Longitudinal Evaluation of Bioactive Strip Implanted into the Distal Condyle of New Zealand White Rabbits

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Statement of Purpose: The study evaluated and compared the systemic and local reactions to NovaBone Bioactive Strip bone void filler used in a critical sized bone defect repair the distal femur of New Zealand White rabbits to the predicate material, NovaBone OS-Si+.

Methods: Twenty-four (24) NZW rabbits randomly assigned to three (3) study groups (8 per group) underwent bilateral surgery to create a critical sized defect in the distal femoral condyle. The animal's left leg received the Test and the contralateral side (the animal's right leg) received the Control Device. Test article consisted of 95% Bioglass and % type 1 collagen as seen in Figure 1. Control device consisted of 100% bioglass. Animals in Group 1 were sacrificed 22 days post-surgery, those in Group 2 were sacrificed 43 days post-surgery, and those in Group 3 were sacrificed 83 days post-surgery. All animals survived to scheduled termination.

Each femoral specimen was trimmed into a mechanical testing cube the lateral portion of each specimen was processed for undecalcified plastic embedding. The histological specimens were taken from the lateral portion of the filled bone defect, approximately 4.0 mm from the cortical surface. Histological specimens underwent progressive dehydration in a graded series of alcohols, before infiltration and were embedded in methyl methacrylate (MMA). Microtome sections were obtained from each specimen. Sections were cut in the sagittal plane through the axis of the lateral defect region and the surrounding bone.

Figure 1: NovaBone Bioactive Strip test Article that consist of 95%(w) Bioglass and 5%(w) Type 1 Collagen

Results: Histopathologic and histomorphometry evaluation found both materials to be substantially equivalent in the ability to induce new bone formation in and around the defect. Defects implanted with the test article showed a statistically significant increase in new or native bone in and around the defects at Day 84 compared to those treated with the control device.

At Day 21, femoral defects are characterized by moderate to large amounts of new bone forming at the outer margins of the defect and progressing inwards. The new bone formation is primarily woven bone, with small amounts of lamellar bone formed at the outer edges of the defect. The new woven bone is actively undergoing remodeling as evidenced by prominent osteoid seams lined by activated osteoclasts and osteoblasts. By the Day 42 time point, the femoral defects are characterized by mildly increased amounts of new bone forming at the outer margins of the defect and progressing inwards compared to the Day 21. The new bone formation is now mixed woven and lamellar bone, and it is more mature compared to the Day 21 time point as evidenced by a modest decrease in osteoblastic and osteoclastic activity. By the Day 84, new bone formation has increased mildly compared to the Day 42 time point, and the new bone formation is variably mixed woven and lamellar bone or mostly lamellar bone. Mechanical compression testing indicated that both materials were substantially equivalent 3 weeks following surgical implantation. At 6 and 12 weeks, maximum load, stiffness, maximum compressive stress, and elastic modulus values for specimens treated with the Bioactive Strip Test Device were significantly higher than for those treated with the predicate Control Device.

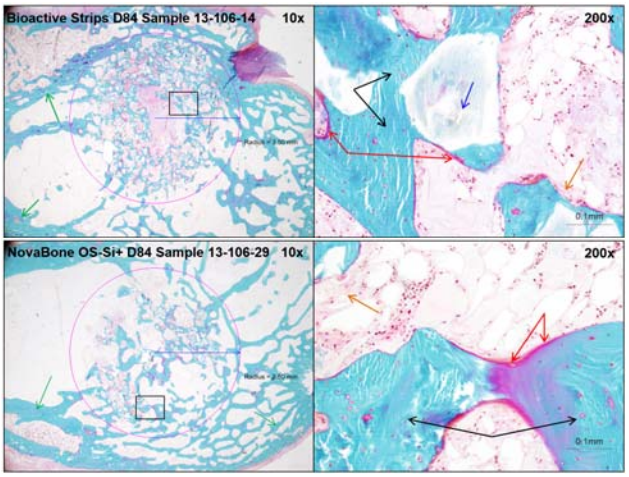

Figure 2: Photomicrographs of representative femoral defects from 84 time point. Each left panel is a low magnification image of the defect area that is outlined. Each right panel is a higher magnification image of the inset box in the left panel. New bone formation is present within each defect. Some of the implant material appears to have fallen out of the sections – it was likely present in clear areas noted with blue arrows. Goldner's trichrome stain; 10x and 200x magnification.

Conclusions: The in *vivo* performance of the BIOACTIVE Strip is substantially equivalent to that of the predicate NovaBone Porous device as demonstrated by implantation in a rabbit model.