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Short term results of the Mobility Total Ankle System: Clinical and radiographic outcome

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ABSTRACT

Background: Ankle arthroplasty is increasingly used to reduce pain and improve or maintain joint mobility in end-stage ankle arthritis. The aim of this study was to assess the clinical and radiographic short term results of the Mobility prosthesis.
Methods: Complications, secondary operations, failures and the survival rate were retrospectively examined in 67 primary Mobility total ankle arthroplasties. Prosthesis alignment was measured and patient reported outcomes were assessed with the use of questionnaires.
Results: There were two intraoperative and 13 postoperative complications, requiring seven reoperations. Failure occurred in three cases, with a survival of 95% after 61 months. Clinical scores improved after surgery and alignment was correct in 93% of the tibial and 93% of the talar components.
Conclusion: Despite few intraoperative complications and satisfactory clinical and radiological outcome, the incidence of postoperative complications, reoperations and failure indicate the importance of further development and research in the field of ankle arthroplasty.

1. Introduction

End-stage osteoarthritis of the ankle is a chronic condition associated with progressive joint pain and dysfunction. Patients with end-stage ankle arthritis report a severely affected health-related quality of life and experience more pain and reduced physical and social functioning compared to the general population [1].

As an alternative to ankle arthrodesis, total ankle arthroplasty has become a common treatment of end-stage ankle arthritis to reduce the pain and to maintain or possibly improve joint mobility. Both treatments show similar results with regard to functional outcome scores and sport related activities. However, the rates of complications and reoperations were higher after ankle replacement [2–5]. This was particularly the case for the first implant designs, with more promising results for newer designs [6,7].

One of these newer designs is the Mobility Total Ankle System (DePuy International, Leeds, United Kingdom). The Mobility prosthesis is used in our clinic since 2008 and was the successor of the Scandinavian Total Ankle Replacement (STAR). Unfortunately, despite several years of experience with the STAR, no improvement in the number of postoperative complications, clinical outcome and the alignment of the talar component were observed [8,9]. Therefore, it was decided to switch to the use of another prosthesis type in our hospital.

In recent literature there are different studies presenting short term results of the Mobility prosthesis. All studies describe an improvement of functional outcome, however complication rates vary widely, ranging from 9 to 37%. The 4-year survival rates range between 84 and 98 percent [10–16].

Due to the transition from the STAR to the Mobility prosthesis, we were interested in the clinical and radiological results of the Mobility prosthesis. Therefore, the aim of this retrospective study was to determine the short term results of the Mobility Total Ankle System. More specific, short term results included the frequency of complications, reoperations and failure, the survival rate, patient reported outcomes and the prosthesis alignment.

2. Patients and methods

2.1. Patient demographics

Between March 2008 and September 2013, 67 primary total ankle arthroplasties with the Mobility Total Ankle System were performed, in 64 patients, by one experienced foot and ankle surgeon (JWKL). The indications for surgery were disabling pain

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and radiographic degenerative joint changes. A varus or valgus malalignment up to 15° in the frontal plane was accepted and ankles with major instability were excluded. Patients with a minimal follow-up period of one year were invited to participate in the study. In the three patients who had bilateral procedures, each ankle arthroplasty was considered as a separate case.

All 67 cases were available for retrospective radiological evaluation and analysis of complications. Two patients were lost to follow-up; they died of unrelated causes and two patients continued their treatment in another hospital. Consequently, 63 ankles were available for clinical evaluation with the use of questionnaires at a mean follow-up period of 40 months (±16 months).

The study was approved by the hospital's investigational review board and all patients provided written informed consent. Demographic data and the underlying diagnoses for surgery are shown in Table 1.

2.2. Prosthesis design

The Mobility Total Ankle System is an uncemented three-component mobile bearing ankle design. Both the tibial and talar component are made of a cobalt-chromium alloy and are porous coated to promote bone ingrowth after press-fit implantation. The talar component is designed to leave the malleolar surfaces intact. The tibial component has a short conical stem and short talar fins both provide mediolateral and rotational stability without the risk of penetrating the articular surface of the subtalar joint. The insert is made of Ultra-High Molecular Weight Polyethylene and allows movement to minimize shear stresses across the bone-implant interface and thereby reduce the risk of loosening [17].

2.3. Surgical technique and postoperative management

The ankle arthroplasty with the Mobility Total Ankle System was performed in accordance with the surgical technique described by the manufacturer [17].

Patients were mobilized in a lower leg cast for four weeks, the first two weeks non-weightbearing, followed by two weeks weightbearing. After these four weeks the plaster was converted to a removable walker. Active and passive movement was initiated under the guidance of a physiotherapist and after two weeks the use of the walker was gradually reduced.

2.4. Clinical evaluation

The baseline data obtained retrospectively from the patient records included: demographic data, the diagnoses for surgery, preoperatively assessed Foot Function Index (FFI) and the surgical report with details on surgical procedure, the duration of the operation, additional procedures and intraoperative complications. Additionally, postoperative complications, reoperations and implant failures were noted. Failure was defined as exchange of the tibial and/or talar component or implant removal and arthrodesis.

Patient reported outcomes were assessed with the use of the FFI score, visual analogue scale (VAS) for pain, a patient satisfaction questionnaire and questions to determine participation in sport. All patients received the questionnaires accompanied by information regarding the study by mail.

For the FFI score the validated 18-item five point Dutch version was used, to measure pain and disability as the effect of foot complaints and problems of foot function [18]. The FFI score runs from 0 to 100, with 0 indicating no pain and no limitations and 100 indicating severe pain and limitations. We reported a missing FFI score if more than five items were "not applicable". To specify the location of the pain, the VAS score (0 = no pain, 100 = the worst pain imaginable) was divided into the following regions: calf, Achilles tendon, ankle, forefoot, midfoot, heel, dorsum of the foot and toes. In the satisfaction questionnaire patients were asked whether the operation improved their pain and daily functioning, if they were satisfied with the outcome of the surgery, whether they would undergo the same surgery again and if they would recommend this operation to relatives. The sport questionnaire asked if patients were able to run a short distance (for example to catch a bus) and which sport they conducted before and after surgery.

2.5. Radiological evaluation

The weightbearing anteroposterior and lateral radiographs of the ankle, which were made 14–19 weeks postoperatively, were used to determine the alignment of the prosthesis. The alignment was measured according to the procedure described by Rippstein et al. [10]; all radiographs were assessed by the first author.

On the anteroposterior radiograph the angle between the talar and tibial component was measured (Fig. 1a), with an ideal angle of 0°. To assess the alignment of the tibial component in the frontal plane, the angle between the mechanical axis of the tibia and the tibial plateau was measured (Fig. 1b), with an ideal angle of 90°. A deviation of more than 5° was considered as valgus or varus malalignment.

On the lateral radiograph the posterior slope of the tibial component with respect to the mechanical axis of the tibia was measured, with an angle of 90–95° as the target range (Fig. 1c). A deviation of more than 5° from this target range was considered as malalignment in the sagittal plane. Furthermore, the position of the tibial and talar component with respect to each other was analyzed. In case of proper alignment, both the anterior and posterior metallic marker of the polyethylene insert should be outside the zone created by extending the lines marking the borders of the tibial stem (Fig. 1d).

2.6. Statistical analysis

Descriptive statistics were used for analysis of patient characteristics, complications and reoperations and clinical and radiological outcome. Preoperative and postoperative results were compared with the use of paired *t*-tests and when assumptions where violated the non-parametric equivalent was used.

The survival curve was established using the Kaplan-Meier method, where survival was defined as time from surgery to failure. Data was analyzed using IBM SPSS Statistics 22.

Table 1
Patient characteristics.

Total number of ankles	67
Gender (Male:Female)	41:26
Age (Years)[a]	63 (±10.2)
Body Mass Index[a]	27 (±3.7)
Affected side (Right; Left)	40; 27
Smoking status negative	52
Diagnosis	
Primary osteoarthritis	23
Post-traumatic osteoarthritis	30
Inflammatory arthritis (Rheumatoid arthritis; Hemochromatosis)	12; 2

[a] Values are given as the mean with the standard deviation in parentheses.

3. Results

3.1. Operative characteristics

The mean duration of the operation was 114 min (±25 min). During surgery, in 26 cases a total of 30 additional surgical procedures