SAFETY ASPECTS RELATED TO IMPLANTED BREAST PROSTHESES

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ABSTRACT

Silicone implants are largely used both in aesthetic and reconstructive medicine, thanks to their recognized biocompatibility. The damage of breast prostheses as a consequence of accidental impacts, is however one of the possible critical situations in their use. The behaviour of silicone breast prostheses in case of accidental impacts, for example in a car accident, is studied by experimental crash tests, accounting for the action exerted by seat belts during impact. Possible effects of aging over the mechanical response of the implants are also considered and approached. Static compression tests performed after long term aging indicate a possible degradation of prosthesis mechanical performance, which should be considered when analysing the possible consequences of an accidental damage.
Keywords: breast prostheses, mechanical impact, car accident, crash test, aging, damage.

1 INTRODUCTION

Silicone gel breast implants have been used worldwide for over 50 years, since their invention by Cronin in the early 1960s [1]. The number of women undergoing breast insertion, either for aesthetical reasons and for post mastectomy surgery, has steadily grown throughout the years; in 2018 more than 1.8 million implants were inserted for augmentation only and it has been estimated that 5 to 10 million women have received breast implants worldwide. The market of breast prostheses has undergone in the years a somewhat oscillatory trend, often as a result of discussions over the safety of silicone implants after long term use (e.g., activation of breast implant associated – anaplastic large cell lymphoma, BIA-ALCL) and/or in allegedly critical conditions (e.g., use of airplane or scuba diving activity) [2], [3]. Among the multiple potential complications associated with the use of breast implants, this research focuses on the implant rupture as consequence of mechanical impacts as, for instance, car accidents. In particular, the possibly incorrect use of safety belts may enhance the probability of implant rupture due to mechanical overstress in case of accident.

Data regarding the incidence of rupture rates are published by the three-major silicone gel breast implant producers (Allergan, Mentor and Sientra) [4], [5], but today there are still only limited studies that can give us an idea about the overall, actual incidence of breast implant rupture causes [6], [7]. It is especially difficult to render comparable rupture rates among different types of breast implants, manufacturers, and rupture detection methods. Among the different mechanisms proposed for implant rupture, the most common is the damage from surgical instruments (50%–64% of all causes), followed by unidentified opening/rent without indication of cause (no evidence of sharp instrument damage, 35%–37%), fold flaw (8%), shell swelling (reduction of the shell strength due to migration of the silicone fluid from the gel to the shell), delamination, manufacturing defect, surgical impact and trauma to the implant, like an external pressure to the chest or closed capsulotomy. Focusing on the traumatic rupture, it is reported that most trauma do not cause a prosthetic rupture, except in case of impact with sharp objects. On the other hand, it recognized that many rupture can

www.witpress.com, ISSN 1743-3509 (on-line)
doi:10.2495/SSR220151

remain silent for long time with, without evident sign for the patient [6]. An accurate review of the scientific literature shows that there are no studies regarding the relationship between the impact loads, which typically can occur in a car accident, and the risk of breast implants rupture. Although there is a wealth of scientific papers related to the medical consequences of implant rupture and to the clinical methods of detecting damages [7]–[9], engineering-based investigations about the possible conditions leading to rupture are very limited [10].

As a matter of fact, in the event of a car accident, loads from the compression exerted by the seat belt may be transferred to the breast. Of course, even worse is the case of accident with no seat belt used, leading to direct impact with steering wheel or other parts of the vehicle. For this reason, our group approached a preliminary study at the mechanisms and the physical aspects of the impact and how this is related to the possible damages of the breast implants. It is important to stress that, as evidenced by the cited papers, a damage of the implant following a car accident does not necessarily require surgical intervention, but in many cases a visit by a physician and/or an instrumental check is highly recommended.

A discussion about the danger of rupture should consider also the possible aging state of the prosthesis at the time of the accident. Silicon rubber employed in breast prostheses is selected also on the basis of its long-term properties, which guarantee a long endurance to the implants. The duration of an implanted prosthesis is estimated in the range of 12 to more than 35 years [11]; moreover, it should be considered that in most cases, removal or replacement is the result of causes not related to the implant aging or defects. However, from the clinical point of view, the aging is usually intended in terms of swelling or diffusion of internal gel, or in terms of biomedical effects over the surrounding tissue. Such effects are object of common testing procedures by producers, as required by national and international standards and regulations, e.g., EN ISO 14607:2018. On the other hand, from a mechanical point of view, the aging of cross-linked shell rubber may lead to mechanical stiffening and reduced deformability, which can result in degradation of mechanical performances in case of accidental impacts. In order to estimate the possible relevance of such phenomena, mechanical tests after periods of permanence in biological saline solution at the body temperature were performed.

For the explanted implants, a sensitivity on aging was presented, although no correlation between aging, dimensions and shape of the implant could be defined at present, since previous history of the patients and implants could not be retrieved in detail. Further investigations with both new and explanted implants are being performed to better evidence and estimate possible aging effects.

2 EXPERIMENTAL

Prostheses explanted from living patients for medical reasons, not related to previous mechanical impacts or damages, were selected for the tests. Two different shapes (round and raindrop implants) were selected, which were produced by a primary breast prostheses manufacturer. The round and raindrop implants had a volume of 150 cm^3 and 180 cm^3 respectively.

Compression tests were carried out to determine rupture loads and deformations. A maximum pressure limit was identified after which the implant developed a permanent deformation and was more prone to rupture. Tests were carried out with a MTS858 Mini Bionix II testing machine, by pressing the prostheses between two flat metal plates at constant, slow crosshead rate (1 mm/min). Squeezing deformation at failure and internal pressure were estimated during the tests. The internal pressure was estimated as the ratio between applied force and measured footprint of the deformed implants just before the rupture. Data from these tests were used for a preliminary identification of possible critical conditions for subsequent static test after aging and for dynamic impact tests.

To estimate possible effects of aging of shell rubber, prostheses were maintained in 0.9% NaCl saline solution at 40°C for about one year and three months, when rupture occurred during tests. DSC and dynamic-mechanical analysis of aged shell material were performed during this time span which, however, could not evidence detectable changes in the glass transition or other thermal properties. Static compression tests were carried out on a prosthesis (raindrop shape) aged for different times, until rupture occurred. The specimen was periodically compression tested at a force, which was 70% of the rupture compression load initially measured on an equal prosthesis.

Dynamic tests simulating a car accident were carried out with a specific instrumentation commonly employed to test the effects of structural crash impacts and, in particular, to assess the safety of seat belts. The test facility consists of a sled that can be moved along a 80 m long rail, to a desired speed and stopped with a selected deceleration program. Deceleration is controlled by a set of plastic deformable aluminium beams connected to the sled, which undergo extensive buckling during impact.

An anthropomorphic dummy (Hybrid II; H2-50) with a round breast prosthesis applied, was placed on a seat with belts, which was mounted on the sled for the tests. Accelerometers placed on the sled and directly connected to the dummy allowed to record the actual deceleration history. Visual inspection of breast prostheses was done to evidence failure signs after deceleration tests, in particular to detect possible leakage of internal gel.

3 RESULTS AND DISCUSSION

Static tests were carried out on two different kinds of prosthesis (round and raindrop shape) and evidenced a limit of the static load and pressure that these can sustain. Fig. 1 shows the round prosthesis before and after complete rupture by compression.

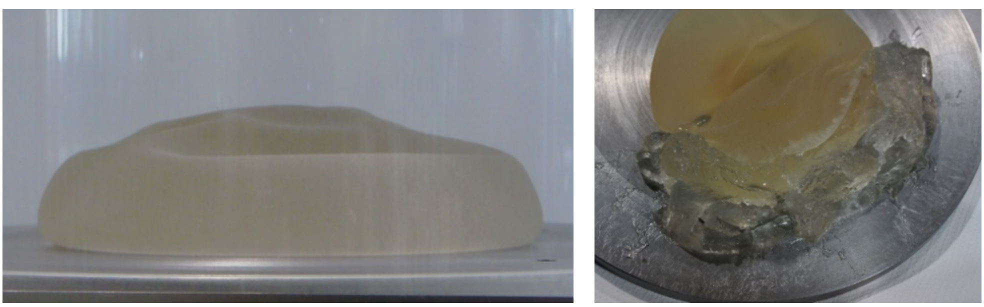

Figure 1: Round prosthesis before and after rupture in compression test.

Fig. 2 shows the compression set-up before and during tests. The load, plates positions and contact area between deformed prosthesis and plates was recorded throughout the test. The results of compression tests are compared and reported in Fig. 3.

Rupture occurred at about 3 and 4 kN of pressing force for round and raindrop implants. Considering that the shell material is the same for the two implant shapes, it is not surprising that in both cases the rupture starts at a very similar internal pressure, of about 2 bar. It is to be noted that the estimated internal pressure at rupture is not at all related to the limit hydrostatic pressure that the implant can sustain, for example during a scuba diving

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www.witpress.com, ISSN 1743-3509 (on-line)

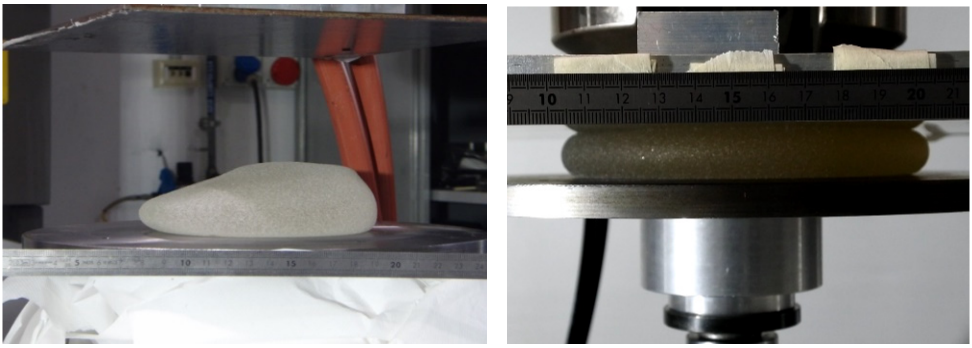


Figure 2: Compression test set-up of rain drop shape prosthesis.

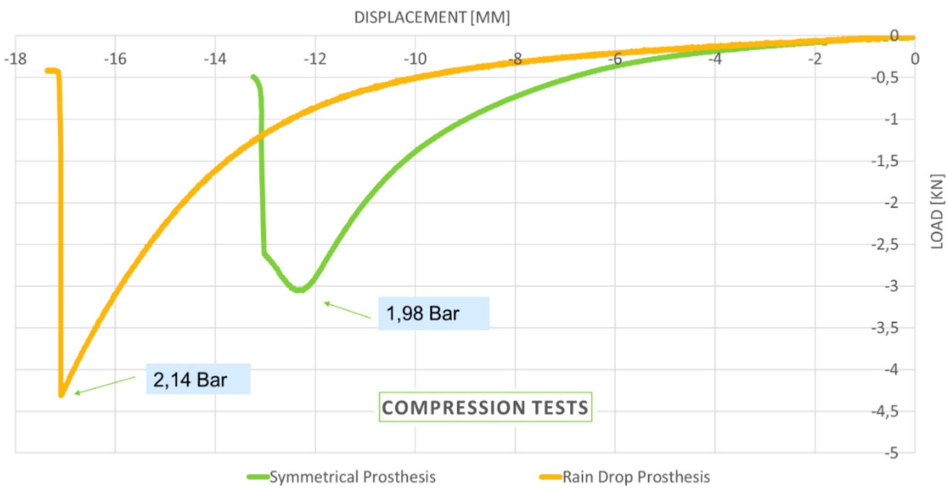
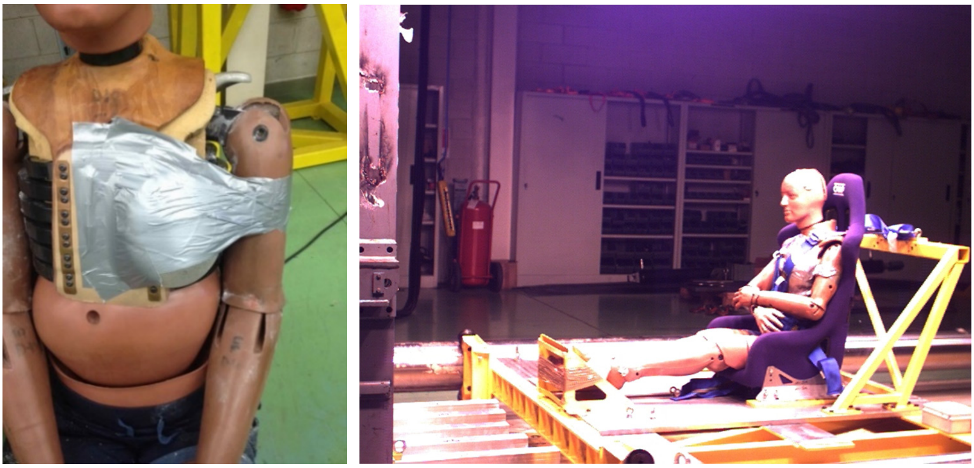


Figure 3: Compression test results of two different shaped prostheses.

immersion or in a hyperbaric chamber. However, it can be considered relevant in a number of situations of impacts against blunt objects, as for example a car accident with a safety belt passing on top of the breast or a bad fall on a flat surface from a consistent height. It is also to be noted that such impacts can result substantially more critical than those indicated for the testing of new prostheses as required by EN ISO 14607:2018. The results were also relevant in the selection of impact velocity and maximum deceleration in case of vehicle impact tests later preformed.

To assess possible influence of ageing over shell rupture elongation and, in general, on the overall behaviour of the prostheses, static tests were repeated with the same loading program, after selected aging periods (few months) up to more than one year. In these tests the specimen pressing was stopped at 70% of the rupture load measured before aging; this corresponds to an inner pressure slightly lower than 70% of rupture pressure. No visual signs of material changes were detected after tests with implant aged up to about one year. However, after 15 months aging, rupture with internal gel leaking was evidenced. This result suggests that a significant physical modification of shell properties may occur with aging time. Considering the very limited number of loading cycles before rupture, possible effects of repeated tests are not deemed relevant.

Dynamic impacts were tested to simulate car accidents at different vehicle speed. Breast implants were mounted on an anthropomorphic dummy by adhesive tape, positioning a safety belt passing over the prosthesis. This may appear an incorrect position, but breast damages due to the pressure of seat belts are certainly not unusual [12]. Fig. 4 shows the dummy assembly for the tests.



(a) (b)

Figure 4: (a) Prosthesis implant fixed on Hybrid II dummy; and (b) Crash test facility.

Two crash conditions, simulating impacts at 50 km/h and 90 km/h were selected. In the first situation, no evident rupture was visually observed. In the second crash conditions a clear rupture, with loss of gel, was observed (Fig. 5). The measured maximum deceleration was of about 25 g for both impacts, but in the second crash the time span was of course longer. Fig. 6 shows two instant frames of the impact events recording.

Figure 5: Damage of the prosthesis and gel leakage after impact.

Figure 6: Instant pictures of the dummy during impact.

It should be noted that car accidents in such conditions may produce important damages to the car occupants; safety features, i.e. belts and airbags, are intended to be highly efficient right in these situations, to avoid primary consequences [13]. On the other hand, the chance of "secondary" or minor consequences of impacts, which are not immediately detectable, should not therefore be neglected.

4 CONCLUSIONS

Breast implants for aesthetical or medical purposes are nowadays very common. Their production and use is subjected to quite stringent regulations regarding their body compatibility and durability. On the other hand, there are situations which may require additional attention, related to a safer use of such prostheses. In particular, in case of relatively high energy impacts as those involved in car accidents or similar impacts, prostheses may undergo to damages not immediately detectable, which, on the other hand, may produce delayed effects. In addition, the long-term use of such implants may lead to ageing of the physical and mechanical properties that, although little relevant in terms of body compatibility or reaction, can result in a variation of mechanical performances and response during potentially critical impacts. In this paper, some evidence of such behaviour is reported, which strongly suggests a better attention to such aspects and more thorough investigation about possible long term aging effects of implanted prostheses.

ACKNOWLEDGEMENT

The financial support of Project MUR-PRIN 2020, Prot. 2020LYY27Z, "Breast implants safety: is our knowledge enough?" is gratefully acknowledged.

REFERENCES

[1] Cronin, T.D. & Gerow F.J., Augmentation mammoplasty: A new "natural feel" prosthesis. *Transactions of the Third International Congress of Plastic Surgery*, Excerpta Medical: Amsterdam, pp. 41–49, 1964.

[2] Jalalabadi, F., Doval, A.F., Neese, V., Andrews, E. & Spiegel, A.J., Breast implant utilization trends in USA versus Europe and the impact of BIA-ALCL publications. *Plastic and Reconstructive Surgery – Global Open*, **9**(3), e3449, 2021. DOI: 10.1097/GOX.0000000000003449.

[3] EU, Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), Final opinion on the safety of breast implants in relation to anaplastic large cell lymphoma, 26 March 2021. https://health.ec.europa.eu/system/files/2021-04/scheer_o_018_0.pdf.
[4] Hammond, D.C., Migliori, M.M., Caplin, D.A., Garcia, M.E. & Phillips, C.A., Mentor contour profile gel implants: Clinical outcomes at 6 years. *Plastic and Reconstructive Surgery,* **129**, pp. 1381–1391, 2012. DOI: 10.1097/PRS.0b013e31824ecbf0.
[5] Spear, S.L. & Murphy, D.K., Allergan silicone breast implant U.S. core clinical study group. Natrelle round silicone breast implants: Core Study results at 10 years. *Plastic and Reconstructive Surgery,* **133**, pp. 1354–1361, 2014. DOI: 10.1097/PRS.0000000000000021.
[6] Hillard, C., Fowler, J.D., Barta, R. & Cunningham, B., Silicone breast implant rupture: A review. *Gland Surgery*, **6**(2), pp. 163–168, 2017. DOI: 10.21037/gs.2016.09.12.
[7] Handel, N., Garcia, M.E. & Wixtrom, R., Breast implant rupture: Causes, incidence, clinical impact, and management. *Plastic and Reconstructive Surgery,* **132**, pp. 1128–1137, 2013. DOI: 10.1097/PRS.0b013e3182a4c243.
[8] Glazebrook, K.N., Doerge, S., Leng, S., Drees, T.A., Hunt, K.N., Zingula, S.N., Pruthi, S., Geske, J.R., Carter, R.E., McCollough, C.H. & Fletcher, J.G., Ability of dual-energy CT to detect silicone gel breast implant rupture and nodal silicone spread. *American Journal of Roentgenology*, **212**(4), pp. 933–942, 2019. DOI: 10.2214/AJR.18.20138.
[9] Bengtson, B.P. & Eaves, F.F. 3rd., High-resolution ultrasound in the detection of silicone gel breast implant shell failure: Background, in vitro studies, and early clinical results. *Aesthetic Surgery Journal*, **32**(2), pp. 157–174, 2012. DOI: 10.1177/1090820X11434507.
[10] Janszen, G., Vinci, V. & Klinger, M., Mechanical characterization of breast prosthesis: Static analysis. Presented at *3rd Global Conference and Expo on Applied Science, Engineering and Technology and 6th Global Congress and Expo on Materials Science and Nanoscience*, Dubai, UAE, 2019.
[11] Prasad, K., Zhou, R., Zhou, R., Schuessler, D., Ostrikov, K.K. & Bazaka, K., Cosmetic reconstruction in breast cancer patients: Opportunities for nanocomposite materials. *Acta Biomaterialia*. **86**, pp. 41–65, 2019. DOI: 10.1016/j.actbio.2018.12.024.
[12] Song, C.T., Teo, I. & Song, C., Systematic review of seat-belt trauma to the female breast: A new diagnosis and management classification. *Journal of Plastic, Reconstructive and Aesthetic Surgery,* **68**(3), pp. 382–389, 2015. DOI: 10.1016/j.bjps.2014.12.005.
[13] Pipkorn, B. & Kullgren, A., Effects of active structures on injuries in medium severity frontal impacts. *Proceedings of the 21st (ESV) International Technical Conference on the Enhanced Safety of Vehicles*, Paper No. 09-O380, Stuttgart, Germany, 2009.