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Research paper

Failure of silicone gel breast implants: Is the mechanical weakening due to shell swelling a significant cause of prostheses rupture?

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ABSTRACT

Silicone gel-filled breast implants nowadays are commonly used in breast surgery. Despite the improvements carried out during the years in the device design and manufacturing technologies, the long-term reliability of such prostheses is still doubted and the phenomena involved in the prostheses failure not yet clearly defined. This study investigates rupture causes by analysing the mechanical properties of failed and intact implants in the recent generation of silicon gel breast implants. The main scope is to assess whether the mechanical weakness of the shells should be considered as a major cause of breast implant rupture or, on the contrary, the prosthesis shell damage is likely due to other random factors. Some tests were performed on the shells of a wide number of explanted prostheses, to evaluate the mechanical properties as a function of prostheses status at explantation (intact/ruptured) and variable degree of swelling. A weakening of the shell mechanical properties, so as a significant difference in the ultimate strength and stiffness of intact versus ruptured prostheses, was found. This attenuation of the properties may be justified as a consequence of the shell swelling phenomenon during implantation and has to be considered as a significant mechanism for silicone gel breast implant failure.

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1. Introduction

Silicone gel-filled breast implants, nowadays commonly used for breast augmentation or reconstruction, are composed by a silicone rubber shell filled with a fixed amount of silicone gel. Both the shell and the filler are made of an elastomeric material (i.e. polydimethylsiloxane, PDMS). They differ only

in the PDMS cross-linking degree, which is lower in the gel. In more recent designs a barrier layer (usually in fluoro- or phenyl-siloxane) is sandwiched between the shell PDMS layers.

Despite the improvements carried out during the years within device design and manufacturing technologies, the long-term reliability of such prostheses is still doubted and

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