RUPTURE OF BREAST IMPLANTS: A MECHANICAL ANALYSIS USING UNIAXIAL TENSILE TESTS

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ABSTRACT

The main goal of the present work was to study the mechanical behavior and its influences in ruptured PIP Breast Implants. From the data acquired by the tensile testing equipment - applied force and consequent deformation - it is possible to compare the behavior of all different regions of the PIP breast implants and study the influence of several factors (type of shell rupture, discoloration, duration of implantation, etc).

Keywords: mechanical behaviour, PIP, rupture.

INTRODUCTION

For a long time a decay in the mechanical properties of the implant shell due to material ageing was indicated as the primary factor responsible for the prostheses failure.

An unexpected high prevalence of rupture and silicone leakage have been reported for the Poly Implant Prothèse (PIP) manufacturer, which culminated in the withdrawal of these implants from the European market in 2010. Following revelations that the company were using nonmedical grade silicone for the production of their implants there has been growing concern over the increased rupture rate of these implants and the implications this may have on patient.

In the last few decades, the first concern associated to breast implants is rupture and silicon leakage. Recent studies concluded that silicone gel filled breast implant will be ruptured at 10 years comparatively with PIP breast implant that rupture prevalence rate is 24% (Maijers, 2012). However, there is no evidence that PIP implant rupture causes long-term adverse health effects in humans so far. Thus, this preliminary study attempts to understand the rupture causes by analyzing: (1) the mechanical properties; (2) appearance of implant; (3) duration of implantation and (4) three different regions of the breast implants (anterior, equatorial and posterior).

MATERIAL AND METHODS

The PIP breast implants were collected from Centro Hospitalar de Gaia/Espinho, Serviço de Cirurgia Plástica, reconstrutiva e maxillofacial. Wherein the most frequent reason for undergoing implant revision was the suspicion of rupture. Upon arrival, the implants were visually examined and the presence and appearance of any implant shell rupture (hole, split or
V-shaped), discoloration, opacity or other unusual features were recorded for future comparisons.

In this research, a total of four hundred and three individual tests were performed, according to ISO14607:2007 (non-active surgical implants - mammary implants), ISO 37:2005 and following the protocol from Schubert (Schubert, 2013). To map all shell, each implant was divided into 12 segments counted clockwise. Each segment provided a total of five specimens. Therefore, each implant provided a minimum of sixty specimens. Dog-bone shaped specimens (shaft length 12 mm, width 2 mm) were chosen to allow an investigation of the homogeneity of the mechanical properties. The mechanical tests were performed at slow displacement rate (20 mm/s) and at room temperature (≈25º C).

RESULTS

The authors analyzed seven ruptured implants with round shape, textured shell surface and various volumes (210-310cc) from PIP manufacturer. PIP breast implants were explanted from seven women, following implantation for a median of 49 (range 39-61) months. After visual inspection of the implanted silicone shells verified that the implants with V-shaped ruptured comparison with the other types of ruptured demonstrated significant yellowing of exposed gels.

In this first analysis, there was any significant difference between the different regions of the breast implants (Anterior: 8,80MPa±0,90; Equatorial: 8,48MPa±1,03; Posterior: 8,10MPa±0,86), as seen in Figure 1.

The seven PIP implants showed no significant correlation between the duration of implantation and the mechanical properties despite each implant have a different duration of implantation. There are differences in the breast implant with more pronounced ruptures and yellowish appearance (7,72MPa ± 1,40), comparatively to implants with a small hole, split and a clear aspect (10,09MPa ± 1,22; 9,12MPa ±1,10). Figure 2 show these results.
CONCLUSIONS

Also in the present study, visual inspection of PIP gels revealed a variable consistency, ranging from non-adhesive to brittle. The probable reason for this is that in vivo exposure of the silicone gel leads to degradation and cross-link scission. This conclusion was demonstrated by Yildirimer (2013) and Necchi (2011). The yellowish appearance in the implants with larger area of exposure of the silicone gel in woman body, is according with literature. It has been reported that PIP implants are softer and more likely to have yellow discoloration than other implants. This observation, which is not unique to PIP implants has been attributed to higher liquidity of the silicone and a higher tendency of cholesterol absorption into the implants (Beretta, 2013), (Berry, 2007), (Yildirimer, 2013) and (Necchi, 2011).

The data presented in this study does not suggest a direct relationship between duration of implantation of PIP breast implants and a weakening of shell mechanical strength. Also, it was verified a homogeneity of the shell properties.

Further tests should be performed in order to understand questions implied in biodegrading of the implants within women body. Also, it is necessary to extend the study to a higher number of implants. These novel studies may reveal significant influences of duration of implantation on the shell properties.

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