Long term follow-up of subtalar arthrodesis patients: what induces adjacent joint arthritis?

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Ethical review Approved WMO **Status** Recruiting **Health condition type** Joint disorders

Study type Observational non invasive

Summary

ID

NL-OMON36782

Source

ToetsingOnline

Brief title

STAA, subtalar arthrodesis: what induces adjacent joint arthritis?

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

fixation ankle joint

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

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Intervention

Keyword: subtalar arthrodesis, Subtalar fusion

Outcome measures

Primary outcome

pain over the adjacent joints

radiologic progress of arthritis in the 3 adjacent joints compared to the

contralateral side and earlier X-rays from the ipsilateral side

Secondary outcome

SF-36 questionnaire

FAAM questionnaire

FAOS questionnaire

Foot Function Index

Kellgren-Lawrence radiological score per joint.

Physical examination.

Complications

Study description

Background summary

Subtalar arthrodesis is considered to be the gold standard operative treatment for end-stage subtalar arthritis. However, the effect of fusing the subtalar joint on the surrounding joints remains largely unknown. One long-term outcome study of 23 patients showed that there was significantly more arthritis seen in the ipsilateral foot than on the contralateral side, but not in the knee.

1 However this study could have overlooked the presence of arthritic changes in the joints before the fusion. Sheridan and colleagues looked at pre-operative radiographs of 70 patients who underwent arthrodesis of the ankle. They found hind- and midfoot arthritis present in almost all of the patients and conclude that these changes may not be a consequence of the arthrodesis.

2 For the subtalar joint this has not arrived in literature in detail yet. A biomechanical study after changes of pressure in the talonavicular, tibiotalar, and calcaneocuboid joints before and after rigid subtalar joint immobilization showed data consistent with the theory of adjacent joint arthritis being the result of an ankle fusion. A substantial pressure increase in the talonavicular and calcaneocuboid joints at dorsalflexion may be responsible for the secondary tarsal joint degeneration occurring in late subtalar arthrodesis.

3 Further investigations might provide evidence supporting either of both possibilities: adjacent joint arthritis being the result of pre-existing pantalar arthritis or as a result of the subtalar fusion.

Study objective

The purpose of this study is to perform a clinical and radiographic follow up of approximately 100 consecutive patients who received fusion of the subtalar joint between 1990 and 2010 in the AMC for end-stage ankle arthritis, to determine the long-term effect of the arthrodesis on the development of osteoarthritis in the tibiotalar, talonavicular and calcaneocuboid joints.

Study design

A retrospective study is undertaken, for which approval is obtained from the local Research Ethics Committee of the AMC.

Inclusion criteria: patients with an end-stage osteoarthritis of the subtalar joint, who have been treated in the AMC by means of arthrodesis of the subtalar joint between januari 1990 and december 2010.

Primary exclusion criteria: pantalar fusion (combination of subtalar fusion and ankle fusion in the same setting), ankle fusion prior to subtalar fusion, re-arthrodesis after failed arthrodesis performed elsewhere, re-arthrodesis after failed arthrodesis performed in the AMC before 1990. Secondary exclusion criteria: inability to understand the patient information and the questionnaires (e.g. mental retardation, severe language barrier), age under eighteen years, ankle trauma 6 months or less before follow-up.

All arthrodeses of the subtalar joint that have been performed in the AMC between 1990 and 2010 will be investigated.

Study burden and risks

The patient has to come to the hospital for about one and a half hour for anamnese, physical examination, X-rays and questionnaires. 0,004mSv radiation

Contacts

Public

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Scientific

Academisch Medisch Centrum

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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 with an end-stage osteoarthritis of the subtalar joint, who have been treated in the AMC by means of arthrodesis of the subtalar joint between januari 1990 and december 2010.

Exclusion criteria

Primary exclusion criteria: pantalar fusion (combination of subtalar fusion and ankle fusion in the same setting), ankle fusion prior to subtalar fusion, re-arthrodesis after failed arthrodesis performed elsewhere, re-arthrodesis after failed arthrodesis performed in the AMC before 1990. Secondary exclusion criteria: inability to understand the patient information and the questionnaires (e.g. mental retardation, severe language barrier), ankle trauma 6 months or less before follow-up

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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): 20-04-2011

Enrollment: 100

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

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 NL34949.018.11