Treatment of degenerative lumbar spinal stenosis with Aperius™ PerCLID™ system and Falena® interspinous spacers: 1 year follow-up of clinical outcome and quality of life

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Aims and objectives

Lumbar spinal stenosis (LSS) is a clinical entity characterized by a narrowing of vertebral canal and/or intervertebral foramen, determining the onset of a neurogenic claudication due to compression of the spinal nerves and associated vasculature [1]. Amundsen et al. reported that, in patients affected by spinal canal stenosis, the most frequent symptoms are back pain (95%), followed by neurogenic claudication (91%), lower limb pain (71%), weakness (33%), urinary incontinence and uncontrolled defecation (12%) [2].

Interspinous spacers (IS) implants have been proposed as a less invasive alternative to surgical approaches, providing a dynamic spinal stabilization, with a less risk of adjacent segment degeneration [3].

In this study, we report multicentric data from patients implanted with Falena® and Aperius™ PerCLID™ IS during one-year clinical follow-up.
Methods and materials

We retrospectively analyzed data from 59 patients affected by symptomatic degenerative LSS. 24 patients (20 male and 4 female; mean age ± SD: 61 years ± 7) were treated with implantation of a single Aperius™ PerCLID™ system (Medtronic-Sofamor Danek) (Aperius group), and 35 (29 male and 6 female; mean age ± SD: 65 ± 9 years) were treated with Falena® interspinous device (Mikai S.p.a., Genova - Italy) (Falena group).

All patients had symptoms as neurogenic claudication and leg, buttock or groin pain, with or without back pain while standing or walking. All treated patients failed previous conservative treatment for at least six months. The clinical diagnosis was confirmed in all cases by MR scans. Exclusion criteria were: permanent motor deficit, cauda equina syndrome, previous lumbar surgery, Grade II spondylolisthesis (score range I-IV) at the affected level. A contra-indication to IS implantation was finally severe osteoarthritis, affecting facet joints or vertebral bodies with bone bridges between each other or vertebral fusion.

All procedures were performed in angiographic suite under fluoroscopic-CT guidance with patient in prone position with the spine extended. After localizing the operative segment fluoroscopically, paraspinous local anesthesia was administered with 10 mL of lidocaine 2% and 10 mL of naropine 7.5%.

In the Falena group a sovraspinous skin sagittal incision of approximately 4 cm was performed and, then, the musculature was dissected to the level of the laminae and facets preserving the supraspinous ligament. A curved dilator was inserted in the interspinous space, piercing the interspinous ligament. Then, a sizing distractor was inserted in the same area to determine the implant size. Using an insertion instrument, the device was inserted under fluoroscopic guidance into the interspinous space. Once the skin incision was closed, anteroposterior and lateral fluoroscopy views were taken to verify the proper position of the implant.

A similar procedure was performed for patients of the Aperius group. A unilateral skin incision was made about 10 cm from the midline. The Aperius™ PerCLID® system is composed by a set of color-coded distractor trocars of increasing sizes (8 mm, 10 mm, 12 mm, 14 mm) that allow to increase the interspinous space. There are also 4 color-coded preloaded inserters (8 mm, 10 mm, 12 mm, 14 mm) with a curved shape to facilitate the positional of the system. The 8 mm distractor trocar, which is first introduced in the skin lesion, has a sharp pointy tip to pierce the interspinous ligament. After the
correct distractor was inserted to determine the implant size, the corresponding color-code preloaded inserter was introduced in the same area to release the device.

Patients were allowed to mobilize independently and discharged the day after the procedure, in absence of clinical complications. Pain intensity was evaluated by a ten-point visual analog scale (VAS) score (where "0" means "no pain" and "10" means unbearable pain) collected before (baseline) and at 1 month, 6 months and 1 year after the interventional procedure. Assessment of quality of life impairment was evaluated by Oswestry Disability Index (ODI) questionnaire administered before (baseline) and at 1 month, 6 months and 1 year after the interventional procedure. All of them present moderate/severe disabilities at the first visit.

In all patients vertebral canal area was measured by using a freehand region of interest on MRI scans obtained before the treatment and at 1 year follow-up.

The comparison of the VAS and ODI score values, as well as the vertebral canal diameter, among the single groups at different follow-up times was performed using the Wilcoxon matched pairs signed-rank test, with two tailed "P" values and a confidence interval of 95%.
An overall statistics of the VAS and ODI score values obtained from both groups is shown in Tables 1 to 4.

Both VAS and ODI scores were statistically significantly reduced at 1 month ($P_{\text{value}}<0.0001$), 6 months ($P_{\text{value}}<0.0001$) and 12 months ($P_{\text{value}}<0.0001$) in the Falena group (Fig. 1, 2). A similar result was obtained in the Aperius group, with a statistically significant reduction of the VAS and ODI score at 1 month ($P_{\text{value}}<0.0001$), 6 months ($P_{\text{value}}<0.0001$) and 12 months ($P_{\text{value}}=0.0075$) (Fig. 1, 2). A statistically significant increase in the vertebral canal area at the treated level was observed both in the Falena group ($p<0.0001$) and in the Aperius group ($p=0.0003$) (Fig. 3, 4).

An overall statistical analysis of the vertebral canal area measurements obtained from both groups at one year (Table 5, 6) demonstrated statistically significantly higher increase of vertebral canal area diameter in patients treated with the Falena® device, compared with subject treated with the Aperius™ one ($P_{\text{value}}<0.001$).
**Fig. 1**: The graphic shows the decrease of the VAS score values in patients treated with both Falena and Aperius PERclid interspinous devices.

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**Fig. 2:** The graphic shows the decrease of the ODI score values in patients treated with both Falena and Aperius PERclid interspinous devices.

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Table 1: VAS score values statistics of the "Falena group".

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Table 2: VAS score values statistics of the "Aperius group".

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### Table 3: ODI score values statistics of the "Falena group".

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Table 4: ODI score values statistics of the "Aperius group".

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Table 5: Vertebral canal area statistics of the "Falena group".

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Table 6: Vertebral canal area statistics of the "Aperius group".

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**Fig. 3:** Pre-procedural T2-weighted axial MRI scans. Vertebral canal area measurement.

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Fig. 4: Post-procedural T2-weighted axial MRI scans. Vertebral canal area measurement.

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Conclusion

Before the introduction of IS, surgical decompression with or without arthrodesis represented the gold standard treatment for moderate to severe lumbar spinal stenosis when conservative therapies failed [4]. The IS have been introduced for the treatment of degenerative LSS with the aim to obtain a dynamic motion-preserving decompression, providing an unloading distractive force, and stabilization.

Now a day, the X-Stop® device is the most examined in literature [5, 6, 7]. X-Stop® is implanted with a 5-7 cm skin incision on the midline and without the removal of the interspinous ligament. Zucherman et al. reported results obtained in 191 patients with symptomatic degenerative LSS treated either with conservative therapy or with X-Stop® implantation [6]. During a two-year follow-up, the authors observed significantly better results in patients treated operatively [7].

Recently a rigid IS device, the Aperius™ PERclid™, has been introduced in clinical practice [8]. This interspinous device has an implant core manufactured of Titanium alloy (TiAl6V4 alloy) and an external shell composed of commercially pure Titanium [8]. It can be implanted without the removal of the interspinous ligament obtaining decompression through interspinous process distraction and, like the X Stop®, it is possible to implant up to two devices in consecutive levels.

The Falena® device is composed of a winged structure, formed by a main pin with two wings at the extremities and a cap which allow a traumatic crossing of the interspinous ligament, and a "C"- spring available in a range of height sizes (8-10-12-15mm). The wing structure of the device is alloy Titanium, the "C"- spring is PEEK OPTIMA® polymer, widely used in orthopedics for its mechanical properties (bone-like stiffness, high biocompatibility and good resistance to wear). Falena® is implanted with a percutaneous technique without the removal of the sopraspinous ligament.

Our post-operative results confirmed the effectiveness of treatment with Falena® and Aperius™ PerCLID™ percutaneous interspinous device in terms of pain reduction, function and quality of life improvement, with evidence of greater efficacy with implantation of the Falena® device.

According to our data, it is confirmed as treatments with both Falena® and Aperius™ PerCLID™ result in a significant reduction of symptoms secondary to LSS at 1 month with further stabilization at 6 month, attributable to healing of surgical access and reduction
of inflammatory reaction secondary to mechanical distraction of the spine; these effects remain remarkably stable up to approximately six months from treatments in all patients only with a slight reversal of the trend and a modest recovery of symptoms until the end of the follow-up period. However, despite a slight recurrence of symptoms in both groups, patients treated by Falena® implantation presented a lower persistence or recurrence of symptoms at 1 year; this difference can be justified by evidence of a greater restoring of vertebral channel amplitude in patients implanted with the Falena® device.

Because these percutaneous interspinous devices are not implanted adjacent to the nervous structures as spinal cord or nerve roots, there is a minimal risk of neurologic deficit after treatment, so no complications were observed in our trial, also thanks to the experience of the operators.

This study has some limits. We did not referred to a control group treated with conservative therapies or surgery. A prospective, double-blind controlled trial for each IS is needed.

Finally it is possible to conclude IS implantation is an alternative therapeutic choice to surgery in patient with degenerative LSS. For the surgeon or the interventional radiologist, the choice of the correct device is very important in according to its mechanical features and properties.
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