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1.4.1 Metals, surfaces, and tissue interactions

Implant requirements

The selection of implant material depends predominantly on the function to be accomplished and also on the manner in which the implant will be applied. Materials applied for internal fixation must fulfill various fundamental mechanical requirements. Of the potential biomaterials available, only metal can currently provide the stiffness and strength required as well as ductility and, importantly, biopassivity for the majority of craniomaxillofacial (CMF) fracture fixation applications. Resorbable and nonresorbable polymers are also used for specific CMF applications when the implants are subjected to relatively low stress.

In terms of bone fracture fixation and eventual bone healing, material stiffness is essential since it functions to avert buckling at the injury site as well as reducing fracture-site movement so that tissue repair will occur correctly. The ductility of a material determines the degree to which a device can be deformed or contoured. As titanium (Ti) has a lower ductility compared with stainless steel (SS), Ti provides less warning and can be a cause of handling issues resulting in breakage for the surgeon. The strength of a device (level of load that can be tolerated by the implant before failure) is also a consideration as it is required to maintain reduction and stability of the fracture site. Even more significant is a material resistance to fatigue brought on by repetitive load. Although SS has a better resistance to static load compared with Ti, Ti and its alloys prove superior under high cycle fatigue–loading conditions.

1 Metals

Type 316L SS meeting ISO 5832-1 and ASTM F 138/139 material standards has been used for AOCMF implants for more than 20 years. The trend in the last 20 years has been a replacement of SS by Ti for CMF applications because removal is not suggested. The driving force behind this change is primarily related to the superior corrosion resistance, lower stiffness, and enhanced diagnostic imaging compatibility associated with Ti and its alloys.

Implant-quality 316L is an iron-base alloy with approximately 62.5% iron, 18% chromium, 14% nickel, 2.5% molybdenum, and minor elemental additions. Titanium is essentially pure Ti which is available in five grades according to ISO 5832-2 with different ultimate tensile strength, 0.2% yield strength, and elongation or ductility combinations. Minimum tensile properties for annealed Ti grade 1 extra low interstitial, grades 1–4, Ti-6Al-7Nb alloy, and Ti-15Mo alloy are compiled in **Table 1.4.1-1** for bar product. Titanium-15Mo alloy can be provided in either the β or the α+β condition depending on the heat treating temperature that is selected.

Titanium alloys, such as Ti-6Al-7Nb or Ti-15Mo, may be selected when a higher stress resistance is required. Ti-6Al-7Nb tends to exhibit higher tensile strength but lower ductility compared with Ti. Ti-15Mo is a relatively new Ti alloy that offers some improved implant design opportunities

Alloy	Ultimate tensile strength, MPa	0.2% yield strength, MPa	Elongation, %	Standards
Ti grade 1 extra low interstitial	200	140	30	ISO 5832-2
Ti grade 1	240	170	24	ISO 5832-2 ASTM F67
Ti grade 2	345	275	20	ISO 5832-2 ASTM F 67
Ti grade 3	450	380	18	ISO 5832-2 ASTM F67
Ti grade 4	550	483	15	ISO 5832-2 ASTM F67
(β) Ti-15Mo	690	483	20	ASTM F 2066
(α + β) Ti-15Mo	900	800	12	ASTM F 2066
Ti-6Al-7Nb	900	800	12	ISO 5832-11 ASTM F1295

Table 1.4.1-1 Minimum tensile properties for annealed titanium (Ti) implant materials.