Novel two-component interbody fusion device improves bone-implant interface without compromising stability: A cadaver study

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Introduction

A novel two-piece articulating anterior lumbar interbody fusion device (ALIF) allows lordotic adjustments of the treated segment until a supplementary pedicle screw system is rigidly fixed. A potential benefit is the reduction of bone-implant interface motions with a potential positive impact on fusion time and sagittal balance.

The aim of the study is to compare the spinal intersegmental motion and dynamic implant alignment of a two-piece ALIF fusion device with a one-piece ALIF in a 360° setting.

Material and Methods

Seven lumbosacral (L3-S1) human cadaver specimens were tested (aged 50-60, 4 males and 3 females) in a universal spine tester. The flexibility of the intact specimen, the specimen instrumented with a two-component ALIF (Statur® -L, FBC Device ApS, Denmark) and a one-piece ALIF (Pezo™ –A, ulrich GmbH & Co. KG, Germany) (Fig. 1), both supplemented with a pedicle screw system (tangoRS™, ulrich GmbH & Co. KG, Germany) was tested using pure moments of ±7.5 Nm in flexion/extension, lateral bending, and axial rotation. For assessment of relative motions between the interbody devices and the adjoining endplates (Fig. 2), fluoroscopic videos were captured during motion.

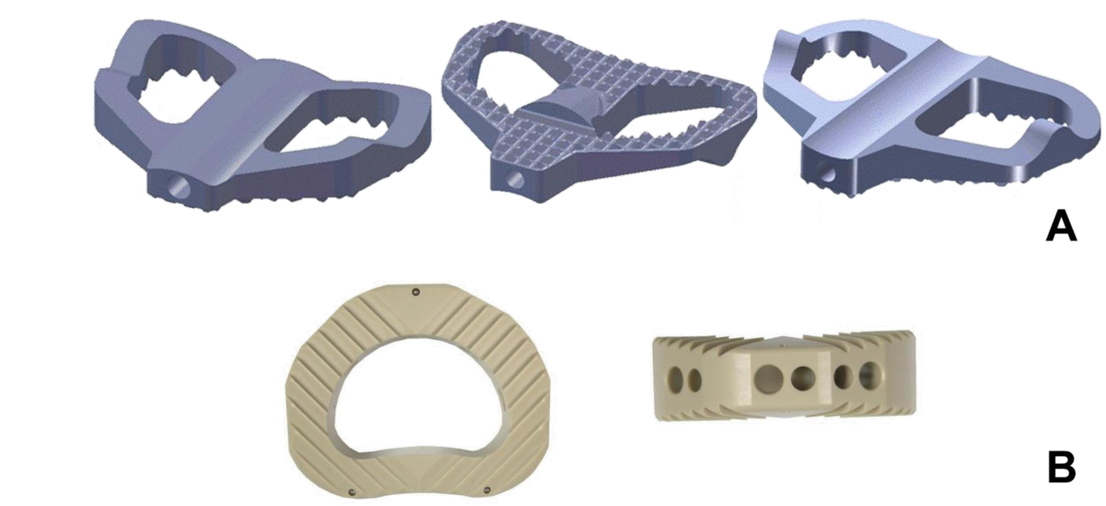

Fig. 1: **A** *Computer model of the two-piece ALIF (From left to right: The bottom component, the top component and the top component inverted to show the articulating region).* ***B*** *One-piece ALIF (Left: View from top; right: View from front).*

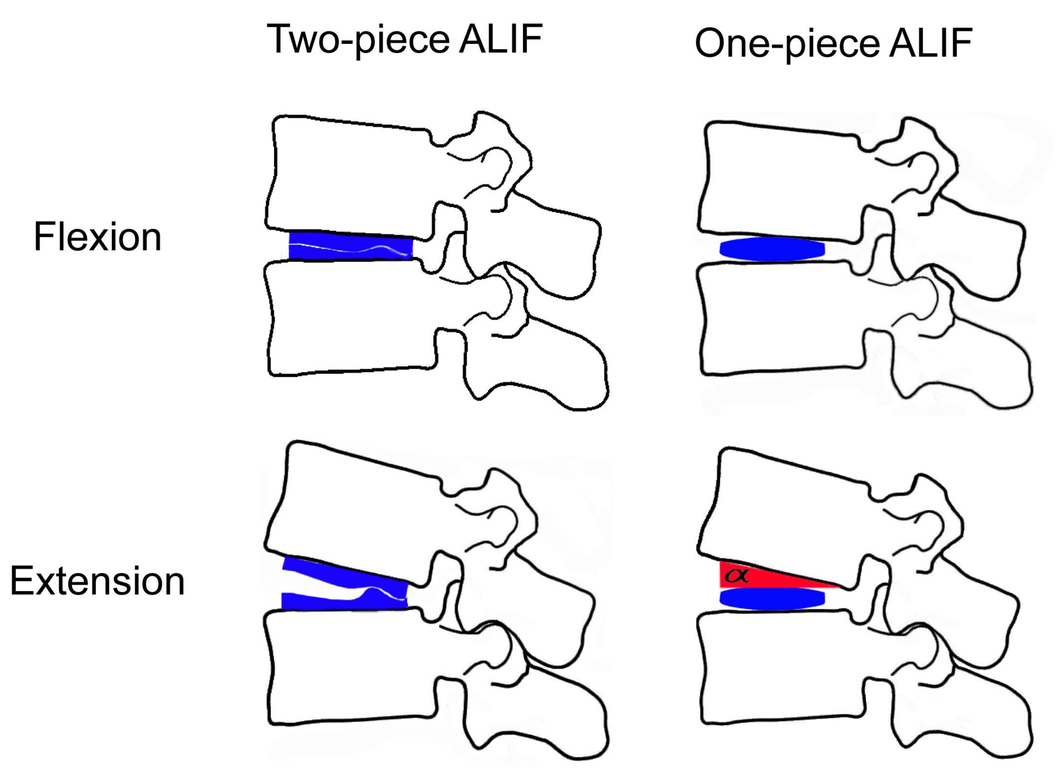

Fig. 2: Articulation characteristics of the one- and two-piece ALIF in flexion/extension. The angle α represents the relative motion between the implants and the adjoining endplates. The design of the two-piece ALIF allows limited motion of the components to achieve better dynamic implant-endplate alignment.

Three-dimensional intervertebral motion was measured using an optical motion motion capturing system (Vicon MX, Vicon, UK). Paired student's t-tests were performed to determine statistical significance at a p = 0.05 level.

Results

No statistically significant differences in rigidity were found between the one- and two-piece ALIF in a 360° setup, while both configurations significantly reduced the range of motion compared to the intact condition (Fig. 3).

Significantly less motion at the implant-endplate interface was found for the two-piece device in comparison to the one-piece ALIF in flexion/extension (the only motion direction investigated for this purpose) (Fig. 4).

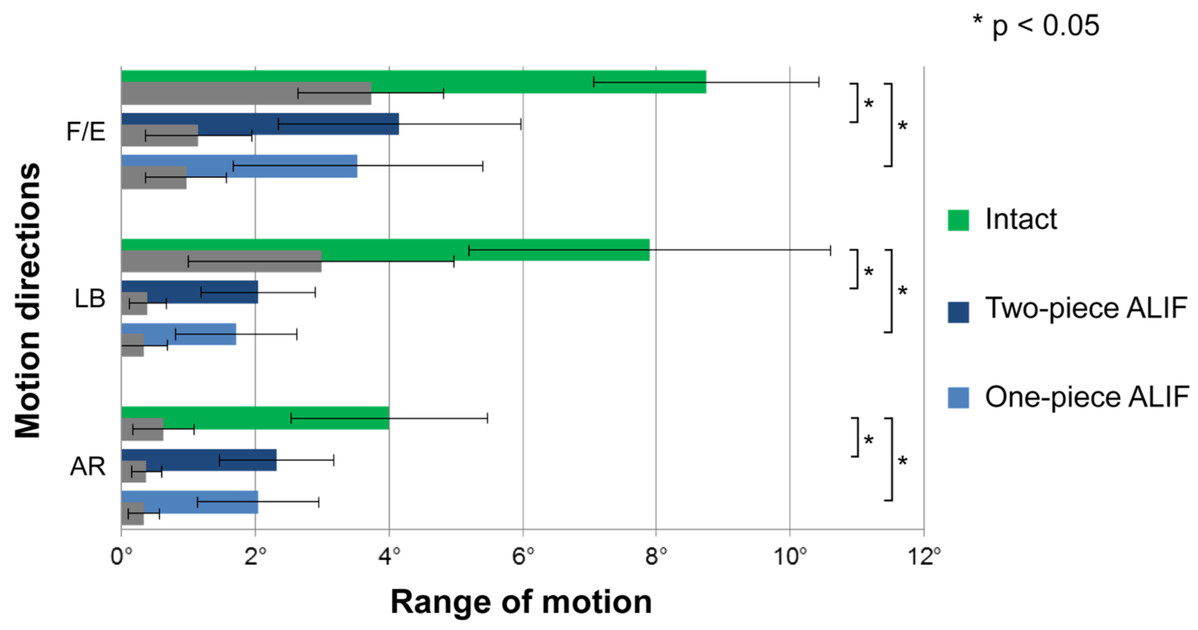

Fig. 3: ROM results for the three principal motion directions flexion/extension (F/E), lateral bending (LB) and axial rotation (AR) at the treated level for the interbody devices in a 360° setting. Colored bars represent the range of motion, whereas grey bars represent the neutral zone.

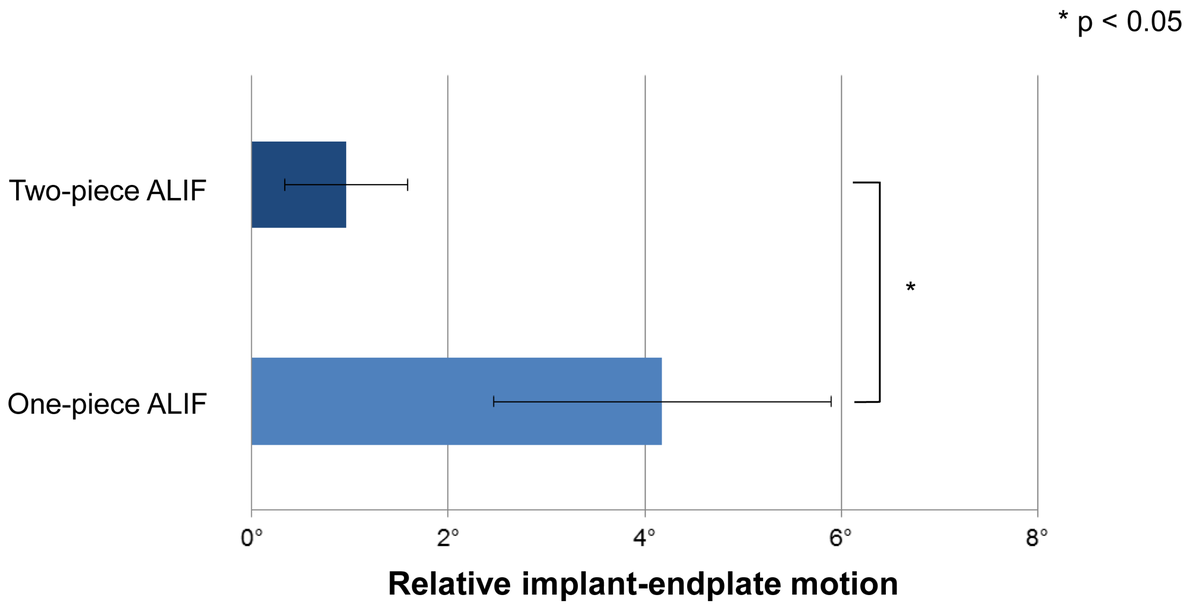

Fig. 4: Relative motion between implants and adjoining vertebral bodies in flexion/extension in a 360° setting.

Discussion

The two-piece ALIF significantly improved the relative motion at the bone-implant interface, which theoretically can reduce the risk of implant subsidence, improve bony healing and establish better sagittal balance.

The study also showed that both ALIF concepts in a 360° setting significantly reduced the range of motion in comparison to the intact state.

Further, there was no statistically significant difference in intervertebral motion between the standard ALIF and the two-component ALIF, when supported with pedicle screws.

Acknowledgements
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