Radiation treatment of the ceramic and polymer implants

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Abstract. Implants are used in medical practice during decades. The ceramic implants are the new trend in medicine. The polymer implants are used for many years, and they are mainly sterilized by the radiation treatment. The article describes the new ceramic and polymer implants that were treated in the Budker Institute of Nuclear Physics.

1. Introduction
Implants are used in medical practice during decades, and the search of the new ones and development of new ideas are going on.

The main requirements for the implants – they ought to be accepted by body (not to be rejected), can be incorporated into the tissues and perform the functions of the replaced tissue.
The ideal implant ought to replace the tissue, be soaked with the interstitial fluids, permit the body cells to settle on and inside it and to form the corresponding tissue and then after passing some time the implant ought to gradually dissolve leaving the tissue on the place of the implant.
We observe the increase in number of illnesses requiring the transplantation, so the need in the implants replacing the organs is increasing.

2. Ceramic implants
Joint stock company “NEVZ-KERAMIKS” situated in Novosibirsk is producing the ceramic medical implants based on Al$_2$O$_3$ and ZrO$_2$ ceramics – implants and endoprostheses [1]. The goods have the bioactive surface from nanostructured hydroxyapatite and can be successfully used in men surgical treatment as well as in stomatology and in oral surgery.
Porous structure firmness is provided by combination of the submicron and nano-sized components of the ceramics.
The hydroxyapatite implants’ surface with nanoparticles facilitate the new bone tissue formation on the border and long and steady implant fixation inside the body.
The ceramic implants can be sterilized only by ionizing radiation – all other sterilization processes are inadmissible due to regulation.
The implants were hermetically packed into the individual packs and then the groups of 8 packed implants were hermetically packed into the big packs. The 2-sided irradiation was carried out by electron beam generated by ILU-6 pulse linear accelerator in the Budker Institute of Nuclear Physics, the electron energy was 2.45 MeV.
Figure 1. Vertebral disk implants.

The vertebral disk implants of various sizes are shown in Figure 1, Figure 2 presents the implant’s drawing, Figure 3 shows the packed implants prepared for sterilization.

Figure 2. Vertebral disk implant drawing.

Figure 3. Packed implants prepared for sterilization.
First time in Russia (and in the whole world) the ceramic vertebral disk implants were implanted in men in Novosibirsk in 2013.

The ceramic implants permit to use the magnetic resonance tomography to monitor the results of the operation – the metal implants do not allow to use this method because of their strong response. And such implants will not cause the problems for the people during passing the metal detectors (inspections in the airports, etc.). Figure 4 shows computer tomography images of the ceramic vertebral disk implant in patient.

![Figure 4. Ceramic vertebral disk implant in patient - computer tomography images.](image)

3. Vascular Implants Produced by Electron Beam Treatment

Vascular implants are now in demand due to increase in operations number. The Institute of Chemical Biology and Fundamental Medicine (Siberian Branch of Russian Academy of Science) in collaboration with Institute of Blood Circulation Pathology named by E.N. Meshalkin is developing the brand new blood vessels implants based on the polymer electrospun 3D matrices.

Electrospinning application areas:
- Cartilage
- Bones
- Muscles
- Nervous tissue
- Skin
- **Vessels**

The requirements to the vascular implants:
- Biocompatibility, including the compatibility with the blood, good cells’ adhesion, the possibility for the cells to migrate into the structure and to germinate inside.
- Stable biodegradation, biodegradation rate ought to correspond the replacement tissue grow rate, absence of the biodegradation toxic products.
- The mechanical firmness enough to endure the mechanical loads during the new tissue formation time (including the fatigue resistance).

The basic sheets were produced by electrospinning from poloycaprolactome, nylon, polylactic-co-glicolide and their mixtures dissolved in hexafluoro-2-propanol. The fibers have the diameter of about
1 micron. The sheets were soaked in the aqueous gelatine solutions containing factors stimulating the vascular cells growing and then were treated by electron beam for grafting.

Figure 5 shows the blood vessel formation process – the various cells are filling the space inside the implant, proliferating and gradually forming the new blood vessel tissue, meanwhile the polymer matrix is subjecting to biodegradation, and so the new blood vessel is forming.
The irradiation of the nylon electrospun 3D matrixes with doses of 50-100 kGy increases elastic properties of the grafts and is a convenient approach for increasing their mechanic properties [2]. It was shown that the dosage up to 25 kGy does not influence on the mechanical properties, while doses in the range from 50 kGy to 100 kGy increase rigidity of the material with subsequent destruction of the materials in dosages higher than 150-200 kGy.

Polymers used in electrospinning technique in the described experiments:

- Nylon 6
- Polycaprolactone (PCL)
- Polycaprolactone (PCL) + gelatin
- Poly lactic co glycolic acid (PLGA)

**Figure 6.** Scaffolds morphology before and after irradiation with 100 kGy dose.

Figure 6 shows the scaffolds morphology before and after irradiation with dose of 100 kGy. Figure 7 shows the endoteliocytes (upper line) and fibroblasts (lower line) growing on different materials. Scanning electron microscopy was performed in the Department of Physical and Chemical Methods of the Institute of Catalysis, Siberian Branch of Russian Academy of Science (LEO-1430 Microscope, Jeol, Japan).

**Figure 7.** Different electrospun scaffolds as cell growth substrates.
4. Conclusions
The ceramic vertebral disk implants were introduced into clinical practice and implanted in men. The modern chemical technologies and physical methods permit to produce the 3D polymer matrices having the properties approaching to the parameters of living tissues. The brand new polymer vascular implants were subjected to various tests and then tested in mice.

The trials show that fibroblasts and endotheliocytes can fasten on the implants and are successfully proliferating. The endotheliocytes are much more sensible to the materials than fibroblasts, and are proliferating only on certain surfaces.

The artificial vascular implants are on the way to clinical practice.

References
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