Publications Overview
Summary of 13 Peer-Reviewed Lapiplasty® Publications

The Leader in Advancing the Scientific Study of Hallux Valgus

PearlDiver Independent Survey
Multicenter Early Radiographic Outcomes of Triplanar Tarsometatarsal Arthrodesis With Early Weightbearing

Justin J. Ray, MD1, Jennifer Koay, MD2, Paul D. Dayton, DPM, MS3, Daniel J. Hatch, DPM4, Brett Smith, DO, MS5, and Robert D. Santrock, MD1

Abstract
Background: Hallux valgus is a complex deformity of the first ray. Traditional correction methods prioritize the transverse plane, a potential factor resulting in high recurrence rates. Triplanar first tarsometatarsal (TMT) arthrodesis uses a triplanar approach to correct hallux valgus in all 3 anatomical planes at the apex of the deformity. The purpose of this study was to investigate early radiographic outcomes and complications of triplanar first TMT arthrodesis with early weightbearing.

Methods: Radiographs and charts were retrospectively reviewed for all cases performed between January 2015 and November 2017. Patients were allowed early full weightbearing in a boot walker. Postoperative radiographs were compared with preoperative radiographs for hallux valgus angle (HVA), intermetatarsal angle (IMA), and tibial sesamoid position (TSP).

Results: Radiographic results demonstrated significant improvements in IMA (13.6 ± 2.7 degrees to 6.6 ± 1.9 degrees), HVA (13.6 ± 9.3 degrees to 9.7 ± 5.1 degrees), and TSP (11.6 ± 2.1 degrees to 9.7 ± 1.9 degrees) at final follow-up (P < .001). Lateral radiographs were present in 2 of 62 (3.2%) at final follow-up, compared with 32 of 62 feet (51.6%) preoperatively. At final follow-up, recurrence was 3.2% (3/62 feet), and the symptomatic nonunion rate was 1.6% (1/62 feet). Two patients required hardware removal, and 2 patients required additional Akin osteotomy.

Conclusion: Early radiographic outcomes of triplanar first TMT arthrodesis with early weightbearing were promising with low recurrence rates and maintenance of correction.

Level of Evidence: Level IV, retrospective case series.

Keywords: hallux valgus, modified Lapidus, tarsometatarsal arthrodesis, bunion, triplanar

Introduction
Hallux valgus is a complex deformity of the first ray. Traditional correction methods for hallux valgus primarily correct in the transverse plane based on anteroposterior (AP) radiographs. In particular, traditional methods of correction primarily target improvement of the hallux valgus angle (HVA) and intermetatarsal angle (IMA). Both the severity of the deformity and the method of operative correction have been largely based on this 2-dimensional representation, resulting in variable outcomes and some studies reporting high long-term recurrence rates ranging from 15% to 78% with these traditional approaches.1-5

Recent evidence suggests that hallux valgus is a multiaxial deformity with significant contributions from the frontal and sagittal planes.6-10 With the addition of early weightbearing computed tomography (CT) scans, the 3-dimensional nature of hallux valgus is better characterized. Recent studies utilizing weightbearing CT scans have shown that patients with hallux valgus have abnormal initial metatarsal pronation, greater 3-dimensional displacement at the first TMT joint.

Abbreviations: IMA - Intermetatarsal Angle; HVA - Hallux Valgus Angle; TSP - Tibial Sesamoid Position

Study Summary
- Multicenter retrospective review of 62 feet with average follow-up of 13.5 months
- Triplanar TMT arthrodesis with Lapiplasty® System and weight-bearing in a surgical boot at average 10.9 days
- 96.8% patients maintained their 3-plane correction (IMA, HVA, TSP); 2 feet with recurrence (3.2%)
- 1.6% patients experienced symptomatic nonunion

Radiographic Results

### Recurrence Measurements

<table>
<thead>
<tr>
<th></th>
<th>6 Weeks Postop, n (%)</th>
<th>4 Months Postop, n (%)</th>
<th>12 Months Postop, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVA &gt; 20 degrees</td>
<td>3/62 (4.8%)</td>
<td>4/62 (6.4%)</td>
<td>2/62 (3.2%)</td>
</tr>
<tr>
<td>Loss of correction &gt; 50%</td>
<td>2/62 (3.2%)</td>
<td>2/62 (3.2%)</td>
<td>2/62 (3.2%)</td>
</tr>
</tbody>
</table>

Abbreviations: IMA - Intermetatarsal Angle; HVA - Hallux Valgus Angle; TSP - Tibial Sesamoid Position

Case Example from Publication

“Triplanar TMT arthrodesis resulted in significant improvements in IMA, HVA, and TSP at final follow-up with low recurrence rates. Patients tolerated early weightbearing and early return to normal athletic shoes with minimal complications.”
Study Summary
• Retrospective review of 109 feet with average follow-up of 17.4 months
• 3-plane TMT arthrodesis with bipolar plating and weight-bearing in a surgical boot within first week
• 99.1% patients maintained their 3-plane correction (IMA, HVA, TSP); 1 foot with recurrence (0.9%)
• 100% patients achieved bony fusion with 0% hardware failure

Radiographic Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVA</td>
<td>109</td>
<td>22.9</td>
<td>7.6</td>
<td>21.4 to 24.3</td>
</tr>
<tr>
<td>Preoperative</td>
<td>109</td>
<td>8.0</td>
<td>4.5</td>
<td>7.1 to 8.9</td>
</tr>
<tr>
<td>Postoperative</td>
<td>109</td>
<td>7.4</td>
<td>4.5</td>
<td>6.1 to 8.7</td>
</tr>
<tr>
<td>IMA</td>
<td>109</td>
<td>13.3</td>
<td>2.4</td>
<td>12.9 to 13.8</td>
</tr>
<tr>
<td>Preoperative</td>
<td>109</td>
<td>7.7</td>
<td>2.4</td>
<td>5.2 to 6.1</td>
</tr>
<tr>
<td>Postoperative</td>
<td>109</td>
<td>7.7</td>
<td>2.7</td>
<td>5.2 to 6.1</td>
</tr>
<tr>
<td>TSP</td>
<td>Preoperative</td>
<td>109</td>
<td>4.6</td>
<td>2.7</td>
</tr>
<tr>
<td>Postoperative</td>
<td>109</td>
<td>2.0</td>
<td>0.8</td>
<td>1.9 to 2.2</td>
</tr>
<tr>
<td>Change</td>
<td>109</td>
<td>2.6</td>
<td>1.3</td>
<td>2.0 to 3.0</td>
</tr>
<tr>
<td>MRA</td>
<td>Preoperative</td>
<td>92</td>
<td>7.8</td>
<td>8.0</td>
</tr>
<tr>
<td>Postoperative</td>
<td>77</td>
<td>7.8</td>
<td>6.8</td>
<td>5.9 to 9.3</td>
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<tr>
<td>Change</td>
<td>72</td>
<td>12.3</td>
<td>9.5</td>
<td>14.5 to 10.0</td>
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<tr>
<td>DMAA</td>
<td>Preoperative</td>
<td>109</td>
<td>19.6</td>
<td>9.2</td>
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<tr>
<td>Postoperative</td>
<td>109</td>
<td>5.3</td>
<td>3.8</td>
<td>4.6 to 6.1</td>
</tr>
<tr>
<td>Change</td>
<td>109</td>
<td>14.3</td>
<td>8.7</td>
<td>12.9 to 15.7</td>
</tr>
</tbody>
</table>

Abbreviations: HVA - Hallux Valgus Angle; IMA - Intermetatarsal Angle; TSP - Tibial Sesamoid Position; MRA - Metatarsal Rotation Angle (Frontal Plane); DMAA - Distal Metatarsal Articular Angle

Study Conclusion
“Triplane arthrodesis provides patients with robust and reliable correction of all planar components of the deformity, with low recurrence and low rate of healing problems at a mean of 17 months postoperatively.”

Case Example from Publication 18 months post-op

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Progression of Healing on Serial Radiographs Following First Ray Arthrodesis in the Foot Using a Biplanar Plating Technique Without Compression

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ARTICLE INFO
A review of 195 first ray arthrodesis feet with a biplanar-plate construct, without interference-fragment compression, is presented. This fixation construct was evaluated in a consecutive cohort of patients undergoing first metatarsophalangeal joint (MTP) arthrodesis or the first tarsometatarsal joint (TMT) arthrodesis. Multiple radiographs were used to assess the progression of healing at the following postoperative time frames: 4 to 5 weeks, 10 to 12 weeks, and the final follow-up. In total, 85 feet underwent first MTP arthrodesis, and 110 feet underwent first TMT arthrodesis. At the final radiographs follow-up, 97.9% of all cases had shown progressive osseous gap filling at the arthrodesis site, stable position of the bone segments, and intact hardware without loosening. 98.4% of the first MTP arthrodesis group and 96.2% of the first TMT arthrodesis group. Four (5.4%) feet had the presence of lucency at the fusion interface at the final follow-up, without positional change or hardware failure. Pain (3.8%) feet had a failure of the hardware, loss of position, or frank gaping at the fusion site. Lameness decreased consistently over time in this series of patients (p < 0.0001). Progressive increase in callus density at the fusion site on serial radiographs was used to be a consistent finding for both procedures and was the primary indicator of secondary bone healing at the noncomprised, relatively stable arthrodesis site. Our results confirm that biplanar plating construct without interference-compression produces high fusion rates following the first MTP or TMT arthrodesis, with early weightbearing.

bone healing stability

Bone is a dynamic tissue, and its healing process is an essential component of the fracture treatment and reconstructive surgery. The healing potential of bone has been shown to be similar in fracture and fusion models, where a complex cascade of events takes place over weeks, months, and years as the overlapping stages of the healing process [1]. Owing to the similar healing of fusion and fracture models, the internal fixation methods for arthrodesis procedures have progressed in a manner similar to fracture fixation. Common methods include wires, compression screws, rigid plates, and combinations of these fixation strategies. As our understanding of the ideal mechanical environment for bone healing evolves, the role of fixation in optimizing healing and fusion is gradually changing from a priority of rigid fixation with compression to relative stability, which can be achieved with locking plates, intramedullary constructs, and external fixation [2]. As compared with other types of fusion, bone is especially dependent on the mechanical environment to guide its repair process [3]. In the context of arthrodesis, this mechanical environment is determined by fixation mechanics and weightbearing. Inadequate stability with excessive load can cause a failure of osseous healing [4,5]. Likewise, excessive rigidity can impede the progression of osseous healing [4,5]. Fixation for small bone arthrodesis most commonly employs interfragmentary compression screws, either alone or as compression screw and plate combinations. Compression techniques provide direct

Radiographic Results

Case Example from Publication 1st TMT Fusion - Left; 1st MTP Fusion - Right

Study Summary
• retrospective review of 195 feet with average follow-up of 9.5 months
• 3-plane TMT arthrodesis (110 feet) or 1st MTP arthrodesis (85 feet) with Biplanar™ Plating
• Weight-bearing in a surgical boot within the first week
• 97.4% patients achieved bony fusion and 98.9% maintained a stable joint position
• 3.1% patients underwent hardware removal

Study Conclusion
"In conclusion, our results demonstrate the ability of a biplanar plating construct to provide reliable stability sufficient to withstand early weightbearing and return to function, resulting in progressive bone healing and ultimately stable fusion for the first MTP arthrodesis and first TMT arthrodesis procedures."
Comparison of the Mechanical Characteristics of a Universal Small Biplane Plating Technique Without Compression Screw and Single Anatomic Plate With Compression Screw

Paul Dayton, DPM, MS, FACFAS,¹ Joe Ferguson, MS,² Daniel Hatch, DPM, FACFAS,² Robert Santrock, MD,² Sean Scanlan, PhD,² Bret Smith, DO²

¹Converse Clinic; and Assistant Professor, De Montfort University College of Podiatric Medicine and Surgery, Foot Dodge, IA
²TheraMed Medical Concepts, Inc., Peoria, Illinois, IL

ABSTRACT

To better understand the mechanical characteristics of biplane locked plating in small bone fixation, the present study compared the stability under cyclic cantilever load testing of a 2-plate biplanar biplane (BPP) construct without interfragmentary compression with that of a single-plate locked construct with an additional interfragmentary screw (IPS) using surrogate bone models simulating Lapidus arthrodesis. In static ultimate plantar bending, the BPP construct failed at significantly greater ultimate load than did the IPS construct (506.2 ± 33.4 N versus 466.6 ± 33.6 N, p < 0.05). For cyclic fatigue testing in plantar bending at a 150-N starting load, the BPP construct failed at a significantly greater number of cycles (221,837 ± 10,681 versus 11,731 ± 6,471 cycles) and failed load (242.5 ± 23.0 N versus 188.0 ± 8.7 N) than the IPS construct (p < 0.05). The results were not significantly different between the BPP and IPS constructs for the number of cycles (45,293 ± 8,930 versus 41,836 ± 11,836) or failure load (130-N plantar bending load, all BPP constructs tension side) of the 5 IPS constructs reached 250,000 cycles without failure. Overall, the present study found that the BPP construct has superior or equivalent stability in multiplanar orientations of bone applications in both static and fatigue testing. Thus, the concept of biplane locked plating, using 2 bone profile plates and unicortical screw insertion, shows promise in small bone fixation, because it provides consistent stability in multiplanar orientations, making it universally applicable to many clinical situations.

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Osteosynthesis is a vital component of orthopedics for both trauma and reconstructive surgery. The mechanical characteristics of orthopedic fixation influence bone healing by a complex cascade of biologic events. The biomechanical response of the bone varies depending on the design of the fixator (size, material, stiffness) and the forces placed across the fracture or osteotomy. Knowledge of the biologic effects that external mechanical forces induce in bone has led to new paradigms in fracture and osteotomy fixation. We can see from the published data that the success with many of the new techniques is still not fully understood. With our understanding of how the biology of bone healing is influenced by both fixed angle plates and traditional compression fixation, new recommendations for implants are emerging. Construct stability can be achieved in several ways using fixed angle plates. Memoskeletal plate application across the axis of the bone requires the plate to have sufficient stiffness to resist the multiplane bending, traction, and rotational forces constantly experienced during function.

Study Conclusion

“The results of the study demonstrated that a small biplane plating construct without compression screw has superior or equivalent mechanical stability to a single anatomic plate with interfragmentary compression screw under both static and dynamic fatigue conditions.”

Study Summary

• Biomechanical testing of Biplanar™ Plating (Gen 1) versus dorsal Lapidus plate + 4.0 mm interference screw
• Cantilever static and cyclic bending loading simulating Lapidus arthrodesis in surrogate bone models
• Biplanar™ Plating demonstrated greater biomechanical performance:
  - Static ultimate failure load: 556N vs 242N (130% increase)
  - Cycles to failure @180N start load: 158,322 ± 13,718 cycles (1,054% increase)
  - Cycles to failure @120N start load: 207,646 ± 159,334 cycles (30% increase)

Biomechanical Test Setup
Triplane Hallux Abducto Valgus Classification

Summary: Rather than the 2D hallux valgus classification systems traditionally referenced, this manuscript presents a novel 3-plane (3D) classification system for the evaluation and procedure selection for hallux valgus treatment.

Class 1 - No metatarsal rotation;
Class 2A - Metatarsal rotation without sesamoid subluxation;
Class 2B - Metatarsal rotation with sesamoid subluxation;
Class 3 - Metatarsus adductus bunion;
Class 4 - Degenerative (DJD) bunion.

Biomechanical Characteristics of Biplane Multiplanar Tension-Side Fixation for Lapidus Fusion
Dayton P, Hatch DJ, Santrock RD, Smith B

Summary: Biomechanical study comparing the Lapiplasty® Plantar Python® tension-side fixation construct to Lapiplasty® Biplanar™ Plating, demonstrating a 17% improvement in maximum load to failure and a 103% increase in the cycles to failure (simulating post-operative weight-bearing).

Comparison of Tibial Sesamoid Position on Anteroposterior and Axial Radiographs Before and After Triplane Tarsal Metatarsal Joint Arthrodesis
Dayton P, Feilmeier M

Summary: Clinical study of 21 feet at 5.2 month average follow-up demonstrating the ability of the Lapiplasty® Procedure to successfully correct the three-dimensional (3D) deformity (including metatarsal frontal-plane rotation) in 95.2% of cases, and also restore the intermetatarsal angle to 5.5°, hallux valgus angle to 7.3°, and tibial sesamoid position to 1.8.

Hallux Valgus Deformity and Treatment. A Three-Dimensional Approach: Modified Technique for Lapidus Procedure
Santrock RD, Smith B

Summary: Manuscript reviews the 3-plane hallux valgus classification system, the novel surgical steps of the Lapiplasty® Procedure, the Lapiplasty® Biplanar™ plating biomechanical results, and presents clinical outcome data from a 49-patient multicenter study demonstrating 96% maintenance of 3-plane correction and 0% non-union rate at 4 months following an immediate weight-bearing protocol with the Lapiplasty® Procedure.

Evidence-Based Bunion Surgery: A Critical Examination of Current and Emerging Concepts and Techniques
Dayton, Paul D. (Ed.)

Summary: This textbook provides a critical examination of the traditions and techniques commonly taught for bunion surgery and contrasts them with new, evidence-based anatomic and surgical concepts (including the Lapiplasty® Procedure).

Multiplanar Alignment System to Guide Triplanar Correction of Hallux Valgus Deformity
Smith WB, Santrock RD, Hatch DJ, Dayton P

Summary: Manuscript presents a novel, instrumented approach to 3-plane (3D) Lapidus fusion (Lapiplasty® Procedure) for correction of the hallux valgus deformity, including indications/contraindications for 3-plane Lapidus arthrodesis, 3-plane x-ray views for preoperative planning, detailed surgical technique steps of the novel, instrumented Lapiplasty® Procedure, and potential complications.

Additional Lapiplasty® Publications
The Evidence-Based Triplanar Solution
Backed by 13 Peer-Reviewed Lapiplasty® Publications

Lapiplasty® offers

- **97-99% reproducible 3D correction**\(^1,2\)
- **<2 weeks return to weight-bearing**\(^1,2,5\)
- **10.4mm average reduction in foot width**\(^3\)
- **3.0mm or less average shortening of first ray**\(^4\)
- **2-3% non-union rate**\(^1,5\)
- **3% hardware removal rate**\(^5\)
- **1-3% recurrence rate**\(^1,2\)
- **30% increase in cycles to failure with Biplanar® Plating**\(^6\)
  (compared to dorsomedial Lapidus plate + compression screw)
- **130+ patients treated** in a 5-year, prospective multi-center clinical trial

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\(^3\) TMC data on file.  
\(^4\) TMC data on file.  