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Investigation of Wear Behavior of Biopolymers for Total Knee Replacements Through Invitro Experimentation

Y. Sandeep Kumar*, K. V. S. Rajeswara Rao, Y. Sunil R.

Department of Industrial Engineering and Management, Rashtreeya Vidyalaya College of Engineering, Bengaluru, India

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ABSTRACT

The average life span of knee prosthesis used in Total Knee Replacement (TKR) is approximately 10 to 15 years. Literature indicates that the reasons for implant failures include wear, infection, instability, and stiffness. However, the majority of failures are due to wear and tear of the prosthesis. The most common biopolymer used in TKR is Ultra High Molecular Weight Polyethylene (UHMWPE). Prevailing research reports that implants are restrained by tiny UHMWPE debris generated by long term friction between the femoral component and polyethylene articulating surface. This necessitates an alternative material with high wear-resistance to reduce the wear rate. Polyether ether ketone (PEEK) is one of the biopolymers expected to possess better mechanical properties and biocompatibility with surrounding tissue and hence can be suitable for orthopedic applications. In this regard, a study on UHMWPE and PEEK biopolymers was carried out and tribological behavior was examined. The effect of process parameters such as normal load and speed on the tribological performance of biopolymers were evaluated. The experiment plan was designed as per Taguchi's Design of Experiments methodology. An empirical relation between wear and process parameters was established using linear regression analysis. Microanalysis and failure analysis of worn-out surfaces of both the biopolymers was carried out using Scanning Electron Microscopy(SEM). Results exhibit that UHMWPE had deep grooves as compared to finer grooves on PEEK indicating a low wear rate in the latter. This was also supported by the experimental results suggesting PEEK as a suitable alternative biopolymer for TKR.

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1. INTRODUCTION

The reduction of knee implant failures is the main concern for the orthopaedics. The reasons behind the failure of the prosthesis in Total Knee Replacement (TKR) include instability due to improper fixation and wear between the femoral component and tibia insert. These two factors are the major issues to focus on orthopaedic research. The proper fixation of knee prosthesis can be possible by modelling the patient-specific implants using medical image processing from Computerized axial Tomography/Magnetic Resonance Imaging [1, 2]. Another factor, which affects the failure of the prosthesis, is the generation of wear particles

Corresponding Author Email: ssandeep539@gmail.com (Y. Sandeep Kumar)

from biopolymers into the adjacent tissue. This is the major focus of ongoing research. The formation of wear particles depends on multiple factors including sliding distance, contact pressure, lubricating effect, the surface roughness of implant, and friction factor between the mating components. The friction factor for different biomaterials that are in contact can vary from 0.05 to 0.16. Literature reports that Ultra High Molecular Weight Poly Ethylene (UHMWPE) had maximum wear against Ti6Al4V [3].

The average life span of UHMWPE is 7.8 years with linear wear of 3.8 μm/year. To reduce the wear rate and improve the longevity of the implant, the alternative bearing materials have been introduced. In the 1990s, Polyetheretherketone (PEEK) and its carbon fiber composites were also introduced as a bearing material for TKR [4] but the results were unsatisfactory. A

similar type of study was conducted with a combination of UHMWPE and carbon fiber, resulted in the enhancement of tribological wear performance. But, the biological tissue response was unsatisfactory [5 – 6]. This drawback made polymer composites non-biocompatible. The selected material for TKR surgery requires exposure to good wear resistance including biocompatibility.

Another way of reducing the wear rate is the application of lubricant. The tibia and femoral joints are enclosed with a synovial fluid which serves as a lubricant. The wear behaviour under the lubricating condition of synovial fluid was studied [7]. The different concentrations of Human Serum Albumin (HSA), Immunoglobulin G (IgG), and Dipalmitoylphosphatidylcholine (DPPC) of lubricating medium were investigated. The results showed minimization of wear rate by changing the additives in the lubricant. The amount of wear rate can be found by a suitable experimental setup as per the American Society for Testing and Materials (ASTM) standards. Several studies have been conducted to evaluate the wear rate of biopolymers for TKR. The results of a pin on disc study have been used for many years to evaluate wear characteristics [8]. It is observed that wear is increased by increasing the contact pressure in a lubricating medium. This contact pressure could be taken as the equivalent of the patient weight.

The statistical methods are applied in most of the fields that involve decision making. These methods play an important role in predicting the wear rate of polymers by modelling the suitable regression equation. Different process parameters are influencing the wear rate [9-12]. Analysis of variance (ANOVA) can investigate the relationship between several factors like process parameters which influence the dependant variable [13-15].

This research work involves investigating the wear rate of biopolymers in artificial knee implants. For this purpose, the pin on disc tribometer has been used with different operating conditions. The design of experiments is conducted as per Taguchi design and the process parameters are optimized.

2. MATERIALS AND METHODS

The different stages adopted for investigating wear characteristics of biomaterials are divided into preparation and characterization of biomaterials, evaluation of tribological behavior of biomaterials by a pin on disc, optimizing and developing regression equation by using ANOVA.

2. 1. Specimen Preparation   The steps involved in the preparation of experimental specimens are detailed.

2. 1. 1. Additive Manufacturing   Additive manufacturing is a process of building a part by adding a successive layer of the material rather than subtracting the material [16]. In this technique, there is no wastage of material compared with conventional manufacturing techniques. Figure 1 shows the flowsheet for optimization of wear rate.

The reason for adopting this technology is because the melting point temperature of Ti6Al4V is 1604^OC – 1660^OC and it is not possible to create a part by conventional manufacturing methods. Also, the present research is mainly focusing on the patient-specific knee implants, which are produced from the Magnetic Resonance Imaging (MRI) data. These MRI datasets could be converted into the specific 3-Dimensional model of the knee by using medical image processing software by generating Standard Tessellation Language (STL) files [17].

This layered manufacturing is divided into liquid, powder, and solid form, depending on the build material. In the present research, the print material Ti6Al4V is taken in the form of powder. So the suitable method should be taken for conversion of metal powder into desired 3D parts. In this regard, Direct Laser Metal Sintering (DMLS) was considered. In this technique, the
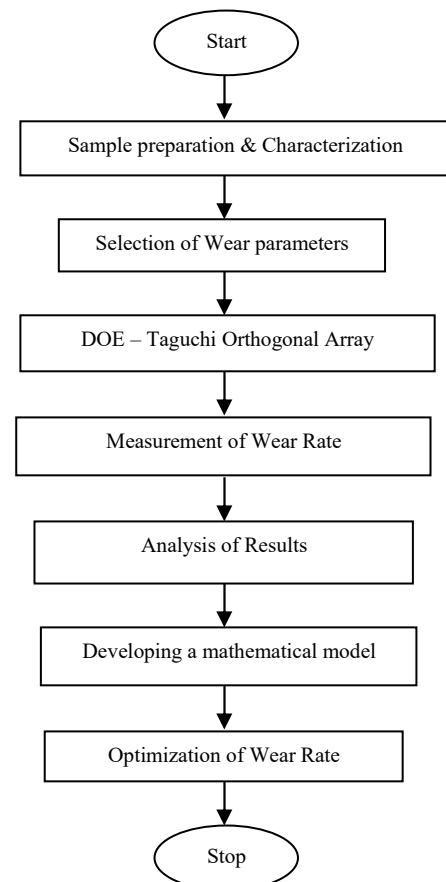

Figure 1. Flow chart for optimization of wear rate

power source was used in the form of laser to sinter the Ti6Al4V powder.

Figure 2 shows the formation of layers to build the model by rotating the roller. The closed chamber was used to control the entire process. However, the drawback of this method is oxidation; to minimize this nitrogen gas is filled in this chamber. The biodegradable metals like Ti6Al4v, CoCr, stainless steel and Ni based alloys etc. are used as build materials by this method.

The most common biomaterials which are used for the total knee replacement are Ti6Al4V and CoCrMo [18]. In the current research Ti6Al4V, powder particles are taken with the chemical composition of 90% of titanium, 6% of aluminium, and 4% of vanadium. The samples are prepared by using DMLS technology in the form of a 30 mm diameter and 10 mm thickness.

2. 1. 2. Blasting   In general, the surface modification of a specimen can be done by the normal machining methods. By using this method, there may be a chance of changing the surface composition and the implant biocompatibility. Blasting is one of the techniques to reduce these surface contaminants. The abrasive particles like ceramics are used to minimize the surface roughness under high pressure. The size of abrasive particles can affect surface roughness. The surface roughness of samples can be set up as per the ASTM G75 test standards and the required R_a value of the implant. Biocompatibility is another factor to be considered when selecting the abrasive particles [20]. Figure 3 shows the PEEK specimens and chemical structure of PEEK.
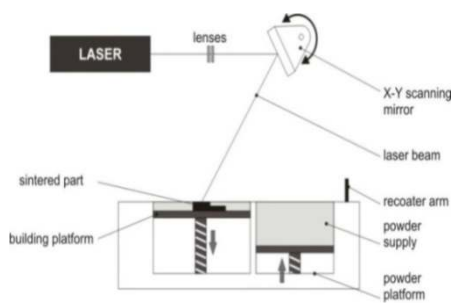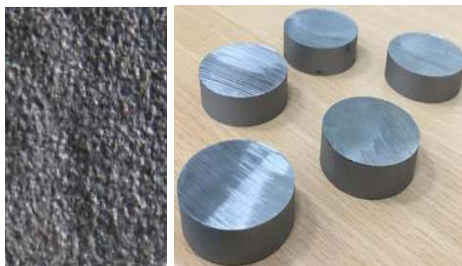

Figure 2. DMLS Technology

Figure 3. Ti6Al4V samples (a) before and (b) after blasting technique

2. 2. Experimental Details   The prosthesis used in TKR consists of a femoral component, tibial tray, and tibial insert, which are made from CoCr alloy, titanium alloy, and UHMWPE respectively shown in Table 1. The mechanism that is observed in the knee joint, the femoral component and tibial tray are fixed rigidly whereas the tibial insert is mating with the femoral component. If these two components mesh with each other, it leads to the loosening of the implants due to wear and tear resulting in failure of the prosthesis. The minimization of this drawback can be possible by understanding the wear mechanism of UHMWPE or replacing it with another biopolymer. To fulfil this objective, the experiments were conducted through a pin on disc friction and wear testing machine [21]. In the present research, the UHMWPE is replaced with PEEK biopolymer to investigate the wear behavior.

In the pin on disc tribometer, the PEEK specimens shown in Figure 4 (rectangular shape of 8 x 8 x 32 mm^3) are held stationary while a cyclic rotation was applied to the Ti6Al4V disc with 30 mm diameter and 10 mm thickness.

The standard orthogonal arrays for three levels and two factors (3x2) design are L9, L18, and L27. In this present research, nine experiments are sufficient to optimize the parameters according to the Taguchi method. Each process parameter has three levels namely low (1 m/sec speed, 20 Kg weight), medium (2 m/sec, 40 Kg) and high (3 m/sec, 60 Kg) respectively. The wear rate was investigated through experimentation under dry and atmospheric condition in DUCOM pin on disc instrument as shown in Figure 5. This instrument is capable of measuring wear rate from 0µm to 2000µm with a least count of 1µm, and friction force from 0 N to 200 N with a least count of 0.1 N.

To explore the effect of normal load on the wear rate of biomaterials, the three values of normal forces 20 N, 40 N, and 60 N were considered. After completion of each test, the volume loss was calculated based on the difference between initial and final weight. The output values of wear and friction values are continuously stored with concerning test time.

TABLE 1. Properties of biomaterials [22-25]

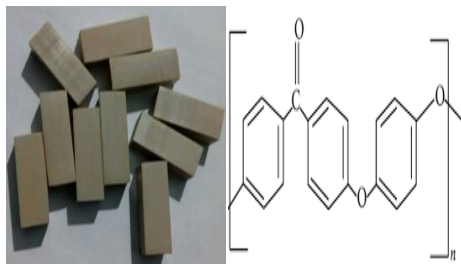| Property of Material	Ti6Al4V	PEEK	UHMWPE
Modulus of Elasticity (GPa)	113	3.6	0.5
Poisons Ratio	0.34	0.37	0.42
Tensile Strength (MPa)	950	97	35
Density (kg/m^3)	4430	1320	970
Melting Point (^{O}C)	1600	340	137

Figure 4. (a) PEEK specimens (b) chemical structure of PEEK

Figure 5. Pin on Disc experimental setup

3. RESULTS AND DISCUSSIONS

3. 1. Wear and Friction Behavior   The major focus in orthopedic knee replacement research is to reduce the wear rate of polyethylene articulating surface. The generation of wear debris is the primary source of implant degradation and it leads to loosening of the patient implant. In the majority of cases, revision surgery is necessary due to this drawback.

In this study, the wear rate of different biopolymers has been investigated to minimize the revision surgery. Tables 2 gives clear information about the wear behavior of UHMWPE and PEEK. The amount of wear rate is calculated by measuring volume loss (∇v) from Equation (1).

$$\text{Wear Rate} = \frac{\nabla V}{WNL} \tag{1}$$

where ∇V = Volume loss in mm^3
          W = Normal load in N
          L = Sliding distance in m

The linear wear rate was monitored using a LVDT (Linear Variable Differential Transducer) which is displayed on the controller. The generation of a graphical plot for wear and friction behaviour results are shown in Figures 6 and 7. These plots for both PEEK and UHMWPE were drawn for different loads concerning time variation of 0.064 sec.

3. 2. Sample Characterization   The investigation of different phases presented in ti6al4v, uhmwpe and peek, the combination of x-ray diffraction and scanning electron microscopy characterization techniques were used [26]. To characterize the wear behaviour of these biopolymer surfaces, sem analysis of warn out surfaces was done. Figures 8 and 9 show typical micrographs for low and high wear out surfaces for these two polymer specimens respectively.

The worn out surfaces of the UHMWPE shown in Figure 8 reflects the high wear rate due to its deep grooves, whereas SEM images of PEEK shown in Figure 9 indicates the low wear rate due to its finer grooves.

3. 3. Taguchi Method   To obtain optimum results with a minimum number of experiments, the Taguchi method is employed to design the experiments for the investigation of wear rate. Taguchi proposed the experimental designs which involve the usage of Orthogonal Array (OA) to organize the factors affecting the process to complete the experiments with a minimum number of trials which reduces time, money, and resources [27].

TABLE 2. L9 orthogonal array with wear rate

| S.No	Load (Kg)	Speed (m/s)	PEEK			UHMWPE		
			Volume Loss	Wear Rate	S/N Ratio	Volume Loss	Wear Rate	S/N Ratio
1	20	1	0.151515152	7.57576E-06	102.411	0.322580645	1.6129E-05	98.848
2	40	1	0.151515152	3.78788E-06	**108.432**	0.430107527	1.07527E-05	99.373
3	60	1	0.454545455	7.57576E-06	102.411	0.322580645	5.37634E-06	**105.39**
4	20	2	0.227272727	1.13636E-05	98.890	0.430107527	2.15054E-05	93.349
5	40	2	0.227272727	5.68182E-06	104.910	0.430107527	1.07527E-05	99.370
6	60	2	0.454545455	7.57576E-06	102.411	1.075268817	1.79211E-05	94.933
7	20	3	0.303030303	1.51515E-05	96.391	0.322580645	1.6129E-05	95.848
8	40	3	0.378787879	9.4697E-06	100.473	0.537634409	1.34409E-05	97.431
9	60	3	0.378787879	6.31313E-06	103.995	0.322580645	1.79211E-05	94.933
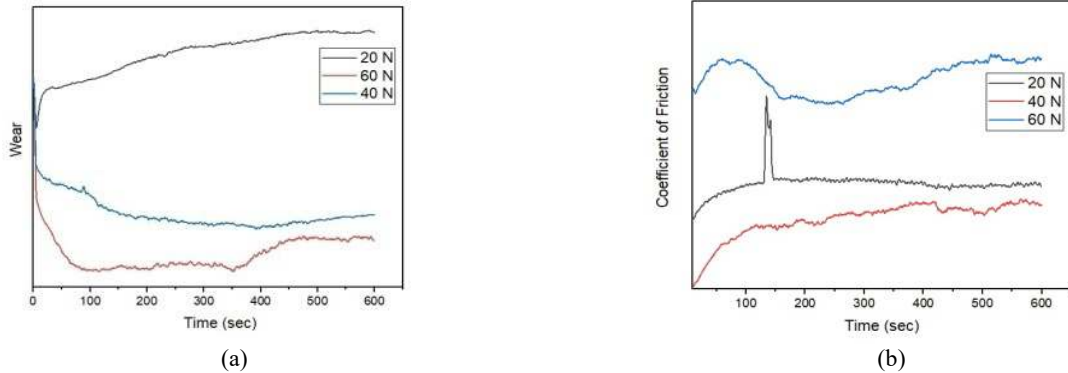
Figure 6. (a) wear behaviour (b) friction coefficient for different loading conditions for PEEK material
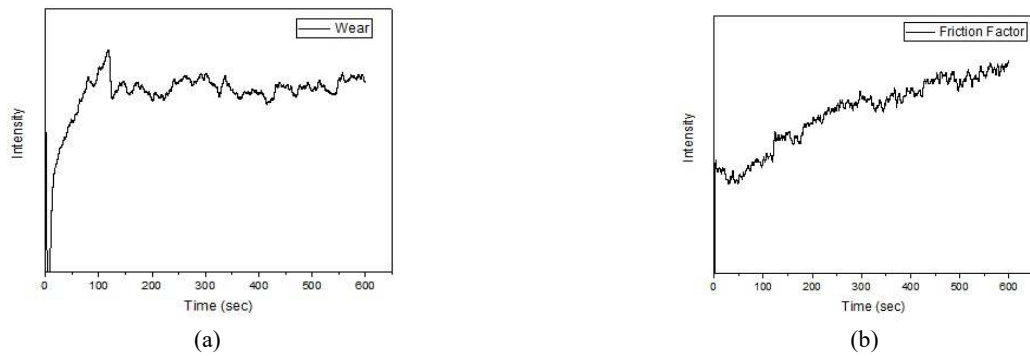

Figure 7. Variation of (a) wear rate (b) friction coefficient on time for UHMWPE material
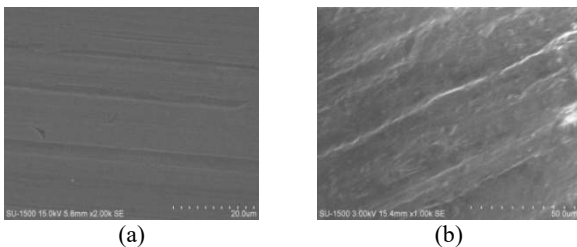

Figure 8. (a) Scanning electron micrographs of UHMWPE specimen with low and (b) High wear rate
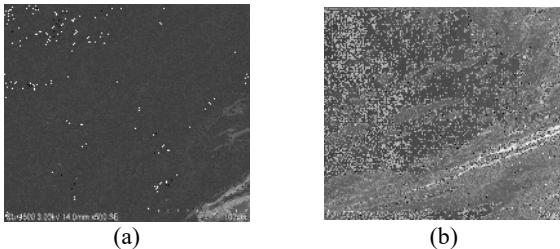

Figure 9. (a) Scanning electron micrographs of PEEK specimen with low and (b) High wear rate

3. 4. S/N (Signal to Noise) Ratio   The S/N ratio was used to find the sensitivity of process parameters affecting the wear rate. The main focus of this research is to minimize the wear rate of a biopolymer, hence it can enhance the life of the prosthesis. In this regard "Smaller–is–better" filter is applied. The S/N ratio's for different process conditions can be calculated by Equation (2).

$$= -10 \log_{10}\left(\frac{1}{n}\sum_{i=1}^{n} y_i^2\right)\frac{s}{N} \tag{2}$$

where n = no. of observations

The graphs are plotted under "smaller – the - better" condition to wear loss for both the cases and the same are shown in Figures 10 and 11 respectively.

3. 5. Regression Equation   It is a widely used technique for prediction, forecasting the dependent
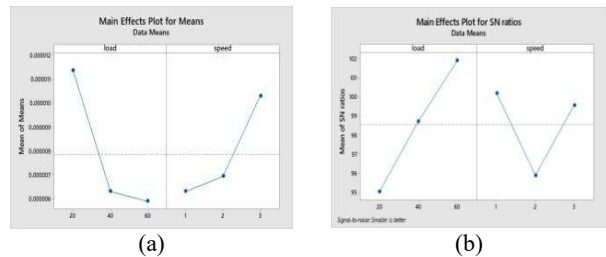

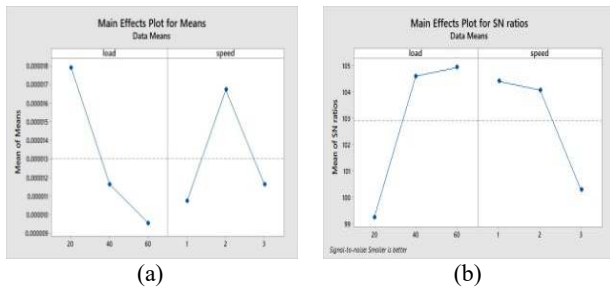**Figure 10.** Graphical representation of means and S/N Ratios of PEEK

Figure 11. Graphical representation of means and S/N Ratios of UHMWPE

variable [28]. The pin on disc instrument used for conducting wear tests is limited to 200N and 2000 rpm. The estimation beyond this range is difficult. In this regard, the regression equation (Equation (3)) is capable for prediction of wear rate.

$$\text{Wear Rate} = 0.000067 + 0.000004 \times \text{Normal Load} + 0.000067 \times \text{Speed} \qquad (3)$$

4. CONCLUSIONS

The objective of this research is to propose an alternate material to UHMWPE that can have minimal wear rate and reduce the wear rate in a knee prosthesis. For this, a pin on disc tribometer was used. The effect of process parameters on wear performance was examined. The maximization of the S/N Ratio signifies the maximization of the desired effect i.e minimization of wear rate. Based on this study, an optimal combination of 40 kg load and 1 m/s speed for minimum wear rate of 3.78788E-06 with maximum S/N ratio 108.432db is suggested.

The linear regression equation helps in establishing the relation between process parameters and wear rate, which was beyond the scope of experimentation. Results indicate that PEEK is the best suitable material for TKR, as it exhibits a lesser wear rate compared to UHMWPE.

The present research is limited to the dry sliding condition only. The same methodology can also be carried out in a lubricating medium with synovial fluid as a lubricant. Surface modification of biopolymers can also be considered for further studies.

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Persian Abstract

چکیده

طول عمر پروتز زانو مورد استفاده در جایگزینی توتال زانو (TKRتقریباً ۱۰ تا ۱۵ سال است. ادبیات نشان می دهد که دلایل خرابی کاشت شامل سایش، عفونت ، بی ثباتی و سفتی است. با این حال، اکثر خرابی ها ناشی از ساییدگی و پارگی پروتز است. متداول ترین بیوپلیمر مورد استفاده در TKR ، پلی اتیلن با وزن مولکولی فوق العاده بالا (UHMWPE) است. گزارشهای تحقیقاتی حاکم بر اینکه ایمپلنت ها توسط آوارهای کوچک UHMWPE ایجاد شده توسط اصطکاک طولانی مدت بین اجزای استخوان ران و سطح مفصلی پلی اتیلن مهار می شوند. این امر به یک ماده جایگزین با مقاومت بالا در برابر سایش برای کاهش میزان سایش نیاز دارد. کتون پلی اتر (PEEK) یکی از بیوپلیمرهایی است که انتظار می رود دارای خواص مکانیکی بهتری و سازگاری زیست سازگار با بافت اطراف باشد و از این رو می تواند برای کاربردهای ارتوپدی مناسب باشد. در همین راستا، مطالعه ای در مورد بیوپلیمرهای UHMWPE و PEEK انجام شد و رفتار تریبولوژیکی مورد بررسی قرار گرفت. تأثیر پارامترهای فرآیند مانند بار و سرعت عادی بر عملکرد ترسیمی بیوپلیمرها مورد بررسی قرار گرفت. این طرح طبق روش طراحی آزمایشات تاگوچی طراحی شده است. رابطه تجربی بین پارامترهای سایش و فرآیند با استفاده از تحلیل رگرسیون خطی برقرار شد. میکروآنالیز و تجزیه و تحلیل شکست سطوح فرسوده هر دو بیوپلیمر با استفاده از میکروسکوپ الکترونی روبشی (SEM) انجام شد. نتایج نشان می دهد که UHMWPE دارای شیارهای عمیق نسبت به شیارهای ظریف تر در PEEK است که نشان دهنده میزان سایش کم در دومی است. این همچنین توسط نتایج تجربی نشان می دهد PEEK به عنوان یک بیوپلیمر جایگزین مناسب برای TKR پشتیبانی می شود.