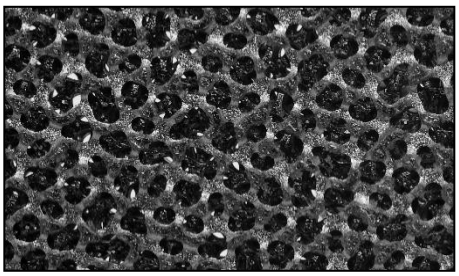
Abrasion Characteristics of *OsteoSync™ Ti*

Sites Medical Research and Development

Introduction

OsteoSync™ Ti* is a three-dimensional, open-celled titanium scaffold for bone and tissue ingrowth (Figure 1). An important trait is its resistance to abrasive mass loss during implantation, which is superior to that of other clinically available porous coatings.

Figure 1:

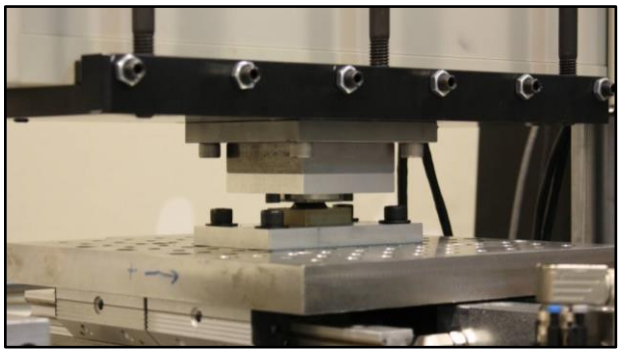


A close-up view of the *OsteoSync* Ti microstructure.

Materials and Methods

To simulate *OsteoSync* Ti abrasion due to implantation and/or micromotion after implantation, the procedure outlined in the FDA guidance document "Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement" was followed[1,2]. To summarize, a hardened cylinder was pressed against a test specimen at a specified normal load and cycled back-and-forth for 10 cycles (Figure 2). Seven different normal forces were used, and 3 different specimens were tested for each load. Abrasion was measured by quantifying the % mass loss of the test coupons.

Figure 2:

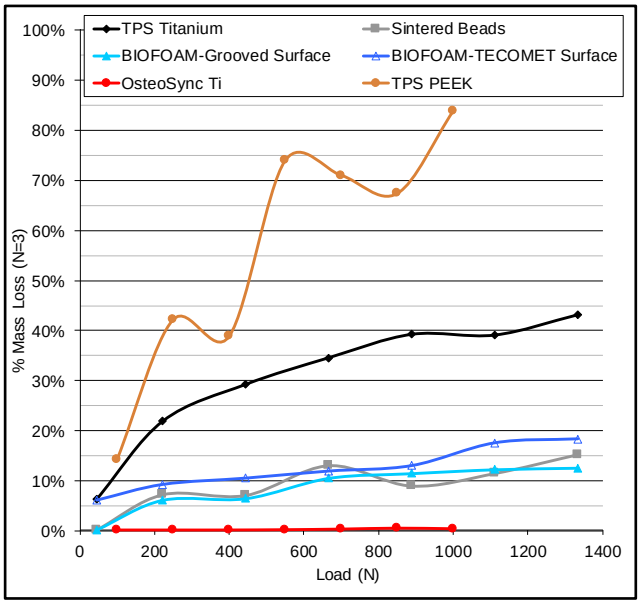


The abrasion test. The cylinder has been pushed into the *OsteoSync* Ti specimen at a specified normal force and is cycled normal to its axis.

Results

It was found that *OsteoSync* Ti is highly resistant to abrasion, as an insignificant amount of mass loss (0.193%) was measured at the largest test load (1000 N, Figure 3). This compares favorably to other commercially available coatings tested per the same FDA guidance document procedure. For example, the percentage mass loss of titanium plasma spray (TPS) applied to titanium, titanium sintered beads, and Biofoam have been reported as ~39%, ~9% and ~11-13% at a test load of 890 N[3]. Likewise, percentage mass loss of TPS applied to a PEEK substrate has been measured as 84% at a test load of 1000N (Figure 4)[4]. Thus, mass loss of *OsteoSync* Ti due to abrasion was significantly less than that of these clinically used coatings, even when tested at higher normal loads.

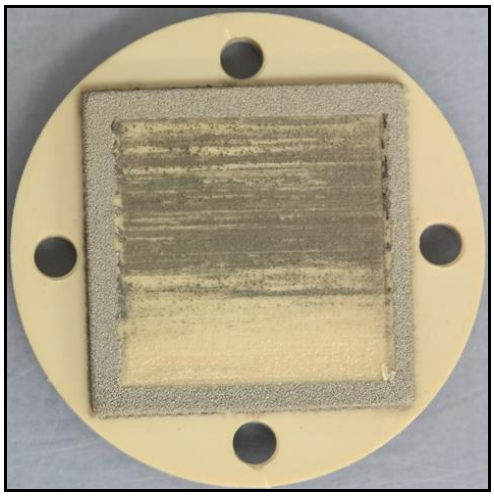
Figure 3:



Percent Mass Loss %Δm as a function of applied load[2-4]. Data points for TPS Titanium, Sintered Beads, and Biofoam were taken from a graph in the literature and are estimated to be accurate to ±1%[3]. At all loads tested, *OsteoSync* Ti abrasion was negligible and significantly lower than that for the other porous scaffolds.

* Also marketed as *BioSync Ti*® and *FortiCore*®

Figure 4:



TPS PEEK abrasion after application of a 1000N load. The TPS coating in the 25 mm x 25 mm test region has been completely removed.

Conclusion

OsteoSync Ti is inherently resistant to abrasive wear, and it exhibits significantly less abrasive mass loss than other clinically available porous coatings.

References

1. Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement. FDA. 1994.
2. Sites Medical Report 2007-001-20. "BioSync Ti: An Assessment of Abrasion During Implantation." REV B. 2011.
3. Biofoam Technical Monograph MI023-109. Wright Medical. 2009.
4. Sites Medical Report 2011-006-03. "Ti Plasma Coated PEEK: An Assessment of Abrasion During Implantation." REV A. 2015.