# Strength retention of self-reinforced poly-*L*-lactide screws and plates: an *in vivo* and *in vitro* study

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Self-reinforced poly-*L*-lactide (SR-PLLA) screws and multilayer plates were studied for their initial mechanical shear and/or tensile strength and strength retention *in vivo* and *in vitro* up to 48 weeks. The plates were studied *in vitro* up to 68 weeks. The loss of strength was faster *in vivo* than *in vitro*. The screws retained more than half of their initial shear strength up to 12 weeks *in vivo* and over 24 weeks *in vitro*. By 48 weeks they had lost nearly all of their mechanical strength in both groups. The plates retained over 54% of their initial tensile and 71% of shear strength up to 24 weeks *in vivo*. The shear strength did not particularly diminish up to 52 weeks of follow-up *in vitro* whereas the tensile strength was slightly decreased after 36 weeks. After this follow-up time the loss of strength was more rapid and by 68 weeks the shear strength had decreased to 17% and the tensile strength to 0%.

## 1. Introduction

The material development of fixation devices (rods, pins, wires, tacks, plates and screws) has increased the treatment of fractures by open reduction during the past two decades. Metal plates and screws have been used successfully in the reduction of osteotomies and fractures. However, the use of these implants is not totally without problems. The bone underlying the plate can become osteoporotic because of stress protection, and corrosion of the device is known to cause inflammatory and allergic reactions [1–4]. Oncogenic potential has also been reported related to metallic implants [5].

These disadvantages in mind, many clinicians remove the implants in a second operation. To avoid this removal operation, the development of bioabsorbable implants started over 20 years ago [6].

Polylactide (PLA) was one of the first resorbable materials studied in this development. PLA sutures, sheets, plates and screws have been used in experimental fracture and osteotomy fixation during the past three decades [6–14]. These implants are as-polymerized, compression or melt moulded, and they have not yet been reported to have been used widely in clinical fracture fixation.

When the self-reinforcing (SR) technique was introduced [15], it was possible to make implants strong enough, even for an extensive clinical use. The number of clinical operations in human and veterinary surgery, where SR-PLA and SR-polyglycolide (SR-PGA) rods and screws have been applied successfully, has exceeded 2000 in Finland [16–28]. SR-poly-*L*-lactide (SR-PLLA) plates have been successfully used in the fixation of experimental osteotomies [29, 30].

The aim of this study was to investigate the initial strength and strength retention of SR-PLLA screws and multilayer plate assemblies both *in vivo* and *in vitro*. These plates and screws are designed to be used in maxillofacial surgery.

## 2. Materials and methods

### 2.1. Implants

#### *2.1.1. Screws*

The raw material poly-*L*-lactide was supplied by CCA Biochem b.v., The Netherlands. The specific details as



0957–4530 

given in the certificate of analysis are as follows:

| | |
|---|---|
| Lot number | DB-032F |
| Batch number | 89-F-09c |
| Molecular mass (determined by viscosity measurement) | 727 000 |
| Intrinsic viscosity (in chloroform, $T = 25\,^{\circ}C$) | 10.36 |
| Specific rotation (in chloroform, $T = 20\,^{\circ}C$) | − 158 |
| Melting point (°C) | 186.9 |
| Melting range (°C) | 174–187 |
| Heat of fusion (J $g^{-1}$) | 61.1 |
| Residual solvent (%) | 0.07 |

A Perkin-Elmer DSC 7 (Perkin Elmer, USA) 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 heat of fusion was estimated from the area enclosed by the DSC curve and the baseline. Crystallinity was calculated from this value compared with that for fully crystalline poly-*L*-lactide, 93.7 J $g^{-1}$ estimated by Fisher *et al.* [31]. The heat of fusion and crystallinity for the raw PLLA, PLLA fibre and SR-PLLA screw (both manufactured by Biomaterials Laboratory, Tampere University of Technology, Finland) are shown in Table I.

TABLE I

| Material | Heat of fusion (J $g^{-1}$) | Crystallinity (%) |
|---|---|---|
| MM 727.000 | | |
| raw PLLA | 61.1 | 65 |
| PLLA fibre | 57.3 | 61 |
| PLLA screw | 69.3 | 74 |
| MM 720.000 | | |
| raw PLLA | 65.1 | 69 |
| PLLA plate | 50.0 | 53 |

The screws were manufactured with the self-reinforcing technique, described by Törmälä *et al.* [15]. In this technique the matrix and the fibres are of the same material, i.e. poly-*L*-lactide. The maximum thread diameter of the screw was 4.5 mm and the core diameter was 3.2 mm (Fig. 1). The length of the screw was 50 mm. The initial bending strength of the screw was 200 MPa, bending modulus 7 GPa, shear strength 110 MPa and maximum torque 0.2–0.3 N m [27, 28, 32].

### 2.1.2. Plates

The raw material PLLA was supplied by CCA Biochem b.v., The Netherlands. The supplier's certificate of analysis gives the following specifications of the polymer:

| | |
|---|---|
| Lot number | PLLA-(E009) |
| Batch number | 89-A-13 |
| Molecular mass (determined by viscosity measurement) | 720 000 |
| Intrinsic viscosity (in chloroform, $T = 25\,^{\circ}C$) | 10.3 |
| Specific rotation (in chloroform, $T = 20\,^{\circ}C$) | − 158 |
| Melting point (°C) | 186.9 |
| Melting range (°C) | 174.3–186.9 |
| Heat of fusion (J $g^{-1}$) | 65.1 |
| Residual solvent (%) | 0.02 |

The plates were manufactured in the Biomaterials Laboratory, Tampere University of Technology, Tampere, Finland. The raw material was melted in the AXON BX-15 extruder and formed in extrusion die with a $3 \times 12$ $mm^2$ plate (zone temperatures 205, 220, 225 and 230 °C in the plate die with tape 30°). The plates were cooled after extrusion. The plates were warmed again and self-reinforced in a solid state by die-drawing at 150 °C to draw ratio 4 ($1 \times 9$ $mm^2$). In this die-drawing the fibres orientate parallel to the long axis of the plate. After drawing the plate was cut into pieces 50 mm long, which were compression moulded to a 0.5 mm thick plate (130 °C, 30 MPa). In this compression moulding the fibres orientate perpendicular to the long axis. The plates were then cut to $0.5 \times 12 \times 40$ $mm^3$ plates. The plates were supplied as four-layer assemblies (Fig. 2). The heat of fusion and crystallinity for the raw material PLLA and SR-PLLA plate can be seen in Table I.

The plate assemblies were sterilized by gamma-radiation with a dose of 2.5 Mrad ($2.5 \times 10^4$ Gy). After sterilization, the four-layer plate assemblies were attached together with six stainless steel screws (thread diameter of 2.7 mm), so that the thickness of the plate assembly was 2 mm.

The advantage of these assemblies is that the plates can be one by one easily adjusted to fit the bone. The holes are drilled through the plates after the fitting. When the plates are fixed together (and to the bone) with screws, the assembly stiffens to that form. The use of these assemblies in experimental fracture fixation is described in our earlier papers [29, 30].

Initially the SR-PLLA plates can tolerate a tensile force of 850 ± 150 N parallel to the long axis, hence

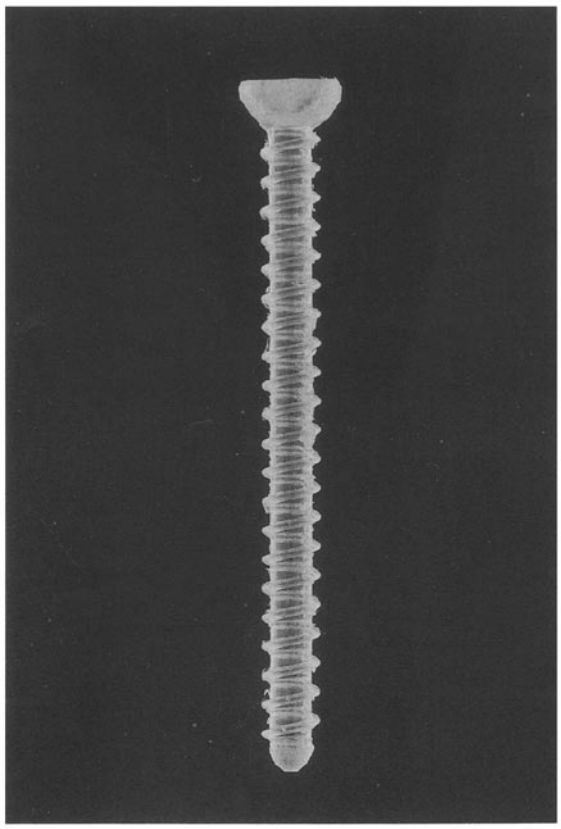

*Figure 1* The SR-PLLA screw.

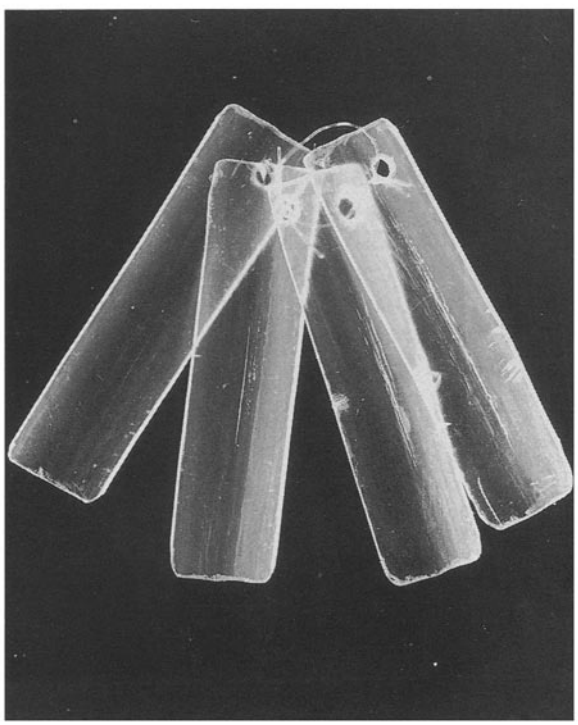

*Figure 2* The SR-PLLA plate assembly.

they had an initial tensile strength of 130 ± 10 MPa. With the holes drilled, the values are 550 ± 100 N and 100 ± 10 MPa, respectively [29].

The initial shear strength of the plates is 100 ± 20 MPa perpendicular and 60 ± 10 MPa parallel to the long axis. The six holes drilled did not weaken the shear strength. At its weakest point (i.e. at the site of a screw hole) the plate can initially tolerate a 550 ± 150 N shear force perpendicular to the long axis [29].

## 2.2. *In vivo* studies

Adult rabbits with mass greater than 3 kg were used as experimental animals. Two plate assemblies or three screws were implanted in the dorsal subcutaneous tissue of 26 rabbits (Tables II, IV and V).

TABLE II *In vivo* shear strength retention of SR-PLLA screws

| Follow-up (weeks) | No. of screws | Mean shear strength (MPa) | Standard deviation (MPa) |
|---|---|---|---|
| 48 | 6 | 4.2 | 0.67 |
| 24 | 6 | 35.8 | 15.51 |
| 15 | 6 | 65.1 | 12.24 |
| 12 | 6 | 65.0 | 6.98 |
| 9 | 6 | 83.1 | 7.69 |
| 3 | 6 | 92.3 | 19.40 |

TABLE III *In vitro* shear strength retention of SR-PLLA screws

| Follow-up (weeks) | No. of screws | Mean shear strength (MPa) | Standard deviation (MPa) |
|---|---|---|---|
| 48 | 9 | 3.3 | 0.81 |
| 24 | 7 | 79.6 | 7.18 |
| 12 | 7 | 76.0 | 19.01 |
| 9 | 4 | 86.0 | 15.54 |
| 6 | 4 | 80.0 | 7.59 |
| 3 | 4 | 82.1 | 13.14 |

TABLE IV *In vivo* shear strength retention of SR-PLLA plates

| Follow-up (weeks) | No. of plates | Mean shear strength (MPa) | Standard deviation (MPa) |
|---|---|---|---|
| 48 | 8 | 0.0 | 0.00 |
| 24 | 8 | 71.6 | 6.30 |
| 15 | 8 | 95.0 | 11.01 |
| 12 | 11 | 64.9 | 9.36 |
| 9 | 8 | 63.3 | 5.99 |
| 6 | 8 | 80.0 | 13.10 |
| 3 | 8 | 86.1 | 8.90 |

TABLE V *In vivo* tensile strength retention of SR-PLLA plates

| Follow-up (weeks) | No. of plates | Mean tensile strength (MPa) | Standard deviation (MPa) |
|---|---|---|---|
| 48 | 8 | 0.0 | 0.00 |
| 24 | 4 | 54.5 | 2.54 |
| 15 | 7 | 87.6 | 10.53 |
| 12 | 11 | 77.5 | 9.00 |
| 9 | 8 | 75.1 | 9.49 |
| 6 | 8 | 89.5 | 7.31 |
| 3 | 8 | 101.0 | 8.62 |

### 2.2.1. Operative procedure

The rabbits were anaesthetized with subcutaneous (s.c.) medetomidine 0.3 mg $kg^{-1}$ (Domitor$^R$ 1 mg $ml^{-1}$, Lääkefarmos) and ketamine hydrochloride 50 mg $kg^{-1}$ (Ketalar$^R$ 50 mg $kg^{-1}$, Parke-Davis). They also received 150 000 IU benzylpenicillin procaine s.c. (Procapen$^R$ 300 000 IU $ml^{-1}$, Orion) and 0.5 mg $kg^{-1}$ atropine (Atropine$^R$ 1 mg $ml^{-1}$) 30 min pre-operatively. The back skin was shaved and scrubbed with polyvidon iodine (Betadine$^R$ 100 mg $ml^{-1}$, Leiras) and chlorhexidine gluconate (Klorhexidos$^R$ 5 mg $ml^{-1}$, Lääkefarmos). After implantation, the incision was closed with absorbable sutures (Vicryl$^R$ 2–0, Johnson & Johnson).

### 2.2.2. Follow-up

Follow-up intervals were 3, 6, 9, 12, 15, 24 and 48 weeks (Tables II, IV and V). At each interval six screws or four 4-plate assemblies were achieved. At removal, the rabbits were anaesthetized as described above and the implants removed carefully and transferred into saline solution. The mechanical testing was carried out within 24 h. The implants were tested wet.

## 2.3. *In vitro* studies

The plates and screws were embedded in a similar way (four-layer assemblies) as the *in vivo* test, into a phosphate buffer (pH 6.10, 37 °C) aqueous solution. The follow-up intervals were 3, 6, 9, 12, 24 and 48 weeks for the screws and 6, 9, 16, 24, 36, 52 and 68 weeks for the plates (Tables III, VI and VII). Four screws and two or three 4-plate assemblies for each follow-up interval were obtained. These implants were tested mechanically in the same way as the *in vivo* implants.

TABLE VI *In vitro* shear strength retention of SR-PLLA plates

| Follow-up (weeks) | No. of plates | Mean shear strength (MPa) | Standard deviation (MPa) |
|---|---|---|---|
| 68 | 6 | 16.5 | 3.08 |
| 52 | 6 | 90.7 | 9.83 |
| 36 | 6 | 102.0 | 7.59 |
| 24 | 6 | 106.5 | 17.10 |
| 16 | 5 | 82.8 | 12.09 |
| 9 | 4 | 73.8 | 14.50 |
| 6 | 4 | 94.5 | 9.18 |

TABLE VII *In vitro* tensile strength retention of SR-PLLA plates

| Follow-up (weeks) | No. of plates | Mean tensile strength (MPa) | Standard deviation (MPa) |
|---|---|---|---|
| 68 | 6 | 0.0 | 0.00 |
| 52 | 6 | 67.2 | 11.64 |
| 36 | 6 | 78.0 | 4.86 |
| 24 | 6 | 93.7 | 5.35 |
| 16 | 5 | 97.8 | 11.63 |
| 9 | 4 | 89.3 | 14.39 |
| 6 | 4 | 104.8 | 14.98 |

## 3. Testing procedure

The mechanical testing was performed at room temperature with a J. J. Lloyd testing machine (J. J. Lloyd Instruments, Southampton, UK) at a testing speed of 10 mm $min^{-1}$ (Figs 3, 4a and 4b). The standard engineering procedures for measuring and calculating the strength properties were followed.

### 3.1. Screws

The shear forces needed to break the screw were measured. The testing arrangements can be seen in Fig. 3. The shear strength was calculated with a formula

$$\text{shear strength} = F/2A$$

where $F$ is the ultimate shearing force and $2A$ is the area of the two cut surfaces.

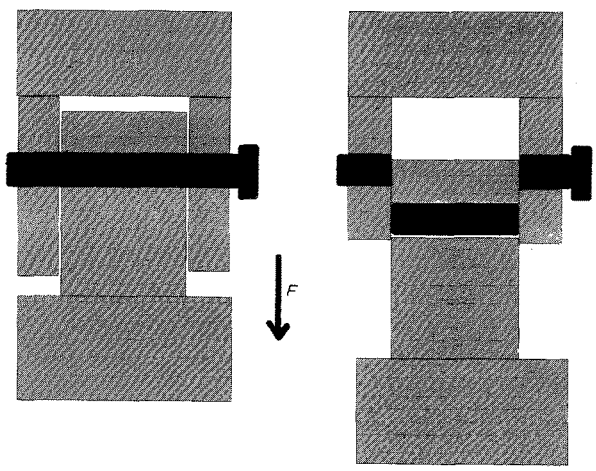


*Figure 3* The testing arrangements for SR-PLLA screws.

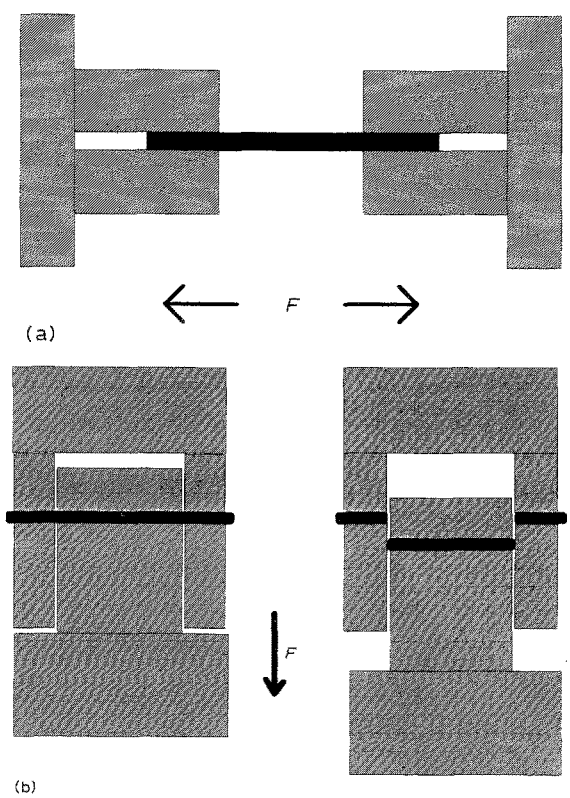


*Figure 4* The testing arrangements for SR-PLLA plates: (a) tensile strength test; (b) shear strength test.

### 3.2. Plates

The metallic screws were removed from the plate assemblies and each plate was tested individually. The tensile and shear forces needed to break the plate were measured. The tensile strength was measured along the long axis (Fig. 4a). The plates were attached by 10 mm in both ends, hence free testing length was 20 mm. The tensile strength was calculated with a formula

$$\text{shear strength} = F/A$$

where $F$ is the ultimate shearing force and $A$ is the area of the cut surface.

The shear strength test was performed perpendicular to the long axis (Fig. 4b). The shear strength was calculated with a formula

$$\text{shear strength} = F/2A$$

where $F$ is the ultimate shearing force and $2A$ is the area of the two cut surfaces.

## 4. Statistic evaluation

The test results obtained were compared by using a two-way variance analysis with Student's $t$-test.

## 5. Results

### 5.1. Screws

The results can be seen in Tables II and III, and Fig. 5. By three weeks of follow-up the screws implanted in the rabbit subcutaneous tissue had lost about 16% of their original shear strength. The implants embedded in the phosphate buffer showed a faster loss of strength (25%). By nine weeks the loss of strength was 24% and 27%, respectively. Thereafter the screws lost their strength faster *in vivo* than *in vitro*. By 12 weeks the loss of strength was 41% and 31%, respectively. By 24 weeks of follow-up the screws *in vivo* had lost their strength profoundly faster than *in vitro* ($p < 0.001$). The screws *in vivo* had only 33% of their original strength left, whereas the screws *in vitro* still presented 72% of their initial strength. The screws lost their strength in both groups by 48 weeks, when the comparative strengths were only 0.04% *in vivo* and 0.03% *in vitro*.

### 5.2. Plates

The retention of tensile strength can be seen in Tables IV and VI, and Fig. 6 and that of the shear strength in Tables V and VII, and Fig. 7. The plates retained their shear and tensile strength longer *in vitro* than *in vivo* throughout the study. In the tensile strength test, the plate broke always at the site of a screw hole. By six weeks of follow-up the plates had lost 10% of their initial tensile strength and 20% of their shear strength *in vivo* compared to 0 and 6% *in vitro*. During the next 10 weeks of follow-up the strength loss was only minimal in both groups. By 24 weeks the plates still exhibited 55% of their original tensile strength and 72% of the shear strength *in vivo*, whereas the values were 94% and 106%, respectively, *in vitro* ($p < 0.001$). The plates had lost all their strength by 48 weeks *in vivo* but retained still 67% of tensile strength and 91% of shear strength after 52 weeks *in vitro*. By 68 weeks the plates had lost all their tensile strength *in vitro* and possessed only 17% of their initial shear strength.

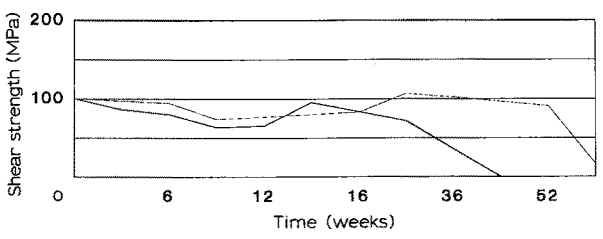


*Figure 5* Retention of shear strength of the SR-PLLA screws: (——) *in vivo*, (----) *in vitro*.

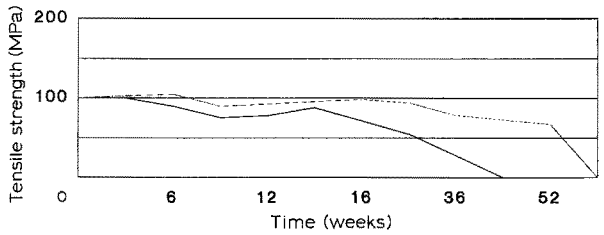


*Figure 6* Retention of tensile strength of the SR-PLLA plates: (——) *in vivo*, (----) *in vitro*.

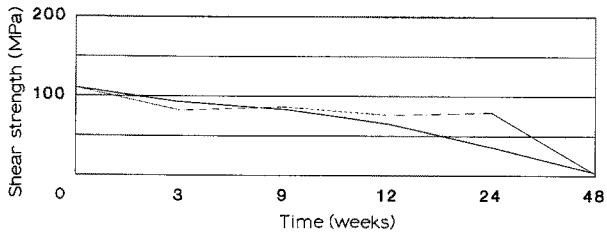


*Figure 7* Retention of shear strength of the SR-PLLA plates: (——) *in vivo*, (----) *in vitro*.

## 6. Discussion

Absorbable implants have been under constant research for over two decades. Investigations concerning polylactide in fracture fixation devices started over 20 years ago. Studies have shown that tissues tolerate PLA well [14, 33–36]. When post-operative radiotherapy is needed, the implants can be regarded as tissue-equivalent [37]. PLA sutures were used for fixation of mandibular midline fractures of rhesus monkeys [1]. PLA sheets have been used to repair fractures of orbital floor of rhesus monkeys and goats [7, 38]. Many studies concerning polylactide plates and screws in maxillofacial osteotomies and fractures have been published [8–14]. These non-reinforced implants were manufactured with compression or melt-moulding, and have not been reported used widely in clinical fracture fixation.

Our implants are manufactured with the self-reinforcing techniques, with which the mechanical properties can be multiplied. One feature of the reinforcing units of SR-PLLA is the high degree of orientation, which makes the implants stiff and strong in the direction of their long axis. With this technique it is possible to increase the mechanical properties of

biopolymers at best by 500% in rods and screws and 200% in plates [15, 32]. These implants gradually lose their strength and hence transfer the stresses to the healing bone. These implants require no removal operation.

In this study the strength loss was faster *in vivo* than *in vitro*. These results agree with earlier strength retention studies on absorbable sutures, rods and plates and verify the fact that cellular enzymes or other biological or biochemical factors do have a profound effect on the degradation process [14, 39–43]. Bos in his thesis concluded that stress-cracking phenomenon causes rapid strength loss *in vivo* [44]. The mechanical stresses caused to the implants in our study by rabbits' movements may also have contributed to the faster strength loss.

In this study the screws retained 75% of their initial shear strength for nine weeks *in vivo*. By 12 weeks the screws still *in vivo* exhibited 59% of the original shear strength. The plates retained 63% of their initial tensile strength and 71% of their initial shear strength over 24 weeks *in vivo*.

The high initial strength of the implants as well as the long strength retention time suggest that these implants are suitable for bone fracture fixations in such places where the initial strengths of the implants meet the biomechanical demands of the tissue environment in question.

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