

## 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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This study compares capsular contracture rates between smooth and textured round silicone implants in 2560 women. This subset of patients was extracted from the 5-year results of Sientra's U.S. Food and Drug Administration–approved prospective study. Besides the large population and single implant variable examined other than size, another strength is the statistical analysis methodology used. Although the study period is long overall, the number lost to follow-up is not specified. While claimed to be the first study to compare the two implant types, the exact question asked has been investigated for over 20 years.<sup>1,2</sup>

A few comments are in order regarding commercial bias before discussing the results. The original manuscript was written by a nonphysician, stock-holding employee of the manufacturer, assisted by a company consultant. Most of the physician coauthors also have a financial relationship with the company. Although this combination of author types is hardly new,<sup>3</sup> there was a distinct promotional thread running through the original submission. Fortunately, this issue was adequately addressed in the revision.

The study findings are largely confirmatory of previous publications, with some nuance added. The capsular contracture rate of 7.6 percent is normative. The authors analyze causative variables and describe two groups composed of unadjusted single risk factors and those that emerge after a multivariate regression analysis. The latter, deemed to be more valid, include subglandular plane, smooth surface, periareolar incision, smaller implant size, hematoma/seroma, and the use of a surgical bra. Subglandular placement and smooth surface were the strongest associated factors, with the highest incidence of contracture seen in patients having both.

This study, like previous ones, has demonstrated that textured implants have a real advantage in the subglandular plane but a more marginal effect in the subpectoral plane. The latter finding has led to a popular preference for subpectoral placement of smooth round implants because of perceived advantages in consistency and rippling compared with textured devices. Not mentioned is that surface texturizing has a second role today: to provide grip to shaped implants while the capsule forms, thereby reducing the chance of malrotation. As a last comment on implant texture, there is no proof that any particular method of surface texturizing is superior (Fig. 1).

The finding that periareolar incisions may be associated with a higher rate of contracture supports the growing suspicion about this point, so much so that isolating the nipples from the field with adhesive sheeting is becoming popular. However, challenging anatomy such as a high, tight inframammary crease and tubular breast shapes favors periareolar incisions despite an increased contracture risk, as the study points out. Patient preference may also justify this choice, at least until a more prohibitive spread in contracture rates involving incisions becomes evident (here, a 2.4 percent difference).

This study confirms that hematoma and seroma are associated with the development of capsular contracture. It has been this author's clinical impression that meticulous hemostasis, perhaps to the point of excessiveness, does contribute to a low capsular contracture rate. Seroma appears to be more of a factor in secondary cases.

The finding that smaller implants and surgical bras are associated with an increased risk of capsular contracture is both novel and puzzling. No convincing explanation is offered for either. In any event, the evidence presented is not sufficient to influence practice approach. Similarly,

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the antibiotic issue in this study could be dissected further, but there is such strong evidence elsewhere to support its value that there is no challenge to current recommendations.

Breast augmentation has its share of murky subjects fit for debate. Implant massage is one of them. It was popularized in the 1970s to prevent capsular contracture, or at least to make the patient share responsibility for its development if not rigorous enough in its practice. There has not been a single study on massage that satisfies the requirements of randomization, adequate follow-up, and objective outcome measurement, including the one cited in this study. In the meantime, the development of low-bleed implants, no-touch technique, effective antibiotic irrigation, and more recently skin protection has collectively contributed to steadily decreasing contracture rates. This study offers evidence that massage is associated with a higher incidence of capsular contracture in its unadjusted risk factor analysis, perhaps by prolonging the inflammatory phase of healing. In any event, massage, having never been standardized or proven to be effective, is a relic that should probably be abandoned.

An opportunity missed in the study is a more complete report on the sizable number of patients who developed contracture. Almost half were bilateral, and it would be informative to know whether their treatment was as successful as the treatment of unilateral contractures. It seems that early bilateral contracture is a more biologically unfavorable condition compared with patients in whom at least one side has demonstrated normal healing. Were there many smokers among that subset? Also, how did 21 percent of contractures resolve without treatment and to what degree? Further data on the effectiveness of leukotriene

inhibitors used in some of the patients would be welcome even as enthusiasm for this treatment modality wanes.

The study makes the strongest statement in the comparison between the group of surgeons with a 17 percent incidence of capsular contracture and those with a 2 percent incidence (Fig. 2). The mysterious bra factor aside, surgeons with the high incidence of contracture never used textured implants and used the subpectoral plane less than half as often as those with the low contracture rates.

Extrapolating from the results of this study to arrive at practical recommendations suggests that using a subpectoral plane, textured implants, and inframammary incisions would be the optimal default formula for preventing capsular contracture. Anatomy and patient preferences can modify the surgical plan, realizing that capsular contracture avoidance, although very important, does not trump all other goals. If this is the implied take-home message of the study, it is a good one.

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