

Postmortem Retrieved Porous Coated Total Knee Components: Mineral Content Variations

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Statement of Purpose: In order to gain a better understanding of skeletal attachment dynamics, it would be important to understand the mineral content levels of bone at the implant interface since studies of mineral content have determined that there is a direct relationship to biomechanical properties and bone strength. Studies performed on postmortem retrieved porous coated components have quantified bone ingrowth into the porous coated region and the corresponding interface and host bone regions. These studies have not yet been extended to include mineral content analysis of bone in postmortem retrieved total knee replacement (TKR) components. The objective of this study was to compare the mineral content at the implant interface region and >3 mm distal in the host bone region. The hypothesis tested was that the mineral content at the implant interface would be similar to the mineral content at the host bone region. The rationale for the hypothesis was based on the assumption that the interface would have had adequate implantation time to adapt mineral content levels equal to the host bone.

Methods: Appropriate IRB approval was obtained to collect 14 postmortem retrieved porous coated TKR components from previously clinically successful patients. These specimens have been previously reported to have extensive bone ingrowth. These specimens were used in the current investigation to measure the mineral content. The components were of the Natural Knee design with a commercially pure titanium porous coating. All surgeries were performed by one surgeon. The entire set of 14 patellas and tibias were analyzed, while only 12 femurs were analyzed due to processing complications caused by incomplete polymerization. Average age of the donors at death was 76±6 years (66 to 87 years) and included an all male population. The implants were *in situ* for 7±3 years. The specimens were embedded in methylmethacrylate, cut longitudinally into 3 mm thick sections, and ground and polished to an optical finish using a variable-speed grinding wheel. Each section was carbon coated within two days of imaging. Backscattered Electron (BSE) imaging enables the quantification of mineral content of bone at the implant interface *in-situ* at high resolution. BSE imaging was conducted using a JEOL 6100 SEM and Oxford ISIS imaging software. Operating conditions included an accelerating voltage of 20 kV, working distance of 15 mm, and probe current of .75nA. Brightness and contrast were kept constant throughout the study. Digital BSE images taken at 200x magnification with a resolution of 512 x 400 pixels and 8 bits/pixel (256 distinct graylevels) were captured. Calibration was performed at 20 minute intervals using pure aluminum and carbon to correct for fluctuations of the microscope along with two bone standards consisting of whale tympanic bulla and deer antler. Images of the bone and element standards were obtained and the weighted mean gray level (WMGL) measured using Scion Image software. Ten images of each bone section were obtained, 5 along the implant interface and 5 >3mm into the host bone

region. Three WMGL were measured from each image at randomly selected areas. Ash percents were calculated from WMGLs using a calibration curve and linear regression model of bones with known mineral content. The calibrated WMGL measurements from sections of bone were averaged to obtain a single regional value per patient (n=14 patella & tibia, n=12 femur) for each of the interface and host bone regions. These values were compared using sample t tests. The p values from these t tests were then adjusted for multiple comparisons using Finner's p value adjustment multiple comparison procedure.

Results/Discussion: The periprosthetic region of the femur measured a WMGL of 110.1±8.4 correlating to an ash percent of 63.6± 1.7%. The host bone of the femur measured a WMGL of 121.2±8.4 correlating to an ash percent of 65.8±1.7%. The periprosthetic region of the patella measured a WMGL of 97.4±9.3 correlating to an ash percent of 64.7± 1.7%. The host bone of the patella measured a WMGL of 108.4±9.0 correlating to an ash percent of 66.7±1.7%. The periprosthetic region of the tibia measured a WMGL of 72.6±11.6 correlating to an ash percent of 63.7± 0.9%. The host bone of the tibia measured a WMGL of 82.0±9.9 correlating to an ash percent of 65.0±0.8%. Statistical analysis determined that there was a significant difference (p<0.01) between the interface mineral content when compared to the host bone mineral content for all three components.

Conclusions: There was a lower mineral content at the implant interface when compared to the host bone in each component. Vose and Kubala found that even a small difference in mineral content can cause an exponential difference in mechanical strength. Thus, the lower mineral content found at the periprosthetic region in this study suggests that the bone biologically adapted to achieve mechanical and fatigue properties that may have made it advantageous at the site of the implant interface under cyclical ambulatory conditions. The difference in mineral content at the two regions could also be due to the application of autograft bone chips at the time of implantation. Future studies would be required to understand the relationship between bone volume, fatigue properties, and mineral content for achieving durable skeletal attachment in porous coated implants.

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