Immediate Weight-bearing Following Three-Plane 1st TMT Correction with the Lapiplasty® Procedure

Introduction

The majority of hallux valgus deformities are treated by metatarsal osteotomy. While over 100 different metatarsal osteotomy options have been described, they can be generally characterized as two-dimensional (2D) procedures focused on correcting the transverse-plane deformity. In the short-term these procedures allow early return to weight-bearing and normal shoe wear, however longer-term results demonstrate 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 deformity,[3] and failure to correct the 3D deformity has been implicated in the high recurrence rate. In fact, following metatarsal osteotomy there is a 10.0X and 12.7X likelihood of recurrence with incomplete reduction of sesamoid position or metatarsal frontal-plane rotation (“lateral round sign”) respectively (Fig. 1).[4-5]

Correction at the 1st tarsometatarsal joint (Lapidus fusion) is a powerful option for both restoring anatomic alignment in all three planes and correcting at the apex of the deformity (i.e. the anatomic CORA). While a traditional drawback of the Lapidus procedure is the need for extended immobilization, recent studies have challenged this standard with weight bearing beginning at 2-3 weeks.[6-7] Moreover, the AO group’s recommendations on internal fixation has also evolved to advocate relative stability for a biological incorporation via secondary bone healing.[8] Thus, a multiplanar plating construct was developed based on relative stability principles that may allow for even more accelerated weight-bearing.[9]

The objective of this study was to perform an early evaluation of a novel procedure that allows for three-plane correction and immediate weight-bearing after Lapidus arthrodesis.

Methods

A retrospective, multi-center study was performed on a consecutive series of 49 symptomatic hallux valgus patients (average 41.9±17.9 years; follow-up 4.3±1.0 months) that underwent correction via the Lapiplasty® Procedure and participated in an immediate weight-bearing protocol. 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.
Pre- and final post-operative radiographs were measured to assess the 1-2 intermetatarsal angle (IMA), hallux valgus angle (HVA), lateral shape of the metatarsal head (lateral round sign) and tibial sesamoid position (TSP). TSP was measured using the Hardy and Clapham 1 to 7 scale. Additionally, the final post-operative radiographs were reviewed for assessment of radiographic fusion. Paired t-tests were conducted to determine the change in the anatomic radiographic measures.

The results of the study demonstrated a significant improvement in IMA, HVA, and TSP (Table 1). Elimination of the metatarsal round sign, indicating correction of frontal-plane metatarsal rotation, was observed in 47 of the 49 feet (95.9%). Under the immediate protected weight-bearing protocol, 0 of the 49 feet (0%) demonstrated evidence of non-union at final follow-up.

Regarding complications, there were two cases (4.1%) of under-correction and one case (2.0%) of hardware removal for soft-tissue irritation.

**Table 1.** Mean radiologic measurements (pre-operative and following three-plane correction with the Lapiplasty® Procedure).

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Pre-Op</th>
<th>Final Post-Op</th>
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<tr>
<td>IMA</td>
<td>15.0±3.1*</td>
<td>5.9±3.2**</td>
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<td>HVA</td>
<td>23.7±10.1*</td>
<td>8.3±5.5**</td>
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<td>TSP</td>
<td>5.1±1.2</td>
<td>2.0±0.9*</td>
</tr>
<tr>
<td>Lat. Round Sign</td>
<td>44 of 49</td>
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<td>Non-Union</td>
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*p < 0.001

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 with the Lapiplasty® Procedure, as evidenced by the elimination of the lateral round sign on AP radiograph in 95.9% 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, and failure to correct metatarsal rotation has been linked to a 12.7X increased likelihood of radiographic deformity recurrence.

Taken together, the results support the Lapiplasty® Procedure’s ability to both reliably attain a three-plane hallux valgus correction and allow immediate weight-bearing following 1st TMT fusion with multiplanar plate fixation.

**Discussion**

The results of the study support the hypothesis that immediate weight-bearing is possible following 1st TMT fusion with two low-profile, unicortical locking plates at 90° orientation without an interfragmentary screw. These results demonstrated maintenance of the three-plane correction without increased risk of non-union. This represents important clinical evidence, as Biplanar™ Plating was shown to have superior strength and endurance compared to an anatomic plate and compression screw construct in a biomechanical model simulating Lapidus cyclic loading. Further biomechanical testing of the Plantar Python® Plate tension-side construct demonstrated a 103% increase in the number of cycles to failure compared to straight Biplanar™ Plating. Both two-plate locked constructs are specifically designed to take advantage of multiplanar stability principles and relative stability bone healing, utilizing the mechanical stimulation of early weight-bearing to promote a robust and rapid “biological” secondary bone healing process via callus formation.

**References**

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The radiographic results demonstrated a significant improvement in IMA, HVA, and TSP (Table 1). Elimination of the metatarsal round sign, indicating correction of frontal-plane metatarsal rotation, was observed in 47 of the 49 feet (95.9%). Under the immediate protected weight-bearing protocol, 0 of the 49 feet (0%) demonstrated evidence of non-union at final follow-up. Regarding complications, there were two cases (4.1%) of under-correction and one case (2.0%) of hardware removal for soft-tissue irritation.

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Discussions

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All patients underwent the Lapiplasty® Procedure, which is an instrumented approach to 1st TMT fusion that enables a controlled three-plane correction (including metatarsal frontal-plane rotation). The procedure utilizes the Lapiplasty® Positioner to correct and hold the metatarsal alignment in all three planes, and the Lapiplasty® Cut Guide to deliver controlled cuts with the metatarsal held in the corrected position (Fig. 2). For fixation, two low-profile, 4-hole locking titanium plates were applied utilizing unicortical screws with the 1st TMT held in compression. Two different fixation construct options were used in this study. The first construct (28 of 49 patients), Biplanar™ Plating, places one straight plate on the dorsal surface and another straight plate on the medial surface, 90° to each other (Fig. 3). The second construct (21 of 49 patients) places a straight plate on the dorsal surface and the Plantar Python® anatomic tension-side plate from the medial surface of the cuneiform to the plantar surface of the 1st metatarsal (Fig. 4). For the post-op regimen, all patients were placed into a protective, cushioned dressing with a rigid-bottom shoe or boot and allowed to immediately weight-bear as tolerated.