

Evaluation of 2 Cement Techniques for Augmentation of Stripped 1.5 mm Screw Sites in the Distal Metaphysis of Feline Radii

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Objective—To evaluate the effect of 2 cement augmentation techniques on pullout strength of 1.5 mm screws placed in stripped 1.5 mm screw sites in the distal metaphysis of feline radii.

Study Design—Experimental study.

Sample Population—Feline radii (21 pairs).

Methods—Treatment groups (n = 4) were allocated according to a Latin square design to 4 sites in each pair of radii. Positive and negative controls were a 1.5 mm screw and a screw of the same diameter in a previously stripped screw hole, respectively. Treatment groups were a 1.5 mm screw implanted in a previously stripped screw hole after injection of polymethylmethacrylate (PMMA) or a bioresorbable calcium phosphate cement (CPC, Norian[®] skeletal repair system (SRS)). The ultimate pullout strength was compared between groups.

Results—The mean (\pm SEM) pullout strength of screws augmented with either bone cement was less than that of the positive control group and greater than that of the negative control. Injection of CPC or PMMA before screw implantation increased the pullout strength of the negative control by $86.8 \pm 22.9\%$ and $104.1 \pm 32.1\%$, respectively. Holding power of the positive control screws differed from these 2 groups, and was $274.8 \pm 39.17\%$ higher than that of the negative control.

Conclusion—Injection of CPC or PMMA increases but does not restore the holding power of stripped 1.5 mm diameter screws.

Clinical Relevance—The use of CPC (Norian[®] SRS) augmentation of stripped 1.5 mm diameter screws warrants clinical investigation as it combines biomechanical results similar to PMMA with osteoconduction and resorbability.

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Key words: screw holding power, stripped screw holes, cement augmentation, polymethylmethacrylate, resorbable ceramic cement, Norian[®] skeletal repair system, radius, metaphysis, cat.

INTRODUCTION

MINISCREWS MEASURING ≤ 2 mm diameter have gained popularity in veterinary surgery for use in combination with miniplates, cuttable plates, and craniomaxillofacial titanium plates.^{1–3} Use of these screws is indicated in the management of small bone fractures,

craniofacial surgery in dogs, as well as fracture fixation in toy breeds, cats, and birds.^{1,2,4–7} The torque required to “strip” a screw hole increases linearly with the diameter of the screw.^{7,8} Miniscrews are thus predisposed to mechanical stripping, especially when placed in soft metaphyseal bone.⁹ This is especially relevant to fractures of the distal aspect of the radius in miniature breeds of dogs and cats:

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Presented at the American College of Veterinary Surgeons Annual Symposium, Denver, CO, October 2004, the 5th combined meeting of the Orthopedic Research Society, Banff, Canada, October 2004, and the scientific meeting of the Orthopedic Research Society, Washington, DC, February 2005.

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Submitted August 2004; Accepted December 2004

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0161-3499/04

doi:10.1111/j.1532-950X.2005.00034.x

the fracture configuration and bone stock limit the number of screws that can be inserted distal to the fracture site, and minimize the ability to redirect screws if a screw site is stripped.⁵ Although the predisposition of fractures of the distal aspect of the radius to nonunion has been attributed to their reduced vascularity, biomechanical instability associated with stripped screws may further compromise bone healing.^{5,10–15}

Strategies to deal with a stripped screw site include redirection of the screw, replacement with a screw of larger diameter, or with a specially designed “emergency” screw.^{5,12,16} These strategies may be limited by bone stock, fit of the replacement screw head in the plate, stress-rising effect of larger screws, lack of soft-tissue coverage, and availability of emergency screws. Injection of bone cement into the medullary canal of long bones or in screw holes before insertion is a simple and versatile technique to increase the holding power of orthopedic screws.

Polymethylmethacrylate (PMMA) was the 1st cement used that would double the resistance to axial pullout of screws when injected directly into screw holes.^{17–19} This technique has been applied clinically to enhance screw fixation in osteoporotic patients with intertrochanteric fractures, in pathologic fracture repairs, or pedicle screw fixations in humans.^{20–23} Injection of antibiotic-impregnated PMMA in the marrow of allografts is used for skeletal reconstruction after tumor excision in humans and dogs, to provide local delivery of antibiotics, but also to strengthen the allograft and prevent implant failure.^{24–26} However, the clinical applicability of PMMA is limited by its lack of biodegradability, which may compromise healing of adjacent fractures, complicate implant removal, act as a nidus for infection, and raises concerns about long-term biotoxicity of particulate debris.^{22,27,28} The curing of PMMA is exothermic, reaching a peak temperature of 86.9°C, thereby inducing potential thermal necrosis of surrounding tissues.^{18,29}

These limitations have prompted the development of resorbable ceramic cements. Clinical application of these resorbable cements in human orthopedics has been best documented with Norian[®] skeletal repair system (Norian[®] SRS, Synthes, Paoli, PA). This material consists of a powder containing monocalcium phosphate, α -tricalcium phosphate, and calcium carbonate, which is mixed with liquid sodium phosphate to form a paste.³⁰ The paste can be injected into bone defects and solidifies in situ by an isothermic reaction. The cement reaches a compressive strength of 10 MPa in 10 minutes and hardens to 90% of its ultimate strength in 4 hours.^{31,32} Complete curing takes 24 hours, with a final tensile strength of 2.1 MPa.³³ The ultimate compressive strength of Norian[®] SRS (55 MPa) is greater than those of hydroxyapatite cements (37 MPa) and cancellous bone (1.9 MPa) but less than PMMA (107 MPa).^{18,30,33–35}

From a biologic standpoint, the cement sets up into dahllite, a carbonated form of apatite that closely resembles the mineral composition of bone.³⁶ This osteoconductive material undergoes osteoclastic resorption and stimulates new bone formation, thereby re-establishing the integrity of the cortex and torsional strength of metaphyseal defects within 8 weeks in dogs.³¹ Clinically, this calcium phosphate cement (CPC) decreases postoperative morbidity and promotes early return to function in human patients with fractures of the distal aspect of the radius.^{37,38} Experimental data also support the use of Norian[®] SRS for augmentation of large screws used for femoral neck fracture fixation and spinal surgery.^{19,39} Although the cement has been reported to restore the holding power of stripped 4.0 mm cancellous screws in canine femurs, its use with mini- and microscrews has not been documented.⁴⁰

Our objective was to evaluate the ability of 2 cement augmentation techniques to restore 1.5 mm cortical screw fixation in the distal metaphysis of feline radii. Our hypothesis was that screws placed in previously stripped sites and augmented with either bone cement would have a resistance to pullout similar to screws placed in intact bone.

MATERIALS AND METHODS

Specimens

Pairs of radii ($n = 21$) were harvested from young to middle-aged adult cats within 24 hours of euthanasia performed for reasons unrelated to this study. Age was estimated based on dental examination and radiographic documentation of growth plate closure on all specimens. Bones were double wrapped in polyethylene tubing as previously described, and stored at -70°C until testing.⁴¹

Dual-Energy X-Ray Absorptiometry (DEXA)

Four regions were identified within each matched pair of radii, located approximately 5 and 15 mm from the articular surface of the radiocarpal joint in each radius. The bone mineral density (BMD) of each region of interest was measured with high-resolution DEXA (QDR 2000, Hologic, Waltham, MA). Matched radii were placed in a container filled with 10 cm of water and were scanned simultaneously in a standardized position throughout the study.⁴² BMD was measured over 2 standard regions of interest (measuring 4 mm \times 4 mm) located over the implantation sites within each distal radius.

Screw Implantation and High-Resolution Radiographs

A 1.5–2 mm veterinary cuttable plate (Synthes) was used as a template to standardize the location of implantation sites. The landmark for the distal implantation site was the insertion of the radiocarpal joint capsule. The 2nd implantation site was located over the 2nd screw hole of the plate, proximally. Specimens were secured in C-clamps, with the cranial aspect

of the bone facing up and covered with moist towels to minimize dehydration. Moist foam was placed against the caudal aspect of each bone to simulate soft tissues normally surrounding the far cortex. All bone screws were 20 mm long, 1.5 mm diameter 316L stainless-steel screws (Synthes). The same individual (D.G.) inserted all screws.

Treatments were assigned to each of the 4 locations according to a Latin square design, so that each treatment was evaluated in all combinations of locations (distal and proximal) and radii (right and left). The Latin square design was also selected to control the variability between cats and sites, and provide a precise comparison of treatment means.⁴³ The radius thickness at each implantation site was measured with a depth gauge before tapping. The positive control was a 1.5 mm screw inserted according to AO principles,⁴⁴ whereas the negative control was a 1.5 mm screw overtightened using a previously reported technique.¹² The screw was placed in a hole of a 1.5–2 mm veterinary cuttable plate and advanced through both cortices. Continual torque was manually applied after the screw head contacted the plate until the screw turned freely, and the bone engaged by the threads was biomechanically “stripped”. The screw was turned for an additional 3 complete loose turns before removal. The plate was removed, and a new 1.5 mm screw was inserted into the site. For both treatment groups, a 1.5 mm diameter screw site was “stripped” as described.

The screw and plate were removed and PMMA (Surgical Simplex[®] P, Howmedica Int. Ltd., Rutherford, NJ) or CPC(Norian[®] SRS, Synthes) was injected into the hole. Each cement was mixed according to the manufacturer’s recommendations and aspirated into 3 mL syringes. Hypodermic needles (18 g [0.9 mm diameter]) were cut to 15 mm length to facilitate cement injection directly into screw holes. The needle was inserted into the screw hole until it reached the far cortex and then cement was injected as the needle was slowly withdrawn until the screw hole was completely filled. A new 1.5 mm diameter cortical bone screw was inserted into each hole within 7 minutes of mixing, according to the manufacturer’s recommendation for Norian[®] SRS. All screws protruded from the far cortex by 3 threads, and from the cranial aspect of the bone by at least 6 mm (depending on the diameter of the bone) to allow placement in the test fixture. Complications and approximate amount of cement injected per hole were recorded.

Craniocaudal and lateral high-resolution radiographs (Faxitron Series Model #43805-N, Hewlett Packard Corp., McMinnville, OR) were obtained on all specimens using a nonscreen film (Kodak X-OMAT TL Film, Eastman Kodak Co., Rochester, NY) to confirm the appropriate location of screws and absence of pathology in the radii. The absence or presence of cement around screws was evaluated in a blind fashion for all sites.

All radii were incubated in a water bath at 37°C for 24 hours, to allow complete curing of the CPC before biomechanical testing.³³

Pullout Testing

After curing, a small oscillating saw was used to cut each radius halfway between the proximal and distal implantation

sites. Pullout testing was then conducted using a 100 kN capacity load frame (MTS, Minneapolis, MN) with a 10 kN hydraulic actuator and a closed-loop computer control system (Instron 8500, Canton, MA). Data acquisition was by a 32-bit data acquisition and signal interface between a computer and the load frame. A 4000 N full-scale load cell (Lebow, Troy, MI) was used to measure loads during pullout tests. Because maximum loads measured were approximately 500 N, the load cell was dead weight calibrated and was accurate to within 1% over the experimental load range. Displacements were measured with a 150 mm full-scale linear variable differential transformer. Calibration was performed in the experimental range, and was accurate to within 1%.

A fixture consisting of 2 sections was constructed to perform pullout tests (Fig 1). The load frame and fixture were sufficiently rigid so that measured displacements were almost entirely caused by specimen deformation. Each bone specimen was secured by passing the screw shaft through a 5 mm diameter hole in a piece of rectangular aluminum tubing measuring 50 mm × 75 mm, with a wall thickness of 3 mm. The

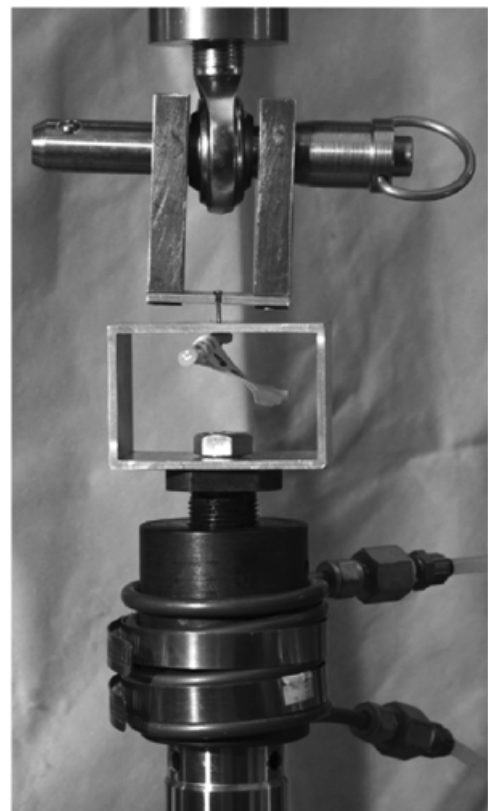


Fig 1. Holding fixture connecting the screw to the materials testing machine load cell. Each construct was secured by passing the screw shaft through a 5 mm-diameter hole in a piece of rectangular aluminum. The head of each screw was gripped by a 2 mm slot in the upper portion of the fixture, which was free to pivot on a ball joint pin to facilitate positioning of the construct into the fixture and to ensure that the pullout force was applied axially.

head of each screw was gripped by slipping it into a narrow (2 mm) slot in the upper portion of the fixture. This upper portion was free to pivot on a ball joint pin attachment to facilitate specimen placement into the fixture and ensure that the pullout force was applied directly along the screw axis. The screw was loaded in tension to failure at a constant displacement of 0.1 mm/s, in accordance with ASTM standards for determining pullout strength of medical bone screws.⁴⁵ Load and displacement data were collected at 50 ms intervals using computer software (Labview, National Instruments Corp., Austin, TX); approximately 200–300 data points were generated per pullout test.

Statistical Analysis

The ultimate pullout strength of each specimen was normalized to bone thickness (N/mm). The pullout of each positive control and augmented screw was compared with that of the corresponding negative control (“stripped” screw) by calculating the percentage of augmentation within each matched pair of radii:

$$\text{Augmentation (\%)} = \frac{\text{NPS of screw(positive control or augmented)} - \text{NPS of negative control}}{\text{NPS of corresponding negative control} \times 100}$$

where NPS is the normalized pullout strength (N/mm). BMD, bone thickness, mean pullout strength, and mean percentage of augmentation were separately analyzed for statistical significance using ANOVA with treatments as repeated measures. When indicated, Bonferroni-adjusted *P*-values were used to compare several pairs of treatments.

The standard deviation of pullout strengths was greater in the CPC group than in the other 3 groups, requiring transformation of all data before statistical analysis. A Box-Cox analysis showed that a cube-root transformation of all data in this study was appropriate.⁴⁶ Statistical significance was set at *P* = .05 in all tests.

RESULTS

Although the mean thickness of radii did not differ between treatment groups and implantation sites (range, 6.0–11.8 mm; mean ± SEM, 8.60 ± 0.12 mm), pullout data were normalized by thickness to eliminate individual variations and allow comparison with previous studies. All needles engaged the stripped screw holes without difficulty and reached the far cortex in all specimens. Approximately 0.25 mL of either cement was injected to fill each screw hole. The number of screw holes that could be augmented with each batch of cement was limited to 7, because of time constraints after mixing rather than volume of cement required. Implantation of screws in the distal metaphysis was documented in all specimens with high-resolution radiographs (Fig 2). Proximal screws were consistently located 8–10 mm from the distal site. The presence of cement in augmented sites was correctly

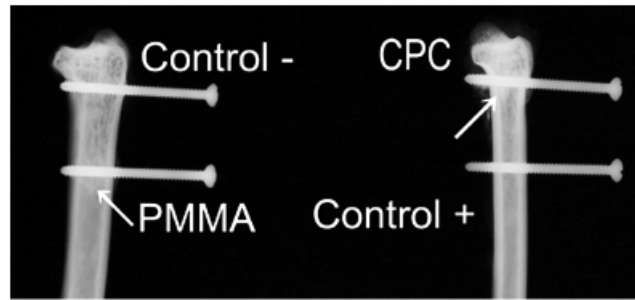


Fig 2. High-resolution radiographs of the distal aspect of radii. A mild increase in radiopacity (arrows) could be detected in approximately 68% of sites injected with cement. Control +, 1.5 mm diameter cortical screw; calcium phosphate cement (CPC), stripped screw augmented with CPC; polymethylmethacrylate (PMMA), stripped screw augmented with PMMA; control –, stripped screw.

identified on high-resolution radiographs in 68% of specimens. Cement fill was variable and extended up to 2 mm from the shaft of the screw. All sites that were incorrectly diagnosed as augmented (false positive) were located proximally. Nonaugmented sites (negative and positive control screws) were correctly identified in 89% of specimens. All sites where cement had been injected but could not be identified (false negative) were located in the distal radial metaphysis. The sensitivity of the radiographic technique and the quality of cement fill seemingly did not differ between cement types.

All screws had typical load–deformation behavior and complications were not encountered during pullout tests (Fig 3); 84 results were analyzed.

In 4 cats, none of the screws in the PMMA, CPC, and negative control groups tightened before stripping. The pullout strength of the positive control screws in these 4 cats with clinically “soft” bone (8.2 ± 0.42 N/mm) was comparable with that of negative control screws (12.4 ± 1.07 N/mm; *P* = .06), and lower than positive control screws (42.77 ± 3.57 N/mm) in the other 17 cats (Table 1). Because the variances in the 2 groups of cats were heterogeneous, a Kruskal–Wallis test was used to compare the positive control screw in the 4 cats with clinically “soft” bone with that of negative control screws in the other cats. Bone thickness (9.82 ± 0.7 mm) did not differ, but the overall BMD (0.16 ± 0.02 g/cm²) was decreased (*P* < .01) in these radii compared with the other cats (thickness, 8.57 ± 0.23 mm; BMD, 0.23 ± 0.01 g/cm²). BMD for each treatment group in these 4 cats was lower than that of the corresponding group in the other cats, except for the PMMA group (Fig 4). The only statistical differences between treatment groups in this small population were detected between the PMMA group and control groups (both positive and negative, Table 1). The pullout resistance of screws augmented by

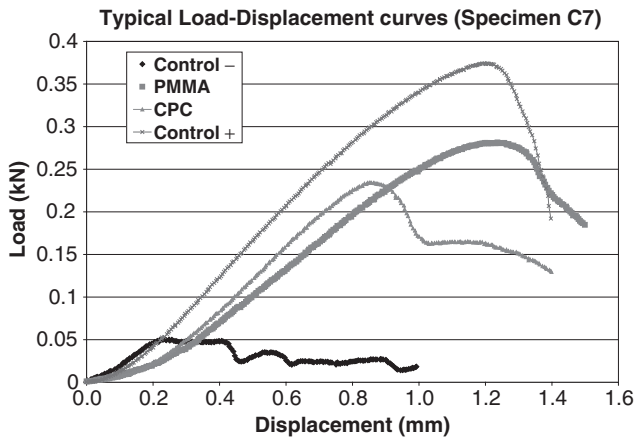


Fig 3. Typical load–displacement curves obtained for 1.5 mm screws (control +), negative control (“stripped”), and screws placed in stripped screw holes augmented with polymethylmethacrylate (PMMA) and calcium phosphate cements (CPC). The maximum load reached during testing was recorded as the ultimate strength to failure.

PMMA or CPC was greater than that of the matching negative control (“stripped”) screw by 370% ($\pm 170.4\%$) and 238% ($\pm 254.4\%$), respectively. The experimental design assumed that all bones would be similar, but because of the difference in BMD, separate analyses of pullout strength and percentage augmentation were carried out for the 4 cats with low bone density and for the other cats. This analysis appeared more clinically relevant than normalizing pullout strength by BMD, as feline bones will likely behave clinically as specimens belonging to 1 or other group.

In 17 cats, BMD was similar in all 4 locations and treatment groups (Fig 4). The mean pullout strength of screws augmented with either bone cement was lower than that of the positive control group but greater than that of matching negative control (“stripped”) screws (Table 1). Injection of CPC or PMMA before screw implantation increased the pullout strength of a matching negative control screw by $86.3 \pm 22.9\%$ and $104.1 \pm 32.1\%$, respectively. The holding power of the control screw differed from these 2 groups ($P < .01$) and was $274.8 \pm 39.17\%$ higher than the negative control.

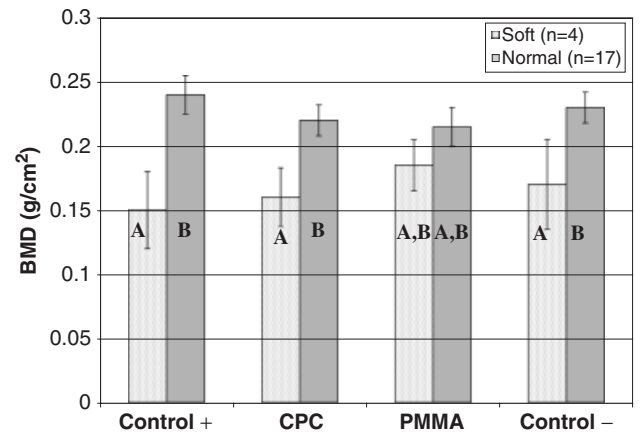


Fig 4. Mean (\pm SEM) bone mineral density (BMD) of implantation sites within the distal aspect of radii of 21 cats. Within each treatment group, different letters (A, B) denote statistical difference ($P < .05$). Control +, 1.5 mm diameter cortical screw; calcium phosphate cement (CPC), stripped screw augmented with CPC; polymethylmethacrylate (PMMA), stripped screw augmented with PMMA; control –, stripped screw.

DISCUSSION

Our model was designed to challenge the ability of bone cements to augment stripped bone screws in areas of limited bone stock. Feline radii were selected to limit size variation in bones and approximate clinical application of 1.5 mm screws in orthopedic surgery. The screw diameter that selected was within AO recommendations for the size of the radii. Although 2 mm diameter miniscrews are often used in toy breed dogs with fractures of the distal aspect of the radius, these screws have the same pullout strength as 1.5 mm screws, and would have been too large for several of our smaller bones (6 mm thickness).³ The NPS of our positive control group was lower than previously reported for 1.5 mm screws implanted in the *cis*-cortex of radii harvested from medium to large dogs,³ and this discrepancy most likely reflects a difference in experimental design between studies.

Resistance to pullout increases with cortical content and with the diameter of the bone engaged at the implantation site.^{9,47} Both of these variables are greater in

Table 1. Mean \pm SEM Ultimate Pullout Strength (Normalized by Bone Thickness) of Positive Control Screws, Negative Control Screws, and Screws Augmented with CPC or PMMA

	Positive Control	PMMA	CPC	Negative Control
Normal bones (n = 17)	42.8 \pm 3.6 ^A	21.34 \pm 2.0 ^B	21.52 \pm 2.6 ^B	12.47 \pm 1.1 ^C
“Soft” bones (n = 4)	8.2 \pm 0.4 ^D	30.5 \pm 2.0 ^E	14.4 \pm 5.7 ^{D, E}	8.5 \pm 1.9 ^D

CPC, calcium phosphate cement, PMMA, polymethylmethacrylate. Within rows, different superscripts denote statistical difference ($P < .05$) between treatment groups.

the radial diaphysis of medium-to-large dogs than in the metaphysis of feline radii. Screw insertion in the previous study was limited to 1 cortex to prevent microfractures from occurring during tapping and screw insertion into the *trans*-cortex. Pullout strength was normalized by cortex thickness, which represented the portion of bone providing holding strength; however, we normalized by bone thickness rather than cortex thickness because the bone in contact with the entire length of the augmented screws contributed to their holding power.

PMMA was the 1st bone cement used as an adjunct in fracture fixation.⁴⁸ It has not gained general acceptance in human orthopedics because of a lack of resorption, exothermic curing, potential toxicity, and risk of infection. We included PMMA augmentation because it is used in veterinary orthopedics and is biomechanically superior to biodegradable bone cements,^{25,26,49–51} and is thus commonly used as a positive control for comparison of biomechanical properties of new bone cements. Several bone cements have been developed to mitigate the limitations of PMMA in humans. CPC are particularly appealing because of their resorbability, isothermic curing, and osteoconductive properties. We selected Norian[®] SRS because of experimental and clinical data supporting its use in fracture management and its ready availability.^{19,31,37–39} Indeed, this cement is commercialized for use as a gap filler in the entire skeletal system, including the extremities, spine, and pelvis. All screws were inserted within 7 minutes of mixing either cement, according to the manufacturer's recommendations for Norian[®] SRS. Screws placed in doughy PMMA also exhibit greater pullout strength than those placed after cement curing.^{17,52}

Our inability to tighten any screw in radii of 4 cats was unlikely to result from inadvertent overtightening of all screws in these radii. The lower bone density measured in these radii was unexpected, but would explain these results. Indeed, pullout strength has been found to correlate highly with bone quality and BMD in humans.⁵³ A similar relationship has been established between decalcification, bone mineral content, and bending strength of feline femurs.⁵⁴ However, the reason why BMD was lower in the distal aspect of the radii of these cats remains unclear. Bone thickness did not differ from the rest of the population and these cats did not appear older than the others. None of the cats studied were immature, based on radiographs of the radii. Unfortunately, the lack of previous history precludes further interpretation of potential causes for decreased BMD in these radii. Reports of DEXA are scarce in cats,^{42,55} and our findings may warrant further investigation to elucidate the incidence and origins of decreased BMD in clinically normal cats. Injection of PMMA increased resistance to pullout of screws in these cats, a finding that corroborates other studies supporting cement augmentation of screws in osteoporotic

bone.^{22,23,56,57} Because of the small sample size, the risk of type II error precludes any conclusion about the efficacy of CPC augmentation in feline radii with decreased BMD.

Both cement augmentation techniques increased the pullout strength of screws inserted into stripped sites in the other cats, which is consistent with previous studies that used larger screws. Although the compressive and bending strengths for PMMA compare favorably with resorbable cements, no difference was found between the restoration of pedicle and hip screws with PMMA or Norian[®] SRS in human bone.^{39,58} These data support the use of Norian[®] SRS, as it provides a similar degree of screw augmentation without the disadvantages of PMMA. In these studies, injection of cement before insertion of screws in previously stripped holes increased the resistance to pullout compared with intact screws, by as much as 147%.^{39,58} Similar findings were reported by Mermelstein et al⁴⁰ with 4 mm cancellous screws inserted into canine femurs.

Our results differ because the pullout strength of screws augmented with either technique remained lower than our control group and may have occurred because of decreased bone stock and screw diameter. Indeed, previous studies evaluated screws of ≥ 4 mm diameter, inserted into lumbar vertebrae and femurs of larger species. The technique used to strip the bone also differed from our model because in those studies, resistance to pullout of an intact screw was tested before evaluation of the augmentation technique in the same hole. Whereas this design eliminates variation associated with location of implantation sites, it differs from the clinical setting where a screw site is stripped by excessive torque during insertion rather than axial pullout.

Insertion of a screw of a larger diameter into a previously stripped screw site is a common strategy in veterinary orthopedics.¹² Certainly, replacement with a 2.0 mm diameter screw could be considered in radii large enough to accommodate this screw size; however, overtightening of orthopedic screws not only removes a cylinder of bone equal to the outer diameter of the screw but also damages bone beyond that level, resulting in a loss of holding power of "emergency" and other larger screws inserted into previously stripped sites.^{16,59} Resistance to pullout of 1.5 and 2.0 mm screws inserted into intact bone is similar³; thus, the pullout strength of 2.0 mm screws inserted into a previously stripped 1.5 mm hole should be less than that of a 1.5 mm screw inserted into intact bone (our positive control group). This reasoning and the small size of some of our specimens prompted us to exclude this option from our study.

We concluded that injection of calcium-phosphate or PMMA cements increases, but does not restore, the holding power of stripped 1.5 mm diameter screws in feline radii. Use of CPC (Norian[®] SRS) for augmentation

of stripped 1.5 mm diameter screws warrants in vivo investigation because it has biomechanical results similar to PMMA, with advantages of osteoconduction and resorbability. Future studies may focus on combining local plate luting with screw augmentation as a potential option to restore the holding power of a stripped screw or augment screws inserted in to weak bones.

ACKNOWLEDGMENTS

The authors acknowledge Synthes for donation of implants and cement, and Howmedica for providing the PMMA.

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