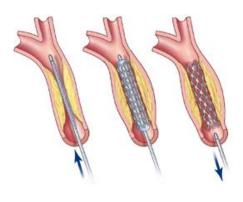
Classes of Materials Used in Medicine:

Metals

Large segments of the medical device industry rely on implants with one or more metallic parts



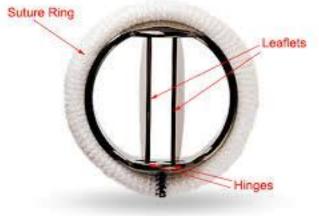
Stents



artificial hip joints



dental implants



heart valves



Injured sea turtle gets 3D printed jaw/http://www.bbc.com/news/technology-32780674



Akut-3



Video- Akut-3

Surg

Interact Cardiovasc Thorac Surg. 2014 Feb; 18(2): 234–236.

Published online 2013 Nov 13. doi: 10.1093/icvts/ivt408

Reconstruction with a patient-specific titanium implant after a wide anterior chest wall resection

Akif Turna,^a Kuthan Kavakli,^{b,*} Ersin Sapmaz,^b Hakan Arslan,^c Hasan Caylak,^b Hasan Suat Gokce,^d and Ahmet Demirkaya^a

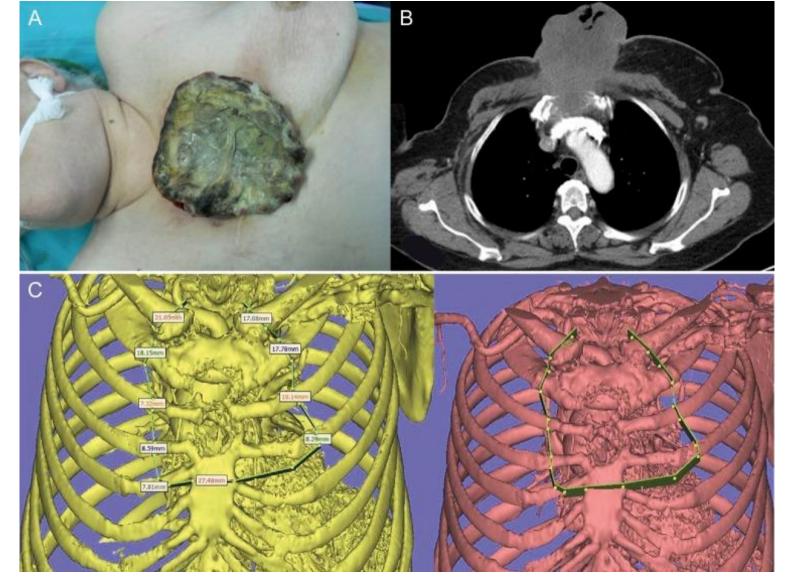
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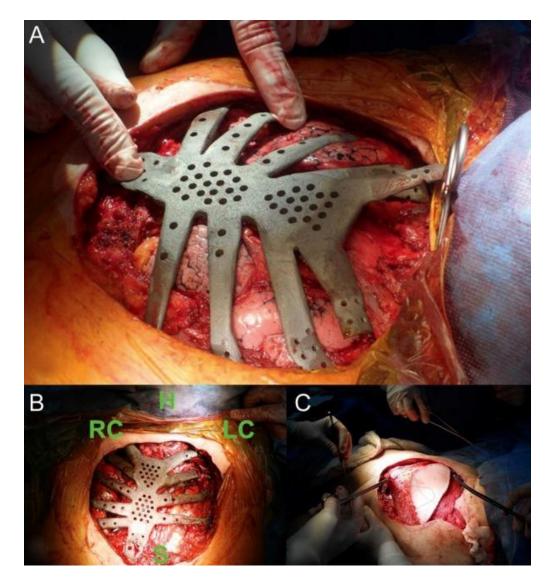
Abstract Go to: ♥

The reconstruction of full-thickness chest wall defects is a challenging problem for thoracic surgeons, particularly after a wide resection of the chest wall that includes the sternum. The location and the size of the defect play a major role when selecting the method of reconstruction, while acceptable cosmetic and functional results remain the primary goal. Improvements in preoperative imaging techniques and reconstruction materials have an important role when planning and performing a wide chest wall resection with a low morbidity rate. In this report, we describe the reconstruction of a wide anterior chest wall defect with a patient-specific custom-made titanium implant. An infected mammary tumour recurrence in a 62-year old female, located at the anterior chest wall including the sternum, was resected, followed by a large custom-made titanium implant. Latissimus dorsi flap and split-thickness graft were also used for covering the implant successfully. A titanium custom-made chest wall implant could be a viable alternative for patients who had large chest wall tumours.

Keywords: Chest wall resection, Reconstruction, Implant, Thoracic surgery



Preoperative view of the chest wall tumour. The mass involves the skin and anterior chest wall including manubrium sterni (A). The preoperative computed tomographic scan of the patient reveals no invasion to the vascular structures of the mediastinum. It also shows that most parts of the anterior chest wall bone structures were invaded by the mass (B). The resection plan was marked on the 3D reconstruction of the computed tomography scan (C).



The patient specific titanium implant is compatible with the bony structures of the chest wall of patient. The angle between the clavicula and first rib can be seen clearly (A). The orientation view of the operative field. H: head of the patient, RC: right clavicula, LC: left clavicula, S: one-third distal part of the sternum (B). The soft tissue coverage of titanium implant with latissimus dorsi musculocutaneous-rotated flap (C).

• Any of metallic devices must support high mechanical load and resistance of material against breakage is essential.

A comparison of general material properties

		,	
	Ceramics	Metals	Polymers
Hardness	Very High	High	Very Low
Elastic Modules	Very High	High	Low
Ductility	Low	High	High
Thermal Expansion	Low	High	High
Corrosion Resistance	High	Low	Low
Resistance to Wear	High	Low	Low
Density	Low	High	Very Low
Electrical Conductivity	High/Low	High	Low
Heat Conductivity	High/Low	High	Low

Metals have a highly significant place in the biomaterials market.

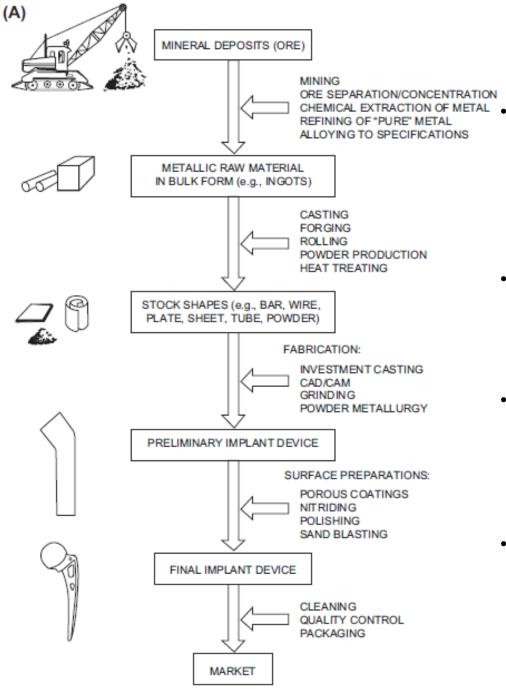
Application	Biomaterials Used	Number/Year – World (or World Market in US\$)
skeletal system		
Joint replacements (hip, knee, shoulder)	Titanium, stainless steel, polyethylene	2,500,000
Bone fixation plates and screws	Metals, poly(lactic acid) (PLA)	1,500,000
Spine disks and fusion hardware		800,000
Bone cement	Poly(methyl methacrylate)	(\$600M)
Bone defect repair	Calcium phosphates	_
Artificial tendon or ligament	Polyester fibers	_
Dental Implant-tooth fixation	Titanium	(\$4B)
ardiovascular system		
Blood vessel prosthesis	Dacron, expanded Teflon	200,000
Heart valve	Dacron, carbon, metal, treated natural tissue	400,000
Pacemaker	Titanium, polyurethane	600,000
Implantable defibrillator	Titanium, polyurethane	300,000
Stent	Stainless steel, other metals, PLA	1,500,000
Catheter	Teflon, silicone, polyurethane	1B (\$20B)
Organs		
Heart assist device	Polyurethane, titanium, stainless steel	4000
Hemodialysis	Polysulfone, silicone	1,800,000 patients (\$70B)
Blood oxygenator	silicone	1,000,000
Skin substitute	Collagen, cadaver skin, nylon, silicone	(\$1B)
Ophthalmologic		
Contact lens	Acrylate/methacrylate/silicone polymers	150,000,000
Intraocular lens	Acrylate/methacrylate polymers	7,000,000
Corneal bandage lens	hydrogel	_
Glaucoma drain	Silicone, polypropylene	(\$200M)
Other		,,
Cochlear prosthesis	Platinum, platinum-iridium, silicone	250,000 total users
Breast Implant	Silicone	700.000
Hernia mesh	Silicone, polypropylene, Teflon	200,000 (\$4B)
Sutures	PLA, polydioxanone, polypropylene, stainless steel	(\$2B)
Blood bags	Poly(vinyl chloride)	_
Ear tubes (Tympanostomy)	Silicone, Teflon	1,500,000
Intrauterine device (IUD)	Silicone, copper	1,000,000

^{*}Data compiled from many sources – these numbers should be considered rough estimates that are changing with growing markets and new technologies. Where only US numbers are available, world usage is estimated at approximately 2.5× of US usage.

NOTE: M = millions, B = billions.

STEPS IN THE FABRICATION OF METALLIC BIOMATERIALS

- Understanding the structure and properties of metallic implant materials requires an appreciation of the metallurgical significance of the material's processing history.
- Typically, any metallic medical device will differ in exactly how it is manufactured.



1 Metal-Containing Ore to Raw Metal Product

With the exception of noble metals such as gold (which do not represent a major fraction of implant metals), **metals exist in the Earth's crust in mineral form**, wherein the metal is chemically combined with other elements.

- These mineral deposits, or "ore," must be located, mined, separated, and enriched for further processing into pure metal or various alloys.
- In the case of multicomponent metallic implant alloys (i.e., made up of more than one element), the raw metal product will usually have to be further processed both chemically and physically.
- Processing steps can include remelting, addition of specific alloying elements, and controlled solidification from the melt, in order to produce an alloy that meets certain chemical and metallurgical specifications

FIGURE I.2.3.1 (A) Generic processing history of a typical metallic implant device, in this case a hip implant.

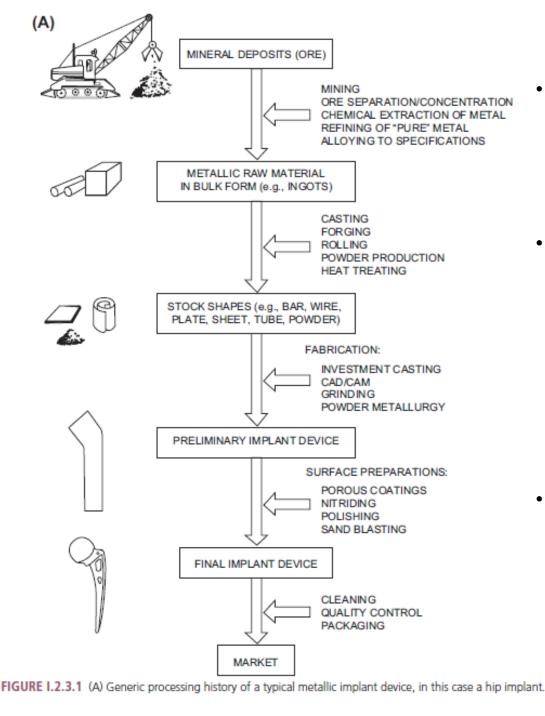
- For example, to make ASTM (American Society for Testing and Materials) F138 316L stainless steel, iron is alloyed with specific amounts of carbon, silicon, nickel, and chromium; and to make ASTM F75 or F90 alloy, cobalt is alloyed with specific amounts of chromium, molybdenum, carbon, nickel, and other elements.
- Table I.2.3.1 lists ASTM designations and typical properties of common metallic alloys for surgical implants.

Material	ASTM Designation	Condition	Young's Modulus (GPa)	Yield Strength (MPa)	Tensile Strength (MPa)	Fatigue Endurance Limit Strength (at 10^7 cycles, $R = -1^c$) (MPa)
Stainless steel	F745	Annealed	190	221	483	221–280
	F55, F56, F138, F139	Annealed	190	331	586	241-276
		30% Cold-worked	190	792	930	310-448
		Cold forged	190	1213	1351	820
Co-Cr alloys	F75	As-cast/annealed	210	448-517	655-889	207-310
•		P/M HIPb	253	841	1277	725-950
	F799	Hot forged	210	896-1200	1399-1586	600-896
	F90	Annealed	210	448-648	951-1220	Not available
		44% Cold-worked	210	1606	1896	586
	F562	Hot forged	232	965-1000	1206	500
		Cold-worked, aged	232	1500	1795	689–793 (axial tension <i>R</i> = 0.05, 30 Hz)
Ti alloys	F67	30% Cold-worked Grade 4	110	485	760	300
	F136	Forged annealed	116	896	965	620
		Forged, heat treated	116	1034	1103	620–689

a Data collected from references noted at the end of this chapter, especially Table 1 in Davidson and Georgette (1986).

b P/M HIP: Powder metallurgy product, hot-isostatically pressed.

^c R is defined as $\sigma_{\min}/\sigma_{\max}$.



2 Raw Metal Product to Stock Metal Shapes

- A metal supplier will typically **further process** the bulk raw metal product (metal or alloy) **into stock bulk shapes**, such as bars, wire, sheet, rods, plates, tubes or powders.
- These stock shapes may then be sold to implant manufacturers, who typically want a stock shape that is closer to the final implant shape
 - e.g., a maker of screw-shaped dental implants would often buy rod stock of the appropriate metal as feedstock for screw-manufacturing machines.
- A metal supplier might transform the raw metal product into stock shapes by a variety of processes, including
 - remelting
 - continuous casting
 - hot rolling
 - Forging
 - cold drawing, etc.

3 Stock Metal Shapes to Preliminary and Final Metal Devices

- An implant manufacturer will buy stock material and then fabricate preliminary and final forms of the device.
- Final geometry of the implant depends on a number of factors such as the forming and machining properties of the metal, and the costs of alternative fabrication methods.
- Typical fabrication methods include
 - investment casting
 - conventional and computer-based machining (CAD/CAM)
 - Forging
 - o powder metallurgical processes

and a range of grinding and polishing steps.

- A variety of fabrication methods are required because not all implant alloys can be feasibly
 or economically fabricated into a final form in the same way.
 - o For example, cobalt-based alloys are extremely difficult to machine into the complicated shapes of some implants by conventional machining methods. Therefore, many cobalt-based alloys are frequently shaped into implant forms by investment casting (e.g., Figure I.2.3.1B) or by powder metallurgy.



FIGURE 1.2.3.1 (B) Image of one step during the investment casting ("lost wax") process of manufacturing hip stems; a rack of hip stems can be seen attached to a system of sprues through which molten metal can flow. At this point, ceramic investment material composes the mold into which the molten metal will flow and solidify during casting, thereby replicating the intended shape of a hip stem.

Video # 5

 On the other hand, titanium is relatively difficult to cast, and is therefore often machined.

MICROSTRUCTURES AND PROPERTIES OF IMPLANT METALS

- The most common metallic biomaterials are;
 - ✓ stainless steels
 - ✓ Co-Based alloys
 - ✓ Ti-based alloys.

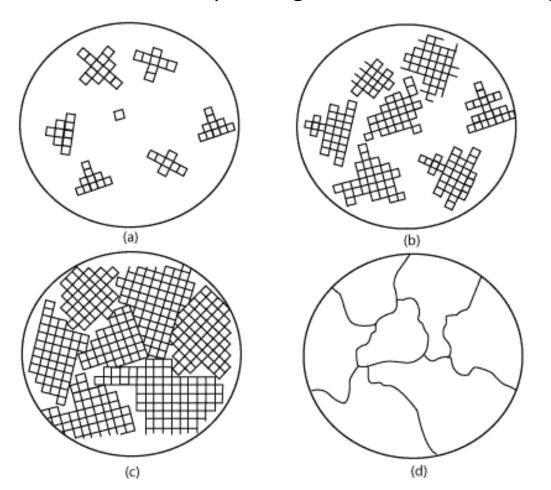
so discussion on microstructure-mechanical property relation on these metallic biomaterials may be meaningful.

- > 316L Stainless Steel.
- In this alloy, two common strengthening methods are cold-working and controlling grain size.
- <u>In cold-working</u>, the idea is to introduce more and more plastic deformation such that additional plastic flow becomes even more difficult.
 - With 316L stainless (ASTM F138), typically it is used in a 30% cold-worked state, because this cold-worked metal has a markedly increased yield, ultimate tensile, and fatigue strength relative to the annealed state.

Video # 6

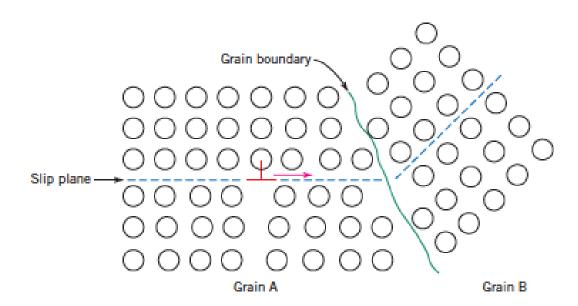
• <u>In decreasing grain size</u>, the idea is to have more grain boundaries to interfere with the flow of dislocations on slip systems within each grain.

- Polycrystalline or multicrystalline materials, or polycrystals are solids that are composed of many crystallites of varying size and orientation. Crystallites are also referred to as grains.
 - They are small or even microscopic crystals and form during the cooling of many materials.
 - Their orientation can be random with no preferred direction, called random texture, or directed, possibly due to growth and processing conditions.
 - The areas where crystallite grains meet are known as grain boundaries.



- a) Nucleation of crystals
- b) crystal growth
- c) irregular grains form as crystals grow together
- d) grain boundaries as seen in a microscope.

Dislocations are defects or disturbed regions in the crystal lattice.



- •The grain boundary acts as a barrier to dislocation motion for two reasons:
 - 1. The two grains are of different orientations, a dislocation passing into next grain must change its direction of motion \rightarrow becomes more difficult as the misorientation increases.
 - 2. The atomic disorder within a grain boundary region results in a discontinuity of slip planes from one grain into the other.

- A key determinant of grain size is manufacturing history including details on
 - solidification conditions
 - cold-working
 - annealing cycles
 - recrystallization.

TABLE 1.2.	TABLE 1.2.3.1 Typical Mechanical Properties of Implant Metals ^a								
Material	ASTM Designation	Condition	Young's Modulus (GPa)	Yield Strength (MPa)	Tensile Strength (MPa)	Fatigue Endurance Limit Strength (at 10^7 cycles, $R = -1^c$) (MPa)			
Stainless steel	F745	Annealed	190	221	483	221-280			
	F55, F56, F138, F139	Annealed	190	331	586	241–276			
		30% Cold-worked	190	792	930	310–448			
		Cold forged	190	1213	1351	820			
Co-Cr alloys	F75	As-cast/annealed	210	448-517	655-889	207–310			
		P/M HIPb	253	841	1277	725–950			
	F799	Hot forged	210	896-1200	1399-1586	600–896			
	F90	Annealed	210	448-648	951-1220	Not available			
		44% Cold-worked	210	1606	1896	586			
	F562	Hot forged	232	965-1000	1206	500			
		Cold-worked, aged	232	1500	1795	689–793 (axial tension <i>R</i> = 0.05, 30 Hz)			
Ti alloys	F67	30% Cold-worked Grade 4	110	485	760	300			
	F136	Forged annealed	116	896	965	620			
		Forged, heat treated	116	1034	1103	620–689			

^a Data collected from references noted at the end of this chapter, especially Table 1 in Davidson and Georgette (1986).

b P/M HIP: Powder metallurgy product, hot-isostatically pressed.

^c R is defined as $\sigma_{min}/\sigma_{max}$.

- Cobalt-Based Alloys.
- Cobalt-based alloys include (ASTM F75 and F90), forged Co-Cr-Mo alloy (ASTM F799), and multiphase (MP) alloy MP35N (ASTM F562).

Material	ASTM Designation	Condition	Young's Modulus (GPa)	Yield Strength (MPa)	Tensile Strength (MPa)	Fatigue Endurance Limit Strength (at 10 ⁷ cycles, <i>R</i> = -1 ^c) (MPa)
Stainless steel	F745	Annealed	190	221	483	221–280
	F55, F56, F138, F139	Annealed	190	331	586	241-276
		30% Cold-worked	190	792	930	310-448
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•		P/M HIPb	253	841	1277	725-950
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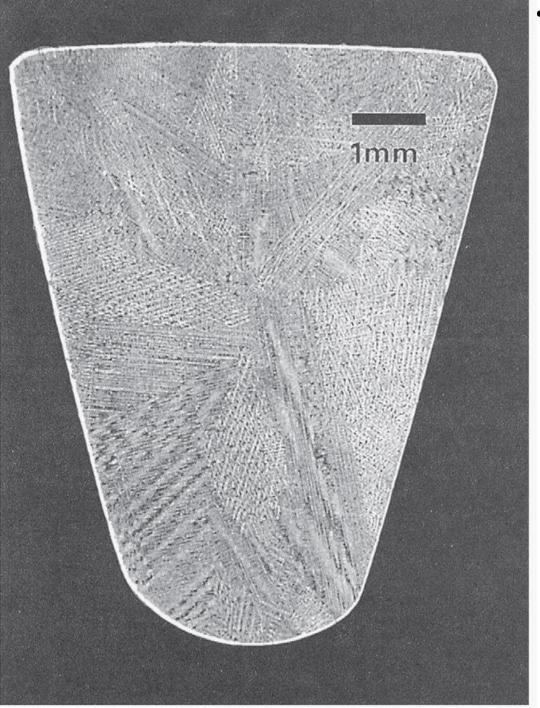
^a Data collected from references noted at the end of this chapter, especially Table 1 in Davidson and Georgette (1986).

- The F75 and F799 alloys are virtually identical in composition, each being about 58–70% Co and 26–30% Cr, with the key difference in their processing history.
- F90 and F562, have slightly less Co and Cr, but more Ni (F562) or more tungsten (F90).

^b P/M HIP: Powder metallurgy product, hot-isostatically pressed.

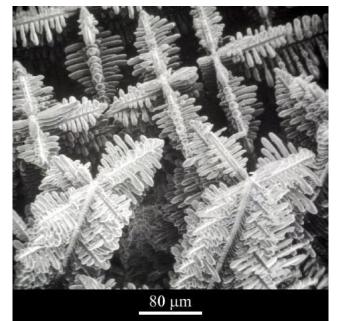
^c R is defined as $\sigma_{min}/\sigma_{max}$.

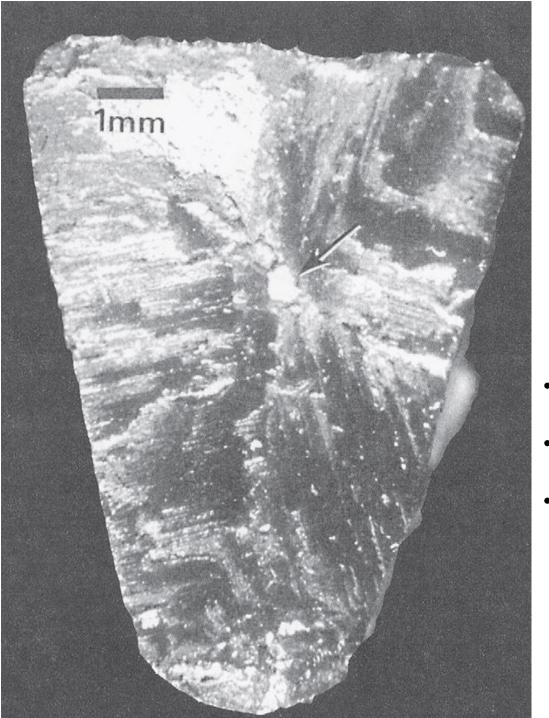
- F75 alloy has been frequently used in both the aerospace and biomedical implant industries because of its high corrosion resistance in chloride environments, which is related to its bulk composition and surface oxide (nominally Cr₂O₃).
- When F75 is cast into shape by investment casting
 - the alloy is first melted at 1350–1450°C
 - then poured or pressurized into ceramic molds of the desired shape
 - √ femoral stems for artificial hips
 - √ oral implants
 - ✓ dental partial bridgework
- Depending on the exact details of the casting process, at least three microstructural features can come into play as strong determinants of implant properties.
 - "cored" microstructures that develop due to non-equilibrium cooling
 - relatively large grain sizes. This is generally undesirable because it decreases the yield strength
 - Inclusions may arise because of casting defects



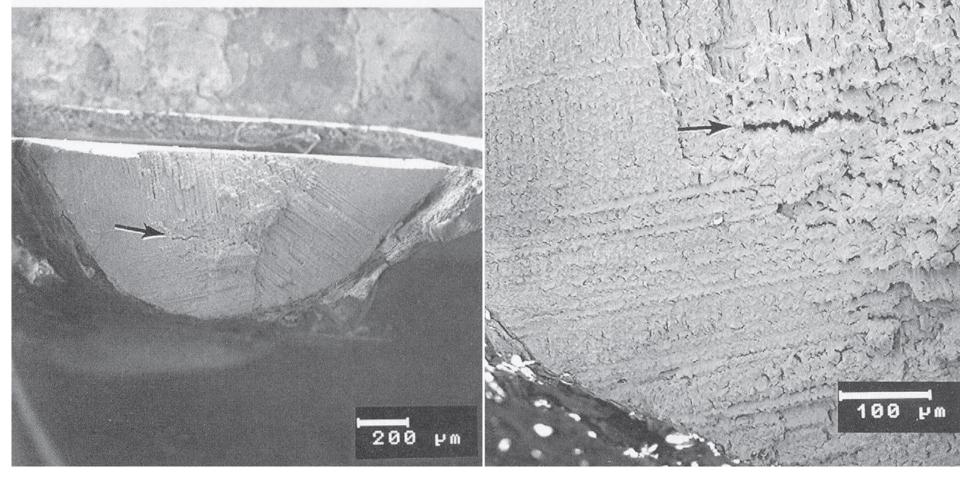
 Macrophoto of a metallographically polished and etched cross-section of a cast Co–Cr–Mo ASTM F75 femoral hip stem, showing dendritic structure and large grain size.

3D structure of dendrites in a cobalt-samarium-copperalloy



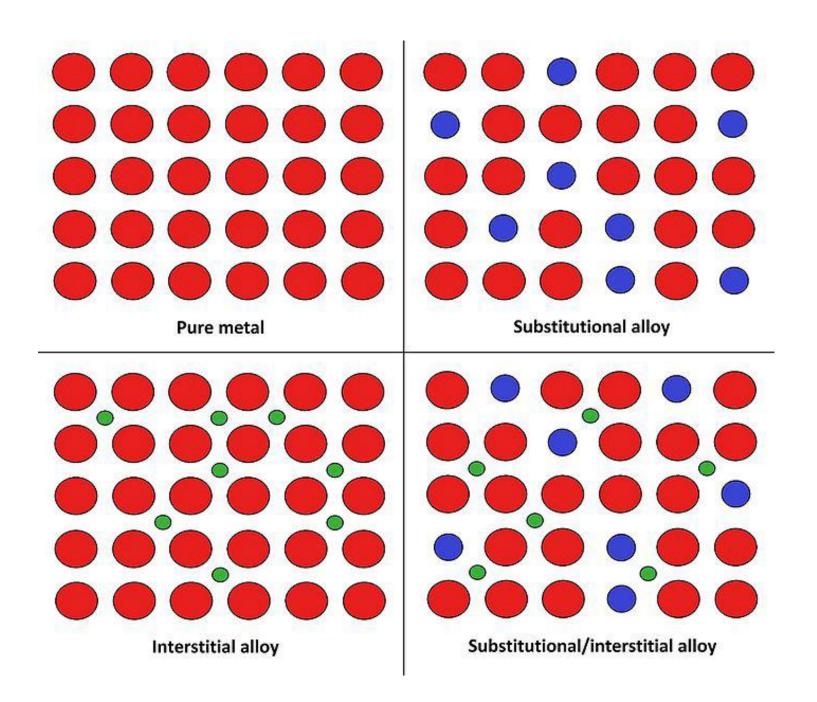


- Macrophoto of the fracture surface of the same femoral hip stem
- Arrow indicates large inclusion within the central region of the cross section
- Fracture of this hip stem occurred in vivo

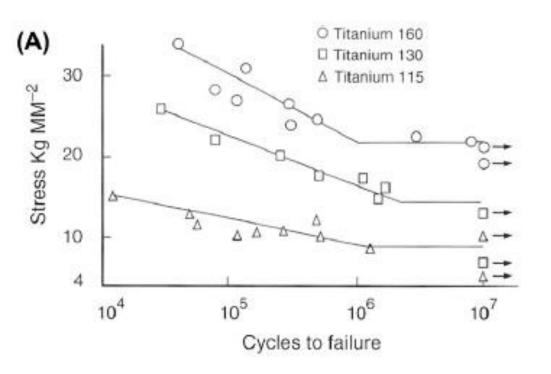


Scanning electron micrographs of the fracture surface from a cast F75 subperiosteal dental implant. Note the large grain size, dendritic microstructure, and interdendritic microporosity

- > Titanium-Based Alloys.
- Commercially pure (CP) titanium and Ti-6AI-4V alloy are the two most common titanium-based implant biomaterials (there are four grades of CP Ti).
- The oxygen content of CP Ti, as well as the content of other interstitial elements (e.g., C and N), affect its yield, tensile, and fatigue strengths significantly.
- For CP titanium implants typical microstructures are made up of single-phase alpha titanium, in which there is typically mild (30%) cold-work and grain diameters in the range of 10–150 microns, depending on manufacturing.
- Beyond cold-work, interstitial elements (O, C, N) in both CP titanium and the Ti-6Al-4V alloy strengthen the metal with nitrogen having approximately twice the hardening effect (per atom) of either carbon or oxygen.
- The tensile strength increases with oxygen content.
- Fatigue limit of unalloyed CP Ti is typically increased by interstitial content, in particular the oxygen content.



Fatigue study on vacuum-annealed CP Ti having a grain size in the range 200–300 microns in tension-compression at 100 cycles/sec.

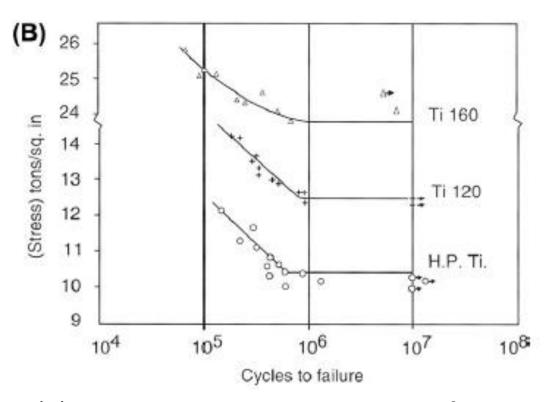


The 10⁷ cycle endurance limit, or fatigue limit

oxygen content	Endurance(fatigue) limit
(wt%)	(Mpa)
0.085 (grade 1)	88.3
0.125 (grade 1)	142
0.270 (grade 3)	216
	(wt%) 0.085 (grade 1) 0.125 (grade 1)

FIGURE I.2.3.3 (A) S–N curves (stress amplitude–number of cycles to failure) at room temperature for CP Ti with varying oxygen content, from Beevers and Robinson (1969).

> Fatigue study on CP Ti (tension-compression, 160 cycles/sec) having a grain size in the range 26–32 micrometers.



HP Ti	0.072	(grade :	1)	142	
Ti 120	0.087	(grade	1)	172	
Ti 160	0.32	(grade 3)	295	
ha fat	tigue	limit	again	increased	\\/it

oxygen content

(wt%)

substrate

Endurance(fatigue) limit

(Mpa)

the fatigue limit again increased with increasing oxygen content.

Video #9

(B) S–N curves at room temperature for CP Ti with varying oxygen content, from Turner and Roberts (1968a).

It seems clear that interstitial content affects the yield, tensile and fatigue strengths in CP Ti

Material	ASTM Designation	Condition	Young's Modulus (GPa)	Yield Strength (MPa)	Tensile Strength (MPa)	Fatigue Endurance Limit Strength (at 10^7 cycles, $R = -1^c$) (MPa)
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•		P/M HIPb	253	841	1277	725-950
	F799	Hot forged	210	896-1200	1399-1586	600-896
	F90	Annealed	210	448-648	951-1220	Not available
		44% Cold-worked	210	1606	1896	586
	F562	Hot forged	232	965-1000	1206	500
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^a Data collected from references noted at the end of this chapter, especially Table 1 in Davidson and Georgette (1986). ^b P/M HIP: Powder metallurgy product, hot-isostatically pressed. ^c R is defined as $\sigma_{min}/\sigma_{max}$.

TITANIUM

- Titanium and its alloys have attracted much attention in the medical implants field as
 - they have unique mechanical properties
 - their superior corrosion resistance when compared to other metals and alloys
 - they do not initiate an allergenic response and have the probably the best tolerance among metallic biomaterials in the body.
- Currently only three alloy systems have extensive use in the industry,
 - commercially pure titanium (cpTi)
 - Ti-6Al-4V
 - Ti-6A1-7Nb.

Corrosion Resistance

- With the exception of noble metals such as gold or platinum, the common implantable metals and alloys rely on the formation of **protective oxide films** to control corrosion of the material to acceptable levels. These oxides are commonly referred to as **passive films**.
- They are very thin (typically less than 100 microns), dense, and adhere strongly to the underlying substrate.
- They limit transport of metallic ions to the implant surface.
- This is attributed to the spontaneous formation of a few nm thick titanium dioxide film that protects the metal from further oxidation. This behavior depends on alloy composition and corrosive medium
- Ti-13Nb-13Zr confirmed the potential of Ti, Nb, and Zr to develop highly protective passive layers, resulting in a better corrosion resistance compared to Ti-6Al-4V

Biocompatibility and Surface Modification

- The biocompatibility of a metallic alloy has to be understood in terms of both the biocompatibility of the alloy itself, which is closely associated with its corrosion resistance, and the biocompatibility of its by-products as a result of corrosion.
- It is generally accepted that Ti and its alloys are relatively "bioinert," and exhibit acceptable *in vitro* and *in vivo* responses for the desired application.
- When implanted in bone, tissue forms new bonds at the bone implant material (osteointegration), however there maybe a thin fibrous layer separating the metallic implant and the bone leading to fail of the implant.
- In order to improve osteointegration, bioactivity, biocompatibility, and corrosion resistance, several surface treatments based on chemical and physical modifications have been developed.

Mechanical Properties

- Ti and its alloys are very attractive for use in different biomedical devices, particularly orthopedics, due to their elastic modulus which is closer to that of bone in comparison to other alloys.
- The mechanical properties of cpTi and some Ti-based alloys

TABLE A.1 Titanium Alloys Developed for Orthopedic Applications and Their Mechanical Properties (Adapted from Long and Rack, 1998)								
Alloy	Microstructure	Elastic Modulus E (GPa)	Yield Strength YS (MPa)	Ultimate Strength UTS (MPa)				
фTi	α	105	692	785				
Ti-6Al-4V	α/β	110	850-900	960–970				
Ti-6Al-7Nb	α/β	105	921	1024				
Ti-5Al-2.5Fe	Metastable β	110	914	1033				
Ti-15Mo-5Zr-3Al	Metastable β	82	771	812				
Ti-Zr	Cast α'/β	N/A	N/A	900				
Ti-13Nb-13Zr	α'/β	79	900	1030				
Ti-15Mo-3Nb-0.30	Metastable β + silicides	82	1020	1020				
Ti-35Nb-5Ta-7Zr	Metastable β	55	530	590				
Ti-35Nb-5Ta-7Zr-0.40	Metastable β	66	976	1010				
Stainless steel 316L	-	205-210	170-750	465–950				
Co-Cr-Mo	_	220-230	275-1585	600-1785				
Bone	-	10–40		90–140				

- Much effort is currently being carried out to develop new alloys with low elastic modulus that mimic that of bone tissue.
- Among the alloys under investigation, the Ti–Nb–Ta– Zr system known as Gum metal (Ti-29Nb-13Ta-4.6Zr) is gaining attention in the field because of its super elastic properties.
 - Young's modulus of 40 Gpa
 - elastic strain of 2.5%
- Ti-35Nb-7Zr-5Ta is an alloy that has shown
 - enhanced osseointegration
 - improved ductility
 - adequate mechanical strength
 - optimal hot and cold workability
 - low elastic modulus (55 Gpa)

STAINLESS STEELS

- There are a large number of stainless steels available commercially but only a few of these alloys are used as biomaterials for implantable devices.
- The performance of these alloys depends on their chemical composition and processing history. While 316L is the most common stainless steel, alloys with enhanced corrosion resistance and mechanical properties are available.
- chemical composition ranges specified for several common implantable stainless steels

TABLE B.1	TABLE B.1 Compositions of Common Implantable Stainless Steels (Weight Percent)											
Alloy	Cr	Ni	Mn	Мо	С	N	Nb	V	Si	Cu	P	S
316L ASTM F138, ISO 5832-1	17–19	13–15	<2 max	2.25–3	<0.030	<0.10	-	-	<0.75	<0.5	<0.025	<0.010
22-13-5 ASTM F1314	20.5–23.5	11.5–13.5	4–6	2–3	<0.030	0.2-0.4	0.1–0.3	0.1-0.3	<0.75	<0.5	<0.025	<0.010
Rex 734, Ortron 90 ASTM F1586 ISO 5832-9	19.5–22	9–11	2–4.25	2–3	<0.08	0.25-0.5	0.25-0.8	-	<0.75	<0.25	<0.25	<0.010
BioDur® 108 ASTM F 2229	19–23	<0.050	21–24	0.5–1.5	<0.08	0.85–1.10	-	-	<0.75	<0.25	<0.03	<0.010

- Chromium is present in these alloys, primarily to form a protective Cr_2O_3 surface layer (passive film) that is crucial to their corrosion resistance.
- <u>Nitrogen</u> additions increase mechanical strength and corrosion resistance.
- Molybdenum additions have a beneficial impact on the pitting corrosion resistance of stainless steels.
- <u>Carbon</u> is controlled to be at low levels to prevent the formation of chromium carbides (the "L" in 316L designates low carbon).
 - Formation of these carbides can result in a phenomenon known as sensitization.
 - If enough carbon is available, chromium carbides can form along grain boundaries, leaving the adjacent areas with depleted chromium levels which are prone to attack by corrosion.

Corrosion Behavior

- The alloys that contain substantial amounts of chromium cobalt base alloys form a Cr_2O_3 layer while alloys rich in titanium form a TiO_2 layer.
- In general terms, the austenitic stainless steels are not considered to be quite as corrosion resistant as either cobalt-chromium alloys or titanium alloys
- Another factor which influences the corrosion of stainless steels is the presence of foreign particles, known as **inclusions**.
 - These are typically oxide particles such as alumina or silicates which are formed during the initial melting of the alloy and become trapped within the material during subsequent processing.
- Since these inclusions have different corrosion behavior than the alloy, they can
 act as corrosion initiation sites if they are found at the surface of a component.

Mechanical Properties

- The mechanical properties of metals and alloys depend on their chemical composition and processing history.
- Chemical composition influences strength by a process known as solid solution strengthening.
 - In stainless steels the metallic alloying elements (Cr, Ni, etc.)
 replace iron atoms at random locations within the crystal
 structure.
 - Since the various atoms are not the same size, additions of alloying elements lead to distortion of the crystal lattice.
 - This distortion makes deformation of the material more difficult (dislocation movements), thus increasing strength (and generally decreasing ductility).

- Another strengthening mechanism available for these materials involves work hardening (also known as "cold-working").
- As the amount of cold-work increases, strength parameters (yield strength and ultimate strength) increase, while the ductility decreases.
- This behavior gives designers the ability to specify a wide range of mechanical properties by proper selection of the alloy composition, processing temperature, and the amount of cold-work.

• Table B.2 lists approximate tensile and fatigue strength properties for some implantable stainless steels produced under different conditions.

TABLE B.2	TABLE B.2 Approximate Mechanical Properties of Stainless Steels									
Alloy	Material Condition	Ultimate Tensile Strength (MPa)	Yield Strength (MPa)	%Elongation	!0 ⁷ Cycle Endurance Limit (MPa)	Reference				
316L	Annealed	550	240	55	180	Shetty & Ottersberg, 1995				
316L	30% Cold-worked	896	827	20	380	Shetty & Ottersberg, 1995				
316L	60% Cold-worked	1240	1000	12	450	Shetty & Ottersberg, 1995				
Rex 734	Hot forged	1140-1230	1050-1179	15-19	585	Windler & Steger, 2003				
22-13-5	Annealed	965	760	35	380	Shetty & Ottersberg, 1995				
22-13-5	30% Cold-worked	1240	1170	15	530	Shetty & Ottersberg, 1995				
22-13-5	60% Cold-worked	1585	1480	9	670	Shetty & Ottersberg, 1995				
BioDur®108	Annealed	827–930	517–605	30–50	380	ASTM F 2229 and Technical Data Sheet BioDur®108				
BioDur®108	35% Cold-worked	1580	1350	15		Technical Data Sheet BioDur®108				
BioDur®108	65% Cold-worked	2000	1790	5		Technical Data Sheet BioDur®108				

• A high level of fatigue strength is necessary for many stainless steel medical devices