IARJSET

ISSN (Online) 2393-8021
ISSN (Print) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology
Vol. 3, Issue 6, June 2016

In-vitro Biomechanical Assessment of a Newly Designed Cement less Femoral Stem

Rahul Ribeiro[1], Beni Ram Rawal[2]

Associate Professor, Department of Mechanical Engineering, Alliance University, Bangalore, Karnataka India[1]

Assistant Professor, Department of Mechanical Engineering, Shri G.S. Institute of Technology and Science, Indore, Madhya Pradesh, India[2]

Abstract: The stability of an artificial cement less femoral stem depends on its fit within the femoral cavity. In this study, a cement less hip joint stem was designed based on the anthropometric data of 98 femurs of patients of Indian (Asia) origin. The design was manufactured on a standard CNC milling machine and was made of Ti6Al4V. In vitro stability studies were carried out using standard test protocol incorporating standard potting cement, a selective laser sintered (SLS) femur and a dry cadaveric femur. The micro-motion of the stem was measured using LVDTs attached at various locations along the designed implant. The entire setup was placed in an Instron test machine with an applied static axial load of 2500N. For the test in potting cement, the strains ranged between 320 and 1211 □m over the measured sites. Strain on the lateral side was found to be less for the new design as compared with a conventional design, while on the medial side it was almost the same for both. The maximum micro motion for the stem-dry femur construct was found to be 1800 □m whereas for the stem-SLS femur combine, it was found to be 380 □m. The finite element models developed were found to closely match the behavior of the stem-potting cement construct and stem-SLS femur.

Keywords: Include at least 4 keywords or phrases

I. INTRODUCTION

Total hip arthroplasty (THA) is the most common surgical treatment for hip osteoarthritis, rheumatoid arthritis and fall injuries. Revision surgery is necessary if loosening leads to relative motion between the prosthetic stem and femur, causing pain and mechanical instability. A potential cause of a cement less femoral stem's loosening is bone loss in the proximal femoral cortex. This bone loss is due to non-uniform distribution of stresses around the implant. These stresses are mainly hoop stresses caused by press-fitting of the stem into the medullary cavity with the additional imposition of body load [1-4]. The large number of revision operations undertaken each year as a result of implant failure emphasizes the need for a better understanding of the biomechanics of the femur-implant system [5-6]. The cement less femoral stems have been associated with surface strain changes and stress protection after total hip arthroplasty. Several studies were carried out to determine the effect of different cement less stem designs on the surface strains of the femur as well as on the implant that may lead to post-operative bone resorption, implant micro-motion, micro-fracture and implant failure [7-9]

During mechanical stabilization, peri-prosthetic adaptive bone remodelling plays an important role for long-term stability, because it can lead to proximal bone loss due to stress shielding. Decking et. al estimated the stress protection in vitro surface strain measurements [10]. Mechanical stability comprises not only the strain changes and stress protection, but also reversible implant–bone micro-motion that arises under dynamic loading into the femoral canal occurring during the first postoperative implantation period [11-12]. The critical threshold of micro-motion at the bone–implant interface to allow osseointegration was indicated as being 150 µm (microns) [13-14].The vertical axial micro-motion of more than 1.5 mm within the first 2 years was reported to be associated with higher revision rates of up to 50% [15].

In this study, experimental and numerical methods have been used to determine the micro-motion of a newly designed stem based on the anthropometric details of an Asian population and having a wedge cross section.

II. EXPERIMENTAL METHODOLOGY

A. Mechanical testing of newly designed cementless femoral stem (Construct A)

The distal end of the femoral stem was placed in a cylindrical steel chamber filled with cement. The testing and specimen preparation were done as per ASTM standard specification for femoral prosthesis- metallic implants (F 2068- 09).The newly designed cement less femoral stem was used as a specimen and four linear strain gauges (FLA – 3 – 120, TML Japan) were adhered to the most proximal lateral and medial (R1 and R3) and distally at the mid of lateral and medial (R2 and R4) profile of stem. The test rig was secured in an Instron machine (Instron 8874,Instron Inc., Canton, MA, USA) with a capacity of ± 25 kN, and a resolution of 0.1 N, and having an accuracy of ± 0.5%. It was secured to the frame using machine clamps (Fig. 1).The Instron machine's ram was used to apply load to this stem. Load values were recorded through an installed load cell. Load (N) and strain gauge

IARJSET
ISSN (Online) 2393-8021
ISSN (Print) 2394-1588
International Advanced Research Journal in Science, Engineering and Technology
Vol. 3, Issue 6, June 2016

data (in Micro strain) were recorded through the 8-channel data logger (KDM – P 6800advanced microcontroller based modular universal data acquisition, ±0.05, KAPTL Instrumentation, India) System directly into excel sheet. A computerized window based program (K-CDAS-1700) was used to record the strains readings. Readings were taken three times at the gap of one hour for static load 2500N. This leads to an average estimate of the strains and this minimize the effect residual strain due to the load.

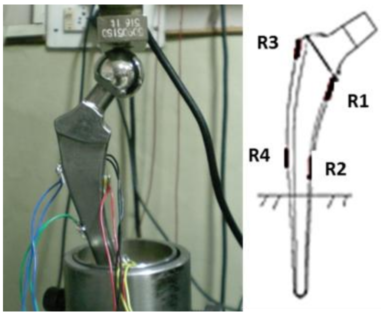

Fig.1Position of LVDTs for construct A

The tests were conducted according to ASTM standard protocol F 2068-69. The distal end of the femoral stem was placed in a metal cylindrical container and secured with standard potting cement. Six LVDTs were placed at different positions along the stem as shown in Fig. 1. The test rig was then secured in an Instron machine (Instron 8874, Instron Inc., Canton, MA, USA) with a capacity of ±25 kN, a resolution of 0.1 N and an accuracy of ±0.5%) using machine clamps. The machine's ram was used to apply a static load of 2500N and the micro-motion was measured three times with an interval of one hour between readings. A computerized window based program (K-CDAS-1700) was used to record the strain readings.

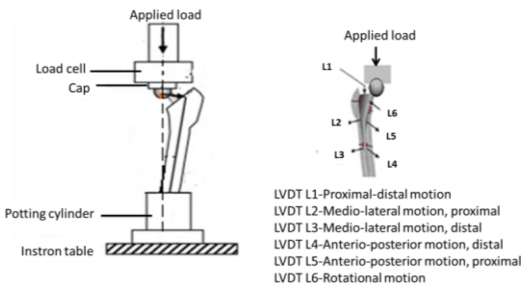

Fig. 2a. Position of LVDTs for constructs B and C

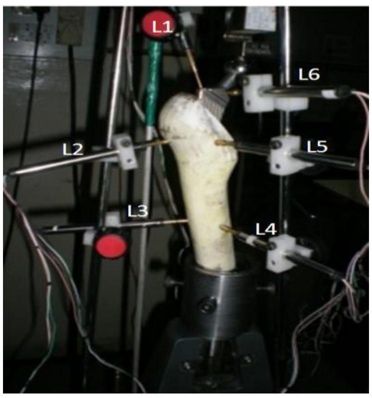

Fig. 2b Construct B (RP femur)

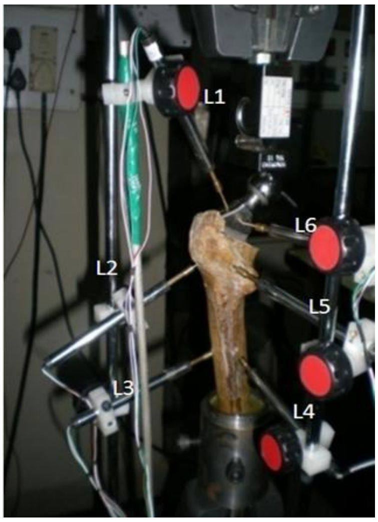

Fig. 2c Construct C (dry cadaver femur)

B. Mechanical testing of femoral stem-femur systems (Constructs B and C)

In vitro tests were performed with the femoral stem implanted in a rapid prototyped (RP) femur model and a cadaveric dry femur separately. The femurs were secured by potting cement in a cylindrical container (Fig. 2a). The fit and fill were analyzed physically. In-vitro bone-implant interfacial motion was measured using LVDTs (L1-L6, Model ACL-10-9 with a range of 0 to 10 mm, least count 10 micrometer, KAPTL Instrumentation, India). They were positioned as shown in Fig. 2a. The test rig was then secured in an Instron machine (Instron 8874, Instron Inc., Canton, MA, USA) with a capacity of ±25 kN, a resolution of 0.1 N and an accuracy of ±0.5%) using machine clamps. Load and micro motion data were recorded through an 8-channel data logger (KLM-1000-8 advanced microcontroller based modular universal data acquisition, KSPTL Instrumentation, India). The readings were stored in MS Excel. The machine's ram was used to apply a static load of 2500N and the micro-motion was measured three times with an interval of one hour between readings. Figures 2b and 2c show photographs of the assembly with the RP femur and dry cadaveric femur respectively.

C. Finite Element (FE) Models

FE models of the femoral stem alone and the femoral stem – femur were developed. The strain and the micro-motion contour plots were generated for the three constructs A, B and C.

The femoral stem - femur systems were created in Pro/ENGINEER by assembling the individual models of the femoral stem and the femur. The assembly was exported to ANSYS Workbench 11.0 for FE analysis. CONTA174 in ANSYS is a three-dimensional 8-node surface-to-surface contact element that was used in this study. This type of contact element was located on a deformable surface of a three-dimensional solid element that contacts and slides on a target surface, i.e., TARGE170 in this study. CONTA174 had three degrees of freedom at each node, namely, translations in the nodal x, y, and z directions. It had the same geometric

DOI 10.17148/IARJSET.2016.3655

IARJSET
ISSN (Online) 2393-8021
ISSN (Print) 2394-1588
International Advanced Research Journal in Science, Engineering and Technology
Vol. 3, Issue 6, June 2016

characteristics as the solid element face with which it was connected. Contact occurred when the element surface penetrated its associated target element, i.e., TARGE170. CONTA174 and TARGE170 shared the same real constants. All contact elements were set to frictional bonding with a coefficient of friction of 1. Bonded contact was used to simulate full bony ingrowth and press fitting of the stem into the femur bone.

For the calculation of strain distribution in the stem and micro-motion at stem-bone interface of the total hip joint replacement, the loading represented by the concentrated static force was considered. The value of the force was F= 2.5 kN, which is equivalent to load acting on the joint of a man weighing 70 kg and walking with speed 1.1 m/s walking with speed 1.1 m/s toward the distal direction along the femoral axis [16]. The loading scheme of the femoral stem for all constructs is shown in Fig. 3.

D. Meshing and Material Properties

ANSYS Workbench 11.0 was used to generate meshes. For Construct A, the number of nodes and elements were 33270 and 22644 respectively. For Construct B, the number of nodes and elements was 56577 and 37847. Body elements included 10-node quadratic tetrahedrons for cortical bone and stem. SLS synthetic femurs were isotropic and linearly elastic, with material properties for cortical (E = 3.3 GPa, ν = 0.41) as material was Polyamide - Nylon 6, 6. Young's Modulus for cortical bone (E = 10 GPa) was an average of compressive (7.6 GPa) and tensile (12.4 GPa) values. The femoral stem was manufactured solely from Ti-6Al-4V. Titanium-based alloys have a typical Young's modulus range of 100 to 120 GPa. Thus, material properties for both of these titanium-based implants were set in the middle of the range for titanium alloy (E = 110 GPa, ν = 0.36).

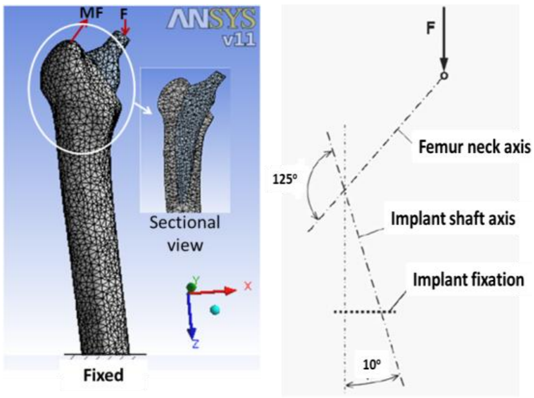

Fig. 3 Loading condition for the FE models

E. FE Analysis

FE analysis was done using ANSYS Workbench 11 suite to replicate experimental conditions. For all constructs, the distal 80 mm of the stem was constrained. Vertical forces were applied at the ball with motion restricted in all but the axial direction (i.e., z-axis). Bonded contact was modeled between stem-bone interfaces. The FE models for Construct B and C (femoral stems implanted into femurs) mimicked the long-term stability of the implants. The stem-bone interfaces, modeled as fully bonded, would be representative of the bony ingrowth around the hip stems that would be expected to occur over the long-term.

III.RESULTS AND DISCUSSION

The micro-strain vs. force at different locations for construct A is shown in fig. 4. The behavior for the newly designed stem and a conventional stem are superimposed. The curves showed that the strain magnitude increased linearly with increasing force at all measured sites. The strains ranged between 320-1211μm, depending on the measured sites.The new design was based on better contact between prosthesis and bone. Strain at positions R1 and R3 matched closely for the new design and conventional design. However, for positions R2 and R4, there was less strain indicated for the new design as compared to the conventional design. This indicates that less load is taken up by the newly designed stem as compared to the conventional stem leading to more even distribution of load over the stem and bone. Therefore there is chance of less stress shielding with the new design. For Construct A, the percentage difference between the FE model and experimental strain at Locations 1 to 4 were calculated as described earlier. The average difference for Locations 1 to 4 at axial loads of 2500 N was 5.8 ± 5.7% (range, 0-12.5%), as shown in fig. 5.

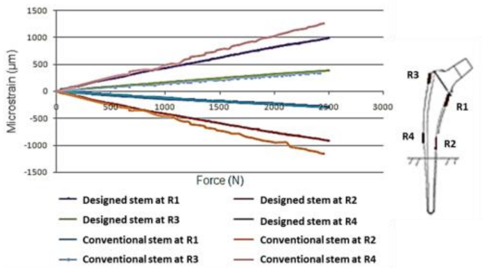

Fig. 4 Micro-strain vs. Force for newly designed and conventional stems

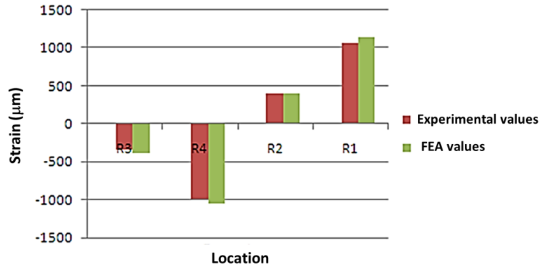

Fig. 5Comparison of experimental and FEA values of strain at different locations along the stem

Figures 6 and 7 show the micro motion behavior for the stem-SLS femur and stem-dry cadaveric femur constructs respectively. The experimental and FE curves have been superimposed. The curves showed that the micro motions magnitude increased non-linearly with increasing force for both the construct B and C. For construct B, the average percentage difference between the FE model and experimental axial micro motion values was 5.5% and for construct C, the average percentage difference between the

FE model and experimental micro motion values was 96.5%. This is probably due to the change in properties due to drying and deterioration over a period of time. Future tests with a moist or fresh cadaveric bone might produce more realistic results.

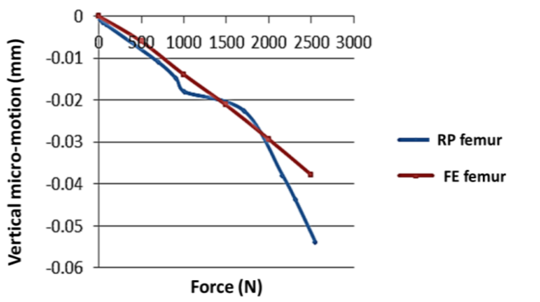

Fig.6 Micromotion vs. Force for the stem-SLS femur construct with experimental and FE values superimposed

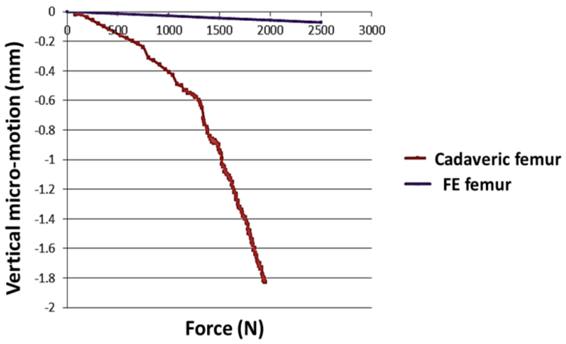

Fig.7Micromotion vs. Force for the stem-dry cadaver femur construct with experimental and FE values superimposed

IV. CONCLUSION

The Biomechanical assessment was carried out for the newly designed cementless femoral stem with wedge cross-section. The dimensions based on the primary stability for anthropometry of an Asian population. The obtained results showed an improved design over a conventionally used stem. This recommended design is expected to reduce the stress shielding by 37.3% at higher loads as compared with a conventionally used cementless femoral stem, due to the lower strain values measured. Micro-motion at certain locations was found to be higher than allowable values, which calls for an improvement in the design. Artificially synthesized bones like SLS femur may be a good option for biomechanical assessment with realistic geometries, as an alternative to the human cadaveric femur bone. A fresh or moist cadaveric bone might produce more realistic results.

ACKNOWLEDGMENT

The authors with to acknowledge the contribution of the Council of Scientific and Industrial Research (CSIR), NMITLI project for a generous grant to undertake this study on selected medical implants, RP01841. The contribution of the faculty and staff at the Indian Institute of Technology, Delhi is also acknowledged.

REFERENCES

[1] M. K. Harman, A.Toni, A., L. Cristofolini, M. Viceconti, M., “Initial Stability of Uncemented Hip Stems: an In-Vitro Protocol to Measure Torsional Interface Motion,” Medical Engineering and Physics, vol. 17(3): pp. 163-171, 1995

[2] B.P. McNamara, L.Christofolini, L., “Relationship between Bone-Prosthesis Bonding and Load Transfer in Total Hip Reconstruction.” Journal of Biomechanics, vol. 30(6), pp. 621-630, 1997

[3] B. Van Rietbergen, H.W.J. Huiskes, H. Weinans, D.R. Sumner, T.M. Turner, J.O. Galante, “The Mechanism of Bone Remodeling and Resorption Around Press-Fitted THA Stems,” Journal of Biomechanics, vol. 26(4-5), pp. 369-382, 1993.

[4] L. Cristofolini, C. Metti, M. Viceconti, “Strain Patterns Induced by Press- Fitting and by an External Load in Hip Arthroplasty: a Photoelastic Coating Study on Bone Models,” J. Strain Analysis,vol. 38(4), pp. 289-301, 2003

[5] J. Hua, P.S. Walker, “Closeness of Fit of Uncemented Stems Improves the Strain Distribution in the Femur,” J. Orthop.Res.,vol. 13, pp. 339–346, 1995.

[6] L. Cristofolini, “A Critical Analysis of Stress Protection Evaluation of Hip Prostheses,” Crit. Rev. Biomed.Eng.,vol. 25, pp. 409–483, 1997.

[7] R.D. Crowninshield, W.J. Maloney, D.H. Wentz, D.L. Levine, “The Role of Proximal Femoral Support in Stress Development Within Hip Prostheses,”Clin. Orthop. Rel. Res.,vol. 420, pp.176-180, 2004.

[8] R. Decking, W. Puhl, U. Simon, L.E.Claes, “Changes in Strain Distribution of Loaded Proximal Femora Caused by Different Types of Cementless Femoral Stems,” Clinical biomechanics,vol. 21, pp. 495-501, 2006.

[9]. Y.H. Kim, J.S. Kim, S.H. Cho, “Strain Distribution in the Proximal Human Femur. An in-vitro Comparison in the Intact Femur and after Insertion of Reference and Experimental Femoral Stems,” J. Bone Joint Surg. Br.,vol. 83, pp. 295–301, 2001.

[10] R. Decking, W.Puhl, U. Simon, L.E.Claes, “Changes in Strain Distribution of Loaded Proximal Femora Caused by Different Types of Cementless Femoral Stems,” Clin. Biomech.,vol. 21, pp. 495–50, 2006.

[11] D.W. Buhler, U.Berlemann, K.Lippuner, P. Jaeger, L.P. Nolte, “Three-Dimensional Primary Stability of Cementless Femoral Stems,” Clin. Biomech.,vol. 12, pp. 75–86, 1997.

[12] A. Aamodt, J. Lund-Larsen, J. Eine, E. Andersen, P. Benum, O. Schnell Husby, “Mechanical Stability of Custom and Anatomical Femoral Stems: an Experimental Study in Human Femora,” Hip Int.,vol. 12(3), pp. 263 – 273, 2002.

[13] R.M. Pilliar, J.M. Lee, C.Maniatopoulos, “Observations on the Effect of Movement on Bone Ingrowth into Porous-Surfaced Implants,” Clin. Orthop.Relat.Res.,vol. 208, pp. 108–113, 1986.

[14] C.A. Engh, D. O'Connor, M.Jasty, T.F. McGovern, J.D.Bobyn, W.H. Harris, “Quantification of Implant Micromotion, Strain Shielding, and Bone Resorption with Porous-Coated Anatomic Medullary Locking Femoralinto Porous-Surfaced Implants,” Clin. Orthop.Relat.Res.,vol. 208, pp. 108–113, 1992.

[15] J. Karrholm, B.Borssen, G.Lowenhielm, F.Snorrason, “Does Early Micromotion of Femoral Stem Prostheses Matter? 4–7-Year Stereoradiographic Follow-Up of 84 Cemented Prostheses,” J. Bone Joint Surg. Br.,vol. 76, pp. 912–917, 1994.

[16] G.N. Duda, E. Schneider, E.Y.S.Chaot, “Internal Forces and Moments in the Femur During Walking,” J. Biomechanics, vol. 30(9), pp. 933-941, 1997.