Dynamic Intraspinous Stabilization reduces Spinal Mobility After Bilateral Laminotomy

Marin Guentchev1,3, Levente Peter1*, Christian Preuss1, Martin HM Sailer2 and Jochen Tuettenberg1*

1 Trinity Medical Center, Spine Unit, 117 Zaichar St, BG-1309 Sofia, Bulgaria
2 Department of Neurosurgery and Spine Surgery, Schulthess Klinik, Lengghalde 2, CH-8008 Zurich, Switzerland
3 Department of Neurosurgery, Klinikum Idar-Oberstein, D-55743 Idar-Oberstein, Germany

*Both have contributed equally to this manuscript

Abstract

Dynamic stabilization devices were developed to reduce spinal hypermobility while preserving a certain degree of physiological motion. Our goal was to assess radiographic and clinical outcomes of patients treated with surgical decompression and stabilization with the Limiflex™ implant.

We investigated the effect of Limiflex™ implantation on post-operative translation and angulation in 36 patients with spinal stenosis and degenerative spondylolisthesis Meyerding Grade I treated with decompression and dynamic stabilization.

Significant improvements following lumbar decompression were observed. The average Oswestry Disability Index (ODI) score fell from 45.9 Pre-operatively to 29.6 at dismissal and 26.5 at first follow up. The average visual analog scale (VAS) score fell from 7 Pre-operatively to 3 at dismissal and 3 at follow up. Pre-operatively the median translation within the operated segment was 2.0 mm. Post-operatively the translation was reduced to 0.7 mm (p=0.006, Student’s t-test). Pre-operatively the median rotation within the operated segment was 4.6°. Post-operatively the rotation was reduced to 3.5° (p=0.08, Student’s t-test). The re-operation rate was 6 out of 36 (16.7 %).

Here we provide evidence suggesting that the dynamic paraspinous stabilization implant Limiflex™ is well tolerated in patients with degenerative spondylolisthesis and lumbar spinal canal stenosis. Our data show that within 3 months after the operation it limits hypermobility in the operated segment. This might be well suited in cases such as spinal stenosis with Grade I degenerative spondylolisthesis, where instability at the operated segment is likely to happen, but a patient is not indicated for a spinal fusion.

Keywords: Dynamic intraspinous stabilization; Spinal stenosis; Laminotomy

Introduction

Lumbar spinal stenosis with degenerative spondylolisthesis is a common cause for lower extremity pain in elderly patients. Patients treated surgically have a significantly better long term outcome compared to those treated non-surgically [1]. The most common surgical methods are conventional laminectomy; unilateral laminotomy for bilateral decompression, bilateral laminotomy and split-spi- nous process laminotomy [2,3]. About one-third of all surgically treated patients are not satisfied with the clinical outcome [4]. Post-operative spinal instability is one of the potential complications. Thus, several studies have suggested that decompression and fusion was a superior treatment strategy [1,5,6]. Unfortunately, rigid spinal implants followed by fusion cause increased stresses of the neighboring spinal segments often leading to adjacent segment degeneration (ASD) [7-9].

Additionally, a recent study showed no significant difference in decompression alone and decompression and rigid fusion in patients with lumbar spinal canal stenosis and spondylolisthesis with a motion range less than 3 mm [10].

As an alternative treatment, dynamic stabilization devices were developed to reduce spinal hypermobility while preserving a certain degree of physiological motion [11,12], thus reducing the risk of ASD. The dynamic stabilization systems are either pedicle screw-based [13] or interspinous [12,14].

Our goal was to assess radiographic and clinical outcomes of patients treated with surgical decompression and stabilization with the Limiflex™ implant by Simpircia Spine. We investigated the effect of Limiflex™ implantation on post-operative translation and angulation. Clinically the most important measure was the secondary need for re-operation and fusion.

Material and Methods

Patient selection

Between August 2012 and April 2014, 36 patients (Table 1) at one center (Klinikum Idar-Oberstein, Germany) received the Limiflex™ implant (Simpircia Spine Inc, San Carlos, CA, USA). The median age was 74 ranging from 44 to 85 years. Twenty of the patients were female and 16 male. The average baseline ODI score was 45.9 and VAS 7.5. All patients suffered from lumbar spinal stenosis requiring decompression at one or two levels accompanied by degenerative spondylolisthesis Meyerding Grade I. In the flexion/extension the spondylolisthesis showed a translation equal or less than 3 mm.

The Limiflex™ Paraspinous Tension Band was approved for clinical use in Germany since 2009. Prior to the procedure an informed consent was obtained in accordance to German and European law. The study was approved by the regional ethic committee (Landesärzte kammer Rheinland-Pfalz, decision 837.170.15/9938).

Surgical intervention

Decompression: A surgical decompression of up to two levels was performed in all patients. Each stenotic segment was decompressed...
spondylolisthesis all patient received a LimiFlexTM implant. The cranial joints was removed. The pars interarticularis was preserved and not more than 1/3 of the facet (HiLAN, Aesculap, Tuttlingen, Germany) were used. In all cases the microscope (Möller-Wedel, Wedel, Germany) and a high-speed drill by either unilateral or bilateral laminotomy. In all cases a surgical tomography myelography or magnetic resonance imaging) were obtained Pre-operatively to confirm the diagnosis. Flexion and extension radiographs were obtained Pre-operatively and in most cases during the first week post-operatively (Figs. 2 and 3). Quantitative and qualitative radiographic analyses were performed using the Impax Software (Agfa, Germany). In 11 patients either pre- or post-operative radiographs were not available through our electronic system or poor quality did not allow evaluation.

Dynamic (flexion and extension) lumbar digital radiographs were used to measure translation in millimeters. Degree of angulation (sagittal rotation angle) was calculated from digital flexion-extension radiographs as well. Maximal height of disc space was determined on the sagittal reconstruction of pre-operative CT scans. Facet angle was determined by calculating the angle generated by a line connecting the end points of each facet on a pre-operative axial lumbar CT and a line connecting the 2 dorsal points of each facet joint. When the facet angles were different (right side vs. left side), the average value was used. Spinal instability was thought to have occurred if more than 3 mm of translation or more than 15° angulation were present.

**Informed consent**
A written informed consent was obtained from every patient taken part in this study according to German and European law.

**Statistics**
A paired Student's t-test was used for comparisons between groups. GraphPad Prism software was used for all calculations. A p-value of ≤ 0.05 was considered as significant.

**Results**
In all cases the LimiFlex™ Paraspinous Tension Band was implanted without implant-related complications. During follow-up, no implant failure could be detected.

**Clinical outcomes**
Significant improvements following lumbar decompression were observed. Improvement was documented using both ODI and VAS assessments (p<0.001). The average ODI score fell from 45.9 Pre-operatively to 29.6 at dismissal and 26.5 at first follow up. The average VAS score fell from 7 Pre-operatively to 3 at dismissal and 3 at follow up.

**Radiologic outcomes**
Pre-operatively the median translation within the operated segment was 2.0 mm (Figures 1 and 2). Post-operatively the translation was reduced to a median of 0.7 mm (p=0.006, Student's t-test). In the inclination x-ray there was no difference between pre and post-operatively (6.0 vs. 5.8 mm) while in the reclination x-ray there was a statistically significant reduction from 8.2 mm to 7.0 mm (p=0.006, Student's t-test). In the flexion-extension lumbar digital radiographs were obtained Pre-operatively to 29.6 at dismissal and 26.5 at first follow up. The average VAS score fell from 7 Pre-operatively to 3 at dismissal and 3 at follow up.

**Re-operation data**
The re-operation rate was 6 out of 36 (16.7%). All patients

| Patient number | Sex | Age at OP | Level of LimiFlex implantation | Level of decompression |
|----------------|-----|-----------|-------------------------------|------------------------|
| 1              | f   | 73        | L4/5                          | L4/5                   |
| 2              | f   | 79        | L3/4/5                        | L3/4/5                 |
| 3              | m   | 73        | L4/5                          | L4/5                   |
| 4              | m   | 63        | L4/5                          | L4/5                   |
| 5              | f   | 74        | L4/5                          | L4/5                   |
| 6              | f   | 61        | L4/5                          | L4/5                   |
| 7              | f   | 64        | L4/5                          | L4/5                   |
| 8              | m   | 67        | L4/5                          | L4/5                   |
| 9              | f   | 77        | L3/4                          | L3/4                   |
| 10             | m   | 55        | L3/4                          | L3/4                   |
| 11             | m   | 75        | L4/5                          | L4/5                   |
| 12             | m   | 80        | L3/4/5                        | L3/4/5                 |
| 13             | f   | 84        | L4/5                          | L4/5                   |
| 14             | f   | 73        | L4/5                          | L4/5                   |
| 15             | f   | 77        | L4/5                          | L4/5                   |
| 16             | f   | 85        | L4/5                          | L4/5                   |
| 17             | f   | 81        | L4/5                          | L4/5                   |
| 18             | f   | 77        | L4/5                          | L4/5                   |
| 19             | m   | 74        | L4/5                          | L4/5/5/S1              |
| 20             | f   | 70        | L4/5                          | L4/5                   |
| 21             | m   | 74        | L4/5                          | L3/4/5                 |
| 22             | f   | 74        | L4/5                          | L4/5                   |
| 23             | m   | 84        | L3/4                          | L3/4                   |
| 24             | f   | 74        | L4/5                          | L4/5/5/S1              |
| 25             | f   | 75        | L4/5                          | L4/5/5/S1              |
| 26             | f   | 77        | L3/4                          | L3/4                   |
| 27             | m   | 78        | L3/4/5                        | L3/4/5                 |
| 28             | m   | 69        | L4/5                          | L4/5                   |
| 29             | m   | 56        | L4/5                          | L4/5                   |
| 30             | m   | 55        | L3/4                          | L3/4                   |
| 31             | m   | 57        | L4/5                          | L4/5                   |
| 32             | m   | 67        | L4/5                          | L4/5                   |
| 33             | f   | 44        | L4/5                          | L4/5                   |
| 34             | m   | 56        | L4/5                          | L4/5                   |
| 35             | f   | 74        | L4/5/5/S1                     | L4/5/5/S1              |
| 36             | f   | 69        | L4/5                          | L4/5/5/S1              |

**Table 1:** Clinical data.
implanting a paraspinous dynamic stabilization implant (Limiflex™ Paraspinous Tension Band) in a real life setting of patients with lumbar spinal stenosis and degenerative spondylolisthesis. Radiographically, we were able to show that such an implant statistically decreases the post-operative translation. Most likely the degree of rotation is reduced as well, but here we could show only a trend and not a statistically significant result. However, as all patients had Meyerding Grade I spondylolisthesis and received surgical decompression, we can say that there was no progression of instability, as is commonly proposed in these patients who are typically recommended for fusion [15]. We believe that the effect observed is most likely to be attributed to a compression of the facet joint in the respective segment.

In a previous study of the same implant [14], patients reported to have a significant clinical improvement in self-reported pain and disability scores 2-years after operation. Our data support this statement.

The results presented here regarding the decreased level of translation by using Limiflex™ Paraspinous Tension Band are consistent with previous biomechanical cadaver studies [16,17], showing that application of increasing compressive preload did not substantially change segmental range of motion, but did significantly increase the segmental stiffness in the high-flexibility zone. Interestingly these studies were able to show that under these circumstances a decrease of the sagittal segmental angle occurs as well. We could not confirm this finding. In our hands, pre- and post-operative angulation angle was not significantly different. This is most likely due to the different study model used.

In our study the overall re-operation rate was 16.7 %, slightly higher, but within the same range (12 %), as previously reported [14], and less than in the recent decompression vs. fusion studies [10,17,18]. Notably, with exception of one patient who was emotionally and physically uncomfortable with the device, none of the re-operations were considered related to the Limiflex™ device, and would have been considerably more complex had the patients initially received fusions.

Our finding suggests that the implantation of the Limiflex™ Paraspinous Tension Band is simple and there might not be a great variability of results between different surgeons.

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Discussion

In this study, we demonstrate the biomechanical effect of
patients profit from the implantation of the Limiflex™ Paraspinous Tension Band. Second, we failed to evaluate the long-term impact on the quality of life on the patients due to lack of compliance in filling out the questionnaires.

Conclusion

Here we provide evidence suggesting that Limiflex™ Paraspinous Tension Band is well tolerated in patients with degenerative spondylolisthesis and lumbar spinal canal stenosis. Our data show that within 3 months after the operation it limits hypermobility in the operated segment. This might be well suited in cases such as spinal stenosis with Grade I degenerative spondylolisthesis, where instability at the operated segment is likely to happen, but a patient is not indicated for a spinal fusion.

Further prospective randomized studies however should prove whether the mechanical effect of the Limiflex™ Paraspinous Tension Band improves the patient outcome on the long run as well.

Conflict of Interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers’ bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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Table 2: Causes for reoperation in Limi-flex patients.

| Patient number | Age at OP | Time after initial OP (mo) | Cause for reoperation | Limiflex explanted | Limiflex reimplanted |
|----------------|-----------|---------------------------|-----------------------|-------------------|---------------------|
| 4              | 63        | 8                         | Extraforaminal disc herniation | no                | no                  |
| 7              | 64        | 22                        | Synovialcyst at a lower level | no                | no                  |
| 19             | 74        | 1                         | CSF leak               | yes               | no                  |
| 24             | 74        | 2                         | Stenosis at the next two lower levels | yes              | no                  |
| 28             | 69        | 1                         | Spondylodiszitis       | no                | no                  |
| 33             | 44        | 9                         | Emotional/physical diskomfort | yes              | no                  |

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