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Original Research

Association between sesamoid position and long-term outcomes following triplanar tarsometatarsal arthrodesis at 4-year follow-up

Daniel J. Hatch, DPM, FACFAS^{a,*}, Avneesh Chhabra, MD^b, Paul D. Dayton, DPM, MS, FACFAS^c,
Mindi Dayton, DPM, MHA, FACFAS^c, Daniel C. Farber, MD^d, George Liu, DPM, FACFAS^e,
JP McAleer, DPM, FACFAS^f, Abdi Raissi, MD^g, Robert D. Santrock, MD^h,
Robert P. Taylor, DPM, FACFASⁱ, Jennifer Koay White, MD^j, Dane Wukich, MD^e

^a Foot and Ankle Center of the Rockies, Greeley, Colorado, USA^b University of Texas Southwestern Medical Center, Dallas, Texas, USA^c Foot and Ankle Center of Iowa/Midwest Bunion Center, Ankeny, Iowa, USA^d Lehigh Valley Orthopaedic Institute, Bethlehem, PA, USA^e UT Southwestern Medical Center, Dallas, TX, USA^f Jefferson City Medical Group, Department of Podiatry, Jefferson City, MO, USA^g Desert Orthopaedic Center, Las Vegas, NV, USA^h Duke Orthopedics, Durham, NC, USAⁱ Stonebriar Foot & Ankle, Frisco, Texas, USA^j West Virginia University, Morgantown, WV, USA

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ABSTRACT

Background: Hallux valgus (HV) is recognized as a triplanar foot deformity with optimal surgical results achieved when all three planes are addressed. We have previously reported on an ongoing 5-year, prospective, multicenter, clinical study using instrumented correction of the first tarsometatarsal joint (1st TMT) in patients with HV.

Purpose: This report details interim 48-month results of this study, evaluating the impact of early postoperative tibial sesamoid position (TSP) on radiographic recurrence (postoperative hallux valgus angle (HVA) measurements of $>15^\circ$), and whether radiographic recurrence impacted patient-reported outcomes.

Study design: One hundred seventy-three patients were included in this multicenter study, of whom 146 patients achieved their 48-month visit. Radiographic parameters were presented at baseline, 6 weeks and 48 months. This included intermetatarsal angle (IMA) along with TSP and HVA.

Methods: Institutional review board approval was obtained for each study site. A consecutive cohort of patients were enrolled from November 2018 to April 2021 who received 1st TMT arthrodesis to correct their hallux valgus deformity. Inclusion and exclusion criteria were established.

Results: At the 48-month follow-up, 12 patients (8.2%) had radiographic recurrence with an HVA $>15^\circ$. Evaluation of TSP position at 6-weeks postoperative found that a TSP ≤ 3 reduced the likelihood of recurrence by 95% compared to a TSP >3 .

Conclusion: The results of this interim analysis suggest that initial correction of axial rotation and sesamoid position of the first ray is important in maintaining correction long term and favorable patient reported outcomes.

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Introduction

Hallux valgus (HV) is a prevalent musculoskeletal deformity of the foot that affects approximately 23% of adults aged 18–65 years and 35.7% over 65 years [1]. Traditional approaches to HV correction have focused on assessing and correcting the deformity based on

transverse plane measures, such as the intermetatarsal angle (IMA) and hallux valgus angle (HVA). Historically, the most common surgical approaches for HV correction have involved two-dimensional (2D) metatarsal osteotomies or tarsometatarsal (TMT) arthrodesis with soft tissue balancing procedures. These 2D corrective approaches have reported recurrence rates up to 30%–78% [2–5]. A recent systematic review by Lalevee et al. reported a 64% recurrence rate in distal osteotomies using a recurrence definition of a postoperative HVA of 15° [5].

*Corresponding author.

E-mail address: dhatch@fackrockies.com (D.J. Hatch).



Fig. 1. Preoperative (A) and Postoperative (B) radiographs illustrating the IMA^a correction, sagittal plane alignment and the sesamoid alignment.^aIntermetatarsal Angle

HV has been recognized as a triplanar deformity, with a common contribution of first ray axial rotation as part of the deformity [6–9]. A three-dimensional (3D) computed tomography (CT) study of HV patients found that approximately 87% of HV deformities involve a pronated position of the metatarsal [10]. Dayton et al. in 2014 demonstrated that the lateral position of the sesamoid apparatus in HV deformities was associated with first metatarsal pronation/eversion, not solely lateral translation [11]. Several authors have reported that incomplete sesamoid reduction following HV correction increases the risk of recurrence. In a series of patients with proximal metatarsal osteotomies, incomplete sesamoid reduction was associated with a 10-fold increased risk of HV recurrence [12]. Similarly, Shibuya et al. found that, in a mixed cohort including metatarsal osteotomies and Lapidus, postoperative tibial sesamoid position strongly influenced maintenance of HV correction, with a 50% recurrence rate reported when early postoperative tibial sesamoid position (TSP) was greater than four on the 7-point scale [13]. The importance of correction of axial rotation has also been demonstrated in third generation minimally invasive (MIS) distal osteotomy, where Yoon et al. found that 1 month postoperative TSP > 4 predicted a 13-fold increased risk of recurrence [14]. Bello-Tejeda et al. revealed the importance of sesamoid reduction in surgery on patient functional outcomes [15]. Veracruz-Galvez et al. and Chen et al. found that normal sesamoid position postoperative correlated with improved patient satisfaction [16,17]. Recently, there has been increased interest in instrumented 1st TMT arthrodesis systems designed to achieve anatomic sesamoid reduction and triplanar HV correction, yet the association between early sesamoid correction and related factors on long-term recurrence and patient reported outcomes has not been evaluated.

We have previously reported interim results of a five-year, multicenter, prospective study on instrument-assisted triplanar 1st TMT arthrodesis with early weightbearing [18]. This study has shown significant improvements in radiographic correction, low radiographic recurrence rates, low non-union rates, low complication rates, and significant improvement in patient reported outcomes. To explore the potential role of axial rotation of the first ray on long term results, we looked at early postoperative TSP as a predictor of radiographic recurrence and then compared patient reported outcomes between the recurrence and non-recurrence groups at 48 months follow-up.

Patients and methods

This is a prospective, multicenter, clinical trial involving seven centers and 13 foot and ankle surgeons. Surgeons were all board-certified foot and ankle surgeons familiar with the procedure and instrumentation. A consecutive cohort of patients were enrolled from November 2018 to April 2021. All patients in this study underwent instrumented 1st TMT joint arthrodesis for symptomatic HV deformity correction with early return to protected weightbearing. The system utilized was a Lapiplasty® system by Treace Medical Concepts, Ponte Vedra, Florida. Institutional review board approval was obtained for each study site. Inclusion criteria were symptomatic HV in patients between 14 and 58 years of age, an IMA value between 10.0–22.0°, and a HVA value between 16.0–40.0°. Exclusion criteria included: a prior history of HV surgery, BMI >40 kg/m², diabetes with HbA1c ≥7, evidence of peripheral neuropathy, significant metatarsus adductus (≥23°), moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex, and current use of nicotine products. If the patient had bilateral procedures only one case was utilized.

Surgical technique and postoperative protocol

The detailed surgical technique utilized for this patient cohort has been previously published [19]. Representative preoperative and postoperative radiographs are shown in Fig. 1.

Radiographic and clinical outcomes

Radiographic imaging was obtained preoperatively, and at protocol defined assessments through 48-months postoperative. Two independent fellowship trained experienced musculoskeletal radiologists [AC; JKW] reviewed the blinded radiographic data and performed all measurements using a picture archiving and communication system (Judi by AG Mednet™, Boston, Massachusetts version 7.10.) All measurements were performed blinded to the clinical data and other reader's measurements; and the measurements from the two radiologists were averaged. Formal training was also provided by the principle investigator including a handbook for reference. Imaging included weightbearing anterior-posterior (AP), lateral, and sesamoid axial (SA) radiographs. HVA was defined as the angle between the longitudinal anatomic axis of the first metatarsal and proximal phalanx on AP radiographs. TSP was graded from 1 to 7 and defined as the position of the medial sesamoid in relation to the longitudinal anatomic axis of the first metatarsal on AP radiographs based on the Hardy and Clapham classification [20]. Given that there is not a standard definition of HV recurrence, and the literature commonly utilizes 15° and 20° of postoperative HVA, we evaluated radiographic recurrence utilizing both thresholds of postoperative HVA >15° and HVA >20° [5,21,22]. We then selected the more conservative threshold of HVA >15° for additional statistical analysis given that only one patient had HVA >20°.

Patient-reported outcomes for the operative foot were assessed by Manchester-Oxford Foot Questionnaire (MOXFQ) and Patient-Reported Outcomes Measurement Information System (PROMIS) before the procedure and at protocol defined intervals through 48-months postoperative. Additional endpoints included clinical complications related to the surgical procedure and/or implants. The clinical complications were previously published [18].

Statistical analysis

Patients with 48-month visit data were included in the analysis. All statistical analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC). Continuous variables were summarized using calculated means and 95% confidence intervals (CIs). Categorical variables were summarized using frequencies and percentages. Inferential statistics were performed on changes from baseline using a paired t-test. *p*-values less than 0.05 were considered statistically significant.

Exploratory analysis was conducted to identify potential associations between covariates of interest and the outcome of recurrence. The covariates explored were demographics, operative characteristics, and radiographic measures at 6 weeks (HVA, IMA, TSP, sagittal plane). Generalized linear models were generated to explore the relationship between the categorical dependent variable of recurrence (HVA >15°) and the covariates of interest. Model building used a backward selection technique. Backwards selection was performed on covariates that were found to be statistically significant (*p* < 0.05) upon univariate inspection. Univariate inspection also identified the covariates that did not have observations present for all levels of the dependent variable. These covariates were excluded from further analysis. Model results are presented as odds ratios and accompanying *p*-values. The Wilcoxon Rank-Sum test for independent samples assessed whether 48-month patient reported health-related quality of life outcomes (MOXFQ, PROMIS-29) were different between the recurrence and non-recurrence groups. Statistical significance was assessed without correction for multiple testing.

Results

A total of 146 (84.4%) patients completed their 48-month post procedure visit. Demographic information is summarized in Table 1. Overall, significant improvements from baseline in HVA, IMA, and TSP were observed beginning at six weeks post procedure and maintained through 48 months post procedure in Table 2. In identifying recurrence,

Table 1
Demographic and baseline characteristics (N = 146).

Characteristic	Category	Non-Recurrence (n = 134)	Recurrence (n = 12)	p-value
Age (years), mean (SD ^a)		41.3 (12.2)	37.9 (12.8)	0.3584
Sex, n (%)	Male	12 (9.0%)	2	
	Female	122 (91.0%)	10	
Race, n (%)	Black or African American	5 (3.7%)	0	
	White	122 (91.0%)	12	
	Other	4 (3.0%)	0	
	N/A	3 (2.2%)	0	
Ethnicity, n (%)	Hispanic or Latino	17 (12.7%)	0	
	Not Hispanic or Latino	117 (87.3%)	12	
BMI ^b (kg/m ²), mean (SD ^a)		26.0 (4.6)	25.5 (5.9)	0.7252
BMI ^b category, n (%)	Underweight	1 (0.7%)	2	
	Normal weight	59 (44.0%)	5	
	Overweight	47 (35.1%)	3	
	Obese	27 (20.1%)	2	
Index Foot, n (%)	Left	67 (50.0%)	7	
	Right	67 (50.0%)	5	
Diabetes, n (%)	Yes	1 (0.7%)	0	
	No	133 (99.3%)	12	
Labor Class, n (%)	Sedentary	24 (17.9%)	2	
	Light work	46 (34.3%)	3	
	Medium work	54 (40.3%)	6	
	Heavy work	8 (6.0%)	1	
	Very heavy work	2 (1.5%)	0	

^a Standard Deviation.

^b Body Mass Index.

Table 2
Radiographic measures (N = 146).

	Non-Recurrence (n = 134) Mean (95% CI ^a)	Recurrence (n = 12) Mean (95% CI ^a)	p-value
Baseline	134	12	
HVA	25.5 (24.4, 26.7)	31.6 (28.9, 34.3)	0.0024
IMA	13.2 (12.7, 13.7)	14.9 (13.3, 16.5)	0.0379
TSP	5.0 (4.8, 5.2)	5.4 (5.0, 5.8)	0.2188
Week 6	132	12	
HVA	8.3 (7.5, 9.1)	13.8 (10.3, 17.3)	0.0001
IMA	3.8 (3.4, 4.2)	5.7 (4.2, 7.3)	0.0036
TSP	1.3 (1.2, 1.5)	2.5 (1.5, 3.5)	<0.0001
Month 48	134	12	
HVA	5.9 (5.0, 6.8)	17.3 (16.0, 18.6)	<0.0001
IMA	5.2 (4.8, 5.6)	7.6 (6.6, 8.6)	0.0014
TSP	2.6 (2.4, 2.8)	4.3 (3.4, 5.2)	<0.0001

^a Confidence Interval.

using a recurrence definition of HVA > 20°, there was one patient in the study who met this criterion (1/146; 0.7%). Using a more conservative recurrence definition of > 15° postoperative HVA, the recurrence rate was 12/146 (8.2%) at 48 months.

Subgroup analysis showed overall improvement in radiographic measurements (Table 2), within both the recurrence and non-recurrence groups. Univariately, there was a statistically significant relationship between recurrence and the following: 6-week TSP category (≤ 3 vs > 3), 6-week HVA, and 6-week IMA. Demographics, operative characteristics, and the remaining radiographic measurement of sagittal plane did not show a significant relationship with recurrence at the univariate level. Six-week IMA fell out of the model upon backward selection. Model results showed that there was a significant association between 6-week TSP and recurrence (OR = 0.05 [95% CI: 0.01, 0.39], $p = 0.0041$) and between six-week HVA and recurrence (OR = 1.38 [95% CI: 1.15, 1.67], $p = 0.0007$), indicating that the odds of 48-month recurrence was 95% lower in patients for whom 6-week TSP was ≤ 3 versus > 3 . Furthermore, for each additional degree increase in 6-week HVA measurement the odds of recurrence increased by 38%. Representative

images from a 6-week TSP > 3 that went on to recur and a 6-week TSP ≤ 3 that maintained long-term correction are shown in Fig. 2.

Comparing patient reported outcomes between the recurrence and non-recurrence groups at 48 months follow-up, there were no statistically significant differences in any of the MOxFAQ (Table 3) domains nor for seven of the eight PROMIS domains (Table 4) with Depression showing a significant difference favoring the non-recurrence group.

Discussion

This interim analysis of a prospective, multicenter study on instrumented 1st TMT arthrodesis for HV correction with early return to protected weightbearing showed overall favorable results with excellent anatomic correction and patient-reported outcomes at 48 months postoperative. Using a conservative threshold of postoperative HVA $> 15^\circ$ to define radiographic recurrence, a total of 12 patients (8.2%) experienced a radiographic recurrence at 48 months. Using a regression model, we found that early postoperative measurements of TSP and HVA were significant predictors of later recurrence. We did not identify any demographic, operative characteristics or any other radiographic measures that suggested later recurrence. Our findings are similar to those found by other groups. Shibuya et al. conducted a retrospective cohort analysis to identify predictors of early loss of HV correction and found that TSP was the only factor associated with recurrence [13]. They found that an early postoperative TSP > 4 was associated with a ~50% increase in HV recurrence. Similarly, Okuda et al. found that an early postoperative follow-up TSP > 5 significantly increased the risk of recurrence compared to a TSP < 4 [7]. More recently, Yoon et al. reported that a TSP of 3 or less at one month postoperative, significantly reduced the risk of HV recurrence in patients in MIS metatarsal osteotomy HV surgery [14]. In a larger retrospective review of 729 HV corrected feet, Lam et al. found a higher proportion of malreduced sesamoids in the recurrence group [23].

There are several noteworthy findings in this observational clinical study. First, there was consistent maintenance of the HVA correction from first to final radiographic examination. This finding suggests correction with the 3D correction method provides lasting anatomic alignment and that this can foster low recurrence rates. This is in sharp



Fig. 2. Representative images demonstrating a subject with (A) TSP^a > 3 at 6-weeks post-operatively with recurrence (B) at 48-months and a subject with (C) TSP ≤ 3 at 6-weeks post-operatively and maintenance of correction (D) at 48 months.^aTibial Sesamoid Position

Table 3

Patient reported outcomes (N = 146): MOxFAQ^a by recurrence subgroup.

	Non-Recurrence (n = 134) Mean (95% CI) ^b	Recurrence (n = 12) Mean (95% CI) ^b	p-value ^c
Social Interaction	4.8 (2.9, 6.8)	8.9 (0.1, 17.6)	0.3179
Walking/Standing	4.9 (2.9, 6.9)	7.1 (−0.6, 14.9)	0.4197
Pain	10.0 (7.7, 12.4)	14.2 (1.8, 26.5)	0.6175
Index Score	6.5 (4.6, 8.3)	9.8 (0.9, 18.6)	0.5129

^a Manchester-Oxford Foot Questionnaire.

^b Confidence Interval.

^c p-value is computed using the Wilcoxon Rank-Sum test for independent samples.

Table 4

Patient reported outcomes (N = 138): PROMIS^a by recurrence subgroup.

PROMIS Domain	Non-Recurrence n, Mean(95%CI) ^b	Recurrence n, Mean(95%CI) ^b	p-value ^c
Ability to Participate in Social Roles/Activities	127, 62.5 (61.7, 63.3)	11, 63.1 (60.6, 65.6)	0.6968
Anxiety	127, 42.6 (41.7, 43.5)	11, 43.1 (38.9, 47.3)	0.8883
Depression	127, 42.0 (41.4, 42.6)	11, 44.7 (41.2, 48.1)	0.0053
Fatigue	127, 41.2 (39.7, 42.7)	11, 43.1 (36.6, 49.6)	0.5330
Pain Intensity	127, 0.5 (0.3, 0.7)	11, 0.5 (0.0, 0.9)	0.8528
Pain Interference	127, 42.9 (42.2, 43.5)	11, 42.9 (40.0, 45.7)	0.8430
Physical Function	127, 55.8 (55.1, 56.4)	11, 54.8 (51.5, 58.2)	0.4320
Sleep Disturbance	127, 44.4 (42.9, 45.8)	11, 45.9 (39.8, 52.1)	0.5233

^a Patient-Reported Outcomes Measurement Information System.

^b Confidence Interval.

^c p-value is computed using the Wilcoxon Rank-Sum test for independent samples.

contrast to 2D osteotomy in which we often see a lateral drift of the hallux and increase in the radiographic HVA in the first few months post-operative with significantly higher overall rates of recurrence. In this study, evaluation of the initial degree of correction of the rotational aspect of HV deformity showed that TSP position in the immediate postoperative period is a strong indicator of risk of recurrence of HV, with a 6-week postoperative TSP ≤ 3 having a 95% reduced risk of recurrence compared to TSP > 3.

Patient-reported outcomes have been used as a measure of physical and mental function after musculoskeletal surgery and have been used to measure health-related quality of life improvement after HV surgery [24–26]. In the current study, we examined whether those patients with a radiographically defined recurrence reported different patient-reported outcome scores compared to non-recurrence patients. In both groups, patients demonstrated improvements through 48 months

across all MOxFAQ domains, and an improvement in PROMIS-29 domains. When comparing the recurrence and non-recurrence groups at 48 months follow-up, there was no difference in the mean score in any of the four MOxFAQ domains and no differences were observed in any of the PROMIS-29 domains, except for Depression, in which the recurrence group had a higher mean depression score. Our findings contrast with those observed by Chen et al. who found that a TSP of 4 or less reported improved patient functional outcomes, satisfaction, and postoperative pain 2-years after surgery [17].

A meta-analysis of HV recurrence by Lalevee et al. based on HVA found recurrence rates of 64%, 10%, and 5% using HVA values of >15°, >20°, and >25°, respectively [5]. In our study, we used an HVA >15° to define recurrence, as there were no patients with an HVA >25° and 1 patient with an HVA >20°. The conservative cutoff of HVA >15° along with the fact that no patients required revision surgery for recurrence likely explain the similar improvements in both MOxFAQ and PROMIS-29 outcomes in our two groups. These results are similar to those found by Lam et al., who observed in their series no difference in index MOxFAQ score at final follow-up between patients with recurrence compared to those without recurrence [23]. In contrast, in a study assessing the association of first metatarsal pronation correction with patient reported outcomes in a series of modified Lapidus patients, Conti et al. found that a decrease in first metatarsal pronation resulted in greater improvement in PROMIS physical function domain scores compared to no change/increased first metatarsal pronation [27]. The fact that they had a greater overall rate of recurrence relative to the current study, and they utilized a more lenient recurrence threshold of postoperative HVA >20°, may explain the difference in findings of association between triplanar deformity correction and clinical outcomes between the studies.

We recognize several limitations in this study. This is an interim report of a five-year study, with a small sample size in the recurrence group. Of the 12 patients with radiographic recurrence with postoperative HVA > 15°, one patient had HVA > 20°, thus these patients all had relatively minor degrees of radiographic recurrence. Additionally, this is a single arm study without a control or a comparison group, therefore, meaningful comparisons on outcomes of recurrence and patients reported outcomes are based on reported historic results. Lastly, since patient-reported outcomes were evaluated without adjustment for multiple comparisons, the observed difference in Depression between recurrence subgroups should be interpreted cautiously, as it is an exploratory finding that may be due to chance and warrants further investigation in future studies.

In conclusion, in this prospective, multicenter study of an instrumented system for triplanar 1st TMT correction of HV deformities, we

found a significant association between correction of sesamoid position with lower rates of radiographic recurrence at 48 months follow-up. Favorable patient reported outcomes and radiographic improvement were reported even in the group of patients with radiographic recurrence, which is attributed to the relatively small number of recurrence patients and the conservative definition of recurrence utilized. Overall, these results support the importance of achieving triplanar correction and sesamoid reduction for long term maintenance of correction following hallux valgus surgery.

Authorship contributions

Daniel J. Hatch: Writing original draft; resources: Patient site.
 Avneesh Chhabra: Resources radiographic data curation.
 Paul Dayton: Writing- review and editing; resources: Patient site.
 Mindi Dayton: Writing – review and editing; resources: Patient site.
 Daniel Farber: Resources: Patient site.
 George Liu: Resources: Patient site.
 JP McAleer: Writing- review and editing; resources: Patient site.
 Abdi Raissi: Resources: Patient site.
 Robert Santrock: Supervision- Study Pl.
 Robert Taylor: Resources- Patient site.
 Jennifer Koay White: Resources- radiographic data curation.
 Dane Wukich: Resources- Patient site.

Disclosures

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