Does a Lateral Plate Adequately Reinforce an Expandable Interbody Device in the Context of Minimally Invasive Lateral Procedures, or is Further Supplemental Fixation Required?

Randall Dryer MD (1); Manasa Gudipally MS (2); Brandon Bucklen PhD (2)
(1) 2205 Far Gallant Drive, Austin, TX
(2) Globus Medical Inc., Audubon, PA

Introduction

Minimally invasive expandable spacers such as CALIBER-L® (C-L) (Globus Medical, Audubon, PA), have the advantage of minimal insertion height as well as in-situ expansion. This may reduce the force on the vertebral endplate, otherwise caused by repeated impaction while inserting a traditional spacer. Also, we hypothesize that the height restoration of the anterior column with C-L signficanlty restores the stability.

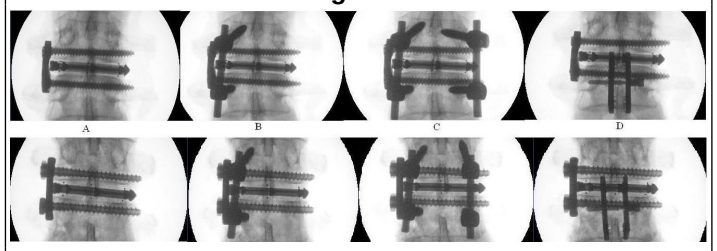
Learning Objectives

The objective of the current study was two-fold :1) to compare the biomechanics of adding a lateral plate versus bilateral pedicle screws to C -L; 2) to compare the biomechanical stability of the PLYMOUTH™ (PLY) (Globus Medical) lateral plate versus the XLP® (XLP) (Nuvasive, San Diego, CA) lateral plate.

Methods

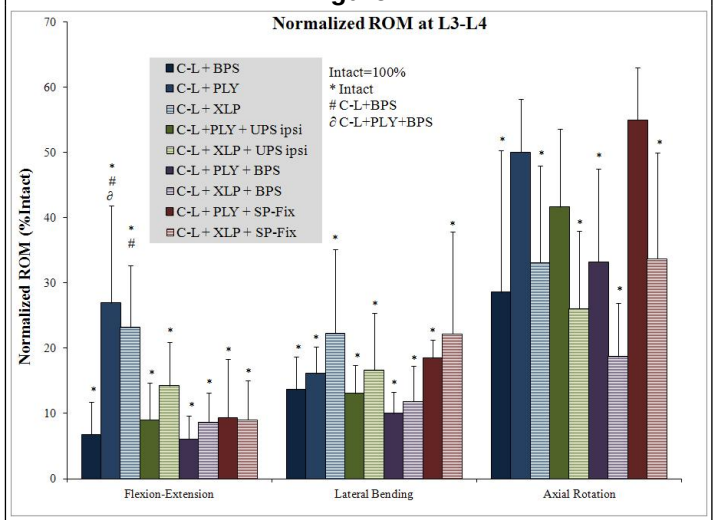
Ten human lumbar (L2-L5) cadaveric spines were tested in two groups of five specimens, on 6DOF spine simulator in flexion-extension (FE), lateral bending (LB), and axial rotation (AR), using a load of ±6.5Nm. A 360° fusion was simulated using either bilateral pedicle screws (BPS)or unilateral pedicle screws (UPSips) or spinous process fixation device (SPF) with C-L and lateral plate (LP) at L3-L4. All the specimens were sequentially tested in 1) Intact; 2) C-L+BPS; 3) C-L+LP; 4) C-L+LP+UPSips; 5) C-L+LP+BPS; 6) C-L+LP+SPF (Figure 1- only shown from C-L+LP). PLY and XLP were the LPs used in group 1, and 2, respectively.

Figure 1



Anterior-Posterior radiographs of the test constructs. A) C-L+LP, B) C-L+LP+UPSips, C) C-L+LP+BPS, D) C-L+LP+SPF. Top-PLYMOUTH™, Bottom-XLP®.

Figure 2



Normalized ROM of all test constructs in all three loading modes at L3-L4.

FDA Status:

The FDA has cleared all medical devices for the use described in this E-poster.

Results

The C-L+PLY construct reduced ROM to 27%, 16.1%, and 50.1%, and the C-L+XLP construct reduced ROM to 23.3%, 22.3%, and 33.2% in FE, LB, and AR, respectively, compared to intact. In FE, ROM of the C-L+BPS construct was significantly lower than the C-L+PLY construct by 20.2%, and the C-L+XLP construct by 16.4% (Figure 2).

Conclusions

Caliber-L®, an expandable LLIF spacer, may be highly advantageous in treating patients with collapsed disc, due to its minimal insertion height and in-situ expandable spacer design. Nevertheless, supplemental instrumentation is necessary.This biomechanical study showed that adding PLYMOUTH™ to CALIBER-L® significantly reduced range of motion. The addition of bilateral pedicle screws to CALIBER-L® demonstrated the highest stability in flexion -extension. However, the simulated 360° fixation (with unilateral pedicle screws, CALIBER -L®, and PLYMOUTH™), a construct which can be inserted without patient repositioning, showed similar biomechanical stability as bilateral pedicle screws. Furthermore, the addition of SP-Fix spinous process fixation also provided reinforcing stiffness in flexion-extension. There was no significant difference between the biomechanical stability of PLYMOUTH™ and XLP lateral plates when supplemented CALIBER-L®. While this study is limited to an in vitro model of immediate stability, long term clinical studies may validate these results.