

Comparison of Time and Cost Savings Using Different Cost Methodologies for Patient-Specific Instrumentation vs Standard Referencing in Total Ankle Arthroplasty

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Abstract

Background: Patient-specific 3-D printing cutting blocks (PSI) have been used instead of traditional intramedullary cutting guides. We hypothesized that PSI would lead to significantly decreased operating room (OR) time and significant cost savings to our institution with noninferior radiographic outcomes and no difference in expected vs actual implant size when compared with standard referencing (SR).

Methods: Patients who had undergone total ankle replacements at our institution from 2013 through 2016 were included in the study. Associations between demographic variables and postoperative alignment in the SR vs PSI group were calculated using the Wilcoxon rank-sum test and the intraclass correlation coefficient. The cost of the operation was calculated using both an institutionally based fixed cost of OR time and using Time Driven Activity Based Cost (TDABC) accounting. A total of 43 patients were included in the study, 13 in the SR group and 30 in the PSI group.

Results: Operative time (168 vs 137 minutes) and tourniquet time (123 vs 113 minutes) were significantly lower in the PSI vs the SR group. PSI predictions were accurate 100% of the time for tibial components and 83% of the time for talar components. Average costs of TAA using PSI were significantly reduced by \$7597.00 when using traditional OR accounting, whereas PSI was \$836.00 more expensive on average using TDABC accounting.

Conclusion: Further research is needed to determine the cost-effectiveness of PSI vs SR in TAA; however, it does appear to save time intraoperatively. The long-term effect on clinical outcomes requires further study.

Level of Evidence: Level III, case-control study.

Keywords: total ankle arthroplasty, cost-effectiveness, patient-specific instrumentation, standard referencing, value-based care

Introduction

The popularity of total ankle arthroplasty (TAA) for end-stage ankle arthritis has been significantly growing in popularity over the past 10 years.¹⁷ During this period of growth, TAA has undergone multiple evolutions in surgical technique, culminating most recently with the advent of 3-D printing cutting guide techniques. The use of patient-specific 3-D printing cutting blocks based on an individual's unique arthritis pattern, dubbed patient-specific instrumentation (PSI), may potentially reduce costs while maintaining similar outcomes during TAA.⁷ Patients undergo customized thin-slice CT scans from knee to foot to map out their

specific arthritis pattern. Afterwards, a 3D printer creates a custom cutting block tailored to the patient's specific anatomic alignment, avoiding the task of intramedullary guide setup. PSI has been used in other forms of orthopedics with

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equivocal results.¹⁴ PSI offers several theoretical advantages including the ability to template preoperatively, reduced intraoperative decision making, decreased operative time, decreased blood loss, and decreased blood transfusions. However, PSI cost effectiveness has also been questioned, particularly in its current generation.¹⁰

There are many methods currently available for measuring cost efficiency, with continued debate in the literature as to which is superior. Hamid et al⁷ found that SR and PSI produced similar radiographic outcomes, with a cost savings threshold of \$863, below which PSI was cheaper than SR as analyzed via Time Driven Activity Based Cost Analysis (TDABC). Additionally, 87% of patients in this study underwent adjunct procedures, and therefore the operative time and cost analysis sample consisted of 7 patients.⁷ Other cost analysis methods used to measure effectiveness have been based on operating room (OR) charges, billing costs, cost of materials, and out-of-pocket cost paid by payers.^{5,16} Similarly, estimates of OR time per minute and other input variables used in cost analysis vary widely.⁶ We are not aware of any other studies comparing TDABC to other cost analysis methodologies in TAA.

The purpose of this study was to compare the results of TAA using PSI vs SR, focusing on time in the OR and to compare the cost-effectiveness of the procedure using 2 popular cost analyses, TDABC and standard accounting, based on OR time dollar cost averaging. We hypothesized that PSI would show noninferior radiographic outcomes to SR while also demonstrating a significantly reduced operative and tourniquet time. We also hypothesized that PSI would demonstrate no significant cost savings using TDABC or facility-based cost analysis.

Methods

Demographic Variables

Patients who had undergone total ankle replacements by a single fellowship-trained foot and ankle surgeon at our institution from July 2010 through December 2016 were included in the study. Exclusion criteria included anyone undergoing any secondary arthroplasty procedure(s), including revision TAA or conversion from fusion to TAA. Demographic variables recorded include name, age, sex, date of surgery, size of prosthesis, number and size of cuts made, size of stem inserted, and additional procedures. Other non-demographic variables include operative time, tourniquet time (taken from operative report), predicted component size (recorded preoperatively), and actual component size used. Preoperative predictions were made by the senior author and documented preoperatively in the patient chart.

A total of 43 patients were included in the study, 13 in the standard referencing (SR) group and 30 in the PSI group. Three patients were excluded based on the criteria above. There was no significant difference in demographic data between the SR and PSI groups (Table 1).

Table 1. Patient Demographics.

	SR	PSI
Age, mean	64.8	59.9
Sex, n/N (%)		
Male	7/13 (54)	16/30 (53)
Female	6/13 (46)	14/30 (47)
Side, n/N (%)		
Right	4/13 (31)	10/30 (33)
Left	9/13 (69)	20/30 (67)
Implant, n/N (%)		
Inbone	13/13 (100)	18/30 (60)
Infinity	0/13 (0)	12/30 (40)

Abbreviations: SR, standard referencing; PSI, patient-specific instrumentation.

Primary outcome measures included postoperative weight-bearing tibial component coronal and sagittal alignment, surgical time, tourniquet time, and accuracy of component sizing based off preoperative plans. Predicted tibial and talar components were recorded from preoperative reports and compared to actual implant size based on operative notes. Analysis of alignment was conducted using previously described techniques with 3-month standing postoperative radiographs. Radiographic measurements were independently recorded by a fellowship-trained foot and ankle surgeon and a senior orthopedic resident, who were both blinded to the patient's information and the surgical technique employed (PSI vs SR).

Surgical Technique

All TAA procedures were performed using either SR intramedullary implants or PSI. SR procedures were performed using the INBONE system (Wright Medical Technology, Memphis TN), whereas PSI procedures were completed using the PROPHECY implant system (Wright Medical Technology). The operative technique for TAA has been previously described.³ The INBONE technique includes the creation of a 3D printing cutting guide prior to surgery based off of a standardized preoperative CT scan from the knee to the midfoot and subsequent 3-D bone models. Individual patient CT data was converted to 3-D computer models via coronal and sagittal alignment measurements that were taken using previously published techniques.

Cost Analysis

Cost of the preoperative CT scans was based on the average cost of CTs billed to insurance/patients at our facility, as reported by our institution records. The cost of the operation was determined using Time Driven Activity Based Cost Analysis (TDABC) with cost/minute data previously used for total ankle arthroplasty.⁷ For facility-based cost analysis, OR expense time was specific to our institution and was taken per our historical data, which was received directly from OR administrative personnel.

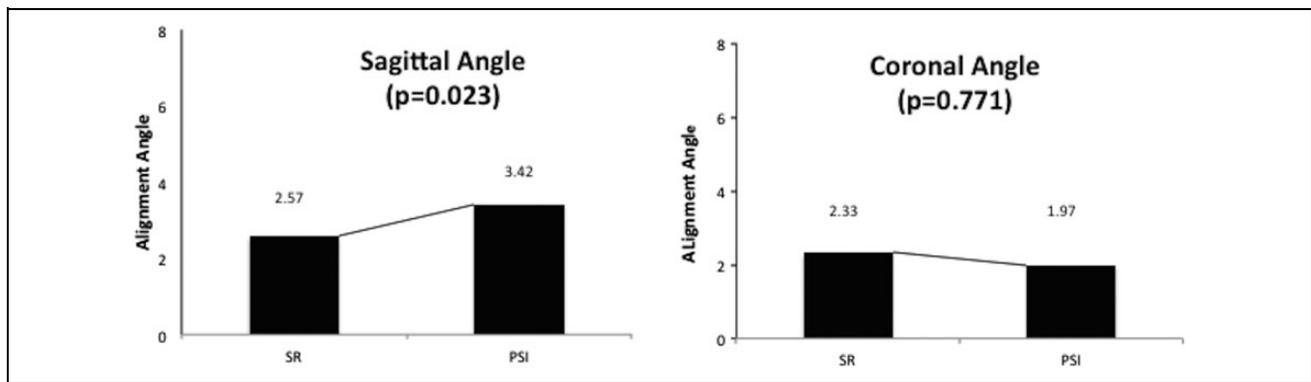


Figure 1. Coronal vs sagittal angle in the SR vs PSI groups.

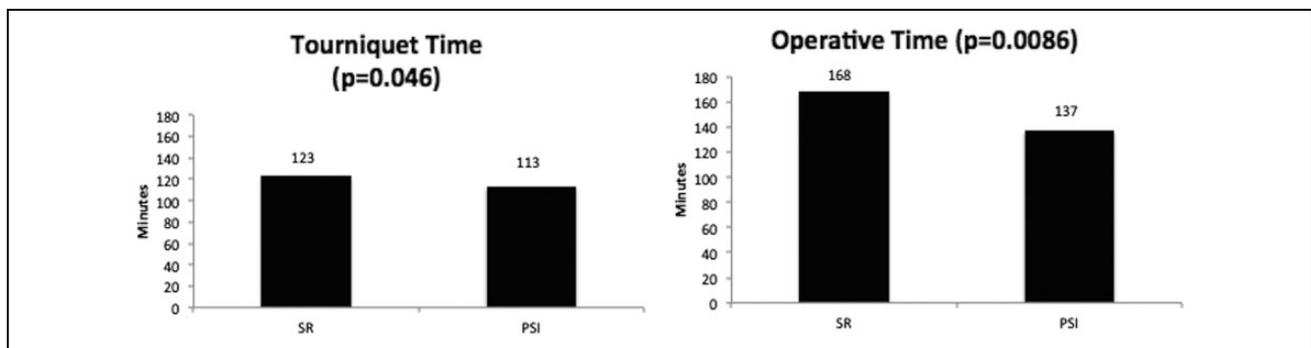


Figure 2. Operative and tourniquet time.

Statistical Analysis

Descriptive statistics were calculated for demographic and clinic variables of interest. Associations between these variables and the primary outcomes of postoperative alignment in the SR vs PSI group were determined using the Wilcoxon rank-sum test. Interobserver reliability was judged via intraclass correlation coefficient. Similar secondary analyses were performed to evaluate differences between SR and PSI patients including age, sex, side, and implant used.

Results

Coronal and Sagittal Alignment

Coronal vs sagittal alignment angles are listed for the 2 groups in reference to the anatomic axis of the ankle (Figure 1). Sagittal alignment differed significantly between the 2 groups ($P = .0229$).

Operative and Tourniquet Time

Operative time was 168 minutes for the SR and 137 minutes for the PSI group ($P = .0086$). Tourniquet time was similarly reduced in the PSI group ($P = .0446$) by 10 minutes (Figure 2).

Component Size Prediction

PSI predictions were accurate 100% of the time for tibial components and 83% of the time for talar components.

Cost Savings—Traditional Accounting Methods

OR time was determined to be billed at \$4293.00 per half hour as per our institutional records. Cost savings in the SR group was determined to be \$8872.00 ($31/15 \times 4293.00 = \8872.00). After subtracting the cost of the preoperative CT scan (\$1275.00), cost savings for this group was \$7597.00.

The cost savings using the TDABC method was \$440.20, based on operative time saved during the procedure. With the addition of the cost of the preoperative CT scan, the PSI procedure was \$834.80 more expensive than the SR method (see Addendum 1 for TDABC accounting).

Additional Procedures

Eight patients underwent additional procedures, 2 in the SR and 6 in the PSI group, the most common of which was plating or screw fixation of the medial malleolus. There was no significant difference in concomitant procedures between the 2 groups.

Discussion

We found that preoperative CT scans used for the creation of 3D cutting guides resulted in significant time savings of 31 minutes, resulting in a cost savings of 7597.00 after incorporating the value of the preoperative CT scan using traditional cost analysis. When TDABC cost analysis was applied, the procedure was determined to be more costly than SR by \$834.80. Similarly, Hamid et al⁷ found PSI to be more costly than SR by \$863.00 using TDABC. Their cost reduction was influenced by a greater reduction in OR time vs our study. Additionally, our study also contains a larger group of patients undergoing TAA without adjunct procedures (31 patients vs 11 patients) than the cohort of Hamid et al.⁷

To our knowledge, this is the first study to comparatively analyze TAA using multiple different cost analyses. TDABC has been validated in other areas of orthopedics, including both total hip and knee arthroplasty.^{1,9} Akhavan et al¹ found TDABC to be inherently more accurate than traditional cost methodology when estimating the cost to charges in arthroplasty procedures and speculated that TDABC is a more effective means of determining inefficiencies in care. In contrast to our TDABC cost analysis findings, PSI was significantly cheaper when looked at from a traditional facility-based accounting methodology. Previous studies in total hip arthroplasty have found that traditional accounting methodologies overestimate the cost of different arthroplasty procedures, whereas TDABC provides a more accurate measure of the true resources. Although TDABC may be an accurate measurement of cost analysis, the use of institutional cost and minutes of operating time and cost of major materials to estimate the total procedure cost remains a cost analysis that remains popular in the literature.⁵ As hospitals move toward a value-based care model, with value defined as outcomes divided by costs, accurate and standardized tracking of procedural costs must be better defined as these figures will continue to grow in importance.¹²

PSI also significantly decreased the tourniquet time in our study. Reduced tourniquet time has been associated with decreased infections, blood loss, and complications following arthroplasty procedures.¹¹ Tourniquet times >100 minutes is a known risk factor for postoperative complications in other areas of arthroplasty.¹¹ It is our institutional policy to let down the tourniquet after 2 hours, which may create an inequality in our tourniquet time when compared with overall operative time between the 2 groups. These areas should be further studied so that the ideal tourniquet time at which point risk reduction is achieved without compromising outcomes in TAA can be better understood, as well as to determine the clinical significance of tourniquet time reduction in TAA.

PSI resulted in 100% and 83% accuracy in prediction of tibial and talar implants, respectively. This is consistent with other studies in the literature where talar implant accuracy

has been lower than that of the tibial component. Our accuracy is consistent with previous studies, with one recent PSI cohort predicting tibial implants accurately in 73% of cases in a similar series (55 of 75 cases).¹⁵ Previous retrospective studies on the accuracy of PSI vs SR has been done by Hsu et al,⁸ who reviewed 42 patients, all of whom underwent preoperative CT for surgical planning prior to TAA. They found that regardless of preoperative deformity, there were accurate predictions of 100% of SR vs 92% of PSI cases. Again here talar implant accuracy was significantly greater (76%) for SR cases vs PSI (46%) cases, and was not attributable to any other variable studied. Saito et al¹⁵ noted 3 instances where PSI failed intraoperatively and the authors were forced to revert to traditional TAA cutting blocks, which could be considered an inaccuracy of the PSI system. The costs of these conversions to traditional methods have not been studied directly, but surely have negative implications on the overall effectiveness of the PSI system. Although previous studies have shown that PSI preoperative plans may be a poor predictor of implant sizing as they overestimate sagittal balance, further research into the usefulness of these preoperative templates and their further improvement could be beneficial.

Our sagittal alignment using PSI differed significantly from our SR group. In contrast, Hamid et al⁷ noted sagittal alignment to be similar between their 2 groups (0.9 ± 3.4 vs 0.7 ± 3.3 for SR and PSI, respectively, $P = .14$) and sagittal alignment to be slightly smaller in the PSI group. Sagittal alignment of the talar component in previous generation implants was thought to be critical to long-term longevity of prosthesis in TAA, with anterior malpositioning leading to decreased range of motion and bearing liftoff in in vitro studies.¹⁸ Barg et al² noted that proper positioning of the talar component in the sagittal plane, as judged by the anteroposterior offset, may be a more important outcome predictor vs coronal plane positioning. However, minor variations in both coronal and sagittal alignment may or may not be significant clinically with newer-generation prosthesis. Pyevich et al¹³ found that >40 valgus lead to significantly increased pain in a study of 95 patients treated with TAA with AGILITY prosthesis at mean follow-up 4.8 years (range 2.8-12.3), whereas Braito et al⁴ found that the same radiographic parameters did not affect clinical outcomes in their population of 84 HINTEGRA ankles at 48 months. In fact, the latter authors found that all radiographic measurements, including lateral and anterior distal tibia angle, postoperative tibiotalar angle, tibial axis-talus ratio AP offset ratio and contact point ratio measurement had no effect on clinical outcomes in their series.⁴ Further study of the long-term outcomes of patients with mild differences in sagittal/coronal alignment will continue to elucidate the importance of minor differences in alignment and possible variability in these trends among different ankle prostheses.

Limitations to this study include biases inherent to its retrospective nature, the size difference between the SR and PSI groups (13 and 30, respectively), the use of a single surgeon, possible selection biases in PSI vs SR patient selection, and the accuracy of OR cost accounting. The first 3 of these are inherent to the retrospective nature of the study; however, it should be noted that there were no demographic differences between the 2 groups. Considering the selection of patients, it is possible that patients with the least amount of deformity or small size were preferentially selected given an unfamiliarity with the new PSI technology. In our study, there were more patients in the PSI as compared to the SR group, and therefore we believe this implicit bias was not found in our study; however, it cannot be ruled out given the retrospective nature of the study. Regarding our OR cost accounting, estimates of the cost of OR time are known to vary widely among different institutions.⁶ The cost of operating time used in our study is higher than that of other institutions as described in a recent systematic review by Childers et al.⁶ As noted in their article, financial perspective has a huge influence on cost calculation. While their article looks at the hospital perspective, our cost valuation comes from a billing perspective for our traditional cost analysis, which may contribute to the increased cost analysis. Altered cost measurement leads to huge reimbursement discrepancies for procedures, and the inability to properly and accurately measure and compare costs among both providers and hospitals. Similarly, cost-effectiveness analysis needs to take into account societal perspectives, including the opportunity cost of a practice. For example, TAA adds another radiation dose. The cost of changing component sizes intraoperatively or of having to abandon PSI secondary to problems with the cutting block were not taken into account in this study, but are another area of interest for future research. As potential cost saving mechanisms continue to come to the forefront, the necessity of traditional training and ability to convert to traditional methods cannot be overstated. Finally, the surgical technique employed in PSI may lend itself to radiographic identification of the PSI technique, which could bias the results. Reviewers were blinded to surgical technique in an attempt to reduce this bias; however, it still may be present.

Conclusion

We found that PSI significantly reduced operative and tourniquet time vs SR in total ankle arthroplasty. The cost effectiveness of this time reduction when examined using traditional OR time-based cost methodology resulted in a significant cost reduction with similar radiographic outcomes in our study. When comparing the cost effectiveness of PSI using TDABC, TAA appears to have a cost effectiveness threshold of \$834.80. The cost analysis of TAA represents an area of increased importance as payers and payees shift to a value-based health care paradigm, and establishing cost effectiveness and effective cost determination—an

integral part of value—continues to be of utmost importance and debate.

Declaration of Conflicting Interests

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