3D symmetry determination for improvement of autologous breast reconstruction

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26745

Source
NTR

Brief title
TBA

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Medisch Spectrum Twente en Ziekenhuisgroep Twente
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Developing a valid clinical applicable method for symmetry determination of the breasts pre- and postoperative

Secondary outcome

Insight in the symmetrie change pre- and postoperative, satisfaction of the patient correlating to the symmetry determination, insight in the different parts of the DIEP flap procedure

Study description

Background summary

Pre- and postoperative 3D images will be taken of DIEP flap reconstruction patients. The 3D images will be used as surgery preparation and monitoring of the patients after surgery. In this study, the symmetry of the breasts will be investigated. The 3D images will be used to develop a valid method for symmetry analysis. The participants have to be fill in the Breast-Q questionnaire for clinical validation. During surgery, the duration of different parts of the surgery will be monitored. With this study, the aim is to obtain more insight in the DIEP flap procedure.

Study objective

Better symmetry corresponds with a higher satisfaction of the breasts

Study design

preoperative and two times postoperative

Contacts

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Eligibility criteria

Inclusion criteria

Women 18+, suitable for a DIEP flap surgery, signed informed consent

Exclusion criteria

Smoking or nicotine supplements, BMI => 30

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-04-2021
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	NL9421
Other	MEC-U : W21.031

Study results