



At admission to the study, patients were randomized to TLIF using unilateral (n = 40) or bilateral (n = 40) pedicle screw fixation and fusion with titanium screws. To ensure a tight fit of the graft into the disc space, compression was applied to the screws above and below the level of the TLIF. A sponge was placed into the interbody cage and into the intertransverse process spaces.

To compare outcomes between the 2 groups, patients were followed at week 2, months 3 and 6, year 1, and then biannually. At 6-month follow-up, the 36-item Short-Form Health Survey (SF-36) scores were obtained.

Radiographic data was also obtained at each follow-up period and evaluated by a single designated film reviewer. Fusion was assessed on anteroposterior /lateral x-rays by the presence of newly formed trabeculated bone between 2 adjacent fusion segments. In unclear cases, computed tomography was used. Other imaging (eg, magnetic resonance imaging) was used if indicated by a patient's clinical course. After one year, if bony healing had not occurred, radiographic pseudarthrosis was documented.

With a mean follow-up of 52 months (range 37 to 63 months), the study showed that all patients after TLIF, regardless of screw type, had a significant physical improvement as measured by SF-36 ( $P < .001$ ). Also, significantly more patients treated with TLIF using unilateral instrumentation developed pseudarthrosis compared with patients treated with bilateral instrumentation (17.5% vs 2.5%;  $P = .05$ ). For patients undergoing TLIF with unilateral pedicle screw instrumentation, the relative risk of developing pseudarthrosis was 7.

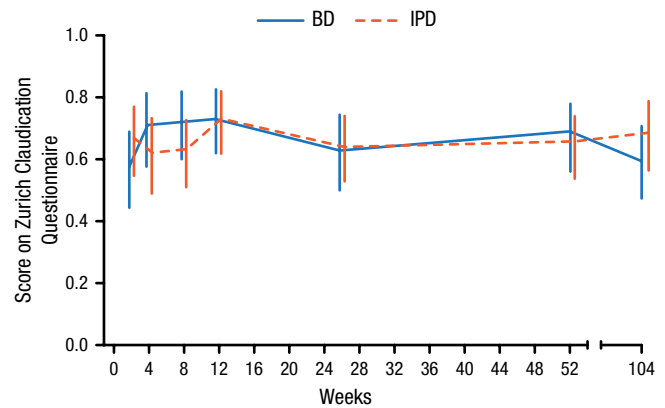
Under multivariate analysis, unilateral instrumentation ( $P = .021$ ) and sex ( $P = .002$ ) were found to be independent predictors for developing pseudarthrosis. According to Dr Steinberger, when unilateral pedicle screws are used, decreased rates of fusion occur because the screws do not appear to stabilize the TLIF construct as well as bilateral constructs.

## Conventional Decompression Remains the Gold Standard for Treating Lumbar Spinal Stenosis

Written by Mary Beth Nierengarten

Surgical interspinous implants have been used to treat intermittent neurogenic claudication in patients with lumbar spinal stenosis. Some evidence has suggested it provided better outcomes compared with no (conservative) treatment [Moojen WA et al. *Eur Spine J.* 2011]. In 2011, >30% of spine centers used implants [Overdevest GM et al. *Acta Neurochir (Wien).* 2014]. However, no

Figure 1. Zurich Claudication Questionnaire Results



BD, bony decompression; IPD, interspinous process distraction.

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clinical trial has been conducted to compare the efficacy of surgical interspinous implants with the gold-standard spinal bony compression.

Wouter A. Moojen, MD, PhD, MSc, Leiden University Medical Center, Leiden, The Netherlands, presented the 2-year results of the Surgical Interspinous Implant versus Conventional Decompression for Lumbar Spinal Stenosis trial [Moojen W et al. *Spine.* 2014] that compared surgical interspinous implants to conventional decompression for patients with 1- or 2-level lumbar spinal stenosis.

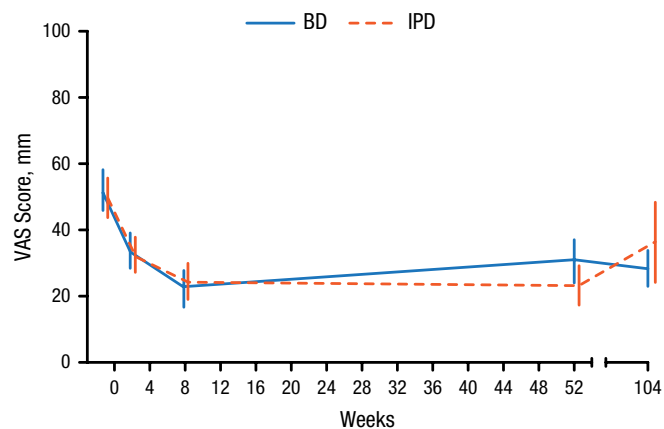
In this multicenter controlled, double-blinded trial, Moojen and colleagues randomized 159 patients with 1- or 2-level lumbar spinal stenosis for whom conservative treatment had failed to interspinous implant (n = 80) or bony decompression (n = 79).

The baseline characteristics, incision size, and post-operative care were similar in both groups. Surgery was performed on 2 levels in 18% of patients in the decompression group and 26% in the implant group. The visual analog scale (VAS) leg-pain score was between 52 and 58, and the VAS back pain score was between 60 and 49.

The investigators evaluated symptom severity, physical function, and patient satisfaction at 8 weeks using the Zurich Claudication Questionnaire and found no difference between the 2 groups at 1 year or 2 years (Figure 1). Further, no difference was found between the 2 groups at 8 weeks, 1 year, or 2 years for back pain as measured with the VAS score (Figure 2). The analyses were intention-to-treat.

For patients treated with implants, the study found a significantly higher rate of re-operations compared with the bony decompression group (33% vs 8%;  $P$  value not

Figure 2. VAS Back Pain Results



BD, bony decompression; IPD, interspinous process distraction; VAS, visual analog scale. Reproduced with permission from WA Moojen, MD.

reported). The rate of successful recovery after re-operation was lower than after the first operation.

In summary, this study found that clinical outcomes were similar with surgical interspinous implants and conventional bony decompression at 2 years. Back pain, as measured by the VAS score, was not reduced with surgical interspinous implants. Further, it was associated with the need for additional surgery.

Prof Moojen stated that similar results were obtained in other clinical trials of implants in this setting [Davis RJ. *Spine*. 2013; Strömquist BH. *Spine (Phila Pa 1976)*. 2013; Richter A. *Eur Spine J*. 2010]. Taken together with the data from the present study, Prof Moojen concluded that surgical interspinous implant confers no advantage over conventional bony decompression in patients with lumbar spinal stenosis. Conventional decompression should remain the standard for treatment.

## Position of Pedicle Screws During Lumbar Fusion Surgery Significant in Reducing Complications

Written by Mary Beth Nierengarten

Hao Dingjun, MD, Xi'an Jiaotong University, Xi'an, China, presented the results of a prospective comparative study—Effect of Superior Adjacent Segment Degeneration after Lumbar Posterolateral Fusion Using Two Different Pedicle Screw Insertion Positions With Nine-Year Minimum Follow-Up [Yan L et al. *Spine*. 2014]—of patients with low-grade isthmic spondylolisthesis (IS), which assessed the effect of different pedicle

screw insertion positions on adjacent segment degeneration (ASD).

From January 1999 to December 2003, 210 patients who underwent posterolateral fusion for low-grade IS were randomized to 2 groups according to different pedicle screw insertion positions. In group A (n=102), the method by Du and Zhao [*Chin J Spine Spinal Cord*. 2001] was used to place the pedicle screw insertion. In group B (n=108), the method by Magerl and colleagues [*Clin Orthop Relat Res*. 1984] was used, which needs more lateral and steeper angles for insertion.

Inclusion criteria included patients who were aged 18 to 55 years and had single-level IS (grade 1 or 2), persistent low back pain for >6 months, and loss of quality of life with neurologic claudication. The follow-up period was at least 108 months. Patients were excluded from the study if they had undergone revision surgery, had  $\geq$  grade 3 spondylolisthesis or concomitant scoliosis of  $>15^\circ$ , or had an implant removed during the follow-up period.

Of the 210 patients, 178 (84.7%) were available for at least a 9-year clinical and radiologic follow-up. Of these, 87 (85.3%) were patients in group A, and 91 (84.3%) were in group B.

Patient characteristics between the 2 groups were comparable. The majority of the patients were women in both groups (about 53%), with an average age of 46 years, a mean body mass index of about 24.3 kg/m<sup>2</sup>, and a fusion level at L5-S1 (about 78%).

The study found significant differences (all  $P < .001$ ) between the pre- and postoperative measures for all patients, using the Oswestry Disability Index (ODI) and the visual analog scale (VAS) for back and leg pain. In terms of postoperative ODI and VAS scores, no differences were found between the ASD and non-ASD groups nor between group A and group B. However, when the ODI scores were compared in terms of ASD, significantly more patients in group A had ASD compared with group B (28.6% vs 15.7%;  $P < .001$ ).

According to Dr Dingjun, these findings show that the position of the pedicle screws during lumbar fusion surgery is closely related to superior ASD and that reducing the superior ASD can be done by inserting the pedicle screw in a position farther from the facet joint surface.



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