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Analysis of Additive Manufactured Tibial Spacer Used In Total Knee Replacement Implant

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Abstract: -- **There is a huge demand for biomedical implants in recent years especially for Total Knee Replacement (TKR) implants. The complex geometries of patient-specific biomedical implants are tedious and time consuming to fabricate using conventional manufacturing methods. Emerging technology like Additive Manufacturing (AM) has a wide scope by allowing complexity in geometry and huge reduction in manufacturing times of these implants. In a total knee replacement of posterior cruciate retaining type, tibial spacer is one of the important components of the implant. In this research tibial spacer was fabricated by Fused Deposition Modeling (FDM) process using bio-compatible material Poly Carbonate-ISO (PC-ISO). The fabricated component tibial spacer made of PC-ISO was analysed for wear and strength, it was found that production time by AM technology is less when compared with the conventional processes, it also exhibited higher hardness and higher resistance than the most widely used material Ultra High Molecular Weight Poly Ethylene (UHMWPE). The experimental test results were within the limits as per medical journals. The surface roughness was also tested and found to be within the satisfactory range required for the knee mechanics.**

Keywords: ***Additive Manufacturing, FDM, PolyCarbonate -ISO, Total Knee Replacement (TKR), Tibial Spacer Insert***

1. INTRODUCTION

Additive Manufacturing (AM) is defined as layer by layer fabrication of 3D physical models directly from CAD data without tools, dies and human intervention. The production of prototypes and patterns using classical technologies is very demanding and time-consuming. AM is a flexible and fast way to create parts, but material availability and suitability has traditionally limited the technology for its widespread application. The most interesting and challenging applications of AM technologies are in the field of medicine.

Using AM in medicine is a quite complex task which implies a multidisciplinary approach and very good knowledge of engineering as well as medicine; it also demands many human resources and tight collaboration between doctors and engineers. AM technology has the ability to fabricate models with complex geometric forms, and so is very suitable to reproduce the intricate forms of human body. By using of AM models, visualization of intricate and hidden details of traumas of patients by surgeon is enhanced. It is a very significant discovery in medicine and the first step on the way to making other complex human organs.

AM systems like fused deposition modeling (FDM), 3D printing (3-DP) and selective laser sintering (SLS) have been proved to be convenient for making porous structures for use in tissue engineering. There are also many new trends of applying AM in orthopedics, oral and maxillofacial surgery and other fields of medicine. A rapid increase in the number of surgical procedures involving prosthesis implantation is evolved, because as the human body ages, the load-bearing joints become more prone to ailments. This has resulted in an urgent need for improved biomaterials and processing technologies for implants, more so for orthopedic and dental applications. Human joints are complex and delicate structures capable of functioning under critical conditions [6].

Currently, one of the main achievements in the field of arthroplasty is total knee replacement (TKR), where the entire load bearing joint is replaced surgically by ceramic, metal, or polymeric artificial materials. Recent research has led to the development of the AM process building and improving upon artificial bone implants which are strong enough to support a new bone yet, at the same time, porous enough to be absorbed and replaced by the body. Cobalt, chromium, and molybdenum alloys are the metals used most frequently. Plastic materials are made from thermoplastics especially the tibial spacer insert.

1.1 Components of TKR Implant

The knee is an important consideration in the study of biomechanics because it is one of the most commonly injured areas of the body; susceptible to degenerative joint diseases. The knee joint joins the femur, tibia, and

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surrounding supportive muscle and ligament groups. Total knee replacement implants vary greatly by design, fixation and materials depending on patient.
TKR implant components consists of four main parts depicted in figure1.1; femoral component which is attached to the thigh bone, tibial tray which is locked to the shin bone, polyethylene or thermoplastic surface which is located between both of the knee bones and plastic surface at the back of patella. The components are designed so that metal articulates against plastic, providing smooth movement and minimal wear. The femoral component curves around the end of the femur and has an interior groove so the patella can move up and down smoothly against the bone as the knee bends and straightens.
The fixation of femoral component and tibial tray with bones can be made using a Polymethylmethacrylate (PMMA) cement to adhere the components to the bone. Both the superior tibia and inferior femur have a covering of cartilage. This layer of cartilage, known as the meniscus, separates the bone surfaces. Motion in joint is supported on a thin fluid film that sits atop the cartilage layer, which leads to low wear and friction in the healthy knee [6,12].
In Posterior Cruciate Retaining (PCL) designs, backward movement of the tibia continues to be resisted by an intact PCL, which creates stability. The femoral and tibial prostheses have notches to accommodate the ligament and the plastic insert also has a flat central surface.

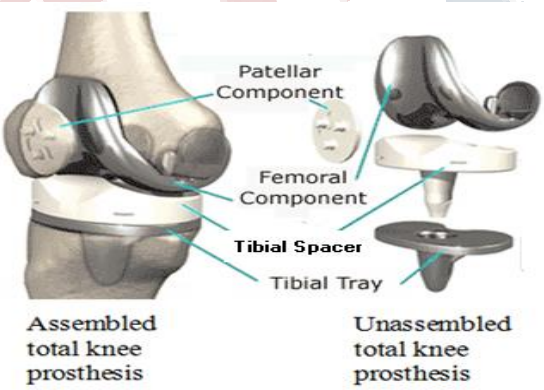

Fig 1.1: TKR implant components

1.2 Tibial Spacer Insert

The spacer is one of the important components of the knee implant, attached and mounted on the tibial tray that provides smooth movement of other components against it and also wears out minimally. In many cases, it replaces the worn out cartilage meniscus present in between the femur and tibia. Spacer is fabricated using biocompatible biomaterials according to medical standards.
Generally used spacer material is ultra-high molecular-weight polyethylene (UHMWPE) and Poly Carbonate-ISO (PC-ISO). For the present work PC-ISO has been selected as the spacer material. PC-ISO is an industrial thermoplastic, which in its raw state, is biocompatible (ISO 10993 and USP Class VI) and can be gamma or Ethylene Oxide (EtO) sterilized. It has been found to have high strength and shows high wear resistance. The major functions of the spacer include;

- Provide less friction between mating components and hence leading to minimal wear
- As a substitute for the meniscus in case it is absent
- Provide smooth movement between the rubbing components
- Ease of bending and straightening of the knee
- Extend the life of the knee implant.

The medical requirement for surface roughness of the insert is in the range of 0.2 - 2μm.

2. EXPERIMENTAL WORK

A. Design and Modeling of spacer insert and test specimens

All data and requirements of the spacer were acquired based on the suggestions provided by the orthopedic surgeon of vast experience. The preliminary step was to design the spacers and test specimens to be built using FDM. Commercial software used was CATIA V5 R20.

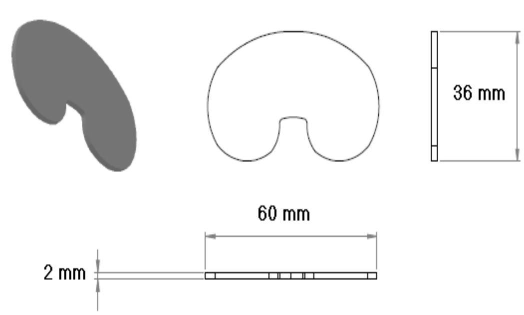

Fig 1.2: CAD model of small size tibial spacer

Test specimens for tensile, compression, wear and SEM tests were also designed according to ASTM standards.

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B. Fabrication of components using FDM technique and conduction of tests

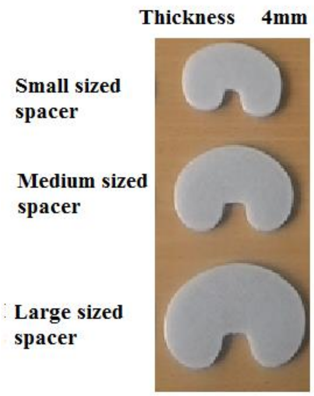

Fig 1.3: Fabricated tibial spacer inserts in three basic sizes

Based on the ASM Handbook [2] three standard sizes of tibial spacer used for a normal patient is of 4mm thickness. The build orientation for all three components was horizontal i.e. 0° build orientation using FDM Titan-Ti machine. Nature of support structures were water soluble and total time for fabrication of all tibial spacer inserts and test components were one hour.

2. RESULTS AND DISCUSSIONS

a) Hardness Test Result

Hardness of hard elastomers is usually measured using Shore D Scale of ASTM D2240 Standard. The hardness test revealed that the hardness value of PC-ISO material is 79-80 in shore D scale. This experimental result unerringly ties up with the theoretical hardness value for PC-ISO material of 80 in shore D scale. Also, it proves that it is a harder material than UHMWPE which has hardness 68 in Shore D scale.

b)Pin on Disc Test Results

Wear testing was carried out according to ASTM G99, PC-ISO being the pin and Steel as Disc. Wear was measured by the amount of material removed. Variables selected for the test were load and distance. Velocity was kept constant as 1m/s.

Load in steps of 10 N and distance in steps of 500m up to 1500 m were considered. Mass loss (in gms) and the wear of material under varying conditions was recorded.

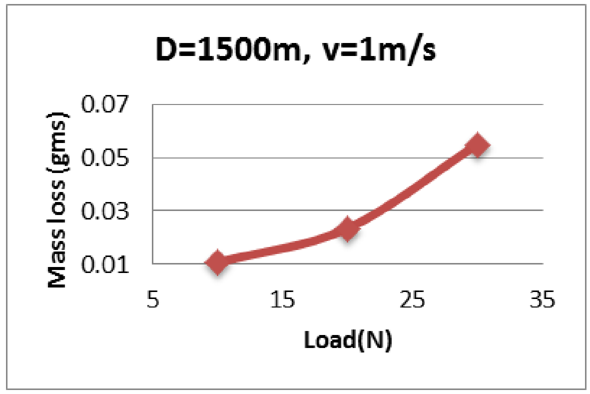

Fig 2.1: Mass loss for distance of 1500 m and velocity 1 m/s for PC-ISO

Table -1: Pin On Disc Results for PC-ISO

Load (N)	Mass loss (gms)
10	0.0107
20	0.0234
30	0.0549

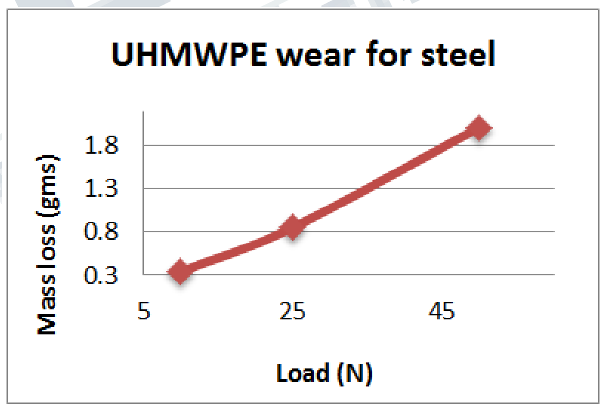

Fig 2.2: Mass loss for distance 1500 m and velocity 1m/s for UHMWPE

Table-2: Results of Pin on Disc Tests Carried out on UHMWPE [11]

Load (N)	Mass loss (gms)
10	0.34
25	0.85
30	1.01

It can be observed that as the load was increased mass

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lossalso increased linearly but mass loss exhibited by PC-ISO is very much lesser than UHMWPE at similar loading conditions.

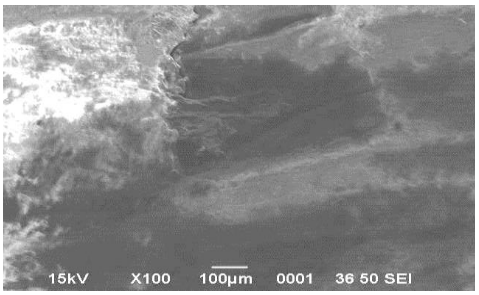

Fig 2.3: SEM image at 100x magnification giving surface deformation

c) Tensile Test Result

Specimen was of ASTM D638 Type I standard. Load was applied in steps of 2.5 kN. Report says that the peak load or load at specimen break is 3.20 kN. The load at yield point is 2.8 kN. It is evident from the report that the yield strength is 40.64 N/mm2 and tensile strength of the material is 46.44 N/mm2. This experimental value is in correspondence with the theoretical value, 50 N/mm2.

Fig 2.4: Fractured tensile specimen

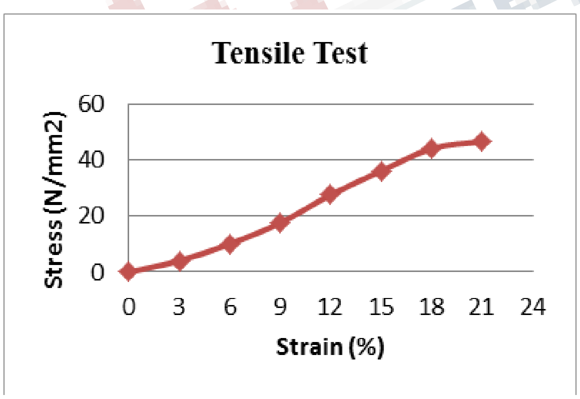

Fig 2.5: Plot depicting Stress v/s Strain for PC-ISO tensile specimen

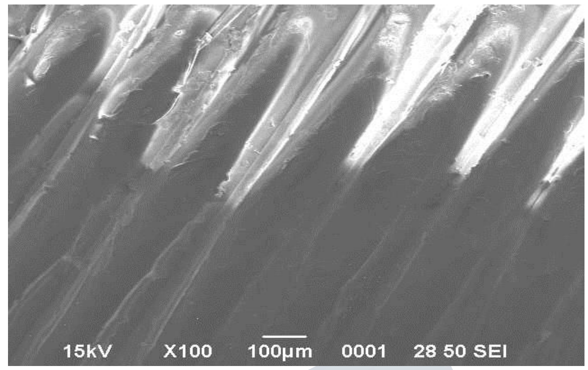

Fig 2.6: SEM image at 100x magnifications before fracture

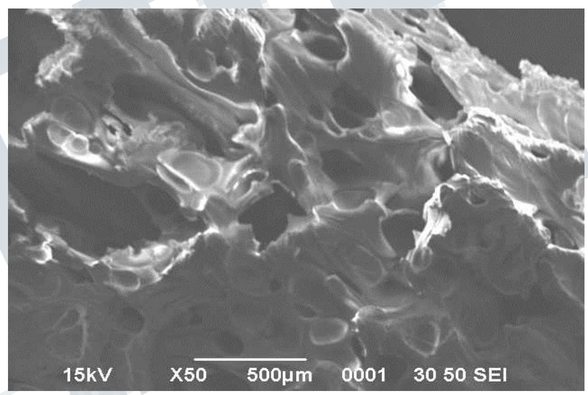

Fig 2.7: SEM image at 50x magnification after tensile fracture

From the SEM images, it was seen that fracture occurred at the place where internal stresses were high causing stress concentration and finally fracture which was observed at magnifications 100x and 50x.

d) Compression Test Result

Fig 2.8: Compression test specimen after fracture

The specimen was conformed to ASTM D695 standard and maximum load applied was 37.8 kN. The report declares that the compressive strength of PC-ISO material is 284.75 N/mm2.

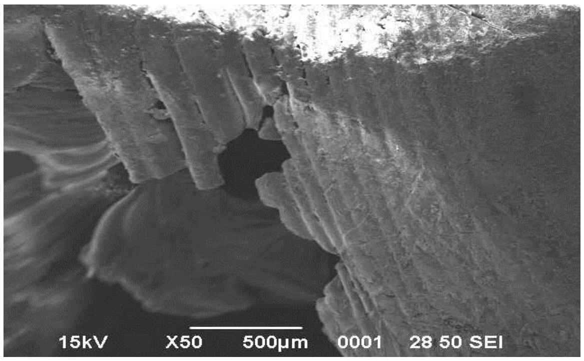

Fig 2.9: SEM image at 50x magnification after compression fracture

e) Surface Roughness Test Result

The surface roughness Ra value was found to be 2.61µm. This is in near agreement with the medical requirement. It can be improved by sanding process before implantation, which helps to reduce friction by minimizing abrasion between the surfaces as well as minimizes the shear stresses on contact surface.

3. CONCLUSIONS

The present work was concerned with the selection of appropriate material, design, fabrication and testing of Tibial spacer insert of knee implant according to the geometrical, physical and bio-medical requirements in three standard sizes. Poly Carbonate (PC)-ISO material was opted for fabrication of tibial knee spacer component using Fused Deposition Modeling (FDM) technique, in 0° build orientation. PC-ISO was found to be a harder and exhibited lower wear rate compared to UHMWPE.

• The results obtained by tensile and compression tests were within the satisfactory range as prescribed by the medical standards.
• Surface roughness Ra value of the fabricated component was found to be well within the prescribed range.
• Compared to UHMWPE material, the PC-ISO material showed minimal deformation and low wear which enhances longevity of the spacer and the implant.

Hence it can be concluded that PC-ISO is a better bio-material for tibial spacer in the TKR implants than UHMWPE material.

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