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The Rationale for Silicon Nitride Bearings in Orthopaedic Applications

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1. Introduction

The history of silicon nitride (Si_3N_4) has been described previously; detailed analyses of particles of meteoritic rock have been shown to contain silicon nitride crystals, suggesting that this material exists naturally in the galaxy.¹ Synthetic Si_3N_4 was probably developed by Deville and Wöhler in 1859. Commercial interest in this material increased in the 1950s, as the material properties of silicon nitride were better understood, and its application in internal combustion engines was contemplated.

Today, industrial applications of silicon nitride ceramics and related composites are common; these include bearings, turbine blades, and glow plugs, related to the fact that silicon nitride has high fracture toughness, strength, and attractive wear properties.² Ceramic ball bearings made of silicon nitride, for example, have been used in technical applications, and their extreme strength has been validated using a number of techniques.³ These material qualities have led many investigators to speculate that silicon nitride may also have applicability in biomedical fields, especially since it exhibits biocompatibility^{4, 5} and is visible on plain radiographs as a partially radiolucent material. Because of the fortuitous combination of these properties, silicon nitride has been investigated for applications in skeletal repair, and for the bearings of prosthetic replacements of arthritic hip and knee joints.

Since clinical data are yet sparse, this review will attempt to give the reader an overview of the rationale for the use of silicon nitride in biomedical, specifically orthopaedic applications. As of the present time, surgical screws, plates, and bearings for use in prosthetic hip and knee joints have been developed and tested, using silicon nitride as the source material.⁶⁻⁸ Cervical spacers and spinal fusion devices made of silicon nitride composites are presently in use, although clinical results have yet to be reported given the relatively short follow-up time. The goal of this chapter is to examine the scientific rationale to support the adoption of silicon nitride ceramics for use in biomedical, specifically, orthopaedic applications.

2. Clinical rationale for ceramics

Modern biomaterials, such as titanium alloys, polished cobalt-chromium, and high-density polyethylene have revolutionized orthopaedic surgery since the 1970's, such that at the

present time, total hip replacement and total knee replacement for diseased joints are commonplace around the world, with very predictable and durable outcomes.^{9, 10} One concern, over the long-term, is the host biological response to accumulated, microscopic wear debris particles in the periprosthetic joint space. Strategies to decrease bearing wear in the ball-and-socket joint of artificial hip joints, and the sliding-rolling articulation of artificial knee joints have been pursued vigorously by orthopaedic implant manufacturers and material scientists, with variable success.

The bearing surface credited with ushering in modern hip and knee replacement surgery is metal-on-polyethylene, specifically, a highly polished cobalt chromium surface articulating against a polyethylene surface. In total hip replacements, cobalt-chromium femoral heads are still used widely by surgeons, usually with prosthetic socket components made of ultrahigh-molecular-weight or cross-linked polyethylene. In total knees, the femoral components are made of cobalt-chromium that articulate with a polyethylene spacer, designed to reproduce, at least in part, the complex articular geometry of the human knee joint.

The cross-linking of polyethylene is a manufacturing strategy designed to reduce the incidence of bearing wear in prosthetic hip and knee joints.^{11, 12} Low wear is desirable since particulate wear in hip and knee replacement ultimately results in inflammation, periprosthetic bone loss, and premature implant loosening, necessitating repeat surgery. These considerations apply even more acutely to the young and active patients who will place greater demands on the prosthetic joint. Alumina and zirconia ceramics were introduced to replace metal surfaces in joint replacement surgery; the goal was to offer a smooth, low-friction surface that could reduce wear more than the metal-polyethylene bearings. Evidence has shown reduced wear when ceramic surfaces are used in hip^{13, 14} and knee¹⁵ replacement surgery, instead of metal.

Despite their promising role in orthopaedic bearings, zirconia and alumina ceramics have had their drawbacks. Zirconia is an unstable material that can undergo phase transformation *in vivo*, leading to catastrophic failure; this material has been largely withdrawn from the medical market.¹⁶ In comparison studies with cobalt-chromium, zirconia femoral heads have not shown superior wear reduction in total hip replacements.^{17, 18} Alumina is the most widely used ceramic material in biomedical applications today; despite very attractive wear reductions, sporadic cases of catastrophic bearing failure requiring major repeat surgery continue to be reported.^{19, 20} Clearly, there is a need for even tougher ceramic materials that are biocompatible, and can provide reliable, long-term service in orthopaedic bearings, with negligible wear rates.

2.1 Material Properties of Silicon Nitride

Silicon nitride has been developed as an industrial ceramic for more than 50 years, and during that time, its mechanical properties have been significantly improved by refining processing methods, and using additives to create composite structures. Of the different processing methods used to make silicon nitride, there are two typical processing routes, known as reaction-bonding and hot isostatic processing (HIP), respectively. Reaction-bonded silicon nitride processing is a method to produce ceramic material by incorporation and nitridation of silicon powders; this method was developed in the 1950s with the goal of developing internal combustion engines with hot-zone components made entirely from ceramics.¹ The resulting material has relatively low density, high porosity, and low strength. The HIP method was developed to address these concerns; it uses silicon nitride powder as the raw material and various sintering additives to produce bulk Si₃N₄ in confined graphite dies under a hot,

nitrogen environment. Silicon nitride thus prepared has improved strength, albeit at a higher manufacturing cost.²¹ A compromise is to combine the two technologies; thus, Si_3N_4 can be made by post-sintering the reaction-bonded silicon nitride in order to achieve a relatively high strength, at a fraction of the fabrication cost of HIPed Si_3N_4 .

Polished test bars with a shape of 3 x 4 x 30 mm made of silicon nitride with 10% Y_2O_3 and Al_2O_3 as additives have shown an initial bending strength of approximately 600 MPa; ion implantation of the structural ceramic can increase this strength significantly, as shown by Shi et al.²² These investigators found increases in specimen bending strength of 56%, 66%, and 35% by the implantation of Ti, Zr, and Cr ions, respectively.²² Silicon nitride, like other ceramics, is a brittle material; typical material property tests have shown that silicon nitride has a Vickers hardness of 12-13 GPa; Young's modulus of 299 GPa, Poisson's ratio of 0.270, and a typical grain size of 0.59 μm .²³

Composites of silicon nitride with 6 wt% yttrium oxide and 4 wt% alumina were fabricated to measure mechanical strength and related properties, according to ASTM C-1161 standards, using specimens with dimensions of 3 x 4 x 45 mm; results showed a near 100% theoretical material density (3.20 g/cm³), average grain width of 1.5 μm , flexural strength of 923 \pm 70 MPa, with a Weibull modulus of 19 and a fracture toughness of 10 \pm 1 MPa.m^{1/2}.²⁴ Both material strength and toughness are at least an order of magnitude higher than typical values reported for alumina, the most common ceramic bearing material in orthopaedic bearings today. These data have been validated by other authors; using two less favorable compositions of silicon nitride doped with yttrium and aluminum, Guedes et al reported a fracture toughness of 5 MPa m^{1/2} and Vickers hardness values of 13 GPa.²⁵

The intrinsic material properties of silicon nitride make it suitable for articulation against bearing steel, which is a softer material than ceramic. Thus, silicon nitride has been used in rolling contact applications in automotive, turbomachinery, and power industries, where it has a significant advantage due to its low density (half that of bearing steel), low friction, corrosion resistance, and reliable performance under extreme conditions.²¹ In modern aircraft and space vehicles, very demanding bearing operating conditions such as high vacuum (<10⁻⁶ Torr), extreme temperatures (e.g. +230 to -150°C), long life (both wear and fatigue life, usually 10-15 years without maintenance) and low friction are common requirements.²⁶

Fully densified Si_3N_4 has many advantages in such extreme applications; all-ceramic silicon nitride ball or roller bearings can operate against silicon nitride rolling elements and rings at temperatures up to 1000°C, at very high speeds. Hybrid ceramic-steel bearings perform just as well under these conditions; silicon nitride ceramic bearings in industry have met the requirements of higher efficiency, greater stiffness, higher speed, higher reliability, higher accuracy, lower friction, corrosion-resistance, and non-conductivity.²⁶ Thus, from a mechanical standpoint, silicon nitride ceramic should be adaptable to orthopaedic bearings, whether articulating against polyethylene, metal, or silicon nitride itself.⁸ Practical barriers to widespread adoption of this technology are related to material and processing costs, and the need for reproducibility and reliability; these problems are common to all ceramic-powder blending and sintering processes.

3. Tribological properties of silicon nitride

The suitability of silicon nitride for hip and knee bearings has been debated in the literature, but most authors agree that in the absence of material oxidation *in vivo*, silicon nitride has

the low friction necessary to articulate against itself, even when water is the only lubricant.²⁷ Published friction and wear data for different types of silicon nitride show a wide scatter due to different test conditions used in various studies.²⁸ Prototype total hip bearings have been fabricated using sintered Si_3N_4 composites (Amedica Corporation, Salt Lake City, Utah, USA); these have confirmed improved fracture toughness and strength over medical-grade alumina, and when tested in a hip simulator, both cobalt-chromium and silicon nitride femoral heads produced low wear rates against silicon nitride acetabular bearings that were comparable to $\text{Al}_2\text{O}_3\text{-Al}_2\text{O}_3$ wear rates, which are the lowest of any orthopaedic bearing.²⁴ Other work has validated the observation that water-lubricated silicon nitride has very low friction when sliding against itself.²⁹ The *in vivo* environment should be more favorable yet, since human synovial fluid is an excellent lubricant, regardless of the bearing material used.^{30, 31}

Studies on the tribological behavior of ceramics have shown that the wear mechanisms depend on contact conditions during laboratory testing. In most structural ceramics such as silicon nitride, wear occurs through a small-scale surface fracture process if the contact load exceeds a threshold value specific to that material. Another mechanism whereby wear can be generated is surface oxidation of the material. In laboratory testing with pure silicon nitride, both mechanisms of wear have been confirmed.²⁸ Accordingly, for stable, long-term steady performance of silicon nitride orthopaedic bearings, a chemically-inert material composition that is impervious to surface oxidation is mandatory. Precise control of the raw powders and processing parameters is critical in manufacturing bearing components with predictable, reliable *in vivo* behavior that can last for the remaining decades of a patient's lifespan.

Laboratory investigations using finite element analyses support the use of silicon nitride in load-bearing hip resurfacing components; these differ from hip replacement in that the diseased femoral head is resurfaced with a prosthetic cap, rather than being cut out and replaced entirely.³² Stress distributions in the proximal femur bone with implanted silicon nitride hip prostheses are similar to those of intact, healthy bone. Mazzocchi et al investigated silicon nitride ceramics for their potential use in orthopaedic implants, and validated several properties that are critical to biomedical applications, such as wetting behavior and wear performance that simulates conditions typical of a hip joint prosthesis.³³ In three different silicon nitride ceramic materials prepared, these investigators found a lower contact angle of water when compared to oxide ceramics such as alumina and zirconia. Also, very low friction coefficients were consistently measured with undetectable surface modifications and wear tracks in the silicon nitride materials tested, using a disc-on-ball model of wear detection.³³

4. Material stability of silicon nitride

A key concern in evaluating the use of any new material for *in vivo* implantation is the long-term stability of that material, i.e., a lack of corrosion, oxidation, and other chemical alterations that can affect material properties after implantation. Silicon nitride in raw, unimplanted form, when exposed to flowing oxygen, rapidly forms oxides on the surface that are populated with cracks and pores. Investigations with additives of other materials can dramatically change this corrosive behavior, such that the resulting composites are suitable for long-term material stability, with imperviousness to oxidative degradation.

Surface modifications for different silicon nitride material preparations were investigated for a duration of 45 days, using liquid media water and isotonic physiological saline solution.³³ Both weight changes in the specimens, and scanning electron microscopic examination of the exposed surfaces were done to identify morphological and chemical modifications. These experiments showed a very limited surface modification related to exposure to oxygen-containing media; the newly formed phases were limited to the boundary zone, in the nano-scale.³³ Silicon nitride ceramics contain, besides silicon nitride grains, the grain boundary phases formed by sintering additives, and SiO₂ that usually exists on the surface of the starting silicon nitride powders. Independent of additives, during sintering, SiO₂ partially decomposes forming surface gradients, or even leads to metallic Si inclusions in the ceramic. The often-used additive Al₂O₃ partially dissolves into the Si₃N₄ grains by a chemical reaction; the resulting boundary phase has a decisive influence on the mechanical properties and oxidative behavior of the bulk ceramic. Different Y₂O₃/ Al₂O₃ containing silicon nitride ceramics with amorphous grain boundaries exhibit varying degrees of corrosion-resistance, even to acids.³⁴

Aluminum implantation into raw silicon nitride is a valid strategy to control material oxidation that is mediated by sodium.³⁵ The beneficial role of aluminum is in surface modification of the ceramic, so that sodium-accelerated oxidation processes can be reversed. In addition, the surface morphology and phase characteristics of the oxides are enhanced, resulting in smooth and glassy oxide layers that may play a protective role during oxidation. Related work has identified the optimal concentrations of aluminum ion implantation necessary for the optimization of the oxidation resistance of Si₃N₄ ceramics.³⁶

Accelerated aging *in vivo* was modeled using autoclaving of prototype Si₃N₄ bearings; the autoclave environment exposes the material to high temperatures and humidity. Despite exposure to autoclaving for 100 hours, composite silicon nitride doped with Al₂O₃ and Y₂O₃ (Amedica Corporation, Salt Lake City, UT) showed no phase changes on x-ray diffraction, and the material maintained its superior flexural strength.⁸ Thus, while phase changes and material degradation are a concern with implantable materials, and the history of catastrophic failures of zirconia bearings in total hip replacement³⁷⁻³⁹ sound a cautionary note in this regard, existing evidence concerning the properties of silicon nitride composites, and the successful use of silicon nitride in critical industrial environments attest to the stability of this material, and to its suitability for use in the *in vivo* environment. Finally, the material has been implanted in spinal applications in the United States for at least two years now, with no adverse reports concerning any implant.

5. Biocompatibility of silicon nitride

A requirement of any material used for *in vivo* applications is that it must be bioinert, i.e., the material must not demonstrate toxicity in bulk or particulate form. Oxide ceramics, such as zirconia and alumina were attractive as initial ceramic materials in orthopaedic applications because of their excellent biocompatibility, in addition to their wear resistance. Recent evidence with cytotoxicity assays shows that silicon nitride ceramics may have a similar, favorable biocompatibility profile.

Not only are silicon nitride ceramics non-toxic, but the material may encourage cell adhesion, normal proliferation, and differentiation. Neumann et al investigated silicon nitride ceramics of different surface properties, with titanium alloy as a reference; cytotoxicity testing, cell viability, and morphology assessment were performed applying the

L929-mice fibroblast cell culture model in a direct contact assay.⁴⁰ These investigators reported favorable results with all silicon nitride materials tested; cell growth, viability, and morphology were comparable to titanium, and polished silicon nitride surfaces appeared to promote cell growth. Further investigation compared industrial-grade silicon nitride using the L929-cell culture model, with alumina and titanium alloy as controls.⁴¹ Again, silicon nitride ceramics showed no cytotoxicity and favorable physicochemical properties. Investigators concluded that silicon nitride ceramic should be considered for biomedical applications.

The biocompatibility of Si_3N_4 has also been assessed in an *in vitro* model using the human osteoblast-like MG-63 cell line.⁴² Results showed that silicon nitride is a non-toxic, biocompatible ceramic surface for the propagation of functional human bone cells *in vitro*. Its high wear resistance and ability to support bone cell growth and metabolism make silicon nitride an attractive candidate for clinical application. Cappi et al performed mechanical investigations and cell culture tests with mouse fibroblast cells (L929) and human mesenchymal stem cells on silicon nitride; excellent cytocompatibility was demonstrated by live/dead staining for both types of cells.⁴³ Furthermore, the human mesenchymal stem cells were able to differentiate towards osteoblasts on all silicon-based ceramic materials tested. Guedes et al implanted silicon nitride ceramic constructs into rabbit tibias for 8 weeks, and showed no adverse reaction, with bone ingrowth occurring into and around the implants.⁴⁴ In a separate investigation, the authors also found that silicon nitride-based ceramics did not elicit any toxic response when tested with standard cell culture models.²⁵

Howlett et al investigated the effect of silicon nitride on rabbit marrow stromal cells and their differentiation when grown *in vitro* and *in vivo*.⁴ *In vitro*, marrow stromal cells attached to the ceramic discs; fresh marrow stromal cells formed cartilage, bone, and fibrous tissue when implanted with silicon nitride, or without, into the intraperitoneal cavity of rabbits. When inserted into living bone, silicon nitride promoted the formation of a cuff of bone, conferring osseous stability; the material itself remained unchanged during the animal's life, with morphologically normal tissue found adjacent to the implant upon autopsy.⁴

6. Orthopaedic applications of silicon nitride

Ceramic materials have been used in orthopaedic bearings for several decades; their advantages over cobalt-chrome metal in terms of low friction and improved wear qualities are well known, and have been reviewed extensively.⁴⁵ Silicon nitride ceramic materials are markedly different from the other, alumina-based ceramics presently used in orthopaedic surgery. While alumina, and oxidized zirconium are used presently in the bearings of total hip⁴⁶⁻⁴⁹, and total knee replacements⁵⁰⁻⁵³, one unique property of silicon nitride ceramics pertains to its ability to be formulated into a porous substrate as well as a hard glassy bearing surface. As a porous material, silicon nitride is capable of direct bone ingrowth. Of all ceramic materials used in biomedical applications therefore, silicon nitride is the only one that addresses the possibility of monolithic implants, capable of an articulating smooth surface on one side, with a porous ingrowth surface fabricated on the opposing side of the same implant. Thus, several skeletal applications of silicon nitride are feasible.

Total joint replacements, like prosthetic hip and knee arthroplasty, require materials with low wear rates and favorable frictional coefficients that remain stable *in vivo*, for several

decades of service life. Silicon nitride articulating against itself, or metal, or polyethylene seems to satisfy this requirement since under test conditions, the contact surface of silicon nitride becomes ultra-smooth due to tribochemical polishing, and the friction becomes very low at increasing sliding distances.²⁷ Thus, silicon nitride should be an excellent material for total hip bearings, especially in light of very favorable tribological properties when this material articulates against itself in water. In theory, if oxidation were a significant concern, non-oxide ceramics like silicon nitride should not be suitable for hip and knee bearings, but as studies have demonstrated, surface oxidation can be controlled or eliminated by doping raw silicon nitride with selected additives, thereby increasing its resistance to oxidation.^{24, 54} Osteofixation using plates and screws, such as in maxillofacial surgery is another potential application of silicon nitride. Unlike metal devices, silicon nitride is partially radiolucent, which means that both the implant and the underlying bone can be visualized on plain radiography. Such is not the case with metal implants. Reaction-bonded porous silicon nitride yields an implant material suitable for spinal surgery, particularly fusion of intervertebral bodies; in this application, silicon nitride has already been in clinical use in the United States for at least two years, with no reports of adverse effects.⁵⁵ Other potential biomedical applications of silicon nitride include drug-release devices, microelectromechanical systems (Bio-MEMS), and traumatic reconstructions of otorhinolaryngologic skeletal defects.⁵⁶⁻⁵⁹

A cancellous-structured porous silicon nitride composite ceramic has been developed and is in commercial use as a spinal fusion implant; cylindrical implants have shown bone ingrowth rates similar to those reported for porous titanium, indicating that porous silicon nitride is an excellent substrate for implants designed for direct, biological skeletal fixation.⁶⁰ New bone forms even in the cortical region of the rabbit tibia, and around silicon nitride implants, suggesting that the material is osteoconductive, and promotes stable osseous fixation.⁶¹

7. Conclusions

Ceramic materials have remarkable properties that have fueled speculation about their potential applications in the biomedical field, where the need for improved biocompatibility, strength, endurance, reliability, and related properties is especially acute. Oxide ceramics such as zirconium and alumina have been used in skeletal reconstruction; specifically as bearings in total hip and knee replacements. Today, alumina is the most common ceramic bearing used in orthopaedic surgery, and oxidized zirconium has replaced zirconia as a bearing surface.

As the world population increases, the demand for maintaining an active, healthy lifestyle has increased and will likely do so for the foreseeable future. Consistent with this demand, the need for artificial hip and knee replacements has continued a steady upward trend, especially in economically developed nations.⁶² The limitations of the materials used in orthopaedic joint reconstructions are evident in the significant burden of repeat surgery, with attendant increases in costs and morbidity, associated with failed total hip and knee replacements.^{63, 64} Improved materials, such as silicon nitride composites, when thoroughly investigated in terms of their mechanical properties and suitability for *in vivo* implantation, may play a role in the development of future orthopaedic implants that can relieve human suffering and dysfunction in the years to come. A half century after industrial silicon nitride ceramics were developed, this material may yet fulfill its promise in the biomedical field.

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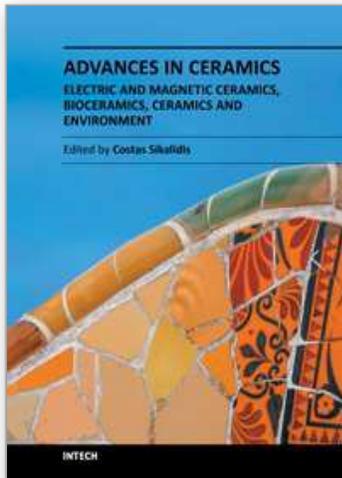
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