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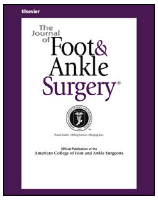

Editor's Note: This report represents scientific evaluation of fixation methods performed by investigators associated with the company selling the device under investigation. Nowadays, with unbiased funding scarce, this is commonplace. The report underwent blind peer review, editing, and the authors have disclosed their conflicts. Readers are encouraged to critically appraise the report, and to use the information as they see fit to do so.

Original Research

Biomechanical Characteristics of Biplane Multiplanar Tension-Side Fixation for Lapidus Fusion

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ABSTRACT

Although plating on the plantar, tension-side of the metatarsocuneiform joint provides an inherent biomechanical advantage for Lapidus arthrodesis, it has not been widely adopted owing to the morbidity associated with plantar application. To overcome these limitations, a modification to 90-90 locked biplanar plating was developed to provide the biomechanical advantages of multiplanar fixation and tension-side fixation, allowing application through a conventional incision. We tested the hypothesis that biplanar plating with tension-side fixation (low-profile straight dorsal plate and anatomic medial-plantar plate) would demonstrate improved mechanical stability compared with a previously tested 90-90 biplanar construct (small straight plate dorsally and medially) under cyclic loading. Both constructs were tested in static load to failure (3 pairs) and cyclic loading (10 pairs) with plantar cantilever bending using surrogate anatomic bone models. With static ultimate failure, the biplanar plate construct with tension-side fixation failed at a significantly greater failure load than did the straight biplanar plate construct (247.3 ± 18.4 N versus 210.9 ± 10.4 N; $p = .04$). With cyclic failure testing, the biplanar plate construct with tension-side fixation endured a significantly greater number of cycles (206,738 ± 49,103 versus 101,780 ± 43,273; $p < .001$) and a significantly greater dynamic failure load (207.5 ± 24.3 N versus 162.5 ± 20.6 N; $p < .001$) compared with the straight biplanar plate construct. These results have demonstrated that under simulated static and cyclic Lapidus arthrodesis loading, biplanar plating with tension-side fixation provides superior strength compared with the straight biplanar construct. Thus, this construct shows promise for clinical application as a practical approach to tension-side fixation and an early return to weightbearing after Lapidus fusion.

Lapidus arthrodesis is gaining renewed popularity for hallux abducto valgus correction owing to its ability to treat any severity and correct all 3 anatomic planes of the deformity, including frontal plane metatarsal rotation (1,2). A drawback of the Lapidus procedure has been the extended period of immobilization required when conventional rigid fixation techniques are used that incorporate primary bone healing. As our understanding of the biology of bone healing with various types of osteosynthesis has improved, new fixation recommendations and paradigms have emerged. With the developments in the technology and science of locked plating, the AO group's recommendation for internal fixation has evolved to advocate fixation with relative stability for a rapid, biologic osseous incorporation by way of secondary bone healing and callus formation (3,4). Such relative stability constructs aim to maintain the reduction but allow for controlled micromotion to stimulate a biologic bone healing process, theoretically supporting earlier weightbearing after osteotomy or fusion. One

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Fig. 1. Anteroposterior radiographic appearance of the (*A*) straight 90-90 biplanar plating construct and (*B*) biplanar plating with tension-side fixation.

such relative stability construct for Lapidus fusion is 90-90 biplanar locked plating (Fig. 1*A*), using 2 small locking plates oriented at 90° to each other. A recent study investigated the biomechanical properties of 90-90 biplanar plating versus a traditional anatomic Lapidus plate with an interfragmentary screw construct and found the former to be superior in both cyclic and static load to failure (5).

Tension-side plating is a desirable approach for improved stability to allow weightbearing after osteotomy and fusion procedures in the foot. A plantarly placed plate acts as a tension band to naturally counteract the bending moment produced during weightbearing (6,7). However, although theoretically advantageous, traditional attempts at plantar plating for the Lapidus procedure have not been widely adopted owing to the practical challenges associated with the exposure required with this approach. To address these limitations, a modified fixation construct was developed that combines the biomechanical advantages of tension-side fixation with the biologic healing benefits and ease of application of 90-90 locked biplanar plating (Fig. 1*B*). This new approach applies a low-profile plate dorsally and an anatomic plate from the medial aspect of the cuneiform to plantarly on the first metatarsal—providing tension-side support and multiplanar stability, and still allowing application through a conventional incision. The purpose of the present study was to test the hypothesis that this biplanar locking plate construct with tension-side fixation (straight dorsal plate and anatomic medial-plantar plate) would provide improved biomechanical stability compared with the previously tested 90-90 straight biplanar construct (straight plate dorsally and medially) under cyclic loading (5).

Materials and Methods

Mechanical testing was performed using 2 different 2-plate Lapidus fixation constructs: a straight 90-90 biplanar pate construct and a biplanar construct with tension-side fixation. The straight biplanar plate construct (CONTROL-360® System, Treace Medical Concepts, Inc., Ponte Vedra Beach, FL) consisted of 2 straight low-profile titanium 4-hole locking plates. One was placed on the dorsal surface and the other on the medial surface, 90° to each other (Fig. 2). The biplanar plate construct with tension-side fixation consisted of the same straight low-profile 4-hole locking plate placed on the dorsal surface but with an anatomic tension-side locking plate (PLANTAR-PYTHON® Plate; Treace Medical Concepts, Inc.) wrapping from the medial surface of the cuneiform to the plantar surface of the first metatarsal (Fig. 3). The anatomic tension-side plate was machined from a solid titanium block to provide the anatomic contour without introducing prestresses from manual bending. Both constructs were fixated with 2.5-mm unicortical locking screws, 12-mm length distally and 14-mm length proximally, with no interfragmentary screw. To isolate and directly compare the relative mechanical performance of the fixation constructs, test specimens were constructed using standardized surrogate anatomic bone models (fourth-generation sawbones cuneiform and first metatarsal composite models; Pacific Research Laboratories, Vashon, WA) to simulate the morphology and biomechanical properties of the cuneiform and first metatarsal and reducing interspecimen variability. All plates and screws were installed manually according to the manufacturer's surgical technique guides. The constructs were tested using a servohydraulic materials testing machine (MTS Systems Corporation, Eden Prairie, MN). Loading was performed in plantar cantilever bending, with the load applied from the plantar direction at a 30-mm moment arm from the arthrodesis site to simulate functional first tarsometatarsal (TMT) joint loading.

A static test with displacement control at a rate of 10 mm/min was first performed to determine the ultimate failure for each construct (n = 3 per group). Cyclic (fatigue) failure testing was performed (n = 10 per group) to simulate the number of

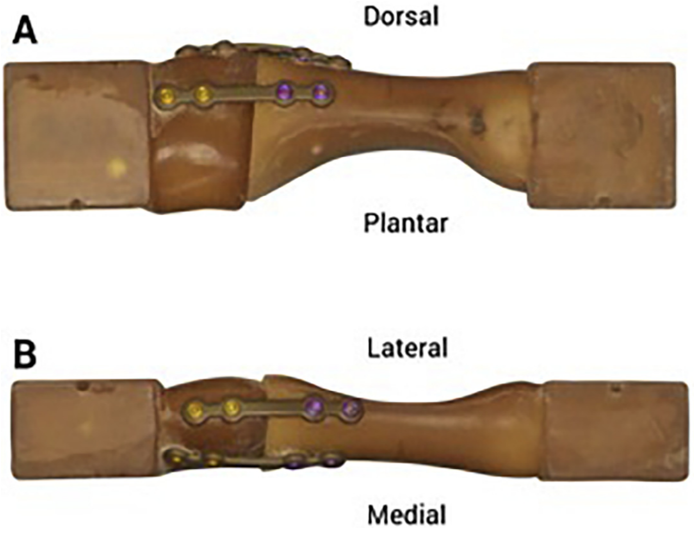

Fig. 2. Test specimen with straight 90-90 biplanar plating as viewed from the (*A*) medial aspect and (*B*) dorsal aspect.

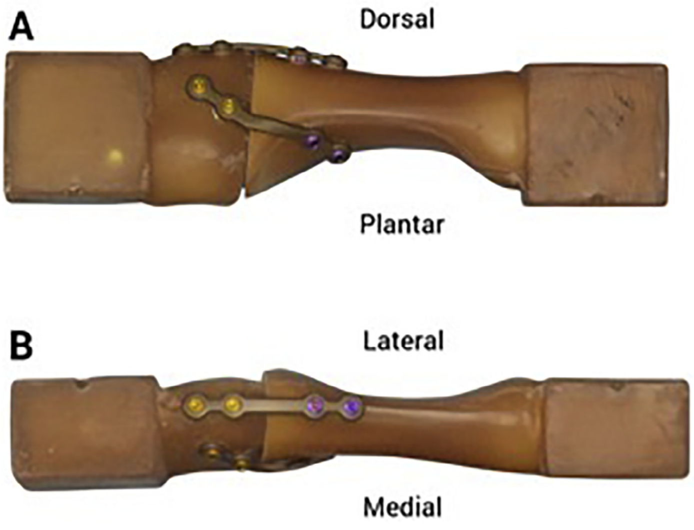

Fig. 3. Test specimen with biplanar plating and anatomic tension-side plate as viewed from the (*A*) medial aspect and (*B*) dorsal aspect.

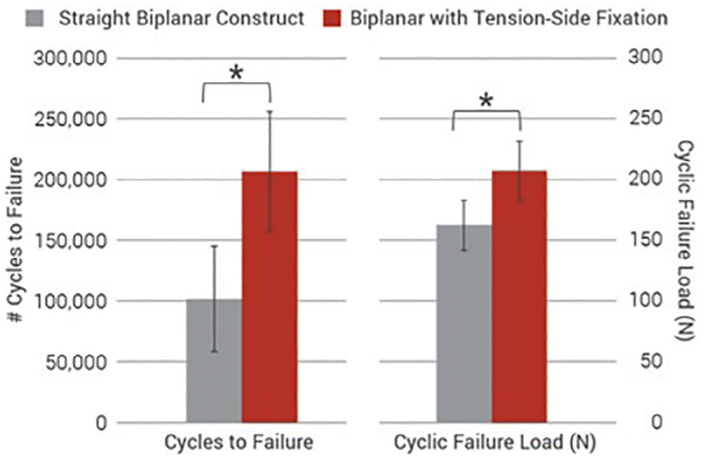

Fig. 4. Number of cycles to failure and cyclic failure load for the 2 constructs. The biplanar construct with tension-side plate was significantly superior in both cyclic to failure and cyclic failure load (*$p < .001$).

cycles and increase in loading experienced clinically in the postoperative period (5). Cyclic testing was conducted under sinusoidal load control parameters at a constant frequency of 5 Hz. An initial 120 N (3.6 N*m bending moment) plantar cantilever bending load was applied for the first 50,000 cycles and then increased by 25 N for each successive 50,000 cycles until failure or reaching 250,000 cycles. Failure was defined as permanent deformation or mechanical failure of the plates and/or screws.

Testing based on the engineering principles noted was completed by Focus Medical and Design (Oakland, TN). The testing and recording of the measurements was performed by technicians according to the specific parameters in the study protocol, and the raw data were provided to us in a written report. Several days of testing was required to run all constructs through cyclic loading according to the methods. The failure load was collected for both static and cyclic cantilever testing, and statistical analysis was performed using unpaired t tests to determine the differences in mechanical performance between the 2 constructs.

Results

Static Ultimate Failure Testing

For the 3 pairs of constructs tested to static ultimate failure in plantar cantilever bending, the biplanar plate construct with tension-side fixation failed at a significantly ($p = .04$) greater failure load (247.3 ± 18.4 N; 7.4 ± 0.6 N*m) than that of the biplanar plate construct (210.9 ± 10.4 N; 6.3 ± 0.3 N*m).

Cyclic Failure Test

For the 10 pairs of constructs tested in cyclic fatigue failure in plantar cantilever bending, the biplanar plate construct with tension-side fixation failed at a significantly ($p < .001$) greater number of cycles (206,738 ± 49,103 versus 101,780 ± 43,273 cycles) and significantly ($p < .001$) greater corresponding cyclic failure load (207.5 ± 24.3 N; 6.2 ± 0.7 N*m versus 162.5 ± 20.6 N; 4.9 ± 0.6 N*m) than did the straight biplanar plate construct (Fig. 4). Three biplanar plate constructs with tension-side fixation reached 250,000 cycles without failure compared with none of the straight biplanar plate constructs.

Discussion

The results of the present study have demonstrated that a biplanar plating construct with medial-plantar tension-side fixation significantly improves the biomechanical properties of straight 90-90 biplanar plating under both static and cyclic loading conditions simulating first TMT joint loading. These results are particularly relevant given that the tension-side plate is designed for application through a standard dorsal incision, suggesting that this construct might provide a practical balance between the biomechanical benefits of tension-side fixation and surgical application on the plantar aspect of the first TMT joint.

Biomechanical principles advocate for placement of fixation on the tension-side of a fracture or arthrodesis site to act as a dynamic tension band and resist the mechanical forces of weightbearing most efficiently (6,7). When placed on the tension side, a locking plate will naturally neutralize the tensile forces generated under an applied bending load, effectively converting the tensile forces of the bending moment to stabilizing compressive forces at the far cortex. The results of the present study support the biomechanical benefits of tension-band plating, because the biplanar construct with a dorsal plate and plantar, tension-side plate resisted approximately twice the cyclic loading cycles of the 90-90 biplanar construct with the plates placed dorsally and medially. These findings are consistent with several other biomechanical studies of various plantar plating constructs for Lapidus fusion. Marks et al (8) compared a plantarly applied tubular plate to crossing cortical screws in a cadaveric biomechanical model and found the plantar plate provided a significantly stronger construct. Klos et al (9) compared a dorsally to medially fixed-angle H-plate and a plantarly applied fixed-angle anatomic plate (both supplemented with a compression screw) in a cadaveric biomechanical model and demonstrated a significantly greater ultimate load for the plantar construct. Roth et al (10) compared an intramedullary device to a plantar plate (both supplemented with a compression screw) in a cadaveric biomechanical model under cyclic loading and found the plantar plate construct to be significantly stronger and stiffer. In contrast to these cited studies and principles, a recent biomechanical study reached a contrasting conclusion about the mechanical benefits of plantar plating (11). In that study, a medial locking plate with interfragmentary screw placed from distally to plantarly to dorsally to proximally was compared with a plantar plate with compression screw applied through the plate in a cadaveric biomechanical model. The results demonstrated a reduced ultimate load for the plantar plate construct (11). Although these findings appear paradoxical, a closer inspection of the radiographic and clinical images in their report appear to suggest that the plantar plate was actually applied more on the medial aspect of the arthrodesis site, potentially explaining the apparent discrepancy in the biomechanical findings. It could be that the medial application of the plantar plate in that study might be reflective of the technical difficulty and potential soft tissue morbidity associated with placing the plate on the true plantar surface of the medial cuneiform and first metatarsal.

Lapidus arthrodesis has historically required extended periods of immobilization to limit the risk of nonunion. However, several recent clinical studies have challenged this conventional approach, allowing patients to return to limited weightbearing within 3 weeks and still demonstrating high union rates (12–15). This trend toward early weightbearing has been enabled by the synergistic improvements in the understanding of the mechanobiology of bone healing with the advancement in anatomic and locked fixation technology (3,6,16).

Owing to the previously discussed biomechanical advantage of tension-band plating, plantar Lapidus plates have emerged as an option for early weightbearing with promising initial clinical results. Klos et al (13) performed a clinical study of 59 feet with immediate protected weightbearing using a plantar plate and compression screw construct. They demonstrated excellent clinical results and a nonunion rate of <2% (13). Gutteck et al (17) performed a clinical study of 17 feet with immediate protected weightbearing using a plantar plate construct. They demonstrated superior clinical results compared with medial plating and a nonunion rate of 0% (17). However, despite these initial successful clinical results, plantar plating has not been widely adopted owing to concerns about the morbidity associated with

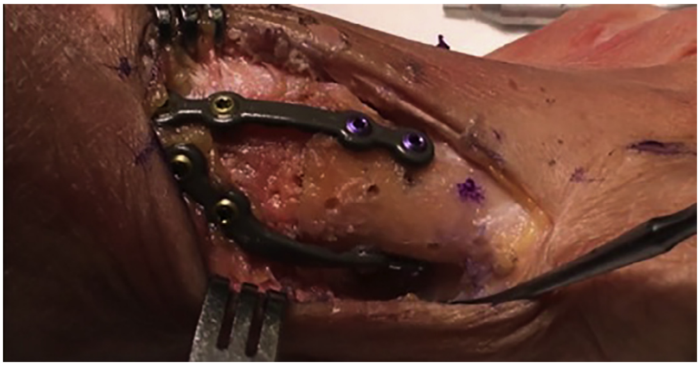

Fig. 5. Application of biplanar plating with tension-side fixation through a conventional dorsal incision.

surgical application. To better understand the soft tissue structures of the first TMT joint relevant to plantar plating, Plaass et al (18) performed an anatomic study of the fit and placement of 6 different Lapidus plantar plates relative to the tibialis anterior (TA) and peroneus longus tendon insertions in an open, cadaveric model. The results indicated that bending of the plates was necessary for an anatomic fit with all 6 of the plantar plate options. Also, all 6 contacted the TA tendon insertion to some degree (18). Although they still concluded that all 6 plating options could be placed with most of the plate in an anatomic "safe zone" between the TA and peroneus longus insertions, it is important to note that the "safe zone" on the central-plantar portion of the TMT joint was accessed by open dissection in their cadaveric model. In fact, the investigators cautioned that placement of the plates in practice cannot be performed visually without extensive soft tissue dissection and "therefore the placement of the plates in vivo may not be as optimal as it could be done in our study" (18). Another relevant finding from Plaass et al (18) was the observation that most of the TA tendon insertion was on the medial cuneiform, with an 87% greater insertion area relative to its insertion on the first metatarsal. This is an important finding in light of the present results, because the manufacturer has claimed that the tested anatomic tension-side plate is designed to avoid interference with the TA tendon by wrapping from the anterior margin of the TA tendon on the medial cuneiform, around the medial flare of the first metatarsal, and distally to the metatarsal's plantar surface (Fig. 5). Although not placed entirely on the plantar surface of the first TMT joint, this construct with the tension-side plate can be placed through a standard dorsal incision, potentially providing a practical solution that achieves a balance between the biomechanical benefits of tension-side plating and the clinical drawbacks of first TMT plantar access.

The development of locked plating technology is another advancement that has provided fixation properties conducive to bone healing under accelerated weightbearing conditions (3,6,16). Even a locked plating positioned on the dorsomedial surface of the first TMT joint has demonstrated successful clinical results with early protected weightbearing (12,15,19). In particular, when locked plating is used without a compression screw, such as in the 2 constructs tested in the present study, the construct can act as an "internal external-fixator," such that the independent stability of the construct is provided by the interlocking components rather than relying on the continued compression of the bone surfaces with compression screws (5,6,16). Such a locked bridging construct can take advantage of multiplanar stability principles and relative stability of bone healing, harnessing the mechanical stimulation and controlled micromotion of early weightbearing to promote a robust and rapid "biologic" secondary bone healing process by callus formation (3,4,16). This evolution in understanding has led to a shift in focus from mechanical to biologic healing principles and, ultimately, a change in osteosynthesis recommendations by the AO, which now supports flexible, relative stability fixation for "biologic" healing instead of the historical approach of primary bone healing using rigid compression fixation under absolute stability conditions (3). The results of the present study have expanded on a previous biomechanical comparison of the straight 90-90 biplanar plating without interfragmentary compression to a commonly used locked anatomic Lapidus plate with compression screw construct (5). Using a cyclic loading protocol similar to that used in the present study, the previous study demonstrated a superior number of cycles and cyclic load to failure for the biplanar plating construct (5). This previous investigation was the first study to show the biomechanical advantages of biplanar plating relative to a commonly used Lapidus arthrodesis construct, providing foundational support for the robust and multiplanar stability potential of 2 small locked plates positioned at 90° to each other with unicortical locking screws. Although the straight biplanar fixation used in the present study was the same as that in the previous study, some important factors should be considered when interpreting the findings of the studies. The previous study used idealized cylindrical surrogate bone models. In contrast, the present study used anatomic metatarsal and cuneiform surrogate bone models. Additionally, the previous study used a computer numeric control machine to precisely position and drill the holes for the screws. In contrast, the present study used a manual plate positioning and drilling technique more representative of actual clinical practice. Therefore, although the relative findings of the studies can be used for comparison purposes, the absolute failure load values and number of cycles should not be directly compared between the studies owing to these differences in experimental design.

When interpreting the results of the present study, one must consider the testing was performed in a nonclinical, laboratory setting. Care was taken in the design and execution of the present study to apply the fixation constructs in a manner clinically relevant to foot and ankle surgeons. The use of standardized artificial bone specimens reduced the variability that would have been present in a cadaveric trial. The initial force application was determined from similar biomechanical studies, which might not represent actual mechanical loading in vivo (5). Thus, although these results provide a fundamental understanding of the biomechanical properties of the tested fixation constructs, future clinical studies are needed to test the in vivo application and investigate their performance under the actual mechanical loads experienced with weightbearing after Lapidus arthrodesis.

In conclusion, the results of the present study have demonstrated that a biplanar plate construct with tension-side fixation significantly improves the biomechanical properties of straight biplanar plating under both static and cyclic loading conditions simulating Lapidus postoperative weightbearing. Designed for application through a dorsal incision, this tension-side approach offers the mechanical advantages of tension-band fixation and the biologic benefits of relative stability healing and avoids the extensive plantar dissection associated with conventional plantar plating. Taken together, this fixation construct shows promise for clinical application as a more practical approach to tension-side fixation and an early return to weightbearing after Lapidus arthrodesis.

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