A New Fastener With Improved Bone-To-Implant Interface Shows Superior Torque Stripping Resistance Compared With the Standard Buttress Screw

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Objective: The conventional AO buttress screw used for fracture fixation relies on a historic buttress thread design, which is prone to stripping at the bone–implant interface. We hypothesized that a new Bone-Screw-Fastener with an innovative interlocking thread design demonstrates increased resistance to torque stripping forces compared with the buttress screw, without compromising pullout strength.

Methods: A biomechanical model was established in 6 matched pairs of adult human cadaveric tibiae to test torque resistance between the 3.5 mm Bone-Screw-Fastener and the 3.5 mm cortical AO buttress screw until failure. Uniaxial pullout testing of both screw types was performed as an internal control experiment.

Results: The 3.5 mm Bone-Screw-Fastener had a significantly increased resistance to torque failure compared with the standard 3.5 mm AO buttress screw ($P = 0.0145$). In contrast to the buttress screws, none of the Bone-Screw-Fasteners stripped from the bone but rather failed at the screwdriver–implant interface in terms of a metal-on-metal failure. The internal control experiments revealed no significant difference in axial pullout strength between the 2 implants ($P = 0.47$).

Conclusions: These data demonstrate the superiority of the new Bone-Screw-Fastener over the conventional AO buttress screw regarding protection from torque stripping forces. In addition, the new thread design that interlocks to the bone does not sacrifice axial pullout resistance conveyed by the buttress screw. Future controlled trials will have to validate the in vivo relevance of these findings in a clinical setting.

Key Words: AO screw, buttress screw, Bone-Screw-Fastener, screw design, torque stripping, bone–implant interface, failure of fixation

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BACKGROUND

Since the introduction of the AO buttress screw in the 1950s, orthopaedic screws used for fracture fixation have been relying on the historic buttress thread design.[1] Although buttress screws generally provide solid resistance against unidirectional axial loading forces, their underlying design offers no resistance to multidirectional forces and suffers from a lack of resistance to torque stripping at the bone–screw interface.[2–4] Interestingly, the buttress design of the conventional AO screw dates back to the times of Robert Danis,[5] the "father of modern osteosynthesis," and the buttress thread remains an unaltered paradigm in the modern AO screw of the 21st century.[6,7] A new patented and FDA-cleared Bone-Screw-Fastener was recently introduced, which uses the first technology that instantaneously locks the implant to the bone via an interlocking thread technology.[8] The innovative screw design relies on a circumferential interlocking interface between the threads and bone in analogy to a "loaded nut-and-bolt" concept where the nut is interlocked to the bolt.[8] This new technology resists off-axis loads and protects the fastener from stripping.[8] A previous study reported the early clinical experience with the new Bone-Screw-Fastener for fracture fixation by open reduction with internal fixation in conjunction with standard AO plates.[8] In this early pilot series, a total of 29 fractures in 29 patients were managed by 123 fasteners without any evidence of screw stripping, screw loosening, or delayed failure of fixation at an average follow-up interval of 10 months postoperatively (SD, 3.5 months; range, 3–15 months).[8] However, the anecdotal notion of superior resistance by the new fastener to torque stripping forces is purely based on the empirical clinical experience until present. The current biomechanical study was designed to test the hypothesis that the new Bone-Screw-Fastener would provide increased resistance to torque stripping forces compared with the standard AO buttress screw, without sacrificing pullout strength.

METHODS

Specimens

Six matched pairs of human tibiae were obtained from a tissue bank (Science Care, Phoenix, AZ). There were 3 female donors (59, 61, and 86 years of age) and 3 male donors (45, 67, and 86 years of age). The specimens were randomized for the implant testing conditions (fastener vs. buttress screw) within each pair. Randomization was repeated for each torque stripping and axial pullout testing experiment. The central and distal thirds of each tibia were scanned by dual-energy x-ray absorptiometry for comparison of bone mineral density between matched pairs. To exclude specimens with osteopenia or osteoporosis, all donors were selected to have a femoral neck T-score of greater than −1. The bone density parameters of the individual specimens and of the respective anatomic testing location are shown in Table 1. This project followed the Institutional Review Board requirements at the University of Colorado for cadaveric laboratory research.

Implants

All implants used in this study were small fragment 3.5 mm screws or fasteners. The concept and design of the new Bone-Screw-Fastener (SMV Scientific, Austin, TX) have been previously described in meticulous detail.[8] Conceptually, the innovative fastener thread design allows for improved distribution of forces across the multiple thread faces when off-axis loading forces are applied, compared with a standard screw with buttress threads (Fig. 1).[8] The Bone-Screw-Fastener received FDA clearance on June 23, 2015, for clinical use in fracture fixation, nonunion revision, and osteotomies in both adults and skeletally immature patients [510(k) #K150981]. Of note, the 3.5 mm stainless steel fastener was designed to be compatible with the standard instrumentation for the 3.5 mm AO buttress screw by relying on identical 2.5-mm diameter drill bits and matching to the conventional small-fragment AO plates. The thread pitch of 1.25 mm and the inner (2.4 mm) and outer (3.5 mm) diameters are also identical between the new fastener and conventional buttress screw (Fig. 2). The standard 3.5 mm cortical AO buttress screws (DePuy-Synthes, Paoli, PA) were used in the control group. All implants used in this study were made of stainless steel. To avoid a potential confounding variable using implants of different lengths, the screws and fasteners were standardized to be at 34 mm length, which was sufficient to ensure bicortical purchase across the far cortex in all bone specimens.

Testing of Torque Stripping Forces

For the torque stripping tests, one tibia from each pair was randomly assigned to the new 3.5 mm Bone-Screw-Fastener (group 1), with the contralateral tibia from the same donor assigned to the traditional 3.5 mm AO cortical buttress screw (group 2). All bone specimens were rigidly mounted in a holding fixture (see **Figure, Supplemental Digital Content 1**, http://links.lww.com/JOT/A618). To standardize each specimen's screw insertion site, the midshaft of the tibia was determined as the center between the tibial tubercle and tibial plafond. The fixture was placed in a vice on a drill press

TABLE 1. Bone Density Parameters and Cortical Thickness of the Individual Specimens and Respective Anatomic Testing Location Used for Torque Testing and Pullout Testing Experiments

Factor	#1		#2		#3		#4		#5		#6	
Gender	M		F		F		F		M		M	
Age (y)	86		86		59		61		67		45	
Weight (lbs)	185		153		150		170		240		194	
Height (in)	69		59		67		61		71		66	
T-score (femoral neck)	−0.1		0.3		−1.4		−1.2		2.5		0.8	
Z-score (femoral neck)	1.6		2.8		−0.5		−0.2		3.1		1.1	
Midshaft tibia BMD (g/cm^2)	1.022	1.149	1.077	0.911	1.102	1.107	1.067	0.999	1.669	1.481	1.22	1.244
Distal tibia BMD (g/cm^2)	1.148	1.204	0.934	0.777	1.068	0.982	0.964	0.899	1.602	1.534	1.147	1.051
Cortical thickness in torque tests (mm)	12.00 (AO)	10.04 (BSF)	8.42 (BSF)	8.54 (AO)	10.25 (AO)	10.63 (BSF)	8.96 (BSF)	9.49 (AO)	15.14 (BSF)	14.44 (AO)	8.98 (BSF)	9.57 (AO)
Cortical thickness in pullout tests (mm)	9.67 (AO)	9.55 (BSF)	9.44 (AO)	8.58 (BSF)	9.95 (BSF)	10.11 (AO)	8.32 (AO)	8.48 (BSF)	7.87 (AO)	7.59 (BSF)	9.16 (AO)	9.68 (BSF)

AO, cortical thickness in the AO buttress screw experiments; BSF, cortical thickness in the Bone-Screw-Fastener experiments; BMD, bone mineral density; F, female; M, male.

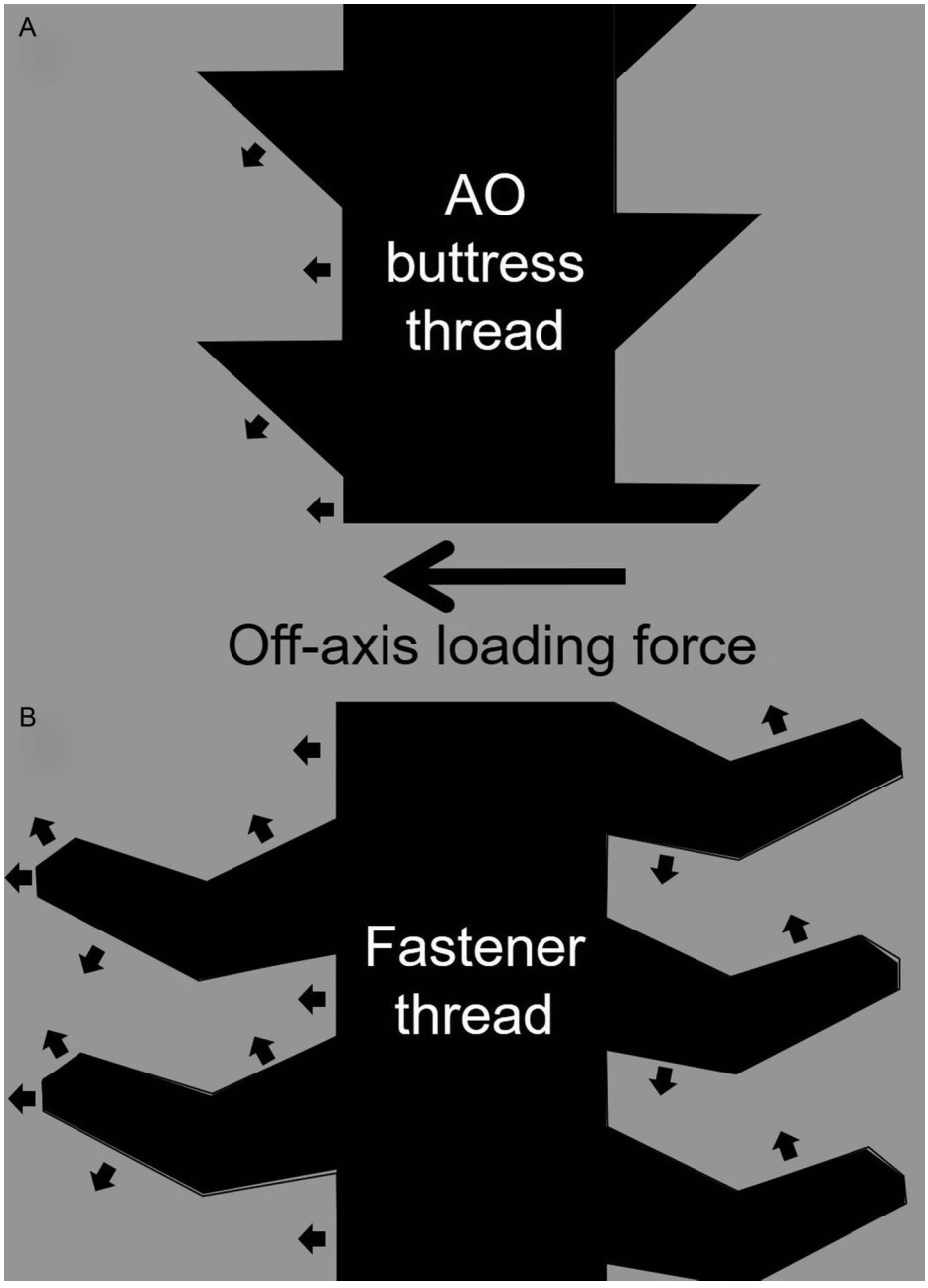

FIGURE 1. Schematic cross section of the new Bone-Screw-Fastener thread configuration (A) and comparison of the resulting load vectors on the threads of the fastener with the conventional AO buttress thread (B) during application of a translational loading force.

and a 2.5 mm bicortical pilot hole was drilled through the center of the tibia from medial to lateral. The drill press was used to ensure the pilot hole was perpendicular to the tibia and would be aligned with the torsion axis of the testing apparatus. The holding fixture and tibia were then mounted into the base of a servo-hydraulic test machine (Instron, Norwood, MA), with the axis of the pilot hole aligned with the axis of the actuator (see **Figure, Supplemental Digital Content 1**, http://links.lww.com/JOT/A618). The screws were inserted through a #8 stainless steel washer and screwed into the bone until perceived as "two-fingers tight."[9] The washers were used to prevent the screw head from penetrating into the bone during maximum torque testing. A new washer was used for each testing condition. A hexagonal screwdriver extension was rigidly fixed to the actuator and lowered into the screw head with a constant compressive force of 100 N and torqued to failure at a rate of 1 degree per second. The torsional loading rate was selected based on the standardized recommendations by the American Society for Testing and Materials (ASTM International, West Conshohocken, PA). **Supplemental Digital Content 2** (see **Figure**, http://links.lww.com/JOT/A619) demonstrates the biomechanical testing condition for the torque experiments.

Failure was defined as a decrease or loss in torque resistance, irrespective of the underlying failure mode. During implant testing, the torque generated was continuously measured by the Instron and graphed in real time. A

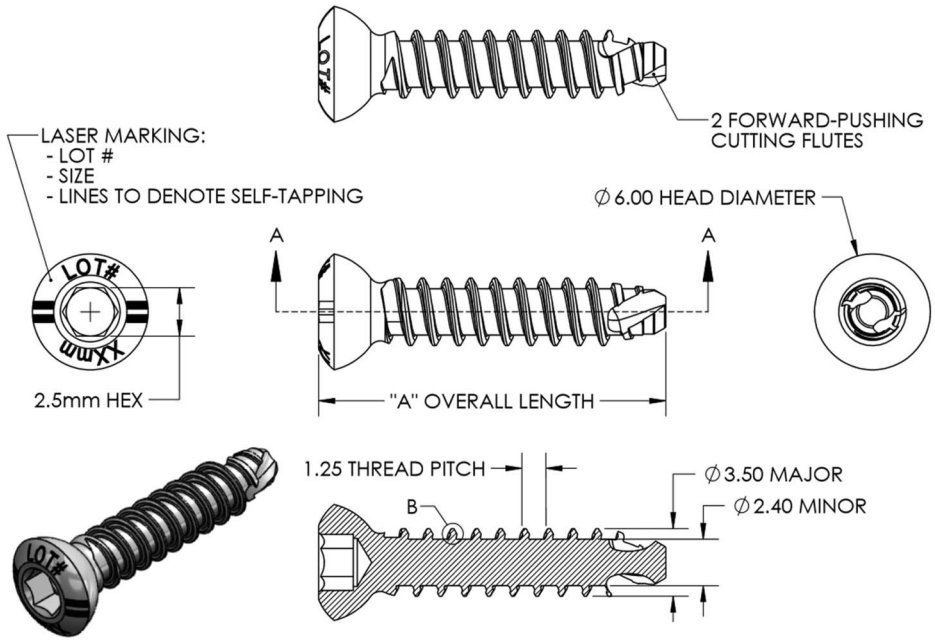

FIGURE 2. Design and dimensions of the self-tapping 3.5 mm Bone-Screw-Fastener. (Image reproduced with permission under the terms of the Creative Commons Attribution 4.0 International License, adapted from: Stahel, et al, Introducing the Bone-Screw-Fastener for improved screw fixation in orthopedic surgery: a revolutionary paradigm shift? *Patient Saf Surg* 2017;11:6.)

torque–time graph was monitored continuously during each experiment, and testing was stopped as soon as an exponential decrease in torque resistance was observed. The highest value of torque resistance before failure was retrospectively recorded from the torque–time chart. The respective cause of failure was noted for each testing experiment.

Testing of Axial Pullout Forces

The distal third of the tibia was used for testing of axial pullout forces. One tibia from each pair was randomly assigned to testing with the 3.5 mm Bone-Screw-Fastener, whereas the contralateral tibia was used for testing the 3.5 mm AO buttress screw. The distal third of the tibia was determined as the center between the previous midshaft insertion site from the torque experiments and the tibial plafond. The bone specimens were mounted in the same holding fixture attached to the base of an Instron test machine and predrilled in an identical technique as described for the torque testing experiments. In contrast to the torque testing experiments, the screw heads were left prominent to allow the test fixture to be inserted between the screw head and bone for axial pullout testing. The head of the screws was then mounted to a fixture attached to the load cell and actuator and pulled by axial force at a rate of 5 mm/min. The axial pullout loading rate was selected based on the standardized recommendations by the American Society for Testing and Materials (ASTM International). Failure was defined as a decrease in loading forces in a load–displacement curve. **Supplemental Digital Content 3** (see **Figure**, http://links.lww.com/JOT/A620) shows the biomechanical testing condition for the axial pullout experiments, before (panel A) and after (panel B) the test was completed. The near and far cortices of the specimens were measured to further determine whether the matched pairs were in similar cortical thickness. After the testing experiments, all screws were manually removed. The specimens were then transversely sectioned at the site of the previous screw insertion with a band saw. The thickness of the near and far cortex was measured with a digital caliper (Mitutoyo Corp, Aurora, IL).

Data Acquisition and Statistical Analysis

The load and torque were measured with an Instron model 2527-303 biaxial load cell. The torque was calibrated to less than 0.98% error, and the load was calibrated to less than 0.60% error. The displacement was measured with a crosshead and calibrated to less than 0.319% error. All data were recorded at 50 Hz on a PC equipped with an analog-to-digital data acquisition board (Tektronix, Inc, Beaverton, OR), using data acquisition software (Capital Equipment Corp, Billerica, MA). Data were analyzed using the paired Student t test. P value of <0.05 was considered statistically significant.

RESULTS

As shown in Table 1, the dual-energy x-ray absorptiometry scan analysis revealed bone mineral density in a similar range without a statically significant difference between the 2 groups for the torque testing experiments (group 1: 1.21 $\pm$ 0.23 g/cm^2, group 2: 1.13 $\pm$ 0.21 g/cm^2; $P = 0.50$) and the axial pullout testing experiments (group 1: 1.09 $\pm$ 0.26 g/cm^2, group 2: 1.13 $\pm$ 0.25 g/cm^2; $P = 0.79$). The 3.5 mm Bone-Screw-Fastener had a significantly increased resistance to torque failure compared with the standard AO buttress screw (4.48 $\pm$ 0.43 Nm vs. 3.67 $\pm$ 0.50 Nm; $P = 0.0145$). The data from the individual torque testing experiments are shown in Table 2. All Bone-Screw-Fasteners in group 1 failed at the interface of the hexagonal driver and the screw via screw head stripping, and none of these implants stripped at the bone–implant interface. By contrast, all buttress screws in group 2 failed because of loss of peak torque generation attributed to stripping at the bone–screw interface.

TABLE 2. Results From the Individual Torque Stripping Experiments in Both Testing Groups

Factor	#1		#2		#3		#4		#5		#6	
Laterality	R	L	R	L	R	L	R	L	R	L	R	L
Group	2	1	1	2	2	1	1	2	1	2	1	2
Implant	AO	BSF	BSF	AO	AO	BSF	BSF	AO	BSF	AO	BSF	AO
Maximal torque at failure (Nm)	4.36	4.48	4.59	3.2	3.78	4.86	4.46	3.29	3.66	3.24	4.81	4.12
Failure mode	SBI	SHS	SHS	SBI	SBI	SHS	SHS	SBI	SHS	SBI	SHS	SBI

AO, AO cortical buttress screw; BSF, Bone-Screw-Fastener; SBI, screw–bone interface; SHS, screw head stripping.

The internal control pullout experiments revealed no significant difference in pullout resistance between the 2 implants (group 1: 3348 ± 568.2 N, group 2: 3306 ± 660.1 N; $P = 0.47$). All implants in both groups failed by pulling out of the bone. There was no fracturing of implants observed in either group, under any testing condition (Table 3).

There were no statistically significant differences in the cortical thickness measurements between the specimens tested in torque and pullout. In both experimental settings on torque and pullout testing, the cortical thickness was in a similar range between the specimens tested with the buttress screws and those tested with the Bone-Screw-Fasteners (+3.47% in torque experiments and +1.45% in pullout experiments; $P = 0.80$).

DISCUSSION

This biomechanical study demonstrates superiority of resistance to torque stripping forces by a new Bone-Screw-Fastener compared with the conventional cortical AO buttress screw. The innovative design of the fastener thread is based on an interlocking thread technology that allows for the fastener to resist loads in multiple directions rather than just axial loads. The comparison of load vector distribution to an off-axis force on the threads of the Bone-Screw-Fastener compared with the conventional AO buttress threads is schematically depicted in Fig. 1. Conceptually, the fastener is protected from stripping because of its unique geometry that is designed to maximize bone volume, preserve bone architecture, and create a circumferential interlocking interface between the fastener and bone. In simpler words, the fastener threads are engaged in the surrounding bone in an analogous fashion as a "loaded nut-and-bolt" technology, whereby the nut is protected from stripping inside the bolt independent of the number of revision applications. This notion is supported by the data from the present study, which demonstrate that none of the Bone-Screw-Fasteners stripped at the bone–implant interface. Instead, failure of the fasteners occurred exclusively at the hexagonal recess of the screw head at torque loading forces that were significantly higher than the peak bone stripping forces of the AO buttress screws.

The strongest feature of the buttress screw is resistance to uniaxial pullout forces.[10] Interestingly, the origin of the modern AO screw dates back to the times of Robert Danis, who significantly innovated the contemporary industrial screw design to be applicable to fracture fixation in human bone by changing the ratio of the exterior screw diameter to the core diameter (from 4:3 in industry screws to 3:2 in orthopaedic screws); by reducing the thread surface area to one sixth (because of bone strength being only about one-sixth of the metal strength); and by modifying the classic, industrial, V-shaped thread design to the buttress thread with the intent of improving uniaxial pullout resistance in bone.[6,11] Robert Danis' pioneering screw design was adopted in the modern AO buttress screw and has not been modified conceptually since the 1940s.[6,12] The data from the present study support the notion that the strongest feature of the AO buttress screw is characterized by resistance to uniaxial pullout forces.[13] These data also demonstrate that the new Bone-Screw-Fastener provides a similar extent of axial pullout resistance as the buttress screw, implying that the superiority of the fastener design related to stripping forces does not come at the price of reduced pullout resistance.

Because of the persisting technical shortcoming of the standard buttress screw, orthopaedic trauma surgeons are forced to navigate the thin line between applying sufficient screw torque to assure adequate compression and friction between implant and bone while attempting to avoid accidental overtightening of the screws with the imminent risk of stripping and screw–bone interface failure.[9,13] A recent

TABLE 3. Results From the Individual Axial Pullout Experiments in Both Testing Groups

Factor	#1		#2		#3		#4		#5		#6	
Laterality	R	L	R	L	R	L	R	L	R	L	R	L
Group	2	1	2	1	1	2	2	1	2	1	2	1
Implant	AO	BSF	AO	BSF	BSF	AO	AO	BSF	AO	BSF	AO	BSF
Axial pullout resistance (N)	2732	2953	2700	2880	3347	3493	2831	2875	4579	4488	3498	3545
Failure mode	SBI	SBI	SBI	SBI	SBI	SBI	SBI	SBI	SBI	SBI	SBI	SBI

AO, cortical buttress screw; BSF, Bone-Screw-Fastener; SBI, screw–bone interface.

biomechanical study on human cadaveric femurs was designed to determine the difference between "stopping torque," defined as the subjective "two fingers tight" feel by orthopaedic surgeons to obtain adequate fracture fixation, and the objective "stripping torque" determined by a 3.5 mm torque screwdriver.[9] The authors reported that the average stopping torque to stripping torque ratio was only 66.6% in human femur specimens.[9] A different cadaveric study in human humeri revealed no direct relationship between screw torque and axial pullout strength beyond 50% of maximal torque force.[3]

Previous biomechanical studies have shown that the stripping of 3.5 mm cortical screws by overtightening resulted in 76%–82% decreased pullout resistance and increased risk of subsequent failure of fracture fixation.[14] A prospective clinical trial reported that at least one screw stripped during open reduction with internal fixation of unstable ankle fractures in 88% of all patients included in the study.[15] A pilot clinical trial using the new Bone-Screw-Fastener for open reduction with internal fixation of 29 fractures was recently reported.[8] In this early "proof-of-concept" study, none of the 123 fasteners showed any signs of intraoperative stripping or delayed loosening without failure of fixation at a mean follow-up time of 9.5 months (range, 5–15 months).[8] An additional feature of potential value related to improving the biology of fracture fixation is represented by the preservation of surrounding bone at the interface with the Bone-Screw-Fastener, as the insertion of conventional buttress screws has been conceptually associated with microfracturing of the surrounding bone.[4,8]

Limitations of this study include the small sample size of 6 matched pairs of adult human cadaveric tibiae tested. In addition, the biomechanical testing may not be directly extrapolated to the clinical setting with off-axis in vivo loading forces. The study was designed to test for biomechanical differences between the AO buttress screw and Bone-Screw-Fastener and not for differences in bone quality. To ensure the bone quality was similar in both groups, matched pairs of tibias were used. To further ensure similar bone quality between the 2 groups, the bone mineral density and cortical thickness of the specimens used were measured and found to be in a similar range, without statistically significant differences. These measures of the specimens used in testing added confidence that the conclusions made were because of the differences in the biomechanical performance of the fasteners and not because of the differences in bone quality. Finally, this study was exclusively designed to test stripping failure and uniaxial pullout resistance, and multiaxial testing was not applied in the experimental setting.

The benefit of the new interlocking thread technology related to improved bone preservation and resistance to multiaxial failure remains to be scientifically validated in future studies using off-axis loading experiments.

CONCLUSIONS

This study demonstrates the superiority of a new 3.5 mm Bone-Screw-Fastener in resisting torque stripping forces compared with the conventional 3.5 mm AO cortical buttress screw, in a biomechanical investigation on cadaveric human tibia specimens. In addition, the established strength of uniaxial pullout resistance by the conventional buttress screw remains retained with the new fastener design. This innovative new implant may lead to a paradigm shift in the technology of fracture fixation by reducing complications related to the delayed failure of fixation and thereby contributing to improved patient outcomes. This notion will have to be validated in well-designed future prospective clinical trials.

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