The Use Of A Versatile Dynamic-Hybrid Stabilization Device In Lumbar Stenosis: Preliminary Experience

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Citation

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Abstract

Objective. Dynamic stabilization aims at limiting movement of a functional spinal unit. Some patients with lumbar stenosis require decompression, stabilization, and preservation of the vertebral movements to avoid the adjacent segment disease. The Flex+TM rods (SpineVision®) used with pedicle screws allow dynamic or hybrid (i.e: dynamic stabilization at one level and rigid fixation) stabilization.

Methods. Twenty patients affected by lumbar stenosis and impending spine instability underwent laminectomy and Flex+TM stabilization. The indication for a dynamic stabilization was a preoperative MRI evidence of a pathological disc. The hybrid stabilization was used for multilevel laminectomies with associated initial degenerative scoliosis, first grade spondylolisthesis or a rostral pathological disc.

Results. The VAS and ODI scores improvement was statistically significant. There was no outcome difference between dynamic or hybrid fixations.

Conclusions. Patients treated with laminectomy and Flex+TM stabilization have a good clinical outcome but further data are necessary to confirm those preliminary results.

INTRODUCTION

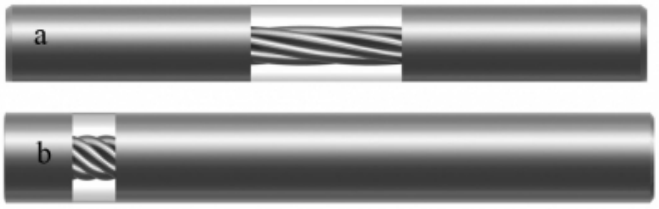
Spine fusion has been commonly used to treat spinal instability. There is now growing evidence that fusion may have a long term degenerative effect on the disc adjacent to a rigid stabilization [3, 12, 25]. Adjacent segment disease (ASD) may be produced by the altered biomechanics of the fused spine producing abnormal forces on the adjacent spinal levels and causing degeneration of the rostral disc adjacent to a rigid stabilization [1]. The posterior dynamic stabilization could ensure a quite normal range of motion of the instrumented segments avoiding the rapid degeneration of the adjacent intervertebral disc [6, 17, 20, 22]. Dynamic stabilization is indicated in cases of a degenerative disc disease (DDD) or it could be used in patients with lumbar spinal stenosis treated with wide laminectomy in order to prevent a late spinal instability, especially when preoperative magnetic resonance imaging (MRI) shows a pathological disc at the same or adjacent level to the planned laminectomy [4, 15, 18, 21, 23]. Nowadays many devices are available for the lumbar spine dynamic stabilization and each of them has proper technologies to preserve the physiological range of motion [5, 9, 24]. This study has been performed to evaluate the clinical outcome in a series of patients operated for spinal lumbar stenosis by a wide laminectomy and dynamic or hybrid stabilization device (Flex+TM system, SpineVision®, Antony Cedex, France).

MATERIALS AND METHODS

The Flex+TM device is a rod that can be used with pedicle screws. It is made of rigid Titanium Alloy (TA6V) extremities and a dynamic part consisting of a twisted Titanium Alloy cable overmolded with polycarbonate urethane polymer (Fig. 1).

Figure 1

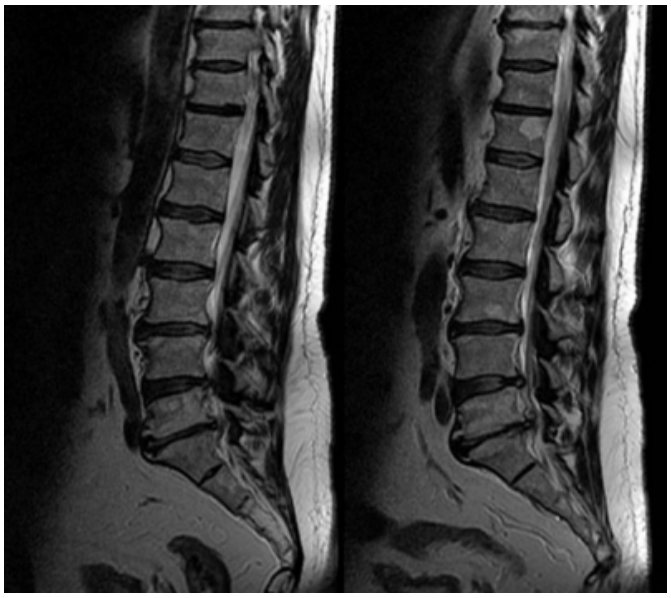
The Flex+TM device is a rod that can be used with pedicle screws. It is made of rigid Titanium Alloy (TA6V) extremities and a dynamic part consisting of a twisted Titanium Alloy cable overmolded with polycarbonate urethane polymer



Twenty patients were included in this study from September 2008 to October 2010 (10 males and 10 females). Mean age at the time of surgery was 64.3 (range: 49-77). All patients were affected by lumbar stenosis and impending spinal instability treated with wide laminectomy (i.e: including a partial demolition of the facet joint), posterior foraminotomy and Flex+TM stabilization (dynamic or hybrid construct, SpineVision®, Antony Cedex, France). The indication for a one level dynamic stabilization was a preoperative MRI evidence of a pathological disc (Pfirmann 2-3-4) at the same level of the planned laminectomy (Fig.2).

Figure 2

The indication for a one level dynamic stabilization was a preoperative MRI evidence of a pathological disc (Pfirmann 2-3-4) at the same level of the planned laminectomy



The hybrid device (i.e: dynamic stabilization at one level and rigid fixation) was used in cases of a multilevel laminectomy with associated initial degenerative scoliosis (Schwab classification VB0), first grade spondylolisthesis or a rostral pathological disc [10, 19]. None of our patient had previous spinal surgery. We used the dynamic device in 12 patients (Group A) and the hybrid device in 8 patients (four patients at two levels, four patients at three or more levels – Group B). All operated patients had disabling low back pain that was not responsive to a conservative treatment continued for at least six months. Patients with infections, tumours, severe scoliosis and spondylolisthesis, diabetes and metabolic diseases were excluded from this study. Preoperative clinical and radiological evaluation consisted in a neurological examination, Visual Analog Scale (VAS) and Oswestry Disability Index (ODI), preoperative MRI and dynamic X-ray. Follow-up visits, including the same clinical and radiological assessments, were done 3-12-24 months (mean FuP: 12 months) after surgery (Fig.3, 4) [25].

Figure 3

Follow-up visits, including the same clinical and radiological assessments, were done 3-12-24 months (mean FuP: 12 months) after surgery

Figure 4

Follow-up visits, including the same clinical and radiological assessments, were done 3-12-24 months (mean FuP: 12 months) after surgery

All operations were performed under general anaesthesia in neutral prone position, the surgical approach was done along the midline, the extension of laminectomy was performed according to the clinical data, and screws (P.L.U.S.TM, X-P.L.U.S.TM pedicular screws, SpineVision®, Antony Cedex, France) were placed under fluoroscopic visualization. Statistical analyses were performed by the Mann-Whitney test and T-test. All patients granted their permission for this study before surgery. All preoperative patients data are summarized in table 1.

Table 1

Patient data

Pts	Gender	Age	Symptoms	Surgical indications	Levels	Pfirrmann grade (of the flexible treated disc)	Dynamic system
1	F	57	Radiculopathy and claudicatio	Lumba stenosis and spondylolisthesis (grade I)	L3-L5	2	Hybrid (L3-4 flexible, L4-5 rigid)
2	M	49	Low back pain and claudicatio	Lumbar stenosis	L4-L5	2	Dynamic
3	F	76	Low back pain and claudicatio	Lumbar stenosis and spondylolisthesis (grade I)	L4-S1	3	Hybrid (L4-5 flexible, L5-S1 rigid)
4	M	57	Radiculopathy and claudicatio	Lumbar stenosis	L3-L4	2	Dynamic
5	M	69	Radiculopathy and claudicatio	Lumbar stenosis and pathological rostral disc	L2-L5	3	Hybrid (L2-3 flexible, L3-5 rigid)
6	F	69	Radiculopathy	Lumbar stenosis	L4-L5	2	Dynamic
7	M	59	Low back pain and claudicatio	Lumbar stenosis	L4-L5	2	Dynamic
8	F	60	Radiculopathy and claudicatio	Lumbar stenosis	L4-L5	2	Dynamic
9	M	77	Claudicatio	Lumbar stenosis	L4-L5	2	Dynamic
10	M	67	Radiculopathy	Lumbar stenosis and scoliosis (Schwab: VB0)	L3-S1	2	Hybrid (L3-4 flexible, L4-S1 rigid)
11	M	66	Radiculopathy	Lumbar stenosis and pathological rostral disc	L2-L5	3	Hybrid (L2-3 flexible, L3-5 rigid)
12	F	55	Radiculopathy	Lumbar stenosis and pathological rostral disc	L2-L4	3	Hybrid (L2-3 flexible, L3-4 rigid)
13	F	61	Radiculopathy	Lumbar stenosis	L3-L5	3	Hybrid (L3-4 flexible, L4-5 rigid)
14	M	68	Claudicatio	Lumbar stenosis	L2-L3	3	Dynamic
15	F	62	Radiculopathy	Lumbar stenosis	L4-L5	4	Dynamic
16	F	74	Radiculopathy and claudicatio	Lumbar stenosis	L4-L5	4	Dynamic
17	F	54	Radiculopathy and claudicatio	Lumbar stenosis	L4-L5	4	Dynamic
18	F	65	Radiculopathy and claudicatio	Lumbar stenosis	L4-L5	4	Dynamic
19	M	72	Radiculopathy	Lumbar stenosis	L4-L5	4	Dynamic
20	M	69	Radiculopathy and claudicatio	Lumbar stenosis and scoliosis (Schwab: VB0)	L3-S1	3	Hybrid (L3-4 flexible, L4-S1 rigid)

RESULTS

The mean preoperative ODI and VAS score was 40.1% and 7.2 while the postoperative one was 12.7% and 2.2. These variations resulted statistically significant ($p<0.0001$ and $p<0.0001$ - Table 2). The mean ODI and VAS score improvement in group A was 23.2% and 4.8 ($p= 0.0005$ and $p= 0.0001$, respectively - Table 3). The postoperative VAS score modification in group B was statistically significant ($p= 0.0006$) as well as the ODI score ($p= 0.0003$). In this group the mean ODI and VAS improvement was 33.6% and 5.3 (Table 4). Matching the patients with pre-operative ODI score >40% and <40% we obtained a greater improvement in the first group with a mean variations of 34.3% and 19.4% ($p= 0.0068$ - Table 5).

Table 2

Pre and postoperative VAS and ODI score

Pts	VAS pre	VAS post	VAS improvement	ODI pre	ODI post	ODI improvement
1	8	2	6	50	13	37
2	8	2	6	46	4	42
3	9	4	5	60	22	38
4	5	1	4	10	4	6
5	8	5	3	52	32	20
6	4	1	3	38	6	32
7	8	0	8	4	2	2
8	7	1	6	40	7	33
9	8	3	5	36	30	6
10	9	1	8	56	6	50
11	8	1	7	38	8	30
12	9	1	8	38	8	30
13	10	4	6	69	47	22
14	8	1	7	38	4	34
15	7	1	6	24	8	16
16	6	6	0	36	22	14
17	6	1	5	40	6	34
18	3	1	2	24	0	24
19	6	8	0	64	22	42
20	7	1	6	40	4	36
Mean value	7.2	2.2	5.05	40.1	12.7	27.4
			P<0.0001			P<0.0001

Table 3

Pre and post-operative VAS and ODI score (dynamic device, group A)

Pts	VAS PRE	VAS POST	VAS IMPROVEMENT	ODI PRE	ODI POST	ODI IMPROVEMENT
1	8	2	6	46	4	42
2	5	1	4	10	4	6
3	4	1	3	38	6	32
4	8	0	8	4	2	2
5	7	1	6	40	7	33
6	8	3	5	36	30	6
7	8	1	7	38	4	34
8	7	1	6	24	8	16
9	6	6	0	36	22	14
10	6	1	5	40	6	34
11	3	1	2	24	0	24
12	7	1	6	40	4	36
Mean value	6.4	1.5	4.8	31.3	8.08	23.2
			P=0.0001			P=0.0005

Table 4

Pre and post-operative VAS and ODI score (hybrid device, group B)

Pts	VAS PRE	VAS POST	VAS IMPROVEMENT	ODI PRE	ODI POST	ODI IMPROVEMENT
1	8	2	6	50	13	37
2	9	4	5	60	22	38
3	8	5	3	52	32	20
4	9	1	8	56	6	50
5	8	1	7	38	8	30
6	9	1	8	38	8	30
7	10	4	6	69	47	22
8	6	8	0	64	22	42
Mean value	8.3	3.2	5.3	53.3	19.7	33.6
			P: 0.0006			P: 0.0003

Table 5

ODI improvement

Pre operative ODI > 40	Pre operative ODI < 40
37	6
42	32
38	2
20	6
22	30
50	30
22	34
34	16
42	14
36	24
34.3 (mean value)	19.4 (mean value)
	P: 0.0068

No significant difference was obtained comparing VAS and ODI score variations between patients treated with dynamic or hybrid device (p = 0,4636 and p= 0,1325).
Correct screws and rods placement was achieved in all patients, but one. We had two complications (1 dural tears and 1 screw malpositioning) requiring a second operation of dural repair and screw repositioning. So far, no instrumentation failure has been recognized.

DISCUSSION

The adjacent segment disease (ASD) after a lumbar fusion may be very troublesome, especially in case of severe back pain not addressed by conservative treatment [2, 7, 21]. This condition, at least from the radiological point of view, is quite often related to a failed back spinal surgery. The ASD is still a debated issue, being uncertain if it is the natural evolution of an aging spine or if it is related to the clinical symptoms [20]. However, the literature reports a rate of clinical ASD of nearly 30%, age of the patients and a long fusion might be predisposing factors [8, 16]. Another cause of failure in spine surgery may be the late post-laminectomy instability that requires a subsequent spinal fixation, creating a predisposing condition to an ASD development [15, 23]. Over the past twenty years many lumbar dynamic devices have been introduced aiming at reducing the incidence of the adjacent segment disease. In the present series we used the dynamic device (Flex+TM system, SpineVision®, Antony Cedex, France) to stabilize a single spinal segment and the hybrid device to treat two or more segments to prevent the evolution of the DDD and the development of a post-laminectomy instability. In fact, at 12 months follow up, patients treated either with the dynamic or hybrid system, experienced a pain reduction without any neuroradiological evidence of spinal instability and further disc degeneration. Moreover the hybrid device seems to be useful in patients operated by a multilevel laminectomy in order to ensure stability at the decompressed levels and protection to the adjacent disc. The dynamic stabilization along with the spinal decompression seems to permit a good clinical

outcome also in patients with a strongly disabling preoperative pain as documented by the considerable ODI improvement in patients with preoperative ODI score >40%. The clinical improvement of patient treated with dynamic versus hybrid device was not statistically significant indicating that the two types of constructs work well, but proper indications are necessary. We had no complications related to the implants or materials used in the system. Until now, none of the patients presented pedicle screw loosening as reported in the literature for dynamic devices [11, 13, 14]. The Flex+TM device (SpineVision®, Antony Cedex, France) is a recent available dynamic and hybrid stabilization option that may be useful in preventing the post-laminectomy instability and the adjacent disc degeneration. In the present series we used the dynamic device for a single segment stabilization in order to protect the involved disc against a further degeneration. In case of a multilevel laminectomy with associated initial degenerative scoliosis (Schwab classification VB0), first grade spondylolisthesis or a pathological adjacent disc, a hybrid device was implanted to stabilize the decompressed level, protect the adjacent disc and avoid a late spinal instability. We are aware that this is a small series and that the follow-up is relatively short for developing the ASD, but the preliminary results are quite promising in terms of clinical improvement.

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