Sterilization of an Electronic Medical Device

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ABSTRACT

Radiosterilization was applied to a medical device with a “programmable memory” to allow in vivo implantation. Irradiation on a Cobalt-60 facility at 25 kGy at a dose rate of 2kGy/h corrupted the memory. Therefore an alternative sterilization method using UV was developed and validated based on ISO 11737-1-1 and ISO 14937. These procedures may be useful and effective for research purposes when only a small number of items might be involved but applicability at an industrial scale is unlikely.

Introduction

The question of how to effectively sterilize biomedical devices for research, either for in vitro or in vivo use, is of outermost importance. The choice of the sterilization method is dependent on the initial bioburden, on the device characteristics, on environmental and safety considerations [1,2]. Many materials do not withstand dry heat or autoclave sterilization and high energy irradiation procedures. Irradiation exerts its effects on programmable memories and flash memory cells, like those integrating some biomedical devices [3,4]. Ultraviolet irradiation is a ready available and cost-effective method of expedite surface sterilization and, depending on the bioburden, it is possible to eliminate microorganisms without affecting the material properties. The analyzed devices could not be sterilized by gamma irradiation or heat . The objective of this study was to develop and validate an alternative sterilization method.

Experimental

A. The Device

The devices aimed to sterilize (Figure 1) were composed of a 16-bit processor, powered by lithium battery and encapsulated in polymethylmetacrilate (PMMA) and a set of six sensors/actuators composed of polyvinylidene fluoride (PVDF) and silver electrodes.

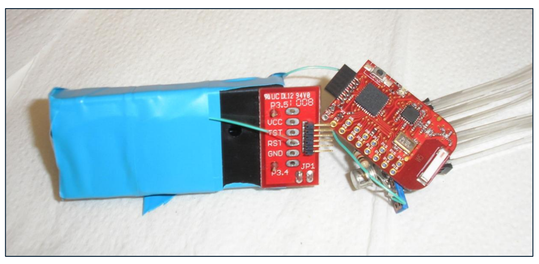

Figure 1. Device before encapsulation in PMMA.

B. Bioburden Assessment

The method for bioburden determination was based on the ISO 11737-1 guidelines. The procedure was validated by repetitive sampling. The microbial growth evaluation after exposition to potential inactivation procedures was carried out using the validated bioburden determination method or by immersion of samples devices into Tryptone Soy Broth (TSB) and monitorization of culture medium turbidity during incubation at 30ºC during 21 days.

Results

The estimated average devices bioburden was 10^2 CFU/sample and the most frequent types of microorganisms isolated were gram-negative rods (43%) and gram-positive rods (29%).

A group of devices (n=3) was subjected to the following treatment: five minute wash in water (21ºC) in a automatic washing machine (Miele Professional G7883), followed by immersion in sterile 10% sodium hypochlorite for 20 minutes, without agitation, washing in sterile water, and immersion in 10% hydrogen peroxide for 30 minutes, without agitation, followed by rinse in sterile water and drying under laminar flux, before 2 hours of exposure to UV (in two different positions).

The devices subjected to this treatment, presented no microbial growth after 21 days of culture in TSB. The proposed sterilization treatment was applied to a device that was efficiently implanted in vivo and no signs of infection were detected clinically or in the histological exam (Figure 2), after one month implantation.

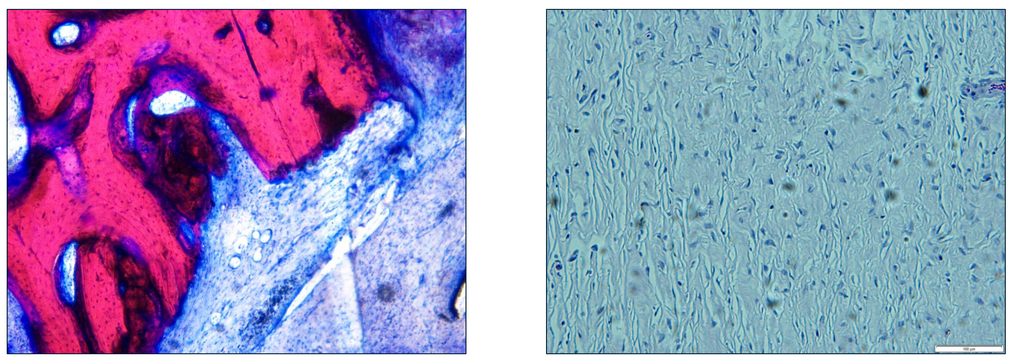

Figure 2. Microphotograph of implantation site; on the left, undecalcified bone is separated from the device by a fibrous capsule; there is absence of leukocyte infiltration and no microorganisms are observed. On the right, detail of the fibrous capsule, without evidence of inflammatory cells.

Conclusion

The developed and validated treatment was effective, for the experimental conditions, by its combination of procedures; the action of washing, chemicals and UV radiation act synergistically.

References

[1] ISO11737-1, “Sterilization of medical devices — Microbiological methods Part 1: Determination of a population of microorganisms on products”, ISO , April 2006. [2] ISO14937, “Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process”, International Standard Organization, Oct 2009. [3] C. Claeys, H. Ohyama, E. Simoen, M. Nakabayashi and K. Kobayashi, “Radiation damage in flash memory cells”, *Nucl. Inst.and Meth. in Phys. Res. Sect. B: Beam Interactions with Materials and Atoms*, vol. 186, pp. 392-400, Jan 2002. [4] M. Vujisic, P. Osmokrovic and B. Loncar, “Gamma irradiation effects in programmable read only memories”, *J.of Physi: Applied Physi*,vol. 40, pp. 5785–5789, Sept 2007.