

Abstract: 70

Biomechanical Evaluation of a Single Level Selectively Constrained Anterior PEEK Lumbar Disc and its Effect on Adjacent Level Kinematics: An *in-vitro* Cadaveric Study

T.K. Daftari¹, S.R. Chinthakunta², M. Gudipally², M. Hussain², S. Khalif²

¹WellStar Kennestone Hospital, Orthopaedics, Atlanta, GA, USA, ²Globus Medical Inc, Research, Audubon, PA, USA

Aim: The current study investigates the biomechanical effect of a novel total disc replacement (TDR) versus interbody fusion cage and pedicle screw instrumentation (BPS) on the operated and adjacent level.

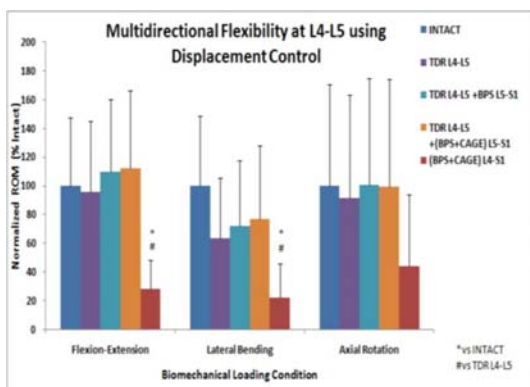
Methods: Nine osteo-ligamentous human spines (L1-S1) were tested. Surgical constructs included:

- 1) Intact,
- 2) BPS L5-S1,
- 3) TDR L4-L5,
- 4) TDR L4-L5 + BPS L5-S1, and
- 5) TDR L4-L5 + (BPS + Cage) L5-S1.

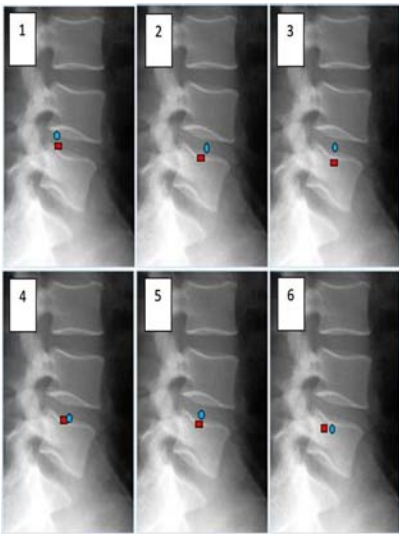
Range of motion (ROM), center of rotation (COR), stiffness, and concurrent translation were calculated. Statistical analysis was performed using a two-sample t-test assuming unequal variances ($\alpha=0.05$). Load control protocol was used to establish intact values. Flexibility testing using a hybrid test protocol (displacement control) was then performed in flexion-extension (FE), lateral bending (LB) and axial rotation (AR) for all other surgical constructs. ROM was recorded at L3-L4, L4-L5, and L5-S1. COR (L4-L5) was calculated according to the method of perpendicular bisectors by obtaining two stepwise lateral fluoroscopic images (ranging from full-flexion to full-extension) for intact and TDR L4-L5 constructs. Stiffness was calculated as a ratio of maximum applied moment and ROM achieved at that load. Concurrent translation was measured on the lateral radiographs as the distance between postero-inferior margin of the superior vertebra and the postero-superior margin of the inferior vertebra.

Results: BPS L5-S1 increased ROM at the adjacent L4-L5 level in FE(115%), LB(109%), and AR(107%); and at the adjacent L3-L4 level in FE(112%), LB(108%), and AR(106%). ROM decreased at L5-S1 level in FE(50%), LB(39%), and AR(67%). TDR L4-L5 preserved motion close to intact in FE (96%) and AR(92%) ($p>0.05$). There was a decrease in ROM in LB(63%), which was not statistically significant ($p>0.05$) (Fig.1). Adjacent level ROM for the TDR L4-L5 construct was similar to intact at L3-L4 in FE(99%), LB(108%), AR(91%), and also at L5-S1 in FE(104%), LB(97%), and AR(94%). The construct with TDR adjacent to screws/rods alone (TDR L4-L5 + BPS L5-S1) had similar stiffness compared to TDR adjacent to interbody fusion cage and screws/rods (TDR L4-L5 + BPS + Cage L5-S1) construct. ROM values for TDR L4-L5 + (BPS + Cage) L5-S1 were as follows: L3-L4 FE(112%), LB(114%), AR(99%); L4-L5 FE(112%), LB(77%), AR(99%); and L5-S1 FE(41%) LB(33%) AR(54%). The normal center of rotation was preserved with TDR (Fig.2). There was no significant change in stiffness and concurrent translation following TDR implantation ($p>0.05$).

Conclusions: The biomechanical study shows that the selectively constrained TDR preserves motion at the level of reconstruction and successfully stabilizes the spine. The testing also demonstrates the motion-preserving properties of TDR adjacent to fusion. Clinical evaluation using the anterior TDR is necessary to evaluate device performance *in vivo*.



[Fig1: Normalized ROM at L4-L5]



[Fig2:COR in FE.Rectangle-Intact;Circle-TDRL4-L5]