Metal and Ceramic Biomaterials

Volume II
Strength and Surface

Chapter 1

MECHANICAL PROPERTIES OF SELECTED IMPLANT METALS USED FOR ARTIFICIAL HIP JOINTS

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I. IMPLANT METALS IN CLINICAL USE

It is estimated that every day about 1000 artificial hip joints are implanted throughout the world in patients suffering from disabling hip joint disease in order to provide relief of pain and to restore or improve their joint function. This means replacing the femoral head and the acetabular socket with artificial prosthetic components so that motion then takes place on the articulating joint surfaces.

Iron-, titanium-, and cobalt-base alloys marketed under various trade names have been hitherto used in manufacturing artificial hip joints (Table 1). The chemical composition, structure, and mechanical properties of these alloys are described in national and international standard specifications.[20] These metallic materials are used for prosthetic components in combination with polymeric plastics (ultrahigh molecular weight polyethylene and polyoxymethylene) and aluminum oxide ceramic (Table 2).

II. CHEMICAL COMPOSITION OF IMPLANT METALS

On the basis of their chemical composition (Table 3), the clinically applied implant metals are iron-, titanium-, and cobalt-base alloys. The alloying elements contained in the metallic materials form homogeneous solid solutions of high corrosion resistance. The specific pure-element properties, such as the toxic and allergic reactions to cobalt, nickel, and vanadium,[15] become entirely insignificant in the alloy. This fact should be particularly stressed with regard to the well-known biocompatibility of these implant alloys with passive oxide films of good adherence at the implant surface.[11,30-32]

III. INFLUENCE OF PROCESSING METHODS ON THE MICROSTRUCTURE

The structure of an implant alloy is on one hand determined by its chemical composition and on the other hand by the manufacturing process used in the production of the alloy. Every alloy is primarily formed in a melting process, whereby this can be done in air, in an inert gas, or under vacuum. Because of the high requirements on the purity and mechanical strength of the alloy, preference is to be given to vacuum-melted materials.

The required implant shapes are produced by various methods. Casting is the most economical process, and with very complicated shapes it is generally also the only feasible method.[2]

Highly stressed components made in vacuum cast Co-Cr-Mo alloy may be subsequently also subjected to an isostatic hot-pressing process (HIP) in order to eliminate the pores and thus to increase its strength.[8,35] Another method of manufacturing implant components is the sintering process in combination with HIP of metal powders.[38] This process allows very homogeneous microstructures to be preserved at a high strength of the material. Because of the very high manufacturing costs, implants produced by powder metallurgy are very expensive.

Highly stressed implant components should be preferably manufactured by hot pressing and forging.[16] This extremely strength-increasing manufacturing process has been used for iron-, titanium-, and cobalt-base alloys for many years now.

Wrought Fe-Cr-Ni-Mo stainless steel — is the longest clinically used implant alloy. In the forged condition, this alloy shows an austenitic (face-centered-cubic) crystalline structure. For hip prostheses, the low carbon quality is used either in the recrystallized condition (Figure 1A) or in the cold-worked state with about 50% deformation (Figure 1B). In order to increase the corrosion resistance of hip prostheses made of stainless steel, utmost attention must be given to the optimum shaping of the implant and the selection of a special quality.[1,29,41] A modified steel quality with an increased chromium and nitrogen content and a low niobium content has been recently introduced for Charnley hip prostheses.[26]

Table 1
IMPLANT METALS IN CLINICAL USE FOR ARTIFICIAL HIP JOINTS

ISO	Composition	Condition	Trade name	No.
5832-1	Fe-18Cr-14Ni-3Mo	Wrought	AISI-316 L	1
			AISI-316 LVM	
	Fe-21Cr-9Ni-4Mn-3Mo-Nb-N	Wrought	Ortron 90	2
5832-3	Ti-6A1-4V	Wrought	IMI-318A	3
			Protasul-64 WF	4
			Tioxium	5
			Tivaloy	6
			Tivanium	7
5832-4	Co-28Cr-6Mo	Cast	Alivium	8
			Endocast	9
			Orthochrome	10
			Orthochrome plus	11
			Protasul	12
			Protasul-2	13
			Vitallium cast	14
			Zimaloy	15
	Co-28Cr-6Mo	Wrought	Endocast hot worked	16
			Protasul-21 WF	17
			Vitallium FHS	18
	Co-28Cr-6Mo	P/M	Micro Grain Zimaloy	19
5832-6	Co-35Ni-20Cr-10Mo	Wrought	Biophase	20
			MP-35N	21
			Protasul-10	22

Note: Trade names: American Society for Testing and Materials (1); Ceraver, France (5); DePuy U.S. (10,11); Fried. Krupp GmbH, BRD (9, 16); Howmedica Inc., U.S. (14, 18); Imperial Metal Industries, GB (3); OEC Orthopaedic Ltd. (6, 8); Richards Manufacturing Company, U.S. (20); SPS Technologies Inc., U.S. (21); Sulzer Bros. Ltd., Switzerland (4, 12, 13, 17, 22); Thackray Ltd., GB (2); Zimmer Inc. U.S. (7, 15, 19).

Table 2
COMBINATION OF IMPLANT MATERIALS IN USE FOR THE SOCKET, BALL, AND STEM OF ARTIFICIAL HIP JOINTS

Socket	Ball	Stem	Design
Co-Cr-Mo, cast	Co-Cr-Mo, cast	Co-Cr-Mo, cast	McKee-Farrar
Polymer	Fe-Cr-Ni-Mo, wrought	Fe-Cr-Ni-Mo, wrought	Charnley
Polymer	Co-Cr-Mo, cast	Co-Cr-Mo, cast	St. Georg Weller
		Co-Ni-Cr-Mo, wrought	Mueller Weber
		Co-Cr-Mo, wrought	Harris
		Ti-Al-V, wrought	Stanmore
Polymer	Ti-Al-V wrought	Ti-Al-V wrought	STH (Sarmiento)
Polymer	Al_2O_3, sintered	Co-Ni-Cr-Mo, wrought	Mueller Weber, Weber-Stuehmer
		Ti-Al-V, wrought	Zweymueller
		Fe-Cr-Ni-Mo, wrought	Shikita
		Co-Cr-Mo, cast	Lord
Polymer	Co-Cr-Mo, P/M	Co-Cr-Mo, P/M	TR-28 (Amstutz)
Al_2O_3, sintered	Al_2O_3, sintered	Ti-Al-V wrought	Boutin
		Co-Cr-Mo, cast	Mittelmeier

Table 3
CHEMICAL COMPOSITION OF IRON-, TITANIUM-, AND COBALT–BASE ALLOYS USED FOR ARTIFICIAL HIP JOINTS

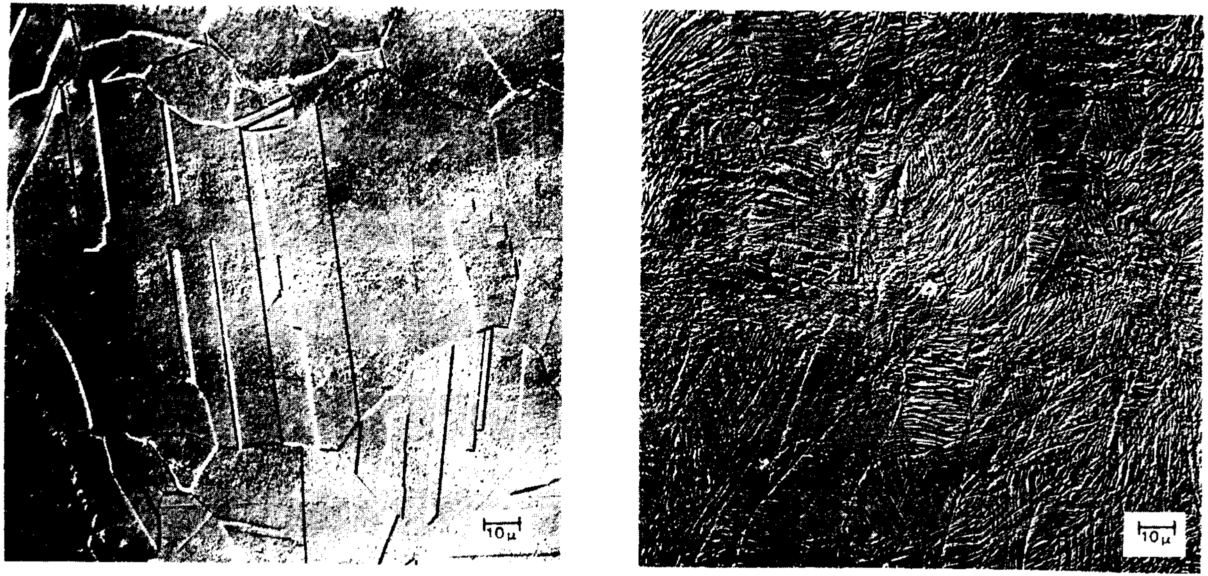
Elements, Wt%	Fe-Cr-Ni-Mo ISO 5832/1	Ti-Al-V ISO 5832/3	Co-Cr-Mo ISO 5832/4	Co-Ni-Cr-Mo ISO 5832/6
Al, aluminum		5.50—6.75		
C, carbon	—0.03	0.08	—0.35	—0.025
Co, cobalt			Balance	Balance
Cr, chromium	16.0—19.0		26.5—30.0	19.0—21.0
Cu, copper	—0.50			
Fe, iron	Balance	—0.30	—1.0	—1.0
H, hydrogen		—0.015		
Mn, manganese	—2.0		—1.0	—0.15
Mo, molybdenum	2.0—3.5		4.5—7.0	9.0—10.5
N, nitrogen		—0.05		
Ni, nickel	10.0—16.0		—2.5	33.0—37.0
O, oxygen		—0.20		
P, phosphorus	—0.25			—0.015
S, sulfur	—0.015			—0.010
Si, silicon	—1.0		—1.0	—0.15
Ti, titanium		Balance		—1.0
V, vanadium		3.50—4.50		

Wrought Ti-Al-V alloy — has been used as an implant alloy since the 1950s.[12,38] This alloy used for the anchorage stems of total hip prostheses with a Al_2O_3 ceramic ball head has proven itself clinically in more than 10,000 cases since 1972.[4,5] The alloy is obtained with two phases (hexagonal α plus cubically body-centered β-phase) at forging temperatures in the β-range with a lamellar grain structure (Figure 2A) and in the α/β-range with a globular structure of Protasul-64WF® (Figure 2B). Lower deformation rates result in a nonequiaxed globular phase mixture (Figure 2C). Heat treatment at 700 to 750°C in vacuum does not alter these structures as seen in light microscopy.

Cast Co-Cr-Mo alloy — which was first employed for hip joint cups (cup arthroplasty) about 40 years ago,[28] is still the most commonly used alloy for total hip prostheses.[17] The carbon-containing alloy has an austenitic crystalline structure with interdendritically arranged block carbides of type $M_{23}C_6$ (M = Cr + Mo + Co) in the as-cast condition of Protasul® (Figure 3A) and in the heat-treated (below 1180°C) condition of Protasul-2® (Figure 3b). These block carbides, which are readily dissolved in the solution-annealed condition (heat treatment temperature approximately 1240°C), give rise to "Kirkendall holes" (Figure 3C).

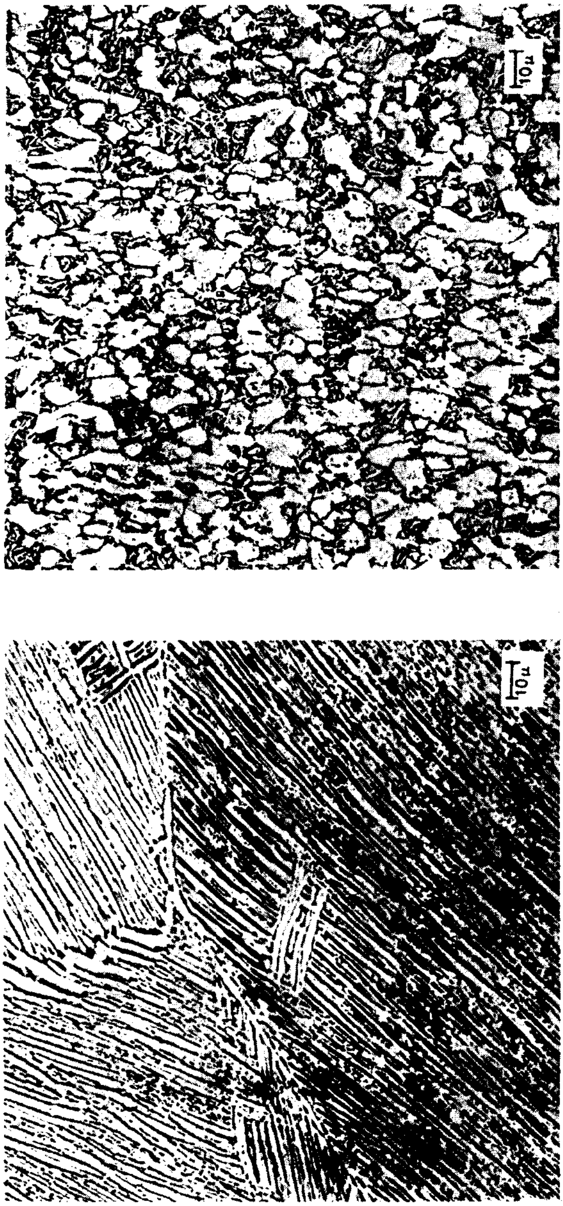
Wrought Co-Cr-Mo or P/M alloy — is a further development of the well-known and clinically proven cast Co-Cr-Mo alloy.[3,6,10,14,21,22,23] As a result of hot forging and the powder metallurgy process, respectively, the alloy shows a higher density, a much smaller grain size, and a finer distribution of block carbides (Figure 4A and B). To attain maximum strength, this material can be hot-forged at optimum deformation rates without recrystallization of the austenitic structure. A forging process of this kind results in a longitudinal orientation of the austenitic grain structure of Protasul-21WF® (Figure 4C).

Wrought Co-Ni-Cr-Mo alloy — is the first high-strength implant alloy developed at the end of the 1960s[16,20] to be used for the manufacture of highly stressed anchorage stems of artificial joints of the hip (Mueller, Weber, and Weber — Stuehmer design), the knee (GSB design), the elbow (GSB design), and the hand (Meuli design). In the recrystallization annealed condition, the alloy shows a fine-grained, totally austenitic structure (Figure 5A). Hot forging above 650°C also produces a totally austenitic structure of Protasul-10[18] with elongated grains and a lattice dislocation configuration that is hardly movable after cooling



A B

FIGURE 1. Microstructure of wrought Fe-Cr-Ni-Mo stainless steel AISI-316 L; (A) Austenitic grain structure in the annealed condition; (B) cold-deformed austenitic structure with elongated grains.



A B

FIGURE 2. Microstructure of wrought Ti-Al-V alloy. (A) Lamellar mixture of the α- and β-phase after hot forging in the β-range; (B) globular mixture of the hexagonal α-phase (light) and cubically body-centered β-phase in the hot-forged condition (Protasul-64WF® of globular quality); (C) nonequiaxed globular mixture of the α- and β-phase after hot forging in the α/β-range with a low deformation rate (Protasul-64WF® of nonequiaxed globular quality).

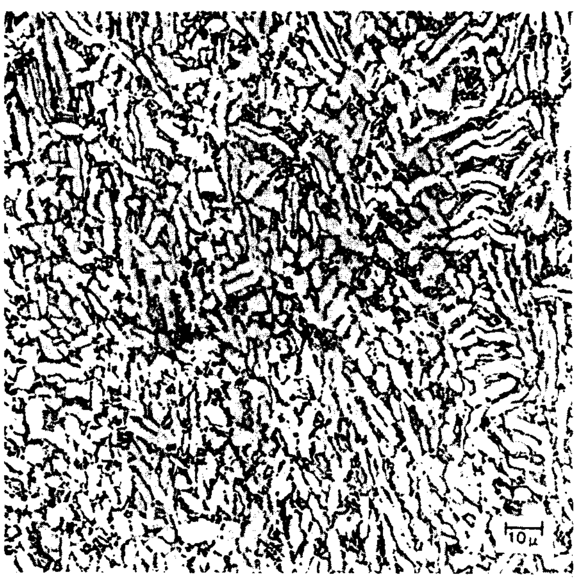


FIGURE 2C.

(Figure 5B). 50% Cold working enhances the lattice imperfection density of MP-35N® and the formation of an ϵ-martensite phase with hexagonal structure.[7,33] Subsequent heat treatment at 520 to 620°C results in precipitation of an intermetallic Co_3Mo phase (Figure 5C).

Cast Co-Cr-Mo/wrought Co-Ni-Cr-Mo double alloy — of TIG-welded composite construction[17] has been used since the early 1970s for the earlier-mentioned prosthesis types with wear-resistant cast components (Co-Cr-Mo Protasul® or Protasul-2®) and fatigue-resistant anchorage stems (Co-Ni-Cr-Mo Protasul-10®). Welding in an inert argon gas atmosphere results in an intimate combination of the two cobalt-base alloys (Figure 6A and B) of high corrosion resistance in the human body environment.

IV. MECHANICAL PROPERTIES UNDER STATIC AND DYNAMIC LOADS

Artificial hip joints implanted in the body are subjected to about 1 to 2 $\times$ 10^6 times a year by a multiple of the patient's body weight, hence, the requirement for implant materials of high mechanical strength under static and dynamic loading. These characteristic data are determined in static tensile tests and in dynamic rotating bending tests.[13] On the basis of clinical long-term experience with over 500,000 original standard Mueller and Weber total hip prostheses, stringent minimum requirements must be imposed on the strength of the metallic materials used with these total hip prosthesis types. The following strength values are therefore of vital importance in clinical application.

1. Yield strength as the measure of safety against permanent deformation of a body-loaded hip prosthesis stem (if an implanted femoral component stem is to be deformed only elastically and not plastically, a minimum yield strength of 450 N/mm^2 or higher is required.) (Figure 7)
2. Ultimate tensile strength as the measure of safety against the risk of fracture of a femoral component stem in case that it is subjected to a forced load (a minimum ultimate strength value of 800 N/mm^2 or higher is consequently required (Figure 8)

A B

FIGURE 3. Microstructure of cast Co-Cr-Mo alloy. (A) Austenitic coarse-grained structure with eutectic block carbides (dark) in the as-cast condition (Protasul®); (B) the same microstructure as in Figure 3A after heat treatment at 1180°C (Protasul-2®); (C) austenitic grain structure with "Kirkendall holes" seen in the place of interdentritically arranged block carbides after solution annealing at 1240°C.

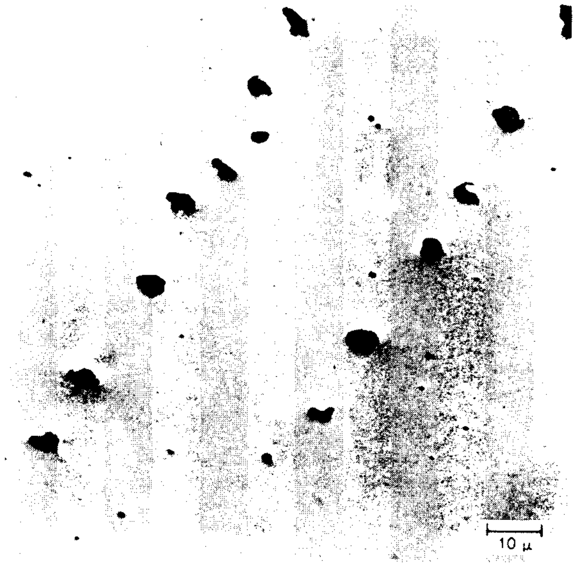


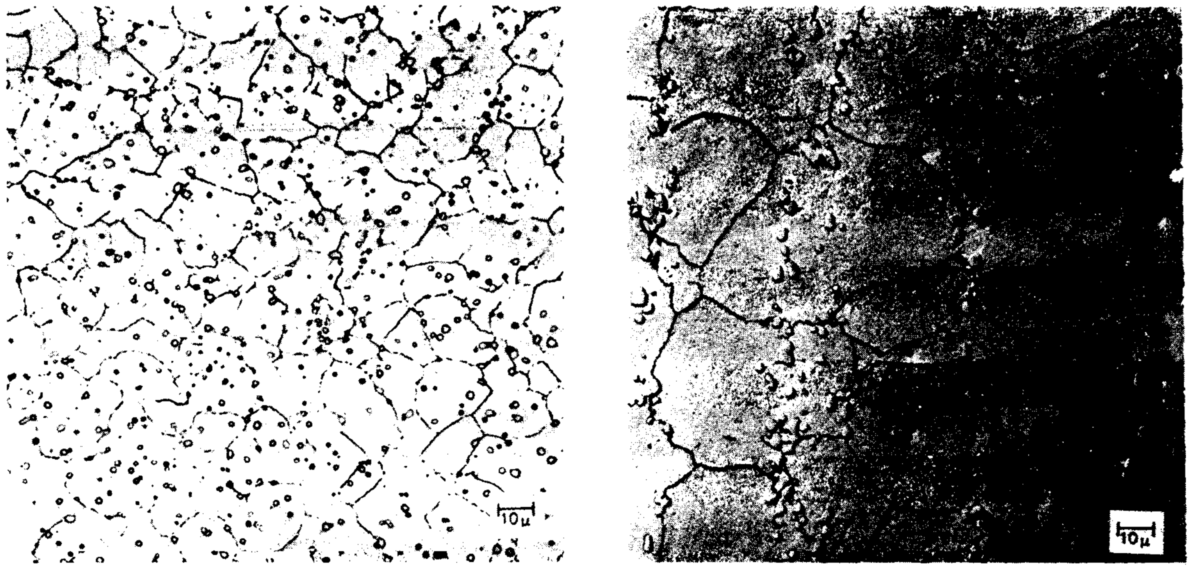
FIGURE 3C.

to protect the patient with an implanted hip prosthesis in the case of a fall. The ultimate tensile strength is, however, also decisive for the height of the fatigue strength (30 to 60% of the tensile strength) and is consequently also of great significance

3. Elongation as the measure of the metallic material's toughness should be at least 8% or higher (Figure 9). If the orthopedic surgeon requires additional bending of the anchorage stem for optimum matching to the configuration of the bone, high elongation values are recommendable.
4. Fatigue strength as the measure of safety against fatigue fracture of a femoral component stem subjected to a millionfold load in bending and torsion in the body; this especially in the case of loosened anchorage stems. Minimum fatigue strength values of 400 N/mm^2 or higher are to be attained (Figure 10) to protect the anchorage stem of the femoral component against fracture. With fatigue strength values determined in air, allowance should be made for the fact that in the case of wrought Fe-Cr-Ni-Mo stainless steel a decrease in this value is to be reckoned with under the corrosive conditions in the human body environment.[27,36] This applies to cobalt- and titanium-base alloys to a minor extent only.

When comparing the fatigue strength values of implant alloys of different makes, the following points should be particularly taken into consideration:

1. Manufacturing process used in the production of the implant material, e.g., casting cold working, hot forging or powder metallurgy process
2. Origin of the test specimens used for determining the mechanical strength values (the most conclusive values are obtained with specimens taken from the implant itself. Less conclusive are the data obtained with separately prepared test pieces, as is frequently the case with cast femoral prostheses.)
3. Surface condition (longitudinally polished or shot-peened) of flat or cylindrical test pieces used for determining the fatigue strength at 10 million load cycles with indication of the scatter values and confidence limits (It is generally known that shot peening



A B

FIGURE 4. Microstructure of high-strength Co-Cr-Mo alloy. (A,B) Austenitic fine-grained structure with a fine distribution of small block carbides in the annealed condition after the P/M process (Micro Grain Zimaloy®) and after hot forging (Protasul-21WF® of annealed quality); (C) hot-forged austenitic structure with elongated grains and finely distributed small block carbides (Protasul-21WF® of medium-hard quality).

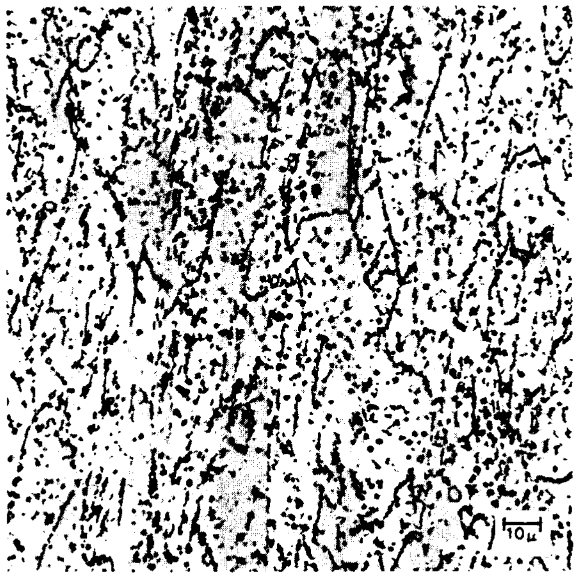


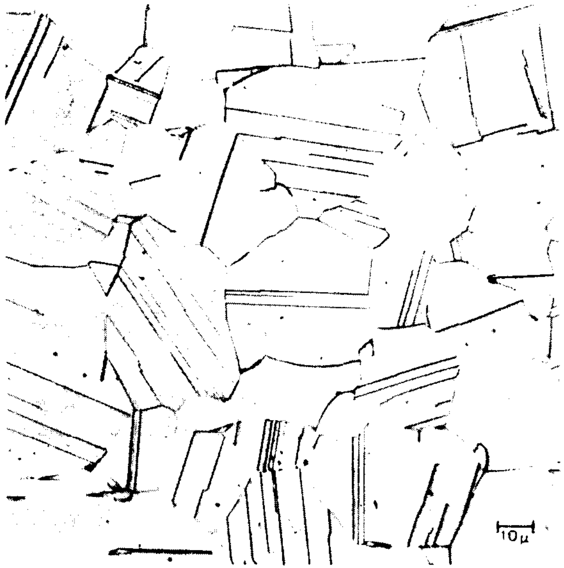
FIGURE 4C.

induces residual compressive stresses in the metallic material, whereby its fatigue strength can be increased by another 10 to 30%, as compared with mirror-finished test specimens) (Figure 11).

On the basis of the fatigue strength values obtained in rotating bending tests, the clinically applied metallic materials may be divided into two groups. The first group includes wrought Fe-Cr-Ni-Mo stainless steel and cast Co-Cr-Mo alloy, which — irrespective of the hitherto applied treatment conditions — never reaches a rotating bending strength of 450 N/mm^2. The second group with much higher values of up to 870 N/mm^2 includes wrought or P/M-produced Co-Cr-Mo alloy as well as Ti-Al-V and Co-Ni-Cr-Mo alloys in the hot-forged state.

V. CORROSION FATIGUE STRENGTH OF HIP REPLACEMENTS

When designing a hip prosthesis, the stresses expected in the human body should be known in order to be able to provide a safety factor against failure of the selected implant material. This applies in particular to loosened anchorage stems of the femoral component. For practice-oriented static and dynamic strength testing, the stem of the femoral component to be tested is inserted into a standard femur[34] in the neutral position and cemented in up to 50 mm below the collar (Figure 12). This allows severe loosening of the femoral component stem to be simulated. The distribution of stresses at the back of the stem is first determined in static bending tests by means of strain gauges (Figure 13). In this connection, the peak stresses at measuring point 3 are of major interest. For an original Mueller standard hip prosthesis made of hot-forged Co-Ni-Cr-Mo alloy Protasul-10® (yield strength = 1000 to 16000 N/mm^2) and subjected to a load of 5000 N (5 times the body weight of 100 kg), a bending stress of 1000 N/mm^2 was attained. Under this load, the stem shows a visible elastic deflection, but no plastic permanent deformation of the stem is registered. A Mueller hip prosthesis of the same design made of a material with a lower yield strength could not be loaded so highly. However, if the stem cross section to be loaded is increased, or if th



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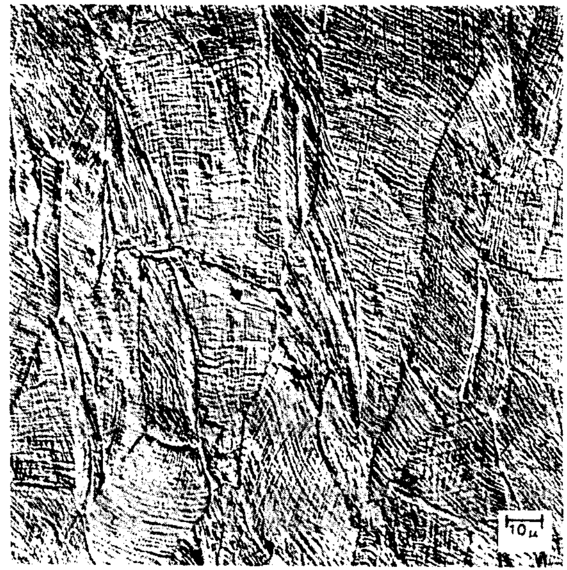

B

FIGURE 5. Microstructure of wrought Co-Ni-Cr-Mo alloy. (A) Austenitic grain structure in the annealed condition after heat treatment at 1050°C (MP-35N®/Protasul-10® of annealed quality); (B) hot-forged austenitic structure with elongated grains and subgrains showing dislocations on a submicroscopic scale (Protasul-10® of hard quality); (C) 50% Cold-deformed austenitic structure with elongated grains, hexagonal ε-martensite, and precipitated intermetallic Co_3Mo phase after heat treatment at 520 to 610°C (MP-35N of extra-hard quality, Biophase®).

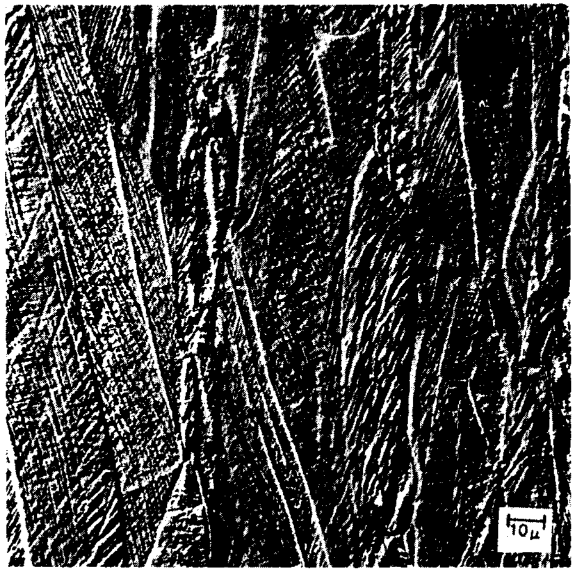

FIGURE 5C.

shape of the femoral prosthesis stem is generally changed (in the direction of lower peak stresses), the lower strength of the material (e.g., stainless steel or cast Co-Cr-Mo alloy) can be compensated through this.

As far as clinical application is concerned, it is ultimately the corrosion fatigue strength of the simulation-loosened femoral component stem (submerged in a corrosive air-fluxed Ringer's solution at 37°C) of up to 5 million cycles at a cyclic frequency of 5 to 10 Hz that is of major significance.[9,19] The latter test procedure, which has proven itself in research and production already since 1970 at Sulzer in Winterthur, may pave the way for international standardization. Determined is the maximum sustainable loadability of the simulation-loosened femoral component stem, whereby neither permanent deformation nor a fatigue crack or fracture of the prosthetic stem must occur.

The load limit of 5 million cycles has been settled upon on the basis of clinical experience with loosened femoral components which would — under similar conditions of loosening — never remain in the body for more than 1 year (1 to 2 million stress cycles). A femoral component stem that has been severely loosened for a period of several months to 1 year should certainly be able to withstand a severe overload without any failure. Consequently, this should contribute to preventing the removal of loosened femoral components under aggravated conditions involving risks to the patient and thus facilitate reoperation of loosened femoral prostheses that have not undergone any fatigue fracture.

The conclusiveness of this test method for the safety of a femoral prosthesis model against fracture is illustrated by the example of the Mueller hip prosthesis manufactured from two different implant alloys of different strength. Following the so-called staircase technique, as many as 10 hip prostheses are pulsated at varying loads of up to a maximum of 5 million cycles (some of them even up to 10 million cycles). To determine the corrosion fatigue strength, the ruptures obtained in this test and the pulsated prostheses without rupture are entered into a Woehler diagram (Figure 14).

At the same stem geometry of the Mueller hip prosthesis and under the same test conditions, this reveals that the safe limit of corrosion fatigue loading is of the order of 1400 *N* (corresponding twice the body weight of 70 kg) for annealed wrought Fe-Cr-Ni-Mo stainless

A B

FIGURE 6. Microstructure of the TIG-welded combination of two cobalt-base alloys in the case of Weber total hip prostheses. (A) Articulating component (above) made of cast Co-Cr-Mo Protasul-2® alloy welded to a hot-forged Co-Ni-Cr-Mo Protasul-10® anchorage stem; (B; detail from Figure 6A showing the transition from the welding zone (above) to the recrystallized structure of the Protasul-10® alloy.

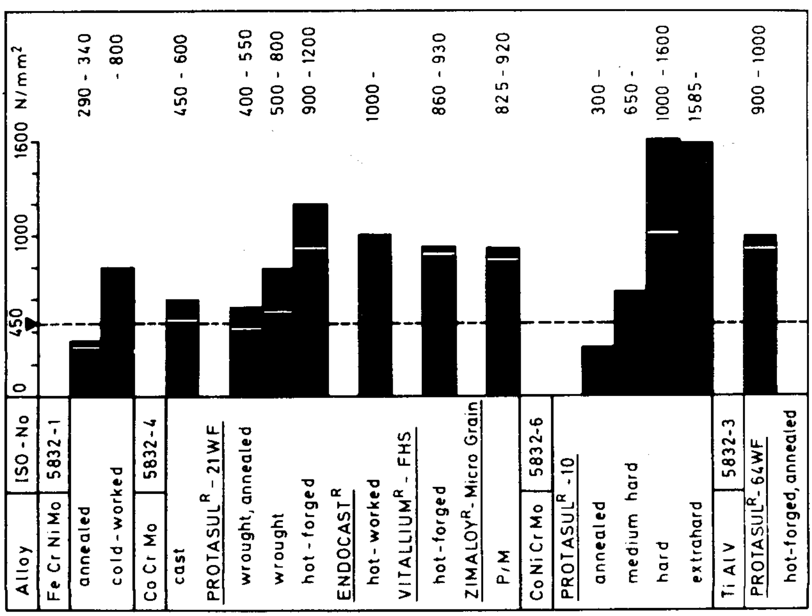

FIGURE 7. Yield strength values at 0.2% elongation of implant materials used for artificial hip joints.

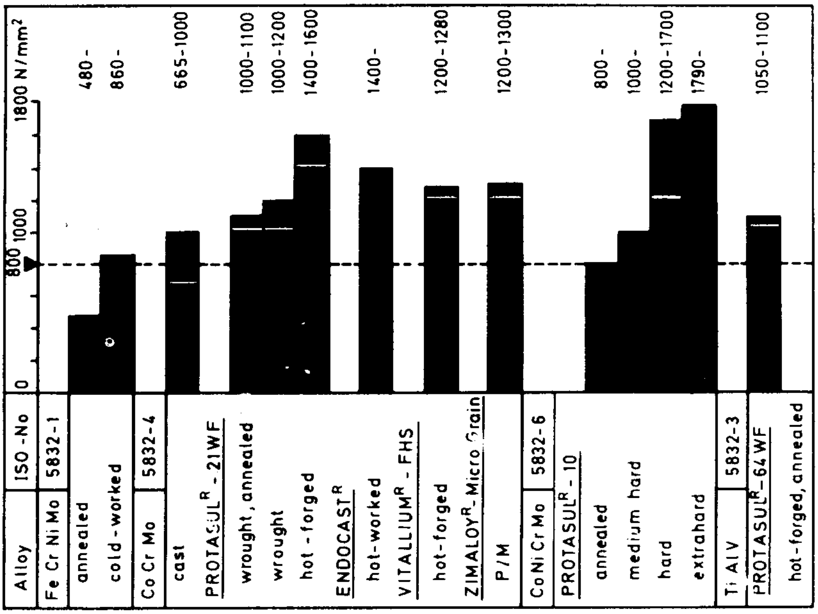

FIGURE 8. Ultimate tensile strength values of metallic implant materials used for artificial hip joints.