CrossRoads Extremity Systems®

Biomechanical Comparison of the DynaBunion™ System with Integrated Anti-Drift Bolt™ and Bi-Planar Plating for 3-dimensional Correction of Moderate to Severe Hallux Valgus

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Featuring Discussion By
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Abstract

Severe to moderate hallux valgus deformity often requires resection, correction, and arthrodesis of the first tarsometatarsal (TMT) joint. The Lapidus procedure is commonly performed to treat this deformity and is often referred to as 3-dimensional correction. Instrumentation, techniques, and fixation have recently been developed to facilitate an efficient and reliable Lapidus surgery. DynaBunion™ from CrossRoads Extremity Systems® is an advanced procedure designed for 3-dimensional correction and arthrodesis of the first TMT joint with a minimal surgical exposure. This system also incorporates the "4th Dimension" of continuous dynamic compression across the fusion site. Another unique feature of the system is the integration of an "Anti-Drift Bolt™" directly into the plate construct. This lag bolt spans the proximal end of the 1st and 2nd metatarsals to resist drift forces that can lead to recurrence of the deformity.

This biomechanical study was designed to compare the mechanical performance of the DynaBunion™ System with its unique Anti-Drift Bolt™ to a typical bi-planar plate construct. The two systems were fixated to simulated 1st and 2nd metatarsal bone models and subjected to lateral to medial forces in both static and fatigue conditions. The DynaBunion™ with Anti-Drift Bolt™ yielded an impressive 152% stiffer construct in static loading and a 60% improvement in fatigue loading resistance.

Introduction

With recognition of the 3-dimensional anatomy of hallux valgus deformity, there has been an explosion of different treatment approaches. Numerous systems have been developed to enable surgeons to reproducibly correct this deformity in moderate to severe cases in a consistent fashion. In these cases, arthrodesis of the tarsometatarsal (TMT) joint of the first ray may be indicated to correct the deformity. This procedure was popularized by Paul Lapidus, MD in 1934 and is commonly referred to as the "Lapidus procedure." During this type of procedure, resections about the joint enable multi-planar correction of the deformity also referred to as 3-dimensional correction. Subsequent to these resections and re-alignment, the joint is prepared and fixated into place to facilitate bony fusion. One popular fixation construct involves the use of bi-planar plates that are placed dorsally and medially across the joint. These plates each have 4 in-line screws—two on either side of the joint.

Over time, Lapidus procedures have evolved to include the use of a lag screw to join the proximal end of the first metatarsal to the second metatarsal base or intermediate cuneiform to provide additional stability to the TMT joint fusion construct and to resist "drift forces" that may lead to recurrence of the deformity. The DynaBunion™ System (CrossRoads Extremity Systems®) incorporates an "Anti-Drift Bolt™" (ADB™) directly into the plate construct. This system also includes two proximal screws, one distal screw, and a nitinol staple across the joint which provides continuous dynamic compression. The purpose of this study is to compare the lateral-to-medial static and fatigue performance of the DynaBunion™ System with ADB™ against a typical bi-planar plate construct in a simulated Lapidus procedure.

Methods

Anatomical bone models were designed to simulate an idealized first TMT joint **(Figure 1)**. Two types of blocks were fabricated to maximize conformity to the respective plates. The DynaBunion™ plates have an anatomically curved undersurface, and the blocks were designed with a similar curvature. Blocks for the bi-planar straight plates utilized flat surfaces to correspond with the undersurface of the flat plates. The blocks were manufactured from polyurethane foam (30 PCF, SawBones, Vashon Island, WA). The second metatarsal, intermediate cuneiform, and medial cuneiform were all simulated as a single rigid unit (second metatarsal unit). The first metatarsal was completely independent from this unit with the exception of the fixation plates and screws that were being studied. The first metatarsal analog was pressed firmly against the second metatarsal unit during the application of the fixation.

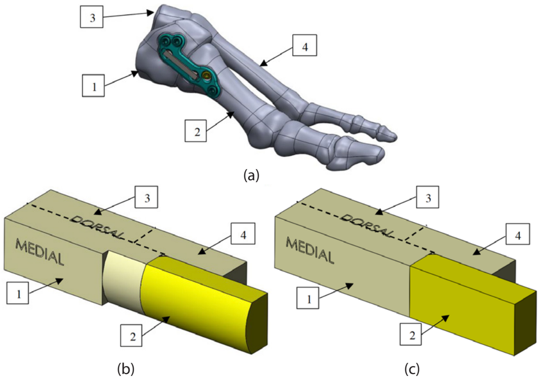
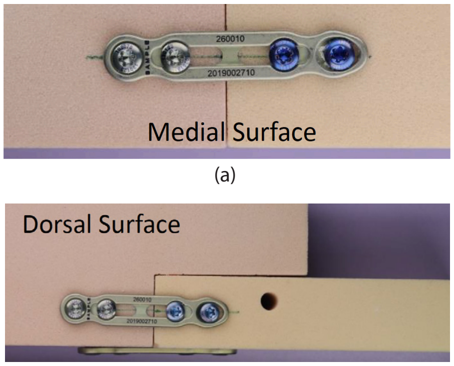


Figure 1: Test Block Analogs (a) DynaBunion™ plate, (b) Curved tarsal/metatarsal analog, (c) Flat tarsal/metatarsal analog 1 – Medial Cuneiform, 2 – 1st Metatarsal Base, 3 – Intermediate Cuneiform, 4 – 2nd Metatarsal Base

Figure 2 shows the bi-planar plate construct applied to its respective analog. The 2 proximal screws in both of these plates were 3.0 mm diameter locking screws while the 2 distal screws of the dorsal plate were 3.5 mm diameter non-locking screws, and the 2 distal screws of the medial plate were 3.5 mm diameter non-locking screws. The distal medial screws were 16mm long to avoid penetration into the 2nd metatarsal. The bi-planar plates were 44 mm long x 8.3 mm wide.

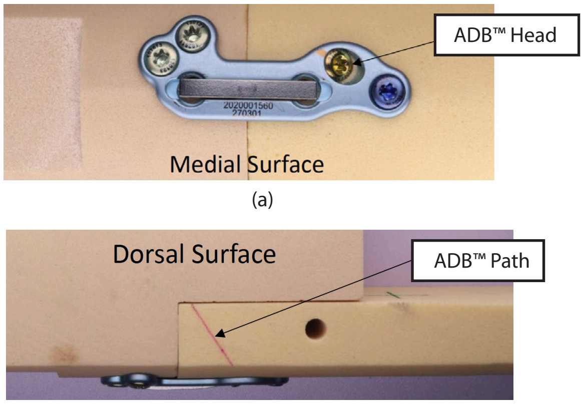


(a)

(b)

Figure 2: Bi-Planar Plate Test Set-up

Figure 3 shows the DynaBunion™ System applied to its analog. The DynaBunion™ plate is approximately 42mm long and 1.7mm thick. This construct utilized two 3.0 mm diameter locking screws placed proximally, one 3.5 mm diameter non-locking screw placed distally, an 18 x 18 mm HiMax™ nitinol staple across the joint, and a 3.5mm non-locking ADB™.



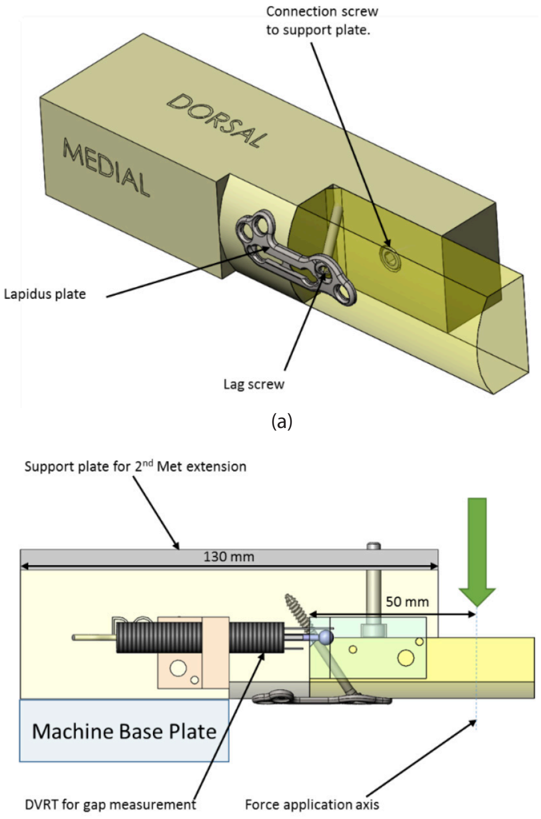
(a)

(b)

Figure 3: DynaBunion™ Plate Test Set-up

All screws were inserted normal to the plate surface and prepared with a 2.5 mm drill. The ADB™ was placed with an angular trajectory of approximately 57 degrees from its location in the plate (the proximal end of the first metatarsal) to the proximal end of the second metatarsal, approximately 3-4 mm from the joint. It was prepared with a 1.4 mm k-wire and a 2.5 mm cannulated reamer.

The second metatarsal unit was rigidly fixated into the hydraulic testing set up. The loading ram applied a lateral to medial force against the lateral aspect of the first metatarsal 50mm from the joint line. **(Figure 4 & 5)** This loading condition was selected to evaluate the two constructs' resistance to these medial "drift forces" which can cause medialization of the first metatarsal. The test set-up was warmed to 98.6 ° Fahrenheit for 10 mins prior to testing.



(a)

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Figure 4: Test Set-Up

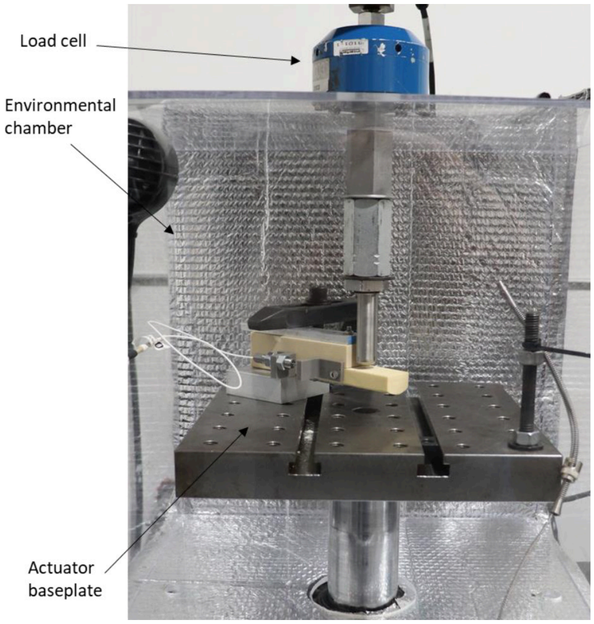


Figure 5:Test Set-up

Static Testing

The testing unit applied a load at a rate of 25.4 mm/minute. Load level continued to increase until failure of the construct was observed. Failure was defined as implants pulling out from the blocks, permanent deformation of the plate, or any other failure of the bone or construct. Time, force and displacement were recorded. Force-displacement data was used to calculate initial stiffness, and forces at 1 mm and 2 mm vertical displacement were recorded.

Fatigue Testing

For fatigue testing, the set-up was identical to the static set-up. Cyclic loading was applied to the construct at 1 Hz. Loading was applied in alternating fashion between 10% and 100% of the test load. Test load for each specimen started at 10N and was progressively increased after 1000 cycles if no failure was observed. Load levels utilized are shown in **Table 1**. Failure was defined as pull-out of the implants, permanent deformation of the plate, failure of the bone foam construct, or a 2 mm gap at the arthrodesis site.

Level	F (N)	Cycles
1	10	1000
2	20	1000
3	30	1000
4	50	1000
5	75	1000
6	100	1000
7	125	1000
8	150	1000
9	175	1000
10	200	1000

Table 1: Fatigue Loading Progression

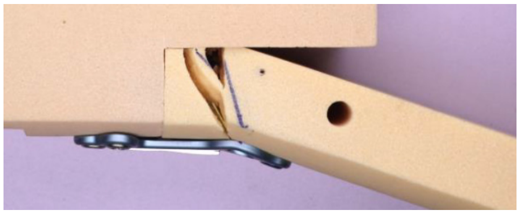
Results

Static Testing

The DynaBunion™ System with ADB™ exhibited 152% more initial structural stiffness than the bi-planar plate construct (n=1). The difference in force required to displace the joint medially by 1mm and 2mm was 226% and 244% higher, respectively, for the DynaBunion™ with ADB™ system vs bi-planar plates **(Table 2 and Chart 1)**.

Construct	Initial Structural Stiffness (N/mm)	Force at 1mm of Vertical Displacement	Force at 2mm of Vertical Displacement	Failure Mode
DynaBunion™ System with ADB™	120.8	98.1	172.8	Foam bone failure at the ADB™ Plate Deformation
Bi-Planar Plate Construct	47.9	30.1	50.2	Plate Deformation
% increase of DynaBunion™ w/ADB™ vs Bi-Planar Plate	152%	226%	244%	

Table 2: Static Results



DynaBunion™ with ADB™ Post-Static

Bi-Planar Plate Construct Post-Static

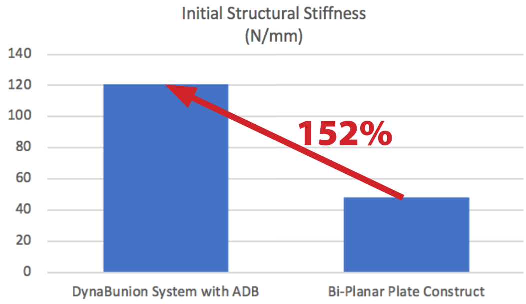


Chart 1: Initial Structural Stiffness Comparison

Fatigue Testing

The DynaBunion™ with ADB™ construct successfully achieved a load level of 200N and total cycle count of 10,000 cycles with no failure observed. The bi-planar plate construct, however, failed at a load of 125N at 7995 cycles and exhibited permanent deformation of the medial plate and a joint gap of 2 mm. This resulted in a 60% increase in fatigue performance for the DynaBunion™ with ADB™ over the bi-planar plate construct (n=1). The test protocol specified the test to be halted once 10K cycles are achieved, so it is possible that the performance delta is even greater.

Construct	Fatigue Runout (N)	Failure Mode
DynaBunion™ System with ADB™	200	Runout @ 10k cycles no failure observed
Bi-Planar Plate Construct	125	2mm gap at the TMT joint reached @ 7995 cycles plate deformation
% increase of DynaBunion™ w/ADB™ vs Bi-Planar Plate	60%	

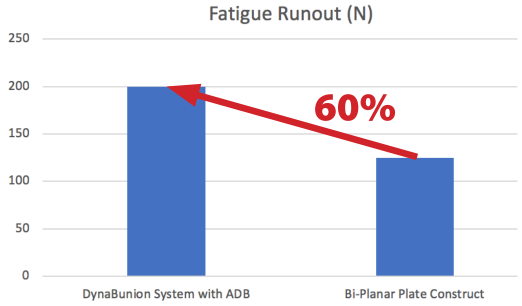


Chart 2: Fatigue Performance Comparison

Discussion

3-dimensional correction is a desirable treatment option for moderate to severe hallux valgus deformity. The Lapidus procedure has become increasingly popular as techniques and instrumentation have been developed to provide surgeons a straightforward and repeatable surgical experience. DynaBunion™ from CrossRoads Extremity Systems® is one such system. The DynaBunion™ construct incorporates an ADB™ that is integral to the plate fixation and spans the base of the first and second metatarsals providing the construct increased stability over a typical bi-planar plate construct. This biomechanical study displayed an impressive increase in both static and fatigue performance of the DynaBunion™ System with ADB™ over a typical bi-planar plating construct. The DynaBunion™'s superior mechanical performance, ease of use, minimal surgical exposure, and continuous dynamic compression across the fusion joint are compelling reasons to consider this system for 3-dimensional correction of moderate to severe hallux valgus deformities.

Ancillary Findings and Surgeon Perspective

Does integrating the Anti-Drift Bolt™ into the plate increase stability?

The DynaBunion™ System is unique in that it incorporates the Anti-Drift Bolt™ directly into the plate construct. An additional arm of this study was included to determine the effect of this feature. Static and fatigue constructs were built of the DynaBunion™ System with the ADB™ placed outside the plate (a few millimeters dorsal to plate adjacent to its standard location). A fourth non-locking screw replaced the ADB™ in the plate. Static and fatigue testing of this DynaBunion™ with "standalone" ADB™ construct was performed as described previously, and results were compared to that of the integrated ADB™ construct. The integrated ADB™ construct yielded a 33% increase in initial structural stiffness and a 14% increase in load resistance in fatigue indicating that the integration of the ADB™ directly into the plate construct has a beneficial biomechanical effect.

How does the DynaBunion™ System with integrated ADB™ compare to bi-planar plates with a standalone transmetatarsal bolt?

In order to answer this question, a standalone transmetatarsal bolt was added to the bi-planar plate construct and tested. The addition of this bolt did increase the stability of the construct. However, the DynaBunion™ System with the integrated Anti-Drift Bolt™ still achieved 10% greater load resistance at 2mm of displacement further indicating the importance of integrating the Anti-Drift Bolt™ directly into the plate construct.

Surgeon Perspective *- Scott Shawen, MD, FAOA*

"From the beginning of my training, my mentors were always afraid of performing a Lapidus or first tarsometatarsal joint (TMT) fusion. The primary concern was that of potential non-union. However, as multiple other surgeons and practices have championed the Lapidus or TMT fusion, I have embraced it as part of my practice. One of the primary sources that convinced me was the work done by Donald Bohay and John Anderson out of Grand Rapids, Michigan (Foot Ankle Int, 2005 Sep;26(9):698-703). In this study, they looked retrospectively at their experience over a 4-year period. During that time, they performed 201 first TMT fusions with a 96% healing rate, substantially better than previously reported rates of 80-85%.

As I looked into the success of the "Grand Rapids" technique employed by Anderson and Bohay, I noted that they utilized intermetatarsal as well as intercuneiform screws in addition to crossed screws at the first TMT joint. I believe that the addition of these screws provided increased stiffness to the construct, provided increased fusion rates, and prevented late recurrence of deformity, especially when treating the increased intermetatarsal angle of moderate to severe hallux valgus.

One of the primary focuses of the DynaBunion™ System is not only the ability to provide a 3-dimensional correction, but to provide lasting correction that give the best results. Not only do I believe that the system will provide excellent correction, but that this will provide a high fusion rate with the lowest chance for recurrence. It achieves this by providing constant compression at the fusion site and the addition of the Anti-Drift Bolt™, which provides stability to the construct and prevents late recurrence of the deformity."

What is the clinical relevance of placing a trans metatarsal Anti-Drift Bolt™?

"The Anti-Drift Bolt™, in my opinion, provides increased stability to the construct, which clinically increases the chance for a successful arthrodesis, but also decreases the possibility of late deformity recurrence. In addition, during the procedure, the Anti-Drift Bolt™ gives the surgeon the opportunity to dial in the amount of intermetatarsal angle correction."

What patients are candidates for the Anti-Drift Bolt™?

"I think that all patients undergoing a Lapidus or first tarsometatarsal fusion procedure are candidates for the Anti-Drift Bolt™. It provides increased stability to the fusion construct which cannot be ignored."

Indications and Risks

The MotoBAND® CP Implant System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. When used for these indications, the MotoBAND® CP Implant System with the exception of the 2-hole plate may be used with the MotoCLIP®/HiMAX® Implant System. There are potential risks associated with the use of these devices some of which include: allergic reaction to the implant material, fracture of the implant, soft-tissue complication (e.g., infection at the implant site, prolonged healing), and revision surgery. Refer to IFU for all contraindications, warnings, and risks.

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