

Breast Capsular Contracture: A Retrospective Study of Textured versus Smooth Silicone Implants

Harlan Pollock, M.D.

Dallas, Texas

Recent media attention has transformed breast augmentation, a routine surgical procedure, into a highly controversial one. Capsular contracture is cited in both the lay press and scientific literature as the most frequent complication of breast augmentation. This retrospective study compares two similar groups of breast augmentation patients. The first group consists of 98 consecutive patients utilizing smooth-surface silicone implants, and the second group consists of 99 consecutive augmentations using textured-surface silicone implants. The operative technique and postoperative care were identical—with the surface differences being the only significant variable. Textured-surface silicone implants are shown statistically to reduce capsular contracture to 4 percent, compared with a 21 percent incidence with smooth-surface silicone implants. (*Plast. Reconstr. Surg.* 91: 404, 1993.)

Since the introduction of silicone breast implants by Cronin and Gerow⁸ in 1964, capsular contracture has been the most common complication of breast augmentation.^{6,22} The formation of a fibrous capsule around a foreign object is a normal physiologic response.⁶ However, in the case of breast augmentation, when the capsule contracts significantly around the noncompressible implant, a firm unnatural breast results.

Although many etiologic factors have been suggested, including hematoma, infection, implant immobility, silicone gel bleed, etc., there appears to be no single etiology of capsular contracture.^{5,6,9,15} With use of a smooth-surface silicone implant and any combination of techniques and modalities, rates of capsular contracture of 10 to 30 percent result.^{5,16,18,19} In studies utilizing polyurethane foam implants,

the textured surface alters the periprosthetic scar, thereby reducing the rate of capsular contracture to 5 to 20 percent.^{4,6,21,26} However, because of lingering questions regarding the long-term effectiveness²⁵ and safety of polyurethane, a textured-surfaced silicone implant was recently introduced.

RETROSPECTIVE STUDY

This retrospective study (Table I) compares two similar groups of breast augmentation patients. The first group consisted of 98 consecutive breast augmentations with low-bleed, double-lumen, smooth-surface silicone implants carried out between 1983 and 1984. The second group involved 99 consecutive augmentations using SILTEX textured-surface silicone implants carried out between 1988 and 1990. Both types of implants were manufactured by the same company (Mentor) and the shells were made of identical silicone material.

The two groups were identical, with all sur-

TABLE I
Summary of Breast Augmentation Cases

Year	Patients (Bilateral)	Location of Placement	
		Subpectoral	Retromammary
I. Smooth-surface implant			
1983	39	9	30
1984	59	15	44
TOTAL	98	24	74
II. Textured-surface implant			
1988	26	0	26
1989	40	1	39
1990	33	0	33
TOTAL	99	1	98

gery being performed in the same facility, by the same surgeon, using a comparable technique, and with similar postoperative care. All cases were done under local infiltration anesthesia, intercostal blocks, and intravenous sedation. Retromammary pockets were large, extending from the midaxillary line to the sternum and the inframammary fold to the clavicle, allowing for mobility of the implant. All patients received perioperative antibiotics (cephalosporin), and all pockets were irrigated with 5% povidone-iodine solution. In the smooth-surface implants, intraluminal antibiotics also were used. Small drains were used routinely for postoperative wound suction and were left in place an average of 2 days.

Postoperative care of the two groups of patients was identical. During the first week, no compressive dressings were utilized, and the patient was allowed full nonvigorous activity. Patients were allowed to wear a brassiere for comfort as required. At the end of 1 week, gentle manual compression was carried out as needed to ensure an open retromammary pocket, and the patient was instructed to begin daily breast massage. By the end of 1 week and thereafter, mobility of the textured-surfaced implant was similar to that of the smooth-walled implant, suggesting a lack of tissue ingrowth with this type of texturing. During the early postoperative period (2 months), manual compression was performed if any restriction of motion was noted. This early immobility of some of the textured implants was not regarded as a contracture, since it was easily and effectively reversed with gentle pressure.

RESULTS

In both series, all patients were evaluated at 3 months, 6 months, 1 year, and annually thereafter as long as patients returned. The mean follow-up times were 21.5 and 16.5 months for smooth and textured implant patients, respectively. Patients were evaluated by the author using the Baker classification. The statistics cited are per patient, although all cases were bilateral augmentations. The criteria used for significant contracture were those patients with Baker classification II, III, and IV, which were breasts that were unyielding to manual compression. The results of these two comparable groups of patients were significantly different ($p < 0.001$). Textured-surface implant patients had a contracture rate of only 4 percent compared with a 21 per-

cent incidence in the smooth-surface implant patients (Table II). These results are consistent with those reported by Ersek³ and Zarem²³ in separate studies and subsequently by Coleman et al.²⁸

Other complications were infrequent (Table III). Hypertrophic scars were seen only in patients with inframammary incisions. Of the two seromas that occurred in the textured-surface implant patients, only one required surgical drainage. Palpable wrinkling, which has been described with other textured implants, was rarely observed in this series and, when present, was not troublesome to patients. The overall rate of significant complications was 5 percent in the textured-surface implant series.

DATA ANALYSIS

Table IV presents a summary of data for all follow-up periods. The chi-square statistic of 13.4 is significant, with a $p < 0.001$, suggesting an association between outcome (Baker score $> I$) and type of implant. For the smooth-surface implants there were 21.4 percent in the $> I$ category, while this percentage is only 4.0 percent for the textured-surface implants. The relative risk for these data is estimated at 7.22, with a 95 percent confidence interval for the relative risk of (2.33, 22.33). This means that it is estimated that the smooth-surface implants are 7.22 times as likely as the textured-surface implants to have a Baker score $> I$.

TABLE II
Follow-Up Times and Results of Augmentation
Patients

Length of Follow-Up (mos.)	Patients	Baker I	Baker II	Baker III	Baker IV
I. Smooth-surface implant					
3	10	9	1	0	0
6	7	4	1	1	1
12	23	21	1	0	1
24	13	11	1	1	0
36	45	32	4	4	5
TOTAL (21.5 mos.)	98	77	8	6	7
II. Textured-surface implant					
3	8	8	0	0	0
6	15	15	0	0	0
12	28	27	0	1*	0
24	29	26	2	1	0
36	19	19	0	0	0
TOTAL (16.5 mos.)	99	95	2	2	0

* This patient had bilateral contractures; all others were unilateral.

Note: Baker classification: Baker I, augmented breasts that feel as soft as an unoperated breast; Baker II, minimal contracture, implant palpable; Baker III, moderate contracture, breast firm with visible distortion; Baker IV, severe contracture, hard, tender, cold with marked distortion.

TABLE III
Complications

	Smooth	Textured
Hypertrophic scars	4	4
Hematoma	2	0
Seroma	0	2*
Rupture	0	0
Infection	0	0

* One seroma resolved spontaneously and was not considered significant.

TABLE IV
Summary of Results

Type of Implant	Baker Classifications		Total
	II, III, or IV (>1)	I	
Smooth	21 (21.4%)	77	98
Textured	4 (4.0%)	95	99
TOTAL	25	172	197

Note: Chi-square = 13.439, $p < 0.001$.

DISCUSSION

The two groups of patients compared in this series were virtually identical, as were the surgical procedures and postoperative management. Both types of implants were manipulated after the first week in order to maintain the retromammary pockets. As previously described, this ability to move the textured implant indicates a lack of tissue ingrowth into this type of texturing (SILTEX).

The only variable in these two groups of patients was the type of implant surface. The textured surface therefore alters the periprosthetic scar formation, resulting in a thinner capsule and softer breasts. This clinical impression is confirmed by the study in minipigs by Cohen et al.,²⁷ which clearly demonstrates a thinner scar capsule resulting from textured implants.

Statistical analysis shows that smooth-surface implants are 7.22 times as likely as textured-surface implants to have Baker scores > I.

I acknowledge that this study may be criticized for its lack of objectivity, since the clinical results were, by necessity, evaluated by the surgeon. However, this study was performed in a solo private practice setting, with follow-up evaluations performed in a clinical context, and most examinations were done prior to the initiation of this retrospective review. Further, as an additional objective parameter, the rates of reoperation of the two groups were compared (Table V). This includes only those patients requiring surgery for significant fibrous contracture—Baker II to IV. Only 1 percent of the textured implant patients underwent reoperation, compared with 10

TABLE V
Reoperation for Capsular Contracture

	Operative Cases	Surgery Recommended
Smooth-surface silicone implant patients	10	6
Textured-surface silicone implant patients	1	0

percent for the smooth-walled implant patients, with surgery recommended but not performed in an additional 6 percent of this latter group.

The exact mechanism of the effect of the textured-surface implants needs further study. Clinically, however, this type of texturing is effective in preventing significant capsular contractures without increasing complications.

CONCLUSION

Since the only significant variable in the two series of patients was implant surface, it is hypothesized that the marked improvement in contracture rate observed is a function of the textured surface. Textured silicone implants appear to be more effective in preventing scar contracture when followed up to 36 months. Further, these benefits were obtained with a pure silicone implant that is biologically inert and which resulted in an overall complication rate of less than 5 percent.

Harlan Pollock, M.D.
8305 Walnut Hill Lane
Suite 210
Dallas, Texas 75231

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