# AS: Ankle Spacer for Talar Osteochondral Defects (AS)




ClinicalTrials.gov Identifier: NCT03303690

Recruitment Status : Terminated (Arthrex stopped manufacturing the device)
First Posted : October 6, 2017
Last Update Posted : July 15, 2020



**Sponsor:**
Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)

**Information provided by (Responsible Party):**
Jari Dahmen, Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)

Brief Summary:

By means of the Ankle Spacer patients will be implanted, the clinical and radiological results of which will be prospectively recorded and analyzed at different points in time.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|
| **Osteochondral** Defect of Talus | Procedure: Ankle Spacer (AS) | Not Applicable |

Detailed Description:

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 Design

Go to

**Study Type :**

Interventional (Clinical Trial)

**Actual Enrollment :**

2 participants

**Allocation:**

N/A

**Intervention Model:**

Single Group Assignment

**Masking:**

None (Open Label)

**Primary Purpose:**

Treatment

**Official Title:**

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

**Actual Study Start Date :**
December 5, 2017

**Actual Primary Completion Date :**
March 11, 2020

**Actual Study Completion Date :**
March 11, 2020

## Arms and Interventions

Go to

| Arm | Intervention/treatment |
|---|---|
| Experimental: Ankle Spacer (AS)<br>This arm will surgically receive the to be implanted ankle spacer in their ankle. | Procedure: Ankle Spacer (AS)<br>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. |

## Outcome Measures

Go to

Primary Outcome Measures :

1. NRS during walking/weightbearing [ Time Frame: 2 years postoperatively ]

   The primary study parameter is the measurement of the NRS

Secondary Outcome Measures :

1. NRS at rest and during stairclimbing [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include pain evaluation using the NRS pain at rest and during stair climbing

2. NRS during stairclimbing [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include pain evaluation using the NRS pain at rest and during stair climbing

3. AOFAS (American Orthopedic Foot and Ankle Score) [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include the AOFAS.

4. FAOS (Foot and Ankle Outcome Score) [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include FAOS

5. SF-36 (Short-Form 36) Physical Component Scale [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include SF-36 Physical Component Scale

6. SF-36 (Short-Form 36) Mental Component Scale [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include SF-36 Mental Component Scale

7. ROM (range of motion) [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other outcome measures will include Range of Motion (ROM) in degrees of dorsi- and plantarflexion and will be measured using a goniometer

8. demographic data: sex [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other study parameters that will be recorded are demographic data 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.

9. demographic data: age [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

   Other study parameters that will be recorded are demographic data 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.

10. Radiographic evaluation [ Time Frame: pre-operatively, follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, 1,2,3,4,5 year postop. ]

    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.

## Eligibility Criteria

Go to

**Information from the National Library of Medicine**

*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.*

**Ages Eligible for Study:**

18 Years to 80 Years (Adult, Older Adult)

**Sexes Eligible for Study:**

All

**Accepts Healthy Volunteers:**

No

**Criteria**

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 / rheumathoid 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)

## Contacts and Locations

Go to

**Information from the National Library of Medicine**

*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):* ***NCT03303690***

### Locations

#### Netherlands

Academic Medical Center
Amsterdam, Noord Holland, Netherlands, 1105AZ

### Sponsors and Collaborators

Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)

### Investigators

Principal Investigator: G.M.M.J. Kerkhoffs, MD PhD Academic Medical Center (AMC Amsterdam)

## More Information

Go to

**Responsible Party:**

Jari Dahmen, Local Study Investigator, Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)

**ClinicalTrials.gov Identifier:**

NCT03303690 History of Changes

**Other Study ID Numbers:**

GK2017AS

**First Posted:**

October 6, 2017 Key Record Dates

**Last Update Posted:**

July 15, 2020

**Last Verified:**

July 2020

**Individual Participant Data (IPD) Sharing Statement:**

**Plan to Share IPD:**

No

**Studies a U.S. FDA-regulated Drug Product:**

No

**Studies a U.S. FDA-regulated Device Product:**

No

**Product Manufactured in and Exported from the U.S.:**

No

**Additional relevant MeSH terms:**

Osteochondrosis

Bone Diseases

Musculoskeletal Diseases