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Survey on Metallic Implant Materials

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Metallurgy Division
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NATIONAL BUREAU OF STANDARDS, Richard W. Roberts, Director

ABSTRACT

The application of metallic materials as orthopedic implants in the human body is reviewed, concentrating on materials presently in clinical use and undergoing laboratory evaluation for possible future use. The criteria considered explicitly are tissue compatibility, mechanical properties, corrosion resistance, and toxicity. The three principal metallic implant materials, stainless steel, cobalt alloys, and titanium, are discussed in detail. Wherever possible, comparisons are made between the materials in terms of the intended application.

INTRODUCTION

This report concerns metallic biomaterials used in orthopedic surgery. Orthopedics can be defined as the medical specialty concerned with the preservation and restoration of the form and function of the musculoskeletal system and supporting structures. The focus of this report will be on orthopedic implants, both protheses and fixation devices. It will not consider external prostheses, e.g., artificial limbs; it further excludes non-orthopedic implants, e.g., artificial heart valves. Artificial biomaterials is itself a large category, including metals, ceramics, plastics, composite materials, glasses, etc. The focus of this report will be on metallic materials, however, this is not to suggest that equally important problems and solutions do not involve ceramic implants, for example. Other material types would require complete studies in themselves. The aim of this report is to survey the available literature on the subject, summarize the principal findings, and suggest items of future importance. Other review articles on this and on allied subjects are available, including those by Cohen[1], Weisman[2], Katz[3], Hulbert et al.[4], and others[5-7], and may be consulted for additional information. Several symposia on this subject are referenced later in specific connections. A recent National Academy of Science workshop report[8] is available.

Metals have been used as internal fixation devices since the days of Hippocrates, ca. 400 B. C. At first, pure metals alone were available, including gold, silver and iron. Around 1900, plated steel bone plates and screws were applied. Cobalt-base alloy devices were introduced in about 1911, and in 1926 stainless steel was first utilized as an implant. At present time, three metallic materials dominate the field,

stainless steel, cobalt (Vitallium type*) alloys, and titanium. Each alloy was developed initially for other applications but each exhibits particular properties that are crucial for successful implant materials.

Implant Material Requirements

The concept of an ideal implant material is of little importance since the demands associated with different applications are found to vary a great deal. However, the general requirements can be set down as follows, after Weisman[2].

1. Tissue compatability
2. Suitable mechanical properties (including wear resistance)
3. Corrosion resistance
4. Non-toxic, non-carcinogenic
5. Appropriate cost

Each requirement will have a different effective weighting factor, depending on the application. For example, short-time fixation devices do not need the high degree of tissue compatability that an implanted artificial joint might require. However, every implant material must have documented performance in the above areas.

Tissue compatability test protocol has been discussed by Cohen[1] and others; a uniform testing method would be desirable and is not presently available. Long-time compatability data is essential as surgeons begin to implant devices in younger patients. Certain mechanical properties values can be accurately determined by laboratory testing in air or in vitro, for example, tensile strength and durability. Other properties such as fatigue life, require careful environmental control during measurement.

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*Identification of proprietary materials by trade name is made solely for the purpose of adequate description and connection with reported data.

We note that strength beyond the required level may not be desirable, since loss of ductility frequently accompanies increased strength. A certain amount of ductility is required in implants to prevent fracture on sudden impact loading, and to permit tailoring the device to fit to the patient.

The required corrosion resistance of an implant material also depends on many factors; expected implant time, body reaction to corrosion products, effect of corrosion on mechanical strength, and others. Design factors can be important; crevices should be avoided where low pH and oxygen concentrations can destroy the passive, protective film on the metal implant. Installation problems, such as the coupling of dissimilar metals, must be avoided. The inertness of the implant and its products, whether corrosion-or wear-produced, is obviously essential. Attention has recently been focussed on the migration of particles from artificial implants through the body to remote locations. Clearly, it is of great concern to obtain as complete an understanding as possible of such processes. Infections do occur at the implant site and it is important to clarify the role of the implant metal and its products in that matter.

Properties of Bone

It is essential to consider the response of bone to the attachment of implants that will transmit mechanical loads for various periods of time. Accurate knowledge of the mechanical properties of bone *in vivo* are required. Bone consists of oriented fibers of collagen, hydroxyapatite crystals, amorphous calcium phosphate and mucopolysaccharides, combined to form a dynamic, viscoelastic, anisotropic material. The compressive strength of human bone is about 20,000 psi** The strength varies significantly with bone type, age, and physiological status. The elastic modulus of wet human femur is about 2×10^6 psi, longitudinally, and about one-third of that value, radially. Bone is highly strain-rate sensitive. Since damage is repairable

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**English units are employed in this report to be consistant with convention in the field. Conversion to SI units is shown in some cases.
Note: 1 psi = 6.9x10^3 N/m^2 = 6.9KPa

in living bone, the resistance to fatigue failure is very high. One important mechanical factor in connection with artificial implants concerns the elastic modulus mismatch with bone. Ideally, a material substituting for bone should have a comparable modulus value, thus avoiding local elastic stress concentrations at the joint interface. Given the viscoelastic and anisotropic properties of bone, an ideal match is nearly impossible. Recent attention to porous implant materials (or coatings on solid implants) where tissue ingrowth can take place, is of interest here in terms of the intermediate modulus values offered in such materials in the region of ingrowth. Further information on the properties of bone is available in several sources[4,9,10].

Format of this Report

An extensive discussion will follow on the three metallic materials principally used in clinical orthopedic implant activities; stainless steel, cobalt alloys, and titanium. The physical properties and corrosion behavior of each metal will be discussed, followed by a presentation of past and current information on implant applications. A concluding section will discuss other metals applied in this connection. Where possible we attempt to compare materials for use in a given application, however, conflicting requirements associated with the application and the lack of accurate data makes this a difficult task and leads to very qualitative conclusions.

II. STAINLESS STEEL

Physical Properties

Stainless steels, as the name implies, are more corrosion resistant than plain carbon steels or low alloy steels. This superior resistance to corrosion is produced principally by the addition of chromium. Small amounts of other elements such as copper, aluminum, silicon, nickel and molybdenum can further reduce corrosion. Combinations of chromium and nickel are particularly useful.

The American Iron and Steel Institute (AISI) designate 12% chromium as the cutoff point between "alloy" steel and "stainless" steel. Between the limits of 12% and about 30% chromium, with additions of other elements, are a spectrum of types of stainless steels. First, there is the group of stainless steels which are ferritic and not hardenable by heat treatment (for example, AISI types 405, 430, 430F and 446). Typical applications of these steels are in automotive and architectural trim, manufacture handling of nitric acid, and medium temperature unstressed machine parts. Second, there are the martensitic stainless steels (designated AISI type 403, 410, 414, 501 and 502 for example). Unlike ferritic stainless steels, these steels are hardenable by heat treatment, have good wear characteristics and have found applications as tools and cutlery. Neither of these two types of stainless steels have application in the implant field due to poor corrosion resistance. The martensitic type 440C is used extensively in surgical instruments.

Third, and most important from an implant materials standpoint are the austenitic stainless steels. Some AISI types are 301, 304, 304L, 316, 316L, 317 and others. Virtually all stainless steels implants are manufactured from steels in this group[11]. The austenitic stainless steels are not hardenable by heat treatment. However, a wide range of tensile, hardness and related properties can be obtained through cold working*, provided the shape of the product lends itself to such treatment, i.e., rods, bars, sheets, and forgable shapes. In the fully annealed state, austenitic stainless steels have an average tensile strength of about 1.0×10^5 ps (2.0×10^{10} N/m^2). In a heavily cold-worked state the tensile strength may increase to 2.0×10^5 psi or more. Ductility, on the other hand, is greatly reduced by cold-work, going from about 50% (elongation to rupture) in the annealed state to about 4% in a fully work-hardened condition. Similarly, impact strength or toughness (ability to withstand shock loading) is reduced by cold work.

The modulus of elasticity of the austenitic stainless steels is approximately 28×10^6 psi. This modulus is at least twice as high as cortical bone[12] and an order of magnitude higher than that of trabecular bone[13]. The importance of this modulus difference will become evident later.

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*Deformation of a metal at a temperature below the recrystallization temperature to produce a permanent strain.

The average fatigue limit, the stress level below which failure due to cyclic stresses does not occur, is approximately 4.0×10^4 psi for the austenitic steels. Fatigue strength is somewhat dependent on work hardening, increasing with tensile strength values. However, it is more affected by such variables as orientation texture, temperature, surface finish, microstructure and environment.

In summary, the austenitic stainless steels are strong, ductile, impact resistant and have adequate fatigue properties for many design situations. Additional technical information concerning austenitic stainless steels is readily available from several sources[14,15].

Corrosion Behavior

The corrosion resistance of austenitic stainless steels is high, compared to the ferritic and martensitic steels. The combination of chromium and nickel additions produces high corrosion resistance, even in some active chemical environments. Like many other corrosion resistant metals and alloys, the austenitic stainless steels develop this resistance by forming an adherent, inert, passive metal-oxide film[16,17]. This film, when formed, inhibits further oxidation or corrosion. The presence of nickel with small amounts of molybdenum can significantly improve the stability of the passivating film[18]. The nature and mechanism of passivation are discussed in various corrosion texts[19].

There are circumstances where a passive film breaks down and corrosion will occur. Environments which are oxidizing usually strengthen the passive film, whereas, a reducing environment may break down the film, causing the metal to corrode. For example, in a high-temperature oxidizing atmosphere, i.e., heat exchangers, jet engines, etc., there may be negligible corrosion. However, in sulphurous gases

(such as hydrogen sulphide) rapid attack can take place. There are also circumstances under which stainless steels will undergo local corrosion. A localized disruption of the passivating oxide layer can take place followed by continuing attack. Possible reasons include wear or fretting, galvanic coupling, intergranular corrosion (at grain boundaries), corrosion at crevices and inclusions, and mechanical surface damage. Under certain circumstances, austenitic stainless is subject to any of these corrosion phenomena.

Galvanic corrosion and fretting corrosion are perhaps the most basic and well understood of the corrosion effects mentioned. These problems can be largely overcome through adequate design and knowledgeable application of corrosion principles. Dissimilar metals having different electrochemical potentials should not be placed in contact in a corrosive electrolytic media. Likewise, continuous mechanical disruption (fretting) of the passive film of a metal in a corrosive environment should be avoided. Intergranular corrosion, once a major problem of austenitic stainless used in high temperature service, has been largely overcome. This type of corrosion was caused by the precipitation of chromium-rich carbides at grain boundaries following high temperature exposure. This left small areas directly adjacent to these boundaries deficient in chromium and thus less corrosion resistant. Through the efforts of Bain et al.[20] and others in the 1930's this problem was isolated and remedies developed. During World War II, the low carbon type austenitic stainless steels (304L and 316L) were developed. The low carbon content of these steels effectively prohibits carbide precipitation and subsequent pitting attack.

Not yet as well understood are pitting corrosion, crevice corrosion, corrosion fatigue, and stress corrosion of austenitic stainless steels. In marine environments, it is well documented[14] that austenitic stainless steels show crevice and pitting corrosion. As stated earlier, however, the addition of molybdenum significantly improves the stability of the passive film and can retard, but not eliminate pitting and crevice type corrosion. Similarly, stress corrosion and corrosion fatigue processes are accelerated in chloride and caustic solutions. For example, data[21] on corrosion fatigue indicates up to a 50% increase in corrosion fatigue damage of austenitic stainless tested in salt water as opposed to fresh water. Other sources[22] report substantial loss of tensile strength (up to 90% in 42% boiling $MgCl_2$) of stressed austenitic stainless steels in chloride solutions due to stress corrosion cracking. Additions of molybdenum have little effect on these types of corrosion. Damage can be minimized, however, by lowering stresses and/or by altering the environment. For additional information the reader is referred to the work by Fontana and Green[23] which provides discussion and examples of all the types of corrosion mentioned above.

In summary, the corrosion characteristics of the austenitic stainless steels, like the mechanical properties, are generally very good. These steels are not inherently inert, however, but become resistant due to the formation of a protective oxide film. The metal itself, with no such film has poor corrosion resistance. This will be a significant problem in low oxygen concentration environments.

Stainless Steel as an Implant Material

In the 1930's, orthopedic surgeons had become disenchanted with the open reduction of fractures using bone plates. This disenchantment was due to a rather high rate of

failure caused by adverse tissue reactions or cracking of the carbon or vanadium steel plates[24]. When the austenitic stainless steels became available to the medical community, they were naturally applied as fixation devices.

The basic type 302 stainless steel was the first to be used. The success rate of open fracture reduction immediately improved. However, corrosion-related failures of the fixation devices and adverse tissue reactions remained as significant problems. Later, the more corrosion resistant types 304, 316 and 317 stainless steels were employed[24,25]. With the advent of World War II and the associated injuries the demand for and use of implant materials increased greatly. It was during these years that the reputation of stainless steel, mainly type 316 was established. It was also during this period that cobalt alloys (see III), developed originally for dental use, gained wide acceptance as an orthopedic implant material. Results from the use of 316, 316L and 317 material as implants have, in general, been good despite problems that are detailed below. They are regarded as some of the best orthopedic implant materials available. Some property and composition values are given in Tables I and II.

Strength, Corrosion and Bio-Acceptance

Most surgeons and engineers agree that the mechanical properties of stainless steels type 316, 316L, and 317 are entirely adequate for many implant situations. Barring design or manufacturing flaws, improper application or insertion of a device, or critical time-dependent degradation (corrosion, fatigue, etc.), stainless steel should function well as an implant material. Unfortunately, the above mentioned problems are very much a reality and some failures of stainless steel implants occur.

Fatigue and corrosion-related fatigue have been isolated as a source of failure of stainless orthopedic implants. This is not totally unexpected. Orthopedic devices such as bone plates, hip nails and joint prostheses are subject to cyclic loads of a magnitude up to four times body weight[26,27]. Much higher localized stresses can result from improper insertion, design or manufacturing flaws, and flaws induced by localized corrosion. The presence of notches, such as screw threads, can drastically reduce fatigue strength[28]. To date, relatively little data is available concerning *in vivo* fatigue processes. Grover[28] and Cohen[1] point out the difficulties in acquiring complete information on actual, failed implants. However, some information is available. Cohen[29] examined many implants removed for various reasons and reported definite evidence of fatigue failures. Likewise, investigations by Cahoon and Paxton[30] and others[31-34] indicate fatigue initiated by corrosion to be a major cause of failure. Wheeler and James[35] and Colangelo[33] report accelerated fatigue failure of type 316 stainless steel in simulated body fluids as compared to that in air.

Somewhat less information is available concerning the stress corrosion failure of stainless steel implants. As mentioned earlier, it is well known that austenitic stainless steel is subject to stress corrosion in chloride or caustic environments. It is then a very real possibility that a highly stressed stainless orthopedic device in physiological solutions could fail as a result of stress corrosion. Indeed, some investigators have indicated stress corrosion to be a problem. Hughes and Jordon[31], Williams[36] and earlier, Zapffe[37] report cases of stress corrosion in stainless steel implants. *In vitro* experiments by Fink and Smathe[38] indicate that stressing an implant increases corrosion. Other investigators allude

to stress corrosion as a possible explanation of observed failure of stainless orthopedic devices. On the other hand, recent experiments reported by Galante[39] showed no evidence of stress corrosion in 316 stainless steel.

Intergranular corrosion should not be a problem in stainless steel implants of the 316 and 317 variety, provided the materials have undergone the proper heat treatments. Several cases have been reported[31,36,40] where faulty heat treatment (particularly in regard to welded devices) or failure to meet compositional specifications (including mislabeling) has been isolated as the problem. The best practice is to use low carbon type (316L, 0.03% carbon max.) stainless steel for implants[41].

Crevice corrosion can be a problem in stainless steel implants. Susceptible locations include, for example, screw hole regions of bone plates or other devices fixed by screws. Work by Colangelo and Green[34] indicated that 45% (24 out of 53) of the stainless steel orthopedic devices studied after removal were corroded. The predominant form of corrosion in the devices was crevice attack. In multi-component devices, 91% showed significant corrosion. Other surveys[31,42] of stainless steel implants removed for various reasons support the above findings. Several *in vitro* studies[43,44] also indicate crevice corrosion and/or pitting to be the predominant type of corrosion in stainless steel implants. For these reasons stainless steel can only be considered marginally satisfactory[45,46] in terms of resistance to corrosion in the body. The importance of proper passivation and pre-treatment of implants, particular stainless steel, has been noted[47].

In multi-component devices, mechanical disruption of the protective oxide film may lead to corrosion attack. It has been suggested[46,47] that crevice corrosion

is initiated by "fretting" of screws and plates and maintained by virtue of the low oxygen environment of the screw hole. In this respect, stainless steel is probably inferior to both titanium and chromium-cobalt alloys in that its protective film is not as resistant to damage nor so easily repaired once breached. Recent work by Homsy et al.[48] and Williams[49] has been directed toward this problem of crevice corrosion in stainless steel multi-component devices.

Galvanic coupling of stainless steels of different types or of entirely different metals is no longer the problem that it was. However, even now mislabeling, compositional discrepancies, inhomogeneities, or lack of consideration of the phenomena does occasionally result in the failure of an implant. Scales et al.[42] reported instances of incorrect labeling as to type of materials used in implants, notably steel implants. In several cases, the result was severe corrosion. Other cases of incorrect labeling and compositional discrepancies in steel implants[40,50] have been reported. Note that stainless steel, being less noble, would undergo galvanic corrosion if used together with either titanium or cobalt alloy components.

Absence of a quantitative definition of biological acceptance or biocompatability of an implant material, combined with the lack of any standardized compatability test, has led researchers down widely varied paths in determining the "degree of compatability" of various materials. Stainless steel is certainly no exception. Having been used rather successfully for thirty or more years, the data base amassed on the compatability of stainless steel is extensive; however, much of it is unconnected.

In either bulk or particulate form, intact, passivated stainless steel appears to be well tolerated by both calcified and soft tissue. That is, barring the hazard of bacterial infection or purely mechanical irritation of tissue, no major detrimental effect is ordinarily found. The normal tissue reaction is to isolate the implant. In the case of solid metal implants, isolation is accomplished by

sequestration of the implant by a fibrous tissue membrane[51,52]. This reaction has been detailed by numerous researchers and is reproducible in laboratory animals. Histologic study of the encapsulating tissue, particularly in regard to thickness and cellularity, provides some measure of the compatability of the material. In comparing stainless steels with other prosthetic materials, Laing et al.[51] found types 316 and 316L to be as well tolerated as the cobalt alloys and many ceramics. Titanium exhibited an even greater degree of tolerance. This study also correlated the degree of tissue reaction with the measured amount of corrosion products observed in adjacent tissues. The relative toxicity of released ions was considered an important factor. Previously, Cohen and Faultz[50] and Cohen and Hammond[40] had pointed out the importance of corrosion products, following studies of tissue surrounding corroded stainless steel fixation devices. Other reports[42,53] corroborate this picture all of which indicates that stainless steel may have insufficient in vivo corrosion resistance compared to other implant materials. Various in vitro corrosion studies[43,54] have indicated that type 316 stainless steel is inferior in corrosion resistance to titanium and cobalt alloys.

The tissue reaction to stainless steel in particulate form is much the same as that to the bulk material. If large enough, the particules may become encapsulated. Otherwise, they are phagocytised (intercellularly isolated) by histiocytes or in some instances, remain extracellular and migrate, thus reducing the metallic particle concentration. Long distance migration of particles or corrosion products is a potential hazard that requires more study. In recent experiments, Galante[39] evaluated fibroblastic and histocytic reactions in the tissues surrounding various particulate

materials. Stainless steel was well tolerated, ranking near a cobalt alloy studied. No severe or unusual reaction was noted.

Oppenheimer et al.[55] and others[56] have reported the possibility of stainless steel being a carcinogen. An earlier study[57] also linked nickel with cancer, bone necrosis and inflamation. These reports have been to some extent ignored[45,52] since cancerous growths have not been positively correlated in practice with the implanation of stainless steel or other currently used prosthetic metals. It has been suggested[45,53] that metal ions or corrosion products, in combination with complex host chemistry could produce antigens and thereby evoke an immunological rejection of a metallic implant. Like the potential carcinogenic properties just mentioned, this idea has not been confirmed. It should be noted, however, that recently Barranco and Soloman[58] reported a case of allergic skin reaction (eczematous dermatitis) from exposure to nickel from a stainless steel screw in the patella.

Another source of possible irritation is incompatability between the physical or mechanical properties of the implant and the host bone or tissue. For instance, the difference in coefficient of friction between an implant and cartilage is a possible source of irritation[11]. Another is the incompatability resulting from differences in elastic modulus of the implant material and adjacent bone[13]. Such differences can result in high stress concentrations at the bone-implant interface. Bone reaction to these stresses is poorly documented, however, instances of bone resorption and/or loosening of implants and even bone necrosis are known. In the case of type 316 stainless steel the modulus mismatch with bone is approximately an order of magnitude. Various approaches have been taken which reduce this problem in cases where modulus mis-match is obviously a disadvantage. The use of self-curing

methacrylate[59] as a filler provides a buffer-zone of compatable modulus between the stiff implant (a hip prothesis for example) and the more elastic host bone. Other possibilities for reducing the modulus mismatch include the use of porous metal or sintered fiber metal materials[60]. These ideas and materials will be discussed in subsequent parts of this report.

To conclude, it is clear from some thirty years of successful implantation that stainless steel is well tolerated in most instances. However, considerable evidence indicates that a build-up of corrosion products in tissues adjacent to the implant can occur and evoke acute reactions. With this in mind, the long time compatability of stainless steel must still be questioned. In cases where implants are expected to remain in situ for many years, it may be appropriate to use materials deemed more corrosion resistant, provided their mechanical properties are adequate. Further, the mismatch in elastic moduli of bone and stainless steel can have serious biologic implications.

Summary

At present, stainless steels (316, 316L and 317) are used for many prothestic implants. Results are usually quite good, however, there are failures[61] reported. Such failures can usually be traced to one of four broad problem areas; surgical insertion, biologic-pathologic problems, materials failure, or a combination of any of the above. Of primary interest in this report are materials failures or combinations of problems involving materials failures, i.e., corrosion and subsequent biologic reaction to corrosion products or released ions. With this in mind, some comments regarding stainless steel as an implant material follow.

1. Type - AISI types 316, 316L and 317 are used almost exclusively today. In the United Kingdom, 316, 316L and 317 may be covered under one standard, EN58J, or more recently appear as 316SI2, 316SI6 and 317SI6. Most other countries use the standard AISI codes.

2. Physical Properties - Stainless steel is a strong and a ductile material. The physical properties are more than adequate for most orthopedic implant situations. Corrosion can degrade the physical strength of a device with time. The modulus of elasticity of stainless steel is much higher than that of bone. In temporary, short time rigid fixation (bone plating) this may be an advantage. In the case of a permanent prosthesis, however, adverse reaction to localized high stresses induced by modulus mis-match can occur.

3. Fatigue - Stainless steel can and does fail in situations of cyclic stress, provided the endurance limit of the metal is exceeded. Corrosion can accelerate the fatigue process. Fatigue failures occur in orthopedic implants of stainless steel. This is largely a design problem, and can be overcome in many cases. However, long-time implant situations involving cylical loading constitute a difficult area.

4. Corrosion Resistance and Bio-Compatability - In the human body, stainless steel is subject to localized corrosion by various mechanisms. Pitting and crevice corrosion are the greatest problems. Evidence also supports the existence of stress-corrosion-cracking and corrosion-fatigue as failure mechanisms. Intergranular corrosion does not appear to be a problem since the introduction of 316, 316L and 317 as implant materials. However, in view of the corrosion problems found, performance of stainless steel implants must be considered only marginally satisfactory. Stainless steel is well tolerated by adjacent tissues, provided corrosion does not occur to any great extent. There are some reports of severe tissue reaction, however. Additional research and development is required to improve these alloys for long term and critical function applications.

5. Manufacture - Stainless steel is the least expensive and most formable implant metal of those in current use. Recent vacuum melting techniques have improved the metal quality. Controls on composition accuracy are important, since multi-component devices are manufactured from different production lots.

III. COBALT ALLOYS

Physical Properties

Cobalt-based alloys have found many engineering uses, including magnetic materials, high temperature creep-resistant materials, electrical resistance alloys, cutting tool materials, and in the dental and medical fields. The elements and proportions added to the cobalt-base will be determined by the requirements of the application. Elements usually added are chromium, nickel, molybdenum, titanium, tungsten, and iron. Cobalt alloys may exist in either cubic or hexagonal crystal structure, or a mixed phase of those two, depending on the alloy composition and processing treatments. While the alloys of interest generally have large amounts of other element additions, many of the characteristics of pure cobalt are also found in the alloys. These include low coefficient of friction, good wear resistance, good resistance to oxidation and the effects of sulfurous environment, and excellent high temperature properties. There are many heat-resistant alloys, for example, HS31, HS36, HS95 and others. They were developed since 1941 for hot gas turbine applications, and will not be discussed further here. However, one of the wrought alloys, HS25, is used for implant applications.

The cobalt alloys vary considerably in strength and ductility. Both cast alloys and wrought alloys are available[14]. Yield strengths vary from 65 to 175,000 psi, depending on composition and structure. The elastic modulus ranges from 29 to 36 x 10^6 psi depending on the alloy composition. The wrought alloys are hardened by precipitation, usually chromium-carbide precipitates, by solid-solution hardening, usually tungsten and chromium solute additions, and by plastic deformation hardening during forming operations. The cast alloys are hardened by the first two mentioned

mechanisms. Recent production advances include the use of high purity raw materials, vacuum melting (particularly useful to reduce porosity) and improved de-oxidizing methods. These advances have led to improved corrosion resistance, ductility and strength[62-64].

Corrosion Behavior

The cobalt alloys generally exhibit a high resistance to corrosion, even in aggressive environments[65]. They show a good resistance to sulfurous corrosion, much superior to stainless steel in that regard. The high chromium content contributes significantly to this property. In most environments a passive, adherent, oxide film develops on the alloy, consisting in part of chromium oxide layers[19]. Cobalt alloys are significantly more resistant to nitric acid (10 to 40% concentration) sodium hydroxide, and concentrated acetic acid than is austenitic stainless steel[14]. Nickel additions and molybdenum additions (about 10%) to the wrought alloy improve corrosion resistance. The alloys will differ in resistance to local pitting or crevice corrosion, depending on composition and other factors. However, in most applications involving aqueous, saline environments, local corrosion has not been noted as a problem. Galvanic corrosion can occur when the cobalt alloy is coupled with a less noble metal.

Cobalt Alloys as an Implant Material

The alloy Vitallium was first used as an implant material in 1937. Originally, the alloy had been developed and applied as a dental inlay material. Improvements in casting methods, inspection, and machining techniques have led to the production of a wide variety of orthopedic devices from this alloy. Other applications include artificial valves for the human heart, using the cast HS21 alloy[66]. One example of

production problems that can develop through poor casting is shown by Williams[64]. One difficulty that remains today concerns the casting of small objects (i.e., screws) where the large grain size may result in having only a few grains across the section of the object, a potentially weak situation[45]. The initial low ductility of the cast alloy can be significantly improved by solution heat-treatment procedures that lead to a more homogeneous microstructure. New cast alloys have been developed in recent years, principally for high temperature applications, however, they have low ductility[53] (order of 1%) and this would limit most implant applications.

Wrought cobalt alloys that were suitable for implant applications became available in 1952. Several advantageous properties are offered by alloys such as HS25 (also referred to as wrought Vitallium, an unfortunate term since the composition and properties differ considerably from Vitallium). These include improved ductility, higher strength, greater fatigue strength and impact strength. The composition is given in Table III together with other pertinent specifications. The chromium concentration is reduced from about 30% to 20%, while about 10% nickel and about 15% tungsten are added, relative to cast Vitallium. There are important property differences between the wrought and the cast alloys that will be discussed below (see also Table I for mechanical properties values).

Implants constructed from the cobalt-base alloys now enjoy a wide acceptance throughout the medical world. A great deal of data has been accumulated from both research and clinical studies that justifies much of the confidence in applying these alloys. Simple fixation devices from both wrought and cast alloys find constant application; complex devices such as the total hip prosthesis in cobalt alloy form

have been implanted in many individuals. Principal findings and conclusions from both research and clinical studies are summarized in the following sections.

Implant Strength, Corrosion and Bio-Acceptance

Mechanical properties of both the cast and wrought form of cobalt-based alloys are summarized in Table I, together with the current ASTM specification values. The range of strengths and ductilities for the wrought alloys arise from different thermo-mechanical processing methods. Increased forming deformation leads to higher tensile strengths and to low ductility values. It is seen that considerably improved strength values and ductility values can be obtained in wrought alloys compared to cast alloys. Ductility is important whenever shape changes must be imposed during installation of a device to obtain a proper fit. Certain devices lend themselves to production by casting; others due to size or shape require mechanical forming. The hardness of cast Vitallium is greater than the wrought material, and this is of importance in joint prostheses, such as the femoral head of an artificial hip. Note, however, that the impact strength of the cast alloy is only about 10% that of wrought HS25. The elastic modulus, hence the stiffness, of these alloys is slightly higher than stainless steel. This could be advantageous where rigid fixation[32] (for example, of a bone fracture) is required. The high surface hardness of these alloys has the further advantage of minimizing damage and scratching during installation of an implant.

Since cobalt-base alloys are in use in articulating prosthetic designs (total hip or knee devices) it is important to consider the wear and friction properties of the material. Moral[63] discusses some data obtained from vacuum studies that show the importance of surface crystallographic orientation and structure. He points out that relatively low wear rates are found in most applications but that little data was then

available pertaining to implants. Recently, several studies have been reported concerned with wear in simulated prosthetic joint situations. Duff-Barclay and Stillman[67] used a simulator machine under dry, saline, and blood plasma environments. They found cobalt alloy metal-to-metal prostheses to give the lowest wear rate. Titanium and stainless steel materials exhibited high wear rates and were judged impractical. Scales et al.[68] also concluded that a cobalt-chromium-molybdenum alloy bearing on itself was the most likely long-term satisfactory combination. They emphasized the importance of surface finish on the frictional values. They found that the alloy bearing in a cup of RCH1000 polymer (polyethylene) gave even lower frictional torques and wear rates (although long-time use was not as favorable). Recently, Galante and Rostoker[69] have also reported that Vitallium bearing on RCH1000 showed the lowest wear rates of several metals and ceramics tested. It appears that cobalt-base alloys do offer good wear resistance, hardness, and acceptable friction values for joint prostheses applications.

There is ample evidence in the literature of the generally high corrosion resistance of cobalt alloy implants. In a 1959 study, Scales et al.[42] reported on 15 cobalt alloy implants removed from patients, some of which showed evidence of corrosion. The other implants removed in this study, a total of 549 mostly iron-chromium-nickel alloys, showed evidence of corrosion in 228 instances, about 41%. Scales et al.[70] reported no sign of corrosion in two cobalt alloy hip nails removed from patients after 5 and 28 months. Hoar and Mears[43] concluded that vitallium alloys could tolerate long exposures to chloride solutions, as a result of a comparative study of different materials. Subsequently, Bultitude and Morris[44] reached the same conclusion after studying three vitallium implants in vitro. On the basis of this

and other evidence, it appears that general corrosion of the cast cobalt alloy implants is minimal. However, there is evidence of local, pitting corrosion problems and of a variation of corrosion amount with composition of the cobalt alloy. Rose et al.[71] report a study of a removed nail plate, broken in situ, where subsequent analysis showed the nail to be Vitallium and the plate HS25, wrought alloy. The failure was identified as a fatigue-induced fracture, influenced by corrosive pitting attack associated with the different corrosion resistance of these two alloys. In vitro studies by Arndt et al.[72] have also shown that HS25 is more susceptible to crevice corrosion than is cast Vitallium. Coupling of these two different cobalt alloys should be avoided. The accumulated experience with cast Vitallium implants should not be thought to apply directly to wrought alloys of other compositions.

The surface preparation of implants may have a significant effect on the subsequent behavior. Revie and Greene[73] studied a wrought cobalt alloy in vitro and found a significant, beneficial effect of pre-treatment in establishing a passive film (initial polarization current densities were decreased by a factor of over 100). They also found an improved resistance of electropolished surfaces relative to rougher, finished surfaces. Recently, Homsy et al.[74] have considered the problem of tissue and bone adhesion to surfaces of cobalt alloy prostheses. While these cast surfaces show excellent corrosion resistance, the oxide film present together with the as-molded surface roughness produces an interface that permits some ingrowth or adhesion. Such a characteristic can make removal of the implant a difficult procedure. These authors found that filling the surface pores with a polymer by a burnishing technique can reduce this adhesion problem.

The biological acceptance of cobalt alloys has been demonstrated by over 30 years of implantation of various devices. An even longer period of successful dental applications (referring to cast Vitallium material) can be cited. However, specific long-term data, greater than 10 years continuous implant time, is difficult to locate. In a 6 month study of tissue reactions to implantation of both cast and wrought cobalt alloy specimens in rabbits, Laing et al.[51] found satisfactory tissue acceptance of both alloy groups. While the concentration of released elements was lower for the cobalt alloys than for titanium, the tissue reaction was thicker for the cobalt alloys. A significant release of elements into the surrounding tissue was found, even in this short period of time. An excellent discussion of methods and the results of determining tissue tolerance has been given by Cohen[1]. He notes that characteristically, cobalt alloy implants show thin scar encapsulation with no continuing inflamation. However, the implant is never strictly inert; some interaction is always noted. An indication of possible long term problems of great concern is given in the report of a carcinogenic response of rat muscle to wear particles from a cobalt-alloy prosthesis. Heath et al.[75] injected wear debris from a machine-operated prosthesis into muscle tissue. Subsequently, 14 tumors were detected in periods of time up to 15 months; 7 of the tumors were analyzed. The authors point out that finely divided cobalt alloy wear debris may pose a serious long term problem in humans and that little if any relevant data is on hand.

Summary

Cobalt alloy prostheses and fixation devices have been implanted with generally successful results for over 30 years, following even longer experience with application in the dental area. The good corrosion resistance, biological acceptance, and mechanical properties of these alloys indicates continuing use. This material was one of the

first used for artificial heart valves, chosen because of the good experience to date. Some problems that appear worthy of current attention include corrosion in multi-component devices using different cobalt alloys, local corrosive attack on wrought alloy surfaces, and the body tolerance of wear particles from articulating devices. A summary of the properties of these alloys is as follows:

1. Type - Both cast cobalt-chromium-molybdenum and wrought cobalt-chromium-nickel-tungsten alloys are available as orthopedic devices. The longest experience is with the cast alloy (Vitallium type).

2. Physical Properties - The alloys show a high hardness, high elastic modulus, and moderately high strength and ductility values. The porosity and impurity content of the cast alloy has been markedly reduced in recent years by production controls. Greater ductility and strength are found in the wrought alloys. Wear rates (between identical surfaces) are relatively low, and excellent surface finishes can be obtained and maintained.

3. Fatigue - The fatigue limit is typically about 30 to 40% of the tensile strength a similar ratio as that of austenitic stainless steel. Corrosion induced fatigue failure has been observed in an implant.

4. Corrosion Resistance and Bio-Compatability - The cobalt alloys of interest are not subject to significant general corrosion in the human body. Examples of local, pitting or crevice attack have been noted on the wrought alloys. Biologic acceptance of the cast alloy is excellent; the usual tissue reaction is minimal. There is some concern over body response to wear particles of this alloy, particularly over long time periods.

5. Manufacture - The investment-casting of Vitallium and related alloys is an established procedure, applicable to many devices excepting small sizes and unusual shapes. The wrought alloy types are possible to heat-treat and mechanically form into a variety of shapes. Machining and polishing methods are established.

IV. TITANIUM

Physical Properties

Titanium is a relatively new engineering material. Despite the fact that it was first discovered as early as 1791, it was not available on a commercial basis until about 1950[76]. Prior to commercial production, titanium was in many cases a chemical nuisance - an impurity. Today, titanium is surpassed in commercial, structural uses only by aluminum, iron and magnesium[66].

Currently, titanium is manufactured by the Kroll process. Discovered by W. J. Kroll in 1938, this process made it economically feasible to produce titanium on a commercial basis. In 1947, before implementation of the Kroll process, the cost of a pound of titanium was approximately $3000. By the end of the 1950's, titanium was priced at about $3.00 a pound[14]. The process takes titanium from the ores rutile (TiO_2) or ilmerrite ($FeO \cdot TiO_2$) and combines it with chlorine to form titanium-tetrachloride ($TiCl_4$), a heavy colorless liquid. The titanium-tetrachloride is then reduced in an inert atmosphere with molten magnesium or sodium to form magnesium chloride ($MgCl_2$) or sodium chloride (NaCl) and pure titanium in the form of a porous solid (sponge). The porous solid is melted (again under an inert atmosphere) in an electric furnace and cast into an ingot.

The metal resulting from the above process is light, strong and ductile. The density is about 60% that of steel. The strength-to-density ratio is greater for titanium than annealed austenitic stainless but less than cold worked stainless[77]. The mechanical properties of unalloyed titanium are strongly dependent on the impurity content of the finished product. Titanium has a strong affinity for the gases

hydrogen, nitrogen and oxygen. Hydrogen can be absorbed at elevated temperatures from water vapor, acids, oils, or other hydrocarbons. Absorbed hydrogen beyond 0.02% can cause severe embrittlement. Fortunately, most absorbed hydrogen can be removed by vacuum annealing. Oxygen and/or nitrogen can also embrittle titanium. However, within specified limits, contamination by these elements can have a strengthening effect. There are four grades (ASTM) of commercially pure titanium available in the U.S. Grades 1 and 2 are the most pure being at least 99.2% titanium, with tensile strengths from 40,000 to 60,000 psi. The tensile strengths of grades 3 and 4 (99.0% pure) are from about 70,000 psi to 95,000 psi.

Grades 1 and 2 are slightly more ductile than the higher grades. The higher grades are more sensitive to stress concentrations (notch sensitivity) and have reduced toughness. Fatigue strength is very good, about equivalent to stainless steel, and increases slightly with grade. The modulus of elasticity is 15.0×10^6 psi, slightly more than half that of stainless steel. Unalloyed titanium is not hardenable by heat treatment. Some hardening by plastic deformation is possible but not nearly to the extent of stainless steel.

At room temperature, titanium exists in a hexagonal structure, termed the alpha phase. At 1625°F a transition to a cubic structure, the beta phase, occurs which remains stable to the melting point of approximately 3140°F. By selective addition of alloying elements, advantage can be made of this two-phase behavior and a wide range of properties can be obtained. There are three basic alloying effects. First, additions of aluminum will raise the alpha phase transition temperature. These alpha alloys have several attributes: weldability and retention of strength and oxidation resistance at elevated temperatures. Second, some elements when added to titanium do not affect the transition temperature but act simply as a solid

solution strengthener. Tin and zirconium are often used to achieve this effect. Third and most important is the alloying effect of chromium, columbium, copper, iron, manganese, tantalum and vanadium. Additions of these elements reduce the alpha-beta transition temperature so that a stable two-phase alpha-beta alloy is obtainable at room temperature. These two-phase alloys can be significantly strengthened by heat treatment. One example is titanium-6% aluminum, 4% vanadium (Ti-6Al-4V). Over 50% of the titanium produced is used in making this alloy. It shows considerable promise as a prothestic metal[67].

In the fully annealed state, Ti-6Al-4V has a tensile strength of 135,000 psi and a yield strength of 120,000 psi. Heat treatment can increase the tensile strength to 170,000 psi and the yield strength to 150,000 psi. The strength of this alloy matches that of all but the most heavily work-hardened stainless steel. The modulus of elasticity, 16.5×10^6 psi, is near that of the commercially pure titanium. Ti-6Al-4V is less ductile (8% elongation to failure) and harder than unalloyed titanium. It has a higher fatigue strength than pure titanium, being over 50% of the tensile strength. This ratio is better than most stainless steels. However, tests on notched Ti-6Al-4V show a decrease in fatigue/tensile strength ratio to about 20%.

In summary, titanium and some titanium alloys (Ti-6Al-4V) are strong, light materials. The fatigue strength of titanium and its alloys are generally good. Impact resistance is likewise good. Additional information can be obtained from the ASM Metals Handbook[14] and manufacturing sources.

Corrosion Behavior

The corrosion resistance of titanium is very good[18,23]. At ordinary temperatures, commercially pure titanium is nearly unattacked by strongly oxidizing acids, aqueous chloride solution, moist chlorine gas, sodium hypochlorite, sea water, brine solutions and many other equally corrosive mediums. Most titanium alloys are nearly as resistant. Titanium and its alloys are protected by an inert, tightly adherent, passive oxide film. When passivated in this manner, titanium acts as the noble metal when coupled galvanically with all structural alloys. Consideration must be given to this relation if titanium is used in conjunction with another metal in a multi-component device in a corrosive medium.

Titanium and most of its alloys are rather immune to localized corrosion, such as pitting and crevice corrosion. However, in locations of restricted geometry in an acidic and a low oxygen environment, crevice corrosion can take place in titanium. McMaster[78] reports that the fatigue behavior of titanium is nearly unaffected by corrosive media, although a slight decrease in fatigue strength was noted in brine solutions. Other sources[14] corroborate this observation. For practical purposes, stress corrosion cracking is not a problem in titanium or its alloys.

In certain applications, wear is a significant problem in titanium and titanium alloy devices. In cases of titanium bearing on titanium or on another metal, wear may be excessive despite lubrication. Galling is one significant type of wear[77]. Surface treatments and/or alloying may provide an answer to this problem.

Titanium and Titanium Alloys as an Implant Material

As early as 1940, research was being conducted to determine if titanium could

be used as an implant material. In that year, after conducting animal experiments, Bothe *et al.*[79] reported that "titanium was fully as well tolerated as stainless steel and Vitallium." In 1951, after experimental work on rabbits and rats, Leventhal[80] came to the same conclusion. *In vitro* tests by Clark and Hickman[81] further confirmed the inertness of titanium in physiological solutions. About this time, titanium was beginning to be produced commercially. The price of the material dropped and quality improved. By 1957, Leventhal[82] had reported on fifteen cases in which titanium prostheses were inserted in humans. By the mid-1960's nearly every type of implant previously made with stainless steel or cobalt alloys had been successfully constructed from titanium[77].

Acceptance of titanium as an implant material, particularly for orthopedic use, has been slow. This is especially true in the United States. Reasons for this reluctant acceptance are many. First, for approximately thirty years, stainless steel and cobalt-chromium alloys have proven generally successful, although certainly less than perfect. Hence, there is a hesitance to adopt a new implant material that would require modified procedures, additional experience, etc. Second, until recently, the cost of raw titanium and titanium products was high relative to those two alloys. Thirdly, there still remains some doubt among manufacturers and physicians whether titanium and titanium alloys are actually superior to other currently available prosthetic metals. Titanium and titanium alloy devices are in clinical use at this time. Widely varied research studies are still being conducted. The following sections summarize the major conclusions thus far.

Implant Strength, Corrosion and Bio-Acceptance

As discussed earlier, the yield strength of grades 1 and 2 titanium is from 40,000 to 60,000 psi. Rose[7] and others have noted that this level of strength may be insufficient for bone plate and other stressed applications. However, clinical evidence[41,83] available indicates mechanical failures of titanium are not a problem. Naturally, other factors enter in here, such as degree of load bearing and duration of implantation. In applications where strength is a factor, the stronger Ti-6Al-4V alloy should prove adequate. Table I lists some mechanical properties values for the two alloys.

In a previous section the modulus of elasticity of implant materials was discussed in terms of its effect on adjacent tissue. There are two schools of thought here. First, there are researchers and clinicians who feel that a stiff, high modulus material such as stainless steel is a necessity if completely rigid fixation of fractures is to be accomplished[45,64]. In this view the lower modulus of titanium is a disadvantage. However, adverse stress-induced biologic reactions, implant loosening, and reduced damping or energy absorbing ability have led to a second school of thought. Katz[3] and others[77] have indicated that a modulus of elasticity more comparable to that of bone would be desirable, especially in cases where removal of the implant is not anticipated. In this view the stresses are transferred between the implant and the bone more uniformly. Here the lower modulus of titanium and titanium alloys is an advantage.

The fatigue strength of titanium is approximately the same as that of the austenitic stainless steels. The fatigue properties of the Ti-6Al-4V alloy appear to

be better than stainless steels currently in use for surgery[28]. Fatigue failures have not been reported clinically.

The corrosion resistance of titanium and Ti-6Al-4V in saline solutions has been shown to be high. Hoar and Mears[43] studied titanium *in vitro* and found a greater resistance to corrosion that for stainless steel and the cobalt alloys. Mueller and Greener[54] and others[44] also report a high degree of passivity. Fraker *et al.*[84] have reported electrochemical measurements and electron microscope surface studies of titanium and several alloys. They find very good resistance to attack, but point out the need for careful initial surface preparation. Available information indicates that titanium may be the most corrosion resistant implant material among the principal three materials.

The tissue reaction to titanium is that found for most compatible materials, isolation in a fibrous tissue envelope. Small particles of titanium may be phagocytised or remain extracellular. Early work in rabbits by Laing *et al.*[51] indicated that titanium was equally as well tolerated as stainless steel or cobalt-based alloy materials. More recent experiments confirm this, and in fact, it appears that titanium and Ti-6Al-4V may actually be better tolerated than stainless steel or cobalt alloys. Galante[39] reports good tissue acceptance of bulk titanium and titanium particles. Likewise, Predecki *et al.*[85,86] indicate excellent tolerance of titanium in tissue adhesion studies in animals.

In connection with the question of bio-compatibility, it is appropriate to carefully consider the growing interest and work on porous implants. In such materials the surface/volume ratio is greatly increased relative to a solid, bulk implant. The purpose is to promote adhesion by tissue ingrowth. The large tissue-implant interface places particular demands on the compatibility and corrosion resistance of the implant material.

After initial success in fabricating a porous cobalt alloy implant[87], several groups became interested in titanium materials. Hahn and Palich[88] applied a titanium oxide coating on a wrought titanium implant. They reported no compatibility problems and a large increase in fixation strength. Galante et al.[60] fabricated and studied ingrowth on sintered fiber titanium aggregates, having bulk densities between 45% and 65%. Implantation in rabbit and dog femora demonstrated ingrowth and good shear strength, in the range of that of bone. Following a previous study of porous cobalt alloy materials, Hirschhorn et al.[89] prepared and studied porous titanium and porous Ti-6Al-4V materials. They also reported good ingrowth and tissue acceptance, noting however, the need for careful corrosion studies on such materials. Recently, Nilles et al.[90] have studied porous Ti-6Al-4V materials, having controlled pore size and density, with applications to knee prostheses attachment. Young[91] has reported a current study of porous titanium dental implants.

Wear is a significant problem in applications of titanium to articulating surfaces. In view of the recent interest in total joint replacement, serious consideration has been given to this matter[46,64,78]. Recent in vitro experiments by Galante et al.[69] and others concerning wear in artificial joints have indicated the difficulties. On the other hand, clinical results of the orthoplasty series of Emenus et al.[84] did not indicate a wear problem. With the aim to produce joint protheses with projected lifetimes considerably longer than at present, wear phenomena

must be considered in greater detail. Investigation into specific surface treatments or perhaps new alloying combinations is essential if titanium materials are to be used in this application.

Most of the available information concerning the clinical use of titanium as an orthopedic implant material comes from abroad. Emneus and Berg[83] reported on a series of 110 Moore arthroplasties done between 1961 and 1965. Of the prostheses used, 55 were titanium and 55 were a cobalt alloy. No differences were reported between the groups. In cases where titanium appliances were removed, there was no apparent irritation of tissue even though in some instances where multi-component (plates and screws) devices were used, a discoloration appeared. Part of this observed pigment was phagocytised and part remained extra-cellular. Previously, Emneus and Stenram[52] reported on favorable tissue acceptance of titanium in animal experiments. Although compatibility was excellent, in some cases a dark pigment (Turnbull negative) was noted in tissue adjacent to the implant. Subsequent x-ray spectroscopy and quantitative analysis revealed titanium to be the principle constituent of the discoloring pigment. Long range implications of this finding have not been reported.

More recently, Williams and Meachin[41] reported examination of implants and adjacent tissue in 190 cases. Of these 190 implants, 49 were of titanium. The titanium implants were well-tolerated and did not corrode to any observable extent. Local tissue, however, showed titanium contents (dark particles) in concentrations that varied from patient to patient. The maximum found was about 0.2%. There was no definite adverse reaction to released titanium observed. However, the authors suggest a more detailed study of the possibility of systemic release of titanium

and also distant hypersensitivity effects, if any. Additional information concerning the compatibility of titanium comes from the field of oral surgery. At present, titanium oral endosteal implants are being used routinely with clinical success[92]. These blade implants are inserted directly into the alvellar bone ridge. Stabilization is dependent upon bone growth around and into vents in the implant. Weiss et al[92] report that titanium is the metal of choice in this application, and that 90% of the endosteal implants inserted in the free world are titanium.

Summary

Virtually all implant devices constructed of stainless steel or cobalt-based alloys have been also constructed from titanium. The use of titanium and its alloys is more widespread abroad than in the U.S. Available clinical reports are generally favorable, particularly in regard to corrosion resistance and compatibility. There is some concern among researchers and clinicians that unalloyed titanium does not have the mechanical strength to perform adequately in highly stressed situations. As of yet, however, clinical results do not reveal this problem. Experimentally, wear appears to be a problem in articulating prostheses. These findings and others are summarized as follows:

1. Type - Several grades of unalloyed titanium and a Titanium-6 Aluminum-4 Vanadium alloy have been used as implant metals.

2. Physical Properties - Unalloyed titanium is not as strong as stainless steel. The stronger Ti-6Al-4V alloy can be used where high strength is required. Elastic modulus mismatch with bone is less with titanium and titanium alloys than with stainless or cobalt-based alloys.

3. Fatigue - The fatigue properties of unalloyed titanium are as good as most stainless steels. The fatigue properties of Ti-6Al-4V are better than stainless steel.

4. Corrosion Resistance and Bio-Compatibility - In the human body, titanium and its alloys do not appear subject to significant corrosion, local or general. Titanium alloys are very well tolerated by adjacent tissues. Some titanium is apparently released resulting in dark local pigmentation of the tissue.

5. Manufacture - Titanium and its alloys are nearly as formable and machineable as stainless steel, if proper equipment is available and procedures followed. The machineability of Ti-6Al-4V is as good as stainless steel. At present, costs of finished products should not be more than 20% higher than stainless steel and about the same as cobalt-based alloy devices.

V. OTHER METALS

Early history of the use of metallic surgical implants includes many metals that are no longer thought suitable. These include iron, silver, bronze, aluminum, brass, magnesium and others[24]. However, there are other metals and alloys that are in current use or thought of as being worthy of further study and evaluation, as prosthetic implants. These will be discussed briefly below.

Tantalum

The metal is used as wire sutures and gauze for abdominal wall repair. It is quite inert and compatible, however, its low strength prevents application to structural repair problems. Considerable tissue reaction in terms of the membrane thickness surrounding the tantalum implant has been reported[51].

Zirconium

Some results are available on the implantation of zircalloy (1.5% tin, 0.15% iron, 0.1% chromium, balance zirconium) in animals. Galante and Rostoker[93] implanted specimens in the back muscles of rabbits for twelve months. Evidence of pitting corrosion was found in two of the four specimens. The authors concluded, however, that the alloy was suitable for consideration as an implant material, without appearing to offer any advantages over presently available materials. Laing *et al.*[51] report that measurements on the membrane thickness surrounding zirconium implants are quite variable; a strong tissue response is found.

Nitinol

This alloy is a nearly equi-atomic binary alloy of nickel and titanium, first developed at the Naval Ordinance Laboratory, Washington, D. C. By suitable processing, items can be fabricated from this alloy that will undergo a specific, controllable shape change at some later time, as a result of an impressed thermal change. Implant applications

include bone plates, fasteners, and artificial muscle fibers. Corrosion data and bio-compatibility data are becoming available and early results[94,95] appear encouraging.

Cobalt-Nickel-Chromium-Molybdenum Multi-Phase Alloy

This wrought, quarternary alloy[96] is both age-hardenable and work-hardenable. It is quite different in metallurgical properties from the cobalt alloys discussed earlier. Plastic deformation as a result of forming operations produces a mixture of cubic and hexagonal phase. Heat treatment can bring about additional strengthening through precipitation of a Co_3Mo phase. Yield strength values from 60,000 to over 200,000 psi are attainable[96], with elongations from 70% to 10%, respectively. The corrosion resistance in saline solutions appears good. Preliminary implant studies in animals have been conducted. Tissue compatibility in rabbits appears as good as Vitallium.

CONCLUSIONS

The lack of an ideal implant material is made clear after one becomes familiar with the results to date using presently available materials. In many cases, compromises are made, for example, in the tensile strength of a material, in order to obtain improved corrosion resistance or acceptable tissue response. There is clearly room for further development of new materials for implant purposes. It is the authors' view that this probably involves only minor modifications or deviations from the presently available materials, rather than the introduction of completely new materials. The period of time required for a thorough and accurate evaluation of a new implant material is so long and the entire testing protocol so extensive, that completely new thrusts become a major effort. Further, it appears to us that a minor tailoring of a set of a few basic materials to suit specific implant problems may produce the "arsenal" of implants that the surgeon requires. As an example, an extensive choice of alloys with their associated properties is available in the cobalt-base system. Very high strength wrought alloys exist and could be further improved for specific purposes, such as fracture fixation devices. Other cobalt alloys show excellent wear resistance for consideration as artificial joint prostheses, particularly if further tissue tolerance data are obtained in connection with the wear debris that is produced. The problem of variation in the susceptibility to local corrosive attack among the cobalt alloys of different compositions can surely be attacked and solved by minor alloy modifications. It is hoped that this report will highlight some of these specific areas that need attention.

In attempting to compare the results of studies by different investigators on the same implant material, the need for a more uniform method of testing and evaluation became apparent. Laboratory corrosion testing, for example, is today a relatively well-defined area. Procedures are established and validated. Further studies of implant materials would be well served by establishing a specific procedure for

determining the corrosion resistance and tissue compatibility of implants in vivo. Many excellent test methods already exist and need only be formulated together into one program. Joint activity among the American Academy of Orthopedic Surgeons, the American Society for Testing and Materials, and other appropriate groups is envisaged. Guidance could be obtained from the materials screening and evaluation activities associated with the artificial heart program supported by the Federal government through the NIH.

One implant area worthy of special attention concerns artificial joint prostheses. It appears that a significant increase in the use of this surgical procedure should be expected in the next decade. The success in total hip implantations in recent years is certainly outstanding, and this effort will be expanded to other joints of the body. Serious materials problems exist here today, primarily involving wear, adequate fixation, and body tolerance to wear and corrosion products. A programatic approach to activities in this implant area would be of benefit to all concerned.

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Table I. Mechanical Property Values and Specifications for Selected Implant Materials. Values may vary substantially with state and composition of the material.

	Stainless Steel			Cobalt Alloy				Titanium		
Property	316L	ASTM F56-71 Specification Type B material cold-finished	cold-worked	Cast (Vitallium) (HS-21)	Wrought (HS-25)	ASTM F75-67 Specification Cast	ASTM E90-68 Specification Wrought	Ti Grade 3	Ti-6Al-4V heat-treated	ASTM F67-66 Specification Grade 3
Tensile Strength* (1000 psi)	100	88	125	100	145-250	95	125	70	170	60
Yield Strength* (1000 psi)	70	43	100	80	65-110	65	45	60	150	50
Elongation (%)	36	35	12	8	9-70	8 min.	-	25	6	18 min.
Youngs Modulus* (10^6 psi)	29	-	-	36	35	-	-	15	16	-
Hardness (Rockwell)	B76-90	-	-	C30	C21-56	C25-34	-	B90	-	-
Fatigue limit / Tensile strength (%)	45	-	-	43	32	-	-	45	50	-

*Note: 1000 psi = 6.9 x 10^6 N/m = 6.9 MPa

Table II. Composition and Specifications for Stainless Steel (amounts in weight percent) for Surgical Implants.

Element	Material	
	316L	ASTM F56-71 Specification (Type B)
Chromium	16-18	17-20
Nickel	10-14	10-14
Molybdenum	2-3	2-4
Manganese	2	2 max.
Carbon	0.03 max.	0.03 max.
Phosphorous	0.045	0.03 max.
Sulfur	0.03	0.03 max.
Silicon	1	0.75 max.
Iron	bal.	bal.

Note: British specifications are nearly the same (BS 3531; 1968).

Table III. Composition and Specifications for Cobalt Alloys (amounts in weight percent) for Surgical Implants.

Element	Material			
	Vitallium, cast (HS21 similar)	Wrought alloy (HS25)	ASTM F75-67 Specification Cast	ASTM F90-68 Specification Wrought
Chromium	30	20	27-30	19-21
Nickel	-	10	2.5 max.	9-11
Molybdenum	5	0.1	5-7	-
Manganese	0.5	1.4	1 max.	2 max.
Tungsten	-	14	-	14-16
Carbon	0.4	0.01	0.35	0.05-0.1
Silicon	0.3	0.5	1 max.	1 max.
Iron	0.7	0.2	0.75 max.	3 max.
Cobalt	bal.	bal.	bal.	bal.

Note: British specifications are nearly the same (BS 3531; 1968).

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The application of metallic materials as orthopedic implants in the human body is reviewed, concentrating on materials presently in clinical use and undergoing laboratory evaluation for possible future use. The criteria considered explicitly are tissue compatibility, mechanical properties, corrosion resistance, and toxicity. The three principal metallic implant materials, stainless steel, cobalt alloys, and titanium, are discussed in detail. Wherever possible, comparisons are made between the materials in terms of the intended application.

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