

# Electrospun Bone Void Filling Material Augments Revision Pedicle Screw Pullout Strength

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**INTRODUCTION:** The prevalence of spine surgery and osteoporosis increases with age, increasing the importance of pedicle screw augmentation in low-quality bone. Bone cement is an option for pedicle screw augmentation, but it has the potential for leakage into vulnerable areas and its exothermicity can damage surrounding tissue. Electrospun bone-void fillers (EBVFs) are a potential replacement for bone cement in pedicle screw augmentation because they are easy to implant, do not leak, and can be made from materials that support bone growth, but their effect on pedicle screw fixation strength is unknown. The purpose of this study was to determine the effect of EBVF augmentation on the pullout strength of pedicle screws in bone foam and cadaveric bone.

**METHODS:** The pullout strengths of three pedicle screw (5.5mm and 6.5mm, Legacy, Medtronic) configurations were tested in osteoporotic bone foam analog (10 PCF, SawBones), healthy bone foam analog (20 PCF, SawBones), and cadaveric pedicle bone. The three configurations tested were (1) a 5.5mm screw (N = 20 (10 PCF), N = 17 (20 PCF), and N = 6 (cadaver)), (2) a 6.5mm salvage screw in a 5.5mm stripped hole (N = 10 (10 PCF), N = 10 (20 PCF), and N = 3 (cadaver)), and (3) a 6.5mm salvage screw in a 5.5mm stripped hole augmented with EBVF (N = 4 (10 PCF), N = 3 (20 PCF), N = 3 (cadaver)). Approximately 0.25g of EBVF (ReBOSSIS, ORTHOREBIRTH, Kyocera) was used in each augmentation. The EBVF was injected into the salvaged hole prior to screw insertion. All pedicle screws were inserted 40mm into the bone foam or cadaveric bone after drilling a 3.8mm pilot hole. Screws were pulled out at constant rate of 5mm/min using a custom fixture in a uniaxial load frame (858 Bionix, MTS). Tension was measured during the entire pullout process. The maximum load was determined from each trial. Because of the small sample sizes, the group averages are presented as mean  $\pm$  standard deviation.

**RESULTS:** EBVF augmentation increased the mean pullout strength of a 6.5mm revision screw in a 5.5mm stripped hole by 106  $\pm$  30 N in 10 PCF bone foam, 262  $\pm$  149 N in 20 PCF bone foam, and 22  $\pm$  312 N in cadaveric pedicle (Figure 1). Analysis after pullout showed the EBVF was circumferentially distributed around the screw (Figure 2).

**DISCUSSION:** This study tested the effect of electrospun bone-void filler (EBVF) augmentation on the pullout strength of revision pedicle screws in bone analogs and cadaveric bone. The EBVF augmentation had a larger impact on pullout strength in the bone foams than in the cadaveric pedicle. The pullout strengths were increased in 10 PCF foam by 30%, in 20 PCF foam by 20%, and in cadaveric pedicle only by 3%. Varghese et al. [1] found similar pullout strengths in 10 PCF foam with 5mm screws, 540  $\pm$  20 N, and 6.5mm revision screws, 430  $\pm$  20 N, but smaller pullout strengths in cadaveric bone with 5mm screws, 270  $\pm$  110 N, and 6.5mm revision screws, 190  $\pm$  20 N. Injection of the EBVF into the pedicle resulted in a uniform circumferential distribution of graft product along the long axis of the screw. The impact of EBVF augmented pedicle screws is likely to improve in vivo due to the favorable bone growth properties of these materials. Use of bone graft products to augment revised pedicle screws in the osteoporotic condition could improve the clinical outcomes. The study was limited by small sample sizes and a lack of comparison to bone cement augmentation.

**SIGNIFICANCE/CLINICAL RELEVANCE:** Preliminary results indicate that electrospun bone void fillers which create a conducive biological environment for bone growth and have no negative exothermic effects do not have a negative impact on the pullout strengths of pedicle screws.

**REFERENCES:** [1] V Varghese et al. Medical Engineering and Physics 74 2019.

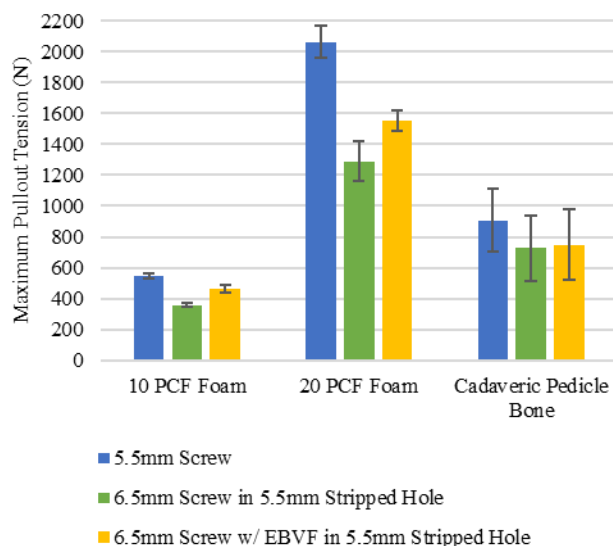


Figure 1: Pedicle screw pull out strengths as a function of screw size, hole condition, and material.



Figure 2: Circumferential distribution of EBVF around pulled out pedicle screw.