



Axial loading during MRI reveals insufficient effect of percutaneous interspinous implants (Aperius™ PerCLID™) on spinal canal area

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Abstract

Purpose To evaluate the effect on the spinal canal at the treated and adjacent level(s), in patients treated for lumbar spinal stenosis (LSS) with percutaneous interspinous process device (IPD) Aperius™ or open decompressive surgery (ODS), using axial loading of the spine during MRI (aMRI).

Materials Nineteen LSS patients (mean age 67 years, range 49–78) treated with IPDs in 29 spine levels and 13 LSS patients (mean age 63 years, range 46–76) operated with ODS in 22 spine levels were examined with aMRI pre- and 3 months postoperatively. Radiological effects were evaluated by measuring the dural sac cross-sectional area (DSCSA) and by morphological grading of nerve root affection.

Results For the IPD group, no DSCSA increase was observed at the operated level ($p=0.42$); however, a decrease was observed in adjacent levels ($p=0.05$). No effect was seen regarding morphological grading (operated level: $p=0.71$ /adjacent level: $p=0.94$). For the ODS group, beneficial effects were seen for the operated level, both regarding DSCSA ($p<0.001$) and for morphological grading ($p<0.0001$). No changes were seen for adjacent levels (DSCSA: $p=0.47$ /morphological grading: $p=0.95$). Postoperatively, a significant difference between the groups existed at the operated level regarding both evaluated parameters ($p<0.003$).

Conclusions With the spine imaged in an axial loaded position, no significant radiological effects of an IPD could be detected postoperatively at the treated level, while increased DSCSA was displayed for the ODS group. In addition, reduced DSCSA in adjacent levels was detected for the IPD group. Thus, the beneficial effects of IPD implants on the spinal canal must be questioned.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.

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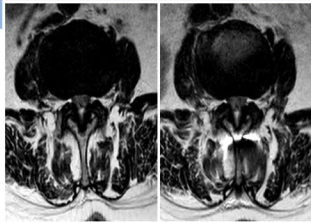
Key points

1. With axial loading during MRI (aMRI), no significant radiological effects of the interspinous process devices (IPD) could be detected 3 months postoperative at the operated level, neither regarding the DSCSA nor regarding morphological grading of nerve root affection, as opposed to beneficial effects for the open decompressive surgery (ODS) group.
2. With aMRI the DSCSA significantly reduced in levels adjacent to the operated level in the IPD group while adjacent levels within the ODS group were not affected.
3. Thus, the beneficial effects of IPD implants on the spinal canal must be questioned.

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Example of an individual with preoperative aMRI at the stenotic L4-L5 level (left) in comparison to the postoperative result after insertion of an IPD (right).



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Take Home Message

With the spine imaged in an axial loaded position, no significant beneficial effects are seen at the operated level after IPD implantation while negative effects in adjacent levels appeared. Thus, the beneficial effects of such IPD implants on the spinal canal must be questioned.

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Keywords Spinal stenosis · Axial loading during MRI · Interspinous process device · MRI · Decompression

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Introduction

Degenerative lumbar spinal stenosis (LSS) is becoming more frequently diagnosed due to the aging population and, to some extent, better access to advanced imaging facilities such as magnetic resonance imaging (MRI). Spinal stenosis is the most common reason for spinal surgery in patients over 65 years [1] and the most common cause of disability in elderly and middle-aged patients [2]. Common symptoms of LSS include neurogenic claudication, radiating leg pain, decreasing walking distance with or without low back pain and reduced quality of life [3]. However, it is well recognized that clinical findings in LSS not always correlate with radiological findings. Mildly affected patients can have signs of severe stenosis on MRI and vice versa [4, 5].

Conservative treatment is the standard of care in early stages of the disorder and involves analgesics as nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants or paracetamol. Epidural steroid injections and physiotherapy have also been suggested as treatments, but the evidence for the success of non-operative treatments is controversial and lacking [6]. Traditionally, the surgical intervention has been open decompressive surgery (ODS). However, due to risks of morbidity and mortality associated with general anesthesia and open surgery methods, especially in the elderly patients with severe or multiple comorbidities, less invasive surgical treatments such as interspinous process devices (IPDs) have been developed [7]. Such IPDs are inserted between the spinal processes of the stenotic level aiming to increase the interlaminar space, the central spinal canal area and the vertebral foramina at the symptomatic level. Biomechanically, such IPDs aim to position the spinal segment treated in a slightly flexed position to relieve the clinical symptoms [8].

Postoperatively, IPDs have shown good short-time clinical effects, but the long-term results have been less clear and a high reoperation rate compared to ODS has been reported [9–11]. In contradiction to the lack of long-term improvement in subjective symptoms and high reoperation rates, some studies have shown beneficial radiological effects [12–14].

Not many studies have been published on the radiological effects of IPDs, either by conventional MRI or with the spine in a loaded position, such as upright MRI or axial loading during MRI (alMRI). A few studies have reported a small but statistically significant increase regarding the dural sac and spinal canal cross-sectional area after IPD insertion [12, 15, 16], even up to 2 years postoperatively. However, these studies all lack a control group and do not provide any information regarding the effect on adjacent levels.

The aim of the current study was therefore to evaluate the effect on the spinal canal at the operated level and in

adjacent levels, in patients treated for LSS with an IPD in comparison with a group operated with ODS, using alMRI.

Materials and methods

Patients

Patients undergoing surgical treatment for LSS were included: 19 patients (mean age 67 years, range 49–78) operated with Aperius™ PerCLID™ (Medtronic) in a total of 29 spine levels and a group of 13 patients (mean age 63 years, range 46–76) operated with ODS in 22 spine levels.

The patients recruited were a subgroup from a randomized control trial (RCT) (still not published) including 200 patients with neurogenic intermittent claudication (NIC), all with MRI-verified degenerative LSS, defined as a dural sac cross-sectional area (DSCSA) < 100 mm². These 200 patients were enrolled from referred patients at the outpatient's clinic at the Department of Orthopedics, The Spine Team Unit at the Sahlgrenska University Hospital. The patients were randomly divided between surgeries with either IPD Aperius™ or conventional ODS, with the aim of 100 patients within each group. During the RCT, 32 patients were included in the present study and the patients enrolled here were all asked whether they agreed to be investigated with alMRI pre- and postoperatively in addition to the conventional MRI that was a part of the RCT study. The selection of patients asked for inclusion was random and based on the available time for adding the alMRI investigation.

The present study was approved by the Regional Ethical Review Board in Gothenburg at The Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden.

Imaging with axial loading

alMRI was performed preoperatively and 3 months postoperatively on a 1.5 Tesla Philips scanner (Achieva). The alMRI was performed using a non-magnetic loading device with 50% of the patient's body weight applied, equally distributed to each leg, to simulate the loading conditions during upright position (Dynawell, diagnostics AB, Las Vegas, USA) (Fig. 1) [17]. The load was applied for at least 5 min before the MRI was performed.

The MRI protocol included sagittal T2-weighted (W) sequences (TR 4500 ms, TE 120 ms, matrix 640×640), sagittal T1 W (TR 400 ms, TE 7.4 ms, matrix 704×704) and axial T2 W sequences (TR 2700, TE 120, matrix 512×512).

Fig. 1 aMRI performed with the patient in a supine position with extended hips and knees. To prevent flexion of the spine during compression, and simulate lordosis in upright position, a small cushion was placed beneath the lumbar spine. The feet were positioned against a footplate, attached with side straps to a harness worn by the patient. Applied load is regulated by tightening or loosening adjustment knobs on the compression device



Radiological parameters determined

In both cohorts, the DSCSA (mm²), which is a highly rated and well-documented quantitative MRI parameter for LSS evaluation [2, 18, 19], was measured at the operated level and at the adjacent cranial and caudal levels. Due to few observations, no sub-analysis between adjacent cranial and caudal levels was made. The DSCSA was manually outlined with a polygonal measurement tool on mid-axial

T2W images at the level of the intervertebral disk (Fig. 2). The smallest DSCSA obtained was used.

As qualitative radiological parameters sometimes are considered superior to quantitative parameters when evaluating LSS [19, 20], the morphological stenosis grading, as described by Schizas et al., was included to evaluate affection of the nerve roots (Table 1) [20]. This grading was evaluated at the same axial image as the DSCSA.

All measurements were performed by a senior radiology resident and repeated after 1 month, blinded to previous

Fig. 2 Example of one level with spinal stenosis at the preoperative MRI (left) and the corresponding postoperative MRI (right) in a patient operated with IPD (above) and ODS (below), respectively

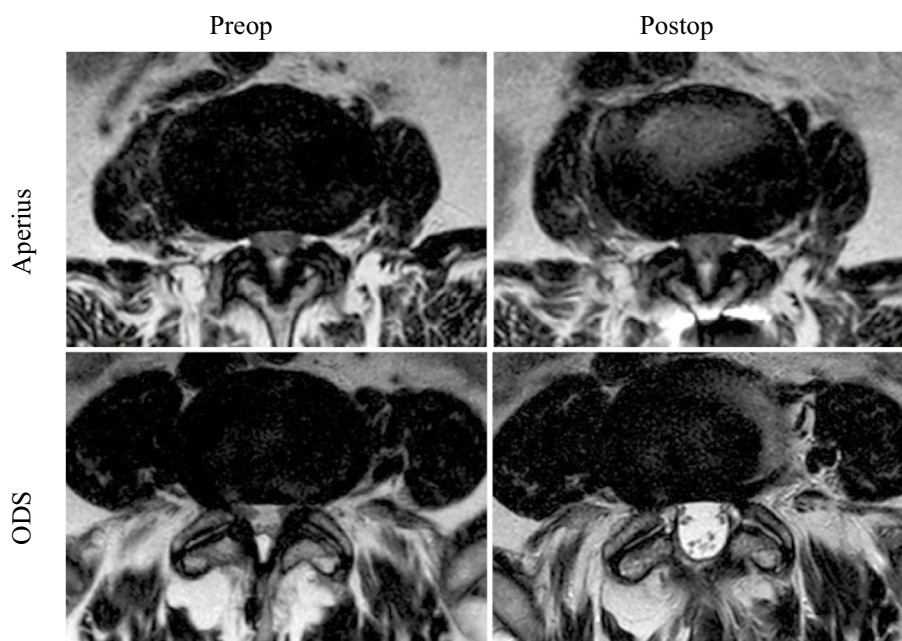


Table 1 Description of the morphological classification of spinal stenosis according to Schizas et al. [20]

A1	The rootlets lie dorsally and occupy less than half of the dural sac area
A2	The rootlets lie dorsally, in contact with the dura but in a horseshoe configuration
A3	The rootlets lie dorsally and occupy more than half of the dural sac area
A4	The rootlets lie centrally and occupy the majority of the dural sac area
B	The rootlets occupy the whole of the dural sac, but they can still be individualized. Some CSF is still present giving a grainy appearance to the sac
C	No rootlets can be recognized, the dural sac demonstrating a homogeneous gray signal with no CSF signal visible. There is epidural fat present posteriorly
D	In addition to no rootlets being recognizable, there is no epidural fat posteriorly

measurements, in order to evaluate the reproducibility of the measurements. To investigate inter-observer agreement, the measurements were repeated by an experienced senior radiologist.

Statistics

The IBM SPSS Statistics for Windows, version 22.0., Armonk, NY: IBM Corp., was used for all analyses. For comparison between pre- and postoperative radiological measurements, paired *t* test was employed with significance level set at $p < 0.05$. Wilcoxon rank test was used for pre- and postoperative comparison regarding morphological stenosis grading. For between-group comparison, Mann–Whitney U test was used for the morphological stenosis grading and paired *t* test for the DSCSA. Inter-observer reproducibility and intra-observer reproducibility for the quantitative radiological measurements were calculated using the intraclass correlation coefficient (ICC), two-way random effects, absolute agreement, single rater/measurement [21]. For the qualitative evaluation, weighted kappa was used [22]. ICC values

< 0.4 represent poor agreement, values between 0.4 and 0.75 represent fair to good agreement, and values exceeding 0.75 indicate excellent reliability. Weighted kappa values between 0.61 and 0.8 represent good reliability, and values between 0.8 and 1.00 represent excellent reliability.

Results

All the enrolled patients in both the IPD group ($n = 19$ patients/29 levels) and the ODS group ($n = 13$ patients/22 levels) were successfully examined with aLMRI pre- and 3 months postoperatively.

In the Aperius™ group, there was no significant increase in the DSCSA at the operated level (mean 3 mm^2 , 95% CI -4 to 10), while at the adjacent level, a significant decrease was observed pre- versus postoperatively (mean -10 mm^2 , 95% CI -20 to -0.3). No significant changes were observed regarding the morphological grade, neither at the operated level nor at the adjacent levels (Table 2). A number of levels

Table 2 DSCSA and morphological grading of nerve root affection for the IPD cohort in comparison to the ODS cohort

	Aperius™			Open decompressive surgery			Between-group difference (<i>p</i> value)	
	Preop	Postop	<i>p</i> value	Preop	Postop	<i>p</i> value	Preop	Postop
Mean DSCSA (SD, 95% CI) op. level (mm^2)	69 (26; 60–80)	72 (29; 61–84)	0.42	70 (56; 45–95)	144 (51; 123–167)	< 0.001	0.99	< 0.0001
Mean DSCSA (SD) adjacent level (mm^2)	145 (44; 123–153)	135 (40; 118–151)	0.04	139 (70; 104–169)	152 (44; 132–176)	0.47	0.88	0.14
Morphological grade (median)	C	C	0.71	C	B	< 0.0001	0.26	< 0.003
Number of differences preop. versus postop. negative; positive	7; 7			0; 16				
Morphological grade adjacent (median)	A2	A2	0.94	A2	A2	0.95	0.47	0.19
Number of differences preop. versus postop. negative; positive	3; 4			5; 3				

changing in morphological stenosis grade at the postoperative MRI compared to preoperative MRI are displayed in Table 2.

In the ODS group, there was a significant change at the operated level pre- versus postoperatively, with both increased DSCSA (mean 74 mm², 95% CI 58–90) and reduced affection of the nerve rootlets. Postoperatively, the morphological stenosis grade improved at 16 levels (Table 2). At the adjacent level, the morphological stenosis grade improved at three levels, but a higher compression of the nerve roots was detected in five levels, hence no significant change (Table 2). Between-group comparison revealed significant differences in postoperative outcome at the operated level regarding both DSCSA ($p < 0.0001$) and morphological stenosis grade ($p < 0.003$) (Table 2).

ICC for DSCSA was 0.96 for both intra- and inter-observer analyses. The weighted kappa for intra-observer evaluation of morphological stenosis grade was 0.83 and was 0.82 for inter-observer grading.

Discussion

No significant DSCSA increase or major change of morphological stenosis grade could be seen 3 months after IPD Aperius™ implantation in this aMRI study. In the adjacent level, there was, however, a small but significant decrease in the DSCSA. Contrarily, the ODS group displayed a DSCSA increase in changing from an absolute stenosis preoperatively to close to what is considered normal DSCSA postoperatively (Table 2). The failure of the IPD to show radiological improvement postoperatively in aMRI might, at least to some extent, explain the general lack of long-term functionality and high reported reoperation rates among LSS patients treated with IPD [8–11, 23].

The reason why postoperative clinical outcome regarding IPD implants is reported poor in spite of improvement in radiological IPD studies [8–14, 23], could be explained by the fact that previous radiological studies have been performed with the patient in supine relaxed position. As clinical symptoms of LSS are typically induced or exacerbated by walking, standing or hip extension and tend to decrease during forward flexion, squatting or lying supine, the conventional supine MRI may underestimate the severity of the spinal canal stenosis [24]. As such, IPDs are intended to assert its effect during spinal loading. With aMRI, a more realistic image of the spine, as compared with supine MRI without load applied, is achieved by straining the spine during imaging [25]. aMRI is known to induce or increase detection in spinal changes as compared with conventional MRI. Examples of such load-induced changes are as follows: disk bulging, thickening of the ligamentum flavum, altered shape of the dorsal fat pad and deformation of the dural sac

[24, 26]. aMRI can also increase the diagnostic accuracy of LSS by revealing LSS “hidden” at conventional MRI and reveal stenosis at more levels compared to the supine non-loaded MRI, changing single-level stenosis to a multi-level stenosis [27]. This positional difference at MRI can obviously impact the LSS diagnosis and affect the choice of treatment. Likely also postoperatively, aMRI provides a more realistic image of the spine morphology during spinal loading, compared to conventional MRI. Hence, the insufficient radiological effects of the IPD in the current study provide a reasonable patho-anatomical explanation to reported clinical treatment failure and high reoperation rates [8–11].

The few previous studies investigating the radiological effects of IPDs for LSS have been performed with great variability within study design, which makes comparison between studies challenging. For example, there is a large discrepancy in the selected patient groups, differences in radiological methods and parameters investigated, and also great variability at what time point the postoperative effects are evaluated [12, 15, 16, 28–31]. Nevertheless, there are MRI studies with spinal loading that, opposed to the current study, indicate increase in DSCSA or spinal canal area (SCA) after IPD implantation. Some of these studies have, however, used a patient group with mean preoperative DSCSA above 100 mm² (150 mm² for SCA), meaning that those patients can hardly be considered to fulfill the radiological criteria for LSS, and therefore, conclusions based on these studies have to be questioned [30, 31]. Some previous studies evaluating IPD effect with MRI in a loaded position used preoperative DSCSA comparable to the absolute stenosis in the current study, reporting an DSCSA increase from absolute stenosis (DSCSA ~ 75 mm²) up to ranges indicating moderate stenosis (DSCSA ~ 90 mm²) [12, 15, 16, 32]. In the current study, the DSCSA did not change significantly postoperatively in the IPD group while the DSCSA in the ODS group changed from an absolute stenosis preoperatively to close to what is considered normal DSCSA postoperatively (144 mm²). Even though some previous IPD studies report a small increase in spinal canal or DSCSA postoperatively, they never come close to postoperative measures within the normal range and not even to the cutoff value for relative stenosis of 100 mm². Differences between the current and previous studies could be attributed to methodological issues, such as applied load in an upright position versus supine position.

Comparison between IPD and ODS cohorts has previously not been performed with the spine in a loaded position. Besides from improvements in DSCSA, the ODS group in our study also showed a beneficial change in the morphological stenosis grade (Table 2), indicating also less impingement of the neural tissues after the surgery [20], an effect that was not seen for the patients treated with IPD. The current study clearly displays the large postoperative differences between

the groups as well as provides data on the IPD effects at adjacent levels, thereby filling a gap in the literature. Although the design of such IPDs varies, resulting in some differences in range of motion and flexibility, they are all based on the same principle, i.e., distracting the spinal processes to limit extension and, to some extent, distracting the neural foramina and unloading the intervertebral disk [8]. It therefore seems reasonable to investigate the spine in a position in which the IPD is intended to affect the spine the most. In spite of the fact that clinical improvement is the most important treatment outcome, a lack of significant improvement in radiological measures indicates insufficient treatment effect and provides a likely patho-anatomical explanation to why IPDs implants lack long-term functionality [9–11, 23]. Even though the current data are not directly applicable for all IPDs, this study shows insufficient treatment effect already after 3 months postoperatively, and likely previous studies have failed to show this insufficient radiological effect by using MRI without spinal loading. Another explanation for lack of DSCSA increase postoperatively with the IPD can be due to wear or destruction of the spinal processes during the first month postoperatively. In a biomechanical study, Baranto et al. demonstrated wear of the spinal processes in patients treated with Aperius™ [32]. They concluded that this is due to the fact that the Aperius™ implant is of metal, and that this is the main reason for failure or recurrence of symptoms already after 3–6 months postoperatively in patients treated with IPD.

The small DSCSA decrease in adjacent levels in the IPD group has not previously been reported and might have clinical effects in patients with multi-level disease. This finding strengthens the argument for using aMRI to diagnose LSS and also to evaluate the effect of different LSS surgical treatments.

Limitations

The time of follow-up is a potential limitation of this study. It cannot be excluded that the effects of the implanted IPD were better immediately after surgery than at our follow-up time point at 3 months, but if so that effect then diminishes after a short period of time postoperatively. No sub-analysis between adjacent cranial and caudal levels was made because of few observations in this small sample size, which is a limitation.

Conclusion

With the spine imaged in an axial loaded position, no significant radiological effects of the IPD could be detected 3 months postoperatively at the operated level, neither on the DSCSA nor regarding qualitative estimated stenosis grade,

while beneficial effects clearly were displayed for the ODS group. In addition, reduced DSCSA in adjacent levels was shown for the IPD group. Thus, the beneficial effects of such IPD implants on the spinal canal must be questioned. Studies aiming to investigate the spinal canal in LSS patients, and particularly in studies of new treatment methods, are encouraged to use aMRI for evaluation of the decompressive effect in the treated as well as adjacent levels.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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