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Design of a new intervertebral disc prosthesis: a numerical approach

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Abstract

In the degenerative disc disease, an alternative treatment to the traditional arthrodesis, consisting in the fusion of the two adjacent vertebral bodies, is the artificial intervertebral disc. The advantage of an artificial intervertebral disc is that the d.o.f. of the vertebral segment can be saved and the mobility of the spine could be almost restored. Many solutions were proposed in the last decades, most of them consisting in metallic rigid joints able to assure the mobility and to maintain the correct distance between the vertebrae but subject to corrosion, wear and interface problems due to the different stiffness with the biological tissues.
Purpose of this paper is the design of a prosthetic device substituting the disc to be placed in the intervertebral zone. Different types of artificial prostheses have been proposed by the authors, based on similarity with physiological discs, then with a central part (nucleus) made of hyperelastic material and an outer containment frame (annulus) consisting of a plastic material with a stiffness high enough to assure the reaction force and to avoid large radial displacements. In our solutions, the external parts (annulus and plates) were modeled by HDPE and the inner part (nucleus) by silicone and hydrogel. All the materials are highly biocompatible. The intention of the authors, moreover, is to permit an easier surgical technique. The prosthesis, in fact, could be mounted void of the nucleus, allowing an easier placement, and filled only after the frame insertion, by injecting the silicone through a syringe.
The nucleus was modeled by the Mooney-Rivlin parameters related to elastomers, being the disc subject to large deformations that the materials have to be able to withstand in elastic conditions. The discs are subjected to compressive loads either in the mounting phase or, after the silicone filling, due to the physiological loads.

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1. Introduction

Lumbar disc disease is certainly one of the most common pathologies in western countries, recognized as one of the main causes of pain and disability in the active population between 25 and 60 years. This pathology has a socio-economic impact (direct and indirect costs) already estimated in many tens of billion dollars of national health budget in U.S.A.. The low back pain affects a large part of the human population at least once in their lifetime. The deterioration of the disc and its loss of height provokes the gradual eccentricity of intervertebral kinematics with a progressive deterioration of the disc itself, because a significant variability of the instantaneous axis rotation (IAR).

Many may be the causes of back pain, but, studying the mechanisms of load transfer in the spine, it has been established that in most cases it derives from the degeneration of the intervertebral discs. The process begins naturally after the second decade of life and leads to a different distribution of the stress on the spine, causing instability and localized pain (Schultz et al. 1982, White and Panjabi 1990, Ferguson and Steffen 2003).

Although initially attempting to have a less invasive approach, surgical treatment is the most practiced way. The surgical solutions are essentially spinal fusion and total or core replacement of the disc. Each of these techniques has advantages and disadvantages and the surgeon must choose the best solution by evaluating the patient's clinical conditions (Szpalski et al. 2002, Lee et al. 2004, Lee and Goel 2004, Bono and Garfin 2004, Denozière and Ku 2006, Galbusera et al. 2006, Mayer and Siepe 2006, Rohlmann et al. 2006, Chen et al. 2009).

Among all the surgical treatments able to assure the spine stability, the most physiological is the replacement by an artificial intervertebral disc. The main advantage of this solution is the mobility restoring, so the kinetics of the spine could be saved. Many solutions were proposed for the intervertebral disc, most of them based on two metallic plates with anchorage elements to connect the prosthesis to the vertebral bodies (Goel et al. 2005, Rohlmann et al. 2005, Zander et al. 2009, Nandan et al. 2010). In many cases, the inner part is realized by a metallic ball joint or by a polymeric body to assure the spine mobility. In the former case the mobility is assured but not the damping effect, in the latter case, on the contrary, the damping is assured but the control of the mobility of the spine segment strongly depends on the material properties of the insert itself.

This paper deals with the design of a new prosthetic device finalized to substitute the disc in the intervertebral space as similar as possible to the physiological one, in order to allow both the mobility and the damping performances. The study was carried out by numerical simulation of different possible solutions, considering the highly hyperelastic properties of the materials (Lealhy and Hukins 1997, Sayed et al. 2008, La Rosa et al. 2018 1-2).

2. Numerical models

The numerical models were defined based on the shape of the physiological intervertebral disc. The idea was to respect as soon as possible the two main components of the disc: the nucleus inside, realized by a homogeneous silicone, surrounded by an external annulus, constituted by a more resistant polymeric belt.

Different models were drawn down using SolidWorks and imported in ANSYS by the authors, in order to verify the amount of the compressive load that the prosthesis is able to amortize. The models are characterized by a different geometry; however, each artificial disc has an upper and a lower plate, corresponding to the the upper and lower vertebral bodies; a central core between them, representing the nucleus, surrounded by an outer belt, representing the annulus.

Then, the prosthesis was modeled with dimensions similar to those characteristic of the vertebral plate of a lumbar vertebra. A maximum width of about 53 mm and a length of about 30 mm (Figure 1a) characterize the prosthesis. It consists of a shell made of two plates having the vertebral body shape, in high-density polyethylene (HDPE), with a thickness of 2 mm each, and an outer belt, with thickness h variable from 0.5 mm to 2 mm, fixed to the upper and lower plates. The inner part consists of a central core, 12 mm height, made of silicone. Therefore, the overall height of the model is 16 mm. The total volume of the prosthesis is about 10500 mm^3.

The numerical simulations were performed in displacement control. Then, all the proposed prostheses were subjected to a vertical displacement of 1 mm and the reaction force was calculated. The value considered physiologically correct is about 2500 N for a lumbar disc, in a patient under moderate activity.

As previously highlighted, in order to simulate the insertion of the shell prosthesis by the surgeon in the first surgical phase, a second load case without the inner core was considered, always compressing the plates, therefore

foreseeing the silicone core inflating in a liquid form in a subsequent moment. This procedure could facilitate the insertion in the first and most delicate surgical phase.

The models previously described do not present good results in terms of maximum stress induced. Therefore, new models were proposed consisting in a box with sliding cover (Figure 1b). Finally, in order to improve the damping performances of the disc prosthesis, hydrogel slides were inserted in correspondence of the floating floor and the bottom, together with a Gore-Tex capsule all around the core (silicone + hydrogel) to contain the hyperelastic part (Figure 1c). Table 1 shows the dimensions of the various components of the box prosthesis. Obviously, for these models, the analysis if the void shell was not performed, being the models itself at floating roof.

a   b   c
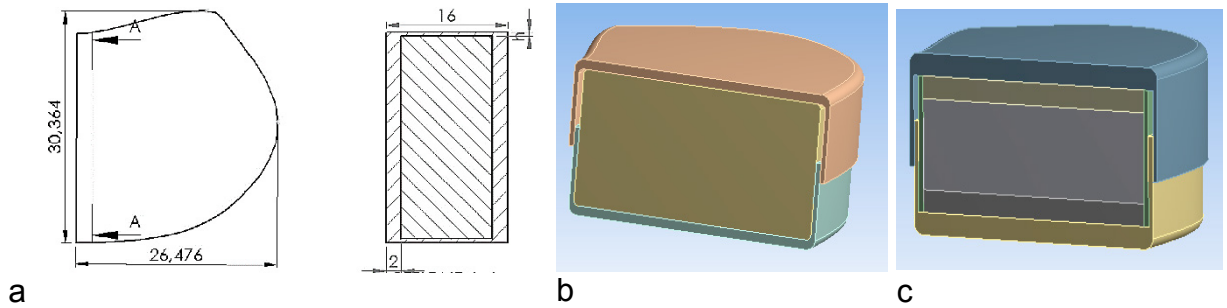
Fig. 1. Prosthesis dimensions for the shell model (a); numerical model of the box with sliding lid (b) and with hydrogel slices (c).

Particular care was dedicated to avoid the contact of the prosthesis with the spinal cord during the lateral expansion in the compressive phase. The maximum admitted value for the lateral displacement was 1 mm. The flow diagram explaining the numerical simulation procedure is shown in Figure 2a.
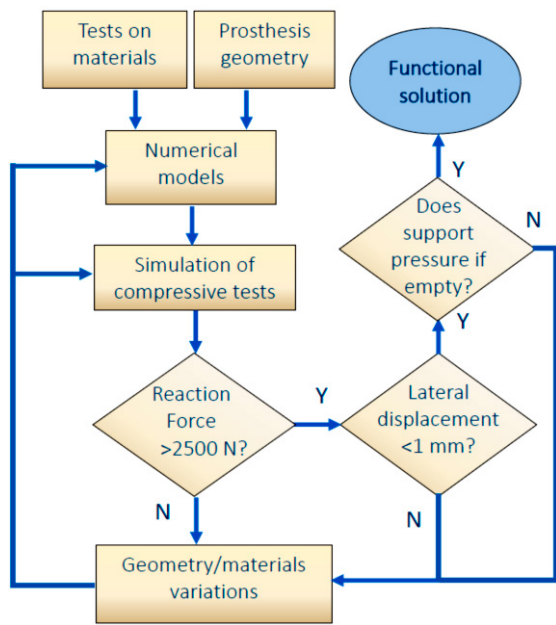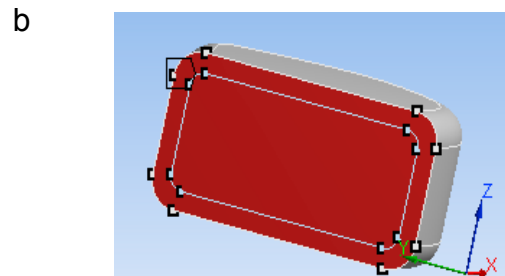

Figure 2b. Numerical model of the half part of the prosthesis. The red face is the symmetry plane.

a   c

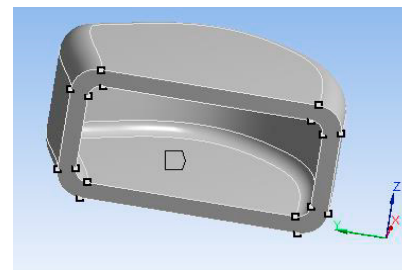Figure 2a. The scheme of the procedure for the simulation analysis.   Figure 2c. Numerical model of the void shell.

Only half part of the prosthesis was modeled, considering the total symmetry respect to the sagittal plane (Figures 2b and 2c for the prosthesis or for the shell alone respectively). The bottom plane was totally constrained and the displacement was applied to the top plane. The shell hemi-model is constituted by 4842 nodes and 3050 elements, the box hemi-models vary from 11595 nodes and 3768 elements to 15655 nodes and 5178 elements.

Table 1. Dimensions of the box prosthesis components.

Dimension (mm)	Basic box	Lateral hydrogel	Up and bottom hydrogel
Lateral wall	0.5	0.5	0.5
Base height	9.0	9.0	9.0
Cover height	9.0	10.0	10.0
Base thickness	1.0	2.0	2.0
Cover thickness	1.0	2.0	2.0
Silicone height	14.0	14.0	12.0
Hydrogel height		0.5	1.0

3. Materials

Four materials were considered for the numerical simulations: high density polyethilene (HDPE) for the external shell or the box walls, silicone for the inner core, hydrogel for the upper and lower slices and Gore-Tex for the capsule.

3.1. Silicone

The core of the prosthesis is realized with a silicone bulk. Even if it is not similar to the hydrogel constituting the nucleus of the physiological intervertebral disc, able to be hydrophilic, their mechanical characteristics can be considered comparable in terms of hyper-elasticity and pressure transfer to the surrounding belt. Silicone is a material largely used in biomedical applications due to their biocompatibility and the possibility to be coupled with other biomaterials in medical devices.

Tests were performed by Zwick-Roell testing machine (La Rosa et al. 2018-2) using compression plates and a 100 kN load cell. The stress-strain behavior was very similar to this found in literature and in the ANSYS materials library. Then, the mechanical characteristics of the silicone core were adopted as in literature, characterized by the elastomeric behavior derived by the Mooney-Rivlin model with the five parameters reported in Table 2.

Table 2. Mooney-Rivlin parameters (5 parameters).

Parameter	MPa	Parameter	MPa
C_{10}	0.21	C_{11}	-0.28
C_{01}	0.69	C_{20}	0.29
C_{02}	0.07	D_1^{-1}	4.15

3.2. High Density Polyethylene (HDPE)

HDPE is one of the most common plastics used in the field of prosthetic devices, playing a fundamental role for the large number of applications, because of their good mechanical properties and high range of deformations. It exhibits an elastic non-linear behavior, mechanical strength, good toughness, large flexibility in a wide temperature range and high ductility. The choice of HDPE is justified in cases where high mechanical performances and good chemical performance are required.

In the design relating to our prosthesis, this material is used for the construction of the shell representing the annulus into a natural disc and the connection with the vertebral bodies. The properties of the material, in a more complete way, were acquired by literature (Kurtz et al. 2007, La Rosa et al. 2018-1) and were described in Table 3. In particular, three different types of HDPE were used.

Table 3. Mechanical characteristics of the HDPE used for the prosthesis.

Material	Tensile Young modulus (MPa)	Yield (MPa)	Poisson coefficient	Density (kg/m^3)	Shear modulus (MPa)
HDPE1	400	35	0.38	930	145
HDPE2	500	40	0.38	930	181
HDPE3	600	45	0.38	930	217

3.3. Hydrogel

This material is a copolymer of polyacrylonitrile (non-hydrophilic) and polyacrylamide (hydrophilic); one of the properties of this material is the ability to inflate anisotropically (mainly along the axial direction). In the prostheses presented in this paper, the role of hydrogel is that of partially replacing the nucleus in order to improve the damping effect, to evenly distribute the pressure and to assure a partial hydrophilic behavior of the nucleus. From a mechanical point of view, this material has a highly non-linear elastic behavior, and the properties obtained from the literature (Stammen et al. 2001, Bertagnoli et al. 2005, Boelen et al. 2006, Borges et al. 2010, La Rosa et al. 2018-2) were assumed. Under compressive loading, when hydrated, hydrogel is almost incompressible and it transfers the pressure to the surrounding cage.

3.4. Gore-Tex

Polytetrafluoroethylene (PTFE) is considered a material with good biocompatibility, high chemical inertia that makes it stable over time, good anti-friction properties but modest mechanical properties. It can be loaded with other materials to obtain composites of greater mechanical properties, it also has excellent dielectric qualities. Its good properties as biocompatible material are well known and appreciate, in particular in cardio-vascular surgery.

A particular PTFE fabric is Gore-Tex (oriented microfibrils held together by solid nodes also in PTFE). Gore-Tex is typically constituted by different layers of thermo-mechanically expanded PTFE and other polymers, in order to realize fabrics resistant to the abrasion, allowing assuring the transpiration, however preventing fluid from escaping by means of the particular membrane. Gore-Tex fabrics are commonly used in a wide variety of applications such as technical fabrics, medical implants and sealants. The mechanical characteristics were derived by previous tests performed on some particular fabrics (La Rosa et al. 2018-2)

4. Analysis of results

As an example, the numerical results in terms of Von Mises stresses and displacements performed on the shell filled with silicone and belt thickness h = 1 mm are reported in Figures 3a-b for the HDPE 3 material. Table 4 shows the values of the reaction force for the different materials and dimensions.
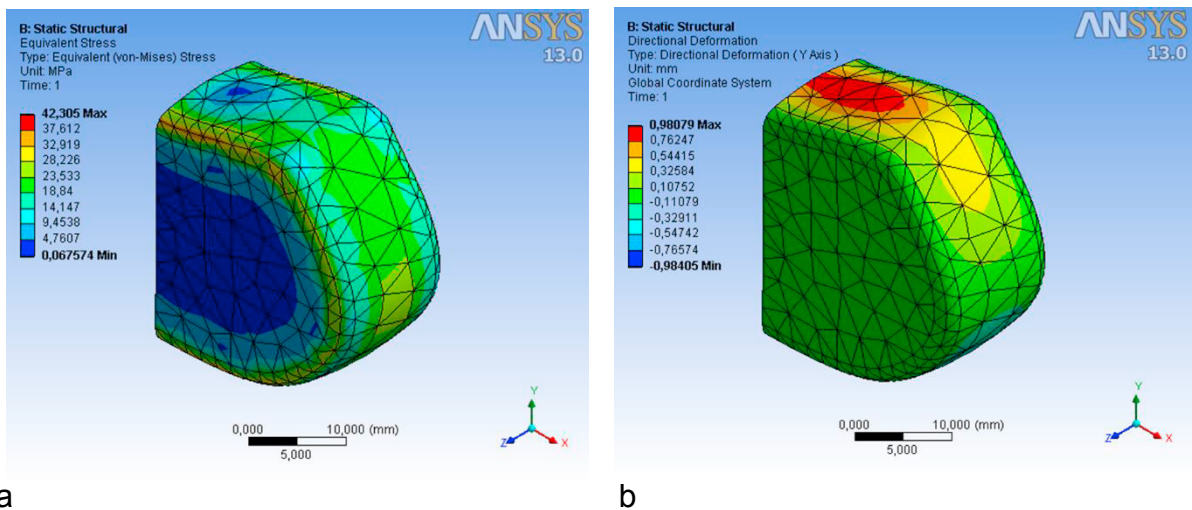

Figure 3. Von Mises stresses (a) and displacements (b) for the filled shell prosthesis with h =1 mm and HDPE 3.

The configurations able to give a sufficient safety factor (considering the model with half section) were essentially those highlighted in Table 4. They were subjected to the analysis with the shell void of its silicone core under displacements of 1 mm to 4 mm. The results showed that the maximum stress induced for the material of the shell,

even if strictly localized, is only bearable for displacements of the order of 1 mm (Figure 4a). Consequently, the attempt to make a shell resistant to compression but flexible enough to be decidedly reduced in volume in order to be inserted in the first surgical phase did not provide reliable results, at least with these geometries and materials. For this reason, therefore, we have moved on to the box model.

Table 4. Reaction forces for different geometries and HDPE types.

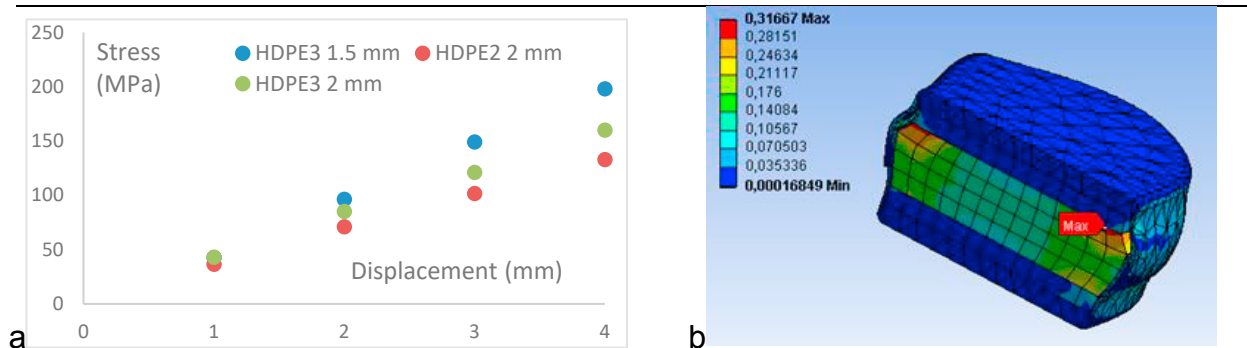| Material	h thickness (mm)	Reaction force (N)	Material	h thickness (mm)	Reaction force (N)	Material	h thickness (mm)	Reaction force (N)
HDPE1	0.5	729	HDPE2	0.5	870	HDPE3	0.5	1011
	1.0	1028		1.0	1255		1.0	1461
	1.5	1178		1.5	1432		1.5	<u>1687</u>
	2.0	1410		2.0	<u>1720</u>		2.0	<u>2030</u>

Figure 4, Maximum stress induced in the void shell model (a) and equivalent strain in the box model with top and bottom hydrogel insertion (b).

Also in this case, the simulation was performed in displacement control, moving the cover downwards by 1 mm. The results of the reaction forces are shown in Table 5, as a function of the model and of the materials.

Table 5. Reaction forces for different geometries and HDPE types.

Model	Material	Reaction force (N)	Equivalent strain	Model	Material	Reaction force (N)	Equivalent strain
Lateral hydrogel	HDPE1	1000	0.301	Lateral + bottom hydrogel	HDPE1	1147	0.253
	HDPE2	1181	0.308		HDPE2	<u>1375</u>	0.253
	HDPE3	<u>1360</u>	0.318				
Lateral + top-bottom hydrogel	HDPE1	1237	0.313	Lateral + top-bottom hydrogel + Gore-Tex	HDPE1	1270	0.391
	HDPE2	<u>1465</u>	0.317		HDPE2	<u>1498</u>	0.397
					HDPE3	<u>1726</u>	0.401

The underlined configurations still offer reliable solutions in terms of reaction force even if the lateral displacement, in some case lightly exceeding the maximum displacement admitted. Considering that the latter was very conservative and that some authors allow a total equivalent strain until $\varepsilon = 1.1$, the solution could be considered acceptable yet.

5. Conclusions

The study was performed with the aim of proposing a new intervertebral disc prosthesis more similar to the physiological one compared to those currently used in the surgical field. The proposal was to exploit the hyperelastic capacities of silicone, to be used in place of the pulpy nucleus, enclosed and contained within a more resistant plastic shell in plastic material, corresponding to the fibrous annulus. Moreover, the intention was to have a prosthesis that could easily be inserted during the first and most critical surgical phase, without the shock absorbing part in silicone,

which could be inserted in the semi-liquid phase at a later time through a syringe. This would have led to a lower implantation risk, considering the need to reduce the size of the prosthesis, in order to avoid any contact with the spinal cord.

For this reason, therefore, a shell structure was initially proposed and numerous numerical simulations were performed to verify its performance in terms of reaction force, material stress and functional deformation, as a function of the HDPE lateral wall thickness. The HDPE shell structure has shown good strength but is rigid in the numerical tests simulating the crushing of the shell without the silicone core.

A novel series of proposals were considered, realized by a box structure consisting of two separate parts, a base box and a floating cover with an overlapping of the lateral walls. Also in this case the silicone core could be inserted in a second phase. To complete the prosthesis, two slices of hydrogel (up and down) together with a Gore-Tex capsule were inserted. Hydrogel assures a better distribution of the pressure, as well as Gore-Tex improves the containment of the hyperelastic core, still showing good results.

The study carried out verified the capabilities of this kind of prosthesis and encourage the authors to prosecute along this way in order to realize a more reliable and physiologically-like device.

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