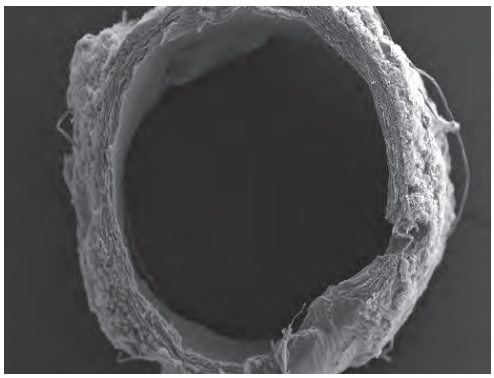
Fraunhofer FEP

Fraunhofer Institute for
Organic Electronics, Electron Beam
and Plasma Technology FEP

Microbe growth on agar plate

Sterilization of biological tissues with electrons



Cross-section through the aorta of a rat, Ø 1.7 mm

The human body contains approximately 150,000 km of blood vessels to supply tissues!

Cardiovascular disease, in particular arteriosclerosis, is among the most common causes of death worldwide today. The replacement of native blood vessel sections with prosthetic implants is unavoidable in some cases. Synthetic vessel replacements made of polymers such as PTFE and PET are currently limited to vessel diameters of 6 mm and more due to the risk of thrombosis.

Biological replacements are used for smaller vessel diameters. Autologous vessels, for example the vena saphena magna from the inside of the patient's leg, are preferred here. Allografts (from donors) and xenografts (animal material) are of minor significance only. Sterilization is one problem with these replacements.

The goal with the sterilization of biological vessel replacements is to avoid damaging the cells inside the vessel wall, which serve to maintain the vessel functions, in the course of the sterilization process. Traditional sterilization methods based on heat and toxic chemicals are out of the question. Using antibiotics is being criticized because of resistant strains. Physical sterilization using accelerated electrons is an alternative approach that is already being used successfully in many cases. The challenge associated with the electron treatment of vessels lies in determining the optimum penetration depth of the electrons into the vessel wall. Here the survival of the cells in the inner layers of the vessel walls has to be assured while achieving adequate sterilization.

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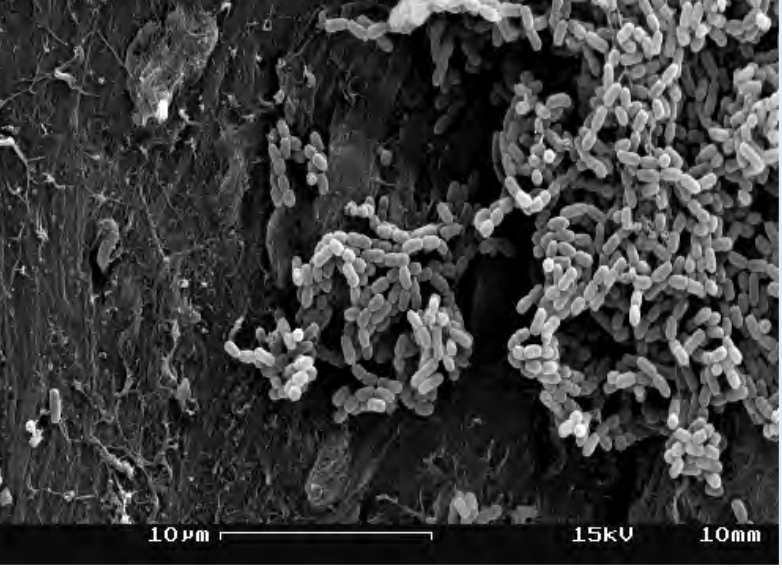

Bacteria deposit on vessel wall

REAMODE electron beam test facility at Fraunhofer FEP

Experimental

Rat aortas were used as a model for a biological vessel replacement. The electron treatment was performed by Fraunhofer FEP using a test facility with a non-thermal process, i. e. substrate temperatures below 40°C. The penetration depth was approximately 23 µm and therefore in the range of the outermost connective tissue layer of the vessel wall.

Two different electron dosage values were also tested within the range of the radiation sterilization dosage prescribed by law (25 kGy): 22 kGy and 44 kGy. An untreated control served as a reference.

Results

The electron treatment led to a significant microbe reduction.Immediately after the treatment with 22 kGy, the vessel function was not impaired. The following were examined:

- Wall tension
- Endothelium-independent relaxation
- Endothelium-dependent relaxation

24 hours after the electron treatment, only the endothelium-independent relaxation decreased by 15%. At 44 kGy, the primary negative influence was on the endothelium-dependent reaction.

The results show that the electron treatment of the rat aortas at 22 kGy and 23 µm penetration depth is suitable for sterilization.

Our offer

Based on these results, many different applications are possible in life sciences and medical technology, especially in the surface sterilization of biological implant materials. The adaptation of the technology is specific to the respective substrate. Additional examination methods, e. g. for changes of the extra-cellular matrix and their effects on biocompatibility, are also established in the biomedical laboratory unit of Fraunhofer FEP:

- FTIR and UV/VIS spectroscopy
- Scanning electron microscopy including critical point drying
- Testing for biocompatibility with human cells from various tissues: morphology, vitality, proliferation of the cells

Penetration depth		23 µm	
Dosage		22 kGy	44 kGy
Sterility		+	+
directly after ET	Wall tension	o	o
	Endothelium-independent relaxation	o	o
	Endothelium-dependent relaxation	o	–
24 h after ET	Wall tension	o	o
	Endothelium-independent relaxation	–	–
	Endothelium-dependent relaxation	o	–

+ positive effect, o no effect, – negative effect;
ET: electron treatment