Exploring the Effect of Pore Size and Distribution on Shear Strength of Surface Porous Polyetheretherkeytone (PEEK)

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Exploring the Effect of Pore Size and Distribution on Shear Strength of Surface Porous Polyetheretherkeytone (PEEK)

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LIST OF ABBREVIATIONS

PEEK	Polyetheretherkeytone

SUMMARY

Cervical spinal fusion cages are primarily used to stabilize intervertebral space and promote fusion between two vertebrae. Current cervical cages are made of either titanium or polyetheretherketone (PEEK), with PEEK recently becoming the more favorable choice due to its MRI compatibility. While previous research reveals ranges of pore diameters ideal for bone ingrowth, the effect of pore size, porosity, layer thickness and strut thickness on mechanical properties such as shear strength for PEEK, are not known at this time.

The goal of this study was to determine the effect of pore size and other parameters on shear strength of surface porous PEEK. Micro-computed tomography (μCT) was used to analyze the porous layers on PEEK and the samples will then undergo shear testing. The data obtained was used to look at trends in parameters and their effect on shear strength in hopes of ultimately optimizing those parameters to promote osseointegration, while maintaining the ability to withstand shear stresses the device will face while implanted in the cervical spinal region of the body.

CHAPTER 1

INTRODUCTION

A cervical spinal fusion cage is a device inserted during arthrodesis to stabilize intervertebral space and allow fusion. Approved by the FDA in 1996[1], this device is estimated to be implanted in over 5,000 patients in the U.S each month[2]. Current cervical cages are made of either titanium or polyetheretherketone (PEEK), with PEEK recently becoming the more favorable choice due to its radiolucent material and mechanical properties similar to that of bone. Clinical research has shown that fusion rates of PEEK are higher than titanium after 12 months, but current PEEK cage designs do not integrate into bone[3]. The addition of a porous scaffold design has been researched with hopes that it will improve the fusion and stability of PEEK, but unfortunately, the specific pore sizes, porosity percentages, layer thickness and strut thickness values for optimal mechanical properties remains unknown[3].

The porosity percentage and pore diameter of bone and biomaterials designed for osseointegration have been determined through previous research. According to a review of 3D biomaterial scaffolds and osseogenesis, trabecular bone has a porosity of approximately 50-90% (1mm pore diameter), while cortical bone has a porosity of 3-12%[4]. Although specific pore sizes and void volumes were not suggested by Karageorgiou et al, it was recommended that a porous scaffold designed for bone ingrowth should have a minimum pore size of 100 µm, with larger pores (>300 µm) favoring direct osseogensis[4]. According to another study on bone tissue engineering by Green et al, pore diameters 150 - 500 µm in scaffold architecture can lead directly to mineralized bone[5]. While previous research reveals ranges of pore diameters ideal for bone ingrowth, the effect of pore size on mechanical properties, such as shear strength, are not known at this time.

The goal of this study was to determine the effect of pore size and other parameters on shear strength of surface porous PEEK. Micro-computed tomography (μCT) was used to analyze various porous PEEK layers of samples that will undergo shear testing. The data obtained was used to look at trends in parameters and their effect on shear strength in hopes of ultimately optimizing those parameters so that the layer will promote osseointegration, while maintaining the ability to withstand shear stresses the device will face while implanted in the cervical spinal region of the body.

CHAPTER 2

LITERATURE REVIEW

Current cervical cages are made of either titanium or polyetheretherketone (PEEK), with PEEK recently becoming a favorable choice of implant due to its radiolucent material and mechanical properties similar to that of bone. Clinical research has shown that fusion rates of PEEK are higher than titanium after 12 months, but current PEEK cage designs do not integrate into bone[3]. The addition of a porous scaffold design has been researched with hopes that it will improve the fusion and stability of PEEK, but unfortunately, the specific pore size for optimal mechanical properties remain unknown[3].

Much research has been done to compare PEEK cages with other cages made out of various materials such as titanium, tricortical bone graphs, and carbon fiber. Chou et al investigated the efficacy of cervical fusion of polyetheretherketone (PEEK) cages, in comparison to titanium cages, and tricortical bone grafts[6]. Physicians implanted the three different types of cages into groups of subjects, and after a 6-month follow up found that there was 100% fusion for the PEEK cages and tricortical bone grafts, and 46.1% for the titanium cages. It was determined that the stiffness and toughness of the PEEK material is similar to cortical bone, which helps contribute to the overall fixation and high fusion rates between the spinal cage and bone within the subjects. This in-vivo study highlighted the high-fusion percentages for both PEEK and tricortical bone grafts in comparison to titanium cages. However, the sample sizes for this study were not consistent across each type of cage. For titanium, PEEK and tricortical bone graft groups, samples sizes were n= 27, n=9, and n=19 respectively, which may have skewed the results for titanium in that there were many more patients and more room for error. Also, the particular PEEK cage used in this experiment had two titanium spikes on the upper and lower frames which helped aid fixation.[6] PEEK cages without this extra mechanical fixation component do not yet exhibit fusion percentages that high[7]. In a study performed by Kersten et al, PEEK cages were compared to titanium cages, bone grafts, and carbon fiber cages in a clinical trial. Although PEEK did exhibit high fusion rates and good clinical outcome scores in this comparative study, there were no differences found between PEEK, titanium and carbon fiber cages.[7] One major difference between these two studies is that the PEEK cages examined were PEEK material with an autograft compared to PEEK cages with two titanium spikes. Without this mechanical fixation component, no differences were found between PEEK and other materials, and it was concluded that PEEK still exhibits a lack of osseointegration[7]. With the clinical evidence from the studies mentioned above, its MRI compatibility characteristics, and opportunity for improvement, PEEK was chosen as the material of choice in this research to examine the addition of a porous layer and improve osseointegration for cervical spinal fusion cages.

One possible method to increase osseointegration of PEEK is the addition of a porous layer. In one particular study, Zhao et al presents various methods used to create a 3D porous layer on PEEK, and then examines the characteristics of this layer both *in vitro* (cellular behavior) and *in vivo* (osseointegration). Two types of treatments tested in this study were SPEEK-W and SPEEK-WA, both of which involved sulfonation, water immersion, water rinsing (SPEEK-W) and an additional acetone rinsing (SPEEK-WA) on PEEK discs. After various analysis techniques including micro-CT, scanning electron microscopy and cell adhesion assays, it was determined that the SO_3H groups on SPEEK-

WA caused greater cytocompatibility, osseointegration and bioactivity in comparison to SPEEK-W and the PEEK control[8]. There are multiple methods of creating a porous layer in recent research, and although these studies give great insight on the successful porous potential of PEEK, little is known about the effect of porosity on mechanical properties. Porosity percentage and pore diameter of bone has been researched and can be a model for the porosity properties PEEK should exhibit for high osseointegration. According to a review of 3D biomaterial scaffolds and osseogenesis, trabecular bone has a porosity of approximately 50-90% (1mm pore diameter), while cortical bone has a porosity of 3-12%[4]. Although specific pore sizes and void volumes were not suggested by Karageorgior et al, it was recommended that a porous scaffold designed for bone ingrowth should have a minimum pore size of 100 µm, with larger pores (>300 µm) favoring direct osseogensis[4]. According to another study on bone tissue engineering by Green et al, pore diameters 150 - 500 µm in scaffold architecture can lead directly to mineralized bone[5]. While previous research creates a foundation for ranges of pore diameters ideal for bone ingrowth, the effect of pore size on mechanical properties, such as shear strength, are not known at this time.

CHAPTER 3

MATERIALS AND METHODS

Microcomputed tomography (μCT) was used to scan and evaluate two types of cervical spinal cages provided by Vertera Inc. The first type of cage (n=4) had a porous layer that was created using an oven, and the second type (n=4) had a porous layer that was created using a hot press. A 8.31mm^2 area of each cage was evaluated for various parameters including BV/TV (PEEK volume/total volume), Tb.Sp (average distance between PEEK struts), Tb.Th (average thickness of PEEK struts), and (1-BV/TV)*100% (porosity). Layer thickness and connectivity were determined once the cage was evaluated using algorithms developed by SCANCO medical.

Shear testing was performed on samples following a procedure adopted from ASTM-1044-05 after μCT scanning is completed. A thin layer of 3M Scotch-weld 2214 non-metallic filled epoxy was used to combine two porous PEEK layers of equal surface area, and samples were then placed in a vacuum oven set to 121°C for one hour to cure. The samples were loaded into test fixtures placed between Instron jaws according to the aligned interfacial test setup as described in ASTM-1044-05 (See **Figure 1**). The test rate was set at 2.54mm/min (0.1in/min), and the test was complete once the sample failed, broke, or the load cell limit was reached. The failure mode was recorded, as well as the first maximum load (ultimate failure load). Shear strength was calculated by normalizing the ultimate failure load by the area of the interface.

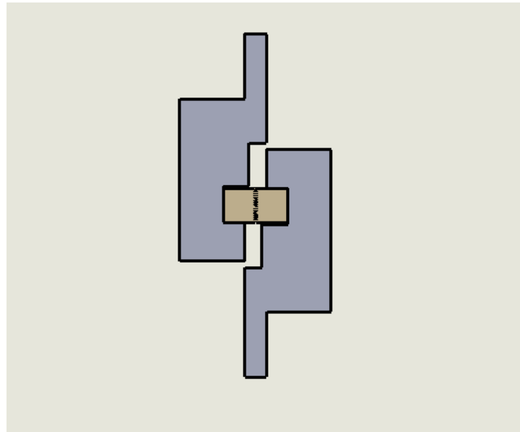

Figure 1: ASTM-1044-05 interfacial test setup for shear testing

CHAPTER 4

RESULTS

Microcomputed tomography (μCT) was used to scan and evaluate two types of cervical spinal cages provided by Vertera Inc. The first type of cage (n=4) had a porous layer that was created using an oven, and the second type (n=4) had a porous layer that was created using a hot-press (see **Figure 2**).

A

B

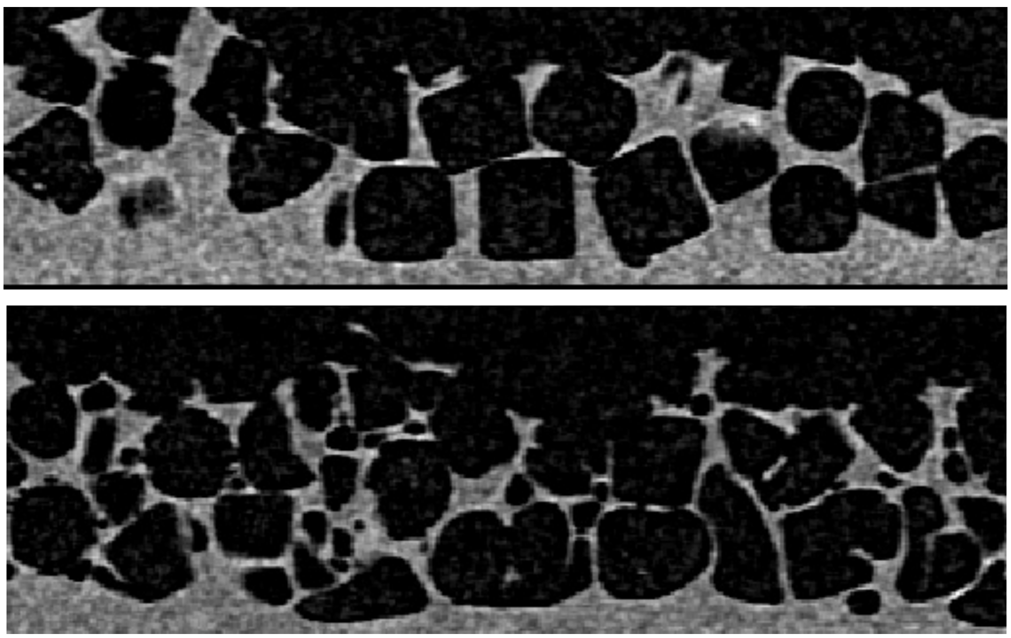

Figure 2. μCT images of cervical spinal cage porous layers created by using **A**) Oven and **B**) Hot-press.

Various parameters including porosity, strut thickness, pore size, layer thickness, and void volume (percent of volume with pores less than 100 μm) were computed for both sets of pore layers. See **Figure 3** for graphs comparing these parameters.

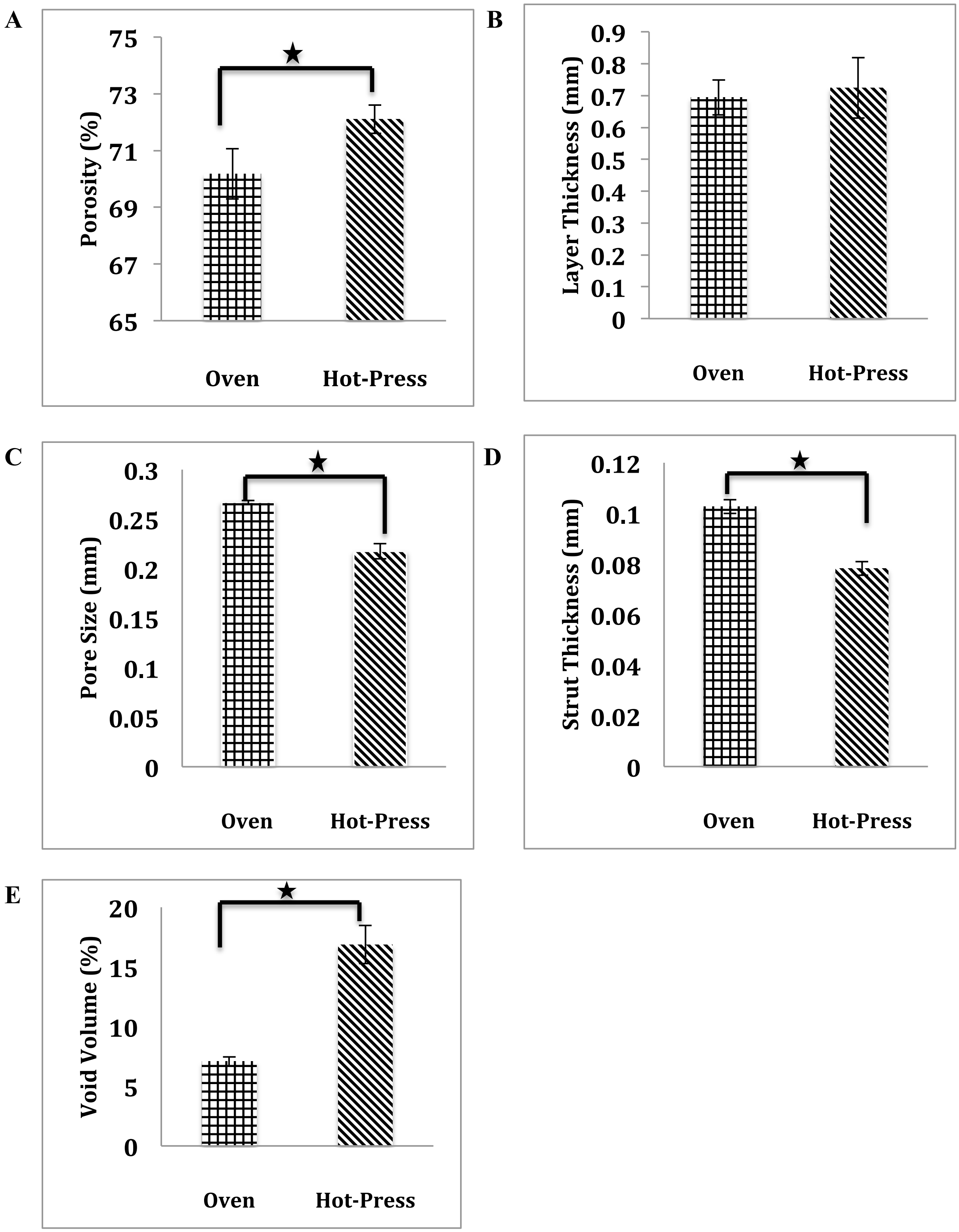

Figure 3: Bar graphs comparing oven and hot-press porous layer samples with parameter averages of **A**) Porosity **B**) Layer thickness **C**) Pore size **D**) Strut thickness and **E**) Void volume

Shear testing was performed on samples following a procedure adopted from ASTM-1044-05 after µCT scanning was completed. See **Figure 4** below.

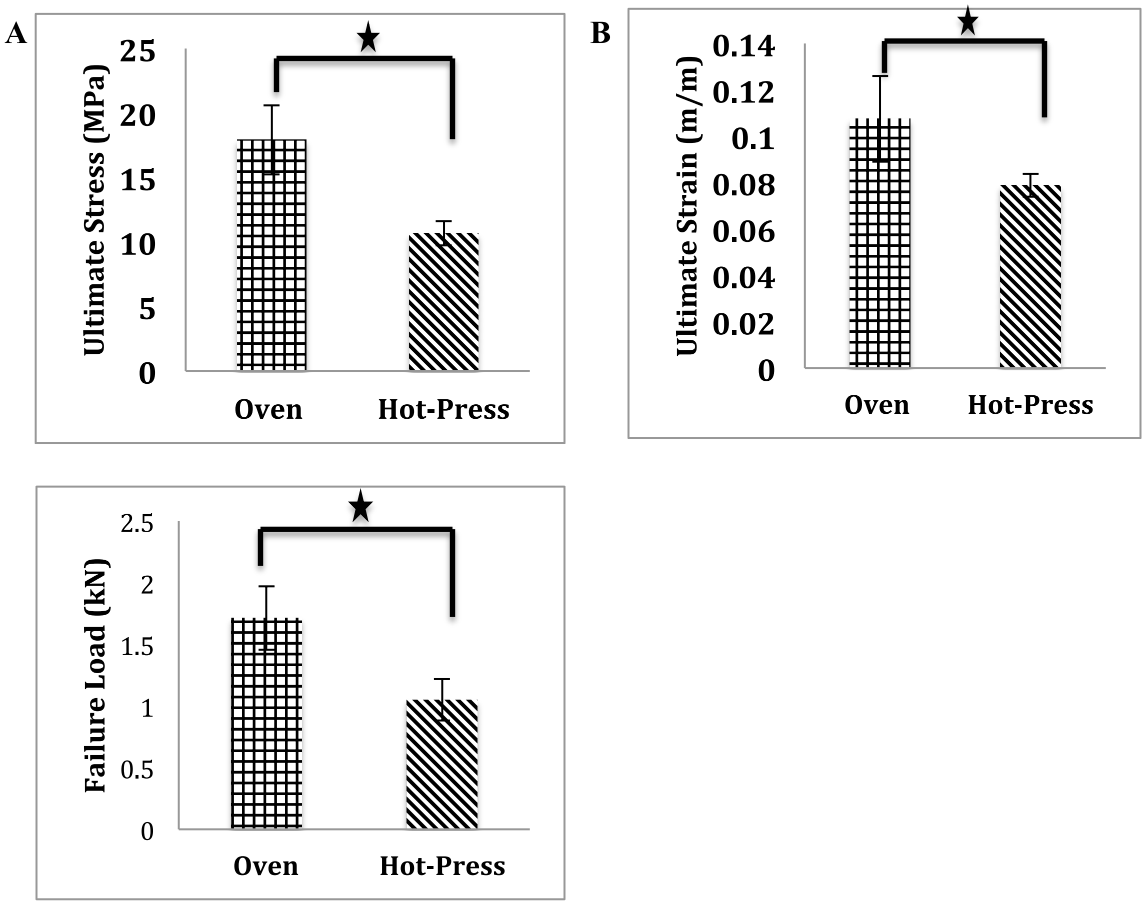

Figure 4: Bar graphs comparing average **A**) Ultimate stress **B**) Ultimate strain and **C)** Failure Load results for oven and hot-press samples during shear testing.

CHAPTER 5

DISCUSSION AND CONCLUSION

Adding a porous layer to a cervical spine cage has many benefits such as improved osseointegration and stabilization in the vertebral region, however, it is unknown how the layer affects mechanical properties such as shear strength. The purpose of this study was to analyze two different sets of porous layers on cervical cages and perform shear testing on those samples.

When comparing porosity, layer thickness, pore size, strut thickness and void volume (defined as the total percent of pore layer with pores less than 100 μm), the only parameter in which the two types of cages were not significantly different was layer thickness with a p value of 0.609 (see **Figure 3**). In terms of shear testing, shear stress, ultimate strain and the failure load were all significantly different for the two sets of samples (see **Figure 4**).

With nearly all parameters significantly different between the two sets of samples, each parameter was graphed against ultimate stress and ultimate strain to determine if there were any correlations between the parameters and shear results. There were no significant correlations between the oven parameters and ultimate stress, with the highest R^2 value obtained being 0.153 for layer thickness. In terms of ultimate strain and oven parameter values, there were no significant correlations, for the highest R^2 value obtained was 0.159 for pore size. There were trends seen when comparing the hot-press sample parameter values to stress and strain values. In terms of ultimate stress, it was suggested that as layer thickness increases, ultimate stress decreases (R^2 = 0.787), as strut thickness increases, ultimate stress increases (R^2 = 0.744) and as void volume increases, ultimate stress increases ($R^2 = 0.859$). For ultimate strain, there were no trends detected, with the highest R^2 value as 0.272 for pore size.

These results suggest that manipulating certain parameter values such as void volume and layer thickness may in fact influence ultimate stress, however due to the nature of the data no definite conclusions can be drawn from simply looking at these trends. It is suggested that future studies look into manipulating each parameter individually, while attempting to keep all others constant to see trends more clearly. Also, it is suggested a larger sample size is used for each group in order to better uncover any significant differences if they happen to exist.

Although the addition of a porous layer to a cervical spinal cage can have added benefits such as better fixation and bone ingrowth, it is important to evaluate its potential effects to shear strength. The results of this experiment, although not extremely significant due to a small sample size (n=4), provide initial insight into the different components of a pore layer in comparison to its ultimate stress and strain values. It is my hope that this research paves a path for improvement of porous layers in future studies and ultimately leads to the success of this technology in the cervical spinal region.

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VITA

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