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Original Research

Four-year outcomes following triplanar tarsometatarsal arthrodesis with early weightbearing for Hallux Valgus: A multicenter prospective study

Daniel J. Hatch, DPM, FACFAS[a,*], Avneesh Chhabra, MD, MBA, FACR[b,c,d,e], Mindi Dayton, DPM, MHA, FACFAS[f], Paul D. Dayton, DPM, MS, FACFAS[f], Daniel C. Farber, MD[g], Deidre A. Kile, MS[h], Jennifer Koay, MD[i], George T. Liu, DPM, MPH, FACFAS[j], Jody P. McAleer, DPM, FACFAS[k], Robert D. Santrock, MD[l]

[a] *Foot and Ankle Center of the Rockies, Greeley, Colorado, USA*
[b] *Professor Radiology and Orthopedic Surgery, UTSW, Dallas, TX, USA*
[c] *Adjunct faculty, Johns Hopkins University, Baltimore, MD, USA*
[d] *Walton Center of Neurosciences, Liverpool, UK*
[e] *University of Dallas Biomedical Engineering, Richardson, TX, USA*
[f] *Foot & Ankle Center of Iowa, Bunion Surgery Specialists, Ankeny, IA, USA*
[g] *Lehigh Valley Orthopaedic Institute, Bethlehem, PA, USA*
[h] *Biostatistician, Evergreen, CO, USA*
[i] *Department of Radiology, West Virginia University, Morgantown, WV, USA*
[j] *Department of Orthopaedic Surgery, University of Texas Southwestern Medical Center, Dallas, TX, USA*
[k] *Jefferson City Medical Group, Department of Podiatry, Jefferson City, MO, USA*
[l] *Department of Orthopaedics, Duke University, Durham, NC, USA*

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ABSTRACT

Background: Traditional hallux valgus surgery has been focused on two-dimensional repair with high reported recurrence rates.

Purpose: We report the 4-year interim analysis of a prospective, 5-year, multicenter study of radiographic, clinical, and patient-reported outcomes following triplanar first tarsometatarsal arthrodesis with early weightbearing.

Study Design: This is a prospective, multicenter, clinical trial involving 7 US-based centers and 13 surgeons. One-hundred and seventy-three patients were treated, of whom 139 (80.3%) achieved their 48-month visit. Clinical and radiographic parameters were evaluated at all follow-up visits along with patient-reported outcomes [Visual Analog Scale (VAS), Manchester-Oxford Foot Questionnaire (MOxFQ) and Patient-Reported Outcomes Measurement Information System (PROMIS).

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 first TMT arthrodesis to correct their symptomatic hallux valgus. Inclusion and exclusion criteria were established.

Results: Significant improvements in triplanar radiographic correction (hallux valgus angle, intermetatarsal angle, tibial sesamoid position, sagittal-plane IMA, and osseous foot width) were maintained at all timepoints. Using recurrence definitions of > 15° and 20° postoperative hallux valgus angle, recurrence rates were 8.4% (95% CI:4.27%, 14.53%) and 0.8% (95% CI:0.02%, 4.18%) at 48 months, respectively. Mean (95% CI) time to weightbearing in a boot walker was 7.7 (6.6, 8.8) days.

Conclusion: The 4-year interim results of this prospective, multicenter study demonstrate favorable improvement of the triplanar hallux valgus deformity, maintenance of correction, low complication rate, and favorable patient-reported outcomes with early return to protected weightbearing.

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*Corresponding author.
E-mail address: dhatch@facrockies.com (D.J. Hatch).

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Introduction

Hallux valgus (HV) is one of the most common orthopedic problems of the foot, affecting approximately 23% of adults aged 18 to 65 years and 35.7% over 65 years old [1].Traditional approaches to HV correction have focused on assessing and correcting the deformity based on two-dimensional (2D) transverse plane measures, primarily utilizing the intermetatarsal angle (IMA) and hallux valgus angle (HVA) to drive treatment decisions. A systematic review by Lalevee et al. reported on long-term outcomes (minimum 5-year follow-up) of distal metatarsal osteotomies and found pooled HV recurrence rates of 64% and 10% when defining recurrence based on postoperative HVA of 15° and 20°, respectively [2].

Hallux valgus has been recognized as a three-dimensional (3D) deformity with contributions in the transverse, sagittal and frontal (coronal) planes to various degrees [3–6]. A 3D computed tomography (CT) study found that approximately 87% of HV deformities involve a frontal plane component with an abnormal first metatarsal pronation angle [7]. A magnetic resonance imaging study showed strong correlation between sesamoid rotation angle related to its axial plane rotation and HVA [8]. Clinical studies have supported the importance of addressing all three planes of the deformity when correcting HV [7,9–11]. Failure to address the frontal plane rotation component of HV deformity, which is directly related to sesamoid position, has been attributed to a 10- and 12- fold increased risk of HV recurrence [4,12].

An instrumented system was developed for reproducible triplanar HV correction through first tarsometatarsal (TMT) arthrodesis. This technique uses biplanar plating to allow early weightbearing in a CAM boot at < 2 weeks and has demonstrated favorable early clinical results based on early return to activity, patient reported outcomes scores, maintenance of radiographic correction and high union rates [13–15]. The purpose of this study is to report the interim four-year results of a prospective, multicenter study assessing the radiographic, clinical, and patient-reported outcomes in patients undergoing an instrumented approach for triplanar HV correction. Many studies do not have sufficient follow up to assess recurrences. Jeuken et al. found high recurrence rates in HV surgery at 27 months post operatively [16]. We believe the four-year results are important to report since most hallux valgus studies are short term in nature and do not have this length of follow up.

Patients and Methods

This is a prospective, multicenter, clinical trial involving 7 US-based centers and 13 surgeons. While the 13 surgeons were trained in this technique, there could be inherent variabilities based upon surgeon preferences. The advantage of 13 surgeons illustrates the reproducibility of the technique. 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 first TMT arthrodesis to correct their symptomatic HV. Inclusion criteria were as follows: symptomatic HV in patients between 14 to 58 years of age, an IMA between 10.0-22.0°, and a HVA between 16.0-40.0°. Exclusion criteria included the following: a prior history of HV surgery, previous surgeries on the operative foot involving joint fusion (other than lesser toes/digits), additional arthrodesis outside the first TMT joint (other than intercuneiform or hammertoe arthrodesis), BMI>40 kg/m^2, diabetes with glycosolated hemoglobin, evidence of peripheral neuropathy, flatfoot (symptomatic or asymptomatic), significant metatarsus adductus (≥23°), moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex, and current use of nicotine products. At the time of analysis of the 48-month data, 16 patients had been lost to follow-up and 9 patients had withdrawn consent for participation in the study. Nine patients still had pending 48-month visits at the time of analysis.

Surgical Technique and Postoperative Protocol

The details of the surgical technique utilized for this study were previously published [14]. The surgical technique utilized a positioner device for correction of the 1st metatarsal in all three planes and a cut guide for the first TMT joint cuts. A compressor device was utilized for apposition of the TMT joint, and a biplanar plating construct consisting of two 4-hole titanium plates was applied at the first TMT joint. The surgeon had the option of supplementing the biplanar plating with additional interfragmentary screws across the TMT joint and/or from the medial to intermediate cuneiform to address intercuneiform instability. Patients were placed in a bandage, splint, cast, or controlled ankle motion (CAM) boot immediately following surgery. At the first postoperative visit (0-3 weeks), patients were instructed to begin weightbearing as tolerated in a CAM boot. Patients were transitioned from the boot to an athletic shoe at six weeks postoperatively and allowed to return to full activity at four months postoperatively. Representative preoperative and postoperative radiographs are shown in Fig. 1.

Data Collection

Two independent fellowship-trained musculoskeletal radiologists (blinded) reviewed the radiographic images and performed measurements using a picture archiving and communication system (AG Mednet Judi/Imaging, version 7.10). The measurements from the radiologists were averaged for statistical analysis. At 36 months, only the senior radiologist performed the remaining reads. The radiographic measures reported were IMA, HVA, Tibial Sesamoid Position (TSP), osseous foot width, and sagittal-plane IMA (defined as the angle between the longitudinal dorsal cortex of the first and second metatarsals on lateral radiographs, with first metatarsal dorsiflexion defined as a positive value) [17,18]. Shortening of the first ray was measured as a change from baseline in sagittal first ray length and 1-2 metatarsal length in lateral and AP radiographs, respectively, using a previously reported method [19]. As there is not a standard definition of HV recurrence, and the literature commonly utilizes >15° and 20° of postoperative HVA, we report utilizing both thresholds for comparison [2,20,21]. Nonunion was assessed at 12 months and defined as clinical pain at the TMT plus one or more of the following radiographic findings: lucency, hardware failure, or recurrence. All three radiographic views were evaluated (AP, lateral, and axial) for radiographic lucency (darker appearance at the arthrodesis site due to diminished bone density compared to adjacent bone).

Patient-reported outcomes for the operative foot were measured by VAS, MOxFQ,

and PROMIS-29. VAS was reported based on pain associated with the base of the big toe (bunion-related) preoperatively and at 6 weeks, 6-, 12-, and 24-months postoperatively. Quality of life via MOxFQ and PROMIS-29 was collected preoperatively and at 6-, 12-, 24-, 36- and 48-months postoperatively. Additionally, data were collected on time to return to work (or normal household activities) and time to return to full work, while noting work classification (sedentary, light, medium, heavy, very heavy work). For Quality of Life (QoL) outcomes, if a single item within any domain is unanswered then all item responses for that domain are set to missing. No other missing data methods were

Fig. 1. Representative preoperative (A) and postoperative images (B).

employed. There was n=16 subjects who were lost to follow up prior to their 48-month visit.

All statistical analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC).

Results

One hundred and seventy-three patients were treated, of whom 16 (92.5%) were lost to follow-up prior to their 48-month visit and 139 (80.3%) achieved 48-month post-procedure follow-up. Demographic information is summarized in Table 1. Patients underwent an early return to weightbearing in a CAM boot (mean [95% CI]: 7.7 [6.6, 8.8] days) of whom 22.3% (n=31) started weightbearing immediately following surgery and 54.7% (n=76) were weightbearing within the first week. Average (95% CI) time to athletic shoes and to unrestricted activity was 6.5 (6.2, 6.7) weeks and 4.1 (3.9, 4.3) months. Average (95% CI) days to return to work and to full work was 27.4 (21.2, 33.1) and 56.9 (49.0, 64.8), respectively. One hundred and thirty-six patients (97.8%) had at least one concomitant procedure (Table 2).

Significant improvements from baseline in HVA, IMA, sagittal-plane IMA, and TSP, were observed at six weeks post-procedure and maintained through the 48-month visit (Table 3). Using recurrence definitions of > 15° and 20° postoperative HVA, recurrence rates were 8.4% (95% CI: 4.27%, 14.53%) and 0.8% (95% CI: 0.02%, 4.18%) at 48 months. Clinically and statistically significant reductions in osseous foot width were observed with a mean (95% CI) 24-month reduction of 8.4 mm (7.8 mm, 9.0 mm), p<0.0001. Mean (95% CI) reduction in sagittal first ray length and 1-2 metatarsal length at 24 months were 2.9 mm (2.4 mm, 3.4 mm) and 4.0 mm (3.7 mm, 4.3 mm), respectively.

Regarding MTP joint range of motion, at 12 months there was a mean (95% CI) 2.1° (0.4°, 3.7°) residual plantarflexion deficit (p=0.0149) and no significant difference over baseline in dorsiflexion range of motion of the first MTP (mean [95% CI]: 1.6° [-0.6°, 3.8°]). At 24 months, dorsiflexion range of motion of the first MTP showed significant improvement over baseline (mean [95% CI] change: 4.4° [2.2°, 6.6°]; p=0.0001) and there was no longer a significant plantarflexion deficit (mean [95% CI] change: -1.0° [-2.9°, 0.8°]; p=0.2749).

Significant improvements in patient-reported outcomes were observed, with improvement in VAS over baseline continuing through 24 months (final time point for VAS measure) (Fig, 2). MOxFQ domains of Social Interaction, Walking/Standing, and Pain improved over baseline and continued to improve through 48-month visit (Table 4). For PROMIS-29, domains of Physical Function, Anxiety, Ability to Participate in Social Roles/Activities, Fatigue, Pain Interference, Sleep Disturbance, and Pain Intensity improved over baseline and continued to improve through the 48-months. (Table 5).

Nineteen (8.7%) patients in the overall treated cohort of 173 required reoperation for removal of hardware [13 (7.5%) due to pain; 4 (2.3%) per patient request; 1 (0.6%) due to infection] and 1 (0.6%) reoperation for pain and non-protocol defined nonunion. Twelve (6.9%) of 173 patients experienced at least one clinical complication not requiring surgical intervention, with pain being the most reported event (n=3, 1.8%) (Table 6). Union of the 1st TMT was assessed at 12 months in 148 patients. Three patients of 148 (2.0%) experienced symptomatic nonunion, one requiring a surgical intervention. Of the 127 patients with baseline and 24-month follow-up metatarsalgia data, two patients (1.6%) reported symptomatic metatarsalgia at 24 months. None (0%) of the 23 patients who reported baseline metatarsalgia report metatarsalgia at 24 months postoperatively. Of the 104 patients who reported no metatarsalgia at baseline, 2 (1.9%) reported metatarsalgia at 24 months.

Table 1
Demographic and Baseline Characteristics.

Characteristic	Category	Patient Population (N=139)
Age (years), mean (SD)		41.0 (12.2)
Sex, n (%)	Male	14 (10.1%)
	Female	125 (89.9%)
BMI category	Underweight	3 (2.2%)
	Normal Weight	62 (44.6%)
	Overweight	47 (33.8%)
	Obese	27 (19.4%)
Index Foot	Left	70 (50.4%)
	Right	69 (49.6%)
Diabetes	Yes	1 (0.7%)
	No	138 (99.3%)
Labor Class at Baseline	Sedentary	26 (18.7%)
	Light work	46 (33.1%)
	Medium work	56 (40.3%)
	Heavy work	9 (6.5%)
	Very heavy work	2 (1.4%)

Abbreviations: SD, Standard Deviation; BMI, Body Mass Index (underweight: BMI<18.5; normal: 18.5≤BMI<25; overweight: 25≤BMI<30; obese≥30).

Table 2
Additional procedures performed with triplanar first tarsometatarsal correction.

Additional Procedures	Number (%)
Total number with at least 1 concomitant procedure	136/139 (97.8%)
Lateral release (modified McBride)	134/139 (96.4%)
Traditional medial eminence resection	56/139 (40.3%)
Stabilization screw(s) medial to intermediate cuneiform	28/139 (20.1%)
Other	23/139 (16.5%)
Akin osteotomy	20/139 (14.4%)
Bone graft harvest	13/139 (9.4%)
Hammertoe (any)	13/139 (9.4%)
Tailor's bunion	11/139 (7.9%)
Compression screw at TMT	10/139 (7.2%)
Dorsal metatarsal bone resection	9/139 (6.5%)
Rongeur of the medial capsular ridge	7/139 (5.0%)
Weil osteotomy	2/139 (1.4%)

Abbreviation: TMT, tarsometatarsal.
Note: the concomitant procedures presented occurred on the date of the index procedure Other concomitant procedures are: cheilectomy (n=10), gastrocnemius recession (n=11), exostectomy (n=1), excision neuroma (n=1).

Discussion

This interim analysis of the prospective, five-year, multicenter study demonstrates favorable results of first TMT arthrodesis with an early return to protected weightbearing, excellent triplanar radiographic correction, high union rates, and improvement in patient-reported outcomes. When assessing the primary study endpoint, the low rate of radiographic recurrence maintained postoperatively through 48 months (8.4% and 0.8% recurrence using postoperative HVA thresholds of 15° and 20°, respectively) suggests a beneficial role of complete correction, including frontal plane rotation, in achieving long-term correction of HV. In contrast, a recent systematic review of studies focused on two-dimensional distal osteotomy procedures with five or more years follow-up, found pooled recurrence rates of 64% and 10% using the same HVA thresholds of 15° and 20°, respectively [2]. Recurrence rates by other authors on lapidus procedure range from 17% to 38% utilizing the 20° HVA threshold [21,22]. Our reported findings are consistent with studies that demonstrated the association between metatarsal rotational and sesamoid alignment in restoration of coronal plane MTP joint anatomy and maintenance of HV correction [4,23,24].

Reduction in foot width is an important parameter in hallux valgus correction assessment [25]. As opposed to previously published distal osteotomy techniques with reported osseous reduction of 5% and soft tissue reduction of 2%, the current study demonstrated a mean osseous foot width reduction of 9.3% [25].

Table 3
Radiographic measures and change from baseline: baseline, 6 week, 6 month, 12 months, 24 months, 36 months, 48 months, mean (95% CI).

	HVA(°) Mean (95% CI)	IMA(°) Mean (95% CI)	TSP Mean (95% CI)	Sagittal Plane IMA(°) Mean (95% CI)	Osseous Foot Width(mm) Mean (95% CI)
Baseline (N=139)	26.0 (24.8, 27.1)	13.3 (12.8, 13.7)	5.0 (4.8, 5.1)	1.2 (0.9, 1.6)	89.1 (87.1, 91.1)
Week 6 (N=137)	8.9 (8.0, 9.7)	3.9 (3.6, 4.3)	1.4 (1.3, 1.6)	0.2 (-0.4, 0.8)	[not measured]
Change from Baseline	−17. 2(-18.5, -15.8) p<0.0001	−9.3 (-9.8, -8.8) p<0.0001	−3.5 (-3.7, -3.3) p<0.0001	−1.1 (-1.6, -0.5) p=0.0003	
Month 6 (N=137)	7.5 (6.6, 8.4)	4.8 (4.4, 5.2)	1.9 (1.7, 2.1)	0.0 (-0.5, 0.5)	80.2 (78.3, 82.1)
Change from Baseline	−18.4 (-19.8, -17.1) p<0.0001	−8.5 (-9.0, -8.0) p<0.0001	−3.0 (-3.3, -2.8) p<0.0001	−1.2 (-1.7, -0.8) p<0.0001	−8.9 (-9.6, -8.3) p<0.0001
Month 12 (N=132)	7.7 (6.6, 8.7)	4.9 (4.5, 5.3)	2.1 (1.9, 2.4)	−0.4 (-0.9, 0.1)	80.4 (78.4, 82.3)
Change from Baseline	−18.2 (-19.6, -16.8) p<0.0001	−8.3 (-8.8, -7.8) p<0.0001	−2.8 (-3.0, -2.6) p<0.0001	−1.7 (-2.2, -1.2) p<0.0001	−8.6 (-9.1, -8.0) p<0.0001
Month 24 (N=137)	7.8 (6.9, 8.7)	5.1 (4.7, 5.6)	2.3 (2.1, 2.6)	−0.5 (-1.0, 0.0)	80.8 (78.9, 82.6)
Change from Baseline	−18.1 (-19.4, -16.9) p<0.0001	−8.1 (-8.6, -7.6) p<0.0001	−2.6 (-2.9, -2.4) p<0.0001	−1.7 (-2.2, -1.2) p<0.0001	−8.4 (-9.0, -7.8) p<0.0001
Month 36 (N=137)	7.2 (6.2, 8.2)	5.5 (5.0, 5.9)	2.6 (2.4, 2.8)	−0.6 (-1.1, -0.1)	[not measured]
Change from Baseline	−18.8 (-20.1, -17.5) p<0.0001	−7.8 (-8.3, -7.3) p<0.0001	−2.4 (-2.6, -2.2) p<0.0001	−1.9 (-2.4, -1.3) p<0.0001	
Month 48 (N=134)	6.8 (5.8, 7.8)	5.3 (4.9, 5.8)	2.8 (2.5, 3.0)	−0.8 (-1.3, -0.3)	[not measured]
Change from Baseline	−19.2 (-20.5, -17.8) p<0.0001	−7.9 (-8.4, -7.4) p<0.0001	−2.2 (-2.4, -2.0) p<0.0001	−2.0 (-2.6, -1.5) p<0.0001	

Abbreviation: CI, Confidence Interval.

The sagittal plane component of the HV deformity affects first MTP range of motion, first ray loading, and transfer metatarsalgia to the adjacent lesser metatarsals. Our reported mean sagittal plane alignment relative to baseline was 2.0° of plantarflexion at 48 months, confirming complete triplanar correction. Adjunctive procedures to prevent lesser metatarsalgia pathology when performing traditional HV procedures are common [26–31]. In the current study, only two (1.5%) patients underwent lesser metatarsal osteotomies (ex. Weil osteotomy) and postoperative lesser metatarsalgia at 24 months was observed in only 1.9% of patients. Studies suggest that triplanar correction can re-establish proper function of the first ray and help protect the lesser rays from overload. This is accomplished by a stable sagittal plane alignment, restoration of the windlass mechanism [32,33] and maintenance of function of the peroneus longus tendon [34]. Our experience shows that this anatomic correction has more influence on foot mechanics than shortening, which is supported by other authors [35] Ahn et al. indicated that in 185 patients no transfer metatarsalgia was observed if first ray shortening was < 5.8mm [36]. We measured the shortening by both the AP projection and sagittal plane methods due to the influence of the sagittal position on first ray length. With the relatively plantarflexed position of the 1st ray in the current study, this would make the 1st ray length measure shorter in the AP projection [18] ^{Our} shortening change from baseline at 24 months in the AP evaluation was a mean (95% CI) of 4.0 mm. (3.7, 4.3) and in the sagittal plane 2.9 mm (2.4, 3.4).

Traditional 1st TMT fusion approaches have typically recommended up to 6 weeks non weightbearing due to the potential concern of nonunion [37]. In the current study, the average time to weightbearing in a CAM boot 7.7 days and return to athletic shoes was 6.5 weeks. Three patients (2.0%) experienced symptomatic nonunion at 12 months, one requiring surgical intervention. This compares favorably with other studies reporting early weightbearing within two weeks following 1st TMT arthrodesis, which have reported nonunion rates ranging from 9.5-10% [38,39]. The authors attribute the high union rates in the current study to the consistent joint preparation from saw cuts utilizing a

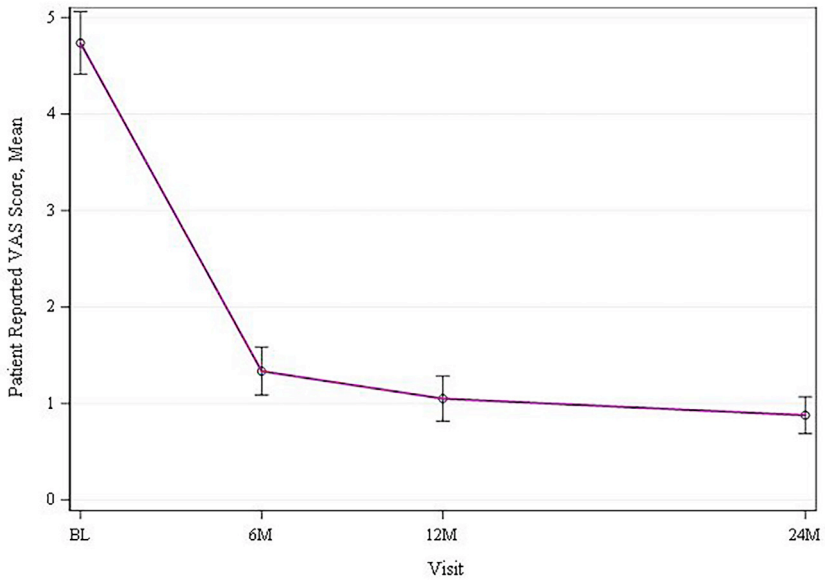

Fig. 2. Improvements in VAS from baseline to 2 years postoperatively.

Table 4
Patient Reported Outcomes: MOxFQ, mean (95% CI).

Visit	Domain	MOxFQ		
		Score	Change from Baseline	
		Mean (95% CI)	Mean (95% CI)	p-value
Baseline (N=139)	Social Interaction	44.9 (41.2, 48.7)		
	Walking/Standing	46.2 (42.2, 50.1)		
	Pain	55.1 (51.5, 58.6)		
Month 6 (N=135)	Social Interaction	13.4 (10.0, 16.8)	−31.8 (-36.0, -27.5)	<.0001
	Walking/Standing	18.1 (14.4, 21.8)	−28.7 (-33.5, -24.0)	<.0001
	Pain	22.7 (19.4, 26.0)	−32.4 (-36.2, -28.6)	<.0001
Month 12 (N=133)	Social Interaction	9.4 (6.4, 12.5)	−34.7 (-38.9, -30.5)	<.0001
	Walking/Standing	11.6 (8.6, 14.5)	−35.2 (-39.6, -30.8)	<.0001
	Pain	19.4 (15.8, 23.0)	−35.6 (-39.9, -31.3)	<.0001
Month 24 (N=139)	Social Interaction	7.3 (4.7, 9.8)	−37.6 (-41.5, -33.7)	<.0001
	Walking/Standing	9.0 (6.0, 12.0)	−37.9 (-42.2, -33.5)	<.0001
	Pain	13.8 (10.8, 16.8)	−41.3 (-45.3, -37.3)	<.0001
Month 36 (N=138)	Social Interaction	6.9 (4.5, 9.3)	−38.0 (-42,1, -33.9)	<.0001
	Walking/Standing	6.8 (4.4, 9.1)	−40.1 (-44.3, -35.9)	<.0001
	Pain	12.0 (9.3, 14.6)	−43.2 (-47.1, -39.3)	<.0001
Month 48 (N=139)	Social Interaction	5.1 (3.2, 7.1)	−39.8 (-43.6, -36.0)	<.0001
	Walking/Standing	5.0 (3.0, 7.0)	−41.8 (-45.8, -37.7)	<.0001
	Pain	10.4 (8.0, 12.8)	−44.7 (-48.3, -41.0)	<.0001

Abbreviations: MOxFQ, Manchester-Oxford Foot Questionnaire; CI, Confidence Interval.

Table 5
Patient Reported Outcomes: PROMIS, mean (95% CI).

Visit	Domain	PROMIS				
		Score		Change from Baseline		
		N	Mean (95% CI)	N	Mean (95% CI)	p-value
Baseline	Social Roles*	130	53.2 (51.7, 54.6)			
	Anxiety		46.8 (45.5, 48.1)			
	Depression		43.2 (42.3, 44.0)			
	Fatigue		45.1 (43.4, 46.7)			
	Pain Interference		55.8 (54.5, 57.1)			
	Physical Function		45.5 (44.0, 46.9)			
	Sleep Disturbance		48.0 (46.8, 49.2)			
Month 6	Social Roles*	127	59.4 (58.1, 60.7)	126	6.3 (4.6, 8.1)	<.0001
	Anxiety		43.7 (42.6, 44.8)		−3.2 (-4.7, -1.8)	<.0001
	Depression		42.5 (41.7, 43.2)		−0.7 (-1.8, 0.4)	0.1979
	Fatigue		41.3 (39.8, 42.7)		−4.1 (-5.7, -2.5)	<.0001
	Pain Interference		47.4 (46.2, 48.7)		−8.3 (-10.0, -6.7)	<.0001
	Physical Function		51.5 (50.2, 52.8)		6.1 (4.3, 7.8)	<.0001
	Sleep Disturbance		45.1 (43.7, 46.4)		−2.8 (-4.2, -1.4)	<.0001
Month 12	Social Roles*	125	60.4 (59.1, 61.7)	124	7.0 (5.3, 8.8)	<.0001
	Anxiety		43.4 (42.4, 44.6)		−3.5 (-4.8, -2.2)	<.0001
	Depression		42.4 (41.6, 43.2)		−0.8 (-1.9, 0.3)	0.1706
	Fatigue		41.2 (39.7, 42.7)		−3.5 (-5.1, -1.9)	<.0001
	Pain Interference		45.3 (44.1, 46.5)		−10.5 (-12.0, -8.9)	<.0001
	Physical Function		53.9 (52.8, 54.9)		8.4 (6.8, 10.1)	<.0001
	Sleep Disturbance		45.4 (44.0, 46.7)		−2.5 (-4.0, -1.0)	0.0013
Month 24	Social Roles*	131	61.0 (59.8, 62.1)	130	7.8 (6.1, 9.4)	<.0001
	Anxiety		43.4 (42.4, 44.4)		−3.4 (-4.7, -2.0)	<.0001
	Depression		42.7 (41.9, 43.4)		−0.5 (-1.5, 0.5)	0.3695
	Fatigue		41.8 (40.3, 43.3)		−3.2 (-4.7, -1.7)	<.0001
	Pain Interference		44.2 (43.2, 45.1)		−11.6 (-13.0, -10.1)	<.0001
	Physical Function		54.8 (53.9, 55.7)		9.3 (7.8, 10.8)	<.0001
	Sleep Disturbance		44.7 (43.4, 46.1)		−3.0 (-4.6, -1.5)	0.0002
Month 36	Social Roles*	130	61.9 (60.9, 62.9)	129	8.7 (7.2, 10.2)	<.0001
	Anxiety		43.5 (42.5, 44.6)		−3.3 (-4.8, -1.8)	<.0001
	Depression		42.6 (41.9, 43.3)		−0.5 (-1.5, 0.5)	0.3478
	Fatigue		41.4 (39.9, 42.9)		−3.6 (-5.2, -2.0)	<.0001
	Pain Interference		43.6 (42.7, 44.4)		−12.2 (-13.6, -10.8)	<.0001
	Physical Function		55.3 (54.5, 56.1)		9.9 (8.4, 11.4)	<.0001
	Sleep Disturbance		43.9 (42.5, 45.3)		−4.0 (-5.6, -2.4)	<.0001
Month 48	Social Roles*	131	62.5 (61.7, 63.3)	130	9.3 (7.7, 10.9)	<.0001
	Anxiety		42.7 (4.18, 43.7)		−4.1 (-5.5, -2.7)	<.0001
	Depression		42.2 (41.5, 42.8)		−1.0 (-2.0, 0.0)	0.0619
	Fatigue		41.2 (39.8, 42.6)		−3.8 (-5.3, -2.2)	<.0001
	Pain Interference		42.9 (42.2, 43.5)		−12.9 (-14.2, -11.6)	<.0001
	Physical Function		55.6 (54.9, 56.3)		10.1 (8.7, 11.6)	<.0001
	Sleep Disturbance		44.6 (43.2, 46.1)		−3.2 (-4.7, -1.7)	<.0001

Abbreviations: PROMIS, Patient-Reported Outcomes Measurement Information System; CI, Confidence Interval.
* Ability to Participate in Social Roles/Activities.

Table 6
Clinical Complications up to 48 months postprocedure.

Complications Requiring Surgical Intervention	n (%) N=173	Complications Not Requiring Surgical Intervention	n (%) N=173
Hardware removal due to pain	13 (7.5%)	Hardware failure (hardware not removed)	4 (2.3%)
Hardware removal per patient request	4 (2.3%)	Other pain	2 (1.2%)
Hardware removal due to infection	1 (0.6%)	Nonunion**	2 (1.4%)
Reoperation due to nonunion*	1 (0.6%)	Infection	1 (0.6%)
		Paresthesia and pain	1 (0.6%)
		Post-op nerve hypersensitivity	1 (0.6%)
		Wound complication	1 (0.6%)

* Not a protocol defined nonunion because pain was not present at TMT joint. Hardware was not removed. Patient also reported pain AE.
** Protocol defined nonunion assessed in n=148 patients at 12 months. One patient also reported pain.

cutting guide and the relative stability and micromotion achieved with the biplanar plating construct under early weightbearing [15,40,41].

In this study, patients reported a statistically significant decrease in pain on VAS through 24 months and improvement across all MOxFQ and PROMIS (except for depression) domains which was maintained from 12 months to 48 months (Fig, 2, Table 4, and Table 5, respectively).

While surgical interventions for hallux valgus have been shown to improve PROs, few studies have evaluated the impact of first TMT fusion with triplanar hallux valgus correction on HRQoL [42]. Paranjape et al. retrospectively reported on 73 1st TMT fusion procedures in 68 patients with median follow-up of 5.7 months with no significant improvement of PROMIS physical function domain between pre- and postoperative visits at one year [43]. This lack of detected difference was likely attributable to a 51% survey response rate and median follow-up of 5.7 months [42]. Asafo et al. retrospectively reported on 213 1st TMT fusion procedures in 185 patients with a mean follow-up of 5.4 years. Using the Foot and Ankle Ability Measure validated PRO, 74.8% patients scored >90 points out of 100, 16.6% scored between 70-90 points, and 8.6% < 70 points. Accordingly, 93% of patients were satisfied with their procedure [44]. In their consecutive series of 39 patients who underwent 1st TMT fusion procedures, Conti et al. demonstrated that improved correction of first metatarsal pronation was associated with both a statistically significant improvement in PROMIS physical function and lower recurrence rates at 2-year follow-up [24].

We recognize several limitations in this study. This is an interim report of a five-year study. Patients were continuously enrolled and will be followed for up to 60 months for radiographic measures, recurrence rates, healing, complications, and patient reported outcomes. Additionally, radiographic measurements have known degrees of error in both radiographic technique and angular assessment. We controlled these variables by providing training to study sites regarding image acquisition and a standard technique manual for interpretation as well as interim quality surveillance. Additionally, CT could provide for a more complete assessment of union rates and three-dimensional correction. All surgical centers had access to conventional radiography and images were reviewed in all three planes. Surgeons were deemed experienced in the instrumented system. This is a single arm study without a control or a comparison group, therefore, meaningful comparisons on time to weightbearing (historically 6 weeks), fixation types (screws vs biplanar plating), and complication rates (recurrence rates) related to this specific technique are based on reported historic results and not direct clinical comparisons to a control. The comparison with historic results should be interpreted considering inherent study biases and differences in methods, study designs, and patient populations Lastly, as is typical in prospective clinical studies, inclusion/exclusion criteria were defined based on patient age, BMI, and diabetes status to limit these potentially confounding variables and isolate the results to the 1st TMT procedure. Future studies with appropriate power are needed to understand the potential impact of these patient factors with the results of the study procedure.

This is an interim report with 4-year follow-up of a prospective, multicenter study of an instrumented system for 1st TMT correction of HV deformities with early return to weightbearing. It demonstrates statistically significant and favorable improvements in three-dimensional radiographic correction, low recurrence of deformity, early return to activity with low complication rates, and improvements in patient-reported outcomes.

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