Bone Analog Development for Orthopaedic Device Evaluation

K. L. Calvert[1], L. A. Kirkpatrick[2], K. P. Trumble[1], T. J. Webster[3]
[1]School of Materials Engineering and [3]Weldon School of Biomedical Engineering, Purdue University, West Lafayette, IN
[2]Coorporate Research, Zimmer Inc, PO Box 708, Warsaw, IN 46581-0708

Statement of Purpose: A stable bone-implant interface is the foundation of long term stability for an orthopaedic implant. Aseptic loosening, characterized by micromotion, can occur at the tibial tray in total knee replacements (TKRs). Micromotion is defined as the movement, or amount of motion, between the bone and implant interface. It is reported that micromotion of greater than 150 µm can inhibit or drastically decrease bone in-growth [1]. Thus, micromotion can lead to failure of an implant. To determine if an orthopaedic device, such as a knee implant, will be successful, it is necessary to test for micromotion in a material that is similar to bone (a bone analog). Currently available bone analogs (polyurethane foams) used for medical device evaluation [2] are not completely representative of human bone; therefore, a better bone analog construct needs to be developed. Bone has been studied numerous times and it has been found to be highly anisotropic based on the well known Wolf's Law. However, there have been no reports on the mechanical properties of the trabecular bone with the orientation as exhibited on the tibial plateau when prepared for implantation. The resection orientation of the tibia during a TKR can be 7 degree posterior slope. In addition, previous studies on the mechanical properties of the tibial plateau have not taken into consideration the size differences of bones. There has not been a reported study that shows the properties of the plateau relative to size. For these, the purpose of this study is two fold: 1) to assess the static and dynamic properties of the trabecular bone at the tibial plateau with testing sites determined by peg location of the tibial trays and 2) to characterize the current polyurethane (PU) foam in comparison to the trabecular properties in selecting a better material.

Methods: Static and dynamic bone/PU foam testing methods were developed using previously published studies in combination with a novel method of prepping the proximal tibia plateau for evaluation [3, 4, 5].

Bone/Foam Preparation: A total of twenty-four cadaveric tibias (twelve pairs), void of macroscopic damage or disease, stored in a fresh-frozen method were used for bone testing. The Zimmer NexGen® complete knee solution extramedullary tibial resector surgical technique [6] was used to perform resections of the proximal tibia. This method created a 7 degree slope on the plateau after the condyles were removed. A second, parallel resection was made distal to the first resection, resulting in a 15 mm-thick layer of bone. Coring locations were predetermined for the five sizes based peg location for the three most commonly used types of tibial trays. Specimens (7.5 mm diameter) were cored out of the sectioned slice using a trephine, tabletop drill press and a Plexiglas cutting guide. During the coring process the plateau was constantly irrigated to prevent tissue damage. Polyurethane foam (General Plastics, Tacoma, WA) cylinders (7.5 mm dia. x 15 mm) of four different grades were prepared using the same drill press and trephine.

Mechanical Static/Dynamic Testing: All mechanical static and dynamic testing was performed using a servo-pneumatic testing machine (EnduraTEC). The 7.5 mm diameter cylinders of both bone and polyurethane foam were statically tested in compression. Bone specimens were randomly chosen for static testing (either right or left for a given location). Then the opposite but corresponding (right or left) cored out cylinder was used for dynamic testing. Dynamic testing was performed on both bone and polyurethane foam cylinders. 50% of the ultimate load, obtained from the static test of the corresponding specimen, was selected as the ultimate load for dynamic testing. The cyclic testing was carried out by ten cycles of the following: loaded to the 50% value, unloaded at the same rate as loaded, and dwelled for 4 sec at the original staring position.

Results / Discussion: A map of the elastic modulus and ultimate strength values based on location at the tibia plateau for similar sizes was developed. Figure 1 shows the ranges for three of the different sizes for the modulus values of bone. As expected, and reported elsewhere, medial side has a higher modulus in general than the lateral with the central portion of the plateau having the lowest modulus [7, 8]. Modulus and ultimate strength values for the PU foams of differing grades were evaluated and compared to the tibial plateau values obtained. Secant modulus was obtained and compared for bone and foam dynamic testing.

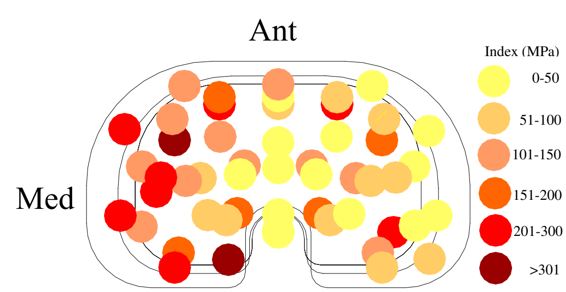

Figure 1: Elastic modulus distribution for tibia plateaus of differing sizes.

Conclusions: Due to the variability of the properties of bone over the surface of the tibia, it is difficult to select one analog material to accurately provide equivalent structural characteristics of the proximal tibia. Methods of creating a similar map of properties may be beneficial in the evaluation of tibial implants.

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