ALIGN3D™

Lapiplasty® Clinical Study

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. Though these methods are routinely used, such approaches have been associated with high radiographic recurrence rates ranging between 30-73%.[1-3]

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.[4] 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.[5,6] 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.[7,8] 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 128 patients following instrumented 1st TMT arthrodesis (24 months minimum follow-up) and early weightbearing with the Lapiplasty® System (Treace Medical Concepts, Ponte Vedra, FL) **(Figure 1)**. Mean patient age was 42.0 years (range 15 to 58 years), mean BMI was 25 (range 17 to 40), and 115 (89.8%) 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, and 36 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 at 36 months.

Patient reported outcomes for the operative foot were measured by visual analog scale (VAS), Manchester-Oxford Foot Questionnaire (MOxFQ), and a patient satisfaction questionnaire at intervals up to 36 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.

Results

At time of data cut-off for the interim analysis, there were 128 of 173 patients who achieved at least their 24-month follow-up visit with mean follow-up time of 28.9 months. Patients underwent early return to weightbearing, with an average transition to walker boot at 8.1 (95% CI: 6.9, 9.3; n=128) days, athletic shoes at 6.6 (95% CI: 6.3, 6.8; n=128) weeks, and unrestricted activity at 4.1 (95% CI: 3.9, 4.3; n=127) months **(Table 3)**. Radiographic results demonstrated a significant improvement in IMA, HVA, and TSP that was maintained through 36 months postoperatively **(Table 1)**. There was one patient with recurrence (1/114, 0.9%) at 24 months and 0 patients with recurrence (0/34, 0.0%) at 36 months, where recurrence is defined as two of the following criteria being met: IMA of ≥12°, HVA ≥20°, TSP ≥4.

Significant improvements over baseline were observed in VAS through 24 months post-op and in MOxFQ through 36 months post-op **(Table 2)**. There were limited total hardware complications, with five patients (5/128, 3.9%) with hardware failure, which did not require reoperation and did not result in loss of radiographic correction. Nine patients underwent clinically-relevant hardware removal (9/128, 7.0%). A total of nine (9/128, 7.0%) patients experienced minor, non-hardware related clinical complications, of which 5 have resolved **(Table 5)**.

Figure 1 | Representative preoperative (left) and 24 month postoperative (right) radiographs.

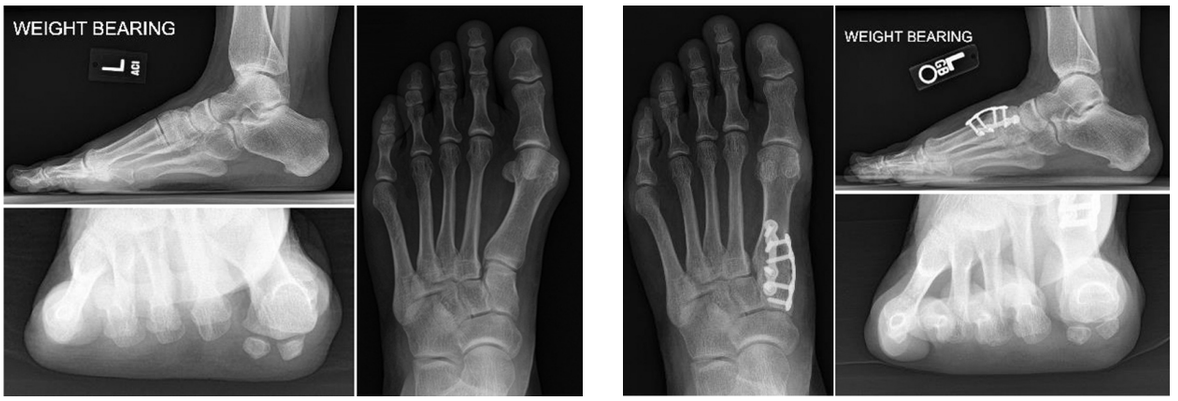

Table 1 | Radiographic measures, mean (95% confidence interval)

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 a positive value

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

Table 2 | Patient reported outcomes, mean (95% confidence interval)

Measure	N	Baseline	N	6 Month	N	12 Month	N	24 Month	N	36 Month
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 (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)
MOxFQ (Walking/Standing)	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 (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)

Measure	N	Baseline	N	6 Week	N	6 Month	N	12 Month	N	24 Month
VAS Pain Score	128	4.7 (4.4, 5.1)	126	1.8 (1.5, 2.0)	124	1.3 (1.0, 1.6)	116	1.0 (0.8, 1.2)	128	0.9 (0.7, 1.1)

* VAS pain scores were collected through 24 months only.

Table 3 | Post-operative time to return to activity/work, mean (95% confidence interval)

Activity	
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)

Table 4 | Patient reported satisfaction with procedure at 36 months, 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%)

Table 5 | Clinical complications/adverse events

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

* Did not require reoperation. Patients are considered healed per protocol definition. Hardware status by patient: broken medial plate and 2 broken screws; broken dorsal plate and 2 broken screws; broken screw; broken medial plate (N=2 patients).

** Includes 1 patient who underwent reoperation for non-union.

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 28.9 months. The results demonstrated successful early return to full weightbearing in a walker boot (mean 8.1 days), improvement and maintenance of triplanar radiographic measures (IMA, HVA, TSP, sagittal plane IMA) through 36 months, and improvements in patient reported outcomes (MOxFQ, VAS, and patient satisfaction) through 36 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.[7,8] Specifically, TSP position was corrected and maintained with a mean of 2.2 and 2.1 at 24 and 36 months, respectively, which has been found to be an important risk factor for recurrence.[6] Mean sagittal plane position was improved to measurements of -0.1° and 0.2° at 24 and 36 months, respectively, which has been shown to be important for normal MTP range of motion,[9] reestablishing first ray weightbearing and preventing lesser metatarsal overload.[10] Additionally, this study represents the first patient satisfaction data to date for the Lapiplasty® Procedure, demonstrating positive results at 36 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.

References

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