Discussion: Risk Factor Analysis for Capsular Contracture: A 5-Year Sientra Study Analysis Using Round, Smooth, and Textured Implants for Breast Augmentation

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In the article by Stevens et al.,[1] a large study analysis based on 5 years of data is presented to establish risk factors for capsular contracture in Sientra's round, smooth, and textured silicone breast implants. The authors conclude through multivariate analysis that both submuscular placement and surface texturing are statistically significant factors in the prevention of this persistent problem.

As we look critically at breast augmentation in the United States in comparison with the rest of the world, it seems we are only now discovering the influence of these important factors. The volume of breast augmentation around the world is nearly three times that of the United States, and almost all implants used are textured.[2,3] International data reported in the past two decades have supported the use of texturing to prevent capsular contracture.[4–9] Alternatively, American surgeons have evolved because of regulatory restrictions into a smooth, round implant world. The breast implant moratorium in the 1990s shifted the U.S. market to saline implants. Surgeons quickly learned that textured saline implants placed in the subglandular position were unacceptably firm and rippled, and when placed in the submuscular position they had both unacceptable firmness and high rates of deflation. Therefore, smooth saline implants became popular and provided acceptable shape and capsule rates, despite some firmness, rippling, and occasional deflation.

As the moratorium was lifted in 2006, my generation of breast surgeons who had become accustomed to smooth saline implants continued habitually with smooth submuscular implants, simply incorporating silicone devices back into their technique. In addition, because of the softer gel, some selectively resumed using silicone in the subglandular position. Although capsular contracture was improved with this generation of implants, the rate was still unacceptably high.

Even though textured devices have been available for decades, with the U.S. Food and Drug Administration approval of shaped implants in the last year for all three manufacturers, U.S. plastic surgeons are only now starting to increase their use of textured implants. Whether for commercial or clinical reasons, U.S. surgeons are again exploring the benefits of textured devices. All three companies' shaped study data demonstrate decreased capsular contracture rates as compared with their core study data, which included both traditional round smooth (and textured) devices.[10–12] Although some may debate whether the decrease is a result of a more cohesive gel, the key characteristic in all three companies' implants is a textured surface designed to minimize rotation. As additional follow-up data are obtained from each company's core study, they are encouraged to perform analysis similar to that performed by Stevens et al. It should be presented with further exploration to include implant pocket and incision location. This analysis could further stratify benefits, complications, and predictors for reoperation.

This current study and a recent study by Namnoum et al.[13] both show significant reduction in capsular contracture rates based on surgical decisions. In both studies, implant texturing and submuscular position are statistically significant in preventing capsular contracture (as is use of the inframammary incision). It is my personal experience that the use of textured devices, both round and shaped, requires more accurate preoperative

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dimensional planning, and therefore reduces the potential for intraoperative bleeding, hematoma, errors in pocket dissection, and pocket contamination. Overall, these results should challenge the modern breast surgeon's preconceived notions, enable further data-driven surgical decisions, and help reduce reoperation in breast surgery to record low levels with even further improvements in patient satisfaction. I applaud the authors for their diligent data collection and evaluation and Sientra for its transparency in making these data available, and I encourage all plastic surgeons to enroll patients in postapproval studies and into future national society data collection systems. Only by using our collective experience and resources can we hope to finally approach solving this and other holy grails of our specialty.[14]

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