

Early Weight-bearing Following Three-Plane 1st TMT Correction with the Lapiplasty® Procedure: 13.5-Month Multicenter Outcomes*

Introduction

While over 100 different hallux valgus treatment approaches have been described in the literature, they have primarily been focused on correcting the transverse-plane deformity and thus can be generally characterized as two-dimensional (2D) approaches. Metatarsal osteotomies make up the majority of these procedures, and the literature demonstrates inconsistent results of osteotomies with radiographic recurrence rates of 30-78%.^{1,2} Recent CT studies have indicated that 87% of bunions are three-dimensional (3D) deformities with a frontal-plane metatarsal rotational deformity³, and failure to correct the 3D deformity has been implicated in the high recurrence rate. In fact, metatarsal osteotomies have been shown to have a 10.0X and 12.7X likelihood of recurrence with incomplete reduction of sesamoid position⁴ or metatarsal frontal-plane rotation (i.e. lateral round sign⁵) respectively | **Figure 1**.

Correction at the 1st tarsometatarsal joint (Lapidus arthrodesis) is a powerful and convenient option for both restoring anatomic metatarsal alignment in all three planes and correcting at the apex of the deformity (i.e. the anatomic CORA).⁶ While a drawback of the traditional Lapidus procedure is the need for extended immobilization (6-8 weeks), recent studies have challenged this standard with early weight-bearing beginning at 2-3 weeks.^{7,8} Thus, a two-plate, multiplanar fixation construct^{9,10} was developed based on relative stability principles¹¹ that may allow for even more accelerated weight-bearing.

The objective of this study was to perform a 12-month retrospective review of patients treated with the Lapiplasty® Procedure, which enables three-plane correction and early weight-bearing after 1st TMT arthrodesis.



Figure 1 | With frontal-plane rotation (left), the rounded profile of the plantar condyle creates a positive “lateral round sign.” The lateral round sign is not present with a metatarsal in neutral frontal-plane alignment (right).

Methods

A retrospective, multicenter study was performed on a consecutive series of 77 symptomatic hallux valgus feet (72 patients) that underwent 1st TMT correction via the Lapiplasty® Procedure and participated in an early weight-bearing protocol. Mean final follow up was 13.5 months, with mean patient age of 39.3 ± 18.1 years and 74/77 (96.1%) female. The exclusion criteria for the study was revision procedures, additional arthrodesis outside the 1st TMT joint, and moderate to severe arthritis of the 1st MTP joint.

All patients underwent the Lapiplasty® Procedure, an instrumented approach to 1st TMT fusion that enables a controlled three-plane correction (including metatarsal frontal-plane rotation) | **Figure 2**. There were no

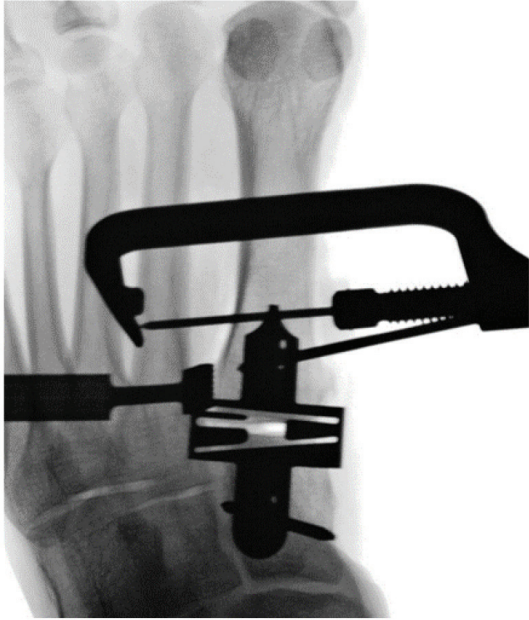


Figure 2 | Fluoroscopic image demonstrating correction of the three-plane metatarsal alignment with the Lapiplasty® Positioner, and application of the Lapiplasty® Cut Guide.



Figure 3 | Pre-op (left) and 12 month (right) AP and sesamoid axial radiographs of a patient fixated with the straight 90-90 Biplanar™ Plating construct.

Akin osteotomies or adjunct 1st metatarsal osteotomies performed in conjunction with the 1st TMT fusion. A lateral release was performed in 97.4% of the cases. For fixation, two low-profile, 4-hole locking titanium plates were applied with the 1st TMT held in compression. Two different fixation construct options were used in this study (based on surgeon preference): 90-90 Biplanar™ Plating, with two straight plates placed 90° to each other (dorsal and medial) | **Figure 3**; and Biplanar™ Plating with the medial-plantar Plantar Python® Plate for tension-side support | **Figure 4**. For the post-op regimen, all patients were placed into a protective, cushioned dressing with a boot walker and allowed to weight-bear as tolerated at 0-2 weeks. Sixty-four out of 77 patients (83.1%) were allowed to weight-bear immediately as tolerated.

Charts and radiographic imaging were reviewed pre-operatively, and at 6 weeks, 4 months, and 12 months (or final follow up if longer than 12 months). Radiographic review was performed by an independent musculoskeletal radiologist and radiographic measures included hallux valgus angle (HVA), intermetatarsal angle (IMA), tibial sesamoid position (TSP), and lateral round sign.⁴ Time to weight-bearing, wearing athletic shoes, and return to full activity was also noted. Recurrence was defined as HVA greater than 20° and complications were also recorded. For statistical analysis, t-tests were performed.

Results

Mean final follow-up was 13.5 months. Mean time to weight-bearing was 10.5 days, normal shoe wear 57.2 days, and full activity 102.4 days.

Radiographic results demonstrated significant improvements in IMA ($13.7 \pm 3.0^\circ$ to $6.1 \pm 1.7^\circ$), HVA ($23.4 \pm 9.6^\circ$ to $8.5 \pm 4.7^\circ$), and TSP (4.9 ± 1.3 to 1.9 ± 0.8) from pre-operative to final follow-up ($p < 0.001$) | **Table 1**. Lateral round sign was present in 2 feet (2.6%) at final follow-up compared to 66 feet (85.7%) preoperatively. At the time of final follow-up, recurrence was noted for 2 feet (3.3%), and the symptomatic non-union rate was 1.7% (one foot). Regarding complications, there were two hardware removals due to irritation (3.3%), and two feet (3.3%) required hardware removal with addition of an Akin osteotomy.



Figure 4 | Pre-op (left) and 12 month (right) AP and sesamoid axial radiographs of a patient fixated with the Plantar Python® Plate construct.

Discussion

These 13.5-month clinical results support the hypothesis that early weight-bearing is possible following 1st TMT fusion with the Lapiplasty® System. The results demonstrated successful maintenance of 3-plane correction over the 13.5-month follow-up, including correction of metatarsal frontal-plane rotation, with low incidence of non-union and other complications. This represents supportive clinical evidence to published biomechanical tests that have established the two locked plate construct

(placed 90 degree offset to each other) to have superior strength and fatigue properties compared to a conventional anatomic locked plate and compression screw construct in simulating Lapidus cyclic loading.^{9,10}

While the biomechanical testing supports the strength of this construct, they were specifically designed to not be excessively-rigid at the same time. Thus, this multiplanar construct supports early weight-bearing based on relative stability bone healing principles, where it is designed to utilize the controlled mechanical stimulation of early weight-bearing to promote a “biological” secondary bone healing process via callus formation.¹¹

The results of the study also indicate that the novel Lapiplasty® Procedure is able to successfully restore anatomic alignment in all three planes. Specifically, unlike conventional surgical approaches, successful correction of the frontal-plane metatarsal rotational deformity was achieved, as evidenced by the improvement in TSP position and the elimination of the lateral round sign on AP radiograph in 97.4% of the cases. This is an important finding given that prior studies have observed a frontal-plane rotational deformity (metatarsal pronation) in 87% of hallux valgus patients,³ and failure to correct metatarsal rotation has been linked to a 12.7X increased likelihood of radiographic recurrence.⁴

Taken together, these 13.5-month results support the Lapiplasty® System’s ability to both reliably attain a 3-plane anatomic correction and allow rapid weight-bearing with low complication and recurrence rates following 1st TMT arthrodesis.

	Pre-Op	6 Week	4 Month	12 Month/Final	P-value
IMA	13.7° ± 3.0°	5.6° ± 1.8°	5.6° ± 2.0°	6.1° ± 1.7°	< 0.001
HVA	23.4° ± 9.6°	9.9° ± 5.4°	8.6° ± 5.1°	8.5° ± 4.7°	< 0.001
TSP	4.9 ± 1.3	1.6 ± 0.7	1.7 ± 0.8	1.9 ± 0.8	< 0.001

Table 1 | Mean radiologic measurements (pre-op and following 3-plane correction with Lapiplasty® Procedure).

References

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