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Biodegradable polylactide plates and screws in orthognathic surgery: technical note

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SUMMARY. **In orthognathic surgery, the bone fragments are usually fixed with metallic plates and screws. Metallic devices other than titanium plates are usually removed after the osteotomy has consolidated, which often requires general anaesthesia. Titanium plates, supposed to be biotolerable, have been introduced in order to overcome this need for secondary intervention. However, due to corrosion, titanium particles have been found in scar tissue covering these plates and in locoregional lymph nodes. Therefore, their removal is also advocated.**

Self-reinforced poly (L-lactide) homopolymer (PLLA) and poly (L/D-lactide) stereocopolymers with a L/D molar ratio up to 85/15 have sufficient strength to overcome the need for additional support for the fixation of fractures. The plates can be bent at room temperature. The surgical technique and early results of a case of bimaxillary surgery and genioplasty fixed with bioresorbable material without postoperative rigid maxillomandibular fixation are reported.

INTRODUCTION

In orthognathic surgery, the bone fragments are usually fixed with metallic plates and screws. Metallic devices other than titanium plates are usually removed after the osteotomy has consolidated, which often requires general anaesthesia. Titanium plates have been introduced in order to overcome this need for secondary intervention, as this material is supposed to be biocompatible. However, due to corrosion, titanium particles have been found in scar tissue covering these plates and in locoregional lymph nodes (*Rosenberg* et al., 1993; *Schliephake* et al., 1993; *Jorgenson* et al., 1997). Although it is uncertain if the presence of these particles in soft tissues and lymph nodes has an influence on the patient's long-term health status, some authors recommend removal of the osteosynthesis material (*Kim* et al., 1997). Nevertheless, depending on the size of the plate, hypersensitivity to cold or an awareness of the presence of a foreign body is often encountered (especially in the Nordic countries) and this eventually leads to the need for plate removal (*Iizuka* and *Lindqvist*, 1992).

Research on biodegradable devices for fracture fixation has been in progress for the past 30 years (*Kulkarni* et al., 1966; *Cutright et al.*, 1971). In the beginning, the strength of these biodegradable devices was poor and maxillo-mandibular fixation (MMF) was needed to support the fixation. Clinical applications in craniofacial surgery in children, where less strength is needed, have been reported with these materials (*Illi* et al., 1991). Successful application of poly(L-lactide) osteosynthesis material for the treatment of zygomatic and mandibular fractures in pilot studies (*Bos* et al., 1989; *Gerlach*, 1993) and in clinical series (*Bos* et al., 1987; *Bessho* et al., 1997) has also been reported. By using self-reinforcement technology in poly (L-lactide) (PLLA) and poly (L/D-lactide) stereocopolymers with a L/D molar ratio up to 85/15, the strength of the devices could be increased even more (*Suuronen*, 1991; *Suuronen* et al., 1992a, *Suuronen* et al., 1992b; *Törmälä* et al., 1997).

In the field of orthopaedic surgery, they have been used for over a decade (*Rokkanen* et al., 1985), and in the field of maxillofacial traumatology they have now been used successfully for over 2 years (*Kallela* et al., 1996). Experimental studies in sheep on the feasibility of fixing mandibular osteotomies (*Suuronen* et al., 1992c; *Suuronen* et al., 1997) and sagittal split osteotomies (*Suuronen* et al., 1992d), as well as prospective clinical stability studies (*Suuronen* et al., 1994), have shown results comparable with metallic rigid internal fixation for advancement of the mandible. Technically, the operations were uneventful and during the short follow-up period no clinical manifestations of foreign body reactions were seen. In this report, a case of bimaxillary surgery with simultaneous genioplasty in which all osteotomies were fixed with biodegradable plates and screws is reported.

OSTEOSYNTHESIS MATERIAL

The purified medical grade PLA raw polymer for the plates and 2 mm screws (Fig. 1) is Resomer LR 708 (Boehringer Ingelheim, Ingelheim am Rhein, Germany), whereas the raw material for the 2.7 mm

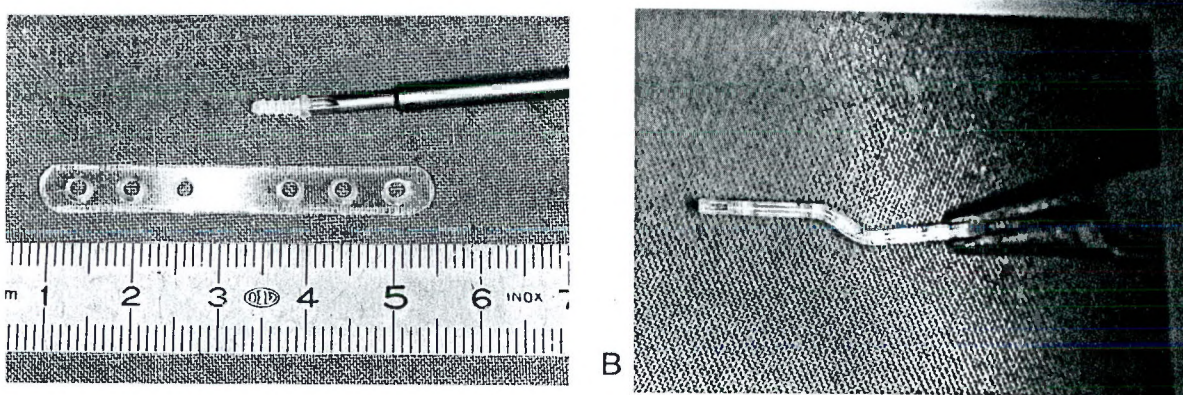


Fig. 1 – Left: Illustration of the 2 mm screws and plates together with the screwdriver. Right: The plates are bent with flat forceps, without requiring a heating device to maintain the desired form.

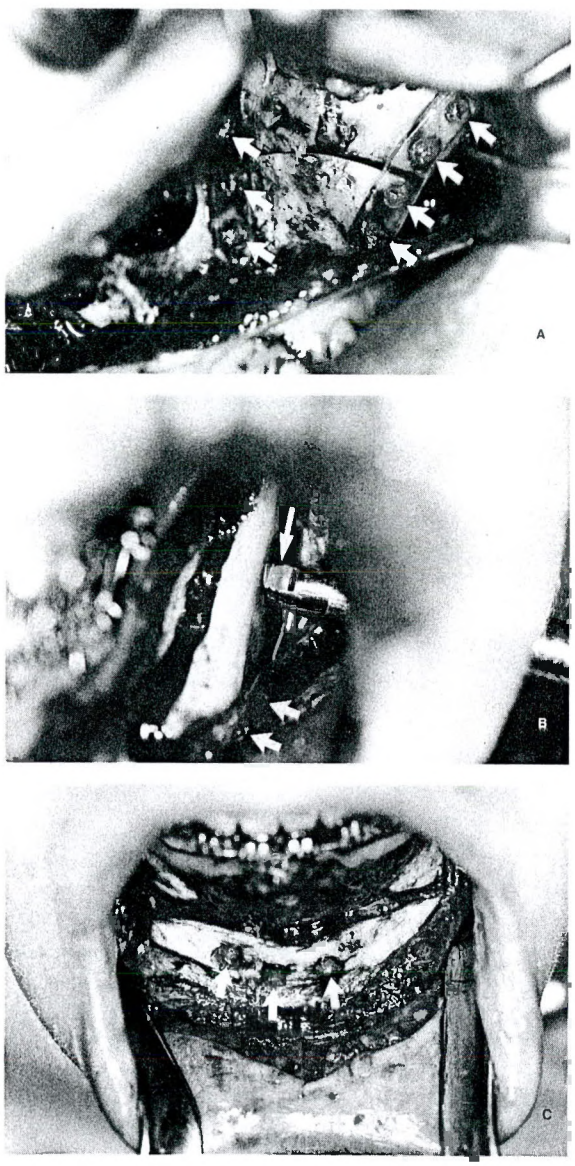


Fig. 2-a – View of the upper jaw with the plates and screws in situ (arrows). **b**. View of the insertion of a bicortical screw in the retromolar area via a transbuccal approach behind the 2.0 mm plate (arrows). **c**. Three bicortical screws were used for osteosynthesis of the chin fragment (arrows).

screws with a viscosity mean molecular weight of 675 000 was supplied by PURAC Biochem bv. (Gorinchem, The Netherlands). SR-PLA screws were manufactured in the biomaterials laboratory of the Tampere University of Technology, Finland. The polymer was first melted in a single extruder (Axon BX-15, Sweden) and formed into cylindrical tablets, which were allowed to cool. The partially crystalline (spherulitic) poly-L-lactide tablets were then reheated and mechanically drawn in the solid state through a tapered die into oriented, at least partly fibrillated, self-reinforced preforms, which were compression-moulded in the solid state into screws. The finished implants were sterilized by gamma radiation at a minimum dose of 25 kGy (Willy Rüsch, Kernen-Rommelshausen, Germany). The screws are inserted following drilling of the holes and pretapping with a special device corresponding to the unique profile of the threads. The preparation of the bone is done under saline irrigation to avoid thermal damage.

SURGICAL TECHNIQUE

The osteotomies were carried out intraorally in a standardized way (*Haers* and *Sailer*, 1996). The maxilla was repositioned following mobilization by means of an intermediate wafer in intermaxillary fixation. SR-P(L/D)LA (85/15) miniplates (2.0 mm system) were fixed bilaterally in the paranasal area and along the zygomatic buttress with two SR-P(L/D)LA (85/15) screws (diameter 2 mm, length 4–6 mm) on each side of the osteotomy gap (Fig. 2A). Following removal of the wafer, the bilateral sagittal split osteotomies (BSSO) were completed and the mandible was brought into its correct position by means of a removable occlusal wafer and (IMF). The fragments were fixed with one SR-P(L/D)LA miniplate (2.0 mm system) on each side and two monocortical screws (diameter 2.0 mm) in each segment. All plates were bent at room temperature without the use

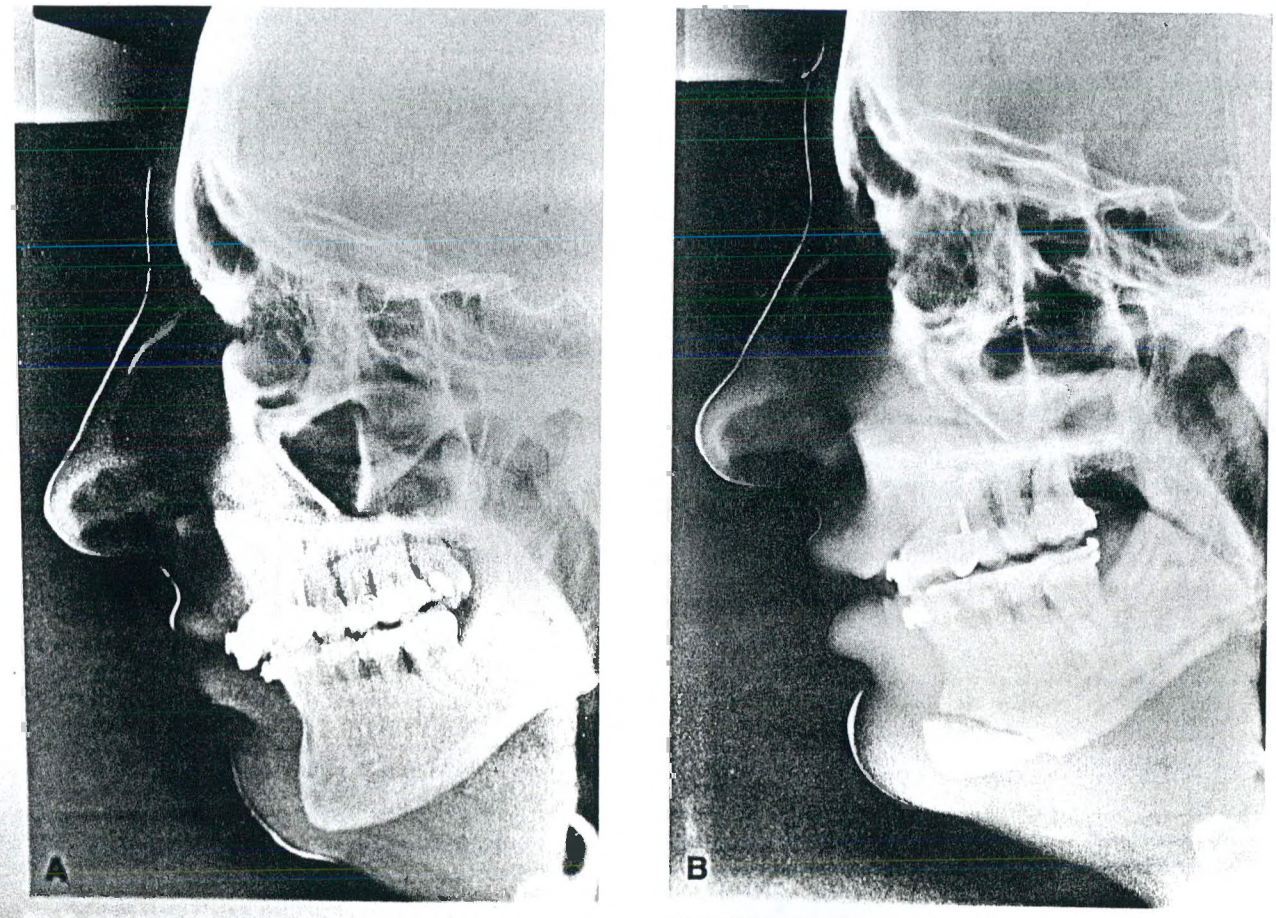


Fig. 3 – a Lateral cephalogram taken preoperatively (A), immediately postoperatively (B) and at 6 weeks postoperatively (C), illustrating the dysgnathia and the stable pattern of its correction. The occlusal wafer was removed 4 weeks postoperatively.

of a heating device. For safety reasons, two additional SR-PLLA bicortical screws (diameter 2.7 mm, length 16 mm) were used on the right side and one on the left side (Fig. 2B). The lingually pedicled chin fragment of the advancement genioplasty was fixed with three SR-PLLA screws (diameter 2.7 mm, length 18 mm) (*Fig. 2c*). Correction of the occlusion with and without an occlusal wafer was done immediately following removal of the temporary intermaxillary fixation. Wound closure was achieved with a non-resorbable continuous suture in the upper jaw, double-layer closure in the area of the BSSO and single-layer closure in the symphyseal area following suturing of the m. mentalis with resorbable material.

CASE REPORT

This orthognathic procedure was performed on a 33-year-old female patient presenting with a class II occlusion (overbite 4 mm, overjet 6 mm) due to sagittal hypoplasia of the mandible. The patient complained of intermittent clicking in both temporomandibular joints

and mastication problems. Aesthetic considerations were secondary. Following orthodontic alignment, a bimaxillary procedure was planned in order to correct the dental midline deviation in the upper jaw and to advance both mandible and chin. Following extensive information as described in the protocol approved by the ethics commission, the patient agreed to undergo osteosynthesis with biodegradable material. The bimaxillary procedure was carried out as described above. The maxilla was moved 3 mm forward and 2 mm downward in I-point and the midline was shifted 2 mm to the right. Mandibular advancement in B was 7 mm and in Me the additional movement of the genioplasty anterior to the mandibular body was 4 mm. Training elastics were inserted on the third postoperative day, at which time the patient was dismissed from the hospital. There were no dehiscences or infection. Postoperative oedema was as usually seen following bimaxillary procedures. Both elastics and occlusal wafer remained in situ for 4 weeks. Lateral cephalograms (Fig. 3) and orthopantomograms (Fig. 4) were taken preoperatively, 3 days postoperatively and after 6 weeks.

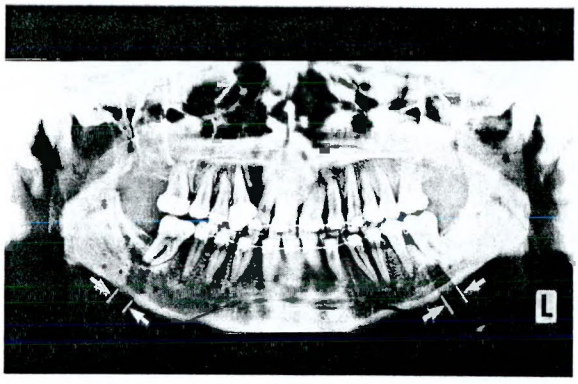


Fig. 4 – Orthopantomogram taken immediately postoperatively illustrating the amount of mandibular advancement (arrows).

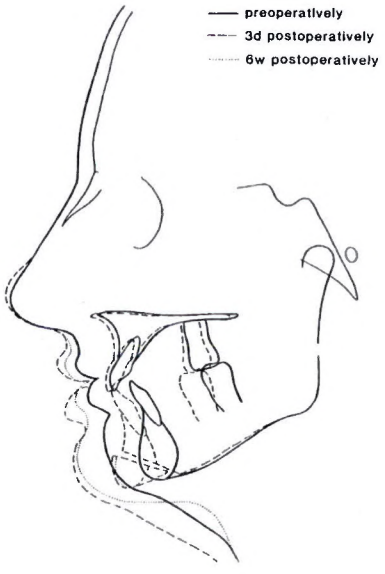


Fig. 5 – Cephalometric analysis of the surgical movements and the stability pattern as seen 6 weeks postoperatively.

RESULTS

Healing was uneventful. Six weeks postoperatively, clinical examination revealed a stable maxilla and mandible. The occlusion was stable in the planned position and postoperative orthodontic treatment was started. Digitalized cephalometric analysis was done on a magnetic D-MAC table with software developed at the Zürich Department of Orthodontics. There was no detectable dental or skeletal relapse in the upper and lower jaw, except for Me-point where a relapse tendency of 0.5 mm was seen (Fig. 5).

DISCUSSION

To our knowledge, bimaxillary surgery and simultaneous genioplasty in which osteosynthesis was done entirely with biodegradable material has not yet been published. The favourable results published with SR-PLLA devices for osteosynthesis of maxillofacial osteotomies over the last 10 years and the outcome of comparative studies of this resorbable material with metallic rigid fixation, allowed the performance of this application (*Suuronen* et al., 1992a; *Suuronen* 1992b). The first osteotomies were carried out in sheep, and these devices have been used for osteosynthesis of fractures and osteotomies in patients for over 6 years (*Kallela* et al., 1996). Technically, the operations were uneventful and no clinically manifested foreign-body reactions were noted during the follow-up. Bilateral sagittal split osteotomies have been fixed in 85 patients with SR-PLLA positional screws. A study concerning skeletal stability following mandibular advancement and rigid fixation with polylactide screws showed results comparable with those obtained with other forms of rigid fixation (*Kallela* et al., 1998). As there are no results yet available with osteosynthesis of sagittal split osteotomies of the mandible with a single plate and monocortical screws, in this case the option was taken to insert additionally 2 mm bicortical screws for reasons of safety. Mandibular fractures have been fixed with SR-PLLA lag screws in 11 patients and in 2 patients with SR-P(L/D)LA (85/15) miniplates and SR-PLLA screws. Technically, the operations were uneventful and during the follow-up period, which is now over 6 years at the longest, no clinical problems have been encountered. The chin fragment was fixed with bicortical lag screws similar to the lag screw fixation of the mandibular fractures. The osteosynthesis of the Le Fort I osteotomy was also uneventful. The plates were

easily bendable with forceps at room temperature and maintained the desired position without requiring a heating device which is advocated for bending other resorbable osteosynthesis materials (*Weissberger* and *Eppley*, 1994).

This pilot case and the available data on stability patterns following mandibular advancement show that a prospective study on stability patterns of bimaxillary osteotomies fixed with biodegradable material can be carried out.

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