# Outcomes after Total Ankle Replacement

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Total ankle replacement is gaining acceptance as a viable option for treating patients with end-stage ankle osteoarthritis. However, there is limited number of literature addressing long-term results in patients who underwent total ankle replacement. The objectives of this study were therefore to determine: prosthesis component stability including surgical revision for any reason, postoperative pain relief, functional outcome including range of motion.

Materials and Methods: 388 consecutive patients (208 ♀, 180 ♂, mean age 63.4 years, range 23.2 to 90.0 years) with 415 primary total ankle arthroplasties were including into this prospective study. Preoperative diagnosis was posttraumatic osteoarthritis (n=315), primary osteoarthritis (n=42), and secondary osteoarthritis (n=58). All patients were clinically and radiologically assessed after 5.5 years (range, 4 to 10 years).

Results: 35 ankles had to be revised (27 revision total ankle arthroplasties and 8 ankle fusions) at a mean of 3.2 (0.5 – 7.9) years. Most likely the revision was performed in patients with 1st generation prosthesis with single coating with hydroxyapatite (n=17), rather than in patients with 2nd (n=10) or 3rd (n=8) generation prosthesis. The revision reasons were loosening of one or both components (n=23), subsidence of talar component (n=5), cyst formation (n=2), deep infection (n=1), unmanageable instability (n=1), and painful arthrofibrosis (n=3). The VAS pain score has significantly decreased from 7.2 preoperatively to 1.7 (p < 0.001). The AOFAS score has significantly increased from 39 preoperatively to 76 (p < 0.001). The mean ROM at latest follow-up was 34.3° (preoperative 22.5°, p < 0.01).

Conclusion: In our study we observed a postoperative revision rate of 8.4% which is comparable to other series recently published in the current literature. Our data suggest TAR in patients with end-stage ankle OA produces significant pain relief and functional improvement. Overall favorable results support the belief that TAR has become a viable and superior alternative to ankle fusion.

## Introduction

In the last two decades total ankle replacement gained an increasing acceptance among foot and ankle surgeons as a valuable treatment option in patients with end-stage ankle osteoarthritis. Total ankle arthroplasty has a relatively short history compared with total replacement of the hip and knee joints (1). Most first-generation total ankle replacements were two component prostheses with two main prosthesis designs - constrained and unconstrained (2–4). In most cases, cement fixation was used on both sides - talar and tibial. The predominantly unsatisfactory results and extremely high failure rate substantially delayed the further development of total ankle designs and limited acceptance among foot and ankle surgeons making the ankle arthrodesis the only one reasonable treatment option in patients with end-stage ankle osteoarthritis. Therefore, in an editorial of British Volume of Journal of Bone and Joint Surgery (5) in 1985 the main statement was: "Clearly the answer to the question of replacing the ankle joint using current techniques must be "no"."

Discouraging results of 1st generation total ankle replacement have clearly suggested that only substantial improvement in prosthetic design (e.g. improve the intrinsic stability), change of fixation principle (e.g. cementless fixation and use of biological surfaces for improved osseous integration), and improved anatomical approach (e.g. in order to avoid the perioperative complications like wound healing disturbance or infection) would help to accept total ankle replacement as an alternative treatment in patients with end-stage ankle osteoarthritis. Therefore, a thorough analysis of the common failure reasons for the 1st generation total ankle replacement was crucial and essential for the development of the 2nd generation total ankle designs. All four main 2nd generation total ankle replacement designs – Agility, Buechel-Pappas, STAR, and TNK prostheses – have been used in patients with end-stage ankle osteoarthritis with encouraging and promising mid- and long-term results (6–8). Several factors which may be responsible for inacceptable high failure rate of the 1st generation total ankle replacement design have been extensively analyzed and considered during the design development of the 2nd generation total ankle replacement designs.

The encouraging results of 2nd generation total ankle replacement design led to further clinical and biomechanical research resulting in substantial improvement of clinical outcome and survivorship of 3rd generation total ankle replacement components. Recently, the December issue of Foot Ankle Clinics was dedicated to the total ankle replacement. Norman Espinosa, editor of this issue, has summarized the most important improvements of the current total ankle replacement designs: "more anatomical design, better biomechanical behavior, and accurate instrumentation" (9).

Today, different ankle designs are available, which can be divided into two main groups: two- and three-component systems (10,11). Modern three-component prostheses have demonstrated favorable mid-term clinical results and improved survivorship of up to 90% at ten years or longer (6,12–17). Our group has already reported on short- to mid-term results using HINTEGRA prosthesis (18–20). The objectives of the present study were to determine: (1) prosthesis component stability including surgical revision for any reason, (2) postoperative pain relief, and (3) functional outcome including range of motion.

## Materials and Methods

### Patient Demographics

This prospective study was conducted in accordance with the Declaration of Helsinki and the Guidelines for Good Clinical Practice (21,22). The protocol was approved by the ethics committee of the University of Basel, Switzerland. All participants provided informed written consent prior to surgery and study participation. In total, 388 consecutive patients with 415 primary total ankle arthroplasties were included into this study. There were 208 men (53.6%) and 180 women (46.4%) with a mean age of 63.4 years (range, 23.2 to 90.0 years). Twenty patients underwent bilateral procedures, with all surgeries performed in one stage as bilateral simultaneous total ankle replacement (23,24). In the remaining seven patients, the second total ankle replacement took place 3.6 ± 2.7 years (range, 0.5 to 8.6 years). Preoperative diagnosis was posttraumatic osteoarthritis in 315 ankles (75.9%), primary osteoarthritis in 42 ankles (10.1%), and secondary osteoarthritis in 58 ankles (14.0%). The mean follow-up duration was 5.5 years (range, 4 to 10 years).

### HINTEGRA Prosthesis Design Description

The HINTEGRA prosthesis (Newdeal, Lyon, France/ Integra, Plainsboro, New Jersey) is a non-constrained three-component system consisting of a tibial compo-

*Figure 1 The HINTEGRA total ankle system consists of three components. (A) Talar component is conically shaped with a smaller radius of curvature on the medial side. (B) The tibial component is anatomically shaped and has a 4 mm thick flat plate with six pyramidal peaks. (C) Three-component HINTEGRA total ankle prosthesis.*

nent, a talar component, and an ultra-high molecular weight polyethylene mobile bearing (Fig. 1) (18,25). HINTEGRA prosthesis design evolution includes three generations (Fig. 2).

The tibial component is anatomically shaped and consists of a 4-mm-thick flat loading plate with six pyramidal peaks and an anterior shield. In the current 3rd generation, anterior and posterior peaks are 6 mm and 3 mm high. The flat surface allows optimal contact with the subchondral bone of the entire resection area including the cortical rim of the tibial metaphysic.

The talar component is conically shaped with a smaller radius of curvature on the medial side. It corresponds to the shape of the native talus (26,27). It has a 2.5-mm-high rim on both sides to provide mediolateral stability to the polyethylene bearing and to serve as a guide for anteroposterior translation. A wing on each side serves to cover the anatomical articular surface. The anterior shield may increase support on the talar neck and increase the intrinsic stability in the sagittal plane while preventing adherence of scar tissue that may restrict range of motion.

The ultra-high molecular weight polyethylene mobile bearing has a flat surface on the tibial side and a concave conical surface on the talar side. It has a minimum thickness of 5 mm (further available thicknesses are 6, 7, and 9 mm). The position and movement of the mobile bearing is restrained by the compressive action of the collateral ligaments and adjacent soft tissues. In a previous study, it has been shown, that the position of the mobile bearing remains constant over time. Therefore, bearing dislocation is a rare complication (28).

## Surgical Technique
Surgical technique has been described previously in detail (18,25,29). An anterior longitudinal approach
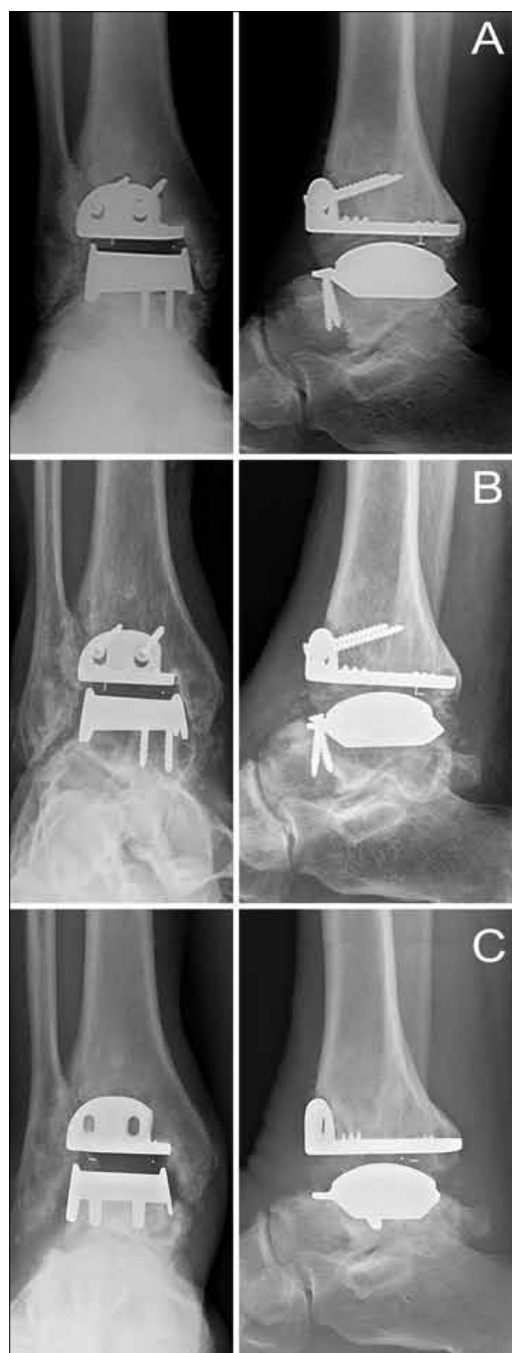


*Figure 2 Three generation of HINTEGRA total ankle prosthesis. (A) Postoperative radiographs of a male 65-year-old patient 8 years after total ankle replacement (using 1st generation prosthesis) due to post-traumatic osteoarthritis. (B) Postoperative radiographs of a male 65-year-old patient 8 years after total ankle replacement (using 2nd generation prosthesis) due to post-traumatic osteoarthritis. (C) Postoperative radiographs of a male 65-year-old patient 8 years after total ankle replacement (using 3rd generation prosthesis) due to post-traumatic osteoarthritis.*

was used to expose the ankle joint. If necessary, tibial and talar osteophytes were removed after capsulotomy was performed. The tibial tuberosity was used as the proximal anatomical mark for alignment of the tibial cutting block. The resection block was aligned considering the natural slope of the tibial plafond of 4°. Tibial resection was performed using an oscillating saw with removal of approximately 2-3 mm of the tibial plafond. A gauge was used to determine the size of the tibial component with posterior cortex as the reference. Correct position and alignment were checked using the tibial trial component. Maximal distraction was applied to the ankle joint to achieve the maximal tension of the collateral ligaments. Then the talar resection block was fixed into the tibial cutting block. The foot was held in neutral position in the sagittal plane, and talar resection block was fixed to the talus. The horizontal osseous cut was performed using an oscillating saw. Then talar cutting block was fixed to the talus with the size of the block usually according to the tibial component. After remaining talar cuts were finalized, the talar trial component was impacted and two holes for talar pegs were drilled. Before final implantation, tibial and talar surfaces were carefully checked for cysts or defects and debrided and filled with allograft (e.g. bone matrix) if necessary. Final prosthesis component were inserted in press-fit technique using a hammer and special impactor using the following order: talar component, tibial component, mobile bearing. The correct position of the component was checked using the fluoroscopy. The wound was closed in layers, a dressing was applied, and a splint was used to keep the foot/ankle in a neutral position.

## Postoperative Care/Rehabilitation

The wound drain (without suction) was removed on the 2nd postoperative day, and then the dressing and splint were changed. A pneumatic foot/ankle cuff (with intermittent pressure up to 130 mmHg) was used to reduce postoperative swelling. Active dorsal extension of the ankle joint should be avoided in the first four postoperative weeks to ensure the proper wound healing and healing of the extensor tendon retinaculum. However, the active and passive mobilization in the first metatarsophalangeal joint may increase venous blood flow in the affected extremity resulting in antiedema and thromboprophylactic effect (30). All patients received thromboprophylaxis with subcutaneous low-molecular-weight heparin (Frag-

min, 5000IU; Pfizer AG, Zürich, Switzerland), starting 12 hours preoperatively and continuing daily for 6 weeks postoperatively (31). When the wound conditions were appropriate, the foot was placed in a stabilizing walker or cast for 6 to 8 weeks. Weight-bearing was allowed as tolerated with the exception of patients who underwent additional corrective osteotomies (32–34).

After the walker or cast was removed, free ambulation and the rehabilitation program were initiated. The physiotherapeutic program included active and passive ankle motion, stretching and strengthening of the triceps surae, and proprioceptive exercises. Low level (e.g. hiking, swimming, biking, golfing) and normal level (e.g. doubles tennis, downhill skiing) activities were allowed according to rehabilitation status, usually after 3 and 6 months, respectively. Contact sports or activities with excessive impact forces were prohibited (35).

## Radiographic Assessment

The affected ankle was evaluated using weight-bearing radiographs in the sagittal and coronal planes. In patients with varus or valgus deformity a Saltzman view (36) was also acquired. To delineate alignment and component migration, angular and linear values were defined digitally (ImageAccess; Imagic AG, Glattbrugg, Switzerland) (18,37). Loosening of the tibial component was defined as a change in the position of the flat base by >2° relative to the long axis of the tibia and/or a progressive radiolucency of >2° on the anteroposterior and/or lateral radiograph (18). Loosening of the talar component, as seen on the lateral radiograph, was defined as subsidence into the talus by >5° relative to a line drawn from the top of the talonavicular joint to the tuberosity of the calcaneus (18,38). Minor changes in the position of the talar component on the anteroposterior radiographs were difficult to detect, and it was not possible to evaluate radiolucencies beneath the talar component on either view. In cases with suspicion of loosening of subsidence, a CT scan or single-photon emission computed tomography (SPECT-CT) (39) was performed.

## Clinical Assessment

All patients were evaluated preoperatively and postoperatively by two independent reviewers, who did not perform an operation on any of the patients. Clinical and radiographic follow-up was performed in our outpatient clinic at four months, one year, and annually
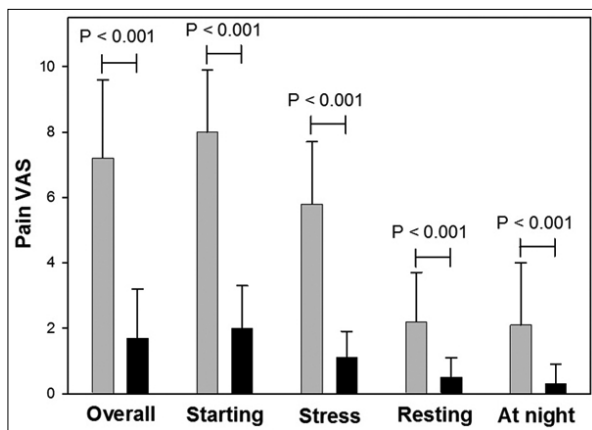
Figure 3 A graph showing preoperative (gray columns) and postoperative (black columns) levels of pain (VAS) for all patients. Data are presented as mean ± standard deviation.
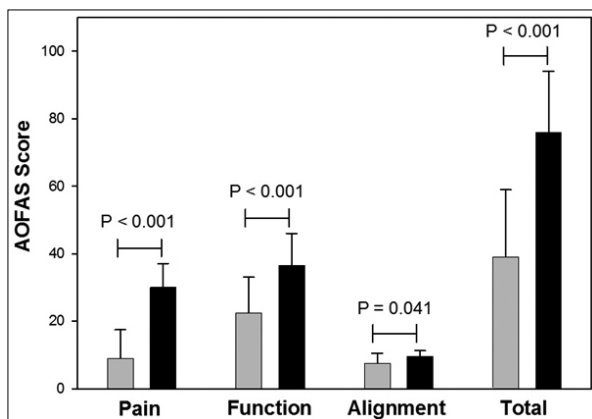


Figure 4 A graph showing preoperative (gray columns) and postoperative (black columns) AOFAS-hindfoot scores for all patients. Data are presented as mean ± standard deviation.

thereafter. The mean time to final follow-up was 5.1 years (range, 4 to 9 years).

Ankle range of motion was determined with a goniometer placed along the lateral border of the leg and foot (40). All goniometer measurements were performed in the weight-bearing position, comparable with the method described by Lindsjö et al. (41). The accuracy of the goniometric measurements was assessed by direct comparison with ankle range of motion measurements obtained from radiographs (18,40,42,43). Patients rated their pain on a visual analogue scale (VAS), from 0 (no pain) to 10 points (maximal pain) (44). In addition, the American Or-

thopaedic Foot & Ankle Society (AOFAS) hindfoot score was calculated (45).

## Statistical Analysis

A Kolmogorov-Smirnov normality test was performed to verify weather data were normally distributed or not. Paired Student t-test and Wilcoxon matched pairs test were used for data comparison in normally and not normally distributed data, respectively. A p value ≤ 0.05 was considered to be statistically significant. Data were analyzed using SPSS v20.0 (SPSS Inc., Chicago, IL) and SigmaPlot 2004 (Systat Software Inc., San Jose, CA).

## Results

Thirty-five ankles (8.4%) had to be revised at a mean of 3.2 years (range, 0.5 to 7.9 years) after the index surgery. Twenty-seven revision total ankle arthroplasties (6.5%) (using HINTEGRA total ankle prosthesis (46,47)) and eight ankle arthrodeses (1.9%) (using anterior double plating system (48)) were performed. Most likely the revision was performed in patients with 1st generation prosthesis with single coating with hydroxyapatite (n=17), rather than in patients with 2nd (n=10) or 3rd (n=8) generation prosthesis. The revision reasons were aseptic loosening of one or both component (n=23), subsidence of talar component (n=5), cyst formation (n=2), deep infection (n=1), unmanageable instability (n=1), and painful arthrofibrosis (n=3).

In 16 of the remaining 380 ankles (4.1%) radiolucency around the prosthesis components was seen. However, in none of the ankle progression of radiolucency was observed over the time.

The average VAS pain score decreased from 7.2 ± 2.4 (range, 5 to 10) to 1.7 ± 1.5 (range, 0 to 3) (p < 0.001) (Fig. 3). The average AOFAS hindfoot score increased significantly from 39 ± 20 (range, 15 to 78) to 76 ± 18 (range, 52 to 97) (p < 0.001) (Fig. 4). The average range of motion increased significantly from 22.5 ± 10.6° (range, 11° to 52°) to 34.3° ± 9.4° (range, 28° to 56°) (p < 0.01).

## Discussion

The treatment of patients with severely painful end-stage ankle osteoarthritis remains controversial. Two main surgical approaches are recommended in the current literature (49): total ankle replacement

(50,51) and ankle arthrodesis (52). In 2009, Saltzman et al. (53) performed a prospective controlled trial of total ankle replacement versus ankle arthrodesis showing that total ankle replacement provides better functional outcomes and equivalent pain relief.

In the current study, the revision rate was 8.4% which is comparable to other series recently published in the current literature. In a recent systematic review, including 13 Level IV peer-reviewed studies with 1105 TAR, the overall survival rate was approximately 90% at 5 years with a wide range between 68% and 100% (14). Haddad et al (54) also performed a systematic review between 1990 and 2005 where the survival rate was 78% and 77% after 5 and 10 years, respectively (54). Recently, we analyzed the risk factors for prosthesis component failure in a cohort including 722 consecutive ankles (55). Following independent risk factors for prosthesis component failure have been identified: HINTEGRA prosthesis generation (1st prosthesis generation Odds Ratio 15.04; 2nd prosthesis generation Odds ratio 5.95), etiology of ankle osteoarthritis (primary osteoarthritis Odds Ratio 7.19; posttraumatic osteoarthritis Odds Ratio 6.20), and patient age (age ≥ 70 years Odds Ratio 0.26) (55).

In our study, the majority of all patients experienced substantial pain relief postoperatively. However, Gougoulias et al. (14) reported in their systematic review of the literature that the residual pain in the hindfoot after a total ankle replacement was observed in considerable part of all patients - in up to 60%. In a previous study, we have shown that the patients with neutrally aligned talar component had significantly higher postoperative pain relief and better functional outcome including range of motion of replaced ankle (42). Total ankle replacement is a technically demanding procedure with a steep learning curve demonstrated in several clinical studies (56–59). Specifically, sagittal malposition of the talar component is a common intraoperative complication of this procedure (60,61), which may have negative biomechanical consequences such as reduced ankle motion and/or increased peak and average implant contact stresses (62–64). A substantial part of patients with remaining pain in replaced ankles is localized on the medial side and may be partially explained by medial pain syndrome (65).

In our patient cohort, the ankle range of motion substantially improved after total ankle replacement. In the current literature, a postoperative range of motion improved by approximately 4° to 14° (14). Therefore, the range of motion improvement should not be one of the most expected benefits from this procedure. In our previous studies addressing outcome of total ankle replacement in patients with secondary ankle osteoarthritis a relatively low improvement of range of motion was observed (66–68). However, the preserved range of motion of approximately 20° may be sufficient for the most all day activities resulting in usually high satisfaction of patients who underwent total ankle replacement.

In conclusion, the mid-term results with a minimum follow-up of 4 years in patients who underwent total ankle replacement are encouraging. Postoperatively, majority of the patient cohort experienced a substantial pain relief and functional improvement. However, total ankle replacement remains a technically demanding procedure and should be performed only by experienced foot and ankle surgeons who are familiar with this procedure and know how to address the concomitant hindfoot deformities and instabilities.

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Total ankle replacements have not met with as much success as total hip and knee replacements, and they may loosen within a few years of service. This is mainly due to the high load transfer demand over the relatively small ankle surface area and the need to replace three articulating surfaces (tibial, talar and fibular). Mechanical testing of total ankle replacements can also occur after implantation in cadaveric specimens. A mechanical joint simulator, shown in Fig. Optimizing outcomes begins with patient selection. The factors that I take into consideration are the patient's activity level, lifestyle, and interest in exercise. The limb alignment, the quality of the bone, and the presence of adjacent joint arthritis are important. Ankle joint replacement is an operation for hip and knee joints. Ankle Joint Replacements usually involves ankle fusion. Read about Ankle Joint Replacements. Gross C, Erickson BJ, Adams SB, et al; Ankle Arthrodesis After Failed Total Ankle Replacement: A Systematic Review of the Literature. Foot Ankle Spec. 2015 Jan 5. pii: 1938640014565046. DiDomenico LA, Anania MC; Total ankle replacements: an overview. Clin Podiatr Med Surg. 2011 Aug28(4):727-44. doi: 10.1016/j.cpm.2011.08.002. Total ankle replacement, also known as ankle arthroplasty, is carried out under general anesthetic or nerve block. Your surgeon will make an incision at the front or side of your ankle to expose the joint and cut away worn surfaces of your shin bone, called the tibia, and uppermost foot bone, called the talus. Good outcome scores and high satisfaction rate after primary total ankle replacement. Acta orthopaedica, 88(6), 675–680. https://doi.org/10.1080/17453674.2017.1366405. Company History.