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An experimental analysis of shell failure in breast implants

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ABSTRACT

Breast implant durability and the mechanisms of rupture are important topics in the medical community, for patients, manufactures and regulatory medical agencies. After concerns about the Poly Implant Prosthesis (PIP) implants, the need for understanding the adverse outcomes and the failure mode to improve the breast implants increased. The objective of this research is to analyze and describe the rupture characteristics of failed explanted PIP implants to study the modes and causes of rupture.

Eleven explanted PIP implants were analyzed by visual inspection and scanning electron microscopy (SEM). To simulate hypothetical ruptures caused by cyclic mechanical stress (fatigue) in the implant shell, two control implants were submitted to fatigue tests, and analyzed with SEM.

Small ruptures (either Hole or split) striations were found, which normally appear due to fatigue phenomena. Similar striations were also found in specimens (control) tested under laboratory controlled conditions.

In the context of this work, the striations found in explants constitute a significant finding as they point to the occurrence of fatigue phenomena associated with mammary implants rupture. This research, also demonstrates that rupture surface analysis of explanted breast implants has the potential to become a useful indicator for assessing implant rupture mechanisms.

1. Introduction

Breast implant rupture has been an important topic for the plastic surgery community, regulatory agencies and particularly for patients (FDA, 2006; SCENIHR, 2012; TGA, 2013). Concerns about the safety of silicone implants were intensified since the 2010 scandal involving Poly Implant Prothèse (PIP) manufacturer. Recent studies concluded that the probability of early rupture (life time lower than 10 years (Maijers and Niessen, 2012; Spear et al., 2014) is higher for PIP implants. Based on published studies, rupture rates for PIP implants ranged from 14.5 to 31% after 5 to 10 years of implantation (Berry and Stanek, 2013; Khan, 2013; Maijers and Niessen, 2012; Oulharj et al., 2014; Quaba and Quaba, 2013), while other implants showed a rupture rate from 1 to 11.6% (Maijers and Niessen, 2012; Spear et al., 2014).

The failure of breast implants is influenced by different factors: material ageing following implantation; surgical procedure quality (e.g., inadvertent damage); manufacturing defects; shell wrinkling; patch detachment, among others (Brandon et al., 2012). Another factor that possibly explains implant failure is the loading frequency imposed to the breast due to daily activities such as running and walking. This mechanism is called mechanical fatigue. Trauma injuries, such as shocks from car accidents (Bandyopadhyay and Bose, 2013) may play a role in the damage mechanism that causes implant failures.

Current literature states that a large percentage of PIP implants ruptures are possibly related to the shell quality over a large number of batches (SCENIHR, 2012; Yildirimer et al., 2013). This may point to a considerable variability in the manufacturing process.

Even though the literature indicates the manufacturing process as a principal factor leading to PIP implants failure, few studies have been conducted to characterize the type of failure (e.g. damage due to surgical instruments, cyclic loading/fatigue). Therefore, the objective of this study was to determine the causes of rupture by analyzing failed explanted breast implants, compared to the ruptures caused by cyclic mechanical stress (fatigue) in the control implant shell.

2. Material and methods

2.1. Materials

To understand how and why PIP implants show significant rates of premature failure, eleven ruptured implants, explanted in the Department of Plastic Surgery of the Hospital Center of Gaia,

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Portugal, were analyzed. Sealed controls were supplied by the National Authority of Medicines and Health Products (INFARMED, Portugal).

The explants underwent a disinfection procedure, following the health regulatory authority's standard procedure (FDA, 2006; SCENIHR, 2012).

The diagnostic techniques for explants were: Stage 1 - visual inspection; Stage 2 - scanning electron microscopy (SEM)); Stage 3 - Mechanical testing.

The last two stages will be described in Section 2.2 Scanning electron microscopy analysis and 2.3 Fatigue test.

During Stage 1, failure regions, shell rupture (hole, split or v-shaped), discoloration, opacity and other features were recorded. In this work, the methodology reported by the Department of Health Therapeutic Goods Administration (Australia) was followed (TGA, 2013).

2.2. Scanning electron microscopy (SEM) analysis

After inspection and disinfection of explants, several samples were cut from the rupture region for examination by SEM at CEMUP (University of Porto, Portugal).

Virgin (control) implants were used to simulate the implant rupture caused by a cyclic mechanical stress in the implant shell.

Fractographic studies of fatigue cracks were conducted with SEM to identify characteristic features of crack initiation and growth. Such analyses provide data on local deformation, loading conditions, crack initiation, and propagation path leading to fracture.

For SEM analysis, samples were coated with an Au/Pd thin film, by sputtering, using the SPI Module Sputter Coater equipment, for 120 s and with a 15 mA current.

2.3. Fatigue test

Fatigue tests were carried out to simulate a mechanism of fatigue crack growth, particularly the fractographic features in the implant material (Polydimethylsiloxane). The samples were fatigue loaded in a mechanical testing prototype (uniaxial/biaxial), with two load cells with 50 N capacity, developed at INEGI Biomechanics Laboratory.

The main fatigue test parameters were waveform, frequency, force or displacement levels, loading mode, and test duration (Bandyopadhyay and Bose, 2013). The samples were tested at 1 Hz because it is similar to that of walking or a beating heart (Bandyopadhyay and Bose, 2013). The displacement amplitude was 15 mm, equivalent to ~20% strain in the narrow region of the specimen. This displacement was used following tensile tests carried out in control implants. Two sample geometries were used. One a dog bone-shaped type 4 (shaft length 12 mm, width 2 mm). The other a biaxial geometry, 5 × 5 mm central square region, to induce similar stresses on both axes, as illustrated in Fig. 1. The biaxial test tries to mimic the planar stresses occurring on the implanted shell, due to cyclic loading, which should be closer to real life.

A defect was introduced in the center of the sample, using a needle of 2.3 µm diameter tip.

3. Results

3.1. Visual inspection of Implants

Eleven ruptured explants and two control implants were analyzed to characterize modes and causes of implant failure.

All the explants had round shape, textured shell and volumes ranging between 210 and 310 cc. These implants were implanted on a period ranging from 6 to 95 months, with an average of 57.36 ± 19.96 months.

Two round shaped and textured control implants were used in this study. One implant with a volume of 265cc and two with 365cc.

Following the nomenclature of TGA (2013) to describe implant rupture, four explants had a v-shape split, three had a hole, two a split and the remaining two presented gross damage.

3.2. SEM analysis of shells and failure regions

Implant failure was analyzed through SEM images from the rupture site at the cross section (magnifications of 75× and 200×).

The four implants with v-shape split ruptures had volumes between 225 and 310cc, yellow coloration and large ruptures that covered an extensive area. Rupture size varied from 80 mm to 140 mm. Four to six samples were removed (depending on rupture size), to enable the SEM analysis. Fig. 2 shows examples of gross damage and v-shape rupture.

It was not possible to identify the origin of the rupture through SEM analysis. The cross-sectional images of four implants (with v-shape split) were inconclusive, as seen in the Fig. 3.

It was also impossible to identify the origin of the implant rupture with gross damage, as shown in Fig. 4. The implants with gross damage had volumes of 245cc and 260cc; they present extensive shell rupture, covering all regions of the implant. The same procedure, used in the v-shaped split implants, was used for sample collection on the gross damaged implants.

The implants with small ruptures had volumes between 210cc and 250cc. They are almost translucid, as shown in Fig. 5a and c. Due to the small size of the damaged area, it was analyzed one sample from each implant (taken from the ruptured area). These samples (with hole or split) provide more conclusive results. In Fig. 5(c,d,e and f), the damage starting point is clearly visible. Moreover, there is visible striation normally associated to fatigue (Bandyopadhyay and Bose, 2013; Branco et al., 1999; Hosford, 2005; Ramião et al., 2017), although fatigue crack growth can occur without striation formation (Branco et al., 1999). Macroscopic marks such as “beachmarks” can be formed by thousands of striations. Each striation is formed due to one load cycle, although not all load cycles produce a striation.

In the context of this work, this constitutes a significant finding as it points (with a high degree of certainty) to the occurrence of fatigue phenomena associated with breast implants rupture (Ramião et al., 2017).

3.3. Fatigue tests results

The features identified in the crack surfaces of ruptured implants with small defects, shown in Fig. 5(c,d,e and f), seem to indicate that the defects grow by a fatigue mechanism.

Hypothetically, fatigue failure may be one of the mechanisms involved in implant rupture. To study this effect, automated fatigue crack growth tests were conducted on control implants samples.

This technique provides information on the relative strength of different breast implants, through standard fatigue test conditions applied to implant shell samples. The failure surfaces of the fatigued shell samples were examined using SEM, and the details of both the inside and outside surfaces of the shell at the failure location were described. The samples failed after ~10.000 cycles.

Two round, textured controls (volume of 365cc) were used, to simulate the effect of fatigue on the implant shell. Table 1 describes the information available about each implant.

Figs. 6 and 7 shows biaxial samples' SEM results. The striations observed are strong indicators that a fatigue process took place as a consequence of the cyclic loading. These results suggest that striations do appear in the implant shell material as a consequence of fatigue processes (Fig. 5c,d,e and f).

4. Discussion

The physical characteristics of PIP implants were analyzed. Both ruptured and virgin implants were studied. Control implants were