

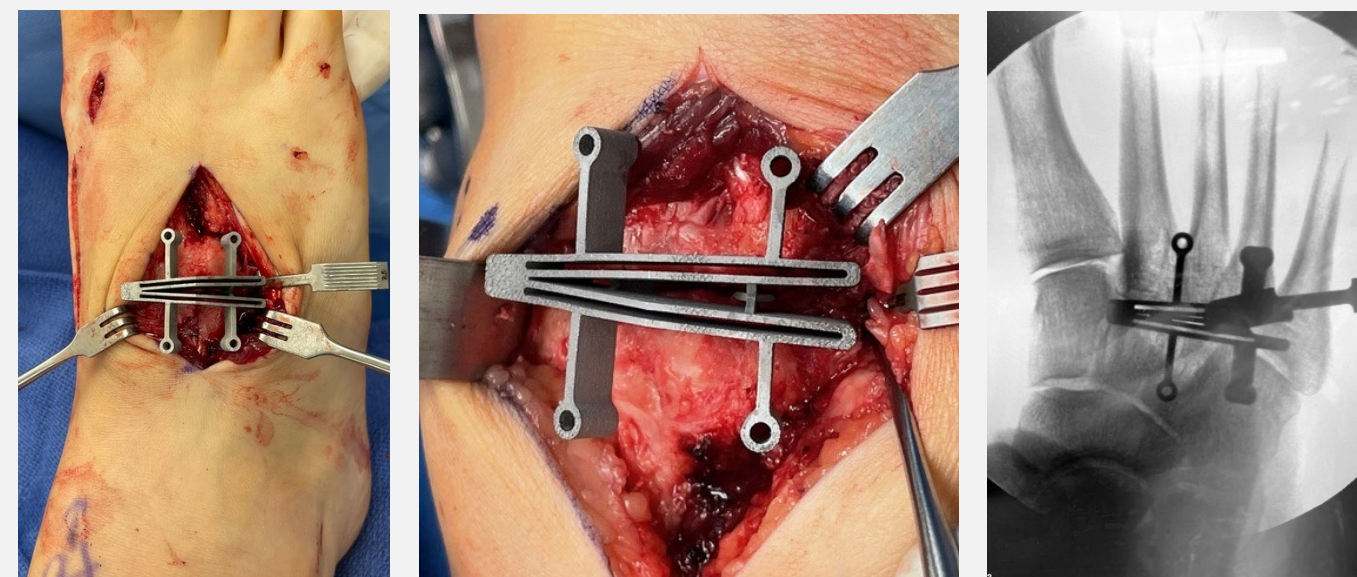
# Interim 1-Year Analysis of a Prospective Multicenter Study Assessing Radiographic and Patient-Reported Outcomes Following Combined Metatarsus Adductus and Hallux Valgus Correction through 3<sup>rd</sup>, 2<sup>nd</sup>, and 1<sup>st</sup> Tarsometatarsal Arthrodesis with Early Weightbearing

P Dayton, DPM, FACFAS<sup>1</sup>; M Dayton, DPM, FACFAS<sup>1</sup>; A Chhabra, MD<sup>2</sup>; A Chokan, DPM, FACFAS<sup>3</sup>; W DeCarbo, DPM, FACFAS<sup>4</sup>; D Hatch, DPM, FACFAS<sup>5</sup>; J Kaldenberg-Leppert, DPM, FACFAS<sup>1</sup>; D Kile, BA, MS<sup>6</sup>; JP McAleer, DPM, FACFAS<sup>7</sup>; C de Cesar Netto, MD, PhD<sup>8</sup>; R Santrock, MD<sup>3</sup>; P Steinke, DPM, FACFAS<sup>9</sup>; L Tenorio, MD<sup>2</sup>; B White, DPM, FACFAS<sup>10</sup>; M Easley, MD<sup>8</sup>

1. Foot and Ankle Center of Iowa, Ankeny, IA | 2. University of Texas Southwestern Medical Center, Dallas, TX | 3. Ohio Foot and Ankle Center, Stow, OH | 4. Greater Pittsburgh Foot and Ankle Center, Pittsburgh, PA | 5. Foot and Ankle Center of the Rockies, Greeley, CO | 6. Actalent, Hanover, MD | 7. JCMG Podiatry, Jefferson City, MO | 8. Duke University, Durham, NC | 9. Foot and Ankle Associates of North Texas, Keller, TX | 10. Coastal Maine Foot and Ankle, Yarmouth, ME

## Statement of Purpose

This study evaluated the clinical, radiographic, and patient-reported outcomes in patients undergoing instrumented 3-2-1 tarsometatarsal (TMT) arthrodesis for correction of combined hallux valgus and metatarsus adductus (MTA) deformities.



Clinical (left) and radiographic (right) image of the cut guide utilized to correct the MTA deformity. A continuous closing wedge cut is made across the 2nd and 3rd TMT joints with the apex at the medial aspect of the 2nd TMT joint.

## Introduction

MTA is a complicating factor in 29% of HV patients and poses significant issues for under-correction and recurrence of HV if not addressed.<sup>1</sup> A reliable and reproducible method is needed to provide anatomic correction of the midfoot deformity so that the first ray alignment can be normalized. To date there are few studies proposing a reliable method for correction. We are using an instrumented technique to realign the second through fifth rays setting the stage for complete triplane correction of the first ray.

## Methods

This is an interim analysis of a prospective multicenter study on patients with symptomatic HV and MTA treated utilizing cut guides for angular correction arthrodesis of the 2<sup>nd</sup> and 3<sup>rd</sup> TMT and 1<sup>st</sup> ray correction at the 1<sup>st</sup> TMT. Titanium 4-hole locking plates were utilized for fixation at each joint. Patients were allowed to weight bear in a CAM boot within two weeks. Outcomes included radiographic correction of HV and MTA deformities, patient-reported outcomes (VAS, MOxFQ, and PROMIS-29), and clinical complications. The metatarsus adductus angle (MAA) was measured using the traditional Sgarlato's method, and True IMA was calculated as IMA+MAA-15.<sup>2</sup>

## Results

Thirty-eight eligible patients (mean [range] age: 41.3 [14-65] years) underwent HV and MTA correction, of whom 18 completed 12-month visits. Mean (95% CI) time to protected weightbearing and return to full unrestricted activity were 7.5 (4.3, 10.7) days and 3.7 (3.4, 4.1) months, respectively. Clinically significant improvements from baseline in HVA, IMA, TSP, MAA angle, True IMA, and osseous foot width were maintained through 12 months. Improvements in patient-reported outcomes were maintained through 12 months for VAS, MOxFQ, and PROMIS-29. There were no complications that required subsequent surgery.

## Results: Patient Demographics

The interim results of 38 patients with mean (SD) follow-up of 8.0 (4.4) months\*.

Baseline Characteristic	Category	Value
Age (yrs), Median (Min, Max)		42.5 (14.0, 65.0)
Sex, n (%)	Female	35 (92.1%)
BMI, Median (Min, Max)		28.4 (21.8, 40.0)
Index Foot	Left	20 (52.6%)

\*Follow-up is duration of time from date of index procedure to date of latest post-procedure visit.

## Return to Weightbearing

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=35)	7.5 (4.3, 10.7)
Return to work (days, n=33)	28.1 (19.6, 36.6)
Return to shoes (weeks, n=34)	7.1 (6.2, 8.0)
Return to unrestricted activity (months, n=25)	3.7 (3.4, 4.1)

## Radiographic Measures

Clinically significant **improvement over baseline in radiographic measures (HVA, IMA, TSP, MAA, True IMA, and Osseous Foot Width)** through 12 month post-op.

Radiographic Measures, Mean (95% Confidence Interval)				
Radiographic Measure	Baseline (n=37)	Week 6 (n=35)	Month 6 (n=28)	Month 12 (n=16)
Hallux Valgus Angle (HVA)	28.8° (25.6, 31.9)	8.0° (5.8, 10.1)	8.4° (5.6, 11.1)	9.1° (5.1, 13.2)
Intermetatarsal Angle (IMA)	11.8° (10.9, 12.7)	4.7° (4.0, 5.5)	5.5° (4.5, 6.4)	5.4° (4.4, 6.3)
Tibial Sesamoid Position (TSP)	4.4 (4.0, 4.8)	1.8 (1.5, 2.2)	2.4 (1.9, 2.8)	2.5 (1.9, 3.1)
Metatarsus Adductus Angle (MAA)	20.5° (18.4, 22.5)	9.9° (8.6, 11.3)	9.4° (7.7, 11.1)	10.7° (8.1, 13.3)
True IMA	17.3° (15.2, 19.4)	-0.3° (-1.9, 1.2)	-0.1° (-2.1, 1.8)	1.1° (-1.8, 3.9)
Osseous Foot Width (mm)	94.5 (92.3, 96.8)	84.3 (81.8, 86.7)	87.2 (84.5, 89.8)	85.4 (80.1, 90.7)

## References

1. Aiyer et al, FAI 2016; 37 (165-171)
2. Sgarlato TE, Compendium of Podiatric Biomechanics Vol 1971; Chapter 5

## Patient Reported Outcomes

Clinically significant improvement over baseline in VAS, MOxFQ, and PROMIS-29 through 12 months post-op.

VAS Mean (95% Confidence Interval)				
Measure	Baseline (n=38)	Week 6 (n=37)	Month 6 (n=28)	Month 12 (n=17)
VAS Pain Score	4.4 (0.0, 7.0)	1.7 (0.0, 6.0)	1.8 (0.0, 5.0)	1.1 (0.0, 3.0)

MOxFQ, Mean (95% Confidence Interval)			
Measure – MOxFQ Domain	Baseline (n=38)	Month 6 (n=28)	Month 12 (n=17)
Social Interaction	43.4 (36.6, 50.2)	13.6 (6.7, 20.5)	9.6 (1.1, 18.0)
Walking/Standing	46.4 (39.5, 53.4)	21.2 (13.0, 29.3)	14.5 (4.7, 24.3)
Pain	56.7 (50.5, 62.9)	27.9 (20.9, 34.8)	21.8 (12.7, 30.9)
Index Score	48.9 (43.2, 54.6)	21.4 (14.3, 28.4)	15.5 (6.8, 24.3)

PROMIS-29 (Adults), Mean (95% Confidence Interval)*			
Measure	Baseline (n=35)	Month 6 (n=27)	Month 12 (n=15)
Ability to Participate in Social Roles/Activities	53.4 (50.5, 56.4)	59.0 (56.1, 61.8)	58.1 (53.9, 62.3)
Pain Interference	54.5 (51.8, 57.1)	47.7 (44.7, 50.7)	46.8 (42.8, 50.7)
Physical Function	44.4 (41.5, 47.3)	51.0 (48.3, 53.7)	52.7 (49.0, 56.3)

\*An increase from baseline in Ability to Participate in Social Roles/Activities and Physical Function indicates improvement. A decrease from baseline in Pain Interference indicates improvement.

## Clinical Complications

A total of 2 adverse events (AEs) were reported and 1 hardware complication; none of which experienced healing issues or required surgical intervention.

Complications presented at the patient level	
Not Requiring Surgical Intervention	n (%) (N=38)
Broken Screw at 3 <sup>rd</sup> TMT plate	1 (2.6%)
Infection	1 (2.6%)
Wound Complication	1 (2.6%)

## Representative Pre- and 12-month Radiographic Results



## Conclusion

These interim results of this 5-year prospective, multicenter study of an instrumented approach to HV and MTA correction via 3-2-1 TMT arthrodesis with early weightbearing demonstrated favorable radiographic correction of the HV and MTA deformities, positive patient-reported outcomes, and a low rate of clinical complications.

- Early return to weight-bearing in a CAM boot (mean 7.5 days).
- Maintenance of HV (IMA, HVA, TSP) and MTA (MAA, True IMA) radiographic correction through 12 months.
- Clinically significant reduction in pain (VAS) and patient reported outcomes (MOxFQ, PROMIS-29) through 12 months.