Mechanical integrity of PEEK bone plate in internal fixation of femur: experimental and finite element analysis towards performance measurement

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Abstract: Materials, including stainless steel and titanium, have been used in prosthetic plates. The issue, called stress shielding is associated with the use of metals plates caused by the mismatch of stiffness between tissue and prosthetic plate. Polymers with a stiffness close to the human bone could be a better solution for this issue. The research aims to investigate the effectiveness of poly-ether-ether-ketone (PEEK) plate in stress transformation into the fractured bone and to conduct performance measurement between PEEK and steel. Uniaxial tensile test and fatigue tests are conducted to measure mechanical properties such as tensile strength, modulus of elasticity and fatigue strength. The measured mechanical properties are further used in finite element analysis to measure the stress transformation between plate and femur. The simulation results from fatigue analysis also reveals that PEEK plate is more desirable in terms of reducing stress shielding in the femur than that of stainless steel.

Keywords: femur; stress shielding; prosthetic plate; internal fixation; biocompatible; fractured bone; thermoplastic.

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1 Introduction

Trauma has been the major cause of death in many countries. Bone fracture is the most common type of trauma. Many attempts have been made to treat the fracture in the past, including immobilisation, amputation, internal and external fixation. With the advancement of surgery techniques as well as new manufacturing methods, internal fixation is becoming a more preferred option. A proper fracture healing is of utmost concern, especially for load bearing bones such as femur or thighbone. Femur fracture is by far the most common fracture type and mostly caused by trauma. Stabilisation of this bone is the main determinant of its healing. Internal fixation using prosthetic plates provide the best immobilisation of femur so far. Stainless steel and titanium are two biomaterials which are used by bone plate industry for many decades. However, the major concern about metal bone plates is that they cause an inferior bone healing due to their higher mechanical properties than bone. Almost all bones, even the non-load-bearing ones, require a minimum amount of compressive stress in order for an optimum healing. Metal bone plates prevent the transformation of stress to the fractured bone area and lead to a phenomenon in the bone which is called stress shielding. This is manly caused by the difference of modulus between the bone plate and the fractured bone. The effect of stress shielding has been investigated and discussed by many researchers (Brunner and Simpson, 1980; Carter et al., 1980; Deluca et al., 1988; Hidaka and Gustilo, 1984; Olerud and Danckwardt-Lillieström, 1968; Paavolainen et al., 1978; Rae et al., 2007; Slätis et al., 1978; Terjesen and Benum, 1983; Thompson et al., 1985; Tonino et al., 1976). New materials have been considered by researchers in order to counter the stress shielding. One of these materials is poly-ether-ether-ketone (PEEK) which possess excellent mechanical properties similar to those of human bone and it is considered to be the best alternative to metal plates for trauma implants (Johansson et al., 2016). In order to study the performance of PEEK bone plates, the mechanical properties of the material need to be measured.

Finite element analysis (FEA) is a fast and great tool to study the effect of stress distribution in human bone and bone plates. It discretises the model into many small segments called elements and nodes through which the displacement variable is measured. Picher-Martel and Hubert (2012) conducted 2D simulation on macroscopic squeeze flow behaviour of carbon/PEEK material during forming. This study was done in order to predict the flow of material during the manufacturing of ribs like implants. Maharaj et al. (2013) conducted simulation on bone plates made of stainless steel, titanium, alumina, nylon and PMMA and reported the stress distribution over the plates. Ferguson et al. (2006) investigated mechanical integrity of non-reinforced PEEK-OPTIMA polymer for spinal applications. Fujihara et al. (2006) investigated experimentally the bending performance of the braided composite bone plate. They also presented a critical design procedure for composite bone plate targeting stiffness as well as strength (Huang and Fujihara, 2005). Veerabagu et al. (2003) calculated magnitudes of strains induced in bone plate subjected to loading and reported that there is no danger of fibre and matrix separation for strain up to 1%. Frankel and Nordin (1980) discovered that cortical bone is more susceptible to fail due to shear stress than tensile stress and it is strongest in resisting the compressive stress.

Moreover, compressive strength of cortical bone is found to be equal to 140 MPa (Havaldar et al., 2014). The shear strength of the cortical bone is found to be about 52 MPa (Turner et al., 2001).

Regarding the configuration of bone-plate-screw, Stoffel et al. (2003) suggested that for mid-diaphyseal fractures, two screws on either side of the fracture is needed in order to achieve a stable assembly construct. The study also shows that a minimum distance to fracture zone plays a role in the healing of the bone. Bergmann et al. (2001) discovered a method to find the hip joint force reaction as well as abductor force muscle on the femur. Chakladar et al. (2016) investigated an ulnar transverse fracture of stainless steel composite-plate through FE to investigate the feasibility. MacLeod et al. (2018) investigated numerically and experimentally the load bearing of locking screws.

Though many materials including some polymers have been studied in the past, the study of stress distribution on prosthetic plate-bone-screws assembly is warranted.

In this research, FE study was carried out on femur, femur-screw-PEEK plate assembly and femur-screw-steel plate assembly. The Von-Mises stress distribution over the assembly, tensile stress and shear stress on femur bone were assessed. The fatigue analysis of the plate was also conducted to evaluate the life of the PEEK plate under cyclic loads. These performance analyses show the advantage of using polymeric material for bone plate application towards the cost reduction.

2 Material and methodology

2.1 Tensile test

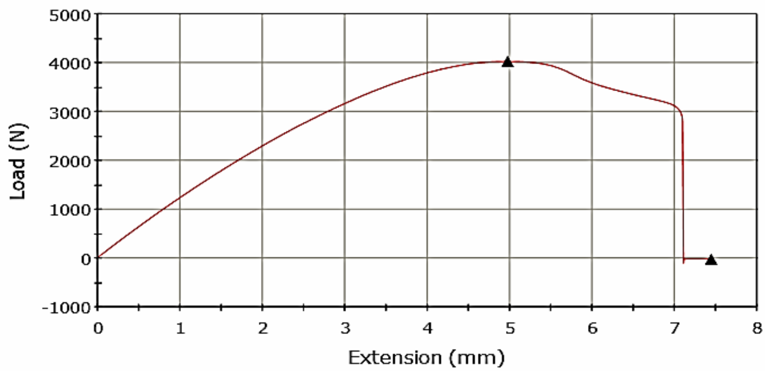
PEEK is a semi-crystalline thermoplastic resin manufactured only by VICTREX Plc. It offers superior mechanical, chemical, thermal and water resistance properties. It is more suitable for low wear, dimensional stability and long life applications. They are mostly available in the form of powders, granules, sheet or rod, unfilled or filled with carbon or glass fibres. In order to prepare dumb bell specimen, initially, Victrox PEEK 150PF fine powders were extruded to prepare dumb bell specimens and then machined to the required dimension as per ASTM D638-14 (ISO 527-1). Firstly, equidistant points for the extensometer were marked on the sample in order to provide an accurate measurement of the material uniaxial deformation. The sample was attached to Instron 3366 and the load was applied gradually at the low strain rate of 5 mm/minute till the specimen fractures. The strain-stress data of the sample was measured through extensometer and recorded. Five samples were tested to account for the repeatability of the tests. Figure 1 shows the uniaxial tensile test being conducted [Figure 1(a)] and the fractured sample [Figure 1(b)].

Figure 2 depicts the load-deformation graph of one particular sample measured from tensile test. To identify the elastic region from the graph, the length of the fractured specimen is measured to be about 2 mm which corresponds to plastic deformation. Subtracting this from overall longitudinal deformation (7 mm) confirms that the elastic region ended at 5 mm deformation. From these test results, the average elastic modulus and yield strength are observed to be 4 GPa and 105 MPa, respectively.

Figure 1 Uniaxial tensile testing and fractured samples (see online version for colours)

(a) (b)

Figure 2 Load-extension data of a PEEK sample (see online version for colours)



2.2 Fatigue test

The uniaxial tension-tension fatigue test was conducted on PEEK as per ASTM standard D7791–12 for fatigue properties of rigid plastic. According to the standard, the specimen is cyclically loaded in tension to a specific stress or strain level at a uniform frequency until the specimen ruptures or yields or reaching the end of the tests cycles (106 cycles). Three stress levels; 95%, 90% and 70% were selected from the tensile strength of the material. The sample was loaded into Instron 8874 fatigue testing machine and the load was gradually applied at the frequency of 5 Hz. Interestingly, none of the samples were failed and all tests reached the end of cycle (106 cycles). It is also noticed that the strain stayed below the proportional region of the material throughout the test and no plastic deformation was recorded. Hence, the fatigue strength of the material was considered as highest stress level, 100 MPa.

2.3 Geometry and materials

A CAD model for a typical bone plate was sketched in Solidworks, converted to neutral file format called, IGES file and imported to ANSYS. Also, the geometry of a left femur was captured using 3D scanning and the corresponding data were used to render a model of bone models. Four bi-cortical ideal screws with standard diameters were sketched to be used in order to fasten the plate onto the bone. Femur, like any other bone in the body, is heterogeneous in nature. In general, femur can be divided to two major parts; cortical which corresponds to main shaft of the bone (diaphysis) trabecular bone (or the spongy bone) which is above at the neck where the hip joint is located. Assuming an isotropic property of the bone, elastic modulus of cortical bone and trabecular bone were set to 19 GPa and 14.8 GPa respectively (Keaveny and Hayes, 1993). In Figure 3, the trabecular (femur neck) and cortical bone are shown in bright and dark grey, respectively. A four-screw configuration was chosen to render the assembly models. All the screws were modelled with SS-316L material. In general, femur in human body is eccentrically loaded that creates tension and compression on each side. Hence, bone plates were locked on to the tension side of the bone during the fixation in order to overcome the tensile stresses in the bone and convert it into compressive stress. Moreover, fixing of the plate on the compressive side of the bone causes the plate to undergo bending and eventually fail due to fatigue. The plate was placed on the anterior side of the femur in order to absorb the tensile stress from the bone. In the assembly, a four-screw configuration was used to mount the plate onto the bone. These bi-cortical screws were mated both to the bone and plate. These are ideal screws, hence no displacement (axially nor radially) and rotation are involved when the assembly is under load. Table 1 shows the material properties used for the analysis. FE models with bone-PEEK-screw and bone-SS 316L-screw materials were done as explained above.

Table 1 Material properties

Material	*Elastic modulus (GPa)*	*Poison's ratio*
Femur – cortical	19 GPa	0.3 (Reilly and Burstein, 1974)
Femur – trabecular	14.8 GPa	0.12
PEEK bone plate	4 GPa	0.38
Stainless steel 316L	19 GPa	0.31

2.4 Meshing and FEA

Due to irregular geometry of the entire assembly, a mesh was generated using patch independent method with tetrahedrons elements. This algorithm in ANSYS ensures refinement of the mesh where necessary, but maintains larger element where possible, allowing faster computation. The minimum edge length was found to be 0.41 mm. Therefore, in order to capture the edges of the bone, the minimum size limit of the mesh was set to 0.41 mm. Furthermore, the relevance of the mesh was modified to obtain a reasonable mesh by decent quality. At the end of meshing, the number of nodes and elements are found to be 31,789 and 19,462 respectively. Element quality under mesh metrics showed a vast majority of elements have element metric of at least 0.80, which regarded as high quality of mesh. Regarding the boundary conditions, the typical forces on the femur were initially studied. Generally, patients, who undergo physiotherapy sessions following internal fixation surgery, are typically advised to exert a certain amount of weight (10 kg to 15 kg) on the injured leg after the surgery for an optimum healing (Schimmelpfennig et al., 2004). One of the activities that patients with internal fixation plates are encouraged to do regularly is slow walking. The two corresponding boundary conditions; a force of 242% of the bodyweight exerted on the femoral head in an angle of 14° with respect to the z-proximal angle (Bergmann et al., 2001) and abductor muscle force (AMF) which is equivalent to one bodyweight at 33° to vertical in frontal plane exerted on the greater trochanter (Dickinson et al., 2010). The distal joint (knee joint) is assumed to act as a fixed support. To obtain the bodyweight, the length of the femur is measured to be 46 cm. In the literatures, the mean ratio of femur length to stature in 51 different populations of contemporary humans is 26% (Knauss, 1981). The estimated body height is calculated to be 177 cm. Assuming an upper-range of normal region of body-mass-index (BMI = 25), bodyweight is approximately 78 kg or approximately 800 N. The orientation of the force is 12° with respect to the z-proximal angle. The distal joint (knee joint) is assumed to act as a fixed support. Therefore, assuming W = 800 N, the forces on the femoral head are as below:

$$F_x = 2.42xW \cos 14° = 1878.5N$$

$$F_y = 2.42xW \sin 14^\circ \cos 16^\circ = 450N$$

$$F_z = -2.42xW \sin 14^\circ \sin 16^\circ = 129N$$

Figure 3 Boundary conditions on the femur (see online version for colours)

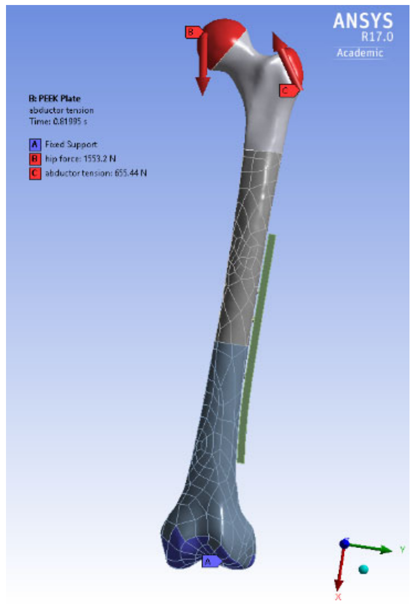
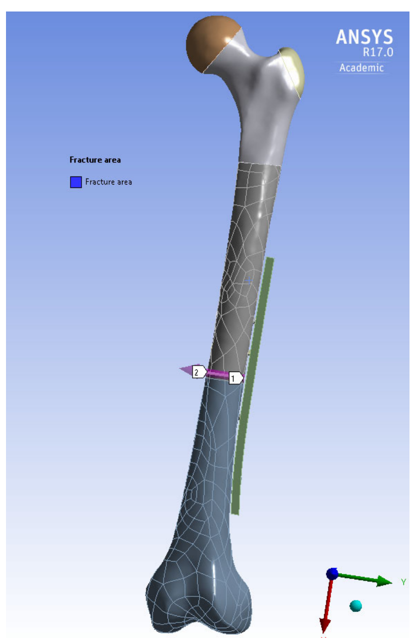


Figure 4 Definition of the fracture path in the diaphysis (see online version for colours)



Forces on the greater trochanter:

$$F_x = -W\cos 33° = -436N$$

$$F_y = -W\sin 33° = -671N$$

Figure 3 demonstrates assembly model with boundary conditions. The simple transverse fracture was assumed to be located between the two screws in the middle of femur. To simulate the fracture, a line was extruded across the bone with a slicing feature as shown in Figure 4. To assess the stress variation in fracture area, a path was defined in the construction geometry. It started from the tension side and ended up at the opposite side which is the compression side. The horizontal path consists of 47 sampling points. The distance between each two point is 0.058 mm.

3 Results and discussions

3.1 Stress analysis

Figure 5 illustrates the Von-Mises stress contour induced in the plate when mounted on femur under typical boundary conditions. It can be seen that the maximum stress is well below the yield strength of the PEEK material. Thus, the plate is safe under stresses during defined boundary conditions. Figure 6 illustrates the shear and principal stress contours in a femur mounted with a prosthetic plate made of PEEK. Considering the shear stress and compressive strength of the bone to be 52 MPa and 140 MPa respectively, the induced stresses are found below the strength of the bone when PEEK plates are used. Figure 7 compares the equivalent stress in femur when mounted with plates made of SS316L [Figure 7(a)] and PEEK (Figure 7(b)]. Ignoring singularities, the maximum Von-Mises stress recorded in the femur with SS316L is about 24 MPa while the stress in femur with PEEK plate is 42 MPa. Moreover, a more particular study was also conducted in a specific fracture region.

Figure 8 shows the principal stresses induced in the fracture region of femurs mounted with bone plates of PEEK and SS316L. As apparent from the left half of the graph, which represents the region of the femur between the vicinity of plate and centre of the bone, both PEEK and Stainless steel 316L performed well by removing the excessive stress from the bone. However, in the second half of the graph (right side), PEEK allows more compression (negative stress) to occur in the fractured bone than SS 316L plate. This could be beneficial for the bone to heal more quickly due to compression forces. Thus, the PEEK plates can be considered as an alternative to conventional steel plates in terms of stress shielding. Figure 9 shows the shear stress induced across the fracture section. Since excessive shear stress is unwanted for the bone, it can be observed that the conventional steel plate outperforms the PEEK polymer by allowing less shear stress to occur in the bone, hence a safer environment for the fractured bone to heal. It is worth noting the linear V-shape stress plot was expected to form as this is similar scenario to the shear stress induced in an equivalent cantilever beam.

Figure 5 Von-Mises stress in the prosthetic PEEK plate (see online version for colours)

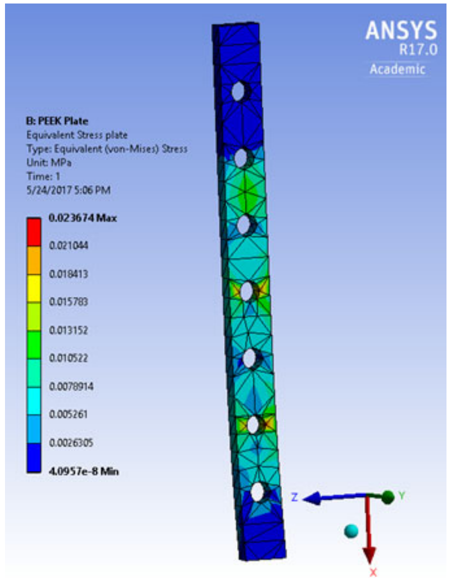


Figure 6 Principal and shear stress in femur mounted with PEEK plate (see online version for colours)

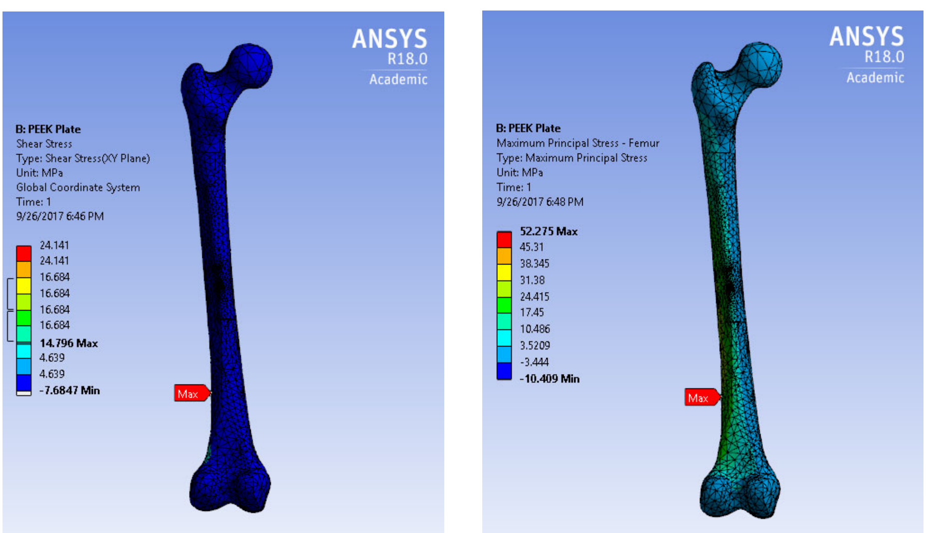
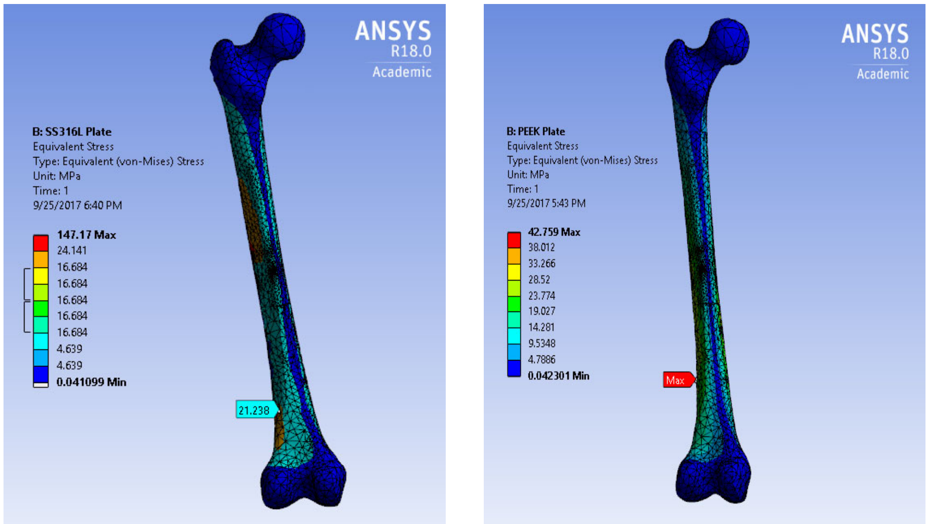
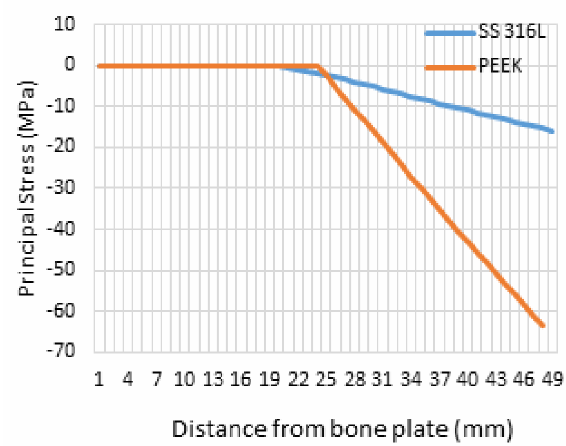


Figure 7 Von-Mises stress in femur with (a) SS316L plate (left) and (b) PEEK plate (see online version for colours)



(a) (b)

Figure 8 Comparison of principal stress induced in femur (see online version for colours)



3.2 *Fatigue analysis*

Fatigue analysis was conducted using fatigue tool in ANSYS focusing on life of the plate. Since no plastic deformation occurred by the end of the fatigue test (applied stresses remain elastic), stress life analysis was selected.

Figure 9 Shear stress induced in the fracture region of femur with plate (see online version for colours)

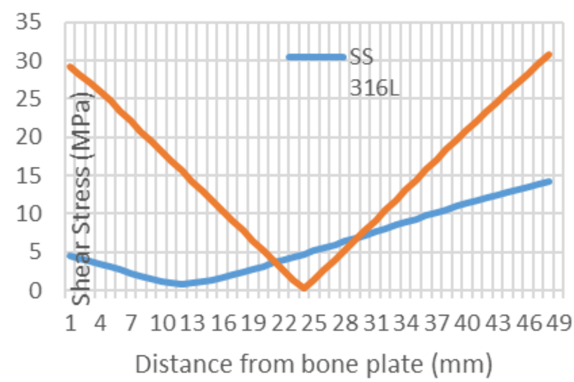
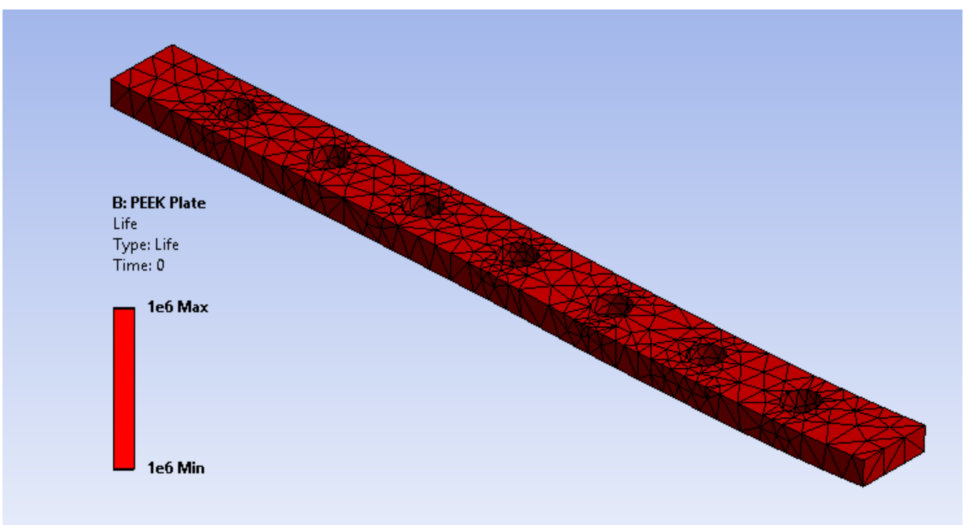


Figure 10 FEM results for life of the PEEK plate (see online version for colours)



The same boundary conditions as discussed in the previous section were considered. A zero-based loading type was chosen (stress ratio of zero and amplitude of one). Von-Mises stress using Soderberg mean stress theory, which is the most conservative line, was used as fatigue failure criteria. Figure 10 shows the life of the plate under cyclic loads. It is observed that no fatigue failure occurs up to one million cycles. This highlights the potential of PEEK material to be used in prosthetic applications where high cycle performance is of crucial importance.

3.3 Taguchi analysis: principal stress, shear stress vs. material and distance

It is perceived from the Taguchi analysis that the PEEK (M1) is the best appropriate selection than SS316L (M2) for stress transformation in to the fractured bone in inducement of principal stress and shear stress point of view. Taguchi method is a quality control method through which defects can be eliminated in the product design and manufacturing. This has been used in manufacturing for different reasons (Sathiyamoorthy et al., 2015; Suresh et al., 2014). The responses from the analysis are shown in Table 2. A graph between principal/shear stresses and material/distances were plotted to verify the input dependency. Figure 11 and 12 show the main effect plot for the stresses and material. It is evident from the plots that the material PEEK performs well at initial. It decreases at later, which is due to more negative stress.

Figure 11 Main effect plot for SN ratios – principal stress (see online version for colours)

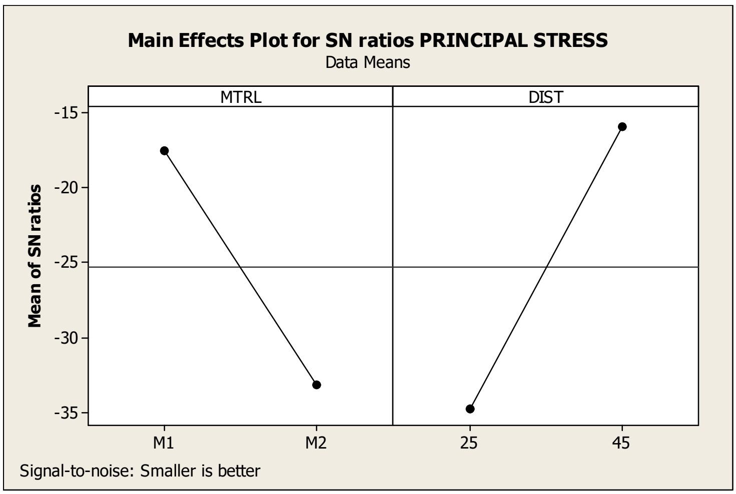


Figure 12 Main effects plot for SN ratios – shear stress (see online version for colours)

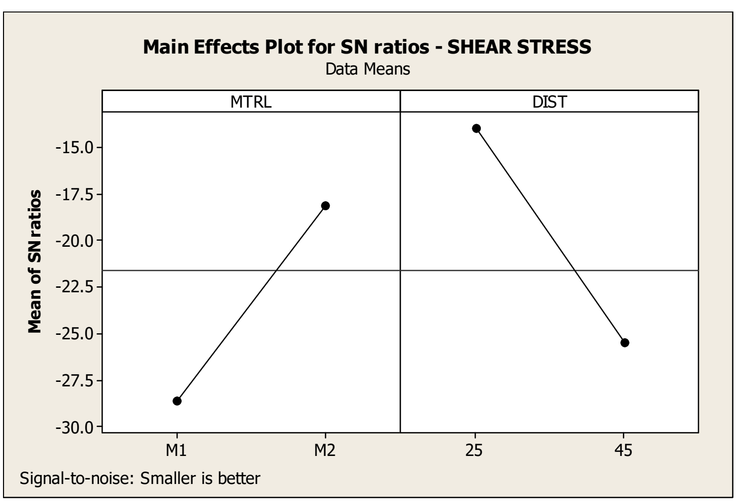


Table 2 Response obtained from Taguchi analysis on principal stresses and shear stresses

S/N ratio			*Means*		
Level	*Material*	*Distance*	*Level*	*Material*	*Distance*
1	–17.48	–34.72	1	28.5	54.5
2	–33.15	–15.91	2	46	20
Delta	15.67	18.81	Delta	17.5	34.5
Rank	2	1	Rank	2	1
1	–28.63	–13.98	1	13.5	2.5
2	–18.13	–25.45	2	9	20
Delta	10.5	11.47	Delta	4.5	17.5
Rank	2	1	Rank	2	1

4 Conclusions

The biomaterial, PEEK was proposed for the internal fixation of fractured human femur bone in order to avoid the stress shielding. PEEK and SS 316L were considered for the performance measurement. The FE studies were carried out on femur, femur-screw-PEEK plate assembly and femur-screw-steel plate assembly. The Von-Mises stress distribution over the assembly, shear stress as well as tensile stress on femur bone were assessed. The fatigue analysis of the plate was also conducted to evaluate the life of the PEEK plate under cyclic loads. Excellent properties as well as its biocompatibility have made this material to be an alternative to the issues associated with the metal bone plates. The performance measurement results show the material integrity and the cost benefit of PEEK plate. As the in-vitro study is not sufficient, the biomechanics of the plated fractured bone will be studied in the future through experiments, from which the appropriate loads and stresses acting on the fractured bone during the daily activities will be observed.

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