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Research Paper

Static and dynamic fatigue behavior of topology designed and conventional 3D printed bioresorbable PCL cervical interbody fusion devices

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ABSTRACT

Recently, as an alternative to metal spinal fusion cages, 3D printed bioresorbable materials have been explored; however, the static and fatigue properties of these novel cages are not well known. Unfortunately, current ASTM testing standards used to determine these properties were designed prior to the advent of bioresorbable materials for cages. Therefore, the applicability of these standards for bioresorbable materials is unknown. In this study, an image-based topology and a conventional 3D printed bioresorbable poly(ε)-caprolactone (PCL) cervical cage design were tested in compression, compression–shear, and torsion, to establish their static and fatigue properties. Difficulties were in fact identified in establishing failure criteria and in particular determining compressive failure load. Given these limitations, under static loads, both designs withstood loads of over 650 N in compression, 395 N in compression–shear, and 0.25 Nm in torsion, prior to yielding. Under dynamic testing, both designs withstood 5 million (5 M) cycles of compression at 125% of their respective yield forces. Geometry significantly affected both the static and fatigue properties of the cages. The measured compressive yield loads fall within the reported physiological ranges; consequently, these PCL bioresorbable cages would likely require supplemental fixation. Most importantly, supplemental testing

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methods may be necessary beyond the current ASTM standards, to provide more accurate and reliable results, ultimately improving preclinical evaluation of these devices.

1. Introduction

Over the past two decades, the number of anterior cervical decompression and fusion (ACDF) procedures performed in the United States has more than doubled, increasing from approximately 61,000 procedures in 1993, to nearly 160,000 procedures in 2011 (Healthcare Cost and Utilization Project (HCUP), 2011). The goal of these procedures is to decompress nerve roots (Majd et al., 1999), maintain disc height (Miller and Block, 2011), and achieve solid fusion(Hacker et al., 2000; Moreland et al., 2004), typically through the use of a spinal cage enhanced with biologics that promote bone growth.

In order to achieve fusion, the spinal cage must provide sufficient mechanical strength to withstand the physiological loads placed on the spine (Kandziora et al., 2001; Weiner and Fraser, 1998; Greene et al., 2003). Designs composed of nonresorbable materials, such as titanium or PEEK (Chen et al., 2013; Cabraja et al., 2012), provide the mechanical strength necessary to withstand these loads; however, due to their substantially larger modulus of elasticity compared to the vertebral bodies, stress shielding (Vavruch et al., 2002; Kanayama et al., 2000) and implant subsidence into the vertebrae is a significant concern. Alternatively, bioresorbable cages have been developed, in part, to address such concerns (Thomas et al., 2008); however, the mechanical properties of such devices, especially dynamic fatigue behavior, have not been widely reported. Therefore, the safety of using these cages in the cervical spine, either as stand-alone cages or cages supplemented by additional fixation, has not been established.

Improved 3D printing technologies, which enable fabrication of topology optimized designs, allow for improvements in the mechanical design of scaffolds to withstand typical loads by placing material in critical load bearing paths, but leaving sufficient porosity and permeability for bone ingrowth and biologic delivery (Coelho et al., 2009; Kang et al., 2013). Combining topology design and optimization with 3D printing technologies such as laser sintering, allows for the realization of complex topology designed cages fabricated for resorbable polymers (Kang et al., 2013; Williams et al., 2005) However, despite the sophisticated 3D printing and optimization capabilities, the effects of these designs and resorbable polymer properties on the structural strength of the implants is not well known. As bioresorbable cages tend to have weaker material properties than their nonresorbable metal and permanents polymer (PEEK and PEKK) counterparts, optimum designs must be utilized to maximize their mechanical and structural strength.

In order to establish the mechanical properties of bioresorbable cages prior to use in patients, spinal cages are typically tested using ASTM standard F2077 (ASTM F2077-11, 2011), as mandated by the FDA special controls guidance document for intervertebral body fusion cages (U.S. Food and Drug Administration, 2007). Thus, these tests are required to obtain FDA approval of spine cages via the 510(k) premarket approval pathway. This preclinical standard was developed to evaluate the compressive, shear, and torsional structural mechanical properties of the devices under both static and dynamic loading conditions. However, this testing standard was initially established for hollow cylindrical and rectangular shapes made of solid nonresorbable materials such as titanium or PEEK, representative of the most common devices available when the standard was initially drafted. Therefore, it is not clear whether these testing methods are equally appropriate for spine cages composed of bioresorbable materials which tend to be more porous and ductile, and vary widely in geometry. This is especially true given that fusion must be obtained with bioresorbable cages to stabilize the cervical spine, as failure to obtain fusion at 1 year with bioresorbable cages would lead to instability. Thus, the 5 million cycles recommended in ASTM F2077 would go well beyond that required for successful spinal fusion. Moreover, while previous studies have measured the properties of bioresorbable materials under various static loading setups (Kang et al., 2013; Claes, 1992; Smit et al., 2007, 2008; Engels et al., 2010), there has been limited investigation into dynamic and fatigue properties of these implants (Shikinami and Okuno, 2003). In fact, to our knowledge, no previous dynamic fatigue testing under ASTM F2077 of any 3D printed bioresorbable cages has been previously reported.

The purpose of the present study was first, to test and evaluate the applicability of ASTM standard F2077 for the testing of PCL bioresorbable 3D printed spinal cages. Second, the study determined the static and fatigue properties of two different bioresorbable spine cage designs to the extent that the ASTM standard could be applied dependably. The two different cage designs were: (1) a cylindrically shaped design replicating clinically available and conventionally utilized ring-shaped solid cages, and (2) a novel, optimized, rectangular design with porous topology, engineered for simultaneous maximal apparent diffusivity and elastic modulus (Kang et al., 2010, 2013). The standard static and dynamic loading protocols described by ASTM F2077 were implemented and the results of these tests were used to evaluate the effectiveness of the standard. Specifically, we determined the mechanical properties of the PCL cages under standard preclinical testing criteria as a function of loading mode and cage design.

2. Methods

2.1. Materials

Two biodegradable cervical cage designs composed of PCL were tested: (1) a ring-shaped cage (standard ring), which has