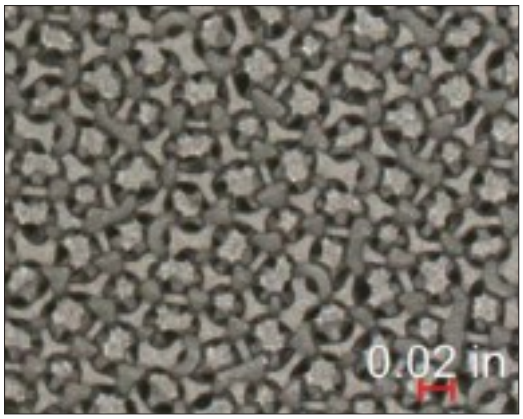
Bone Ingrowth Performance of Arthrex® BioSync® Structure

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 F672. 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]

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

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) or 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 the polymer while still maintaining a region of fully porous BioSync structure for bone ingrowth.

Ingrowth Assessment using a Canine Cementless Total Hip Model (Dynamic Model)

The first animal study for assessing the bone ingrowth characteristics of BioSync structure employed a canine cementless total hip model.[6] A hip model was selected because of the preference to use a dynamic model rather than a static one. A dynamic model results in micromotion between the bone and scaffold. This is the worst case situation for ingrowth structures. Thus, a dynamic hip model allowed this effect to be examined during the study.

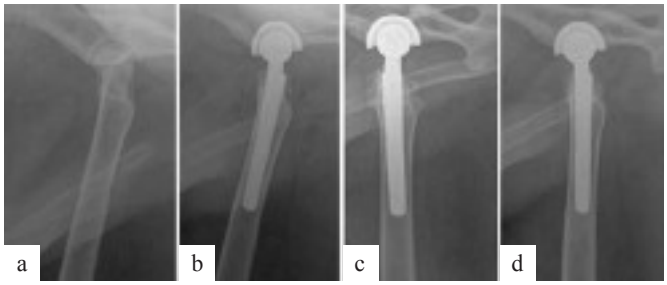
Figure 2:

The device for the canine total hip study. Clinically available canine hip stems (BioMedtrix BFX) were modified to remove the standard sintered beaded coating and replace it with BioSync pads on the anterior and posterior surfaces in the proximal region of the stem.

A cementless hip stem with BioSync structure was implanted unilaterally into six animals at Purdue University. Clinically available hip stems (BioMedtrix BFX) were modified to remove the standard beaded coating and replace it with BioSync pads on the anterior and posterior surfaces in the proximal region of the stem (Figure 2). The endpoints assessed were subsidence and bone and tissue ingrowth into the BioSync scaffold at a time point of 12 weeks.

Using open leg lateral radiographs, stem subsidence was assessed by comparing the stem position at 6 weeks and 12 weeks post-surgery to its location immediately after surgery to measure distal displacement (Figure 3). Subsidence was less than 3 mm in all cases. A previous study considered stem subsidence to be present if distal displacement was 3 mm or more.[7] Thus, stem subsidence for this study was negligible, demonstrating good fixation and performance of the implant.

Figure 3:



Open leg lateral radiographs used to assess subsidence. a) Pre-surgery. b) Post-surgery. c) 6 weeks. d) 12 weeks.

Bone ingrowth was quantitatively assessed through morphometric analysis of transverse sections taken through the femur and implant in the proximal, middle, and distal regions of the BioSync® pads (Figure 4). The results indicated excellent bone and tissue ingrowth into BioSync structure. At 12 weeks, bone and tissue ingrowth, defined as the percentage of available void space filled with bone and tissue, was 75.4%. Comparative results from the literature:

- Average bone ingrowth for fiber metal ranging from 23-38% was reported in 12 week studies using a canine THR model[8,9]
- Average bone ingrowth for fiber metal ranging from 14.1-37.3% was reported in 6 month studies using a canine THR model[10-14]
- Average bone ingrowth for sintered beads ranging from 23.2-23.3% was reported in 6 month studies using a canine THR model[13,15]
- Average bone ingrowth for Trabecular Metal (Hedrocel®) ranging from 10.8-20.9% per histological site was reported in a 6 month study using a canine THR model[16]

Figure 4:

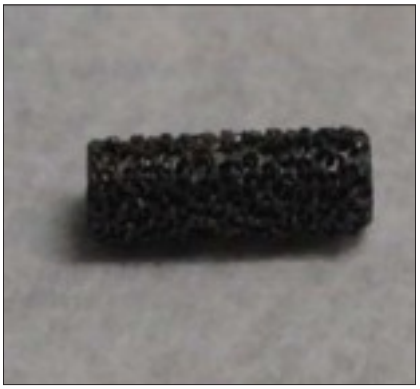
A proximal histological slide used to assess bone ingrowth.

It must be emphasized that this was a 12-week study, so greater ingrowth into other scaffolds might have been expected at time points longer than 12 weeks. However, this was not the case. In comparing this study to the literature cited above via two sample t-tests, ingrowth into BioSync structure was statistically greater than that for fiber metal at 12 weeks and 6 months, sintered beads at 6 months and trabecular metal at 6 months when similar models (canine THR) were employed.

Ingrowth Assessment using a Canine Long Bone Model (Static Model)

Bone ingrowth into BioSync structure has been assessed in a static canine long bone model as part of a larger study conducted by Medtronic.[17] Ø4 mm x 10 mm long cylindrical pins were implanted in five cortical and two condylar locations (medial and lateral) along the femur (Figure 5). Two time points were examined, 6 and 24 weeks. Integration of test pins was assessed through push-out testing and histology. Push-out testing was performed on three cortical pins for each time point. Likewise, a qualitative histological assessment was performed on two cortical and three condylar pins for each time point.

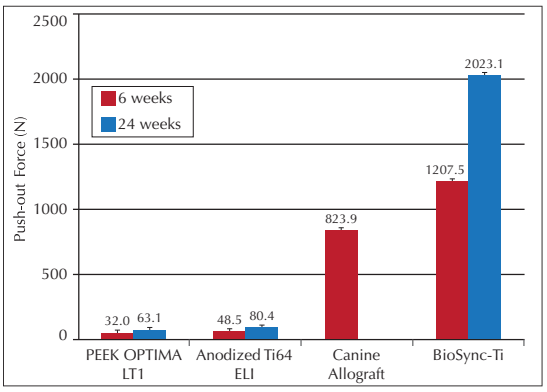
Figure 5:



The BioSync structure test pin.

BioSync structure displayed push-out strengths that were significantly higher than the PEEK, anodized Ti64, and canine allograft controls (Figure 6). At 6 weeks, BioSync structure had an average push-out force of 1207.5 N, which was 38X the push-out force for PEEK (32.0 N), 25X the push-out force for anodized Ti64 (48.5 N), and 1.5X the push-out force for canine allograft (823.9 N). At 24 weeks, BioSync structure had an average push-out force of 2023.1 N, which was 32X the push-out force for PEEK (63.1 N) and 25X the push-out force for anodized Ti64 (80.4 N). (To date, allograft push-out data for 24 weeks has not been received).

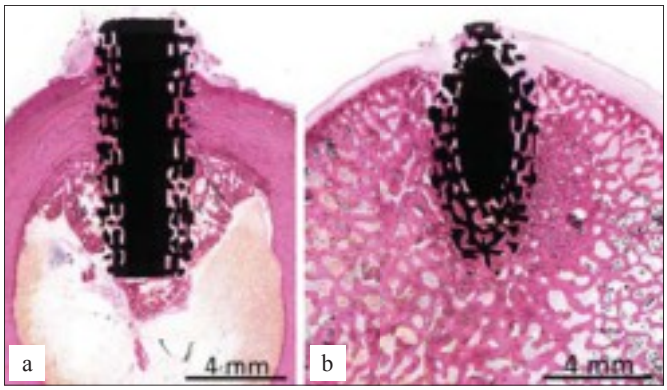
Figure 6:



BioSync structure push-out results.

The push-out results correlated well to the histological assessment of BioSync® structure, which showed excellent cortical and trabecular bone ingrowth at both 6 and 24 weeks (Figure 7). Cortical pins showed nearly complete infiltration of the BioSync scaffold with cortical bone at both 6 and 24 weeks, with no apparent difference in ingrowth between the two time points. Based upon a qualitative assessment of the slides, 90-100% of the available BioSync structure void space was filled with cortical bone. Similarly, the condylar pins showed good infiltration of BioSync structure with trabecular bone, with a qualitative estimate that more than 75% of the available void space was filled with bone. As with the cortical pins, no difference between the amounts of bone ingrowth at the two time points was apparent. These data compared well with data from an earlier study where a canine hip model was used to assess bone ingrowth into BioSync structure.[6] As indicated in the earlier study, bone ingrowth results for BioSync structure compared favorably to the literature.[8-16]

Figure 7:



6 week BioSync structure histological slides.
a) Cortical plug. b) Condylar plug.

Ingrowth Assessment using a Canine Osteochondral Model (Dynamic Model)

Ingrowth into BioSync structure has been examined using a canine osteochondral model.[18] The 10 mm SynACART osteochondral plugs, consisting of a polycarbonate urethane articulating surface injection molded into a BioSync component, were implanted into six animals at the University of Missouri (Figure 8). Implantation was in either the medial (n=3) or lateral (n=3) femoral condyle on the right knee. At a time point of 11 weeks, a qualitative assessment of bone ingrowth into the BioSync component was made.

Figure 8:

A 10 mm SynACART osteochondral implant. The polycarbonate urethane articulating surface is backed by a BioSync structure bone ingrowth region.

Based upon radiographs obtained at sacrifice, the location and orientation of all implants appeared unchanged. An arthroscopic examination of the joints revealed stable implants that did not move when probed with a blunt obturator.

Histological slides were used to make a qualitative assessment of bone ingrowth into the BioSync component of the implant (Figure 9). Osteoconductivity was defined as degree of definitive bone ingrowth into the implants and was categorized as poor (<25%), fair (25-50%) or good (>50%). Osteoconductivity of the BioSync component of the implants ranged from fair (4 of 6) to good (2 of 6). Similarly, integration was defined as total tissue ingrowth into the implants in conjunction with the presence or absence of associated necrosis, inflammatory or immune cell response, or absence of tissue (interface gap), and was subjectively categorized as poor, fair or good. Integration of the BioSync component of the implants was considered good for all six implants.

Figure 8:

A histological slide used to qualitatively assess bone ingrowth.

Bone Ingrowth Comparisons to Other Scaffolds

As discussed above, the bone ingrowth characteristics of BioSync structure compare favorably to other clinically used porous coatings and bone ingrowth scaffold. For reference, Figure 9 displays the bone ingrowth characteristics of BioSync structure along with those of some other bone ingrowth scaffolds.

Conclusion

The bone ingrowth performance of BioSync structure, an open-celled titanium scaffold for bone and tissue ingrowth, has been assessed through multiple animal models. In all studies, BioSync structure has displayed excellent bone ingrowth results, especially when compared to other clinically available bone ingrowth scaffolds and porous coatings.

	Arthrex® BioSync®	Zimmer® Trabecular Metal™*	Zimmer Fiber Metal	Wright Medical™ BIOFOAM®*	Biomet Regenerex®*
Ingrowth at 2 weeks		13.3%[19]			16%[22]
Ingrowth at 3 weeks		23.0%[19]	9.5%[20]	45%[21]	
Ingrowth at 4 weeks		41.5-52.9%[19]	16.6%[13]		55%[22]
Ingrowth at 6 weeks			22.4%[20]	62%[21]	
Ingrowth at 12 weeks	75%[6]		23-35%[8]	62%[21]	
Ingrowth at 16 weeks		63.1-69.2%[19]			74%[22]
Ingrowth at 24-26 weeks	85-95%[17]		32.4-37%[11,13]		85%[22]
Ingrowth at 52 weeks		70.6-79.7%[19]	29.9%[11]		

The bone ingrowth characteristics of BioSync structure as compared to other clinically used porous coatings and bone ingrowth scaffolds. Differences in these values compared to ones found in the discussion of the canine hip model used to assess BioSync structure are due to the fact that animal models other than the canine hip model are included in this data.

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