Table 1. Complications in the Riluzole Registry Groups

	Riluzole (n = 36)		Registry (n = 36)		
	Patients, no.	Incidence, %	Patients, no.	Incidence, %	*P* Value
Infection	14	0.389	13	0.361	.81
Pulmonary	11	0.306	16	0.444	.22
Neuropsychiatric	10	0.278	10	0.278	1.00
Hematological	7	0.194	9	0.250	.57
Cardiovascular	5	0.139	11	0.306	.09
Gastrointestinal/genitourinary	5	0.139	9	0.250	.19
Skin	4	0.111	3	0.083	.69

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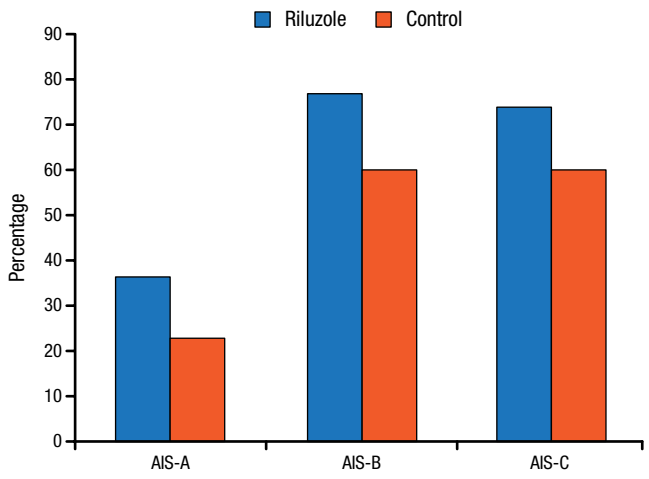
Figure 1. Percent Conversion of AIS Grade



AIS, American Spinal Injury Association Impairment Scale.
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Enrollment into the phase 3 trial began in January 2014. Patients with acute traumatic SCI (n = 351) from 35 international sites will be randomized in a 1:1 fashion to riluzole 100 mg BID for 24 hours, followed by riluzole 50 mg BID for 13 days after the injury or to the same dosing regimen of placebo.

Patients included in the study must be able to receive the study drug within 12 hours of injury, have an ISNCSCI impairment scale grade of A, B, or C, and have a neurological level of injury C4 to C8 based on the first ISNCSCI assessment after arrival to the hospital.

Patients excluded from the study are those with an injury arising from a penetrating mechanism and those with significant concomitant head injury.

According to Dr Fehlings, the study will use an adaptive sequential design to allow sample size changes during the interim analysis. To date, the study has enrolled 11 patients. Dr Fehlings hopes to come up with a neuroprotective strategy that could influence clinical practice in treatment of SCI.

Pseudarthrosis Increased After Unilateral-Instrumented TLIF for Lumbar Spondylosis

Written by Mary Beth Nierengarten

Although the use of either unilateral or bilateral segmental pedicular instrumentation with transforaminal lumbar interbody fusion (TLIF) is effective in the treatment of lumbar spondylosis, patients who underwent TLIF buttressed by unilateral instrumentation were 7 times more likely to suffer pseudarthrosis and were more likely to require a reoperation.

Jeremy Steinberger, MD, Icahn School of Medicine at Mount Sinai, New York, New York, USA, presented the results of a prospective cohort study that looked at the incidence of complications in patients with lumbar spondylosis who underwent TLIF with either unilateral or bilateral instrumentation.

The study included 80 consecutive patients (40 men and 40 women), with a mean age of 44.2 years (range, 24–68 years). Patients were excluded from the study if they had an infection, tumor, spondylolisthesis, or fracture. All patients underwent 1- or 2-level TLIF between October 2007 and November 2009 for either degenerative disc disease or lumbar spondylosis. All surgeries were performed by the same 2 surgeons.

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.

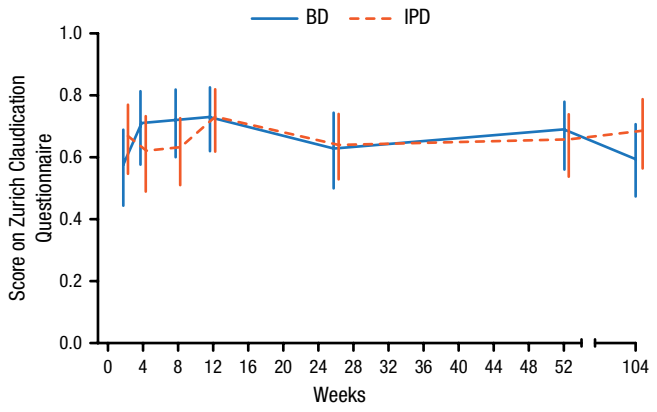
Under multivariate analysis, unilateral instrumentation ($P = .021$) and sex ($P = .002$) were found to be independent predictors for developing pseudarthrosis. According to Dr Steinberger, when unilateral pedicle screws are used, decreased rates of fusion occur because the screws do not appear to stabilize 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 clinical trial has been conducted to compare the efficacy of surgical interspinous implants with the gold-standard spinal bony compression.

Figure 1. Zurich Claudication Questionnaire Results



BD, bony decompression; IPD, interspinous process distraction.

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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 postoperative 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