

PEEK Versus Trabecular Metal™ Implants for Cervical Spinal Fusion in a Goat Model

^{+1,2}Sinclair, S K; ³Konz, G; ³Dawson, J; ^{1,2}Bloebaum, R D

⁺¹ Bone and Joint Research Laboratory, DVAHCS, Salt Lake City, UT; ²Department of Orthopaedics, University of Utah, Salt Lake City, UT;

³Zimmer Spine, Inc., Minneapolis, MN

sarina.sinclair@hsc.utah.edu

INTRODUCTION: Degenerative disc disease (DDD) of the cervical spine is a common pathology affecting the aging population. Fusion procedures have been effective in alleviating pain and other symptoms of DDD when non-operative treatments have failed. A number of synthetic devices have been developed that facilitate fusion while providing necessary stability and restoring disc height. Polyetheretherketone (PEEK) devices are widely used for cervical interbody fusion due to their radiolucency and an elastic modulus that is close to bone.¹ *Trabecular Metal* devices have an elastic modulus close to cancellous bone, structural characteristics similar to cancellous bone, and are currently used in several orthopedic applications.² The purpose of this study was to directly compare PEEK and *Trabecular Metal* cervical interbody fusion implants in a goat model.

METHODS: Twenty-five skeletally mature goats (n=5 in 12 week *Trabecular Metal* cohort, n=4 in all other groups) were implanted with *Trabecular Metal* or control (PEEK) devices at the C2-C3 or C3-C4 levels for up to twenty-six weeks. Both devices contained a center ‘graft hole’ (GH) that was filled with autograft bone at implantation. Animals were sacrificed at 6, 12 and 26 weeks. The vertebral segments were embedded in poly (methyl methacrylate) and cut into two-millimeter thick sagittal sections. Three cross-sections were examined per animal. Evidence of bone bridging through the GH region was characterized by the amount of incorporation of the autograft bone with the caudal and cranial vertebrae (Table 1) using 12x-magnified scanning electron microscope images. Fluorochrome double labeling was used to assess autograft viability. The two groups were compared using the Wilcoxon-Mann-Whitney test for rank ordering. The appropriate institutional animal care and use committees approved this study.

Grade	Description
0	None
1	Autograft bone connected to one vertebra – not continuous
2	Autograft bone connected to two vertebrae – not continuous
3	Autograft bone connected to two vertebrae – continuous

RESULTS: The evidence of bone bridging assessment (Table 2) showed that a greater number of animals with *Trabecular Metal* implants demonstrated Grade 2, connection between the autograft bone and both vertebrae without continuous bridging in the GH, compared to the PEEK implants. Two animals with *Trabecular Metal* implants, one at 6 weeks and one at 26 weeks, had Grade 3 connection to both vertebrae with continuous bridging through the GH (Figure 1). No PEEK animals had Grade 3 continuous bone bridging through the GH region. There was a significant difference ($p \leq 0.05$) in bone bridging scores between the two implant materials.

Implant	Score			
	Number of Animals with Score (% of Group)			
	0	1	2	3
PEEK N=12	5 (41.67)	2 (16.67)	5 (41.67)	0 (0.00)
<i>Trabecular Metal</i> N=13	0 (0.00)	2 (15.38)	9 (69.23)	2 (15.38)
P-value	*0.01			

Double fluorochrome labels within the autograft bone confirmed the presence of viable bone where bridging was evident.



Figure 1: Grade 3 bone bridging through the GH region of a *Trabecular Metal* implant. (12x)

In the 6-week PEEK animals (Figure 2), calcified fibrocartilage (CFC) created a boundary between the autograft bone and the vertebrae. The CFC inhibited integration of the autograft tissue within the GH with the vertebrae or through the device. There were no fluorochrome labels within the autograft of animals with remnant CFC, indicating that the autograft was no longer viable.

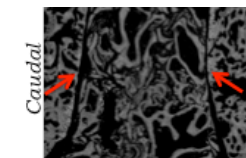


Figure 2: Image from a 6-week PEEK animal showing calcified fibrocartilage boundaries (arrows) within the GH.

DISCUSSION: The open cell porous structure of the *Trabecular Metal* devices facilitated host bone ingrowth and bone bridging through the GH better than the commonly used PEEK devices. Other regions of the *Trabecular Metal* implants, particularly the ventral and dorsal borders, also exhibited bone ingrowth (data not shown). The structure of the *Trabecular Metal* devices may have contributed to increased blood supply to the autograft, allowing incorporation with the vertebrae and bone attachment into the device. As seen in this study, when CFC remains on the cortical endplate after implantation, the non-vascularized autograft bone cannot integrate with the vertebrae. These findings could be beneficial for improved long-term mechanical support and successful treatment of DDD with interbody fusion.

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