ROLE OF METAL IN SPINE STABILIZATION

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Spinal instrumentation is perhaps the most quickly changing and expanding field for the spine surgeon to master. The goals of this short text are to enable the practitioner and scientist to better understand the more commonly used spinal instrumentation system and more important, to encourage many people related to this work being interested in the basic science of metallic alloys.

To accomplish this goal, I will present the general characteristics of metallic alloys commonly used in spinal surgery, their electrochemical properties, biocompatibility and some area of biomechanical consideration.

HISTORICAL DEVELOPMENT OF SPINAL INSTRUMENTATION

Although two surgeons in New York in 1911 reported successful fusion technique, Hadra of Galveston had used wires to stabilize a fracture-dislocation of cervical spine exactly 20 years earlier in 1891 Hadra appearently learned this technique from Dr. W Wilkins, who had performed the same operation at the thoracolumbar junction. Lang from Munich in 1909 reported the first attempts to stabilize the spine with a true instrumentation system. He used rigid celluloid (later changing to steel) rods affixed to either side of the spinous processes with silk threads and steel wires. Lang's construct is strikingly similar to that developed by Enduardo Luque in mexico in the 1970.

The evolution of Harrington rod system began in 1953 when Dr. Paul Harrington in Houston assumed the care of children with progressive neuromuscular scoliosis secondary to polio, which was of epidemic proportion at the time. As clinical indication for Harrington rod instrumentation expanded, modifications were made to improved stability, capability and adaptability. These modifications included Moe's squaring of the end of the rod and distal hook.

Luque instrumentation, developed in the 1970s by Dr.Enduardo Luque in Mexico City, exemplifies necessity as the mother of invention. The system employs smooth 3/16 inch or 1/4 inch rods that can be confiqured into different shapes and fixed segmentally with sublaminar wires. To address the need for fixation for lumbosacral arthrodesis, Ferguson and Allen developed the Galvestion technique, which entails driving the lower part of the Luque rod between the tables of the wings of the ilium bilaterally, thereby effecting substantial mechanical purchase.

In the early 1980 Cotrel and Dubousset in Paris developed a "universal" spinal instrumentation system with particular application to scoliotic deformity named the C-D system which was designed to restore sagittal curvature which correcting the obvious coronal abnormality.

Transpedicular fixation was originally described by Michele and Krueger in 1949. The popularity of this technique, however, has blossomed in only the last ten to fifteen years.

Posterior cervical instrumentation has historically been limited to wire, wire-bone graft constructs, Dabb plate, Roy-Camille plated and Halifax interlaminar clamp.

Morscher and co-workers developed a titanium anterior plate and screw system designed with a set screw in order to provide a stronger plate plate-screw interface and eliminate the need for the screw to go into the posterior cortex of the vertebral body.

All the synthetic-origin material used for the fabrication of spinal implants is largest from metallic alloys based upon the primary elements of iron, cobaltor titanium. Metal as single-element compositions, such as titennium (Ti) or Zirconium (Zr) do find applications, however, strength considerations of spinal implants are a significant limitation for most nonalloy structures.

The biomaterial components of devices have physical and mechanical properties that depend directly on the material of construction, the internal metallurgical conditions of the material and the shape, form and surface of the final device. After passivation to produce an oxide surface, the alloys used are more ductile and are conductors of heat and electricity. The conductivity characteristics of metal are important when considering biodegradation phenomena, combinations of biomaterials for device construction and clinical application near the skin surface.

Design criteria are dependent on the basic elastic properties of synthetic substances for tissue replacement. Elastic criteria for properly matching is best expressed by the modulus of elasticity. This property is the shape of the mechanical stress-versus-strain relationship for each biomaterial or tissue. The modulus is a basic measurement of a substance's inherent elastic flexibility. Some confusion arises related to relative interpretation of moduli. Generally this is because most clinicians consider elasticity as a measure of elastic strain or deformation. High-magnitude elastic strains are directly correlated with lower-elastic moduli. Conversely higher-elastic moduli materials, have low-magnitude elastic strain characteristics.

One reason for the extensive use of metallic alloys in spinal implants related to the availibility of relatively strong and inert materials over recent history. Prior to 1925, most available metallic systems were evaluated and the selection of the electrochemically noble elements was most common. Alloys of iron and cobalt followed with the introduction of titanium in 1951 and since that time, most alloy systems have been based upon iron, cobalt, or titanium. In contrast to the noble metals, these alloys are used in an oxidized or passivated surface condition, which provides stability as related to corrosion. This has resulted in national (ASTMF4) and international (ISO) materials standards for most classes, metallurgical conditions, and surface finishes. These specifications provide detaile requirements for nominal chemical analyses, mechanical properties, and surface conditions. Limits with respect to minimally acceptable property values are provided in these standards. Becauses of the availability of specific property information and clinical experience, design criteria have evolved to optimize device longevities. New applications for devices are often simple changes of shape or surface conditions to better control the biomaterial tissue inferface.

Spinal instrumentation devices are most ofter fabricated from the iron-based surgical stainless steel because of the inherent strength and ductility. However, this stainless steel should not be used for porous implants owing to its susceptivility to crevice corrosion. The more commonly used metallic systems and selcted properties are summarized in Table 1-1

Table 1-1 Metallic Biomaterials Commonly Used for the Construction of Orthopedic Surgical Implants.

Mateial	Nominal Composition (w/o)	Tensile Strength Mpa(ksi)	Modulus of Elasticity Gpa (Psi X10°)	Surface Condition
Cobalt alloys				
Cast	Co-27Cr-7Mo	655(95)	235(34)	Cr_xOy
Wrought	Co-26Cr-(Ni,Mo,W,Fe)	1172(170)	235(34)	Cr_xOy
Surgical stainless steel (316L)	Fe-18Cr-12Ni	480-1000 (70-145)	193(28)	Cr_xOy
Titanium alloy	Ti-6Al-4V	860-896 (125-130)	177(17)	Ti_xOy

The various metallic biomaterials exhibit significantly different magnitude moduli. strength, and surface properties. It is useful to think of these property characteristies as a ratio to the similar measurements for compact bone comparative data and ratios are provided in Table 1-2.

Table 1-2 Metallic Biomaterial and Tissue Properies

Material or Tissue	Modulus of Elasticity GPa (psi x 10°)	Tensile Strength Mpa (ksi)	Elongation to Fracture (%)	Ratio(Material-Bone) Modulus	Strength	Fracture Elongation
Compact bone	21(3)	138(20)	1	1	1	1
Cobalt alloys	235(34)	655-1172(95-170)	> 8	11	5-9	> 8
Stainless steels	193(28)	480-1000(70-145)	> 30	9+	4-7	> 30
Titanium alloy	117(17)	860-896(125-130)	> 12	5+	6-7	> 12
Titanium	96(14)	240-550(25-70)	> 15	5+	1-4	> 15

Note that all alloys have moduli of elasticity that are at least five times higher than compact bone. Also strains (elongations) to fracture greatly exceed the limits of bone. This therefore, directly influences design criteria for spinal implants.

The alloys of iron and cobalt have chromium oxide-based surface when prepared in a passivated (oxidized) surface condition. The oxide is like a ceramic coating, although it is a very thin film and not visible under normal lighing. This thin surface layer provides improved resistance to biodegradation. It is most critical for the iron alloy ststems, which are subject to crevice or pitting corrosion if the oxide surface layer is broken down in vivo.

Titanium alloy might have a titanium oxide surface that will form very rapidly in room temperature air or titanium nitride surface which is need special preparation. This oxide or nitride passivation reaction make titanium systems resistant to surface breakdown when used in a porous condition. The titanium based system have a lower modulus of elasticity compared to the iron alloys. This basic material property is less by a factor of about two times and must be taken into account when designing, load-bearing device. Design changes should include size or shape alteration to accommodate elastic property differences.

ELECTROCHEMICAL PROPERTIES.

Another physical consideration in the selection and use of implant devices is the basic electrochemistry and property relationsphis of biodegradation phenomena. For metallic systems, these phenomena can be described by corrosion mechanisms.

One of the more useful characterization of metallic materials is the galvanic series, which provides electrochemical comparison in saline solutions. This series also permits theoretieal predictions of galvanic coupling, or the relative corrosion behavior of two conductors that are electrically coupled within the host and therefore the same electrolyte environment. Galvanic coupling, with an associated enhancement of in vivo corrosion, is depend on a number of environmental factors. The magnitude and rate of increased (or decreased) corrosion depends on the environment (eg., fluid, soft tissue, or bone) and local transport phenomena, surface interaction such as wear (fretting or local oxide removal) : relative surface area ratios of the components ; galvanic potential differences ; metallurgical condition of the alloys ; localized oxygen potential difference ; and localized oxygen and ionic species concentrations and gradients. Increases in vivo corrosion are to be avoided because of biocompatibility considerations

that emphasize the importance of this type of biomaterial and host information. A general rule is that surgical stainless steel should not be coupled with other alloys or carbon. In cantrast, titanium, titanium alloy, and cobalt alloys have relatively similar electrochemical potentials. Studies of the in vivo coupling of titanium and cobalt based alloys have not demonstrated significant increases in the corrosion of either component.

Potentiostatic and dynamic polarization data have provided detailed comparisons of solid and porous alloy implant systems (Table 1-3)

Table 1-3 Corrosion Data From Potentiostatic Polarization

Material	Equilibrium Corrosion Potenital and Rate From Potentiostatic Polarization E_C(mV)	i_C (a/cm^2)
Ti		
Solid	-14	0.013
Porous	-10	0.044
Ti-6Al-4V		
Solid	-50	0.003
Porous	-75	0.014
Co-Cr-Mo		
Solid	-10	0.011
Porous	-35	0.028
Fe-Cr-Ni (316L SS)		
Solid	-49	0.008

BIOMECHANICAL FEATURES.

Correlations of biomaterial properties and in vivo performances have been a major activity of the researches and clinial communities. As a broad evaluation, material of the highest-possible, strength, ductility, biodegradations resistance have been selected. However, these selections have also include the important consideration of availability fabricability and cost.

WEAR

Alloys demonstrate varying degrees of wear resistance. Most are susceptible to breakdown (fretting) if the localized contact stresses are excessive. However, iron alloy is more wear resistant than titanium alloy. Titanium alloys, if exposed to metallic contact and relative movement, undergo surface galling (roughening) and breakdown. This phenomenon is characteristic for reactive - group metals and alloys and is related to the oxidation and environmental behavior of the matals involved. In vivo breakdown associated with titanium is normally seen as a black zone within the tissues; cobalt alloys show green-blue and iron alloys are noted as a dark brown coloration in the adjacent zones.

BIOCOMPATIBILITY

The principal alloying elements in Ti-6Al-4V have been evaluated with respect to in vivo biocompatibility. Aluminium and vanadium ions in vivo have been associated with adverse tissue responses. Thus, some manufacturers have initiated the introduction of alloys with other elements as principal constituents. This is a most interesting situation in that corrosion potentials, currents, and device evaluation don't support significant clinical or tissue problems with Ti-Al-V alloy. Comparisons of structure, property, and application relationships should provide greater insights into the long-term tissue responses to this alloy series.

Manufacturing quality control and assurance is one aspect of device longevities. Industries fabricate implant devices with precision and accuracy standards that exceed most other industrial application requirements. Implant devices should have a "zero defect" specification and this is the desirable recommendation. National (ASTMF4) and international (ISO) consensus standards and recommended practices are available for most metallic materials utilized for orthopedic devices. The ASTM F4 standards volume provides an excellent reference for biomaterials properties and standardized manufacturing practices. These publication also include test methods, practices for biocompatibility testing.

BIOLOGIC ASPECTS

Biodegradation from environmental exposure results in substances such as particulate and ionic forms entering the in vivo milieu. The questions related to metallic ion release and tissue responses can be categorized into areas of local tissue reaction (toxicity), allergy or hypersensitivity and carcinogenicity. Well known data document that

tissues have limited tolerance related to metallic product concentrations. Fortunately, the amounts of productions transferred from devices to local and systemic tissues have, for the most port, been within the tissue tolerance limits. This is demonstrated by a general evaluation of the numbers of metallic devices used over the past 50 years and the associated device longevity profiles. Recent literature shows that hypersensitivity to metallic components should be considered in more detail. A small, but significant, potion of the population will react to nickel-or cobalt-based alloys. Since surgical stainless steel and cobalt alloys contain nickel, applications of these alloys in allergic patients should be carefully evaluated. Some reports exist on ion accumulations within organs and metallic debris at device or corrosion sites. Area-specific sarcomas have been reported at these locations, although the number of reports have been limited. This entire area has been of concern to all involved and reporting of any available clinically relevant data is strongly recommended.

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