Textured surface breast implants in the prevention of capsular contracture among breast augmentation patients: a meta-analysis of randomized controlled trials

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CRD summary
This review assessed the effects of textured surface breast implants on capsular contracture in women undergoing breast augmentation. The authors concluded that textured implants reduce capsular contracture compared with smooth implants. The conclusion was supported by the results presented, but poor reporting of review methods and some study details makes it difficult to confirm the reliability of the authors' conclusion.

Authors' objectives
To evaluate the effects of textured surface breast implants on capsular contracture in women undergoing breast augmentation.

Searching
MEDLINE, EMBASE and the Cochrane CENTRAL Register were searched from inception to March 2004 using the reported search terms.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion. The duration of follow-up in the included studies ranged from 5 months to 8 years 4 months.

Specific interventions included in the review
Studies that compared textured versus smooth breast implants were eligible for inclusion. The included studies evaluated different types of implant (saline and silicone), surface texturing (Silhex and Biocell) and sites of implant placement (subglandular and submuscular).

Participants included in the review
Studies of women undergoing breast augmentation were eligible for inclusion.

Outcomes assessed in the review
Studies that assessed capsular contracture were eligible for inclusion. The primary review outcome was clinically significant capsular contracture, which was defined as class III or IV contracture using either the Baker or the Breast Augmentation Classification systems. The review also assessed complications, infection and reoperation for either complications or infection.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Validity was assessed and scored using the Jadad scale, which considers the reporting and methods of randomisation, blinding and handling of withdrawals. The maximum possible score was 5 points; studies obtaining a score of 3 or greater were considered to be of a high quality. Two authors appear to have independently assessed validity.

Data extraction
Two reviewers independently extracted the data using a standardised form. For each study, the number of events of
interest was extracted for each treatment group and an odds ratio (OR) with 95% confidence interval (CI) was calculated.

**Methods of synthesis**

How were the studies combined?
The studies were combined using a random-effects meta-analysis and a pooled OR with 95% CI was calculated. The authors considered that there were too few studies for a funnel plot to be useful in the assessment of publication bias.

How were differences between studies investigated?
Statistical heterogeneity was assessed but the method was not reported. Fixed-effect subgroup analyses were used to examine the influence of type of implant (saline or silicone), type of surface texturing (Silentex or Biocell), placement (subglandular or submuscular) and duration of follow-up.

**Results of the review**

Seven RCTs (480 implants) were included in the meta-analysis of efficacy. The evaluation of complications was based on 532 patients. Reasons for the discrepancy between the numbers analysed for efficacy and safety were not reported.

One study was assigned a Jadad score of 2 for quality; all other scores ranged from 3 to 5 out of 5 points.

There was a statistically significant reduction in the rate of capsular contraction associated with textured compared with smooth breast implants (OR 0.19, 95% CI: 0.07, 0.52). Significant statistical heterogeneity was found (p=0.006). Four of the seven studies reported no significant difference between treatments, while three studies reported a statistically significant reduction in capsular contraction with textured compared with smooth breast implants.

Subgroup analyses showed a significant reduction in capsular contracture with textured versus smooth breast implants for both saline or silicone implants, for implants with either Siltex or Biocell surfaces, for studies with longer duration of follow-up (more than 3 years) and for subglandular placement of the implant. There was no significant difference between textured and smooth implants for submuscular implants (based on one study that the authors considered might have been underpowered; 104 implants).

Some studies reported complications without stating which treatment group the patients had been allocated to; as such, these events could not be included in the meta-analysis.

There was no significant difference between textured and smooth breast implants in the number of complications (4 of 271 patients versus 5 of 261 patients), reoperation for complications (3 out of 271 versus 5 out of 261), infection (3 out of 271 versus 1 out of 261), or reoperation for infection (2 out of 271 versus 1 out of 261).

**Authors’ conclusions**

Compared with smooth breast implants, textured surface breast implants reduce the risk of capsular contracture in women undergoing breast augmentation.

**CRD commentary**
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Three relevant databases were searched, but specific attempts to identify unpublished studies were not reported and this raises the possibility of publication bias. It was not clear whether any language restrictions had been applied to the search, so the potential for language bias could not be assessed. Methods were used to minimise reviewer errors and bias in the data extraction and validity assessment processes, but it was unclear whether similar steps were taken at the study selection stage. Validity was assessed using appropriate criteria, although only aggregate scores were presented.

No information on the participants was presented, hence the generalisability of the results could not be assessed. The methods used to statistically combine the studies seem appropriate, and some attempts were made to investigate statistically significant heterogeneity. The authors’ conclusion is supported by the results presented. However,
incomplete reporting of review methods and some study details makes it difficult to confirm the reliability of the authors' conclusion.

**Implications of the review for practice and research**

Practice: The authors stated that concerns about post-operative infection and other complications should not deter surgeons from using textured rather than smooth implants. The authors advised caution in extrapolating the review's results to the reconstructive population, because the meta-analyses were only based on augmentation patients.

Research: The authors stated that further research is required to determine the reasons for the reduced risk of capsular contracture with textured breast implants, and to evaluate the place of textured surface implants in breast reconstruction.

**Bibliographic details**


**PubMedID**

16772915

**DOI**

10.1097/01.prs.0000218184.47372.d5

**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Breast /pathology; Breast Diseases /etiology /prevention & control; Breast Implantation /adverse effects /instrumentation; Breast Implants /adverse effects; Female; Fibrosis /etiology /prevention & control; Humans

**AccessionNumber**

12006003570

**Date bibliographic record published**

31/05/2007

**Date abstract record published**

31/05/2007

**Record Status**

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.