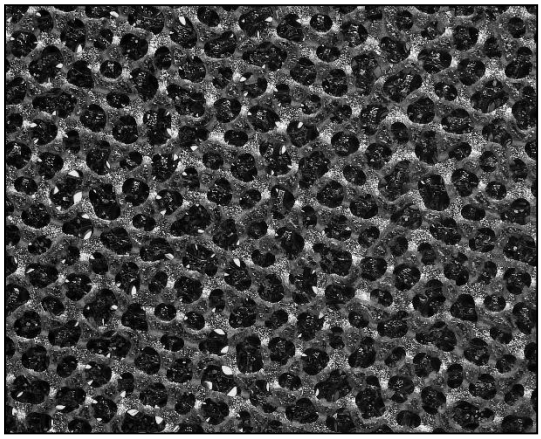
Mechanical Characteristics of *OsteoSync™ Ti*

Sites Medical Research and Development

Introduction

OsteoSync™ Ti* is a three-dimensional, open-celled titanium scaffold for bone and tissue ingrowth (Figure 1). It can be used as a standalone implant or combined with metal or polymer components to provide a region for bone ingrowth.

Figure 1:



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

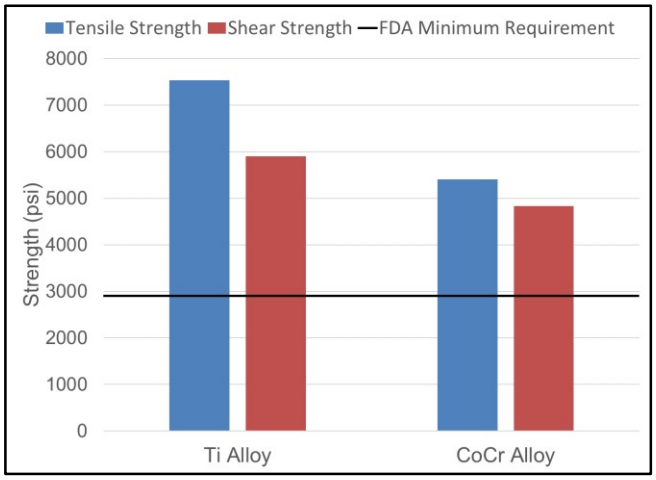
OsteoSync Ti has a mean porosity of 58.8%, pore sizes ranging from 434-660 µm, and a mean pore interconnectivity of 229 µm[1]. It is manufactured from grade 2 commercially pure titanium satisfying ASTM F67[2]. *OsteoSync* Ti can be manufactured in thicknesses of 0.5 mm and greater. The standard thickness for most implants is 1 mm. If desired, *OsteoSync* Ti can be machined before or after it is attached to a substrate.

OsteoSync Ti can be metallurgically attached to pure Ti, Ti alloy, or CoCr alloy substrates using a proprietary diffusion bonding process. *OsteoSync* Ti also can be combined with a polymer via injection or compression molding.

Mechanical Strength

Strength requirements for metallic scaffolds are specified in the FDA's 1994 guidance document "Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement"[3]. The scaffold and scaffold/substrate interface must satisfy a static strength of 20 MPa in both tension and shear, and the scaffold must be fatigue tested to 10 million cycles. Figure 2 displays the static strength results of *OsteoSync* Ti when combined with different metal substrate types as tested per ASTM defined methods[4-7]. Due to fixture failure rather than sample failure during some of these tests, these reported strengths are lower than the actual *OsteoSync* Ti/substrate strengths. Still, all results satisfied FDA requirements. Likewise, 10 million cycle fatigue testing for each of these substrate/*OsteoSync* Ti combinations exceeded 10 MPa, a strength level reported for the porous coating on a hip implant already cleared by the FDA[4-5,8-9].

Figure 2:



Static strengths of *OsteoSync* Ti when combined with various metal substrates. Due to fixture failure rather than sample failure during some of these tests, these reported strengths are lower than the actual sample strengths. Even so, all strengths satisfied FDA requirements.

Corrosion

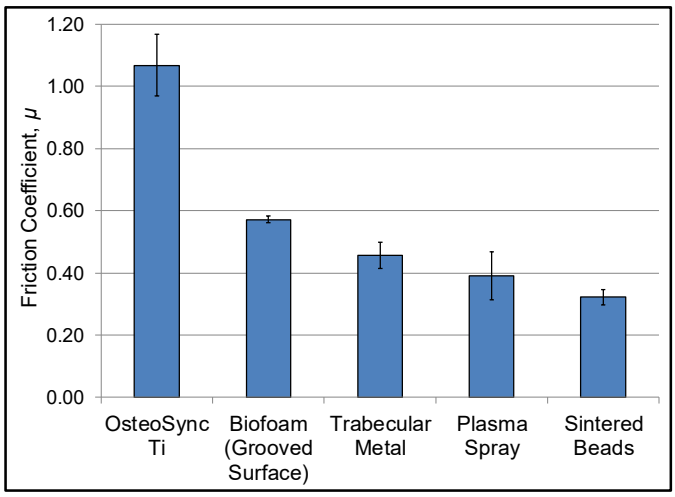
Implant corrosion was assessed for the cases where *OsteoSync* Ti is diffusion bonded to a dissimilar substrate (CoCr)[10,11]. Long-term and accelerated soak tests based on the methods outlined by Medlin were performed[12]. To summarize, *OsteoSync* Ti was diffusion bonded to either wrought or cast CoCr substrates. These specimens were then submerged in mammalian Ringer's solution for either a minimum of 6 months at 37±1°C and or a minimum of 3 months at 50±2°C. Throughout the soak tests, the specimens were removed from the tanks periodically and inspected for signs of corrosion. Corrosion was not detected on any specimen at any point, whether at the interface between the CoCr substrate and *OsteoSync* Ti scaffold or within the *OsteoSync* Ti scaffold. This was the case regardless of specimen type, soak test condition, or manufacturing history of the parts.

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

Friction Coefficient

The frictional characteristics of *OsteoSync* Ti were assessed by performing friction testing of *OsteoSync* Ti against simulated bone using the methods outlined by Shirazi-Adl[13,14]. To test, a vertical load normal to the *OsteoSync* Ti/10 pcf sawbone bone interface was applied to the material couple. Then, a horizontal displacement was applied at a constant rate to the simulated bone. The resulting friction force was recorded. Friction coefficient was then defined as the peak friction force divided by the nominal normal force. A friction coefficient of 1.07 (St. Dev = 0.10) was determined. This was significantly greater than the reported friction coefficient values for Biofoam®, Trabecular Metal®, plasma-sprayed Ti, and sintered beads tested against simulated bone (Figure 3)[15].

Figure 3:

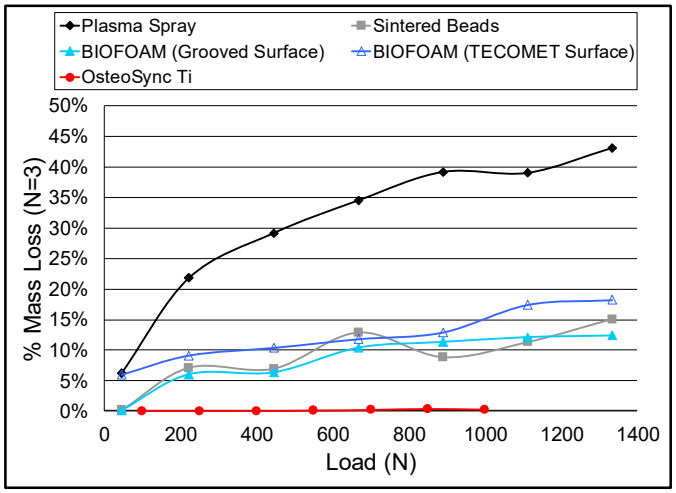


Friction coefficient of bone ingrowth materials tested against 10 pcf SAWBONE. Results for materials other than *OsteoSync* Ti were taken from Brownhill[15].

Abrasive Wear Analysis

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[3,16]. To summarize, a hardened cylinder was pressed against a test specimen at a specified normal load and cycled back-and-forth for 10 cycles. 7 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. It was found that *OsteoSync* Ti is inherently resistant to abrasion, as an insignificant amount of mass loss (0.193%) was measured at the largest test load (1000 N, Figure 4). For comparative purposes, the percentage mass loss of commercially available coatings such as titanium plasma spray, titanium sintered beads, and Biofoam have been reported as ~39%, ~9% and ~11-13% at a test load of 890 N[17]. 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 4:



Percent Mass Loss %Δm as a function of applied load. Data points for materials other than *OsteoSync* Ti were taken from a graph in the literature and are estimated to be accurate to ±1%[17]. At all loads tested, *OsteoSync* Ti abrasion was negligible and significantly lower than that for the other porous scaffolds.

Mechanical comparison to other bone ingrowth scaffolds

As discussed above, the mechanical characteristics of *OsteoSync* Ti compare favorably to other clinically used porous coatings and bone ingrowth scaffolds. For reference, Figure 5 displays the mechanical properties of *OsteoSync* Ti along with those of some other bone ingrowth scaffolds.

Conclusion

The mechanical performance of *OsteoSync* Ti, an open-celled titanium scaffold for bone and tissue ingrowth, has been assessed through extensive testing. *OsteoSync* Ti satisfies FDA strength requirements, and it does not corrode when combined with a CoCr implant substrate. It has better friction characteristics and results in less abrasive wear than other clinically available bone ingrowth scaffolds.

Figure 5:

	OSTEOSYNC Ti	ZIMMER TRABECULAR METAL	ZIMMER FIBER METAL	WRIGHT MEDICAL BIOFOAM	BIOMET REGENEREX	DEPUY GRIPTION
MANUFACTURING PROCESS	Diffusion Bonding	Chemical Vapor Deposition[19]	Diffusion Bonding[21]			Sintering[23,24]
POROSITY	58.8%[1]	75-80%[20]	40-50%[21]	60-70%[17]	67%[21]	63%[23]
MEAN PORE SIZE (µm)	523[1]	440[20]	100-400[21]	530[17]	300[21]	300[23]
COEFFICIENT OF FRICTION	>1[14]	.46-.98[15,21,22]	0.63[21]	.58[17]		1.2[23]
MASS LOSS TO ABRASION	0.19%[16]			13%[17]		
STRUCTURAL STIFFNESS (GPa)	8.8[18]	2.5-3.9[21]	106-115[21]	2.9[17]	1.6[21]	

The mechanical characteristics of *OsteoSync* Ti as compared to other clinically used porous coatings and bone ingrowth scaffolds.

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