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

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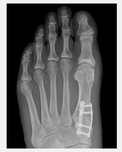
Introduction



- **Some traditional metatarsal osteotomies demonstrate high recurrence rates**
  - 30% recurrence Scarf at 10 yrs[1]
  - 73% recurrence distal chevron at 14 yrs[2]
- **87% of HV deformities are three-dimensional with frontal-plane metatarsal rotation[3]**
  - 12x recurrence risk when frontal-plane deformity not corrected[4]
- **Instrumented system developed for reproducible triplanar 1st TMT arthrodesis with early weight-bearing (*Lapiplasty® System, Treace Medical Concepts, Ponte Vedra, FL)***
  - Method of "correct then cut" to minimize shortening and obtain optimal 3D correction
  - Biplanar plating with early (7.8 days avg) return to weight-bearing in a CAM boot*[5]

*Interim analysis from the ALIGN3D study of 117 patients with at least 12 months of follow-up of whom 40 patients have at least 24 months of follow-up (out of 173 total study patients).

Purpose

Assess interim results from a 5-year prospective, multicenter study (ALIGN3D™ Study) to evaluate radiographic correction/recurrence and healing, return to weight-bearing/activity, pain and patient-reported outcomes, clinical complications, and range of motion in patients undergoing instrumented triplanar HV correction with biplanar plating and protected early weightbearing.

Methodology & Procedure

- **Prospective multicenter study:** 5-year post-operative follow up
- **Key Inclusion Criteria:** Age: 14-58 years with symptomatic HV (IMA and HVA between 10.0-22.0° and 16.0-40.0°, respectively); treatment with Lapiplasty® Procedure
- **Key Exclusion criteria:** Prior HV surgery; BMI > 40 kg/m2; 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 musculoskeletal radiologists through 24-month follow-up; starting at 36m, only one radiologist performed the reads
- **Outcomes evaluated:** Radiographic correction, return to weightbearing and activities, pain measured by visual analog scale (VAS), Manchester-Oxford Foot Questionnaire (MOxFQ), patient satisfaction, as well as clinical complications

References

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Results: Patient Demographics

The interim results of 128 patients with **mean (SD) follow-up of 28.9 (5.9) months**

Baseline Characteristic	Category	Value
Age (yrs), Median (Min, Max)		42 (15, 58)
Sex, n (%)	Female	115 (89.8%)
BMI, Median (Min, Max)		25 (17, 40)
Foot, n (%)	Right	66 (51.6%)
Diabetes, n (%)	Yes	1 (0.8%)

Radiographic Measures

Significant **improvement over baseline in radiographic measures (HVA, IMA, TSP)** through 36 mo post-op. 1/114 (0.9%) and 0/34 (0.0%) patients exhibited recurrence by 24m and 36m, respectively

Radiographic Measures, Mean (95% Confidence Interval)						
Radiographic Measure	**Baseline (n=128)**	**6 Week (n=126)**	**6 Month (n=123)**	**12 Month (n=115)**	**24 Month (n=118)****	**36 Month (n=34)**
Hallux Valgus Angle (HVA)	25.3° (24.1, 26.5)	8.8° (7.9, 9.7)	7.2° (6.1, 8.2)	7.3° (6.2, 8.5)	7.7° (6.7, 8.7)	5.9° (3.9, 8.0)
Intermetatarsal Angle (IMA)	13.2° (12.7, 13.7)	4.0° (3.6, 4.4)	4.7° (4.3, 5.1)	4.8° (4.3, 5.2)	5.2° (4.7, 5.6)	5.9° (4.5, 7.4)
Tibial Sesamoid Position (TSP)	4.9 (4.7, 5.1)	1.4 (1.3, 1.6)	1.9 (1.7, 2.1)	2.1 (1.9, 2.3)	2.2 (2.0, 2.5)	2.1 (1.8, 2.5)
Sagittal-Plane Intermetatarsal Angle*	1.4° (1.0, 1.7)	0.6° (0.0, 1.1)	0.2° (-0.3, 0.7)	-0.3° (-0.8, 0.3)	-0.1° (-0.7, 0.4)	0.2° (-0.6, 0.9)

*Dorsiflexion is positive value ** Sample size at 24 months for sagittal-plane intermetatarsal angle is n=119

Patient Reported Outcomes

Significant **improvement over baseline in VAS** through 24 mo post-op and significant **improvement over baseline in MOxFQ** through 36 mo post-op

VAS Mean (95% Confidence Interval)					
Measure	**Baseline (n=128)**	**6 Week (n=126)**	**6 Month (n=124)**	**12 Month (n=116)**	**24 Month (n=128)**
VAS Pain Score	4.7 (4.4, 5.1)	1.8 (1.5, 2.0)	1.3 (1.0, 1.6)	1.0 (0.8, 1.2)	0.9 (0.7, 1.1)

MOxFQ, Mean (95% Confidence Interval)										
Measure	**N**	**Baseline**	**N**	**6 Month**	**N**	**12 Month**	**N**	**24 Month**	**N**	**36 Month**
MOxFQ (Walk/Stand)	127	46.9 (42.9, 50.8)	124	17.4 (13.6, 21.2)	118	11.6 (8.4, 14.7)	128	8.5 (5.6, 11.3)	41	3.5 (0.7, 6.3)
MOxFQ (Pain)	128	56.4 (52.7, 60.1)	124	22.5 (19.1, 25.9)	118	19.1 (15.4, 22.8)	128	12.8 (10.0, 15.5)	41	10.2 (6.5, 14.0)
MOxFQ (Social Interaction)	128	46.1 (42.2, 50.0)	124	13.2 (9.7, 16.7)	118	9.0 (5.9, 12.0)	128	6.6 (4.1, 9.0)	41	4.6 (1.9, 7.3)
MOxFQ (Index Score)	127	49.5 (46.0, 53.0)	124	18.0 (14.6, 21.3)	118	13.3 (10.2, 16.3)	128	9.3 (6.8, 11.9)	41	5.9 (3.4, 8.3)

Return to Weight-bearing

Patients underwent an **early weightbearing** protocol

Post-Operative Time to Return to Activity/Work	
Activity	**Mean (95% Confidence Interval)**
Weightbearing in CAM boot (days, n=128)	8.1 (6.9, 9.3)
Return to athletic/running shoes (weeks, n=128)	6.6 (6.3, 6.8)
Return to unrestricted activity (months, n=127)	4.1 (3.9, 4.3)

Patient Reported Outcomes

At 36 months post-op, **satisfaction with overall results of the procedure was 97.3%** with satisfaction in specific aspects of the procedure ranging from 78.4% to 91.9%

Mean (95% Confidence Interval) N=37		
Measure		**Number (%)**
Satisfaction with overall results of procedure	Satisfied / Very Satisfied Very Unsatisfied	36 (97.3%) 1 (2.7%)
Would you recommend procedure to your relatives?	Yes No	35 (94.6%) 2 (5.4%)
Satisfaction on specific aspect of the procedure: Pain	Satisfied / Very Satisfied Neutral Very Unsatisfied	31 (83.8%) 4 (10.8%) 2 (5.4%)
Satisfaction on specific aspect of the procedure: Function	Satisfied / Very Satisfied Neutral Very Unsatisfied	32 (86.5%) 2 (5.4%) 3 (8.1%)
Satisfaction on specific aspect of the procedure: Alignment	Satisfied / Very Satisfied Very Unsatisfied	34 (91.9%) 3 (8.1%)
Satisfaction on specific aspect of the procedure: Aesthetics	Satisfied / Very Satisfied Neutral Unsatisfied Very Unsatisfied	29 (78.4%) 5 (13.5%) 1 (2.7%) 2 (5.4%)

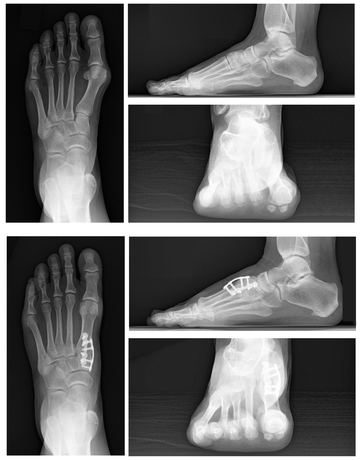
Clinical Complications

Limited clinical complications: **9 (7.0%) of the 128 patients required non-elective reoperation** whereas 2 (1.6%) elected to have hardware removed.

Clinical Complications/Adverse Events			
Complication	**Number (%)**	**Complication**	**Number (%)**
Hardware removal *(due to pain)*	8/128 (6.3%)	Pain*	4/128 (3.1%)
Hardware failure *(hardware not removed)*	5/128 (3.9%)	Wound complication	1/128 (0.8%)
Hardware removal *(per patient request)*	2/128 (1.6%)	Post-op nerve hypersensitivity	1/128 (0.8%)
Hardware removal *(due to bursal cyst)*	1/128 (0.8%)	Paresthesia	1/128 (0.8%)

*Includes 1 patient who underwent reoperation for non-union

Representative Pre- and 36-month Post-Op Radiographs



Discussion

Hallux valgus recurrence rates in the literature for metatarsal osteotomies can range up to 30-78%.[1,2] Patient dissatisfaction reported by Chong et al. was 25.9% after 5.2 years follow up.[6] Our study revealed a 0.9% recurrence rate by 2 years. In those patients with 36m radiographic data (n=34), similar trends are reported.

Conclusion

Results demonstrate favorable clinical and patient reported outcomes 3 years post-procedure.

- Early weight-bearing in a CAM boot (**mean 8.1 days**).
- Radiographic HV **maintenance of correction** (IMA, HVA, TSP).
- 1/114 (0.9%) patient exhibited recurrence by 24m with similar trends being seen by 36m
- Favorable patient reported outcomes (VAS, MOxFQ), patient satisfaction of **97.3%.**

Disclosures

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Daniel Hatch, DPM serves as a consultant and receives research funding from Treace Medical Concepts, Inc. He is also JFAS Section Editor.

Paul Dayton, DPM serves as a consultant and receives research funding from Treace Medical Concepts, Inc. He is also JFAS Section Editor.

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