Polylactide screws in the fixation of olecranon osteotomies

A mechanical study in sheep

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We studied absorbable self-reinforced poly-L-lactide screws in the fixation of osteotomies in sheep. A left olecranon osteotomy in 10 sheep was fixed with polylactide screws and in an additional 10 sheep with metallic AO cortical screws. Follow-up times were 6 and 12 weeks. 8 polylactide fixations healed and 2 failed. All metal fixations united; one of them had a fracture of the proximal fragment resulting in malposition. After killing the sheep the olecranons were radiographed and the shear strengths of the osteotomies were compared with those of the non-operated contralateral bones. After 6 weeks the mean comparative strength was 74 percent in the polylactide group and 83 percent in the metallic control group. After 12 weeks the corresponding values were 112 and 47 percent ($P < 0.05$).

Our study demonstrated that the mechanical weakening of fixed bone can be avoided by using absorbable polylactide screws instead of metallic screws. However, polylactide screws are not recommended for use without external support in places of high mechanical strain.

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Absorbable fixation devices made of self-reinforced polyglycolide have been in clinical use more than 5 years, and the results of low-stress bearing cancellous bone fixations have been good (Rokkanen et al. 1985, Vainionpää et al. 1989, Hirvensalo 1990, Partio et al. 1990). A limitation is the rather rapid loss of mechanical strength: polyglycolide devices maintain sufficient strength for fracture fixation during 4–8 weeks (Törmälä et al. 1991). Poly-L-lactide is another promising absorbable polyester, which is well-tolerated by tissues (Kulkarni et al. 1966, Cutright and Hunsuck 1971, Getter et al. 1972, Eitenmüller et al. 1987, Bos et al. 1991, Majola et al. 1991) and which has better strength-retention properties than polyglycolide (Pohjonen et al. 1989).

We have developed a new generation of self-reinforced poly-L-lactide screws with good strength properties. The present study was carried out to evaluate the strength of these new screws, and the strength of bone after fixation of cancellous bone osteotomies exposed to high mechanical strain.

Materials and methods

20 mature (18 females, 2 males), healthy Finnish sheep with an average weight of 57 (45–81) kg were used. An osteotomy of the left olecranon was fixed with a metallic screw in 10 sheep, and with a polylactide screw in an additional 10 sheep.

The metallic AO cortical screws were 50 mm in length, 3.2 mm in core and 4.5 mm in thread diameter. The polylactide screws had the same dimensions; they were produced by a sintering reinforcing technique (Törmälä 1988, Pohjonen 1989); the molecularly highly-oriented poly-L-lactide fibers with a poly-L-lactide matrix were compression-molded to form screws. The screws were composed of 35 percent Mw 250000 poly-L-lactide produced by CCA Biochem (Gorinchem, Holland) and 65 percent Mw 250000 poly-L-lactide produced by Boehringer Ingelheim (Ingelheim, Germany). The thread profile was shallower and the thread configuration was coarser in the polylactide screws than in the metallic ones (Figure 1). The polylactide screws were sterilized with a 2.5 mrad dose of gamma radiation. Thereafter they were tested with a rotational moment of 0.1 Nm to screen out weak ones.

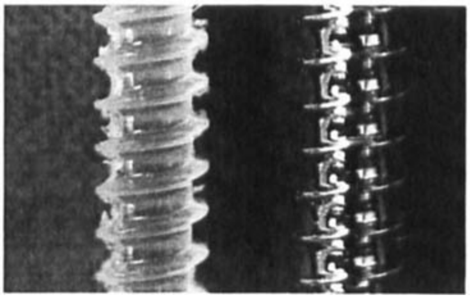


Figure 1. The screws used for fixation of olecranon osteotomies in sheep. The thread profile was shallower and the surface was coarser in the polylactide screws (left) than in the metallic AO screws (right). The threads were 4.5 mm in diameter and the cores 3.2 mm in diameter.

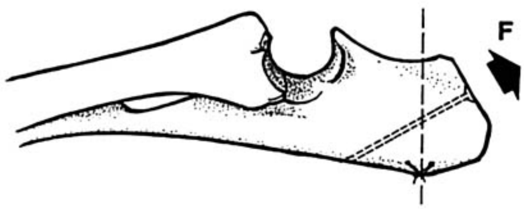


Figure 2. The left radius and ulna of sheep. The osteotomy line is presented by the dashed line and the fixation screw by the double dashed line. Note the polyglyconate suture which was used to prevent rotation of the proximal fragment. The main tensile force direction caused by the tendon of the triceps brachii muscle is indicated with an arrow.

In a pilot study, polylactide screws, similar to those used in this study, were mechanically tested in vitro after hydrolyzation. The mean initial shear strength of the sterilized screws was 75 MPa and during hydrolysis in 37 °C, pH 6.10 phosphate buffer it remained at a level over 60 MPa until the 16th week. At 24 weeks, the strength had decreased to 31 MPa and after 48 weeks' incubation the shear strength was 7 MPa. Moreover, two cadaver sheep olecranons were osteotomized as described below, and after fixation with polylactide screws the bones were tested to determine the shear force and strength of the screws in the drill channel without the effect of the healed bone. The forces needed to break these fixations were 200 and 340 N, corresponding to 17 and 29 MPa in screw strength, which was less than half of the strength measured on the screws. In this pilot test, the cancellous bone around the screw gave way, and thus simultaneous bending stress during the shearing caused delamination of the reinforcing fibers of the screw and resulted in the lower strength values.

Just before the operation, 1 mg of atropine subcutaneously and 1.2 million IU of benzylpenicillin procaine intramuscularly (i.m.) were administered to the sheep. They were anesthetized with i.m. medetomidine in a dose of 0.025 mg/kg, and i.m. ketamine hydrochloride in a dose of 1.0 mg/kg. Every 30–60 minutes the sheep received half of the original dose of medetomidine and ketamine intravenously in accordance with the response to a surgical stimulus. They were maintained in right recumbency during surgery to ensure good exposure of the left olecranon.

The left cubital region was shaved and scrubbed with polyvidon iodine (Betadine®) and chlorhexidine gluconate (Klorheksidos® 5 mg/mL). After a standard lateral approach to the left olecranon, a 3.5 mm channel was drilled from the tip of the olecranon through the lateral cortex of the ulna, about as far from the intended line of the osteotomy as the point of introduction (Figure 2). An osteotomy was performed with an oscillating saw between the triceps tendon and the cubital joint. After prefixation with supporting bone clamps and a Kirschner wire, the drill channel was tapped with a 4.5 mm AO tap in the metallic group and with a special 4.5 mm tap made for Biofix® absorbable screws (Bioscience, Tampere, Finland) in the polylactide group. A 50 mm metallic or polylactide screw was then introduced to fix the osteotomy. One 2 mm hole was drilled tranversely through both fragments, and three 1–0 polyglyconate (Maxon®) sutures were inserted through the drill holes in a figure-eight tension band fashion to prevent rotation of the proximal fragment (Figure 2). The pre-fixation clamps and Kirschner wire were removed. The incision was closed in a standard fashion. The right olecranon was left intact.

Immediately postoperatively, 400 mg phenylbutazone (Reumuzol® 200 mg/mL) was administered i.m. to the sheep and they were transferred to their pens. They were kept on a daily dose of phenylbutazone i.m. and 1.2 million IU benzylpenicillin procaine i.m. for 5 days and their ability to walk was observed. The sheep were allowed to move freely, without any external support. Normal food and water were available. 3 weeks after the operation all sheep were anesthetized to obtain radiographs of the operated elbow. 5 sheep in each group were killed at 6 weeks and the rest at 12 weeks, excluding 2 sheep from the polylactide group which were killed at 5 weeks because of ambulatory difficulties. After killing, both the left and right radius and the ulna were exarticulated and dissected. The healing of the osteotomies was checked manually. The metallic screws were removed.

No complications with regard to anesthetic management or postoperative infection occurred. One polylactide screw broke following introduction into the drill

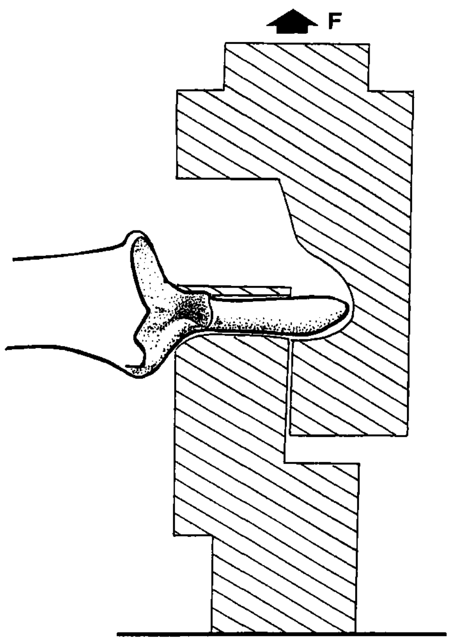


Figure 3. Shear force measurement of sheep olecranon using tensile testing equipment JJ 5003. F = force.

channel, and it was impossible to remove it. A new hole was then drilled and another polylactide screw was introduced. All sheep from the metallic group and 8 out of 10 sheep from the polylactide group, including the one with double-drilled olecranon, moved normally one week postoperatively. The 2 sheep killed at 5 weeks, as described above, had total failures of the polylactide screws.

After death, radiographs of both the operated on and the contralateral olecranons were taken in anteroposterior and lateral projections. Fixation, visibility of the osteotomy line, malpositions, callus formation, and healing of the osteotomy were evaluated.

The bone specimens were stored in a 20 °C saline solution, and the shear tests were performed within 40 h. The shear force needed to break the bone at the osteotomy line was measured in the operated left ulna and in the same manner in the unoperated right ulna (Figure 3) with a mechanical testing unit (JJ 5003, JJ Lloyd Instruments, Southampton, England). When the operated olecranon was fixed to the testing instrument, the site of the osteotomy, and accordingly the site for shear testing, was checked from the radiograph. The testing speed was 10 mm/min at room temperature. The shear strength τ was calculated from the formula

$$\tau = F / A,$$

where F is the ultimate shear force and A is the surface area determined from the drawing made of the shear surface. To avoid mistakes due to differences in the bone structure of the individual sheep, the shear force and strength of the healed osteotomies were divided by those of the non-operated olecranons, which gave comparative shear forces and comparative shear strengths.

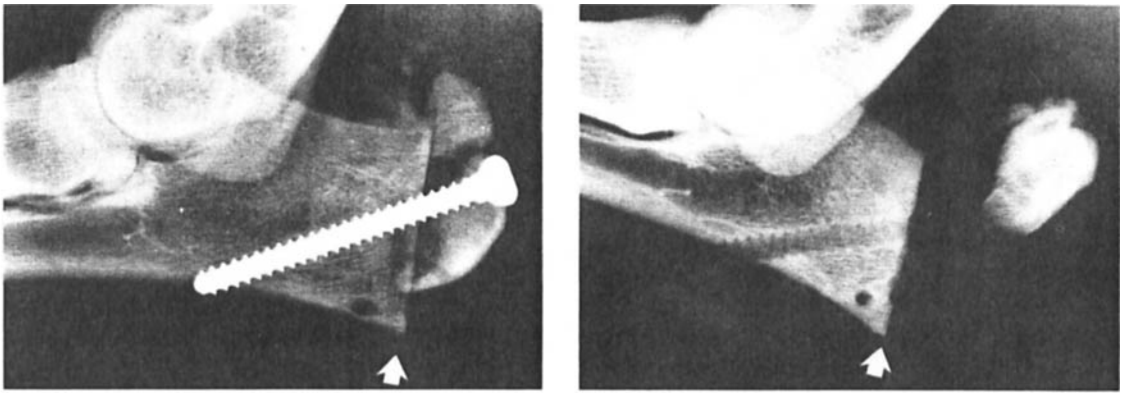
For statistical analysis, two way analysis of variance and the Student's t-test with a two-tailed interpretation were used.

Results

In the radiographic evaluation at three weeks all metallic screws had maintained fixation. However, in one sheep the proximal fragment had a horizontal fracture and there was an 8 mm anterior displacement of the proximal fragment, but no diastasis was seen at the osteotomy line (Figure 4). In another sheep from the metallic group the polyglyconate threads had snapped and there was a 90° rotation of the proximal fragment. 8 out of 10 polylactide fixed olecranons were radiographically intact at 3 weeks. The two remaining polylactide fixations had failed at this point, but the proximal fragment was intact in both (Figure 4). The osteotomy line was clearly visible in every olecranon. No differences were found in the radiographic evaluation between the groups. No external callus was noticed at three weeks in either group.

On the final radiographs at 6 and 12 weeks all metallic and 8 polylactide fixations showed bony union. The 2 failed polylactide fixations belonged to the 12-week group. The osteotomy was visible at 6 weeks in every olecranon in both groups, but at 12 weeks the line had totally disappeared in two metallic and two polylactide fixations. In 8 of 10 sheep in each group healing occurred without deformation; in the metallic 6-week group the 2 sheep with proximal fragment fracture and rotational malposition showed union. The healing of the osteotomy was evaluated as good in 3 metallic and 5 polylactide-fixed olecranons at 6 weeks, and in 4 metallic and 3 polylactide-fixed olecranons at 12 weeks. No differences were found between the metallic and the polylactide groups in the radiographic results at the end of the follow-up.

One out of 5 olecranons in the metallic 6-week group was not accepted for shear testing because the malposition and massive external callus prevented fitting of the bone into the testing instrument. The 2 totally failed polylactide fixations had no bony connection to be measured and were therefore excluded from mechanical testing. The absolute shear force of the operated olecranons and the comparative shear



At 3 weeks, a fractured proximal fragment was seen in the largest sheep in the metallic group. This caused malposition of the fragment, but it nevertheless united.

At 3 weeks, two fixation failures were observed radiographically, both in the polylactide group.

Figure 4. The operated on olecranons that healed with difficulty. The osteotomy lines are shown by arrows.

Table 1. Shear testing results. Comparative values were calculated by dividing the forces and the strengths of the operated olecranons by those of the controls and they are presented in percent. Only 4 sheep were included in the 6 weeks metallic group because of massive callous bone in one specimen, making the shear testing impossible. In the 12 weeks polylactide (PLLA) group only 3 were included because of two failed fixations

Material of screw	Follow-up time (wk)	Shear force (kN)		Comparative shear force (percent)	Shear strength (MPa)		Comparative shear strength (percent)
		operated	control		operated	control	
Metal	6	1.00	1.90	53	5.6	14.6	38
		1.90	2.10	90	13.1	14.5	90
		1.57	0.90	174	6.3	7.8	81
		1.44	1.18	122	11.7	9.7	121
Mean		*1.48*	*1.52*	*110*	*9.2*	*11.7*	*83*
PLLA	6	1.60	2.20	73	8.3	13.8	60
		1.25	2.40	52	7.2	13.2	55
		1.25	1.90	66	4.7	14.7	32
		2.65	1.55	171	13.5	10.2	132
		2.75	1.65	167	10.4	11.4	91
Mean		*1.90*	*1.94*	*106*	*8.8*	*12.7*	*74*
Metal	12	2.40	2.76	87	11.4	27.1	42
		1.05	2.05	51	4.4	17.1	26
		0.90	1.70	53	3.9	10.8	36
		1.95	2.00	98	8.8	14.7	60
		1.60	1.25	128	7.0	9.8	71
Mean		*1.58*	*1.95*	*83*	*7.1*	*15.9*	*47*
PLLA	12	2.95	1.68	176	18.0	10.7	168
		3.40	3.14	108	12.8	16.4	78
		2.00	1.65	121	8.4	9.2	91
Mean		*2.78*	*2.16*	*135*	*13.1*	*12.1*	*112*
Mean of all		1.86	1.88	105	9.0	13.0	75
SD of all		0.74	0.56	46	4.0	4.0	39

strength showed the polylactide group to be better than the metallic group ($P < 0.05$ in both) (Table 1). No differences between the groups were found in absolute strength or in comparative shear force.

Discussion

Fixation with polylactide devices has been successful in non-weight bearing fractures (Cutright and Hunsuck

1972, Getter et al. 1972, Bos et al. 1987, Rozema et al. 1990), but the results have been less satisfactory in regions subjected to high mechanical strain (Eitenmüller et al. 1987). The molecular, structural and mechanical information about devices used have often been incomplete, and therefore the comparison of devices has been difficult. Vert et al. (1981) reported that the bending strength of their poly-L-lactide devices was 58 MPa. Poly-L-lactide rods (MW 800 000) used by Eitenmüller et al. (1987) had a bending strength of 122 MPa and a bending modulus of 3.8 GPa. Leenslag et al. (1987) presented poly-L-lactide plates and screws (Mw 950 000) with a tensile strength of 75 MPa and a bending modulus of 5 GPa. The self-reinforcing technique presented by Törmälä et al. (1988) increased the bending strength of MW 250 000 self-reinforced poly-L-lactide rods up to 180–300 MPa, the bending modulus to 7–10 GPa, and the shear strength to 110–220 MPa (Pohjonen et al. 1989). The self-reinforced poly-L-lactide screws used in our study were manufactured by the same technique using the same materials, but the strengths were decreased due to the shape of the screw threads.

In a study of 6 beagle calcaneus osteotomies fixed with high MW polylactide screws Tunc et al. (1986) released little information on the polylactide used. Although all 6 fixations healed successfully, the facts that a postoperative cast was used and the weight of a beagle is only 20 percent of the weight of a sheep, indicate that forces acting on the fixed osteotomy were many times higher in our study. Räihä et al. (1990) had one non-union out of 6 beagle trochanteric osteotomies fixed with self-reinforced poly-DL-lactide/poly-L-lactide screws, the failed fixation being attributed to poor reduction, which allowed cyclic loading forces to act on the screw and thus result in fatigue. The reduction of the two failed fixations in our study was excellent, and thus we draw the conclusion that the shear strength of the screws was not great enough or that the micromovements of the osteotomy plane caused rapid polylactide screw fatigue. There were some individual differences in the properties of each polylactide screw because each one was individually manufactured by hand and the production process was very demanding.

The polylactide screws were impossible to remove from the thread channels prior to mechanical testing and thus they increased the shear force of the polylactide group. The mean force needed to break the polylactide screw in the bone was 270 (200 and 340) N in the pilot study. This was 15 percent of the mean shear load carrying capacity of all the operated olecranons or 12 percent of that of the polylactide-fixed olecranons. If a polylactide screw is used as a fixation device and if micromovements at the fracture act on the screw, it can be assumed that because of fatigue the strength of the screw will decrease more rapidly than it does during in vitro hydrolysis. Quantitative data of this process are not available.

We had one failure of the proximal fragment in the metallic group caused by the high forces acting on the fragment in the largest sheep in the group, perhaps associated with a microfracture of the fragment during surgery. This kind of fracture problem was absent in the polylactide group. It was noticed that the operation technique using the polylactide screw was more demanding because of the rather poor rotational strength and coarse surface structure of this screw resulting in high frictional forces. This, perhaps associated with an individual poor inner structure of the screw, resulted in the peroperative failure of one polylactide screw. The high friction between the screw and the bone can also be beneficial; it is impossible for a well introduced polylactide screw to unscrew by itself.

The strengths of the intact bone specimens ranged from 7.8 MPa to 27 MPa. Such large variations in the strength of cancellous bone are common (Goldstein 1987).

The modulus of elasticity of stainless steel used in metallic fixation devices is more than ten times higher than that of bone (Tonino et al. 1976). The rigidity of metallic fixation devices may cause osteopenia, atrophy, and weakening of the bone (Uhthoff and Dubuc 1971, Tonino et al. 1976, Paavolainen et al. 1978, Paavolainen et al. 1979). We found weakening of the metallic screw-fixed olecranons between 6 and 12 weeks (83 versus 47 percent), while the successful polylactide-fixed osteotomies increased in strength (74 versus 112 percent). The tensile forces on the olecranon act mainly in the direction of the screw; a rigid metallic screw which passed through two cortexes carried part of these forces (Figure 2).

Our study indicated that the use of self-reinforced poly-L-lactide screws, instead of metallic screws, in the fixation of olecranon osteotomies in sheep prevented stress-protection and weakening of the fixed bone. However, this version of the polylactide screws is not sufficiently strong to be used without external support in places of high mechanical strain.

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