Four-Year Analyses of a Five-Year Prospective Multicenter Study Assessing Radiographic and Patient Reported Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing

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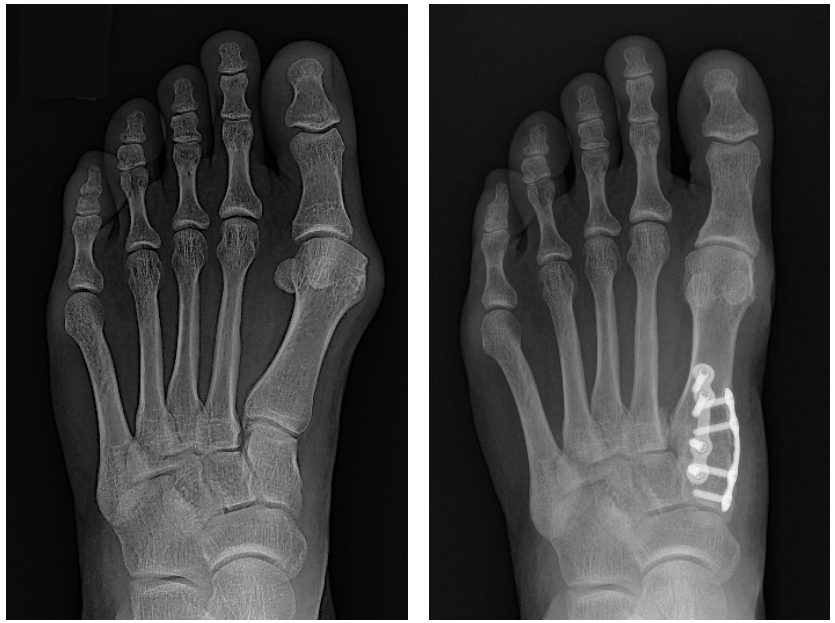
Introduction

Interim results from a 5-year prospective multicenter study to evaluate the use of an instrumented system for triplanar 1st TMT correction of HV deformities:

- Reproducibility of correction
- Outcomes of early weightbearing
- Long-term maintenance of correction
- Patient-reported outcomes



Study Methods

ALIGN3D™ prospective multicenter study (7 sites and 13 surgeons)**:** 5-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 ≥ 23°
- Moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex
- Current use of nicotine

Radiographic readers: Two independent fellowship trained musculoskeletal radiologists

Outcomes evaluated:

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

Results: Demographic and Baseline Characteristics

- To date, 78% (135/173) patients have completed their 4 year visit with a mean 47.9 months.
- Early protected weightbearing in average of 8.4 days.

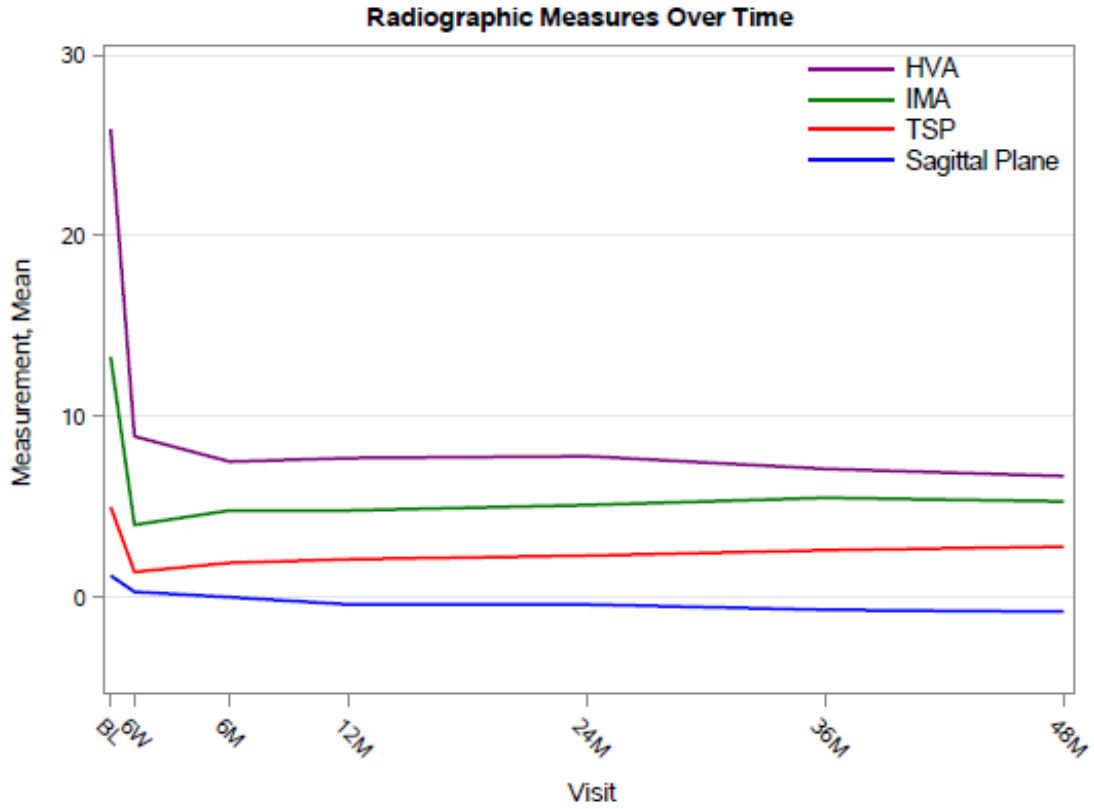
Baseline Characteristic	Category	Patient Population (N=173)
Age (years), mean (SD)		41.0 (12.0)
Sex, n (%)	Male	14 (8.1%)
	Female	159 (91.9%)
BMI (kg/m^2) mean, (SD)		26.0 (4.9)
Index Foot	Left	83 (48.0%)
	Right	90 (52.0%)
Diabetes	Yes	1 (0.6%)
	No	172 (99.4%)

Results: Radiographic Measures

- Significant improvements ($p<0.05$) from baseline observed at all post-operative timepoints indicating that improvements were maintained over time.

Radiographic Measures, Mean (95% Confidence Interval)					
Radiographic measure	**Baseline (n=173)**	**6 Week (n=171)**	**24 Month (n=155[b])**	**36 Month (n=149[c])**	**48 Month (n=133[d])**
Hallux Valgus Angle (HVA)	25.9° (24.9, 26.9)	8.9° (8.2, 9.6)	7.8° (7.0, 8.7)	7.1° (6.1, 8.1)	6.7° (5.7, 7.8)
Intermetatarsal Angle (IMA)	13.3° (12.9, 13.7)	4.0° (3.6, 4.3)	5.1° (4.7, 5.5)	5.5° (5.1, 5.9)	5.3° (4.9, 5.7)
Tibial Sesamoid Position (TSP)	5.0 (4.8, 5.1)	1.4 (1.3, 1.6)	2.3 (2.1, 2.5)	2.6 (2.4, 2.8)	2.8 (2.5, 3.0)
Sagittal-Plane Intermetatarsal Angle[a]	1.2° (0.9, 1.5)	0.3° (-0.2, 0.8)	-0.4° (-0.9, 0.0)	-0.7° (-1.2, -0.2)	-0.8° (-1.3, -0.3)

[a] Sagittal Plane Intermetatarsal Angle (dorsiflexion is positive value)
[b] Sample size for sagittal plane intermetatarsal angle at 24 months is 156
[c] Sample size for sagittal plane intermetatarsal angle at 36 months is 147
[d] Sample size for sagittal plane intermetatarsal angle at 48 months is 132



Results: Radiographic Recurrence

- Recurrence was defined using two thresholds: Post-op HVA >20° or HVA >15°.
- At 48 months, 0.8% with HVA >20 and 7.7% with HVA >15

Visit	Recurrence Definition Rate (95% CI of the proportion)	
	HVA >20°	**HVA >15°**
24 Month	0.7% (1/151) (0.02, 3.63)	7.3% (11/151) (3.69, 12.66)
36 Month	1.4% (2/146) (0.17, 4.86)	6.2% (9/146) (2.86, 11.38)
48 Month	0.8% (1/130) (0.02, 4.21)	7.7% (10/130) (3.75, 13.69)

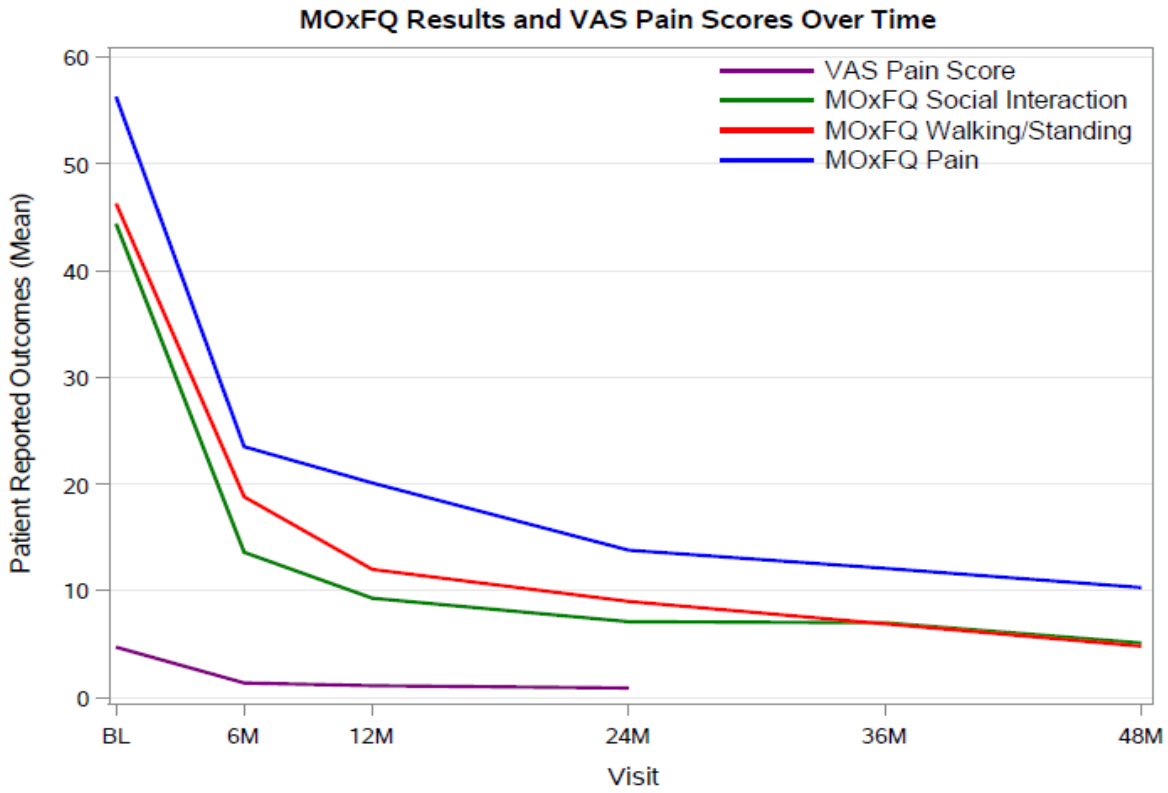
Results: Patient-Reported Outcomes

- Significant improvements ($p<0.05$) from baseline in VAS and all MOxFQ domains at all post-operative timepoints.

VAS Score, Mean (95% CI)				
Baseline (N=173)	**Week 6 (N=171)**	**Month 6 (N=160)**	**Month 12 (N=148)**	**Month 24 (N=156)**
4.7 (4.4, 5.0)	1.8 (1.5, 2.0)	1.4 (1.1, 1.6)	1.1 (0.9, 1.3)	0.9 (0.7, 1.1)

MOxFQ Score by Domain, Mean (95% CI)					
Domain	**Baseline (N=173[a])**	**6 Month (N=160)**	**12 Month (N=150)**	**24 Month (N=157)**	**48 Month (N=135)**
Social Interaction	44.4 (41.2, 47.7)	13.6 (10.6, 16.6)	9.3 (6.5, 12.1)	7.1 (4.8, 9.4)	5.1 (3.1, 7.1)
Walking/ Standing	46.3 (42.9, 49.7)	18.8 (15.5, 22.1)	12.0 (9.2, 14.8)	9.0 (6.3, 11.7)	4.8 (2.8, 6.8)
Pain	56.3 (53.2, 59.3)	23.5 (20.5, 26.5)	20.1 (16.6, 23.6)	13.8 (11.1, 16.4)	10.3 (7.8, 12.7)

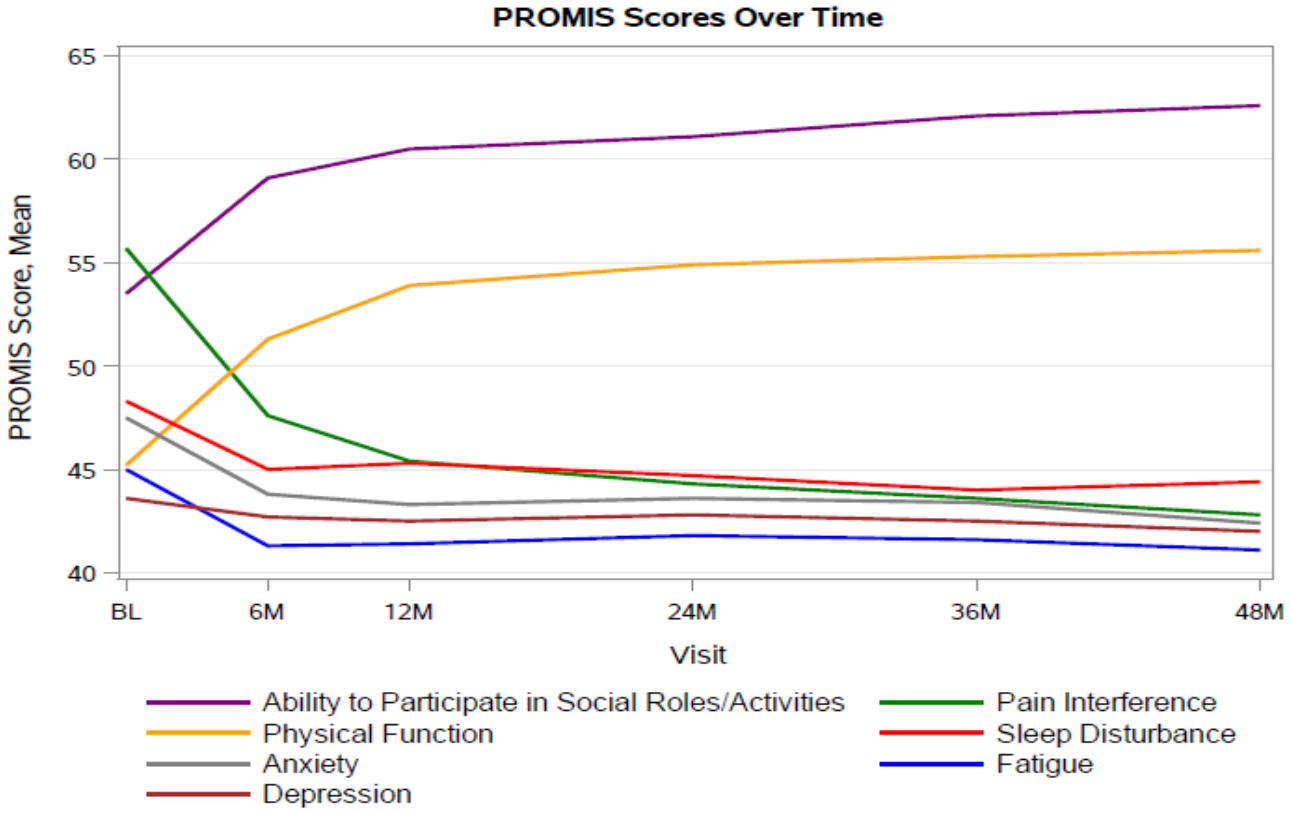
[a] Baseline N=172 for the domain of Walking/Standing



Results: Patient-Reported Outcomes

- Significant improvements ($p<0.05$) across all PROMIS domains at all post-operative timepoints except Depression which first showed significant improvement at 48 months.

PROMIS Score by Domain, Mean (95%, CI)				
Domain	**Baseline (N=163[a])**	**6 Month (N=152)**	**24 Month (N=149[b])**	**48 Month (N=127)**
Ability to Participate in Social Roles/Activities	53.5 (52.2, 54.8)	59.1 (58.0, 60.3)	61.1 (60.0, 62.1)	62.6 (61.7, 63.4)
Physical Function	45.2 (43.9, 46.5)	51.3 (50.1, 52.5)	54.9 (54.1, 55.7)	55.6 (54.9, 56.4)
Anxiety	47.5 (46.2, 48.8)	43.8 (42.8, 44.8)	43.6 (42.6, 44.6)	42.4 (41.5, 43.3)
Depression	43.6 (42.7, 44.5)	42.7 (41.9, 43.4)	42.8 (42.1, 43.5)	42.0 (41.4, 42.6)
Pain Interference	55.7 (54.5, 56.8)	47.6 (46.4, 48.7)	44.3 (43.4, 45.1)	42.8 (42.2, 43.5)
Sleep Disturbance	48.3 (47.1, 49.4)	45.0 (43.7, 46.3)	44.7 (43.4, 46.0)	44.4 (43.0, 45.8)
Fatigue	45.0 (43.5, 46.5)	41.3 (39.9, 42.6)	41.8 (40.4, 43.2)	41.1 (39.7, 42.5)
Pain Intensity	4.5 (4.2, 4.9)	1.3 (1.1, 1.6)	0.8 (0.6, 1.0)	0.5 (0.3, 0.7)



[a] Sample size for Sleep Disturbance and Anxiety at baseline is N=162
[b] Sample size for Pain Intensity at 24 Months is N=148

Complications

- 15 (8.7%) of the 173 patients required non-elective reoperation due to the situations listed below; 4 (2.3%) patients requested hardware removal without medical indication or complication.
- 12 (6.9%) patients experienced at least one clinical complication not requiring surgical intervention.
- 2 (1.4%) patients experienced a protocol-defined non-union; one non protocol-defined non-union required operation.

Complications Requiring Surgical Intervention	N (%) N=173
Hardware removal due to pain	13 (7.5%)
Hardware removal due to infection	1 (0.6%)
Reoperation due to pain (not at TMT) and non-union*	1 (0.6%)
Hardware removal per patient request	4 (2.3%)

Note: pain reported in this table is not pain at TMT joint.

*Not a protocol defined non-union because pain was not present at TMT joint. Hardware was not removed.

**Protocol defined non-union was assessed in n=148 patients at 12 months.

Complications Not Requiring Surgical Intervention	N (%) N=173
Other pain	2 (1.2%)
Non-union**	2 (1.4%)
Infection	1 (0.6%)
Paresthesia and pain	1 (0.6%)
Post-op nerve hypersensitivity	1 (0.6%)
Wound complication	1 (0.6%)
Hardware failure (hardware not removed)	4 (2.3%)

Discussion

- Overall favorable results of first TMT arthrodesis with an early return to protected weightbearing, excellent anatomic correction, high union rates, and improvement in patient-reported outcomes.
- LaLevee (FAI 2023) recent systematic review of distal osteotomy with 5+ years follow-up found pooled recurrence rates of 64% and 10% using similar thresholds to the current study of HVA <15° and 20°, respectively[1].
- Our study revealed a recurrence rate of 0.8% and 7.7% at 48 months post-op using HVA thresholds of 20° and 15°, respectively.

Limitations

- Interim results of a 5-year multicenter, prospective study.
- Single arm study without a control or comparison group.
- Hallux valgus deformities were selected per these parameters: HVA between 16°- 40° and IMA between 10°- 22°.
- Hypermobility was not a study parameter.
- Study sites included surgeons who were considered experienced users of the HV multiplanar correction instrumentation system.

Conclusions

- Early protected weightbearing was possible in average of 8.4 days.
- Significant improvements in radiographic correction (HVA, IMA, TSP, Sagittal IMA) at 6 weeks and maintained through 48 months.
- Low radiographic recurrence of 0.8% and 7.7% at 48 months (using HVA thresholds of 20° and 15°, respectively).
- Significant improvements in patient-reported outcomes (VAS, MOxFQ, PROMIS) through 48 months.
- Low rate of non-unions.
- Low rate of clinical complications and re-operation.

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References

1. LaLevee M, de Cesar Netto C, ReSurg, Boublil D, Coillard J-Y: Recurrence Rates With Longer-Term Follow-up After Hallux Valgus Surgical Treatment With Distal Metatarsal Osteotomies: A Systematic Review and Meta-analysis. Foot Ankle Int 2023;44:210-22.10711007231152487.