

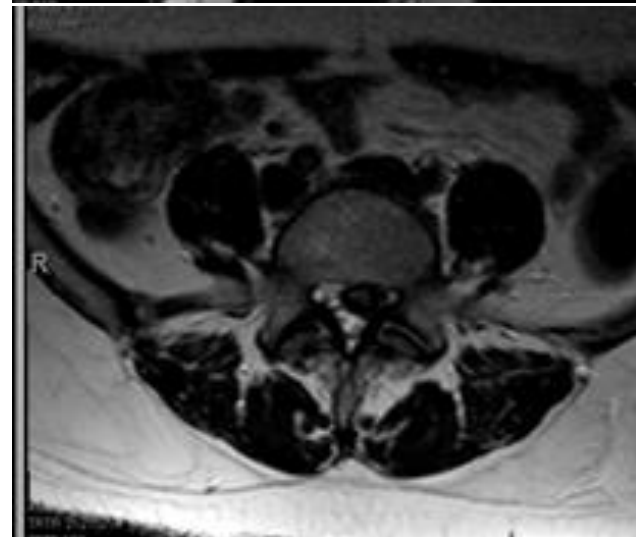


Lumbar disc herniation surgery with microdiscectomy plus interspinous stabilization: Good clinical results, but failure to lower the incidence of re-operation.

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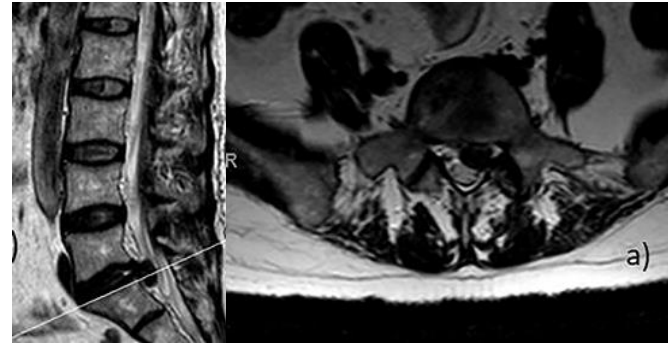
Introduction.

- Prevalence of symptomatic herniated lumbar disc is about 1–3%. *Jordan J, Konstantinou K, O'Dowd J. Herniated lumbar disc. BMJ Clin Evid 2009;1118.*
- Annually, it is estimated that 2.75 out of 1000 will suffer an episode of hospitalization. *Heliövaara M, Knekt P, Aromaa A. Incidence and risk factors of herniated lumbar intervertebral disc or sciatica leading to hospitalization. J Chronic Dis 1987; 40:251-8.*
- Traditionally, the accepted surgical treatment has been discectomy. *Wang JC, Dailey AT, Mummaneni PV, Ghogawala Z, Resnick DK, Watters WC 3rd, Groff MW, Choudhri TF, Eck JC, Sharan A, Dhall SS, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine: Part 8: lumbar fusion for disc herniation and radiculopathy. J Neurosurg Spine 2014;21(1):48-53*
- Discectomy is sometimes associated with recurrence of disc herniation and pain after decompression. *Parker SL, Mendenhall SK, Godil SS, Sivasubramanian P, Cahill K, Ziewacz J, McGirt MJ. Incidence of Low Back Pain After Lumbar Discectomy for Herniated Disc and Its Effect on Patient-reported Outcomes. Clin Orthop Relat Res 2015 Jun;473(6):1988-99.*
- The evidence to use an IDSS in association with disc excision remains controversial and inconsistent, with low number of cases, and therefore, no definitive conclusions could be made. *Xu D, Xu HZ, Chen YH, et al. Discectomy and discectomy plus Coflex fixation for lumbar disc herniation, a clinical comparison study. Zhonghua Wai Ke Za Zhi 2013;51:147-51.. Floman Y, Millgram MA, et al. Failure of the Wallis interspinous implant to lower the incidence of recurrent lumbar disc herniations in patients undergoing primary disc excision. J Spinal Disord Tech 2007; 20:337-41*
- The objective of our study was to analyze the clinical efficacy and safety of surgery with microdiscectomy plus IDSS in patients with lumbar disc herniation. A secondary goal was to measure length of stay (LOS), in-hospital cost, 90-day readmission rate, and 1-year re-operation rate.



Methods.

- Study design: This is an observational prospective case series study including patients with lumbago/sciatica due to lumbar disc herniation (ICD-10-CM M51.06/ICD-9-CM 722.73).
- Inclusion criteria: MR with a massive 1–2 level lumbar disc herniation, (size-2 or size-3 herniations according to the MSU Classification).
- Age 18–50 years.
- Body mass index (BMI) 18.5–35.0 kg/cm².
- Failure of non operative management for 12 weeks.
- Operative techniques. Md+ IS



Methods.

- Demographic evaluation : Sex, age, body mass index (BMI), tobacco consumption, and Charlson comorbidity index (CCI).
- Clinical evaluation:
 - Oswestry disability index (ODI) spanish version.
 - Visual analogue scale for pain(VAS) from 0 to 10mm
- Surgical safety: The perioperative 90-days complication rates were assessed by these data items:
 - Major medical complications , including mortality, respiratory failure (pneumonia or unplanned reintubation), pulmonary embolism, acute renal failure, myocardial infarction, and cerebrovascular accident.
 - Minor medical complications , including deep venous thrombosis, urinary tract infection, peripheral nerve injury, and ileus.
 - Surgical complications, such as, cerebrospinal fluid leakage,seroma.woundinfection, dehiscence rates.
- 90 -day readmission rates.
- 1year Implant related complications rate.
- Incidence of 1-year re-operations
- Length of stay (LOS).
- In-Hospital Cost.
- Statistics: Longitudinal changes in clinical outcomes were assessed with repeated measures analysis of variance (ANOVA) and T-student Tests.
- Sample size: Based on our primary outcome, to detect a ODI difference of 30% before and after the intervention (with a statistical power of 0.80, and a two-sided alpha of 0.05) a sample size of 27 patients was needed. For all analyses significance was set at $p < 0.05$

Results

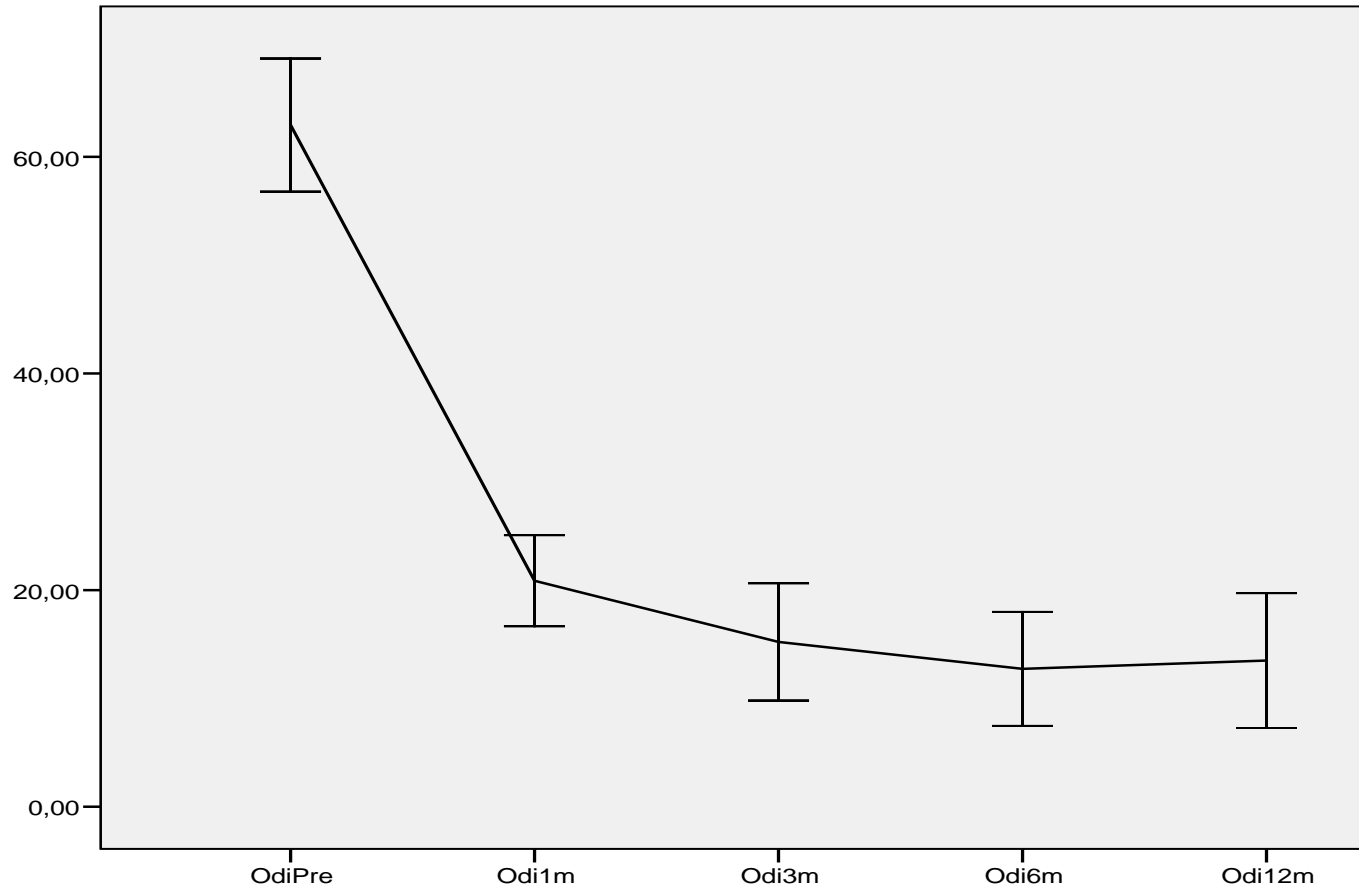
	Discectomy plus Interspinous.	95% confidence interval (CI)
Total Number	n=30	
Demographics		
Age*	38.6 (\pm 9.2)	(35.1-42.0)
Female ⁺	12 (40.0%)	22.5-57.5
BMI*	28.1 (\pm 3.6)	(24.7-27.4)
Smoking ⁺	12 (40.0%)	22.5-57.5
Charlson comorbidity index scoring⁺		
CCI=0	25 (83.3%)	
CCI \geq 1	5 (16.6%)	
Instrumented levels⁺		
1 level	24 (80%)	
2 levels	6 (20%)	

Table 1: Demographic and Co-Morbidity profile.

* Mean and standard deviation

+ Number of patients and percentage.

Results.



ODI scores changed from 62.93 (± 16.45) to 13.50 (± 16.67), representing a 78.54% (95% C.I 68.07–88.66%) improvement of the baseline score after one year ($p < 0.001$)

Results.

- VAS back pain severity decreased from 8.56 ± 1.27 mm to 2.70 ± 2.52 mm at 1 year, while VAS leg pain decreased from 8.90 ± 1.51 mm to 2.10 ± 2.20 mm, representing a 68.45% (95% C.I 57.69– 79.35%) and a 75.26% (95% C.I 65.16– 85.36%) improvement of the baseline score through 1 year respectively (both $p < 0.001$).
- At 1 year 93.30% (95% C.I 84.4–100%) of subjects achieved clinical success (more than 30% of ODI improvement of baseline score).

Results.

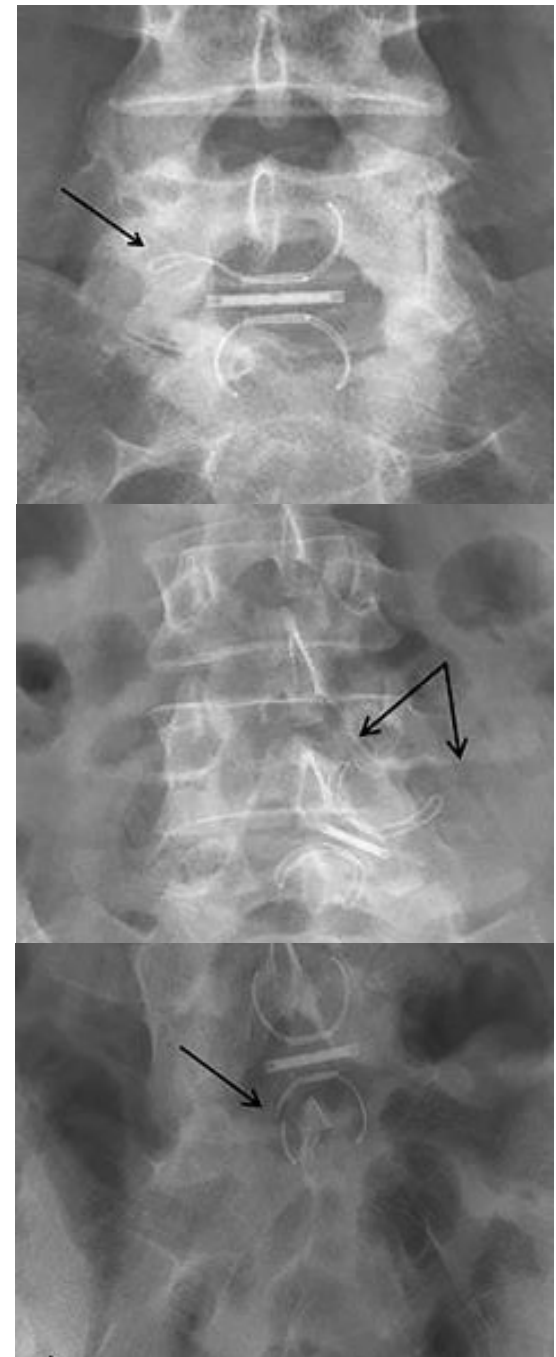
90-days medical complications, surgical complications and 1-year implant related complications

	Microdiscectomy plus Interspinous.	95% C.I
Patients	30	
Surgical Complications[‡]	1(3.2%)	0 - 9.5%
- Dural tear	1 (3.2%)	0 - 9.5%
- Seroma	0	
Implant Related Complications	12 (40%)	22.5-57.5%
	Anchorage wings complications	7(23.3%) 8.2-38.4%
	Implant rupture	4 (13.3%) 1.1-25.5%
	Dislocated implant	2 (6.7%) 0 – 15.6%
Medical complications[†]	0	

* **Number of patients and percentage by groups.**

[‡] There was no case of Fistula, Wound infection, Wound dehiscence, Nerve injury, Blood transfusion.

[†] There was no case of Myocardaial Infarction, Pulmonary embolism, Cerebrovascular accident, Acute Renal Failure, Mortality, Deep venous thrombosis, Ileus, Urinary tract infection



Results.

Length of stay, In- hospital costs, re-admission and re-operations rates

	Microdiscectomy plus Interspinous.	95% confidence interval (CI)
Total Number	n=30	
Length of Stay*	2.16 (\pm 1.20) days	1.71-2.61
Total In-Hospital Costs* ‡	1069.82 (\pm 288.48) €	962.10-1177.55
The length of stay cost (laundry, catering).	289.58 (\pm 156.79) €	
Complementary tests cost.	5.08 (\pm 7.28) €	
Human resources cost.	598.70 (\pm 160,85) €	
Surgical or medical material cost. ‡	176.45(\pm 111.14)€	
90 Days Readmission ⁺	4 (13.3%)	1.1%-25.5%
360 Days Re-operation ⁺	3 (10%)	0% -20.1%

Mean and standard deviation

⁺ Number of patients and percentage.

[‡] Implant price, interspinous device (1500€)not included

Discussion- Conclusion.

- Complications..
 - Implant Related Complication : Our percentage was similar to that reported with others interspinous devices such as Diam, Wallis, and Coflex where implant related complication rated up to 32.3% .Lee SH, Seol A, Cho TY, Kim SY, Kim DJ, Lim HM. A Systematic Review of Interspinous Dynamic Stabilization. *Clin Orthop Surg* 2015 Sep;7(3):323-9..
- Reintervention.
 - 12.2% (766/6274) within 4 years. In this sense, our 1 year re-operation reintervention rate (13.3%) was similar or slightly higher to those published with discectomy alone. According to this, Heinddel et al revealed re-operation rate following single-level discectomy of 3.95% (539/13654) within 3 months and 12.2% (766/6274) within 4 years .Heindel P, Tuchman A, Hsieh PC, et al. Reoperation Rates After Single-level Lumbar Discectomy. *Spine (Phila Pa 1976)* 2017; 42:E496-E501.].
- Socioeconomic perspective
 - .The LOS (2.18 days) with the addition of an interspinous device are similar to surgery with discectomy alone, which range from 0,3 to 4 days. German JW, Adamo MA, Hoppenot RG, Blossom JH, Nagle HA. Perioperative results following lumbar discectomy: comparison of minimally invasive discectomy and standard microdiscectomy. *Neurosurg Focus*. 2008;25(2):E20.
- Limitations.
 - The absence of a control group with microdiscectomy alone did not allow us to directly compare our results when we added IDSS Follow up.
 - The 1-year follow-up. This time is sufficient for the estimation of the stay, the cost, perioperative complications and re-operation; although some long term complications related to the implant could be underestimated
- Conclusion.
 - Our short-term experience indicates that microdiscectomy plus interspinous device is safe and it shows good clinical results, although the clinical improvement seems to be due to microdiscectomy, without the implant adding any extra benefit. The addition of IDSS did not protect against re-operation, and it increased the surgical expenses.
- **Declaration of interest:** The authors declare that they have no competing interests. The authors declare that they have no financial or personal relationship with any institution or manufacturers of spinal implants related to the content of this publication that could cause a conflict of interest.