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THE INFLUENCE OF BEARING MATERIAL ON THE WEAR PRODUCED, APPLICATION ON THE PRODISC-C CERVICAL PROSTHESIS

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Cervical disc prostheses are designed to replace the degenerated intervertebral disc and recover movement between the vertebrae. These prostheses are made of at least two elements with a ball and socket design; this allows movement between the elements. The articular surfaces wear out, the polyethylene cores deteriorate (failure of polyethylene), and produce wear debris. This study focused on the Prodisc-C cervical disc prosthesis model with the design ball and socket and three degrees of freedom (3 DOF). The aim is to clarify the difference between the two bearings materials, Metal-on-Polyethylene (MoP) and Metal-on-Poly-ether-ether-ketone (MoPEEK), in terms of contact and wear. We designed this prosthesis model in 3D using Solidworks design software. Then, we imported this model to the Ansys Workbench simulation software to do the numerical analysis. We have fixed the lower plate and a fixed compressive load of 150 N was first applied on the upper plate, Next, this compressive load was combined with a rotational displacement of 7.5° in flexion, 6° in lateral bending, and 4° in axial rotation on the upper plate. After the simulation, we found that the contact pressure for the bearing material MoP is 5.53 MPa and justified this value using the Hertzian theory P_0 = 4.9 MPa. Then the contact pressure for the bearing material MoPEEK is 11.09 MPa, justified by the Hertzian theory P_0 = 10.74 MPa. The clinical reference polyethylene-on-cobalt alloy (prosthesis with polyethylene core MoP) was 1.05mm3/million cycles, compared to 0.83 mm3/million cycles MoPEEK, a 20.95% discount has been won.

Keywords: Disc prosthesis, contact pressure, sliding distance, Hertzian contact, Archard law.

Nomenclature

Variable	Definition
R1	Ball radius
R2	Socket radius
c	Radial clearance
E*	Equivalent modulus of elasticity
Rx	Equivalent radius
F_n	Normal force
a	Semi-axis of Hertzian contact ellipse
P_0	Maximum pressure (Hertzian theory)
$\Sigma\rho$	Curvatures sum
E	Young's modulus
υ	Poisson's ratio
W_V	Volume wear
Kw	Wear coefficient
P	Contact pressure
A	Contact area
SL	Sliding distance

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1. Introduction

Total replacement of human joints (hip, knee, cervical disc, lumbar disc, shoulder, etc.) is a well-established treatment option for treating degenerative diseases [1]. Discs prostheses are designed to replace degenerated intervertebral discs, recover movement between vertebrae, reduce pain and preserve the expected average height of the biological disc. Disc prosthesis consists of at least two parts connected; the first contact model was proposed in 1881by Hertz [2].

One of the issues concerning artificial disc prostheses is the long-term wear characteristics of the implant components and whether biologically activewear particles may be generated during the lifetime of the implant [3, 4, 5]. The study results of André van Ooij et al. [6] demonstrate the presence of polyethylene (UHMWPE) wear particles in periprosthetic tissue in patients after 6.5 and 12.9 years of implantation. So the wear debris is the consequence of degradation of the articular surfaces; it affects the primary function of the prosthetic disc, which is to maintain the movement of the vertebrae; the wear debris initiates inflammation responsible for periprosthetic osteolysis and bone resorption at the implant-bone interfaces [7]. UHMWPE's wear particlestend to be spherical and range between 0.5 and 10 microns in diameter [8, 9]. The long history of hip and knee prostheses shows that articulating prostheses produce wear debris; this problem also affects disc prostheses [10]. In hip arthroplasty, it was noticed that Metal-on-Polyethylene (MoP) bearing surfaces made high volume wear rates compared to Metal-on-Metal (MoM) devices. UHMWPE joints can wear at a rate of over 100 microns per year [11]. Another study by (Lee et al., 2008) [12] on hip replacement implants indicates that the wear rate of MoM bearing surfaces is more minor than MoP combinations [12]. This prompted us to conduct this study to determine the best bearing materials that produce less wear debris. Therefore, we can say that the wear causes mechanical problems (the failure of the PE components, the positioning of the prostheses was not ideal) [6] and biological (the presence of the wear particles of the PE in the periprosthetic tissues in patients after 6.5 to 12.9 years of implantation, and lead to osteolysis) [6]. Polyether-Ether-Ether-Ketone (PEEK) is a material with great potential for cervical total disc replacement. This material generally shows high radiation and thermal aging resistance with good mechanical and tribological performance [13]. Shepherd and colleagues [14] measured a mean wear rate of 2.5 mg/Mega-cycles for the NuNecs cervical disc prosthesis and designed the two-piece Polyetheretherketone PEEK-on-PEEK and adopted the conventional ball-in-socket design configuration. Since PEEK belongs to the polymer family but has more brutal characteristics than polyethylene, it has been proposed to replace polyethylene with PEEK to minimize the production of wear debris.

This article aims to study the influence of the change of bearing materials Metal-on-Polyethylene (MoP) and Metal-on-PEEK (MoPEEK) on the maximum pressure that occurs in disc prostheses and the production of wear debris.

2. Material and method

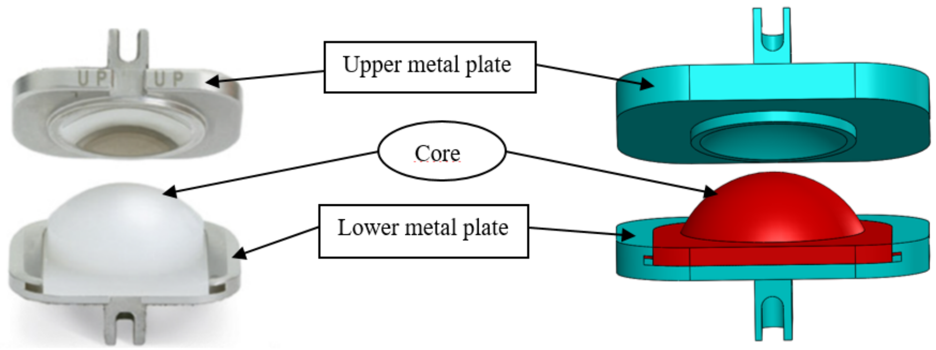
2.1. Geometry of disc prostheses

The mechanical disc prosthesis consists of at least two components [15]; there are several models of disc prosthesis with different degrees of freedom (DOF), 6 DOF like Brayane, 5 DOF like Mobi-C, 4DOF like Prestige LP, and 3DOF like Prodisc-C. In this study, we focus on the Prodisc-C prosthesis with 3 DOF.

The Prodisc-C model consists of three elements, an upper metal plate with a concave articulation surface in CoCrMo cobalt alloy, a lower metal plate in CoCrMo cobalt alloy, and a core with a convex articulation surface in ultra-high molecular weight polyethylene (UHMWPE).

The bearing surface is a ball and socket design with a convex dome core and a concave articulation surface in the upper metal plate; this design allows rotation on all three axes, with the constraint of translation.

The two metallic plates, both upper and lower, have slotted keels to provide initial bony fixation and a titanium plasma spray backing for bony ingrowth (Fig. 1). The fixed center of rotation is inferior to the disk space [16]. According to the Prodisc-C operating technical catalog [17], there are six sizes of this model M, MD, L, LD, XL, XLD, with Three heights (5, 6, and 7 mm) are available for adjustment of the implant to dimensions of the disc of each patient. In this study, we chose the size L (14×17mm), with the optimal diameter d = 11mm (therefore R = 5.5 mm) found in the study by Amadji et al. [18].



a) ProDisc-C cervical disk prosthesis [16]　　　b) design of the Prodisc-C prosthesis

Fig. 1. Geometric and functional description of Prodisc-C prosthesis

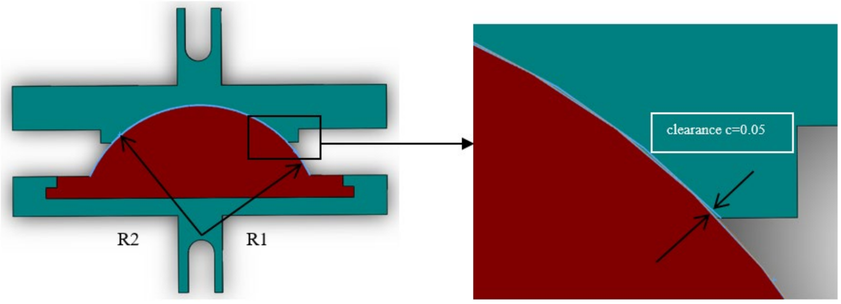


Fig. 2. Illustration of the clearance between ball and socket

2.2. Materials Selection

The biomaterials used in disc prostheses must have good corrosion resistance, good biocompatibility, and excellent resistance to friction. In this study, we focus on three biomaterials, the cobalt alloy CoCrMo, polyethylene (UHMWPE), and the PEEK (Table 1), where we studied the same Prodisc-C prosthesis model, with two different bearing materials, case 1 with CoCrMo-on-Polyethylene (MoP), and case 2 with CoCrMo-on-PEKK, the ball radius R1 is considered 5.5 mm, the socket radius R2 is 5.55 mm, and radial clearance c is 0.05 mm (Fig. 2).

Table 1.

The mechanical characteristics of the biomaterials used in the simulations [19, 20]

Biomaterials	***E Young's modulus MPa***	***υ Poisson coefficient***
CoCrMo alloy	210000	*0.3*
Polyethylene UHMWPE	1000	*0.4*
PEKK	3600	*0.38*

2.3. Hertzian contact theory

the ball and socket geometry is equivalent to the ball on plane geometry, defined by the equal radius Rx and equivalent modulus of elasticity E* [21, 22]:

$$R_x = \frac{R_1.R_2}{R_2 - R_1} = \frac{R_1.(R_1 + c)}{c} \tag{1}$$

$$\frac{1}{E*} = \frac{1}{2}.\left(\frac{1-v_1^2}{E_1} + \frac{1-v_1^2}{E_2}\right) \tag{2}$$

The equivalent elastic modulus and friction coefficient values for CoCrMo-on-Polyethylene bearing materials are 2369 MPa and 0.07, respectively.

The maximum pressure that occurs between the articular surfaces (ball and socket) of the disc prosthesis could be calculated with the following formula [19]:

$$P_o = \frac{3.F_n}{2.\pi.a^2} \tag{3}$$

Where: Fn is the normal force, and a is the semi-axis of the Hertzian contact ellipse. Semi-axis of the contact ellipse is given by:

$$a = \sqrt[3]{\frac{3.F_n}{E^*.\sum \rho}} \qquad (4)$$

Where Σρ is the sum of the curvatures and is defined by:

$$\sum \rho = 2.\left(\frac{1}{R_1} - \frac{1}{R_1 + c}\right) \qquad (5)$$

The theoretical estimations of maximum pressure have been done only in dry conditions.

2.4. Wear analysis

The wear distribution on the bearing surface is calculated on the basis of the theory wear between sliding bodies proposed by Archard (1953). One of the main limitations of tribology theory is the fact that it relies heavily on empirically determined proportionality constants, which are determined for specific cases [23].

The linear wear is computed from Archard law [23]

$$W_L = K_w\, P\, S_L\, (mm) \qquad (6)$$

Where Kw is the wear coefficient, P is the contact pressure, and S_L is the sliding distance.

The volumetric wear is obtained from the product of the linear wear by the contact area A

$$W_V = K_w\, P\, S_L\, A\, (mm^3) \qquad (7)$$

Where:
W_V = Volume wear (mm^3)
K_w = Wear coefficient (mm^3/N-mm)
P = Contact pressure (MPa)
A = Contact area (mm^2)
S_L = Sliding distance (mm)
This law is mainly utilized for the evaluation of abrasion and adhesion wear. The wear coefficient Kw that wer used for metal-on-polythylene and metal-on-PEEK 19.84 x 10^{-10} mm^2/N-mm [24].

2.5. Mesh generation

We did a convergence study with five different element sizes (2, 1.5, 1, 0.75, 0.5 mm), where we noticed that after the 0.75 mm size, the contact pressure stabilizes at the value of 6.5 MPa. And the von Mises stress stabilizes at the importance of 29.6 MPa (Figure 3). In our work, we made the study with the fifth size (0.5 mm) to facilitate the numerical calculation (Figure 4).

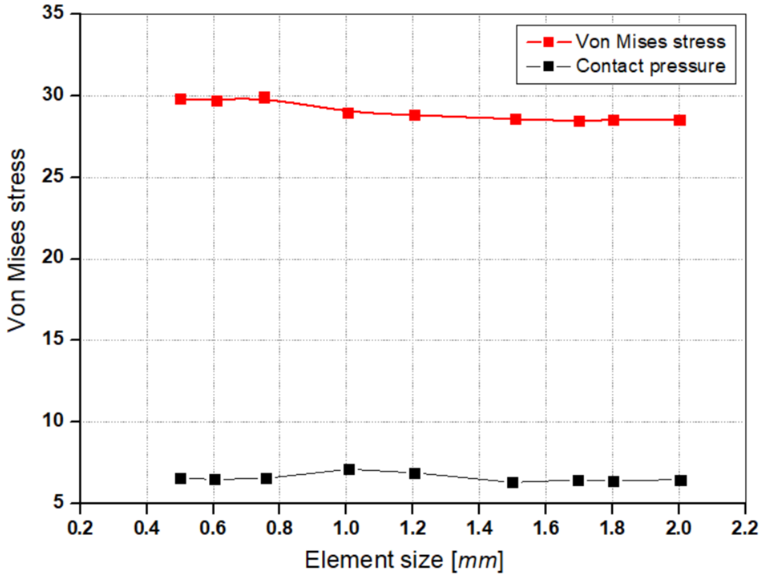
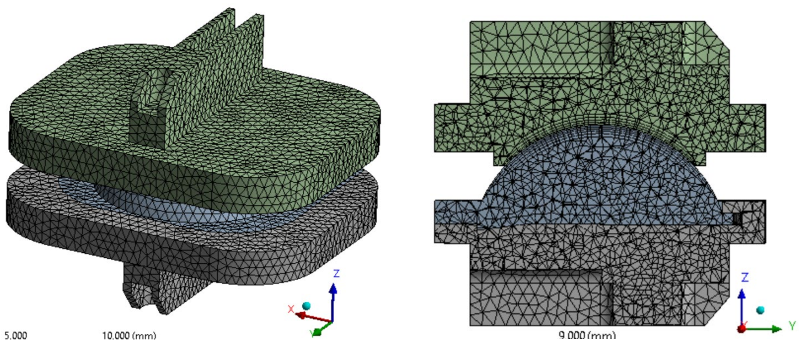


Fig. 3. Meshes convergence

The Prodisc-C prosthesis mesh was performed using commercial ANSYS 18.0 software using the ten tetrahedral node elements (Tet10). The types SOLID187 with 73549 elements and SOLID186 with 5970 elements were used for the solid assembly parts of the disc prosthesis. The features CONTA174 with 7307 elements, TARGE170 with 4838 elements, and SURF154 with 1824 elements were used to define the contact surfaces, whose total is 93488 elements and 129720 nodes (Figure 4).


a) Full model b) Cut view
Fig. 4. Meshes of the Prodisc-C

To locate the concentration of the contact pressure and Von-Mises stress, we applied the boundary conditions following; the Lower Metal Plate (LMP) has been completely fixed, the average weight of the head is 5Kg, and by inter-support lever kinematics, we find that the force applied to the cervical spine is 73.6N [25, 26, 27]. to check the efficiency of this prosthesis model we have used the double of this value which is 150N [7]. Therefore, the maximum compressive loading for the cervical disc was assumed to be 150 N, selected according to the recommended value from the ISO 18192-1 standard for testing intervertebral disc prostheses [28], combined with 7.5° angular displacement to simulate flexion motion, 6° to simulate lateral bending, and 4° to simulate axial rotation (Figure 5), according to Song Wang et al. [29], and Sanghita Bhattacharya et al. [7] we did only a quarter (25%) of the cycle, so we must multiply the wear volume results by four. A constant isotropic coefficient of friction of 0.07 [19] was used for the CoCrMo-on-UHMWPE and CoCrMo-on-PEEK [19].

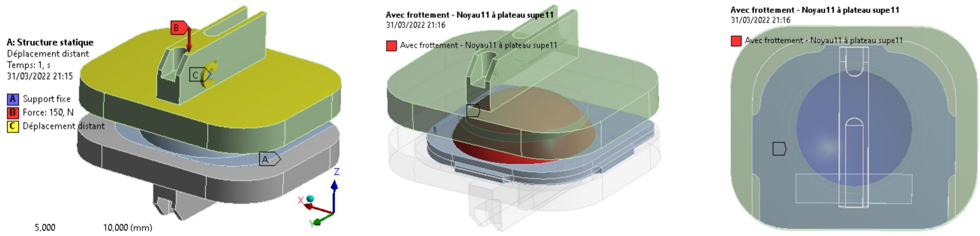


Figure 5. The boundary conditions applied

3. Results and discussions

The Von-Mises stress contour is illustrated in Figure 6, where we noticed that the stress is significant and almost stable (34.9 MPa to 36.1 MPa) for the prosthesis, which contains a PEEK core in all positions (flexion 0°, 8°, and lateral bending 8°) except in the axial rotation position a drop in this stress was recorded (0.27 MPa). The maximum Von-Mises stress is concentrated on the Upper Metal Plate (UMP), and along the peripheral edge of the concave articular surface of the UMP; on the other hand, the Von-Mises stress is low and stable (29.6 MPa) for the prosthesis with a polyethylene core in all positions (flexion 0°, 8°, and lateral bending 8°) except in the part of axial rotation a reduction in this stress was recorded (10.7 MPa), this stress is concentrated on along the periphery edge of the concave articular surface of the UMP.

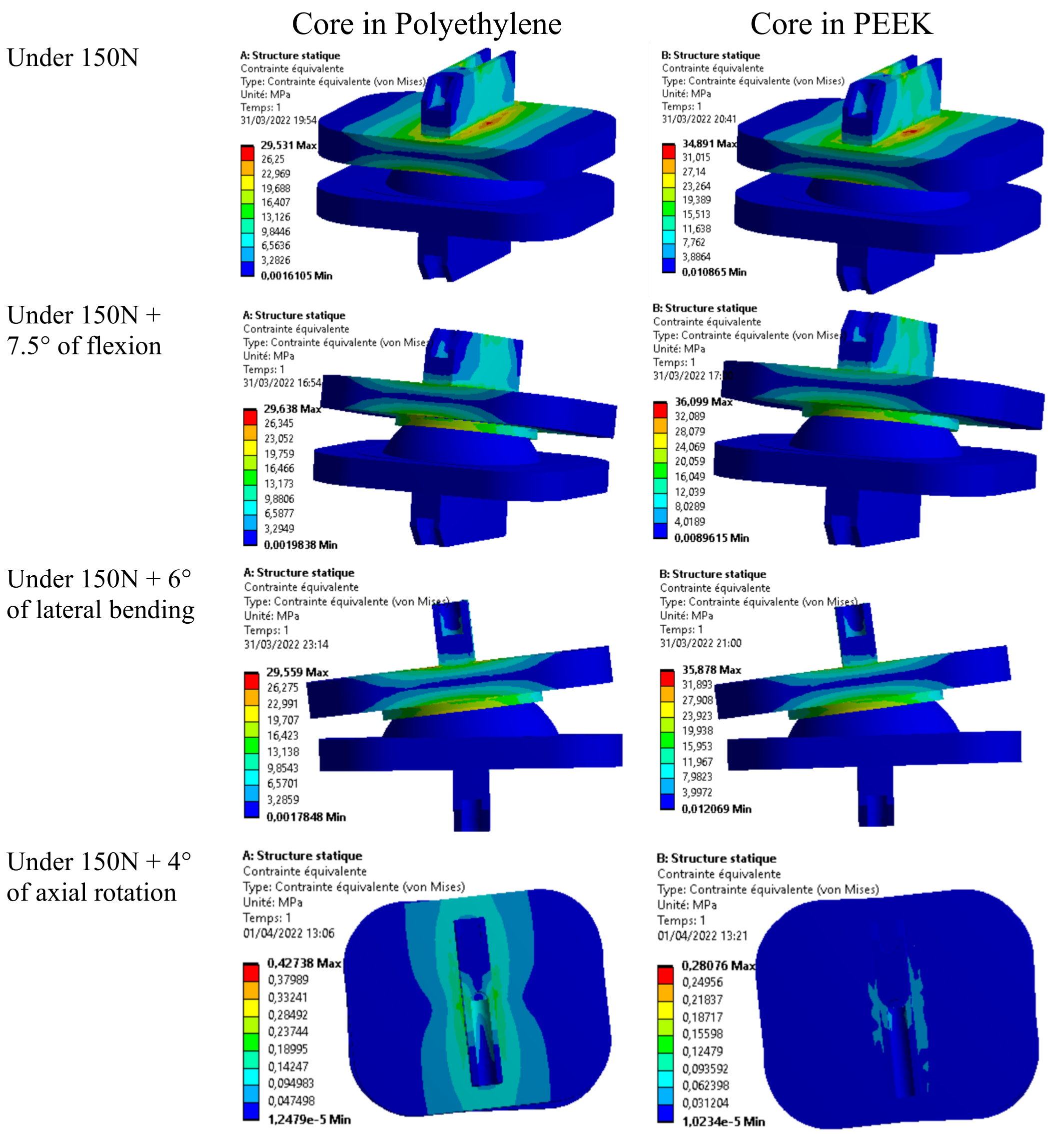


Figure 6. Comparison of the Von-Mises stress contour (MPa) between core in Polyethylene and core in PEEK

We calculated the equivalent modulus of elasticity E * of the two bearing materials using equation (2); we found that E*(CoCrMo-on-Polyethylene)= 2369 MPa, and E*(CoCrMo-on-PEEK)= 8323.27 MPa.

Then using equations (3, 4, and 5), we get:

$$\sum \rho = 0.0034$$

Table 2.

Presentation of theoretical results

E* (MoP)	a (MoP)	P_0 (MoP)	E* (MoPEEK)	a (MoPEEK)	P_0 (MoPEEK)
2369 MPa	3.82 mm	4.9 MPa	8323.27 MPa	2.51 mm	11.33 MPa

The maximum contact pressure was 5.53 MPa concentrated on the top of the dome in the Prodisc-C prosthesis with a polyethylene core, verified by equation (3), where we found that P0 = 4.9 MPa. and 10.74 MPa for Prodisc-C with a PEEK core, verified by equation (3) where we found that P0 = 11.33 MPa under the same boundary and load conditions at 150 N as the normal force (Figure 7). Therefore we can mention that in the bearing material Metal-on-Polyethylene the semi-axis of the contact area a = 3.82 mm is essential compared to the bearing material Metal-on-PEEK a = 2.51 mm. It is crucial to select the correct long-term implantable biomaterials for the various components of the disc prosthesis to maintain its design function [20]. We can also notice that the contact pressure corresponds to the direction of movement applied to the UMP (flexion, lateral bending, and axial rotation).

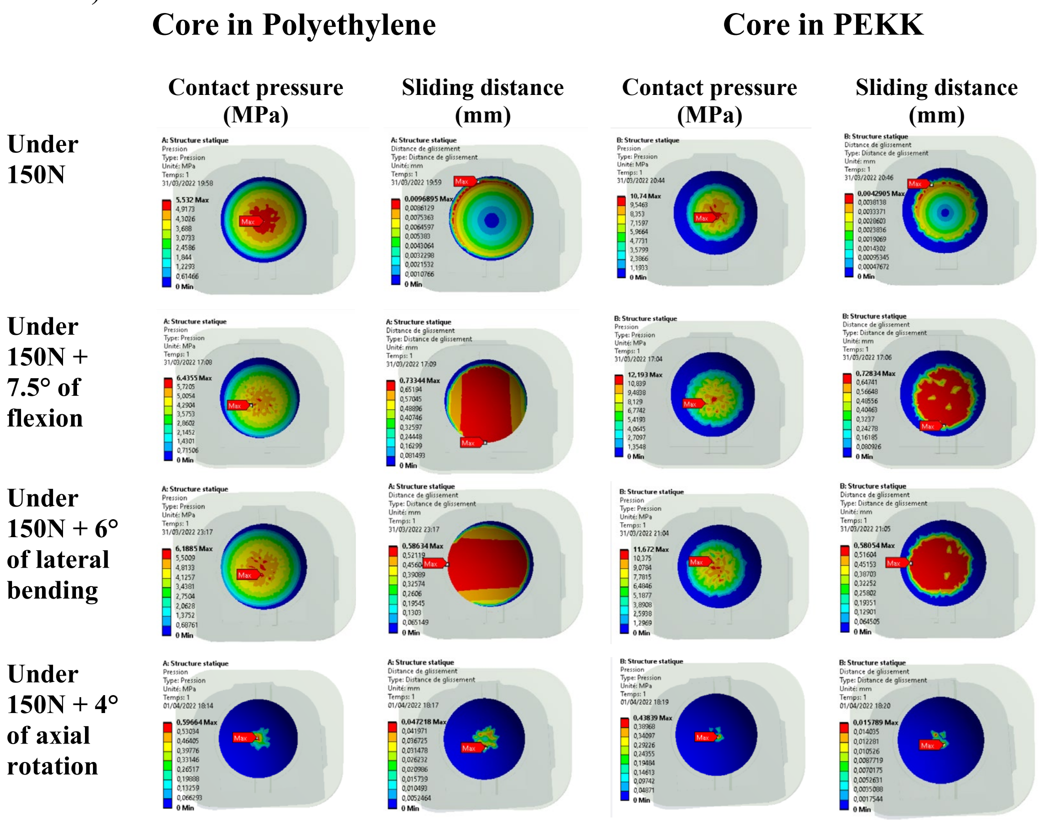


Fig. 7. Distribution of contact pressure, and sliding distance in contact surfaces

Fig. 8 presents a comparison between the theoretical values (Hertzian theory) and the numerical values (simulation of contact by finite element) of the contact pressure of the two cases (Prodisc-C with a polyethylene core and Prodisc-C with a core in PEEK). It has been noticed that the theoretical values are closer to the values of contact simulation and compatible with the increase in normal (axial) force applied. In addition, the contact pressure for the bearing material MoPEEK is always necessary (great) compared to the bearing material MoP. This is due to the clear difference between the equivalent modulus of elasticity E* values of each bearing material (2369 MPa for MoP and 8323.27MPa for MoPEEK). However, what concerns the frictional stress is that the bearing material MoP has a high value of 0.96 MPa compared to the bearing material MoPEEK 0.73 MPa. So we can say that the bearing material MoPEEK produces less wear debris.

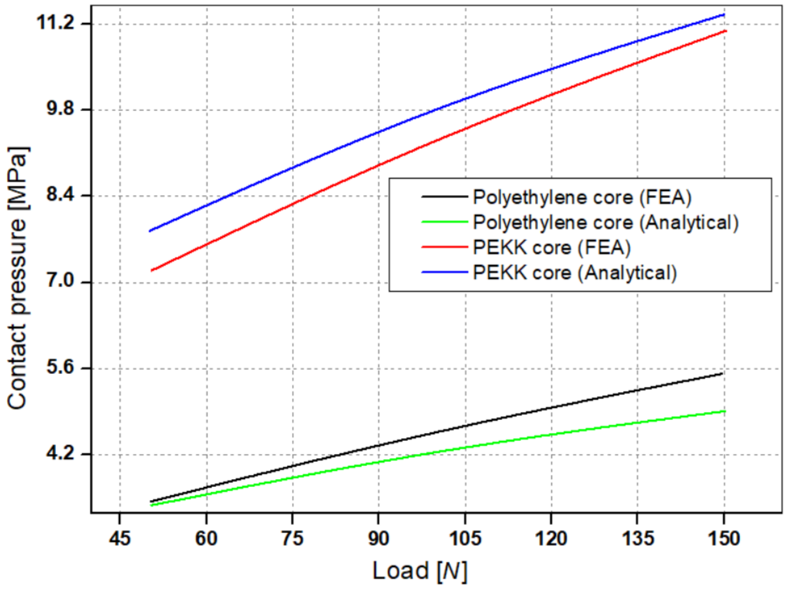


Fig. 8. Comparison of the contact pressure (MPa) between theoretical and simulation results

The effect of PEEK wears particles was investigated by various groups [30, 31] and summarized in a literature study by Stratton-Powell et al [32]. They found that the wear particles from the PEEK bearings were mainly in the phagocytozable size range, i.e., from 0.1 µm to 10 µm. The cytotoxicity of the PEEK particles was "within acceptable limits" compared to the UHMWPE control.

After validation of the contact pressure simulation results by the Hertzian theory, the sliding distance (SL) and the maximum contact pressure (P) were obtained from the results of ANSYS simulations. In addition to the know wear coefficient (KW) value 19.84 x 10^{-10} mm^2/N-mm [7, 33, 24]. The Contact area was calculated from the semi-axis of Hertzian contact ellipse (a); we moved on to the calculation of wear volume produced after a cycle of movement, using equation (7). The wear volume calculation results are shown in Table 3.

Table 3

	Bearing materials	P = Contact pressure (MPa)	S_L = Sliding distance (mm)	W_V = Volume wear (mm^3/cycle)
Under 150N	MoP	5.53	0.0096	1.93×10^{-8}
	MoPEEK	10.74	0.004	6.74×10^{-9}
Under 150N + 7.5° of flexion	MoP	6.43	0.73	1.7×10^{-6}
	MoPEEK	12.19	0.72	1.37×10^{-6}
Under 150N + 6° of lateral bending	MoP	6.18	0.58	1.3×10^{-6}
	MoPEEK	11.67	0.58	1.06×10^{-6}
Under 150N + 4° of axial rotation	MoP	0.59	0.047	1×10^{-8}
	MoPEEK	0.43	0.015	1.01×10^{-9}

We can notice that the volume of wear produced by the bearing material MoP is always higher than that made by the bearing material MoPEEK and in all the positions studied. Sanghita Bhattacharya et al. [7] reported an average volumetric wear rate was 1.70 mm^3/million cycles for the Prodisc-C model with bearing material MoP, Thomas M. Grupp et al. [28] reported a volumetric wear rate of 1.07 mm^3/million cycles for the activ®C model with bearing material PE-on-CoCr, In the current study, the average volumetric wear rate for three degrees of freedom 7.5° of flexion, 6° of lateral bending, and 4° of axial rotation is 1.05 mm^3/million cycles for the Prodisc-C model with bearing material MoP. And 0.83 mm^3/million cycles for the Prodisc-C model with taking material MoPEEK. We can also note the inverse proportion between each contact pressure and the resulting wear volume, the same balance between the contact pressure and the wear volume found by K.N. Chethan et al. [34].

4. Conclusion

After the numerical simulation of contact of the two cases of the Prodisc-C prosthesis (polyethylene core and PEEK core), and after checking the numerical contact pressure values (numerical simulation of contact) with the theoretical values (Hertzian theory). We can conclude that the contact pressure for the bearing material (MoPEEK) is essential in all positions (flexion, lateral bending, and axial rotation); on the other hand, the bearing material (MoP) has low-pressure values of contact, which confirms that the change of bearing material directly influences the contact pressure without forgetting the influence of the contact area. We can also notice that the volume of wear produced by the bearing material MoP is higher than the bearing material MoPEEK, a difference of 20.95%, which confirms that the bearing material (MoPEEK) has good friction resistance and produces less wear debris. We promote PEEK in prostheses cores to prevent damage (failure) to discs prostheses and reduce the rate of wear.

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