

Clinical Study

# Aperius interspinous implant versus open surgical decompression in lumbar spinal stenosis

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## Abstract

**BACKGROUND CONTEXT:** Few studies have analyzed the results of an interspinous distraction device in patients with lumbar spinal stenosis. It is still unknown whether the outcomes of an interspinous implant are related to the severity of stenosis.

**PURPOSE:** To determine the success rate of the Aperius implant and open decompression with the aim of defining better the indications for the two modalities of treatment.

**STUDY DESIGN:** Comparison of two cohorts of patients with moderate or severe stenosis treated with the Aperius or by open decompression.

**PATIENT SAMPLE:** The sample comprises 36 patients who had the Aperius implant and 35 who underwent open decompression, both groups followed prospectively. In the two cohorts, central or lateral stenosis was present in similar proportions, and in both, the patients had pure intermittent claudication or symptoms at rest and on walking. In both groups, preoperative diagnosis was made by magnetic resonance imaging (MRI).

**OUTCOME MEASURES:** Patients of both groups were evaluated with the Zurich Claudication Questionnaire (ZCQ) and Oswestry Disability Index. The results were rated as good or poor based on the ZCQ.

**METHODS:** The patients of both cohorts were evaluated at 1 month and 3, 6, and 12 months after operation, the final follow-up being carried out at least 2 years after surgery. Severity of stenosis was determined based on preoperative MRI scans. In 17 patients of the Aperius group, MRI studies were repeated at the 6-month or final follow-up and compared with the preoperative studies.

**RESULTS:** Of the patients in the Aperius group, six had removal of the implant and open surgical decompression at 2 to 17 months after operation; these patients were considered to have a poor result. At the final follow-up, the result was rated as good in 47% of all patients who had had the Aperius implant. The percentage of good outcomes was 60% in moderate stenosis and 31% in severe stenosis. When considering all not reoperated patients, 57% had good outcomes; however, if only the scores in the patient satisfaction domain of the ZCQ were considered, 67% of these patients were somewhat satisfied with the result of Aperius. No significant relationship was found between patients with pure intermittent claudication and those with leg symptoms also at rest. In 71% of cases in which preoperative and postoperative MRIs were compared, no significant change in size of the spinal canal was found after operation, whereas in the remaining patients a slight increase in size of the canal was detected. In the open decompression cohort, the results were good in 80% of cases and poor in 20%. The outcomes were satisfactory in 69% of moderate stenosis, with no significant difference with the similar subgroup of the Aperius series. In severe stenosis, the 89% rate of good results was significantly higher than in the severe Aperius subgroup ( $p < .0001$ ).

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**CONCLUSIONS:** The Aperius interspinous implant is poorly indicated for severe lumbar stenosis, which is significantly improved only in a small minority of cases, whereas decompression procedures ensure high chances of good results. The implant may be indicated for selected patients with moderate stenosis. The outcomes of the Aperius are not influenced by the type of clinical presentation of lumbar stenosis. © 2011 Elsevier Inc. All rights reserved.

**Keywords:** Lumbar spinal stenosis; Severity of stenosis; Interspinous implant; Open surgical decompression

## Introduction

The standard operative procedure for lumbar spinal stenosis is open surgical decompression. The first interspinous process implant was developed by Senegas et al. [1], who used the device also in lumbar stenosis but only to stabilize the motion segment after open decompression. In previous years, several interspinous devices have been developed to obtain indirect decompression of neural structures in lumbar stenosis by posterior segmental distraction. The most often used implant has been the X-Stop, which is inserted by an open approach centered on the interspinous space [2–8].

The Aperius, introduced in the clinical practice in 2007 (Medtronic, Memphis, TN, USA), has been the first interspinous device developed to be implanted percutaneously, usually under local anesthesia.

During the past few years, there has been a widespread use of the interspinous spacers in patients with central or lateral lumbar stenosis of any severity. But, the clinical results of these devices, implanted by open surgery or percutaneously, are still controversial [2,3,6–8]. Furthermore, only one study [9], carried out on very small groups of patients, compared the X-Stop with open decompression.

We compared the results of the Aperius implant with those of open decompression with the aim to better define the indications for the two types of procedures in patients with lumbar stenosis.

## Patients and methods

### Aperius

From September 2007 to April 2008, 36 consecutive patients with lumbar stenosis were treated with the Aperius and followed prospectively. Exclusion criteria in 20 other cases were severe motor deficits (muscle strength less than or equal to 3 of 5), spinal stenosis at greater than two levels, degenerative spondylolisthesis (DS) greater than or equal to 15%, degenerative scoliosis, or severe osteoporosis (total *T* score in the lumbar spine less than or equal to 3 with dual-energy X-ray absorptiometry) because of the risk of fracture of spinous processes.

There were 20 women and 16 men, aged 52 to 87 years (mean, 68 years). The mean duration of leg symptoms was

8 months. Preoperative diagnosis was made by MRI. Central stenosis was diagnosed in 29 patients, and lateral stenosis in seven patients. Degenerative spondylolisthesis with an average vertebral slipping of 11% was present in six cases. Radicular symptoms only on walking (pure intermittent claudication) were reported by 61% of patients, whereas in 39% radicular pain was present both at rest and on walking (Table 1). Mild motor deficit of a single lumbar nerve root was present in 11 cases. Major comorbid illnesses were reported by 28% of patients (Table 1).

Preoperative clinical status was evaluated by the Zurich Claudication Questionnaire (ZCQ) and Oswestry Disability Index (ODI). Zurich Claudication Questionnaire is an outcomes measurement specific to lumbar stenosis, consisting of three domains: symptom severity (SS), physical function (PF), and patient satisfaction (PS) [10,11]. The Aperius was implanted at L4–L5 level in 25 cases, L3–L4 in 6 cases, L2–L3 in 2 cases, and both L3–L4 and L4–L5 in 3 cases. Thickness of the device was 10 mm in 16 cases, 12 mm in 15, and 14 mm in 5 (Fig. 1). It was consistently inserted

Table 1  
Clinical data of patients (in numbers) treated with the Aperius or by open decompression

	Aperius	Open decompression
Clinical presentation		
Intermittent claudication	22	20
Pain at rest and on walking	14	15
Type of stenosis		
Central	29	28
Lateral	7	7
Severity of stenosis		
Moderate	20	16
Severe	16	19
Degenerative spondylolisthesis	6	5
Major comorbidities	10*	8†
Operative complications	0	3
Comparison of MRIs	17	
Increased size of spinal canal	5	
Increased size of neuroforamen	4	

MRIs, magnetic resonance imagings.

\* Previous heart infarction or other cardiac diseases, chronic respiratory conditions, diabetes, and hip or knee osteoarthritis.

† Cardiac diseases, chronic respiratory conditions, previous deep venous thrombosis, diabetes, and hip or knee osteoarthritis.

under local anesthesia. Mean postoperative hospitalization was 1.3 days.

Follow-up evaluations were made at 1 month and 3, 6, and 12 months, and the final follow-up at an average of 26 months after operation (range, 24–31 months). However, we also evaluated the patients between or after the short-term follow-ups in case of persistent or recurrent symptoms. At each scheduled follow-up, clinical evaluation was made by ZCQ and ODI. Patients were evaluated by one of us who was not involved in the treatment.

After 2 to 16 months of the spacer implantation, six patients underwent removal of the implant and open decompression because of no improvement in leg pain or recurrence of pain after a pain-free period.

At final follow-up, the 31 patients, 28 with the Aperius and 3 reoperated on, who attended our hospital were evaluated by the ZCQ and ODI, and those who still had the Aperius underwent X-rays of the lumbar spine. Of the remaining five patients, who were asked to fill in the questionnaires that were mailed, two returned them, whereas three, all reoperated, did not. Thus, the final clinical follow-up was carried out in 33 cases. In 17 patients who had no open decompression, MRI studies were repeated at the 6-month, or the final, follow-up.

#### Outcomes assessment

At the time of this study, preoperative MRI scans of each case were independently evaluated by two of the authors and a neuroradiologist who were unaware of the clinical outcome. They were asked to identify two categories of stenosis: moderate and severe.

The severity of central stenosis was evaluated on axial scans by measuring either the midsagittal diameter of the spinal canal and the transverse diameter between the most medial border of the ligamenta flava covering the posterior joints. Measurements were made on the axial scan at the intervertebral level where the spinal canal was narrowest.

## EVIDENCE & METHODS

### Context

Interspinous spacers for spinal stenosis were initially developed as an alternative for patients medically unfit for open decompression. However, their use has expanded in some centers to be considered a general alternative to open decompression for the treatment of lumbar spinal canal stenosis. This matched-cohort study compares these two approaches.

### Contribution

For patients with moderate or severe stenosis, respectively, the interspinous device provided good outcomes in 60% and 31% of patients as measured by the Zurich Claudication Questionnaire (ZCQ). Following open decompression, results were good in 69% and 89%, respectively. Seventeen percent of the interspinous spacers required removal and revision to open decompression.

### Implication

This independent study suggests that in cases of severe stenosis, open decompression affords better results than interspinous spacers. In light of reliably good outcomes with open decompression (as demonstrated in the SPORT and Maine spinal stenosis studies), the role for interspinous devices as a general treatment for lumbar spinal stenosis is yet to be determined.

—The Editors

Stenosis was classified as moderate when the midsagittal and/or transverse dimensions were decreased up to 40% than those of the first not stenotic level above or below and severe when the decrease was greater than or equal to 41%. Lateral stenosis was evaluated by measuring the

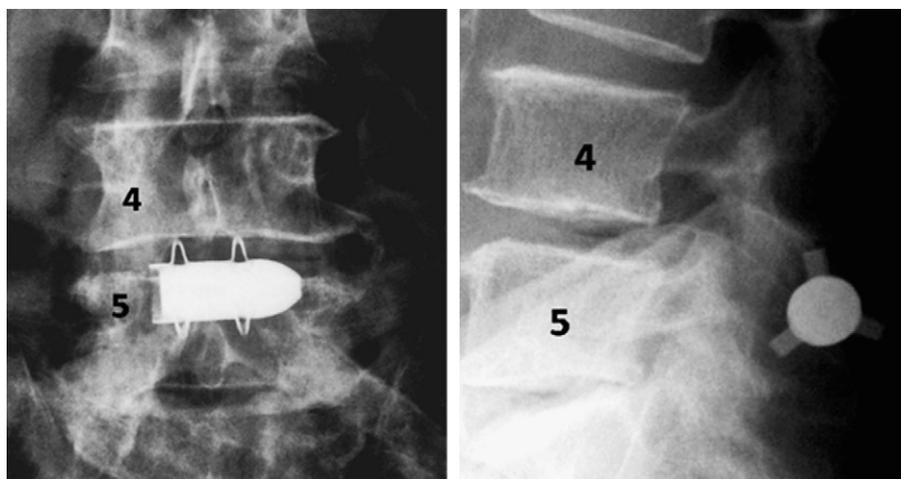


Fig. 1. Anteroposterior (Left) and lateral (Right) radiographs of a 12-mm-thick Aperius interspinous spacer implanted at L4–L5 level.

sagittal dimension of the most medial part of the lateral spinal canal. Stenosis was classified as moderate when the decrease in width was up to 40% than that of the ipsilateral canal of the first normal level above or below and severe when narrowing was greater. Evaluation of the neuroforamen was made on parasagittal images. Stenosis was considered as moderate when the sagittal dimensions of the midportion of the foramen were decreased up to 40% than those of the first normal foramen above and severe when narrowing was more marked.

The preoperative scores of ZCQ and ODI in patients undergoing the Aperius implant or revision surgery were compared with those obtained at the early and final follow-ups. As in similar previous studies [2,3,6,7], the clinical results were rated as good or poor, based on the scores of the ZCQ. The outcome was classified as good when the score in the PS domain was less than or equal to 2.0, that is, the patient was at least somewhat satisfied with the result of operation, and the scores in both the SS and PF domains were improved by at least 0.5 points [10,11]. For the ODI, the treatment was considered successful when there was an improvement of at least 15 points after surgery.

The X-rays obtained at final follow-up were compared with the immediate postoperative ones. In the 17 not reoperated cases in which both preoperative and postoperative MRIs were available, the two sets of images were compared by the same examiners who determined the severity of stenosis, using similar modalities. There were three options: no change, slight increase, or considerable increase, in size, when the increase was 0% to 10%, 11 to 20%, or greater than 20%, respectively. Interrater correlations were assessed for measurements on preoperative and postoperative MRIs.

### Open decompression

We identified, from the clinical charts, 38 consecutive stenotic patients who had undergone surgery between January 2004 and January 2007. They were all the patients operated in that time frame, once 61 cases presenting with conditions considered contraindications to implantation of Aperius, except osteoporosis, were excluded.

All patients, either if they entered into the study or not, had been included in a prospective trial on the long-term results of open surgery in lumbar stenosis. Of 38 patients, 3 could not be traced, thus leaving 35 cases. There were 18 women and 17 men, aged 53 to 81 years (mean, 65 years). Leg symptoms lasted 2 months to 4 years (mean, 13 months).

Preoperative diagnosis, made on MRI, was central stenosis in 28 cases and lateral stenosis in seven. Degenerative spondylolisthesis with a mean slipping of 12% was present in five patients, four of whom had no vertebral hypermobility on functional X-rays. Pure intermittent claudication was reported by 57% of patients; in the remaining 43%, leg symptoms were present both at rest and on walking (Table 1). Mild uni- or bilateral motor deficit of L4, L5, or

S1 root were present in six cases. There were major comorbid conditions in 23% of cases (Table 1). Preoperatively, patients had filled in the ZCQ and ODI questionnaires.

Operation was performed at L4–L5 level in 23 cases, L3–L4 in 5 cases, L2–L3 in 1 case, and L3–L4 and L4–L5 in 6 cases. Decompression procedures consisted almost always of unilateral or bilateral laminotomy, including seven patients with DS. Complications included a tear of the thecal sac with no clinical sequelae in two cases and one case with transitory motor deficit of L5 root. Mean postoperative hospitalization was 4.6 days.

All patients were followed up for 1 month and 3, 6, and 12 months after surgery. At each follow-up, they filled in the ZCQ and ODI questionnaires. At the time of this study, they were asked to attend for clinical evaluation; the 32 who accepted filled in the ZCQ and ODI, whereas three were asked to respond by mail. The mean time interval between operation and final follow-up was 31 months (range, 24–46 months). In one patient with moderate stenosis, repeat surgery was performed 3 months after the original operation because of persistent leg pain; the result was rated as poor.

### Outcomes assessment

Preoperative severity of stenosis on imaging studies was determined by the same examiners who evaluated the Aperius patients, using the same methods. The clinical result was rated as good or poor based on the ZCQ scores, using the same methods used for the Aperius group.

### Statistical analysis

Statistical analysis was carried out using SPSS version 12.0 software (SPSS Inc., Chicago, IL, USA). Fisher exact test was used as the test of significance. Values of *p* less than .05 were deemed to be statistically significant, and only these are reported in the comparison between subgroups in the Aperius and open decompression groups or subgroups of a single group.

## Results

### Aperius

Stenosis was moderate in 20 cases and severe in 16. The type of stenosis is reported in Table 1 and the severity of narrowing as related to the type of stenosis in Table 2. Of

Table 2  
Severity of narrowing in patients with central or lateral stenosis of the spinal canal

Aperius		Open decompression	
Central	Lateral	Central	Lateral
Mod. 14	Mod. 6	Mod. 12	Mod. 4
Sev. 15	Sev. 1	Sev. 16	Sev. 3

Mod., moderate; Sev., severe.

the six patients who underwent open surgery, two had moderate stenosis and four had severe stenosis; in these patients, the result was rated as poor.

The mean preoperative and postoperative scores in the ZCQ and ODI of the 31 not reoperated patients are reported in Table 3. The rate of good results was slightly higher at 6-month follow-ups compared with previous follow-ups in moderate stenosis but not in severe stenosis. No significant change was found in both subgroups in subsequent evaluations. At final follow-up, 17 of the 36 patients (47%) were considered to have a good result (Table 4). The percentage of good outcomes was 60% (12 of 20 cases) in the subgroup of moderate stenosis and 31% (5 of 16 cases) in that of severe stenosis, with a significant difference ( $p < .002$ ). When considering all the not reoperated patients, 57% (17 of 30 cases) had good outcomes. However, from the PS domain of the ZCQ, 67% (20 of 30 cases) were found somewhat satisfied with the result of Aperius. The results of the ZCQ agreed with those of ODI in all cases except for 2.

Age, sex, level or levels involved, and thickness of the spacer did not affect the result of operation. No significant relationship was found between patients with pure intermittent claudication and those with leg symptoms also at rest. The proportions of good outcomes in patients with DS (66% in moderate stenosis and 33% in severe stenosis) were similar to those of patients without olisthesis, and in no case did the vertebral slipping increase after Aperius implant.

In all patients who had plain X-rays at final follow-up, the position of the spacer was unchanged and no adjacent bone resorption was seen. In 12 (71%) of the 17 cases in which preoperative and postoperative MRIs were compared, no significant change in size of the spinal canal was found postoperatively, whereas in 5 (29%) a slight increase in size (mean, 16%) of the canal was detected ( $p < .002$ ) (Table 1). The increase appeared to be mainly because of a decrease in thickness of the ligamenta flava or to decreased ligament infolding with resultant reduced encroachment on the spinal canal (Fig. 2). The intervertebral foramen was slightly enlarged at the operated level or levels in 24% of cases (Table 1). On the other hand, no significant relationship was found between the increase in size of the spinal canal or neuroforamen and the clinical result. The

Table 3  
Mean preoperative and postoperative ZCQ and ODI scores in the Aperius group

Preoperative	1 mo	3 mo	6 mo	2-y Follow-up
ZCQ				
42	25	22	18	20
ODI				
68	39	40	37	40

ZCQ, Zurich Claudication Questionnaire; ODI, Oswestry Disability Index.

To better understand the scores of ZCQ, see the description of the questionnaire in the section Patients and methods.

Table 4

Good and poor results in the Aperius and open decompression groups at final follow-up

	Good results		Poor results	
	Aperius (%)	Op. dec (%)	Aperius (%)	Op. dec. (%)
Overall	47	80	53 (6 Re-op*)	20
Moderate stenosis	60	69	40 (2 Re-op*)	31 (1 Re-op <sup>†</sup> )
Severe stenosis	31	89	69 (4 Re-op*)	11

Op. dec., undergoing primarily to open decompression.

\* Re-op: patients undergoing removal of Aperius and open decompression.

<sup>†</sup> Re-op: patient undergoing revision surgery after open decompression.

interrater reliability coefficients for measurements on preoperative and postoperative MRIs were 0.89 and 0.84, respectively. All six patients who had undergone open surgery had a satisfactory result at final follow-up.

### Open decompression

Type and severity of stenosis, as well as severity of narrowing as related to type of stenosis are reported in Tables 1 and 2.

The preoperative and postoperative ZCQ and ODI scores are reported in Table 5. Patients with moderate stenosis improved in the first 6 months, whereas most of those with severe stenosis reached the final result for leg symptoms after 4 months of operation. At 12-month follow-up, satisfaction with the outcome of surgery in the PS domain of the ZCQ was reported by 10 patients (62%) with moderate and 16 (84%) with severe stenosis. At final evaluation, 28 patients (80%) had a good result, whereas 7 (including the 1 reoperated) had a poor outcome (Table 4). In moderate stenosis, the percentage of good results was 69% (11 of 16 cases), with no significant difference compared with the moderate subgroup of Aperius (Table 4). In the severe subgroup, the good outcomes were 89% (17 of 19 cases), the difference with the similar Aperius subgroup being significant ( $p < .0001$ ).

In patients with DS, the 60% rate of good results was lower than in the entire cohort because of persistence of moderate back pain. No relationship was found between the result of surgery and age, sex, type of leg symptoms, and type of stenosis.

### Discussion

Interspinous spacers have been used in various degenerative diseases on the lumbar spine [12]. However, few studies have analyzed the results of implantation of a spacer, with no additional neural decompression, in lumbar stenosis, and in all trials, the X-Stop was used [2–9,12–14]. Zucherman et al. [2], in a prospective randomized multicenter study evaluating the 1-year outcome of the interspinous implant using the ZCQ, reported a success rate of

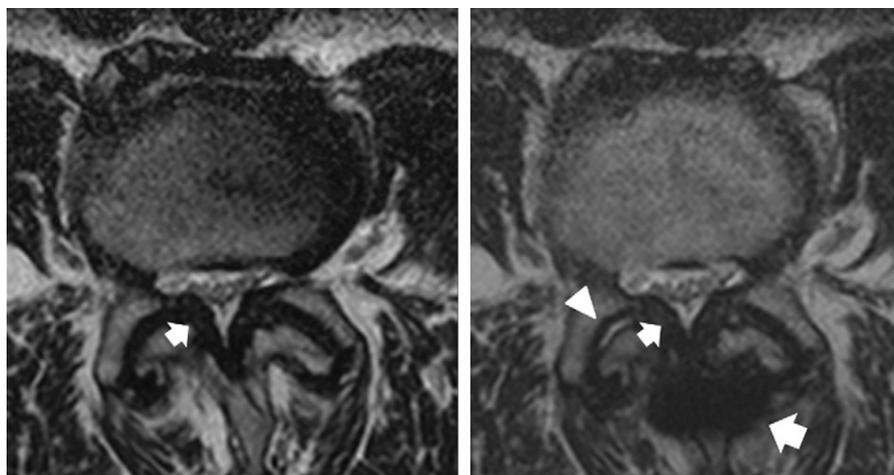


Fig. 2. MRI scans of a patient who underwent implantation of the Aperius for L3–L4 central lumbar stenosis. Left: Preoperative axial scan showing enfolding of thickened ligamenta flava (small arrow) that encroached on the spinal canal. Right: On the postoperative axial image, obtained at 6-month follow-up, there was less encroachment of the ligamenta flava (small arrow) onto the spinal canal due to thinning of the ligaments, and slight increase in size of the thecal sac. Synovial fluid is visible in the right facet joint (arrowhead). The large arrow points the interspinous spacer.

59%. The same authors [3], in a study on 100 patients followed up for 2 years, found a clinically significant improvement in the SS and the PF domains of the ZCQ in 60% and 57% of patients, respectively, whereas 73% were somewhat satisfied. Only slightly worse results were reported by Siddiqui et al. [6] in a group of 24 patients. However, Brussee et al. [7] found a good outcome, when considering all three domains of the ZCQ, in only 31% of 62 cases. Similar results were reported by Verhoof et al. [8], who had a failure rate of 58% in patients with DS. In the only study [9] comparing the X-Stop with open decompression, the success rate was 78% in 18 who had a spacer and 33% in 12 decompression procedures.

We compared a group of patients undergoing the Aperius implant and one treated by open decompression. Although the latter was a historical one, the two cohorts were entirely comparable because both patients were followed prospectively using the same methods of evaluation. Moreover, in the open decompression group, we excluded all patients with conditions representing contraindications for an interspinous device.

No trial has related the results of an interspinous implant to the severity of stenosis. Furthermore, in most studies, the indication for the implant was pure intermittent claudication [2,3,5–7,9,13,14]. Nonetheless, claudication, while

being the most characteristic clinical feature, is not the unique presentation of lumbar stenosis. In many patients, leg pain is also present at rest and exacerbates on walking to a varying extent [15]. We compared the outcome of treatment in patients with different types of clinical presentation and severity of stenosis.

In our series, the outcomes of Aperius or open decompression were not affected by the type of clinical presentation; this suggests that a spacer may be indicated also for patients with leg symptoms at rest. Conversely, a clear-cut difference was found between moderate and severe stenosis. In the Aperius series, the rate of good results was significantly higher in moderate, than in severe, stenosis. In the latter subgroup, 25% of patients underwent open decompression and the success rate in the entire subgroup was 31%. In patients with severe stenosis in the open decompression group, the percentage of good results (89%) was significantly higher. Aperius spacer may thus be a therapeutic option in selected patients with moderate stenosis, whereas it is poorly indicated for severe stenosis.

Schonstrom et al. [16] measured the size of the spinal canal and the area of the thecal sac on axial computed tomography scans in central stenosis. Measurement of the area of the sac was found to be the most reliable for diagnosis of central stenosis, the critical value being 100 mm [2]. Nevertheless, neither in that study nor in others, a differentiation was made between moderate and severe stenosis. Furthermore, in the study by Schonstrom [16], no evaluation was made of the lateral canal or intervertebral foramen. In our patients, we evaluated MRIs, which allow better visualization than computed tomography of the ligamentum flavum and intervertebral disc. The preoperative evaluation of severity of central stenosis was based on measurements, on axial scans, of the size of the central spinal canal, compared with that of the first adjacent not stenotic level above or below, rather than on the area of the canal or the thecal sac at the stenotic level. A

Table 5

Mean preoperative and postoperative ZCQ and ODI scores in the open decompression group

Preoperative	1 mo	3 mo	6 mo	2-y Follow-up
ZCQ				
51	17	17	14	13
ODI				
69	20	15	12	12

ZCQ, Zurich Claudication Questionnaire; ODI, Oswestry Disability Index.

similar method was used for the lateral canal and neuroforamen and the effects of Aperius on the three spinal structures. The evaluation of severity of stenosis based on measurements of the area of the spinal canal or thecal sac, or the area of the lateral canal, may have limited relevance. In severe stenosis, in which the thecal sac may be poorly visible on axial scans, the area of the sac may not be measured exactly; and severe compression of nerve roots in their extrathecal course may occur in the presence of narrowing of lateral canals and a normal area of the spinal canal. We considered 40% constriction of the central or lateral spinal canal or neuroforamen, compared with the adjacent vertebral levels, as the critical value between moderate and severe stenosis. This is consistent with the observation that stenotic patients with less narrowing usually have less severe symptoms than those with greater constriction [17].

Unlike previous studies, we used an interspinous device that is inserted percutaneously rather than by open surgery. We do not know whether the success rate of the two procedures may be related to the type of spacer used. However, because the mechanical effects of the X-Stop [18] were found to be similar to those of the Aperius [19], it is conceivable that the clinical outcomes are not affected by the type of implant.

It is unclear whether interspinous devices are indicated in the presence of DS. In a study [4], 42 patients with olisthesis of less than 25% treated with the X-Stop had an overall success rate of 63%. In another trial [8], however, 7 of 12 patients with a slipping up to 30% underwent open decompression within 2 years. In six of our patients with a mean slipping of 11% and moderate stenosis, the presence of olisthesis did not affect the result of treatment.

In a study [20] using positional MRI preoperatively and after implantation of the X-Stop, the spacer was found to increase the cross-sectional area of the spinal canal and thecal sac as well as the area of the neuroforamen at least on one side. The authors, however, do not speculate on the anatomical changes leading to the increase in size. In our study, the comparison of standard preoperative and postoperative MRIs showed no significant changes in the size of the spinal canal in 71% of cases, whereas in the remainder a slight increase was observed, which appeared to be mainly because of decrease in thickness of the ligamenta flava; in a few patients, an increase in size of the neuroforamen was found. In none of the cases, yet, was any relationship found between the change in the size of the neuroforamen and the outcome.

We analyzed a relatively limited number of patients who had the Aperius implant. Furthermore, the study was prospective and, although the Aperius group was compared with a group of patients undergoing open decompression, there was no true control group, that is, one undergoing sham surgery, that might even be conceivable considering the minimally invasive nature of the procedure, performed under local anesthesia. A randomized trial with an appropriate control group might be useful to confirm the available data on the results of Aperius or other spacers.

## References

- [1] Senegas J, Etchevers JP, Vital JM, et al. Recalibration of the lumbar canal as an alternative to laminectomy in the treatment of lumbar canal stenosis. [in French]. *Rev Chir Orthop Reparatrice Appar Mot* 1998;74:15–22.
- [2] Zucherman JF, Hsu KY, Hartjen CA, et al. A prospective randomized multi-center study for treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year result. *Eur Spine J* 2004;13:22–31.
- [3] Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine* 2005;30:1351–8.
- [4] Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X-STOP device in patients with lumbar degenerative spondylolisthesis. *J Neurosurg Spine* 2006;4:463–71.
- [5] Kondrashov D, Hannibal M, Hsu K, Zucherman J. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year clinical follow-up study. *J Spinal Disord Tech* 2006;19:323–7.
- [6] Siddiqui M, Smith FW, Wardlaw D. One-year results of X-STOP interspinous implant for treatment of lumbar spinal stenosis. *Spine* 2007;32:1345–8.
- [7] Brussee P, Hauth J, Donk RD, et al. Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication. *Eur Spine J* 2008;17:200–3.
- [8] Verhoof JO, Bron JL, Wapstra HF, van Royen BJ. High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. *Eur Spine J* 2008;17:188–92.
- [9] Kondrashov DG, Hannibal M, Hsu KY. X-STOP versus decompression for neurogenic claudication: economic and clinical analysis. *Internet J Minim Invasive Spinal Tech* 2007;1.
- [10] Stucki G, Liang MH, Fossel AH, Katz JN. Relative responsiveness of condition-specific and generic health status measures in degenerative lumbar stenosis. *J Clin Epidemiol* 1995;48:1369–78.
- [11] Stucki G, Daltroy L, Liang MH, et al. Measurement properties of a self-administered outcome measure in lumbar spinal stenosis. *Spine* 1996;7:796–803.
- [12] Kabir SMR, Gupta SR, Casey ATH. Lumbar interspinous spacers. A systematic review of clinical and biomechanical evidence. *Spine* 2010;35:E1499–506.
- [13] Lee J, Hida K, Seki T, et al. An interspinous process distractor (X-STOP) for lumbar stenosis in elderly patients: preliminary experiences in 10 consecutive cases. *J Spinal Disord Tech* 2004;17:72–7.
- [14] Kuchta J, Sobottke R, Eysel P, Simons P. Two-year results of interspinous spacer (X-Stop) implantation in 175 patients with neurologic intermittent claudication due to lumbar spinal stenosis. *Eur Spine J* 2009;18:823–9.
- [15] Postacchini F. Lumbar spinal stenosis. Chapter VII. New York, NY: Wein, 1989:101–2.
- [16] Schonstrom NSR, Bolender N-F, Spengler DM. The pathomorphology of spinal stenosis as seen on CT scans of the lumbar spine. *Spine* 1985;10:806–11.
- [17] Postacchini F. Management of lumbar spinal stenosis. *J Bone Joint Surg Br* 1996;78:154–64.
- [18] Richards JC, Majumdar S, Lindsey DP, et al. The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. *Spine* 2005;30:744–9.
- [19] Hartmann F, Dietz S-O, Hely H, et al. Biomechanical effect of different interspinous devices on lumbar spinal range of motion under pre-load conditions. *Arch Orthop Trauma Surg* 2011;131:917–26.
- [20] Siddiqui M, Karadimas E, Nicol M, et al. The positional magnetic resonance imaging changes in the lumbar spine following insertion of a novel interspinous process distraction device. *Spine* 2005;30:2677–82.