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Original Article

Implementation of Rapid Prototyping in Orthopaedic Implant and Analysis of Process Parameters

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Abstract: *The field of biomedical implants has experienced huge developments. Conventional methods of manufacturing are usually found unbefitting in fabricating complex geometries of biomedical implants. Newer and emerging technologies like additive manufacturing open wide scope by allowing complexity in geometry and huge reduction in manufacturing times. In this paper, we are going to design prosthesis for knee joint fracture as a CAD model and fabricate it by Additive manufacturing process (FDM) using Polycarbonate material which as used in many bio medical implants. It is necessary to change and improve existing technology and develop product with reasonably priced. So, it is necessary control the process parameter in any manufacturing process. An attempt is made to review the literature on optimizing the process parameters of rapid prototyping in orthopaedic implants. Optimization of process parameters and also need to determine which parameters are most significant for required output.*

Keywords: *Orthopaedic, Process Parameters, Polycarbonate Material.*

I. INTRODUCTION

3D Printing is a process for making a physical object from a three-dimensional digital model, typically by laying down many successive thin layers of a material. It brings a digital object (its CAD representation) into its physical form by adding layer by layer of materials.

There are several different techniques to 3D Print an object. We will go in further details later in the Guide. 3D Printing brings two fundamental innovations: the manipulation of objects in their digital format and the manufacturing of new shapes by addition of material.

Technology has affected recent human history probably more than any other field. Think of a light bulb, steam engine or, more latterly, cars and aeroplanes, not to mention the rise and rise of the World Wide Web. These technologies have made our lives better in many ways, opened up new avenues and possibilities, but usually it takes time, sometimes even decades, before the truly disruptive nature of the technology becomes apparent.

It is widely believed that 3D printing or additive manufacturing (AM) has the vast potential to become one of these technologies. 3D printing has now been covered across many television channels, in mainstream newspapers and across online resources. The most basic, differentiating principle behind 3D printing is that it is an additive manufacturing process. And this is indeed the key because 3D printing is a radically different manufacturing method based on advanced technology that builds up parts, additively, in layers at the sub mm scale. This is fundamentally different from any other existing traditional manufacturing techniques.

There are a number of limitations to traditional manufacturing, which has widely been based on human labour and made by hand ideology rooting back to the etymological origins of the French word for manufacturing itself. However, the world of manufacturing has changed, and automated processes such as machining, casting, forming and moulding are all (relatively) new, complex processes that require machines, computers and robot technology.

Knee replacement, also called knee arthroplasty or total knee replacement, is a surgical procedure to resurface a knee damaged by arthritis. Metal and plastic parts are used to cap the ends of the bones that form the knee joint, along with the kneecap. This surgery may be considered for someone who has severe arthritis or a severe knee injury.

Various types of arthritis may affect the knee joint. Osteoarthritis, a degenerative joint disease that affects mostly middle-aged and older adults, may cause the breakdown of joint cartilage and adjacent bone in the knees. Rheumatoid arthritis, which causes inflammation of the synovial membrane and results in excessive synovial fluid, can lead to pain and stiffness. Traumatic arthritis, arthritis due to injury, may cause damage to the cartilage of the knee.

The goal of knee replacement surgery is to resurface the parts of the knee joint that have been damaged and to relieve knee pain that cannot be controlled by other treatments.

II. LITERATURE SURVEY

Bing Qiu, Fei Liu, Bensen Tang, Biyong Deng, Fang Liu of Department of Joint, Guizhou Orthopaedic Hospital, Guiyang, China proposed a paper on "**Clinical Study of 3D Imaging and 3D Printing Technique for Patient-Specific Instrumentation in Total Knee Arthroplasty"** in which they stated Patient-specific instrumentation (PSI) was designed to improve the accuracy of preoperative planning and postoperative prosthesis positioning in total knee arthroplasty (TKA). However, better understanding needs to be achieved due to the subtle nature of the PSI systems. In this study, 3D printing technique based on the image data of computed tomography (CT) has been utilized for optimal controlling of the surgical parameters. Two groups of TKA cases have been randomly selected as PSI group and control group with no significant difference of age and sex ($p > 0.05$).

S. P. Krishnan, et al **review of rapid prototyped surgical guides for patient-specific total knee replacement**. In that Improvements in the surgical technique of total knee replacement (TKR) are continually being sought. There has recently been interest in three-dimensional (3D) pre-operative planning using magnetic resonance imaging (MRI) and CT. The 3D images are increasingly used for the production of patient-specific models, surgical guides and custom-made implants for TKR.

Hitesh Lal, Mohit Kumar, Patralekh - **et al** stated that With rapid emergence of 3D printing technology, surgeons have recently started to apply this for nearly all areas of orthopaedic trauma surgery. Computed tomography or magnetic resonance images of trauma patients can be utilized for making graspable objects from 3D reconstructed images.

Gareth G. Jones et al describes the concept of detailed UKA planning in 3D, and the 3D printing technology that enables a plan to be delivered intraoperatively using patient-specific instrumentation (PSI).The varying guide designs that enable accurate registration are discussed and described. The system accuracy is reported.Future studies need to ascertain whether accuracy for low-volume surgeons can be delivered in the operating theatre using PSI, and reflected in improved patient reported outcome measures, and lower revision rates.

Swathi Harish, et al present work, tibial spacer of bio-compatible material Poly Carbonate-ISO (PC-ISO) has been fabricated using Fused Deposition Modeling (FDM) process. Wear and strength analysis of the fabricated components were performed to understand the behaviour of the material. The manufacturing time of the spacer was lesser than conventional processes and it also exhibited higher hardness and higher resistance to wear than the commonly used material Ultra High Molecular Weight Poly Ethylene (UHMWPE). The experimental test results were well within the limits of knee implant requirements. The surface roughness value of the spacer was found to be within the satisfactory range required for the knee mechanics.

Knee replacement surgery is usually performed on patients aged around 55 or above, after years of enduring knee pain followed by limited mobility. Also known as arthroplasty, total knee replacement surgery is among the most common joint surgeries in the world. It allows patients to not only get rid of knee pain caused by arthritis, injury, or some other joint disease or trauma but also improves mobility. Many prospective candidates for surgery are curious to know about knee replacement surgery cost. In India, the average knee replacement surgery cost ranges from ₹1.5 lakh to ₹2.3 lakh, according to a report by The Hindu. Since the government placed a cap on knee implant prices, knee replacement surgery cost has reduced drastically and the procedure now become more affordable. Apart from the cost of implants, the knee replacement surgery cost also depends on the hospital charges and the fee charged by the surgeon.

During the surgery, the orthopedic surgeon replaces the damaged part of the knee with an artificial part made of metal or plastic. The artificial joint is then attached to the thigh bone, shin and kneecap with a special material called the acrylic cement. A total knee replacement usually requires between one and a half to three hours of operative time. Post-surgery, it generally takes 8-12 weeks to complete the rehab process and start returning to the pre-surgery daily regime.

III. MATERIAL AND PROCESS SELECTION

A. Ultra High Molecular Weight Polyethylene

Medical-grade polyethylene (UHMWPE with an average molecular mass of >2,000,000 a.m.u.) is a semi crystalline polymer that can be depicted as a set of ordered regions (crystalline lamellae) embedded in a disordered amorphous phase. The degree of crystallinity is an important parameter: higher crystallinity gives a larger modulus of elasticity, superior yield strength, improved resistance to creep deformation and enhanced fatigue strength, all of which are desirable properties for joint components. The degree of crystallinity, within the range commonly used for medical-grade UHMWPE, does not substantially affect the wear resistance, which is related to the molecular mass. The resistance to creep deformation of the UHMWPE is important to evaluations of the relative contribution of deformation or wear to the penetration of the femoral head into the insert. The fatigue strength is also very important, since it relates to the ability of UHMWPE to resist cyclic damage modes, which are very common in knee components and also in hip components, although prevalent in the rims of malpositioned cups.

Medical-grade UHMWPE orthopaedic implants are machined from stocks and sheets made from UHMWPE powders by compression moulding or ram extrusion and subsequent annealing the ASTM F 648-07 designation (standard specification for UHMWPE powder and fabricated form for surgical implants) defines the characteristics required for medical-grade orthopaedic UHMWPE: density excluded, there are no upper limits on any of the starting parameters, and the characteristics of the material are determined before processing and sterilization. It is clear that commercially available UHMWPE inserts can be very different from each other after processing, sterilization and packaging, which is very relevant to their clinical applications.

B. Material Properties of UHMWPE

Table 1: Material properties of UHMWPE

	UNITS	ASTM TEST	UHMW-PE
Tensile strength	psi	D638	3,100
Flexural modulus	psi	D790	110,000
Izod impact (notched)	ft-lbs/in of notch	D256	18.0*
Heat deflection temperature @ 264 psi	°F	D648	-
Maximum continuous service temperature in air	°F		180
Water absorption (immersion 24 hours)	%	D570	slight
Coefficient of linear thermal expansion	in/in/°Fx10^{-5}	D696	11.1

C. About FDM technology

Fused Deposition Modeling (FDM) is a 3D printing technique pioneered in the 1990s by Stratasys. In fact, the term 'FDM' is the trademark of Stratasys. The company continues to be a leader in manufacturing 3D printers all over the world, including India. Alternatively, the 3D printers that are based on this technology are also called as Fused Filament Fabrication (FFF), Plastic Jet Printing (PJP) or material extruding printers, which is the generic name for these 3D printers. The 3D printers that work on FDM technology consist of the printer platform, a nozzle (also called as printer head) and the raw material in the form of a filament.

The printer platform or the bed is typically made of some metal, ceramic or hard plastic, and each successive layer is deposited on this platform.

The nozzle of FDM printers is attached to a mechanical chassis which uses belt and / or lead screw systems to move it. The entire extrusion assembly is allowed to move in X, Y and Z dimensions by a motorized system. A fourth motor called as the stepper motor is used to advance the thermoplastic material into the nozzle. All the movements of the head and the raw material are controlled by a computer.

The raw material is typically production grade thermoplastics, though sometimes metal is used as well. The thermoplastic material is capable of being repeatedly melted when exposed to heat and re-solidified when the heat is withdrawn. The thermoplastic filament or metal wire is wound as a coil on a mounted spool. It is then fed through the printer nozzle. The better class of 3D FDM printers allows the temperature of the nozzle to be maintained just close to the glass transition temperature of the material being extruded. This allows the material to be extruded in a semi-liquid state, but return to solid state immediately. This results in a better dimensional accuracy.

In principle, any thermoplastic can be used as raw material for FDM printers. Commercially, a few of the popular choices of raw material include nylon, Acrylonitrile Butadiene Styrene (ABS) and its variations, polycarbonates, ply-lactic acid, polystyrene and thermoplastic urethane. MED610, a raw material that Stratasys provides is bio-compatible. Their ULTEM material too is certified by the aerospace industry.

When the FDM printer begins printing, the raw material is extruded as a thin filament through the heated nozzle. It is deposited at the bottom of the printer platform, where it solidifies. The next layer that is extruded fuses with the layer below, building the object from the bottom up layer by layer. Most FDM printers first print the outer edges, the interior edges next and lastly the interior of the layer as either a solid layer or as a fill in matrix.

In some objects / models, there are fragile 'overhangs' that will droop unless they are given some support. FDM printers incorporate a mechanism whereby these support structures (called struts) are printed along with the object. They are later removed once the build is complete. These struts are usually of the same material as the object. Some printers have a second extruder to specifically deposit soluble thermoplastic struts when there is a need to prevent the overhangs from drooping. These struts may be of a different composition than the thermoplastic used for the 3D model. They are later dissolved by an appropriate solvent.

IV. PROPOSED MODEL

The field of surgical implants and prostheses is continuously developing to allow for more cohesive integration of these foreign objects within their surrounding tissue, as well as to increase their functionality. Design of implants and prostheses requires a multidisciplinary approach that combines principles of materials science, engineering, biomechanics, molecular biology, pharmaceuticals and long-term clinical monitoring. AM can help bridge the gap between biology and engineering by creating complex biocompatible and bioactive constructs that take advantage of unique material properties, such as osteoconductivity and osteoinductivity, to promote tissue regeneration and integration of the implant with the surrounding tissue.

Figure 1: D Model of Upper Knee Joint

Current radiological imaging technology, such as computed tomography (CT), can allow for creation of very accurate CAD models of a defect that can serve as models for 3D printing to ensure a perfect fit into the desired tissue. The proposed model of knee is obtained from the CT data.

Figure 2: D Model of Lower Knee Joint

Parameters refer to constraints whose values determine the shape or geometry of the model or assembly. Parameters can be either numeric parameters, such as line lengths or circle diameters, or geometric parameters, such as tangent, parallel, concentric, horizontal or vertical, etc. Numeric parameters can be associated with each other through the use of relations, which allows them to capture design intent.

Figure 3: Assembled Model

A. Design of Prosthesis by Solid Works

SolidWorks is a solid modeling computer-aided design (CAD) and computer-aided engineering (CAE) computer program that runs primarily on Microsoft Windows. While it is possible to run SolidWorks on MacOS, it is not supported by SolidWorks SolidWorks is published by Dassault Systems.

SolidWorks is a solid modeler, and utilizes a parametric feature-based approach which was initially developed by PTC (Creo/Pro-Engineer) to create models and assemblies. The software is written on Parasolid-kernel.
Design intent is how the creator of the part wants it to respond to changes and updates. For example, you would want the hole at the top of a beverage can to stay at the top surface, regardless of the height or size of the can. SolidWorks allows the user to specify that the hole is a feature on the top surface, and will then honor their design intent no matter what height they later assign to the can.

Features refer to the building blocks of the part. They are the shapes and operations that construct the part. Shape-based features typically begin with a 2D or 3D sketch of shapes such as bosses, holes, slots, etc. This shape is then extruded to add or cut to remove material from the part. Operation-based features are not sketch-based, and include features such as fillets, chamfers, shells, applying draft to the faces of a part, etc.

Building a model in SolidWorks usually starts with a 2D sketch (although 3D sketches are available for power users). The sketch consists of geometry such as points, lines, arcs, conics (except the hyperbola), and splines. Dimensions are added to the sketch to define the size and location of the geometry. Relations are used to define attributes such as tangency, parallelism, perpendicularity, and concentricity.

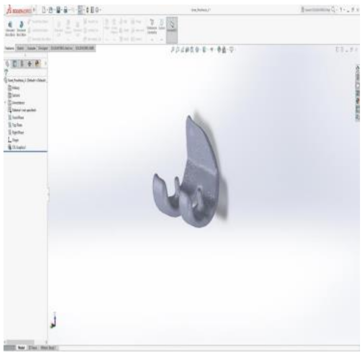

Figure 4: D Model of an Upper Knee Cup

The parametric nature of SolidWorks means that the dimensions and relations drive the geometry, not the other way around. The dimensions in the sketch can be controlled independently, or by relationships to other parameters inside or outside the sketch.

In an assembly, the analog to sketch relations are mates. Just as sketch relations define conditions such as tangency, parallelism, and concentricity with respect to sketch geometry, assembly mates define equivalent relations with respect to the individual parts or components, allowing the easy construction of assemblies. SolidWorks also includes additional advanced mating features such as gear and cam follower mates, which allow modeled gear assemblies to accurately reproduce the rotational movement of an actual gear train.

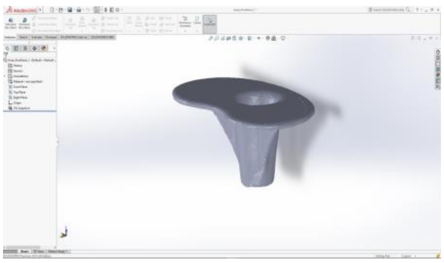

Figure 5: D Model of Lower Knee Fixture

Finally, drawings can be created either from parts or assemblies. Views are automatically generated from the solid model, and notes, dimensions and tolerances can then be easily added to the drawing as needed. The drawing module includes most paper sizes and standards (ANSI, ISO, DIN, GOST, JIS, BSI and SAC). File format

V. ANALYSIS OF MODEL

The Analysis of Prosthesis model is carried out in ANSYS Workbench. FEA software typically uses a CAD representation of the physical model and breaks it down into small pieces called finite “elements” (think of a 3-D puzzle). This process is called “meshing.” The higher the quality of the mesh (collection of elements), the better the mathematical representation of the physical model. The primary purpose of an element is to connect nodes with predictable mathematical equations based on stiffness between nodes; the type of element used often depends upon the problem to be solved. The behaviour of each element, by itself, is very well understood. By combining the behaviours of each element using simultaneous equations, one can predict the behaviour of shapes that would otherwise not be understood using basic “closed form” calculations found in typical engineering handbooks.

General purpose, modern mechanical FEA programs typically use a select set of elements chosen for their versatility, robustness, and their overall contribution to product ease of use. Workbench Simulation uses several primary element types and will default to high-order (10 node quadratic) tetrahedral (H) elements (SOLID 187 in ANSYS-Speak) for solid model geometries if they are not sweep able, in which case high-order (20 node) brick elements (SOLID 186) are employed. On closed surface models, “quad-dominate” (4 node) shell elements (SHELL 181), are used providing both accuracy and efficiency while being suitable for the robust automatic meshing algorithms used in Workbench Simulation. And, for part-to-part interaction within assemblies, high-end surface-to surface contact elements (CONTACT 170/174) are used. For mixed beam/shell models and for spot-weld features, beam elements are employed (BEAM 188). ANSYS Workbench Simulation applies these various element types automatically.

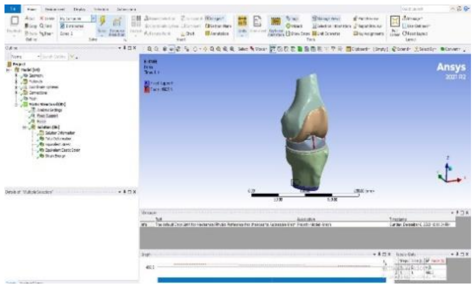

Figure 6: Boundary Condition

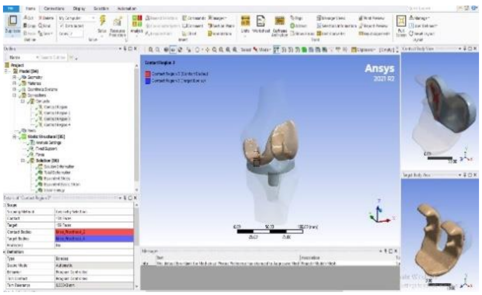

Figure 7: Contact Bodies

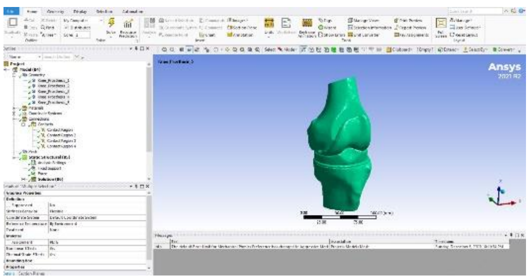

Figure 8: Assigning Material Properties of PETG

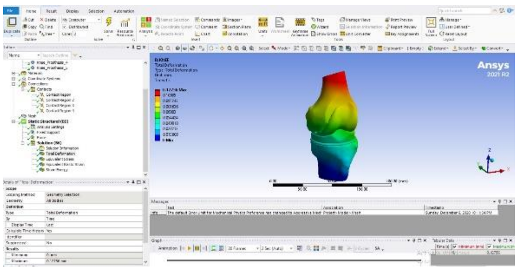

Figure 9: Deformation Under Load

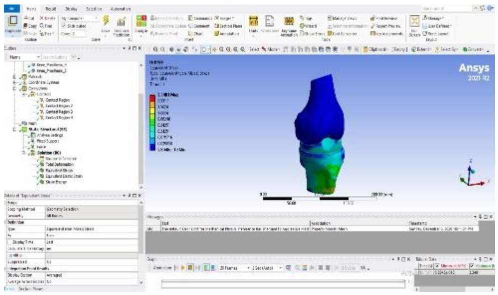

Figure 13: Stress Acted Upon the Prosthesis under Load

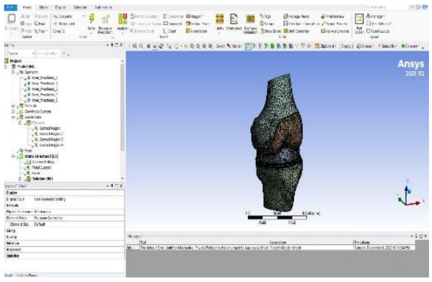

Figure 14: Meshing

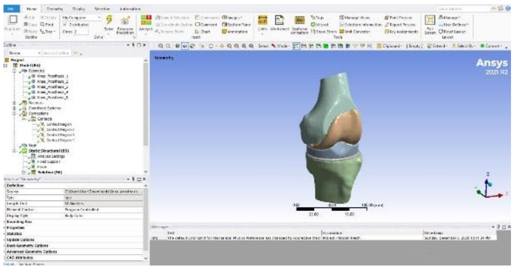

Figure 15: Geometry

VI. DESIGN OF EXPERIMENTS

Design of experiment (DOE) is a statistical tool developed by R.A Fisher (England 1920's) in order to study the effect of multiple variables simultaneously. In his early experiment, he wanted to estimate how much sun-light, fertilizers, water etc. are required to produce the good crop. There are two main approaches to DOE, Full Factorial design (FFD) and the Taguchi's method. The FFD is a set of an experiment whose design consists of more than one factor each with discrete possible level and whose experiment units takes all possible combinations of all those levels across all such factors. For example, if there are K factors each at 3 levels, FFD has 4K runs. This for 4 factors at 3 levels it would take 81 trials runs. The Taguchi method is a statistical tool developed by Genier Taguchi (1940's) a Japanese engineer, proposed a model for experiment design. The Taguchi experiment array design is used to arrange the parameters affecting the process and the levels of which they should be varied. Instead of having all possible experiments like FFD, Taguchi model provides a minimum number of experiments. In case of 4 factors and 3 levels, it would take 9 trials runs. The experiments are not randomly generated but they are based on judgmental sampling. It reduces time, resources and cost. The Taguchi experimental array design is used to arrange the parameters affecting the process and the levels of which they should be varied.

The following steps that is necessary for doing the experiment.

1. Selection of predictors (V, K, r and σ)
2. Selection of the number of levels for each predictor (3 levels)
3. Selection of the orthogonal array
4. The result of response variables based on predictors assign to each column to estimate the value of a PD based on the predictors in all combinations
5. Conduct the experiment and analyse the data (applying ANOM and ANOVA to get results.

The ANOM and ANOVA are used to conduct the analysis to decide which independent variable does not have much effect (or which one affects more on option pricing formula) and also the percentage contributions of the independent variables. Three levels are chosen for all the three parameters (also called factors). The levels for different parameters were established on the basis of preliminary studies conducted. These selected factors and their levels are given in Table 2

Table 3: Factors and values

	L	T	S
1	0.1	230	60
2	0.1	240	80
3	0.1	250	100
4	0.15	230	80
5	0.15	240	100
6	0.15	250	60
7	0.2	230	100
8	0.2	240	60
9	0.2	250	80

Table 4: L9 Orthogonal Array

Notation	Parameter	Level 1	Level 2	Level 3
L	Layer thickness (,mm)	0.1	0.15	0.2
T	Printing Temperature (^{o}C)	230	240	250
S	Printing Speed (mm/s)	60	80	100

In my project, L9 orthogonal array has been chosen which is shown in Table 4

Table 5: Experimental Layout of Orthogonal Array

	A	B	C
1	1	1	1
2	1	2	2
3	1	3	3
4	2	1	2
5	2	2	3
6	2	3	1
7	3	1	3
8	3	2	1
9	3	3	2

The selected parameters and its values are fitted in the orthogonal array table as shown in Table 5

VII. CONCLUSION & FUTURE WORK

3D printing is already well integrated in medical practice and the literature. Applications vary from anatomical models (mainly for surgical planning) to surgical guides and implants. The main advantages are reduced surgical time, improved medical outcome, and decreased radiation exposure. Unfortunately, the subjective character and lack of evidence supporting majority of these advantages does not allow for conclusive statements. The increased cost of this new technology, and the often limited or unproven advantages, make it questionable whether 3D printing is cost effective for all patients and applications. In this paper, a cost effective 3D printing prosthesis is proposed and analysed.

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