The holy grail of intervertebral joint fusion is to create a biologically and mechanically stable bony union across the disc space using a fusion device that also enables easy radiographic assessment of the fusion site. This stability is dependent upon the fusion device forming direct contact with bone to create a strong, secure interface. To address this clinical paradigm, device manufacturers are adding various chemical and topographical surface treatments to the fusion device. This White Paper aims to (1) present key findings from the literature on the role of implant surface on stability at the interface and (2) compare the biomechanical performance of two new surface technologies being applied to fusion devices.

**Chemistry vs. Topography: What Matters?**

- **PEEK** (polyether-ether-ketone) is an advantageous implant material due to its durability, modulus matching bone, biocompatibility and radiolucency.\(^1\)

- Titanium (Ti) has shown to exhibit superior osseointegration capabilities compared to PEEK. Instead PEEK produces a fibrous capsule layer that compromises the stability of the bone-implant interface (Figure 1).

- Surface roughness has shown to enhance the osteogenic cell response leading to increased bone formation. Likewise, studies have demonstrated that porous surfaces support bone tissue in-growth, begging the question: do rough or porous surfaces perform better? And does it matter?

- Walsh et. al compared the bone healing response and mechanical properties at the bone-implant interface of various surface treatments (Figure 2) in an ovine model.\(^2,3\)

- Results showed that porous titanium surfaces achieved the highest shear strength compared with plasma-sprayed rough titanium surfaces. There was no difference in shear strength between smooth PEEK and titanium surfaces (Figure 3).

These studies suggest that the strength of the bone-implant interface is dictated by the degree of mechanical interlocking formed between the surface and bone, and NOT by the implant surface chemistry. This mechanical interlocking can also be achieved by providing a 3D porous interconnected network versus a 2D micro-scale rough topography. These results have led manufacturers to add plasma-sprayed “micro-rough” or porous titanium coatings to PEEK implants.
Study Objectives

Based on the suggested advantages described above for porous surfaces, the objective of this study was then to evaluate the mechanical performance of a novel biomaterial PEEK Scoria™ and a rough titanium coating plasma-sprayed on PEEK, a current clinically-used treatment on fusion devices. PEEK Scoria integrates a porous PEEK surface with solid bulk PEEK. Because the porous surface is grown from the bulk material (and not fabricated as a laminated surface), it is hypothesized that this surface will exhibit superior mechanical properties compared with surface-coated PEEK.

Test Methods

(A) Static Tensile Adhesion Strength

Static adhesion testing was performed on both plasma-sprayed Ti on PEEK and PEEK Scoria per modified ASTM F1147-05. Epoxy was applied to the surface-treated side of cylindrical samples (ϕ = 20 mm). Adhered constructs were loaded on an Instron mechanical tester and pulled in tension at 0.25 cm/min until the test sample components had separated. The failure load was determined from the load-displacement curves and strength was defined as the failure load normalized by cross sectional area (n=6). To compare the effects of sample geometry, testing was repeated with each surface treatment on interbody devices with the same surface area (n=10).

(B) Shear Fatigue

Shear fatigue testing was performed following ASTM F1160-05 test methods. Cylindrical samples (ϕ=20mm) were adhered to stainless steel cylinders using epoxy and then tested under force control on the Instron to 8.1 MPa at 40 Hz with an R ratio of 0.18. The test ended when the specimen failed or until a run out of 10^7 cycles had been reached (n=3).

Results: Tensile Adhesion Strength

Scoria exhibited higher tensile adhesion strength compared with plasma-sprayed Ti on both cylinder and cage samples. The strength of both surface treatments was reduced on cage samples that had less surface area compared with the cylinders. Values represent average +/- standard deviation.
Results: Shear Fatigue Strength

At an 8 MPa maximum stress level (above the reported range of shear strength for trabecular bone\(^4\),\(^5\)), none of the PEEK Scoria samples failed after 10,000,000 cycles. All of the plasma-sprayed Ti samples failed at the Ti coating-PEEK interface before 10,000,000 cycles.

Conclusions

- These results indicate that surface porous PEEK Scoria adheres more strongly to bulk PEEK compared with plasma-sprayed titanium suggesting PEEK Scoria could be a more durable surface treatment on PEEK cage devices.

- Static tensile adhesion testing demonstrated that the strength of surfaces on ASTM test coupon geometries does not translate to the same adhesion strength on actual device geometries. The reduced strength on cage samples can partially be attributed to the presence of more edges on the perimeter, where usually more flaws are present, relative to the cross sectional area.

- Because Scoria is grown directly from the bulk device to form one continuous layer, the interface between surface porous PEEK and solid PEEK is almost twice as strong as plasma-sprayed Ti on PEEK in the final

References:


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