

# The contribution of the cortical shell to pedicle screw fixation

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**Background:** A pedicle screw insertion technique known as “hubbing” involves the removal of cortical bone around the screw insertion with the aim of improving fixation and decreasing screw loosening. However, the efficacy of this procedure relative to bone density and early loading have not been fully explored. The purpose of this study is to establish the contribution of the cortical layer (hubbing), cancellous density, early loading (toggling) in an idealised model. This is an in vitro laboratory study.

**Methods:** Synthetic bone blocks with cancellous bulk and a simulated cortical shell were implanted with 6.5 mm pedicle screws. Three key variables were evaluated in this study; density of the simulated bone (10–20 lb/ft<sup>3</sup>), toggling ( $\pm 0.5$  mm for 10,000 cycles), and the presence or absence of the surrounding cortex (hubbing). Pullout testing after toggling was performed to determine maximum load, stiffness and energy. Results were analyzed to assess interaction and main effects.

**Results:** Removal of the cortex decreased the pullout loads by approximately 1,100 N after toggling. Toggling in the presence of the cortical shell had no effect. However, once the cortical shell is removed damage to the weaker cancellous bone accumulates and further compromises the fixation.

**Conclusions:** The addition of a cortical layer in the Sawbone model is significant and provides a more realistic model of load sharing. The cortex plays a considerable role in the protection of underlying cancellous bone as well as contributing to initial pullout strength. The results of this study demonstrate a negative synergistic effect when both toggling and hubbing are applied to the weaker bone.

**Keywords:** Toggle; pedicle screw; hubbing; cortical; cancellous; pullout; load sharing

Submitted Aug 04, 2016. Accepted for publication May 16, 2017.

doi: 10.21037/jss.2017.06.07

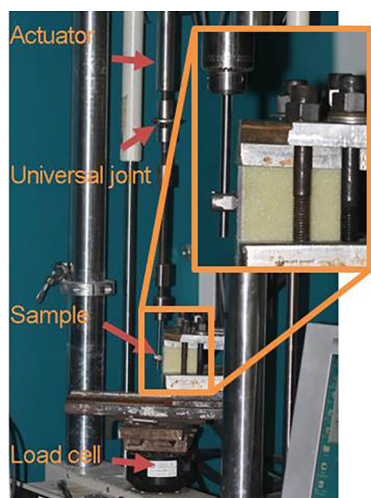
View this article at: <http://dx.doi.org/10.21037/jss.2017.06.07>

## Introduction

Pedicle screw and rod systems are commonplace in spinal fusion surgery. Pedicle screws require initial rigid fixation and longevity to stabilise the spine while the fusion mass forms. This procedure is broadly successful with low rates of screw loosening for standard screws (1-3) and increased rates for dynamic systems (4-7). Screw loosening is a concern, with radiolucency around screws detrimental to fixation (8) and often warranting revision surgery (9).

Pedicle screws implanted using traditional techniques produce a characteristic butterfly shaped defect following Caudo-cephalad loading (10). Achieving bicortical screw fixation provides anchoring of the screw in the far

cortex to improve stability (11), but not without risks to structures near the exiting screw (12-14). A technique known as “hubbing”, whereby the cortical shell is removed immediately adjacent to the pedicle screw insertion hole, allows deeper insertion of the screw. This is intended to reduce the lever arm thereby reducing load and ultimately motion at the tip of the screw to achieve fixation similar to bicortical placement (15). Paik *et al.* (15) investigated early loading (toggling) on specimens with and without hubbing and found that hubbed and toggled specimens had lower pullout strength as compared to those that were only toggled, osteoporotic specimens also showed lower pullout than their normal BMD counterparts. A directly comparative assessment of pullout without toggling is still



**Figure 1** Toggle testing setup, inset image shows close up of the sample.

lacking.

It is well known that BMD is an important factor affecting pullout loads (16-18). However, it is unknown if an alteration in BMD can predispose bone to toggling damage following hubbing. Screw loosening has been shown to be more common in osteoporotic patients (19). The majority of screw stability is attained through fixation with cortical bone which suggests that hubbing may pose a greater risk to these patients (20). This study used a reproducible biomechanical model for evaluating toggling to investigate individual and interaction effects of toggling, hubbing, and bone quality.

## Methods

Synthetic bone blocks (60 mm × 40 mm × 62 mm) with cancellous bulk and a simulated cortical shell of 2 mm thick short fiber filled epoxy layer (Sawbones, Vashaw, WA) were used in this study. The cortical shell was predrilled with a three fluted 3.2 mm drill bit (Surgibit, Orthopedic Innovations, Collaroy, NSW, Australia) followed by a 5 mm tap and the placement of the screws. G5 multiaxial pedicle screws (diameter × long: 6.5 mm × 45 mm) (KH Medical Pty Ltd, Sydney, Australia) were implanted into the bone block followed by the G5 Rod 6.5 mm and G5 Cap using the manufacturer's instrumentation and according to instructions for use.

Three key variables evaluated in this study were density of the simulated bone, toggling before pullout testing, and

the presence or absence of the surrounding cortex (hubbing). This resulted in eight groups with  $n=8$  samples per group based on pre-hoc power calculations. The cancellous core was normal density, 10# cellular foam (10 lb/ft<sup>3</sup>) or low density, 20# cellular foam (20 lb/ft<sup>3</sup>). Dynamic toggle testing was performed in reverse cycle tension-compression at 5 Hz in air at room temperature at  $\pm 0.5$  mm for 10,000 cycles on a calibrated servo hydraulic mechanical testing machine (MTS Systems Corporation, Eden Prairie, MN). Samples were rigidly mounted to the load cell and the actuator incorporated a universal joint and chuck to accommodate alignment (Figure 1). Hubbed samples had the cortex removed to a radius of 5 mm hole using a high-speed handpiece (Midas Rex, Medtronic, Fort Worth, TX, USA) with a matchstick burr (M-8/9MH30). Each sample was tested in uniaxial pullout (tension) at 5 mm per minute after the toggling loading. Maximum load, stiffness of the linear region, and energy to peak load were determined. Results were analyzed with a multivariate ANOVA. Post hoc *t*-tests with a significance level of 0.05 were performed to identify differences between individual groups where appropriate using SPSS.

## Results

All samples completed the toggling without evidence of failure. Qualitatively, it was evident that the load versus displacement pull-out curves varied between groups. Samples with the cortex typically exhibited a steep climb and a sharp drop off during failure while groups with the cortex removed showed a more gradual failure (Figure 2).

The ANOVA results indicated main effects for Density and Cortex (hubbing) were present for maximum force and energy along with interaction effects (Tables 1,2). Stiffness had no interaction effects and has a more straightforward interpretation. Stiffness was decreased by the removal of the cortex for all but the non-toggled high-density group with the cortex in place (Figure 3). While the effect of decreasing cancellous density on stiffness was clearly negative, toggling did not have an effect on this property.

Maximum force and energy to failure both showed interaction effects of density/cortex and cortex/toggle. The effects of cortex removal are apparent due to the downward sloping lines in all samples. The interaction effects of cortex/toggle appear as crossed lines within the same density, showing additional loss of pullout load and energy of failure (Figures 4,5) when hubbing and toggling are combined. The interaction effects of density/cortex

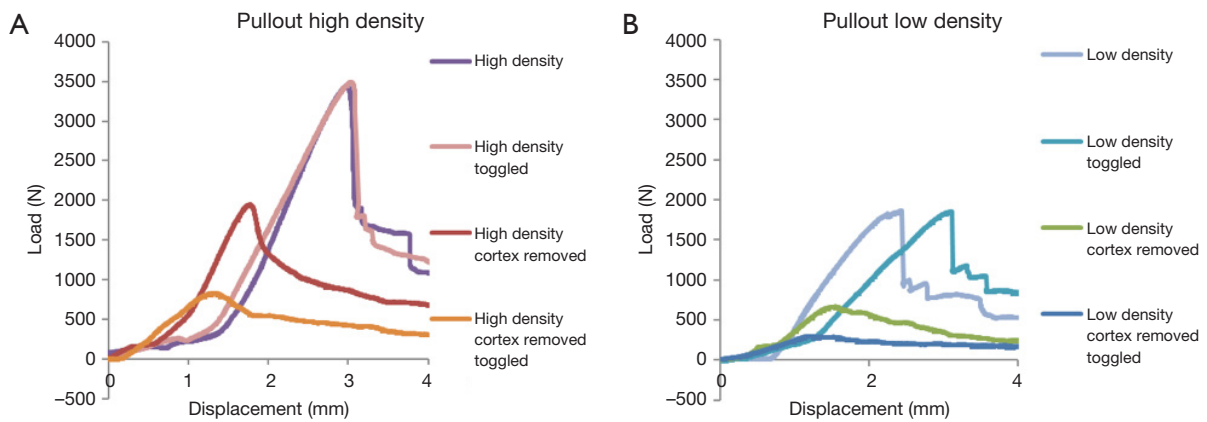


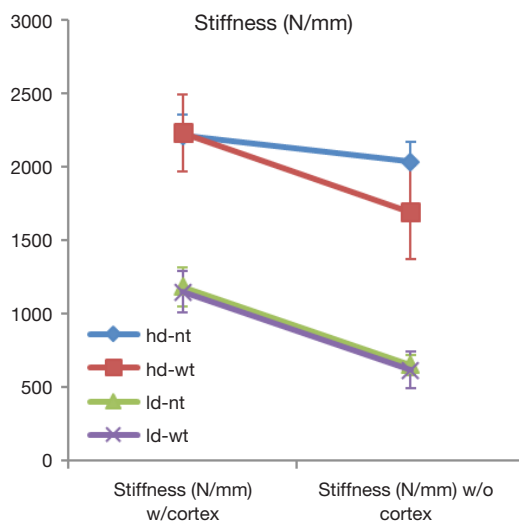
Figure 2 Typical load displacement curves. (A) High density groups; (B) low density groups.

Dependent variable	Main effects			Interaction effects			
	Density	Cortex	Toggle	Density/cortex	Density/toggle	Cortex/toggle	Density/cortex/toggle
Max force	<0.001*	<0.001*	0.144	0.011*	0.678	<0.001*	0.116
Stiffness	<0.001*	<0.001*	0.070	0.108	0.242	0.096	0.095
Energy	<0.001*	<0.001*	0.597	0.012*	0.519	0.004*	0.806

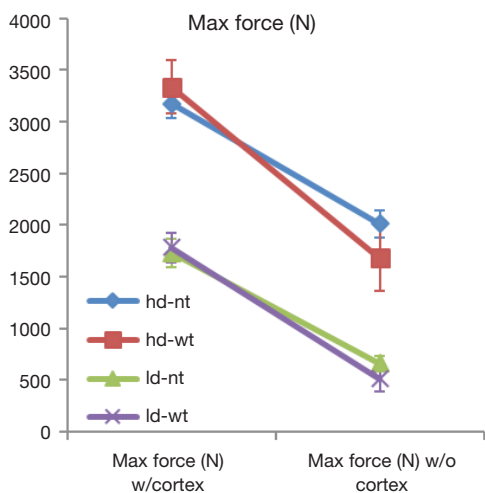
\*, significant factors noted in bold (P<0.05).

Effect	Groups compared	Max force	Stiffness	Energy
Toggling in high density w/o cortex	hd/nc/nt-hd/nc/wt	0.023*	0.051	0.172
Cortex on pullout in high density w/o toggle	hd/nc/nt-hd/wc/nt	<0.001*	0.124	<0.001*
Toggling in high density w/cortex	hd/wc/nt-hd/wc/wt	0.154	0.850	0.181
Cortex on pullout in high density with toggle	hd/nc/wt-hd/wc/wt	<0.001*	0.005*	<0.001*
Toggling in low density w/o cortex	ld/nc/nt-ld/nc/wt	0.013*	0.648	<0.001*
Cortex on pullout in low density w/o toggle	ld/nc/nt-ld/wc/nt	<0.001*	<0.001*	<0.001*
Toggling in low density w/cortex	ld/wc/nt-ld/wc/wt	0.462	0.634	0.218
Cortex on pullout in low density with toggle	ld/nc/wt-ld/wc/wt	<0.001*	<0.001*	<0.001*
Density on pullout w/o cortex w/o toggle	hd/nc/nt-ld/nc/nt	<0.001*	<0.001*	<0.001*
Density on pullout w/o cortex w toggle	hd/nc/wt-ld/nc/wt	<0.001*	<0.001*	<0.001*
Density on pullout w cortex w/o toggle	hd/wc/nt-ld/wc/nt	<0.001*	<0.001*	<0.001*
Density on pullout w cortex w toggle	hd/wc/wt-ld/wc/wt	<0.001*	<0.001*	<0.001*

\*, significant factors noted in bold (P<0.05). hd, high density cancellous foam; ld, low density cancellous foam; wc, with cortex present; nc, no cortex (hubbed); nt, non-toggled samples; wt, samples that were toggled.



**Figure 3** Mean and standard deviation of stiffness. hd, high density cancellous foam; ld, low density cancellous foam; nt, non-toggled samples; wt, samples that were toggled.

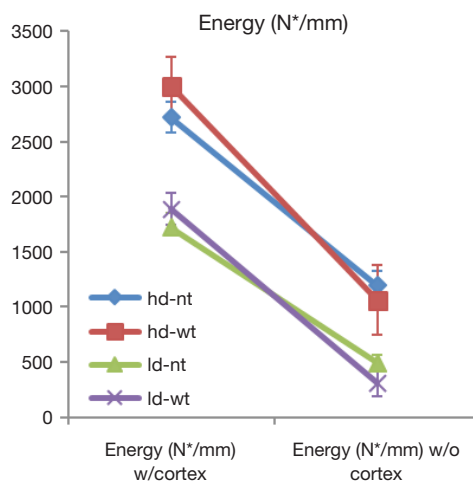


**Figure 4** Mean and standard deviation of maximum force. hd, high density cancellous foam; ld, low density cancellous foam; nt, non-toggled samples; wt, samples that were toggled.

are slightly more challenging to see plainly but the higher density Sawbones pullout properties were reduced to a greater extent than the low-density samples.

**Discussion**

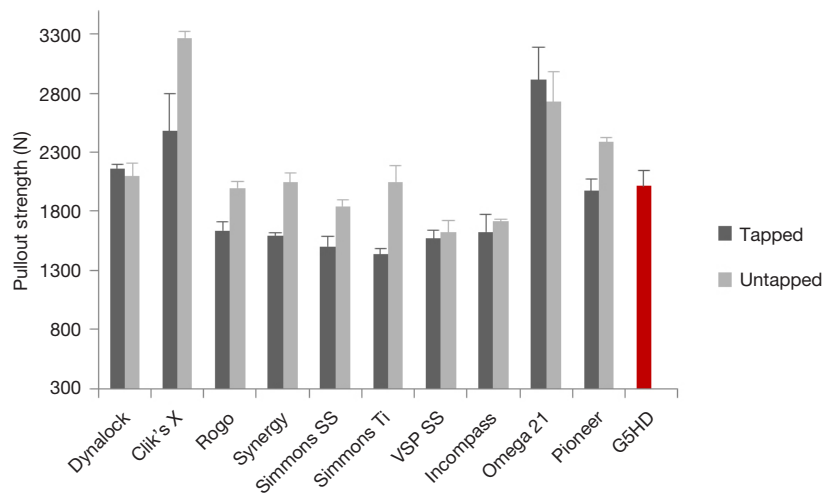
Bone density and strength vary based on patient health and underlying pathology. Osteopenic and osteoporotic



**Figure 5** Mean and standard deviation of energy of failure. hd, high density cancellous foam; ld, low density cancellous foam; nt, non-toggled samples; wt, samples that were toggled.

bone is often encountered when performing spine surgery, influencing not only fracture risk also hardware fixation (9,21). Polyurethane foam is a well-established bone surrogate for biomechanical testing (22,23) and although there are some limitations, simulation of normal and osteoporotic bone can be achieved with 0.32 g/cc<sup>3</sup> (20 lb/ft<sup>3</sup>) and 0.16 g/cc<sup>3</sup> (10 lb/ft<sup>3</sup>) foam respectively (24). This study used two densities of simulated bone in a pedicle screw pullout model with and without toggling and hubbing. These factors were chosen to simulate clinically relevant variables.

Several studies have investigated factors influencing pedicle screw stability, such as trajectory (25,26), hole preparation (27), reuse of pilot holes (28) and screw back out (29). The removal of the cortex immediately surrounding the pedicle screw simulates a variation on screw placement known as hubbing. Concerns regarding this technique include reduced pullout loads (15,30). In our study, removal of the cortex not only decreased the pull-out loads alone but further weakened the fixation of the screws when subjected to toggling. Toggling simulates Caudocephalad loading occurring during activities of daily living (10). Toggling in the presence of the cortical shell had no effect. However, once the cortical shell is removed, damage to the weaker cancellous bone accumulates and further weakens the fixation. This demonstrates that this combination of treatments is worse than either alone. Weaker cancellous bone produced lower pull-out strength, as expected, and this difference was considerable for the group with the removed cortical layer, decreasing maximum



**Figure 6** Summary of the peak loads for 6.25–7.5 mm pedicle screws from Pfeiffer and Abernathie (27). The red sample represents the comparative group from the present study (low density no cortex, no toggle).

pull-out load to less than one third that of the normal density samples. This value was similar for both low and high-density groups but due to the lower starting point of the low density group the proportional reduction and final properties were considerably greater. This suggests that screw fixation is more vulnerable in the presence of cortical damage in weaker, or potentially osteopenic bone.

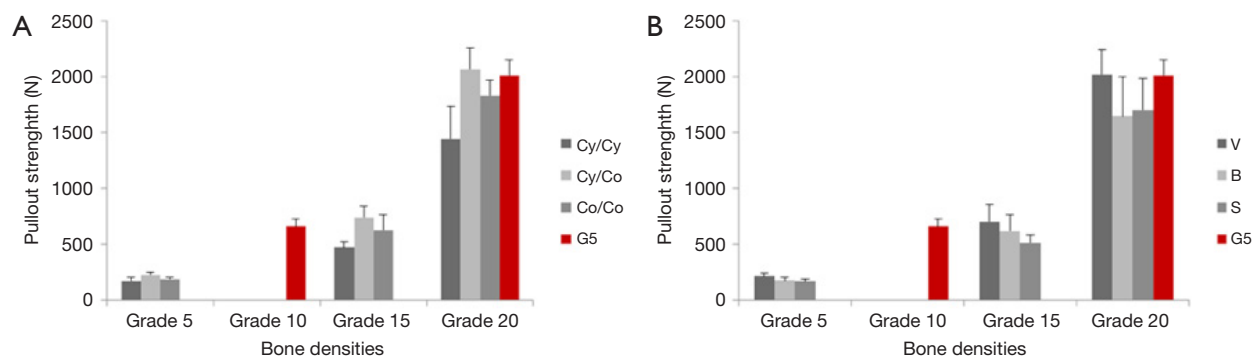
### Comparison to existing literature

Screw pull-out studies using human cadaveric tissues report a wide range of values from 102 to 1,741 N (15,26,28,31–34). Similarly, screw pull-out with the calf model reports values from 747 to 7,300 N, depending on treatment (30,35). Polyurethane blocks have been reported in the literature and offer a wealth of data to compare against. High density blocks demonstrate pullout loads of 2,908 N (27) for 7.5 mm screws, 2,115–2,227 N (29) and 2,133 N (36) for 7.0 mm screws, 2,652 N (37) for 6.5 mm screws and 1,420–2,176 with a 6 mm (38) screws. The comparable condition in the current study generated 2,011 N with 6.5 mm screws. Pfeiffer and Abernathie (27) have evaluated 6.25, 6.5, 6.75 and 7.5 mm sizes, the results of which are more fully compared in *Figure 6*. These values are higher than the majority of cadaveric pullout studies and are more closely comparable to the calf or porcine spine results (37,39).

A few studies have investigated lower density foam as well and are comparable to the low-density group in the present study. Low density with 6.5 mm generated 688 N (36). With

6 and 6.2 mm screws, it is 307–727 N (38). This compares well with the current loads of 661 N. Kim *et al.* (40) have extensively investigated the effects specific design factors (inner and outer diameter shape and thread shape and tested them in 3 density ranges (5, 15 and 20 lb/ft<sup>3</sup>). These results are compared in *Figure 7*. Design variations included diameters (6.5 mm as in the current study) that were cylindrical or conical and threads including V, buttress, and square shapes. Results showed that V-shaped threads had the maximum pullout strength, regardless of bone density, diameter, shape and type of threads. The screw tested in the current study had a conical outer diameter and a two-stage outer diameter for cortical/cancellous bone and buttress shaped threads. When comparing these results, we see that the current screw achieves pullout loads in 10 lb/ft<sup>3</sup> bone surrogate that are reported in 15 lb/ft<sup>3</sup> foam. The current study evaluated pedicle screw pullout characteristics in simulated bone in the presence of a cortex. This feature was structurally significant and added approximately 1,100 N to the pullout load.

Caudo-cephalad loading in an *in vitro* setting (10) is well established and can be used as a preconditioning step prior to pullout or can itself be an endpoint for loosening (41–46). Toggling generally decreases the stability of the screw/bone construct (11,32), however, this is not always the case. Lotz *et al.* (47) reported pullout loads of 809±467 N without cyclic loading and 801±265 N following cyclic loading. Likewise, there are some reports that do not agree as closely with the current study. Patel *et al.* (48) evaluated



**Figure 7** Results of Kim *et al.* (40). (A) The pullout strengths of pedicle screws according to the outer/inner diameter configurations; (B) the pullout strengths of pedicle screws according to the shape of the threads. The red line indicates the results of the comparison group in the current study. Cy/Cy, cylindrical/cylindrical type; Cy/Co, cylindrical/conical type; Co/Co, conical/conical type in outer/inner diameter configuration, V, a V-shaped thread; B, a buttress shape; S, a square shape.

the effect of toggling with 4.7 and 6.5 mm pedicle screws in 20 and 10 lb/ft<sup>3</sup> foam bone. They found no difference with toggling despite having a more aggressive toggling protocol ( $\pm 1$  vs.  $\pm 0.5$  mm). Also of note, the loads were much lower than the current study: 1,110 N (6.7 mm screw) vs. 2,011 N (6.5 mm screw) for high density non-toggled pullout. There are several possible reasons for this, including a screw length of 30 vs. 45 mm. Stiffness of the testing setup is very important for a displacement controlled toggle and, although the test setup shown in the paper appeared sound, the use of test block anchor screws rather than a plate to restrain the block may have allowed the anchor screws to toggle as well as the pedicle screw, minimizing the motion at the pedicle screw/foam interface. Likewise, Mehmanparast *et al.* (49) performed a comparable study and found that toggling decreased pullout loads significantly for 20 lb/ft<sup>3</sup> but not 10 or 30 lb/ft<sup>3</sup> foam while stiffness was affected for all. Values were again lower but this may have been due to the smaller, 5mm screw. Interestingly, both of these studies report a non-significant increase in pullout strength for the low-density foam following toggling.

Investigations into hubbing are less common. A key publication on the topic comes from Paik *et al.* (15) who examined pullout following hubbing and toggling for cadaveric samples that were classified as normal or osteoporotic. A significant drop in pullout load from 772 to 418 N (normal) and from 414 to 243 N (osteoporotic) was found. This represents a drop of 41% and 46% of the intact values. On a comparative basis, our results demonstrate a decrease of the intact value of 47% for the high-density group and a more substantial 70% drop in the low-density

group. The trend was similar but the greater magnitude of the differences may be due to the relative differences between the foam densities being greater than that found in cadaveric cancellous bone. Unfortunately, all samples were toggled and the effects of toggling, hubbing and bone density could not be individually assessed. Lill *et al.* (35) tested screws in calf spines and removed the effect of thicker cortex, as compared to humans, by over-drilling the dorsal cortex to 8 mm diameter and a depth of 2 mm. Although this study did not state the intention to evaluate hubbing, the procedure was very similar. The loads in this study were high (1.8–7.3k N) and unexpectedly, suggest that the bone became stronger following toggling.

Finally, Kang *et al.* (30) also tested the calf spine and found significantly lower pullout following toggling, also noting dorsal cortex deformation and micro fractures in cases after hubbing plus toggling.

The use of synthetic Sawbone bone surrogates has limitations. The properties of maximum pullout load and stiffness are much higher than that reported for human cadaveric bone. This is well documented and considering the reduced variability, this material is useful for comparative tests. The addition of a cortical layer is significant and demonstrates a more realistic model of load sharing. The addition of simulated pedicle geometry with cortical and cancellous layers would further aid in improving the accuracy of the model.

## Conclusions

This study has presented an evolution of a well-established

screw pullout/toggle testing model. The cortex plays a considerable role in the protection of underlying cancellous bone as well as contributing to initial pullout strength. Removal of the cortex not only decreased the pullout loads alone but further weakened the fixation of the screws when subjected to toggling. Toggling in the presence of the cortical shell had no effect. However, once the cortical shell is removed damage to the weaker cancellous bone accumulates and further weakens the fixation. Our idealised *in vitro* results suggest the existence of a detrimental interactive effect when both toggling and hubbing are applied to pedicle screws implanted in weaker, osteoporotic bone.

### Acknowledgements

This work was supported by KH Medical Pty Ltd., Sydney, Australia who provided all implants, instruments for implantation and consumables.

### Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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*Contributions:* (I) Conception and design: All authors; (II) Administrative support: M Pelletier, N Bertollo, W Walsh; (III) Provision of study materials or patients: W Walsh; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

**Cite this article as:** Pelletier MH, Bertollo N, Al-Khawaja D, Walsh WR. The contribution of the cortical shell to pedicle screw fixation. *J Spine Surg* 2017;3(2):184-192. doi: 10.21037/jss.2017.06.07