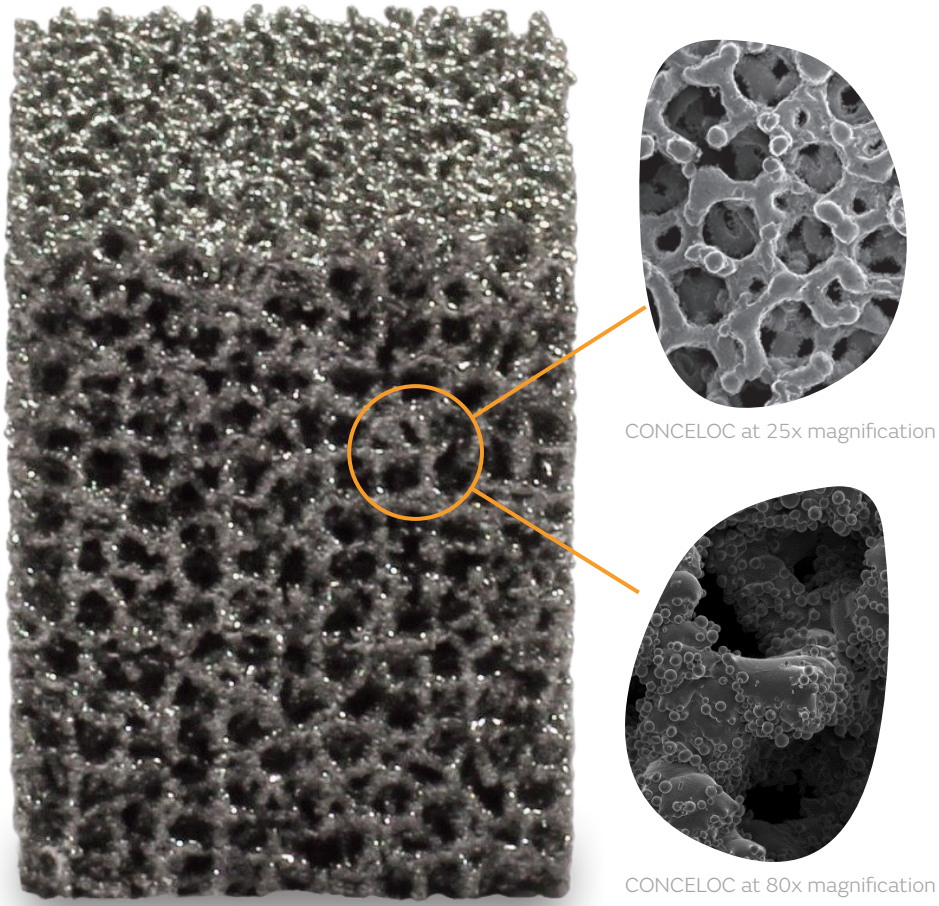


CONCELOC at 25x magnification

CONCELOC at 80x magnification

Smith+Nephew

CONCELOC◊

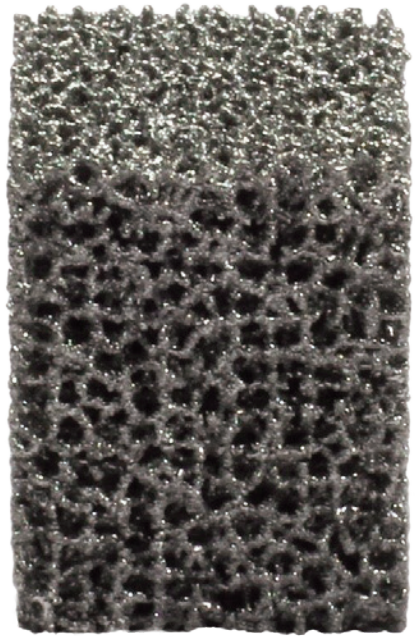
Advanced Porous Titanium

Material specifications

CONCELOC◊ Advanced Porous Titanium

Customized, proprietary porous structure technology

Through our pioneering approach to design, Smith+Nephew engineers have developed a proprietary method for creating a fully randomized porous structure with predictable porosity, pore size and node interconnectivity. Devices incorporating the patented CONCELOC Advanced Porous Titanium are created in a virtual environment and then fabricated at Smith+Nephew via additive manufacturing.



Design flexibility

Additive manufacturing (AM), commonly referred to as 3D printing, is a novel manufacturing method that involves the use of a laser or electron beam, for example, to sinter polymer or metal powders into a solid part that is built layer-by-layer. This unique fabrication method provides greater design flexibility compared to standard, subtractive manufacturing, i.e., machining. AM has also enabled Smith+Nephew to develop this custom porous structure for biological fixation combined with complex device geometries that would be difficult, expensive or impractical to attain through conventional fabrication methods. This design flexibility was leveraged to produce a roughened texture that is mapped on to the bone-interfacing surfaces of the virtual models to provide friction for enhanced initial stability. Furthermore, solid reinforcements can be added as an integral part of the porous structure where desired, since both solid and porous features are fabricated layer-by-layer at the same time.

Material

CONCELOC is made from Ti-6Al-4V and meets the ASTM and ISO standards for that alloy, with a good clinical history and over 40 years of use in medical devices.[1-4]

Porosity

CONCELOC Advanced Porous Titanium has an interconnected network of pores with an average porosity of 80% in the near-surface regions where the initial fixation will occur, and an average overall porosity of 63%.[5] These porosities are within the range of 60-80% porosity reported for other advanced porous structures.[6-9]

Pore size

CONCELOC has pore sizes greater than 100 µm, which the literature suggests is beneficial to biological fixation.[10-12] CONCELOC Advanced Porous Titanium has an average pore size that ranges from 202 to 342µm overall and from 484 to 934µm at the surfaces of the porous structure.[5,13]

Mechanical properties*

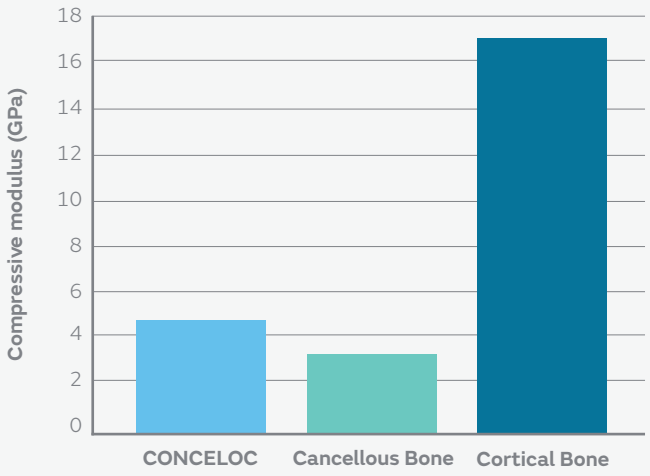


Figure 1: Compressive modulus measured for the CONCELOC◊ Advanced Porous Technology[14] compared to values reported for cancellous[15] and cortical[16] bone.

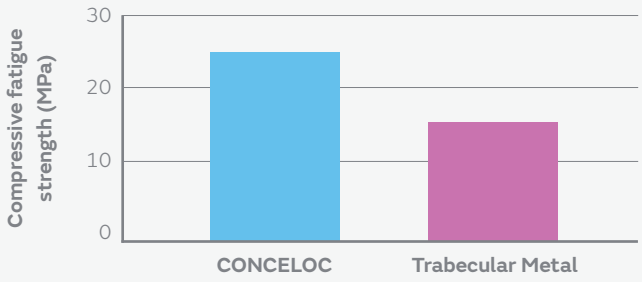


Figure 3: Compressive fatigue strength of the CONCELOC Advanced Porous Technology[19] compared to that reported for Trabecular Metal.[18]

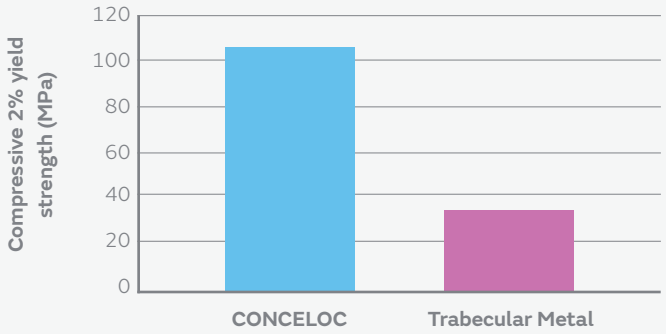


Figure 2: Compressive yield strength of the CONCELOC Advanced Porous Technology[17] compared to that reported for Trabecular Metal.[18]

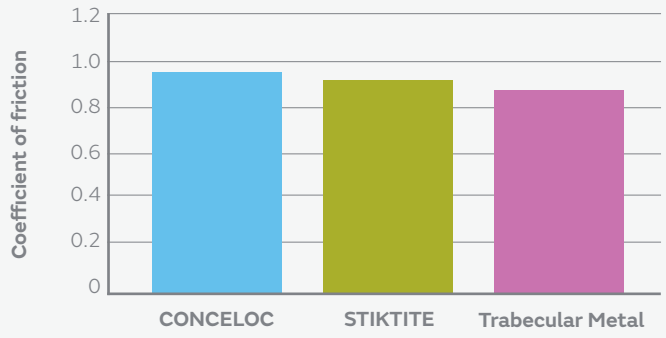


Figure 4: Coefficient of friction of CONCELOC Advanced Porous Technology[20] compared to that reported for STIKTITE[20] porous coating and Trabecular Metal.[21]

The CONCELOC and STIKTITE◊ porous structures were tested against 10 lb/ft (0.16 g/cm) foam.[11] The test method for these porous structures differed from that used for Trabecular Metal that was tested against cancellous bone.

Material properties*

	CONCELOC	STIKTITE	Trabecular Metal	Tritanium	Regenerex	Gription
Material	**Titanium Alloy**	**CP Titanium**	**Tantalum[23]**	**CP Titanium[23]**	**Titanium Alloy[24]**	**CP Titanium[6]**
Modulus of Elasticity	4.3 GPa[14]	113 GPa**[25]	1.3-3.9 GPa[18,26]	113 GPa**[25]	1.9 GPa[24]	113 GPa**[25]
Compressive 2% Yield Stress	101.2 MPa[17]	N/A	36.9 MPa[18]	N/A	N/A	N/A
Porosity	Up to 80%[5]	62%[27]	80%[22]	72%[28]	67%[24]	63%[29]
Pore Size (Ave)	202-934µm[5,13]	194µm[27]	430µm[21]	311-546µm[28]	100-600µm[24]	300µm[29]
Coefficient of Friction	0.95[20]	0.93[20]	0.88[21]	1.01[28]	N/A	1.2[6]
Porous Matrix or Coating	Porous Matrix	Coating	Porous Matrix	Both	Both	Coating

* Data for competitive porous structures was obtained from the referenced literature with test methods that differ between porous structures. Data is tabulated for general comparisons only.

**Ti-6Al-4V substrate with coating.

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116
USA

www.smith-nephew.com

03955 V3 04/20

References

1. Sidambe A. Biocompatibility of Advanced Manufactured Titanium Implants-A Review. Materials. 2014;7(12):8168-8188. **2.** Williams D. Titanium and Titanium Alloys. In: Williams D, ed. Biocompatibility of clinical implant materials Boca Raton, Fla: CRC Press; 1981. **3.** Smith + Nephew 2017. Technical Memo TM-17-031. **4.** Smith + Nephew 2016. Internal Report PCS028-18-02 V3. **5.** Smith + Nephew 2015. Orthopaedic Research Report OR-14-091A. **6.** Minter J, Rivard K, Aboud b. Characterization of a New Rougher Porous Coating for Revision Reconstructive Surgery. Poster presented at: The 54th Annual Meeting of the Orthopaedic Research Society 2016. **7.** Patil N, Lee K, Goodman S. Porous tantalum in hip and knee reconstructive surgery. J Biomed Mater Res B Appl Biomater. 2009;89(1):242-251. **8.** Scholvin D, Linton D, Moseley J. Poster No: 0459 - Bonding of Titanium Foam to Cobalt Chrome Substrates. Poster presented at: Orthopaedic Research Society 2013 Annual Meeting 2013; San Antonio, Texas. **9.** Stryker. Tritanium Advanced Fixation Technology. Available at: https://www.strykermeded.com/medical-devices/hips-knees/hips/tritanium/. Accessed 30th January 2020. **10.** Kienapfel H, Sprey C, Wilke A, Griss P. Implant fixation by bone ingrowth. J Arthroplasty. 1999;14(3):355-368. **11.** Bobyn J, Pilliar R, Cameron H, Weatherly G. The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. Clin Orthop Relat Res. 1980(150):263-270. **12.** Smith + Nephew 2019. Technical Memo TM-19-067. **13.** Smith + Nephew Research report. OR-15-119. **14.** Morrison M, Taylor ME, Weaver C. Characterization of a Reticulated, Randomized Porous Structure Produced by Additive Manufacturing. ORS Annual Meeting Poster. 2016;2004. **15.** Morgan EF, Keaveny TM. Dependence of yield strain of human trabecular bone on anatomic site. J Biomech. 2001;34(5):569-577. **16.** Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials. 2005;26(27):5474-5491. **17.** Smith + Nephew Research report. OR-15-114. **18.** Zardiackas LD, Parsell DE, Dillon LD, Mitchell DW, Nunnery LA, Poggie R. Structure, metallurgy, and mechanical properties of a porous tantalum foam. J Biomed Mater Res B. 2001;58(2):180-187. **19.** Smith + Nephew Research report. OR-15-022A. **20.** Morrison M, Woodard E. Comparison of Friction between Traditional Porous Coatings and an Additive-Manufactured Porous Structure. ORS Annual Meeting Poster. 2017;1095. **21.** Bobyn JD, Hacking SA, Chan SP, Toh KK, Krygier JJ, Tanzer M. Characterization of a new porous tantalum biomaterial for reconstructive orthopaedics. AAOS, Anaheim, CA. Feb 4-7, 1999. **22.** U.S. Food and Drug Administration. K032344, 2003. **23.** Stryker. Triatanium Acetabular Shell. Available at: http://www.stryker.com/en-us/products/Orthopaedics/HipReplacement/Acetabular/TritaniumAcetabularShell/index.htm. Accessed: Aug 23th 2016. **24.** Bertollo N, Matsubara M, Shinoda T, Chen D, Kumar M, Walsh WR. Effect of surgical fit on integration of cancellous bone and implant cortical bone shear strength for a porous titanium. J Arthroplasty. 2011;26(7):1000-1007. **25.** Boyer R, Welsch G, Collings EW. Materials Properties Handbook: Titanium Alloys, Materials Park, OH. ASM International. 1994. **26.** Krygier JJ, Bobyn JD, Poggie R, Cohen R. Mechanical characterization of a new porous tantalum biomaterial for orthopaedic reconstruction. SIROT, Sydney, Australia. 1999. **27.** Heuer DA. Structural comparison of advanced and conventional bone ingrowth technologies. Orthop Res Soc, Long Beach, CA. Jan 13-16, 2011, 1034. **28.** Stryker. Tritanium primary acetabular shells. SODTR-SS. 2008. **29.** Pinnacle Hip Solutions: Design Rationale. DePuy Orthopaedics. 2013; EO-129 (Rev 1)