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Rejection rate, modifications, and turnaround time for patient specific instrumentation plans in total ankle replacement

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ABSTRACT

Patient specific instrumentation (PSI) in total ankle replacement (TAR) has been reported to be accurate and time saving. However, there has been criticism regarding accuracy and an overreliance on the preoperative plan. This is a retrospective review of a single surgeon's PSI plans from 2016-2024. We report rejection rates, modifications, and turnaround time. A total of 101 plans were reviewed and found an overall rejection rate of 17.8 %, with 18 reports rejected. Average turnaround time was 29:07 hours. When comparing the 1st half of the study period to the second half, a statistically significant increase in rejection rate was found, 0 % to 45 %, $p < 0.0001$. In addition, there was a higher rate of rejection on more complicated stemmed implants or revision implants compared to low profile implants. This report shows there is not a blind trust of the engineer's plan, and with experience with PSI rejection rate increases. Also, the engineer's understanding of complicated cases is addressed with higher rates of rejection in complicated cases. This report refutes charges that surgeons that use PSI for TAR are overly reliant on CT-derived engineer produced plans. Further studies with national data or multiple surgeons should be undertaken to explore this further.

Introduction

Patient specific instrumentation (PSI) for total ankle replacement (TAR) has been used extensively in the United States and Canada. In 2020 it was reported that 21,222 patient specific plans through a single company had been performed between 2012 and 2019 [1]. Current information reports over 65,000 patient specific scans through the same company have been performed as of July 2024 [2]. The purported benefits of PSI are increased accuracy, precision and reproducibility, efficiency, and ultimately value [3]. Most studies have shown been able to show good accuracy and efficiency [4–11] and have compared well with standard instrumentation [12–17].

There has been some caution regarding the adoption of PSI in TAR. A study in 2022 compared PSI and traditional instrumentation and found no difference in accuracy but was the only report with longer times with PSI [17]. A different study in 2022 also discussed that decreased procedure time does not include the "surgeon time required to submit, review, and modify the preoperative plan." The actual procedure time in this study was also the highest average reported for PSI at an average of 188 minutes for primary ankle replacement. That same study showed an average difference of 3.3° in the coronal plane of expected vs actual alignment ($p = 0.821$), and a statistically significant difference in the sagittal plane of 9.6°, $p = 0.004$). These authors stated, "…we caution against blindly trusting the engineer-provided preoperative plan…" The authors pointed out there is a concern for change in the surface match process from the time of the scan to surgery and have no ability to judge an engineer's experience or ability to address complex cases [5]. The same senior author stated that "…the theoretical benefits remain a matter of conjecture"[18]. Again, the same senior author in an editorial published in 2022 stated that he felt "…like the child in [The Emperor's New Clothes] seeing the truth while everyone else remains 'pluralistically blind." He lamented "…at the blind conviction providers hold regarding TAR with PSI…" and stated that in total hip, knee, and shoulder replacement PSI has essentially been abandoned [19].

While PSI for TAR allows for plans to be evaluated and rejected or changed as needed, there is very little information regarding rejection rate. Biela, et al. reported the senior author has only rejected 2 plans since 2016 [5]. The present study was undertaken to evaluate and report on a single surgeon's experience with a single PSI system. The surgeon is fellowship trained, a non-consultant / non-design surgeon who has been performing TAR since 2008 and started PSI in 2016. The main outcomes are rejection rate, modification made, and turnaround time for changes

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made. Examination regarding experience with the system and varying implants was undertaken as well.

Patients and methods

The study involved only pooled, non-identified data requested and obtained through the device manufacturer (Stryker™, Portage, MI) regarding the surgeon's PSI plans that were obtained and completed with a single PSI system (Prophecy®) regarding one of 3 implants: a Low Profile implant (Infinity®), a Medullary Stemmed implant (Inbone®), or a Revision implant (Invision®, Stryker™, Portage, MI). As there was no patient contact or identification possible, IRB approval was not needed or obtained. Data from all plans ordered from January 2016-June 2024 was collected, with no assessment on conclusion or results of surgery, or even if surgery was ultimately performed. Plans may be posted without ultimately proceeding to surgery for a variety of reasons including be not limited to: surgery cancellation, switching implants, switching to arthrodesis, or patients going to a different provider.

Data available from the pulled report included the year of the report, number of reports each year, and number of plans rejected each year resulting in a rejection rate. Each rejected case then had which implant was used, details of reasons for rejection, and modifications needed. These modifications were then categorized into size, position, implant type, or deactivation reasons. Reports rejected with more than one change needed were reported. The total number of each of the 3 types of implants was reported. Finally, turnaround time from rejection to revised plan being sent back was reported (Figs. 1A and B).

Statistical analysis

Categorical data consisting of cases and rejections per year as well as rejections based on implant type are reported as count and percentage. Rejection rate of each of the 3 implants was compared. Rejection rate of years 2016-2020 were compared to 2021-2024 to reflect experience with the system. These categorical variables were then compared using chi-square test. Statistical significance was set at $p \leq 0.05$. All statistics were performed with Microsoft Excel (Microsoft, Redmond, WA).

Results

There were 101 reports that were run during the study period. This did include reports that were rejected for modification or deactivation. This also included reports that were rejected multiple times. Two cases had 2 rejections (1 Low Profile and 2 Medullary Stemmed implants) and 2 cases had 3 rejections (1 Medullary Stemmed and 1 Revision implant). Overall, there were 83 reports for the Low Profile implant, 10 reports for Medullary Stemmed implants, and 8 reports for Revision implants. There was an overall rejection rate of 17.8 % (18 out of 101 reports).

Rejection rate was 18 out of 101 reports (17.8 %), but there was a total of 28 modifications made as reports could have more than 1 modification made. There were 7 changes (25 %) in size (4 in the tibia, 2 in both talus and tibia, and 1 unspecified). There were 15 changes (53.6 %) in position (4 talus height, 3 tibial height, 3 medial-lateral position of tibia, 3 talar resection angle, 2 varus-valgus angle of the tibia). There were 4 changes (14.3 %) in implant technology (2 changes in implant, 2 changes in talus only). There were 2 cases (7.1 %) of deactivation (1 change to gutter decompression only, 1 change to different company implant) (Table 1).

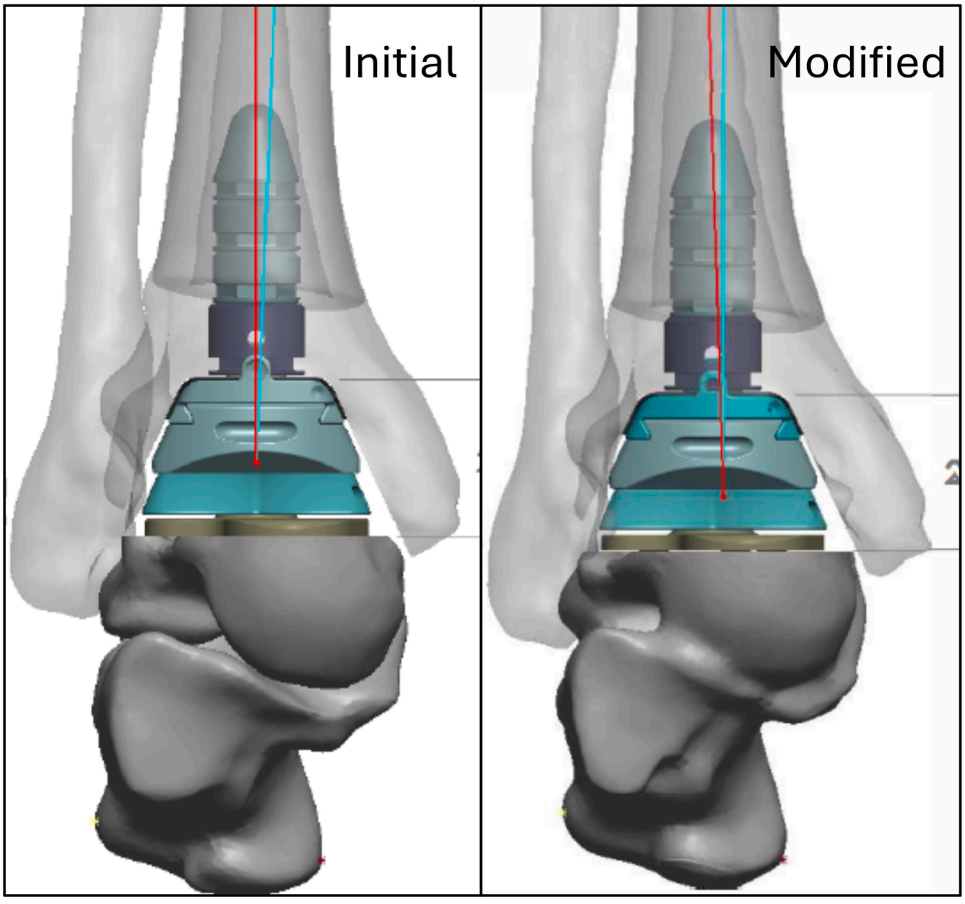

Fig. 1A. Patient specific plans showing the planned outcome of the AP alignment. The initial plan on the left was modified to move the tibial implant 2 mm lateral based on anatomy and alignment.

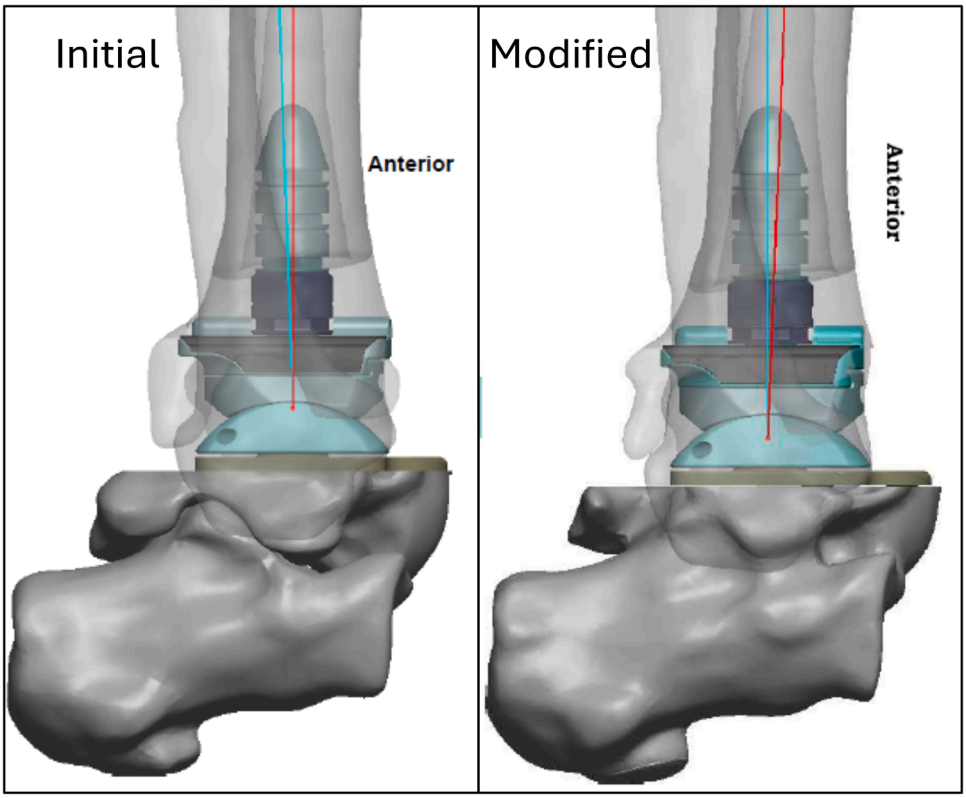

Fig. 1B. Patient specific plans showing the planned outcome of the lateral alignment. The initial plan on the left was modified to move the tibial component 2 mm posteriorly, and the tibial and talar resection height 2 mm distal to accommodate anatomy pathology.

Table 1
Modifications requested in rejection.

Category	N	Subgroups
Size	**7**	
Tibia		4
Tibia and Talus		2
Unspecified		1
Position	**15**	
Talus - Resection Height		4
Tibia - Resection Height		3
Tibia - ML Position		3
Talus - Resection Angle		3
Tibia - VV Angle		2
Implant Technology	**4**	
Implant - Type		2
Talus - Type		2
Deactivated	**2**	
Different Implant		1
Gutter decompression only		1
Total	**28**	

ML, Medial and Lateral; VV, Varus or Valgus

There was a change in rejection rate over time. There was no rejection of reports from 2016 to 2021, representing 75 reports. In 2022 there was a rejection rate of 2 out of 4 reports (50 %), 2023 11 out of 14 reports were rejected (78.6 %), and 5 out of 8 reports rejected through June 2024 (62.5 %), or 18 out of 26 reports in those years (69.2 %). When comparing the first half of the study (2016-2020) to the second half of the study (2021-2024) there was a statistically significant increase in rejection rate of 0 out of 61 reports (0 %) in the first half, to 18 out of 40 (45 %) in the second half, $p < 0.0001$ (Table 2).

There was also a statistically significant difference in rejection rate of the reports for different implant types. There were 83 Low Profile reports, and 7 were rejected (8.4 %), 10 Medullary Stemmed reports and 5 were rejected (50 %), and 8 Revision reports and 6 were rejected (75 %). This was compared and there was a statistically significant difference in rejection rate between the implants, $p < 0.0001$. The Low Profile implant was used throughout the study period, the Medullary Stemmed in 2019-2021 and 2023, and the Revision was used only from 2022-2024 (Tables 2 and 3).

The turnaround time from time of rejection to a new report was 29:07 ± 14:55 hours (Range 4:27-60:44 hours).

Discussion

Patient specific instrumentation in TAR is expanding in the United States. It is reported that 21,222 Prophecy® implants were used from 2012-2019[1], and as of June 2024 over 65,000 of these reports have been performed[2]. A 2021 study of 503 low profile implants in the United Kingdom reported that 99 (19.7 %) used PSI[20], and another study of 85 ankles has 27 (31.8 %) that used PSI[21]. A systematic review in 2021 compiled data from 9 studies and concluded several points about PSI in total ankle. First, PSI is equal to standard instrumentation for alignment. Second, implant size is somewhat variable with PSI, but better in the tibia compared to the talus. And third, PSI can shorten operative time and intraoperative fluoroscopy exposure[22]. A more recent study of 168 low profile implants supported increased accuracy and alignment, decreased time and radiation exposure for PSI over standard instrumentation, but also showed some functional benefits in walking and standing[23].

Technology to assist in total joint replacement surgery is common and a growing part of the total joint market in the US. Enabling technology examples include PSI, computer navigation, and robotic surgery. This technology changes over time and could include augmented reality surgery in the future. In 2023 enabling technology represented a $1.3 billion market, and is expected to grow 7.5 % in 2024, and represent over $1.8 billion by 2027 [24]. Australian registry data for primary total knee replacement shows that 65.8 % of primary total knee replacements

Table 2
Rejection rate and implant type per Year.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total	16-'20	21-'24
Posted	7	15	12	15	12	14	4	14	8	101	61	40
Rejected	0	0	0	0	0	0	2	11	5	18	0	18
Rejection Rate	0 %	0 %	0 %	0 %	0 %	0 %	50 %	78.6 %	62.5 %	17.8 %	0 %	45 %
											$p < 0.0001$	
Implant	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**Total**		
Low Profile	7	15	12	11	10	12	2	7	7	83		
Medullary Stemmed				4	2	2		2		10		
Revision							2	5	1	8		
Rejected	0	0	0	0	0	0	2	11	5	18		
Low Profile							2	3	2	7		
Medullary Stemmed								5		5		
Revision								3	3	3		

Table 3
Rejection rate per implant.

	Low Profile	Medullary Stemmed	Revision	
Posted	83	10	8	
Rejected	7	5	6	
Rejection Rate	8.4 %	50 %	75 %	$p < 0.0001$

use technology assistance. Computer navigation has been used since 2003 but has been decreasing since 2017. Robotic surgery was introduced in 2016 and has been rapidly increasing. PSI has been used since 2009, has been roughly stable since 2016, and in 2022 represents 11.4 % of all primary total knee replacements [25]. In the United States, at least 17.5 % of primary knee replacements use enabling technology [26]. One market report of 14,500 total joint cases using enabling technology in the US reported that while the majority (81 %) of cases used robotic surgery, 7 % used custom cutting guides. This was spread among at least 7 different orthopedic companies offering patient specific cutting guides [27]. Ankle replacement is inherently different in approach and instrumentation to hips, knees, and shoulders in one way because of the access to medullary alignment in the long bones of these procedures compared to the access to the distal tibia in ankle replacement. Enabling technology such as PSI may help alleviate this inherent alignment difficulty. An opinion offered in 2022 regarding PSI in orthopedics said it was controversial in knee replacement and helpful in complex shoulder replacement surgeries. No opinion was offered regarding ankle replacement [28]. While robotic and computer assisted navigation is more commonly used in total knee replacement than PSI, these technologies are not currently available in TAR. As enabling technology emerges, perhaps other technologies may be used, but only PSI is available for TAR, and using state of the art enabling technology in joint replacement has not been abandoned.

Surgeon judgement is important in TAR and reports have warned that "blindly trusting the customized guides and preoperative reports may lead to errors in positioning and sizing of components"[14]. The present report shows that more experience and comfort with the PSI system leads to higher rejection rates. Through the course of the retrospective review, more modifications were made to the plan on size, position, and even implant type and technology. This indicates a learning curve to the PSI system, and an understanding of translating the report to actual surgery. While almost all literature shows a decrease in procedure time, there is time spent outside the operating room in preparation for the case to review and approve the engineer's plan. This is outside of the constraints of anesthesia, tourniquet time, and blood loss and should allow for a thoughtful approach to changes in the plan. While there is no way to quantify the time the surgeon spends considering the plan, we have shown that in reports that are rejected, the turnaround time is about 29 hours, just over a day. While the surgeon does not spend all of this time thinking about that case, in these revisions the changes and considerations made should still be fresh in the surgeons mind.

Complicated cases in particular may benefit from this consideration and decision-making outside of the operating room. As stated, there is no way to judge the experience of the engineer preparing the plan, or their ability to assess complicated cases[5]. This was reflected in the present study as well. There was a higher rate of rejection and modification in more complicated cases, as represented by the use of a Medullary Stemmed or Revision implant. The authors see this decision making and adjustments to the plan being made prior to the case, outside of the pressure and time constraints of the surgery, as a benefit to the patient and surgeon. In less complicated cases, as represented by the use of a Low Profile implant, the initial plan from the engineer was more often accepted, indicating a greater degree of predictability in these cases. This however does not indicate "blind trust" in the engineer as has been stated [5,6,14,18].

Patient specific instrumentation in TAR has been said to be "unnecessary for experienced surgeons to achieve satisfactory total ankle arthroplasty alignment"[12]. This may be true for procedure time as well as one of the only reports that showed increased time with PSI compared to standard instrumentation was with a very experienced TAR surgeon, who concluded no advantage in PSI [17]. However, a report by Giardini, et al. in 2020 may show the benefit in inexperienced surgeons. The authors reported that in a 3-year study period they surgically treated 49 patients for end stage arthritis of the ankle, and of these 34 were treated with TAR, and 17 of these used the Low Profile implant in the present study. Of these 17 ankles, 10 were treated with PSI and 7 with standard instrumentation. They reported 100 % of the ankles with PSI were within 3°of alignment, compared to 40 % with standard instrumentation [13]. PSI may help those surgeons that are still gaining experience.

Overall, this report challenges several claims made by detractors of the use of PSI in TAR. Blind trust in the engineer CT-derived plan was not found in the present report, and in fact with increased experience with PSI more modifications were made. The engineer's experience and ability to assess complicated cases also was negated as more complicated cases were more often modified. The authors believe that the immeasurable costs and time for reviewing and modifying the preoperative plan is time well spent considering and planning for surgery outside of the natural pressure and constraints of decision making in the operating environment. In rejected reports, the turnaround time is just over 29 hours, keeping the plan familiar to the surgeon. Of course, surgeons should be prepared for unexpected complications that may arise in surgery when using PSI, even requiring a change to standard instrumentation, but the same can be said for every surgery performed. Finally, technology assisted total joint replacement is very common throughout orthopedics. As with all new technology, PSI may one day be replaced by a different enabling technology, but PSI is the current state of the art in TAR and is still used in other joints.

This report has important limitations. First, this is not a clinical outcome study, only a review of the fate of PSI plans for potential TARs. There is no report on how the changes were reflected in the surgery, and

there is no way to measure whether these changes affected the outcomes. The authors have previously reported on outcomes and alignment in TAR using PSI, which would include the plans in the present study [4]. This is also only one surgeon's experience and may not reflect all surgeon's experience and use of PSI. The author is fellowship trained, trained on standard instrumentation, and is a non-consultant, non-design surgeon to decrease bias. However, a national review of surgeon utilization of PSI systems from various companies would be very helpful, but this was not available for this study. This might also help elucidate what information in the reports is most useful for surgeons. The overall numbers of plans are small, and a complete discussion of rejection rates, changes, and turnaround time for all PSI plans, across multiple companies would be more useful. This could be done in the future for more transparency. Finally, the comparison of the first half of the study time frame from 2016-2020 (representing 5 years of data), to 2021-2024 (representing 4 years of data) is arbitrary, and comparing different years, such as 2016-2019 to 2020-2024 would result in different numbers. Year by year data is available in Table 2. However, the trend and pertinent point would remain; as experience with the system increased, so did rejection and adjustment of the plans.

In conclusion, PSI in TAR is increasing and is accurate and predictable. While there is warranted criticism and caution in the adoption of PSI for TAR, most reports are positive. Increased experience with PSI may lead to more modifications and rejection of the initial plan, and complicated cases may require a more discerning look at the initial plan. The general negative connotation toward users of PSI as blindly trusting an engineer's plan and not capable TAR surgeons is not warranted or well founded. The authors hope this initial report will spur transparency from companies that offer PSI system to aggregate information across all users or at least lead to multicenter studies from many surgeons.

IRB statement

Not applicable, no patient contact or information, computer data review.

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Declaration of competing interest

None.

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