

# Surface patterned Silicone Implants Decrease Contracture for Soft Breast Prostheses

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## ABSTRACT

*The rate of capsular contracture using surface-patterned silicone breast implants was studied at six surgical centers. The authors compared contracture rates in their patients with the incidence of contracture reported in long-term retrospective studies by Baker<sup>1</sup> and Moufarrege<sup>2</sup> in which only smooth-surfaced silicone breast implants were used. These two studies included five to ten years of postoperative follow-up. They reported contracture rates of 25% and 22%, respectively, for the first 12-month postoperative period. Ultimately, 89-93% of all contractures that occurred in these smooth-surfaced implant pa-*

*tients appeared by the twelfth month. The multicenter study reported herein shows a dramatically reduced incidence of contracture for the six-month and 12-month postoperative periods when the surface-patterned mammary implants were used. Six- and 12-month contracture rates for surface-patterned breast implants were 1.5% and 1.8%, respectively, as compared with 16% and 25% reported by Baker, and 17% and 22% reported by Moufarrege for the smooth-surfaced implants. These results justify further clinical evaluation. [Contemp Surg 37(3):25-29, 1990.]*

## INTRODUCTION

Authors of many studies have reported development of a thick, contracted scar capsule in the presence of a smooth-surfaced silicone breast implant.<sup>3,4</sup> Its spheroid shape undergoes substantial contracture until the entrapped prosthesis becomes compressed. The patient may experience pain, discomfort, and spherical deformity of the augmented breasts. The contracture symptoms of smooth-surfaced implants have been related to infection (either acute or chronic), hematoma at the

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time of operation, or subsequent mechanical trauma.<sup>5,6</sup>

Although several theories have been proposed regarding the etiology of this thick capsule contraction, the presence of unilateral contracture in approximately one-half of the cases confounds the theoretician. The works of Picha,<sup>7</sup> Homsey,<sup>8</sup> and others imply that an irregular implant surface will enable the host/prosthesis interface to become mechanically bound and, therefore, eliminate micromotion. Collagen fibrils develop random alignment on textured surfaces. As a result, any contractile forces that may occur naturally in the wound healing process will tend to cancel each other out.<sup>9</sup> These principles were first applied to silicone breast prostheses in 1977.<sup>10</sup> Animal studies that support these views culminated in the development of a variety of textured silicone implants in 1987, and clinical applications began in early 1988.<sup>4</sup>

Previous studies by Baker<sup>1</sup> and Moufarrege<sup>2</sup> have shown rates of 25% and 22%, respectively, for the first 12-month postoperative period. Moufarrege reported a 17% incidence of contracture after six months. The results reported by Baker demonstrated a 16% contracture rate at six months after operation, with an increase to a total of 25% by the end of the first postoperative year. Sixty percent of the contractures reported in his study occurred within the first six months and an additional 33% occurred by the end of the first postoperative year. Moufarrege also reported that approximately 89% of all contractures that occurred did so during the first year after implantation.

In this study, we compare the incidence of capsular contracture in surface-patterned prostheses implanted at six surgical centers with contractures after implantation of smooth-surfaced silicone prostheses.

## MATERIALS AND METHODS

The participating surgeons agreed to use a uniform Confidential Patient Evaluation Report form, which would be filled out prior to operation and continuously updated to provide a complete record of care for each patient admitted to the study. Three patients who could not be examined in person due to physical distance were interviewed by telephone or contacted by letter at

specified intervals. In addition to general information about the operation (type of prosthesis selected, steroid/antibiotic use, placement, incision, and anesthesia), the form provided a section for the surgeon to report complications, patient satisfaction, cosmetic result, and Baker classification for each period.

Each surgeon selected the operative procedure and the type of implant (single or double-lumen) he would use. These selections were as follows:

**Group 1** — Used only double-lumen silicone, surface-patterned prostheses. Both submuscular and subglandular placements were used. Periareolar, inframammary, and transaxillary incisions were variously used. Steroids and antibiotics were placed in both the outer lumen of the prosthesis and the surgical site. Local anesthetic was used for most patients.

**Group 2** — Used only double-lumen silicone surface-patterned prostheses. Incisions were transaxillary, periareolar, or inframammary, selected on an individual basis. Placements were subglandular except in transaxillary cases where partial submuscular placement was used. Methylprednisolone (Solu-Medrol®) 12.5mg was added to the outer lumen of the prosthesis. Ceforanide (Precef®) 1gm was given intravenously during the operation, and sterile cefazolin (Ancef®) 500mg was used to irrigate the surgical pocket prior to insertion of the implant. All procedures were performed under local anesthetic.

**Group 3** — Used only single-lumen silicone, surface-patterned prostheses. Both submuscular and subglandular placements were used. Most procedures were performed by transaxillary incision under general anesthesia. No steroids or antibiotics were placed in the surgical site.

**Group 4** — Used only single-lumen silicone, surface-patterned prostheses and inframammary incisions with mostly subglandular placement. No steroids or antibiotics were placed in the surgical site. Procedures were performed under local anesthetic.

**Group 5** — Used only single-lumen silicone, surface-patterned prostheses, subglandular placement, and inframammary incisions. Sterile triamcinolone acetonide (Kenalog®) 40mg and cephalothin (Keflin®) 500mg were added to the surgical site. Most procedures were performed under local anesthetic.

**Group 6** — Used only single-lumen silicone,

**TABLE I**  
Number of Implants Reported

	Total # Reported	Baker 1	Baker 11	Baker III	Baker IV
3 Months	523	484	31	8	0
6 Months	278	257	18	3	1
12 Months	109	99	8	1	1

**TABLE II**  
Percent Baker Classification

	Baker 1	Baker 11	Baker III	Baker IV
3 Months	92.5	5.9	1.5	
6 Months	92.1	6.5	1.1	0.4
12 Months	90.8	7.3	0.9	0.9

**TABLE III**  
Chi-square Analysis of MISTI™ and Smooth Breast Implants  
Six-month and Twelve-month Contracture Rates

	# Reported by Implant			# Reported by Patient		
	# w/ Contracture	# w/o Contracture	X <sup>2</sup>	#w/ Contracture	# w/o Contracture	X <sup>2</sup>
MISTI™						
6-month data	4	271		4	137	
			46.03			30.78
Smooth-surfaced implants						
6-month data	169	798		114	368	
MISTI™						
12-month data	2	107		2	55	
			25.09			17.74
Smooth-surfaced implants						
12-month data	211	753		143	339	

(df = 1, p<0.001 X2 critical value = 10.83)

\*Moufarrege Retrospective Study.

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surface-patterned prostheses. Most placements were submuscular, using a transaxillary incision; however, a few were subglandular using an inframammary incision. No steroids were placed in the surgical site. Bacitracin 50,000 units was used to irrigate the surgical site. Operations were performed under general anesthesia.

## RESULTS

We have studied surface-patterned prostheses that have been implanted in a total of 292 patients. With the exception of nine cases, all augmentations were bilateral. No reconstructions following mastectomy were included in this study. One hundred nineteen (21%) of the implants in this study were secondary implants following removal of smooth-surfaced silicone prostheses. As a percentage of all implants, the total incidence of contracture is 1.5% and 1.8% at six and 12 months, respectively. This represents a significant reduction in the incidence of contracture when compared with the 16% and 25% reported by Baker and the 17% and 22% reported by Moufarrege for the same periods.

The incidence of contracture for 523 implants followed for three months was eight Baker III; for 278 implants followed for six months was three Baker III and one Baker IV; the incidence for 109 implants followed for 12 months was one Baker III and one Baker IV (Table I).

A Chi<sup>2</sup> test of statistical significance was conducted comparing the contracture experience of these authors to results reported by Moufarrege. The test was performed on both six- and 12-month postoperative patient data. Separate analyses were conducted comparing the contracture rates by the number of implants and by the number of patients. The reduction in contracture was found to be statistically significant at  $p < 0.001$  (Table III).

## DISCUSSION

The variability in the incidence of capsular contracture using smooth-surfaced breast implants has been previously reported.<sup>4</sup> Authors of studies exceeding one year in duration report an incidence of contracture of 10-30%. This rate increases the longer an implant is in place and appears to stabilize at approximately 35%.

The incidence of contracture at six and 12

## CONTRACTURE RATES SIX MONTHS POSTOPERATIVE Three Studies Compared

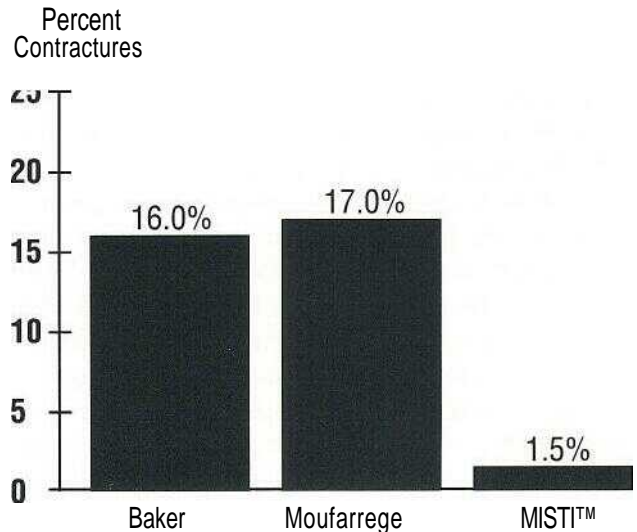


Fig. 1 The studies by Baker and Moufarrege used smooth-surfaced silicone implants. Six-month contracture rates for surfaced-patterned implants are significantly lower.

## CONTRACTURE RATES 12 MONTHS POSTOPERATIVE Three Studies Compared

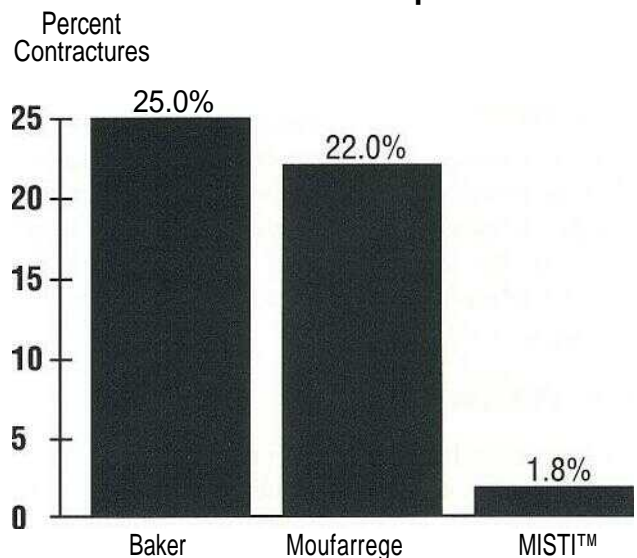


Fig. 2 At 12 months postoperatively, the rate of contracture in each of the smooth-surfaced implant studies is at least 18 times greater than that experienced in the surfaced-patterned implant study.

months postoperatively for smooth-surfaced silicone implants in previously published retrospective studies is compared with those of surface-patterned silicone implants in this multicenter study (Fig. 1,2). The authors of the retrospective studies discussed in this paper report 16% and 17% incidence of contracture after six months and 25% and 22% after one year. The incidence of contracture in our study is 1.5% at six months and 1.8% at 12 months. If the surface-patterned prostheses had no effect on the host/prosthesis interface, a similar rate of contracture would be expected among the patients in this study. It is important to note that in the retrospective studies, 89-93% of all contractures reported during the trial had already occurred by 12 months after operation. From the data in Table I and Table II, it can be seen that this relationship is also true for the present study. Therefore, the reduction in the incidence of contracture may be expected to be maintained in long-term follow-up.

In the current study, each surgeon selected the operative procedure and type of implant he would use. Other variables left to the surgeon's discretion were type of incision, implant placement, type of anesthesia, and the use of antibiotics and/or steroids. The incidence of contracture of the entire group, however, differs markedly from the rate reported in the retrospective studies.

One factor that may be expected to increase the incidence of contracture in this study is the large number of surface-patterned implants (a total of 119) that were placed in secondary breast augmentation patients. However, the occurrence of contractures is evenly split between the primary and secondary breast augmentation patients. If any of the other variables has had an effect on the incidence of contracture, it has not outweighed the benefits of using the surface-patterned implants.

The reduced incidence of contracture associated with surface-patterned implants, when compared to the experience of Moufarrege with smooth-surfaced implants, was found to be statistically significant.

## CONCLUSION

One year may be too brief an experimental period to make any definitive conclusions, but the dramatic reduction in the incidence of contracture seen in this initial six-month and 12-month data establishes a significant trend toward decreased incidence of capsular contracture in patients implanted with surface-patterned silicone prostheses. This promising, statistically significant reduction

in contractures has encouraged the authors to continue this multicenter study.

## REFERENCES

1. Little G, Baker JL: Results of closed compression capsulotomy for treatment of contracted breast implant capsules. *Plast Reconstr Surg* 65(1):30, 1980.
2. Moufarrege R, Beauregard G, Bosse JP, et al.: Outcome of mammary capsulotomies. *Ann Plast Surg* 19(1):62-64, 1987.
3. Taylor SR, Gibbons DF: Effect of surface texture on the soft tissue response to polymer implants. *J Biomed Mater Res* 17:205, 1983.
4. McCurdy JA: Capsular contraction following augmentation mammoplasty: Etiology, management, and prevention. *Am J Cosm Surg* 6(3):141, 1989.
5. Ersek RA: Prostheses for breast augmentation: Progress in materials and design of these implants continues. *Travis County Med Soc J* 35(5):8-10, 1989.
6. McGrath MH, Burkhardt BR: The safety and efficacy of breast implants for augmentation mammoplasty. *Plast Reconstr Surg* 74(4):550, 1984.
7. Picha GJ: The Effect of Ion Milled Surface Structure on Soft Tissue Wound Healing (Abstract of symposium), In *Ion Texturing and the Soft Tissue Response*. Plastic Surgery Research Council, Cambridge (MA), 1987.
8. Westfall RL, Homsy CA, Kent JN: A comparison of porous composite PTFE/graphite and PTFE/aluminum oxide facial implants in primates. *Oral Maxillo Surg* 40(12):771, 1982.
9. Ersek RA, Beisang III AA: Molecular impact surface textured implants (M.I.S.T.I.) scientific abstracts. *Am Soc Aesth Plast Surg*, San Francisco, 1988.
10. Gibbons DF: Effect of surface texture by ion beam sputtering in implant biocompatibility and soft tissue attachment. First Annual Report, NASA grant, NSG-3126, Washington D.C., 1977.

**EDITOR'S NOTE:** At least two of the authors may own stock in Bioplasty, Inc., the manufacturer of MISTI® surface-patterned silicone breast implants.