

Are There Differences in Gait Mechanics in Patients With A Fixed Versus Mobile Bearing Total Ankle Arthroplasty? A Randomized Trial

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Abstract

Background Total ankle arthroplasty (TAA) is an alternative to arthrodesis, but no randomized trial has examined whether a fixed bearing or mobile bearing implant provides improved gait mechanics.

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This work was performed at Duke University, Durham, NC, USA.

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Questions/purposes We wished to determine if fixed- or mobile-bearing TAA results in a larger improvement in pain scores and gait mechanics from before surgery to 1 year after surgery, and to quantify differences in outcomes using statistical analysis and report the standardized effect sizes for such comparisons.

Methods Patients with end-stage ankle arthritis who were scheduled for TAA between November 2011 and June 2013 (n = 40; 16 men, 24 women; average age, 63 years; age range, 35–81 years) were prospectively recruited for this study from a single foot and ankle orthopaedic clinic. During this period, 185 patients underwent TAA, with 144 being eligible to participate in this study. Patients were eligible to participate if they were able to meet all study inclusion criteria, which were: no previous diagnosis of rheumatoid arthritis, a contralateral TAA, bilateral ankle arthritis, previous revision TAA, an ankle fusion revision, or able to walk without the use of an assistive device, weight less than 250 pounds (114 kg), a sagittal or coronal plane deformity less than 15°, no presence of avascular necrosis of the distal tibia, no current neuropathy, age older than 35 years, no history of a talar neck fracture, or an avascular talus. Of the 144 eligible patients, 40 consented to participate in our randomized trial. These 40 patients were randomly assigned to either the fixed (n = 20) or mobile bearing implant group (n = 20). Walking speed, bilateral peak dorsiflexion angle, peak plantar flexion angle, sagittal plane ankle ROM, peak ankle inversion angle, peak plantar flexion moment, peak plantar flexion power during stance, peak weight acceptance, and propulsive vertical ground reaction force were analyzed during seven self-selected speed level walking trials for 33 participants using an eight-camera motion analysis system and four force plates. Seven patients were not included in the analysis owing to cancelled surgery (one from each

group) and five were lost to followup (four with fixed bearing and one with mobile bearing implants). A series of effect-size calculations and two-sample t-tests comparing postoperative and preoperative increases in outcome variables between implant types were used to determine the differences in the magnitude of improvement between the two patient cohorts from before surgery to 1 year after surgery. The sample size in this study enabled us to detect a standardized shift of 1.01 SDs between group means with 80% power and a type I error rate of 5% for all outcome variables in the study.

Results This randomized trial did not reveal any differences in outcomes between the two implant types under study at the sample size collected. In addition to these results, effect size analysis suggests that changes in outcome differ between implant types by less than 1 SD. Detection of the largest change score or observed effect (propulsive vertical ground reaction force [Fixed: 0.1 ± 0.1 ; 0.0–1.0; Mobile: 0.0 ± 0.1 ; 0.0–0.0; $p = 0.051$]) in this study would require a future trial to enroll 66 patients. However, the smallest change score or observed effect (walking speed [Fixed: 0.2 ± 0.3 ; 0.1–0.4; Mobile: 0.2 ± 0.3 ; 0.0–0.3; $p = 0.742$]) requires a sample size of 2336 to detect a significant difference with 80% power at the observed effect sizes.

Conclusions To our knowledge, this is the first randomized study to report the observed effect size comparing improvements in outcome measures between fixed and mobile bearing implant types. This study was statistically powered to detect large effects and descriptively analyze observed effect sizes. Based on our results there were no statistically or clinically meaningful differences between the fixed and mobile bearing implants when examining gait mechanics and pain 1 year after TAA.

Level of Evidence Level II, therapeutic study.

Introduction

Ankle arthritis is a debilitating disease that may lead to deformity, recurrent pain [1], cartilage breakdown, and subsequent gait dysfunction [1, 14]. Each year more than 50,000 patients are diagnosed with this condition in the United States [4]. Changes in gait and pain are the most obvious signs of impairment, whereas other measures such as quality of life and self-reported physical function are compromised with increasing ankle arthritis severity [11, 14]. The degree of patient-reported physical impairment associated with ankle arthritis is equivalent to congestive heart failure [29], end-stage kidney disease [29], and end-stage hip arthritis [11, 29]. The current treatment options for end-stage ankle arthritis include total

ankle arthroplasty (TAA), ankle fusion (arthrodesis), and ankle distraction arthroplasty, none of which has been identified as the most-favorable treatment [28]. Ankle fusion is currently the standard surgical intervention for end-stage ankle arthritis [15, 18, 30]; however, TAA is increasing as a promising alternative and undoubtedly will replace arthrodesis as familiarity with the technique improves [3, 13, 16, 17, 25, 28, 30–33].

During the past decade, substantial advancements have been made to TAA implant designs that have resulted in two important types of implants: implants with a mobile UHMWPE bearing (mobile bearing) and those with a fixed polyethylene bearing (fixed bearing). The Scandinavian Total Ankle Replacement (STAR™ Ankle; Stryker Orthopaedics, Mahwah, NJ, USA) is a three-component design with a mobile polyethylene bearing that is designed to reduce rotational stress at the fixation interface of the implant [7, 22]. The STAR™ Ankle (Fig. 1A) has a 93% survival rate at 5 years followup and 80% at 10 years followup [33]. When assessing function, the STAR™ Ankle replacement has been reported to improve dorsiflexion moments, ROM, and walking speed after surgery [9, 27]. Conversely, the two-component, fixed bearing Salto Talaris® (Integra Life Sciences, Plainsboro, NJ, USA) limits frontal-plane movement and maintains congruency in flexion and extension [3, 7, 20]. Previous research has indicated that patients who have received the Salto Talaris® implant (Fig. 1B) have substantial clinical and functional improvements after surgery with short-term (2-year followup) results indicating they are capable of returning to moderate exertional activities [5, 20, 25].

Clinical outcomes [2, 8, 21], radiographic alignment [8, 32], and survival rates [2, 32] of some implants have been assessed, but few gait analysis studies have examined longitudinal functional and biomechanical outcomes associated with TAA [6, 23–25, 27]. Patient-reported outcomes and the assessment of physical performance are important for understanding surgical outcomes because they provide complementary information [19]. Although patient-reported outcomes have been assessed in multiple studies [3, 7, 9, 24–26, 29], few studies have directly compared the effect of implant type on gait mechanics after TAA [27, 29]. These studies have indicated that most ankle mechanics are not substantially altered based on implant selection [25, 27]. For some previous studies [27, 29], TAA implant selection was at the discretion of the treating physician and, to our knowledge, no previous studies have examined the effect of fixed and mobile bearing TAA implant selection on gait mechanics in a randomized trial.

We therefore performed a randomized trial to determine whether fixed or mobile bearing TAA implants result in a larger improvement in gait mechanics and decrease in pain from before surgery to 1 year after surgery.

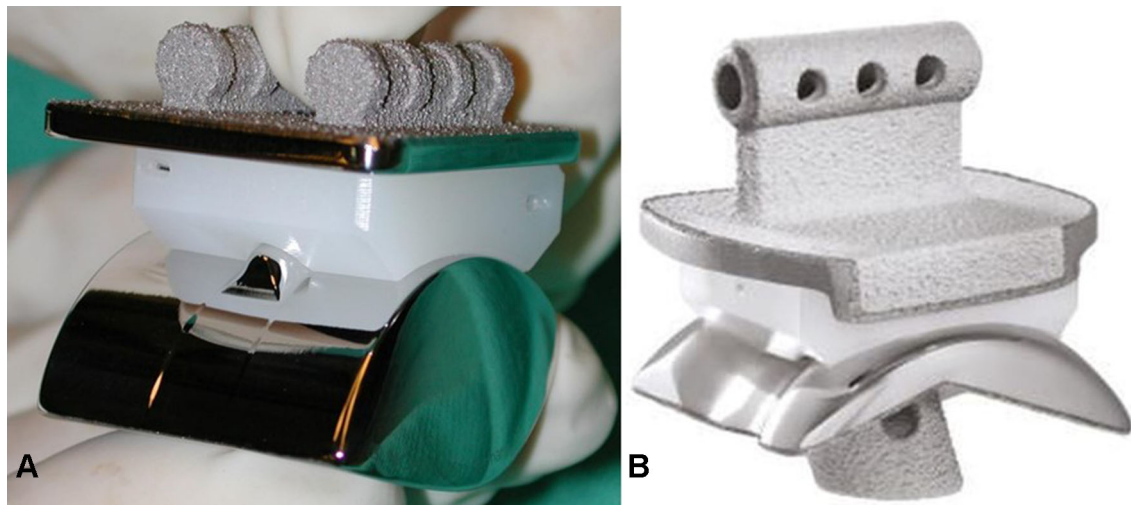
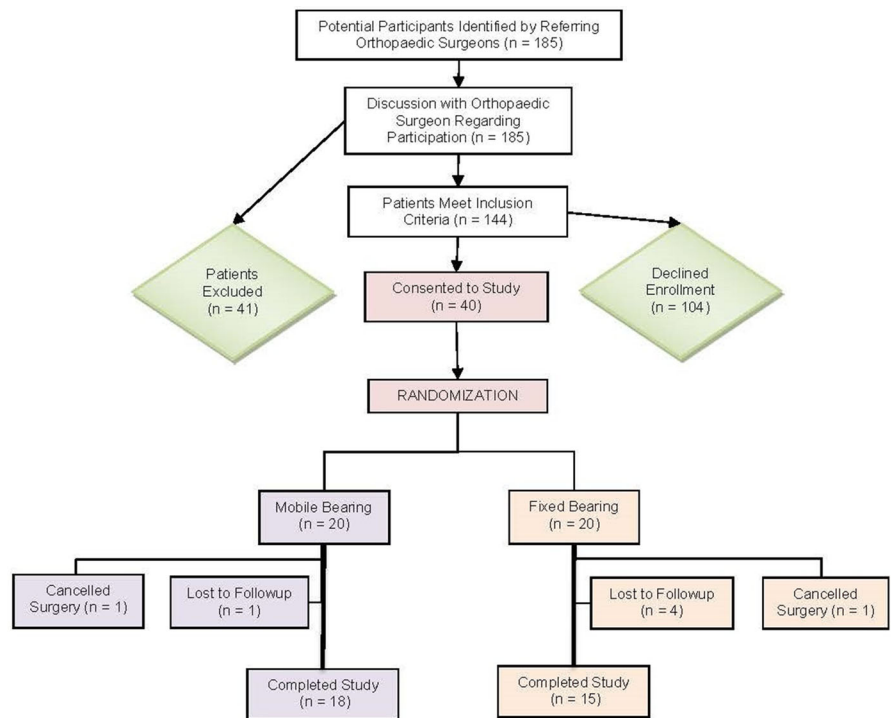


Fig. 1 A-B The (A) Scandinavian Total Ankle Replacement (STAR™) (mobile bearing) and (B) the Salto Talaris® implant (fixed bearing) are shown.

Fig. 2 The study flow diagram is shown.



Materials and Methods

Forty patients between 40 and 78 years old with end-stage ankle arthritis who were considering TAA for pain relief were prospectively enrolled between November 2011 and June 2013 in this study and were provided informed written consent before participation. During this time there were 185 patients scheduled for TAAs, and of these, 144 patients were eligible for study enrollment. Of these 144 eligible patients, 40 consented to participate in this randomized

trial (Fig. 2). This study was registered as a clinical trial at clinicaltrials.gov (Trial Number: NCT01504438) and institutional review board approval was obtained from Duke University for the primary data collection and from Virginia Tech for the data analysis. During the consent process, the patients were informed that they would be randomly assigned to one of two implant groups (either the mobile bearing STAR™ Ankle implant [n = 20] or the fixed-bearing Salto Talaris® implant [n = 20]) (Fig. 1) by a research assistant (TS and AS) who was not a member of

the surgical team. The research assistant then informed the treating surgeon of the implant that was selected. Any patients with a previous diagnosis of rheumatoid arthritis, contralateral TAA, bilateral ankle arthritis, revision TAA, ankle fusion revision, or who could not walk without the use of an assistive device were excluded from the study. In addition, patients who had any of the following were excluded: weight 250 pounds (114 kg) or greater, a sagittal or coronal plane deformity greater than 15°, avascular necrosis of the distal tibia or talus, neuropathy, age younger than 35 years, or a history of a talar neck fracture. All procedures were performed by a fellowship-trained foot and ankle orthopaedic surgeon (JD, JN, ME) in a single orthopaedic practice. All patients were scheduled for TAA within 2 weeks of their preoperative data collection and were tested again 1 year after surgery. Data were not collected past 1 year because previous studies have indicated limited improvement in gait mechanics after the 1-year postoperative assessment [25, 27].

An eight-camera motion analysis system sampling at 120 Hz (Motion Analysis Corporation, Santa Rosa, CA, USA) was used in conjunction with four force plates embedded in the walkway, sampling at 1200 Hz (AMTI, Watertown, MA, USA) to collect ground reaction forces during self-selected speed level walking. Each participant was asked to wear form-fitting shorts and a shirt and to walk barefoot during testing to control for changes in the ground reaction forces associated with variations in footwear. A modified Helen Hayes marker set which included the addition of a heel triad and modifications to the pelvic markers was used for testing as has been described in previous TAA gait mechanic studies [12, 24–26]. Seven self-selected speed walking trials were collected along a 10-m walkway. Participants were asked to walk at a comfortable speed that was similar to the speed they would walk when grocery shopping. For a walking trial to be used in the analysis, the participant had to contact the force plate on the affected side without targeting the force plate and all of the marker data had to be collected during the trial.

All participants completed an instrumented three-dimensional (3-D) lower extremity gait assessment and a paper-based visual analog pain scale preoperatively and again 1 year after surgery. The visual analog pain scale was given to each patient when they were preparing to complete the gait assessment. Each patient was asked to mark the level of pain they currently were experiencing with an X on a 100 mm line. The line was bounded from no pain to the worst pain imaginable. The distance from the no-pain starting line to where the X crossed the line was measured in millimeters and recorded. Walking speed, peak dorsiflexion angle, peak plantar flexion angle, sagittal plane ankle ROM, peak ankle inversion angle, peak plantar flexion moment, peak plantar flexion power during stance,

peak weight acceptance, and propulsive vertical ground reaction force were collected bilaterally during each of the walking trials; however, this project focused on the affected side (surgical side). Time-synchronized 3-D coordinate data and ground reaction force data were exported from the motion analysis system and imported to Visual3D (C-Motion Inc, Germantown, MD, USA) to complete data processing for the kinetic and kinematic data. Joint angles were calculated as the Cardan angles between adjacent local segments, whereas ankle moments were calculated through inverse dynamics and transferred to the segment coordinate system and expressed as internal moments. Ground reaction forces were normalized to body mass and joint moments were normalized to body mass and height. Data were normalized to the stance phase of gait (initial ground contact to toe-off) and analyzed during the stance phase of the gait cycle. The dependent variables of interest were obtained using custom software developed in MATLAB R2010a (MathWorks, Natick, MA, USA).

Statistical Analysis

Demographic data (age, height, body mass, BMI, pain, and walking speed) were compared using an independent-samples t test to ensure that the groups were not significantly different at baseline (Table 1). The primary purpose of the analysis is to report effect sizes for postoperative and preoperative changes (ie, increases) in outcomes on the basis of this randomized study. The mean postoperative and preoperative differences were compared between mobile and fixed bearing implant types using two-sample t-tests. Data were graphically inspected and all measures in this study appear plausibly normally distributed with equal variance in each group. Cohen's d was computed as a measure of effect size in this analysis. Cohen's d measures the number of SDs between sample means, that is, the difference between sample means divided by the pooled SD. The pooled SD is a measure of variability common to both groups. The variables of interest were patient-reported pain (VAS pain), walking speed, peak dorsiflexion angle, peak plantar flexion angle, sagittal plane ankle ROM, peak ankle inversion angle, peak plantar flexion moment, peak plantar flexion power during stance, peak weight acceptance, and propulsive vertical ground reaction force. Thirty-three patients (Table 1) completed the entire research protocol and were included in the statistical analysis. Of the seven patients who were not included in the statistical analysis, two cancelled surgery (one participant from each group) after signing informed consent, and five (four in the fixed bearing group and one in the mobile bearing group) did not return for the 1-year postoperative gait assessment. This sample size provides 80% power to detect standardized shifts of $d = 1.01$ in the

Table 1. Demographic variable comparison between patients who were randomized to the fixed bearing and the mobile bearing implant groups

Demographic	Fixed bearing (n = 15)	Mobile bearing (n = 18)	p Value
Age (years)	61 ± 13 (40–78)	65 ± 9 (41–75)	0.262
Mass (kg)	77 ± 15 (60–110)	85 ± 20 (54–107)	0.131
Height (m)	1.69 ± 0.07 (1.55–1.87)	1.68 ± 0.08 (1.60–1.80)	0.765
BMI (kg/m ²)	27 ± 5 (19–35)	30 ± 6 (22–41)	0.084
Walking speed (m/second)	0.94 ± 0.28 (0.53–1.19)	0.86 ± 0.20 (0.56–1.52)	0.185
Gender	Male = 7 (47%) Female = 8 (53%)	Male = 4 (22%) Female = 14 (78%)	
Surgical side	Right = 12 (80%) Left = 3 (20%)	Right = 11 (61%) Left = 7 (39%)	

Mean ± SD (range) for age, mass, height, BMI, and preoperative walking speed.

Table 2. Preoperative differences in variables of interest between fixed and mobile bearing implant groups

Variable	Fixed bearing (n = 15)	Mobile bearing (n = 18)	Cohen's d	p Value
VAS pain	72.4 ± 23.8 (59.2–85.6)	73.9 ± 17 (65.4–82.3)	0.073	0.835
Walking speed (m/second)	0.9 ± 0.3 (0.8–1.1)	0.9 ± 0.2 (0.8–1.0)	−0.318	0.370
Peak plantar flexion angle (°)	3.2 ± 3.8 (1.1–5.3)	1.2 ± 3.7 (−0.7 to 3.0)	−0.542	0.131
Sagittal plane ankle ROM (°)	9.7 ± 2.8 (8.2–11.3)	9.9 ± 4.6 (7.7–12.2)	0.060	0.866
Peak ankle inversion angle (°)	6.2 ± 2.5 (4.8 to 7.5)	5.6 ± 2.6 (4.3 to 7)	−0.199	0.573
Peak plantar flexion moment (Nm/kg)	1.2 ± 0.3 (1.0–1.3)	1.1 ± 0.3 (0.9–1.2)	−0.470	0.189
Peak plantar flexion power (W/kg)	0.4 ± 0.2 (0.3–0.6)	0.3 ± 0.2 (0.3–0.4)	−0.600	0.096
Peak weight acceptance ground reaction force (body weight)	1.0 ± 0.1 (1.0–1.0)	1.0 ± 0.1 (1.0–1.1)	0.158	0.655
Peak propulsive ground reaction force (body weight)	1.0 ± 0.1 (1.0–1.0)	1.0 ± 0.1 (0.9–1.0)	−0.020	0.955

Mean ± SD (95% CI) in the patients undergoing total ankle arthroplasty before surgery.

postoperative and preoperative changes in outcomes between implant types. The Cohen d effect size was computed in the mobile compared with fixed bearing direction; hence positive d values correspond to larger average increases in outcomes among patients with mobile bearing implants than patients with fixed bearing implants. All statistical analyses were completed using R version 3.3.3 (<https://www.r-project.org/>; The R Foundation for Statistical Computing, Vienna, Austria) (with the level for statistical significance set at $\alpha = 0.05$). An analysis using a series of t tests indicated that no difference existed between the two implant groups at the preoperative assessments (Table 2).

Results

There were no differences between the two implant groups when comparing the change score from preoperative to 1 year after surgery (Table 3), with the numbers available in this study. For example, the propulsive vertical ground reaction force (Fixed: 0.1 ± 0.1 , 0.0–1.0; Mobile: 0.0 ± 0.1 , 0.0–0.0; $p = 0.0051$) in this study had the largest observed effect. To detect a difference between implant

types a future trial would require the enrollment of 66 patients (33 patients in each implant group). In addition, walking speed (Fixed: 0.2 ± 0.3 , 0.1–0.4; Mobile: 0.2 ± 0.3 , 0.0–0.3; $p = 0.742$) had a small observed effect. To detect a difference between implant types for walking speed a future trial would require the enrollment of 2336 participants (1168 patients in each implant group) to detect a significant difference with 80% power at the observed effect sizes. On the basis of this randomized trial, these data suggest a less than 1-SD difference between implant types.

Discussion

Patients who have end-stage ankle arthritis often have debilitating pain that limits mobility and can dramatically alter quality of life. The current treatment options for end-stage severe ankle arthritis include ankle fusion and TAA. However, the selection of the implant used during the TAA is currently dependent on surgeon preference and, to our knowledge, no randomized trials have assessed changes in gait mechanics after TAA. Previous studies have indicated that implant selection does not alter gait mechanics when

Table 3. Comparisons in outcome increase or decrease from preoperative to postoperative condition for fixed and mobile bearing total ankle arthroplasty implant groups

Variable	Fixed bearing (n = 15)	Mobile bearing (n = 18)	Cohen's d	p Value	Total number to detect this effect
VAS pain	-57.9 ± 24.8 (-71.6 to -44.1)	-52.3 ± 23.1 (-63.8 to -40.8)	0.231	0.513	592
Walking speed (m/second)	0.2 ± 0.3 (0.1-0.4)	0.2 ± 0.3 (0-0.3)	-0.116	0.742	2336
Peak plantar flexion angle (°)	1.5 ± 5 (-1.3 to 4.2)	3.1 ± 4.1 (1.0-5.1)	0.354	0.318	254
Sagittal plane ankle ROM (°)	2.5 ± 3.5 (0.5-4.4)	1.8 ± 5.4 (-0.9 to 4.5)	-0.139	0.694	1628
Peak ankle inversion angle (°)	0.3 ± 2.3 (-1 to 1.6)	-0.4 ± 3 (-1.9 to 1.1)	-0.268	0.449	440
Peak plantar flexion moment (Nm/kg)	0.2 ± 0.3 (0-0.3)	0.1 ± 0.3 (0-0.3)	-0.201	0.569	780
Peak plantar flexion power (W/kg)	0.2 ± 0.3 (0-0.3)	0.1 ± 0.2 (0-0.3)	-0.161	0.648	1214
Peak weight acceptance ground reaction force (body weight)	± 0.1 (0-0.1)	0 ± 0.1 (0-0.1)	-0.355	0.318	252
Peak propulsive ground reaction force (body weight)	± 0.1 (0-0.1)	0 ± 0.1 (0-0)	-0.708	0.051	66

Mean ± SD (95% CI) in the patients undergoing total ankle arthroplasty; total number to detect = sample size (to be split evenly between two implant groups) required to detect the observed effect sizes in this study.

the implant is selected by the treating physician [25, 27]. In addition, previous studies have shown that patient-reported outcomes are not substantially different between fixed bearing and mobile bearing implants during retrospective comparisons between these two implant types [10, 25]. Therefore, the purpose of our study was to determine whether the selection of TAA type altered patient gait mechanics and pain when the implant was randomized between a fixed and a mobile bearing implant. At 1 year after surgery, we found no differences between the fixed and mobile bearing TAA implant groups. To our knowledge, the Cohen's d statistics in this study are the first published estimates based on a randomized trial of the true standardized delta between groups in the population, hence this study furnishes effect sizes that are useful when considering further randomized trials comparing fixed and mobile bearing implants.

This study has some limitations. The study examined patients with severe ankle arthritis before TAA. Although this patient selection allowed for randomization of patients into both implant groups, these results are applicable only to patients who meet all of the study inclusion criteria (no previous diagnosis of rheumatoid arthritis, a contralateral TAA, bilateral ankle arthritis, previous revision TAA, an ankle fusion revision, or able to walk without the use of an assistive device, less than 250 pounds (114 kg), a sagittal or coronal plane deformity less than 15°, no presence of avascular necrosis of the distal tibia, no current neuropathy, age older than 35 years, no history of a talar neck fracture, or an avascular talus). These results may not be applicable to patients with severe hindfoot deformities, those having a revision TAA or fusion takedown procedure, or patients who need an assistive device during ambulation. Patients with severe arthritis could be using pain-relieving

medications, which was not considered in this study but could affect walking mechanics. While gait mechanics may not be different based on these two implants of each type (fixed versus mobile bearing), other differences between implant types could exist. For example, polyethylene wear rates and potential differences in failure rates between implants need to be examined in future work through an expansion of this randomized trial to assess whether these measures are different between implant types. Therefore, these results cannot be generalized to all fixed bearing and mobile bearing implants. In this study, surgery cancellation and loss to followup reduced sample size by seven patients, with five in the fixed bearing and two in the mobile bearing groups. Fisher's exact test concludes that these losses between groups were not statistically disproportionate ($p = 0.408$). Even though our reported Cohen's d statistics are novel estimates of the standardized delta between fixed and mobile bearing implants, this study is only powered to detect $d = 1.01$ sized shifts between groups, which is a rather large difference. We have used these estimates to calculate the size a future clinical trial would need to be to detect differences such as those observed. While we cannot interpret the findings of this study to conclude there is no true difference between the groups, we have established estimates of how large the differences are on the basis of these data and provided guidance to the appropriate-sized trial that would be necessary to further refine these estimates in the context of statistical significance (Table 3). Future studies may include larger sample sizes to render smaller effects statistically detectable.

To our knowledge, there have not been any previously published randomized trials assessing the effect of implant type on patient gait mechanics after surgery. Previous studies of surgeon-selected implant groups indicated that

there are no differences in patient gait mechanics based on implant selection [25, 27], which is similar to the results of our study. Therefore, our study supports previous work that has indicated that there are limited differences in gait mechanics and pain relief after TAA based on implant type [25, 27]. In this randomized controlled trial of patients with fixed and mobile bearing implants, we found little evidence that TAA implant type alters postoperative walking mechanics for most of the kinematic and kinetic variables that we assessed.

The results of this randomized clinical trial indicate that no statistically or clinically significant differences exist between patients with fixed and mobile bearing implants when examining gait mechanics and pain after TAA. Based on this study and previous research it is clear that TAA is an effective intervention for maintaining ankle motion, decreasing pain, and improving mechanics independent of implant type. The improvements in gait mechanics after surgery should allow for improved mobility and increased physical activity after TAA; however, this will need to be examined in future studies and compared with outcomes after ankle fusion. There is large variability among patients in most of the outcome measures of interest, therefore requiring large patient samples to detect a statistically significant difference. While a larger randomized clinical trial would enable detection of smaller differences between implant types these differences may be so small that they are not clinically relevant.

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