NUMERICAL STUDY OF THE BIOMIMETIC M6-C PROSTHESIS WITH VISCOELASTIC CORE

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In this work we present a new biomimetic disc prosthesis imitating the fibro-reinforced osmotic, and viscoelastic properties of the biological intervertebral disc (BID). For this, we proposed to study the second-generation biomimetic prosthesis "the M6-C prosthesis" which contains two metal plates, a core and a fiber fabric. First, a 3D model was established, the finite element analysis (FEA) under the ANSYS©2015 was conducted. Secondly, a biomimetic material, the silicone rubber, was compared with the polyethylene to find the material that mimics the behavior of a biological disk. Finally, the analysis of the results found the polymer has the same mechanical properties as the nucleus pulposus, in particular the viscoelastic behaviour compared with that of polyethylene.

Keywords: Disc prosthesis, M6-C prosthesis, Biomimetic, Viscoelastic, Hyper elastic.

Nomenclature

Variable	Definition
E_0	Elasticity module of spring
η	Viscosity coefficient of damper
σ	Stresses
σ_s	Spring stress
σ_d	Damper stress
ε	Deformations
ε_s	Deformation of spring
ε_d	Deformation of damper
σ_{ij}	Stress tensor
ε_{ij}	Strain tensor
E	Young's modulus
υ	Poisson's ratio
λ	Lamé coefficient
μ	Lamé coefficient
G	Shear modulus
K	Bulk modulus

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1. Introduction

The spine or rachis has essential functions to ensure the stability and mobility of the trunk and to protect the spinal cord [1, 29]. The movements of the spine are possible thanks to the existence of a complex articular system [2, 30]. This system contains a main element, which ensures the movement between the vertebrae is the intervertebral disc, which has 6 degrees of freedom (dof): three in rotations and three in translations. Some researchers considering the neck as a visco-elastic damped system gave an interpretation more realistic to the mechanics of the thorax-head bond assimilating it to a damping spring system [3].

During daily activities that lead to stress concentrations in the intervertebral disc, these stresses result in progressive wear of the intervertebral disc that generates a disease called degenerative disc disease [4]. In order to remedy this problem, a surgical operation is often necessary. This is to replace the intervertebral disc degenerated by a disc prosthesis to preserve biological mobility. The prosthesis must restore disc prostheses are designed to preserve the joint movement between the vertebrae, to avoid disadvantages of inter-somatic fusion, to achieve a quick recovery, and to help subjects return to their everyday life and work as soon as possible. The objectives of prosthetic surgery were to maintain the height of the disc, to eliminate all the pathological conditions of compression of the nerve [5]. There are varieties of prostheses with different components, as well as cinematic models are currently available for clinical use [5]. Figure 1 presents five models of cervical disc prostheses.

Fig. 1. Examples of cervical disc prostheses. From left to right Bryan, Mobi-C, Prodisc-C, Prestige, and Prestige LP (with spherical interlocking)

All these prostheses are in contact with the biological tissues and move between their components. It is therefore necessary to use materials with biomechanical features such as osseointegration bone, good resistance to friction, excellent corrosion resistance and biocompatibility. Among the most commonly used materials, we quote the cobalt alloy (CoCrMo), the titanium alloy (Ti6AL4V), stainless steel (316L), polyethylene (PE) and ceramics Alumina (Al2O3) and Zircon [6].

In biomechanics, there are four main types of friction: Metal / metal, Metal / Polyethylene, Ceramic / Ceramic, Ceramic / Polyethylene [7].

Virtually the metal / polyethylene couple is the most used in prostheses including the hip [8, 9, 10]. Nevertheless, these models still belong to the category ball and socket which does not imitate the behavior typically nonlinear of a biological intervertebral discs (BIDs).

The current Disc Prostheses (DP) have a ball and socket design, which, unlike the in vitro diagnostic procedure, are almost rigid in the axial direction and do not withstand moments of flexion or rotation. The movement they provide is therefore different from a biological intervertebral discs (BIDs). The current disc prostheses cause changes in range of motion [11], to a modification of the movement pattern and to a lordosis different segmental [12]. These modifications can cause an overload on the facet joints and increase the risk of degradation of these surfaces. Therefore, when a PD is not able to imitate the function of BID, this can affect the behavior of the movement segment, and have deleterious effects on the surrounding tissues [13].

To overcome the concerns and disadvantages current clinical devices, a new generation of disc prostheses DP is under development, diverging from the 'ball-and-socket' design. These PDs include the conforming nature of BID and aim to mimic the behavior physiological of BID more closely.

Work of Lee et al. [13], proposed a DP elastomer device, using a deformable material to mimic the deformable body construction of DIN. However, it has been found that a homogeneous elastomer has not been able to mimic the motion in axial compression and torsion with a set of material properties [13]. They have proposed an annulus-like part to the elastomer design, either by adding a stiffer elastomer layer or by adding fibers, hence the axial rigidity and twist has been improved in both versions.

In our work, we studied the biomechanical behavior of a biomimetic material by comparing the behavior of two materials, the first is polyethylene and the second is a material viscoelastic silicone rubber of a M6-C cervical prosthesis using finite element simulation with software ANSYS© 2015.

2. Description of the prosthesis M6-C

The M6-C Cervical Disc Prosthesis is a novel, next-generation artificial disc designed to replicate the anatomic, physiological, and biomechanical characteristics of the BID. The core is composed of a polycarbonate urethane polymeric material that is surrounded by a polyethylene woven-fiber construct. The compressible polymer core is designed to simulate the stiffness and function of the nucleus, and the fibers are designed to simulate the annulus. The fiber annulus is an assembly of high–tensile strength, ultrahigh-molecular weight polyethylene fibers wound in multiple redundant layers around the polymer nucleus, providing progressive resistance to motion. The core construct is attached to titanium alloy endplates to form the cervical disc prosthesis (Fig. 2).

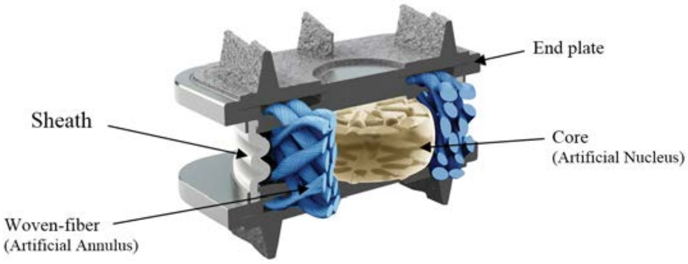


Fig. 2. Cervical disc prosthesis M6-C [14]

This design enables the device to have all six dof, including axial compression with independent angular motions in flexion-extension, lateral bending, and axial rotation, allowing independent translations along the three anatomic axes (table 1).

The disc prosthesis also has a polymer sheath encasing the core and fiber construct to inhibit any tissue ingrowth as well as to capture any potential wear debris. The endplates are attached to the vertebral body by three low-profile keels on the superior and inferior surfaces. The endplates and keels are coated with porous titanium to promote bone contact surface area and osseointegration [14].

Table 1

Main features of M6-C

Implant type	Mechanical
Concept	Viscoelastic core
Number of component	Five
plate alloy	Ti6Al4V
Core	Urethane polymer polycarbonate
Center of rotation	Mobile, self centering
Biomechanics	6 DOF, non-constrained prosthesis
Primary stability	3 pins
Secondary stability	Porous titanium coating

Several authors are doing experimental studies on the movement of the cervical spine. We have noticed that the movement is important at C5-C6 level by contribution to the other levels of the lower cervical spine.

The results of amplitude of flexion-extension in degrees at C5-C6 is presented in (Table 2) for the M6-C cervical prosthesis [15].

They found that motion quality assesses the extent to which the movement of an implanted functional spine unit approaches the movement of a healthy unit over the entire range of motion (ROM), not just its extremities. Thanks to biomechanical tests, a load curve as a function of the angular displacement ("kinematic signature") is generated which makes it possible to evaluate the quality parameters of the movement (Fig. 3).

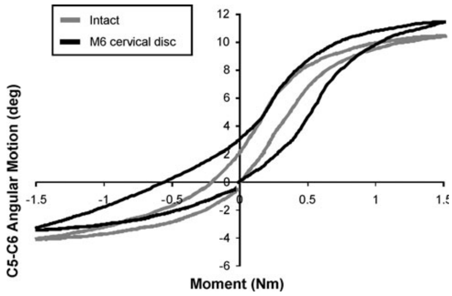


Fig. 3. Shape of load–displacement curves in flexion–extension [15].

Biomechanical results showing the M6 cervical disc prosthesis maintained total ROM. the intact disc with excellent Quality of Motion. The “kinematic signatures” of the intact disc and M6 cervical disc are nearly identical (Fig. 3), table 2.

Table 2

The flexion-extension of (C5-C6) and the M6-C prosthesis

authors	Watier [16]	Panjabi et al [17]	Frobin [18]	Cédric Barrey et al. [19]	A. G. Patwardhan et al. [15]
Year	1997	2001	2002	2012	2012
C5-C6	13.4°	9.9°	15°	12.5°	10°
M6-C	-	-	-	-	12°

This paper aim is to study the viscoelastic behavior of an artificial nucleus. We made a comparative study between two biomaterials: silicone rubber and polyethylene.

Silicone rubber exhibits a list of excellent characteristics including biocompatibility, oxidation resistance, thermal stability, climate resistance, low surface tension and unique high permeability because of the unique structure of polysiloxane [20]. Silicone rubber has a viscoelastic behavior with a Kelvin-Voigt rheological model, this model results from the parallel association of a module spring of elasticity E_0 and a viscosity coefficient damper η.

He is particularly well adapted to represent the behavior of a solid (figure 5).

3. Modeling of the M6-C prosthesis

Some researchers considering the neck as a viscoelastic damped system gave an interpretation more realistic of the mechanics of the thorax-head bond, assimilating it to a damping spring system [3]. This representation serves as the basis for most mathematical models hitherto realized (Fig. 4).

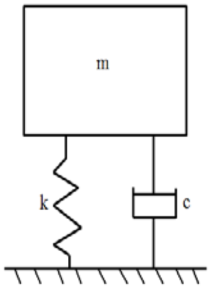


Fig. 4. Mechanical representation of the head-neck by a damping spring system

Witch, *m* = head, *k* = stiffness of the elastic system, *ç* = damping coefficient.

The M6-C prosthesis replaces the degenerated intervertebral disc, it mimics the functioning of an intact (BID) and thanks to the existence of a polymer core, and the M6-C prosthesis has the same rheological model as (BID) (Fig. 5).

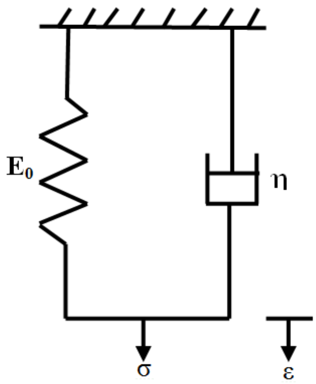


Fig. 5. Kelvin-Voigt's Model

Let the stresses, respectively in the spring and in the damper.

We have:

$$\begin{cases} \sigma_s = E_0 \varepsilon_s \\ \sigma_d = \eta \dfrac{d\varepsilon_d}{dt} \end{cases} \quad (1)$$

According to the laws of parallel association, the total deformation and stress are written:

$$\begin{cases} \varepsilon = \varepsilon_s = \varepsilon_d \\ \sigma = \sigma_s + \sigma_d \end{cases} \quad (2)$$

The rheological equation is written:

$$\sigma = E_0 \varepsilon + \eta \frac{d\varepsilon}{dt} \quad (3)$$

Solving the differential equation (3) gives the expression of the Kelvin-Voigt creep function:

$$J(t) = \frac{1}{E}(1 - e^{-\frac{t}{\tau}}) \quad (4)$$

With $\tau = \dfrac{\eta}{E_0}$, possessing the dimensions of a time is called delay time.

Relaxation is impossible with this model, because it cannot undergo an instantaneous deformation that would lead to infinite stress [21]

4. Behavior of an elastomer in a quasi-static regime

The simplest law of behavior for an elastic solid is naturally that of isotropic linear elasticity. The theory of linear elasticity lies within the framework of the description of slowly deformed solids, by imposing that the elastic law of behavior connecting the tensor of the stresses to that of the deformations is linear. When in addition the elastic solid has an isotropic behavior (that is to say, it does not privilege any direction of the space), one obtains the Hooke’s law [22]

$$\sigma_{ij} = \lambda \sum_{k=1}^{3} \varepsilon_{kk}(u)\delta_{ij} + 2\mu\varepsilon_{ij}(u) \ , \quad (5)$$

where λ and μ are Lamé coefficients. The linear system that constitutes equation (5) is easily reversed:

$$\varepsilon_{ij}(u) = \frac{1+\nu}{E}\sigma_{ij} - \frac{\nu}{E}\sum_{k=1}^{3}\sigma_{kk}\delta_{ij} \quad (6)$$

with $E = \dfrac{\mu(3\lambda + 2\mu)}{\lambda + \mu}$ as the Young's modulus

and $\nu = \dfrac{\lambda}{2(\lambda + \mu)}$ the Poisson's ratio.

In practice, it is the Young's modulus and Poisson's ratio that are known experimentally for a given homogeneous material and we can calculate the Lamé coefficients:

$$\begin{cases} \lambda = \dfrac{\nu E}{(1+\nu)(1-2\nu)} \\ \mu = \dfrac{E}{2(1+\nu)} \end{cases} \tag{7}$$

It is easy to calculate the relationships linking the Young's modulus *E*, the shear modulus *G*, the Poisson's ratio ν and the compressibility modulus ("bulk modulus") *K*:

$$\begin{cases} G = \dfrac{E}{2(1+\nu)} \\ K = \dfrac{E}{3(1-2\nu)} \\ E = \dfrac{9GK}{3K+G} \end{cases} \tag{8}$$

E and *G* reflect the rigidity of the material, while *K* gives the change in volume of a material when the pressure applied to it is changed. In general, *K* is given by:

$$K = -V\frac{dP}{dV} \tag{9}$$

In the literature dealing with the elasticity of silicone rubber, many theoretical models can be found; most approaches are based on a function of the strain energy density, or elastic potential *W*, corresponding to a change in Helmoltz free energy of the deforming material.

The simplest nonlinear law is certainly the neo-hookean law:

$$W = \frac{\mu}{2}(I_1 - 3) + \frac{K}{2}(J - 1)^2 \qquad (10)$$

where μ is the shear modulus

I_1 the 1st invariant of the Cauchy-Green tensor

K is the bulk modulus

J is the ratio of the deformed elastic volume to the initial volume [22].

5. Prosthetic design

In this study, we modeled the 3D M6-C prosthesis using SolidWorks© 2016 software. We chose a size of 14×17mm, with a height of 6.5 mm (Figure 6).

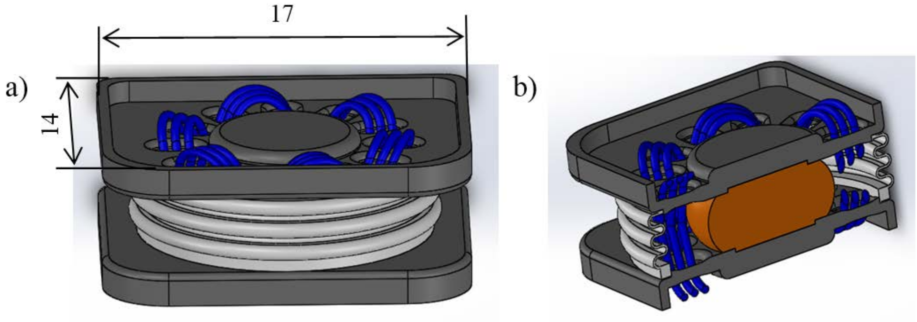


Fig. 6. The design of the cervical disc prosthesis M6-C
a) the total prosthesis, b) sectional view

Then, we imported this 3D prosthesis into the finite element simulation software ANSYS© 2015.

6. Boundary and loading conditions

To observe the biomechanical behavior of these two biomaterials (Table 3), the lower metal plate was totally fixed. Force and moment were calculated by the anthropometry and kinematics lever inter-support [3, 23], a vertical load of 73.6 N combined with a bending moment of 1.5 Nm were applied to the upper plate of the prosthesis [24], having a contact with friction between the plates and the woven-fiber with a coefficient of friction of 0.05.

All components of two models were meshed in standard mesh elements, 3-D type 8-node tetrahedra elements. It can tolerate irregular shapes without loss of precision. The mesh of the M6-C prosthesis contains 38808 tetrahedral elements and 81147 nodes (Figure 7).

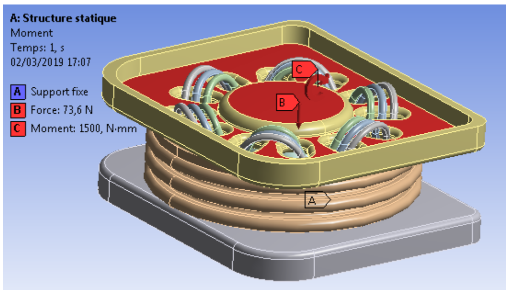


Fig. 7. Boundary conditions applied on M6-C

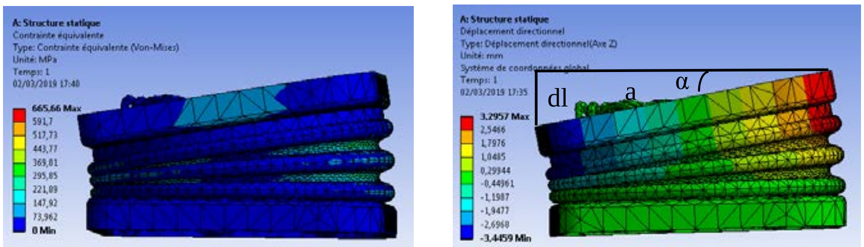
Table 3

Material properties used in the simulations [25, 26]

biomaterials	Young's modulus (MPa)	Poisson's ratio
Ti6Al4V	114000	0.32
Polyethylene	1100	0.49
Silicone rubber	50	0.47

7. Results and discussion

Study 1: Silicone rubber core



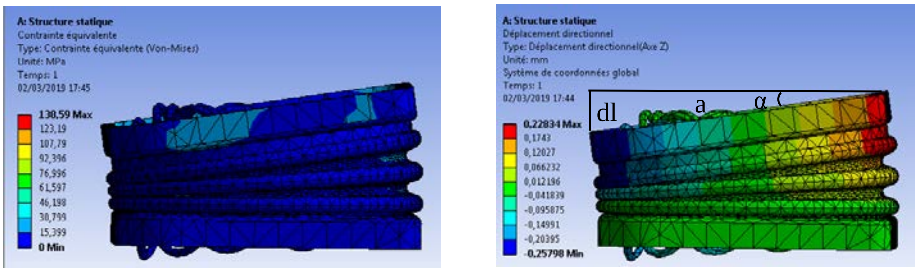
a) b)

Fig .8. Results of disc prosthesis with a polymer core: a)von-Mises stress, b) displacement along the Z axis

$$\sin\alpha = \frac{dl}{a} = \frac{3.2}{14}$$
$$\sin\alpha = 0.22$$
$$\alpha = 13^{\circ} \qquad (10)$$

Therefore, the flexion of the prosthesis with a core of viscoelastic material (silicone rubber) is 13°, (figure 8).

Study 2: Polyethylene core



a) b)

Fig. 9. Results of disc prosthesis with a polyethylene core:
a)von-Mises stress, b) directional displacement along the Z axis

$$\sin\alpha = \frac{dl}{a} = \frac{0.22}{14}$$
$$\sin\alpha = 0.016$$
$$\alpha = 0.90^{\circ} \quad (11)$$

Therefore, the flexion of the prosthesis with a polyethylene core is 0.90°, (figure 9).

The behavior of the pure elastomer is called linear viscoelastic, since the deformation of the sample can be described as the sum of independent elastic and viscous components [22].

In the first case, for the silicone rubber core, the von Mises stress of 665 MPa is concentrated on the upper plate of the prosthesis and is below the elastic limit of the Ti6AL4V titanium alloy, and the displacement along the Z axis is of the order of 3.2 mm (figure 8). Using the trigonometric equation (10), we divided the displacement over the width of the prosthesis to find the sinus of the nail-bending angle. We found the angle of flexion α= 13° of the prosthesis under the force 73.6 N and the moment of flexion of 1.5 Nm. Or we noticed that this angle of flexion in simulation is closer than the flexion of a biological disc (BID) and even the M-6 prosthesis in experimental study, see the study by Patwardhan et al. [15]. The M6-C prosthesis is constituted by an internal silicone rubber core and an external annulus in polyethylene fabric, belting the core and containing the pressure transmitted by the compressed core, the simulation performed on this prosthesis have good results in terms of confining the pressure generated on the silicone rubber core. It showed similar behavior to the natural human disk, added to the biocompatibility and non-biodegradability [31].

In the second, case where the polyethylene core von Mises stress of 138 MPa is concentrated on the core and is below the elastic limit of polyethylene. The directional displacement along the Z axis is of the order of 0.2 mm (Fig. 9). Using the trigonometric equation (11) we found that the bending angle is α = 0.90°, so this value confirms that the polyethylene cannot mimic the behavior of nucleus pulposus.

Figure 10, shows a curve of flexion-extension as a function of moment applied on the M6-C prosthesis. Range of motion (ROM) was calculated in flexion–extension under a 1.5 Nm moment combined with vertical load of 73.6 N using the trigonometric equation.

The horizontal axis (x) shows the moment variation in Nm, and the vertical axis (y) shows the angular movement in degrees

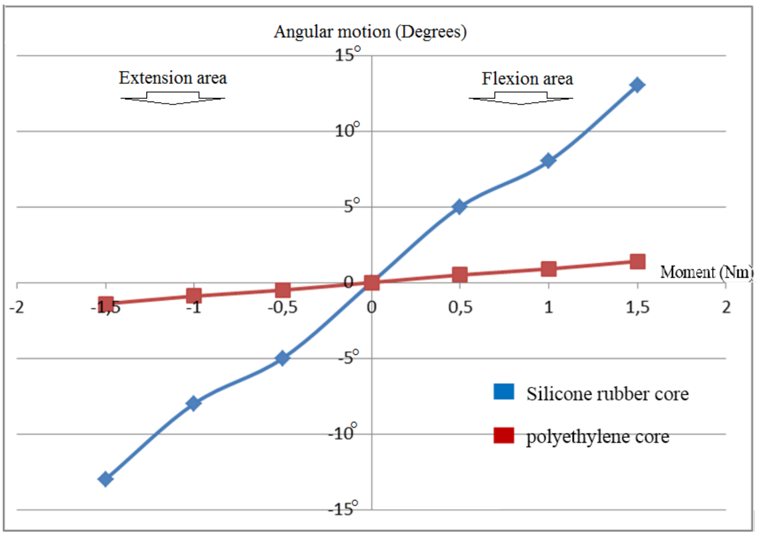


Fig. 10. Allure of Load–displacement curves in flexion–extension

We observed that the viscoelastic material (silicone rubber) mimics the behavior of nucleus pulposus, which comprises about 85% of water and is in the form of a gel, incompressible in the case of an adolescent, which becomes more and more fibrous in the adult body. It is mobile, deformable but incompressible, distributing pressure in all directions and damping shocks [27, 28].

8. Conclusion

Biomechanical testing with the M6-C artificial cervical disc has demonstrated equivalent quality of motion, compared to the healthy disc. The innovative artificial fiber annulus and nucleus construct of the M6-C is the critical component in replicating this physiologic motion, as it is designed to provide the necessary restraint and control needed throughout the spine’s natural range of motion.

We concluded that the hypothesis, the more we imitate the structure and material of a biological disc, the more we imitate its functionality and prove its effectiveness. The silicone rubber material has a viscoelastic behavior closer to the nucleus pulposus, and this material has the same rheological pattern (Kelvin-Voigt), which help the prosthesis imitating the functioning of a biological disc. Hence the interest of its use by considering this viscoelastic material.

Future works for further research: -Simulate this prosthesis in a model that contains vertebrae, ligaments, and intervertebral discs. -Make an experimental study of this prosthesis with a silicone rubber core. -A clinical study of this prosthesis contains a silicone rubber core.

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