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Comparison of shear strength of osteotomies fixed with absorbable self-reinforced poly-*L*-lactide and metallic screws

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Nine experimental osteotomies on the neck of a sheep's left mandibular condyle were fixed with self-reinforced poly-*L*-lactide (SR-PLLA) screws. Metallic screws were used in a group of nine sheep for the same fixation of the osteotomy. The right condyle of each sheep acted as a control. Radiographic analysis was carried out at 3 weeks and at sacrifice (6, 12 or 24 weeks) when the shear force needed to break the osteotomy site was measured. No significant differences were detected at 3, 6 or 24 weeks, but at 12 weeks the SR-PLLA-fixed condyles seemed to tolerate shear force somewhat better.

The results are very promising and have led us to continue with development of smaller screws and a self-reinforced poly-*L*-lactide plate.

1. Introduction

Absorbable devices, especially rods, have already shown their advantages in fracture fixation [1–4]. The device has a bending modulus close to that of bone [5] and it decomposes slowly transferring the stress gradually to the healing bone. These properties of the implant prevent osteoporosis of the bone. A metallic fixation being very stiff prevents the rapid formation of primary callus and deprives bone of the normal stress pattern. Paavolainen and his co-workers [6] showed changes at the first week of stiff plate fixation: some Haversian canals had become enlarged and the regular orientation of collagen bundles had been disrupted. By 17 weeks resorption areas had caused a derangement in the structure of the entire bone under the plate. This leads to osteoporosis and atrophy and may even lead to a refracture of the bone [6–8]. Many attempts have been made to produce a fixation device that would not interrupt the normal healing pattern of a fractured bone. The development of a fixation device that gradually biodegrades and does not interfere with healing or cause any systemic or local disorders and is strong enough, has been under constant research [9–15]. So far only cancellous bone fractures have been repaired with biodegradable screws clinically in humans in larger numbers [16].

An absorbable fixation device needs no removal operation after the fracture has healed. This is very important especially in maxillofacial surgery, because bruises in facial area cause disability for work for several days. In addition, other disadvantages of a second operation are avoided.

The purpose of the present study was to compare the shear strength of an experimental osteotomy on the neck of a sheep's left mandibular condyle fixed with absorbable and metallic screws. The right condyle of each sheep was used as a control.

2. Materials and methods

2.1. Materials

Eighteen adult sheep (Finnish sheep) of mass 34–54 kg were used. Nine self-reinforced poly-*L*-lactide (SR-PLLA) screws (group A) and nine metallic screws (group B) were used in the fixation of experimental osteotomies in the neck of the left mandibular condyle. The right condyle of each sheep acted as a control. No osteotomies were left unfixed because in our earlier studies we showed that this particular osteotomy needs to be fixed [17]. The core of the screws used was 3.2 mm and the thread diameter was 4.5 mm. The length of the metallic screw ranged between 20 and 30 mm. The raw PLLA was manufactured by Boehringer Ingelheim, BRD (molecular mass 750 000, crystallinity 37%) and the screws were manufactured by using a specific self-reinforcing technique in the Tampere University of Technology. In this technique parallel polymeric fibres are added (by means of sintering) at a high temperature into the matrix of the

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same polylactide material. This fibre-reinforcing (self-reinforcing) technique increases the mechanical properties of the implant so that the initial elastic bending modulus of the PLLA-screw is 7 GPa, bending strength 200 MPa, shear strength 110 MPa and maximum torque 0.2–0.3 N m. A Perkin Elmer DSC II differential scanning calorimeter (DSC) calibrated with indium and operated at scan speed of 20 °C min^{-1} was used to determine the heat of fusion (H_f) of PLLA samples. The H_f was estimated from the area enclosed by the DSC curve and the baseline. Crystallinity was calculated from the H_f compared with the H_f for fully crystalline poly-(*L*-lactide) 93.7 J g^{-1} estimated by Fischer *et al.* [18]. These values for the raw material are 54.9 J g^{-1} and 59%, for the fiber 54.3 J g^{-1} and 58% and for the SR-PLLA screw 66.1 J g^{-1} and 70%.

2.2. Operative procedure

Preoperatively the sheep were given 1 mg atropine (Atropin® 1 mg ml^{-1}, Orion) subcutaneously, and 1 200 000 IU benzylpenicillinprocaine (Procapen® 300 00 IU ml^{-1}, Orion) intramuscularily (i.m.). The sheep were anaesthetized with i.m. medetomidine (Domitor® 1 mg ml^{-1}, Lääkefarmos), 0.025 ml kg^{-1}, and i.m. ketaminehydrochloride (Ketalar® 50 mg ml^{-1}, Parke-Davis), 1.0 mg kg^{-1}. Every 30–60 min the sheep received intravenously 50% of the original amount of medetomidine and ketaminehydrochloride.

The left cheek of the sheep was shaved and scrubbed with polyvidon iodine (Betadine® 100 mg ml^{-1}, Leiras) and chlorhexidine gluconate (Klorheksidos® 5 mg ml^{-1}, Lääkefarmos) antiseptic solutions. Incision was made on the lateral side of the neck of the condyle from the temporomandibular joint and down to the angle on the mandible. The soft tissues were reflected down to the bone to expose the neck of the condyle. The capsule of the temporomandibular joint as well as the discus were left untouched. In some cases branches of the facial artery had to be ligated or lymph nodes excised to allow thorough exposure of the bone.

A drill channel was made with a 3.2 mm drill. The channel was drilled from the lateral surface of the mandible and directed towards the medial process on the condyle (Fig. 1a, b). The average length of the channel was 25 mm. An oblique osteotomy was made with an oscillating saw (blade width 14 mm) in the neck of the mandibular condyle. In an attempt to avoid thermal damage, bone preparation was made under flowing saline solution. The osteotomy was reduced and the threading was made with a 4.5 mm metal tap. The osteotomy was fixed with 4.5 mm absorbable polylactide (group A) or metallic (group B) screw. The heads of the SR-PLLA screws were cut with a heated knife to the right length after the fixation of the osteotomy. The incision was closed in layers by absorbable sutures (Vicryl®, Johnson & Johnson). All operations were performed by the first author using a standardized technique.

Postoperatively the sheep were given 400 mg phenylbutazone (Reumuzol® 200 mg ml^{-1}, Lääkefarmos) and returned to their pens. The sheep were given

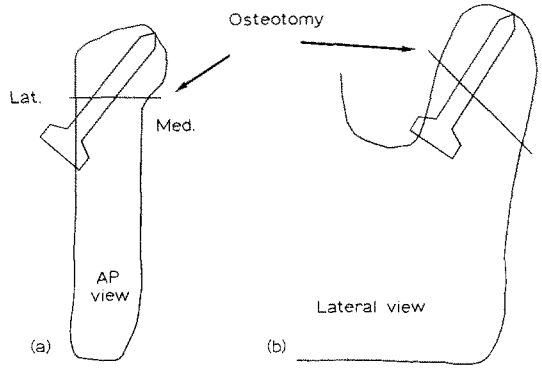


Figure 1 (a) Schematic drawing of the technique, lateral view. (b) Schematic drawing of the technique, anteroposterior view.

400 mg phenylbutazone and 1 200 000 IU benzylpenicillinprocaine daily for five days. All sheep started to eat soft food one day after the operation. On the sixth postoperative day the sheep were given hay and all ate and ruminated normally.

The follow-up times were 3 (for radiographic control), 6, 12 and 24 weeks.

2.3. Examination methods

Three weeks after the operation an oblique lateral radiograph was taken (Siemens Polyphos 30 M, Kodak T-MAT G film sizes 18 cm × 24 cm and 24 cm × 30 cm, intensifying screen Kodak Lanex medium, 55 kV, 10 mAs, 120 cm focus–object). Radiographs were analysed for the condition of the reduction and dislocation, relapse of the fixation, external callus, the visibility of the osteotomy line and the drill channel, and the possible ossification of the osteotomy. All radiographs were analysed by the same person. The evaluation was easier in the PLLA-group (group A) than in the metallic group (group B), because the screw is slightly radiolucent and does not obscure the fracture line.

After the animals were killed, the mandible was carefully dissected, inspected visually and radiographed (AP and lateral, Siemens Polyphos 30 M, Kodak T-MAT G film size 18 cm × 24 cm, intensifying screen Kodak Lanex medium, 44 kV, 4 and 4 mAs, 120 cm focus–object). Metallic screws were removed. The specimens were transferred to saline solution and the shear force needed to break the fixed osteotomy was measured within 24 h. The unoperated right condyle of each sheep acted as a control. The test arrangements can be seen in Fig. 2. The shear strength was measured by the J. J. Lloyd Instruments (UK) testing machine at room temperature (22–23 °C). The testing speed used was 10 mm min^{-1}).

3. Results

3.1. Three weeks

An oblique lateral radiograph was taken to evaluate the status of the fixation of the osteotomy. In both groups reduction was considered to be good and no diastasis, relapse of the fixation or callus could be detected.

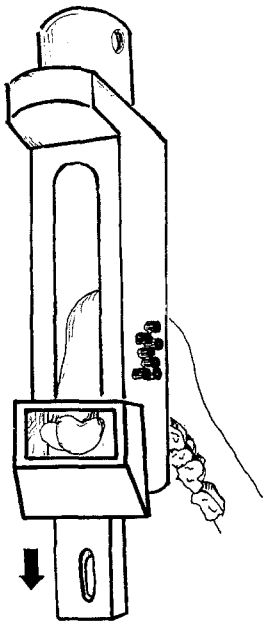


Figure 2 Test arrangements for measuring shear strength.

3.2. Six weeks

3.2.1. Group A

In radiographs no relapses of the fixation were detected (Fig. 3a). A slight callus formation was seen in two condyles. The visibility of the screw channel was not good because the screw is slightly radiolucent. The osteotomy line could still be detected in two cases but in one case it had already disappeared. The shear force to break the operated pieces of bone varied from 1100 N to 2000 N. In the control pieces the force varied from 1700 N to 2250 N. The average shear force needed to break the osteotomy site was 81% compared to the unoperated condyle of the same sheep. If the residual strength of the osteotomy (i.e. the full assumed residual strength of the screw 445 N [19] is subtracted from the results) is taken into account, the values were from 655 N to 1555 N (58%). Hence, all the operated pieces were weaker than the controls.

3.2.2. Group B

In radiographs the reduction of the osteotomy was good in all cases. The visibility of the osteotomy line had also started to decrease. In all condyles a slight external callus was observed. The shear force needed to break the osteotomy varied from 1200 N to 1550 N (controls 1400 N to 2150 N). The average shear force needed to break the osteotomy site was 77% compared to the unoperated condyle.

3.3. Twelve weeks

Radiographic analysis revealed a slight external callus in all condyles (Fig. 3b). The osteotomy line was slightly detectable in one case. All osteotomies were considered consolidated. All osteotomies that were fixed with PLA-screws were stronger than or equal to the controls. The shear force to break the operated condyles varied from 1100 N to 3300 N. In the control pieces the force varied from 1525 N to 2800 N. The average shear force needed to break the bone was in PLA-screws 112% and in metallic screws 85% compared to the unoperated condyle. At 12 weeks of follow-up, the residual strength of the SR-PLLA screw was 23 MPa. If this is taken fully into account, the average force needed to break the SR-PLLA-screw-fixed osteotomy was 103% compared to the unoperated condyle.

3.4. Twenty-four weeks

In radiographs all osteotomies in both groups were united and no callus could be seen (Fig. 3c). The fixation method did not seem to affect the strength of the osteotomy after 24 weeks. In both groups the operated side was nearly as strong as the unoperated side (97% in PLA, 99% in metallic fixation). By this time the strength of the PLLA had decreased to 8.7 MPa, which does not change these results.

4. Discussion

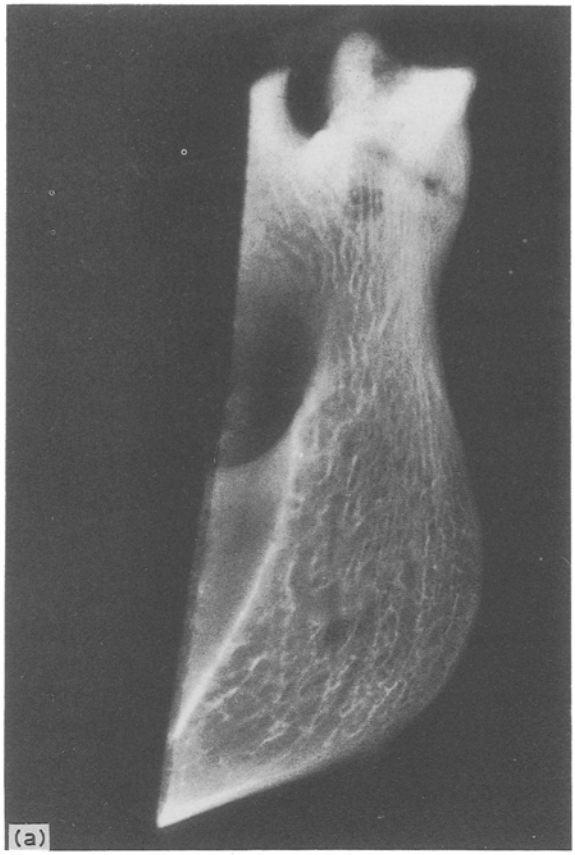
We have already shown in our previous work that the fixation of this osteotomy is essential. The unfixed condyle head dislocates and malaligns severely [17]. Sheep were chosen as a model for this operation because of the similarities in the shape and size of condyle to human condyle [20].

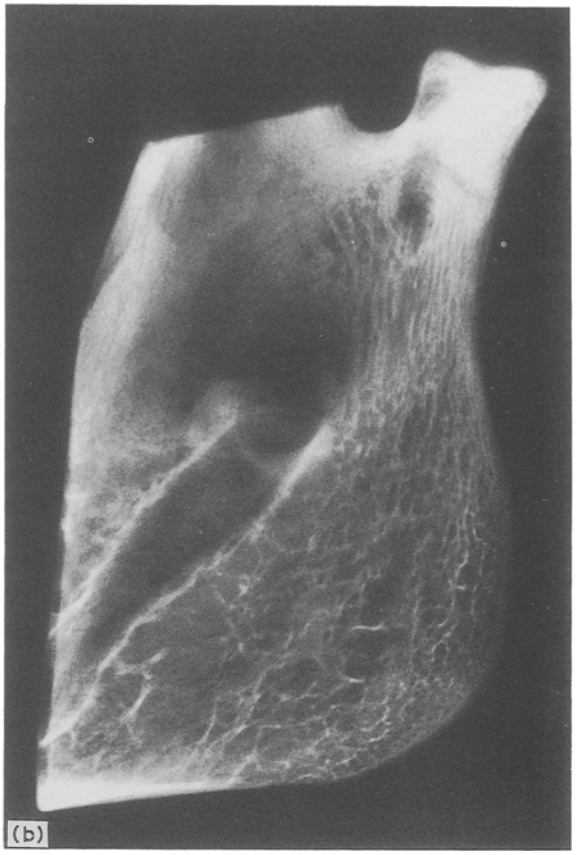
Open reduction of condyle fractures and experimental osteotomies have been described with different fixation device by many authors. Wire ligatures were the first device used [21–24], Stephenson and Graham [25] and Brown and Obeid [26] used Kirschner pins and Koberg and Momma [27], Klotch [28] and Chuong and Piper [29] used miniplates. Screws have been used also in some studies to fix human mandibular condyle fractures. In human cadavers Petzel and Bülles [30] used a traction-screw applied through a drilled central slide canal in the ascending ramus and Kitayama [31] applied a cancellous bone screw through the mandibular crest.

Open reduction and sufficient fixation is essential for the temporomandibular joint especially when the fracture is grossly displaced [22]. Wood, Lindahl and Lindahl and Hollenger observed that conservative treatment of condylar fractures led to a limited mouth opening and apparent deviation especially with adults [32–34]. The head of the condyle was also significantly remodelled in many patients.

This present study demonstrates that both PLA and metallic screws were strong enough to hold the fixation and no redislocations were detected. In this work the consolidation of the osteotomy seemed to be faster in the PLA-group than in the metallic group. Twelve weeks after the operation those osteotomies fixed with PLA-screws seemed to be stronger than those fixed with metallic device. Twenty-four weeks postoperatively the fixation material did not affect the force needed to break the bone.

The difference observed at 12 weeks can be due to better healing of the fracture as well as due to an incomplete biodegradation and strength loss of the screw. The studies concerning the strength loss of





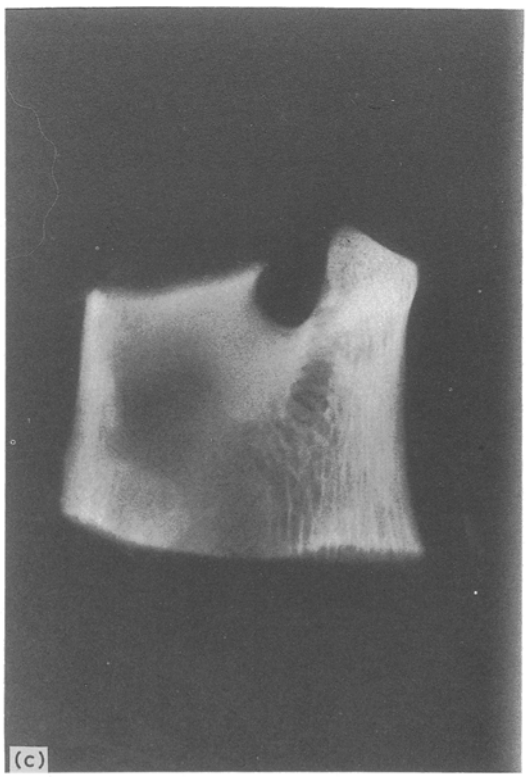


Figure 3 Radiograph of a PLLA-fixed condyle: (a) 6 weeks, (b) 12 weeks, (c) 24 weeks after the operation.

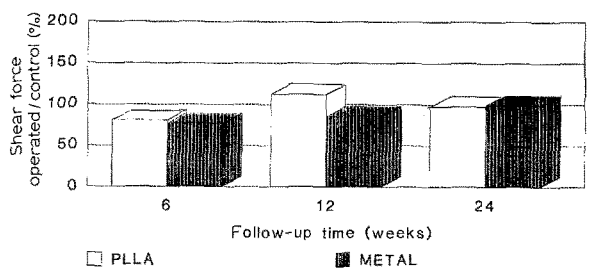


Figure 4 Shear strength of the fixed osteotomy compared to the control side 6, 12 and 24 weeks after the operation.

SR-PLLA-screws *in vivo* and *in vitro* are in process [19]. The bending modulus of SR-PLLA-screws is close to that of bone which may lead to faster healing of the osteotomy [5].

The SR-PLLA-screw starts to biodegrade from the periphery (threads), which is simultaneously replaced by new bone. This led to our test arrangement where metallic screws were removed before measuring the shear strength of the fixation of the osteotomy but SR-PLLA-screws were not because it was impossible to extract the screw.

The original torsion strength of the screw needed to be improved because in the pilot study some screws were broken when introduced to the channel. The torsion strength has since been improved and breaking of the screw can be avoided by performing the threading very carefully and by flushing the drill channel thoroughly before entering the screw into the channel.

This experimental study has encouraged us to start developing an absorbable self-reinforced poly-*L*-lactide plate, which together with smaller absorbable screws could be used to fix other fractures of the mandible.

Acknowledgements

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