

Aesthetic satisfaction after direct reconstruction with the Deep Inferior Epigastric Perforator flap procedure .

Published: 18-01-2008

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The aim of this study is to evaluate patients and surgeons aesthetic satisfaction and to assess the impact on self-esteem with immediate breast reconstruction using DIEP- flap procedure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON31573

Source

ToetsingOnline

Brief title

Satisfaction after DIEP-flap reconstruction.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym

breast reconstruction, plastic surgery

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer surgery, DIEP- flap reconstruction, patient satisfaction

Outcome measures

Primary outcome

Aesthetic satisfaction

Self-esteem

Secondary outcome

Discrepancy between aesthetic satisfaction of the patient, the surgeon and the plastic surgeon after direct reconstruction with the DIEP-flap procedure.

Study description

Background summary

Sometimes women, with breast cancer, have to make difficult choices about treatment options, breast conserving surgery or mastectomy, with or without reconstruction, immediate or delayed. For those undergoing mastectomy, immediate reconstruction may offer significant quality-of-life benefits and often constitutes a vital option for breast cancer recovery. Immediate breast reconstruction with autologous tissue has become the preferred method of breast reconstruction over the last few years. The Deep Inferior Epigastric Perforator (DIEP) free flap spares the whole rectus abdominis muscle, includes skin and fat only, and therefore, preserves adequate abdominal wall competence. A (reconstructive) surgeon or breast care nurse is responsible for supplying the patient with adequate information about her options to allow her to make an informed decision.

Study objective

The aim of this study is to evaluate patients and surgeons aesthetic satisfaction and to assess the impact on self-esteem with immediate breast reconstruction using DIEP- flap procedure.

Study design

This study is a cross-sectional survey conducted in January 2008. A postal

questionnaire was sent to each patient at least 6 months postoperatively.

Study burden and risks

Women only once have to answer a questionnaire, therefore we conclude that there is no risk involved.

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

Inclusion criteria:

- Women who had a direct reconstruction using the Diep flap procedure.
- Women treated for curable breast cancer.

- Women with hereditary increased risk of breast cancer who underwent prophylactic mastectomy, uni - or bilateral.
- Women able to speak and read Dutch.
- Women able to give informed consent.

Exclusion criteria

Exclusion criteria:

- women who developed breast cancer in the contralateral breast.
- women treated for recurrent breast cancer.
- women who developed metastasis.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-02-2008

Enrollment: 35

Type: Actual

Ethics review

Approved WMO

Date: 18-01-2008

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL20201.068.07