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Novel Support Device Improves Pedicle Screw Retention

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Abstract

Osteoporosis is one of the most challenging diseases facing orthopedic surgery. Implants may exhibit poor bone retention due to the decreased density of osteoporotic bone, leading to mechanical failure. Our study aimed to design a pedicle screw for vertebral implantation that exhibited pullout strengths that were higher than the current industry standard screw. We created three prototypes to address pullout failure with varying numbers of helices and one design that was a two-part hybrid (triple helix and pedicle screw). Each screw was subjected to pull-out testing in foam blocks (n=3). Ultimate pull-out load, ultimate extension, and screw removal energy were determined based on testing results. Based on the results, the two-part assembly demonstrated significantly improved pull-out strength to 102.76 ± 2.52 N ($P < 0.0002$), ultimate extension to 8.787 ± 0.242 ($P < 0.002$), and screw removal energy of 2.37 ± 0.03 kJ ($P < 0.0003$) vs 1.66 ± .08 kJ in the control screw, and the other two screw designs. It is noteworthy that the flexible and stiff helix designs by themselves did not exhibit improved performance, but when combined into a dual-threaded screw the helix features improved performance. The results for the two-part design suggested that there is utility in this design or variations thereof for improving screw-to-bone retention in osteoporotic patients.

Keywords: Osteoporosis, pedicle screw, spine surgery

1. INTRODUCTION

Osteoporosis affects 1 in 3 women and 1 in 5 men in the US over the age of 50. A total of 8.9 million osteoporosis-related fractures occur every year with a cost of $37.5 billion [1]. Vertebra, specifically, are at a higher risk of osteoporosis-related fractures than all other bones with the exception of femurs [1]. Tests have been conducted to compare dual-threaded pedicle screws to cement-augmentation screws in osteoporotic bone. Zhuang et al., tested dual-threaded pedicle screws and cement-augmented screws in osteoporotic vertebral bone with varying bone mineral densities (BMDs). Augmentation provided increased bone retention in lumbar bone with BMDs between 0.6-0.7 g/cm^2. However, when the dual-threaded and augmented screws were compared in lumbar bone with BMDs less than 0.6 g/cm^2 there was negligable fixation for either option [2]. In the current study, preliminary tests with helical bone-purchasing coils rather than a traditional pedicle screw demonstrated increased pullout strength. Three different helical coil screws were constructed by evenly offsetting the coils such that a single screw was assembled from one, two, or three coils. After initial tests with compliant single, double, and triple coils, the following revised prototypes were tested: (1) screws made with one or two stiff coils (similar to a corkscrew), as well as (2) a hybrid two-part design composed of (A) a dual-threaded pedicle screw combined with (B) a shortened bone purchasing triple coil. The goal of the current study was to compare differences in pull-out failure between prototype screws and a commonly used dual-thread pedicle screw.

2. MATERIALS AND METHODS

2.1 Prototype Design:

Flexible coil prototype: preliminary design with compliant 1, 2 or 3 coils evenly spaced 180 or 120 degrees apart in a nut with epoxy (Fig. 1A).

Stiff coil prototype: a variation on the compliant coil, a stiff corkscrew (1-coil or 2-coil screw) attached to a nut with epoxy (Fig. 1B).

Hybrid design: Combining the gold standard Solera screw with a compliant triple coil, then attached to a mechanical connector allowing forces to be transmitted through the entire device in parallel (Fig. 1C).

Control: Solera 6.5 x 50, 5.5/6.0 dual-threaded screw (Medtronic, Minneapolis, MN)

Figure 1: Examples of the three primary prototype designs. (A) Single flexible coil preliminary design (Length: 4.818 cm, Diameter: 2.54 cm, Pitch: 0.569 cm). (B) Single helix stiff coil mechanical prototype made using corkscrew (Length: 5 cm, Diameter: 1.735 cm, Pitch: 0.900 cm). (C) Hybrid two-part mechanical prototype with a custom grip that allowed for screws to attach and simultaneously engage both parts of the state, leading to combined tension throughout the device.

2.2 Mechanical testing:

Mechanical pullout testing (n=3) was performed with a uniaxial test machine (Bose Electroforce) to measure forces (Newtons) and extension (millimeters). Screw was inserted in a foam block (Young's modulus=0.3 MPa) and displaced at a constant rate (5 mm/min) until failure. The peaks of the load vs extension plots were used to determine the ultimate load, ultimate extension, and screw removal energy (area under the curve) for each screw.

2.3 Statistical Analysis:

A Two way t-test ($\alpha = 0.05$) with a Bonferroni correction was used to analyze results. Error bars are 95% CI.

3. RESULTS AND DISCUSSION

3.1 Compliant coils:

The initial study was performed comparing a compliant, spring-like design (single, double, and triple coils) to the control screw through pullout testing. Preliminary data showed that there was a roughly 20 Newtons and 60 Newtons improvement in comparison to the control for the triple and double helix, respectively, however none of the prototypes exhibited failure within the testing range. The compliant prototypes also demonstrated greater displacement in comparison to the control. A fitting equation was used to determine the theoretical failure load.

$$Load = Load_f(1 - e^{-\Delta k}) \quad (1)$$

where $Load_f$ is the extrapolated theoretical failure load, Δ is the grip displacement, and $\frac{1}{k}$ is the characteristic displacement.

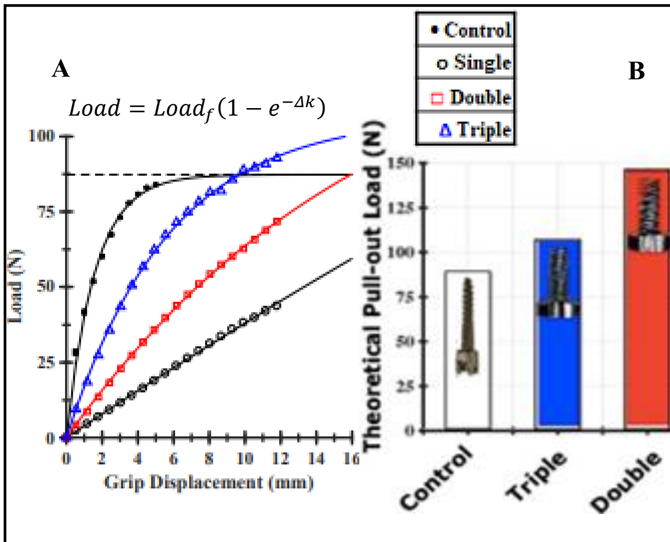

Figure 2: Pull-out testing comparison between flexible coil prototypes and the control pedicle screw. (A) Increasing loads were generated with an increasing number of helices. (B) The theoretical pull-out load of the control, triple, and double flexible coil prototypes suggested increased pull-put load for the triple and double helix prototypes in comparison to the control.

3.2 Stiff coils and two-part assembly:

The second study examined the stiff coil (single and double corkscrew designs) and the hybrid two-part design. All tests were performed as described above. Mean ultimate load for the control screw (81.86 ± 1.41 N), and the ultimate loads for stiff single coil (85.69 ± 28.09), stiff double coil (49.15 ± 11.09), and two-part device (102.76 ± 2.52 N), respectively. Mean ultimate extensions were 6.82 ± 0.43 (control), 7.29 ± 2.98 (stiff single coil), 3.78 ± 0.68 (stiff double coil), and 8.79 ± 0.24 mm (two-part assembly) respectively. It is noteworthy that screw removal energy was the greatest in the two-part assembly (2.37 ± 0.03 kJ vs 1.66 ± .08 kJ in control). Statistically significant differences were exhibited by the double corkscrew (lower), and the two-part assembly (higher), but the stiff single coil screw's ultimate load/extension was not significantly different from the control screws. The two-part assembly's ultimate load, extension, and removal energy were all higher than the control screws. Thus, the data suggested that the two-part assembly could have significantly better retention in osteoporotic bone than dual-threaded pedicle screws in isolation.

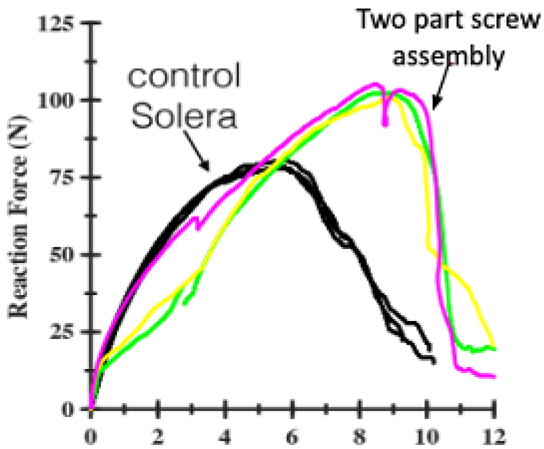

Figure 3: Uniaxial pullout force vs displacement graph for control (black) vs two-part design (colored). The two-part design exhibited a 26% higher pullout strength than the control screw.

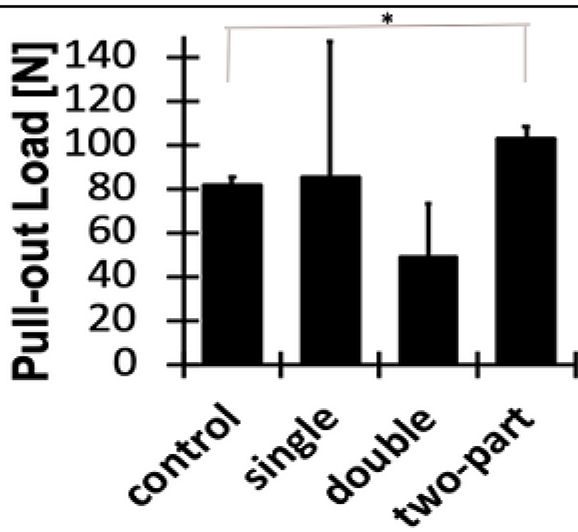

Figure 4: Pull-out loads of the control pedicle screw, stiff coil and two-part prototypes. Two-part screw assembly demonstrated a 26% increase in ultimate load compared to the control pedicle screw. * $p<0.05$.

4. CONCLUSION

These experiments suggested that a flexible coil-like attachment to the industry-standard control screw could be a useful alternative to the industry standard screw alone. The Young's modulus of the foam block used here (0.3 MPa) was significantly lower than that of osteoporotic bone (approximately 5 GPa), so an osteoporotic bone study would be a logical next step.

ACKNOWLEDGEMENTS

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