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Anterior Lumbar Interbody Fusion Using Reaction Bonded Silicon Nitride Implants: Long-Term Case Series of the First Synthetic Anterior Lumbar Interbody Fusion Spacer Implanted in Humans

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Key words
- ALIF spacer
- Anterior lumbar interbody fusion
- Human implantation
- Intervertebral spacer
- Reaction bonded Si_3N_4
- 30 years outcome
- Silicon nitride

Abbreviations and Acronyms
ALIF: Anterior lumbar interbody fusion
CT: Computed tomography
ODI: Oswestry Disability Index
Si_3N_4: Silicon nitride
VAS: Visual analog scale

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BACKGROUND: **In this study, a historical case series is reported of reaction bonded silicon nitride (Si_3N_4) implants for anterior lumbar interbody fusion (ALIF) for a patient population of 30 and surgery levels L3/4, L4/5, and/or L5/S1. Before the study, the only work on Si_3N_4 as a biomedical material was associated preliminary work, which involved animal trials using a rabbit model. The objective was to undertake the first use of Si_3N_4 as a biomedical material for humans, as an implant for ALIF.**

METHODS: **The Si_3N_4 implants were prepared by die-pressing silicon powder and reaction bonding in 95 N_2/5 H_2 at ~1400°C for ~50 hours. The surgeries involved a retroperitoneal approach for L3/4 and L4/5 levels and a transperitoneal approach for L5/S1 level. The patient follow-up involved assessment of radiologic fusion up to 30 years and clinical outcomes to 10 years.**

RESULTS: **The reaction bonded Si_3N_4 implants were found to be biologically safe and to show high fusion rates with minimal subsidence, no abnormal reaction, and no other complications. The primary outcome measure, visual analog scale back pain, improved from a preoperative mean of 8.4 (range, 6–10) to a mean of 3.7 (range, 0–9) at 5 years and a mean of 4.9 (range, 0–9) at 10 years. The Oswestry Disability Index improved from a preoperative mean of 48 (range, 26–84) to a mean of 35 (range, 4–76) at 10 years.**

CONCLUSIONS: **This study confirms that Si_3N_4 is biologically safe in the long-term, with capacity for excellent radiologic osseointegration.**

INTRODUCTION

The pioneering biomedical experimental work on silicon nitride (Si_3N_4), which used dense glass-bonded Si_3N_4, was reported by Griss et al. in 1980.[1] The presence of a multicomponent glass (containing magnesium and iron) was responsible for the low biocompatibility of these samples. However, the first consideration of Si_3N_4 as a potential biomaterial (in this case, as porous reaction bonded Si_3N_4) predates this study, having been patented by McCartney et al. in 1979.[2] This form of Si_3N_4 is different because it is nearly pure, with only a small amount of single-component SiO_2 glass contamination and usually a minute amount of unreacted silicon.[3-5] This group's work continued with the earliest reports on Si_3N_4 as a potential orthopedic implant material in 1988[6] and in a morphologic study using a rabbit model.[7] The existence of the potential to form fibrous morphologies of both α-Si_3N_4 and β-Si_3N_4 had been established for many years by this time,[3-5] which motivated simultaneous studies of the biological effects of Si_3N_4 in both fibrous and nonfibrous forms.[8,9] Since this time, there have been many reports discussing Si_3N_4 as a biomedical material.[10-16]

Si_3N_4 was viewed as a promising biomaterial initially because its low free energy makes it stable and hence of low susceptibility to corrosion or reaction in vivo.[3-5] In addition, its processing is effectively net-shaped[4,17,18] and the pore size can be controlled with a high degree of accuracy, neither of which can be achieved easily through conventional densification. Si_3N_4 can be fabricated with relatively high purity, depending on the purities of the silicon metal and the nitriding gas. It possesses several attractive physical and mechanical properties,[3-5,19,20] which are summarized in Table 1.

In its dense form, Si_3N_4 shows outstanding mechanical properties,[3-5,19] which are responsible for its potential in joint arthroplasty.[21-28] Conversely, porous Si_3N_4 has applications for bone scaffolds or in arthrodesis.[1,29,30] Although the biocompatibility of Si_3N_4 is known.[1,7-9,20,31,32] its low partial radiolucency establishes it as an excellent radiographic material.[22,31,32] Further, it shows decreased bacterial

Table 1. Representative Properties of Reaction Bonded Si_3N_4

Property	Apparent Porosity Range (%)	Value	Reference
True density (kg/m^3)			
Typical	0	3180	3
α-Si_3N_4	0	3170–3190	5
β-Si_3N_4	0	3190–3200	5
Bulk density (kg/m^3)	55–21	1500–2500	3
Apparent porosity (%)	—	18–40	3
	—	7–30	5
Elastic modulus (GPa)	30–18	120–180	3
	35–6	75–330	19
	70–45	4–17*	20
Shear modulus (GPa)	35–6	30–80	19
Poisson ratio	35–6	0.20	19
3-point bend strength (MPa)	40–18	80–300	3
4-point bend strength (MPa)	55–12	20–250	5
Compressive strength (MPa)	70–45	20–75*	20
Fracture toughness (MPa/m$^{1/2}$)	30–12	1.5–2.8	5
Vickers microhardness (GPa)	30–12	1.6–2.2	5

*Data for gel-cast Si_3N_4.

activity compared with polyether ether ketone and medical-grade titanium.[33-35] Si_3N_4 has applications in several surgical fields including faciomaxillary, dental, and orthopedic surgery.[14] It is well suited for an interbody material because of its low elastic modulus relative to those of most other metallic and ceramic orthopedic biomaterials.[14]

According to a review conducted by Phan et al.,[36] the first reported synthetic anterior interbody spacer was implanted in 1992. During 1986–1988, the Si_3N_4 anterior lumbar interbody fusion (ALIF) implants were designed, manufactured, and implanted in 30 patients in Australia. This development makes the Si_3N_4 interbody spacer the world's first synthetic ALIF spacer. This work was performed under license by Sialon Ceramics Pty. Ltd. in Sydney and the surgery was performed in Perth.[37-41] After preoperative assessment, partial populations of the patients were subjected to follow-up at the approximate time points 1, 5, 10, and 30 years. Documentation of the radiologic and clinical outcomes for the 1-year and 5-year follow-ups[21] and the 5-year and 10-year follow-ups[42] has been published. The present work reports the long-term outcomes in terms of fusion and biocompatibility for the 30-year follow-up. This long-term program represents the longest radiologic and clinical study for any spinal interbody synthetic implant in history.

METHODS

Si_3N_4 Implant Preparation

Design. Two types of implants were used:

1) Type I: These implants were produced by single-stage uniaxial pressing of silicon of −44 μm grain size and they were microstructurally homogenous and of dimensions ~30 mm × 15 mm ×15 mm. These implants were processed initially but phased out at an early stage.
2) Type II: These implants consisted of a duplex microstructure of 4 dense

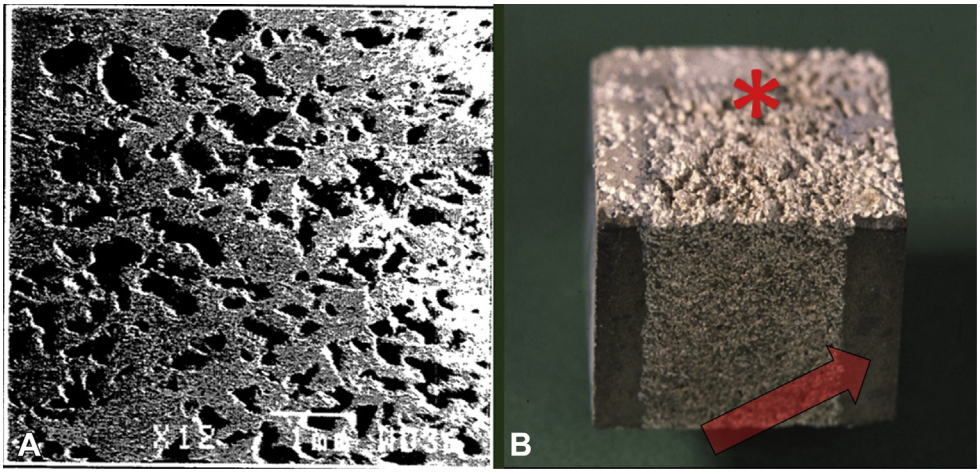

Figure 1. Structure of silicon nitride implants. (**A**) Microstructure (×12 Magnification). (**B**) Macrostructure showing load-bearing outer edge (*arrow*) and porous internal structure (*asterisk*).

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