

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

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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
- Lower recurrence rates have been reported but recurrence parameters were not established³
- 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 ALIGN3D™ 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 (*Laplasty® 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, patient-reported outcomes (VAS and MOxFQ), cosmetic scar appearance (POSAS), and forefoot circumference were assessed through 6- and 12-month follow-up.

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Results: Patient Demographics

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

Baseline Characteristic	Category	Value
Age (yrs), Median (Min, Max)		42 (14, 57)
Gender, n (%)	Female	96 (93.2%)
BMI, Median (Min, Max)		24.5 (16.8, 39.8)
Incision Length (cm), Median (Min, Max)		3.5 (3.0, 4.0)

Return to Weight-bearing

Patients underwent an early weightbearing protocol.

Post-Operative Time to Return to Activity/Work	
Activity	Mean (95% Confidence Interval)
Weightbearing in CAM boot (days, n=102)	7.8 (6.6, 9.0)
Return to work (days, n=98)	25.6 (21.1, 30.0)
Return to athletic/running shoes (weeks, n=94)	5.9 (5.7, 6.1)
Return to unrestricted activity (months, n=80)	3.6 (3.4, 3.8)

Radiographic Measures

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.

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 (HVA)	26.7* (25.4, 27.9)	6.2* (5.0, 7.5)	6.0* (4.5, 7.6)	6.6* (4.7, 8.5)
Intermetatarsal Angle (IMA)	14.2* (13.6, 14.7)	3.6* (3.0, 4.2)	4.7* (4.0, 5.5)	4.5* (3.6, 5.4)
Tibial Sesamoid Position (TSP)	5.1 (4.9, 5.3)	1.7 (1.5, 1.9)	2.3 (1.9, 2.6)	2.5 (2.1, 2.9)
Sagittal-Plane Intermetatarsal Angle*	0.4* (0.0, 0.8)	1.8* (1.3, 2.4)	1.5* (0.9, 2.2)	2.0* (0.9, 3.0)
Osseous Foot Width (mm)	97.4 (84.8, 109.9)	—	83.7 (81.6, 85.8)	83.9 (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 Circumference	20.6 (20.0, 21.3)	20.8 (20.1, 21.4)	20.0 (19.3, 20.8)	19.4 (18.4, 20.4)
Midfoot Circumference	20.2 (19.6, 20.8)	20.9 (20.2, 21.6)	20.3 (19.6, 20.9)	20.0 (18.9, 21.0)
Calf Circumference	33.3 (32.4, 34.2)	31.4 (30.5, 32.3)	32.2 (31.1, 33.3)	32.6 (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

VAS Mean (95% Confidence Interval)				
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 Month (n=75)	12 Month (n=37)	
MOxFQ (Walk/Stand)	41.4 (36.8, 46.0)	16.7 (12.4, 20.9)	7.4 (2.6, 12.2)	
MOxFQ (Pain)	50.3 (46.6, 54.0)	22.0 (17.9, 26.1)	13.1 (7.8, 18.4)	
MOxFQ (Social Interaction)	43.0 (38.9, 47.2)	13.3 (9.6, 16.9)	6.4 (2.1, 10.7)	
MOxFQ (Index Score)	44.6 (40.9, 48.3)	17.5 (13.7, 21.2)	9.0 (4.6, 13.3)	

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 (13.0, 15.6)	11.9 (10.9, 13.0)	10.0 (8.7, 11.4)
Patient	22.8 (20.3, 25.2)	18.1 (15.6, 20.6)	12.3 (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



Discussion

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, post-procedure.

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

Disclosures

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