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ELECTROSTATIC CHARGING OF PLASTIC BIOIMPLANTS

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Abstract

The development of medical techniques and wide use of new materials for bioimplantation were induced by the industrial application of the results of organic chemistry. Nowadays these new materials showing good chemical stability and good biocompatibility are used in routine microsurgery operations. However, after frequent ophthalmologic operations, the implantation of intraocular lenses (IOLs), mild or rarely serious cellular reactions were observed around the IOL. This postoperative reaction called the author's attention to the electrostatic attitudes of intraocular lenses and other instruments. In order to determine the procedure how non-toxic implants made of highly insulating materials carry harmful contamination to the eye on their surface the electrostatic properties of the implant materials and the charging level of the implants were examined. Mathematical and physical models were created in order to examine both the charging phenomena and the precipitation.

Keywords: postoperative reaction, electrostatic charging, PMMA, insulator, sterility.

Introduction

The authors examined the process of manufacturing, packing and implantation (App. 1). Based on laboratory measurements of the electric field, the surface charge density, and field experiments significant charging of the surface of the IOLs has been detected just before the implantation. The usual materials of IOLs are Polymethylmetacrilate (PMMA), Polypropylene and Silicone but the most popular is the PMMA lens. These materials are known as very good insulators with 10^{17}–10^{18} Ωm specific resistance. In basic state the charge carriers of both positive and negative signs are distributed in the materials uniformly, so materials seem to be electrically neutral. Transitional and definite disintegration of this neutral state results electrostatically charged state of materials. Separation of charges can be caused by three essentially different processes that are the following: addition of charges, removal of charges and separation of charges. These types of charges and separation of charges are naturally formed by various physical, chemical and other effects.

Electrostatic Charging

During the manufacturing processes all types of the IOLs become highly charged caused by the manufacturing technology. At the same time most of the package materials are very good insulators, too. The ethylene-oxide sterilised average IOLs are generally packed in four layers: a paper box, two gas permeable paper-foil bags and a plastic container (dry-pack package). All of the packing materials (except the paper box) became highly charged while opening regardless on the type and origin.

The usual closing process of the foil is the welding. Welding, as a local thermal effect refracts the polymer chains near the surface (not more then a few μm). The refracted polymer chains and free valence electrons (caused by the surface) render to catch high electron affinity materials, for example oxygen. If closing the foil bags electrical double layers are got. While opening the bag, after parting the two materials, the aforesaid separation of the charges can partially remain. So, in one of the materials positive and in the other one negative charges will be predominant. The original homogeneous distribution of charges, both of the materials become electrostatically charged.

The resultant surface charge density is highly influenced by the side chains of polymers and their positions. The level of the surface charge density is decreased by the tunnel effect and the Townsend effect, that result a perfect non uniform surface charge density on the IOLs surface. The measured field strength on the gas permeable packing after being torn up was well above the sparking limit.

The measured electric field strength near the freshly unpacked IOL was between ± 0.1 and ± 8.0 kV/cm regardless of its type and origin. Washing the lens in a stream of saline solution decreased, but the surface of the IOL was never neutralized. Rinsing the implant handled by a grounded forceps in saline solution had the same effect on the surface charges. After dropping down the last bit the IOL regained some new charge, so ± 0.1 to ± 8.0 kV/cm field strength was detected around the IOL.

To document the contamination of different particles to the surface of IOLs the following experiments were carried out. Different PMMA IOLs were properly opened, and placed before slit-lamp under sterile conditions. The forceps was grounded for fixing the IOL in vertical position by the haptic. The use of polarized light and a 90°-crossed analyzer filter on the biomicroscope was found very useful in revealing any surface irregularities, deposits and any other contamination, even in low level magnification. Nearly linear air flow was created around the IOL by an infrared heated metal plate below the area. Between the metal plate and the lens an average cotton swab was mounted and vibrated by a machine, to model floating particles. Three different types of dust in which the cotton swab was previously plunged: talc powder, perlon flock and organic fibres were used and recorded. Finally, lycopodium and minium powder were used in order to map the distribution of surface charge polarity. Lycopodium was attracted to the local positive charges, while minium was more affined to the negative charges.

To estimate and measure the attractive force of a charged IOL it was mounted horizontally before the beam of a polarized slit-light. After detecting its surface charge density, a grounded horizontal metal plate approached the lower surface of the lens. Previously cotton-flock had evenly been sprinkled over the metal surface. 2–3 mm were measured when the first fibres were picked up.

To estimate the attractive force in special conditions, the lover surface of a charged IOL was covered with a thin layer of viscoelastic material that continuously reached the grounded forceps for fixing the lens. The specific resistance of all viscoelastic materials is extremely low due to their water content. The coatibility of viscoelastic materials like hyaluronate and hydroxypropyl-methyl-cellulose, on the hydrophobic surface was not ideal, but the coated surface of the IOL was able to approach cotton fibres as near as the upper side already picked up particles from the metal plate. The lower side was inactive. No difference was found between the effects of two represent materials.

Physical Models of Particle Precipitation

The aim of the model computation was to define a dangerous distance, where contamination (solid particles, droplets, bacteria levitating in the air of the operation theatre or bacteria sitting on conjunctiva, near the operation area) will be led to the surface of the charged IOL by electrostatic forces. The model was created to demonstrate that there is a real possibility for both the particle and bacterial contamination. Within the dangerous distance the lens is working as an electrostatic precipitator regardless of the environment of IOL.

The IOL has a rather complicated geometric form so our basic condition is that the process may be described in a two dimensional coordinate system (App. 2). It means that we eliminated the handles of the lens and we examined the problem as a rotation symmetrical problem. The conclusion of our computations and experiments is that this simplification hasn't got definitive influence to the results. Two different models were created. The first model is very simple which basis is that several reports pointed out the bacterial origin of chronic inflammations around the IOL underlining the pathogenic role of periocular flora. The virulence of some harmless organisms might be promoted by a lens put into the eye and creating excellent conditions for their intra ocular survival. The medium size of a bacterium is in the 10^{-7}–10^{-6}m range. It means that the linear size of a lens is larger by three orders of magnitude. In the above model homogeneous electrostatic field was used, and the equation of motion was solved for an electrostatically charged flying bacterium moving in the air flow (App. 3).

For better understanding the possible mechanism of infection related to the most common bacteria: Staphylococcus epidermidis and Propionibacterium acnes were suspended in saline solution at controlled concentration. Besides the living bacteria heat denaturated (dead) bacteria were also used. Droplets of these suspensions were put on the surface of charged and neutralized lenses, and lenses placed in uniform electrostatic field. After a short time all of the lenses were washed in saline solution, and were prepared for microscopic examination.

The attachment of the bacteria was slightly determined by the electrostatic field and the charges. The number of bacteria examined on the surface of the lenses was close to zero (the number was two orders of magnitude smaller, than in other cases) in case of neutralized IOLs. The bacteria were fixed individually and uniformly by using homogeneous electrostatic field, while they were attached in small clusters when the surface of the lenses was charged up. Significant differences were not found if changing polarity or using living or dead bacteria. Charge approximation was created by the Pauthegnier limit value and initialisation of the flying bacterium is a useful technical abstraction. Based on the aforesaid model computation the function shown in App. 4 was got, if using different models for the medium velocity distribution nearby the surface. Adequacy of these functions may be the subject of a debate in medical practice.

The second model uses flattened rotation ellipsoid coordinates. In this case the surface of IOL is equivalent with one of two coordinates (App. 5). The usual method of computation charged insulators' static electrical field is completely inapplicable, because the surface charge density is not defined by an analytical formula. Accordingly, the static electrical field is computed by solving Laplace equation (App. 6). Solving Laplace equation close formulae are resulted if the surface of the IOL is equipotential. In this case the equation of motion will be a nonlinear differential equation and its solution can be got by the help of numerical method (e.g. fourth order Runge–Kutta formula).

One of the most complicated problems is to define the resistance of medium's influence. The movement is in viscous medium drift space. Figure of critical dirty particles, the bacteria are varied, depending on temperature, medium and their life cycle. After studying microbiological literature spherical particle was supposed. This is a realistic model because the most dangerous bacteria Staphylococcus epidermidis and Propionibacterium acnes are spheres all and partly some periods of their age of life. In this case flow near the particle is defined by Reynolds the number. Medium resistance force was created by modified Newton's frictional equation. Reynolds number and particle's dimension were taken into consideration by the constants of Newton's equation.

Own charge of dirty particles, practically the own charge of bacteria was approached by the following facts.

The extract content of a bacteria is approximately 90%. It is theoretically equivalent a water droplet which charge is given by Rayleigh limit. Maximum charge is in direct ratio to the square root of surface tension. It is apparent that surface tension is necessary to determine maximum charge, but it depends on the wall structure of bacteria.

Both of bacteria have thick wall (20–30 nm) and their figure is determined by this layer. It means that primary bands of the dominate layer are guaranteed stronger structure than a water droplet. Consequently, the maximum charge as the worst case is not given by Rayleigh limit. Maximum charge must be smaller than Rayleigh limit, but on the basis of extract content suppose solid particle is not in perfect order. Consequently, the exact value is undeterminable so the charge approximation was based on the Pauthegnier limit, too.

Theoretically electrophoretic methods are suitable for detecting physical parameters of bacteria. There are two different separations, one being carried out at a constant pH, the other is carried out in a pH gradient, which is established between two electrodes and is stabilized by carrier ampholytes. In this technique proteins or full bacteria migrate until they align themselves at which point a protein possesses no net overall charge and will therefore concentrate at this point as migration stop. Further, being in progress medical and bacteriological studies requirement parameters are needed to determine.

Laminar flow was supposed nearly the IOL and parabolic medium velocity distribution was built into the nonlinear differential equation based on the experiences of the homogeneous model.

The computations were produced by two different numerical methods. The first was the fourth order Runge – Kutta formula, which is a one step method.

The results had at least two remarkable experiences. The first is that the computation is practically independent of the medium velocity distribution. The second is that the numerical method is not suitable considering the computation time and fourth order accuracy (App. 7).

Two steps, explicit Adams method was used as the final solution. The accuracy of Adams method is of second order but the computation time and the annual results were fitted with the first method. The published results were computed by Adams method and included different medium models, air and an artificial material having kinematic viscosity close to the glycerine.

Conclusions

'Electrostatic Sterility' as a new requirement has to be fulfilled in case of different medical implantation. Electrostatically charged bioimplants can not be considered as sterile object in practical situations. Neutralization during manufacturing, packaging and implantation is necessary but not sufficient condition of sterility. On the basis of the model computations the effect of the cleaness of the operation theatres was cleared. In contradiction with the wide spread opinion, regarding the collecting effect of the charged IOLs, the effect of the quantity of particles in the air of the operating theatre is negligable. So, neither solid particles and liquid droplets, nor bacteria are gathered on the sterile package to the patient. The contamination of the charged bioimplant can be produced very close to the wound or may be inside it. These results force the authors to carry on the research work, especially regarding the phenomena inside the wound coming into existence during the operation.

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APPENDIX

1. Bioimplantation of intraocular lenses (Fig. 1)

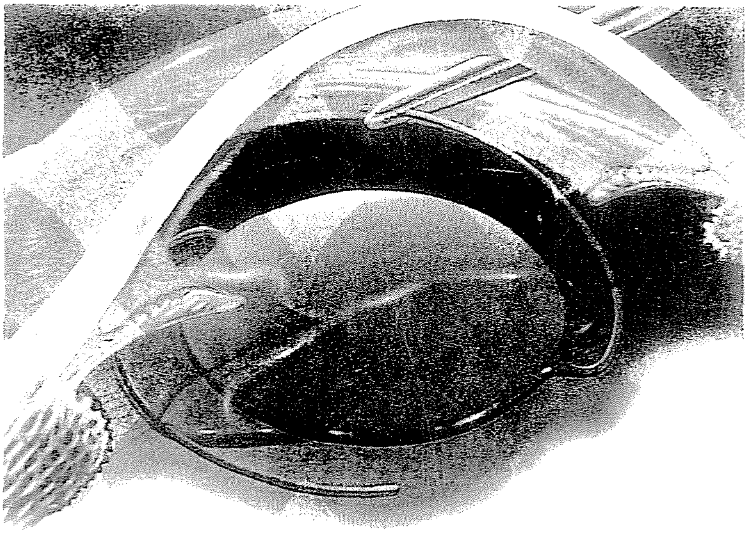

Fig. 1.

2. Typical Intraocular Lenses (Fig. 2)

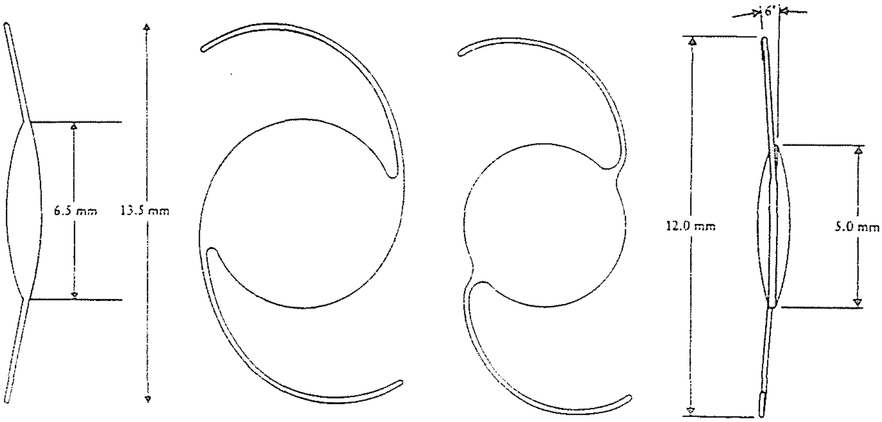

Fig. 2.

3. Suppose of Homogenous Field

$$m\frac{d^2\mathbf{r}}{dt^2} = \mathbf{F}_g + \mathbf{F}_e + \mathbf{F}_m \tag{3.1}$$

$$m\frac{d^2\mathbf{r}}{dt^2} + 6Da\pi\tau\frac{d\mathbf{r}}{dt} = -m\mathbf{g} + Q\mathbf{E} + Da\pi\tau\mathbf{v}_m. \tag{3.2}$$

The full solution of the equation of motion is: $\mathbf{r}(t) = \mathbf{r}_h(t) + \mathbf{R}(t)$. After initiation of $b = \frac{2\sigma a^2}{9D\tau}$, the full solution was given by following formula:

$$\mathbf{r}(t) = \mathbf{r}_0 + \mathbf{v}_0 b(1 - e^{\lambda t}) - \mathbf{g}bt + \mathbf{E}qbt + \mathbf{v}_m t. \tag{3.3}$$

If $\mathbf{v}_m = \mathbf{v}_m(t)$, the particular solution of the equation of motion can be produced too.

Symbols:

D	medium's thickness;
a	particle's radius;
$\mathbf{v}_m$	medium's velocity;
τ	medium's kinematic viscosity;
σ	particle's thickness.

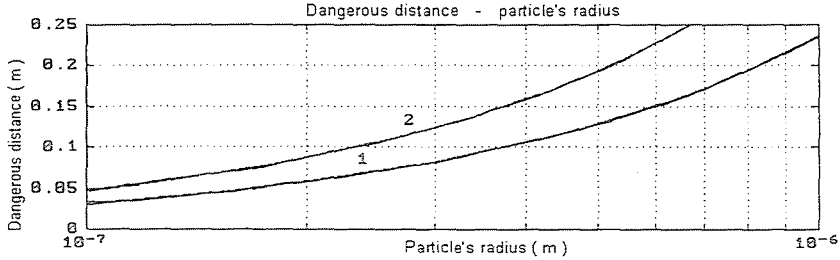

Fig. 3. Constant medium velocity in z direction (1). Parabolic medium velocity distribution in z direction (2). $\mathbb{E} = 5$ kV/cm, $v_{0x} = 0.01$ m/s, $v_{mz} = 0.01$ m/s

4. Homogenous Model

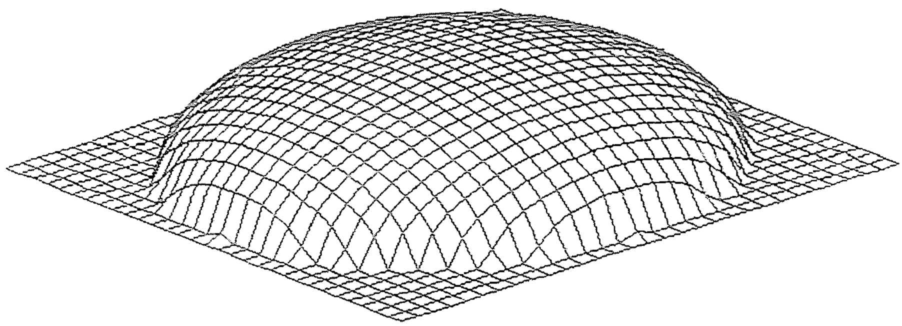

Fig. 4. IOL model

5. Flattened rotation ellipsoid IOL model.

The hendles of the lens were eliminated.

6. Suppose of Flattened Rotation Ellipsoid Electrical Field

Special form of Laplace equation in two (x and z) dimensions:

$$\frac{\partial}{\partial\lambda}[(1+\lambda^2)\frac{\partial\varphi}{\partial\lambda}] + \frac{\partial}{\partial\mu}[(1-\mu^2)\frac{\partial\mu}{\partial\mu}] = 0. \qquad (6.1)$$

The Fourier Method can be used accordingly the desired function of several variables is sought as a product of function:

$$\frac{1}{M}\frac{\partial}{\partial\lambda}[(1+\lambda^2)\frac{\partial M}{\partial\lambda}] = -\frac{1}{N}\frac{\partial}{\partial\mu}[(1-\mu^2)\frac{\partial N}{\partial\mu}] = n(n+1). \tag{6.2}$$

Legendre equation of $N(\mu)$ function was got after separation:

$$(1-\mu^2)\frac{d^2N}{d\mu^2} - 2\mu\frac{dN}{d\mu} + n(n+1)N = 0. \tag{6.3}$$

The general solution is equivalent with the following series:

$$N(\mu) = \sum_{n=0}^{\infty} A_nP_n(\mu) + B_nQ_n(\mu). \tag{6.4}$$

The differential equation of $M(\lambda)$ function is: $(1+\lambda^2)\frac{d^2M}{d\lambda^2} + 2\lambda\frac{dM}{\lambda} = 0$

The general solution is: $M(\lambda) = \int \frac{K_1}{(1+\lambda^2)}d\lambda = K_1\mathrm{arctg}(\lambda) + K_2$.

Answer conditions were created by the model conditions:

- equipotential ellipsoid, $\varphi(\lambda) = M(\lambda) = N(\lambda)$;
- $\lim_{\lambda\to\infty,\mu}\varphi(\lambda,\mu) = 0$;
- regular solution;
- $\mathbb{E}_\lambda\partial\varphi\partial\lambda = -\frac{1}{g_x}N(\mu)\frac{\partial M}{\partial\lambda}$ measured value.

x and z components were needed to the numerical mouving simulation:

$$\mathbb{E}_x = -\frac{1}{g_x}\frac{\partial\varphi}{\partial x} = -\frac{\partial\varphi}{\partial\lambda}\frac{\partial\lambda}{\partial x} = \frac{K_1}{(1+\lambda^2)}\frac{X\lambda}{x^2+z^2-r_0^2-2\lambda^2r_0^2} \tag{6.5}$$

$$\mathbb{E}_z = -\frac{1}{g_z}\frac{\partial\varphi}{\partial z} = -\frac{\partial\varphi}{\partial\lambda}\frac{\partial\lambda}{\partial x} = \frac{K_1}{(x^2+z^2-r_0^2-2\lambda^2r_0^2)\lambda}. \tag{6.6}$$

The solution of Laplace equation in three dimensions or the real time solution (take into consideration permeability and conductivity of medium) can be represented the different situations. Equation of motion:
$m\frac{d^2\mathbf{r}}{dt^2} + 6Da\pi\tau\frac{d\mathbf{r}}{dt} = -m\mathbf{g} + Q\mathbb{E}(\mathbf{r}) + Da\pi\tau\mathbf{v}_m$.

7. Nonlinear Model

Both the initial velocity of the medium and the velocity of the corpusculum are zero. The field strength was 5 kv/cm in every cases.

- The linear *initial distance* was equivalent with the *half of IOLs diameter* (*Fig. 3*).
- The linear *initial distance* was the *half of IOLs diameter and plus one millimeter* (*Fig. 4*).
- The linear *initial distance* was equivalent with the *half of IOLs diameter*. Model medium was used for the computation (*Fig. 5*).
- The linear *initial distance* was equivalent with the *half of IOLs diameter*.

Model medium and foliated medium structure were used for the computation (*Fig. 6*). $\varepsilon_r = 3$ (inner layer), $\varepsilon_r = 2$ (external layer).

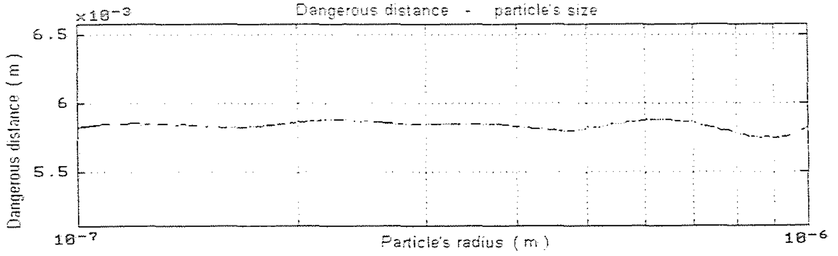

Fig. 5.

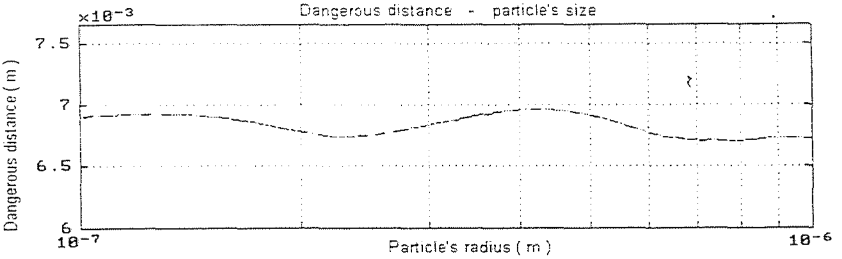

Fig. 6.

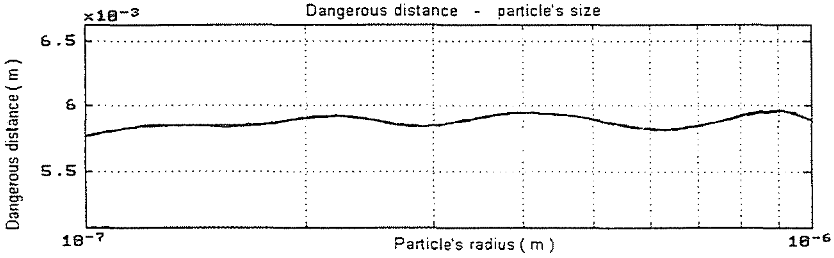
Dangerous distance - particle's size
×10⁻³
6.5
6
5.5
Dangerous distance (m)
10⁻⁷
Particle's radius (m)
10⁻⁶

Fig. 7.

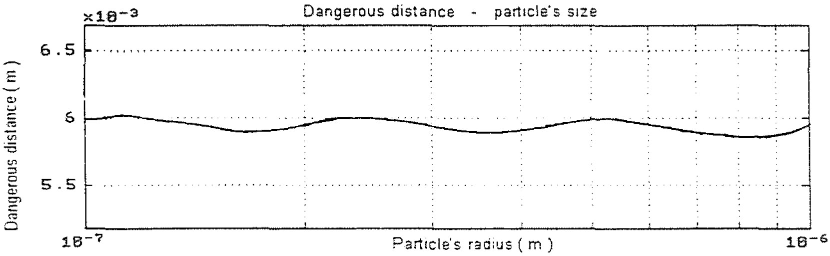
Dangerous distance - particle's size
×10⁻³
6.5
6
5.5
Dangerous distance (m)
10⁻⁷
Particle's radius (m)
10⁻⁶

Fig. 8.