INTRODUCTION
Distal radius osteosarcoma accounts for nearly 10% of all cancer-related maladies within the canine population. Traditional methods of treatment include amputation and/or chemotherapy. A major increase in survival rates (from 10% to 60%) with the combined use of these two techniques has now directed research towards saving the limbs of these patients. Massive cortical bone allografts, metal endoprosthesis and distraction osteogenesis are some of the available limb sparing approaches that have been investigated. Distraction osteogenesis requires surgeon expertise and significant post-operative intervention. Cortical allografts require the maintenance of a bone bank. Furthermore, they are associated with increased infection rates and ultimately result in amputation of the affected limb. Metal endoprostheses are a viable alternative to these methods. A metal endoprosthesis has previously been developed for limb sparing of distal radius osteosarcoma patients. However, a clinical trial of this device demonstrated failure rates of approximately 40%. The major causes of failure were screw pullout and shear failure of the proximal radius screws. A computational finite element study conducted in our laboratory corroborated these findings and provided critical information as regards to the structural causes of failure for these implants.

Based on the results obtained from the aforementioned clinical and computational studies, a novel modular endoprosthesis was developed. This prosthesis design aimed to address all of the mechanical shortcomings of the current generation endoprosthesis. The current study evaluated the structural efficacy of this new design using a validated and converged finite element model of the canine antebrachial, carpal and metacarpal regions. Our hypothesis was that the new design would significantly reduce the stresses within the fixation screws thus mitigating the screw failure and pullout issues observed in the older endoprosthesis.

MATERIALS AND METHODS
A previous study from our group highlighted the structural shortcomings of the current endoprosthesis implant. Extensive discussions with surgeons from the Veterinary Teaching Hospital (SDR & NE) led to the following design requirements for the new design:

- Modular design
- Ease of alignment between the proximal radius and carpus
- Reduction of stresses within the proximal radius screws

The finite element model of the canine antebrachium consisted of thirteen bones which included the radius, ulna, seven carpal bones and four metacarpal bones. Cartilage was extruded from all articulating surfaces. This resulted in a total of 23 finite-sliding contact pairs. The model was developed using well established meshing, validation and convergence protocols.

An iterative design process was employed in developing the new endoprosthesis. For satisfying the modular design requirement, the implant consisted of three interlocking parts: the distal endoprosthesis component (DEC), the mid-diaphyseal endoprosthesis component (MEC) and the proximal endoprosthesis component (PEC). As a stress-reduction feature, the PEC fixation screws were offset by 45 degrees with respect to the sagittal plane. The distal end of the resected radius rested on a flat surface of the PEC. An ellipsoidal plate provided additional stability and increased HA coating surface area.

An intramedullary stem was implemented in this design for increased support to the radial fixation screws. The MEC incorporated a simple
design for ease of manufacturing. Different lengths of the MEC could also provide for a custom fit of the prosthesis. The DEC was similar to the distal end of the current implant as high stresses were not observed in this location. For maintaining alignment of the proximal radius and carpal section during surgery a custom implantation apparatus was developed [Figure 2]. This device ensured perfect alignment for the two sections after radius resection.

To test the mechanical integrity and efficacy of the new design, the complete construct was implanted in the intact finite element model [Figure 3]. The radius was resected by 50% of its length as suggested by the surgical protocol. The entire construct was loaded to 110% BW (400N). This simulated the load seen at the forelimb during a trot gait. The distal ends of all four metacarpal bones were fixed and the construct was loaded at the proximal ends of the radius and ulna. The effect of support to DEC from the radial carpal bone was also investigated. The contribution of the intramedullary stem was also investigated.

RESULTS
The FE model predicted von Mises stresses within the proximal radius screws reduced by a factor of 50% (167.2MPa) as compared to the current generation implant. The peak von Mises stress at the bone screw interface reduced by a factor of 10 (47MPa). The peak von Mises stress within the distal metacarpal screws was 153MPa. The removal of the intramedullary stem did not increase the peak stress predictions within the proximal radius screws however, a increase in bending stresses was observed. The addition of support to the DEC from the radial carpal bone decreased the peak stress within the proximal radius screws to 135MPa.

DISCUSSION
The requirement of a modular design was successfully met by the new three-part system of the endoprosthesis. This will provide the surgeons the ability to provide a better fitting prosthesis for the distal radius osteosarcoma patients. The design was successful in obtaining large scale reduction in stresses at the proximal radius fixation screw site. The endurance limit for 316L surgical stainless steel in a biological environment is 200MPa. The peak predicted stresses at all locations fell well under this limit. The proposed design of a custom apparatus for proper alignment of the modular endoprosthesis will ensure proper alignment of the three parts of the new prosthesis during surgery.

As with all prosthesis design investigations the final evaluation can only happen in a clinical setting. Hence, future work with this study will involve extensive biomechanical analyses which will include fatigue testing. This will be followed by prototype development and clinical trials at the Colorado State University's Veterinary Teaching hospital.

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REFERENCES
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