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TECHNOLOGY UPDATE

Stiffness and Imaging Characteristics

Two Overriding Benefits of Silicon Nitride Spinal Implants

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Optimal stiffness and superior postoperative visualization are two characteristics vital to the long-term success of spinal implant procedures. When set against other materials, AMEDICA's Silicon Nitride implant (Si_3N_4), compares very favorably to other available options on the market.

STIFFNESS

It's been frequently argued that an implant's material may affect bone remodeling, skeletal attachment, and bone maintenance. The belief is that when implant stiffness closely matches that of bone, it reduces the incidence of stress shielding and transfers compressive load to graft material packed inside. This stimulates bone growth and promotes a satisfactory clinical result.

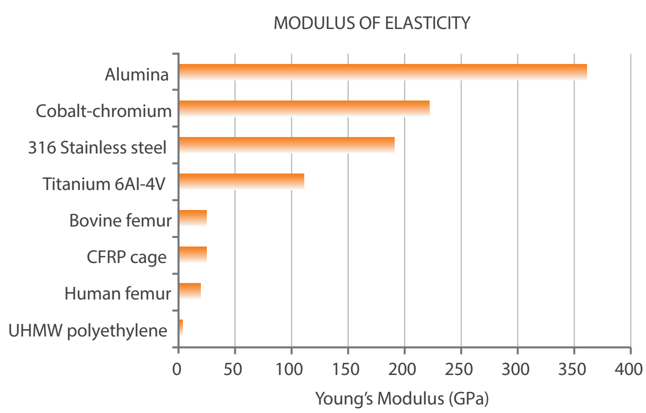
On the other hand, implants made of materials that are more stiff than bone, like silicon nitride, titanium, cobalt chrome, and stainless steel, will inhibit bone growth and skeletal attachment. AMEDICA's Silicon Nitride (Si_3N_4) is 100 times more stiff than cancellous bone, and 60 times more stiff than PEEK and Femoral Ring Allograft.

HERE ARE FOUR REASONS TO CONSIDER WHY SPINAL IMPLANTS SHOULD BE MADE FROM SI_3N_4.

1. MATCHING MODULUS IS A MYTH

Figure 1 compares various implant materials and demonstrates that the modulus of elasticity of a CFRP or PEEK cage is similar to that of a human femur. Given this, an implant made of these materials will move with adjacent bone and transmit forces to bone within and surrounding it. This generates a biomechanically invisible interface.[1]

Figure 1. Modulus of Elasticity of Various Biomaterials. Reproduction.



The femur is the longest and strongest bone in the human body.[2,3] Dong et al. measured the modulus of elasticity of femoral cortical bone at 16.6 Gpa.[4] By comparison, the trabecular bone between the vertebral endplates is even more porous. Jensen et al measured its modulus of elasticity at 3.8 GPa.[6]

Two studies examining implants retrieved from knee arthroplasty patients after as many as 14 months in-situ report a regional acceleratory phenomenon in bone apposition rate.[7,8] Bone apposition rate adjacent to the implants was greater than in bone 3mm away from the implant.

It was hypothesized that cyclic implant loading lead to localized stress risers in adjacent bone. Those stress risers caused micro fractures in the bone, promoting a remodeling response.

Generating this localized "boost" in bone growth requires an implant stiff enough to stress and fracture it.

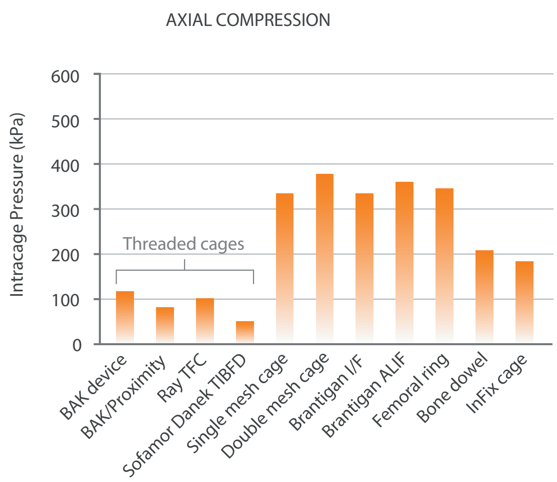
CFRP and PEEK implants induce bone growth not because they are less stiff, but because they are stiffer than adjacent bone.

2. STIFFNESS IS A RESULT OF MATERIAL AND DESIGN

Kanayama et al. introduced the measurement of intracage pressure as a technique to quantify stress shielding.[9,10] In this frequently cited study, 11 implants were compressed between cadaveric L4-L5 vertebral bodies. The resulting pressure in graft material packed inside was measured and compared.

Study results shown in Figure 2 suggest implants made of low stiffness materials would have a higher intracage pressure than implants made of stiffer materials. Additionally, higher pressure would promote bone growth within the implant.

Figure 2. Intracage Pressure of Various Implants in Axial Compression Between L4-L5 Vertebral Bodies. Reproduction.

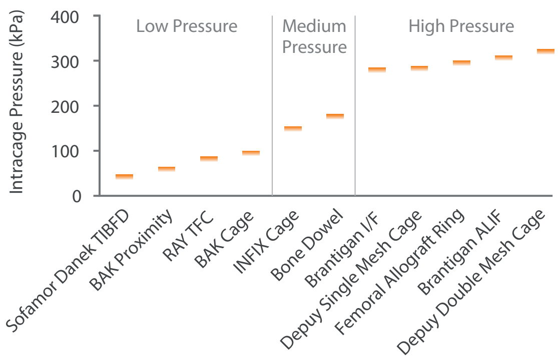


Pressure differences between the threaded cages and all other implants were significant. If threaded cages are excluded, pressures measured inside the other implants were not different. This is noteworthy because the implants were made of materials of varying stiffness. It was concluded that the difference in pressure was due to the mismatch in modulus of elasticity between bone and the implants.[1]

The data is shown again in Figure 3, this time ordered from lowest to highest pressure. Presenting the data in this manner identifies design variables, such as area of contact, implant height, geometry, and implant design that contributed to intracage pressure.

Based on this data, it is erroneous to conclude that an implant made of a low stiffness material will provide superior clinical results without considering the effects of design.

Figure 3. Intracage Pressure of Various Implants in Axial Compression Between L4-L5 Vertebral Bodies in Ascending Order. Reproduction.



3. STIFFNESS AND SUBSIDENCE: IS THERE A CORRELATION?

It has been assumed that an implant's stiffness will affect its susceptibility to subside. For example, a stiff implant:

- Will not move with adjacent vertebral bodies
- Will generate localized stress
- Will subside while a low stiffness implant will not

A standardized test (ASTM F2267) evaluates the propensity of spinal implants to subside.[11] It prescribes loading an implant in compression between polyurethane foam blocks and measuring the load applied to subside it into the foam. In this test, the polyurethane foam is considered a mechanical analog for bone.

To better understand the relationship between material stiffness and subsidence, spinal implants of identical geometry were fabricated of PEEK and Si_3N_4 and tested according to this standard.

Six of each implant type were compressed between steel blocks to determine their stiffness.

Implants made of Si_3N_4 were over 17 times more stiff than those made of PEEK.

Six of each implant type were then compressed between foam blocks to determine the subsidence load.

There was no significant difference in the subsidence load despite the large difference in implant stiffness. These tests demonstrate that if an implant is more stiff than bone, its constituent material has no bearing on its likelihood to subside.

4. PUTTING IMPLANT STIFFNESS INTO CONTEXT

Consider this exercise: spinal implants of identical geometry are fabricated in PEEK, CFRP, titanium, and Si_3N_4. In addition, consider theoretical implants made of femoral cortical bone, vertebral body cortical bone and vertebral body trabecular bone.

Now imagine each implant being compressed under a load of 450 N (approximate weight of a North American adult male above the pelvis). In response, each implant flexes or displaces, a certain distance (Figure 4) shows the resulting theoretical displacement of the implants. Obviously it appears that implants made of stiff materials like Si_3N_4 are at a distinct disadvantage.

Placing the implants in a clinical context is even more revealing. Figure 5 shows the same displacement data plotted beside the thickness of a sheet of paper. In the first month following surgery, adjacent vertebral bodies typically subside 1mm to 2mm into a spinal implant. With this subsidence plotted next to the data in Figure 6, it's apparent that any pressure generated inside the implant by its ability to flex is insignificant when compared to the pressure created by endplate subsidence.

Figure 4.

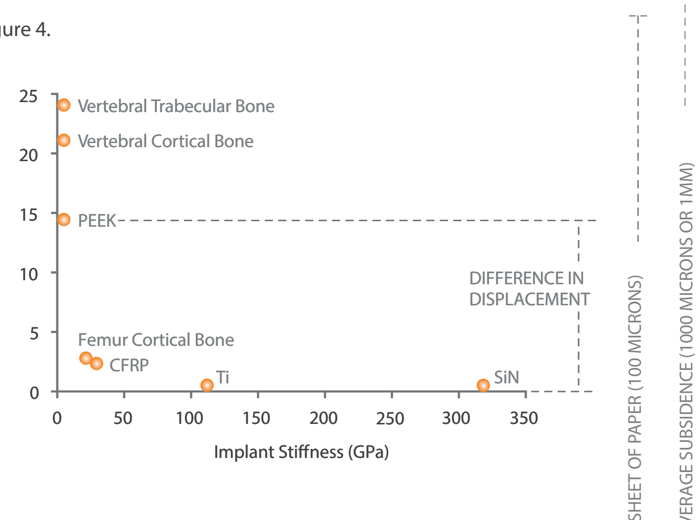


Figure 5.

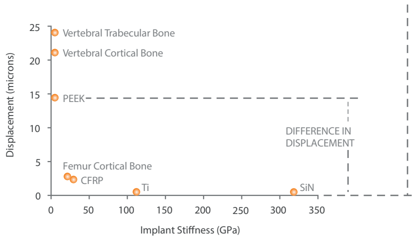
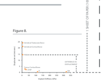


Figure 6.



What we can conclude from these four points is that the stiffness of an implant's material is not:

- The only determinant of intracage pressure
- The only cause of subsidence
- The only predictor of clinical success

Many factors influence the success of spine surgery. Material stiffness is only a part of a much larger story.

IMAGING

Numerous published reports have examined the compatibility of various orthopedic biomaterials with x-ray, CT, and MR imaging techniques—but none have included ceramic materials. Material selection is a key factor that influences postoperative visibility.

From an imaging standpoint, the ideal implant material would be easy to identify on fluoroscopy, and allow for postoperative evaluation of bony and soft tissue structures using CT and MRI. To better understand the effect of material on imaging performance, identical cylinders (7mm H x 15.5mm D) were manufactured from the following materials:

METAL

- Titanium (Ti)
- 316L stainless steel (316L)
- Cobalt chromium steel (CoCr)
- Porous tantalum (Ta) hemi cylinder1

POLYMER

- Poly ether ether ketone (PEEK)
- Ultra high molecular weight polyethylene (UHMWPE)

CERAMIC

- Silicon nitride (Si_3N_4)
- Alumina (Al)
- Zirconia toughened alumina (ZTA)
- Zirconia (Zr)

The cylinders were tested under identical parameters in the following medical imaging devices: (Axial and sagittal images were collected to fully evaluate material performance).

- Magnetic Resonance Imaging (MRI)
- Computer Tomography (CT)
- Plain Film X-ray
- Fluoroscopy

FLUOROSCOPIC IMAGING

Radiographic and Fluoroscopic lucency is heavily influenced by the material, density and thickness of an implant. Polymer implants, including PEEK and UHMWPE, are completely invisible under fluoro and plain film x-ray. This radiolucency can make it difficult to place the implant intraoperatively. Metal markers, either titanium or tantalum, are inserted into the device to aide in intraoperative placement.

The lucency is highly beneficial for evaluating bony ingress into the implant. However, this same lucency makes it impossible to determine the level of cellular adhesion and skeletal attachment.

On the other end of the spectrum are radiopaque implants. Dense materials, especially metals like titanium, cobalt chrome, stainless steel, and tantalum are completely radiopaque. Histologically, titanium has shown favorable results for cellular and skeletal attachment. However, many doctors have turned to polymer implants because evaluating the ingress of new bone into a metal implant is not currently possible on plain film x-ray or fluoroscopy.

Ceramics have varying degrees of radiolucency. Atomically dense ceramics, such as ZTA and zirconia, are completely radiopaque. Other ceramics, such as alumina and silicon nitride become more radiopaque as they increase in thickness.

The difference in lucency between the sagittal and axial films confirms this relationship. It is possible to evaluate bony ingress into the cage, as well as skeletal attachment and cellular adhesion to the cage itself, as long as wall thickness is kept below a certain level.

MAGNETIC RESONANCE IMAGING (MRI)

MRI is vital for evaluating soft tissue structures in and around the spine—especially neural structures, the intervertebral disc and intravertebral abscesses or tumors. The quality of MRI is heavily influenced by implant material.

Dense, metallic materials obscure the computer's ability to read an image, resulting in a large "bloom" that obstructs visualization of surrounding tissue. In the study, 316L stainless and cobalt chrome exhibited the greatest amount of artifact, while titanium exhibited the least.

This bloom is one of the primary reasons spinal surgeons have moved away from metal implants. The interference obscures visibility of key neural structures and makes postoperative evaluation much more difficult. Non-metallic polymer and ceramic implants are visible under MRI without creating any bloom. This allows doctors to identify the implant and the surrounding tissue accurately.

COMPUTER TOMOGRAPHY IMAGING (CT)

CT scans help doctors evaluate the integrity of bony structures, nucleus pulposa health, and the degree of bony impingement on neural structures. The quality of CT images is heavily dependent on the equipment used. Metal implant artifact can have a significant impact on visualization, especially with older and less sensitive machines.

Metal cylinders all exhibit some degree of streaking, with 316L being the most prevalent and titanium being the least. The zirconia ceramic cylinder also exhibited prominent streaking and artifacting. These obstructions preclude evaluation of bony attachment at the implant interface.

With the exception of the solid zirconia and zirconia doped cylinders, the polymer and ceramic cylinders had little to no streaking, and did not interfere with the visualization of surrounding tissues. This clarity aided significantly in evaluation of the bone/implant interface.

CONCLUSION

What we can conclude is that various methods of imaging aide the diagnosis of spinal disease and the treatment of these conditions.

Metal implants, while demonstrating adequate cellular and bony adhesion, obscure post operative evaluation of bony and neural structures in all three imaging modalities. Polymer based implants, such as PEEK and UHMWPE, are invisible on fluoroscopy, aiding in post operative evaluation, but making intraoperative placement difficult.

In polymer implants, the embedded metal markers may obscure CT and MRI scans. Ceramic implants have constituent materials that affect their imaging performance. Atomically dense materials, such as ZTA and zirconia, behave like metals.

However, silicon nitride and alumina ceramics can be manufactured to allow intraoperative visualization without compromising postoperative evaluation.

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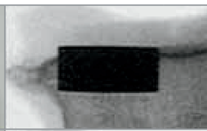
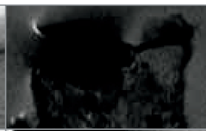
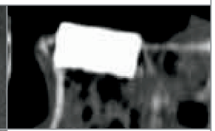
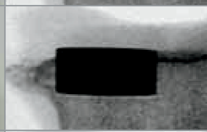
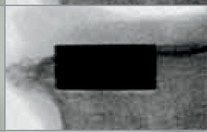
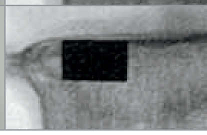
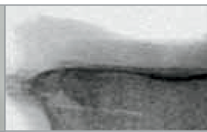
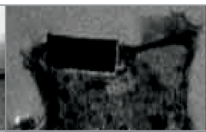
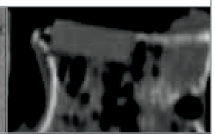
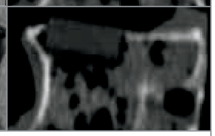
SAGITTAL VIEWPOINT OF DIFFERENT MATERIALS

	PRODUCT	FLUOROSCOPIC IMAGING	**MRI:** Magnetic resonance imaging	**CT:** Computer Tomography Imaging
METAL				
Titanium (Ti)				
316L Stainless steel (316L)				
Cobalt chromium (CoCr)				
Porous tantalum (Ta) hemi cylinder 1				
POLYMER				
Poly ether ether ketone (PEEK)				
Ultra high molecular weight polyethylene (UHMWPE)				
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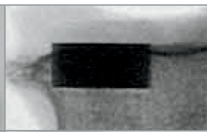
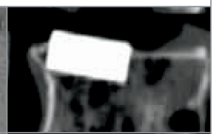
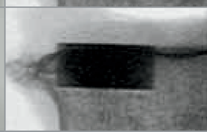
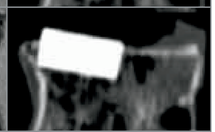
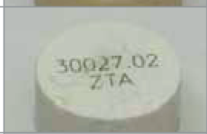
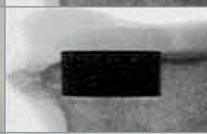
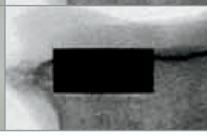
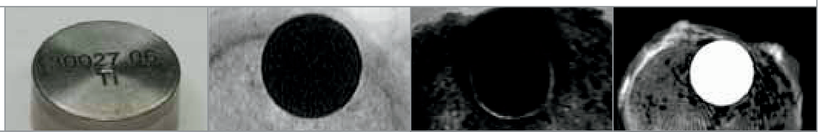
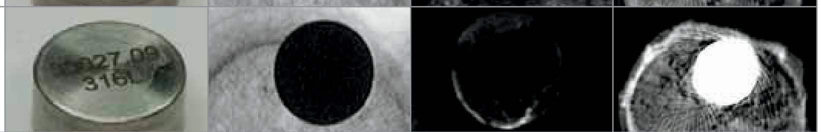
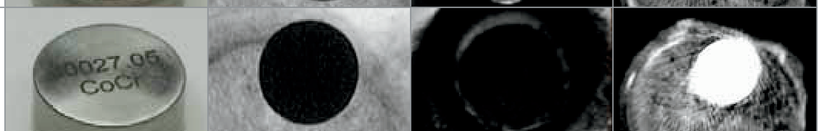
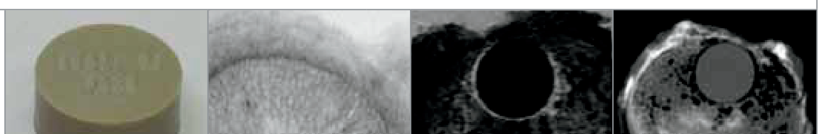
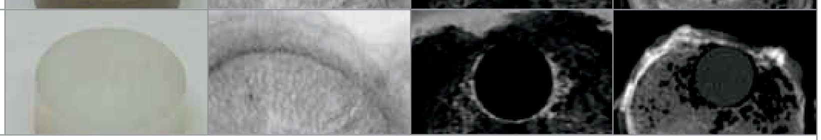
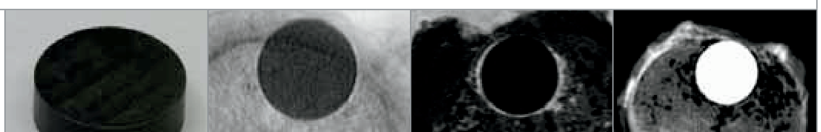
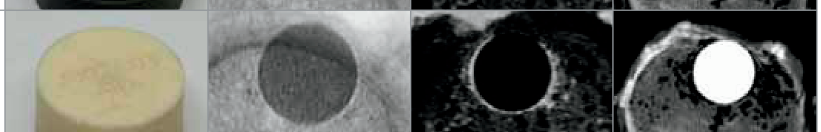
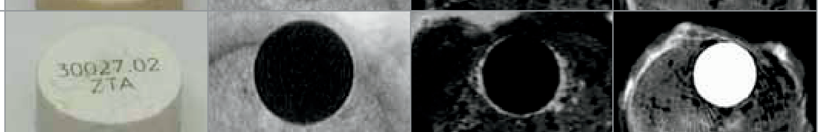
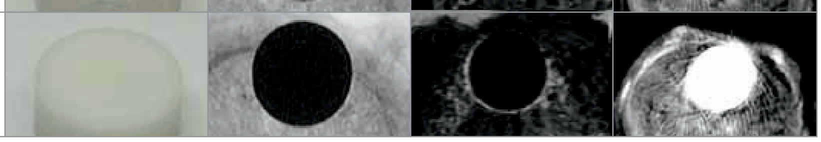
Silicon nitride (Si_3N_4)				
Alumina (Al)				
Zirconia toughened alumina (ZTA)				
Zirconia (Zr)				

AXIAL VIEWPOINT OF DIFFERENT MATERIALS

	PRODUCT	FLUOROSCOPIC IMAGING	MRI: Magnetic resonance imaging	CT: Computer Tomography Imaging
METAL				
Titanium (Ti)				
316L Stainless steel (316L)				
Cobalt chromium (CoCr)				
Porous tantalum (Ta) hemi cylinder 1				
POLYMER				
Poly ether ether ketone (PEEK)				
Ultra high molecular weight polyethylene (UHMWPE)				
CERAMIC				
Silicon nitride (Si_3N_4)				
Alumina (Al)				
Zirconia toughened alumina (ZTA)				
Zirconia (Zr)				

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