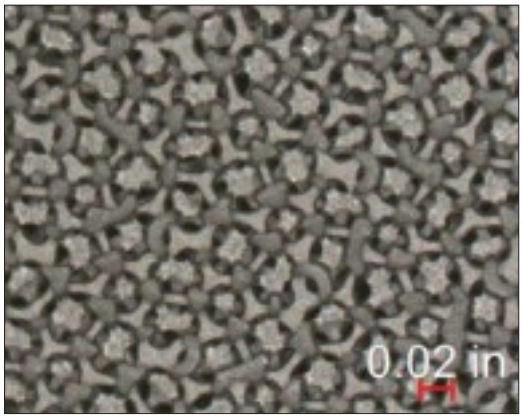
Mechanical Characteristics of Arthrex® BioSync® Structure

Arthrex Research and Development

Introduction

Arthrex BioSync structure 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 BioSync microstructure.

BioSync structure 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] BioSync structure can be manufactured in thicknesses of 0.5 mm and greater. The standard thickness for most implants is 1 mm. If desired, BioSync structure can be machined prior to its attachment to a substrate.

BioSync structure can be metallurgically attached to pure Ti, Ti alloy, or CoCr alloy substrates using a proprietary diffusion bonding process. More specifically, the following substrate materials have been verified and fully characterized:

- Commercially pure (CP) Ti satisfying ASTM F67[2]
- Wrought Ti64 ELI satisfying ASTM F136[3]
- Wrought CoCr alloy satisfying ASTM F1537, alloys 1 or 2[4]
- Cast CoCr alloy satisfying ASTM F75[5]

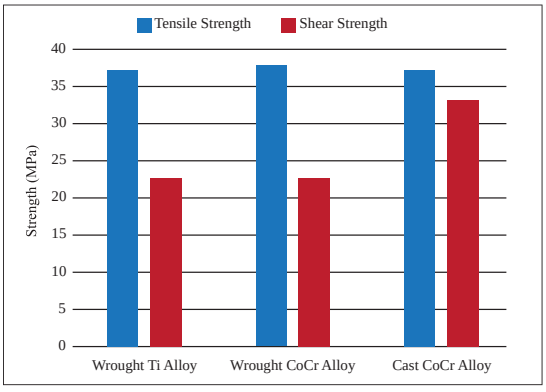
BioSync structure also may be applied to substrate types other than the ones specified above after the completion of all necessary testing.

BioSync structure can be combined with a polymer via injection or compression molding. For example, injection molding a polycarbonate urethane articulating surface onto a BioSync cylinder (SynACART) and PEEK between two BioSync endplates to create a spine fusion cage. Likewise, UHMWPE has been compression molded into a BioSync base (e.g. acetabular shells, tibial components). In all of these cases, the polymer flows into a portion of the BioSync structure without filling it completely during molding. This creates a mechanical interlock between the BioSync structure and polymer while still maintaining a region of fully porous BioSync structure for bone ingrowth.

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"[6]. 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 BioSync structure when combined with three different metal substrate types as tested per ASTM defined methods.[7-11] Due to fixture failure rather than sample failure during some of these tests, these reported strengths are lower than the actual BioSync structure/substrate strengths. Still, all results satisfied FDA requirements. Likewise, 10 million cycle fatigue testing for each of these three substrate/BioSync structure combinations exceeded 10 MPa, a strength level reported for the porous coating on a hip implant already cleared by the FDA.[7-9,12]

Figure 2:



Static strengths of BioSync structure 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

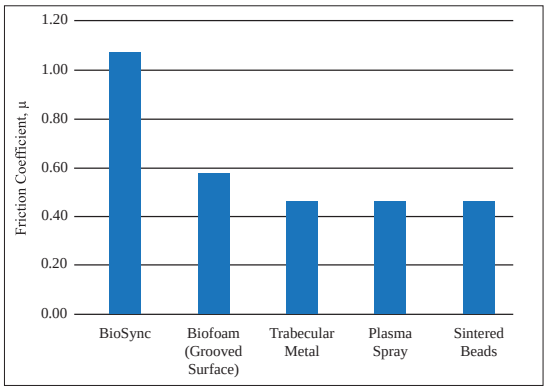
Implant corrosion was assessed for the cases where BioSync structure is diffusion bonded to a dissimilar substrate (CoCr).[13,14] Long-term and accelerated soak tests based on the methods outlined by Medlin were performed.[15]

To summarize, BioSync® structure 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 BioSync scaffold or within the BioSync scaffold. This was the case regardless of specimen type, soak test condition, or manufacturing history of the parts.

Friction Coefficient

The frictional characteristics of BioSync structure were assessed by performing friction testing of BioSync structure against simulated bone using the methods outlined by Shirazi-Adl.[16,17] To test, a vertical load normal to the BioSync structure/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 Wright Biofoam®, Zimmer Trabecular Metal®, plasma-sprayed Ti, and sintered beads tested against simulated bone (Figure 3).[18]

Figure 3:

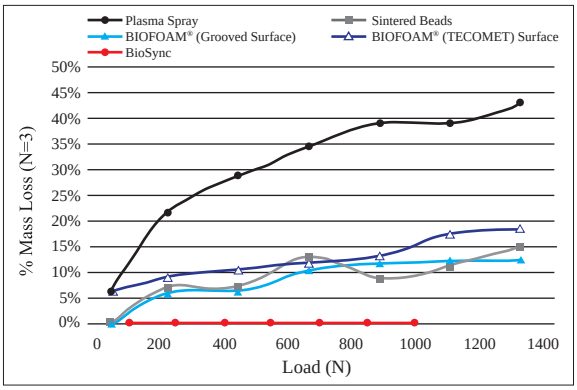


Friction coefficient of bone ingrowth materials tested against 10 pcf SAWBONE. Results for materials other than BioSync structure were taken from Brownhill.[18]

Abrasive Wear Analysis

To simulate BioSync structure 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.[6,19] To summarize, a hardened cylinder was pressed against a test specimen at a specified normal load and cycled back-and-forth for 10 cycles. Seven different normal forces were used, and three different specimens were tested for each load. Abrasion was measured by quantifying the mass loss of the test coupons. It was found that BioSync structure 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.[20] Thus, mass loss of BioSync structure 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 BioSync were taken from a graph in the literature and are estimated to be accurate to ±1%.[20] At all loads tested, BioSync structure 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 BioSync structure compare favorably to other clinically used porous coatings and bone ingrowth scaffold. For reference, Figure 5 displays the mechanical properties of BioSync structure along with those of some other bone ingrowth scaffolds.

Conclusion

The mechanical performance of BioSync structure, an open-celled titanium scaffold for bone and tissue ingrowth, has been assessed through extensive testing. BioSync structure 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.

	Arthrex® BioSync®	Zimmer® Trabecular Metal®*	Zimmer Fiber Metal	Wright Medical™ Biofoam®*	Biomet Regenerex®*	DePuy Gription®*
Manufacturing Process	Diffusion Bonding	Chemical Vapor Deposition[22]	Diffusion Bonding[24]			Sintering[26,27]
Porosity	58.8%[1]	75-80%[23]	40-50%[24]	60-70%[20]	67%[24]	63%[26]
Mean Pore Size (µm)	523[1]	440[23]	100-400[24]	530[20]	300[24]	300[26]
Coefficient of Friction	>1[17]	0.46-0.98[18,24,25]	0.63[24]	0.58[20]		1.2[26]
Mass Loss to Abrasion	0.19%[19]			13%[20]		
Structural Stiffness	3.2[21]	2.5-3.9[24]	106-115[24]	2.9[20]	1.6[24]	

The mechanical characteristics of BioSync structure as compared to other clinically used porous coatings and bone ingrowth scaffolds.

References

1. Sites Medical Report 2007-001-18. BioSync Ti: A Microstructure Assessment. REV B. 2011.
2. ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant.
3. ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.
4. ASTM F1537, Standard Specification for Wrought Cobalt -28Chromium -6Molybdenum Alloys for Surgical Implants.
5. ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants.
6. Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement. FDA. 1994.
7. Sites Medical Report 2007-001-16. Bonding BioSync Ti to a Wrought Ti64 Substrate: A Strength Assessment. REV A. 2011.
8. Sites Medical Report 2007-001-15. Bonding BioSync Ti to a Wrought CoCr Substrate: A Strength Assessment. REV B.
9. Sites Medical Report 2007-001-32. Bonding BioSync to a Cast CoCr Substrate: A Strength Assessment. REV A. 2014.
10. ASTM F 1147, Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings.
11. ASTM F 1044, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings.
12. FDA PMA P050016. Cormet Hip Resurfacing System. Approved 2007.
13. Sites Medical Report 2007-001-22. A Corrosion Assessment of BioSync Ti Bonded to Wrought CoCr Alloys. REV A.
14. Sites Medical Report 2012-001-01. A Corrosion Assessment of BioSync Bonded to Cast CoCr Femoral Knees Manufactured with Castings from IMDS. REV B. 2014.
15. Medlin, D.J., Scrafton, J., and Shetty, R. Metallurgical Attachment of a Porous Tantalum Foam to a Titanium Substrate for Orthopedic Applications. Journal of ASTM International v.2 n.10 (2005).
16. Sites Medical Report 2007-001-23. The Friction Properties of BioSync Ti. REV A. 2011.
17. Shirazi-Adl A, Dammak M, Paiement G. Experimental determination of friction characteristics at the trabecular bone/porous-coated metal interface in cementless implants. *J Biomed Mater Res.* 1993;27(2):167-175.
18. Brownhill J, Wong K, Obert R, et al. Biofoam Cancellous Titanium Fixation for Orthopedic Implant Applications: Lateral Column Lengthening. Wright Medical Document FA499-909. 2010.
19. Sites Medical Report 2007-001-20. BioSync Ti: An Assessment of Abrasion During Implantation. REV B. 2011.
20. Biofoam Technical Monograph MI023-109. Wright Medical. 2009.
21. Arthrex Test Report APT2444. "BioSync, Compression Test Cylinder. REV 0. 2014.
22. Bobyn JD, Stackpool GJ, Hacking SA, Tanzer M, Krygier JJ. Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. *J Bone Joint Surg Br.* 1999;81(5):907-914.
23. Bobyn JD, Hacking SA, Chan SP, et al. Characterization of new porous tantalum biomaterial for reconstructive orthopaedics. Scientific Exhibition: 66th Annual Meeting of the American Academy of Orthopaedic Surgeons; 1999; Anaheim, CA.
24. Levine, B. A New Era in Porous Metals: Applications in Orthopaedics. Advanced Engineering Materials. 10 (2008): 788-792.
25. Zhang Y, Ahn PB, Fitzpatrick DC, Heiner AD, Poggie RA, Brown TD. Interfacial frictional behavior: cancellous bone, cortical bone, and a novel porous tantalum biomaterial. *J Musculoskelet Res.* 1999;3(4):245-251.
26. Gription. The New Look of Fixation. DePuy Form 0612-38-506. 2007.
27. Pinnacle Acetabular Cup System Design Rationale. DePuy Form 0612-25-505. 2007.

**Registered by respective owner*
BioSync® is a registered trademark of SMED-TA/TD, LLC