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Experimental evaluation of a novel concept of an implant for direct skeletal attachment of limb prosthesis

PIOTR PROCHOR

Institute of Biomedical Engineering, Faculty of Mechanical Engineering,
Bialystok University of Technology, Białystok, Poland

Purpose: The aim of the study was to experimentally evaluate a proposed two-part implantation system (medullary part made of PEEK composite and percutaneous part made of Ti6Al4V) for bone-anchored prosthesis and to compare it to typical press-fit design (also made of Ti6Al4V) used for the same purpose. *Methods*: Simplified prototypes of both implants were prepared for the research. Both implants were evaluated *in vitro* with the use of porcine femur (6 bones for each implant). ARAMIS vision system was used to measure strains in selected area of bone shaft, generated when putting an axial load on the implants to simulate static load bearing exercises performed during rehabilitation activities in primary stabilisation. *Results*: Obtained maps revealed high concentrations of strains, located near to distal part of the implant, during using a typical press-fit design with relatively low strain around the implant's shaft. In the case of proposed design, noticeable strains occurred in the entire examined area of bone, with stronger concentration towards the proximal direction. *Conclusions*: Presented experimental results suggest that proposed design provides more appropriate implant-bone load transfer than typically used press-fit design. This may result in obtaining more beneficial mechanobiological stimulus which enables the researchers to achieve appropriate primary stability and maintain appropriate bone quality during its long-term use after achieving full osseointegration.

Key words: *residual limb, strain, bone, implant, ARAMIS*

1. Introduction

Despite the centuries of use and countless attempts to develop an appropriate construction and material solution for the prosthetic socket, or the use of elements improving its use, prosthetic sockets still do not provide a fully satisfying connection between residual limb and artificial limb [18]. Nearly all issues that arise within residual limb during the use of a prosthesis suspended on a prosthetic socket, result from the anatomical maladjustment of soft tissues to the altered biomechanical conditions caused by amputation [23]. The most important disadvantages resulting from the use of prosthetic socket include: allergies, irritations, abrasions and skin infections as well as swelling [18], inability to use them with a short residual limb [4], requirement of frequent modifications and/or replacements [4], difficulties in the correct distribution of forces acting on the surface of residual limb [15], difficulties in creating computer models for biomechanical analyses of the socket-stump connection [8], frequent difficulties in adjusting the prosthetic socket to the geometry of a residual limb [18], unnatural control over the prosthesis resulting in gait asymmetry [4], possible damage leading to the need for reamputation, consisting in shortening the residual limb [1] or general discomfort leading to a reduction in the quality of everyday life [4]. The described factors caused the process that have started in the second half of the 20th century, which goal is to develop a new and more functional solution for connecting a limb prosthesis with the user's body.

This process resulted in the development of direct skeletal attachment (DSA) of prosthesis to the limb, by the use of appropriately designed implants placed

* Corresponding author: Piotr Prochor, Institute of Biomedical Engineering, Faculty of Mechanical Engineering, Bialystok University of Technology, ul. Wiejska 45c, 15-351 Białystok, Poland. E-mail: p.prochor@pb.edu.pl
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in the medullary cavity, with the abutment penetrating soft tissues, that contains a head on which adapters of external prosthesis are attached. The use of these implants provides the user with a number of advantages over a prosthetic socket. These include: easy connection of a prosthesis to a residual limb [32], the possibility of using a limb prosthesis even on a short residual limb [32], elimination of problems with skin abrasions and sliding the prosthesis off the residual limb [32], natural control of prosthesis while walking and running [4], [32], facilitating the use of bioelectric signals to control external prosthesis [32], the so-called osteoperception [6], reduced energy cost of walking [32], lacking the need to introduce continuous modifications to the variable geometry of residual limb [11]. However, implants for DSA are also characterised by few disadvantages, which include: the risk of infection at the site of skin penetration [17], rejection of an implant due to individual factors [9], the need for an invasive procedure [4], damage to implant and bone that might cause the need for a revision surgery [31].

Two main methods of anchoring the implant for DSA can be distinguished. In the first method, the connection with bone is achieved by screwing the anchoring part of the implant into the medullary cavity. The second method involves the use of a press-fit, obtained by driving implant into bone. Both the threaded and press-fit connections are characterised by advantages and disadvantages. Threaded implants have high rotational and axial stability through a sufficiently large implant-bone contact surface, significantly increasing friction [32]. However, during loading, large stresses arise in bone near the top of the implant thread, which may cause local bone resorption and, as a result, loosening the structure. In the case of press-fit implants, the axial stability is significantly lower than in the case of threaded implants. For this reason, they include additional elements to increase the functionality of the connection with the bone. At the same time, press-fit implants ensure a more natural implant-bone load transfer [2]. The method of connection and the additional elements used to increase its functionality significantly affect the probability of structural damage at the time of sudden overload of the implant, e.g., during user's fall [11], [32]. Incorrectly selected implant parameters may also cause bone fracture during implantation and the necessity to terminate the surgery, which was already noticed in the 1990s [14].

The current state of knowledge indicates the existence of a number of numerical analyses of implants for bone-anchored prostheses. However, apart from the research presented by Tomaszewski and co-authors, there are no reports in the literature showing typical mechanical analyses [33]. They used a series of strain gauges placed on the surface of the femoral shaft, which allowed for the evaluation of strains in selected bone fragments. Despite the fact that it was possible to measure the value strains, the limitation of their method was conducting tests only on measuring sections. The lack of information on deformations of the entire bone shaft may effectively influence an objective comparison of the functionality of the tested implants.

The lack of specialised scientific articles complicates the development of a correct and objective method for the evaluation of the implants for bone-anchored prostheses. However, experimental evaluations of other orthopaedic implants, such as hip endoprosthesis, might be helpful in developing the correct research method [13]. For their evaluation, the vision systems are used allowing for the observation of the entire bone segment, which is the area of interest in the conducted research. In such analyses, implants are placed in human or animal bones (e.g., porcine, sheep or calf bones) collected post-mortem, as well as in specially developed composite models of human [13], [33]. All types of bones significantly influence the results obtained during the experiment. Human bones collected after the donor's death (usually after death as a result of old age) are characterised by altered mechanical properties due to the aging processes of the organism [16]. The process of storing organic material may also significantly affect the parameters of the examined tissues [20]. The use of human bones allows for a relatively closer, in relation to animal bones (which also require scaling of the studied implants), reflection of the conditions of implants planned for use in the human body. However, their use is associated with an ethical conflict, due to the reluctance to use human remains in research [22]. In the case of the composite model, no artificial material that perfectly reflects the behaviour of bone tissues during loading has been developed so far [13]. Regardless of the bone used, they are usually fixed with resins that allow for effective and relatively correct support of the complex bone geometry [13]. In addition, they do not affect bone continuity, which would be compromised if nail or screw fasteners were used.

An attempt to evaluate the functionality of implants for bone-anchored prostheses using a vision system and animal bones may indicate the possibility of their evaluation. Therefore, the aim of the experimental studies presented in this manuscript was to conduct *in vitro* evaluation with the use of porcine post-mortem bones of the implant-bone load transfer during post-

-implantation rehabilitation procedure conducted by static load bearing exercises (SLBE). A novel design proposed by the author, which was developed to combine the advantages of threaded and press-fit connections, was used in the research. In order to objectively determine the functionality of the proposed implant, the analyses were also conducted for typical press-fit implant. It should be emphasised, however, that the use of post-mortem bone makes the examination of primary osseointegration possible. Nevertheless, a properly conducted experiment should allow for the examination of load transfer efficiency during SLBE, which has not been presented in the available literature at present.

2. Materials and methods

2.1. The design of a novel concept of implantation system for bone-anchored prostheses

The proposed Limb Prosthesis Osseointegrated Fixation System (LPOFS) (Fig. 1), was developed to directly connect prosthesis to bone in order to avoid the disadvantages resulting from the use of prosthetic sockets [27].

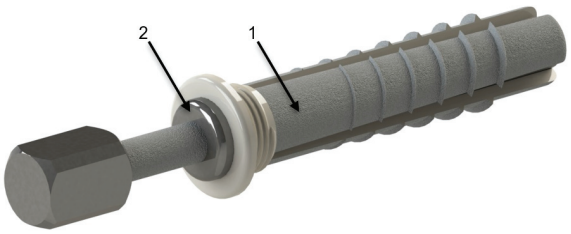

Fig. 1. Proposed implantation system:
1 – medullary part, 2 – percutaneous part

The system consists of two parts (Fig. 2): a medullary part (made of PEEK GRF30) placed in the reamed medullary cavity of a long bone and a percutaneous part (made of Ti6Al4V), which penetrates soft tissues, allowing to attach an exoprosthesis. Biofunctionality of materials considered to be used in proposed implant was proved in the recent author's papers [25], [26]. Placing the percutaneous part into medullary part expands its conical section, leading to obtainment of press-fit features. At the same time, helical tooth placed on the outer surface, gives the advantages of threaded connection. As proposed system is characterised by new features, it has been covered by patent protection (patent no. 229715) [30].

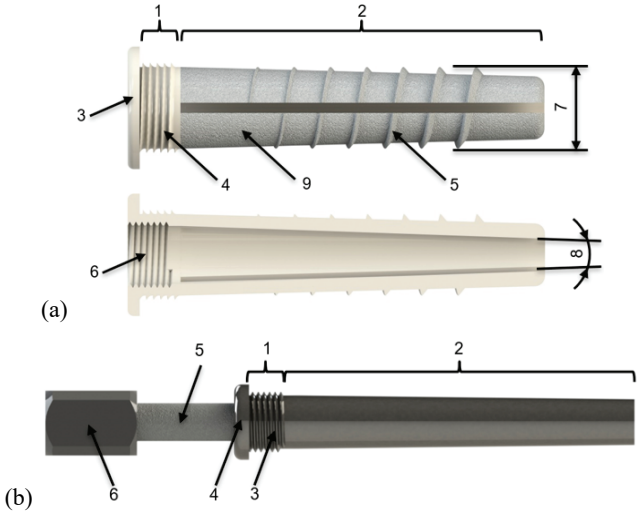

Fig. 2. Parts of proposed implantation system:
(a) general view and cross-section through the medullary part: 1 – cylindrical segment, 2 – triple cut conical segment, 3 – blocking segment, 4 – adjusted HA thread, 5 – spiral anchor tooth, 6 – metric thread, 7 – diameter of the cylindrical segment, 8 – internal cone, 9 – titanium porous layer; (b) general view of percutaneous part: 1 – cylindrical segment, 2 – conical segment, 3 – metric thread, 4 – retaining segment, 5 – shaft with porous layer of titanium, 6 – head

2.2. Initial numerical evaluation of proposed implantation system

Proposed implant was initially evaluated with the use of numerical methods. Several simulations with the use of finite element method were conducted to estimate implant's overall functionality.

Stresses generated during implantation

The implantation of press-fit implant relies on driving it into a properly prepared medullary cavity. This results in the formation of internal forces in the bone tissues, which can cause local bone damage, preventing the implant from achieving proper primary and secondary stabilisation. In critical cases, these forces may cause bone splitting, which results in the necessity to remove the implant [2]. In one of experiments, Bishop and co-authors assessed bone damage and its impact on the stability of the implant-bone connection when using press-fit structures [3] however, without assessment of stresses arising during implantation [7]. This phenomenon should be particularly intense in the case of highly porous layers, used to increase the likelihood of obtaining osseointegration. In addition, implant-bone interference is also necessary to consider as it affects the stresses arising in the bone. For this reason, the author conducted simulations of stresses

generated during implantation of proposed implant, while considering radial interference of 0.05 mm up to 0.25 mm (increment of 0.05 mm) and 3 different surfaces, characterised by various roughness (Ra of 0.11 μm, 32.60 μm and 133.00 μm). The results were compared to those obtained for press-fit implant, due to the similarity of the surgery procedures.

Nearly in all analysed cases, stresses generated within the bone tissue adjacent to the implant surface or in deep bone tissue were significantly higher in the case of typical press-fit implant than stresses obtained during implantation of proposed implant. This suggested that the author's construction is characterised by safer implantation procedure, which increases the chances of obtaining appropriate primary stabilisation. For a deeper insight into obtained results, readers are encouraged to get acquainted with externally published data [24].

Implant stability in primary stabilisation and the possibility of performing functional rehabilitation process

The possibility of achieving appropriate osseointegration depends on the correct implantation and the adopted rehabilitation process. Rehabilitation usually involves the use of SLBE, in the form of axial loading of the implant with the patient's own weight. Thus, it is possible to stimulate the bone tissue remodelling to prepare it to new biomechanical conditions [10]. The lack of a stimulus may slow down or even prevent achieving complete osseointegration of the implant [34]. Moreover, incorrect (e.g., excessive) loading or insufficient anchoring of the implant in bone tissues may lead to its micromovements in the bone [12]. According to Brunski [5], implant micromovements above 50 μm may lead to the formation of fibrous tissue at the implant-bone interface, making it impossible to achieve secondary stabilisation. The quantitative description of the impact of the loads occurring during the rehabilitation process on the emerging micromovements of implants may allow for a more correct selection of rehabilitation conditions, based not only on the patient's individual parameters (e.g., bone tissue quality) but also on the basis of the implant's design features (push-fit or threaded). The length and diameter of the implant also have a direct impact on the functionality of anchoring the implant in the bone tissue, due to the increase of implant-bone contact surface. Thus, the author decided to evaluate the impact of both these features (length in the range 75–130 mm with an increment of 5 mm and diameter in the range of 19–21 mm with an increment of 1 mm) on the development of the rehabilitation program in primary stabilisation during the use of the proposed implant and two reference implants (press-fit and threaded).

On the basis of obtained results, it can be concluded that the threaded structure ensures the smallest micromovements during SLBE in the primary stabilisation. However, the implant proposed by the author is characterised by similar, high functionality in terms of analysed feature. This suggests that it makes it possible to carry out rehabilitation exercises. In the case of press-fit implant, the loads used during rehabilitation should be selected with particular care. This is due to the risk of micromovements stimulating the bone to form fibrous tissue at the implant-bone contact site, making it impossible to obtain adequate primary stabilisation. As a result, it may also be impossible to achieve long-term secondary stabilisation. More detailed descriptions and data obtained is published within [29].

Bone remodelling around implant in secondary stabilisation

Regardless of the implant type, the bone is exposed to a decrease in mechanical properties, which progresses with the use of the implant [35]. This is especially common in the case of using materials with Young's modulus, which significantly exceeds bone tissues' (e.g., steel alloys, titanium alloys), which results in a stress-shielding effect. The lack of a bone remodelling stimulus in the distal part of the bone reduces bone density, that causes bone tissue atrophy and a decrease in their mechanical properties, which leads to the loosening of the implant and the necessity to remove it [21]. In addition, stress-shielding also causes a concentration of stresses in the proximal part of the bone, which also leads to local bone loss due to significant overload [19]. An obstacle in the evaluation of bone tissue remodelling around implants is the presence of several concepts that have been used mainly in biomechanical analyses of the craniofacial bone or a femur. So far, little research has been done on bone remodelling around implants for bone-anchored prostheses [36]. For this reason, the author simulated the bone tissue remodelling around the proposed implant and two reference implants (threaded and press-fit) using the three selected concepts of reconstruction.

The obtained results show that despite bone remodelling concept the implant proposed by the author allows to maintain appropriate bone mass around implantation site. This suggests that it is a more effective orthopaedic construction than currently used implants. More detailed analyses, as well as supplementary results, are presented within the published manuscript [28].

2.3. Experimental evaluation of proposed implantation system

The functionality of the proposed system has been estimated through previous analyses [24]–[29]. To finally confirm its effectiveness, experimental verification was carried out, which is described in the next subsections.

Experimental setup

On the basis of technical documentation (Fig. 3), simplified and properly scaled versions of a typical press-fit implant and the proposed implant were prepared for the study (Fig. 4). In the case of the implant proposed by the author, the modified thread of HA type placed on the cylindrical segment of the medullary part was not considered (due to the small influence on the load transfer). The use of the press-fit implant to obtain reference data was dictated by its closest similarity, in terms of shapes and the method of implantation, to the implantation system developed by the author.

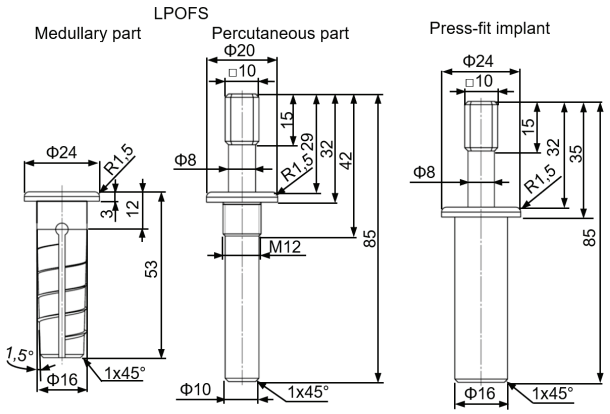

Fig. 3. Diagrams of prototypes evaluated in the presented experimental study

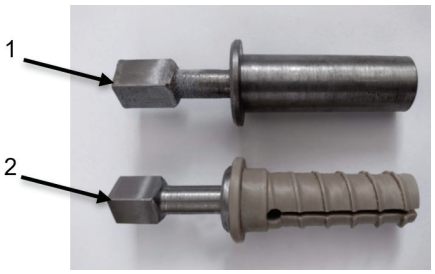

Fig. 4. Simplified and scaled prototypes prepared for the study: 1 – press fit implant, 2 – proposed implant (LPOFS)

Six femoral porcine fresh bones were prepared for each implant. The pre-frozen bones were placed in saline solution for transport. Then, to reflect the post-amputation conditions, the bones were cut in half, leaving the proximal part for testing. After cutting, the bones were cleaned of the external soft tissues to allow for the correct application of the markers for examinations using a vision system at a later stage. The medullary cavity was appropriately reamed to obtain a radial interference of 0.1 mm at bone-implant connection site. In order to obtain adequate support for samples, polyester resin was used on the level of greater trochanter and femoral head. Rectangular aluminium form was used to stabilise bones in resin (Fig. 5). Two laser levels (AutoCross 2, Laserliner) set to each other at an angle of 90° were used to properly establish the axes of the bone and the implant placed in it, perpendicular to the support.

Two hours after pouring the resin into the mold and cooling it in the open air, the samples were transferred to a refrigerator for 22 hours and stored at 4 °C. The part of the bone not covered with resin was immersed in saline solution. All actions taken during the bones' transport or storage were aimed to reduce the degree of degradation of their mechanical properties that occurs after their removal from the body. The

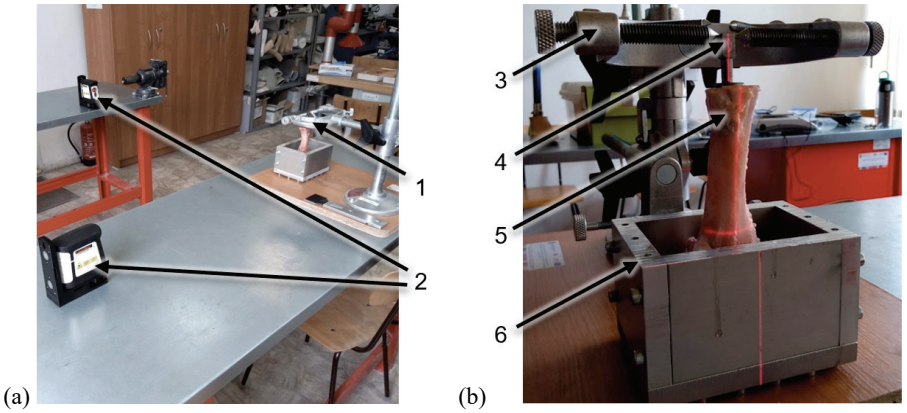

Fig. 5. Photograph of a sample positioning setup in aluminium form and the use of laser levels:
a) positioning of laser levels: 1 – sample stand, 2 – laser levels;
b) samples positioning in aluminium form: 3 – adjustable handle, 4 – implant, 5 – bone, 6 – aluminium form

samples were dried in the open air before testing with the vision system and marking with black and white spots was applied on the samples using paints (Fig. 6), enabling further tests.

Fig. 6. Photograph of a sample prepared for further evaluation with the use of vision system

ARAMIS 3D 4M (GOM) vision system as well as the 858 Mini Bionix (MTS Systems Corporation) testing machine were used in the research. ARAMIS system records the deformation of the tested samples on the basis of changes in the position of the reference points (in the form of previously applied black and white markers on the entire surface of the sample) while loading the observed body. After the system was calibrated, the observed bone segment was set at 60 mm and the sampling frequency (number of photos per second) at 50 Hz. The previously used aluminum form was also used as a sample holder to limit its movements in a plane perpendicular to the hydraulic axis of the testing machine. The stand for testing with the use of a vision system is shown in Fig. 7.

The ARAMIS system was used to evaluate strains of the bone shaft during the axial loading of the implant. The applied axial force was simulating SLBE performed as rehabilitation activities. The method of bone deformation during SLBE can effectively indicate the areas of the formation of a biological bone remodelling stimulus. As a result, it makes it possible to assess the effectiveness of the rehabilitation process in primary stabilisation and bone preparation for new biomechanical conditions, after achieving full osseointegration of the implant with the bone, i.e., secondary stabilisation. The GOM Correlate 2018 (GOM) program was used to process the results. In order to allow an objective comparison of the functionalities of the tested structures, the area of the bone shaft of 50 mm × 15 mm was selected for each of the samples, starting 30 mm below the head of the implants, determined each time from the direction of the frontal plane (Fig. 8a). In

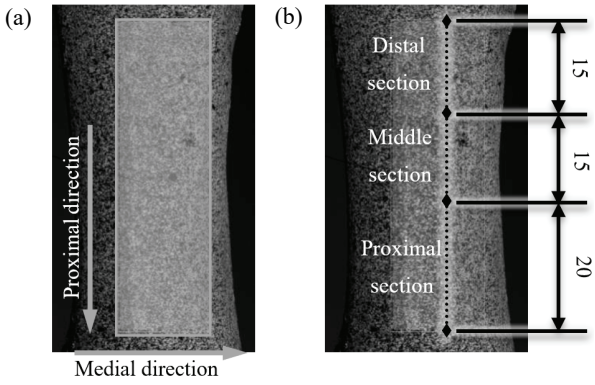

Fig. 8. Selection of areas and sections for further research: (a) an example of the selection of the analysed area of bone strains during axial loading of implants; (b) the position of the sections for measuring bone strains in the axial direction

Fig. 7. Stand for testing with the use of a vision system: 1 – aluminium form with the tested sample, 2 – load cell, 3 – ARAMIS 3D 4M vision system

addition, due to the fact that reading the results from the strain maps may be difficult, the author decided to determine strains in the axial direction along bone sections with a total length of 50 mm, located parallel to the axis of the implants (Fig. 8b).

3. Results

The strain maps obtained for the areas previously characterised in Fig. 8 are shown in Fig. 9. The maps were generated for an applied axial force equal to 5000 N. A high value of the force was necessary to observe the deformation occurring on the bone surface.

The results of the linear strain, determined for the defined sections (Fig. 8), are shown in Fig. 10.

4. Discussion

The present work presented an experimental evaluation of the functionality of the implantation system developed by the author for bone-anchored prosthesis. This was done by comparing porcine bone strains obtained during axial loading of the implant with the results obtained for a typical press-fit implant. The obtained results can be indirectly related to the behaviour of human bone tissue during SLBE, as part of rehabilitation exercises carried out during the primary stabilisation.

When analysing the results, the author did not focus on direct comparison of the obtained values, as they depend, among others, on factors that are not clearly known in the study, such as mechanical properties of porcine bone tissue or the stiffness of the supports. Although some of them are described in relevant scientific articles (i.e., the mechanical properties of porcine bones), they depend on too many factors to make it possible to refer to the literature data [20]. For this reason, further analysis is based primarily on the interpretation of the strain distributions or the comparison of the obtained characteristics of the linear deformation. This was to identify load-bearing bone areas to estimate the possibility of obtaining stress-shielding effect.

In the case of the press-fit implant, the obtained maps present local strain concentrations in the central part of the analysed area, with no noticeable strain in the further part of the bone. This suggests that load is transferred along the entire length of the implant and its concentration in bone tissues occurs with the end of the stem of the structure. The obtained results for the press-fit implant are approximately confirmed by the results of numerical analyses carried by the author [27]–[29], as well as in the relevant lit-

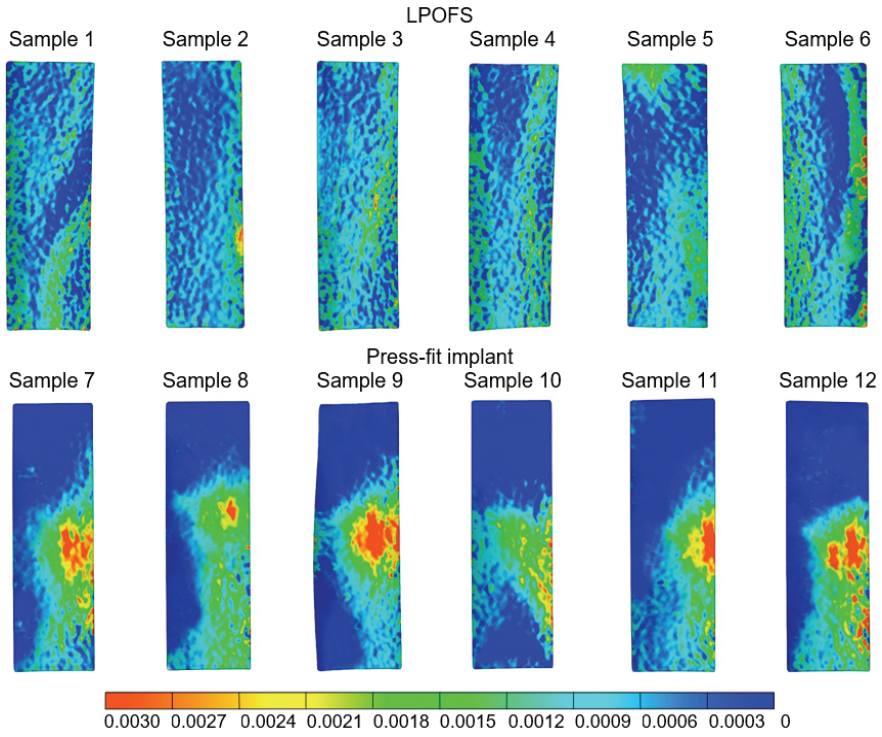

Fig. 9. Maps of strains (ln(mm/mm)) of the bone, created during axial loading of the analysed implants

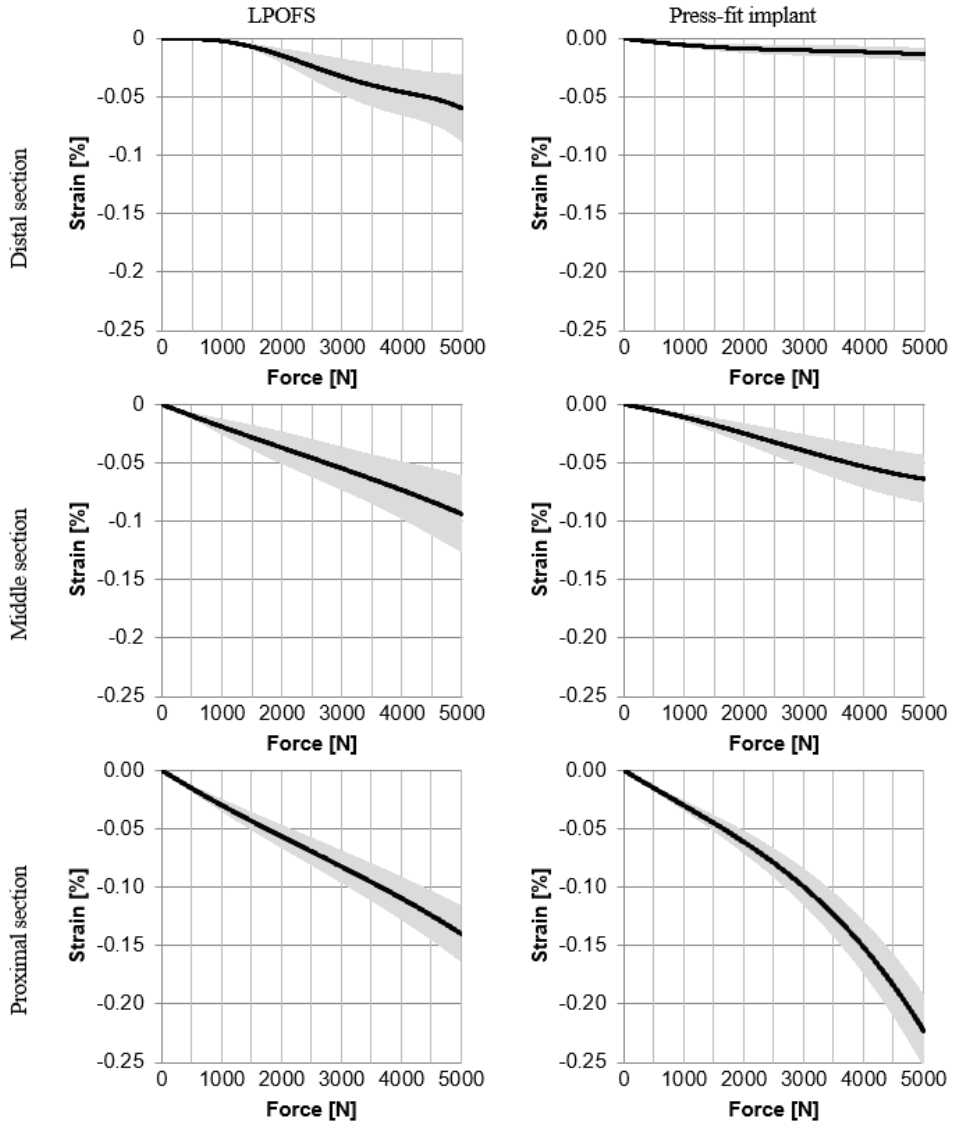

Fig. 10. The values of bone strains in the axial direction measured along the measurement sections

erature, which shows the transfer of loads by a rigid implant in relation to bone tissue and their local concentration in the bone, near the end of the structure stem [33]. In the case of the strain maps obtained for the proposed design, there are noticeable strains occurring in the entire examined area of the bone, with a stronger concentration towards the proximal direction. Moreover, they are characterised by a strong heterogeneity in relation to the strain obtained in the case of press-fit implant. This can be caused by the asymmetrical shape of the LPOFS, characterised by triple notched medullary part (Fig. 2a, element 2). Achieved strains over the entire analysed part of a bone could be also obtained by the use of material (PEEK GRF30) that is characterised by a relatively low stiffness in relation to bone tissues and which, during loading, can adapt to the medullary cavity, allowing the load to be transferred over the entire length of the bone shaft. The obtained data indicate greater functionality, in terms of the load transfer, of proposed design in comparison to a typical press-fit structure.

A relatively unequivocal comparison of the loads transferring method by the analysed structures was obtained in the case of a linear strain parallel to the bone axis, determined for defined sections that simulate the physical use of three extensometers. In the case of comparing the force-strain characteristics for the distal section, a significantly greater strain of the bone is noticeable in the case of loading the proposed design than the press-fit implant. Smaller disproportions can be observed in the case of the middle section, which again suggests a more correct load transfer through a discussed bone area at the time of loading the LPOFS. Greater strain in the case of using a press-fit implant is noticeable for the proximal part. All the

observed relationships obtained for the measuring sections approximately confirm the previously presented analysis of the obtained deformation maps. Moreover, an important feature is the relative linearity of the obtained characteristics, which confirms that performed analysis is within range of elastic deformation of bone tissues.

The applied axial loads of 5000 N should not occur in real conditions at the time of performing SLBE. However, the use of high-value axial forces was necessary for the effective observation of strain on bone surface. The obtained results directly show in which areas deformations in the bone shaft should be expected, so that, despite the applied forces, they should adequately allow for the comparison of the functionality of the analysed implants. It is possible due to obtaining the already described linear relationships that suggest observations in the elastic range of bone behaviour, which ultimately allows for the correct scaling of the results and relating them to the forces of smaller values.

The obtained relatively low strain values with the applied forces suggest that the bone transferred loads along its entire length. The femoral head, which is filled with spongy tissue with shock-absorbing features, widely described in the available literature, should definitely play a significant role. In addition, the force transmission was probably also affected by the resin used (constituting a support), which could also be subjected to deformation (but impossible to observe in the case of the measurement method used). It should also be remembered that although the strain may be relatively small in relation to the applied force, this strain is only noticeable on the surface of the samples. Tissues at the bone-implant interface were most likely characterised by far greater strain than the one observed on the surface.

Limiting the examined area only to a selected bone fragment does not allow to effectively assess the strain of the entire bone during axial loading of the implant placed in it. All these difficulties make the observation of changes on the outer surface of the bone particularly handicapped, despite the use of an advanced vision system. Nevertheless, the obtained strain maps or the results strain along the measurement sections may suggest potential bone areas that are not bearing load and which may be characterised by the presence of intense stress-shielding. As a result, despite the above-mentioned difficulties, an appropriate vision system may allow for the assessment of the functionality of the implant in terms of transferring loads from the implant to bone tissues during rehabilitation activities.

5. Conclusions

The conducted experimental verification of the proposed design enabled the researchers to roughly confirm its increased functionality in comparison with a typical press-fit structure, in terms of the load transferring efficiency. However, it should be emphasised that due to the applied limitations, the presented experiment does not allow for an unambiguous reflection of the conditions analysed in the previously described numerical studies. Nevertheless, the obtained data suggest that despite the simplifications taken into account, adapted methodology allowed to evaluate implants for bone-anchored prostheses.

Limitation of the study

The limitations of the experimental research are mainly due to the use of porcine femurs in the place of human bones, the use of which would raise ethical problems. Despite the general similarity in shape, the animal bones used are, compared to human bones, characterised by, e.g., other mechanical properties or other overall dimensions, which made it necessary to properly scale the analysed structures (which again had a decisive impact on the results). Other limitations, such as a relatively small number of bones, examination of dead bones after their previous storage in a cold store, or a simplified method of supporting the bones, result from the adopted method of analysis. Moreover, the applied vision measurement system limits the observations only to deformations of the outer surface of the bone, making it impossible to assess the load transfer in the bone tissues directly in contact with the implants. However, the applied limitations are applicable in practice, which is confirmed by the available literature. At the same time, it should be emphasized that the author has made a comparative analysis of the functionality of the analysed implants, taking into account the same conditions, which should effectively allow for their objective comparison with each other.

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Conflict of interest

The author declares that there is no conflict of interest regarding the presented study.

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