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Mechanical assessment of a hip joint stem model made of a PEEK/carbon fibre composite under compression loading

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Purpose: The aim of the work was to manufacture a composite stem model consisting of carbon fibres (CF) and polyether ether ketone (PEEK) and to perform the surface strain and stress distributions in the stem-femoral bone model under compression loading. *Methods*: Composite stems differing in elasticity were prepared. Three types of composite stems having different arrangements of carbon fibre reinforcements (carbon fibre roving, carbon fibre sleeves and their combinations) in the polymer matrix were made. The stems were cementless fixed in the femoral bone model channel or with the use of the polymer bone cement (PMMA). Mechanical behaviour of composite stems under compression loading was compared with a metallic stem by strain gauge measurements at different parts of stem/bone model systems. *Results*: The values of stresses in the proximal part of the bone model for cemented and cementless fixations of the composite stem in the femoral bone channel were higher than those noted for the metallic stem. The increase in proximal bone stress was almost similar for both types of fixation of composite stems, i.e., cemented and cementless fixed stems. *Conclusions*: The optimal range of mechanical stiffness, strengths and work up to fracture was obtained for composite stem made of carbon fibre sleeves and carbon fibres in the form of roving. Depending on the elasticity of the composite stem model, an increase in the stress in the proximal part of femoral bone model of up to 40% was achieved in comparison with the metallic stem.

Key words: *hip prosthesis, carbon fibres, PEEK matrix, stress shielding, composite stem*

1. Introduction

For several years, metals and metal-based alloy implants, due to their high strength and toughness, good fatigue and wear properties, have been the predominant materials on the medical market for load-bearing implants. They are, however, susceptible to corrosion in the living organism, resulting in toxic products which may cause allergic or even carcinogenic reactions. Moreover, metallic implants have a significantly higher stiffness than bone tissue, leading to a reduction in bone density as a result stress shielding [7], [16]. The high elastic modulus of metallic biomaterials used for the treatment of bone fractures may mean that the healing process and union with the bone are hampered by the decreased strain in bone [1], [9], [22]. A drawback of metallic implants is also the limited possibility of using modern diagnostic methods based on computer tomography (CT) and nuclear magnetic resonance (NMR) [6]. Ceramic materials are mechanically too weak and brittle, which, despite their high biocompatibility, significantly limits the range of their applications in the treatment of the skeletal system, especially in the case of high external loads [6], [8]. Pure biocompatible polymers possess insufficient mechanical strength to be used as load-bearing implants [15], [21].

For these reasons, attempts have been made to develop non-metallic materials for bone surgery, including polymer and ceramic composites and nanocomposites [13], [14], [18], [19]. Carbon fibre-reinforced polymer matrices have attracted interest for applications in medicine due to their tailored mechanical properties combined with light weight and confirmed good biocompatibility with the living organism [12], [24].

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PEEK/CF is a composite which seems to be a particularly good candidate to replace metallic implants used in various medical areas, including load-bearing implants [3], [4], [10], [12]. The use of this composite as a suitable material for load bearing implants is increasing in popularity. However, the related knowledge still needs to be progressed for reliable clinical implementation. More research, particularly involving experimental data related to compression static and dynamic fatigue behavior of the composites with different fibre orientations in thermoplastic matrix with respect to the loading direction should be made. The changes in behavior of such composites are of direct, practical interest to the implant designer.

The aim of the work was to manufacture a composite model consisting of PEEK matrix and CF reinforcements, as well as to analyse the surface strain and stress distributions in the composite stem-femoral bone model under compression loading. Composite stem models with different elastic moduli were prepared. As the reference system, a stem made of the Vitallium alloy with Young's modulus of 200 GPa was applied. For the manufacture of composite stems with different elasticity, carbon fibre reinforcements in the form of braided sleeves and roving were used. Such forms of fibrous reinforcements were selected with the purpose of reducing the risk of composite failure by way of splitting of PEEK/CF.

The work investigated whether the stress shielding of a rigid metallic stem can effectively be reduced by the use of a composite stem made of a braided carbon fibre-reinforced polymer matrix. The responses of hip bone model to composite stems under compressive load were compared using strain gauge measurements. The surface strains and stresses in proximal and distal sites of femoral bone model were determined.

2. Materials and methods

For composite manufacture, the following materials were used: medium-modulus carbon fibres (Torayca FT300) in the form of roving and carbon braids in the form of fibrous sleeves, manufactured by Siltex Flecht- und Isoliertechnologie Holzmüller GmbH & Co. KG. Three types of sleeves differing in their diameter were used. The characteristics of carbon fibres in the form of braided sleeves are given in Table 1. Polyether ether ketone (PEEK 150PF, 344.6 °C melting point, and 130 Pa*s melt viscosity at 400 °C), delivered by Victrex, was used as the matrix.

Table 1. Carbon fibre braided sleeves, technical characteristics

Braided Sleeve Type	5 mm	8 mm	10 mm
Width, (mm)	2.0 (flat)	4.0 (flat)	6.0 (flat)
Wall Thickness, (mm)	0.15	0.11	0.34
Threats	24	24	32
Diameter range, (mm)	1.5–7.0	1.0–10.0	3.0–12.0

PEEK/CF composite samples were obtained by the heat compression moulding method. The optimal conditions (time, temperature, pressure) were chosen on the basis of an earlier study [20]. To prevent polymer degradation during the manufacture of the composite samples, the formation temperature range was determined based on a thermal analysis of the polymer (TG, DSC), Fig 1.

The figure shows the mass loss characteristics of polymer matrix and containing carbon fibres as a function of temperature. Glass transition temperatures (T_g) determined from DSC curve for pure polymer was 321.3 °C, and for polymer containing carbon fibres 336.8 °C. The mass loss characteristics (TG) of pure PEEK polymer and PEEK/CF composite has shown

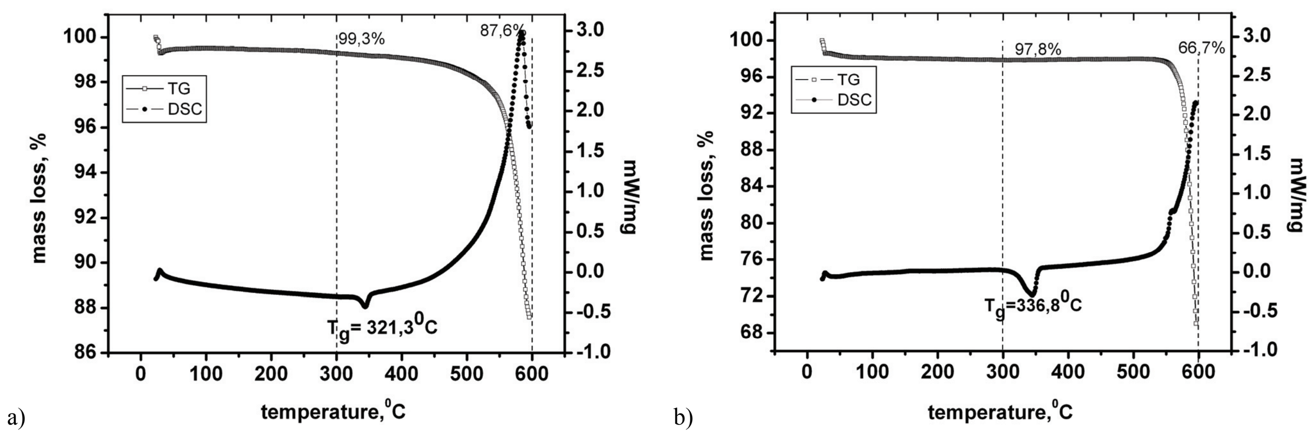

Fig. 1. TG and DSC curves for (a) pure PEEK and (b) PEEK/CF

that this parameter determined at 300 °C and 600 °C became significantly higher for the composite samples, e.g., it amounts to 12.4% for pure PEEK and 33.3% for the composite samples at 600 °C. The analyses of TG curves for composites indicated that the optimum temperature range for the composite molding process is between 400–420 °C.

The samples were compression moulded in a cylindrical metallic mould, with the fibre reinforcement in the form of roving (1-D), carbon braided sleeves (MD) and the composition fibre roving/braided sleeves (MD/1-D) (Fig. 2). In each case, before carbon fibres were placed in the metallic mould, they were oversaturated by the proper amount of pulverised polymer powder in such a way as to ensure good impregnation of the fibres by the molten matrix. Depending on the type of composite samples the fibre volume fraction ranged from 42 to 53%. Differences in fibre volume content in composite samples fraction resulted from various arrangement of fibres in polymer matrix.

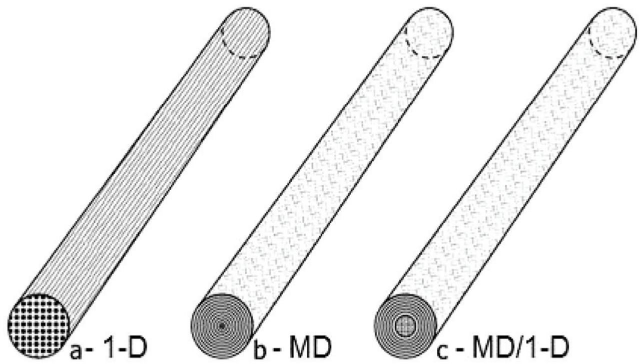

Fig. 2. Composite samples used to prepare composite stems; (a) 1-D carbon fibre roving, (b) MD carbon fibre sleeve, and (c) MD/1-D fibre roving in core part and fibre braided sleeve in outer part of stem

The following composite-forming conditions were selected: pressure 1.5 MPa, formation temperature 420 °C, formation time 10 minutes [5].

After the selected time at a constant pressure, the mould was cooled down to room temperature. The latter was next used to mould samples of a proper size for mechanical tests.

The following types of stems were manufactured:

- PEEK/CF composite sample made of unidirectional carbon fibre-reinforced PEEK matrix – denoted as 1-D (Fig. 2);
- PEEK/CF composite sample; the core of stem was made of a unidirectional carbon fibre-reinforced PEEK matrix, and the outer part was made of carbon fibre sleeves –denoted as MD/1-D;
- PEEK/CF composite sample; made of a carbon fibre braided sleeves-reinforced PEEK matrix – denoted as MD;
- Reference sample made of Vitallium alloy – denoted in the work as Vitallium.

To analyse the mechanical interaction occurring at the implant-bone interface with the use of a model system, a femoral bone model was elaborated and manufactured.

The bone model was manufactured with the use of epoxy resin (Epidian 601) with a Z-1 hardener, E-type glass fibres in the form of chopped fibres (5 mm long), and a silk weave glass fibre fabric.

To obtain a complex structure of the bone model with mechanical properties similar to that of a femoral bone, two types of composites were prepared. A model of a cancellous bone was made of chopped glass fibres with an epoxy resin matrix, whereas a model of a cortical bone was obtained by combining epoxy resin with a glass fibre fabric. Both composite components were combined in such a way to fabricate a tubular femoral bone model in which the inner part was made from chopped glass fibres/epoxy resin and outer part from glass fibre fabric/epoxy resin.

The obtained tubular two-component bone model was verified by mechanical tests in axial compression mode. The mechanical properties of both composites forming the bone model as well as of the resulting bone model consisting of two composite components in comparison with a natural bone are compiled in Table 2, [11].

Table 2. Mechanical properties of composite bone model and natural bone tissue

Material	Compressive strength, MPa	Compressive modulus, GPa
Cortical bone composite analog	288.7 ± 14.9	11.3 ± 0.5
Cancellous bone composite analog	28.3 ± 3.1	1.3 ± 0.1
Natural cortical bone [11]	50–230	7–30
Natural cancellous bone [11]	2–20	0.05–0.5

The experimental model developed was reduced in size as compared to the actual skeletal system by a proportion of 1:2 on the cross-section. The size reduction of the model arose from the practical aspects related to the implementation of the planned experimental research. In the test methodology regarding the biomechanical analysis of the composite stem, it was assumed that the latter should transfer the axial load equalling a six-fold mass of an adult human. Such overloads can occur, e.g., during jumping off the stairs, a tram or bus trip, or a fall. Assuming that the average human weight is about 70 kG, a composite stem in the actual scale should carry an overload of about 3.9–4.2 kN. Therefore, in the assumed 1:2 model, the composite stem should support a load of about 1.9–2.1 kN. These values were assumed as the upper load limit in the further considerations of the model.

To determine the mechanical properties of the composite samples used to manufacture various composite stems, the mechanical tests were conducted by means of a universal testing machine (Zwick 1435) controlled by TestXpert (v.8.1) software, under uniaxial compression. Apparent interlaminar shear strength of the composite samples was measured in bending mode by short beam method with span-to-depth ratios of 4:1.

The tests were conducted with a strain rate of 1 mm/min.

For each type of composite samples, five individual measurements were made. The results are presented as mean ± SD.

To prepare the stem composite models, PEEK/CF composite samples were mechanically treated to form the shape corresponding to a truncated cone, as shown in Fig. 3 (A, B). Such a model meets the shape of the hip joint prosthesis stem, which assures the effect of mechanical fixation under a compression force. The stems were mechanically fixed in the bone model channel at a depth constituting 75% of the stem's length or with the use of the polymer bone cement (PMMA) Duracryl Plus delivered by SpofaDental. A complete experimental bone/glue/composite stem model system is presented in Fig. 3 (C).

For both elements of the particular model systems, longitudinal strain under compression loading was measured using strain gauges. The strain-gauges in bridge connection were equipped with an amplifier (TMX-0101-SE model) and computer system for monitoring and collecting data from experimental setup.

The strains occurring in particular surface zones (sites) of the bone model, i.e., strains in the proximal part of bone (ε_1) and in the distal part of the artificial bone (ε_2) were measured. The zones constitute the joint areas of the component elements of the model. Figure 4 shows the sites of fixation of the strain gauges corresponding to the zones analysed. Compression loading (F) in the test setup was applied vertically to the top surface of the composite stem.

The tests made it possible to evaluate and compare the strains and stresses occurring in the particular sites of the model, as well as to compare them with the total strains of the model. The total longitudinal strains of stem/bone models caused by axial compression loading were determined by measuring the displacement of the head of the testing machine at a constant rate of 1 mm/min.

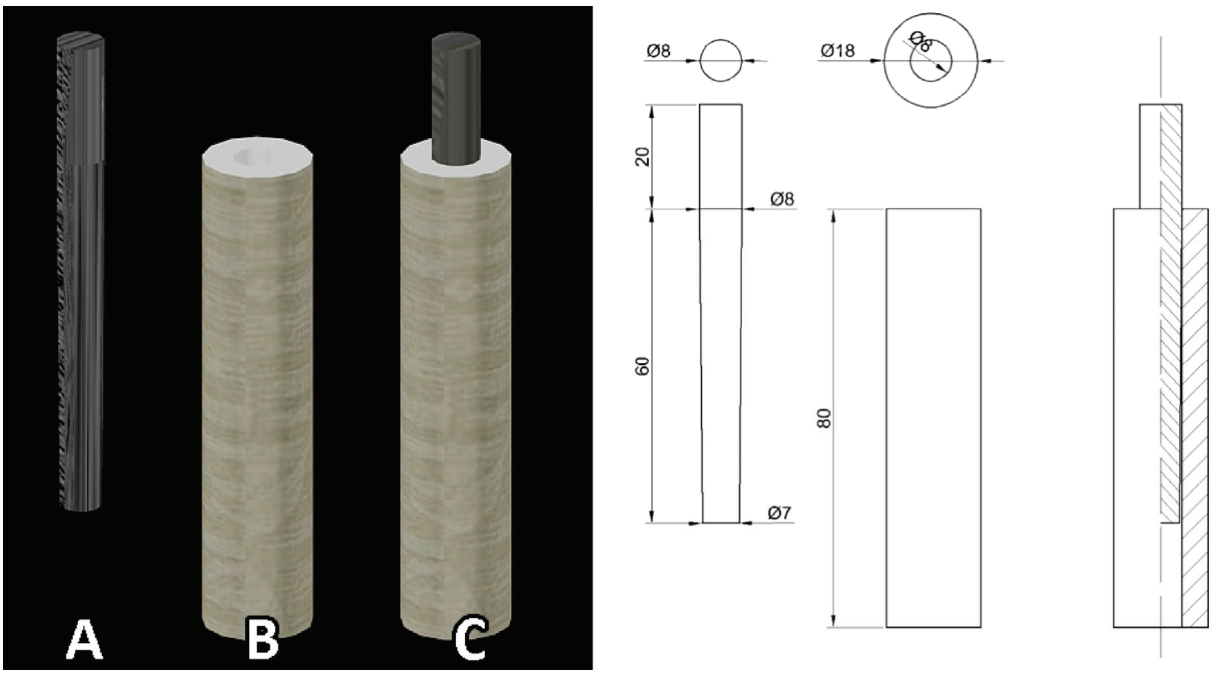

Fig. 3. Bone/stem model showing geometry and dimensions of composite specimens;
A – composite stem, B – femoral bone model, C – femoral bone/stem model

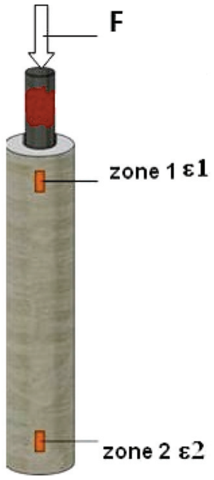

Fig. 4. Bone/stem model; fixation sites of strain gauges: ε_1, ε_2 – relative strains determined from strain gauge measurements

3. Results

Representative parameters of the composites determined in bending and compression tests are gathered in Table 3. As seen in the table, the range of both the strength and elasticity values obtained for three types of composite stems is sufficient for such materials to be used to design and manufacture structural implants. Taking into consideration the assumed upper load limit (1.9–2.0 kN) the composite stems can support such a loading. The lowest compression strength obtained for the MD stem, equalling about 231.5 MPa, corresponds to 11.6 kN (compression failure force), which still distinctly exceeds the assumed upper load limit. The upper value

Table 3. Mechanical properties of various composite specimens determined in bending and compression tests

Composite type	Bending	Compression	Work to fracture	Interlaminar shear strength
	Strength [MPa]		[kN*mm]	[MPa]
1-D	477.3 ± 23.9	403.5 ± 20.2	8.9±0.8	75.6±4.2
MD	416.8 ± 20.8	231.5 ± 11.6	7.3±0.6	59.4±3.1
MD/1-D	640.7 ± 32.0	427.0 ± 21.4	9.9±0.7	89.9±4.3
	Modulus [GPa]			
1-D	34.7 ± 1.7	38.4 ± 1.9	–	–
MD	19.7 ± 1.0	24.1 ± 1.2	–	–
MD/1-D	29.7 ± 1.5	34.9 ± 1.8	–	–

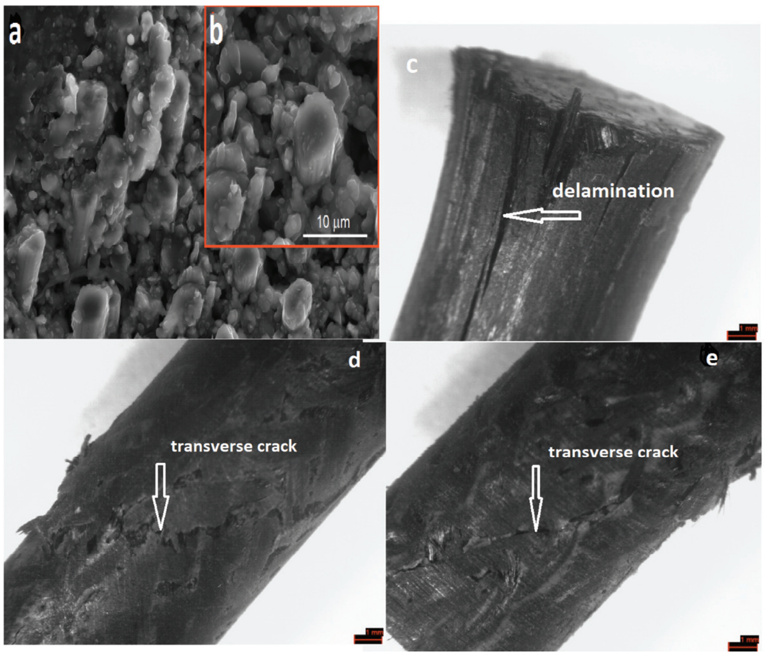

Fig. 5. Microphotographs of composites, (a) SEM of 1-D composite fracture surface, mag. 3000×, (b) mag. 10000×, (c) 1-D composite stem showing delamination crack, (d) MD/1-D stem with transverse crack, (e) MD stem with transverse crack

of the bending strength, equalling about 650 MPa, is similar to the strength of titanium and vanadium-based alloys (Ti-6Al-4V), used in alloplasty of hip and knee joints. Moreover, the rigidity range represented by the elastic moduli for all composite stems is much closer to that of bone as compared to titanium alloys [20].

Figure 5 shows microphotographs comparing three types of composite stems after compression fracture test.

Figure 5 a shows the fracture surface area of 1-D composite and indicates a good fibre–matrix integrity. Despite the good integration between the fibres and the matrix and the relatively high value of the composite shear strength (see Table 3), this type of composite under compression test is fractured by splitting. An obvious feature in this figure is that stem made from 1-D composite is destructed by delamination along the stem axis. A representative crack in 1-D composite extends through the entire longitudinal stem length, while in MD/1-D and MD stems transverse cracks are observed after compression destruction tests. Table 3 contains the values of work to fracture of composite stems. Due to combination of two types of fibrous reinforcements (fibrous sleeves and roving), MD/1-D stem performs the highest value of work to fracture (fracture energy). The higher work to fracture of this composite stem is consistent with the observed rise in bending strength and is also supported by mechanism of crack formation. MD stem shows a higher deformability under compression and similar to MD/1-D stem mechanism of transverse crack formation, while its lower work up to fracture is attributed to lower strength.

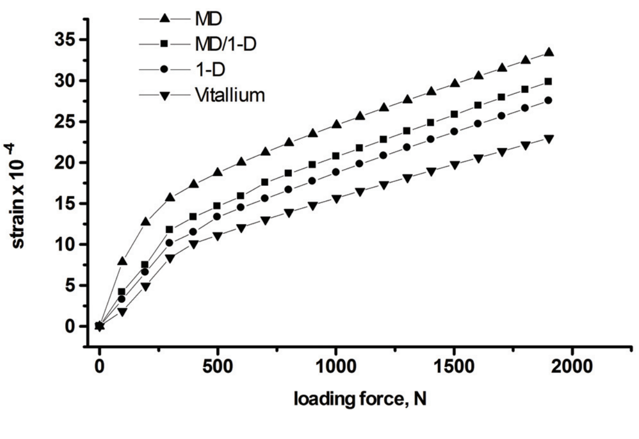

Fig. 6. Total relative strains caused by axial compression load imposed on various composite stem models; fixation with PMMA cement

Figures 6 and 7 compare the changes in the total longitudinal strains of the stem/bone models. Measurements were made for two cases, the stems fixed with bone cement (PMMA) and mechanically interlocked into the bone channel (cementless fixation). The models were exposed to the loading of an axial compression stress up to 38 MPa (1900 N).

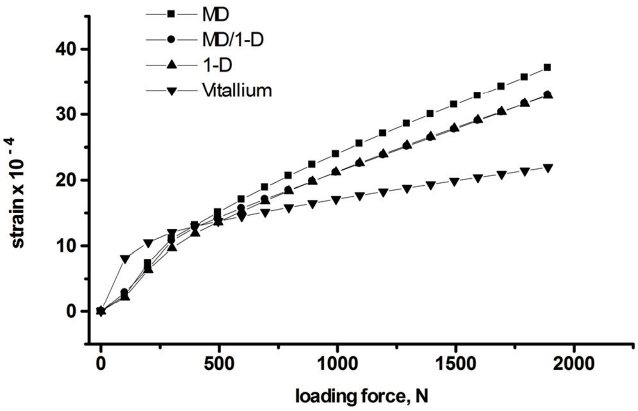

Fig. 7. Total relative strains caused by axial compression load imposed on various composite stem models; cementless fixation

The highest total strain for the composite MD stem cementless fixed in the bone channel was found to equal 0.37%, whereas the smallest total strain, equalling 0.22%, occurred for the metal stem model. As can be seen from Figs. 4 and 5, the level of the total axial deformation under the maximal loading force for the metal stem is almost the same for both types of fixation, while for MD stem a slightly higher total strain was reached for cementless fixation, i.e., 0.37% compared to 0.32%. This difference may probably be explained by a weaker friction bond formed between MD surface stem and internal surface of the composite bone model (cancellous bone) as compared to the PMMA-fixed MD stem.

The relative strain values occurring in the particular zones of the hip model are collected in Table 4.

Table 4. Strains occurring in cortical bone model (proximal, distal part) due to axial compression force imposed on various stems

Zone	Stem type	Stem loading, MPa	Bone strain, %	
			Cement fixation	Cementless fixation
1	1-D	38 (1.9 kN)	0.043	0.042
	MD/1-D		0.045	0.044
	MD		0.046	0.045
	Vitallium		0.033	0.033
2	1-D		0.102	0.099
	MD/1-D		0.103	0.101
	MD		0.103	0.102
	Vitallium		0.097	0.096

The changes in the strains in the particular zones (Fig. 4) were monitored by means of strain gauges.

Zone 1 corresponds to the surface area of the proximal part of the cortical bone model, i.e., the joint area of the component elements of the particular model system. The highest strain (0.046%) at this site in the model under study was found for the MD composite stem, fixed with the polymer cement, whereas the smallest one was found for the cementless fixed metal stem (0.033%).

Zone 2 corresponds to the surface of the distal part of the cortical bone model. The strains measured in this zone were distinctly higher than those determined for proximal zone. The values of strains were almost similar for all composite stems for both types of fixations, whereas the smallest strain (0.096%) was found for the metallic stem.

4. Discussion

Mechanical tests of composite stems performed under compression tests revealed significant differences in their behaviour. The 1-D composite stems show a decreased mechanical performance manifested in inferior work to fracture and a tendency for delamination under compressive loading. Taking in consideration their potential future use the best results were obtained for stems consisting of two different components, inner part made of 1-D composite, and outer layer consisting of fibrous braided sleeves. Under compression load such composites inhibit development of longitudinal cracks along the stem axis and represent a better mechanical characteristics in comparison with 1-D and MD stems.

The strain gauge tests performed in this study showed that the mechanical characteristics of the four types of stem/femoral bone model systems, with two types of fixations, differ from each other. Knowing the elastic modulus of femoral bone model made it possible to determine the stress values in the zones examined.

In this analysis, the upper part of the stem/bone model, denoted as zone 1, is to be particularly important, which signifies a state of deformation and stresses on the surface of the cortical bone model. Due to the location of the strain gauges (surface), these tests do not allow the strain states induced directly inside the cortical bone to be evaluated. However, the calculated stress values in this zone showed that all the composite stems lead to a higher stress value on the surface of the cortical bone model, as compared to the metallic stem. For the metal/cement model, the highest stress value in this zone was found to be 3.7 MPa, whereas for the remaining models, containing a composite stem fixed with cement, these values were within the range from 4.9 MPa to 5.2 MPa. The effectiveness of "load transfer" from the composite stems to the cortical femoral bone does not differ for cemented stem, e.g., for the 1-D composite, the stress value in zone 1 equalled 4.9 MPa, whereas for the same system with a cementless fixed stem, the value amounted to 4.8 MPa. All composite stems were more effective in terms of load transfer in comparison with the metallic stem. The comparative results of the stresses occurring in different areas of the model systems are provided in Fig. 8.

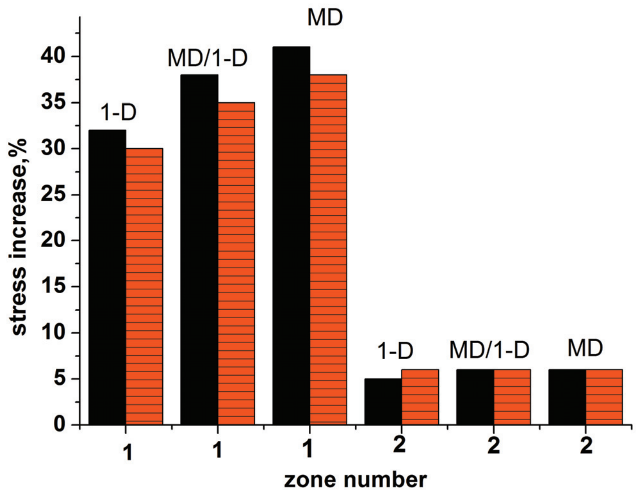

Fig. 8. Stresses increase in proximal (1) and distal part (2) of femoral bone

Bone stress increase in the proximal and distal part of a femur model ranged from 30% to 41%, and in the range from 5 to 8%, respectively.

The aim of this work was to verify whether the elasticity of the composite stem material affects stress transfer in the upper part of the femoral bone model. What is particularly important is the possibility of increasing the stresses in bone tissue, in direct contact with a stem, in order to avoid stress shielding in the skeletal system. In comparison with metallic implants with limited ability to modify their elastic properties, polymers and CF- based composites can be designed with optimum strength, stiffness and fracture energy.

The crucial area of analysis is zone 1, which reflects the area of a direct effect of the stem's elasticity in contact with cancellous bone, i.e., in the upper part of the model. The results indicate that the effect of the composite stem's elasticity on the transfer of external loads to the cortical bone is evident.

A physical consequence of a low level of mechanical stress in the upper part of the hip bone is the resorption of bone tissue (according to Wolff's law). Such a phenomenon takes place in the case of commonly used hip prostheses with a metal stem. The cobalt-chromium stems which are rigid and create conditions for stress shielding around the total hip prosthesis, which deprives a certain part of the bone of its optimal load, constitute a mechanical stimulator for the bone to adapt to the changing external conditions [23]. This may lead to a reduction in the density of the hip bone (osteoporosis). The selection of various types of carbon fibre reinforcements allowed for providing the composite stem having a bone-like elasticity.

The studies of the strain and stress distributions in stem and bone models have made it possible to verify the hypothesis that a more flexible composite stem may substantially reduce stress shielding around the femoral bone. The comparison of the values of stresses in the upper part of the bone for both types of interlocking the composite stem in the bone channel (bone cement or cementless fixed stem) showed that these stresses have a higher value than in the case of the metallic stem. Taking into consideration the future clinical use of such materials to be applied to design the components of total hip prostheses, a primary importance is to assure the long-term stable fixation of a composite stem with surrounding bone. Numerous studies have been made to date to add bioactivity function to a relatively bioinert PEEK matrix [17]. Coating the bioinert material surface with HA and TCP, as well as embedding the ceramic component into the near surface region of polymer or creation of blended PEEK/HA composites have been developed. However, achieving a stable fixation of PEEK-based biomaterial matrices in combination with carbon fibres for composite stems requires further *in vivo* research. PEEK-based matrices for composite biomaterials may be an attractive way of further development of novel load bearing bioactive implants as alternative for metallic ones.

5. Conclusions

This study investigated the possibility of applying a PEEK/CF composite as a material for hip joint replacements. The optimal range of mechanical stiffness and strengths is offered by combining carbon fibre sleeve-based PEEK composites with 1-D carbon fibre component for load-bearing implants. Stem models with a different architecture of carbon fibres in the polymer matrix were compared with a rigid metallic stem by strain gauge measurements at various stem/hip bone sites. The stiffness of the composite stem affects the stress in the whole bone/composite stem system. The effectiveness of load transfer from the composite stem to the cortical bone is higher for the composite stem in comparison with Vitallium-based stem.

The composite stems allowed for an increase in the stresses in the proximal part of the femoral bone, depending on the type of the composite stem, from 30 to 40%, as compared to the metal stem. The increase in proximal bone stress was almost similar for both types of interlocking the composite stems, i.e., cemented and cementless fixed stems.

By using two types of fibre reinforcement, i.e., fibre roving and carbon fibres in the form of sleeves it is possible to reduce the risk of delamination in the composite stem and increase its work up to fracture.

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