Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: a systematic review
Wong C H, Samuel M, Tan B K, Song C

CRD summary
The authors concluded that findings suggest that textured breast implants in subglandular breast augmentation reduce the risks of early capsular contracture compared with smooth implants, but more long-term research is required. Overall, this was a well-conducted review and the authors’ cautious conclusions are likely to be reliable.

Authors’ objectives
To compare the effects on capsular contracture of textured versus smooth implants in subglandular breast augmentation.

Searching
MEDLINE, the Cochrane CENTRAL Register and EMBASE were searched without language restrictions from inception to March 2005; the search terms were reported. In addition, the reference lists of selected reports were screened.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion. In the included studies, implants were randomly allocated within patients (different type of implant in each breast) or to patients (same implant in both breasts). The duration of follow-up in the included studies ranged from 1 to 10 years.

Specific interventions included in the review
Studies that compared textured versus smooth breast implants were eligible for inclusion. The included studies evaluated saline and silicone implants. They were conducted in Sweden, the UK and the USA.

Participants included in the review
Studies of patients undergoing primary subglandular breast augmentation were eligible for inclusion. Studies of patients receiving submuscular breast implants or unilateral augmentation were excluded, as were those of patients undergoing breast reconstruction. In all of the included studies, patients received bilateral breast implants for aesthetic breast augmentation. The participants were aged from 16 to 55 years and all were women.

Outcomes assessed in the review
The primary review outcome was capsular contracture measured by physical examination using the Baker scale (with grades III and IV representing capsular contracture), subjective assessment by the patient, or objective evaluation of breast compressibility using applanation tonometry. The review assessed outcomes at 1 year, 3 or more years and 7.5 or more years.

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
Two reviewers independently assessed study validity using the following criteria: method of randomisation; concealment of allocation; baseline comparability of the treatment groups; treatment protocol; definition of the outcomes; cointerventions; length of follow-up; intention-to-treat analysis; blinding; confounding factors; conflict of interest; and ethical approval. Any differences between the reviewers were resolved through discussion with the entire study group.
Data extraction
Two reviewers independently extracted the data onto a standardised form. Any differences between the reviewers were resolved through discussion with the entire study group. For each study, the numbers of events of interest, and mean values for continuous data, were extracted. Authors of primary studies were contacted for additional data if required.

Methods of synthesis
How were the studies combined?
Pooled relative risks (RRs) and 95% confidence intervals (CIs) were calculated for dichotomous data and pooled weighted mean differences and 95% CIs for continuous data. Fixed-effect models were used in the absence of significant statistical heterogeneity; random-effect models were used where heterogeneity was significant.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the chi-squared statistic. Subgroup analysis was used to examine the influence on the results of type of implant filling (saline or silicone).

Results of the review
Six RCTs (n=470 breasts) were included.

All studies reported allocation concealment and blinding. Two studies reported power calculations. Two studies were subject to potential confounding by co-interventions. One study reported intention-to-treat analysis. Overall, 90% patients were followed up at 1 year. Studies reporting longer-term follow-up had significant numbers of patients having implants removed or exchanged, and some were lost to follow-up.

The risk of capsular contracture was significantly higher for patients who had received smooth compared with textured breast implants at 1 year (RR 4.16, 95% CI: 1.58, 10.96; 6 studies, n=422) and at 3 years or more (RR 7.25, 95% CI: 2.42, 21.69; 2 studies, n=148), but not at 7.5 or more years (RR 2.98, 95% CI: 0.86, 10.37; 2 studies, n=134). Significant heterogeneity was found for studies reporting 1-year’ follow-up (p=0.006) and 7.5 or more years’ follow-up (p=0.06).

There was no significant difference in breast hardness (measured using breast applanation) between smooth and textured breast implants at 1 year (3 studies) or 7.5 years (1 study).

Patient preference was split equally between no preference, smooth and textured implants (4 studies).

Authors’ conclusions
Findings suggest that textured breast implants reduce the risks of early capsular contracture compared with smooth implants, but more long-term research is required.

CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched and attempts were made to minimise language bias, but the limited attempt to locate unpublished studies raises the possibility of publication bias. Validity was assessed using defined criteria and the results reported. Methods were used to minimise reviewer error and bias in the assessment of validity and extraction of data, but it was unclear whether similar steps were taken at the study selection stage.

The studies were combined in a meta-analysis and statistical heterogeneity was assessed. Significant heterogeneity was found for most meta-analyses, but forest plots indicated a similar direction of treatment effect across studies. The authors correctly highlighted that long-term data were infrequently reported and subject to attrition bias. This was a well-conducted review and the authors’ cautious conclusions are likely to be reliable.
Implications of the review for practice and research

Practice: The authors stated that clinical judgement that takes into account the needs of individual patients is required for the choice between textured and smooth breast implants.

Research: The authors stated that higher quality long-term studies are required to evaluate the effects of textured breast implants on capsular contracture. They suggested that studies should assess patient preference, satisfaction and perception of outcome. There is also a need for a better objective measure to evaluate breast hardness.

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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.