# IN WHICH PATIENTS IS IT POSSIBLE TO PERFORM STANDALONE LATERAL LUMBAR INTERBODY FUSION WITHOUT CAGE SUBSIDENCE?

## *EM QUAIS PACIENTES É POSSÍVEL REALIZAR FUSÃO INTERSOMÁTICA LOMBAR POR VIA LATERAL SEM SUBSIDÊNCIA DO CAGE?*

## *CUÁLES SON LOS PACIENTES QUE PUEDEN SER SOMETIDOS A FUSIÓN INTERSOMÁTICA LUMBAR POR VÍA LATERAL SIN SUBSIDENCIA DEL CAGE?*

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## ABSTRACT

Objective: To identify the factors related to the non-occurrence of cage subsidence in standalone lateral lumbar interbody fusion procedures. Methods: Case-control study of single level standalone lateral lumbar interbody fusion (LLIF) including 86 cases. Patients without cage subsidence composed the control group (C), while those in the subsidence group (S) developed cage subsidence. Preoperative data were examined to create a risk score based on correlation factors with S group. The proven risk factors were part of an evaluation score. Results: Of the 86 cases included, 72 were in group C and 14 in group S. The following risk factors were more prevalent in group S compared to C group: spondylolisthesis (93% vs 18%; p<0.001); scoliosis (31% vs 12%; p=0.033); women (79% vs 38%; p=0.007); older patients (average 57.0 vs 68.4 years; p=0.001). These risk factors were used in a score (0-4) to evaluate the risk in each case. The patients with higher risk scores had greater subsidence (p<0.001). Scores ≥2 were predictive of subsidence with 92% sensitivity and 72% specificity. Conclusions: It was possible to correlate the degree of subsidence in standalone LLIF procedures using demographic (age and gender) and pathological (spondylolisthesis and scoliosis) data. With a score based on risk factors and considering any score <2, the probability of non-occurrence of subsidence following standalone LLIF (negative predictive value) was 98%.

Keywords: Spine; Lumbar vertebrae; Spinal fusion; Complications; Risk factors; Patient selection.

## RESUMO

*Objetivo: Identificar os fatores relacionados a não ocorrência de subsidência de cage em procedimentos de fusão lombar intersomática por via lateral em um só nível. Métodos: Estudo de caso controle em fusão intersomática lombar por via lateral (LLIF) em um só nível, incluindo 86 casos. Os pacientes sem subsidência do cage formaram o grupo controle (C), enquanto os do grupo subsidência (S) desenvolveram subsidência do cage. Os dados pré-operatórios foram examinados para criar um escore de risco com base em fatores de correlação com o grupo S. Os fatores de risco comprovados fizeram parte de um escore de avaliação. Resultados: Dos 86 casos incluídos, 72 estavam no grupo C e 14 no grupo S. Os seguintes fatores de risco foram mais prevalentes no grupo S com relação ao grupo C: espondilolistese (93% vs. 18%; p < 0,001); escoliose (31% vs. 12%; p = 0,033); mulheres (79% vs. 38%; p = 0,007); pacientes idosos (média de 57,0 vs. 68,4 anos; p = 0,001). Esses fatores de risco foram utilizados em um escore (0-4) para avaliar o risco em cada caso. Os pacientes com escores mais altos de risco tiveram maior subsidência (p < 0,001). Os escores ≥ 2 foram preditivos de subsidência com sensibilidade de 92% e especificidade de 72%. Conclusões: Foi possível correlacionar o grau de subsidência em procedimentos LLIF em um só nível com a utilização de dados demográficos (idade e sexo) e patológicos (espondilolistese e escoliose). Com um escore baseado em fatores de risco e considerando qualquer pontuação <2, a probabilidade de não ocorrência de subsidência depois de LLIF em um só nível (valor preditivo negativo) foi de 98%.*

*Descritores: Coluna vertebral; Vértebras lombares; Fusão vertebral; Complicações; Fatores de risco; Seleção de pacientes.*

## RESUMEN

*Objetivo: Identificar los factores relacionados con la ausencia de subsidencia de cage en los procedimientos de fusión intersomática lumbar por vía lateral en un solo nivel. Métodos: Estudio de caso–control en la fusión intersomática lumbar por vía lateral (LLIF) en un solo nivel, incluyendo 86 casos. Los pacientes sin subsidencia del cage formaron el grupo control (C), mientras que el grupo de subsidencia (S) desarrolló subsidencia del cage. Los datos preoperatorios fueron examinados para crear una puntuación de riesgo basada en factores de correlación con el grupo S. Los factores de riesgo comprobados formaron parte de una puntuación de evaluación. Resultados: De los 86 casos incluidos, 72 formaron el grupo C y 14 el grupo S. Los siguientes factores de riesgo son más prevalentes en el grupo S con respecto al grupo C: espondilolistesis (93% vs. 18%, p <0,001); escoliosis (31% vs. 12%, p = 0,033); mujeres (79% vs. 38%, p = 0,007); ancianos (media de 57,0 a 68,4 años; p = 0,001). Estos factores de riesgo se utilizaron en una puntuación (0-4) para evaluar el riesgo en cada caso.*

Study conducted at the Universidade Federal de São Paulo (UNIFESP), Departamento de Diagnóstico por Imagem, São Paulo, SP, Brazil.
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*Los pacientes con puntuaciones más altas de riesgo tuvieron mayor subsidencia (p < 0,001). Las puntuaciones ≥ 2 fueron predictivas de la subsidencia con una sensibilidad del 92% y una especificidad del 72%. Conclusiones: Se ha podido relacionar el grado de subsidencia en los procedimientos LLIF en un solo nivel con el uso de los datos demográficos (edad y sexo) y patológicos (espondilolistesis y escoliosis). Con una puntuación basada en factores de riesgo y considerado un puntaje < 2, la probabilidad de no ocurrencia de subsidencia después de LLIF en un solo nivel (valor predictivo negativo) fue del 98%.*

*Descriptores***:** *Columna vertebral; Vértebras lumbares; Fusión vertebral; Complicaciones; Factores de riesgo; Selección de paciente.*

## INTRODUCTION

Lateral lumbar interbody fusion (LLIF) has evolved into an effective and less invasive treatment option adopted for different toracolumbar conditions.[1–3] Biomechanical features of LLIF constructions provide better rigidity than other constructions.[4,5] It uses large diameter, hollow spacers that can engage the peripheral margins of the endplate, the design and positioning of which seems to be superior to others.[6] In conventional lumbar fusion techniques, the interbody cage is always supplemented by internal fixation. In LLIF, the anterior and posterior longitudinal ligaments (ALL and PLL, respectively) are preserved. For this reason, a stand-alone construction can provide good stabilization, comparable to a TLIF supplemented with pedicle screws.[4] Good results and complications from non-supplemented LLIF have been reported;[7–11] however, the ideal indication is not clear.

Cage settling and vertebral body fracture are potential and significant complications. When using LLIF standalone constructions, this risk may be even higher. The severity of cage subsidence is correlated with its extension.[12] The consequences may range from a lack of clinical symptoms, to loss of disc height, loss of segmental angulation, acute low back pain, restenosis, or even a fracture of the adjacent vertebral bodies.[12–16] Prevention of cage subsidence is, therefore, an issue of great research interest.

Some study groups have recently discovered that the use of wider LLIF cages results in more stable biomechanical constructions[4] and decreased subsidence rates.[12,14,17] Based on this data, the use of 22mm or even wider cages is now recommended. Even more recent evidence has revealed that impaired bone quality[18] and inadvertent intraoperative endplate damage[19,20] can contribute to a poorer outcome. Despite the lack of research on cage settling issues, the case selection for standalone LLIFs that do not evolve to subsidence needs elucidation; the objective of this work was to identify the factors correlated with lack of cage subsidence in standalone LLIF procedures.

## METHODS

A single center retrospective case-control study with a database spanning the years 2008 to 2015. This observational study was reviewed by the research ethics review board of our institution. The informed consent was waived because it was a retrospective research involving medical records. Inclusion criteria: single-level stand-alone lumbar LLIF. Exclusion criteria: cages with 18mm anteroposterior dimension (due to their demonstrated inferiority;[12,14,17] any previous lumbar arthrodesis/arthroplasty surgery; any kind of supplementation (posterior/lateral/anterior). The interbody cages were packed with synthetic bone substitute.

The patients were grouped into Control group (C) and Subsidence group (S), according to the degree of interbody cage settling. Subsidence grading was evaluated in 3-month lateral orthostatic radiographs and classified on a 4-point scale (0-III) described previously[12] (Grade 0, 0%–24%; Grade I, 25%–49%; Grade II, 50%–74%; and Grade III, 75%–100% collapse of the level). The choice of the 3-month time point was based on a previous 12-month follow-up study in which patients who presented subsidence at the 12-month time point already presented a detectable subsidence in the 3-month evaluation. The C group comprised grade 0 and I cases (low-grade), while the S group had the grades II and III cases (high-grade), this division was based on the clinical impairment (pain outcome) that had already been demonstrated[12] in the S group, in comparison with the C group.

The preoperative diagnosis and images were reviewed, to identify the presence of spondylolisthesis and scoliosis. The intraoperative fluoroscopy images and surgical reports were reviewed aiming to identify the occurrence of unintentional anterior longitudinal ligament (ALL) rupture or cortical bone breaks during the preparation of the intervertebral space. These cases were excluded from the analysis. The anteroposterior dimension and height of the cage were measured. The influence of each factor in each subsidence grade subgroup was analyzed. A risk score was established based on preoperative factors with significant correlation with cage subsidence.

Statistical analyses were performed using SPSS software (SPSS, Version 10, SPSS, Chicago, Ill., USA). The Mann-Whitney U test was used for unpaired data, analysis of variance (ANOVA), Fischer's exact test, and the Chi-square test with Pearson's correlation were used with an alpha of 0.05.

## RESULTS

Of 719 cases treated with LLIF, 100 stand-alone LLIF cases were identified; 14 were excluded due lack of images, and 86 cases were eligible for analysis (86 levels). Average age of 58.8 years(25-84, range), mean body mass index (BMI) of 27.9 (19-49, range), 38 were females (44%). The surgeries involved L4L5 in 83% (71/86) of the total cases (L1L2, 1 case; L2L3, 5 cases; L3L4, 8 cases; L5VT, 1 case). Twenty-six cases (30%) had spondylolisthesis (grade I), 13 cases (15%) had degenerative scoliosis, and the remainder had either degenerative disc disease (DDD), instability and/or stenosis.

Subsidence analysis in the 3-month follow-up images revealed the following results: grade 0= 62 cases (72%); grade I= 10 cases (12%); grade II= 10 cases (12%); grade III= 4 cases (5%). The C group had 72 cases (84%) and the S group had 14 cases (16%). Surgical revision was necessary in seven cases from the S group (50%) and only 1 case from the C group (1%).

The following preoperative factors were more prevalent in the S group than in the C group: (Table 1) spondylolisthesis (93% vs 18%; $p<0.001$); scoliosis (31% vs 12%; $p=0.033$); female sex (79% vs 38%; $p=0.007$); older patients (average 57 vs 68 years; $p=0.001$). BMI and surgery at L4L5 did not show statistical difference.

Surgical factors were also compared between groups. Non-intentional ALL rupture occurrence was too low in this sample, and no significance was seen (1 vs 1 case; $p=0.301$). Another factor that did not show a statistical trend for either the S or C group was cage AP dimension ($p=0.351$; 22 vs 24 vs 26mm; Table 2). The cage height was observed to be higher in the S group than in the C subset (9.8 vs 10.9mm; $p=0.035$), while in the S group 50%, of the cases had 12mm cages and only 22% had 12mm cages in the C group.

To investigate whether there was a cumulative effect of the individual risk factors found above, the cases were scored by adding one unit for each risk factor found. The *SCORE* was comprised of the following criteria: female gender; spondylolisthesis; scoliosis; age > 61 years (confidence interval upper bound value from C group = 60.5 years). Minimum *SCORE* = 0 and maximum *SCORE* = 4. Accordingly, it was demonstrated that higher *SCORES* were correlated with higher severity of subsidence. (Table 3; $p<0.001$)

Table 4 shows the association between exposure (*SCORE* ≥ 2) and outcome (subsidence). The specificity and sensitivity of a *SCORE* < 2 for predicting which case would not develop high-grade cage subsidence are 75% and 93%, respectively. So, for any particular positive *SCORE* result (≥2) in our sample, the probability that it is true positive was 42% (positive predictive value; PPV). For any particular negative *SCORE* result (<2), the probability that it is true negative was 98% (negative predictive value; NPV).

**Table 1.** Preoperative risk factors analysis per study subgroup.

| | Study subgroup | | p value |
|---|---|---|---|
| | Control | Subsidence | |
| Age (years) | 57 ± 13 | 68 ± 7 | 0.001* |
| Gender (female) | 38% | 79% | 0.007* |
| Spondylolisthesis | 18% | 93% | <0.001* |
| Scoliosis | 12% | 31% | 0.033* |
| L4L5 | 81% | 93% | 0.447 |
| BMI (kg/m2) | 28 ± 5 | 28 ± 7 | 0.467 |

Values are represented as mean ± standard deviation or absolute incidence within each subgroup. Body mass index (BMI). * statistically significant

**Table 2.** Intraoperative risk factors analysis per study subgroup.

| | Study subgroup | | p value |
|---|---|---|---|
| | Control | Subsidence | |
| Cage AP (mm) | 25 ± 3 | 25 ± 3 | 0.351 |
| Cage HT (mm) | 9.8 ± 2 | 10.9 ± 1 | 0.035* |

Values are represented as mean ± standard deviation or in absolute incidence within each subsidence grade subgroup. Cage height (Cage HT) and cage anteroposterior dimension (Cage AP). * statistically significant

**Table 3.** Score results per subsidence grade and study subgroups.

| | Subsidence grade | | | | p value | Study subgroup | | p value |
|---|---|---|---|---|---|---|---|---|
| | 0 | I | II | III | | Control | Subsidence | |
| SCORE | 1.0 ± 0.9 | 1.7 ± 1.2 | 2.6 ± 0.8 | 3.5 ± 1.0 | <0.001* | 1.1 ± 0.9 | 2.9 ± 0.9 | <0.001* |

Values are expressed as mean ± standard deviation for each subsidence grade subgroup. * statistically significant

**Table 4.** Sensitivity and specificity of the SCORE as a predictor of subsidence.

| | Grade 0/I | | | Grade II/III | | | Total |
|---|---|---|---|---|---|---|---|
| | n | % | | n | % | | |
| SCORE < 2 | 54 | 75% | Specificity | 1 | | | |
| SCORE ≥ 2 | 18 | | | 13 | 93% | Sensitivity | |
| Total | 72 | | | 14 | | | 86 |
| Chi-square analysis | | | | | | | $\chi^1$ = 23.41 |
| | | | | | | | p<0.001 |

## DISCUSSION

Standalone LLIF procedures are feasible, but carry the risk of cage subsidence. Cage selection to prevent subsidence is only now beginning to be understood. The present report shows subsidence risk factors in a retrospective case-control study in a LLIF cohort with only single-level standalone cases. Preoperative risk factors were identified: elderly and female patients, and also diagnoses of scoliosis and spondylolisthesis at the index level. A score based on those factors was applied, to determine in which case a standalone indication would evolve without subsidence. The test showed great sensitivity, with extremely low false negative test results (2%).

Lumbar interbody fusion performed with lateral implants has been shown to be biomechanically superior to other constructions,[4,5] as the larger diameter hollow spacers appear to be favorable for engaging the peripheral margins of the end plate.[6] The good stiffness achieved with lateral wide implants enables standalone constructions to be performed in some cases. However, it remains an off label indication to date. The selection of the appropriate instrumentation option is still a topic of debate. Recently, Tohmeh[21] published a video lecture with a preliminary scoring system to guide the choice of internal spinal fixation modality. Based on a literature review and author's opinion, this algorithm attributes scores according to the severity of the spondylolisthesis, degenerative disc, facet disease and adjacent segment disease.

The occurrence of cage settling generates radiological and clinical consequences. In the radiological field, Tohmeh et al.[17] and Marchi et al.[12] demonstrated loss of both disc and foramen height, decreased lordosis gain, but no negative effects on bone fusion. Inadvertent endplate fracture following lateral cage placement is a fracture that can impair the biomechanical stability.[19] Although there is no congruent data regarding the clinical impact of subsidence,[7,9,16] some groups have found poorer clinical outcomes in short,[12,15] medium[8] and long-term[17] follow-up for subsidence in LLIF. The short-term results were attributed to transient painful micromotion, in addition to pain from the fracture itself. Moreover, along with the loss of correction, restenosis may occur in high-grade subsidence, and there is the need of further direct decompression. Including the results from the current work, the rate of re-intervention due to subsidence varies from 0% to 50%, depending on the supplementation option chosen. Vertebral fracture is rare, but possible.[15] Considering the possible consequences of cage settling, the topic must be better understood in order to avoid subsidence.

The first strong evidence of subsidence prevention in LLIF came from retrospective comparative studies[12,14] which demonstrated that cages with a larger anteroposterior diameter (22 x 18mm) could decrease the rate of cage settling. It is now known that other intraoperative features also influence the occurrence of subsidence: endplate damage during preparation and overdistraction of the disc space. Santoni et al.[19] reported the harmful role of intraoperative endplate damage in a cadaveric model. Accordingly, a clinical study[17] demonstrated that the magnitude of subsidence is lower if the cage does not sink into the endplates during surgery. Taller interbody grafts are correlated with higher distractive and compressive forces in vitro.[22] In clinical practice, we observed more cases with 12mm-height cages in subsidence versus the control group, as was also seen by other reports on LLIF.[17,20] Other possible issues include insufficient contralateral annular release, and improper cage sizing in the lateral dimension, which may result in failure to cover the apophyseal ring.

A significant trend of increasing subsidence rates has been correlated with LLIF with longer constructions[14] and more instable pathologies.[10,11,23] Another pathology-related criterion has been studied in LLIF subsidence: poor bone quality. Similarly to the present study, Tempel et al.[18] conducted a case-control study to analyze bone mineral density (BMD) in cases that evolved with subsidence following LLIF. They found that a DEXA T score of less than -1.0 predicts subsidence, with sensitivity and specificity of 78.3 and 63.2%, respectively. Female sex and age may be potential confounders of the association between osteoporosis and cage subsidence, as the incidence of osteoporosis and osteoporotic fractures increases markedly with age and female sex.[24] Along with poorer bone quality, spinal muscular atrophy could negatively affect cage stabilization and spinal bone mineral density in the elderly postmenopausal population.[25]

Some limitations of this study must be pointed out. (1) The major limitation is inherent to the study design: a retrospective study. However, it is feasible as a preliminary investigation of a suspected risk factor, and sometimes a case-control study is the only ethical way to investigate an association. (2) The study only analyzed single-level constructions. Readers must, therefore, be cautious when extrapolating the conclusions for multi-level fusion. (3) The DEXA scan results were not available for all patients, so they could not be included in the analysis. (4) The results are based in a single-center experience.

## CONCLUSION

The present study correlated cage subsidence in stand-alone LLIF procedures with the following preoperative risk factors: age, gender, spondylolisthesis and scoliosis. With a score based on those risk factors, in our sample, the probability of a particular stand-alone LLIF procedure with a score of <2 evolving without subsidence was 98%. This could be the first step towards the understanding of case selection for LLIF with no internal fixation.

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