

New lumbar disc endoprosthesis applied to the patient's anatomic features

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Purpose: The paper describes the process of designing, manufacturing and design verification of the intervertebral of a new structure of lumbar disc endoprosthesis – INOP/LSP.1101. **Methods:** Modern and noninvasive medical imaging techniques, make it possible to record results of tests in a digital form, which creates opportunities for further processing. Mimics Innovation Suite software generates three-dimensional virtual models reflecting the real shape and measurements of components of L4-L5 spinal motion segment. With the use of 3D Print technique, physical models of bone structures of the mobile segment of the spine as well as the INOP/LSP.1101 endoprosthesis model were generated. A simplified FEA analysis of stresses in the endoprosthesis was performed to evaluate the designed geometries and materials of the new structure. **Results:** The endoprosthesis prototype was made of Co28Cr6Mo alloy with the use of selective laser technology. The prototypes were subject to tribological verification with the use of the SBT-03.1 spine simulator. **Conclusions:** The structure of the endoprosthesis ensures a full reflection of its kinematics, full range of mobility of the motion segment in all anatomical planes as well as restoration of a normal height of the intervertebral space and curvature of the lordosis.

The results of the tribological tests confirmed that SLM technology has the potential for production of the human bone and joint-endoprostheses.

Key words: custom design, degenerative disc disease, finite element analysis, medical imaging, total disc replacement, custom design, total disc replacement, selective laser melting (SLM), friction and wear tests

1. Introduction

Approximately 80% of adults suffer from back-aches at least once in their lifetime [1], [27], [33]. Low back pain is one of the most common problems in aging society and often it is connected within degenerative disc disease [1]. Mechanical loads and biochemical lesions occurring within the intervertebral disc cause gradual dehydration of the nucleus pulposus. The progressing disease results in a decrease of height of the intervertebral disc, worsening of its shock-absorbing properties, limitation of physiological mobility of the spinal motion segment and excessive load of intervertebral joints [31], [25]. Further development of the disease leads to a decrease of the spine canal cross-

section area [21]. A lumbar spine and, in particular, L4-L5 and L5-S1 [19] are most liable to be affected by degenerative lesions. At the height of those motion segments there is a center of gravity in the human body and the strongest compression forces affecting the components of the spine.

Intervertebral disc arthroplasty is alternative to spinal fusion [22]. This procedure involves a removal of the degenerated disc and replacement of it using an artificial disc. The aim of implantation of an artificial intervertebral disc is re-establishing of normal kinematics in operated spinal motion segment. Since the middle of the last century a lot of structures of endoprostheses of intervertebral discs have been developed [18]. The complexity of issues connected with implantation of artificial discs and, therefore, the struc-

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ture of the very endoprostheses, may be proved by the fact that presently there are several structural solutions admitted to clinical practice [13]. Examples of endoprostheses implanted in patients more or less successfully include: SB Charite III (Depuy, Johnson and Johnson), ProDisc-II (Synthes-Stratec), Maverick (Medtronic), Flexi-core (SpineCore) and Mobidisc (LDR Medical) [17]. In SB Charite III, ProDisc-II and Mobidisc friction surfaces create a “metal-on-polyethylene” articulation. Metal plates are made of Co–Cr–Mo alloys, whereas the plastic inserts are made of ultra high molecular weight polyethylene (UHMWPE). SB Charite III differs from other structures in that the insert is not connected with metal plates. This enables translational movements of the cup in all directions. The polymer insert in ProDisc-II is put in a special seat in the bottom plate. However, the insert can move forwards and backwards in relation to the bottom plate [14]. In the Mobidisc endoprosthesis the polymer insert can move in all directions on the transverse plane, however its movements are limited by four external limiters equipped with a bottom plate [16].

Because of osteolysis related to polyethylene wear debris and the need to operate even younger patients, activities have been undertaken aimed at development of a structure of endoprosthesis that could form a “metal-on-metal” type of articulation [15], [30]. Endoprostheses which use the “metal-on-metal” include Maverick and Flexi-core. Components of both endoprostheses are made of Co–Cr–Mo alloys. The difference in the convexity radii in the bottom plate in relation to the concavity of the top plate in Maverick ensures translational mobility during bowing or hyperextension. What makes Flexi-core different is that on surfaces of external components characteristic bulges are made. The convexities are to ensure more stable seating of the implant in the intervertebral space [29].

Requirements for metallic biomaterials prompted researchers around the world to develop new alloys and methods of modifying the properties of materials already applied. This gives the chance to include the use of additive manufacturing technology (Rapid Manufacturing, RM). There is currently an increased interest in generation of metal implants, using the selective laser melting technology (SLM). The use of high power laser technology provides complete melting of the powder and allows materials to be obtained with density comparable to a solid counterparts [11]. The advantage of RM is no doubt that the process of generating three-dimensional structures is carried out based on computer data, CAD (Computer Aided De-

sign). De Beer et al. [8] found that by proper selection of the shape and size of the intervertebral disc prosthesis has a beneficial effect on reducing the risk of both vertebral fracture and risk of collapse of the components of the endoprosthesis into them.

The aim of this paper was to present methodology of designing, manufacturing as well as design verification of the intervertebral of a new structure of lumbar disc endoprosthesis – INOP/LSP.1101. The process of construction [5], [31] required using Computer-Aided Systems (CAD), Computer-Aided Manufacturing (CAM) and Computer-Aided Engineering (CAE) with the use of the simplified Finite-Element Analysis (FEA) for verification of the geometry, strength of material and tribological effects. What distinguishes the INOP/LSP.1101 endoprosthesis is that all the components of the endoprosthesis were made of Co28Cr6Mo alloy, using the SLM technology. The design of the prosthesis provides a complete representation of the kinematics, the normal range of mobility in all anatomical planes. Because the virtual model of the INOP endoprosthesis is parametric, it is possible to modify the dimensions of the individual components and to better fit to the spine intervertebral spaces (custom design).

2. Materials and methods

With the use of specialist Mimics software (Materialise, Belgium) three-dimensional virtual models of bone structures of the L4-L5 motion segment were generated. Input data for spatial modeling of bone structures of the spine included files recorded in DICOM (Digital Imaging and Communication in Medicine). The generated three-dimensional virtual models were used for determination of the anatomical geometrical features of the intervertebral bodies and space. The structure of the intervertebral disc endoprosthesis with features reflecting anatomy of bone tissues of the spine was made with the use of PRO/Engineer software (Parametric Technology Corporation, USA).

In order to verify the suggested structure of the endoprosthesis with respect to selection of geometrical and ergonomic features, a physical model was generated of the endoprosthesis placed in the intervertebral space. For this purpose a standard ZPrinter[®] 650 (ZCorporation, USA) was applied.

A simplified FEM models of L4-L5 motion segment was prepared and the FEM analysis of stress distribution in the endoprosthesis was made

with the use of ADINA system (Adina R & D, Inc., USA). Both the bone tissue and the endoprosthesis material were initially simulated as a pliable isotropic material. The soft tissue, process and articular surfaces were not considered here. The load was applied to the upper surface of the L4 vertebra and amounted to 1.3 MPa, which corresponds to the life size $F = 1200$ N. Initial Young's moduli for Co28Cr6Mo of 200 GPa and bone 12 GPa were used. Poisson's ratio for both materials was 0.3. The calculation model of the system of the endoprosthesis loaded by simplified models of the L4 and L5 vertebrae is shown in Fig. 1.

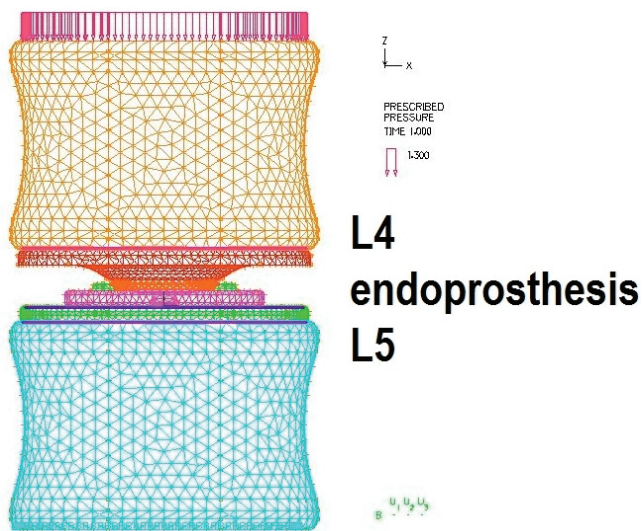


Fig. 1. The model of the INOP/LSP.1101 endoprosthesis with simplified models of the L4 and L5 vertebrae body

The structures of the INOP/LSP.1101 prototype were made from Sandvik Osprey Co28Cr6Mo (ASTM F75) alloy powder with the grain diameter of 20–60 μm using selective laser melting technology (SLM). An SLM[®]250HL (SLM-Solutions GmbH, Germany) equipment was used for this purpose. The

thickness of the layer of powder spread was 30 μm . The melting laser wavelength was 1070 nm with the spot diameter of 200 μm . The speed of scanning, i.e., radiation of the powder with laser beam, was 685 mm/s.

Wear and friction tests were performed with the use of SBT-03.1 spine simulator [Patent application No. P.399070]. The device is equipped with two servomotors installed that enable simulation of the two basic movements of the spine: bending in the sagittal or frontal plane and axial twisting with ultrapure distilled water lubrication [28]. The most important test parameters are presented in Table 1.

Table 1. Work parameters of SBT-03.1 simulator

Parameter	Value
number of cycles	1 000 000
frequency	1.25 Hz
range of motion:	
• flexion / extension	+8°/–5°
• axial rotation	± 3°
max. load	1 500 N
lubrication	ultrapure distilled water
temperature	21±23 °C
mode	uninterrupted

Weight measurements (before and after the tribological tests) were performed with the use of R200D (Sartorius, Germany) laboratory scales with the accuracy of 0.1 mg.

3. Results

The INOP/LSP.1101 lumbar disc endoprosthesis is made of three elements. The individual components include a top plate, a bottom plate and an insert (Fig. 2).

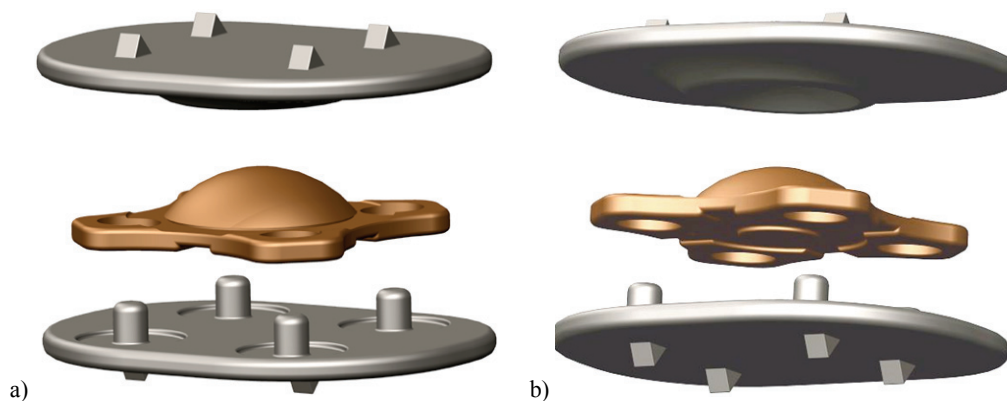


Fig. 2. The INOP/LSP.1101 endoprosthesis – components: (a) anteverted, (b) retroverted

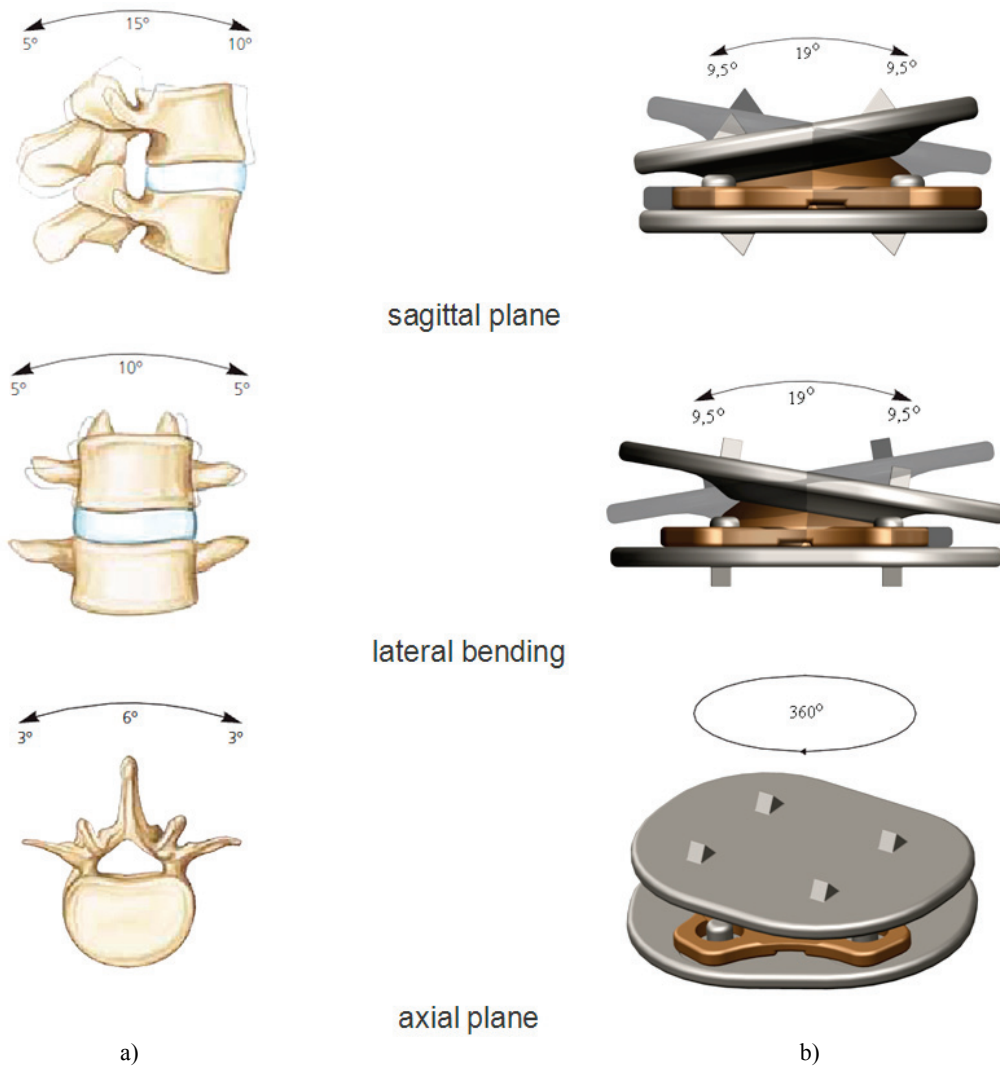


Fig. 3. Comparison of the range of movements in three anatomical planes: (a) for L4-L5 (<http://www.synthes.com>), (b) INOP/LSP.1101 intervertebral disc endoprosthesis

Both plates are characterized by elliptical shapes with no sharp edges. The specially profiled working surface of the top plate (on the side of the insert) ensures an appropriate range of movements for the endoprosthesis and, at the same time, protects the endoprosthesis against dislocation. The working surface of the bottom plate on the side of the insert was equipped with four symmetrically spaced fixing bolts with the diameter of holes located in the flange of the insert. This allows smooth translational movements of the insert and ensures variability of rotating axis location during work and, consequently, better reflection of kinematics of the natural intervertebral disc. The heights of the bolts were selected not to limit the anatomical mobility of the operated mobile segment (Fig. 3).

The INOP/LSP.1101 was equipped, on the side of the bottom plate, with a specially grooved system of small canals with their shape resembling a “roundabout” (Fig. 4). This solution increases smooth-

ness of flow through the bodily fluid friction loop creating a thin lubricating film as well as ensures effective evacuation of wear and tear products that initiate the phenomenon of secondary wear and tear.



Fig. 4. INOP/LSP.1101 insert as seen from the side of the bottom plate – the system of small canals

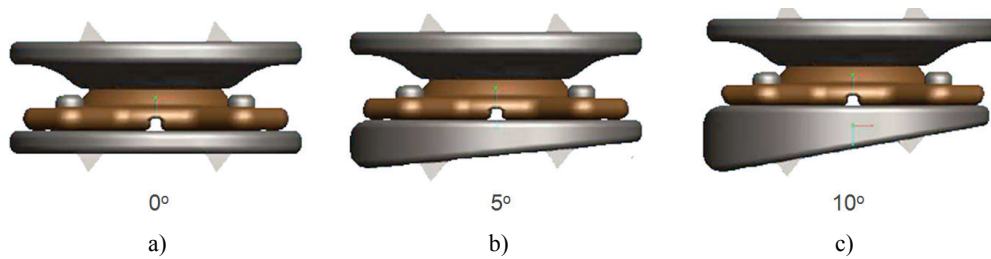


Fig. 5. The INOP/LSP.1101 endoprosthesis as seen from the side, angle of the lordosis: (a) 0°, (b) 5°, (c) 10°

In order to reconstruct the correct curvature of the lordosis one should select an endoprosthesis with its bottom plate characterized by appropriate geometry. If the angle of the lordosis is greater than 0°, the height of the bottom plate is uneven. Moving forwards on the sagittal plane, the height of the bottom plate increases. Examples of INOP/LSP.1101 with its bottom plate characterized by a different angle of the lordosis are presented in Fig. 5.

The external surfaces of the top and bottom plates having a direct contact with the bone tissue of the vertebral bodies were equipped with four symmetrically spaced needle fixations. The fixations ensure short-term permanent seating of the endoprosthesis in the intervertebral space. In order to ensure long-term stable seating for the endoprosthesis, the external surfaces of the plates were coated with a layer of hydroxyapatite (HA) or titanium (Ti) through plasma spraying. The chemical composition and appropriate porosity of coats ensure effective progress of the process of osteointegration of the endoprosthesis and bone tissue of the vertebral bodies.

The INOP/LSP.1101 virtual model of the endoprosthesis is a parametrical model. Thus, it is possible to modify individual dimensions of the model. Such a solution allows quick changes in the structure and adjustment of the endoprosthesis to the geometry of the intervertebral space of a patient's motion segment (custom design). Characteristic dimensions that are subject to modification include the length and width of the plates, total height of the endoprosthesis adjusted by the height of the insert and angle of the curvature of the lordosis. Unfortunately, modification of the structure increases the costs of delivery of the endoprosthesis. A change of values of some parameters may also directly affect the range of movements of the endoprosthesis and, therefore, the measurements of individual components cannot be changed freely. Each change of measurements has to be verified.

The physical model of the INOP/LSP.1101 endoprosthesis seated within the L4-L5 intervertebral space generated with the use of 3DP technology is presented in Fig. 6.



Fig. 6. 3DP model of L4-L5 spinal motion segment with the INOP/LSP.1101 endoprosthesis placed in the intervertebral space

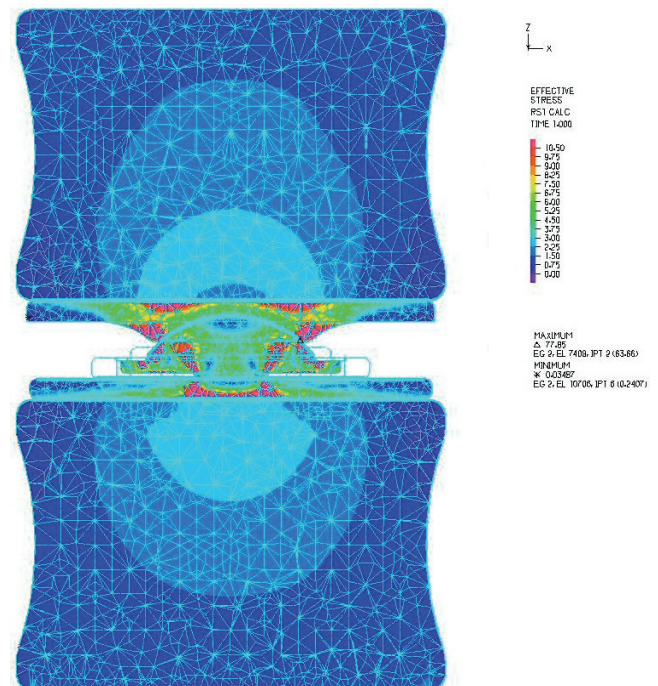


Fig. 7. Distribution of stresses in the x-z plane of the segment model

The load in the analyzed segment is transferred from the L4 to the L5 vertebra through the spherical cup of the endoprosthesis insert (Fig. 7). The cup causes a concentration of stresses in the medial part of the surface of the L4 and L5 vertebrae cooperating with the surfaces of the endoprosthesis plates.

The spherical cup of the top plate of the endoprosthesis transfers the stresses circumferentially (along the circle) onto the spherical cup of the endoprosthesis insert (the internal contour of the circle visible in Fig. 8a). It can be concluded that when loading the endoprosthesis the circumferential stress is distributed on the surface of the insert cup causing wear (see Fig. 8b showing the insert following other tests). On the part of the cup subject to small loads of the range of 6÷12 MPa (Fig. 8a) no visible scratches of wear traces were observed. This seems to indicate here that simplified FEM model may be sufficiently accepted in the CT/CAD/CAE/CAM methodology.

The bottom surface of the endoprosthesis insert is considerably loaded locally on the edges of small canals of the “roundabout”, i.e., up to 70 MPa. There are also visible signs of wear on the bottom surface (see Fig. 9b), which corresponds to zones of increased stress (see Fig. 9a). The increased stresses result from the fact that the surface of contact of the endoprosthesis insert with the bottom plate is decreased by technological grooves in the bottom plate near the bolts limiting the movements of the endoprosthesis insert. The distributions of stresses in the bottom and top plate are shown in Figs. 10 and 11, respectively.

A successful FAE and 3DP verification of the structure of the INOP/LSP.1101 endoprosthesis as regards its functionality and geometrical adjustment to bone structures allowed us to create a prototype of the endoprosthesis with the use of SLM technology (Fig. 12).

Afterward the endoprostheses were subjected to tribological tests. The friction coefficient values for the endoprostheses tested were on a comparable

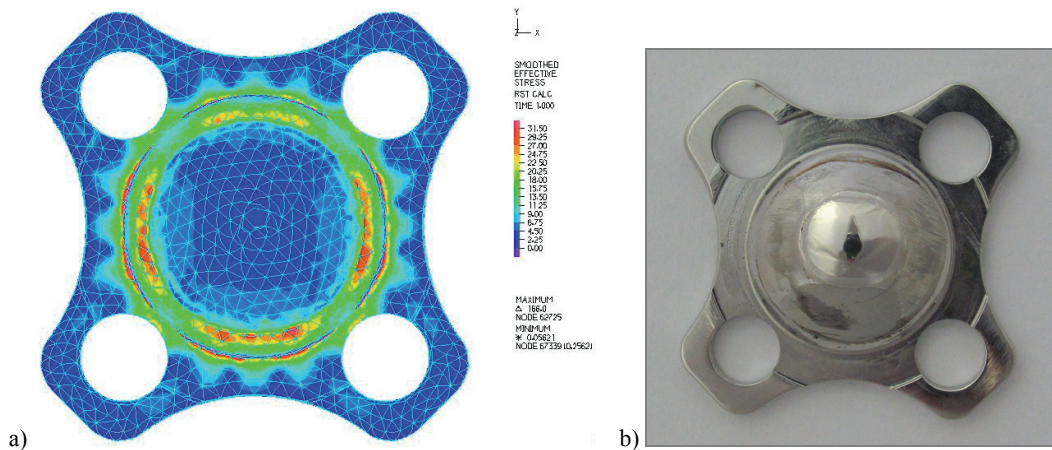


Fig. 8. Distribution of stresses: (a) in the endoprosthesis insert (view from the top), (b) analogical view of the endoprosthesis insert following the tribological tests with the use of the SBT.03.01 simulator

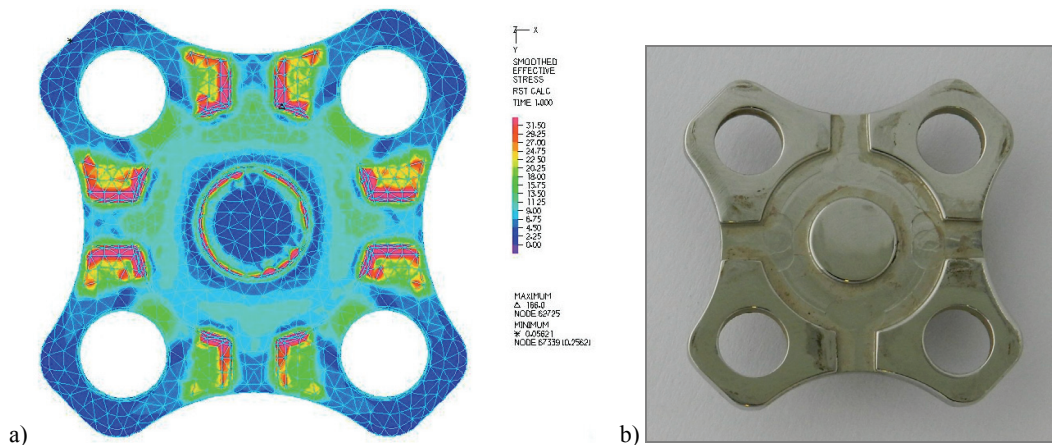


Fig. 9. Distribution of stresses: (a) in the endoprosthesis insert (view from the bottom), (b) analogical view of the endoprosthesis insert following the tribological tests with the use of the SBT.03.01 simulator

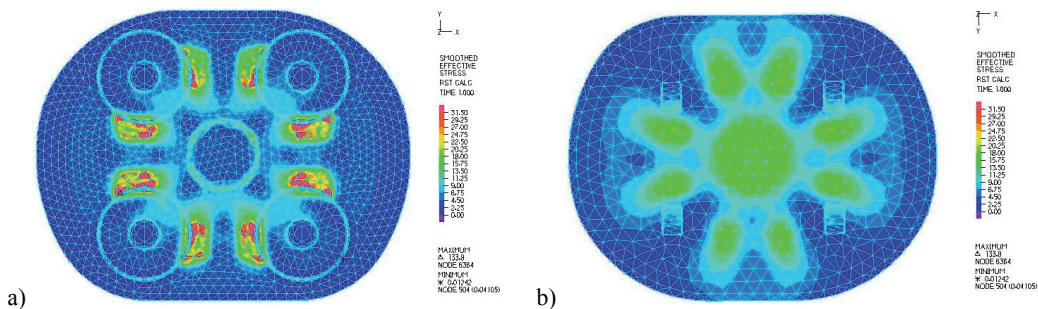


Fig. 10. Distribution of stresses in the bottom plate of the endoprosthesis: (a) view from the top, (b) view from the bottom

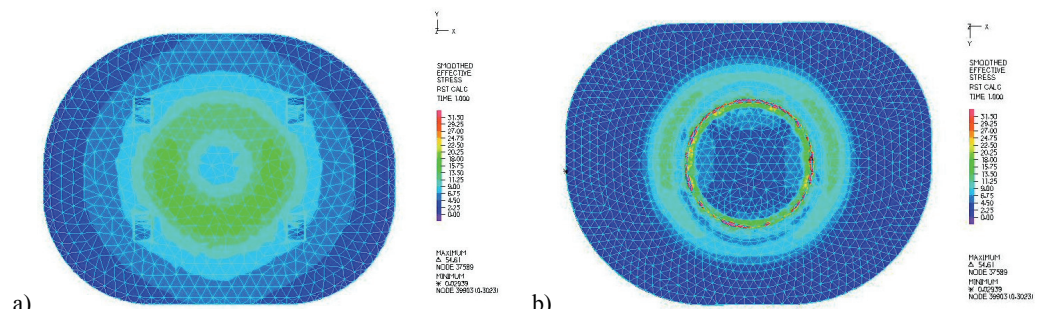


Fig. 11. Distribution of stresses in the top plate of the endoprosthesis: (a) view from the top, (b) view from the bottom

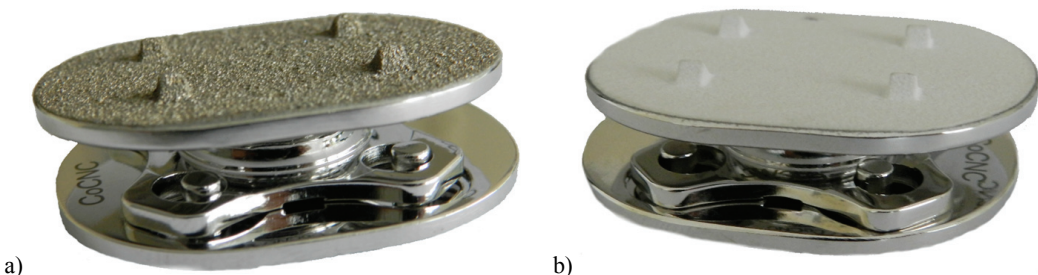


Fig. 12. The prototype of the INOP/LSP.110 endoprosthesis: (a) plates with Ti coat, (b) plates with HA coat

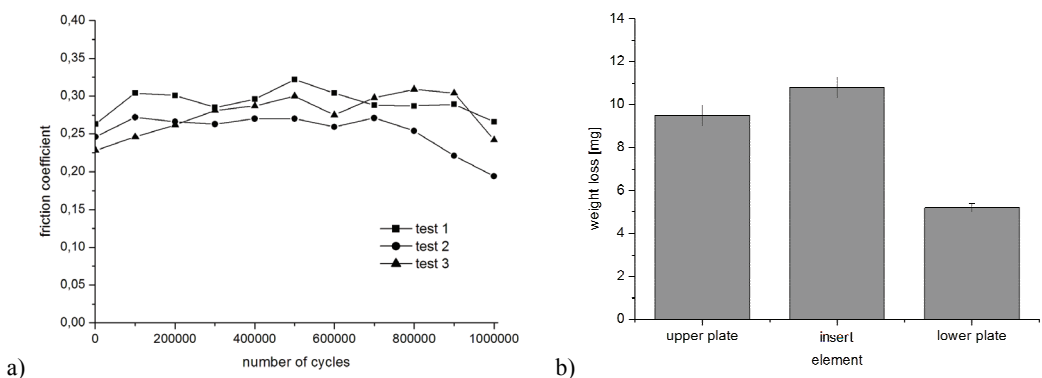


Fig. 13. Tribological tests results: (a) friction coefficient against number of cycles, (b) weight loss for different elements

level and they fell within the range from 0.25 to 0.30 (Fig 13a). In the final stage of the tests we observed that the value of the friction coefficient decreased to the range from 0.20 to 0.25.

The average weight loss values for the individual elements of the endoprosthesis presented in Fig.13b. The results of the measurements indicate that the inserts were exposed to the greatest weight loss.

4. Discussion

Alf Nechmson, a Swedish scientist, today considered as a pioneer of intervertebral disc arthroplasty, was the first to attempt at replacing the nucleus pulposus with an artificial material. His research was limited to load tests on post-mortem specimens. The research initiated by Nechmson inspired other researchers to undertake their own investigations [4], [23].

At the turn of the 1950s and 1960s, Fenström performed the first implantation in a group of patients suffering from a degenerative disc disease. The implant had a form of a metal ball inserted in the intervertebral space to replace the previously removed nucleus pulposus [3], [4]. In the second half of the 1970s, Fassio designed and patented a structure made of a silicon insert placed in a polyurethane horseshoe-shaped insert [2]. The contact surfaces of the implant were very limited, which caused a concentration of high stress at the contact points with the bony tissue of vertebral bodies. Additionally, the failure to match mechanical properties of the applied materials led to the sinking of the implants into the vertebral bodies [2], [4].

In 1982, a group of German surgeons, based on their experience of hip and knee joint arthroplasty, designed an endoprosthesis operating similarly to an articulated joint. The structure of SB Charite I endoprosthesis was made of a polymer insert limited with metal plates at the top and bottom. After the first clinical tests it turned out that also in this case the contact surface between the endoprosthesis and vertebral bodies was insufficient. A modification of the geometry of the metal plates involving an extension of their sideways eliminated the problem. Unfortunately, the materials used in SB Charite and SB Charite II showed insufficient fatigue strength [4]. The above-mentioned problems as well as confirmed satisfactory tribological properties of the new materials used for hip endoprosthesis elements led to another modification of the structure in 1987. Metal components in SB Charite III are still made of CoCrMo alloy while the polymer insert is made of UHMWPE [12].

In 2003, the Maverick endoprosthesis was implanted for the first time [33]. What distinguishes the structure of the endoprosthesis from the pioneer ones was the fact that the friction components constituted a MoM type tribological system. The MoM type material despite its lower sensitivity to wear is not devoid of defects. The wear products of nanometric value generated as a result of friction may be transported by the body system fluids and then penetrate the tissues. The initiation of corrosive processes enhances the

increase of the concentration of metal ions in the organism [9].

The treatment of a spine degeneration disease is one of contemporary medicine interdisciplinary problems. Home scientists have also their contribution to the development of the sciences connected with an implantation of artificial discs. The authors of the work [24] undertook interesting research on the description of the influence of an intervertebral disc degeneration disease development on the chosen mechanical properties of anulus fibrosus; whereas the authors in the paper [29] took up the issues connected with FEM numerical simulations of a movable section. The advanced works on the creation of a new construction of disc prosthesis were jointly conducted by the researchers, e.g., see paper [6].

Despite the undisputed progress in the advancement of medical and technical sciences, designers of endoprostheses still encounter a variety of problems. The present research in the design of new structures of intervertebral disc endoprostheses is conducted in three directions. Firstly, a limited resistance to wear, susceptibility to corrosive processes and tribological-chemical reactions in the case of biocompatible metal alloys forces researchers to search for new materials or to modify the existing microstructures. The second direction of research involves a development of new biocompatible materials of flexible properties. The materials may be used in, as we call it, mono-block endoprostheses. The materials are distinguished by the use of elastomeric seals [25] that connect the external plates and tightly insulate the tribological endoprosthesis system from the environment. This allows a greater flexibility of the implant and limits the risk of growth of the bony tissue into the friction loop and, at the same time, protects the system against migration of wear products to the peri-implant tissues. Mono-block endoprostheses of the lumbar spine are successfully used in clinical practice. A perfect example of these are LP-ESP (FH Orthopaedics) and M6-L (Spinal Kinetics) [27]. The third and the last direction in the development of intervertebral disc endoprostheses involves works on the development of structures adjusted to anatomical features of a mobile segment of an individual patient. The work results show [8] the influence of the adjustment of metal plates to the geometry of intervertebral bodies on the stability of the seating of the plates and an increase of the risk of sinking of the same into the bodies. This trend is perfectly manifested in research undertaken by the authors of this paper.

Before the commencement of designing, a database for CT and MRI was prepared for patients quali-

fied for total lumbar disc endoprosthesis. Owing to the use of a specialist software characteristic measurements of anatomical features of the vertebrae and intervertebral discs were prepared on the basis of clinical cases collected in the database.

The use of 3DP technology in generating a physical model of endoprosthesis placed in the intervertebral space of the bony structures of the L4 and L5 vertebrae allowed verification of the suggested structure of the endoprosthesis as regards the selection of its geometrical and ergonomic features.

The structure of the endoprosthesis ensures a full reflection of its kinematics, full range of mobility of the segment in all anatomical planes as well as restoration of a normal height of the intervertebral space and curvature of the lordosis. A provision of special needle fixation on the external surfaces of the bottom and top plates and, additionally, coating of the entire external surfaces with a layer of porous material (HA or Ti) with osteointegrative properties guarantee a short and long-term stable seating of the endoprosthesis.

We realize that to analyze real segment of the spine advanced FEM models are used [29]. The aim of the work was not to present a new FEA model of the spinal motion segment, but an estimate of the burden of the proposed design of the prosthesis to adopt tribological pairs and load conditions. For this purpose, one needs adequate modeling of elastic substrate, which is running and through which the prosthesis is loaded.

Simplified numerical analyses were conducted, with the aim to determine the influence of the selection of material combination on reduced stress distribution in the particular endoprosthesis components.

The tribological test results indicate that friction coefficient values occurring in tribological systems of the tested endoprostheses are comparable to available commercial MoM designs. In similar conditions (frequency: 1 Hz, bearing load 1500 N, ball radius 13 mm), friction coefficient for MoM articulation is in the range between 0.20 and 0.30 [7], [21].

As compared to other components, the inserts had two friction surfaces. The bottom plates were characterized by lower wear as compared to the top plates. This may be explained by the fact that the top plates participated in the movements in the sagittal plane as well as in the torsion movement. However, the bottom plates participated in the translation movements of the insert only.

The presented test results are one of the first that relate to tribological properties of IVD endoprostheses made of CoCrMo alloy with the use of the SLM technology. The tests were conducted under the conditions of real loads occurring in the natural L4-L5 motion segment. Undoubtedly, owing to its advantages, the

SLM technology has the potential for production of the human bone and joint system endoprostheses. This is particularly visible in the production of custom design endoprostheses [8].

Summing up, the originality of the INOP/LSP.1101 design is characterized by: geometry (parametrical model – easy to change dimensions for better fitting to intervertebral space), functionality (translational movements of the insert – six degrees of freedom), materials (alternative technology for metal powder consolidation). The results of the tribological tests performed with the use of the SBT.03. 1. simulator confirmed the correctness of the results obtained from the FEA. The design of the INOP/LSP.1101 intervertebral disc endoprosthesis is an invention No. P.397825.

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