

Textured or smooth implants for breast augmentation? Three year follow-up of a prospective randomised controlled trial

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SUMMARY. Silicone breast implant surface texturing has been shown to reduce the short-term incidence of adverse (Baker III/IV) capsular contracture in augmentation mammoplasty in double-blind randomised controlled trials. It is, however, undetermined whether the textured surface merely delays the onset of severe contracture or its effect on capsular contraction is persistent.

The current study reviewed, after three years, 49 of the 53 patients who had undergone subglandular breast augmentation mammoplasty in a randomised double-blind study with textured or smooth silicone gel-filled implants in 1989. The incidence of adverse capsular contracture was 59% for smooth implants and 11% for textured ones ($P=0.001$; $\chi^2=10.60$). Eight patients (31%) with smooth prostheses underwent breast implant exchange for severe capsular contracture between the one and three year assessments, compared with a revisional surgery rate of only 7.4% (2/27 patients) for the textured group ($P<0.04$).

These adverse capsular contracture and revisional breast implant surgery rates clearly demonstrate that the effect of textured implants in reducing capsular contracture in augmentation mammoplasty found at one year is maintained at three years, and suggest that it may be long lasting.

Fibrous capsular contraction around silicone breast implants is the most frequent complication of augmentation mammoplasty^{1–4} and the most important cause of patient dissatisfaction following such surgery.⁵ Its aetiology remains obscure.^{6–8} Apart from the well established effect of submuscular implant position in markedly reducing the incidence of capsular contracture compared to the subglandular position,^{2, 9–11} only implant surface texturing has been shown to consistently decrease adverse (Baker grade III and IV) capsular contracture.

A number of retrospective clinical studies have suggested that surface texturing reduces the incidence of capsular contracture around both static^{12–18} and dynamic implants^{19,20} compared to smooth devices. Short-term randomised prospective clinical studies^{1, 21–23} have independently shown that different textured surfaces significantly reduce the incidence of adverse capsular contracture in retromammary breast augmentation with silicone gel-filled^{1,21} and saline-filled prostheses.^{22,23} Interestingly, animal experiments designed to elucidate the mechanism of action of the silicone textured surface in achieving the above effect have given contradictory results, some showing that textured surface prostheses lessen capsular contracture^{24–30} while others have suggested that they may increase capsular contracture.^{27,31–33} Additionally it has not been established whether the effect of implant surface texturing may similarly be as transient as that of the polyurethane foam-covered prostheses^{23,34,35} merely delaying the onset of capsular contracture rather than having a permanent effect.²³ It has also been suggested that the clinical progression from mild capsular contracture (grade III) to severe capsular

contracture (grade IV) in humans may occur any time from the early postoperative period to 22 months.²²

This review was therefore undertaken to determine if the lowered adverse capsular contracture rates observed in the short-term with textured silicone gel-filled breast implants in comparison with smooth ones^{1,21,22} persisted in the medium-term in patients undergoing subglandular breast augmentation. It presents the three year follow-up results of Coleman et al.'s double-blind randomised controlled trial.¹

Patients and methods

Fifty-three patients, randomly assigned to one or other breast implant type, had undergone primary subglandular breast augmentation at the start of the trial. The details of the randomisation and double-blind nature of the study were reported earlier.¹ One group of patients received Siltex textured surface silicone gel-filled implants (Mentor Medical Systems [UK], Newbury, Berks). The second group received smooth surfaced silicone gel-filled implants with otherwise identical characteristics. Although the randomisation code had been broken in 1991 to allow data analysis, no record of this was made in the individual patient case notes and the investigators were unaware of which patients had received which implants. After tabulating the results for each patient, the randomisation code was broken and the figures were not "adjusted" in any manner thereafter.

Patients were reviewed initially at 12 months (Fig. 1) and then at three years after the original

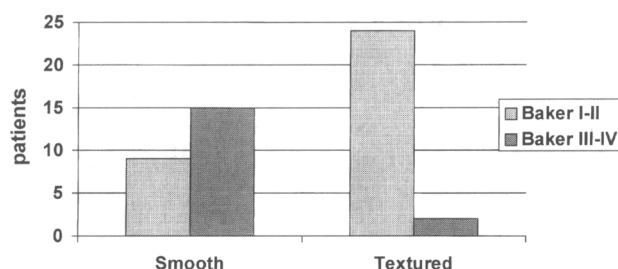


Fig. 1

Figure 1—Incidence of capsular contracture at 1 year. Significant difference between textured and smooth implants ($P < 0.001$, Yates' correction of the Chi squared test).

surgery. All the patients were independently assessed in a specially organised review clinic by three investigators, one of whom was the surgeon who carried out the surgery. The degree of capsular contraction of the breasts was determined using the Baker Scale.³⁶ The investigators did not discuss their results with each other. Where assessors disagreed on the capsular contracture grade of a particular breast the majority view was accepted. Neither the assessor nor the patient knew the type of implant each individual patient had received. Patients with Baker grade III or IV were held to have an adverse or severe degree of capsular contracture and were grouped together.^{1,21,23}

Statistical analysis of the frequency of mild (Baker I and II) vs. severe (Baker III and IV) was undertaken using Yates' continuity correction of the Chi squared test, while the revisional surgery rates were compared using the Fisher's exact test because some of the expected frequencies were less than five.³⁷ Statistical analysis was based on the number of patients showing a given degree of capsular contracture, contrary to the suggestions of others.^{1,23,38} The raw data at one year¹ were therefore re-analysed using the numbers of patients rather than the numbers of breasts (Fig. 1).

Results

A re-analysis of the one year follow-up data based on the numbers of patients rather than breasts still showed a significantly lowered incidence of capsular contracture with textured implants compared with smooth devices (Fig. 1, Table 1). Two patients in the

Table 1 The frequency of mild and severe capsular contracture by implant type at one year follow-up

Implant type	No. of patients		Total
	Baker I-II	Baker III-IV	
Smooth	9	15	24
Textured	24	2	26
Totals	33	17	50

($P < 0.001$ $\chi^2 = 14.35$, $df = 1$; Yates' correction of the Chi squared test.)

The incidence of adverse capsular contracture in the smooth group was 62.5% and 7.7% in the textured group.

“smooth” implant group had asymmetrical severe contracture and were therefore counted as having adverse capsular contracture, although their contralateral breasts had only mild capsules.

Initially, 26 patients had received smooth implants and 27 textured ones (Fig. 2). Six patients, all in the smooth-surfaced implant group, were lost to follow-up at three years. The remaining 47 (89%) were all seen by all three assessors, giving a total of 282 opinions on the capsular contracture grades of 94 breasts. Forty-eight (17%) Baker grade assessments were discordant. However, only 10 (3.5%) of these disagreements were clinically important, being between Baker grades II and III. These patients were counted as having severe capsular contracture. In the three years since the beginning of the study some patients had had further breast implant surgery. This was only determined after the three year clinical assessment by reference to the case notes.

In the smooth implant group ($n = 26$), of the six patients lost to follow-up at three years, two of them (four breasts) were known to have had their implants exchanged because of adverse capsular contracture (Fig. 2). They are included in the calculation of the revisional surgery and definitive capsular contracture rates because the outcome of their breast augmentation was known.^{22,23} Therefore only four “smooth” implant patients (15%) were truly lost to follow-up because in the other two their endpoint outcome was already known. Six other patients with severe bilateral capsular contracture also underwent capsule surgery and implant exchange. Of the remaining 14 patients, nine (18 breasts) had mild capsules while five (10 breasts) had grade III-IV capsules. Therefore, of the 22 “smooth” implant patients (26 less 4 lost to follow-up and outcome unknown) whose breast implant outcomes were known, 13 (59%; 26 breasts) had grade III-IV capsular contracture and 9 (41%; 18 breasts) had mild capsules (Table 2).

Of the original 27 patients in the textured implant group, two had bilateral anterior disc capsulectomy and implant exchange because of severe capsular contracture and only one had adverse capsules (in both breasts) at three year follow-up. (The latter was operated on after the data analysis). Therefore only 3 patients in all (11%; 6 breasts) had grade III or IV capsules while the remaining 24 (89%; 48 breasts) had mild capsular contracture (Table 2).

The effect of implant surface texturing on the overall incidence of mild and severe capsular contracture at three years is summarised in Table 2 and

Table 2 Capsular contracture by implant type at three year follow-up (includes all patients whose breast fates were known)

Implant type	No. of patients		Total
	Baker I-II	Baker III-IV	
Smooth	9	13	22
Textured	24	3	27
Totals	33	16	49

($P = 0.001$, $\chi^2 = 10.60$, $df = 1$; Yates' correction of the Chi squared test).

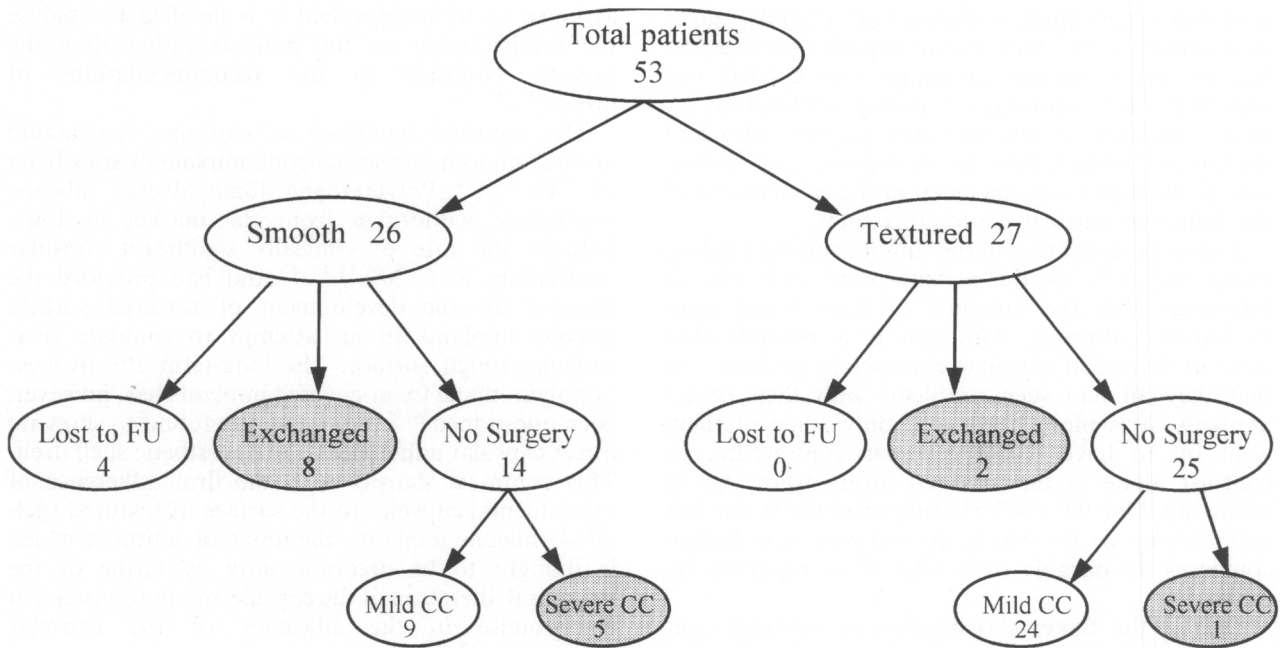


Fig. 2

Figure 2—Patients' fates in first three years. Shaded patient groups had severe (III–IV) capsular contracture.

graphically illustrated in Figure 3. The differences in adverse capsular contracture rates between the textured and smooth implants at three years is highly statistically significant (Fig. 3, Table 2).

Ten patients (eight smooth and two textured) required surgery for adverse clinical capsular contracture after one year and were treated with anterior disc capsulectomy and bilateral replacement of implants; five with Mème polyurethane foam-covered implants, three with textured-surface silicone gel-filled (Siltex) prostheses and two with saline-filled textured surface implants. One of the two patients with saline-filled Siltex prostheses developed a further capsular contraction and this was exchanged for a Siltex gel-filled one. At three years this last patient had no recurrence of her clinical contracture. Of these 10 patients undergoing revisional surgery, three (five breasts) had Grade III or IV capsules at three years, highlighting the high risk for further capsular contraction in patients undergoing revisional breast implant surgery.

There was a statistically significant difference in

the revisional breast implant surgery rates for the two patient groups (Fig. 4, two-tail $P < 0.04$, Fisher's exact test). As all revisional surgery was undertaken for adverse capsular contracture, this suggests a clinically significant difference in the early severe capsular contracture rates for the two implant groups.

It was interesting to note that, in the patients with textured implants undergoing revisional surgery, the capsule was invariably lined with a synovial-like fluid and there was no close adherence of the textured implant envelope to the capsule.

Discussion

This prospective double-blind randomised controlled trial clearly shows that the beneficial effect of surface textured silicone breast implants on adverse capsular contracture in patients undergoing breast augmentation is not transient. This is not only demonstrated by the lower incidence of capsular contracture for the textured implant group but also by its smaller

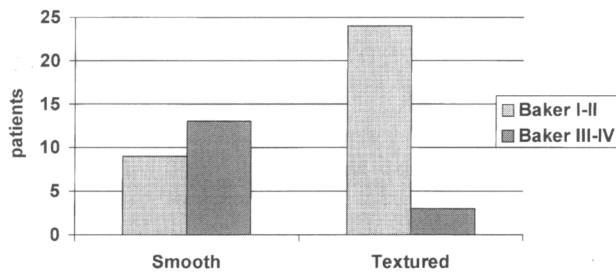


Fig. 3

Figure 3—Incidence of capsular contracture at 3 years (including implants exchanged). Significant difference between textured and smooth implants ($P = 0.001$, Yates' correction of the Chi squared test).

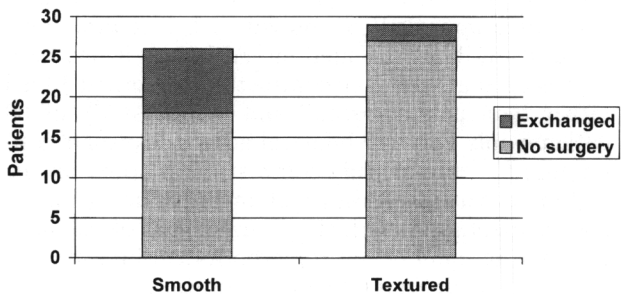


Fig. 4

Figure 4—Breast implant revisional surgery rates for smooth and textured implants. Significant difference between textured and smooth implants ($P < 0.04$, Fisher's exact test).

revisional breast implant surgery rate. The latter gives an estimate of the early severe capsular contracture because such implant exchange was carried out exclusively for significant capsular contracture. A direct corollary of this was that patients who had implant exchange (all for severe capsular contracture and all bilateral) were included in the calculations of the definitive capsular contracture rates.

It must be noted that in the smooth surface implant group only 15% of the patients were truly lost to follow-up with the outcome of their breast augmentation unknown. Although it is possible that none of them had capsular contracture problems or that they all had such problems with their breast implants, it is more likely that only some of them went on to have severe capsular contracture. In contrast, none in the textured group were lost to follow-up. Our 92% (47/51) rate of patients not lost to follow-up or for whom the outcome was known compares favourably with the 87% reported by others.²³

Despite the Baker classification of capsular contracture^{1,36} being partly subjective, it remains the most popular and most practical method of assessing clinical firmness of the breast after augmentation mammoplasty.^{36,39-41} Although initially designed only for breast augmentation, it has recently been modified to describe breast reconstruction more accurately.³⁹ Four independent prospective studies^{1,21-23} using the Baker classification of capsular contracture all came to the same conclusion regarding the efficacy of textured silicone implants in reducing the incidence of capsular contracture. In the present study the subjectivity was reduced by having three assessors each working independently and not discussing the results with each other. In addition to the subjective clinical breast augmentation classification scale⁴² and the patient's opinion, Hakelius and Ohlsén²¹ also employed applanation tonometry although the reliability of this objective means of evaluating breast compressibility⁴³ has been questioned by others.⁴¹ (This may be because the instruments available for applanation tonometry may not be as sensitive as the finger tips in detecting breast firmness).

The double-blind nature of our study and the importance of randomisation are obvious. However, in the present study unlike those of the other three prospective controlled trials reported to date²¹⁻²³ it was the patients and not the breasts who were randomised. It would be impossible to obtain ethical committee approval for individual breast randomisation in the United Kingdom. Although it has been suggested that capsular contracture is "breast-based rather than patient-based" and in one study of 60 patients only two had bilateral adverse capsular contracture,^{23,38} this sharply contrasts with both our one and three year results in which most patients (following augmentation) had the same degree of capsular contracture (mild or severe) in both their breasts. The very low incidence of bilateral contracture reported by Burkhardt and Eades²³ reflects the fact that no two breasts in the same patient had the same implant type or were irrigated similarly. Because the two breasts of any single patient cannot be reasonably

assumed to be independent it is justified to analyse the results based on the patients rather than the breasts, contrary to the recommendations of others.^{23,38}

The reported incidence of capsular contracture around smooth surface silicone implants varies from 10-74%.^{6,40,44} Polyurethane foam-covered silicone prostheses, withdrawn from the market in 1991, reduced the rate of clinically significant capsular contracture to 5-20%^{34,45-47} and had provided the impetus for the development of textured surface silicone implants in an attempt to simulate their irregular/rough surface. The long-term effectiveness of polyurethane foam-covered implants has, however, been questioned^{34,35} and they were found to show no direct capsular adherence to the prosthetic shell itself. This contrasts sharply with the firm adherence of experimental capsules to the surface of textured (gel-filled) silicone implants, the mode of action of which is thought to be predominantly by virtue of the structural alteration of the capsule and the consequent compromise in the efficiency of the capsular contraction.^{13,48}

Textured surface silicone gel-filled prostheses became available for general clinical use in January 1988. Preliminary experimental and clinical studies by the manufacturers suggested a substantial reduction in the incidence of capsular contracture around these implants.¹² A cumulative report of 1444 Biocell implants placed by 72 surgeons showed a 3.67% incidence of Baker grade III and IV capsular contracture.¹² Subsequent clinical data supporting the benefit of textured silicone implants in reducing adverse capsular contracture rates (compared with smooth implants) were mostly retrospective.^{12-18,20}

McCurdy¹³ using three different textured surfaces (Même, Biocell and Siltex) found in a retrospective study of 585 implants for subglandular breast augmentation that implant surface texturing gave a lower incidence of capsular contracture compared to smooth double lumen implants with or without steroids. Although the prostheses were placed at different times (smooth 1984-1987; textured from 1987 onwards), he found no incidence of grade III or IV capsular contracture around any of the three types of textured silicone implants in his series after at least 12 months follow-up. Interestingly, there was an almost identical incidence of capsular contracture around Biocell textured surface silicone and Même polyurethane foam-covered implants.

In a multicentre trial with molecular impact surface textured implants (MISTI) for breast augmentation, Vogt et al.¹⁴ documented capsular contracture rates of 1.5% and 1.8% at 6 and 12 months respectively with these surface patterned prostheses, which contrasted sharply with the 16-25% reported for their historical controls comprised of smooth implants.^{44,45} Apart from being retrospective and using historical controls, this study was very heterogeneous in terms of implant location, types, surgery, the use or otherwise of antibiotics, antiseptics and steroids. Additionally, the one year results were on less than one quarter of the breasts originally augmented.

Ersek's¹⁵ breast augmentation study with the

Bioplasty MISTI implants, although not well controlled, also suggested that textured implants decreased capsular contracture. This is a different texturing from the Mentor surface¹ or the McGhan surface,²¹ suggesting that the precise nature of the texture is probably not as important as "the mere act of interrupting the smooth surface of a silicone elastomer".⁸

More recently Pollock¹⁷ evaluated 197 breast augmentation patients equally divided between (Mentor manufactured) smooth surface (low-bleed, double lumen) and textured surface silicone implants (Siltex) and showed capsular contracture rates of 21% and 4% respectively (mean follow-up less than two years, $P < 0.001$, χ^2 test). Although the two implant types were made of identical silicone material, there was temporal separation between the two patient groups (1983–1984 vs. 1988–1990) and intraluminal antibiotics were used for the smooth surface implants only. This large study conceivably had a large subjective component because the clinical results were evaluated by the "unblinded" surgeon who had performed the augmentations. But, after a follow-up of up to 36 months in this retrospective study, textured surface silicone implants still appeared to be more effective in preventing scar contracture.

Wickham et al.,¹⁸ in a study of 18 postmastectomy breast reconstruction patients undergoing surgery for capsular contraction or improperly sited prostheses, surprisingly found that the thickness of textured capsules was greater than that of smooth capsules due to the possession of an additional inner rugged capsule layer. This contrasts with the experimental^{26,29,48,49} and histopathological⁵⁰ findings of others who have documented that textured implants produced significantly thinner and less uniform capsules than those induced by smooth implants.

The improved cosmetic results reported with textured surface implants have been previously attributed to better tissue fixation.^{1,27,28} Contrary to the observations with other implants,^{27,28,47,48} there was no close adherence of the implant envelopes in those three patients (6 breasts) in the textured implant group undergoing revisional surgery, as confirmed by others.²³ Their capsules were invariably lined with a synovial-like fluid and this may possibly be a result of synovial metaplasia, which could be the result of frequent movement and may be a factor in maintaining reduced capsular contracture in textured implants.⁵¹ There may well be more than one mechanism by which textured surface implants decrease capsular contracture, as fibrous tissue ingrowth has been demonstrated in both polyurethane foam-covered implants^{34,45–47} and other gel-filled textured silicone implants.⁴⁸

It has been suggested that textured surface silicone soft-tissue expanders induce less capsular contraction than smooth ones as evidenced by their lower resistance to inflation.¹⁹

Despite the many retrospective studies referred to above, there are still only two published prospective randomised controlled trials of gel-filled implants with respectable patient numbers.^{1,21} Coleman et al.,¹ in the early results of this paper, demonstrated

adverse (grade III–IV) capsular contracture rates of 58% (smooth) vs. 8% (textured) at one year using Mentor gel-filled Siltex and smooth implants (Fig. 1). Hakelius and Ohlsén²¹ in a similarly well structured prospective controlled randomised investigation of 25 patients undergoing subglandular breast augmentation (each patient acting as their own control) showed, after one year, that, "breasts augmented with textured implants had a lower tendency to develop contracting capsules than the breasts augmented with smooth implants". Their grade III capsular contracture incidence was 44% for smooth implants vs. 0% for textured implants. (Only one patient at one year had a harder breast on the textured side than the breast with a smooth implant). They used Intrashiel (smooth silicone gel-filled implant, McGhan Medical Corporation, Santa Barbara, Calif.) versus textured surface silicone gel-filled prostheses (McGhan Biocell) made specifically for that study by McGhan, with the surface identical to the company's textured Biocell prosthesis which has a pore diameter of 300–800 μm .

More recently Burkhardt and Demas,²² in a prospective controlled blinded clinical study of 56 patients undergoing retromammary breast augmentation comparing Mentor Siltex textured with Mentor smooth saline-filled implants in the same patient, found that the textured surface devices had a markedly decreased incidence of severe capsular contracture (Baker class III–IV) at 2% versus 40% for the smooth inflatable prostheses. (Interestingly, however, most patients preferred the smooth devices despite the higher contracture incidence because the Siltex device was more easily palpable and visible. This is because the saline-inflatable Siltex implant unlike its gel-filled counterpart has an apparently thicker shell with increased palpability.) Seventy-seven per cent of these patients were followed up for more than one year.

In a prospective controlled series of 60 patients followed up for an average of 20 months, Burkhardt and Eades showed that, in general, McGhan's Biocell textured surface devices had a lower incidence of capsular contracture than smooth prostheses (again suggesting that it is the texturing rather than the type/nature of the texturing which may be important in lowering capsular contracture).²³ Prospective randomised studies reported to date therefore suggest that textured surface implants seem to be efficacious in reducing the incidence of adverse capsular contracture whether they are filled with saline or silicone.

Because our three-year incidences of capsular contracture with smooth vs. textured implants (Table 2 and Fig. 3) show little difference from those observed at one year, and long-term studies (5–10 year post-operative follow-ups) with smooth implants have documented that more than 90% of all contractures occurred by the 12th month,^{40,44} it is very likely that the significant trend towards decreased capsular contracture rates in breast augmentation patients receiving textured surface implants we have observed in the medium-term will be maintained in the long-term. Although our results were exclusively in patients with primary breast augmentation, data from other work-

ers who have used textured surface implants to treat capsular contractures induced by smooth implants have also shown the benefit of implant surface texturing^{14,47,52,53} in reducing recurrent capsular contracture. We also successfully treated eight smooth implant patients who developed significant capsular contracture in the present study by implant exchange for textured implants, with only three patients (five breasts) developing recurrent capsule contracture after a follow-up ranging from 6 to 23 months.

Conclusions

This prospective randomised study shows that in cosmetic augmentation mammoplasty, similar to the results at one year, the Siltex textured surface used on the Mentor silicone gel-filled breast prostheses significantly reduced the incidence of adverse capsular contracture at three years as compared with otherwise identical Mentor smooth devices. It is very likely that this trend will persist in the long term. However, it will still be interesting to see to what degree silicone breast implant surface texturing reduces capsular contracture at five and ten years postoperatively.

References

- Coleman DJ, Foo IT, Sharpe DT. Textured or smooth implants for breast augmentation? A prospective controlled trial. *Br J Plast Surg* 1991; 44: 444-8.
- Biggs TM, Yarish RS. Augmentation mammoplasty: a comparative analysis. *Plast Reconstr Surg* 1990; 85: 368-72.
- Biggs TM, Cukier J, Worthing LF. Augmentation mammoplasty: a review of 18 years. *Plast Reconstr Surg* 1982; 69: 445-52.
- Williams JE. Experiences with a large series of silastic breast implants. *Plast Reconstr Surg* 1972; 49: 253-7.
- Hetter GP. Satisfaction and dissatisfactions of patients with augmentation mammoplasty. *Plast Reconstr Surg* 1979; 64: 151-5.
- McGrath MH, Burkhardt BR. The safety and efficacy of breast implants for augmentation mammoplasty. *Plast Reconstr Surg* 1984; 74: 550-60.
- Malata CM, Sharpe DT. On the safety of breast implants. *The Breast* 1992; 1: 62-75.
- Caffee HH. The effect of Siltex texturing and povidone-iodine irrigation on capsular contracture around saline inflatable breast implants (Discussion). *Plast Reconstr Surg* 1994; 93: 129-30.
- Mahler D, Hauben DJ. Retromammary versus retropectoral breast augmentation: a comparative study. *Ann Plast Surg* 1982; 8: 370-4.
- Puckett CL, Croll GH, Reichel CA, Concannon MJ. A critical look at capsule contracture in subglandular versus subpectoral mammary augmentation. *Aesth Plast Surg* 1987; 11: 23-8.
- Vasquez B, Given KS, Houston GC. Breast augmentation: a review of subglandular and submuscular implantation. *Aesth Plast Surg* 1987; 11: 101-5.
- McGhan Medical Corporation, 700 Word Drive, Santa Barbara, Calif. 93111. Biocell update on human clinical follow-up. Through 1990—Product data 1990.
- McCurdy JA. Relationships between spherical fibrous capsular contracture and mammary prosthesis type: a comparison of smooth and textured implants. *Am J Cosm Surg* 1990; 7: 235-8.
- Vogt PA, Seider HA, Moufarrege R, Leikensohn JR, Ersek RA, Eisenberg HV, Armstrong DP. Surface-patterned silicone implants decrease contracture for soft breast prostheses. *Contemp Surg* 1990; 37: 25-9.
- Ersek RA. Rate and incidence of capsular contracture: a comparison of smooth and textured silicone double-lumen breast prostheses. *Plast Reconstr Surg* 1991; 87: 879-84.
- Zarem HA. Augmentation mammoplasty with textured silicone implants. Presented at the Annual Meeting of the American Society of Aesthetic Plastic Surgery, New York, April 1991.
- Pollock H. Breast capsular contracture: a retrospective study of textured versus smooth silicone implants. *Plast Reconstr Surg* 1993; 91: 404-7.
- Wickman M, Johansson O, Olenius M, Forslind B. A comparison of the capsules around smooth and textured silicone prostheses used for breast reconstruction. *Scand J Plast Reconstr Surg Hand Surg* 1993; 27: 15-22.
- Maxwell GP, Falcone PA. Eighty-four consecutive breast reconstructions using a textured silicone tissue expander. *Plast Reconstr Surg* 1992; 89: 1022-34.
- Beasley ME. Eighty-four consecutive breast reconstructions using a textured silicone tissue expander (Discussion). *Plast Reconstr Surg* 1992; 89: 1035-6.
- Hakelius L, Ohlsén L. A clinical comparison of the tendency to capsular contracture between smooth and textured gel-filled silicone mammary implants. *Plast Reconstr Surg* 1992; 90: 247-54.
- Burkhardt BR, Demas CP. The effect of Siltex texturing and povidone-iodine irrigation on capsular contracture around saline inflatable breast implants. *Plast Reconstr Surg* 1994; 93: 123-8.
- Burkhardt BR, Eades E. The effect of Biocell texturing and povidone-iodine irrigation on capsular contracture around saline-inflatable breast implants. *Plast Reconstr Surg* 1995; 96: 1317-25.
- Cherup LL, Antaki JF, Liang MD, Hamas RS. Measurement of capsular contracture: the conventional breast implant and the Pittsburgh implant. *Plast Reconstr Surg* 1989; 84: 893-901.
- Cohen M, Tran A, Marshall M, Campana J, Rona S. Capsular contracture around various types of silicone breast implants. Presented at the Annual Scientific Meeting of the American Society of Plastic and Reconstructive Surgeons, Boston, Mass, October 1990.
- Picha GJ, Drake R, Mayhan K. Soft tissue response to ion textured surfaces. *Artif Organs* 1990; 14(suppl 3): 32-7.
- Barone FE, Perry L, Keller T, Maxwell GP. The biomechanical and histopathologic effects of surface texturing with silicone and polyurethane in tissue implantation and expansion. *Plast Reconstr Surg* 1992; 90: 77-86.
- Brohim RM, Foresman PA, Hildebrandt PK, Rodeheaver GT. Early tissue reaction to textured breast implant surfaces. *Ann Plast Surg* 1992; 28: 354-62.
- Malata CM, Naylor IL, Timmons MJ. Smooth or textured breast implants? A rodent study. *Br J Surg* 1993; 80: Suppl 12.
- Smahel J, Hurwitz PJ, Hurwitz N. Soft tissue response to textured silicone implants in an animal experiment. *Plast Reconstr Surg* 1993; 92: 474-9.
- Caffee HH. Textured silicone and capsule contracture. *Ann Plast Surg* 1990; 24: 197-9.
- Bern S, Burd A, May JW Jr. The biophysical and histological properties of capsules formed by smooth and textured silicone implants in the rabbit. *Plast Reconstr Surg* 1992; 89: 1037-42.
- Bucky LP, Ehrlich HP, Sohoni S, May JW Jr. The capsule quality of saline-filled smooth silicone, textured silicone and polyurethane implants in rabbits: a long-term study. *Plast Reconstr Surg* 1994; 93: 1123-31.
- Pennisi VR. Long-term use of polyurethane breast prostheses: a 14-year experience. *Plast Reconstr Surg* 1990; 86: 368-71.
- Slade CL, Peterson HD. Disappearance of the polyurethane cover of the Ashley Natural-Y prosthesis. *Plast Reconstr Surg* 1982; 70: 379-82.
- Baker JL Jr. Augmentation mammoplasty. In: Owsley JQ Jr, Peterson RA, eds. *Symposium on aesthetic surgery of the breast*. St. Louis: Mosby, 1978: 256-63.
- Siegel S, Castellan NJ. *Nonparametric statistics for the behavioural sciences*. 2nd ed. New York, McGraw-Hill Book Company: 1988: 102-24.
- Burkhardt BR. Comparing contracture rates: probability

- theory and the unilateral contracture. *Plast Reconstr Surg* 1984; 74: 527-9.
39. Spear SL, Baker JL Jr. Classification of capsular contracture after prosthetic breast reconstruction. *Plast Reconstr Surg* 1995; 96: 1119-23.
 40. Little G, Baker JL Jr. Results of closed compression capsulotomy for treatment of contracted breast implant capsules. *Plast Reconstr Surg* 1980; 65: 30-3.
 41. Shah Z, Lehman JA, Stevenson G. Capsular contracture around silicone implants: the role of intraluminal antibiotics. *Plast Reconstr Surg* 1982; 69: 809-12.
 42. Gylbert L, Asplund O, Jurell G, Olenius M. Results of subglandular breast augmentation using a new classification method: 18 year follow-up. *Scand J Plast Reconstr Surg Hand Surg* 1989; 23: 133-6.
 43. Moore JR. Applanation tonometry of breasts. *Plast Reconstr Surg* 1979; 63: 9-12.
 44. Moufarrege R, Beauregard G, Bosse JP, Papillon J, Perras C. Outcome of mammary capsulotomies. *Ann Plast Surg* 1987; 19: 62-4.
 45. Capozzi A, Pennisi VR. Clinical experience with polyurethane-covered gel-filled mammary prostheses. *Plast Reconstr Surg* 1981; 68: 512-18.
 46. Handel N, Silverstein MJ, Jensen JA, Collins A, Zierk K. Comparative experience with smooth and polyurethane breast implants using the Kaplan-Meier method of survival analysis. *Plast Reconstr Surg* 1991; 88: 475-81.
 47. Hester TR Jr, Nahai F, Bostwick J, Cukic J. A 5-year experience with polyurethane-covered mammary prostheses for treatment of capsular contracture, primary augmentation mammoplasty and breast reconstruction. *Clin Plast Surg* 1988; 15: 569-85.
 48. Malata CM, Naylor IL, Nutbrown M, Timmons MJ. Modulation of experimental capsular contracture around silicone gel-filled breast prostheses in a rodent model. *Eur J Surg Res* 1994; 26(SA): 57.
 49. Taylor SR, Gibbons DF. Effect of surface texture on the soft tissue response to polymer implants. *J Biomed Mater Res* 1983; 17: 205-27.
 50. Kasper CS. Histologic features of breast capsules reflect surface configuration and composition of silicone bag implants. *Am J Clin Pathol* 1994; 102: 655-9.
 51. Copeland M, Choi M, Bleisweiss IJ. Silicone breakdown and capsular synovial metaplasia in textured-wall saline breast prostheses. *Plast Reconstr Surg* 1994; 94: 628-33.
 52. Malata CM, Varma S, Scott M, Liston JC, Sharpe DT. Silicone breast implant rupture: common/serious complication? *Med Prog Technol* 1994; 20: 251-260.
 53. Ersek RA, Glaes KL, Navarro JA. Results of reaugmentation with MISTI prostheses after failure of smooth silicone prostheses. *Plast Reconstr Surg* 1992; 89: 83-7.

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