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1.4.2 Biodegradable osteosynthesis: past, present, and future

1 Introduction

Today, most orthognathic procedures and facial skeletal fractures are fixed by using titanium plates and screws. Titanium fixation systems can be used safely and effectively, are easy to handle, and the intrinsic mechanical properties ensure that the device dimensions are kept within acceptable limits. However, these metal systems have some disadvantages. Potential adverse effects associated with metal implants are hot and cold sensitivities, plates palpable under the skin, possible mutagenic effects, interference with later diagnostic or therapeutic radiological investigations, and interference with function and/or growth. Consequently, a second operation to remove the implants is performed after bone healing in 5–40% of patients. Biodegradable plates and screws, degrading after healing time and with gradual transfer of functional forces to the healing bone during disintegration of the biodegradable devices, seem to be the perfect solution for most of the above-mentioned potential disadvantages. There is no need for another surgical intervention to remove the plates and screws. This implies reduction of additional discomfort, risks, operation time, and associated socioeconomic costs.

2 History

Biodegradable devices have been used in the medical field for more than four decades. In 1962, polyglycolic acid (PGA) (Dexon™) was developed by the American Cyanamid Co. as the first absorbable synthetic suture. It has been commercially available since 1970. A copolymer of 92% PGA and 8% polylactic acid (PLA) (Vicryl®) entered the market in 1975 as a competitive resorbable suture. Since 1966 different research groups have been developing resorbable osteosynthesis systems. In 1966, Kulkarni published an article on the implantation of poly(L-lactide) (PLLA) films and membranes. The polymeric films disappeared from the subcutaneous implantation sites in guinea pigs within 6 weeks, causing only a mild inflammatory reaction. A fibrous tissue layer was formed around the implants.

Several other animal experiments with PLLA implants followed in the next few years. Mandibular and blowout fractures were repaired with PLLA implants.

Although good biocompatibility and bone healing were reported in these experiments, they did not result in any clinical trial. This may be due to the fact that the implants were neither strong enough nor small enough for clinical use. Clinical trials were first performed in the 1980s.

Rokkanen, Tormälä, and others from Finland have produced numerous reports on biodegradable PLLA and PGA implants for fracture fixation. They performed clinical implantations in both children and adults. Törmälä et al developed the first commercially available biodegradable PGA/PLA rods (Biofix®) that were suitable for fracture fixation.