Surface Porous PEEK Implants Resist Instability in an Unconstrained Femoral Defect

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INTRODUCTION: The stability of orthopaedic implants greatly influences their fixation strength within bone. Excessive movement or micromotion at the bone-implant interface can lead to fibrous layer formation and, ultimately, failure to heal. Two characteristics that influence an implant's susceptibility to motion (and potential failure) are its surface chemistry and topography. Currently used implants made from polyether-ether-ketone (PEEK) provide a relevant clinical example of this concept and motivate the following study. PEEK is the most common material selected for spinal fusion implants; however, recent debate has formed around its poor osseointegration potential. These arguments often reference PEEK's hydrophobic, 'bioinert' surface chemistry as a contributing factor to its poor integration. However, many current PEEK implants are also macroscopically smooth, which could further contribute to instability by not having sufficiently rough features to 'grip' the bone to stay in place. Here we describe the stability and functional performance of smooth PEEK compared to our group's surface porous PEEK (PEEK-SP) technology. PEEK-SP implants possess a thin pore layer (400-600 µm thick) at the bone-implant interface that provides a roughened surface for initial fixation and porous volume for bone ingrowth and long term stability.

METHODS: All implants were Ø 5 mm x 8 mm long solid cylinders made from Zeniva® 500 PEEK (Solvay). All smooth implants possessed a machined surface at both faces ($S_a = 0.38 \pm 0.08$ µm). PEEK-SP surfaces were created only on the proximal face of the implant as described previously using a melt extrusion/porogen leaching process [1]. Three pore sizes of PEEK-SP were studied: 250 µm (SP250), 350 µm (SP350), 450 µm (SP450). All implants contained Teflon radiotracers to aid image analysis. An established rat femoral segmental defect model [2] was utilized to compare PEEK-SP and smooth PEEK surfaces. All surgical procedures were approved under IACUC protocol No. A14045 at Georgia Tech. Briefly, bilateral 8 mm femoral defects were made in the central diaphyses of 13-week old female Sasco Sprague–Dawley rats (Charles River), totaling 50 defects. Femurs were stabilized prior to defect creation using a polysulfone plate. Implants were press-fit into each defect, but no further stabilization was provided (n = 10). Ten defects received autograft bone from the contralateral leg. Animals were scanned using microCT at 4 and 12 weeks. Bone ingrowth was determined by thresholding grayscale images to 50% of native bone density and normalizing bone volume within pores to the empty implant pore volume. Based on percent ingrowth from microCT, a representative sample set was mechanically tested to obtain the failure torque of each interface. Instability was measured by the change in angle between the implant tracers and fixation plate from 4 to 12 weeks, representing axial rotation of the implant over time. Some samples were lost due to imaging artifact or extremely weak interfaces that fell apart prior to mechanical testing. Strength of intact bone was taken from historical lab data. Statistical analysis between groups was conducted using a Kruskal-Wallis 1-way ANOVA followed by Dunn's multiple comparison test (Graphpad Prism). All curve fitting was conducted using Excel (Microsoft). All data is reported as mean ± S.E.M.

RESULTS: Failure torque for each group was: Smooth 0.03 ± 0.01 N-m (n=4); SP250 0.05 ± 0.01 N-m (n=6); SP350 0.10 ± 0.06 N-m (n=7); SP450 0.22 ± 0.09 N-m (n=5); Autograft 0.13 ± 0.03 N-m (n=6) (**Figure 1**). Though the mean failure torque increased with increasing pore size, no significant differences were detected between groups. However, in two cases of robust ingrowth, samples exceeded the failure torque of intact bone. Percent ingrowth for the porous group was: SP250 6.6 ± 3.8 % (n=7); SP350 18.2 ± 11.8 % (n=6); SP450 36.8 ± 14.1 % (n=5). As expected, percent ingrowth was highly correlated with failure torque ($R^2 = 0.921$, $p < 0.001$) (**Figure 2**), though no statistical differences were found between pore sizes. Implant rotation between 4 and 12 weeks for each group was: Smooth 22.3 ± 8.1° (n=7); SP250 5.9 ± 2.7° (n=7); SP350 6.5 ± 4.1° (n=6); SP450 0.6 ± 0.3° (n=5) . Smooth PEEK implants underwent significantly more axial rotation than SP450 ($p < 0.01$) (**Figure 1**). When all porous samples were grouped together, failure torque exhibited a sharp decrease with only a slight increase in axial rotation ($R^2 = 0.53$, $p < 0.05$) (**Figure 2**).

DISCUSSION: The current study investigated the extent to which a single-sided surface porous PEEK implant could resist instability in an unconstrained scenario and assessed what implications this instability had on fixation strength. Overall, smooth PEEK implants exhibited more instability over time than PEEK-SP and this was associated with a general decrease in fixation strength (**Figure 1**). PEEK-SP could contribute to enhanced stability in multiple ways. First, the higher coefficient of frication previously measured for PEEK-SP implants compared to smooth PEEK implants could provide initial stability. Second, bony ingrowth into the porous volume provides longer term fixation through mechanical interlock. Third, the compliant porous interface could keep the bone-implant interface under compression longer than smooth implants, further stabilizing the implant. When all pore sizes are analyzed together, the relationship between instability and fixation becomes more apparent (**Figure 2**). It is interesting that the larger pores seem to resist instability more than smaller pores. One potential explanation is that a larger pore size could require more displacement to break off any stabilizing bony protrusions within the pores on the nearest pore wall, thereby propagating instability. Taken together these results suggest PEEK-SP could substantially improve patient outcomes compared to current clinical practice where the migration, failure and costly revision of PEEK implants is not uncommon.

SIGNIFICANCE: Surface porous PEEK implants could provide a more stable bone-implant interface than current smooth PEEK implants, leading to less implant migration and stronger fixation, which is critical for spinal implants and larger arthroplasty devices.

REFERENCES: [1] Evans, N., et al Acta Biomater, vol. 13, pp. 159-67. 2015.; [2] Oest, M. E. et al J Orthop Res, vol. 25, pp. 941-50, 2007.

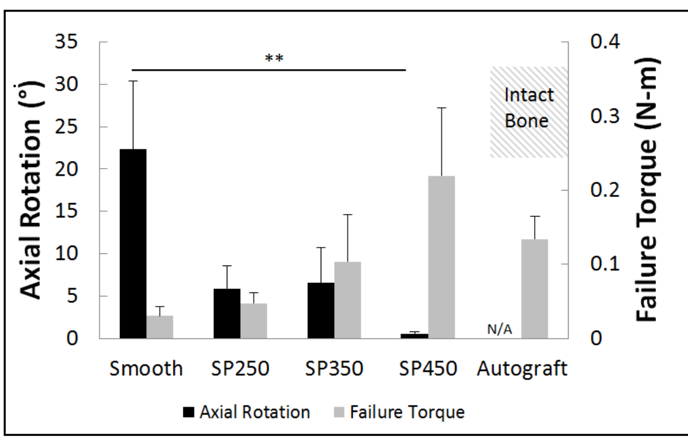

Figure 1: Change in axial rotation of implants from 4 to 12 wks and failure torque of bone-implant interface at 12 wks. Historical range of intact bone is shown for reference. ** p < 0.01

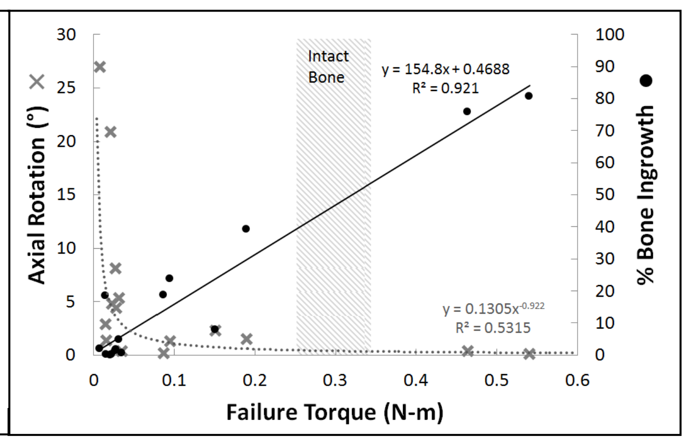

Figure 2: Relation of failure torque with axial rotation and % bone ingrowth of all three pore sizes grouped together.