Measuring the dynamic characteristics of skin tension of the human body

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Research question: What is the influence of anatomical position changes on the skin tension and direction of highest tension in healthy participants at different locations of the body?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON49377

Source
ToetsingOnline

Brief title
Skin tension measurements

Condition

- Skin and subcutaneous tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
scar formation, Scarring

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dynamic, Measurement, Skin, Tension

Outcome measures

Primary outcome

The primary study parameter is skin tension in N/mm, which is compared between

five locations on the body and between three anatomical positions per location.

Secondary outcome

The secondary study parameter is the direction of highest and lowest tension in

degrees from longitudinal compared to the direction of the Langer lines,

relaxed tension skin lines and BEST lines.

Study description

Background summary

Knowledge about the mechanical properties of the skin is important for skin surgery and wound healing. Langer was the first in 1861 to investigate skin tension systematically. He punched circular holes in cadaveric skin at different locations and observed the change of shape of the holes. Based on these observations he drew a map of skin tension lines. It was proven that incisions parallel to the so-called Langer lines require less force to be closed and due to reduced tension heal better and show less scarring. As pathological scarring of the skin is a global problem, guidelines like the Langer lines are still used to plan incisions for skin surgery and wound closure. However, these lines turn out not to be universal and they are a static representation of the tension on the skin, whereas it has been found that the direction of highest tension on the skin changes (e.g. switching between facial expressions). To improve the results of skin surgery, the direction of an incision and skin closure should be adapted to individual variations and to dynamic characteristics of the patients skin.
To continue searching for the best incision lines, several researchers have tried to build a device that measures skin tension in vivo in a non-invasive way, prior to an operation. However, most devices are not yet suited for use in the operation room due to their size and function. Additionally, the measurements have only been done on a few anatomical locations of the body and

little is known about the dynamic characteristics of skin tension on each location. If a surgeon knows the important differences in skin tension between various locations on the body and the influence of certain daily activities on the skin tension, he/she could anticipate to design the most desirable direction of incision and wound closure in order to induce as little scarring as possible.
In this study, a new skin tension measurement device is used to quantify the skin tension at different locations all over the body in several anatomical positions.

Study objective

Research question: What is the influence of anatomical position changes on the skin tension and direction of highest tension in healthy participants at different locations of the body?

Study design

This is a prospective observational study.

Study burden and risks

Every participant is submitted to measurements during one session of approximately an hour. The small disadvantageous effects that might result from participation are skin irritation due to the used stickers and small blisters at the site of the pads of the device.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy person, willing to participate.

Exclusion criteria

- Physical movement impairment
- Skin disease present
- Connective tissue disease present, including all heritable connective tissue disorders and the autoimmune connective tissue disorders except for rheumatic arthritis and Sjögren*s disease, which do not influence the skin.
- A scar, wound or damaged skin at one of the investigating sites
- Contact allergy for glue/plasters (especially product used in this study: 3M *red dot* stickers)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2020
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Skin Tensiometer
Registration:	No

Ethics review

Approved WMO Date:	02-11-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL73290.058.20

Register	ID
Other	NL8476