Safety and efficacy of a new percutaneously implantable interspinous process device.

Abstract:

Lumbar spinal stenosis is a degenerative disease of the elderly population. Although microsurgical decompression has shown good long-term results, percutaneous techniques could provide an alternative in the presence of significant comorbidities. Eighty-seven interspinous process decompression devices (In-space; Synthes, Umkirch, Germany) were implanted percutaneously in up to three segments of 50 patients. Outcome was assessed directly after surgery, at 6-8 weeks, and at average follow-up of 1 year (11.8 ± 6 months). Assessment included complications, pain and spinal claudication, neurodeficit, time to recurrence of symptoms, and time to second surgery. Subgroups with additional low back pain at presentation and mild spondylolisthesis were analyzed separately. Intraoperative complications were rare (one misplacement and two cases of failed implantation); average operation time was 16.4 ± 12.2 min per segment. Initial response was very good with 72% good or excellent relief of symptoms. After a 1-year follow-up, 42% reported of lasting relief from spinal claudication. Thirteen percent of these complained about lasting or new-onset low back pain. A second surgery had been performed in 22%. Subgroup analysis was performed for patients presenting with additional low back pain and spondylolisthesis patients. No significant differences
The In-space is a percutaneous treatment option of claudication in patients with lumbar spinal stenosis. Compared with microsurgical decompression surgery, recurrence rate within 1 year is, however, high and the device seems not suitable for the treatment of low back pain. Therefore, the authors suggest that the device should presently be used primarily in controlled clinical trials in order to get more information concerning the optimal indication.

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