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Strains in trussed spine interbody fusion implants are modulated by load and design

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ABSTRACT

Titanium cages with 3-D printed trussed open-space architectures may provide an opportunity to deliver targeted mechanical behavior in spine interbody fusion devices. The ability to control mechanical strain, at levels known to stimulate an osteogenic response, to the fusion site could lead to development of optimized therapeutic implants that improve clinical outcomes. In this study, cages of varying design (1.00 mm or 0.75 mm diameter struts) were mechanically characterized and compared for multiple compressive load magnitudes in order to determine what impact certain design variables had on localized strain. Each cage was instrumented with small fiducial sphere markers (88 total) at each strut vertex of the truss structure, which comprised of 260 individual struts. Cages were subjected to a 50 N control, 1000 N, or 2000 N compressive load between contoured loading platens in a simulated vertebral fusion condition, during which the cages were imaged using high-resolution micro-CT. The cage was analyzed as a mechanical truss structure, with each strut defined as the connection of two vertex fiducials. The deformation and strain of each strut was determined from 50 N control to 1000 N or 2000 N load by tracking the change in distance between each fiducial marker. As in a truss system, the number of struts in tension (positive strain) and compression (negative strain) were roughly equal, with increased loads resulting in a widened distribution (SD) compared with that at 50 N tare load indicating increased strain magnitudes. Strain distribution increased from 1000 N ($+156 \pm 415\,\mu\varepsilon$) to 2000 N ($+180 \pm 605\,\mu\varepsilon$) in 1.00 mm cages, which was similar to 0.75 mm cages ($+132 \pm 622\,\mu\varepsilon$) at 1000 N load. Strain amplitudes increased 42%, from 346με at 1000 N to 492με at 2000 N, for 1.00 mm cages. At 1000 N, strain amplitude in 0.75 mm cages (481με) was higher by 39% than that in 1.00 mm cages. These amplitudes corresponded to the mechanobiological range of bone homeostasis + formation, with $63 \pm 2\%$ ($p < .05$ vs other groups), $72 \pm 3\%$, and $73 \pm 1\%$ of struts within that range for 1.00 mm at 1000 N, 1.00 mm at 2000 N, and 0.75 mm at 1000 N, respectively. The effective compressive modulus for both cage designs was also dependent on strut diameter, with modulus decreasing from 12.1 ± 2.3 GPa (1.25 mm) to 9.2 ± 7.5 GPa (1.00 mm) and 3.8 ± 0.6 GPa (0.75 mm). This study extended past micro-scale mechanical characterization of trussed cages to compare the effects of design on cage mechanical behavior at moderate (1000 N) and strenuous (2000 N) load levels. The findings suggest that future cage designs may be modulated to target desired mechanical strain regimes at physiological loads.

1. Introduction

The load-bearing behavior of spine interbody fusion devices (cages) may dictate the mechanobiological mechanisms by which bone forms. Bone formation and remodeling involve mechanobiology, a complex process by which mechanical loads influence the osteogenic biological response (Cowin and Hegedus, 1976; Frost, 2003; Mow and Huiskes, 2004; Oftadeh et al., 2015; Turner, 1998). With controlled loading *in vitro* or *in vivo,* strain amplitudes up to ~200 με (microstrain, 10^{-6} strain) result in net bone resorption, ~200–1500 με preserve bone

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homeostasis, and > 1500 με promote bone formation (Akhter et al., 1998; Burger et al., 1992; Cullen et al., 2001; Duncan and Turner, 1995). Bone, including its indwelling cells, is sensitive to tissue strain, induced fluid flow in canaliculi, and induced streaming potentials (Dallas et al., 2013). For remodeling bone attached to surfaces of a fusion device subjected to compressive and tensile loads, mechanobiological strain regimes may be useful to stimulate bone growth in fusion devices (Reid et al., 2011; Zhao et al., 2015). The lack of bone formation within and around a cage may lead to cage subsidence and/or stress shielding after implantation and negatively affect fusion outcome (Blumenthal and Ohnmeiss, 2003; Reid et al., 2011). Many orthopaedic devices are designed to minimize the effects of stress shielding, in which low post-implant bone tissue strains lead to resorption (Kanayama et al., 2000). The effective mechanical stiffness and modulus of an implant consider both the material and structure to convey the overall implant behavior under load (Parthasarathy et al., 2010). By altering cage design, the effective stiffness may be modulated to reduce the effects of stress shielding.

Several different cage designs have been developed for spinal fusion devices, though mechanical characterization has been mostly limited to numerical estimation or overall structural properties. Numerical methods, such as the finite element method, enable estimation of implant stresses and strains under load, but make assumptions in loading, particularly for a complex structure such as a spine cage (Fan et al., 2010; Xu et al., 2013). Experimental mechanical analyses of fusion devices are typically limited to overall structure properties or range of motion measures, using x-ray or biplane radiography (Fogel et al., 2014; Kanayama et al., 2000; Nayak et al., 2013). However, the mechanics of spine cages can be complex due to cage architecture and the interfaces between cage and loading platen. In addition, with the growth of additive manufacturing, 3-D printed titanium cages with internal architectures have been introduced. One such cage was developed with an open space truss design. This anterior lumbar interbody fusion (ALIF) cage design (4WEB Medical) distributes load throughout the cage, allows lateral and axial communication, and provides space for bone incorporation throughout the implant (Kiapour et al., 2011).

Recently, the mechanical properties of struts in a trussed lumbar fusion cage under induced load have been characterized. In that study, a cage design with 1.25 mm strut diameter and an anterior instrumentation attachment plate was loaded up to 2000 N in repeated measures and for multiple cages with vertebral and contoured plastic loading platens (Caffrey et al., 2016). Spherical fiducials were affixed to vertices of the cage truss struts and tracked by micro-CT during loading to determine individual strut deformations and strains. In that study, struts deformed in a manner statistically dependent on load amplitude, with macroscopic strut strains primarily in the homeostatic range (37–64% at 1000 N and 2000 N loads, respectively) and very few struts in the formation range (0–1% at 1000 N and 2000 N, respectively). As the number of struts in the homeostatic and formation strain ranges may be an important factor for implant bone ingrowth, study of similar cage designs with thinner, and thus more compliant, struts was warranted. Thus, the objective of this study was to extend the previous studies and quantify and compare the strut strains for a trussed cage design with thinner (0.75 mm or 1.00 mm) struts and no instrumentation attachment plate, and to assess what the effect of these designs would have on strut strain levels, in particular, the range predicted to affect bone mechanobiology.

2. Materials and methods

2.1. Study design

This overview of the experimental and analysis approach describes the measures and statistical comparisons used in the study. Strut deformation and strain were determined for multiple cages (n = 2) for truss strut diameters of 1.00 mm or 0.75 mm (Table 1). Cages were loaded by contoured plastic platens to 50 N or 1000 N for 0.75 mm strut diameter and 50 N, 1000 N, or 2000 N for 1.00 mm strut diameter. Loads of 1000 N and 2000 N were selected to represent physiological lumbar load amplitudes of moderate and strenuous activities, respectively (Nachemson, 1975; Schultz et al., 1982). Strain distribution variance, indicative of strut amplitudes in either compression (negative) and tension (positive), was compared for 1000 N and 2000 N loads using Levene's tests (median). (Levene's tests were used to directly compare variance between groups, which other statistical tests, such as ANOVA, assumed to be equal between groups.) Strut strain amplitude and corresponding percentage of struts exhibiting strains within the combined mechanobiological homeostasis + formation (≥ 200 με) ranges were described statistically for each group to show the effect of loading and cage design on potential mechanobiological osteogenic effects. Strut-averaged strain amplitudes (mean of all struts for each cage) and homeostasis + formation percentages were compared between groups by 1-way ANOVA with *post-hoc* Tukey tests. Mean strain was compared with value 0 between all groups for vertically oriented struts to show overall implant axial behavior; in contrast, as a control analysis, the mean strain in all struts was compared to an unloaded mechanical truss (which exhibits net zero strains by definition) and thus was not expected to show a difference. Strut deformation and strain data are reported as mean ± SD calculated in two ways, by assessing (1) the distribution within cages (indicated as cage-averaged) to quantify the distribution of deformation and strain internal to individual cages, or (2) the average of all struts within each cage (indicated as strut-averaged) to quantify the variation between cages. In each study, deformation and strain are reported as the distribution, vertical strut distribution, and amplitudes. Groups were tested for normality by the Kolmogorov-Smirnov test. Sample size was selected based on previous study effective modulus (12.1 ± 2.3 GPa) and 46% projected modulus reduction (strut cross-sectional area change with diameter decrease from 1.25 mm to 1.00 mm) with power of 80%. The significance threshold for all statistics was set to α = 0.05. Statistics were performed using Excel (v2013, Microsoft, Redmond, WA, USA) and SPSS (v23, IBM, Armonk, NY, USA).

Table 1
Study groups for 1.00 mm and 0.75 mm cages loaded at 50 N, 1000 N, or 2000 N.

Study	Strut Diameter [mm]	Load [N]	N
1	0.75	50	2
		1000	2
2	1.00	50	2
		1000	2
		2000	2

2.2. Cage preparation

Cage implants, similar to those studied previously, but with thinner struts and no instrumentation attachment plate, were provided by 4WEB Medical. Contoured polysulfone (an autoclaveable inert plastic; elastic modulus 2.5 GPa) platens that were designed to conform to the biconvex surface of the cage were used to allow distributed compressive loading. Contour match was achieved by designing platens surface curvature to match that of a representative cage, based on μCT imaging. The implants had a trussed design (40 mm ×x 27 mm × 16 mm, L × W × H) and biconvex contour on the top (superior) and bottom (inferior) faces with roughened titanium struts (0.75 mm or 1.00 mm diameter, Fig. 1). Zirconia spheres (0.5 mm diameter) were attached using cyanoacrylate at each vertex (intersection of multiple truss struts) to serve as fiducial markers (88 total).