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 recent 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 & ankle surgeons. This study analyzed interim results for 160 patients following instrumented 1st TMT arthrodesis and early weightbearing with the Lapiplasty® System (Treace Medical Concepts, Ponte Vedra, FL) (Figure 1). Mean patient age was 41.2 years (95% confidence interval (CI), 39.3 to 43.2 years), mean BMI was 26.0 (95% CI, 25.2 to 26.7), and 146 of 160 (91.3%) were female. Radiographic imaging (AP, lateral, and sesamoid axial radiographs) was obtained preoperatively and at 6 weeks, 4 months, 6 months, 12 months, and 24 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).

Patient reported outcomes for the operative foot were measured by visual analog scale (VAS), Manchester-Oxford Foot Questionnaire (MOxFQ) and Patient-Reported Outcomes Measurement Information System (PROMIS-29) preoperatively and at intervals up to 24 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) and time to return to full work.

Results

At time of data cut-off for the interim analysis, there were 160 patients with mean follow-up time of 16.7 (95% Confidence Interval: 15.5, 17.9; n=160) months. Patients underwent early return to weightbearing, with an average transition to walker bootat 8.5 (7.3, 9.7; n=160) days, athletic shoes at 46.2 (44.5, 48.0; n=160) days, and unrestricted activity at 121.3 (115.7, 127.0; n=158) days. On average, patients returned to work28.2 (22.6, 33.9; n=160) days and to full work in 56.8 days (49.6, 64.1; n=155). These results were with a 95% Confidence Interval.

Radiographic results demonstrated a significant improvement in IMA, HVA, and TSP that was maintained through 24 months postoperatively **(Table 1)**.

There was one recurrence (0.9%) at 12 month follow-up, where recurrence is defined as two of the following criteria being met: IMA of ≥12°, HVA ≥20°, TSP ≥4.

A significant improvement from baseline in patient reported outcomes was also observed through 24 months for VAS score, all MOxFQ domains, and all PROMIS-29 domains except depression **(Table 2 and Table 3)**.

There were limited total hardware complications, with seven patients (4.4%) requiring non-elective reoperation, four patients (2.5%) with hardware failure not requiring reoperation, and two patients (1.3%) electing to have the hardware removed (Table 4). All 13 patients have maintained radiographic correction. There were limited total clinical complications, with seven patients (4.4%) experiencing clinical complications (Table 5).

Figure 1 | Representative pre-operative (left) and 24 month post-operative (right) radiographs.

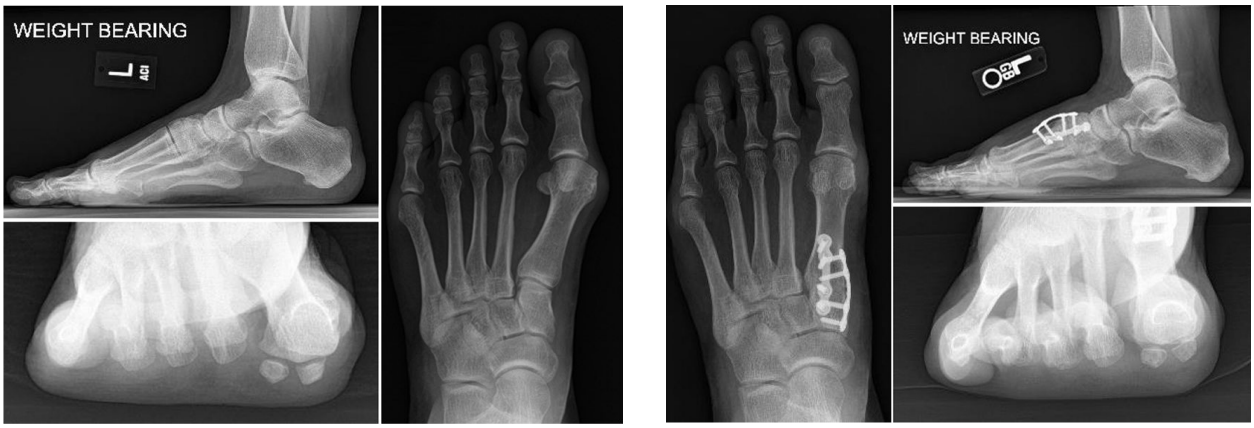

Table 1 | Radiographic measures, mean (95% confidence interval)

Radiographic Measure	Baseline (n, 160)	6 Week (n, 158)	4 Month (n, 149)	6 Month (n, 153)	12 Month (n, 119)	24 Month (n, 52)
Hallux Valgus Angle (HVA)	25.9° (24.9, 27.0)	8.8° (8.0, 9.6)	8.1° (7.3, 8.9)	7.4° (6.5, 8.3)	7.3° (6.2, 8.4)	7.5° (6.0, 8.9)
Intermetatarsal Angle (IMA)	13.3° (12.8, 13.7)	3.9° (3.6, 4.3)	4.5° (4.1, 4.9)	4.8° (4.4, 5.1)	4.8° (4.4, 5.2)	5.3° (4.6, 6.1)
Tibial Sesamoid Position (TSP)	4.9 (4.8, 5.1)	1.4 (1.3, 1.6)	1.7 (1.5, 1.8)	1.9 (1.7, 2.1)	2.1 (1.9, 2.4)	2.1 (1.8, 2.4)
Sagittal-Plane Intermetatarsal Angle*	1.3° (1.0, 1.6)	0.3° (-0.2, 0.8)	-0.2° (-0.7, 0.3)	0.0° (-0.5, 0.4)	-0.3° (-0.9, 0.2)	0.2° (-0.5, 1.0)

*Dorsiflexion is a positive value

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

Measure	N	Baseline	N	6-Month	N	12-Month	N	24-Month
VAS Pain Score	160	4.7 (4.4, 5.0)	157	1.3 (1.1, 1.5)	129	1.0 (0.8, 1.3)	63	0.8 (0.5, 1.0)
MOxFQ (Walking/Standing)	159	46.3 (42.8, 49.9)	157	18.2 (14.9, 21.5)	130	11.7 (8.7, 14.8)	63	7.5 (4.4, 10.7)
MOxFQ (Pain)	160	55.8 (52.6, 59.0)	157	22.8 (19.9, 25.8)	130	19.3 (15.7, 22.9)	63	12.1 (8.6, 15.5)
MOxFQ (Social Interaction)	160	44.3 (40.8, 47.7)	157	13.1 (10.2, 16.1)	130	8.9 (6.0, 11.9)	63	6.7 (3.8, 9.7)
MOxFQ (Index Score)	159	48.6 (45.6, 51.7)	157	18.4 (15.5, 21.3)	130	13.4 (10.4, 16.3)	63	8.8 (5.9, 11.6)

Table 3 | PROMIS-29[a], mean (95% confidence interval)

Measure (PROMIS Domain)	Baseline (n, 150)	6 Month (n, 149)	12 Month (n, 123)	24 Month (n, 61)
Ability to Participate in Social / Activities	53.5 (52.1, 54.9)	59.4 (58.2, 60.5)	60.4 (59.1, 61.8)	62.1 (60.8, 63.3)
Anxiety	47.2 (45.9, 48.5)	43.6 (42.6, 44.6)	43.1 (42.0, 44.1)	42.8 (41.5, 44.2)
Depression	43.2 (42.4, 44.1)	42.5 (41.8, 43.2)	42.2 (41.6, 43.2)	42.0 (41.1, 42.9)
Fatigue	44.7 (43.2, 46.2)	41.0 (39.7, 42.3)	41.0 (39.6, 42.5)	41.7 (39.6, 43.8)
Pain Interference	55.7 (54.5, 56.9)	47.4 (46.2, 48.5)	45.2 (44.1, 46.3)	43.7 (42.6, 44.7)
Physical Function	45.3 (44.0,.46.6)	51.4 (50.3, 52.6)	53.9 (52.9, 55.0)	55.8 (55.0, 56.6)
Sleep Disturbance	47.7 (46.6, 48.8)	44.8 (43.5, 46.0)	44.7 (43.4, 46.0)	43.8 (41.8, 45.8)
Pain Intensity	4.5 (4.1, 4.8)	1.3 (1.0, 1.6)	1.1 (0.8, 1.3)	0.6 (0.4, 0.8)

Table 4 | Hardware complications

Complication	Number (%)
Hardware removal (due to pain)[2]	5/160 (3.1%)
Hardware failure (hardware not removed)[1]	4/160 (2.5%)
Hardware removal (per patient request)[2]	2/160 (1.3%)
Hardware removal (due to infection)[2]	1/160 (0.6%)
Hardware removal (due to bursal cyst)[2]	1/160 (0.6%)

1 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. 2 Required reoperation

Table 5 | Clinical complications

Complication	Number (%)
Pain	2/160 (1.3%)
Non-union[1]	1/160 (0.6%)
Wound Complication	1/160 (0.6%)
Post-operative nerve hypersensitivity	1/160 (0.6%)
Parathesias	1/160 (0.6%)
Infection	1/160 (0.6%)

1 Required reoperation

Discussion and Conclusion

This is a 12 and 24 month interim analysis of a prospective, five-year, multicenter study of the Lapiplasty® System (ALIGN3D™ study). The results demonstrated successful early return to full weightbearing in a walker boot (mean 8.5 days), improvement and maintenance of triplanar radiographic measures (IMA, HVA, TSP) at 24 months, improvement in patient reported outcomes (VAS, MOxFQ, PROMIS-29) at 24 months (except depression), and successful return to activities and full unrestricted work within 9 weeks of the procedure.

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 2.1 at 24 months, which has been found to be an important risk factor for recurrence.6 Mean sagittal plane position was maintained at 0.2°, which has been shown to be important for normal MTP range of motion,[10] reestablishing first ray weightbearing and preventing lesser metatarsal overload.[11] Additionally, this study represents the first patient reported outcomes to date for the Lapiplasty® Procedure, demonstrating positive early results at 12 and 24 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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TREACE® Medical Concepts, Inc.

203 Fort Wade Rd., Suite 150 | Ponte Vedra, FL 32081 | 904.373.5940 | www.treace.com