Design, manufacture, and fatigue analysis of lightweight hip implants

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Abstract
Background: This study aims to design, analyze and manufacture lightweight hip implants which have sufficient fatigue performance to enable use in total hip arthroplasty (THA).

Methods: The lattice structure was applied on an implant geometry, which is frequently used in THA, to provide a reduction in mass and increase flexibility. The implant surfaces were roughened using semispherical pores to improve the osseointegration. The specimens were manufactured by means of direct metal laser sintering (DMLS) and fatigue tests were performed according to ISO 7206-4:2010. Moreover, fatigue analyses of the designed implants were numerically carried out using the finite element method.

Results: The applied lattice structure on implant geometry leads to 15–17% reduction in the masses of implants compared to a solid one. It has also been determined that the lightweight implants show more flexible behavior with increasing pore diameter used on the implant surfaces while keeping the lattice structure geometry constant. The fatigue test and finite element analysis (FEA) results are in reasonable agreement. In addition, additively manufactured solid implants have exhibited similar fatigue performance with one produced by conventional methods.

Conclusions: This paper presents design, analysis, manufacturing and fatigue test processes of lightweight hip implants. The lattice structure and the semispherical pores were applied on a reference implant geometry and they were manufactured by DMLS. The fatigue tests and FEA were performed to evaluate newly designed implant performance. All the implants successfully completed the fatigue tests without any damage.

Keywords
Additive manufacturing, fatigue test, finite element analysis, lightened hip implant, direct metal laser sintering

Introduction
The femur, which joins with the pelvis in proximal and tibia in distal, is the longest and the most load-bearing bone of the human body. Its length varies from person to person and is about 25% of body length (average 45–50 cm). Contrary to synarthrosis or amphiarthrosis, the hip joint has a great importance due to its ball–socket joint feature in fulfilling daily activities such as sitting, walking, jumping, and squatting.1

The forces acting on the hip joint can be at different values depending on the physical activities. The forces acting on the hip joint during walking are about 2.6–2.8% of the body weight, whereas they are 10 times the body weight in activities such as lifting, running, and jumping.2

Fractures may occur on a hip joint which is under the influence of constantly variable loads, depending on age, sex, heritage, nutrition, and lifestyle. Femur neck fractures, which constitute a significant part of the femur fractures, are mostly seen in elderly people due to osteoporosis. They can also occur in younger age groups after high-energy traumas.

The treatment of femur neck fractures is one of the important issues that negatively affect the health sector in terms of medical, social, and economic aspects. The worldwide hip fracture total was calculated at 1.6 million in the

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1990s. With the increase in average life expectancy, it is estimated that this amount may rise to 3.2 and 4.5 million in 2025 and 2050, respectively. The American National Osteoporosis Foundation claims that there are about 2 million fracture cases in a year in the United States. Approximately 300,000 of them are hip fractures, which are a burden of more than 19 billion dollars to the national economy.

In cases involving high body weight and physical activity, the load on the femur increases, which in turn results in bending and torsional stresses in the femoral component of an implant. If these stresses are repetitive and variable, fatigue fractures or deformations may arise in hip implants. A hip implant placed in the femur during a total hip arthroplasty (THA) operation not only destroys the main arterial supply of the cortex but also damages the medullary space. After implantation, new vessels grow around the implant and change the endosteal perimeter. The decreasing of blood supply in this region may cause resorption of the cortical bone, which may lead to reduction in the bone density of the proximal cortex. Previous studies have shown that a hip implant with more medullary space can help medullary revascularization and improve blood circulation. This results in a reduction of cortical bone resorption and a contribution to endosteal remodeling.

Yang et al. suggested that the implant should be lightened to achieve more space to provide medullary revascularization. In addition, it has been mentioned that holes might be added to the implant surfaces to create a connection between inner and outer region of the implant body. Moreover, studies on subject animals showed that the lightened and surface-roughened implants provide a good integration with the bone in the implantation area. Koch et al. studied the histopathological findings concerning the bone–implant interface of a titanium mesh acetabular cup after 27 years in a human body. The findings indicated an adaptive bone remodeling at the interface to the deep solid core of the acetabular cup. Furthermore, the experiments in the human body of open-cellular Ti6Al4V implants produced by additive manufacturing are highly encouraging in terms of osseointegration.

Those research efforts have shown that additively manufactured implants having special geometry provide better osseointegration compared to standard ones that are produced by metal cutting operations. The lightening of the implant may reduce the stem strength. Additionally, the proper lightening may provide enough strength to the stem by considering stress distributions in the design and analysis procedures. In some cases, stem strength might even be close to that of a solid implant. The experimental studies performed by Moulton et al. and Ridzwan et al. indicated that the adaptation of the uncemented stem geometry to the inner region of the cortical bone of proximal femur is important for optimizing load takeover and a better mechanical stability in THA.

### Material and Methods

#### Material

Titanium alloys are high-strength, low-density (4.41 g/cm³), corrosion-resistant materials and have a wide application range in biomedical applications. Especially, Ti6Al4V alloy, one of the α + β type titanium alloys, was used in many studies due to its high biocompatibility. Therefore, Ti6Al4V alloy metal powder was preferred in this study.

#### The implant design and manufacture

The implant geometry was determined according to a survey conducted of expert surgeons and academicians working at different universities and hospitals. The survey results showed that the rotation stability of the rectangular sectioned type hip implant is high in the femur. Hence, an implant with stem length of 160 mm was selected as reference geometry for three-dimensional (3D) modeling, as shown in Figure 1(a). The chosen implant was then modeled in Solid Works® (Figure 1(b)). The solid model was modified to obtain desired geometry.

The unique geometry consists of outer and inner regions that are linked to each other (Figure 2). The outer region...
has semispherical pores and cylindrical cell development channels. These pores provide roughness to the surface and cell development channels connect the outer region to the inner one. The semispherical pores, modeled on the side surfaces of the implants, have different diameters varying from 0.3 mm to 1 mm with 0.1 mm increments. The implant surfaces roughened with 0.3 mm and 0.6 mm pores are shown in Figure 3.

The inner region was created by subtracting a volume from the reference implant body. A Kubisch Raumzentrierten (KRZ) type lattice structure was applied to the subtracted volume in Netfabb®. By doing so, a porosity of 78.3% was achieved in the volume. Then, the surface-roughened hollow implant body and its inner region were combined together. The longitudinal section of the lightened implant is illustrated in Figure 4.

Successfully designed implants were then imported into Magics® in order to adjust building orientation and create support structures. Each implant was placed on the virtual building platform with 10° angle to the y-axis while keeping roughened surfaces clear from support structures, as shown in Figure 5. The reader may note that the block support type defined in Magics® was used. As is well known, 3D printing technology uses sliced data of the solid model. Therefore, the implant geometries were sliced in EOS RP Tools® while Magics® was employed to slice support structures. The sliced data were then loaded to EOS PSW® to build the implants. The exposure parameters were defined as: 170 W laser power, 1000 mm/s scanning speed, and 0.09 mm hatching distance. These parameters were selected based on a previous study, which provides the highest compressive strength for the manufactured parts.

In total, nine specimens (three of each 0.3 mm, 0.6 mm, and solid) were built using an EOS M280 direct metal laser sintering (DMLS) machine. All the specimens were annealed to stress relieving for 3 h at 650°C in an argon atmosphere after the DMLS process. Then, they were cut from the platform using a wire electrical discharge machine. Sandblasting with 3 bar pressure and duration of 10 min was applied to the specimens for deburring. In Figure 6, solid specimens (T1, T2, T3), large pore (0.6 mm) specimens (BG1, BG2, BG3) and small pore (0.3 mm) specimens (KG1, KG2, KG3) are shown together with the reference implant (O) produced by machining.

Finite element analysis
The finite element models were created in accordance with the requirements of ISO 7206-4:2010 standard using Ansys® Workbench 16.2 software. The finite element analysis (FEA) model includes two suppression blocks (transmit the loads to the stem), a femoral head and the implant embedded in cement 80 mm distance from the femoral head center with angle of 10° adduction and 9° flexion. For the aforementioned parts, the material properties used in FEA are given in Table 1.

The bounded contact type was defined for bone cement–implant, conical head of the implant–inner surface of the femoral head, the outer surface of the femoral head, and...
the lower suppression interfaces. Furthermore, the contact type “no separation” was assigned between upper suppression block and the lower one. In addition, the bottom plane of the cement was described to be fixed support and the side surfaces of the upper suppression block was specified as frictionless support (Figure 7).

All the parts in the FEA model were meshed using 10-node tetrahedral elements (SOLID187) and 20-node tetrahedral elements (SOLID186) included in Ansys® Workbench. The number of elements was increased in critical areas such as the implant neck and the contact surfaces to improve prediction accuracy. It is worth to note that the FEA model with solid implant has approximately 650,000 elements and the other ones, which contain lightened implants (pore sizes of 0.3 mm to 1 mm), have about 12,000,000–3,500,000 elements.

The sinusoidal load with a frequency of 15 Hz was acted vertically from the top surface of the upper suppression block to the femoral head center. The lower and upper force limits were 300 N and 2300 N (loading ratio: 0.1304), respectively. According the fatigue test standard mentioned in the previous section, the implants must withstand loads during 5 million cycles without any damage to be able to successful. The stress-life fatigue criterion and Goodman mean stress theory were used in FEA fatigue analyses. Since the multi-axial stresses might occur in the model during loading, the equivalent stresses were calculated according to the von-Mises yield criterion.

**Fatigue tests**

Fatigue tests of all the implants were performed on servo hydraulic fatigue test machine (Instron 8872) that has a 25 kN load and a 100 N m torque capacity at room temperature. The acrylic based bone cement, which is frequently preferred in THA and resistant to dynamic tests, was employed for fixing the implant in the defined position. The specimens were positioned in accordance with the aforementioned standard that provides maximum loading in the proximal femur region and allows the stem to be complexly loaded. A gripping device (fixing clamp)
shown in Figure 8 was used for positioning at the appropriate angles. Then, the specimens on the fixing clamp were placed in a stainless steel cup where bone cement was poured into.

The sinusoidal compressive loads (with 15 Hz frequency and limits between 300 N and 2300 N) were applied to the implants during the test. The vertical displacements of the implants were measured via displacement sensor connected to an actuator in the test machine at every 50,000 load cycles. The detailed test conditions are given in Table 2.

### Results and discussion

The FEA for each designed implant are successfully completed and the vertical displacement, maximum equivalent stress and fatigue life results after 5 million load cycles are given in Table 3.

### Table 1. Material properties used in FEA.

| Material                  | Poisson ratio | Elasticity modulus (GPa) |
|---------------------------|---------------|--------------------------|
| Steel (suppression blocks) | 0.3           | 210                      |
| Ti6Al4V (implant)         | 0.342         | 110                      |
| Cr–Co (femoral head)      | 0.33          | 200                      |
| Bone cement               | 0.3           | 3.8                      |

### Table 2. Fatigue test conditions.

| Frequency      | 15 Hz       |
|----------------|-------------|
| Maximum load   | 2300 N      |
| Minimum load   | 300 N       |
| Test environment | Air        |
| Temperature    | Room temperature (~22°C) |
| The environment in which the stem is embedded | Bone cement |
| Offset angle α (frontal) | 10 ± 1° |
| Offset angle β (sagittal) | 9 ± 1° |
| The part of the stem outside the bone cement | 80 mm |
| Offset (vertical distance between the center of the head and the axis of the stem) | 35 mm |

### Table 3. FEA results.

| Pore size (mm) | Displacement (mm) | Equivalent stress (MPa) | Life (for 5 × 10⁶ cycles) |
|----------------|-------------------|-------------------------|----------------------------|
| Solid          | 0.22451           | 211.50                  | Infinite                   |
| 0.3 (KG)       | 0.24214           | 232.63                  | Infinite                   |
| 0.4            | 0.24584           | 233.59                  | Infinite                   |
| 0.5            | 0.24946           | 234.73                  | Infinite                   |
| 0.6 (BG)       | 0.25308           | 235.85                  | Infinite                   |
| 0.7            | 0.25910           | 237.85                  | Infinite                   |
| 0.8            | 0.26548           | 238.46                  | Infinite                   |
| 0.9            | 0.27293           | 239.58                  | Infinite                   |
| 1              | 0.28187           | 240.04                  | Infinite                   |
As expected, the displacements are directly proportional to the pore diameters on the implant surfaces. The reduction in the cross-sectional area with increasing pore diameter leads to higher displacements. It is worth noting that the deformation on the implants is in the elastic region. The maximum equivalent stresses occur on the neck region of all implants. This observation is similar with the ones presented by Jameel et al. and Sivasankar.\textsuperscript{20,30} As seen in Table 3, the solid implant contains the smallest equivalent stress (211 MPa) compared to lightened ones. Additionally, lightened implants experience much bigger stresses under the same loading, which is due to the smaller and complex cross-sectional area. In addition, all the implants were found to be successful after five million load cycles. The fatigue life for all implants has been determined to be infinite.

The mean displacements in the implants during the fatigue tests versus number of cycles are illustrated in Figure 9. The reader may note that three fatigue tests for solid, BG, and KG implant types were completed and the mean displacement values for each group were then obtained by taking the average for each specimen data. Additionally, Table 4 includes a comparison between the measured mean displacements from fatigue tests and ones predicted by FEA. The mean displacements during the test for both solid implants (O and T group) are similar. The percent difference between them is only 2.97%. This means that DMLS is able to manufacture implants with sufficient fatigue performance compared with a machined one. On the other hand, it has been observed that BG and KG implants exhibit similar deflection during the tests. Implants with increased pore diameters cause 3.82% higher displacement values. However, the solid implants show lower displacement compared to the lightened ones. This verifies that solid implants have higher stiffness than lightened ones.

Table 4. Mean displacement values of specimen groups after 5x10^6 load cycles.

| Specimen | Fatigue test displacement (mm) | Mean displacement (mm) | FEA displacement (mm) |
|----------|-------------------------------|------------------------|-----------------------|
| O        | 0.235                         | 0.235                  | -                     |
| T1       | 0.170                         |                        |                       |
| T2       | 0.273                         | 0.228                  | 0.22451               |
| T3       | 0.240                         |                        |                       |
| KG1      | 0.280                         | 0.277                  | 0.24214               |
| KG2      | 0.225                         |                        |                       |
| KG3      | 0.327                         |                        |                       |
| BG1      | 0.191                         | 0.288                  | 0.25308               |
| BG2      | 0.346                         |                        |                       |
| BG3      | 0.328                         |                        |                       |

Those differences might result from two issues. First, there are small regions that were not intended to be sintered during manufacture. As mentioned before, the lightened implant has a lattice structure inside and pores on the surface. Those structures have very small cross sections that are lower than the heat-affected zone diameter (Figure 11). This phenomenon could cause undesired sintered areas. The second is the force applied on the corresponding layer by the recoater blade while spreading the powder. The deflection of small and narrow angled sections by this force may cause small dimensional errors. Hence, the pores in the KG were only partially formed compared to the desired geometry, as can be seen in Figure 12(a). But the pores and cell development channels in the BG were successfully manufactured compared to the KG ones as the pore size of BG specimens was bigger than the KG ones (Figure 12(b)). It can also be noted that there are less partially sintered regions and that the deflections by recoater blade in the small sections are lower in BG specimens.

In addition, all the implant masses were measured using a precision mass balance to determine the lightening rates. The measurement results are provided in Table 5. There is a small difference between the reference implant manufactured by machining and the solid one built via DMLS. This might be caused by the coating (thin hydroxyapatite layer), which has been performed by supplier, on the reference implant. However, there is no coating applied on the implants manufactured in this study. As expected, a lower mass in the lightened implants was obtained with a lightening rate of 14.81% and 16.97% for KG and BG, respectively. Further lightening of an implant might bring strength and stability issues, while less lightening could negatively affect the bone tissue development at the implantation region. Therefore, it is necessary to consider those situations in the lightweight implant designs.

Conclusions

In this study, the implant geometry, which is widely used in THA, was determined according to the opinions of
expert surgeons and faculty members. The chosen geometry was specially designed with surface pores and lightened by using the KRZ lattice structure. Thanks to the ability of additive manufacturing technologies that make it possible to build complex shaped and hollow parts, approximately 15–17% lighter implants were manufactured compared to solid ones with the same geometry. All the implants produced with DMLS have been shown to exhibit enough fatigue performance according to the requirements of the ISO 7206 standard. In addition, FEA findings are highly consistent with fatigue test results. Thus, the displacements outside of the investigated pore size range can be predicted with sufficient accuracy by FEA. This enables us to save production costs and obtain an idea about the implant performance without carrying out any building process.

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Declaration of Conflicting Interests

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References

1. Ertem M. Corrosion fatigue characteristics of total hip prosthesis in simulated body fluid. Master Thesis, Dokuz Eylul University, Turkey, 2006.
2. Harkess JW. Hip arthroplasty. In: Canale ST (ed) Campbell’s operative orthopaedics. 10th ed. Philadelphia, PA: Mosby, 2003, pp.316-320.
3. Dhanwal DK, Dennison EM, Harvey NC, et al. Epidemiology of hip fracture: worldwide geographic variation. Indian J Orthopaedics 2011; 45: 15-22.
4. Keklikçi K, Çilli F, Pehlivan Ö, et al. Femur boyun kırıkları [Femur neck fractures]. Türk Ortopedi Travmatoloji Birliği Dergisi 2009; 8: 1-6.
5. Kannus P, Parkkari J, Sievänen H, et al. Epidemiology of hip fractures. Bone 1996; 18: 57-63.
6. Cooper C, Campion G and Melton LJ. Hip fractures in the elderly: a world-wide projection. *Osteoporosis Int* 1992; 2: 285-289.

7. Kamel HK, O’Connell MB. Introduction: Postmenopausal osteoporosis as a major public health issue. *J Manag Care Pharm* 2006; 12(6)(suppl S-a): S2-S3.

8. Pazzaglia UE, Zatti G, Cattanen S, et al. Evaluation of hollow and full stems implanted in the rabbit tibia: preliminary results. *Biomaterials* 1993; 14: 883-886.

9. Pazzaglia UE. Periosteal and endosteal reaction to reaming and nailing: the possible role of revascularization on the endosteal anchorage of cementless stems. *Biomaterials* 1996; 17: 1009-1014.

10. Yang CT, Wei HW, Kao HC, et al. Design and test of hip stem for medullary revascularization. *Med Eng Phys* 2009; 31: 994-1001.

11. Suzuki K, Aoki K and Ohya K. Effects of surface roughness of titanium implants on bone remodeling activity of femur in rabbits. *Bone* 1997; 21: 507-514.

12. Grizon F, Aguado E, Hure G, et al. enhanced bone integration of implants with increased surface roughness: a long term study in the sheep. *J Dent* 2002; 30: 195-203.

13. Wang H, Su K, Su Leizheng, et al. The effect of 3D-printed Ti6Al4V scaffolds with various macropore structures on osteointegration and osteogenesis: a biomechanical evaluation. *J Mech Behav Biomed Mater* 2018; 88: 488-496.

14. Kayacan MC, Baykal YB, Karaaşlan T, et al. Monitoring the osseointegration process in porous Ti6Al4V implants produced by additive manufacturing: an experimental study in sheep. *J Appl Biomater Funct Mater* 2018; 16: 68-75.

15. Koch FW, Koch AK, Amling M, et al. Histopathological findings at the 3D titanium fiber mesh-bone interface of a porous coated acetabular cup after a lifetime of 27 years. *Osteologie* 2018; 27: 165-171.

16. Shujun L, Xiaokang L, Wentao H, et al. Fabrication of open-cellular (porous) titanium alloy implants: osseointegration, vascularization and preliminary human trials. *Sci China Mater* 2018; 61: 525-536.

17. Viceconti M, Toni A and Giunti A. Effects of some technological aspects on the fatigue strength of a cementless hip stem. *J Biomed Mater Res* 1995; 29: 875-881.

18. Moulton DL, Lindsey RW and Gugala Z. Proximal femur size and geometry in cementless total hip arthroplasty patients. *F1000Research* 2015; 4: 161.

19. Ridzwan MIZ, Solehuddin Shuib, Hassan AY, et al. Problem of stress shielding and improvement to the implant designs: a review. *J Med Sci* 2007; 7: 460-467.

20. Jameel AN, Majeed WI and Razzaq AM. Fatigue analysis of hip prosthesis. *J Eng* 2012; 18: 1100-1114.

21. Chao J and Lopez V. Failure analysis of a Ti6Al4V cementless hip prosthesis. *Eng Fail Anal* 2007; 14: 822-830.

22. ISO 7206-4:2010: Implants for surgery – partial hip prostheses. Part 4. Determination of implant properties of stemmed femoral components.

23. Scientific and Technological Research Council of Turkey. Biyomalzemeler [Biomaterials], www.bilimteknik.tubitak.gov.tr/system/files/biyomalzemeler.pdf 2002, accessed 22 December 2017).

24. Williams DF. Titanium for medical applications. In: *Titanium in medicine. engineering materials*. Berlin: Springer, 2001, pp.13–24.

25. Liu X, Chu PK and Ding C. Surface modification of titanium, titanium alloys and related materials for biomedical applications. *Mater Sci Eng* 2004; 47: 49-121.

26. Eldesouky I, Abdelaal O and El-Hofy H. Femoral hip stem with additively manufactured cellular structures. In: *IEEE conference on biomedical engineering and sciences*, Miri, Sarawak, Malaysia, 8–10 December 2014.

27. Barui S, Chatterjee S, Mandal S, et al. Microstructure and compression properties of 3D powder printed Ti-6Al-4V scaffolds with designed porosity: experimental and computational analysis. *Mater Sci Eng* 2017; 70: 812-823.

28. Croitoru ASM, Paccioga BA and Comso CS. Personalized hip implants manufacturing and testing. *Appl Surf Sci* 2017; 417: 256-261.

29. Kayacan MC, Delikanlı YE, Duman B, et al. Ti6Al4V toz alaşımı kullanılarak SLS ile üretilen geçişli (değişken) gözenekli numunelerin mekanik özelliklerinin incelenmesi [Examining of mechanical properties of transitive (variable) porous specimens produced by sls using ti6al4v alloy powder]. *J Faculty Eng Archit Gazi Univ* 2018; 33: 127-143.

30. Sivasankar M. *Failure analysis of hip prosthesis*. PhD Thesis. India: Indian Institute of Technology Guwahati, 2007.