

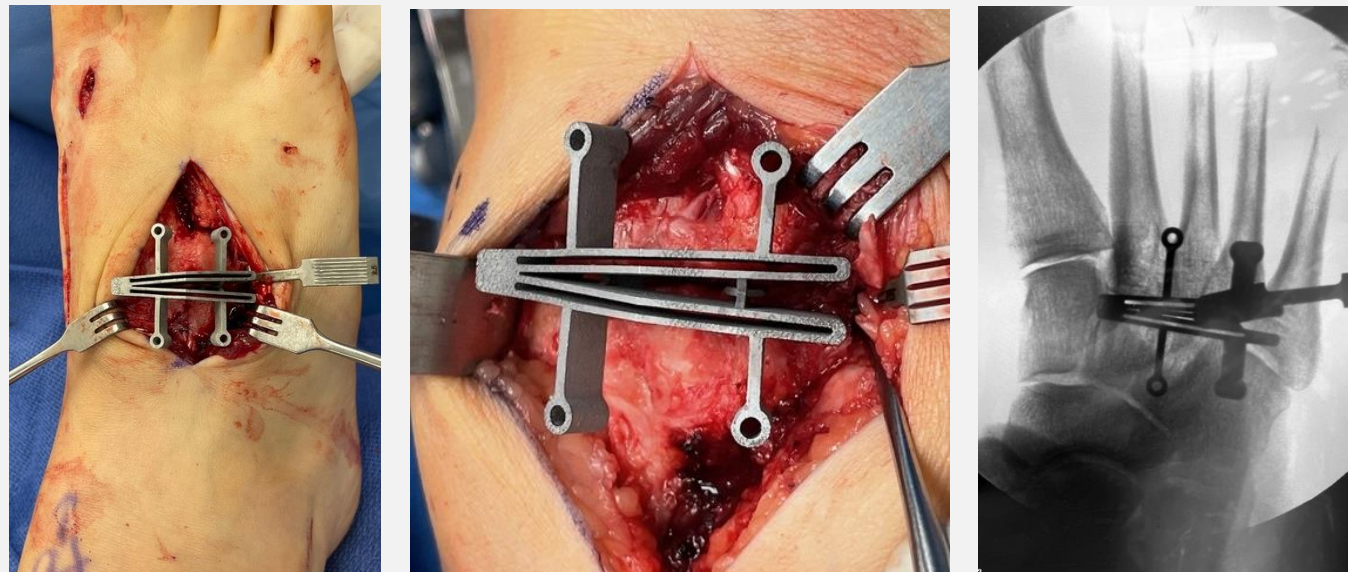
# Interim 1-Year Analysis of a Multicenter Prospective Study Assessing Radiographic and Patient Outcomes Following Combined Metatarsus Adductus and Hallux Valgus Correction with Early Weightbearing

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## 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 (HV) 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, MOxFAQ, 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

Sixty eligible patients (mean [range] age: 41.2 [14-77] years) underwent HV and MTA correction, of whom 33 have completed 12-month visits to date. Mean (95% CI) time to protected weightbearing and return to full unrestricted activity were 7.9 (5.5, 10.2) days and 3.8 (3.6, 4.0) months, respectively. Clinically significant improvements from baseline in HVA, IMA, TSP, MAA, True IMA, and osseous foot width were maintained through 12 months. Improvements in patient-reported outcomes were maintained through 12 months for VAS, MOxFAQ, and PROMIS-29. One patient 3.0% (1/33) has a non-union. There were no complications that required subsequent surgery.

## Results: Patient Demographics

The interim results of 60 patients with mean (SD) follow-up of 11.6 (8.2) months\*.

Baseline Characteristic	Category	Value
Age (yrs), Mean (SD)		41.2 (16.0)
Sex, n (%)	Female	54 (90.0%)
	Male	6 (10.0%)
BMI, Mean (SD)		29.0 (5.2)
Index Foot	Left	34 (56.7%)
	Right	26 (43.3%)

\*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=57)	7.9 (5.5, 10.2)
Return to work (days, n=52)	34.0 (26.5, 41.5)
Return to shoes (weeks, n=53)	8.4 (5.9, 10.9)
Return to unrestricted activity (months, n=43)	3.8 (3.6, 4.0)

## Radiographic Measures

Statistically significant improvement (p<0.05) over baseline through 12-month post-op.

Radiographic Measures, Mean (95% Confidence Interval)				
Radiographic Measure	Baseline (n=56) <sup>a</sup>	Week 6 (n=52) <sup>b</sup>	Month 6 (n=40)	Month 12 (n=31)
Hallux Valgus Angle (HVA)	29.3° (27.0, 31.6)	8.5° (6.8, 10.1)	8.6° (6.2, 11.1)	8.9° (6.3, 11.5)
Intermetatarsal Angle (IMA)	12.4° (11.6, 13.1)	4.9° (4.0, 5.7)	5.5° (4.7, 6.4)	5.8° (5.0, 6.7)
Tibial Sesamoid Position (TSP)	4.6 (4.3, 4.9)	2.1 (1.8, 2.4)	2.5 (2.1, 2.9)	2.5 (2.1, 2.9)
Metatarsus Adductus Angle (MAA)	19.5° (17.8, 21.1)	9.1° (8.0, 10.1)	9.5° (8.1, 10.8)	9.6° (8.0, 11.3)
True IMA	16.9° (15.2, 18.5)	-1.1° (-2.4, 0.2)	0.0° (-1.6, 1.5)	0.5° (-1.3, 2.3)
Osseous Foot Width (mm)	94.3 (92.5, 96.1)	83.7 (81.8, 85.6)	86.9 (84.8, 89.0)	86.2 (83.2, 89.2)

<sup>a</sup> Sample size for osseous foot width at baseline is 55

<sup>b</sup> Sample size for osseous foot width at 6 weeks is 51

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

## References

## Patient Reported Outcomes

Statistically significant improvement (p<0.05) over baseline through 12-month post-op.

VAS, Mean (95% Confidence Interval)				
Measure	Baseline (n=60)	Week 6 (n=56)	Month 6 (n=46)	Month 12 (n=33)
VAS Pain Score	4.1 (3.6, 4.6)	1.7 (1.4, 2.1)	1.9 (1.4, 2.3)	1.1 (0.7, 1.6)

MOxFAQ, Mean (95% Confidence Interval)			
Measure – MOxFAQ Domain	Baseline (n=60)	Month 6 (n=47)	Month 12 (n=33)
Social Interaction	38.0 (32.5 43.5)	13.6 (8.6, 18.5)	10.8 (4.0, 17.6)
Walking/Standing	43.6 (37.6, 49.6)	23.6 (17.2, 30.1)	16.1 (8.8, 23.5)
Pain	54.8 (49.5, 60.0)	27.7 (21.6, 33.7)	23.3 (16.2, 30.4)
Index Score	45.7 (40.7, 50.7)	22.4 (16.8, 27.9)	17.0 (10.3, 23.8)

PROMIS-29 (Adults), Mean (95% Confidence Interval)*			
Measure	Baseline (n=53)	Month 6 (n=45)	Month 12 (n=32)
Ability to Participate in Social Roles/Activities	54.6 (52.3, 56.8)	58.7 (56.5, 60.9)	58.5 (56.0, 61.1)
Pain Interference	54.0 (51.8, 56.1)	48.3 (45.8, 50.7)	46.9 (44.4, 49.4)
Physical Function	45.9 (43.5, 48.3)	50.8 (48.6, 52.9)	53.0 (50.8, 55.1)

\*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

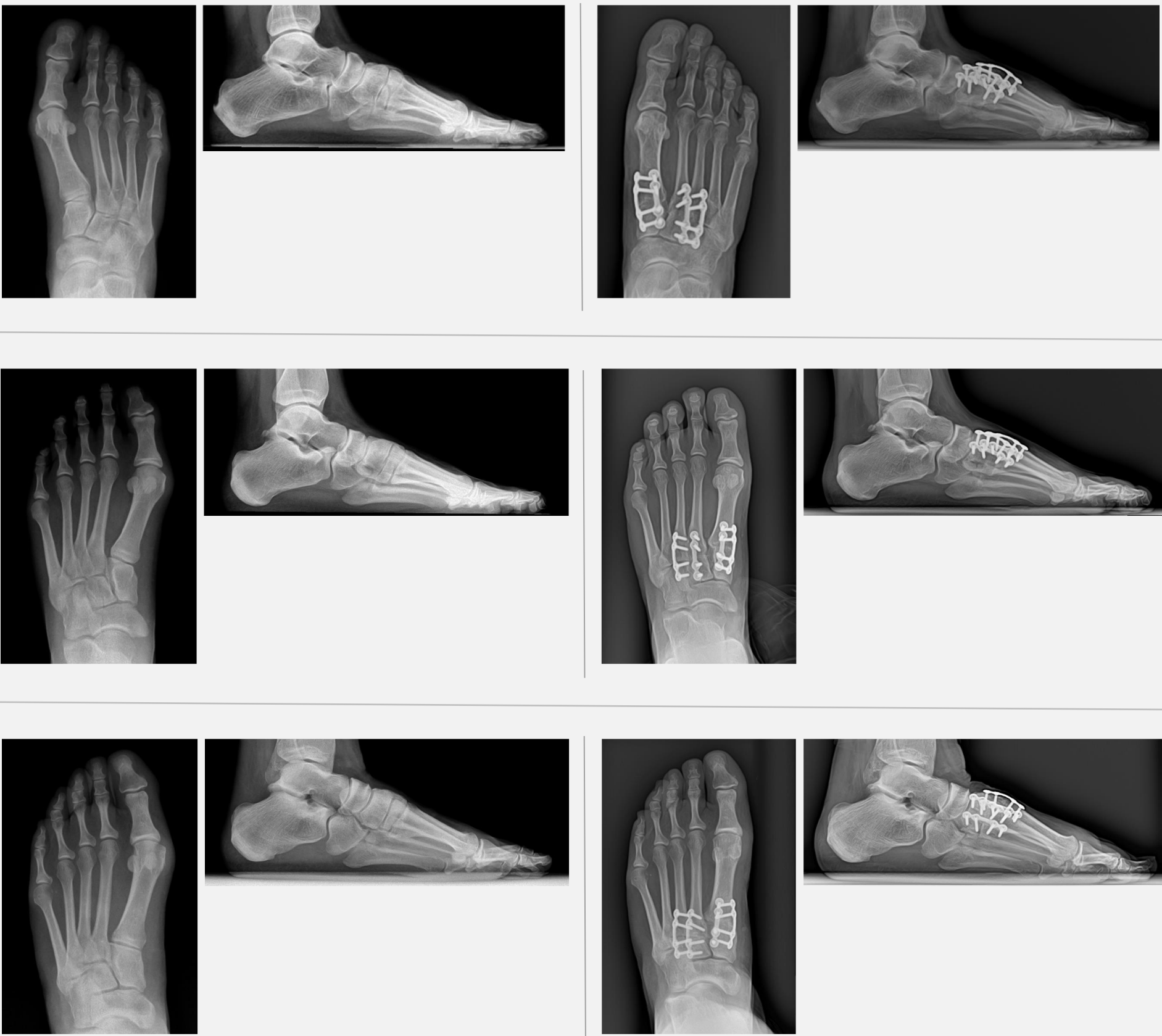
No patients required surgical intervention. 6.7% (4/60) of patients experienced an adverse event (AE), with two hardware failures 3.3% (2/60). One of 33 (3.0%) patients at 12-months experienced a non-union.

Complications Not Requiring Surgical Intervention	n (%) (N=60)
Hardware failure, hardware not removed	2 (3.3%)
Pain	2 (3.3%)
Infection	1 (1.7%)
Wound Complication	1 (1.7%)
Non-union at 12 months**	1 (3.0%)*
Hardware removal per patient request	1 (1.7%)

\*Sample size with 12-month data is 33

\*\*Non-union defined as pain and lucency at the 1<sup>st</sup>, 2<sup>nd</sup>, and/or 3<sup>rd</sup> TMT joint at 12 months post Adductoplasty\* and Lapiplasty\* Procedure

## 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.

- Early return to weight-bearing in a CAM boot (mean 7.9 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 (MOxFAQ, PROMIS-29) through 12 months)
- Low complication rate