Does the Canadian Orthopaedic Foot and Ankle Society Postoperative COFAS End-Stage Ankle Arthritis Classification System Correlate With Pre- and Postoperative PROMIS Scores for Total Ankle Arthroplasty?

Maksim A. Shlykov, MD, MS[1], Ian Savage-Elliott, MD[1], Timothy M. Lonergan, MD[2], Sandra E. Klein, MD[1] (iD), Jonathon D. Backus, MD[1] (iD), Jeffrey E. Johnson, MD[1] (iD), and Jeremy J. McCormick, MD[1]

Abstract

Background: Recently, the Canadian Orthopaedic Foot and Ankle Society (COFAS) proposed a classification system addressing adjunct procedures in the treatment for end-stage ankle arthritis. We reviewed Patient-Reported Outcome Measures Information System (PROMIS) data to determine if outcomes of total ankle arthroplasty (TAA) correlated with postoperative COFAS classification. We hypothesize that as COFAS classification increases, patients will demonstrate greater improvement in the change between pre- and postoperative PROMIS scores.

Methods: From June 2015 to December 2018, a total of 127 patients underwent 132 TAA. Demographic factors and preoperative and most recent postoperative PROMIS scores were collected. Univariate, multivariate and post hoc analyses with a significance threshold of $P < .05$ were performed.

Results: Eighty-seven patients with a mean follow-up of 13.6 ± 7.3 months and complete PROMIS scores were classified into COFAS types 1-4. Significant differences were identified in the PROMIS Pain Interference domain comparing COFAS types 2 and 4 and COFAS types 3 and 4. These results demonstrate that more complex ankles with a higher COFAS score had worse interval improvement in PROMIS scores. Additionally, multivariate linear regression showed that age and BMI were associated with worse physical function and depression, whereas diabetes and a history of prior surgeries were associated with improved postoperative function.

Conclusion: The COFAS postoperative classification system is useful for categorizing end-stage ankle arthritis. Further research into the ideal timing of surgery and higher-level studies to better determine TAA efficacy with different classification systems is warranted. This information can be helpful with preoperative counseling about treatment outcomes.

Level of Evidence: Level IV, retrospective analysis of prospectively collected data.

Keywords: total ankle arthroplasty, total ankle replacement, ankle arthritis, patient reported outcomes, COFAS, PROMIS

Introduction

End-stage arthritis of the ankle as a result of osteoarthritis, inflammatory arthritis, or posttraumatic arthritis is a debilitating condition for patients.[32] Historically, the gold standard for treatment has been ankle arthrodesis. In the last few decades, total ankle arthroplasty (TAA) has made a resurgence.[7,20,28,30] As implant designs have improved, and with a better understanding of ankle mechanics, more complex total ankle arthroplasties are performed.[11,13,21,24] These include arthroplasties in the face of deformity correction,

Table 1. The COFAS Preoperative and Postoperative Classification System for End-Stage Ankle Arthritis.

	Type 1	Type 2	Type 3	Type 4
Preoperative classification	Isolated ankle arthritis	Ankle arthritis with intraarticular varus or valgus deformity, ankle instability, and/or a tight heel cord	Ankle arthritis with hindfoot deformity, tibial malunion, midfoot abductus or adductus, supinated midfoot, plantarflexed first ray, etc	Types 1-3 plus subtalar, calcaneocuboid, or talonavicular arthritis
Postoperative classification	AA or TAR with no procedure requiring a second incision except syndesmosis fusion	AA or TAR with a soft tissue procedure requiring a separate incision	AA or TAR with an additional osteotomy including midfoot arthrodesis	AA or TAR with an additional hindfoot arthrodesis
Concurrent procedures	None, hardware removal	Deltoid ligament release, ligament reconstruction, tendo-Achilles lengthening, gastrocnemius recession, tendon transfer, capsule release, forefoot reconstruction, metatarsal osteotomy, dissection of neurovascular structures, plantar fascia release, syndesmosis reconstruction	Fibular osteotomy, calcaneal osteotomy, midtarsal arthrodesis	Arthrodesis: triple, subtalar, talonavicular, calcaneocuboid

Abbreviations: AA, ankle arthrodesis; COFAS, canadian orthopaedic foot and ankle society; TAR, total ankle replacement.
Source: Adapted from Krause et al.[23]

contracture releases, and even combined with arthrodesis procedures of the hindfoot and/or midfoot.

As orthopaedic foot and ankle surgeons turn to ankle arthroplasty for more difficult pathologies, it is important to evaluate and document these outcomes with patient-reported outcomes (PROs). Computerized adaptive testing (CAT) is making this easier for both patients and clinicians.[3,5] The Patient-Reported Outcomes Measurement Information System (PROMIS), developed by the National Institutes of Health, is one such CAT that had been developed and used in orthopaedic research since 2004.[2] It has been shown to be a validated method for measuring outcomes for patients with foot and ankle surgeries.[12,14,17]

The Canadian Orthopaedic Foot and Ankle Society (COFAS) proposed both a preoperative and a separate postoperative classification system for end-stage ankle arthritis (Table 1).[22,23] In contrast to the preoperative classification, the postoperative classification considers what was performed during surgery rather than what was intended to be

performed. Thus, the designers of the postoperative COFAS classification set out to create a system to provide a better way to compare the degrees of pathology and to facilitate further research into the outcomes of various treatments for end-stage arthritis. The resultant postoperative classification system has demonstrated inter- and intraobserver reliability in its ability to describe and classify procedures commonly performed in conjunction with total ankle arthroplasty.[23]

The purpose of this retrospective review was to identify whether prospectively collected PROMIS scores correlate with the COFAS postoperative end-stage ankle arthritis classification. More specifically, we asked whether more complex total ankle replacements have better or worse outcomes than total ankle replacements without any other concomitant procedures. We hypothesized that as COFAS classification type increased, patients would have a greater change (Δ) between preoperative and postoperative PROMIS scores.

[1]Department of Orthopaedic Surgery, Washington University in St Louis, St Louis, MO, USA
[2]TriStar Health, Brentwood, TN, USA

Corresponding Author:
Jeremy J. McCormick, MD, Washington University School of Medicine, Campus Box 8233, 660 Euclid Ave, St Louis, MO 63110, USA.
Email: mccormickj@wustl.edu

Methods

Study Design

After obtaining IRB approval, all patients undergoing total ankle arthroplasty at a single institution between June 2015 and December 2018 were identified using billing data. The group included 132 primary total ankle arthroplasties in 127 patients performed by 3 fellowship-trained orthopaedic surgeons (mean follow-up 13.6 ± 7.3 months, range 6-30 months). Patients with (1) less than 6-month follow up, (2) incomplete patient-reported outcome data, and (3) factors unrelated to their index TAA surrounding their last postoperative follow-up that were deemed likely to impact PROMIS scores were excluded, resulting in 90 TAA in 90 patients. Based on our exclusion criteria, 3 patients were excluded because of injuries (onset of extreme distal midshaft tibia pain while exercising 10 days before final postoperative visit), surgeries (right wrist fusion for rheumatoid arthritis 1 month before final visit), or life events (death in family, contralateral ankle pain).

Variables and Data Sources

Patient factors including age at the time of arthroplasty, presence of diabetes mellitus (DM), body mass index (BMI), and previous surgery of the hindfoot or ankle were recorded based on patient's preoperative visit. Stage of and previous care for patient factors (ie, last HbA_{1c} for diabetes patients) were not recorded.[6,8,26,29] PROMIS scores have been collected routinely on all foot and ankle patients since 2015 at our institution. This outcome instrument measures 4 domains: Anxiety, Depression, Pain Interference (PI), and Physical Function (PF). PROMIS scores from these domains were recorded at the last preoperative visit (non-standardized timing) and the most recent follow-up.

After reviewing all operative reports, the patients were stratified based on the COFAS postoperative classification system. The classification system includes 4 types based on additional procedures performed in addition to TAA or ankle arthrodesis in order to address associated pathology (Table 1). The concomitant procedures performed on patients classified as COFAS types 2-4 in our cohort are listed in Supplementary Table S1 (Appendix).

Statistical Analysis

Continuous data were expressed as means $\pm$ SDs and compared using analysis of variance. Post hoc comparisons were carried out using the least squares means method with *P* value adjustment using the Tukey-Kramer adjustment method. Categorical data were compared with the Pearson chi-square test or Fisher exact test. All tests were 2-sided, and differences were statistically significant if the *P* value was less than .05. The minimal clinically important difference (MCID) for the PROMIS PF (3-30; median 11.3) and PI (3-25; median 8.9) domains for foot and ankle conditions have been established, whereas they have not for the Depression and Anxiety domains.[1,15] Estimate (E) values were used in the multivariate analysis. An E value is defined as the minimum strength of association on the risk-ratio scale that a confounding variable would need to disrupt the association between a treatment and an outcome. High E values imply significant confounding would be needed to disrupt an association between 2 variables, whereas low E values imply small amounts of unmeasured confounding could account for an effect estimate.[33] Statistical analysis was performed using the Statistical Analysis System (SAS) statistical software package (SAS Institute Inc).

Results

Baseline Demographics

Baseline characteristics of the full patient cohort and each COFAS subgroup are summarized in Table 2. The mean age for the patient cohort was 64.3 ± 7.9 years with no differences between COFAS groups ($P = .4$). There were no significant differences in BMI between COFAS groups (mean 30.8 ± 5.9; $P = .58$). All patients had at least 6 months of follow-up (mean 13.4 ± 7.4 months) with similar follow-up duration between COFAS groups ($P = .36$). There were no differences in proportions of patients with DM between groups ($P = .99$). There were differences across COFAS types in patients with a history of prior surgery on their hindfoot or ankle ($P < .001$). The etiology of ankle arthritis was posttraumatic in 36 patients, primary in 47 patients, and inflammatory in 4 patients. There were no differences in arthritis etiology between COFAS types ($P = .64$).

Patient-Reported Outcomes Assessment

The baseline and latest postoperative PROMIS scores were compared between COFAS type 1 through 4 patients. Univariate analysis showed no differences in baseline PROMIS scores between patient groups (Table 3). Postoperative PROMIS scores were similar between groups. The change in preoperative and postoperative PROMIS scores demonstrated a difference in the means between COFAS types in only the PI domain ($P = .025$). A post hoc analysis was then performed in order to determine which specific COFAS types differed in PROMIS PI domain scores. Significant differences in the change in PROMIS scores were identified between COFAS types 2 and 4 ($P = .0072$) and COFAS types 3 and 4 ($P = .0464$)

Table 2. Baseline Characteristics of Patients Undergoing TAA With or Without Concomitant Procedures.

Factor	Total (N=87)	1 (n = 15)	2 (n = 47)	3 (n = 10)	4 (n = 15)	P Value[a]
Age at surgery, y	64.3±7.9	64.9±8.5	63.2±7.6	63.6±9.6	67.3±6.8	.40
Body mass index	30.8±5.9	28.9±4.0	31.3±7.0	30.9±5.3	31.2±4.2	.58
Follow-up length, mo	13.4±7.4	15.9±7.1	12.6±7.4	11.9±7.0	14.7±7.5	.36
DM						.99
No	80 (92.0)	14 (93.3)	43 (91.5)	9 (90.0)	14 (93.3)	
Yes	7 (8.0)	1 (6.7)	4 (8.5)	1 (10.0)	1 (6.7)	
Previous surgeries on hindfoot or ankle						**<.001**
No	44 (50.6)	10 (66.7)	30 (63.8)	4 (40.0)	0 (0.0)	
Yes	43 (49.4)	5 (33.3)	17 (36.2)	6 (60.0)	15 (100.0)	
Etiology of arthritis						.64
Posttraumatic	36 (41.4)	6 (40)	22 (46.8)	5 (50)	3 (20)	
Primary	47 (54)	9 (60)	25 (53.2)	4 (40)	10 (66.7)	
Inflammatory	4 (4.6)	1 (6.7)	0 (0)	1 (10)	2 (13.3)	

Abbreviations: DM, diabetes mellitus; TAA, total ankle arthroplasty.
[a]Boldface indicates significance.

Table 3. Univariate Analysis of Preoperative and Postoperative PROMIS Scores According to COFAS Type.

Factor	Total (N=87)	1 (n = 15)	2 (n = 47)	3 (n = 10)	4 (n = 15)	P Value
Preoperative						
PROMIS Anxiety	51.1±9.9	53.1±7.2	52.1±9.9	48.3±11.1	48.0±11.5	.35
PROMIS Depression	46.3±8.6	47.8±7.0	46.8±8.0	40.6±9.0	46.9±10.5	.16
PROMIS Physical Function	36.3±5.1	37.4±5.6	36.4±4.8	37.2±4.6	34.4±5.5	.39
PROMIS Pain Interference	64.0±6.8	63.1±7.0	65.3±5.4	62.7±4.1	61.7±10.7	.25
Postoperative						
PROMIS Anxiety	44.8±9.4	46.0±9.5	45.4±9.9	42.5±10.5	43.2±7.1	.70
PROMIS Depression	43.5±8.5	44.3±10.2	43.6±8.3	41.1±8.8	44.0±7.6	.81
PROMIS Physical Function	42.4±6.2	41.7±6.1	43.3±6.2	41.7±6.9	40.8±5.5	.51
PROMIS Pain Interference	53.6±8.8	55.6±6.3	52.7±8.8	50.4±12.3	56.7±7.5	.22
Difference						
PROMIS Anxiety	−6.4±10.2	−7.1±8.1	−6.8±9.9	−5.8±15.1	−4.8±9.8	.92
PROMIS Depression	−2.7±8.2	−3.4±8.9	−3.2±7.2	0.58±8.3	−2.8±10.4	.60
PROMIS Physical Function	6.1±6.2	4.3±8.7	7.0±6.1	4.4±4.1	6.4±4.1	.40
PROMIS Pain Interference	−10.4±9.5	−7.5±10.0	−12.6±8.5	−12.3±11.0	−5.0±9.1	**.025**

Abbreviations: COFAS, Canadian Orthopaedic Foot and Ankle Society; PROMIS, Patient-Reported Outcome Measures Information System.
Statistically significant findings were noted as bold text ($P < 0.05$).

with improved pain relief in COFAS types 2 and 3 when compared to type 4 (Appendix; Supplementary Table S2). COFAS types 2 and 3 met MCID for PROMIS PI, whereas COFAS types 1 and 4 did not.

Multivariate analysis found age to be a negative predictor of postoperative physical function (estimate [E] −0.17, standard error [SE] 0.084; $P = .047$; Table 4) and to be correlated with worse postoperative depression (E 0.29, SE 0.141; $P = .044$). Increasing BMI predicted worse postoperative anxiety (E 0.44, SE 0.215; $P = .044$), postoperative

depression (E 0.42, SE 0.168; $P = .015$) and postoperative physical function (E −0.22, SE 0.101; $P = .030$). Diabetes was associated with improved postoperative physical function (E 7.14, SE 2.312; $P = .003$). A history of previous surgeries was associated with improved postoperative physical function (E 3.26, SE 1.34; $P = .018$) and decreased postoperative pain interference (E −5.74, SE 2.516; $P = .026$). Using COFAS type 1 as the reference, multivariate analysis did not find an association between COFAS type and PROMIS domains.

Table 4. Multivariate Analysis of Comorbidities and Preoperative and Postoperative PROMIS Scores.

Effect	Anxiety			Depression			Physical Function			Pain Interference		
	Estimate	SE	P	Estimate	SE	P	Estimate	SE	P	Estimate	SE	P
Age	0.26	0.180	.1500	0.29	0.141	**.0437**	−0.17	0.084	**.0468**	0.03	0.159	.8751
Body mass index	0.44	0.215	**.0435**	0.42	0.168	**.0146**	−0.22	0.101	**.0300**	0.01	0.190	.9712
DM	−2.92	4.920	.5551	−6.91	3.857	.0780	7.14	2.312	**.0029**	−5.62	4.344	.2005
Previous surgery	−4.99	2.849	.0846	−3.91	2.233	.0847	3.26	1.339	**.0176**	−5.74	2.516	**.0258**
Surgery date	−0.04	0.125	.7582	−0.03	0.098	.7357	−0.02	0.059	.7070	0.04	0.110	.7003
PROMIS date	0.03	0.126	.8297	0.03	0.099	.7571	0.03	0.059	.6300	−0.04	0.112	.7048
FU length	−1.02	3.801	.7888	−0.74	2.980	.8036	−0.63	1.786	.7238	1.50	3.356	.6556
COFAS classification												
Type 1	Reference			Reference			Reference			Reference		
Type 2	−1.67	3.300	.6147	−0.73	2.587	.7801	1.30	1.551	.4043	−4.27	2.914	.1477
Type 3	0.34	4.522	.9400	5.49	3.545	.1265	−2.43	2.125	.2568	−4.05	3.993	.3141
Type 4	1.86	4.479	.6793	1.78	3.511	.6134	−0.33	2.105	.8764	7.37	3.955	.0669

Abbreviations: COFAS, Canadian Orthopaedic Foot and Ankle Society; DM, diabetes mellitus; FU, follow-up; PROMIS, Patient-Reported Outcome Measures Information System.
Statistically significant findings were noted as bold text ($P < 0.05$).

Discussion

End-stage ankle arthritis is a debilitating condition that is increasingly addressed with total ankle arthroplasty rather than arthrodesis.[7,20,28,30] Even though ankle arthrodesis can be a reliable option, ankle arthroplasty has comparable outcomes and is often preferred by patients. The indications for TAA have greatly expanded, as has the confidence in the ability to correct underlying deformities through TAA alone.[11,13,21,24] However, additional soft tissue and/or bony procedures are frequently required in either a combined or staged fashion to fully address the patient's pathology. The COFAS postoperative classification system was created to better characterize and define end-stage ankle arthritis severity by the additional procedures performed, as well as to promote research into the outcomes of such treatments. The purpose of this study was to determine how patient reported outcomes compare between straightforward and complex TAA as measured by PROMIS scores.

The patients in each of the 4 COFAS groups had similar demographics and at least 6 months of follow-up. Univariate analysis showed no differences in baseline PROMIS scores between patient groups (Table 4). Although we anticipated patients with higher COFAS type to have worse preoperative baseline PROMIS scores, our results do not support this. It is possible that patients across COFAS types experience similar levels of baseline dysfunction as measured by PROMIS scores even though patients with higher COFAS types having worse pathology require more extensive surgeries. We identified a difference in the change between pre- and postoperative PROMIS

scores (Δ) in the PI domain. Post hoc analysis localized these differences to exist between COFAS types 2 and 4, as well as COFAS types 3 and 4. Multivariate analysis showed age to be a negative predictor of postoperative physical function. Age was also associated with worse postoperative depression. This is consistent with current depression prevalence rates, which increase with age (highest 18-29 years old; 21%), decrease in middle age (30-44 years old; 15.8%), and again increase in old age ($\geq$65 years; 18.4%; CDC National Health Survey 2019).[36] Increasing BMI was associated with worsening postoperative anxiety, depression, and physical function. Diabetes had a strong association with improved postoperative physical function, whereas a history of prior surgeries was associated with improved postoperative function and decreased pain.

PROMIS instruments, curated from legacy test items and validated for use in foot and ankle orthopaedics, are precise and have sufficient coverage to detect high and low levels of pain, function, and disability while minimizing test burden.[12,14,17,18] The MCID is the smallest change in scores that is considered clinically meaningful by the patient.[4,19] Hung et al[16] established the MCIDs for the PROMIS PF (3-30; median 11.3) and PI (3-25; median 8.9) domains for foot and ankle conditions, which varied depending on the methods used. In a separate study, Hung et al[15] also established the responsiveness (ability to detect differences over time) of the PROMIS PI and PF domains, whereas Gausden et al[9] demonstrated no significant floor or ceiling effects for the PROMIS PF domain in foot and ankle conditions. The lack of improvement in the PF domain highlights that whereas TAA is a pain-relieving

procedure, improvements in physical activity and/or motion may be variable.

One of the goals for the developers of the preoperative and postoperative COFAS classification systems was the promotion of outcomes research using the classification system. Although the postoperative classification system has since been shown to have excellent inter- and intraobserver reliability, a literature search did not result in many outcomes studies using the postoperative classification system.[22,23] A study by Veljkovic et al[34] compared patient-reported outcomes for COFAS type 1 patients undergoing either TAA or open (OAA) vs arthroscopic ankle arthrodesis (AAA). All patients had similar Short Form-36 (SF-36) scores. Although total and disability Ankle Osteoarthritis Scale (AOS) scores were significantly different for the TAA and AAA groups compared to the OAA group, the difference did not meet MCID.[34] No similar studies were identified using PROMIS instruments. The use of global health measures vs anatomic outcome measures highlights the heterogeneity of outcomes reporting in foot and ankle surgery, which is an area that requires additional research and standardization.

We demonstrated significant differences between pre- and postoperative PROMIS PI scores meeting MCID for COFAS type 2 and 3 when compared with COFAS type 4, which did not meet MCID. In effect, COFAS type 4 showed less improvement in pain, thus supporting the null hypothesis and suggesting that more procedures and bigger correction can improve patients in some domains, but cannot be expected to provide the same level of pain relief as an isolated total ankle. Patients of all COFAS types saw improvement after total ankle replacement in domains studied although not all met MCID. Our finding that COFAS type 1 patients did not meet MCID for PF or PI and did not show the same significance in pain improvement compared to COFAS type 2 and 3 is difficult to explain. Based on our hypothesis, we would expect this finding, but the preoperative PROMIS scores were not significantly different. Further investigation is required to understand these nuances, and to investigate the specific time periods in the disease process when surgery can be of the most benefit.

Patient factors including age at the time of arthroplasty, presence of DM, body mass index (BMI), and previous surgery of the hindfoot or ankle have previously been found to have an effect on PROs.[6,8,26,29] Our multivariate analysis demonstrated age and BMI to be a predictor of worse physical function and depression, whereas BMI was also associated with worse anxiety. In our cohort, DM was a strong predictor of improved physical function. It is plausible that these patients have lower baseline function and thus have a more significant perception of improvement in their function. A study evaluating diabetic lumbar spine surgical patients showed lower PROMIS PF scores preoperatively and at all time points postoperatively out to 12 months. However, a significant proportion of these patients still obtained a meaningful improvement in physical function.[31] Lastly, our finding of prior surgeries predicting improved function and decreased pain is unexpected. In general, revision surgeries across orthopaedics are associated with worse and less predictable outcomes and more complications.[25,27] On the other hand, a COFAS type 4 patient who was initially misdiagnosed or had unaddressed deformity with their prior surgeries could perceive significant benefit in regard to pain and function from a definitive TAA with appropriate concurrent bony procedures.

Limitations

One of the limitations of the study is its retrospective nature. As a retrospective analysis of prospectively collected data, it is impacted by recall bias.[35] Our mean follow-up of 13 months reports short-term outcomes and future studies looking at mid- and long-term outcomes could potentially be useful. Further, the relatively small number of patients in the study could mean that we were underpowered to find significant differences across all domains, and a power analysis was not performed. Although the study has comparison groups given it uses a recognized classification system, there are no direct controls. Similarly, as with any study using a classification system, inherent weaknesses in the classification system may be present. Specific to the COFAS, varying surgeon preferences regarding which ancillary procedure to perform can directly affect COFAS classification grade, and thus the classification has inherently based on surgeon variability. Based on chart review and as detailed in the Methods section, we excluded 3 patients who had significant injuries, surgeries, or life events that surrounded their last postoperative follow-up appointment and PROMIS administration. These events clearly affected their PROs in a way that would have skewed the data. Because we were attempting to isolate the treatment effect for end-stage ankle arthritis, we felt that this was an appropriate application of exclusion criteria. Lastly, although we met the median MCID for PROMIS PI based on previously published data (3-25; median 8.9), the concept of the MCID remains imperfect. Its calculation is population and condition specific, as highlighted by the wide range dependent on which methods are used for its calculation.[16] We did not find a difference in PROMIS anxiety and depression

domains. Although these domains provide a more holistic view of patient well-being, PF and PI domains are more specific to orthopaedics and those that have been validated in foot and ankle conditions, in one of which we did find a difference. The MCID cutoffs for PROMIS Depression and Anxiety are not well established in the foot and ankle literature.[1] Furthermore, the PROMIS Depression domain has been shown to have a floor effect that is associated with hasty completion with up to 20% of patients not accurately complete the CAT.[10] It is likely that a portion of the population is reluctant to report mental health (depression and anxiety) symptoms because of a multitude of reasons, including stigma, or carefully consider them while filling out the CAT. Finally, preoperative PROMIS scores may influence postoperative recovery scores, and this was not analyzed in our regression analysis.[12]

Conclusion

In conclusion, our study found clinically meaningful differences in PROMIS PI scores for COFAS types 2 and 3 when compared to COFAS type 4 at short-term follow-up. More complex TAAs requiring hindfoot arthrodesis procedures did not appear to obtain as much pain relief (ΔPI) as less complex TAAs requiring more conservative soft tissue procedures or mid- or hindfoot osteotomies. We also found that patients with prior surgeries may also get reliable relief from a well-done TAA that addresses any additional sources of pathology through concurrent procedures. Future studies involving longer-term follow-up and prospective, level I data may be warranted to further investigate the COFAS classification system. These data can potentially help provide for preoperative counseling regarding expected outcomes and potential complication rates following TAA.

Appendix

Table S1. List of concomitant procedures performed on patients classified as COFAS types 2-4.

<u>Soft Tissue Procedures</u>
Deltoid reconstruction
Deltoid release
Flexor digitorum longus to navicular transfer
Gastrocnemius lengthening
Lateral ligament reconstruction
Plantar fascia release, open
Peroneus longus/brevis lengthening
Peroneus longus to brevis tendon insertion transfer
Posterior tibial tendon lengthening
Repair of peroneal tendon dislocation
Tibialis anterior tendon repair
Tibialis anterior tendon transfer to 3rd cuneiform
<u>Bony Procedures</u>
Cuboid osteotomy
Distal tibia osteotomy
Dorsiflexion 1st metatarsal osteotomy
Exostosis resection, fibular
Exostosis resection, dorsal midfoot
Lateral displacement calcaneal osteotomy
Medial column arthrodesis
Medial cuneiform opening wedge osteotomy
Medial displacement calcaneal osteotomy
Midfoot derotation osteotomy
Subtalar joint arthrodesis
Subtalar joint removal of ossicle
Talonavicular arthrodesis
Transverse tarsal joint closing wedge osteotomy
Triple arthrodesis
<u>Miscellaneous Procedures</u>

Hardware removal
Medial malleolar anti-fracture screw
Navicular debridement
Talonavicular joint debridement

Table S2. Post-hoc analysis of preoperative and postoperative PROMIS pain interference domain scores according to COFAS type.

Least Square Means

COFAS	Estimate	Standard Error	Degrees of Freedom	t-Value	t-Value Error (Pr>|t|)	Alpha	Lower	Upper	Adjustment	Adjusted p-Value	Adjusted Lower Confidence Interval	Adjusted Upper Confidence Interval
1	−11.6	3.2	65	−3.7	.0005	.05	−17.9	−5.3				
2	−15.9	2.4	65	−6.7	<.0001	.05	−20.6	−11.2				
3	−15.7	3.4	65	−4.6	<.0001	.05	−22.6	−8.8				
4	−4.3	3.5	65	−1.2	.2260	.05	−11.2	2.7				
Differences of Least Squares Means												
1 2	−4.3	2.9	65	−1.5	.1477	.05	−10.1	1.5	Tukey-Kramer	.4641	−12.0	3.4
1 3	−4.1	4.0	65	−1.0	.3141	.05	−12.0	3.9	Tukey-Kramer	.7415	−14.6	6.5
1 4	7.4	4.0	65	1.9	.0669	.05	−.5273	15.3	Tukey-Kramer	.2537	−3.1	17.8
2 3	−.2	3.4	65	−.1	.9491	.05	−7.1	6.6	Tukey-Kramer	.9999	−9.2	8.8
2 4	−11.6	3.5	65	−3.4	.0013	.05	−18.6	−4.7	Tukey-Kramer	.0072	−20.8	−2.5
3 4	−11.4	4.3	65	−2.7	.0096	.05	−20.0	−2.9	Tukey-Kramer	.0464	−22.7	−.1

ORCID iDs

Sandra E. Klein, MD, https://orcid.org/0000-0003-2416-1186
Jonathon D. Backus, MD, https://orcid.org/0000-0003-2426-170X
Jeffrey E. Johnson, MD, https://orcid.org/0000-0003-2055-9998

References

1. Bernstein DN, Mayo K, Baumhauer JF, Dasilva C, Fear K, Houck JR. Do patient sociodemographic factors impact the PROMIS scores meeting the patient-acceptable symptom state at the initial point of care in orthopaedic foot and ankle patients? *Clin Orthop Relat Res*. 2019;477(11):2555-2565. doi: 10.1097/CORR.0000000000000866

2. Cella D, Yount S, Rothrock N, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Med Care*. 2007;45(5 Suppl 1):S3-S11. doi: 10.1097/01.mlr.0000258615.42478.55

3. Chakravarty EF, Bjorner JB, Fries JF. Improving patient reported outcomes using item response theory and computerized adaptive testing. *J Rheumatol*. 2007;34(6):1426-1431.

4. Cook CE. Clinimetrics Corner: the minimal clinically important change score (MCID): a necessary pretense. *J Man Manip Ther*. 2008;16(4):E82-E83. doi: 10.1179/jmt.2008.16.4.82E

5. Cook KF, O'Malley KJ, Roddey TS. Dynamic assessment of health outcomes: time to let the CAT out of the bag? *Health Serv Res*. 2005;40(5 Pt 2):1694-1711. doi: 10.1111/j.1475-6773.2005.00446.x

6. Cunningham DJ, DeOrio JK, Nunley JA, Easley ME, Adams SB. The effect of patient characteristics on 1 to 2-year and minimum 5-year outcomes after total ankle arthroplasty. *J Bone Joint Surg Am*. 2019;101(3):199-208. doi: 10.2106/JBJS.18.00313

7. Daniels TR, Younger AS, Penner M, et al. Intermediate-term results of total ankle replacement and ankle arthrodesis: a COFAS multicenter study. *J Bone Joint Surg Am*. 2014;96(2):135-142. doi: 10.2106/JBJS.L.01597

8. Demetracopoulos CA, Adams SB Jr, Queen RM, DeOrio JK, Nunley JA 2nd, Easley ME. Effect of age on outcomes in total ankle arthroplasty. *Foot Ankle Int*. 2015;36(8):871-880. doi: 10.1177/1071100715579717

9. Gausden EB, Levack A, Nwachukwu BU, Sin D, Wellman DS, Lorich DG. Computerized adaptive testing for patient reported outcomes in ankle fracture surgery. *Foot Ankle Int*. 2018;39(10):1192-1198. doi: 10.1177/1071100718782487

10. Guattery JM, Dardas AZ, Kelly M, Chamberlain A, McAndrew C, Calfee RP. Floor effect of PROMIS Depression CAT associated with hasty completion in orthopaedic surgery patients. *Clin Orthop Relat Res*. 2018;476(4):696-703. doi: 10.1007/s11999.0000000000000076

11. Haskell A, Mann RA. Ankle arthroplasty with preoperative coronal plane deformity: short-term results. *Clin Orthop Relat Res*. 2004;(424):98-103. doi: 10.1097/01.blo.0000132248.64290.52

12. Ho B, Houck JR, Flemister AS, et al. Preoperative PROMIS scores predict postoperative success in foot and ankle patients. *Foot Ankle Int*. 2016;37(9):911-918. doi: 10.1177/1071100716665113

13. Hobson SA, Karantana A, Dhar S. Total ankle replacement in patients with significant pre-operative deformity of the hindfoot. *J Bone Joint Surg Br*. 2009;91(4):481-486. doi: 10.1302/0301-620X.91B4.20855

14. Hung M, Baumhauer JF, Latt LD, et al. Validation of PROMIS (R) Physical Function computerized adaptive tests for orthopaedic foot and ankle outcome research. *Clin Orthop Relat Res*. 2013;471(11):3466-3474. doi: 10.1007/s11999-013-3097-1

15. Hung M, Baumhauer JF, Licari FW, Bounsanga J, Voss MW, Saltzman CL. Responsiveness of the PROMIS and FAAM instruments in foot and ankle orthopedic population. *Foot Ankle Int*. 2019;40(1):56-64. doi: 10.1177/1071100718799758

16. Hung M, Baumhauer JF, Licari FW, Voss MW, Bounsanga J, Saltzman CL. PROMIS and FAAM minimal clinically important differences in foot and ankle orthopedics. *Foot Ankle Int*. 2019;40(1):65-73. doi: 10.1177/1071100718800304

17. Hung M, Clegg DO, Greene T, Weir C, Saltzman CL. A lower extremity physical function computerized adaptive testing instrument for orthopaedic patients. *Foot Ankle Int*. 2012;33(4):326-335. doi: 10.3113/FAI.2012.0326

18. Hunt KJ, Lakey E. Patient-reported outcomes in foot and ankle surgery. *Orthop Clin North Am*. 2018;49(2):277-289. doi: 10.1016/j.ocl.2017.11.014

19. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10(4):407-415. doi: 10.1016/0197-2456(89)90005-6

20. Jiang JJ, Schipper ON, Whyte N, Koh JL, Toolan BC. Comparison of perioperative complications and hospitalization outcomes after ankle arthrodesis versus total ankle arthroplasty from 2002 to 2011. *Foot Ankle Int*. 2015;36(4):360-368. doi: 10.1177/1071100714558511

21. Kim BS, Choi WJ, Kim YS, Lee JW. Total ankle replacement in moderate to severe varus deformity of the ankle. *J Bone Joint Surg Br*. 2009;91(9):1183-1190. doi: 10.1302/0301-620X.91B9.22411

22. Krause FG, Di Silvestro M, Penner MJ, et al. Inter- and intraobserver reliability of the COFAS end-stage ankle arthritis classification system. *Foot Ankle Int*. 2010;31(2):103-108. doi: 10.3113/FAI.2010.0103

23. Krause FG, Di Silvestro M, Penner MJ, et al. The postoperative COFAS end-stage ankle arthritis classification system: interobserver and intraobserver reliability. *Foot Ankle Spec*. 2012;5(1):31-36. doi: 10.1177/1938640011433051

24. Lee GW, Wang SH, Lee KB. Comparison of intermediate to long-term outcomes of total ankle arthroplasty in ankles with preoperative varus, valgus, and neutral alignment. *J Bone Joint Surg Am*. 2018;100(10):835-842. doi: 10.2106/JBJS.17.00703

25. O'Connor KM, Johnson JE, McCormick JJ, Klein SE. Clinical and operative factors related to successful revision arthrodesis in the foot and ankle. *Foot Ankle Int*. 2016;37(8):809-815. doi: 10.1177/1071100716642845

26. Odum SM, Van Doren BA, Anderson RB, Davis WH. In-hospital complications following ankle arthrodesis versus ankle arthroplasty: a matched cohort study. *J Bone Joint Surg Am*. 2017;99(17):1469-1475. doi: 10.2106/JBJS.16.00944

27. Patton D, Kiewiet N, Brage M. Infected total ankle arthroplasty: risk factors and treatment options. *Foot Ankle Int*. 2015;36(6):626-634. doi: 10.1177/1071100714568869

28. Pugely AJ, Lu X, Amendola A, Callaghan JJ, Martin CT, Cram P. Trends in the use of total ankle replacement and ankle arthrodesis in the United States Medicare population. *Foot Ankle Int*. 2014;35(3):207-215. doi: 10.1177/1071100713511606

29. Schipper ON, Jiang JJ, Chen L, Koh J, Toolan BC. Effect of diabetes mellitus on perioperative complications and hospital outcomes after ankle arthrodesis and total ankle arthroplasty. *Foot Ankle Int*. 2015;36(3):258-267. doi: 10.1177/1071100714555569

30. Singh JA, Ramachandran R. Time trends in total ankle arthroplasty in the USA: a study of the National Inpatient Sample.

31. Squires MD, Brodke DS, Neese A, et al. Physical function computer adaptive test outcomes in diabetic lumbar spine surgical patients. *Spine J*. 2019;19(6):1048-1056. doi: 10.1016/j.spinee.2018.12.008

32. Valderrabano V, Horisberger M, Russell I, Dougall H, Hintermann B. Etiology of ankle osteoarthritis. *Clin Orthop Relat Res*. 2009;467(7):1800-1806. doi: 10.1007/s11999-008-0543-6

33. VanderWeele TJ, Ding P. Sensitivity analysis in observational research: introducing the E-value. *Ann Intern Med*. 2017;167(4):268-274. doi:10.7326/m16-2607

34. Veljkovic AN, Daniels TR, Glazebrook MA, et al. Outcomes of total ankle replacement, arthroscopic ankle arthrodesis, and open ankle arthrodesis for isolated non-deformed end-stage ankle arthritis. *J Bone Joint Surg Am*. 2019;101(17):1523-1529. doi: 10.2106/JBJS.18.01012

35. Zini MLL, Banfi G. A narrative literature review of bias in collecting patient reported outcomes measures (PROMs). *Int J Environ Res Public Health*. 2021;18(23):12445. doi:10.3390/ijerph182312445

36. National Center for Health Statistics. Survey Description, National Health Interview Survey, 2019. Hyattsville, Maryland. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2019/srvydesc-508.pdf