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Biomechanical comparison of bone-screw–fasteners versus traditional locked screws in plating female geriatric bone

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ABSTRACT

Objectives: To biomechanically compare plated constructs using nonlocking bone–screw–fasteners with interlocking threads versus locking screws with traditional buttress threads in geriatric female bone.

Methods: Eleven matched pairs of proximal and distal segments of geriatric female cadaveric tibias were used to create a diaphyseal fracture model. Nonlocking bone–screw–fasteners or locking buttress threaded screws were applied to a locking compression plate on the anterolateral aspect of the tibia placed in bridge mode. Specimens were subjected to incrementally increasing cyclic axial load combined with constant cyclic torsion. Total cycles to failure served as a primary outcome measure, with failure defined as 2 mm of displacement or 10 degrees of rotation. Secondary outcome measures included initial stiffness in compression and torsion determined from preconditioning testing and overall rigidity as determined by maximum peak-to-peak axial and rotational motion at 500 cycle intervals during cyclic testing. Group comparisons were made using paired Student's *t*-tests. Significance was set at $p < 0.05$.

Results: Bone–screw–fastener constructs failed at an average of 40,636 ± 22,151 cycles and locking screw constructs failed at an average of 37,773 ± 8433 cycles, without difference between groups ($p =$ =0.610). Total cycles to failure was higher in the bone–screw–fasteners group for 7 tibiae out of the eleven matched pairs tested. During static and cyclic testing, bone–screw–fastener constructs demonstrated increased initial torsional stiffness (7.6%) and less peak-to-peak displacement and rotation throughout the testing cycle($p < 0.05$).

Conclusions: In female geriatric bone, constructs fixed with bone–screw–fasteners incorporate multiplanar interlocking thread geometry and performed similarly to traditional locked plating. These novel devices may combine the benefits of both nonlocking and locking screws when plating geriatric bone.

Introduction

Plate fixation conventionally employs screws that utilize buttress thread morphology around a leading and trailing flank angle and screw head options to included locking modifications to provide stable coupling of the implant to the plate. Buttress threaded screws for orthopedic use were designed many decades ago, with the goal to primarily resist coaxial pull out forces. From a design standpoint, to achieve this, the load bearing surfaces of the threads are typically perpendicular or slightly inclined to the axis of the inner core (Fig. 1) [1–4].

Under physiologic conditions, however, constructs must withstand multidirectional loads to resist bending, torsional, and shear forces. This disparity has led to poor fixation in many circumstances and subsequent development of locking screws (LS) coupled with the traditional buttress thread, in which the screw head locks into the plate to create a fixed angle construct. Locking screws are designed to provide more stable fixation than conventional screws that generate compression at the plate-bone interface for stability through friction [5,6].

Conventional nonlocking screws (which have buttress threads) are often unable to develop sufficient insertion torque in metaphyseal or osteopenic bone to provide enough compression at the plate-bone interface to resist shear forces, leading to early implant loosening [6]. In this clinical scenario, fixed angle constructs with

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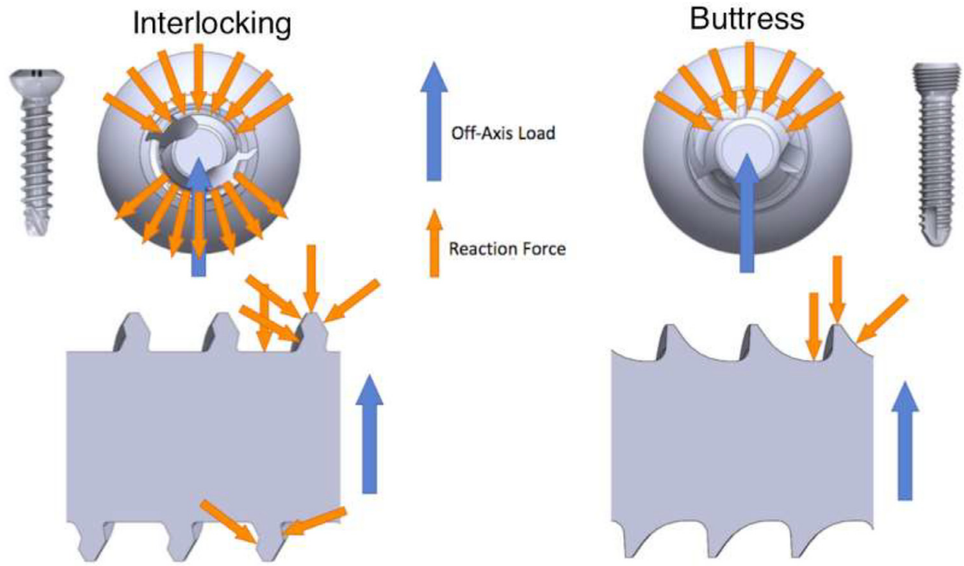

Fig. 1. Bone–screw–fasteners have interlocking screw threads that are multiplanar and designed to resist multidirectional load compared to locking screws with the traditional buttress threads designed primarily to resist coaxial pull out force [3,4].

locking screws may be indicated given the stability of fixation has important implications for fracture healing [7,8].

Despite historical and prevalent use, buttress thread design may not provide maximal performance due to a mismatch between screw thread designed to resist only coaxial forces and the multidirectional stresses experienced in vivo. Novel interlocking screw threads may be superior in mechanical performance by addressing the engineering shortcomings of traditional buttress threaded screws. Theoretical advantages include a thread pattern that can better distribute loads across multiple thread surfaces, and better resist multi-directional loads when subjected to both axial and off-axis loading scenarios while allowing for higher insertional torque (Fig. 1) [3].

Bone–screw–fasteners (BSF) are designed with screw threads that interlock within the bone differently than buttress threads with the aforementioned advantages and have nonlocking heads that generate compression through friction at the plate-bone interface to provide stable fixation. We hypothesized that constructs using nonlocking bone–screw–fasteners would be biomechanically comparable to constructs utilizing locking buttress threaded screws (LBuS) in plating female geriatric bone in bridge mode.

Methods

Six matched pairs of human female cadaveric tibias were used in the study (age: 87 ± 6.7 yrs, range: 79–94 yrs). Dual-energy x-ray absorptiometry scans (Lunar iDXA, GE, Chicago, IL) were performed on all specimens, and areal bone mineral density (BMD, avg 1.33 g/cm^2) was determined at the approximate locations of plate fixation. Specimens underwent two freeze-thaw cycles, the first for dissection, and the second for instrumentation and mechanical evaluation.

On the day of dissection, specimens were thawed and all soft tissue was removed from the bone. The proximal 5.5 cm of the tibia was removed and the medial malleolus was osteotomized and discarded to facilitate potting of the specimens. The remaining bone was transected 12.5 cm from both the distal and proximal ends. The central tibial fragment was discarded. This created 12 matched diaphyseal tibia pairs for testing. Specimens then were wrapped in phosphate buffered saline soaked towels (PBS) and stored in a −20 °C freezer.

On the day of mechanical testing, the distal end of the tibia was randomly assigned to plating with either three 3.5 mm (2.4 mm minor diameter; 1.25 mm pitch) bone–screw–fasteners (First Generation Bone Screw Fasteners, Unifi OsteoCentric, Austin, TX) or 3.5 mm (2.8 mm minor diameter; 1.25 mm pitch) locking screws (DePuy Synthes, Raynham, MA). Following predrilling with the manufacturer's recommended sized drill bit (BSF: 2.5 mm dia; locking screw: 2.8 mm dia), fasteners or screws were inserted in bicortical fashion perpendicular to the nonlocking or locking plate hole, respectively, of an eight hole 3.5 mm locking compression plate which has hybrid holes that accommodate either compression screws or locking screws (Depuy Synthes, Raynham, MA). LBuS or BSFs were centered on the anterolateral aspect of the tibia in holes 6, 7, and 8 in a concentric position. Drill sites were selected to locate the centerline of the plate 5 mm proximal to the diaphyseal end of the bone by measuring and predrilling occurred prior to plate application.

Before testing, the free end of the plate was rigidly attached to an aluminum fixation block using three M4 machine screws in holes 1, 2, and 3 [9]. The distance between the transected tibia and aluminum block was set to 10 mm with holes 4 and 5 being empty. This configuration approximates a half model of a 10 mm osteotomy. The utilization of a half model allows for two test specimens from each tibia, resulting in a sample size of 12 specimens per group.

The proximal tibial fragment was plated with screws from the remaining test group. Following manufacturer recommendations, all LBuS were tightened to 1.5 Nm torque. BSF were tightened using tactile feedback until fully tight to provide maximum compression at the plate bone interface without stripping the fastener at the discretion of the orthopaedic surgeon. Insertion torque for all screws was recorded using a Model DID-4 digital torque screwdriver (Imada Inc, Northbrook IL). The digital torque screwdriver had a resolution of 0.001 Nm and an accuracy of ±0.5% full scale, ±1 least significant digit. Proximal and distal fixation group assignment was reversed in the contralateral tibia.

The proximal and distal bone segments were then potted in polymethylmethacrylate (PMMA) blocks to facilitate attachment to the materials testing machine. Fixation in PMMA was augmented by placing wood screws in the cortical bone below the level of the plated bone.

Fig. 2. Experimental set-up for mechanical evaluation of the fracture fixation constructs. PBS soaked towels have been removed for clarity. The fracture fixation plate was fixed to an aluminum block attached to the base of the test machine. The tibial fragment was secured to a universal joint attached to the loading actuator with the bone centerline coaxial to the test machine actuator. Data from the motion tracker sensors (black triangular objects) was used to verify actuator rotary motion during testing.

Mechanical testing was performed on an ElectroPuls E10000 materials testing system using a 10 KN/100 Nm biaxial load cell (Instron Corporation, Norwood MA) (Fig. 2). The test machine actuator motion is accurate to 0.03 mm and 0.5°. The fracture fixation plate was fixed to an aluminum block attached to the base of the test machine using three M4 screws tightened to 3.5 Nm torque. The tibial fragment was secured to a universal joint attached to the loading actuator with the bone centerline coaxial to the test machine actuator. The universal joint allows for angulation of the tibial fragment relative to the aluminum fixation block. This boundary condition is similar to that used by Bottlang et al. [10]. The distance between the universal joint and osteotomy was 13.5 mm for all specimens.

Specimens were preconditioned for 10 cycles in compression from 50 to 200 N at 1 mm/min, followed by 10 preconditioning cycles in torsion from 0.1 to 5 Nm internal rotation (IR) at 1°/s while maintaining a constant axial compressive load of 200 N [11]. The upper limits for both compression and torsion have been used in previous studies [12,13] and were selected to mimic partial weight bearing [14,15]. The slope of the loading curves for the last three preconditioning cycles in compression and torsion were averaged to determine initial axial and rotational stiffness.

Specimens were then subjected to combined cyclic axial compression (50–200 N) and torsion (0.1–5 Nm IR) for 5000 cycles at 5 Hz, followed by incremental increases in maximum compressive load of 300 N every 5000 cycles. Minimum (0.1 Nm) and maximum (5 Nm) IR torque limits were held constant for the duration of cyclic testing. Testing was performed until catastrophic failure, defined as 5 mm actuator displacement or 25° rotation. Specimens were maintained moist with PBS during the preparation and testing procedures.

Load, displacement, and rotation data were monitored at 100 Hz. The biaxial load cell has a resolution of 0.0001 N and 0.0001 Nm. It is calibrated annually to within ±1% accuracy and ±1% repeatability in both axes.

The primary outcome for this study was total cycles to failure as defined by either 2 mm axial displacement or 10° rotation, measured from the compliance-corrected motion of test machine actuator [16,17]. This endpoint was chosen to reflect biomechanically and clinically relevant fixation failure. Specimens were further tested to catastrophic failure to identify overall gross failure mode. Secondary outcome measures included initial stiffness in compression and torsion determined from preconditioning testing and overall rigidity as determined by average maximum peak-to-peak axial and rotational motion (the difference between the maximum positive and negative positions) at 500 cycle intervals during cyclic testing.

Data was checked for normality using Shapiro Wilk's test. Group comparisons were made using paired Student's *t*-tests. For peak-to-peak axial displacement/rotation, a p-value was calculated for each increase in 500 cycles separately and expressed as a range of cycles that were significantly different between testing groups. Significance was set at $p < 0.05$.

Results

One matched specimen was excluded in each group due to a breach in the plating methods. No difference in BMD was observed between the two test groups (BSF: 1.35 g/cm^3 vs LBuS: 1.34 g/cm^3) (Table 1). Average screw insertion torque for the BSF was 2.3 ± 0.5 Nm. Although marginal, torsional stiffness during initial static testing was significantly higher in the BSF group compared with the LBuS group (BSF: 1.4 ± 0.1 Nm/deg vs LBuS: 1.3 ± 0.2 Nm/deg, $p = =0.008$), although this may be a subclinical difference. No difference in initial static axial stiffness was found between the two test groups.

Cycles to failure, as defined by 2 mm actuator displacement or 10° rotation, was higher in the BSF group for 7 out of the 11 matched pairs tested (Fig. 3). No statistically significant difference was observed in average cycles to failure between the two test groups (BSF: 40,636 ± 22,151 cycles vs LBuS: 37,773 ± 8433 cycles, $p = 0.610$). Nine out of 11 LBuS specimens failed via axial loosening, while 8 out of 11 specimens in the BSF group failed by axial loosening. Catastrophic failure modes are listed in Table 2. A single specimen in the BSF group failed by compression of the plate into the bone near cortex, without loss of screw fixation (Supplemental Digital Content 1, photograph of compression failure).

Peak-to-peak axial displacement was analyzed to demonstrate the average difference between the maximum positive and negative amount of displacement from neutral during cyclical testing. Peak-to-peak axial displacement was significantly higher on average in the LBuS group at cycle 15,500 ($p = 0.033$), between cycles 17,000 and 27,000 ($p < 0.05$), and between cycles 31,500 and 33,500 ($p < 0.05$) (Supplemental Digital Content 2, Graph A). Peak-to-peak axial rotation was significantly greater on average in the LBuS group between cycles 1000 and 6500 ($p < 0.05$), cycle 9500 ($p = 0.031$), cycle 10,000 ($p = 0.036$), and between cycles 11,500 and 31,000 ($p < 0.05$) (Supplemental Digital Content 2, Graph B).

Discussion

Innovation in screw head and thread design has sought to improve fracture fixation. In this study, we tested locking buttress threaded screws (LBuS), the current standard for plate fixation in compromised bone, against novel nonlocking bone–screw–fasteners (BSF) with interlocking threads. The results of this study confirmed our hypothesis that no significant differences were

Table 1
Bone quality and initial stiffness determined from static testing (average ± standard deviation).

Group	BMD (g/cm^2)	Screw insertion torque (Nm)	Torsional stiffness (Nm/deg)	Axial stiffness (N/mm)
Locked screws	1.33 ± 0.28	1.5 ± 0	1.3 ± 0.2	4012 ± 513
Bone–screw–fasteners	1.35 ± 10.26	2.3 ± 0.5	1.4 ± 0.1	4319 ± 716
p value	0.580	–	0.008	0.198

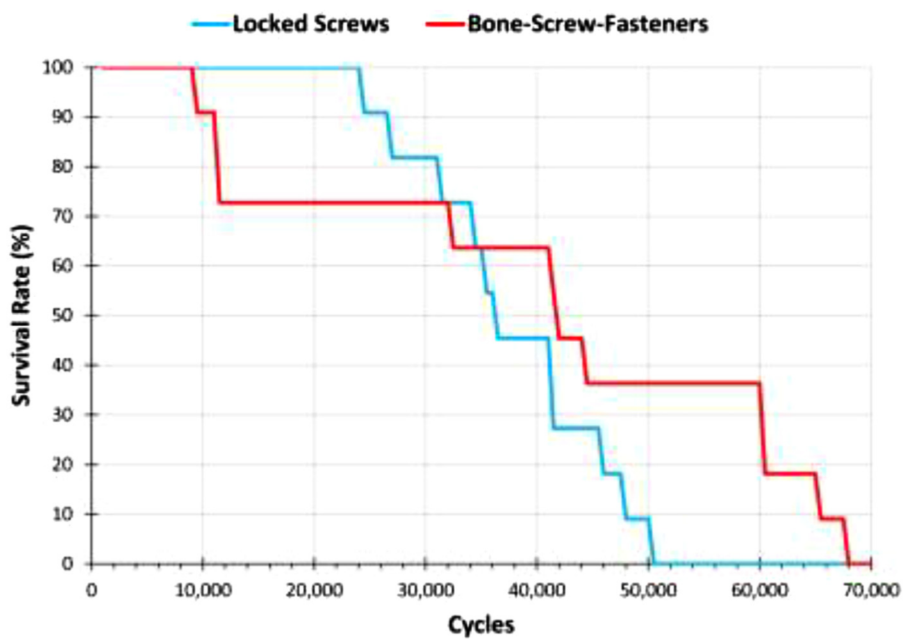

Fig. 3. Specimen survival rate versus number of cycles. Cycles to failure were higher in the bone–screw–fasteners group for 7 out of the 11 matched pairs tested.

Table 2
Failure modes from fatigue testing to catastrophic failure. Screw toggling was defined as movement at the screw–bone interface.

Failure mode	Locked screws	Bone–screw–fasteners
Screw toggling	5/11	2/11
Longitudinal fracture	5/11	5/11
Screw head shearing	l/11	–
Screw bending beneath plate	–	3/11
Near cortex compression longitudinal fracture[a]	–	1/11

[a] See Supplemental Digital Content 1.

demonstrated between constructs fixed with nonlocking BSF and LBuS, specifically with respect to average total cycles to failure. Collectively, BSF constructs withstood more total cycles to failure than LBuS constructs.

Peak-to-peak motion during cyclic testing is related to construct rigidity. BSF demonstrated greater initial torsional stiffness and overall rigidity during static and cyclic testing, respectively. The stability of a nonlocking construct is directly related to the frictional force generated from compressing the plate against bone with the screw [18,19]. Increased screw insertion torque results in greater compression, and consequently higher friction between the plate and bone. If the force on the bone exceeds the frictional force, stability will be compromised. Locking screws thread into the plate and therefore do not generate compression at the near cortex.

Osteopenic bone may not be able to withstand the shear forces generated by buttress threaded screws in nonlocking constructs, leading to cortical stripping and insufficient screw purchase [6]. In this clinical scenario, it becomes difficult to apply adequate insertion torque to the screw that compresses the plate to the bone thereby preventing plate bone motion. In this study, we compared bone–screw–fasteners to locking constructs in plating geriatric female bone because we see the potential application of both technologies in this patient population especially where bone quality could be compromised. Locking technology was created to provide improved stability in clinical scenarios were conventional screws my not provide adequate fixation. The novel bone–screw–fasteners integrate a locking mechanism into the screw thread design, as opposed to the head, to provide multiplanar stability. Therefore, we chose to compare constructs that lock via differing mechanisms incorporated into either the screw thread or head.

The interface between the bone and screw thread is critical in nonlocking plate construct stability. This can be improved by increasing the contact area between the screw and bone [20]. For example, cancellous screws are designed with a higher outer to inner thread diameter ratio than traditional cortical screws at the expense of having an increased screw pitch to provide fixation in metaphyseal bone with thin cortices. In comparison to cortical buttress screws, the multiplanar thread design of bone–screw–fasteners increases the contact area between the thread and bone with a comparable screw pitch. Consequently, cortical stripping is minimized, and final insertional torque is optimized which accentuates compression at the plate-bone interface. Further study is warranted to test bone–screw–fasteners in various clinical scenarios such as testing its ability to function as a lag screw or for unicortical fixation.

A unique mode of failure was observed in the BSF group in which the fasteners generated compressive forces through the plate that exceeded the strength of the near cortical bone, which led to intrusion of the plate through the cortex rather than stripping at the bone–screw interface. Rotary toggling during cyclic loading resulted in a compression fracture at the near cortex on this specimen without losing fixation between the fastener and far cortex. We suspect that this mechanism contributed, in part, to some of the other early failures seen in the BSF group. Further study would be needed to elucidate this unique mode of failure. Based on the results of this study, however, caution should be used to not over tighten the fasteners and compromise the integrity of the near cortex.

There are several limitations to this study. Foremost, we used a cadaveric model of which the conclusions may not precisely translate clinically. Although an in vivo study would provide more relevance to fracture fixation, a biomechanical study offers more equipoise over testing conditions. Caution, nonetheless, should be utilized before extrapolating these results to inform clinical practice. While this is a clinically relevant model of testing, maintaining physiologic loads throughout testing can lead to many days of testing for each specimen until failure. In order to have a more logistically feasible protocol for our lab staff, while still providing us the ability to detect subtle differences, we used a load "ramp-up" model, where the axial load was increased by 300 N every 5000 cycles.

Second, we used a half-osteotomy model for testing matched pairs with the free end of the plate fixed to the materials testing system. This was to increase our study numbers and account for the possibility of excluding compromised samples, which was realized in one specimen. Third, we compared nonlocking fasteners to locking buttress threaded screws, which differ in both screw thread and head designs. We chose this comparison because locking screw fixation is often indicated in compromised bone quality and non-locking fasteners may be an alternative that provides stable fixation, while still compressing the plate to bone for a friction fit that may be advantageous in situations (e.g. compression plating) were conformity at the plate bone interface is desired. An alternative study design would be to test locking BSF to LBuS. This was deferred because locking BSF are not yet clinically available. We also chose to specifically use female geriatric specimens as this patient population is at increased risk of fragility fractures with compromised bone quality where screw fixation can be tenuous and locking technology is often indicated in our experience. Ideally, specimens could have been selected preferentially based upon BMD prior to the study, however, this option was not available. Therefore, we scanned all specimens to primarily determine if their BMD in the region of interest was consistent between matched pairs from the same cadaver to avoid bias.

In conclusion, bone–screw–fasteners should be considered as a fixation alternative to locking constructs in plating female geriatric bone. It appears that this novel thread design is able interlock into the bone generating fixation similar to locking constructs while allowing for compression of a nonlocking head to the plate. The results of this study warrant future clinical investigation of bone–screw–fasteners to determine efficacy in fracture management.

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American Orthopaedic Association	Board or committee member
Conventus	Paid consultant; Stock or stock Options
Current Opinion in Orthopaedics	Editorial or governing board
Genesis Innovations Group	Stock or stock Options
Globus Medical	Paid consultant
Imagen Technologies	Stock or stock Options
Intelligent Implants	Stock or stock Options
Journal of Bone and Joint Surgery - American	Publishing royalties, financial or material support
Journal of Orthopaedic Trauma	Editorial or governing board
KCI	Paid consultant; Paid presenter or speaker
Medtronic	Research support
Orthopaedic Research Society	Board or committee member
Orthopaedic Trauma Association	Board or committee member
OsteoCentric	Paid consultant; Research support
SI-Bone	Paid consultant
SmartMedical Devices	Research support
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Innomed	IP royalties
Journal of Orthopaedic Trauma	Editorial or governing board
KCI	Paid consultant
Stryker	Paid consultant
Malcolm R. DeBaun	
Orthofix, Inc.	Research support
OsteoCentric	Research support

Declaration of Competing Interest

The authors have no affiliation with any organization with a direct or indirect financial interest in the subject matter discussed in the manuscript.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2019.10.032.

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