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Fabrication of Low-Cost Hip Implant using Direct Metal Laser Sintering Technique

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Abstract*: Total hip replacement (THR) is the most popular surgery been performed in orthopedic surgery due to the inclination of musculoskeletal disorder and the aging population worldwide. However, the implant's cost-burdened the patient, especially in the ASEAN region. The main objective of this study was to fabricate the low-cost hip implant using direct laser metal sintering (DMLS). The framework starts with the three dimensional of hip anthropometric datasets from computed tomography scanner, followed with the design of hip implant, computational analysis using finite element, and finally fabrication using DMLS technique. The morphological results demonstrated the value of neck-shaft angle was 130.46º, and the femoral head offset of 30.35 mm. The finite element analysis showed strain distribution was 65 MPa for the implant in metaphyseal region and 110 MPa for intact femur under staircase physiological loading which indicated inhibition of stress shielding at medical calcar region, and micromotion was 4.8 µm which prevent the formation of fibrous tissue and promoting osseointegration between implant-bone interfaces. This study proposed the fabrication using the DMLS technique, which produced accurate implant with low-cost, which suits the ASEAN hip morphology that prolongs implant lifetime.

***Keywords*: hip implant, morphology, finite element analysis, direct metal laser sintering**

I. INTRODUCTION

Total hip replacement (THR) has become the most extensive orthopedic surgery to restore the function of hip joint lost due to musculoskeletal degenerative diseases [1]. The high prevalence of osteoarthritis and rheumatoid arthritis in the United States alone projected to the 512 000 procedure in primary THR in 2020 [2]. This trend inclination leads the implant's manufacturer to produce better designs that cater to all populations. However, there is no universal off shelves hip implant that suits all populations [3-5]. The peculiar hip morphology for the ASEAN population, especially at the neck-shaft angle, femoral head offset, isthmus location, and mediolateral region promote the development of an appropriate implant's design that complies ASEAN hip anthropometric [6-7].

Direct metal laser sintering (DMLS) technique generally built the implant layer by layer using powdered metal, radiant heaters, and computer-controlled heaters, which enable to regulate of the three-dimensional architecture of the implant [8]. Besides, DMLS also permitted the fabrication of complex shapes of peculiar ASEAN hip morphological and reduced metal powder waste during fabrication [9]. The previous study by the researcher using the investment casting technique [10] and metal injection molding (MIM) technique [11] demonstrate a higher shrinkage rate compared to the DMLS technique.

Furthermore, the lack of a study related to implant development using the DMLS technique promote the development of hip implant using this technique. The convincing implant survival at 95.8% and low complication rates reported using the DMLS custom made subperiosteal implant [12]. Besides, the study using additive manufacturing method, particularly in DMLS with surface roughness 10µm, demonstrated significant results in bone growth through a mechanical testing and micro-computed tomography scanning within the intramedullary canal distal femur [13]. Thus, the main objective of this study was to fabricate the hip implant using a direct metal laser sintering (DMLS) technique, which designed based on the ASEAN morphological hip datasets that produced an accurate implant with low-cost production.

II. METHODOLOGY

A. Femoral Morphology and Design Process

This prospective study was performed from October 2017 until December 2018 after attaining approval from the hospital ethics committee. We performed morphological studies on 120 femoral, as showed in Fig. 1. A four-row multi slices computed tomography (CT) scanner was conducted using 120 kV, 90 mAs.

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The DICOM format images imported into Mimics 10.0 software with the threshold profile fixed to 661-1980 HU for compact bone and 145-660 HU for spongy bone. The femoral mask converted into three-dimensional stereolithography (STL) model. The measurements were statistically analyzed using SAS 4.3 software for design purposes. The principles used in the design, as shown below:

a) The width is following the medullary canal diameter to achieve optimal fit and fill.

b) The length and distal size did not exceed the position of the isthmus level.

c) The neck followed standard 12/14 taper.

d) The medial and lateral curvature followed the actual femora proximal radius, which provides three contact points between the implant and bone.

e) The distal was designed straight with a 1° taper.

f) The safety factor was more significant than 1.0.

g) The finite element analysis displayed no stress shielding with acceptable micromotion (< 40 μm).

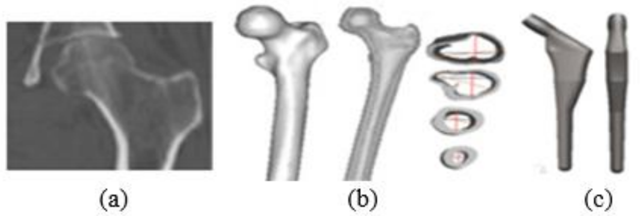

Fig. 1. Design process of hip implant (a) morphological analysis, (b) three-dimensional femoral model, (c) hip implant.

B. Finite Element Analysis

The hip implant was designed using computer-aided design software to achieve optimal fit and fill. The implant model imported to finite element software in geometric data file format to convert the triangle into the tetrahedral node mesh. The model input file converted into a stereolithographic format. The bone surgery fixed at 20 mm above the center of the lesser trochanter. A perfect contact fit between the implant and endosteal canal performed by creating a 'virtual surgery femur' from the surface mesh-like Boolean operation in MAGICS. An average of 12000 elements with 3500 nodes was found to be optimal for the implant, and the 'virtual surgery femora' consisted of 8000 nodes and 42000 elements. The model was restrained entirely distally with one static stair climbing physiological loads was simulated as showed in Fig. 2 and Table- I. The micromotion algorithm was validated experimentally in the house was written using Compaq Visual Fortran software as the subroutine. The result focused on strain distribution and micromotion.

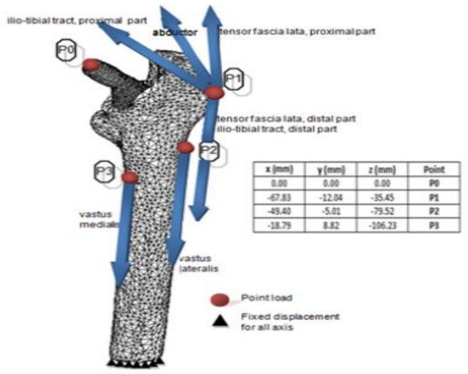

Fig. 2. Muscles point load configuration in physiological loading during finite element analysis.

Table- I: Physiological loading for stair climbing

Muscles point load (N)	x	y	z	Point Load
Hip contact	-415.1	-424.2	-1654.1	P0
Abductor	490.7	201.6	594.3	P1
Ilio-tibial tract, proximal part	73.5	-21.0	89.6	P1
Ilio-tibial tract, distal part	-3.5	-5.6	-117.6	P1
Tensor fascia lata, proximal part	21.7	34.3	20.3	P1
Tensor fascia lata, distal part	-1.4	-2.1	-45.5	P1
Vastus lateralis	-15.4	156.8	-945.7	P2
Vastus medialis	-61.6	277.2	-1869.7	P3

C. Fabrication using Direct Laser Metal Sintering

The direct laser metal sintering technique was carried out using the EOSINT M280 machine, as showed in Fig. 3. The chamber filled with argon gas with a purity of 1.3%. The process parameters in this study, as stated in Table- II. The implant was built on a stainless steel base plate and detached using wire Electrical Discharge Machining (EDM) wire cut. The prototype surface roughness is measured using a hybrid surface contour machine (Formtracer CS-5000, Mitutoyo America Company, IL, USA). The parameters fixed to a measured length of 5 mm, a measurement pitch of 1 μm, speed 0.1 mm/s, roughness pitch of 0.5 μm, and a cutoff at 0.8.

Fig. 3. Fabrication of hip implant using direct laser metal sintering.

Table- II: Direct metal laser sintering parameter used in the fabrication of hip implant

Parameters	Value
Metal temperature (°C)	1330
Laser power (W)	95
Layer thickness (μm)	40
Scan speed (mm/s)	200
Hatching space (μm)	140
Part density (%)	99.9

III. RESULT AND DISCUSSION

Table- III demonstrated the femoral anthropometric in three different populations; Asian, Caucasian, and Swiss, which varied notably in neck-shaft angle, femoral head offset, anteversion and bowing angle, and canal flare index (CFI). The CFI was in normal shape femur, which within the range of 3.0 – 4.7. However, the femoral head offset and diameter were shorter due to the smaller skeletal framework compared to the European size.

Table- III: Comparison of femoral anthropometric in different populations

Parameter	Asian	Caucasian	Swiss
Neck shaft angle (°)	130.46	125.40	122.90
Femoral head offset (mm)	30.35	-	47.00
Femoral head position (mm)	53.14	-	56.10
Femoral head diameter (mm)	28.95	34.42	-
Anteversion (°)	19.10	10.00	-
Bowing angle (°)	2.28	9.00	-
Canal flare index	4.65	-	3.36

The strain distribution for intact femur demonstrated in Fig. 4 showed the maximum strain of 110 MPa at medial calcar. The maximum strain for surgery femur demonstrated 65 MPa at the proximal region, and the minimum strain was 1.3 MPa at a distal region in Fig. 5. The strain generally distributed at the metaphyseal region in Fig. 6, which is crucial for primary stability fixation and preventing stress shielding at the proximal level. The stress shielding caused the bone atrophy at the calcar region, which closely related to the implant's design and the interface between bone-implant. The safety factor computed as 2.50 supported the finite element analysis, which not damaging calcar region.

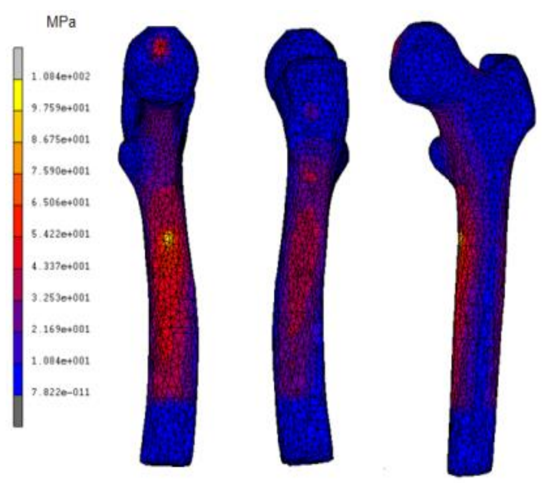

Fig. 4. Contour plot of strain distribution for the intact femur.

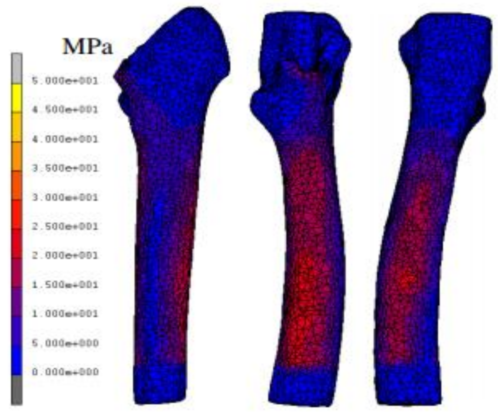

Fig. 5. Contour plot of strain distribution for surgery femur.

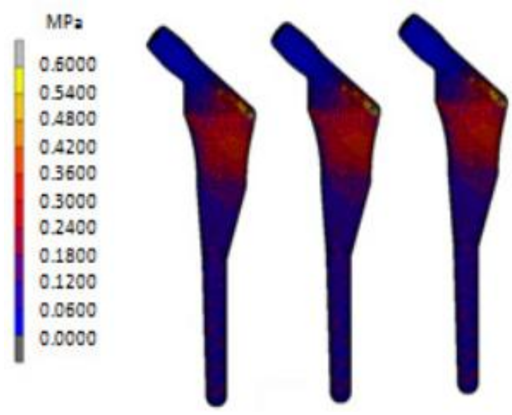

Fig. 6. Contour plot of strain distribution for a hip implant.

The micromotion was 4.80 μm, closely related to the promotion of bone growth and preventing fibrous tissue generation, as showed in Fig. 7. The surface roughness given by the hybrid surface contour machine was 9.87 μm which adequate for osseointegration.

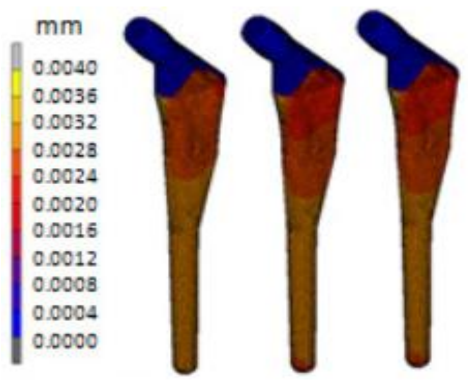

Fig. 7. Contour plot of micromotion for a hip implant.

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IV. CONCLUSION

The fabrication of hip implant using direct metal laser sintering (DMLS) coupled with the reverse engineering method demonstrated promising results which encompass better design, preventing stress shielding and lower micromotion that prolong the lifetime of the implant.

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