

# Long term results of the use of a fusion-promoting, new generation interspinous processes device (IPD), Bacfuse®: a monocentric prospective study

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**Abstract. – OBJECTIVE:** Lumbar micro instability is a diffuse problem mostly in elderly population. Interspinous processes devices (IPDs) have been introduced in the clinical practice for relieving the dynamic compression on the nerve roots due to instability. First-generation IPDs did not achieve bone fusion so their good immediate postoperative results did not last in the long term. More recently, a new version of IPD, Bacfuse®, has been introduced with the aim of achieving postoperative fusion.

**SUBJECTS AND METHODS:** We started using this new device in 2015. We investigated prospectively the long-term results of a series of 41 patients with small-to-moderate lumbar instability. In 29 of them the IPD was placed as an adjunct to decompressive surgery whilst in 12 patients it was implemented as a stand-alone technique.

**RESULTS:** Immediate post-operative results showed significant clinical improvement in all cases. This improvement was still present in 32 of them at the last follow-up, 2.5 to 4 years following surgery. The dynamics of clinical symptoms did not change after two years of observation, a fact that indicates that no changes are to be expected afterward. Spinal fusion was obtained in more than 2/3 of the patients and not surprisingly was correlated with better clinical results. Excessive body weight appeared to be a negative factor for achieving both spinal fusion and good results.

**CONCLUSIONS:** Bacfuse® seems to be a very good surgical tool for patients bearing small to moderate lumbar instability whether or not submitted to direct decompressive surgery.

*Key Words:*

Lumbar micro instability, Interspinous process devices (IPDs), Spinal fusion, Nerve root decompression.

## Introduction

Lumbar “micro-instability” is a major cause of back pain, an extremely diffused clinical prob-

lem, mostly in elderly population, which has become a real social emergency in developed countries with enormous impact in the society by causing significant loss of working days and increasing costs for healthcare systems<sup>1,2</sup>.

Interspinous devices (or interspinous process devices, IPDs) have been introduced relatively recently in the clinical practice with the aim of recalibrating the spinal canal-stenosed as a consequence of the vertebral misalignment- and of increasing the width of neural foramina for relieving the dynamic compression on the nerve roots. First-generation IPDs were not designed for obtaining spinal stabilization, a fact which led to inconsistent and in most cases unsatisfactory long-term results<sup>3</sup>. This fact has stimulated search for other approaches and eventually led to the introduction in the clinical practice of second-generation IPDs which are supported to promote interspinous processes fusion and subsequent stabilization<sup>4</sup>.

In a previous study we evaluated the long-term results of a first-generation IPD-Bacjac® – and conclude that in general its immediately postoperative good results lasted for approximately one year<sup>5</sup>.

For this reason, we started using a second-generation IPD, the Bacfuse®, a technological evolution of the Bacjac® which is conceived for promoting postoperative fusion. We report here the long-term results of the use of this IPD in 41 patients harboring lumbar micro-instability and submitted to surgery during a 3-year-period.

## Subjects and Methods

### Subjects

Forty-one patients undergoing lumbar surgery with implantation of a Bacfuse® device in the years 2015-2018 were enrolled prospectively in the present study. Bacfuse® was implanted as

an adjunct to decompression surgery in 29 cases and as a dynamic “stand alone” procedure in 12 cases. Five patients underwent a “redo” surgery. In all the “redo” surgery the implantation of the Bacfuse® was associated to decompression surgery. The operations were performed at L2-L3 in 2 patients, L3-L4 8 patients, at L4-L5 in 22 patients, at L5-S1 in 9 patients. Demographic information, diagnosis and preoperative pain levels were recorded. Preoperative and postoperative clinical assessments of the patients performed using the visual analogue scale (VAS) and on the Oswestry Disability Scale (ODI). A minimum of 48 months follow up was available in all cases. Patient satisfaction and postoperative pain outcomes were also assessed using the rating scale of Finneson and Cooper, a lumbar disc surgery questionnaire that categorizes the postoperative assessment of patients into a 5-grade classification, from excellent to poor.

Lumbar spine antero-posterior and lateral X-rays were performed before and 3 months and 12 months after the implantation.

### ***Inclusion Criteria and Surgical Management***

Inclusion criteria for Bacfuse® implantation were persistent lumbar radiculopathy accompanied by low back pain in the presence of the mild-to-moderate signs of local instability at the preoperative dynamic radiological investigations, subjective improvement while flexing the spine possibly (but not obligatory) matched by the reduction of the vertebral misalignment at the dynamic X-Rays, was considered the most important clinical sign for indicating surgery while using IPD. Focal lumbar canal stenosis indicated IPD using when the patients had a documented instability. “Redo” microdiscectomy patients requiring consistent removal of ligament and joint capsule without compromising joint stability were treated with IPD.

Surgery was performed *via* bilateral lumbar spine approach using a 6 cm incision (long enough to accommodate the device). After a fascial incision and bilateral stripping of the paravertebral muscles, disk and/or foraminal pathology was treated as needed and the device was implanted from the top of the spinous process of the interested vertebrae. The device implantation was performed under fluoroscopic control and the measure of the device was selected intraoperatively. Particular attention was paid to proper in-

terspinous ligament incision and spinous process cleaning as well as to choose of proper size of the device (they can range from 8 to 16 mm and are chosen according to the level of the required distraction).

After its implantation and satisfactory X Ray control (i.e., the disk space and/or the foraminal width were increased compared to the pre-operative studies) the wound was copiously irrigated with antibiotic solution and subsequently closed in layers.

### ***Clinical-Radiological Data***

Pre- and post-operative clinical evaluation of back pain and radiculopathy, if present, were conducted. before and immediately (T0), 3 months (T1), 24 months (T2) and 48 months (T3) after surgery. Dynamic X-rays were performed before, 3 and 12 months after surgery.

### ***Statistical Analysis***

Statistical analysis was conducted by using the ANOVA for repeated measures. Spearman rank correlation test was used to evaluate the possible correlation between postoperative outcome and possibly influencing factors. Tukey Honest Significant Difference test was used for all post hoc analyses. *p*-values less than 0.05 were considered to indicate statistical significance. All values are expressed as mean ± SE.

## **Results**

### ***Clinical Outcomes***

The mean age of the patients was 59 years (range 31-90). The ratio male/female was 0.86 (19 males, 22 females). Directly postoperatively, each patient experienced a significant improvement of symptoms as demonstrated by the significant reduction of VAS ( $p < 0.05$ ) and ODI ( $p < 0.05$ ). At the last follow up assessment (48 months), VAS and ODI were still significantly reduced in 32 out of 41 patients enrolled. According to the Finneson and Cooper questionnaire, 24 patients were very satisfied, 8 patients were somewhat satisfied, and 9 patients were not satisfied with the results of surgery after a minimum of 2 years of follow-up. In the patients who completed the 48 months follow up assessment, we did not observe any significant difference between the 24 months and the 48 months evalu-

ation. Among the 9 patients who had a not satisfactory outcome, 4 patients had a “stand-alone” Bacfuse®, 4 patients had a Bacfuse® added to decompression surgery and 1 patient was “redo”. Therefore, a not satisfactory outcome was present in 13% of patients who had Bacfuse® + decompression, 33% of “stand-alone” patients and 20% of “redo” patients.

The clinical outcome did not correlate with age, gender, baseline weight and site of implantation (L2-L3+L3-L4 vs. L4-L5+ L5-S1) ( $p > 0.05$ ). We found a positive correlation between VAS and ODI postoperative values and the gain weight in the 48 follow-up months ( $r = 0.68$ ;  $p < 0.05$ ).

### **Radiological Outcomes**

All patients underwent a lumbar spine antero-posterior and lateral X-rays before and 3 months after the implantation. We observed an interbody fusion in 21 patients (46% of patients) at 3 months and in further 7 patients at 12 months (68%) Figure 1. By comparing the clinical outcome of patients with and without interbody fusion, we observed that patients with interbody fusion had significantly lower VAS and ODI scores that patients without interbody fusion at the last follow up assessment ( $p < 0.05$ ).

### **Discussion**

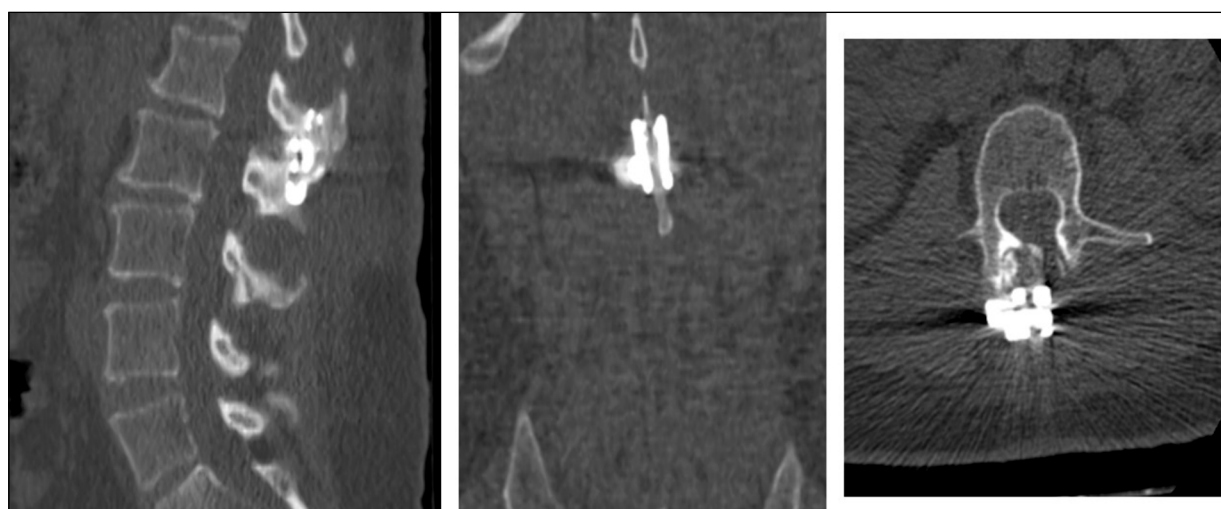
The Bacfuse® Device is a posterior, non-pedicle supplemental fixation device, intended for use

at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Bacfuse® device is intended for use with bone graft material (i.e., allograft or autograft).

The present study was undergone for evaluating the clinical efficacy of a second-generation IPD specifically designed for obtaining postoperative fusion. The use of IPDs has evident advantages over the surgical method for inducing spinal fusion due to the extremely simple surgical technique required for implementing them, as well as its definitive miniminvasiveness<sup>6</sup>. However, surgical indications should be very strict<sup>7-10</sup>, and its use should be limited to patients with relatively minor lumbar instability who report definite back-pain relieve while flexing the spine.

Ideally, subjective patient’s improvement while bending forward should be coupled with radiological evidence of reduction of vertebral malalignment as demonstrated by dynamic lumbar X-rays.

Strict patients’ selection reduces the number of potential candidates to be operated on with this-relatively simple- technique but it is obviously of crucial importance in order to obtain the expected satisfactory results in the long-term. For this reason, post-traumatic patients, patients with significant lateral instability and/or scoliosis, and those



**Figure 1.** CT-Scan 1 year post operative show a satisfactory spinal fusion.

with spondylosynthesis grade greater than Meyer1, should not be submitted to IPD implementation<sup>6</sup>.

In our case material selection, we strictly applied these guidelines, even more strictly than we had done in a previous study from group in which another non-fusion, “dynamic” IPD had been tested<sup>4,5</sup>. In particular, we avoided surgical manipulation of spaces adjacent to the site of IPD implementation and did not consider for Bacfuse<sup>®</sup> surgery patients with recurrent disk diseases a definite lumbar instability which improved with flexion was present. Immediate postoperatively there was a significant improvement of symptoms, as in the previous study<sup>5</sup>. This lasted in a significant proportion of patients at the time of last follow-up a significant improvement as compared to the results of the previous study. However still a non-negligible number of patients were unsatisfied in the long term.

Long-term results did not change after one year of observation, something which was already observed in a recent study performed in a large case material managed with the same device<sup>10</sup>.

We analyzed several patients’ characteristics potentially related to unsatisfactory results and found that two factors had a significant impact: lack of fusion; and body weight, either increased or kept excessive following surgery.

As far as the first factor, approximately 20% of the present patients did not exhibit sign of radiological fusion at the last follow-up: these patients did worse than those in whom fusion occurred. As to body mass, excessive weight-and in particular weight gain following surgery-had a significant negative impact on the clinical results as already observed in the aforementioned previous study from our group.

In this study we avoided performing disk and/or foraminal surgical manipulation in a space adjacent to the one in which IPD was applied, a strategy suggested by our previous negative experience<sup>6,9</sup>. Also, we strictly reserved IPD implementation to patients with radiologically-demonstrated lysis, whether or not previously submitted to lumbar surgery. Again, our case selection has been very strict, and this is a very likely key factor for achieving reasonably good long-term results. Accordingly, we do not think that spinal stabilization should be routine in redo lumbar surgery, but it should be indicated – using the appropriate surgical method for each individual case – only in the presence of postoperative lumbar instability.

## Conclusions

The use of fusion-promoting IPDs such as the one used in the present patients, unlike what happened with the first-generation, “dynamic” IPDs, appears to be able to produce satisfactory long-term results in patients harboring minimal-to-moderate lumbar instability, if properly selected. Wise postoperative control of patient’s life habits, in particular avoidance of smoking-a well-recognized negative factor for postoperative spinal fusion-and of excessive body weight, represent also important adjunctive factors for achieving satisfactory long-term surgical results.

## Conflict of Interest

The Authors declare that they have no conflict of interests.

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