

Evaluation of the use of PEEK material in a knee joint endoprosthesis insert by FEM analysis

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Abstract. This study contains a comparative analysis of two polymers: PEEK and UHMWPE. A stress distribution pattern in a knee joint endoprosthesis insert was determined for both materials. A numerical model of the insert generated by means of the SOLIDWORKS software was used in calculations. For the purpose of the calculations it was assumed that the insert is loaded consistently and symmetrically, and the value of the load applied was determined for a person of a total weight of 120 kg.

Keywords: endoprosthesis; finite elements methods; polyetheretherketone; implant devices

1. Introduction

The ageing population increases demand for medical services. Knee joint replacement is one of the most frequent operations in orthopaedic surgery. The procedure involves the replacement of structures damaged or destroyed (due to illness or accidents) with a specially designed and manufactured implant. The demand for such procedures is growing, leading to a constant increase in the number of patients awaiting such operation (Moran and Horton 2000). Patient life expectancy after the surgery is also on the rise. Consequently, implants must enable an increasingly longer safe service life. It is necessary to design new, improved and more durable prostheses.

A complete knee joint endoprosthesis consists of a tibial component, a femoral component, a patellar component and a polymer insert (spacer) (see Fig. 1). The polymer insert is the weakest part of the implant (Gierzyńska-Dolna and Nabrdalik 2005). For this reason, work on the improvement of knee joint endoprostheses focuses on the insert. In order to enhance its durability, research concentrates on the improvement of polyethylene, as well as replacing it by other, more durable materials.

This study analyses the capabilities provided by the potential use of polyetheretherketone (PEEK) as a material forming the polymer insert-the most vulnerable component of a knee joint endoprosthesis. The assessment of PEEK in the study takes into account the implantation capabilities of the material. FEM-based numerical analysis involves a comparison between PEEK and the

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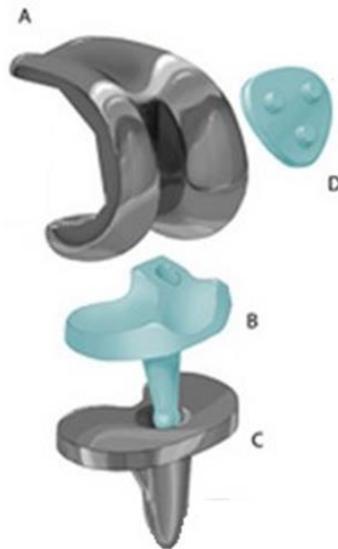


Fig. 1. Knee joint endoprosthesis-an overview: A)-femoral component, B)-insert (spacer), C)-tibial component, D)-patellar component (Wojnarowska 2018)

material currently used for manufacturing inserts, i.e., ultra-high molecular weight polyethylene (UHMWPE).

1.1 Plastics

Plastics have become widely applied in medicine, as their mechanical and physical-chemical properties are significantly different from those of metallic or ceramic materials.

Polymer plastics can be categorised according to various criteria. In terms of technological and performance properties of such materials, they can be divided into two groups:

a) elastomers-plastics which demonstrate elongation of over 100% (in room temperature) in tensile tests;

b) plastomers-elongation at break during the tensile test in room temperature does not exceed 100%. Elastomers include two groups: thermoplastics and duroplastics.

Thermoplastics can be shaped multiple times. They achieve plastic state when heated, and they harden when they cool down. Processing in higher temperatures does not lead to loss of plasticity or mouldability. Polyethylene is the most common plastic in endoprosthetic surgery (Kaczmar and Trzaska 2011).

1.1.1 Ultra-high molecular weight polyethylene (UHMWPE)

UHMWPE is one of the most frequently used thermoplastics. It is characterised by a paraffin-like gloss. It is manufactured in several varieties, which are distinguished by spatial structure and size of macromolecules. UHMWPE has a broad application in arthroplasty. It is used e.g., to make acetabula in hip joint endoprostheses or inserts for knee joint endoprostheses,

The first clinical application of ultra-high molecular weight polyethylene was in 1971. UHMWPE is a network polymer, which means it can be obtained by suitable chemical reactions or the use of ionising radiation.

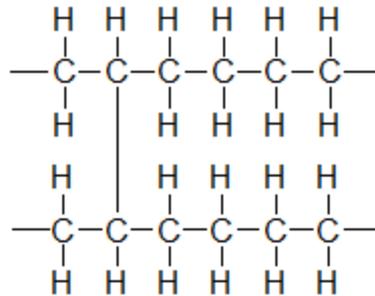


Fig. 2. Structure of ultra-high molecular weight polyethylene (UHMWP)

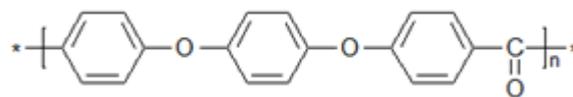


Fig. 3 Chemical structure of polyetheretherketone

Polyethylene’s mechanical properties depend on its density and level of crystallinity. Its bending strength and tensile strength increase with density; the same holds true for its hardness and coefficient of elasticity. UHMWPE is biologically compatible with surrounding tissues.

Long-term use of a polyethylene implant reduces its fatigue strength. The operating temperature of polyethylene ranges from -120°C to 120°C . Consequently, it cannot be thermally sterilised. It is sterilised by radiation, albeit its structure and properties may alter when irradiated. The conditions of radiation sterilisation must be controlled (Łaskawiec and Michalik 2002).

Despite many drawbacks, polyethylene remains the material of choice for making acetabula for endoprostheses.

1.1.2 Polyetheretherketone (PEEK)

Polyetheretherketone (PEEK) is a semi-crystalline thermoplastic polymer from the polyaryletherketone (PAEK) family. Its chemical structure is based on a chain composed of two ether groups (at the core of which are two benzene rings linked to each other by oxygen) and a single ketone group based on a double bond between carbon and oxygen (see Fig. 3) (Kaczmar and Trzaska 2011).

Such structure ensures PEEK’s high stability in high temperatures (even up to 300°C). However, PEEK offers moderate heat resistance in comparison to other members of the family. The processing temperature of the polymer is $370\text{-}400^{\circ}\text{C}$ (Kaczmar and Trzaska 2011).

The chemical structure of PEEK makes it resistant to chemical degradation. The material has been proved resistant to most solvents except for concentrated acids (sulphuric, nitric) (Kurtz and Devine 2007). It also displays resistance to radiation and is capable of forming homogeneity mixtures with a considerable number of reinforcing ingredients. Compared to many metallic materials, it is characterised by higher specific strength.

Thanks to the above factors, PEEK is widely used in many areas of technology as a cheaper and lighter substitute for metals and their alloys while maintaining comparable properties. Other applications include e.g., in aviation, automotive, construction and chemical industry. It also used to manufacture e.g., pump and valve components, gear wheels, slide bearings, piston rings and a whole range of other structural components.

Due to the above properties, in addition to flexibility and elasticity of the material, its compatibility with many bioactive substances or its responsiveness to sterilisation, PEEK is found also in biomedical applications.

For several decades PEEK's clinical applications include the treatment of spinal disorders. One of the reasons is that its presence in the body does not lead to image artifacts in X-ray tests. In spinal implant prosthetics, PEEK is used e.g., to build intervertebral cages which stabilise the axial skeleton. However, the material's high corrosion resistance is a far more important advantage (Kurtz 2012).

Mechanical and physical properties of PEEK are similar to those of the bone and dentine. For this reason, the material has multiple applications in dentistry. BIOHPP (a type of PEEK), a clinically inert, biocompatible, antiallergic and sterilisation-responsive material, is applied in prosthodontics. It also serves as material for prosthetic restorations (dental implants). Classic materials used for this purpose are rigid and may have a negative impact on the entire stomatognathic system (Wojnarowska and Sandecki 2018).

1.2 Clinical evaluation of PEEK

Products implanted in a living organism must be assessed for their influence on the body. Among the characteristics which need to be assessed are: cytotoxicity, allergic activity and genotoxicity (International Organization for Standardization [ISO], 2018). Polyetheretherketone has so far been subjected to numerous pre-clinical and clinical trials aimed at ascertaining whether the polymer could be used in components which are to be placed in a living organism.

In vivo studies by Williams *et al.* (1987) reported that the polymer causes a minimum immune response when surrounded by tissues. PEEK was also exposed to living cells in vitro, and no negative effect on the cells or material degradation was observed (Wenz *et al.* 1990).

PEEK has also been tested for cytotoxicity and mutagenicity. Katzer *et al.* (2002) found that the polymer is not cytotoxic and does not display any mutagenic effect. In addition, Stratton-Powell *et al.* (2016) demonstrated that, in nearly all cases, friction and wear products from PEEK bio-bearings ranged within values which rendered them phagocytal (0,1–10 μm). The cytotoxicity of those particles was on an acceptable level and comparable to the cytotoxicity of UHMWPE wear products. Satisfactory results of biocompatibility tests to which PEEK was subjected, along with its good mechanical properties, suggest that the material may be used for making inserts for knee joint endoprostheses.

2. Comparative analysis of PEEK and UHMWPE

The material for making a knee joint insert must offer good mechanical properties. Compared to ultra-high molecular weight polyethylene, PEEK has much better mechanical properties (as shown in Table 1). First of all, PEEK is harder. Both materials are characterised by a relatively low friction coefficient. In addition, UHMWPE has good sliding properties (Łaskawiec and Michalik 2011).

Young's modulus values for the tibia and UHMWPE are similar. On the other hand, general mechanical properties of PEEK are on a level approximating those of tibial osseous tissue. In this respect, PEEK seems a better material for components which are designed to replace osseous structures.

Table 1 Mechanical properties of bone tissue, UHMWPE and PEEK (Wojnarowska and Sandecki 2018, Bracco *et al.* 2017, Herman 2007)

Characteristic	Unit	Tibia	UHMWPE	PEEK
Young's modulus (E)	MPa	1740	1930	4044
Poisson ratio ν	–	0.3	0.42	0.34
Yield point σ_y	MPa	115	23	116
Tensile strength σ_u	MPa	133	33	116
Elongation (A)	%	–	17	15
Friction ratio μ	–	–	0.29	0.3

Ultra-high molecular weight polyethylene and polyetheretherketone are plastics. Medical applications have specific requirements which are to be met (Łaskawiec and Michalik 2011)-materials must:

- offer easily obtainable repeatability of material quality in different product lots,
- be easy to form in order to enable obtaining the correct usable form without material degradation,
- be of suitable physical and chemical quality,
- be easy to sterilise,
- be biocompatible,
- be biologically inert.

Biocompatibility is a very important criterion in the selection of materials for medical applications, particularly in the case of implants. The characteristic takes into account interaction between the foreign body and the living organism. The question of biotolerance of plastics is far more complex than in the case of other biomaterials (Black 2005, Marciniak 2013).

Catalysts, stabilizers or other substances used in the polymerisation process may have toxic or allergic effect on surrounding tissues. The following characteristics must be taken into account when determining biocompatibility of any material (Black 2005):

- non-toxicity,
- non-mutagenicity,
- non-carcinogenicity,
- no effect on the immune system.

Available data concerning toxicity, immunogenicity and animal research shows that UHMWPE and PEEK are characterised by very good biocompatibility. Both materials are biologically inert in the human body, which means that they do not cause adverse effects. They are resistant to body fluids.

Another characteristic which a polymer material should possess is bioactivity, in other words the implant's capacity for interaction with surrounding tissues. A bioactive material may contribute to osseointegration, e.g., by being grown over by bone tissue. UHMWPE is reported to be moderately bioactive (Del Prever *et al.* 2009). Meanwhile, PEEK, which does not contain any additional layers or modifications, is not a bioactive material (Ma and Tang 2014, Goharian *et al.* 2017). As a consequence, special locks must be included between the bone and the implant in order to keep the latter in its designed position. As the knee joint spacer is held in position by means of bone cement or special catches, bioactivity is not required in this situation.

Table 2 Summary of UHMWPE and PEEK characteristics (Kurtz and Devine 2007, Kurtz 2012, Wojnarowska and Sandecki 2018, Łaskawiec and Michalik 2002, Bracco *et al.* 2017)

CHARACTERISTIC	UHMWPE	PEEK
Biocompatibility	•••	•••
Bioactivity	•••	•••
Image artifacts	•••	•••
Abrasion resistance	•••	•••
Crack resistance	•••	•••
Thermal sterilization	•••	•••
Radiation sterilization	•••	•••
Mechanical strength	•••	•••
Cost of production	•••	•••
Intraoperative shape correction	•••	•••

Ferromagnetic metal implants may create risk for patient's health and life during magnetic resonance imaging (MRI). What is more, images acquired by computed tomography (CT) contain multiple artifacts which make interpretation of results difficult. Polymer materials offer good permeability to X-rays, which enables the implant location to be correctly visualised, and thus to follow up the effects of treatment by means of radiographic techniques. Plastics do not generate image artifacts (Kurtz 2012).

Wear products may be released to the body as a result of abrasion processes in the insert. They may accumulate in surrounding tissues, leading to inflammations. Because PEEK is more abrasion-resistant than UHMWPE, abrasive wear is lower (Geringer *et al.* 2011, Patrica *et al.* 2016). Consequently, the probability of inflammation developing in the patient's body is lower.

Properties of materials designed for implantation in the human body should not deteriorate after sterilisation. Polyethylene cannot be sterilised thermally due to its operating temperature range. It may still be sterilised by irradiation, although the process must take place in specific conditions. In unsuitable conditions, the structure of polyethylene may be changed along with its properties (Herman 2007, Del Prever *et al.* 2009). In contrast, PEEK demonstrates excellent resistance to typical sterilisation methods. It can be sterilised thermally as well as by irradiation. No changes of mechanical properties are reported even after multiple exposure to the process. No other negative effects such as strain cracks, discoloration or calcification have been reported (Kumar *et al.* 2018). Polyethylene is a relatively inexpensive material. It also has good machining properties. The price of PEEK is much higher than the price of polyethylene. It may be processed by conventional methods such as extrusion, press moulding or milling, but its machinability is inferior to that of UHMWPE.

The comparative analysis of UHMWPE and PEEK indicates that the latter has superior mechanical properties. Both materials meet criteria for polymer materials used in medicine.

3. Materials and methods

A FEM- (finite element method) based simulation was performed to compare both materials. The simulation allowed us to measure the effect of forces applied during patient's movements and values of stress depending on the material used. Only the insert of the knee joint endoprosthesis was analysed.

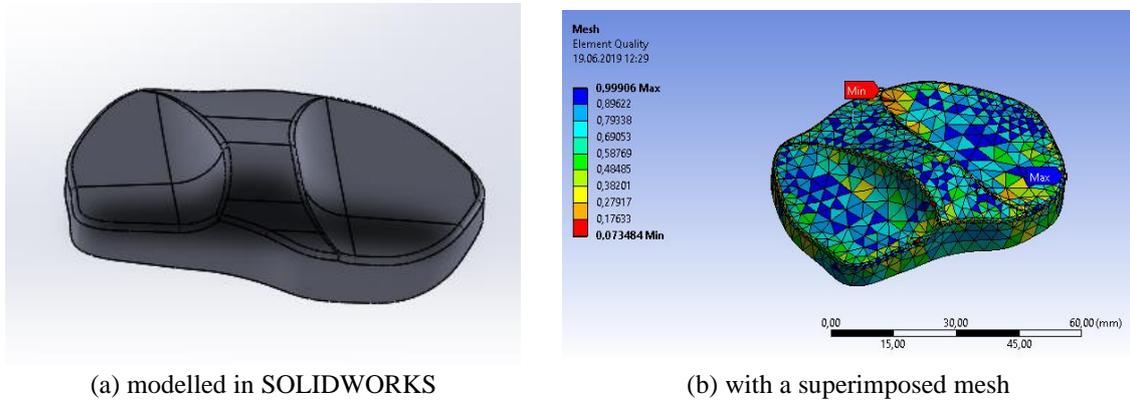


Fig. 4 A model of the knee joint endoprosthesis

Table 3 Skewness coefficient value vs. mesh quality

Perfect	Very good	Good	Acceptable	Bad	Unacceptable
0-0.25	0.25-0.5	0.5-0.8	0.8-0.95	0.95-0.98	0.98-1

The numerical model was created on the basis of a real object, taking into account its geometry and material data. The insert used in the analysis was modelled in the SOLIDWORKS software (Fig. 4(a)). The model was imported in Ansys Workbench 19.2, and then subjected to discretisation by means of the finite element method. Mesh quality is of critical importance for the credibility of results. A visualisation of the quality of individual mesh elements was generated in the software (see Fig. 4(b)).

Mesh quality was assessed through the use of coefficients available in the programme. Low orthogonal quality or high skewness values are not recommended. Generally, orthogonality should be lower than 0.1, while skewness lower than 0.95.

Highest quality coefficients could not be achieved due to the mesh element limit imposed by the licence. In our analysis, skewness equalled 0.33, which means that the mesh can be described as very good (see Table 3).

Model discretisation was performed correctly. Because of a fairly low number of finite elements (31257) the model is not heavy on the computing resources of the system. However, limits imposed by the software made it necessary to make calculations for a quite simplified model.

For the purpose of the calculations it was assumed that the insert is fixed (the lower part of the insert had been immobilised), and the force is applied on the model in the ‘z’ direction. Loads were distributed uniformly over both parts of the endoprosthesis and applied to load-bearing surfaces.

The analysed case involved a walking patient, which means that the highest force exerted on a single knee joint was 261% of total body mass. The value of the load applied was assumed on the basis of a study by Kutzner *et al.* (2010). For a walking person of 120 kg total body mass, the force equalled 3072 N. Material properties on which the simulation was based are presented in Table 1.

4. Stress analysis results

Higher reduced tension values according to Huber’s hypothesis were achieved for the insert made

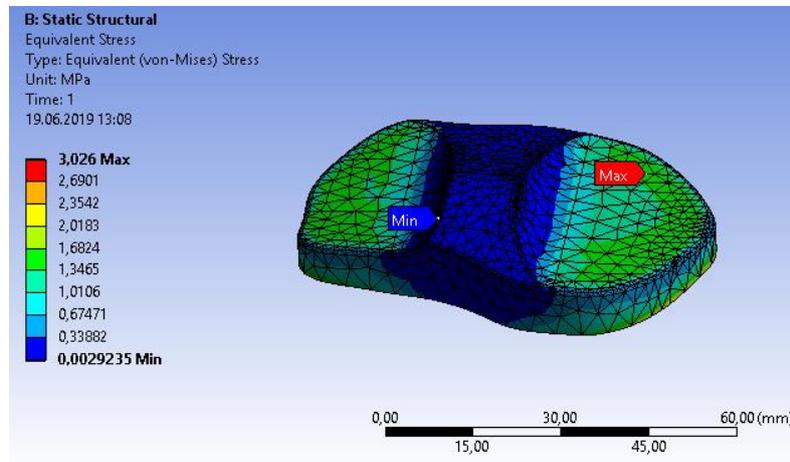


Fig. 5 Visualization of stress in the UHMWPE insert

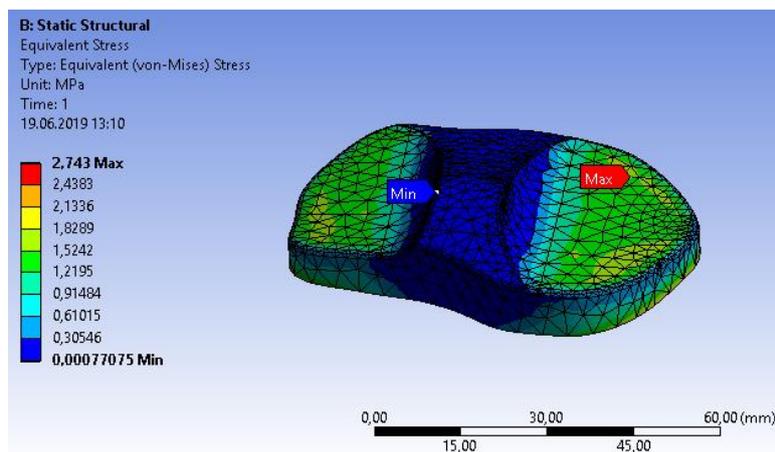


Fig. 6 Visualization of stress in the PEEK insert

of ultra-high molecular weight polyethylene (see Fig. 5). The maximum value of such tensions was approx. 3.026 [MPa]. In contrast, for polyetheretherketone it was 2.743 [MPa] (see Fig. 6).

The yield point was not exceeded in either case, despite the high values of forces exerted when the patient was in motion. As the yield point of PEEK is 5 times greater, we may conclude that the polyetheretherketone can withstand much greater forces without the risk of failure. Stress concentrations occurred on the insert's surface of contact with the femoral component of the endoprosthesis, i.e., in typical locations of surface degradation caused by long-term use. Tensions present in the PEEK insert are lower than in the UHMWPE insert. Nevertheless, considering that PEEK's strength is higher than UHMWPE, and that the knee joint is almost invariably subjected to some load, the service life of the PEEK insert can be much longer than the one made of UHMWPE. Long-term benefits, such as extended service life, lower wear over time or reduced release of wear products to the body, weigh in favour of the PEEK insert.

The results of the simulations carried out in this study are a part of a master's thesis on the analysis of the application of PEEK in modelling a knee joint endoprosthesis (Wojnarowska 2019).

5. Conclusions

Overall, it was found that polyetheretherketone meets all requirements concerning plastics applied in medicine, and as such can be implanted in living organisms. Its mechanical parameters are closer to those of the bone than in the case of ultra-high molecular mass polyethylene. In many respects it is superior to UHMWPE in its physical and mechanical properties. One of the main advantages of PEEK is that it can be sterilised not only by irradiation but also thermally. In addition, it is characterised by very high abrasion resistance.

The analysis of simulation results led to the conclusion that the yield point was not exceeded in any of the investigated cases, despite high load force levels. Stress concentration appeared on the contact surface between the insert and the femoral component, i.e., on load-bearing surfaces. The area is characterised by the highest risk of failure. Higher stress values were reported for the UHMWPE insert.

On the basis of analyses, it was reported that polyetheretherketone is a suitable material for making knee joint components such as the polymer insert. Its application could extend the service life of the component, and consequently of the entire endoprosthesis.

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