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Biomechanical stability of five stand-alone anterior lumbar interbody fusion constructs

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Abstract Anterior lumbar interbody fusion (ALIF) cages are expected to reduce segmental mobility. Current ALIF cages have different designs, suggesting differences in initial stability. The objective of this study was to compare the effect of different stand-alone ALIF cage constructs and cage-related features on initial segmental stability. Human multi-segmental specimens were tested intact and with an instrumented L3/4 disc level. Five different ALIF cages (I/F, BAK, TIS, SynCage, and ScrewCage) were tested non-destructively in axial rotation, flexion/extension and lateral bending. A cage ‘pull-out’ concluded testing. Changes in neutral zone (NZ) and range of motion (ROM) were analyzed. Cage-related measurements normalized to vertebral dimensions were used to predict NZ and ROM. No cage construct managed to reduce NZ. The BAK and TIS cages had the largest NZ increase in flexion/extension and lateral bending, re-

spectively. Cages did reduce ROM in all loading directions. The TIS cage was the least effective in reducing the ROM in lateral bending. Cages with sharp teeth had higher ‘pull-out’ forces. Antero-posterior and medio-lateral cage dimensions, cage height and wedge angle were found to influence initial stability. The performance of stand-alone ALIF cage constructs generally increased the NZ in any loading direction, suggesting potential directions of *initial* segmental instability that may lead to permanent deformity. Differences between cages in flexion/extension and lateral bending NZ are attributed to the severity of geometrical cage-endplate surface mismatch. Stand-alone cage constructs reduced ROM effectively, but the residual ROM present indicates the presence of micromotion at the cage-endplate interface.

Key words Biomechanics · Implant · Interbody fusion · Segmental flexibility · Lumbar spine

Introduction

Interbody fusion is preferred over postero-lateral fusion because it warrants a stronger biomechanical construct [12] and higher fusion rate [11]. It favors load transmission via the anterior column, full restoration of disc height and lordosis, annular fiber tensioning and least demands of bone graft volume [12]. A successful interbody construct provides adequate axial support to resist graft subsi-

dence or collapse and reduces the post-operative segmental mobility to permit graft incorporation [30]. As such, the axial compressive strength and relative three-dimensional stability of an interbody construct are biomechanical measures describing the likelihood of a successful bone fusion [5].

Anterior lumbar interbody fusion (ALIF) and posterior lumbar interbody fusion (PLIF) are two accepted approaches of grafted interbody fusion, the latter often combined with pedicle instrumentation [11]. The ALIF proce-

ture easily permits direct and complete removal of disc tissue [14, 18], while avoiding a trauma to the posterior para-spinal muscles. Operative time, blood loss and hospital stay can be reduced [14, 18] compared to PLIF procedures. Moreover, an ALIF can be performed using minimally open [22, 44] or laparoscopic surgical techniques [4, 21, 53], thus further reducing the operative trauma.

Cases have been reported of both autogenous and allogeneous cortical and cancellous bone grafts lacking the structural strength required in interbody fusion, which has inevitably led to collapse [9, 19, 42], displacement [34] or extrusion [19]. Harvest of bi-cortical or tri-cortical bone graft can moreover cause up to 30% donor site complications [13, 41, 52], with donor site pain often persisting for more than 1 year [13]. The need for rigid axial mechanical support has led to the development of interbody implants or the so-called 'cages' [2, 6, 39, 48]. The cage is expected to provide mechanical support and improve the three-dimensional initial stability, so cancellous grafting material housed within and around the cage can successfully incorporate to a biologic fusion. Current ALIF cages have quite different designs and insertion techniques, suggesting differences in the initial stability provided.

Few studies have been done so far to evaluate the biomechanical behavior of ALIF cage constructs. A threaded stand-alone ALIF cage construct has shown reductions in segmental motion [26]. ALIF cages have demonstrated equivalent initial stability to femoral ring allografts [15] and a significantly better disc space distraction [40] and neuroforaminal clearance [7] than autografts. The stiffness of cylindrical and conical threaded ALIF cage constructs has been compared [46] in a calf model and found to be similar. The compressive strength of ALIF cage constructs was shown not to be affected by either a central cage-endplate contact or a central endplate decortication [45]. The fatigue characteristics of an ALIF cage construct [24] were evaluated in swine and baboon models and deemed of sufficient strength. The same ALIF cage was finally implanted in a baboon [25], and showed similar in vitro fatigue strength with an effective biologic fusion.

ALIF cages supplemented with posterior fixation systems such as pedicle [15] or translaminar [38] screw systems have shown superior initial stability. However, stand-alone ALIF cages may still provide adequate initial stability for biologic fusion. To our knowledge, no study has directly compared the initial stability provided by different stand-alone ALIF cage constructs. Therefore, the aim was to compare the initial three-dimensional stability of five different stand-alone ALIF cages and their resistance to 'pull-out' force. Similarly, the effect of design characteristics such as cage width, length, height or wedge angle on the initial stability was also examined.

Materials and methods

Specimen preparation

Forty-two lumbar spines (L1–S1) with ages between 20 and 65 years (mean age: 47 ± 11 years) and with no history of spine pathology were harvested during autopsies. Antero-posterior bone mineral density (BMD) was acquired for the L3 and L4 vertebral bodies (DPX-L, Lunar Radiation Corporation, Madison, WI) and specimens with a mean L3/4 BMD between 0.735 g/cm^2 and 1.410 g/cm^2 were included in the study. These boundaries were chosen to include specimens with BMD between -3 and $+1$ standard deviations from the population mean ($1.26 \pm 0.150 \text{ g/cm}^2$ [23]). Specimens were vacuum-sealed in polyethylene bags and stored at -20°C until testing.

Prior to testing, the specimens were removed from the freezer, and placed in a refrigerator at 4°C for 24 h prior to testing, so that they thawed slowly. The L1/2 and L5/S1 vertebral levels of the multi-segmental specimens were blocked using screws and fixed into cylindrical dental plaster molds (Quickstone Laboratory Stone Buff, Louisville, KY) while maintaining the mid-plane of the L3/4 intervertebral disc parallel to both upper and lower molds. The prepared multi-segmental specimen had the L2/3, L3/4 and L4/5 motion segments left intact. Tissue was kept moist with hydrated gauzes at all times during the preparation.

Experimental design

The 42 specimens were each assigned into a gender, age and BMD group. Two age groups ranging from 15 to 39 and 40 to 64 years respectively, as well as two L3/4 BMD groups ranging from 0.735 to 1.035 g/cm^2 (-3.5 to -1.5 SDs from the population mean) and 1.036 to 1.410 g/cm^2 (-1.5 to $+1$ SDs from the population mean) respectively were defined. Specimens were systematically stratified using these groups into six experimental groups (five cages and one control) each of seven specimens (Fig. 1).

The cage models used were:

1. The paired BAK cage (SpineTech Inc., Minneapolis, MN)
2. The Anterior Lumbar I/F cage (Acromed Corp., Cleveland, OH; acronym: I/F), an oval fenestrated carbon fiber implant with saw teeth
3. The Titanium Interbody Spacer (Synthes Spine, Paoli, PA; acronym: TIS), a round titanium implant with long serrated teeth
4. The SynCage (Mathys Ltd., Bettlach, Switzerland), an oval titanium implant with short serrated teeth

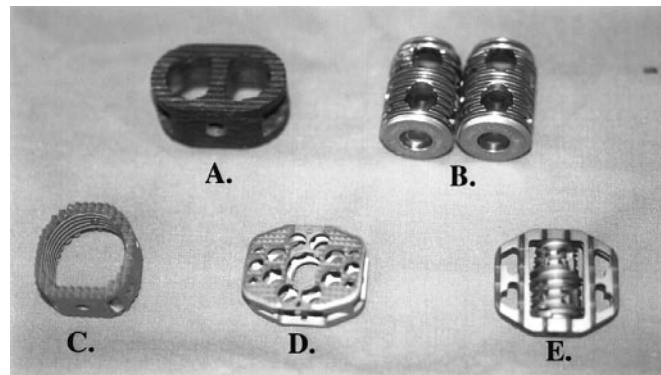


Fig. 1 A–E The anterior lumbar interbody fusion cages used in the study. **A** Anterior Lumbar I/F cage; **B** Paired BAK; **C** Titanium Interbody Spacer; **D** SynCage; **E** ScrewCage

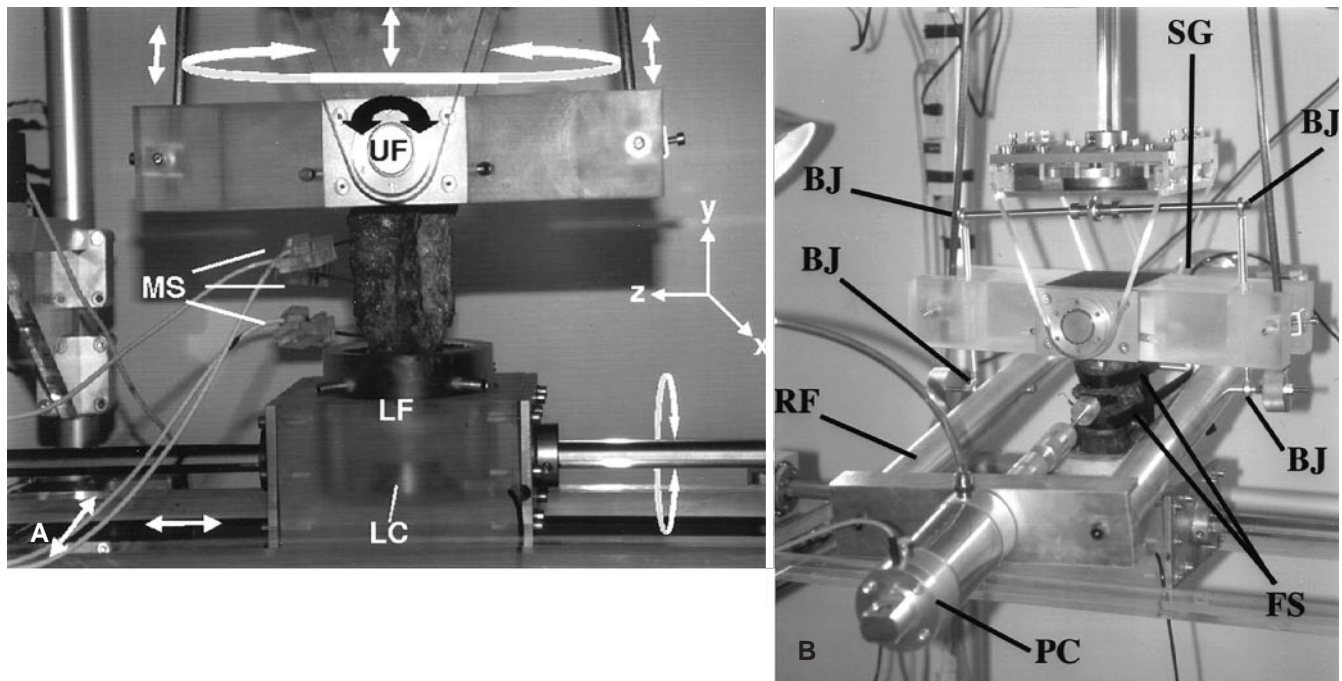


Fig. 2 **A** The custom made mechanical testing machine without the ‘pull-out’ device mounted (*UF* upper fixation, *LF* lower fixation, *LC* load cell, *MS* motion sensor). **B** The cage ‘pull-out’ device setup (*RF* rectangular frame, *BJ* supporting ball joints enabling the device to ‘float’, *PC* pneumatic cylinder, *FS* reactive force straps that counteract the anteriorly directed cage ‘pull-out’ force, *SG* strain gauge force transducer)

5. The ScrewCage (Mathys Ltd., Bettlach, Switzerland), a rectangular titanium frame with saw teeth, housing a conical threading component

The multi-segmental specimens were first tested intact and again with cages inserted into the L3/4 disc space using the same loading protocol. The control group had no cage inserted but was loaded again after 2 h to account for the specimen behavior when cage groups were compared, and to validate a loading protocol. The cage-endplate contact and cage position were documented prior to testing with antero-posterior and (AP) lateral (LAT) radiographs. Finally, an anteriorly directed force pulled cages out of the disc space. The testing order of cage constructs was done in a block randomized fashion to ensure that the learning curve of surgical insertion and mechanical testing would not favor any of the cage models. The overall testing time of each specimen from start (including specimen preparation) to finish (including pull-out test) was on average 330 min.

Custom testing machine

The custom testing machine (Fig. 2A) used for segmental flexibility testing consisted of a position-controlled upper platform capable of applying axial compression, axial rotation and flexion/extension (or lateral bending) to the specimen. A lower platform allowed for passive movements in lateral bending (or flexion/extension) and translation in the two horizontal axes. It incorporated a strain gauge load transducer (Intelligent Multi-Axis Force/Torque Sensor System, Assurance Technologies Inc., Garner, NC) that continuously measured Cartesian force/torque components in six degrees of freedom. An electromagnetic tracking system (Fastrak,

Polhemus, Colchester, VT) was used to measure relative segmental motion (for each of L2/3, L3/4 and L4/5) by rigidly attaching lightweight (17 g) motion sensors to the L2, L3, and L4 vertebral bodies of the multi-segmental specimen. A fourth sensor was attached to the lower platform of the testing machine (spatial invariant position, relative to the strain gauge transducer built into the lower fixation platform, as well as to the L5 vertebra embedded in the plaster mold). The segmental movements were expressed in a right-handed coordinate system [32].

To investigate whether the static accuracy of the electromagnetic tracking system was appropriate to measure segmental motion, a validation study prior to the present study was undertaken. Two sensors spaced at a distance similar to the one used for the biomechanical testing were rigidly mounted onto a rotating Plexiglas® disc. Static measurements of relative sensor displacement were obtained at 10° disc rotation increments with a total movement of 30° in each direction. Testing was repeated three times for each of the spatial orientations (*x*, *y* and *z*). Due to the rigid montage, the relative displacement was expected to be zero; any deviation from the expected zero value was considered error. The static accuracy was determined at 0.10° root mean square (RMS) for angular displacements and 0.23 mm RMS for linear displacements.

The ‘pull-out’ device (Fig. 2B) (a modular unit that was removed during flexibility testing), consisted of a rectangular frame, suspended from the testing machine through two ball joints. The device was designed to ‘float’ during force application, thereby applying a pure anterior force to the cage (‘pull-out’ force). A pneumatic cylinder (PFC-702-XBP, Bimba Mfg Co., Monee, IL) mounted on the rectangular frame was attached to the cage anterior face. Opposite the pneumatic cylinder, straps placed around the L3 and L4 vertebral bodies were connected to a strain-gauge force transducer (60001-1K, Intertechonology, Don Mills, Ontario) mounted on the rectangular frame. This method allowed for reactive forces on the L3 and L4 vertebrae to counteract the ‘pull-out’ force.

Surgical procedure

The BAK cages were inserted using manufacturer recommendations. All other cages underwent identical disc space preparation,

but techniques for distraction and cage insertion were somewhat different. The disc space preparation consisted of cutting a rectangular window, the size of a cage, into the anterior annulus and anterior longitudinal ligament while preserving as much lateral annulus as possible. The nucleus pulposus and endplate cartilage was removed while preserving the posterior longitudinal ligament and cortical endplate. An external distractor kept the disc space open while the I/F and TIS cages were tapped into place. The SynCage employed a customized distractor, permitting the cage to be slid between the two arms of the distractor into optimal position. The ScrewCage employed a conical threading component housed within its rectangular frame, to distract and pull the cage into the disc space without external distraction. The time required for surgical insertion of either cage model was typically 20 min, but never more than 30 min.

Measurement method

A static axial preload of 300 N was initially applied for 15 min preceding the flexibility testing to correct for possible intervertebral disc hyper-hydration [33, 35]. Later throughout testing, a 200 N axial preload was maintained. Two pre-conditioning load cycles were applied in each loading direction with a third cycle used for data acquisition. The loading protocol consisted of:

1. Axial rotation applied in 2-Nm steps from -8 Nm left rotation to $+8$ Nm right rotation, and back to -8 Nm
2. Flexion/extension applied in 1-Nm steps from -4 Nm flexion to $+4$ Nm extension, and back to -4 Nm
3. Lateral bending applied in 1-Nm steps from -4 Nm left lateral bending to $+4$ Nm right lateral bending, and back to -4 Nm.

The cage ‘pull-out’ force was applied at a rate of 100 N/s, while maintaining a 600 N axial preload. The maximal reactive force recorded from the strain gauge transducer was used for analysis. The reactive force measured for the paired BAK cage was half that obtained from the strain gauge transducer, since the setup applied a ‘pull-out’ force to both cylinders of the construct.

Neutral zone (NZ), and range of motion (ROM) were extracted from the load-displacement curves [31, 50] of each loading direction for both intact and instrumented testing conditions. The mean NZ and ROM obtained for each instrumented condition of the groups was normalized to the respective mean intact values. From the AP and LAT radiographs, a LAT and AP cage dimension was measured and normalized to the respective mean L3/4 disc space endplate dimensions. The LAT cage dimension of the BAK was calculated as the span of the lateral borders of each cylinder. A mean disc space height after cage insertion was also measured from the LAT radiographs. The wedge angle was calculated from the cage’s physical dimensions.

Statistical analysis

All statistical tests were conducted with Statview 5.0 (SAS Institute Inc., Cary, NC). To examine whether differences existed in

NZ or ROM between the two loading conditions with all cage constructs combined or for the control group, paired Student *t*-tests were performed. To identify differences between cage constructs in NZ and ROM we used a single-factor repeated measures analyses of variance (rmANOVA). The control was included into the rmANOVA to remove possible biases arising from repetitive loading of specimens. To compare the maximal ‘pull-out’ force obtained of different cages an analysis of variance (ANOVA) was performed. Any significant differences observed between cages in ‘pull-out’ force, NZ or ROM were further evaluated using Fisher’s Protected Least Significant Difference pairwise comparisons. Finally, to examine whether different cage design features affected the NZ and ROM of instrumented specimens, stepwise linear regressions were employed. All statistical tests used a 0.05 level of significance (α).

Results

The control showed no significant change in NZ between the two consecutive loadings in axial rotation (0%) or flexion/extension (-7%), but a significant decrease in lateral bending (-37%). The ROM did not significantly change in any loading direction (axial rotation: 2%; flexion/extension: -14% ; lateral bending: 3%).

Segmental flexibility

Cage-related measurements are presented in Table 1, and a summary of all normalized to intact changes in NZ and ROM is found in Table 2.

Neutral zone (NZ)

The combined NZ of stand-alone cage constructs (Figs. 3–5) demonstrated a significant increase ($P < 0.0212$) in all loading directions (axial rotation: 98%; flexion/extension: 109%; lateral bending: 53%).

No significant differences were found between cage constructs (Fig. 3) for NZ in axial rotation. Although not significant, the ScrewCage (-2%) did not change its NZ from intact in this movement, while the TIS (272%), and I/F (201%) cage constructs demonstrated the highest positive changes.

Significant differences in NZ between cage constructs were found in flexion/extension (Fig. 4; $P < 0.0053$) and

posterior endplate dimension, *disc space height* mean anterior and posterior disc space height after cage insertion, *implant wedge angle* wedge angle measured from the cages: the I/F cage had two different wedge angles)

Table 1 Mean values and standard deviations for various cage-related measurements, calculated for each cage group (*Norm LAT width* lateral cage dimension normalized to the mean L3/4 disc space lateral endplate dimension, *norm AP width* antero-posterior cage dimension normalized to the mean L3/4 disc space antero-

| Cage features | TIS | SynCage | I/F | BAK | ScrewCage |
|-------------------------|-------------|------------|------------|------------|------------|
| Norm AP width (%) | 78.8 ± 11.3 | 69.6 ± 9.2 | 72.4 ± 5.1 | 63.2 ± 4.7 | 75.5 ± 9.2 |
| Norm LAT width (%) | 54.8 ± 4.6 | 65.5 ± 4.2 | 82.2 ± 6.4 | 75.6 ± 2.7 | 65.4 ± 6.0 |
| Disc space height (mm) | 12.1 ± 1.8 | 13.1 ± 1.8 | 13.1 ± 1.0 | 12.5 ± 1.1 | 13.6 ± 0.9 |
| Implant wedge angle (°) | 7.89 | 11.77 | 4.09/4.77 | 0 | 8.75 |

Table 2 Normalized to intact percentage changes in neutral zone (NZ) and range of motion (ROM). Positive values (+) reflect an increase and negative ones (-) a decrease

| Implants | Axial rotation | | Flexion/extension | | Lateral bending | |
|-----------|----------------|--------|-------------------|--------|-----------------|---------|
| | NZ(%) | ROM(%) | NZ(%)* | ROM(%) | NZ(%)* | ROM(%)* |
| Control | 0 | 2 | -7 | -14 | -37 | 3 |
| TIS | 272 | 15 | 43 | -28 | 293 | -41 |
| SynCage | 128 | -28 | 145 | -36 | 46 | -80 |
| I/F | 201 | -34 | 4 | -37 | -19 | -59 |
| BAK | 37 | -16 | 278 | -43 | 51 | -81 |
| ScrewCage | -2 | -44 | 123 | -46 | -30 | -76 |

* Significant difference between cage constructs ($P < 0.05$)

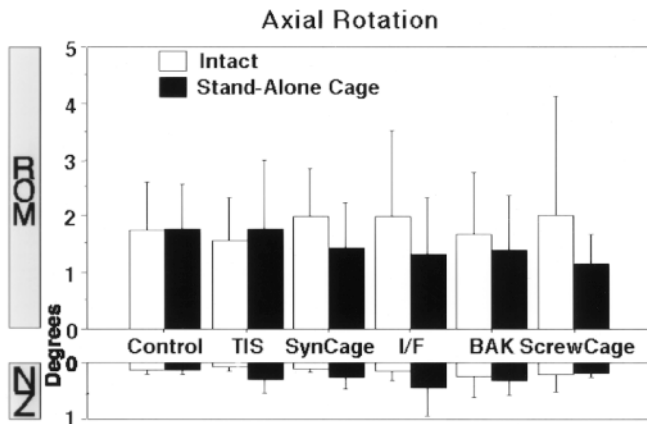


Fig.3 Average NZ and ROM in axial rotation for intact and instrumented testing conditions. Error bars indicate one standard deviation. No significant differences were observed between cage constructs

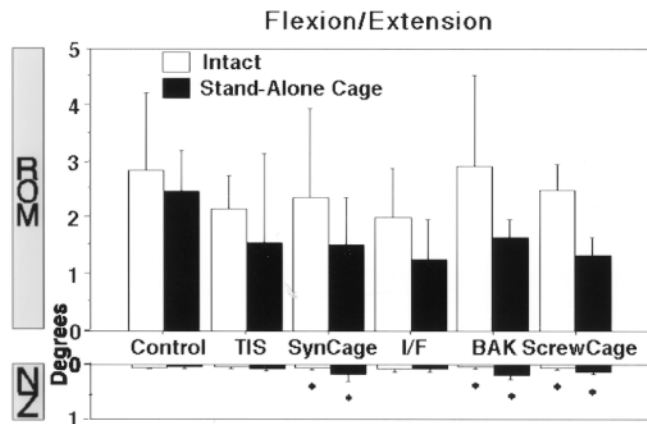


Fig.4 Average NZ and ROM in flexion/extension for intact and instrumented testing conditions. Error bars indicate one standard deviation. Significant differences between stand-alone cage constructs are marked with an asterisk (*)

lateral bending (Fig.5; $P < 0.0007$). The BAK (278%), SynCage (145%) and ScrewCage (123%) cage constructs significantly increased NZ in flexion/extension from intact when compared to the control (-7%), and the I/F (4%), TIS (43%) cage constructs. The TIS (293%) construct significantly increased the NZ in lateral bending

from intact, and was the only cage construct that significantly increased NZ compared to the control (-37%). Its NZ in lateral bending was also significantly higher than the remaining cage constructs (SynCage: 46%; I/F: -19%; BAK: 51%; ScrewCage: -30%).

Range of motion (ROM)

The combined ROM of stand-alone cage constructs (Figs. 3-5) demonstrated a significant decrease ($P < 0.001$) in flexion/extension: (-63%) and lateral bending (-69%) and a marginally significant decrease ($P < 0.0745$) in axial rotation (-23%).

No significant differences were found between cage constructs for ROM in axial rotation (Fig.3) and flexion/extension (Fig.4). Even though not significant, the ScrewCage was observed as the cage construct that most efficiently reduced ROM in both axial rotation (-44%), and flexion/extension (-46%). Conversely, the TIS was the only cage construct that increased ROM in axial rotation (15%), and provided the least efficient ROM reductions in flexion/extension (-28%).

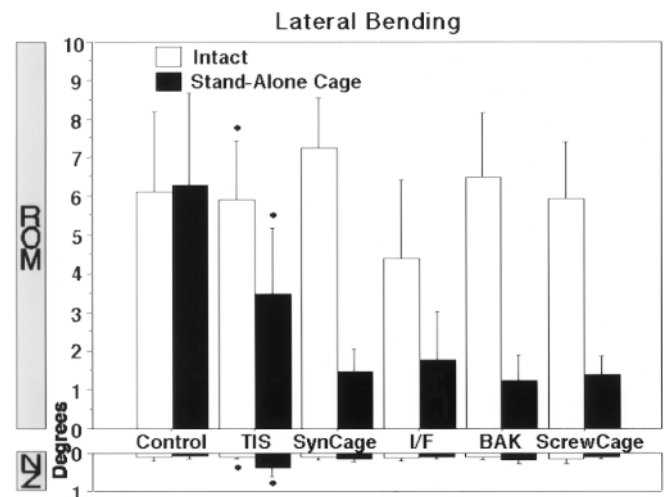


Fig.5 Average NZ and ROM in lateral bending for intact and instrumented testing conditions. Error bars indicate one standard deviation. Significant differences between stand-alone cage constructs are marked with an asterisk (*)

Significant differences between cages ($P < 0.0001$) were observed for the ROM in lateral bending (Fig. 5). All cage constructs significantly decreased their respective ROM when compared to the control (3%), but the reductions observed for the TIS cage construct (-41%) were significantly less than those for all other cage constructs (SynCage: -80%; I/F: -59%; BAK: -81%; ScrewCage: -76%).

Cage 'pull-out' force

Significantly different 'pull-out' forces were found ($P < 0.0012$) between cages (Fig. 6). The TIS (957 ± 197 N), SynCage (1033 ± 291 N) and ScrewCage (938 ± 141 N) cages required higher forces than the I/F (653 ± 135 N) or BAK (642 ± 176 N) cages.

Cage design characteristics

The results of the stepwise linear regression analyses predicting initial segmental stability from cage-related measurements are presented in Table 3. The antero-posterior (*norm AP width*) dimension of a stand-alone cage signifi-

cantly influences (inverse relationship; $P < 0.05$) the segmental NZ in flexion/extension (adjusted $r^2 = 0.081$). The medio-lateral dimension (*norm LAT width*) and wedge angle (*implant wedge angle*) of a stand-alone cage significantly influence (inverse relationships; $P < 0.008$) the segmental NZ in lateral bending (combined two variable adjusted $r^2 = 0.322$). The medio-lateral dimension (*norm LAT width*) and distractive capabilities of a stand-alone cage (*disc space height*) significantly influence (inverse relationship; $P < 0.0026$) the segmental ROM in lateral bending (combined two variable adjusted $r^2 = 0.267$). No other relationships between cage-related measurements and segmental NZ or ROM were found. The wedge angle (*implant wedge angle*) of a stand-alone cage significantly influences (direct relationship; $P < 0.0001$) its 'pull-out' force (adjusted $r^2 = 0.375$).

Discussion

This study compared five different stand-alone ALIF cage constructs with emphasis on defining cage characteristics crucial to initial stability. To preserve ligaments spanning more than one motion segment, multi-segmental specimens were used [1, 50]. The L3/4 disc space was chosen for cage insertion as it was separated from the fixation to the testing machine by an additional intact disc space (L2/3 and L4/5), which reduced constraints resulting from specimen fixation [16]. A control group weighted the effect of repetitive loading on the biomechanical behavior of cadaveric specimens and concurrently allowed for validation of a loading protocol. The sample size per experimental group ($n = 7$) was similar to other studies [7, 26, 27, 38]. It did, however, present a limitation due to the considerable inter-specimen variability common to most biomechanical studies.

Interbody fusion implants should restore normal disc space height. However, healthy cadaveric specimens, as the ones used in our biomechanical study (mean age: 47 ± 11 years, severe degeneration excluded), tend to have different distractive properties than degenerated spines, which are typically selected for fusion procedures. Given this experimental design shortcoming, the initial L3/4 disc height of the specimens used was not measured and actual cage distraction was not determined.

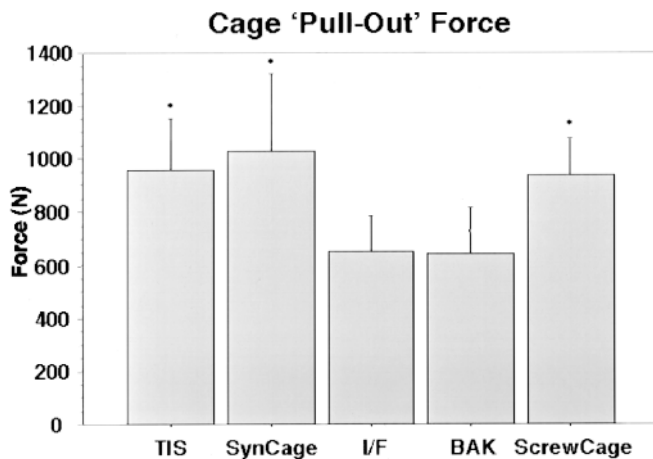


Fig. 6 Mean and standard deviation of 'pull-out' forces observed for each cage. Significantly higher 'pull-out' forces (ANOVA, $P < 0.05$) were obtained for cages marked with an asterisk (*) when compared to the remaining cages

Table 3 Significant findings obtained from the stepwise linear regressions when cage-related measurements were used to predict segmental stability parameters (NZ, ROM and 'pull-out' force)

| Movement | Dependent variable | Independent variable(s) | Relationship | Significance | Adjusted r^2 |
|-------------------|--------------------|-------------------------|--------------|--------------|----------------|
| Flexion/extension | NZ | Norm AP width | Inverse | $P < 0.05$ | 0.081 |
| Lateral bending | NZ | Norm LAT width | Inverse | $P < 0.008$ | 0.322 |
| | | Implant wedge angle | Inverse | | |
| | ROM | Norm LAT width | Inverse | $P < 0.0026$ | 0.267 |
| | | Disc space height | Inverse | | |
| Cage 'pull-out' | Force | Implant wedge angle | Direct | $P < 0.0001$ | 0.375 |

Physiological axial and cyclic loading favor cage anchorage, but both are absent in a cadaveric model. Radiographs documented the cage-endplate contact with no axial compressive load, while the initial stability and cage resistance to ‘pull-out’ force was examined with a 200-N and a 600-N axial compressive load, respectively. Despite this limitation of radiographs, cageendplate contact suggests that cageanchorage occurred during flexibility resting, and therefore was used with the cage design characteristics to discuss the initial stability of cage constructs. Following, a discussion will address three distinct issues: (1) cage design characteristics; (2) the performance of individual cage constructs; (3) the efficacy of a stand-alone cage construct.

Cage design characteristics

The NZ concept (also called laxity), introduced by Panjabi [31], is the region of physiologic intervertebral motion where the passive osteoligamentous restraints (ligaments, intervertebral disc or endplates) of a functional spinal unit (FSU) do not provide resistance to motion when loads are applied in one particular direction. Increases in NZ have been considered as indicative of injury to osteoligamentous tissue [8, 28, 29]. This concept applied to a cage construct may provide a quantitative assessment of construct laxity and suggest possible osteoligamentous injuries/ruptures. Furthermore, an irregular lumbar endplate shape as described by others [10], and from an ongoing study in our laboratory [43], can certainly influence cage anchorage and cage-endplate micromotion, if no optimal cage contact surface exists.

The NZ of a cage construct demonstrated in our study sensitivity to the cage wedge angle and size. A wedge angle may permit a better cage-endplate surface match with minimal endplate injury, while large cage dimensions may increase the contact area. The cage design characteristics may decrease NZ by improving cage anchorage and reducing osteoligamentous strains beyond the elastic region that lead to injury/rupture. The combination of cage features such as a large lateral dimension and height allow tensioning of remaining ligaments and annular tissue, which can contribute to the reduction of ROM in lateral bending. This mechanism has already been described as the “distraction-compression” by Bagby [2]. It is not known, however, whether the sustained osteoligamentous tensioning may create strains that in the long run can lead to subsequent tissue injury/rupture. Further studies are needed to characterize the morphology of lumbar endplates for an optimal cage design.

Assuming sufficient cage-endplate contact at 600 N axial compressive load, the cage ‘pull-out’ force can indicate how well teeth designs anchor and resist shear forces. Thus, cages with higher resistance to ‘pull-out’ forces are probably better anchored within the interbody space. The

cage material onto which a particular teeth design is fabricated appears to affect the cage’s ability to anchor. The carbon fiber saw teeth of the I/F cage did not provide as high resistance to ‘pull-out’ forces as the titanium saw teeth of the ScrewCage or the titanium serrated teeth of the SynCage (short teeth) and TIS (long teeth) cages. In addition, the resistance to ‘pull-out’ forces of each bilateral BAK cylinder (642 ± 176 N) was similar to the I/F; this is also indicative of incomplete anchorage. It should be noted, though, that the axial load transmitted through each cylinder was half that experienced by other cages, since two cages were inserted in each interbody space. Similar ‘pull-out’ forces have been reported by Rapoff et al. [37] for the BAK cage (650 ± 106 N). The presence of teeth on a cage has been shown to increase shear resistance to ‘pull-out’ forces [17], but more studies are needed to specifically address the effect of different teeth designs on initial segmental stability.

The performance of individual cage constructs

Stand-alone interbody cages are supposed to anchor onto adjacent endplates to provide segmental ROM reductions and remove any strains that could lead to injury/rupture of osteoligamentous tissue by decreasing NZ. Increases in segmental NZ combined with decreases or no change in respective ROM suggest that strains beyond the elastic region experienced by osteoligamentous tissue were responsible for providing segmental stabilization. This was a general finding observed for all stand-alone cages in some of the movements. Tissue rupture may be evident if an increase in segmental NZ was combined with an increase in respective ROM, such as the increase observed for the TIS in axial rotation (15%). Finally, no change or decrease in segmental NZ and respective ROM likely implies cage anchorage. The ROM reductions observed for the ScrewCage construct in axial rotation (–44%) and lateral bending (–76%), as well as those of the I/F in flexion/extension (–37%) and lateral bending (–59%) were indicative of cage anchorage. The NZ during the respective loading directions was not increased from intact. In fact, during lateral bending the NZ was actually decreased for these cage constructs (ScrewCage: –30%; I/F: –19%).

The threading mechanism used for the BAK construct appears not to provide anchorage during flexion/extension. Nibu et al. in two independent studies [26, 27] showed a significant NZ increase during flexion/extension for the BAK cage when compared to a BAK plug with no threads. The lack of a wedge angle may hinder uniform threading of this cage and cause the failure observed, as suggested by others [3]. The ScrewCage construct similarly failed to reduce NZ during flexion/extension (123%), but to a lesser extent than the BAK construct, probably due to the presence of a wedge angle.

The efficacy of a stand-alone cage construct

Stand-alone cages were overall effective in significantly reducing the segmental motion (ROM) in flexion/extension (−63%) and lateral bending (−69%) and marginally in axial rotation (−23%). The residual ROM present in all cage constructs suggests the presence of micromotion at the cage-endplate interface. The amount of micromotion (with no compromise in biologic fusion) that can be afforded at the cage-endplate interface is not known. In a study where a cage prototype was implanted in baboons [25], fibrous tissue was shown to develop around the cage. The authors believed this finding was due to post-operative cage micromotion. Pilliar et al. [36] studied the effect of micromotion on bone ingrowth into porous surfaced implants, and found that while small micromotion of up to 28 μm does not affect bone ingrowth, large micromotion of over 150 μm can produce fibrous tissue development at the implant-endplate interface. Micromotion might in fact be beneficial to biologic fusion, provided it is not excessive.

Contrary to the overall ROM reductions, a significant overall increase in NZ was present for all loading directions (axial rotation: 98%; flexion/extension: 109%; lateral bending: 53%). Muscle contraction, which is expected to reduce NZ [51], was absent in the cadaveric model. Clinically, an increase in NZ may depict failure of an FSU to sustain appropriate alignment while supporting physiological loads, thus indicating potential directions of segmental instability [8, 28, 29] that may lead to permanent deformity.

If increases in NZ or micromotion at the cage-endplate interface are of concern, then our findings suggest supplementing an ALIF cage with posterior fixation. PLIF cages supplemented with pedicle screw fixation have shown

better reductions in both NZ [47] and ROM [20] when compared to stand-alone PLIF cages, suggesting decreased osteoligamentous injury/rupture strains and decreased cage micromotion. Furthermore, ALIF cages combined with either translaminar [38] or transarticular [49] fixation have also shown reduced ROM compared to stand-alone ALIF cages. In combination with an ALIF cage, the strength of these fixation systems is perhaps inferior to that of a pedicle screw system, but the surgery is less invasive and even a percutaneous procedure is feasible. However, no biomechanical study has determined the effectiveness of such systems in reducing NZ.

Conclusion

The performance of stand-alone ALIF cage constructs generally increased the NZ in any loading direction, suggesting potential directions of *initial* segmental instability that may lead to permanent deformity. Differences in NZ detected between cage constructs in flexion/extension and lateral bending were attributed to the geometry mismatch between cage and endplate, which did not allow optimal cage anchorage. Stand-alone cage constructs reduced ROM effectively, but the residual ROM present indicates the presence of micromotion at the cage-endplate interface. Cage design characteristics seem to have an effect on initial stability and need to be further studied, while the cage ‘pull-out’ force was higher for cages featuring a sharp teeth design. Finally, the relevance of observed increases in NZ and residual ROM with regards to positive fusion outcome is unclear.

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