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Polyetheretherketone as a biomaterial for spinal applications

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Abstract

Threaded lumbar interbody spinal fusion devices (TIBFD) made from titanium have been reported to be 90% effective for single-level lumbar interbody fusion, although radiographic determination of fusion has been intensely debated in the literature. Using blinded radiographic, biomechanic, histologic, and statistical measures, we evaluated a radiolucent polyetheretherketone (PEEK)-threaded interbody fusion device packed with autograft or rhBMP-2 on an absorbable collagen sponge in 13 sheep at 6 months. Radiographic fusion, increased spinal level biomechanical stiffness, and histologic fusion were demonstrated for the PEEK cages filled with autograft or rhBMP-2 on a collagen sponge. No device degradation or wear debris was observed. Only mild chronic inflammation consisting of a few macrophages was observed in peri-implant tissues. Based on these results, the polymeric biomaterial PEEK may be a useful biomaterial for interbody fusion cages due to the polymer's increased radiolucency and decreased stiffness.

Keywords: Polyetheretherketone; Bone morphogenetic protein (BMP); PEEK; Spinal surgery; Spine fusion; Spine fusion cages

1. Introduction

Back or spine musculoskeletal impairment has been reported to represent more than half (51.7% or 15.4 million incidences) of the musculoskeletal impairments reported in the United States [1]. In the 18–84 age group, back or spine impairment is the leading cause of activity limitation and results in more lost productivity than any other medical condition [1]. It has been estimated that 4.4 million people 25–74 years of age report intervertebral disc problems in the United States [1]. While it has been reported that 80–90% of patients with low-back pain recover by 12 weeks with non-surgical therapies such as bed rest and anti-inflammatory medications [2], non-surgical therapies are occasionally unsuccessful for certain injuries/pathologies, including degenerative disc disease/stenosis, spondylolysis, and/or spondylolisthesis.

When conservative treatment fails, spinal fusion (arthrodesis) may be performed. In the United States, there were 279,000 operations for low-back pain in 1990 with 26 lumbar fusions performed per 100,000 persons[2]. In 1995, there were approximately 160,000 spine fusion surgeries [1]. In a literature review of 47 studies, Turner et al. [3] reported that 68% of the patients had a satisfactory outcome after lumbar fusion, but the range was between 16% and 95%. Of most concern was a 20–40% failure rate reported for lumbar spine fusion [3].

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Since the approval of spinal fusion cages by FDA in 1996, the use of these devices has become prevalent for lumbar interbody fusion (LIF) [4–12]. Clinically, on the basis of primarily radiographic evaluation, lumbar interbody fusion with titanium spinal fusion cages has been reported to be effective for single-level LIF, with a fusion rate of 90% or higher at 1–2 years post-operatively [5,7,8,12]. Fusion rates may be between 70% and 80% in patients with multi-level fusions or with risk factors such as obesity, tobacco use, or metabolic disorders. A central question still exists with regard to the use of these radiopaque devices: "Is radiographic determination of fusion possible with titanium interbody fusion devices?" This question has been intensely debated in the recent literature [13,14]. In 2000, Cizek and Boyd [13] published an experimental study that has shown that plain radiographs and CTs of cage-instrumented cadavers showed "considerable metallic artifact." In 2001, a prominent panel of spine surgeons and researchers were unable to develop a consensus for "successful arthrodesis" following interbody fusion with titanium interbody fusion devices [14]. Thus, the development of radiolucent spine fusion devices that are mechanically competent and biocompatible would be a great asset to the armamentarium of spine surgeons.

One non-absorbable biopolymer that has been evaluated as a biomaterial is polyetheretherketone (PEEK). PEEK has been used in a variety of industries, from aerospace and aviation to medical devices. According to InVibio®, the manufacturer of PEEK-OPTIMA® (the biomedical formulation of the PEEK material), the polymer can be processed through conventional techniques including injection molding, extrusion or machining, allowing medical device manufacturers broad design and manufacturing flexibility. PEEK has well-established mechanical and good wear characteristics, as well as excellent biocompatibility in both bulk and particulate form [15–19]. Rivard et al. [20] found neither necrosis nor swelling when PEEK particles were injected in tissues adjacent to the spinal cord and nerve roots of 12 New Zealand white rabbits. In 2002, Senegas [21] reported that a PEEK interspinous system of non-rigid stabilization is efficacious against low-back pain due to degenerative instability. Recently, Cho et al. [22] have evaluated PEEK cages for cervical disc disease in a group of 40 patients. They showed that the PEEK devices were able to facilitate stability and space maintenance during cervical fusions, increase cervical lordosis, and increase foraminal height [22].

Previously published studies have shown that autograft as well as cages and other spine fusion devices, alone or packed with autograft, may not produce solid fusions [24–30]. Using the ovine LIF model, previous studies have shown that the augmentation strategy (augmentation of rhBMP-2) has significantly increased the fusion rate of cages compared to the same implant with autograft or alone [10,24]. The current study addresses the efficacy of autograft or rhBMP-2 loaded on a collagen sponge to achieve radiographic, biomechanic, and histologic fusion with a threaded cylindrical PEEK device.

The goals of this study were (1) to evaluate the osteocompatibility of the radiolucent PEEK polymeric device, (2) to evaluate the efficacy of the PEEK device filled with autograft or rhBMP-2 on a collagen sponge to achieve lumbar interbody spine fusion using blinded radiographic, biomechanic, and histologic measures, and (3) to evaluate the augmentation strategy of adding rhBMP-2 on a collagen sponge to stimulate bony healing in conjunction with the PEEK biomaterial.

2. Materials and methods

2.1. Animal model

The sheep lumbar spine model was specifically chosen because of the biomechanical similarities between the sheep and human lumbar spine [31,32,34]. Wilke et al. [31] characterized the biomechanical parameters (range of motion, neutral zone, and level stiffness) of sheep spines and made comparisons with data from human specimens previously published by White and Panjabi [33]. Wilke et al. found that the "ranges of motion of sheep spines for the different load directions are qualitatively similar in their craniocaudal trends to those of human specimens reported in the literature" [31]. They concluded that "based on the biomechanical similarities of the sheep and human spines demonstrated in this study, it appears that the sheep spine…can serve as an alternative for the evaluation of spinal implants" [31].

2.2. Materials and study design

The PEEK interbody fusion device was evaluated in 13 skeletally mature female sheep at a 6 month survival period. Seven sheep received a PEEK cage filled with autograft. Six sheep received a PEEK cage filled with rhBMP-2 on a collagen sponge. Eight sheep levels were used for the biomechanical sham group (described below). This study was approved by the Institutional Animal Care and Use Committee. Colorado State University is in compliance with recommendations of the American College of Laboratory Animal Medicine and the PHS Guide for the Care and Use of Laboratory Animals. Animals were fasted for 24 h prior to surgery. Water was not restricted during this time. Anesthesia was induced with ketamine (4 mg/kg) and valium (7.5 mg total). After induction, sheep were maintained with isofluorane(1.5–3%) in 100% oxygen (2 L/min) during the surgical procedure. Muscle relaxants were not used. In the PEEK + autograft group, tricortical iliac crest autograft was harvested using an osteotome and mallet, and further morselized so that it could be packed into the cages. The surgical technique involved positioning the sheep in right lateral recumbency for single-level lumbar discectomy and interbody fusion at L4–L5 via a