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THE RELIABILITY OF THE MEDICAL MECHANICAL SYSTEMS INTERVERTEBRAL DISC PROSTHESES

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Abstract: *The Intervertebral Disc Prostheses consist of a modular system and his function is based on low intervertebral friction. As a result of friction forces acting to the spine structures, the intervetebral disc prostheses can develop wear phenomena of the polymeric nucleus. From a tribological point of view the most important problems are the friction and the wear, specifics to the endoprostheses system, because these two phenomena dictate their durability. The development of friction processes at the most tribosystems level can be made in direct mode. In this sense, the development on the tribomodels who simulates the normal joint function is the most used solution. As a measuring method of these tribological parameters was used different versions of these laboratory installations or stands, we observed the wear of the moving prosthetic devices and we calculated the tribological parameters.*
Keywords: *prostheses, tribosystem, wear, stands, parameters.*

1. INTRODUCTION

The main function of the intervertebral disc is to transmit and attenuate compressive and torsional forces, and stabilize the intervertebral joint. Unfortunately, the disc may be displaced or damaged due to trauma or disease causing the nucleus to herniate and protrude into the vertebral canal or intervertebral foramen. A more desirable situation would involve removing the nucleus pulpous and part or all of the annulus fibrosis and implanting a suitable biofunctional equivalent. Such prosthesis should attenuate stresses and prevent abnormal stress at adjacent intervertebral joints.

The Intervertebral Disc Prostheses consist of a modular system and his function is based on low intervertebral friction. [2]

Fig. 1. Intervertebral disc prostheses [2]

As a result of friction forces acting to the spine structures, the intervetebral disc prostheses can develop wear phenomena of the polymeric nucleus. From a tribological point of view the most important problems are the friction and the wear, specifics to the endoprosthesis system, because these two phenomena dictate their durability.

2. APLICATION AREA

The artificial total disc is designed to replace the entire disc: annulus, nucleus, and (very often) endplates. Because the function of the endplate is more biological than biomechanical, it often does not need to be preserved after the disc is replaced with nonbiological material(s), unless the design entails articulating the artificial disc surface with the endplate for reduced friction and wear.[1] The artificial disc prostheses on the market (or in development) to date, however, have been reported to frequently undergo failure due to wear and degeneration of the materials, to the surgery techniques used for the implantation, or to the mismatch between the mechanical properties of the devices and the natural tissue. Local reactions to wear debris generated by intervertebral disc replacement device have been shown to lead to failure of some devices via osteolysis and component loosening.[4]

3. METHODS

The development of friction processes at the most tribosystems level can be made in direct mode. In this sense, the development on the tribomodels who simulates the normal joint function is the most used solution. As a measuring method of these tribological parameters were used different versions of these laboratory installations or stands were used in order to underline the importance of various different friction couples as well as specific electronic instrumentation very sensitive concerning real data measured.

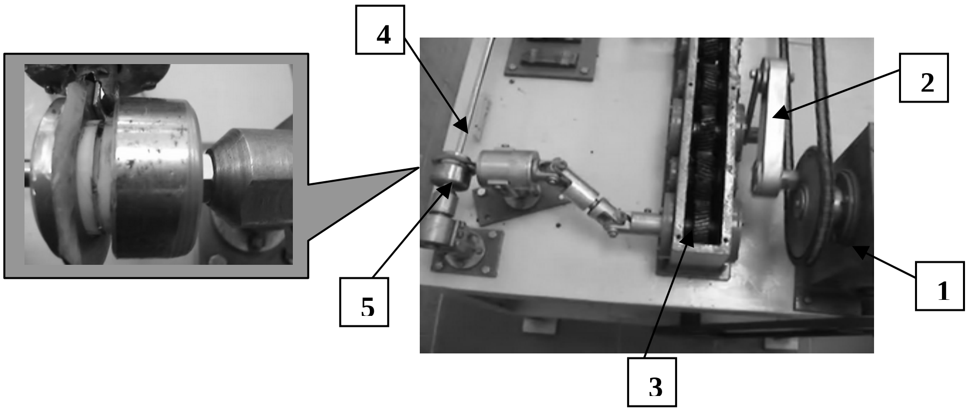

Fig. 2. The prosthesis prototype (left), the laboratory installation (right)
(1-reductor; 2- four sided mechanism; 3- denticulate wheels; 4- charge system; 5- prosthesis prototype)

This installation is conceived only for the measurement of friction coefficient in dynamical regime specific to the friction couple and the wear, but we can test only the biomaterials and not the endoprosthesis. The friction couples used consists of a UHMWPE nucleus for the disc nucleus and Co-Cr alloy for the endplates. The device is designed so that the movement is transferred from the engine using a reductor; the movement transformed in flexion-extension is then transferred to the prosthetic device through a four sided mechanism. The charge on the prosthetic device is transmitted from a cam that receives the movement from the same reductor. We measured the wear rates and we determined the wear type for the polymeric nucleus and for the metallic endplates.

4. WEAR PARAMETERS

For calculate the wear parameters we consider the second part of experiment after 20 000 and 30 000 charging cycles.

1. The gravimetrical wear was the first parameter mesured with a analitical balance and for 15 000 charging cycles.

$$Ug = 0,0015 \text{ g} = 1,5 \text{ [mg]} \quad (1)$$

Because this value is obtained for 15000 charging cycles this means: for a million charging cycles we have a wear by 0, 1 mg.

2. The velocity of gravimetrical wear was the second parameters calculated using gravimetrical wear and time.[2]

$$V_{ug} = \frac{U_g}{t}$$

(2)

Witch represent the rapport between gravimetrical wear and the time for making 15 000 charging cycles; that means 4, 25 h. We find the velocity of gravimetrical wear by 0,35 mg/h.

3. Volumetrically wear

Because we now the wear mass and the density of polyethylene – UHMWPE we can calculate the volumetrically wear.

$$\rho_{UHMWPE} = \frac{m}{V} \Rightarrow V = \frac{m}{\rho_{UHMWPE}} = \frac{1,5}{0,938} = 1,599\,\left[mm^3\right] \quad (3)$$

$$\rho_{UHMWPE} = 0,938\,\left[mg/mm^3\right]$$

$U_v = 1,599\ [mm^3]$

Were: ρ_{UHMWPE} - is the density of polyethylene, m - is the wear mass and U_v - is the volumetrically wear.

4. The velocity of volumetrically wear is the rapport between volumetrically wear and the time for 15 000 charging cycles.[2]

$$V_{uv} = \frac{U_v}{t} = \frac{1,599}{4,25} = 0,37\,\left[mm^3/h\right] \quad (4)$$

Were: V_{uv} – is the velocity of volumetrically wear, U_v – volumetrically wear and t is time necessary for 15 000 cycles.

5. The intensity of gravimetrical wear is the rapport between the velocity of gravimetrical wear (2) and friction length (5).

$$\overline{\omega}(t) = 1,10556\,\left[rad/s\right]$$

$$r_{np} = 22,41\,\left[mm\right]$$

$$L_f = \left|\overline{\omega}(t)\right| \cdot \left(r_{np} \cdot 10^{-3}\right) = 1,10556 \cdot 22,41 \cdot 10^{-3} = 0,0247\,\left[mm\right] \quad (5)$$

$$I_g = \frac{V_{ug}}{L_f} = \frac{1,5}{0,0247 \cdot 10^3} = 0,0607\,[mg/km] \quad (6)$$

Were: I_g – is the intensity of gravimetrical wear,V_{ug} – is the velocity of gravimetrical wear and L_g – is the friction length.

6. The intensity of volumetrically wear is the rapport between the velocity of volumetrically wear (3) and friction length (5).

$$I_v = \frac{V_{uv}}{L_f} = \frac{1,599}{0,0247 \cdot 10^3} = 0,0647\,[mg/km] \quad (7)$$

Were: I_v – is the intensity of volumetrically wear, V_{uv} – is the velocity of volumetrically wear and L_f – is the friction length.

5. RESULTS

After each 50 000 cycles we weighted and measured the polymeric nuclei and every time the wear particles were collected. The polymeric nuclei are cleaned and retested after each 50 000 cycles using a high precision scales so we can determine both the gravimetrical and the volumetrically wear of the polymeric nucleus and the intensity of wear.

In the table 1 there are presented numerical values determined by the relations (2) to (7).

Table 1. Values of the wear parameters

Parameters					
Wear		**Velocity of wear**		**Intensity of wear**	
Type of wear	**Values**	**Type of velocity**	**Values**	**Type of intensity**	**Values**
G [mg]	1.5	G [mg/h]	0.35	G [mg/km]	0.0607
V [mm^3]	1.599	V [mm^3/h]	0.37	V [mm^3/km]	0.0647

Were: G = gravimetrical, V= volumetrically

Fig. 3. The effect of wear on the prosthetic components: metallic endplate (left) and polymeric nucleus (right).

In these figures we observed the wear effect, in the metallic endplate concavity at margins is present the wear area and at the polymeric nuclei surfaces we can see the wear particles, these are a mixture between polymeric and metal particles. The polymeric particles represent the most important part of wear particles and these have a irregular form at the beginning of experiment but in time this form transiting to the circularly form. The metallic particles are spherically to the beginning from the end of experiment.

6. CONCLUSIONS

In conclusion the wear phenomena for the disc prostheses occur in the same way as for the hip prostheses. We observed the wear of the moving prosthetic devices and the strongest wear was determined for the polymeric nucleus. For one million charging cycles we have a wear by 0.1 [mg] and the volumetrically wear for 15 000 cycles is 3.38 [mm^3]. The material most expose to wear is polyethylene and this represent the majority of wear material in all tribosystems composed by a polymer component and a metal component.

Because the osteolysis depend by the form, shape and dimensions of wear particles we must study in the future the wear particles by optical and electronically microscopy and determine the dimensions and the characteristics of these particles.

7. REFERENCES

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