Decompression and paraspinous tension band: a novel treatment method for patients with lumbar spinal stenosis and degenerative spondylolisthesis

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Decompression and paraspinal tension band: a novel treatment method for patients with lumbar spinal stenosis and degenerative spondylolisthesis

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ABSTRACT

BACKGROUND CONTEXT: Prior studies have demonstrated superiority of decompression and fusion over decompression alone for treatment of lumbar degenerative spondylolisthesis with spinal stenosis. More recent studies have investigated whether non-fusion stabilization could provide the durable clinical improvement after decompression and fusion.

PURPOSE: To examine the clinical safety and effectiveness of decompression and implantation of a novel flexion restricting paraspinous tension band (PTB) for patients with degenerative spondylolisthesis.

STUDY DESIGN/SETTING: Prospective Clinical Study

PATIENT SAMPLE: Forty-one patients (7 men and 34 women) aged 45-83 years (68.2±9.0) were recruited with symptomatic spinal stenosis and Meyerding grade 1 or 2 degenerative spondylolisthesis at L3/4 (8) or L4/5 (33).

OUTCOME MEASURES: Self-reported measures included visual-analog scales (VAS) for leg, back and hip pain as well as the Oswestry disability index (ODI). Physiologic measures included quantitative and qualitative radiographic analysis performed by an independent core laboratory.

METHODS: Patients with lumbar degenerative spondylolisthesis and stenosis were prospectively enrolled at four European spine centers with independent monitoring of data. Clinical and radiographic outcome data collected pre-operatively were compared with data collected at three, six, 12 and 24 months after surgery. This study was sponsored by the PTB manufacturer (Simpirica Spine Inc., San Carlos, CA, USA), including institutional research support grants to the participating centers totaling approximately US $172,000.

RESULTS: Statistically significant improvements and clinically-important effect sizes were seen for all pain and disability measurements. At 24 months follow-up, ODI scores were reduced by an average of 25.4 points (59%) and maximum leg pain on VAS by 48.1mm (65%). Back pain VAS scores improved from 54.1 by an average of 28.5 pts (53%). There was one postoperative wound infection (2.4%) and an overall reoperation rate of 12%. Eighty-two percent of the patients available for 24 month follow-up with a PTB in situ had a reduction in ODI of >15 points, and 74% had a reduction in maximum leg pain VAS >20mm. According to Odom's criteria the majority of these patients (82%) had an excellent or good outcome with all except one patient satisfied with surgery. As measured by the independent core laboratory, there was no significant increase in spondylolisthesis,
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CONCLUSIONS: Patients with degenerative spondylolisthesis and spinal stenosis treated with decompression and a PTB demonstrated no progressive instability at 2 years of follow-up. Excellent/good outcomes and significant improvements in patient-reported pain and disability scores were still observed at 2 years with no evidence of implant failure or migration. Further study of this treatment method is warranted to validate these findings.
INTRODUCTION

Decompression alone was the standard surgical treatment for lumbar degenerative spondylolisthesis with spinal stenosis [1,2] until several landmark articles suggested that decompression and fusion was a superior mode of treatment [3-5]. While there has been recent pressure to reduce rates of spinal fusion, payers and medical societies consistently recommend that fusion be determined medically necessary for lumbar degenerative spondylolisthesis with spinal stenosis [6-8], and it remains the dominant procedure for this indication in the US shown by a 95% fusion rate in the SPORT study [9]. However, fusion is clearly an imperfect treatment due to the short-term morbidity involved in adding a fusion to the decompression, as well as the longer term associated risk of adjacent-level degeneration and instability [10,11]. To circumvent these problems “dynamic stabilization” systems were introduced [12,13], but the majority are pedicle screw based and associated with many of the same problems as instrumented fusion, notably complex implant loading [14-18] and facet joint violation during screw placement [19-21]. For this reason simpler constructs have been suggested, such as that by Lee et al who reported a series of 65 patients with degenerative spondylolisthesis treated with decompression and posterior tension band stabilization using a figure of eight suture. They found that back pain relief and functional improvement were significantly correlated with achievement of total and segmental lumbar lordosis after a mean follow-up of 72.5 months [22] and equivalent outcomes could be achieved in comparison to posterior lumbar interbody fusion [23].

Based on the need for segmental stabilization in this patient population, the relative drawbacks of fusion and pedicle screw-based dynamic stabilization, and the promising outcomes of tension band stabilization reported by Lee et al, a novel paraspinous tension band (PTB; LimiFlex™ Spinal Stabilization System, Simpirica Spine Inc., San Carlos, CA, USA) has been developed to provide segmental sagittal plane stability through biasing the segment into lordosis. The facet joints are more engaged and afford more sagittal plane stability in segmental extension than in flexion due to the coronal orientation of the caudad portion of the joint [24], and thus their biomechanics allow for this indirect mechanism of providing stability. The PTB utilizes titanium coil tension springs to restore segmental flexion stiffness, and is attached to the spinous processes with ultra-high molecular weight polyethylene (UHMWPE) bands. A preclinical large-animal implantation study demonstrated that the PTB is well tolerated by the surrounding tissues, and retains its function after anatomical incorporation [25]. Cadaveric biomechanical testing has
demonstrated restoration of the kinematics of a destabilized spinal segment to that of an intact segment, with increased flexion stiffness and reduced sagittal translation [26]. The device does not bear any axial loads, and therefore the forces transmitted by the PTB to the spinal elements are an order of magnitude less compared to pedicle screw-based systems. The PTB was designed to be easily implanted after a standard lumbar decompression with minimal additional exposure.

We aimed to prospectively assess clinical and radiographic outcomes of patients treated with surgical decompression and stabilization with the LimiFlex PTB device over a two year follow-up period. We questioned whether these patients would become progressively more unstable from a radiographic standpoint over this length of follow-up, and whether their clinical improvement in back and leg pain would deteriorate. This study was intended to provide initial data to demonstrate the clinical feasibility of this treatment method.

MATERIALS AND METHODS

Patient Selection

Between January 2010 and October 2011, 41 patients at four centers (Royal Infirmary of Edinburgh, Edinburgh, Scotland, UK; Universitaire Ziekenhuizen KU Leuven, Leuven, Belgium; Berufsgenossenschaftliche Unfallklinik, Frankfurt am Main, Germany; Universitätsklinikum Bonn, Bonn, Germany) were enrolled in clinical studies and followed for 24 months postoperatively. Informed consent was obtained from each of the patients in the series. All patients had degenerative spondylolisthesis (Meyerding grade 1 or 2) and spinal stenosis requiring decompression of at least one level (1-3 levels). Patients were excluded if they had spinous processes or posterior element anatomy inappropriate for implant fixation, severe osteoporosis (T-score \(\leq -2.5\) with fragility fracture) [27], isthmic spondylolisthesis of the segment to be instrumented, active systemic or local infection, or if they were pregnant or planning to become pregnant. These patients were felt to be otherwise candidates for lumbar fusion by their operating physician. The data presented here represent patients from this prospective, post-market case series that were approved by the Ethics Committees of each participating institution. This study was sponsored by the PTB manufacturer (Simplirica Spine Inc., San Carlos, CA, USA), including institutional research support grants to the participating centers totaling approximately US $172,000.
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Surgical Intervention

Decompression

All patients received a direct surgical decompression of up to three levels from L1-S1 to address their spinal stenosis, preserving at least 50% of the spinous processes. All decompressions were performed using an operating microscope, undercutting the facet joints and decompressing the foraminae as necessary. The structural integrity of the pars interarticularis was preserved and resection of the articular surface of the facet joints minimized. In some cases the midline supraspinous/ interspinous ligamentous complex was preserved and in other cases not according to the preference of the treating surgeon. Decompression characteristics are summarized in Table 2.

Paraspinous Tension Band Implantation

Following their decompression, all patients were implanted with a PTB at the level of the degenerative spondylolisthesis. The PTB comprises a pair of titanium coil springs secured to ultra-high molecular weight polyethylene (UHMWPE) straps (Fig. 1). The straps were passed around the cranial and caudal spinous processes, piercing the interspinous ligament of the segments adjacent to the treated segment. The patient was then repositioned, if necessary, by adjusting the amount of flexion on the spinal frame / table using intraoperative fluoroscopy so that local lumbar sagittal alignment approximated a standing lordotic position. This alignment was estimated by the treating surgeon; no fixed threshold values were used. The device could then be tensioned and secured using instruments that allowed a consistent nominal preload to the springs (approx. 20N). The decompression was reassessed after the application of the device.

Outcome assessment

Preoperatively, and at 3, 6, 12, and 24 months postoperatively patients rated their back, leg, and buttock/hip pain on a 0-100mm longitudinal VAS and their back pain disability (ODI) [28,29]. Patient outcomes were also assessed according to patient-reported satisfaction with their surgery and Odom’s criteria [30]. Clinical success was evaluated using the composite clinical success criteria utilized by Davis et al for this indication [31], whereby to be considered a clinical success a patient was required to meet all the following criteria: 15-point reduction in ODI, no reoperations, no major device-related complications, and no postoperative epidural injections.
Intraoperative and postoperative complications were noted and compiled, and then attributed as either being related or unrelated to the device or the procedure by the study site investigator. All serious adverse events (SAEs) were adjudicated by an independent medical monitor who was a board certified orthopaedic spine surgeon.

Radiological assessment
Diagnostic axial imaging studies (CT or MRI) were obtained preoperatively to confirm spinal canal stenosis and to evaluate degenerative lumbar pathology. Flexion, extension, standing lateral, and anterior/posterior (AP) radiographs were obtained preoperatively, as well as at 3, 6, 12, and 24 months postoperatively (Figs. 2,3). Quantitative and qualitative radiographic analyses were performed by a radiographic core laboratory using Quantitative Motion Analysis (QMA™, Medical Metrics, Houston, TX) [32]. Quantitative radiographic analysis included:
- Static measurements of disc angle, anterior slip, disc height, and total lumbar (L1-S1) angle in flexion, neutral and extension.
- Dynamic measurements of rotation and translation in flexion-extension.

The qualitative radiographic analysis included assessments by a board-certified radiologist for device condition, device migration/dislocation, spinous process fracture, bone-implant interface remodeling, and exuberant bone formation.

Statistical analyses
Data were assessed for normality, and changes in ODI and VAS were assessed using 2-tailed, paired Student’s t-tests. A significance level of $p \leq 0.05$ was used. Confidence intervals for parametric statistics were calculated assuming a t-distribution. Binomial confidence intervals were calculated for success criteria using the Normal Approximation Method.

RESULTS
Patient demographics, operative results and follow-up
Patient demographics are summarized in Table 1. The ratio of approximately 5:1 female to male and ages of the 41 patients are typical of those reported for degenerative
spondylolisthesis [1,3]. These patients represent a relatively high-risk group, with a mean Charlson comorbidity index of 3.8 [33].

Operative results including decompression characteristics are summarized in Table 2. All forty-one patients received decompressions and were successfully implanted with the PTB with a mean implantation time of 28 minutes (range: 10-58 minutes), which included initial learning curve procedures. Thirty-four patients with the PTB in situ were available for 24-month follow-up evaluation. One died from a traumatic head injury and one patient was lost to follow-up. The device was explanted prior to final follow-up in five patients as described further below.

Clinical outcomes

Clinical outcomes are presented for the group of patients with all follow-up data, as well as for the sub-group of patients with the PTB in situ at 24 months. Statistically significant improvements and clinically important effect sizes were seen for all pain and disability measurements. Disability according to ODI was reduced by an average of 25.4 points (59% compared to baseline). Maximum leg pain VAS was reduced by an average of 48.1 mm (65%). Back pain VAS averaged 54.1 preoperatively, and the postoperative value at two years was 22.6 mm, representing an improvement of 28.5 mm (54%) (Table 3). Improvement in patient self-reported outcomes showed a significant improvement at the first (3 months) follow-up visit, which was sustained with a trend toward increased improvement throughout follow-up to 24 months (Figure 4). The clinical success rate according to the criteria established by Davis et al was 66.7% [31].

Eighty-two percent of patients available for 24 month follow-up with the PTB in situ had a reduction in ODI of at least 15 points, and 74% had a reduction in maximum leg pain VAS of at least 20 mm. Eighty-two percent (82%) of these patients were evaluated to have excellent or good outcomes according to Odom’s criteria, and 97% were satisfied with the surgery. (Table 4)

Radiographic results
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Quantitative analysis

No change in vertebral angulation or olisthesis was noted on device implantation or seen in radiographic measurements at 3 months follow-up. Segmental stability and lordosis were maintained to 24 months (Table 5). There were no significant increases in anterior slip, dynamic sagittal translation, or flexion-extension range of motion (ROM). Three-level ROM of the index, supradjacent and subjacent levels was relatively low preoperatively, indicating low patient effort in flexion-extension, with a trend towards increased overall motion at 24 months follow-up, in comparison to the index level ROM which showed no significant change during follow-up. Exemplary images are shown in Figures 2 and 3. Six patients with 24-month follow-up and the PTB in situ did not have all radiographic films necessary for quantitative analysis.

Qualitative analysis

Throughout the follow-up period, at all time-points, there were no x-ray findings of device breakage, disassembly, migration or dislocation; bone-implant interface remodeling; or exuberant bone formation. There were no findings of resorption at the strap-spinous process interface. There was one spinous process fracture with an unclear time of origin that will be discussed below, which was found on a postoperative CT scan.

Complications

Seven intra-operative adverse events were reported, including six dural tears and a superficial fracture of the tip of a spinous process. The dural tears all occurred during the decompressions prior to the implantation of the device, were all directly sutured at the time of decompression, and did not affect device implantation. There were no post-operative CSF leaks but there was one postoperative infection (2.4%) that was treated with irrigation and debridement, implant removal and fusion.

During the follow-up period there were two other patients in the study who underwent conversion to fusion. One had persistent pain postoperatively and a sclerotic spinous process fracture was found on CT imaging 6 months after surgery. Instability was apparent on the flexion/extension films. It was not clear whether the fracture happened during the decompression or at a later date. An L4/5 fusion was performed. A second patient, who complained of persistent leg pain, was found on repeat imaging to have foraminal stenosis at
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the level below her L4/5 treated segment with no evidence of progressive instability or recurrent stenosis at L4/5. She was fused from L4 to S1.

Three days after surgery one patient presented with a symptomatic epidural hematoma leading to paraparesis. An emergency laminectomy was performed and the device removed. One patient developed a proximally migrated disc extrusion at the inferior adjacent segment nine months after surgery, and underwent discectomy. The device was removed to allow for easier access to the fragment. These complications represent an overall 12% reoperation rate.

Explanted devices were sent to independent laboratories for examination (Exponent, Philadelphia, PA) and histopathology (Histion, LLC, Everett, WA). Examination of the removed implants found no device failures. Histopathology findings were that the implant was well integrated with fibrous tissue with no adverse tissue response.

**DISCUSSION**

All PTBs were easily implanted without implant-related complication and a median insertion time of 25 minutes. At two-year follow-up, this cohort of patients with degenerative spondylolisthesis showed significant clinical improvement in self-reported pain and disability scores from first follow-up at 3 months, with sustained improvement through the 24 months follow-up period. Radiographically there was no evidence of progression in static or dynamic translation. Intraoperatively there was incidental durotomy in six of the 41 patients (14.6%), probably a reflection of the elderly population studied (mean age 68yrs). The overall re-operation rate (12%) was slightly higher than expected but may have simply reflected an initial experience with a new technique; complications were generally either unrelated or of indeterminate relationship to the PTB. The simplicity of the primary surgery avoiding damage to the facets at the instrumented level meant that any revision surgery was generally straightforward. Analysis of explanted devices found no device failures and that the implant was well integrated into the paraspinal tissue with no adverse tissue response. There were no radiographic findings of spinous process resorption at the strap interface, which is consistent with the large animal implantation study previously conducted on the PTB [25] and implying that there was no functional loss of device tension due to remodeling of the bone-implant interface.
As this work represents a preliminary series from a small cohort without a control group, we have evaluated our results in context with published literature for general comparative purposes. The 118 minute average surgical time for decompression and PTB implantation compares favorably to the 210.5 minutes and 202.7 minutes reported for the randomized and non-randomized cohorts of surgical patients with degenerative spondylolisthesis (treated with fusion in 95% of cases) in the SPORT study [9]. The in-patient stay reported here at a median of 5 days also compares favorably with the 7 to 9.5 day stays reported for posterolateral fusion in Europe [34,35]. In the US, decompression and PTB implantation would likely be performed as a short-stay procedure (<24hrs admission) similar to that typical of decompression alone [36], compared to the 3-5 day US hospital stay typical of instrumented fusion [37,38]. The mean 24.1 point improvement in ODI (58% reduction), 44.7 mm reduction in mean VAS leg pain and 28.5 mm mean improvement in VAS back pain are similar to those obtained in other studies of decompression and fusion for degenerative spondylolisthesis [3,4,9,31]. Applying the composite clinical success criteria reported by Davis et al resulted in a 66.7% success rate for the patients in this series, which is comparable to their success rates of 62.8% for coflex® subjects and 62.5% for instrumented fusion controls for the subset of patients with degenerative spondylolisthesis in their randomized FDA study [31]. The maintained postoperative segmental stability was in contrast to the marked increased inolisthesis and translation in flexion-extension that has been seen in prior studies of decompression alone for this indication [3]. Mean disc height at baseline was 6.8mm; Blumenthal et al reported that disc height > 6.5 mm was associated with a 45% rate of reoperation at 3.6 years mean follow-up in patients receiving decompression without fusion for Grade I degenerative spondylolisthesis [39]. Review of the subset of patients with greatest preoperative instability (>2mm translation), all of whom were satisfied with their surgery, demonstrated similar sustained clinical improvement and stability at 24 months follow-up in the more unstable group (Fig. 5).

This work represents the initial clinical feasibility of the PTB for postoperative stabilization after decompression for lumbar degenerative spondylolisthesis with spinal stenosis. While the patient sample size is small and follow-up duration limited to 24 months, we believe that the results are encouraging but accept that Level I / II evidence is required. It is worth noting that the PTB is not intended to correct or reduce the deformity associated with degenerative spondylolisthesis, but rather to provide postoperative sagittal plane stability.
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This is in contrast to inter-spinous process devices that provide indirect or mechanical neural decompression through distraction of the posterior elements. As described previously, the device was designed to provide segmental stabilization, thereby optimizing the residual facet joint biomechanics through maximizing effective engaged articular surface area, minimizing the risk of progressive translation and a poor clinical result. Perhaps of greater importance however is that surgical ‘insult’ from PTB insertion is minimal, making the procedure particularly attractive for the elderly and frail who represent a significant proportion of the population with this indication [1,3].

There are several limitations of this non-randomized study without a control group. While the patients with degenerative spondylolisthesis represented a broad range of instability, the number of patients (41) was low with relatively short follow-up (2 years), and the small sample size could create unintentional selection bias by the patient or institution. This work was sponsored by the manufacturer of the PTB, and institutional research support was provided to the centers involved. The authors have also noted that preoperative ROM and translation measured in flexion-extension were relatively low. There was however a small ROM and translation of adjacent segments and that with the limitations in methodology when obtaining standing radiographs probably indicate low levels of flexion effort rather than a lack of instability. All subjects were deemed candidates for instrumented fusion by their treating surgeons had they declined inclusion in the study or a PTB implantation. Seated flexion-extension radiography may allow for improved patient effort during image acquisition without subjecting this elderly population to standing maneuvers. Whether flexion restriction stabilization will ultimately limit vertebral slippage and prevent progressive stenosis or avoid adjacent segment degeneration in the long-term is unknown, but decompression and stabilization with PTB does seem to be a reasonable alternative for many patients who either do not want or are otherwise not good candidates for fusion and merits further investigation.

CONCLUSIONS

We report here encouraging results for patients with grade 1-2 lumbar degenerative spondylolisthesis and spinal stenosis treated with decompression and stabilization with a PTB flexion restriction device. Over the two year period of follow-up, the patient cohort showed improvements in VAS, ODI and clinical success criteria consistent with those
reported in the literature for patients with this pathology treated with decompression and fusion. Our series represents the preliminary clinical feasibility of this treatment for this patient population, and further investigation is merited.
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## Tables

### Table 1  Patient demographics

| Total patients enrolled (male:female) | 41 (7:34) |
| Age, mean±SD (range) | 68.2±9.0 (45-83) years |
| Body Mass Index (BMI), mean±SD (range) | 28.6±4.5 (21-40) |
| Patients with previous spinal procedures, N (%) | 3 (7.3%) |
| Smoking history, N (%): |  |
| Current smokers | 10 (24%) |
| Former smokers | 14 (34%) |
| Patients with relevant concurrent medical conditions, N (%) |  |
| Renal/urinary | 5 |
| Cardiovascular | 24 |
| Endocrine | 10 |
| Pulmonary | 6 |
| Musculoskeletal | 21 |
| Liver / Gastrointestinal | 4 |
| Other | 20 |
| Charlson comorbidity index, mean±SD | 3.8±1.4 |

### Table 2  Operative results

| Total surgery time, mean±SD (median, range) | 118±48.5 (107, 61-300) minutes |
| Implant insertion time, mean±SD (median, range) | 28±13 (25, 10-58) minutes |
| Estimated blood loss, mean±SD (median, range) | 271±255 (200, 50-1400) ml |
| Level of degenerative spondylolisthesis and PTB implantation (N) |  |
| L3/L4 | 8 |
| L4/L5 | 33 |
| Levels decompressed (N) |  |
| 1 level | 31 |
| 2 levels | 6 |
| 3 levels | 4 |
| Decompression characteristics (PTB index level) |  |
| Bilateral | 39 / 41 |
| Unilateral | 2 / 41 |
| ISL/SSL resection | 10 / 41 |
| Hospital length of stay, mean±SD (median, range) | 6.2±5.5 (5, 1-35) days |
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### Table 3 Summary of clinical outcomes (ODI and VAS)

<table>
<thead>
<tr>
<th>All patients, all available follow-up data</th>
<th>Baseline (N=41)</th>
<th>24 months (N=37)</th>
<th>P (b)</th>
<th>Effect (c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODI (%) (a)</td>
<td>45.6±15.4 (40.7, 50.4)</td>
<td>20.3±19.2 (13.9, 26.7)</td>
<td>&lt;0.001</td>
<td>-1.59</td>
</tr>
<tr>
<td>Maximum Leg Pain, VAS (0-100mm) (a)</td>
<td>74.5±21.1 (67.8, 81.1)</td>
<td>28.8±35.0 (17.1, 40.4)</td>
<td>&lt;0.001</td>
<td>-1.13</td>
</tr>
<tr>
<td>Maximum Hip Pain, VAS (0-100mm) (a)</td>
<td>57.7±34.4 (46.9, 68.6)</td>
<td>21.8±28.5 (12.3, 31.3)</td>
<td>&lt;0.001</td>
<td>-0.87</td>
</tr>
<tr>
<td>Back Pain, VAS (0-100mm) (a)</td>
<td>54.1±30.1 (44.6, 63.6)</td>
<td>22.5±26.0 (13.8, 31.1)</td>
<td>&lt;0.001</td>
<td>-0.72</td>
</tr>
</tbody>
</table>

**Patients with PTB in situ at 24 month follow-up**

<table>
<thead>
<tr>
<th>All patients, all available follow-up data</th>
<th>Baseline (N=34)</th>
<th>24 months (N=34)</th>
<th>P (b)</th>
<th>Effect (c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODI (%) (a)</td>
<td>43.4±15.2 (38.1, 48.7)</td>
<td>18.0±17.6 (11.8, 24.1)</td>
<td>&lt;0.001</td>
<td>-1.76</td>
</tr>
<tr>
<td>Maximum Leg Pain, VAS (0-100mm) (a)</td>
<td>73.5±22.5 (65.6, 81.3)</td>
<td>25.4±33.0 (13.8, 36.9)</td>
<td>&lt;0.001</td>
<td>-1.25</td>
</tr>
<tr>
<td>Maximum Hip Pain, VAS (0-100mm) (a)</td>
<td>55.5±34.8 (43.4, 67.7)</td>
<td>20.5±27.8 (10.8, 30.2)</td>
<td>&lt;0.001</td>
<td>-0.83</td>
</tr>
<tr>
<td>Back Pain, VAS (0-100mm) (a)</td>
<td>49.6±30.8 (38.8, 60.3)</td>
<td>20.5±24.5 (12.0, 29.0)</td>
<td>0.001</td>
<td>-0.64</td>
</tr>
</tbody>
</table>

(a) mean±SD (t-distribution 95% confidence interval lower limit, upper limit)
(b) 2-tailed paired student’s t-test of baseline vs. 24 months
(c) Standardized effect size (group difference in means divided by SD of difference)

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### Table 4 Clinical success rates at 24 months follow-up

<table>
<thead>
<tr>
<th>Quantitative endpoint</th>
<th>Success rate (95% CI (a))</th>
</tr>
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<tbody>
<tr>
<td>ODI reduction ≥ 15 points</td>
<td>28/34, 82% (70%-95%) (b)</td>
</tr>
<tr>
<td></td>
<td>29/37, 78% (65%-92%) (c)</td>
</tr>
<tr>
<td>VAS leg pain reduction ≥ 20mm</td>
<td>25/34, 74% (59%-88%) (b)</td>
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<td></td>
<td>26/37, 70% (56%-85%) (c)</td>
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</table>

<table>
<thead>
<tr>
<th>Subjective endpoints</th>
<th>N (%) (b)</th>
<th>N (%) (c)</th>
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<tr>
<td>Patient outcome per Odom’s criteria at 24 months follow-up</td>
<td>Excellent 17 (52%)</td>
<td>17 (47%)</td>
</tr>
<tr>
<td></td>
<td>Good 10 (30%)</td>
<td>7 (19%)</td>
</tr>
<tr>
<td></td>
<td>Fair 6 (18%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Poor 0 (0%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Self-reported patient satisfaction at 24 months follow-up</td>
<td>Satisfied 32 (97%)</td>
<td>33 (92%)</td>
</tr>
<tr>
<td></td>
<td>Not satisfied 1 (3%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Composite endpoint</th>
<th>Success rate (95% CI (a))</th>
</tr>
</thead>
</table>
Composite Clinical Success per Davis *et al* [Error! Reference source not found.]  
26/39, 66.7% (52%-81%) *(d)*

(a) Binomial confidence interval, normal approximation method  
(b) Patients with PTB *in situ* at 24 months follow-up  
(c) All patients, all available follow-up data  
(d) Subjects with evaluable composite clinical success

<table>
<thead>
<tr>
<th>Table 5  Quantitative radiographic results</th>
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<tbody>
<tr>
<td><strong>Parameter</strong></td>
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<tr>
<td>----------------</td>
</tr>
<tr>
<td>Index level ROM</td>
</tr>
<tr>
<td>Index level ROM, as % of three-level ROM <em>(b)</em></td>
</tr>
<tr>
<td>Three-level ROM <em>(b)</em></td>
</tr>
<tr>
<td>Anterior slip (mm)</td>
</tr>
<tr>
<td>Translation (mm) <em>(c)</em></td>
</tr>
<tr>
<td>Standing disc angle (lordosis &gt; 0°)</td>
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<tr>
<td>Standing disc height (mm)</td>
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</tbody>
</table>

All results presented as mean ± SD (t-distribution 95% CI)  
(a) 2-tailed paired student’s t-test, 24 months vs. baseline  
(b) Sum of flexion-extension ROM at index, supradjacent and subjacent levels  
(c) Measured in flexion-extension images as described by Hipp *et al* [31]
Figure Legend

**Fig. 1** Paraspinous tension band (LimiFlex Spinal Stabilization System, Simpirica Spine, Inc., San Carlos, CA, USA)

**Fig. 2** Patient with L4-L5 Grade 1 degenerative spondylolisthesis and spinal stenosis with translational instability and 12.5° of degenerative lumbar scoliosis. Preoperative 4.9mm slip in standing radiographs is reduced in the supine MRI and fluid is present in the facet joints. At 24 months postoperatively there is 44% reduction of translation and no progression of the spondylolisthesis. The landmarks used by the radiographic core laboratory are shown on the endplates of the index and adjacent segments.

**Fig. 3** Patient with L3-L4 degenerative spondylolisthesis (7.2mm) and spinal stenosis as well as bulging intervertebral disc. At 24 months postoperatively there is a 39% reduction of dynamic translation and no progression of the spondylolisthesis.

**Fig. 4** Summary of clinical outcomes (mean and 95% confidence interval)

**Fig. 5** Summary of clinical and radiographic results for subjects with >2mm translation at preoperative baseline (Mean and SD)
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