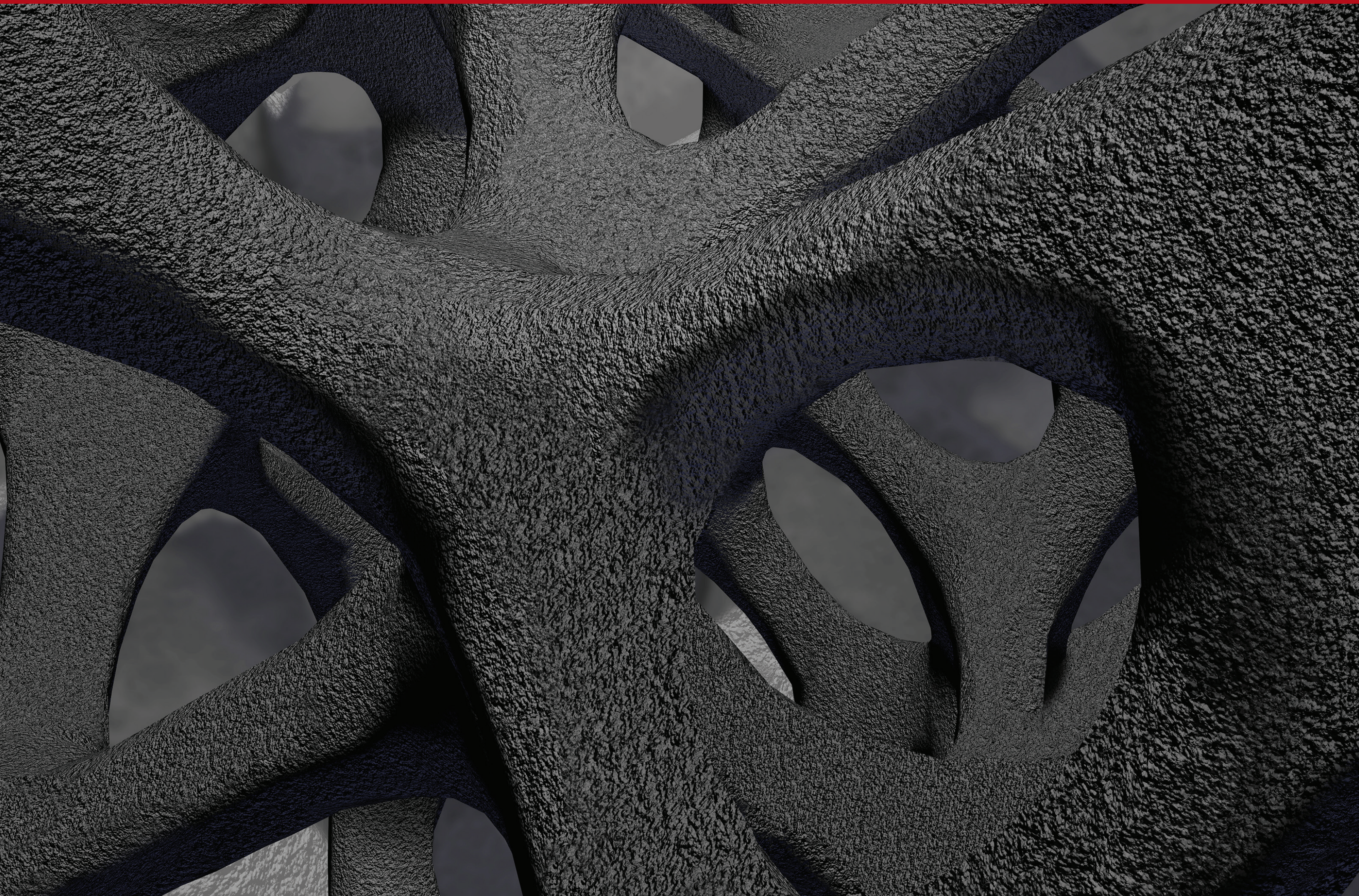
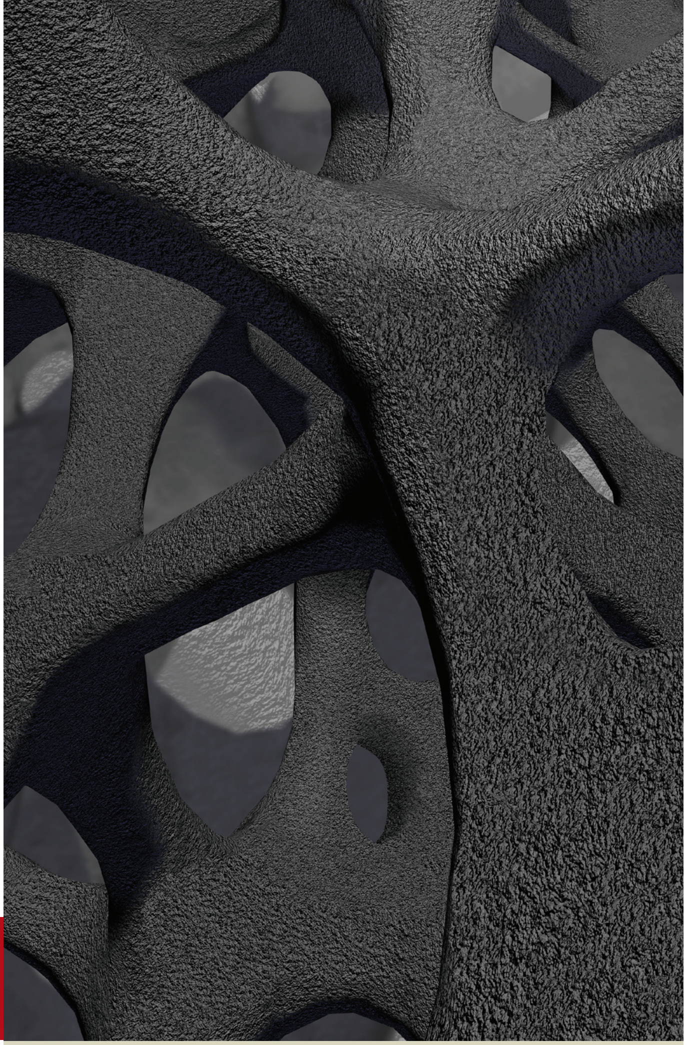
Tesera Trabecular Technology® (T³) Porous Structure

Designed and built to promote biologic fixation and long-term stability





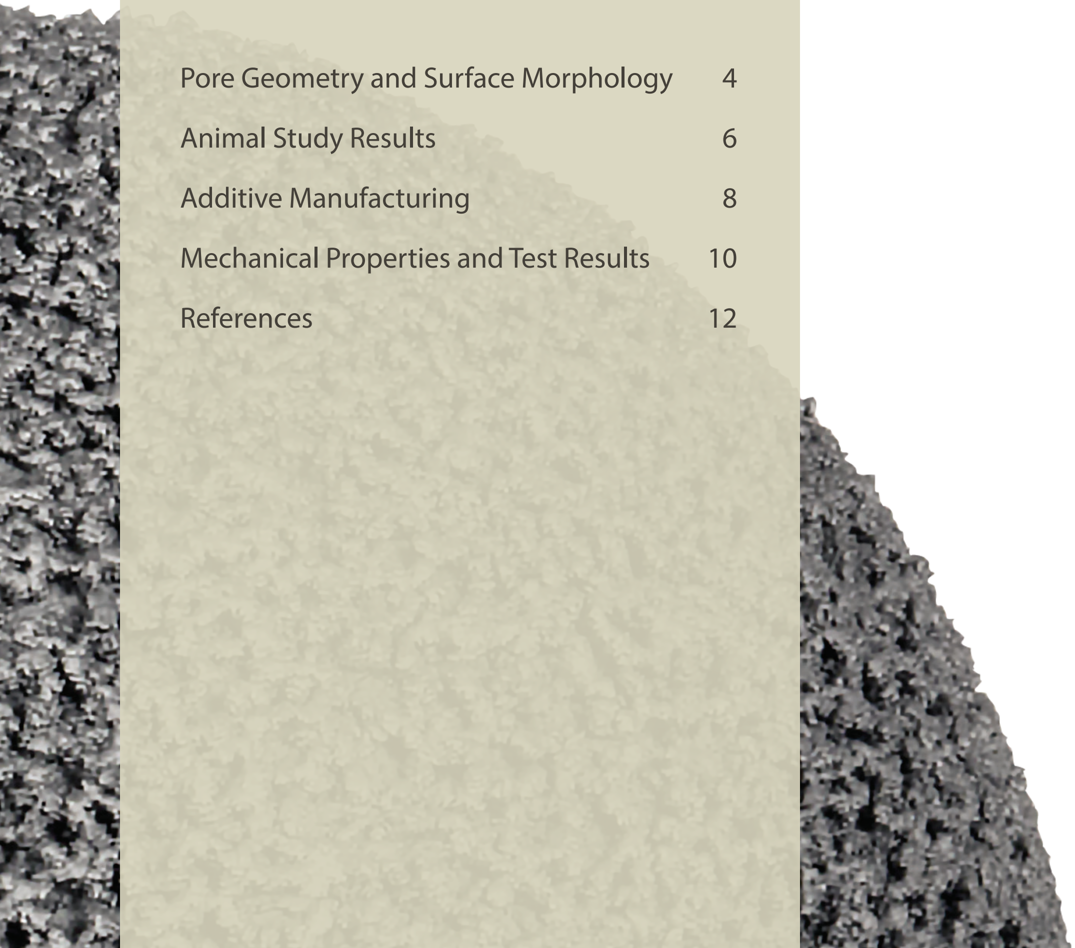
Tesera Trabecular Technology® (T^3) Porous Structure

Biocompatible
Produced from “gold standard” titanium-alloy

Designed for biologic fixation
Highly porous, with large interconnected pores

Proven in animal study
In-growth by 12 weeks with continuing bone formation at 24 weeks

Contents



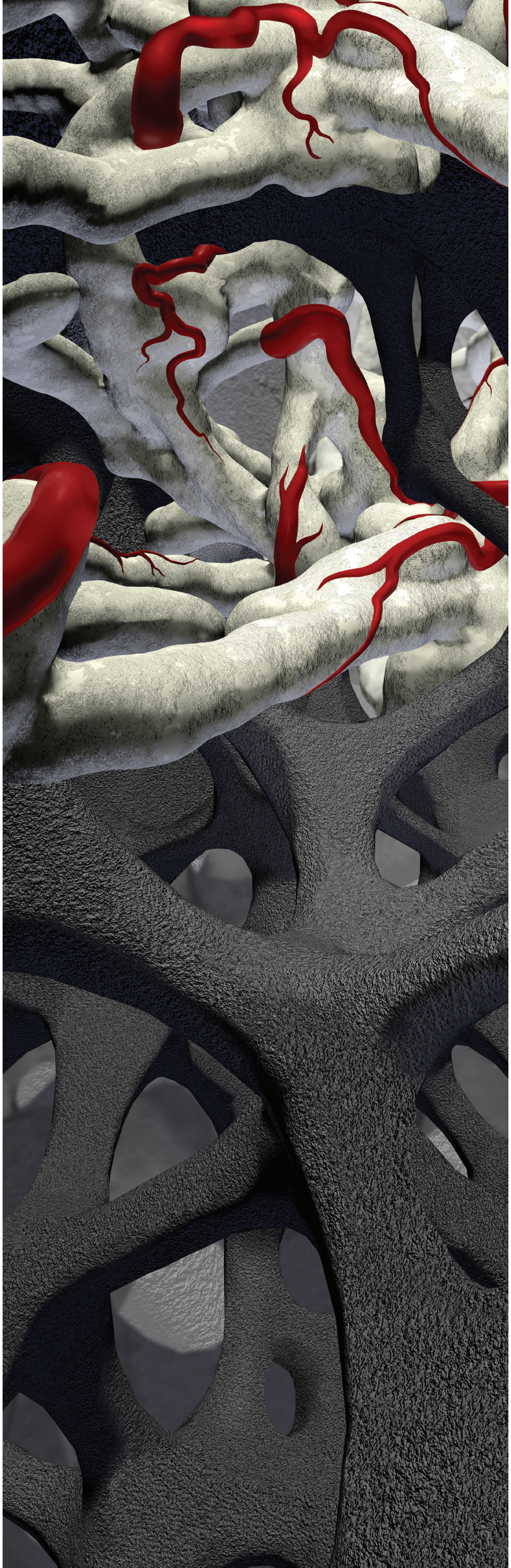
The rough surface grips into the bone providing mechanical interlock.

... designed and built to promote biologic fixation and long-term stability

Each parameter of the Tesera Trabecular Technology porous structure—from pore size and shape to surface roughness—was designed based on decades of published research on bone in-growth surfaces.

This highly porous structure provides initial mechanical stability as the rough surface grips into the bone upon implantation; the mechanical interlock of bone growing into the structure provides long-term mechanical stability.

The production of the Tesera porous structure is enabled by electron beam manufacturing (EBM) or direct metal laser sintering (DMLS). With these processes, devices are built up layer-by-layer, allowing the repeatable production of complex geometries not possible with other manufacturing methods.



Tesera Trabecular Technology porous structure is highly porous, with an average pore diameter of about 500 µm. Pores of this size can accommodate bone in-growth and the vascularization required to sustain living bone. (Artist rendering)

Pore Geometry and Surface Morphology

Ideal Porous Structure: Summary of the Literature

Designing a porous structure for successful bone in-growth is a multi-factorial problem that depends on variables such as pore shape and size and surface roughness. Researchers have not reached consensus on the precise values required for these variables. However, clinical experience and animal studies have demonstrated that bony fixation can be achieved reliably within certain ranges of values.

The following are some guiding principles for bone in-growth, as established in the literature.

Guiding Principles for Surface Characteristics

Microscopic factors related to bone growth onto the porous structure's surface.

Material Composition

Titanium alloy has been used clinically for more than 35 years and remains the gold standard for bone on-growth. The titanium oxide layer that forms on the surface is well-recognized to have excellent biocompatibility. Importantly, this oxide layer is stable but is not bioinert; studies have demonstrated that the biologic response elicited adjacent to the surface facilitates osteoblast attachment and proliferation along the surface.[1,2]

Surface Roughness

Surface roughness has been shown to positively affect the physiologic processes of bone growth (e.g. proliferation, matrix synthesis, and local factor production).[2,3] The roughened surface also provides physical anchorage for osteoblasts and increased surface area for cell adhesion.[4,5] In particular, osteoblasts have proven most responsive to surfaces with roughness in the range produced by grit blasting (0.45 to 7 µm).[6,7]

Guiding Principles for Pore Morphology

Macroscopic factors related to growth of viable bone within the structure.

Pore Interconnectivity

To allow migration and proliferation of cells and vascularization (the key to sustaining live bone within the porous structure) the pores must be connected to one another.[4,5]

Pore Diameter

Pore sizes in the range of 100-500 µm have been observed to result in bone in-growth, with pore sizes at the upper range recommended to allow vascularization.[8-11]

Percent-Volume Porosity

Generally, studies show that higher porosity results in more bone in-growth.[12,13] Researchers have suggested a minimum porosity of 55-60%.[5]

Shape

Increased bone in-growth has been noted with angular (as opposed to round) pores; that is, a rugged, irregular pore cross-section is preferred.[5]

Designed based on the science of bone in-growth

The Tesera Trabecular Technology porous structure meets or exceeds the published guiding principles for promoting and supporting bone in-growth. (Table 1)

Table 1: Guidelines for successful bone in-growth structure

Parameter	Published Guideline	Tesera Trabeular Technology	Meets / Exceeds Requirements
Material Composition	Ti-alloy "gold standard"[1,2]	Ti-alloy	✓
Pore Volume	55-60%; higher is better[5,12,13]	64±6.2[15]	✓
Interconnected Pores	Yes	Yes	✓
Surface Micro-Roughness	Approximate grit-blasted (0.45-7.0 μm)[6,7]	Yes (Figure 2)	✓
Average Pore Diameter	100-500 μm; in upper range for vascularization[8-11]	504[15]	✓
Pore Shape	Rugged, irregular	Yes (Figure 1)	✓

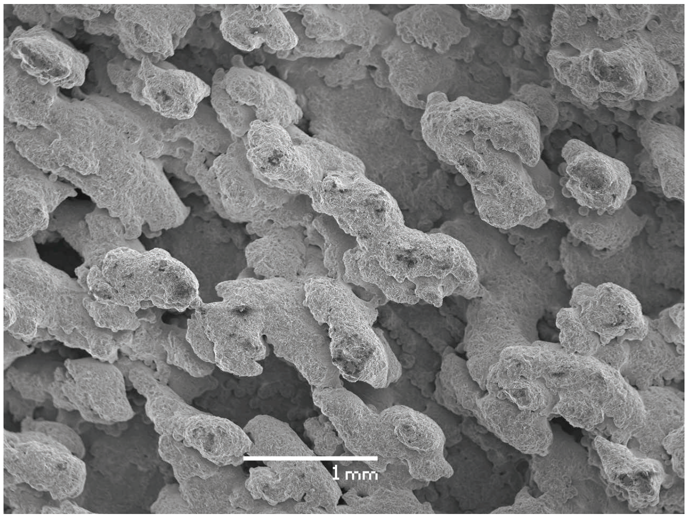


Figure 1: SEM image of the outer surface of the Tesera porous structure.[14]

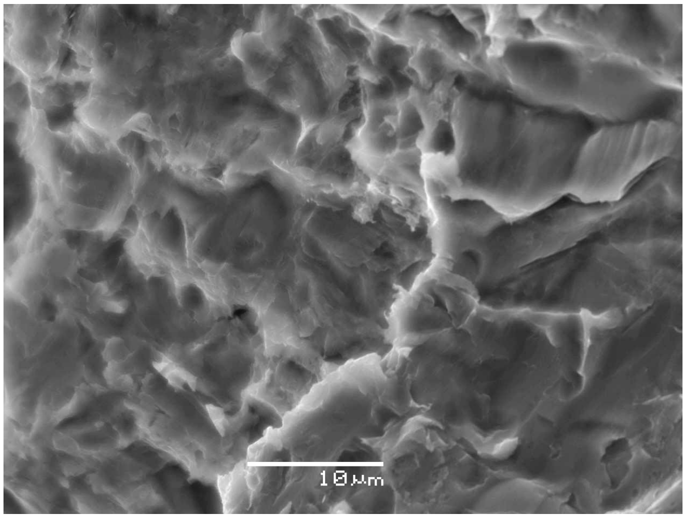


Figure 2: SEM showing the microroughness of the surface of the Tesera porous structure. Original magnification = 2500X.[14]

Proven biocompatibility and biologic fixation

Bone In-growth into Tesera Trabecular Technology® Porous Structure

A Weight-Bearing Ovine Study

Abstract

A study of bone in-growth into Tesera Trabecular Technology bone plugs was conducted in a sheep femur model.[16] *The results revealed no implant-associated adverse effects on the host bone and demonstrated excellent new bone formation and remodeling within and adjacent to the porous structure.*

Materials and Methods

As a clinically relevant model of early bone growth into the Tesera structure, a study involving weight-bearing bone plugs in sheep was designed based on the work of Willie, et al.[26] Analyses including percent bone area, mineral apposition rate, and histological examination were completed for time 0, 12-week, and 24-week specimens.

Results

Bone area analysis

SEM images with BSE detection were taken at three levels along the length of the plug: within the porous structure, in the periprosthetic region immediately adjacent to the implant, and in host bone (3-5 mm from the implant). The amount of bone was measured quantitatively in each image and reported as percent area. The bone area in the periprosthetic and host bone regions did not change significantly from time zero to 12 weeks and showed a slight increase at the 24-week endpoint. However, the amount of bone within the porous structure increased significantly at both the 12- and 24-week end points. (Table 2)

Mineral apposition rate

All of the 12- and 24-week samples exhibited double-labeled trabeculae at the porous structure interface, indicating viable and actively remodeling bone. (Figure 3)

Light microscope

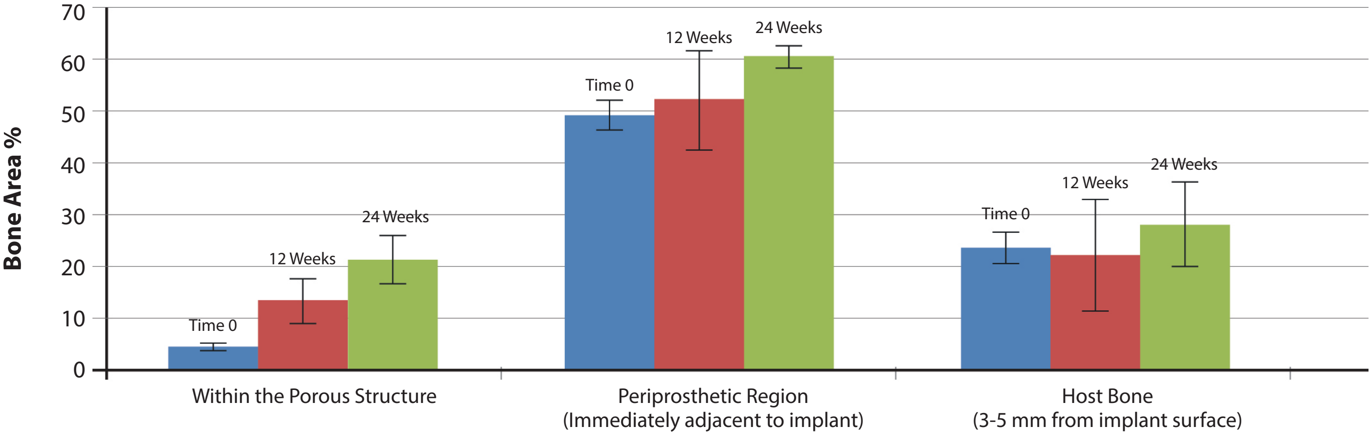
The histological evaluation found no adverse cellular reaction in response to the porous structure. Excellent bone attachment and osteoblast activates were observed within the porous structure of 12- and 24-weeks specimens. (Figure 4 and 5)

Conclusion

Histological and histomorphomic examination of explanted Tesera bone plugs revealed no implant-associated inflammation or other adverse effects on the host bone. Bone area analysis of SEM images found significant bone in-growth within the 12-week specimens, which doubled for the 24-week specimens. Mineral apposition rate imaging revealed the formation of viable bone trabeculae within the porous structure. Light microscopy also showed continuing bone formation with osteoblast activity at the 12- and 24-week time points.

The experimental results of this animal model demonstrated excellent early new bone formation and remodeling within and adjacent to the porous structure, suggesting that the Tesera Trabeucaler Technoloby porous structure provides excellent skeletal attachment.

Table 2: Bone Area Analysis: Quantitative measurement of bone in and around the porous structure on SEM images[16]



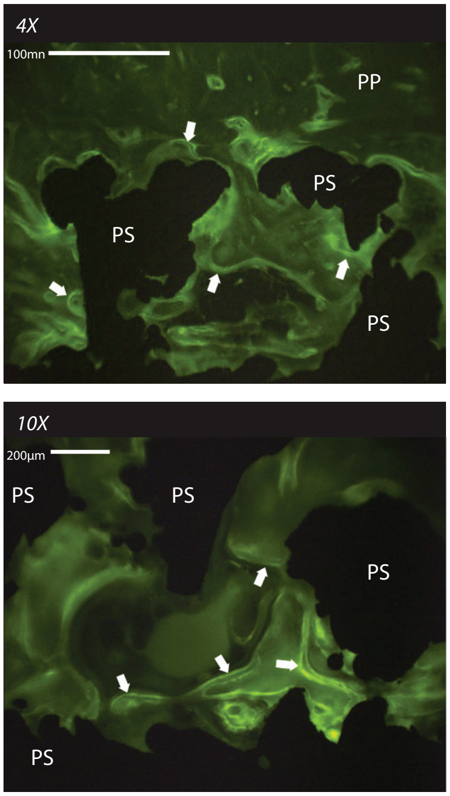


Figure 3: Flourochrome double-labeled trabeculae (arrows) within the porous structure (PS) and periprosthetic (PP) regions at 12 weeks.[16]

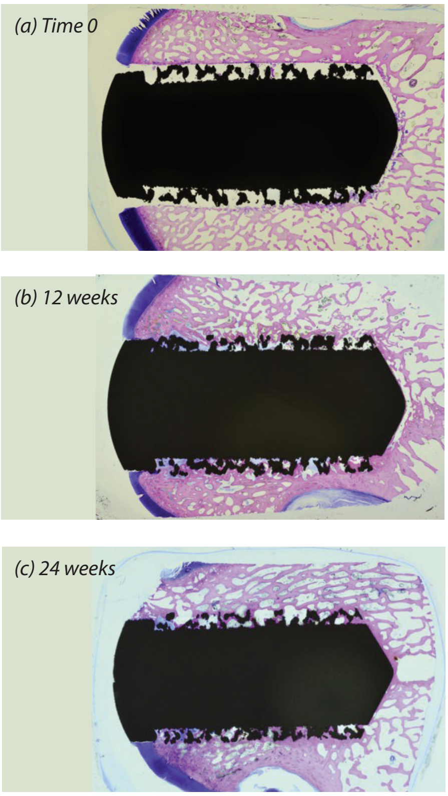


Figure 4: Light microscope images of full specimens, showing excellent bone in-growth by the 12 week time point and continued bone growth at 24 weeks.[16]

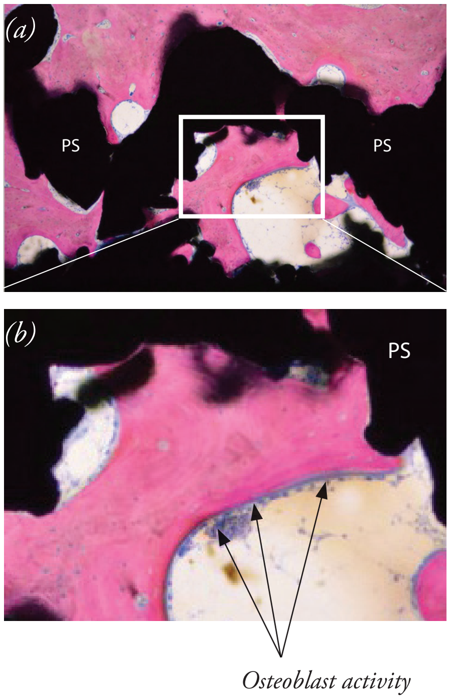


Figure 5: Light microscope image of a 12-week specimen. (a) 10X magnification demonstrating bone attachment to porous structure (b) Detail image showing osteoblast activity (arrows) within the porous structure.[16]

Additive Manufacturing

Revolutionary process for revolutionary results

Enabling Technology

Components with the Tesera structure are created using electron beam manufacturing (EBM) or direct metal laser sintering (DMLS). With these additive manufacturing processes, components are built up layer by layer from titanium-alloy powder. Additive manufacturing—and the mass customization it enables—is sparking an industrial revolution by allowing the repeatable production of complex geometries not possible with traditional manufacturing methods.

Tesera Acetabular System and Tesera Stand-Alone ALIF System

Additive Manufacturing Process

1. Model

A 3D computer model of the component, including the porous structure, is created and uploaded to the machine.

2. Build

Titanium-alloy powder is selectively melted by electron beam or laser exposure to the precise geometry defined by the model. The component is built up layer-by-layer, essentially directly printing the component from the computer model.

3. Finish

To enhance microroughness, the Tesera structure is HA-blasted. The final shape and smooth surfaces are then machined, and the components are passivated and cleaned.

Mechanical Properties and Test Results

Initial stability for bony fixation. Strength and bone-like modulus for long-term success.

Tesera Trabecular Technology implants provide the initial stability required for early fixation, the strength required for weight-bearing, and a scaffold for bone in-growth and long-term fixation.

Initial Stability

The large pore size of the Tesera structure results in surface prominences that grip into the bone upon implantation. In laboratory testing of the Tesera structure on cancellous bone, the coefficient of friction was substantially improved over plasma-strayed coating and better than a contemporary highly porous tantalum structure.[18-20] (Table 3) A higher frictional coefficient enhances initial stability and promotes in-growth by limiting micromotion at the bone-to-implant interface.[21,22]

Strength

The EBM and DMLS processes produce solid titanium-alloy that has properties similar to those of wrought materials.[23]

Bone-like Modulus

The Tesera porous structure has a modulus of elasticity that matches that of cancellous bone; this has been shown to avoid the fibrous tissue growth associated with stress shielding.[24,25] (Table 4)

Not a coating

The EBM and DMLS processes allow for the production of both the solid and porous portions of the component in one manufacturing step. Thus, the Tesera structure is integral to the component, eliminating problems associated with coatings, like delamination. (Figure 6)

Table 3: Coefficient of Friction on Cancellous Bone

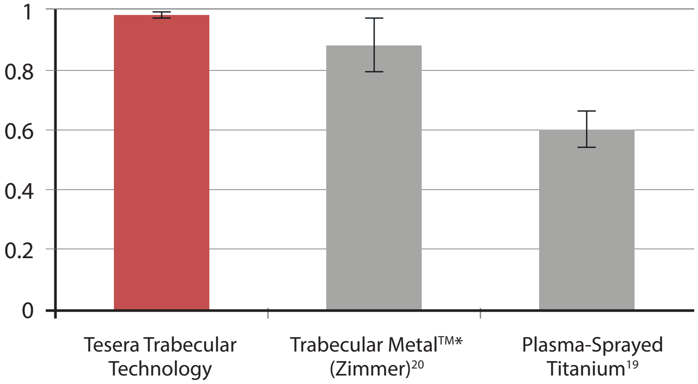
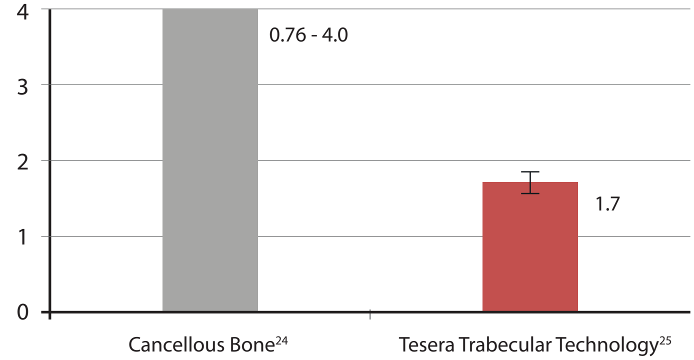


Table 4: Modulus of Elasticity (GPa): The modulus of the Tesera structure falls within the range of values reported for cancellous bone. (Compressive modulus shown.)



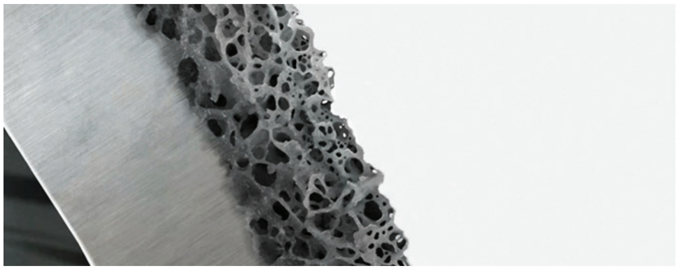


Figure 6: The Tesera structure is not a coating; the solid and porous portions of the device are built up in one continuous process. (Artist rendering)

**Trabecular Metal is a trademark of Zimmer, Inc. (Warsaw, Indiana).*

Summary

Optimal Characteristics for Porous Structure

Each parameter of the Tesera Trabecular Technology porous structure—from pore size and shape to surface roughness—was designed based on decades of published research on bone in-growth surfaces.

Biocompatibilty and bone in-growth were proven in an animal study that found viable bone within the porous structure and excellent skeletal attachment.

Tesera Acetabular System and
Tesera Stand-Alone ALIF System

Key Characteristics of Optimal/Successful Porous Structures		Tesera Trabecular Technology Meets or Exceeds Requirement
Process	Not a coating	✓
Material	Biocompatible; Ti- alloy "gold standard"	✓
Micro-Roughness	Approximate grit-blasted (0.45-7.0 µm)	✓
Interconnected Pores	Yes	✓
Average Pore Diameter	100-500 µm; in upper range for vascularization	✓
Pore Volume	55-60%; higher is better	✓
Pore shape	Rugged, irregular, not rounded	✓
Coefficient of Friction (Cancellous)	>0.66; maximize	✓
Modulus of Elasticity	0.76 – 4.0 GPa; lower is better	✓

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