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Evaluating Prospective Patient-Reported Pain and Function Outcomes After Ankle and Hindfoot Arthrodesis

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Abstract

Background: Hindfoot and ankle fusions are mechanically limiting procedures for patients. However, patient-reported outcomes of these procedures have not been well studied. This study assessed outcomes of hindfoot and ankle fusions by using Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function (PF) and Pain Interference (PI) Computer Adaptive Tests (CATs).

Methods: Between 2014 and 2018, 102 patients were prospectively enrolled after presenting to a tertiary care facility for ankle and hindfoot fusions, including tibiotalar, tibiotalocalcaneal, subtalar, and triple arthrodeses. Study participants completed preoperative and 12-month postoperative PF and PI CATs. The differences between mean 12-month postoperative and preoperative PROMIS PF and PI T scores were analyzed with paired t tests. The relationship between the 12-month PF and PI differences for the overall sample and patient factors was examined using multiple regression modeling.

Results: The sample had mean age of 57.69 years; 48% were male, and 55% were obese. Patients who underwent ankle and hindfoot arthrodesis had statistically significant improvements from preoperative to 12 months postoperative in mean PF (36.26 ± 7.85 vs 39.38 ± 6.46 , P = .03) and PI (61.07 ± 7.75 vs 56.62 ± 9.81 , P = .02). Triple arthrodesis saw the greatest increases in physical function ($\Delta PF = 7.22 \pm 7.31$, P = .01) and reductions in pain ($\Delta PI = -9.17 \pm 8.31$, P = .01), achieving minimal clinically important difference (MCID). Patients who underwent tibiotalar fusion had significant improvement in physical function ($\Delta PF = 4.18 \pm 5.68$, P = .04) and pain reduction that approached statistical significance ($\Delta PI = -6.24 \pm 8.50$, P = .09), achieving MCID. Older age (≥ 60 years) was associated with greater improvements in PF ($\beta = 0.20$, P = .07) and PI ($\beta = -0.29$, P = .04). Preoperative PF and PI *T* scores were significantly associated with the 12-month change in PF and PI *T* scores, respectively ($\beta = -0.74$, P < .01; $\beta = -0.61$, P < .01).

Conclusion: Hindfoot and ankle fusions are procedures with favorable patient outcomes leading to increased physical function and decreased pain at 12 months postoperation relative to preoperation. **Level of Evidence:** Level II, prospective comparative study.

Keywords: hindfoot fusion, ankle fusion, PROMIS, patient-reported outcomes

Introduction

Hindfoot and ankle arthritis and deformity constitute a significant disease burden on affected patients, leading to reduced quality of life.¹⁷ These conditions lead to physical impairment at levels commensurate to those of end-stage renal disease and congestive heart failure.^{28,48} In such patients, operative hindfoot and ankle arthrodesis procedures are indicated for pain and instability as well as for severe deformity and malalignment of the involved joints.

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Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (https://creativecommons.org/licenses/by-nc/4.0/) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (https://us.sagepub.com/en-us/nam/ open-access-at-sage). Traditional operative options include tibiotalar arthrodesis,¹ tibiotalocalcaneal (TTC) fusion,³ subtalar arthrodesis,^{12,47} and triple arthrodesis.⁴¹

Each procedure can result in pain relief, deformity correction, and improved function. However, they are typically used as salvage procedures for significant pathology as they are not without drawbacks and complications. For example, tibiotalar arthrodesis leads to loss of ankle motion and can result in diminished gait efficiency³⁰ as well as adjacent joint supraphysiologic motion and stress leading to adjacent joint disease.^{11,49} TTC fusion complication rates have been reported as high as 60%, with the most common complications being nonunion, malunion, infection, and implant problems.^{3,43} Triple and subtalar arthrodesis necessarily limit the transverse tarsal joints during ambulation, which eliminates the function to unlock the hindfoot during the stance phase, compromising the smooth transition from heel strike to stance phase. Complications include infection, nonunion, adjacent joint arthritis, and hardware issues. Additionally, fusion in a malaligned position confers significant functional consequences.47

Various studies have examined postoperative outcomes of these procedures using validated questionnaires, including the 36-Item Short Form Health Survey (SF-36), the American Orthopaedic Foot & Ankle Society (AOFAS) Ankle-Hindfoot Score, and the Musculoskeletal Functional Assessment; visual analog scale (VAS) for pain; subjective measures of pain and satisfaction; and rates of return to daily activity and return to work.^{2,5-10,13,18,20,21,24,31,33-35,37,38,41,42,44,46,52,54} However, to our knowledge, no studies have thus far assessed patient-reported outcomes of these procedures using computer adaptive tests as with the Patient-Reported Outcome Measurement Information System (PROMIS).

PROMIS is a validated outcome measure providing patients the opportunity to report their experiences with classes of symptoms due to chronic illness.^{16,50} It addresses multiple issues inherent to other patient-reported outcomes scoring tools such as floor/ceiling effects, excessive time to complete, and lack of generalizability.¹⁴ Domains include Physical Function (PF) and Pain Interference (PI), administered as Computer Adaptive Tests (CATs). These incorporate branching logic that specifically hones in on the most salient aspects of a patient's experience to best characterize his or her physical function and the effect of pain on their lives. This outcome measurement system is not only generalizable but is also better than many other outcome measurements for orthopedic pathophysiology and interventions.^{15,32}

The purpose of this study was to assess the outcomes and prognosis of various hindfoot fusion subtypes along with ankle fusion by using 2 validated patient-reported outcome measures: the PROMIS PF and PI CATs. We evaluated these procedures to determine if they are effective as a salvage method and truly improve physical function and pain in a patient population that is often severely limited with regards to general mobility and activities of daily living.

Materials and Methods

Participants

Patients between 18 and 89 years of age who presented to a single university-affiliated hospital between 2014 and 2018 for primary ankle and hindfoot fusion surgeries, including tibiotalar arthrodesis, TTC fusion, subtalar arthrodesis, and triple fusion, were included in the study. The surgeries were performed by 2 fellowship-trained orthopedic foot and ankle surgeons. All patients included had a minimum 2-year follow-up. They were enrolled prospectively in the study after obtaining consent. Patients were only excluded on the basis of polytraumatic injuries necessitating orthopedic intervention besides the studied procedures. This single exclusion criterion was used to avoid the confounding effect of other injuries and surgeries while still ensuring the greatest generalizability of these results owing to the diverse indications and comorbidities of the typical patient population undergoing the studied procedures. Approval from the academic medical center's institutional review board (84014) was granted prior to study commencement.

Data Collection

A total of 102 patients were enrolled in the study. Patients were contacted by phone with multiple attempts on multiple days conducted for those unable to be reached. Forty-two patients were able to be contacted and surveyed by a single author using a prewritten script and standardized, branchinglogic PROMIS CAT questions within REDCap. Demographic information (ie, sex, age, race, body mass index, and smoking history), medical history (ie, type 2 diabetes mellitus and rheumatoid arthritis), and type of procedure performed (ie, triple fusion, TTC fusion, tibiotalar fusion, and subtalar fusion) were extracted from the electronic medical record (EMR) for outcome stratification. Charlson Comorbidity Index (CCI) was calculated based on medical history and age. Participants completed preoperative and 12-month postoperative PROMIS PF and PI CATs via the REDCap electronic data capture tool.¹⁹ This interval was chosen based on typical recovery time and scheduled postoperative visits. The PROMIS PF v1.2 CAT uses a 121-item question bank, and the PROMIS PI v1.1 CAT draws from a 40-item question bank. The CATs uniquely decrease patient burden and survey fatigue by choosing questions from the item bank that adapt using prior patient answers.^{25,27} PROMIS PF and PI domains are reported as T scores ranging between 0 and 100. The PROMIS PF scale measures a patient's selfreported ability to perform physical activities, including dexterity, mobility, and activities of daily living. The PROMIS PI scale measures the degree to which pain hinders a patient's daily life physically, socially, emotionally, and cognitively. Functional improvement in patients has a positive correlation to PF T scores whereas PI T scores are inverselv correlated with improvements in a patient's reported pain.16



Figure 1. Physical function and pain interference T scores. Data is reported for the overall sample and by each surgery type as the mean difference between 12-month postoperative and preoperative T scores for PF and PI CATs. ***P < 0.05.

Statistical Analysis

Differences in preoperative and 12-month postoperative CAT PROMIS T scores were calculated for each patient, and mean values were used as a measure of changes in pain and physical function at 1 year postoperation. The distributions of PROMIS PF and PI T scores were assessed for normality using a Shapiro-Wilk test. Paired t tests were used to compare differences in mean PF and PI T scores prior to surgery and at 12-month follow-up. Sex, age group, surgery type, and preoperative T scores were selected a priori as potential predictive factors associated with the difference between 12-month postoperative and preoperative PF and PI T scores for the overall sample in a multiple regression model. Body mass index (BMI) was analyzed as a categorical variable according to Centers for Disease Control and Prevention BMI classification. Age was analyzed as a categorical variable (<60 and \geq 60 years of age) based on previously reported cutoffs described in the orthopedic foot and ankle literature.^{22,53} Minimum clinically important difference (MCID) was determined using the 0.5 SD method, which is a variation-based estimate of the MCID commonly used in the literature.^{26,45,51} A P value less than .05 was deemed statistically significant. All data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 26 (IBM Corp, Armonk, NY).

Results

Patient Characteristics

The final sample was composed of 42 patients who underwent ankle or hindfoot arthrodesis: 10 triple fusions, 7 TTC fusions, 8 tibiotalar fusions, and 17 subtalar fusions. The average age of participants was 57.69 \pm 11.62, and there was a slight female predominance (52.4%). A majority of patients were obese (54.7%), and common comorbidities included present or past smoking history (42.9%), type 2 diabetes mellitus (21.4%), and rheumatoid arthritis (16.7%). Mean CCI was 2.36 \pm 1.72. A summary of patient demographic characteristics and comorbidities is outlined in Table 1.

Twelve-Month Changes in Physical Function and Pain Interference

Overall, patients who underwent ankle or hindfoot arthrodesis had statistically significant improvements in physical function ($\Delta PF \ T \ score = 3.12 \pm 9.09, \ t = 2.22, \ P = .03$) and pain ($\Delta PI T$ score = -4.66 + 11.39, t = 2.53, P = .02) at 12-month follow-up. Triple fusions saw the largest increases in physical function ($\Delta PF T$ score = 7.22 \pm 7.31, t = 3.12, P= .01) and reductions in pain ($\Delta PI T$ score = -9.17 + 8.31, t = 3.49, P = .01). Patients who underwent tibiotalar fusion had significant improvement in physical function ($\Delta PF T$ score = 4.18 + 5.68, t = 2.40, P = .04) and improvement in pain reduction, which did not reach statistical significance $(\Delta PI \ T \text{ score} = -6.24 + 8.50, t = -1.90, P = .09).$ Mean differences in PF and PI T scores were not found to be individually statistically significant for TTC and subtalar fusions (Figure 1). The MCID was achieved for improvements in physical function and pain at 12 months for triple fusion and tibiotalar fusion patients (Table 2).

Multiple Regression

The multivariable β coefficients were determined after controlling for sex, age group, type of surgery, and

Characteristic	Overall	Triple Fusion	TTC Fusion	Tibiotalar Fusion	Subtalar Fusion	
n (%)	42 (100)	10 (23.8)	7 (16.7)	8 (19.0)	17 (40.5)	
Sex	· · · ·					
Males	20 (47.6)	5	4	4	7	
Females	22 (52.4)	5	3	4	10	
Age, y	57.69 ± 11.62	60.50 ± 13.24	59.43 ± 7.72	57.13 ± 13.02	55.59 ± 11.82	
Age group						
<60 y	22 (52.4)	4	2	7	9	
≥60 y	20 (47.6)	6	5	I	8	
Race	()					
White	23 (54.8)	5	5	3	10	
Black	4 (9.5)	I	I	0	2	
Native American	l (2.4)	I	0	0	0	
Other	2 (4.8)	0	0	0	2	
Unidentified	12 (28.5)	3	I	5	3	
BMI	32.60 ± 7.29	32.03 ± 7.43	35.61 ± 4.53	32.36 ± 8.52	31.80 ± 7.79	
BMI classification						
Normal (18.5-25)	8 (19.0)	2	0	2	4	
Overweight (25-30)	II (26.2)	3	I	2	5	
Class I obesity (30-35)	6 (14.3)	0	2	I	3	
Class II obesity (35-40)	10 (23.8)	4	3	2	I	
Class III obesity (>40)	7 (16.7)	I	I	I	4	
Smoking history	()					
Never smoker	24 (57.1)	8	6	2	8	
Past/current smoker	18 (42.9)	2	I	6	9	
Type 2 diabetes mellitus	9 (21.4)	2	3	0	4	
Rheumatoid arthritis	7 (16.7)	I	2	I	3	
Charlson Comorbidity Index	2.36 ± 1.72	$2.20~\pm$ 1.32	3.29 \pm 2.21	2.00 ± 1.07	2.24 ± 1.95	

Table I. Demographic Characteristics.^a

Abbreviation: TTC, tibiotalocalcaneal.

^aData are reported as n (%) or as mean \pm SD. Percentages are not indicated for n <20.

Table 2. Physical Function and	Pain	Interference	Т	Scores."
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Procedure	Preoperative PF CAT T score	Preoperative PI CAT T score	12-mo PF CAT T score	12-mo PI CAT T score	$\Delta PF CAT$ T score	P Value	$\Delta PI CAT$ T score	P Value
Overall (n = 42)	36.26 ± 7.85	61.28 ± 7.75	39.38 ± 6.46	56.62 ± 9.81	3.12 ± 9.09	.03	-4.66 ± 11.39	.02
Triple fusion $(n=10)$	31.94 ± 6.28	65.12 ± 7.33	39.16 ± 5.13	55.95 ± 9.40	7.22 ± 7.31	<.01	-9.17 ± 8.31	<.01
TTC fusion (n=7)	36.80 ± 8.99	59.40 <u>+</u> 9.96	36.39 ± 3.67	59.59 ± 5.34	-0.41 ± 8.94	.90	0.19 ± 9.15	.96
Tibiotalar fusion $(n=8)$	36.89 ± 7.20	61.24 ± 4.89	41.06 ± 5.75	55.00 ± 10.50	4.18 ± 5.68	.04	-6.24 ± 8.50	.09
Subtalar fusion $(n=17)$	38.28 ± 8.16	59.82 <u>+</u> 7.72	39.94 \pm 8.18	56.55 \pm 11.51	I.66 ± 10.90	.54	-3.26 ± 14.29	.36

Abbreviations: CAT, computer adaptive test; PF, Physical Function; PI, Pain Interference; TTC, tibiotalocalcaneal.

^aData are reported as mean \pm SD. Δ PF and Δ PI CAT *T* scores indicate the difference between 12-month postoperative and preoperative *T* scores. *P* values <.05 are bolded.

preoperative PF and PI *T* scores. Age greater than or equal to 60 was positively associated with improvements in physical function ($\beta = 0.20$, P = .07) and pain ($\beta = -$ 0.29, P = .04). Higher preoperative PF *T* scores were inversely associated with improvements in physical function ($\beta = -0.74$, P = <.01), and higher preoperative PI *T* scores were positively associated with reductions in pain interference ($\beta = -0.61$, $P \le .01$). No significant relationships were observed between sex or surgery type and 12-month changes in physical function or pain (Table 3).

Discussion

To our knowledge, this is the first study analyzing the outcomes and prognosis of various hindfoot fusion subtypes and ankle fusion using PROMIS to assess the effectiveness of this group of procedures. We evaluated these surgeries as a group because they are typically used in a patient population that is often severely limited with regard to general mobility and activities of daily living due to foot and ankle impairment. This study found that, overall, patients who underwent ankle and hindfoot arthrodesis had improved physical

Standardized Beta Coefficient	P Value
0.03	.83
0.01	.92
0.20	.07
-0.74	<.0I
-0.01	.96
-0.07	.71
-0.29	.04
-0.6 I	<.0I

Table 3. Multiple Regression of PROMIS T Scores and PatientFactors.

Abbreviation: PROMIS, Patient-Reported Outcome Measurement Information System.

^aThe regression was performed for Δ PF score measuring the difference between the 12-month and preoperative PF T scores. P values <.05 are bolded.

^bThe regression was performed for ΔPI score measuring the difference between the 12-month and preoperative PI T scores. P values <.05 are bolded.

function and reduced pain at 12 months postoperation relative to preoperation. Those that specifically had a triple fusion or a tibiotalar fusion procedure showed clinically significant increased physical function and decreased pain at 12 months. Moreover, we assessed potential prognostic factors associated with changes in PROMIS scores. Older age was associated with greater improvements in PF and PI. Higher preoperative PROMIS PF scores were associated with lower 12-month changes in score, whereas higher preoperative PROMIS PI scores were associated with higher 12-month changes in score.

The use of the PF and PI PROMIS questionnaires is an integral component of this study because these surveys evaluate patient-reported outcomes in a comprehensive manner shown to be better than other traditionally used outcome measurements for orthopedic pathophysiology and interventions.^{4,15,23,29,36,39,40} In 2018, Gausden et al¹⁵ found that PROMIS was superior to legacy foot and ankle outcome scores for evaluating patients following ankle fracture surgery in terms of lower floor and ceiling effects and greater ability to distinguish clinically significant changes in patients between time points following surgery. PROMIS literature is currently growing as researchers recognize its favorable performance in terms of reliability, accuracy, decreased patient burden, and increased sensitivity, and the current study adds to this body of literature.

With regard to triple fusion outcomes, this study's findings are supported by the existing literature. Stegeman et al⁵² found that in patients with mean follow-up of 21 months, Foot Function Index (FFI) improved with postoperative foot function considered better than preoperative by 89% of subjects. In a study with a mean follow-up of 5.25 years, triple fusion patient outcomes were evaluated with AOFAS, which showed that ankle and hindfoot pain and disability improved significantly.⁶ Considering a more extended longitudinal perspective, Klerken et al³¹ assessed FFI and AOFAS for triple fusion patients at 15 years postoperative and found that FFI pain decreased significantly whereas FFI disability and AOFAS showed no significant differences. Patient satisfaction rate after triple fusion was high, ranging from 74% to 97%.^{5,6,52} Moreover, in multiple studies, patients were asked if they would have the surgery again, and affirmative responses ranged from 72% to 90% of subjects.^{10,31,41}

Other studies corroborated the patient-reported outcomes we found following tibiotalar arthrodesis as well. Daniels et al conducted a multicenter trial analyzing complication rates, Ankle Osteoarthritis Scale (AOS), and SF-36 in 89 tibiotalar arthrodesis patients with mean follow-up of 5.2 years. They found a 7% major complication rate and significantly improved AOS total, pain, and disability scores and SF-36 physical component summary score from preoperative to final follow-up.9 Another study found that tibiotalar arthrodesis patients at 3-year postoperative follow-up had significant improvement in SF-36 and Musculoskeletal Functional Assessment scores.⁷ Ajis et al² found that patients with at least 2-year follow-up had low VAS pain score (2.8) and a return to work rate of 77.4%, and 84.6% of patients reported they would have the surgery again. Satisfaction rates with tibiotalar fusion were approximately 91% across multiple studies.^{2,20,21}

The current study found no significant 12-month postoperative PF and PI differences for TTC fusion or subtalar fusion procedures: however, studies using other outcome measures found improved results following these surgeries. This may be due, in part, to our study's limited sample size or the different outcome measurement tools used. Muckley et al³⁸ found that 93% of TTC fusion patients evaluated with the SF-36, Mazur Ankle Arthrodesis score, and AOFAS had patient-reported subjective improvement in mobility and were satisfied with their outcome. Another study of 64 TTC fusion patients with at least 2-year follow-up found they had low VAS pain score (2.8), high satisfaction (87.5%), and a return to work rate of 73%, and 81% of patients said they would have the surgery again.² Carranza-Bencano et al⁸ studied subtalar fusion patients and found that they had good outcomes based on Angus and Cowell criteria with improvement in AOFAS, SF-36, and a patient satisfaction questionnaire at 12 months postoperation. Hollman et al²⁴ reported that 90% of their studied subtalar fusion cohort would recommend the surgery to another in the same situation, 76%experienced less pain, and 69% had improved walking ability. Thus, although our study did not find significant effects, the overall body of literature supports the utility of these procedures.

We conducted a multiple regression analysis to assess potential predictive factors of greater improvements in PROMIS scores at 12 months postoperation. The literature is currently sparse in reporting prognostic factors related to PROMIS in the foot and ankle population. After controlling for other covariates, we found that age greater than or equal to 60 is a positive indicator of potentially greater improvement in postoperative physical function and reduced pain. Intuitively, higher baseline or preoperative PF scores (ie, more similar function levels relative to the normative population mean) were associated with smaller changes in PF at 12 months, whereas higher baseline or preoperative PI scores (ie, worse pain relative to the normative population mean) were associated with greater changes in PI at 12 months.

Limitations

There are limitations to consider when interpreting the findings of this study. The patient population was restricted to a tertiary care center causing possible sampling biases by selecting for increased disease severity relative to the general ankle and hindfoot population. By the nature of relying on individual self-reporting, the study lends itself to possible bias by patients who expected vastly different outcomes relative to what the surgeons advised them to expect. Another limitation of the study is the sample size. Although the patients who were enrolled but did not complete a 12-month postoperative PROMIS CAT did not differ significantly across demographic characteristics from those included in the study, a larger sample size would have led to more robust support for the study's conclusions. We also were able to report on 42 of 102 patients, and it is definitely possible those who were not available for follow-up would have different patient-reported outcomes. Those patients who did not complete their 12-month postoperative visit may have more barriers to accessing health care, and, while limited access to medical care was not measured in the registry, it could be an additional confounding variable. The limited sample size also influences the strength of the conclusions that can be drawn from the multiple regression analysis. Further study would involve improving on these factors and incorporating a longer follow-up period. This would lead to a more thorough analysis of patient-reported outcomes following these surgeries.

Conclusion

When considered as an overall group, hindfoot and ankle fusions are effective procedures with favorable patient outcomes, leading to increased physical function and decreased pain at 12 months postoperation relative to preoperation. To our knowledge, this is the first study using PROMIS to analyze the outcomes and prognosis of various hindfoot fusion subtypes and ankle fusion. When procedures were examined individually, triple fusion and tibiotalar fusion surgeries showed clinically significant improved patient physical function and pain at 12 months postoperation.

Ethical Approval

Ethical approval for this study was obtained from Northwestern University's Institutional Review Board (84014).

Declaration of Conflicting Interests

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