Long-term results of two-stage breast reconstruction with polyurethane-covered versus textured implants: a prospective, multicenter randomized controlled trial

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Primary Objective: to determine whether polyurethane covered silicone implants (PCI) give a different capsular contracture rate than textured silicone implants (TI) in two-stage implant breast reconstruction after mastectomy in women.Secondary...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50674

Source
ToetsingOnline

Brief title
TIPI TRAIL: Textured Implants versus Polyurethane-covered Implants

Condition

- Breast therapeutic procedures

Synonym
breast implant hardening, capsular contracture, capsule contracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: POLYTECH Health & Aesthetics B.V.,POLYTECH Health & Aesthetics GmbH

Intervention

Keyword: Breast Implants, Capsular Contracture, Long Term Adverse Effects, Mammaplasty

Outcome measures

Primary outcome

The primary outcome is capsular contracture. This is a clinical diagnosis classified in the modified Baker classification, which allows for correct interpretation of capsular contracture in a reconstructed breast. Baker grade 3 or 4 capsular contractures are considered clinically relevant. A breast with a grade 3 contracture feels and looks moderately firm, but this firmness is still compatible with an acceptable outcome, although the patient may be dissatisfied. Reoperation is not necessarily required. Grade 4 represents an excessively firm reconstructed breast, resulting in a poor aesthetic result and/or significant patient symptoms such as pain. Surgical intervention is required.

Secondary outcome

- Other complications: e.g. cutaneous rash, hematoma, seroma, infection, skin necrosis, implant rupture, malposition, exposure, and visibility/palpability. Also, explantation is registered together with its indication.

- Quality of life and patient satisfaction

- Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

- User-friendliness of PCI*s

Study description

Background summary

Two-step implant-based breast reconstruction is a common reconstructive technique after mastectomy. It is associated with some implant specific complications. Capsular contracture is a complication which develops when internal scar tissue forms a tight or constricting capsule around a breast implant, contracting it until it becomes misshapen and hard. As a result, the breast may feel painful and stiff, and the capsule may affect the appearance or shape of the breast. On average one out of every six patients has developed a capsular contracture after 10 years. Much of the etiology is still unknown, but there are indications which suggest influence of the outer surface of the implant. Compared to smooth implants, textured implants show lower capsular contracture rates. Based on the current literature we hypothesize that polyurethane-covered implants reduce or delay the development of capsular contracture compared to textured implants.

Study objective

Primary Objective: to determine whether polyurethane covered silicone implants (PCI) give a different capsular contracture rate than textured silicone implants (TI) in two-stage implant breast reconstruction after mastectomy in women.

Secondary Objectives: to compare revision surgery rate, complication rates, patient satisfaction, user friendliness and long-term patient safety between PCI*s and TI*s.

Study design

Multicenter, prospective, open-label, randomized controlled trial

Intervention

Patients in both cohorts will receive a two-step implant-based breast reconstruction after mastectomy. In the second step of the breast reconstruction procedure a definite implant is placed. These will differ for the cohorts: our intervention cohort will receive a polyurethane covered implant and the control cohort will receive a standard textured implant.

Study burden and risks

The is no definite proof in the current literature whether polyurethane covered implants reduce the risk of capsular contracture in our study population. We hypothesize that polyurethane covered implants have a lower capsular contracture rate. Patients in the intervention cohort might benefit with a lower risk of capsular contracture or delayed development of capsular contracture. However, this is no certainty.

There are no known additional risks with using polyurethane covered implants for breast reconstruction. The burden of this study for the participants comprises of the screening consultation and three extra outpatient clinic visits and the requirement to fill out three questionnaires at seven moments during the course of this study. These are health surveys. We believe this is proportional to the academic worth of the study results.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

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 (If a patient receives radiotherapy unexpectedly at a later point in time, she will be excluded retroactively)
• Secondary reconstruction
• Revision surgery of a previous 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
Primary purpose:	Treatment

Recruitment

NL

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

Medical products/devices used

Generic name:	Breast implant: Polytech Sublime Line® with Microthane® surface
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-09-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-09-2020

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL63959.078.18