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Clinical Study

Microdiscectomy with and without insertion of interspinous device for herniated disc at the L5–S1 level

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ABSTRACT

The role of interspinous devices (ISD) after lumbar herniated disc surgery for the prevention of postoperative back pain is controversial. The aim of this comparative prospective study was to determine outcomes in a selective cohort with L5–S1 disc herniation and degenerative disc changes after microdiscectomy with or without insertion of an ISD. One hundred and two consecutive patients underwent an L5–S1 microdiscectomy with or without implantation of an ISD. Group 1 consisted of 47 patients, with mild (n = 22), moderate (n = 14) or severe (n = 11) degenerative disc changes who had microdiscectomy alone. Group 2 comprised 45 patients with similar types of disc changes who underwent microdiscectomy with an ISD implant. The Visual Analogue Scale (VAS) was used to grade low-back pain and postoperative clinical status was rated according to the modified MacNab criteria. Mean VAS score for low-back pain improved significantly at 1 year follow-up from 7.3 at baseline to 2.75 ($p < 0.001$) in Group 1 and from 6.7 to 1.5 ($p = 0.001$) in Group 2. VAS score at 1 year showed significant improvements in 21 Group 1 patients *versus* 30 Group 2 patients ($p = 0.001$). Forty four percent of Group 1 patients and 80% of Group 2 patients showed improvement using the modified MacNab criteria. Patients in both groups reported significant improvement in sciatic pain and disability after microdiscectomy with or without an ISD implant. Patients with mild degenerative disc changes were more likely to achieve improvement of their low-back pain when treated with both microdiscectomy and ISD insertion.

1. Introduction

The decision to perform a microdiscectomy with or without dynamic spinal fusion in patients with a disc herniation is controversial [1–3]. Yet, the presence of low-back pain and degenerative disc disease can support the placement of an interspinous device (ISD) [4–8]. Although the insertion of dynamic devices has become a relatively common procedure for the treatment of lumbar stenosis and degenerative disc disease [9,10], its concomitant use with standard microdiscectomy is not clear given the lack of comparative studies [11–14]. ISD, although made of various materials [9,3,8,15], all have the mechanical goal of distracting the interspinous space thus increasing intervertebral space height. The reported treatment indications are variable, ranging from treatment of degenerative spinal stenosis, discogenic low-back pain, facet syndrome, disc herniations, and instability [2,3,5,10,16]. These devices have become an alternative treatment for a variety of lesions, including lumbar spondylosis and spinal stenosis [9,10]. This nonspecific and "useful for all" indication [11] makes its use controversial [1] among spinal surgeons.

ISD have been used for more than a decade, and may be static or dynamic depending on the technique, implant design and material composition [2,5,9,10,12,15]. A hard dynamic stabilisation system was designed in 1986 to stiffen unstable operated degenerated lumbar segments with an interspinous blocker and to limit extension; it also contained tension bands around the spinous processes to secure the implant and to limit flexion [8]. The procedure was reversible and if low-back pain persisted or recurred, the device was removed and stability was achieved using rigid fusion. Minns [17] first introduced an interspinous silicone implant for posterior lumbar stabilisation in 1997. Later, Taylor [18] developed a posterior interspinal dynamic stabilisation or balancing device. Since then, the use of soft dynamic techniques in lumbar spinal surgery has grown considerably [5,7,12,13], mainly for degenerative disc disease.

We present our experience in a selected cohort of patients with L5–S1 disc herniation and degenerative disc disease treated with

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microdiscectomy alone compared with a group of similar patients treated with both microdiscectomy and insertion of an ISD.

2. Materials and methods

From February 2009 through February 2011, 102 consecutive patients underwent L5–S1 microdiscectomy for herniated disc and concomitant degenerative disc disease at the same level. This approach was performed by the same surgeon who is experienced in lumbar spinal dynamic fusion. Ethics Board approval was granted and written informed consent was obtained in all patients. Blinded randomisation of patients into Group 1 or 2 was carried out.

Categorisation of degenerative disc disease was made based on Pfirrman et al.'s [19] criteria as:

- mild (Pfirrman Grade III), where the structure of the disc is inhomogeneous, with an intermediate gray signal intensity. The distinction between nucleus and annulus is unclear, and the disc height is normal or slightly decreased
- moderate (Pfirrman Grade IV), where the structure of the disc is inhomogeneous, and has an hypointense dark gray signal intensity. The distinction between nucleus and annulus is lost, and the disc height is normal or moderately decreased
- severe (Pfirrman Grade V), where the structure of the disc is inhomogeneous, and it shows a hypointense black signal intensity. The distinction between nucleus and annulus is lost, and the disc space is collapsed.

Grading was performed on T2-weighted midsagittal (repetition time 5000 ms/echo time 130 ms) fast spin-echo MRI. Herniated discs (Pfirrman Grade I and II) were excluded from the study. Group 1 consisted of 47 patients (22 men, 25 women), with a mean age of 42.5 years (range, 21 to 52 years), with mild (n = 22), moderate (n = 14) and severe (n = 11) changes; this group underwent L5–S1 microdiscectomy alone. Group 2 consisted of 45 patients (23 men, 22 women), with a mean age of 38.5 years (range, 20 to 57 years) with similar disc changes to Group 1 who underwent microdiscectomy with implantation of an ISD (Table 1, 2). The average duration of sciatic and low-back pain before surgery was 12.5 months (range, 4 to 34 months) in Group 1 and 14.5 months (range, 5 to 45 months) in Group 2. The indications for surgery were herniated lumbar disc and associated degenerative disc disease at the L5–S1 level which was unresponsive to conservative treatment for at least 3 to 6 months. All patients underwent preoperative anteroposterior, lateral and flexion-extension radiographs of the lumbar spine.

MRI was performed in all patients (Fig. 1, 2). Exclusion criteria included extraforaminal herniated disc, recurrent disc herniation, same level or other level post-discectomy surgery, upper level symptomatic degenerative disc disease with foraminal stenosis including black disc, all other types of previous spinal fusion, all grades of spondylolisthesis, absence of the lamina in the affected level observed on plain lumbar radiographs, severe osteoporosis, obesity greater than 60% of ideal body mass, significant circulatory or cardiac disease, cancer or active infection. A rehabilitation specialist made the preoperative and postoperative evaluations. The Visual Analogue Scale (VAS) was used to grade low-back and leg pain. All patients had radicular pain, with typical clinical manifestations of S1 radiculopathy present in 90% of patients in both groups. No patient had paresis or cauda equina syndrome.

Table 1
Demographic data of Group 1 (microdiscectomy alone) and Group 2 (microdiscectomy combined with interspinous device implant)

	Group 1	Group 2
Patients, n	47	45
Males/Females	22/25	23/22
Mean age, years	42.5	38.5
Mean symptom duration, months	12.5	14.5
Preoperative VAS back pain	7.3	6.7

VAS = Visual Analogue Scale.

Table 2
Preoperative classification of severity of degenerative disc changes in Group 1 (microdiscectomy alone) and Group 2 (microdiscectomy combined with interspinous device implant)

	Group 1	Group 2
Mild	22	21
Moderate	14	14
Severe	11	10
Total	47	45

The mean score improvement from baseline in the VAS domain was compared between Group 1 and 2 using an analysis of variance with a level of significance of 0.05. The percentage of patients who had significant clinical improvement according to their degenerative disc changes domain was compared between groups using Fisher's exact test with a level of significance of 0.05.

Data were collected prospectively, and clinical outcomes were graded using a modified version of the MacNab criteria for evaluation of lumbar dynamic fusion (Table 3).

Surgery was performed after induction of general (n = 40) or spinal (n = 62) anaesthesia, equally distributed among groups, with the patient placed prone on a radiolucent table and the spine flexed on a soft spinal frame. Conventional foraminotomy and microdiscectomy were performed with adequate radicular decompression achieved in all patients. No nerve root anomalies were found. Excessive curettage of the disc was avoided, however osteophytes of the end plates were removed when present.

We used two ISD of similar characteristics: the Device for Intervertebral Assisted Motion (DIAM; Medtronic Sofamor Danek, Memphis, TN, USA) in 23 patients, and the IntraSpine (Dynamic Interlaminar Device, Cousin Biotech, Wervicq-Sud, France) in 22 patients. Both are silicone interspinous-interlaminar process implants with laces to secure around the spinous processes.

We performed the technique of ISD lumbar implantation as previously described by Taylor [18] with slight modifications. A 3 to 4 cm midline incision was performed in the ISD group. After skin incision, bilateral muscle fascia openings were made along and next to the superior interspinous ligament. After muscle distraction and radiographic confirmation of the correct level, the interspinous ligaments were divided, preserving the supraspinous ligament. The middle part of the interspinous ligament was removed with a rongeur. Subsequently, interspinous distractor insertion and gradual distraction were undertaken over the middle or inferior aspect of both spinous processes of the vertebra. Utmost care was taken not to break the spinous process during distraction. The ligamentum flavum over the midline was removed and the superior and inferior edges of the exposed laminae were defined with sharp dissection and Kerrison rongeurs. At this point, the interspinous distractor was moved down over the lamina or the spinous process and lamina boundary to distract the exposed level further. After the standard technique for foraminotomy and discectomy, a trial probe was inserted to measure the interspinous space, and the size of the ISD was chosen accordingly. The distractor was then removed and the ISD positioned in its final position at the spinous process and lamina interface and subsequently secured with its polyethylene strings to both the superior and inferior spinous process. The laces were then passed through loops on the ISD, tensioned, and secured. The wound was closed in layers and no drain was left in place. Final intraoperative lumbar radiographs are taken