ARTICLE IN PRESS

The Journal of Foot & Ankle Surgery xxx (2016) 1–5

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Original Research

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 [1], Joe Ferguson, MS [2], Daniel Hatch, DPM [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*
[4] *Chief, 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 ± 37.1 N versus 241.6 ± 6.3 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 ± 50,609 versus 13,718 ± 10,471 cycles) and failure load (242.5 ± 25.0 N versus 180.0 ± 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 ± 45,253 versus 159,334 ± 69,430) or failure load (205.0 ± 22.4 N versus 185.0 ± 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.

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 during dynamic activities. The addition of an interfragmentary compression screw increases construct rigidity but can compromise the biologic healing process by inducing excessive gap strain and selecting for primary healing only (1). In some applications, monolateral application can lead to suboptimal load distribution at the fracture site owing to the need for larger and stiffer materials that can resist weightbearing forces. This is seen in the case of a plate applied to the compression side of a bone, such as commonly occurs

Financial Disclosure: None reported.
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, 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).

http://dx.doi.org/10.1053/j.jfas.2016.01.020

Fig. 1. Image of a test specimen (*A*) and schematic of the cross-section (*B*) of the biplane plating construct with dorsomedial and medial–plantar plates fixated unicortically with 2.5 × 14-mm locking screws. LAT, lateral; MED, medial.

with Lapidus fusion. The plate must be robust to resist tension gapping on the far side, but if it is too stiff, it will maintain a gap, slowing or preventing healing. Therefore, a fine balance must be maintained between plate design and clinical application for fracture repair or reconstruction.

One method of balancing the need for multiplane stability without excessively rigid plates is to use 2 plates of smaller dimension along the axis of the bone at 90° and 180° to each other without an interfragmentary compression screw. Watts et al (2) compared the mechanical stability of a single large fragment plate with that of 2 small fragment plates side by side and noted improved stability with the 2-plate construct. Denard et al (3) noted superior construct stability of a biplanar construct compared with a uniplanar construct for both bicortical and unicortical screw insertion techniques. Kwaadu et al (4) reported favorable results with biplane locking plates in complex comminuted fibular fractures. Biplane plating has been used in applications in the arm with mechanical comparisons to single plates that have demonstrated favorable results (5,6). We have used this concept for small bone fixation in the foot using small flexible plates in >1 plane, and we are preparing the clinical results for publication.

With the recent extension of the biplane plating technique to small bone fixation in the foot, further clarification of the stability achieved for this method and comparison with standard fixation construct stability is needed to better understand the mechanical performance of this novel construct. Therefore, the purpose of the present study was to report the mechanical testing findings for multiplane loading of a biplane plating construct and a single anatomic plate with compression screw tested for cyclic failure (fatigue) to simulate the loading that occurs with progressive postoperative weightbearing.

Materials and Methods

Mechanical testing was performed using 2 distinct Lapidus fixation constructs. The biplane plating (BPP) construct consisted of two 1.2-mm-thick titanium 4-hole straight locking plates (Biplanar™ Plating System, Treace Medical Concepts, Ponte Vedra Beach, FL) placed at 90° circumferentially to each other (dorsomedial and medial–plantar) and fixated unicortically with 2.5 × 14-mm locking screws to produce a biplane construct with no interfragmentary screw (Fig. 1). The single locking plate (SPS) construct consisted of a 1.5-mm-thick titanium anatomic Lapidus locking plate placed dorsally with four 3.5-mm locking screws engaged bicortically and a single 4.0-mm interfragmentary screw also engaged bicortically (DARCO LPS™ 0-step plate and DART-FIRE™ headed screw; Wright Medical, Memphis, TN; Fig. 2). Test specimens were constructed using standardized surrogate bone models (Sawbones, Pacific Research Laboratories, Vashon, WA) on servo-hydraulic material testing machines (MTS Systems Corporation, Eden Prairie, MN; Fig. 3). Each bone model test specimen consisted of two 50-mm-length composite cylinders (27-mm outer diameter with a 2-mm wall thickness) filled with polyurethane foam. All specimens were prepared using a computerized mill to position and drill the appropriate holes to receive the screws. The plating constructs were placed in accordance with the associated manufacturer's surgical technique guides.

Static Ultimate Failure Test

A static cantilever test was first performed (BPP, n = 2; SPS, n = 2) to determine the ultimate failure for each construct and set the loading parameters for the fatigue tests. The static tests were conducted in displacement control at a rate of 10 mm/min, with load and displacement data collected. For static testing, the load was applied from the plantar direction. The maximum static failure load for the constructs was determined, and approximately 50% and 75% of the minimum construct failure load were used as the starting point for the medial-lateral cyclic testing and plantar cyclic testing, respectively.

Cyclic Failure Test

Cyclic (fatigue) cantilever failure testing was then performed (SPS, n = 9; BPP n = 9) to simulate the number of cycles and increase in loading experienced post-operatively. Both the SPS and BPP constructs were cyclically tested under plantar (SPS, n = 4; BPP, n = 4) and medial to lateral (SPS, n = 5; BPP, n = 5) bending load applications. All cyclic tests were conducted under sinusoidal load control parameters at a constant frequency of 5 Hz, with the load and displacement data collected. Failure was defined as permanent deformation or mechanical failure of the plate and/or screws. The failure mode, number of cycles to failure, peak failure load, and photographs were recorded for each specimen.

For the cyclic testing, an initial 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 250,000 cycles were reached. Two sets of cyclic testing were performed at different starting load magnitudes. The first set of cyclic testing had an initial starting load of 180 N (5.4 N·m bending moment) in the plantar loading direction (BPP, n = 4; SPS, n = 4). Because of the early observed failure of the SPS construct with the 180-N plantar starting load, the second set of cyclic testing was performed with a starting load of 120 N (3.6 N·m bending moment) for the plantar loading direction (BPP, n = 5; SPS, n = 5) and at a 90° offset from the plantar load direction (medial-lateral bending; BPP, n = 5; SPS, n = 5) to simulate alternative plate positions and surgical applications.

Fig. 2. Image of a test specimen (*A*) and schematic of the cross-section (*B*) of the single locking plate construct with anatomic Lapidus locking plate placed dorsally with four 3.5-mm locking screws engaged bicortically and a single 4.0-mm interfragmentary screw engaged bicortically. LAT, lateral; MED, medial.

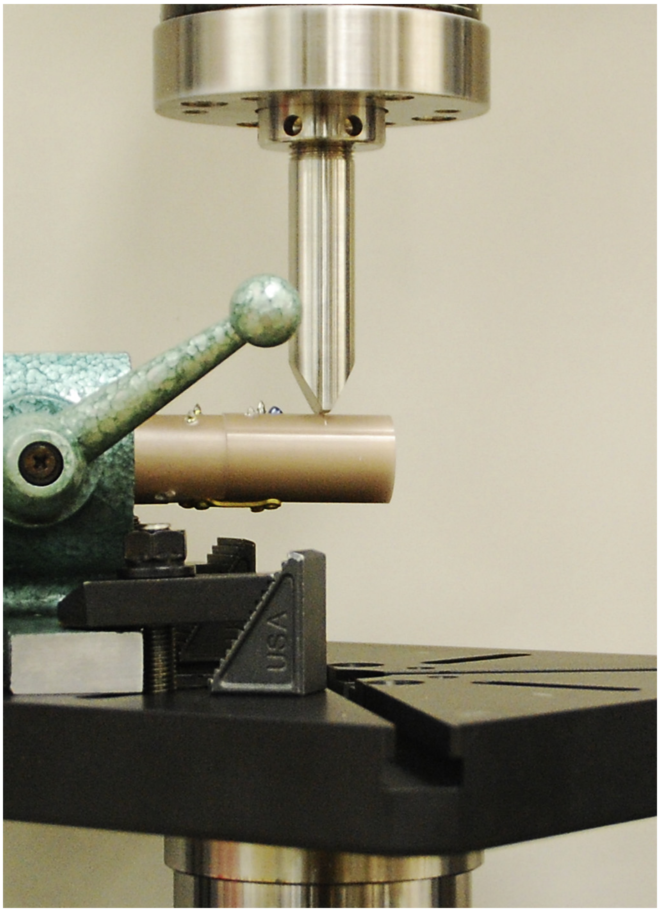

Fig. 3. Test setup for mechanical testing of static and cyclic cantilever bending.

A pretrial power analysis was performed to determine the minimum number of specimens to detect an effect size of 1.40 at a power of 0.50. These assumptions were used in planning because of the consistency of the materials, accuracy of the set up, and sensitivity of the mechanical testing equipment. Bonferroni-corrected *t* tests were used to determine the differences between the mechanical performance of the BPP and SPS constructs.

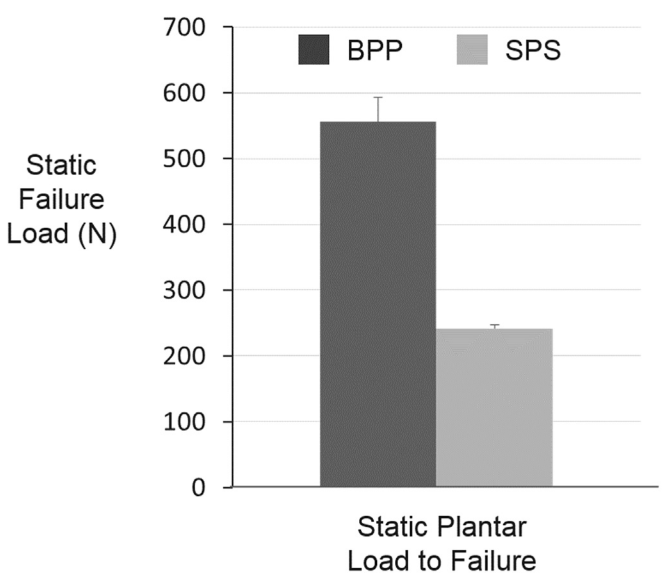

Fig. 4. Static ultimate failure load under plantar bending for the biplane plating (BPP) construct *(black bar)* and single locking plate (SPS) construct *(gray bar)*. Note that the BPP failure load was significantly greater than the SPS.

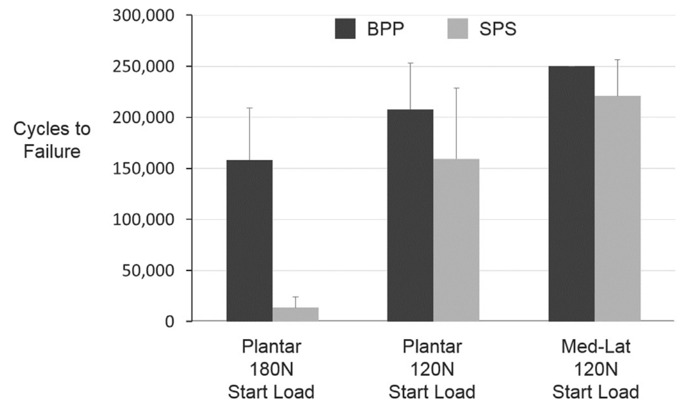

Fig. 5. Number of cycles to failure for the different combinations of load direction and starting load magnitude. Note that biplane plating construct (BPP; *black bar*) cycles to failure was significantly greater than the single locking plate construct (SPS; *gray bar*) for cyclic plantar loading starting at 180 N.

Results

Static Ultimate Failure Testing

The results from static ultimate failure test for plantar bending was 556.2 ± 37.1 N (16.7 ± 1.1 N•m moment) for the BPP construct and 241.6 ± 6.3 N (7.3 ± 0.2 N•m moment) for the SPS construct ($p = .007$). (Fig. 4). The ultimate displacement at the point of load application was 10.3 ± 5.0 mm for the SPS construct and 4.7 ± 0.4 mm for the BPP construct.

Cyclic Failure Test

For cyclic failure testing in plantar bending at a 180-N starting load (Figs. 5 and 6), the BPP construct failed at a mean of 158,322 ± 50,609 cycles at a load of 242.5 ± 25.0 N (7.3 ± 0.8 N•m moment), and the SPS construct failed at a mean of 13,718 ± 10,471 cycles at a load of 180.0 ± 0.0 N (5.4 ± 0.0 N•m moment; $p = .002$). For cyclic failure testing in plantar bending at a 120-N starting load (Figs. 5 and 6), the BPP construct failed at a mean of 207,646 ± 45,253 cycles at a load of 205.0 ± 22.4 N (6.2 ± 0.7 N•m moment), and the SPS construct failed at a mean of 159,334 ± 69,430 cycles at a load of 185.0 ± 33.5 N (5.6 ± 1.0 N•m moment; $p = .300$). Of the 5 BPP constructs and 5 SPS constructs, 2 and 1, respectively, reached 250,000 cycles (220 N load, 6.6 N•m moment) without failure. For the cyclic testing with 90°

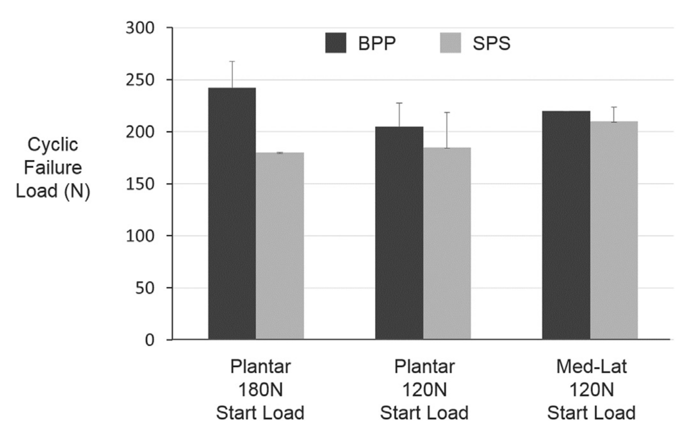

Fig. 6. Cyclic failure load for the different combinations of load direction and starting load magnitude. Note that the biplane plating construct (BPP; *black bar*) failure load was significantly greater than the single locking plate construct (SPS; *gray bar*) for cyclic plantar loading starting at 180 N.

offset loading (i.e., medial to lateral bending) at a 120-N starting load (Figs. 5 and 6), all 5 BPP constructs (tension side) reached 250,000 cycles without failure. The SPS construct failed at a mean of 220,933 ± 35,795 cycles at a load of 210.0 ± 13.7 N (6.3 ± 0.4 N•m moment; $p = .14$), with 2 of the 5 SPS constructs reaching 250,000 cycles (220 N load, 6.6 N•m moment) without failure.

Discussion

The results of the present study have 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 simulating the loading environment experienced with small bone fixation in the foot. These findings indicate that the 1.2-mm-thick, low-profile, titanium plates and unicortical screws (BPP) can provide a versatile fixation platform that achieves robust, multiplanar relative stability with controlled micromotion, potentially eliminating the drawbacks associated with compression screws and absolute stability techniques.

Compression fixation with screws relies on absolute stability (i.e., rigidity) to stabilize the bone segments. By definition, no motion is present at the fracture or osteotomy gap interface. The stability achieved is intimately associated with the bite of the screw and the ability to produce friction between the surfaces. This technique is therefore reliant on the quality and hardness of the bone. When bone segments are rigidly fixated, primary bone healing predominates. Some question exists regarding whether primary fracture healing alone without endosteal and periosteal callus is the most efficient and rapid course to stable bony union (1,7). It is known that the natural process of callus healing adds to the cross-sectional stability of the fracture or osteotomy, and this, in addition, to limiting the gap strain might provide a faster method of achieving stable union (1,8).

The concept of relative stability is easily understood in the example of an external fixator. The fixator has independent stability provided by the interlocking components. When applied to a bone segment, the fixator controls the relative position and apposition of the fragments without the need for interfragmentary compression. Studies have shown that under certain conditions, cyclic or dynamic compression stimulates new bone formation (7,8). This concept of dynamic or cyclic compression is much different than the concept of statically compressed surfaces that are the goal of rigid compression screw fixation. Using biplane plating without interfragmentary compression, we attempted to attain a construct in which relative stability of the segments is achieved, at the same time, some flexibility is retained to allow for cyclic movements along the fracture surfaces.

The design, materials, and application of a locking plate directly influence this flexibility, which under proper circumstances might stimulate new bone formation and, in the case of an excessively stiff plate, could impair healing. Multiple researchers have reported this concept of excessively stiff locking plates interfering with bone development and leading to an increased incidence of nonunion. Roderer et al (9) concluded that increased stiffness and lower interfragmentary movement induce the low bone formation seen with the use of stiff locking plates. They noted that the loads acting on locking plates are carried exclusively by the screws and the plate, which requires these plates to be rather thick to avoid fatigue fractures. This also results in increased stiffness of the implant, which results in reduced tissue formation. Lujan et al (10) reported asymmetric callus formation, with the far cortex having on average, 64% more callus than the anterior and posterior cortices owing to reduced interfragmentary motion at the cortex adjacent to the plate. More flexible titanium plates enhanced callus formation compared with stainless steel plates. Bottlang et al (11) and Henderson et al (12) concluded that deficient healing could be caused by the high stiffness and asymmetric gap closure of stiff locked-plate constructs.

An important clinical question when comparing rigid screw fixation and various forms of plate fixation is the performance during cyclic force application or fatigue. This is most important in vivo because in the clinical situation, cyclic forces of partial weightbearing during the postoperative period are typically less than the force expected to cause ultimate failure; therefore, it is important to resist many cycles of subultimate force to prevent fatigue failure. Also, the strain or micromotion threshold for direct compression fixation is much lower, possibly biologically compromising the healing and stability of compression constructs before gross construct failure. In the present trial, cyclic testing was performed at 2 different orientations to simulate the plate orientation and loading with weightbearing in the Lapidus tarsal metatarsal arthrodesis procedure. The mean survivability of the BPP constructs was equivalent or superior to the larger plate and compression screw construct in the various loading scenarios. Theoretically, this would indicate that the BPP would maintain stability during early weightbearing in the postoperative period better than would the single plate compression model. When considering clinical bone fixation, a construct must have enough strength to prevent load failure; however, even more importantly, if the patient is to walk early in the postoperative course, the construct must prevent cyclic failure with the repeated loading seen with weightbearing. Considering these facts and the recent data indicating controlled micromotion can be beneficial for biologic healing, our priority was to find a construct strong enough to resist load failure, stable enough to prevent cyclic failure, and flexible enough to allow for controlled micromotion during biologic repair by callus formation. Using cyclic loading for the basis of our mechanical testing, we have more closely estimated the expected behavior of these constructs with the patient weightbearing. However, we recognize that mechanical testing cannot predict the clinical results.

Our testing method used an idealized bone model and loading environment to reduce experimental variability to isolate and directly compare the relative mechanical performance of a novel BPP versus a construct representing the current clinical standard (SPS). Thus, one must be cautious when attempting to directly extrapolate the absolute values of the cycles and load to failure of the study to in vivo, clinical loading scenarios. However, for the purposes of interpreting the results of the present study, the bending moment experienced at the tarsometatarsal joint during normal, healthy walking is estimated to be approximately 15 to 30 N•m (13,14). Although the loading conditions were idealized in our study, it is clear that we applied loads that approximate those of partial and/or full weightbearing during the early postoperative period. Thus, our findings suggest that the BPP could withstand the cyclic forces of weightbearing and also provide controlled micromotion of the bone surfaces to maintain the stimulus for biologic repair by callus formation.

Mechanical comparison studies (15–17) have shown the locking plate with compression screw to be superior to a single plane plate in resisting ultimate load failure. The use of a flexible plate, a biplane construct with unicortical screws seems to strike a balance between appropriate stability and avoidance of excessive rigidity. It is clear that plate thickness and size are key components that determine the rigidity or flexibility of a plate. Additionally, the number of screws and technique of screw insertion have a bearing on stability and flexibility. Unicortical screws have been shown to provide robust stability when used in multiplanar configurations (3). A biplane construct of 2 smaller flexible titanium plates has the advantage of multiplane stability and some retained flexibility. Also, this construct performs well under cyclic loading conditions using unicortical screw insertion, as shown by our testing. Unicortical insertion requires less time for application because measuring is not needed and allows the opportunity for standardized plate systems not requiring multiple screw lengths in a large set. A simple straight flexible plate can be contoured to the surgical anatomy and unicortical screws with a predetermined length can be inserted. A second identical plate and screw is contoured to the anatomy approximately 90° to the first plate to achieve multiplane stability. Because the failure of a locking plate does not result from individual screw pull out or maintenance of static compression across the surfaces, the screw thread purchase or “bite” in the bone is not the priority. When considering the mechanics of static compression fixation, it is the screw bite that is the most vital component producing stability. Therefore, screw fixation and nonlocking plate fixation, which also rely on the surface friction of the plate to the bone produced by the screw bite and compression, are less reliable in soft bone and in unicortical applications (1). We applied the locking plates in the BPP with unicortical screws and the SPS construct with bicortical screws for both the plate and the interfragmentary screw. Despite this, the BPP construct mechanically outperformed the SPS construct. This highlights the importance of component orientation over screw insertion and purchase.

As with all studies, our trial had certain shortcomings. First, testing was performed in a nonclinical setting. Care was taken in the design and execution of the trial to apply the fixation constructs in a manner clinically familiar to foot and ankle surgeons. The use of standardized artificial bone specimens and computer milling techniques for application of the components reduced the variability that would have been present in a cadaveric or clinical trial using a surgeon-specific manual technique. The initial force application was calculated as the average percentage of the ultimate failure force of the 3 constructs, which might not represent the actual mechanical loading forces in vivo. Despite this somewhat arbitrary assignment of the initial force, the testing was consistently applied to all specimens, adding to the reliability of our comparative results. Additionally, fatigue testing more closely simulates the forces encountered at a surgical site when the patient moves or walks postoperatively resulting in fatigue rather than ultimate or total load failure.

A comparison of the BPP constructs and SPS constructs showed superior or equivalent stability in multiplanar orientations of force application in both static and fatigue testing. This concept shows promise for clinical applications in small bone fixation, because it provides consistent stability in multiplanar orientations using low-profile plates and unicortical screw insertion. These factors make it universally adaptable to many clinical situations. In addition, stability is maintained despite the absence of an interfragmentary screw, thereby eliminating surface preload and gap strain and potentially making this technique enable more biologic healing. Using this idea of biplanar placement of locking plates, the plates can theoretically be made smaller and more flexible and still provide appropriate overall mechanical stability. This construct concept might be advantageous when the anatomy prevents placement of a single plate in the most desirable mechanical orientation.

References

1. Perren SM. Evolution of the internal fixation of long bone fractures. J Bone Joint Surg 84:1093–1110, 2002.
2. Watts A, Weinhold P, Kesler W, Dahners L. A biomechanical comparison of short segment long bone fracture fixation techniques: single large fragment plate versus 2 small fragment plates. J Orthop Trauma 26:528–532, 2012.
3. Denard PJ, Doornink J, Phelan D, Madey SM, Fitzpatrick DC, Bottlang M. Biplanar fixation of a locking plate in the diaphysis improves construct strength. Clin Biomech 26:484–489, 2011.
4. Kwaadu K, Fleming J, Lin D. Management of complex fibular fractures: double plating of fibula fractures. J Foot Ankle Surg 54:288–294, 2015.
5. Penzkofer R, Hungerer S, Wipf F, von Oldenberg G, Augat P. Anatomical plate configuration affects mechanical performance in distal humerus fractures. Clin Biomechan 25:972–978, 2010.
6. Schwartz A, Oka R, Odell T, Mahar A. Biomechanical comparison of two different periarticular plating systems for stabilization of complex distal humerus fractures. Clin Biomechan 21:950–955, 2006.
7. Karnezis I. Biomechanical considerations in “biological” femoral osteosynthesis: an experimental study of the bridging and wave plating techniques. Arch Orthop Trauma Surg 120:272–275, 2000.
8. Hente R, Fuchtmeier B, Schlegal U, Ernstberger A, Perren S. The influence of cyclic compression and distraction on the healing of experimental tibial fractures. J Orthop Res 22:709–715, 2004.
9. Roderer G, Gebhard F, Duerselen L, Ignatius A, Claes L. Delayed bone healing following high tibial osteotomy related to increased implant stiffness in locked plating. Injury 45:1648–1652, 2014.
10. Lujan T, Henderson C, Madey S, Fitzpatrick D, Marsch J, Bottlang M. Locked plating of distal femur fractures leads to inconsistent and asymmetric callus formation. J Orthop Trauma 24:156–162, 2010.
11. Bottlang M, Doornink J, Lujan T, Fitzpatirick D, Marsh JL, Augat P, von Rechenberg B, Lesser M, Madey SM. Effect of construct stiffness on healing of fractures stabilized with locking plates. J Bone Joint Surg Am 92(suppl 2):12–22, 2010.
12. Henderson C, Kuhl L, Bottlang M, Fitzpatrick D, Marsh J. 2010 mid-America Orthopaedic Association Physician in Training Award: Healing complications are common after locked plating for distal femur fractures. Clin Orthop Relat Res 469:1757–1765, 2011.
13. Scott SH, Winter DA. Biomechanical model of the human foot: kinematics and kinetics during the stance phase of walking. J Biomech 26:1091–1104, 1993.
14. Wearing SC, Urry SR, Smeathers JE. Ground reaction forces at discrete sites of the foot derived from pressure plate measurements. Foot Ankle Int 22:653–661, 2001.
15. Scranton PE, Coetzee JC, Carreira D. Arthrodesis of the first metatarsocuneiform joint: a comparative study of fixation methods. Foot Ankle Int 30:341–345, 2009.
16. Cottom J, Rigby R. Biomechanical comparison of a locking plate with intraplate compression screw versus locking plate with plantar interfragmentary screw for Lapidus arthrodesis: a cadaveric study. J Foot Ankle Surg 52:339–342, 2013.
17. Cottom J. Fixation of the Lapidus arthrodesis with a plantar interfragmentary screw and medial low profile locking plate. J Foot Ankle Surg 51:517–522, 2012.