

### **Letter to the Editor**

# Comments on "Commentary on: The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience"

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The authors of the "The Modern Polyurethane-Coated Implant in Breast Augmentation: Long-Term Clinical Experience" would like to thank Dr Frame for his Commentary on our paper and for giving us the chance to highlight once more the results of the study.

The significance of a retrospective study has undoubtedly been well documented over the decades in medicine. There is minimal need to advocate the significance of reporting and documenting surgeons' experience and observations.

Even though the constructive criticism is appreciated, we would like to point out that describing this work "of little statistical significance" is quite unfortunate since the study was conducted by respecting methodological criteria that guarantee the accuracy of the estimates. Obviously, the level of evidence of a retrospective study is not comparable to that of a randomized controlled trial, but that was explicitly stated on the first page, where this study is classified as "level 3" according to the classification for levels of evidence for clinical studies.<sup>1</sup>

Our goal was to describe the incidence of capsular contracture (CC) in a cohort of women who underwent primary breast augmentation or mastopexy augmentation with Microthane (Polytech Health & Aesthetics, Dieburg, Germany) implants, and compare the results with those reported in the international literature. In doing this, we used all methodological precautions. Moreover, the variability of the results due to the smallness of the sample was measured by 95% confidence intervals (CI), reported both for incidence and risks.

Despite the small numbers of our sample, we can still state, with a confidence of 95%, that the cumulative incidence of CC for 14.6 years is not greater than 3.7% (1.2%; 95% CI, 0.4%-3.7%), in any case a particularly low rate.

The modern polyurethane implant differs from the first generations not only in the vulcanization and sterilization processes, but also in the number of basic shell layers, a feature that renders the shell stronger than the previous generations. However, the rupture rate shown in our paper can be considered low, especially when compared to similar published data. In addition, we did not mention the incidence of delamination simply because we have never seen this complication with Microthane implants.

As already mentioned in the paper, two or more members of the surgical team conducted each postoperative consultation and not any "rotating junior staff" as wrongfully stated in the Commentary.

Even though the author of the Commentary mentions late reoperations due to sliding ptosis, we did not experience such a complication; therefore, this response cannot

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be discussed further. On the contrary, we state quite clearly that implant malposition during operation was the most common reason for reoperation.

Finally, we would like to emphasize that any comparison done by the author of the Commentary regarding implant manufacturers, these manufacturers' profiles, commercial history, and company background will not be acknowledged since it is not in the scope of this study nor this response letter.

### **Disclosures**

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