To succeed in life, humor does not cost --- Goyal

BIOMECHANICS OF HIP AND KNEE PROSTHESES[1]

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Abstract - **Hip and a joint replacement for the human body is a complex and dynamic field. Engineers and orthopedics combine to makes a person's life a normal a painless life. Biomechanics is the study of body movement in order to design and produce the ideal prosthesis. Materials are selected because of their properties like their modulus of elasticity, corrosion resistance and their biocompatibility. Innumerable tests are performed before an implant is to be used in daily surgery. This paper discusses the materials used commonly for hip and knee implant: stainless steel 316, chrome cobalt and titanium and titanium alloys. It is an overview from the engineer's point of view of the criteria used in selecting biocompatible materials. It does not promote a material in particular. The paper is based on real investigations and information from books and internet sites.**

Key words – **Biocompatibility, Implants, Osseointegration, Prosthesis, Titanium, Stainless Steel, Chrome Cobalt, Nickel Titanium, Corrosion,**

INTRODUCTION

Total joint replacement has become a widely accepted treatment for many destructive joint diseases including osteoarthritis, rhematoid arthritis, osteonecrosis and very severe pathologic fractures. Of total joint replacements, the two most commonly replaced joints and most successfully replaced joints are the knee and the hip. Sir John Charnely, a British Orthopedic surgeon who was knighted for his development of joint replacements, developed the fundamental principles of the artificial hip and designed a hip in the mid 1960's that sees widespread use today. Frank Gunston developed one of the first artificial knee joints in 1969. Since then, joint replacement surgery has become one of the most successful orthopedic treatments. The numbers of hip replacements done in the world per year are between 500,000 and 1 million. The total number of knee replacements done in the world per year is less, but probably are between 250,000 and 500,000. Of all the factors leading to total hip replacement, osteoarthritis or (OA), is the most common, accounting for 65% of all total hips

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The basic idea of joint replacement surgery is to replace the diseased articular surface with one made from a synthetic material. This new joint surface must then be part of the artificial joint which itself is fixed to the bone near the joint. The major design issues in artificial joint replacement are: 1. The geometric and material design of the articulating surfaces; and 2. Design of the interface between the artificial joint and the surrounding bone. Most joint replacements use a polyethylene for the bearing surface and either a titanium alloy or a chrome-cobalt alloy for the rest of the joint. It is the metal part of the joint in most cases that interfaces with the bone. There are two widely used methods for interfacing the joint with the bone: 1. using a Polymethylmethacrylate (PMMA) cement to adhere the metal to the bone or 2. Using a porous metal surface to create a bone ingrowths interface.

CLINICAL PERFORMANCE OF JOINT REPLACEMENTS [18]

The three major determinants of total joint performance are:

1. Surgical Factors
   a. Surgical experience and skills.
   b. Patient selection.

2. Prosthetic Factors
   a. Prosthetic materials.
   b. Shape.
   c. Prosthetic fixation.
   d. Surgical instrumentation.

3. Patient Factors
   a. Patient compliance to surgical instructions.
   b. Patient activity.
   c. Patient weight.
   d. General health.
   e. Patient bone quality.

The most common cause of total joint failure is asceptic or mechanical loosening. A critical determinant of joint longevity is the fixation between the prosthesis and the bone. The Chrome alloy material fixation has a pain free joint. When the bone implant interface starts to fail, a soft fibrous tissue develops at the interface that allows more relative motion between the implant and the bone under loading. This leads to migration of the implant and causes pain to the patient. After a certain period the pain becomes intolerable and the implant must be replaced, a procedure known as a revision. There are number of factors that may contribute to asceptic or mechanical loosening. Among these factors is bone necrosis (death) due to head from cement polymerization, mechanical damage done during surgery, wear debris, and mechanical loosening from fatigue at the

interface. The last two factors are mechanical in nature and can be accounted for in implant design.

The best indicator of clinical performance of a given prosthesis is the percent of revisions that are performed for a given prosthesis. Of course, this indicator itself is not perfect since orthopedic surgeons tend to choose specific prostheses based on individual preference, so there is some influence of surgical skill on revision indicators. One of the most extensive studies as cited in the text was carried out in Sweden. The number of revisions at multiple total joint centers was tabulated from a total of 92,675 cases, due to the unique ability to track patients in a national database.

Hip replacement surgery is generally a successful operation, but the time has come to question the more traditionally used materials so that patients can benefit from currently available advanced technology**.**

The optimization of materials used in orthopedic implants has been a goal ever since the Mistokles Gluck reported his results on the ivory implants he used in 1891. These implants ultimately failed because any implant has to satisfy three main criteria: load transfer capacity, fixation and biocompatibility. These are all intimately connected and interdependent.

Fixation of dead material to living tissue in general has relied on a mechanical interlock of either a roughened surface (including fixation by screws) or an interdigitation of acrylic cement between implant and bone. Furthermore this fixation has to remain firm in the long term, where the bone is constantly being remodeled depending on system requirements, local forces and material biocompatibility.

The load transfer capacity of the material must take into account the high mechanical forces at maximum peak strain and the dynamic loading over many millions of cycles. Forces generated across the hip joint can be as much as six times body weight during some physical maneuvers. Many of these characteristics are shown in table 1.

Table 1. Forces generated across joints

Tensile strength	Ksi	40
Yield strength	Ksi	60
Elongation	%	Nil
Rockwell Hardness	Rev per min	55-59
Density	Lb/inch^3	0.317

The implant material must also be totally inert or bioactive such that it causes no tissue reaction or inflammatory response, which may jeopardize either fixation or load bearing capacity. In the case of joint prostheses this biocompatibility must include the material in its particulate form, as wear debris will be

formed at the articulation surface and also at the implant/bone interface. This wear debris has been found to be biologically active.

The most common combination of materials used for hip replacements throughout the world is metal (cobalt chrome or stainless steel) and high-density polyethylene fixed into place using bone cement (polymethyl methacrylate). These replacements tend to last about 10 years before becoming loose and needing a revision.

It has been found that wear debris from all these materials causes an inflammatory response severe enough to lead to the destruction of the healthy bone that supports the actual implant. This not only leads to destabilization of the implant but also to the loss of bone stock to support a replacement implant. The ingestion of particles by macrophages causes the secretion of cytokines which stimulate bone resorting cells and which also decreases the activity of bone forming cells. This cellular cascade can occur at any bone interface accessible to the joint fluid being pumped around the implant during activity.

Non mechanical Requirements [6]

The most important non-mechanical requirement of an orthopedic biomaterial is "inertness." Ideally an implant material should not degrade at all. In reality, however, such a state is unachievable, and (figure 1) therefore a relative degree of implant degradation is considered acceptable. The degradation process, however, must not impair significantly the mechanical strength of the device nor allow the release locally or systemically of by-products that might evoke a deleterious biologic response.

The corrosion of metals in biologic fluids is an electrochemical reaction that results in the release of metal ions into the surrounding aqueous electrolyte. This dissolution reaction is coupled with a corresponding reduction reaction of constituents in the aqueous environment to maintain charge neutrality. The alloys currently used as orthopedic biomaterials are protected from accelerated corrosion rate by a passivating oxide layer that acts like an electrical resistor to retard the anodic dissolution of metal

Oseointegration and internal bone growth [13]

Oseointegration is fundamental in orthopedic. In 1989, Johansson et al compare the interface zone between bone and a Ti implant and observed, after 3 months, organize bone growth directly over the implant. Special treatment of the surface of the implant (anonidizing) helps the biocompatibility and bone recovery.

Corrosion

a. Due friction

When 2 articulated implants in contact with one another some wear cause by the friction can happen. Corrosion cause by friction is a big problem since it releases metallic ions that could cause a tissuelar reaction. Ti and Ti alloys implants form thin and passive oxide titanium coat that inhibits the implant from releasing those ions. The steel implants wear takes more time which increases the corrosion. Fraker et al compare the wear of the commonly used implants and revealed the following order (decreasing) of surface wear: Ti and Ti alloys, Cr-Co and the last the stainless steel 316.

b. Due to the use of different metals in surgery

The use of dissimilar metals in surgery is of great concern since there is a possibility that it could cause corrosion *in vivo*. In 1980, Ruedi et al studied different combinations of the implants in sheep and humans. They combine plates and bolts of steel and Ti. The results were that both combinations of Ti and steel were tolerated *in vivo* but those relations with Ti were better.

Hip endoprosthesis for *in vivo* measurement of joint force and temperature.

Friction between the prosthetic and acetabular cup increases the temperature in hip implants during activities like walking. A hip endoprosthesis was instrumented with sensors to measure the joint contact forces and the temperature distribution along the entire length of titanium implant. Sensors and two inductively powered telemetry units are placed inside the hip implant and hermetically sealed against body fluids. Each telemetry unit contains an integrated 8-channel telemetry chip and radio frequency transmitter. Force, temperature and power supply data are transmitted at different frequencies by two antennas to an external twin receiver. The inductive power supply is control by a personal computer. Force and temperature are monitored in real time and all data are stored on a video tape together with patient's images.

Influence of the stiffness of the bone defect implants on the conditions at interface – a finite element analysis with contact.

The study on the influence of the implant material stiffness on the stress distribution and micromotion at the interface of the bone defect implants. They hypothesized that a low-stiffness implant with a modulus closer to that of the tabecular bone would yield a more homogeneous stress distribution and less micromotion at the interface with the bony bed. To prove this hypothesis we generated a three-dimensional, non-linear, anisotropic finite element (FE) model. The FE model corresponds to a previously developed animal model in sheep. A prismatic implant filled a standardized defect in the load bearing area of the tabecular bone beneath the tibia plateau. Interface was described by face to face contact element, which allows press fits, friction, sliding ands gapping. They assume a physiological load condition and calculated contact pressures, shear stresses and shear movements and the interface for two implants of different stiffness (Ti, E = 110 GPa; Composite E = 2.2 GPa). The FE model showed the stress distribution was more homogeneous for the low-stiffness implant. The maximum pressure for the composite implant (2.1 MPa) was lower for Ti implants (5.6 MPa). Contrary to their hypothesis, they found micromotion for the composite (up to 6 μm) than for Ti implants (up to 4.5 μm). However, for both implants peak stresses and micromotion were in the range that predicts adequate conditions Oseointegration. This was confirmed by the histological results from the animal studies.

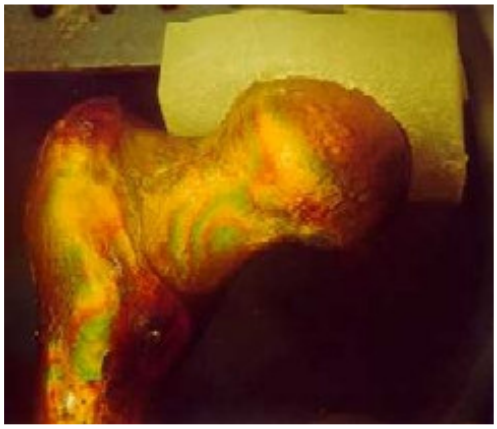

Figure 1: MRI of hip prosthesis [3]

THE IDEAL BIOMATERIAL FOR JOINT REPLACEMENT

Implanting metals into bone reduces the load on the bone surrounding the implant and, because new bone remodels itself depending on the loads applied to it, bone resorption occurs around the implant, which leads to loosening. An ideal material for more successful joint replacements needs similar stiffness, but higher strength compared with cortical bone. It also needs to be bioactive, encouraging bone growth onto the implant.

1. CHROMIUM COBALT [18]

There are basically two types of cobalt chromium alloys; one is the cobalt CoCrMo alloy (which is usually used to cast a product) and CoNiCrMo alloy, (which is usually wrought by hot forging). The castable CoCrMo alloy has been used for many decades in dentistry and recently, in making artificial joints. The wrought CoNiCrMo alloy is a relative newcomer now used for making the stems of prosthesis for heavily loaded joints such as the knee and hip.

Cobalt-based alloys are highly resistant to corrosion and especially to attack by chloride within crevice. As in all highly alloyed metals in the body environment, galvanic corrosion can occur, but to a lesser extent than in the iron-

based alloys. Cobalt-based alloys are quite resistant to fatigue and to cracking caused by corrosion, and they are not brittle, since they have a minimum of 8% elongation. However, as is true of other alloys, cobalt based alloys may fail because of fatigue fracture (but less often than stainless steel stems).

The abrasive wear properties of the wrought CoNiCrMo alloy are similar to the cast CoCrMo alloy. However, the formula is not recommended for the bearing surface of joint prosthesis because of its poor frictional properties with itself or other materials. The superior fatigue and ultimate tensile strength of the wrought CoNiCrMo alloy make it suitable for the applications, which require long service without fracture or stress fatigue. Such is the case for the stems of the hip joint prosthesis. Both the cast and wrought alloys have excellent corrosion resistance.

The modulus of elasticity for the CrCo alloys does not change with the changes in ultimate tensile strength. The values are higher for stainless steels. This may have some implications of different load transfer modes to the bone in artificial joint replacements, although the effect of the increased modulus on the fixation and longevity of the implants is not clear.

Composition Of Chrome – Cobalt Alloy

As far as nickel-chrome alloys are concerned chromium content of at least 20% is required for these alloys to be corrosion-resistant and thus biocompatible. Chromium protects the metal underneath through the formation of mechanically and chemically stables oxide layers. In the case of non-precious alloys, chromium corresponds to the paint and the chromium concentration corresponds to the quantity of paint. In DIN 13 912 from 1996 a minimum chromium concentration of 20% is required in the composition. Furthermore, it stipulates that through the formula "Cr content + 3.3 * (Mo content + 0.5 * W content)" a value greater than 30 should be attained. A carbon content of less than 0.02% ensures that no carbide precipitation that would lead to brittleness of the marginal areas of the seam occurs during laser welding. This would then result in an increased risk of fracture.

Highly pure base metals are used to make alloys. However, there are no 100% pure metals. For example, platinum ores contain palladium and sometimes also nickel impurities; cobalt is accompanied by nickel (and conversely), etc. Complete separation of the elements is never possible. The relevant standards stipulate a maximum nickel content of 0.1 %. Concentrations of greater than 0.1% have to be declared. Alloys with less than 0.1% of nickel can be designated as nickel-free. The claim that a cobalt-chrome alloy is absolutely nickel-free would be objectively false and can only be understood on the basis of marketing aspects.

If a restoration made of a cobalt-chrome alloy weighed 10 g the entire restoration would contain a maximum of 0.07 g (= 70 mg) of nickel. The latter, however, is not only found on the alloy surface, but is spread homogeneously throughout the restoration. If one assumes that nickel is detached from the alloy to the same extent as cobalt (which is probable although nickel is nobler than cobalt), the release of nickel will amount to approx. 0.00003 mg/cm² (0.03 µg /cm²) in the first week and constantly decline thereafter. If one compares this to the daily uptake in food, i.e. approx.

Mechanical properties of bone, Chrome Cobalt alloy and other materials used in joint replacement one shown in table 2

Table 2. Comparison chromium cobalt properties [6].

Material	Young's Modulus (GPa)	UTS (MPa)	K_{IC} ($MN.m^{-3/2}$)	G_{IC} ($J.m^{-2}$)
Cobalt-chromium alloy	230	430-1028	~100	~50000
Austenitic stainless steel	200	207-1160	~100	~50000
Ti-6%Al-4%V	105	780-1050	~80	~10000
Cortical Bone	7-25	50-150	2-12	600-5000
Cancerous bone	0.1-1.0			

0.19 – 0.90 mg, (190 – 900 µg), toxicological or allergic stress appears very improbable. In the case of alloys with veneering capacity, the available area is additionally reduced considerably due to the veneered ceramics.

Corrosion

Chromium is important for corrosion resistance. It can be tested with an immersion test. Test objects are suspended in a solution consisting of sodium chloride and lactic acid (0.1 mol /l each) and the dissolved alloy components are determined by means of a suitable analytical method (e.g. atomic absorption spectrometry, AAS).

The ion quantities can then be compared to other alloys. By comparing the corrosion rates of comparable and clinically proven alloys. This study method is therefore suitable as a pre-clinical screening test.

It has been shown that cobalt-chrome alloys display an ion release that is somewhat higher than that of gold alloys, but is still on the same order of magnitude. It is known that dental processing, such as casting, grinding or ceramic veneering, may influence the corrosion characteristics of replacement alloys. In the case of cobalt-chrome alloys, this influence is.

2. Contemporary (2nd Generation) Metal-On-Metal (MOM) Hip designs [17]

Starting in the 1980s, members of the clinical community in Europe became intrigued by observations of long-term successful survivorship among some first-generation MOM designs. Studies in England and Scandinavia, published in the 1980s and 1990s, suggested that the long-term survivorship of McKee-Farrar prostheses was comparable to the Charnley designs.

Second-generation MOM designs were clinically introduced during 1988 by Sulzer Orthopedics (currently Centerpulse Orthopedics, Winterthur, Switzerland). Sulzer's design was approved for marketing in the U.S. by the FDA in August, 1999. Between 1988 and 2000, it is estimated that 125,000 of these 2nd generation MOM components have been implanted worldwide.

Sulzer's 2nd generation MOM designs incorporated a CoCr articulating surface, but the acetabular component consisted of a modular shell, and a UHMWPE liner embedded with a CoCr insert. A cross-section of the contemporary "sandwich" type design, distributed under the trade name METASUL (Centerpulse Orthopedics, Winterthur, Switzerland).

UHMWPE continues to be used in 2nd generation MOM and, as we shall see, in certain COC designs as well, primarily as a means for achieving implant fixation. However, UHMWPE is also used in these alternative bearing designs for the objective of preserving intraoperative modularity. According to Rieker, "This embedded solution was chosen to assure complete compatibility with the shells already commercially available (same operative technique and instruments". Also, by incorporating UHMWPE into the bearing design, the same acetabular shell could be used for a wider range of liner designs, both conventional and alternative.

Other contemporary MOM designs, employing a modular taper-fit connection between the CoCr insert and the metal shell, have also been clinically introduced by companies such as Biomet (Warsaw, IN), Wright Medical (Arlington, TN), and Smith & Nephew (Memphis, TN). Unlike the METASUL design, these other taper-lock modular MOM designs do not incorporate an interpositional UHMWPE layer.

Potential Biological Risks Associated With MOM Joints

Despite the ultra-low wear rates afforded by 2nd generation MOM hip implants, concerns remain about the potential health risks associated with long-term metal ion exposure. The wear particles in MOM articulations range between 6 nm and 5 µm. Due to their smaller wear particle size, MOM hip implants have been estimated to release about a 100 times greater number of wear particles than conventional UHMWPE hip implants. In particular, the nanometer-sized metallic wear particles are more easily digested by cells, bound into proteins, and/or dissolved into body fluids than the larger UHMWPE wear particles.

The wear products of MOM joint articulation are transported systemically and are manifested in elevated chromium and cobalt levels in a patient's serum and urine, raising the potential risk for carcinogens. However, epidemiological studies of cancer risk in patients with MOM remain inconclusive, due to the relatively small patient populations evaluated, the Scandinavian basis of the studies, and the typically rare incidence of the disease. There have also been reports of metal hypersensitivity associated with the implantation of MOM prostheses, but the incidence of this complication is reported to be extremely rare. In summary, for the reasons outlined above, the orthopedics community continues to study the biological and carcinogenic implications of metallic wear debris, which are not fully understood at the present time. Due to ongoing clinical concern, researchers are continuing to monitor the long-term health effects associated with MOM alternate bearings.

Pre - Clinical Conclusion Drawn From The Studies

Pre-clinical tests were undertaken on the total joint system, which contains the Fossa-Eminence to demonstrate that the TMJ implants, Inc. prosthetic devices have adequate strength and durability for their intended use. The total joint system has an estimated fatigue limit of 130 lbs. The fatigue limit of the partial joint is unknown, but due to the limitations of testing with a natural condyle the testing of the total joint is sufficient since the natural condyle will do less damage to the fossa-eminence than the metal condyle of the total joint system.

a. Clinical

The subject device is a Class III preamendments device, which has been marketed since the 1960's. Temporomandibular Joint Disease (TMD) is thought to be a disease of multifactor origin with several recognized therapeutic alternatives, each with its own strong proponents and detractors.

b. Safety

A review of the types of adverse events reported within the Prospective Clinical Study TMJ-96-001 demonstrates an incidence rate of all events that is not unexpected of this patient population. FDA also considered a retrospective review of patient charts and X-ray graph by a clinical investigator in the prospective study. The study was intended to determine the effect of the partial joint implant (TMJ, Fossa-Eminence Prosthesis) on the remaining natural condyles, as evidenced by the clinical outcomes of patients implanted with the TMJ Implants Inc. Fossa-Eminence Prosthesis. This review indicates that the selected patients who have had the Fossa-Eminence prosthesis for greater than 3 years in this investigator's practice do not have an unusually high incidence of bony changes to the natural condyle. This study did not find evidence of degradation of the natural condyle as a result of the use of the metal fossa liner. The cohorts derived from the Registry data through 3 years duration demonstrated a reduction in perceived pain and improvement in interincisal opening. The data from the ongoing Prospective Clinical Study, TMJ-96-001,

demonstrated a similar trend in pain scores and an average decrease of 2 mm in interincisal opening from the preoperative opening data.

c. Summary Of Pre - Clinical Studies

Biocompatibility

Tests were conducted to assess the biocompatibility of the cobalt chrome used in these devices. The tests conducted included: in-vitro Cytotoxicity, Genotoxicity, Mutagenicity, Irritation/Intracutaneous reactivity, Systemic Toxicity, and Contact Sensitization. All test results demonstrated the biocompatibility of the implant material. Results of a literature search also support the suitability of this material for the chosen application. A one-year assessment of the effects of wears particulates of cobalt-chrome on the temporomandibular joint space of 12 New Zealand white rabbits was conducted. This study indicated that after an early mild to moderate reaction to the particles, the joint spaces showed no lasting inflammatory response. No foreign body reaction was seen, and no giant cells were noted at any time. All other organ pathologies were normal, as were the results of all blood studies.

Material Characterization

Material Characterization confirmed the chemical composition and material properties of the implant materials. Potentiodynamic testing conducted on the cobalt-chrome alloys confirmed the low corrosion potential of these materials. Dimethylglyoxime testing determined the amount of nickel released from the cobalt-chrome alloy was below the detectable limits of the test. Even with undetected nickel release, nickel sensitive patients should continue to be warned about the presence of nickel in this device.

Modeling

Both Finite Element Analyses and Kinematics modeling of the implant components were conducted to determine the effects of stress and movement on the performance of the devices. These Finite Element and Kinematics models confirmed that the stock devices were mechanically a worse case scenario as compared to the patient specific devices. In the Kinematics model, the calculated joint forces in patients with total joint implants were lower than in patients with partial joint implants. Normal subjects (without implants) were found to generate the highest forces.

Mechanical testing

Mechanical testing relating to the performance of the devices included Fatigue, Wear, Static Load, and Contact Stress Analysis. Because it is not possible to conduct these tests using natural bone against a metal fossa, these mechanical tests were performed with Metal-on-Metal total joint prosthesis configurations, using a metal-headed TMJ Condylar Prosthesis with a Fossa-Eminence Prosthesis. Fatigue tests were performed on 14 metals-on- metal combinations for 10 million cycles or to failure, but the tests were done at three different times under 2 protocols. Loads ranged from 130 lbs. to 336 lbs. Five (5) samples achieved run-out condition (10 million cycles). All 14 points were plotted along a load/number of cycles curve. A statistical justification was provided to justify pooling the different test groups together on one curve. The fatigue limit was estimated to be 130 lbs.

Wear

Wear testing was conducted for 2 million cycles at a rate of 2 Hz, in bovine serum at 37° C. A cyclic load pattern varying from 10 to 35 lb was applied to the components, while the condylar head applied a 30° arc of motion over the fossa component. Wear patterns in the in- vitro test samples showed single wear zones with parallel surface scratches oriented in a uni-axial direction of motion. Surface profiling, both before and after the wear testing, indicated the average wear of the metal-on-metal TMJ implants was 0.197 mm^3 per million cycles. Mass measurements showed an increase in mass after testing so the mass measurements were set aside as being erroneous. The wear test results were compared with the results of an analysis of explanted devices. The in- vivo results showed evidence of randomly oriented scratches, indicating multi-axial motion. Also, the contact surfaces of the retrieved explanted devices were significantly smaller and were characterized as smoother as and more polished than the in-vitro wear test samples. The in- vivo results are probably a better indicator of wear patterns Static Load Static load tests indicated that the maximum loads the devices will withstand are greater than those seen *in- vivo*. The metal-on- metal devices were subjected to forces of at least 448 lb before failure. Failure was defined as implant fracture, extensive bending, or component dislodgment from the mounting.

Contact stress analysis

Contact area was measured and contact stress was analyzed for the metal-on- metal components. Contact areas ranged from 1.62 to 4.84 mm^2 for the metal-on- metal configuration. As expected, for increased loads, the contact areas also increased. The average contact pressure, assuming a uniform pressure distribution, ranged from 2592 psi to 7011 psi for the metal-on- metal configuration. All stress measurements were below the yield strength for ASTM F 75-98 cast Cobalt-Chrome alloy (65,000 psi).

Finished product analysis

In addition, Casting and Finishing, and Mating Tolerance analyses were performed. The Casting and Finishing report characterized the effect of the manufacturing process on the microstructure of the cast CoCr components. Random scratches and surface features were noted, believed due to the hand-polished nature of these devices. The etched metal surfaces revealed a microstructure. This microstructure is common for metallic materials. It is unclear what influence, if any, the microstructure has on the failure mode. The mating tolerance analysis was conducted to determine the contact interference between the fossa and condylar TMJ components. The results indicate that the vertical distance

between the fossa surface and the condylar head increases with increasing distance from the point of contact. The total angle of freedom in the mating tolerance is 70 degrees. Since this system is designed for point contact its mating tolerance is very large compared to other total joint systems.

Sterilization

Sterilization validation and bioburden studies confirm that the materials can withstand the sterilization process and sterility assurance levels of 10^-6 are achieved. Sterilization validation was conducted per AAMI/ISO 11137, Method I. Quarterly bioburden studies and dose audits were conducted to confirm the continuing validity of the sterilization process. The packaging materials used for the implantable products are PETG medical grade blister stock and DuPont Tyvek medical grade stock.

News: LEVELS OF METALS ARE HIGHER IN BLOOD OF PATIENTS WITH SURFACE HIP REPLACEMENT [6]

All metal total joints corrode once placed in the body, due to the corrosive action of body liquids. The composition of the metal alloy is one factor that determines the speed of the corrosion, the total area and the finish of the joint surfaces is another such factor. The products of corrosion, metal ions, enter into the blood of the patients with total joint implants and raise the levels of the metals, mainly chrome and cobalt, there. There is a concern that the elevated levels of metal ions may influence some body functions, e.g. immune defense, in a negative way. The metallic shells of the modern surface replacement devices have larger diameter (mean 48 mm) and thus larger surface area than modern metal on metal (MON) total hip joints (head diameter usually 28 mm). The common sense would tell that the larger the area accessible to corrosion, the more corrosion products would there be. But things are not so simple in the world of artificial joints. Some scientists proposed a contrary theory. This convolute theory said that lubrication in surface hip replacement devices would be better than in the MOM total hip joints, just because the surface shells have greater diameter. Proponents of this theory predicted that patients with surface hip replacement would have lower blood levels of chrome and cobalt metal ions than patients with MOM total hips. Curiously enough, although surface hip replacements have been carried out on more than 80 000 patients as yet, the surgeons did not care to test this theory.

A group of American and British surgeons published recently a study comparing the blood levels of cobalt and chrome ions in two patient groups 16 months after the surgery, [Clarke 2003]. Patients in both groups have had similar weight and physical activity levels, as well as similar length of follow up. Thus, patients in both groups wore their hip replacement devices similarly and for similar periods. The one patient group consisting of 22 patients had operated on a surface hip replacement device (16 patients Birmingham Hip, six patients Cormet 2000 device). The other group, also 22 patients, had a MOM total hip device (Ultima) operated on. The report found that patients in both groups have had much higher blood levels of chrome and cobalt ions than the general population. The somewhat surprising result, however, showed that patients with hip resurfacing have had 10.6 times higher chromium levels and 7.6 times higher cobalt levels than normal population. These levels were significantly higher then the levels in the blood of patients with MOM total hips.

The MOM total hip replacement patients have had "only" 3.8 times higher blood levels of chromium and "only" 4.4 times higher blood levels of cobalt than general population.

These results are contrary to the convolute theory that surface replacement hip devices would produce low quantities of wear and would not raise the blood levels of metal ions.

An interesting finding in this report: Cormet surface replacement device released 1, 5 times more metal ions in the blood of patients than did Birmingham Hip. Both components have very different surface finish that might cause this difference.

3. Stainless steel

Stainless steel is the generic name for a number of different steels used primarily because of their corrosion resistance. All stainless steels share a minimum percentage of 10.5% chromium. Chromium is always the deciding factor, although other elements, particularly nickel and molybdenum, are added to improve corrosion resistance. The success of the material is based on the fact that it has one unique advantage. The chromium in the stainless steel has a great affinity for oxygen, and will form a film of chromium oxide on the surface of the steel at a molecular level. The film itself is extremely thin, about 130 Angstroms and one Angstrom is one millionth of a centimeter. This layer is described as passive (does not react or influence other materials), tenacious (clings to the layer of steel and is not transferred elsewhere) and self-renewing (if damaged, more chromium from the steel will be exposed to the air and form more chromium oxide). Figure 2 shows relatives of corrosion by percentage of chromium alloy.

Benefits of stainless steel [1]

a. Corrosion resistance: Lower alloyed grades resist corrosion in atmospheric and pure water environments, while high-alloyed grades can resist corrosion in most acids, alkaline solutions, and chlorine bearing environments, properties which are utilized in process plants.

b. Fire and heat resistance: Special high chromium and nickel-alloyed grades resist scaling and retain strength at high temperatures.

c. Hygiene: The easy cleaning ability of stainless makes it the first choice for strict hygiene conditions, such as hospitals, kitchens, abattoirs and other food processing plants

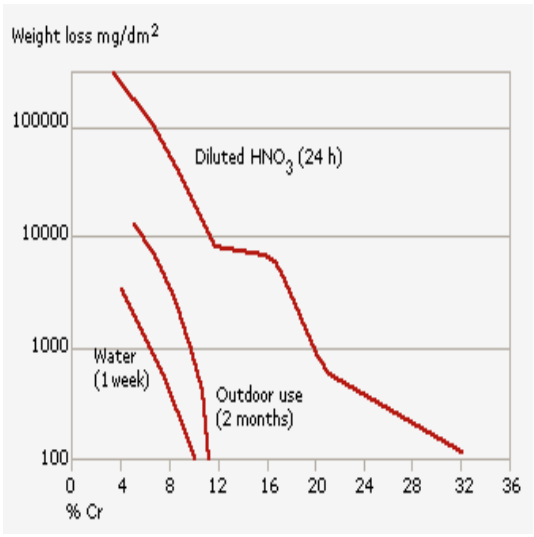

Figure 2. Reduction of corrosion by percentage of Chromium in alloy [1].

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d. Aesthetic appearance: The bright, easily maintained surface of stainless steel provides a modern and attractive appearance.

e. **Strength-to-weight advantage**: The work-hardening property of austenitic grades, that results in a significant strengthening of the material from cold-working alone, and the high strength duplex grades, allow reduced material thickness over conventional grades, therefore cost savings.

f. Ease of fabrication: Modern steel-making techniques mean that stainless can be cut, welded, formed, machined, and fabricated as readily as traditional steels.

g. Impact resistance: The austenitic microstructure of the 300 series provides high toughness, from elevated temperatures to far below freezing, making these steels particularly suited to cryogenic applications.

h. Long term value: When the total life cycle costs are considered, stainless is often the least expensive material option.

There are more than 60 grades of stainless steel. However, the entire group can be divided into five classes. Each is identified by the alloying elements which affect their microstructure and for which each is named. Stainless steel 316L is the type mainly used for biomedical implications (table 3 and figure3) such as joint replacements (figure3). It combines good availability in all forms and size ranges with great strength and corrosion resistance. This class of stainless steel falls under the mayor classification of austenite stainless steel.

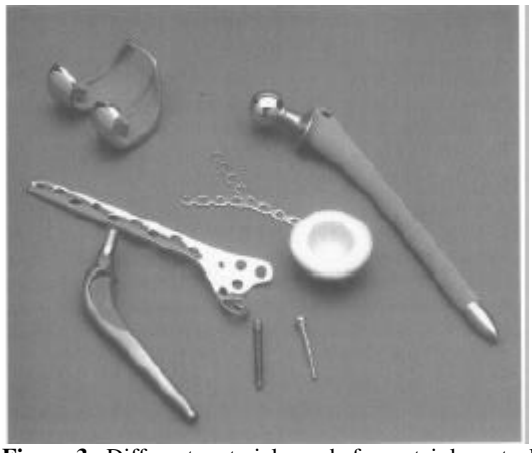

Figure 3. Different materials made from stainless steel. Used in orthopedic implants [8].

Table 3. The chemical composition of stainless steel 316L [7].

Carbon	0.03 max
Chromium	16 – 18
Iron	Balance
Manganese	2 max
Molybdenum	2 – 3
Nickel	10 - 14
Phosphorus	0.045 max
Silicon	1 max
Sulphur	0.03 max

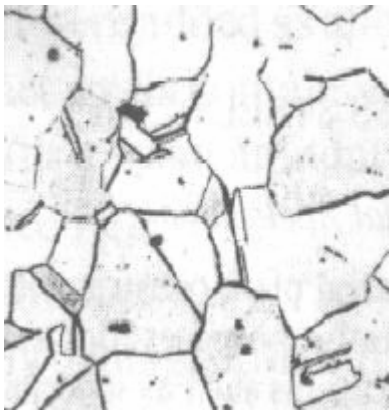

Figure 4. The microstructure 316L [2].

In terms of mechanical properties, stainless steels can be roughly divided into four groups with similar properties within each group: martensitic and ferritic-martensitic, ferritic, ferritic-austenitic, austenitic. The difference in the mechanical properties of different stainless steels is perhaps seen most clearly in the stress-strain curves shown in figure 5 and 6.

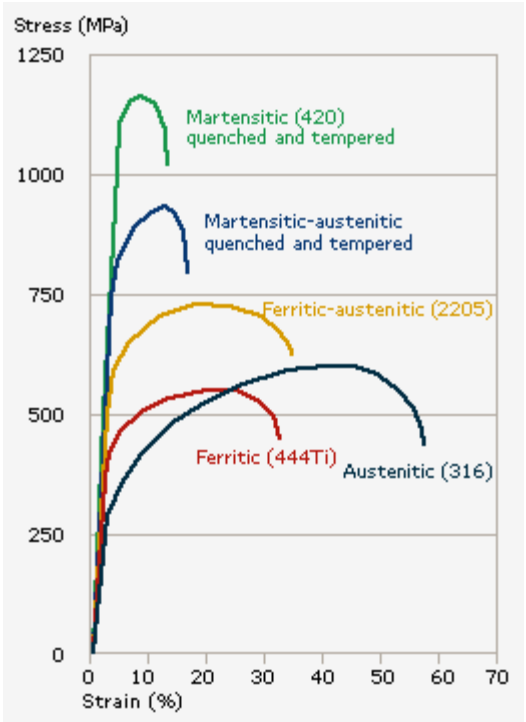

Figure 5. Stress strain diagram for stainless steel [1].

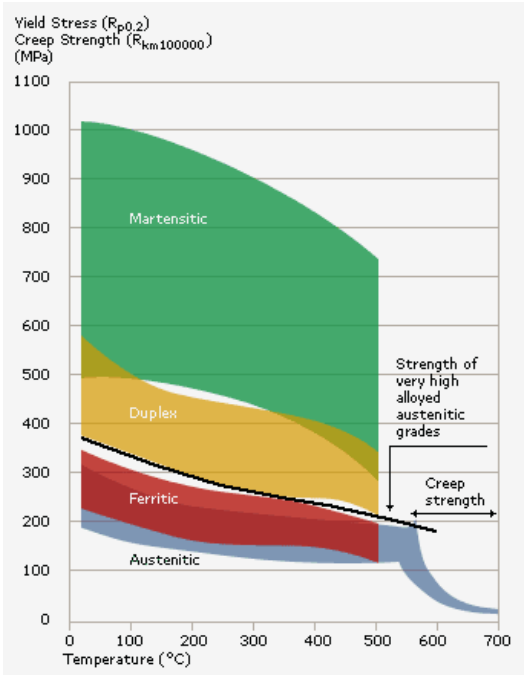

Figure 6. Yield Stress versus temperature [1].

Biocompatibility [3]

The addition of nickel causes the austenite structure to be maintained at room temperature. Thus, this steel is known as an austenite stainless steel. However due to potential long term release of Ni2+, Cr3+ and Cr6+ into the body stainless steel are restricted to temporary devices in orthopedics. The use of these implants can be extended to ten years or a few more years before the effects can be detected

Development [3]

Easy and safe manipulation of invasive stainless-steel in medical devices is possible with an improved lubricious coating. Developed by STS Biopolymers Inc. (Henrietta, NY), Slip-Coat is thin and flexible and adheres to both wet and dry metal substrates. It is also permanent and nonthrombogenic and has a smooth, nonslip feel when dry. Immediately upon contact with bodily fluids or water, the coating becomes ultraslippery, reducing friction and increasing a physician's ability to control the material during insertion.

Through the use of the Slip-Coat formula, biocompatibility can be achieved at a low cost without changing the materials from which the devices are made. According to STS, earlier formulations have been used successfully on various polymeric, titanium, the coatings can be formulated for short-, intermediate, or long-term effects. Coating services include plasma pre-treating, coating application, and development of custom coating technologies.

4. Nickel Titanium

From the point of view of practical applications, NiTi can have three different forms: martensite, stress-induced martensite (superelastic), and austenite. When the material is in its martensite form, it is soft and ductile and can be easily deformed (some-what like soft pewter). Superelastic NiTi is highly elastic (rubber-like), while austenitic NiTi is quite strong and hard (similar to titanium). The NiTi material has all these properties, their specific expression depending on the temperature in which it is used.

Superelasticity

Superelasticity refers to the ability of NiTi to return to its original shape upon unloading after a substantial deformation. This is based on stress-induced martensite formation.

Mechanical properties of NiTi

For orthopedic biomaterial applications, the two properties of major importance are strength (mechanical) and reactivity (chemical). Generally, there are two basic mechanical demands for the material and design of the implant. Service stresses must be safely below the yield strength of the material, and in cyclic loads the service stress must be kept below the fatigue limit. The mechanical properties of NiTi depend on its phase state at a certain temperature. Fully austenitic NiTi material generally has suitable properties for surgical implantation.

NiTi has an ability to be highly damping and Vibration-attenuating. From the orthopedic point of view, this property could be useful in, for example, dampening the peak stress

between the bone and the articular prosthesis. The low elastic modulus of NiTi (which is much closer to the bone elastic modulus than that of any other implant metal) might provide benefits in specific applications. NiTi has unique high fatigue and ductile properties, which are also related to its martensitic transformation. These properties are usually favorable in orthopedic implants. Also, very high wear resistance has been reported compared to the CoCrMo alloy. NiTi is a non-magnetic alloy. MRI imaging is thus possible. Electrical resistance and acoustic damping also change when the temperature changes. Figure 7 shows stress strain behavior of our implant material.

Muscle response to NiTi

The first published study on the reaction of tissue to 55-NiTi was reported by Cutright *(*1973). In that study, NiTi wire sutures were placed subcutaneously in forty-five rats, which were followed for 9 weeks. The tissue reaction was minimal at all checkup points. The reparative process was initiated within 1 to 2 weeks and resulted in a dense, relative avascular fibrous connective tissue capsule by 5 to 6 weeks, with little change beyond that. When compared to the tissue reaction to stainless steel seen in earlier experiments, NiTi was indistinguishable from stainless steel within similar time periods. It was concluded that 55-NiTi compares favorably with stainless steel and could be used in deep tissues. The lack of a simultaneous control group, the short implantation time (nine weeks) and the non-standardized (subcutis or muscle) implantation site may have caused some uncertainty to the results.

The first attempt at a profound biocompatibility evaluation of NiTi was made by Castleman (1976). The methods of that study were versatile and the approach was well-advised. This study has often been used as a reference study when discussing the biocompatibility of NiTi. There were, however, some weaknesses in the study, which were also pointed out by the authors. First, the total number of test animals was quite small. There were three dogs in the NiTi implant group and one Co-Cr implant and one "sham" as a control at each killing point. The complete NiTi data consisted of 12 beagles examined after exposures of 3, 6, 12, and 17 months. The maximum follow-up time can be considered sufficient for the conclusions; at least as far as implant use in fracture fixation is concerned. The NiTi alloy used in the experiment was laboratory-prepared and had no commercial counterpart. The analysis of scar capsule membrane thickness seems to be based on an invalid hypothesis. Statistical tests were used, expecting no significant differences between the mean thickness values of the scar capsules associated with NiTi and those associated with the Co-Cr alloy.

However, the authors admitted earlier that "considerable variation was evident between the capsules of different specimens of same material and between the capsules of different metals and also depending on implantation time". Thus, it seems that the statistical data in this case cannot be used as a basis of relevant conclusions. The muscle tissue in dogs exposed to NiTi implants for 17 months showed some variability. The areas adjacent to or overlying the screw head showed a looser arrangement of striated muscle fiber bundles with larger areas of areolar connective tissue between the muscle fibers. Overall, the gross clinical, radiological, and morphological observations of tissue at the implantation sites at autopsy revealed no signs of adverse tissue reactions resulting from the implants.

The study warranted the conclusion that NiTi had no clearly toxic effects *in vivo*. The authors concluded that no significant differences were noted between the samples taken from the controls and those taken from the dogs exposed to the implants, and that NiTi alloy is sufficiently compatible with dog tissue to warrant further investigation of its potential as a biomaterial. It is astonishing that no further comprehensive studies on the tissue reaction to NiTi have been published so far. Recently, one comparative study was published, in which the corrosion resistance and tissue biocompatibility of NiTi and Ti50Ni50-xCux (x = 1, 2, 4, 6, 8) alloy were investigated. Electrochemical and quantitative histomorphometric methods were used. The connective tissue layer covering the Ti50Ni42Cu8 plates was statistically significantly thicker than that of Ti50Ni50, Ti50Ni48Cu2, or Ti50Ni44Cu6 plates after one month. The numbers of connective tissue cells, polynucleated cells, macrophages and round cells were higher for Ti50Ni42Cu8 plates than those of the other three types of plates, but no statistically significant differences were detected. There were no significant differences in the tissue reaction parameters after two and three months between the four alloys. After three months' implantation, no corrosion was observed on the plate surfaces. It was concluded that Ti50Ni50-xCux (x = 2, 6, 8) shape memory alloys also have good biocompatibility.

Bone response to NiTi

NiTi is one of the most innovative concepts introduced in the field of metallic biomaterials in the recent years, but its biocompatibility remains controversial, especially in bone. The first attempts to study NiTi as a bone implant were made also by Castleman (1976). A prototype of NiTi bone plates was made and implanted into the femurs of 12 beagles. Commercial cobalt-chromium (Co-Cr) alloy bone plates served as reference controls (1 per time period). The plates were removed from the animals and examined after exposure for 3, 6, 12, and 17 months. There was no evidence of either localized or general corrosion on the surfaces of the bone plates and screws. No signs of adverse tissue reactions resulting from the NiTi implants were seen. Decalcified histological samples showed no evidence of bone resorption in specimens adjacent to the plate. Nor were any significant differences noted in the sham-operated controls. The data used in neutron activation analyses suggested that there is no nickel contamination in bone due to the implants.

However, the authors suggested that there does appear to be some chromium contamination from the Co-Cr alloy implants in the adjacent bone. The results of neutron activation analysis implied some uncertainty associating with the contamination of samples during the cuttingprocedure. In the NiTi group, some high nickel

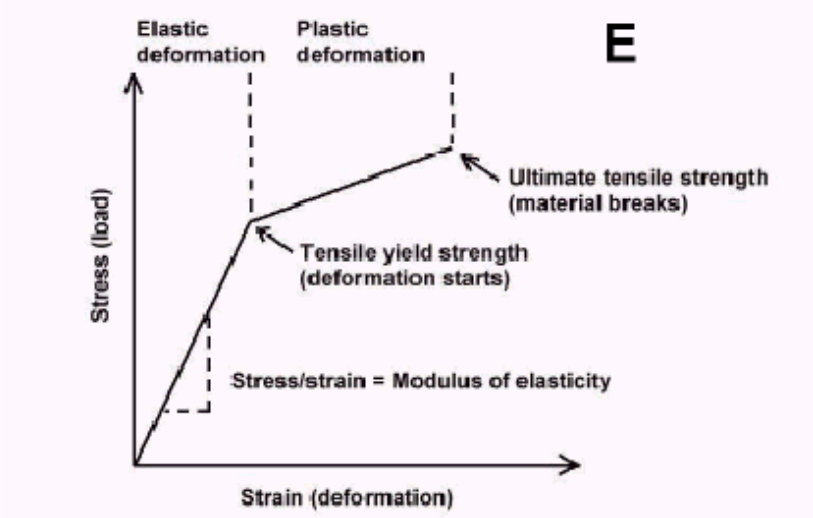

Figure 7. Schematic representation of the stress-strain behavior of ordinary implant metal [21].

concentrations were also observed, but these were attributed to contamination. They made their own internal fixing device of NiTi and applied it to fractured femoral shafts of dogs. Comparison was made with a 316L stainless steel plate-screw system. Osteotomy on both sides of the femoral diaphyses was performed in 15 dogs. One side was plated with a bone plate and the other with a NiTi device. Five animals in each group were killed at 4, 8, 12 weeks after operation. Radiographic examination, light microscopy and transmission electron microscopy methods were used. The fracture healing and the course of callus remodeling were similar in these two groups, but the cortical bone remodeling underneath the fixator near the osteotomized area was significantly different.

The authors suggested that since the elastic modulus of the NiTi shape memory alloy is lower, the stress-shielding effect in the bone underneath the NiTi device is less. The axial compression stress of the fracture line is kept greater and the contact of that NiTi device with the bone was not so close. This might be beneficial for the recovery of blood supply and bone remodeling. The material has a controllable open structure that provides a possibility for the ingrowths of bony tissue into the body of the implant, resulting in desirable firm fixation to bone. Eight uncoated porous NiTi implants (average pore size 300 m; 50% average void volume) were placed to either side of the frontal bone of rabbits. In the other frontal location, a coralline hydroxyapatite implant of was fitted as a control. The animals were killed at post-surgical intervals of 2 (n=2), 6 (n=2), and 12 (n=3) weeks. The implants were evaluated for gross biocompatibility, bony contact, and in growth.

Overlaying soft tissues and connective tissues readily adhered to the implants even after 2 weeks. No adjacent macrophage cells were seen for either implant type. Both materials made bone contact with the surrounding cranial hard tissue, and the percentage of ingrowths increased with the surgical recovery time. The bone histology and microhardness parameters showed that the bone in contact with the implants was similar in quality to the surrounding cranial bone. Porous NiTi implants appear to allow for The

NiTi implants demonstrated a trend for less total apposition and more total ingrowths after 6 and 12 weeks of implantation. The authors concluded that porous NiTi appears to be suitable for craniofacial applications. The small number of animals used in this study can be criticized. It allows no quantitative conclusions. The implantation time was also quite short, but the bone response was still good.

Further studies are needed for the conclusions on final biocompatibility and the value of porous NiTi in craniofacial or other bone-related applications. A new type of ear stapes prosthesis made of nickel-titanium shape memory alloy wire was developed by Kasano & Morimitsu (1997). Its biocompatibility was examined in 24 ears of 12 cats. The prosthesis was implanted at the long crus of the incus and the incus was examined 27-355 days after operation. In 23 ears, the prosthesis was found macroscopically well implanted at the intended position. In one ear, the prosthesis was found to be dislocated, and in another, it was slightly loosened. The incudes were removed, and five specimens were prepared for scanning electron microscopy, while the other specimens were observed under a light microscope. Histological studies revealed severe bone resorption of the long crus in the dislocated case and moderate bone resorption in the slightly loosened case. These instances of bone resorption were found to have been caused by inadvertent removal of the mucosal membrane during the implant operations. Slight bone resorption was seen at the contact area of the prosthesis in seven ears under a light microscope and in one ear under a scanning electron microscope. This bone resorption was induced by the mechanical pressure of the prosthesis and was not progressive due to the diminishing pressure. With the exception of pressure-induced bone erosions, there was no progressive bone resorption which was prosthesis-induced.

The authors concluded that the biocompatibility of the nickel-titanium alloy stapes prosthesis with the long crus of the incus was hereby proven. The above studies suggested that NiTi is quite well accepted into bone. However, there are two conflicting studies, in which NiTi has been found to have inferior properties compared to the other implant materials.

Berger-Gorbet (1996) evaluated the biocompatibility of NiTi screws using immunohistochemical methods. The distribution of bone proteins during the bone remodeling process around a NiTi implant was observed. The control materials were screws made of Vitallium, c.p. titanium, Duplex austeniticferritic stainless steel (SAF), and stainless steel 316L. The test materials were implanted in rabbit tibias for 3 (n=2), 6 (n=2), and 12 (n=2) weeks. The embedding was done in hard resin, and undecalcified sections with bone-anchored implants were used for the immunohistochemical procedure. The authors concluded that the immunostaining method developed by them seemed to be a reliable technique for staining proteins in undecalcified sections. The biocompatibility results of the NiTi screws compared with the other screws showed a slower osteogenesis process characterized by no close contacts between the implant and bone, disorganized migration of osteoblasts around the implant, and a lower activity of osteonectin synthesis.

The study included some uncertainties, however. The number of samples was too small to allow statistically significant histomorphometry. No characterization of the surface was done. Careful saline cooling was used while drilling the hole in the bone, but the material of the drill was not specified. Authors said that "on all NiTi sections black granules could be observed along the screws". Microparticles from the drill are possible and may affect the results. The authors used mouse anti-osteonectin and goat anti-collagen type III antibodies. There might be some problems in cross-reaction if rabbits are used as test animals. The assessment of osteonectin was good because it is an important protein in the bone remodeling process. The role of CIII was considered to be less useful even by the authors.

The bone reaction to NiTi implants inserted transcortically and extending into the medullary canal of rat tibiae was quantitatively assessed using an image-processing system by Takeshita *(*1997). The control materials were composed of pure titanium, anodic oxidized titanium (AO-Ti), Ti-6Al-4V alloy and pure nickel. Three rats were killed 7, 14, 28, 84 and 168 days after operation (n=3). Essentially the same histological findings were made for NiTi, Ti, Ti-6Al-4V and AO-Ti implants. While NiTi and the other materials were progressively encapsulated with bone tissues, Ni was encapsulated with connective tissues and showed no bone contact through the 168-day experimental period. Histometric analysis revealed no significant differences between the tissue reactions to Ti, AO-Ti and Ti-6Al-4V, but NiTi implants showed a significantly lower percentage of bone contact and bone contact area than any of the other titanium or titanium alloy materials. In terms of bone contact thickness, however, there were no significant differences between NiTi and the other three materials (Ti, AO-Ti and Ti-6Al-4V).

Bone response to NiTi in Humans

NiTi has also be used as a bone implant material in humans, but worldwide medical applications have been hindered for a long time because of the lack of knowledge of the biocompatibility of NiTi. A bone anchor (Mitec G2®) which includes a small piece of super-elastic NiTi wire has been lately approved by FDA. In the USA, FDA limits the marketing of long-term implanted NiTi devices because the biocompatibility has not been proved. There are reports that NiTi material has been successfully used in bone-related human applications in Russia and China in a large number of patients. Very few well-monitored studies have been published in peer-reviewed journals. Also, no controlled or randomized studies have been published so far. It was tested the clinical application of Ti50Ni48.7Co1.3 alloy shape-memory clamps for the fixation of mandibular fractures using transoral access. The clamps were used to treat all types of fractures occurring between the mandibular angles. The clamps were removed after a period of at least 6 weeks, and tissue samples were taken for microscopic examination. Seventy-seven patients with mandibular fractures were treated using the clamps. Altogether 93 fractures were treated, involving 124 clamps. There were 56 cases of single fracture and 21 cases of multiple fractures. In 72 patients the treatment progressed satisfactorily, while in five cases infections occurred. Tissue samples for histologic examination were taken from 58 patients after removal of the clamps.

There were no pathologic or atypical tissue reactions or signs of disturbed cell maturation. The authors concluded that the application of shape memory clamps for the surgical treatment of mandibular fractures facilitates treatment while ensuring stable fixation of the bone fragments. There are also two other studies in which NiTi implants were used in the surgical correction of maxillofacial fractures. The results showed that the surgical treatment of these fractures by NiTi devices was simple, ensured a good stability of the fracture surfaces, reduced the time needed for operative procedures and rehabilitation, and allowed rapid bone healing.

The results of ventral intercorporeal lumbar spondylodesis with a NiTi implant were reported by von Salis-Soglio (1989). The operative technique was characterized by primary stabilization of the moving segment by means of a memory implant that was inserted intercorporeally following ventral removal of the intervertebral disc. The results included 51 cases of bony fusion within an average postoperative period of 9 months, one case of pseudoarthrosis and 11 cases of delayed bony fusion. The author concluded that, in view of the easier operative technique, the earlier advantages over the transplantation of bone chips only. The use of a NiTi staple to lock a tri-cortical iliac bone graft in cervical anterior fusion was used by some people. Fifty patients with various clinical diagnoses were treated. Good and very good clinical results were reported in 80% of the cases and the average bone

fusion rate was fast (7 weeks). Other studies reported that on 84 patients with fractures, tumors or intervertebral disc disease of the cervical and lumbal spine were treated with anterior fusion and porous NiTi implant grafts.

They concluded that porous NiTi implants can be successfully used, probably because their mechanical properties are similar to those of the vertebral bodies, and the material itself shows a high degree of biocompatibility.
Thirty-six metatarsal osteotomies using internal fixation of a shape memory metal compression staple for hallux valgus were performed in a study by Tang. The recovery period preceding return to light work averaged 19 days and normal work and normal walking were resumed an average of 41 days postoperatively. Twenty patients (35 feet) experienced complete pain relief. Only in one foot was the pain transferred under the second metatarsal head. Radiographic analysis of the feet showed that all the osteotomies united, and the average angle of hallux valgus and the intermetatarsal angle improved. The distal fragment during the healing of the osteotomy was stable. No external fixation by plaster splintage was needed. According to the authors, the benefits of this internal fixator were that the period of bone healing was shortened and the patients were allowed to bear weight earlier than usual.

Three aspects were studied: bone union, wound healing problems and histology. Non-union occurred in 4 patients treated with only one fixative. Two clamps implanted in non-parallel planes seem to be advisable to exclude the need for longer immobilization. Neither toxic manifestation nor episodes of allergic reaction occurred. No suppuration appeared when a heat stimulus was applied by using a contact resistance heater. Histological evaluation of the tissue covering the implants in 22 patients did not reveal any adverse reactions. The study suggests that by using NiTi clamps in an appropriate way, satisfactory outcomes could be achieved with respect to both biofunctionality and biocompatibility. In conclusion, on the basis of a few studies, it seems the NiTi material in itself has no deleterious effects in human use. The clinic relevance of the devices will not be discussed here.

Current status of NiTi in medicine

Since the first attempts to introduce this material into medicaluse in the early 1970s certain progress has taken place (Castleman. 1976). NiTi superelastic wires were first introduced into orthodontic use. Nowadays, there are some commercial products available worldwide. At the present, the breakthrough of self-expand-able stents in gastroenterology, radiology and cardiovascular applications seems convincing. By using stents, major surgical operations can be avoided. Sometimes a stent may be the only choice in critically ill patients. Stents have shown NiTi with certain criteria to be a material with huge possibilities.

5. Titanium and titanium alloys [15]

Titanium had been used for more than thirty years for implants, surgical devices and pacemaker cases. It is the most bio-compatible of all metals because of its resistance and tolerance to body fluids. The high strength, low weight, outstanding corrosion resistance possessed by Ti and Ti alloys has led to this diversified range of successful applications. Medical grade Ti alloys have a significantly higher strength to weight ratio than competing stainless steel. Requirements for joint replacement continue to grow as people live longer or damage themselves more in by hard sports play or jogging, or are seriously injured in road traffic and other accidents.

Performance

The natural selection of titanium is determined by a combination of the more favorable characteristics including immunity to corrosion, bio-compatibility, strength, low modulus and density and the capacity for joining with the bone and other tissue – Osseo integration. The mechanical and physical properties of Ti alloys combine to provide implants which are highly damage tolerant. The human anatomy naturally limits the shape and volume of the implants. The lower modulus of elasticity of Ti alloys compared to steel is a positive factor in reducing bone resorption. Two further parameters define the usefulness of the implantable alloy, the notch sensitivity, the ratio of tensile strength vs. un-notched condition, and the resistance to crack propagation, or fracture toughness. Ti scores well in both cases. Typical NS/TS ratios for titanium and its alloys are 1.4-1.7 (1.1 is a minimum for an acceptable implant material). Fracture toughness of all high strength implantable alloys is above 50 MPam-1/2 with critical crack lengths well above the minimum for detection by the standard methods of non-destructive testing. Forms and material specifications of Ti are detailed in a number of international and domestic specifications (ASTM and BS7252/ ISQ 5832) as shown in table 4.

Types of titanium alloys [11]

There are three structural types of titanium alloys as described below:

a. Alpha (α)

Alloys are non-heat treatable and generally very weldable. They have low to medium strength, good notch toughness, reasonably good ductility and possess excellent mechanical properties at cryogenic temperatures. The more highly alloyed alpha alloys and near-alpha alloys offer optimum high temperature creep strength and oxidation resistance as well.

b. Alpha-Beta (α-β)

Alloys are heat treatable and most are weldable. Their strength levels are medium to high. Their hot- forming qualities are good, but the high temperature creep strength is not as good as in most alpha alloys.

c. Beta (β)

Beta or near-beta alloys are readily heat treatable, generally weldable, and capable of high strengths and good creep resistance to intermediate temperatures.

Excellent formability can be expected of the beta alloys in the solution treated condition. Beta-type alloys have good combinations of properties in sheet, heavy sections, fasteners and spring applications.

Table 4. Titanium medical specifications [12]

ASTM Standard	BS/ISQ	Alloy(s) and designation(s)
F67	Part 2	Unalloyed Ti – CP Grades 1-4 (ASTM F1341 specifies wire)
F136	Part 3	Ti-6Al-4V ELI wrought (ASTM F620 specifies ELI forgings)
F1472	Part 3	Ti-6Al-4V standard grade (SG) wrought (F1108 specifies SG castings)
F1295	Part 11	Ti-6Al-7Nb wrought
-	Part 10	Ti-5Al-2.5Fe wrought
F1580	-	CP and Ti6Al4V SG powders for coating implants
F1713	-	Ti-13Nb-13Zr wrought
F1813	-	Ti-12Mo-6Zr-2Fe wrought

Ti and Ti alloys in organic media

Titanium alloys generally exhibit excellent resistance to organic media. Mere traces of moisture and / or air normally present in organic process streams assure the development of a stable protective oxide film of titanium. Titanium is highly resistant to hydrocarbons, chloro-hydrocarbons, fluorocarbons, ketones, aldehydes, ethers, esters, amines, alcohols and most organic acids. Titanium equipment has traditionally been used for production of terephthalic acid, adipic acid and acetaldehyde. Acetic acid, tartaric acid, stearic acid, lactic acid, tannic acids and many other organic acids represent fairly benign environments for titanium. However, proper titanium alloy selection is necessary for the stronger organic acids such as oxalic acid, formic acid, sulphamic acid and trichloroacetic acids. Performance in these acids depends on acid concentration, temperature, degree of aeration and possible inhibitors present. The Grade 7 and Grade 12 titanium alloys are often preferred materials in these more aggressive acids.

Properties of titanium and Ti alloys

The pure metal has a relatively low density (4.5 gm/cm^3), a high melting point [1668˚C (3035˚F)], and an elastic modulus of 107 GPa (15.5 x 10^6 psi). Ti alloys are extremely strong; with tensile strengths as high as 1400 MPa (200,000 psi) Furthermore, the alloys are highly ductile and easily forged machined. Typical composition of Ti6Al4V is shown bellowing table 5.

Table 5. Composition of Ti6Al4V alloy [5]

Element	Content
C	<0.08%
Fe	<0.25%
N_2	<0.05%
O_2	<0.2%
Al	5.5-6.76%
V	3.5-4.5%
H_2(sheet)	<0.015%
H_2(bar)	<0.0125%
H_2(billet)	<0.01%
Ti	Balance

Biocompatibility of Ti-6Al-4V [13]

Biocompatibility not only concerns to toxicity, but to all the adverse effects of a material in an organic media. There are innumerable ways to test biocompatibility. Ti-6Al-4V had been proved almost 100 % biocompatible. In 1988, Hoffman compares two knee implants: one Ti and one Cr-Co, and observed that months after the surgery the Ti implant was surrounded by healthy bone recovery. In contrast the Cr-Co implant didn't help in the interphase as well as the Ti implant.

At first the Ti-6Al-4V implant had some problems because Vanadium was classified as a toxic element. But it had been proven that this element in the really low quantity (4 % of the total composition) is a biocompatible alloy. Ti-6Al-4V is an excellent alternative for joint implants, either for partial or total replacement. Some observations had revealed bone discoloration close to the implant, but it ha d not been proven that 'metallosis' is toxic. The study concluded that both combinations could be safely. In another study, Rosenberg et al compare the tissue's response to Ti vs. Stainless steel 316 implants. They response to Ti versus stainless steel 316 implants. They noticed that macroscopically 25.6 % of the tissue around the Ti implant have been pigmented and the stainless steel wasn't. Microscopically, 71.8 % of the tissue around the Ti and 65.3 % around the Stainless steel were pigmented. The color around the Ti implant was titanium oxide which is harmless, but the steel it was the release of toxic metallic ions (Cr, Ni and Fe) As a consequence the stainless steel implant had to be extract. Overall Ti-6Al-4V is excellent, especially direct

contact with tissue or bone is required. Ti-6Al-4V's poor shear strength makes it undesirable for bone screws or plates. It also has poor surface wear properties and tends to seize when in sliding contact with itself and other metals. Surface treatments such as nitriding and oxidizing can improve the surface wear properties. Properties of all biomaterial are compared in table 6.

SUMMARY

The advances in technology that have being developed in the past have helped human being with incapacities to live a more normal live with the help of implants. In this paper we analyzed the different facets that are needed in the development of prosthesis. First we saw the resistance of the material subjected to various loadings. Also we analyzed the biocompatibility of the material. This is very important because the human body has a natural tendency to reject substances. Therefore it is important to find a material that has a good biocompatibility so that the body does not reject its. Given the result of biocompatibility we studied materials that are used on joint replacements. We studied data such as the angle of deflection and the heat resistance of the prosthesis. In this paper, we studied the following materials: Titanium, Chromium- Cobalt, Stainless Steel, and Nickel-Titanium, during the compilation of data we saw that different processes are used to meet the specific application.

ACKNOWLEDGEMENT

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Table 6. Physical Properties of Selected Biomaterials [9].

Properties	Units	Stainless Steel 316L	Chromium-Cobalt	Nickel-titanium	Titanium
Tensile Strength	ksi MPa	84 579	---- 430-1028	80 ----	145 1000
Yield Strength	ksi MPa	42 290	---- 200-823	100-800 ----	132 910
Elongation	%	55	20-32	12-40	18
Hardness		B80	----	----	36
Young Modulus of Elasticity in Tension	Msi GPa	28 193	 230	70-110	17 114
Young Modulus of Elasticity in Torsion	Psi*10^6 GPa	12.5 86.2	----	----	----
Density	Lb/in^3 Kg/m^3	0.29 8060	 7190	----	.159 4420
Specific Heat	Btu/lb/F J/kg x K	.12 503	0.127 540	----	.134 560
Thermal Expansion Coefficient	10^{-6}/F 10^{-6}/C	9.6 – 10.4 17.3 – 18.8	5.6 9.1	----	4.8 8.6
Melting Point	°F °C	2550 1400	3272 1875	----	3000 1649

Other properties of Ti and Ti alloys [5]

Mean Co-Efficient of Thermal Expansion 0-100°C /°C (0-212°F /°F)	$8.6x10^{-6}$ (4.8)
Mean Co-Efficient of Thermal Expansion 0-300°C /°C (0-572°F /°F)	$9.2x10^{-6}$ (5.1)
Beta Transus °C ±15°C (°F)	999 (1830)

Property (Mechanical)	**Minimum**	**Typical Value**
Tensile Strength MPa (ksi)	897 (130)	1000 (145)
0.2% Proof Stress MPa (ksi)	828 (120)	910 (132)
Elongation Over 2 Inches %	10	18
Reduction in Area %	20	
Elastic Modulus GPa (Msi)	----	114 (17)
Hardness Rockwell C	----	36
Specified Bend Radius < 0.070 in x Thickness	----	4.5
Specified Bend Radius > 0.070 in x Thickness	----	5.0
Welded Bend Radius x Thickness	6	----
Charpy, V-Notch Impact J (ft x lbf)	----	24 (18)

REFERENCES

1. http://www.avestapolarit.com/template

2. http://www.ao-asif.ch/literature/injury/supplement

3. www.astm.com

4. www.abayfor.de

5. www.azom.com

6. www.fda.org

7. www.hghouston.com/ss_comp.html

8. www.materials.qmw.ac.uk/casestud/implants

9. www.matweb.com

10. www.ssina.com

11. www.titanium.org

12. www.tsi.com

13. Anne Hover, Titanium for fracture fixation.

14. Berger-Gorbet M, Broxup B, Rivard C & Yahia LH 1996. Biocompatibility testing of NiTi screws using immunohistochemistry on sections containin metallic implants. J. Biomed . Mater. Res. 32: 243-248.

15. Burstein, G.T., I.M. Hutchings, and K. Sasaki. 2000 Electrochemically induced annealing of stainless steel surfaces. *Nature* 407(Oct.19):885.

16. Callister William D., 2003 Material Science and Engineering an Introduction, John Wiley & Sons Inc.

17. Castleman LS & Motzkin SM 1981. The biocompatibility of Nitinol. In: Williams DF (ed.) Biocompatibility of clinical implant materials, Volume 1. CRC Press, Inc., Boca Raton, Florida,p 129-154.

18. Clarke Metal : J Bone Joint surg – Br 2003: 85-B : 913-17

19. Cutright DE, Bhaskar SN, Perez B, Johnson RM & Cowan GSJ 1973. Tissue reaction to nitinol wire alloy. Oral Surg. Oral Med.Oral Pathol. 578 - 585

20. Gere James M., Mechanics of Materials Fifth Edition Brooks /Cole Thomson Learning 2001

21. Kasano F & Morimitsu T 1997. Utilization of nickel titanium shape memory alloy for stape s prosthesis. Auris. Nasus. Larynx. 24: 137 - 142. 22. eckner D., Handbook of Stainless Steel, 2000

23. Sendriks John, Corrosion of Stainless Steel, 1996.

24. Simon U., Augat A., Ignatius L., Institute of Orthopedics Research and Biomechanics, University of Ulm, Helmholtzstrabe

25. Takeshita F, Takata H, Ayukawa Y& Suetsugu T 1997. Histomorphometric analysis of the response of rat tibiae to shape memory alloy (nitinol). Biomaterials 18: 21-25.

GLOSSARY

Annealing: Process involving heating to & holding at a temp high enough for recrystallization to occur and then cooling slowly.

Austenite: The high-temperature (parent) phase of material.

Biocompatibility: The ability of a material to perform with an appropriate host response in a specific application.

Biomaterial: A material intended to interface with biological systems to evaluate, treat, augment or replace any tissue, organ or function of the body.

Biomaterials science: The study and knowledge of the interactions between living and non-living materials.

Bone-bonding: The establishment, by physicochemical process, of continuity between implant and bone matrix.

Composites - a multiphase material. The constituents must be chemically dissimilar & seperated by a distinct interface (matrix & dispersed phases). It should provide distinctive properties that cannot be obtained by the individual components alone. High strength to weight ratio.

Corrosion - Destruction of metal by electrochemical action.

Creep - Continued straining of a material under constant stress. It is stress, time & temp dependent (fatigue is stress & time dependent only).

Elastic Limit- The stress at which the material starts to behave in a non-elastic manner.

Hysteresis: The difference between the temperatures at which the material is 50% transformed to austenite upon heating and 50% transformed to martensite upon cooling.

Implant: A medical device made from one or more biomaterials that is intentionally placed within the body, either totally or partially buried beneath an epithelial surface.

Martensite: Low temperature phase of material

Martensitic transformation: A lattice transformation involving shearing deformation and resulting from cooperative atomic movement.

Osseointegration (or osteointegration): Direct bone-to-biomaterial interface without fibrous tissue for a functioning implant at the optical microscopy limits of resolution (0.5 μM). It is a description of clinical performance devices and is not applicable to the description of biomaterial interactions.

Osteoconduction: The ability to guide bone formation on material surface in a bony environment.

Osteoinduction: The ability to induce bone formation in non-osseous tissues.

Passive – does not react or influence other materials.

Superelasticity (pseudoelasticity): The ability of an alloy specimen to return to its original shape upon unloading after a substantial deformation.

Shape memory effect: When an alloy in which some fixed shape has been stored is deformed at low temperatures and then subsequently heated above the transition temperature, it reverts to its original shape.

Shape memory alloy: Material with an ability to return to some previously defined shape or size when subjected to an appropriate thermal procedure.

Strain - L-Lo/Lo = a ratio = how far atoms are being pulled apart.

Stress - F/A= N/m²= Pa= the force pulling atoms at a point in a material apart. (measure of the intensity of a force on an object).

Tenacious - Clings to the layer and is not transfer elsewhere.

Transition temperature: Temperatures at which changes of material phases occur.