

Instrumented Three-Plane Hallux Valgus Correction: Radiographic Results of the Lapiplasty® Procedure

Introduction

Though surgical correction of the hallux valgus (i.e. bunion) deformity via metatarsal osteotomy is a commonly-performed surgical procedure, a review of the recent literature demonstrates radiographic recurrence rates of 65-78% at less than 10 years.¹⁻³ If one examines the over 100 different metatarsal osteotomy surgical variations, it is clear that the correction has been limited to the transverse and sagittal planes. However, there is increasing evidence that bunions are complex, three-plane deformities that involve frontal-plane rotation of the 1st metatarsal (i.e. pronation) in up to 87% of patients.⁴⁻⁷ Recent studies have established the clinical significance of recognizing and treating the complete three-plane deformity, as uncorrected metatarsal frontal-plane rotation, characterized by incomplete reduction of the sesamoid apparatus and positive metatarsal head “lateral round sign” | **Figure 1**, has been correlated with increased risk of radiographic recurrence.^{8,9}

Correction at the 1st tarsometatarsal joint (Lapidus fusion) is a powerful option for restoring anatomic alignment in all three planes at the apex of the hallux valgus deformity. However, conventional Lapidus techniques have not addressed frontal-plane rotation and have historically been viewed as challenging, freehand procedures.¹⁰ Thus, novel instrumentation and a Biplanar™ Plating implant system (Lapiplasty® System, Treace Medical Concepts, Inc., Ponte Vedra Beach, FL) was developed to reliably perform a precise, three-plane correction at the 1st TMT joint.

The objective of the study was to evaluate the three-plane metatarsal alignment and 1st TMT union rate following hallux valgus correction with the Lapiplasty® Procedure and early weight-bearing.

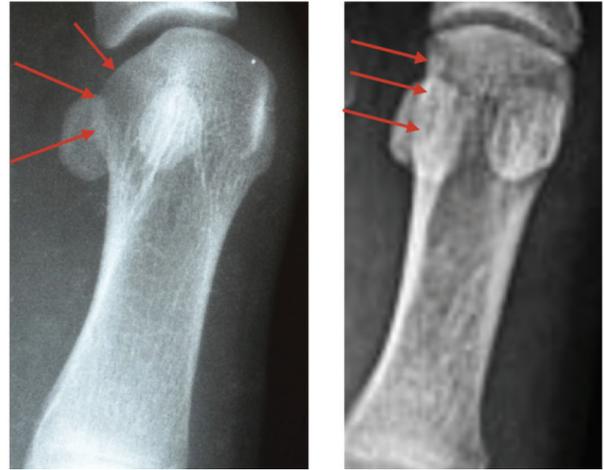


Figure 1 | Arrows indicating the lateral shape of the metatarsal head. With the metatarsal rotated in the frontal-plane (left), the rounded profile of the lateral plantar condyle becomes visible creating a positive “lateral round sign.” The lateral round sign is not present with a metatarsal in neutral frontal-plane alignment (right). An uncorrected lateral round sign is associated with increased risk of radiographic recurrence.⁹

Methods

A retrospective analysis was performed on a consecutive series of 19 symptomatic hallux valgus patients (19 female, 21 feet, 32.4±15.9 yrs) whom had undergone a three-plane correction with the Lapiplasty® System. Average follow-up was 5.2±1.6 months (range 2-8 months). The criteria for inclusion in the study included at least 2 months of post-operative follow-up, availability of pre- and post-operative AP radiographs, and participation in an early weight-bearing protocol.

The Lapiplasty® Procedure is a novel instrumented approach to 1st TMT fusion that differs from conventional Lapidus techniques in several ways. In this study, a dorsal incision was made over the 1st TMT joint and the Lapiplasty® Positioner was applied to the proximal portion



Figure 2 | Fluoroscopic image demonstrating correction of the three-plane metatarsal alignment with the Lapiplasty® Positioner, before any bone preparation cuts were made.



Figure 3 | Terminally-threaded olive wire(s) were used to provisionally fixate and pre-compress the 1st TMT joint.

of the 1st and 2nd metatarsals to correct the alignment in all three planes before making any bone preparation cuts | **Figure 2**. Intra-operative fluoroscopy was used to adjust and confirm the metatarsal correction. With the metatarsal alignment secured by a K-wire driven through the cannulation in the Lapiplasty® Positioner and into the 2nd metatarsal, precision saw cuts were made in the corrected alignment. After the bone slices were removed and aggressive fenestration was performed, the prepared 1st TMT joint was provisionally fixated and pre-compressed with threaded olive wire(s) | **Figure 3**. Two small-profile, 4-hole titanium Biplanar™ Plates (Control 360® System, Treace Medical Concepts, Inc., Ponte Vedra Beach, FL) were then applied at 90° orientation, using unicortical locking screws. One plate was located dorsally and the other medial or medial-plantar. Optionally, the Biplanar™ Plating construct was supplemented with a 28mm screw inserted at the base of the 1st to 2nd metatarsals for additional stabilization of the three-plane correction. No compression screw was utilized with this fixation approach. Post-operatively, patients underwent an early¹¹ weight-bearing protocol with average start of protected weight-bearing in a removable walking boot at 13.3±3.1 days (range 0-14 days).

The pre- and final post-operative AP radiographs were measured to assess the 1-2 intermetatarsal angle (IMA), hallux valgus angle (HVA), lateral shape of the metatarsal head (lateral round sign)⁹ and tibial sesamoid position (TSP). TSP was measured using the Hardy and Clapham 1 to 7 scale. Additionally, the final post-operative AP radiographs were reviewed for assessment of radiographic fusion. The incidence of complications was also evaluated and defined as deformity recurrence, delayed or non-union, hardware removal or other revision surgical procedure. Paired t-tests (corrected for multiple comparisons) were conducted to determine the change, and maintenance of, the radiographic morphological measures.

Results

At a mean follow-up of 5.2±1.6 months, a significant improvement in IMA, HVA, and TSP was measured | **Table 1**.

A negative metatarsal round sign, indicating correction of frontal-plane metatarsal rotation, was observed in 20 of the 21 feet (95.2%). Under an early protected weight-bearing protocol, all 21 of the feet (100%) demonstrated clear evidence of 1st TMT union at final follow-up | **Figures 4 and 5.**

Regarding complications, there was one case (4.8%) of under-correction of frontal-plane rotation and one case (4.8%) of symptomatic hardware (broken intermetatarsal screw) requiring hardware removal.

Discussion

The results of the study indicate that the novel Lapiplasty® System is able to successfully correct the complete hallux valgus deformity and fuse the TMT joint in the corrected alignment. Specifically, unlike conventional surgical approaches, successful correction of the frontal-plane

metatarsal rotational deformity was achieved with the Lapiplasty® System, as evidenced by the elimination of the lateral round sign of the metatarsal head on AP radiograph. This is an important finding given that prior studies have observed a frontal-plane rotational deformity (metatarsal pronation) in 87% of hallux valgus patients and failure to correct metatarsal rotation has been linked to an increased likelihood of radiographic deformity recurrence.⁵

The results of the study also support the hypothesis that two low-profile, unicortical locking plates at 90° orientation without an interfragmentary screw (Biplanar™ Plating), can provide adequate multiplanar stability under early weight-bearing conditions to achieve robust healing and union of the 1st TMT joint. This is important clinical evidence, as Biplanar™ Plating has previously demonstrated superior strength and endurance compared to an anatomic plate and compression screw construct in a biomechanical

Measurement	Pre-Operative	Final Follow-Up
IMA (deg)	13.2±2.3°	5.5±1.9°*
HVA (deg)	19.3±8.5°	7.3±3.9°*
TSP	4.8±1.1	1.8±0.7*
Lat. Round Sign	21 of 21	1 of 21* (4.8%)
1 st TMT Union	N/A	21 of 21 (100%)

**p* < 0.001

Table 1 | Mean morphologic measurements (pre-operative and following three-plane correction with the Lapiplasty® System).



Figure 4 | Pre-op and 3 month AP radiographs of a 47 yr female demonstrating maintenance of the three-plane correction and 1st TMT union.



Figure 5 | Pre-op (A) and 5 month (B) AP radiographs of a 76 yr female demonstrating the three-plane deformity correction and 7s1 TMT union. The axial pre-op radiograph (C) clearly shows frontal-plane rotation of the metatarsal (note sesamoids positioned anatomically on either side of the crista) which is corrected in the post-operative axial image (D).

model simulating progressive Lapidus cyclic loading.¹² Biplanar™ Plating is designed to mechanically function similar to a multiplanar external fixator, providing multiplanar stability to allow the mechanical loading of weight-bearing to stimulate a biological bone healing process via callus formation, while avoiding the drawbacks of compression screw fixation.

Taken together, the results of the present study demonstrate that the Lapiplasty® System can both reliably attain a three-plane hallux valgus correction and achieve a high rate of TMT union under early weight-bearing conditions.

References

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