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Application of Single Point Incremental Forming for Biomedical Implants: A Review

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***Abstract* — Single Point Incremental Forming (SPIF) is an advance, dieless sheet metal forming technique. The application of SPIF is to produce intricate, symmetric, small batch, custom made products of various shapes and dimensions. As compared to traditional metal forming techniques, SPIF is a best alternative to manufacture the custom made implants. SPIF also offers great flexibility and material formability.**

Biomedical implants are generally manufactured by various processes such as deep drawing, rapid prototyping, abrasive machining, grinding etc. These process having some disadvantages over SPIF process. In the paper described, the review of SPIF technology was applied to manufacture custom biomedical implants. The main objective of research was to concentrate on SPIF technology applications regarding biomedical field.

Keywords— Single Point Incremental Forming (SPIF), Biomedical Implants, Manufacturing Process.

I. INTRODUCTION

In the recent years the biomedical sector is increasing because of improved life style of the peoples. Some peoples are suffering from various bone diseases like arthritis. For this type of disease Arthroplasty is a best alternative. Arthroplasty makes use of biomedical implants and replacements to restore functionality of the joints. It is an elective procedure that is done to relieve pain and restore function to the joint after damage by arthritis or some other type of trauma. Biomedical engineering in arthroplasty is an ever increasing field of interest as a result of its innovative improvements to surgical quality [01]. Prosthesis is an artificial device used to replace missed human body Parts which can occur due to tumors, infections and fractures. Manufacturing thin walled customized prosthesis for each person, like in the case of skull or facial implants, is mostly performed by deep drawing, casting, additive machining or intra-operative manual dynamic mesh modeling [02]. But as compared to these implant manufacturing processes Single Point Incremental Forming (SPIF) process is a best alternative.

Metal forming is the backbone of modern manufacturing industry besides being a major industry in itself. Throughout the world, hundreds of million tons of metals go through metal forming processes every year. Besides, it fulfills a social cause by providing job opportunities to the millions of workers [03]. Incremental sheet forming (ISF) process is an advanced flexible manufacturing process to produce complex 3D products. In conventional forming process, the products are produced by dedicated tools, i.e. die and punch. However, ISF does not require any dedicated tool. ISF process is categorized by Single-Point Incremental Forming (SPIF) also known as Negative Dieless Forming, Two-Point Incremental Forming (TPIF) or Positive Dieless Forming and Hybrid Incremental Sheet Forming (HISF) [04].

Single point incremental forming (SPIF) is a new innovative and feasible solution for the rapid prototyping and the manufacturing of small batch sheet parts. Also feasible to manufacture customized prosthesis parts. The process is carried out at room temperature (cold forming) and requires a CNC multi axis (Five and more) machining centre, a spherical tip tool and a simple support to fix the sheet being formed [05].

II. LITERATURE REVIEW

Literature review has been made on the recent manufacturing technologies related to manufacturing of biomedical implants, focusing principally on Single Point Incremental Forming. The literature review is categorized according to the manufacturing process of implants.

A. Additive Manufacturing/ 3D Printing

3D printing, also known as additive manufacturing (AM), refers to various processes used to manufacture three-dimensional objects of bio implants. In 3D printing, successive layers of material are formed under computer control to create bio implants. These implants can be of almost any shape or geometry, and are produced from a 3D model or other electronic data source. There are some other techniques which encompass in 3D printing as rapid prototyping.

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 [06]. 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.

Other researchers studied the use of Additive Manufacturing (AM) within orthopedic implant manufacturing, especially for the customization of implants [07]. 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 [08].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.

But by the rapid prototyping technique the surface roughness of biomedical implants was extensively more. There are also limited biocompatible materials which are available in powder form for additive manufacturing. The bio implant sizes and manufacturing limitations are also should taken in to consideration while going for this additive manufacturing.

B. Grinding and Abresive Machining

In abrasive machining sintered bioceramics can be machined only by grinding and polishing processes. Bioceramics (CoCr-PE) can also be used in total knee joint endoprostheses [09].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 compare to incremental forming. Grinding machine feed size range is wide. Also it is not easy to get a fine final product and grinding efficiency is low.

C. Investment Casting

For dimensional accuracy of hip joint prepared by investment castings process using conventional wax and Acrylonitrile Butadiene Styrene (ABS) as pattern material [10]. Two controllable process variables namely: numbers of slurry layers and type of pattern material have been considered for comparison. An approach to model dimensional accuracy of hip joint has been proposed and applied. International Tolerance (IT) grade of cast components was tested and found acceptable as per ISO standard UNI EN 20286-I (1995) and further at proposed parametric settings, process has been found to be statistically controlled.

Production technology of knee joint replacement by using rapid prototyping technology has been carried out. The aim of the work was to outline the manufacturing technology intended for prototype production with the use of rapid prototyping and investment casting technology for use in orthopedics and the surgery of knee joint replacement [11]. The research results should make an effective contribution in the attempts to minimize the invasive surgical procedure, shorten the production time of knee joint replacement as well as reduce the cost. At present, the research is focused on the preparation of STL data from CT (Computed Tomography) and verification of the production technology of prototypes made using available RP technology and its evaluation. Fig. 1 shows wax pattern and metal custom knee implant.

Fig.1 (a) prototype of Wax Pattern for investment Casting (b) Prototype of a new metal knee joint replacement [11].

Investment castings require very long production-cycle times versus other casting processes. This process is expensive, is usually limited to small casting, and presents some difficulties where cores are involved. In casting various defects are unavoidable. Many of the advantages of the investment casting process can be achieved through other casting techniques if principles of thermal design and control are applied appropriately to existing processes that do not involve the shortcomings of investment castings.

D. Single Point Incremental Forming

Unlike many other sheet metal forming processes, incremental forming does not require any dedicated dies or punches to form a complex shape and is therefore well adapted to rapid prototyping, as confirmed by several authors [01][12-20]

The manufacturing of titanium_based plate implants in the bio-medical sector was done at University of Stellenbosch, South Africa [01]. Specially focusing on knee Arthroplasty implants manufactured using SPIF process. This also 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 as shown in fig 2.

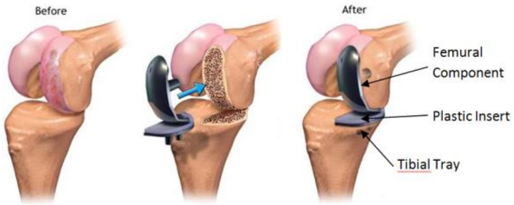

Fig. 2. Unicondylar knee Arthroplasty using standard designs [01]

Manufacturing of cranial implant by ISF using a biocompatible polymer was used to obtain real cranial geometry of a feasible prosthesis [12]. The real geometry of a cranial fracture was acquired from a computer tomography and treated until get a CAD model as shown in fig. 3. From it, the trajectories have been defined and the cranial geometry manufactured. However, to improve the accuracy it would be necessary to use a full negative die, hence shift into Two Point Incremental Forming. Moreover, several iterations involving the modification of the tool-path could be necessary. It is necessary to deeply characterize the material and to obtain knowledge about the polymer behavior under the ISF conditions. Furthermore, it was not only crucial to obtain a satisfactory dimensional accuracy; also the mechanical properties of the manufactured cranial implant should be tested in order to guarantee the biomechanical requirements.

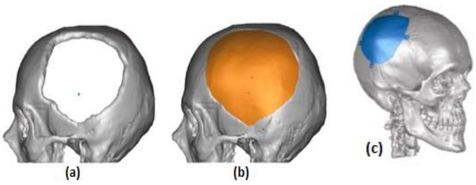

Fig. 3. (a) Damaged Skull (b) and (c) Cranial Constructed Geometry [12] [13]

Evaluation of SPIF process for producing titanium customized maxillofacial implants and demonstration of this technology in manufacturing customized medical parts had discussed [14]. However, this process is very promising to provide customized prosthesis for the medical area, as it allows manufacturing a product that perfect fit the patient. It was demonstrated that using an integrated methodology that uses medical images, 3D CAD models and a CNC machine enables the production of tailored titanium parts for the medical area.

The potential of SPIF for producing a customized maxillofacial implant has been evaluated [15]. Titanium (grade 2) was used for producing the implant and the corresponding mechanical characterization as well as the determination of the formability limits by necking and fracture was performed by combining classical sheet metal forming testing procedures with circle grid analysis. The finite element simulation of the process was performed by means of a numerical model developed by the authors and the predicted estimates of formability by two representative failure criteria were compared with the experimentally determined formability limits of the material. The correlation between the numerical estimates and experimentation is good both in the location and in the amount of vertical tool displacement.

This paper discusses the challenges associated with the manufacture of cranio-facial implants with extreme forming angles using medical grade titanium sheets [16]. While on one hand, the failure wall angle is an issue of concern, the parts also need to be manufactured with accuracy at the edges where the implants fit into the human body. Systematic steps taken to overcome these challenges, using intelligent intermediate part design, feature analysis and compensation, are discussed. A number of case studies illustrating the manufacture of accurate parts in aluminum, stainless steel and titanium grade-2 alloy were discussed.

Using the Double Side Incremental Forming (DSIF) process, a systematic approach has been developed in both geometric reconstruction and physical fabrication for cranial plate manufacturing [17]. By developing a NURBS based approximation method, the missing geometry of the defective skull can be reconstructed and the Grade 1 pure titanium cranial implant can be produced using the DSIF process. Based on the reconstructed cranial geometry, tool paths for DSIF processes can be generated by using different forming strategies including the peripheral and local supports. Experiments on cranial reconstruction 541 suggested that the peripheral support strategy could provide cranial plate with a better quality in both geometric accuracy and surface finish. The conclusions of this work may be summarized as follows:

- The developed surface approximation procedure including approximation of the construction curves and fitting of the NURBS based surfaces was proven to be a feasible approach in the geometric reconstruction of cranial shape.
- The peripheral support strategy was considered as a better option as compared to the local support in using DSIF to manufacture the cranial plate in terms of geometric accuracy, thickness distribution and surface finish.
- Double side increment forming could produce the cranial plates without using a backing plate, which suggested considerable benefits in the application of cranial reconstruction.

Orthopedic products have been used in the recovery and rehabilitation of upper and lower limbs [18]. 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. For economical reasons the ISF process is better for customized implants.

SPIF technology was applied for manufacturing of a denture base (framework) of a complete denture [19]. By applying reverse engineering, CAD and CAM techniques, product and process design is done in an easy and effective way as shown in fig. 4. The research included two base materials: low carbon steel EN DC04 and stainless steel EN X6Cr17. The main objective of the research was to compare the geometry of the denture base shaped by SPIF, with an existing denture base made by the lost wax technique. The denture bases were made from two different materials (carbon and stainless steel) with initial thickness of 1mm and 0.5mm, respectively. In both cases surface quality as well as dimensional accuracy were satisfied. Dimensional discrepancies, with respect to the original were less than 1mm. New procedure (SPIF technology) enabled additional mass reduction of the dental base (sheet thickness 0.5mm against the 0.8mm thickness of the original) which is highly desirable from viewpoint of patient and comfort of wear.

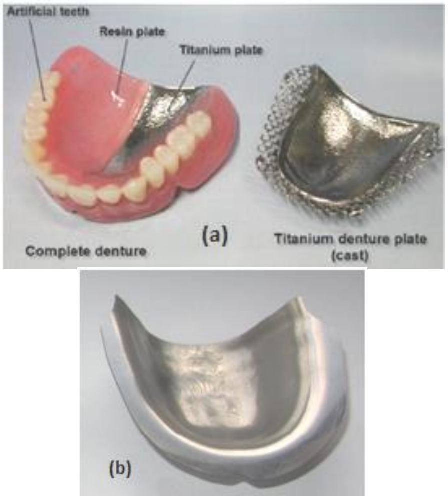

Fig.4 (a) Titanium denture plate manufactured by long casting procedure (b) Denture manufactured by SPIF process. [19]

The experimental research on the surface quality of the medical implants used for the partial resurfacing of the femoral condylar surface of the knee obtained by single point incremental forming process was discussed [20]. The present paper discusses the measuring of the roughness of parts obtained through the previously mentioned process and highlights the factors that influence it. The initial roughness of the punch, the punch diameter, and the friction coefficient between the punch and the blank were considered. Also, the mathematical models that define different roughness parameters were determined.

The overall summery of literature show that SPIF is an appropriate manufacturing process to fabricate medical implants. Future research work will focus on improving surface finishing and dimensional compliance of the final geometry. Different lubricants, feed rates, spindle speeds, step-downs feeds and biomaterials for the tool will be investigated as well as other methodologies based on multi-stage forming strategies and spring-back compensation procedures. Double side incremental forming (DSIF) procedures will also be considered.

III. CONCLUSION

Apart from various techniques used to manufacture biomedical orthopedic implants the SPIF is the best alternative. There are various advantages of SPIF over other manufacturing process are as follows.

- Customized implants having symmetric behavior can be manufactured with the help of SPIF process
- 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.
- For SPIF process no die is required as is in traditional sheet metal forming. The elimination of the die in the manufacturing process reduces the cost per piece.
- Several authors recognize that the formability of metal materials under the localized deformation imposed by incremental forming is better than in conventional deep drawing
- Beneficial for Minimal Invasive Surgery (MIS) implants. MIS Implants should cause the least amount of possible damage and discomfort to the patient during and after surgery

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