Introduction: Plasmapore® pure Titanium porous coatings have been applied to Titanium orthopedic and spinal implants for over twenty years. The osteoconductive coating is intended to increase primary and secondary implant stability by creating a favorable foundation for bone ingrowth due to the balanced relationship between pore depth, porosity, and roughness. When combined with primary implant fixation, the increased surface roughness of the Plasmapore coated implant ensures immediate stability of the motion segment. Secondary stability is provided by the Plasmapore coating when bone growth into the coating occurs after a short period of time. Pull-out tests have shown and documented complete bony integration of Plasmapore coated Titanium implants after 16 weeks.

Aesculap modified the original Plasmapore coating technology to develop Plasmapore XP, an osteoconductive pure Titanium porous coating that is applied to PEEK interbody implants. The roughened surface provided by the Plasmapore XP coating is projected to have a substantial mechanical effect on the pull-out force and stability of the coated PEEK interbody implants, similar to that of Plasmapore on Titanium implants. The roughness provided by the Plasmapore XP coating allows for a greater surface area of the implant to be in direct contact with bone. Mechanical testing has shown that the addition of the Plasmapore XP coating increases the resistance to expulsion of the PEEK implant in the lumbar spine by 4 times without the use of supplemental fixation.

Mechanical testing was performed to evaluate the adhesion strength of the Plasmapore XP coating to PEEK interface. Static tensile strength and static shear strength tests were performed according to a Center for Devices and Radiological Health (CDRH) recognized industry guidance document. This industry guidance document contains recommended evaluation criteria, test methods and end points per American Society for Testing and Materials (ASTM) standards for metallic spray coatings. In summary, the static tensile strength and static shear strength results for the Plasmapore XP coating were substantially higher than the requirements recommended in the industry guidance document, and Plasmapore XP was found to have a high adhesion strength to the PEEK implant surface.

Methods

I. Static Tensile Strength (ASTM F1147-05)

To determine the static tensile strength of the Plasmapore XP coating at the coating-PEEK interface, a test was conducted by the method described in ASTM F1147-05. ASTM F1147-05 covers tension testing of porous metal coating/substrate combinations, and is designed to provide information on the adhesive or cohesive strength of coatings under uniaxial tensile stress. The test consisted of an assembly of a Plasmapore XP coated PEEK sample and a TiAl6V4 counterpart, attached together with an adhesive (FM1000 adhesive film). A test sample is shown in Figure 1.

Samples were assembled and fixed in a tensile testing machine (Z1485, Zwick GmbH & Co.KG). The test setup is shown in Figure 2. Once positioned, a tensile load was applied normal to the plane of the coating (see red arrow in Figure 2) at a constant speed (.25cm/min). The test was concluded once the specimen was completely separated, and the maximum load applied was recorded.
II. Static Shear Strength (ASTM F1044-05)

To determine the static shear strength of the Plasmapore®XP coating at the coating-PEEK interface, a test was conducted by the method described in ASTM F1044-05. ASTM F1044-05 covers shear testing of porous metal coating/substrate combinations, and is designed to provide information on the adhesive or cohesive strength of coatings under a uniaxial shear stress. The test consisted of an assembly of two Plasmapore®XP coated PEEK samples, attached together with an adhesive (FM1000 adhesive film). A test sample is shown in Figure 3.

Samples were assembled and fixed in a tensile testing machine (Z1485, Zwick GmbH & Co.KG). The test setup is shown in Figure 4. Once positioned, a load was applied in line with the plane of the coating (see red arrow in Figure 4) at a constant speed (.25cm/min). The test was concluded once the specimen was completely separated, and the maximum load applied was recorded.

Results

I. Static Tensile Strength (ASTM F1147-05)

The fracture surfaces of the sample specimens were examined after static tensile strength testing. A fracture surface of a sample is shown in Figure 5. The failure of the PEEK is indicative of the adhesion strength between the PEEK and coating. The PEEK breakage indicates that the adhesion strength of the coating on the substrate exceeds the tensile strength of the PEEK material.

Testing results show that the adhesion strength of the Plasmapore®XP coating to the PEEK implant surface was significantly higher than the minimum requirement recommended by the industry guidance document per ASTM standard test method F-1147. Tensile strength

| Average Tensile Strength per ASTM F1147-05 |
|----------------|-----------------|
|                | MPa             |
| Plasmapore®XP  | Industry Rec.   |
| 35              | 20              |
| 30              | 15              |
| 25              | 10              |
| 20              | 5               |
| 15              | 0               |

Figure 6: Comparison of mean tensile strength of Plasmapore® coated samples to the industry recommended requirement.
testing results are shown in Figure 6. The mean tensile strength measured for the Plasmapore®XP coated samples was 30.2 MPa, which is well above the minimum industry recommended tensile strength requirement of 22 MPa. Therefore, Plasmapore®XP has a high adhesion strength to PEEK.

II. Static Shear Strength (ASTM F1044-05)

The fracture surfaces of the sample specimens were examined after static shear strength testing. A fracture surface of a sample is shown in Figure 7. The PEEK breakage indicates that the adhesion strength of the coating on the substrate exceeds the shear strength of the PEEK material.

Testing results show that the shear strength of the Plasmapore®XP coating to the PEEK implant surface was significantly higher than the minimum requirement recommended by the industry guidance document per ASTM standard test method F-1044. Shear strength testing results are shown in Figure 8. The mean shear strength measured for the Plasmapore®XP coated samples was 32.4 MPa, which is well above the minimum industry recommended shear strength requirement of 20 MPa.

It has been reported that the maximum physiological shear forces existing in situ are approximately 400N in the intact lumbar spine. The highest stress would be on the smallest implant, approximately 530mm² of contact area. Therefore the stress at the implant/bone interface should never exceed 0.75 MPa. This translates into a high factor of safety for the Plasmapore®XP coating in regards to shear stresses that occur in the Lumbar spine.

Discussion

Analysis of qualitative and quantitative results for testing described in this document reveals that the Plasmapore®XP coating has a high adhesion strength to the PEEK implant surface. It can be concluded that the adhesion strength of the Plasmapore®XP coating to PEEK interbody implants is strong enough to ensure continuous attachment in vivo.

References

1 Data on file

Note: The data presented in this report is based on mechanical testing of the Plasmapore® coating and may not be predictive of clinical performance.