

1.3 **Implants and materials in fracture fixation**

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1.3 Implants and materials in fracture fixation

1 General requirements

- The implant material of choice for internal fixation remains metal, which offers high stiffness and strength, good ductility, and is usually well tolerated biologically.

Metal implants are made either of stainless steel (ISO 5832-1), commercially pure titanium (cpTi) (ISO 5832-2), or titanium alloys such as titanium aluminum niobium (TAN) (ISO 5832-11). Recently titanium alloys such as titanium molybdenum (Ti-15Mo) (ASTM F2066) have been used for special applications. Ceramics, polymers, carbon composites, and degradable materials are also used, although mainly for special applications [1]. They are usually not used in situations, where high loads are to be expected, unless a metal fixation is also present.

Implant materials used for internal fixation must conform to certain basic requirements; reliable function and minimal side effects are obvious and equally important. Less evident is the need for appropriate handling qualities. The selection of material properties and implant design must respond to several conflicting requirements. The aim of this chapter is to introduce the surgeon to the basic principles used when selecting materials and designing internal fixation devices.

2 Material properties

2.1 Stiffness

Stiffness is the ability of a material to resist deformation and is measured as the relationship between load applied and the resulting elastic deformation. The inherent stiffness of a material is its modulus of elasticity. The stiffness of an implant results from the modulus of elasticity and the shape and dimensions of the implant itself. As an example, the modulus of elasticity of cpTi is about half that of stainless steel, and so, under similar load conditions, it will deform twice as much (Fig 1.3-1). However, the dimension of the implant is important as well: Increasing the thickness of a standard cpTi plate by a few tenths of a millimeter will augment its bending stiffness. Fracture of a bone can be understood as discontinuity of bone stiffness.

- Osteosynthesis restores bone stiffness temporarily; fracture healing restores it permanently.

![Fig 1.3-1 Under similar bending condition and with identical cross sections, the titanium plate deforms nearly twice as much as the steel plate. This is due to the lower modulus of elasticity of titanium (titanium approximately 110 GPa, steel about 200 GPa).]
When we consider an implant (nail, plate, or external fixator) spanning a fracture, the stiffness of the implant must prevent deformity at the fracture site. To allow proper healing the device must reduce fracture mobility to below the critical level at which healing tissue will form. Granulation tissue and cartilaginous callus will form under conditions of higher dynamic deformation (strain) than the final mineralization, since the bone cannot tolerate strain as much as the granulation tissue can (approximately 2% cortical bone compared to approximately 15% cartilage and 100% granulation tissue) (chapter 1.2; 3.3.2).

In the past, attempts have been made to produce implants that have a material stiffness similar to bone, using plastic or carbon reinforced composites [2, 3]. These implants reduce the stress shielding that occurs with stiff, metal implants that take the load away from the bone. However, implants with very low material stiffness do not as a rule offer an acceptable balance between biological and mechanical advantages.

- Less stiff implants reduce but do not abolish stress shielding.

Research has shown that early temporary porosis of bone in contact with implants does not depend upon the degree of unloading (stress shielding) but rather on the amount of direct vascular damage caused by the implant [4].

### 2.2 Strength

Strength is the ability of a material to resist the application of forces without deformation. Thus, strength determines the level of load an implant can resist. Before a metal breaks it may irreversibly deform (this is called plastic deformation). Here again, the dimensions of the implant are often more important than the strength of the material. The strength of cpTi is about 10% less than that of steel (Tab 1.3-1), but an increase of implant cross section will compensate for the difference in material strength. Strength determines the limit of stress (force per unit area), which results in deformation.

- For internal fixation, the resistance of an implant to repeated load, which may result in failure by fatigue, is a critical issue.

Compared to steel, cpTi is somewhat less resistant to single loads, but superior when high-cycle repeated loads are applied (Fig 1.3-2) [5].

<table>
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<th>Elongation</th>
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<td>Stainless steel (cold-worked)</td>
<td>ISO 5832-1</td>
<td>960 MPa</td>
<td>15%</td>
</tr>
<tr>
<td>Unalloyed (commercially pure) titanium grade 4B (cold-worked)</td>
<td>ISO 5832-2</td>
<td>860 MPa</td>
<td>18%</td>
</tr>
<tr>
<td>Ti-6Al-7Nb</td>
<td>ISO 5832-11</td>
<td>1060 MPa</td>
<td>15%</td>
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**Tab 1.3-1** Typical mechanical properties of implant materials used for bone screws.
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4.5 mm narrow plate
- LC-DCP titanium
- DCP titanium
- DCP steel

Number of cycles at failure

Fig 1.3-2 Fatigue resistance—the influence of material and design. Fatigue tests of dynamic compression plates comparing stainless steel and commercially pure titanium under conditions of controlled angular deformation. Under low-cycle conditions steel is better. In internal fixation where high-cycle fatigue conditions are more relevant commercially pure titanium is superior. The influence of the design was demonstrated, whereby the LC-DCP with its continuous stiffness along the plate proved to be superior to the DCP.

2.3 Ductility

The ductility of a material is the degree of permanent (plastic) deformation it tolerates before it breaks.

- The ductility of a material determines the degree to which an implant, such as a plate, can be contoured.

As a general rule, materials of high strength such as titanium alloys and highly cold-worked cpTi offer less ductility than steel. Ductility provides some forewarning of impending failure, for instance during insertion of a screw. According to international standards, a 4.5 mm cortex screw (ISO 6475) must tolerate more than 180° of elastic and plastic angular deformation before breakage (Fig 1.3-3). However, cpTi, having lower ductility, provides less prewarning, which means that the surgeon should first acquire some bench experience leading to a different handling technique. The possible problems due to lower ductility of cpTi may be overcome by the design of the implant. In a clinical test series with more than 2,000 locked head (without thread on screw head or plate) PC-Fix screws, failure was observed neither at insertion nor thereafter [6]. This demonstrates that the choice of an implant material must be matched with the correct design for its application.
2.4 Corrosion resistance

- Corrosion is an electrochemical process that results in the destruction of metal by the liberation of ionic metal.

Corrosion differs in implants made of one single component to implant systems with several metal components. Stainless steel, cpTi, TAN, and Ti-15Mo, if tested as a single element (ie, only as a plate or screw and not as a combination of the two), are highly resistant to corrosion, even in the environment of body fluids. This is due to a protective, passive layer which forms on their surfaces. Titanium and titanium alloys have extreme chemical inertness. An oxide passivation film forms on titanium and its alloys that is much more corrosion resistant and thermodynamically stable than the chromium oxide film that forms on stainless steel. The passive layer on titanium is formed very quickly, is electrically isolating, and the implant shows literally no corrosion (Fig 1.3-4). Since the polarization plots for cpTi, TAN, and Ti-15Mo are similar, the materials could be used for multicomponent device applications; galvanic corrosion would not be expected. Cobalt alloys, which are successfully used in single element endoprosthetic implants, are not currently used in internal fixation implants due to their susceptibility to galvanic corrosion when in contact with steel.

- Erosion is a physical process that results in structural degradation of the implant surface, with the release of material debris that ranges in size down to a few nm.

In orthopedic medicine, the major form of erosion is fretting [7] encountered in modular implant systems (such as when a screw head moves in relation to the plate hole). Fretting occurs with micromotion between two adjacent implant surfaces. This results in the release of submicron sized particles into nearby tissue. Fretting particles cause a number of clinical complications. Experimentally produced debris from steel, cpTi, and an alloy Ti-15Mo, when examined in vitro, showed phagocytosis of particles of all three materials by macrophages in a dose dependent response. Steel particles also inhibited cell proliferation, even when the particles were not in direct contact with the cells, and caused cell membrane damage. When two implants made of cpTi are moved against each other under load, metal debris from abrasion may be observed in the local surrounding area (with particle sizes often larger than 10 μm [8]), giving a harmless discoloration in the tissues. Steel wear debris has been observed in organs remote from the site of the implant, showing that it can disseminate around the body [9]. When steel fretting occurs, the particles produced are less than 0.5 μm in size [8] and can be easily transported away from the implant site. If submicron titanium particles are transported away from the implant site, they should not elicit a tissue reac-

![Fig 1.3-4 Repassivation behavior of titanium in 0.9% NaCl solution after scratching the surface with a needle.](image-url)
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Implants and materials in fracture fixation due to their high biocompatibility. Up until now, no publications have shown tissue reactions in organs remote from the site of a cpTi implant. For flexible internal fixation where motion and thus fretting is to be expected, titanium or its alloys are the materials of choice.

2.5 Surface structure

- When placing an implant into the body, protein adsorption and cell adhesion usually occur within minutes, followed by either soft-tissue adhesion or matrix adhesion before mineralization [10]. Without protein adsorption and cell adhesion, under the presence of micromotion, fibrous capsule formation occurs.

The development of a stable bone-implant interface is critical for the success of osteosynthesis implants, such as screws. The surface structure of an implant in contact with bone is important because force transmission occurs at this interface. In conventional applications, the force transmission of a plate or nail relies on friction between the implant and the bone. An in vivo study in rabbits showed that simple surface roughness modification of steel internal fixation plates induced more bone formation towards the implant surface without fibrous tissue formation in between (Fig 1.3-5). These results support the hypothesis that bony integration is increased on implant surfaces with higher amounts of protruding microdiscontinuities. Strong bony integration between the screw thread and bone is a disadvantage when considering removal of screws, and the surface microstructure is the major determinant of this. Bony integration is minimized by using surfaces with minimal microstructure reducing the forces required to remove screws.

Movement between soft tissue and an implant-plate surface may cause fibrous capsule formation surrounding a liquid.

Fig 1.3-5a–b Histological appearance of the undersurface of plates after 12 weeks implantation in rabbits in a nonfractured model.

a A smooth stainless steel plate above the bone with a soft-tissue capsule between plate and bone.

b A rough stainless steel plate above the bone with bone growth towards the plate and bony attachment onto the plate undersurface.
filled void at the interface. The liquid phase of the void allows accumulation of cellular detritus and any fretting particles that may be produced from screw/plate interfaces. There is no vascularization in the void, which predisposes to infection since mobile cellular defense mechanisms are lacking.

- In clinical practice, fibrous capsule formation has been observed to be more prevalent with standard stainless steel than with cpTi plates (Fig 1.3–6).

Microroughness or microdiscontinuities on the surface reduce fibrous capsule formation and the presence of the liquid filled void. However, there are situations in hand, foot and ankle, shoulder, and craniomaxillofacial surgery, where adherence of implant surfaces to soft tissues such as tendons or muscles is undesirable. Recent work with polished titanium and titanium alloys has shown the surfaces to be favorable for such areas. The microstructure of the implant surface is more important than the implant surface chemistry.

### 2.6 Magnetic resonance imaging (MRI) compatibility

AO approved implants (made either of cpTi or titanium alloys (TAN and Ti-15Mo) are completely nonmagnetic and MRI in patients with these implants does not pose any difficulties [11]. They produce less MRI artifacts when compared to stainless steel.

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**Fig 1.3-6a–b** Histological appearance of the upper surface of plates after 12 weeks implantation in rabbits in a nonfractured model.

a  A smooth stainless steel plate with fibrous capsule formation and a dead space or void filled with liquid between.

b  A cpTi plate with contacting connective tissue and without the presence of a liquid filled void. After an initial nonspecific reaction, little inflammation and no encapsulation was observed with the cpTi plates tested.
steel implants including low-nickel steels. AO approved implant quality 316L stainless steel is classified as a paramagnetic or nonferromagnetic material. It is safe to perform MRI on patients who have these implants [11].

- The term MRI safe is used for devices that can be utilized in or around an MR scanner without risk to patients, but with possible effects on image quality. The term MR compatible is used for devices that are safe and without influence on the diagnostic information. External fixation devices can contain magnetic parts and are contraindication for MRI.

3 Biocompatibility

An implant material, which correspond to international standards, generally manifests an adequate level of biocompatibility. There are, however, differences as shown in studies of metal applications in humans [12]. In general, cpTi and titanium alloys have better biocompatibility than stainless steel. Beside the material, the optimal combination of implant design (presence/absence of dead space/liquid filled void) and surface properties (soft-tissue adhesion and vascularization at the implant surface) can result in improved bacterial resistance. In experimental studies, the effect of the plate material on infection under conditions of fretting was observed. The difference between steel and titanium is greater in a multi-component plate and screw system than when nails (single element implants) are used. The incidence of infection is higher for steel implants than for titanium implants. When dynamic compression plates made of steel or cpTi were tested in animals, in vivo there was significantly better resistance to local infection with cpTi when compared to steel.

- cpTi may provide better local resistance to infection than stainless steel [13, 14].

3.1 Local toxic reactions

Tissue cultures and organ cultures with bone specimens have been used to assess the toxicity of soluble corrosion products [10]. Such tests are used for screening prior to implantation in an animal. In vivo studies on animals and from retrieved tissue samples in humans [9] indicate biological reasons for favoring cpTi over stainless steel.

3.2 Allergic reactions

Today’s implant quality stainless steels include between 13 and 16 weight % nickel (Ni), even though Ni ions belong to the most common skin contact allergens [15]. Patch testing shows that 10–20% of people may be sensitive to nickel [16]. Sensitized persons may develop allergic reactions when nickel is released from stainless steel medical implants. Hence, cpTi or titanium alloy implants should be used for internal fixation in patients with known nickel allergies. Similar allergic reactions to skin contact are known for cobalt and chromium.

- Clinically relevant allergic reactions to nickel-containing stainless steel implants after internal fixation are estimated to occur in 1–2% of cases. Exact data are, however, not available. On the other hand, currently there have been no testified allergic reactions if cpTi has been used exclusively.

Newly developed low-nickel (approximately 0.03%) stainless steels are not nickel free. They reduce the allergic risk, but it is not yet known whether there really is no risk at all.

3.3 Induction of tumors

Continuous irritation of tissues may, in exceptional cases, lead to a neoplastic reaction. This is known for scar tissue as well as a result of heavily corroding metal, such as particles of ammunition. The incidence of carcinogenesis from internal
fixation material, ie, primary tumors induced by an implant, seems to be extremely low in humans given the millions of such implants that are not removed after fracture healing. Dogs have been reported to produce sarcomas near stainless steel implants, although infection and physical irritation were contributing factors [17].

4 New metal implant materials

4.1 High-strength alloys

Many materials have been proposed to solve special problems, such as avoiding implant failure under extreme mechanical load. Improved strength may be achieved by using alloy components for titanium (eg, vanadium), that are less biocompatible than nickel. The extremely good corrosion resistance of titanium alloys compensates for part of this potential disadvantage. The choice of implant material depends on the priority given to mechanical advantages or biological tolerance. Ti-15Mo is a relatively new alloy that due to its superior notch sensitivity and reverse bending properties offers improved implant design opportunities, eg, for mandibular plates and hand plates.

4.2 Shape memory alloys

Metal alloys with a so-called shape memory effect [18] are an attractive proposition. However, the currently available materials with shape memory have not seen general use because of the following problems:

- The memory effect must be reliably inducible.
- The amount of force developed must be controllable.
- The material must be properly machineable.
- The cost must be appropriate in relation to the advantages offered.

- The biocompatibility must be good.
- Where implant removal is considered the shape memory effect should be reversible.

Today’s shape memory implant materials are very hard and thus difficult to machine. Their effect is more or less an all-or-nothing mechanism, while costs are above average. Nitinol is a shape memory titanium alloy that has potential for fracture treatment in osteoporotic bone, providing a complex shape, low modulus of elasticity, and low stiffness porous foam that allows bone ingrowth. Nitinol foam produced with nickel-cpTi powder can have interconnected pores with porosity between 40–80% and a similar modulus of elasticity to subchondral bone. This offers interesting future possibilities as it can be premolded, but must be tested for the production of wear debris, due to the 50% of nickel. One possibility is using these foams as solid sponges for holding screws in osteoporotic bone. Shape memory alloys, like Nitinol, exhibit an interesting material property—super elasticity: They are able to exert a recoil effect over a large range of deformation. This effect seems to promise interesting applications such as correction of spine deformities.

5 Coatings

Implant loosening and pin-track infection are unresolved complications associated with external fixation. It is generally accepted that loosening may be overcome by modifying the implant-bone interface for improved osseous integration. It is also thought that pin-track infection may be reduced by the same modifications for improved soft-tissue integration at the implant-soft tissue-air interface.

Improved tissue integration may be obtained by the use of hydroxyapatite (HA) or tricalcium phosphate coatings, provided
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that the initial stability of the interface allows ingrowth. Experimental and clinical studies have shown that hydroxyapatite coated pins are capable of forming a tight link with living bone tissue and also reduce pin-track infection [19], possibly by improving the soft-tissue integration at the implant-soft tissue-air interface. This bioceramic material has good biocompatibility, no systemic toxicity, a low degradation rate, and may even become chemically bonded to bone. Unfortunately, the use of hydroxyapatite has been limited by its low adhesive strength to the implant surface, its high stiffness and weak cohesion within its layers (10–60 μm thickness). These factors cause the coating to detach from the implant.

Recent work on anodic plasma-chemical (APC) treatment to incorporate electrolytes into a metal surface showed the product of APC to adhere with four times the strength of hydroxyapatite to a cpTi surface, and the coating could be produced as thinly as 3–5 μm [20]. In vitro and in vivo work with APC coated titanium surfaces showed the APC product to be as biocompatible as hydroxyapatite [21]. This may have future potential for pin coating and coating of spine cages, as it can be used on any 3-D shape.

6 Polymeric implants

6.1 Biodegradable polymeric implants

It is recommended that implants are removed after fracture healing in a number of clinical situations. Biodegradable materials, after a certain period of implantation, are resorbed in vivo in the body in the form of nonharmful by-products, such as H₂O and CO₂, which are finally eliminated from the body by normal metabolic processes.

- Polylactides and polyurethanes are synthetic in origin and offer fair tissue tolerance. Due to limited mechanical properties they are of interest for implants which must resist only minor loads and where surgical removal is a major undertaking.

Examples of such implants are pins for the fixation of small chondral or osteochondral defects of articular surfaces, suture anchors [22], or thin plates and screws used for fracture treatment in the maxillofacial area, including the orbit [23, 24] and skull [25]. Resorbable membranes have been tested for the treatment of bone defects [26]. They are also being tested for the potential release of osteogenic substances to enhance bone healing. Some caution is advised in situations susceptible to infection as degradable material sometimes exhibits a reduced resistance to infection compared to the best metal implants.

6.2 Nonbiodegradable polymeric implants

Polyaryletherketone polymers including polyetheretherketone (PEEK) and polyetherketoneketone (PEKK) thermoplastics are considered biocompatible in bone and can be sterilized by most methods including steam, though they have around 5% loss in strength when exposed to γ-radiation. They are x-ray translucent and not magnetic, therefore not heated by MRI, and do not cause magnetic artifacts that distort images of the soft tissue (MR compatible). They do not corrode like metals, but there are concerns about possible leakage of their original components (softeners, accelerators, nonpolymerized base components, and solvents). The tensile strength of PEEK is about 90–100 MPa, which can be improved by carbon reinforcement. However, this may cause problems due to possible release of microfibers after implant breakage, or fretting, or wear, as the bond strength of the fibers to the polymer decreases over time. Barium sulfate is sometimes added as a
contrast media for x-ray imaging. These materials have high chemical resistance and are resistant to the surrounding body milieu, but are hydrophobic and, without coating or surface modification, will not allow bony integration. The high costs of these materials limit applications. The main use for this type of polymer is currently in spine cages for interbody lumbar fusion.

7 Methods and materials for filling bone defects

The surgeon is frequently confronted with the need to treat a bone defect that may stem from the initial trauma or is the result of infection and/or avascularity. Bone may be replaced immediately or after an interval during which the host site is prepared. The gold standard remains autogenous cancellous, corticocancellous or cortical bone, either as free standalone or vascularized bone grafts. Though autogenous bone is superior to any other substitute, the supply for grafting is limited and the donor site is often painful. To take optimal advantage of autogenous cancellous bone, the graft may be protected by using different types of biodegradable membranes [26]. As studied by Klaue et al [27], the formation of a biological envelope may be induced by the membranes and thereafter the autogenous bone graft is inserted. The ingenious and successful technique of distraction osteogenesis as presented by Ilizarov [28] can be understood as being an optimally vascularized autogenous bone graft of ideal shape and dimension. The technique is quite reliable but demanding for the patient because of limited mobility, the length of treatment, and the risk of pin-track infections. To cope with some of these problems, other techniques have been proposed (chapter 5.2; 5.3). The use of allograft bone requires great caution in respect to infection, resistance to infection and immunological reaction. Deproteinized bone (Kiel bone) behaves rather like an inert filler conducting only limited bone formation [29].

7.1 Replacement of bone by synthetic fillers

These substitutes appear attractive. They must, however, provide an appropriate combination of reliable mechanical strength, minimal interference with bone healing, osteoconduction and/or osteoinduction. Resorption must occur without compromising the healing process, including local resistance to infection.

The synthetic materials most commonly used for filling bone defects are calcium phosphates including hydroxyapatite, β-tricalcium phosphate (β-TCP), and hydroxyapatite/β-TCP composites (biphasic calcium phosphate, BCP). These materials provide excellent osteoconduction. However, they are also brittle, which reduces their field of application to low-load or non-load bearing applications.

The resorption rate of hydroxyapatite is counted in decades, so hydroxyapatite has to be considered as nonresorbable. The solubility of β-TCP is very close to that of the mineral part of bone. Therefore, β-TCP granules or blocks are generally resorbed within 1 or 2 years in vivo. β-TCP is degraded by osteoclastic activity in the same way as necrotic bone is degraded. The biological properties of BCP are intermediate between those of β-TCP and HA and degradation rate depends on the ratio of the two: It is faster with an increase in the amount of the β-TCP content.

Calcium phosphate (CaP) materials are normally made porous during manufacture. Two types of pores have to be distinguished: micropores and macropores. Micropores have a size smaller than 10–30 μm, typically close to 1 μm. Micropores are too small to enable bone ingrowth. Macropores have a size larger than 30–50 μm. Bone can penetrate macropores and provide good mechanical anchoring. Porous materials have much lower mechanical properties in terms of compression strength than dense materials. However, their resorption rate
is much faster, particularly for interconnected macroporous materials.

Injectable bone substitutes, such as so-called CaP cements, have good handling properties, are mechanically stable (up to about 50 MPa in compressive strength), and are very porous (close to 50% volume). However, the small average pore size (typically 1 μm) prevents cell migration within the material. Additionally, these CaP cements are absorbed layer by layer rather than uniformly.

A combination of fillers with bone-inducing (osteoinductive) substances such as bone morphogenic proteins, and slow drug release, seems to offer an attractive potential for the future. The choice of the proper filler material depends largely upon the surgical priority to produce balance of the biological and mechanical properties required in the individual patient. The development of some of these materials is further discussed in chapter 1.4.

### Bibliography


1 AO philosophy and basic principles


9 Acknowledgments

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