

# Interim Analysis of ALIGN3D™ Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following the Lapiplasty® Procedure

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## Introduction

Traditional approaches to hallux valgus (HV) correction have been primarily based on a two-dimensional (2D) analysis of the deformity, with a focus on the transverse plane severity. Accordingly, the most common surgical approaches for HV correction have involved 2D metatarsal osteotomies. Though these methods are routinely used, such approaches have been associated with radiographic recurrence rates ranging up to 30-73%.<sup>1-3\*</sup>

Hallux valgus has been increasingly recognized as a triplanar deformity, with a 3D CT study indicating that approximately 87% of bunions involve a pronated position of the metatarsal in the frontal plane.<sup>4</sup> Failure to address the triplanar components of the deformity, such as incomplete sesamoid reduction and uncorrected metatarsal lateral round sign, have been associated with a 10- and 12- fold increased risk for HV recurrence, respectively.<sup>5,6</sup> Thus, restoration of radiographic alignment in all three planes has been recognized as an important factor in potentially reducing the chance of recurrence after HV surgery.

A new method of HV correction was developed for triplanar correction for first tarsometatarsal (TMT) arthrodesis using precision instrumentation and a biplanar plating construct for stability (Lapiplasty® System). The initial retrospective reports of this method have demonstrated successful radiographic correction of the triplanar deformity, early return to weightbearing in a walker boot, and low complication rates.<sup>7,8</sup> The purpose of this paper was to report interim findings of the ALIGN3D™ prospective, multicenter study on radiographic, clinical, and patient reported outcomes after triplanar first TMT arthrodesis and early weightbearing with the Lapiplasty® System.

## Methods

This is an interim report of an ongoing prospective, multicenter, clinical study (ALIGN3D™) with seven US centers and thirteen foot and ankle surgeons. This study analyzed interim results for 173 patients following instrumented 1st TMT arthrodesis (33.4 months follow-up) and early weightbearing with the Lapiplasty® System (Treace Medical Concepts, Ponte Vedra, FL) (**Figure 1**). Mean (standard deviation) patient age was 41.0 (12), mean BMI was 26 (4.9), and 91.9% (159 of 173 patients) were female. Radiographic imaging (AP, lateral, and sesamoid axial radiographs) was obtained preoperatively and at 6 weeks, 4 months, 6 months, 12 months, 24 months, 36 months and 48 months postoperatively. Two independent fellowship-trained musculoskeletal radiologists reviewed the blinded radiographic data and performed measurements of intermetatarsal angle (IMA), hallux valgus angle (HVA), tibial sesamoid position (TSP), and sagittal-plane intermetatarsal angle (angle between the longitudinal axis of the first and second metatarsals in lateral radiographs). Only 1 radiologist performed the radiological measurements starting at 36 months.

Patient reported outcomes for the operative foot were measured by visual analog scale (VAS), Manchester-Oxford Foot Questionnaire (MOxFAQ), and a patient satisfaction questionnaire at intervals up to 48 months postoperatively. Additional endpoints included clinical complications related to the surgical procedure and/or implants. Additionally, data were collected on time to weightbearing in a boot, return to work (or normal household activities if non-working), return to full work, and return to unrestricted activity.

\*Lower recurrence rates have been reported but recurrence parameters were not established<sup>9</sup>

## Results

At time of data cut-off for the interim analysis, there were 157 of 173 patients who achieved at least their 24-month follow-up visit with mean follow-up time of 33.4 months. Patients underwent early return to weightbearing, with an average transition to walker boot at 8.4 (95% CI: 7.3, 9.5; n=173) days, athletic shoes at 6.6 (95% CI: 6.4, 6.8; n=173) weeks, and unrestricted activity at 4.0 (95% CI: 3.9, 4.2; n=170) months (Table 4). Radiographic results demonstrated a significant improvement in HVA, IMA, TSP and Sagittal-Plane IMA that was maintained through 36 months and favorable trends at 48 months

postoperatively (Table 1). Using a recurrence threshold of HVA 15° and 20°, recurrence was 7.3% and 0.7% at 24 months and 6.3% and 1.1% at 36 months, respectively. (Table 2).

Significant improvements over baseline were observed in VAS through 24 months post-op and in MOxFQ through 48 months post-op (Table 3). There were limited clinical complications, with 14 (8.1%) of the 173 patients required non-elective reoperation, with the majority for hardware removal for pain; whereas 2 patients (1.2%) elected to have hardware removed. (Table 6).

Figure 1 | Representative preoperative (left) and 48 month postoperative (right) radiographs.



Table 1 | Radiographic measures, mean (95% confidence interval)

Radiographic Measure	Baseline (N=173)	6 Week (N=171)	6 Month (N=160)	12 Month (N=147)	24 Month (N=155)	36 Month (N=98) <sup>b</sup>	48 Month (N=20)
Hallux Valgus Angle (HVA)	25.9° (24.9, 26.9)	8.9° (8.2, 9.6)	7.5° (6.7, 8.4)	7.7° (6.7, 8.7)	7.8° (7.0, 8.7)	7.1° (5.8, 8.3)	5.2° (2.7, 7.7)
Intermetatarsal Angle (IMA)	13.3° (12.9, 13.7)	4.0° (3.6, 4.3)	4.8° (4.5, 5.2)	4.8° (4.4, 5.1)	5.1° (4.7, 5.5)	5.6° (5.1, 6.1)	5.5° (4.1, 7.0)
Tibial Sesamoid Position (TSP)	5.0 (4.8, 5.1)	1.4 (1.3, 1.6)	1.9 (1.7, 2.1)	2.1 (1.9, 2.3)	2.3 (2.1, 2.5)	2.5 (2.2, 2.7)	2.6 (2.0, 3.2)
Sagittal-Plane Intermetatarsal Angle <sup>a,b</sup>	1.2° (0.9, 1.5)	0.3° (-0.2, 0.8)	0.0° (-0.4, 0.5)	-0.4° (-0.9, 0.1)	-0.4° (-0.9, 0.0)	-0.3° (-0.8, 0.3)	-0.2° (-1.3, 0.9)

<sup>a</sup> Dorsiflexion is a positive value

<sup>b</sup> Sample size for sagittal-plane intermetatarsal angle at 24 months is N=156, at 36 months is N=97.

Table 2 | Radiographic recurrence definition N(%) 95% confidence interval

Recurrence Definition	24 Month	36 Month
HVA>15°	11/151 (7.3%) (3.69, 12.66)	6/95 (6.3%) (2.35, 13.24)
HVA >20°	1/151 (0.7%) (0.02, 3.63)	1/95 (1.1%) (0.03, 5.73)

Table 3 | Patient reported outcomes, mean (95% confidence interval)

Measure	Baseline N=173	6 Week N=171	6 Month N=160	12 Month N=148	24 Month N=156
VAS Pain Score	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)

  

Measure	Baseline N=173 <sup>a</sup>	6 Month N=160	12 Month N=150	24 Month N=157	36 Month N=100	48 Month N=20
MOxFQ (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)	6.3 (3.5, 9.0)	2.5 (-1.0, 6.0)
MOxFQ (Walk/Stand)	46.3 (42.9, 50.8)	18.8 (13.6, 21.2)	12.0 (8.4, 14.7)	9.0 (5.6, 11.3)	5.9 (0.7, 6.3)	3.0 (0.0, 6.1)
MOxFQ (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)	11.1 (8.2, 13.9)	13.0 (5.5, 20.5)

<sup>a</sup> One subject did not provide a baseline response to a Walking/Standing domain question. They are not included in this data set.

Table 4 | Post-operative time to return to activity/work, mean (95% confidence interval)

Activity	
Time to weight-bearing: CAM <sup>a</sup> boot (days, N=173)	8.4 (7.3, 9.5)
Time to weight-bearing: shoes (weeks, N=173)	6.6 (6.4, 6.8)
Time to weight-bearing: unrestricted activity (months, N=170)	4.0 (3.9, 4.2)
Time to return to full work (days, N=173)	29.6 (24.0, 35.3)
Time to return to full work (days, N=167)	57.9 (50.8, 65.0)

<sup>a</sup> Controlled ankle motion

Table 5 | Patient reported satisfaction with procedure at 36 and 48 months, mean (95% confidence interval)

Measure		36 Month N=96 Number (%)	48 Month N=20 Number (%)
Satisfaction with overall results of procedure	Satisfied / Very Satisfied	86 (89.6%)	17 (85.0%)
	Neutral	6 (6.3%)	2 (10.0%)
	Unsatisfied / Very Unsatisfied	4 (4.1%)	1 (5.0%)
Would you recommend procedure to your relatives?	Yes	88 (91.7%)	19 (95.0%)
	No	8 (8.3%)	1 (5.0%)
Satisfaction on specific aspect of the procedure: Pain	Satisfied / Very Satisfied	81 (84.4%)	18 (90.0%)
	Neutral	8 (8.3%)	2 (10.0%)
	Unsatisfied / Very Unsatisfied	7 (7.3%)	0 (0.0%)
Satisfaction on specific aspect of the procedure: Function	Satisfied / Very Satisfied	86 (89.6%)	17 (85.0%)
	Neutral	5 (5.2%)	2 (10.0%)
	Unsatisfied / Very Unsatisfied	5 (5.2%)	1 (5.0%)
Satisfaction on specific aspect of the procedure: Alignment	Satisfied / Very Satisfied	89 (92.7%)	19 (95.0%)
	Neutral	2 (2.1%)	0 (0.0%)
	Unsatisfied / Very Unsatisfied	5 (5.2%)	1 (5.0%)
Satisfaction on specific aspect of the procedure: Aesthetics	Satisfied / Very Satisfied	74 (77.1%)	16 (80.0%)
	Neutral	14 (14.6%)	2 (10.0%)
	Unsatisfied / Very Unsatisfied	8 (8.4%)	2 (10.0%)

**Table 6** | Clinical complications - presented at the patient level

Complication Requiring Surgical Intervention	Number (%) N=173	Complication Not Requiring Surgical Intervention	Number (%) N=173
Hardware removal due to pain	11 (6.4%)	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%)	Nonunion <sup>b</sup>	2 (1.2%)
Reoperation due to pain and nonunion <sup>a</sup>	1 (0.6%)	Infection	1 (0.6%)
Revision due to pain	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.  
<sup>a</sup> Not a protocol defined nonunion because pain was not present at the TMT joint. Hardware was not removed.  
<sup>b</sup> One patient also reported pain (not at TMT joint).

## Discussion and Conclusion

This is an interim analysis of a prospective, five-year, multicenter study of the Lapiplasty® System (ALIGN3D™ study) with mean follow-up of 33.4 months. The results demonstrated successful early return to full weightbearing in a walker boot (mean 8.4 days), improvement and maintenance of triplanar radiographic measures (IMA, HVA, TSP, sagittal plane IMA) through 48 months, and improvements in pain (VAS) through 24 months and patient reported outcomes (MOxFAQ and patient satisfaction) through 48 months. On average, patients returned to athletic shoes at 6.6 weeks and to unrestricted activities within 4 months.

There are several noteworthy findings in this study. First, this interim analysis for the ALIGN3D™ prospective clinical trial presents radiographic results consistent with prior retrospective studies.<sup>7,8</sup>

A recent meta analysis demonstrated recurrence rates for metatarsal osteotomies at 5 or more years to be 64% and 10% using similar thresholds of as the current study of HVA >15 and >20 degrees.<sup>10</sup> The current results demonstrated recurrence of 6.3% and 1.1% at 36 months using HVA of >15 and >20 degrees, respectively.

Specifically, TSP position was corrected and maintained with a mean of 2.3, 2.5 and 2.6 at 24, 36 and 48 months, respectively, which has been found to be an important risk factor for recurrence.<sup>6</sup> Mean sagittal plane position was improved to measurements of -0.4°, -0.3° and -0.2° at 24, 36 and 48 months, respectively, which has been

shown to be important for normal MTP range of motion,<sup>11</sup> reestablishing first ray weightbearing and preventing lesser metatarsal overload.<sup>12</sup> Additionally, this study represents the first patient satisfaction data to date for the Lapiplasty® Procedure, demonstrating positive results at 48 months.

In conclusion, these interim results of a prospective, multicenter study support the Lapiplasty® Procedure's ability to allow early weightbearing in a walker boot and return to activities, reliably attain a 3-plane anatomic correction, and improve patients' health-related quality of life.

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