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Research Paper

Aging of retrieved gel breast implants: A comparison between two product generations

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ABSTRACT

In order to get a marketing authorization, breast implants (BI) must meet a number of standard requirements. French and European standards ISO 14607 list a number of official tests to be performed before an implant can be used clinically. However, the BI material characteristics evolution over implantation time remains a research field which is unexplored. The goal of the present study is to compare the mechanical ageing of two breast implant generations and assess if the use of one generation rather than the other is advantageous in terms of durability. For that purpose, 21 explanted BI were analyzed in terms of biomechanical characteristics and compared. Twelve BI were textured anatomic specimens of 5th generation and 10 BI were round textured specimens of 4th generation. All the specimens were produced by the same manufacturer. Implantation time ranged from 3 to 130 months. Both the shell and the gel of every specimen were analyzed. Results show that the mechanical properties go down with the implantation time for all the implants. Moreover, the shell of round implants appear to be less resistant than the shell of anatomic specimens with 25% lower rupture forces. With regard to the gel, whatever the specimen, results show that the properties change with implantation time. The color changes from transparent to milky to finally become yellow, while the cohesion goes down especially for the round specimens. Globally, the study brings out that BI get degraded with implantation time and provides information which could help predicting the durability of the implant.

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1. Introduction

Silicone gel-filled breast implants are commonly used for breast augmentation and breast reconstruction procedures. In France, breast implant marketing authorization is controlled throw the CE marking procedure. Several regulatory testing are undertaken to control biomechanical properties before utilization (NF EN ISO 14607 standard 2009–11) (NF EN ISO 2009). Minimal standards are defined concerning tensile strength, elongation at break, gel cohesion, perspiration and other. However, the qualities of breast implants are never checked after implantation and there is a lack of information concerning material kinetic ageing. For regularity authorities, the only ways to assess the real performance of silicone breast implants are observational study based on implant failure rate. National retrospective evaluations are biased by the incompleteness of incident reports (ANSM 2014), whereas only a few prospective systematic analyses have been conducted with sometimes conflict of interest (Spear and Murphy 2014; Brandon et al., 2003; Greenwald et al., 1996; Marotta et al., 2002; Wolf et al., 1996; Caplin 2014).

In this preliminary report, we performed independent analyses of explanted breast implant quality. We studied the biomechanical property of 21 explanted breast implants and two virgin implants coming from the same manufacturer. Several testing were applied on silicone shells and gels. The goal of this study was collecting independent data about in vivo breast implant quality and initiate kinetic ageing knowledge. Mechanical properties of two different types of silicone gel-filled implants were compared according to the implantation duration. The first type was a round shape implant from the fourth-generation with a less cohesive gel, whereas the second one was an anatomical shape implant from the fifth-generation containing a great cohesive silicone gel. The ultimate objective of the work was to compare the

Table 1 – Breast implants studied.

No.	Implantation date (mm/yyyy)	Explantation date (mm/yyyy)	Implanta-tion duration (months)	Type of prosthesis	Reason for explantation	Unbroken	Broken
5	05/2007	04/2012	59	anatomical	Aesthetical reason	X	
10	01/2012	04/2012	3	anatomical	Aesthetical reason	X	
12	03/2002	06/2012	124	anatomical	Aesthetical reason	X	
13	03/2002	06/2012	124	anatomical	Aesthetical reason	X	
15	01/2009	08/2012	43	anatomical	Suspected rupture		X
17	10/2005	10/2012	84	anatomical	Aesthetical reason	X	
23	04/2005	06/2013	98	anatomical	Aesthetical reason	X	
24	05/2011	08/2013	27	anatomical	Aesthetical reason	X	
25	07/2006	09/2013	86	anatomical	Aesthetical reason	X	
27	06/2013	11/2013	5	anatomical	Aesthetical reason	X	
28	09/2006	11/2013	87	anatomical	Suspected rupture		X
6	10/2002	11/2011	110	round	Aesthetical reason	X	
7	07/2006	09/2011	62	round	Suspected rupture		X
9	10/2010	01/2012	16	round	Contracture	X	
11	06/2002	06/2012	120	round	Aesthetical reason	X	
18	05/2009	11/2012	42	round	Suspected rupture		X
19	08/2007	12/2012	64	round	Suspected rupture		X
21	03/2009	05/2013	51	round	Suspected rupture		X
26	07/2006	09/2013	86	round	Suspected rupture		X
29	07/2007	11/2013	77	round	Suspected rupture		X
31	04/2003	01/2014	130	round	Suspected rupture		X