ADVANCE® BIOFOAM™

Cancellous Titanium

Fixation With Bite

TECHNICAL MONOGRAPH

WRIGHT.

Contents

Introduction

With the recent advances in biological ingrowth and porous coatings in the orthopaedic industry, the prospects for reliable, long-term cementless fixation continue to become a reality. BIOFOAM™ Cancellous Titanium represents a new generation in cementless fixation. This novel material provides a true trabecular structure and enhanced rigid fixation to allow ingrowth through the osteoconductive matrix.

chapter 1

In vivo Animal Testing

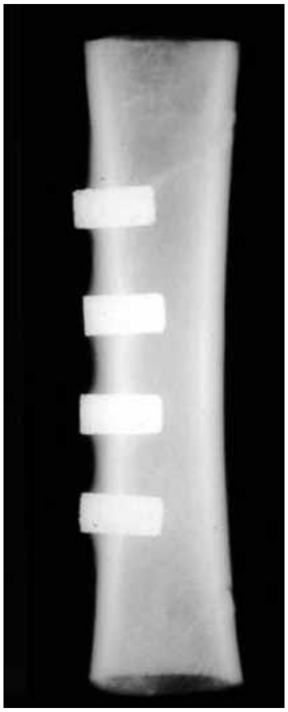


Figure 1 Canine Diaphyseal Bone Model

Study 1: Canine Diaphyseal Model[1]

An *in vivo* canine study was performed at Rush University Medical Center to determine shear strength and early bone ingrowth of BIOFOAM™ Cancellous Titanium at 3, 6, and 12 weeks. This model has been used extensively over the last twenty years to analyze porous coatings. More recently, it has been utilized by J.D. Bobyn to analyze Trabecular Metal™ (*Zimmer, Inc.*). The goal of this study was to provide a basis of comparison for BIOFOAM™ Cancellous Titanium to published results for Trabecular Metal™[2] and porous bead coatings.

Method

Cylindrical implants measuring 5.3mm x 10mm were placed in the femoral diaphyses of nine dogs (three at each time point). **Figure 1** Implants fabricated from sintered titanium beads were used as controls. Specimens implanted in one femur were used for biomechanical testing. Identical implants placed in the contralateral limb were used for histology.

Shear Strength: At the end of the in-life period, the femurs were harvested and high resolution contact radiographs were taken. Implants from the limb designated for histology were isolated and immediately placed in 10% buffered formalin for fixation. Individual implant sites from the limb designated for mechanical testing were isolated with approximately 2-3cm of surrounding bone. The specimens were then individually packed and frozen until testing.

When testing commenced, specimens were thawed to room temperature while immersed in saline. Endosteal bone that had grown around the portion of the implant within the medulary canal was carefully removed so only the cortical bone ingrowth would contribute to the observed strength.

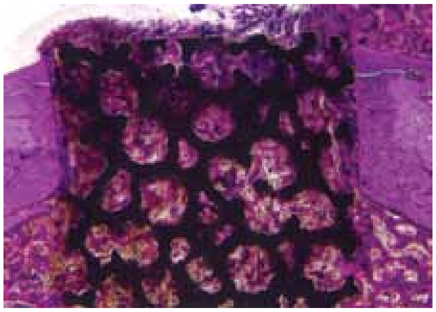
Custom fixtures were used to hold the specimens, with the specimen axis parallel to the load train of the test machine, during potting with fast curing acrylic. Implants were pushed into the bone at a constant rate of 0.5mm/min using an Instron servo-hydraulic test frame. Values were determined for the maximum load, and the shear stress was calculated as the load divided by the surface area of the porous coating in contact with bone. Non-parametric statistical analysis was used for comparisons.

Histological Analysis: Fixed specimens were plastic embedded, ground to the mid-line of the implant, and sputter coated for scanning electron microscopy. Specimens were then stained with basic fuscia and toluidine blue for histological analysis. **Figures 2 and 3** Point counting was used to determine the percentage of bone, soft tissue, and metal within each section and group means were calculated. In addition the percentage of bone was normalized to the amount of available space for ingrowth (normalized % = bone% / percent porosity) for comparison to published literature.

Sintered Beads

Figure 2 Histology of Sintered Bead specimens at 3 weeks (T) and 12 weeks (B). Original magnification = 20X*

BIOFOAM™ Cancellous Titanium



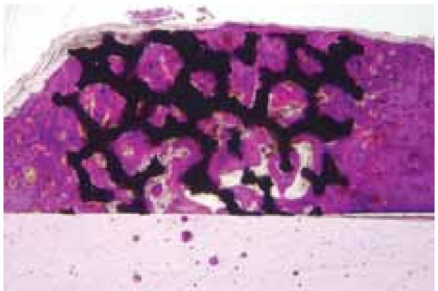


Figure 3 BIOFOAM™ Cancellous Titanium – Grooved at 3 weeks (T) and 12 weeks (B) Original magnification = 20X*

Results

The push-out force at the three and 12 week samples can be seen in **Figure 4 and Figure 5** for BIOFOAM™ Cancellous Titanium and conventional sintered metal beads. The mean push-out strength for the BIOFOAM™ metal group was higher at both the three and 12 week intervals over conventional beads but the difference was not statistically significant (p=0.155 at 3 weeks and 0.083 at 12 weeks). Both groups had a significantly higher shear strength at 12 weeks compared to the three week data (p=0.05).

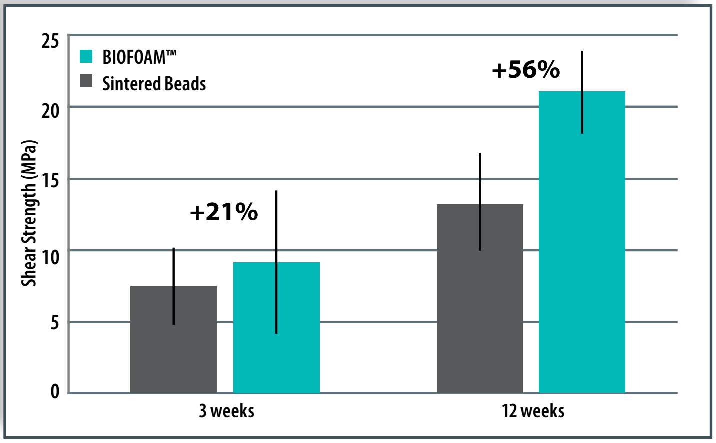


Figure 4

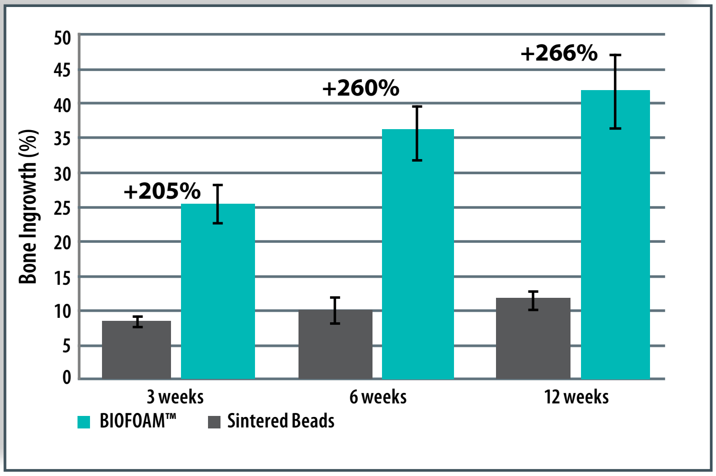


Figure 5

Qualitatively the stained sections showed excellent incorporation, with direct apposition of new bone to BIOFOAM™ metal. There was no evidence of an inflammatory reaction and the new bone tissue appeared normal. The mean percentage of bone within the implant sites was higher for the BIOFOAM™ metal at all three time points, but the difference was only statistically significant at 12 weeks (p=0.027). Notably, there was more bone present in the metal foam specimens than there was space available for bone ingrowth in the sintered bead controls.

Discussion

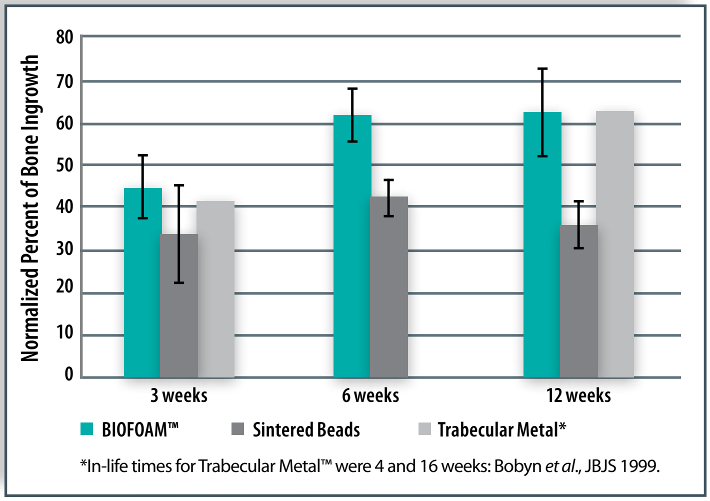


Figure 6

BIOFOAM™ Cancellous Titanium demonstrated excellent incorporation into the host bone and exhibited significantly higher amounts of bone ingrowth compared to traditional sintered bead specimens. In order to allow comparisons with published literature from similar studies, the amount of bone in BIOFOAM™ metal was normalized to the amount of open space within the implant. The results of this transformation are shown in **Figure 6** along with data for a reticulated tantalum foam *(Trabecular Metal™, Zimmer, Inc.)* taken from a study by Bobyn *et al.*,[2] in which a biomaterial with similar morphology and porosity was studied in a canine trans-cortical model. This comparison shows that BIOFOAM™ Cancellous Titanium and Trabecular Metal™ support similar levels of bone ingrowth when implanted into equivalent sites. A similar comparison could not be made with shear strength data because Bobyn *et al*. employed a testing method which did not give meaningful results at longer in-life times due to deformation of the tantalum foam specimens during the test.

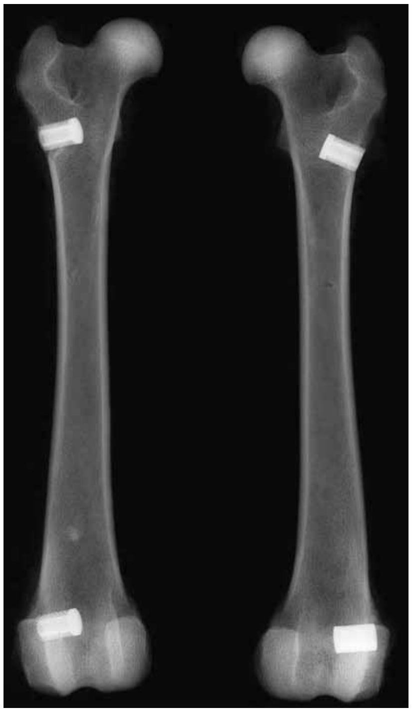


Figure 7 Canine Metaphyseal Bone Model

Study 2: Canine Metaphyseal Model[3]

An *in vivo* canine study was performed to determine the amount of bone ingrowth and apposition, and the shear strength and mode of failure of bone attachment to BIOFOAM™ Cancellous Titanium and conventional metal bead coating at six weeks. This is a unique model developed at Rush University Medical Center to estimate the ingrowth properties of a porous coating in bone that closely approximates proximal tibial bone.

Method

Cylindrical implants measuring 8mm x 12mm were implanted bilaterally into the proximal and distal femoral metaphyses of four dogs. **Figure 7** Each dog received a control cylinder with sintered titanium beads and three foam metal-coated cylinders ranging in porosity and pores size.

After 6 weeks the animals were euthanized and the implant sites were taken en-bloc with approximately 4cm of surrounding bone. Specimens were individually packed and frozen until testing.

Prior to testing, the implants were thawed in saline. Custom fixtures were designed to imbed the bone specimens such that the axis of the cylindrical implant was parallel to the axis of the test machine actuator. A threaded rod was screwed into the implant axis and the implant was pulled out at a rate of 0.5mm/min. Shear strength of attachment to bone (pull-out force divided by the bone-porous coating contact area) was determined.

The amount and depth of bone ingrowth and the interface apposition of bone were determined from backscattered scanning electron microscope (SEM) images of undecalcified histological sections prepared from the implants after mechanical testing.

Results

The mean area fraction of bone ingrowth was greater in the foam metal implants (14.6± 4.3%) compared to the bead implants (9.9±1.3%) but the difference was not statistically significant (p=0.165). The mean interfacial shear strengths ranged from 4.6 to 5.0 MPa for BIOFOAM™ Cancellous Titanium implants compared to 5.7 MPa for the bead controls. The greater apposition of bone with the BIOFOAM™ implants was primarily reflected in the sample's mode of failure, which tended to be in the surrounding bone compared to the bead implants, which failed at the bone-implant interface. **Figure 8** For this reason, the biomechanical tests may have underestimated the true strength of the BIOFOAM™ metal bone interface, which most likely was greater than the strength of the surrounding native bone.

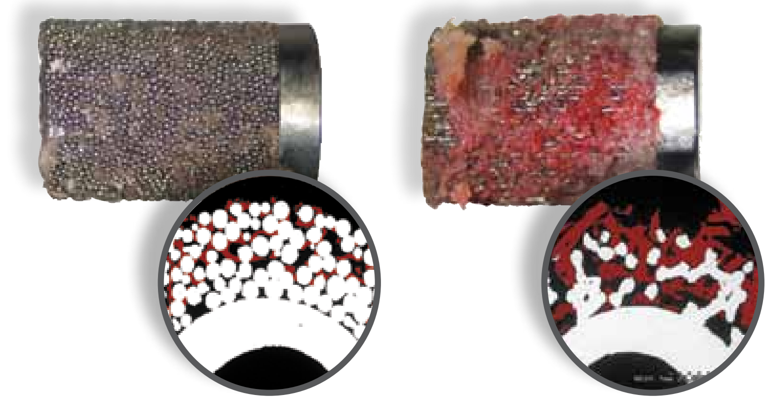


Figure 8 Notice the integration of bone completely down to the substrate with the BIOFOAM™ Implant as compared to traditional sintered beads.

Discussion

This unique canine model is a more accurate representation of how BIOFOAM™ metal will incorporate into metaphyseal bone when implanted as a surface coating on a titanium implant. The full interconnecting porosity of the material allows deep bone ingrowth through the porous layer and to the substrate within a 6 week interval. This type of ingrowth indicates early bone incorporation leading to a well-fixed implant.

Mechanical Properties

chapter 2

BIOFOAM™ Metal Structure

Cancellous or trabecular bone is composed of a network of rod- and plate-like elements that provide porous macrostructure for blood vessels and marrow. Trabecular bone accounts for only 20% of total bone mass, but has nearly ten times the surface area of compact bone.[4]

The structure of BIOFOAM™ Cancellous Titanium resembles that of trabecular bone. **Figure 9** The pore cell size averages 530µm and the diameter of interconnecting pores averages 200µm. The porosity is between 60 and 70%, demonstrating equivalent compressive and flexural strength to commercially available porous tantalum products.

The resemblance to bone and the open cell structure allows deep bone ingrowth that is responsible for long-term stability.

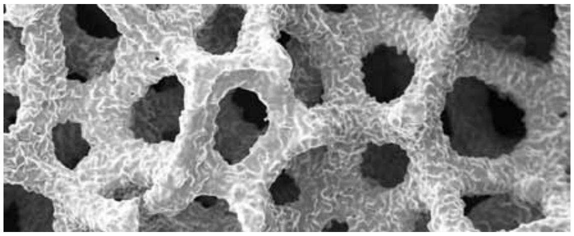


Figure 9 Scanning Electron Micrograph (SEM) of BIOFOAM™ metal coating. (100x original magnification).

Compressive Modulus

The compressive modulus is defined as "the ratio of compressive stress to compressive strain below the proportional limit." It is a normalized measure of a material's stiffness. It measures how much a material compresses under load without permanently deforming. To reproduce the natural loading properties of trabecular bone, BIOFOAM™ titanium was engineered to have an open cell structure similar to bone. This facilitates even and consistent bone loading to prevent stress shielding, promote long-term ingrowth, and enhance stability.

Cylinders measuring 8mm in diameter and 12mm in length were machined from BIOFOAM™ and Trabecular Metal™. A total of seventeen cylinders were obtained from three bulk BIOFOAM™ lots ranging from 67% to 71% porosity. A total of seven cylinders were machined from the porous tantalum parts. The specimens were tested on a load frame at a strain rate of -0.333mm/sec. The percent porosity was estimated for each cylinder based on cylinder weight and volume and the published densities of pure titanium and tantalum.

The compressive strength of BIOFOAM™ metal is between that of trabecular bone and cortical bone, shown in **Figure 10**. BIOFOAM™ metal also appears to have greater compressive strength than Trabecular Metal™ in the limited sample size. The compressive modulus of BIOFOAM™ material compared to bone and Trabecular Metal™ can be seen in **Figure 11**. BIOFOAM™ Cancellous Titanium will not only stay strong in compression to withstand impaction and repeated load, its compressive modulus will potentially transfer applied load in a natural fashion to the native bone. This may reduce radiolucent lines and stress shielding.

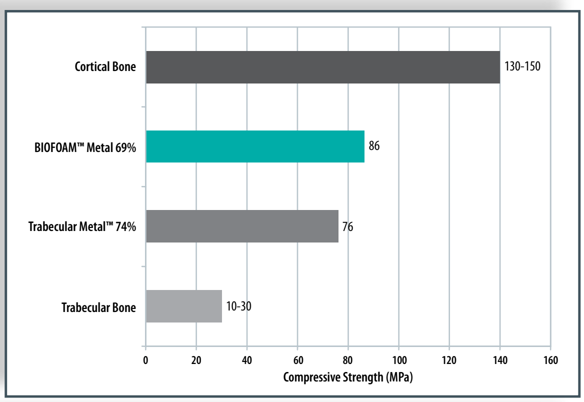


Figure 10 Compressive strength of BIOFOAM™ metal as compared to bone and Trabecular Metal™

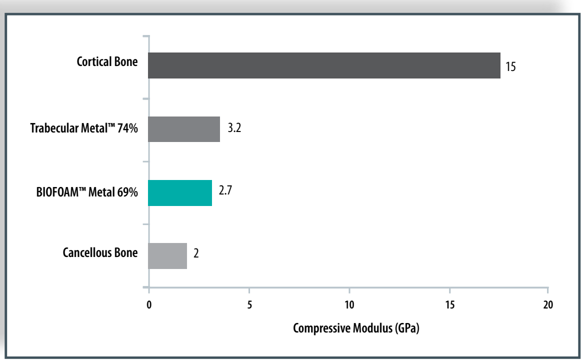


Figure 11
Compressive modulus of BIOFOAM™ metal as compared to bone and Trabecular Metal™

Abrasion Properties[4]
Since the advent of the press-fit coating, particulate debris from those coatings has been a concern for surgeons. Abrasion testing was performed on BIOFOAM™ titanium to ensure it would not scratch, break, or flake off in the body, creating third body particles.

Three coating types, shown in **Table 1**, were bonded to Ti6Al4V substrates (30x30x6mm). BIOFOAM™ titanium surfaces were textured by wire electro-discharge matching.

Table 1

Group	Description	% Porosity
A	3-layer CP Ti porous beads	30-40%
B	0.5mm CP Ti plasma spray	0%
C	BIOFOAM™ Cancellous Titanium	67%

Abrasion Test Results
Abrasion testing was performed per the FDA guidance for modified metallic surfaces. A hardened metal cylinder was held against the porous surfaces at a constant load and cycled back and forth over the same 25x25mm portion of the specimen surface for ten cycles. The minimum load (the lowest load that produced a detectable loss on the specimen surface) and the maximum load (the load that removed at least 50% of the specimen or caused significant deformity) were determined. The specimens were then tested at five loads equally spaced between the minimum and maximum load.

Abrasion results are shown in **Figure 12**. Plasma spray showed a much lower abrasion resistance than both the porous beads and BIOFOAM™ Cancellous Titanium. There was no significant difference between beads and BIOFOAM™ titanium. The ability to withstand abrasion comparable to conventional porous coatings, combined with an almost 100% increase in porosity, gives BIOFOAM™ titanium a distinct advantage over other ingrowth and ongrowth surface. It has the ability to withstand surgical impaction and still maintain a 70% porous stratum to allow complete osseous integration.

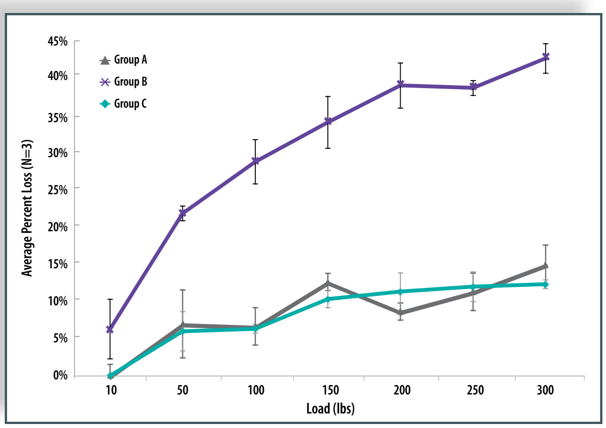


Figure 12 Abrasion resistance of BIOFOAM™ Cancellous Titanium compared to sintered beads and plasma spray

Frictional Properties

Frictional resistance provides initial stability between the implant and bone, thereby helping prevent the implant from movement immediately following implantation. Immediate rigid fixation is crucial to the ingrowth process. If the implant is moving, it is no longer working as a stable construct for bone growth, and the bone will not be able to attach itself to the implant for long-term fixation. The results in **Figure 13** demonstrate the coefficient of friction of the four tested coatings: BIOFOAM™ Cancellous Titanium, Trabecular Metal™ porous tantalum (*Zimmer, Inc.*), titanium plasma spray, and titanium sintered beads.

Frictional properties were measured based on a prior study with cadaver tibiae.[1] Foam bones* were used to represent tibial cancellous bone. The test was conducted on a biaxial test machine with a linear bearing attached to the vertical load cell. A 25mm piece of foam bone was mounted against a larger, flat piece of porous material. The interface was adjusted so the samples were parallel to the selected bone samples. A vertical load of 65N was applied normal to the contacting surfaces and horizontal displacement was applied to the foam bone at a rate of 0.025mm/sec. Vertical load, horizontal load, and horizontal displacement were recorded and used to calculate the coefficient of friction by dividing peak horizontal load by the nominal normal force (65N).

The coefficient of friction results for each group are shown in **Figure 13**. BIOFOAM™ had a significantly higher coefficient of friction than both plasma spray and sintered beads. Based on previously published results, BIOFOAM™ titanium frictional properties are also superior to trabecular tantalum metal.[6] *(Zimmer, Inc.)*

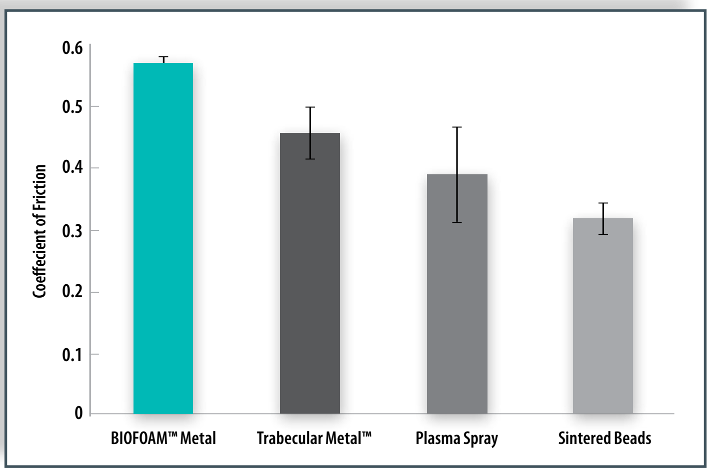


Figure 13 Frictional properties of BIOFOAM™ metal compared to traditional ingrowth coatings and Trabecular Metal™[6]

(10 pcf , pcf refers to the weight of foam in pounds per cubic foot and indicates density / thermal properties of foam)

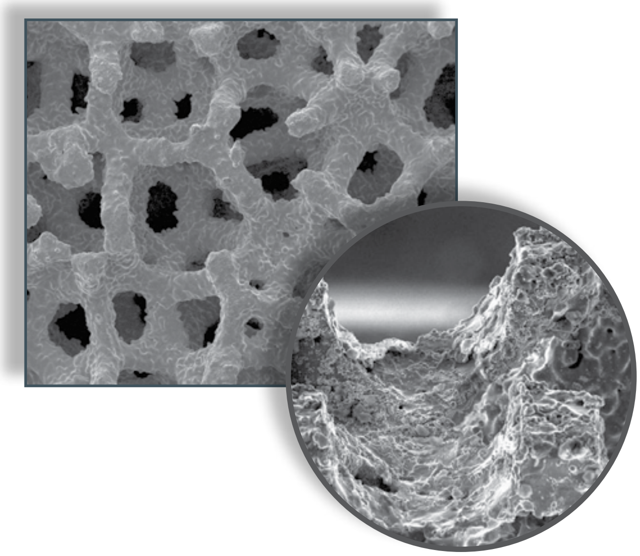
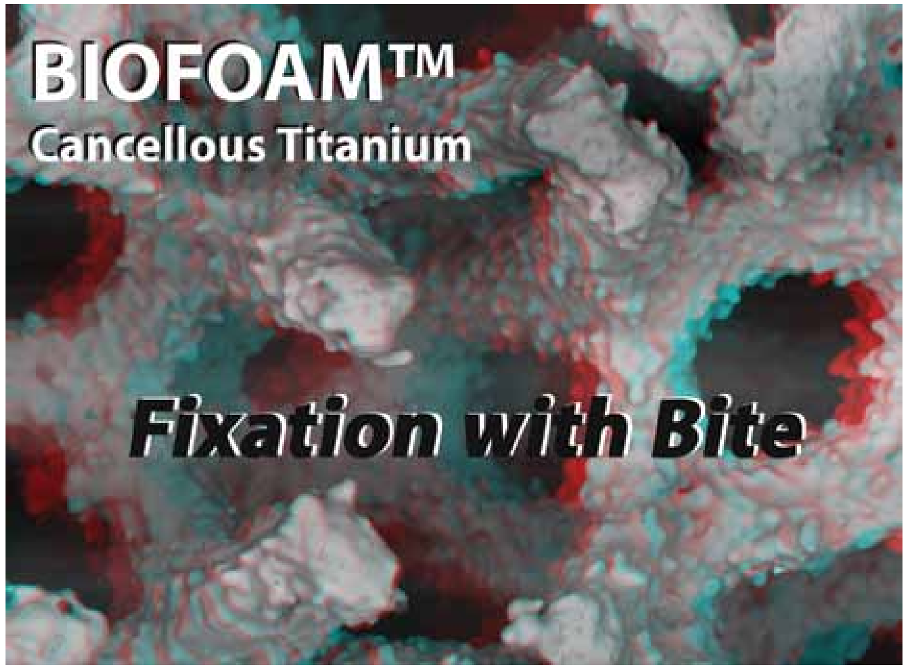


Figure 14 Microscopic surface of BIOFOAM™ metal. Top: Trabecular structure of BIOFOAM™ titanium, 200x original magnification. Bottom: BIOFOAM™ titanium bone interface.

BIOFOAM™ metal frictional properties are in part due to the microscopic ongrowth surface of the foam metal struts **Figure 14**. This roughness will provide a better initial "bite" against bone which may reduce early motion. Also, the surface microtexture of the struts contribute to the overall osteogenic response. Studies have shown microtextured surfaces such as those produced by grit blasting are highly osteophilic and will likely attract bone more quickly than smoother constructs.[1]

Figure 15 Friction test set-up



Conclusion

BIOFOAM™ Cancellous Titanium is a biocompatible implant that is designed to provide tremendous early fixation without compromising the long-term demands that are required in today's increasingly young and more active patients. This material allows the body deep osseous ingrowth into the implant, creating a biological fixation that will hold the implant stable without the introduction of third body particles or bone cement. The plateau of cemented fixation has been reached. BIOFOAM™ Cancellous Titanium has the potential to reach higher levels of clinical success and provide better results for young, active patients.

References

chapter 3

References

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