Degenerative lumbar spinal stenosis with neurogenic intermittent claudication and treatment with the Aperius PercLID System: a preliminary report

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Object. The aim of this study was to evaluate whether clinical improvement is noticeable after a minimally invasive procedure such as that used with the Aperius PercLID System in patients with degenerative lumbar spinal stenosis (DLSS) and neurogenic intermittent claudication (NIC).

Methods. The patients were treated with the aforementioned system at 3 different centers. The initial requirement to be included in the study was a minimum follow-up of 12 months. The authors studied 40 cases of DLSS in patients with NIC (age 72.7 ± 8.08 years). Symptom severity, physical function, quality of life, and self-rated pain were assessed preoperatively and at the 12-month follow-up using the Zurich Claudication Questionnaire (ZCQ) and a visual analog scale. The procedure was conducted under spinal (35 patients) or local (5 patients) anesthesia, using biplanar fluoroscopy for visualization.

Results. Single-level treatment was performed in 28 patients and 2-level treatment was performed in 12 patients. Based on time recordings in 24 cases, the mean procedural time was 19.9 ± 5.0 minutes. The mean pain visual analog scale score improved significantly from 8.1 ± 2.19 at baseline to 3.44 ± 2.89 at the 1-year follow-up. The ZCQ score for patient satisfaction showed 90% of the patients being satisfied with the procedure. The mean rates of improvement in ZCQ score for symptom severity and physical function at 1 year were 38.7 ± 33.3% and 33.8 ± 29.7%, respectively, and both proved to be statistically significant. Most improvement was seen in mobility, pain/discomfort, and ability for self-care.

Conclusions. In this preliminary study, the Aperius system provided clinically significant improvement after 1 year of follow-up in patients older than 65 years with DLSS and NIC. (DOI: 10.3171/2010.3.FOCUS1034)

Key Words • lumbar spinal stenosis • neurogenic claudication • Aperius PercLID System • treatment • interspinous process device

In an older or high-risk population, a short minimally invasive procedure may represent an added value when treating lumbar spinal stenosis. For that purpose, a variety of spinal devices have been developed. Interspinous process devices for the lumbar spine are intended to mechanically distract the spinous processes to increase the size of the spinal canal and neural foramina. However, the alleged treatment objectives are quite variable, including management of degenerative spinal stenosis, discogenic low-back pain, facet syndrome, disc herniations, and instability. A hard dynamic stabilization system designed in 1986 to congeal unstable operated degenerative lumbar segments with an interspinous blocker and to limit extension, the device also had a tension band around the spinous processes to secure the implant and limit flexion.28 The procedure was reversible and if low-back pain persisted or recurred, the device was removed and stability was achieved using fusion. Since this prototype other interspinous extension-limiting devices—also referred to as interspinous process devices—have been developed, their use has been rapidly increasing in recent years. Different extension-limiting devices, from static spacers to dynamic devices, composed of various different materials, are now available for the treatment of lumbar spine diseases. A landmark technical advance is attributed to Minns and Walsh,21 who in 1997 first reported a novel soft implant design for resisting the instability of the lumbar spine in the sagittal plane. Meanwhile, the development of a less invasive approach has favored the acceptance of these techniques by patients and treating physicians.7,12 These devices represent an effective treatment option for a variety of lesions, including lumbar spondylosis and lumbar spinal stenosis, as recognized by

Abbreviations used in this paper: DLSS = degenerative lumbar spinal stenosis; NIC = neurogenic intermittent claudication; NSAID = nonsteroidal antiinflammatory drug; VAS = visual analog scale; ZCQ = Zurich Claudication Questionnaire.
some experts in the field. All have in common that, at the treated level, they increase the interspinous space, limit extension movement while reducing loading on the disc, anulus, and the facet joints. The results of an MR imaging study conducted in cadaveric spine samples in extension demonstrated that insertion of an interspinous device resulted in an increase in the spinal canal area of 18%, spinal canal diameter of 10%, and subarticular diameter of 48%. The exit space of the nerve root was remarkably enlarged, showing an increase of 25% in foramen area and of 41% in foramen width. This was achieved without significant modification of the adjacent spinal levels.

A percutaneous technique for the Aperius PercLID System (Medtronic) was introduced to the market about 3 years ago. The minimally invasive procedure may represent a treatment option in older or high-risk patients with DLSS and NIC with or without low-back pain.

Methods

Three different centers played a role in the study. Of 116 patients treated with a percutaneous system for NIC, we found 40 patients older than 65 years and with a minimum follow-up of 1 year. Fifty patients had a follow-up of less than a year—20 of them less than 6 months. Twenty-two of 62 patients with 1 year of follow-up were younger than 65 years. Four patients were lost to follow-up. All patients had undergone a previous course of conservative treatment, including pain and physical rehabilitation, which failed to provide adequate NIC and pain relief.

We selected 40 patients with DLSS and NIC with a minimum of 1 year of follow-up after treatment with the Aperius PercLID System. Data were collected prospectively, and clinical outcomes were graded using modified Macnab criteria (Table 1). Also, symptom severity, physical functioning, quality of life, and self-rated pain were assessed preoperatively and at 12 months after surgery using the ZCQ and the VAS. The study group comprised 19 men and 21 women whose mean age at operation was 72.7 ± 8.08 years. Relevant medical history included hypertension (38 patients), heart valvulopathy (12 patients), chronic vascular disease (8 patients), diabetes (8 patients), asthma (4 patients), chronic lung disease (4 patients), and thyroid disease (4 patients).

Single-level treatment was performed in 28 patients and 2-level surgery in 12 patients. In 11 patients a single-level procedure was performed at L3–4; in 12 at L4–5; and in 7 at L5–S1 (Fig. 1). In 6 patients a 2-level procedure was performed at L3–4 and L4–5 and in 6 at L4–5 and L5–S1. Based on time recordings in 24 cases, the mean procedural time was 19.9 ± 5.0 minutes. No drainage was necessary at the implant site and blood loss was minimal. The Aperius implantation procedure was conducted under general spinal (35 cases) or local (5 cases) anesthesia using continuous biplanar fluoroscopy for visualization (Fig. 2).

### Table 1: Summary of modified Macnab criteria outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>excellent</td>
<td>free of pain; no restriction of mobility; able to return to normal work &amp; activities</td>
</tr>
<tr>
<td>good</td>
<td>occasional nonradicular pain; relief of presenting symptoms; able to return to modified work</td>
</tr>
<tr>
<td>fair</td>
<td>some improved functional capacity; still handicapped &amp;/or unemployed</td>
</tr>
<tr>
<td>poor</td>
<td>continued objective symptoms of root involvement; additional op intervention needed at index level irrespective of repeat op or length of postop period</td>
</tr>
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</table>

Fig. 1. Photographs showing the Aperius PercLID System. The system is composed of a set of color-coded distraction trocars of increasing sizes (8, 10, 12, and 14 mm) (left), and of the preassembled inserter devices with implants (right). There are 4 individually packaged color-coded inserters for adequate implant deployment and release, each with implants of 8, 10, 12, and 14 mm, respectively. Each device is for a single use. The 8-mm distraction trocar (yellow) has a sharp pointed tip to facilitate piercing of the interspinous ligament for the subsequent trocars and for the implant. Each trocar and each inserter has a curved shape, which facilitates convenient access to the target level and optimal positioning of the implant. Each implant is preassembled on the inserter so it can be inserted without intermediate steps once the desired distraction is achieved. The implant core is made of titanium (TiAl6V4) alloy, whereas the external shell is composed of commercially pure titanium. Both of these materials are MR imaging compatible and offer resistance over time to keep the interspinous space open.
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Results

Postoperatively, the type of analgesic agent required, the frequency of analgesic agent use, and the time to ambulation were recorded to classify the degree of wound pain. Patients who needed only oral NSAIDs for pain relief and who were ambulatory on the day of surgery or the 1st postoperative day were classified as having mild wound pain (25 patients); those requiring an NSAID and 4 or fewer narcotic injections for pain relief and who were ambulatory on the 2nd postoperative day were classified as having moderate pain (15 patients); and those needing an NSAID and 5 or more narcotic injections and who were ambulatory only on or after the 3rd postoperative day were classified as having severe wound pain, which was not seen in any case.

Patients were mobilized 6–12 hours postoperatively or as soon as possible and allowed to ambulate on the same day or on postoperative Day 1 to be discharged home on postoperative Day 2. All patients were advised to wear a lumbosacral nonrigid vest for 40 days. In addition most patients received rehabilitation for pain and lower-extremity motor function.

Follow-up durations ranged from 12 to 18 months (mean 16 months). Postoperative clinical status was rated according to the modified Macnab criteria. Overall results were excellent in 70% of the cases, good in 20%, and fair in 10%. No poor results were seen. Dynamic spinal radiography was performed at 2, 6, and 12 months postoperatively to measure lumbar stability and the extent to which preexisting instability, if it existed, worsened after the operation, but this was not seen. No implant migration was reported.

The mean overall pain VAS score improved significantly from 7.1 ± 2.19 at baseline to 3.44 ± 2.89 at 1 year (p < 0.0001).

Mean rates of improvement in ZCQ score for symptom severity and physical function at 1 year were 38.7 ± 33.3% (p = 0.0002) and 33.8 ± 29.7% (p < 0.0001), respectively, and both proved to be statistically significantly. The ZCQ score for patient satisfaction showed that 90% of the patients were satisfied with the procedure.

Discussion

We report our preliminary experience from 3 different centers using the Aperius system to treat patients with DLSS. Symptomatic DLSS with NIC represents the most common, and rapidly increasing, surgical indication in patients older than 65 years. Nearly 8% of the adult population presents with DLSS; of these, 5% of patients with low-back pain consulting a general medical practitioner present with DLSS, whereas 15% of patients with low-back pain who consult a medical specialist present with DLSS. It is worthy of recognition that surgical procedures for DLSS in patients older than 65 years have shown an 8-fold rise in number in the last 20 years.

Clinical Findings and Relevance

Lumbar spinal stenosis was first described by Verbiest, in the early 1950s, after he observed that laminectomy relieved sciatic symptoms in 4 patients with narrowed spinal canals in the absence of disc herniations. Graded cauda equina or radicular syndromes can also be exacerbated by acute disc intrusions. Patients typically present with complete or near-complete canal or lateral recess obliteration before development of classic NIC or activity-induced leg pain. Therefore, the diagnosis of lumbar stenosis should be reserved for those patients in whom the classic features are demonstrated on clinical examination and diagnostic imaging. Patients with predominant complaints of low-back pain or atypical or nonradicular leg pain, and in whom moderate stenosis is evident on spinal imaging, respond poorly to surgery and should probably not be considered to have a diagnosis of lumbar stenosis. This is reflected in the fact that many patients will require reintervention for persistent symp-
TABLE 2: The rate of reintervention due to persistent symptoms in lumbar spine surgery*  

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>No. of Patients Needing Reintervention</th>
<th>Follow-Up (mos)</th>
<th>Rate of Reintervention (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caputy &amp; Luessenhop, 1992</td>
<td>16 of 88</td>
<td>60 yrs</td>
<td>18</td>
</tr>
<tr>
<td>Markwalder, 1993</td>
<td>12 of 100</td>
<td>33</td>
<td>12</td>
</tr>
<tr>
<td>Jönsson &amp; Strömqvist, 1994</td>
<td>19 of 105</td>
<td>6–54</td>
<td>18</td>
</tr>
<tr>
<td>Katz et al., 1996</td>
<td>20 of 88</td>
<td>96</td>
<td>23</td>
</tr>
<tr>
<td>Atlas, 1996</td>
<td>5 of 76</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Hansraj et al., 2001</td>
<td>4 of 103</td>
<td>24–60</td>
<td>5</td>
</tr>
<tr>
<td>Atlas, 2005</td>
<td>NA</td>
<td>98–120</td>
<td>23</td>
</tr>
<tr>
<td>Jansson et al., 2005</td>
<td>628 of 9664</td>
<td>120</td>
<td>11</td>
</tr>
</tbody>
</table>

* NA = not applicable.

Age-Related Complications of Spinal Surgery

The postoperative morbidity and mortality rate following traditional lumbar surgery, predominantly for lumbar stenosis and disc disease, is highest in the geriatric population, which may be defined as comprising patients older than 70 years of age. Risks for hospitalized patients, along with hospital charges, similarly increased with advancing years. Fusions in geriatric patients carried the highest complication rate and demanded the greatest hospital resources. In a series reported by Smith and Hanigan of 78 patients undergoing lumbar laminectomies for stenosis or herniated disc without fusions, 85.2% experienced improvement after discectomy, whereas 81.4% with stenosis had fair to good outcomes. Those at greatest risk harbored 3 or more preoperative medical risk factors (for example, cardiovascular or pulmonary disease, diabetes, and hypertension). All our patients have some relevant medical history including heart or lung disease.

On the other hand, Quigley and colleagues reported on 143 patients older than 70 years of age who underwent 155 operations. Averaging 74.9 years of age, most patients had disc disease together with stenosis, or had stenosis alone. Hospital stay was not prolonged by advanced age, and the overall incidence of major morbidity without mortality was 6.9%. All our patients were older than 65 years, and we did not have morbidity associated with surgery. Most patients left the hospital on the 1st postoperative day.

Stand-Alone Treatment

In 2007 Palmer et al. introduced a posterior dynamic stabilization system that was tested in human cadaveric spines dissected from L-2 to L-5, and leaving all ligamentous structures intact. Neuroimaging analysis showed 84% less compression of the posterior disc of the instrumented spines during extension, and no difference during flexion, compared with intact spines. The main conclusion was that the posterior dynamic stabilization system has the benefit of being a completely percutaneous technique, which can be used at all levels of the lumbar spine, including S-1. This system, similar to the open surgical technique, limited spinal motion, enlarged the foramina, and achieved disc decompression.

Similarly, the Aperius PercLID System is a stand-alone percutaneous interspinous decompression system that achieves neural element decompression solely through interspinous process distraction. The system offers, by limiting extension, a percutaneous procedure without open decompression surgery. The ipsilateral and contralateral wings prevent lateral migration, minimizing the risk of neural damage. Additionally, the procedure can be carried out using a local anesthetic with sedation when general anesthesia represents a high risk to the patient.

The typical profile of a candidate for Aperius PercLID System is generally a patient older than 50 years of age with mild to moderate symptom severity in whom initial conservative treatment has failed, and who is experiencing NIC symptoms—with or without back pain—exacerbated by prolonged standing or by activities in the upright posture, and relieved by a flexed position of the lumbar spine. There is imaging evidence of DLSS with clinical confirmation of NIC, and the interspinous process spaces from L-1 to L-5 are anatomically suitable for placement of the device.

Relative and absolute contraindications are the following: lumbar degenerative spondylolisthesis greater than Grade 1 (on a scale of 1–4) at the affected level; significant hypermobility observed during radiological imaging; proven allergy to device material (titanium and titanium alloy); scoliotic deformity with a Cobb angle higher than 25°; proven radiological ankylosis of the affected level; kyphosis that requires surgical correction; proven spinous process fracture at the affected level; Paget disease; and active infection or tumor of the spine.

There are certain precautions that the surgeon must take—for example, a patient with a fixed motor deficit, or angina pectoris, active rheumatoid arthritis, peripheral vascular disease, advanced diabetes, or any other systemic disease that may affect directly or indirectly the am-
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bulatory capabilities of the patient, may not benefit after insertion of an Aperius device. Additionally, patients with severe osteoporosis (bone mineral density of the spine or hip of −2.5 T-score) may be at risk for unsuccessful stand-alone treatment.

Most of our patients did not have osteoporosis, and of those who did have some, none was of the severe type.

Conclusions

Increasing life expectancy has made lumbar spinal stenosis a common pathology in the elderly. Also, the number of old or high-risk patients requiring neurosurgical intervention for the treatment of NIC is rapidly increasing. In this preliminary report of 40 patients older than 65 years with DLSS, NIC, and a minimum follow-up duration of 1 year, treated with the Aperius PercLID System in 3 hospitals, we observed adequate clinical improvement for degenerative spinal disease. The system’s dynamic or reversible condition allows, if necessary, for subsequent conventional arthrodesis in selected cases. A caveat of this study is the relatively short follow-up period. Although all our patients underwent a previous course of conservative treatment, we did not study a comparative cohort of patients who had undergone either traditional open surgery or other minimally invasive technique.

Disclosure

Dr. Fabrizi is a senior consultant for Medtronic. All other authors do not have any commercial interest with the product described in this study.

Author contributions to the study and manuscript preparation include the following. Conception and design: M Galarza. Analysis and interpretation of data: M Galarza, R Gazzeri. Drafting the article: M Galarza. Critically revising the article: M Galarza, R Gazzeri, JP Martínez-Lage. Reviewed final version of the manuscript and approved it for submission: all authors.

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