Evaluation of a Bioresorbable Anterior Cervical Plate: A Pilot Study in Sheep

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) is a surgical procedure used to treat the symptoms of a damaged disc in the cervical spine. Symptoms often include pain associated with compressed spinal nerves as a result of a damaged, herniated or bulging disc. In an ACDF procedure, partial or a complete discectomy is performed to relieve the compressed nerve. The procedure may be done at a single level or multiple levels. The disc space is then typically filled with bone graft, sometimes in conjunction with an interbody device, in order to maintain the original space between adjacent vertebrae, to promote fusion, and ultimately provide stability to the affected area.

One challenge faced in ACDF procedures is to prevent migration of the interbody device and/or bone graft prior to fusion taking place. Containment or “kickout” plates are often placed anteriorly in ACDF procedures to provide stability and prevent migration of the interbody device or bone graft. Typically, a metallic plate is used for this purpose. However, a bioresorbable plate may offer advantages over a metallic one because it can theoretically resorb by hydrolysis after fusion has occurred, thus mitigating any stress shielding osteopenic effects associated with rigid instrumentation. Furthermore, the plates are radiolucent and eliminate imaging artifact. The purpose of this study was to determine the histological response elicited by a bioresorbable containment plate at a 12 week time point in an ovine model.

METHODS:

Six skeletally mature ewes underwent C2-C3 and C4-C5 distraction and discectomies. A PEEK cage augmented with autograft bone harvested from the iliac crest was then inserted into the disc space and the distraction device removed to allow compression of the cage. A bioresorbable polymeric plate (70/30 PDLLA/PGA) and four screws were placed on the anterior surface of the spinal unit over the intervertebral disc spacer at each of the two levels. After 3 months of healing, the animals were humanely euthanized and functional spinal units were harvested for undecalcified histological processing and evaluation. Additionally, X-rays and MRI images were acquired post-sacrifice, and gross observations were documented.

Undecalcified sections were taken in the sagittal plane to yield the PEEK cage, adjacent vertebrae, and the resorbable polymeric plate and screws within a single section. Initial sections were taken using an Exakt diamond blade bone saw at a thickness of approximately 300 μm. All sections were ground using an Exakt microgrinder to approximately 20 μm thickness and stained with Sanderson’s Rapid Bone stain and counterstained with Van Gieson structure at increased distance from implants, 40X. Sections were stained with Sanderson’s Rapid Bone stain and counterstained with Van Gieson.

RESULTS:

Grossly, it was observed that 6 of the 12 specimens had either a broken screw or cracked plate. These gross observations were confirmed within the histological sections as shown in Figure 1. Histologically, it was found that the tissue surrounding the plate and interbody device consisted of vascularized fibrous tissue with islands of active woven bone within the fibrous tissue; bone was not observed directly adjacent to the polymeric plate without an interposed fibrous tissue layer between (Figure 2). Bone was relatively active in close proximity to the implants. Osteoblastic activity decreased as distance from the implants increased. For all specimens sclerosis was observed as indicated by the thickening of the trabecular bone within the screw threads and within areas of the vertebral body that were in closer proximity to the disc device (Figure 3). The screws were typically surrounded by reactive woven bone and lamellar bone. Inflammatory cells were not frequently observed. Fusion at C2-C3 was successful in three of the six sheep; none of the fusions were successful at C4-C5.

DISCUSSION:

In this study we have shown that although the bioresorbable plates/screws did not illicit an iatrogenic tissue response, a high percentage of them mechanically failed. This phenomenon was difficult to observe radiographically, as the radiopaque markers were not able to convey these instrumentation failures. These findings suggest that resorbable implant materials with an acutely stiffer mechanical behavior are required for anterior cervical plating applications.