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Cross-elements to enhance fixation in osteoporotic bone with application to proximal humeral locking plates: a biomechanical study

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Background: Proximal humeral fractures occur predominantly in elderly, osteoporotic individuals, especially women, with surgery performed in one-fifth. Proximal humeral locking plates are the gold standard operative treatment; however, complications are frequent, partially because of poor screw purchase in osteoporotic bone. A new method uses threaded posts through which threaded cross-elements orthogonally pass to create a 3-dimensional scaffold for bone engagement. We examined the pullout characteristics of the posts with (1 or 2) or without the cross-elements and tested 2 types of 3.5-mm cortical locking screws for comparison.
Methods: Low-density closed-cell polyurethane foam served as a model osteoporotic bone substrate. Following implantation in the substrate, the devices were axially loaded by a mechanical test system. Quantities of interest included failure mode, peak load, displacement to peak load, initial stiffness, and work expended.
Results: The post groups outperformed the 3.5-mm screw groups, as expected. Relative to posts with no cross-elements, 1 and 2 cross-elements increased the peak load by 29% and 87% and increased the work to peak load by 126% and 343%, respectively. After reaching peak load, 1 and 2 cross-elements increased the work-resistance to further displacement by 158% and 330%, respectively.
Conclusion: Cross-elements significantly increased the ability of the threaded posts to resist axial displacement from a model osteoporotic bone substrate. This suggests that posts, used in conjunction with cross-elements, have the potential to enhance the stability of proximal humeral locking plates in osteoporotic bone.
Level of evidence: Basic Science Study; Biomechanics

Keywords: Screw; fixation; cross-elements; osteoporotic bone; proximal humeral locking plates; biomechanical

Proximal humeral fractures (PHFs) comprise 4% to 5% of all fractures, commonly affecting the elderly after low-energy trauma such as may occur after a fall.[5,18,22] This is the fourth-most prevalent fracture among geriatric patients after distal radius, proximal femur, and vertebral fractures.[11,40] PHFs are associated with osteoporosis, and 78% are seen in patients older than 65

Institutional Review Board approval was not required for this basic science study.

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years.[27] Between the ages of 30 and 60 years, men and women are equally affected; however, after the age of 50 years, the female-to-male ratio is 4:1, underscoring the role of osteoporosis.[32] In 2008, there were 370,000 emergency department visits in the United States for PHF, a number expected to increase to more than 490,000 by 2030.[18]

Nearly 75% of PHF patients are treated nonoperatively, with the balance undergoing surgery.[16] Surgical treatment is generally considered for unstable, displaced 3- and 4-part fractures.[25] The primary goal of surgery is to restore shoulder function and bone union with good alignment.[1] Surgical treatments include open reduction and internal fixation with proximal humeral locking plates, closed reduction and percutaneous pinning, intramedullary nailing, hemiarthroplasty, and reverse total shoulder arthroplasty.[7,23,30] Proximal humeral locking plates are the gold standard.[31] Long-term clinical results are excellent and good in approximately two-thirds of patients, with moderate and poor results reported in one-third.[26] Complications including avascular necrosis of the humeral head, secondary varus displacement, and concomitant cutting out of screws into the glenohumeral joint occur in up to 35% of patients.[2,28,38] Reduction loss has been reported to occur in 4.2%-13.7% of cases and results from several conditions, including age, osteoporosis, severe comminution, technical errors, and patient noncompliance.[2,15]

Fracture fixation in osteoporotic bone is challenging because of (1) poor implant anchorage[3,19] and (2) slow bone metabolism, which delays healing.[3] Decreased bone density compromises the holding strength of screws and increases the risk of implant failure and loss of reduction.[20,35,36] Methods to enhance proximal humeral locking plate effectiveness include medial support screws, bone grafts to enhance medial support, bone void fillers to increase stiffness, and PMMA bone cement augmentation of screws.[6,34] Although all show promise, the clinical evidence is weak.[34]

Failure of internal fixation in osteoporotic bone is typically due to bone failure rather than implant breakage.[9] One strategy is to design the fixation device to distribute the load vector along the implant-bone interface such that local stress remains below the bone failure threshold. This can potentially be achieved by passing threaded implants orthogonally across the axis of plate fixation screws, effectively forming a "+" configuration to enhance anchorage. The PANTERA Proximal Humerus Fracture Fixation Plate System (Toby Orthopaedics, Miami, FL, USA) includes threaded posts and cross-elements (CEs) as well as locking and nonlocking cortical screws to fix the plates to the proximal humerus. The purpose of this study was to characterize the pullout strength of these threaded implants and to explore the cross-element biomechanics in a model system.

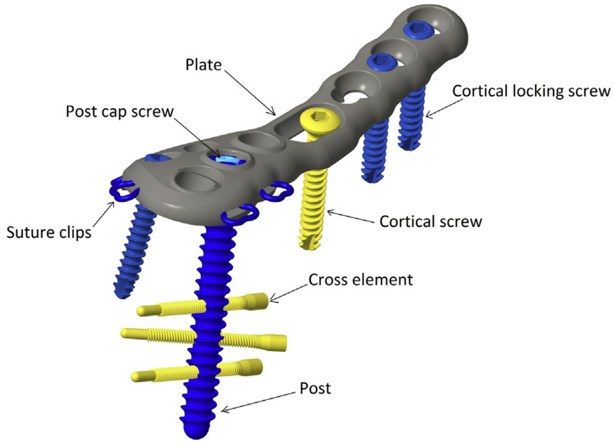

Figure 1 The PANTERA Proximal Humerus Fracture Fixation Plate and screws/cross-elements. The shortest post (30 mm) can accommodate 2 CEs, whereas the longer posts can accommodate 3.

Materials and methods

Plate-screw system description

The PANTERA Proximal Humerus Fracture Fixation Plate System is shown in Figure 1. The plates contain a series of holes to accommodate locking and nonlocking 3.5-mm cortical screws and posts. Table I summarizes the various configurations available and the screw, post, and CE lengths that were tested (plates were not included in the testing protocol). Note that the central CE is rotated 30 degrees from the plane defined by the proximal and distal CEs to create a 3-dimensional scaffold to maximize purchase with osteoporotic cancellous bone. A guide indexes with the proximal aspect of the post ensuring the proper trajectory of the CEs to pass through the cross-holes (Fig. 2).

Pullout test

The pullout test was conducted per ASTM F543-07. Forty-millimeter posts, 30-mm CEs, and 3.5 × 40-mm cortical locking screws were obtained from Toby Orthopaedics, Inc. Cortical locking screws of dimension 3.5 × 40 mm were obtained from DePuy Synthes (Raynham, MA, USA). Five screw configurations were tested: (1) Post-only, (2) Post+1CE, (3) Post+2CE, (4) Toby 3.5-mm cortical screw (T 3.5), and (5) Synthes 3.5-mm cortical locking screw (S 3.5) for comparison.

The test substrate consisted of closed-cell polyurethane blocks (Pacific Research/Sawbones, Vashon Island, WA, USA) with physical and mechanical properties as listed in Table II. Rectangular blocks were used with the posts alone as well as the 3.5-mm cortical locking screws. Cylindrical blocks (30 mm diameter × 40 mm length) were used with the post+CE constructs.

Pilot holes of the following diameters were prepared in the substrate blocks prior to screw insertion per the manufacturers' instructions: posts (4.0 mm), T 3.5 screws (2.5 mm), CEs (1.6

Table I Basic implant configurations

Manufacturer	Implant	Material	Length range, mm	Length tested, mm	Diameter, mm		Thread pitch, mm	Driver
					Major	Minor		
Toby Orthopedics	Plates	Ti6Al4V ELI	73-220	N/A	N/A	N/A	N/A	N/A
	Cortical screws (locking)		10-45	40	3.5	2.4	1.25	Hex or star
	Cortical screws (nonlocking)		10-40	Not tested	3.5	2.4	1.25	Hex or star
	Posts		30-50	40	5.28	3.8	1.75	Cruciform
	Cross-elements		20-35	30	1.98	1.55	0.4	Square
DePuy Synthes	Cortical locking screws	316L stainless steel	10-60	40	3.5	2.9	0.8	Star

Figure 2 The guide system ensures proper positioning and trajectory of the CEs to align with the cross-holes in the post.

mm), and S 3.5 screws (2.8 mm). In the case of the post+CE constructs, the post pilot hole passed through the cylinder axis with the CEs inserted radially through the cylinder to intersect with and pass through the post (Fig. 3).

The screws were inserted through a hole in a metal pullout fixture whose diameter was sized to allow the threaded shaft to pass through the hole but smaller than the head. The block was then restrained to be stationary on the base of the test apparatus while the pullout fixture was firmly attached to the moveable crosshead of an MTS 858 Mini BIONIX II mechanical test system (MTS Systems, Eden Prairie, MN, USA) (example shown in Fig. 4). The crosshead was engaged to move upward at a rate of 0.1 mm/s, transferring tensile load to the screw, with the system recording the force-displacement curve. The test was terminated on catastrophic failure, which occurred with an instantaneous step-decrease in load, or when the load reached at least a 30% reduction in peak value. The protocol specified that tests be performed in triplicate with an additional Post+1CE and S 3.5 configuration tested during the setup procedure. The initial setup tests proceeded as designed; hence, the respective configurations included 4 replicates.

The following quantities were obtained from the force-displacement curves and used to compare the 5 screw configurations: (1) peak load; (2) initial slope obtained via linear regression as a measure of the stiffness of the screw–bone block interface; (3) the displacement at peak load; (4) the area under the curve, or work, required to displace the screw; and (5) whether catastrophic failure occurred.

Statistical analysis

Excel, version 16.23 (Microsoft Corp., Redmond, WA, USA) was used to perform linear regression on the initial slope of the force-displacement curves and to calculate the area under the curves. Descriptive statistics (mean and standard deviation) were computed for each screw configuration. Differences among multiple means were statistically compared by 1-way analysis of variance followed by a post hoc Student-Newman-Keuls test. Comparisons of proportional data were made via the χ^2 test. Statistical significance was taken for $P < .05$.[12]

Results

It was apparent that some of the test runs exhibited a small initial lag in their force-displacement curves; that is, displacement occurred before there was a continual upswing in the force. This was due to suboptimal restraint with residual laxity in the test system. However, once the crosshead reached the laxity limit, the expected force-displacement curve became manifest. The affected test runs were corrected by performing linear regression on the initial portion of the curves and extrapolating the regression line to intersect the displacement axis, thereby establishing an effective starting point for the run. The curve was then left-shifted to coincide with the origin as shown in Figure 5.

The force-displacement curves for the 5 screw systems all exhibited the expected initial linear portion indicative of elastic behavior over small displacements, then reaching a peak load after which further displacement resulted in steadily decreasing loads (Fig. 6). Although the S 3.5 group appears to have 2 peak loads, none of the individual test runs exhibited this. This is a composite curve of the means of all 4 runs, with 2 of these runs displaying lower peak

Table II Properties of synthetic bone blocks

Density			Compression		Tension		Shear		Shore D hardness
ASTM D1622		Volume fraction	ASTM D1621		ASTM D1623		ASTM C273		
lb/ft^3	g/cm^3		Strength, MPa	Modulus, MPa	Strength, MPa	Modulus, MPa	Strength, MPa	Modulus, MPa	
5	0.08	0.07	0.6	16	1.0	32	0.59	7.1	10

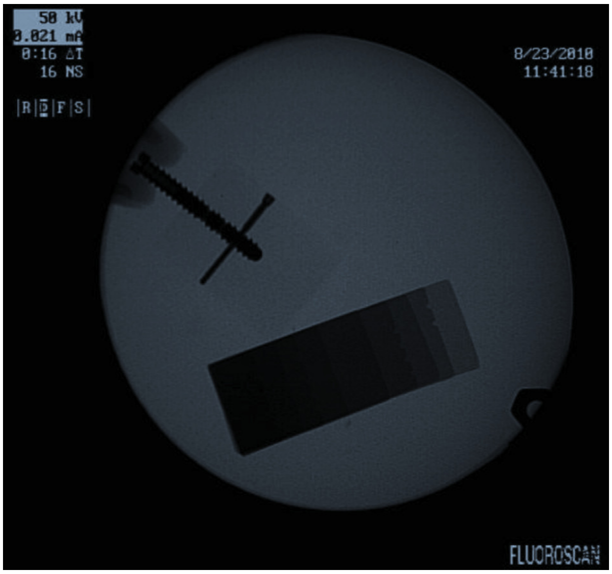

Figure 3 Fluoroscopic image of cylindrical substrate with post inserted axially and CE inserted radially through the post.

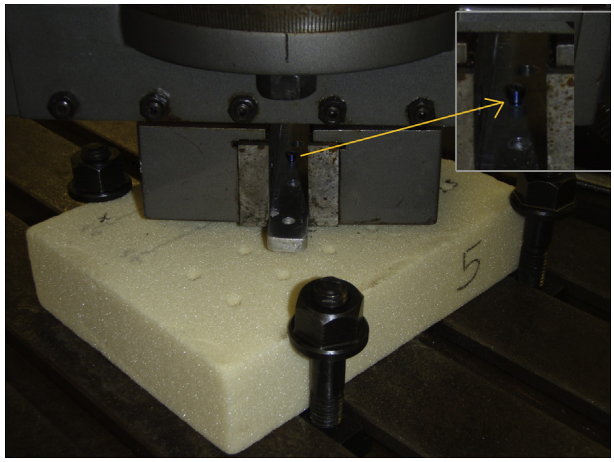

Figure 4 The pullout test setup of the post (no CEs) from a rectangular substrate block. Inset shows detail of the post head and pullout fixature.

load and displacement values than the other 2 runs. The initial linear regions of the 3 post configurations had similar slopes, and all retained substantial resistance to further displacement more than approximately 3-6 times the displacement to peak load, with the effects of the CEs clearly evident in terms of their ability to sustain greater loads. The typical failure mode for all test configurations was substrate failure with no evidence of screw deformation or breakage.

Table III presents the descriptive statistics for the pullout test results. The mean peak loads exhibited by the 5 screw groups were all significantly different from each other, in the order S 3.5 < T 3.5 < Post-only < Post+1CE < Post+2CE. Importantly, the peak loads for the 3 post groups increased with the number of CEs; that is, relative to the post-only group, the mean peak loads for the Post+1CE and Post+2CE groups increased by 29.1% and 86.9%, respectively.

Statistical analysis of the stiffness data revealed several significant differences among the 5 groups. Interestingly, there was no apparent relationship between the number of CEs used with the posts and stiffness (range: 236.6-249.4 Nmm, $P > .05$). Collectively, the post-associated values were approximately 50% and 150% greater than those for the T 3.5 and S 3.5 groups, respectively; however, not all such comparisons reached significance. The mean stiffness of the T 3.5 group (164.6 Nmm) was significantly greater than that of the S 3.5 group (99.5 Nmm).

The mean displacements at peak load for the 5 groups were within a narrow range of 0.62-1.31 mm. The only difference that was significant was for the post+2CE group (1.31 mm) compared with the Post-only group (0.62 mm).

The work to peak load was highly dependent on the number of CEs associated with the post groups. The use of 1 and 2 CEs significantly increased the mean work to peak load by 126% and 343%, respectively. There was, however, no significant difference between the mean values for the zero CE post, the S 3.5, or the T 3.5 groups.

Figure 7 shows the mean cumulative work along the path to 3.5-mm displacement for the 3 post groups. Up to a displacement of about 1.0 mm, the work profiles were essentially the same regardless of whether CEs were used. However, beyond 1.0 mm displacement, the work profiles diverged considerably, with the work required to reach 3.5 mm for the 1CE and 2CE post groups being approximately 2 and 3 times that for the non-CE post group, respectively. For the displacement range of 1.5-3.5 mm, which is beyond the peak load displacement in these groups, the work-displacement curves were essentially linear. The regression slopes of these lines represent the work resistance to further

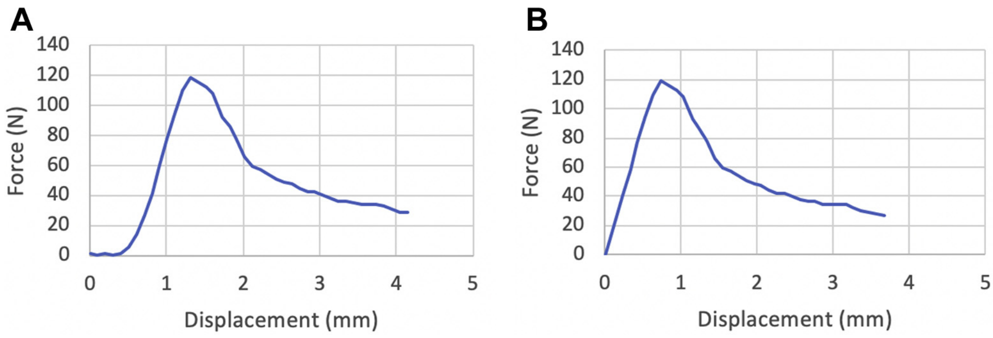

Figure 5 (**A**) Raw force-displacement curve for a single Post-only configuration test run. (**B**) Force-displacement curve for the same raw curve after extending the linear portion of the curve to the X-axis via linear regression and left-shifting the curve to the origin.

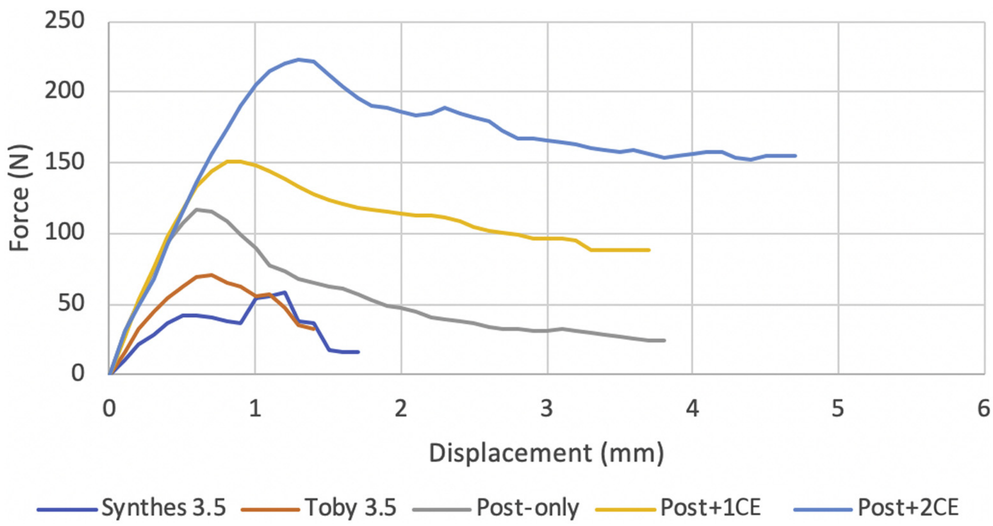

Figure 6 Plots of the mean force-displacement curves for each of the screw configurations.

displacement in this region. Relative to the zero CE group, the mean work resistance increased by 158% and 330% for the 1CE and 2CE groups, respectively.

Only the S 3.5 group exhibited catastrophic failure, occurring in 2 of the 4 (50%) experimental runs. There was, however, no statistically significant difference among the 5 groups in this regard.

Discussion

The goal of bone fixation is for fracture stabilization to allow anatomic healing to occur. The fixation should be sufficient to withstand transient loads and not result in destabilization of the fracture. Such fixation is particularly challenging in osteoporotic bone because of the low mineral density and compromised screw purchase.[20,35,36] There have been several prior biomechanical investigations of the use of proximal humeral plates and screws.[17,33,41,43] In general, these studies investigated the use of plate and screw systems in cadaveric humera. To a lesser extent, such studies have been performed in other substrates as well, including saw bones, animal bones, and wood.[10] To our knowledge, no prior studies have focused on only the screw aspects of proximal humeral fixation. Likewise, there exist many reports of the effects of screw design, insertion technique, and variation in natural and synthetic bone substrates on pullout strength, but none are specific to the proximal humerus nor included consideration of cross-elements.[8,13,14,21,37,39,42] As such, our study is unique in both implant design and application.

We chose a synthetic substrate to provide a uniform base material from test to test and avoid the variability inherent in cadaveric bone.[24] Our substrate was a closed-cell polyurethane foam of density 0.08 g/cm^3 and a solid volume fraction of 0.07 (0.93 total void volume). For comparison, the density of cancellous bone from the anterior iliac spine of 80-year-old women and the bone volume fraction of thoracolumbar spine cancellous bone from 69 $\pm$ 18-year-old women is approximately 0.23 g/cm^3 and 0.089 $\pm$ 0.010, respectively.[4,24] Nagaraja and Palepu[24] examined the screw pullout properties from a variety of closed- and open-cell polyurethane foams, concluding a substrate like the one we used well represented osteoporotic female thoracolumbar

Table III Descriptive statistics for the 5 screw groups

Configuration	Peak load, N	Stiffness, N/mm	Displacement at peak force, mm	Work at peak load, Nmm	Work per mm from 1.5-3.5-mm displacement, Nmm/mm	Catastrophic failure, %
Post-only (n = 3)	119.7 ± 1.4^{a}	236.6 ± 51.0^{a,b}	0.62 ± 0.10^{a}	41.3 ± 4.6^{a}	42.0 ± 6.7	0.00
Post+1CE (n = 4)	154.5 ± 14.7^{a}	249.4 ± 44.9^{c}	0.96 ± 0.20	93.3 ± 21.9^{a,b,c,d}	108.6 ± 17.5	0.00
Post+2CE (n = 3)	223.7 ± 5.4^{a}	238.8 ± 13.2^{d}	1.31 ± 0.04^{a}	183.1 ± 11.9^{a,b,c,d}	181.0 ± 2.0	0.00
Synthes 3.5 (n = 4)	54.9 ± 9.0^{a}	99.5 ± 36.8^{a,c,d,e}	0.90 ± 0.42	31.0 ± 17.9^{c}	N/A	0.50
Toby 3.5 (n = 3)	75.6 ± 3.1^{a}	164.6 ± 36.2^{b,e}	0.79 ± 0.27	37.4 ± 13.4^{d}	N/A	0.00
Statistical analysis						
ANOVA, *P* value	<.001	<.001	.070	<.001	<.001	N/A
SNK, *P* value	<.05	<.05	<.05	<.05	<.05	N/A
χ^2	N/A	N/A	N/A	N/A	N/A	P = .118

ANOVA, analysis of variance; *SNK*, Student-Newman-Keuls; *N/A*, not applicable.
Screw configurations sharing the same superscript letter are significantly different from each other.

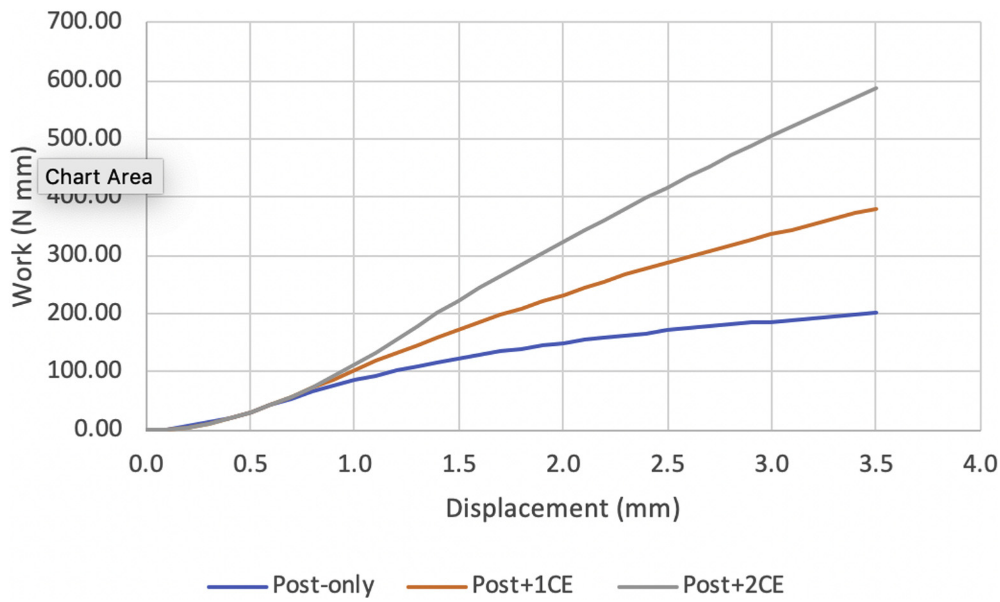

Figure 7 Plot of average work (area under the force-displacement curve) for the 3 post configurations.

vertebrae in this regard. This suggests that the synthetic substrate used in our study aligned, at least to a first approximation, with the osteoporotic proximal humeral characteristics of the target population. Although there are certainly mechanical and structural differences between our substrate and osteoporotic proximal humeral bone, we would expect to see similar trends in screw pullout characteristics in both materials.

The strength of fixation, in general, is a function of the mechanical properties of the fixation device, the substrate, and the interface between the two. In the case of screw fixation of bone, the strength of fixation will depend on the structure and density of the bone, the design of the screw and the material from which it is composed, the geometric nature of the interface between the screw and the bone, and the nature of the applied force vector.

During screw pullout testing, the force-displacement curve exhibits an initial linear region that reaches a peak load, then the load decreases with further displacement. The linear region is elastic, meaning that deformation that occurs here is reversible and on load removal the displacement will resolve back to zero. In this region, deformation that occurs in the substrate and the screw is elastic, and no relative motion (slippage) occurs between the screw and the substrate. After sufficient displacement has occurred for the peak load to be reached, further displacement results in permanent, or plastic, deformation of the substrate and relative motion of the screw within the screw tract that is not recoverable on load removal. Note that the mechanical properties of stainless steel and titanium alloy used for orthopedic screws are 1-2 orders of magnitude greater than that for bone, so in general a metal screw will not reach its yield point as the bone will typically fail before the screw.[9,29]

The force-displacement curve provides several types of information that can characterize the strength of fixation. First, the initial slope of the curve, expressed as force-displacement, reflects the stiffness of the construct to resist movement, or deformation. All else being equal, the greater the stiffness the less will be the displacement that occurs in response to a given load. Thus, greater stiffness corresponds to increased stability. Second, the peak load will define the upper limit of the force that the construct can withstand before elastic failure occurs. As a first approximation, the peak load represents the end of the elastic limit, but practically some permanent deformation will begin to occur just before reaching it as indicated by nonlinearity in the curve as the peak load is approached. In general, the greater the peak load that the construct can withstand, the greater the stability will be. Third, the area under the force-displacement curve represents the work required to reach a particular point of displacement or deformation. Work is defined as force × distance and has units of energy. It represents the physical effort required to deform the construct under an applied load. The more work that is required to reach a certain point of displacement or deformation, the greater is the stability.

As explained above, the peak load sustained by the screw constructs broadly defines the boundary between reversible elastic behavior and permanent deformation. Not unexpectedly, the peak load for the post constructs was greater than that for the 3.5-mm screws. Also, as expected, the peak load for the posts increased substantially with increasing number of CEs. The weak link in metal screw fixation is failure of the screw-substrate interface, whereby the force generated by the moving cross-head begins to pull the screw through the substrate. The CEs provided additional anchorage to the post to raise the force threshold required for the onset of this to occur.

The mean stiffnesses of the 3 post constructs were greater than those of the two 3.5-mm screw constructs. This was expected as the posts were of greater diameter than the 3.5-mm screws, which resulted in distributing the tensile load over a greater interfacial area and reducing the intensity of the interfacial stress (force/area) at any given point. Also, all else being equal, larger-diameter screws are stiffer than smaller-diameter screws and present a more extensive thread-substrate contact area. Both of these factors contributed to the superior stiffness of the post constructs. It is interesting that the initial stiffnesses of the 3 post systems were the same and did not increase with the number of CEs, suggesting that the posts were the dominant influence on stiffness. It is possible that a finite element analysis might explain this empirical result, but such analysis was outside of the scope of our study.

Whereas stiffness and peak load each take 1 aspect of the force-displacement curve into account, the work to peak load considers both. Although the post-only group exhibited substantially greater stiffness and peak load than either of the 3.5-mm cortical screw groups, the work to peak load among these 3 groups was similar (31.0-41.3 Nmm) because the post-only group displayed the lowest mean displacement to peak load. One way of demonstrating the biomechanical advantage associated with the CEs is by examining the work to peak as a function of the number of CEs used. The use of 1 CE increased the work by 126%, whereas 2 CEs increased it by 340%. Another way to characterize the utility of CEs is by their effect on the portion of the force-displacement curve to the right of peak load where irrecoverable movement of the screw through the substrate is occurring, that is, the region where load decreases with increasing displacement. Clinically, it is important to minimize the potential for complete destabilization to abruptly occur as might happen during a fall. Hence, the more work that is required to achieve a unit of displacement here can correspondingly reduce the risk of catastrophic failure in these circumstances. In the post peak load region of 1.5-3.5-mm displacement, the mean work per unit of displacement was 42.0, 108.6, and 181.0 Nmm/mm for the Post-only, Post+1CE, and Post+2CE systems, respectively, representing corresponding increases of 158% and 330% for the 1CE and 2CE systems compared with zero CEs (ie, Post-only). Consequently, CEs enhance fixation stability throughout both the elastic and inelastic regions of the force-displacement curve.

Finally, the above concepts can help to explain the biomechanical differences between the T 3.5 and S 3.5 cortical screws, that is, significantly greater stiffness and peak load and a trend toward greater work to peak load for the former. Although both screws have the same major diameter, the T 3.5 screw has more than a 2-fold greater thread pitch and a minor diameter that is 0.5 mm smaller. Both of these differences allow a greater amount of substrate to be captured between adjacent threads that increases the threshold for substrate failure. Synthes 3.5-mm cortical screws are available in both stainless steel and titanium alloy. We chose the stainless steel variant because this version is ubiquitous in internal fixation and served as a reference. Although the S 3.5 screw was made of a stiffer material than the T 3.5 screw, the material difference did not appear to dominate the failure behavior.

In summary, we have characterized the biomechanical properties of fixation devices used with PANTERA plates and included testing of a Synthes 3.5-mm cortical screw for reference. Multiple means of analyzing the data allowed a more complete understanding of the relationship between screw design and construct stability. As expected, the larger post constructs afforded greater stability than the smaller 3.5-mm cortical screws, and the inclusion of CEs with the posts enhanced stability profoundly.

This study had some limitations. First, the sample sizes for the various screw groups were small, which increased the difficulty of statistical analysis. Despite this, many statistically significant comparisons existed that, coupled with observed trends, painted a coherent picture of the overall results. Second, a low-density closed-cell polyurethane foam was used as a screw substrate to mimic osteoporotic bone. Bone is a complex anisotropic material, which the synthetic material can only approximate. Nevertheless, the literature suggests that this substrate was a reasonable approximation to osteoporotic bone from a screw pullout standpoint and eliminated substrate variability, inherent with cadaver bone, from consideration.[24]

Third, only 1 length of screw and/or CE was tested. These devices are available in a range of lengths, and a more comprehensive test would have included additional sizes to allow a more complete understanding of the relationship between form and function.

Future work should be directed toward performing additional biomechanical studies to address the limitations expressed above, that is, increased sample size, use of an osteoporotic bone substrate to more closely mimic the clinical condition, and testing a greater variety of screw sizes. In addition, it is important to remember that these screws are part of a complete proximal humerus fixation system used to secure the PANTERA plate to bone. Consequently, future work should also examine the biomechanical properties of screw-plate-bone constructs to better characterize their suitability for the clinical conditions for which they were designed to treat. Although the introduction of cross-elements may help to address one of the principal limitations of proximal humeral plating, that is, poor purchase in osteoporotic bone, the ultimate validation of this concept lies in clinical outcome analysis and examination of any challenges introduced by this method.

Conclusions

The studied proximal humerus plating system is designed to fix proximal humeral fractures in elderly patients with osteoporotic bone. It uses a combination of cortical screws and threaded posts to attach the plate to the proximal humerus. A unique aspect of this system is the use of threaded cross-elements that pass through the posts to enhance bone fixation. Biomechanical pullout testing showed that the use of CEs with the posts provides a profound biomechanical advantage to enhance the fixation properties.

Disclaimer

Eduardo Gonzalez-Hernandez reports that he has ownership and stock in Toby Orthopaedics that is related to the subject of this work.

William S. Pietrzak reports that he has received consultant payments from Toby Orthopaedics that is related to the subject of this work.

Saaransh Jain reports that he is an employee and receives salary from Toby Orthopaedics that is related to the subject of this work.

The other author, his immediate family, and any research foundations with which he is affiliated has not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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