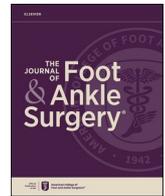




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Original Research

Distal tibial osteophytes are more accurate than medial malleolar anatomy when using patient specific instrumentation in total ankle replacement

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ABSTRACT

Total ankle replacement (TAR) is a treatment for end stage ankle arthritis. Patient specific instrumentation (PSI) has been used and shown to allow for accurate placement and alignment in TAR in the coronal and sagittal plane. PSI systems are available and use different anatomic landmarks for the cutting guides. This is a retrospective matched case control study comparing accuracy in alignment using 2 different PSI systems. The case series uses a medial malleolar landmark (MM Group), and each case patient was matched based on preoperative coronal plane alignment with 2 ankles in the control series using the distal tibial osteophytes as landmarks (DT Group), as this system has been in use and studied more. A total of 48 ankles were studied, 16 in the MM Group and 32 in the DT Group matched by coronal plane alignment. There was a difference in accuracy of postoperative coronal plane alignment, with the MM Group deviated from expected by $1.6^\circ \pm 1.3^\circ$ compared to the DT Group at $1.1^\circ \pm 0.6^\circ$, $p = 0.04$. This corresponded to 68.8 % of MM Group ankles being within 2° of expected compared to 93.4 % of DT Group ankles. There was no statistically significant difference in sagittal plane alignment between the groups, $p = 0.57$. Procedure time was the only other statistically significant difference with the MM Group taking longer than the DT Group, 97.4 min and 80.6 min, respectively, $p = 0.04$. While both groups show good accuracy, alignment based on the distal tibial osteophytes is more accurate than using the medial malleolus.

Introduction

Total ankle replacement (TAR) has continued to increase in its use for treating end stage ankle arthritis [1–3]. Alignment in TAR is important, and poor positioning of the implant has been shown to lead to high contact pressures and may lead to eventual implant failure [4,5]. One of the technologies that has emerged in TAR is the use of Patient Specific Instrumentation (PSI). Using a preoperative computer tomography (CT) scan, 3D printed custom guides are designed to help assist the surgeon in obtaining alignment in surgery by interfacing with the patient's anatomy. The goals of PSI are to improve accuracy, be efficient, and to add value [6]. PSI has been shown to have excellent accuracy in TAR, indicating that the predicted alignment of the plan is observed in the actual postoperative alignment [7–13]. The authors presented their findings on 97 TARs implanted with PSI and found that 87.6 % were within 2° of predicted in the coronal plane, and 88.7 % in the sagittal plane [14].

Coronal plane deformity, whether in varus or valgus, can be corrected with TAR, and there are several different approaches and techniques that are employed, even in severe cases [15–19]. However, different techniques and deformity correction limitations are described for varus versus valgus ankles. This difference is exemplified by most studies that will study either varus [20–22] or valgus [23–25]. Therefore, while both varus and valgus can be corrected in TAR, it is reasonable to consider preoperative varus or valgus coronal plane deformity in ankles as a defining and differentiating feature when considering TAR.

All PSI systems for TARs currently use CT scans to image the patient's existing anatomy, and then the guides are 3D printed to fit this anatomy. However, there are different landmarks that are used as key features of interaction of the guides and patients' anatomy. Specifically, the Prophecy® PSI system (Stryker™, Kalamazoo, MI) uses the distal tibial osteophytes (Fig 1). Per the company technique guide, the custom guide is "designed to incorporate fixed osteophytes on or near the articulating

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surfaces, and therefore should not be removed during the surgical exposure of the ankle.” In addition, the distal tibia that must surface match to the guide needs to be completely free of soft tissue, requiring meticulous removal at the level of the ankle joint [26]. In contrast, the Maven® PSI system (Paragon 28™, Engelwood, CO) uses the medial malleolar surface anatomy (Fig 2). The guides use a medial malleolus wrap which is proposed to “reinforce stability,” and “preserve periosteum and anterior talar cartilage during joint preparation” by having the guide connect to the anatomy medially and proximally to the ankle joint [27]. No study has been published comparing the different landmarks used in various PSI systems in TAR.

This study aims to compare the accuracy of two different PSI systems with different anatomic landmarks used for reference. Accuracy of the guides will be determined by the difference in CT-based plan predicted alignment and actual postoperative weight bearing alignment. The hypothesis is that both systems will allow for accurate and predictable alignment based on the preoperative plans. All surgeries were performed by non-consultant, non-design surgeons.

Patients and methods

Following IRB approval (23.025ET), a Current Procedure Terminology code search for 27702 was conducted to identify all patients who underwent total ankle replacement by one of two fellowship trained foot and ankle surgeons experienced in total ankle arthroplasty (JGD, BS). Both surgeons performed each of the studied PSI systems, and have been performing TAR in residency, fellowship, and private practice since 2007. All patients were evaluated preoperatively in clinic and found to be candidates for TAR. The primary indication for TAR was end stage ankle arthritis. All included patients underwent lower extremity CT per manufacturer protocol for preoperative evaluation and PSI development. In all cases the PSI system was designed for the implant to be set to the mechanical axis of the ankle to the knee as identified by preoperative CT. A total of 164 ankles were performed with PSI, 16 used the medial malleolar reference point (Maven®, Apex 3D®, Paragon™, Englewood, CO), and 127 used the distal tibial reference point (Prophecy®, Infinity®, Stryker™, Kalamazoo, MI). The medial malleolar (MM Group)

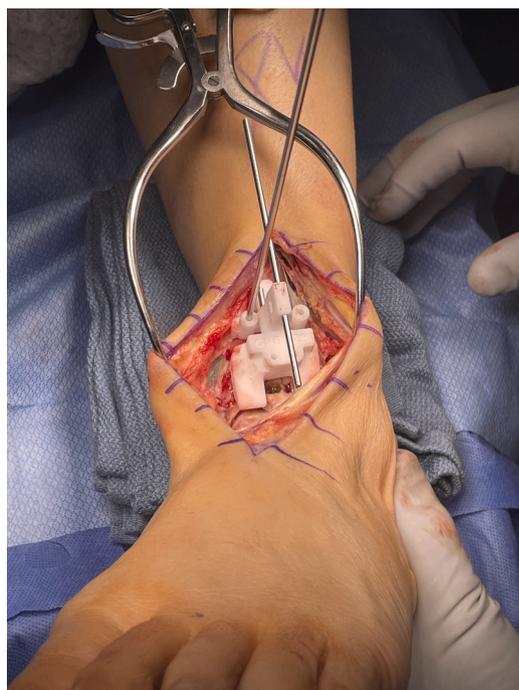


Fig. 1. Clinical image of custom 3D printed guide aligning by interlocking with the distal tibial osteophytes in an arthritic ankle.

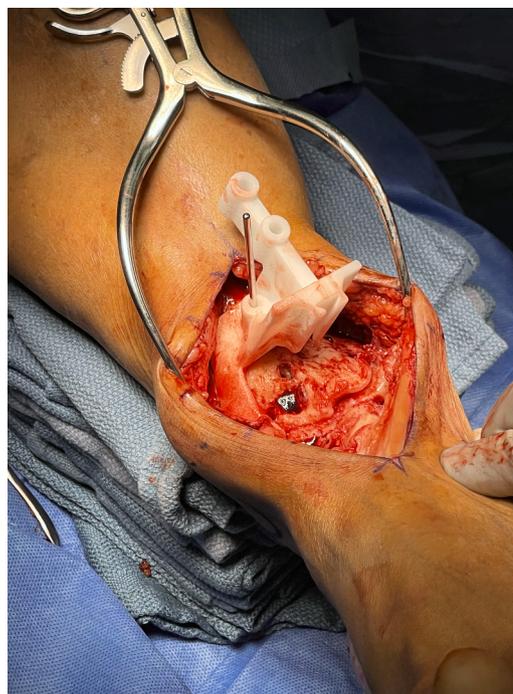


Fig. 2. Clinical image of a custom 3D printed guide aligning by using the anterior surface anatomy of the medial malleolus in an arthritic ankle.

referenced PSI ankles will be used as the case series because of the paucity of literature evaluating this system, and the distal tibial osteophyte (DT Group) referenced PSI ankles will be used as the control because of the extensive reporting in the literature [7–13], as well as the higher volume used by the operating surgeons who have published their outcomes [14]. The remainder were other PSI systems or implants. The choice of implant was at the operating surgeon’s discretion.

Inclusion criteria included age >18 years, use of one of the 2-part fixed bearing TARs utilizing PSI with either a medial malleolar (MM Group) or distal tibial osteophytes (DT Group) reference and surgery performed at one of two operating centers by one of two senior authors. Exclusion criteria included age under 18 years, lack of pre- or post-operative weight bearing radiographs, TAR performed with different implant or without PSI, revision TAR or ankle arthrodesis revision to replacement. All patients were treated between July 1, 2014 and July 1, 2024. As a radiographic alignment study, not a clinical follow-up study, follow up was only 4-6 weeks, whenever the first weight bearing films were obtained.

Simple demographic information was collected from chart review. This included age, sex, laterality, and BMI. Surgical variables such as procedure time and adjunctive procedures were taken from the operative report. Soft tissue rebalancing is required in ankle deformity and is reported in adjunctive procedures. Post operative protocol was 2 weeks non weight bearing in a splint, followed by 2 weeks in a weight bearing cast. First weight bearing radiographs were obtained at 4 weeks post operative. Patient was then placed into a weight bearing boot for 4 weeks and started physical therapy. This protocol was adjusted in the case of hindfoot fusion or osteotomy, and patient was placed into a nonweight bearing cast from weeks 2 to 6, and at the six week mark the first weight bearing radiographs were obtained.

Radiographic measurements from AP, lateral, and mortise weight bearing radiographic images of the ankle were taken pre- and post-operatively. The postoperative images were the first weight bearing images available and were used to more closely represent how the ankle will function in gait. The AP and lateral views were utilized for analysis. Electronic picture archiving and communication systems (PACS) imaging (McKesson, Irving, TX) was utilized for measurements. Angular

measurements as described by Heisler et al. [28] were performed to evaluate the deformity. On the AP images the α angle was found from the axis of the tibia and the tibial joint surface, and the β angle is the tibial axis and the talar joint surface. The γ angle on the lateral image was the axis of the tibia and the distal tibial joint line. The values are reported as the difference from 90° and reported as varus or valgus in the coronal plane and as dorsiflexed or plantarflexed in the sagittal plane. Joint congruency was determined as the difference of the α and β angles (Figs. 3A and 3B).

The study is a case-controlled study with 1:2 matching using the coronal plane angle to control for degree of deformity. The 16 ankles in the MM Group were used as the case group. From the 127 control ankles available in the DT Group, preoperative coronal plane deformity was used to match cohorts in a 1 (case): 2 (control) ratio where preoperative coronal plane deformity between matched cases and controls were within 1° , although this was not possible in all cases of larger deformity. Preoperative coronal plane alignment was chosen as the match variable as this is a well-studied variable that can affect TAR alignment and outcomes and is often used as the variable of study in TAR literature [16–25]. The authors chose the β angle to capture both congruent and incongruent deformity. An incongruent ankle may have a normal α angle and not reflect true deformity seen. No ankles in the control series were used twice. A total of 48 ankles were used in the study, 16 in the MM Group case group, and 32 matched ankles from the DT Group control group. A record of the case and matched control data is available in the Appendix.

The PSI report generated from preoperative CT was evaluated for expected postoperative alignment, deviation between mechanical and anatomical axes. The implants were placed according to the mechanical axis, whereas the angles measured represented the anatomic axis. The

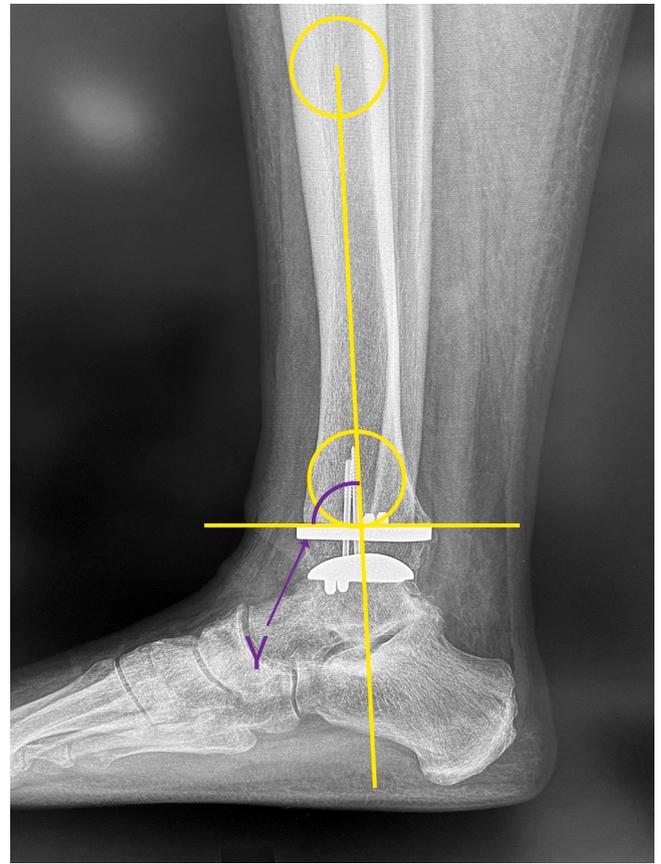


Fig. 3B. Illustration of Sagittal plane γ angle. Values are presented as difference from 90° .

mechanical axis is measured from the ankle to the tibial plateau based on pre-operative CT scans. These results were compared to postoperative weightbearing radiographs to evaluate the difference between expected postoperative alignment and actual postoperative alignment of the tibial implant relative to the distal tibia. This difference of expected versus actual postoperative alignment was defined as accuracy of the PSI system. Postoperative coronal plane alignment accuracy (predicted vs actual alignment) was also reported as the β angle for consistency. Due to 100 % of implants being set to mechanical axis, the difference in expected outcomes was calculated by subtracting the post operative α radiographic angle that references the anatomic axis from the expected post operative angle generated in PSI plan (varus denoted as positive, valgus negative). All measurements were performed by one of the authors (T.S.T.), trained in radiology and given training specifically in the needed measurements. This author was not involved in any surgery, patient care or interaction, and was blinded to any patient identifiers.

The surgical procedure was performed utilizing standard operative technique according to manufacturer's specifications. In all cases the tibial alignment guide was placed first and confirmed with intra-operative imaging. Based on deformity, flexibility, and reducibility, the talar cut was then determined. If the initial joint preparation and soft tissue release was able to completely reduce the tibiotalar deformity according to the preoperative plan, the cuts were coupled. If further deformity was noted and not able to be completely reduced before the cuts, then the talar implant cut guide was placed in an uncoupled technique. As these variables could affect accuracy, only tibial alignment was used for reporting in this study. Ancillary procedures were performed as needed.

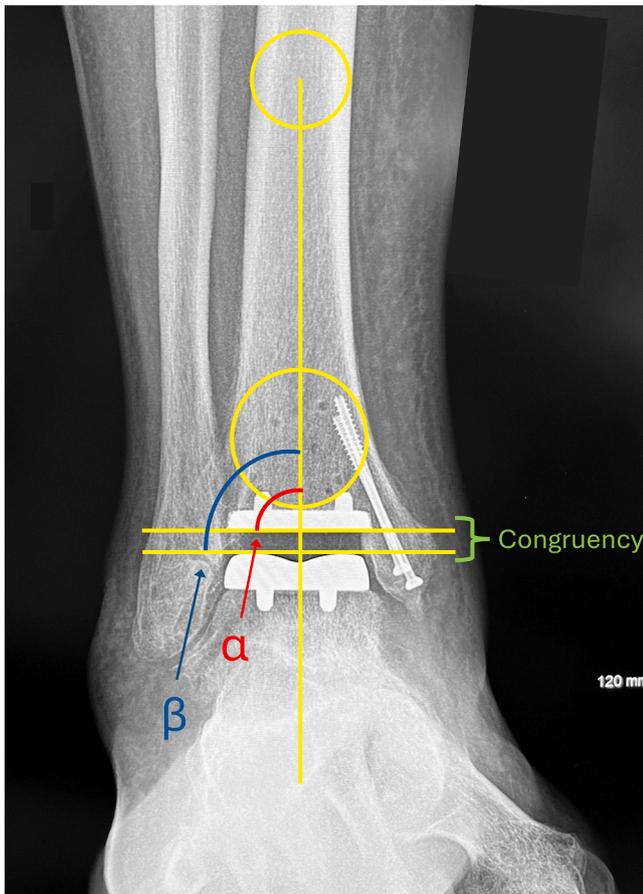


Fig. 3A. Illustration of Coronal plane measurements. Values for α and β are presented as difference from 90° .

Statistical analysis

Demographic information and radiographic measurements were evaluated. Mean, standard deviation, and range were determined for continuous outcome variables, whereas categorical variables were represented as a count and percentage. Outcome variables were tested for normality with Kolmogorov-Smirnov test. For non-parametric data, Kruskal-Wallis test was used to detect when stochastic dominance was present. Categorical data was compared with Fisher's exact test. Comparisons of continuous variables between groups and differences in matched pairs were evaluated utilizing matched 2-tailed T-tests. Statistics were calculated via Google Sheets (Google, Mountain View, CA). Significance for all calculations was set at $p < 0.05$.

Results

Demographics were compared between the 2 groups, with no significant difference between groups in any of the compared characteristics. The average age in the DT Group was 63.4 ± 8.7 years (range 43.4-79 years) and was similar to 62.3 ± 11.3 years (range 46.4-91.7 years) in the MM Group, $p = 0.72$. There were 34.4 % males in the DT Group, and 37.5 % males in the MM Group, $p = 0.84$. Laterality showed 53.1 % left and 50 % left in the DT and MM Groups, respectively, $p = 0.84$. Finally, body mass index (BMI) was 34.9 ± 7.2 kg/m² (range 22.8-47.3 kg/m²) in the DT Group and 34.5 ± 6.6 kg/m² (range 26.4-46.6 kg/m²) in the MM Group, $p = 0.85$ (Table 1).

Preoperative coronal and sagittal plane alignment was compared between the groups. Coronal plane alignment was the primary variable used to create the matched pairs, and by design there was no statistically significant difference between the groups. The groups were compared in 3 subgroups based on preoperative coronal plane alignment into valgus ($>5^\circ$ valgus), varus ($>5^\circ$ varus) and neutral ($\leq 5^\circ$ coronal plane alignment). Of the 16 patients in the MM Group, 5 were valgus, 6 were neutral, and 5 were varus, and this was matched within 1° to the DT Group to 10 valgus ankles, 12 neutral ankles, and 10 varus ankles in the DT Group. The average of varus in the MM group was $13.6^\circ \pm 5.2^\circ$ (range $7.7^\circ - 21.6^\circ$ varus) and in the DT Group was $12.6^\circ \pm 3.3^\circ$ (range $7.6^\circ - 17.1^\circ$ varus), $p = 0.66$. The neutral ankles averaged 0.2° valgus $\pm 3.3^\circ$ (range 4.8° valgus to 4.8° varus) and 0.3° valgus $\pm 3.3^\circ$ (range 5.7° valgus to 5° varus) in the MM Group and DT Group respectively, $p = 0.94$. The valgus ankles in the MM Group averaged $12.4^\circ \pm 6.7^\circ$ (range $7.6^\circ - 23^\circ$ valgus), compared to the DT Group with $11.8^\circ \pm 5.3^\circ$ (range 6.9° to 20° valgus), $p = 0.84$ (Table 2).

The groups were compared for accuracy of the plan to the postoperative results. The average postoperative β angle for the MM Group was 0.7° varus $\pm 1.8^\circ$ (range 1.9° valgus to 4.9° varus) compared to the DT Group at $0.6^\circ \pm 1.8^\circ$ (range 3.6° valgus to 3.5° varus), $p = 0.79$. There was a statistically significant difference in the groups when comparing accuracy with the MM Group alignment deviating from expected by $1.7^\circ \pm 1.3^\circ$ (range $0.2^\circ - 4.8^\circ$) and the DT Group deviating an average of $1.1^\circ \pm 0.6^\circ$ (range $0.1^\circ - 2^\circ$), with a $p = 0.04$. This corresponded to 93.4 % of DT Group ankles being within 2° of predicted compared to 68.8 % in the MM Group. This difference in accuracy was not found in the sagittal plane. The average postoperative γ angle for the MM Group was 1° varus $\pm 2^\circ$ (range 1.5° valgus and 4.6° varus)

compared to the DT Group at $1^\circ \pm 2.1^\circ$ (range 4.3° valgus to 4.7° varus), $p = 0.94$. The MM Group deviated an average of $1.5^\circ \pm 1.2^\circ$ (range $0^\circ - 4.2^\circ$) in the sagittal plane, compared to the DT Group at $1.3^\circ \pm 0.9^\circ$ (range $0.1^\circ - 3.6^\circ$), $p = 0.57$. This corresponded to 87.5 % of DT Group ankles being within 2° of predicted compared to 68.8 % in the MM Group (Table 3).

Other operative data included adjunctive procedures and procedure time. The MM Group had an average of 1.4 ± 1.2 additional procedures (range 0-4 procedures), and the DT Group had 1 ± 1 (range 0-4 procedures), $p = 0.18$. There was a statistically significant difference in procedure time between the groups. The MM Group took an average time of 97.4 ± 22.1 min (range 62-141 min), and the DT Group took 80.6 ± 28 min (range 42-166 min), $p = 0.04$. (Table 3)

Discussion

The results of this study add to the body of literature supporting the use of PSI in TAR. Reported outcomes of coronal plane accuracy of $0.1^\circ - 3.3^\circ$ have been shown, with sagittal plane accuracy having a larger reported difference of $0.6^\circ - 9.6^\circ$ [7-13]. The authors have previously presented 97 TARs using a PSI and reported accuracy of $0.7^\circ \pm 1.2^\circ$ in the coronal plane and $0.7^\circ \pm 1.5^\circ$ in the sagittal plane [14].

Most reports in the literature, including all references in the current study addressing PSI [6-14,28], use a single PSI system that references off the distal tibial osteophytes. Other systems use different reference points to interlock with the tibia for the alignment of the tibial cut. While we looked at one specific system aligning off the medial malleolus to compare against alignment using distal tibial osteophytes as the standard, other options are present in the market that may key off different anatomic landmarks. Different techniques have been evaluated to help in the PSI system to allow for accurate plans to be made [29]. However, to the author's knowledge there has been no comparison of different landmarks used in PSI for TAR.

In this case-control report comparing accuracy of TAR placement with the use of PSI, the authors compared a PSI system using the medial malleolus as the case group (MM Group) to the more well reported system using the distal tibial osteophytes as the control group (DT Group). Several observations are made in this report. First, both systems can be reported as fairly accurate, with the MM Group averaging accuracy of 1.7° and the DT Group as 1.1° as a deviation of predicted to actual alignment. However, this was a statistically significant difference in accuracy, with the MM Group being less accurate, $p = 0.04$. In addition, 93.4 % of the DT Group was within 2° of predicted, compared to only 68.8 % in the MM Group. The sagittal plane accuracy was not statistically significantly different between the groups, but more ankles were within 2° of predicted in the DT Group compared to the MM Group, 87.5 % vs 68.8 %, respectively.

The authors believe there could be several reasons for this difference in accuracy. First, the distal tibial osteophytes are closer to the ankle joint itself. By referencing nearer to the joint, this may allow for less movement or angulation of the guide affecting alignment, such as can happen with torque of the instruments or vibration of the saw. Second, the joint osteophytes may allow for a more varied, angular, and therefore stable interlocking of the guide to the patient's anatomy. The smoother surface of the anterior surface of the medial malleolus may

Table 1
Demographics.

	DT Group (n = 32)			MM Group (n = 16)			P-Value
	Average	SD / %	Range	Average	SD / %	Range	
Age (years)	63.4	8.7	43.4 - 79.0	62.3	11.3	46.4 - 91.7	0.72
Sex (%male)		34.4 %			37.5 %		0.84
Laterality (%left)		53.1 %			50 %		0.84
BMI (kg/m ²)	34.9	7.2	22.8 - 47.3	34.5	6.6	26.4 - 46.6	0.85

BMI = Body Mass Index, SD = Standard Deviation.

Table 2
Pre-op β measurements.

	DT Group (n = 32)				MM Group (n = 16)				P-value:
	Average	SD	Range	Count	Average	SD	Range	Count	
Varus ($^{\circ}$)	12.6	3.3	7.6-17.1	10	13.6	5.2	7.7 - 21.6	5	0.66
Neutral ($^{\circ}$)	-0.3	3.3	-5.7 - 5.0	12	-0.2	3.3	-4.8 - 4.8	6	0.94
Valgus ($^{\circ}$)	-11.8	5.3	-20 - -6.9	10	-12.4	6.7	-23 - -7.6	5	0.84

SD = Standard Deviation.

*Negative values are valgus.

Table 3
Post-op data.

	DT Group (n = 32)			MM Group (n = 16)			P-value:
	Mean/ %	SD	Range	Mean/ %	SD	Range	
Post-op β angle ($^{\circ}$)	0.6	1.8	-3.6 - 3.5	0.7	1.8	-1.9 - 4.9	0.79
Deviation from Expected Coronal (Abs. Value)	1.1	0.6	0.1 - 2.0	1.7	1.3	0.2 - 4.8	0.04
Percentage within 2$^{\circ}$	93.4%			68.8%			
Post-op γ angle ($^{\circ}$)	1	2.1	-4.3 - 4.7	1	2	-1.5 - 4.6	0.94
Deviation from Expected Sagittal (Abs. Value)	1.3	0.9	0.1 - 3.6	1.5	1.2	0.0 - 4.2	0.57
Percentage within 2$^{\circ}$	87.5%			68.8%			
# of adjunctive procedures	1	1	0 - 4	1.4	1.2	0 - 4	0.18
Procedure time (minutes)	80.6	28	42-166	97.4	22.1	62 - 141	0.04

SD = Standard Deviation; Abs = Absolute.

* Negative values are valgus.

allow for more sliding and slipping of the guide on the tibial surface. Third, the authors are more familiar with the DT Group system and have done many more implants with this system compared to the MM Group. This inaccuracy of the MM Group may be part of the learning curve. A systematic review of the learning curve in TAR does indicate some improvement with added experience [30–31]. However, both surgeons performing the surgery have fellowship training, extensive TAR experience, and are non-consultant surgeons to minimize any potential bias or conflict. Literature has indicated that the learning curve is minimal in newer implants and with experience [32]. And finally, there may other differences in technique, instrumentation, or implants between the two systems that could have contributed.

Another difference that was identified in this comparison was procedure time. The MM Group had an average time of 97.4 min compared to the DT Group with an average time of 80.6 min, $p = 0.04$. This was not the primary objective of the paper and is also most likely due to more familiarity with the implant system in the DT Group compared to the MM Group. Another possible source of difference in time is the ancillary and adjunctive procedures performed, but there was not a significant difference in this regard between the groups. While there is a difference in procedure time, the authors do not feel this is a clinically relevant difference and likely would become more similar with time.

The current study does have several weaknesses. First, the study only looked at accuracy of postoperative alignment between two systems. There were no patient outcome measures, and no evaluation of other

implant and PSI systems. Second, the study is relatively small with 16 ankles in the case series, the MM Group. This was addressed by comparing each case ankle to 2 control ankles (DT Group) to increase numbers and provide more statistical power. Third, the study looked at varus, valgus, and neutral ankles and with the available numbers there was no ability to break down and compare each of these groups to each other based on deformity level. The authors have previously reported that varus ankles may be less accurate than valgus ankles when using PSI [14]. Fourth, postoperative images were the 1st weight bearing films at 4 – 6 weeks postoperatively to minimize variability of position but cannot account for long term maintenance of deformity correction, only initial correction. Fifth, soft tissue and osseous rebalancing is very important in this tibial – talar (β) alignment, and accounts for a portion of coronal plane alignment, not only the implant cuts. This soft tissue and osseous reconstruction does add a level of variability to the results, but is a common and necessary practice in TAR, and cannot be avoided. Sixth, while there is a statistically significant difference in coronal plane accuracy between the DT and MM group of 1.1 $^{\circ}$ and 1.7 $^{\circ}$ ($p = 0.04$), respectively, the authors cannot confirm a clinically relevant difference. However, accurate placement of implants has been shown to improve results [4,5] so any assistance in placement may have value. Finally, as mentioned, the authors are more familiar with the system in the DT Group compared to the MM Group, and there is a possibility of learning curve error in the study. This should be minimized with overall experience, training, and lack of any industry bias.

In conclusion, PSI in TAR is accurate and this has been demonstrated in this article and many other published studies. However, it does appear that the cutting guides that interlock with the distal tibial osteophytes are more accurate than those that use the anterior surface anatomy of the medial malleolus, at least in the coronal plane. Further studies including larger sample sizes, randomization, and more implant systems should be conducted to further elucidate this difference.

IRB Statement

IRB Approval obtained through the Advocate Research Institute, approval # 23.025ET

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Declaration of competing interest

none

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none

Supplementary Materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1053/j.jfas.2025.03.012>.

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