

## Accuracy of patient-specific instrumentation in total ankle arthroplasty: A comparative study

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### ABSTRACT

**Background:** Patient-specific instrumentation (PSI) for TAA is a novel technology with several potential benefits. The primary goal of this study was to compare the use of PSI with the standard referencing guide (SRG) in regards to accuracy of tibial implant positioning. Operative time, fluoroscopy time and accuracy of PSI preoperative reports were also evaluated.

**Methods:** A retrospective analysis of 99 patients who underwent a primary TAA with the INFINITY prosthesis (Wright Medical, Memphis, TN) was performed. Patients were divided in two groups based on the type of instrumentation used during the TAA (75 in the PSI group vs 24 in the SRG group). There was no significant difference between groups in regards to age at the time of surgery ( $P=0.122$ ), sex ( $P=0.138$ ), number of concomitant procedures performed during surgery ( $P=0.567$ ) and etiology ( $P=0.841$ ). However, preoperative deformity was significantly smaller in the PSI group ( $P=0.002$ ).

**Results:** Tibial implant positioning was similar between groups. In the coronal plane, the absolute deviation of the tibial implant from the intended alignment was  $1.7 \pm 1.4^\circ$  for the SRG and  $1.6 \pm 1.2^\circ$  for PSI ( $P=0.710$ ). In the sagittal plane, the absolute alignment deviation of the tibial implant was  $1.8 \pm 1.4^\circ$  for the SRG and  $1.9 \pm 1.5^\circ$  for PSI ( $P=0.675$ ). Operative time (167 vs 190 min,  $P=0.040$ ) and fluoroscopy time (85 vs 158 s,  $P<0.001$ ) were significantly decreased in the PSI group. The PSI preoperative plan report correctly predicted the implant size in 73% of cases for the tibial component and in 51% of cases for the talar component.

**Conclusions:** PSI provided similar tibial component alignment as standard instrumentation. Additionally, PSI preoperative plan reports were poor predictors of implant sizing. Therefore, the final decision should always be based on surgeon's experience in order to prevent errors in implant sizing and positioning.  
**Level of evidence:** Level III, retrospective comparative study.

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### 1. Introduction

New technologies are constantly being developed with the final purpose of improving medical treatments. Based on preoperative computed tomography, patient-specific instrumentation (PSI) for total ankle arthroplasty (TAA) allows the construction of preoperative plans with respect to bone resections, implant positioning and sizing of the implants. PSI has demonstrated variable results for total knee arthroplasty (TKA) in the past decade. Even though some authors [1–3] have shown improvement of alignment and decreased operative time in TKA with the use of PSI, recent studies

[4,5] have failed to confirm these results. However, it is still unclear whether PSI is a reliable tool when applied in TAA.

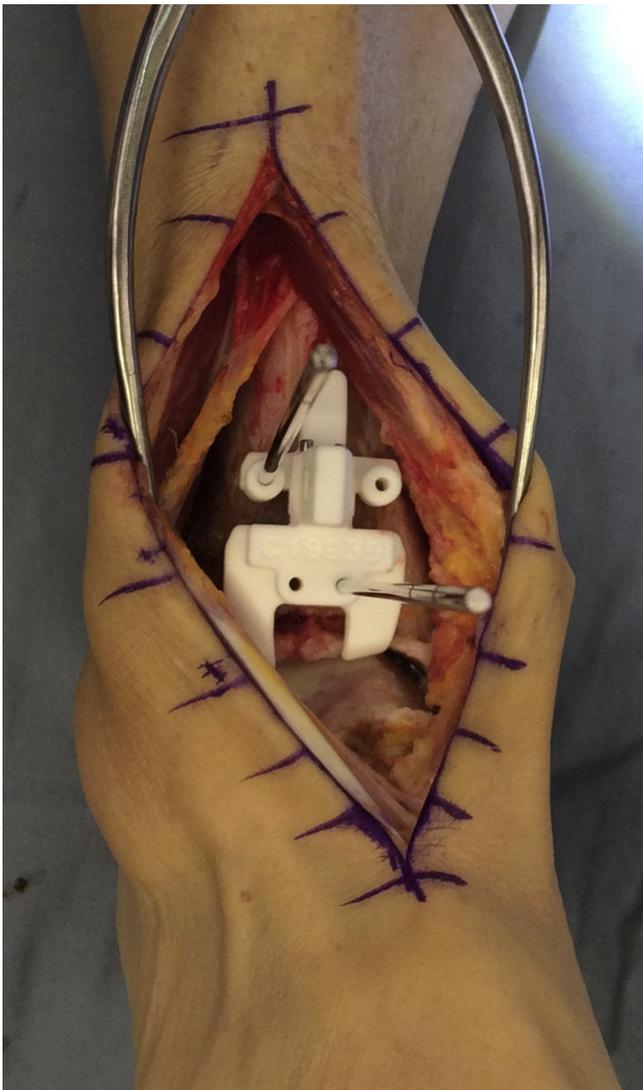
Despite the recent increase in the adoption of total ankle replacement, the rate of complications and need for revision remains high after TAA [6–9]. Previous studies have shown that adequate positioning of the implants is essential for a satisfactory clinical outcome [10,11]. Moreover, biomechanical studies have demonstrated that poor alignment of implants may lead to early component wear, compromising the longevity of the prosthesis [12,13].

A great variety of implant types and instrumentation systems are available. However, there is no consensus in the literature regarding which type of device is capable of providing better alignment and positioning of the components in the most accurate and reproducible way. In recent years, patient-specific instrumentation (PSI) via preoperative computed tomography for TAA was developed and made available in the US through PROPHECY

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(Wright Medical Technology, Memphis, TN). This new technology has the potential benefit of providing more accurate and reproducible positioning of the components. The guide is customized with respect to the specific anatomy of each patient (Fig. 1). In addition, by facilitating the implantation of the tibial and talar components, PSI may potentially reduce operative time and radiation exposure. One main disadvantage of PSI is the additional cost of this technology [14].

Since an accurate alignment of components is essential in TAA, the primary goal of the present study was to compare PSI with the standard referencing guide (SRG) in regards to accuracy of tibial component placement. Additionally, the accuracy of the PROPHECY preoperative plan report regarding prediction of tibial and talar component sizes, reliability of reported preoperative ankle deformity, and documented instances in which PSI was abandoned for standard instrumentation were evaluated. Operative time and fluoroscopy time were also calculated and compared between groups. We hypothesized that through the use of specific guides based on patient-specific anatomy, PSI would provide a more accurate tibial component alignment in comparison to the SRG group, possibly justifying its additional costs.



**Fig. 1.** PROPHECY tibial alignment guide is pinned on the distal tibia after proper fit is achieved. The guide is customized according to patient-specific anatomy, based on preoperative computed tomography.

## 2. Methods

### 2.1. Population demographics and study design

Medical records of 99 patients who underwent primary TAA with the INFINITY prosthesis (Wright Medical Technology, Memphis, TN) between July 2014 and December 2016 were retrospectively analyzed. Inclusion criteria included a diagnosis of end-stage ankle arthritis and TAA with the INFINITY prosthesis. Patients were excluded if they had a prior history of ankle arthroplasty, prior ankle arthrodesis, or avascular necrosis. The study was approved by the Institutional Review Board of the hospital. All procedures were performed by 4 fellowship-trained foot and ankle orthopedic surgeon with extensive experience in total ankle arthroplasty. The operative technique was carried out according to the manufacturer's guideline.

Twenty-four patients who underwent a primary INFINITY TAA with the standard extramedullary referencing guides, and 75 patients who underwent TAA using PSI were included in the study. Four patients who did not have postoperative weightbearing radiographs (2 patients in each group), and one patient from the PSI group who had a proximal tibial deformity were excluded. Additionally, in 3 cases the use of PSI was abandoned intra-operatively and converted to the SRG. These patients were also excluded from the study, but the rationale for abandoning the PSI was recorded through review of the operative notes and medical records. By the time the 4 surgeons started performing the INFINITY TAA, PROPHECY (PSI) was already available in the market, which allowed operative procedures of both groups to be performed in the same timeframe, with both types of instrumentation systems used interchangeably during the whole period of the study. The choice on which type of instrumentation to be used was made at the discretion of the surgeon, but PSI was not used in patients with preoperative ankle deformity greater than 15°. Patients with a severe preoperative deformity greater than 25° underwent an INBONE TAA (Wright Medical Technology, Memphis, TN), and therefore were not included in the study.

There was no significant difference between groups in regards to age at the time of surgery ( $P=0.122$ ), sex ( $P=0.138$ ), number of concomitant procedures performed during surgery ( $P=0.567$ ) and etiology ( $P=0.841$ ) (Table 1). Since concomitant procedures performed during TAA have a direct effect over operative and fluoroscopy time, we further stratified the concomitant procedures by type and observed no difference between the two groups. However, there was a significant difference in the degree of preoperative deformity observed between groups. Patients who underwent surgery with the SRG method had an average absolute preoperative deformity of 11.4°, compared to 6.3° for the PSI group ( $P=0.002$ ).

**Table 1**

Distribution according to age, additional procedures, sex, etiology and preoperative deformity.

	PSI	SRG	P value
Age	64.5 ± 8.7	60.6 ± 11.0	0.122
Additional procedures			
Yes	55 (73%)	19 (79%)	0.567
No	20 (27%)	5 (21%)	
Sex			
Male	37 (49%)	16 (67%)	0.138
Female	38 (51%)	8 (33%)	
Etiology			
Posttraumatic osteoarthritis	26 (35%)	7 (29%)	0.841
Primary osteoarthritis	47 (62%)	16 (67%)	
Rheumatoid osteoarthritis	2 (3%)	1 (4%)	
Preoperative deformity	6.3 ± 5.2	11.4 ± 6.5	0.002

All patients in the PSI group underwent a nonweightbearing CT scan from the knee through the ankle, according to the manufacturer's guidelines. A 3D model was produced and the preoperative anatomy was assessed. The intended alignment and predicted component sizes were determined from the model. The intended alignment of the tibial component was set perpendicular to the mechanical axis of the tibia in the PSI group, and perpendicular to the anatomic axis in the SRG group.

## 2.2. Radiographic evaluation

Radiographic outcomes were assessed and measurements were made through previously validated methods, which have shown high intra and interobserver reliability [11,15,18,19]. All measurements were performed by a fellowship-trained foot and ankle orthopedic surgeon, who did not perform an operation on any of the patients in the study. The angles were measured to the nearest 0.1° using our institutions digital PACS (picture archiving and communication system) (General Electric Healthcare, UK).

Preoperative deformity was assessed through anteroposterior (AP) weightbearing radiographs of the ankle [19,20], and was defined as the angle between the anatomic axis of the tibia and a line perpendicular to the talar dome. All postoperative measurements were based on the first postoperative weightbearing radiograph, generally 8 weeks after surgery.

Postoperative ankle alignment was assessed on the AP radiograph. The angle between the anatomic axis of the tibia and a line tangential to the superior surface of the talar component was measured (Fig. 2). Neutral ankle alignment was defined as less than 5° of deviation from 90°, as reported in a previous study [20].

Tibial implant alignment was assessed in the coronal and sagittal planes, with the use of AP and lateral radiographs [18]. For the SRG group, a proximal circle was drawn tangential to both cortices of the tibia. Another circle was drawn in the distal tibia, in contact with the two cortices and the lower portion of the tibial component. A line was drawn connecting the center of the two circles, providing the anatomic axis of the tibia. Another line was drawn through the lower border of the tibial component. The final alignment of the implant was defined as the medial angle for coronal alignment (Fig. 3), and the anterior angle for sagittal alignment (Fig. 4).

Preoperatively, the PROPHECY template allows the surgeon to choose the desired alignment for the tibial component. The alignment of the tibial component was set perpendicular to the mechanical axis for all cases in the PSI group. In the SRG group, the limited view provided by the intraoperative fluoroscopy does not allow an accurate alignment of the tibial component in relation to the mechanical axis of the tibia. Therefore, in all SRG cases the surgeons aimed to place the tibial component perpendicular to the anatomic axis.

For all patients, postoperative radiographic measurements of the tibial component alignment were measured relative to the anatomic axis of the tibia. This technique has been utilized in previous studies and has been shown to be reliable, and the most clinically relevant method to assess deformity [11,15,16,18,19]. Since in the PSI group the intended alignment of the tibial component was set to be perpendicular to the mechanical axis of the tibia, we corrected our postoperative measurements to determine variation from intended alignment by taking into account the discrepancy between the anatomic and mechanical axis of each patient. This was provided for each patient in the preoperative PROPHECY plan (Fig. 5). The average difference in absolute values between the mechanical and the anatomic axes for patients in the PSI group was  $1.2 \pm 0.9^\circ$  in the coronal plane and  $1.4 \pm 1.0^\circ$  in the sagittal plane.

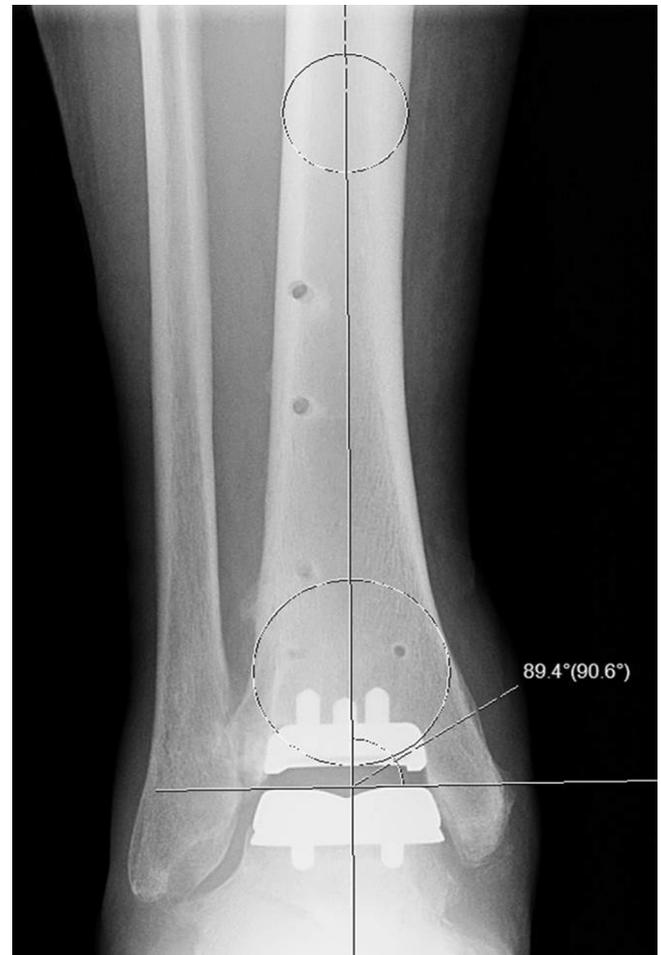


Fig. 2. Anteroposterior radiograph demonstrating the postoperative ankle alignment. The angle is measured between the anatomic axis of the tibia and a line tangential to the superior surface of the talar component.

## 2.3. Preoperative plan reports and other outcomes

The accuracy of the PROPHECY preoperative plan was also analyzed in this study. Predicted tibial and talar implant sizes were recorded from preoperative reports and compared to the actual size implanted during the operative procedure.

Preoperative deformity measurements performed on weight-bearing radiographs were compared to the preoperative deformity values provided by the PROPHECY preoperative plan reports, which are based on nonweightbearing CT scans. Surgery length was calculated from the moment of incision until the final dressing was applied, and compared between the two groups. Fluoroscopy time was also recorded and compared between the groups.

## 2.4. Statistical analysis

Normally distributed data were analyzed using independent samples t-tests. Chi-square tests were used to compare categorical data. Bivariate correlations were used to determine differences between absolute preoperative deformity and final implant deviation, pre-operative deformity and post-operative ankle deviation, and differences in predicted versus actual implant size used. Fisher's exact test was used to determine how often the PSI was abandoned for SRG. A P value of less than 0.05 was considered statistically significant.



**Fig. 3.** Anteroposterior radiograph demonstrating the tibial component alignment in the coronal plane. The angle is measured between the anatomic axis of the tibia and a line drawn through the lower border of the tibial component. An angle of less than  $90^\circ$  represents varus alignment, whereas an angle of more than  $90^\circ$  represents valgus alignment of the tibial component.

### 3. Results

#### 3.1. Tibial component alignment

Average tibial component alignment in the coronal plane was  $89.0 \pm 2.0^\circ$  for SRG and  $89.3 \pm 1.9^\circ$  for PSI ( $P=0.638$ ). Average tibial component alignment in the sagittal plane was  $89.2 \pm 2.1^\circ$  for SRG and  $89.0 \pm 2.2^\circ$  for PSI ( $P=0.751$ ).

In the coronal plane, the absolute deviation from the intended alignment of the tibial implant was  $1.7 \pm 1.4^\circ$  for the SRG and  $1.6 \pm 1.2$  for PSI ( $P=0.710$ ). In the sagittal plane, the absolute



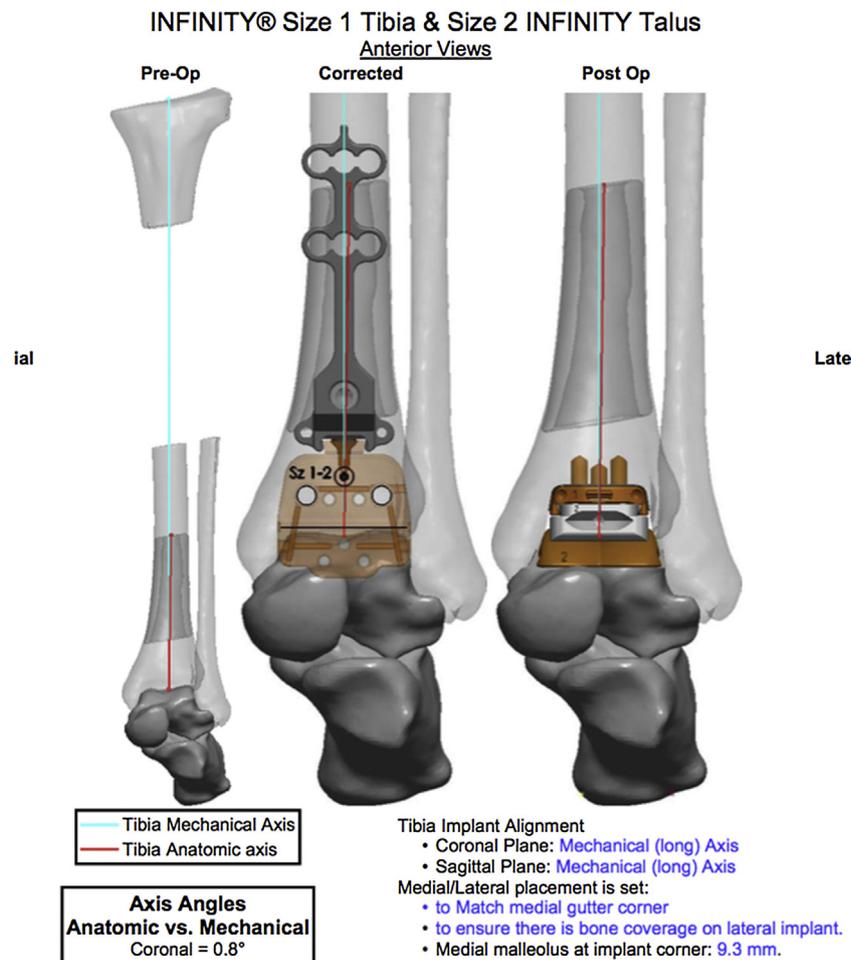
**Fig. 4.** Lateral radiograph demonstrating the tibial component alignment in the sagittal plane. The angle is measured between the anatomic axis of the tibia and a line drawn through the lower border of the tibial component. An angle of less than  $90^\circ$  represented a positive slope, whereas an angle of more than  $90^\circ$  represented a negative slope of the tibial component.

deviation from the intended alignment of the tibial implant was  $1.8 \pm 1.4$  for the SRG and  $1.9 \pm 1.5$  for PSI ( $P=0.675$ ) (Table 2).

Accuracy of the tibial component placement was similar between groups in both the coronal and sagittal planes. In the coronal plane, 88% of cases from the SRG group had less than  $3^\circ$  of deviation, 8% had a deviation from 3 to  $5^\circ$ , and only 1 patient (4%) had a deviation of more than  $5^\circ$ , whereas 85.3% of cases from the PSI group had less than  $3^\circ$  of deviation, 13.3% had a deviation from 3 to  $5^\circ$ , and 1 patient (1.3%) had a deviation of over  $5^\circ$  ( $P=0.575$ ). In the sagittal plane, 88% of cases from the SRG group had less than  $3^\circ$  of deviation, 8% had a deviation from 3 to  $5^\circ$ , and 4% had a deviation of more than  $5^\circ$ . In the PSI group, 85% had less than  $3^\circ$  of deviation, 11% had a deviation from 3 to  $5^\circ$ , and a deviation of over  $5^\circ$  was observed in 4% ( $P=0.884$ ) (Table 3).

#### 3.2. Preoperative plan

Preoperative plan reports accurately predicted implant size used during the operative procedure in 55 of 75 cases (73%) for the tibial component. Out of the 20 tibial component mismatches, the plan predicted an implant size larger than what was actually



**Fig. 5.** PROPHECY preoperative report provides the intended implant alignment, the predicted implant sizes, and the angle difference between the anatomic and mechanical axes.

used in 19 cases, and an implant size smaller than what was actually used in 1 case. Talar implant size was correctly predicted in 38 of 75 cases (51%). Out of the 37 mismatches, the plan predicted an implant size larger than what was actually used in 35 cases, and an implant size smaller than what was actually used in 2 cases. The use of PSI had to be abandoned intraoperatively in 3 cases (3.8%). In 2 of these cases, the surgeon observed excessive external rotation of the tibial cutting guide, and in one case the tibial guide was located too close to the medial malleolus.

**Table 2**  
Average tibial implant deviation from intended alignment in the coronal and sagittal planes, by group (mean ± SD).

	PSI	SRG	P value
Coronal tibial deviation (degrees)	1.6 ± 1.2	1.7 ± 1.4	0.710
Sagittal tibial deviation (degrees)	1.9 ± 1.5	1.8 ± 1.4	0.675

**Table 3**  
Distribution of postoperative coronal and sagittal alignment of the tibial component, by degrees of deviation from the intended alignment.

	Coronal plane			Sagittal plane		
	<3°	3°–5°	>5°	<3°	3°–5°	>5°
SRG	88% (21/24)	8% (2/24)	4% (1/24)	88% (21/24)	8% (2/24)	4% (1/24)
PSI	85.3% (64/75)	13.3% (10/75)	1.3% (1/75)	85.3% (64/75)	10.7% (8/75)	4% (3/75)
P value	0.575			0.884		

A strong correlation was observed between the preoperative deformity value provided by the preoperative PROPHECY reports and the measurements performed manually on weightbearing radiographs (ICC = 0.950).

**3.3. Operative time and fluoroscopy time**

Operative time and fluoroscopy time were significantly different between groups. The average operative time for the SRG group was 190 ± 46 min, while in the PSI group it was 167 ± 42 min (P = 0.040). The average fluoroscopy time for the SRG group was 158 ± 51 s, against 85.6 ± 28 s in the PSI group (P < 0.001).

**3.4. Postoperative alignment of the ankle**

Neutral ankle alignment, defined as less than 5° of coronal deformity [20] was obtained postoperatively for all patients in the PSI group, and for all but 1 patient in the SRG group, who had 5.7° of

varus deviation postoperatively. The ankle alignment was corrected postoperatively to an average of 88.7° in the PSI group and 89.8° in the SRG group.

#### 4. Discussion

Correct implant positioning is critical for TAA longevity [10–13,21–23]. In an *in vitro* study using finite element models, Espinosa et al. [12] noted that version malalignments of more than 5° of the components induced increased contact pressures that reached the yield stress of polyethylene. Thus demonstrating that alignment of the prosthetic components is critical to the long-term success of the ankle replacement. In the present study, PSI provided accurate positioning of the tibial component, which is in agreement with previous reports [14–17]. However, no significant difference in the final alignment of the tibial component was observed between groups. In a study with 44 patients undergoing the INBONE II TAA using PROPHECY, Daigre et al. [16] found that in all cases, the tibial component alignment was within 5° of the intended alignment.

Operative and fluoroscopy times were significantly decreased in the PSI group. However, the PSI group presented with a significantly smaller preoperative deformity (6.3 vs 11.4°), which could have influenced the results. On the other hand, the number of concomitant procedures performed during surgery was similar between groups. In a consecutive series of 762 primary TAAs, Gross et al. [24] found that mean operative time was significantly longer in patients who had postoperative wound complications. Therefore, a potential benefit of PSI would be a decrease in the risk of complications associated with operative time.

When examining the predicted size of the talar and tibial components, PSI preoperative reports were especially poor predictors of talar implant size, correctly predicting it in only 51% of cases. In addition, the use of PSI had to be abandoned intraoperatively in 3 cases due to inaccuracy of the tibial guide, which was detected by the surgeon after positioning of the guide on the tibia. In these cases, PSI was abandoned and SRG was used during the whole procedure. It is therefore imperative that a surgeon knows the standard instrumentation so that he or she is able to use their best judgment to select a different implant size or abandon the PROPHECY guides when necessary. Thus, PSI should not be used by inexperienced surgeons as an attempt to flatten the learning curve, since blindly trusting PSI can possibly lead to errors in implant positioning and sizing.

The calculated preoperative deformity based on nonweightbearing CT scans provided by the PROPHECY reports strongly correlated with the measurements performed in weightbearing radiographs (ICC=0.950). A previous study [16] used the preoperative deformity values provided by PROPHECY reports, but the reliability of these measurements had not yet been demonstrated. This is the first report to validate the preoperative deformity values provided by PROPHECY preoperative plan.

We believe this study is of great value in providing additional evidence of the potential benefits and limitations of PSI. The main question that remains is whether the potential benefits outweigh the additional financial burden of this technology. Hamid et al. [14] identified a cost-savings threshold of \$863 below which PSI was less costly than standard referencing instrumentation. In that study, only the objective reduction of costs resulting from a decrease in operative time was considered. Potential factors such as a decrease in radiation exposure and the potential for decreased perioperative complications resulting from decreased operative time were not considered, and may represent additional benefits of PSI. On the other hand, not only the costs for customization of the guides, but also the cost of the CT scan from the knee through the ankle must be taken into account when PSI is being considered, even though a considerable amount of patients receive a CT Scan prior to TAA.

The strength of this study is that it directly compares two groups that underwent TAA with the same type of implant in the same timeframe, using a cohort of patients from a single center. To our knowledge, this is the largest population analyzed in a study regarding the use of PSI in TAA thus far.

There are also several limitations in this study. As a consequence of the retrospective design of the present study, patients in the PSI group presented with a significantly smaller degree of preoperative deformity than the SRG group. Operative and fluoroscopy time may have been affected by this difference, representing a bias favoring the use of PSI. It should be emphasized that the accuracy of tibial component alignment, which was the main outcome of this study, was not influenced by this difference between groups, since the tibial cuts are referenced to the tibial axis only and are not contingent upon ankle deformity. Secondly, in this study PSI failed to provide a more accurate tibial implant alignment than the SRG. However, operative procedures were performed by four surgeons with extensive experience in TAA. Results may differ among less experienced surgeons, and PSI could conceivably provide a more reproducible positioning of components in that scenario. Additionally, the choice of whether or not to use PSI was made at the discretion of the surgeons, which could have caused a selection bias.

#### 5. Conclusion

We believe that PSI may be a useful tool for TAA, helping to provide accurate and reliable implant positioning. However, surgeon experience and judgment are imperative while using PSI, since blindly trusting the customized guides and preoperative reports may lead to errors in positioning and sizing of the components. Moreover, according to the present study, a superior accuracy in tibial implant alignment should not be expected with the use of PSI. While accuracy in implant positioning cannot be used to justify its additional costs, further studies are needed to determine whether other potential benefits of PSI, such as a decrease in operative time, fluoroscopy time and a decrease in perioperative complications, may outweigh the financial burden of this technology.

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#### Conflict of interest

All authors were fully involved in the study and preparation of the manuscript and the material within has not been and will not be submitted for publication elsewhere.

J.T.D is a paid consultant for Zimmer and Arthrex, Inc.

S.J.E is a paid consultant for Wright Medical Technology.

C.A.D. is a paid consultant for Integra LifeSciences, Wright Medical Technology, Stryker and RTI Surgical.

The remaining authors declare that they have nothing to disclose.

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