Prospective Randomized Clinical and Radiographic Evaluation of a Novel Bioabsorbable Biocomposite Tibial Tuberosity Advancement Cage Implant

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Objective: To evaluate the suitability of a novel bioabsorbable biocomposite cage (BC) implant for use in tibial tuberosity advancement (TTA) surgery in dogs with cranial cruciate ligament (CrCL) disease and to compare radiographic osteotomy healing scores and complications between groups that received either a BC or stainless steel cage (SSC).

Study Design: Prospective randomized clinical study.

Animals: Dogs with unilateral CrCL rupture (n=56).

Methods: TTA was performed in 60 consecutive dogs using either a BC (30 dogs) or SSC (30 dogs). Patient parameters, 6 week and 6 month postoperative radiographic osteotomy healing scores, time elapsed to postoperative rechecks, and complications were compared between groups. Osteotomy healing was graded using a 5-point (0–4) scale. Data were analyzed using Wilcoxon Rank Sum tests and χ^2 tests with significance set at $P<.05$.

Results: Fifty-six dogs (30 BC, 26 SSC) had complete medical and radiographic records at 6 months for inclusion in data analysis. Three complications occurred in the BC group (1 major, 2 minor) and 2 occurred in the SSC group (2 minor). There was no statistical difference in patient parameters, 6 week healing scores, or complications between BC and SSC groups. Healing scores at 6 months were significantly higher in the BC group (3.3 ± 0.52) compared to the SSC group (2.9 ± 0.69; $P=.04$).

Conclusion: Based on improved BC osteotomy healing scores 6 months after surgery with no significant differences in complications compared to SSC, BC TTA cages are a viable alternative to SSC.

Tibial tuberosity advancement (TTA) is a well-established osteotomy-based technique for neutralizing cranial tibial thrust in the cranial cruciate ligament (CrCL)-deficient canine stifle. Like the tibial plateau leveling osteotomy, TTA creates a patellar tendon-tibial plateau angle of 90° that allows the quadriceps mechanism to dynamically stabilize the stifle joint.[1–4] The TTA osteotomy is typically stabilized with technique–specific stainless steel (SS) or titanium cage and plate implants. These cages and plates, like many implants used to treat other orthopedic conditions, become superfluous once the osteotomy has adequately healed.

The majority of human and veterinary orthopedic implants are permanent, yet their role in the body is often temporary. In people, planned removal of orthopedic implants is one of the most commonly performed elective orthopedic procedures worldwide.[5] The rationale for removal is to eliminate the possibility of metallic implant-associated morbidity developing over time. Such morbidities include inflammation and immune-mediated reactions from metallic corrosion, stress shielding of bone, implant-associated neoplasia, bone pain, infection, and MRI artifact production. However, elective surgery to remove these implants is a significant source of patient morbidity and has a massive economic impact. The latter may explain why elective removal of implants is less commonly performed in veterinary patients even though the same implant-related issues can and do occur.[6,7] Removal is typically reserved for when an implant-associated problem has already occurred. For all of these reasons, orthopedic implants composed of materials that could gradually and completely absorb in the body once healing is completed have been under intense investigation for over 30 years.

In the early 1990's, bioabsorbable implants began replacing metallic implants in some key human orthopedic applications, most notably the use of bioabsorbable interference screws in anterior cruciate ligament reconstructions. Not only do bioabsorbable implants eliminate the late-term morbidity issues associated with metal implants, they can also be easily trimmed and drilled or cut. Good clinical results with minimal evidence of inflammation and consistent gradual, complete degradation was reported using the first-generation interference screws made of poly L-lactide homopolymer.[8,9] Additionally, these bioabsorbable screws stabilized grafts with

Figure 1 The biocomposite cage composed of 30% bicalcium phosphate dispersed in amorphous poly L-lactide-co-D,L-lactide polymer accepts either titanium or SS wings that clip onto a T-shaped post and can be rotated 360° to the desired location. The end is tabbed to facilitate cutting the cage to the desired length based on the proximal tibial osteotomy depth.

strength comparable to their metal counterparts.[10] However, these materials did little to enhance or encourage bone ingrowth as they degraded.[11] While complete implant degradation is the goal, the materials used should also promote tissue ingrowth to an extent that the implant site completely fills in with bone.

Calcium phosphate bioceramics, such as hydroxyapatite (HA) and beta-tricalcium phosphate (ß-TCP), have been used for bone defect filling and as implant coatings to enhance osteointegration for over 20 years.[12] HA and ß-TCP have well-established osteoinductive and osteoconductive properties and are available in a variety of orthopedic products to enhance bone healing. However, HA has a very slow resorption rate (on the order of years) and the ingestion of its particulates by adjacent tissues can create granulomatous-type reactions.[13] By contrast, ß-TCP tends to resorb so fast that new bone may not be produced in time to replace the material void.[14] To address these issues, biphasic calcium phosphates (BCP) were created by combining HA and ß-TCP in different ratios, producing a bioceramic with a more controllable and desirable resorption profile. BCP also supports new bone formation more quickly than either HA or ß-TCP can alone.[15]

Orthopedic biocomposites, also referred to as bioresorbable scaffolds, are made by dispersing a bioactive ceramic in a polymer matrix producing a composite material that has superior structural, absorption, and biologic properties.[16] A biocomposite block composed of HA and poly D/L lactide copolymer evaluated in a canine tibial defect model showed similar bone formation and superior cell and tissue infiltration when compared to the ß-TCP alone.[17] Despite the now common use of bioabsorbable orthopedic implants in human surgery, only a single clinical report exists on the successful use of a biodegradable orthopedic implant in dogs.[18] The majority bioabsorbable orthopedic implant use in animals is in research with animals as models of human disease.

The objective of this study was to prospectively evaluate a novel proprietary poly L-lactide-co-D,L-lactide (PLDLA) and BCP biocomposite TTA cage by measuring radiographic osteotomy healing and reporting any complications over a 6 month postoperative period. We hypothesized that healing scores and complication rates would be similar between a group of dogs receiving BCs and a control group of dogs receiving SS TTA cages.

MATERIALS AND METHODS

Biocomposite Cage Implant

The biocomposite cage (BC) material was composed of 30% BCP dispersed in a bioabsorbable polymer matrix based upon amorphous PLDLA (TESco Associates Inc, Tyngsborough, MA). BC were manufactured under ISO class-7 clean room conditions and were cold sterilized immediately before implantation by immersing them in Accel Cs20 chemosterilant (Virox Technologies Inc, ON, Canada) for 20 minutes. Separately autoclaved 15 mm (9 mm cage) or 17 mm (12 mm cage) SS wings, which accepted 2.4 mm screws, clipped onto the BC T-shaped post and could be rotated 360° (Figs 1 and 2). The end of the BC is tabbed in order to facilitate cutting it to the desired length to match the depth of the proximal tibial osteotomy. Before this clinical evaluation, the BC was evaluated for in vivo molecular weight loss over time using a validated in vitro time and temperature superposition shift soak in 80°C phosphate buffered saline.[19] Additionally, the cage's

Figure 2 Radiographic appearance of the biocomposite cage in situ 6 months following implantation.

in vitro compression load resistance properties were evaluated at different levels of degradation using ASTM standard testing methods.[20] These proprietary results predicted a near complete loss of molecular weight in vivo over 48 weeks with the majority of the loss expected to occur between 25 and 48 weeks in vivo.

Inclusion Criteria

As determined by physical examination, medical history, complete blood count, and biochemistry profiles, otherwise healthy client-owned dogs examined between January 2014 and June 2014 for evaluation and treatment of CrCL disease with a TTA were prospectively enrolled. Dogs were diagnosed with CrCL disease by clinical and radiographic findings.

Inclusion criteria included no concurrent stifle pathology unrelated to unilateral CrCL disease, no previous surgery performed on the affected stifle, and either a 9 or 12 mm cage size deemed necessary for TTA. Additionally, 6 week and 6 month follow-up radiographs and physical examinations had to be completed for final study inclusion.

Before study enrollment all owners were counseled to ensure they understood that their dog might receive a BC that was a novel implant that had not been previously tested in a clinical setting. We specifically informed owners that while this implant was evaluated using the aforementioned tests and the biocomposite material has been used in human applications safely and effectively for years, this was in fact a clinical trial for this application. A written consent form and an agreement to return their dogs for all required reevaluations was signed by each owner before enrollment of their dog. Owners received financial incentive for their participation in this study. Dogs were then randomly assigned by coin flip to either the experimental group (BC) or the control group (SS cage; stainless steel cage, SSC) until each group had 30 dogs enrolled.

Accurate medical records were maintained and clinical, radiographic, and technical data were collected and reviewed. Patient information gathered included age, sex, breed, body weight (kg), 0–9 scale body condition score (BCS),[21] TTA cage size, dates of follow-up radiographs, and any observed or reported complications (radiographic or clinical).

Anesthesia

Although this was a prospective study, the anesthesia protocol was not standardized. All dogs were premedicated with a combination of hydromorphone (0.1 mg/kg) and either midazolam (0.1 mg/kg) or acepromazine maleate (0.1 mg/kg) IV 15–20 minutes before induction with propofol (4 mg/kg IV). Anesthesia was maintained with isoflurane and oxygen. Every dog received a preservative-free morphine (0.1 mg/kg) and bupivacaine (0.5 mg/kg) lumbosacral epidural and an injection of cefazolin (22mg/kg IV) 30 minutes or less before skin incision. Lactated Ringer's solution (10 mL/kg/h IV) was administered throughout anesthesia.

Surgery and Implants

Pre-operative lateral fully-extended stifle radiographs were taken for TTA planning and to exclude any other radiographic abnormalities of the stifle. The surgical planning and TTA technique were no different between groups and was as previously described using forkless plates without the use of any grafting of the osteotomy gap as is standard practice for the surgeon (MB) with years of experience performing TTA.[17] Cuttable 9 or 12 mm, 316L SS TTA cages (Securos, Fiskdale, MA) were used in the control group while the experimental group received 9 or 12 mm BC (Everost, Sturbridge, MA). All TTA cages were placed in the fashion identical to that previously described.[4]

Postoperative Management

All dogs remained hospitalized overnight after surgery. A self-adhesive wound dressing (Primapore, Smith and Nephew, Hull, UK) covered the incisions upon completion of surgery and remained in place until dogs were discharged. Dogs received cefazolin (22 mg/kg IV) 8 hours after the initial preoperative dose and either hydromorphone (0.05 mg/kg IV or IM) or morphine (0.5 mg/kg IV or IM) if evaluation indicated a need for additional analgesia. Cryotherapy (Game Ready CoolSystems Inc, Alameda, CA) was performed immediately after surgery then every 4 hours after for 20 minutes and passive range of motion (PROM) was performed on the operated limb every 8 hours. Cephalexin (22 mg/kg orally every 8 hours), nonsteroidal anti-inflammatory drugs (NSAID; firocoxib 5 mg/kg orally once daily, carprofen 2.2 mg/kg orally every 12 hours, meloxicam 0.1 mg/kg orally once daily, or deracoxib 1–2 mg/kg orally once daily), and tramadol (3–5 mg/kg orally every 8 hours) were administered for 7 days postoperatively. NSAID selection was not standardized and was chosen based on which drug the dogs were already being administered when presented for surgery. All dogs were discharged the day after surgery. Cold pack application and PROM were continued for 1 week. Skin staples were removed at 10–14 days. Dogs were restricted to leash-based activities for 6 weeks and allowed a progressive return to normal activities after their 6 week re-evaluation.

Follow-Up Evaluations

Dogs were evaluated at ∼6 weeks and 6 months after surgery by the surgeon who performed the TTA (MB). Evaluation consisted of physical and radiographic examinations and owner queries as to any observed complications or concerns. All lateral radiographic projections of the stifle at 6 weeks and 6 months were randomly assigned a number and then evaluated for osteotomy healing by a board certified radiologist (AW) blinded to patient information and postoperative time frames. Healing of the osteotomy was scored using a 0–4 scale previously published in multiple manuscripts: 0, no osseous healing; 1, early bone production without bridging between the tibial tuberosity and the shaft of the tibia; 2, bridging bone formation at 1 site; 3, bridging bone at 2 sites; and 4, bridging bone at 3 sites. The 3 sites of the osteotomy

Table 1 Comparison of patient parameters between biocomposite cage (BC) and stainless steel cage (SSC) groups

Patient parameter	Median (Range)		P-value
	SSC	BC	
Age (years)	6 (1.8–16)	5 (2–9)	.36
Weight (kg)	35.8 (23–59)	35.9 (21–58.2)	.63
Body condition score (out of 9)	7 (5–8)	6 (4–8)	.14
Sex (% female-spayed)	69.2	76.7	.53
Cage size (% 9 mm)	19.2	10.0	.33
Time to 6 week follow-up (days)	46 (37–65)	46 (41–67)	.76
Time to 6 month follow-up (days)	211.5 (180–282)	211 (153–333)	.61

evaluated were the areas proximal to the cage, between the cage and the plate, and distal to the plate.[23,24] Any radiographic complications were also recorded.

Upon completion of the study, the medical records for each dog were reviewed for any recorded complications in addition to the aforementioned owner interviews. Complications were rated as minor or major based on previously published recommendations.[25] Major complications were those that required a second surgical procedure to remedy while minor complications resolved without surgery or long-term medical treatment.

Statistical Analysis

All statistical analyses were performed using statistical analysis software (SAS version 9.4, Cary, NC). Age, despite being measured as a discrete number of years, was included in statistical analysis as if it were continuous along with the other continuous variables (body weight, age, time elapsed to follow-up visits). The underlying distribution of these data was examined and, in all cases, the distribution was not normal so Wilcoxon Rank Sum tests were performed to compare these measurements between the 2 groups. For categorical measurements (cage size, sex, BCS, healing score, NSAID type used, complication presence), χ^2 tests for equal probabilities within categories were used. For analysis of changes in healing scores over time, differences between the 6 week and 6 month healing scores for each dog were calculated and a Wilcoxon Signed Rank Test was performed to determine if the healing score differences were greater than zero on average (Table 1). Statistical significance was set at $P<.05$ for all testing.

RESULTS

Patient Parameters

Of the 60 consecutive dogs enrolled in this study, 56 had complete records and radiographs for inclusion in data analysis. There were 20 mixed breeds (36%), 12 Labrador Retrievers (21%), 5 Rottweilers (9%), and the remaining 24

dogs were other medium to large purebreds. The BC group had 30 dogs (mean age 5.1 years, range 2–9; mean weight 33.8 kg, range 21–52.8; mean BCS 6.2/9, range 4–8). The SSC group had 26 dogs (mean age 6.1 years, range 1.8–16; mean weight 36.0 kg, range 23–59; mean BCS 6.4/9, range 5–8). The owners of the 4 missing SSC dogs were interviewed by telephone 6 months after surgery and did not report any complications. They were unable to return their dogs for the final reevaluations. No significant differences existed between the experimental and control groups relative to dog age, weight, BCS, cage size, types of NSAID used, or sex (Table 1).

Healing Scores

The mean time to postoperative follow-up for the 6 week (BC group 47.0 days, range 41–67; SSC group 46.7 days, range 37–65; $P=.76$) and 6 month (BC group 217.5 days, range 153–333; SSC group 216.3 days, range 180–282; $P=.61$) radiographs was not significantly different between groups. There were a significantly greater proportion of dogs in the BC group with healing scores of 3 and 4 at 6 months after surgery compared to the SSC group ($P=.04$; Table 2). Healing scores for 56 dogs improved significantly within both groups between the 6 week and 6 month time periods ($P<.005$ for both groups; Table 3). There was not a significant difference in scores between groups at the 6 week recheck ($P=.34$); however, the BC group had significantly higher healing scores than the SSC group at the 6 month recheck ($P=.04$; Table 3).

Complications

Three BC (2 minor [7%] and 1 major [3%]) and 2 SSC dogs (2 minor [8%]) experienced postoperative complications. There was no significant difference in number or types complications between the 2 groups ($P=.76$). No intraoperative complications were encountered.

The minor complications in the BC group included 1 dog with a broken cage wing noted on 6 month radiographs and 1 dog that developed a 3 mm draining skin ulcer at the distal aspect of the healed TTA incision site 3.5 months after surgery. The broken wing appeared to be an incidental finding as the dog had an otherwise routine recovery and excellent outcome after surgery. Additionally, the osteotomy was well-

Table 2 Percentage of the biocomposite cage (BC) and stainless steel cage (SSC) dogs with various healing scores

Healing score	6 weeks			6 months		
	SSC	BC	Total	SSC	BC	Total
1	3.9	6.7	5.4	0.0	0.0	0.0
2	57.7	40.0	48.2	26.9	3.3	14.3
3	34.6	53.3	44.6	53.9	66.7*	60.7
4	3.9	0.0	1.8	19.2	30.0*	25.0

*Indicates significant difference between BC and SSC in the proportion of dogs with healing scores of 3 and 4 at 6 months following surgery.

Table 3 Mean healing scores for the biocomposite cage (BC) and stainless steel cage (SSC) groups at 6 weeks and 6 months

	6 weeks	6 months	N
BC	$2.5 \pm 0.63^*$	$3.3 \pm 0.52^{*\dagger}$	30
SSC	$2.4 \pm 0.64^*$	$2.9 \pm 0.69^{*\dagger}$	26

Mean ± SD.
*Indicates significant differences within group between time points.
†Indicates significant difference between groups at a single time point.

healed at 6 months with no evidence of any other radiographic changes when compared to the 6 week postoperative images.

In the case of the skin ulcer, a superficial culture and sensitivity of the lesion grew a methicillin-resistant *Staphylococcus pseudintermedius*. The infection was treated with a 3 week course of minocycline and, according to the owner, has not recurred to date 9 months after completion of treatment.

Two SSC dogs developed postoperative seromas and transient increases in lameness at 7 and 9 days after surgery. These resolved with conservative management only (warm compresses 3 times daily for 5 days and carprofen [2.2 mg/kg orally every 12 hours] for 3 days). Both seromas were confirmed as such by cytologic evaluation and negative bacteria cultures of aspirated fluid.

The single major complication occurred in 1 BC dog that developed persistent purulent drainage from his incision after self-mutilation of his surgery site 5 days after surgery. Two cultures performed on different dates failed to grow any bacteria. Ultimately, a methicillin-resistant *Staphylococcus pseudintermedius* was isolated by direct culture of the explanted metal TTA implants 9 weeks after the original surgery. The BC itself was not removed (Fig 3A). The infection resolved after metal implant removal and 1 week of chloramphenicol administration (50 mg/kg orally every 8 hours) with no recurrence observed by the owners to date 10 months later. The short duration of antibiotic administration post-metallic implant removal was because the owners became unable to administer medications to the dog. This dog was not removed from the study and completed its final evaluations (Fig 3B).

DISCUSSION

Our results indicate that dogs receiving BC had significantly improved osteotomy healing by 6 months after surgery compared to dogs with SSC. We therefore rejected the portion of our hypothesis that healing scores would be similar between BC and SCC groups. Since the number and types of complications did not differ significantly between the groups, we accepted the portion of our hypothesis that theorized complications would be similar between SSC and BC dogs. To the authors' knowledge, this is the first study reporting the findings after the use of a biocomposite implant in dogs in a clinical setting.

Since the use of bioabsorbable suture was approved by the Food and Drug Administration almost 50 years ago, poly-

meric materials such as polylactide and polyglycolic acid have been used in countless surgical applications. Combining its two stereoisomeric forms, L-(PLLA) and D-lactide (PDLA), in specific ratios produces a PLDLA composite with degradation and strength features different than the parent polymers. The BC in this report were composed of a modified amorphous PLDLA (70:30 L:DL isomer %) that has a calculated degradation profile that falls between that of PDLA (12–16 months), and PLLA (36–60 months).[26] Histologic evaluation of beagle femurs after implantation of rods of similar biocomposite composition into cortical defects revealed near complete resorption and normal bone replacement by 24 months with no evidence of inflammatory reaction.[27] Late-term histologic examination of tibias implanted with BC would be required to determine if these implants are ultimately completely replaced by bone and do not produce inflammation.

The BCP combined with PLDLA releases calcium and phosphate ions that are used by osteoblasts to initiate new bone formation while providing a scaffold to support and guide the new bone growth.[15] These ions also buffer the acidic by-products produced by polylactide hydrolysis that would otherwise lower the pH locally and favor osteoclastic activity and the formation of resorptive bone lesions.[28]

While an orthopedic biocomposite implant should have favorable biocompatibility characteristics, it must also have the necessary mechanical properties to perform its function while the patient's bone heals. The TTA cage is a particularly well-suited application for a biocomposite material because of its location within the bone and because of its required function in the TTA construct. The TTA osteotomy is stabilized by plate and cage implants that function as a tension band construct. The plate counters the tension vector produced by the quadriceps mechanism and converts it to compression force against the cage. As such, the cage must have material composition and structural characteristics that are able to withstand compression until the osteotomy gap fills in with bone. Both PLDLA and porous BCP tend to fragment when subjected to bending or torsional loads but have excellent compressive strength and stiffness properties.[29,30] Blending these compounds imparts the beneficial compression resistance characteristics to the resultant composite and further modification of the blend formulation can impart toughness, mitigating fragmentation issues.[31] Such composites have demonstrated mechanical strength well within the range required for bone fixation materials when evaluated in a rabbit segmental bone defect model.[16]

The differences in healing scores between the BC and SSC groups cannot be explained by differences in patient parameters. The 2 patient variables that could most affect bone healing scores are age and the amount of time elapsed from surgery to when the radiographs were taken. Immature dogs would be expected to heal more quickly than older dogs and the more time that passes after surgery, the more mineralized bone should fill in the TTA gap. However, both groups in this study contained skeletally mature dogs and no significant differences existed between the experimental and control groups relative to age or time to the 6 month follow-up visits.

Figure 3 (A) Infection with methicillin-resistant *Staphylococcus pseudintermedius* caused by self-mutilation of the TTA incision required removal of all metal implants 9 weeks following the original surgery. The biocomposite cage was not removed (circle). (B) The biocomposite cage appeared to have been partially replaced by bone (arrow) 6 months following the original surgery and the infection remains resolved to date.

It is unlikely that the aforementioned biologic benefits of BCP enhanced healing along the entirety of the osteotomy because its beneficial effects should be limited to the microenvironment only in immediate proximity.

Another possible explanation for the improved healing scores in the BC group is that the progressive loss of osteotomy support by the absorbing implant stimulated more bone production and mineralization than the rigid SCC did. Molecular weight loss because of hydrolysis results in a less stiff implant, one that transitions from rigid and hard, to semi-compliant, and then to a soft friable composition. If this loss of stiffness occurs after early bone healing has begun, the increased strain at the osteotomy site could optimize the gap healing.[32] A predicted 15–30% loss of molecular weight over a 6 month period likely correlated with our observations that the BC appeared less radiopaque with time. It might also explain the single case that had broken wings at the 6 month reevaluation. Presumably, increased stress on the wings lead to fatigue failure. However, why it only occurred in 1 dog and when it actually happened after the 6 week radiographs is unknown.

Another factor that might influence healing is the practice of bone grafting. No grafting of the TTA osteotomy sites was performed in either group in our study. However, because TTA grafting with autogenous cancellous bone or any number of commercially available calcium phosphate bioceramic products is commonly performed, its potential influence on our results should be considered. Given that prior studies report grafting provides inconsistent radiographically apparent healing benefits and has no positive or negative impact on complications, it is likely that it would either offer no additional healing benefit or equally improve healing scores in both groups.[22,24,33]

To the authors' knowledge no studies have evaluated for healing differences in TTA patients between the 2 most commonly used cage materials: SS and titanium (Ti). Compared to SS, Ti has been reported to have accelerated osseointegration properties, more direct bone anchorage without tissue superimposition, and support of osteoblast migration because of its surface morphology.[34–36] Whether or not these Ti characteristics would provide improved radiographic osteotomy healing scores versus SS and thereby compare more favorably to BC scores, is not known. SS was chosen for our study simply because it is what is used most commonly in our practice. Further investigation would be required to make any meaningful comparisons between BC and Ti cages.

The overall complication of rate of 8% for our study compares favorably to previously reported ranges of 8–24%.[4,37–43] The one major complication occurred in a BC dog and was a deep surgical site infection (SSI) that required all metal implants to be removed for resolution. Reported TTA SSI rates range from 2.6 to 8.7% but the required implant removal rate after infection appears to be low, with a prevalence of 1.3% reported in a single study.[4,37–42] When required, cage removal is challenging because it extends into the proximal tibia and its open lattice design permits tissue ingrowth. Furthermore, the large tibial defect created by cage removal is adjacent to the straight patellar ligament insertion, which can lead to subsequent tuberosity avulsion fracture. While BC are expected to ultimately resorb and therefore not remain a nidus for late-term infection, they may not be any more resistant to the development of short-term SSI.

As with metallic implants, bacterial interactions with bioresorbable polymers are very complex and numerous factors influence their adhesion and ability to form biofilms.[44]

It has been reported in prior studies that the biodegradability of a polymer does not alter the amount or ability of bacterial adhesion nor does the degradation of the substrate cause attached bacteria to release.[43] It is speculated that bacteria produce multiple surface contact adhesion points so that

while some contact points may dissolve, others reform on the newly exposed polymer layers.[45] These findings make it more difficult to explain why the dog's deep SSI resolved despite the BC remaining in place. It is possible that the *Staphylococcus pseudintermedius* infection simply did not involve the cage or did not form a biofilm on it. With only this single case to reference, a recommendation cannot be made as whether a BC suspected of infection should always be removed or can remain in place.

Limitations of our study include the small size of experimental and control groups evaluated, which limits its power. Radiographic scoring of TTA osteotomy healing is inherently subjective and there is no single accepted method for doing so. The protocol for scoring TTA used in our study has been published more than any other technique and our radiologist has participated in multiple studies using this method. To maximize objectivity, the radiologist was unaware of patient parameters and postoperative time frames; however, the type of cage used for each dog was obvious. Additionally, because the cage becomes less radiopaque with time, the radiologist could surmise that some radiographs were taken later in the postoperative period than others. These variables could have introduced some level of bias into our study. Since NSAID drug type was not standardized in our study, it is possible that the different types could have had different detrimental effects on bone healing. Even though all dogs were prescribed 7 days of these medications and different NSAID types did not differ significantly between the 2 groups, it is feasible that some dogs were not administered the drug as recommended or were given additional drug without our knowledge. Additionally, the two SS group dogs that developed seromas and increased lameness were put back on a short course of NSAID. Since these variables were not specifically assessed they should be considered as a limitation. Another limitation of our study was the informal collection of complication data. While our methodology was consistent with similar previously published studies, a complication-specific client questionnaire may have provided an opportunity to extract more information. Lastly, while the owners of the 4 SSC dogs that failed to complete the study were interviewed by telephone 6 months after surgery reported no complications, it is possible that exams could have revealed issues. As such, their possible contribution to the complication rates reported in our study cannot be completely excluded.

In conclusion, the BC evaluated in our study is a viable alternative to currently used SSC with some highly appealing realized and potential advantages over metal implants. The BC performed as well as a SSC relative to complication occurrence and 6 week osteotomy healing but provided significantly better TTA healing by 6 months after surgery.

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DISCLOSURE

Dr. Barnhart is a paid lecturer for Securos and Everost and receives royalties from the sales of some of their products. Dr. Wotton is the president of Everost and Dr. Thatcher is the president of TESco Associates. The remaining authors declare no conflicts of interest related to this report.

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