INTRODUCTION
Predictable, long-term stable fixation of cementless tibial components remains problematic, particularly in younger, more active patients. While clinical studies using radiostereometric analysis (RSA) have demonstrated the superiority of cemented over standard cementless fixation [1], addition of a hydroxyapatite (HA) coating has been shown to improve fixation [2] and prospective, randomized clinical studies support the notion that the long-term stability of HA-coated tibial components can be as good or better than that of cemented components [3]. A new, solution-deposited form of hydroxyapatite (Peri-Apatite™; Stryker Orthopaedics, Inc.) is currently in use for cementless tibial fixation. The specific aim of this study was to use a clinically relevant canine TKA model to determine the patterns of bone healing around a Peri-Apatite-coated tibial baseplate and to quantify the mechanical properties of the bone-implant interface.

METHODS
Eighteen skeletally mature male Hounds (25-30 kg body weight) underwent unilateral TKA surgery under an IACUC-approved protocol. A cemented cobalt-chromium alloy (CoCr) femoral component and a cementless CoCr tibial component were used in all animals. The fixation surface on the tibial component consisted of CoCr beads (~700 µm in diameter) coated with a 20-µm layer of solution-deposited Peri-Apatite (PA). Animals were randomly assigned to groups of n=6 dogs and followed for periods of 6, 12 or 26 weeks. At the end of the study period, animals were euthanized with a barbiturate overdose and the right stifle joint was photographed, radiographed, explanted and prepared for mechanical testing and histomorphometry.

Implant micromotion: The stability of the tibial component was determined by applying cyclic loading (100 N axial load, 0.25 Hz) via a pivot plate to the medial and lateral sides of the implant. Relative motion between the bone and the implant was measured with medial and lateral clip gages that monitored relative motion between the implant and a reference pin in the proximal tibia. The primary outcome measures for this test were varus-valgus tilt (°) and superior-inferior motion (mm).

Interface strength: Upon completion of the non-destructive testing, the tibia was sectioned in the sagittal plane to produce three slabs representing the medial, central and lateral one-thirds of the bone-implant interface. The central slab was then sectioned in the frontal plane to produce small test pieces from the cranial, middle and caudal regions of the tibial implant. These specimens were then secured to an MTS machine and tested to failure using a displacement rate of 1 mm per minute. The primary outcome measure was peak interface strength, calculated by dividing the peak load by the projected cross sectional area of the test specimen, as determined with digital callipers.

Histomorphometric analysis: The medial and lateral tibial slabs were dehydrated and processed undecalcified into PMMA. Ground sections were prepared and these were carbon-coated and examined by backscattered scanning electron microscopy (BSEM). Bone ingrowth (% volume fraction of bone within the voids of the beaded surface) and apposition (% linear contact between bone and the beaded surface) were determined along the entire bone-implant interface. In addition, periprosthetic bone volume (%) was determined in a region of interest located 1 mm distal to the bone-implant interface.

Statistical analysis: Continuous data from the histomorphometric and mechanical analyses were compared using a one-way analysis of variance (ANOVA), with time as the dependent variable. The relationship between histological and mechanical parameters was explored using regression analysis. A significance level of p<0.05 was used throughout.

RESULTS
Histomorphometry: There were statistically significant increases in bone apposition (p=0.0004) and bone ingrowth (p<0.0001) over the course of the study. For both outcome measures, post-hoc tests revealed that the significant increases occurred between 12 and 26 weeks post-surgery (Figure 1).

A similar trend was seen for periprosthetic bone volume fractions (Figure 1); these were similar at 6 and 12 weeks (26.4±6.1% vs. 25.1±6.4%) but then increased significantly to 36.4±8.3% at 26 weeks (p<0.05 versus 6 and 12 weeks).

Micromotion: There were no significant differences in varus-valgus tilt or superior-inferior motion at the three time points. All of the implants were stable, with motions of less than 2.5 µm and 0.14°.

Interface Strength: Strength values doubled from 6 weeks to 12 weeks and again from 12 weeks to 26 weeks. The differences between the three time points were statistically significant (p<0.05 for 6 weeks versus 12 weeks; p<0.0001 for 26 weeks versus 6 or 12 weeks).

Relationship between histological and mechanical parameters: There were strong correlations between interface strength and both bone ingrowth (r²=0.74; p<0.0001) and bone apposition (r²=0.56; p<0.0001). The relationship between varus-valgus tilt and superior-inferior motion was weak and not statistically significant. The two measures of micromotion were not significantly correlated with the histomorphometric variables.

DISCUSSION
In this preclinical canine model of total knee arthroplasty, remodeling at the bone-implant interface led to increases in both histomorphometric and mechanical indices of implant fixation. The majority of the increases in fixation appeared to develop between weeks 12 and 26. This is perhaps not surprising since we have previously demonstrated that there is significant disuse osteopenia in the first 6 weeks following TKA in the dog [4]. Periprosthetic bone volume fractions increased significantly from weeks 12 to 26, indicating that there is active ongoing new bone formation in response to the implant. None of the histological specimens demonstrated evidence of periprosthetic osteolysis or PA fragmentation. Based on these data, we conclude that the use of PA on a cementless tibial component supports the development of biological ingrowth that produces a mechanically competent bone-implant interface. The long-term stability of PA-coated tibial components in vivo is currently being evaluated using RSA in the canine TKA model.

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