Breast Implants: Comparative Clinical Effectiveness
Authors: Michelle Clark, Kaitryn Campbell, Aleksandra Grobelna


Acknowledgments:

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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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

<table>
<thead>
<tr>
<th>Population</th>
<th>Patients requiring breast implants</th>
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<tr>
<td>Intervention</td>
<td>Breast implants and expanders (e.g., Natrelle, Mentor)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Another type of breast implant and expander</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Clinical effectiveness (benefit/harm), safety, post-operation infection rates</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials</td>
</tr>
</tbody>
</table>
**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 SR\(^2\) 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-analysis\(^3\) 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**


**Randomized Controlled Trials**


Appendix — Further Information

Previous CADTH Reports

Randomized Controlled Trials – Alternative Outcomes

Non-Randomized Studies


Review Articles


**Protocols**