**Title:** Randomized Controlled Trial Comparing Early Mobilization vs. Six Weeks of Immobilization in a Walking Cast Following Total Ankle Replacement

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**Author contributions:**

Participant recruitment for the study and data abstraction were done by J.R. Gait analyses were carried out by J.R. and P.H. Surgery was performed by M.S. Radiographic measurements were done by D.R., and outcome assessments were done by J.R. Statistical analyses were carried out by S.K. Discussion section was compiled by R.K. Manuscript was written and revised by J.R with supervision by N.C and reviewed by all co-authors before submission.

Abstract

Rehabilitation for patients after total ankle replacement traditionally involves weeks of immobilization in a plaster cast followed by progressive mobilization. Using a small randomized trial, we compared outcomes after implantation of a three-component cementless, unconstrained, mobile-bearing prosthesis for patients who had initial immobilization in a plaster cast for six weeks and patients who instead had early mobilization. Gait, clinical, patient-reported, and radiologic outcomes were measured. The study included 20 patients, 10 in the plaster cast group and 10 in the early mobilization group, and the demographics of the groups did not differ significantly. All patients were followed for 24 months. There were no significant differences between the two groups two years after surgery in ankle dorsiflexion, spatiotemporal gait characteristics, AOFAS ankle-hindfoot scores, Timed Up and Go Test times, WOMAC (pain, stiffness, function) scores, SF-36 (quality-of-life) scores, or patient satisfaction (pain relief, daily-living, recreational activities, and overall) (all *P*>0.05). Bone mineral density decrease of the medial malleolus and increase at middle tibia, calculated with DEXA scans, was significantly better in early mobilization than plaster cast group at one and two years postoperatively, but this was also the case preoperatively. The lack of differences in outcomes suggest that early ankle mobilization may be a safe and reliable method to enhance recovery following ankle arthroplasty with a three-component cementless, unconstrained, mobile-bearing prosthesis. Compared to traditional plaster casting, patients who are engaged in early mobilization after arthroplasty may enjoy similar functional, mobility, quality-of-life, pain relief, activity level, and satisfaction outcomes.

Level of Evidence: 2

Key Words: total ankle replacement, rehabilitation, postoperative management, walking plaster, early mobilization

Introduction

Total Ankle Replacement (TAR) is evolving into a valid alternative surgical treatment to ankle arthrodesis for patients with end-stage ankle arthritis (1, 2). Ankle prostheses designed for cementless insertion have demonstrated better results than earlier prostheses that were intended to be inserted with the use of bone cement (3). More recently, prostheses designed as three-component mobile-bearing implants have been used with encouraging results (4-7).

Rehabilitation for patients after TAR has typically included four to six weeks of immobilization in a plaster cast followed by progressive partial- or non-weight-bearing mobilization (8, 9). However, although the risk of venous thromboembolism after foot and ankle surgery is low, that risk is much higher when patients remain immobilized after surgery (10-12). Furthermore, prolonged periods of lower extremity immobilization are associated with bone and muscle atrophy and weakness (13-15).

The preferred early postoperative management of patients after TAR at our institution, guided by surgeon preference, has been early mobilization, without the use of below-knee weight-bearing plaster walking casts. Part of the rationale for this approach has been that it allows regular wound inspection and more straightforward management of wound issues when required.

However, there remains no standard postoperative management protocol for patients after TAR, so each institution has postoperative regimes that vary and are based on surgeon preference, patient bone quality, concurrent surgical procedures being performed, and patient capacity for rehabilitation. This approach has led to inconsistencies in the rehabilitation of patients after TAR, and it may have contributed to variability in the TAR results that have been reported in the literature.

Consequently, there is a need for additional research into the postoperative management of patients after TAR, with the goal of determining the optimal approach to rehabilitation. In this study, our aim was to compare gait, clinical, patient-reported, and radiologic outcomes for patients who were managed after TAR with either immobilization in a plaster cast for six weeks or early mobilization.

Patients and methods

The study was designed as a prospective randomized controlled trial (RCT) involving patients from a single center who had TAR performed by a single surgeon. It was approved by the National Health Service, Health Research Authority, National Research Ethics Committee North East - Newcastle and North Tyneside.

Patients who underwent primary TAR by the senior author (M.S.) between 5/1/2010 and 4/30/2014 for a diagnosis of primary or post-traumatic osteoarthritis were invited to enroll in the study. Exclusion criteria included the following: principal diagnosis other than osteoarthritis, prior history of ankle or foot reconstructive surgery, prior history of ankle infection, need for an additional procedure at the time of TAR (e.g. calcaneal osteotomy), peripheral vascular disease, marked osteoporosis of the ankle and foot, osteonecrosis of the talus, neurological disorder affecting the lower limb, inability to understand information about the study or to respond to questionnaires because of cognitive or language deficiencies, and refusal to consent to involvement in the study.

Written consent for the study was obtained from all patients. For patients who were enrolled, basic demographic information was collected and baseline outcome measures were performed, as described below. Patients were randomized the day before surgery using computer randomization to one of the two postoperative intervention arms: immobilization in a plaster walking cast for six weeks or early mobilization.

*Surgical technique and prosthesis*

All TAR surgery was performed by the senior author (M.S.). Cefuroxime 1.5 g was administered intravenously at induction, and 2 additional 750 mg doses were given every 8 hours after surgery. Patients were placed in a supine position and the affected side raised 20° using a thigh support. The limb was exsanguinated by elevation and an Esmarch bandage with tourniquet was applied up to the mid-thigh. A 12-cm midline anterior incision was made, centered over the middle of the talus at the level of the ankle joint, and carried over the extensor hallucis longus. The medial branch of the superficial peroneal nerve in the distal half of the wound was identified and retracted. The ankle joint was approached through the extensor hallucis longus sheath, leaving the tibialis anterior sheath intact, and the neurovascular bundle was retracted laterally. The ankle capsule was incised vertically to expose the distal tibial plafond and talus.

The yoke tibial adjustment tube was positioned over the anterior crest of the proximal tibia and secured with 2.5-mm pins. A tibial cutting block was angled to allow for a 5º slope posteriorly. A tibial rod was positioned parallel to the long axis of the tibia using the vertical regulator of the adjustment. A 4-mm segment of the distal tibia was resected using the non-depth-marked oscillating saw blade, keeping the blade in the midline to avoid the lateral and medial malleoli and the medial neurovascular structures. The joint was distracted using bone spreaders, and a reciprocating sawblade was used to release the medial edge of the tibial plateau by making a vertical cut in line with the medial side of the talus. The resected bone was removed, taking care not to fracture the medial malleolus.

A parallel 4-mm cut was made, removing the talar dome. Anterior and posterior chamfers were formed and peg holes drilled with appropriate instrumentation. A central tibial peg-cut was made and a prosthesis trial performed. The polyethylene thickness was measured, radiographs were obtained, and the correct size of components was confirmed. An uncemented prosthesis implantation was carried out after the final prosthesis trial was satisfactory. A bone window was created at the anterior tibia and the wound closed in layers. A Radivac drain was placed. An Opsite dressing was applied followed by wool and crepe bandages, all of which remained in place for 2 days. Patients were typically hospitalized for two nights after surgery.

The Mobility™ Total Ankle System (DePuy International Ltd., Leeds, UK), a three-component cementless, unconstrained, mobile-bearing prosthesis, was used for each patient. The system consists of Cobalt-Chrome tibial and talar components and an ultra-high-molecular-weight polyethylene (UHMWPE) mobile-bearing insert. The system offers six component size options and five bearing insert thickness choices.

*Post-operative follow-up and rehabilitation*

All patients had drain removal 24 hours after surgery. They had regular follow-up visits with the surgeon 2 weeks, 4 weeks, 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery.

Patients who were randomized to the plaster cast group had a backslab splint applied in the operating theater, which was replaced with a below-knee short-leg plaster cast after the drain was out. The plaster cast ensured that the ankle was maintained in a plantigrade position, so that patient weight was transferred through the heel when walking. Physiotherapy visits began once the plaster cast was applied, and they included training for eventual walking and ankle mobilization. While in the cast for six weeks, patients were limited to partial weight-bearing and walking with elbow crutches. The plaster cast was removed at the six-week visit, and patients were allowed to begin walking with the use of crutches and to progress to full weight-bearing over the subsequent six weeks. It was not until the second six-week period that these patients began a progressive physiotherapy program, which included ankle mobilization exercises followed by progressive ankle strengthening exercises, as well as posture, gait re-education, and balance exercises.

Patients who were randomized to the early mobilization group began partial to full weight-bearing once the drains were out, including performing active or active-assisted exercises. Physiotherapy visits commenced post-surgery and continued every 2 weeks for 12 weeks. Patients were provided with a splint to wear during the day when not exercising and at night when in bed. If patients were able to maintain the ankle in a plantigrade position at the six-week follow-up visit, they were advised to discard the splint. These patients also followed a progressive physiotherapy program, which included ankle mobilization exercises followed by progressive ankle strengthening exercises, as well as posture, gait re-education, and balance exercises; however, their program began one week after surgery.

*Outcome measures*

Most of the gait, clinical, and patient-reported outcomes were assessed preoperatively and at one year and two years postoperatively. However, patient satisfaction was measured just once, 2 years after surgery.

Gait outcomes were determined by measuring ankle dorsiflexion range-of-motion (ROM), which was calculated using 3-dimensional analysis, and by assessing spatiotemporal gait characteristics, which were calculated using gait analyses. Gait analysis was performed with a 12-camera VICON 3D motion capture system (Vicon Motion Systems Ltd, Oxford, UK) (16) and a Helen Hayes surface-marker set (17). For this analysis, patients were asked to walk along a 10-meter walkway at a self-selected, comfortable speed, and 12 walking trials, each with at least 2 complete gait cycles, were recorded for each patient at each session. Mean values for ankle dorsiflexion and spatiotemporal characteristics (cadence, step length, step time, stride length, stride time, and walking speed) were determined for each patient at each evaluation session by one of two examiners (J.R. or P.H.).

Clinical outcomes were determined using the American Orthopaedic Foot and Ankle Society (AOFAS) (18) ankle-hindfoot score (18-23) and the Timed Up and Go Test (TUG) (24, 25). For the TUG test, patients were asked to rise from a standard armchair, walk to a marker three meters away, turn, walk back, and sit down again; results were reported as the time needed to complete the test. A standard pro forma document, which included a list of possible intraoperative and postoperative surgical complications, medical complications, and procedures required to address complications, was used to record complications for the study.

Patient-reported outcomes were determined using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) (26) and the Short-Form Health Survey (SF-36) (27-31). Patient satisfaction was assessed using a short self-administered questionnaire that has produced valid and reliable measurements of patient satisfaction following primary hip and knee arthroplasty (32).

*DEXA scan bone mineral density (BMD) analysis*

Measurements of the BMD of six different bony areas around the prosthesis (medial malleolus, middle tibia, lateral malleolus, middle fibula, tibial component, talar component) were carried out using DEXA (Dual Energy X-ray Absorptiometry) scans. DEXA scans were performed before and one year after surgery, using HOLOGIC Delphi-W and Discovery-A DEXA scanners (HOLOGIC, Inc., Manchester, UK) and their recommended calibrations and quality controls. Patients were scanned in the seated position with the index leg fully extended, parallel to the couch side, and internally rotated approximately 15°, based on a mortise radiographic view (Fig. 1). The scans were carried out from the proximal half of the metatarsals to the distal third of the tibia and fibula.

Rectangular 17 x 17 pixel regions-of-interest (ROI) were positioned to measure the 6 areas of interest on each DEXA scan (Fig. 1). A template from the preoperative scan of each patient containing the six ROI was developed and then transferred (using software) to the postoperative scan. This technique allowed the comparison of identical ROI in the two DEXA scans that each patient had, with calculations performed by a single examiner (D.R.), who was blinded to which group the patients were in.

*Plain radiographic analyses*

Plain anteroposterior (AP) and lateral ankle weight-bearing dorsiflexion and plantarflexion radiographs of the ankle were obtained at 6 weeks, 12 weeks, 6 months, 1 year, and 2 years after surgery.

*Statistical methods*

Results were presented as means and standard deviations (SD) or as frequencies. Demographic characteristics of the two groups were compared using the unpaired t-tests. Outcomes in the two groups, including ankle dorsiflexion ROM, spatiotemporal gait characteristics, as well as AOFAS, TUG, WOMAC, and SF-36 scores, were compared using the repeated measures ANOVA, as the data analyzed represented multiple assessments on the same patients over time. Patient satisfaction levels in the two groups were compared using the Chi-square test. All tests were two-tailed and statistical significance was defined at the 5% (*P* ≤ 0.05) level.

As this study was constrained by the inclusion of a relatively small sample of 20 patients, a retrospective (post-hoc) statistical power analysis was performed for power estimation, using the T-test to compare outcomes, preoperatively to 2 years postoperatively, by group. We set alpha to .05 and deemed a power of .80 or more to be optimal (though we report all power results greater than .60). This was done to determine whether power was sufficient to provide support for clinical significance when significant differences were not observed.

Statistical analyses were performed with SPSS software, version 19 (SPSS, Inc., Chicago, Illinois).

Results

*Patient Demographics*

The follow-up for all patients was 24 months. There were a total of 20 patients in the study; 10 patients were in the plaster cast group and 10 patients were in the early mobilization group. For the total population, mean (SD) age was 63.6 (10.9) years and mean (SD) body mass index (BMI) was 29.4 (4.1). There were no significant differences in age, gender, primary diagnosis, side of surgery, or BMI between the two groups (all *P* > 0.05) (Table 1).

*Gait outcomes*

None of the differences in mean ankle dorsiflexion ROM between the plaster cast group and the early mobilization group were significant, not only preoperatively but also at 1 year and 2 years postoperatively (all *P* > 0.05). Mean ROM increased for both groups from preoperatively to 2 years postoperatively (plaster cast group, 6.1° to 8.4°; early mobilization group, 4.4° to 8.8°), but these increases were not statistically significant (both *P* > 0.05).

Based on gait analyses, mean cadence was significantly lower in the plaster cast group than in the early mobilization group (96.1 steps per minute vs. 107.8 steps per minute, *P* = 0.047) preoperatively, but it did not differ significantly between them at 1 year (*P* = 0.32) or 2 years (*P* = 0.35) postoperatively (Table 2). Mean step time was significantly higher in the plaster cast group preoperatively (0.66 seconds vs. 0.56 seconds, *P* = 0.02), but no difference was observed between the 2 groups postoperatively (all *P* > 0.05).

At 1 year after surgery, walking speed was significantly faster in the early mobilization group than in the plaster cast group (1.07 m/sec vs. 0.83 m/sec, *P* = 0.002) (Table 2). However, no significant differences were observed between the plaster cast and early mobilization groups at 2 years postoperatively in mean step length (*P* = 0.64), step time (*P* = 0.26), stride length (*P* = 0.64), stride time (*P* = 0.36), and walking speed (*P* = 0.08).

Mean cadence increased from before to 2 years after surgery in the plaster cast group (from 96.1 steps per minute to 101.4 steps per minute; *P* = 0.66), while it decreased in the early immobilization group from 107.8 steps per minute to 107.5 steps per minute (*P* = 0.90); however, neither of these changes was statistically significant. Likewise, mean walking speed before surgery was compared to 2 years after surgery and increased from 0.75 meters per second to 0.91 meters per second in the plaster cast group (*P* = 0.13), as well as from 1.04 meters per second to 1.10 meters per second in the early mobilization group (*P* = 0.29), but neither of these increases was significant.

*Clinical outcomes*

No significant differences in mean AOFAS scores were identified between the plaster cast and early mobilization groups preoperatively (22.7 vs. 27.1, *P* = 0.40), or at 1 year (80.8 vs. 84.7, *P* = 0.49) and 2 years (76.2 vs. 83.4, *P* = 0.27) postoperatively (Fig. 2). However, mean AOFAS scores increased significantly from before to 2 years after surgery for both groups (plaster cast group, 22.7 to 76.2, *P* = 0.001; early mobilization group, 27.1 to 83.4, *P* = 0.02).

Also, no significant differences in TUG time were observed between the plaster cast and early mobilization groups preoperatively (*P* = 0.48) or 1 year (*P* = 0.13) and 2 years (*P* = 0.95) after surgery (Fig. 3). However, mean TUG times decreased significantly from before to 1 year after surgery for both groups (plaster cast group, 12.8 seconds to 9.7 seconds, *P* = 0.001; early mobilization group, 12.1 seconds to 9.8 seconds, *P* = 0.03).

*Patient-reported outcomes*

No significant differences were identified in the WOMAC scores between the plaster cast and early mobilization groups preoperatively or 1 year and 2 years postoperatively (all *P* > 0.05) (Fig. 4). However, for both the plaster cast and early mobilization groups, mean WOMAC scores for pain (*P* = 0.02 and *P* = 0.03, respectively), function (*P* = 0.03 and *P* = 0.02, respectively), and stiffness (*P* = 0.04 and *P* = 0.045, respectively) improved significantly for both groups from before to 2 years after surgery.

No significant differences in the SF-36 scores were found between the plaster cast and early mobilization groups preoperatively or 1 year and 2 years postoperatively (all *P* > 0.05) (Fig. 5). For both groups from baseline to 2 years postoperatively, SF-36 scores improved significantly for 5 out of 8 domains (physical function, role physical, bodily pain, vitality, and social function) (all *P* < 0.05) and did not improve significantly for 3 out of 8 domains (mental health, role emotional ,and general health) (all *P* > 0.05).

No significant differences were identified between the plaster cast and early mobilization groups for patient satisfaction related to pain relief (*P* = 0.29) (Fig. 6), activities of daily living (*P* = 0.62) (Fig 7), and recreational activities (*P* = 0.64) (Fig. 8), or for overall satisfaction with surgery (*P* = 0.29) (Fig. 9).

*Bone Mineral Density*

BMD was significantly higher in the early mobilization than the plaster group at both the medial malleolus and middle tibia at 1 year (*P* = 0.01 and *P* = 0.01, respectively) and 2 years (*P* = 0.04 and *P* = 0.01, respectively) postoperatively, but this was observed preoperatively as well (*P* = 0.02 and *P* = 0.03, respectively) and (Table 3). BMD was significantly lower in the plaster cast than the early mobilization group at the lateral malleolus preoperatively (*P* = 0.02), but then it was significantly higher in the plaster cast group at 1 year postoperatively (*P* = 0.04). It was also significantly higher in the early mobilization group at the middle fibula, but only at 1 year postoperatively (*P* = 0.03).

From preoperatively to 2 years postoperatively, there was a significant increase in BMD in the medial malleolar and middle tibial regions in the plaster cast group (0.5594 to 0.6993 g/cm2, *P* = 0.01; 0.658 to 0.7977 g/cm2, *P* = 0.001; respectively) and in the early mobilization group (0.8116 to 0.8488 g/cm2, *P* = 0.009; 0.8322 to 1.0558 g/cm2, *P* = 0.001; respectively). In contrast, the lateral malleolar BMD decreased from preoperatively to 2 years postoperatively in the plaster group (0.4748 to 0.451 g/cm, *P* = 0.08) and in the early mobilization group (0.6957 to 0.5438, *P* = 0.36), though neither change was significant.

*Complications*

Medial malleolar fractures occurred in two patients in the plaster cast group and two patients in the early mobilization groups, and they all occurred within three months of TAR surgery. These fractures were undisplaced and did not require surgical fixation and were managed conservatively. No other complications on the pro forma list were reported.

*Power Analysis*

The observed power for the improvement in ankle dorsiflexion in the plaster cast group was 79.9%; the observed power for the remainder of the gait outcome variables in both groups was less than 60%. The observed power for differences in BMD in both groups was less than 60% and for the improvements in AOFAS and TUG score in both groups were 100% and 81.4%, respectively. For WOMAC scores, the observed power for both groups was 100% for the pain domain, 60.8% for the function domain, and 62.4% for the stiffness domain. For SF-36 scores, the observed power for both groups was 70.7% for physical function, 72.5% for physical role, and 71.2% for bodily pain.

Discussion

To the best of our knowledge, there have been no studies comparing different postoperative rehabilitation approaches following TAR. The aim of this small RCT was to determine whether there were any clinically significant differences in outcomes between patients who were immobilized for six weeks and patients who had early mobilization after TAR. We observed no significant differences between these two groups postoperatively in ankle dorsiflexion ROM, almost all spatiotemporal gait characteristics, AOFAS scores, TUG times, WOMAC scores, SF-36 scores, patient satisfaction, or complication rates. The only significant differences between the groups were observed in BMD. Among these, we found that postoperative medial malleolar and middle tibial BMD were significantly higher in the early mobilization group than in the plaster cast group, but this was the case preoperatively as well.

For many years, the traditional gold standard treatment for end-stage ankle arthritis has been ankle fusion (arthrodesis). More recently, TAR (arthroplasty) has gained in popularity, and the newer third-generation ankle arthroplasty prosthetic designs have demonstrated predictable early- and mid-term improvements in the functional status and gait of patients who have received these devices (4-7).

After both arthrodesis and arthroplasty procedures, the ankle has traditionally been immobilized during the immediate postoperative period, to allow for soft tissue and bone healing. However, the duration of immobilization needed following ankle arthroplasty has generally been determined by the personal preferences and experiences of surgeons. Indeed, in the published literature, the period of time that patients spend in a below-knee cast after TAR has varied from 10 days to 6 weeks (33, 34)

The amount of early ankle stability after surgery has been considered important in determining the optimal postoperative rehabilitation approach. The forces exerted on the ankle can be substantial. The tibiotalar articular surface has an approximate surface area of 7 cm2 (24). Approximately 77% to 90% of patient weight-load during walking is transmitted through the tibial plafond to the talar dome (25). The average compressive load per unit area at the tibiotalar interface during gait is estimated to be about 3.5 MPa (equivalent to 507 psi) in an average patient with a body weight of around 700 Newtons (equivalent to 157 lbs.) (26). The intensity of these forces elevates the importance of determining the best approach to rehabilitation after placement of third-generation arthroplasty prostheses, particularly because most of these are inserted in a cementless fashion.

We began our outcomes analysis by measuring ankle dorsiflexion ROM. Ankle dorsiflexion is important to knee stability during the early-stance gait phase and to developing a healthy gait pattern (35). We observed no significant differences between the plaster cast patients and early mobilization patients in ankle dorsiflexion ROM at one and two years after surgery, suggesting that neither rehabilitation approach resulted in superior mid-term dorsiflexion ROM. At the same time, when comparing results before and two years after surgery, we did note improvements in ankle dorsiflexion ROM in both groups, though these were not statistically significant. These results could be considered similar to the limited improvements in ankle dorsiflexion reported in other comparable studies (28,30-32,36).

We also performed gait analyses on all patients, including at one year and two years after TAR. We found that most of the spatiotemporal gait characteristics did not differ significantly between the two groups postoperatively, except that walking speed was significantly faster in the early immobilization group than in the plaster cast group, but only at one year postoperatively. These findings suggest that neither rehabilitation approach resulted in superior mid-term gait outcomes.

We also observed that a low cadence improved over time in the plaster cast group, while a high cadence was maintained over time in the early mobilization group, and stride length was also maintained over time in both groups. Improved cadence and stride lengths after TAR have been documented by Queen et al (36) with the STAR™ implant and by Brodsky et al (37, 38) with the SALTO™ implant. However, many previous reports about gait changes after arthroplasty have compared the results in their study populations to those for age-matched controls (39-41). Instead, similar to Hahn et al (42), we used preoperative gait analysis results in the same patients as the controls in our study. Furthermore, our results may be helpful to others as we are not aware of any previous prospective studies using gait analysis in patients who have had TAR with the Mobility™ Total Ankle System.

We measured clinical outcomes using AOFAS scores and TUG times. Though there were no significant differences in AOFAS scores between the two groups in our study, both groups did demonstrate significant improvements in AOFAS scores from preoperatively to 2 years after surgery. These are similar to the results from a meta-analysis of 1,086 patients having TAR, which was published by Stengel et al in 2005 (43). We also observed no significant differences in the TUG times between the two groups. However, we did find that TUG times improved significantly in both groups from before to one year after surgery. The TUG test has previously been shown to yield valid results when assessing ankle mobility (44, 45). Similar to our results, Queen et al also reported significant improvements in TUG times postoperatively in their 51 who underwent TAR (46). Taken together, these AOFAS and TUG test results also indicate that neither rehabilitation approach resulted in superior early- or mid-term mobility.

Like with other outcomes that we measured, we also found no significant differences between the plaster cast and early mobilization groups postoperatively for the following patient-reported outcomes: WOMAC pain, function, and stiffness scores; SF-36 scores; and satisfaction related to pain relief, activities of daily living, recreational activities, and overall. These results suggest that neither rehabilitation approach resulted in superior mid-term patient perceptions or satisfaction after TAR. That said, WOMAC scores for pain, function, and stiffness, as well as SF-36 scores, all improved significantly from preoperatively to 2 years postoperatively. Similar improvements in patient-reported outcomes have been reported in the literature pertaining to other types of ankle implants (47-51).

Finally, in contrast to most of our findings, we did observe significantly better BMD in the early mobilization than the plaster cast group postoperatively in the medial malleolus, middle tibia, and middle fibula. However, most of these differences were also present preoperatively. Thus, the role that different rehabilitation approaches played in short- and mid-term ankle BMD improvements was indeterminate. Within each group, we also found that BMD in the medial malleolus and middle tibia improved significantly between baseline and 2 years after surgery. An improvement in the bone density of the distal tibia has been previously reported by Zerahn et al, when it was measured 12 months after implantation of the cementless STAR™ ankle prosthesis (52, 53). Increased trabecular remodeling has also been noted by others on plain radiographs of the distal tibia following arthroplasty (42). In contrast, we noted a reduction two years after surgery in the BMD of the lateral malleolus in both groups, and although the difference did not achieve statistical significance, we wonder whether such changes could occur as a result of stress shielding. A longer-term study would be necessary to determine if there are any BMD deficiencies that occur after TAR and, if so, whether they might improve with the passage of time. It would be preferable to see diffuse peri-prosthetic bone density increases over the long term, as this would be more likely to be associated with a stable bone-implant interface.

This study has several limitations. The patient populations in the two groups were relatively small, so that despite the fact that it was a randomized trial, this may have made it difficult to demonstrate differences between the groups. Using a retrospective power analysis, we determined that the study had a power of more than 70% for only the improvements identified over time in ankle dorsiflexion, AOFAS scores, TUG times, WOMAC pain domain, and 3 of the 4 physical SF-36 domains. Thus, a study with a larger sample size would be required to confirm our findings for the variables that did not have sufficient power. As such, we hope that ours may serve as a pilot study upon which a more robust RCT might be based. Another limitation is that we did not perform an in-depth analysis of the plain radiographic images over time, and although we used these images to measure anterior and lateral distal tibial and tibiotalar angles, we did not analyze this data for inclusion in this manuscript. Finally, because the study focused on comparing the two rehabilitation options, we did not perform a detailed analysis or comparison of complications. It is possible that complications other than those reported might have influenced some of the outcome results.

In conclusion, early ankle mobilization may be a safe and reliable method to enhance recovery following ankle arthroplasty with a three-component cementless, unconstrained, mobile-bearing prosthesis. Compared to traditional plaster casting, patients who are engaged in early mobilization after arthroplasty may enjoy similar functional, mobility, quality-of-life, pain relief, activity level, and overall satisfaction outcomes. This study could serve as the basis for a more robust RCT to confirm these findings.

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