11th World Congress on Computational Mechanics (WCCM XI)
5th European Conference on Computational Mechanics (ECCM V)
6th European Conference on Computational Fluid Dynamics (ECFD VI)
July 20 - 25, 2014, Barcelona, Spain

Failure of silicone gel breast implants – Mechanical tests on a mammary implant in its implantable state to determine the shell integrity

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Key Words: *Mechanical properties, breast implants, shell integrity, uniaxial test, Poly Implant Prosthesis (PIP)*

Background: Breast implants are medical devices used to augment and or reconstruct the physical shape of the breast. Breast implants consist of a silicone outer shell and filler (the cohesive gel). Known complications of silicone breast implants are rupture and silicone leakage. The recent events surrounding Poly Implant Prostheses (PIP) breast implants have renewed the debate about the safety of silicone implants [1],[2]. According to the findings of the French Health Authorities [1], a french manufacturer (PIP) used low-quality material (industrial silicone) different from the one it had declared in the documents submitted for conformity assessment (medical grade silicone). It is now necessary to improve the bifunctionality of the breast implants at the biomechanical level, taking the mechanical compatibility and toxicological safety of the involved materials into consideration, thus reducing the risks to public health. For this it is necessary to understand the rupture causes by analyzing the mechanical properties of failed and intact implants in the recent generation of silicone gel breast implants. Thus, contribute to a localized reinforcement of implant areas prone to rupture. A study to evaluate the differences in mechanical properties of failed and intact silicone implants shells marketed by PIP and Polytech silicone implant was undertaken. Surface characterization of shells and gels was carried out to determine structural changes occurring after implantation**.** The preliminary study verified that future work is required to evaluate the etiological factors influencing the mechanical proprieties of breast implants and compare this information with other mechanical data.
Methods: PIP silicone breast implants were obtained from Gaia Hospital Center- Plastic reconstructive and maxillofacial. PIP implants were compared with Polytech silicone implants used for control. This work reported was focused on the mechanical behaviour of the implant evaluated using tests in conformance with the international standard EN ISO 14607 (2007) and ISO 34-1 (2004). The mechanical tests were performed on a mammary implant in its implantable state to determine the resistance of the implant to fatigue, impact and the static rupture; uniaxial tensile tests were also performed (test shell integrity). To the fatigue test the

implant shall be compressed with to a frequency of 3,3 Hz (corresponding to 200 cycles per minute). The impact resistance is based on the vertical drop of a mass 4.4kg on the implant from a standard height. This test includes an adjustment mechanism such that the implant force is varied by adjusting the vertical distance from which the mass is allowed to fall. Static test the implant is put in between two compression plates (a fixed plate and a mobile plate) and slowly subjected to an increase in pressure until it ruptures.

Results: In a first approach the thirty intact implants were subjected to static and fatigue tests in order to verify existence of changes in the shell. The implants were tested for fatigue; no deterioration was observed in any of the implants tested. The evidence presented suggests that the frequency used in test does not cause any damage to the implant (up to a frequency of 3,3 Hz). The test shows that in all cases the samples withstand the impact without rupture, regardless of height that been launched. Static testing results showed that if the height of the implant increases the deformation is larger, and achieved a maximum ruptured force of 12988, 8N. Shell Integrity study revises the hypothesis regarding the rupture causes in recent generation of silicon gel breast implants, by analyzing the mechanical properties of failed and intact implants. The main scope is to assess whether mechanical weakness of the shells should be considered as a major cause of breast implant rupture or, on the contrary, if the prosthesis shell damage is likely due to other unknown factors. Hence, the shell resistance to tensile and tear stress were evaluated on a number of explanted prostheses following an ad hoc testing protocol. A total number of forty-nine specimens were analyzed and two different implants brands were compared (Polytech and PIP). From the data presented, it was observed that Polytech implants sustain larger stresses than PIP implants. Preliminary tests did not show evidence of significant differences in mechanical properties of the shell material between anterior and posterior parts. However comparing the average of three specimens in each implant it is possible to observe that silicone shell sustains a higher tensile strength (Shell base with a mean=12.70, StDev=4.74; and front shell with a mean=11.59, StDev=4.00), when compared to the patch area (mean=5.186 N, StDev=2.29).

Conclusion: This study demonstrated an increased weakness of PIP shells with time and therefore supports the argument for prophylactic removal of PIP breast implants. In conclusion, future work is requires to evaluate the etiological factors influencing the mechanical proprieties of breast implants, such as age, duration of implantation, device placement, and compare these information with mechanical data of breast implants.

A multidisciplinary effort between the biomechanical properties of the breast implants, in this case the PIP implants, may allow a better understanding of the questions implied in biodegrading of the implants within women body or the concerns of rupture of breast implants Hopefully, this effort will contribute to establish a methodology based on the finite element method to simulate a realistic 3D model between the breast and breast implants.

Acknowledgments

Funding by Ministério da Ciência, Tecnologia e Ensino Superior, FCT, Portugal, under grant SFRH / BD / 85090 / 2012 is gratefully acknowledged

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