Abstract Preview - Step 3/4

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Category: Basic Science

Topic: Cutting Edge Innovations/Non-conventional therapies

Title: Novel two-piece ALIF device improves bone-implant alignment without compromising stability. A cadaver study.

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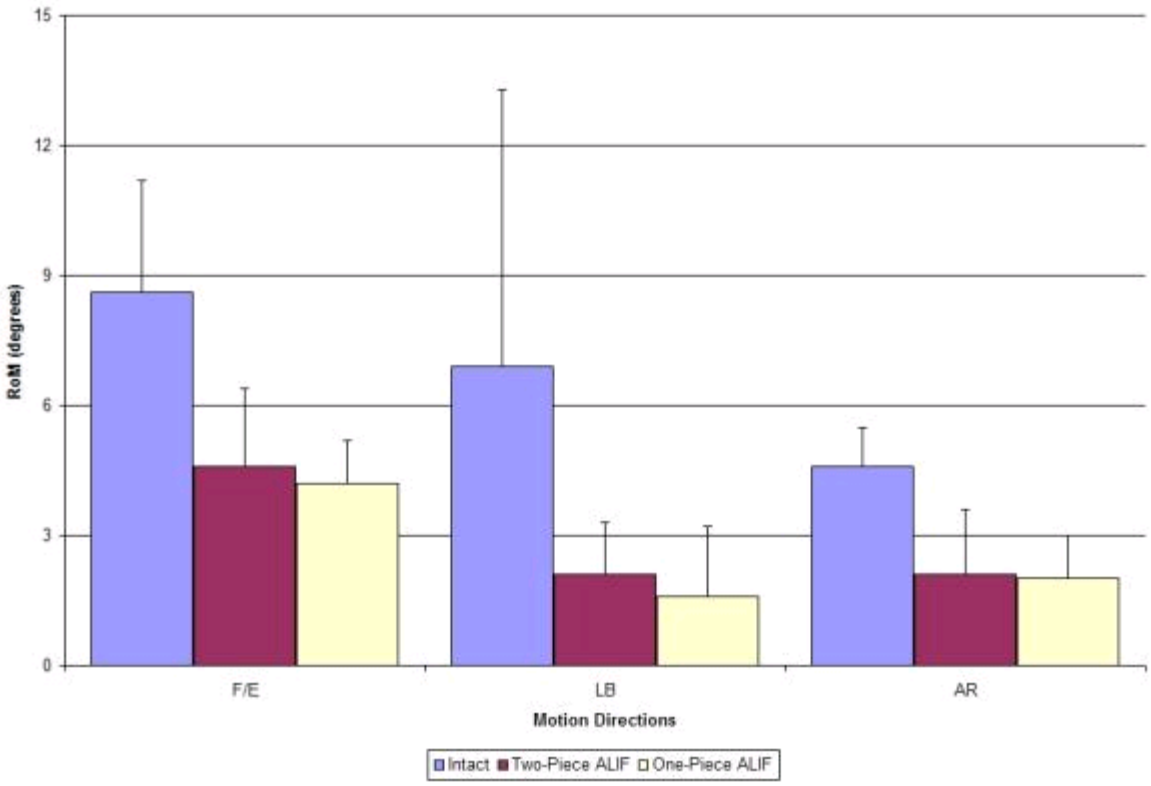
Text: **Introduction:** A novel two-piece anterior lumbar interbody fusion (ALIF) device allows lordotic adjustment until pedicle screws are locked to the rod. A potential benefit includes improving the bone-implant interface anteriorly with a potential positive impact on sagittal balance and clinical outcomes. The aim of the study is to analyze the spinal segment motion and implant alignment of a two-piece ALIF fusion device compared with standard one-piece ALIF device in a 360° setting.

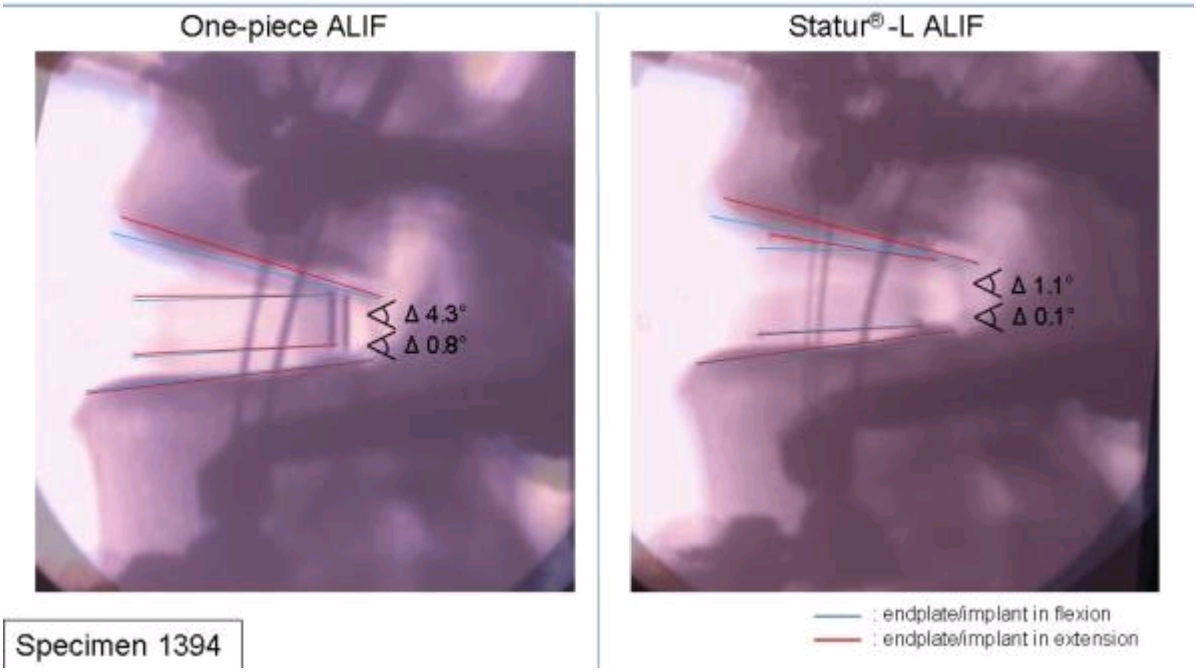
Materials/Methods: Seven lumbosacral (L3-S1) human cadaver specimens were tested (aged 50-60, 4 males and 3 females). The intact segment, the specimen instrumented with a two-piece ALIF device (Statur(R)-L, FBC Device ApS, Denmark) and a one-piece standard ALIF (Pezo A, Ulrich, Germany) with pedicle screws were analyzed. Pure moment loads of ±7.5 Nm were applied in flexion/extension, axial rotation and lateral bending. Fluoroscopic images were captured during motion. Three-dimensional intersegmental motion was measured using a motion analysis system (Vicon MX, Vicon, UK). Relative motion between the implant and endplate was measured from the images. Paired t-tests were performed to determine statistical significance at a $p < 0.05$ level.

Results: No significant segment motion differences were identified between the one and two-piece ALIF concepts used in a 360 set-up. For both implant types in all three directions, the 360 constructs significantly reduced the motion of the spinal segment in comparison to the intact condition ($p < 0.05$) (Fig. 1).



[Fig. 1. RoM for Intact and 360 ALIF Devices]

There was significantly less motion at the implant-endplate interface for the two-piece device (median 1.2°, range 1.4°) in comparison to the one-piece ALIF (median: 5.1°, range: 4.1°) ($p < 0.05$) when moving in flexion/extension (Fig. 2). On average, ninety percent of the relative motion occurred between the superior face of the implant and the upper vertebral body which was independent of the type of implant.



[Fig. 2. Implant-Endplate Relative Motion]

Discussion: We found the Statur-L two-piece ALIF significantly reduced the relative motion at the bone-implant interface in comparison to a standard, one-piece ALIF. Theoretically, this can reduce the risk of implant subsidence, improve bony healing and establish better sagittal balance. The study also showed that the two very different ALIF concepts significantly reduced total motion in comparison to the intact state. Further, there was no statistically significant difference in total motion between the standard ALIF and the Statur-L, when supported with pedicle screw systems.

Conclusion: The novel two-piece interbody fusion device has the potential of improving the implant-bone interface resulting in less implant subsidence and improved sagittal balance without compromising stability.

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