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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 explanation	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

ageing of both types and try to predict the date of rupture for each model.

2. Material and methods

2.1. Sample preparation

Between 2011 and 2014, 21 silicone implants made by the same manufacturer and used for breast reconstruction ($n=11$) or breast augmentation ($n=10$) were collected. Breast reconstructions were all performed with the same anatomical shaped implant, while aesthetical bilateral breast augmentation and contralateral breast augmentation associated to breast reconstructions were all performed with the same round shape implants. Different surgeons explanted the 21 implants. The two types of tested prosthesis were textured silicone gel-filled implants with a low-bleed barrier. The 10 round shape specimens belonged to the fourth-generation, while the 11 anatomical shapes specimens belonged to the fifth-generation. Breast volume ranged from 180 to 685 cc. The mean duration of implantation was 76 months in average for the round shape (range 16–130 months), and 67 months in average for the anatomical shape (range 3–124 months). Implant removals were indicated for one perisprosthetic contracture, nine shell ruptures and 11 aesthetical reasons. In the case of contracture, the patient was suffering from a hard and painful breast classified as grade IV of Baker. Esthetical reasons were most often the need to improve mound shape in the second stage of breast reconstruction or in delayed reoperation. Seven round implants (70%) and two anatomical implants (18%) were ruptured at time of removal. The main characteristics of the prostheses are summarized in Table 1. To serve as reference, one virgin (non-used) implant was added to each implant type group. All the tests performed in this work were carried out on both explanted and virgin specimens using identical testing protocol.

At time of reception, visual characteristics as well as integrity of the specimens were evaluated and all explants were photographed. The gel was then removed and transferred to labeled container to be photographed and macroscopically analyzed. The shell of the implant specimens was then cleaned with isopropyl alcohol and dried. The thickness of the shell was measured with a KES–FB3 (Kawabata evaluation system of fabric). The thickness (T_0 in mm) was determined under a pressure of 0.5 cN/cm^2.

The shell thickness of each implant was measured in at least 10 locations around each shell. Moreover, for the anatomical shape, the thickness between the patch side and the opposite side to the patch were compared.

2.2. Gel cohesion testing

The silicone gel from only 15 breast implants was available for characterization: six round style specimens (included the non-used implant) and nine anatomical style specimens (included the non-used implant). The test was assessed according to the national and international standards ISO 37 and NF EN ISO 14607 (NF EN ISO 2009). The equipment consists of a 61.9 mm$\pm$1 high cone, with an upper diameter of 70 mm$\pm$1 and a lower diameter of 15 mm$\pm$0.1. This cone was machined from a block of aluminum with a surface roughness of 0.2 μm. It was fixed over a container to catch any pieces of gel that may flow. Before and after each test, the cone was cleaned with isopropyl alcohol.

In all specimens, the gel was removed from its shell, and then introduced into the cone. Precautions specified in Annex D of the standard have been respected. The gels were handled with smoothness, without stirring and avoiding air inclusions. The flow of gel was observed during 30 min. The gel hanging

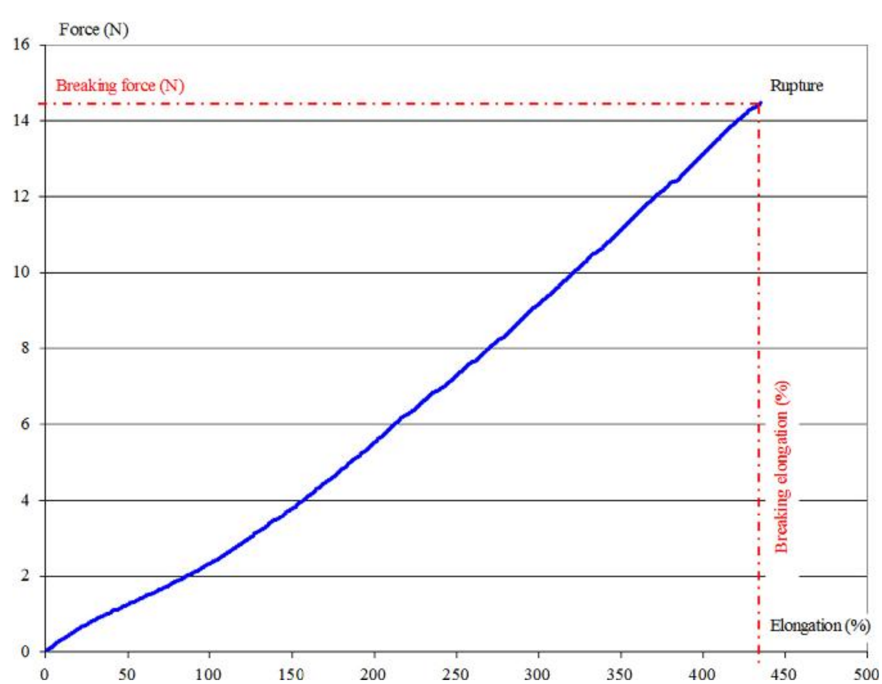

Fig. 1 – Typical force elongation curve.

length at the lower end of the cone was measured. If this length was greater than or equal to 30 mm, the test was invalid because the cohesion was not considered as good enough. Moreover, the general appearance of the gel and its color were analyzed.

2.3. *Shell mechanical properties assessment*

All 21 implants were studied at mechanical level. Mechanical properties were assessed according to the national and international standards ISO 37 and NF EN ISO 14607 (NF EN ISO 2009). All tests were performed in a conditioned atmosphere (temperature: 20±2 °C; relative humidity: 65%±2%). Testing samples were cut in empty shells using a cutting press according to a predefined H2 cutting scheme.

Tensile tests were performed on the samples with an Adamel Lhomargy (MTS) dynamometer equipped with a 100-N load cell and pneumatic grips. A test specimen of type H2 was fixed in corrugated dynamometer grips, ensuring that 40 mm of material was taken between the clamps. Samples were tested up to rupture (extension rate=500 mm min^{-1}) and a force–strain curve was plotted for each test (Fig. 1). The breaking force (N) as well as the elongation at break (%) was determined from the obtained curve. In order to compare the two types of implants and overcome the dimensional characteristics, which are different from one implant type to the other, the stress applied on the samples was calculated from the measured force. The stress (MPa) is defined as the ratio between the value of the force applied on the sample and its cross-sectional area (mm^2). The stress and strain curve was then plotted. The elastic modulus for each specimen was calculated as the slope of stress-strain curve taken at 50% strain. Data outside the zone of interest for each specimen's stress–strain curve were eliminated until the least-squares regression of remaining data point yielded a coefficient (r^2) >0.95. The toughness before rupture was calculated from the following formula $CT = \int_0^{Rupture} \sigma \, d\varepsilon$. All the results were given with average values and standard mean deviation. In some cases, up to four specimens of a same sample could be tested. In other cases due to the lack of material only one specimen was tested.

3. Results

3.1. *Gel cohesion testing*

The results obtained for the two types of prostheses are presented in Table 2. For the round style, the gel obtained from the reference prosthesis (0 months) was transparent and colorless. As seen in Fig. 2 according to implantation periods, the gel color was generally first milky, then yellow. At qualitative level, from the six gel samples, four had all lost their original shape and tended to spread out. The two gels left had kept their original shape (virgin prosthesis and gel explanted at 86 months). At quantitative level, only two gel

Table 2 – Results of gel cohesion tests.

No.	Implantation duration (months)	Gel cohesion	Hanging portions of gel (mm)	Gel color	Gel aspect and remark
Anatomical prostheses					
Ref.	0	Validated	2	Transparent	Cohesive
27	5	Validated	0	Transparent	Cohesive
24	27	Validated	0	Not transparent and whitish	Cohesive
15	43	Validated	0	Not transparent and slightly yellow	Cohesive
17	84	Validated	0	Not transparent and yellow	Cohesive
28	87	Not validated	40	Cloudy and yellow	Aspect broken. Pieces were detached
23	98	Validated	0	Not transparent and yellow	Cohesive
12	124	Validated	0	Not transparent and yellow	Cohesive
13	124	Validated	0	Not transparent and slightly yellow	Cohesive
Round prostheses					
Ref	0	Validated	0	Transparent	Cohesive
9	16	Validated	18	Transparent slightly whitish	Aspect broken, a little sticky.
29	77	Not validated	40	Transparent yellow	Aspect broken.
26	86	Validated	0	Transparent slightly yellow	Cohesive
11	120	Not validated	100	Slightly whitish	Aspect broken. Pieces were detached
31	130	Validated	5	Transparent yellow (lemon)	Aspect broken. Gel with little cohesion but extremely sticky

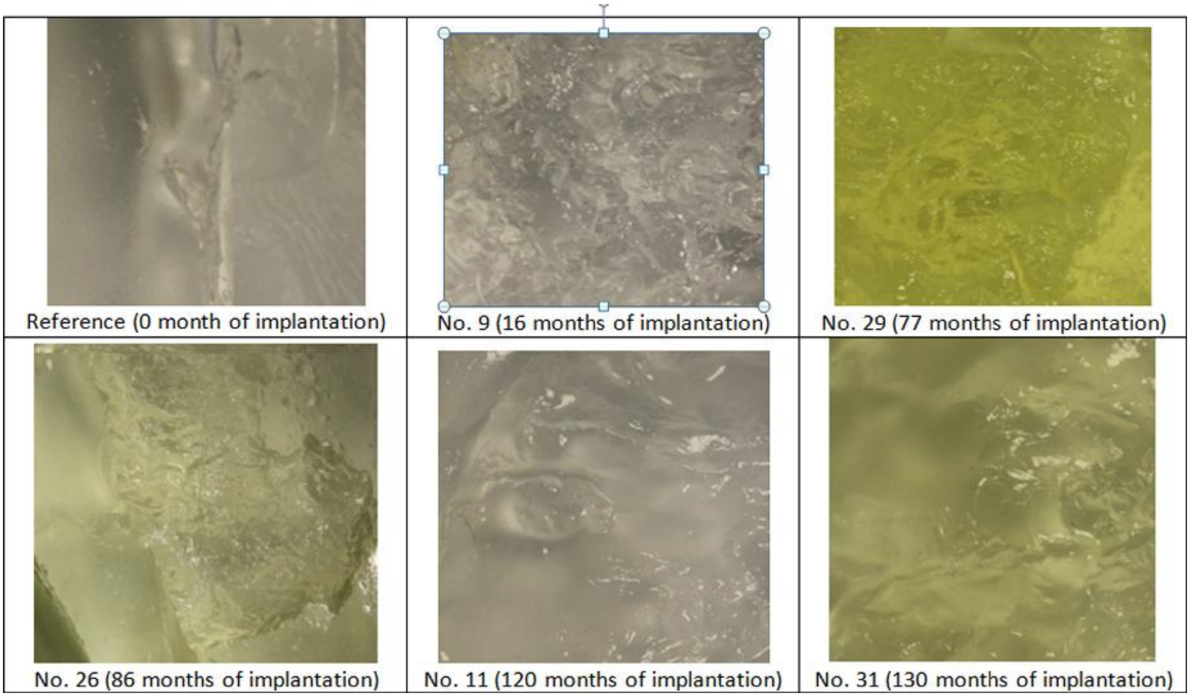

Fig. 2 – Gel cohesion (round). (For interpretation of the reference to color in this figure, the reader is referred to the web version of this article.)

samples did not satisfy the requirements of the test. The hanging portions from the 77 months and 120 months old gels measured 40 mm and 100 mm respectively. The four remaining gel samples satisfied the requirements of the test, with hanging portions of gel between 0 and 18 mm.

For the anatomical style, as seen in Fig. 3 the gel color depends on the implantation duration. Two gels (0 and 5 months) were transparent and colorless. The others lost their transparency to become slightly translucent. The 27 months sample was milky while the older ones became yellow. One exception was, however, one of both 124 months gels, which remained white despite the long implantation time. Regarding the gel cohesion, it was kept for all samples but one. The cohesion test showed that, among nine samples, only the 87 months old gel did not meet the test requirements. The hanging portion of this gel measured 40 mm. Regarding the gel from the virgin prosthesis, the pending portion was 2 mm.

Finally, among all the tested samples and whatever the implant type, 12 specimens out of 15 satisfied the gel testing conditions and showed appropriate flowing behavior. The hanging length was ranged between 2 and 18 mm with the lowest value for the virgin prosthesis.

3.2. *Shell mechanical properties assessment*

3.2.1. *Breaking force*

The mechanical properties of the two types of prostheses are presented in Fig. 4a and b. Among the round shape implants, the virgin specimen was the only one in accordance with the standard. All the other specimens showed important drop in strength ranging from 7.2 to 63.7% with already 31% after only 42 months of implantation. The implant having the weaker breaking strength was the 64 months (dating back to 2007). Regarding the anatomical style specimens, the resistance of all but one (3 months) fell below the value recommended by the NF14607. It appears that the implants with the lowest mechanical resistance were those explanted after 84–86 months from 2006 to 2005. Actually, for those, the breaking strength value was even lower than what could be observed with the explants dating from 2002. Globally, the results bring out that the breaking strength goes down with the implantation duration in a range from 3.5 to 40.5%.

3.2.2. *Breaking stress*

The evolution of the breaking stress values versus the implantation time is given in Fig. 5. Each plot symbol represents the average value of breaking stress for all implants and the error bars represent the standard deviation. On can observe that, whatever the implant type considered, round or anatomical, the breaking stress goes down progressively up to 86–87 months of implantation. Above that time threshold, the drop tends to stabilize. However, it is notable that the drop in strength is lower for the anatomical style implants after 87 months of implantation (37%) than for the round style (52%) after only 64 months.

3.2.3. *Elongation at break*

Results are presented in Fig. 6a and Fig. 6b. Regarding the round style implants, only one implant respected the standards. Average elongation at break was 403% (Table 4). Moreover, one can observe that the value decreases rapidly over the 51 months of implantation (by 26%) to reach a minimum after 64 months (42%). The drop was then stabilized (Fig. 6). The implant characterized by the lowest elongation at break was the 64 months from 2007 (lower value than for the implant produced in 2002). With respect to the anatomical

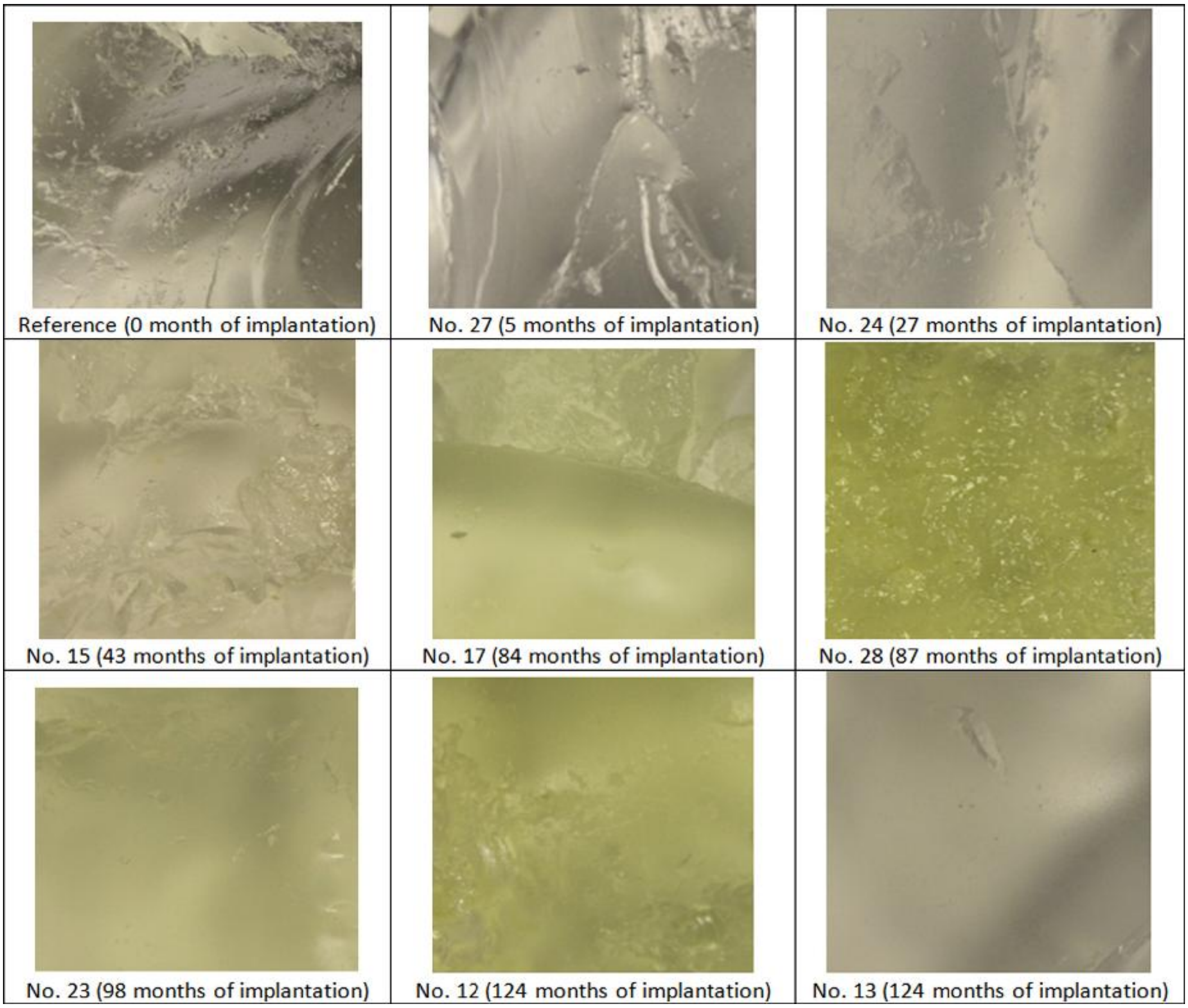

Fig. 3 – Gel cohesion (anatomical). (For interpretation of the reference to color in this figure, the reader is referred to the web version of this article.)

shape, only the 84 months implant was below the standard with 450% elongation. It appears that the prosthesis characterized by the lowest elongation value was the one explanted after 84 months dating from 2005. In that case, the elongation at break value was lower than the value observed for the implants produced in 2002. This result needs however to be confirmed with future additional tests. Average elongation at break was 503% for the anatomical type (Table 4).

3.2.4. *Elastic modulus*

Forty percent of round style implants were characterized by elastic modulus values lower than the one for the reference implant. The value remained more or less constant over the time of implantation. Regarding anatomical style implants, 91% were characterized by lower elastic modulus than the reference implant (Table 3). For these specimens the modulus value appeared to drop slightly after 64 months up to 87 months and then remained fairly stable.

3.2.5. *Toughness*

Regarding the round style, the toughness drops suddenly after 42 months of implantation (by 41%) and then more progressively to reach 69% after 64 months of implantation (Table 3). In the case of anatomical specimens, the toughness value droped in general by 12% after 43 months of implantation and by 50% after 86 months. The value was then stabilized.

3.2.6. *Shell thickness*

The shell thickness of each implant is presented in Table 3. Globally, for round style implants, a decrease in thickness could be observed especially after 51 months of implantation. The average decreasing rate was 16%. On the contrary, with respect to anatomical implants, the thickness varied less over the implantation time. The average decreasing rate was 8%. Moreover, one observes in Fig. 7 that the shell thickness on the patch side was greater than on the opposite side for the anatomic implant (around 8% difference).

4. Discussion

Currently, breast implant should be tested before implantation to control mechanical property with standards ISO 37 and NF EN ISO 14607 (NF EN ISO 2009). As no standard exist for explanted prosthesis, we decided to compare remaining mechanical properties to the official pre implantation standards, being

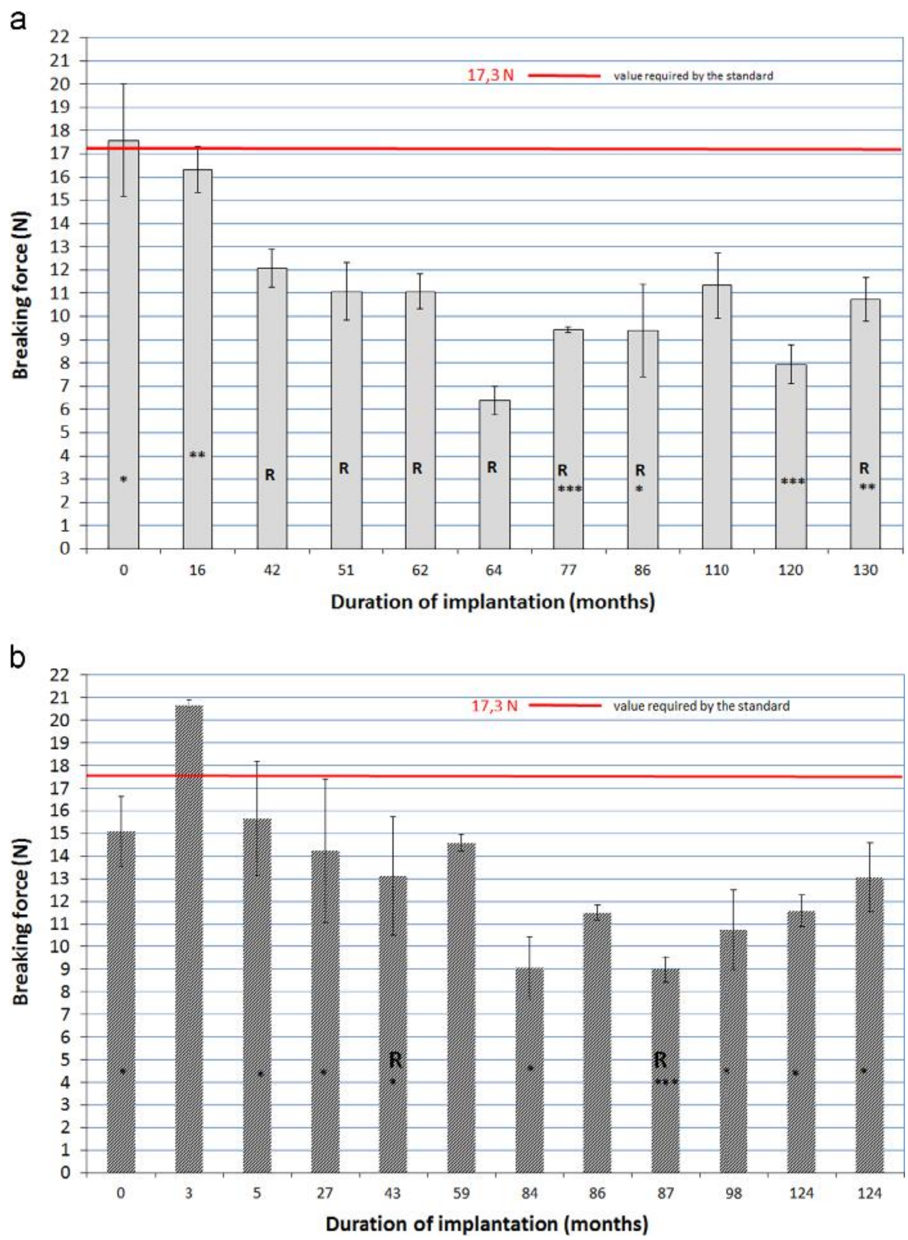

Fig. 4 – (a) Breaking force (round) and (b) breaking force (anatomical).

aware that this standard is not fitted for used implant. This special feature explains why many results are under the standards. For example, regarding the breaking stress, all explanted implants but one were tested under the value required by the standards. This result did not necessary mean that breast implant quality were insufficient. It simply shows that, in vivo, breast implants quickly lose their mechanical property. This highlight also the lack of standards concerning breast implant normal wear.

Several studies on silicone breast implant have demonstrated that shells weaken over time in vivo. The rupture rates were always correlated to the number of implantation years (Robinson et al., 1995; Peters et al., 1994). Mechanical tests repeatedly showed that shell strength, shell toughness and shell elasticity reduced with the age of implantation (Greenwald et al., 1996; Van Rappard et al., 1988). Those observations were however made with old manufacturing implant process until the third generation and it should be confirmed with new generations. In this study, the textured round shape implants were from the fourth generation (Maxwell and Baker, 2006) and the textured anatomical shape implants were classified as fifth-generation with great cohesive gels. By definition, the fifth generation implant was created by manufacturers to better fulfill the upper pole of the breast. In order to maintain the anatomic shape, the shell was filled with a silicone gel of greater cohesiveness (Colobrace and Capizzi 2014). The results showed that the mechanical values of the shells globally decrease over time for both generations. With regard to the stress at break, one can notice that the stress value goes down in general with implantation time. This brings out that the implantation environment tends to degrade the material whatever the implant considered.

More than wear over time, it was interesting to specify the strength curves relative to the implantation duration in order

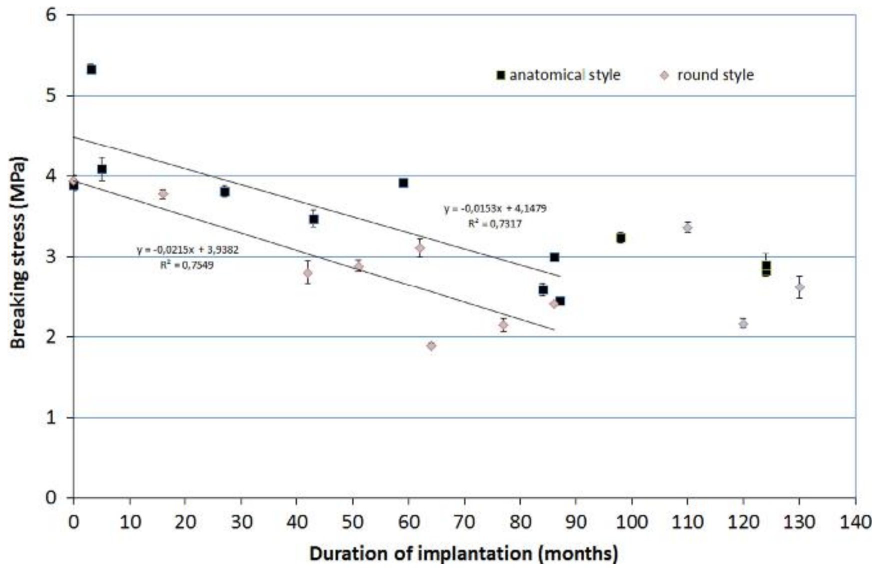

Fig. 5 – Breaking stress.

to understand mechanisms of ageing and to be able to estimate a mean rupture date. Is there a linear correlation between duration of implantation and quality or are there other evolutions? As noted by Brandon et al. (2003), who studied prostheses of 1st, 2nd and 3rd generations, the properties of Silastic II explants were observed to initially decrease after the implantation process and then reach an equilibrium values. The properties drop was theoretically explained by the diffusion of non-cross-linked silicone from the gel into the shell during the early years. In this study, all the results showed a regular drop of the shell mechanical properties until around 86 months of implantation whatever the implant type. For longer implantation times, the values seem to remain relatively stable. However, it may be observed that old round specimens implanted between 2002 and 2003 have surprisingly not undergone any damage. Conversely, those implanted between 2006 and 2010 have all broken. Similar observations can be made with the anatomic implants. Only those implanted in 2006 and 2009 went broken, with weaker mechanical properties than those implanted before 2003 despite shorter implantation time. Those results have to be confirmed with more implants specimens before founding any explanation in the variability of implant quality the day of implantation due to manufacturing process change or shelf storage variability.

However, a closer look to the anatomic reference implant shows that the shelf storage time can already be critical for the mechanical resistance of the implant. The anatomic reference was outdated and was characterized mechanically after 88 months storage on the shelf. The measured braking strength value was below the accepted limit given by the ISO (15 N vs 17.3 N). With regard to the gel, if the color was not modified out of the body, the cohesion was slightly reduced with time (2 mm hanging length), while for some explanted specimens the gel does not even reach the cone extremity. This result have to be confirmed, but it probably means that implants used close to the expiration date (60 months) have already undergone some mechanical degradation and will not last as long as expected once implanted. Storage time should be therefore limited.

The current study compare for the first time the mechanical property of explants from the fourth-generation with explants from the fifth-generation. Whatever the test applied, anatomic implants (5th generation) seem to be characterized with better performances in general. It is notable that anatomical implant types are less impacted by the reduction of breaking stress (11% strength reduction vs 29% after respectively 43 and 42 months of implantation), which underlines that anatomic implants are more resistant over time. This superiority is also significant for elongation at break tests: anatomical implants are characterized with larger values on average than round ones (503% vs 403%). Moreover, the elongation value decreases with implantation time in a faster way for the round specimens than for the anatomic ones (30.5% vs 11.6%). Most of retrospective studies conducted by manufacturers point out a global rupture rate after six or ten years but never compare different implant types to each other (Spear and Murphy, 2014; Maxwell et al., 2012; Spear et al., 2007). These works did not investigate differences in rupture rate and mechanical properties between round implants of fourth generation and anatomic implants of fifth generation. The only sponsored comparative study was conducted by Caplin (2014). Rupture rates were lower with anatomical shaped implants than with round shaped implants at 8 years after primary augmentation procedures (3.1% versus 103%, $P<0.05$).

According to Colobrace and Capizzi (2014): “the fifth-generation implants have the same silicone elastomer and low-bleed shell present in previous generations”. This assertion has to be seriously confirmed with more virgin implants. It would be desirable to check if the manufacturing process and low-bleed barrier are really similar in both generations. Indeed, Adams et al. (1998) demonstrated evidence of neutral lipid and phospholipid in the silicone elastomer. The absorption of lipid species from blood would be directly linked to the mechanism of elastomer degeneration and would be more pronounced in the low bleed barrier. Considering that fifth and fourth generation implants had the same manufacturing

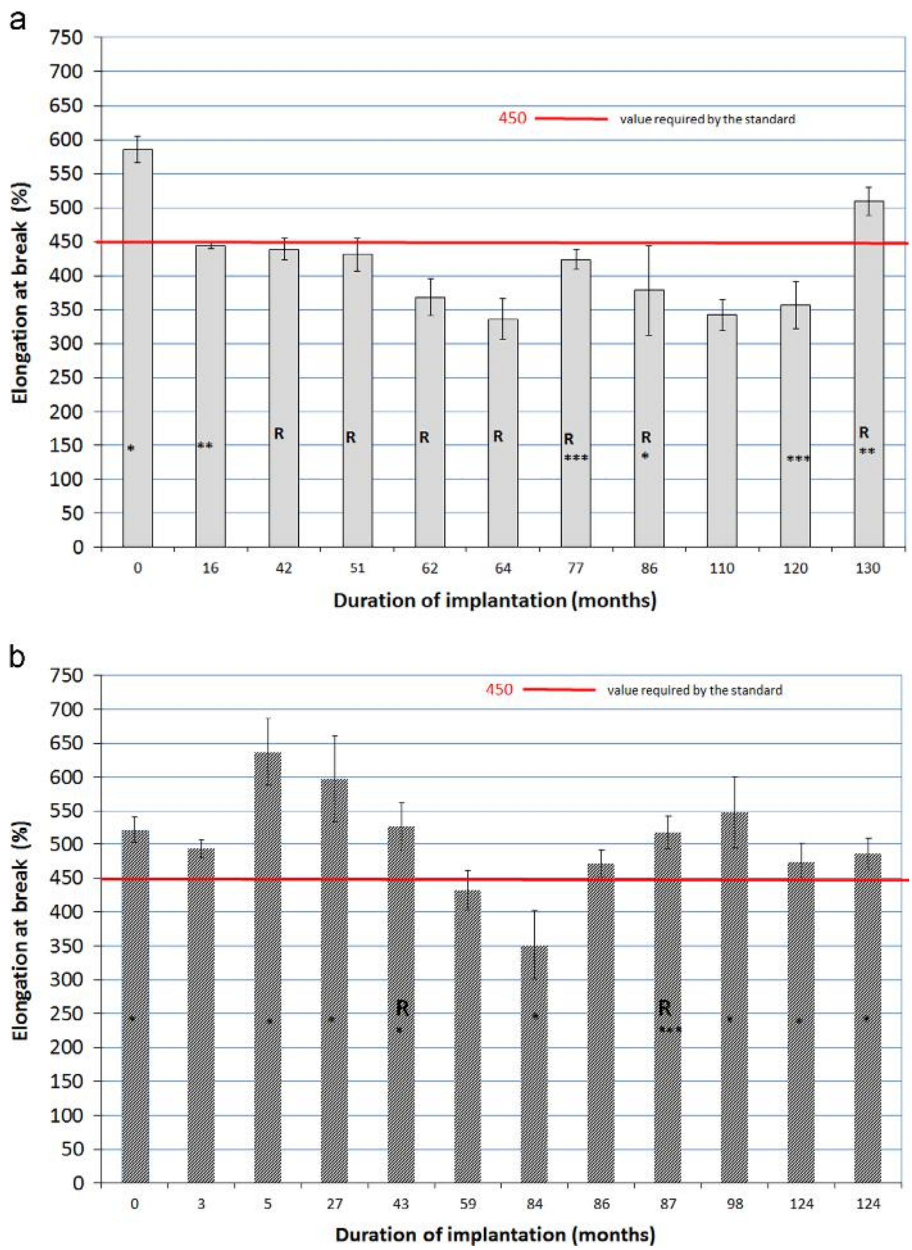

Fig. 6 – (a) Elongation at break (round) (b). elongation at break (anatomical).

process and the same shell elastomer, several parameters are able to explain differences in explanted shell properties. The implant geometry might influence mechanical constraints in favor of anatomical shape. But we suspect that gel properties and implant fill rates are more important involved parameters.

Gel properties are able to influence shell resistances in different ways. The evolution of the gel color seems to be similar from one prosthesis type to the other. Initially transparent, the gel color becomes generally milkier with time, to finally become yellow. This coloration may come from biological medium diffusion that occurs through the membrane from external to internal. However, in two cases from each implant type, the gel color remained white showing that the phenomenon does not happen all the time. Moreover, the color evolution can be different for two prostheses implanted in one patient at the same time. It seems to be patient and location dependent. With regard to the viscous behavior of the gel, the tests bring out qualitatively that the cohesion is kept at high level in the anatomic implants whatever the implantation duration. In only one particular case, the cohesion appeared to be broken. This can be explained by the fact that the gel of the anatomic implants is more cohesive already at manufacturing level in order to ensure that the anatomic shape is kept on the long term. Conversely, the gels from the round style implants appeared all broken, except for one specimen. The results are then showing that the more cohesive gel of the fifth generation is more resistant in time than the gel of the fourth generation. The broken gel of the round implant may increase the level of non-cross-linked silicone that accentuate the mechanism of shell diffusion theorized by Brandon et al. (2003) and accentuate the process of shell progressive deterioration.

However, no systematic and direct correlation can be established between the gel integrity and the shell rupture,

Table 3 – Overall detailed results.

No.	Duration of implantation (months)	Toughness (MPa)	Standard deviation	Elastic Modulus (MPa)	Standard deviation	Thickness (mm)	Standard deviation	Breaking stress (MPa)	Standard deviation
Round style									
Reference	0	9.55	0.70	0.635	0.013	1.116	0.060	3.94	0.06
9	16	9.41	0.30	0.750	0.052	1.085	0.055	3.77	0.04
18	42	5.52	0.33	0.668	0.094	1.076	0.069	2.80	0.07
21	51	5.63	0.83	0.696	0.126	0.959	0.090	2.89	0.09
7	62	6.41	0.21	0.717	0.012	0.866	0.065	3.11	0.05
19	64	2.94	0.49	0.583	0.011	0.844	0.021	1.89	0.02
29	77	4.28	0.47	0.514	0.001	1.098	0.080	2.15	0.08
26	86	5.50	0.31	0.658	0.013	0.935	0.005	2.41	0.06
6	110	6.60	0.62	0.813	0.067	0.799	0.023	3.36	0.02
11	120	3.52	0.35	0.614	0.010	0.917	0.044	2.16	0.04
31	130	6.23	0.05	0.555	0.046	1.081	0.108	2.62	0.11
Anatomical style									
Reference	0	8.99	0.20	0.751	0.062	0.970	0.066	3.89	0.07
10	3	13.89	0.68	0.888	0.026	0.969	0.060	5.33	0.06
27	5	13.12	3.22	0.686	0.074	0.958	0.141	4.08	0.14
24	27	11.68	3.50	0.639	0.091	0.935	0.069	3.81	0.07
15	43	7.89	1.31	0.659	0.136	0.944	0.108	3.47	0.11
5	59	8.77	1.20	0.742	0.066	0.931	0.035	3.92	0.04
17	84	4.44	1.10	0.745	0.021	0.875	0.079	2.59	0.08
26	86	6.62	0.09	0.663	0.034	0.960	0.005	2.99	0.01
28	87	6.28	0.66	0.499	0.036	0.916	0.040	2.45	0.04
23	98	6.15	1.82	0.554	0.059	0.829	0.049	3.24	0.05
12	124	6.08	0.36	0.601	0.049	1.024	0.145	2.83	0.15
13	124	6.90	1.15	0.585	0.053	1.125	0.151	2.90	0.15

Table 4 – Results summary.

		Round style	Anatomical style
Number of explants		10	11
Observed average	Breaking stress (MPa)	2.83	3.46
	Elongation (%)	403	503
Number of prostheses corresponding to the values given by the NF 14607 (considering only average)	Force (N)	0 (0%)	1 (9%)
	Elongation (%)	1 (10%)	9 (82%)
Number of broken prostheses		7 (70%)	2 (18%)
Elastic modulus (MPa)		0.65	0.66
Toughness (MPa)		5.96	8.40
Thickness (mm)		0.98	0.95

suspecting the effects of other factors. When comparing anatomic implants characterized by ruptures in the membrane, the gel was broken in case no. 28 aged of 87 months, while cohesion was maintained in case no. 15 aged of 43 months. When comparing round implants no. 26 and no. 11, respectively aged of 86 month and 120 months, following observations can be made. Shell is ruptured in the first case while gel is characterized by good cohesion properties. Conversely, in the second case, the gel spread out while the shell was not ruptured. Moreover, the ruptured shells did not seem to be less resistant than the non-ruptured shells. This result is in contradiction with other publications (Necchi et al., 2011; Yildirimer et al., 2013) and brings out that the knowledge of shell mechanical properties is not sufficient to predict if the membrane is going to disrupt or not. The chemical degradation of the polymer in the biological environment could be one cause of rupture beside the mechanical stress.

Indeed, other parameters must be taken in account to explain early shell ruptures. Low gel cohesiveness and law fill implant are suspected to cause more folding of the elastomer in the body. Those characteristics may lead to increase the shell stress due to body movement and lead to premature implant wear as described by Brody (1988) as "fold flow phenomenon". No official information is actually published, but according to the manufacturer, round implants of this study were filled at a level of about 86% whereas anatomic implant had a filling rate of about 98%. Therefore, we found a high difference in rupture rate between less filled round explants (70%) and high cohesive anatomic explants (18%). These results tend to confirm the "fold flow theory" also

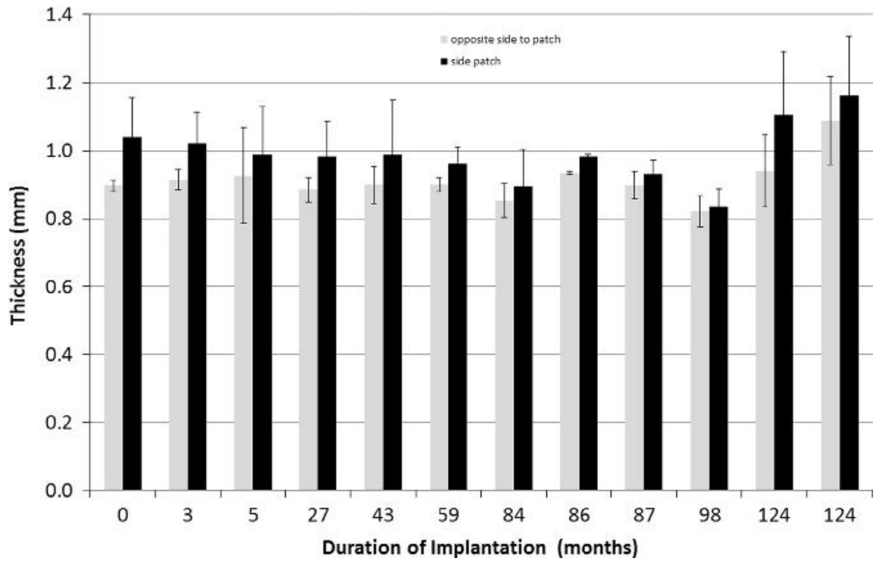

Fig. 7 – Shell thickness measurements.

supported by Hammond (2011), Per Hedèn et al. (2006) and Colobrace and Capizzi (2014); the prevention of shell collapse produces less shearing forces, reduce wear and tear on the shell and lead to decreased rupture rates. From a mechanical point of view, if the gel is more cohesive, the shell undergoes reduced deformation amplitude during daily use. The generation of local folds that can occur in the breast implant membrane is therefore limited. The membrane is less stressed and more durable. This seems to be confirmed with the results presented in this work.

5. Conclusion

In this work, two generations of implants were tested and compared, an anatomic of fifth generation and a round one of fourth generation. Results show that both the shell and the gel undergo modifications with implantation time, whatever the implant considered. Globally, the biological environment and the cyclic stress applied on the implant tend to degrade the material. However, according to the observations made in this study, anatomic implants appear to be characterized by improved mechanical characteristics compared to round ones. Actually, the higher rupture rate observed for round implants cannot be justified only by the shell mechanical properties, the shell material being not different from one generation to the other. The results show that the gel cohesion must be involved in the long term durability of gel implants. Anatomic gel is more cohesive to maintain the shape of the implant. During daily use, shell undergoes therefore reduced deformation amplitude and the generation of local folds that can occur in the breast implant membrane is limited. The membrane is less stressed and more durable. In further work, more systematic and independent analyses should be performed on a larger amount of implants to confirm the obtained results. This would improve the understanding of the ageing mechanisms and help controlling and increasing the quality of breast implants.

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