

Unalloyed titanium for implants in bone surgery

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Summary¹

Commercially pure (c.p.) titanium has proven its suitability as an implant material in bone surgery over many years in the fields of osteosynthesis, oral implantology, and in certain applications in joint prosthetics. Excellent biocompatibility and corrosion resistance are outstanding features. Furthermore, c.p. titanium is known for not causing allergic reactions. The different grades of c.p. titanium and their minimum mechanical properties are specified in ISO and ASTM standards for implant materials. Typical mechanical properties are given for AO ASIF implant applications. The properties and clinical performance of c.p. titanium are discussed and compared to those of implant stainless steel and titanium alloys.

In brief some specific features relating to c.p. titanium implant material are treated, including biocompatibility and soft tissue and bone response and taking into account the effects of implant surface configurations at the same time. In addition, issues are addressed which arise from frequent inquiries from clinics.

Keywords: titanium implants, bone surgery, biocompatibility, osseointegration, allergy
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Introduction

As early as 1965 Dynamic Compression Plates (DCP's) and corresponding screws made of pure titanium were introduced by the AO/ASIF. The reasons for the choice

of this material were its impressive biocompatibility, its high corrosion resistance and specific mechanical properties. To date, titanium has found increasing application as an implant material.

Titanium was discovered much later than the other common metals. The existence of an unknown element was suspected when the Periodic Table of chemical elements was developed and it was named "Titanium" in 1795. A corresponding metallic substance was detected in 1825, but it took another hundred years before it was possible to obtain the pure titanium metal.

Only with modern 20th century technology was it possible to recover the metallic titanium from its minerals, mainly from the highly resistant oxide ore TiO_2 rutile, and transform it into a pure and useful metal. The high affinity between titanium and oxygen and other gaseous elements (H, N, C) and the high thermodynamic stability of the titanium dioxide require high-energy and vacuum techniques to produce this metal. The industrial production of titanium metal with acceptable properties only started in 1946. Its light weight combined with strength, and the development of titanium alloys of even higher strength, made this material indispensable in aircraft construction. The light weight, which is only half of that of steel, is also an advantage in bone surgery in cases in which massive implants must be applied.

Chemical composition

The unalloyed pure metal is described as commercially pure (c.p.) titanium. The mechanical properties of the titanium depend very much on the amount of trace elements present. Thus, 4 grades of titanium are distin-

¹ Abstracts in German, French, Italian, Spanish, Japanese and Russian are printed at the end of this supplement.

guished for technical as well as biomedical applications. The international standard ISO 5832-2 (1999) Implants for surgery – Metallic materials – Part 2: Unalloyed titanium, specifies the chemical and mechanical properties for c.p. titanium as a surgical implant material. Similar requirements are given in the American ASTM F 67 standard.

Table 1 indicates the chemical composition of the 4 titanium grades of ISO 5832-2. In this 1999 version an additional extra low interstitial (ELI) grade was introduced. In Table 2 the corresponding requirements for the mechanical properties are shown. For grade 4 an annealed (4A) as well as a cold-worked (4B) condition is specified. It is obvious that with increasing amounts of trace elements (predominantly oxygen) the tensile strength increases while the elongation (a measure of ductility) declines. In order to favour increased strength combined with sufficient ductility, a titanium material with a restricted chemical composition which still fulfils the requirements of the ISO and ASTM standards is used for most of the AO/ASIF implants.

Table 1: Chemical Composition for Various CP Titanium Grades corresponding to ISO 5832-2: 1999
Maximum Compositional Limits in Weight-%

Element	Grade 1 ELI	Grade 1	Grade 2	Grade 3	Grades 4A / 4B
Nitrogen	0.012	0.03	0.03	0.05	0.05
Carbon	0.03	0.10	0.10	0.10	0.10
Hydrogen	0.125*	0.125*	0.125*	0.125*	0.125*
Iron	0.10	0.20	0.30	0.30	0.50
Oxygen	0.10	0.18	0.25	0.35	0.40
Titanium	balance	balance	balance	balance	balance

* for billets hydrogen maximum 0.0100%; for flat products hydrogen maximum 0.015%

Table 2: Mechanical Properties for Various CP Titanium Grades corresponding to ISO 5832-2: 1999

Grade	Condition	Ultimate Tensile Strength min MPa	Proof Stress $R_{p0.2}$ min. MPa	Percentage Elongation* min. %
1 ELI	Annealed	200	140	30
1	Annealed	240	170	24
2	Annealed	345	275	20
3	Annealed	450	380	18
4A	Annealed	550	483	15
4B	Cold-worked	680	520	10

* Gauge length 50 mm or $5.65 \sqrt{S_0}$, where S_0 is the original cross-sectional area in square millimetres.

Microstructure

Titanium has a hexagonal close packed atomic lattice structure (α titanium) which is stable up to 882°C, and transforms into a cubic face centred structure (β titanium) above this temperature. Below 882°C this β -structure can only be stabilized through the addition of specific alloying elements, resulting in β - and $\alpha+\beta$ alloys (see section on Titanium Alloys). In contrast, the implant stainless steel has a cubic face centred crystal lattice; and certain differences in the mechanical behaviour of titanium and steel are explained by the different deformation mechanisms of their crystal structures.

A micrograph of a typical c.p. titanium micro-structure is shown in Figure 1a. For comparison Fig. 1b shows an $\alpha+\beta$ structure of the titanium-6aluminium-7niobium alloy, the material which is used for AO ASIF implants where higher strength is desired than c.p. titanium can offer (e.g. for certain spine implants, screws, intramedullary nails etc.).

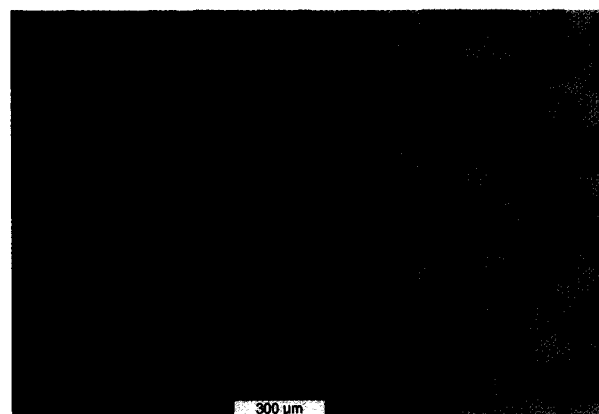


Fig. 1a: Microstructure of c.p. titanium

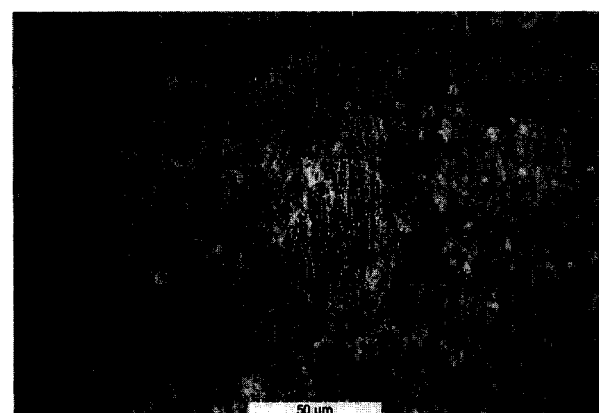


Fig. 1b: Typical microstructure of the two-phase $\alpha+\beta$ titanium alloy Ti-6Al-7Nb.

Mechanical properties

Tensile properties

Table 2 presents the mechanical properties for the different grades of c.p. titanium as specified by the ISO 5832-2 standard. For most AO ASIF implant types the strength level of 680 MPa as given in this standard for grade 4B cold-worked titanium is greatly exceeded; typical ultimate tensile strength values are 800-830 MPa with a minimum percentage elongation of about 10%.

Ductility

In general, the mechanical properties of the material are adjusted to the type of AO ASIF implants and their typical clinical performance requirements. For example, for plates which have to be contoured to fit the shape of the bone surface, sufficient plastic deformability (ductility) must be provided. This restricts the level of tensile strength to certain practical limits because the ductility usually decreases with increasing strength (Table 2).

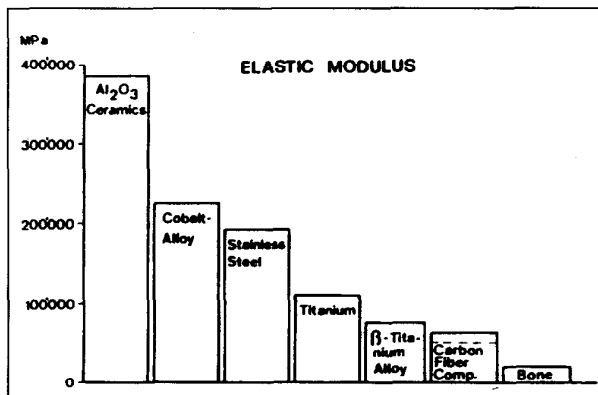


Fig. 2: Comparison of the elastic moduli of different implant materials.

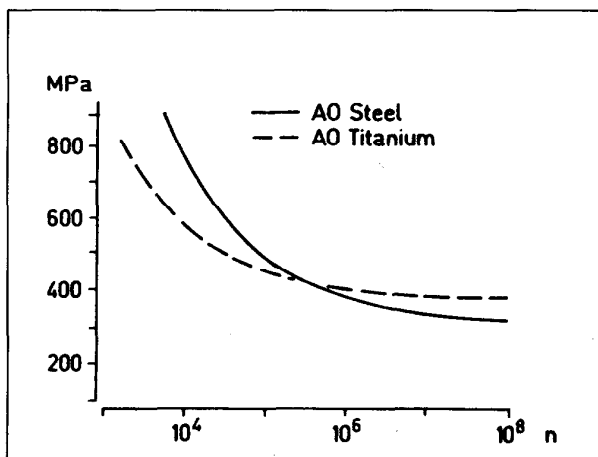


Fig. 3: Diagram showing applied stress versus number of cycles to failure with Wöhler curves of fully reversed bending fatigue-tests for implant c.p. titanium and stainless steel.

Due to its hexagonal crystal structure, c.p. titanium does not have the same extraordinary range of deformability as implant steel; the latter being outstandingly "forgiving" compared with other technical materials. Therefore, the contouring of c.p. titanium implants has to be performed very carefully.

The subtle differences observed in the behaviour of titanium bone screws compared with steel screws (see chapter on Stainless Steel) are also a result of reduced plastic material flow due to the nature of the atomic structure of the c.p. titanium.

Elastic modulus

The c.p. titanium and its alloys typically have a lower elastic modulus, this means higher flexibility than other biomaterials except for polymers. As seen in Fig. 2, the elastic modulus of titanium is thus much closer to that of bone. Consequently, the elastic deformation of titanium implants is closer to that of bone whereby local stress concentrations in the bone are reduced which might otherwise build up in connection with a stiffer implant. Within a certain load range the fatigue resistance of implant titanium is increased compared with steel because stresses are reduced due to the lower elastic modulus of the titanium material [1]. Figure 3 shows fatigue curves for implant stainless steel and titanium where the fatigue strength of titanium surmounts that of steel in the high cycle fatigue range. Alloying offers a possibility to raise the tensile and fatigue strength of titanium.

Fatigue fractures

Depending on the clinical situation, occasionally titanium implants can fail by a fatigue fracture mechanism if, beyond a certain critical stress level, cyclic loads are exerted on an implant. As for implants made of other materials, this may occur under conditions of instability and delayed bone healing. The fatigue mechanism generally follows the same stages of (a) crack initiation on the surface, (b) crack propagation through the implant, and (c) final overload fracture after severe reduction of the cross sectional area, as has been described for stainless steel implants [2].

During crack propagation the individual load cycles (e.g. a loading/unloading weight bearing step) leave a microscopically small deformation mark at the crack front. These lines running parallel appear as so-called fatigue striations on the fracture surface. The sequences of striations each represent increments of crack propagation and are unmistakable signs of a fatigue fracture mechanism (see Figures 4 and 5).

In general, the formation of the crack propagation is influenced by the applied load and the microstructure of the material; and therefore in addition to the fatigue

striation patterns other morphological structures can appear on the fracture surface. These additional morphological patterns reflect the crystallographic microstructure and orientation and, consequently, are different for stainless steel and titanium materials. They are mainly found in the early stages of crack propagation before a uniform crack front has formed. Figure 4 shows such structures on a c.p. titanium fracture surface where deformation twins and terraces are visible beside fatigue striations. In contrast, Fig. 5 shows a stainless steel fracture surface where horizontally oriented fatigue striations are superimposed on vertically oriented cubic slip systems.

Biocompatibility and surface interactions

Titanium is well known for its excellent biocompatibility. This is expressed by two major observations: (a) the very favourable response of tissues to titanium surfaces, and (b) the absence of allergic reactions to titanium.

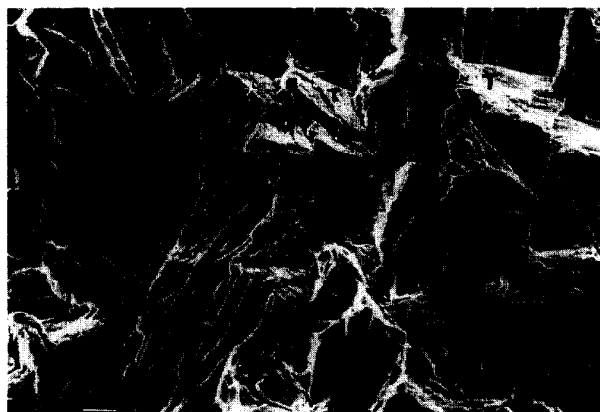


Fig. 4: C.p. titanium fracture surface with deformation twins (arrows) and terraces (T) besides mostly horizontally oriented fatigue striations indicating the crack front.



Fig. 5: Stainless steel fracture surface with horizontally oriented fatigue striations superimposed on longitudinally oriented slip systems characteristic of cubic face centred metals.

Besides the long-term clinical experience, the latter is also demonstrated by the fact that titanium dioxide is used as a basis for many ointments and cosmetics because it has proved not to cause allergies. This titanium dioxide forms spontaneously on c.p. titanium surfaces as long as oxygen is present and protects it from corrosion by forming a thin film, the so-called *passive film*. This passive film regenerates immediately after mechanical destruction, as can be demonstrated in a scratch test in 0.9% NaCl solution, where the electrochemical potential is monitored over time (Fig. 6). Thus, titanium implant surfaces that were damaged by contouring or wear will be protected again instantaneously. This is the reason why morphologically no corrosion attack is found under fretting conditions such as relative motion between titanium screw heads and plate holes, although mechanical wear may take place [3].

Similar protective oxide films of variable thickness can be created by electrochemical means through "anodizing". As a function of the film thickness different colours are generated through light diffraction at the thin films. This technique is highly reproducible and is also used for colour coding of AO ASIF titanium implants, e.g. to distinguish different sizes, applications etc. Slight colour shifts can be observed on anodized titanium implants after multiple sterilization. This has no adverse effect because it is usually the result of a slight increase of the film thickness through oxidation. When alteration or dulling of the colour is caused by surface contamination such as fingerprints, grease etc., rinsing with medical grade alcohol or standard hospital cleaning procedures will usually bring out the original colour.

For internal fixation, titanium implants are always an alternative to stainless steel implants for patients who are allergic to nickel. Clinical experience shows that the exchange of the steel implant with a similar replacement implant or a custom-made device of c.p. titanium or Ti-6Al-7Nb will result in disappearance of the sensiti-

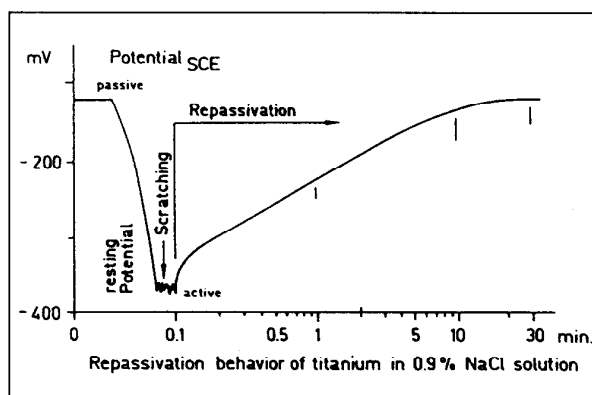


Fig. 6: A titanium implant was exposed to a 0.9% NaCl solution, and potential over time was recorded. After a stable open circuit potential was reached, the surface was scratched and became active due to destruction of the passive film. Repassivation occurred as soon as the scratching was stopped.

zation symptoms. Furthermore, clinical experience indicates that in cases where infection is a risk [4,5], the application of titanium implants is preferable.

In various studies within the AO ASIF group in which soft tissue samples were excised from the contacting titanium plates at routine implant removal, healthy tissues without inflammatory responses on the histological sections were always found, even when wear particles were present locally. In cases of instability, wear between implant components can cause tissue impregnation with small wear particles of an average size of 1-5 microns which creates a blue-grey tissue staining. Such events are rare and are usually found very locally at the tissue sites [3,6,7]. Bone resorption as reported in connection with cemented titanium alloy prostheses was never observed nor reported for osteosynthesis implants of c.p. titanium or titanium alloys.

As a general remark it might be pointed out that titanium and its alloys are known for not having particular good wear properties.

In comparison with other metals, titanium ranks always very high regarding the favourable response of the biological environments. This is found in *in vitro* testing in cell culture and organ culture assays [8]. The same is observed in *in vivo* tests with implants placed subcutaneously, in contact with muscle and connective tissues [9,10], and bone [11].

Soft tissue response

In a test model where small plates of different materials were mounted on the tibiae of rabbits [9], the soft tissue mantle that covered the plate was investigated histologically and the cell population and tissue capsule were evaluated quantitatively. The tissue response to the titanium surfaces was always the mildest. A tissue capsule is almost absent in contact with the c.p. titanium surface; a thin uniformly oriented tissue layer is more likely to occur (Fig. 7a). Although no inflammatory responses have been observed, a greater reaction found to the stainless steel implant surfaces has been observed (Fig. 7b).

An additional factor has to be considered in the investigation of tissue reactions. As this and other studies [10] clearly indicate, the tissue response is not only a reaction to the material as such, but also to its surface texture. Highly polished surfaces allow a certain relative motion of the tissue along the implant surface causing an additional tissue reaction to the motion; furthermore, the formation of a fluid-filled space at the interface is propagated. On the other hand, rough surface textures can stabilize soft tissue motion through increased friction and the propagation of cell attachment. This might inhibit the formation of fluid-filled spaces at the interface. Such a mechanism is thought to counteract the spreading of infectious microbial contamination.

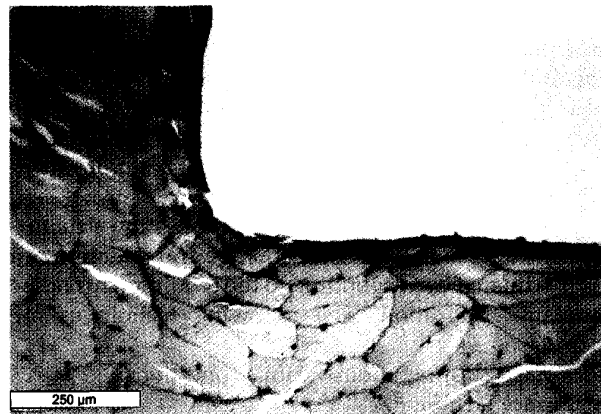


Fig. 7a: Histological section through soft tissue in contact with a titanium implant surface

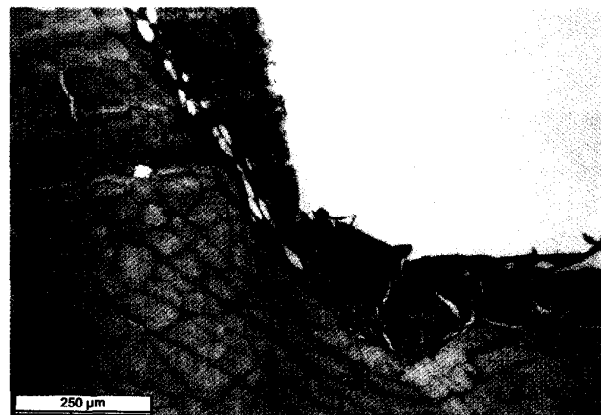


Fig. 7b: Histological section through soft tissue in contact with a steel implant surface

Bone response

There is a fascination with the observation of the immediate bone apposition to titanium surfaces. Long-term clinical experience in the fields of osteosynthesis, dental surgery and prosthetics, as well as histological studies show that bone is able to "integrate" titanium implants. Bone cells and mineralized bone matrix are laid down on titanium surfaces without interposition of other tissues, although coverage of the implant surface with organic molecules may occur first.

The precondition for primary bony attachment is a critical minimum of primary implant stability, and a critical minimal distance between implant surface and bone.

Early in the observation of bone apposition on titanium implant surfaces and its effectiveness [11], the term "osseointegration" (later also termed "osteointegration") was introduced [12]. Today there are models proposed which can explain the powerful bonding between titanium surface and bone [13].

The effect of bone anchorage on titanium implants can be enhanced by roughening or 3-dimensional structuring of the surfaces. Implant retention is caused by various factors such as the increase of the surface area, the increase of friction, and by surface interlocking on a microscopic scale in the case of undercuts and 3-dimensionally porous structures.

With the intensity of surface roughness and structuring, the degree of implant anchorage and retention can be modulated corresponding to the requirements of the implant application. The following techniques are popular:

- Surface blasting under various conditions
- Surface etching
- Surface blasting and etching
- Titanium plasma spraying
- Beaded layers
- Fine wire networks
- Texturing by various means

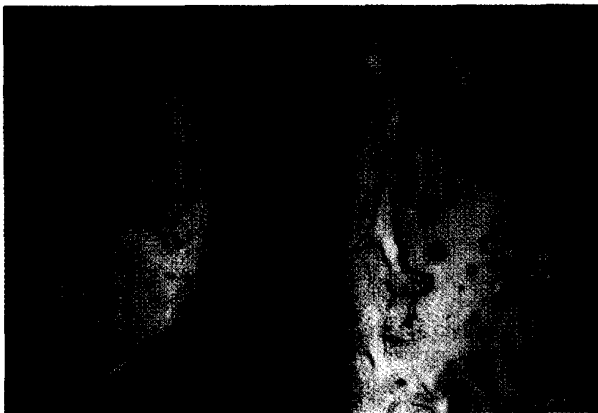


Fig. 8: Overview of an osseointegrated plasma sprayed titanium implant which is still in situ (black area). Newly formed bone is attached to the implant fenestrations which were empty originally.



Fig. 9: Histological section with titanium plasma sprayed bone screw in situ (black). Apposition of new bone (dark) directly on the implant surface and in connection with the old bone (light) after 4 weeks.

In order to improve implant retention, for joint replacement components almost all of the listed techniques are applied, the last three of them somewhat exclusively. Plasma sprayed surfaces and etching techniques are predominantly used for dental implants such as artificial tooth roots which are intended to remain permanently in the body like prostheses [14].

Figure 8 demonstrates the osseointegration of a clinically loaded titanium plasma sprayed dental implant where new bone formation took place in the originally empty implant fenestrations and along the implant surfaces. The apposition of new bone at a titanium plasma sprayed bone screw surface is seen in Fig. 9 four weeks after implantation. After 12 weeks new bone covers almost the entire implant interface and new osteons have formed. By then the holding resistance or retention of the screws is so much increased that the torque moment necessary to retrieve the screws is 14 times higher than for standard smooth steel screws of the same design [15].

Osteosynthesis implants are frequently retrieved after bone healing. This limits the degree of surface roughness because otherwise the implants could not be removed. Selected blasting and etching techniques are applied for osteosynthesis AO ASIF implants. In cases in which screws are to be seated in bone of weak quality (osteoporosis, radiation damage), titanium plasma sprayed surfaces have been applied (e.g. on screws which are used in the fixation of tumour resections).

It might be mentioned here that the coverage of implant surfaces with calcium phosphates (hydroxyapatite, tricalcium phosphate) is another means of stimulating bone apposition. Such treatments are also applied in combination with textured surfaces.

Imaging

The c.p. titanium implants are not ferromagnetic and do not cause harm to the patient in magnet resonance imaging (MRI) units. Furthermore, they have the advantage that less image destruction occurs in their vicinity than with implants of stainless steel or cobalt alloys. (About 40% less than with implant steel).

Conclusions

c.p. titanium is an excellent implant material because of its high corrosion resistance and outstanding biocompatibility. It is known for not causing allergic reactions and it is preferred when infection is a risk. Its low elastic modulus and flexibility are advantages in many applications.

The mechanical properties can be modified in a certain range by choosing a suitable titanium grade and by work strengthening. Its ductility is not as high as that of

implant stainless steel, but higher than that of $\alpha+\beta$ titanium alloys. Where higher strength is required than offered by the c.p. titanium, the application of a suitable titanium alloy is an alternative.

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