

Increased Bone Attachment to Silicon Nitride (Si3N4) Materials Used in Interbody Fusion Cages (IBF) Compared to Polyetheretherketone (PEEK) and Titanium (Ti) Materials - An In vivo Study

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Introduction

Bony on-growth is an important requirement for interbody fusion devices. It was demonstrated that PEEK spinal fusion implants develop a fibrous tissue layer around the implant which compromises its attachment strength to bone. Clinically, this raises concerns of graft dislodgement as well as pseudoarthrosis. While titanium implants have demonstrated greater osteointegration, clinical assessment of bone integration is limited due to the poor imaging characteristics of this material. Silicon nitride (Si3N4) is a novel biomaterial with favorable imaging characteristics utilized in spinal interbody fusion devices. The purpose of this study was to conduct an *in vivo* comparison of the osteointegration characteristics of Si3N4, PEEK and Ti with and without bacterial inoculation.

Methods

Uniform samples of Si3N4, PEEK, and Ti were implanted into the calvaria (skull) of Wistar rats (2 years old) using standard techniques. Rats were sacrificed at 3, 7, and 14 days. Resected samples of bone and implants were subjected to a mechanical push-out test to assess the bony integration strength using a Micro Tester 5848 (Instron) with a 1-kN load cell. In half of the animals receiving each biomaterial, the surgical site was randomly inoculated with a standard aliquot of 1×10^4 *S. epidermis* (ATCC, Manassas, VA, strain #35984); the other half received a matching aliquot of saline as control.

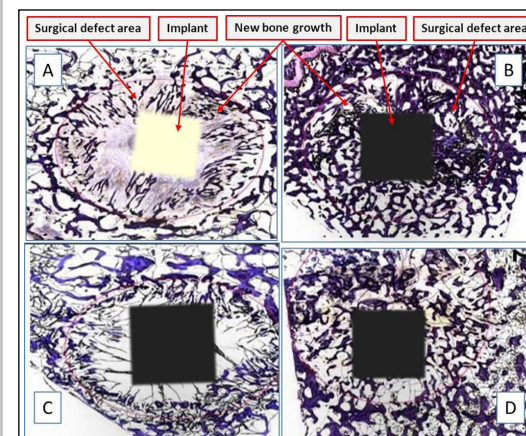
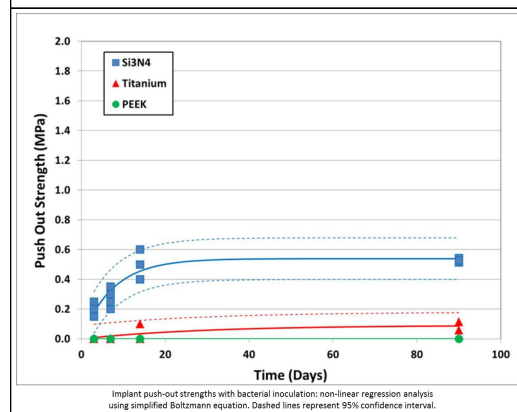
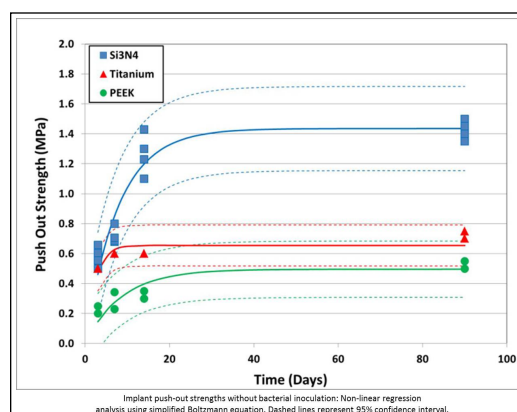
Results

Under conditions of no bacteria, the PEEK and Ti implants were structurally unstable so adequate histology sectioning at the 3 and 7 day time periods was not possible. Conversely, Si3N4 implants were stable and showed reasonable osteointegration even at these short time periods. For inoculated implants, histology could only be performed at 14 and 90 days respectively. PEEK or Ti implants showed no or minimal osteointegration regardless of the implantation times. For Si3N4, significantly greater new bone formation occurred in calvarial defects, including material on-growth, when compared to PEEK and Ti at all implantation times. Si3N4 implants also exhibited considerably decreased biofilm formation in comparison to that of PEEK and Ti. At 90 days post-implantation, live bacteria were present in the calvariae with PEEK implants (88%) and Ti implants (21%), while no bacteria could be identified in defects containing Si3N4 implants.

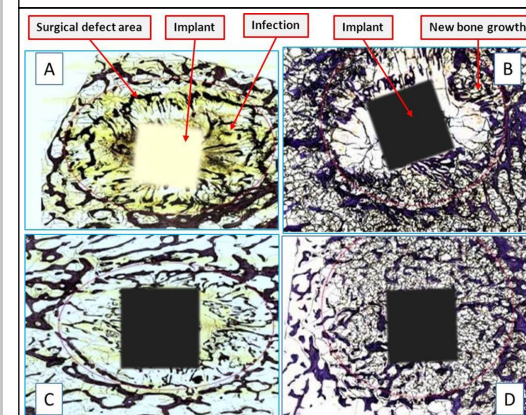
Push-out strengths for Ti were higher than PEEK, while Si3N4 samples had strengths which were more than double that of Ti at all-time points.

Conclusions

The present *in vivo* study was done to examine the propensity for infection, and the osteointegration behavior of different commercially available biomaterials, in the presence of *S. epidermis*. The results demonstrated that Si3N4 has substantially improved antibacterial and osteoinductive properties in comparison with Ti or PEEK.



Wistar rat calvaria histology 3 months after implantation without bacterial inoculation: (A) PEEK – 8% new bone at implant interface, 24% new bone in surgical area; (B) Si3N4 – 65% new bone at implant interface, 71% new bone in surgical area; (C) Ti – 19% new bone at implant interface, 36% new bone in surgical area; (D) Si3N4 – 52% new bone at implant interface, 66% new bone in surgical area.

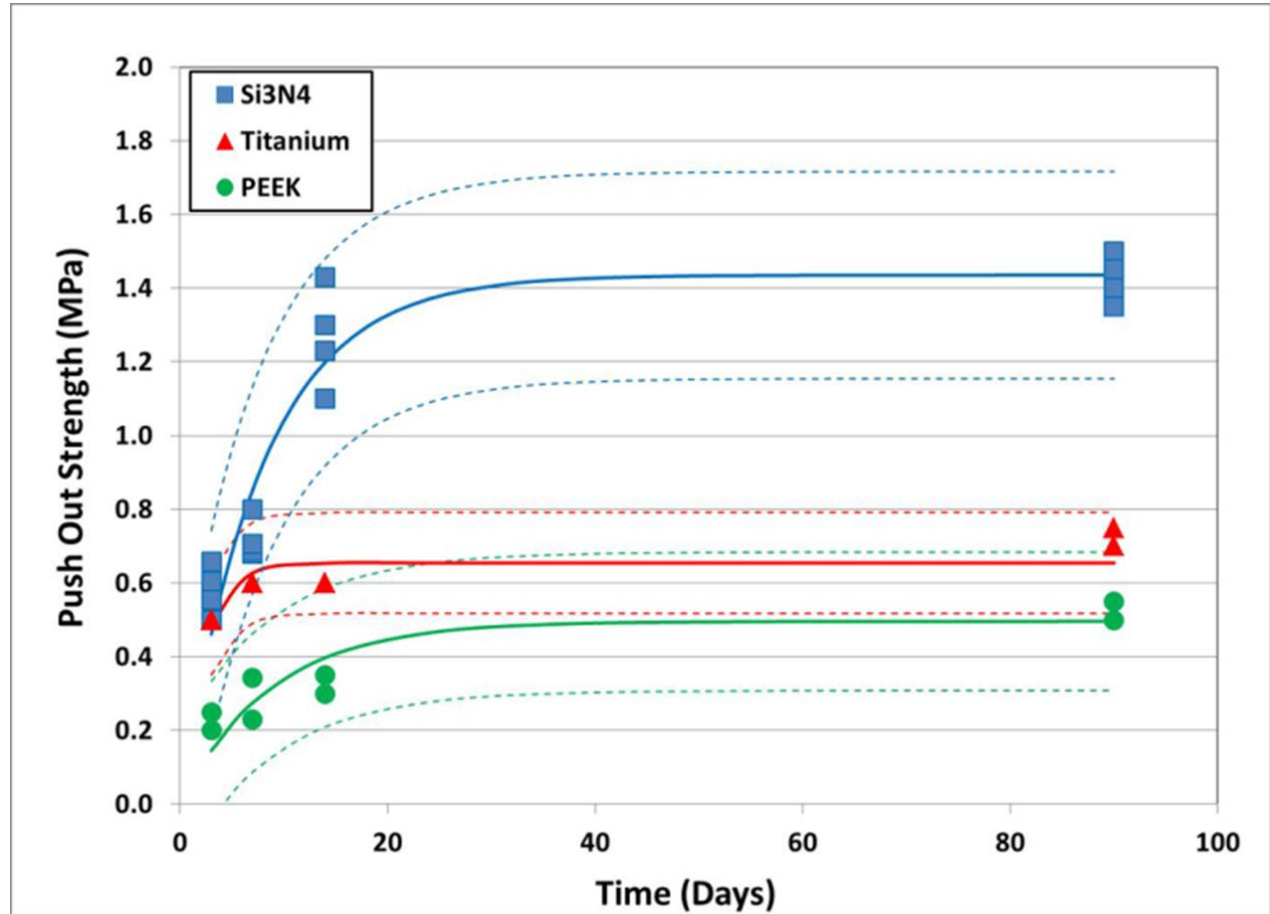


Wistar rat calvaria histology 3 months after implantation with bacterial inoculation: (A) PEEK – 5% new bone at implant interface, 95% bacteria at implant interface, 21% new bone growth in surgical area, 88% bacteria growth in surgical area; (B) Si3N4 – 25% new bone at implant interface, 0% bacteria at implant interface, 39% new bone growth in surgical area, 0% bacteria in surgical area; (C) Ti – 9% bone at implant interface, 67% bacteria at implant interface, 26% new bone growth in surgical area, 21% bacteria in surgical area; (D) Si3N4 – 21% new bone at implant interface, 0% bacteria at implant interface, 42% new bone growth in surgical area, 0% bacteria in surgical area.

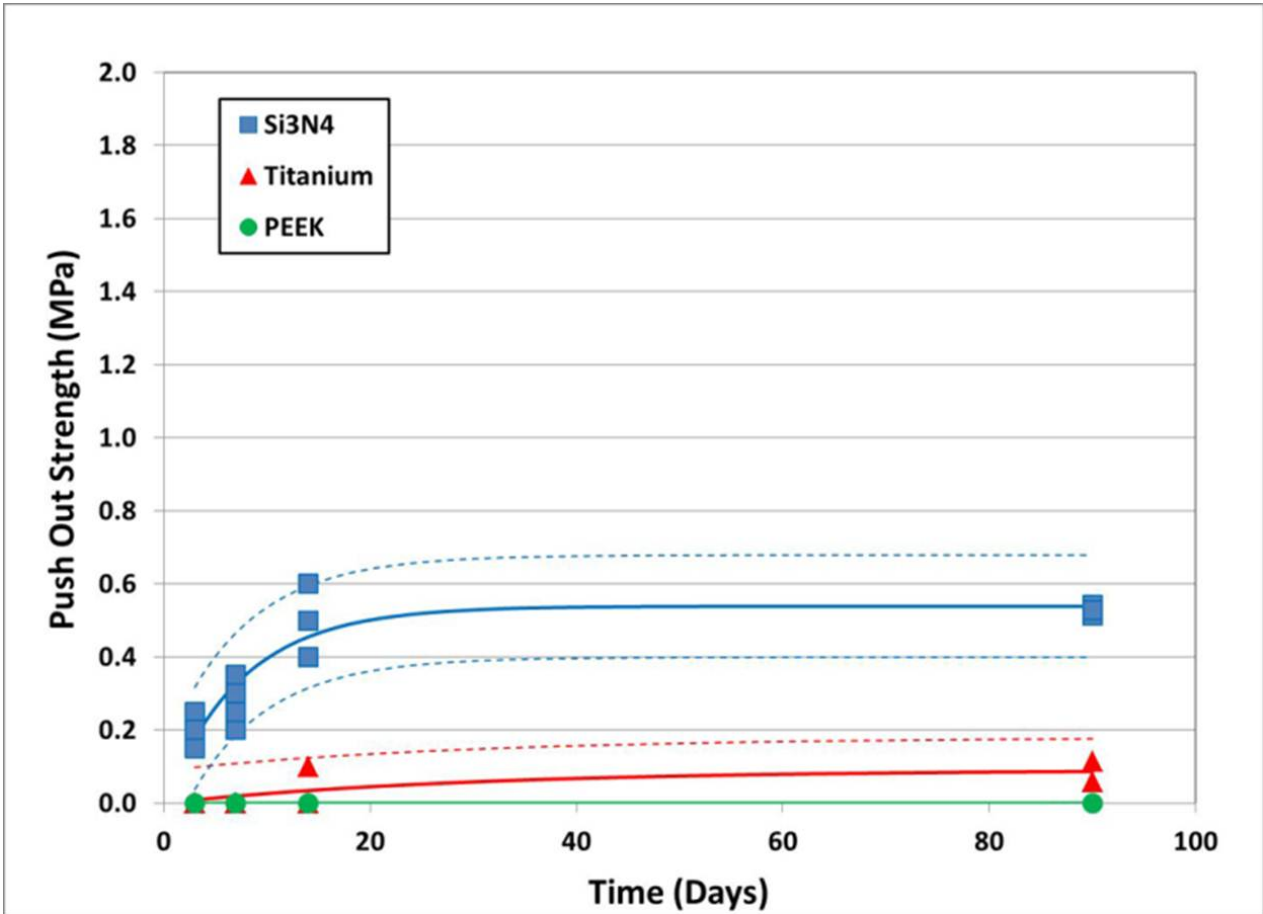
References

1. Neumann A, Unkel C, Werry C, et al. Prototype of a silicon nitride ceramic-based miniplate osteofixation system for the midface. *Otolaryngology - Head & Neck Surgery*. 2006;134(6):923-930.

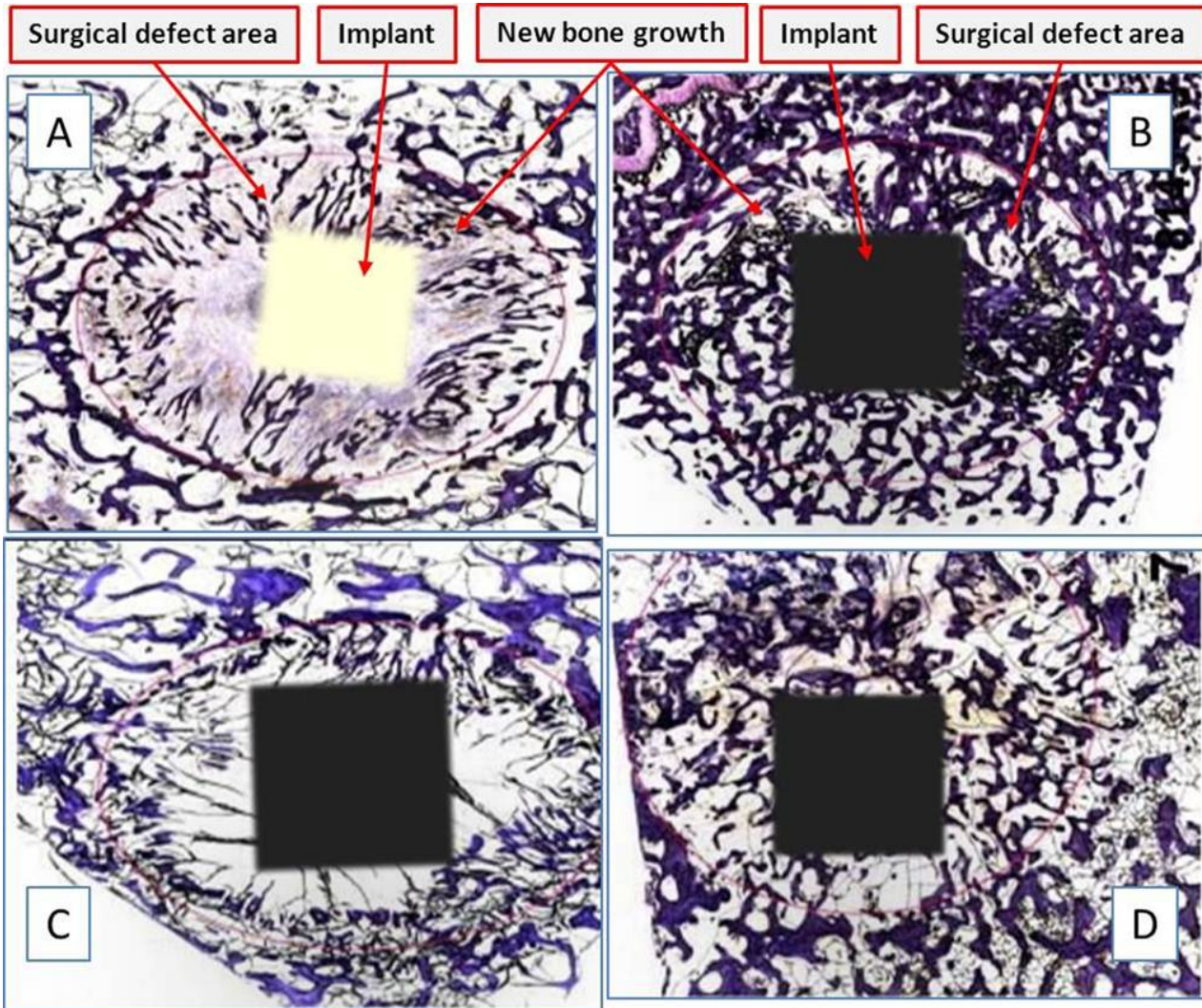
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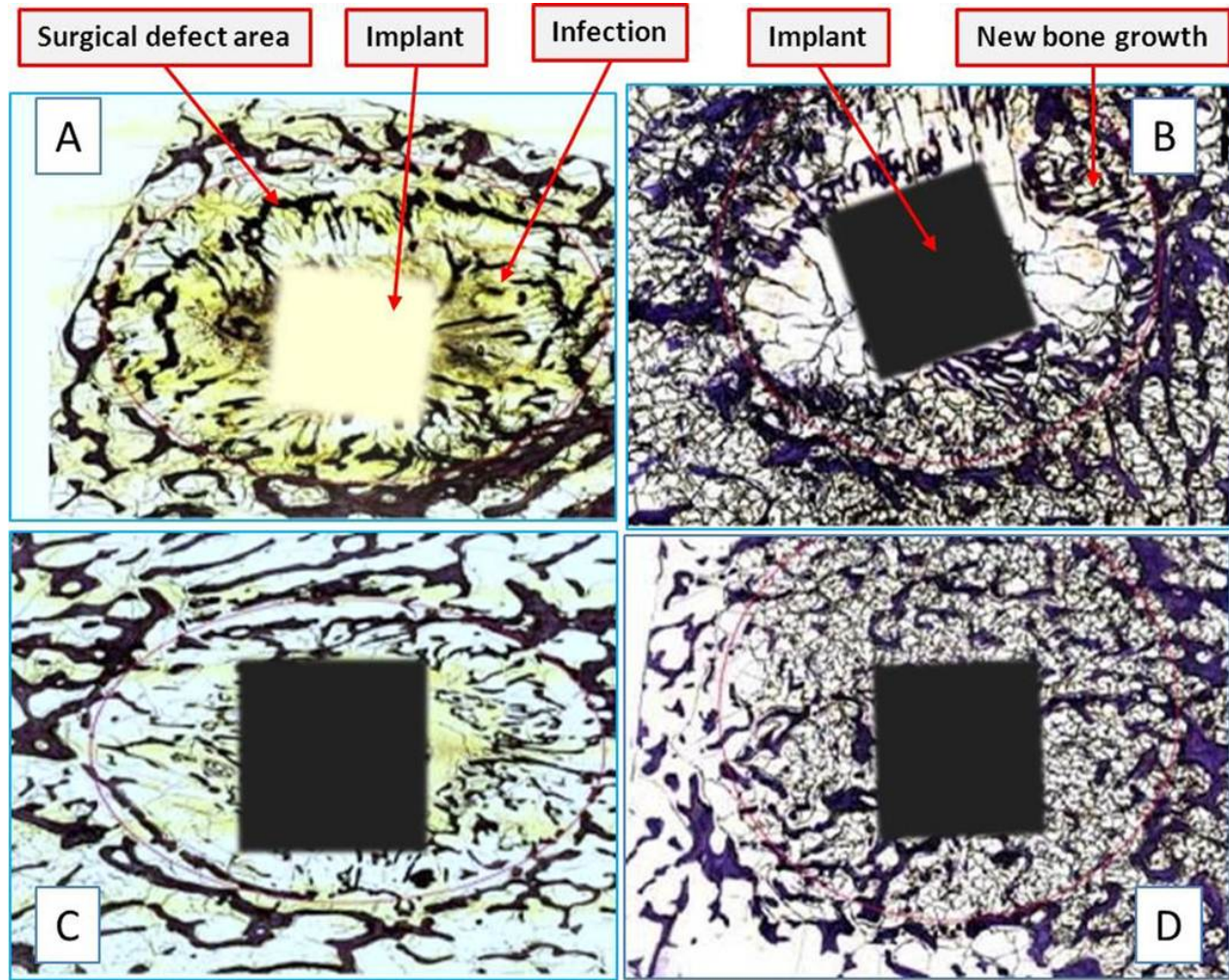
Implant push-out strengths without bacterial inoculation: Non-linear regression analysis using simplified Boltzmann equation. Dashed lines represent 95% confidence interval.



Implant push-out strengths with bacterial inoculation: non-linear regression analysis using simplified Boltzmann equation. Dashed lines represent 95% confidence interval.



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