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Interim Performance Report

Name and Address of the University: Board of Regents of the University of Wisconsin System

Title of Project: The Effect of Cementation and Autogenous Bone Grafting on Allograft Union and Incorporation

Grant Number: N00014-93-1-0745

Principle Investigator: Mark D. Markel, DVM, PhD

Covered Time Period: June 1 through September 30, 1994

Progress:

This study is designed to examine the reconstruction of bone after segmental bone loss. Project milestones may be divided as follows:

I. Phase I: *In vitro* evaluation of allograft/host bone constructs.

Status: Active. Changed. While the initial *in vitro* testing was completed in May, those tests were performed on larger bones utilizing an 8-mm diameter interlocking nail with 4.5-mm cortical screws. As noted in the last progress report, the dogs we received for the study were smaller and necessitated custom designed 4-mm and 5-mm diameter interlocking nails with 2.0-mm and 2.7-mm cortical screws, respectively. Since these constructs are considerably different than those previously tested, to apply the *in vitro* testing results to the rest of the study requires the use of similar sized bones and fixation devices.

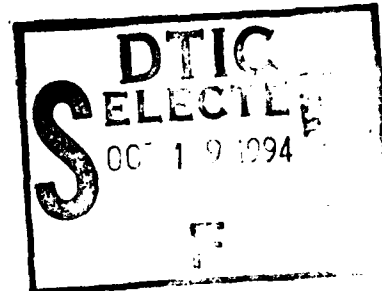
Accomplishments: Cadaver bones for completion of testing with the smaller interlocking nails are currently being collected and stored for subsequent testing.

II. Phase II: *In vivo* study - effects of cementation and cancellous graft.

A. Immunologic mismatching and base line values for dogs (radiographs, bone mineral density, and force plate analysis).

Status: Active. On schedule.

Accomplishments: (i) Twenty-five of 32 dogs have been immunologically mismatched to date. The remaining dogs should be completed over the next 4 weeks. In July we encountered a 6 week period of time where the mixed lymphocyte culture assays were not functioning. After considerable investigation, the problem was traced to excessive lipid being present in the



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dogs' blood samples. This problem was solved by fasting the dogs 12 hours prior to collecting blood samples, and the assay has been working well since then. (ii) Radiographic and bone mineral density base line evaluation has been completed on all dogs. Force plate gait analysis has been completed on 20 of 32 dogs. The remaining dogs will be completed over the next 3 weeks.

B. Surgical procedures - segmental allografts plus treatments.

Status: Active. On schedule.

Accomplishments: As noted in the previous progress report and above, owing to the smaller size of the dogs in this study, we had to custom design interlocking nails to fit their femurs. The first 3 fixation devices failed at 17 to 21 days after surgery. Femur-allograft constructs from these dogs were harvested and frozen for possible analysis at a later date. Design changes were made in the nail, as well as reducing the allograft size to 2.5-cm (20 to 25 percent of the bone's length). Since completing these changes, 8 dogs have undergone surgery. Without further complications, all surgeries should now be completed by late November.

C. Dog follow up - radiographs, bone mineral density, and force plate analysis.

Status: Active. On schedule.

Accomplishments: The first 2 week post-operative checks have been completed. Analysis of follow up evaluations will not be completed until the *in vivo* phase is completed in 8 months.

D. Biomechanical testing and histologic analysis at 6 months post-surgery.

Status: Inactive. Will begin March, 1995, and finish June, 1995 (mechanical testing), and approximately August, 1995 (histology).

III. Publication and presentation of results.

Status: Inactive. With the minor delays encountered to date, it appears unlikely that results will be ready for submission to the meeting listed in the last progress report (submission due February, 1995). A more realistic target is submission of an abstract to the Orthopedic Research Society, due in July, 1995.

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