The Effect of Endplate Preparation and Fatigue on the Implant-Bone Interface of a Prodisc-C Total Disc Replacement

Nathaniel R. Ordway1, Rong Tan3, Byeong Rim2, Rebecca Hickman1, Matthew J. Allen1, Amir H. Fayyazi1
1Orthopedic Surgery, SUNY Upstate Medical University, Syracuse, NY; 2Orthopedic Surgery, ChungBuk National University Hospital, Cheongju City, South Korea; 4Orthopedic Surgery, 306 Hospital of PLA, Beijing, China
ordwayn@upstate.edu

Introduction: Cervical total disc arthroplasty devices are currently under FDA phase III evaluation and are expected to be released to the market in the near future. These motion preserving devices are fundamentally different than interbody devices used in fusion procedures in that they have to function for the remainder of the patients’ life. It is therefore essential to fully understand the interaction between the metal-bone endplate since subsidence of the implant will result in loss of motion and foraminal stenosis which can be symptomatic. The removal of the endplate has been demonstrated to affect the strength of the vertebral endplate although not in a controlled fashion. In some studies, removal of the endplate resulted in significant loss of endplate strength using an indentation technique. On the other hand, in studies where an actual implant was investigated, the preparation of the endplate did not significantly decrease the strength of the construct. In general, the implant interface is an important component of the overall strength of a construct. However, some cervical prostheses require partial or aggressive burring (depth can vary) of the endplate, while others do not require any. The overall strength of a construct is just one aspect of subsidence. The subsidence of the metal endplate into the vertebral body may be due to endplate fracture, biological remodelling, or fatigue failure. A better understanding of how burring can effect the endplate subsidence is needed. The purpose of this study was to examine the effect of repetitive physiological loads as well as failure loads on the implant-bone endplate interface with or without decortication.

Materials and Methods: Six cervical specimens (C3 to T1, average age of 67±19, 3 female, 3 male) were harvested and dissected of all soft tissue. Each vertebral body (n=36) was placed in either an intact or a decorticated group (1mm of the endplate was removed using an endmill). The stratification of each vertebra into the two groups was based on cervical level and spine specimen in order to minimize geometric and structural differences between the groups. Each vertebra was partially embedded in a body filler mold to level the superior endplate surface for biomechanical testing of the endplate. The superior endplate of each vertebral body was fitted with an appropriately sized Prodisc-C (Synthes Spine) implant and the constructs were placed into a saline bath for testing. Each construct was ramp loaded in compression (range -25 to -250N) for 5 cycles prior to and following 10k sinusoidal cycles of fatigue loading (2 Hz) for determination of construct stiffness and graft subsidence. The pre- and post-fatigue stiffness was calculated by averaging the stiffness (load range from 100-250N) of cycles 3-5 from the ramp loaded phases of testing. In addition, the pre- and post-fatigue peak displacement for each specimen was determined by the peak displacement at 250N of cycle 5. Overall graft subsidence was measured from the fatigue loading regimen. Following the fatigue testing, each specimen was tested to failure at a displacement rate of 12mm/min. Two vertebrae from each group were not tested to failure and instead examined histologically for fatigue effects. Two-way ANOVA’s were performed on stiffness and peak displacement with time (pre, post) and group (intact, decorticated) as the main factors. Student t-tests were used to examine differences in overall subsidence and ultimate failure. A significance level of p<0.05 was used for all tests.

Results: There were significant main effects for both stiffness and peak displacement of the constructs. The pre-fatigue stiffness of the implant-endplate interface was 1260±170 N/mm and 1470±180 N/mm for the intact and decorticated groups (p=0.002), respectively. Following cyclic loading, the stiffness was 1680±140 N/mm and 1990±110 N/mm for the intact and decorticated groups (p=0.0001), respectively. During the pre-fatigue loading cycles, there was no significant difference in peak displacement (~0.4mm for both groups, p=0.15). Following 10k compression cycles, 0.66±0.14 mm of peak displacement was noted in the intact and 0.53±0.12 mm in the decorticated endplate, p=0.005. The post-fatigue failure load was 1250±230N and 1110±350N for the intact and decorticated groups (p=0.27), respectively. The histological sections showed clear evidence of implant-bone contact across the entire implant both pre and post fatigue for the decorticated group, while there were large gaps along the midline and loading mainly on the vertebral rim in the intact group (Figure 1).

Discussion: The long term effect of cervical total disc arthroplasty on the endplate is not well understood. During implantation of these devices, a certain amount of endplate preparation is needed, which is dependent on the device used. In this study, we evaluated the effect of endplate removal in a simulated fatigue protocol using the Prodisc-C. Removing 1mm of endplate did result in a much stiffer construct both prior to and after the repetitive compressive loading and at the same time, significantly less subsidence was noted in the decorticated endplate group. This difference (~0.1mm) is not clinically significant. This study showed that removal of the endplate does not necessarily result in reduced biomechanical performance of Prodisc-C implant under physiological loading conditions. Following fatigue testing, the decorticated endplates were weaker than the intact endplates; however, this difference was not significant. Both the fatigue and ultimate failure results do stress the importance of maximizing the contact surface at the implant-bone interface.

Figure 1. Midsagittal and lateral histological sections showing implant-bone contact for both intact and decorticated vertebra.