A systematic review and meta-analysis of complications associated with acellular dermal matrix-assisted breast reconstruction
Ho G, Nguyen TJ, Shahabi A, Hwang BH, Chan LS, Wong AK

CRD summary
This review concluded that acellular dermal matrix-assisted breast reconstructions were associated with a higher risk of seroma, infection and reconstructive failure compared with prosthetic-based breast reconstructions using traditional musculofascial flaps. Given the potential for language bias and low quality of evidence identified, these conclusions should be interpreted with caution.

Authors' objectives
To assess the risks associated with acellular dermal matrix-assisted breast reconstruction.

Searching
The databases MEDLINE, Web of Science and The Cochrane Library were searched up to September 2010 for studies in English. Search terms were reported. Reference lists of relevant publications were screened. Abstracts were excluded.

Study selection
Studies that reported complications in patients who underwent primary prosthesis-based breast reconstruction using acellular dermal matrix were eligible for inclusion. Case reports or studies with less than 10 patients were excluded. Studies had to report raw data or complication rate for at least one of the following complications: seroma, cellulitis, infection, skin flap necrosis (including both major and minor form of necrosis), haematoma, capsular contracture, and reconstructive failures (defined as the need to abort the reconstruction by removing the prosthesis and/or the acellular dermal matrix secondary to a complication). Studies were included only if they reported the number of complications based on the number of reconstructed breasts performed.

The included study designs were cohort studies or non-cohort studies. The mean age of patients in included studies ranged from 44.5 to 58 years; their mean body mass index ranged from 23.8 to 29.8 (where reported).

Two reviewers independently assessed studies for inclusion, with any disagreement resolved by discussion.

Assessment of study quality
The quality of evidence for outcomes was assessed using the GRADE criteria based on study design, limitations, consistency and directness of the evidence.

The authors did not state how many reviewers performed quality assessment.

Data extraction
Data on event rates were extracted. Where data were provided for both acellular dermal matrix groups and non-acellular dermal matrix groups, odds ratios and 95% confidence intervals were calculated.

The authors did not state how many reviewers performed data extraction.

Methods of synthesis
The studies were combined in a meta-analysis. The pooled odds ratios and 95% confidence intervals were calculated in a random-effects model. Statistical heterogeneity was assessed using $I^2$. Sensitivity analyses for some outcomes (infection, reconstructive failure and skin flap necrosis) were used to investigate the potential sources of heterogeneity. Publication bias was assessed using funnel plots and the Egger's and Begg's tests.

Results of the review
Sixteen studies were included in the review (4,876 breast reconstructions). All were retrospective studies, including five...
cohort studies and 11 non-cohort studies. The quality of evidence for all outcomes was graded as low. The mean length follow-up in most studies ranged from 10 to 25 months (where reported); in two studies the mean length follow-up ranged from 203 to 238 days.

The pooled complication rate of acellular dermal matrix-assisted breast reconstruction was 10.9% (95% CI 8.7 to 13.5) for skin flap necrosis, 6.9% (95% CI 5.3 to 8.8) for seroma, 5.7% (95% CI 4.3% to 7.3%) for infection, 2.0% (95% CI 1.2 to 3.1) for cellulitis, 1.3% (95% CI 0.6 to 2.4) for haematoma, 0.6% (95% CI 0.1% to 1.7%) for capsular contracture, and 5.1% (95% CI 3.8 to 6.7) for reconstructive failure.

Traditional prosthetic-based breast reconstructions using traditional musculofascial flaps, acellular dermal matrix-assisted breast reconstructions were associated with a higher risk of seroma (OR 3.9, 95% CI 2.4 to 6.2; four studies), infection (OR 2.7, 95% CI 1.1 to 6.4; five studies), and reconstructive failure (OR 3.0, 95% CI 1.3 to 6.8; five studies). No significant differences were found between the two groups for outcomes of haematoma, cellulitis and skin flap necrosis. Significant heterogeneity was observed in the pooled outcomes of infection (Ι²=62.4%), reconstructive failure (Ι²=57.9%), and skin flap necrosis (Ι²=79.2%).

Sensitivity analyses showed that one study was an outlier; after excluding this study from the analysis, there was no statistical heterogeneity in the pooled outcomes of infection and reconstructive failure, but other results were not significantly altered. Sensitivity analyses also showed that, when excluding an outlier study, acellular dermal matrix-assisted breast reconstructions were significantly associated with a higher risk of skin flap necrosis compared with traditional prosthetic-based breast reconstructions, but there was no statistical heterogeneity on the outcome.

There was no evidence of publication bias.

Authors' conclusions
Acellular dermal matrix-assisted breast reconstructions were associated with a higher risk of seroma, infection and reconstructive failure compared with prosthetic-based breast reconstructions using traditional musculofascial flaps. Acellular dermal matrix assisted breast reconstructions were associated with a lower rate of capsular contracture.

CRD commentary
The review question and inclusion criteria were clear. Relevant databases were searched. Efforts were made to find published studies but not for unpublished studies, which increased the potential for publication bias. Publication bias was assessed and little of evidence was found, although the investigation of publication bias using statistical tests in a small number of studies may be not reliable. Only studies in English were included, which may have increased the risk of language bias. Attempts were made to minimise the reviewer errors and biases during study selection, but it was unclear whether data extraction and quality assessment were also performed in duplicate.

Appropriate criteria were used to assess the overall quality of evidence for outcomes, although study design-related criteria may have also been useful for the assessment of quality of individual studies. Appropriate methods were used to pool the results. Statistical heterogeneity was assessed and, where necessary, heterogeneity was explored in a sensitivity analysis.

The authors' conclusions should be interpreted with caution given the potential for language bias and low quality of evidence identified.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further randomised controlled trials were required to assess the safety and efficacy of acellular dermal matrix-assisted breast reconstructions.

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