Can High-friction Intraannular Material Increase Screw Pullout Strength in Osteoporotic Bone?

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Abstract

Background Osteoporotic bone brings unique challenges to orthopaedic surgery, including a higher likelihood of problematic screw stripping in cancellous bone. Currently, there are limited options to satisfactorily repair stripped screws. Additionally, nonstripped screws hold with less purchase in osteoporotic bone.

Questions/purposes This study attempts to answer the following questions: (1) Does high-friction intraannular (HFIA) augmentation increase pullout strength in osteoporotic and in severely osteoporotic bone; and (2) can

HFIA repair stripped bone thread in osteoporotic and severely osteoporotic bone?

Methods We measured screw pullout strength using a synthetic bone model in three groups: (1) predrilled nonstripped control holes as controls; (2) predrilled nonstripped augmented with HFIA; and (3) predrilled stripped holes repaired with HFIA. We tested this in osteoporotic and severely osteoporotic synthetic bone for a total of six test groups. We measured screw pullout force using an electromechanical tensile-testing machine comparing pullout force between the test groups and controls.

Results HFIA augmentation did not increase pullout force compared with the control group in the osteoporotic bone model (489 ± 175 versus 607 ± 76 , respectively; effect size = 0.94 [95% confidence interval {CI}, -1.75 to 0.08], $p = 0.06$). However, in severely osteoporotic cancellous bone that was augmented, the HFIA material generated more pullout force than the control (51 ± 18 versus 35 ± 16 , respectively; effect size = 0.94 [95% CI, -0.02 to 1.82], $p = 0.05$). In stripped holes, HFIA partially restored pullout strength but remained weaker than controls in both osteoporotic and severely osteoporotic bone models (osteoporotic: 320 ± 59 versus 607 ± 76 , respectively; effect size = -4.28 [95% CI, -5.57 to -2.51], $p < 0.001$; severely osteoporotic: 21 ± 8 versus 35 ± 16 , respectively; effect size = -1.13 [95% CI, -2.0 to 0.12], $p = 0.027$).

Conclusions HFIA effectively augmented severely osteoporotic bone for screw purchase, but this effect was not seen for osteoporotic bone. In a model simulating both osteoporotic and severely osteoporotic bone, we found that HFIA can be used to repair stripped screw holes, but the resulting construct remains weaker than nonstripped controls.

Clinical Relevance The HFIA material looks promising as a potential solution to stripped screws in osteoporotic

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bone. However, this material has yet to be tested in human bone. Furthermore, the fine mesh material could be damaged by autoclaving and could break off in vivo causing unknown tissue reactions. We recommend additional testing in a living animal model to better understand how living bone will react to the HFIA material.

Introduction

Osteoporosis is becoming increasingly prevalent as the population in the United States ages. Osteoporotic bone brings unique challenges to orthopaedic surgery. Specifically, screws in osteoporotic cancellous bone in one study had approximately 54% less pullout strength than nonosteoporotic bone [13] and up to 9% of screws in osteoporotic bone were found to have inadvertently stripped in another report [3]. Once a screw is overtightened and the bone thread of the screw hole is stripped, the options to remedy the situation are limited and often unsatisfactory [1, 4]. Rescue screws only moderately increase pullout strength [2, 14]. Wire augmentation has also been described to increase pullout force, but with uncertain clinical significance [9]. Using a new screw location or using supplemental fixation is often not an option. As a last option, modifying postoperative physical rehabilitation can reduce loading forces across unstable fixation.

Stripped screws are common, and perhaps even more common than we realize [10]. Given this problem, we sought a material that would reestablish the material void created and friction force lost by screw stripping. We propose a novel high-friction intraannular (HFIA) material to increase screw pullout force in osteoporotic bone. The HFIA material was chosen to increase pullout force by (1) increasing the coefficient of friction at the screw-hole interface (“high-friction”); and (2) filling the gap in the screw-hole annulus (“intraannular”), thus creating an interference fit between the screw and bone.

The purpose of this study was to determine if HFIA material can improve screw pullout force in two bone types. Specifically, we asked: (1) Does HFIA augmentation increase pullout strength in osteoporotic and in severely osteoporotic bone; and (2) can HFIA repair stripped bone thread in osteoporotic and severely osteoporotic bone?

Materials and Methods

The HFIA material used in this study is a commercially available product, Mr. Grip[®] (Wodmate Corporation, Grimes, IA, USA; Fig. 1), which is designed to repair stripped threads in various home construction materials

Fig. 1 This image is a photograph of the HFIA material.

like wood, plastic, and cement. The material is a thin steel mesh measuring $6.5 \times 100 \times 1.5$ mm and is abrasive and toothy in texture. The material is best envisioned as being similar to home window screen but more rigid and with the texture of coarse sandpaper. This material is not an FDA-approved product. However, the alternatives at this point are so poor that we believed it is worthy of inquiry.

Testing was conducted in two types of synthetic bone models: osteoporotic cancellous bone (0.16 g/cm^3 ; Pacific Research Labs, Vashon, WA, USA) and severely osteoporotic cancellous bone (0.09 g/cm^3). We tested 6.5×80 -mm fully threaded, noncannulated cancellous screws (Synthes[®], Solothurn, Switzerland) in each group. The 0.16-g/cm^3 and 0.9-g/cm^3 synthetic bone densities are regarded as the most representative of osteoporotic and severely osteoporotic human cancellous bone, respectively [5–8, 11, 12].

Study Design

To test the HFIA material, we measured screw pullout strength in 0.09-g/cm^3 and 0.16-g/cm^3 models using the following three groups: (1) nonstripped holes (ie, control group); (2) nonstripped with HFIA (augmented screws); and (3) stripped screw hole bone threads with HFIA (repaired). For the two bone density models (osteoporotic and severely osteoporotic) tested in three groups, 10 screw pullouts were performed for a total of 60 unique screw extractions.

Description of Experimental Manipulations: Preparation and Screw Insertion

To insert the nonstripped screws (control), bone blocks were initially predrilled with a 3.2-mm diameter drill bit. An 80-mm length screw of 6.5 mm outer diameter was inserted 60 mm into the bone model. The 80-mm screws initially passed through a flat plate, a washer, and a custom-made steel jig that measured 20 mm thick with a hole measuring 7 mm in diameter (Fig. 2). This steel jig construct was used to apply extraction force to the screw head

Fig. 2 This image shows the Instron tensile testing machine and steel jig loaded with synthetic bone and a screw in place, ready for testing.

Fig. 3 This is a schematic of the test device in cross-section view.

(Fig. 3). A single orthopaedic surgeon (DB) inserted all screws and tightened them to achieve maximal construct stability.

To insert the nonstripped screws augmented with HFIA (augmented), the same testing protocol as the control group was used with the exception of inserting two 3.25×60 -mm

Fig. 4 This is a cross-sectional schematic (perpendicular to the axis of the screw) showing the HFIA material in the gap between the screw and bone. For the larger repair application, three pieces were used instead of the two HFIA pieces depicted.

HFIA strips into the predrilled hole before screw insertion. The HFIA material completely lined the inner surface of the hole. Two HFIA strips were used, because this was the maximum that would fit in an unstripped 3.2-mm hole (Fig. 4). The same surgeon then tightened the screw with the screw making contact exclusively with HFIA material.

To prepare bone blocks for the stripped screws repaired with HFIA (repaired), the control blocks were retained and reused after screw extraction (which caused stripping). Four 3.25×60 -mm HFIA strips were placed into the stripped hole, parallel to the long axis and 90° apart, such that they completely lined the inner surface of the hole. A screw was then inserted into the stripped hole by the same surgeon, making contact exclusively with the HFIA material.

After screw insertion, the steel jig was attached to an electromechanical tensile-testing machine (Instron®, Norwood, MA, USA). Control, augmented, and repaired screws were pulled out at 5 mm/minute. LabView software (National Instruments Corporation, Austin, TX, USA), at a sampling frequency of 120 Hz, recorded reaction force and displacement.

Statistical Analysis

A one-way analysis of variance (ANOVA) of the data was performed. Significance was determined with a two-sided Dunnett's procedure post hoc analysis against control using XLStat software (Addinsoft, New York, NY, USA). The level of significance was set at $p \leq 0.05$. One of our four

test scenarios found no significant difference ($p > 0.05$). The magnitude of the effect estimated when calculating sample size during study power analysis was a 40% reduction in force.

Results

HFIA improved pullout mechanics in stripped holes for both OP and severely OP bone models and in nonstripped severely OP cancellous bone. ANOVA analysis of the osteoporotic bone group yielded $p = 0.001$, and ANOVA of the severely osteoporotic bone group yielded $p < 0.001$. HFIA material used to augment screws did not increase pullout force compared with the control group in the osteoporotic bone model (489 ± 175 versus 607 ± 76 , respectively; effect size = 0.94 [95% confidence interval {CI}, -1.75 to 0.08], $p = 0.15$) (Fig. 5; Table 1). However, in severely osteoporotic cancellous bone that was augmented, the HFIA material generated more pullout force than the control (51 ± 18 versus 35 ± 16 , respectively; effect size = 0.94 [95% CI, -0.02 to 1.82], $p = 0.049$) (Fig. 6).

In a stripped hole in osteoporotic cancellous bone that otherwise had a pullout force of essentially zero, the HFIA material partially restored pullout force to 53% (320 ± 59 versus 607 ± 76 , respectively; effect size = -4.28 [95% CI, -5.57 to -2.51], $p < 0.001$) of the control group (Fig. 5). Similarly, the HFIA material inserted into a stripped hole in severely osteoporotic cancellous bone partially restored pullout force to 61% (21 ± 8 versus 35 ± 16 , respectively; effect size = -1.13 [95% CI, -2.0 to 0.12], $p = 0.031$) of the control group (Fig. 6).

Discussion

Osteoporotic bone brings unique challenges with regard to screw stripping events in orthopaedic surgery. There are options to repair stripped screws [2, 9, 14], but each of them has important shortcomings. Because of this, we investigated a HFIA material used to increase pullout strength of stripped screws, assessing augmentation and repair applicability of HFIA in osteoporotic and severely osteoporotic bone models. We found the HFIA material partially restored pullout force to 53% ($p < 0.001$) and

Fig. 5 This graph shows pullout force in osteoporotic cancellous bone for all three test groups (with 95% CI bars).

Fig. 6 This graph shows pullout force in severely osteoporotic cancellous bone for all three test groups (with 95% CI bars).

Table 1. Summary of raw force data

Bone type	Force (N)	Mean	SD	p value versus control of the same bone type
OP cancellous bone	Nonstripped (control)	607	76	—
	Nonstripped + HFIA (augmented)	489	175	0.15
	Stripped hole + HFIA (repaired)	320	59	< 0.001
Severely OP cancellous bone	Nonstripped (control)	35	16	—
	Nonstripped + HFIA (augmented)	51	18	0.049
	Stripped hole + HFIA (repaired)	21	8	0.031

OP = osteoporotic; HFIA = high-friction intraannular.

61% ($p = 0.03$) of the control group pullout force in osteoporotic and severely osteoporotic bone, respectively. Additionally, the HFIA material produced a substantial increase in pullout force of 47% ($p = 0.05$) greater than the control in nonstripped (augmented) severely osteoporotic bone. However, HFIA did not improve pullout strength in augmented osteoporotic bone ($p = 0.06$).

Limitations of this study include only one type of screw (6.5×80 -mm fully threaded, noncannulated cancellous screws) used. Another potential limitation of the study was that only synthetic bone was used, although this was chosen to eliminate other variables such as inter- and intracavernous bone densities. Another limitation was inserting screws by hand instead of using a torque-limiting device. Using a torque-limiter would have reduced intertest variability. However, it is important to note that not every stripped screw can be tightened with the exact same amount of torque. We also do not know how living bone will react to HFIA material; animal models are called for to evaluate this important question. Additionally, we do not know how HFIA will respond to autoclaving, although it will likely not affect it. Lastly, one of the four test scenarios yielded a nonsignificant result with $p = 0.066$. It is possible that increasing sample size and study power could provide significant results and also further reduce confidence intervals.

HFIA effectively augmented severely osteoporotic bone for screw purchase, but this effect was not seen for osteoporotic bone. In the literature, screws in osteoporotic cancellous bone had approximately 54% less pullout strength than nonosteoporotic bone [13]. Thus, HFIA may offer the possibility of increasing screw purchase in severely osteoporotic bone.

In both osteoporotic and severely osteoporotic bone, HFIA may be used to repair stripped screw holes, but the resulting construct remains weaker than nonstripped controls. In other studies, rescue screws only moderately increase pullout strength [2, 14]. Wire augmentation has also been described to increase pullout force [9].

In conclusion, the HFIA material used in a rescue application partially restored stripped screw pullout strength in osteoporotic and severely osteoporotic synthetic bone. In a screw augmentation application, the HFIA material only increased pullout force in severely osteoporotic synthetic bone, but not in osteoporotic bone. There are

a number of key unanswered questions generated by this study. Specifically, it is not clear how living human bone will respond to HFIA. HFIA needs to be tested in an animal model. Additionally, it is unclear if HFIA will withstand autoclaving. HFIA seems like a promising potential solution to stripped screws in osteoporotic bone, but we recommend additional testing to address these unanswered questions.

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