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Clinical outcome results of total ankle replacement and ankle arthrodesis: a pilot randomised controlled trial

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ABSTRACT

Background: Ankle arthrodesis (AA) and replacement (TAA) are widely accepted options in managing end-stage ankle arthritis (ESAA). We hypothesize that clinical outcomes would be similar for both interventions.
Methods: We conducted a multicenter randomized controlled trial that collected data on patient demographics, complication rates, Ankle Osteoarthritis Scale (AOS) and Short Form-36 (SF-36) scores. We evaluated pre and postoperative scores within and between cohorts.
Results: The thirty-nine ankles enrolled had a mean follow-up of 5.1 ± 2.8 years. Total AOS scores improved significantly in both groups; 59.4 ± 15.9 to 38 ± 20 (p-value = 0.002) for TAA and 64.6 ± 19.7 to 31.8 ± 16.5 (p-value < 0.001) for AA at last follow-up. Complication rate was higher in the AA cohort with four major complications (20%).
Conclusion: We observed a statistically significant benefit with TAA and AA. As a pilot trial, this study is meant to inform on design and feasibility of future RCTs.
Level of evidence: II

1. Introduction

Ankle arthrosis or arthritis is a chronic condition with the ability to significantly impair daily function and quality of life. A 2008 study by Glazebrook et al. demonstrated the effect of ankle arthrosis on health-related quality of life, pain, and physical function to be at least as severe as that seen in end-stage hip arthrosis [1]. The true prevalence of ankle arthritis is difficult to ascertain given observed disparities between degree of degenerative change and clinical correlation [2]. Ankle arthrosis or arthritis are common progressively degenerative conditions causing pain and decreased function. Both conditions are commonly referred to as ankle arthritis and treated in a similar manner since end stage pathology on weight bearing radiographs for both include cartilage loss, subchondral sclerosis, with osteophyte and cyst formation [3,4]. Trauma to the ankle has been cited as the most common cause of ankle arthritis. An epidemiologic study by Saltzman and colleagues identified 70% of ankle arthritis diagnoses to be posttraumatic [5]. Traditionally, management of symptomatic ankle arthritis is dictated by disease stage. Conservative treatment involves any combination of activity modification, analgesic/anti-inflammatory medications, corticosteroid injections, orthotic devices, and footwear modification [2].

The most common operative treatments for ankle arthritis are fusion or Ankle Arthrodesis (AA) and replacement or Total Ankle Arthroplasty (TAA), both of which provide definitive treatment [6]. Ankle Arthrodesis has traditionally been the treatment modality of choice in managing end-stage ankle arthritis (ESAA), however, with recent advancements in operative techniques and TAA implant designs there is now data from retrospective and prospective studies showing equivalence between the two procedures [7–9]. A recent prospective cohort study by Daniels et al. demonstrated both AA and TAA to be independently effective treatments for end stage ankle arthritis [10]. Regardless, a consensus on which operative intervention is superior has not been reached [8]. We do acknowledge TAA & AA are not interchangeable interventions for all patients with ESAA requiring surgical treatment, however, high quality literature does not currently exist to guide which procedure is applied in any particular patient. We established inclusion & exclusion criteria that fit patients that are likely to be good candidates for either TAA or AA.

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As a pilot, this study is meant to identify potential uncertainties, such as in recruitment, prior to a large scale trial that may help avoid pitfalls and optimize the study design [11]. Pilot studies can be viewed as a subset of feasibility studies. Feasibility studies ask whether or if a project should be undertaken, pilot studies ask the same questions and additionally allows for evaluation of treatment effect on a small scale [12].

2. Methods

2.1. Patient enrollment

Patients were recruited from the three centers involved in the Canadian Orthopedic Foot and Ankle Society (COFAS) multicenter Ankle Arthritis Outcome study which was published in 2014. MOBILITY, STAR, and HINTEGRA total systems were used in this study. Inclusion criteria were established that make TAA and AA a reasonable choice for participants in this study with end stage ankle arthritis. These included age between 18–85 with appropriate history and physical examination for symptomatic end-stage ankle arthritis, skeletal maturity, symptomatic ankle arthritis no longer amenable to non-operative management, and ability to give informed consent. The aforementioned age range was chosen as an inclusion criterion because, although rare, it is feasible to have young patients undergo AA to treat ESAA secondary to significant ankle trauma. Key components of the exclusion criteria include obesity (BMI > 35) given the increase in risk of complications with ankle arthroplasty, avascular necrosis of the talus, and severe osteoporotic or osteopenic bone. Coronal deformity greater the 15 degrees was considered a relative contraindication for TAA but not for AA. Randomization occurred on the day the patient consented to an operative procedure and study participation. A sealed envelope with ankle replacement or fusion was drawn from a block of 10 each time (consisting of 5 replacements and 5 fusions). This ensured adequate allocation concealment and allows for equal number of patients per group. Consent was attained by the study coordinator independent of the treating surgeon. Fig. 1 is a study flow diagram that depicts the randomization and patient allocation process. Unfortunately Fig. 1 does not capture the surgical candidates who declined participation in the study or had a treatment preference.

2.2. Outcome measures

The primary outcome of interest was the total score on the ankle osteoarthritis scale (AOS); a reliable self-assessment tool that measures patient symptoms and disabilities as relates to ankle arthritis [13]. Secondary outcomes of interest included AOS pain, AOS disability subscales, the physical and mental component summaries of the SF-36 questionnaire. The SF-36 questionnaire is a valid, reliable, and responsive generic health status measure, which captures numerous aspects of health. For all outcome measures of interest outlined above we compared preoperative scores (AOS, SF-36) to that at time of last follow-up. We also report on the incidence of complications and reoperations in the postoperative time period.

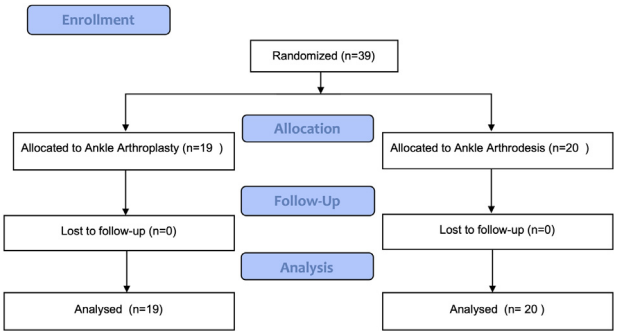

Fig. 1. Study flow diagram depicting participant enrolment and allocation to respective treatment arms.

2.3. Data collection

Data collection was carried out via a web-based system in clinic. A chart review was conducted to gather key demographic and clinical preoperative and postoperative information. Details of each patient's operation were collected prospectively using the Halifax Joint Replacement Registry Form.

2.4. Statistical analysis

We report on the demographics of the patient population with AA and TAA cohorts as subpopulations. A paired *t*-test was used to evaluate improvements in AOS (pain, disability, and total) and SF-36 (PCS and MCS) scores from baseline to latest follow-up for each cohort.

Improvements in AOS and SF-36 scores from baseline to last follow-up between the two cohorts (AA Vs TAA) were then assessed using an unpaired *t*-test model (examining two independent samples). We calculate standard effect sizes as an alternative way of quantifying the differences within and between the subgroups. Studies with small sample sizes, such as ours, require large effect sizes in order to make meaningful inferences from differences observed. Traditionally an effect size "d" of 0.2 confers a small effect, 0.5 confers a medium effect and 0.8 or greater confers a large effect [14].

Analysis of clinical outcomes was in two parts: (1) comparison of pre and postoperative data for each cohort separately; and (2) comparison of outcome scores, and revision rates between cohorts. We examined postoperative complication and reoperation rates in the study population using the standardized coding system for reoperations following ankle replacement and arthrodesis recently developed by Younger et al. [15].

We also conducted post hoc power analyses on key comparisons made within the study; preoperative AA AOS total versus postoperative AA AOS total, preoperative TAA AOS total versus postoperative TAA AOS total, and AA AOS total difference versus TAA AOS total difference. Our post hoc analyses allow us to retrospectively calculate power, given our sample size as a pilot study, assuming each of the aforementioned comparisons were the basis of individual studies. The G*Power 3 program was employed in our power analysis. It is a stand-alone power analysis program for statistical tests commonly used in social, behavioural, genetics, pharmacology, and medical research [16]. Conducting a post hoc power analysis informs on the sample size required, for each comparison, in order to determine the risk of a type II error (false null hypothesis).

2.5. Role as pilot study

We conducted this pilot study to inform on recruitment, randomisation, and data collection. For example, in this study participants had outcome measures collected in person during clinic follow-up. As a pilot RCT the study's objective is to first assess the effect of TAA and AA in treating ESAA, then inform on potential challenges presented by the current study design.

3. Results

The study enrolled a total of thirty-nine ankles from thirty-nine subjects from all three sites. Nineteen were randomized to TAA and

Table 1
Baseline Patient Characteristics.

	Total N = 39	Ankle Replacement N = 19	Arthrodesis N = 20
Follow-up (years)	5.1 ± 2.8	5.6 ± 2.7	4.6 ± 2.8
Male	24 (62%)	9 (37%)	15 (63%)
Age	65 ± 9	63.2 ± 9.1	66.9 ± 8.7
BMI (kg/m2)	28.6 ± 4.4	28.5 ± 4	28.7 ± 4.7
Smoking History			
Never	19 (49%)	10 (53%)	9 (45%)
Not in last 12 mo	13 (33%)	6 (32%)	7 (35%)
Within last 12 mo	3 (8%)	1 (5%)	2 (10%)
No response	4 (10%)	2 (11%)	2 (10%)
Diabetes	5 (13%)	3 (16%)	2 (10%)
Inflammatory Arthritis	2 (5%)	0	2 (10%)
Pre-op Scores			
AOS Pain	56.3 ± 18.2	53 ± 16.8	59.3 ± 19.3
AOS Disability	67.6 ± 20	65 ± 17	69.6 ± 22.7
AOS Total	62 ± 18	59.3 ± 16	64.6 ± 19.76
SF-36 PCS	30.7 ± 8.4	30.4 ± 8.4	31 ± 8.6
SF-36 MCS	50.6 ± 11.9	48.3 ± 12.5	53 ± 11

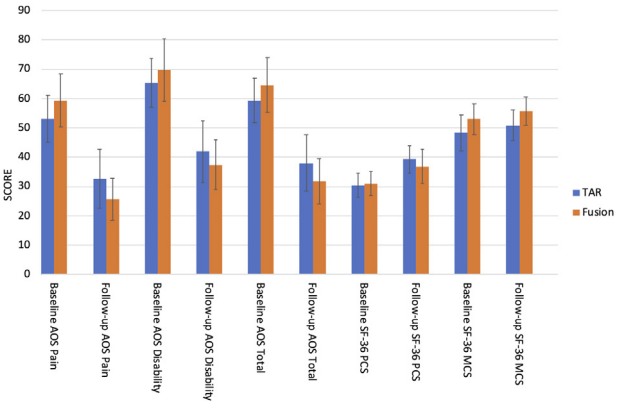

Fig. 2. Outcome scores at baseline and at time of latest follow-up in total ankle replacement (TAR) and ankle Arthrodesis (Fusion) groups, graphed as the mean with confidence interval. The number of patients who answered individual questions ranged from eighteen to twenty in the arthrodesis cohort and was consistent at nineteen in the ankle replacement cohort.

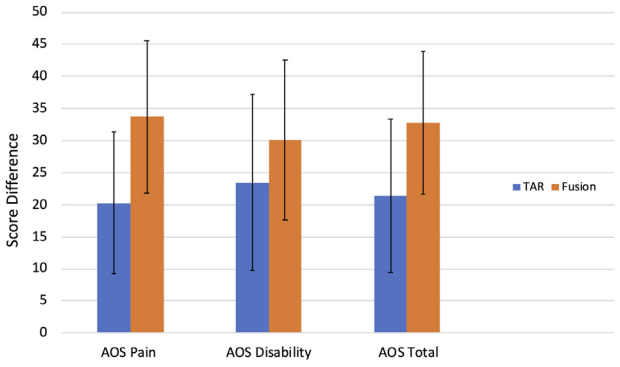

Fig. 3. Change in AOS outcome scores (absolute difference) from baseline to time of last follow-up for ankle replacement and arthrodesis cohorts, expressed as difference in mean and the confidence interval.

twenty to AA. Baseline characteristics of the entire study population and the two subgroups are outlined in Table 1. The overall mean follow-up was 5.1 ± 2.8 years (TAA 5.6 ± 2.7 and AA 4.6 ± 2.8). The average age at time of surgery was 65 ± 9, with the TAA group being slightly younger (63.2 ± 9.1) and the AA group 66.9 ± 8.7. The youngest patient enrolled in the study was 47 years of age and oldest was 81. Body mass index scores (BMI) stayed consistent between the two groups with a total average of 28.6 ± 4.4. Approximately 49% (19/39) of patients enrolled had never smoked, 33% (13/39) quit at least twelve months prior to surgery, and 8% (3/39) had smoked within twelve months leading to surgery. Unfortunately, we are missing smoking history data on four patients (10%). The overall incidence of diabetes was 13% (5/39).

Ankle osteoarthritis scale pain, disability, and total scores improved significantly between the preoperative and latest follow-up time points in both groups. As seen in Fig. 2, the average baseline AOS total score for TAA went from 59.4 ± 15.9 to 38 ± 20 at last follow-up (*p-value = 0.002*) while the AA group saw an improvement from baseline AOS total of 64.6 ± 19.7 to 31.8 ± 16.5 at latest follow-up (*p-value < 0.001*).

Differences in AOS scores (baseline to last follow-up) favoured the AA group with an AOS total mean absolute difference of 32.8 ± 23.7 compared to TAA's 21.4 ± 25.0, however, this absolute difference was not statistically significant (Fig. 3). Similarly, greater differences in SF-36 scores (baseline to last follow-up) were observed with ankle arthrodesis. This was also not statistically significant (*p-value = 0.15*). The complete findings for all difference in outcome scores from baseline to time of last follow-up (AOS and SF-36) are outlined in Table 2. We report p-values and corresponding effect sizes for key comparisons of AOS scores within and between our subgroups, as seen in Table 3. As stated above, the TAA average baseline AOS total score improved at the time of last follow-up with a *p-value of 0.0015* and an effect size of 1.2 (large effect). The post hoc power analysis on this comparison yielded a power of 1, factoring in study sample size. Similarly, the AA average baseline AOS total score also improved at the time of last follow-up with a *p-value < 0.001*, an effect size of 1.8 (large effect), and yielded a power of 1. The AA cohort saw a greater improvement in average AOS total score from baseline to time of last follow-up when compared to the ankle replacement cohort, however, this difference was not statistically significant with a *p-value of 0.15* and an effect size of 0.47 (small effect). This comparison yielded a power of 0.4.

There were slight improvements in SF-36 scores from baseline to last follow-up within each cohort. For TAA, mean SF-36 physical component scores (PCS) saw a statistically significant improvement from 30.4 ± 8.4 to 39.2 ± 9.7 (*p-value = 0.003*) at last follow-

Table 2
Difference in Outcome Scores from Baseline to Latest Follow-up.

	Ankle Replacement		Ankle Arthrodesis	
	Mean and Std. Dev.	95% CI	Mean and Std. Dev.	95% CI
AOS	N = 19		N = 20	
Pain	−20.3 ± 23.0	−31.4 to −9.23	−33.7 ± 25.4	−45.6 to −21.8
Disability	−23.5 ± 28.4	−37.1 to −9.8	−30.1 ± 26.6	−42.5 to −17.6
Total	−21.4 ± 25.0	−33.4 to −9.3	−32.8 ± 23.7	−43.9 to −21.7
SF-36	N = 19		N = 18	
PCS	5.0 ± 17.8	−3.5 to −13.6	6.1 ± 11.9	0.26 to 12.1
MSC	6.1 ± 18.9	−3.0 to −15.2	2.6 ± 11.5	−3.1 to 8.3

Table 3
P-values and effect sizes for comparisons of AOS scores within and between subgroups.

Score Comparison	P-value (< 0.05)	Effect size
TAR baseline AOS pain vs. TAR follow-up AOS pain	0.001	1.08
TAR baseline AOS disability vs. TAR follow-up AOS disability	0.002	1.20
TAR baseline AOS total vs. TAR follow-up AOS total	0.002	1.19
Fusion baseline AOS pain vs. Fusion follow-up AOS pain	1.02E-05	1.94
Fusion baseline AOS disability vs. Fusion follow-up AOS disability	7.81E-06	1.58
Fusion baseline AOS total vs. Fusion follow-up AOS total	6.15E-06	1.81
TAR AOS pain difference vs. Fusion AOS pain difference	0.091 *	0.56
TAR AOS disability difference vs. Fusion AOS disability difference	0.458 *	0.24
TAR AOS total difference vs. Fusion AOS total difference	0.151*	0.47

Table 4
Post-Operative Complications.

Complications	Total N = 39	Ankle Replacement N = 19	Arthrodesis N = 20
None	27 (69%)	12 (63%)	15 (75%)
Isolated hardware removal	2 (5%)	2 (10.5%)	0
Repeat Operation	3 (7.7%)	2 (10.5)	1 (5%)
Debridement ± poly exchange	1 (2.6%)	1 (5.3%)	0
Revision of Arthrodesis	3 (7.7%)	0	3 (15%)
Revision secondary to implant failure	1 (2.6%)	1 (5.3%)	0
Revision secondary to Infection	1 (2.6%)	1 (5.3%)	0
Amputation	1 (2.6%)	0	1 (5%)
Smokers with complications	2 (5%)	1 (5.3%)	1 (5%)

up. Mean SF-36 mental component scores (MCS) for TAA also improved from 48.3 ± 12.5 to 50.8 ± 11 (*p-value = 0.4*) at time of last follow-up, however this did not reach statistical significance. Neither SF-36 PCS nor MCS for AA saw statistically significant improvements between baseline and latest follow-up scores with p-values of 0.09 and 0.4 respectively. There were no statistically significant differences observed in the absolute difference of SF-36 scores (baseline to last follow-up) between TAA and AA.

Complications and reoperation rates are summarized in Table 4. Two major complications (10.5%) were observed in the TAA cohort, both revisions of metal components with one due to implant failure and the other secondary to infection. The ankle arthrodesis cohort saw four major complications (20%), including one amputation and three revisions due to non-unions/mal-unions. Overall, twelve of the nineteen ankles in the replacement arm (63%) and fifteen out of twenty ankles in the arthrodesis arm (75%) had no complications requiring a reoperation in the postoperative time period. One patient in the arthrodesis arm who went on to have an amputation had persistent non-unions after multiple revisions, not related to infection, over a five-year period. Three patients enrolled in the study had a positive smoking history within the last twelve months. Two underwent AA of which one had no postoperative complications and the other ended up with a revision arthrodesis. The one patient in the TAA group with a positive smoking history underwent isolated hardware removal two years after the index procedure.

4. Discussion

As a pilot study, this multicenter randomized controlled trial assessed key clinical outcomes of ankle replacement and ankle arthrodesis in thirty-nine patients at varying lengths of follow-up. Detailed analysis of the groups indicated affirms the widely accepted benefit of both ankle replacement and arthrodesis as viable operative options in treating ESAA.

Our results showed statistically significant improvements in all AOS scores from baseline to time of last follow-up for both ankle replacement and arthrodesis independently, with large effect sizes. Despite the limited sample size, our post hoc analyses for AOS total score comparisons within each cohort further confirms the efficacy of TAA (N = 19) and AA (N = 20) independently as effective operative interventions for ESAA. The SF-36 outcome scores at last follow-up were not as compelling when compared to that at baseline for both ankle replacement and arthrodesis. There were improvements in SF-36 scores across the board from baseline to last follow-up, majority of which were not statistically

significant. Although we had expected uniformly significant improvements in SF-36 scores (PCS and MCS), our sample size was likely not large enough for this expected effect to be realised. The lack of statistical significance in baseline to last follow-up scores observed may also partly be due to baseline scores not being poor enough, a function of ESAA impact on overall physical and mental function. A recent study by Waly and colleagues found that patients with the worst scores at baseline (AOS, AAS, SF-36) made the greatest gains in function and pain postoperatively [17]. Regardless, our baseline SF-36 scores were similar to that reported in a 2008 study that compared baseline SF-36 scores in patients with ESAA and hip arthrosis [1].

Although not statistically significant, we found that patients who underwent AA reported better AOS scores (pain, disability, and total) at latest follow-up compared to patients in the TAA arm, with small to medium effect sizes observed. The lack of statistical significance in AOS scores between TAA and AA is attributable to the study's small sample size. As a pilot RCT this remains informative; to reliably compare the effect of AA to TAA in treating ESAA we recommend future studies perform a priori power analysis to accurately ascertain a target number of participants to enrol. Our post hoc analysis for the aforementioned comparison yielded a power of 0.4. A power of 0.4 implies the slight difference observed, in favor of AA, is not significant enough to be used as the basis clinical decision making on ESAA. A prospective study, published in 2014, on intermediate term results of ankle replacement and arthrodesis found that intermediate-term AOS scores favoured the ankle replacement group [10]. However, they do clarify that "an adjusted analysis showed that a substantial portion of this difference was explained by differences in patient characteristics and surgeon".

Overall postoperative complications requiring a revision occurred in six of the thirty-nine patients enrolled in the study, at a rate of (15.3%). Within our subgroups, the rates were comparable with 16% (3/19) and 20% (4/20) in the TAA and AA respectively. We expected revision rates to be higher with TAA compared with AA, this study's finding is again likely in part due to our small sample size. Overall reoperation rates were higher than anticipated with TAA at 37% (7/19) and 15% (4/20) for AA. Daniels et al., in a 2014 prospective study on replacement and arthrodesis, also report a higher re-operation rate of 19% with replacement (52/281) compared to 7% with fusion (7/107) [10]. Another study by SooHoo and colleagues on reoperation rates reported that while TAA led to a significantly higher rate of major revision surgery (hazard ratio, 1.93[95% confidence interval, 1.50–2.49]; $p < 0.001$), it also resulted in a significantly less risk of future subtalar fusion (hazard ratio, 0.28 [95% confidence interval, 0.09 to 0.87]; $p = 0.03$) [18]. As a pilot RCT, our small sample size likely amplifies the magnitude of any reported complications and reoperations.

One major strength of our study is that as a pilot randomized controlled trial it is the first of its kind to explore the comparative effectiveness of the two interventions by assessing clinical outcome results. The small sample size was a limitation to the study, however, as a pilot study our aim was to test the feasibility of such a trial on a smaller scale. There were challenges in consistent recruiting across centers involved in the study; one site identified 135 eligible patients during the study period, of which 36 were randomized after screening. In this study the first patients were recruited in 2007 and the last in 2017, majority of the patients evaluated for ESAA in this time period were resistant to randomization to two different interventions. This resistance stemmed largely from preconceived notions of the effect either intervention may have on their long-term function and quality of life. Additionally, when recruitment began in 2007, TAA was still relatively novel to the general population and complications rates from earlier designs had not been favorable. Based on mock priori power analyses with a target effect size of 0.8 (large effect in total AOS score improvement with either AA or TAA) we propose future studies aim for a total study sample size of at least 80 participants. The patients who declined participation in the study were treated based on surgeon expertise and patient preference, they were enrolled into the TAA vs. AA COFAS database for prospective non-randomized trials. No incentives, monetary or other, were offered to patients who did agree to enrol in the study and undergo randomization.

Adjacent degenerative joint disease, specifically subtalar or talonavicular, is a known long-term complication of AA. The average follow-up time period in this study was 5.1 ± 2.8 years. Considering that subtalar arthritis secondary to AA may not be clinically symptomatic for up to ten years, future studies need to strive for follow-up time points that capture known and unknown long-term complications of both TAA and AA. We recommend ten to fifteen year follow-up where possible. Despite this study's role as a pilot trial, the lack of long-term follow-up was a limitation.

Postoperative outcome measurements were largely dependent on scheduled follow-up visits. This meant if a patient could not make a follow-up clinic visit then data for that time point was not collected. For structured measurement of outcomes, we recommend additional follow-up visits or emailed questionnaires that coincide with predetermined follow-up time points of interest in the study (i.e. 6 months, 1 year, 2 years, 3 years, and after 5 years). Another study limitation was the use of different ankle arthroplasty implant systems at each centre involved in the study. We recommend future RCTs comparing these interventions reach a consensus on implant system to be used across the centers enrolling patients.

5. Conclusion

This multicenter randomized controlled pilot trial assessed key clinical outcomes of ankle replacement and ankle arthrodesis at varying lengths of follow-up (average of 5 years). Furthermore, it affirms the widely accepted benefit of both AA and TAA as viable surgical options in treating end-stage ankle arthritis.

This study should be considered a level II study at best and the limited results should serve as a pilot trial for a larger more appropriately powered Level I RCTs.

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The Canadian Orthopaedics foundation played no role in the study's design, data collection or analysis, writing of the manuscript, and decision to submit for publication.

Declaration of conflict of interest

Dr. Glazebrook has nothing to disclose.

Dr. Burgesson has nothing to disclose.

Dr. Younger reports consultancy from Wright Medical, Accumed, Cartiva, Zimmer, Bioventus, Ferring, all outside the submitted work.

Dr. Daniels reports consultancy from Wright Medical, Stryker, Integra, personal fees from Integra, all outside the submitted work.

Appendix A

Sample effect size formula (TAA Pre-op AOS Total vs. Post-op AOS Total)

$$\text{Effect Size} = \frac{(\text{Pre} - \text{Op Mean AOS Total} - \text{Post} - \text{Op Mean AOS Total})}{\text{Average Standard Deviation}}$$

Sample effect size formula (TAA AOS Total vs. AA AOS Total)

$$\text{Effect Size} = \frac{(\text{TAA Mean Difference AOS Total} - \text{AA Mean Difference AOS Total})}{\text{Average Standard Deviation}}$$

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