Interim Analysis of a Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following a Mini-Open Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing

JP McAleer, DPM, FACFAS¹; Jeffrey E. McAlister, DPM, FACFAS²; Avneesh Chhabra, MD, MBA, FACR³; Robert D Santrock, MD⁵; Deidre Kile, BA, MS⁵

1. JCMG Podiatry, Jefferson City, MO | 2. Phoenix Foot and Ankle Institute, Phoenix, AZ | 3. University of Texas Southwestern Medical Center, Dallas, TX | 4. Dovetail Orthopedics, Fernandina Beach, FL | 5. Treace Medical Concepts, Inc.

Value

42 (14, 57)

96 (93.2%)

24.5 (16.8, 39.8)

3.5 (3.0, 4.0)

Mean (95% Confidence Interval)

(6.6, 9.0)

25.6

(21.1, 30.0)

(5.7, 6.1)3.6

(3.4, 3.8)

Introduction

- Traditional metatarsal osteotomies for hallux valgus (HV) correction have demonstrated varying rates of deformity recurrence
- 30% recurrence Scarf at 10 yrs¹
- 73% recurrence distal chevron at 14 yrs*²
- 87% of HV deformities are three-dimensional with frontal-plane metatarsal rotation⁴
- 12x recurrence risk when frontal-plane deformity not corrected⁵
- An instrumented system for reproducible triplanar 1st tarsometatarsal (TMT) joint arthrodesis has been developed
- Interim results of prospective, multicenter study demonstrated early return to weightbearing (7.8 days), maintenance of 3D radiographic correction, and significant improvements in pain and patient-reported outcomes**6



**Interim analysis from the ALIGN3DTM study of 117 patients with at least 12 months of follow-up; of whom 40 patients have at least 24 months of follow-up (out of 173 total study patients)

Purpose

Recently a new instrumented 1st TMT system was developed to perform a triplanar 1st TMT arthrodesis through a mini-open approach (Lapiplasty® Mini-Incision System, Treace Medical Concepts, Ponte Vedra, FL). Therefore, the purpose of this study is to assess the radiographic and patient-reported outcomes for HV correction performed with this system through a mini-open approach (<4cm) with early return to weightbearing.

Methods

This is an interim analysis of a prospective multicenter study on patients with symptomatic HV without a prior history of HV surgery. Patients were treated with an instrumented 1st TMT procedure through a mini-open ≤4cm dorsal incision which is approximately 50% smaller than the typical instrumented triplanar TMT arthrodesis approach used by the surgeon authors. A biplanar fixed-angle locking plate construct is applied to maintain reduction with protected early weightbearing. Radiographic triplanar correction, patientreported outcomes (VAS and MOxFQ), cosmetic scar appearance (POSAS), and forefoot circumference were assessed through 6- and 12-month follow-up.

References

- 1. Bock, P., et al (2015). The Scarf Osteotomy with Minimally Invasive Lateral Release for Treatment of Hallux Valgus Deformity: Intermediate and Long-Term Results. *The Journal of* Bone and Joint Surgery, American volume, 97(15), 1238–1245.
- 2. Jeuken, R., et al. (2016). Long-term Follow-up of a Randomized Controlled Trial Comparing Scarf to Chevron Osteotomy in Hallux Valgus Correction. Foot & Ankle International, 37(7),
- 3. Lagaay, P. M., et al (2008). Rates of revision surgery using Chevron-Austin osteotomy, Lapidus arthrodesis, and closing base wedge osteotomy for correction of hallux valgus deformity. The Journal of Foot and Ankle Surgery : official publication of the American College of Foot and Ankle Surgeons, 47(4), 267–272.
- 4. Kim, Y., et al. (2015). A New Measure of Tibial Sesamoid Position in Hallux Valgus in Relation to the Coronal Rotation of the First Metatarsal in CT Scans. Foot & Ankle International, 36(8), 944–952.

Radiographic Measures

Results: Patient Demographics

Baseline Characteristic

Incision Length (cm), Median (Min, Max)

Return to Weight-bearing

Weightbearing in CAM boot (days, n=102)

Return to athletic/running shoes (weeks, n=94)

Return to unrestricted activity (months, n=80)

Return to work (days, n=98)

Patients underwent an early weightbearing protocol.

Age (yrs), Median (Min, Max)

BMI, Median (Min, Max)

Significant improvement over baseline in radiographic measures (HVA, IMA, TSP, and Osseous Foot Width) through 12 mo post-op. 96.8% (91/94) of patients achieved correction at 6 weeks post-op.

The interim results of 103 patients with mean (SD) follow-up of 7.2 (4.2) months.

Post-Operative Time to Return to Activity/Work

Category

Radiographic Measures, Mean (95% Confidence Interval)					
Radiographic Measure	Baseline (n=103)	6 Week (n=94)	6 Month (n=71)	12 Month (n=34)	
Hallux Valgus Angle	26.7°	6.2°	6.0°	6.6°	
(HVA)	(25.4, 27.9)	(5.0, 7.5)	(4.5, 7.6)	(4.7, 8.5)	
Intermetatarsal Angle (IMA)	14.2°	3.6°	4.7°	4.5°	
	(13.6, 14.7)	(3.0, 4.2)	(4.0, 5.5)	(3.6, 5.4)	
Tibial Sesamoid Position (TSP)	5.1	1.7	2.3	2.5	
	(4.9, 5.3)	(1.5, 1.9)	(1.9, 2.6)	(2.1, 2.9)	
Sagittal-Plane	0.4°	1.8°	1.5°	2.0°	
Intermetatarsal Angle*	(0.0, 0.8)	(1.3, 2.4)	(0.9, 2.2)	(0.9, 3.0)	
Osseous Foot Width (mm)	97.4	_	83.7	83.9	
	(84.8, 109.9)	_	(81.6, 85.8)	(81.2, 86.5)	

*Dorsiflexion is positive value

Metatarsalgia Analysis

Significant resolution of pre-op metatarsalgia reported at 4, 6, and 12 mos post-op.

Metatarsalgia Analysis Compared to Baseline Reporting						
Baseline Status (n=103)	4 Months		6 Months		12 Months	
	Yes	No	Yes	No	Yes	No
YES (n=35)	1 (3.2%)	30 (96.8%)	1 (3.8%)	25 (96.2%)	0 (0.0%)	10 (100.0%)
NO (n=68)	2 (3.9%)	49 (96.1%)	1 (2.0%)	48 (98.0%)	1 (3.7%)	26 (96.3%)

Proportions are calculated, using for the denominator, the number of subjects by baseline metatarsalgia status.

Circumferential Measurements

Significant forefoot circumference reduction was observed at 12 months.

Circumferential Measurements in cm, Mean (95% Confidence Interval)					
Swelling Measures	Baseline (n=103*)	6 Week (n=95)	6 Month (n=75)	12 Month (n=37)	
Forefoot	20.6	20.8	20.0	19.4	
Circumference	(20.0, 21.3)	(20.1, 21.4)	(19.3, 20.8)	(18.4, 20.4)	
Midfoot	20.2	20.9	20.3	20.0	
Circumference	(19.6, 20.8)	(20.2, 21.6)	(19.6, 20.9)	(18.9, 21.0)	
Calf	33.3	31.4	32.2	32.6	
Circumference	(32.4, 34.2)	(30.5, 32.3)	(31.1, 33.3)	(31.1, 34.1)	

*One subject was missing measurements for Forefoot and Midfoot

Patient Reported Outcomes

Significant improvement over baseline in VAS through 12 mo post-op and significant improvement over baseline in MOxFQ through 12 mo post-op

Measure	Baseline (n=103)	6 Week (n=95)	6 Month (n=75)	12 Month (n=37)		
VAS Pain Score	3.5 (3.2, 3.9)	1.7 (1.4, 2.0)	1.2 (0.9, 1.5)	0.9 (0.5, 1.3)		
MOxFQ, Mean (95% Confidence Interval)						
Measure	Baseline	(n=103) 6 N	Month (n=75)	12 Month (n=37)		
MOxFQ (Walk/Stand)	41 (36.8,		16.7 (12.4, 20.9)	7.4 (2.6, 12.2)		
MOxFQ (Pain)	50 (46.6,		22.0 (17.9, 26.1)	13.1 (7.8, 18.4)		
MOxFQ (Social Interaction)	43 (38.9,		13.3 (9.6, 16.9)	6.4 (2.1, 10.7)		
MOxFQ	44.		17.5	9.0		

VAS Mean (95% Confidence Interval)

Scar Analysis

Clinically meaningful cosmetic appearance of the scar was observed over time.

POSAS* (Mean 95% Confidence Interval)					
	4 Month (n=82)	6 Month (n=75)	12 Month (n=37)		
Observer	14.3	11.9	10.0		
Observer	(13.0, 15.6)	(10.9, 13.0)	(8.7, 11.4)		
Patient	22.8	18.1	12.3		
	(20.3, 25.2)	(15.6, 20.6)	(9.8, 14.8)		

*POSAS (Patient and Observer Scar Assessment Scale) – Total POSAS score can range from 6 to 60 and is calculated by summing the 6 component scores. A lower score denotes similarity to normal skin.

Clinical Complications

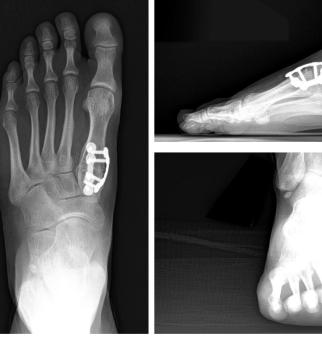
Limited clinical complications: 1 (1.0%) of 103 patients required hardware removal due to pain. A total 9 adverse events (AEs) were reported, 7/9 (78%) have resolved.

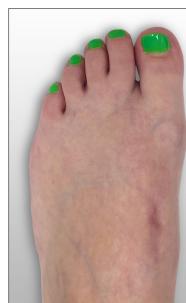
Complications presented at the patient level				
Requiring Surgical Intervention	Number (%) (n=103)	Not Requiring Surgical Intervention	Number (%) (n=103)	
Hardware removal due to pain	1 (1.0%)	Other pain	2 (1.9%)	
		Infection	2 (1.9%)	
		Other AE*	4 (3.9%)	

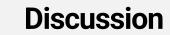
*Other AEs are: Cuneiform fracture, stiffness, allergic reaction to surgical glue, skin abrasion/superficial abscess

Representative Pre- and 12-month **Radiographic and Clinical Results**









HV recurrence rates in the literature for metatarsal osteotomies can range up to 30-78%. 1,2,7 The current results support consistent radiographic HV correction and maintenance of correction through 12 months post-procedure with this new mini-open instrumented 1st TMT approach. There was a small increase in sagittal-plane position post-procedure, but clinically there was only 1 patient (of 37) at 12 months with symptomatic metatarsalgia despite 34% (35 of 103 patients) reporting metatarsalgia pre-operatively.

Conclusion

Results demonstrate favorable clinical and patient-reported outcomes with mini-open approach (median incision length: 3.5 cm) one-year, postprocedure.

- Early return to weight-bearing in a CAM boot (mean 7.8 days).
- Maintenance of HV radiographic correction (IMA, HVA, TSP) through 12
- Significant reduction in pain (VAS) and patient reported outcomes (MOxFQ) through 12 months.
- Scar quality with favorable POSAS scores.

5. Okuda, R., et al. (2007). The Shape of the Lateral Edge of the First Metatarsal Head as

6. Liu, G. T., et al. (2022). One- and Two-Year Analysis of a Five-Year Prospective

American College of Foot and Ankle Surgeons, 61:1308-1316.

and Meta-analysis. Foot & Ankle International, 44(3), 210-222.

American volume, 89(10), 2163-2172.

a Risk Factor for Recurrence of Hallux Valgus. The Journal of Bone and Joint Surgery.

Multicenter Study Assessing Radiographic and Patient-Reported Outcomes Following Triplanar First Tarsometatarsal Arthrodesis With Early Weightbearing for Symptomatic

Lalevee, M., et al. (2023). Recurrence Rates With Longer-Term Follow-up After Hallux

Valgus Surgical Treatment With Distal Metatarsal Osteotomies: A Systematic Review

Hallux Valgus. The Journal of Foot and Ankle Surgery: official publication of the