Optimizing the skin graft procedure: micrografts versus meshed skin grafts

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To assess long-term scar quality of deep/sub dermal (burn) wounds after skin grafting with micrografting technique compared to meshed grafting technique.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52696

Source
ToetsingOnline

Brief title
Meek versus Mesh

Condition

- Other condition
- Skin and subcutaneous tissue therapeutic procedures

Synonym
burns and other skin defects

Health condition

(brand)wonden

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Ziekenhuis Gent
Source(s) of monetary or material Support: FWO België (T000319N)

Intervention

Keyword: Burnwounds, Micrografts, Split skin grafts

Outcome measures

Primary outcome

Long-term scar quality 12 months after skin transplantation assessed with the Patient and Observer Scar Assessment Scale (POSAS).

Secondary outcome

1. Long-term scar quality 3 and 12 months after skin transplantation

- Possible differences in scar quality between micrografting or meshing technique will be assessed 3 months post-operative at the outpatient clinic. Color and pigmentation are objectively measured with the Mexameter or Dermaspectrometer and skin elasticity with the Cutometer.
Subjectively assessment of the scar will be conducted by both researcher and patient with the Patient and Observer Scar Assessment Scale (POSAS).

2. Donorsite size and ratio of donorsite size and actual graft size (cm2)

- Surface areas will be calculated with a 3D-camera (Woundworks inSight)

3. Take rate of skin grafts

- Take rate will be clinically assessed at 8 +/- 2 days and expressed as

the percentage of micrografted and meshed graft take

4. Healing time

- Clinical assessment of wound healing 14 and 21 days +/- 2 post

application expressed as percentage of the total wound surface area healed

- Time to complete wound closure where complete wound closure is defined as

> 95% re-epithelialization of the wound with the absence of drainage

and no longer needing a substantial wound dressing

5. Bacterial load

- Wound swabs for semi-quantitative investigation

- Semi-quantitative bacteriology in both groups

- Percentage of patients within both groups with clinical wound infection

requiring systemic antimicrobial

therapy.

Clinical infection is defined as the presence of cellulitis and/or

visible purulence and/or lymphangitis combined with one or more of the

following:

local wound pain/erythema/edema/malodor.

6. Pain

- Will be evaluated in the autografted target wounds with help of a Visual

Analogue Scale (VAS score) on day 2 post surgery, before and after

removal of Surfasoft®/Urgotul in case of meshed skin grafts or plissees

in case of micrografting, and thereafter once weekly during the hospitalization period. After hospital discharge pain will be evaluated again at the 3 and 12 months follow ups

7. Number of secondary procedures

- Re-interventions in study areas due to insufficient take or necessity of reconstructive surgery.

8. Mobility at 3 and 12 months

- If articulations of limbs are involved the Quick Dash for upper extremities and the Lower extremity functional scale for lower extremities, the range of motion will be assessed with a goniometer.

9. Quality of life

- Assessed at the time of hospital discharge and at 3 and 12 months after the procedure. 3 quality of life measures, the EQ5D-5L, SF36 and DLQI will be used at different points in time: at the time of hospital discharge and 3 and 12 months post wound healing

10. Health economics:

- Differences in operation time, costs of materials/equipment used and staff/personnel and impact of re-interventions and the need for reconstructive surgery will be evaluated. Using regression analysis based on the processing of the EQ5D-5L, SF36 and the DLQI we will be

able to construct an economic model. The model will incorporate the short-term costs involved of both skin expansion techniques as well as the long- term costs.

11. Incidence of AE and SAE

- There are no Adverse Events (AEs) expected, relating to this study (comparison of two already existing types of skin grafting
- A Serious Adverse Event (SAE) is any untoward medical occurrence in a subject who is participating in a clinical study performed. This is defined as an event that is:

a) fatal

b) life-threatening

c) requires or prolongs inpatient unexpected hospitalization

- These SAEs will be reported directly to the METc.
- SAEs related to surgery in general will be noted in a line-listing and will be reported yearly to the METc. These are defined as an event that results in a:

a) pneumonia

b) urinary tract infections

c) sepsis

d) pulmary embolism

e) re-operation

12. Skin graft technique preferred by patient

- Patient gives overall indication as to what skin graft technique he/she

would prefer if he/she were to require skin grafting again: weekly during

hospital admission and 3 and 12 months follow up.

Study description

Background summary

Patients with deep dermal/subdermal (burn) wounds often have an indication for a skin transplantiation. Most common method is split skin grafting (SSG). Surface area of the skin graft is mostly expanded to retain a small donorsite (wound after harvesting of the skin graft). Skin graft expansion is generally performed by the meshed skin grafting technique, seen this method is considered to be quick and easily applicable. Yet, this technique also has several limiations. For the surgeon this method becomes more cumbersome when the expansion ratio increases. Moreover, the actual expansion of the skin graft is usually lower then the intended expansion ratio and the "fish-net" pattern often stays visible in the eventual scar. An alternative for skin graft expansion is the micrografting technique (Meek technique). In comparision with meshed skin grafting this technique is able to reach large expansion ratio's and thereby maintain small donorsites. As a consequence, this technique is used in particular for very extended (burn) wounds. Both expansion methods are used worldwide in specialized burn centers. Wound healing seams to be similar according to previous published literature. Experience shows an possible advantage of micrografting on scar quality. Three studies compared these two expansion techniques, however none primarily investigated possible differences within long-term scar quality. Given the increasingly prominent role of scar quality in (burn) wound care, a randomized controlled trial to compare long-term scar quality of both skin grafting techniques is highly preferred.

Study objective

To assess long-term scar quality of deep/sub dermal (burn) wounds after skin grafting with micrografting technique compared to meshed grafting technique.

Study design

Multicentre randomized intra-patient controlled trial.

Intervention

Prior to surgery two comparable (burn) wounds or two equal parts in one (burn)

with a minimum size of 36 cm2 per wound will be selected. These wounds will be randomly allocated to the intervention method (micrografting) or the comparison method (meshed skin grafting).

Study burden and risks

All patients will have to undergo surgery, independent of skin grafting method. Seen both skin grafting techniques are already been considered as standard treatments, there is no additional risk micrografting compared to meshed skin grafting. Follow-up broadly corresponds with standard follow-up for (burn) wounds. The duration of check-up at outpatient clinic is slightly increased to 60 minutes, due to additional examinations and surveys. Moreover, as mentioned above possible subtle asymmetry of the scar is a risk.

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

- 18 years and older
- deep burn or deep skin defect requiring skin grafting
- two comparable deep partial and/or full thickness burns, confirmed with Laser Doppler Imaging, or deep skin defect, of a minimum of 36 cm2 per wound, requiring skin grafting after assessment of a (plastic) surgeon/burn physician
- mentally capable to give legal consent or legal representative when patient is (temporarily) incompetent (e.g. sedated/ventilated)

Exclusion criteria

- patient has participated in another study utilizing an investigational drug or device within 30 days
- wounds covering face, hands or joints
- patient has one or more medical condition(s) that in the opinion of treating physician would make the patient an inappropriate candidate for this study
- patient who is expected (according to the responsible physician) to be non-compliant to study protocol. (This includes patients with severe cognitive dysfunction/impairment and sever psychiatric disorders).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2022
Application type:	Amendment
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	NL74274.029.20