

# SHORT-TERM CLINICAL OUTCOMES OF AWAKE AND OUTPATIENT TRANSFORAMINAL ENDOSCOPIC LUMBAR FORAMINOTOMY AND INTERSPINOUS SPACER DEVICE

*RESULTADOS CLÍNICOS DE CURTO PRAZO DA COMBINAÇÃO DE FORAMINOTOMIA LOMBAR ENDOSCÓPICA TRANSFORAMINAL COM ESPAÇADOR INTERESPINHOSO EM REGIME AMBULATORIAL SOB SEDAÇÃO*

*RESULTADOS CLÍNICOS A CORTO PLAZO DE LA COMBINACIÓN DE FORAMINOTOMÍA LUMBAR ENDOSCÓPICA TRANSFORAMINAL CON ESPACIADOR INTERESPINOSO EN RÉGIMEN AMBULATORIO BAJO SEDACIÓN*

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## ABSTRACT

**Objective:** To evaluate the clinical outcomes achieved with the combined surgical management of Transforaminal Endoscopic Lumbar Foraminoplasty (TELF) with an Interspinous Spacer Device (ISD) in patients with DS grades I and II and LSS. **Methods:** A retrospective observational study was conducted using clinical records of patients who underwent a TELF procedure plus the placement of an ISD for LSS and DS. Demographic variables and Patient-Reported Outcome Measures (PROMs), including the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI), were analyzed to evaluate the clinical outcomes of the combined procedures. A total of 37 patients (54.05% women, 45.95% men) were evaluated. The mean age was  $59.59 \pm 15.89$  years (95% CI 55.29 – 64.89); 43.24% (n=16) of the sample were women aged 60 or older and 32.43% of the patients were “pensioner-retired.” The most common presenting symptom was radicular pain: 30.30% on the right side and 48.48% on the left side. A total of 49 TELF procedures were performed, and 45 ISD were placed in the 37 patients. The average procedure duration was  $85.77 \pm 28.54$  minutes, and the average blood loss was  $23.28 \pm 21.96$  ml. The most frequently operated level was L4-L5. **Results:** The VAS and ODI scores improved significantly differences ( $p < 0.001$ ) before and after the procedure. Two complications were observed (5.4%). The overall reoperation rate was 10.81% (n=4). **Conclusion:** Transforaminal endoscopic decompression with ISD represents a feasible and safe outpatient alternative for patients with low-grade spondylolisthesis and stenosis. This combined minimally invasive technique provides significant clinical improvement with a low reoperation rate and offers a compelling alternative to more invasive surgery. **Level of Evidence IV; Case Series.**

**Keywords:** Spondylolisthesis; Surgical Procedures, Minimally Invasive; Endoscopy.

## RESUMO

**Objetivo:** Avaliar os resultados clínicos obtidos com o tratamento cirúrgico combinado de foraminoplastia lombar endoscópica transforaminal com um dispositivo espaçador interespinhoso em pacientes com espondilolistese degenerativa de grau I e II e estenose espinhal lombar. **Métodos:** Realizou-se uma análise retrospectiva, observacional e descritiva dos prontuários clínicos de pacientes submetidos a um procedimento endoscópico transforaminal mais a colocação de um espaçador interespinhoso para estenose espinhal lombar e espondilolistese degenerativa. Variáveis demográficas e medidas de resultados relatados pelo paciente, incluindo a escala visual analógica e o índice de incapacidade de Oswestry, foram analisadas para avaliar os resultados clínicos dos procedimentos combinados. Um total de 37 pacientes (54,05% mulheres, 45,95% homens) foram avaliados. A idade média foi de  $59,59 \pm 15,89$  anos (IC 95% 55,29 – 64,89); 43,24% (n=16) da amostra eram mulheres com 60 anos ou mais e 32,43% dos pacientes eram aposentados. A queixa mais frequente foi dor irradiada: 30,30% no lado direito e 48,48% no lado esquerdo. Um total de 49 procedimentos endoscópicos transforaminais foram realizados e 45 espaçadores interespinhosos foram implantados em 37 pacientes. A duração média do procedimento foi de  $85,77 \pm 28,54$  minutos e a perda sanguínea média foi de  $23,28 \pm 21,96$  ml. O nível mais frequentemente operado foi L4-L5. **Resultados:** A escala visual analógica e o índice de incapacidade de Oswestry mostraram diferenças estatisticamente significativas

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( $p < 0,001$ ) antes e depois do procedimento. Apenas duas complicações foram encontradas (5,4%). A taxa geral de reoperação foi de 10,81% ( $n = 4$ ). Conclusão: A descompressão endoscópica transforaminal com espaçador interespinhoso é uma opção ambulatorial viável e de baixo risco para pacientes com espondilolistese e estenose de baixo grau. Essa técnica combinada minimamente invasiva proporciona melhora clínica significativa com baixa taxa de reoperação e oferece uma alternativa atraente à cirurgia mais invasiva. **Nível de Evidência IV; Série de Casos.**

**Descritores:** Espondilolistese; Procedimentos Cirúrgicos Minimamente Invasivos; Endoscopia.

## RESUMEN

**Objetivo:** Evaluar los resultados clínicos obtenidos con el tratamiento quirúrgico combinado de la foraminoplastia lumbar endoscópica transforaminal con un dispositivo espaciador interespinoso en pacientes con espondilolistesis degenerativa grados I y II y estenosis espinal lumbar. **Métodos:** Se realizó un análisis retrospectivo, observacional y descriptivo de las historias clínicas de pacientes sometidos a un procedimiento endoscópico transforaminal más la colocación de un espaciador interespinoso para estenosis espinal lumbar y espondilolistesis degenerativa. Se analizaron variables demográficas y medidas de resultados reportadas por los pacientes, incluyendo la escala visual analógica y el índice de discapacidad de Oswestry, para evaluar los resultados clínicos de los procedimientos combinados. Se evaluó un total de 37 pacientes (54,05% mujeres, 45,95% hombres). La edad media fue de  $59,59 \pm 15,89$  años (IC 95%: 55,29–64,89); el 43,24% ( $n=16$ ) de la muestra correspondía a mujeres de 60 años o más y el 32,43% de los pacientes eran jubilados. La queja más frecuente fue dolor irradiado: 30,30% en el lado derecho y 48,48% en el lado izquierdo. Se realizaron 49 procedimientos endoscópicos transforaminales y se implantaron 45 espaciadores interespinosos en 37 pacientes. La duración media del procedimiento fue de  $85,77 \pm 28,54$  minutos y la pérdida sanguínea media fue de  $23,28 \pm 21,96$  ml. El nivel operado con mayor frecuencia fue L4-L5. Resultados: La escala visual analógica y el índice de discapacidad de Oswestry mostraron diferencias estadísticamente significativas ( $p < 0,001$ ) antes y después del procedimiento. Solo se registraron dos complicaciones (5,4%). La tasa general de reintervención fue del 10,81% ( $n = 4$ ). **Conclusión:** La descompresión endoscópica transforaminal con espaciador interespinoso constituye una opción ambulatoria viable y de bajo riesgo para pacientes con espondilolistesis y estenosis de bajo grado. Esta técnica combinada minimamente invasiva proporciona una mejora clínica significativa con baja tasa de reintervención y ofrece una alternativa atractiva a la cirugía más invasiva. **Nivel de Evidencia IV; Serie de Casos.**

**Descriptorios:** Espondilolistesis; Procedimientos Quirúrgicos Minimamente Invasivos; Endoscopia.

## INTRODUCTION

Lumbar spinal stenosis (LSS) and degenerative spondylolisthesis (DS) are closely related degenerative spinal conditions that have a substantial impact on quality of life in patients over 50 years of age. LSS is a condition characterized by a narrowing of the spinal canal, lateral recesses, or neural foramina, which compresses the surrounding neurological and vascular elements and can cause disabling symptoms such as neurogenic claudication and back or leg pain. DS is the displacement of one vertebra relative to the adjacent vertebra, in the absence of isthmic lysis<sup>1</sup>.

The development of these conditions is associated with the degenerative processes of aging, and a higher prevalence has been associated with women<sup>2-4</sup>. Aging leads to progressive changes in the anatomy of the intervertebral discs and facet joints (hypertrophy and subluxation), resulting in instability of the vertebral segment<sup>5</sup>. These changes lead to a reduction in the spaces surrounding the spine's neurovascular structures, resulting in LSS, which co-occurs with the progression of degenerative DS from grade I to II<sup>5</sup>.

The prevalence of LSS in individuals aged 60–69 years may reach 47%<sup>6</sup>. In turn, DS accounts for 20.7% of spine pathologies, with the most affected segment being L4-L5 in 71.5% of cases, followed by L3-L4 and, on rare occasions, L5-S1<sup>1,3</sup>. Regarding severity, 84.3% of DS are Grade I, while the remaining 15.7% are Grade II, according to the Meyerding classification<sup>7,8</sup>. According to this distribution, the most common presentation of these pathologies is LSS and DS with low-grade instability<sup>5,9</sup>.

Conservative management has been reported to be effective in up to 90% of cases<sup>5</sup>. However, some patients present with debilitating pain that significantly affects their quality of life and requires surgical treatment<sup>2,6</sup>. The choice of surgical management for this pathology remains a subject of debate<sup>10</sup>. The controversy currently centers on which procedure produces better results: decompression alone or combined with fusion. Many surgeons consider laminectomy and fusion with additional instrumentation to be the gold standard treatment for LSS associated with DS<sup>7</sup>. However, a reoperation rate of 22% at 8 years has been reported with these types of open techniques<sup>11</sup>. Added to this factor are the high costs and associated risks for elderly patients.

In contrast to conventional techniques, minimally invasive

approaches such as Transforaminal Endoscopic Lumbar Foraminoplasty (TELF) combined with Interspinous Spacers Devices (ISD) preserve the biomechanical structure of the vertebral segment<sup>12</sup>. Furthermore, it can be performed under regional anesthesia and sedation, making it safer for elderly patients<sup>13</sup>. The rationale for combining lumbar endoscopy with interspinous spacers is to improve the durability and clinical outcomes of both techniques and enhance the quality of life for patients suffering from this pathology.

The objective of this research is to evaluate the clinical benefits (PROMs) of combined surgical management of TELF with ISD in patients with LSS and DS grade I and II. We hypothesized that combining endoscopic decompression (to address radicular symptoms) with interspinous spacers (to address mechanical back pain) would provide synergistic benefits, overcoming the known limitations of each procedure when used in isolation, such as the high reoperation rate for standalone spacers.

## MATERIALS AND METHODS

### Study design and patient selection criteria

A retrospective, observational, and descriptive analysis was performed. The clinical records of patients operated on in the spine surgery service were evaluated, with a diagnosis of LSS associated with grade I–II DS on the Meyerding scale, and who, after failure of medical and interventional management with selective injections, underwent a TELF procedure plus the placement of an ISD. Two experienced specialists in spinal pathology confirmed the diagnosis: a neuroradiologist and an expert spine surgeon (orthopedist/neurosurgeon), based on clinical and imaging findings. Data on occupation were collected using the ISCO-08 classification to investigate potential relationships with disability level and the pain scale. This study was approved by the institutional review board (CEIFUS #2714-25).

### Inclusion and exclusion criteria

Patients with symptoms and an established diagnosis of LSS with grade I and II DS who were operated on with the combination of TELF and ISD were included. Endoscopic decompression was

performed at stenotic levels and the level for ISD placement was those with spondylolisthesis. Patients with additional spinal pathologies such as previous fractures or lumbar tumors, patients with any previous spine surgery, a history of neurodegenerative disease, a history of vascular disease, additional lumbar spine pathology such as fractures and tumors, the use of transpedicular fixation, patients under 18 years old, and incomplete medical records were excluded.

### Positioning and access planning

The procedure is performed under regional anesthesia and sedation, with the patient in a prone position on a radiolucent table under a fluoroscope. To improve the opening of the intervertebral spaces, a support was placed under the legs, allowing 90° hip flexion. The level to be operated on was determined intraoperatively using fluoroscopic marking.

### Transforaminal endoscopic lumbar foraminoplasty (TELF)

The skin entry point, used to determine the location depending on the anatomy, was situated between 8 cm and 14 cm lateral to the midline, at the level of the affected disc. The estimated needle trajectory was infiltrated with abundant local anesthetic. An 18-G spinal needle was inserted and advanced toward the intradiscal space at an angle of 40°–45° to the sagittal plane, adjusting the direction according to fluoroscopic images. With the needle tip in position, intraoperative discography was performed with a non-ionic contrast medium mixed with methylene blue to confirm the disc and stain the nucleus pulposus for better intraoperative identification. The spinal needle was then replaced with a thin metal guidewire, and a small incision was made. The dilator from the endoscopy set (Eliquence LLC, Baldwin, NY) was advanced until its tip was firmly fixed in the annular window. The dilator was held firmly, and the guidewire was removed. The next step was the annular fenestration. A working cannula was passed over the dilator using circular movements until it entered the annulus, and, after the removal of the dilator, the endoscope was passed through this cannula. Once full access to the herniated disc was achieved, decompression was completed with forceps, burrs, trephines, and radiofrequency. The Eliquence Trigger Flex radiofrequency system (Eliquence LLC, Baldwin, NY) was used for thermal annuloplasty and nucleoplasty to complete the discectomy by reducing worn annular and disc tissue. Finally, adequate decompression was confirmed by visual inspection of the mobility of a free-floating dural sac.

### Interspinous spacer device (ISD)

Under fluoroscopic vision, a 2.0 mm x 570 mm smooth guidewire was introduced with an inclination of 10 to 15 degrees, as anteriorly as possible, until it passed through the interspinous space (between the spinous processes) approximately 3 to 4 cm. An incision in the skin and fascia was made over the guidewire. With blunt dissection of the muscles, sizers with their handle were introduced to determine the size of the intervertebral space (8mm, 10mm, 12mm, 14mm). The sizer was gently pushed until it met resistance, but without separating the spinous processes. In all cases, implants of the same size as the sizer that fit properly were used. The final sizer was removed, leaving only the smooth guidewire (and the dilator, if necessary). Once the appropriate implant was selected, it was mounted on the inserter and fully secured for placement. The ISD was introduced over the smooth guidewire until it rested on the spinous process, then turned clockwise until a click was felt, indicating the spacer was in position. The correct placement of the implant was confirmed on AP and lateral fluoroscopic projections.

### PROMs Evaluation

Three criteria were selected as perioperative evaluation methods: the visual analog scale (VAS) for pain and the Oswestry disability index (ODI), which quantifies the percentage of disability caused by the pathology. These two criteria were evaluated in the preoperative and postoperative periods. The modified MacNab criterion, determining the degree of patient satisfaction with the procedure,

was assessed during postoperative follow-up. Intra- and post-surgical complications, as well as the need for reoperation, were also collected.

Sociodemographic variables of the participants were analyzed. Patients' age was categorized as follows: youth (19–26 years); adults (27–59 years); and seniors ( $\geq 60$  years). To determine the type of evolution for each patient, the duration of symptoms was established according to what was reported and using as reference the categorization from the most recent "Clinical Practice Guideline of the American College of Physicians"<sup>14</sup>, which defines acute pain as pain with a duration of less than 4 weeks, subacute pain between 4 and 12 weeks, and chronic pain as any back pain that exceeds 12 weeks.

### Statistical Analysis

The statistical analysis was performed using Stata 15 for Windows. Descriptive statistics were performed with measures of central tendency, dispersion, and frequencies. The variables of interest were compared between the two groups using the t-Student and ANOVA tests, based on the type of variable and the normality previously established using the Kolmogorov-Smirnov normality test and Levene's test for homogeneity of variances. Statistical significance was determined at a p-value of less than  $p < 0.05$ .

## RESULTS

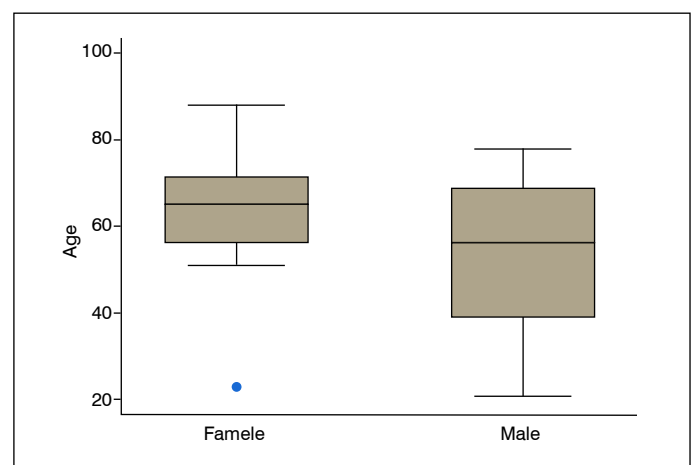
### Demographics

A total of 37 patients met the inclusion criteria. The distribution was 54.05% (n=20) women and 45.95% (n=17) men. The average age of the sample was  $59.59 \pm 15.89$  years (95% CI: 55.29–64.89). The mean age in women [ $64 \pm 13.71$  years (95% CI 57.58–70.41)] was significantly higher than in men [ $54.41 \pm 17.08$  years (95% CI 45.62–63.19)] ( $p=0.03$ ) (Figure 1).

The distribution of age categories was 56.76% seniors, 37.84% adults, and just 5.41% youth. No statistically significant differences were found between age categories stratified by sex ( $p=0.317$ ); however, 43.24% of the sample were women over 60 years of age. Regarding occupation, 32.43% of the patients were in the "pensioner-retired" category, and 22.03% of the sample were homemakers, all of whom were women. 68.57% of the patients reported a chronic pain evolution, higher than the 22.86% subacute and 8.57% acute. The most common reason for consultation was "lumbar radicular pain" in 89.19% of patients. Of these patients, 18.92% reported bilateral pain radiation, 29.73% indicated pain on the right side, and 43.24% pain in the left leg.

### Procedure

The average duration of the procedure, including anesthetic time, was  $85.77 \pm 28.54$  minutes ( $p50 = 80$  minutes). The shortest surgery time was 37 minutes, and the longest was 170 minutes. The



**Figure 1.** Box plot of the difference in age distribution between men and women.

average blood loss for the technique was  $23.28 \pm 21.96$  ml (95% CI 15.85–30.71). A total of 49 TELFs were performed, and 45 ISDs were placed in 37 patients. The transforaminal endoscopic procedure was performed most frequently at the L4–L5 level, followed by L5–S1. In 14 patients, multiple levels were treated, including one case involving three levels. Spacer placement was carried out in 5 patients at two levels, and in 1 patient across three different levels. The L4–L5 segment was the most commonly operated level using the spacer technique ( $n=25$ ), followed by L3–L4 and L5–S1 ( $n=7$  each) (Table 1).

The duration of the procedures showed no correlation with the number of levels operated, neither with endoscopic surgery nor with spacers.

**Table 1.** Levels operated on with each procedure.

LEVEL	Spacer		TELF	
	n	%	n	%
L1-L2	1	2.2%	0	0.0%
L2-L3	4	8.9%	2	6.1%
L3-L4	7	15.6%	5	16.3%
L4-L5	25	55.6%	25	55.1%
L5-S1	7	15.6%	17	20.4%
L6-S1	1	2.2%	0	2.0%

### PROM's

The median follow-up time was 8 months (IQR 3 – 20). The maximum follow-up reached 96 months. The visual analog scale showed statistically significant differences ( $p < 0.001$ ) before and after the surgical procedure, from  $8.56 \pm 1.21$  (95% CI 8.16 – 8.97) to  $3.97 \pm 2.59$  (95% CI 3.07 – 4.86). The ODI showed a similar pattern, decreasing from  $51.09 \pm 15.74$  (95% CI 45.50 – 56.67) to  $21.93 \pm 16.38$  (95% CI 15.92 – 27.94) ( $p < 0.001$ ). According to the MacNab criteria, the reported by the patients was 62.86% excellent or good satisfaction, 28.57% indicated some improvement, and only three patients reported poor results.

#### Complications and reoperations

The sample reported only two complications (5.4%). One was due to a postoperative infection in a 63-year-old woman who underwent TELF with an ISD at the L4–L5 level, which required reoperation with an open technique, and the second was a 78-year-old man who underwent TELF at the L3–L4 and L4–L5 levels and an ISD at L4–L5, who presented with radiculitis without needing reoperation. On the other hand, the overall reoperation rate was 10.81% ( $n=4$ ). The reason for three reoperation was persistent radiculopathy. Early reoperations (<3 months) occurred in 8.1% of cases ( $n=3$ ), while no intermediate reoperations (3–6 months) were recorded. Late reoperations (6–12 months) accounted for 2.7% of cases. Overall, 75% of the reoperated patients were women, all aged 63 years or older (63, 63, and 70 years). Two of the four patients had a history of arterial hypertension. In one case, the reoperation was due to infection, necessitating open surgery; this was not considered a failure of the endoscopic technique.

## DISCUSSION

Lumbar spinal stenosis (LSS) combined with degenerative spondylolisthesis (DS) is a common condition<sup>1,2,4,5</sup>. Severe lumbar pain may lead to functional disability and loss of independence, markedly reducing autonomy and quality of life among older adults, thereby constituting a significant public health problem<sup>3</sup>. The failure of conservative therapeutic measures means that a significant percentage of patients require a surgical procedure. Recent studies have suggested that interspinous spacers after endoscopic decompression of a severely degenerated lumbar spinal motion segment can improve clinical symptoms<sup>13</sup>. Interspinous spacers are attractive due to the ease of its minimally invasive implantation and the extensive clinical evidence supporting its use in managing claudication in spinal stenosis<sup>14</sup>.

This research focused on analyzing the results of 37 patients who presented for consultation due to intense pain (>7 out of 10 on the VAS score) and with a diagnosis of LSS and DS in grades I and II with failed previous conservative management, who were offered the treatment option of surgical placement of an ISD and TELF.

The study population consisted predominantly of older adults (56.76% of patients over 60 years), consistent with previous reports<sup>3,4,6</sup>. Regarding the sex distribution, it has been reported that women can have double the prevalence of men (8.4% vs 2.7%)<sup>15</sup>. However, although the prevalence was higher in women in the present study (54.05% vs 45.95%), the distribution between the sexes did not mirror this pattern. The sample size could explain this, as the study by Bydon et al (2019)<sup>15</sup> evaluated more than 4,000 patients with lumbar pathologies. Although the female predominance was less pronounced in women, this sample highlights that one in three people treated with minimally invasive techniques for the studied pathology were women over 60, many of them homemakers or retirees. Additionally, it should be emphasized that the pain and degree of disability that led patients to surgery were significantly higher in women than in men ( $p < 0.05$ ). These findings may explain the trend in Bydon's study.

Conventional decompression has been associated with spine instability, requiring fusion. Likewise, complications have been reported, including spinal cord injury, nerve root injury, epidural hematoma, cerebrospinal fluid fistulas, epidural fibrosis, and iatrogenic instability, surgical site infections, pneumonia, pulmonary embolism, urinary tract infection, and transfusions that can be devastating for an elderly patient<sup>1,5,15,16</sup>. In contrast, by using percutaneous techniques, the sample analyzed in this study showed only two complications. No patient in this sample required transfusions, as the volume of blood loss was very low.

The literature has reported a significant correlation between the duration of surgery and the need for an extended hospital stay<sup>5</sup>. Likewise, longer surgeries are associated with increased risk of infections or anesthesia-related complications<sup>16</sup>. Surgical times reported in conventional techniques range from 89.7 min to 201 min<sup>2</sup>. These values largely depend on the number of levels to be operated on and, of course, the surgeon's skill<sup>16</sup>. In contrast, the median duration of surgery in this report was 80 minutes, with no correlation between the number of levels and the duration. It is important to clarify that the reported surgery duration in this study included the regional anesthesia technique used. Hospital stay is an important factor, as the average for elderly patients undergoing conventional techniques was  $9 \pm 7.4$  days, with a range of 1 to 90 days. In comparison, the patients operated on in this cohort with minimal invasion did not require hospitalization and were discharged the same day.

To the best of the authors' knowledge, studies on the combination of spacers and endoscopic decompression for treating LSS combined with DS are scarce. Li et al (2020)<sup>11</sup> reported 18 patients treated with transforaminal endoscopic decompression for LSS and DS (grade I and II by Meyerding criteria) with an average follow-up of 27.7 months (range: 24–33 months). The authors reported statistically significant improvements in ODI and VAS for leg and back pain. Complications were minimal: two dural tears (10%) and one patient (5%) requiring additional surgery, highlighting advantages such as reduced blood loss, shorter recovery time, and preservation of stabilizing structures. These results are comparable to those obtained in this study, although with a longer follow-up.

Lewandrowski et al. (2022)<sup>12</sup> conducted a meta-analysis of the efficacy of ISDs versus endoscopic decompression for the treatment of LSS. The researchers found that the combined effect size for both procedures was similar. However, when stratified by certain variables, ISDs showed a greater reduction in low back pain (VAS-back), although this difference was not statistically significant. Endoscopy was superior for ODI and VAS scores for pain radiating to the leg, and ISDs alone show short-term efficacy with higher reoperation rates (23.7% vs. 8.5% in traditional decompression). The meta-analysis authors hypothesized that combining both techniques could be beneficial, leveraging the strengths of each. This study suggests that

combining ISDs with endoscopic decompression could decrease the high risk of reoperations. Likewise, the results align with previous studies supporting transforaminal endoscopic surgery for lumbar stenosis. However, they also highlight that the addition of interspinous spacers could reduce the risk of postoperative instability. Prospective analytical studies with larger samples and long-term follow-up are needed to compare the different alternatives and validate these findings, while evaluating possible late deterioration.

Among the most studied factors and the one that generates the most controversy in the use of minimally invasive techniques, especially using ISDs, is the high rate of reoperations reported when used as the sole treatment for lumbar stenosis<sup>12</sup>. The present study reports a reoperation rate of approximately 10%, which is lower than that for open surgery, where some studies have reported reoperation rates after a laminectomy of up to 43.3%<sup>5</sup> and a 20% frequency of instability requiring revision surgery<sup>16</sup>.

An interesting finding in the sample is the frequency of pain radiating to the left lower limb; nearly half of the sample presented with gluteal and left leg pain as the reason for consultation. These results are comparable to those reported by Kanat et al. (2017)<sup>17</sup>, who reported a higher prevalence in discectomies performed on the left side of their patients (53% left vs 40% right). Likewise, in the evaluation of a large cohort, researchers in Japan analyzed nearly 3000 surgical cases and found the same trend of a higher prevalence in patients with left radiating pain<sup>18</sup>. It has been suggested that this asymmetric distribution could be related to manual dominance, as people, by using their right side more, make their left side the base and pivot of force<sup>18</sup>. Nevertheless, neither in the reported investigations nor in the present work were significant differences found in the distribution of pain or pre-surgical disability, nor in the difference of VAS or ODI pre- and post-surgery between the groups ( $P > 0.005$ ).

## Limitations

The study has several limitations inherent to the retrospective observational design. Because of the recruitment strategy, there was a substantial risk of selection bias. Further, since this is not a comparative study, the superiority of the treatment over conventional techniques cannot be established. Also, we present a highly variable and relatively short median follow-up period which may have led to underestimation of late reoperations. Another limitation of this study is its focus on clinical outcomes, without a correlative follow-up radiographic analysis. While the improvement in PROMs was significant, this omission means the study cannot determine whether vertebral stability was maintained, or quantify the specific contribution of the ISD implant to the observed clinical outcomes.

## CONCLUSION

Based on the findings of this sample analysis, the combined TELF and ISD technique may be considered a safe outpatient strategy that provides meaningful short-term improvements in pain and disability. In addition, it retains the inherent advantages of minimally invasive surgery, including reduced tissue dissection and muscle injury, improved visualization, lower blood loss, decreased epidural fibrosis and postoperative scarring, faster functional recovery, enhanced quality of life, shorter hospital stay, and superior cosmetic outcomes. Proper patient selection remains a critical determinant of success; thus, thorough evaluation of clinical and radiological criteria is strongly recommended, with careful correlation between symptoms (e.g., neurogenic claudication, relief with lumbar flexion) and imaging findings (MRI/CT). Future studies incorporating radiographic follow-up are warranted to determine whether ISD confers additional benefits beyond endoscopic decompression alone.

## CONFLICT OF INTEREST

The author(s) declared no potential direct (employment, stock ownership, grants, patents) conflicts of interest concerning this article's research, authorship, and/or publication. The coauthors JFR, JGR, CRM, and NPR have indirect conflicts of interest may exist due to honoraria, consultancies to other vendors, and companies including Elliquence, LLC and Ortomac. The authors NASR, VMPB, JPB and GOAC have no direct or indirect conflicts of interest.

## CONTRIBUTIONS OF THE AUTHORS

JFRL: conceptualization, methodology, supervision, writing - original draft; YAFV: conceptualization, methodology, formal analysis, writing - original draft; CRM: validation; NPR: validation, research; JGRO: writing - review and editing; VMPB, JPB: writing - review and editing; GOAC: conceptualization, methodology, formal analysis, writing- Original draft. All authors approved the final version of the paper.

## DATA AVAILABILITY DECLARATION

The contents underlying the research are available in the manuscript.

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