

Resorbable poly(D,L)lactide plates and screws for osteosynthesis of condylar neck fractures in sheep

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Abstract

We made osteotomies in the condylar neck in 12 adult sheep to simulate fractures, and joined the two ends with 2 poly(D,L)lactide (PDLLA) plates and 8 PDLLA screws 2 mm in diameter. The animals were killed after 2, 6, and 12 months and bony healing was assessed macroscopically and histologically. The plates and screws remained intact and there was no displacement of the bony ends. The degrading plates, which were still visible in the specimens after 6 months, had been replaced by bone. At 12 months the PDLLA had been resorbed with no foreign body reaction and no resorption of underlying bone. The articular discs showed no signs of degeneration.

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Introduction

Improved methods of osteosynthesis with miniplates, lag screws, and resorbable materials have provoked discussion about the treatment of fractures of the condylar neck of the mandible. When there has been gross condylar displacement conservative treatment has been abandoned because of poor functional and anatomical results.

Removal of metal that has been used for osteosynthesis in the area of the condyle may put the patient at risk of complications. Metal is more often left in place than in other parts of the facial skeleton. Resorbable material is therefore of special interest in the treatment of this type of fracture. Mechanical stress in the area of the condylar process involves complex forces and vectors of the muscles of mastication,

and the free movement and varying load of the joint. Testing the mechanical and healing properties of resorbable material for osteosynthesis in that region in an animal model is therefore appropriate. Sheep have a similar pattern of chewing and remodelling of bone as humans, and chewing forces should be at least equal to those of humans. The temporomandibular joint undergoes adaptive changes even when there is only minor displacement of the condylar head and degenerative changes may develop earlier in adults because of their poor capacity for remodelling.

We undertook this study of osteosynthesis with resorbable plates to find out whether the plates and screws were adequate to withstand the loads in the area of the condylar neck, whether there was displacement of the proximal fragment, and whether the bone healed when postoperative intermaxillary fixation could not be applied.

We also wanted to find out whether there were adaptive or degenerative changes in the fossa and condyle, and how

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long did it take for the poly(D,L)-lactide plates and screws to be resorbed.

Material and methods

We used poly-(D,L)-lactide (PDLLA) (Resorb X[®], Martin Medizin-Technik GmbH, Tuttlingen, Germany) for osteosynthesis. The time for its resorption was estimated to be between 52 and 77 weeks in soft tissue and a year in bone. Its bending strength was 101.6 MPa at 4 weeks after implantation, and was similar to the initial values.^{1,2}

Twelve Austrian mountain sheep (six male, six non-pregnant female) were operated on. They were about 2 years old and had a mean weight of 60 kg (range 56–62 kg). The study was authorized by the ethics committee of the University of Vienna. Animals were operated on under general anaesthesia and given two doses of penicillin-G 10 mega units and oxacillin 1 g as perioperative prophylaxis, and metamizole 5 mg intravenously twice a day for 3 days for postoperative analgesia.

We made a preauricular incision and identified and preserved the buccal and zygomatic branches of the facial nerve. The condylar neck was divided with an oscillating saw below the insertion of the lateral pterygoid muscle, and the proximal fragment was dislocated and repositioned. The two ends were joined with 2 PDLLA-plates 2 mm thick, and 8 PDLLA-screws 2 mm in diameter, of which 4 were placed in the proximal fragment (Fig. 1). Fixation was monocortical (5 and 7 mm screws) and the insertion of the lateral pterygoid muscle was preserved.

Polychromic stains were applied as follows:

Oxytetracycline (Terramycin[®], Pfizer Corp. Austria Ges.m.b.H, Vienna, Austria) 14 days postoperatively; calcein (Merck KGaA, Darmstadt, Germany) 28 days postoperatively; alizarin-3-methylamine *N,N*-diacetic acid dihydrate (Merck KGaA, Darmstadt, Germany) 56 days postoperatively; and xylenol orange tetrasodium salt (Merck KGaA, Darmstadt, Germany) 150 days postoperatively.

All fluorochromes were injected subcutaneously with 2% lignocaine 2 ml (with epinephrine 1:100,000).

The animals were cared for at the Center for Biomedical Research for a week and then put out to pasture. Food and water were not rationed. One sheep died from aspiration immediately after operation. Three animals were killed after 8 weeks, 5 after 6 months, and 3 after 12 months.

Specimens of the operated and non-operated sides were retrieved for anatomical and histological examination. The mandibular ramus and the temporal bone with the adjacent soft tissue were harvested as a single block.

Specimens were prepared for histological examination by a modified grinding-sawing technique.³ After fixation and dehydration the samples were embedded in either polymethylmethacrylate (PMMA) or Technovit[®] 7200 VLC

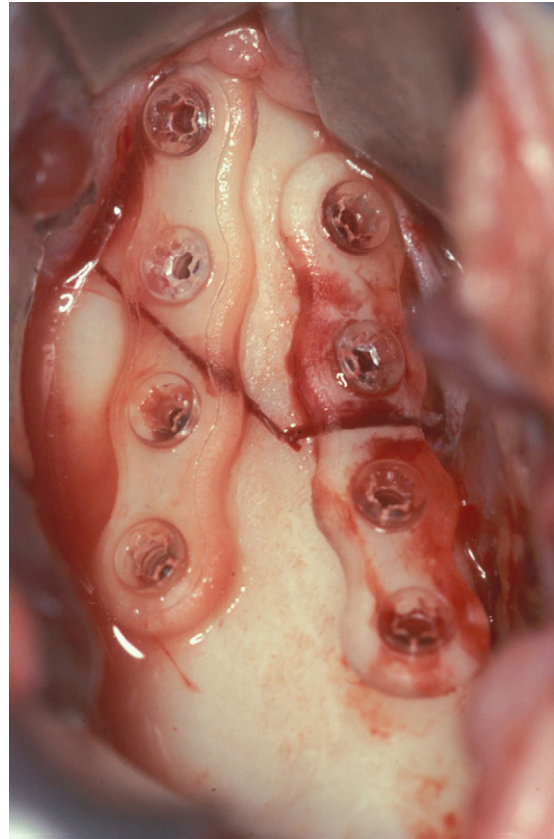


Fig. 1. Condylar neck fracture stabilised with two PDLLA-miniplates.

(Heraeus Kulzer GmbH, Wehrheim, Germany). Twelve slices of each joint were cut in a sagittal or coronal plane, ground down to a thickness of 10 μ m, and stained with toluidine – blue 1%. Slides were examined by epifluorescence and light microscopy.

Results

Healing was uneventful in all 11 remaining cases. The animals showed no sign of deterioration in feeding or behaviour at any time. They were examined monthly and at the time of sequence staining, and showed no swelling or infection at the site of operation.

Gross examination

All the bony cuts had healed in an anatomically correct position without deviation of the proximal fragment. There were no pseudoarthroses.

Histological examination

At no stage (from 8 weeks to 12 months) were there any histological signs of damage or degeneration of the disc or fossa.

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