

# Long-term Results for the BacJac Interspinous Device in Lumbar Spine Degenerative Disease

Aldo Spallone<sup>1,2</sup> Luigi Lavorato<sup>3</sup> Daniele Belvisi<sup>4</sup>

<sup>1</sup>Department of Clinical Neurosciences, Section of Neurosurgery, Neurological Centre of Latium-Neuromed, Rome, Italy

<sup>2</sup>Department of Biomedicine, University of Rome "Tor Vergata", Rome, Italy

<sup>3</sup>Department of Neurosurgery, Sapienza University, Rome, Italy

<sup>4</sup>NEUROMED, IRCCS Neuromed Institute, Pozzilli, Italy

Address for correspondence Daniele Belvisi, PhD, NEUROMED, IRCCS Neuromed Institute, Via Atinense 18, Pozzilli 86077, Italy (e-mail: dbelvisi@hotmail.it).

J Neurol Surg A 2019;80:3–7.

## Abstract

**Objective** To evaluate the long-term results of using the BacJac interspinous device (Pioneer Surgical Technology Inc.) in a series of patients with degenerative lumbar spine disease.

**Methods** Forty-one patients undergoing lumbar surgery with implantation of a BacJac device from 2009 to 2012 were enrolled in the present study. Patients were evaluated using the Oswestry Disability Scale (ODI).

**Results** Although all patients showed a significant improvement of the ODI score immediately after surgery, only 41% of patients showed a satisfactory outcome. We observed worse results in the patients operated on at the L3–L4 level and in whom the device was implanted in a segment different from the one where surgical decompression had been performed. Weight gain in the months after surgery was also a poor outcome-influencing factor.

**Conclusions** This study confirms what is already suggested in the relevant literature regarding the long-term inefficacy of the so-called dynamic stabilization devices.

## Keywords

- ▶ lumbar instability
- ▶ lumbar stenosis
- ▶ lumbar surgery

## Introduction

The use of prosthetic devices in spinal surgery has become increasingly widespread.<sup>1</sup> Interspinous process devices (IPDs) were introduced in spinal surgery in recent years to reduce the risks related to more technically demanding procedures for spinal instability.<sup>2</sup> The use of such devices has also been proposed being a so-called minimally invasive surgical solution for lumbar spinal stenosis<sup>3–5</sup> with or without associated spondylolisthesis. Several types of IPDs available on the market were also tested in clinical studies.<sup>1,5–9</sup> The BacJac (Pioneer Surgical Technology Inc., Marquette, Michigan, United States) is an IPD whose use has been recommended to achieve so-called dynamic stabilization. In 2015, Gazzeri et al studied 1,108 patients in whom various

types of IPDs had been implanted. They observed that in 70% of the patients who had received a BacJac, the outcome was good to excellent after a 24-month follow-up.<sup>1</sup> However, clinical reports of IPD implantation are frequently contradictory.<sup>9</sup> In the present study, we describe our long-term results in a series of patients with degenerative lumbar spine disease in whom the BacJac device was used.

## Material and Methods

Forty-one patients who underwent lumbar surgery combined with the implantation of the BacJac device from 2009 to 2012 were enrolled in this single-institution retrospective study. The prerequisites for inclusion were adequate follow-up data and fulfillment of the strict indications for surgery.

received  
March 3, 2016  
accepted after revision  
January 19, 2018

© 2019 Georg Thieme Verlag KG  
Stuttgart · New York

DOI <https://doi.org/10.1055/s-0038-1641180>  
ISSN 2193-6315.



**Fig. 1** Magnetic resonance imaging of a 72-year-old woman with right-side sciatica as the main complaint. Axial scan shows a large right lateral disk compression.

The latter included persistent lumbar radiculopathy accompanied by low back pain in the presence of mild to moderate signs of local instability at the preoperative dynamic radiologic investigations (►Figs. 1 and 2), minor instability while flexing the spine at the dynamic lumbar radiographs (►Figs. 3 and 4), focal lumbar canal stenosis, and “redo” microdisectomy requiring consistent removal of the ligament and joint capsule without compromising joint stability.

The Bacjac device was implanted as an adjunct to decompression surgery in 26 cases, as a dynamic stand-alone pro-

cedure in 6 cases, and as an adjunct following surgery for recurrent disk diseases in 9 cases. The operations were performed at L2–L3 in 1 patient, at L3–L4 in 10 patients, at L4–L5 in 17 patients, and at L5–S1 in 13 patients. Patients were evaluated using the Oswestry Disability Scale (ODI) (obtained either directly or by telephone interview) before surgery (T0) and 1 (T1), 6 (T2), 12 (T3), 24 (T4), and 36 (T5) months after surgery. Patients with a score > 40 at the last follow-up were classified as having a “poor outcome,” those with a score of between 20 and 40 as a “fair outcome,” and those with a score ≤ 20 were classified as a “good outcome.”

The statistical analysis was conducted using the analysis of variance for repeated measures. Spearman’s rank correlation test was used to evaluate any correlation between postoperative outcome and potential influencing factors. Tukey’s honest significant difference test was used for all post hoc analyses. The *p* values < 0.05 were considered to indicate statistical significance. All values are expressed as mean ± standard error.

### Surgical Management

Surgery was performed via a unilateral lumbar spine approach using a 6-cm incision (long enough to accommodate the device). After a curvilinear fascial incision and unilateral stripping of the paravertebral muscles, disk and/or foraminal pathology were treated as required, and the device was implanted on the side of the fascial incision. Implantation of the device was performed under fluoroscopic control, and the size of the device was selected intraoperatively. After its implantation and satisfactory radiographic control (i.e., the disk space and/or the foraminal width increased if compared with the preoperative values), the wound was copiously irrigated with antibiotic solution and subsequently closed in layers.



**Fig. 2** (a, b) Pre- and postoperative radiographs of the same patient as in ►Fig. 1, showing a moderate spondylolisthesis. Note the clear increase in the disk space after surgery.



**Fig. 3** Radiograph of a 40-year-old man. (a) Extension. (b) Flexion. This radiograph shows the increased height of the foramen during maximum flexion.

## Results

The mean age of the patients was 62 years (range: 32–89). The male-to-female ratio was 0.68 (17 men and 24 women). At the last follow-up, a poor outcome was observed in 13 patients (32%), a fair outcome in 11 (27%), and a good outcome in 17 (41%) (► **Table 1**). We observed a significantly

lower ODI score at T1 than at T0, which indicated a clinical improvement in all the patients ( $p < 0.05$ ). This reduction remained significant at 12 months (T3), 24 months (T4), and 36 months (T5) only in those patients in whom the outcome was good. The ODI score was similar in all the patients at 12 months (T3), 24 months (T4), and 36 months (T5), which indicates the final outcome was already defined 1 year after surgery. Patients with radicular symptoms displayed a persistent improvement after surgery regardless of whether low back pain improved or not.

To investigate any factors that might have influenced the postoperative clinical course, we analyzed the effect of the patients' demographic data (including age, sex, and pre- and postoperative weight) and the relation between the implantation site and decompression segment, and we compared the results of patients who underwent a “stand-alone” with those who underwent a “redo” surgical procedure. Age was similar in patients with a poor, fair, and good outcome ( $p > 0.5$ ). The male-to-female ratio in patients with a good outcome and poor outcome was similar (46% and 47%, respectively), whereas that in patients with a fair outcome was lower (27%), although the difference was not significant.

Absolute weight was similar preoperatively in poor, fair, and good outcome patients. Although patients with a good or fair outcome did not display a significant weight gain following the intervention ( $p > 0.5$ ), the weight in patients with a poor outcome increased at 6 months, with the gain becoming statistically significant at 12 months ( $p < 0.05$ ).

At the last follow-up, three patients operated on at L3–L4 (28%), eight patients operated on at L4–L5 (45%), and six patients operated on at L5–S1 (46%) had a fair outcome. Hence there was a trend toward worse results in the patients operated on at the upper lumbar spine level, although the difference was not statistically significant. Only one patient



**Fig. 4** Same patient as in ► **Fig. 3**. The listhesis disappeared after surgery. Note the significant increase in the disk space.

**Table 1** Oswestry Disability Index values of all patients

Outcome	BJ + decompression	BJ stand-alone procedure	BJ in redo procedure	ODI values					
				T0	T1	T2	T3	T4	T5
Good	12	3	2	59	12	14	14	13	13
Fair	8	1	2	60	14	39	38	39	40
Bad	6	2	5	64	16	62	65	66	64

Abbreviation: BJ, BacJac device; ODI, Oswestry Disability Index.

was operated on at L2–L3; the result in this patient was good but could not obviously be considered for the statistical analysis.

A group of five patients underwent a dynamic stabilization procedure at a segment other than that at which radicular decompression had been performed. The outcome was poor in 3 of these 5 patients (23% of the cases [3/13]), fair in 1 (9% of the cases [1/11]), and good in 1 (5% of the cases [1/17]).

The BacJac was implanted as a dynamic stand-alone procedure in six cases with symptomatic canal stenosis. The outcome in two of these patients was poor (15% of the 13 patients with a poor outcome), fair in 1 (9% of the 11 patients with a fair outcome), and good in 3 (18% of the 17 patients with a good outcome).

Nine patients had recurrent disk diseases. The outcome was poor in 5 of these 9 patients (38% of the cases [5/13]), fair in 2 (18% of the cases [2/11]), and good in 2 (11% of the cases [2/17]). However, given the small number of recurrent disk patients, this difference was not statistically significant.

Lumbosacral spine radiographs were performed before and after surgery in all the patients. We observed that the foramen height and intervertebral disk space were unchanged after surgery; the interspinous space was increased. This increase was stable for 24 months after surgery (T4) in all the patients. An interspinous space reduction was observed after T4 in all the patients with a poor outcome.

The weight increase (calculated as the ratio between the weight at 6, 12, 24, and 36 months and the baseline weight) correlated positively with the long-term results of patients in the group with a poor outcome ( $p < 0.5$ ). This means that the greater the weight gain, the worse the postoperative course.

We observed a trend toward worse results in patients operated on at L3–L4 and in whom the device was implanted in a segment other than the one in which surgical decompression was performed, although the difference did not reach statistical significance.

Six of our 41 patients underwent revision surgery during the follow-up period. The revision surgery included removal of the BacJac device, foraminotomy, and pedicle screw fixation.

## Discussion

The normal evolution of spinal degeneration includes disk degeneration and loss of water and of collagen fibers. This

results in the disk losing weight and elasticity, which in turn leads to a loss of resistance and probable extrusion of the nucleus pulposus finally resulting in stenosis of the lumbar canal, combined with instability due to the misalignment of the facet joints. Low back pain associated with radiculopathy and/or neurogenic claudication are the symptoms related to stenosis and instability.

IPDs were introduced in lumbar spine surgery to recalibrate the spinal canal and enlarge the neural foramina so as to decompress indirectly the nerve roots that are functionally compromised by degenerative spinal disease caused by facet hypertrophy and/or lumbar instability. Several studies have yielded contradictory results on the efficacy of IPDs when compared with transpedicular fusion used either alone or in combination with other lumbar devices.<sup>2,10</sup> Nevertheless, IPDs have gained popularity because IPD implantation is in theory markedly easier and minimally invasive compared with other types of spinal stabilization, such as transpedicular screw fixation, which is technically more demanding and associated with procedure-related risks. Several first-generation dynamic stabilization interspinous process devices, not designed to subsequently provide fusion, such as the Wallis system<sup>6</sup> (Abbott Spine, Austin, Texas, United States) (the first to become popular among spinal surgeons), the X-Stop (Medtronic, Memphis, Tennessee, United States),<sup>11–15</sup> and the Coflex 7 (Paradigm Spine, New York, New York, United States), among others,<sup>5,8,16,17</sup> have been the subject of clinical studies.

The BacJac device was introduced in Italy in 2009 but has yet to be approved by the Food and Drug Administration despite being produced in the United States. A previous multicenter study that investigated the failure rates and complications of IPD implantation showed that the clinical outcome following implantation of the BacJac device was not fully satisfactory in 41 of 141 patients,<sup>1</sup> with 16 patients requiring revision surgery.<sup>1</sup>

The general idea of using the BacJac device was to provide stability while not aiming for subsequent fusion. As with other dynamic stabilization devices available on the market, it was even proposed as a stand-alone treatment for lumbar stenosis, although we used it for this purpose in only a minority of our patients. Our indications for the use of the BacJac device were fairly homogeneous and comprise lumbar disk disease and/or foraminal stenosis with radiologic signs of mild to moderate spondylolisthesis that improves while flexing the spine. Because its mechanism

of action requires a substantial modification of the sagittal alignment of the spine, we never used more than one device in a single patient. The ease with which the device can be placed in the spine renders the use of the BacJac device particularly appealing, although its construction has given rise to concerns regarding its long-term efficacy.

The results of the present study confirmed that those concerns are justified. The early postoperative results were fair and remained so for the first year, but the long-term results were good in only a minority of patients. In particular, devices implanted in the upper lumbar spine and in segments other than those in which surgical decompression had been performed were more likely to yield an unsatisfactory long-term outcome, particularly in patients who gained weight after surgery. We implanted this device in association with surgery at other levels at which there had been a loss of disk height and spinal canal stenosis resulting from ligament hypertrophy.

Body weight emerges as a relevant factor in the development of clinical signs related to spinal instability, with the upper lumbar spine more prone to developing postoperative instability, particularly after redo surgery, because the size of the facets at the upper levels requires extensive drilling to adequately expose the neural structures that need to be decompressed. Regarding the routine use of the BacJac device in surgery for recurrent lumbar disk, the present, somewhat limited, experience does not allow any clear conclusions to be drawn.

One interesting finding of our study is that the combination of dynamic stabilization and disk foraminal decompression in different, although adjacent, segments yielded poor long-term results, even though the relatively small number of cases analyzed did not allow statistical significance to be reached. We believe the implantation of the BacJac device in a segment adjacent to a discectomy site exerts further stress on the operated segment, which in turn subsequently reduce the efficacy of the decompression. Thus, we do not recommend an interspinous device be implanted in a segment adjacent to a site of decompression of a nerve root in the same surgery.

This study confirms previous data in the literature on the long-term inefficacy of the dynamic stabilization devices,<sup>3,10,11</sup> although one study did report a high rate of fusion many years after implantation of the Wallis system, which was the first interspinous device on the market.<sup>6</sup> In addition, changes in reimbursement regulations in Italy have contributed to a significant decrease in the use of the BacJac device in the last few years. The manufacturers of the BacJac device have introduced a new version, the BacFuse, designed to promote solid bone fusion. We are currently planning a single-institution prospective study, including a control group, to verify the long-term efficacy of this supposedly fusion-promoting new interspinous device.

## References

- Gazzeri R, Galarza M, Neroni M, et al. Failure rates and complications of interspinous process decompression devices: a European multicenter study. *Neurosurg Focus* 2015;39(04):E14
- Gonzalez-Blohm SA, Doulgeris JJ, Aghayev K, Lee WE III, Volkov A, Vrionis FD. Biomechanical analysis of an interspinous fusion device as a stand-alone and as supplemental fixation to posterior expandable interbody cages in the lumbar spine. *J Neurosurg Spine* 2014;20(02):209–219
- Moojen WA, Arts MP, Jacobs WC, et al; Leiden-The Hague Spine Intervention Prognostic Study Group. Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomized controlled trial. *BMJ* 2013;347:f6415
- Eichholz KM, Fessler RG. Is the X STOP interspinous implant a safe and effective treatment for neurogenic intermittent claudication? *Nat Clin Pract Neurol* 2006;2(01):22–23
- Mariottini A, Pieri S, Giachi S, et al. Preliminary results of a soft novel lumbar intervertebral prosthesis (DIAM) in the degenerative spinal pathology. *Acta Neurochir Suppl (Wien)* 2005;92:129–131
- Sénégas J, Vital JM, Pointillart V, Mangione P. Clinical evaluation of a lumbar interspinous dynamic stabilization device (the Wallis system) with a 13-year mean follow-up. *Neurosurg Rev* 2009;32(03):335–341; discussion 341–342
- Richter A, Schütz C, Hauck M, Halm H. Does an interspinous device (Coflex) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. *Eur Spine J* 2010;19(02):283–289
- Kim DH, Shanti N, Tantorski ME, et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. *Spine J* 2012;12(06):466–472
- Gazzeri R, Galarza M, Alfieri A. Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future. *BioMed Res Int* 2014; 2014:975052
- Wang H, Wang X, Chen W, et al. Biomechanical comparison of interspinous distraction device and facet screw fixation system on the motion of lumbar spine: a finite element analysis. *Chin Med J (Engl)* 2014;127(11):2078–2084
- Verhoof OJ, Bron JL, Wapstra FH, van Royen BJ. High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. *Eur Spine J* 2008;17(02):188–192
- Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. *J Neurosurg Spine* 2006;4(06):463–471
- Bowers C, Amini A, Dailey AT, Schmidt MH. Dynamic interspinous process stabilization: review of complications associated with the X-Stop device. *Neurosurg Focus* 2010;28(06):E8
- Puzzilli F, Gazzeri R, Galarza M, et al. Interspinous spacer decompression (X-STOP) for lumbar spinal stenosis and degenerative disk disease: a multicenter study with a minimum 3-year follow-up. *Clin Neurol Neurosurg* 2014;124:166–174
- Miscusi M, Trungu S, Forcato S, et al. Long-term clinical outcomes and quality of life in elderly patients treated with interspinous devices for lumbar spinal stenosis. *J Neurol Surg A* 2018;79:139–144
- Alfieri A, Gazzeri R, Prell J, et al. Role of lumbar interspinous distraction on the neural elements. *Neurosurg Rev* 2012;35(04): 477–484; discussion 484
- Alfieri A, Gazzeri R, Prell J, Röllinghoff M. The current management of lumbar spondylolisthesis. *J Neurosurg Sci* 2013;57(02): 103–113