Capsular Contracture in Subglandular Breast Augmentation with Textured versus Smooth Breast Implants: A Systematic Review

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Background: There are conflicting recommendations in the literature regarding the use of textured implants to reduce capsular contracture in subglandular breast augmentation. The authors reviewed the literature to evaluate the effectiveness of surface texturization in reducing capsular contracture.
Methods: The electronic databases MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials were searched for randomized controlled trials comparing textured with smooth implants for subglandular breast augmentation. Study quality was evaluated, and data were extracted from the relevant studies by two reviewers. Outcome measures were reduction in capsular contracture as defined by Baker grade, applanation tonometry, and patient self-assessment. Overall, the treatment effects were expressed as relative risk for dichotomous data and as weighted mean differences for continuous data.
Results: Six randomized controlled trials were identified with a total of 235 patients (470 breasts). Textured implants were associated with less capsular contracture as evaluated by Baker grade at 1 year (relative risk, 4.16; 95% CI, 1.58 to 10.96), 3 years (relative risk, 7.25; 95% CI, 2.42 to 21.69), and 7 years (relative risk, 2.98; 95% CI, 0.86 to 10.37) of follow-up. Applanation tonometry used as an objective measure of firmness, however, was not sensitive enough to detect any significant difference in contractures in the two groups (weighted mean differences, −1.54; 95% CI, −6.83 to −3.75). Interestingly, the self-assessment questionnaire revealed that capsular contracture or firmness is one (albeit a very important factor) of many facets in patient overall satisfaction.
Conclusions: This systematic review suggests that implant texturization reduces the incidence of early capsular contracture in subglandular breast augmentation. However, further studies are needed to evaluate the long-term effect of texturization and confirm the long-term benefits noted in this study. (*Plast. Reconstr. Surg.* 118: 1224, 2006.)

Capsular contracture is the most common complication and cause for patient dissatisfaction after breast augmentation. Overall prevalence of capsular contracture after breast augmentation in large-scale studies has been reported to range from 4 to 17 percent.[1–5] Texturization of implants has been reported by many investigators to reduce the incidence of this complication.[6–8] However, this strategy remains controversial, with many preferring the use of smooth implants.[9–14] Proponents of smooth implants have cited comparable contracture rates with smooth implants.[1,2,15] Contour irregularities (wrinkling and palpable edges) and the theoretical increased risk of bacterial adherence because of the greater surface area present have also been attributed to texturization of implants.[1,9–14] Randomized controlled trials done in this area comparing textured with smooth implants have also shown conflicting results. Although many earlier studies reported a clear advantage with the use of textured implants,[16–21] later studies found no significant improvement in terms of reduction of capsule formation.[15,22] Furthermore, it is unclear whether texturization actually reduces the incidence or merely delays the onset of capsular contracture.

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Table 1. Methodological Quality of Trials

Criterion	Hakelius and Ohlsen[16]	Coleman et al.,[17] Malata et al.,[18] and Collis et al.[19]	Tarpila et al.[22]	Fagrell et al.[15]	Burkhardt and Demas[20]	Burkhardt and Eades[21]
Randomization	Yes	Yes	Yes	Yes	Yes	Yes
Ethics approval	Yes	Yes	Yes	Yes	Yes	Yes
Concealment of allocation	Yes	Yes	Yes	Yes	Yes	Yes
Comparability of baseline	Not applicable*	Not reported	Not applicable*	Not applicable*	Not applicable*	Not applicable*
Treatment protocol	Yes	Yes	Yes	Yes	Yes	Yes
Outcome definitions	Yes	Yes	Yes	Yes	Yes	Yes
Cointerventions	No	No	No	No	Yes†	Yes†
Length of follow-up	1 yr	1, 3, and 10 yrs	1 yr	1 and 7 yrs	1 yr	1 yr
Intention to treat	Yes	No	No	No	No	No
Blinding	Yes	Yes	Yes	Yes	Yes	Yes
Confounding factors	No	No	No	No	Yes†	Yes†
Conflict of interest	Not reported	No	Not reported	Not reported	No	No

*Comparability of baseline was not applicable, because these studies randomized the right or left breasts of the same patients to receive a textured or smooth implant.
†Each breast was also randomly assigned either irrigation with saline or 5% povidone–iodine solution as a cointervention. This was taken to be a potential confounding factor.

Although numerous articles on the effects of texturization on contracture rates have been reported, many investigations were flawed by inadequate study designs. The retrospective nature of many studies, lack of randomization, lack of controls, inconsistent diagnostic criteria, insufficient patient numbers, inadequate follow-up, and inappropriate statistical methodology resulted in a dearth of sound clinical data, despite the widespread use of these implants.[1,23–27] On the basis of evidence from all randomized controlled trials performed in this area, we performed a systematic review to resolve the conflicting opinions on rates of contracture of textured versus smooth implants in subglandular augmentation. Stronger evidence from a meta-analysis will certainly help in the formulation of future guidelines for the use of these implants.

METHODS

Search Strategy

We conducted a literature search, following established guidelines,[28] using the electronic databases MEDLINE (1966 to March of 2005), the Cochrane Central Register of Controlled Trials, CENTRAL (issue 1, 2005), and EMBASE (1974 to March of 2005). We used the search terms breast implant, mammary implant, smooth implant, textured implant, saline implant, silicone implant, capsular contracture, subglandular, submuscular, and augmentation. We performed a free text search or an MeSH search wherever appropriate and used the Boolean operators to combine the terms. The search was limited to randomized controlled trials, and there was no language restriction. We reviewed the completed reference lists of all studies identified through the electronic search and wrote to the corresponding authors of the selected publications requesting assistance in clarifying and furnishing additional data when necessary.

Study Selection

Our stated selection criteria were prospective randomized trials including patients undergoing primary subglandular breast augmentation comparing textured with smooth implants. Patients participating in the selected trials received bilateral breast implants for aesthetic breast augmentation. The implants were placed in a subglandular position. Selected trials had specifically compared smooth with textured breast implants. All patients received a pair of breast implants. They either randomly received a smooth implant on one side and a textured implant on the other side (within-patient comparison) or randomly received a pair of smooth or textured implants (between-patient comparison). No distinction was made between saline and silicone implants. Although many studies reported that filler materials affect the contracture rates (with saline implants associated with

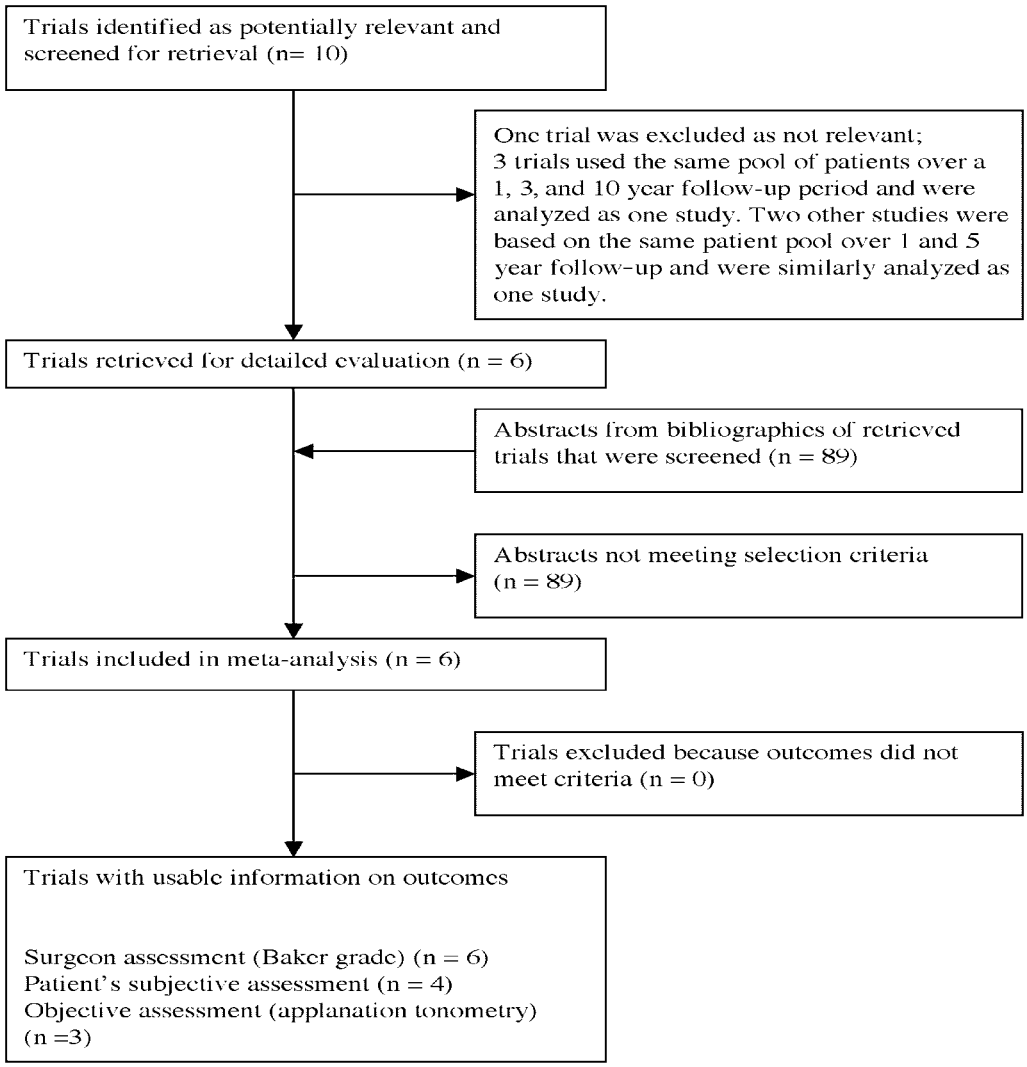

Fig. 1. Trial selection process.

a lower incidence of contractures),[29–33] the use of implants with the same filler in each individual randomized controlled trial internally controlled for any effect on the primary outcome (contracture rates) resulting from the filler materials used.

The primary outcome we sought was capsular contracture as defined by the following: (1) physical examination by the surgeon using the Baker scale (grades III and IV were defined as capsular contracture); (2) patient subjective assessment; and (3) objective evaluation of breast compressibility using applanation tonometry as described by Moore.[34] Studies in which the breast implants were placed in a submuscular plane, those in which unilateral augmentation was used, and those in which implants were placed for the purpose of breast reconstruction were excluded from this analysis.

Study Description and Validity Assessment

Independently and in duplicate, two authors extracted data from the six identified trials. We developed a standard data collection form that included 12 validity criteria to evaluate internal as well as external validity (Table 1). Two independent reviewers extracted data from the identified trials and assessed the quality of the trials from the level of concealment of allocation, method of randomization, degree of blinding used, and losses to follow-up. Any difference in opinion was settled after consultation with the entire study group.

Statistical Analysis

We used dichotomous and continuous variables that reflected each outcome. Analysis was not confined to intention to treat because of sparse information in some selected studies.

Pooled effect estimates and heterogeneity between studies were tested with the RevMan version 4.2.1 statistical package.[35] We calculated relative risk for dichotomous outcomes, weighted mean difference for continuous outcomes, and 95% confidence intervals to estimate the precision of treatment effects. Heterogeneity between trial results was tested using a standard chi-square test. When heterogeneity was significant with a fixed-effects model, a random-effect model was used instead.

RESULTS

Study Selection

The electronic search identified 10 randomized controlled trials reported between 1991 and 2001 that fulfilled our selection criteria. One study was excluded because the implants were placed in the submuscular plane.[36] One study was reported three times to describe the outcomes at different years (1, 3, and 10 years) of follow-up; all data were analyzed as a single study.[17–19] Another study was reported twice to describe findings at 1 year and 5 years; these data were also analyzed as a single study.[16] We reviewed the abstracts of 89 publications from the bibliographies of these trials, but none of them were suitable for this study. Therefore, six studies were selected for this meta-analysis (Fig. 1).

Study Description and Validity

All the studies were conducted in Europe and United States and reported in English[15–22] (Table 2). All studies were performed at a single institution. The number of patients enrolled in these studies ranged from 20 to 60. A total of 235 patients (470 breasts) were recruited into the six trials. At 1 year of follow-up, 211 patients (422 breasts) were available for assessment (overall 1-year follow-up rate, 90 percent). Two studies justified their sample size by an explicit statement of the expected treatment effect, power, and significance level.[17,22] All patients were female and of comparable age. Other baseline patient characteristics were not reported in these studies, but given the nature of patients undergoing breast augmentation, most would be in good health. All patients received bilateral breast augmentation. Patients either randomly received a pair of smooth or textured implants (between-patient comparison)[17–19] or randomly received a smooth or a textured implant in each breast (within-patient comparison).[15,16,20–22] All studies described concealment of allocation and blinding. Therefore, selection and performance biases were minimized. The technique used for breast augmentation was similar in all six studies, with subglandular placement of the implant by means of either an inframammary or inferior areolar approach. Overall complication rates of 5 percent were reported in the randomized controlled trials, with rates ranging from zero to 12 percent in the individual studies. Postoperative hematoma was by far the most common complication reported. At 1 year of follow-up, data for 90 percent of all patients enrolled in the six trials were available for review.

Of the six trials, two used silicone gel implants and four used saline implants. Although saline implants were reported to be associated with a lower incidence of contractures than silicone gel implants,[29–33] the use of implants with the same filler in each individual randomized controlled trial internally controlled for any biases that may have resulted from the filler materials used. In other words, because the conditions within each trial were strictly controlled, in this instance by the use of the same fillers within the trial, any differences in the contracture rates can be attributed to the parameter under investigation (i.e., surface texturization of the implants). The results can therefore be pooled and analyzed in a meta-analysis.

Hakelius and Ohlsen[16] performed a well-designed study with clear outcome definitions. Double blinding, however, was terminated at 1 year of follow-up. When the authors reported their 5-year follow-up results, 17 of 25 patients (68 percent) with smooth implants and one of 15 (4 percent) with textured implants had had the implants replaced. Analyses were therefore based on data for the remaining 24 patients in the textured implant group and for eight patients in the smooth implant group. This major attrition bias together with the lack of blinding in the subsequent study severely limits the strength of their later analysis.

The study by Coleman et al.[17] was the only investigation of the six selected randomized controlled trials that randomized patients to receive a pair of textured or smooth implants (rather than randomizing right or left breasts). This study was well designed and double blinded, with the Baker scale being the only outcome definition of capsular contracture. Subsequently, Malata et al.[18] and Collis et al.[19] reported the 3-year and 10-year follow-up outcomes, respectively, for this cohort of patients. However, the randomization code was broken after 1 year, which may bias subsequent assessment. Although Coleman et al. reported the

Table 2. Randomized Controlled Trials Comparing the Incidence of Capsular Contracture in Textured versus Smooth Mammary Implants Placed in a Subglandular Plane

Study	Country	No. of Patients (no. who completed follow-up)	Mean Patient Age, yr (range)	Method of Randomization	Implants Used	Surgical Technique	Length of Follow-up, Follow-up Rate	Outcome Definitions	Outcomes
Hakelius and Ohlsen[16]	Sweden	25 (25)	31 (20–45)	Patients randomly received a smooth or textured implant in each breast	Smooth silicone intrashiel style 40 (McGhan) and textured Biocell implant (custom made by McGhan)	Subglandular placement	1 yr, 100%	Surgeon assessment (Baker scale)	Compared with smooth implant, textured surfaced implant significantly reduced adverse contractures ($p < 0.001$)
						Inframammary incision		Patient's subjective assessment and objective assessment (applanation tonometry)	
Coleman et al.[17]	United Kingdom	53 (50)	30 (21–44)	Patient randomized to receive a pair of smooth or textured implants	Siltex textured and smooth silicone implant (Mentor)	Subglandular placement	1 yr, 94%	Surgeon assessment (Baker scale)	Compared with smooth implant, textured surfaced implant significantly reduced adverse contractures ($p < 0.0001$); this effect was maintained at prolonged follow-up (10 yrs)
						Inframammary incision			
Malata et al.[18]		53 (49)					3 yrs, 92%		
Collis et al.[19]		53 (44)					10 yrs, 83%		
Tarpila et al.[22] Sweden	21 (21)	33 (22–48)	Patients randomly received a smooth or textured implant in each breast	Textured saline (Biocell, style 168) prosthesis and smooth saline (McGhan)	Subglandular placement	1 yr	Surgeon assessment (Baker scale)	Textured saline implants did not reduce the incidence of capsular contracture ($p > 0.1$)	
						Inframammary incision	100%	Patient's assessment (questionnaire) and objective assessment (applanation tonometry)	

continued

Table 2. Continued.

Study	Country	No. of Patients (no. who completed follow-up)	Mean Patient Age, yr (range)	Method of Randomization	Implants Used	Surgical Technique	Length of Follow-up, Follow-up Rate	Outcome Definitions	Outcomes
Fagrell et al.[15]	Sweden	20 (18)	30 (16–43)	Patients randomly received a smooth or textured implant in each breast	Fine textured saline implant (Siltex, style 2800) and smooth saline implant (Mentor, style 1800)	Subglandular placement	1 yr , 90%	Surgeon assessment (Baker scale)	This study showed no significant difference of contracture rates with smooth versus textured implants
						Inframammary incision		Patient's assessment (questionnaire) and objective assessment (applanation tonometry)	
Burkhardtand Demas[20]	U.S.	56 (45)	34 (20–48)	Patients randomly received a smooth or textured implant in each breast	Mentor smooth saline implant (Mentor i600 series Siltex device) and Mentor textured implant (Mentor 2600 series Siltex device)	Subglandular placement	7.5 yrs, 90% 1 yr, 80%	Surgeon assessment (Baker scale)	Compared with smooth implant, textured surfaced implant significantly reduced adverse contractures ($p < 0.01$)
				Each breast was also randomly assigned either irrigation with saline or 5% povidone–iodine solution		Inferior periareolar incision		Patient's preference	Povidone irrigation did not demonstrate any significant benefit in this study
Burkhardt and Eades[21]	U.S.	60 (52)	33 (22–55)	Patients randomly received a smooth or textured implant in each breast	McGhan series 68 smooth saline implant and McGhan 168 textured implants	Subglandular placement	1 yr, 87%	Surgeon assessment (Baker scale)	Compared with smooth implant, textured surfaced implant significantly reduced adverse contractures ($p < 0.01$)
				Each breast was also randomly assigned either irrigation with saline or 5% povidone–iodine solution		Inferior periareolar incision		Patient's preference	Antibacterial irrigation lowered the incidence of capsular contracture

Table 3. Capsular Contracture in Patients Who Received Textured versus Smooth Implants, as Expressed by Relative Risk and Combined Outcome as Pooled Relative Risk*

Study (first author) or Subcategory	Smooth (*n/N*)	Textured (*n/N*)	RR (random) (95% CI)	Weight (%)	RR (random) (95% CI)
01 At 1 year					
Tarpila, 1997	8/21	6/21		24.25	1.33 (0.56, 3.18)
Burkhardt, 1995	12/52	7/52		24.55	1.71 (0.73, 4.01)
Fagrell, 2001	4/18	1/18		10.42	4.00 (0.49, 32.39)
Coleman, 1991	28/48	4/52		22.68	7.58 (2.87, 20.03)
Burkhardt, 1994	18/45	1/45		11.29	18.00 (2.51, 129.18)
Hakelius, 1997	11/25	0/25		6.82	23.00 (1.43, 370.27)
Subtotal (95% CI)	209	213		100.00	4.16 (1.58, 10.96)
Total events: 81 (smooth), 19 (textured)					
Test for heterogeneity: Chi² = 16.14, df = 5 (p = 0.006), I? = 69.0%					
Test for overall effect: Z = 2.88 (p = 0.004)					
03 At least 3 years of follow-up					
Malata, 1997	26/44	6/54		68.73	5.32 (2.41, 11.76)
Hakelius, 1997	18/25	1/25		31.27	18.00 (2.60, 124.74)
Subtotal (95% CI)	69	79		100.00	7.25 (2.42, 21.69)
Total events: 44 (smooth), 7 (textured)					
Test for heterogeneity: Chi² = 1.45, df = 1 (p = 0.23), I? = 30.9%					
Test for overall effect: Z = 3.54 (p = 0.0004)					
04 At least 7.5 years of follow-up					
Fagrell, 2001	6/18	4/18		45.27	1.50 (0.51, 4.43)
Collis, 2000	26/44	6/54		54.73	5.32 (2.41, 11.76)
Subtotal (95% CI)	62	72		100.00	2.98 (0.86, 10.37)
Total events: 32 (smooth), 10 (textured)					
Test for heterogeneity: Chi² = 3.47, df = 1 (p = 0.06), I? = 71.2%					
Test for overall effect: Z = 1.72 (p = 0.09)					

RR, relative risk.
*Capsular contracture was defined as Baker grade III or IV contracture. Analyses were performed for outcomes at 1 year of follow-up, at least 3 years of follow-up, and at least 7 years of follow-up. Comparison: 01, smooth versus textured implants. Outcome: 02, capsular contracture.

incidence of capsular contracture in terms of the number of breasts that developed capsules, it was unclear why Malata et al. and Collis et al. reported their findings in terms of the number of patients with capsules. It was stated in the latter articles that when both sides were discordant in the Baker grade, the score for the less favorable side was used. It is generally held that contracture commonly occurs as an independent, breast-based phenomenon (rather than patient based).[37] A sig-

Table 4. Capsular Contracture in Patients Who Received Textured Saline versus Smooth Saline Implants, as Expressed by Relative Risk and Combined Outcome as Pooled Relative Risk*

Study (first author) or Subcategory	Smooth (*n/N*)	Textured (*n/N*)	RR (random) (95% CI)	Weight (%)	RR (random) (95% CI)
01 At 1 year					
Tarpila, 1997	8/21	6/21		36.08	1.33 (0.56, 3.18)
Burkhardt, 1995	12/52	7/52		36.68	1.71 (0.73, 4.01)
Fagrell, 2001	4/18	1/18		13.00	4.00 (0.49, 32.39)
Burkhardt, 1994	18/45	1/45		14.24	18.00 (2.51, 129.18)
Subtotal (95% CI)	136	136		100.00	2.66 (0.96, 7.33)
Total events: 42 (smooth), 15 (textured)					
Test for heterogeneity: Chi² = 7.62, df = 3 (p = 0.05), I? = 60.6%					
Test for overall effect: Z = 1.89 (p = 0.06)					
04 At least 7.5 years of follow-up					
Fagrell, 2001	6/18	4/18		100.00	1.50 (0.51, 4.43)
Subtotal (95% CI)	18	18		100.00	1.50 (0.51, 4.43)
Total events: 6 (smooth), 4 (textured)					
Test for heterogeneity: not applicable					
Test for overall effect: Z = 0.73 (p = 0.46)					

RR, relative risk.
*Capsular contracture was defined as Baker grade III or IV contracture. Comparison: 03, smooth saline versus textured saline implants. Outcome: 02, capsular contracture.

Table 5. Capsular Contracture in Patients Who Received Textured Silicone versus Smooth Silicone Implants, as Expressed by Relative Risk and Combined Outcome as Pooled Relative Risk*

Study (first author) or Subcategory	Smooth (*n/N*)	Textured (*n/N*)	RR (random) (95% CI)	Weight (%)	RR (random) (95% CI)
01 At 1 year					
Coleman, 1991	28/48	4/52		89.11	7.58 (2.87, 20.03)
Hakelius, 1997	11/25	0/25		10.89	23.00 (1.43, 370.27)
Subtotal (95% CI)	73	77		100.00	8.56 (3.42, 21.41)
Total events: 39 (smooth), 4 (textured)					
Test for heterogeneity: Chi² = 0.58, df = 1 (p = 0.45), I² = 0%					
Test for overall effect: Z = 4.59 ($p < 0.00001$)					
03 At least 3 years of follow-up					
Malata, 1997	26/44	6/54		85.62	5.32 (2.41, 11.76)
Hakelius, 1997	18/25	1/25		14.38	18.00 (2.60, 124.74)
Subtotal (95% CI)	69	79		100.00	7.25 (2.42, 21.69)
Total events: 44 (smooth), 7 (textured)					
Test for heterogeneity: Chi² = 1.45, df = 1 (p = 0.23), I² = 30.9%					
Test for overall effect: Z = 3.54 (p = 0.0004)					
04 At least 7.5 years of follow-up					
Collis, 2000	26/44	6/54		100.00	5.32 (2.41, 11.76)
Subtotal (95% CI)	44	54		100.00	5.32 (2.41, 11.76)
Total events: 26 (smooth), 6 (textured)					
Test for heterogeneity: not applicable					
Test for overall effect: Z = 4.13 ($p < 0.0001$)					

RR, relative risk.
*Capsular contracture was defined as Baker grade III or IV contracture. Comparison: 02, smooth silicone versus textured silicone implants. Outcome: 02, capsular contracture.

nificant number of patients had their implants removed or exchanged during this prolonged follow-up, and some were lost to follow-up. These factors may contribute to attrition biases of the later studies and made the reported long-term results somewhat less reliable.

Tarpila et al.[22] and Fagrell et al.[15] conducted two well-designed prospective studies. Both studies were similarly structured and randomized patients to receive a textured or smooth implant in each breast. Tarpila et al. used textured implants with large pore diameters (range, 300 to 800 μm), while Fagrell et al. evaluated implants with small pore diameters (range, 30 to 70 μm). Burkhardt and Eades[21] and Burkhardt and Demas[20] performed two studies using the same protocol. The authors simultaneously examined the effects of two variables, surface texturing of the implants and the effects of povidone–iodine irrigation on capsular contracture. Each breast was randomly selected to receive a textured or smooth implant and irrigation with either povidone–iodine solution or physiologic saline. Although the study design was robust, the simultaneous evaluation of two variables known to affect contracture rates inadvertently introduced confounding factors in the individual analysis. The favorable effect of the texturization variable could distort the povidone–iodine solution analysis and vice versa.

Capsular Contracture in Primary Subglandular Breast Augmentation with Textured versus Smooth Breast Implants

When data from the six trials were pooled using a random-effect model, the pooled estimate demonstrated that the risk of having capsular contracture at 1 year of follow-up was significantly higher for patients who had had smooth breast implants than for patients who had had textured implants (relative risk, 4.16; 95% CI, 1.58 to 10.96). A significant heterogeneity result between the studies was observed in the analysis (χ^2 =16.14; p = 0.006), but because both methodological quality of these studies and patient characteristics were similar, the difference cannot be attributed to chance (Table 3). Although all six studies reported their results at 1 year of follow-up, only two had long-term follow-up of more than 1 year. In the studies where long-term follow-up was available, the time when patient data were reviewed was variable. For analysis of long-term follow-up, Hakelius and Ohlsen[16] reported their results at 5 years and Malata et al.[18] reported their results at 3 years. These two studies were analyzed as a subgroup with at least 3 years of follow-up. Similarly, Fagrell et al.[15] and Collis et al.[19] reported their long-term follow-up at 7 and 10 years, respectively. This subgroup was defined as patients with at least 7 years of follow-up. The advantage of textured implants

Table 6. Breast Hardness in Patients Who Received Textured versus Smooth Implants, as Expressed by Weighted Mean Difference

Study (first author) or Subcategory	Smooth No.	Smooth Mean (SD)	Textured No.	Textured Mean (SD)	WMD (random) (95% CI)	Weight (%)	WMD (random) (95% CI)
01 At 1 year							
Hakelius, 1997	25	34.50 (9.55)	25	41.40 (5.56)		24.63	−6.90 (−11.23, −2.57)
Fagrell, 2001	18	27.30 (6.67)	18	27.80 (4.95)		26.33	−0.50 (−4.34, 3.34)
Tarpila, 1997	21	27.60 (8.40)	21	25.00 (4.30)		25.65	2.60 (−1.44, 6.64)
Subtotal (95% CI)	64		64			76.61	−1.54 (−6.83, 3.75)
Test for heterogeneity: $Chi^2 = 10.17$, df = 2 ($p = 0.006$), $I^2 = 80.3\%$							
Test for overall effect: Z = 0.57 ($p = 0.57$)							
02 At 7.5 years							
Fagrell, 2001	18	23.40 (8.34)	18	23.40 (5.82)		23.39	0.00 (−4.70, 4.70)
Subtotal (95% CI)	18		18			23.39	0.00 (−4.70, 4.70)
Test for heterogeneity: not applicable							
Test for overall effect: Z = 0.00 ($p = 1.00$)							
Total (95% CI)	82		82			100.00	−1.16 (−5.09, 2.76)
Test for heterogeneity: $Chi^2 = 10.42$, df = 3 ($p = 0.02$), $I^2 = 71.2\%$							
Test for overall effect: Z = 0.58 ($p = 0.56$)							

WMD, weighted mean difference.
Breast hardness was determined by breast applanation tonometry. Comparison: 01, smooth versus textured implants. Outcome: 04, tonometric assessment.

was maintained when data for the patients were reviewed at 3 years (relative risk, 7.25; 95% CI, 2.42 to 21.69) and 7 years (relative risk, 2.98; 95% CI, 0.86 to 10.37) of follow-up (Table 3). Four studies used saline implants and two used silicone implants. Although the use of the same filler materials (saline or silicone) within each study serves to negate the effect of the filler used in evaluating the incidence of capsular contracture, we performed subgroup analyses on studies that used saline and silicone implants only as a precaution. This gave the same conclusion, favoring the use of textured implants (saline implants: relative risk, 2.66; 95% CI, 0.96 to 7.33; silicone implants: relative risk, 8.56; 95% CI, 3.42 to 21.41) (Tables 4 and 5).

Breast applanation tonometry was used in three randomized controlled trials as an objective measure of breast hardness.[15,16,22] Subgroup analysis of these three studies, however, did not reveal any significance between breasts with textured and smooth implants at 1 year (weighted mean difference, −1.54, 95% CI, −6.83 to 3.75) and 7.5 years (weighted mean difference, 0.00; 95% CI, −4.70 to 4.70) (Table 6). Patient self-evaluation of the augmentation outcome was assessed by means of questionnaires. Two questions were selected for analysis: (1) Which breast feels harder? and (2) Which side do you prefer? (Tables 7 and 8). Thirty-five percent of patients thought that both sides were of equal consistency, and 42 and 23 percent thought that the smooth and textured sides were harder, respectively. Although most patients thought that the smooth implant side was harder, the response to personal preference was more intriguing. Opinions were almost equally split between having no preference and smooth or textured implant side.

DISCUSSION

Our meta-analysis of findings of six prospective randomized controlled trials suggests that surface texturization of the implant reduces capsular contracture in subglandular breast augmentation. All six trials were similarly structured and well designed. The outcome definition used in all studies, the Baker grade, is a universally accepted stan-

Table 7. Three Randomized Controlled Trials in Which Patients Received Either a Smooth or Textured Implant in Each Breast: Evaluation of Patient Self-Assessment of Breast Augmentation by Asking Patients the Question "Which Breast Feels Harder?"*

Study	Same	Smooth Implant	Textured Implant
Hakelius and Ohlsen[16]	7/25	16/25	2/25
Tarpila et al.[22]	10/21	4/21	7/21
Fagrell et al.[15]	6/20	8/20	6/20
Overall	23/66 (35%)	28/66 (42%)	15/66 (23%)

*Data are expressed as number of patients with finding/total number of patients (percent). Most patients thought that the smooth implant side was harder.

Table 8. Four Randomized Controlled Trials in Which Patients Received Either a Smooth or Textured Implant in Each Breast: Evaluation of Patient Self-Assessment of Breast Augmentation by Asking Patients the Question "Which Side Do You Prefer?"*

Study	Same	Smooth Implant	Textured Implant
Tarpila et al.[22]	9/21	6/21	6/21
Fagrell et al.[15]	7/20	8/20	5/20
Burkhardt and Demas[20]	13/45	19/45	13/45
Burkhardt and Eades[21]	19/52	16/52	17/52
Overall	48/138 (35%)	49/138 (35%)	41/138 (30%)

*Data are number of patients with preference/total number of patients (percent). The response to this question was more intriguing. Opinions were almost equally split between having no preference and smooth or textured implant side.

dard for breast firmness assessment. Although it is a subjective measure, it is ratified by both convenience and community experience. The clinically important contractures are Baker grades III and IV, and these were defined as capsular contracture in all studies. Although opinions may differ, a discordant opinion between independent observers regarding the clinically important distinction (i.e., between Baker grades I/II and III/IV) is rare. A high interexaminer concordance rate and agreement with regard to the clinically critical distinction between grades II and III have previously been documented.[16] All six randomized controlled trials used two or more independent examiners for patient evaluation. When opinions were discordant, these were resolved by consensus. In addition, double blinding (at least in the first year of follow-up) ensures that opinions are as objective as possible and serves to minimize selection bias inherent in such investigations.

Some potential limitations of this meta-analysis should be noted. Patient cohorts were diverse and may not have been comparable. Surgical techniques and incision approaches (inframammary versus periareolar) also varied and were not standardized across the centers. This may further confound analysis. Although previous studies showed that capsular contracture is usually apparent within the first year of implantation, contracture is a progressive phenomenon with accumulating risk over the lifetime of the implant.[1,38–40] Long-term results were sparse and, by their nature, prone to bias. Only two studies reported follow-up of more than 1 year,[15–17] and in these studies, blinding was broken after 1 year. In addition, more patients were lost to follow-up or had their implants changed as the trials progressed. Therefore, although the data demonstrated that the advantage of textured implants seemed to be maintained up to 7 years, the quality of the data significantly deteriorated after the 1-year follow-up mark. Long-term follow-up data therefore need to be interpreted with caution. The question as to whether texturization of implants truly reduces capsular contracture or merely delays the onset of contracture[23] cannot be conclusively resolved based on the best currently available evidence, and more long-term studies are needed.

Currently, there is no universally accepted objective measure for breast hardness. First described by Moore,[34] breast applanation tonometry uses a Plexiglas disk of a known weight on the breast. The area imprinted on the disk is then calculated and taken as a measure of breast compressibility or softness. Three trials used breast applanation tonometry to assess hardness. However, this use did not show any significant difference between textured and smooth implant groups. The lack of agreement between clinical examination and applanation tonometry may indicate that the latter method may not be sensitive enough to detect differences detected by the examiners' fingertips. Therefore, a better objective measure is needed in formulating future trials.

Patient self-assessment, however, was more complex. Patient assessments of hardness were generally in agreement with judgments of doctors using Baker grades (Table 7). Although softness or the lack of contracture was an important consideration, some patients preferred smooth implants over textured ones even though the latter were softer (Table 8). In these instances, even though the textured side was softer, wrinkling, palpability, and visibility were reasons cited for preference for smooth implants.[41,42] As Burkhardt and Demas[20] noted, patients consistently express preference for textured implants only when there is severe contracture on the contralateral smooth implant side. When both sides are of comparable firmness, other factors, such as palpability and visibility, become important considerations. Patients tend to prefer smooth implants because they are less palpable and visible in the absence of significant contracture. Palpability and visibility of implants are particularly problematic with the use

Table 9. The One Randomized Controlled Trial That Compared the Incidence of Capsular Contracture in Textured versus Smooth Mammary Implants Placed in a Submuscular Plane*

Study	Country	No. of Patients (no. who completed follow-up)	Mean Patient Age, yr (range)	Method of Randomization	Implants Used	Surgical Technique	Length of Follow-up, Follow-up Rate	Outcome Definitions	Outcomes
Asplund et al.[36]	England and Sweden	61 (55)	30 (19–55)	Patient randomized to receive a pair of smooth or textured implants	Dow Corning textured implant (Silastic MSI microstructured HP) and Dow Corning smooth implant (Silastic II HP)	Submuscular placement; inframammary incision	1 yr, 90%	Surgeon assessment: Baker scale; patient's assessment: questionnaire and objective assessment (applanation tonometry)	Compared with smooth implants, textured surfaced implants appeared to be associated with lower contracture rates, but findings did not reach statistical significance

*This study showed that rates of contracture of textured implants were not significantly different from those of smooth implants in submuscular breast augmentation.

of textured saline implants in thin individuals with very little breast tissue.[1,41,42]

It is widely held that submuscular placement reduces the risk of capsular contracture after augmentation mammaplasty.[2,41,43–49] The role of texturization of the implant to reduce capsular contracture when placed in this plane is less clear. To our knowledge, only one prospective randomized controlled trial on submammary augmentation has been performed to date (Table 9).[36] Asplund et al.[36] compared rates of contracture of smooth and textured silicone implants placed in a submuscular plane. In their study, 61 women were randomly assigned to receive a pair of textured or smooth implants. Fifty-five patients (90 percent) were examined at 1 year, and the authors noted Baker grades III and IV for 9 percent of textured implants versus 16 percent of smooth implants. Although the authors concluded that there was a trend that favored textured implants, this finding was inconclusive because the difference did not reach statistical significance (Table 3). Although it appears that textured implants are associated with a slightly decreased incidence of capsular contracture in submuscular augmentation, this must be balanced against the higher incidence of palpability and visibility when compared with smooth implants. Because the incidence of capsular contracture is much less in the submuscular plane, texturization does not offer a clear advantage when used in this area. From the best currently available data, depending on the needs of individual patients, the choice of textured or smooth implants in submuscular breast augmentation is a matter of professional judgment.

The cause of symptomatic capsular contracture and how texturization reduces this remain largely unknown. It appears that the mere act of texturing the surface was effective, and the particular type of surface texturing [large pore diameter (300 to 800 μm) versus small pore (30 to 70 μm)] was of no consequence.[1,15,16,22] Burkhardt et al.[50] presented compelling evidence that subclinical infection (with *Staphylococcus epidermidis* or other pathogens) is a major causative factor in capsule formation. This hypothesis was supported by both basic science and clinical data from large clinical series and prospective investigations.[11,20,21,51,52] The greatly expanded implant surface from texturization, therefore, should make them more susceptible to contamination and therefore more prone to capsule formation. Animal studies have also yielded perplexing findings. Several carefully designed animal studies performed on rabbits

comparing smooth versus textured surface silicone implants have consistently demonstrated increased contracture and increased capsular thickness around textured implants.[3,53–55] Yet the favorable results seen clinically with textured implants have been consistently reproduced all over the world.[15–23] Certainly, more research in this area is needed to resolve these perplexing and seemingly conflicting data.

CONCLUSIONS

On the basis of the best currently available evidence, we favor the use of textured implants over smooth implants in subglandular breast augmentation. Although the short-term benefit is quite clear, better long-term studies are needed to see whether this advantage is maintained over time. As with any process in which the cause is largely unknown, multimodal treatment and surface texturing are available to reduce capsular contracture. Antibacterial breast pocket irrigation (e.g., intraoperative 10% povidone–iodine), meticulous hemostasis, use of talc-free gloves for handling the implant, perioperative antibiotics, and implant movement exercises all play an integral part in ensuring an optimal outcome of breast augmentation. Patient preference is less well defined. Perhaps future trials focusing on patient preference, satisfaction, and perception of outcome with regard to breast augmentation may yield valuable findings.

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