A PRELIMINARY STUDY OF MECHANICAL PROPERTIES OF BREAST IMPLANTS

ESTUDO PRELIMINAR DAS PROPRIEDADES MECÂNICAS DOS IMPLANTES MAMÁRIOS

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ABSTRACT

The recent events surrounding Poly Implant Prostheses (PIP) breast implants have renewed the debate about the safety of silicone implants. The question of the longevity and durability of silicone implants is still unresolved. In this study the proposed solution to this problem is based on mechanical analysis of the PIP silicone implants. Thus, to evaluate the mechanical properties of the shell material, tensile tests according to the international standard EN ISO 37-1 was performed. A total number of forty-nine specimens were analyzed and two different implants brands were compared (Polytech and PIP), allowing a detailed mapping of the mechanical properties of the silicone shell. Preliminary tests demonstrated mechanical weakening of PIP, compared with Polytech shells. However, it is necessary pay attention that so much the control implant and the PIP implant is not known the time points of implantation -this may skew results, for this further studies is required.

RESUMO

Os recentes acontecimentos que debateram os implantes mamários Poly Implant Prostheses (PIP) têm renovado o debate sobre a segurança dos implantes de silicone. A questão da longevidade e durabilidade destes implantes é uma questão que ainda se encontra por resolver. Neste estudo, a solução proposta para este problema é baseada na análise mecânica dos implantes de silicone PIP. Para avaliar as propriedades mecânicas deste material são realizados ensaios de tração, que estão de acordo com os requisitos específicos da norma internacional ISO EN 37-1. Foram testadas um total de quarenta e nove amostras. Destas amostras foram comparadas duas marcas diferentes (Polytech e PIP), permitindo assim um mapeamento detalhado das propriedades mecânicas do material. Os resultados destes ensaios demonstraram um enfraquecimento mecânico do material dos implantes PIP, em comparação com os implantes Polytech. No entanto, é necessário em trabalhos futuros recolher informação do tempo de implantação dos vários implantes, e verificar se esse é um fator que contribui para o enfraquecimento do material.

1. INTRODUCTION

Breast implants are considered medical devices used to augment, reconstruct the physical shape of the breast. Breast implants consist of a silicone outer shell and filler (like the cohesive Gel), see Fig. 1.

For long time decay in the mechanical properties of the implant shell due to ma-

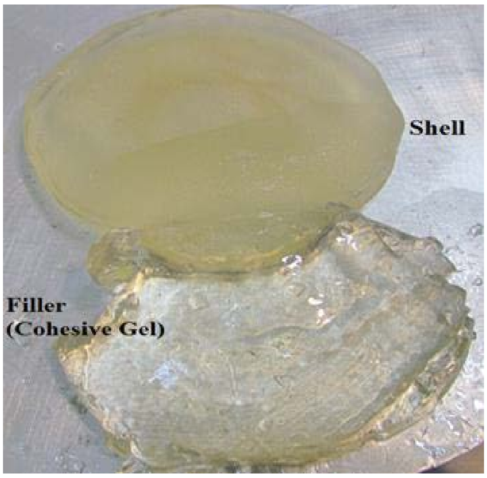

Fig. 1 – Implant Constitution

terial ageing was indicated as the primary factor responsible for the implants failure.

Thus, it is well established that the rupture of breast implants tends to increase with the time since implantation.

Van Rappard and co-workers used a simple test to show that the breaking pressure of explants was negatively correlated with time after implantation. They also found that the pressure used for closed capsulotomy tended to exceed the breaking pressure in older implants, sufficient to cause implant rupture (Van Rappard et al., 1988). They concluded that the first implants presented a fragile shell.

Studies on the mechanical properties of implants have shown mixed results, some indicating a decrease in membrane strength with increasing implantation time (Phillips et al., 1996 and Greenwald et al., 1996) but with significant variation by brand, type and even within lots (Phillips et al., 1996, Greenwald et al., 1996, Brandon et al., 2001 and Marotta et al., 2002).

At first, a negative correlation between implant duration and mechanical resistance (Phillips et al., 1996 and Greenwald et al., 1996) or percent shell failure (Marotta et al., 1999) was found, suggesting a shell ageing. However, at the end of the 1990s, the suggestion that ageing of the shell material during implantation was a primary factor for rupture started to be denied. Instead, the shell–gel coupling was pointed out as the main factor responsible for the decay of the shell mechanical properties (Marotta et al., 1999 and Brandon et al., 1999, 2000). The literature attention was then focused on the time-dependent phenomenon of the swelling of the silicone shell by the inner silicone gel (Marotta et al., 2002, Adams et al., 1998, Brandon et al., 2003 and Birkefield et al., 2004). Thus, concluded that the silicone gel filled breast implants have a limited lifespan, with the risk of rupture increasing over time. It is estimated that 10-15% of any brand of silicone breast implant will be ruptured at 10 years (Marotta et al., 2002).

However, this can be explained by considering shell strength characteristics. Breast implants fail due to the mechanisms that generate damage to the shell. Daily activity body motion, such as walking and running, induces forces on implants. These in vivo forces are cyclic and repetitive. Over time the cumulative in vivo cyclic loading induces damage to the implant which can result in failure. The rate of damage accumulation can be accelerated for implants with thin or structurally weak shells at the time of implantation.

It has been shown in different studies that implant damage at insertion can weaken the implant and probably be responsible, at least in part for a later rupture. Electron microscopy scanning studies of failed implants have shown various types of failure mechanisms, from scalpel, scissor, needle and forceps lesions to abraded, weakened areas, probably caused by surgeons' fingers when they are stuffing an implant into its pocket (Brandon et al., 2001 and SCENIHR, 2012).

According to some studies the implants from the French manufacturer Poly Implant Prothese showed more rupture than expected (SCENIHR, 2012). According to the findings of the French Health Authorities, a French manufacturer (Poly Implant Prothese) fraudulently made use of low-quality material (industrial silicone) different from the one it had declared in the documents submitted for conformity assessment (medical grade silicone).

It is now necessary to improve the bifunctionality of the breast implants at the biomechanical level, taking the mechanical compatibility and toxicological safety of the involved materials into consideration, thus reducing the risks to public health.

2. MATERIAL AND METHODS

2.1- Samples

PIP silicone breast implants were obtained from Centro Hospitalar de Gaia/Espinho, Serviço de Cirurgia Plástica, reconstrutiva e maxilofacial (CHVNG/E).

The authors analyzed implants from PIP and Polytech implants. The implants were of various shapes (anatomical and round) and volumes (270–370cc), and with textured surfaces. Explanted prostheses were assessed by visual inspection and implants were subsequently separated into two groups (intact or ruptured) depending on shell integrity. Most explants were intact but two were ruptured.

Each shell was cut in two parts, anterior and posterior (i.e. the part including the patch). On the back of the breast implants a minimum of six (6) specimens were collected: three (3) of which in the area of the patch and area of the shell. On the front a minimum of three specimens were collected. Each implant provides a minimum of nine (9) specimens.

2.2- Samples Preparation

Prior to sample preparation the explants were treated as follows.

The explants were photographed and inspected optically to document the position of the rupture. Then, the implant was opened by cutting the shell from the tangentially oriented tear (thus the shell was divided in two parts, anterior and posterior) see Fig. 2.

Then, the gel was carefully removed from the shell and the shell gently wiped. The samples should represent the entire surface of the implant, that is, samples must be withdrawn from the anterior, posterior (base of the implant) and the mandrel marks (including the patch), as shown in Fig. 2.

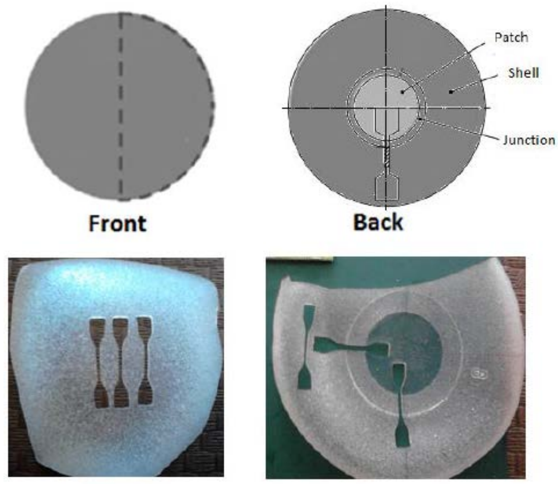

Fig. 2 - Scheme for the samples cutting from the shell of the explanted breast implants (Adapted from Nechhi, 2011)

To evaluate the mechanical properties of the shell material, tensile tests according British Standards (BS ISO 37:2005). When performing uniaxial tensile tests, it is usual to have a geometrically controlled specimen, in order to facilitate calculations and be able to reproduce the tests. Dog-bone shaped specimens (type 4) were chosen to allow an investigation of the homogeneity of the mechanical properties (see Fig. 3). Thickness was measured at three separate locations along the specimen using the digital caliper (accuracy 0-100mm ±0.02 / 100-150mm ±0.03). The mean thickness was used for all further measurements.

To ensure traceability of each sample over the implant envelope, each specimen was labelled with an identification code. This code includes information about the implant designation and location of specimen.

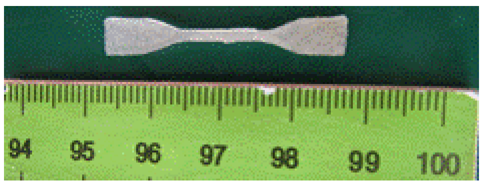

Fig. 3 - Dog-bone shaped specimens (type 4)

2.3-Tensile Tests

The uniaxial tensile test, also called simple tension test used in these study is a prototype developed at IDMEC's Biomechanics Laboratory, equipped by perpendicular aluminum arms that connect separately controlled displacement and force measurement actuators.

All uniaxial specimens were tested until failure at a constant crosshead speed, by applying a displacement rate of 5mm/min along the specimen in one direction. The test is controlled by the software and video image is obtained by the camera positioned over the testing container. The video was used to validate the test, since anomalous occurrences such as slippage or significant misalignment are easily detected. Automated software was used to analyses mechanical properties of the specimens at room temperature.

3. RESULTS

Shell Integrity study revises the hypothesis regarding the rupture causes in recent generation of silicone gel breast implants, by analyzing the mechanical properties of failed and intact implants. The main scope is to assess whether mechanical weakness of the shells should be considered as a major cause of breast implant rupture or, on the contrary, if the prosthesis shell damage is likely due to other unknown factors. Hence, the shell resistance to tensile was evaluated on a number of explanted prostheses following an ad hoc testing protocol. A total number of forty-nine specimens were analyzed and two different implants brands were compared (Polytech and PIP).

According to mechanical testing of silicone shells a simple stress-based criterion (i.e. the rupture of the device occurs when the applied stress in a point overcomes the ultimate stress of the material), these results suggest that the in vivo loading produces an equivalent tensile stress below 4 MPa in the shell of a breast prosthesis (Brandon et al., 1999, 2000, 2003a, Necchi et al, 2011 and Yildirimer et al, 2013). Indeed, no ruptures were found when the ultimate stress of the explanted prosthesis was higher than this stress value.

Obviously, this value is not a rigorous threshold but just a rough indication of the in vivo loading that, in turn, is affected by several variables such as patient activity level or prostheses size and position. Nevertheless, since the values of the ultimate tensile stress reported in the literature and in this study for shell implants are generally higher than 4 MPa, it is reasonable to presume alternative causes for failure (as traumas, undetected damages at time of implantation or explantation, shell weakness due to manufacturing defects, deterioration of the implant shell) for those types of prostheses, as suggested by Brandon and SCHENIHR (Brandon et al., 1999, 2000, 2003a).

According, the present data demonstrated mechanical weakening of PIP, compared with Polytech shells see figure 3 and 3. However, it is necessary pay attention that so much the control implant and the PIP implant is not known the time points of implantation -this may skew results. Mechanical parameters of the intact and ruptured PIP shells were compared, and it was verified minor differences between these two implants. Although differences between intact and ruptured PIP implants were not significant statistically, this trend should not be underestimated; a larger implant cohort may have resulted in a statistically significant difference (see figure 3), as demonstrated by Necchi et al (2011) and Yildirimer et al (2013).

Through visual inspection of the test, it was verified that the patch specimens ruptured in the junction zone, since this region detaches of the shell implant (see Fig. 4).

Thus, by comparing three specimens in each implant, it is possible to conclude that the silicone shell sustains higher forces, base and front of the shell (see Fig. 5 and Fig. 6), when compared to the patch area (see Fig. 5 and Fig.6), though it is necessary to pay attention some specimens of the Polytech implant were not tested until rupture.

The Polytech implants ruptured when stress is applied and occurs a higher displacement (Fig. 6) than with the PIP implants (Fig. 5). Most samples reached to the total distance of equipment without breaking.

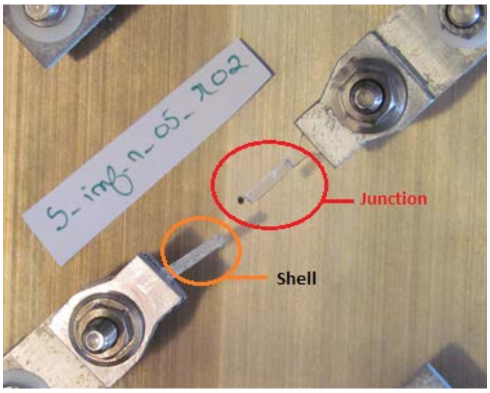

Fig. 4 – Junction region detach of the shell implant.

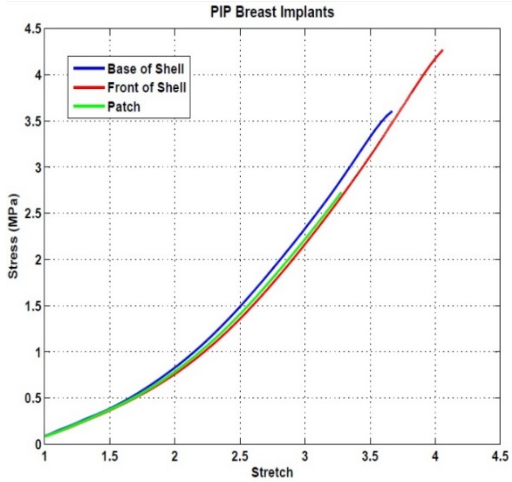

Fig. 5 – Graphic with different parts of the PIP breast implants

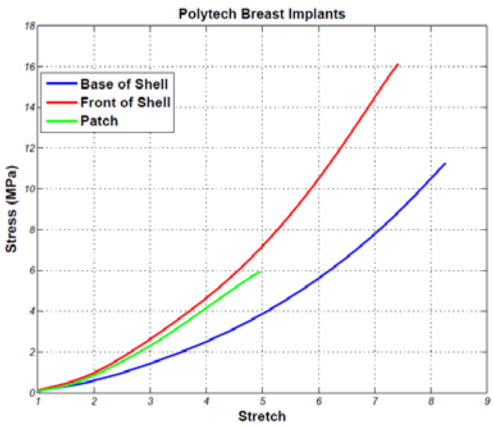

Fig. 6 – Graphic with different parts of the Polytech Implants.

Here it is noticeable that the Polytech implant sustains larger deformations, since the specimen was tested until the maximum stretch the equipment allows and did not break, which permits the observation that silicone has different properties from those of implants PIP.

4. CONCLUSION AND FUTURE WORKS

Virtually all of the extensive published literature on breast implants pertains to silicone gel breast implants in general. These studies include all the generation of implants (implants of the earliest generation to the latest). Data specifically addressing safety and health effects of PIP silicone breast implants are extremely limited until the time.

As noted above, a full assessment of the safety aspects of PIP implants involves balancing the risks associated with leaving the implants in place against the risks of undertaking explantation surgery earlier than might otherwise be necessary. In this context, it is worth bearing in mind that all breast implants have a finite life – data from the FDA suggest that 1 in 5 cosmetic breast implants, and 1 in 2 breast implants following reconstruction surgery, are explanted or replaced within 10 years According, the present data demonstrated mechanical weakening of PIP, compared with Polytech shells see figure 5 and 6. However, it is necessary pay attention that so much the control implant and the PIP implant is not known the time points of implantation -this may skew results.

In literature about the PDMS silicone rubber concludes that the structure and properties of the breast implants may well differ from one part of the shell to another part due to differences in forming temperature, pressure, etc, during formation of the shell (Daniel, 2012). This is a fact that can help to explain part of the data.

In conclusion, future work requires to evaluate the etiological factors influencing the mechanical proprieties of breast implants, such as age, duration of implantation, device placement, and compare these information with mechanical data of breast implants.

A multidisciplinary effort between the biomechanical properties of the breast implants, in this case the PIP implants, may allow a better understanding of the questions implied in biodegrading of the implants within women body or the concerns of rupture of breast implants.

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