ALIGN3D™

Lapiplasty® Clinical Study

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

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. A recent systematic review by Lalevee et al. reported on longer-term outcomes (minimum 5-year follow-up) of distal metatarsal osteotomies and found pooled HV recurrence rates of 64% and 10% when defining recurrence based on postoperative HVA of 15° and 20°, respectively.[1]

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.[2] 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.[3,4] 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.[5,6] 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, thirteen foot and ankle surgeons, and 173 treated patients. This study analyzed interim results for 135 patients with 48 month follow-up following instrumented 1st TMT arthrodesis and early protected weightbearing with the Lapiplasty® System (Treace Medical Concepts, Ponte Vedra, FL) **(Figure 1)**. Mean (standard deviation) patient age was 41.0 (12.0), 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, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 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 one 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 (MOxFQ), and Patient-Reported Outcomes Measuring Information System (PROMIS) at intervals up to 48 months postoperatively (VAS measured through 24 months). 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.

Results

Radiographic results demonstrated a significant improvement in HVA, IMA, TSP and Sagittal-Plane IMA that was maintained through the 48-month post-op visit **(Table 1)**. Using a recurrence threshold of post-operative HVA>15° and HVA>20°, recurrence was 7.7% (10/130) and 0.8% (1/130) at 48 months respectively. **(Table 2)**.

Significant improvements over baseline were observed in VAS through 24 months post-op and in all MOxFQ domains through the 48-month post-op visit **(Table 3)**.

Significant improvements across all PROMIS domains at all post-operative timepoints except depression which first showed significant improvement at 48 months. There were limited clinical complications, with 15 (8.7%) of the 173 patients who required non-elective reoperation, with the majority for hardware removal for pain; whereas 4 patients (2.3%) elected to have hardware removed. **(Table 5)**. Two patients (1.4%) experienced a protocol-defined non-union and one non-protocol defined non-union required operation.

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

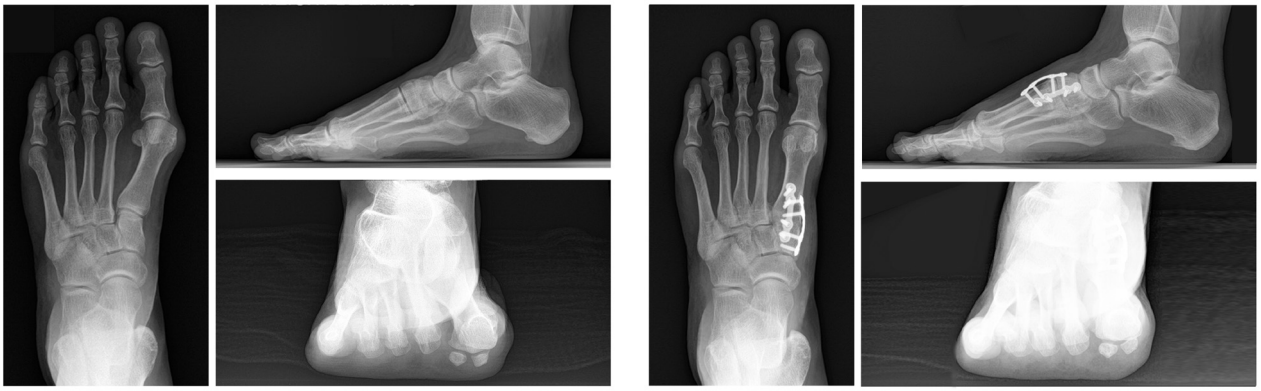

Table 1 | Radiographic measures, mean (95% confidence interval)

Radiographic Measure	Baseline (N=173)	6 Week (N=171)	6 Month (N=160)	12 Month (N=147)	24 Month (N=155[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)	7.5° (6.7, 8.4)	7.7° (6.7, 8.7)	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)	4.8° (4.5, 5.2)	4.8° (4.4, 5.1)	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)	1.9 (1.7, 2.1)	2.1 (1.9, 2.3)	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)	0.0° (-0.4, 0.5)	-0.4° (-0.9, 0.1)	-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

Table 2 | Radiographic recurrence definition, rate (95% confidence interval of the proportion)

Visit	HVA >15°	HVA >20°
24 Month	7.3% (11/151) (3.69, 12.66)	0.7% (1/151) (0.02, 3.63)
36 Month	6.2% (9/146) (2.86, 11.38)	1.4% (2/146) (0.17, 4.89)
48 Month	7.7% (10/130) (3.75, 13.69)	0.8% (1/130) (0.02, 4.21)

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[a]	6 Month N=160	12 Month N=150	24 Month N=157	36 Month N=150	48 Month N=135
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)	7.0 (4.7, 9.4)	5.1 (3.1, 7.1)
MOxFQ (Walk/Stand)	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)	4.8 (2.8, 6.8)
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)	12.1 (9.6, 14.7)	10.3 (7.8, 12.7)

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

Table 4 | Patient-reported outcomes: PROMIS domains (95% confidence interval)

Domain	Baseline N=163[a]	6 Month N=152	12 Month N=142	24 Month N=149[b]	36 Month N=142	48 Month N=127
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)	62.1 (61.2, 63.0)	62.6 (61.7, 63.4)
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)	43.4 (42.4, 44.4)	42.4 (41.5, 43.3)
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)	42.5 (41.9, 43.2)	42.0 (41.4, 42.6)
Fatigue	45.0 (43.5, 46.5)	41.3 (39.9, 42.6)	41.4 (40.0, 42.8)	41.8 (40.4, 43.2)	41.6 (40.1, 43.1)	41.1 (39.7, 42.5)
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)	0.7 (0.5, 0.9)	0.5 (0.3, 0.7)
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)	43.6 (42.8, 44.4)	42.8 (42.2, 43.5)
Physical Function	45.2 (43.9, 46.5)	51.3 (50.1, 52.5)	53.9 (53.0, 54.9)	54.9 (54.1, 55.7)	55.3 (54.5, 56.1)	55.6 (54.9, 56.4)
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)	44.0 (42.7, 45.4)	44.4 (43.0, 45.8)

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

Table 5 | 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	13 (7.5%)	Other pain	2 (1.2%)
Hardware removal due to infection	1 (0.6%)	Nonunion[b]	2 (1.4%)
Reoperation due to pain and nonunion[a]	1 (0.6%)	Infection	1 (0.6%)
Hardware removal per patient request	4 (2.3%)	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%)

Note: pain reported in this table is not pain at TMT joint.
[a] Not a protocol defined nonunion because pain was not present at the TMT joint. Hardware was not removed.
[b] Protocol defined non-union was assessed in n=156 patients at 12 months. 2/148 (1.4%) patients met the protocol definition of nonunion.

Discussion and Conclusion

This is an interim analysis of a prospective, five-year, multicenter study of the Lapiplasty® System (ALIGN3D™ study) with follow-up of 48 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 (MOxFQ and PROMIS) 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.[5,6]

A recent meta-analysis demonstrated recurrence rates for metatarsal osteotomies at 5 or more years to be 64% and 10% using similar thresholds as the current study of HVA >15 and >20 degrees.[1] The current results demonstrated recurrence of 7.7% and 0.8% at the 48 month post-op visit using HVA of >15 and >20 degrees, respectively.

Mean sagittal plane position was improved to a measurement of 0.8 degrees plantarflexion at 48 month post-op visit, which has been shown to be important for normal MTP range of motion,[7] reestablishing first ray weightbearing and preventing lesser metatarsal overload.[8] Additionally, with an average time to protected weightbearing of 8.4 days and a low rate of non-unions.

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 with low complication rates, reliably maintain a 3-plane anatomic correction with low recurrence, and improve patients' health-related quality of life.

References

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