BIO STABILITY AND BIO DURABILITY OF SILICONE IMPLANTS

I - Introduction

The purpose of this document is to study the bio stability and bio durability of silicone implants by a revue of the literature.

Silicone is a well-known material, used as medical device for many years. Medical applications of silicones increased considerably over the last two decades especially in the fields where their elastic properties are useful. The stability of the implants in the long term use, especially in the biological environment is an important criterion for their medical use.

We must differentiate the use of injection of liquid silicone and the implantation of solid silicone devices such as catheters, mammary prosthesis, suspension threads and other silicone implants.

II - Methods

To study the biological stability and bio durability of long-term implants and their local and general side effects we have done a bibliography revue on "pubmed" with the following keyword: "silicone implants, bio stability, long-term safety, long term effectiveness, epidemiological evidence, autoimmunity".

No many implanted devices have been studied as well as silicone implants in terms of safety, in particular the breast implants. However, silicone implants are used in many diseases outside aesthetic medicine and surgery.

In fact, the bio-stability and half-life of elastomers depend on the type and structure, but more important, it depend on the conditions of their use.

1 - Mechanical properties

Measurements of elastic properties in static implantations including subcutaneous location, that corresponds to the suspension threads show a remarkable stability (1.2) as opposed to the settlements in the cardiovascular system where multiple degradation mechanisms involve (hemodynamic conditions, enzyme, absorption of blood lipids and products of oxidation, calcification) resulting in a change of stability.

This is probably related to different oxygen concentrations in the different sites of the body and different modes of mechanical solicitations.
The development of sensitive and non-invasive magnetic resonance (MR) techniques for monitoring the fate of silicones in breast prostheses in vivo requires detailed knowledge of the MR properties of these silicones. To characterize changes in the proton dynamics, relaxation time measurements (T1 and T2) were obtained on virgin and explanted breast prostheses using both spectroscopic and imaging techniques in a magnetic field of 1.5 Tesla. Averaged transverse relaxation times (T2) were observed to depend neither on the measurement technique employed (virgin silicone, $T2 = 160 +/- 5$ msec with imaging and $154 +/- 9$ msec spectroscopically) nor on the effect of being implanted in the body for various periods of time ranging from 4 months to 17 years (explanted silicone, $T2 = 164 +/- 16$ msec with imaging and $159 +/- 25$ msec spectroscopically). Average longitudinal relaxation times (T1) were also found to be similar for virgin and explanted prostheses (virgin silicone $T1 = 899 +/- 32$ msec, explanted silicone $T1 = 879 +/- 75$ msec, measured with imaging), but appeared to depend on the measurement technique employed (virgin silicone $T1 = 764 +/- 17$ msec, explanted silicone $T1 = 765 +/- 23$ msec, measured spectroscopically). Although the measured relaxation times did not reveal any differences between virgin and explanted prostheses, marginal differences were detected between the relaxation times of explanted prostheses from different manufacturers.” (2).

Modification of mechanical properties of silicone bands after implantation in dogs. (1)

<table>
<thead>
<tr>
<th>Implantation period (months)</th>
<th>Change in tensile strength (%)</th>
<th>Change in elongation (%)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>$-2.1$</td>
<td>$+11.3$</td>
<td>Leininger et al.$^2$</td>
</tr>
<tr>
<td>6</td>
<td>$-6.4$</td>
<td>$-8.4$</td>
<td>Swanson, LeBeau$^3$</td>
</tr>
<tr>
<td>24</td>
<td>$-8.0$</td>
<td>$-15$</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>$-6.5$</td>
<td>$-14$</td>
<td>Roggendort$^4$</td>
</tr>
</tbody>
</table>

Because elasticity of silicone is very important (100 to 500%), these changes are minor.

2- Safety studies

Safety studies on stability and long-term evolution have focused on breast implants manufactured for over thirty years.

H. Brandon’s study (3) in 2003 showed good mechanical and biochemical properties of breast prosthesis implanted for 32 years. These breast implants were replaced because of aesthetic modification or contraction of the capsule.

Silicone Gel Explants with Longest Implantation Times (3).

<table>
<thead>
<tr>
<th>Explant</th>
<th>Years</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cronin seamed</td>
<td>32</td>
<td>Intact*</td>
</tr>
<tr>
<td>Cronin seamed</td>
<td>32</td>
<td>Intact</td>
</tr>
<tr>
<td>Silastic 0</td>
<td>28</td>
<td>Intact*</td>
</tr>
<tr>
<td>Silastic 0</td>
<td>28</td>
<td>Intact</td>
</tr>
<tr>
<td>Silastic I</td>
<td>20</td>
<td>Pinhole</td>
</tr>
<tr>
<td>Silastic II</td>
<td>13</td>
<td>Intact</td>
</tr>
<tr>
<td>Silastic II</td>
<td>13</td>
<td>Intact</td>
</tr>
</tbody>
</table>

- Shell damaged during explantation procedure.
The ruptures are rare as shown by Mc Laughin (4) in an epidemiological study. 98% of implants are without rupture at 5 years and more than 85% at 10 years for the third generation of silicone. Of course, these rupture of the silicone capsule with leakage of liquid cannot appear with Spring Thread (presence of a core in polyester and no liquid in the device like in a mammary prosthesis).

Heden in 2009 (5) in a European multicenter study of 163 subjects implanted for 5 to 11 years who had a clinical examination and an MRI (NMR) shows a rupture rate of 1.7% after 8 years of implantation with satisfaction by 91%.

These NMR studies are currently being developed to make a definite diagnosis of rupture (6).

Taylor in 2008 (7) showed by NMR spectroscopy and relaxometry the absence of hydrolysis or chemical degradation on long-term implantation.

In most of these studies, however, there is some through in the measurement because the types of silicone have changed over time. However, there are two of them with the same prosthesis, allowing objective lot comparisons (8).
3- Miscellaneous indications

Silicone implants are also used in other indications (10-14)
In these indications, complications observed are related to the pathology and not to the equipment used:

- Correction of Obesity (complications are due to bounce from BMI),

"Laparoscopic adjustable silicone gastric banding (LASGB) was used as the initial bariatric procedure for more than 36 months. The efficacy and safety of LASGB were studied.

Patients were followed up prospectively in a multidisciplinary center for the perioperative and long-term courses, and for complications.

Between November 1996 and May 1999, 715 patients underwent surgery. The mean age was 34.6 years (range, 16-72) years, and the mean body mass index (BMI) was 43.1 kg/m2 (range, 35-66 kg/m2). The mean operative time was 78 min (range, 36-165 min), and the postoperative hospitalization time was 1.2 days (range, 1-8 days). There were six intraoperative complications (0.8%), eight early postoperative complications (1.1%), and no deaths. For follow-up evaluation, 614 patients (86%) were available. Late complications included band slippage or pouch dilation in 53 patients (7.4%), band erosion in 3 patients, and port complications in 18 patients. In 57 (7.9%) patients, 69 major reoperations were performed. In patients with a follow-up period longer than 24 months, the average BMI dropped from 43.3 kg/m2 (range, 35-66 kg/m2) to 32.1 kg/m2 (range, 21-45 kg/m2).

Laparoscopic adjustable silicone gastric banding is safe, with a lower complication rate than any other bariatric procedure. Most reoperations can be performed laparoscopically with low morbidity and short hospitalizations. On the basis of intermediate-term follow-up evaluation, it is an effective procedure for weight-reducing purposes." (10).

- Fixation of Poland syndrome, opening a single track with good results for the correction of other chest deformities,

"We present a case of a delayed seroma with a fibrous capsule formation after insertion of a textured silicone gel-filled implant for the surgical correction of Poland syndrome, in spite of an uneventful intraoperative and early postoperative course. The result achieved after treatment of the seroma without reinsertion of an implant was aesthetically satisfactory.

Pediatric chest wall and breast deformities present as a wide spectrum of anomalies, and often occur coincidentally. Chest wall abnormalities fall into two categories, congenital (which are largely hypoplastic) and deformational (including both chest wall malignancies and postoperative abnormalities). Breast abnormalities can be categorized into three groups, including hypoplastic, hyperplastic, and deformational anomalies.

Hypoplastic breast anomalies require reconstruction with augmentation techniques and are often associated with significant reoperative rates, as are deformational anomalies; hyperplastic abnormalities require reduction techniques and are less likely to require reoperation. Considerations about surgical correction of pediatric chest wall and breast deformities often require coordinated efforts between pediatric and plastic surgeons with anticipation of continued growth of the child and careful timing for treatment to maximize functional and aesthetic outcomes." (11)

- Use in glaucoma with a follow up of 2 years, silicone compared with polypropylene valves from Ahmed: less complications were found with silicone(12),

- Correction of either congenital or acquired ptosis in children (trauma, gravis myasthenia): 89 children were treated in the study of Morris with a follow up of 1 to 88 months, 22 children in the study of Fogagnolo with a follow up of 18 to 30 months. Clinical results are of medium quality, but complications are rare.

"To evaluate the safety and efficacy of silicone rod frontalis suspension surgery for childhood ptosis. The authors retrospectively studied 89 consecutive children (110 eyelids) who had silicone rod frontalis suspension surgery
for ptosis at Duke University Eye Center from 1983 to 2004. Marginal reflex distance1 (MRD1) elevation of 2
mm or more (vs preoperative MRD1) was considered satisfactory. MRD1 was measured as the vertical distance
from the corneal light reflex in primary gaze to the upper eyelid margin. The postoperative eyelid symmetry (<
or =1 mm = satisfactory) was the difference between the MRD1 of the surgical and fellow eyelid. Median age at
surgery was 45 months (range: 3 to 223 months) and median follow-up was 17 months (range: 1 to 88 months).
Ptosis types (number of eyelids) were unilateral congenital (53), bilateral congenital (30), third nerve palsy (16),
Marcus Gunn jaw wink (7), trauma (2), and myasthenia gravis (2). Median MRD1 elevation was 2 mm or
greater for all ptosis types, whereas satisfactory postoperative symmetry occurred in 60% of unilateral and
100% of bilateral congenital ptosis cases (last follow-up). Complications occurred in 10 eyelids (9%) and
reoperation occurred in 10 eyelids (9%). The use of silicone rod frontalis suspension surgery for ptosis repair in
pediatric patients is modestly effective, with few complications and easy removal and adjustment.” (13)

- The silicone bands are also used in urological or gynecological surgery.

4- Systemic and General complications

General complications were also studied (15)
- No development of connective and other immune diseases,
- No development of cancer,
- No development of neurological diseases
were found.

« Since the 1960s, silicone implants have been successfully used for breast augmentation and reconstruction.
However, safety issues regarding the use of silicone have led to a moratorium by the US Food and Drug

To date, although the moratorium has been removed and women overwhelmingly prefer silicone over saline
implants, local and systemic adverse effects still remain a concern

Silicone-elicited inflammatory fibro-proliferative response and capsular contracture is irrefutable. Studies on
silicone breast implants have not supported a relationship to carcinogenesis, whereas that to autoimmunity
mainly to nondefined autoimmune phenomena seems very plausible. These silicone-related autoimmune adverse
events termed ‘siliconosis’ are probably limited to a small minority of implanted patients.

Risk factors, such as characteristic environmental exposure and/or genetic predisposition, still require further
elucidation. Similarly to antibacterial agents, texturized implants and Zafirlukast that were found to be
beneficial in inhibiting fibro-proliferative response and capsular contracture, elucidating autoimmune-related
risk factors might subsequently enable physicians to accurately predict long-term health status of silicone
implant recipients.”

III - Conclusion

This revue of literature shows that silicone is used as implants for a very long time. We have
studied only the massive silicone implants like Spring Thread.
The different studies show that there are no development of connective and other immune
diseases, no development of cancer, no development of neurological diseases.
The bio stability and bio durability of silicone depends on the location of implantation: If the
device is implanted with blood contact (vascular or cardiac implants), silicone presents a
change in stability with time.
If the device is implanted without blood contact, for example in subcutaneous situation, there
is a good stability and duration.
Spring Thread is implanted in subcutaneous situation and is a very small implant compared
to mammary or facial prosthesis, so it will have a very good durability.
IV - BIBLIOGRAPHY

1- Vondracek P, Dolezel B
Bio stability of medical elastomers: a review
Biomaterials 1984; 5: 209-14

Magnetic resonance study of virgin and explanted silicone breast protheses. Can proton relaxation times be used to monitor their biostability
ASAIO 1994; 40 (3): 625-31

3- Brandon H.J., Jerina K. L., Wolf C. J., Leroy young V.
Biodurability of retrieved silicone Gel breast Implants

4- McLaughlin JK, Lipworth L, Murphy DK, walker PS
The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence
Ann plast Surg 2007;59(5):569-80

Long-term safety and effectiveness of style 410 highly cohesive silicone breast implants
Aesthetic Plast Surg 2009; 33 (3): 430-6, Discussion 437-8

6- Ahn CY, Shaw WW, narayanan K, Gorczyca DP, Sinha S, debruhl ND, Bassett LW
Definitive diagnosis of breast implant ruptures using magnetic resonance imaging
Plast reconstr Surg 1993; 92 (4):681-91
Comment in Plast reconstr 1995; 96(1): 234-5

7- Taylor RB, Eldred DE, Kim G, Curtis JM, Brandon HJ, Klykken PC
Assesment of silicone gel breast implant biodurability by NMR and EDS techniques

8- Stevens WG, Pacella SJ, Gear AJ, Freeman ME, McWhorterC, TenenbaumMJ, Stoker DA
Clinical experience with four generation textured silicone gel breast implant: a review of 1012 Mentor MemoryGel breast implants
Aesthet surg j 2008;28(6):642-7

9- Constantinides MS, Galli SK, Miller PJ, Adamson PA
Malar, submalar and mildfacial implants
Facial plastic surg 2000; 16(1):35-44

10- Szold A, Abu-Abeid S
Laparoscopic adjustable silicone gastric banding for morbid obesity: results and complications in 715 patients
Surg endosc 2002 16(2):230-3

11- Pereira LH, Sabatovich O, Santana KP, Picanço R, sterodimas A,
Surgical correction of poland’s syndrome in males- a purposely designed implant

12- Mackensie PJ, Schertzer RM, Isbiter CM
Comparison of silicone and polypropylene Ahmed glaucoma valves: two years follow up
Can J Ophtalmol 2007; 42 (2):227-32

13-Morris CL, Buckley EG, Enyedi LB, Stinett S, Freedman SE
Safety and efficacy of silicone rod frontalis suspension surgery for childhood ptosis repair
J Pediatr Ophtamol strabimus 2008;45(5):280-8

14-Fogagnolo P, Serafino M, Nucci P
Stability of silicone band frontalis suspension for the treatment of severe unilateral upper eyelid ptosis in children

15-Hajdu SD, Agmon-Levin N, Shoenfeld Y
Silicone and autoimmunity