# Breast Implants Failure: Correlation of Explanted Implants Properties and Patient's Clinical Data

*S. Farè[1], M.C. Tanzi1, A. Pennati[2], G. Catanuto[2], A. Spano[2], M. Nava[2], S. Bertoldi1*
*[1]Department of Bioengineering, Politecnico di Milano, Milan, Italy;*
*[2]Department of Plastic Surgery, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy*
*mariacristina.tanzi@polimi.it*

## Abstract

Silicone gel breast implants are today widely used for breast reconstruction after mastectomy. Unfortunately, they can cause painful complications, such as capsular contracture, leading to the explantation.
This work was aimed at evaluating the effects of the *in vivo* environment on breast implants, after their explantation, and the assessment of a possible correlation between the *status* of explanted prostheses and patients' clinical data (age, implantation time, prosthesis model). Particularly, breast implants in patients treated with radiation therapy were compared to not irradiated ones. The explanted breast implants were investigated by macroscopic analysis and by SEM observation; uniaxial tensile tests were performed on the shells.
The obtained results indicate that the radiotherapy and the time of implantation affect the mechanical properties of the implant, causing an increase in stiffness of the shell. In addition, different implants exhibited some cracks onto the surface of the shell.

## 1 Introduction

Silicones have been used extensively in the biomedical field for many applications, ranging from *in vivo* fluid tubing to a variety of prostheses. Among them, silicone gel breast implants are today worldwide used for breast reconstruction after mastectomy and for cosmetic augmentation [1, 2]. A silicone gel–filled breast implant mainly consists of a cross-linked elastomeric silicone shell containing a lightly cross-linked silicone gel, with variable cohesivity. Breast implant durability is an important issue among surgeons, patients, and regulators. Failure mechanisms must be identified and understood to predict implant lifespan and to improve implant design. To determine the useful life of a breast prosthesis, it is necessary to determine the primary cause of its failure [3]. Among the scientific literature, there are several works dealing with diseases and painful complications occurring after the implantation, such as capsular contracture [4, 5]. Others studies are related to the biological analysis of the bleeding phenomenon [6, 7] or to biological responses of the body to the implant [8-10]. On the contrary, few studies [1-3, 11-15] focus the attention on the morphological, mechanical and chemico-physical characterization of explanted breasts implants.
Aims of the present work are the evaluation, by morphological and mechanical characterization, of the effects of the *in vivo* environment on breast implants, and the assessment of a possible correlation between the *status* of explanted

prostheses and the patients clinical data, such as patients' age, radiation therapy undergone by the patients, implantation time and prosthesis model. For this research, an experimental protocol has been set up, including several analytical methods aimed, on the whole, at detecting all possible changes of the breast prosthesis during implantation.

## 2 Materials and methods

A number of 50 explanted silicone gel breast implant, differing for models and implantation time, were considered.

Data were collected with the purpose to systematically organize the information concerning each explanted prosthesis. For this reason, an index-card containing all the experimental data was set up. Each card was divided into 4 sections, containing respectively:

1. Clinical data (obtained from the surgical staff);
2. Macro observations;
3. Micro observations;
4. Mechanical characterization.

For some explanted prostheses the clinical data, in particular data related to the implant model and possible radiation therapy treatment, are missing as not provided by the medical staff.

In Table 1 the implants models are catalogued according to their model, considering only the implants for which model is known.

Table 1 – List of the different implants model

| MODEL | NUMBER OF IMPLANTS | N. OF IMPLANTS TREATED WITH RADIATION THERAPY |
|---|---|---|
| PIP – PIP Implants | 1 | 1 |
| Becker – Mentor | 1 | - |
| Style 110 - Inamed | 5 | - |
| Style 150 - Inamed | 2 | - |
| Style 153 - Inamed | 9 | - |
| Style 177 - Inamed | 2 | 1 |
| Style 178 - Inamed | 7 | 1 |
| Style 410 - Inamed | 12 | 1 |
| Style 510 - Inamed | 1 | - |

Histograms in Fig. 1 show the distribution of the ranges of implantation time for the different implant models, considering only implants with known model and implantation time.

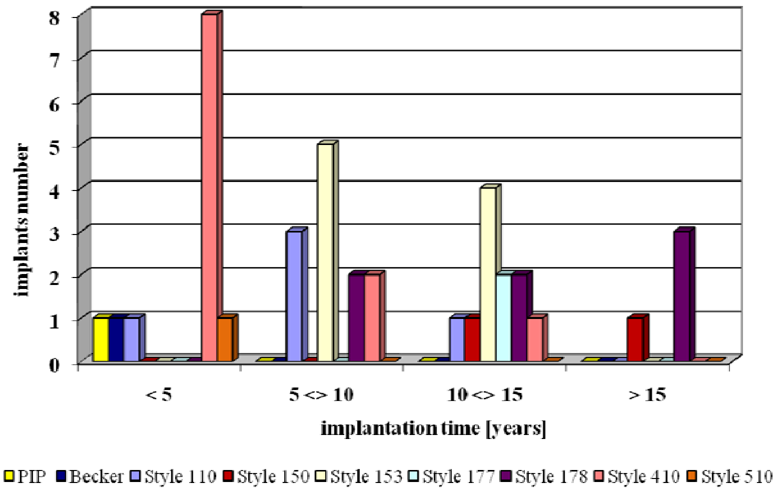


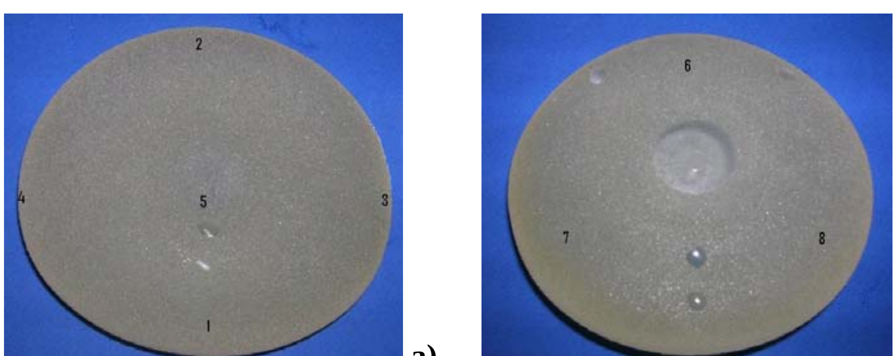

Figure 1 –The different breast implant models with the respective ranges of implantation time

**2.1 Macroscopic observation**

Photos of front and back side, lateral profile, and possible significant surface details were taken for each prosthesis. In addition, some macroscopic characteristics are spotlighted, such as: color, surface typology, presence of spots, consistency.

**2.2 Scanning Electron Microscopy observation**

The results of the macro-observations can be better examined with scanning electron microscopy (SEM). Out of each prosthesis, in well defined front and back zones (Fig. 2), some circular specimens (Ø= 5 mm) were cut with a hollow punch. Each specimen was then sputter coated with gold and observed at SEM, using an environmental SEM (EVO 50VP). EDS (Energy Dispersive X-Ray) microanalysis was also performed to detect the presence of chemical elements at the surface, in particular to identify the nature of possible anomalous deposits.




**a)** **b)**

Figure 2 – Image of an explanted breast implant, a) front and b) back. The numbers identify the zones where the specimens for SEM observations were taken out

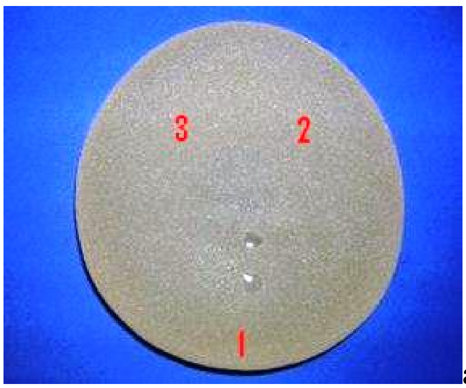
### 2.3 Mechanical characterization by tensile tests

To test the mechanical properties, 4 to 5 specimens were cut out from the front and back side of the silicone shell of each examined prosthesis. Depending on the prosthesis size, 2 or 3 dog-bone specimens were cut out from the front section and 2 of them out from the back (Fig. 3).

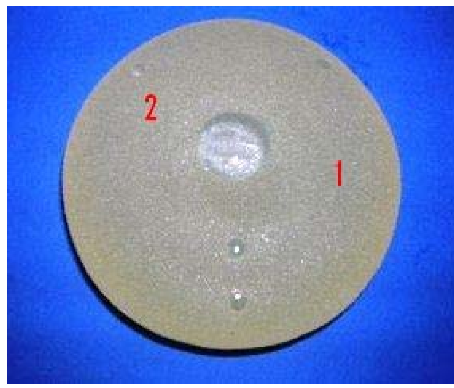
Tensile stress-strain tests were performed using a MTS1/MH electromechanical system with a 5 kN load cell equipped with a high elongation extensometer (MTS EX 44). The instrument is equipped with high capacity pneumatic grips, that assure correct specimen alignment and remove the bending strains. Tensile test results are recorded and elaborated by Testworks.

The evaluated parameters were:

- secant moduli at different elongation values (E10 ÷ 400%);
- stress (σr) and strain (εr) at break.



a)



b)

Figure 3 – Scheme of the sampling zones for mechanical tensile tests; a) front and b) back

## 3 Results

### 3.1 Macroscopic observation

The macroscopic observation of the explanted prostheses allowed to evaluate the breast implant consistence, that can be firm as before the implantation or slack, compared to the consistence of unimplanted prostheses.

Fig. 4 shows representative pictures of two explanted prostheses of the same model (Style 153 – Inamed), implanted respectively for 159 (Fig. 4a) and 162 (Fig. 4b) months. Both implants were explanted from patients not undergone to radiation therapy.

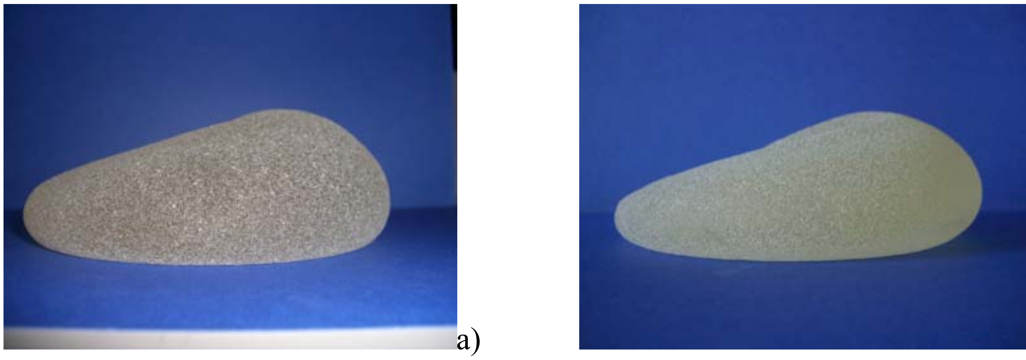

a) b)

Figure 4 – Representative pictures of Style 153 breast implants not subjected to radiation therapy and implanted for 159 (a) and 162 (b) months, respectively

The breast implant shown in Fig. 4a presented a firm consistency, while the one in Fig. 4b resulted slacker, with the presence of some wrinkles in the front part.
On the whole, a change in consistence from firm to slack, and the presence of wrinkles on the surface were detected for the 36 % of all analyzed explanted prostheses.
Clear evidence of a correlation between prosthesis consistency and radiation therapy or implantation time cannot be stated, even though some white spots were detected within the shell of two prostheses explanted from women who underwent radiation therapy (Fig. 5).

Figure 5 – Representative macroscopic image of a spot inside the silicon shell of a breast implant explanted from a patient subjected to radiation therapy

In general, the change in consistency is joined to a change in colour, from white to yellowish-white. 52 % of all the considered prostheses turned to a yellowish shade.

### 3.2 Scanning Electron Microscopy observation

As reported in Fig. 6, by SEM the external surface of the silicone shells showed a textured surface.

Several lacerations were found on the external surface of the front and back side of the shell of a large number of prostheses (Fig. 6). In particular, cracks were detected on the 64 % of all the analyzed prostheses, while for the 43% of the implants the lacerations were present both on front and on back side.
By comparing SEM images of Fig. 6a and Fig. 6b, the presence of cracks seems to be not dependent on the implantation time. Neither the radiation therapy seems to clearly affect the presence of lacerations on the shell, as they were detected on breast implant explanted form patients both treated with radiotherapy (Fig. 6d) and not (Fig. 6 a-c).

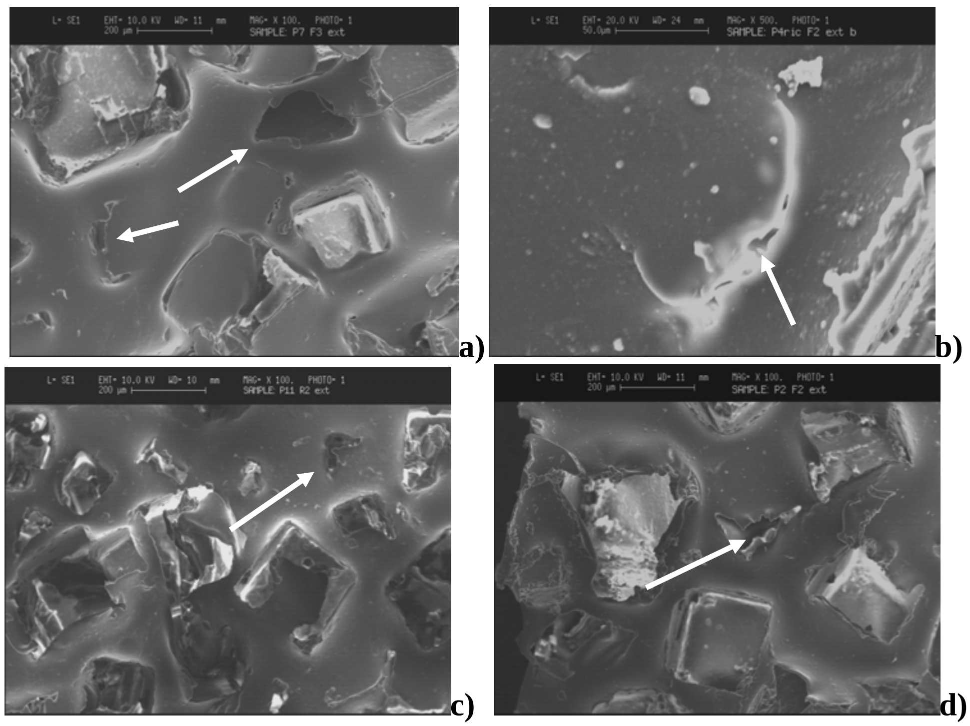
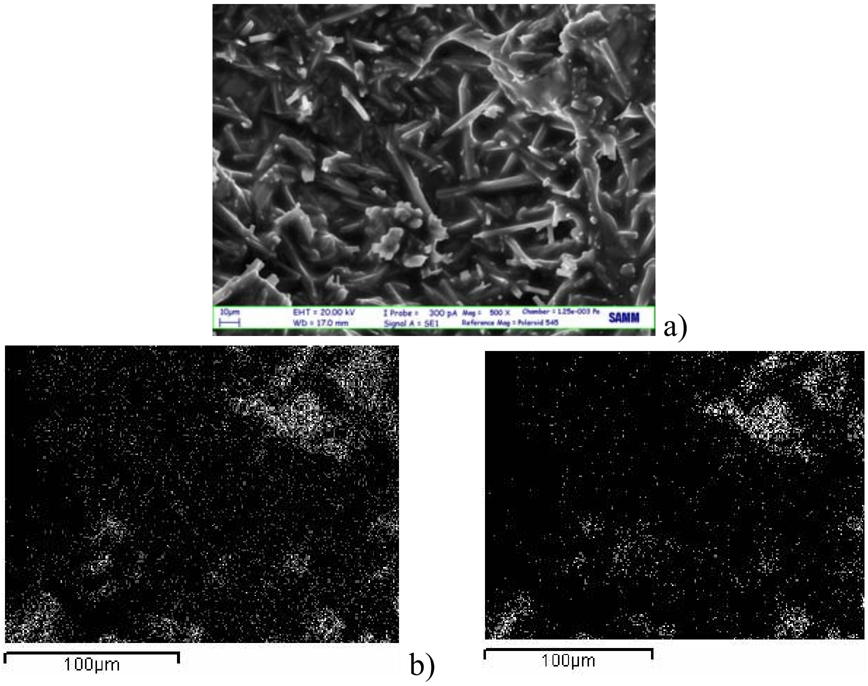



Figure 6 – Representative SEM images of the shell external surface of prostheses not treated with radiation therapy, explanted after 38 months (a), 128 months (b) and 16 months of implantation (c); and of a prosthesis subjected to radiotherapy after 9 months of implantation (d). The arrows indicate the presence of lacerations

A SEM image of the spot shown in Fig.5 and detected inside the shell of a prosthesis explanted from a woman subjected to radiation therapy is reported in Fig.7. The analysis performed with Energy Dispersive X-Ray Spectroscopy evidenced the presence of Chlorine (Fig. 7b) and Sodium (Fig. 7c), indicative of a possible salt deposition inside the shell.




a) b) c)

Figure 7 – SEM image of the spot shown in Fig.5, detected within the surface of an explanted prosthesis (a); images of EDS analysis showing the presence of Cl (b) and Na (c).

### 3.3 Tensile tests characterization

Uniaxial tensile tests showed that the front part of the prostheses shell was stiffer than the back part. Also, the obtained data indicated a correlation between shell stiffness and implantation time, with an increase of stiffness with the implantation time (Fig. 8).

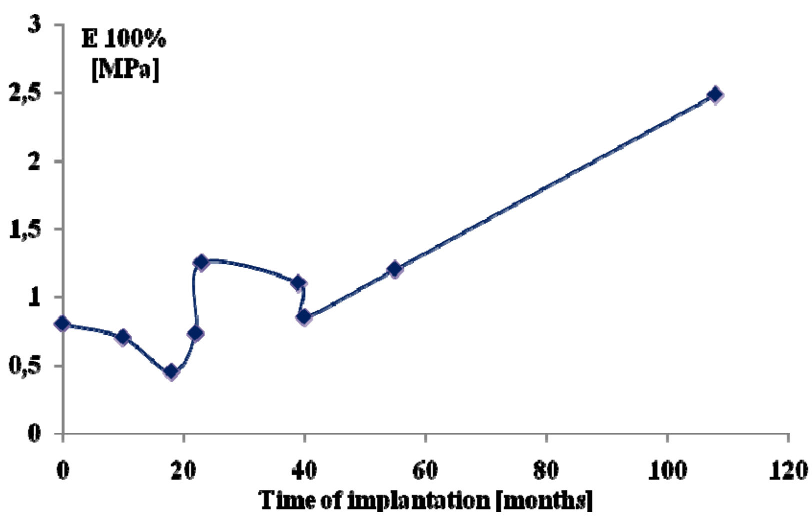



Figure 8 – Secant modulus at 100% of strain (E100%) versus the implantation time

The radiation therapy seems to affect the mechanical properties of the prostheses during the implantation time. An example is given in Fig. 9.

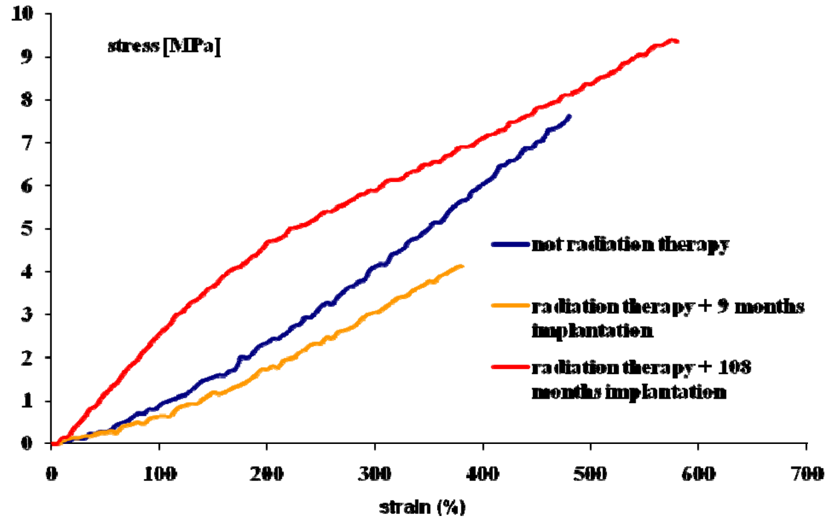



Figure 9 - σ/ε curves of a prosthesis explanted from a patient subjected to radiation therapy (upper trace: 108 months, trace below: 9 months of implantation), compared with a not treated one (middle trace).

## 4 Discussion

The results obtained by the macro and micro analyses do not allow to identify an univocal correlation between clinical data, in particular implantation time and radiation therapy, and morphological properties. Probably, the number of analyzed explanted prostheses is not yet sufficient for a statistical analysis. A comparison with already published results cannot be made as only one paper on explanted breast implants was found [1], and in this work only one explanted prosthesis was analyzed at SEM.

The scientific literature pays more attention to the mechanical characterization of explanted silicone breast implant and to the study of a possible correlation between time of implantation, changes of mechanical properties and consequent implant failure [1, 2, 12-15].

As for the *in vivo* effects of the radiation therapy, the number of analyzed prostheses is not yet sufficient, and the scientific literature does not present studies related to this aspect.

Another fundamental aspect to be considered is that the evaluation of the effects of the time of implantation or of the radiation therapy should be done on breast implants of the same model. In fact, the results reported in literature [14] demonstrated that the mechanical properties of the implants are strongly correlated to the implant model.

## 5 Conclusions and future developments

For a silicone gel implant, it is possible to assume that aging begins at the time of implantation and the primary properties of interest to evaluate implant aging are stiffness, tensile strength, and elongation. Any factor that affects these parameters may directly influence the life of an implant [14]. Therefore, the evaluation of the effects of the *in vivo* environment and of the radiation therapy on the morphological, mechanical and chemical-physical properties of explanted breast prostheses has a fundamental importance.

The results of this work indicate that the time of implantation affects the mechanical properties of the breast implant, causing an increase of stiffness. Further studies are in progress with a higher number of explanted prostheses to better understand the effect of the biological environment on the prosthesis material.

With regards to the radiation therapy effects on silicone gel breast implants, *in vitro* tests are now in progress with the aim to evaluate the effect of the same radiation therapy used in the case of cancer diseases on prostheses of different models.

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