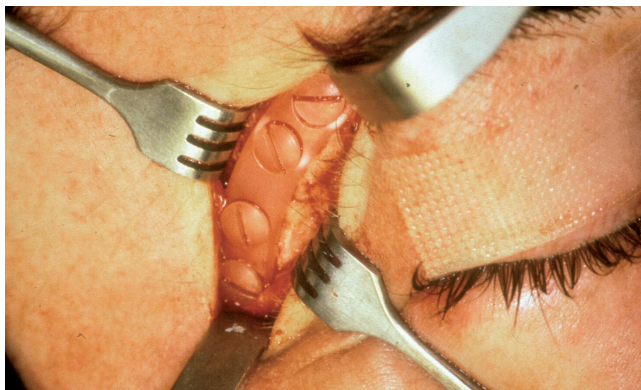


Bos et al fixed zygomaticomaxillary fractures in humans with PLLA plates and screws and reported good early results (**Fig 1.4.2-1**). However, all patients displayed an unfavorable tissue reaction three years after implantation. Swelling at the site of implantation was clinically detectable (**Fig 1.4.2-2**). This swelling seemed to be related to massive disintegration of the PLLA implants into many lamellar crystals (**Fig 1.4.2-3**), as a histological survey after removal indicated.

Bergsma et al performed a number of animal experiments and were able to demonstrate this effect again. They concluded that a semi-crystalline PLLA polymer can induce a late and probably persistent swelling when used in a subcutaneous implantation site.

Although experiments had been done with other materials, for example polydioxanone, most of them were performed with pure PLLA because it has the best strength properties. However, the late unfavorable tissue reaction induced the development of additives to pure PLLA and/or other biodegradable materials for medical implants. Also non-chemical modifications like self-reinforcement were developed in the next decades.



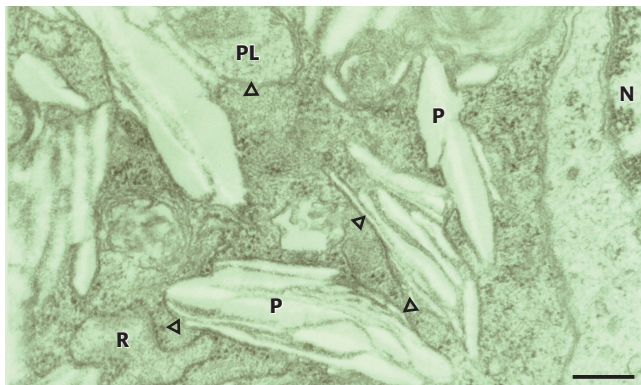
**Fig 1.4.2-1** Fixation of a right zygomaticomaxillary fracture with a 4-hole PLLA plate and PLLA screws in the lateral orbital rim.

Tormälä and Rokkanen developed the self-reinforcing technique in 1985. Extensive research (experimental and clinical studies) has been done on the self-reinforced PLLA plates and screws by different research groups. Short-term results were positive; the devices retained their strength long enough for the fractures to heal. However, degradation of self-reinforced PLLA resulted in the same crystals that can cause swelling after a few years. Self-reinforced (70L:30DL) PLA plates and screws were described by Haers and Sailer. In clinical trials rigid fixation was obtained in internal fixation of the mandible and the maxilla.

Other materials that have been developed in the last few decades are all still based on PLLA but with additives like polyglycolide and D-lactide. Degradation is faster with these additives, however pure PLLA is still stronger. Clinical trials performed with these materials all resulted in rather good short-term outcomes and acceptable stability was obtained. Buijs et al systematically reviewed the available literature and concluded that the implications for the clinical applicability of biodegradable osteofixation systems in the long term remain inconclusive. There is evidence available from



**Fig 1.4.2-2** Swelling at the lateral orbital rim 3 years after implantation of a PLLA plate and screws for fixation of a left zygomaticomaxillary fracture.



**Fig 1.4.2-3** Electron microscopical image, 3.7 years after implantation, of membrane-bound (triangles) phagosomes (P) enclosing crystallites and a combination of a phagosome and a non-crystal-bearing vacuole, designated together as phagolysosome (PL). R indicates swollen rough endoplasmic reticulum; N indicates cell nucleus; bar, 400 μm. Uranyl acetate/lead citrate staining.

randomized controlled trials to support the conclusion that there is no significant difference between biodegradable and titanium osteofixation devices with regard to short-term clinical outcome, complication rate, and infections in the area of orthognathic surgery. Reoperation rates do not significantly differ in the biodegradable and titanium groups. The numerous studies with biodegradable osteofixation devices that have been published hereafter still remain inconclusive; they did not include titanium as a control group, there was no randomization, or only small, unmatched groups of patients were included.

### 3 Polymer chemistry

Metals, ceramics, and polymers are the three major groups of engineering materials. There are polymers of natural origin (eg, polysaccharide, cellulose, silk, natural rubber, cotton, wool, and leather) and synthetic polymers (eg, polyethylene, polystyrene, polyvinylchloride, polyesters, polycarbonates, polyurethanes, and polytetrafluorethylene). Synthetic polymers are, in general, strong, not too expensive to produce, and have good mechanical properties compared with their natural counterparts. The resorbable synthetic polymers used for manufacturing osteosynthesis devices are certain poly(urethanes), certain poly(esters), and poly(carbonates) like poly(lactide), poly(glycolide), poly(dioxanone), poly(trimethylene carbonate), poly( $\epsilon$ -caprolactone), and their copolymers.

#### 3.1 Polymer types

A polymer is a large molecule consisting of covalently bound smaller units, called monomers. These repeating units resemble the links in a chain and therefore the molecules are often referred to as polymer chains.

If only a single type of monomer is used, a homopolymer is formed (-AAAAA-). If two or more types of monomers are used, it is called a copolymer. In a random copolymer the different subunits of a copolymer are arranged randomly (-AAAABBAABBBABABAA-). In a block copolymer the subunits are arranged in alternating long regions (-AAAABBB-BAAAABBBBAAAA-).

The properties of a copolymer differ significantly from the properties of the homopolymers consisting of one of the monomers of the copolymer.

Polymer chains may be linear or form a branched, cross-linked, or 3-D network. Linear polymers are those in which the monomer units are joined together end-to-end in single chains. These long chains are flexible. Branched polymers are polymers in which the side-branch chains are connected to the main ones. The branches, considered to be part of the main-chain molecule, result from side reactions that occur during the synthesis of the polymer. The chain-packing efficiency is reduced with the formation of side branches, which results in lowering the polymer density.

In cross-linked polymers, adjacent linear chains are joined one to another at various positions by covalent bonds. The process of cross-linking is achieved either during synthesis or by an irreversible chemical reaction that is usually carried out at an elevated temperature. Often this cross-linking is accomplished by additive atoms or molecules that are covalently bonded to the chains. Many of the rubber elastic materials are cross-linked.

Trifunctional units, having three active covalent bonds, form 3-D networks creating polymers called network polymers. Actually, a polymer that is highly cross-linked may be classified as a network polymer.

#### 3.2 Molecular weight

Forming a polymer, the chemical reactions do not result in the same molecular weight for every single molecule but rather a bell-shaped distribution is present. Mostly the mean molecular weight is cited to describe this—the higher the mean molecular weight and the narrower the bell-shaped curve, the better the mechanical properties of the polymer. Or, the fewer low molecular weight polymer chains in a sample the better the properties.

#### 3.3 Microstructure

A polymer can have an amorphous or a crystalline microstructure. An amorphous microstructure means that the polymer chains are randomly orientated and therefore can easily slip past each other (Fig 1.4.2-4). The result is a relatively weak polymer. Crystalline polymers are ordered polymers in which the chains lie parallel in close proximity to each other and are densely packed and strong. Repeatability along the length of the polymer is a condition for crystallization. Thus, random polymers have little crystalline parts and are amorphous in character. Even crystalline homopolymers are not totally crystalline and will always contain