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 and ankle surgeons. This study analyzed interim results for 159 patients following instrumented 1st TMT arthrodesis (12 months minimum follow-up) and early weightbearing with the Lapiplasty® System (Treace Medical Concepts, Ponte Vedra, FL) **(Figure 1)**. Mean patient age was 41.0 years (range 14 to 58 years), mean BMI was 25.9 (range 17 to 40), and 145 (91.2%) 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).

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 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 159 of 173 patients who achieved at least their 12-month follow-up visit with mean follow-up time of 22.2 months. Patients underwent early return to weightbearing, with an average transition to walker boot at 8.3 (95% CI: 7.1, 9.4; n=159) days, athletic shoes at 46.2 (95% CI: 44.4, 47.9; n=159) days, and unrestricted activity at 121.5 (116.0, 126.9; n=157) days. On average, patients returned to work at 29.2 (23.2, 35.2; n=159) days and to full work in 58.2 days (50.9, 65.6; n=156). Radiographic results demonstrated a significant improvement in IMA, HVA, TSP, and sagittal plane intermetatarsal angle that was maintained through 36 months postoperatively **(Table 1)**. There were two patients with recurrence (2/144, 1.4%), where recurrence is defined as two of the following criteria being met: IMA of ≥12°, HVA ≥20°, TSP ≥4.

Significant improvements from baseline in patient reported outcomes were also observed for VAS pain score, all MOxFQ domains, and all PROMIS-29 domains (except depression) through 36 months **(Table 2 and Table 3)**. There were limited total hardware complications, with five patients (5/173, 2.9%) with hardware failure, which did not require reoperation and did not result in loss of radiographic correction. Nine patients underwent clinically-relevant hardware removal (9/173, 5.2%) **(Table 4)**. A total of nine (9/173, 5.2%) 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.

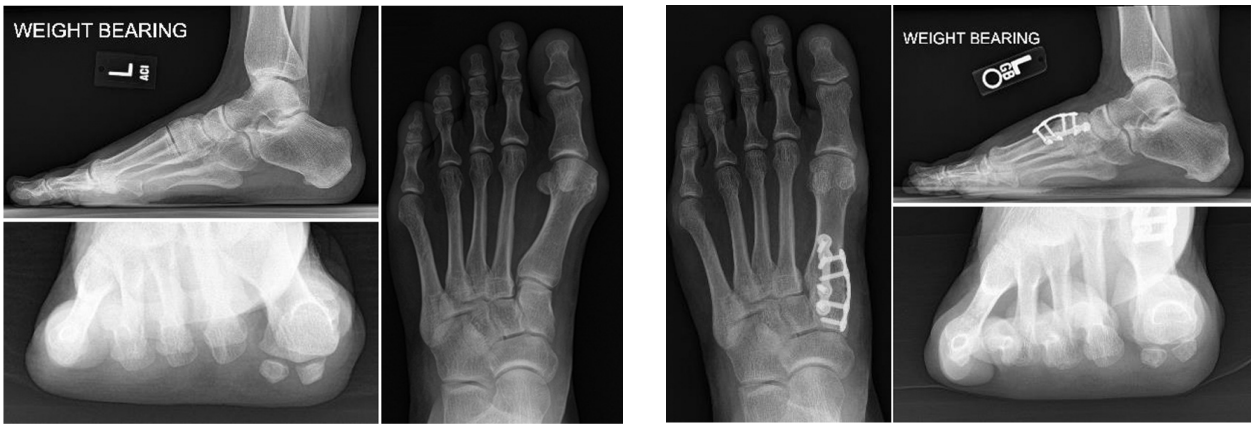

Table 1 | Radiographic measures, mean (95% confidence interval)

Radiographic Measure	Baseline (N=159)	6 Week (N=157)	6 Month (N=154)	12 Month (N=147)	24 Month (N=105)	36 Month (N=19)
Hallux Valgus Angle (HVA)	25.8° (24.7, 26.8)	8.9° (8.2, 9.7)	7.5° (6.6, 8.4)	7.7° (6.7, 8.7)	7.8° (6.8, 8.9)	5.3° (2.4, 8.1)
Intermetatarsal Angle (IMA)	13.2° (12.7, 13.6)	4.0° (3.6, 4.3)	4.8° (4.5, 5.2)	4.8° (4.4, 5.1)	5.2° (4.7, 5.7)	5.9° (3.4, 8.3)
Tibial Sesamoid Position (TSP)	4.9 (4.8, 5.1)	1.4 (1.3, 1.6)	1.9 (1.7, 2.1)	2.1 (1.9, 2.3)	2.2 (2.0, 2.4)	1.9 (1.5, 2.4)
Sagittal-Plane Intermetatarsal Angle*	1.3° (1.0, 1.6)	0.3° (-0.2, 0.9)	0.0° (-0.4, 0.5)	-0.4° (-0.9, 0.1)	0.0° (-0.6, 0.6)	0.1° (-0.9, 1.1)

*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	N	36 Month
MOxFQ (Pain)	159	56.5 (53.3, 59.7)	154	23.1 (20.0, 26.1)	150	20.1 (16.6, 23.6)	107	13.3 (10.3, 16.2)	19	9.2 (3.1, 15.3)
MOxFQ (Index Score)	158	49.0 (45.9, 52.1)	154	18.7 (15.7, 21.7)	150	13.9 (11.1, 16.6)	107	9.5 (6.8, 12.2)	19	4.4 (1.6, 7.3)
MOxFQ (Walking/Standing)	158	46.6 (43.0, 50.2)	154	18.5 (15.1, 21.9)	150	12.0 (9.2, 14.8)	107	8.3 (5.3, 11.3)	19	2.4 (0.1, 4.8)
MOxFQ (Social Interaction)	159	44.5 (41.0, 48.0)	154	13.4 (10.4, 16.5)	150	9.3 (6.5, 12.1)	107	6.9 (4.1, 9.6)	19	2.0 (0.0, 4.0)
VAS Pain Score	159	4.7 (4.4, 5.0)	154	1.3 (1.1, 1.6)	148	1.1 (0.9, 1.3)	107	0.9 (0.7, 1.2)	*	*

* VAS pain scores were collected through 24 months only.

Measure (PROMIS Domain)	Baseline (N=149)	6 Month (N=146)	12 Month (N=142)	24 Month (N=104)	36 Month (N=20)
Ability to Participate in Social / Activities	53.5 (52.1, 54.9)	59.3 (58.1, 60.5)	60.5 (59.2, 61.7)	61.7 (60.6, 62.8)	63.9 (63.3, 64.5)
Physical Function	45.4 (44.1, 46.7)	51.5 (50.3, 52.7)	53.9 (53.0, 54.9)	55.3 (54.5, 56.2)	57.0 (,)*
Anxiety**	47.1 (45.8, 48.4)	43.9 (42.8, 44.9)	43.3 (42.3, 44.3)	42.8 (41.8, 43.7)	42.1 (40.0, 44.3)
Depression	43.4 (42.5, 44.2)	42.8 (42.0, 43.5)	42.5 (41.7, 43.2)	42.4 (41.6, 43.1)	41.5 (40.4, 42.7)
Pain Interference	55.8 (54.6, 57.0)	47.5 (46.4, 48.7)	45.4 (44.3, 46.5)	43.9 (43.0, 44.8)	42.1 (41.0, 43.2)
Sleep Disturbance**	47.9 (46.7, 49.1)	45.0 (43.7, 46.3)	45.3 (44.0, 46.6)	44.1 (42.7, 45.6)	43.6 (39.5, 47.7)
Fatigue	44.8 (43.3, 46.4)	41.2 (39.8, 42.6)	41.4 (40.0, 42.8)	41.1 (39.5, 42.7)	41.9 (37.6, 46.2)

*No confidence interval to generate because there was no variation in subject response to physical function domain questions (all n=20 subjects responded, "Without any difficulty").
**N=148 for Anxiety and Sleep Disturbance responses.

Table 4 | Hardware complications

Complication	Number (%)
Hardware breakage (hardware not removed)[1]	5/173 (2.9%)
Hardware removal (per patient request – non-clinically related)	2/173 (1.2%)
Hardware removal (infection – non-clinically related)	1/173 (0.6%)
Hardware removal (pain)	8/173 (4.6%)
Hardware removal (bursal cyst)	1/173 (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 (N=2 patients).
*Note: Summary of interim safety is performed using all treated patients (n=173) to prevent an undercount of safety events.

Table 5 | Clinical complications

Complication	Number (%)
Infection	1/173 (0.6%)
Pain due to stiffness	1/173 (0.6%)
Pain due to non-union[1]	1/173 (0.6%)
Parathesia	1/173 (0.6%)
Wound Complication	1/173 (0.6%)

[1]Required reoperation for pain due to 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 22.2 months. The results demonstrated successful early return to full weightbearing in a walker boot (mean 8.3 days), improvement and maintenance of triplanar radiographic measures (IMA, HVA, TSP, sagittal plane IMA) through 36 months, and improvements in patient reported outcomes (MOxFQ, PROMIS-29, and VAS) through 36 months. On average, patients returned to full work within 2 months 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 1.9 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 0.0° and 0.1° 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 reported outcomes to date for the Lapiplasty® Procedure, demonstrating positive early results at 24 and 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

1. Bock P, et al. J Bone Joint Surg Am. 2015, 97:1238-1245.
2. Pentikainen I, et al. Foot Ankle Int. 2014, 25:1262–1267.
3. Jeuken RM, et al. Foot Ankle Int. 2016, 37:687-695.
4. Kim Y, et al. Foot Ankle Int. 2015, 36:944-52.
5. Okuda R, et al. J Bone Joint Surg Am. 2007, 89:2163-72.
6. Okuda R, et al. J Bone Joint Surg Am. 2009, 91:1637-4.
7. Ray JJ, et al. Foot Ankle Int. 2019, 40: 955–960.
8. Dayton P, et a. J Foot Ankle Surg. 2020, 59: 291-297.
9. Roukis TS, et al. J Am Podiatr Med Assoc. 1996, 86: 538–546.
10. Espinosa N, et al. Foot Ankle Int. 2008, 29:871-9.

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