Strength retention of drawn self-reinforced polyglycolide rods and fixation properties of the distal femoral osteotomies with these rods. An experimental study on rats

HARRI PIHLAJAMÄKI, E. ANTERO MÄKELÄ, NUREDDIN ASHAMMAKHI, JANNE VILJANEN, HANNU PÄTIÄLÄ, PENTTI ROKKANEN*
Department of Orthopaedics and Traumatology, Helsinki University Central Hospital, Topeliuksenkatu 5, FIN-00260 Helsinki, Finland

TIMO POHJONEN, PERTTI TÖRMÄLÄ
Institute of Biomaterials, Tampere University of Technology, PL 589, FIN-33101 Tampere, Finland

ANTTI JOUKAINEN
Mikkeli Central Hospital, Porrassalmenkatu 35–37, FIN-50100, Mikkeli, Finland

Drawn self-reinforced polyglycolide (SR-PGA) rods, ∅ 2 mm and 26 mm long, were implanted in the dorsal subcutaneus tissue of 16 rats. Osteotomies of the distal femur were fixed with SR-PGA rods (2 mm by 15 mm) in another 38 rats. The follow-up times varied from one week to one year. After sacrifice, three-point bending and shear tests were performed for subcutaneously placed rods. Radiological, histological, histomorphometrical, microradiographic, and oxytetracycline-fluorescence studies of osteotomized and intact control femora were also performed. At three weeks the flexural strength of the rods was 50% of the initial value, and the flexural modulus was 46% of the initial value. Five osteotomy specimens had to be excluded due to dislocation or non-union. One of the 33 evaluated osteotomy specimens showed signs of postoperative infection. Thirty-two osteotomies healed uneventfully. No gross signs of inflammatory or foreign-body reaction were observed. The amount of osteoid surface and active osteoid formation surface reached their highest value in the histomorphometrical analysis at 24 weeks. The present investigation demonstrated that the mechanical strength and fixation properties of the drawn SR-PGA rods are suitable for fixation of cancellous bone osteotomies in rats. The present article is the first report on the successful application of drawn SR-PGA rods for fixation of cancellous bone osteotomies.

Introduction

Polyglycolic acid (PGA) was the first bioabsorbable suture material [1] and commercially available since 1970 [2]. The human mandibular fractures were the first fractures that were fixed with PGA sutures, but together with an intraoral arch bar [3]. Since 1982, our research group has used PGA rods in animal experiments [4–6] and later PGA/PLA copolymer rods [7, 8] experimentally in bone fixations and, from 1984 on, clinically [9]. The self-reinforced technique consists of a bioabsorbable polymeric matrix reinforced with fibers of the same polymer which increases the strength of the rods [8]. In this study, the drawn PGA rod was studied in the fixation of distal femoral osteotomies in the rat.

Materials and methods

Self-reinforced polyglycolide (SR-PGA) drawn rods (Bioscience Ltd., Tampere, Finland), 26 mm (mechanical tests) and 15 mm (osteotomy fixations) long and 2 mm in diameter, were used (raw material = Purasorb-PGA, MFI 28 at 230 °C; manufacturer CCA Purac, Holland). The melting peak temperature and the heat of fusion of the samples were measured using a Perkin-Elmer DSC-7 differential scanning calorimeter calibrated with indium standards. The dried samples, weighing 6 ± 1 mg, were scanned at a heating rate of $20\,^{\circ}\mathrm{C\,min^{-1}}$ under a dry nitrogen atmosphere from room temperature to 250 °C. The degree of crystallinity was estimated from the heat of fusion, assuming $191.3\,\mathrm{J\,g^{-1}}$ [10] for perfectly

*Author to whom all correspondence should be addressed: Helsinki University Central Hospital, P.O. Box 266 (Topeliuksenkatu 5), FIN-00029 HUS, Finland.

crystalline PGA. The SR-PGA rods were sterilized by ethylene oxide and thoroughly degassed. The rod packages were opened just before the tests started.

Mechanical testing

The wet rods were tested by the three-point bending test using an Instron 4411 (Instron plc, High Wycombe, UK). All samples were tested with a 16 mm support span, loading at the middle of the span. The testing speed was 5 mm min^{-1}. The flexural properties were calculated as follows: flexural strength: $\sigma = 8F_mL/\pi D^3$ (F_m = load at break, N, L = support span, mm, D = diameter of rod, mm) and tangent modulus of elasticity (flexural modulus): $E_b = 4L^3m/3\pi D^4$ (L = support span, mm, D = diameter of rod, mm, m = slope of the tangent to the initial straight-line portion of the load-deflection curve, N/mm of deflection).

Thermal characterization

The thermal characterization of the samples was performed by differential scanning calorimetry (DSC). Perkin-Elmer DSC7 (Perkin-Elmer, Norwalk CT, USA) was used with nitrogen carrier gas and cooled by water. All samples received treatment as follows: (1) Heating 30–220 °C at a rate of 20 K min^{-1}, (2) rapid cooling (200 K min^{-1}) and (3) heating 30–220 °C at a rate of 20 K min^{-1}

The glass transition temperature (T_g), cold crystallization temperature (T_c), heat of fusion (H_c), melting temperature as peak value (T_m), and heat of fusion (H_m) were registered, when occurred. The possible crystallization indicated by H_m–H_c during the *in vivo* experiment was studied from the scans.

Morphology

The surface and cross section (cryo-cut) of the rods were studied for morphological changes *in vitro* using Scanning Electron Microscope (SEM, Jeol T100, Tokyo, Japan) and 15 kV. The specimens were gold-coated for SEM studies.

Animal experiments

SR-PGA rods, 26 and 15 mm long and 2 mm in diameter, were used. The rod packages were opened just before the tests started.

For the *in vivo* study, 54 female Wistar rats, 12–18 weeks old and weighing 260–410 g, were operated on. The rats received CO_2 by inhalation, for induction, and the anesthesia was continued with 0.1 mg per 300 g medetomidine (Domitor™, Lääkefarmos, Turku, Finland) and 3 mg per 300 g ketamine hydrochloride (Ketalar™, Parke-Davis, Barcelona, Spain) by subcutaneous injections.

Subcutaneous implantation of the rods in rats for mechanical tests

Four SR-PGA rods, 26 mm long, were implanted in the dorsal subcutaneous tissue of 16 rats, through four separate surgical approaches. The wounds were closed with 4–0 USP PGA sutures (Dexon®, Davis + Geck, USA). Postoperatively the rats were returned into their cages where they recovered from the anesthesia. They were given a regular normal laboratory animal diet. They were followed-up for 1, 3, 6, 12, 24, 36, 48, and 52 weeks.

After sacrifice of 16 rats, two in each follow-up time, the rods were removed from the dorsal subcutaneous tissue of rats and immediately placed in saline. The bending strength tests were determined for the wet rods within 19 h after death and immediately after removal from saline.

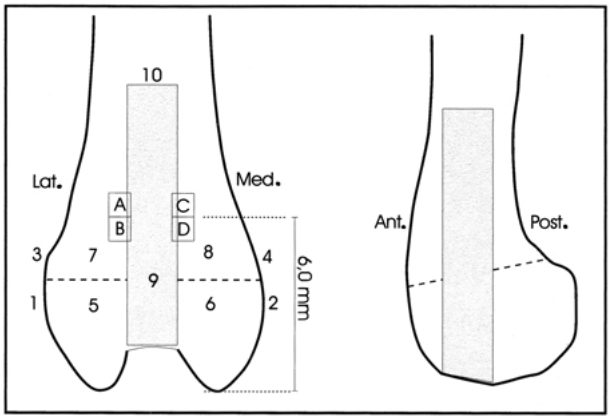


Figure 1 Schematic anterior and lateral views of the distal rat femur showing the site of the osteotomy, the implant, the four standardized sample fields (A, B, C, D), and the ten areas (1–10) analyzed in the oxytetracycline fluorescence study.

Osteotomy fixation in rats

The right knee of 38 rats was shaved and sterilized with antiseptic fluid (Neo-Amisept®, Orion-Farmos, Turku, Finland). An incision was made through the medial side to open the knee. The patella was dislocated laterally, and the distal end of the femur was exposed. A drill hole of 2 mm was made through the intercondylar space. An osteotomy was done using an oscillating saw through the metaphysis leaving the posterior cortex intact to serve as a hinge. A drawn SR-PGA rod, 15 mm long, was introduced through the drill hole to fix the osteotomy (Fig. 1). In this series some of the rods were placed at the level or slightly over the intercondylar cartilage to secure the fixation. The wounds were closed in layers with 4–0 USP PGA sutures (Dexon®, Davis + Geck, USA), and the rats were given 100 000 IU procain penicillin s.c.

Postoperatively, the rats were returned into their cages where they recovered from the anaesthesia. They were given a regular normal laboratory animal diet. The rats were allowed to use their limbs after operation, and no external support or splint was used. They were followed-up for 1, 3, 6, 12, 24, 36, 48, and 52-weeks; each study follow-up group consisted of five rats, except at the 52-week group which consisted of three rats. Two days before sacrifice the rats were given oxytetracycline 50 mg kg^{-1} to make newly-formed bone visible for oxytetracycline (OTC) labeling studies [11]. The rats were sacrificed with an overdose injection of medetomidine and ketalar. The healing of the osteotomies was evaluated radiologically, histologically, microradiographically, histomorphometrically, and using oxytetracycline fluorescence.

TABLE I Differential scanning calorimeter (DSC) analysis of drawn SR-PGA rods *in vivo*

Time (weeks)	Melting peak (°C)	Heat of fusion ($J\,g^{-1}$)	Degree of crystallinity (%)
0	223.4	79.32	41.5
3	223.6	89.6	46.8
3	222.1	93.3	48.8
6	217.4	122.7	64.1
6	219.4	114.1	59.6
33	197.3	44.2	23.1

Examination methods

After sacrifice both femora were disarticulated and dissected in each rat. Radiographs were taken in the anteroposterior and lateral position (distance 100 cm, 40 kV, 12 mA, and 0.03 s). Macroscopic and manual evaluations of the osteotomies were done. The intact left femur served as a control. The distal parts of both femora were taken as specimens, fixed in ethanol, and embedded in methyl methacrylate [12]. For histological analysis, five-micrometer-thick longitudinal sections in the coronal plane were cut with a microtome (Polycut S, Reichert-Jung, Nussloch, Germany) and stained by modified Goldner-Masson method [13]. Sections measuring 80 μm were cut with a Leitz Saw Microtome 1600 (Leitz GMBH, Wetzlar, Germany) for OTC-fluorescence and microradiographic studies. In the microradiographic examinations, Kodak Professional film SO 343 was used, and the technical values were: 50 kV, 9 mA, 12 min exposure time, and 22 cm film-focus distance. Fluorescence microscopy was performed using an HBO 220 UV lamp and a BG 812/6 primary filter.

For semiautomatic quantitative histomorphometric analysis a Leitz microscope was linked via a videocamera (PCO, SensiCam 3.0, Kelheim, Germany) to a computer (Dell Optilex MMP Pentium, Ireland). Magnifications of 20 × and 125 × were used. Image analysing software (AnalySIS Pro 3.00, Soft-Imaging Software GmbH, Münster, Germany) was used. Three specimens in seven follow-up groups (from one to 48 weeks) were analyzed. Both femora were analyzed in each rat. Thus, there were 42 longitudinal histological sections, and, from each, four standardized sample fields (168 altogether) were delineated in the femora at the metaphysis centralizing 6.0 mm from the distal joint level and 1.5 mm apart in horizontal direction (Fig. 1). AnalySIS-program was used in the determination of the corresponding site, in every specimen.

Within the 1.06 mm × 0.84 mm ($0.89\,mm^2$) sample fields, the histomorphometric variables were analyzed. The variables were as follows: total trabecular bone volume fraction (including calcified trabeculae and osteoid), total osteoid surface fraction over the entire trabecular surface, and active osteoid formation surface fraction over the total trabecular surface. Ongoing calcification of the osteoid was confirmed by fluorescence microscopy and microradiography.

For OTC studies, the osteotomized femora were microscopically systematically analyzed in ten different areas as presented in a schematic picture (Fig. 1). Areas 1–4 represent subperiosteal region, areas 5–8 represent intraosseous bone near the implant, area 9 represents intraosseal bone near the osteotomy, and area 10 represents intraosseous bone proximal to the implant. From each area, the intensity of fluorescence was evaluated, and grading 0–3 was used (0 = none, 1 = weak, 2 = moderate, 3 = marked). The mean of the grade of intensity was calculated for areas 1–4, 5–8, 9, and 10. The areas were analyzed as measured variables, not as ranked variables.

For statistical analysis, the one-way analysis of variance was used in the preliminary evaluation of time-related differences of histomorphometric variables. In the final analysis, the regression analysis and paired *t*-test were employed. Kruskal-Wallis test and Tukey's HSD test were used for oxytetracycline labeling results. Tukey's HSD tests were confirmed with Fisher's exact test.

Results

Fifty-four rats were operated on. None of the 16 rats after the subcutaneous implantation for mechanical tests had any complication. Thirty-eight rats had undergone osteotomy fixation. There were five rats in the follow-up groups of 1–48 weeks and three rats in the follow-up group of 52 weeks. Five femora had to be excluded when evaluating the results. The criteria of exclusion were as follows: in four rats (one at 48 weeks, three at 52 weeks) there was a non-union of the osteotomy on the macroscopic, radiographic, and histological analysis of the specimen, in one rat (at one week) a failure of the fixation and a redislocation of the osteotomy were noticed.

Mechanical and material testing

The initial flexural strength of the rods was 270 ± 30 MPa, and the flexural modulus was 13 ± 2 GPa. At three weeks *in vivo*, the flexural strength and the modulus of the rods were 144 ± 29 MPa and 6 ± 0.5 GPa, respectively. At six weeks *in vivo*, the rods had lost their strength totally.

The thermal properties are presented in Table I. SR-PGA had initially the glass transition temperature (T_g) of 37 °C. Polymer crystallized slightly *in vivo*. After three weeks *in vivo* the crystallinity had increased slightly, and more increase of crystallinity was seen at six weeks. The melting peak (T_m) appeared initially at 223 °C. A slight decrease to 217 °C was seen at six weeks *in vivo*. In the second DSC scan polymer was at all weeks amorphous showing that previous heating and cooling cycles had destroyed thermal histories of the material and the crystallinity seen at the first scans was formed during degradation.

In the scanning electronmicrographic (SEM) examination the first signs of degradation were seen on the surface of the SR-PGA rods at one week *in vivo*. Small pinholes could be detected on the surface. At three weeks, the rods started to lose their reinforced structure seen as lamellar structures on the surface and below it. The solid surface was peeling showing subsurface porosity and lamellae. At six weeks, the surface layer

had totally peeled off and the reinforced structure was completely lost. Porosity had further developed.

Radiological results

In the radiographs there were four slight dislocations of the osteotomy: two at three weeks and two at six weeks. The distal and proximal implant channel could be seen in the radiographs through the series, except in two specimens at 36 and 48 weeks. In these two femora the distal implant channel was filled with bone, and the channel could not be seen any more.

One to three weeks. Slight dislocation was seen in two cases at three weeks. All other osteotomies had an exact reduction. The osteotomy line could be seen in all femora but one at one week. There was slight external callus formation at one week and remarkable callus formation at three weeks. Both the proximal and distal part of the channel of the implant were visible in every radiograph.

Six weeks. Slight displacements were seen in two osteotomies at six weeks. The amount of external callus had decreased. Two of the osteotomies were radiologically partially visible and three could not be seen.

12 weeks. The osteotomy lines were hardly visible in one out of five osteotomies. At the osteotomy site, external callus formation was seen in two out of five radiographs. All five osteotomies were consolidated without angular deformity.

24 weeks. All osteotomies were consolidated. The osteotomy line was not visible in any radiograph. The amount of external callus had decreased.

36 weeks. Four out of five osteotomies had healed well, and the osteotomy line could not be seen. One out of five femora showed a defect (osteolysis) of the distal condyle. Remodeling of the bony callus was observed. The distal and proximal part of the implant channels could be seen.

48 weeks. Radiologically, all four osteotomies had consolidated without dislocation. The remodeling was advanced. Osteolytic areas of the femur condyle were seen in two specimens. The distal and proximal parts of the implant channels could still be seen in all but one femur. In that specimen, the distal implant channel was filled with bone.

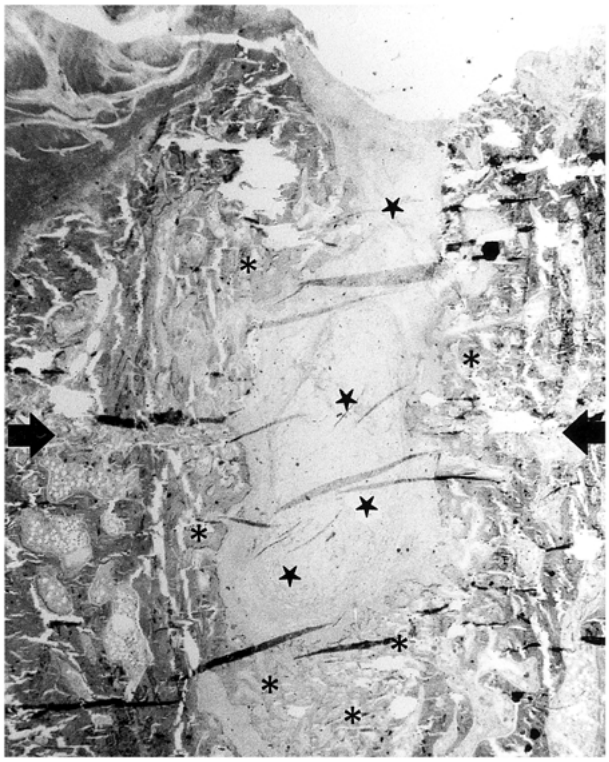
52 weeks. In two specimens, the osteolytic area could be seen. The distal and proximal parts of the implant channels could still be seen in the radiographical analysis, except one distal channel which was filled with bone.

Histological and microradiographic analysis

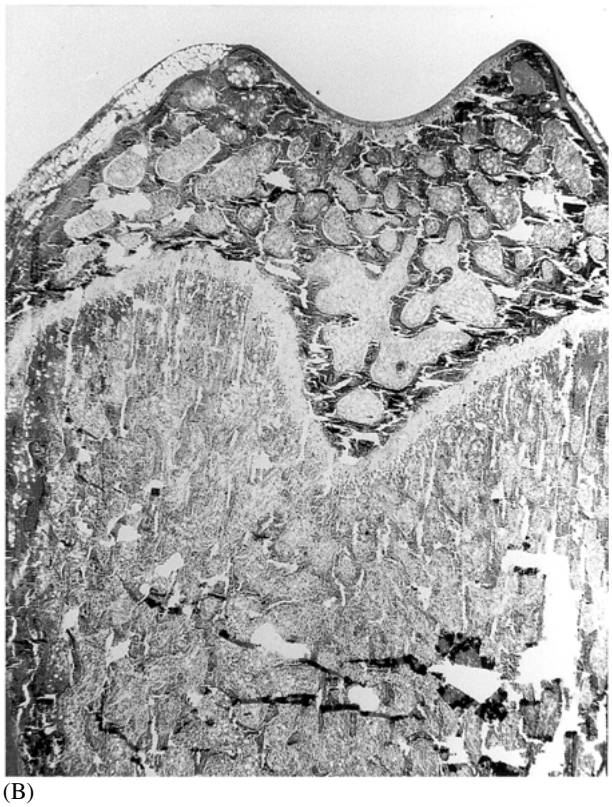
In the histological analysis there was one specimen with signs of infection (neutrophilic leukocyte infiltration near the osteotomy or implant channel). Infection occurred in one specimen at 24 weeks.

One to three weeks. The osteotomies were visible in the histological and microradiographic studies. At three weeks endosteal and strong periosteal new bone formation was seen around the implant at the osteotomy region. Around the rods there was a thin rim of regenerative granulation tissue. There was no accumulation of giant cells.

Six weeks. Three out of five osteotomies showed bony union in the histological and microradiographic studies.



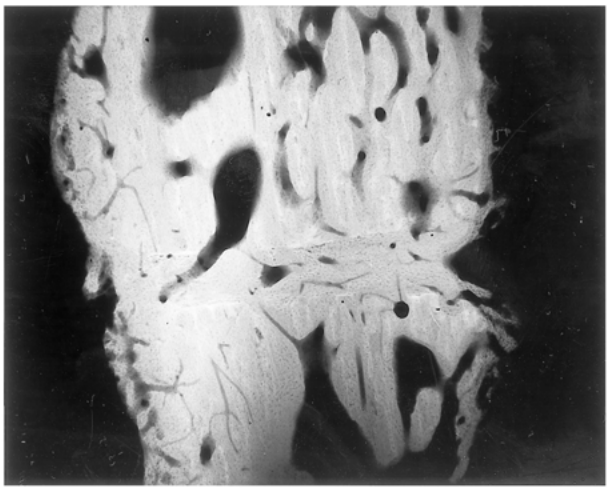
(A)



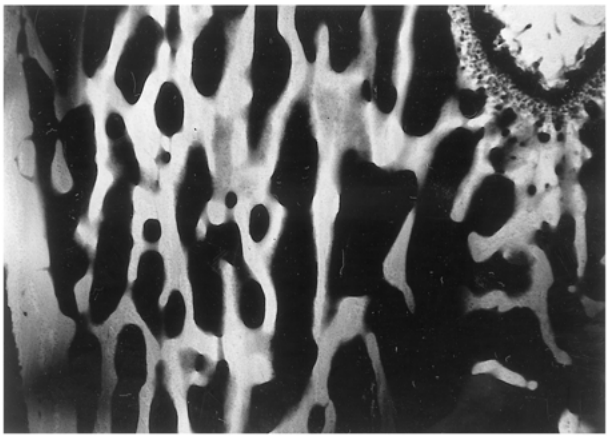
(B)

Figure 2 Photomicrograph of the osteotomized site at 12 weeks. Osteotomy is consolidated (arrows). Implant channel is filled at its edges with trabecular bone (asterisks) and at central area with fibrotic tissue (stars) (A). The control side (B) (modified Masson & Goldner, original magnification × 20).

Histologically, one osteotomy was partially consolidated. The external callus formation had increased, and new bone formation was found around the rods. The proximal and distal implant channel could clearly be seen in the microradiographical and histological sections. Invasion



(A)



(B)

Figure 3 Microradiograph of the osteotomized site at 12 weeks. There are thicker bony trabeculae in the osteotomy area (A) as compared to the control side (B) (modified Masson & Goldner, original magnification × 50).

of granulation tissue into the polyglycolide implant was seen.

12 weeks. All five osteotomies treated with rods showed bony union (Fig. 2). On the histological analysis trabecular bone was seen surrounding the implant. Granulation tissue was noticed between the degraded particles of the polygycolide implant and the trabecular bone. Foamlike macrophages had invased the implant. The distal implant channel could not be seen in three out of five cases, because the orifice of the implant channel was covered with connective tissue. In the microradiographical analysis, the implant channel was not filled with bone in any specimen (Fig. 3).

24 weeks. Four out of five osteotomies were consolidated histologically. In one femur there was a partly visible osteotomy line in the microradiographical analysis. In four consolidated cases, new bone and osteoblasts were seen in the former implant channel area, and the drawn SR-PGA implant had degraded to small particles. The orifice of the implant channel could not be seen in any case, and the proximal channel was also filled in four cases. Microradiographically, the implant channels were open in two out of five osteotomies.

36 weeks. Five osteotomies showed bony union in the histological and microradiographic examination. Histologically, new bone was seen around the implant channel, and the channel itself was filled with fibrous tissue and bone.

Microradiographically, the channel could not be seen in any of the five specimens, and there were large amounts of bone inside the femur.

48 weeks. All four osteotomies had consolidated without dislocation, and the osteotomy line could not be seen histologically or microradiographically. The remodeling had advanced. Bone and connective tissue had replaced the implant solely.

Histomorphometric analysis

In the primary statistical analysis, overall-time-related differences in the osteotomized femora were studied using the one-way analysis of variance. The total trabecular bone volume fraction means, the total osteoid surface fraction means as well as the active osteoid formation surface fraction means were significantly $(p < 0.001)$ different at various times.

The total trabecular bone volume fraction had its highest value (61.3%) at 48 weeks in the osteotomized femora. The control femora had the highest value (40.0%) at three weeks (Table II). The differences between the values obtained from the osteotomized femora were statistically significant at the various follow-up times. According to a more specific statistical analysis, the regression analysis, the total trabecular bone volume fraction of the osteotomized femora was found to be curvilinearly dependent on time with the following model: $Y = 49.2–19.9/\text{weeks}$, correlation $r = 0.28$, mean error of model $= 22.4$.

In the osteotomized femora, the total osteoid surface area and the active osteoid formation surface area reached their highest value at 24 weeks (33%, 20%): the one-way analysis of variance showed statistically different changes in both parameters at different times (Table II). After 24 weeks, the total osteoid surface fraction and the active osteoid formation surface fraction diminished gradually, being 3–4% and 2–5% at 48 weeks. According to the regression analysis, the total osteoid formation surface fraction of the osteotomized femora was found to be curvilinearly dependent on time with the following model: $Y = 26.7 - 24.0/\text{weeks} - 0.189^*$ (weeks)/1000, correlation $r = 0.34$, and mean error of model $= 23.0$.

In the regression analysis, the active the following osteoid formation surface fraction was found to be curvilinearly dependent on time with the following model: $Y = 14.4 - 11.9/\text{weeks} - 0.095^*$ (weeks)/1000, correlation $r = 0.27$, and mean error of model $= 15.0$.

Two-sample comparison testing (paired t-test) was done for the osteotomized and control femora. Many values of T were statistically significant through 3–24 weeks (Table II).

OTC fluorescence (Fig. 4). The OTC fluorescence in the operated femur showed the highest intensity and thus strong new bone formation during 6–12 weeks at the osteotomy region, subperiosteally, and around the implant. The increase in intensity arose first in the subperiosteal regions at three weeks. After 12 weeks, the OTC fluorescence decreased. According to Kruskal-

TABLE II Results of histomorphometric analysis of the tissue–implant interface at various times after implantation of drawn self-reinforced polyglycolide acid rod in the osteotomized rat distal femur (mean and standard deviation, SD)

		Number of weeks							
		1	3	6	12	24	36	48	
Total trabecular bone volume fraction of the total tissue volume (%)	Control	38.4	40.0	27.1	35.9	21.7	18.3	32.0	
		14.7	12.9	12.7	7.5	10.1	10.2	10.2	
	PGA	29.3	42.5	43.4	57.2[1]	44.3[1]	33.0	61.3[2]	$p < 0.0001$ (paired t-test compared to all controls)
		13.2	15.9	19.4	20.1	29.9	22.3	24.3	
Total osteoid surface fraction over the entire trabecular surface (%)	Control	3.2	0.9	0.0	0.0	0.0	0.0	0.0	
		5.5	2.1	0.0	0.0	0.0	0.0	0.0	
	PGA	4.8	14.8[1]	15.7	23.2[3]	33.4[2]	18.4	3.4	$p < 0.0001$ (paired t-test compared to all controls)
		6.9	19.0	26.1	18.3	33.8	31.4	11.7	
Active osteoid formation surface fraction over the total trabecular surface (%)	Control	1.8	0.4	0.0	0.0	0.0	0.1	0.0	
		3.4	0.9	0.0	0.0	0.0	0.2	0.0	
	PGA	3.5	9.9[1]	5.7	12.7[2]	19.9[1]	9.9	2.5	$p < 0.0001$ (paired t-test compared to all controls)
		4.8	12.8	9.6	12.3	23.2	22.1	8.8	

[1] $p < 0.05$ (paired t-test compared to control side).
[2] $p < 0.01$ (paired t-test compared to control side).
[3] $p < 0.002$ (paired t-test compared to control side).

Wallis test, the time-related differences were statistically highly significant ($p < 0.000001$) at the various follow-up times in the subperiosteal and endosteal areas. At the osteotomy area and proximal to the implant, the differences were also statistically significant ($p < 0.01$) at the various follow-up times. The subperiosteal area showed an earlier increase and decrease than the other areas in the OTC fluorescence intensity. These differences were statistically significant (Fig. 4). Tukey's HSD test results were confirmed with non-parametric Fisher's exact test using the original variables. This analysis showed a highly significant difference ($p < 0.005$) at the analyzed follow-up times, confirming the results of Tukey's HSD test (Fig. 4).

Discussion

Several materials have been studied in order to develop an optimal synthetic, bioabsorbable osteosynthesis implant for internal fixation of fractures and osteotomies. The adverse effect of metallic devices is that fixation with them is too rigid, causing weakening of the bone. Rigid fixation reduces normal stress to bone and induces so-called stress-protection atrophy. Stress-protection atrophy develops due to the difference in the modulus of elasticity (Young's modulus) between cortical bone ($E = 10$–30 GPa) and metals ($E = 100$–200 GPa). Loosening and corrosion of the metallic implants often necessitate their subsequent removal [14, 15]. A disadvantage of metallic implants is that in many cases the osteosynthesis material must be removed in a second operation, causing human suffering and economical costs.

The most commonly employed bioabsorbable osteosynthesis materials so far are aliphatic polyesters of α-hydroxyacid derivatives such as polyglycolic acid (PGA), polydioxanone (PDS), polylactic acid (PLA and its derivates), and their copolymers (PGA/PLA). Sintered, self-reinforced SR-PGA implants lose their bending strength *in vitro* in six to eight weeks, which is sufficient for healing of cancellous bone fractures [8]. It has been shown in experimental studies that implants

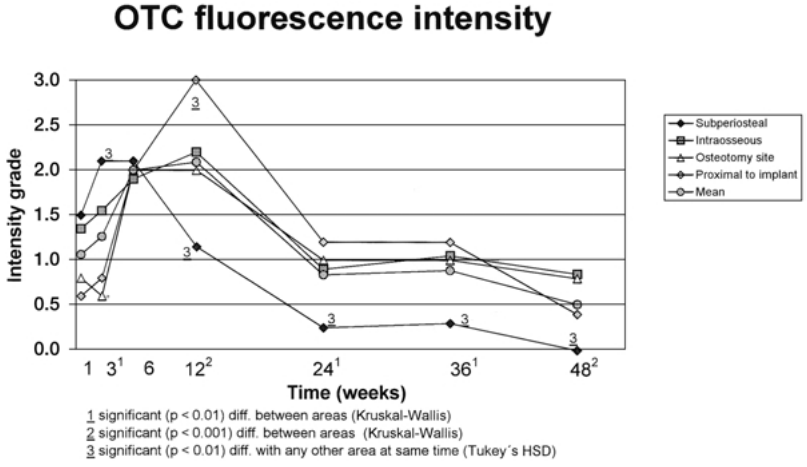


Figure 4 Oxytetracycline labeling results after fixation of the distal femoral osteotomies with drawn SR-PGA rods. Mean of grades (0 = none, 1 = minimal, 2 = moderate, 3 = marked) of fluorescence intensity in different areas. Areas 1–4 represent subperiosteal region, areas 5–8 intraosseous bone near the implant, area 9 represents intraosseous bone near the osteotomy, and area 10 intraosseous bone proximal to the implant.

made of SR-PGA and its copolymers were not suitable for internal fixation of cortical weight-bearing bone [16], but in 1984–1985 PGA/PLA rods and, since 1985, SR-PGA rods have been used in the clinical fixation of cancellous bone fractures and osteotomies with favorable results [17–19].

SR-PLA implants retain their mechanical strength in hydrolytic conditions approximately three to ten times longer than PGA-based implants [20]. After 12 weeks *in vivo*, 50% of the initial bending strength of SR-PLLA was still preserved, and there was no alteration in the shear strength. At 36 weeks the bending strength had decreased to the level of the strength of cancellous bone (10–20 MPa) [21].

The aim of the present study was to determine the mechanical and histological properties of the novel drawn SR-PGA rod. It is possible to make strong biodegradable implants using the die-drawing technique. In this study, the drawn SR-PGA rod lost its mechanical strength in six weeks.

In the present study, the macroscopical and radiological analyzes showed that 33/38 (87%) of the drawn SR-PGA rod fixations were firm. Dislocations or non-unions were observed at one, 48, and 52 weeks of follow-up. One femur proved to have infection on the histological analysis at 24 weeks. All other $(32/38 = 84\%)$ osteotomies healed without delay and malalignment, and the rats used their limbs normally. One explanation for failed fixations was the demanding operative procedure. Failed cases were mainly in the first operated animals of the series, at the beginning of the ''learning-curve''. There were no macroscopically detected inflammatory reactions.

In the drawn SR-PGA rods new bone and active osteoblasts were observed around the rod, and, finally, the rods were totally degraded in 36 weeks. Bone and connective tissue had occupied the former implant area. Total degradation of the SR-PGA rods was observed histologically during 48 weeks also in another study [22].

The radiographs showed still a visible channel in the rat femur even one year after implantation, but histologically the channel was filled with bone and connective tissue.

SR-PGA rods have been described to have an osteostimulatory effect on cancellous bone [22]. In this study, the histomorphometrical analysis showed the most active new bone formation at 24 weeks, which is in concordance with a previous study performed on a different type of SR-PGA [22].

The regression analysis was applied for histomorphometrical variables. Several models were created, and the most applicable one was found to be the same for every variable: after a constant occurs, a correction is inversely dependent on time. However, the models are not mathematically strong, because the mean errors of the models were moderately high.

In the present study, the mechanical properties and strength retention of the drawn SR-PGA rods were sufficient for fixation of cancellous weight-bearing bones in the majority (33 : 38) of fixations. To the knowledge of the present authors, this is the first report on successful application of novel, drawn SR-PGA bioabsorbable rods in the experimental fixation of weight-bearing cancellous bone osteotomies.

Acknowledgments

This study has been supported by grants from the Academy of Finland.

References

1. N. A. HIGGINS, US Pat. 2 676 945 (1954).
2. D. K. GILDING and A. M. REED, *Polymer* **20** (1979) 1459.
3. B. ROED-PETERSEN, *Int. J. Oral. Surg.* **3** (1974) 133.
4. S. VAINIONPÄÄ, *Arch. Orthop. Trauma. Surg.* **104** (1986) 333.
5. S. VAINIONPÄÄ, K. VIHTONEN, M. MERO, H. PÄTIÄLÄ, P. ROKKANEN, J. KILPIKARI and P. TÖRMÄLÄ, *ibid.* **106** (1986) 1.
6. S. VAINIONPÄÄ, J. KILPIKARI, J. LAIHO, P. HELEVIRTA, P. ROKKANEN and P. TÖRMÄLÄ, *Biomaterials* **8** (1987) 46.
7. S. VAINONPÄÄ, K. VIHTONEN, M. MERO, H. PÄTIÄLÄ, P. ROKKANEN, J. KILPIKARI and P. TÖRMÄLÄ, *Acta Orthop. Scand.* **57** (1986) 237.
8. P. TÖRMÄLÄ, S. VAINONPÄÄ, J. KILPIKARI and P. ROKKANEN, *Biomaterials* **8** (1987) 42.
9. P. ROKKANEN, O. BÖSTMAN, S. VAINIONPÄÄ, K. VIHTONEN, P. TÖRMÄLÄ, J. LAIHO, J. KILPIKARI and M. TAMMINMÄKI, *Lancet* **1** (1985) 1422.
10. CC. CHU, *J. Appl. Polym. Sci.* **26** (1981) 1727.
11. R. A. MILCH, D. P. RALL, J. E. TOBIE, J. M. ALBRECHT and G. TRIVERS, *J. Bone. Joint. Surg.* **40A** (1958) 897.
12. R. SCHENK, *Acta. Anat.* **60** (1965) 3.
13. J. GOLDNER, *Am. J. Pathol.* **14** (1938) 237.
14. L. CLAES, *J. Orthop. Res.* **7** (1989) 170.
15. P. PAAVOLAINEN, E. KARAHARJU, P. SLÄTIS, J. AHONEN and T. HOLMSTRÖM, *Clin. Orthop.* **136** (1978) 287.
16. S. VAINIONPÄÄ, in ''Biodegradation and Fixation Properties of Biodegradable Implants in Bone Tissue'' (University of Helsinki, Helsinki and Tampere University of Technology, Tampere, 1987).
17. O. BÖSTMAN, S. VAINIONPÄÄ, E. HIRVENSALO, E. A. MÄKELÄ, K. VIHTONEN, P. TÖRMÄLÄ and P. ROKKANEN, *J. Bone. Joint Surg.* **69B** (1987) 615.
18. O. BÖSTMAN, E. HIRVENSALO, S. VAINIONPÄÄ, A. MÄKELÄ, K. VIHTONEN, P. TÖRMÄLÄ and P. ROKKANEN, *Clin. Orthop.* **238** (1989) 195.
19. E. HIRVENSALO, *Acta. Orthop. Scand.* **60** (1989) 601.
20. A. SAIKKU-BÄCKSTRÖM, R. M. TULAMO, T. POHJONEN, P. TÖRMÄLÄ, J. E. RÄIHÄ and P. ROKKANEN, *J. Mater. Sci.: Mater. Med.* **10** (1999) 1.
21. A. MAJOLA S. VAINONPÄÄ, H. M. MIKKOLA, P. TÖRMÄLÄ and P. ROKKANEN, *ibid.* **3** (1992) 43.
22. P. NORDSTRÖM, H. PIHLAJAMÄKI, T. TOIVONEN, P. TÖRMÄLÄ and P. ROKKANEN, *Clin. Orthop. Rel. Res.* **382** (2001) 247.

Received 18 June
and accepted 10 August 2001