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The use of single point incremental forming for customized implants of unicondylar knee arthroplasty: a review

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Abstract **Introduction**: The implantable devices are having enormous market. These products are basically made by traditional manufacturing process, but for the custom-made implants Incremental Sheet Forming is a paramount alternative. Single Point Incremental Forming (SPIF) is a manufacturing process to form intricate, asymmetrical components. It forms the component using stretching and bending by maintaining materials crystal structure. SPIF process can be performed using conventional Computer Numerical Control (CNC) milling machine. **Review**: This review paper elaborates the various manufacturing processes carried on various biocompatible metallic and nonmetallic customised implantable devices. **Conclusion**: Ti-6Al-4V alloy is broadly used for biomedical implants, but in this alloy, Vanadium is toxic so this alloy is not compatible for implants. The attention of researchers is towards the non toxic and suitable biocompatible materials. For this reason, a novel approach was developed in order to enhance the mechanical properties of this material. The development of incremental forming technique can improve the formability of existing alloys and may meet the current strict requirements for performance of dies and punches.

Keywords: Single Point Incremental Forming (SPIF), Unicondylar knee arthroplasty, Custom implants, Biocompatible material.

Introduction

In the recent years, the biomedical sector has seen a phenomenal growth, among other reasons, because of the higher wealth of people. Therefore, medical prosthesis for bone replacement products has enormous market (Fiorentino et al., 2011). Manufacturing process by which the bio implants are manufactured is, generally by the deep drawing, grinding, molding or hydroforming, etc. These processes are costlier as well as time consuming. For each of these processes there is a necessity of manufacturing new set of active tools, dies, punch, etc. Today there are many processes based on the local deformation of metal sheet enabling the flexible production of complex parts. More recently, a new metal forming process was invented, such as the Incremental Sheet Forming (ISF) process, which eliminates this limitation. Incremental sheet forming (ISF) is a forming method capable of forming intricate, asymmetrical components as a result of highly localized deformations. The ISF process forms the component using stretching and bending while maintaining the material's crystal structure. The process can be performed using any 3-axis (and higher) Computer Numeric Controlled (CNC) machine, making it highly available and cost effective to the manufacturing industry (Araújo et al., 2013; Blaga, 2011; Castelan et al., 2009, 2014; Daleffe et al., 2013; Duflou et al., 2013; Eksteen and Van der Merwe, 2012; Henrard, 2008).

Using ISF technique, the manufacturing of custom medical implants or devices is another field. In this field, with the help of Computer Tomography (CT) scan images of particular damaged restorative part are constructed digitally (Castelan et al., 2009; Joshi, 2011; Jun, 2011). The bio-model implants are physically constructed with the help of 3D Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) systems. The custom made biomodels are cost effective when these are modeled by ISF technique. Also this pre operative manufacturing is very useful to study and plan the surgery for achieving the expected proper results.

Orthopedic biomaterials play an important role for the biomedical implants for particular patients for improving the quality and expectancy of life. The biocompatible materials used for biomedical implants are titanium and its alloys, stainless steel, cobalt chromium, tantalum, polyethylene and zirconium alloys (Barbinta et al., 2013; Bonesmart, 2015. The titanium material is mostly used for implants. In spite of its high biocompatibility and low density, commercially pure titanium presents some disadvantages related to

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its low wear resistance. Ti6Al4V alloy is generally used for implants, but vanadium is toxic so this alloy is not compatible for biomedical implants. Studies was shown that both vanadium and aluminum ions released from Ti-6Al-4V alloy are toxic for human body, causing severe health problems, such as osteomalacia, Alzheimer disease (Barbinta et al., 2013). Titanium alloys corresponding to the Ti-Nb-Zr-Ta alloy, (Titanium, Niobium, Zirconium, Tantalum) composed of non-toxic elements, has attracted the attention of the researchers, because of their unique combination of properties, which make them potential candidates for medical applications in the orthopedic field, such as the new biocompatible titanium alloy Ti-25Nb-10Zr-8Ta, which is produced from pure metals (Ti, Nb, Zr and Ta).

These alloys show advantages involving flexibility and their applicability of the incremental forming process to produce small series, prototypes of sheet components and medical parts (customized implants). The process is developed at ambient temperature and requires a CNC milling machining center, a spherical tip tool and a simple structure to support and fix the sheet in place (Araújo et al., 2013; Daleffe et al., 2013; Eksteen and Van Der Merwe, 2012).

Literature Review

A literature review has been done on the most recent developments in the areas of incremental sheet forming and in the biomedical field focusing principally on biocompatible materials.

Morphological analysis of the human knee joint has been done in Republic of Korea for creating custom-made implant models and had as result a new methodology that creates a customized knee implant model by extracting typical 3-dimensional (3D) geometrical parameters of the knee (Jun, 2011). The feasibility and verification of a custom-made knee implant was described with case study. Also by using Computer Aided Design (CAD) 3D geometrical parameters of patient's knee bones was extracted. This was done to follow the nature of real surgical procedure, so that the procedures are familiar and helpful to the doctors. It indicates that the proposed system was applicable in the early stage of implant design process. The manufacturing of custom made-implants after Morphological analysis is required.

The manufacturing of titanium based plate implants in the bio-medical sector was done at University of Stellenbosch, South Africa (Eksteen and Van Der Merwe, 2012). This investigates the forming of bio-medical titanium plate implants for minimal invasive surgical procedures. It proposes a customizable process chain capability for the production of patient-specific bio-medical implants of titanium using the incremental forming technology. Biocompatible commercially pure titanium material has low density material and its lifetime is only 15-20 years, thus significantly less than Ti-Ta alloy.

In current surgical methodology, surgeons choose a standard design of implant based on the measurement of a patient's morphological aspects from x-ray images for the traditional surgical implementation of knee replacement surgery (Eksteen and Van Der Merwe, 2012). The standard implants require interfering bone structures to be cut away using a series of different bone removal tools so that the implant would fit as shown in Figure 1 (Eksteen and Van Der Merwe, 2012). Due to the variation in morphological aspects of the human femur, complications can arise as the currently available mass manufactured implants offer limited ranges of geometry. But during the post-operational and recovery phases of surgery, pain and discomfort experienced by the patient is probably the main drawback of currently implemented knee replacement surgery. Traditional surgery causes damage to the cartilage (connective tissue) that should be unaffected; bone tissue as well as ligaments.

Current research on new surgical methodologies gives a solution on current surgical methodology. Reverse engineering of the human knee is a topic

Figure 1. Current (traditional) surgical methodology of implementation of standard size Total Knee Replacement (TKR) implants (Eksteen and Van der Merwe, 2012).

currently being researched. The implementation of reverse engineering enables the creation of implants custom-made for every patient as shown in Figure 2 (Eksteen and Van Der Merwe, 2012). Partial knee replacement surgery (unicondylar or unicompartmental) involves covering of affected part of femur (condyles). Benefit of partial replacement includes less post operative pain and faster recovery time. Mismatched or standard implants seen in Figure 1 (Eksteen and Van Der Merwe, 2012) require excessive removal of bone matter, and can often cause a severe balancing problem and short-term durability. Studies concerning the morphological analysis of the human knee joint are being performed for the purpose of creating custom-made implant models for Total Knee Replacement (TKR) applications based on the morphological data of every patient (Eksteen and Van Der Merwe, 2012).

The SPIF process was evaluated for producing titanium customized maxillofacial implants and demonstrated the role of this technology in manufacturing customized medical parts (Araújo et al., 2013). Maxillofacial implant operations are done in very rare cases i.e., in accidental and in implants of cancer patient. There is a research gap to go for another anatomical part.

The manufacturing of the custom-made cranial implants from Digital Image and Communications in Medicine (DICOM) images using 3D printing, CAD/CAM technology and incremental sheet forming was presented (Castelan et al., 2014). From CT images of a fractured skull, a CAD model of the skull (biomodel) and a restorative implant were constructed digitally. The biomodel was then physically constructed with 3D printing, and Incremental Sheet Forming (ISF) was used to manufacture the implant from a sheet of pure grade2 titanium. Before cutting the implant's final shape from a pre-formed sheet, heat treatment was performed to avoid deformations caused by residual stresses generated during the ISF process. In this research the biomaterial taken for manufacturing of skull was pure titanium; this material has low density and its lifetime is only 15-20 years. Heat treatment on formed sheet before cutting is beneficial to minimize the residual stresses.

Development of patient specific implants for Minimum Invasive Spine Surgeries (MISS) from non-invasive imaging techniques by reverse engineering and additive manufacturing techniques has been carried out (Chougule et al., 2014). Reverse engineering and rapid prototyping was extensively used technologies by both research and industrial community for rapid developments in various industrial as well as biomedical applications. But by the rapid prototyping technique the surface roughness of biomedical implants was extensively more.

Bioceramics (CoCr-PE) can also be used in total knee joint endoprostheses. Sintered bioceramics can be machined only by grinding and polishing processes (Denkena et al. 2013). The wear behavior of sample CoCr-PE implant pairs were tested. Due to high quality requirements, there are significant challenges with regard to these machining technologies. An automated precise economical process chain for the manufacturing of a new all-ceramic knee implant design was developed. It was assumed the geometrical accuracy and the shape of implant contact geometry specified during the manufacturing process has a substantial influence on the wear behavior of the prosthesis. The importance of the surface quality of the ceramic implant surface remains unclear and requires future examination. Also the time required for grinding and finishing is larger as compared to incremental forming.

Other researchers studied the use of Additive Manufacturing (AM) within orthopedic implant

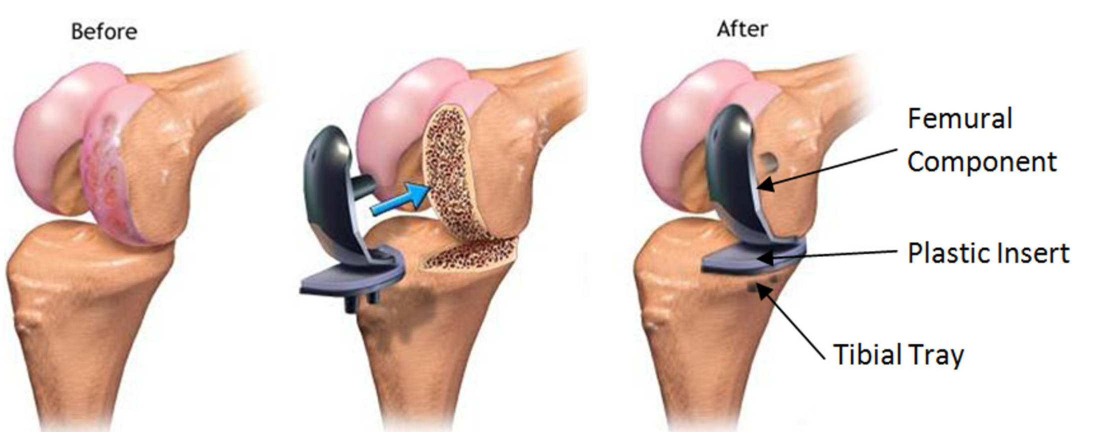

Figure 2. Unicondylar knee Arthroplasty using standard designs (Eksteen and Van der Merwe, 2012).

manufacturing, especially for the customization of implants (Cronskar, 2011). Customization of implants was done from Computer Tomography (CT) scan images and then these CT images are converted in to Stereolitography (STL) file. The .stl file is easily transferable between many software packages. The new orthopedic implant manufacturing process i.e., Additive manufacturing, particularly Electron Beam Melting (EBM) was used to manufacture hip stems and customized plates used in trauma surgery. This manufacturing technique is similar with RP and also takes more time for manufacturing as compared to ISF.

A highly automated CNC-RP for rapid prototyping was created for the manufacturing of bone implants (Joshi, 2011). This process begins CT imaging and results in the automatic generation of process plans for a subtractive RP System. Through RP process the surface of products are rougher, thus meeting a requirement that other manufacturing process do not achieve for customized biomedical implants.

Orthopedic products have been used in the recovery and rehabilitation of upper and lower limbs. The manufacturing of these products in a customized way was done through the use of incremental sheet forming (ISF). For the specific equipment and the process, the total cost incurred was USD 700 (Castelan et al., 2009). For economical reasons the ISF process is better for customized implants.

A systematic methodology for accurate manufacture of cranio-facial implants with large wall angles of milling tool has been described (Duflou et al., 2013). Three different materials, i.e., AA1050, AISI 304 and medical grade titanium were used. The number of case studies has been illustrated on these various materials to manufacture cranio-facial implant using Single Point Incremental Forming (SPIF).

A new biocompatible titanium-tantalum alloy Ti-25Nb-10Zr-8Ta was invented and produced from pure metals (Titanium Ti, Niobium Nb, Zirconium Zr and Tantalum Ta) using the vacuum induction melting method in a levitation furnace (Zhou et al., 2007). Microstructure and phase composition of the titanium alloy were investigated by Scanning Electron Microscopy (SEM) and X-Ray diffraction (XRD). The Ti-Ta alloys are more suitable than pure titanium for biomedical applications due to lower elastic modulus, higher strength and enhanced corrosion resistance. Due to improved quality and non toxicity this material is expected to be excellent for biomedical implants.

(Zhou et al., 2007) described the mechanical properties, corrosion resistance and biocompatibility of the titanium-tantalum alloys together with pure titanium, which was comparatively studied for biomedical applications. The experimental results confirm the previous theoretic investigation that tantalum has a potential to enhance the strength and reduce the elastic modulus of titanium alloys at the same time, and indicate that the titanium-tantalum alloys are more suitable than pure titanium for biomedical applications because of their lower elastic modulus, higher strength and enhanced corrosion resistance than pure titanium used as a standard metallic biomaterial, and the same excellent compatibility to pure titanium.

Another source described about various biocompatible materials for arthroplasty. The replacement knee joint is comprised of a flat metal plate and stem implanted in tibia, a polyethylene bearing surface and a contoured metal implant fit around the end of the femur as shown in Figure 2 (Bonesmart, 2015). The use of components fabricated from metals and polyethylene allows optimum articulation between the joint surfaces with little wear. Materials which can be used in knee implants are described as follows:

1. Stainless steel - Limited ability to withstand corrosion in human body so it is not often used.
2. Cobalt-Chromium alloys - This alloy contains nickel but some patients have allergic reaction to this alloy.
3. Titanium & Titanium alloys - Pure titanium is used where high strength is not necessary due to low density. Ti6Al4V alloy is generally used for the implants but vanadium and aluminum is toxic so this is also not suitable for biomedical implants.
4. Uncemented implants - Knee implants may be ‘cemented’ or ‘cementless’ depending on the type of fixation used to hold the implant in place. The majority of knee replacements are generally cemented into place. There are also implants designed to attach directly to the bone without the use of cement. The cementless designs rely on bone growth into the surface of the implant for fixation.
5. Tantalum – It is a type of pure metal, which has excellent biological and physical properties, namely flexibility, corrosion resistant and biocompatibility.
6. Polyethylene - The tibial and patellar components in knee replacements are made of polyethylene. This material is used where wear is maximum, for example, for the hip joint.
7. Zirconium & its alloys - Zirconium alloy is used in a new ceramic knee implant. The zirconium alloy is combined with an all-plastic tibial

component, replacing the metal tray and plastic insert used in other knee replacements. It is believed that this new knee implant could last for 20-25 years, substantially more than the 15-20 years that cobalt chromium alloy and polyethylene implants are effective. The new combination can be lubricated, which results in a smoother and easier articulation through plastic. Another important characteristic of this material is that it is biocompatible, meaning that people who have allergenic reactions to other metals cannot have knee implants fabricated with cobalt chromium alloy and nickel bearing stainless steel. Zirconium alloy implants eliminate the risk to nickel-allergic patients because this new material contains no nickel (Kanchana and Hussain, 2013).

Other researchers used ceramics among all biocompatible materials as advances in the properties and processing ease of these compounds broaden their uses. New generations of alumina-zirconia nano-composites are expected to see the strongest gains (The Freedonia..., 2006). These high density structures incorporated the greater resistance to cracking, an important advantage in orthopedic implants, fixation devices, and dental repair and restoration products.

The above literature is based on the applications of incremental forming technique for biomedical field and for biocompatible materials.

Conclusion

In this research a fairly complete and updated review about biomedical implants the maximum research has been written on some metallic and non metallic components produced by various manufacturing processes was presented. However, the time required for that forming process is somehow excessive and those implants are not customized for Arthroplasty patients. The research was oriented for developing processes that may enable the use of commercial alloys & biocompatible material for ISF. However, any breakthrough in the forming of sheet materials is more likely to come from the development of new alloys with very high formability that may allow the performance of this process with various strain rates. The development of incremental forming technique can improve the formability of existing alloys and may meet the current strict requirements for performance of dies and punches.

Another important observation is that there are many research opportunities for finite element analysis of forming technology that remains unexploited. Use of numerical analysis techniques has reduced the trial and error procedure followed earlier, thus allowing processing time reduction, cost reduction and enhancement of product quality.

It was observed that the zirconium-ceramic composite is a brittle material and very hard to form using incremental forming so this material requires further study. Ti-6Al-4V material is broadly used for biomedical implants, but vanadium is toxic, so this alloy will be not considered. For this reason, the Titanium-Tantalum alloy (Ti-25Nb-10Zr-8Ta) has very good chances of being used to form the unicondylar femural component by incremental forming process.

The biomedical implant components are radially manufactured by reverse engineering rapid prototyping technique. But the main limitations for wider application of this manufacturing procedure, so far, are: biological incompatibility of the existing materials used in RP processes; relatively high costs of model production; time and work intensive process to achieve an appropriate model quality (surface finish and anatomical accuracy). These disadvantages of RP may be overcome by Incremental forming Process.

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