

Publications Overview

Summary of 16 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

Foot & Ankle Internationals
1-6
© The Author(s) 2019
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/1071100719847700
journals.sagepub.com/home/fai

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

Abstract

Background: Hallux valgus is a multiplanar 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 multiplanar 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 57 patients (62 feet) aged 39.7 ± 18.9 years undergoing triplanar first TMT arthrodesis at 4 institutions between 2015 and 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), tibial sesamoid position (TSP), and lateral round sign. Any complications were recorded.

Results: Radiographic results demonstrated significant improvements in IMA (13.6 \pm 2.7 degrees to 6.6 \pm 1.9 degrees), HVA (24.2 \pm 9.3 degrees to 9.7 \pm 5.1 degrees), and TSP (5.0 \pm 1.3 to 1.9 \pm 0.9) from preoperative to final follow-up (P < .001). Lateral round sign was present in 2 of 62 feet (3.2%) at final follow-up compared with 52 of 62 feet (83.9%) preoperatively. At final follow-up, recurrence was 3.2% (2/62 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 prioritize correction 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. ^{1,3,7,8,19}

Recent evidence suggests that hallux valgus is a multiplanar deformity with significant contributions from the frontal and sagittal planes. 4.10,11 With the addition of 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 first metatarsal pronation, greater 3-dimensional displacement at the first TMT joint,

Corresponding Author:

Justin J. Ray, MD, Department of Orthopaedics, West Virginia University, P.O. Box 9196, Morgantown, WV 26506-9196, USA. Email: justin.ray1@hsc.wvu.edu

1

¹Department of Orthopaedics, West Virginia University, Morgantown, WV, USA

²Department of Radiology, West Virginia University, Morgantown, WV, LISA

³Foot & Ankle Center of Iowa, Ankeny, IA, USA

⁴Department of Podiatric Medicine and Surgery, North Colorado PMS Residency, Greeley, CO, USA

⁵Orthopedics, University of South Carolina, Palmetto Health-USC Orthopedic Center, Lexington, SC, USA

- Multicenter retrospective review of 62 feet with average follow-up of 13.5 months
- 3-plane 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

	Preop, n (%)	6 Weeks Postop, n (%)	4 Months Postop, n (%)	12 Months Postop, n (%)	<i>P</i> Value
IMA	13.6 <u>+</u> 2.7	6.1 <u>+</u> 2.1	6.1 <u>+</u> 2.3	6.6 <u>+</u> 1.9	<.001
HVA	24.2 <u>+</u> 9.3	11.6 <u>+</u> 5.1	10.2 <u>+</u> 5.9	9.7 <u>+</u> 5.1	<.001
TSP	5.0 <u>+</u> 1.3	1.6 <u>+</u> 0.7	1.8 <u>+</u> 0.9	1.9 <u>+</u> 0.9	<.001

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

Recurrence Measurements

	6 Weeks Postop, n (%)	4 Months Postop, n (%)	12 Months Postop, n (%)	
HVA > 20 degrees	3/62 (4.8%)	4/62 (6.4%)	2/62 (3.2%)	
Loss of correction > 50% (IMA, HVA, or TSP)	2/62 (3.2%)	2/62 (3.2%)	2/62 (3.2%)	

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

Case Example from Publication





Study Conclusion

"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."



Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org



Comparison of Radiographic Measurements Before and After Triplane Tarsometatarsal Arthrodesis for Hallux Valgus



Paul Dayton, DPM, MS, FACFAS¹, Stefany Carvalho, BS², Rachel Egdorf, DPM³, Mindi Dayton, DPM, MHA, FACFAS¹

- ¹ Surgeon, Foot & Ankle Center of Iowa/Midwest Bunion Center, Ankeny, IA
- ² Student, Des Moines University College of Podiatric Medicine and Surgery, Des Moines, IA
- ³ Resident, AMITA Saint Joseph Hospital Chicago, Chicago, IL

ARTICLE INFO

Level of Clinical Evidence: 4

Keywords: bunion surgery deformity apex frontal plane recurrence rotation

ABSTRACT

We present a comparison of preoperative and final postoperative first ray measurements in 109 feet after triplane tarsometatarsal arthrodesis at a mean follow-up time of 17.4 months. Preoperative and final postoperative first ray variables including intermetatarsal angle (IMA), hallux valgus angle (HVA), tibial sesamoid position (TSP), distal metatarsal articular angle (DMAA), Seiberg index, metatarsal rotation angle (MRA), sesamoid subluxation, osseous union, and hardware failure were evaluated. Measurements were made by consistently using the middiaphyseal line of the bone segments for both preoperative and postoperative assessments. The mean preoperative HVA, IMA, and TSP were 22.9°, 13.3°, and 4.6. The mean differences (95% confidence interval) in preoperative and postoperative values were -14.9° (-16.3° to -13.4°) for HVA, -7.7° (-8.2° to -7.2°) for IMA, and -2.6 (-2.8 to -2.3) for TSP. Among bunions with MRA measurements, the mean difference was -12.3° (-14.5° to -10.0°). The results of this study suggest that triplane tarsometatarsal arthrodesis produces appropriate correction of hallux valgus radiographic parameters.

 $\hbox{@\,}2019$ by the American College of Foot and Ankle Surgeons. All rights reserved.

Algorithms for selecting a hallux abducto valgus (HAV) procedure rely primarily on 2-dimensional (2D) measurements such as intermetatarsal angle (IMA), hallux valgus angle (HVA), tibial sesamoid position (TSP), and distal metatarsal articular angle (DMAA) measurements (and therefore are 2D). Based on these measurements, it is not surprising that HAV correction is most commonly surgically addressed as a biplanar deformity, with angular and sliding osteotomies and capsular balancing procedures attempting only to correct transverse and sagittal plane angular deformities. This biplane thought process has resulted in recurrence rates as high as 73%, along with other complications, which may be be due to failure to correct all 3 planes of the deformity (1).

Surgeons have complicated the topic of HAV and introduced bias in study results by using dual measurements to assess pre- and postoperative IMA (2). The anatomic IMA (aIMA) is the bisection of the mid-diaphyseal osseous segments of metatarsals 1 and 2. The mechanical

Financial Disclosure: None reported.

Conflict of Interest: P.D. has been performing triplane TMT arthrodesis exclusively for nondegenerative bunions since 2009. He has worked as a consultant and design team surgeon with Treace Medical Concepts, Inc., since 2014. The other authors declare no conflicts of interest.

Address correspondence to: Paul Dayton, DPM, Foot & Ankle Center of Iowa/Midwest Bunion Center, 3720 N. Ankeny Blvd, Suite 103 Ankeny IA 50023.

E-mail address: daytonp@icloud.com (P. Dayton).

IMA is the line connecting the midpoint of the tarsometatarsal joint (TMT) and metatarsophalangeal joint (MTPJ) articular surfaces. When using the alMA before surgery and the mechanical IMA after surgery, which is commonly taught, observation bias occurs. This practice overestimates correction of all of the angular measurements defining HAV deformity (3). Because osteotomy creates a deformity in a normally straight metatarsal, these angular measurements are not valid postoperatively. We believe this practice prevents accurate understanding of the outcomes of the dozens of osteotomy procedures described for bunion correction and prevents the development of best-practice protocols.

In contrast to the more traditional 2D osteotomy approach for bunion correction, the foot and ankle community has seen a renewed interest in the study of the 3D anatomy of the HAV deformity and the application of triplane corrective procedures. Relatively few clinical studies exist reporting the results of the 3D concept for correction. This study is a retrospective analysis of radiographs from a group of patients with HAV who underwent triplane TMT correction. Objectives of this study include comparison of preoperative and final postoperative first ray measurements including IMA, HVA, TSP, DMAA, Seiberg index (SI), lateral round sign (LRS), metatarsal rotation angle (MRA), sesamoid subluxation, osseous union, and hardware failure using a uniform anatomic measurement technique based on the mid-diaphyseal line of the bone segments for both preoperative and postoperative assessments.

1067-2516/\$ - see front matter © 2019 by the American College of Foot and Ankle Surgeons. All rights reserved. https://doi.org/10.1053/i.jfas.2019.08.020

- Retrospective review of 109 feet with average follow-up of 17.4 months
- 3-plane TMT arthrodesis with biplanar 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

/ariable	n	Mean	Standard Deviation	95% Confidence Interval
HVA				
Preoperative	109	22.9	7.6	21.4 to 24.3
Postoperative	109	8.0	4.5	7.1 to 8.9
Change	109	-14.9	7.4	−16.3 to −13.4
MA				
Preoperative	109	13.3	2.4	12.9 to 13.8
Postoperative	109	5.7	2.4	5.2 to 6.1
Change	109	-7.7	2.7	−8.2 to −7.2
rsp °				
Preoperative	109	4.6	1.2	4.4 to 4.9
Postoperative	109	2.0	0.8	1.9 to 2.2
Change	109	-2.6	1.3	−2.8 to −2.3
MRA				
Preoperative	92	7.8	8.0	6.0 to 9.7
Postoperative	77	-4.5	6.8	−5.9 to −3.1
Change	72	-12.3	9.5	−14.5 to −10.0
DMAA				
Preoperative	109	19.6	9.2	17.8 to 21.3
Postoperative	109	5.3	3.8	4.6 to 6.1
Change	109	-14.2	8.7	−15.9 to −12.6

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

Case Example from Publication 18 months post-op



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."



Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org



Original Research

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

Paul Dayton, DPM, MS, FACFAS¹, Robert Santrock, MD², Merrell Kauwe, DPM³, Gary Gansen, DPM⁴, Sean Harper, DPM⁴, Andrea Cifaldi, BS⁵, Rachel Egdorf, BS⁵, lake Eisenschink, BS⁵

- ¹ Surgeon, Foot & Ankle Center of Iowa, Ankeny, IA
- ² Associate Professor and Chief of Foot and Ankle Surgery, Department of Orthopaedics, West Virginia University School of Medicine, Robert C. Byrd Health Sciences Center, Morgantown, WV
- ³ Surgeon, Private Practice, Billings, MT
- ⁴ Resident, Unity Point Health, Trinity Regional Medical Center, Fort Dodge, IA
- ⁵ Student, Des Moines University, Des Moines, IA

ARTICLE INFO

Level of Evidence: 4

Keywords: fusion Lapidus micromotion rigidity secondary bone healing stability

ABSTRACT

A review of 195 first ray arthrodeses fixated with a twin-plate biplanar construct, without interfragmentary 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 9 weeks, 10 to 12 weeks, \sim 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 radiographic follow-up, 97.44% of all cases had shown progressive osseous gap filling at the arthrodesis site, stable position of the bone segments, and intact hardware without loosening, 98.24% of the first MTP arthrodesis group and 96.82% of the first TMT arthrodesis group. Five (5.43%) feet had the presence of lucency at the fusion interface at the final follow-up, without positional change or hardware failure. Four (1.8%) feet had a failure of the hardware, loss of position, or frank gapping at the fusion site. Lucency decreased consistently over time in this series of patients (p < .00001). Progressive increase in callus density at the fusion site on serial radiographs was noted to be a consistent finding for both procedures and was the primary indicator of secondary bone healing at the noncompressed, relatively stable arthrodesis site. Our results confirm that biplanar plating construct without interfragmentary compression produces high fusion rates following the first MTP or TMT arthrodesis, with early weightbearing.

© 2018 by the American College of Foot and Ankle Surgeons. All rights reserved.

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 progress (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, compressive 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 to optimize healing following arthrodesis 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 tissue, bone is especially dependent on the mechanical environment to guide its repair process (3). In the context of foot 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 (6–8). Fixation for small bone arthrodesis most commonly employs interfragmentary compression screws, either alone or as compression screw and plate combinations. Compression techniques prioritize direct

Financial Disclosure: None reported.

Conflict of Interest: R. Santrock and P. Dayton are consultants for Treace Medical Concepts Inc., Ponte Vedra Beach, FL.

Address correspondence to: Paul Dayton, DPM, MS, FACFAS, Foot & Ankle Center of Iowa, 3720 N. Ankeny Blvd, Ankeny, IA 50023.

E-mail address: daytonp@me.com (P. Dayton).

1067-2516/\$ - see front matter © 2018 by the American College of Foot and Ankle Surgeons. All rights reserved. https://doi.org/10.1053/i.ifas.2018.09.001

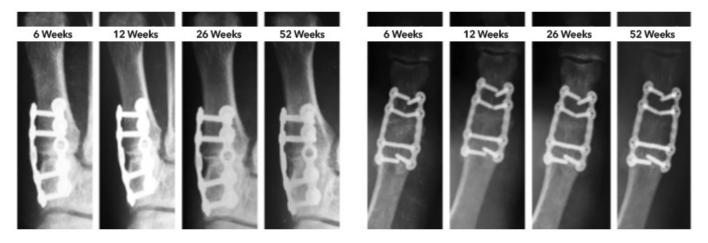
- Retrospective review of 195 feet with average follow-up of 9.5 months
- 3-plane TMT arthrodesis (110 feet) or 1st MTP arthrodesis (85 feet) with Biplanar™ Plating
- Weight-bearing in a surgical boot within the first week
- 97.4% patients achieved bony fusion and 98.9% maintained a stable joint position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

Radiographic Results

	Questions	MTP Arthrodesis		TMT Arthrodesis		Total [*]	
Weeks		Yes	No	Yes	No	Yes	No
6	Presence of lucency?	62.96	37.04	50.48	49.52	55.95	44.05
	Hardware failure or loosening?	0.62	99.38	0.96	99.04	0.81	99.19
12	Presence of lucency?	30	70	30.61	69.39	30.36	69.64
	Stable position?	100	0	98.98	1.02	99.40	0.60
	Hardware failure or loosening?	1.43	98.57	0.51	99.49	0.89	99.11
	Increase in radiodensity and trabecular pattern?	97.14	2.86	97.96	2.04	97.62	2.38
26	Presence of lucency?	11.54	88.46	10.42	89.58	10.95	89.05
	Stable position?	100	0	98.61	1.39	99.27	0.73
	Hardware failure or loosening?	2.308	97.69	1.39	98.61	1.82	98.18
	Increase in radiodensity and trabecular pattern?	97.69	2.31	97.92	2.08	97.81	2.19
52	Presence of lucency?	7.69	92.31	3.77	96.23	5.43	94.56
	Stable position?	100	0	98.11	1.89	98.91	1.09
	Hardware failure or loosening?	1.28	98.72	1.89	98.11	1.63	98.37
	Increase in radiodensity and trabecular pattern?	97.44	2.56	98.11	1.89	97.83	2.17
Final	Is there osseous bone growth in >50% of the arthrodesis site?	98.24	1.76	96.82	3.18	97.44	2.56

^{*}Total refers to the results of the MTP and TMT arthrodeses.

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



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."



Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org



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 ³, Robert Santrock, MD ⁴, Sean Scanlan, PhD ², Bret Smith, DO ⁵

- ¹ UnityPoint Clinic: and Assistant Professor, Des Moines University College of Podiatric Medicine and Surgery, Fort Dodge, IA
- ² Treace Medical Concepts, Inc., Ponte Vedra Beach, FL
- ³ Surgical Director, Northern Colorado Podiatric Medicine and Surgery Residency, Greeley, CO
- ⁴Chief, Department of Foot and Ankle Surgery, West Virginia School of Medicine, Morgan Town, WV
- ⁵ Director, Foot and Ankle Division, Moore Center for Orthopedics, Lexington, SC

ARTICLE INFO

Level of Clinical Evidence: 5

Keywords: arthrodesis internal fixation Lapidus multiplane twin plate

ABSTRACT

To better understand the mechanical characteristics of biplane locked plating in small bone fixation, the present study compared the stability under cyclic cantilever loading of a 2-plate locked biplane (BPP) construct without interfragmentary compression with that of a single-plate locked construct with an additional interfragmentary screw (SPS) using surrogate bone models simulating Lapidus arthrodesis. In static ultimate plantar bending, the BPP construct failed at significantly greater load than did the SPS construct $(556.2 \pm 37.1 \text{ N versus } 241.6 \pm 6.3 \text{ N}, p = .007)$. For cyclic failure testing in plantar bending at a 180-N starting load, the BPP construct failed at a significantly greater number of cycles (158,322 \pm 50,609 versus 13,718 \pm 10,471 cycles) and failure load (242.5 \pm 25.0 N versus 180.0 \pm 0.0 N) than the SPS construct (p = .002). For cyclic failure testing in plantar bending at a 120-N starting load, the results were not significantly different between the BPP and SPS constructs for the number of cycles (207,646 \pm 45,253 versus 159.334 ± 69.430) or failure load (205.0 \pm 22.4 N versus 185.0 \pm 33.5 N; p = .300). For cyclic testing with 90° offset loading (i.e., medial to lateral bending) at a 120-N starting load, all 5 BPP constructs (tension side) and 2 of the 5 SPS constructs reached 250,000 cycles without failure. Overall, the present study found the BPP construct to have superior or equivalent stability in multiplanar orientations of force application in both static and fatigue testing. Thus, the concept of biplane locked plating, using 2 low profile plates and unicortical screw insertion, shows promise in small bone fixation, because it provides consistent stability in multiplanar orientations, making it universally adaptable to many clinical situations.

 $\ensuremath{\texttt{©}}$ 2016 by the American College of Foot and Ankle Surgeons. All rights reserved.

Financial Disclosure: Paul Dayton has a consultant/advisory role with Treace Medical Concepts, Inc. (a company that markets the LapiplastyTM Triplanar Deformity Correction system), receives honoraria from Biomet and Zimmer, and receives research funding from Des Moines University. Sean Scanlan owns stock in Treace Medical Concepts, Inc. Joe Ferguson is employed by Treace Medical Concepts, which financially supported this study. Daniel Hatch is a consultant for and has equity interest in Treace Medical Concepts, Inc. Robert Santrock is a paid consultant for Wright Medical Technology, Treace Medical Concepts, and Amniox Medical; is an owner of/receives royalties from Epic Extremity; and receives royalties from Treace Medical Concepts, Inc. Bret Smith has a consultant/advisory roll with Treace Medical Concepts, Inc. and receives honoraria from Smith/Nephew, Osteomed, and Mimedex.

Conflict of Interest: Treace Medical Concepts, Inc. (Ponte Vedra Beach, FL) funded the mechanical testing; engineering reports from the mechanical tests, which were conducted at an independent firm, are available for review.

Address correspondence to: Paul Dayton, DPM, MS, FACFAS, UnityPoint Clinic, Des Moines University College of Podiatric Medicine and Surgery, 804 Kenyon Road, Suite 310, Fort Dodge, IA 50501.

E-mail address: daytonp@me.com (P. Dayton).

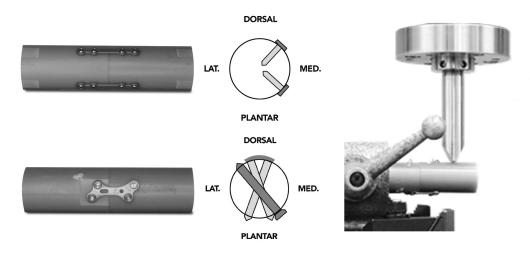
Osteosynthesis is a vital component of orthopedics for both trauma and reconstruction. The mechanical characteristics of orthopedic fixation influence bone healing by a complex cascade of biologic events. The biologic response of the bone varies depending on the design of the fixator (size, material, 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. Monolateral plate application along the axis of the bone requires the plate to have sufficient stiffness to resist the multiplane bending, traction, and rotational forces commonly experienced

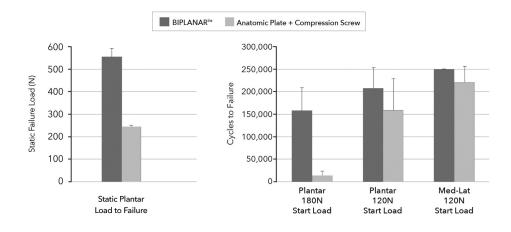
1067-2516/\$ - see front matter © 2016 by the American College of Foot and Ankle Surgeons. All rights reserved. http://dx.doi.org/10.1053/i.ifas.2016.01.020

- Biomechanical testing of Biplanar™ Plating (Gen 1) versus dorsal Lapidus plate + 4.0mm interfrag 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 vs 13,718 cycles (1,054% increase)
 - Cycles to failure @120N start load: 207,646 vs 159,334 cycles (30% increase)

Biomechanical Test Setup



Static and Cyclic Biomechanical Results



Study Conclusion

"The results of the study demonstrated that a small biplanar 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."



Analysis of Shortening and Elevation of the First Ray With Instrumented Triplane First Tarsometatarsal Arthrodesis

Hatch D, Dayton P, DeCarbo W, McAleer J, Ray J, Santrock R, Smith B. Foot & Ankle Orthopaedics 2020, 5(4): 1-8.

Summary: A prospective, multicenter study of 35 patients analyzing shortening and elevation of the first ray after instrumented triplane tarsometatarsal (TMT) fusion with the Lapiplasty* Procedure. At an average follow-up of 6-months, the results demonstrated a mean first ray shortening on sagittal and AP radiographs of 2.4 and 3.1mm, respectively. There was no increase in metatarsal elevation and no patients reported lesser metatarsal pain post-operatively.



Triplane Hallux Abducto Valgus Classification

Hatch DJ, Santrock RD, Smith B, Dayton P, Weil L Jr. J Foot Ankle Surg. 2018, 57:972-981.

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 J Foot Ankle Surg. 2018, 57:766-770.

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 J Foot Ankle Surg. 2017, 56:1041-1046.

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.



Effect on Foot Width With Triplanar Tarsometatarsal Arthrodesis for Hallux Valgus

Vaida J, Ray J, Shackleford T, Decarbo W, Hatch D, Dayton P, McAleer J, Smith B, Santrock R Foot & Ankle Orthopaedics 2020, 5(3): 1-5.

Summary: Multicenter, retrospective study of 144 patients (148 feet) who underwent the Lapiplasty® Procedure. All patients demonstrated a decrease in bony and soft tissue width after surgery. Bony width decreased by 10.4 mm (10.8%) postoperatively, whereas soft tissue width decreased 7.3mm (6.8%) postoperatively after triplanar first TMT arthrodesis.



Hallux Valgus Deformity and Treatment. A Three-Dimensional Approach: Modified Technique for Lapidus Procedure

Santrock RD, Smith B Foot Ankle Clin. 2018, 23:281-295.

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.)
Springer International Publishing [Textbook]. 2018.

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 Techniques in Foot & Ankle Surgery. 2017, 16:175-82.

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

- Ray JJ, et al. Hallux Valgus. Foot and Ankle Orthopaedics. 2019, 4:1-12.
- Smith WB, et al. Understanding Frontal Plane Correction in Hallux Valgus Repair. Clin Podiatr Med Surg. 2018, 35:27-36.
- Feilmeier M, et al. Comparison of Transverse and Coronal Plane Stability at the First Tarsal-Metatarsal Joint With Multiple Screw Orientations. Foot Ankle Spec. 2017, 10:104-108.
- DeCarbo W, et al. Triplanar Correction for First Metatarsophalangeal Fusion. J Foot Ankle Surg. 2021, 60: 1044-1047

The Evidence-Based Triplanar Solution

Backed by 16 Peer-Reviewed Lapiplasty. Publications

	Lapiplasty* offers
97-99% reproducible 3D correction ^{1,2}	✓
<2 weeks return to weight-bearing (in a boot) ^{1,2,5}	✓
10.4mm average reduction in foot width ³	✓
2.4-3.1mm average shortening of first ray⁴	✓
2-3 % non-union rate (9.5 & 13.5 month follow-up) ^{1,5}	✓
3% hardware removal rate⁵	✓
1-3% recurrence rate (at 13 - 17 month follow-up) ^{1,2}	✓
30% increase in cycles to failure with Biplanar [™] Plating ⁶ (compared to dorsomedial Lapidus plate + compression screw)	✓



203 Fort Wade Rd., Suite 150 | Ponte Vedra, FL 32081 | 904.373.5940 | www.treace.com ©2022 Treace Medical Concepts, Inc. All rights reserved. Pat. www.treace.com/patents M646D