Measurement of lymph flow velocity in non-edematous extremities using Transonic Transit Time Ultrasound Microvascular Flowprobe (AureFlo®), a pilot study

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The aim of this study is to measure the lymphflow in the superficial lymphvessels in the dorsal forearm in patients with no history of lymphedema. In order to further study lymphedema and to improve the technique of lymphaticovenous anastomoses, it...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50022

Source
ToetsingOnline

Brief title
Non-edematous lymph flow velocity

Condition

- Other condition
- Skin and subcutaneous tissue disorders NEC

Synonym
lymph flow, lymphedema

Health condition

lymfoedeem, lymfevaten

Research involving
Human

Sponsors and support

Primary sponsor: Plastische Chirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: flow, lymphaticovenous anastomosis, lymphedema, microsurgery

Outcome measures

Primary outcome

Lymph flow velocity (ml/min)

Secondary outcome

/

Study description

Background summary

Research on lymph vessels has been done for years, however, only few studies described lymphatic flow or flow velocity. Lymph flow is generated by lymph production and lymph propulsion. It is known that collecting lymph vessels have a smooth musculature and move lymph fluid actively through pulsation. These muscles are stretch-sensitive and respond according to Starling*s law of the heart, by increasing frequency and stroke volume of pulsation as a result of increased ultrafiltration. One-way valves in the vessels also contribute to lymph propulsion and prevent retrograde flow.

Fischer et al. described measurement of flow velocity in single lymphatic capillaries of humans using fluorescence microlymphography in 1996. After injection of fluorescein isothiocyanate-dextran, direct observation of the dye advancement in the microvessels was used to measure flow velocity. Directly after dye injection, velocities of 5,5 mm/s were reached. However, the median velocity during initial network filling was 0.51 mm/s and the median resting lymphatic capillary velocity was 9.7 µm/s.
Modi et al. (2007) tested whether there is lymphatic pump failure in breast cancer treatment-related lymphedema due to chronically raised lymphatic smooth

muscle afterload. They measured a mean hand-axilla velocity of 8.9±5.8 cm/min (1.48±0.97 mm/s) in uncuffed normal subjects, no significant difference in cuffed normal arms (60mmHg) and a significant decrease of velocity in cuffed swollen arms (3.2±8.9 cm/min; 0.53±1.48 mm/s). Lymphedema was associated with a 38% decrease in pump force.

Until now, the lymph flow could only be measured indirectly by calculating an average speed over a certain distance
(foot-inguinal or hand-axilla). With the invention of the Flowprobe for microsurgical anastomoses, flow can be measured quantitatively and directly. Early results from Chen et al. (2015) were promising, although only lymphedema patients were included in the study. Direct, local flow in healthy patients has not been described yet.

Study objective

The aim of this study is to measure the lymphflow in the superficial lymphvessels in the dorsal forearm in patients with no history of lymphedema. In order to further study lymphedema and to improve the technique of lymphaticovenous anastomoses, it is important to know the healthy situation. This healthy situation will be described, based on the measurements that will be performed in this study.
The primary research question is: What is the lymph flow velocity (ml/min) in the superficial lymphvessels of the dorsal forearm in patients without a history of lymphedema?

Study design

This observational study will not be randomized and will not be blinded. Patients undergoing a free radial forearm flap reconstruction will be included by the plastic surgeon during the preoperative consultation.
Via the incision made for the flap harvesting, a superficial lymph vessel will be chosen, using a microscope. The plastic surgeon will measure the lymph flow according to the protocol, using the Transonic Transit Time Ultrasound Microvascular Flowprobe (AureFlo®). Results will be noted anonymously in standardized tables.

Study burden and risks

The subjects will only be included if a operation of the forearm is indicated. Therefore, no extra incisions or other invasive procedures will be performed for the study. During the measurement, the patient is under general anesthesia. Furthermore, no postoperative consequences can be expected from the measurement. Therefore, te extent of the burden is very limited and there are no risks associated 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 undergoing free radial forearm flap reconstruction
Age > 18

Exclusion criteria

History of lymphedema
axillary lymphnode metastasis
axillary lymphnode dissection
earlier operations or scars in that extremity at the level of the wrist or forearm.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2020
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Transonic Transit Time Ultrasound Microvascular Flowprobe (AureFlo®)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-01-2020
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	NL69899.068.19
Other	TBA