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Research Article

Effect of Geometric Parameters on Ultimate Load Carrying Capacity of Femoral Head of Biomaterial

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Abstract

Hip joint is one of the largest weight-bearing structures in the human body. In the event of a failure of the natural hip joint, it is replaced with an artificial hip joint, known as hip joint prosthesis. The main components of prosthesis consist of femoral stem and acetabular cup. These are made up of either one piece or modular design. In the present work, modular designed femoral head of polyamide material is proposed. Four different models of femoral head (considering 2 head diameters and 2 stem diameters) were manufactured using selective laser sintering process-one of the 3D printing techniques. Physical models were tested for their suitability for brisk walking activity by fracture test (compression testing). After the specimen crosses the load stipulated for brisk walking activity i.e. 3000 N, it is further subjected to gradually increasing load, till it breaks, relieving its ultimate load carrying capacity. The experimental result values were compared with previous data on hip contact forces. All models were tested for brisk walking activity and each one's suitability for the purpose is concluded depending upon its maximum allowable stress.

Keywords: *Hip implant, selective laser sintering, duraform polyamide, femoral head, brisk walking activity, ultimate load carrying capacity*

1. Introduction

Hip arthroplasty is a reconstructive procedure that has improved the management of those diseases of the hip joint that have responded poorly to conventional medical therapy. The hip is one of the body's largest joint. It is a ball-and-socket joint. The socket is formed by the acetabulum and the ball is the femoral head, which is the upper end of the femur (thighbone). The bone surfaces of the ball and socket are covered with the articular cartilage, a smooth tissue that cushions the ends of the bone and enables them to move easily (E. Gentlemen *et al*, 2008, ASOS, 2015).

Components of modular hip prostheses are (U. Holzwarth, 2012):

1. The femoral stem
2. The femoral head
3. The acetabular cup line
4. The acetabular cup shell.

Modular femoral components have become popular among surgeons because neck length and offset can be adjusted intraoperatively, providing increased versatility without any need for a large inventory (Kassim Abdullah, 2010). Hip prosthesis components are shown in the Fig. 1.

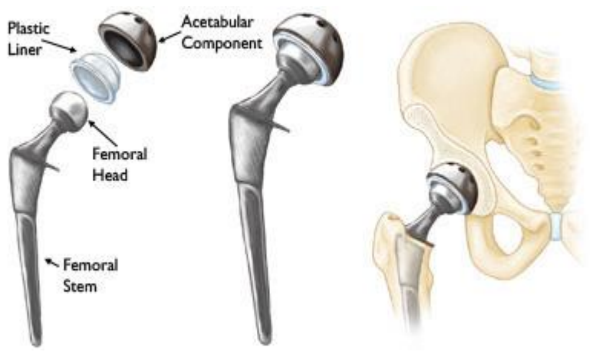

Fig.1 Hip replacement components (ASOS, 2015)

Most recently, in last two decades, there has been considerable interest in biomaterials like (S. Pramanik, (2005), Polyglycolic Acid (PGA), Polylactic acid (PLA), (Polyether ether ketone) PEEK, (Polyamide) PA etc (M. Navarro,2008). Development of these materials has stabilized the femoral stem technique. Development of medical grade polymer and various other apatite materials are under research for hip joint prosthesis

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development. PA (polyamide) based femoral head have been introduced in the proposed work, as a relatively new alternative for enhanced acetabular fixation during hip prosthesis.

Reason for motivation for research on new prostheses material is different drawbacks of current articulation surfaces, which are mentioned in table 1.

Table 1 Issues with surgical implants (M. Navarro *et al*, 2008, S. Pramanik *et al*, 2005)

Surgical Implants	Issues
Stainless Steel 316 L	Early failure, subjected to corrosion in long term
CoCrMo Alloys	Cobaltism (Increased ion metal levels in blood)
Pure Titanium & Ti alloy	Expensive and difficult to machine
Ceramics	Failure due to brittleness

The current work concentrates on following major areas:

- Material selection
- CAD (FEA)
- Fabrication process & testing

1.2 Material Selection

Surgically, both the femoral and acetabular bearing surfaces are replaced with metallic, polymeric, and/or ceramic components during hip arthroplasty. Since the last century,research work has been undergoing on different combinations of materials to find an appropriate candidate for hip arthroplasty. Biomaterials are those materials which are compatible with living tissue. These materials are used to direct, enhance or substitute functions of living tissues of the human body and can be either natural or artificial.

Femur head is a cancellous bone with modulus 0.04-1.0 GPa. During selection of material for femoral head, these mechanical properties plays very important role. Medical grade polyamide has modulus 1.586 GPa. So it can be used for femur head application (E. Rahim, 2010).

Uwe Holzwarth *et al*, 2012, suggested material selection criteria in order to take over the physiological function of a hip joint. Three different compatibility requirements are 1. Structural Requirement 2. Biological Requirement 3. Tribological Requirement. Femur head is cancellous bone with young's modulus varying from 0.5-0.8 depending upon the various parameters like age,sex etc. Medical grade polyamide possesses USP (The United States Pharmacopeia) class VI compliance or biocompatibility and has young's modulus nearer to that of cancellous bone than other hard or stiff materials. Apart from these 2 major properties other features are:

- Excellent surface resolution and feature detail
- Easy-to-process
- Compatible with autoclave sterilization
- Good chemical resistance and low moisture absorption (J. Siopack *et al*,1995, www.3dsystems.com/sites/www.3dsystems.com/files/DS_DuraForm_PA_US.pdf,2015).

1.2 Generating CAD models

Computer aided design of the models is the pre-requisite for 3D printing process. Firstly models were generated in ANSYS software and then transferred to SLS process software MAGICS through Unigraphix as MAGICS had some compatibility issues with ANSYS.

1.3 Fabrication process and testing

Recently, 3D printing technology have shown to be an attractive technique to produce biomedical implant compared with conventional intraoperative molding which can improve the aesthetic outcomes, decreases surgical time, blood loss and risk of infection. In the past 3D printing was expensive and the technology was only used by large corporations,however the development of a desktop, 3D printer has made the technology more accessible to anyone with affordable prices(N. Azila *et al*, 2015).

Brant Hubbard,examined material properties of duraform polyamide on on the micro- and nanoscale that can affect performance, durability, and reliability of materials used in the process using Atomic Force Microscope. The difference in melting ranges shows that the powder is being altered at a microscopic level, not just at the macroscopic level (M. Hafez*et al*,2015). Polyamide femur composite was fabricated using additive manufacturing and various applications of rapid prototyping was discussed (Chua C.K *et al*, 2003), E. Rahim, 2010), Z Yosibash *et al* 2015).Hip prostheses of ceramic material was designed ,modeled in FEA and same were compared with previous std. data.

ISO 7206-10:2003 (E) defines the method to apply a static load for determining the resistance of total and partial hip joint prosthesis (B.W. Stansfield *et al*, 2003).

Project work flow is given in Fig.2. It includes different steps like basic study of femur anatomy, design and modeling of femur using CAD software, fabrication and mechanical compressive testing and finally comparing experimental results with previous standard data and with FEA output results. Before the fabricated models to be tested for fracture load, each specimen has to pass a load test for brisk walking activity where load is stipulated as 3000N. If the specimen passes this test then only it is assumed to be fit for fracture test or else it is declared as unfit for the purpose.

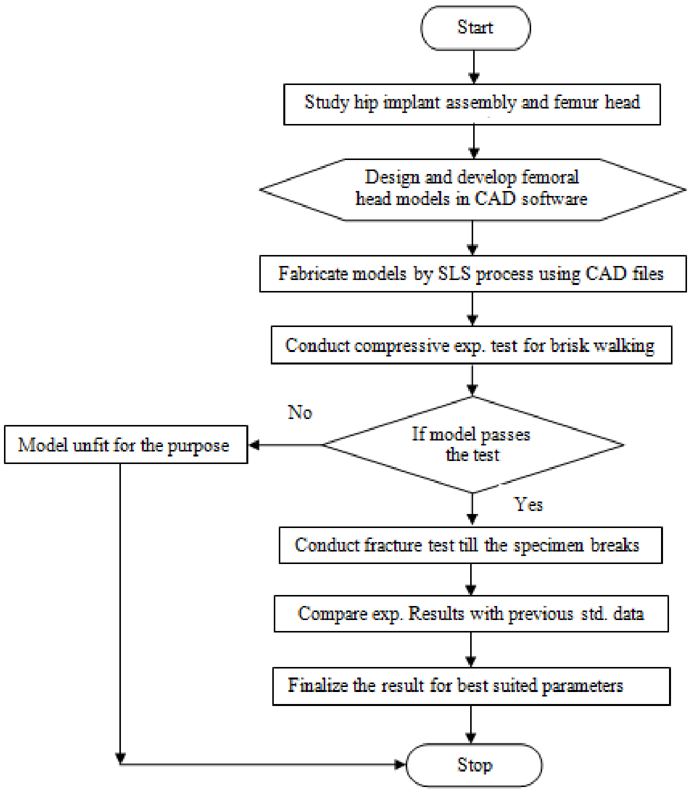

Fig. 2 Process algorithm

2. Methodology

The methodology used for present work is as follows:

1) To study different geometric parameters (head diameter and neck diameter) used for femoral head.
2) To study physical and mechanical properties of polyamide.
3) To design various 4 femoral models using different head and neck diameters using CAD software.
4) To develop these models using selective laser sintering process.
5) To carry out load test for brisk walking activity and if the specimen passes further carry out fracture test and analyse fracture patterns.
6) To generate von mises stress during 2 stages using finite element analysis.
7) To compare experimental results with previous standard data.

2.1 CAD of the models

The finite element method involves modeling the structure using small interconnected elements called finite elements. A displacement function is associated with each finite element. Every interconnected element is linked, directly or indirectly, to every other element through common (or shared) interfaces, including nodes and/or boundary lines and/or surfaces. By using known stress/strain properties for the material making up the structure, one can determine the behavior of a given node in terms of the properties of every other element in the structure. The total set of equations describing the behavior of each node results in a series of algebraic equations best expressed in matrix notation (Daryl L., 2007).

Table 2 Geometric specifications of models

Model	Head Diameter (mm)	Neck Diameter (mm)
Model 1	26	10
Model 2	40	18
Model 3	26	10
Model 4	40	18

Geometric details are given in Fig. 3

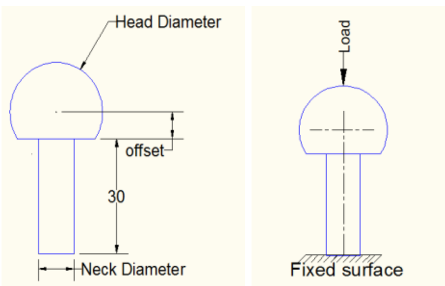

Fig. 3 Geometry, loading and boundary conditions

2.2 Fabrication

4 models were fabricated on SLS machine EOS INT 360. Previously generated computer aided designs were

used for manufacturing. Following working conditions were set for carrying out laser sintering operations.

Table 3 Working conditions specifications

Specifications	Details
Software used	Magics
Layer thickness	0.15 mm
Laser type	CO2, 50 W
Room temperature	18^0c
Recoater speed	65 m/s
Building area temperature	177.9^0 c
Unloading temperature	120^0 c
Cooling time required	3 Hrs.

2.2.1 The EOSINT process applies the following steps (Chua C.K., 2003)

1) Creating of parts
2) Processing of data
3) Preparation of a new layer
4) Scanning and removal of unsintered powder

First, the part is created in CAD system. (The 4 models were created in ANSYS and NX software). Then the CAD data are processed by EOS's software EOSOFT and converted to the cross section format that EOSINT machine use to control the sintering process.

At the build stage, a new powder layer covers the platform. The laser scans the new powder layer and sinters the powder together according to the cross sectional data. Simultaneously, the new layer is joined to the previous layer.

When the sintering of the cross section is completed, the elevator lowers and new layer is prepared for the next step. The processes are repeated, till finally the part is finished. After this the powder around the part is removed. The EOSINT system typically contains a silicon graphics workstation, and an EOSINT machine including the working platform, a laser and an optical scanner calibration system.

The parameters that influence the performance and functionalities of the EOSINT systems are properties of powder material, the laser and the optical scanning system, the precision of the working platform and the working temperature.

The EOSINT P 360 machine has CO_2 laser and builds parts using polyamide or nylon powder materials. Two materials presently available are polystyrene and polyamide (Nylon). The principle application of these materials are primarily for investment casting patterns and functional prototypes, but they can also be used for building geometrical models for visualization or form and fit testing (Chua C.K.*et al*, 2003).

2.2.2 Slicing and Curing

Materialiss Magics Build processor or EOS RP tools repare CAD data in STL or CLI format for the construction process in Additive Manufacturing System can be performed on a step-by-step basis or by means of a preset set of parameters that automatically calls up the required functions in succession. To ensure the easiest possible handling and fast results, EOS supplies its RP Tools with the parameter file <default.par>, which contains several sets of standard parameters. The file can be used on other computers with a valid EOS RP Tools license. Total height, no. of layers and time required for each model is calculated and tabulated below.

Table 4 Layers and SLS time required for different models

Model	Total height	Total no. of layers	Time required for SLS (sec)
Model 1(26)	46.2 mm	307	3684 sec (1 Hr,2 min)
Model 2(40)	66 mm	440	5280 sec (1 Hr,28 min)
Model 3(26)	46.2 mm	307	3684 sec (1 Hr,2 min)
Model 4(40)	66 mm	440	5280 sec (1 Hr,28 min)

For building up parts machine consist cycle of following stages

1) Coating powder on bed (5 sec).
2) Curing by application of laser (5 sec)
3) Lowering the bed by 0.15 mm (2 sec)

So one layer of the object gets completed in 12 (5+5+2)sec i.e. one cycle for completing a single layer is 12 sec. Recoater speed was maintained at 65 m/s.

2.2.3 Cooling and removal

After printing, the trays need to cool as much time as it has printed, and then break out and cleaning starts. Following to cooling, the block of sintered powder was removed and sintered parts were removed by hand. Nylon parts fresh out of the printer typically require cleaning to remove any un-sintered powder from the surface. Each part needs to be broken out of the powder and cleaned manually.

2.2.4 Cleaning

The components were then brushed which removes a large portion of unwanted powder.

2.3.2 Readings of the experimental test are tabulated below

Fig. 4 Cleaning Unit

Weight of each component was measured on digital weighing scale as follows.

Table 5 Weight of fabricated models

Model	Weight
Model 1(26)	13.5 gm
Model 2(40)	30.5 gm
Model 3(26)	9.0 gm
Model 4(40)	25 gm

Manufactured models are shown in Fig. 6

Fig. 5 Fabricated models

2.3 Fracture test

Preclinical endurance test must be performed on a new implant design of various implant sizes to prevent mechanical failure (B.W. Stansfield *et al*, 2003).

Fracture test was carried on all 4 components under the guidelines of ISO 7206: part 10(2003) which is applied to femoral heads of partial or total hip joint replacements of modular construction and describes the method of determining the load required, under specified laboratory conditions, to cause failure of the head (B.W. Stansfield *et al*, 2003).

2.3.1 Procedure followed

The test was carried on UTE 40 FIE MAKE (Calibrated on 7th October 2015,with least count 0.04 kN). Head was mounted onto the EN 24 V block as illustrated in figure. Before starting the test, both loading and head holding fixtures were inspected and no damage found. Installation force of (0.00±0.2)kN at a loading rate of 0.56 kN/s was applied. As per ISO 7206, loading rate to be applied is 0.5±0.1 kN. The load was increased until the fracture of the head or fracture in stem took place.

2.3.2 Readings of the experimental test are tabulated below

Table 6 Fracture test report

Model	Load Rate (kN/min)	Load at termination	Maximum value of test force	Reason for terminating the test	Distance of fracture from flat end of stem
Model 1 (ϕ26ϕ18)	33.6	13120 N	13120 N	Fracture of stem	18.5 mm
Model 2 (ϕ40ϕ18)	33.6	12880 N	12880 N	Fracture of stem	16.5 mm
Model 3 (ϕ26ϕ10)	33.6	3800 N	3800 N	Fracture of stem	32 mm
Model 4 (ϕ40ϕ10)	33.6	2900 N	2900 N	Fracture of stem	26.5 mm

3. Analysis

For the definition of hip joint prosthesis design requirement, characterization of hip joint contact force is essential (J. Rupp *et al*, 2002). Testing results of models 1, 2, 3 and 4 are compared with previous standardized data on hip contact forces

3.1 Previous data on hip contact forces

A study investigated the frontal impact fracture tolerance of the hip in 19 test performed on knee-thigh-hip complexes on 16 unembalmed human cavaders. Out of these 19 results, 3 fractures occurred at the femoral neck region, which is considered for comparison of currents model results.

Derived from the data by Paul, the ISO standard recommends a maximum load of 3kN, and is based on a 75kg patient and equates to a force of approximately four times body weight (G. Bergmann *et al*, 2016).

Table 7 Fracture tolerance test for human cavaders

Sr. No.	Force at fracture (N)	Fractures
1	7.52	Femoral neck
2	7.87	Femoral neck
3	4.67	Femoral neck

1. George Bergemann *et. al*, assessed 4 patients with body weight ranging from 75 kg to 100 kg and measured telemetrically contact forces and synchronous gait data during some activities of daily living. Typical average and high forces for testing hip implants were determined(Z. Yosibash *et al*.,2015).
2. Hip contact forces were measured for 2 males with instrumented hip joint prosthesis and forces were recorded using strain gauges and telemetry systems (J. Rupp *et al*, 2002).

Few critical activities were considered as the most critical ones and the load values for the same were defined (L. Cristofolini, 2003).

Table 8 Peak value of force for various activities

Activity	Health condition	Measured average peak value of force
Walking	75 kg – 100 kg	1500 N-3200 N
Cycling	75 kg – 100 kg	1000 N-2000 N
Stand up	75 kg – 100 kg	1500 N-3800 N
Stairs uP	75 kg – 100 kg	2000 N-3600 N
Stairs down	75 kg – 100 kg	2000 N-4000 N
Jogging	75 kg – 100 kg	2200 N-4800 N
Walking fast	75 kg – 100 kg	1500 N-3750 N
Stand up	75 kg – 100 kg	1000N-2250 N
Stairs up	75 kg	2775N
Stairs down	75 kg	3000N
Stumbling	75 kg	6000 N
Walking	60 kg – 95 kg	1500 N-2500 N
Stairs up	60 kg – 95 kg	1200 N-2800 N

3.2 Comparison of experimental test value with previous standard data

Maximum amount of the load a model can withstand is given below. Maximum load of each model is compared with standard average peak value of forces for various activities mentioned in Table 16. Model 1 and Model 2 is more safe while considering all the activities mentioned above. Whereas model 3 and model 4 a critical for activities like jogging, stairs down and stumbling. Also fracture tolerance test carried on human cavaders (Table 7) showed forces at fracture at femoral neck were in the range of 4.67-7.87 N. In comparison to fracture forces of cavaders, all 4 models shows that they can carry a mean load of 8175 N which is much more higher than 7.87 N.

Table 9 Fracture test- experimental values

Model	Load at termination	Reason for terminating the test
Model 1 (ϕ26ϕ18)	13120 N	Fracture of stem
Model 2 (ϕ40ϕ18)	12880 N	Fracture of stem
Model 3 (ϕ26ϕ10)	3800 N	Fracture of stem
Model 4 (ϕ40ϕ10)	2900 N	Fracture of stem

3.3 Result and Discussion

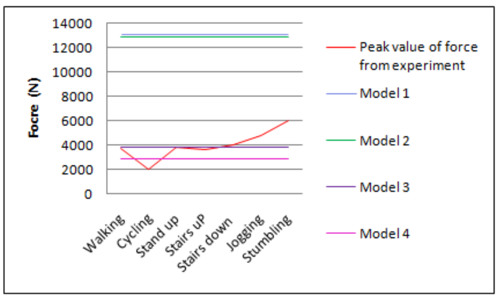

Fig. 6 Comparison of fractrure forces of exp. models with peak value force for various activities

Experimental validation with previous standard data

Fracture test report for the 4 models shows variation in load carrying capacity which is characterized by stem diameter. Models 1 and 2 with bigger stem diameter (ϕ18) showed higher load withstand limit as compared to models 3 and 4 with (ϕ10). So models 1 and 2 showed endurance limit more than the maximum of any crucial activity like stumbling (6kN) or jogging (4.8 kN). Also models 1 and 2 showed safe zone as compared to maximum fracture force on cadavers.

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