

CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Breast Implants: Comparative Clinical Effectiveness

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Research Question

What is the comparative clinical effectiveness of one type of breast implant when compared to another type of breast implant?

Key Findings

Two systematic reviews, one meta-analysis, and two randomized controlled trials were identified regarding the comparative clinical effectiveness of one type of breast implant when compared to another type of breast implant.

Methods

A limited literature search was conducted on key resources including Medline, the Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. A focused search for health technology assessments, systematic reviews, meta-analyses, and randomized controlled trials was conducted. For this search, main concepts appeared in title, abstract, or major subject heading and health technology assessments, systematic reviews, meta-analyses, and randomized controlled trials filters were applied. The search was limited to English language documents published between January 1, 2013 and July 17, 2018. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients requiring breast implants
Intervention	Breast implants and expanders (e.g., Natrelle, Mentor)
Comparator	Another type of breast implant and expander
Outcomes	Clinical effectiveness (benefit/harm), safety, post-operation infection rates
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials.

Two systematic reviews, one meta-analysis, and two randomized controlled trials were identified regarding the comparative clinical effectiveness of one type of breast implant when compared to another type of breast implant. No relevant health technology assessments were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

The authors of one systematic review (SR)¹ evaluated the comparative effectiveness of polyurethane-coated versus textured silicone implants. Eighteen studies were included. For primary reconstruction, the reported capsular contracture rates at six years were 10% to 15% for textured silicone implants and 1.8% to 3.4% for polyurethane implants.¹ For primary augmentation, the reported rates of capsular contracture at six years were 2% to 15% for textured silicone implants and 0.4% to 1% for polyurethane implants. The authors of the review recommended the results for the polyurethane implants be interpreted with some caution due to the design of the studies and the poor patient follow-up reported.¹

The authors of a Cochrane SR² compared different types of breast implants for reconstructive breast surgery. The comparisons examined included: implant envelope surfaces, implant filler material, implant shape, implant volume, brands, and implant generation.² Five randomized controlled trials (202 participants) were included in the descriptive analysis.² Textured implants were associated with worse capsular contracture and more reintervention than smooth implants but the differences were not statistically significant.² Saline implants resulted in less severe capsular contracture than silicone implants and increased patient satisfaction but reintervention was significantly more frequent with saline implants.² Capsular contracture, reintervention, and short-term complications were more common with anatomical implants when compared with round implants but the differences were not statistically significant.² Fixed-volume implants for reconstruction were possibly associated with more women reporting that the results of their reconstruction met their expectations and resulted in fewer reinterventions when compared with variable-volume implants.² There were no studies identified that compared different implant brands or different implant generations.

The authors of one cumulative meta-analysis³ reported the incidence rate of capsular contracture among textured or smooth surface implants. Sixteen RCTs and two retrospective studies were included in the analysis. The results indicated the association with capsular contracture was higher for smooth implants than for textured implants.³

Two RCTs^{4,5} were identified comparing the use of carbon dioxide-based tissue expansion with saline tissue expansion for two-stage breast reconstruction. In the carbon dioxide group, patients were responsible for increasing the volume of the expanders by 10cc increments up to 30 ccs per day. Patients in the saline group had their expanders filled by a physician. The treatment success rate was 96.1% for carbon dioxide and 98.8% for saline.⁴ The rate of overall complications was similar between groups.^{4,5} The authors concluded

that the carbon dioxide-based expander was effective, safe, and more convenient for patients.^{4,5}

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

1. Duxbury PJ, Harvey JR. Systematic review of the effectiveness of polyurethane-coated compared with textured silicone implants in breast surgery. *J Plast Reconstr Aesthet Surg*. 2016 Apr;69(4):452-460.
[PubMed: PM26887685](#)
2. Rocco N, Rispoli C, Moja L, et al. Different types of implants for reconstructive breast surgery. *Cochrane Database Syst Rev*. 2016 May 16(5):CD010895.
[PubMed: PM27182693](#)
3. Liu X, Zhou L, Pan F, Gao Y, Yuan X, Fan D. Comparison of the postoperative incidence rate of capsular contracture among different breast implants: a cumulative meta-analysis. *PLoS ONE*. 2015;10(2):e0116071.
[PubMed: PM25680100](#)

Randomized Controlled Trials

4. Ascherman JA, Zeidler K, Morrison KA, et al. Carbon dioxide-based versus saline tissue expansion for breast reconstruction: results of the XPAND prospective, randomized clinical trial. *Plast Reconstr Surg*. 2016 Dec;138(6):1161-1170.
[PubMed: PM27879582](#)
5. Zeidler KR, Berkowitz RL, Chun YS, et al. AeroForm patient controlled tissue expansion and saline tissue expansion for breast reconstruction: a randomized controlled trial. *Ann Plast Surg*. 2014 May;72 Suppl 1:S51-55.
[PubMed: PM24740025](#)

Appendix — Further Information

Previous CADTH Reports

6. Patient-controlled carbon dioxide tissue expansion for breast reconstruction. (*CADTH issues in emerging health technologies no. 162*). Ottawa (ON): CADTH; 2017: <https://www.cadth.ca/dv/ieht/patient-controlled-carbon-dioxide-tissue-expansion-breast-reconstruction>. Accessed 2018 Jul 23.

Randomized Controlled Trials – Alternative Outcomes

7. Hidalgo DA, Weinstein AL. Intraoperative comparison of anatomical versus round implants in breast augmentation: a randomized controlled trial. *Plast Reconstr Surg*. 2017 Mar;139(3):587-596. [PubMed: PM28234826](#)

Non-Randomized Studies

8. Danino MA, Efanov JI, Dimitropoulos G, et al. Capsular biofilm formation at the interface of textured expanders and human acellular dermal matrix: a comparative scanning electron microscopy study. *Plast Reconstr Surg*. 2018 Apr;141(4):919-928. [PubMed: PM29257002](#)
9. Singh N, Picha GJ, Murphy DK. Natrelle silicone breast implant follow-up study: demographics, lifestyle, and surgical characteristics of more than 50,000 augmentation subjects. *Plast Reconstr Surg*. 2016 Jan;137(1):70-81. [PubMed: PM26710009](#)
10. Bodin F, Jung C, Dieval F, et al. Aging of retrieved gel breast implants: a comparison between two product generations. *J Mech Behav Biomed Mater*. 2015;46:11-22. [PubMed: PM25746931](#)

Doren EL, Pierpont YN, Shivers SC, Berger LH. Comparison of Allergan, Mentor, and Sientra contoured cohesive gel breast implants: a single surgeon's 10-year experience. *Plast Reconstr Surg*. 2015;136(5):957-966. [PubMed: PM26505700](#)

11. Caplin DA. Indications for the use of MemoryShape breast implants in aesthetic and reconstructive breast surgery: long-term clinical outcomes of shaped versus round silicone breast implants. *Plast Reconstr Surg*. 2014 Sep;134(3 Suppl):27S-37S. [PubMed: PM25158767](#)

Review Articles

12. Labadie JG, Korta DZ, Barton N, Mesinkovska NA. Cutaneous hypersensitivity-like reactions associated with breast implants: a review. *Dermatol Surg*. 2018 Mar;44(3):323-329. [PubMed: PM29293108](#)
13. Cifuentes I, Dagnino B, Rada G. Do textured breast implants decrease the rate of capsular contracture compared to smooth implants? *Medwave*. 2017 Aug 31;17(7):e7020. [PubMed: PM28863131](#)

14. Zele DV, Heymans O. Breast implants a review. *Acta Chir Belg.* 2016;104(2):158-165.
<https://doi.org/10.1080/00015458.2004.11679528>.
15. Henderson PW, Nash D, Laskowski M, Grant RT. Objective comparison of commercially available breast implant devices. *Aesthetic Plast Surg.* 2015;39(5):724-732.
[PubMed: PM26206500](#)

Protocols

16. Wang C, Luan J, Panayi AC, Orgill DP, Xin M. Complications in breast augmentation with textured versus smooth breast implants: a systematic review protocol. *BMJ Open.* 2018 Apr 10;8(4):e020671.
[PubMed: PM29643164](#)