INTRODUCTION: Degenerative disc disease of the cervical spine is commonly treated surgically with an anterior cervical disectomy and fusion procedure. Although autologous bone graft strut has been the clinical standard for achieving fusion in these procedures, a number of synthetic devices have been developed to avoid the complications associated with harvesting large amounts of autologous tissue. These devices restore and maintain disc height, ensure proper alignment, and facilitate fusion while providing stability [1]. Polyetheretherketone (PEEK) devices have been used for cervical interbody fusion due to their radiolucency and an elastic modulus that is closer to bone, which is believed to optimize interaction with the host tissue [2]. Trabecular Metal devices are fabricated from porous tantalum. They have a low elastic modulus and are proposed as an alternative to autologous bone graft struts and PEEK for use in cervical fusion procedures.

Trabecular Metal devices have characteristics similar to cancellous bone and are currently used in several orthopedic applications, including hip and knee arthroplasty, spine surgery, and as bone graft substitutes. Their open cell porous structure facilitates host bone ingrowth for better mechanical attachment and support [3]. The purpose of this study was to examine the differences in host bone response to PEEK and Trabecular Metal implants used in cervical interbody fusion in an animal 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 autogenous bone morsels at implantation. Animals were sacrificed at predetermined time periods of 6, 12 and 26 weeks. Following necropsy, the vertebral segments were harvested, processed and embedded in poly(methyl methacrylate) [4]. Two-millimeter thick sagittal sections were generated after grinding and polishing; at least 3 cross-sections were generated per animal that contained the regions of interest (cranial, caudal, ventral, dorsal, within the GH, and periprosthetic to the GH; Figure 1). These sections were then carbon coated, imaged using a scanning electron microscope and evaluated for percentage of bone tissue (% bone) around the implant and appositional bone index (ABI). Sanderson’s Rapid Bone Stain™ was used for histological analysis [4]. The data were compared using mixed effects linear regression statistical analysis. The appropriate institutional animal care and use committees approved this study.

RESULTS: The percent of bone tissue present in the regions of interest, reported as a volume percent, demonstrated that animals implanted with the Trabecular Metal device had significantly greater volumes of bone tissue at the implant interface compared to the animals implanted with the PEEK device throughout the duration of the study (Figure 2, *statistical significance for p<0.05).

Backscattered electron images were also used to measure the percentage of the surface of each implant that was in direct apposition with bone (ABI, Figure 3) within the regions of interest. The data indicate that the Trabecular Metal implants achieved significantly greater amounts of direct contact with the host bone than the PEEK implants at weeks 6, 12 and 26 (*statistical significance for p<0.05).

Histological staining supported the finding that the Trabecular Metal devices elicited improved host bone response over the PEEK implants (Figure 4). The Trabecular Metal implants had bone growth into the pores and more bone in direct apposition to the implants, while fibrous tissue was more prevalent along the margins of the PEEK implants.

DISCUSSION: This study is one of the few in the public domain to directly compare a PEEK device with a porous interbody fusion device within an animal model. The results of this study indicate that the Trabecular Metal implant supports bone growth into and around the implant margins better than commonly used PEEK devices. The bone ingrowth data demonstrated improved mechanical stability and enabled interbody fusion to occur. Tantalum has been used successfully in other orthopedic applications [5]. The positive bone response observed in this study may be attributed to the interconnected network and high volume porosity (70-80%) of the Trabecular Metal implant. The smooth surface of the PEEK implant does not allow for bone ingrowth or surface osseointegration. However, none of the PEEK implants appeared to migrate, despite the lower levels of bone volume and attachment over the time period studied. The stability of the PEEK implant and its record of clinical success may be attributed more to its geometry and less to its ability to integrate with host bone tissue. Additional analysis is in progress to determine if the autogenous bone morsels were consolidated with the host bone and if bone bridging occurred through the graft hole region of these devices.

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