A prospective trial on the clinical efficacy of the Ankle Spacer for the surgical treatment of large, multiple, cystic and secondary or tertiary osteochondral defects of the talus.

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* Primary Objective: determine the functional outcome and clinical efficacy after open surgical implantation of the Ankle Spacer for patients with large, cystic, previously surgically failed and/or multiple OCDs of the talus by means of functional...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON44464

Source
ToetsingOnline

Brief title
AS: Ankle Spacer

Condition

- Bone and joint therapeutic procedures

Synonym
talar osteochondral defect;

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Arthrex

Intervention

Keyword: ankle spacer, bone-sparing, implantation, prosthesis, talar osteochondral defect

Outcome measures

Primary outcome

The primary study parameter is the measurement of the NRS pain during walking/normal weight-bearing.

Secondary outcome

Other outcome measures will include pain evaluation using the NRS pain at rest and during stair climbing, the AOFAS, FAOS, and SF-36 physical and mental component scale. Range of Motion (ROM) will also be registered in degrees of dorsi- and plantarflexion and will be measured using a goniometer

Other study parameters that will be recorded are demographic data (sex, age, etc.) and also radiographic evaluations to evaluate loosening and subsidence (radiographs). Complications, implant survivorship (revision rate), operation time, adverse events, and length of hospital stay will also be recorded.

Study description

Background summary

Ankle sprains can result in talar osteochondral defects (OCDs) which have a significant impact on the quality of life of patients. When these OCDs are of large nature (anterior*posterior or medial*lateral diameter >1.5cm in

diameter), cystic, have failed prior surgical treatment, or when there are multiple present on the talar articular surface, surgical care by means of fixation or bone marrow stimulation is contra-indicated. An ankle arthrodesis or fusion can be considered, but this results in functional limitation due to a decreased range of motion (ROM). In order to serve for a bone sparing prosthesis procedure, preserve range of motion, optimize physical functioning and to resurface the talus, the Ankle Spacer has been developed. It is a one-piece implant system that replaces the articulating upper talus surface of the tibio-talar joint, and offers several implant sizes in order to fit to the different talus sizes. It is anatomically designed to the native upper talus surface to provide an optimal fit to the distal articular surface. It has a rough titanium plasma spray (TPS) coated under surface with two posts and spikes for implant fixation. The rough surface enables secondary fixation by means of bone ingrowth and the spikes at the posterior part of the prosthesis allowing for optimal adherence of the implant and for minimal iatrogenic damage upon fixation. By these means, the anatomical situation and the natural congruency of the ankle joint are mirrored to a optimal extent. Despite the fact that no clinical trials have been published on this specific implant, it is hypothesized that the 5-year postoperative clinical outcomes concerning pain and prosthesis survival will be considered good.

Study objective

* Primary Objective: determine the functional outcome and clinical efficacy after open surgical implantation of the Ankle Spacer for patients with large, cystic, previously surgically failed and/or multiple OCDs of the talus by means of functional outcome questionnaires
* Secondary Objective(s): assess the implant survivorship (revision rate), operation time, adverse events, and length of hospital stay

Study design

The present study concerns a non-randomized, non-blinded, non-comparative prospective trial, with a five-year follow-up period at the outpatient clinic aiming at assessing pain and implant survival, and thereby investigating the clinical efficacy of the Ankle Spacer. Two interim analyses will be included in the present study, one at 6 months postoperatively, and one at 2 years postoperatively to assess short- and midterm results. The short-term follow-up will assess surgical recovery, and the intermediate follow-up clinical efficacy concerning pain levels and implant survival. All patients visiting the outpatient department for large (anterior*posterior or medial*lateral >1.5 cm in diameter), cystic defects, those that failed prior surgical intervention(s) and multiple talar OCDs on the talar surface, eligible for surgical implantation of the Ankle Spacer will be requested if they are willing to participate in the present clinical trial. If they are interested, patients will be informed about this study and are given two weeks to decide upon

participation. In case patients provide their consent, they are screened for meeting the inclusion criteria, and are assessed pre-operatively by means of standard (anteroposterior AP and lateral) standing weight-bearing conventional radiographs, by documenting a questionnaire containing the Numeric Rating Scale (NRS) of pain, the American Orthopaedic Foot and Ankle Hindfoot Score (AOFAS) Foot and Ankle Outcome Score (FAOS) and the Short-Form 36 (SF-36) and assessment of the range of motion (ROM) by means of a physical examination. Additionally patients receive a preoperative CT-scan for surgical planning according to the standard AMC protocol. Subsequently after surgery, patients will be followed-up at two and six weeks, three and six months, one-year post-operatively, and annually thereafter. At these follow-up moments the patients will be requested to fill out a questionnaire, a physical examination will be performed to test the ROM, and radiographs will be taken one day, 6 weeks, 1, 2 and 5-years post-operatively. Patients will also receive a post-operative CT scan at one year post-operatively, as part of the normal work-up/AMC protocol for osteochondral talar defects.

Intervention

All included patients will be treated by means of surgical implantation of the Ankle Spacer prosthesis in an open manner replacing the talar side of the tibiotalar joint.

Study burden and risks

Preoperatively patients will be asked to fill out a questionnaire, and a radiograph will be taken for appropriate sizing of the implant, and range of motion (ROM) will be documented. Postoperatively patients will be asked to visit the outpatient clinic 9 times and five times postoperatively a radiographs will be taken.
Risks or complications associated with this specific surgical technique and all prosthetic ankle surgery techniques are bleeding, infection, venous thrombosis, pain, swelling, reduced ROM, delayed wound healing and damage to superficial nerves. Less frequently occurring risks associated with the surgical procedure are allergies and other reactions to device materials, loosening of the implant, and bone fractures as a result of one-sided overload or weakened bone substance.
Patients may find participation in the present study beneficial as this treatment may provide a successful solution before deciding upon an arthrodesis. In case of failed treatment, an arthrodesis is still an option. Patient risk will be mainly caused by the implantation of a new bone-sparing prosthesis with an unknown success rate, there will be no further burden with regard to extra visits to the outpatient clinic, nor additional radiograph taking. Our normal work up for a biological solution for secondary osteochondral defects comprises the same number of outpatient clinic visits with a radiograph and two additional CT scans.

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

- age ranging from 18 to 80 years;
- talar osteochondral defect (multiple degenerative talar cysts present, and/or prior failed surgical treatment and/or multiple defects and/or large (>15mm))
- willing to receive surgical implantation of the Ankle Spacer
- has been informed of the nature of the study and provided written consent
- The subject and treating physician agree that the subject will return for all required post-procedure follow-up visits
- failed previous conservative treatment
- complaints for at least 6 months

Exclusion criteria

- severe ankle malalignement.(> 5° varus/valgus).
- fracture < 6 months
- tendinitis
- diabetes mellitus / reumathoid arthritis
- advanced osteoporosis
- grade two or higher (Kellgren-Lawrence-Score) ankle joint degeneration on the tibia side.
- any ankle deformation that does not allow proper rasping of the cartilage and/or proper seating of the desired sized implant, as described in the surgical technique.
- blood supply limitations and previous infections, which may retard healing.
- foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- active infection or blood supply limitations.
- conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period, including severe neuro-arthropathy.
- pathological conditions, such as insufficient quantity or quality of bone (e.g., cystic changes or severe osteopenia), which may compromise implant fixation.
- currently participating in an investigational drug or another device study that clinically interferes with the current study endpoints.
- Inability to be brought back to the surgery site for long term follow-up evaluations or the subject is unwilling to fill out the appropriate evaluation forms
- adiposity grade I (BMI > 30 kg/m2)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-11-2017
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Ankle Spacer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-09-2017
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

ID: 26265
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62466.018.17
OMON	NL-OMON26265