

[illegible]

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	Hemato ma														
6	ST –	V	-	-	-	6	94%	No	-	-	-	-	-	-	Yes
	Implant loss	F	-	-	-	6	100%	No	-	-	-	-	-	-	
R9ai i	Reoperation due to complications (augmentation – LT)														
1	LT -	V	-	-	-	6	88%	No	-	-	-	-	-	-	Yes
	Infection	F	-	-	-	6	94%	No	-	-	-	-	-	-	
2	LT – CC	V	-	-	-	5	82%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	94%	No	-	-	-	-	-	-	
3	LT –	V	-	-	-	6	100%	No	-	-	-	-	-	-	Yes
	Malposit ion/displ acement	F	-	-	-	6	100%	No	-	-	-	-	-	-	

4	LT – Rupture/ deflation	V	-	-	-	6	94%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	94%	No	-	-	-	-	-	-	
5	LT – Seroma/ Hemato ma	V	-	-	-	6	88%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	88%	No	-	-	-	-	-	-	
6	LT – Implant loss	V	-	-	-	6	94%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	100%	No	-	-	-	-	-	-	
R9bi	Reoperation due to complications (reconstruction – ST)														
1	ST - Infection	V	-	-	-	6	100%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	94%	No	-	-	-	-	-	-	
2	ST – CC	V	-	-	-	5	65%	No	2	94%	No	-	-	-	
		F	-	-	-	6	69%	No	2	75%	No	-	-	-	

1	LT - Infection	V	-	-	-	5	76%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	88%	No	-	-	-	-	-	-	
2	LT – CC	V	-	-	-	5	76%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	88%	No	-	-	-	-	-	-	
3	LT – Malposit ion/displ acement	V	-	-	-	6	88%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	88%	No	-	-	-	-	-	-	
4	LT – Rupture/ deflation	V	-	-	-	6	82%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	88%	No	-	-	-	-	-	-	
5	LT – Seroma/ Hemato ma	V	-	-	-	5	82%	No	-	-	-	-	-	-	Yes
		F	-	-	-	6	88%	No	-	-	-	-	-	-	
6		V	-	-	-	6	88%	No	-	-	-	-	-	-	Yes

	LT – Implant loss	F	-	-	-	6	100%	No	-	-	-	-	-	-	
R10	Patient reported outcome measure	V	6	82%	No	6	88%	No	-	-	-	-	-	-	Yes
		F	5	71%	No	-	-	-	-	-	-	-	-	-	
R11	Volume of surgical activity	V	5	53%	No	3	41%	Yes	2	94%	No	-	-	-	
		F	6	76%	No	-	-	-	-	-	-	-	-	-	

Note: R refers to relabelled indicator numbers, ^ is % of panellists who scored 5 or 6 (agree), * is % panellists who scored 1 or 2 (disagree), # is disagreement score measured by IPRAS (Inter-Percentile Range Adjusted for Symmetry), where no disagreement is indicated by a score of less than 1, and disagreement is indicated by a score of more than 1, “-” is when it was not voted on in a particular round. Abbreviations: CC is capsular contracture, ST is short-term, LT is long-term.

SUPPLEMENTARY METHODS

The following 12 study types were identified and included in the literature search:

- 1) Controlled clinical trials
- 2) Randomised controlled trials
- 3) Cohort studies (prospective and retrospective)
- 4) Case-control studies
- 5) Cross-sectional studies
- 6) Observational studies
- 7) Retrospective studies
- 8) Longitudinal studies
- 9) Implant registres
- 10) Meta-analyses
- 11) Multi-centre studies
- 12) Systematic review

The type of studies above involving the following keywords were used across Ovid MEDLINE, Ovid EMBASE, and Ovid Cochrane Central Register of Controlled Trials: breast implants/ implantation/ mammoplasty/ augmentation/ reconstruction.

Search Strategy (Ovid MEDLINE resulting in 1727 searches):

Search date: 8th February 2017

#1 Search Breast Implants [MESH]

#2 Search Breast Implantation [MESH]

#3 Search Mammaplasty [MESH]

#4 Search breast implant*.mp. [Title or abstract]

#5 Search mamm?plast*.mp. [Title or abstract, includes mamma/mammo]

#6 Search breast augment*.mp. [Title or abstract]

#7 Search breast reconstruct*.mp. [Title or abstract]

#8 Search (breast* adj2 silicon*).mp. [Title or abstract]

#9 Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

#10 Limit #9 to (controlled clinical trial or randomised controlled trial)

#11 Search case-control studies/ OR cohort studies/ OR longitudinal studies/ OR prospective studies/ OR cross-sectional studies/ [Search each one separately, then combine all with OR function]

#12 Search observational study/ OR meta-analyses/ OR multi-centre study/

#13 Search systematic review*.mp.

#14 Search (implant* adj5 (registry or registries*)).mp.

#15 Search #10 OR #11 OR #12 OR #13 OR #14

#16 Search #9 AND #15

#17 Limit #16 to (English language and yr="1995-Current")

Search Strategy (Ovid EMBASE resulting in 2307 searches):

#1 Search breast Implant [MESH]

#2 Search breast augmentation [MESH]

#3 Search breast reconstruction [MESH]

#4 Search silicone breast implant [MESH]

#5 Search breast implant*.mp. [Title or abstract]

#6 Search mamm?plast*.mp. [Title or abstract, includes mamma/mammo]

#7 Search breast augment*.mp. [Title or abstract]

#8 Search breast reconstruct*.mp. [Title or abstract]

#9 Search (breast* adj2 silicon*).mp. [Title or abstract]

#10 Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9

#11 Limit #9 to (controlled clinical trial or randomised controlled trial)

#12 Search (randomi?ed controlled OR RCT OR randomly allocated OR allocated randomly OR random allocation OR (allocated adj2 random) OR (single adj1 blind*) OR (double adj1 blind*) OR ((treble OR triple) adj1 blind*) OR placebo*).tw.

#13 Search case-control study/ OR longitudinal study/ OR prospective study/ OR observational study/ OR cohort analysis/ [single line command]

#14 Search (cross sectional adj (study or studies)).tw.

#15 (implant* adj5 (registry or registries*)).mp.

#16 Search #11 OR #12 OR #13 OR #14 OR #15

#17 Search #10 AND #16

#18 Limit #17 to (English language and yr="1995-Current")

Search Strategy (EBM Reviews – Cochrane Central Register of Controlled Trials resulting in 361 searches):

#1 Search Breast Implants [MESH]

#2 Search Breast Implantation [MESH]

#3 Search Mammoplasty [MESH]

#4 Search breast implant*.mp. [Title or abstract]

#5 Search mamm?plast*.mp. [Title or abstract, includes mamma/mammo]

#6 Search breast augment*.mp. [Title or abstract]

#7 Search breast reconstruct*.mp. [Title or abstract]

#8 Search (breast* adj2 silicon*).mp. [Title or abstract]

#9 Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

#10 Search (implant* adj5 (registry or registries*)).mp

#11 Limit #10 to (yr="1995-Current" and English language)

Total from 3 databases = 1727 + 2307 + 361 = 4395 articles. After de-duplication = 2939 articles.

Hand-searched articles = 43 articles

Final total of abstracts reviewed = 2982 abstracts

Eligibility criteria for abstracts and full articles

A complete list of the exclusion criteria used in this study is as follows: articles without an abstract; articles focusing on reduction mammoplasty and breast reduction surgeries; retrospective studies (unless limited or absence of evidence from other studies); articles focusing on breast cancer (unless it includes reconstruction); articles that focused on indications for breast reconstruction including giant fibroadenoma (GFA); study groups involving autologous breast augmentation on its own or autologous breast augmentation after explantation; articles that focus solely on breast mastectomy (unless followed up with tissue expander and/or reconstruction), articles focusing on breast quadrantectomy and breast-conserving surgery (BCS); studies with less than 50 patients; articles that focused on outcomes that include type of pathogenic infections due to breast surgery (unless they related to the implant), connective tissue disease or rheumatic diseases (as they have been proven to not be linked to breast implants); studies that focus on types of anaesthesia used in breast surgery and drug/medication induced breast enlargement; studies that were on causes of

augmentation; studies that focused on the additional use of acellular dermal matrix (ADMs) (because it may act as a confounding factor for adverse events and outcomes); any articles (hand-searched literature inclusive) published before 01st Jan 1995; studies linked to anaplastic large cell lymphoma (ALCL); studies related to patient preference as reported outcomes related to revision surgery, and in-vivo and in-vitro studies performed on cells and animals.