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Lumbar lateral interbody cage with plate augmentation: in vitro biomechanical analysis

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Abstract Many studies have concluded that stand alone cages provide limited stabilization to the spine, and this primary stabilization decreases postoperatively due to various factors. A supplemental fixation may, therefore, be needed to improve the stability. Extensive biomechanical analysis was performed in the present study to further evaluate the stabilization achieved by a laterally inserted cage and the role of an anterior lateral supplemental fixation. Eight human cadaver functional spinal units were subjected sequentially to four different test conditions: (1) intact, (2) instrumented laterally with a long cylindrical threaded cage, (3) the same cage supplemented with a lateral fixation plate, the plate being firmly connected to the cage, and (4) removal of the connection between the plate and the cage. Pure moments were applied to each specimen in a quasi static manner, ranging from -7 Nm to 7 Nm in flexion/extension, lateral bending and axial rotation. Three-dimensional segmental motions were simultaneously recorded under each loading condition. Statistical analysis was carried out on the motion parameters, including the range of motion (ROM) and the neutral zone (NZ). Inter-group comparisons were made using the Friedman test and the Wilcoxon test. The results showed that the stand alone lateral cage provided stabilization by increasing seg-

mental stiffness above that of the intact spine. The stiffness increase ratios were: 1.6 in flexion/extension ($P=0.07$), 1.3 in lateral bending ($P=0.4$) and 1.0 in axial rotation ($P=0.67$). A supplemental plate provided significant reinforcement of the stabilization. The stiffness increase ratios relative to the intact spine were: 3.1 in flexion/extension ($P=0.012$), 5.0 in lateral bending ($P=0.012$) and 2.3 in axial rotation ($P=0.012$). After removal of the connection between the cage and the plate, the stiffness ratios were: 2.7 in flexion/extension ($P=0.027$), 4.6 in lateral bending ($P=0.027$) and 2.1 in axial rotation ($P=0.027$). Globally, the cage alone increased the segmental stiffness above that of the intact spine by a factor of 1.1 ($P=0.39$), with the supplemental plate, segmental stiffness increased by a factor of 3.1 ($P<0.01$), and the unconnected cage/plate increased stiffness by a factor of 3.0 ($P=0.02$). Supplemental fixation of the lateral cage with an anterolateral plate was thus shown to provide significant additional stabilization in all directions, which may potentially compensate for the postoperative decrease in segmental stability.

Keywords Lumbar spine · Interbody fusion · Cage · Plate fixation · Biomechanical study

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Introduction

Interbody fusion cages are used to stabilize the spine and to promote bony fusion between two vertebrae [2]. A main requirement in achieving the fusion is the need to obtain adequate stability and maintain it during a period sufficient for bone consolidation [11, 12, 17]. Cage insertion provides an immediate segmental stabilization of the spine, by reducing the intervertebral mobility, although the stabilizing effect varies depending on the surgical approach [12, 19, 20]. Posterior cage insertion reduces the mobility in flexion and in lateral bending, but not in extension or axial rotation [9]. Anterior cage insertion has a better stabilizing effect in axial rotation and in lateral bending than posterior insertion, but neither provides significant stabilization in extension [9, 12, 14, 20]. Generally, the surgical approach destroys either the anterior or the posterior tension band of the spine [1], which causes destabilization, particularly in extension. Moreover, the disc distraction may also result in instability in extension and in axial rotation. The anterolateral insertion of a longer cage, as proposed by Le Huec et al. [7] and McAfee et al. [10], preserves the anterior longitudinal ligament and the posterior supporting elements of the spine. However, it appears that a lack of stability remains in extension and axial rotation [19].

Theoretically, interbody fusion cages provide a primary stabilization to the spine, by distracting the annulus fibers to create a peripheral tension band [3, 11, 14, 15, 18]. However, this tension band effect decreases gradually

along with the interbody fusion, which is a concomitant multi-factorial process: the bone creeping substitution [17], the cage settling into the vertebral endplates due to the repetitive load [6], the loosening of the tension of the annulus fibers due to the viscoelastic property [6], the bone density change [5, 9], etc. Generally, bony fusion may occur if stability is maintained [11, 12, 17], whereas loss of stability before the fusion will probably lengthen the fusion process or result in non-union. Many authors have suggested the utilization of supplementary fixations to reinforce the stability, especially in extension [9, 14, 15]. So far, no study has been performed to investigate the stabilizing effect of laterally inserted cages combined with a supplementary fixation. The purpose of the present study is therefore to evaluate, from a biomechanical standpoint, the stabilizing effects of a laterally inserted cage and the role of lateral supplemental fixation in reinforcing the stability. The clinical relevance of this study lies in the acquisition of further knowledge about the stability of the spine following an interbody fusion procedure, which may help physicians determine the appropriate surgical strategy.

Materials and methods

Specimen preparation

Eight human cadaveric lumbar functional spine units (FSU) were used in this study. These specimens were harvested from four fresh cadavers, ranging in age from 21 to 41 years; they were normal

Fig. 1 **A** Fixation of the vertebra in the test machine. **B** The stand alone cage is inserted into the disc space (1 = cage; 2 = disc). **C** Lateral view of the functional spine unit (FSU), showing a Butterfly plate fixed on the spine with screws (1 = disc). **D** The Butterfly system on a plastic spine model

Fig.2 Global view of the test machine

Fig.3 Typical load-displacement curve, recorded in a complete loading cycle

and without spine deformity. The FSUs were four L4–5 and four L2–3. The specimens were carefully dissected to remove all muscles while preserving the ligamentous and bony structure. They were then sealed in a plastic bag and stored at -80°C . Prior to testing, the specimens were fully thawed at room temperature, and kept moistened with saline. The lower half of the lower vertebra

was embedded in a low-melt-point alloy (MCP 70, MCF, Paris, France) with the mid-plane of the disc horizontally aligned. Before embedding it, several screws were fixed in the lower vertebra to improve the fixation of the vertebra in the alloy (Fig. 1). Care was taken to keep the specimens moist throughout the tests.

Test apparatus and measurement

A 2TM testing machine (ENSAM, Paris, France), specially designed for biomechanical testing of spine, was used in this study (Fig. 2). A long driving arm was rigidly attached to the upper vertebra. The moment loads were applied via a double pulley mechanism to the driving arm in flexion/extension, bilateral bending, and axial rotation. The loading was carried out in a quasi-static manner, with 1-Nm increments at 1 min intervals. Two stirrups were fixed to the vertebrae; these were equipped with the sensors for monitoring the translation and rotation movements with respect to the base. All movements (six degrees of freedom) of the upper vertebral body with respect to the lower vertebra were simultaneously calculated and recorded via a data acquisition system. The system error of the measurements with this machine was estimated to be below 0.5° in rotation and below 0.5 mm in translation. In all cases, the load was applied in a complete loading-unloading cycle. Figure 3 shows a typical load-displacement curve recorded in the flexion/extension direction during a complete loading and unloading cycle.

Test protocol and experimentation

Each specimen was tested sequentially in the four following configurations:

1. *Intact spine (Intact)*. The specimen was tested in an intact state under three loading conditions: flexion/extension, lateral bending, and axial rotation. Two pre-load cycles were applied before each loading, to minimize the effect of the viscous component in the viscoelastic response. Data were collected during the third loading cycle. As recommended [21], the loading ranged from 7 Nm to -7 Nm, starting and ending in the neutral position with zero load. The neutral zone (NZ) was defined as the difference in displacement at zero load for both directions separately. The unconstrained method was used during the entire test [4].
2. *Stabilized with a lateral stand alone cage (+C)*. The specimen was then instrumented with a single long Interfix cage

Fig.4 Schematic of the Butterfly fusion system

(Medtronic Sofamor Danek, Memphis, USA), which is a titanium cylindrical threaded cage. The cage was inserted from a lateral direction by an experienced spine surgeon, using appropriate insertion tools and following the recommended process (Fig. 1). The cage size was adapted to the disc height to obtain the optimal disc distraction. Immediately after the cage insertion, the specimen was re-mounted to the test machine and tested under the previously described loading conditions.

3. *Cage supplemented with Butterfly plate (+C+P)*. The specimen was at this stage supplemented with a Butterfly plate (Medtronic Sofamor Danek, Memphis, USA), which is an anterolateral plate system, made from a titanium alloy (Fig. 4). The Butterfly plate was installed by the same surgeon, using four bone screws anchored into the adjacent vertebral bodies (two in each vertebra). The plate was placed onto the domed end of the cage, and was firmly connected to it via a connection nut. The specimen was then tested again under the same loading conditions.
4. *Connection between the cage and the plate uncoupled (+C+P-N)*. The connection nut was removed in this configuration. The specimen was re-tested under the same loading conditions.

Statistical analysis

For each specimen under each loading condition and test configuration, the range of motion (ROM) and the NZ values in all six directions were determined from the resulting curves.

The ROM values were then regrouped by loading conditions: flexion/extension, lateral bending and axial rotation. For each loading condition group, the ROM value from each specimen in each test configuration group was divided by its respective intact ROM value. This normalization process was done to reduce the error from the variation of the specimens.

Statistical analysis was carried out on the normalized ROM data between the test configuration groups: intact, +C, +C+P and +C+P-N. In the present study, there is no biomechanical or clinical significance to comparisons between loading groups (e.g., lateral bending vs torsion).

Considering the paired and non-parametric characteristics of the data, intergroup analysis was made using the Friedman test in each loading condition group (composed of four test configuration groups). In the case of a significant result, all combinations of the three test configuration groups were then compared using the Friedman test. If all comparisons of the second step had significant results, the Wilcoxon test was used to compare each pair of test configuration groups with $\alpha=0.05$. As we were using closed testing procedures, the significance level was set at $P<0.05$, and no adjustment was needed.

Due to the limited number of the specimens and the wide variations in the measurements from the biomechanical experimental

tion, all the quantified statements in the present study should be considered to indicate trends, and are of limited value as a basis for comparison.

Stiffness

The nominal segmental stiffness (S) for each loading condition is defined as the inverted median of the normalized ROM values (R) in each test configuration group ($S=1/R$). The stiffness increase ratio (r) between two test configurations is defined as the stiffness of the tested FSU divided by its stiffness in the intact state. For example, for the configuration +C+P:

$$r = S_{+C+P} / S_{Intact} = R_{Intact} / R_{+C+P}$$

This value, which is without units, indicates the proportional increase of the stiffness.

Results

The measurements of ROM values obtained in the loading directions and their normalized data are shown in Table 1 and Table 2. Figure 5 presents, in standard box plots, the statistical values (medians and range percentiles) of the normalized data in all three loading directions. A global ROM, defined as the mean ROM values taken from each specimen under three loading directions, is also presented in Fig. 5, in order to simulate a combined loading condition. No significant asymmetry was observed between the loading and unloading curves (less than 5%). The Friedman test was conducted on each loading condition group, and the results demonstrated a significant difference between the test configuration groups (flexion/extension: $P=0.0006$, lateral bending: $P=0.0001$, axial rotation: $P=0.0009$, and combined loading: $P=0.0004$). The sub-set Friedman tests also showed significant results (flexion/extension: $P=0.0015$, 0.0008 , 0.0015 , lateral bending: $P=0.022$, 0.0008 , 0.0022 , axial rotation: $P=0.025$, 0.008 , 0.0051 , global: $P=0.0022$, 0.0005 , 0.0022). Therefore, the Wilcoxon test was performed between each pair of test configuration groups.

Table 1 Measurement of the range of motion (ROM). All values are presented in degrees (+C cages, +C+P cage connected to the plate, +C+P-N removal of the connection nut)

Specimen	Flexion/extension				Lateral bending				Axial rotation			
	Intact	+C	+C+P	C+P-N	Intact	+C	+C+P	C+P-N	Intact	+C	+C+P	C+P-N
S1	14.8	14.5	13.0	13.8	12.0	13.3	9.4	10.7	6.7	6.3	3.9	4.5
S2	10.3	12.3	3.0	3.5	12.9	17.4	2.4	2.7	4.8	7.4	1.7	2.1
S3	9.5	6.3	4.3	4.5	12.9	7.1	2.7	3.0	1.5	2.5	1.3	1.5
S4	8.3	9.6	3.2	3.3	10.6	16.8	1.3	1.4	1.7	3.9	0.7	0.8
S5	13.9	6.8	3.5	3.5	11.6	6.8	3.0	3.0	2.6	2.0	1.1	1.2
S6	10.0	5.8	3.4	4.0	10.7	9.8	3.0	3.3	2.2	2.3	1.0	1.0
S7	11.8	2.7	2.0	2.0	9.0	2.5	0.9	1.0	4.4	1.7	1.0	1.4
S8	6.3	2.5	1.8	1.8	8.5	4.4	1.4	1.4	0.9	0.6	0.5	0.5

Table 2 Measurement of the range of motion (ROM) normalized to intact values. All measurement values are presented in degrees

Specimen	Flexion extension				Lateral bending				Axial rotation			
	Intact	+C	+C+P	C+P-N	Intact	+C	+C+P	+C+P-N	Intact	+C	+C+P	+C+P-N
S1	1.00	0.98	0.88	0.93	1.00	1.11	0.78	0.89	1.00	0.94	0.58	0.67
S2	1.00	1.19	0.29	0.34	1.00	1.35	0.19	0.21	1.00	1.54	0.35	0.44
S3	1.00	0.66	0.45	0.47	1.00	0.55	0.21	0.23	1.00	1.67	0.87	1.00
S4	1.00	1.16	0.39	0.40	1.00	1.58	0.12	0.13	1.00	2.29	0.41	0.47
S5	1.00	0.49	0.25	0.25	1.00	0.59	0.26	0.26	1.00	0.77	0.42	0.46
S6	1.00	0.58	0.34	0.40	1.00	0.92	0.28	0.31	1.00	1.05	0.45	0.45
S7	1.00	0.23	0.17	0.17	1.00	0.28	0.10	0.11	1.00	0.39	0.23	0.32
S8	1.00	0.40	0.29	0.29	1.00	0.52	0.16	0.16	1.00	0.67	0.56	0.56
Median	1	0.62	0.32	0.37	1	0.75	0.20	0.22	1	0.99	0.44	0.47
Max	1	1.19	0.88	0.92	1	1.58	0.78	0.89	1	2.29	0.87	1.00
Min	1	0.23	0.17	0.17	1	0.28	0.1	0.11	1	0.39	0.23	0.32

Fig. 5 Box plots of normalized range of motion (ROM) in different load directions: flexion/extension, lateral bending, and axial rotation. The global ROM takes the mean values of ROM from each specimen in all three loading directions

Flexion/extension

In flexion/extension, lateral cage insertion provided a primary stabilization greater than that of the intact spine, with a stiffness increase ratio of 1.6, but the difference was not statistically significant ($P=0.07$). The addition of a supplemental plate reinforced the stability, resulting in a stiffness increase ratio of 3.1 ($P=0.012$) relative to the intact spine and 1.9 ($P=0.012$) relative to the cage alone. The non-connected cage and plate resulted in a stiffness increase ratio of 2.7 ($P=0.027$) relative to the intact spine – the stiffness in this direction was 14% less than the equivalent value for the connected cage/plate configuration.

Lateral bending

In lateral bending, the increase in primary stabilization over the intact spine achieved with the cage alone was not statistically significant; the stiffness increase ratio over the intact spine was 1.3 ($P=0.4$). Addition of the supplemental plate reinforced the stability significantly, with stiffness increase ratios of 5.0 ($P=0.012$) relative to the intact spine and 3.8 relative to the cage alone ($P=0.012$). The non-connected cage and plate configuration resulted in a stiffness increase ratio of 4.6 ($P=0.028$) relative to the intact spine – a stiffness value 9% below the equivalent for the connected cage/plate configuration.

Axial rotation

In axial rotation, no stability change was observed following cage insertion, the stiffness increase ratio was 1.0 ($P=0.67$) relative to the intact spine. The supplemental plate increased stiffness by a factor of 2.3 over the value for the intact spine ($P=0.012$), and by a factor of 2.3 over the value for the cage alone ($P=0.012$). The non-connected cage and plate configuration had a stiffness increase ratio of 2.1 ($P=0.028$) relative to the intact spine – its stiffness was 6% less than that of the connected cage/plate configuration.

Global stability

Globally, the cage alone in this study provided poor stabilization under the combined loading condition; the stiffness increase ratio was 1.1 over the intact spine, with great uncertainty ($P=0.39$). The supplemental plate considerably reinforced the stability, with a stiffness increase ratio of 3.1 relative to the intact spine ($P<0.01$), and 2.8 relative to the cage alone ($P=0.02$). The non-connected cage and plate resulted in a stiffness increase ratio of 3.0 ($P=0.03$) relative to the intact spine – a stiffness value 3% below the equivalent for the connected cage/plate configuration.

Discussion

The present study showed that a single laterally inserted threaded cage increased the stiffness of the FSU in most cases, and the supplemental plate system significantly reinforced the primary stabilization in all directions. As the plate is secured by the bone screws, the stability augmentation is not directly affected by annulus loosening and bone creeping substitution. The supplemental plate can potentially compensate the postoperative decrease of stability. Early clinical results with the Butterfly plate [8] have confirmed the benefits of the supplemental plate in the improvement of the fusion rate.

Stand alone cages have been shown to provide poor axial rotational stabilization, regardless of the insertion direction [3, 4, 11, 12, 14, 18, 19, 22], and this was confirmed again by the present study. In fact, the lateral stand alone cage did not provide any stabilization to the FSU in axial rotation (stiffness increase ratio: 1.0 over intact spine). However, when a supplemental plate was used, the FSU stiffness ratio increased to 2.3 (130% increase).

A laterally inserted cage is believed to be more stabilizing in extension, because of the preservation of the anterior and the posterior tension bands of the spine. This is

supported by the present study, as no significant asymmetry was observed in the flexion/extension curves.

Like all osteosynthesis devices, the utilization of the supplementary plate risks causing a stress shielding effect and additional complications. It is therefore important to choose an appropriate plate design with appropriate stiffness of the plate according to the given clinical situation and the interbody device used, in order to reap the greatest benefit of the supplemental fixation and reduce potential risks.

There is a notable variation in the results from in vitro studies regarding stiffness of the FSU [9, 13, 14, 15, 20, 22]. This is partly explained by the absence of a clear and standard definition of FSU stiffness [16, 22]. The slope calculation usually results in poorly reliable values due to the high variations of the measurements in the biomechanical test. In the present study, stiffness was defined as the inverted median of the normalized ROM measurements.

It was observed in the present study that the stiffness increase provided by the stand alone cage was highly uncertain ($P=0.4$) compared to the values for the supplemental plate ($P<0.01$). This is probably related to the anatomical variations of the annulus and the endplates in responding to the distraction [3, 15] during the cage insertion, and may therefore indicate a lack of reproducibility of the stabilization with stand alone cages, even if the cage is inserted by the same surgeon using the same technique.

The results of an in vitro study do not directly correlate with the clinical outcome, as they only reveal the in vivo situation at an immediately postoperative time, without taking into account the biological effect in the healing process.

The Butterfly plate was designed to be connected to the cage in order to facilitate plate installation and improve the integrity of the construct. The present study showed that there was not a very great difference in stabilization effect according to whether the plate was connected to the cage or not.

Conclusion

The lateral stand alone cage provides primary stabilization to the FSU, but the axial rotation stability is very poor, which is similar to the stand alone cages inserted from either an anterior or a posterior approach. A supplementary plate significantly reinforces the stabilization in all directions, including axial rotation. The utilization of a supplemental plate is therefore recommended if the stability provided by a stand alone lateral cage is considered unsatisfactory.

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