

Living FRIendly Summaries of the Body of Evidence Using Epistemonikos (FRISBEE)

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Do textured breast implants decrease the rate of capsular contracture compared to smooth implants?

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Abstract

The use of breast implants for aesthetic and reconstructive purposes has become one of the most common procedures performed by plastic surgeons. Several breast implants models exist. They differ in their size, filling, shape and characteristic of the shell, which can be smooth or textured. Capsular contracture is one of the main complications of breast implants. It has been suggested that the use of textured implants could reduce the incidence of capsular contracture. To answer this question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We identified 15 studies overall, of which 13 were randomized trials relevant for the question of interest. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach. We concluded the use of textured breast implants probably decreases the risk of capsular contracture, however, they might be associated to an increased risk of anaplastic large cell lymphoma.

Problem

The use of breast implants for aesthetic and reconstructive purposes has become one of the main performed procedures by plastic surgeons. According to statistics presented by the International Society of Aesthetic Plastic Surgeons, 1.3 million breast implants were implanted during the year 2015 [1]. Capsular contracture, which is a contractile deformation of the periprosthetic capsule, is one of the main complications of breast implants. Its estimated incidence is 7.6% per implant [2] and is responsible of up to 30% of revision surgeries [3]. Although its etiology is not fully elucidated, it appears to be a multifactorial process [4].

Several risk factors have been implicated, such as the presence of postoperative hematoma, the implant site, the access incision and the type of surgery (aesthetic versus reconstructive). Implant risk factors such as the type of filling (silicone versus saline) and the shell texture (smooth versus textured) have also been described [2],[5]. The main studies evaluating the role of breast implant texture have not been conclusive, [6],[7] so there is still controversy.

Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is

maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information we generated a structured

summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

Key messages

- The use of textured breast implants probably reduces the risk of capsular contracture.
- The use of textured breast implants might be associated to an increased risk of anaplastic large cell lymphoma, but the certainty if this evidence is low.

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found five systematic reviews [8],[9],[10],[11],[12] which together include a total of 15 primary studies reported in 18 references [6],[7],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22],[23],[24],[25],[26],[27],[28]. Of these, 13 correspond to randomized controlled trials relevant to the clinical question [6],[7],[14],[15],[16],[17],[18],[20],[21],[23],[25],[26],[27]. The information presented in this table and summary refer to the latter studies.</p>
<p>What types of patients were included*</p>	<p>All trials included patients who received breast implants with a silicone elastomer envelope. Eight trials included patients with breast augmentation [6],[7],[14],[15],[16],[18],[20],[27], three trials with previous mastectomy [21],[23],[25], one with both etiologies [17], and one trial with no clear etiology [26].</p> <p>Seven trials included silicone filled implants [14],[18],[20],[21],[25],[26],[27] while four included patients with saline implants alone [7],[15],[16],[23]. One trial used both implants [17].</p> <p>The implant site also differed between trials. In nine, the implant placement site was subcutaneous [6],[7],[15],[18],[20],[26],[27] whereas in one it was retromuscular [14], and in three it was not specified [21],[23],[25]. Two trials included patients with periareolar incisions [15],[16], two with inframammary incisions [6], and [14] three with transaxillary approach [17],[26],[27]. In three trials the incision previously made for the mastectomy was utilized [21],[23],[25] and in three others no information was provided regarding the approach site [7],[18],[20].</p> <p>In five trials the follow-up was up to one year [14],[15],[17],[18],[23] and in four up to 2 years [16],[25],[26],[27]. In the four remaining trials, follow-up was 3, 5, 7.5 and 10 years respectively [6],[18],[20],[21]. In only four trials, the follow-up rate was 100% [7],[23],[25],[26]</p>
<p>What types of interventions were included*</p>	<p>In the 13 evaluated trials smooth implants were compared to textured implants. In five, the breast side was randomized to receive each type of implant [6],[7],[15],[16],[20], whereas in one trial the patient was randomized [18]. No further information could be obtained from the other trials.</p>
<p>What types of outcomes were measured</p>	<p>The following outcomes were measured:</p> <ul style="list-style-type: none"> • Capsular contracture: by clinical diagnosis using the Baker scale or the BAC (Breast augmented Scale) scale, or by tonometry. Capsular contracture was considered as Baker II / IV and BAC III / IV. • Perception of the patients regarding the type of implants. <p>The median follow-up time, considering all the trials was 2 years (range 1 to 10 years).</p>

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

Summary of findings

The effect of textured implants on the risk of capsular contracture is based on 13 randomized trials involving a total of 2302 breast implants (1255 smooth and 1047 textured) [6],[7],[14],[15],[16],[17],[18],[20],[21],[23],[25],[26],[27]. Data on the risk of long-term adverse effects comes from case reports [28],[29].

The summary of findings is as follows:

- The use of textured breast implants probably reduces the risk of capsular contracture. The certainty of the evidence is moderate.
- The use of textured breast implants might be associated to an increased risk of anaplastic large cell lymphoma, but the certainty if this evidence is low

Textured versus smooth breast implants				
Patients		Women with indication of aesthetic breast implant or postmastectomy		
Intervention		Textured breast implants		
Comparison		Smooth breast implants		
Outcome	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITH Smooth implants	WITH Textured implants		
	Difference: patients per 1000			
Capsule contracture	124 per 1000	59 per 1000	RR 0.41 (0.31 to 0.54)	⊕⊕⊕○ ¹ Moderate
	Difference: 65 implants less per 1000. (Margin of error: 40 to 90 less)			
Long-term adverse effects	Of 258 cases of breast implant associated anaplastic large cell lymphoma, the implant surface was reported to be textured in 129, in contrast to 11 cases in smooth surface implants.		--	⊕⊕○○ ² Low

RR= Risk ratio.
Margin of error = 95% confidence interval (CI).
GRADE: evidence grades of the GRADE Working Group (see later in this article)

* The risk **WITH smooth implant** is based on the risk in the control group of the trials. The risk **WITH textures implant** (and its margin of error) is calculated from relative effect (and its margin of error).

¹ The certainty of the evidence was downgraded in one level because the two trials with highest weight in the meta-analysis had high risk of bias.

² The evidence comes from observational studies with important limitations. However, the certainty of the evidence was increased in one level by the magnitude of the association, since from the 258 cases reported, 50% have been in textured implants and 4.2% in smooth implants.

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision.

Other considerations for decision-making

To whom this evidence does and does not apply

- The evidence presented in this summary applies to women who undergo breast augmentation or breast reconstruction with silicone or saline implants.
-

About the outcomes included in this summary

- The outcomes selected in the summary of findings table correspond to those critical for the decision-making, according to the opinion of the authors of this summary.
 - Other outcomes of surgery such as infection and hematoma were not sufficiently documented in the systematic reviews, despite having some relevance as risk factors for capsular contracture according to observational studies [2].
-

Balance between benefits and risks, and certainty of the evidence

- According to the results summarized in this paper, there is a positive balance with respect to the use of textured implants, regarding capsular contracture.
 - However, cases of anaplastic large cell lymphoma have recently been reported in relation to the appearance of late seroma or in relation to the periprosthetic capsule of textured implants [28],[29].
 - The limitations on the certainty of the evidence do not allow an adequate balance between benefits and risks.
-

Resource considerations

- There are no substantial differences in the costs of textured implants and smooth implants.
 - Uncertainty about serious adverse effects does not allow an adequate balance between cost and benefit.
-

What would patients and their doctors think about this intervention

- A great variability in the decision-making is expected. Although there is a lower risk of capsular contracture associated with textured implants, and no additional expenses should be made, a possible association of these with anaplastic large cell lymphoma may limit its usage.
 - Regarding the preference of the patient, in four trials [6],[7],[15],[16] considering 138 patients, they were asked which side they preferred (blinded to the implant received on each side). One third had no preference, one third favored the side of the smooth implant and one third the textured implant [9].
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Differences between this summary and other sources

- The conclusions of this summary agree with the existing systematic reviews.
 - So far, there are no clinical guidelines that suggest the use of the textured implant over the smooth.
-

Could this evidence change in the future?

- The probability that the conclusion regarding the risk of capsular contracture changes in the future is low, due to the certainty of the existing evidence. However, the association of textured implants and anaplastic large cell lymphoma is not well defined yet.
 - The WHO platform was consulted for possible ongoing studies. No additional studies were retrieved.
-

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.

	Collis N, .. 1991	Fagrell D 2001	Tarpila E 1997	Burkhardt BR 1994	Burkhardt BR 1995	Asplund O 1996	Thuesen B 1995	Hakelius L 1992	May JW 1994	Stevens WG 2013	Pollock H 1993
	x	x	x	x	x	x	x	x	x	x	x
Liu X 2015											
Wong CH 2008	x										
Barnsley GP 2006	x										
Ma SL 2008	x										
Rocco, Nicola 2016	x										

Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The *rows* represent systematic reviews that share at least one primary study, and *columns* display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version**: [Textured versus smooth implant in patients with breast augmentation and reconstruction](#)

Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrices and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here <http://dx.doi.org/10.5867/medwave.2014.06.5997>.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-

makers with technology. Its main development is Epistemonikos database (www.epistemonikos.org). These summaries follow a rigorous process of internal peer review.

Conflicts of interest

The authors do not have relevant interests to declare.

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