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Statistical investigation of biological lubricants influence on the wear of endoprostheses

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The method for evaluating the influence of biological lubricants on the wear of endoprostheses is presented. Randomized block mathematical model for dispersion analysis is developed and calculations using experimental data are done. Experimental results allowing evaluation of the wear of endoprostheses using different lubricants are given.

Key words: acetabular part of the implant, the wear of the implant

1. Introduction

Nowadays, one of the most effective medical treatment procedures applied in oder to restore the movement of the joint destroyed due to illness or accident is the implantation of an artificial joint or its elements. The cost of such a treatment is quite high and because of a the limited service life of the implanted endoprostheses it becomes much more expensive. The durability of endoprostheses depends on many factors such as: endoprosthesis design, materials, fixation method, age of the patient and many other personal factors. So the main problem is how to lengthen the service life of endoprostheses. There are a number of scientific papers concerning the stress distribution that depends on the type and form of the implant [1], [3], [5], effect of implant materials [8], material manufacturing parameters [2], the method of implant fixation [4]–[7] and wear of the endoprosthesis [4], [5], [9]. The wear of an implant is the problem of a crucial importance. Small particles of the endoprosthesis subject to wear are shed into the surrounding synovial fluid and tissues. The body's immune system is trying unsuccessfully to digest these particles, which results in mechanical loosening of the implant. The wear of materials is considered as a serious problem which can be solved by a proper selecting the implant material and by investigating the possibility of additional lubrication of the artificial joints.

2. Method of experimental and statistical investigations

The influence of biological lubricants on the wear of endoprostheses was established by the methods of dispersion analysis. This is due to the fact that there is no possibility to make a quantitative evaluation of the effects of different biological lubricants on the wear of endoprostheses.

For the dispersion analysis the following parameters were selected. The loading force of 100, 300, 400, 800 N and four different types of lubrication (dry friction, blood serum, 15% polyvinylpyrrolidone solution, sodium hyaluronate "Fermathron"). The variety of the loading force applied is based on the fact that the mass of the patients, depending on their age (from 12 to 50), is different. We dealt with two age groups: young patients and grownups. So in this case in the randomised plan, there would be 16 different blocks. However, the statistical laws are valid only if the number of the experiments per one block is sufficiently large. For this reason experiments are repeated not less than ten times.

Table 1. Experimental results of the endoprosthesis wear (values of the wear are given in mg)

Factors	Loading force, N				The mean value of the row, $\bar{y}_{i\bullet}$	Standard deviations $\sigma_{i\bullet}$
	100	300	400	800		
Dry friction	4.47	5.81	8.49	11.18	7.49	0.82
Blood serum	2.91	4.95	5.53	7.28	5.17	0.49
Sodium hyaluronate "Fermathron"	2.27	3.86	4.31	5.68	4.03	0.39
15% polyvinylpyrrolidone solution	2.85	4.85	5.42	7.13	5.06	0.48
The mean value of the columns, $\bar{y}_{\bullet j}$	3.13	4.87	5.94	7.82	$\bar{y}_{\bullet\bullet}$	0,54
Standard deviations, $\sigma_{\bullet j}$	0.26	0.22	0.49	0.64	0.4	

Mean values of the row $(\bar{y}_{i\bullet})$, the columns $(\bar{y}_{\bullet j})$ and $(\bar{y}_{\bullet\bullet})$, r and t (table 1) are defined as follows:

$$\bar{y}_{i\bullet} = \frac{1}{t}\sum_{j=1}^{t} y_{ij}\,, \quad \bar{y}_{\bullet j} = \frac{1}{r}\sum_{i=1}^{r} y_{ij}\,, \quad \bar{y}_{\bullet\bullet} = \frac{1}{rt}\sum_{i=1}^{r}\sum_{j=1}^{t} y_{ij}\,, \quad r = 4, \quad t = 4. \tag{1}$$

Experimental results presented in figure 1 and in table 1 are different. However, we have to check whether these values belong to one or to some different general sets. For this reason we have to determine the standard deviations σ and according to the chosen probability value $p = 1 - \beta$ and number of the degrees of freedom $\nu = n - 1$ we will choose the value of the Student criteria t_β. In other words, we have to determine arithmetical mean value and to evaluate probable minimal and maximal deviation limits of this value. If all values fall under this deviation interval they all belong to the same general set. In other case, separate characteristics belong to different general sets.

In our case, $\nu = 10 - 1 = 9$, $p = 0.95$ and in the appropriate tables we found out that $t_\beta = 2.26$.

The standard deviations $\sigma_{\bullet j}$ and $\sigma_{i\bullet}$ are calculated according to the formulas:

$$\sigma_{\bullet j} = \sqrt{\frac{D_{\bullet j}}{n}}, \quad \sigma_{i\bullet} = \sqrt{\frac{D_{i\bullet}}{n}}, \tag{2}$$

where $D_{\bullet j}$ and $D_{i\bullet}$ are expressed as

$$D_{\bullet j} = \frac{1}{r}\sum_{i=1}^{r}(y_{ij} - \bar{y}_{\bullet j})^2, \quad D_{i\bullet} = \frac{1}{t}\sum_{j=1}^{t}(y_{ij} - \bar{y}_{i\bullet})^2. \tag{3}$$

The interval of dependence is given by the following formula:

$$I_\beta = (\bar{y}_{\bullet j} - t_\beta \sigma_{\bullet j;} \bar{y}_{\bullet j} + t_\beta \sigma_{\bullet j}). \tag{4}$$

The aim of these calculations is to determine whether or not our set belongs to the same general set.

For example, the value $\bar{y}_{ij}$ from table 1 is equal to 3.13 and its possible limits are

$y_{\bullet j} \pm t_\beta \sigma_{\bullet j}$ is $3.13 \pm 2.26 \times 0.26$: $y_1 = 3.13 - 0.588$ and $y_2 = 3.13 + 0.588$.

The interval of dependence $I_\beta = (2.542;\ 3.718)$. So we can say that 3 values belong to the same general set.

For further calculations we will use the method of dispersion analysis. The mathematical model is presented in table 2.

Table 2. Dispersion analysis method

The source of the variations	The number of degrees of freedom	The sum of squares	The mean value of squares
Loading force factor	$r - 1$	$\sigma_F = \frac{1}{t}\sum_{i=1}^{r} y_{\bullet j}^2 - \frac{y_{\bullet\bullet}^2}{rt}$	$\sigma^2 + \frac{t\sum\beta^2}{r-1}$
Lubricant factor	$t - 1$	$\sigma_L = \frac{1}{r}\sum_{i=1}^{t} y_{i\bullet}^2 - \frac{y_{\bullet\bullet}^2}{rt}$	$\sigma^2 + \frac{r\sum\gamma^2}{t-1}$
Differences	$(r - 1)(t - 1)$	$\sigma_D = \sum_{i=1}^{r}\sum_{j=1}^{t}(y_{ij} - \bar{y}_{i\bullet} + \bar{y}_{\bullet j} + y_{\bullet\bullet})^2$	σ^2
Total sum of the squares	$rt - 1$	$\sigma_{fs} = \sum_{i=1}^{r}\sum_{j=1}^{t}\left(y_{ij} - \frac{y_{\bullet\bullet}}{rt}\right)$	–

The parameters used in the method of dispersion analysis (table 2) are defined as follows:

$$y_{\bullet j} = \sum_{i=1}^{r} y_{ij}\,, \quad y_{i\bullet} = \sum_{j=1}^{t} y_{ij}\,, \quad y_{\bullet\bullet} = \sum_{i=1}^{r}\sum_{j=1}^{t} y_{ij}\,, \quad r = 4, \quad t = 4. \tag{5}$$

The values σ_F, σ_L, σ_S, σ_{fs} are calculated using the method presented in table 2.

Table 3. Results of dispersion analysis

The source of the variations	The number of degrees of freedom	The sum of squares	Mean value of total sum of squares	Mean value of squares
Loading force factor	3	25.59	8.53	$\sigma^2 + \frac{4}{3}\sum\beta^2$
Lubricant factor	3	46.35	15.45	$\sigma^2 + \frac{4}{3}\sum\gamma^2$
Differences	9	5.22	0.58	σ^2
Total sum of the squares	15	77.15	5.14	–

In our case, the number of degrees of freedom $\nu_1 = r - 1 = 3$ and $\nu_2 = 9$. When $\alpha = 0.05$ we have $F_\nu = 4.46$.

Now we calculate the ratio of $F_F = \sigma_F/\sigma_D$ = 25.59/5.22 = 4.9 and $F_L = \sigma_L/\sigma_D$ = 46.35/5.22 = 8.87 (table 3).

After evaluation of F_F and F_L with F_ν we can say that lubrication factor has a greater influence upon the wear of endoprostheses. In oder to determine the influence of different lubrication factors upon the wear of endoprostheses we have to calculate the following sums (see table 1):

$$\bar{b} = \frac{4.47 + 5.81 + 8.49 + 11.18}{4} = 7.49\,,$$

$$\bar{c} = \frac{2.91 + 4.95 + 5.53 + 7.28}{4} = 5.17\,,$$

$$\bar{d} = \frac{2.27 + 3.86 + 4.31 + 5.68}{4} = 4.03\,,$$

$$\bar{e} = \frac{2.85 + 4.85 + 5.42 + 7.13}{4} = 5.06\,,$$

where $\bar{b}, \bar{c}, \bar{d}, \bar{e}$ are mean values of the endoprosthesis wear for different lubrication factors.

Standard deviation of the mean value of the full square's sum is calculated:

$$S = \sqrt{\frac{\sigma_S}{4}} = \sqrt{\frac{0.58}{4}} = 0.381 \approx 0.4$$

The results of calculations are presented in table 4. They allow the conclusions that lubrication of the implant surface is very important and that artificial lubricants have proved better.

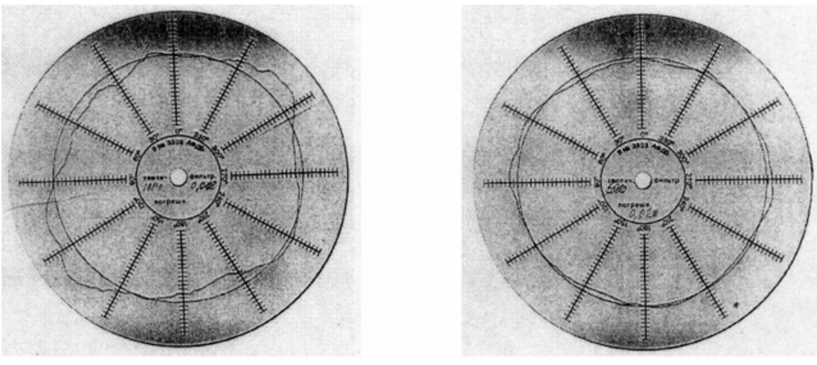
Table 4. The results of the influence of different lubrication factors upon the wear of endoprostheses

$\bar{b}$	$\bar{c}$	$\bar{d}$	$\bar{e}$	Standard deviation of the mean value of the total square's sum
7.49	5.17	4.03	5.06	±0.4

3. Technique of experimental research and analysis of results

The experiments were carried out in oder to evaluate the wear of endoprostheses lubricated with four different types of lubricants. All experiments were conducted under the following conditions: loading force – 100 N, speed of rotation – 450 rot/min and duration of one trial – 5 min. Each specimen was cooled and lubricated every 15 s. The results obtained were evaluated and compared.

The measurements were done by the tolerund. The results of the surface deviations of the stem ball of hip implant are shown in the figures 1 and 2.



a) b)

Fig. 1. Surface deviations of the hip implant (stem ball)
a) before the test (magnification – 1000×); b) after the test with blood serum (magnification – 500×)

Polyethylene like any other plastic ages and looses its elastic properties. For this reason it becomes more brittle and continuous cracks appear in the acetabular part of the implant. We suggest to use a metallic framework in order to reduce the appearance of the cracks in the acetabular part of the implant which allows lengthening the service life of the implant. The results of pilot experiment have shown that it is expedient to use this metallic framework in the acetabular part of the implant (figure 3) because it lengthens its durability and increases working reliability even if the cost of such acetabular parts increases.

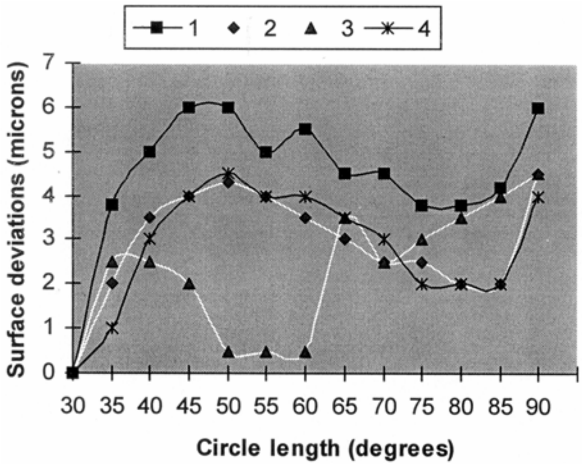


Fig. 2. Influence of different biological lubricants on the wear of endoprostheses:
1 – before tests, 2 – after the test with blood serum,
3 – after the test with sodium hyaluronate "Fermathron",
4 – after the test with 15% polyvinylpyrrolidone solution

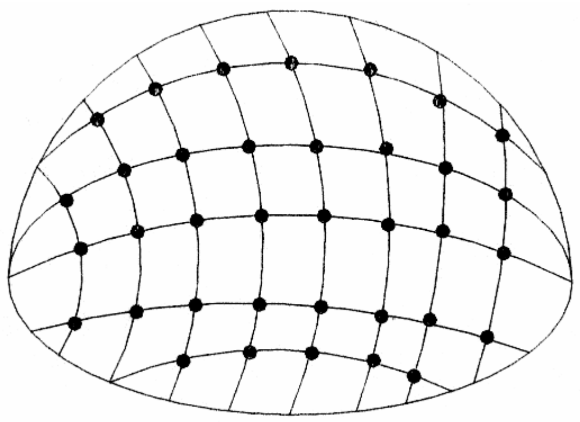


Fig. 3. Metallic framework of the acetabular part of the implant

Experimental results have shown that the endoprostheses wear according to a classical wear law.

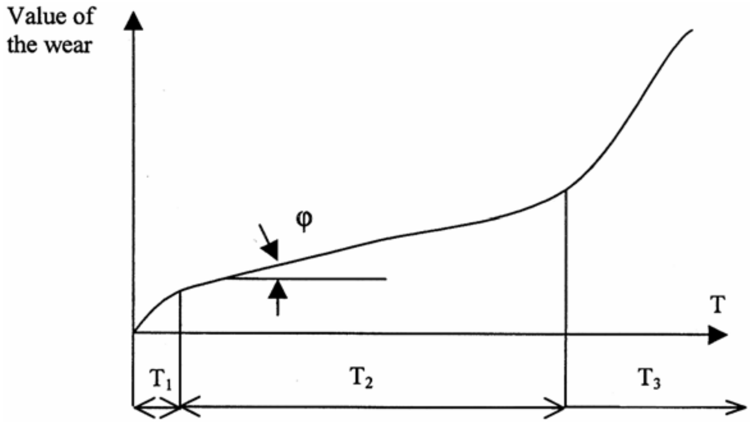


Fig. 4. Changes of endoprosthesis wear in the time

From figure 4 it is evident that 3 main wear stages can be distinguished. There is observed an increased wear in the two of them, i.e. during the time period T_1 the running-in of the implant occurs and during the time period T_3 – significant wearing stage. Usually the latter begins when polyethylene loses its elastic properties due to the ageing or due to some other reasons. During the time period T_2 there is continuos wear of the implant and its duration depends on the material properties, lubrication conditions, loading type and its intensity. The value of the angle φ also depends on the endoprosthesis material, thermal or other kind of material treatment, lubrication and loading conditions. The time period T_1 is approximately equal to 9 hours of continuos endoprosthesis working or it corresponds approximately to 32 000 cycles, or the man can cover the distance of approximately 19 200 m. The value of the angle φ, which characterises the wear of the acetabular part of the implant, can vary from arctan $2.4\cdot10^{-4}$ to arctan $3.5\cdot10^{-4}$ or it corresponds to $2.4\cdot10^{-4}$–$3.5\cdot10^{-4}$ mg per cycle, or these values can be expressed in other relative values. Artificial lubricants have shown lower wear value.

The strength and elastic characteristics of the acetabular part of the implant and the coefficient of the friction suffer mostly from the primary treatment of the polyethylene. The type of sterilisation of polyethylene and the types of lubricants used affect greatly the value of the coefficient of friction. For example, when sterilisation with the γ-rays takes place in radioactive medium the coefficient of friction can be dozen times less compared with that characteristic of sterilisation in air medium. Due to a properly selected lubricant the coefficient of friction can decrease by 1.3–1.4 times and strength and elastic characteristics of polyethylene acetabular part of the implant do not lessen.

Experiments evaluating the influence of biological lubricants on the wear of endoprostheses have not been finished yet. However, the results obtained are very interesting and after the evaluation of the data obtained it can be claimed that biological lubricants reduce the wear of endoprostheses. However, the effect of various lubricants on the wear of endoprostheses is different. In our case, we can say that blood serum had the smallest effect. Artificial lubricants have showed better lubricating properties and caused smaller surface deviations. The surface deviations caused by various artificial lubricants, as it can be seen from the figure, were almost the same. In order to determine which of these lubricants is the best, some new experiments are necessary.

4. Conclusions

1. The results of dispersion analysis method and the plan of orthogonal blocks have shown that artificial lubricants, i.e. sodium hyaluronate "Fermathron" and 15% polyvinylpyrrolidone solution, have the best lubricating properties.

2. There are 3 main stages of the endoprosthesis wear: running-in time, normal exploitation time and significant wearing time. The duration of each wearing stage depends on the primary treatment of polyethylene, the content of the material and the type of the lubricant. An appropriate primary treatment of the acetabular part of the implant and a proper type of the lubricant can reduce by several times the wear of the endoprostheses.

3. In order to increase the durability of the acetabular part of the implant it is advisable to make the polyethylene inlay with the metallic framework that prevents the implant from cracking and increases its working reliability.

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