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Effect of cage design, supplemental posterior instrumentation and approach on primary stability of a lumbar interbody fusion – A biomechanical in vitro study

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ABSTRACT

Background: There are various techniques and approaches for lumbar interbody fusion differing in access, cage type and type of supplemental posterior instrumentation. While a transforaminal access usually includes a hemifacetectomy, the facet joint can be preserved with a more lateral extraforaminal access. The supplemental posterior instrumentation required for both fusion techniques is still debated. The purpose of the present study was to compare primary stability of the two accesses for two different cage types with none, unilateral and bilateral supplemental posterior instrumentation.

Methods: Six monosegmental lumbar functional spinal units (FSUs) were included in each of the two groups, and subjected to a flexibility test. As cages, a newly designed cage was compared to a standard cage in the following states: (a) native, (b) stand-alone cage, (c) bilateral internal fixator, (d) unilateral internal fixator, (e) unilateral facetectomy + bilateral internal fixator, (f) unilateral facetectomy + unilateral internal fixator and (g) unilateral facetectomy with stand-alone cage. For comparison the range of motion was normalized to the native state and the effects of the facetectomy, cage type, and supplemental instrumentation was compared.

Findings: Within the subject comparison showed a significantly higher flexibility for the unilateral facetectomy in all motion directions ($p < 0.001$).

In between subject comparison showed a significant effect of cage type on flexibility in flexion/extension ($p = 0.002$) and lateral bending ($p = 0.028$) but not in axial rotation ($p = 0.322$). The type of supplemental posterior fixation had a significant effect on the flexibility in all motion directions (stand-alone > unilateral fixator > bilateral fixator).

Interpretation: Cage design and approach type are affecting the primary stability of lumbar interbody fusion procedures while the type of posterior instrumentation is the most influencing factor.

1. Introduction

Degenerative disc and facet joint disease is common in the aging population. While it is often asymptomatic without any consequences it is also a frequent cause of pain and disability. Reasons for the degeneration are not fully understood and multiple causes ranging from mechanical overloading to genetic inheritance and biological conditions are reported (Adams and Roughley, 2006; Battie et al., 2004; Roughley et al., 2006; Urban et al., 2004). In cases where conservative treatments and physiotherapy are not effective to treat the pain or disability surgical intervention is indicated. Focusing on the lumbar spine, a surgical approach to treat intervertebral disc degeneration is the lumbar interbody fusion (LIF). There exist various techniques, differing in their access to the disc, cage type and type of supplemental posterior instrumentation. All of these variations can have an effect on the stability of the treated spinal segment.

Regarding posterior approaches, the posterior lumbar interbody fusion (PLIF) is conducted directly from the back of the spine. To access the disc space soft tissue and parts of the lamina are removed and the exposed nerve roots are retracted (Cole et al., 2009). To reduce soft tissue damage to a minimum, the minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) relies on a more lateral incision angle (Cole et al., 2009; Fleege et al., 2015). One drawback of this common TLIF procedure is the applied hemifacetectomy to access the

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disc. As the facet joint contributes to the stability of a spinal segment, the joint can be preserved in the extraforaminal lumbar interbody fusion (ELIF) (Abumi et al., 1990). In an ELIF procedure the disc is approached at a more lateral incision angle via the intervertebral foramen (Recoules-Arche et al., 2014).

Beside the surgical access, the geometry and size of the implanted fusion cage can also contribute to the primary stability of the treated spinal segment. In general, a larger footprint of the cage might reduce the caving into the vertebral endplates and a larger surface area is intended to achieve more segmental stability (Ambati et al., 2014; Lund et al., 1998; Oxland and Lund, 2000).

To further reduce the intersegmental motion and to provide immediate postoperative stability after LIF, supplemental posterior instrumentation is applied (Ambati et al., 2014; Harris et al., 2004). The type of instrumentation is still debated and ranges from none to unilateral pedicle screw fixation or bilateral pedicle screw fixation (Ambati et al., 2014; Ding et al., 2014; Kotil et al., 2013; Wang et al., 2014). While surgical trauma and hardware costs can be reduced for unilateral internal fixation, bilateral instrumentation can decrease cage migration and ensures a consistent distribution of the compressive forces acting on the spine that might be altered with unilateral internal fixators (Duncan and Bailey, 2013; Recoules-Arche et al., 2014; Yuan et al., 2014).

The purpose of the study was to investigate the effect of the surgical approach (ELIF vs. TLIF), the type of intervertebral fusion cage and the supplemental posterior instrumentation on the range of motion (RoM) of a treated single lumbar motion segment.

2. Methods

Six fresh-frozen human lumbar spines (L2–5) were obtained from the local department of anatomy (mean age of 70.5 years, range 59 to 77, 2 female and 4 male). Donors had given their informed consent for their bodies' use for scientific and educational purposes prior to death. Specimens were divided into two groups, each group composed of six monosegmental functional spine units (3 × L2–3 and 3 × L4–5) and used for biomechanical testing. To exclude pre-existing pathologies, preoperative quantitative computer tomography (Lightspeed, VCT 16, GE Healthcare, Milwaukee, WI, USA) scans were performed. Based on these scans trabecular bone mineral density (BMD) of each vertebra was measured using a European Forearm Phantom calibration. The mean and standard deviation of trabecular BMD of the specimens was 83 and 23 mg/ccm, respectively.

Before testing the frozen specimens were thawed overnight at + 6 °C. All soft tissue was dissected and ligaments and joint capsules were preserved. The upper half of the cranial vertebrae and the lower half of the caudal vertebrae were embedded in polymethylmethacrylate (PMMA) cement (Technovit 3040, Heraeus Kulzer GmbH, Wehrheim, Germany), with the intervertebral disc aligned horizontally. Equipped with flanges the specimen was mounted in a spine tester. The intersegmental RoM during specimen loading was measured with an ultrasound-based 3-dimensional motion analysis system (Win Biomechanics, zebris Medical GmbH, Isny, Germany) mounted to the ventral side of the PMMA blocks.

2.1. Implants

Two types of fusion cages were tested in this study. A conventional monobloc cage (Medtronic Capstone®, Medtronic, Memphis, USA) manufactured of polyetheretherketone (PEEK) that is convex-shaped to better fit the disc space anatomy (Fig. 1a).

The novel PROW FUSION™ cage (NLT-SPINE, Kfar Saba, Israel) is comprised of a segmented non-linear structure that can be deflected in situ by pulling an integrated guidance/fixation strap. By this mechanism the chain type structure can be inserted through a straight rectangular tube and can be bent in situ in the intervertebral disc by pulling at the guidance strap. Once the optimal position in the disc space has been reached the guidance strap can be locked and the geometric shape of the chain type cage is fixed (Fig. 1). It consists of a material composite of titanium and PEEK and by its flexibility the new design is intended to increase the footprint. Thus the internal cavity, which is filled with bone graft during surgery, provides a larger surface area compared to a conventional cage.

In all tested specimens the disc space was approached from the right hand side. The size of the annulotomy and the size of the fusion cage were chosen individually for each specimen according to the dimensions of the disc height. Both cages are not expandable in height and do not have a variable lordosis angle to accommodate for different lordosis angles. All implantations of the cages were carried out under fluoroscopic control.

For the internal fixator polyaxial pedicle screws (Ø 6.5 × 45 mm for L2–3 and Ø 6.5 × 50 mm for L4–5) and titanium rods (Ø 6 mm × 60 mm) were used (tangoRS™, Ulrich GmbH & Co. KG, Ulm, Germany).

2.2. Biomechanical testing

The flexibility testing of all specimens was carried out at room temperature in a spine simulator with six degrees of freedom. The specimens were kept moist during experimental testing. Via a stepper motor and cable cords pure bending moments of 7.5 Nm were applied in flexion/extension, lateral bending left/right and axial rotation left/right. The loading of the specimens was controlled by a 6-component load cell (SCHUNK GmbH & Co. KG, Lauffen/Neckar, Germany) with feedback control that is connected to the stepper motor. Each specimen was subjected to three load cycles, from which the third cycle was selected for data analysis and a hysteresis curve was plotted to determine the intersegmental range of motion (RoM) in degrees. The biomechanical testing was carried out according to the recommendations for in vitro testing of spinal implants (Wilke et al., 1998).

Each six specimen in both test groups (conventional cage (CC) and novel cage (n_PF)) was tested in the following seven conditions:

1. *Native* (intact)

Simulated ELIF procedure with intact facet joints:

2. *Stand_alone*: implanted fusion cage without additional internal fixator
3. *Bilat_fix*: additional bilateral internal fixator
4. *Unilat_fix*: unilateral internal fixator to the right hand side

Simulated (MIS) TLIF procedure with the hemifacetectomy to the right hand side:

5. *Facetec_bilat_fix*: additional bilateral internal fixator
6. *Facetec_unilat_fix*: unilateral internal fixator to the right hand side
7. *Facetec_stand_alone*: implanted fusion cage without additional internal fixator

For each specimen the measured RoM values were normalized to the native (intact) state to compensate for differences between the specimens and to reveal the effect of the investigated variables (approach, posterior instrumentation and cage type).

2.3. Statistical analysis

For statistical evaluation the measured data of the flexibility tests were analyzed and plotted using the statistical analysis software SPSS (version 22, SPSS, Chicago, IL, USA). All data were normally distributed and tested with a General Linear Model (GLM) with repeated measures. The state (with and without hemifacetectomy) was chosen as “within