Breast reconstruction: differences in outcome between two types of breast implants?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29142

Source
Nationaal Trial Register

Brief title
TIPI Trail

Health condition

Breast reconstruction; breast implants; capsular contracture

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: POLYTECH Health & Aesthetics B.V.

Intervention

Outcome measures

Primary outcome

capsular contracture rate

Secondary outcome

revision surgery rates, complication rates, patient satisfaction and quality of life, user friendliness

Study description

Study objective

Two-stage implant-based breast reconstruction is the most common reconstructive technique after mastectomy. It is associated with some implant specific complications such as capsular contracture. Capsular contracture is one of the most frequent long-term complications which develops when the capsule surrounding the implant, which always develops as a result of a normal foreign body reaction, becomes constricted and tight, resulting in malposition of the implant, a firm and/or painful breast and deterioration of the aesthetic result, which may require reoperation. On average one out of every six implant breast reconstruction patients will develop a capsular contracture after 10 years. Much of the etiology is still unknown, but a relationship between the outer surface of the implant and the chance of developing capsular contracture has been suggested . For example, compared to smooth implants, textured implants have shown to result in lower capsular contracture rates. Based on the current literature, which comprises of retrospective cohort studies and case-series, we hypothesize that polyurethane-covered implants reduce or delay the development of capsular contracture compared to textured implants.

Study design

Surgery - 2 weeks post-op - 6 months post-op - yearly from 1 year post-op until 10 years post-op.

Intervention

Patients in both cohorts will receive a two-stage implant-based breast reconstruction after mastectomy. In the second stage, the intervention cohort will receive a polyurethane covered silicone implant and the control cohort will receive a standard textured silicone implant.

Contacts

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Eligibility criteria

Inclusion criteria

• Female

• Age of 18 years or older

• Mastectomy is performed

• Eligible for two-stage implant-based breast reconstruction in accordance with the Dutch national breast reconstruction guideline

• First step of two-stage implant-based breast reconstruction (placement of tissue expander) is successfully completed

• Able to understand the patient information sheet, to complete questionnaires and to provide written informed consent

Exclusion criteria

• Additional use of autologous tissues for the breast reconstruction

• The use of acellular dermal matrix or synthetic mesh

• Prior irradiation of the breast or an indication for postoperative radiotherapy

• Revision surgery or tertiary breast reconstruction

• Inflammatory carcinoma

• Evidence of distant metastases

• Active infection at the surgical field or distant locations

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-02-2019
Enrollment:	321
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7067
NTR-old	NTR7265
Other	63959 : ABR

Study results