JOURNAL OF THEORETICAL
AND APPLIED MECHANICS
42, 2, pp. 253-268, Warsaw 2004

NUMERICAL INVESTIGATION OF A NEW TYPE OF ARTIFICIAL LUMBAR DISC

Paweł Borkowski
Krzysztof Kędzior
Grzegorz Krzesiński
Konstanty R. Skalski
Paweł Wymysłowski
Tomasz Zagrajek

Institute of Aeronautics and Applied Mechanics, Warsaw University of Technology
e-mail: kkedzior@meil.pw.edu.pl

The replacement of a damaged lumbar disc by an artificial organ is still not satisfactorily solved problem of surgery. In the study, the finite element method together with CAD programs and experimental validation was used in investigations of a new type of artificial disc for lumbar spine. The presented 3D parametrical FE models take into account nonhomogenous properties of tissues, contact with friction between the parts of the analysed systems, large strains and large displacements. The stress analyses were performed for the prostheses being in clinical use and for some new designs. The conclusions concern most important determinants of the mechanical quality of the intervertebral disc prosthesis.

Key words: spine biomechanics, implants, FEM, disc prosthesis

1. Introduction

Spine is one of the most important and most complex subjects of biomechanics (Będziński, 1997). About 80% people experience back pain at least once in their lifetime, and for many of them spinal disorders and especially the low back disorders are a real problem. The lower part of spine, so called lumbar spine, consists of 5 vertebrae, named L_1 to L_5, connected by the intervertebral discs. The lumbar segment joints the upper body with the pelvis and have a great influence on the mobility and strength of human body. The spine column is a very complex structure which consists of vertebrae, intervertebral discs, ligaments, muscles and spinal cord (Fig. 1). The vertebral bone is mainly the orthotropic trabecular bone tissue surrounded by the cortical shell (White and Panjabi, 1990).

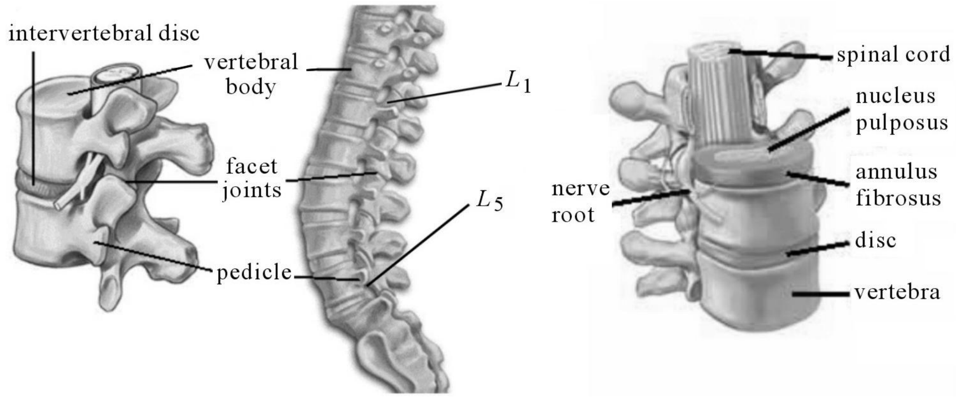


Fig. 1. Anatomy of the lumbar spine

Each disc is composed of three different tissues:

- Annulus – a strong fibrous ligament surrounding the disc.
- Nucleus – a liquid middle, surrounded by the annulus. The internal hydrostatic pressure within the nucleus helps to transfer compression loads in a proper way.
- Endplates – cartilage structures which attach the disc to the vertebral bodies.

Non-surgical treatment for people with neck and back pain caused by disc disorders includes rest, heat, pain medications, chiropractic manipulation and physical therapy. Unfortunately, these treatments fail in a significant number of patients. In the cases when such the treatment fails, surgery is the next possible solution. This usually means spinal fusion surgery. Unfortunately, there are a number of drawbacks to undergoing a spinal fusion. The vertebral bodies often do not fuse well and the fusion itself causes increased stiffness and decreased mobility of the spine. In result, the stresses increase above and below the modified segment. This may cause new problems but in another parts of the spine column. Since the 1960s, when artificial hips and knees were introduced into clinical practice, many surgeons have believed that the artificial disc may improve the results of surgical treatment for many types of back pain (Lemaire *et al.*, 2000; Szpalski *et al.*, 2002).

One of the major advantages of the artificial disc is to preserve the mobility of the adjacent vertebrae. There are, in general, two types of artificial discs in practical use: the nuclear prosthesis – designed to replace only the soft inner core of a disc and the total disc prosthesis – designed to replace a full disc (annulus, nucleus and endplates). The advantage of replacing the entire disc is that the patient may avoid degeneration of the annulus over time. Artificial discs have been in clinical use in Europe for more than 10 years. The most popular are the SB Charite manufactured by Waldemar Link Company and the ProDisc from Aesculap/Spine Solutions. In the USA the total disc arthroplasty is still considered as an experimental technique.

Both, the ProDisc and Charite prostheses (Fig. 2), consist of two metal endplates and the middle made of polyethylene. They have a little different mobility in the frontal plane and saggital plane.

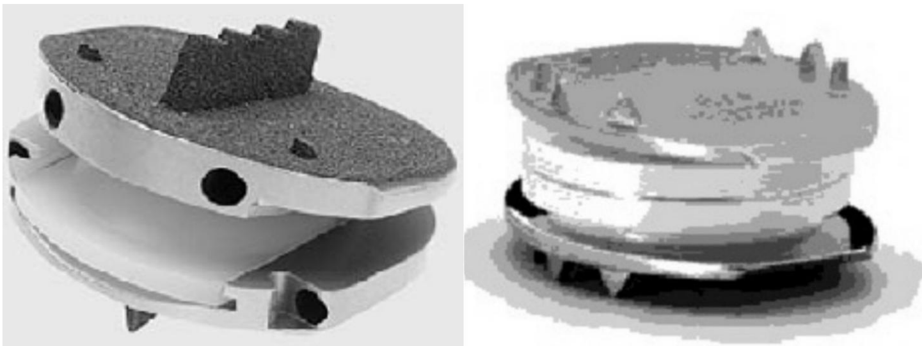


Fig. 2. Total disc prostheses: (a) ProDisc (Waldemar Link) and (b) Charite III (Aesculap)

The rotation about the vertical axis is free and is limited only by the surrounding structures, i.e. ligaments and muscles. The stability is ensured in the case of Charite prosthesis by the teeth-like spikes and in the case of ProDisc by the spikes and the large keel.

There are other devices currently in development, some of them patented (Szpalski *et al.*, 2002). These include devices to replace the nucleus as well as the facet joints. Theoretical and experimental investigations are currently conducted to make a progress in the subject (Pezowicz, 2003).

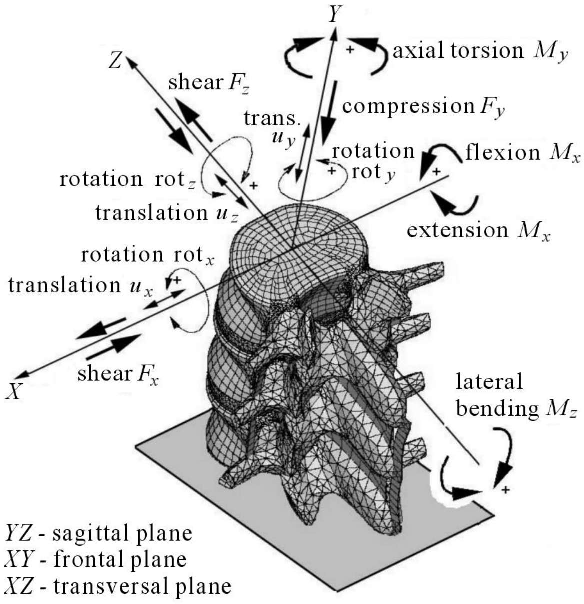
The best way to estimate the quality of a new design is to perform the finite element stress and strain analysis for the model of a structure consisting of the spine segment and the prosthesis. The quality of the implant behaviour depends greatly on the strength of the endoprosthesis and its fixation (Krzesiński, 2003). The failure reasons of the biomechanical implant-living tissues systems are rather complex and are believed to be connected with the non-uniform stress distribution within the bone-implant system. Numerical simulation techniques of bone-implant systems mechanical behaviour can reduce the number of animal experiments and clinical investigations in the process of new implants design. In comparison to experimental techniques they offer great advantages. They enable the same bone model to be used for different devices and make it possible to analyse the influence of different device parameters on the load transfer and stress distribution (Dietrich *et al.*, 1999b). In experimental models, the adequate representation of biological tissues may be, for many reasons, difficult.

The finite element method (FEM) is nowadays the most popular and commonly used tool for strain and stress analysis of engineering structures. The method became widely known in biomechanics. FE computer programs and systems are of general nature and proved to be very useful in building even complex models of living tissue structures. FEM helps also to get information concerning different aspects of spine biomechanics (Dietrich *et al.*, 1991; Kędzior *et al.*, 1996; Skalli, 1999).

2. Mechanical factors determining the quality of total disc replacement

It is usually assumed that the goal of the artificial disc replacement is to replicate the normal motion of the disc in the spine. There are various factors designers must keep in mind as they develop an artificial disc (Bertagnoli and Kumar, 2002). The device should maintain the proper intervertebral spacing, allow for the full range of motion keeping the same axes of rotations and provide the required stability. It has to be made up of parts securely attached to each other in order to facilitate the insertion during the surgical procedure and minimize the possibility of spinal cord injury. The prosthesis must act as a shock absorber and should be very durable. Because the average age of a patient undergoing the disc replacement is about 40 years the strength of the prosthesis must be perfect to avoid the necessity for revision surgery. It must be made of materials that are safe to be implanted in the human body and do not cause allergic reactions. The interaction between the implant and the living tissues should not cause the strong stress concentration in other parts of the spine either. It would be helpful for the surgeons if the artificial disc was made of a material that may be seen using x-ray or other imaging techniques.

In the present study it has been assumed that the disc prosthesis should work in the same way and undergo similar mechanical conditions as the natural disc in healthy spine. Some of the figures presenting these conditions, collected from the literature are presented in Fig. 3.



Loads considered, mobility	
compression	F_y=3000 N
shear	F_z=300 N
shear	F_x=300 N
extension/flexion	M_x=12 Nm
rot_x range: (-5°,+10°)	
lateral bending	M_z=8 Nm
rot_z range: (-7.5°,+7.5°)	
axial torsion	M_y=3.1 Nm
rot_y range: (-2°,+2°)	

Fig. 3. Some of the parameters defining mechanical requirements for the total disc prosthesis

3. FE modeling of the total disc prosthesis-spine segment interaction

The natural intervertebral disc and different designs of the disc prosthesis were examined by performing the stress and strain analysis using finite element method and ANSYS system. Creating the accurate FE model is usually a laborious and time-consuming task. This may be overcome by parametric FEM modelling, recently often used – with different approaches to the problem, by engineers (Whyne *et al.*, 2001; Dietrich *et al.*, 2002, 2003).

In a parametric model many different possible shapes should be taken into account with a limited number of parameters. After a modification of the parameters representing, e.g. geometrical and material properties of the considered object, one can obtain a new model in a relatively short time. Despite many advantages, the parametric model reveals also some drawbacks. The creation of such a FE model is more difficult than in the case of a non-parametric one. Therefore, it is reasonable to do this only in the case when the model will be used many times. In this study, an attempt was made at creating a FE model of a lumbar spine segment and then a more detailed model of two vertebrae motion segment with an artificial disc. Both the vertebrae and the intervertebral disc are described parametrically. Such a model may be helpful in the cases when we deal with the problem of a new design or with the prosthesis of the custom-made type.

In the model, the co-ordinates of characteristic points are assumed to be parameters representing the shape of the bones. A special attention was focused on the accurate representation of a vertebral body. The coordinates of 70 points in 3D space have been used in the description of its shape. A relatively high number of the points allows for accurate representation of the curvatures of upper and bottom vertebrae surfaces, which is important since those surfaces may contact with an artificial intervertebral disc. The shapes of other vertebral parts were described in a simplified way.

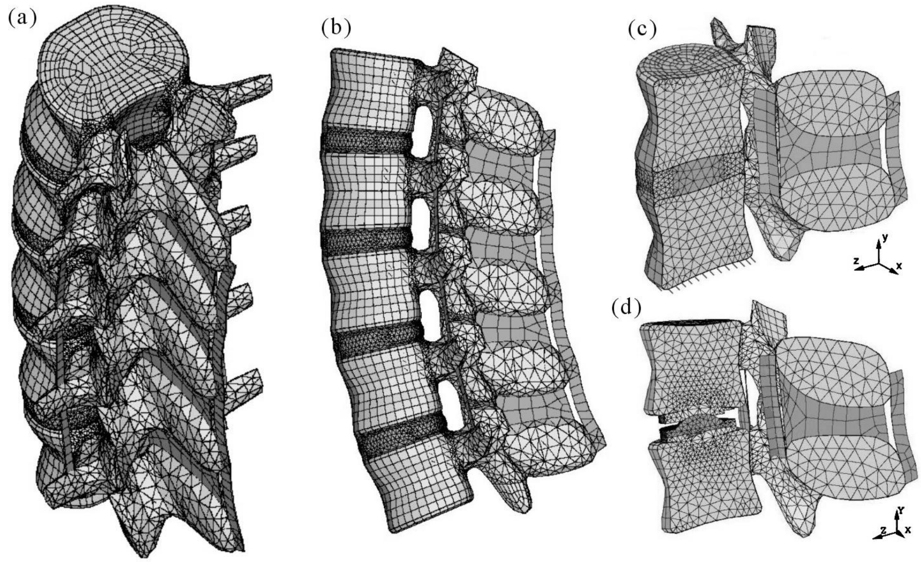


Fig. 4. Finite element model of a spine segment: (a) FE mesh, general view, (b) cross-section in the sagittal plane, (c) cross-section of the motion segment with a natural disc, (d) cross-section of the motion segment with an artificial disc

The points were used to create 3D spline curves over which the surfaces defining the solids were spanned. Those solids were divided into 3D solid finite elements, which represent the region of the spongy bone. The external vertebral surfaces were divided into shell finite elements, which represent the cortical bone. The shell thickness of particular shell elements corresponding to the cortical shell may differ depending on the position and serve also as parameters of the numerical model. The division into the finite elements is performed automatically with a mesh density required by the user. In the similar way, the FE model of an artificial disc is built. An example of such a FEM model is presented in Fig. 4. The standard material properties used in numerical analyses are presented in Table 1. In some cases, orthotropic mechanical properties of the bone tissues were taken into account. Due to the complexity of modeling according to such assumptions and the small influence on the obtained results, the isotropic models of cortical and trabecular tissues were used as the standard in comparative analyses.

Table 1. Material properties used in the comparative analyses

Material	Young modulus E [MPa]	Thickness δ [mm]	Poisson's ratio ν
Cortical shell	12000	1.5	0.3
Cancellous core	100	–	0.4
Nucleus	0.012	–	0.499
Annulus	10	–	0.35
Ligaments	10	2	0.3
Polyethylene	1200	–	0.35
Co-Cr alloy	210000	–	0.3

The main goal of the analyses was the estimation of stresses within the bones and the implant. The design of the intervertebral disc should secure a relatively uniform stress distribution within the bone tissue to enable the proper bone reconstruction processes. The stresses within the implant parts have to remain below the assumed limits.

4. Finite element analyses of the prostheses in clinical use

First analyses were carried out for the ProDisc and Charite III prostheses. Their FEM models are presented in Fig. 5 and Fig. 6, respectively.

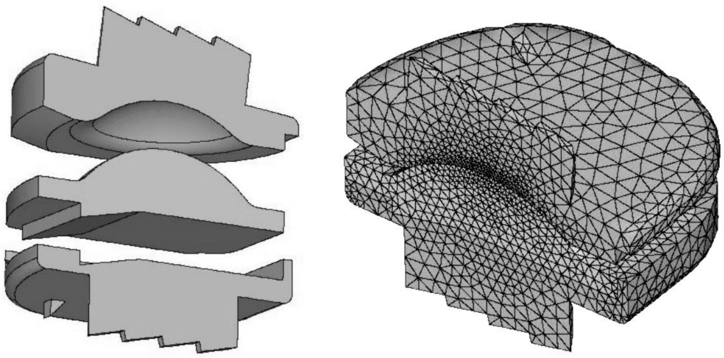


Fig. 5. FE model of the ProDisc prosthesis

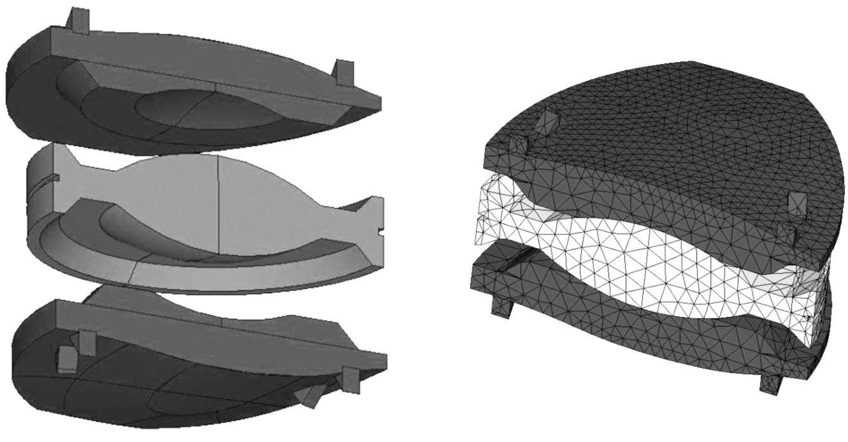


Fig. 6. FE model of the Charite III artificial disc

The prostheses were investigated at the first stage with surrounding structures of the spinal segment. Then the loads and boundary conditions were applied using the simplified model of the prosthesis and the two adjacent vertebrae. Contact with friction ($\mu = 0.05$) was assumed between the metal plates and the polyethylene inlay in the case of the Charite III prosthesis. In the case of the ProDisc prosthesis, the contact elements were used between the upper metal plate and polyethylene inlay but the lower metal plate and inlay were glued. The von Mises equivalent stresses within the metal plates for the compressive force $F_y = 3000\,\mathrm{N}$ are presented in Fig. 7.

The results for the inlays are presented in Fig. 8.

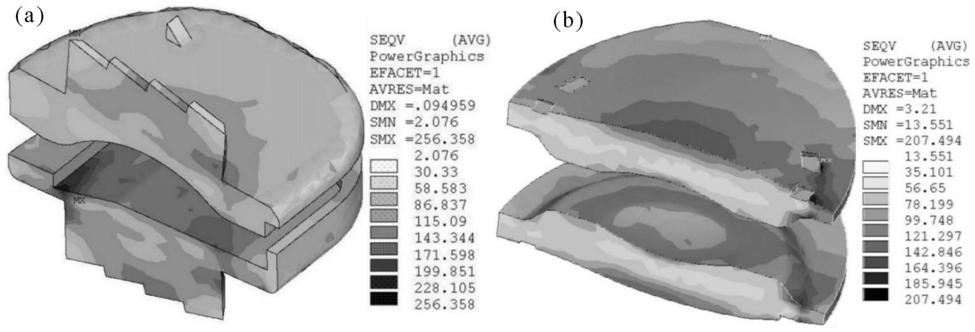


Fig. 7. Von Mises equivalent stresses [MPa] in metal plates of prostheses: (a) ProDisc, (b) Charite III

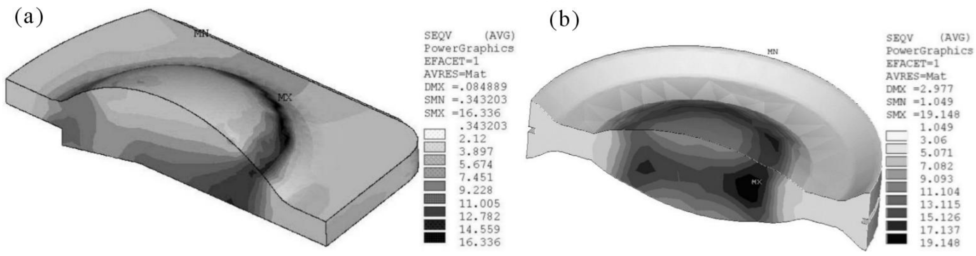


Fig. 8. Von Mises equivalent stresses [MPa] in the polyethylene inlays of prostheses: (a) ProDisc, (b) Charite III

The similar maximum von Mises stresses were obtained for the prostheses (about 200 MPa in metal parts and about 20 MPa in the inlay). It can be mentioned that the metal plate material on the exterior side was extended. and on the interior side was compressed as a result of bending. The highest stress concentrations appeared in the keel-plate and teeth-plate transition regions and were caused by rapid stiffness changes and the notch effect. Nearly the hydrostatic compression state was observed for the spherical parts of the polyethylene inlay.

The important information concerning the quality of the new design may be obtained comparing the behaviour of the analysed system with a natural disc and with the artificial one. In the presented example, the artificial disc causes higher stresses within the bone (Fig. 9, Fig. 10) but the stress distribution is similar to that corresponding to the *natural case*. Greater differences are observed when comparing the vertical displacements which results from the stiffness differences in both considered cases (Fig. 11).

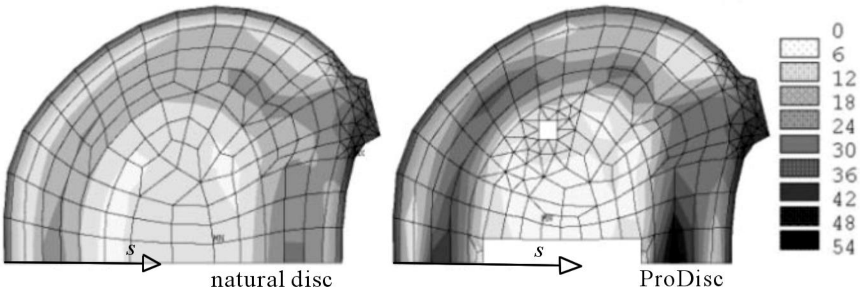


Fig. 9. Von Mises equivalent stress distribution [MPa] on the top surface of the lower vertebra for the compression 3000 N

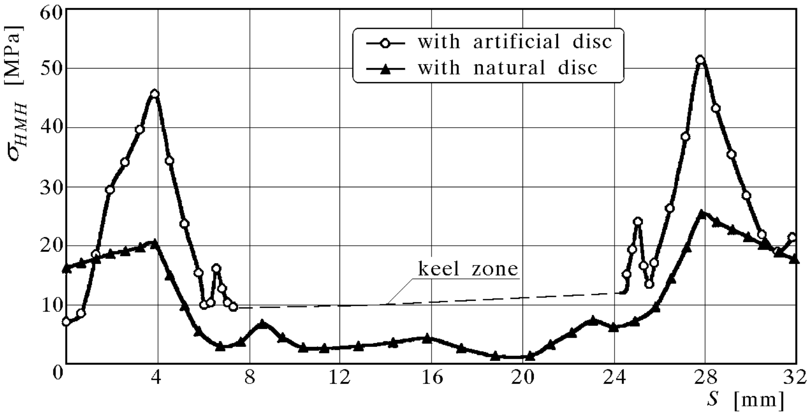


Fig. 10. Von Mises equivalent stress distribution [MPa] on the top surface of the lower vertebra along the path at the symmetry plane YZ (see Fig. 9)

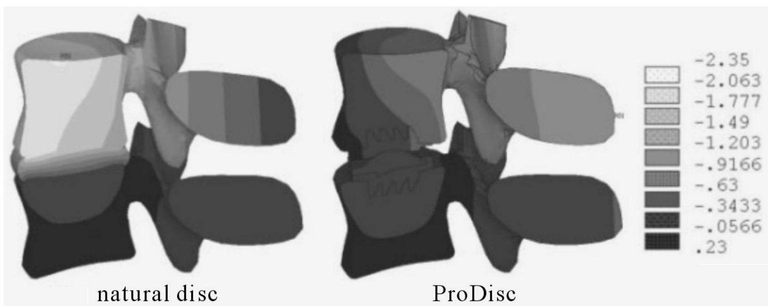


Fig. 11. Vertical displacement [mm] distribution due to the 3000 N compression

5. New solutions and FEA results

Different ideas and solutions to the problem were examined. At the beginning, new designs shown in Fig. 12 and Fig. 13 were taken into consideration. The first consisted of metal plates with toroidal middle; the second was built with metal plates and soft polyethylene cushion with hydrogel inside it. The hyperelastic Money-Rivlin material model was used for hydrogel. In both FE models the contact with friction was assumed between different parts of the structures, and hydrogel was modelled as a material bonded to the polyethylene shell.

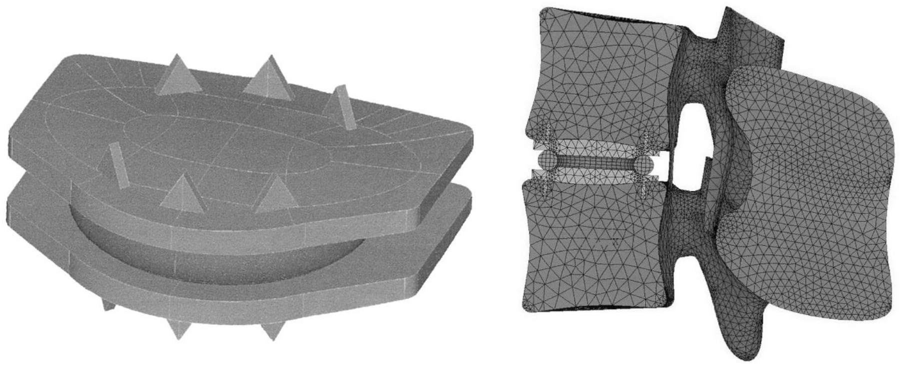


Fig. 12. The artificial disc with toroidal middle

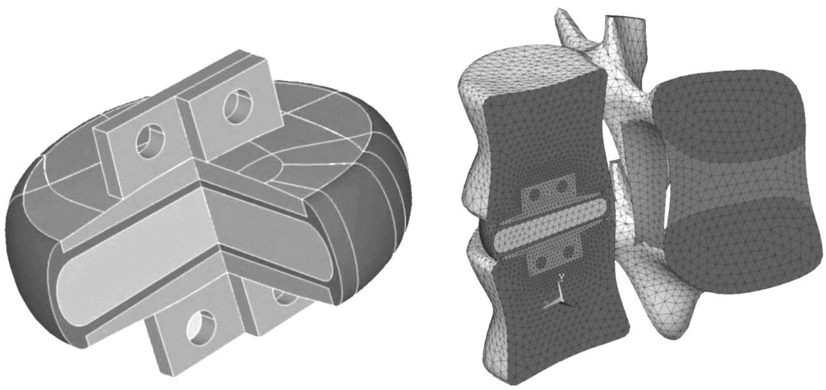


Fig. 13. The artificial disc with the inlay being thick walled container filled with the gel

Unfortunately these solutions (Fig. 12 and Fig. 13) failed because of too high stresses in cushion (Fig. 14).

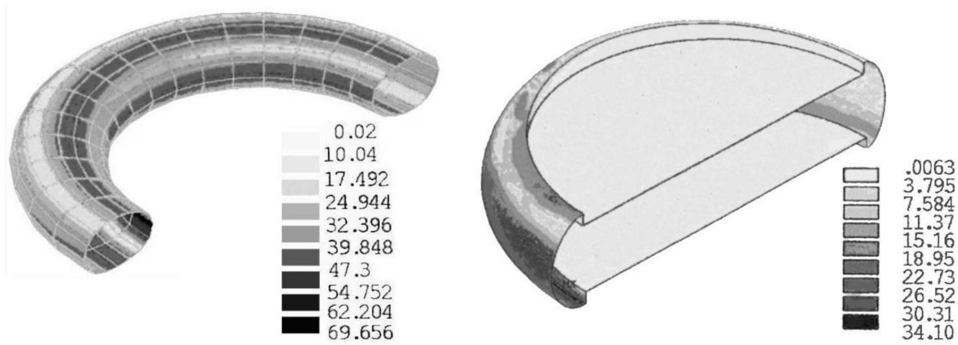


Fig. 14. Von Mises equivalent stresses [MPa] in the polyethylene elements of the new designs (the results correspond to compression analysed for the models shown in Fig. 12 and Fig. 13)

The artificial disc presented in Fig. 15 was designed in order to carry shear forces and to allow a certain range of axial rotation. The design comprises two concave endplates of cobalt-chromium- molybdenum alloy and the elastic inlay. The plates have a large keel and two teeth that grip into the vertebral body above and below the disc. The specially shaped polyethylene middle is placed between the two endplates (Fig. 15 and Fig. 16). The mobility of the structure fulfills the assumed requirements: extension-flexion within the range $(-5°, 10°)$, lateral bending $(-7.5°, 7.5°)$ and axial torsion $(-4.5°, 4.5°)$, respectively.

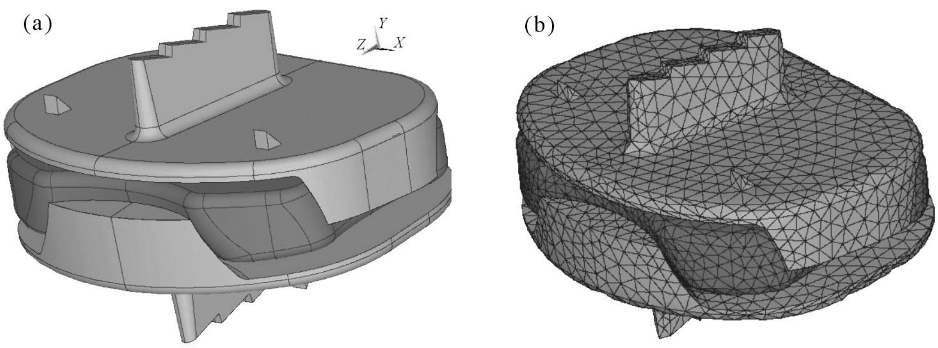


Fig. 15. FE model of the considered new prosthesis: geometrical model (a) and its discretisation (b)

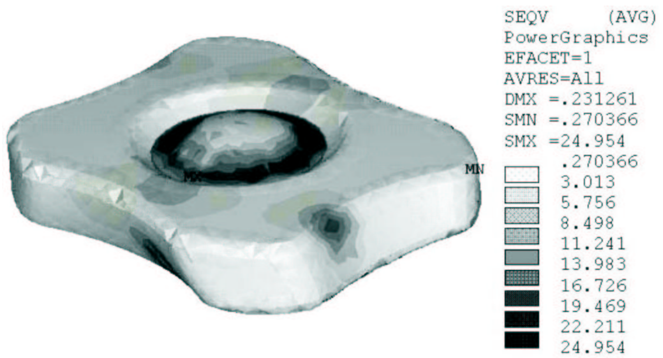


Fig. 16. Von Mises equivalent stresses [MPa] in the polyethylene part of the new prosthesis (compression)

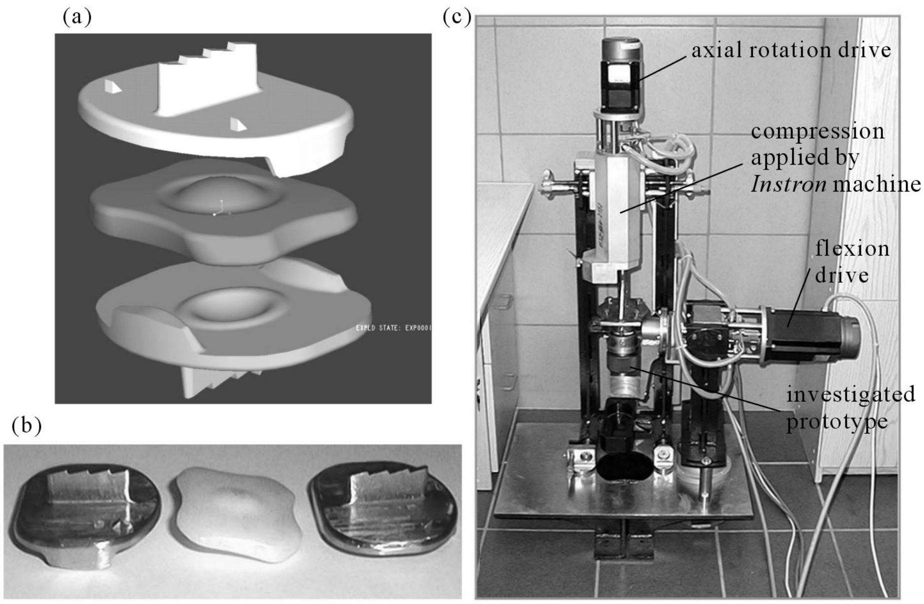


Fig. 17. The CAD model of the new design (a), the prototype (b) and the experimental stand (c)

In the examined case (compression and axial rotation), the boundary conditions were the same as in the ProDisc investigation. The torsional moment $M_y = 3.1\,\mathrm{Nm}$ and compressive force $F_y = 3000\,\mathrm{N}$ were applied. The contact elements were placed between the adjacent metal and polyethylene surfaces (friction $\mu = 0.05$). The maximum stresses in the polyethylene inlay were similar to the ProDisc, and the stress concentrations appeared in the same places

(Fig. 16). The analysis of the design shows a relatively uniform stress distribution within the metal parts and in the surrounding bone tissues. Different modifications of this design are investigated.

The final design, will be checked by experimental *in vitro* measurements. The prototype of the prosthesis should be tested during mechanical experiments to verify the results of the computer simulation. The stand (Fig. 17), fully controlled by the computer, is equipped with two stepping motors which allow imitation of the flexion, compression and axial rotation. It is possible to conduct the investigations either with a dry prosthesis or with a prosthesis immersed in the physiological fluid. The experimental investigations aim at validation of the results of the numerical simulations. The performed experiments include 3D measurements of the relative displacements of the vertebrae and strain gages analysis of the stresses within the prosthesis parts. The stand also enables one to carry out wear and fatique investigations.

6. Conclusions

The reasearch conducted shows that numerical simulation appears to be a very important pre-clinical test of a new design of an intervertebral disc. The FE modeling enables one to estimate the stresses in living structures and within the investigated prostheses.

The first projects appeared to be unsatisfactory because of too high stresses in the prosthesis components. However the design shown in Fig. 15 presents similar mechanical behaviour as that observed in prostheses in clinical use.

Hydrostatic compression in the polyethylene inlay is the advantageous feature because it reduces the equivalent stresses within it. The analyses showed that the important factor of the prosthesis quality is the proper fitting of endplates to the vertebral body surfaces. For that reason the shape of the endplates will be improved in the next modification of the design. In the future step also the size of the keel should be reduced in order to improve the stress distribution and allow for a less invasive implantation technique.

References

1. Bertagnoli R., Kumar S., 2002, Indications for full prosthetic disc arthoplasty: a correlation of clinical outcome against a variety of indications, *European Spine Journal*, **11**, Suppl. 2, 131-136

2. Będziński R., 1997, *Biomechanika inżynierska. Zagadnienia wybrane*, Wydawnictwo Politechniki Wrocławskiej
3. Dietrich M., Kędzior K., Krzesiński G., Zagrajek T., 1999a, Selected problems of orthopaedic implants design – numerical approach, *Proceedings of Tenth World Congress on the Theory of Machines and Mechanisms*, Oulu, Finland, **5**, 1799-1804
4. Dietrich M., Kędzior K., Krzesiński G., Zagrajek T., Zielińska B., 2002, Parametric finite element models of human bones, *Acta of Bioengineering and Biomechanics*, **4**, 135-136
5. Dietrich M., Kędzior K., Skalski K., 1999b, Design and manufacturing of the human bone endoprostheses using computer-aided system, *Journal of Theoretical and Applied Mechanics*, **37**, 3, 481-503
6. Dietrich M., Kędzior K., Skalski K., Zagrajek T., Krzesiński G., Skoworodko J., Borkowski P., Wymysłowski P., 2003, On concurrent engineering and design of an intervertebral disc of lumbar spine, *18-th Conference on Computer-aided Production Engineering CAPE 2003*, Professional Engineering Publishing Limited, UK, 209-219
7. Dietrich M., Kędzior K., Zagrajek T., 1991, A biomechanical model of human spine system, *Journal of Engineering in Medicine*, **205**, 19-26
8. Kędzior K., Krzesiński G., Zagrajek T., 1996, Numerical simulation of the scoliosis as caused by mechanical response of the spinal segment to external load, *Lecture Notes of the Intern. Centre of Biocybernetics Seminars*, **33**, 158-164
9. Krzesiński G., 2003, Numerical methods in analysis and design of implants, *Lecture Notes of the Intern. Centre of Biocybern.: Biomechanics. Customized endoprostheses*, 48-58
10. Lemaire J.P., Skalli W., Lavaste F., Templier A., Mendes F., Diop A., Sauty V., Lalouz E., 1997, Intervertebral disc prosthesis, results and prospectus for the year 2000, *Clin. Orthop.*, **337**, 64-76
11. Pezowicz C., 2003, Analysis of phenomena occuring in the intervertebral disc under different load conditions, *Acta of Bioengineering and Biomechanics*, **5**, Suppl. 1, 379-384
12. Skalli W., 1999, Spine biomechanics. From basic research to clinical applications, *Acta of Bioengineering and Biomechanics*, **1**, Suppl. 1, 379-384
13. Szpalski M., Gunzburg R., Mayer M., 2002, Spine arthoplasty: a historical review, *European Spine Journal*, **1**, Suppl. 2, 65-84
14. White A.A., Panjabi M.M., 1990, *Clinical Biomechanics of the Spine*, J.B. Lippincott Company
15. Whyne C.M., Hu S., Lotz C., 2001, Parametric finite element analysis of vertebral bodies affected by tumors, *Journal of Biomechanics*, **34**, 1317-1324

Komputerowo wspomagane projektowanie nowego typu protezy krążka międzykręgowego

Streszczenie

Zastąpienie lędźwiowego krążka międzykręgowego przez protezę jest wciąż nie w pełni rozwiązanym problemem chirurgii. W pracy zastosowano metodę elementów skończonych, techniki CAD oraz metody weryfikacji eksperymentalnej do poszukiwania konstrukcji nowego typu sztucznego krążka dla odcinka lędźwiowego kręgosłupa. Prezentowane modele metody elementów skończonych uwzględniają niejednorodne właściwości tkanek, występowanie dużych deformacji oraz oddziaływania między poszczególnymi częściami analizowanej struktury. Analizy przeprowadzono dla protez stosowanych obecnie w praktyce klinicznej oraz dla kilku nowych propozycji konstrukcji. Wnioski dotyczą najważniejszych czynników o charakterze mechanicznym, które wpływają na jakość sztucznych krążków międzykręgowych.

Manuscript received January 16, 2004; accepted for print March 5, 2004