Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following an Instrumented Mini-Open Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing

Scientific Conference

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Jefferson City Medical Group

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Disclosures

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Introduction

Results from a 2-year prospective multicenter study to evaluate the use of an instrumented system for triplanar 1st TMT correction of HV deformities through a mini-open incision:

- Reproducibility of correction.
- Outcomes of early weightbearing.
- Maintenance of correction.
- Patient-reported outcomes.

Study Methods

Mini3D™ prospective multicenter study
(9 sites and 9 surgeons): 2-year follow-up

Inclusion criteria:

- 14-58 years of age
- Symptomatic HV (IMA between 10.0 - 22.0°; HVA between 16.0 - 40.0°)

Exclusion criteria:

- Prior HV surgery
- BMI >40 kg/m^2
- HbA1c ≥7
- Evidence of peripheral neuropathy
- Metatarsus adductus angle (MAA) ≥23°
- Moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex
- Current use of nicotine

Radiographic reader: One independent fellowship trained musculoskeletal radiologist

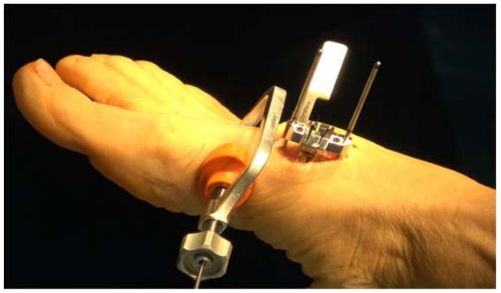
Outcomes evaluated (12 and 24 mo follow-up):

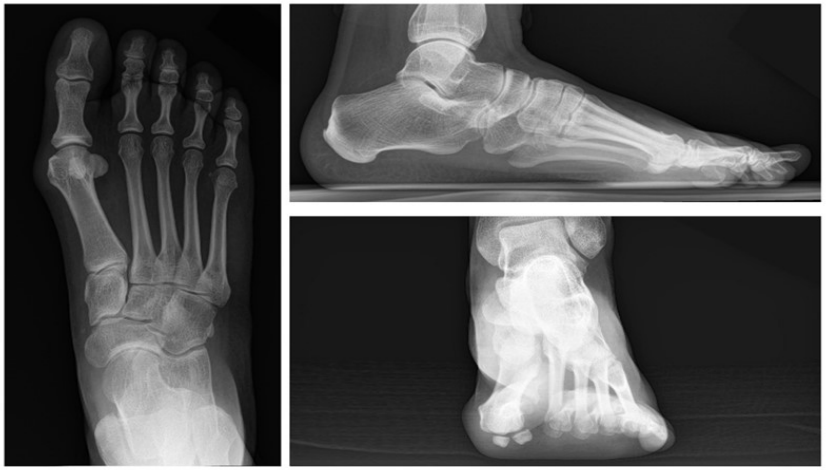
- Radiographic recurrence
- Return to weightbearing and activities
- Pain measured by visual analog scale (VAS)
- Manchester-Oxford Foot Questionnaire (MOxFQ)
- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Circumferential measurements
- Scar analysis
- Complications
- Non-union (defined as pain at the TMT joint plus one or more of the following: lucency, hardware failure, or recurrence

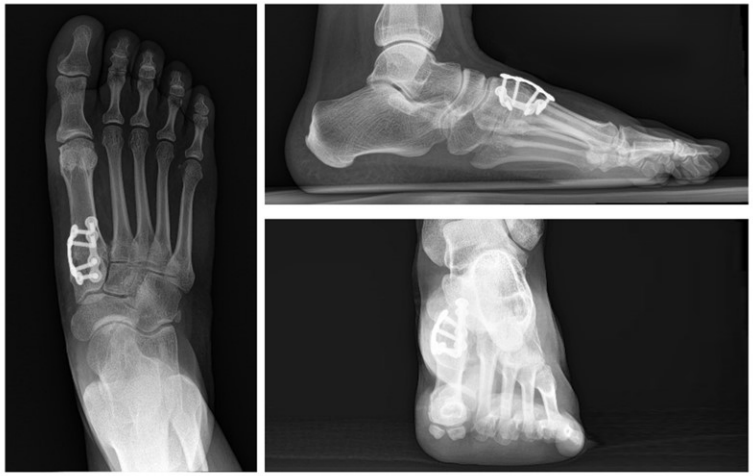
Surgical Methods

Mini-Open 1st TMT Arthrodesis:

- Patients treated with an instrumented 1st TMT procedure through a mini-open (≤4cm) dorsal incision.
- Instrument-assisted triplanar deformity correction with a cut guide for TMT joint cuts.
- Biplanar locking construct with protected early weightbearing.







Results: Demographics and Baseline Characteristics

- 75/105 patients completed their 12-month follow up visit and 11 patients completed their 24-month follow up.
- Early protected weightbearing in an average of 7.9 days (SD=6.0).

Baseline Characteristics	Category	Patient Population	
Age (years), mean (SD)		41.0	(12.4)
Sex, n (%)	Male	7	(6.7%)
	Female	98	(93.3%)
BMI (kg/m^2), mean (SD)		25.5	(4.9)

Results: Radiographic Measures

- Significant ($p<0.01$) improvements over baseline in radiographic measures (HVA, IMA, TSP, osseous foot width) at all post-op time points through 12 months. Continued improvement observed in the n=11 patients with 24-month data.
- 94.2% (98/104) of patients achieved 6-week correction.*
- Average metatarsal shortening of 2.4mm at 12 months.

Radiographic Measures, Mean (95% Confidence Interval)					
Radiographic measure	**Baseline (n=105)**	**6 Week (n=104)**	**6 Month (n=98)**	**12 Month (n=75)**	**24 Month (n=11)**
Hallux Valgus Angle (HVA)	26.6° (25.3, 27.8)	6.4° (5.2, 7.6)	6.5° (5.1, 7.8)	7.1° (5.6, 8.6)	5.6° (3.3, 7.8)
Intermetatarsal Angle (IMA)	14.1° (13.5, 14.6)	3.7° (3.2, 4.3)	4.7° (4.0, 5.3)	4.8° (4.1, 5.6)	3.0° (1.6, 4.3)
Tibial Sesamoid Position (TSP)	5.0 (4.8, 5.3)	1.7 (1.5, 1.9)	2.3 (2.1, 2.6)	2.7 (2.4, 3.0)	1.9 (1.4, 2.5)
Sagittal-Plane Intermetatarsal Angle**	0.3° (-0.1, 0.8)	1.8° (1.2, 2.3)	1.3° (0.8, 1.9)	1.4° (0.8, 2.0)	1.1° (-1.3, 3.5)
Osseous Foot Width (mm)	91.0 (89.1, 93.0)	— —	83.7 (81.7, 85.6)	83.3 (81.1, 85.5)	79.3 (75.6, 83.1)

*Correction is defined as any two of the following 3 criterion being met at 6 weeks post-procedure: IMA <9.0°, HVA <15.0°, and TSP <=3.
**Dorsiflexion is a positive value.

Results: Radiographic Recurrence

- Recurrence was assessed using two thresholds from literature: HVA >15° or HVA >20°.
- None of the patients had recurrence using post-op HVA of >20° at 12 or 24 months.

Visit	Recurrence Definition Rate (95% CI of the proportion)	
	HVA >15°	HVA >20°
12 Month	5.5% (4/73) (1.51, 13.44)	0.0% (0/73)
24 Month	0.0% (0/11)	0.0% (0/11)

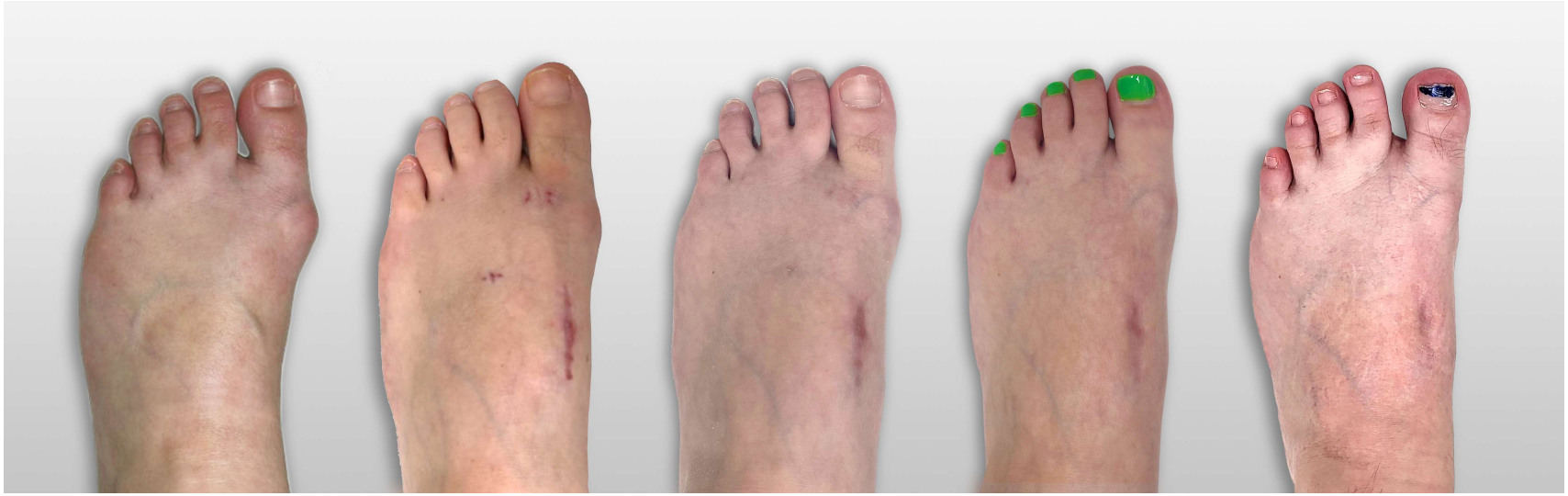
Results: Circumferential Measurements

Circumferential Measurements in cm, Mean (95% Confidence Interval)				
Swelling Measures	**Baseline (n=105*)**	**6 Week (n=104)**	**6 Month (n=98)**	**12 Month (n=75)**
Forefoot Circumference	20.7 (20.1, 21.3)	20.8 (20.2, 21.5)	20.2 (19.5, 20.8)	19.8 (19.1, 20.5)
Midfoot Circumference	20.2 (19.6, 20.8)	20.9 (20.3, 21.5)	20.5 (19.9, 21.1)	20.2 (19.6, 20.9)
Calf Circumference	33.4 (32.5, 34.3)	31.5 (30.6, 32.3)	32.4 (31.5, 33.3)	32.9 (32.0, 33.8)

*One subject was missing measurements for Forefoot and Midfoot

Results: Scar Analysis

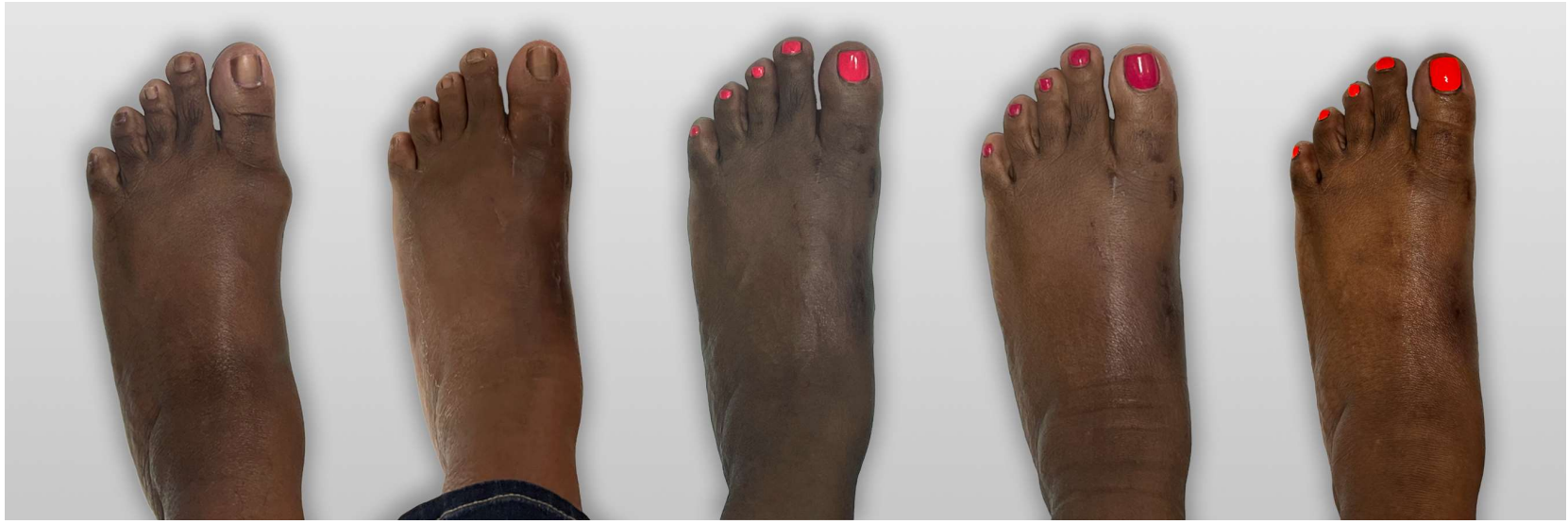
- Representative preoperative (left) and 24-month postoperative (right) incision/scar assessments



Baseline | 6 Week | 6 Month | 12 Month | 24 Month

Results: Scar Analysis

- Representative preoperative (left) and 12-month postoperative (right) incision/scar assessments

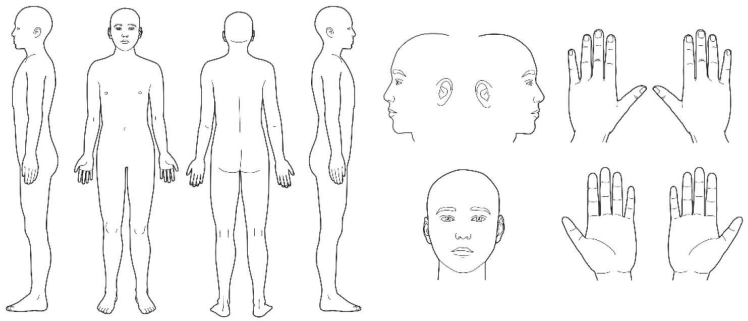


Baseline | 6 Week | 4 Month | 6 Month | 12 Month

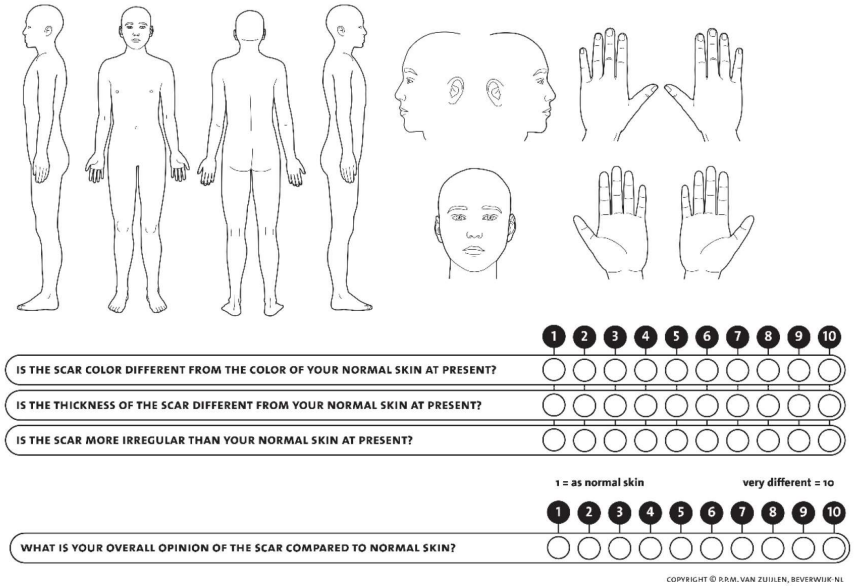
POSAS: Patient and Observer Assessment Scale

Survey question examples

POSAS Observer scale



POSAS Patient scale



Results: Incision Length and Scar Analysis

- High patient satisfaction with post-operative scar appearance.

Incision Length (cm)	
Median (Min, Max)	3.5 (3.0, 4.0)

POSAS* (Mean 95% Confidence Interval)				
	4 Month (n=98)	**6 Month (n=98)**	**12 Month (n=75)**	**24 Month (n=11)**
Observer	14.6 (13.4, 15.9)	12.1 (11.2, 13.1)	10.8 (9.8, 11.8)	7.5 (6.2, 8.7)
Patient	22.7 (20.4, 24.9)	18.2 (16.0, 20.4)	13.4 (11.6, 15.2)	8.8 (5.3, 12.4)

*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.

Results: Patient Reported Outcomes

- Significant improvement over baseline in VAS and MOxFQ through 12m post-op.
- Continued improvement observed in the n=11 patients with 24-month data.

VAS Mean (95% Confidence Interval)					
Measure	**Baseline (n=105)**	**6 Week (n=104)**	**6 Month (n=98)**	**12 Month (n=74)**	**24 Month (n=11)**
VAS Pain Score	3.5 (3.1, 3.9)	1.6 (1.4, 1.9)	1.2 (0.9, 1.5)	0.9 (0.7, 1.2)	1.0 (0.0, 2.0)

MOxFQ Mean (95% Confidence Interval)				
Measure	**Baseline (n=105)**	**6 Month (n=98)**	**12 Month (n=75)**	**24 Month (n=11)**
MOxFQ (Walk/Stand)	41.2 (36.7, 45.8)	17.6 (13.6, 21.7)	8.8 (5.4, 12.1)	7.8 (-1.6, 17.1)
MOxFQ (Pain)	50.2 (46.6, 53.9)	22.8 (19.0, 26.6)	14.5 (10.9, 18.0)	10.5 (-2.6, 23.5)
MOxFQ (Social Interaction)	42.7 (38.7, 46.8)	14.0 (10.5, 17.7)	9.0 (5.9, 12.1)	6.8 (-7.0, 20.7)
MOxFQ (Index Score)	44.4 (40.8, 48.1)	18.4 (14.7, 22.0)	10.6 (7.6, 13.6)	8.4 (-2.9, 19.6)

Results: Patient Reported Outcomes

- Significant improvements were observed across all PROMIS domains at 6 and 12 months post-operatively.
- Continued improvements were also observed in the n=10 24-month subjects.

PROMIS Domain	Baseline (n=99)	6 Month (n=92)	12 Month (n=70)	24 Month (n=10)
Ability to Participate in Social Roles/Activities	54.1 (52.3, 56.0)	59.3 (57.9, 60.7)	61.5 (60.3, 62.7)	61.5 (58.3, 64.7)
Anxiety	48.3 (46.3, 50.2)	44.2 (42.7, 45.8)	43.7 (42.2, 45.1)	44.3 (39.6, 48.9)
Depression	44.9 (43.3, 46.4)	43.3 (42.1, 44.5)	43.8 (42.3, 45.3)	42.9 (40.0, 45.8)
Fatigue	45.8 (43.7, 47.8)	41.9 (39.9, 43.8)	41.2 (39.2, 43.2)	38.9 (34.0, 43.7)
Pain Intensity	3.9 (3.5, 4.3)	1.3 (1.0, 1.7)	0.9 (0.6, 1.2)	1.1 (-0.4, 2.6)
Pain Interference	54.1 (52.4, 55.8)	45.6 (44.2, 47.0)	43.6 (42.6, 44.7)	44.6 (41.0, 48.2)
Physical Function	45.9 (44.2, 47.5)	52.9 (51.6, 54.3)	55.0 (53.9, 56.0)	55.4 (51.6, 59.1)
Sleep Disturbance	49.1 (47.6, 50.6)	44.9 (43.1, 46.8)	44.3 (42.4, 46.2)	44.4 (38.2, 50.6)

Results: Metatarsalgia

- Majority of patients experienced resolution of pre-op metatarsalgia.

Metatarsalgia			
Metatarsalgia at baseline	**Metatarsalgia at 12 months n (row %) (column %)**	**No Metatarsalgia at 12 months n (row %) (column %)**	**Row Total**
Yes	0	28 (100.0%) (38.4%)	28
No	2 (4.3%) (100.0%)	45 (95.7%) (61.6%)	47
Column Total	2	73	

Complications

- 1 (1.0%) of the 105 patients required reoperation (hardware removal).
- 11 (10.5%) patients experienced at least one clinical complication not requiring surgical intervention.
- Symptoms of 3 patients were ongoing at the time of data analysis; symptoms were pain (N=2) and malunion/stiffness (N=1).
- 0 (0.0%) patients experienced a protocol defined non-union.

Complications and AEs at the Patient Level

Requiring Surgical Intervention	Number (%) (n=105)	Not Requiring Surgical Intervention	Number (%) (n=105)
Hardware removal due to pain	1 (1.0%)	Other pain	4 (3.8%)
		Infection	2 (1.9%)
		Malunion & Stiffness	1 (1.0%)
		Other AE*	3 (2.9%)
		Hardware failure (hardware not removed)**	1 (1.0%)

*Other AEs: allergic reaction to surgical glue, cuneiform fracture, skin abrasion.

**Patient is considered healed per protocol definition.

Discussion

- Overall favorable results with triplanar 1st TMT correction of HV deformities through a mini-incision (median incision length: 3.5cm) with an early return to weightbearing, low recurrence rates, and improvement in patient-reported outcomes at 12 months.
- LaLevee (FAI 2023) recent systematic review of distal osteotomy with 5+ years follow-up found pooled recurrence rates of 64% and 10% using HVA thresholds of 15° and 20°, respectively.[1]
- Our study revealed a recurrence rate of 5.5% and 0.0% at 12 months using HVA thresholds of 15° and 20°, respectively.
- There was a small increase in sagittal-plane alignment post-procedure, but clinically there was only 2 patients (of 75) at 12 months with symptomatic metatarsalgia despite 35% (37 of 105 patients) reporting metatarsalgia pre-operatively.

1. LaLevee et al. FAI 2023

Conclusion

Favorable clinical and patient-reported outcomes with mini-open approach (median incision length: 3.5cm) 12 months post-procedure:

- Early protected weightbearing in average of 7.9 days.
- Significant improvements in radiographic correction (HVA, IMA, TSP, osseous foot width) at 6 weeks and maintained through 12 months.
- Low radiographic recurrence.
- Significant improvements in pain (VAS) and patient-reported outcomes (MOxFQ, PROMIS).
- Metatarsalgia was resolved in all 28 patients who exhibited pre-op metatarsalgia, by the 12-month timepoint.
- Scar quality with favorable POSAS scores.
- Protocol-defined non-union rate: (0.0%).
- Low rate of clinical complications and reoperations.

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