Surface Characterization of the Vertebral Body for In-Vitro Wear Testing of Nucleus Replacement Device

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Introduction: Nucleus replacement is an emerging treatment option for the discogenic pain resulting from the degenerative disc disease. Most surgical techniques for nucleus replacement involve preparing the vertebral body endplates with a curette while preserving to some extent the inferior and superior cartilaginous layers. Nevertheless, integrity of the cartilaginous layer may be compromised during the surgery or by the relative motion with the device during its normal functioning.[1] The articulation of the nucleus replacement device against the cortical bone of the endplate may result in the worst conditions for the wear. The dependence of wear on the surface roughness and counterface hardness of the articulating surfaces has been well established in the literature.[2] However, the ISO guidance document for the wear test of nucleus replacement devices does not recommend any specific material, but in fact suggests the use of any material with the average surface roughness of 0.05±0.01µm, which may not truly represent the *in-vivo* worst case scenario. There is no published data about the surface roughness of the cortical and cartilaginous endplates in the spine. Therefore, in this study we evaluated the surface roughness of vertebral body endplates and also investigated the hardness of bovine cortical bone and different polymeric materials. The objective is to identify a bone surrogate to be used as an articulating surface for the biotribological evaluation of nucleus replacement devices. The authors are also conducting a wear study to evaluate the effect of surface roughness and hardness on the wear of nucleus replacement device.

Methods: Two non-osteoporotic fresh frozen cadaveric lumbar spines were used to characterize the surface roughness for vertebral endplates. Case 1: the nucleus pulposus and annulus fibrosus were removed exposing the cartilaginous endplate; and Case 2: the nucleus pulposus, annulus fibrosus and cartilaginous layer were carefully removed to expose the cortical end plate (Figure 1). Cylindrical bone samples with diameter of 8 mm and height of 10 mm were extracted and evaluated for surface roughness using a white light interferometer (NewView™ 5000, Zygo Corp, Middlefield, CT). For the second study, the hardness of the bovine cortical bone and six polymers was quantified using a micro hardness tester (CM-700 AT, SUN-TEC Corp, Novi, MI). The bovine cortical bone specimens were cut between the tibial metaphysis and diaphysis using a band saw. The specimens were grounded using 400 and 600 grit abrasive papers followed by polishing on a polishing pad using diamond slurry (6 µm to 0.05 µm). Discs of 1.25" diameter and 0.25" thickness were prepared from medical grade and industrial grade polyetheretherketone (PEEK), polyetherimide (PEI), polyacetal (PA), polysulfone (PS) and polyphenylene sulfide (PPS). A wear test is currently underway using ISO18192-1 test conditions to investigate a nucleus replacement device against endplates made from these six polymers with the surface roughness determined in this study.

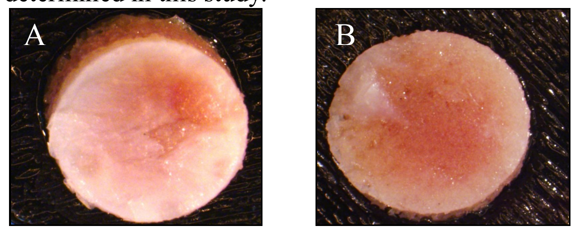

Figure 1: A) Cartilaginous B) Cortical Endplates

Results: The average surface roughness (Ra) of the cortical endplate for the spine 1 was 7.4± 3.4 µm while that for spine 2 was 6.5±1.0 µm. The cartilaginous endplate had the surface roughness of 6.0±2.5 µm for spine 1 and 6.1±2.6 µm for spine 2.
The hardness of the bovine cortical bone was 31.2±3.0 HV whereas hardness for the PA was 18.2±1.6 HV. PS was the least hard material with an average hardness of 12.6±0.97 HV. A Student's t-test demonstrated no statistical difference between the hardness of the medical and industrial grade PEEK, PEI and PA, PA and PPS. The result of this study is shown in figure 2.

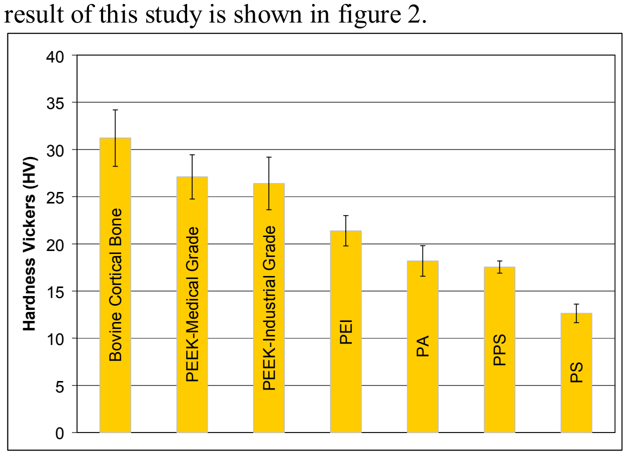

Figure 2: Micro hardness of different materials

Discussion: No significant difference was found between the surface roughness of the cortical and cartilaginous endplates. This could be due to the inherent waviness and biphasic nature of the cartilage. The surface properties of the cortical bone could not only be used to design a relevant *in-vitro* test but can also help in understanding of the *in-vivo* wear of these devices. The characterization of the vertebral body from this study along with the upcoming results from wear testing will help in determining the vertebral body surrogate for wear testing of nucleus replacement devices.

References: 1. Grant JP. Spine 2001;26:889-896. 2. Stachowial GW.Engg Tribology 2001;Butterworth-Heinemann, Boston.