G Chir Vol. 31 - n. 5 - pp. 247-250
Maggio 2010

X-Stop interspinous implant for the treatment of lumbar spinal stenosis. Our experience after 50 consecutive patients

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SUMMARY: **X-Stop interspinous implant for the treatment of lumbar spinal stenosis. Our experience after 50 consecutive patients.**

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The authors report their surgical experience on 50 patients affected by single or two level segmental lumbar canal stenosis who underwent implantation of one or two X-Stop interspinous devices between October 2007 and February 2008 at the Department of Neurosurgery, "Santa Maria alle Scotte" Hospital, Siena, Italy.

In the present study there will be analyzed clinical long-term results and reviewed the relevant literature.

RIASSUNTO: **X-Stop: un nuovo dispositivo per il trattamento della stenosi del canale spinale lombare. Esperienza su 50 casi operati.**

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Gli Autori riportano la loro esperienza chirurgica sull'utilizzo di un nuovo dispositivo interspinoso, in 50 pazienti affetti da stenosi mono- o multi-segmentaria del canale lombare, impiantato tra ottobre 2007 e febbraio 2008 presso l'UOC di Neurochirurgia Ospedaliera del Policlinico "Santa Maria alle Scotte" di Siena.

Vengono analizzati i risultati a lungo termine e si riporta una breve rassegna della letteratura attinente.

KEY WORDS: Lumbar spinal stenosis - Neurogenic intermittent claudication - Laminectomy - X-Stop spacer.
Stenosi lombare - Claudicatio neurogena intermittente - Laminectomia - X-Stop spaziatore.

Introduction

Patients suffering from neurogenic intermittent claudication secondary to lumbar spinal stenosis (LSS) have historically been limited to a choice between a decompressive laminectomy with or without fusion or a regimen of non-operative therapies (2, 3).

A novel alternative therapy to conservative treatment and decompressive surgery has been developed for patients suffering from LSS. The lumbar interspinous process decompression (IPD) devices represent a promising surgical treatment alternative for a variety of spinal pathologies. Intuitively they provide an unloading distractive force to the stenotic middle column part of the motion segment and have the potential to relieve the symptoms of neurogenic intermittent claudication, associated with spinal stenosis (4). The first interspinous implant for the lumbar spine was developed in the 1950s by Knowles. Owing to flaws in the design, material, surgical technique and applied indications its use was abandoned. Several other IPD devices, with significant differences in designs, materials, surgical techniques and indications have appeared in Europe and South America in the 1990s, some of which are beginning to be evaluated in controlled trials for a host of indications (5-7). Most of these implants are placed in the interspinous space to improve clinical outcomes after a diskectomy In contrast with other rigid IPD devices, placement of the X-Stop (Fig. 1) does not violate the supraspinous/ interspinous ligamentous complex, which was found to be the largest contributor to resisting applied flexion moments in the lumbar spine in the animal model (8).

Patients and methods

Patient selection

Fifty consecutive patients underwent X-Stop surgery for LSS between October 2007 and February 2008. There were thirty-three men and seventeen women, with a mean age of 65 years (range 33–

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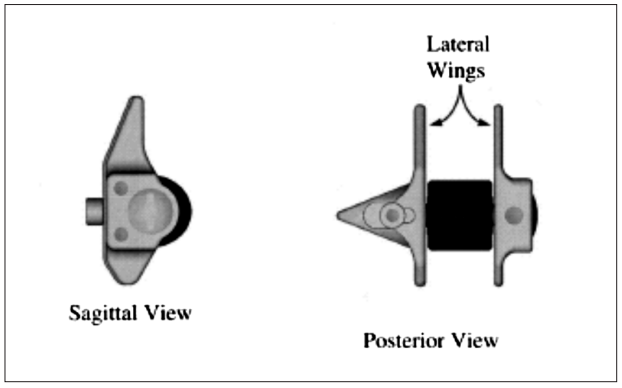


Fig. 1 - Sagittal and posterior schematic views of the X-Stop implant.

76 years) at the time of surgery. All patients had preoperative leg pain with or without back pain that was relieved in flexed positions such as bending forward and sitting or lying down and worsened in extension. Inclusion criteria required that each patient 1) had mild to moderate stenotic symptoms, 2) had pain that was relieved when flexing and worsened when extending, and 3) had dural sac compression in extension and relief in flexion as verified by dynamic MRI. The exclusion criteria included 1) unremitting pain in any position, 2) fixed motor deficit, 3) severe symptomatic LSS at three or more levels, and 4) significant spinal instability. Nine patients were affected by single-level segmental stenosis while forty one suffered from two-level stenosis (Figs. 2A, 2B).

Operative technique

Standard general anesthesia was administered in each case, and surgery was performed with the patient in prone position with the lumbar spine flexed as much as possible. A midline skin incision of approximately 8 cm was made above the spinous processes of the stenotic level. The paraspinal muscle was elevated from both sides of the spinous processes to the level of the facets and laminae. The supraspinous ligament was preserved, and a curved dilator was used to pierce the interspinous ligament and locate the space between the spinous processes. The operative level was verified by fluoroscopy. The interspinous space was gently sized with a sizing distractor. The correct implant size was determined by opening the sizing distractor until significant resistance was encountered. The main body of X-Stop was inserted from the right side as close to the laminae as possible (Figs. 3). The universal wing was attached and locked in position by tightening the nut.

Outcomes assessment

Data were collected prior to the initial treatment, at 3 months and 6 months following the initial treatment using the Zurich Claudication Questionnaire (ZCQ) also known as the Swiss Spinal Stenosis Questionnaire (9) (Table 1).

Statistical analysis

Statistical data analysis was carried out using the chi-square test and contingency coefficient; a probability of less than 0,05 was considered significant

Results

The mean operative time was 32 minutes (range 27-36 minutes) for one level, 35 minutes (range 28-38) for two levels procedure. There were no implant-related complication or additional surgery required. The mean hospital stay after operations was 1, 22 days (range 1-3). In all patients a lumbar corset was applied for at least one month. Outcome data were obtained at a minimum follow-up period of 6 months. The satisfaction domain of the SSS showed that 90% of patients were at least somewhat satisfied with the outcome of their surgery. The best satisfaction rates have been given by patients operated at a double level. Satisfaction results given by patients of elder age or with longest duration of the symptoms, doesn't result statistically significant (Table 2).

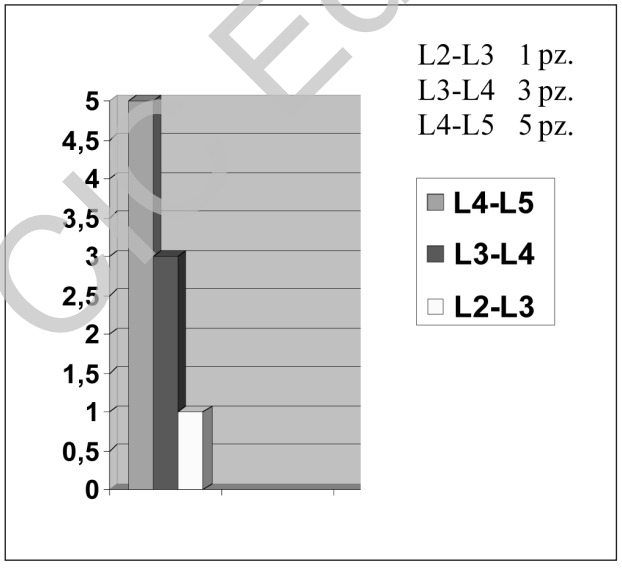


Fig. 2A - Patients single level treated.

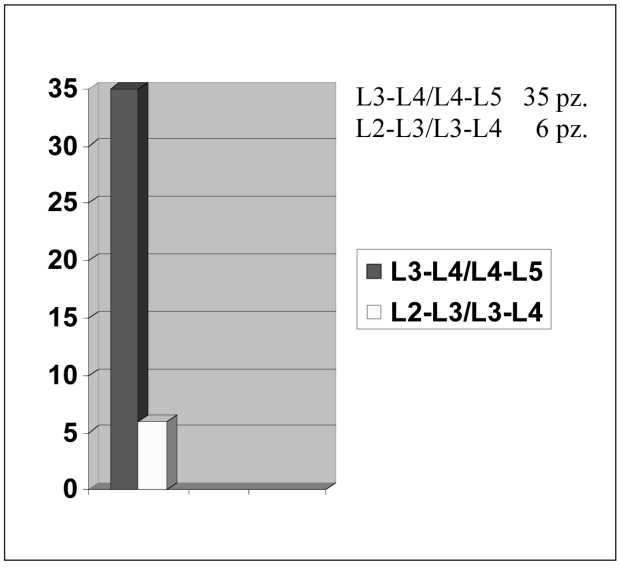
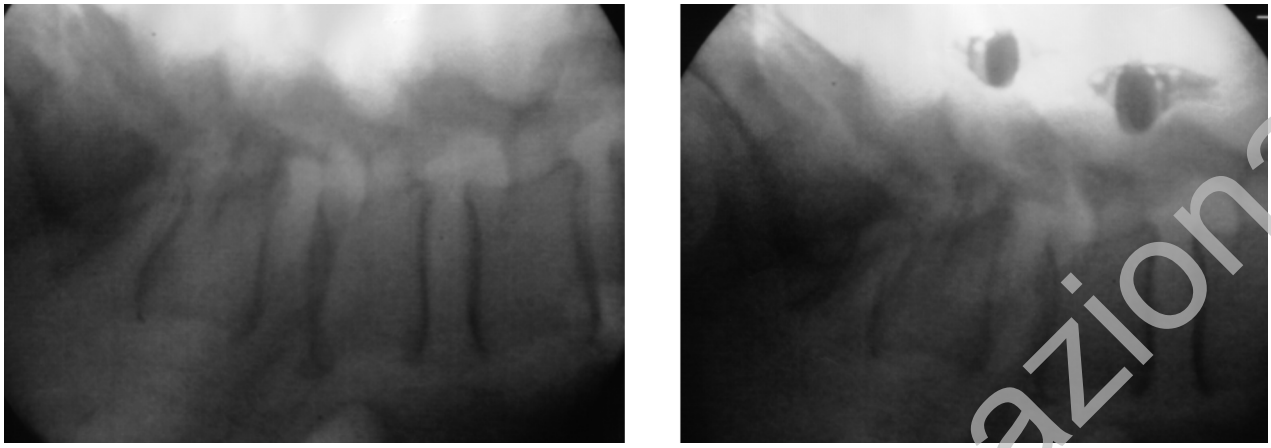


Fig. 2A - Patients double levels treated.



Figs. 3 - X-rays of the same patient before (left) and after (right) implant surgery.

TABLE 1 - SSS QUESTIONNAIRE.

In the past month, how would you describe

1. The pain you have had on the average including pain in your back and buttocks as well as pain that goes down the legs?

❑ None ❑ Mild ❑ Moderate ❑ Severe ❑ Very severe

2. How often have you had back, buttock, or leg pain?

❑ Less than once a week
❑ At least once a week
❑ Every day, for at least a few minutes
❑ Every day, for most of the day
❑ Every minute of the day

3. The pain in your back or buttocks?

❑ None ❑ Mild ❑ Moderate ❑ Severe ❑ Very severe

4. The pain in your legs or feet?

❑ None ❑ Mild ❑ Moderate ❑ Severe

5. Numbness or tingling in your legs or feet?

❑ None ❑ Mild ❑ Moderate ❑ Severe

6. Weakness in your legs or feet?

❑ None ❑ Mild ❑ Moderate ❑ Severe ❑ Very severe

7. Problems with your balance?

❑ No, I've had no problem with balance.
❑ Yes, sometimes I feel my balance is off or that I am not sure-footed.
❑ Yes, often I feel my balance is off or that I am not sure-footed.
❑ In the past month, in a typical day

8. How far have you been able to walk?

❑ More than 2 miles
❑ More than 2 blocks, but less than 2 miles
❑ More than 50 feet, but less than 2 blocks
❑ Less than 50 feet

9. Have you taken walks outdoors or around the shops for pleasure?

❑ Yes, comfortably
❑ Yes, but sometimes with pain
❑ Yes, but always with pain
❑ No

TABLE 2 - FACTORS INFLUENCING THE SURGICAL RESULTS.

Factors	Patients, n	χ^2 test	p-value
Age			
>45	38	3,266	0,325
<45	12		
Number of levels			
one level	9	10,22	0,0018
double level	41		
Onset of symptoms (months)			
>12	46	9,01	0,777
<12	4		

Discussion

Neurogenic intermittent claudication secondary to LSS is a degenerative condition prevalent in the general population 50 years of age and older, and decompressive surgery for LSS is now the most commonly performed spinal surgery in patients age 65 years and over (10). Surgery for lumbar spinal stenosis is generally accepted when conservative treatment (physiotherapy, anti-inflammatory drugs and epidural infiltrations) has failed; it aims at improving the quality of life through a reduction of symptoms. The use of wide decompressive procedures without regard for the integrity of the laminae and facet joint and without preservation of the spinous processes and interspinous ligaments, may lead to mechanical failure of the spine and a chronic pain syndrome. Some recent studies have reported on less aggressive surgical techniques (laminotomy, laminarthrectomy, fenestration) that provide adequate decompression but the possible and frequent complications or the modest satisfac-

tion of the patients indicate the need for more information and solutions concerning the relative efficacy of surgical treatment for spinal stenosis (11, 12). In our opinion the implantation of the X-Stop interspinous device is a safe procedure, minimally invasive and easy to perform, providing early symptom regression in patients, young or old, affected by two-level segmental lumbar canal stenosis.

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