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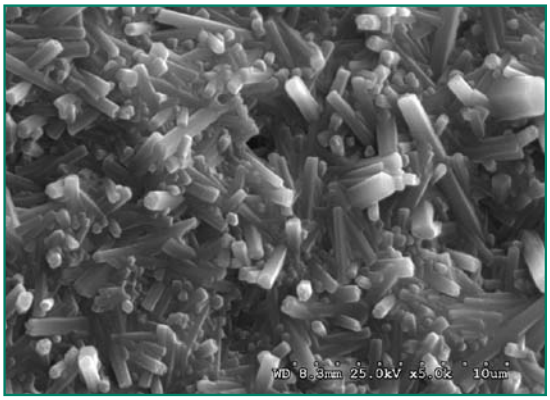
Research Shows Silicon Nitride (Si_3N_4) Exhibits Antibacterial Properties, Superior Bone Growth and More Effective Bone Attachment Compared to Other Biomaterials, and May Lead to Faster Fusion

Infection after spine surgery with instrumentation is becoming a common pathology, with reported infection rates ranging from 0.7% to 11.9%, depending on the diagnosis and complexity of the procedure.[1] Treatment of implant-related infections in spine fusion surgery may require repeat surgery, implant removal and antibiotic therapy, with the result that patients may suffer bone loss, poor bone healing and disability, as well as added costs.

While no strategy has proven effective in completely eliminating the risk of infections related to implant surgery, recent studies have shown certain orthopedic implant materials better resist bacterial colonization and provide superior osteointegration properties than others.

Recent Studies Show Superiority of Silicon Nitride (Si_3N_4) as Compared to Poly-ether-ether-ketone (PEEK) and Titanium (Ti)

Three biomaterials that are used in spinal fusion implants – poly-ether-ether-ketone (PEEK), titanium (Ti) and Silicon Nitride (Si_3N_4) – were recently tested to ascertain their respective susceptibility to bacterial infection with *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli* and *Enterococcus*. Under in-vitro incubation for up to 72 hours, decreased biofilm formation and bacterial colonization were confirmed on both as-fired and polished Si_3N_4 in comparison with PEEK or Ti. Si_3N_4 resisted bacterial proliferation despite the absence of antibiotic pharmaceutical agents.[2]



SEM image of Silicon Nitride surface at 5000X

The proprietary Silicon Nitride, a synthetic non-oxide bioceramic, is supplied by Amedica Corporation (Salt Lake City, UT).

Because protein adsorption on material surfaces affects bacterial adhesion, the adsorption of fibronectin, vitronectin, and laminin on PEEK, Ti, and Si_3N_4 have also been examined. Surface protein adsorption is relevant because previous studies have correlated increased vitronectin and fibronectin adsorption to decreased bacterial activity. Results show significantly greater amounts of these proteins adhered to Si_3N_4 surfaces than to PEEK or Ti.[3]

How Neurosurgeons Are Using Si_3N_4

Grant Skidmore, MD, a neurosurgeon with Neurosurgical Specialists, Inc. in Norfolk, Va., has used Si_3N_4 for the past two years and reports: "The Silicon Nitride biomaterial appears to be superior

to Ti or PEEK in antibacterial properties and osseous fixation. In my experience, patients are healing faster, feeling less pain and progressing to physical activity faster with Si_3N_4 implants." Dr. Skidmore's practice specializes in neurosurgical procedures utilizing state-of-the-art technology.

Chad E. Hartley, MD, a neurosurgeon whose specialties include brain and spinal cord tumors, pituitary tumors, complex spine disorders and neurotrauma, has used Si_3N_4 for three years and states: "Spine surgery is where I use the Silicon Nitride material the most. I use it as an interbody fusion device in spinal fusion surgeries, specifically anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF)."

With regard to fusion, Dr Skidmore reports: "Clinically we are seeing evidence of earlier rates of fusion with Si_3N_4. I perform many spinal nerve decompression surgeries and use Si_3N_4 to rebuild the area with a stabilizing procedure and to support the disk material. We like the rougher surface, which helps prevent movement."

"I've definitely noticed post-op x-ray differences," Dr. Hartley explains. "We do a CT scan at about three months for any type of fusion operation, and with the Silicon Nitride, the area looks almost completely fused at three months."

Si_3N_4 serves as an excellent scaffold for osteoconduction and osteointegration. Push-out strength testing has demonstrated statistically superior bone growth onto Si_3N_4 as compared with PEEK and Ti. Si_3N_4 implants were stable due to sufficient juxtaposed tissue growth and showed reasonable osteointegration even at three and seven day time periods. In one study, three months after surgery, the amounts of new bone at the implant interface and within the surgical defect were 5%, 9% and 23%, and 21%, 26% and 41%, for PEEK, Ti and Si_3N_4, respectively. [4]

"In more than four years and a great many patients, I've seen bone growth and attachment onto the Si_3N_4 devices that I have not seen with titanium or PEEK," reports Alpesh A. Patel, MD, FACS, a spine specialist and surgeon in Chicago, Illinois at Loyola University Medical Center. "From a technical standpoint, the Si_3N_4 systems are easy implants for the surgeon to use, and there is a quick learning curve. The benefits the material has for bone formation and fusion formation include the fact that it doesn't cause the same kind of scatter or artifact that titanium or other metals cause, so if you do need to get a CAT scan or MRI scan on a patient afterwards, it makes for very clean and easy-to-interpret images."

Dr. Patel discloses that he serves as a consultant to Amedica and receives royalties from one of its products, but that his use of the Si_3N_4 material began prior to his relationship with the company.

Dr. Hartley agrees with Dr. Patel: "Si_3N_4 is easy to use. It's easy to see the entire Silicon Nitride fusion device on x-ray as compared to a PEEK spacer, where you only see two little lines. It makes post-op imaging much easier. The material is easier to work with, and I've never had one break on me. I like the space in the middle of these devices for bone graft or amniotic stem cell graft. The Si_3N_4 cages are far superior to the PEEK and Ti spacers."

Superior Anti-Infective and Osteointegration Properties

Results of these recent studies and anecdotal evidence from spine surgeons show that Si_3N_4 has intrinsic antibacterial properties. In addition, Si_3N_4 displays preferential adsorption of fibronectin, vitronectin, and laminin when compared with PEEK or Ti.

Valeo® OL Silicon Nitride Interbody Fusion Device

"As clinicians we can now offer patients a biomaterial (Si_3N_4) that is easy to use, easy to image, provides better bone growth and has some antibacterial properties," Dr. Patel states. "It all adds up step-by-step to an impressive product."

To conclude, the anti-infective, osteopromotive, and osteointegration properties of Silicon Nitride are superior to PEEK and Ti implants. These properties should provide better clinical outcomes and lead to improved patient outcomes as related to the use of orthopedic implant materials in spinal fusion surgery.

For more information about Amedica's flagship material Silicon Nitride (Si_3N_4), and complete product line for spine surgeons, please call (855) 839-3500, or visit our website at www.amedica.com.

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