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Comparison of Torsional Strengths of Bioabsorbable Screws for Anterior Cruciate Ligament Reconstruction*

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ABSTRACT

The goals of this study were to evaluate torsional strength and modes of failure in commercially available bioabsorbable interference screws and to test the effect of screw diameter on torsional strength when screws become jammed during insertion. We tested the Arthrex, BioScrew, Endo-Fix, Phantom, and Sysorb screws, all 20 mm in length. Four major modes of failure were encountered. Analysis of variance revealed that both screw type and diameter had a significant effect on failure torque. The Endo-Fix 7-mm screw had the lowest failure torque (1.07 ± 0.18 N·m) and the Sysorb 8-mm screw had the highest (5.23 ± 0.24 N·m). The Sysorb was significantly stronger than all the other screws. The failure torques were within the range that has been reported for manual screw insertion. We concluded that technical factors, which can affect insertion torque, assume particular importance with the use of bioabsorbable interference screws.

The use of interference screws is a widely accepted technique for graft fixation during knee-ligament reconstruction.[9,11] Secure early graft fixation is essential for accelerated rehabilitation regimens.[16] Early and late postoperative complications can occur with use of permanently implanted metal screws, including intraarticular migration[3,17] and pain requiring implant removal.[10] In addition, postoperative imaging is distorted by metal screws, and screw removal can be difficult during revision procedures. These problems led to the development of bioabsorbable screws.[18] They provide fixation similar to that of metal interference screws at both time 0 and after degradation for up to 28 days.[1,4,8] Clinical results with use of these screws are equivalent to those from metal screws,[2,12] but screw breakage during insertion has been reported both in vivo and in vitro.[7,13,18]

Pull-out strength of interference screws has been widely studied,[5–8,13–15] but less attention has been paid to insertion torque.[4,6,13] The only in vitro study of torque strength found widely varying loads at failure.[19] This study showed that some screws failed at torque levels previously measured during screw insertion in young human bone and in vivo.

Previous studies have not addressed the effect of screw diameter on failure strength, and only one study has compared failure torques of different bioabsorbable screws.[19] The authors tested the screws to failure, leaving only the proximal 1 mm free of rigid fixation. This method did not reproduce the clinical scenario for screw breakage, which often occurs when the screw is halfway into the bone and becomes jammed or locks up. The extra torque required by the surgeon to continue screw insertion in these situations can cause screw failure.[18] We compared the torsional strengths and examined the modes of failure among commercially available bioabsorbable interference screws when they became jammed during insertion. In addition, we tested the effect of screw diameter on torsional strength.

MATERIALS AND METHODS

Five different screw types in each available diameter were tested (Table 1 and Fig. 1). Six screws from each group were tested except for the BioScrew 7-mm group, which included five screws, and the Sysorb 8-mm group, which included four screws. The lower screw numbers for these two groups was caused by limited availability at the time of the study. All screws were mounted in a 10-mm layer of

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TABLE 1
Details of the Different Bioabsorbable Screws Tested

Details	Screw name				
	Endo-Fix	BioScrew[a]	Phantom	Arthrex	Sysorb
Manufacturer	Smith & Nephew Endoscopy Inc. (Andover, Massachusetts)	Linvatec Corp. (Largo, Florida)	Depuy OrthoTech (Warsaw, Indiana)	Arthrex, Inc. (Naples, Florida)	Sulzer Orthopedics Ltd. (Baar, Switzerland)
Polymer	Poly (glycolide-co-trimethylene-carbonate) 67.5%/32.5%	Poly-(L-lactide)	Poly-(L-lactide)	Poly-(L-lactide)	Poly-(D,L-lactide)
Diameters (mm)	7, 9	7, 8, 9	7, 9	7, 8, 9, 10	8
Length (mm)	20	20	20	20	20
Drive system	Torx, driven over 10 mm	Trilobe, fully driven	Square, fully driven	Hexagonal, fully driven	Turbine-like, fully driven

[a] Both the tibial and femoral screws were tested.

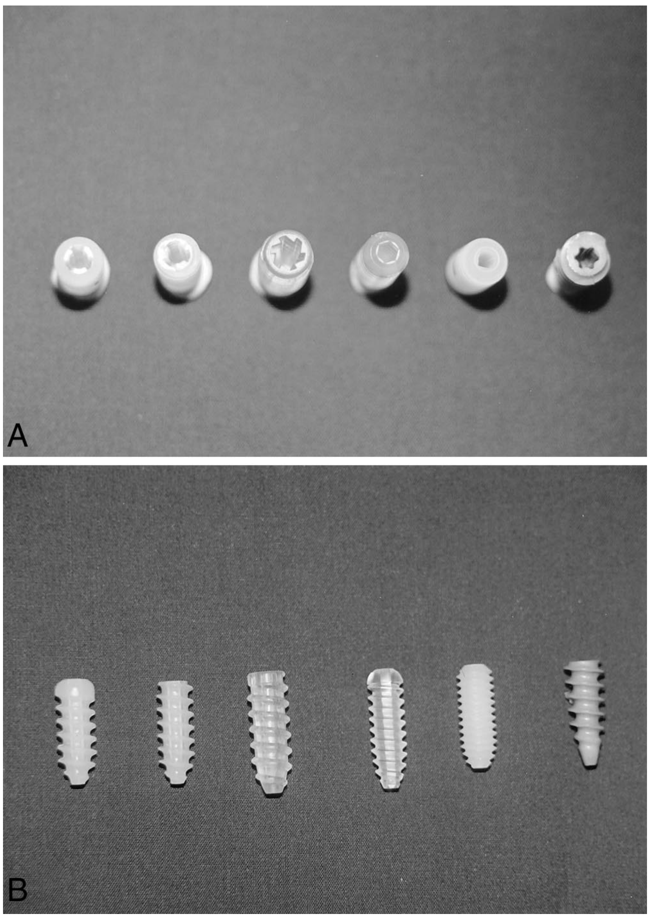

Figure 1. Top (A) and side (B) views of the bioabsorbable interference screws tested. From right, Endo-fix, Phantom, Arthrex, Sysorb, BioScrew tibial, and BioScrew femoral screws.

polyurethane resin (UREOL 5202, Vantico, Duxford, United Kingdom), leaving the proximal 10 mm of the screws unembedded. This mounting reproduced the failure scenario observed in vivo, where only part of the screw length has been inserted and becomes jammed in bone. Polyurethane resin was used to fix the screws instead of polymethyl methacrylate because the polyurethane cured at a lower temperature than polymethyl methacrylate for a layer thickness of 15 mm or less, which prevented screw degradation and deformation during the embedding process.[19]

Torque was applied manually with an instrumented hand-held torque screwdriver calibrated from −12 to +12 N·m with an accuracy of ±0.05 N·m. A Measurements Group 2100 strain amplifying system (Measurements Group Inc., Raleigh, North Carolina) provided the excitation and signal conditioning. The manual method of torque application produced strain rates closer to the situation encountered in vivo than that used in previous studies. The same person applied torque in all cases in an attempt to provide a constant rate of application as well as compression on the screw. Care was taken to ensure that the application of torque was performed without associated bending or excessive compression. Manual application of torque was chosen over mechanical means to allow physiologic feedback control of the test. This control involved stopping the test when the first sign of failure was noticed, to allow accurate documentation of the failure mode.

The data acquisition system used was a DT 2801-A/D board (Data Translation, Marlboro, Massachusetts). The torque values were collected and stored using Global Lab software (Data Translation) on a personal computer for further analysis after testing. Peak failure torque was measured for each screw, and the mode of failure was recorded. Failure of each screw was monitored visually during the manual application of torque and documented immediately after the test was completed. Photos were taken to demonstrate each distinct mode of failure.

Univariate analysis of variance with a factorial structure of screw diameter and type was performed on the dependant variable of failure torque. This analysis looked at the overall effects of each factor as well as the combined effect of screw diameter and type. A new variable called "typesize" was then defined to represent each specific screw on the basis of its type and diameter. For example, typesize 1 defined the Endo-Fix 7-mm screw, typesize 2 defined the Endo-Fix 9-mm screw, and so forth. Analysis

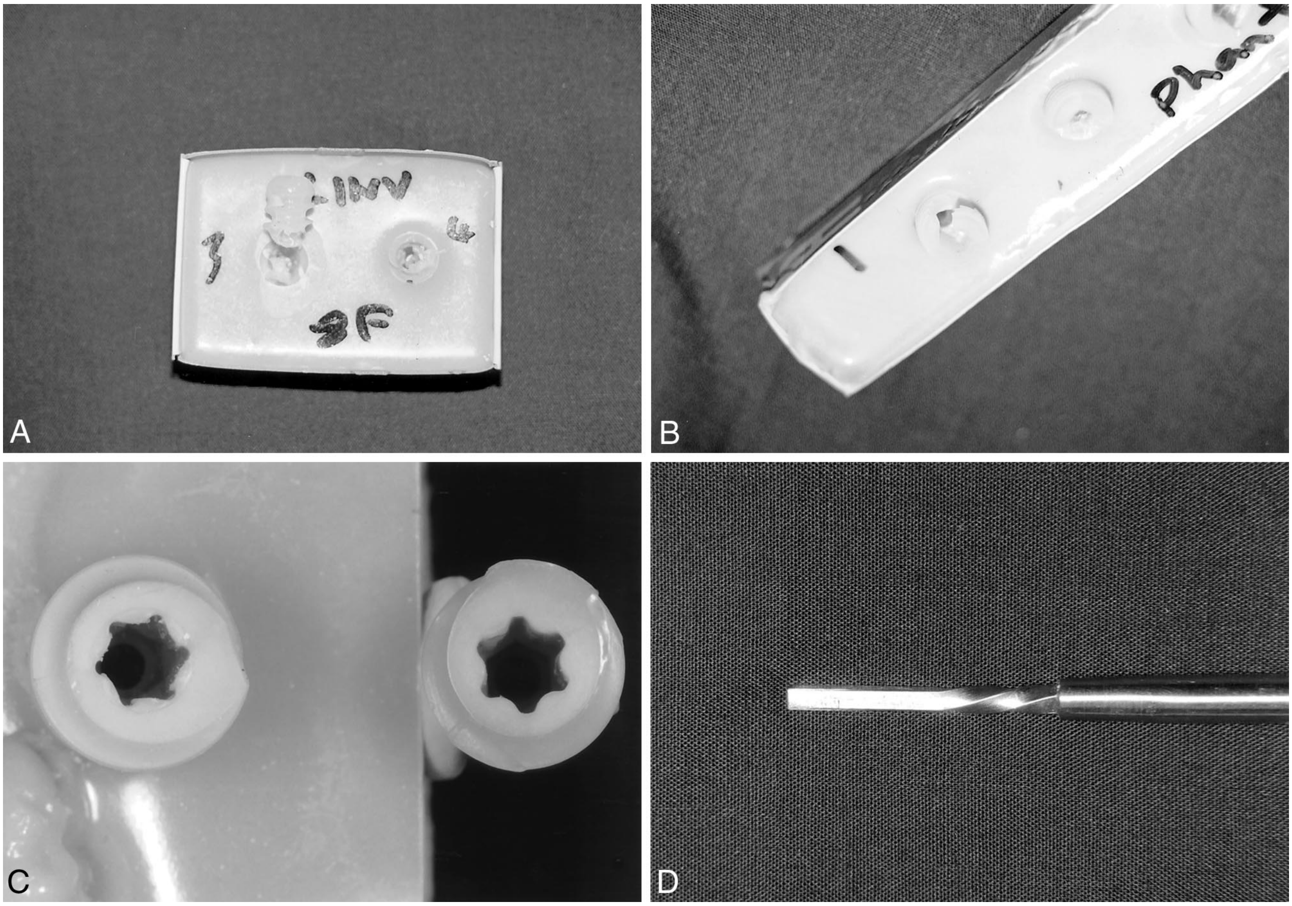

Figure 2. Modes of failure. A, mode 1, screw shear at resin-screw interface. B, mode 2, screw failure by splitting radially out from screwdriver hole. C, mode 3, failure of screw-to-screwdriver hole interface. The screw on the left clearly shows the damaged interface compared with the undamaged screw on the right. D, mode 4, failure of screwdriver shaft in torsion.

of variance based on typesize as the main factor, with failure torque as the dependant variable, was performed to determine whether there was a significant effect between each screw. Significance was based on a *P* value of 0.05 or less.

RESULTS

Four major modes of failure were encountered: mode 1, screw failure by shear at the resin-screw interface; mode 2, screw failure by splitting radially out from the screwdriver hole; mode 3, failure of the screw-to-screwdriver hole interface, that is, stripping of the hole such that the screwdriver no longer could be engaged in the hole; and mode 4, failure of the screwdriver shaft itself. Another failure mode was encountered during testing in which the screw continued screwing into the resin with no subsequent failure. This mode will be referred to as mode 5 for further discussion. Figure 2 shows the four distinct modes of failure.

The modes of failure for each group are summarized in Table 2. Failure modes 1 through 4 represent clinical situations that have been reported during operations. The BioScrew 7-mm screw exhibited mode-5 failure, except for one screw that failed by mode 1. Overall, as this was not a failure, these results were omitted from the statistical analysis. Mode 4 failure was seen in the Phantom 7-mm screw and occurred in three screws used with three separate screwdrivers. Testing of the final two screws for the

TABLE 2
Modes of Failure for Each Group

Group	Number tested	Failure mode (no.)				
		1	2	3	4	5
Endo-Fix 7 mm	6	3		3		
Endo-Fix 9 mm	6			6		
BioScrew 7 mm tibial	5	1				4
BioScrew 7 mm femoral	5					5
BioScrew 8 mm tibial	6	6				
BioScrew 8 mm femoral	6	6				
BioScrew 9 mm tibial	6	6				
BioScrew 9 mm femoral	6	6				
Phantom 7 mm	4		1		3	
Phantom 9 mm	6	6				
Arthrex 7 mm	4	1	2		1^a	1
Arthrex 8 mm	1		1		1^a	
Sysorb 8 mm	4	3	2^b			

[a] Mode 4 failure occurred simultaneously after mode 2.
[b] Mode 2 failure occurred simultaneously after mode 1.

TABLE 3
Mean Failure Torques for Each Group Arranged in Ascending Order

Group	Mean (N·m)	SD (N·m)	95% Confidence interval (N·m)	
			Upper	Lower
Endo-Fix 7 mm	1.07	0.18	0.72	1.41
Phantom 7 mm	1.18	0.17	0.75	1.60
Endo-Fix 9 mm	1.75	0.12	1.41	2.09
BioScrew 7 mm tibial[a]	1.75	0.12	1.40	2.11
BioScrew 8 mm femoral	2.00	0.54	1.66	2.34
BioScrew 9 mm femoral	2.05	0.30	1.71	2.39
BioScrew 7 mm femoral[a]	2.12	0.22	1.77	2.48
Phantom 9 mm	2.30	0.22	1.98	2.62
BioScrew 8 mm tibial	2.40	0.14	2.06	2.74
Arthrex 7 mm	3.00	1.37	2.51	3.49
BioScrew 9 mm tibial	3.02	0.47	2.67	3.36
Sysorb 8 mm	5.23	0.24	4.80	5.65
Arthrex 8 mm ($N = 1$)	5.37			

[a] Mode 5—the torque values shown in these cases was the maximum observed torque because the screw advanced through the resin and did not fail.

Phantom 7-mm group could not be performed because no spare drivers were available. Mode 4 failure occurred simultaneously after mode 2 in the same Arthrex 7-mm screw. Another driver had to be obtained to test the remaining Arthrex screws. Once again, mode 2 failure occurred followed by mode 4 in the first screw tested of the 8-mm size. No further drivers were available to test the remaining 8-, 9-, and 10-mm screws.

The failure torques varied from approximately 1 to 5.4 N·m over the series of screws tested. Table 3 shows the means, standard deviations, and 95% confidence intervals for the failure torques of each group. The torques of the BioScrew 7-mm femoral and tibial screws are shown in Table 3 for comparative purposes only. In these cases, the torque is the maximum observed during screw advancement through the resin. The statistical analysis was therefore performed with the BioScrew 7-mm tibial and femoral screws omitted. The result of the Arthrex 8-mm screw was also omitted because only one screw was tested.

Analysis of variance with a factorial structure of screw diameter and screw type revealed that each variable had a significant effect on failure torque ($P < 0.001$). There was also a significant effect due to the combination of screw diameter and screw type ($P = 0.025$). Because the interaction between screw diameter and screw type was found to be significant, a new variable combining these factors was defined (typesize) to compare each individual screw rather than the overall type and diameter main effects. Analysis of variance, with typesize as the dependent variable, revealed a strong significant effect overall ($P < 0.001$). Multiple comparisons with use of a Bonferroni correction to investigate where the significant differences were seen are summarized in Table 4.

Certain trends were noted from the results shown in Table 4. The Endo-Fix 7-mm screw had the lowest failure torque and failed at significantly lower torques than all of the other screws except for the Phantom 7-mm ($P = 1.000$) and Endo-Fix 9-mm ($P = 0.310$), with which there was no significant difference. The Phantom 7-mm screw also failed at torques significantly lower than those of most other screws except for the Endo-Fix 9-mm screw ($P = 1.000$), the Endo-Fix 7-mm screw ($P = 1.000$), the BioScrew 8-mm femoral ($P = 0.168$), and the BioScrew 9-mm femoral screws ($P = 0.1$). The BioScrew 9-mm tibial screw failed at significantly higher torques than those of most other screws, apart from the Sysorb 8-mm screw and was not significantly higher than the Phantom 9-mm screw ($P = 0.158$), the BioScrew 8-mm tibial and the Arthrex 7-mm screws ($P = 1.000$ in both cases). The Sysorb 8-mm screw had the highest failure torque and was significantly

TABLE 4
Multiple Comparisons using a Bonferroni Correction[a]

	Endo-Fix 9 mm	BioScrew 8 mm tibial	BioScrew 9 mm tibial	BioScrew 8 mm femoral	BioScrew 9 mm femoral	Phantom 7 mm	Phantom 9 mm	Arthrex 7 mm	Sysorb 8 mm
Endo-Fix 7 mm	−0.68	−1.33	−1.95	−0.93	−0.98	−0.11	−1.23	−1.93	−4.16
P value	0.310	<0.001[b]	<0.001[b]	0.016[b]	0.008[b]	1.000	<0.001[b]	<0.001[b]	<0.001[b]
Endo-Fix 9 mm		−0.65	−1.27	−0.25	−0.3	0.58	−0.55	−1.25	−3.48
P value		0.444	<0.001[b]	1.000	1.000	1.000	1.000	0.005[b]	<0.001[b]
BioScrew 8 mm tibial			−0.62	0.4	0.35	1.23	0.1	−0.6	−2.83
P value			0.631	1.000	1.000	0.002[b]	1.000	1.000	<0.001[b]
BioScrew 9 mm tibial				1.02	0.97	1.84	0.72	0.017	−2.21
P value				0.005[b]	0.010[b]	<0.001[b]	0.158	1.000	<0.001[b]
BioScrew 8 mm femoral					−0.05	0.83	−0.3	−1.0	−3.23
P value					1.000	0.168	1.000	0.067	<0.001[b]
BioScrew 9 mm femoral						0.88	−0.25	−0.95	−3.18
P value						0.100	1.000	0.109	<0.001[b]
Phantom 7 mm							−1.13	−1.83	−4.05
P value							0.004[b]	<0.001[b]	<0.001[b]
Phantom 9 mm								−0.7	−2.93
P value								0.866	<0.001[b]
Arthrex 7 mm									−2.23
P value									<0.001[b]

[a] Two values are shown for each group; the difference in means between each group (N·m) and the *P* value. A negative difference in means indicates that the column mean is greater than the row mean (for example, BioScrew 8 mm tibial is greater than Endo-Fix 7 mm).
[b] Statistically significant ($P \leq 0.05$).

higher than those of all other screws ($P < 0.001$ for all comparisons).

DISCUSSION

Intraoperative screw failure is a difficult complication; in failure modes 1 through 3, screw material debris may be shed into the joint and lost. In failure mode 4, it may be impossible to advance or remove a partially inserted screw because of the lack of availability of a second screwdriver. Failure mode 4 occurred only in the Phantom and Arthrex screws. Both the Phantom and Arthrex drivers have straight-sided interfaces of a square and hexagon, respectively, and the Arthrex driver is also tapered. During failure of the Arthrex driver, mode 2 failure occurred first followed immediately by mode 4. Although the driver was fully seated during the test, failure of the driver shaft occurred at a point two-thirds of the distance from the end of the shaft. This was because the tapered end of the driver still engaged in the screw once mode 2 failure had occurred. The splitting of the screw thus caused torsional failure of the shaft, which was still locked in the interface.

If a significant portion of the screw is left protruding, it may impinge on the graft during movement, and if only 10 mm of a 20-mm screw is in contact with the bone block, the pull-out strength may be significantly reduced. Mode 5 is a desirable outcome of screw advancement through the material, rather than a failure. This occurred only in the majority of 7-mm BioScrews. The torque value at failure for the 7-mm BioScrew shown in Table 3 is, in fact, the torque during screw penetration into the resin.

Insertion torque may be reduced in the clinical situation by the use of pretapping. The effect of this maneuver on graft fixation has not been studied, and it is likely to be influenced by bone density. It is recognized that, although extra steps are recommended by the manufacturers, they may be omitted either accidentally or deliberately to save time. Conversely, the screws may be subjected to higher bending forces in vivo if the screwdriver and screw cannot be perfectly aligned because of the limits of arthroscopic portal placement. It is, therefore, possible that the results from our study have overestimated the failure loads that would occur in clinical practice because, in the experimental situation, the screwdriver and screw can always be perfectly aligned without the constraints imposed by the soft tissue envelope of the knee.

Statistical analyses revealed that both screw diameter and screw type each have a strong significant effect on failure torque. Analysis of variance demonstrated that there was also a significant effect due to the combination of screw diameter and screw type, which can also be clearly seen in Tables 3 and 4. This finding supports the contention that both the screw type and the screw diameter play an important role in the assessment of torque strengths but cannot be used on their own as overall predictors of failure strength.

The failure torques encountered in this study are represented in the clinical situation when the screw becomes jammed while being inserted halfway into the bone. Reports of insertion torques from other studies have varied from as low as 0.3 ± 0.19 N·m[13] and 0.59 ± 0.21 N·m[4] for the 7-mm BioScrew in a cadaveric model and 1.40 ± 0.20 N·m for the 8-mm Endo-Fix and 1.77 ± 0.58 N·m for the 8-mm BioScrew in a bovine model[19] to 2.11 ± 0.48 N·m[19] and 2.71 ± 0.35 N·m[6] for the Sysorb 8-mm screw in a bovine model. These figures are from different studies but all were performed with use of bone of similar bone-mineral density (0.7 to 0.8 g/cm^3). The higher insertion torques were all found in bovine models, which have been the most reliable models to date. They demonstrate that insertion torque is close to the failure torques found in our study, with the exception of the Sysorb 8-mm screw.

The reason the 8-mm diameter screws had a greater failure torque overall is primarily because of the superior strength of the Sysorb screw in both its design and material. The material is poly-(D,L-lactide) and appears to be more resilient than the poly-(L-lactide) used in most other screws. The turbine-like drive design is effective in reducing stress concentrations at the drive interface and transferring the load to the screw body.

There are two main limitations of the study: the use of a resin model to simulate screw jamming and the manual application of torque. The use of resin does not have a direct application to the clinical situation because the purpose of this study was to test the torsional strengths of screws when they become jammed. If a cadaveric or animal model had been used, there would be no guarantee that the screw would jam. There would also be variations between bone quality and mechanical properties, which would contribute to undesirable experimental error. The use of resin was an efficient way to achieve the objectives of the study and reduce variation between results and has been shown not to damage the screw on curing.[19]

There are pros and cons regarding the manual application of torque to the screws. Factors such as how much the screw is compressed as well as how fast it is turned will affect the results. We attempted to control these factors by using only one person to apply the torque throughout the whole study. A constant manual rate of application was used as well as a constant compression with minimal bending through the driver shaft. Manual application was chosen over mechanical means to allow for physiologic feedback and to simulate the clinical situation, because most surgeons insert the screws by hand. This method also allowed for finer control of the test. When failure was first noticed, the test could be immediately stopped without further damaging the screw and making it more difficult to determine the correct mode of failure. Furthermore, although the rate of applied torque may affect the results, we believe that the rate we applied was comparable with that used in other studies. They were all quasi-static and therefore effects due to rate would be minimal. Bending through the screwdriver would be of more concern because of the shift in stress concentrations through the screw.

The failure torques seen in our study are lower than those of the only other comparative study that we are aware of in the literature.[19] This is to be expected and reflects the fact that we embedded only half of the screw in an attempt to simulate the jamming situation encountered clinically. It is therefore important that the surgeon be aware of these lower failure torque levels and ensure that care is taken to minimize the risk of breakage. The recommended procedures for preparation of the screw hole should be followed before screw insertion. It is also very important that both screw type and diameter be taken into account when the jamming torsional failure strengths of these screws are considered, as determined under the limitations of this study.

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