Biocompatibility of silicone implants sterilized by gamma radiation

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Introduction

Silicone gel mammary implants have been widely employed for mammary reconstruction and augmentation. Because of prohibition, by some countries, of the utilization of silicone gel implants, the alternative is the use of the saline-filled breast implant. To accomplish the sterility of these implants (ISO 14607:2002) gamma ray radiation is employed. High-energy radiation in addition to killing bacterial life, may also affect material properties. The primary changes can be chain scission and/or crosslinking. Material degradation can leads to a loss of implants biocompatibility. This study evaluated the silicone mammary implant biocompatibility, by cell culture, after gamma radiation sterilization.

Material and Methods

Textured saline-filled breast implant was employed in this study. Thirty implants were used to estimate the bioburden and other two hundred units to evaluate sterility after their sterilization.

Dose setting using bioburden information

An estimate was made of the average bioburden by filtration method employing 30 samples and the verification dose was established by that gives a Sterility Assurance Level (SAL) of 10^{-2} (Table B1 - Annex B - ISO 11137).

Sterilization of implants and Sterility Test

A sample of 100 implants is then exposed to the selected verification dose (8.3 kGy) and each unit was tested individually for sterility. After this step, the other 100 implants was exposed to the selected sterilization dose (21.7 kGy) and the same procedure was made.The sterility test was performed by membrane filtration method employing Triptic Soy Broth and Fluid Tyoglicollate Medium (UNITED STATES PHARMACOPEIA, 2006).

Biocompatibility

The implants irradiated by 21.7 kGy were tested by agar diffusion test as described in ASTM. NCTC clone 929 cell line was used and the biocompatibility was evaluated by macroscopic and microscopic reactions. The samples (pieces of 0.5 x 0.5 cm) was deposited on the agar surface of six dishes and evaluated after 24 hours of incubation (37º C, 5% CO_2). The toxic response is given as negative or positive, taking into account a response index based on the size of the diffusion (decolorized) zone and the percentage of the cell within the lysed zone (UNITED STATES PHARMACOPEIA, 2006).

Results/ Discussion

Table 1 shows the bioburden of different parts of the implants. The verification dose was established employing these values employing a "Standard Distribution of Resistance" (SDR) included in the ISO International Standard 11137 - Annex B.

Table 1– Average bioburden of textured saline-filled breast implant

	Bioburden (CFU)
Saline solution	0.00
Textured silicone elastomer shell	111.12
Plastic Package	12.39

The Table 2 shows the results of sterility test employing irradiated implants with 8.3 kGy (verification dose) and 21.7 kGy (sterilization dose). The biocompatibility is not affected by sterilization according the results of *in vitro* method because of the fact that the zone index found was equal to zero, that is, there was no effect under samples.

Table 2 – Tubes with microbial growth at sterility test of implants sterilized by gamma radiation

	Verification dose (SAL 10^{-2})		Sterilization dose (SAL 10^{-6})	
	Tryptic Soy Broth	Fluid Tyoglicollate	Tryptic Soy Broth	Fluid Tyoglicollate
Textured saline-filled breast implant	0/100	0/100	0/100	0/100

Conclusion

The sterilization dose established from Table B1 in ISO 11137 was effective. This fact is resulted from correct bioburden quantification of implants emphasizing that dose of 21,7 kGy showed itself very efficient to obtain sterile implants, whose biocompatibility was not affected.

References

AMERICAN society for testing materials (ASTM). Standard test method for agar diffusion cell culture screening for cytotoxicity: designation: F 895-84. Philadelphia: ASTM, 1995.

UNITED States pharmacopeia. 29.ed. Rockville: United States Pharmacopeial Convention, 2006.