Donor leg morbidity and function after a fibula free flap; a comparison between the osteocutaneous and osteomyocutaneous flap

Published: 29-09-2010
Last updated: 04-05-2024

To analyse possible differences in functional deficit and donor-site morbidity between the routinely used free osteocutaneous fibular flaps and the free fibula osteomyocutaneous (with flexor hallucis longus) flap.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON34338

Source
ToetsingOnline

Brief title
Donorsite morbidity and function after a free fibula flap

Condition

- Bone and joint therapeutic procedures

Synonym
Donorsite Morbidity after a free fibula flap

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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

Intervention

Keyword: ankle, donor site morbidity, free fibula flap

Outcome measures

Primary outcome

The primary study parameter is the AOFAS Ankle- Hindfoot Scale and Hallux

Metatarsophalangeal- Interphalangeal Scale

Secondary outcome

Secondary study parameters are:

- Flexion- and extension force of the hallux

- Range of motion ankle and MTP-I joint

- Walking distance (6 minutes)

- Stability test

- Sensibility

- Morbidity score (subjective)

- POSAS score

- Ankle lining

- Karlsson score (instability ankle)

Study description

Background summary

The free fibula osteofasciocutaneous flap has become a very popular source of vascularized bone and skin. Developed originally for extremity reconstruction, the fibula flap is now used widely in various other clinical applications including reconstruction of the mandible .

To add bulk, the flexor hallucis longus muscle and part of the posterior tibial and soleus muscles can be included in the flap.
The fibula flap appears to have a relative lack of donor site morbidity.
There are several studies describing the donor leg morbidity after removal of osseous and osteocutaneous fibula flaps , but the effect of flexor hallucis longus harvest (osteomyocutaneous flap) is unknown.

Study objective

To analyse possible differences in functional deficit and donor-site morbidity between the routinely used free osteocutaneous fibular flaps and the free fibula osteomyocutaneous (with flexor hallucis longus) flap.

Study design

Retrospective cross-sectional design

Study burden and risks

No risks with participation

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

Patients who underwent a reconstruction with a free osteocutaneous or a free osteomyocutaneous fibula flap between 1 january 1995 and 1 november 2009

Exclusion criteria

A history of previous surgery or trauma of the contralateral leg.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2010

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33079.029.10