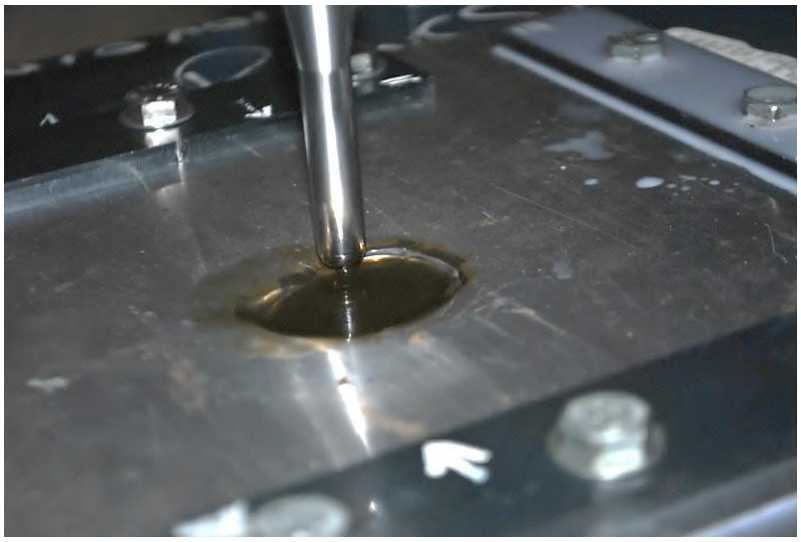


Figure 46: Execution of the first experiment

The first three experimental runs (that produced the three prototypes: *Al 1*, *Al 2*, and *Al 3*) were performed by implementing three different tool paths in the program. The change in depth after each contour is set to 1mm increments as aluminium is known to be highly malleable. The allowed incremental depth size is an indication of the forming limits of this particular metal, and as this is the first experimental procedure, an incremental depth of 1mm was chosen, this is considered as a suitable starting parameter for the forming of AA1200H4 sheets. The first run was carefully observed for any instance of tearing or tool fatigue, but the program was completed successfully within 31 minutes of operation. Upon finishing of the first run, inspections are made to the formed part for any indication of failure or damage to the prototype. The forming tool was also inspected for any signs of fatigue or failure on the tooltip. The process that formed the finished part, although successfully executed, had the potential of being improved by changing certain process parameters. The fourth run (that produced *Al 4*) was programmed with change in only one variable from the third run, the incremental step size. The fourth run was conducted to observe whether the sheet would tear if an abnormally large incremental step size was used. This was done in an attempt to reduce machine time and therefore manufacturing costs of the formed product. The fifth and final run for the first experiment was executed by implementing the second backing plate that implemented the profile-specific cavity as discussed previously.

5.6 Experiment 2 – Titanium based experiments

The second experiment continues on the methodology of the first experiment. The second experimental procedure and setup simply improve on the process in aspects such as the forming tool and lubrication used, but is most importantly applied to a titanium work as opposed to aluminium. In addition to the change of workpiece material, the implementation of a custom made backing plate is used.

5.6.1 Experimental setup

The experimental setup for the second experiment, being based upon the first experiment, is similar to the first as the same OKUMA CNC machine and workpiece frame is used. Certain specifications of the setup will differ from the first experiment, such as the forming tool, backing plate, and lubricant used. For the second experiment, a raster finish was used for the toolpath. For this toolpath, the contact area encounter transitional changes in the x and z planes, but will maintain a constant Y coordinate for each run of the toolpath. At the end of the run, the tool will encounter an incremental shift of Δy=0.3mm followed by a return on a straight (Δy=0) run in the opposite feed direction.

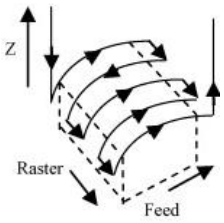


Figure 47: Raster milling toolpath (without retreat)[67]

5.6.2 Execution of the second experiment

The process parameters for the second experiment are given in Table 9. In order to obtain consistency with the process parameters of the two experiments, the maximum number of variables has to be kept constant (when compared to the parameters of *Al 5* of the first experiment). The same process was therefore implemented until a working prototype was formed. The process parameters from the first run of experiment 1 were applied, with the exception of a smaller incremental depth.

Table 9: The process parameters for experiment 2

Exp. 2		Symbol	Unit	Value
Parameters	**Incremental step size**	Δz	mm	0.3
	Feed rate	f	mm/min	1000
	Toolpath	-	-	Raster finish
	rotational speed	n	rpm	100

The first attempt to create the titanium based prototype was performed by using the backing plate that was cut with the top-view profile of the desired part, with the exception of a 2mm offset of the profile's

external boundary. The programming was then implemented in the CNC controller, which executed the first run. After the forming process has been running for 21minutes (approximately 22% from completion), screeching noises could be heard during the beginning of each raster contour run. The process was then stopped and the contact surface was investigated. Visual inspection indicated a tear in the sheet as a result of the tool engaging in too close proximity to the cut profile of the backing plate. The first experimental run was discontinued, as the profile that was cut will cause interference with the toolpath in the rest of the process. The resulting geometry obtained from the first run (referred to as *Ti 1)* is seen in Figure 58 in the experimental results.

In an attempt to improve on the first run, an additional cut was made to the backing plate. The profile offset that is cut into the backing plate was increased from 2mm to 5mm, to reduce chances of tearing or any other possible failure. The upper sharp corners were filed down to further reduce the chances of cutting shear in the sheets to be formed.

Figure 48: The backing plate with profile-specific cavity with 5mm offset

The second run was performed using a raster finish toolpath, but completed without any instances of tearing of any part of the sheet. The toolpath, having an incremental downwards step size of only 0.3mm was completed in 95 minutes. The workpiece was removed and cleaned of any lubricant still attached before visual inspection could be performed. The second experimental run was completed without any instances of tearing in the sheet. The resulting geometry obtained from the second run (referred to as *Ti 2*) can be seen in Figure 58 in Section 7.1.

5.7 Geometry tests

With the acquisition of a proof of concept, geometrical analysis was conducted on the finished parts to determine the geometric attributes of the end products. The main focus with products formed by the IF process is allocated to be the formability of the workpiece [9]. The geometrical tests therefore had the following objectives:

- To identify the repeatability of the formed parts.
- To compare the formed geometry differences of the final titanium prototype geometry to the preliminary aluminium tests.

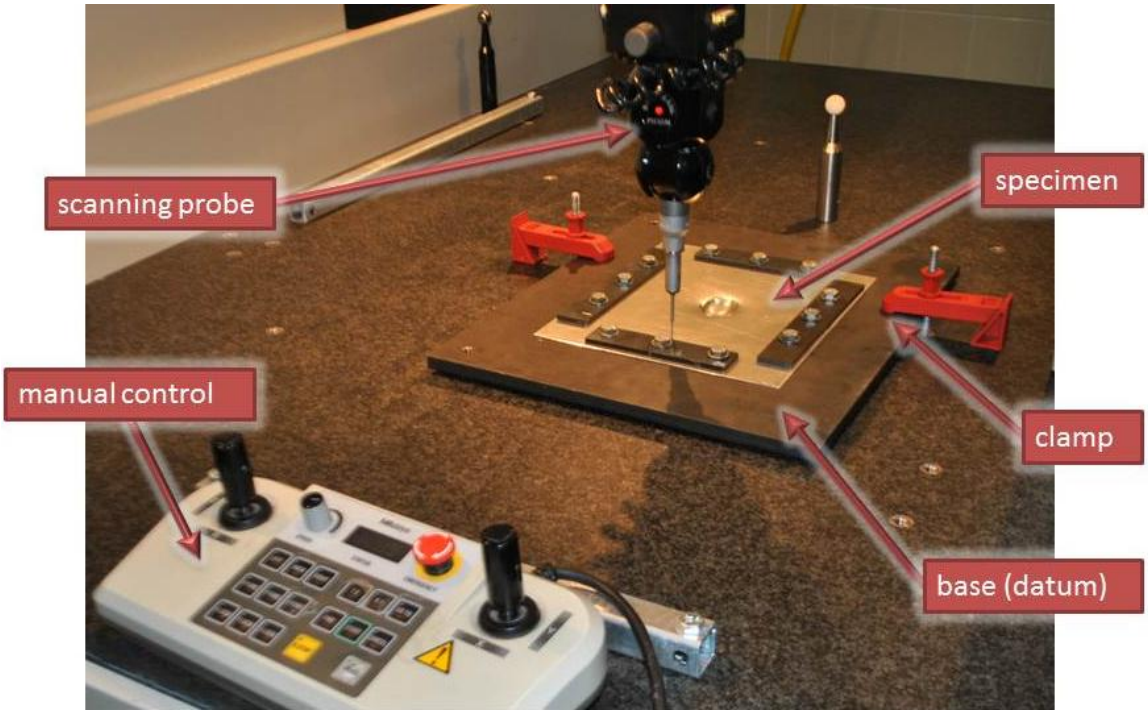


Figure 49: Test setup

The dimensional accuracy of the formed parts was therefore required. In order to obtain the dimensional accuracies of the prototypes, a Mitutoyo bright 710 CMM (Coordinate Measuring Machine) was used. The machine moves a measuring probe by means of a 3-axis CNC positioning system. For this specific application, a Renishaw PH10M analogue scanning probe was used to measure the dimensional changes of the prototype surface. The CMM is capable of measuring changes in dimension of up to 0.1 micron.

5.7.1 Testing setup

Every prototype specimen was clamped onto the base to ensure the most accurate measurements. The tests that were conducted were designed to illustrate the prototype geometry in a simplistic representative manner. The geometrical testing therefore consisted out of two different splines across the operating area (refer to Figure 50). The first test compared the difference in depth (z-axis) in a straight line of measurement by keeping the y-coordinate constant and changing the x coordinate with increments of 0.5mm. The second test compared the difference in depth (z-axis) in a straight line of measurement by keeping the x-coordinate constant and changing the y coordinate with increments of 0.5mm.

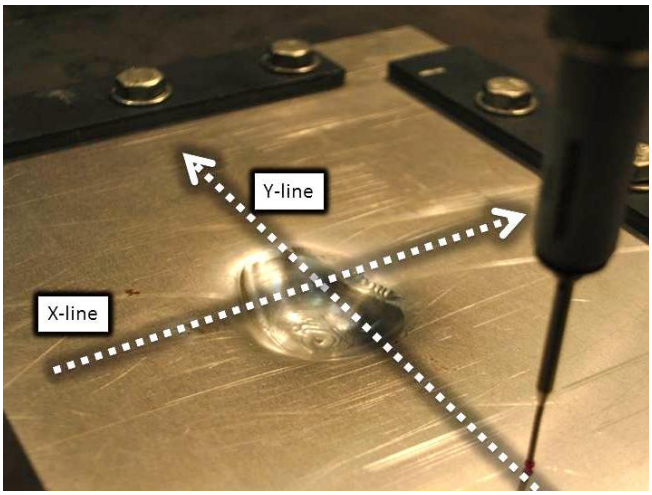


Figure 50: Definition of programmed test lines

For both tests, a program was required to run for every one of the six prototypes. The two programmes were written in GEOPAK CMM learn mode, to be used with and control the Mitutoyo bright 710 CMM. The data was exported and results are shown in Section 7.2.

5.7.2 Comparison of CMM data to desired end product

The obtainable geometrical data exported from the CMM can be compared to the data of the 3D solid implant file. The 3D implant file, of IGES format was imported into Autodesk Inventor software. The implant file, based upon surfaces was made solid by means of surface thickening to virtually slice the implant along the exact two lines as depicted in Figure 50 and obtain data points. A program was written using in Microsoft Visual Basic using the Microsoft Excel 14.0 object library. The written program calls all workpoints of the part, and exports the 3D coordinates to a .xls file as data points. The procedure is shown in Figure 51, and the written program is displayed in Appendix B. The data obtained is plotted on the same graph, to represent the desired end product in the results.

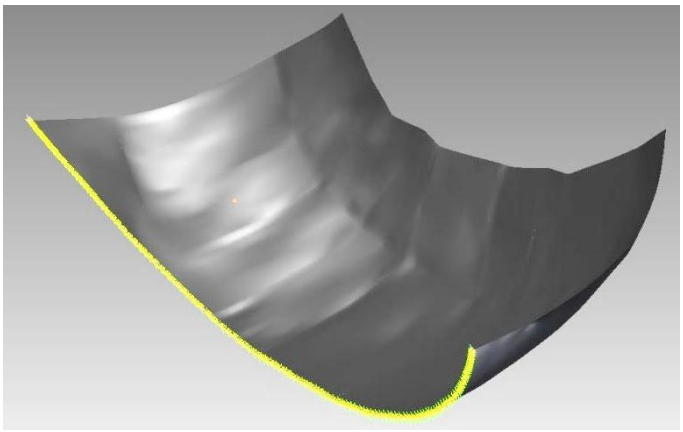


Figure 51: Selection of virtual data points for comparison using Autodesk Inventor

5.8 Tool wear analysis

As IF is based on principles of rolling as a forming method, the presence of friction is always present. The effect of these friction forces could cause wear on the tooltip and workpiece alike, and tests were performed to identify any signs of the presence of wear on these tools. The forming tools that were used for the experiments were inspected using enhanced microscopic imaging. The obtained images are displayed in Section 7.2.5.

5.9 Conclusion

The technical aspect of the research question was solved by the empirical procedures discussed in this chapter. The first aspect is the development of a process chain that enables the manufacturing of patient-specific knee implants. The second aspect validates the process chain by producing a proof of concept, to ensure that the process is capable of meeting the requirements for the implants. The completion of the experiments required analysis of the completed parts. As a result of the main focus area of incremental forming was the forming limitations of the part; the tests were designed to acquire the dimensional accuracy of the prototypes. Geometric analysis was therefore performed on the prototypes using a CMM to acquire dimensional data.

6 COMMERCIAL VIABILITY OF A BIOMEDICAL DEVICE

6.1 Introduction

The purpose of this section is to provide an introduction into the commercialization process that will take place further on in the product development. In this section, investigated areas of commercialisation of a new product include intellectual property acquisition, financial investigation, organisational assessment, and the analysis of product risk. The first step of developing a novel product into a market sector is to secure the intellectual property defining the invention.

6.2 Patent application process

For the commercialization of novel inventions in the biomedical sector, the utilisation of patent law is crucial to protect the intellectual property of the inventor. The significance of patents describing a medical device in R&D is the description of the patented invention. The patent will focus on the application of the device rather than the instrument itself, as an invention having a same function can easily be replicated without violating the legal rights of the original invention[5].

The application of an incrementally formed knee implant can be seen as a novel invention as it has never been applied in the biomedical industry before. A patent enables the state to grant a monopoly (for a limited period) to the inventor in exchange for a full disclosure of the invention to the public. The registration of a patent for this invention will therefore ensure that the University of Stellenbosch, holding the patent rights will be the only party able to utilize the invention for profit or advantage. After expiry of the period of monopoly, any public members are free to utilize the invention[68].

6.2.1 Registration process

The patent registration process was studied and documented as part of the writer's degree in Master of Engineering Management (MSc.Eng) to ensure the understanding and experience of the full patent filing procedure as well as the legal aspects to the patent. The filing process can be described using a process chain that depicts each aspect to the steps followed. The formal steps followed for the filing process of the patent can be seen in Figure 52.

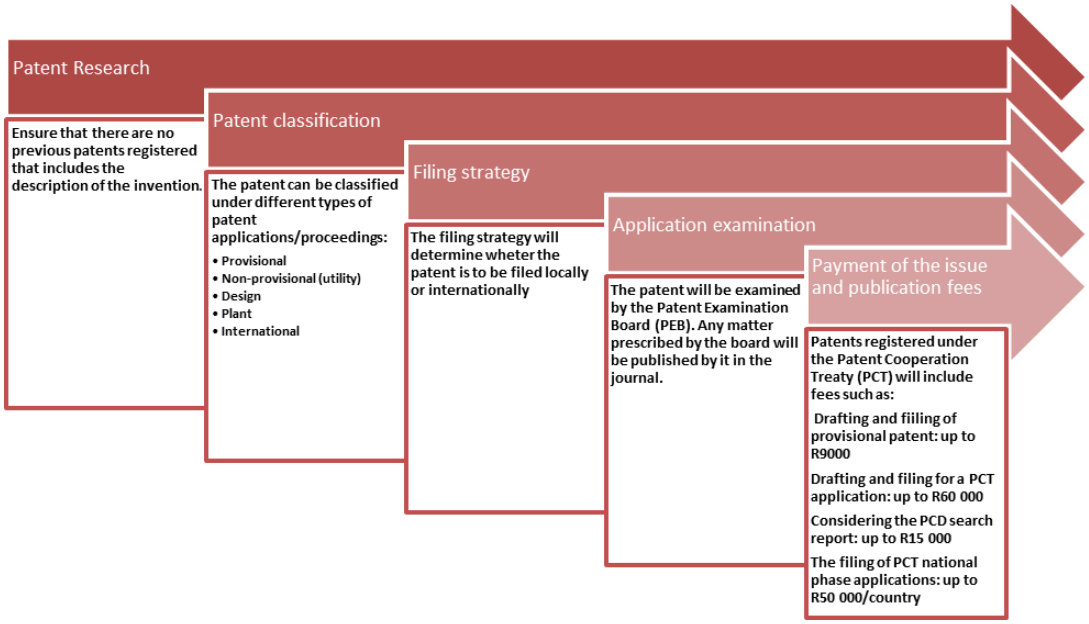


Figure 52: The filing process of patent registration

The process of patent registration, in collaboration with InnovUS, was studied and documented. InnovUS Technology Transfer (PTY) Ltd is owned by Stellenbosch University and manages the university's innovation and intellectual property portfolio.

6.2.2 Meeting requirements for patentability

The invention is required to follow certain criteria to ensure that the invention is patentable and protected under South Africa. The requirements for patentability are that he patent has to be[69]:

- New (Novel)
- Inventive and
- Useful

Some inventions that cohere to the upper requirements cannot however be patentable under the patent registration act of South Africa. Inventions not allowed to be patented include categories such as mathematical methods, discoveries, software and methods of treatment to the human or animal body by surgery, therapy or diagnosis[68]. The invention of this process can therefore come in conflict with regards to the latter omission, as it involves the implementation of the invention by means of surgery. After consultation with Von Seidels intellectual property attorneys, it was concluded that this invention can be patented as the implementation (or surgical) methodology is not patented, and merely listed as a feature of the invention.

Novelty

According to InnovUS, the most important prerequisite for the patentability of an invention is that it must be new as defined in the South African Patent Act. If the invention does not forma part of the

state of the art immediately before the priority date of the invention, the invention can be classified as new. The state of the art comprises all matter (whether a product, process or information about either, or anything else) which has been made public by written or oral description[69]. Care must be given not to disclose the description of the invention by any means, including oral disclosure. The publication of the description of the invention prior to patenting can destroy the novelty of the invention and restrict any possibility of patent registration. During the filing of the patent, all exchanges of information including drawing preparations with the intellectual property attorneys of Von Seidels was done under a written pledge of secrecy to avoid disclosure.

Inventive prerequisite

The invention, although new, can conflict with other similar patented inventions. In order to merit protection of the patent, the patent is to involve an inventive step to the invention. According to InnovUS, a patent can be deemed inventive if it is not classified as obvious to a person skilled in the field of the invention [69]. This test is very subjective however, and the decision to file a patent in South Africa is often dictated more by business strategy than by considerations of the inventiveness of the invention[70].

Utility requirement

Abstract inventions with no application in trade, industry or agriculture cannot be the subject of a patent according to section 25 of the South African patent Act no.57 of 1978. The prerequisite of the patent to be useful in the trade, industry or agriculture ensures that the patent will be capable of being used for a commercial purpose in at least one branch of science and technology[69]. However, if an invention has a practical use and meets the novelty and inventiveness prerequisites, such an invention can be considered as useful[70].

6.2.3 Patent application forms

The disclosure of the invention will be made using a series of forms to be completed during the application phase. These forms can be compiled by the patentee, or with the help of IP attorneys. The forms needed for a provisional patent application consists of[70]:

- P1 (Application for a Patent submitted in duplicate)
- P2 (Patent registration form)
- P3 (Declaration of Power of Attorney)
- P6 (Provisional specification)

The forms mentioned above were submitted accompanied with a technical description of the invention (with detailed drawings if required). The detailed description of the invention was compiled in collaboration with Mike Von Seidel, an intellectual property attorney[71]. The provisional patent application is valid for a 12 month period, in which time will be given for the evaluation of the invention

as well as the manufacturing and marketing, in the case of commercialization of the product. The final application can then be made for a complete patent in South Africa. This filing can only be made through a patent attorney. The complete patent will then be valid for a period of 20 years of which annual renewal is required [70]. The provisional patent was filed on 6 July 2011 under the title: ***"Bio-medical load bearing implants and their production"*** under the patent application number 2011/04960 by Von Seidels intellectual property attorneys.

AS FILED

SOUTH AFRICAN
PROVISIONAL PATENT APPLICATION

Title:
"BIO-MEDICAL LOAD BEARING IMPLANTS AND THEIR PRODUCTION"

Patent Application No: 2011/04960

Date of Filing: 6 July 2011

Applicant(s):
STELLENBOSCH UNIVERSITY

Inventor(s):
Pieter De Waal EKSTEEN
Andre F. van der Merwe
Tiaan OOSTHUIZEN

Figure 53: The filed provisional patent application of the invention

6.3 Regulation

In order for any medical device to be implemented into the medical sector, the device will have to surpass various sections of quality control by means of applying regulatory risk management to the development, production, and preparation, before the product is allowed to be commercialised with FDA approval. Three elements can therefore be identified:

- Regulatory approval
- Risk management
- Quality control

Each of the three elements is required to ensure that the product, being customer based, is safe for biomedical use. This is assured by the conformation of the developed product to certain ISO's (International Organization for Standardization). Applicable standards (such as ISO 13485) describes regulatory steps of implementing medical device QMS (Quality Management System), while ISO

14971 and FDA Q9 directive depicts medical device QRM (Quality Risk Management) and therefore interlinks all three of the elements to assure safe, accurate, and reliable products. Figure 54 depicts the relationship of regulation, risk and quality of a medical device.

Figure 54: The relationship of regulation, quality, and risk by means of standardisation

The infiltration of a bio-medical implant in the medical sector is vast, the release of these devices are also not possible unless certain regulatory steps is passed. A few of the compiled ISO's are applicable when the developments of medical devices are considered.

ISO 14971:2007

The ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. Applicability of the requirements of ISO 14971 spans across all stages of the product life-cycle. The 2007 edition is the revised version of the 2000 edition, and is recognized be the FDA in 2007. The standard requires that top management demonstrate its commitment to risk management by[72]:

- establishing the process,
- setting the policy for acceptable risk, and
- reviewing the effectiveness of the process at predetermined intervals.

Declaration of conformity to the ISO14971 regulation proves that:

1) A process appropriate for medical devices and their accessories, including in vitro diagnostic devices, has been used to identify hazards and hazardous situations, estimate and evaluate

the risks, control those risks including overall residual risk, and monitor the effectiveness of the controls, and

2) Criteria based upon applicable national or regional regulations, relevant international standards, information such as the generally accepted state of the art, and known stakeholder concerns was used to determine risk acceptability.

FDA Q9

The Food and Drug Administration (FDA) requires risk assessment as part of design validation, as stated under Section 820.30(g)[73]. In this light, "design validation" refers to the establishment by objective evidence that device specifications conform with user needs and intended uses, as stated by Section 820.3(z)(2). Risk management, starting at the design phase, is a natural approach to the conformation of the FDA requirements, since medical devices need to be both safe and effective. The FDA provides a Q9 Quality Risk Management (QRM), which recognises the importance of quality systems in the pharmaceutical and medical device industry, and identifies quality risk management as a valuable component of an effective quality system.

The stakeholders of the medical device industry are identified as the patients, the medical practitioners, the government, and the industry. The FDA therefore allocates the protection of the patient as prime importance by managing the risk to quality (as stated in Section 1 of the Q9)[73].

ISO 13485:2003

Risk assessment is required to be performed by ISO 13485 as well, as stated by Clause 7.1, in addition, the records arising from risk management shall be maintained, and this standard refers back to ISO 14971 for guidance related to risk management. Clause 7.3.2 indicates that the design and development inputs include risk management outputs.

6.4 Product risk management

Various factors of risk is present in the development of any medical device the consequences of the resulting cause in certain aspects of failure can prove to be severe. A risk assessment is performed on the proposed device. The FDA, having a requirement of risk assessment performed as part of design validation (stated by Section 820,30(g)), requires the risk assessment to assess the process from the design phase[73].

ISO 14971 risk management, according to BSI Management systems, is a state-of-the-art, international standard that is quickly being recognized as the best process to ensure that all aspects of risk management are considered throughout the product lifecycle for medical devices[72]. Risk management is designed to help manufacturers introduce safe medical devices into the market place. The manufacturer is responsible for the identification and control of not only the risks associated with the medical device, but also the evaluation of interactions with other devices[72]. The intent of risk management is to incorporate a decision making process relating to safety of a medical device throughout the design, development and product lifecycle. Risk management will therefore also[74]:

- Differentiate the most critical product features related to safety.
- Quantify and determine acceptability of risk.
- Provide focus and priority for product development and lifecycle activities.

6.4.1 The principles of quality risk management

The two primary principles of quality risk management defined by the FDA are:

- The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and
- The level of effort, formality, and documentation of the quality risk management process should be commensurate with the level of risk

6.4.2 Scope

The guidance provided by ISO 14971 provides principles of tools for quality risk management that can be applied to different aspects of product design. These aspects include the development, manufacturing, distribution, inspection and submission/review processes throughout the lifecycle of biotechnological products. The FDA, having a requirement of risk assessment performed as part of design validation (stated by Section 820,30(g)), requires the risk assessment to assess the process from the design phase.

6.4.3 Implementing Quality risk management according to FDA standards

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the medical product across. The FDA Q9 provides a model for quality risk management, as depicted in Figure 55. The FDA does allow other models, and the emphasis on each component of the framework can differ from case to case. Responsibilities of a typical quality risk management process (see Figure 55) are usually undertaken by different teams. Quality risk management activities are usually undertaken by interdisciplinary teams. When these teams are formed, it is recommended that they consult experts from the appropriate areas (e.g. quality unit, business development, engineering, regulatory affairs, production operations, sales and marketing, legal, statistics, and clinical)[73].

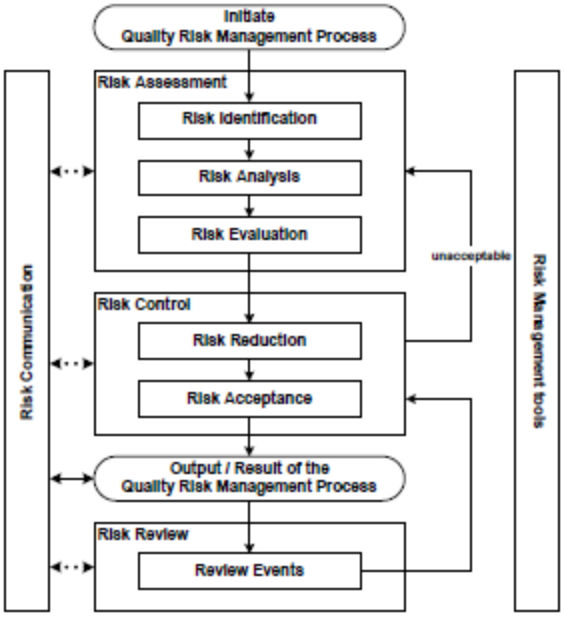


Figure 55: Overview of a typical quality risk management process as depicted by FDA Q9[73]

6.4.4 Risk assessment

Information gathered from various guides ([72, 75, 73, 74]) is used to obtain a systematic approach on conducting quality risk management. A risk assessment can be performed on the scenario of implementing the medical device into the proposed market. ISO 14971 requires the documented risk analysis of both the intended use and foreseeable misuse of the device, as well as the estimation of the risk for each hazardous scenario[76]. Three fundamental questions are asked in order to assist in the creation of a risk assessment:

- What might go wrong? (**scenario**)
- What is the likelihood (**probability**) it will go wrong?
- What are the consequences (**severity**)?

Table 10: Risk assessment level identification

		Description
Probability factor		
5	Definite	Will always occur
4	Frequent	Occurring often or repeatedly
3	Probable	Reasonably likely to occur
2	Remote	Not likely to occur
1	Improbable	Unlikely to ever occur
Severity		
5	Catastrophic	Results in patient death
4	Critical	Results in permanent impairment or life-threatening injury
3	Serious	Professional medical intervention is required
2	Minor	Low risk failure, not likely to cause injury
1	Negligible	Insignificant failure – not serious enough to contribute to an injury

The following risk assessment is compiled to display the possible risks that the patient will face when undergoing the proposed operational procedure. Some risk factors are obtained from previous follow up studies performed on the patients. Some risk probability estimations may vary as a result of variances in a community-based setting, where a different surgical skills, surgical experience and diverse patient demographic factors can affect the risk probability.

Table 11: Risk assessment

Sub step	Event (Failure mode)	Effect/ required action	Probability	Probability factor	Reference	Severity	Risk factor
Design	Inaccurate medical imaging/ thresholding	Unable to fit implant	< 20%	1		3	1.5
	Excessive resurfacing selection	Unnecessary bone removal	< 20%	1		3	1.5
	Inadequate resurfacing selection	Unable to completely resurface	< 20%	1		2	1
Manufacturing	CNC error	Delay in lead time	< 40%	2		2	2
	Inaccurate end-product geometry	Unable to fit implant	< 20%	1		2	1
Preparation	Product not cleaned from lubricant	Infection can be caused	< 40%	2		4	4
	Inadequate sterilization	Infection can be caused	< 20%	1		4	2
Transport/ Storage	Environmental interference (chemical corrosion, deterioration)	Unusable product	< 20%	1		3	1.5
	Inadequate packaging	Damaged/faulty product	< 20%	1		3	1.5
During surgery	Transfusion complications	Immediate dialysis	0.01%	1	[77]	4	2
	Narcotic allergic reaction/misuse	Permanent neurological damage	< 20%	1		4	2
	Excessive bone removal	Unable to fit device	< 40%	2		3	3
	Excessive blood loss	Blood transfusion required	< 20%	1		3	1.5
	Infection during surgery	Possible loss of joint function	< 40%	1.5		4	3
Post operational	Knee revision required (aseptic)	Surgical procedure required	1.10%	1	[78]	3	1.5
	Blood clots (Deep vein thrombosis)		3.90%	1	[77]	3	1.5
	Fatality (< 30 days)		0.20%	1	[79]	5	2.5
	Revision (90 days)		0.12%	1	[79]	3	1.5
	Revision (1 year)		0.91%	1	[79]	3	1.5
	Revision(2 years)		2.96%	1	[79]	3	1.5
	Revision (3 years)		4.72%	1	[79]	3	1.5
	Revision (8 years)		10.14%	1	[79]	3	1.5
	Excessive pain		4.68%	1	[79]	3	1.5
	Infection		1.80%	1	[79]	4	2
	Aseptic loosening		4.51%	1	[79]	3	1.5
	Implant fracture		0.09%	1	[79]	4	2
	Implant failure		0.61%	1	[79]	3	1.5
	Instability		0.84%	1	[79]	3	1.5
	Misalignment		0.69%	1	[79]	2	1
	Stiffness (decrease in ROM)		0.35%	1	[79]	2	1

6.4.5 Risk control and evaluation of risk acceptability

Risk control includes decision making to reduce and/or accept risks. The purpose of risk control is to assess the current severity of the hazard, and if required reduce the risk to an acceptable level. The amount of effort used for risk control should be proportional to the significance of the risk[73]. A risk assessment matrix is compiled to determine if any risks are higher than the acceptable value, where the increasing probability is aligned with the level of hazard severity. In cases of post-operational risk

analysis, the matrix will be displayed in the same manner, with the only exception of the frequency of occurrence replacing the probability of the risk.

Table 12: Risk assessment matrix[75]

		Severity Levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability Levels	Frequent	R2	R2	R3	R3	R3
	Probable	R2	R2	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Improbable	R1	R1	R2	R2	R3

In this instance, the overall risk factor is computed as well. This incorporates the average value of the collective probability factor and severity, to allow quick reference and allocate a Risk Management Plan for the reduction and control of the high risk areas.

6.4.6 Risk reduction and control

The three levels of risk (depicted in Table 12) indicate the level of severity. Any risk that is allocated as a R3 (having a risk factor of 4- 5) risk will have to be reduced to a lower level of risk, according to ISO 14971, Clause 5). If risk reduction is required, the steps of Clause 6.2 to 6.6 are performed. In this instance, there risks factors do not exceed level 3. As there is no risk reduction required, clause 6.7 of ISO 14971 will be followed. Figure 56 is adapted from clause 6 to present the decision making process of risk control.

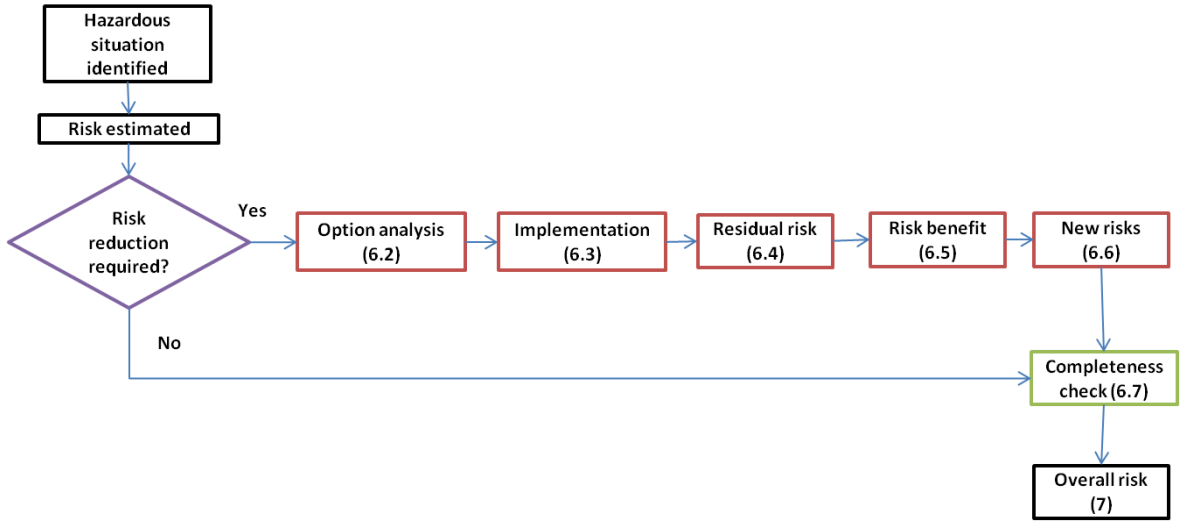


Figure 56: Risk control as defined by ISO 14971 Clause 6[72]

As there are no risks that consisted of a risk factor 4 or higher, the risk reduction process (ISO 14971 clause 6.2 -6.6) is not required for this application, and all the listed risks are considered as manageable.

6.5 Market research

The commercial planning of a medical device is a complex and unique process in various ways. The decision to develop a device capsules many factors, including development and testing costs, production costs, health economic analysis, market share analysis and strategic considerations. Many medical device manufacturers face a somewhat unique hurdle: the nature of the marketplace. In most other markets for goods, and service, the consumer is able to take decision on whether they provide value for money. This allocates the consumer as the main regulator. When considering the medical device markets, the approval of the regulating agency of the healthcare system is required before government and third-party payers can determine the value of the product based on cost-effectiveness[78]. Any new product assessment should take this complex setting into account.

The growth and economical prosperity of any company is highly dependent on the development and introduction of new products. Innovation is required in a response to technological advances, meet regulatory requirements, cope with competitive threats and keep pace with market and consumer needs[80]. A recent survey conducted on 150 European medical device companies reported that 63% had produced an innovative product or service in the previous year and 82% were planning to launch a new product within the next two years[78]. The development of new technology and new project development are associated with risk and uncertainty. Managers are faced with the dilemma of whether or not to invest at any stage of the product development process.

Medical insurance

Medical insurance agencies are as much part of the medical industry as the client, as much of the funding is greatly dependant on the payout offered by the medical aid sector. Interviews were conducted with consultants of two medical aid companies having large customer bases. The main question was based upon the company's reluctance to pay for a medical prosthesis.

Medical aid company	Scheme	Category	Allowance	Note
ProfMed	ProActive	Knee/Hip prosthesis	R 37 000	Per family per year
Discovery	Health	Unilateral joint prosthesis	R 33 000	
Discovery		Bilateral joint prosthesis	R 66 000	

The medical funding by Discovery Health allowance limit includes the prosthetic devices, screws, cement, and any other components used in the arhroplasty. The company has a list of preferred suppliers, if the prosthesis is listed under the preferred suppliers, the limit does not apply. The limit is also not applicable in the case of revisions performed during post operational procedure[81].

Medical aid companies pay hospitals a fixed amount for knee replacement and other procedures for patients with medical aid, who comprise the majority of knee implant recipients. From this sum, they must pay for the implanted device, regardless of the functional level or brand selected by the

surgeon[82]. In recent years, implant manufacturers have produced a steady stream of incremental device improvements, many of which are accompanied by higher prices to compensate for the R&D costs. The cost of knee implants has been rising faster than the growth in medical aid payments over the past several years, causing the implant to eat up more and more of a hospital's reimbursement for a surgical procedure.

6.6 Economic analysis

6.6.1 Finance in the development of a new product

New product development (NPD) in general requires a substantial company investment. The financial cost to a company can be high if a new product subsequently fails to sell adequately. Managers therefore need robust decision-making tools for valuing potential new product investments in order to justify their development strategy and to allow them to screen out new devices that stand little chance of success at an early stage. This section focuses on determining if this medical product can be seen as a lucrative investment by means of business methodology.

6.6.2 Net Present Value (NPV)

The NPV is an indication of the difference between the present (discounted) value of a projected future cash inflow and the investment sum required to purchase that stream[83]. The NPV in simple terms is the sum of the present values of all of the future cash flows. The value of a project's NPV will therefore determine if an investment would be worthwhile and should be undertaken.

Value	Decision
NPV >0	Accept
NPV < 0	Reject
NPV = 0	Indifferent

The increase in NPV will represent a more attractive investment in the proposed project. The advantage of using the NPV is that it is mainly concerned with profitability, as well as the time value of money. The NPV is essentially determined using the discounted cash flow concept, by taking into account the fact that money will experience a reduction in value over time. The DCF method, although considered as superior to traditional techniques such as the payback period and Accounting Rate of Return (ARR), does exhibit some drawbacks. The NPV has no indication of what rate of return a project is earning, and the selected discount rate to apply is subjective. The weakness, according to Firer et al., lies in the fact that they assume all future cash flows are static and do not properly account for the flexibility that may be present in a project. It also neglects real-world choices to stop investing in a project or change course in response to changing levels of demand[84].

6.6.3 Can the project be considered as an economically feasible option?

In order to determine the economic value of the proposed implant, a scenario is generated where the viewpoint of a potential investor is used. Most companies still make use of the traditional discounted cash flow method for project valuation. DCF techniques address the challenges above by considering everything in monetary terms[84]. The scenario created considers the implant being used in the South African orthopaedic clinics and hospitals. According to Stanley van den Heever of Heever Technologies, approximately 11 500-12 000 knee implants are surgically implanted in South Africa each year.

Production costs

The first requirement of determining the NPV of the project is to determine the overall cost of producing the knee implant. The figures used for computing the production cost of the implant are obtained from the methods performed by the author. Refer to Section 5 for further details on the design and manufacture steps.

Table 13: Production cost of the implant

	Tariff	Time (h)	Cost (ZAR)
Design			
Data processing	350	4	1400
Implant design	350	2	700
Manufacture			
Backing plate manufacture			76.51
CpTi Gr2 2mm plate			202.62
Forming tool manufacture			895
Lubricant			102.21
Backing plate profile milling (CNC)	450	0.3	135
Implant manufacture (CNC)	450	1.6	720
Preparation			
Implant preparation and cleaning	350	2	700
Cost of prosthesis			**R 4 931.34**

Future cash flow projections

The income projection for the project estimates the financial gain for a period of five years. Any estimation longer than this period cannot be accurately predicted, and is therefore not included in

calculations. These estimates are however not ignored, and will be taken into account by means of project salvage. The initial year (Year 0) will not display any cash income, as the present value is calculated on the completion of each year. The NPV, as stated previously, is calculated using the sum of the Present Value (PV) of every projected year. The present value is calculated using equation 3.

$$PV = \frac{1 - \frac{1}{(1+i)^n}}{i} . C \qquad (3)$$

Where:

i is the effective interest rate of return

n is the number of years

C is the projected cash flow

The effective interest rate is calculated using the combination of the 1) risk free rate and 2) risk premium. The risk free rate relates to the current stable interest that can be obtained from a low risk investment. The investment rate chosen was therefore 4.99%, the interest rate on 1 year Treasury bills of South Africa (an alternative value of the R154 government bond can be used). The second rate is the risk premium, the interest rate that any investor requires to compensate for the risk involved. The risk premium was taken as 10%, resulting in an effective interest rate of return of 14.99%.

The projected cash flow calculated was determined by firstly introducing a market (selling) price for the product. If the average cost of a commercial knee replacement prosthesis has the approximate cost of R 35 000 (with the selling price ranging from R30 000 to R40 000), the cost of the proposed product can be introduced to the medical market at a very competitive price. The selling price of the product was allocated as R10 000 (for the first year), less than a third of the current prices, to improve the attractiveness of the product in a highly competitive market.

Author's notes:

The proposed market price of R10 000 is not too low for a knee prosthesis. Current partial knee prosthesis are being developed having a market price of R12000-R14000 [16]

If the estimate is made that only 200 products are sold every year, the estimations of total annual revenue can be made. For the period of five years, the annual overall expenses are projected to increase by at least 8%. In order to compensate for this, the market price of the product is also increased by 8% at the end of each year. An annual licensing fee of R200 000 is added to the annual expenses for each case.

The initial cost of the project can also be added to the calculation of the NPV. In this case R80 000 was allocated towards the filing of the patent, and R3 000 000 was allocated towards the equipment and initiation of the project for mass production. The scenario of the project is however a simplified model, various costs are not accounted for. These costs include office space, hardware, manufacturing equipment, clinical trials, marketing, licensing, and transport. Further costs can include company representatives, legal fees, R&D (for improvements) and insurance (including lawsuit insurance). The salvage on the other hand is added in the case of project termination. After the five years, the project can be sold, and the present value is to be calculated with the additional year's PV. The salvage value can therefore include profit earned by selling the patent, or any other project equity, should the owner decide to sell. The projected cash flows can be calculated for the five years

Table 14: Calculating the NPV using discounted cash flows

Description	Year	Cash Flows	Present Values
Initial Cost	0	-R 3 080 000.00	-R 3 080 000.00
Profit	1	R 813 732.00	R 707 593.04
Profit	2	R 894 830.56	R 676 620.46
Profit	3	R 982 417.00	R 645 955.13
Profit	4	R 1 077 010.37	R 615 784.17
Profit	5	R 1 179 171.19	R 586 256.48
Salvage	5	0	0
NPV			**R 152 209.29**

In this case, salvage was not inserted, as the decision was made not to sell the project equity and intellectual property. The inflow of salvage will increase the NPV even further. The positive NPV value is therefore an indication that this project is a good investment opportunity, and the product itself is an economically feasible option, and with the assumptions taken, investors can expect growth of 15% in return.

Sensitivity analysis

Simplified sensitivity analysis was performed on the scenario described in this section. The sensitivity analysis was performed. In this section, different scenarios have been calculated to indicate the effect of market demand on the NPV of the project. Three scenarios are provided, a worst-case scenario, where demand drops with 50%, the most-likely (current) scenario, and best-case scenario. The sensitivity analysis provided is highly simplified as a decision tree that explores every possible scenario in the degree of each possibility would become unmanageable. The three scenario outcomes are displayed in Table 15:

Table 15: Best-and worst-case scenarios for sale projections

Scenario	Unit sales projection	Resulting NPV
Worst-case (-50%)	100	R -1 799 110
Current	200	R 152 209
Best-case (+50%)	300	R 2 103 529

This also indicates that at with the given interest rate, the NPV will increase with R 19 513 per item sold. The complete cost estimation can therefore not nearly be considered as completely covered, but will still provide a basic estimation of the investment potential of the project.

6.7 Benchmarking

6.7.1 The cost of biomedical knee implants

Robinson and Dolan discuss two factors that explain variation in device costs across different theatres. The first of these is the number of knee replacement procedures taking place in a hospital over a given period. Large numbers of procedures, and corresponding device purchases, could lead to volume-related price reduction on implant costs (large overhead costs are divided into more segments, therefore lowering the price per unit). Despite the intuitive appeal of volume discounts, it cannot be assumed that volume purchasing from a vendor is easily aggregated into bulk purchasing by a hospital, as a high total volume of device purchases could be the result of a number of decentralized decisions by individual surgeons. The second factor that could explain variation in device costs is whether a hospital contracts with a small number of device vendors for the purpose of leverage. If a hospital restricts its purchases to the products of just two of six possible vendors, the offered market price for the product may be lowered to acquire business opportunity.

6.7.2 Cost comparison of knee replacements

The total cost of the knee replacement procedure is obtained by means of interviews. The difference in cost that the invention will bring will only differ in the cost of the prosthesis. The invention, having a lower market price will be compared to the current knee replacement costs. Interviews were conducted with surgeons of both the private and government sector to determine the exact cost of surgery for both the total and partial knee replacement. The projected cost of surgery for the proposed prosthesis is displayed, yet since this product is yet undergo clinical trials, the total cost of such a operation cannot be fully determined. Consultation and diagnosis, accommodation and surgical costs (including prosthesis costs) were given by Dr. A.B. Schoeman, a private sector orthopaedic surgeon in Glouchester Square, George. The procedure parameters of operation time and prosthesis cost is obtained from a operation on partial knee replacement performed by Dr. Daan du Plessis[85]. The total costs of knee arthroplasty are documented in Table 16:

Table 16: Cost comparison to current knee replacement procedures

		Total knee replacement		Partial knee replacement		Proposed product	
	Tariff	**Time**	**Cost**	**Time**	**Cost**	**Time**	**Cost**
Hospital bill:							
Consultation & diagnosis			R 6 642.08		R 6 642.08		R 6 642.08
Ct Scan			R 2 341.70		R 2 341.70		R 2 341.70
Accommodation:							
Medical/ Surgical Ward	R 2 280	7 days	R 15 960.60	3 days	R 6 840.27	3 days	R 6 840.27
High Care	R 6 558	1 day	R 6 558.30	1 day	R 6 558.30	1 day	R 6 558.30
Surgical costs							
Theatre use	R 171.3 / min	160 mins	R 27 408.00	40 mins	R 6 852.00	40 mins	R 6 852.00
Theatre stock			R 20 000.00		R 20 000.00		R 20 000.00
Surgeon cost			R 13 299.20		R 13 299.20		R 13 299.20
Cost of prosthesis			R 40 000.00		R 34 000.00		R 10 000.00
TOTAL COST			R 132 209.88		R 96 533.55		R 72 533.55

A reduction in overall surgical and recovery time greatly reduces the overall cost of the operation. This table illustrates the reduction in overall costs when the proposed product is compared to conventional arthroplasty. The projected cost indicated overall cost reductions of 45.14% (R 59 676.33 savings) when compared to total knee replacement, and up to 24.86% (R24 000 savings) when the cost of the proposed product is compared to current partial knee arthroplasty.

7 EMPIRICAL RESULTS

7.1 Experimental results

This section will display and discuss the results obtained by execution of the two experiments that produced the aluminium and titanium prototypes. The experimental results will display all formed prototypes. The main focus of these experiments, as discussed in the objectives, focussed on the end product geometry and formability of the prototypes. Any forming deformations as well as possible reasoning behind the forming defects are discussed as well. The first experiment produced five prototypes, as depicted in Figure 57.

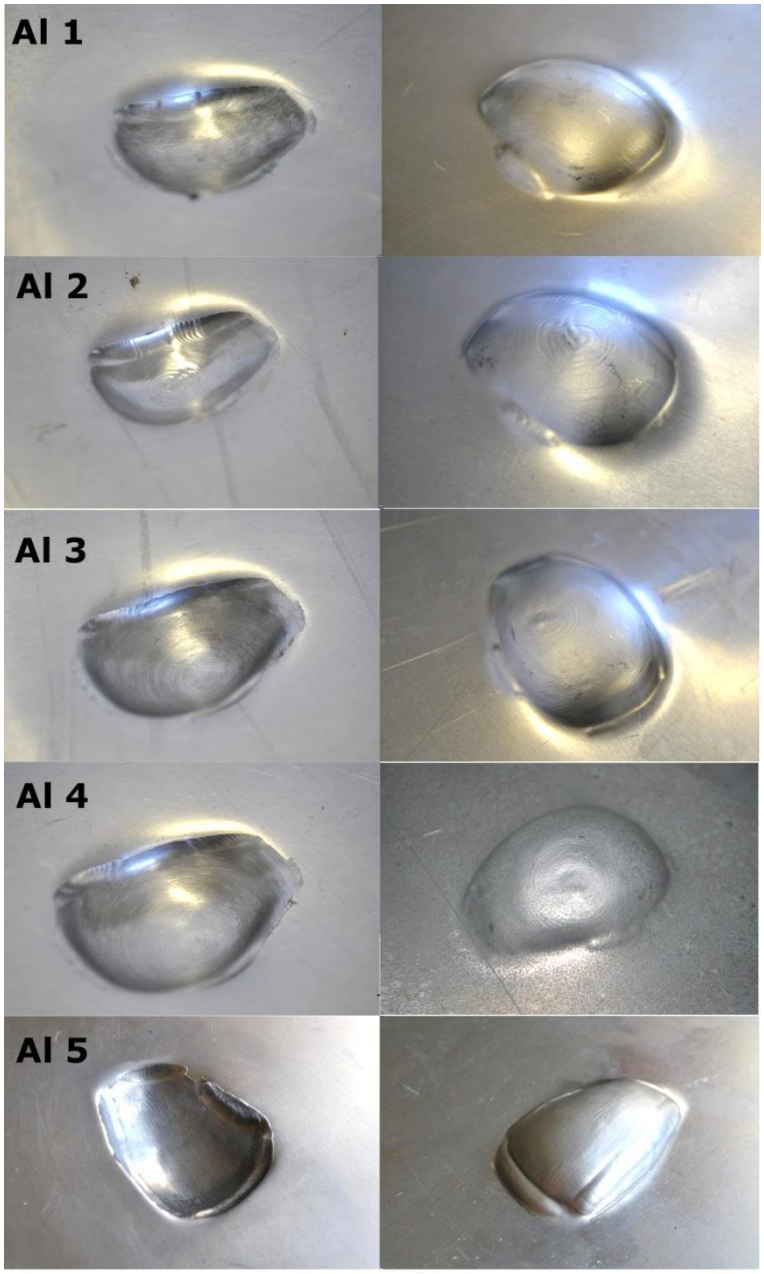


Figure 57: Formed parts of the first experiment

The experimental results obtained by the second experiment resulted in the two titanium based products, *Ti 1* and *Ti 2*. These components can be seen in Figure 57:

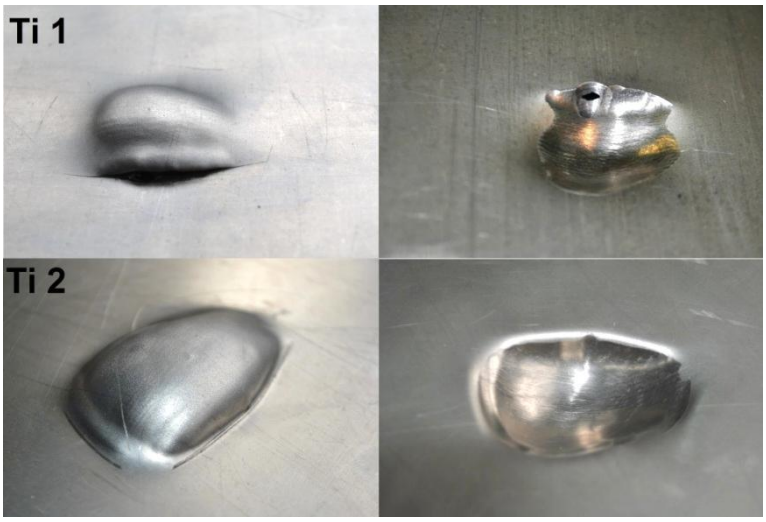


Figure 58: Manufactured titanium components

7.1.1 Experimental result analysis

The finished products were inspected before the following run was performed as to prevent any failures in machining strategy or programming of the tool paths. Analysis will be performed on the completed parts with the main focus placed on the formability of the process. Various aspects can be analysed when the formability of the parts are considered. Additional aspects such as the tooltip surface wear is analysed as well, to give more depth in the analysis of the experiment. The process formability is discussed by documenting the observed flaws such as forming defects or tearing of the workpiece. The geometrical data obtained from the CMM tests will discuss aspects such as process repeatability and maximum draw angle. The final aspect of analysis is the inspection of the tooltips for wear using microscopic imaging.

Surface quality

The surface quality of the finished products are impacted by various parameters of the process, but as certain process variables such as the tool diameter, the blank material type and lubricant used are kept constant throughout all of the experimental runs in order to reduce the presence of excessive parameter variability to reduce the variability in the end product surface quality. The only variables affecting variations in the end product surface quality for the experiments can therefore be allocated as the tool path, the incremental depth size and the tool speed[66, 9]. More thorough tests were designed using surface roughness tester but this was aborted as the depth of the formed part exceeded the measuring capabilities of 5mm for the testing setup. The experimental objective as discussed in Section 1.2 focussed more on end product geometry and formability than obtaining a good surface quality, and research was halted for more in depth future studies.

End-product deformations

The end product geometries are inspected for external forming defects. This section only describes the forming defects that were observed using visual inspection. The geometrical accuracy analysis is documented in the following section (Section 7.2). Two types of forming defects can be found on incrementally formed products, the first being the formation of residual cones forming on the centre of the product, and secondly the irregularities along the external forming boundaries of the product's geometry. The residual forming of cones near the finish of the selected outside to inside toolpath is found as a result that not all of the blank material is deformed at the end of the programmed toolpath. The cones are formed according to the selected toolpath, and minute traces of this can be seen in the second, third and fourth runs. Figure 59 illustrates the residual cone that is found on the second run.

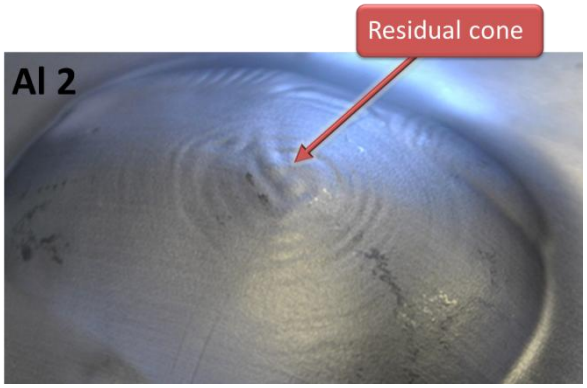


Figure 59: The forming of residual cones during final forming stages

The second defect that can be found on the end product geometries is the defects along the external forming boundaries of the formed product. The two defects found are the collective piling of different tool runs over a certain point of the external boundary, as seen in Figure 60(a). The second defect can be seen as discontinuous contact markings along the external boundaries of the formed part. These effects exist as a result of the plastic deformation of the external sheet not part of the planned forming. This causes the actual part to deviate from the datum, causing irregularities with the program implemented in the CNC machine's processor. This can only be fixed using a very accurate backing plate, allowing only deformation of the designed external z-axis profile of the formed part. The resulting discontinuous contact markings are illustrated in Figure 60(b).

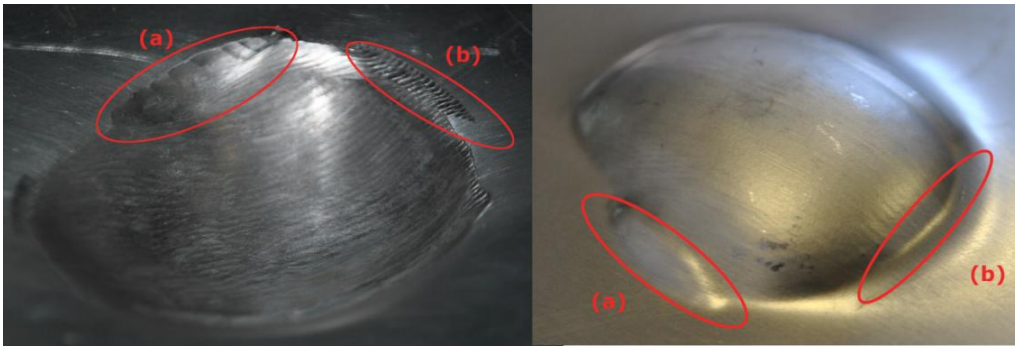


Figure 60: Forming defects found along external forming boundaries

Sheet tearing

As stated in literature, the implementation of IF processes can result in certain defects in the surface quality of the deformed sheet. The main concern in the surface quality of incrementally formed products is the occurrence of tearing of the sheet as a result of excessive wall thinning or large forming angles. The second experiment was executed two times to produce two different prototypes. The first prototype was stopped mid process as interference occurred and signs of workpiece failure could be noted. The prototype (*Ti 1*) can be seen in Figure 61 were signs of sheet tearing can be clearly seen.

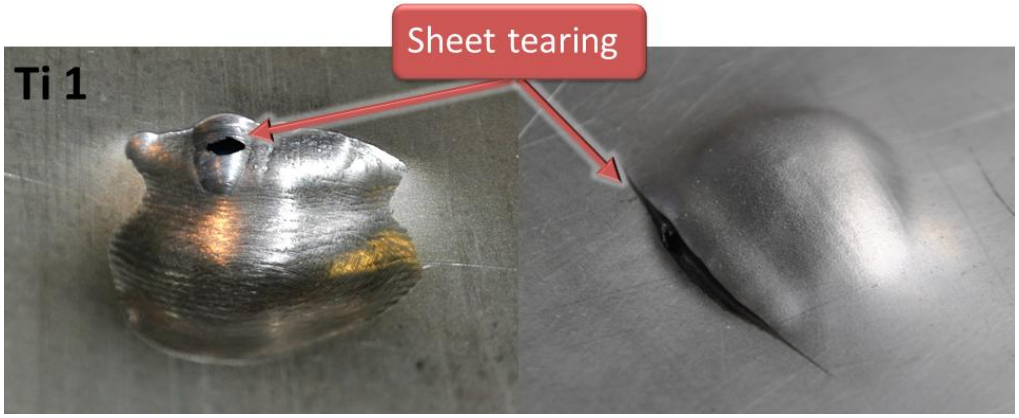


Figure 61: Signs of sheet tearing

This phenomenon can be caused by two different circumstances. The first possible reason is tearing as a result of sheet thinning. The second reason can be allocated towards shear of the sheet when the sheet is pressed on the backing plate. The reason for tearing can be allocated towards the latter rather than sheet thinning as the profile cuts can be clearly seen across the back of the plate as the forming tool pressed the sheet against the backing plate.

7.2 Geometry test results

The geometry test data was exported in data points describing a series of coordinates. Each test therefore produced two data sets for each specimen (one for the y-line, and one the x-line). By means of data analysis, various graphical representations could be obtained.

7.2.1 Repeatability of aluminium prototypes

The first four aluminium prototypes of the first experiment were each produced by means of different toolpaths and feedrates (see Table 8), but various process parameters (such as the CNC machine, backing plate, lubrication, and forming tool) was kept constant. Figure 62 depicts the change in process variables, and the resulting data sets for prototypes *Al 1 – Al 4* are shown in Figure 63:

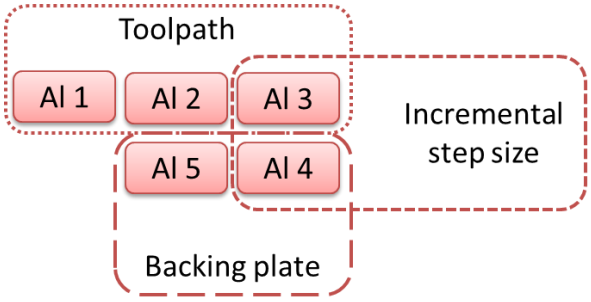


Figure 62: Changed process variables during the first experiment

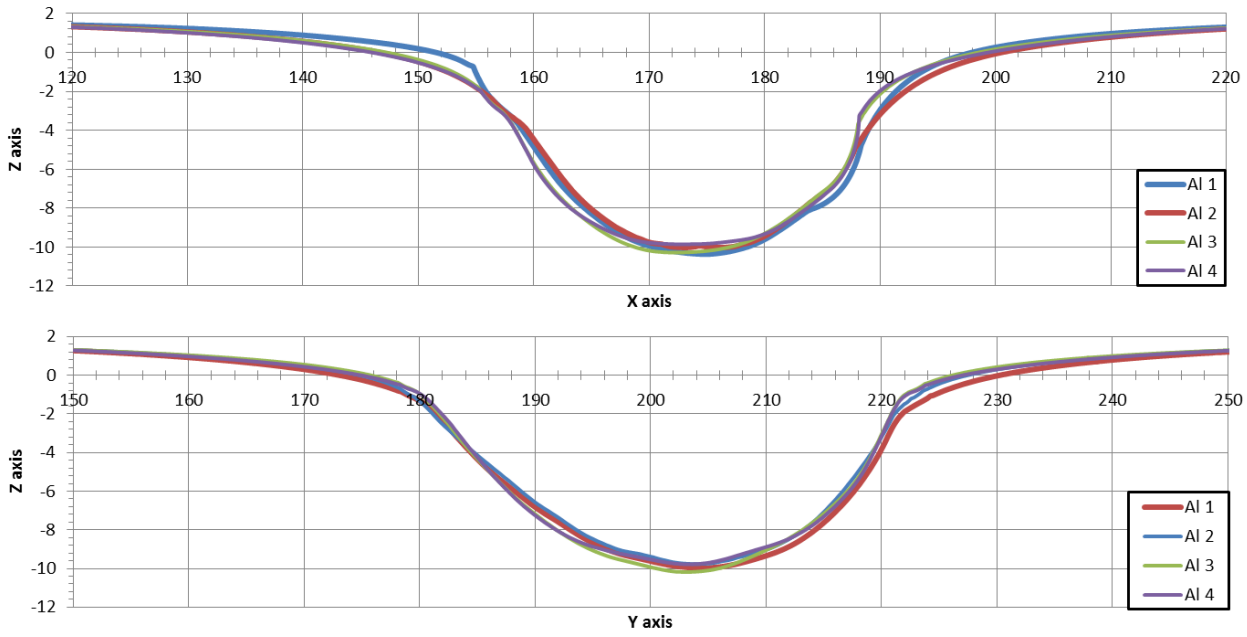


Figure 63: CMM geometrical repeatability tests

The results of the test were therefore used to determine the process repeatability of the SPIF process on aluminium sheets. The table of parameters shown in Table 8 describes the process variables (such as the lubricant, forming tool, backing plate, and CNC machine). The only process variables that was changed was the designed toolpath and incremental step size. Each of the lines represents the geometry of the formed prototypes of the first experiment, labelled *Al 1*, *Al 2*, *Al 3*, and *Al 4* and is compared on the same graph. The cross sectional areas shown in Figure 63 display the correlation in between the four aluminium based prototypes. The maximum depth achieved by the program is shown in Table 17:

Table 17: Maximum depth comparison of aluminium plates

Specimen	Maximum depth (mm)
Al 1	-11.8194
Al 2	-11.5144
Al 3	-11.7731
Al 4	-11.3180

The difference in end-product geometry of the first four aluminium prototypes is found to have a maximum variance in depth of 4.24% (comparison between *Al 1* and *Al 4*).

The change in toolpath strategy therefore does not have a significant effect on the final part geometry, as proven by the geometric analysis of *Al 1 – Al 3* (see Figure 63). In an attempt to examine the effect on the change in process formability, the fourth run was implemented by changing only the incremental step size while all other process parameters were kept constant. The end result of the fourth aluminium prototype resulted in the successful forming of the part. This data correlates with the findings of Ham and Jeswiet that the change in step size has little effect on the overall formability of a part[86].

7.2.2 Geometric results of experiment 2

The second experiment resulted in two different parts that was formed. The result of the first run, Ti 1 (see Figure 61) was stopped before the program was completed, and the second run, Ti 2 was completed successfully. The cross sectional views of the formed parts are shown in Figure 58, and the dotted line represents the lower section of the desired CAD geometry.

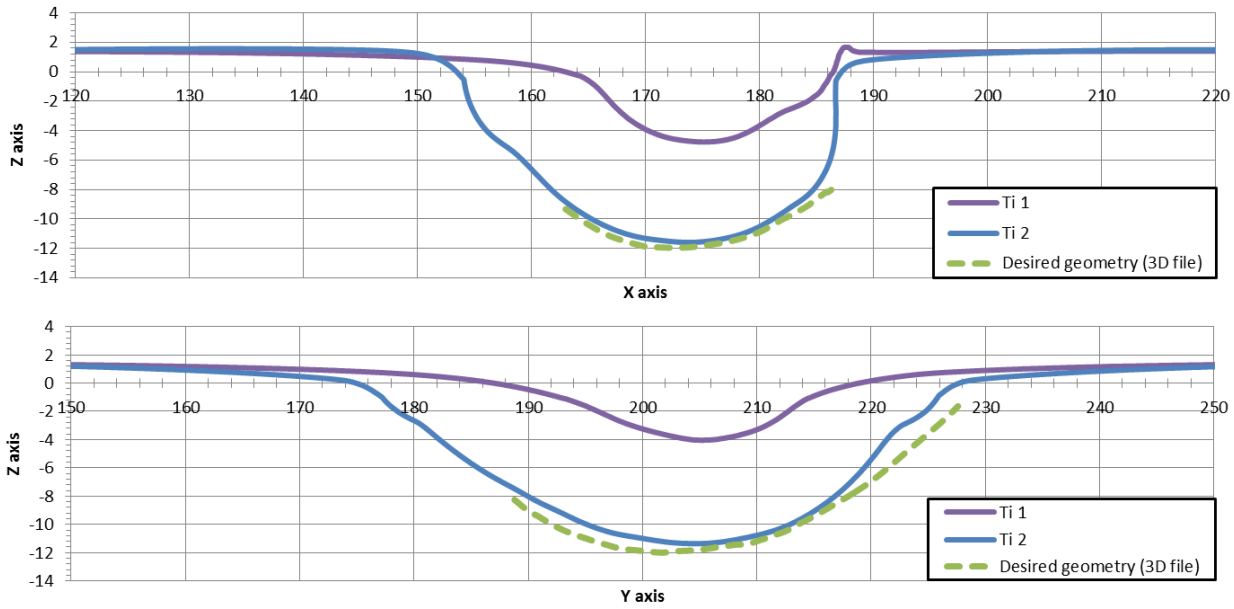


Figure 64: CMM geometrical data of the titanium prototypes

7.2.3 The effect of implementing a profile-specific backing plate

A final experiment was performed by implementing the customised backing plate to the experimental setup of the first experiment, to perform the procedure on an aluminium based workpiece. The results could then be used for the comparison of the newly formed prototype to its predecessors. Geometric accuracy tests could then be performed to assess the change in formability as a result of implementing a backing plate. The second set of profile graphs are used to compare two different

plots. The first plot ("*Average Al 1 – Al 4*") represents the average end-product geometry obtained with the use of a standard Ø70mm allowance backing plate. The second plot ("*Al 5*") represents the end-product geometry obtained with the implementation of a profile-specific backing plate. This cross section clearly illustrates the improvement in both forming angle acquisition as well as the improvement in final depth achieved by the plot.

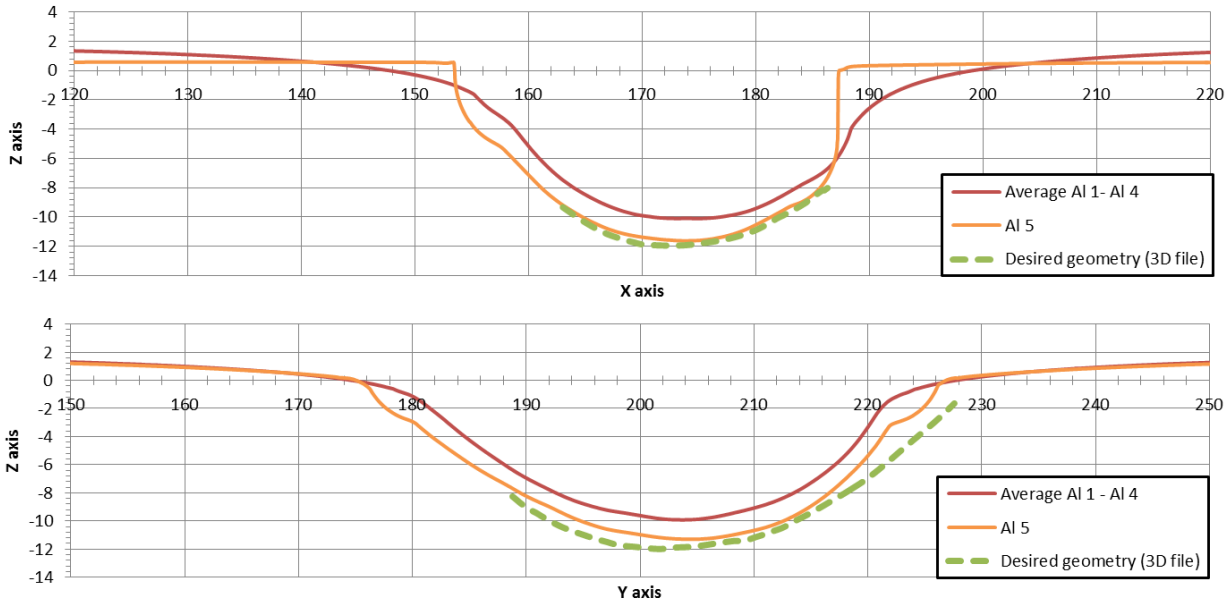


Figure 65: The effect of implementing a profile-specific backing plate

7.2.4 Comparison of final aluminium to titanium prototypes

The final pair of graphs is used to illustrate two aspects of the experimental research. Here, the final prototypes of each base material are displayed after both datasets have been placed on the same external reference points. Aluminium is considered as more ductile, which in turn results in better formability, but is not suitable for biomedical implant use, which leads to the comparison of aluminium to titanium.

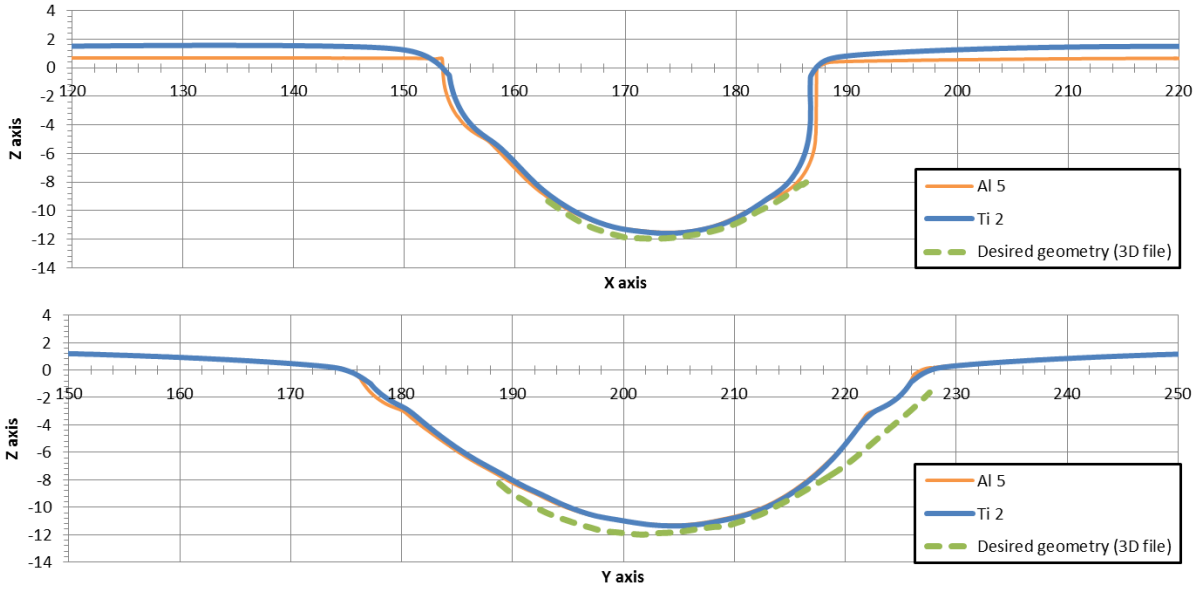


Figure 66: Comparison of the aluminium and titanium prototypes

The top graph indicates that the aluminium prototype is capable of maintaining larger angles at the external boundaries of the toolpath (x = 153mm; x = 187mm). The maximum depth achieved from the aluminium prototype did not differ from the titanium significantly. The effect of springback in titanium products can clearly be seen in the top graph, as the end shape geometry seems slightly scaled down when compared to the aluminium prototype (*AL 5*). The springback in the titanium sheets can be allocated towards the internal stress that is maintained after the forming process. Inspection of the bottom graph of Figure 66 indicates that the aluminium geometry, when placed on the same external reference points, display very close coherence to the final titanium prototype.

7.2.5 Data analysis

Data analysis was performed on the prototypes to obtain information regarding the formability of the process performed. The datasets obtained from the geometrical data was used for the identification of the maximum forming angle achieved, maximum depth and springback of the parts when the final geometry is compared to the desired part.

Formability increase by implementation of a profile-specific backing plate

Formability of the end product is most commonly determined by the draw angle that can be obtained by the forming process[51, 66, 86, 45]. The draw angle is computed by obtaining the angle between two measured coordinates of each data set. The equation for determining the draw angle, φ, is shown in Equation 3:

$$\varphi = Arctan\left(\frac{y_{n+1}-y_n}{x_{n+1}-x_n}\right) \quad (4)$$

The draw angle is determined to document the improvement of implementing a profile-specific backing plate (used to form *Al 5* and *Ti 2*). The maximum draw angle is then compared to illuminate any increase in process formability. The maximum draw angle for the three data sets, as calculated using Equation 3 is shown in Table 18. The second aspect of formability investigation is the effect of springback for each prototype. Springback, as discussed in Section 2.5, can occur as a result of elastic recovery to the plastically formed part geometry. The depth error is calculated to display the degree of divergence obtained by the formed parts to the original (desired) CAD design depth. The maximum error depth is calculated by comparing the coordinates of the maximum depth obtained to the desired depth of the CAD file, using Equation 4:

$$e_{\max\ dept\ h} = \left(\frac{d_{max\ ,CAD} - d_{max\ ,actual}}{d_{max\ ,CAD}}\right) \quad (5)$$

The maximum depth of each prototype is therefore compared to the desired 3D CAD geometry, and the maximum depth error is shown in Table 18:

Table 18: Maximum draw angle obtained by the formed prototypes

Prototype	Maximum draw angle, φ_{max}	Maximum depth	%error
Average AL 1 - Al 4	67.892°	-10.106mm	14.68%
Al 5	89.717°	-11.518mm	3.34%
Ti 2	89.835°	-11.590mm	2.75%

Table 18 indicates the increase in both maximum draw angle (φ_{max}) as well as maximum depth (d_{max}) as a result of the implementation of a profile-specific backing plate. The aluminium prototype that utilised a profile-specific backing plate obtained an increase of 24.33% in maximum draw angle and an increase of 12.26% increase in maximum depth.

7.3 Microscopic analysis

Microscopic analysis was performed after the completion of the experiments to provide more depth into the forming process. Images were obtained to assess the surface quality of the forming tool for any signs of wear. Table 19 provides a brief summary of the composition and conditions that the specimens have undergone.

Table 19: Tool surface contact conditions

Specimen	Utilisation	Tool material	Workpiece material	Lubricant
1	Unused	Ti-6Al-4V	-	-
2	Experiment 1	Mild steel	Aluminium (AA1200H4)	Rocol RTD liquid
3	Experiment 2	K110 tooling steel	Titanium (CP Ti Grade 2)	MoS_2

The first microscopic sample is taken and used as a reference to be compared to the following used samples. The first sample (see Figure 67) is unused and displays the tool without any surface damage.

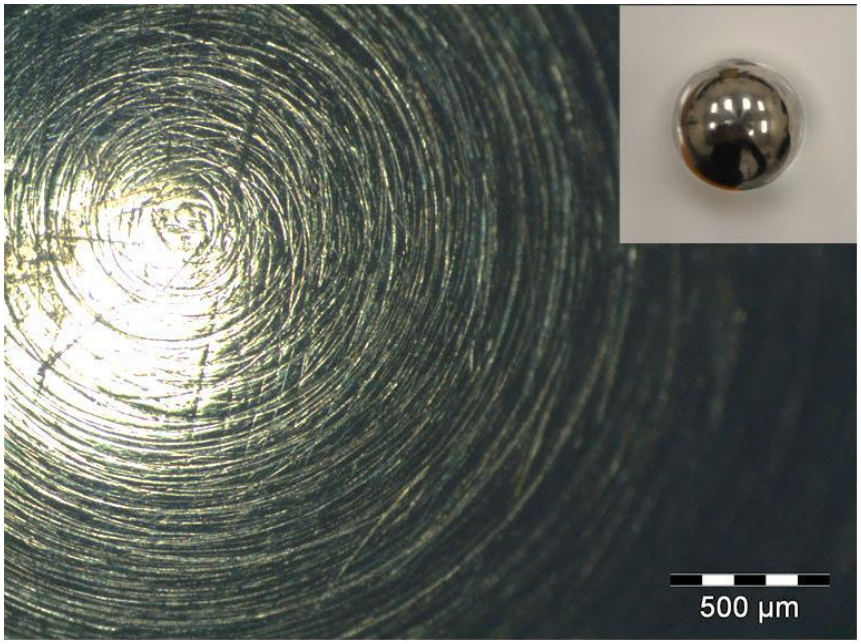


Figure 67: Enhanced microscopic imaging of the unused tooltip surface

The second image displays the surface of the forming tool used for the first experiment. The tool is manufactured from mild steel. The friction conditions therefore involve the contact of untreated mild steel with AA1200 aluminium sheets. Visual inspection only indicated minimal signs of tool wear the contact surface of the tooltip as the AA1200 aluminium sheets are considered very malleable and relatively soft compared to other metal alloys. The enhanced imaging is shown in Figure 68.

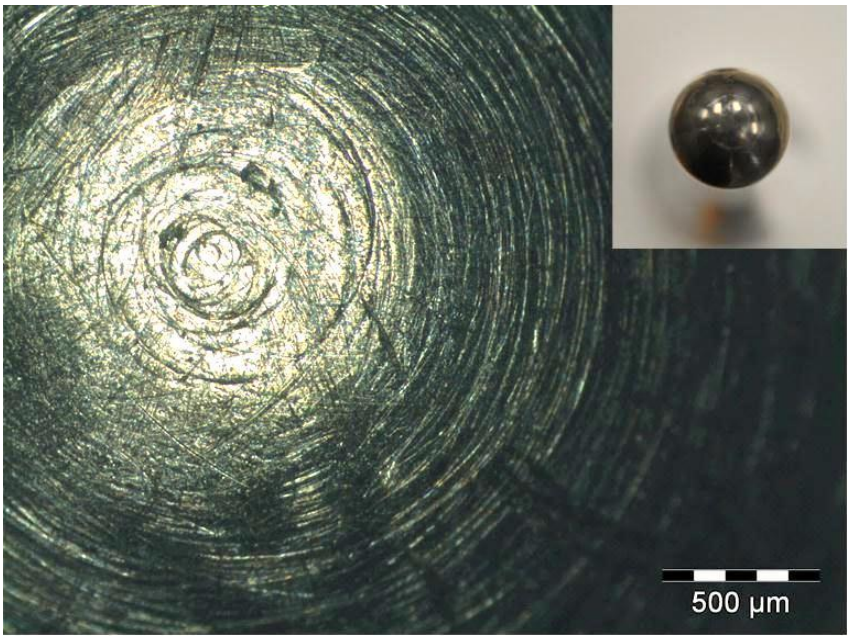


Figure 68: Enhanced microscopic imaging of the mild steel tooltip (Experiment 1)

The signs of wear on the contact area of the mild steel tooltip can be seen in the form of wear scarring on the tooltip surface. This is due to the fact that mild steel is considered to have a softer surface, making it more susceptible to surface damage. The surface damage is however of low severity, and can be reused for the forming of future projects.

The final specimen that underwent analysis was the K110 tooling steel forming tool used in the second experiment. The tooltip seen in Figure 69 is shown after it has been used in experiment 2. The tool was used to from commercially pure titanium grade 2, a softer grade having a lower modulus of elasticity and higher elongation in comparison to grade 4 or 5[8].

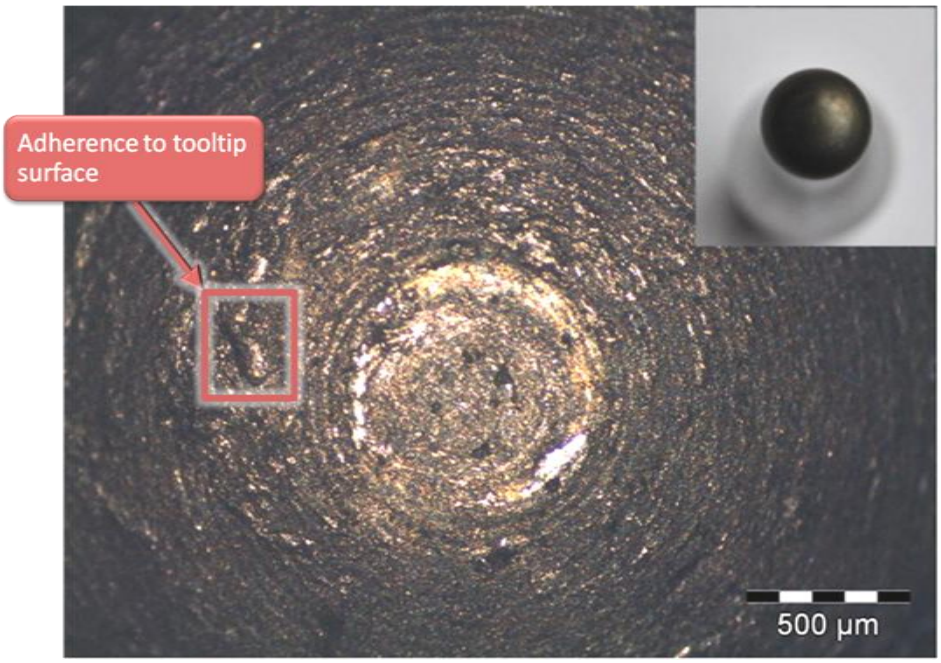


Figure 69: Enhanced microscopic imaging of the K110 tooltip (Experiment 2)

For this instance, there existed almost no signs of wear scarring or tool degradation. The optically enhanced image (seen in Figure 69) revealed deposits on the tool surface itself. The composition of the deposits could not be identified using the equipment made available. Comparison to experiments performed by Hussain et al. and Jeswiet et al. [58, 9] indicated that similar tests proved that titanium from the workpiece is deposited on the tool surface. Further surface analysis of the tooltips can be performed using a Scanning Electron Microscope (SEM) that is equipped with an Energy Dispersive Spectrometer (EDS). This process can identify the percentage of titanium deposited on the tooltip surface. Traces of titanium deposits on the tool surface are few but can be identified by means of comparison to specimens of Hussain et al. having large titanium deposits[58]. The tool can therefore be reused for future ISF experimentation.

8 CONCLUSIONS AND RECOMMENDATIONS

This study was conducted in response to a need that could be met by means of two aspects. The first aspect proposes a surgical methodology capable of using patient-specific implants, reducing trauma and patient recovery time. The second aspect proposes a forming method capable of forming intricate geometries and reducing time and production cost. The above mentioned information initialised a research question concerning the manufacturing of patient-specific arthroplasty implants: "*Is it possible to produce titanium based knee implants using Single Point Incremental Forming (SPIF) as a forming technique?*"

The research question was solved by compiling a set of sub questions to solve the main research question. Each sub question will be discussed as part of the conclusion to be able to fully answer the main research question.

This study proposed and validated a process chain (in Section **Error! Reference source not found.**) that enables the design and manufacture of a patient-specific unicompartmental biomedical knee implant using the ISF process. The process chain utilised technologies regarding Reverse Engineering, CAD software, and Rapid Prototyping for the validation of the procedure. The process chain placed focus on the engineering aspects of the design and development of these implants by producing a proof of concept using the ISF process. It can therefore be noted that a valid process chain can be developed to produce incrementally formed titanium knee implants.

The certain sub processes of the process chain including the data acquisition and data transformation can be considered as processes already validated in their own fields. The process of producing a proof of concept is considered as a novel and completely unique research area. A proof of concept in this research is presented as the production of the proposed biomedical implant in Section 5. This segment of the research provided empirical results, and implant prototypes were produced in both aluminium and titanium. The research did not only focus on the application of the forming method ("ISF in the biomedical sector"), but on the improvement of the IF process as well.

A final step of the manufacturing experiments was the testing and data validation of the completed prototypes. The main focus area of the objective output was the formability of the process. Geometrical tests was therefore initialised on the completed parts using a CMM to compare end product geometries and document changes in process variables such as tool path or incremental step size as well as document any findings of process improvements (see Section 5.7).

The results of the manufacturing experiments performed are documented in Section 7. The third sub question is answered as observations were made using various analysis methods. Certain forming defects was documented and analysed to discuss errors in the forming process. Geometric data was obtained using a CMM and analysed to compare all geometries of the aluminium and titanium prototypes to the desired CAD geometry. The effect of the process variables on the end-product geometry was documented, and the usage of a backing plate custom made for the profile that is

formed was implemented in the study. The application of a custom-made backing plate has not yet been documented by literature, and the change in process formability has been documented in Section 7.2.3. Further aspects of geometrical analysis determined the maximum forming angle and maximum depth achieved. The tooltip was observed using microscopic tests for signs of wear and tool failure. The fourth and fifth sub question can be solved by means of geometrical comparison.

3) The aluminium prototype, when compared to the titanium prototype, displayed a higher degree of formability as the titanium prototype underwent elastic springback after the part was formed. The process formability did therefore decrease slightly with the utilisation of a titanium based workpiece.
4) Geometrical analysis of the completed prototypes analysed the effect of implementing a custom made backing plate for the profile that is formed. The results documented in Table 18 indicated an increase in the maximum draw angle (φ_{max}) by 24.23% and an increase in maximum depth (d_{max}) by 12.26%. The implementation of a profile-specific backing plate will therefore improve the formability of a formed part.

An additional aspect of the process chain investigated the application of 3D printing in the proposed process chain. The manufacturing of a physical 3D representative model was documented, as this can be used as a surgical tool by the orthopaedic surgeon for both demonstrative purposes as well as a more realistic planning tool for the arthroplastic procedure. In answering the main question, with all sub questions answered, it is a feasible option to produce titanium based knee implants using SPIF as a forming technique.

An investigation concerning the commercialisation of a novel invention in the biomedical sector was conducted by documenting the process of a patent application procedure in Section 6.2. The utilisation of patent law is crucial for the protection of intellectual property of the inventor, and is therefore seen as a necessary factor in the commercialisation of the invention .The patent was registered under patent application number 2011/04960. The sub question could then be answered that the proposed invention is patentable.

A commercial viability study was performed on the implant design and development, as well as the surgical procedure. As the chosen manufacturing method is known for its commercial advantages is lower manufacturing costs, a cost model that depicts the complete cost of undergoing knee replacement surgery was compiled and compared to conventional knee replacement costs. The commercial feasibility of this project therefore determined that this project can in fact produce a cost effective solution to knee replacement surgery. The incorporation of a Discounted Cash Flow (DCF) method was used to obtain the Net Present Value (NPV) of a five year project. A scenario was generated that indicated a positive NPV even if only 200 units were sold annually. This is an indication that the invention is economically viable as an investment when implemented into the biomedical sector.

The total costs of knee replacement surgery are also considered. Table 16 documents the costs involved for total and partial knee replacement surgery, and compares this cost to the projected cost of implementing this device. This table illustrates the reduction in overall costs when the proposed product is compared to conventional arthroplasty. The projected cost indicated overall cost reductions of 45.14% (R 59 676.33 savings) when compared to total knee replacement, and up to 24.86% (R24 000 savings) when the cost of the proposed product is compared to current partial knee arthroplasty.

8.1 Future work and recommendations

The implementation of a biomedical implant in the medical sector comprises a vast area of required research. The successful implementation of this invention in the biomedical sector has only been initialized, and a large portion of future work is still required for the completion of a project this great. The following section discusses some possibilities of future work to either improve on certain aspects or continue research on the further development of this project.

8.1.1 Process chain

The developed process chain is used in this project for the medical imaging, implant design and manufacture. Certain aspects of the process chain can however be altered or slightly adapted for different medical applications in other orthopaedic fields such as hip, or spine replacement surgery.

8.1.2 Implant design and validation

Improvements on the process chain can include the streamlining of the implant design process as a whole, that no technician is required for the design of the implant. The process of implant design can be improved by implementing a toolbox for surgeons to simply select the affected area to be resurfaced, followed by the export of a usable CAD format to be manufactured. The toolbox can be created with a Guided User Interface (GUI) using C++ with OpenGL software. This will enable the surgeons to apply medical experience to the implant design aspect. Further aspects such as the resurfacing of the patella or the addition of a tibial implant can also be designed to be implemented with the titanium implant if necessary. An additional aspect of implant design improvement involves the steps of biomechanical testing of the prototype for aspects such as fatigue, load distribution and wear by performing these tests on a cadaver leg.

The final step of the implant approval is the implementation of clinical studies as part of MIS medical research. The clinical studies will form part of a more extensive research program, and will have to adhere and pass regulation according to the Food and Drug Administration (FDA).

8.1.3 Improvements on the ISF process

Improvements on the manufacturability of the implants are recommended, as this segment of the process chain can still be improved. Improvements to the dimensional accuracy of the end-product can be improved, to reduce forming errors. A secondary aspect of process improvement can be made by applying a five-axis rather than the traditional three-axis CNC machine. The process formability, as well as other improvements, listed in Section 2.6 can be made to the process by applying more advanced technology to the manufacturing of the implants. The study on surface quality of the implant on both the outer surface, as well as the inner surface (in contact with the tooltip) can be researched as well. The presence of scallops on the inner surface can even prove useful as the possibility exists that a rougher surface can result in a better environment for bone growth and attachment to the implant.

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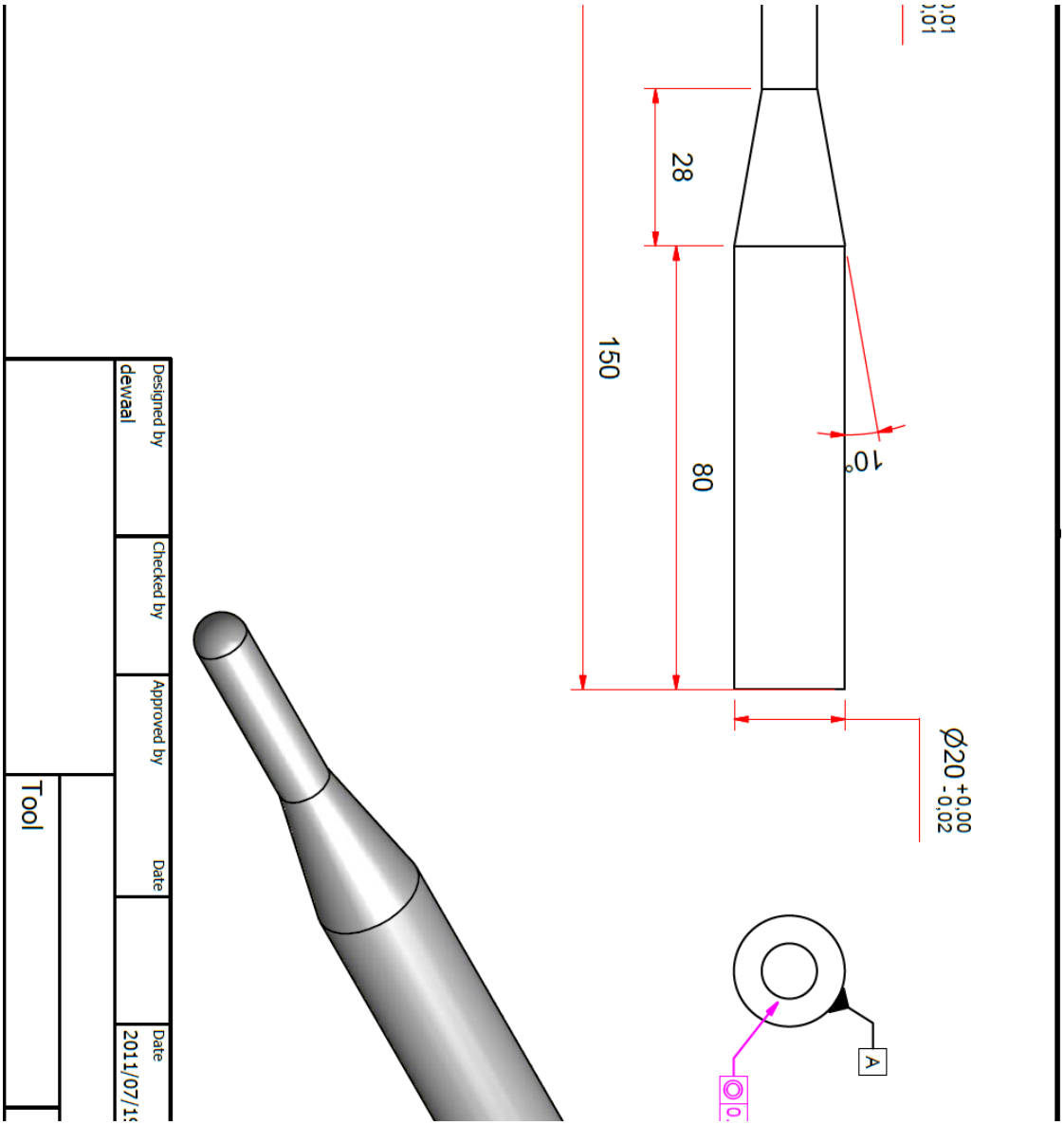
APPENDIX A

Engineering drawing used for manufacture of the mild steel and tooling steel tools for the experiment:



APPENDIX B

Visual Basic program used in inventor to export data points

```
Sub ExportWorkpoints()


   Dim oDoc As PartDocument
   Set oDoc = ThisApplication.ActiveDocument
     Dim oDef As PartComponentDefinition
   Set oDef = oDoc.ComponentDefinition
     Dim oWorkpoints As WorkPoints
   Dim oWP As WorkPoint
   Dim oP As Point
     'Neem alle Workpoints van die model
   Set oWorkpoints = oDef.WorkPoints
        'Skep ‘n nuwe Excel workbook
   Dim oBook As Excel.Workbook
   Set oBook = Excel.Workbooks.Add()
   Dim oSheet As Excel.WorkSheet
   Set oSheet = oBook.ActiveSheet
     Dim nRow As Integer
   nRow = 1
        'Skryf coordinate in aparte kolomme, met een WorkPoint in elke ry
   For Each oWP In oWorkpoints
      Set oP = oWP.Point
      oSheet.Cells(nRow, 1) = oP.X
      oSheet.Cells(nRow, 2) = oP.Y
      oSheet.Cells(nRow, 3) = oP.Z
      nRow = nRow + 1
   Next
         oBook.SaveAs ("c:\CMM_3D_profilepoints.xls")


End Sub
```

APPENDIX C

Information sheet on commercially pure Titanium Grade 2

ALLOY Data

CP Titanium Grade 2

Type Analysis			
Carbon (Maximum)	0.10 %	**Titanium**	Balance
Nitrogen (Maximum)	0.03 %	**Iron (Maximum)**	0.30 %
Oxygen (Maximum)	0.250 %	**Hydrogen (Maximum)**	0.015 %
Other, Total (Maximum)	0.40 %		

*For ASTM B 348-99 Carbon = 0.08% maximum and ASTM F 67-95 = 0.1% maximum.
"Other, Each" = 0.1% maximum and "Other, Total" = 0.4% maximum values applicable for ASTM B 348-99 only.

General Information

Description

Pure titanium undergoes an allotropic transformation from the hexagonal close-packed alpha phase to the body-centered cubic beta phase at a temperature of 882.5°C(1620.5°F).

Commercially pure, or CP, titanium is unalloyed. At service temperature it consists of 100% hcp alpha phase. As a single-phase material, its properties are controlled by chemistry (iron and interstitial impurity elements) and grain size. CP Titanium is classified into Grades 1 through 4 depending on the yield strength and allowable levels of the elements iron, carbon, nitrogen, and oxygen. CP Ti Grade 2 has a minimum yield strength of 275 Mpa (40 ksi), and relatively low levels of impurity elements, which places it between Grades 1 and 3 in terms of strength.

Grade 2 is widely used because it combines excellent formability and moderate strength with superior corrosion resistance. This combination of properties makes CP Grade 2 titanium a candidate for a large variety of chemical and marine as well as aerospace and medical applications.

Applications

CP Titanium Grade 2 may be considered in any application where formability and corrosion resistance are important, and strength requirements are moderate. Some examples of aerospace applications have included airframe skins in "warm" areas, ductwork, brackets, and galley equipment. CP Ti Grade 2 has also been widely used in marine and chemical applications such as condensers, evaporators, reaction vessels for chemical processing, tubing and tube headers in desalinization plants, and cryogenic vessels. Other uses have included items such as jigs, baskets, cathodes and starter-sheet blanks for the electroplating industry, and a variety of medical applications.

Corrosion Resistance

The corrosion resistance of CP Ti Grade 2 is based on the presence of a stable, continuous, tightly adherent oxide layer. This layer forms spontaneously and immediately upon exposure to oxygen. If damaged, it re-forms readily as long as there is some source of oxygen (air or moisture) in the environment. In general, the higher the purity of CP Ti, the greater the corrosion resistance. CP Ti Grade 2, with its relatively low impurity levels, has been widely used because it is capable of performing well in many corrosion-critical applications such as marine environments and chemical processing. In seawater, it is fully resistant to corrosion at temperatures up to 315°C (600°F). The possibility of crevice corrosion must be considered, however, and components appropriately designed to avoid tight crevices.

CP Ti Grade 2 is highly resistant to many chemical environments including oxidizing media, alkaline media, organic compounds and acids, aqueous salt solutions, and wet or dry hot gases. It also has sufficient corrosion resistance in liquid metals, nitric acid, mildly reducing acids, and wet chlorine or bromine gas (as long as a minimal amount of oxygen or water is present).

Conditions under which CP Ti Grade 2 is susceptible to corrosion are strongly reducing acids, alkaline peroxide solutions, and molten chloride salts. Crevice corrosion can occur in hot halide or sulfate solutions (>1000 ppm at 75°C or higher), which can be a consideration in marine applications.

CP Ti Grade 2 is fully resistant to stress-corrosion cracking (SCC) in aqueous solutions, and is largely immune to SCC in general. Conditions under which CP Ti Grade 2 is susceptible to SCC include anhydrous methanol or methanol/halide solutions, red fuming nitric acid, nitrous oxide, liquid or solid cadmium and liquid mercury.

CP Grade 2 titanium is susceptible to hydrogen embrittlement due to the formation of hydrides. Specifications for CP Ti Grade 2 mill products typically specify a maximum hydrogen limit of 150 ppm, but it is possible for degradation to occur at lower levels, especially in the presence of a notch. The presence of a notch or other stress raiser increases the detrimental effect, as hydrogen migrates to the notch area, raising the local concentration of hydrides. It is important to minimize hydrogen pickup during processing, particularly heat treating and acid pickling.

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APPENDIX D

Approval letter of the Journal of New Generation Sciences

Central University of Technology, Free State

JOURNAL FOR NEW GENERATION SCIENCES

REF: JNGS 2013.04

2013-01-25

Mr D Eksteen
Industrial Engineering Department
University of Stellenbosch
dowaal@sun.ac.za

Dear Colleague

RE: ARTICLE SUBMISSION TO JOURNAL FOR NEW GENERATION SCIENCES (JNGS)

1. Many thanks for the submission of your article *"Incremental Sheet Forming: Formability Increase by Means of Profile-Specific Backing Plates"* to the JNGS.
2. The article will now be submitted to the editorial team and to the peer reviewers.
3. The editorial team normally allows 6-8 months for the administrative and review process where-after you will be informed as to the publication possibilities of the article.
4. Please note that due to the high volume of articles submitted for publication, **publication** of articles can take up to 12-18 months since submission.
5. Kindly note that the Editorial Board only corresponds with the corresponding author.
6. Should you have any queries please contact me at any time.

Kind regards

PROF. LAETUS O.K. LATEGAN
EDITOR: JOURNAL FOR NEW GENERATION SCIENCES

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