BONE INGROWTH AND MINERAL APPosition RATES INTO THERMO-CLEANED POROUS COATED PLUGS IN A SHEEP MODEL

+Willie, B M; **Bloebaum, R D; +Bireley, W R; +Watts, C W; ***Szakacs, J G; **Hofmann, A A
+Bone & Joint Research Lab, SLCVA Health Care System, ***Dept of Pathology, **Dept of Orthopedics, Univ. of Utah, Salt Lake City, UT

Introduction: Based on reported cases of implant loosening, Sulzer Orthopedics instituted a new implant manufacturing process named Thermo-Clean™. The present investigation intended to confirm the biocompatibility and efficacy of this manufacturing process by quantitatively and qualitatively examining bone ingrowth and rate of bone remodeling into porous coated plugs in the medial femoral condyle of sheep. The hypothesis for the study was that the Thermo-Clean™ process would allow for bone ingrowth with physiological mineral apposition rate into porous coated plugs used in a sheep model.

Materials and Methods: Seventeen skeletally mature sheep underwent staged bilateral surgical procedures, receiving titanium porous coated implants in the medial femoral condyle. The porous coated plugs were titanium cylinders, 11.3 mm diameter, 22.4 mm in length, with titanium porous coating with an average pore size of 530 µm and 55% porosity. Plugs were manufactured by Sulzer using their new Thermo-Clean™ process, which includes no machining after the application of porous coating at 1500°C, followed by ethylene oxide sterilization. Two animals (4 knees) were sacrificed after implantation to have “time 0” data. The study evaluated three time periods: six, twelve, and twenty-four weeks, with ten knees in each time period. At necropsy sections of synovium, spleen, and lymph node were removed from each sheep and stored at -70°C. Synovial fluid was cultured to detect possible bacterial infection. Following necropsy, medial condyles were dehydrated in ascending grades of ethanol, infiltrated, and embedded in methyl methacrylate. Polymerized blocks were cut, each 2mm thick section was ground, polished, and sputter-coated with gold. High-resolution contact radiographs were made for appositional bone index analysis. Sections were examined in a scanning electron microscope (JSM 6100; JEOL, MA) using a backscattered electron detector (Tetra, Oxford, UK) at X50. Percent bone was measured as area occupied by bone divided by the area of image field, which includes area occupied by bone, pore, and porous coating. Sections were ground to 70 µm thick and viewed at X250 under a mercury lamp light microscope. The mineral apposition rate for bone in the bone ingrowth interface region was 1.07 ± 0.28 um/day, whereas bone in the host bone region was remodeling at a rate of 0.89 ± 0.23 um/day. There was a decreasing trend of remodeling rate in bone present in both the bone ingrowth interface region and the host bone region with time (Figure 3). No significant differences were measured in the mineral apposition rate of the bone ingrown into the porous coated region or host bone regions between the three insitu times.

Results: Synovial fluid cultures indicated bacterial infection in one knee. Histological analysis of the sheep tissue: synovium, spleen, lymph nodes, heart, liver, lung, and kidney, using H&E, oil red O, and bromide-silver nitrate staining demonstrated an absence of mineral oil in all tissue. Appositional bone index resulted in 93±2% bone ingrowth into the porous coated region or host bone regions, expressed in microns per day. Histological analysis examined bone growth into the porous coating and host tissue response to porous coating. Sections were stained with Sanderson Rapid Bone Stain, counterstained with Acid Fuscin. Sections were examined at X 40-600 using transmitted and polarized light microscope (Labophot, Nikon, NY).

Discussion: The most important lesson is that if manufacturing changes are made in the preparation and cleaning of implants intended for human use, then biocompatibility studies should be conducted prior to human implantation. The present investigation showed extensive bone ingrowth and biocompatibility using porous coated plugs manufactured using the Thermo-Clean™ process. The results of this study demonstrate the biocompatibility and bone ingrowth potential of the new Thermo-Clean™ process.