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Dynamic Intraspinous Stabilization reduces Spinal Mobility After Bilateral Laminotomy

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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-spinous 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 Simpirica 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 (Simpirica 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 of 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

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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	57	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	L3/4	L3/4/5
18	f	77	L4/5	L3/4/5
19	m	74	L4/5	L4/5/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/S1
25	f	75	L4/5	L4/5/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/S1	L4/5/S1
36	f	69	L4/5	L4/5/S1

Table 1: Clinical data.

by either unilateral or bilateral laminotomy. In all cases a surgical microscope (Möller-Wedel, Wedel, Germany) and a high-speed drill (HiLAN, Aesculap, Tuttlingen, Germany) were used. In all cases the pars interarticularis was preserved and not more than 1/3 of the facet joints was removed.

LimiFlex™ implantation: At the level of the degenerative spondylolisthesis all patient received a LimiFlex™ implant. The cranial and caudal spinous processes were compressed together by a force of approximately 20 N (as determined by the preload of the springs and design of the surgical instruments).

Outcome assessment: Pre-operatively, at discharge and about 2-3 months post-operatively, patients rated their back and leg pain on a visual analog scale (VAS) and their disability on Oswestry Disability Index (ODI). Implant failure was defined by the need for re-operation and/or spinal fusion. We observed the following complications in 4 patients: synovial cyst at a lower level, cerebrospinal fluid leak, stenosis at the next two lower levels, spondylodiscitis. The questionnaire was filed out by 21 of 36 patients.

Radiologic assessment: Diagnostic imaging studies (computed 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 reclination x-ray there was no difference between pre and post-operatively (6.0 vs. 5.8 mm) while in the inclination x-ray there was a statistically significant reduction from 8.2 mm to 7.0 mm ($p=0.006$, Student's t-test) (Figures 1 and 2).

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) (Figures 1 and 2).

In CT scans, we evaluated the pre-operative facet angle and tried to correlate it with the post-operative outcome. The median angle was 57.1° (17.6° – 98.9°). We could not find a significant correlation between the pre-operative facet angle of the operated segment and the post-operative outcome.

Re-operation data

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

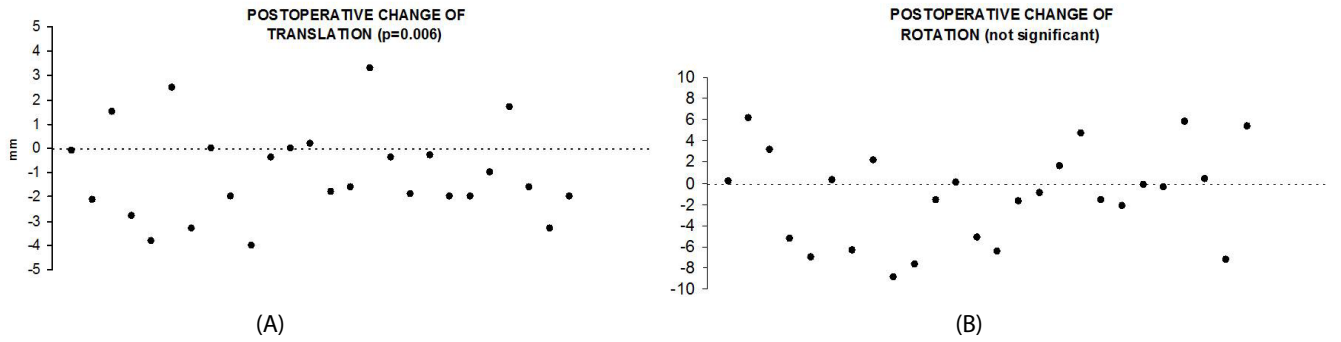

Figure 1: Post-operative decrease of translation (a) and sagittal rotation (b).

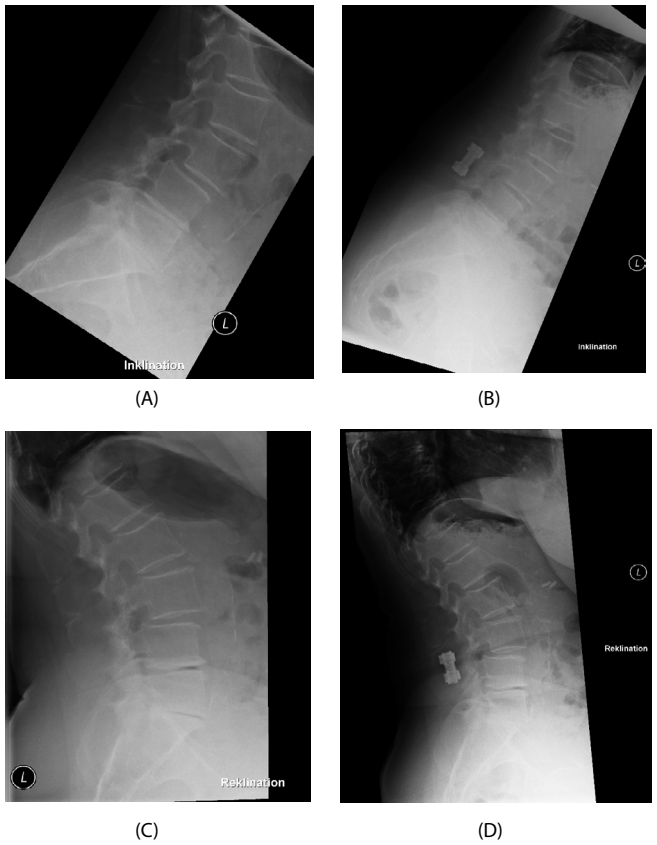

Figure 2: X-ray showing pre- (a, c) and post-operative (b, d) in inclination (a, b) and reclinaction (c, d).

underwent re-operation within 22 months of the initial procedure (Table 2). In two patients, the Limiflex™ implant was removed. In the first case the re-operation was due to a disc herniation at the level below Limiflex™ implantatation. Due to the extensive bone removal and possible post-operative spinous process fracture the implant was removed. The second patient felt uncomfortable (both physically and emotionally) with the implant and asked for removal. In the other four cases, additional levels had to be operated, but the Limiflex™ implant remained or, to gain better access to the spine, was explanted and re-implanted during the procedure. None of the re-operated patients required a spinal fusion.

Discussion

In this study, we demonstrate the biomechanical effect of 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.

It is important to mention that during implantation of the Limiflex™ Paraspinous Tension Band the additional surgical trauma is minimal and the average implantation time is about 20 minutes, making the procedure particularly attractive for old or comorbid patients.

There are of course several limitations of this study. First, here we present data from a non-randomized study. Only a larger prospective randomized study would be able show if and to what extend the

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	Stemosis at a the next two lower levels	yes	yes
28	69	1	Spondylodiszitis	no	no
33	44	9	Emotional/physical diskomfort	yes	no

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

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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