ADDITIVE MANUFACTURING AND ANALYSIS OF TIBIAL INSERT IN TOTAL KNEE REPLACEMENT IMPLANT

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Abstract - *In recent years, 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 total knee replacement (TKR) the entire load bearing joint is replaced surgically by ceramic, metal, or polymeric artificial materials. Tibial spacer is one of the important components of total knee replacement implant which is used to mimic the articular cartilage. In the 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.*

Key Words: Additive Manufacturing, ASTM, FDM, PolyCarbonate -ISO, Total Knee Replacement (TKR), Tibial Spacer Insert

1. INTRODUCTION

Additive Manufacturing 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. RP 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 rapid prototyping technologies are in the field of medicine.
Using RP 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. RP 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 RP 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.
Rapid prototyping 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 RP 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].
The production of total knee joint replacements seems to be a very interesting area for the RP methods application. 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 RP 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

surrounding supportive muscle and ligament groups. Knee implant components consists of four main parts; 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].

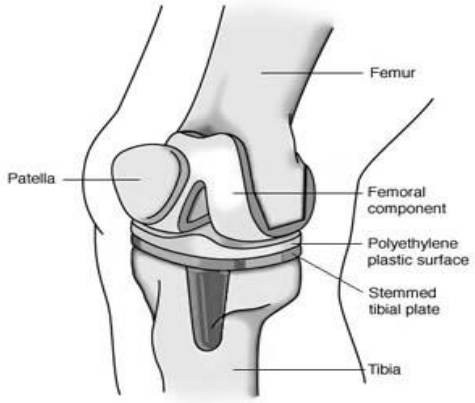

Fig 1.1: Knee implant components

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 standards.

Usually ultra-high molecular-weight polyethylene (UHMWPE) or Poly Carbonate-ISO (PC-ISO) is used as spacer material. PC-ISO has been nominated as the spacer material. PC-ISO 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

The specifications of tibial spacer were acquired based on the Knee implant requirement. The solid models of the spacers and specimens for tensile, compression, wear and SEM tests were created using CATIA V5 R20.

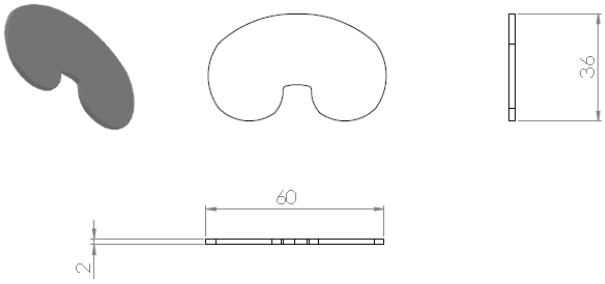

Fig 1.2: Knee implant components

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

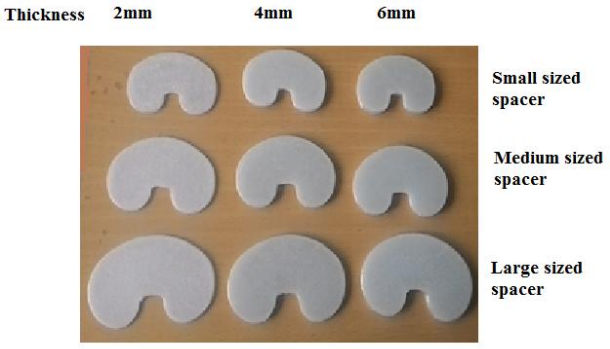

Fig 1.3: Fabricated tibial spacer inserts in three basic sizes

Spacers and Test specimens for were built using FDM Titan-Ti machine. All the components were built in 0° build orientation. Nature of support structures were water soluble and total time for fabrication of all tibial spacer inserts and test components were within three hours.

Table -1: FDM build time for specimens

Component		Time taken to build (min)
Tibial spacer small	2mm thick	07
	4mm thick	11
	6mm thick	15
Tibial spacer medium	2mm thick	09
	4mm thick	13
	6mm thick	17
Tibial spacer large	2mm thick	10
	4mm thick	15
	6mm thick	20
Tensile model		45
Compression model		10
Hardness model		08
SEM model		06
Wear models		05
Total time taken		186 mins =3.1 hours

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.

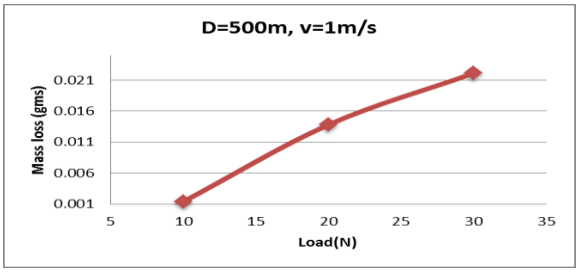

Fig 2.1: Mass loss for distance of 500 m and velocity 1 m/s for PC-ISO

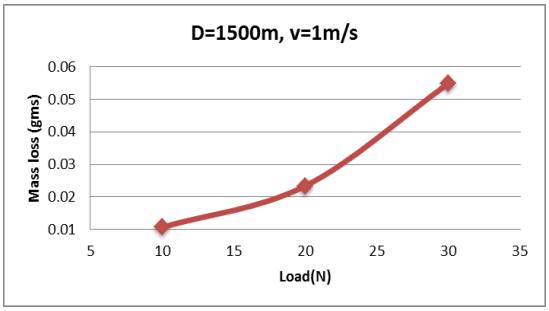

Fig 2.2: Mass loss for distance of 1500 m and velocity 1 m/s for PC-ISO

Table -2: Pin On Disc Results for PC-ISO

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

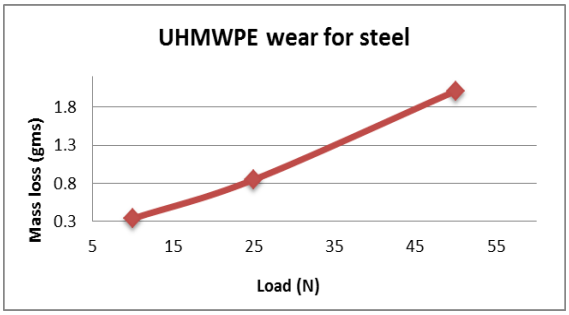

Fig 2.3: Mass loss for distance 1500 m and velocity 1m/s for UHMWPE

Table-3: 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 loss also increased linearly but mass loss exhibited by PC-ISO is very much lesser than UHMWPE at similar loading conditions.

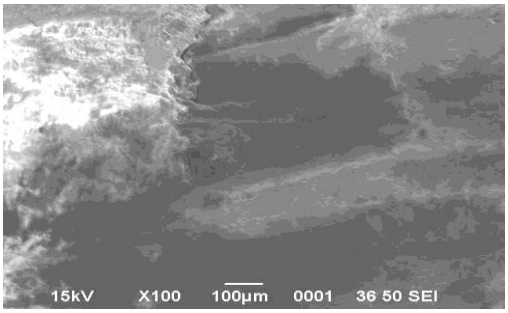

Fig 2.4: SEM image at 100x magnification giving surface deformation

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 2.5: Fractured tensile specimen

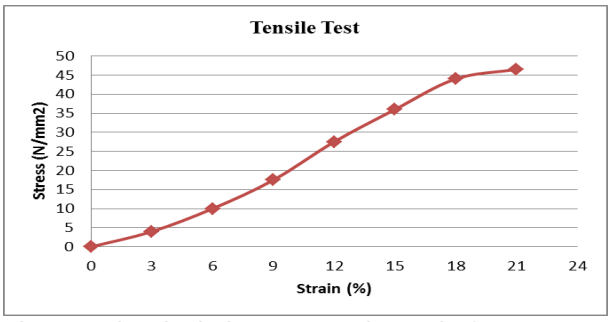

Fig 2.6: Plot depicting Stress v/s Strain for PC-ISO tensile specimen

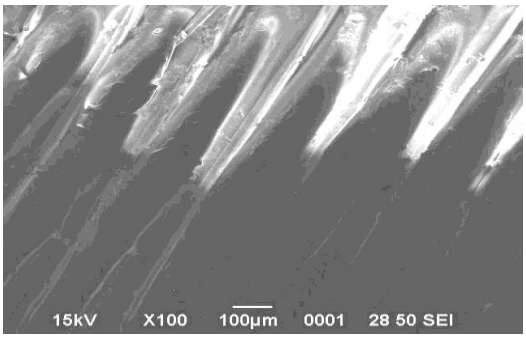

Fig 2.7: SEM image at 100x magnifications before fracture

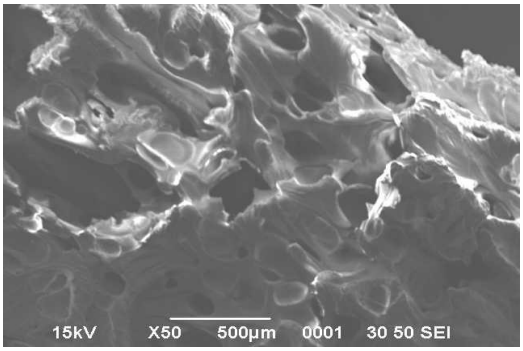

Fig 2.8: SEM image at 50x magnification after tensile fracture

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 2.9: 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.

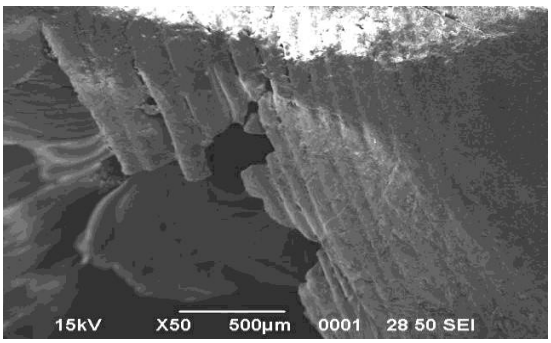

Fig 2.10: SEM image at 50x magnification after compression fracture

e) FEM Analysis

FEM analysis was carried out for prediction and validation of the PC-ISO tibial spacer insert for its strength and sustainability under static loading. The stress distribution and deformation were analyzed. The bottom surface of spacer component was fixed in all DOF as it will be fitted on the tibial tray. Uniform pressures of calculated

magnitudes were applied corresponding to spacer size over the top surface.

Table-3: FEA Results of Deformation, Equivalent and Max Principal Stresses

Parameter	Total Deformation (max) in mm	Von-mises stress MPa	Max Principal stress MPa
Small spacer, 2mm	3.264E-6	0.7698	0.5782
Small spacer, 4mm	6.550E-6	1.049	0.9684
Small spacer, 6mm	9.864E-6	2.031	1.1302
Medium spacer, 2mm	5.056E-6	0.6519	0.4881
Medium spacer, 4mm	5.05E-6	0.9039	0.4811
Medium spacer, 6mm	7.611E-6	1.12	1.1008
Large spacer, 2mm	1.847E-6	0.4069	0.2933
Large spacer, 4mm	3.7047E-6	0.5965	0.6312
Large spacer, 6mm	5.57E-6	0.7221	0.8178

It can be concluded that PC-ISO offers a very low deformation rate irrespective of loading and size conditions. Thus spacer insert of the knee implant is suitable for withstanding static as well as dynamic loading conditions.

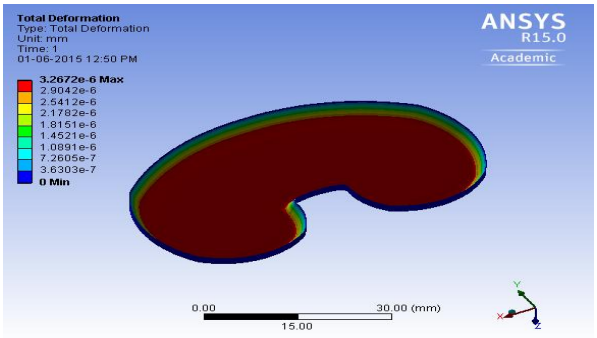

Fig 2.11: Total deformation on the spacer of small size of 2 mm thickness

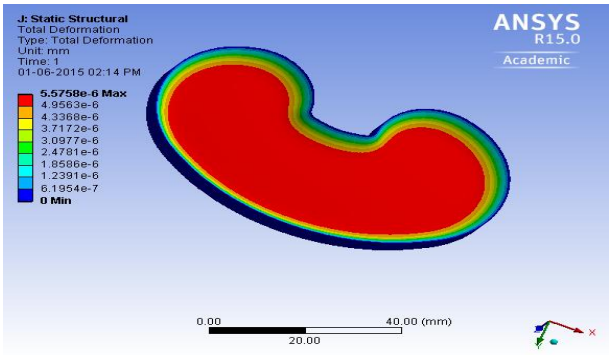

Fig 2.12: Total deformation on large spacer of 6mm thickness

f) Surface Roughness Test Result

The surface roughness was measured using Surf Com Flex Surface Tester and Ra value was found to be 2.61µm. This is in near agreement with the medical requirement. It can be further improved by sanding process before implantation, which helps reduce friction 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 in three standard sizes according bio-medical requirements.

- 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 tensile and compression tests exhibited that the results obtained coordinated with medically satisfactory range. The FEM analysis performed on the tibial spacer models revealed that the stress distributions and concentrations obtained were in near agreement with the results obtained from mechanical tests.
- Surface roughness Ra value of the fabricated component was found to be well within the satisfactory range.
- PC-ISO material tibial spacer component has shown minimal deformation and low wear rate 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 knee replacements than UHMWPE.

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BIOGRAPHIES

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