Lumbar spinal stenosis treated with In-Space

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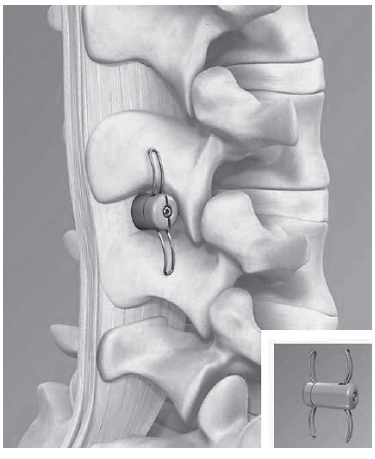
Lumbar spinal stenosis (LSS) is a disabling disease of the spine caused by degenerative changes which result in a compression of the cauda equina nerve roots. Surgery is an accepted, commonly performed treatment of symptomatic LSS. A number of interspinous process devices have been introduced to the lumbar spine market as an alternative to conventional surgical procedures in the treatment of lumbar spinal stenosis. One of these devices is In-Space, an interspinous spacer designed to block or limit lumbar extension.

Background

The clinical problem this case series addresses is the occurrence of bony remodelling or subsidence in patients treated with In-Space. The aim of this case series is to prove that bony remodelling/subsidence after the implantation of In-Space has no influence on the clinical outcome.

Patients and Methods

Thirteen patients, who were all treated at one single site, were included in this retrospective case series. All patients were diagnosed with neurogenic intermittent claudication (NIC) due to lumbar spinal stenosis at one level confirmed by X-rays. Only patients without previous fusion or laminectomy at the operated level and without spondylolisthesis > grade 1 were included. All thirteen patients were regularly clinically evaluated during a follow-up period of up to 24 months.



In-Space – Interspinous Spacer

The clinical outcome was rated using self-assessment questionnaires measuring pain, disability, symptom severity and quality of life.

The radiological outcome for six of the thirteen patients was assessed with X-rays taken in neutral and extended position. The interspinous distance as well as the foraminal height were measured. Device migration, subsidence, bone growth and radiolucency along the implant, osteophyte formation as well as level degeneration were recorded with the help of a Radiograph Information Form at 24 months postoperatively.

Results

The radiological assessments showed clear signs of bony remodelling/subsidence in almost all patients. However, the patients improved significantly ($p<0.05$) on all outcome measurements (pain, disability, symptom severity, quality of life) at all follow-up points when compared to preoperatively.

Discussion

Despite the regressive radiological results at two years postoperatively, the clinical results of this case series show that there was a statistically significant ($p<0.05$) improvement of all measured parameters after the implantation of an In-Space device. The clinical outcome can be considered more important since it directly reflects the physical as well as the psychological well-being of the patients. The clinical outcome also shows that there is no correlation between bony remodelling and bad clinical outcome. Most of the patients showed signs of bony remodelling/subsidence. Nevertheless, they had a satisfactory clinical outcome. The pain as well as the disability were significantly reduced with the implantation of an In-Space device.

Claudia Allemann

Conclusion

The implantation of an In-Space interspinous spacer is a minimally invasive, effective and safe procedure for the treatment of NIC due to LSS. Patients improved significantly on all outcome measurements at all follow-up points when compared to the preoperative measurements. The results of this case series are consistent with other studies on In-Space as well as reference products.

Even though bony remodelling/subsidence occurred in most of the patients being radiologically assessed, no influence on the clinical outcome of these patients could be proven.