ORIGINAL ARTICLE

A Novel Bone-Screw-Fastener Demonstrates Greater Maximum Compression Force Before Failure Compared With a Traditional Buttress Screw

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OBJECTIVES: This study compared the maximal compression force before thread stripping of the novel bone-screw-fastener (BSF) with the traditional buttress screw (TBS) in synthetic osteoporotic and cadaveric bone models.

METHODS: The maximum compression force of the plate–bone interface before loss of screw purchase during screw tightening was measured between self-tapping 3.5-mm BSF and 3.5-mm TBS using calibrated load cells. Three synthetic biomechanical models were used: a synthetic osteoporotic diaphysis (model 1), a 3-layer biomechanical polyurethane foam with 50–10–50 pounds-per-cubic-foot layering (model 2), and a 3-layer polyurethane foam with 50–15–50 pounds-per-cubic-foot layering (model 3). For the cadaveric metaphyseal model, 3 sets of cadaveric tibial plafonds and 3 sets of cadaveric tibial plateaus were used. A plate with sensors between the bone and plate interface was used to measure compression force during screw tightening in the synthetic bone models, while an annular load cell that measured screw compression as it slid through a guide was used to measure compression in the cadaver models.

RESULTS: Across all synthetic osteoporotic bone models, the BSF demonstrated greater maximal compression force before stripping compared with the TBS [model 1, 155.51 N (SD = 7.77 N) versus 138.78 N (SD = 12.74 N), $P = 0.036$; model 2, 218.14 N (SD = 14.15 N) versus 110.23 N (SD = 8.00 N), $P < 0.001$; model 3, 382.72 N (SD = 20.15) versus 341.09 N (SD = 15.57 N), $P = 0.003$]. The BSF had greater maximal compression force for the overall cadaver trials, the tibial plafond trials, and the tibial plateau trials [overall, 111.27 N vs. 97.54 N (SD 32.32 N), $P = 0.002$; plafond, 149.6 N versus 132.92 N (SD 31.32 N), $P = 0.006$; plateau, 81.33 N versus 69.89 N (SD 33.38 N), $P = 0.03$].

CONCLUSIONS: The novel bone-screw-fastener generated 11%–65% greater maximal compression force than the TBS in synthetic osteoporotic and cadaveric metaphyseal bone models. A greater compression force may increase construct stability, facilitate early weight-bearing, and reduce construct failure.

KEY WORDS: trauma, bone screw, screw design, mechanical properties, synthetic bone model, cadaver

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INTRODUCTION

In plate fixation, orthopaedic trauma surgeons must balance applying the appropriate screw compression to achieve adequate stability between the bone and implant while attempting to avoid stripping at the bone–screw interface.[1–3] In plate fixation, the traditional buttress screw (TBS), which is the standard nonlocking screw used in fracture fixation, can strip when the axial load and torque applied overcome the bone resistance.

In response to the shortcomings of the TBS, a novel bone-screw-fastener (BSF) was recently introduced, which uses an interlocking thread technology.[4] The potential benefit of the interlocking thread interface is the ability to protect the fastener from stripping. In addition, the thread pattern of the BSF was designed to distribute loads across multiple thread surfaces that could increase its utility in geriatric or poor quality bone (see **Figure**, **Supplemental Digital Content 1**, http://links.lww.com/JOT/C234).[5] This fastener technology cuts precise grooves to create a bone–screw interface, much like a nut-and-bolt that has been theorized to reduce stripping. Despite the theoretical gains from these designs, there have been mixed results as to the benefits of the BSF design. BSF's purposed advantages seemed to be supported by a biomechanical study that found higher torque stripping forces in the BSF compared with the TBS when placed in the tibia shaft.[6] Another study found that nonlocked BSF was equivalent to locked buttress screws when applying cyclical multiaxial forces in geriatric cadaveric bone.[7]

There is concern that poor quality bone cannot withstand shear forces from TBS in plate constructs, leading to stripping, insufficient screw purchase, lack of plate–bone compression, and therefore poor construct stability.[8] It is important to obtain sufficient compression for fracture

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fixation stability, and the BSF may be able to overcome these difficulties. The purpose of this study was to compare the maximal compression force before stripping between the BSF and TBS in an osteoporotic bone model and a cadaveric metaphyseal bone model.

METHODS

This study compared the maximum compression force at the plate–bone interface before the loss of screw purchase between the self-tapping 3.5-mm BSF (Osteocentric Technologies, Logan, UT) and a self-tapping 3.5-mm traditional cortical buttress screw (Stryker, Kalamazoo, MI). Both screw types had a major diameter of 3.5 mm with a minor diameter of 2.5 mm. 40-mm screws were utilized throughout the bone model trials. For the cadaver trials, the same length of screw was utilized for each paired screw hole.

Synthetic Osteoporotic Bone Models

Three synthetic biomechanical models were used: a synthetic osteoporotic diaphysis with a medulla (Synbone AG, Switzerland) (model 1, Fig. 1A), a 3-layer biomechanical polyurethane foam (Sawbones, WA) with 50–10–50 pounds-per-cubic-foot (PCF) layering (model 2, Fig. 1B), and a 3-layer polyurethane foam with 50–15–50 PCF layering (model 3). Model 2's 10-PCF core had a density of ~16 kg/m^3, and model 3's 15-PCF core had a density of ~24 kg/m^3. Fifty-PCF foam was used to simulate the cortex, while 10-PCF and 15-PCF foams were used to simulate the cancellous bone, allowing for bicortical purchase. All 3 models had a cumulative thickness of 40 mm and utilized a low PCF rating corresponding to poor bone quality. Three models were used to assess the effect that varying bone density had on the maximum compression force before failure. For each model, a new synthetic bone model was utilized. Each screw hole was placed at least 1 cm away from other screw holes to prevent neighboring screw holes from compromising and impacting adjacent cell results.

Five trials of each screw type were done for each bone model group. A 2.5-mm pilot hole was drilled. The respective screw was hand-tightened in the central hole of a 3-hole, 3.5-mm plate (Stryker, Kalamazoo, MI) and hand-tightened into the pilot hole. Compression forces in Newton (N) were measured at the contact portion of the plate against the synthetic bone using 2 sensors (Flexiforce ELF System, Tekscan, Boston, MA).

The maximal compression force before stripping and loss of screw purchase in the bone was measured in N, and the mean maximal compression force and SD were recorded. The same investigator would tighten the screw past its failure point, and a live reading of compression force was recorded. The failure point was defined as a sustained decrease in compression forces following a peak compressive force due to the screw losing purchase and stripping the bone. The maximum force achieved before stripping was defined as the maximal compression force. Stripping was always due to failure of the bone to withstand increasing insertional forces, and there was no mechanical failure on the part of the screws. Before all trials, the sensors were calibrated and the standard error of the measurements was ±3% of the given compression force.

An analysis of variance with Tukey post hoc analysis compared means across the multiple models. Means were compared with an independent-samples t test on Excel Office, and the percent difference between each screw type was calculated (Microsoft, Redmond, WA). Significance was based on an alpha level <0.05.

Cadaveric Metaphyseal Bone Model

The maximum compression force before loss of screw purchase was measured between self-tapping 3.5-mm BSF and 3.5-mm TBS using a calibrated annular load cell

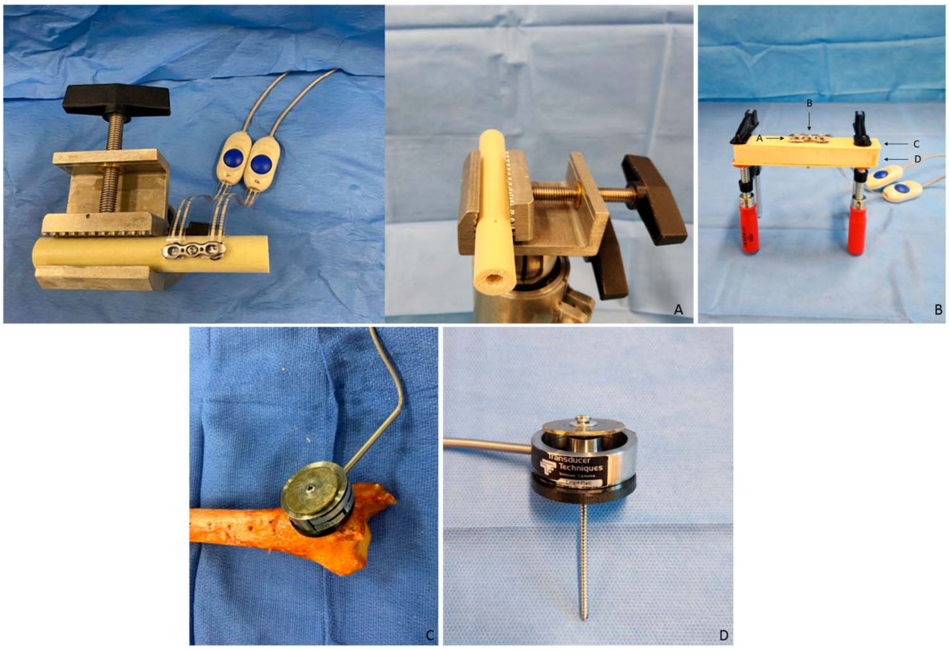

FIGURE 1. A, Osteoporotic bone model. B, Layered synthetic bone model (A, Sensors placed on either side of the screw hole to measure forces along the bone–plate interface. B, A screw placed in the central hole of the plate. C, 50 pounds-per–cubic-foot layer to represent cortical bone placed on the top and bottom of the bone block. D, 10 pounds-per-cubic-foot layer). C, Cadaver model.

(Through Hole Donut Compression Load Cell 1.50 OD, Transducer Techniques, Temecula, CA). A custom 3D-printed guide was created to hold the annular load cell and screw (Figs. 1C, D). A 2.5-mm pilot hole was drilled. Setting up of the annular load cell to measure compressive forces was done by the following steps. First, the screw was placed through a washer that allowed the transmission of the screw's compression force to the annular load cell. Second, the screw was placed through the annular load cell. Third, the 3D-printed guide was placed, and it provided a solid surface that could measure compressive forces on uneven osteologic surfaces. The screw was placed in the pilot hole and hand tightened. The maximum force before failure was recorded, and this measurement was from the force generated at the screw–guide interface. This force was assumed to be equivalent to the plate–bone interface but allowed for the force measurement in the cadaver-based trials given the uneven nature of the bone made it unrealistic to use the plate and force sensors used in the osteoporotic bone measure. The annular load cell had a standard error of ±1% of the given compression force.

In total, there were 3 pairs of tibial plafonds and 3 pairs of tibial plateaus (50% female; age: 80–97 years). A pilot study was conducted on 2 sets of plafond and plateau cadavers to conduct a power analysis. The mean difference in the prior population was 16.68 N (SD 31). In a paired-sample mean with an effect size of 0.538, a single power value of 80%, and a previous mean difference of 16.68 N (SD 31), we would need 30 trials to obtain significance at a level of 0.05. Thirty-six paired trials were completed for each metaphyseal location, controlling for screw type, position of the screw from the joint space, and location anteriorly and posteriorly. Pairing cadaver trials controlled for variation in bone quality between cadavers and differences in bone quality based on local location of the bone and screw. A standardized grid was used for each trial (Fig. 2). Based on this grid, the screw types would alternate between each screw hole. This would then be the inverse for the contralateral side. This alternating gird ensured that each screw type would have a comparison in the contralateral side at the same distance from the joint and position anteriorly and posteriorly. These paired samples allowed for a comparison between screw types as each screw type had a screw positioned in the same location that was directly compared with the contralateral side. This consistent positioning and analysis ensured that similar bone quality based on anatomical location was distributed between groups. Within the same grid plane, it was ensured that the screw trajectories did not converge. In addition, there was at least 1 cm between screw holes to ensure that adjacent trails did not impact each other. For the plateaus, the most proximal row of screws was placed 1.5 cm from the joint line, with each successive row starting 1 cm distal to the last row. Anterior to posterior positioning was controlled by starting 1 cm from the most anterior cortex and allowing 1 cm between each screw hole (see **Figure**, **Supplemental Digital Content 2**, http://links.lww.com/JOT/C235). Screws were drilled parallel to the joint line from the medial side, and both cortices were captured. If an error in trajectory occurred, the hole was not used to avoid re-drilling. A similar grid was created for the plafond, but the screws were drilled from anterior to posterior position, capturing both cortices. The most distal screws were 1.5 cm from the joint line and progressed proximally by 1 cm. The rest of the grid system was the same for both plafonds and plateaus.

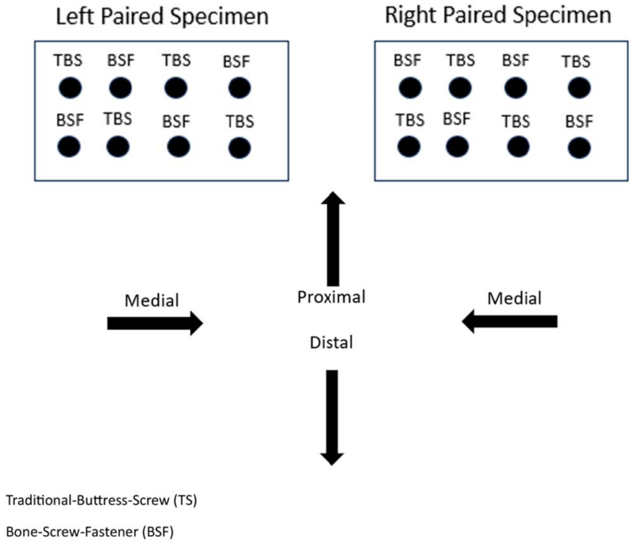

FIGURE 2. Grid of paired cadaveric trials demonstrating alternating screw positions between screw types.

An analysis of variance with Tukey post hoc analysis compared means across the multiple models. Means were compared with a paired *t* test on Excel Office (Microsoft, Redmond, WA). The percent difference between each screw type was calculated. The power analysis was conducted with SPSS 28 (IBM, New York, NY). Significance was based on an alpha level <0.05.

RESULTS

Compression Forces With Varying Bone Densities and Overall Screw Differences

Overall, BSF had a higher force than TBS, 252.13 N (22.40) versus 196.70 N (24.10) ($P < 0.001$). Model 3 generated the greatest compression forces across both screw types and was significantly higher than model 1 or 2, with $P < 0.001$ and $P = 0.023$, respectively (Table 1).

Osteoporotic Diaphysis Bone, Model 1

The BSF had greater bone–plate compression force before stripping compared with the TBS ($P < 0.001$) (Table 2). The BSF outperformed the TBS by 11.4%.

Osteoporotic Model 2 (50–10–50 PCF Layered Model)

The BSF had greater bone–plate compression force before stripping compared with the TBS ($P < 0.001$) (Table 2). The BSF outperformed the TBS by 65.7%.

Osteoporotic Model 3 (50–15–50 PCF Layered Model)

The BSF had greater bone–plate compression force before stripping compared with the TBS ($P < 0.001$) (Table 2). The BSF outperformed the TBS by 11.5%.

TABLE 1. Maximum Compression Force in Newton at the Bone–Plate Interface Before Failure Across 3 Different Osteoporotic Bone Models

Model	Compression Force (N) (Mean (SD))	*P*
Model 1 (a)	147.15 (13.29)	<0.001 (a vs. c); 0.028 (a vs. b)
Model 2 (b)	164.18 (57.89)	<0.001 (b vs. c); 0.028 (b vs. a)
Model 3 (c)	361.91 (27.74)	<0.001 (c vs. a); 0.028 (c vs. b)

Two-factor analysis of variance with Tukey HSD post hoc analysis.
N, Newton.

Cadaveric Metaphyseal Bone

The BSF had greater maximal compression force for the overall cadaver trials, the tibial plafond trials, and the tibial plateau trials (overall, $P = 0.002$; plafond, $P = 0.006$; plateau, $P = 0.03$) (Table 3). The BSF outperformed the TBS by 13.2% overall, 11.8% for the plafond, and 15.1% for the plateau.

DISCUSSION

In plate fixation, orthopaedic trauma surgeons must balance applying the appropriate screw compression to achieve adequate stability between the bone and implant while attempting to avoid failure at the bone–screw interface.[1,2] For traditional nonlocked plate constructs, stability relies on the friction between the bone and plate interface.[8] This frictional force is directly related to the normal force between the plate and bone that is generated by screw tightening. Past studies have validated using axial compression forces until stripping of a screw as a marker for normal force.[2] The BSF has been introduced and been purposed to improve the force generated in screw compression, construct stability, and purchase in poorer quality of bone, given its interlocking thread technology.[5] The major finding of this biomechanical study was that the BSF generated more compression than the TBS in both osteoporotic bone models and the cadaveric metaphyseal bone models. The BSF advantage was demonstrated as the quality of the bone decreased. There was a 65.7% difference between the screw types in model 2, with the lower PCF values mimicking lower bone quality. Unsurprisingly, increasing the PCF or bone quality within each synthetic bone model resulted in higher compression forces in both screw types. Similarly, there was a 15.1% difference between screws in the cadaveric plateaus that had overall the worst bone quality as shown by the lower average compression forces compared with the plafond. Prior research has found that the BSF had higher torque forces before stripping compared with TBS; however, this was in tibia midshafts rather than a model with poor bone quality.[6] The BSF design of an interlocking thread interface likely explains these differences seen in this study and past research. This thread interface creates an interlocking interface between the screw and bone that resists forces in both axial axis and off-axis, protecting the construct from stripping as it preserves bone architecture and volume.

This study seems to support that BSF has superior qualities in osteoporotic bone when compared with TBS. DeBaun et al examined BSF and locking TBS construct strength through cyclical loading and found no differences in the number of cycles until failure in a geriatric female bone model.[7] While this research is not testing the same variable as in this study, it questions the theoretical efficacy of the multiaxial distribution of force. However, this could be explained by varying bone quality in the cadaveric bone, minute variations in locations of plating, and relatively few trials in the study by DeBaun et al. In addition, it is notable that the BSF was equivalent to the locking constructs, which further supports BSF quality in poor bone quality. While studying different variables, this study saw modest effect levels, with percent differences ranging from 11% to 65%; these moderate differences were likely seen due to this study's methodology. There was a great deal of consistency in the synthetic bone models, and the same trends were seen in the cadaveric trials due to conducting paired analysis that standardized screw location and bone quality.

The findings of this study may have clinical implications, as a greater compression force may increase construct stability, thereby facilitating early weight-bearing and reducing construct failure. Another theoretical benefit of increased compressive force between the plate and bone is reduced patient pain from a more stable construct through additional load sharing of the plate/bone construct. However, osteoporotic bone and poor quality of bone may not be able to handle shear forces generated by TBS constructs and could fail through stripping and insufficient purchase.[8] Thus, the TBS is limited by adequate insertional torque to compress the plate without stripping compared with the BSF, especially in poor quality bone. A

TABLE 2. Comparison of Maximum Compression Force in Newton at the Bone–Pate Interface Before Failure Between Screw Types Across 3 Different Osteoporotic Bone Models

Bone Model	Traditional Buttress Screw (N) (Mean (SD))	Bone-Screw-Fastener (N) (Mean (SD))	Percent Difference	*P*
Model 1	138.78 (12.74)	155.51 (7.77)	11.37	<0.001*
Model 2	110.23 (8.00)	218.14 (14.15)	65.72	<0.001*
Model 3	341.09 (15.57)	382.72 (20.15)	11.50	<0.001*

*Independent-samples *t* test; N, Newton.

TABLE 3. Maximum Compression Force in Newton at the Bone–Plate Interface Before Failure in Cadaveric Metaphyseal Bones

Bone	Traditional Buttress Screw (N) (Mean)	Bone-Screw-Fastener (N) (Mean)	SD	Percent Difference	*P**
Overall	97.54	111.27	32.32	13.15	0.002
Plafond	132.92	149.60	31.32	11.81	0.006
Plateau	69.89	81.33	33.38	15.13	0.03

*Paired *t* test; N, Newton.

previous study found that at least 1 TBS stripped in 88% of patients undergoing open reduction and internal fixation of an unstable ankle fracture.[9] Even without stripping entirely, cortical TBS that is overtightened can result in an 82% decreased pullout resistance.[10] BSF potentially offers a solution to these issues as the thread interface integrates a locking mechanism between the screw and bone into the screw thread design, opposed to traditional screw designs.[5] This self-locking mechanism and increased force until stripping allow for greater compression and may be beneficial clinically in osteoporotic bone or fracture locations with poor bone quality.

There are several limitations to this study. First, the cadaveric metaphyseal models were also likely osteoporotic models as well due to the advanced age of the cadavers. While this strengthens the current findings that BSF performs well in poor bone quality, the generalizations from these findings may be limited. An additional limitation is that no bone density scan was done to confirm that the cadavers were osteoporotic. Future research should include this variable and compare across bone density levels. Both synthetic bone models and cadaveric models were used to assess the compression force before failure at the bone–screw interface. It is a strength of this study to utilize both synthetic and cadaveric models, as synthetic bone models and layered synthetic bone models have been used to assess biomechanical properties of fixation in trauma and spine research.[11–13] In an attempt to measure the force generated at the plate–bone interface in cadavers, the force generated at the screw–guide interface was utilized. This had a smaller area of force distribution than a plate but allowed for accurate force measurement on an uneven bone surface. This is a limitation as it is not directly a plate that is measuring compression force, but the benefit of being able to measure a single screw's compression force on an uneven cadaveric surface outweighed this limitation. However, there are several other factors that are important to screw compressions such as pitch or insertional torque, which we did not evaluate. Furthermore, while normal force is proportional to the frictional force for plate constructs and construct stability, this may not factor into clinically significant differences. In addition, the findings in this study are relatively small and may not be clinically significant. However, if there are additional screws, the sum of these small differences may increase the overall stability of the construct. Clinically, an early pilot study of 29 patients managed with BSF did not show any screw stripping, loosening, or nonunion at 1 year of follow-up.[5] While the foundation has been set with biomechanical studies showing BSF performing well in osteoporotic and metaphyseal bone, further clinical studies are needed.

CONCLUSION

In conclusion, this study found that the bone-screw-fastener generated higher maximum compression forces before failure at the bone–screw interface compared with the traditional buttress screw in osteoporotic and metaphyseal bone. Poorer quality of bone led to greater increases in the observed compression. Future studies should evaluate the performance of bone-screw-fastener in clinical scenarios.

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