Double capsule, unpredictability and high revision rates: are we going to have another PIP scenario with the aggressively textured silicone breast implants?

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Abstract

**Background:** Breast Augmentation with implants is probably the most frequently performed cosmetic surgery in the world. The manufacturing industry continues to evolve, constantly introducing different implants shapes and textures to minimize common problems like capsular contraction. Unfortunately, there seems to be a correlation of a new generation of aggressively textured breast implants and a phenomenon called double capsule. We present a retrospective study of 735 patients which 53 had double capsule after breast augmentation with Biocell textured implants.

**Methods:** All patients had submuscular implants (fit to pocket) using Allergan Natrelle round implants. 62 patients presented unsatisfactory results after surgery. We divided the patients in three groups: Group 1 - asymmetries (difference in implants position, n=18), Group 2 - deformities (capsular contracture, n=34) and Group 3 – emergency scenarios (seroma, n=10). The group one was composed of patients that had one breast in a different position than the other 3 months following the original surgery. The second group consisted of patients who presented some hardening of the breasts after 3 months. Finally, the third group constituted patients that had a sudden increase of breast size and had emergency surgery. The follow-up period was 3 years.

**Results:** In Group 1, 50% of the patients who had asymmetry in the implants position, had double capsule and the other half had an over adherence of the implant, similar to what we find with polyurethane implants (Figure 1). Nevertheless, this adherence was not present on the other breast, causing distortion of the breast shape. In Group 2, all patients had double capsule. In Group 3, all patients had seroma and double or multiple capsules. In our series, patients were required to have revision surgery in 8.43% of cases. Double capsules were responsible for 85.48% of all of our breast augmentation revisions on the last 3 years (Figure 2).

![Figure 1 – Right Breast implant in an asymmetric position. 6m post-operative.](image-url)
Figure 2 – Same patient presenting double capsule.

**Conclusion:** Limited information provided by the implants’ manufacturers is misleading and highly disconcerting. There seems to be overwhelming concerns regarding patients’ safety, thus the authors suggest that further investigation in this area is paramount.