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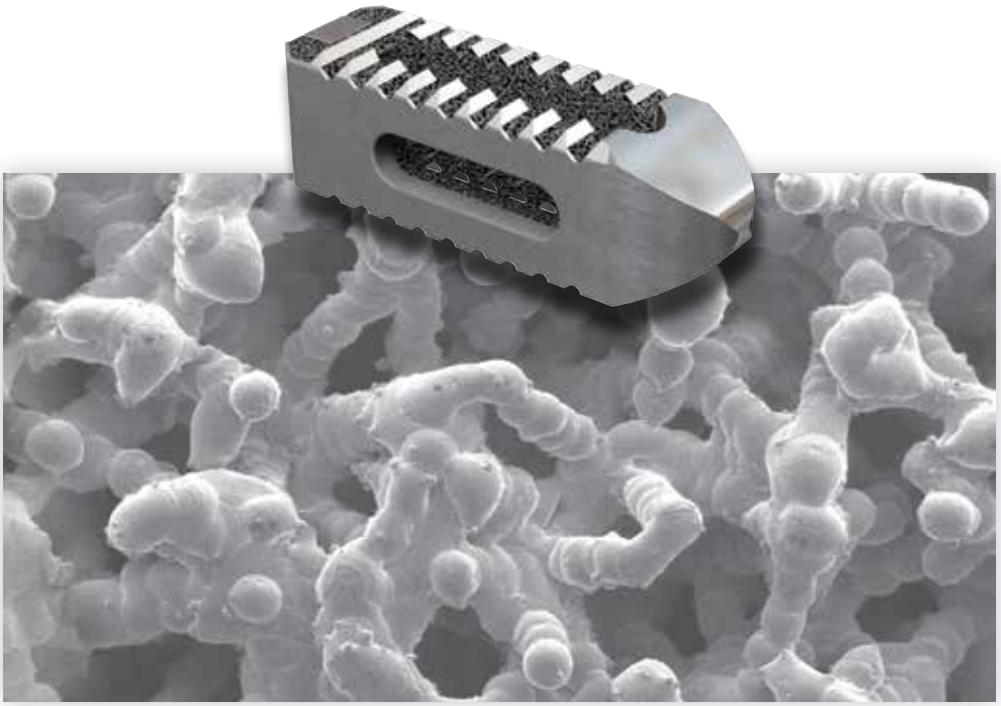
Tritanium®
basic science summary



Technical monograph

Tritanium

basic science summary

Lumbar fusion is a fairly common surgical procedure used to treat a variety of spinal pathologies. Innovations to spinal fusion implants and grafting options have led to advances in surgical techniques and improvements in the rates of successful fusions[4]. Achievement of bony fusion at the target levels is at the cornerstone of a successful clinical outcome for a lumbar spinal fusion procedure. To achieve clinical effectiveness, a scaffold is needed to promote fixation at the bone-implant interface. Since the invention of the first interbody fusion cage in 1988[1], numerous types of implants made from metal, carbon fiber composites or titanium have been designed and used in clinical cases[12]. Over the past several years, implant cage materials and modification to these materials have been an area of interest in an attempt to provide advancements for treating patients with various spinal pathologies.

Titanium and its alloys have a well-established history of use as interbody spacers and the material itself has been studied at length to understand the mechanisms that allow for its clinical success. Since the late 1960s, the scientific community has been investigating the connection between bone and titanium following early success with titanium implants in animal models. These early studies demonstrated good bone-to-implant contact in addition to bony in-growth at different time points resulting in bone consolidation and anchoring[8, 9]. The eventual biological fixation observed in these animal studies was a result of the body's natural response to the titanium implants. The formation of bone around titanium implants involves a surge of cellular and extracellular biological events that take place between the areas where the implant contacts the bone until the implant surface appears covered with a newly formed bone[10]. Additionally, titanium implants are considered beneficial for use in orthopaedic procedures because they can provide sufficient strength under physiologic loads[12].

To build on this information, studies have been conducted to identify the effect, if any, of altering the surface properties for these orthopaedic titanium implants. These studies sought to evaluate human osteoblast (a cell involved in bone formation) cells on titanium implant surfaces and investigators found that titanium alloys stimulated production of these osteoblast cells[5]. Additionally, this difference in osteoblast differentiation and bone-implant contact was even greater when investigators compared roughened surface titanium alloy implants to smooth surface titanium alloy implants demonstrating that titanium alloy allows bone to grow on the surface or down into pores of the implant following sufficient contact time with bone[3, 13].

In an effort to enhance the bony in-growth potential of titanium implants, the scientific community shifted its focus to porous metal implants in the hopes of establishing a material similar in structure and mechanical properties to bone. Several studies sought to understand which geometry and pore size would provide an optimal environment for cells to attach and multiply within this structure. The results from these pore characterization studies found that pore sizes greater than 300 micrometers (μm) provide an environment for enhanced new bone formation[2,7].

To support this technology, pre-clinical and clinical information have been generated from early iterations of the Tritanium technology utilizing a variety of models and patient cohorts, primarily in orthopaedic procedures. A high rate of successful bone integration of the implant in addition to very few device related complications was demonstrated, respectively[6,11]. Stryker's Tritanium technology has been developed with these researched properties of implant material, surface characteristics and porosity in mind. The Spine Division's Tritanium PL Cages are constructed out of Stryker's Tritanium technology. Tritanium is a novel highly porous titanium material designed for bone in-growth and biological fixation[14]. The Tritanium PL Cage carries this technology forward into the advancement of spine care.

Bibliography

1) Bagby, GW. (1988) Arthrodesis by the distraction-compression method using a stainless steel implant. *Orthopedics,* 11, 931-934.
2) Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC. (1980) The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. *Clinical Orthopaedics and Related Research* 150, 263-270.
3) Deligianni, D.D.; Katsala, N.; Ladas, S.; Sotiropoulou, D.; Amedee, J.; & Missirlis, Y.F. (2001) Effect of surface roughness of the titanium alloy Ti-6Al-4V on human bone marrow cell response and on protein adsorption. *Biomaterials*, 22, 1241-1251.
4) Deyo, R.A.; Gray, D.T.; Kreuter, W; Mirza, S.; & Martin, B.I. (2005) United States Trends in Lumbar Fusion Surgery for Degenerative Conditions. *Spine*, 30, 1441-1445.
5) Gittens, R.A.; Olivares-Navarrete, R.; Schwartz, Z.; & Boyan, B.D. (2014) Implant osseointegration and the role of microroughness and nanostructures: Lessons for spine implants. *Acta Biomaterialia*, 10, 3363-3371.
6) Hadley, S.; Howell, R.; Thompson, S.; Eisemon, E.; Ricci, J.; Zhang, R.; Jaffe, W.; & Frenkel, S. (2012) Comparison of Bone Ingrowth into Two Different Porous Metals in a Canine Implantable Chamber. Poster Presented at Annual Orthopaedic Research Society, San Francisco, CA.
7) Karageorgiou, V.; & Kaplan, D. (2005) Porosity of 3D biomaterial scaffolds and osteogenesis. *Biomaterials*, 26, 5474-5491.
8) Linder, L. (1989) Osseointegration of metallic implants: I. Light microscopy in the rabbit. Acta *Orthopaedica Scandinavica*, 60, 129-134.
9) Linder, L.; Obrant, K.; & Boivin, G. (1989) Osseointegration of metallic implants: II. Transmission electron microscopy in the rabbit. *Acta Orthopaedica Scandinavica*, 60, 135-139.
10) Mavrogenis, A.F.; Dimitriou, R.; Parvizi, J.; & Babis, G.C. (2009) Biology of implant osseointegration. *Journal of Musculoskeletal & Neuronal Interactions*, 9, 61-71.
11) Naziri, Q.; Issa, K.; Pivec, R.; Harwin, SF.; Delanois, RE.; & Mont, MA. (2013) Excellent results of primary THA using a highly porous titanium cup. *Orthopedics*, 36, e390-394.
12) Rao, PJ, Pelletier, MH, Walsh, WR, & Mobbs, RJ. (2014) Spine interbody implants: material selection and modification, functionalization, and bioactivitation of surfaces to improve osseointegration. *Orthopedic Surgery*, 6, 81-89.
13) Webster, T.J.; & Ejiofor, J.U. (2004) Increased osteoblast adhesion on nanophase metals: Ti, Ti6Al4V, and CoCrMo. *Biomaterials*, 25, 4731-4739.
14) PROJ0000043909

TRITA-WP-1
SC/GS 01/16

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