8 Mechanical Implant Material Selection, Durability, Strength, and Stiffness

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Abstract

Spinal implants are manufactured from a variety of materials to meet user needs as well as the requirements of the physical and environmental demands upon the device. Commonly used materials include titanium, stainless steel, cobalt-chrome, nitinol, carbon fiber reinforced polymer (CFRP), polyetheretherketone (PEEK), silicon nitride, biodegradable polymers, and allograft bone. Material choices can be driven by requirements for strength, biocompatibility, bone ongrowth, flexibility, and radiolucency. Coatings may also be applied to the implants to further enhance physical or biological properties of the implant. These may include

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hydroxyapatite, titanium plasma, or a combination of these two materials. Additionally, implants may have a porous layer or open structure for improvement of osteointegration. Spinal implants are commonly made using conventional manufacturing methods such as machining and injection molding, but additive manufacturing is becoming more commonly used to produce certain implants.

Keywords

Spinal · Implant · Titanium · PEEK · Cobalt-chrome · Interbody · Pedicle screw · Cage · Rod · Hydroxyapatite

Introduction

Modern spinal surgeries use a variety of implants to decompress neural elements, support spinal segments, and stabilize motion segments. This can be achieved by restricting motion through fusion or preserving the natural motion and kinematics of the spine. Fusion occurs through the interbody space from one end plate to another, and the support of this space is provided by an interbody cage, with stability and compression provided by bone screws or hooks and rods. Spinal plates may also be used to provide stability, restore initial bone mechanics, and speed up the healing process after injury (Caspar et al. 1998; Emery et al. 1997). While the implant must withstand anatomical loading, the implant must not result in stress shielding of the surrounding bone which may result in impeding new bone growth. Additional stability may be provided with the use of bone screws or hooks which are connected to the associated rods using set screws. Multiple materials are used to manufacture these implants. These materials need to provide a balance of strength, stiffness, and biocompatibility, as well as manufacturability. In addition to the base materials, there are often surface treatments and coatings applied which are intended to improve implant performance, usually by increasing the screw's resistance to backing out or pulling out from the bone. This increased resistance to removal is achieved by providing surfaces that have improved ingrowth or adhesion of bone to the implant. When fusion is not the desired outcome, clinicians may opt to use implants such as interspinous process devices (IPDs) or artificial discs for spinal segment stabilization and motion preservation. IPDs, for example, provide indirect decompression of spinal nerve roots and canal. Motion preservation devices aim at allowing for load transfer similar to that of the natural kinematics of the spine (Wilke et al. 2008). When selecting an implant material, multiple factors should be considered such as anatomical location, desired clinical outcome, load sharing capability, desired range of motion (ROM), and degree of biocompatibility. This chapter will focus on implant selection based on material properties.

Metallic Implants

(a) **Titanium** – the most commonly used material to produce bone screws, rods, hooks, and set screws is titanium (Ti). Titanium is a popular choice due to its favorable properties of strength, corrosion resistance, and biocompatibility. Compared to stainless steel, titanium produces a less pronounced imaging artifact during X-ray or computed tomography (CT) scans and is less likely to have bacteria adhere to it (Luca et al. 2013). Titanium has also been shown to have a higher rate of bone ongrowth compared to stainless steel, and when used in pedicle screws, to have an increased resistance to backing out, as measured by removal torque in a mini-pig model (Christensen et al. 2000). Implant grade titanium is available primarily in three varieties: titanium-aluminum-vanadium (Ti-6Al-4V), commercially pure (CP), and titanium-molybdenum (Ti-15Mo). Example mechanical properties of these materials are summarized in Table 1. In general, Ti-6Al-4V is the most commonly used of the three options. Ti-6Al-4V is stronger and stiffer than Commercially Pure Titanium, readily available, and easily to machine. After contouring, such as in the case of spinal rods, Ti-6Al-4V also holds its shape

Table 1 Example implant material properties

Material	Tensile strength, ultimate (MPa)	Tensile strength, yield (MPa)	Modulus of elasticity (GPa)	Elongation at break (%)
Ti-6Al-4V ELI	862	786	110	10
Commercially pure Ti (Grade 4)	550	483	102	15
Ti-15Mo (alpha + beta annealed + aged)	900	800	105	10
316L annealed stainless steel	490	190	193	40
Cobalt- chromium	1290	760	235	25
PEEK		80	4	
CFRP		120	18	

Disegi (2009), Zaman et al. (2017), and Najeeb et al. (2016)
Note: Material properties can vary based on processing and should be verified with the selected supplier

better over temperature changes than commercially pure titanium (Noshchenko et al. 2011). Titanium-molybdenum is more difficult and expensive to obtain, and requires advanced expertise in machining, due to its nature of clogging cutting tools. However, when processed to the alpha+beta phase, Ti-15Mo has superior strength properties and a higher resistance to failure in cyclic loading or crack propagation due to stress risers compared to Ti-6Al-4V.

(b) **Stainless steel** – Stainless steel (SS) has been used for bone screws, rods, and hooks as well. Over the past decade this material has fallen out of favor due to patients with nickel allergies. In the past, stainless steel had historically been the material of choice for spinal rods over titanium when a stronger, stiffer construct was required. The use of a stainless steel rod often drove the use of stainless steel screws, hooks, and set screws. This was intended to prevent galvanic corrosion between dissimilar metals, which was a concern when using titanium bone screws with stainless steel rods. These concerns were proved to be generally unfounded (Serhan et al. 2004). The stainless steel grade used for implants is 316L. This material is available in different treatments, providing multiple strengths and stiffnesses. The material properties of 316L stainless steel are summarized in Table 1.

The material of choice for spinal plates has shifted from stainless steel to titanium alloys such as Ti-6Al-4V. A titanium alloy plate can provide sufficient rigidity and stability to allow for arthrodesis, prevent displacement or collapse of the intervertebral grafts, and maintain cervical lordosis to achieve a better prognosis (Chen et al. 2016). Titanium alloy implants are more ductile than stainless steel implants. It is also a proven biocompatible material.

In general, metal implants produce artifacts that make radiologic interpretation more challenging (Aryan et al. 2007). However, titanium and titanium alloys are more MRI (Magnetic Resonance Imaging) compatible than stainless steel due to its lower X-ray beam attenuation coefficients (Lee et al. 2007; Haramati et al. 1994). Another clinical benefit of titanium implants includes its ability to have a modified surface for improved osseointegration. For example, a rough surface can be induced on titanium implants which results in higher osseointegration compared to the smooth surface present on stainless steel implants.

(c) **Cobalt-chrome** – Cobalt-chrome (Co-Cr) is a relatively new entry into the materials available for implants. It is most commonly used for spinal rods, but not necessarily screws or hooks. The advantages of this material over stainless steel or titanium are numerous.

It provides higher strength and stiffness than titanium given the same rod diameter. This allows for the creation of stiffer constructs with stronger correction, or the use of smaller profile implants. Cobalt-chrome rods that are 5.5 mm in diameter have a greater bending stiffness than 6.35 mm diameter titanium rods. Cobalt-chrome also produces less imaging artifact than stainless steel, and can be combined with titanium screws which have better biocompatibility than stainless steel screws. Although mixing of metals in the body (titanium and cobalt-chrome or titanium and stainless steel) may result in galvanic corrosion, the susceptibility of the Ti-Co-Cr construct to this phenomenon is theorized to be less than in a Ti-SS construct (Piazzolla et al. 2013). Additionally, it has been found that the amount of galvanic corrosion evident with two connected stainless-steel implants is actually greater than the corrosion present between a stainless steel and titanium implant (Serhan et al. 2004). Table 1 summarizes example material properties of cobalt-chromium.

(d) **Nitinol** – Nitinol has been used to manufacture spinal rods with the goal of creating a less stiff construct to help reduce adjacent segment disease and provide a more compliant construct. Nitinol is a nickel–titanium alloy, which can be manufactured to produce unique shape-memory effects. Although it contains nickel, animal studies have found that no measurable amounts of nickel are absorbed into the body after implantation (Kok et al. 2013). Although studied in the literature, Nitinol rods have not proven to be particularly popular in the market. Concerns around fretting or wear and corrosion of the nitinol material where it is connected to conventional titanium or stainless steel screws raise concerns around premature implant failure, and thus would require specially treated screws to be used with nitinol rods. This, along with the processing costs and complexity of nitinol may be factors preventing widespread adoption in the market. An additional potential use of nitinol rods is in sliding growth constructs used in the treatment of early onset scoliosis. The sliding rod component allows for less traumatic adjustment of the construct as the patient grows compared to conventional fixed rod constructs. Nitinol has 100 times greater wear resistance than titanium and similar wear resistance as cobalt-chromium. This increased wear resistance would greatly reduce the amount of wear debris produced by the sliding construct over the implantation period, which spans multiple years, greatly reducing the patient's exposure to metallic particles and the potential irritation these could cause (Lukina et al. 2015)

Porous Metals

Materials having a porous structure have been developed in an attempt to increase the physical integration of bone to the implant structure. For example, with interbody cages, this is intended to result in "enhanced fixation of the device, preventing device migration or movement causing abrasive damage to adjacent tissue" and "may provide a transitional zone between the bone and biomaterial to reduce stress-shielding" (Jarman-Smith et al. 2012). Porous metals such as titanium (PlivioPore, Synthes; Tritanium Stryker), Nitinol (Actipore Biorthex), and Tantalum (Trabecular Metal, Zimmer (Hedrocel, Implex)) have been developed and commercialized to address this issue (Jarman-Smith et al. 2012; Lewis 2013). While these materials may address approximating the modulus of bone and the potential for ingrowth for increased stability, the issue with lack of radiolucency and CT/MRI artifact remains.

Polymers

As more metallic devices were implanted, reported issues with subsidence and stress shielding increased. With interbody cages, for example, metallic implants prevented the assessment of fusion due to lack of radiolucency.

Seaman describes "while Ti (titanium) had favorable fusion rates, a noted shortcoming was subsidence or settling into the adjacent vertebral bodies due to the differences in the modulus of elasticity. As a result, polyetheretherketone (PEEK) cages were introduced in the 1990s as an alternative due to their elastic modulus properties" (Seaman et al. 2017). PEEK allows for improved load sharing within the spine while stabilizing the disease segment and reducing stress on adjacent levels comparing to metallic implants, such as Ti.

Additional materials developed during this time including carbon fiber reinforced polymer (CFRP) cages that consisted of PEEK material with carbon fibers. Both PEEK and CFRP implant materials are biocompatible for safe implantation in the spine.

These polymers have clear advantages of reduced modulus, radiolucency, and reduced CT/MRI artifact in comparison to titanium. The PEEK and CFRP implants have elastic modulus characteristics similar to that of natural bone as compared to titanium. The strength of the CFRP material allows for a reduced implant volume and greater graft volumes as compared to implants manufactured from pure PEEK. Brantigan et al. (1991) reported increased pullout forces and similar compressive strengths for the carbon fiber cage as compared to femoral grafts when placed in cadaveric specimens. The reduced elastic modulus and implant design has been shown to potentially load the interbody graft material to allow for a better load sharing environment (Vadapalli et al. 2006; Kanayama et al. 2000).

In addition to the more commonly used metals, there is some use of PEEK or CFRP for both pedicle screws and spinal rods as well. PEEK has generally been used only for spinal rods, while CFRP has been for screws (Ringel et al. 2017). PEEK/CFRP is obviously much weaker and less stiff than the other metallic choices outlined above. The attraction of PEEK rods was the theory that they would flex as the spine moves and would have a similar modulus of elasticity to a PEEK or CFRP interbody spacer, which would also allow for some compliance. This modulus of elasticity is designed to be between that of cortical and cancellous bone, which allows for improved load sharing while still stabilizing the intended segments, but ultimately reducing the chance of adjacent segment degeneration (Athanasakopoulos et al. 2013). This flexible structure, rather than a completely rigid metal one, would be less likely to result in interbody spacers subsiding into the vertebral end plates and pedicle screws plowing out of or fracturing a pedicle when continually loaded, as in normal activities of daily living. However, PEEK rods have limited application to a smaller number of patients because they are not able to be contoured intraoperatively as compared to titanium or stainless steel rods.

PEEK rods and CFRP screws offer a major advantage over metallic implants when being imaged. They are radiolucent and produce no artifact from magnetic resonance imaging. This is especially useful for patients being treated for spinal tumors, where radiation treatment, planning and execution are negatively impacted by titanium or stainless steel screws (Ringel et al. 2017). PEEK rods have also been used successfully in non-fusion procedures. In these procedures, the flexibility of the rods allows for some motion to be maintained in the segment while still offering support and stabilization to the diseased segments. The results of a multi-patient study were an improvement in pain scores and a reduction in range of motion, with an implant failure rate lower than normally reported in the literature (Huang et al. 2016).

However, there remains a potential concern of direct bone ongrowth onto the implant surfaces of PEEK implants. PEEK is a highly inert, hydrophobic thermoplastic polymer that often results in a lack of direct apposition to bone for proper long-term implant performance. The presence of a fibrous tissue layer between the PEEK implant and the adjacent bone has been documented clinically and in animal studies (Phan and Mobbs 2016; Walsh et al. 2015). Phan has described the resulting radiolucent rim at the bone–implant interface due to the fibrous tissue as a "PEEK-Halo" (Phan et al. 2016).

A number of methods have been used to improve the bioactive surfaces of PEEK implants. Implants have been designed with both PEEK and

titanium materials to allow for the titanium surfaces to contact the underlying bone (Rao et al. 2014). Additionally, PEEK implants have been coated with titanium or hydroxyapatite (HA) to improve biocompatibility to increase the resultant direct apposition of bone to the PEEK implant surface (Rao et al. 2014; Robotti and Zappini 2012). However, an early summary of clinical results with the titanium-coated PEEK indicated similar fusion rates as compared to uncoated PEEK (Assem et al. 2015). PEEK is also currently available with HA incorporated into the material (PEEK-OPTIMA HA Enhanced, Invibio) which allows for typical machining of the implant with exposure to HA at the surfaces of the implant. The PEEK HA Enhanced has been shown in animals to result in more direct bone apposition as compared with PEEK bulk material only (Walsh et al. 2016). The addition of bioactive materials to PEEK, surface modification techniques, processing techniques for deposition coating of PEEK implants, and functional and mechanical properties of PEEK are well described (Robotti and Zappini 2012; Roeder and Conrad 2012; Poulsson and Richards 2012). It should be noted that the desire to improve the bone ongrowth onto the PEEK implants must not be at the risk of potential failure of the applied coating during anatomical loading or insertion of the implant. Investigations of coatings have indicated the potential for wear debris or surface damage to occur as a result of procedural impaction to place the implant (Kienle et al. 2016).

Porous PEEK

The solution to the issue of radiopacity that exists with metallic implants may be the development of porous PEEK materials. This may be accomplished through various methods which include particulate leaching, heat sintering, and selective laser sintering. Jarman-Smith describes case studies of porous PEEK that includes mechanical testing and an animal ingrowth in comparison to solid PEEK (Jarman-Smith et al. 2012). In general, bone ingrowth was present in the porous PEEK materials, and more bone ongrowth of the porous PEEK samples which increased at over the 4- to 12-week time periods was demonstrated. Based on the mechanical requirements for a load bearing application a solid–porous PEEK device may be required to meet the functional demands. A solid–porous hybrid has been described using sodium chloride crystals that are leached out to produce a porous surface structure for bone ingrowth. The mechanical properties of the resulting structure have been estimated to support the functional requirements for an interbody device (Torstrick et al. 2016). The mechanical shear properties have been characterized and compared to bulk sintered PEEK in which the surface porous PEEK produced significantly higher results (23.96 MPa vs. 6.81 MPa, for surface porous and bulk porous, respectively). Early clinical results after 1 year with 100 patients have shown no device-related complications (Torstrick et al. 2017) (Fig. 1).

Silicon Nitride

Silicon nitride (Si_3N_4) is a ceramic that has been implanted as an interbody fusion device since 2008 with approximately 25,000 implants up to the year 2015 (McEntire et al. 2015). The materials have also been studied for its characteristics of osteointegration and anti-infection. New bone formation was found to be increased in the absence and presence of a bacterial injection as compared to titanium and PEEK (Webster et al. 2012). However, long-term 10-year clinical history has indicated a potential of adjacent level degeneration that was proposed to be caused by stress shielding due to elastic modulus mismatch (Sorrell et al. 2004). The elastic modulus of silicon nitride is approximately 300 GPa, while that of cortical bone is roughly 10 GPa (Bal and Rahaman 2012).

Biodegradable Polymers

The high stiffness of metallic implants has potential to shield the loading required within the spine to allow for fusion (Chen et al. 2016). This has led

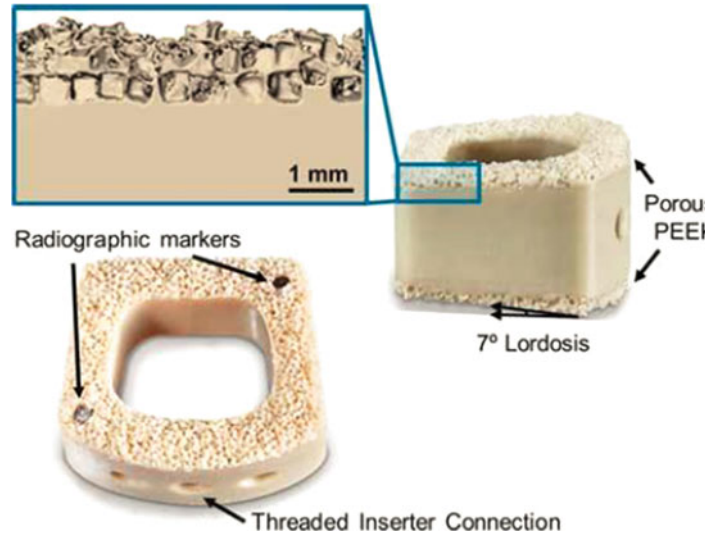

Fig. 1 COHERE implant demonstrating the characteristics of porous PEEK surface (Torstrick et al. 2017)

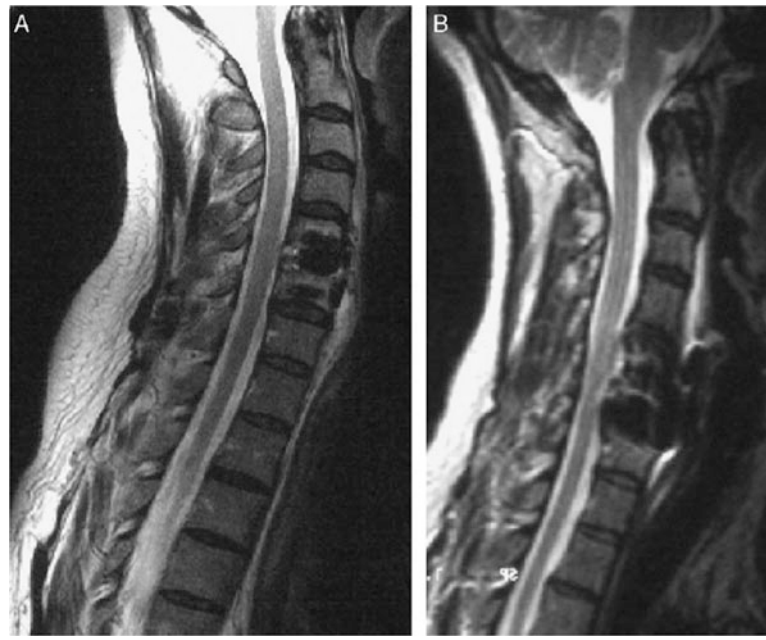

Fig. 2 T2-weighted magnetic resonance imaging of cervical spine showing early postoperative changes after the implantation of bioresorbable plate (**a**) and after implantation of titanium plate (**b**). Notice the obvious imaging artifacts in (**b**) compared with (**a**) (Nabhan et al. 2009)

to the use of biodegradable polymers for use in spine surgery with implants such as cervical plates. The modulus of elasticity of polymers can be altered based on the amount of cross-linking of the polymeric chains present within the material (Cheng et al. 2009). Biodegradable polymers may have lower modulus of elasticity that better represents physiological values when compared to metals (Freeman et al. 2006) which, in turn, can prevent stress shielding. In addition, polymers allow for greater visualization within the interbody space intraoperatively (Aryan et al. 1976) because the material does not produce artifact on MRI or CT scans (Nabhan et al. 2009). This becomes particularly important with specific patient groups, that is, obese patients and patients with shorter necks (Nabhan et al. 2009) (Fig. 2).

One major clinical benefit of biodegradable polymers is the ability of the material to completely hydrolyze within 2 years of initial

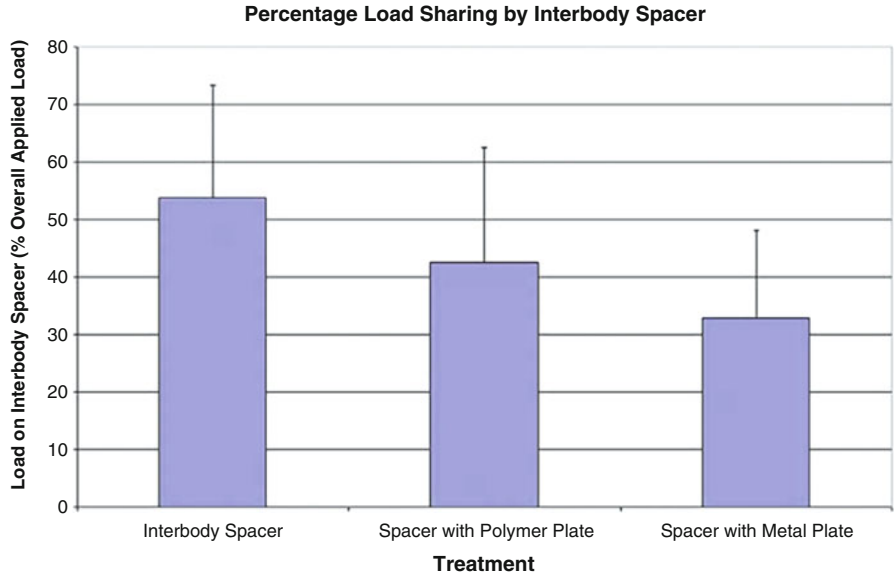

Fig. 3 Graphical representation of percentage load sharing by interbody spacer in the anterior spinal column (Cheng et al. 2009)

surgery. Spinal plates, for example, maintain approximately 90% of its initial strength 6 months post-implantation and approximately 70% of its initial strength 9 months post-implantation. This slow decrease in strength may allow the area of fusion to gradually take more of the load to potentially increase the rate of fusion while reducing stress shielding (Ames et al. 2002; Ciccone et al. 2001). Therefore, there is no need for implant removal in the case of a revision or adjacent segment surgery (Chen et al. 2016). This can reduce the long-term complications that have been historically associated with metallic plating.

In contrast, Boyle et al. compared ROM between an interbody space with a titanium rigid plate and an interbody space fixed with a biodegradable polymer plate (Cheng et al. 2009). They found that the titanium plate in conjunction with the interbody spacer achieved the highest level of motion reduction and also exhibited the lowest mean ROM. In a study by Freeman et al. (2006), the reduction of the ROM for both biodegradable and titanium anterior cervical plates was also compared. The results reported a reduction in the flexion–extension ROM by approximately 50% for a biodegradable plate and approximately 70% with titanium construct.

Boyle et al. also examined the percentage of load sharing with respect to three different conditions:

1. Stand-alone interbody spacer.
2. Spacer with a polymer plate.
3. Spacer with a rigid titanium plate.

The results showed that there was a statistical difference in compressive loading of anterior columns between the stand-alone spacer and the spacer with the Ti plate. However, there was no statistical difference in loading between the stand-alone spacer and the spacer with the polymer plate (see Fig. 3).

Therefore, this study showed that a spacer with a metal plate results in a lower percentage of load shared by the interbody spacer than with a bioresorbable plate. Researchers have reported concerns regarding the reduced rigidity of the biodegradable material and how this will impact its long-term efficacy compared to a rigid metal plate. Brkaric et al. (2007) reported early failure of a bioabsorbable plates, questioning the role of hydrolysis on crack initiation and propagation in polymer plates. In contrast to Boyle's study, there are encouraging clinical results of bioabsorbable

plates (Aryan et al. 1976; Franco et al. 2007; Nabhan et al. 2009; Park et al. 2004; Tomasino et al. 2009; Vaccaro et al. 2002). In regard to imaging, Nabhan et al. (2009) confirmed that a single level bioresorbable plate is MRI and tissue compatible, and shows comparable fusion rates to titanium plate.

Allograft

Allograft is the most commonly used non-autogenous grafting material in spinal surgery (Hamer et al. 1996). Mineralized allograft is primarily osteoconductive, with weak osteoinductive capacity. The majority of allografts are primarily composed of cancellous or cortical bone. Cortical bone allografts provide significant mechanical stability and structural support. Cancellous bone allografts have a faster rate of incorporation. Therefore, the clinical application of an allograft should be considered when selecting graft material. Allografts do not have osteogenic potential because graft cells do not survive the processing/transplantation process. Allograft used for orthopedic applications is fresh frozen, freeze-dried, or demineralized.

One concern with the use of human allograft is the potential of disease transmission from donor to recipient. Donor screening, tissue testing and tissue processing have reduced this risk to less than 1 event per million grafts (Stevenson et al. 1996).

Hydroxyapatite (HA)

HA is composed of calcium phosphate mineral, which has both osteointegrative and osteoconductive properties. Osteointegration results from the formation of a layer of HA shortly after implantation. HA has highly osteoconductive properties, which promote bone growth on a surface (Cook et al. 1994). The material is composed of hydroxylated calcium phosphate and is chemically identical to natural HA of bone (Doria and Gallo 2016). It has the ability to bond directly to bone which reproduces the natural bone-cementing mechanism (Eggli et al. 1988). HA is a very brittle ceramic and is prone to fracture with cyclic loading.

Additive Manufacturing

Currently several manufacturers offer a variety of titanium devices that are produced with additive manufacturing for orthopedic implants. These include porous matrices (Zimmer Biomet OsseoTi Porous Metal, Stryker Tritanium, and Smith & Nephew CONCELOC) and designs with open or porous surfaces (4WEB, Joimax, Renovis, K2M, and Spineart). Lewis published a comparison of commercially available porous metals (Lewis 2013).

The manufacturing technique of additive manufacturing by selective laser sintering (SLS) or electron beam (EB) (termed "powder bed fusion" by ASTM) (ASTM F2792) allows for design options not allowed by subtractive manufacturing methods. An example of this is the truss-based designs (4WEB, Camber Spine) for spinal implants. Due to the variability in processes it is difficult to compare mechanical properties of resultant materials. Some of the available devices incorporate the porous–solid hybrid concept. Since these devices are a continuous structure from the solid to porous structure, the issue of coating delamination should be alleviated.

Additive Manufactured PEKK

An alternative implant material to titanium that is currently used in additive manufacturing for implants is polyetherketoneketone (PEKK) (http://oxfordpm.com/cmf-orthopedics). PEKK is from the same family of polyaryletherketone (PAEK) polymer materials as PEEK (Kurtz and Devine 2007; Kurtz 2012). The material properties are very similar to PEEK. PEKK has been used for cranial repair (FDA 510(k) Feb 2013) and interbody fusion devices (FDA 510(k) July 2015). The PEKK material has recently been investigated for antibacterial properties by Wang et al. The authors concluded from the in vitro testing that

there was "decreased adhesion and growth of *P. aeruginosa* and *S. epidermidis* on nanorough PEKK surface compared with conventional PEEK surfaces" (Wang et al. 2017).

Coatings

In addition to various material choices for implants, there have been attempts made to improve the strength of the interface between the pedicle bone and screw through the use of surface coatings on the threads of the screw. Examples of coatings used include hydroxyapatite (HA) and titanium plasma spray (TPS). Additionally, these coatings have been combined into a composite coating (HA-TPS). Testing of these coating options on a titanium bone screw in a porcine model has shown improvement in screw back out torque compared to an uncoated titanium screw for all 3 of the coating options (Upasani et al. 2009).

Cross-References

- Anterior Lumbar Interbody Fusion and Transforaminal Lumbar Interbody Fusion
- Anterior Spinal Plates: Cervical
- Implant Material Bio-compatibility, Sensitivity, and Allergic Reactions
- Interbody Cages: Cervical
- Interspinous Devices
- Material Selection Impact on Intraoperative Spine Manipulation and Post-op Correction Maintenance
- Pedicle Screw Fixation
- Selection of Implant Material Effect on MRI Interpretation in Patients

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