

Patient-specific instrumentation in total ankle arthroplasty

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Abstract

The recent increase in the adoption of total ankle arthroplasty (TAA) reflects the improvements in implant designs and surgical techniques, including the use of preoperative navigation system and patient-specific instrumentation (PSI), such as custom-made cutting guides. Cutting guides are customized with respect to each patient's anatomy based on preoperative ankle computed tomography scans, and they drive the saw intra-operatively to improve the accuracy of bone resection and implant positioning. Despite some promising results, the main queries in the literature are whether PSI improves the reliability of achieving neutral ankle alignment and more accurate implant sizing, whether it is actually superior over standard techniques, and whether it is cost effective. Moreover, the advantages of PSI in clinical outcomes are still theoretical because the current literature does not allow to confirm its superiority. The purpose of this review article is therefore to assess the current literature on PSI in TAA with regard to current implants with PSI, templating and preoperative planning strategies, alignment and sizing, clinical outcomes, cost analysis, and comparison with standard techniques.

Key Words: Total ankle arthroplasty; Total ankle replacement; Patient-specific instrumentation; Ankle computer navigation system; Preoperative navigation; Prophecy; Infinity; INBONE II

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Core Tip: The recent increase in the adoption of total ankle arthroplasty (TAA) reflects the improvements in implant designs and surgical techniques, including the use of preoperative navigation system and patient-specific instrumentation (PSI). The outcomes of TAA have generally been less satisfactory compared to those of other arthroplasties. Preoperative planning using PSI theoretically improves implant positioning and alignment. This review article assess the current literature regarding PSI in TAA.

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INTRODUCTION

The recent increase in the adoption of total ankle arthroplasty (TAA) reflects the improvements in implant designs and surgical techniques. Nonetheless, the outcomes of TAA have commonly been less satisfactory compared to those of other arthroplasties[1]. Thus, the search for successful TAA continues, and in fact, the interest in implementing this new technology is growing.

The literature on the subject has shown that proper implant positioning and alignment are necessary for achieving good results in TAA. Even the mispositioning of a small implant component has a relevant impact on motion and contact pressure, which may lead to failure[2,3].

As a matter of fact, most of the current TAA instrumentations do not really address patient's variable anatomical features. When using a traditional system, the main parameter considered for tibial cutting block is represented by the tibial tuberosity as proximal reference and the middle of the anterior border of the tibiotalar joint as distal reference. The talar resection is performed with the foot in a visual neutral position[2,3]. This technique allows an experienced surgeon to adopt a good implant positioning; however, many other factors should be considered in order to fully re-establish gait symmetry and natural ankle motion.

Much as with hip and knee arthroplasty, large efforts have been devoted to improving TAA surgical techniques, including the use of preoperative plans based on computer software, and patient-specific instrumentation (PSI), such as custom-made cutting guides. Cutting guides are customized with respect to each patient's anatomy based on preoperative ankle computed tomography (CT) scans, and they drive the saw intra-operatively to improve the accuracy of bone resection and implant positioning.

Nevertheless, there is no unanimous agreement regarding the indication and efficacy of PSI in TAA [4]. The purpose of this review article is therefore to assess the current literature on PSI in TAA. In particular, we will discuss the following topics: (1) Current implants with PSI; (2) Templating and preoperative planning strategies; (3) Alignment and sizing; (4) Clinical outcomes; (5) Cost analysis; and (6) Comparison with standard techniques.

TYPES OF IMPLANTS

Only three implants with PSI for TAA are currently available (Table 1): The INFINITY TAA (Wright Medical Technology Inc, Arlington, TN, United States). The INBONE II Total Ankle System (Wright Medical Technology Inc), and a custom-made version of the BOX TAA (MatOrtho, Ltd., Leatherhead, United Kingdom).

The INFINITY TAA

This implant has a 2-component fixed bearing design, with a low-profile tibia and talar resurfacing, and requires minimal bone resection. The tibial resurfacing component is made of titanium alloy and presents three angled pegs, whilst the talar component has two pegs and is made of cobalt chrome alloy. The INFINITY TAA can be implanted using a CT scan-derived PSI through the PROPHECY Preoperative Navigation System (Wright Medical Technology Inc)[5,6].

The INBONE II total ankle system

This implant is an evolution of the original INBONE design and consists of an intramedullary fixed-bearing two-component design with a polyethylene bearing surface locked into the tibial baseplate. The system retains some main features of the INBONE I design and instrumentations, including the modular tibial stems, thicker polyethylene bearings, and intramedullary guidance. In addition, the INBONE II total ankle system has certain enhancements, including sulcus articulation, additional talar fixation, anteroposterior long tibial trays, trial reduction placement of the talar component, and bone

Table 1 Summary of all actual studies about patient-specific instrumentation in total ankle arthroplasty

Author	Implant type	Study type	No patients	Navigation system	Tibial implant size predicted	Talar implant size predicted	Implant positioning accuracy	Neutral alignment	Comparison with standard technique
Berlet <i>et al</i> [10] (2014)	INBONE	Cadaveric study	15 lower limb	PROPHECY	-	-	Within 3 degree and translational within 2 mm	-	-
Hsu <i>et al</i> [11] (2015)	INBONE II vs INFINITY	Retrospective case series	42	PROPHECY	100% INBONEII vs 92% INFINITY	76% INBONEII vs 46% INFINITY	± 3° coronal and sagittal	100%	-
Hanselman <i>et al</i> [12] (2015)	INBONE II	Case report	1	PROPHECY	-	-	-	Yes	-
Daigre <i>et al</i> [13] (2017)	INBONE II	Retrospective multicenter study	44	PROPHECY	98%	80%	< 3° (79.5%), < 4° (88.6%), < 5° (100%)	93.2%	-
Saito <i>et al</i> [1] (2019)	INFINITY	Retrospective study	99 (75 PSI - 24 SRG)	PROPHECY	73%	51%	Coronal: SRG: 88% < 3°, 8% from 3° to 5°, 4% > 5°; PSI: 85.3% < 3°, 3.3% from 3° to 5°, 1.3% > 5°. Sagittal: SRG: 88% < 3°, 8% from 3° to 5°, 4% > 5°; PSI: 85% < 3° of deviation, 11% from 3° to 5°, 4% > 5°	100% in PSI vs 96% in SRG	P = 0.884 not statistically different
Faldini <i>et al</i> [8] (2020)	BOX	Case report	1	GEOMAGIC CONTROL	-	-	-	Yes	-

PSI: Patient-specific instrumentation; SRG: Standard Referencing Guide.

removal instrumentation. This new sulcus design has twice as much coronal plane stability as the saddle design of the INBONE I TAA; moreover, it has two 4-mm anterior pegs in addition to the single talar stem design of the INBONE I component, resulting in increased rotational stability[7]. The INBONE II total ankle system can be implanted using a CT scan-derived PSI through the PROPHECY Preoperative Navigation System (Wright Medical Technology Inc).

Custom-made version of the BOX TAA

A three-component implant, with cast cobalt-chrome-molybdenum alloy components fixed to the body of the talus and the distal portion of the tibia, along with an interposed mobile biconcave meniscal bearing, designed to be compatible with the movements of isometric fibers within the calcaneofibular and tibio calcaneal ankle ligaments[8,9]. The custom-made BOX TAA can be implanted using a CT scan-derived PSI with GeoMagic Control (3D Systems, Inc).

Considering the low number of implants available on the market, there are also few studies in the pertaining literature regarding PSI for TAA, as reported in Table 1.

TEMPLATING AND PREOPERATIVE PLANNING STRATEGIES

Templating in joint prosthetic surgery facilitates alignment optimization, helps in the selection of the correct implant size, and leads to more reliable and consistent prosthesis placement, theoretically lowering the risk of intra-operative complications.

While pre-operative templating is of great importance in planning hip and knee arthroplasty, its role in TAA is less clear.

Traditional preoperative planning methods for TAA are based on antero-posterior (AP) and lateral weight-bearing radiographs. Standard technique uses the tibial tuberosity as a point of reference and is based on the principle that the mechanical axis of the tibia (MAT) should equal the anatomical axis of the tibia (AAT)[14].

Differently from standard techniques, preoperative planning using PSI for TAA is initiated by obtaining preoperative ankle CT imaging, according to manufacturer established protocols, in order to create the patient-specific 3D model. Although with some differences, all computer navigation systems require preoperative CT scans from the knee through the mid-foot.

CT scans allow us to assess preoperative coronal plane deformity, sagittal plane deformity, and rotational deformity, as well as permitting an evaluation of MAT, and AAT alignments.

On the coronal plane, varus or valgus deformity should be determined (neutral alignment is considered as less than 5 degrees of varus or valgus[4]). The tibial slope must be measured in the sagittal plane considering the anterior distal tibial angle, the angle between the AAT, and the line connecting the distal points on the anterior and posterior tibial articular surface (normal values: 83.0 ± 3.6 degrees)[15].

All these measurements can deviate significantly depending on several factors, such as congenital or post-traumatic femoral or/and tibial deformities[16]. More frequently, in the presence of coronal deformity, AAT deviation from the MAT is accentuated.

In the past, ankle coronal and sagittal plane deformities represented a contraindication to TAA[17]. The recent literature shows a trend toward extending the indication of TAA even in the case of severe deformities. During the templating, deformity correction must be evaluated and addressed. Realignment procedures can be performed before TAA surgery or simultaneously to the prosthesis implantation, acting on bone or soft tissue structures depending on patho-anatomy[18,19].

In addition, during pre-operative planning, the prosthesis size and corresponding bone cuts to prepare implant accommodation and its best possible position should always be considered[8].

Very few reports have evaluated the reliability of templating with PSI. In 2007, Adams *et al*[20] were the first to apply computer-assisted surgery for TAA in a cadaver study. Seven matched-pair lower extremities were used. One leg from each pair was randomized for the conventional tibial preparation arm of the study, using the external alignment guide and tibial cutting block from the Scandinavian Total Ankle Replacement system (STAR, Waldemar Link GmbH & Co., Hamburg, Germany). Since dedicated TAA software did not exist at the time of the study, the other leg from each matched pair underwent computer-assisted tibial cut preparation using the VectorVision navigation system (BrainLAB, Munich, Germany) with total knee arthroplasty software. Pre-operative CT data was used to assess the tibial mechanical axis. In both groups, the accuracy of the tibial plafond preparation relative to the tibial shaft axis in both the coronal and sagittal planes was determined by fluoroscopic, radiographic, and CT analysis. Although the conventional and the computer-assisted measurements were not statistically different when compared to one another, the development of computer-navigation software specific to TAA continued.

The first PSI system for TAA that was able to provide a preoperative plan is the PROPHECY INBONE II and PROPHECY INFINITY Preoperative Navigation System. As in other forms of navigation-assisted surgery, the software generates a highly accurate rendering of the patient's bony anatomy. This technology allows the surgeon to interact with the computer model and develop the surgical strategy through stepwise considerations. This process identifies loose bodies, the osteophytes' location, size, and shape, the presence of bone deficits, the 3-plane nature of any preexisting deformity, and the desired features, position, and size of the final implants.

The PROPHECY template calculates the preoperative deformity and the MAT *vs* the AAT based on anatomic landmarks. Anatomic landmarks are established in order to determine tibia/talus alignment achieving neutral axes. According to Berlet *et al*[10], the tibia landmarks are: The proximal tibia, the distal tibia, the proximal anatomic canal, and the distal medial and lateral gutter. The talus landmarks are: The talar neck, and the proximal medial and lateral gutter. These landmarks are used to combine the 3D bone model with 3D computer-assisted design (CAD) models of the implants and instrumentation to perform a virtual TAA implantation. Implant positioning is usually based on the AAT[13], but the choice is at the discretion of the surgeon[17]. Once templating and preoperative planning are approved, patient-specific guides that reference bony anatomy are built through selective laser sintering.

The first study using the PROPHECY system was conducted by Berlet *et al*[10] in 2014 in order to evaluate the reproducibility of tibia and talus patient-specific guide placement and variation between the pre-operative plan and real component position. Fifteen cadaveric lower extremities were scanned and imported into a CAD environment which created the 3D models based on the ankle CT scan. The 3D bone models were combined with the 3D CAD models of the implants and instrumentation to perform a virtual TAA after choosing the appropriate implant size and position. Patient-specific guides were then manufactured to define the resection planes, and the final implant position was recorded. Mean deviation among pre- and post-operative implant position was less than 2° and 1.4 mm[10].

This preoperative planning strategy has been proposed in other clinical studies, demonstrating overall positive accuracy and reproducibility[1,11,13].

More recently, a new and complete TAA customization process was introduced by Faldini *et al*[8], consisting of patient-specific 3D-printed implants and instrumentation. Images obtained from a CT scan were processed for a 3D customized model of the ankle and the BOX ankle prosthesis (MatOrtho, United Kingdom). Using GeoMagic Control (3D Systems, SC), TAA was performed virtually by selecting the most suitable size for each implant according to the dimensions of the joint about to be replaced. Through the use of GeoMagic Control, it was possible to retrieve the corresponding bone resections and the corresponding PSI, designed to perfectly fit the frontal bone of the ankle and embed all required guides for bone preparation. The obtained models were printed in Acrylonitrile Butadiene Styrene by additive manufacturing for a final check. Upon approval of the planning procedure, the

models were sent for final state-of-the-art additive manufacturing (the metal components using cobalt-chromium-molybdenum powders, and the guides using polyamide).

Overall, preoperative three-dimensional bone imaging, and MAT and AAT axis determination are important aspects of planning and templating for PSI.

Several issues regarding PSI templating and preoperative planning strategies must still be addressed. First, different PSI image acquisition methodologies may influence the results. As a matter of fact, cutting guides are usually produced from a non-weightbearing preoperative CT scan. A weight-bearing CT scan, such as cone beam CT, may produce changes to the plan.

Other factors should also be considered: Dissimilar CT image resolutions and planning software, differences in the production methods used for the cutting blocks and their types, margin of error on the part of the manufacturer, and surgeon learning curve may affect the PSI outcomes, and influence the results.

Full-length weight-bearing lower limb imaging is rarely considered, though a complete lower limb alignment evaluation seems to be crucial in order to provide the most appropriate ankle alignment[14].

Lastly, it would be interesting to clarify whether pre-operative templating is more accurately performed using an AP radiograph or 3D imaging using CT scans, and to investigate if preoperative weight-bearing radiographs correlate with the PSI guide measurements.

ALIGNMENT AND SIZING

PSI was introduced as an innovative approach to also improve ankle alignment, and the accuracy and reproducibility of implant placement and sizing.

The literature has already shown that adequate TAA implant alignment and positioning are essential for achieving good clinical results[15,21]. Even a small implant component malpositioning could result in a significant impact on motion and contact pressure, which may determine its failure[2].

Kakkar *et al*[22] described how an implant misalignment could result in eccentric overloads. Traditionally, every arthroplasty system purpose is to reach a neutral axis[23]. According to certain authors[24,25], neutral coronal ankle alignment is defined as less than 5 degrees of valgus to less than 5 degrees of varus.

There is still a good amount of controversial debate in the literature regarding whether PSI improves the reliability of achieving neutral ankle alignment and more accurate implant sizing.

In the cadaver-based study performed by Berlet *et al*[10], PSI led to a reliable and reproducible position of TAA component and ankle alignment. The mean prosthesis alignment variations between pre-operative plans and final location were all within ± 3 degrees.

Hsu *et al*[11] reported similar results in a retrospective case series of 42 consecutive TAAs using preoperative CT scan-derived patient-specific plans and guides (PROPHECY). Of the 42 TAAs, 29 intramedullary referencing implants (INBONE II) and 13 low-profile tibia and talar resurfacing implants (INFINITY) were used. The study revealed that postoperative weight-bearing alignments were in a range of $\pm 3^\circ$ from the expected coronal and sagittal alignments reported in the surgical plans following CT scans. Moreover, neutral alignments were gained for all TAAs, independently of preoperative coronal deformity.

Surgical plans have forecasted the real tibial component size utilized in 29 of 29 (100%) INBONE II cases and in 12 of 13 (92%) INFINITY cases. Conversely, plans were more inaccurate for talar component and predicted the real talar component size utilized in 22 of 29 (76%) INBONE II cases and 6 of 13 (46%) INFINITY cases. In all cases of predicted tibia or talar size mismatch, surgical plans estimated one implant size larger than the one that was actually used.

In 2015, Hanselman *et al*[12] reported the case of a 54-year-old man with a 29° varus hindfoot deformity treated by TAA using an INBONE II implant with PROPHECY PSI. Three months post operation, a neutral alignment was achieved, with a coronal plane angle of 1.8° .

In 2017, Daigre *et al*[13] reported on a retrospective multicenter study of 44 TAAs (INBONE II) using PROPHECY PSI. In 79.5% of cases, the postoperative tibial implant position corresponded to the preoperative plan within 3° of the planned aim, within 4° in 88.6% and 5° in 100% of cases. The preoperative navigation system aided to reach a postoperative neutral alignment in 93.2% of cases. The tibial component coronal size was properly predicted in 98% of cases, whereas the talar component was correctly predicted in 80% of cases.

When comparing PSI with the Standard Referencing Guide (SRG) on a retrospective analysis of 99 INFINITY TAAs, Saito *et al*[1] reported that the absolute variation of the tibial component from the intended alignment was 1.6 ± 1.2 degrees in the coronal plane, and 1.9 ± 1.5 degrees in the sagittal plane.

The PSI preoperative plan correctly predicted the implant size in 73% of cases for the tibial component, and in 51% for the talar component, whereas among the mismatched cases, the plan tended to predict an implant size larger than what was actually utilized for both implants.

Considering the reported data, imprecision of the computerized navigation system in predicting the talar implant size still exists. Some authors propose to justify the talar component mismatch with the matter of gutter debridement: An aggressive debri-dement may affect the sizing of the talar component,

leading to smaller talar sizes[1,11,13].

CLINICAL OUTCOMES

Theoretically, the advantages that PSI confers on TAA should translate into improvements in clinical outcomes. However, given that PSI is still a novel technique, the current literature is lacking in long-term studies that can assess the differences in instrumentation techniques.

A single case report deals with clinical outcomes. Hanselman *et al*[12] reported good clinical results at 8 mo in a 54-year-old man using the INBONE II Prophecy TAA system. The patient was ambulating without assistance and the ankle range of motion was 40°.

The advantages of PSI in clinical outcomes are still theoretical and need to be confirmed. Conversely to primary arthritis of the hip and knee, end-stage ankle arthritis was frequently post-traumatic and generally involves younger patients. For this reason, looking at the joint replacement, ankle patients are reported to produce greater common physical demands than hip and knee ones; hence, the duration of implants for ankle patients needs to be increased by roughly 10 years. Therefore, obtaining a more accurate anatomic alignment with PSI may reduce the incidence of eccentric wear, component loosening, subsidence, and failure, and indirectly improve longevity and clinical outcomes[10].

COMPARISON WITH STANDARD TECHNIQUES

Advocates for PSI in TAA argue that the advantages conferred by patient-specific cutting block also translate to subsequent improvements in implant positioning, reduced surgical time, and clinical outcomes.

Adams *et al*[20] compared computer-assisted tibia preparation with standard techniques in a cadaveric study. Results showed that the conventional and computer-navigated tibial measurements were not different in the 95% confidence interval for CT, fluoroscopy, or radiographic assessments.

In 2019, Saito *et al*[1] performed a retrospective analysis of 99 patients comparing the utilization of PSI with the SRG. The accuracy of the tibial component placement was similar between the two groups. Neutral ankle alignment was obtained postoperatively for all cases in the PSI group, and for all but one patient in the SRG group, who had 5.7° of varus deviation post operation. The use of PSI had to be abandoned intraoperatively in three cases (3.8%). 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.

COST ANALYSIS

Any new technology, in addition to demonstrating clinical improvements, must undergo an economic analysis to reveal the added cost to the healthcare system in relation to its expected benefits.

Promoters of PSI suggest that PSI will reduce the overall costs of TAA. Although this technology has added associated costs, mostly because of preoperative CT imaging and the creation of custom-made cutting guides, the reduced operative time, the lower processing costs due to fewer sterile trays, the decrease in radiation exposure[4], the reduction in perioperative complications[26], and the better alignment leading to fewer revision surgeries represent the main advantages that can translate to reduced healthcare costs.

Only one study analyzed the costs of PSI in TAA. Hamid *et al*[1] identified a cost-savings threshold of \$863 below which PSI was less costly than SR instrumentation. However, only the objective reduction of costs resulting from a decrease in operative time was considered.

CONCLUSION

PSI for TAA may represent an additional tool for surgeons and patients. However, the current literature does not allow us to confirm the superiority of PSI over standard techniques, and there are still several questions to be answered.

Surgical experience is always necessary in order to consider all the factors influencing lower limb alignment, and bone, soft tissue, or ligament balancing. Moreover, blindly trusting PSI can potentially lead to mistakes in implant placement and sizing. For this reason, a surgeon should always know the SR and select a different implant size or abandon PSI when necessary.

Based on the current data from the pertaining literature, the main strengths of PSI for TAA are represented by good reproducibility and accuracy of implant positioning, good neutral alignment and correction of pre-existing deformities[27], shorter operative and fluoroscopy exposure time, and

therefore, a potential decreased risk of complications as well as cost reductions[1].

The insufficiency of corroborating literature and scarcity of studies (in two cases financed by the manufacturer)[10,13] represent the current and main limitations of PSI. Moreover, it is not clear whether PSI may be more useful in order to restore ankle neutral alignment when dealing with complex deformities involving the whole lower limb.

Further prospective, randomized, and multicenter studies are therefore necessary to better evaluate PSI and confirm its routine use in TAA.

FOOTNOTES

Author contributions: Mazzotti A and Arceri A conceived the presented idea; Mazzotti A made substantial contributions to study conception and design, and data acquisition, analysis, and interpretation, drafted the manuscript, and revised it critically; Arceri A coordinated and supervised manuscript preparation; Zielli S provided documentation, and helped shape the research, analysis, and manuscript; Bonelli S provided documentation and critical feedback; Viglione V contributed to the design and implementation of the research; Faldini C revised the manuscript critically and gave final approval of the version to be published; and all authors read and approved the final manuscript.

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