

Designing an Optimized Novel Femoral Stem

Abstract

Background: After total hip arthroplasty, there would be some problems for the patients. Implant loosening is one of the significant problems which results in thigh pain and even revision surgery. Difference between Young's modulus of bone-metal is the cause of stress shielding, atrophy, and subsequent implant loosening. **Materials and Methods:** In this paper, femoral stem stiffness is reduced by novel biomechanical and biomaterial design which includes using proper design parameters, coating it with porous surface, and modeling the sketch by the software. Parametric design of femoral stem is done on the basis of clinical reports. **Results:** Optimized model for femoral stem is proposed. Curved tapered stem with trapezoidal cross-section and particular neck and offset is designed. Fully porous surface is suggested. Moreover, Designed femoral stem analysis showed the Ti6Al4V stem which is covered with layer of 1.5 mm in thickness and 50% of porosity is as stiff as 77 GPa that is 30% less than the stem without any porosity. Porous surface of designed stem makes it fix biologically; thus, prosthesis loosening probability decreases. **Conclusion:** By optimizing femoral stem geometry (size and shape) and also making a porous surface, which had an intermediate stiffness of bone and implant, a more efficient hip joint prosthesis with more durability fixation was achieved due to better stress transmission from implant to the bone.

Keywords: Atrophy, biological fixation, biomechanical designing, metallic biomaterials, porous materials

Introduction

Total hip joint replacement (THR) is suggested to patients who suffer pain, hip malfunction, and trauma; its significance is mainly due to high prevalence of hip osteoarthritis in the western world (10% of people 60 years or older).^[1] During total hip arthroplasty, bone and damaged cartilage are removed, and then the artificial hip joint is replaced. For many years, implants were fixed in the place through pressure, friction, or screws. Because of insufficiency of these methods, better methods are presented.^[2] Now, there are two popular types of femoral stem fixation: cemented femoral fixation and cementless femoral fixation (biological fixation).^[3] Cementless fixation is considered to be gold standard for hip replacement especially young patients because of its long-term results and clinical success.^[4]

Uncemented femoral fixation is newer method which rectifies disadvantages of cemented femoral stem fixation. Providing a porous area receptive to tissue ingrowth,

can lead to greater interface shear strength, flexibility, and lower modulus of elasticity. In result, mechanical properties of implant would have more similarities to natural bone.^[2] However, biological fixation has shown few undesirable effects. After total hip replacement, natural stress redistributes. Greater metal stiffness makes much of the load be carried in proximal stem to distal femur; thus, compressive stress reduces in proximal femur. In response, to the changed mechanical environment, the shielded bone will remodel according to Wolff's law^[5]; underload bone shows more tissue ingrowth as compared with the time it is filled with stiff femoral stem. Bone receives no natural load, resulting in a loss of bone mass through the biological process called resorption. Resorption can, in turn, cause or contribute to loosening of the prosthesis.^[6] Femoral bone resorption occurs because of atrophy is common phenomenon after cementless THR.^[7] Absence of strong fixation in bone-implant interface results in implant erosion, implant loosening, and thigh pain.^[8-10]

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There are various important parameters in the THR design, include high biocompatibilities, adequate strength, and rather low modulus of elasticity. Co–Cr femoral stems are stiffer and expected to elasticity mismatch.^[5] Besides of choosing alloy, designing and geometry are other important issues. Geometrical factors include stem length, cross-section, and suitable shape. Surface geometry features are as important as designing factors in biological fixation. The porous surface was chosen so that there will be enough microstructure for biological fixation.^[5] Table 1 summarized the various geometrical parameters and their effects on THR operation.

It is supposed that modeling new femoral stem with optimized design parameters and fully porous surface can solve present problems. In this research, a femoral stem made of titanium alloy (Ti6Al4V) is designed. It is presumed that when bone cement is used for implant fixation, many shapes of femoral stem can be fixed with bone cement. In this essay, it is planned to suggest innovative design for uncemented femoral stem. Particular designing elements were recognized and studied to achieve optimized femoral stem shape.

Material and Methods

In this paper, a porous femoral stem with two prominent properties is introduced; lower modulus of elasticity and biological fixation. The femoral stem is designed by CATIA V5R19. CATIA is powerful software for industrial designing and tetrahedral 10 node element was used for analysis. It supports multiple stages of product development. In this research, all design parameters of ideal femoral stem are collected. These elements include: proper shape for prosthesis, femoral stem geometry and adaptable cross-section, optimum length range, determining relevant offset, and correct angles. All these data are given to the software to design ideal porous femoral stem.

Femoral Stem Shape

In this research, curved stem is chosen [Figure 1]. Micro motion in the interface of bone–implant is one of the causes of implant loosening. When micro motion is as much as 40 μm there will be kind of bone ingrowth in bone–implant interface. But if this micro motion exceeds threshold of 150 μm , it prevents bone ingrowth.^[11] Collaghan *et al.*^[12]



Figure 1: Femoral stem shapes: (a) straight stem, (b) curved stem^[60]

Table 1: The role of different geometrical parameter on THR design

Design parameters	Types	Description	References
Femoral stem shape	Straight/curved	Less motion occurred at bone–implant interface of curved stem prosthesis at high torsion. Maximum micro motion in straight stem is significantly more than curved stem. Curved stem has more compatibility with geometry of bone and also sharp corners of curved prosthesis contribute rotational stability. Self-locking within the natural curvature of the femur. Less invasive surgery due to geometrical fitness	[11-12]
	Cylindrical	Distal fixation may lead to proximal bone loss due to stress shielding. There is a possibility of implant fracture while replacing in the medullary canal	[5,10,13]
	Anatomical	Matching the shape of proximal femur. Due to their proximal fixation, they have achieved clinical success. Design limitation because of large variation in shape and size of femur which results in femoral component and canal mismatch	
	Tapered	Triple taper shape supports axial and distal stability. Tapered stem could be replaced in medullary canal without damaging blood supply. More proximal thickness of prosthesis is contributor to fatigue resistance. Clinical reports have shown that tapered stems are successful prosthesis	
Cross-section of femoral stem	Trapezoidal	Distributes load in metaphyseal region. Enhances axial and torsional stability. Preserves maximum cancellous bone in proximal region	[3,10,11]
Optimum length of femoral stem	Long stem	Smaller contact forces on the bone.	[5]
	Short stem	Stress in bone cortex increases as stem length decreases May restore biomechanical properties better than conventional stems. Advantages of shorter stems include bone conserving, reducing atrophy by proper load transfer and ease of inserting femoral stem into femoral canal. Bony ingrowth is more favorable with short stems due to lowered cyclic motion after implantation. Patients who use short femoral stem spend less time in hospital	[14,15]
Role of calcar support*		Transfer homogeneously through both prosthesis and proximal femur	[5]
Offset†		Offset directly influences neck shape and dimensions. Shorter neck length leads to limitations in range of motion, patient doesn't feel comfortable. Longer neck length restore leg length equality tends to loosen earlier	[5]
Angles‡	Neck support angle (D) Neck–shaft angle (E)	These angles reduce the torque at the area during every load cycle	[5]
Prosthesis neck shape§	V-shaped neck is recommended	These angles reduce the torque at the area during every load cycle	[10]

*Calcar (C) is kind of collar which is placed between neck and proximal stem. †Offset is horizontal distance between femoral stem shaft and center of implant ball. ‡See Figure 2. §See Figure 3.

found when large torsional moments (22 N m) were applied to both straight and curved femoral stem, less motion occurred at bone–implant interface of curved stem prosthesis. Curved

stem has more compatibility with geometry of bone and also sharp corners of curved prosthesis contribute rotational stability.^[11]

Femoral Stem Geometry

According Table 1, tapered stem geometry was selected. In tapered stems, there is a deviation between proximal and distal region. This triple taper shape supports axial and distal stability. It achieves proximal fixation and the clinical reports have shown that tapered stems are successful prosthesis.^[131]

Cross-section of Femoral Stem

Among all different shapes of femoral stem, trapezoidal cross-section is more recommended [Table 1]. With fixation of four corners, rotational stability is provided.^[3]

Optimum Length of Femoral Stem

Short stems may restore biomechanical properties better than conventional stems.^[14] Advantages of shorter stems are mentioned in Table 1.

For curved stem prosthesis, optimum length range is recommended between 80 and 105 mm. By choosing this length range, micro motion remains about 20 μm . When patients do heavy activities like fast walking or stair climbing, micro motion increases up to 100 μm . It's still below the threshold of 150 μm .^[16]

Role of Calcar Support

Calcar is kind of collar which is placed between neck and proximal stem. Calcar is controversial design criteria for femoral stem.^[5] Calcar provides physiologic stress but it is only possible when it's in focalized compact bone state. In surgeries, it is not usually probable to accomplish proper templating and neck cut. If adequate contact between calcar and proximal femur couldn't be achieved, designing of calcar is not suggested. Meding *et al.*^[17] found: although the calcar is a feature of many modern implants, but there is no considerable difference in prosthesis function, thigh pain, and radiographic image between collared and collarless uncemented femoral stem.

Implant Offset

As shown in Figure 2, offset is horizontal distance between femoral stem shaft and center of implant ball. Providing optimum offset is significant part of implant design.

Suitable offset should be chosen according to anthropometric ratio. Stem should derive rotational stability from contact in the calcar region; fit in this region is also a priority. A study of 497 X-rays conducted in Switzerland confirmed that optimum offset range is between 37 and 45 mm. A total of 40 mm offset distance covers nearly many of measured patients offset; 70 out of the 497 have exactly the offset length of 40 mm.^[10]

Implant Angles

According to Figure 2, two angles play considerable role in femoral stem design: neck support angle (D) and neck–shaft angle (E).

Desirable range of $135 < \theta < 145^\circ$ is proposed for neck–shaft angle. And also neck support of 35 to 30. These angles reduce the torque at the area during every load cycle. Finding precise value for neck support angle is not easy due to stem's curvature. In this study, a value of 45° is appointed for neck support angle, but in some researches, this angle has been reported with -10° difference.^[5]

Prosthesis Neck Shape

To achieve proper range of motion, V-shaped neck for the femoral stem is recommended as described in Figure 3. These angles reduce the torque at the area during every load cycle. Besides, V-shaped provides good standard for fatigue strength.^[10]

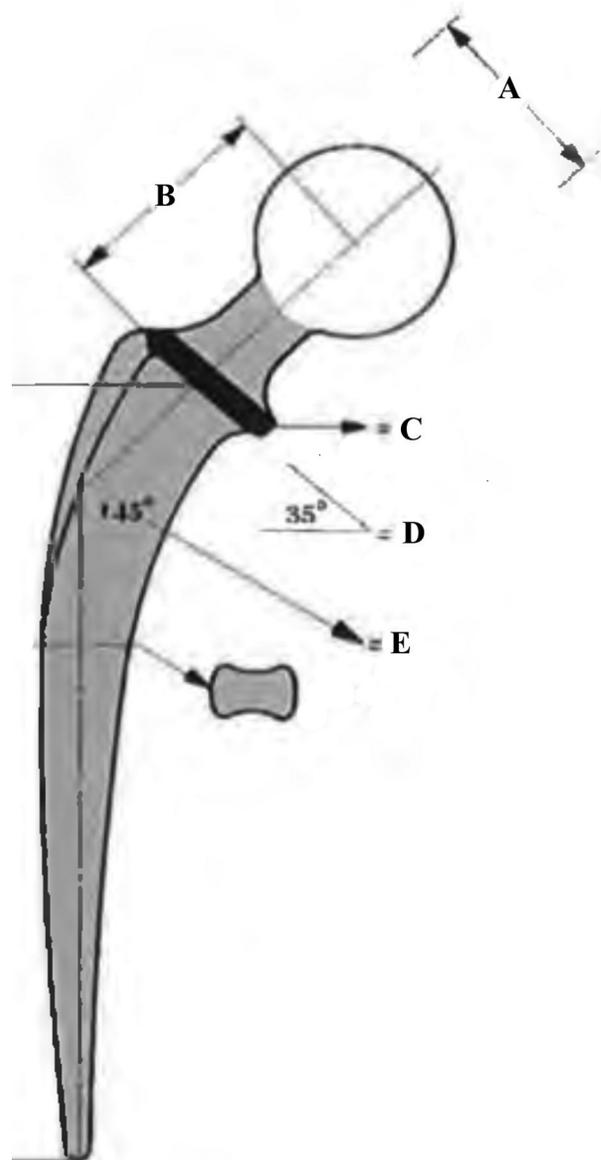


Figure 2: Femoral prosthesis.^[5] (a) Femoral ball, (b) neck length, (c) calcar, (d) neck support angle, and (e) neck–shaft angle

Porosity Creation

Titanium alloys are used in manufacturing of porous implants. Although they are stiffer than bone but its modulus is closer to bone's modulus of elasticity as compared with other current metals. Therefore, the femoral bone resorption and atrophy will be decreased.^[18] When uncemented femoral stem is used, surface porosity is one of the main factors in biological fixation. Femoral stems can be fully coated or proximally coated. Proximally coated stems show bone loss in distal regions; thus, fully porous implant is preferred.^[19,20]

Pore Size

Osseointegration leads to bone formation within an irregular (beads, wire mesh, casting voids, and cut grooves) implant surface.^[21] Pore size greater than 100 μm facilitates the ingrowth. The increasing pore size was associated with enhancing fixation strength. Pores in the range of 150 to 400 μm have shown no relationship between pore size and strength of fixation.^[21] Pores should be interconnected to allow sufficient depth of bone ingrowth and waste/nutrition exchange.^[22,23]

Results and Discussion

Suggested Design for Femoral Stem

In this paper, some biomechanical and biomaterial factors influencing stem performance were identified. Then ideal designed parameters (such as geometry and shape) were chosen for them. Each item was selected by referring clinical experiment and software data. Figure 4 shows suggested design for femoral stem. Young's modulus of titanium alloy is 110 GPa. By assuming about 50% porosity, Young's modulus of porous coating layer would be 30 GPa.

As it is discussed, the stem is curved and its distal part makes 8° angle with vertical axis [Figure 5a]. Also it is tapered stem and its cross-section is larger in proximal region as compared with distal one [Figure 5b].

Prosthesis dimension is portrayed in Figure 6. Also, in Table 2, dimensions and angles of femoral stem is demonstrated obviously. Assigning exact quantities and parameters for

prosthesis preserve leg length and subordinate muscles. Design parameters are optimized and it seems that prosthesis would fix well. Furthermore, necrosis and bone atrophy minimizes. As shown in Figure 7, prosthesis is modeled with V-shaped neck.

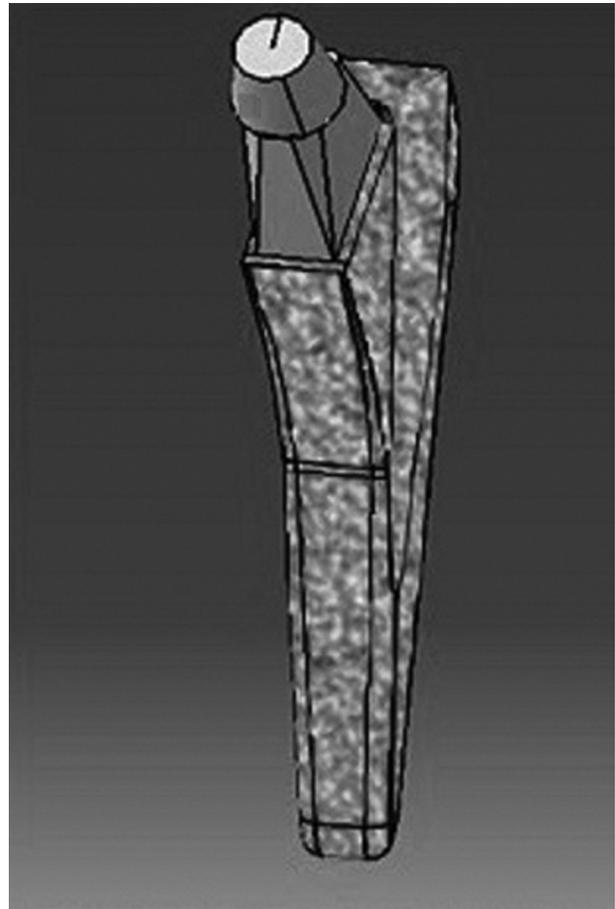


Figure 4: Schematic of suggested femoral stem

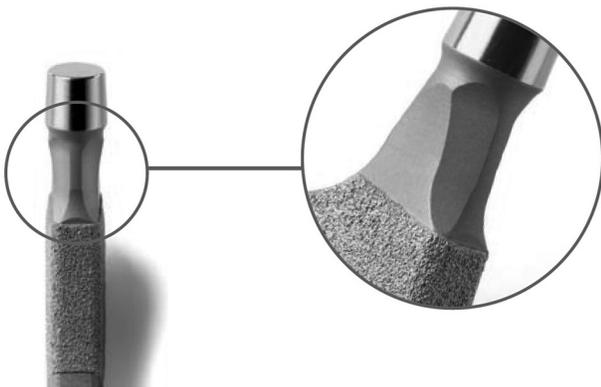


Figure 3: V-shaped neck of prosthesis^[10]

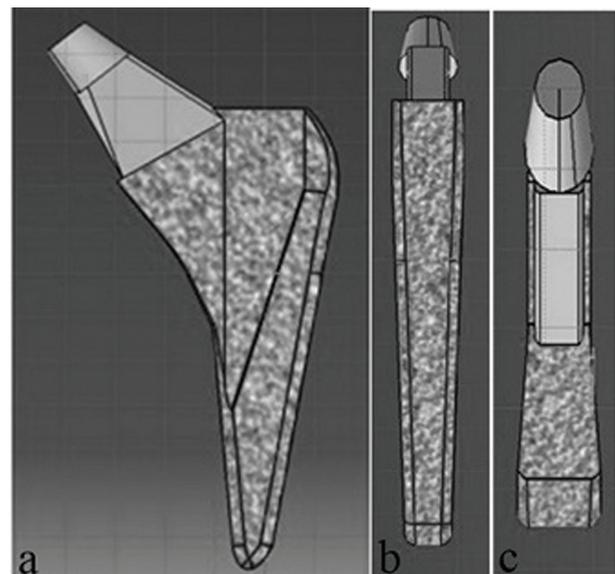


Figure 5: View of suggested femoral stem. (a) xy, (b) yz, and (c) zx directions

Analysis of Designed Femoral Stem

As shown in Figure 8, load was applied to upper surface of implant's neck. Upper face of femoral stem was considered as a support.

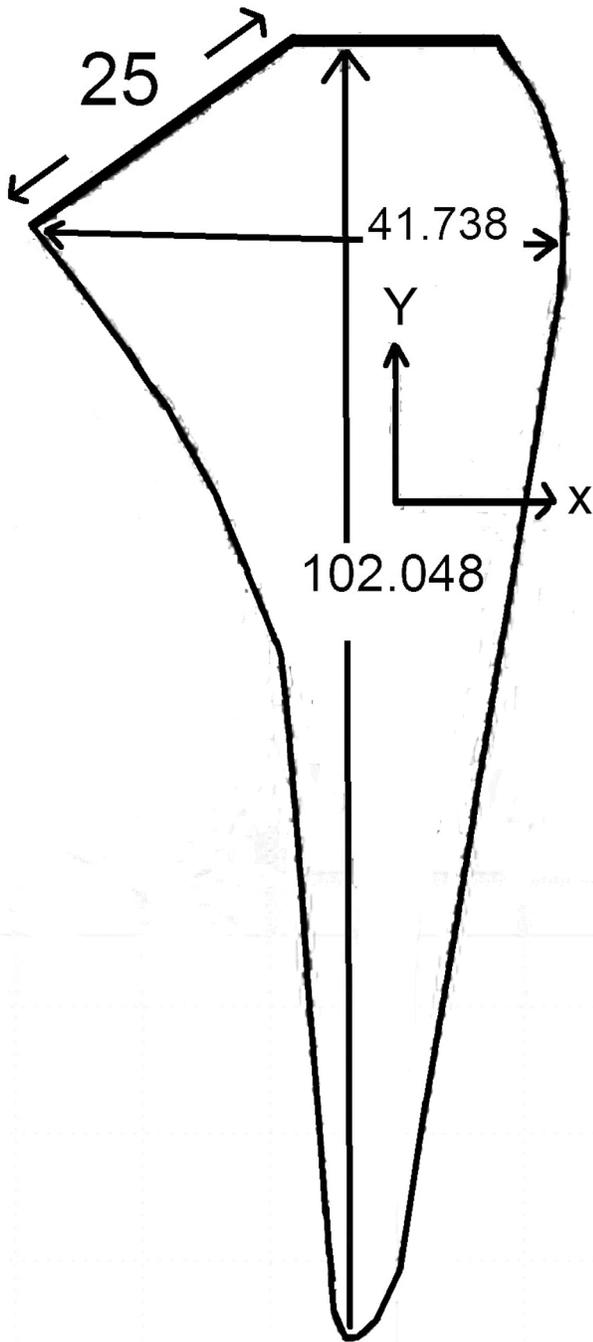


Figure 6: Dimensions are demonstrated in the sketch

To find an appropriate mesh size, analysis process began with the mesh size of 2 mm and decreased at each step. As mesh size decreased to the value of 0.5 mm, calculated stiffness approached same value afterward. By applying force to implant, software reported strain value in all coordination of designed femoral stem. As shown in Figure 9, support face of stem doesn't displace; therefore, zero strain value was reported for it. Also strain value is greater in inferior parts of stem rather than superior ones. Stem's surface is glued to porous layer and strain values were recorded in lowest point of implant geometry; it means coordination of -102.048 [Figure 7].

In accordance with Figure 10, maximum strain occurs at lowest end of stem which is shown by red color. Loads ranging from 300 to 1400 N were applied to femoral stem in

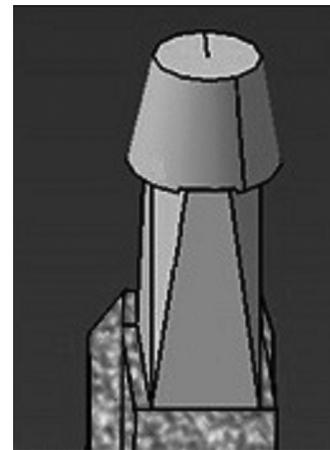


Figure 7: Model of femoral stem neck

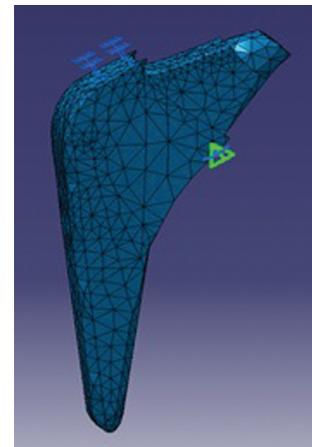


Figure 8: Upper face of implant is considered as support

Table 2: Dimensions and angles of designed implant

Stem's vertical length (mm)	Stem's maximum width (mm)	Stem's maximum neck width (mm)	Offset (mm)	Neck-shaft angle	Neck support angle
102.048	41.738	25	40	151.064	35

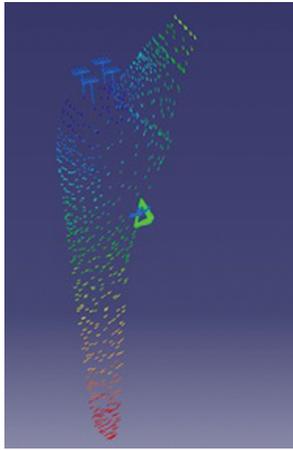


Figure 9: Strain values in different point of stem's geometry

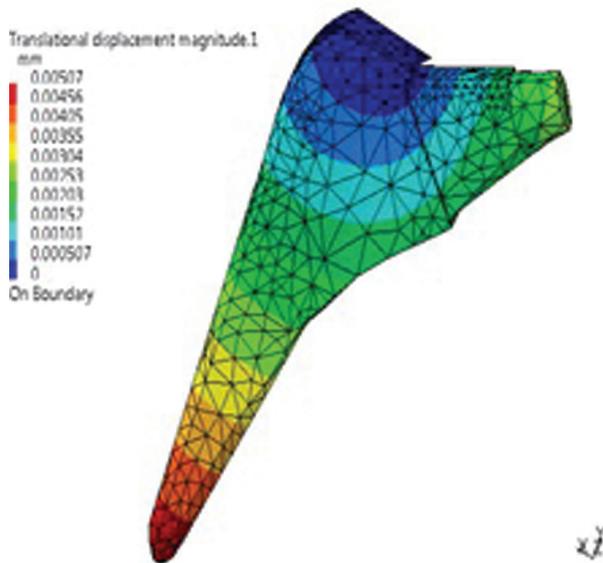


Figure 10: Strain distribution in the designed stem

12 steps, according to Nieter *et al.*^[24] Strain value was reported by the software then, Young modulus of elasticity were calculated by Hooke's law and was reported in Table 3. Average calculated stiffness is 76.96 ± 0.12 ; thus, total stiffness of femoral stem decreased from 110 to 76.96 GPa. As a result, by creating porous layer on implant total stiffness decreased about 30%. Decrease of implant stiffness leads to decline in both atrophy possibility and stress shielding probability. On the other hand, stress distributes normally through bone and implant. Moreover, implant loosening and subsequent high pain diminishes since biological fixation.

Conclusion

Implant stiffness can be reduced by considering biomechanical aspects. Approximating Young's modulus of femoral stem and implant decreases atrophy probability.

Table 3: Strain and Young modulus of elasticity for designed femoral stem

F (N)	σ (MPa)	ϵ ($10e-5$)	E (GPa)
300	3.82	4.97	76.87
400	5.09	6.61	76.98
500	6.36	8.27	76.95
600	7.64	9.90	77.17
700	8.91	11.56	77.06
800	10.18	13.23	76.98
900	11.46	14.90	76.92
1000	12.73	16.56	76.86
1100	14.00	18.23	76.82
1200	15.28	19.90	76.78
1300	16.55	21.46	77.12
1400	17.82	23.13	77.08

Therefore, curved tapered stem with trapezoidal cross-section and particular neck and offset is designed. Metallurgical designing reduces extra stiffness, too. Fully porous surface is suggested in this case. Using aforesaid factors reduces stem's stiffness. Also, designed femoral stem analysis showed the Ti6Al4V stem which is covered with layer of 1.5 mm in thickness and 50% of porosity is as stiff as 77 GPa that is 30% less than the stem without any porosity.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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