Radiographic and Patient Reported Outcomes Following Combined Metatarsus Adductus and Hallux Valgus Correction with Early Weightbearing – 2-year Interim Results of a Multicenter Prospective Study

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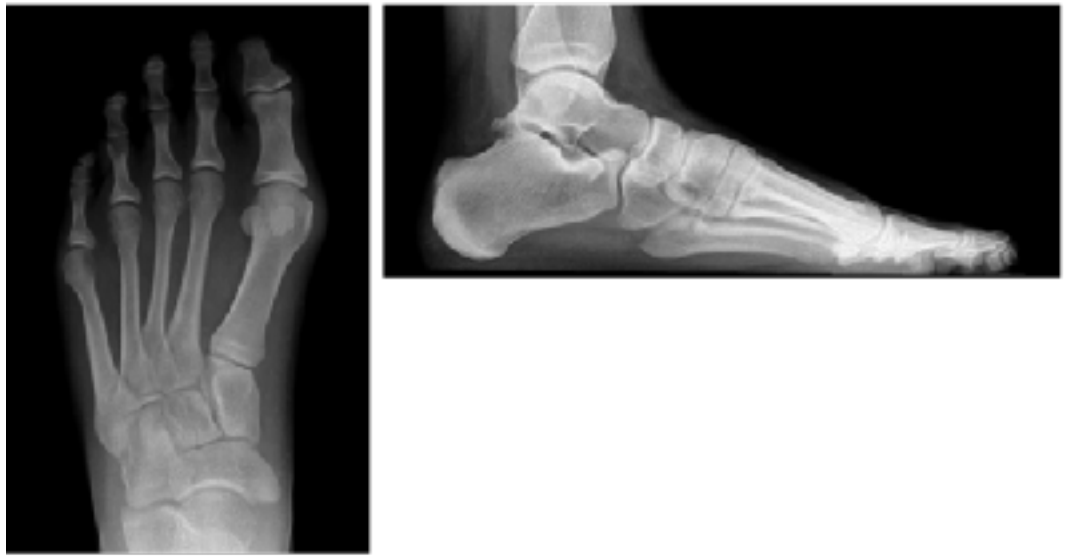
Introduction

Metatarsus Adductus

- Congenital deformity of the lesser metatarsals
- ~0.1% incidence rate in the general population[1,2]
- 30-35%[2,3] incidence in patients with symptomatic hallux valgus
- Up to 30% hallux valgus recurrence without correction of the metatarsus adductus[4]

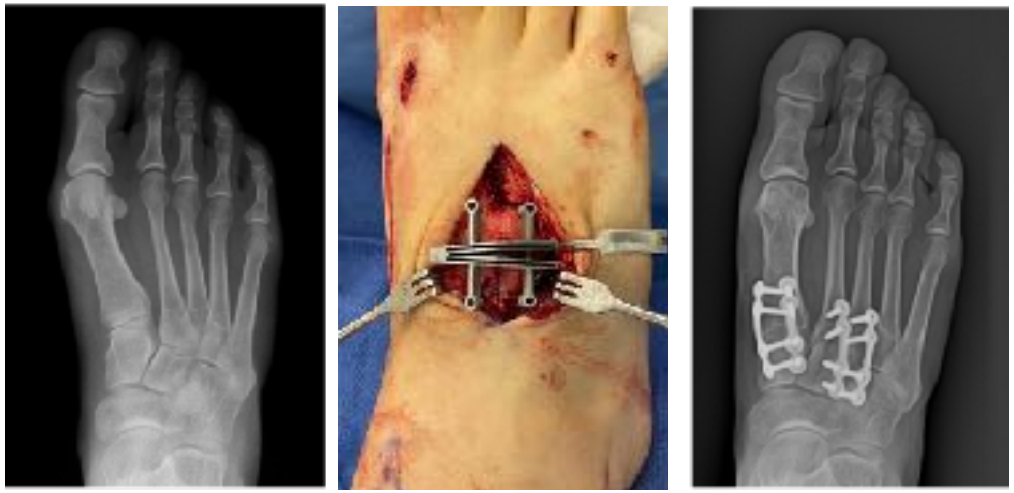


Preoperative radiographs illustrating the HV + MTA deformity.

Introduction

Interim results from a prospective multicenter study to evaluate the use of an instrumented system for 3-2-1 TMT correction of MTA and HV deformities:

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



Pre-operative and post-operative radiographs illustrating instrumented correction of the HV + MTA deformity

Study Methods

MTA3D™ prospective multicenter study (8 sites and 10 surgeons)

Inclusion criteria:

- >14 years of age
- Combined MTA and HV (defined as IMA ≥ 8.0° or True IMA > 10°; HVA ≥ 12°; metatarsus adductus angle ≥ 15°)

Exclusion criteria:

- Prior HV surgery
- BMI > 40 kg/m2
- Clinical diagnosis of diabetes
- Evidence of peripheral neuropathy
- Severe osteoarthritis of the 1st, 2nd, or 3rd tarsometatarsal joints
- Current use of nicotine

Radiographic readers: Two independent fellowship trained musculoskeletal radiologists

Outcomes evaluated:

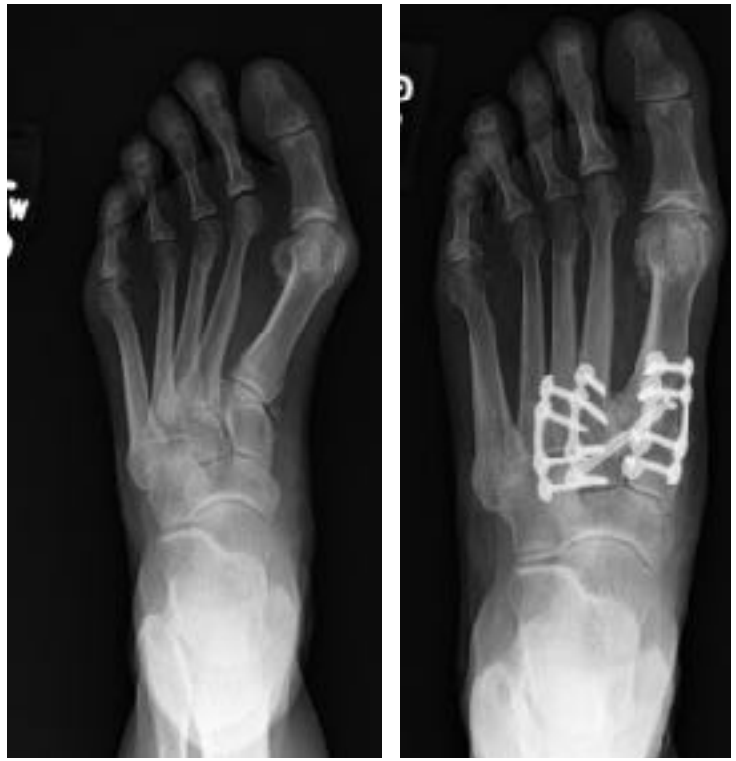
- Non-union
- Return to weightbearing and activities
- Pain measured by visual analog scale (VAS)
- Manchester-Oxford Foot Questionnaire (MOxFQ)
- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Complications

Results: Demographics and Baseline Characteristics

- 66 treated patients
  - 59 patients reached 1-year follow-up
  - 35 patients reached 2-year follow-up

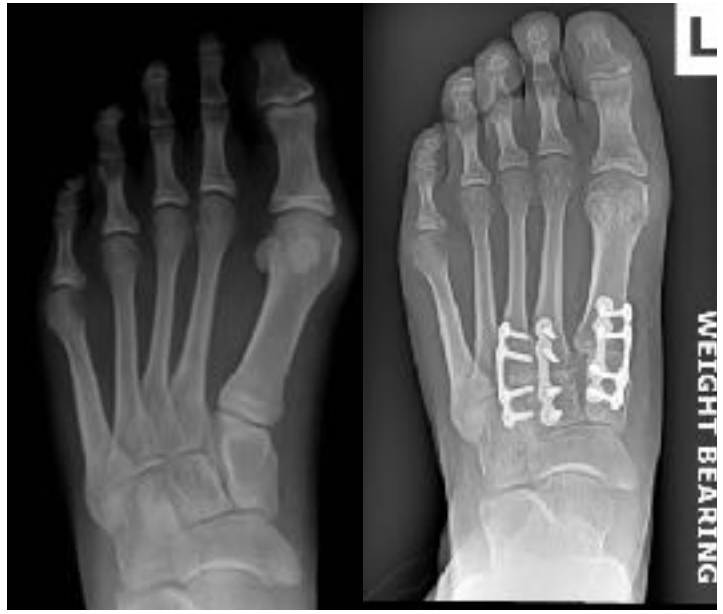
Characteristic	Category	Patient Population (N=66)
Age (yr), mean (SD[a])		41.7 (16.2)
Sex (%)	Female	58 (87.9%)
	Male	8 (12.1%)
BMI[b], mean (SD)		28.7 (5.1%)
Index Foot (%)	Left	35 (53.0%)
	Right	31 (47.0%)
Labor Class (%)	Sedentary	22 (33.3%)
	Light work	22 (33.3%)
	Medium work	15 (22.7%)
	Heavy work	2 (3.0%)
	Very heavy work	2 (3.0%)

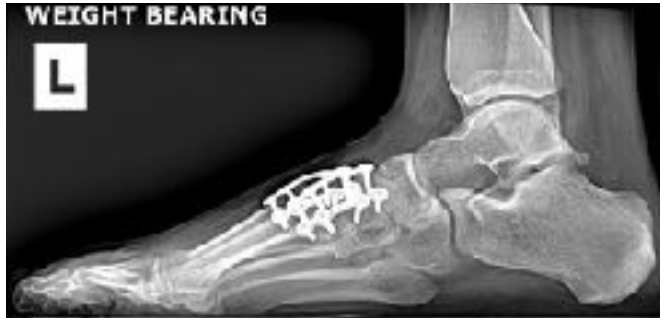
[a]Standard Deviation
[b]Body Mass Index



Results: Return to Weightbearing

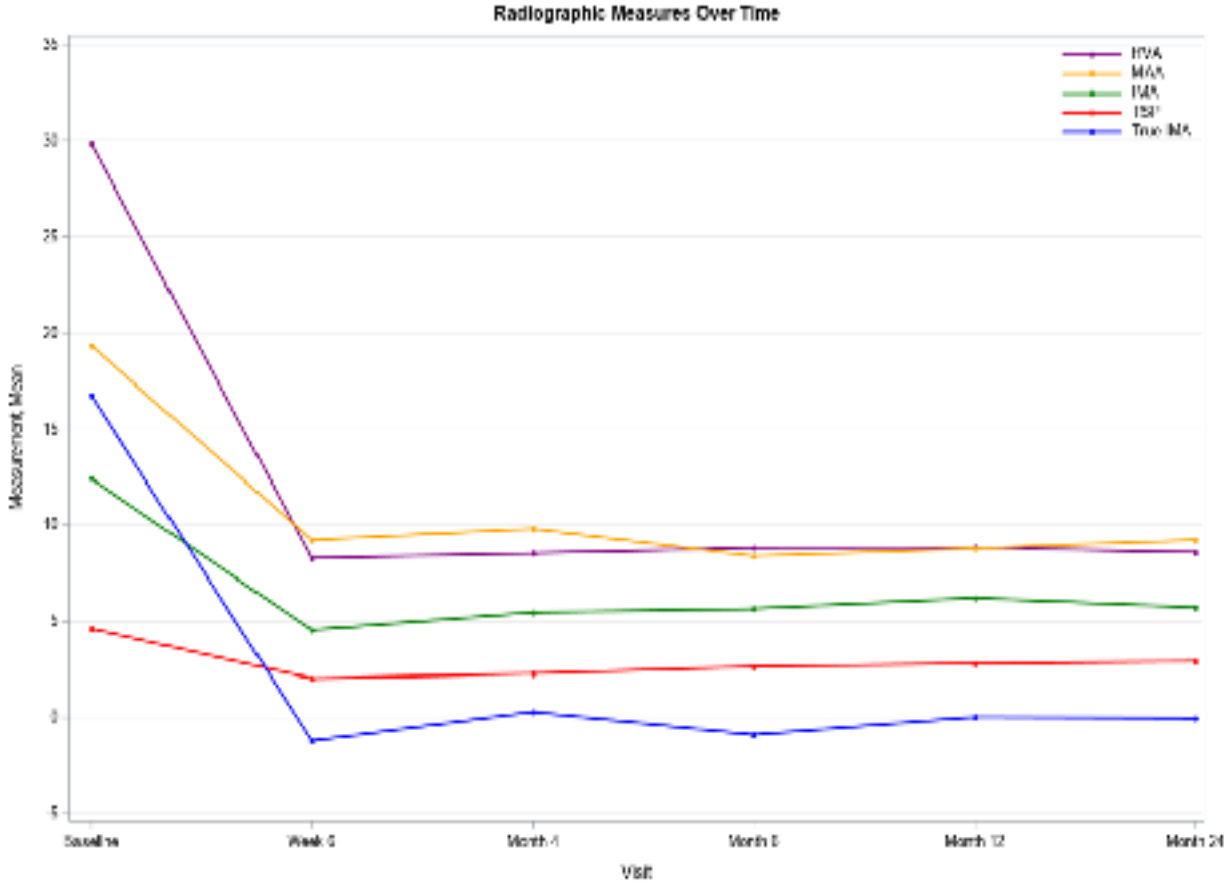
Post-Operative Time to Return to Activity/Work	
Activity	**Mean (95% Confidence Interval)**
Weightbearing in CAM boot (days)	7.6 (5.5, 9.7)
Return to work (days)	38.7 (31.0, 46.4)
Return to shoes (weeks)	7.9 (7.1, 8.7)
Return to unrestricted activity (months)	3.9 (3.7, 4.1)





Results: Radiographic Measures

- There was a statistically significant <u>overall improvement</u> in radiographic measures post-procedure that was maintained through 24 months



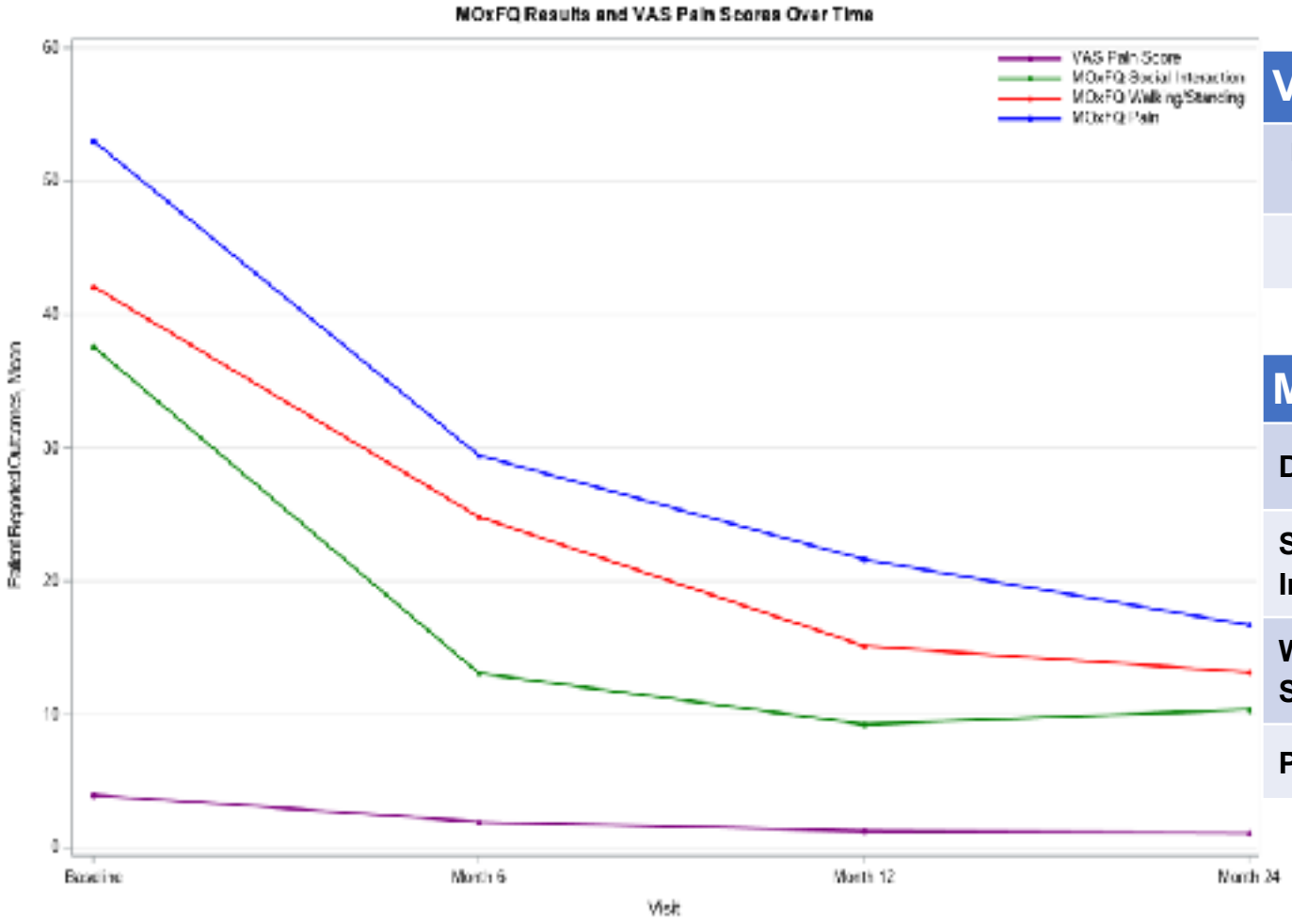
Radiographic Measures, Mean (95% CI)

Visit	Baseline (n=65)	Week 6 (n=66)	Month 6 (n=63)	Month 12 (n=58)	Month24 (n=34)
HVA°	29.9 (27.7, 32.0)	8.3 (6.8, 9.8)	8.8 (6.9, 10.7)	8.8 (7.0, 10.7)	8.6 (5.9, 11.3)
IMA°	12.4 (11.7, 13.1)	4.5 (3.8, 5.2)	5.7 (4.9, 6.4)	6.2 (5.3, 7.1)	5.7 (4.8, 6.6)
TSP	4.6 (4.3, 4.9)	2.0 (1.8, 2.3)	2.6 (2.3, 3.0)	2.8 (2.5, 3.1)	2.9 (2.5, 3.4)
MAA°	19.3 (17.8, 20.9)	9.2 (8.3, 10.2)	8.4 (7.3, 9.5)	8.8 (7.5, 10.0)	9.2 (7.9, 10.5)
True IMA°	16.8 (15.2, 18.3)	-1.2 (-2.4, -0.1)	-0.9 (-2.1, 0.3)	0.0 (-1.5, 1.5)	-0.0 (-1.5, 1.5)
Osseous* Foot Width (mm)	94.5 (92.7, 96.2)	83.7 (82.0, 85.3)	86.1 (84.4, 87.8)	86.1 (84.1, 88.0)	86.9 (84.5, 89.2)

*Osseous Foot Width at Baseline is N=64, Week 6 N=65

Results: Patient-Reported Outcomes

- Pain measured by VAS showed statistically significant improvement that was maintained through 24 months
- There was an overall improvement in all MOxFQ domain scores at 6-, 12- and 24-months post-procedure

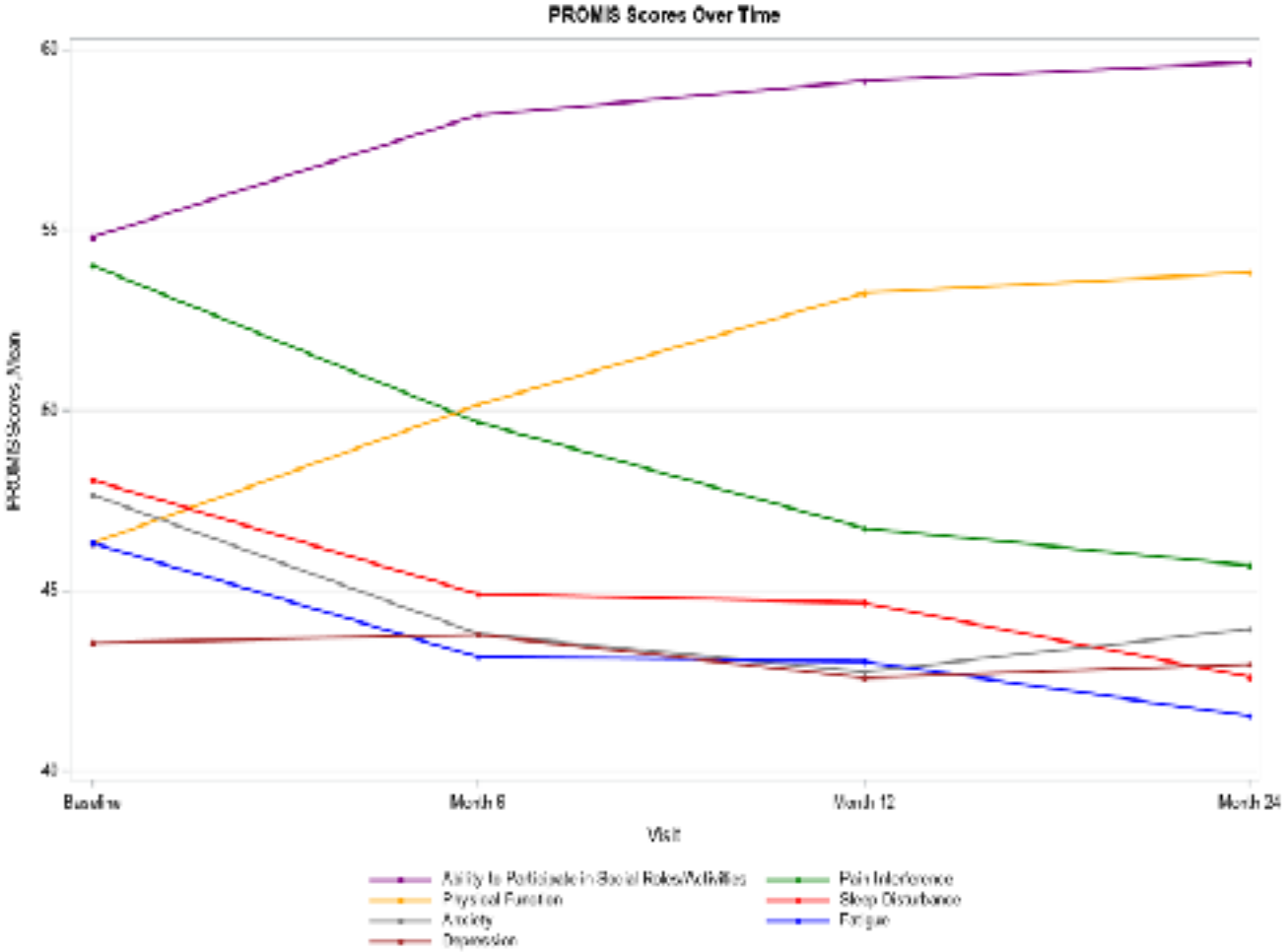


VAS Score, Mean (95% CI)					
Baseline (N=66)	Week 6 (N=66)	Month 4 (N=65)	Month 6 (N=63)	Month 12 (N=58)	Month 24 (N=35)
4.0 (3.5, 4.4)	1.7 (1.4, 2.1)	1.8 (1.5, 2.2)	1.9 (1.6, 2.3)	1.3 (0.9, 1.6)	1.1 (0.4, 1.8)

MOxFQ Score by Domain, Mean (95% CI)				
Domain	Baseline (N=66)	Month 6 (N=63)	Month 12 (N=58)	Month 24 (N=35)
Social Interaction	37.6 (32.2, 43.0)	13.1 (9.0, 17.2)	9.3 (5.1, 13.4)	10.4 (4.6, 16.1)
Walking/ Standing	42.1 (36.2, 48.0)	24.8 (19.4, 30.2)	15.1 (10.0, 20.3)	13.2 (5.2, 21.1)
Pain	53.0 (47.8, 58.2)	29.4 (24.4, 34.5)	21.6 (16.6, 26.7)	16.7 (9.7, 23.7)

Results: Patient-Reported Outcomes

- There was statistically significant improvement in all PROMIS domain scores through 24 months, except for Depression. Statistically significant improvements were maintained through 24 months.



PROMIS-29 Scores by Domain, Mean (95% CI)*

Domain	Baseline (N=58)	6 Months (N=57)	12 Months (N=52)	24 Months (N=33)
Physical Function	46.3 (44.0, 48.6)	50.2 (48.2, 52.1)	53.3 (51.6, 54.9)	53.8 (51.5, 56.2)
Ability to Participate in Social Roles/ Activities	54.8 (52.7, 56.9)	58.2 (56.1, 60.2)	59.1 (57.3, 61.0)	59.7 (56.9, 62.4)
Pain Intensity	4.2 (3.6, 4.7)	1.8 (1.4, 2.2)	1.3 (0.9, 1.7)	1.2 (0.4, 1.9)
Pain Interference	54.0 (52.0, 56.1)	49.7 (47.5, 51.8)	46.7 (44.9, 48.6)	45.7 (43.0, 48.4)
Fatigue	46.3 (44.0, 48.6)	43.2 (40.8, 45.6)	43.0 (40.5, 45.6)	41.5 (38.3, 44.7)
Sleep Disturbance	48.1 (46.1, 50.0)	44.9 (42.6, 47.2)	44.7 (42.3, 47.1)	42.6 (40.0, 45.2)
Anxiety	47.7 (45.3, 50.0)	43.8 (42.1, 45.5)	42.8 (41.2, 45.5)	43.9 (41.3, 46.5)
Depression	43.6 (42.0, 45.1)	43.8 (42.4, 45.2)	42.6 (41.3, 43.9)	43.0 (41.0, 44.9)

*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

Results: Complications

- 4 (6.1%) of the 66 patients required non-elective reoperation due to pain related to the hardware; 1 (1.5%) patient required incisional drainage due to an infection; 1 (1.5%) patient requested hardware removal without medical indication or complication.
- 5 (7.6%) patients experienced at least one clinical complication/adverse event not requiring surgical intervention; 3 (4.5%) patients had a hardware failure (breakage).
- 1 (1.7%) patient experienced a protocol-defined non-union at 12 months.

Complications Requiring Surgical Intervention	n (%) (N=66)
Hardware removal: Pain due to Hardware	4 (6.1%)
Infection (incisional): incision drainage	1 (1.5%)
Hardware removal per patient request[a]	1 (1.5%)

[a] not considered a complication

Complications Not Requiring Surgical Intervention	n (%) (N=66)
Hardware failure, hardware not removed[b]	3 (4.5%)
Infection (incisional)	2 (3.0%)
Pain	1 (1.5%)
Wound Complication	1 (1.5%)
Pain due to non-union at 12 months*	1 (1.7%)**

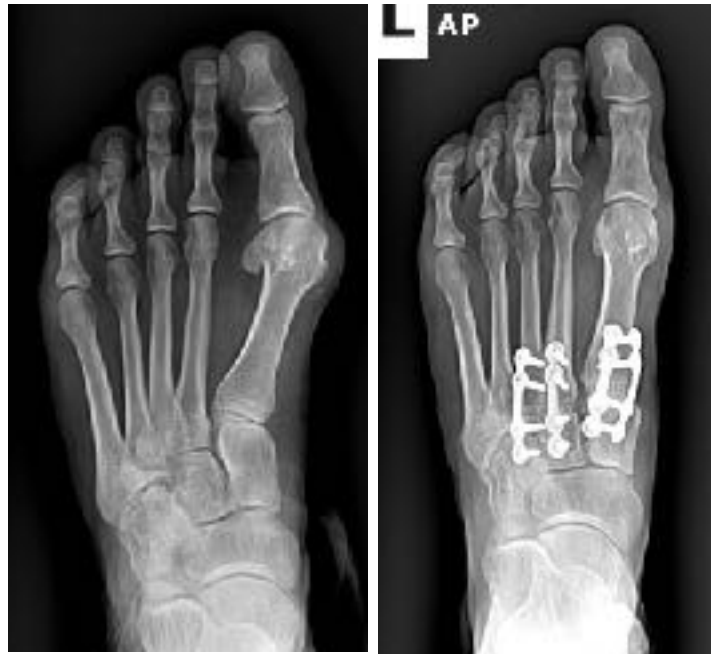
[b] not associated with an adverse event (1 broken screw at 3rd TMT; 2 broken plates at 3rd TMT;
*Non-union defined as pain and lucency at the 1st, 2nd, and/or 3rd TMT joint at 12 months post-procedure
**Sample size with 12-month data is 58

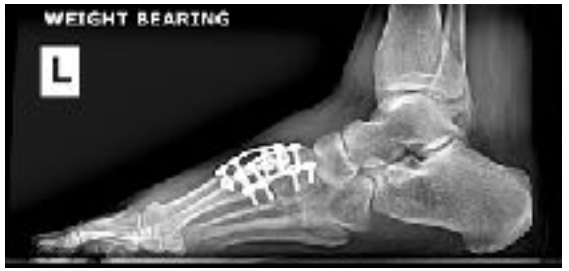
Limitations

- Interim results of a multicenter, prospective study.
- Single arm study without a control or comparison group.
- Study sites included surgeons who were considered experienced users of the 3-2-1 multiplanar correction instrumentation system.

Conclusions

- Early return to weightbearing in a CAM boot (7.6 days)
- Maintenance of IMA, HVA, TSP, MAA correction through 24 months
- Clinically significant reduction in pain (VAS) and improvement in patient reported outcomes (MOxFQ, PROMIS-29) through 24 months
- Low non-union and overall complication rate





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