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Repair of Radial Fractures in Toy Breed Dogs with Self-Reinforced Biodegradable Bone Plates, Metal Screws, and Light-Weight External Coaptation

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Objective—To describe a surgical technique for, and outcome after, treatment of radial fractures with biodegradable self-reinforced polylactide plates and metal screws, and external coaptation.
Study Design—Prospective clinical study.
Sample Population—Eleven Toy breed dogs.
Methods—Radial fractures were repaired by application of a single or 2 stacked biodegradable self-reinforced polylactide plates (poly-L/D, L-lactide, stereocopolymer [LL-and DL-lactide ratio 70/30]; SR-PLA (70/30) implants) secured with metal screws, and light-weight external coaptation. Healing was evaluated clinically and by radiography at 2, 4, 6, 8, 9, 12, 24–26 weeks, and at 1 and 2 years. Owners were interviewed 3 years after surgery.
Results—Radial fracture lines disappeared within 4–14 weeks in 10 dogs; an implant failed in 1 dog. Ambulation was excellent for healed fractures. Excessive skin tension led to removal of implants in 1 dog and suture repair in another dog. No foreign body reaction from implant degradation was observed and the plate was usually no longer palpable at 2 years. One dog had a fracture through a screw hole at 1 year.
Conclusion—Healing and complication rates after repair of radial fractures with SR-PLA (70/30) plates were considered similar or better than reported after repair with metallic plates or external fixation in Toy breed dogs. No radiographic signs of osteopenia were identified under the plate during follow-up.
Clinical Relevance—Biodegradable polylactide plates could be considered as an alternative to metal plates for radial fracture repair in Toy breed dogs, however available plates are likely not strong enough when used as a single plate. Implant removal is usually not needed.

Key words: biodegradable plates, polylactide implants, radius, fracture healing, toy breed dogs.

INTRODUCTION

BIODEGRADABLE IMPLANTS are increasingly used in human orthopedics, mostly to treat cancellous fractures or osteotomies.[1,2] Clinical uses in veterinary surgery have been limited probably because of their relatively high cost compared with metallic implants. However, if metallic implants are removed the higher cost of the absorbable implants may be negated both by the cost of the second surgical intervention and the added patient risks.

Biodegradable implants provide adequate fixation during fracture healing and are absorbed slowly. The bending

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modulus of the implant is similar to cortical bone and stresses are gradually transferred to the healing bone during implant degradation, which diminishes the risk of osteoporosis and stimulates both bone growth and remodeling.[3,4] The self-reinforced (SR) structure of biodegradable implants, where a matrix is reinforced by fibers of the same substance, has enabled production of devices that have initial strength values comparable with that of steel.[5] Intramedullary nails and pins made of self-reinforced poly-L-lactide (SR-PLLA) have been successfully used for repair of osteotomies of the femoral diaphysis in adult rabbits and sheep, and also clinically, in repair of cancellous and diaphyseal fractures in dogs and cats.[6-9]

Radial/ulnar fractures are common and represent 8.5–17% of all bone fractures in dogs.[10,11] Toy breed dogs seem prone to these fractures even after minimal trauma. Complication rates after repair are significantly higher in dogs <5 kg than in larger dogs.[12–15] Osteopenia after external coaptation or metallic implants is seen more often in Toy breeds and makes estimation of the appropriate time for implant removal difficult.[16–18] Delayed union, malunion, non-union, and refracture after implant removal are also not uncommon during healing of these fractures.[12–14,16,19–21]

We hypothesized that a biodegradable plate could provide rapid healing and lower the risk of osteopenia in Toy breed dogs with radial/ulnar fractures. Thus we evaluated prospectively, outcome after application of biodegradable plates to radial fractures in 11 Toy breed dogs with radial/ulnar fractures.

MATERIALS AND METHODS

Biodegradable Implants

Bone plates were made from a poly-L/D, L-lactide, stereocopolymer with a LL- and DL-lactide ratio of 70/30, respectively (Boehringer Ingelheim, Ingelheim, Germany). The inherent viscosity of the raw material was 6.3 dL/g. The amorphous material was extruded and the SR-PLA (70/30) implants were manufactured by a die-drawing method with a draw ratio of 3 (Bionx Implants Ltd, Tampere, Finland). The implants were specifically manufactured for this study and γ sterilized with a nominal dose of 2.5 Mrad (Willy Rüsch AG, Kernen, Germany). Dimensions for mid-diaphyseal (MD) plates were 50–70 mm long $\times$ 7 mm wide. Distal (D) plates were conical conforming to the shape of the distal radius with dimensions of 35–55 mm $\times$ 7–9 mm. The plates were 1 mm thick and had no predrilled screw holes. AO metallic miniscrews (1.5–2.0 mm diameter; Stratec Medical, Oberdorf, Switzerland) were used (Fig 1).

Patients

Toy breed dogs ($n = 11$; mean bodyweight, 3.1 kg; range, 1.6–5.4 kg) with traumatic radial/ulnar fractures were studied.

Fig 1. Biodegradable SR-PLA (70/30) plates and a metallic mini T-plate and 10 mm $\times$ 2.0 mm miniscrew. The conical shaped SR-PLA (70/30) plate (bottom) was used for distal fractures. The mid-diaphyseal plate was similar to the straight commercial SR-PLA (70/30) plate (top), except there were no screw holes.

Breeds included 2 Pomeranians, 2 Italian Greyhounds, 2 Toy Poodles, a Kleinspitz, a medium Poodle, a Bichon Bolognese, a Moscow miniature terrier and an Italian Greyhound–Miniature Pinscher mix. Mean age was 21.6 months (range, 4–70 months) with 6 females and 5 males. All dogs had an acute, unilateral radial/ulnar fracture within 3 days of surgical repair.

Using a mediolateral radiographic view, the distance between the distal end of the radius and the main fracture line was measured, and the result expressed as a percentage of the total length of the radius from distal (0%) to proximal (100%).[12] Seven dogs had distal (range, 13–24%) and 4 had mid-diaphyseal (range, 34–66%) radial/ulnar fractures. There were 1 comminuted, 5 transverse, and 5 short oblique fractures.

Before entering this study an Italian Greyhound had fracture of the distal aspects of the radius and ulna that was repaired with a 2 mm AO mini T-plate and a bone graft. The fracture healed uneventfully and the metal plate was removed at 9 months. The diameter of the radius on the craniocaudal view had decreased from 7 mm preoperatively to 5.5 mm at plate removal. Five months later, the bone refractured exactly along the original fracture line and the dog was enrolled in this study.

Anesthesia and Preoperative Preparation

Dogs were sedated with medetomidine (40 µg/kg intramuscularly [IM]) and anesthesia was induced by propofol (1–2 mg/kg intravenously [IV]) and maintained with 1.5–2% isoflurane in oxygen. Cephalothin (20 mg/kg IV) and meloxicam (0.2 mg/kg IV) were administered before induction, and buprenorphine (0.01 mg/kg IV) was administered during surgery.

Surgical Technique

Standard orthopedic surgical technique for repair of radial/ulnar fractures was used. The sterile plate was placed over the

reduced fracture and the sites for screw holes were marked, and length and width of the plate was estimated according to the available bone. At least 3 screws were required on each side of the fracture line. The plate was then trimmed with scissors and the cut edges were smoothed with a file. Screw holes corresponding to the outer diameter of the screws (1.5 or 2.0 mm) were drilled in the plate. Depressions to countersink screw heads in the plate were made with a 3.2 mm drill bit. In 6 dogs, 2 plates were stacked symmetrically over the fracture to provide increased stiffness. The outer plate was usually a few screw holes shorter than the underlying plate. Implant application followed established AO protocol. After fracture repair, a cancellous graft was harvested from the ipsilateral humerus or ilium in all except 1 dog, and the incision closed.

For postoperative analgesia, meloxicam solution (0.1 mg/kg once daily, orally) was administered for 3–10 days. Cephalexin (25 mg/kg orally twice daily) was administered for 10 days if soft-tissue injury was evident.

Light-weight external coaptation was used in all dogs until bridging callus was detected or the radial fracture line was not evident on radiographs. Soft splint material with a thin aluminum layer inside (Buster® Soft splint No 272285, Kruuse, Marslev, Denmark) or small wooden tongue depressors or Q-tips were used as splints depending on the dogs' weight and length of the limb. Coaptation was changed every 2 weeks and the size of the splint or the number of Q-tips were gradually reduced during healing.

Dogs were followed clinically and by radiography at 2, 4, 6, 9, 12, 24–26 weeks, and at 1 and 2 years. A 4-month old puppy and two 6-month old dogs were examined regularly only until healing of the fracture line was observed, then at 24–26 weeks, and long-term. Comparison radiographs of the contralateral antebrachium were taken at 26 weeks, and at 1 and 2 years. Callus formation was calculated by measuring the largest callus formation seen on any postoperative radiograph and reported as fraction of bone diameter at the fracture site. Primary union was assigned a value of 0%.

Owners were interviewed by telephone 3 years after surgery to determine the long-term tissue tolerance of the implants.

RESULTS

No intraoperative complications occurred. Fracture reduction was adequate and repairs were seemingly stable before wound closure. Immediate postoperative radiographic evaluation indicated good reduction in all dogs.

Most dogs were using the repaired limb continuously by 2 weeks. External coaptation was removed between 2 and 9 weeks (mean, 6 weeks). Duration of splinting was shortened during the study as we gained confidence in the implants. Fracture healing occurred in 10 dogs; and in most dogs the fracture line had almost disappeared between the 6- and 9-week recheck examinations. Complete radial healing was typically seen by 9–12 weeks (range, 4–14 weeks). Mean callus formation was 15.6% (range 0–43%; Figs 2, 3).

Fig 2. Radiographs of a distal radial/ulnar fracture repaired with a distal SR-PLA (70/30) plate and metallic 2.0 mm miniscrews, taken postoperatively (A, B) and at 10 weeks (C, D).

A single plate failure was noticed at 4 weeks in 1 dog. Unfortunately, asystole occurred during sedation in preparation for surgical correction. Resuscitation was unsuccessful and necropsy confirmed cardiac arrest. The plate failed transversely at the mid-diaphyseal fracture site.

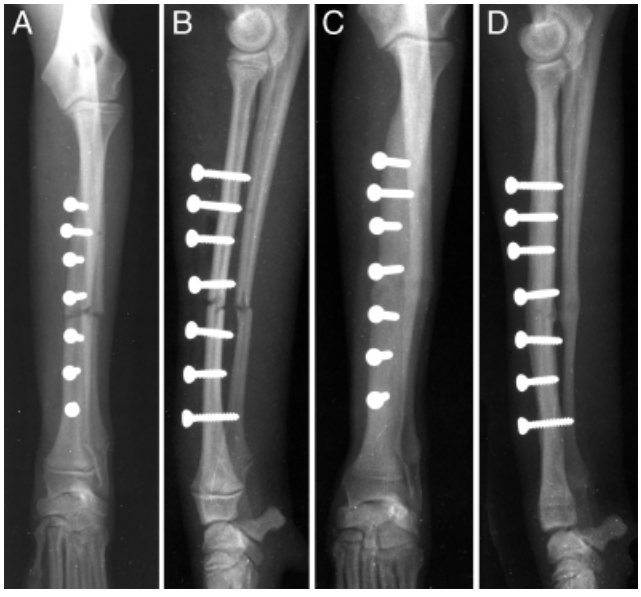

Fig 3. Radiographs of a mid-diaphyseal radial/ulnar fracture repaired with 2 stacked mid-diaphyseal SR-PLA (70/30) plates and metallic 1.5 mm miniscrews, taken postoperatively (A, B) and at 9 weeks (C, D).

Screws were palpable through the skin in all dogs during follow-up. This was not a problem except in an Italian greyhound that had extensive skin bruising from the original trauma and further skin problems because of external coaptation at the initial recheck examination. Because of the thin scar tissue forming at the wound area, some screw heads appeared through the skin intermittently, and all screws were eventually removed, together with loose SR-PLA (70/30) plates, 1 year postoperatively. The plates were brittle and broken in 2–3 pieces. No abnormal bone reaction was observed on radiographs at any time in this dog.

One Toy Poodle developed a small skin wound at the operation scar on 4 occasions. Some implant-induced skin tension occurred at the wound area and the owner reported on 2 occasions that mechanical trauma from brushing this area resulted in an open wound. The wound was revised and a visible screw and a small piece of protruding plate were removed. On cytology of the wound fluid, there was a mild inflammatory reaction with neutrophils, some polylactide particles, and occasional macrophages. There was no cytologic evidence of a foreign-body reaction to the implant material and subsequent recovery was uneventful.

The other Italian greyhound, with 2 previous fractures at the same location, fractured the antebrachium for the third time 1 year after SR-PLA (70/30) fixation. This fracture occurred through a screw hole proximal to the healed original fracture site. The owner declined further surgery and the dog was euthanatized.

The SR-PLA (70/30) plates were no longer palpable at 2 years except in 1 dog. No subcutaneous swelling or discomfort associated with degradation of the plates was observed. Owners reported normal limb use and no adverse soft tissue reactions were noted during the 3 years after surgical repair.

No radiographic signs of osteopenia were observed at any time under the SR-PLA (70/30) plates (Fig 4) even though some loss of bone density was evident in metacarpal and carpal bones in 4 dogs after splint removal. No malposition or functional problems of the legs were seen. Range of motion of the adjacent joints was evaluated as normal in all dogs.

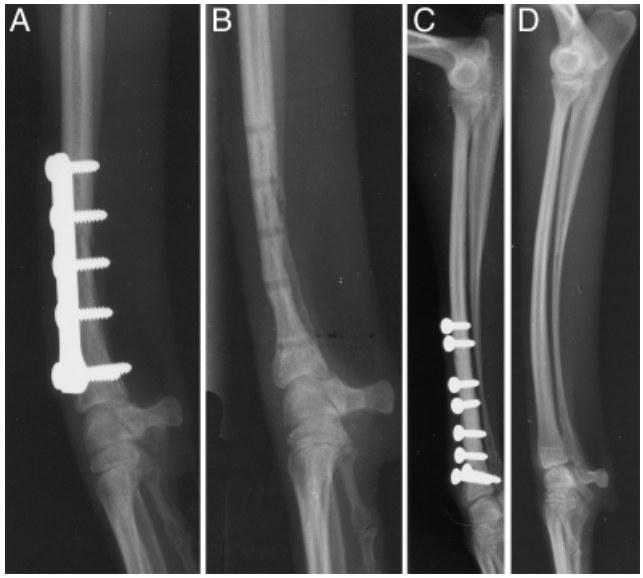

Fig 4. Radiographs of a distal radial/ulnar fracture, taken 6 months after repair with a metal plate (A), and after removal at 9 months (B). The radius refractured 5 months later and was repaired with a distal SR-PLA (70/30) plate and metallic mini-screws. Healing at 6 months (C) with opposite antebrachium shown as a control (D). No signs of osteopenia were seen.

DISCUSSION

Ten radial/ulnar fractures healed completely without malunion and plate failure occurred in 1 dog with a mid-diaphyseal fracture at 4 weeks. This latter outcome might have been avoided, had we used stacked plates in this dog. In reports where metal plates were used to repair radial/ulnar fractures in Toy breed dogs, 3/18 plates failed and 5/18 dogs had persistent limb deformity in 1 study, [17] whereas in another, 1/10 acute fractures and 1/4 chronic fractures resulted in malunion.[12] Inadequately stabilized radial/ulnar fractures in Toy breed dogs can result in serious problems. Up to 40–60% of non-unions reportedly involve fractures of the radius and ulna, some of which result in amputation.[13,16,20,21] Plating or external fixation have been the methods of choice when treating these fracture types in Toy breeds.[12,16] Good or fair return to function in Toy breeds has been reported in 87–89% after plating or external fixation compared with 25% after external coaptation with a cast alone.[14,17,18]

Two of our dogs had skin problems; 1 associated with external coaptation and 1 primarily with implant-induced skin tension. In this pilot clinical study, we used external coaptation to support the fixation until signs of healing were evident on radiographs. External coaptation can result in disuse osteopenia in Toy breed dogs and thus is usually avoided after internal fixation. Despite this, we chose to splint limbs because the SR-PLA (70/30) plates had not been previously used for these fracture types and we were uncertain how robust they would be. Because the splints were typically lightweight (tongue depressors or Q-tips), the minor loss of bone density evident in the metacarpal and carpal bones in some dogs resolved quickly after splint removal. Stacked plates were initially used in 2 fractures (1 mid-diaphyseal, 1 distal) that were considered clinically to need additional support. However, after one of the single plates failed we chose to use

stacked plates also on the last 4 fractures (2 mid-diaphyseal, 2 distal). As we became more comfortable with the technique and the results, we decreased splinting times. Increased use of stacked plates may have reduced or eliminated the need for splinting; however, a single plate with enhanced stiffness would likely be a better solution.

Skin complications were reported after metal plating of radial/ulnar fractures in 3/18 Toy breed dogs; 1 led to intermittent drainage, 1 to amputation after skin grafting failed, and 1 screw pull out was treated by implant removal and subsequent cast application.[17] Thus, our short-term fracture healing rate was comparable and the skin complication rate similar or lower when compared with other studies where metal plates were used to treat radial/ulnar fractures in Toy breed dogs.[14,15,17]

Experimental non-weight-bearing cancellous fractures repaired with different biodegradable polylactide plates have been studied in dogs (since 1972) with good results.[22,23] The strength properties of these plates however have not been adequate for the more demanding repair required for weight-bearing cortical bone. When osteotomies of the femoral shaft of adult rabbits were repaired with non-reinforced PLLA plates, union without displacement was achieved in 67%, and PLLA plate failure occurred in 14%.[24] The mechanically superior SR-PLLA plates have been successfully used in weight-bearing cancellous osteotomies of distal femurs in adult rabbits,[25] but to our knowledge this is the first clinical use of SR-PLA (70/30) plates for repair of weight-bearing diaphyseal fractures. Results of bending tests of human metacarpal fractures repaired with SR-PLA (70/30) plates and screws are comparable with those repaired with a 1.7 mm titanium plating system.[26]

The SR-PLA (70/30) plates allowed individual intraoperative selection for screw sites and thus we were able to place 3–4 screws even in the smallest distal fragments. With standard AO miniplates or T-plates it can be difficult to apply more than 2 screws to the distal fragment if it is very small. The 4-month-old puppy had the only fracture where only 2 screws were inserted distal to the fracture line to avoid the open growth plate.

Bone healing was evident on radiographs from 4 to 14 weeks. Most fractures healed with slight periosteal callus, which indicated minor motion at the fracture site. Evaluation of fracture healing was easy because of the radiolucency of the SR-PLA (70/30) plates. Absolute healing time of fractures repaired by this method are difficult to compare with repair by rigid metal plates because the radiodensity of metal plates interferes with evaluation of the fracture line and healing is often purely by primary union, completeness of which can be difficult to evaluate from radiographs. Repair of distal radial/ulnar fractures in small dogs and cats with an external tubular fixator (F.E.S.S.A.) has been reported.[18] Data included 15 patients quite similar to those in our study (i.e., miniature dogs, weighing 1.3–6 kg; aged 4 months to 10 years) and healing times varied from 7 to 15 weeks, and 1 case, required 29 weeks for healing.

No radiographic signs of osteopenia under the plate were observed. This finding was expected, because the elastic modulus of the SR-PLA (70/30) implant is close to that of bone and weight-bearing load is gradually transferred to the healing bone during biodegradation of the plate. Implant-induced osteoporosis has a multifactorial pathogenesis where early-onset osteonecrosis is elicited mainly through cortical vascular insufficiency because of the original injury, open fracture fixation, and plate induced compression. However, later on, stress protection because of excessive rigidity of the metal implants in comparison with bone may contribute to development of osteoporosis.[3,4,27] Long-term plate application of metal plates for fixation of radial fractures in dogs resulted in no significant differences in radial cortical bone density more than 1 year after plating between the plated radius and the contralateral radius in 14 dogs.[28] However, only 4 miniature dogs (1.6–7.7 kg) were included in the radiographic photodensitometry (RP) analysis and no RP adjustment factor was calculated for dogs <7 kg with 2.0 mm plates in the in vitro phase. In the F.E.S.S.A. fixation study, bone resorption of the radius or ulna was observed in 30% of Toy breed dogs; 1 refracture occurred and 2 dogs were treated by splinting or casting after fixator removal.[18]

One of our dogs had a fracture through a screw hole 1 year after biodegradable plate repair. Before entering the study, this dog had refractured along an original fracture line 5 months after metal plate removal. Delayed healing of distal radial fractures has been reported in Toy breed dogs and the decreased vascularity of their distal antebrachium may be contributory.[19–21,29] The original diameter of the radius had diminished by 21% during the earlier metal fixation and the 2 mm metal screws occupied 36% of the bone diameter, so 1.5 mm screws should possibly have been used. However, uneventful healing of the fracture occurred after SR-PLA (70/30) plating. The third fracture occurred through a screw hole and the original fracture line was not included.

SR-PLA (70/30) is an amorphous polymer that ultimately degrades into carbon dioxide and water. No adverse clinical signs were reported in the general clinical health of our dogs and 2 females subsequently had normal litters. In rabbits, no abnormal findings were observed from degradation of relatively large femoral polylactide implants (blood L- and D-lactate levels and acid base balance were used as indices).[30]

Degradation of the SR-PLA (70/30) plates was well tolerated and induced no clinically apparent foreign-body reactions in our dogs. Foreign body reactions occur

mainly during final degradation of a biodegradable implant,[31] which is why we included long-term follow-up to evaluate our patients. The early onset skin problems observed in 2 dogs were seemingly induced by external coaptation and excessive skin tensions induced by implant mass. It would seem wise to place the surgical incision away from the planned implant site and therefore a medial approach is recommended. When an absorbable implant or a suture degrades in the body, some cellular reaction is to be expected,[32] but no accumulations of foamy macrophages, multinucleated giant cells or lymphocytes, which are associated with foreign body reactions to the polylactide material, were seen on cytology from the dog with a recurrent skin wound.

The SR-PLA (70/30) plate was expected to degrade in <3 years.[33] Degradation of the plate was evaluated by palpation only, as the implant is radiolucent. After 2 years, only 1 plate was still barely palpable. A more reliable, non-invasive evaluation of degradation of polylactide implants in a clinical environment could be achieved by magnetic resonance imaging,[34] however this was not possible in our study. The 100% PLLA has a relatively long degradation time of 5–9 years and has on occasion caused adverse local reactions during final degradation because of highly crystalline polymer residue.[2,31,35] The biocompatibility of the self-reinforced polylactide implants has been well established in many long-term studies and these implants have been in clinical use at the Helsinki University Central Hospital since 1988.[35,36]

The incidence of clinical adverse effects related to bioabsorption of the SR-PLLA implants in humans has been approximately 0.3% and usually results in self-limiting, local, subcutaneous swelling.[37] The production of stereocopolymers, like the SR-PLA (70/30) we used, where L-lactic acid is combined with different amounts of its enantiomeric DL-isomer, has enabled the evolution of implants with shorter degradation times of 1–4 years and low or zero crystallinity, which should further diminish the risk for late foreign-body reactions.[38] Both screws and plates made of SR-PLA (70/30) are in clinical use in human plastic and maxillofacial surgery and the SR-PLA (70/30) screws have been successfully used for arthrodesis of the first metatarsophalangeal joint in humans with no complications reported after 20–28 month follow-up.[39,40] In a recent study, where a small osteotomy of the medial femoral condyle in sheep was secured with three 2.0 mm poly-L-DL-lactide pins (70/30), no implant material remained, and the pin channels were filled with either cancellous bone material or scar tissue at 3 years.[41]

We conclude that absorbable SR-PLA (70/30) plates and metallic miniscrews can be successfully used in combination with light external splinting for repair of radial/ulnar fractures in Toy breed dogs. Radiographic signs of osteopenia under the plate were not observed because the elastic modulus of the SR-PLA (70/30) plate is similar to bone and weight bearing is gradually transferred to the healing bone during plate degradation. Stacked use of plates may have prevented refracture in 1 dog and would also have reduced the need for splinting. Most of the SR-PLA plates (70/30) were no longer palpable at 2 years and their long-term degradation was not associated with clinically apparent foreign-body reactions. Plates with a thicker center that can be positioned over the fracture line and that taper toward the ends are being developed. Biodegradable plates are the preferred fixation technique for radial/ulnar fractures in Toy breed dogs in our practice.

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