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Hyper-elastic modelling of intervertebral disc polyurethane implant

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Artificial materials including various kinds of polymers like polyurethanes are more and more widely used in different branches of science and also in biomedical engineering. The paper presents the process of creating a constitutive equation for a polyurethane nanocomposite which is considered to be hyper-elastic. The constitutive modelling was conducted within the range of application of the material as one of the components of lumbar intervertebral disc prosthesis. In the paper, the biomechanics of the lumbar spine and the most frequently applied intervertebral disc prostheses are described. Also a polyurethane nanocomposite as a new material to be applied in prostheses is presented. The way of formulating a constitutive equation by means of mathematical formulae is described. Four various hyper-elastic potential functions are considered, i.e., Ogden, Neo-Hookean, Yeoh and Mooney–Rivlin. On the basis of monotonic compression tests the best hyper-elastic model for the material considered was chosen and hyper-elastic constants were calibrated. Finally, the constitutive model was validated on the basis of FE analysis. The paper ends with a conclusion and presentation of further plans of research directed towards the development of a constitutive equation and its application in computer simulations by means of the finite element method.

Key words: *constitutive equation, curve-fitting, hyper-elastic constants*

1. Introduction

The lumbar spine is a complicated system of bones, joints, muscles, ligaments and other connective tissues which is to ensure a proper mobility of the upper body part and at the same time to maintain the proper stiffness in order to be able to carry the loads connected with the mobility of the trunk and to protect the elements of the nervous system. A spine segment is defined as a system composed of two neighbouring vertebrae together with an intervertebral disc and with a ligament apparatus. Such a complicated spine structure ensures the mobility of the spine in three mutually perpendicular surfaces (Simon et al. [24]). In the upper part of the lumbar segment the spine shows the greatest mobility in lateral directions (lateral bending), while the lower part of the lumbar segment shows the greatest mobility in the sagittal plane (bending, straightening) (Pope et al. [22]). During bending in the sagittal plane, lateral bending and rotation movements in the horizontal plane, the rotation middle changes its location (Rolander [23]), which additionally complicates the process of an intervertebral disc prosthesis design. Additionally, rotating movements and lateral bending are coupled with each other in the lumbar spine segment (Pope et al. [21]).

A natural intervertebral disc is composed of an annulus fibrosus composed mainly of collagen and a nucleus pulposus which mainly consists of water (90% in young people), proteoglycans and collagen. The hydrophilic nucleus generates a certain state of tension of the annulus fibrosus, which causes that the intervertebral disc is able to carry compressive loads.

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During bending the annulus bulges in the direction of movement, while the nucleus "runs away" in the opposite direction (Krag et al. [11]).

After reaching the age of 30 the nucleus loses water gradually and its volume decreases (Akeson et al. [2]). This leads to an increase of loads which the annulus fibrosus carries. The annulus resistance becomes smaller, it is degenerated and at last its structures are broken. The nucleus hernia comes into being and it is gradually dried, so the intervertebral disc is degenerated (Osti et al. [17], McNally and Adams [15]). This leads to the limitation of spine movements and pain. Disc degeneration may also result from the increase of spine instability, inflammation, hypertrophy and the calcinations of the front soft structures. Before starting an intervertebral disc arthroplasty different kinds of tests are performed which are aimed, among other things, at estimating the state of the bone tissue in which prosthesis is to be implanted. In order to reproduce the spine mobility intervertebral disc prosthesis should have the dimensions similar to the ones of a natural disc.

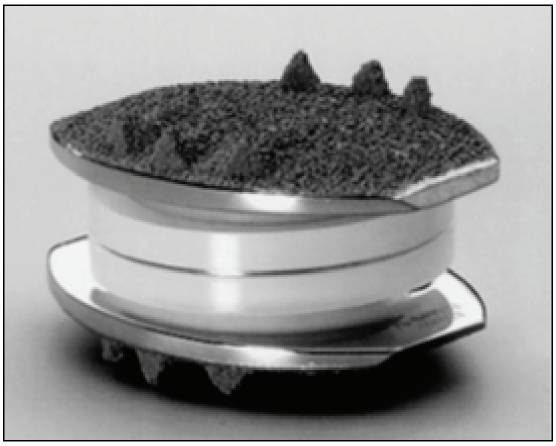

Fig. 1. SB Charité III Disc
(Depuy Spine, Johnson and Johnson, Raynam, MA)
(Gamradt and Wang [7])

One of the most frequently used intervertebal disc prosthesis is the SB Charite' III Disc (Deputy Spine, Johnson and Johnson, Raynam, MA) (Fig. 1). It consists of two plates made of a cobalt-chromium alloy and a polyethylene insert. The plates are additionally covered with a hydroxyapatite layer or a titanium layer in order to improve the stability of the prosthesis set in bone tissue. Biomechanical tests performed on cadaver showed that this prosthesis ensures a proper spine mobility if it is implanted in the L4-L5 segment. An additional advantage of this prosthesis is the fact that rotation centre changes its location and makes an ellipse (Gordon et al. [9], Link [12], Ahrens et al. [1]). Clinical tests (Cinotti et al. [6]) performed on 56 patients showed that a very good and good clinical result was noticed in 63% of patients. The average period of clinical tests was 3.2 years. Other clinical observations (Caspi et al. [5]) carried out for 48 months showed that a satisfactory or good clinical result was achieved in 80% of patients. 20 patients were observed. In two cases prosthesis dislocation was stated.

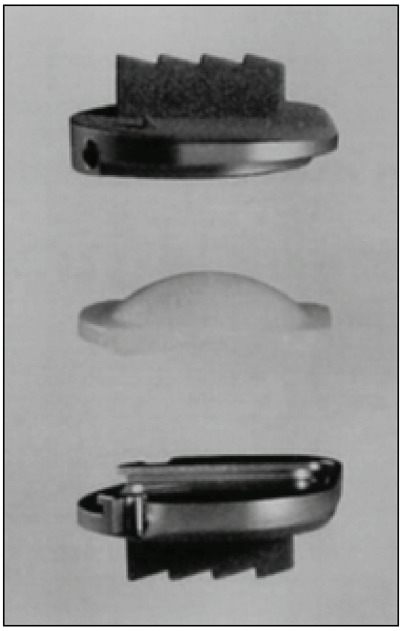

Fig. 2. ProDisc II (Aesculap AG & Co., Tuttlingen, Germany)
(Gamradt and Wang [7])

ProDisc II Endoprosthesis (Aesculap AG & Co., Tuttlingen, Germany) is also composed of three elements. The plates are made of a cobalt-chromium alloy and are covered with a pure titanium layer and they have got the oblong keels in order to make their positioning easier during an operation and to improve the stabilization after implantation. There is a polyethylene insert between the plates (Fig. 2). Clinical tests performed during approximately one and a half year in a group of 53 patients who had ProDisc II prosthesis implanted (in some cases even on two levels) showed good post-operation results (Tropiano et al. [26]). In 72% of the cases the patients could come back to their active vocational lives. There were only five cases of complications connected with breaking the vertebral body (1 case), an improper implant fixation (2 cases) and the feeling of pain within nerve roots (2 cases). In reference sources there is lack of clinical observations of this prosthesis lasting longer than two years, which makes it impossible to estimate it fully in a clinical sense.

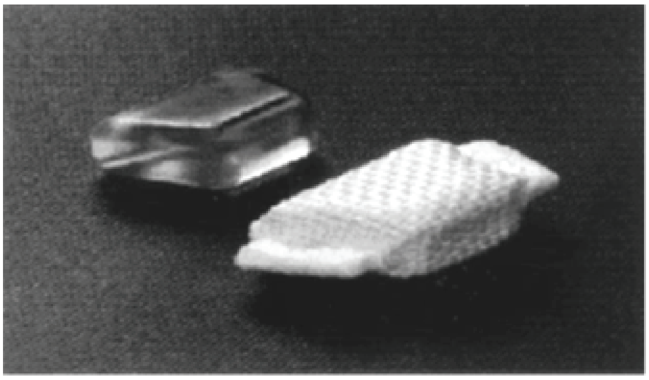

Fig. 3. Prosthetic Disc Nucleus (PDN; RayMedica Inc., Bloomington, MN) (Gamradt and Wang [7])

Prosthetic Disc Nucleus (PDN; RayMedica Inc., Bloomington, MN) is an interesting solution. Its implantation is aimed at reconstructing visco-elastic nucleus properties (Gamradt and Wang [7]). The prosthesis is composed of hydro-gel created of the mixture of polyacrylonitrile and polyacrylamide (HYPAN) set in the package made of polyethylene (Fig. 3). A hydro-gel core is designed in such a way that after the implantation it can absorb the liquid, widen itself and reconstruct a natural disc height (Klara and Ray [10]). The polyethylene package gives a proper shape to the prosthesis and prevents it from an excessive change of its dimensions. The prosthesis was implanted for the first time in 1996. Then in 1999 its construction underwent a certain modification and since that moment it has been implanted to 462 patients (Gamradt and Wang [7]). Unfortunately, the longest period of a clinical observation was only 2 years and it concerned only 24 patients. In 12% of the cases a revision implantation was necessary in order to correct the implant position (Bertagnoli and Schonmayr [3]). In the case of 218 patients, for whom a disc height was measured, it was noticed that its height increased from approximately 8.1 mm to 10.2 mm during 3 months. Unfortunately, this prosthesis can be implanted in an early stage of disc degeneration because its application in the case when an annulus fibrosus is to a significant degree or totally degenerated would not meet the expectations. The change of prosthesis size would lead to the deepening of disc damage and not to the reconstruction of its natural height.

In spite of the great progress in intervertebral disc prosthesis constructions a prosthesis which in terms of its functionality would be similar to a natural disc, has not been manufactured yet. The research aimed at increasing the functionality of all kinds of prosthesis, including intervertebral disc prosthesis, is directed towards designing a new material. Polymers as well as polyurethanes are more and more widely used in this field. In the paper, the authors try to formulate a constitutive equation of a new material that is a polyurethane nanocomposite for clinical use as one of the intervertebral disc prosthesis components. This equation is necessary to carry out a computer simulation of this material under the action of different loads. It will allow optimising a nanocomposite so that its properties be optimal for clinical application as an intervertebral disc substitute. This material is a nanocomposite because it possesses some nanoparticles in the form of carbon nanotubes which increase its mechanical properties.

2. Materials and methods

Constitutive equations are most frequently formulated within a principle "from a general idea to a detail". First of all the most general aspect of an equation is formulated, then the restrictions and requirements are stated which are in agreement with general physical laws and at the same time they do not simplify the whole mathematical formalization too much.

The theory of constitutive equations is based on three basic axioms:

Axiom 1. Determination principle. The elasticity in a given body in a current configuration depends upon the elasticity state in this body in previous configurations. In other words, the elasticity history determinates the current elasticity state in the body. For example, in elastic materials the constructive law determinates the elasticity state which depends upon the strain state which existed in the body between the related configuration, when the body was not loaded, and the current configuration.

Axiom 2. The principle of the influence of local phenomena. The constitutive equation describing the material answer in an optimal area depends upon the answer of this material which came into being in a neighbourhood of this area. This principle puts a restriction of a constitutive equation formulation, which means a dependence of these equations upon the events which take place also in a strictly stated neighbourhood of the area considered in the body.

Axiom 3. Objectivity principle. Material properties and a constitutive law are not dependent upon an observer's choice (independence concerning the orthogonal transformations). This means that constitutive equations cannot depend upon a movement of a given body if this movement does not cause the deformation of this body.

It is possible to distinguish four methods of formulating constitutive equations:

- an axiomatic method – acceptance of an axiom meaning that mechanical properties of a given material are fully described by a chosen tensor equation (sometimes such constitutive equations are called the equations of an ad hoc type);
- a postulate method (for the materials for which the reaction is dependent upon time) – construction of a mechanical model and then on its basis introduction of constitutive equations in the form of a differential equation or postulating so called heredity law in an integral form and using a property chosen empiric function in it;
- a method of thermodynamic considerations – introduction of constitutive equations on the basis of proper laws of thermodynamics (on the basis of the laws of thermodynamics concerning reversible processes it is possible to introduce constitutive equations of linear elasticity, while using the laws of thermodynamics concerning reversible processes it is possible to get constitutive equations of linear visco-elasticity);
- a method of potential functions – acceptance of a scalar function connecting a stress tensor with a strain tensor or their rate measurements (the function has got a physical sense of potential elasticity energy cumulated in a deformed medium).

In one of the previous papers of two co-authors the second method was implemented to formulate a constitutive equation (Pawlikowski et al. [19]). However, in this paper, the last method was applied. As the intervertebral disc, especially nucleus pulposus, indicates hyper-elastic properties the nanocomposite is modelled as a hyper-elastic material (Borkowski et al. [4]). Four forms of hyper-elastic potential functions were taken into consideration

- Ogden:

$$W_O = \sum_{p=1}^{N} \frac{\mu_p}{\alpha_p}(\lambda_1^{\alpha_p} + \lambda_2^{\alpha_p} + \lambda_3^{\alpha_p} - 3),$$

- Neo-Hookean: $W_{NH} = c_1(I_1 - 3)$,
- Yeoh: $W_Y = c_1(I_1 - 3) + c_2(I_2 - 3)^2 + c_3(I_3 - 3)^2$,
- Mooney–Rivlin:

$$W_{MR} = c_{10}(I_1 - 3) + c_{01}(I_2 - 3)^2,$$

where: μ_p, α_p, c_1, c_2, c_3, c_{10}, c_{01} – hyper-elastic material constants, I_1, I_2 – the first and the second invariant of the right Cauchy–Green tensor, respectively, λ_1, λ_2, λ_3 – stretch ratios along the main axis.

The constitutive equation was introduced on the basis of the monotonic compression tests. In such a case a deformation gradient tensor takes the following form

$$F_{ij} = \begin{bmatrix} \lambda_1 & 0 & 0 \\ 0 & \lambda_2 & 0 \\ 0 & 0 & \lambda_3 \end{bmatrix}, \tag{1}$$

while the right Cauchy–Green tensor can be written down as follows

$$C_{ij} = \begin{bmatrix} \lambda_1^2 & 0 & 0 \\ 0 & \lambda_2^2 & 0 \\ 0 & 0 & \lambda_3^2 \end{bmatrix}. \tag{2}$$

It was assumed that the material is incompressible and isotropic. The assumptions result from the rubber-like structure of the material considered. The natural disc is also incompressible due to the high amount of water and can be modelled with the above assumptions, see, e.g., (Łodygowski et al. [13]). In such a case, $\lambda_2 = \lambda_3$ and $\lambda_1\lambda_2\lambda_3 = 1$. Denoting $\lambda_1 = \lambda$ equation (2) can be written as follows

$$C_{ij} = \begin{bmatrix} \lambda^2 & 0 & 0 \\ 0 & \lambda^{-1} & 0 \\ 0 & 0 & \lambda^{-1} \end{bmatrix}. \tag{3}$$

Stretch ratio λ defines the deformation of a sample in the direction of compressive load.

The constitutive equation was formulated with the use of the following equation

$$S_{ij} = 2\frac{\partial W}{\partial C_{ij}} \tag{4}$$

where: S_{ij} – second Piola–Kirchhoff stress tensor, W – an arbitrary potential function. In the case of loading under consideration, a non-zero stress component will be only one, namely S_{11}. Thus, the constitutive equation will show the change of stress S_{11} as a function of deformation defined by means of stretch ratio λ. This is an approach often used and described in reference sources, e.g., Pioletti et al. [8], Goh et al. [8], Pawlikowski [18]. The dependences for the potential functions considered take the following forms

- Ogden:

$$(N=2):\ S_O = \frac{1}{\lambda^2}(\mu_1\lambda^{\alpha_1} + \mu_2\lambda^{\alpha_2} - \mu_1\lambda^{-\frac{1}{2}\alpha_1} - \mu_2\lambda^{-\frac{1}{2}\alpha_2}),$$

- Neo-Hookean:

$$S_{NH} = \frac{1}{\lambda^3}2c_1(\lambda^3 - 1),$$

- Yeoh:

$$S_Y = \frac{2}{\lambda^5}(3(c_3\lambda^6 - 6c_3\lambda^4 + 4c_3\lambda^3 + 9c_3\lambda^2 - 12c_3\lambda + 4c_3)$$
$$+ 2c_2\lambda^4 - 6c_2\lambda^2 + 4c_2\lambda + c_1\lambda^2)(\lambda^3 - 1),$$

- Mooney–Rivlin:

$$S_{MR} = \frac{2}{\lambda^4}(c_{10}\lambda^4 + c_{01}\lambda^3 - c_{10}\lambda^3 - c_{10}\lambda - c_{01}).$$

All the constants in the above equations were determined on the basis of experimental data. Based on this data and matching the theoretical curve to the experimental curve a proper hyper-elastic model for a polyurethane nanocomposite was defined. The constitutive model may also be utilised in computer simulations of the implant material designed. This is very helpful in optimising nanocomposite properties with respect to its clinical application as an intervertebral disc substitute.

The tests of monotonic uniaxial compression were performed with the use of the MTS Bionix Systems machine. Six of such tests were carried out with the use of six cylindrical samples (Fig. 4). The front surfaces of the samples were covered with a thin layer of machine lubricant in order to minimise friction and to eliminate the barrel-like effect of the samples.

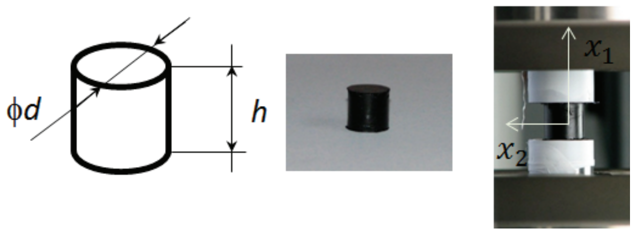

Fig. 4. Cylindrical sample for experimental tests: $d = 11.5$ mm, $h = 12$ mm

During the tests deformation of the samples was measured in the direction of load x_1 and in the perpendicular direction x_2 by means of a video-extensometer. The tests were conducted at the deformation rate equal to 1 mm/min. Figure 5 presents the course of deformation in the direction x_2 vs. time and also a theoretical curve resulting from the assumption of material incompressibility. From this figure it can be stated uniquely that assumption concerning polyurethane noncomposite incompressibility is fully reasonable.

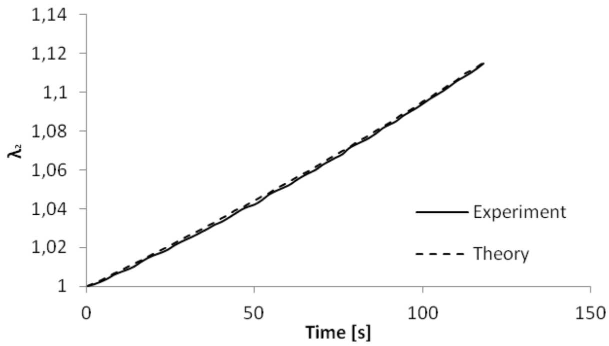

Fig. 5. Theoretical and measured stretch ration in direction x_2

3. Results

In order to match the theoretical courses of stress-deformation curves to the experimental curves a com-

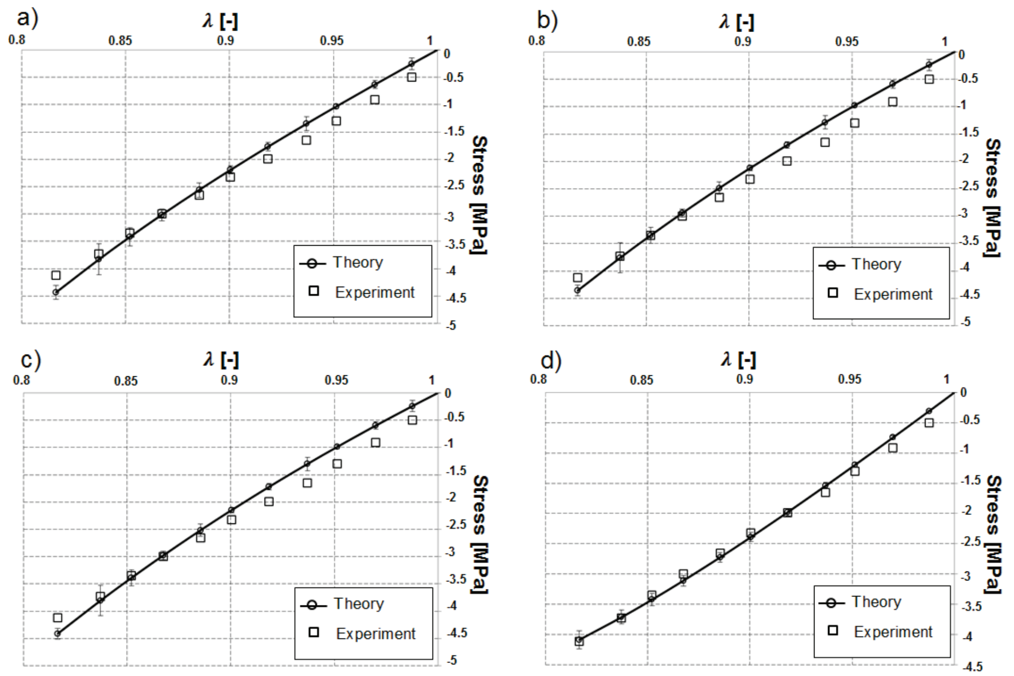

Fig. 6. Theoretical curve fitting to the experimental stress-strain curves for the models: Ogden (a), Neo–Hookean (b), Yeoh (c), Mooney–Rivlin (d)

puter code prepared in MATLAB was utilised. The code realised the algorithm for minimising the distance between the theoretical curve points and the points located on the experimental curve. There are several of such algorithms. In the experiments described the Levenberg–Marquardt (Sun and Yuan [25]) algorithm was applied.

The results of hyper-elastic model identification for the material considered are presented for average deformation-stress characteristics calculated from the six compression tests. In Figure 6, the matching of theoretical curves for particular hyper-elastic models to the experimental data is shown. From this figure it can be seen that the matching of Ogden model (Fig. 6a) to the experimental measurement points is not sufficient. The same can be said about Neo-Hookean model (Fig. 6b) and Yeoh model (Fig. 6c). On the other hand, Mooney–Rivlin hyper-elastic model seems to describe best the mechanical response of the material considered under the influence of the compressive load (Fig. 6d).

In Table 1, values of the constants of the Mooney–Rivlin model for all the samples are presented together with standard deviations.

The hyper-elastic constants for the Mooney–Rivlin model were calibrated with an average relative error of 8%. This error was calculated according to the following equation (Ogden et al. [16])

$$err_i = \frac{|(S(t,p))_i - (\widetilde{S}(t))_i|}{\max(0.5, |\widetilde{S}(t)|} \tag{5}$$

where: $S(t, p)$ – stress calculated by means of equation (4), $\widetilde{S}(t)$ – stress determined on the basis of the experiment, p – vector of material constants c_{10}, c_{01}.

This error was calculated for each measurement point, and then an average value was determined.

4. Discussion

In this paper, a hyper-elastic approach to formulation of a constitutive equation for a new material to be applied in orthopaedic devices (implants) was presented. A method related to choosing a proper potential function was used. Four known potential functions for hyper-elastic materials were considered, i.e., Ogden, Neo-Hookean, Yeoh and Mooney–Rivlin functions. On the basis of experimental tests it was certified that the best model for the description of polyurethane composite hyper-elastic properties is the Mooney–Rivlin model. Using this function a constitutive equation was derived and hyper-elastic constants were defined.

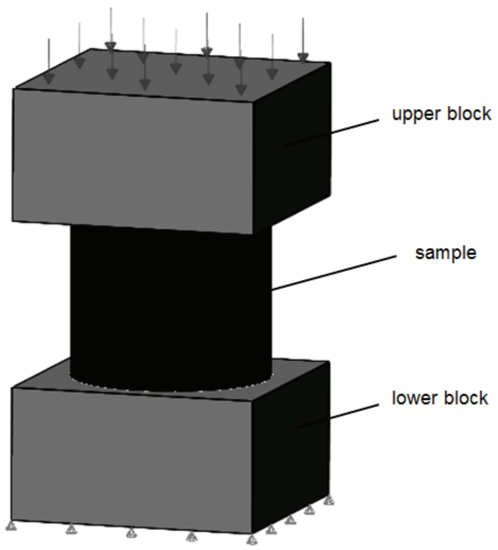

Fig. 7. Numerical model of experimental set-up for compression test

The constitutive model was validated by means of a finite element analysis. The numerical model (Fig. 7) was similar to the experimental set-up, i.e., a cylinder was compressed between two stiff blocks. The cylinder was modelled as a hyper-elastic material (Mooney–Rivlin model) and the values of the constants c_{10}, c_{01} were taken from Table 1. The numerical model was loaded with a pressure corresponding to the force acting on the lumbar intervertebral disc 2000 N. The pressure was applied on the surface of the upper block. There were 60 time steps defined equal to 0.2 s each. After numerical calculations stretch ratio λ in the load direction was determined in each time step and stress was read from the results file. Also stress corresponding to the Mooney–Rivlin model was calculated for the same values of λ using the constitutive equation derived. A comparison of the two curves stress vs. stretch ratio is shown in Fig. 8. It can be seen that the curves are practically overlapping which suggests that the constitutive model describes the material behaviour correctly.

From the analysis of the measurement points on the stress-deformation diagram (eg., Fig. 6a) it follows that Young's modulus of the composite is approximately E = 24.25 MPa. Now, applying the equation relating Kirchhoff modulus G with the hyper-elastic coefficients of the Mooney–Rivlin model in the form of

$$G = 2(c_{10} + c_{01}), \tag{6}$$

the modulus G can be calculated. For average values of these factors stated in Table 1 this modulus is G = 8.36 MPa. Using the following formula

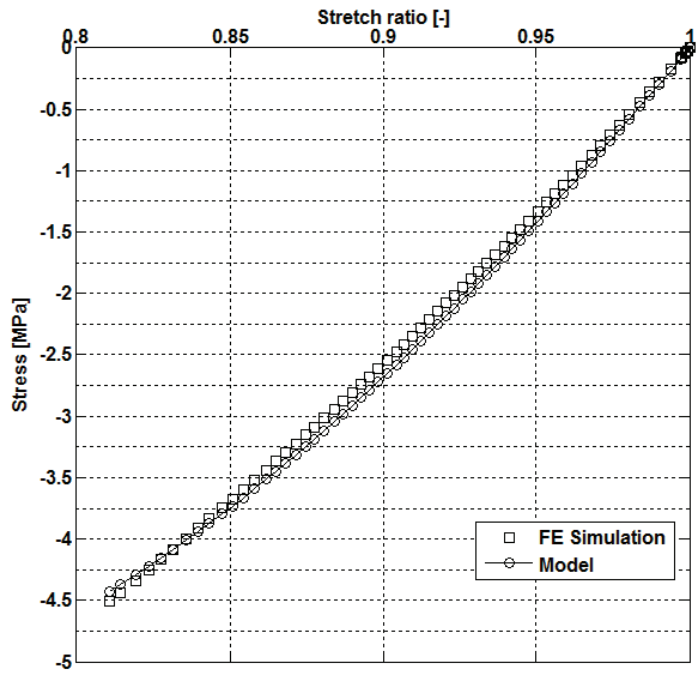

Fig. 8. Simulated by FE method and predicted by the constitutive model stress-strain curves

Table 1. Values of identified hyper-elastic constants

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Average
c_{10} [MPa]	9.20	7.68	9.42	9.46	11.03	9.77	9.43±0.58
c_{01} [MPa]	–5.07	–3.84	–5.19	–5.24	–6.73	–5.46	–5.25±0.46

$$G = \frac{E}{2(1+\upsilon)}, \qquad (7)$$

it is possible to calculate a theoretical value of Poisson's ratio υ, which is $\upsilon = 0.45$. This result is the same as the value of the ratio υ calculated on the basis of the deformation measurement in the direction of load and in the perpendicular direction.

The calculated values of Young's modulus and Kirchhoff modulus for polyurethane nanocomposite seem to be too low. For example, the value of Young's modulus for high-molecular polyethylene – the material used now as an insert between the intervertebral disc prosthesis plates – is 990 MPa (Maksimov et al. [14]). So, further studies will be directed towards increasing the nanocomposite mechanical properties.

It also seems necessary to extend the constitutive equation in such a way that it will describe the nanocomposite visco-elastic properties and the reaction of the material while being loaded and unloaded (hysteresis loop). Additionally, a constitutive equation will be used in stress and deformation simulation states in the intervertebral disc implant by means of the finite element method.

Acknowlegments

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