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The Open Mechanical Engineering Journal, 2013, *7*, 35-39

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The Effect of "Toggling" on the Pullout Strength of Bone Screws in Normal and Osteoporotic Bone Models

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Abstract: This study tests the hypothesis that screw toggling will reduce the pullout strength of bone screws. Pullout strength of cortical (cylindrical) and cancellous (tapered by 4°) bone screws were measured without and after toggling (movement caused by a force perpendicular to the screw axis) by ± 1 mm in polyurethane foam intended to mimic normal (density 0.32 g.cm^{-3}) and osteoporotic (density 0.16 g.cm^{-3}) bone. Toggling had no significant effect in decreasing the strength of fixation of cortical or cancellous screws inserted in the normal and osteoporotic bone models. Analysis of the screws that had been toggled showed that there was no significant difference ($p > 0.05$) between the pullout strength of cancellous and cortical screws (when pulled out from the same material). The results provide insights into some mechanical aspects of the pullout strength of bone screws and will aid understanding of the mechanism of screw toggling *in vivo*.

Keywords: Bone, osteoporosis, pullout, screws, strength, toggling.

INTRODUCTION

Osteoporosis weakens bone; as a result, it is sometimes considered as a contra-indication for screw fixation, especially in the spine [1-5]. Nevertheless, screw fixation to osteoporotic (OP) bone has been performed in the spine for cases of instability (after fracture), deformity, tumours, multi-segmental spinal stenosis (narrowing of the vertebral canal, which causes spinal cord and nerve compression) and neurological deficits that require decompression and stabilisation [6-10]. As a result, a previous study (by the authors) described the effect of screw insertion angle and thread type on the pullout strength of bone screws in normal and OP bone models [11]. Pullout strength is an established method for measuring screw fixation [12]. Pedicle screws that are used for fixation of implants to the vertebrae of the spine are also subjected to bending and rotational moments [13-15]. Two studies have indicated that pullout is still the main mechanism of failure [16, 17]. However, it has also been claimed that pedicle screws are subjected to a bending moment, that would cause toggling, as well as to an axial force [18, 19]. As a result, there have been several studies of pullout of pedicle screws under a wide range of conditions, from many different materials [20-24]. But few studies have considered the effect of screw toggling on pullout strength in OP vertebrae and the effect of toggling on pullout strength is not clear [25, 26].

This paper describes an investigation of the effect of "toggling" (movement induced by force acting at the head of a screw and perpendicular to its axis) on the fixation of screws in normal and OP bone models. The hypothesis to be tested is that screw toggling will reduce the pullout strength of screws.

MATERIALS AND METHODS

PU Foam Models

This study uses polyurethane (PU) foams of differing densities as models for normal and OP cancellous bone [27]. A model material was used because of the wide individual variability in the properties of human (especially OP) bone [28], making it difficult to distinguish effects caused by the fixation method from those resulting from specimen variability. This was the reason for using PU foam as a bone model in a previous study that investigated pullout without toggling [11]. Animal models have a similar range of normal bone mineral densities as human bone [29] and, hence, a similar range of strengths and hardnesses [30]. Therefore, synthetic models are more likely to show any effect of toggling on pullout strength. Normal and OP bone models consisted of closed-cell PU foams of density 0.32 g.cm^{-3} and 0.16 g.cm^{-3}, respectively. The justification for these models has been described previously [27] and they have been used as models in previous tests of screw pullout [11]. Foams were supplied by Sawbones Europe AB (Malmö, Sweden) and were sawn into blocks (45 mm × 60 mm × 40 mm) for testing.

Screws

Two types of screw (designed for fixation in cortical or cancellous bone) were obtained from Surgicraft Ltd. (Redditch, Worcestershire, UK); the spinal products supplied by this company are now available from Centinel Spine (New York City, NY, USA). Both types of screw were manufactured from a medical grade titanium alloy, Ti-6Al-4V, and the dimensions were measured in our previous study [11]. For completeness, the dimensions of each type,

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designed for insertion into cortical and cancellous bone, are given in Table **1**. The cortical screw was cylindrical and the cancellous screw was tapered by 4° [11]. The cortical screw was included in this study to investigate how thread design can influence screw fixation after toggling in a cancellous bone model [11].

Table 1. Screw Dimensions; Defined in Patel *et al.* [11]

	Cortical Screw	Cancellous Screw
Taper	None	4°
Length	30 mm	30 mm
Major diameter	4.7 mm	6.7 mm
Minor diameter	3.2 mm	4.1 mm
Thread pitch	1.8 mm	2.6 mm

Simulating Toggling

Pilot holes were drilled into the PU foam blocks before insertion of cortical (hole diameter 3.0 mm) or cancellous (hole diameter 3.5 mm) screws using the same methods as described previously [11]. A PU foam block was secured in the equipment shown in Fig. (**1**). The toggling fixture (an open steel box) has a hole in its base to enable a screw to be inserted into the block. This fixture was attached to the actuator of an ELF3300 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, USA). The ELF3300 testing machine is fitted with a load cell of full scale 5100 N (maximum error 0.1% of the full scale) and a displacement transducer with full scale 12.7 mm (maximum error 0.28% of the full scale). The toggling fixture was lowered, by means of the actuator, until its hole was aligned with the pilot hole in the box. A screw was inserted into the block, by a single investigator, until the head of the screw met the internal surface of the toggling fixture, i.e. the screw axis was perpendicular to the axis of travel of the actuator; this procedure ensured that all screws were inserted under the same condition. The toggling fixture was then moved 1 mm upwards and 2 mm downwards to simulate ± 1 mm of toggling, (at a rate of 0.1 $mm.s^{-1}$) [11, 31]. According to a published study, the forces generated in normal walking are likely to generate screw head displacements of about 1 mm [32]. In previous screw toggling experiments, the displacement of the screw head has been controlled because the test could otherwise become unstable as the screw loosens [26]. In practice toggling is likely to arise from cyclical loading. In this paper, cyclic loading was not used to simulate toggling because PU foam may not be a suitable bone model when energy dissipation is of concern [27]. A simple method, described above, was used to create a void in the PU foam. This method was chosen because only the end result from toggling was desired to perform axial screw pullout thereafter. The effect is to produce a void which approximates to an isosceles triangle whose height is equal to the screw length and whose base is equal to twice the maximum displacement, since displacement can occur both caudally and cranially in the spine. This method of void creation provides a consistent 'bony' deficit to facilitate the comparison in subsequent pullout force of different bone screws. Apart from this simulated toggling, the methods used in this study were identical to those used in our previous study of cortical and cancellous screw pullout [11].

Measuring Pullout Strength

The apparatus was then remounted so that the screw was aligned with the direction of the actuator on the materials testing machine, as shown in Fig. (**2**). The steel assembly used to secure the block was rigidly attached to the base of the testing machine. The actuator was fixed to the toggling fixture. Raising the toggling fixture then pulled out the screw.

Twelve toggling and axial pullout tests were performed for each screw type (cortical and cancellous) and each foam density (0.16 $g.cm^{-3}$ and 0.32 $g.cm^{-3}$), i.e. a total of 48 tests involving toggling. Results from a further 24 tests in which the screw was not toggled, from our previously published study [11], were used as controls; in these controls six pullout tests were performed for each screw type and foam density. Pullout tests were performed in displacement control at a rate of 0.1 $mm.s^{-1}$ [11, 31]. The screw pullout force was defined as the maximum force in a plot of force versus actuator displacement.

The same cortical and cancellous screws were used for all tests. This has been justified previously [11] by the stiffness of the titanium alloy of the screw being much higher (100-120 GPa) than that of the PU foams (maximum 145 MPa)[27] and its ultimate tensile strength (1 GPa) also being much higher than the yield strength of the foam (maximum 3.6 MPa). The screws showed no sign of permanent deformation or fracture as a result of the tests.

Statistical Analysis

Pierce's criterion was used to test for and exclude statistical outliers [33]. Statistical analysis was performed using SigmaPlot, version 11 (Systat Software Inc, Hounslow, London, UK). A Kruskal-Wallis one way analysis of variance (ANOVA) was undertaken using Dunn's method for multiple comparisons to investigate significant differences between the groups [34]. Results were considered significant if $p < 0.05$.

RESULTS

Table **2** shows the pullout strength of screws without [11] and after toggling. The results show that there was no significant difference ($p > 0.05$) between the pullout strength of screws without and after toggling for cancellous and cortical screws from either normal (higher density PU foam) or OP (lower density PU foam) bone models. Although not statistically significant, the pullout strength of the cortical screw from the 0.16 $g.cm^{-3}$ density foam was greater with toggling than without. Analysis of the screws that had been toggled showed that there was no significant difference ($p > 0.05$) between the pullout strength of cancellous and cortical screws (when pulled out from the same material). Pullout strength from the normal (higher density PU foam) bone model was significantly ($p < 0.05$) greater than for the OP (lower density PU foam) bone model, for both cortical and cancellous screws.

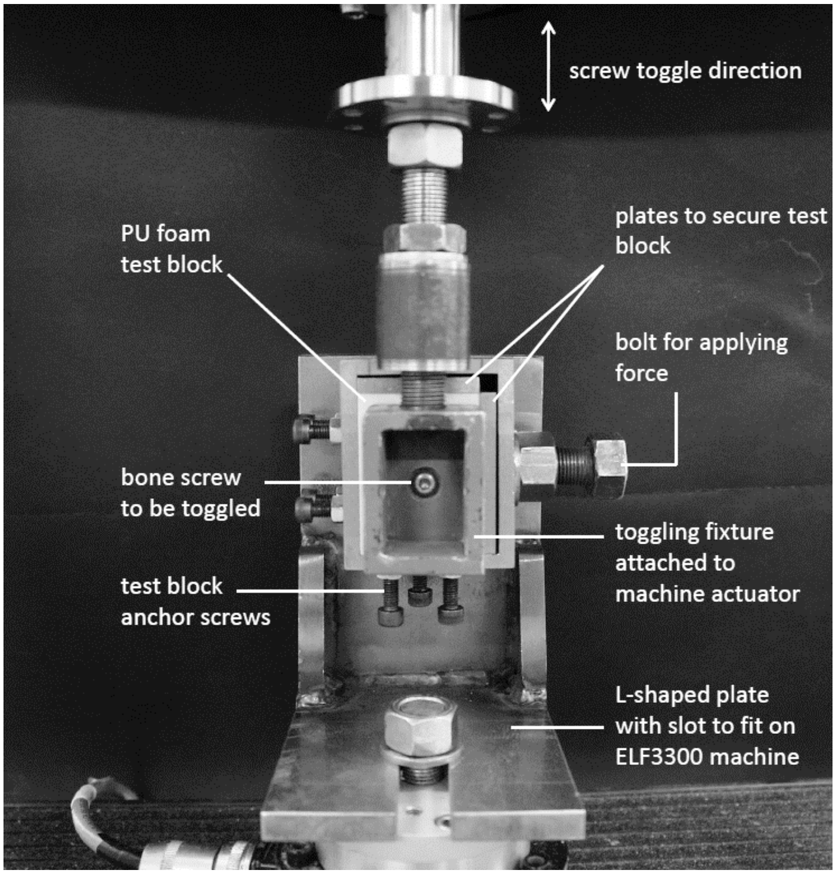

Fig. (1). Configuration of equipment for simulating screw toggling.

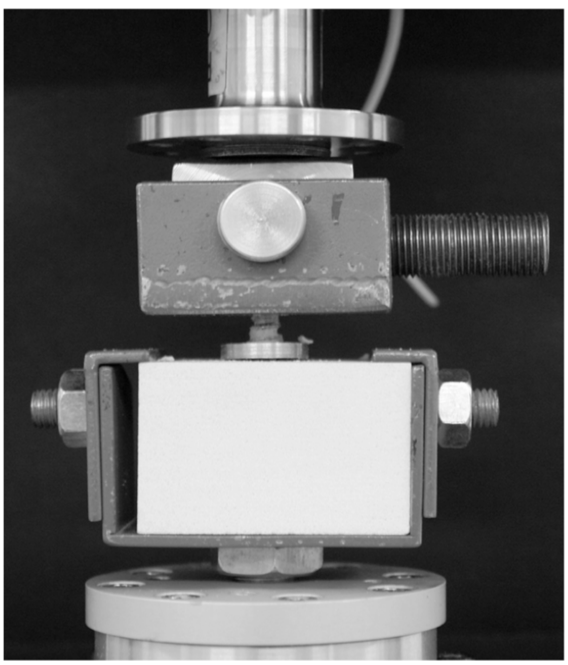

Fig. (2). Configuration of equipment for measuring screw pullout strength.

DISCUSSION

The results presented here show that screw toggling does not affect screw pullout. Burval *et al*. [26] investigated screw pullout from normal and OP cadaveric lumbar vertebrae. They found no significant difference in the pullout strength of screws from OP bone without and after screw toggling (591 N *vs* 398 N). However, for normal bone, screw toggling was found to significantly decrease pullout strength compared to no toggling (811 N *vs* 1002 N). The pullout strength results for OP and normal bone are comparable with the values seen in this study for the bone models. Similar values for screw pullout in the OP bone model were found by Hirano *et al*. [25] who used screw toggling to investigate the pullout strength of screws in cadaveric specimens. The mean maximum pullout force was 501 N and 287 N, respectively, for screws placed in the pedicle/vertebral body and pedicle.

In a published study using calf spines, cyclic toggling (in the cranial-caudal direction) increased the pullout strength of both cylindrical and tapered screws [20]. This result was explained by compression of the bone by the screw as it toggled [20]. This was also found in the current study with the cortical screw in the 0.16 $g.cm^{-3}$ density foam having a greater with toggling than without, although the difference was not statically significant. However, most of the results published by Lill *et al*. [20] do not support the results published here. It has been suggested that a tapered screw displaces material to the side of the pilot hole when it is inserted, leading to compression of surrounding material and additional locking compared with cylindrical screws [35]. It is possible that this compressed material could have supported the tapered cancellous screw so that toggling had less effect than for the cylindrical cortical screw.

Table 2. **Mean (± Standard Deviation) Pullout Strength of Screws without and After Toggling in PU Foam Models for Normal (Higher Density) and OP (Lower Density) Bone. An ANOVA Power Calculation was Undertaken Using SigmaPlot, Version 11 (Systat Software Inc, Hounslow, London, UK) with the Power Calculated to be >99%, Indicating that 12 Tests for Each Set of Results (a Total of 48 Tests) were Sufficient to Investigate Any Differences**

PU Foam Density (g.cm^{-3})	Screw Type	Pullout Strength without Toggling (kN) from Patel *et al.* [11]	Pullout Strength After Toggling (kN)
0.16	Cortical	0.12 ± 0.03	0.25 ± 0.03
0.32	Cortical	1.11 ± 0.05	1.02 ± 0.10
0.16	Cancellous	0.37 ± 0.03	0.34 ± 0.02
0.32	Cancellous	1.15 ± 0.06	1.15 ± 0.24

The reliability of PU foam as a material for modelling the effect of toggling on screw fixation in bone could be questioned. The results reported here do not correspond well with those obtained by Lill *et al.* [20] in their study of screw fixation in calf spines in which the screws were first toggled cyclically. This could be because the PU foams do not replicate the viscoelastic properties of bone [36, 37]. However, comparable results were obtained for PU foam and bovine bone in a study of the screw-bone interface during axial cyclic loading (2.7 kN for foam and 2.5 kN for bone, at a load rate of 0.1 mm/min) [21].

No study of toggling that uses synthetic material or cadaveric bone can take into account biological responses to toggling. This study may only be representative of early effects of toggling where no healing or biological response has occurred. The healing response to screw fixation will affect the nature and strength of the surrounding bone [26, 38]. In practice, toggling is likely to occur over the lifetime of an implant. The screw will then exert a time-dependent force on the bone; as a result the bone is expected to remodel, following Wolff's law, to provide further support for the screw [39]. However, it may not be possible for bone to remodel to resist excessive toggling. The situation could be considered to be analogous to the effect of motion on fracture repair; for example, in sheep metatarsus a small gap (1-2 mm) stimulates callus formation but a larger gap (6 mm) does not [40].

Finally, the effect of toggling of pedicle screws that are used to attach implants to the vertebrae of the spine depends also on the anatomy of the pedicle and the way it influences screw insertion. It has been suggested that toggling is implicated in the failure of pedicle screw fixation [22] and that the screw pivots about a centre of rotation within the pedicle [14] Law *et al.* [41] demonstrated a rotational pattern of pedicle screw motion leading to a "butterfly-shaped" defect in the bone. Tan *et al.* [42] described a complicated pattern of pedicle screw motion involving translation and rotation.

CONCLUSIONS

Toggling has no significant effect in decreasing the strength of fixation of cortical or cancellous screws inserted in PU foams used to mimic normal and OP bone. However, although not statistically significant, the pullout strength of the cortical screw from the 0.16 g.cm^{-3} density foam was greater with toggling than without. The results provide further insights into some mechanical aspects of the pullout strength of bone screws and will help to provide a better understanding of the mechanism of screw toggling *in vivo*.

ACKNOWLEDGEMENTS

We thank Mr. C. Hingley, Mr. L. Gauntlett and Mr. P. Thornton for making equipment and the Arthritis Research Campaign (now Arthritis Research UK) for funding the test machine. Surgicraft Ltd. supplied the bone screws and provided financial support. The School of Mechanical Engineering, University of Birmingham, provided a studentship for PSDP.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Received: July 19, 2013 Revised: September 18, 2013 Accepted: September 19, 2013