

both crystalline and amorphous parts (semicrystalline) (**Fig 1.4.2-4**). When a polymer specimen is loaded, there will be a tendency for the polymer chains to slip and move, resulting in a distortion of the specimen. The longer the polymer chains, the greater the chance that they will entangle. This makes slipping more difficult and increases strength. Finally, under the action of an applied load, a finite amount of time is required for these macromolecules to rearrange and move. A polymer will appear stronger if the load is applied rapidly than if the load is applied slowly. This property of time dependence is called viscoelasticity.

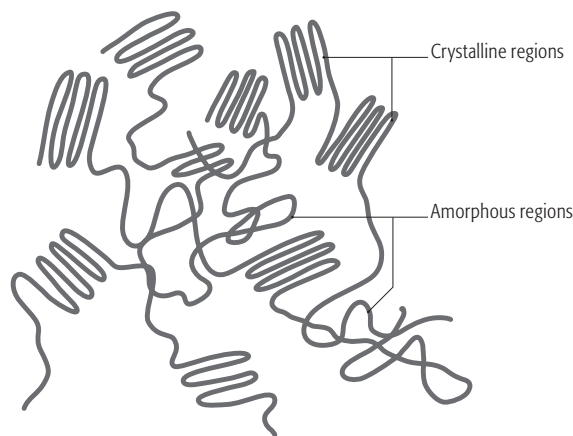


Fig 1.4.2-4 Schematic drawing of the microstructure of a polymer with crystalline and amorphous domains.

3.4 Isomerism

Two or more compounds with the same molecular formula but with a different atomic arrangement are called isomers. For example, lactic acid has two isomers: D-lactide and L-lactide.

3.5 Glass transition temperature

Metals are often categorized by their melting point. Polymers exhibit a glass transition temperature (T_g) that can be used to classify the thermal behavior of many plastics. Below this temperature the polymer is stiff and hard and above the T_g it is soft, flexible, and rubbery. The T_g is characteristic of the amorphous domains of a polymer. Because a polymer implant will be able to sustain greater loads when its temperature is below the T_g , the T_g of polymeric fixation implants should be above body temperature.

3.6 Creep

Creep is a time-dependent plastic deformation of materials subjected to a constant temperature and/or load or stress. This means a reorientation of the polymer molecules by which an implant is deformed. In practice, this could result, eg, in loosening of a screw. No literature can be found on the combination of biodegradable implants and creep.

3.7 Self-reinforcement

Self-reinforcement is a process during which randomly orientated crystals are reorganized into highly orientated fibrils. Hereby the mechanical properties enhance and the elements are stiffer and stronger in the direction of their long axis. These devices must be bent at room temperature with pliers, contrary to non-self-reinforcement devices that require heating. The desired shape retains after bending. The plates can also be cut with scissors and an additional hole can be drilled in.

3.8 Processing methods

The processing methods used at present for preparation of experimental or commercial resorbable internal devices, eg, screws, plates, rods, pins, and fibers usually involve melt-processing and/or machining, extrusion or compression mold of polymeric material. All these methods are far from optimal as they significantly affect the molecular and, hence, mechanical properties of the resulting implants.

3.9 Sterilization

Steam, high-energy (gamma, beta) irradiation, and ethylene oxide (ETO) alone or in mixture with other gases are the media used commonly for sterilization of polymers. Ideally, the medium used for sterilization should adequately sterilize the device without affecting its shape, physical, or chemical properties. In practice this is never the case with biodegradable polymeric devices. Steam and heat treatment at temperatures up to 190° C cause extensive plastic deformation and degradation of resorbable implants and therefore cannot be used at all. High-energy irradiation can result in semicrystalline polymers due to depolymerization, chain scissioning, and cross-linking. Color alterations can appear, caused by a diminished purity. Consequently, material characteristics like tensile strength and elasticity can change by using irradiation. Sterilization with ETO might leave residues in harmful quantities in the implants and on their surface. ETO is mutagenic and carcinogenic. However, when carefully performed, no residues are left. In practice only ETO or high-energy irradiation is used for sterilization of resorbable materials, although both have drawbacks.

4 Ideal material and mechanical properties

4.1 Ideal material

An ideal biodegradable implant is made of a material that meets the following criteria (some of which are discussed in this chapter):

- Can be fabricated and designed with appropriate initial strength to meet the biomechanical demands
- Degrades in a predictable fashion and allows safe progressive loading during each stage of bone healing
- Causes no tissue responses necessitating device removal
- Disappears completely
- Easy to use
- Cost-effective
- Compatible with diagnostic or therapeutic radiation

4.2 Biomechanical demands

The biomechanical demands depend on the maxillofacial area where the device will be used and on the kind of fracture or osteotomy. Generally, a biodegradable osteosynthesis system is exposed to tensile forces, bending forces, shear forces, and compression forces. The screws are especially exposed to torsional forces during insertion. The intrinsic mechanical properties of biodegradable osteofixation systems are less favorable than those of titanium. During screw tightening, large torsional forces develop along its long axis, which can shear off the screw head. In case of a screw breakage, a new hole can easily be drilled through the broken screw and a new screw inserted.

4.3 Degradation

Biodegradable materials usually degrade in vivo through a two-phase process. During phase 1, water molecules hydrolytically attack the chemical bonds, cutting long polymer chains to many short chains. Enzymes can possibly enhance this process. Other factors that can influence degradation are, for example, molecular weight, orientation, isomerism, and crystallinity. The most important effect during phase 1 is a reduction in molecular weight and because it is easier for short chains to slip past each other than for long chains, polymer strength also diminishes. As this process continues, the polymer implant loses its integrity and is fragmented. Phase 2 involves the cellular response whereby macrophages and giant cells metabolize the products of phase 1 degradation into substances, such as water and carbon dioxide. The mass of the implant rapidly disappears. Thus, the implant will have lost its strength long before it loses its mass.

Soon after implantation there is an initial inflammatory response by the body, as normally occurs during wound healing. This is followed by encapsulation of the implant in

a thin, fibrous membrane, which occurs in response to implants made of any material (eg, stainless steel, titanium, polyethylene). At least a residue of the fibrous membrane will remain after total resorption.

Therefore, biodegradable materials are also called bioresorbable or bioabsorbable materials, but in the literature there is no evidence of total in vivo resorption, at least on an electronic microscopic level, of any biodegradable osteosynthesis material. Bergsma et al have concluded that complete resorption of PLLA does not occur after 5.7 years. Amorphous 50:50-poly(D,L)lactide (PDLLA, ResorbX®) and 82:18-poly(L-lactide-co-glycolide) (PGLA, Lactosorb®) completely resorbed after 12 and 14 months on a fluorescence microscopic level. An electronic microscope was not used. Edwards et al also showed complete resorption of PLLA-PGA fixation devices by 18 to 24 months after surgery. Evaluation consisted of x-rays and light microscopy. Residual implant material of amorphous 82:12:6-poly(lactide-co-glycolide-co-trimethylene carbonate) (Inion CPS® baby) was found on gross and histological examination (light microscopy) at 18 months. Nieminen et al could not detect Inion CPS (composed of L-lactide, D-lactide, and trimethylene carbonate in varying proportions per product) in light microscopy after 2 years.

4.4 Handling properties

Although the biomechanical properties and biocompatibility are a precondition in using biodegradable osteosynthesis systems, handling characteristics are also aspects of a well-considered selection and application of osteosynthesis systems (Fig 1.4.2-5).

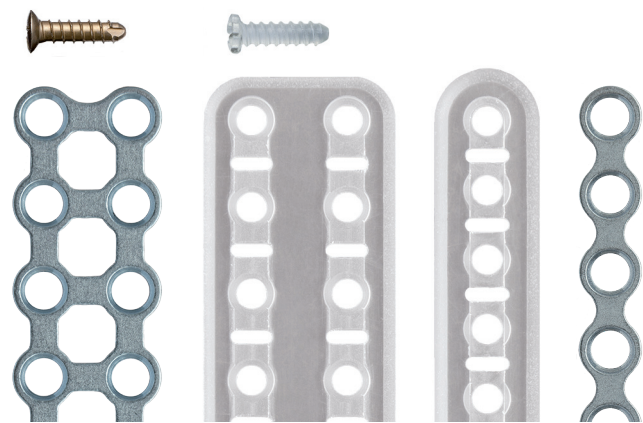


Fig 1.4.2-5 Two different-sized titanium plates and two different-sized biodegradable plates. From left to right: MatrixMIDFACE strut plate, pure titanium; RapidSorb strut plate 1.5; RapidSorb adaptation plate 1.5; MatrixMIDFACE adaptation plate, pure titanium. Above: titanium screw 1.5; rapid resorbable screw 1.5.