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

Interim Analysis of a Prospective Multicenter Study (ALIGN3D™)

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Disclosures

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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

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Study Methods

ALIGN3D™ prospective multicenter study (7 sites and 13 surgeons): 5-year follow-up

Inclusion	Exclusion	Outcomes evaluated
14-58 years of age	Prior HV surgery	Radiographic recurrence
	BMI > 40 kg/m^2	Return to weightbearing and activities
	HbA1c ≥7	Visual Analog Scale (VAS)
Symptomatic mild, moderate, and severe HV (IMA between 10.0° - 22.0°; HVA between 16.0° - 40.0°)	Evidence of peripheral neuropathy	Manchester-Oxford Foot Questionnaire (MOxFQ)
	Metatarsus adductus ≥ 23°	Patient Reported Outcomes Measurement Information System (PROMIS)
	Moderate to severe osteoarthritis of the 1st MTP joint	Complications
	Current use of nicotine	

Radiographic readers: Two independent fellowship trained musculoskeletal radiologists

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Results: Demographic and Baseline Characteristics

- 146/173 (84.4%) patients have completed the 48 month follow up visit to date.
- 92/173 (53.2%) patients have completed the 60 month follow up visit to date.

Baseline Characteristics	Category	Patient Population	
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%)

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Results: Weightbearing

- Return to early, protected weightbearing within an average of 8.4 days (SD=7.43).
- Return to weightbearing in a shoe within an average of 6.6 weeks (SD=1.57).
- Return to full, unrestricted activities within an average of 4.0 months (SD=1.15).

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Example Radiographic Results


Baseline


6 Week


4 Month


6 Month


12 Month


24 Month


36 Month


48 Month


60 Month

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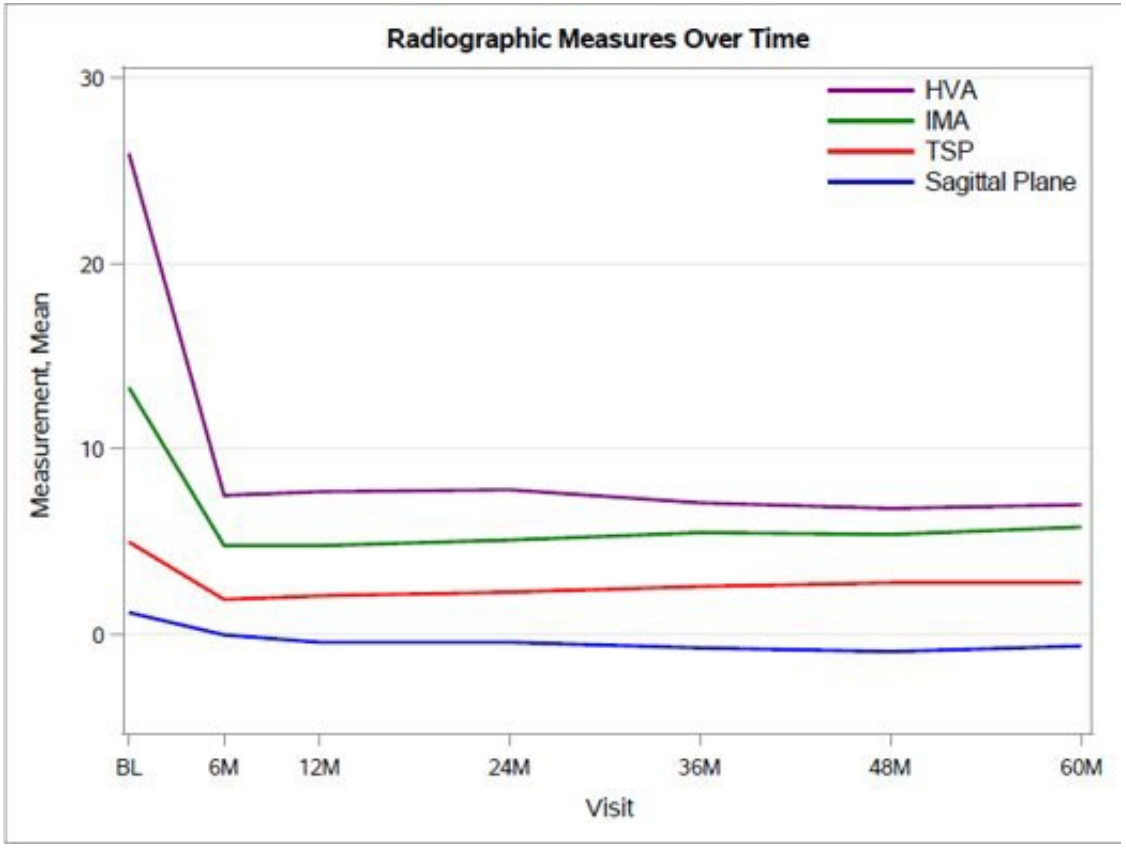
Results: Radiographic Measures

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



Radiographic Measures, Mean (95% CI)

Visit	Baseline (N=173)	6 Week (N=171)	24 month (N=155[b])	36 month (N=149[c])	48 month (N=146[d])	60 month (N=87)
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)	6.8° (5.9, 7.8)	7.0° (5.7, 8.3)
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)	5.4° (5.0, 5.8)	5.8° (5.2, 6.4)
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 (2.6, 3.0)	2.8 (2.5, 3.1)
Sagittal Plane[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)	-0.9° (-1.4, -0.4)	-0.6° (-1.2, 0.1)

[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 145

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Results: Radiographic Recurrence

- Recurrence was defined using two thresholds: Post-op HVA >20° or HVA >15°.

Visit	Recurrence Definition Rate (95% CI of the proportion)	
	HVA >20°	HVA >15°
48 Month	0.7% (1/143) (0.02, 3.83)	7.7% (11/143) (3.90, 13.35)
60 Month	0.0% (0/84)	4.8% (4/84) (1.31, 11.75)

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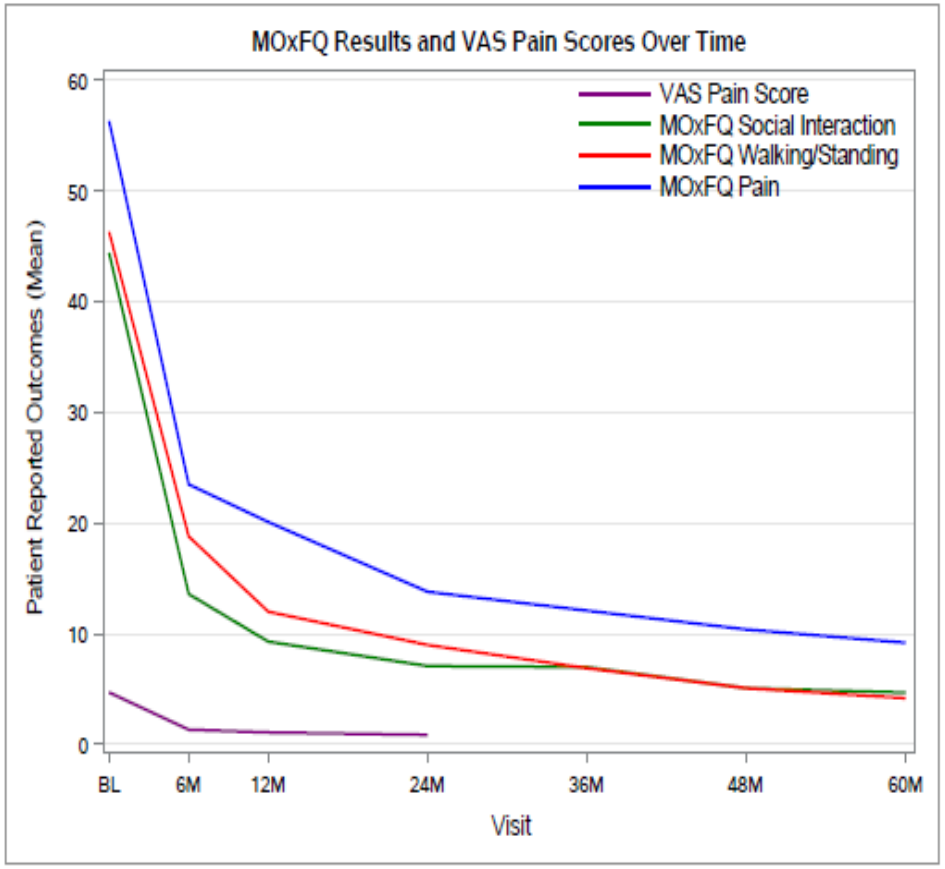
Results: Patient-Reported Outcomes

- 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)**	**36 Month (N=150)**	**48 Month (N=146)**	**60 Month (N=92)**
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)	7.0 (4.7, 9.4)	5.1 (3.2, 7.0)	4.7 (2.6, 6.8)
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)	6.9 (4.6, 9.2)	5.1 (3.2, 7.0)	4.2 (2.1, 6.3)
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)	12.1 (9.6, 14.7)	10.4 (8.0, 12.7)	9.2 (6.2, 12.3)

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

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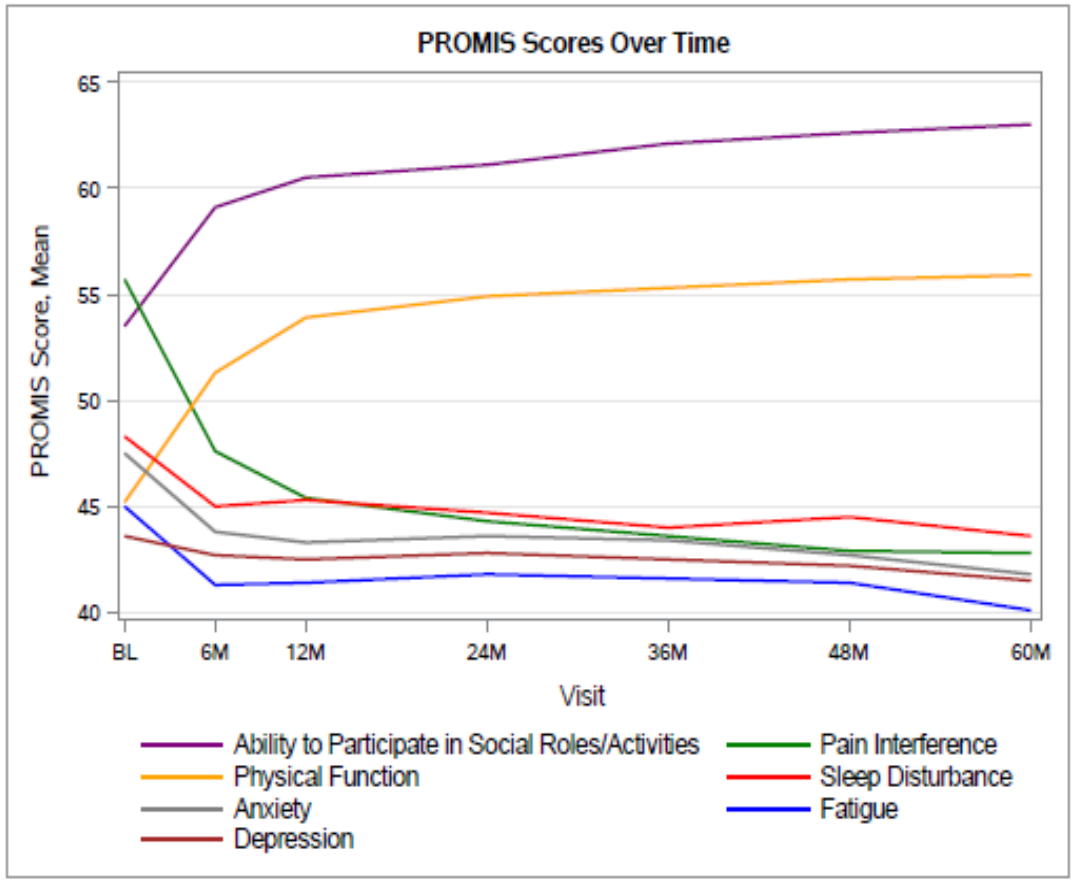
Results: Patient-Reported Outcomes

- Significant improvements ($p<0.05$) across all PROMIS domains at all post-operative timepoints except Depression which exhibited sustained improvement starting 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=138)**	**60 Month (N=89)**
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 (61.8, 63.3)	63.0 (62.3, 63.8)
Physical Function	45.2 (43.9, 46.5)	51.3 (50.1, 52.5)	54.9 (54.1, 55.7)	55.7 (55.0, 56.4)	55.9 (55.1, 56.7)
Anxiety	47.5 (46.2, 48.8)	43.8 (42.8, 44.8)	43.6 (42.6, 44.6)	42.7 (41.8, 43.6)	41.8 (40.9, 42.7)
Depression	43.6 (42.7, 44.5)	42.7 (41.9, 43.4)	42.8 (42.1, 43.5)	42.2 (41.6, 42.8)	41.5 (41.1, 42.0)
Pain Interference	55.7 (54.5, 56.8)	47.6 (46.4, 48.7)	44.3 (43.4, 45.1)	42.9 (42.3, 43.5)	42.8 (42.1, 43.6)
Sleep Disturbance	48.3 (47.1, 49.4)	45.0 (43.7, 46.3)	44.7 (43.4, 46.0)	44.5 (43.1, 45.9)	43.6 (41.9, 45.4)
Fatigue	45.0 (43.5, 46.5)	41.3 (39.9, 42.6)	41.8 (40.4, 43.2)	41.4 (39.9, 42.8)	40.1 (38.3, 41.8)
Pain Intensity	4.5 (4.2, 4.9)	1.3 (1.1, 1.6)	0.8 (0.6, 1.0)	0.5 (0.4, 0.7)	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

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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%)

*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%)

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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 0.7% and 7.7% at 48 months and 0.0% and 4.8% at 60 months post-op using HVA thresholds of 20° and 15°, respectively.

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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.

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Conclusions

- Early protected weightbearing within 8.4 days on average.
- Significant improvements in radiographic correction (HVA, IMA, TSP, Sagittal IMA) at 6 weeks and maintained through 60 months.
- Low radiographic recurrence at 48 months and 60 months (using HVA thresholds of 20° and 15°, respectively).
- Significant improvements in patient-reported outcomes (VAS, MOxFQ, PROMIS) through 48 and 60 months.
- Low rate of non-unions.
- Low rate of clinical complications and re-operation.

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