

Use of interspinous process devices in primary lumbar discectomy. Does it promote recurrent disc herniation?

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ABSTRACT

Objective: The objective of this study was to determine if discectomy with placement of an interspinous DIAM silicone spacer is associated with a different rate of clinical and radiological recurrent ipsilateral disc herniation compared to discectomy alone. **Materials and Methods:** A prospective, observational, randomized study was performed from May 2009 to May 2013 at our center. Of the 123 patients included in the study, 3 were lost to follow-up, leaving 120 patients for data analysis. All patients were operated on by the same surgical team. Patients received one of two types of treatment. Group A consisted of 30 patients (16 women and 14 men) who underwent discectomy with placement of an interspinous DIAM silicone spacer. Group B was comprised of 90 patients (53 women and 37 men) treated by discectomy alone. **Results:** Discectomy at the L4-L5 level was the most common approach, being performed in 90% (27) of Group A patients and 80% (72) of Group B patients. Group A demonstrated clinical and radiological recurrent disc herniation in 6/30 (20%) patients. Recurrent disc herniation developed in 4/90 (4.4%) Group B patients. One patient underwent surgical revision (1.1%). Both recurrence and surgical revision were significantly higher in Group A ($p = 0.007$ and $p = 0.019$, respectively). **Conclusions:** The benefits of interspinous devices for the treatment of lumbar spinal stenosis secondary to disc herniation are controversial, and this study showed a significant intergroup difference. In this study, patients that underwent discectomy and interspinous spacer placement had higher revision and recurrence rates than discectomy patients that did not receive an interspinous spacer. Interspinous spacers may increase the rate of disc herniation by preserving movement at the level of the original disc herniation and changing the physiologic load. Further studies are needed to corroborate and evaluate these trends. **Key words:** lumbar discectomy, interspinous spacer, recurrent disc herniation.

Level of evidence: III

Dispositivos interespinosos en discectomías lumbares primarias. ¿Favorecen la recurrencia de la hernia de discos?

RESUMEN

Objetivo: Evaluar si la colocación de los dispositivos interespinosos siliconados tipo DIAM favorecen una tasa más alta de recidiva de la hernia discal homolateral clínica y por imágenes comparada con la discectomía pura. **Materiales y Métodos:** Se realizó un estudio prospectivo, observacional, aleatorizado desde mayo de 2009 hasta mayo de 2013, en nuestro Centro. Se evaluó a 123 pacientes, 3 se perdieron en el seguimiento; la muestra incluyó 120 sujetos. Todos fueron operados por el mismo equipo quirúrgico. Se formaron dos grupos: grupo A: discectomía más colocación de dispositivo interespinoso siliconado, 30 pacientes (16 mujeres y 14 hombres), con mayor frecuencia L4-L5 (27 pacientes, 90%) y grupo B: discectomías puras, 90 pacientes (53 mujeres y 37 hombres) con más frecuencia L4 y L5 (72 pacientes, 80%). **Resultados:** Seis de los pacientes del grupo A (20%) tuvieron una recidiva clínica y por imágenes, y 3 (10%) fueron operados nuevamente; en el grupo B, hubo 4 recidivas discales (4,4%), uno fue operado nuevamente (1,1%). Se hallaron diferencias significativas en las tasas de recidiva y reintervención entre los grupos ($p = 0,0073$ y $p = 0,0188$, respectivamente). **Conclusiones:** Los beneficios de los dispositivos interespinosos para tratar el canal estrecho lumbar secundario a hernia de disco son controvertidos, pero en nuestro estudio, se halló una diferencia significativa según el grupo. Al mantener el movimiento del segmento y cambiar ligeramente las cargas fisiológicas aumentarían la tasa de recidiva discal; no obstante, son necesarios estudios con mayor evidencia científica para corroborar estas tendencias.

Palabras clave: Discectomía lumbar pura; dispositivos interespinosos; recidiva discal.

Nivel de Evidencia: III

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INTRODUCTION

Lumbar spine degeneration begins with dehydration and loss of height of intervertebral discs, overloading the facet joints, which are not anatomically designed to withstand a greater load. Therefore, spondylosis and facet hypertrophy develop. There is also loss of tension and structural deterioration of the ligaments of the spine, leading to instability.¹⁻³ Said instability is compensated for by hypertrophy of other structures, such as the ligamentum flavum. In the long run, this results in stenosis of the vertebral and intervertebral foramina. The most common clinical outcome of this cascade of pathophysiological events is lumbar or radicular pain, which is very disabling and difficult to manage.⁴

The conventional surgical approach for chronic lumbar pain of degenerative etiology is spinal fusion, which irreversibly avoids movement of the affected segment. However, despite the fact that, with refinement of the approach, fusion rates of 100% have been achieved, comparable clinical results of pain improvement have not been obtained and, on the contrary, the possibility of developing a condition of the adjacent segment warrants exploration of other treatment options.⁵

This need led to stabilization manoeuvres of the lumbar spine without fusion, i.e. preserving movement; this dynamic stabilization would theoretically prevent a condition of the adjacent segments, improving operating times and reducing postoperative rest. From a biomechanical point of view, it limits extension but doesn't affect flexion, axial rotation or lateral flexion.^{6,7}

In this study, only silicone devices were used. This type of implant is an interspinous cushion that acts as a "stop" mechanism. Its nucleus provides stability during extension, and two independent cords fixed to the spinous processes stabilize the segment during flexion, acting as a tension band. Vertebral arch distraction widens the intervertebral foramen to relieve compression.

According to the literature, the rate of disc recurrence after primary surgery without placement of a silicone interspinous device ranges between 5% and 11%.^{3,8-10}

The objective of this study was to determine if the placement of these type of implants achieves a higher rate of clinical and radiological disc recurrence, compared with discectomy alone.

MATERIALS AND METHODS

From May 2009 to May 2013, a prospective, observational and randomized study (the randomization method to assign the two groups was performed according to the availability of the interspinous implant) in 123 patients undergoing lumbar discectomy in our center; three of them (2.4%) were lost to follow-up. Patients were divided into two groups according to the availability of the interspinous implant: Group A was comprised of 30 patients (16 women and 14 men) who underwent discectomy in addition to the placement of a device for assisted intervertebral movement (DIAM). The segments of the lumbar spine most frequently operated on were L4 and L5 (27 patients [90%]). All patients of this group received a DIAM. Group B was comprised of 90 patients who underwent discectomy alone (53 women and 37 men), and the segments of the lumbar spine more frequently operated on were L4 and L5 (80 patients [90%]).

All patients were included in a clinical and radiological follow-up at the first month, at six months and at 24 months after surgery. At the final follow-up, or if patients had new neurological symptoms, an MRI was performed. Generally, preoperative scans were compared with postoperative scans of the operated segment. In both groups, the mean time in which recurrence was confirmed was 8 months (range 6-10) after an asymptomatic postoperative period.

The inclusion criteria were as follows: patients between 20 and 60 years old, with sciatica or crural pain not improving after medical and physical therapy for at least two cycles of 10 sessions each and for approximately six months, or less time in cases of intolerance to pain or neurological impairments. The exclusion criteria were patients with spondylolysis, degenerative spondylolisthesis, tumors, infections or fractures of the lumbar spine, obesity (BMI >30), present or past smoking habits, surgical indication for more than two spine segments, severe osteoporosis, scoliosis, and those who did not attend postoperative follow-up visits.

Patients in both groups underwent an open microdiscectomy with a 2.5 cm approach and, in Group A, the silicone implant (DIAM) was placed—depending on the approach—in the operating room, with the patient under general anesthesia and in the ventral decubitus position, after previous marking of the spinal segment under fluoroscopy. The mean operating time was 55 minutes (range 42-75). Attention was given to avoid segmental kyphosis in all cases.

RESULTS

There were statistical differences in the recurrence rate ($p = 0.0073$) between the groups: in Group A, six of the 30 patients (20%) had a clinical and radiological recurrence, three of them (10%) had surgery again; in Group B, there were four disc herniation recurrences (4.4%) among the 90 patients, and one of them underwent surgical revision. Significant differences were found in the rate of revision surgeries between both groups ($p = 0.0188$).

In [Figure 1](#), preoperative imaging studies of a 40-year-old woman are shown. In AP and lateral X-rays of the lumbosacral spine, and in sagittal and axial MRIs, a herniated disc is observed at L4-L5.



Figure 1. Preoperative AP and lateral X-rays of the lumbosacral spine, and sagittal and axial MRI scans of a 40-year-old woman who underwent surgery for lumbar disc herniation at L4-L5 plus placement of a device for assisted intervertebral movement (DIAM).

Figure 2 shows the same patient, who was ordered an MRI due to recurrence of the symptoms. A recurrent disc herniation at L4-L5 (site of the DIAM placement) plus disc protrusion at L5-S1, both in the sagittal and axial scans, is observed.



Figure 2. X-rays and MRI scans of the same patient of Figure 1, before revision surgery with spinal fusion.

In **Figure 3**, AP and lateral X-rays of the lumbosacral spine of the same patient, showing segmental fusion at two segments, are observed.

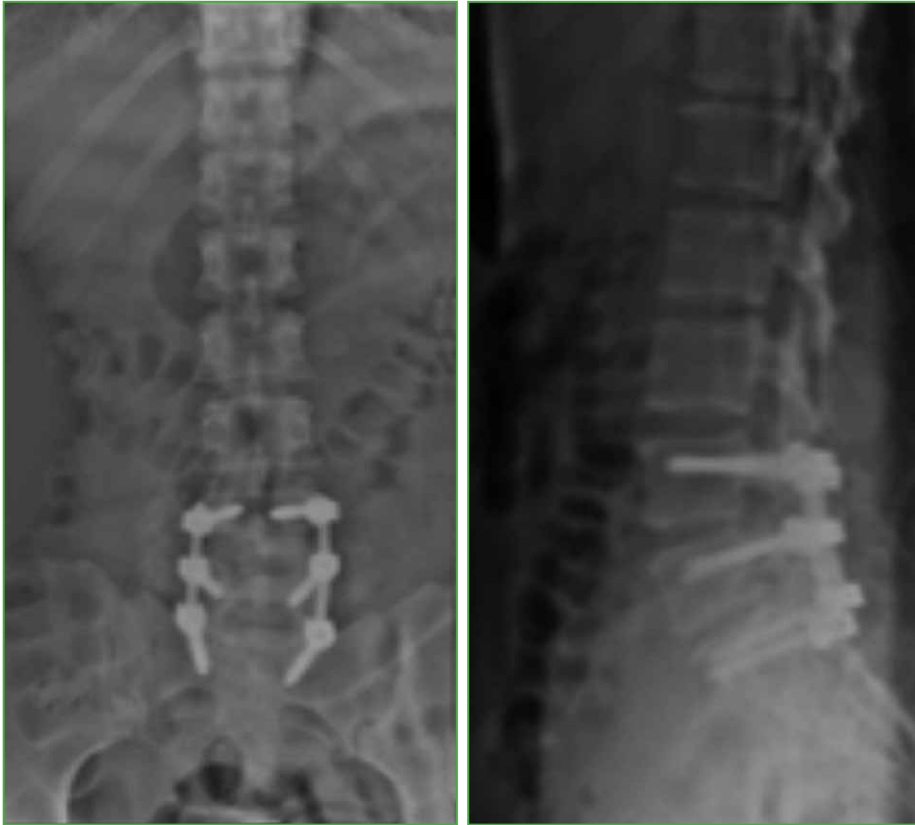


Figure 3. AP and lateral X-rays of the lumbosacral spine of the same patient of Figure 1, after surgery for removal of the DIAM implant and spine fusion.

DISCUSSION

This study showed that the rate of disc herniation recurrence is higher in patients undergoing discectomies with placement of DIAM-type silicone interspinous devices than in those treated with discectomy alone. Likewise, it was found that the rate of surgical revision was higher in patients who underwent DIAM placement.

In several studies, it was shown that patients undergoing placement of interspinous devices achieve better results in the short and long term, compared with those undergoing conservative treatment, although with a higher frequency of surgical revisions due to recurrence of the hernia, compared with discectomy alone.^{6,10,11} Although these studies refer to procedures carried out after presentation of vertebral foramen stenosis, it seemed wise to mention them, since the mere fact of having placed interspinous devices showed a higher rate of revisions.

The rate of disc herniation recurrence after primary surgery without DIAM placement ranges between 5% and 11%, which is even higher than the rates achieved in our study.^{3,9,12}

Regarding microdiscectomy, Martínez Quiñones,¹³ in a retrospective analysis of 142 patients with five years of follow-up, reported that 16 of them (11%) had to be operated on again. This result significantly exceeds the percentage found in our study, both with discectomy alone and with discectomy plus DIAM placement.

Strömqvist *et al.*⁸ obtained results similar to ours. They treated 50 patients with decompression surgery and 50 with interspinous spacer placement. Six percent (three patients) of the decompression group and 26% of the other group underwent a new intervention due to recurrence, including implant removal and decompression surgery ($p = 0.04$).

In his retrospective cohort study, Deyo⁴ found that the likelihood of surgical revision of procedures for vertebral foramen stenosis decreased as patient age and comorbidities increased, but these variables were not considered in our study.

Although the modern trend is to use even less invasive spinal instrumentation systems, there are no data or evidence of studies showing that interspinous DIAM-type devices increase or decrease the rate of disc herniation recurrence. On the contrary, this prospective study was able to detect some shortcomings of interspinous devices, which was the main focus of our research, although it is a topic fairly absent in the literature. The potential benefits of interspinous devices for treating herniated discs or vertebral foramen stenosis remain controversial.

CONCLUSIONS

Although the benefits of interspinous devices to treat vertebral foramen stenosis, mainly due to herniated discs, are controversial, in our study, we found a significant difference in the rate of recurrence and surgical revisions, depending on the group.

Consequently, and in accordance with the time elapsed since implant placement, the placement of interspinous devices has not yield significant benefits or achieved successful results in terms of revision rates. On the contrary, in this study, we showed that the use of these devices increases the rate of disc herniation recurrence. In other words, according to our research, discectomy alone is still the golden standard for decompression of the vertebral foramina of herniated discs.

Conflict of interests: Authors claim they do not have any conflict of interests.

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