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

Interim Analysis of a Prospective Multicenter Study (ALIGN3D)

Scientific Conference

ACFAS 2024

February 1-4 • Tampa

Daniel J Hatch, DPM, FACFAS

Foot & Ankle Center of the Rockies

American College of Foot and Ankle Surgeons®

Proven leaders. Lifelong learners. Changing lives.

Authors*

Hatch[1], Chhabra[2], Dayton[3], McAleer[4], Kile[5], Santrock[6], Taylor[7]

[1] Foot and Ankle Center of the Rockies, Greeley, CO
[2] University of Texas Southwestern Medical Center, Dallas TX
[3] Foot and Ankle Center of Iowa, Ankeny, IA
[4]Jefferson City Medical Group, Jefferson City, MO
[5] Treace Medical Concepts, Inc
[6] Dovetail Orthopedics, Amelia Island, FL/Duke University, Durham, NC
[7] Stonebriar Foot and Ankle, Frisco, TX

Disclosures

- Study was funded by Treace Medical Concepts, Inc.

*All authors are considered consultants and/or receive royalties and/or research funding from Treace Medical Concepts, Inc.

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

- 173 patients with a mean 33.8 months of follow up and latest post-op visit at a mean of 40.5 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 category	Underweight	4 (2.3%)
	Normal Weight	77 (44.5%)
	Overweight	58 (33.5%)
	Obese	34 (19.7%)
Index Foot	Left	83 (48.0%)
	Right	90 (52.0%)
Diabetes	Yes	1 (0.6%)
	No	172 (99.4%)

*latest post-operative visit average is calculated as months to latest follow-up visit in patients with 36m and/or 48m visit data

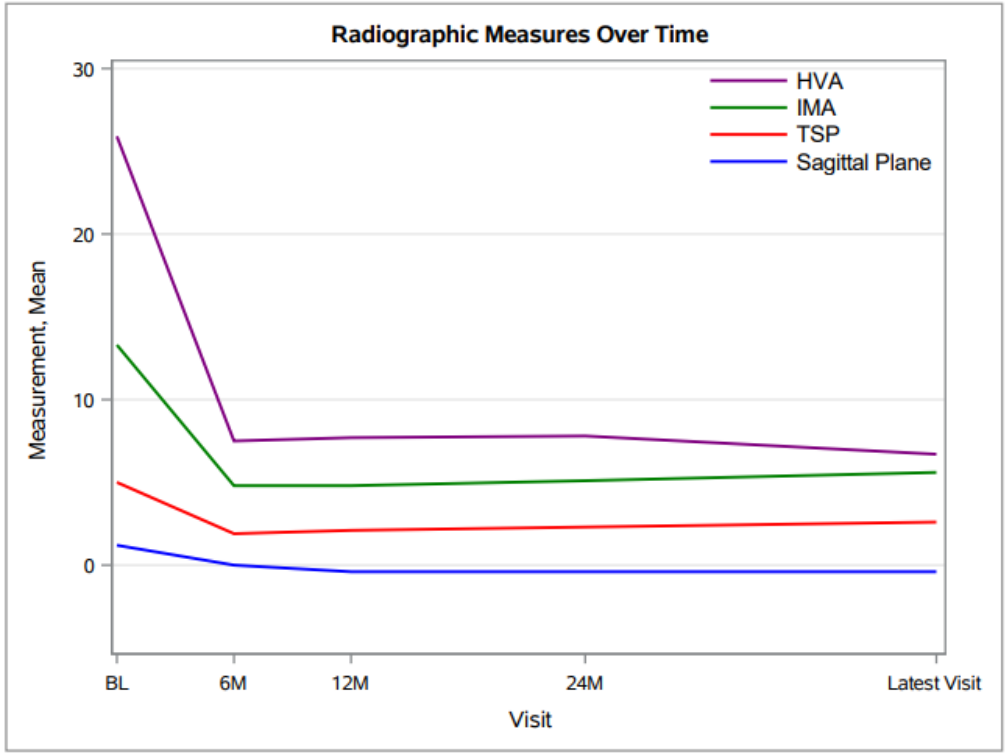
Results: Radiographic Measures

- Significant improvements from baseline observed at all post-operative timepoints ($p<0.05$) through latest post-op visit (mean of 40.5 months)
- Improvements were maintained over time

Radiographic Measures, Mean (95% CI)

Visit	HVA	IMA	TSP	Sagittal Plane[a]
Baseline (N=173)	25.9° (24.9, 26.9)	13.3° (12.9, 13.7)	5.0 (4.8, 5.1)	1.2° (0.9, 1.5)
6 Week (N=171)	8.9° (8.2, 9.6)	4.0° (3.6, 4.3)	1.4 (1.3, 1.6)	0.3° (-0.2, 0.8)
6 Month (N=160)	7.5° (6.7, 8.4)	4.8° (4.5, 5.2)	1.9 (1.7, 2.1)	0.0° (-0.4, 0.5)
12 Month (N=147)	7.7° (6.7, 8.7)	4.8° (4.4, 5.1)	2.1 (1.9, 2.3)	-0.4° (-0.9, 0.1)
24 Month (N=155[b])	7.8° (7.0, 8.7)	5.1° (4.7, 5.5)	2.3 (2.1, 2.5)	-0.4° (-0.9, 0.0)
Latest Visit[c] (N=118[d])	6.7° (5.6, 7.8)	5.6° (5.1, 6.0)	2.6 (2.4, 2.9)	-0.4° (-0.9, 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] Latest post-operative visit average is calculated as months to latest follow-up visit in patients with 36m and/or 48m visit data
[d] Sample size for sagittal plane intermetatarsal angle at Latest Visit is 117



Results: Radiographic Recurrence

- Recurrence was defined using two thresholds: HVA >15° or HVA >20°
- At the 24-month post-op visit, rates ranged from 7.3% to 0.7% depending on definition
- At the latest post-op visit, rates ranged from 5.2% to 0.9% depending on definition

Visit	Recurrence Definition Rate (95% CI of the proportion)	
	HVA > 15°	**HVA > 20°**
24-Month Visit	7.3% (11/151) (3.69%, 12.66%)	0.7% (1/151) (0.02%, 3.63%)
Latest Visit*	5.2% (6/115) (1.94%, 11.01%)	0.9% (1/115) (0.02%, 4.75%)

*latest post-operative visit average is calculated as months to latest follow-up visit in patients with 36m and/or 48m visit data (mean of 40.5 months)

Results: Patient-Reported Outcomes

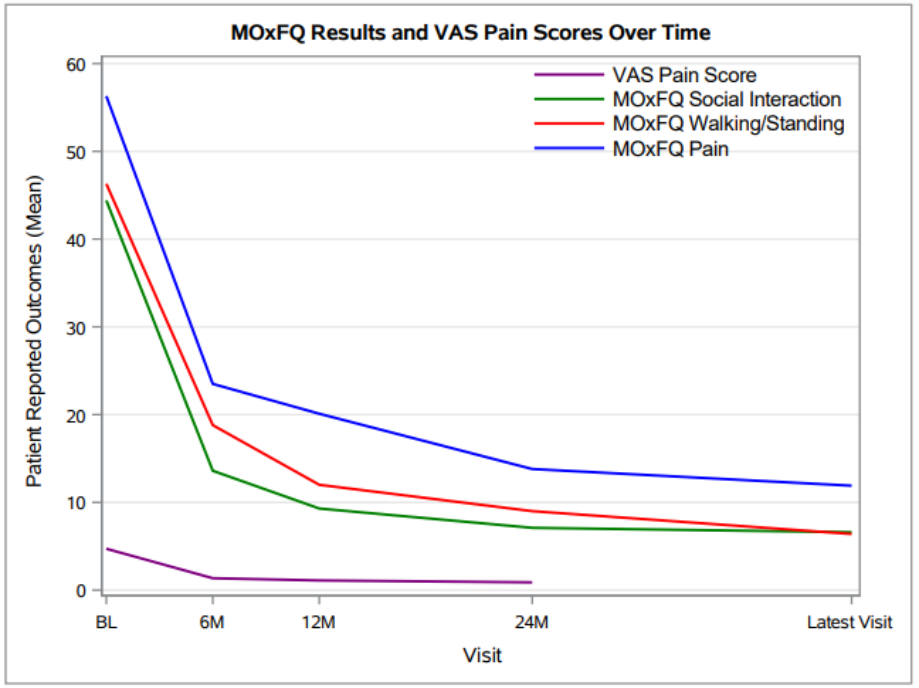
- Significant improvement in VAS and all MOXFQ domains from baseline observed at all post-operative timepoints ($p<0.05$)

MOxFQ Score by Domain, Mean (95% CI)

Domain	Baseline N=173	6 Month N=160	12 Month N=150	24 Month N=157	Latest Visit N=118
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)	6.6 (3.8, 9.4)
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)	6.4 (3.8, 9.0)
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)	11.9 (9.0, 14.7)

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)

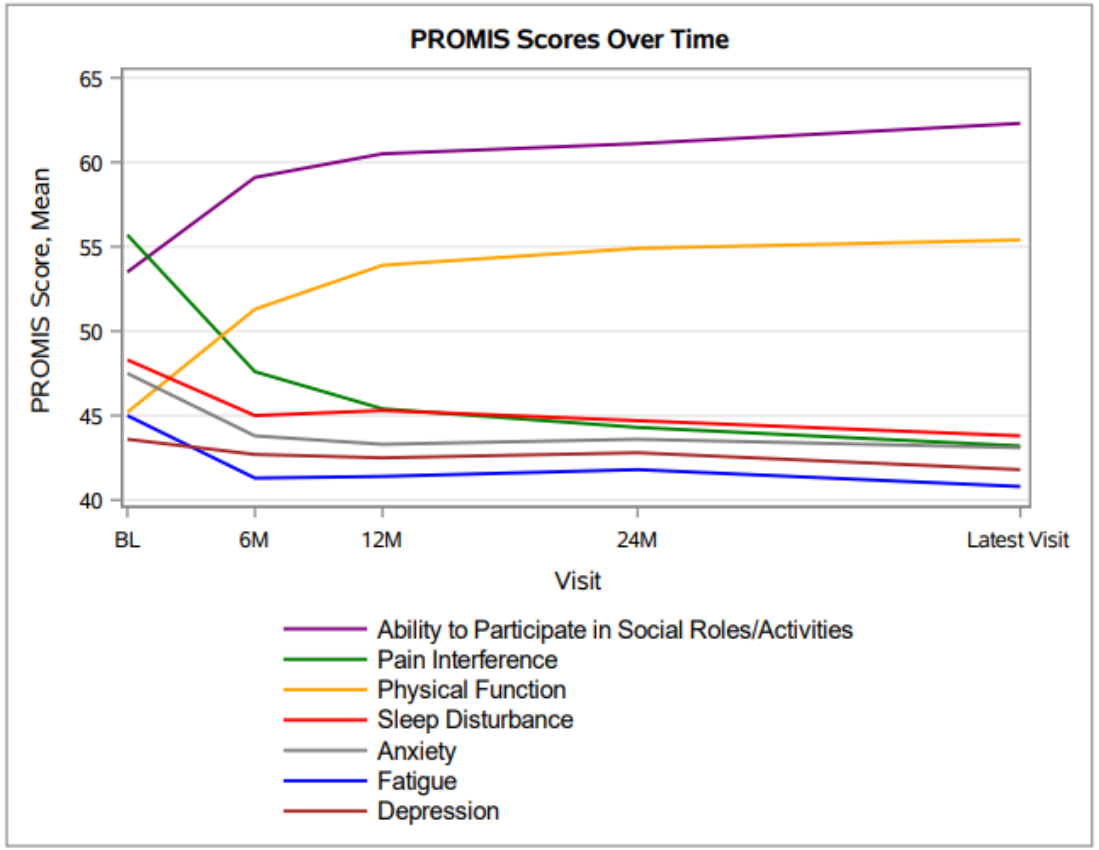


Results: Patient-Reported Outcomes

- Significant improvements across all PROMIS domains

PROMIS Score by Domain, Mean (95% CI)

Domain	Baseline (N=163)	6 Month (N=152)	12 Month (N=142)	24 Month (N=149)	Latest Visit (N=113)
Ability to Participate in Social Roles/Activities	53.5 (52.2, 54.8)	59.1 (58.0, 60.3)	60.5 (59.2, 61.7)	61.1 (60.0, 62.1)	62.3 (61.3, 63.3)
Anxiety	47.5 (46.2, 48.8)	43.8 (42.8, 44.8)	43.3 (42.3, 44.3)	43.6 (42.6, 44.6)	43.1 (42.0, 44.2)
Depression	43.6 (42.7, 44.5)	42.7 (41.9, 43.4)	42.5 (41.7, 43.2)	42.8 (42.1, 43.5)	41.8 (41.3, 42.4)
Fatigue	45 (43.5, 46.5)	41.3 (39.9, 42.6)	41.4 (40.0, 42.8)	41.8 (40.4, 43.2)	40.8 (39.4, 42.3)
Pain Intensity	4.5 (4.2, 4.9)	1.3 (1.1, 1.6)	1.1 (0.9, 1.4)	0.8 (0.6, 1.0)	0.6 (0.4, 0.8)
Pain Interference	55.7 (54.5, 56.8)	47.6 (46.4, 48.7)	45.4 (44.3, 46.5)	44.3 (43.4, 45.1)	43.2 (42.3, 44.0)
Physical Function	45.2 (43.9, 46.5)	51.3 (50.1, 52.5)	53.9 (53, 54.9)	54.9 (54.1, 55.7)	55.4 (54.5, 56.3)
Sleep Disturbance	48.3 (47.1, 49.4)	45.0 (43.7, 46.3)	45.3 (44.0, 46.6)	44.7 (43.4, 46.0)	43.8 (42.2, 45.3)



Complications

- 14 (8.1%) of the 173 patients required non-elective reoperation; 2 (1.2%) of patients elected to have hardware removed
- 13 (7.5%) of patients experienced at least one clinical complication not requiring surgical intervention
- Symptoms for 6 patients were ongoing at the time of data analysis; symptoms for four patients were mild in severity (pain [n=3] nerve hypersensitivity [n=1]) and symptoms for two patients were moderate (pain)
- 3 (1.8%) patients experienced symptomatic non-union (one requiring reoperation)

Complications Requiring Surgical Intervention	**n (%) N=173**	**Complications Not Requiring Surgical Intervention**	**n (%) N=173**
Hardware removal due to pain	12 (6.9%)	Hardware failure (hardware not removed)	4 (2.3%)
Hardware removal per patient request	2 (1.2%)	Other pain	3 (1.7%)
Hardware removal due to infection	1 (0.6%)	Non-union**	2 (1.2%)
Reoperation due to pain and non-union*	1 (0.6%)	Infection	1 (0.6%)
		Paresthesia and pain	1 (0.6%)
		Post-op nerve hypersensitivity	1 (0.6%)
		Wound complication	1 (0.6%)

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.
**One patient also reported pain (not at TMT joint)

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
- Recurrence rates for osteotomy procedures have been reported ranging from 30-78% (1, 2, 3, 4)
  - Some lower rates have been reported but definition of recurrence wasn't defined
- 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 (5)
- Our study revealed a recurrence rate of 5.2% and 0.9% at latest post-op visit using HVA thresholds of 15° and 20°, respectively

1. Lagaay et al. JFAS 2008; 2. Pentikainen et al. FAI 2014; 3. Bock et al. JBJS 2015; 4. Jeuken et al. FAI 2016; 5. LaLevee et al. FAI 2023

Limitations

- Interim results of a 5 year multicenter, prospective study
- 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
- Single arm study without a control or comparison group

Conclusions

- Early protected weightbearing in average of 8.4 days
- Significant improvements in radiographic correction (HVA, IMA, TSP, Sagittal IMA) at 6 weeks and maintained through latest visit
- Low radiographic recurrence of 5.2% and 0.9% at latest visit (using HVA thresholds of 15° and 20°, respectively)
- Significant improvements in patient-reported outcomes (VAS, MOxFQ, PROMIS) through latest visit*
- Low symptomatic non-union rate of 1.8%
- Low rate of clinical complications and re-operation

*VAS only measured through 24 months

Acknowledgements

➢Thank you to our participating Principal Investigators and study sites.

- Jefferson City Medical Group, Jefferson City, MO
  - Jody P. McAleer, DPM, FACFAS
  - William J. Duke, DPM, FACFAS
- Foot and Ankle Center of Iowa/Midwest Bunion Center, Ankeny, IA
  - Paul D. Dayton, DPM, MS, FACFAS
  - Mindi J. Dayton, DPM, MHA, FACFAS
- University of Texas Southwestern Medical Center, Dallas, TX
  - Dane K. Wukich, MD (Lead PI)
  - George T. Liu, DPM, FACFAS
  - Michael D. VanPelt, DPM, FACFAS
  - Katherine M. Raspovic, DPM, FACFAS
- Foot and Ankle Center of the Rockies, Greeley, CO
  - Daniel J. Hatch, DPM, FACFAS
- Stonebriar Foot & Ankle, Frisco, TX
  - Robert P. Taylor, DPM, FACFAS
- University of Pennsylvania Medicine, Perelman School of Medicine, Philadelphia, PA
  - Daniel C. Farber, MD
- Desert Orthopaedic Center, Las Vegas, NV
  - Abdi Raissi, MD

References

1. Lagaay PM, Hamilton GA, Ford LA, Williams ME, Rush SM, Schuberth JM: Rates of revision surgery using Chevron-Austin osteotomy, Lapidus arthrodesis, and closing base wedge osteotomy for correction of hallux valgus deformity. J Foot Ankle Surg 2008;47:267–72.
2. Pentikainen I, Ojala R, Ohtonen P, Piippo J, Leppilahti J: Preoperative radiological factors correlated to long-term recurrence of hallux valgus following distal chevron osteotomy. Foot Ankle Int 2014;35:1262–7.
3. Bock P, Kluger R, Kristen KH, Mittlböck M, Schuh R, Trnka HJ: The Scarf Osteotomy with Minimally Invasive Lateral Release for Treatment of Hallux Valgus Deformity: Intermediate and Long-Term Results. J Bone Joint Surg Am The American Orthopedic Association; 2015; 97:1238–45.
4. Jeuken RM, Schotanus MGM, Kort NP, Deenik A, Jong B, Hendrickx RPM: Long-term Follow-up of a Randomized Controlled Trial Comparing Scarf to Chevron Osteotomy in Hallux Valgus Correction. Foot Ankle Int 2016;37:687–95.
5. 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.

M2736A