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<https://doi.org/10.5109/4055220>

出版情報 : Evergreen. 7 (2), pp.209-215, 2020-06. 九州大学グリーンテクノロジー研究教育センターバージョン :

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(Received March 6, 2020; Revised May 9, 2020; accepted May 22, 2020).

Abstract: The main objective of this study is to check and validate an existing structural design of above knee prosthesis developed by hosmer knee. A CAD model for above knee prosthesis has been developed and Finite element analysis has been done for static and cyclic load. Selection of reference planes and load line positioning has been done using International Organization for standardization (ISO) test procedure. This test is titled as Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2016). A test model have also been designed and fabricated in the lab for the static and cyclic loading. Six trials were conducted in order to check the design and load-bearing part of the prosthesis. Prosthetic Knee joint also performed a deep flexion for the maximum stress condition. A finite element model (FEM) imparting the induced stress distribution in the prosthesis to ensure its safe performance in the fatigue life has been developed. Strains computed in the mechanism from the FEM validate the values obtained from the experimental data obtained in static and fatigue test conducted using ISO 10328:2016 procedure. The average percentage error of simulation in all testing conditions is within 20%. The knee prosthesis is safe under the physical structural test without any failures as calculated in the simulation.

Keywords: (ISO 10328:2016), Prosthetic knee, Finite element modelling, Static and cyclic strength test.

1. Introduction

Many people have lost their natural limbs due to some accidents, chronic medical and other conditions. In the case of lower limb amputation there are no complexity but in the case of above knee amputation a person loses their most complex joint is called knee joint ¹⁾ where the stability, toe clearance and load sharing capacity is the major concern for the prosthetic designers. Mainly, two types of knee prosthetic joint e.g. single axis knee and polycentric knee mechanism prosthesis^{2, 3)} are in use. Polycentric knees are most stable in the stance phase and easy to control voluntarily during swing phase of the normal walking. However, these are expensive. Many researchers have designed polycentric knees to satisfy functional requirements and stability during stance phase of the gait^{4,5)}. In addition to satisfy the stability criteria six bar mechanism used for the investigation of the kinematic and dynamic performance of the knee prosthesis⁶⁾. Safety is an important aspect for the design consideration in addition to aesthetic appearance, stability and easy to use. Prosthesis is subjected to both static and cyclic stress which is varying with time individually. Very few studies are reported^{7,8,9)} to satisfy structural knee strength. In this regard ISO 10328:2016 Standard static and cyclic structural strength test procedure for lower limb

prostheses is explained in ISO 10328:2016¹⁰⁾. Application of FEM is very effective tool for the structural analysis, and thus saving time and cost of manual testing in the laboratories¹¹⁾. After World War II, many researchers were focused to improve its functioning and constructional design. Simplicity of the prosthesis was always demanded by the users. The evaluation of the lower limb knee prostheses and their components required controlled field trial in the addition to the laboratory tests. There is a still need to check the structural strength of a polycentric knee joint for the maximum load. The main objective of this work is to check and modify the existing design of the above knee prosthesis under static and cyclic loading developed by Hosmer Dorrance Corporation, USA. It was estimated that if the knee bends beyond 90° then the forces between tibia and femur are between 4.7 to 5.6 times of the body weight^{12,13)}. Therefore knee prosthesis designer has to apply a higher factor of safety to sustain under these conditions. Many authors have designed Four-bar knee prosthesis using kinematic considerations^{2,3,4,5,6)}. Very few studies were reported to check the structural design of the mechanism used. The novelty of this paper has been presented a comparison between the experimental results of the static and fatigue stress by using the FEM model.

2. Materials and methods

2.1 Material

The physical properties of biocompatible materials used in the analysis of prosthetic knee joint components are

Table 1. Mechanical properties of prosthetic knee materials¹⁴⁻¹⁷.

Material/Properties	Density (gm/cc)	Tensile Yield Stress (M Pa)	Ultimate stress (M Pa)	Poisson's Ratio	Modulus of Elasticity (G Pa)
SUS 304	8.00	250	505	0.29	200
SUS 630(H900)	7.80	1034	1241	0.272	196
Ester Polyurethane(PU)	1.2	56	56	0.4	0.0689
Aluminum ADC 12	2.823	144.35	205.31	0.33	71.0
Aluminum 6063-T6	2.7	214	241	0.33	68.9
Aluminum A356 Alloy	2.67	190	234	0.33	27.2
AISI 304	8.00	206	517	0.29	190

listed in table 1. Aluminum 6063-T6 material is used for the FEM modeling while the mechanisms were fabricated for structural testing.

2.2 Kinematic arrangement of four bar knee Prosthesis

Kinematic arrangement of four-bar knee prosthesis for squatting and heeling embodying the construction of the present study is shown in Figure 2. The prosthesis includes a stump or socket connected with the link 1 and shank connected with link 3. The four-bar mechanism generally includes a fixed link (link 3), a coupler link (link 1), one or more anterior links (link 2) and one or more posterior links (link 4). The positions of the various bars of the four-bar linkages are shown in figure 2 for various degrees of flexion between 0° and approximately 155° flexion, which is the maximum obtainable with this design. The center to center distances or straight line distances between first bearing and the second bearing are determined earlier in kinematic design. An instantaneous centre of rotation (ICR) of four bar knee mechanism must be first defined to identify the load line¹². Four planes including one reference planes are used to analyses the position of the load sharing line whereas one plane must pass through the ICR^{18,19} as shown in figure 3(a), (b)

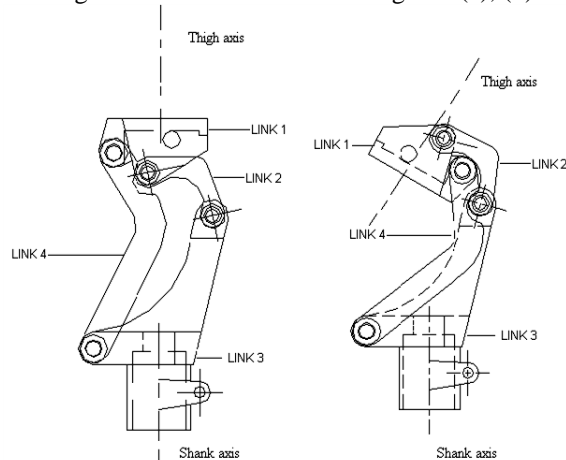


Fig. 2. Schematic diagram of new four-bar linkage knee prosthesis in two extreme positions.

Table 2 Mechanical properties of prosthetic knee materials used

Part No.	Body Name	Material	Mass(Kg)	Volume (m ³)
1	Part1-1	6063-T6	0.017	6.51×10^6
2	Part2-1	6063-T6	0.017	6.51×10^6
3	Part3-1	6063-T6	0.117	4.30×10^5
4	Part4-1	6063-T6	0.070	2.59×10^5
5	Part5-1	6063-T6	0.023	8.60×10^6
6	Rubber Pad	Rubber	0.004	3.94×10^6
7	pin-1	AISI 304	0.011	1.40×10^6
8	pin2-1	AISI 304	0.014	1.77×10^6
9	pin3-1	AISI 304	0.015	1.88×10^6
10	pin4-1	AISI 304	0.014	1.80×10^6

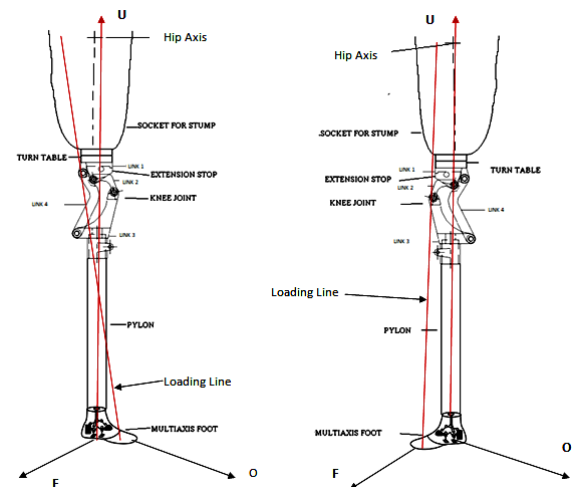


Fig.3 Prosthetic knee with load line (a) Position I (b) Position II

2.3 CAD Modeling

A three dimensional CAD model of a four bar above knee prosthesis was first developed as shown in figure 4. The configuration of this solid model was first evaluated kinematically in order to satisfy the functional requirements of the knee prosthesis¹⁹. This model must be satisfying the ISO 10328:2006 standard²⁰. The shape of the knee prosthesis has a significant influence in its overall performance. The geometrical model was developed in CAD software after determining the linkages parameters as shown in figure 4

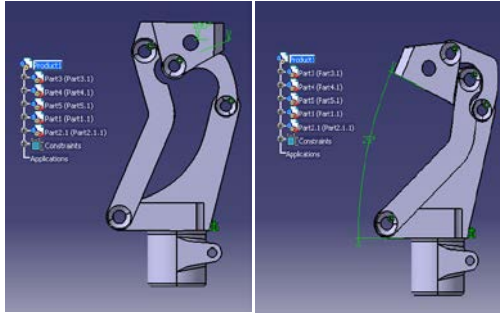


Fig. 4. CAD Model of four-bar linkage Prosthetic knee

2.4 Static and Cyclic strength test

Procedure described in the ISO 10328:2006 is used for static and cyclic strength test on a prosthetic knee. This test is produce compound loadings by the application of a single test force. The compound loads in this test joint is reaching to its peak values of the components of loading which normally occur at different instants during the stance phase at the beginning and end of the normal gait cycle and are described as test Position I and II. Main purpose of conducting this test is to ensure the strength of prosthesis and achieved its life in fatigue test. Depending upon the test conditions and load levels the magnitude and direction of the force are changing. To verify the strength calculation of the FEM of the four bar knee prosthesis an experimental setup for loading on servo-pneumatic testing machine as shown in figure 5 is used as per the procedure described in the ISO 10328:2006. Strain gauges are positioned at eight different predefined locations to measure the strains. Load is applied with the help of servo-pneumatic test machine to calculate static and cyclic tests and data is recorded in the computer. This data is presented in the subsequence sections. Each test is repeated six times to maintain the consistency in results. The load was estimated by using a load cell and given to the controller unit for further processing. The chances of failure were estimated with the standard fatigue criteria on the basis of the FEM results²¹. Initial fatigue calculations used for design were done on the basis of standard mathematical equations used for fatigue failure²². Modified Multi body simulation is an accurate tool for the estimation of the forces²³. Prosthetic socket design is also an important aspect because it is an interface between the residual limb and prosthesis. FEM is also contributing to estimate the interface shear stress on a stump and in the prosthetic design²⁴⁻²⁷.

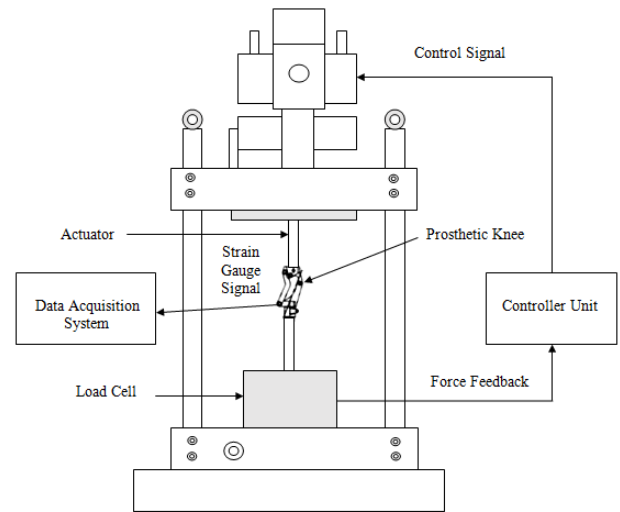


Fig. 5. Experimental Setup for loading on servo-pneumatic test machine

2.5 Testing of A-K Knee prosthesis with an Amputee

A clinical test has been carried out to check the structural strength of the final knee prosthesis and to evaluate its biomechanical performance. Several trials were performed at different levels to confirm the stability criteria. A left leg above knee amputee of 1.65 m height and 590N weight with lower stump length was selected for study. The age of the amputee was about 35 years. The amputee was habitual to the single axis conventional knee prosthesis. A resin socket was casted from the positive mould of his stump. The socket is fixed to the plate of the mechanical knee unit after necessary adjustment of his height and alignment of the prosthesis. Much care has been taken for the positioning of knee during fabrication process. The casting of the socket and fitting of the prosthesis are done in Kiwanis Artificial limb center, Delhi, India under supervision of experienced orthopedic surgeons chief prosthetics and technicians. The amputee was asked to walk on a horizontal surface with a cadence of 1 step/sec as shown in figure 6. It was examined that no crack were appeared during loading cycles. This further validates the structural design of the knee mechanism. The control of the prosthesis was obtained by using eco-control technique by which the movement the active knee prosthesis trajectory was mirrored by the sound side leg.²⁸ A kinetostatic modeling and analysis of Four-bar above knee prosthesis was done to ensure the stability in the extended position of the knee joint prosthesis²⁹. The dynamic analysis of knee joint mechanism depicted that the relationship between balanced force and counter moment was depend on the change of rotation of active part only.



Fig.6 Testing of above Knee prosthesis

3 Results

3.1 Simulation Results

The simulation results of four bar the prosthesis are presented in the figure 7. The stress subjected to the static loading of maximum normal force 4500 N using uniform distribution was recorded. The stress distribution is the von Mises type for the material used Aluminum 6063-T6. Material properties used for the components are presented in the table1. The maximum stress calculated through FEM analysis is 175MPa. This is still below the yield strength of the material used for the prosthetic knee. Results show that this prosthesis is sufficiently strong under the static stress structure analysis. Additionally, the static stress analyses, Mesh information and loading conditions are presented in the table 4 and table 5.

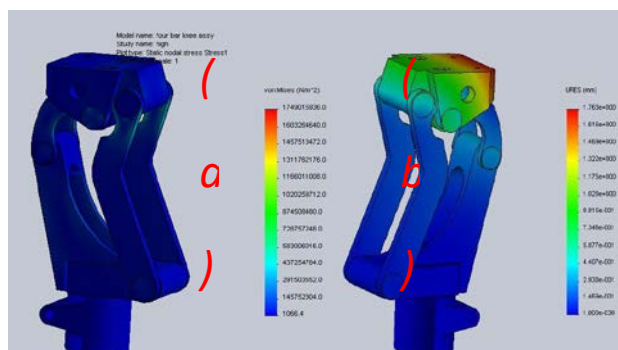


Fig. 7. Stress distributions on a prosthetic knee under static strength test (a) Four bar knee assembly high-Stress analysis. (b) Four bar knee assembly high Displacement analysis.

This has been recorded the test force is gradually applied in the static loading condition in order to avoid any dynamic excitation of the Knee prosthesis. The stress distribution of one loading cycle of cyclic strength test under loading conditions is showing in figure 8. In the cyclic test the knee prosthesis can withstand more than 3×10^6 cycles of mechanical endurance testing to calculate its fatigue strength. The total displacement should not exceed to 5-6mm. The Knee prosthesis joint is sufficiently strong enough to exceed both of the static and cyclic strength tests in the simulation results. The validation results, further, expose that the proposed finite-element model is able to sufficiently compute the

structural stresses in all cases.

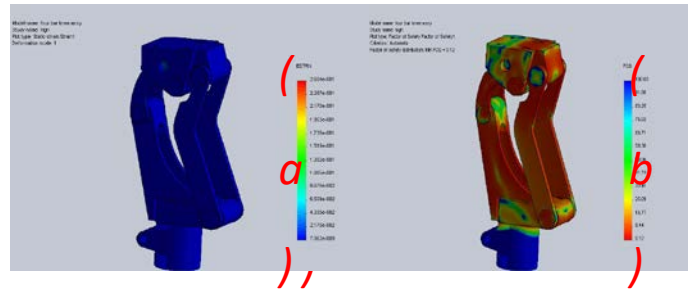


Fig. 8. Stress distribution under cyclic loading (a) Four bar knee assembly high cyclic Strength analysis (b) Four bar knee assembly high Factor of Safety analysis

Table 3. Mesh Information and loading condition

Mesh Type:	Solid Mesh
Number of nodes:	281048
Number of elements:	189795
Mesh Used:	Standard mesh
Smooth Surface:	On
Automatic Transition:	Off
Element Size:	4 mm
Jacobian Check:	4 Points
Tolerance:	0.15 mm
Loads and Restraints	On 1 Face(s) apply normal force 4500 N using uniform distribution Sequential Loading
Time to complete mesh(hh:mm:ss):	00:00:34
Quality:	High

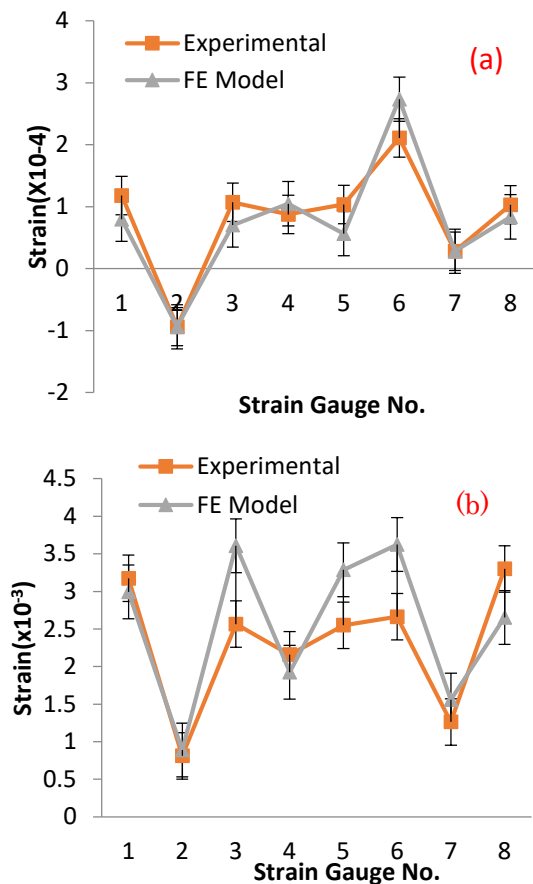
Table 4. Static Results of Above Knee Prosthesis

Name	Type	Min (N/m ²)	Location (mm)	Max	Location (mm)
Stress1	VON: von Mises Stress	1066.44 Node:	(63.91 , -119.72 , 4.14x10 ⁻⁰¹¹)	1.75 x10 ⁺⁰⁰ 9 N/m ² Node: 272883	(9.14 , -9.02, 16.5)
Displacement1	URES: Resultant Displacement	0 mm Node: 29973	(61.19 46 , -120.99 , -1.53 x10 ⁻⁰¹⁵)	1.763 mm Node: 145379	(-32.81 , -10.75 ,

					-
					1.973
)
Strain1	ESTRN: Equivalence nt Strain	0 Elem ent: 17430 2	(67.47 41 , - 79.472 9 , 21.008 5)	0.260 352 Elem ent: 12211 0	(- 21.60 , - 16.11 , - 16.32)

axis presents the strain values. In each loading states six trials were taken and the average strains along with their standard deviations are plotted in the figure 9. The average absolute percentage errors are calculated as 23 and 16% for the loading states I and II respectively which are fairly close to the measured values from the static tests. Figure 10 illustrated the comparison between the FEM and strains in the cyclic test in the laboratory. Six trials were conducted for the calculations of the average percentage error for the loading states I and II are 23 and 19% respectively. These results are shown that induced strains are very close with the expected values. In the experimental cyclic strength test of the prosthetic knee is showing safe values without any failure in the results. The strength predicted of the above-knee prosthesis in the FEM is also validates the same. Thus it may be arrived at a judgment that FEM used in this study is useful tool for the calculation of the strength test of the prosthetic knee.

3.2 Validation results



(a) Loading states I

Fig.9 Static strength test results of strain acquire from experiments and FEM in the (a) loading states I (b) loading states II.

Strains induced in the mechanism from the FEM are validated with the values obtained from the experimental setup to find out the accuracy in the model. Comparison of the strains between the FEM and experiments in the loading conditions I and II in static strength test presented in the figure 8. In these figures the horizontal axis represents the strain gauge numbers whereas the vertical

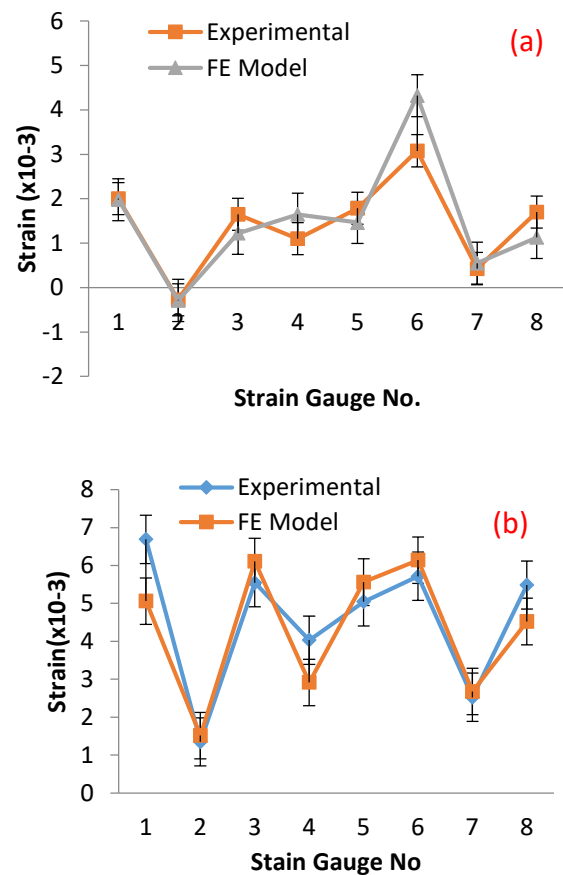


Fig. 10 Cyclic strength test results of strain acquire from experiments and FEM in the (a) loading states I (b) loading states II.

4. Conclusions

In this paper a four-bar above knee prosthesis is tested under static and cyclic stress. A standard test procedure is used from the ISO 10328:2006 structural test. A FEM method is used to calculate the strain produced in the linkages and joints in the prosthesis. It was found that the structure of the prosthesis is sufficiently strong against any type of deformation. In FEM analysis the element size

is taken 4mm, material used 6063-T6 and maximum force 4500N is applied for the consideration of deep knee flexion. It was noticed during the experiment that beyond this force a crack has been initiated at the pins bearing locations connected the linkages of the mechanism. An experimental test procedure is used for the validation of the FEM results under static and cyclic loading. For the measurements of strains at predefined locations of the knee joint, the prosthesis knee joint is instrumented six strain gauges and loaded on the servo-pneumatic test machine. Each test is repeated six times to maintain the consistency in results. It was also noted that the validation results in the proposed FEM analysis is a very strong tool for the structural analysis of the mechanism. The average absolute percentage errors are calculated as 23 and 16% for the loading state I and II respectively which are fairly close to the measured values from the static tests. Whereas the average percentage error for the loading states I and II of the cyclic test are 23 and 19% respectively. These results are clearly reflected that induced strains are very close with the expected values

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