

A Report on the early Results of the BacJac Interspinous Distraction Device: A Prospective Study in Patients with Lumbar Spinal Stenosis

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ABSTRACT

Aims: This is a report on the early clinical outcome of the BacJac interspinous distraction device in patients with lumbar spinal stenosis.

Materials and methods: This is a prospective study on a group of patients who underwent surgery from February 2010 to December 2012. There were 21 consecutive patients who had insertion of a BacJac. Data prospectively recorded included Visual Analogue Scores for leg pain (VL), back pain (VB), the Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and walking distance (WD). Scores were recorded pre- and postoperatively and at final review. The follow-up period varied from 6 to 40 months.

Results: We found all clinical outcome measures improved following surgery. Mean scores for VL improved from 76 to 27, for VB from 49 to 24, and for ODI from 42 to 26 at final follow-up. There were also improvements noted in ZCQ scores and patient-reported WD. We also noted a high rate of osteolysis (76%) around the implant at 1 year from insertion.

Conclusion: This small prospective study suggests that there is a role for the use of the BacJac interspinous distraction devices in selected patients. Osteolysis around the implant remains an issue although this did not appear to compromise the early outcome in this study.

Keywords: Clinical outcome, Interspinous distraction device, Lumbar spinal stenosis, Surgical treatment.

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BACKGROUND

The established surgical treatment for lumbar canal stenosis is decompressive surgery.¹ Over the past few years, the use of interspinous distraction devices (ISPD) has been

introduced as an alternative and less-invasive method. Several interspinous devices are available, including the X-STOP, Coflex, the Wallis Ligament, DIAM, and the BacJac. The stated aim of these devices is to achieve distraction between adjacent spinous processes and restore foraminal height, unload the facet joints, and provide a block to extension.² Reported indications for the use of ISPDs include treatment of spinal canal stenosis, low-back pain caused by disk degeneration, facet syndrome, lumbar disk prolapse, and spinal instability.³ The aim of this study is to evaluate the clinical outcome of a consecutive cohort of 21 patients who have had insertion of a BacJac interspinous device.

MATERIALS AND METHODS

The senior author (MLN) has maintained a prospective database of surgical procedures performed. Outcome data recorded includes Visual Analogue Scores for leg pain (VL), back pain (VB), the Oswestry Disability Index (ODI), and the Zurich Claudication Questionnaire (ZCQ). Data has been prospectively recorded preoperatively and at routine follow-up. Surgical complications have also been recorded prospectively.

From the database, patients were identified who had undergone insertion of a BacJac interspinous distraction device. Their outcome scores were compared preoperatively and at final review. Patients were also asked prospectively to record their walking distance (WD) and about their overall satisfaction with their operative treatment. Standing AP and lateral lumbar radiographs were taken preoperatively, immediately postoperatively, and at 1 year postoperatively.

From February 2010 to December 2012, 21 patients were identified who underwent insertion of a BacJac. All patients had presented with neurogenic claudication with or without back pain and had an underlying diagnosis confirmed by an MRI scan (Table 1). Most had received

Table 1: Underlying diagnosis

	<i>Number of patients</i>
Degenerative stenosis (central and/or lateral recess)	9
Degenerative spondylolisthesis	6
Foraminal stenosis	6

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nonoperative treatment including the use of analgesics and physiotherapy, and all had failed to experience any long-lasting relief with either an epidural injection or a nerve root block.

Operative Technique

The same operative procedure was used in all cases and performed under a general anesthetic. The patient was positioned prone on a Toronto frame, and an image intensifier was used to identify the correct level. Through a midline incision, a right-sided approach preserving the supraspinous structures was used to expose the relevant interspace. A probe was passed through the interspinous ligament and the level checked again. Successive probes were then inserted through the interspinous ligament and a distracter inserted between adjacent spinous processes to open the interspace. The appropriate implant was then inserted and the final position was again checked with the image intensifier. The wound was irrigated and routine wound closure completed. Local anesthetic was infiltrated around the wound, which was covered with a sterile dressing. All patients were allowed to mobilize immediately following surgery.

RESULTS

Data has been included from 1 patient who had died due to metastatic prostate cancer, but had been symptomatically well when last reviewed 12 months following surgery. Follow-up for the whole group ranged from 6 to 40 months with an average of 22.5 months.

There were 14 males and 7 females. The average age at surgery was 65.1 years (30–85 years). The average length of hospital stay following surgery was 0.7 days. Nine patients were discharged on the day of surgery, 10 patients the day after surgery, and two were discharged 2 days following surgery. The levels at which BacJacs were inserted are shown in Table 2. Nine patients had implants inserted at two levels (Fig. 1). The size of the implant inserted is shown in Table 3.

Table 2: Levels at which BacJac was inserted

	L3	L4	L5	S1
L2		2		
L3		1	3	
L4			7	4
L5				4

Table 3: Size of implants used

BacJac size	Number
8	6
10	16
12	7
14	1

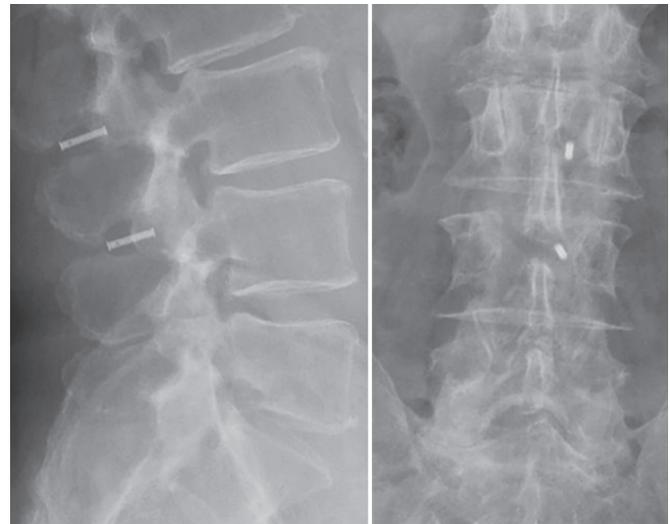


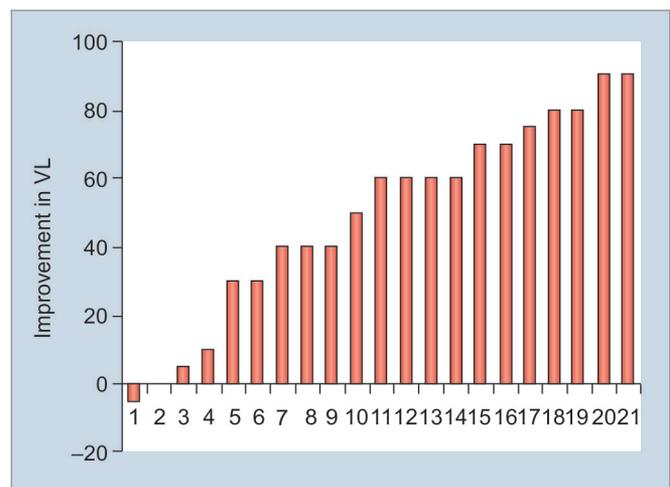
Fig. 1: Postoperative X-ray showing BacJacs at L2 to L3 and L3 to L4

Clinical Outcome

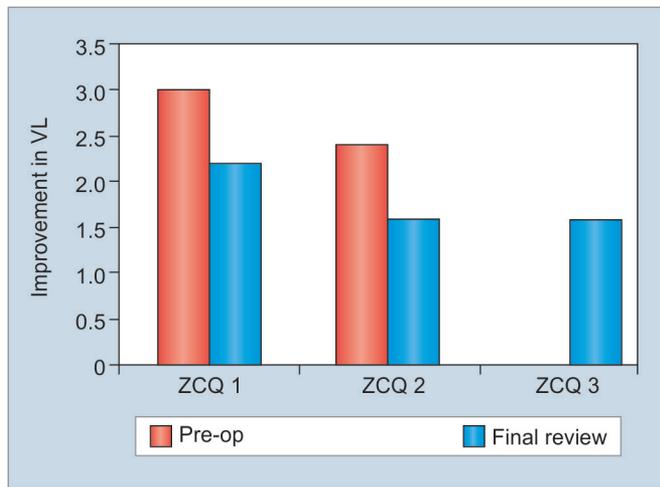
Mean scores for VL had improved from 76 to 27, for VB from 49 to 24, and for ODI from 42 to 25 at final follow-up. Improvement in VL for each individual patient is shown in Graph 1. Preoperative and final scores for ZCQ are shown in Graph 2. Patient-reported WDs improved from a mean of 429 yards to 862 yards.

There were four (19%) patients who had developed a recurrence of preoperative symptoms by 12 months' follow-up. Two patients had degenerative stenosis and one in each of the other diagnostic groups. Overall, 2 patients underwent revision to a formal decompression while the other two declined further surgery.

Fifteen patients graded their treatment as excellent, five graded it as good, and one graded it as fair. At final follow-up, 11 patients felt their current state to be much better as compared to their preoperative state, seven patients felt better than their preoperative state, and three patients felt they were the same compared to their



Graph 1: Change in VL at final review compared to preoperative (positive = improvement)



Graph 2: Average ZCQ scores preoperatively and at final review

preoperative state. The two patients who had developed a recurrence of symptoms but who had declined surgery felt their current state to be the same as before surgery.

Complications

There were three complications. One BacJac was broken intraoperatively during insertion and was replaced uneventfully. One patient had posterior migration of their implant noted at 6 months postoperatively, and 1 patient developed a superficial wound infection, which was managed with antibiotics.

Radiological Outcome

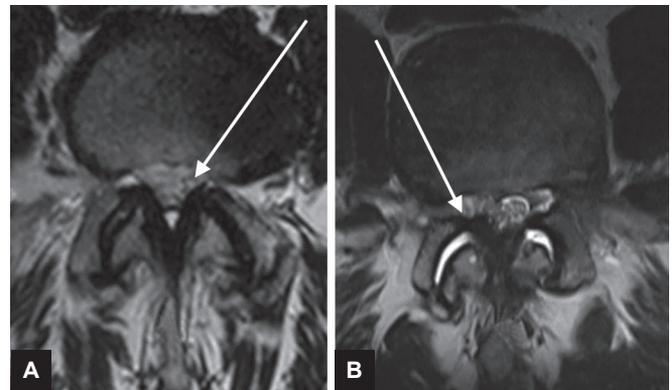
Sixteen (76%) of the 21 cases showed evidence of osteolysis of the adjacent spinous processes at 1 year from surgery (Fig. 2).

DISCUSSION

Our indications for using a BacJac are broadly the same as for a formal decompression. The first indication is clinical



Fig. 2: Postoperative radiograph showing a BacJac at L4 to L5 with osteolysis of the adjacent spinous processes



Figs 3A and B: (A) a patient with predominantly soft-tissue compression who underwent insertion of a BacJac; (B) a patient with an element of bony narrowing who underwent decompression

and based on the pattern and severity of leg symptoms. However, there are then radiological features that in our practice act as contraindicators for this procedure. One feature is related to the severity of stenosis on imaging although we have not attempted to quantify this. The second is more subtle and related to the element of compression, i.e., bony rather than soft tissue. In our practice and through our experience with another ISPD, we believe that outcomes with an ISPD are poor where there is even just a modest element of bony compression in the lateral recess (Fig. 3). These patients are therefore offered a formal decompression.

In keeping with other ISPDs, the BacJac is used as a stand-alone device and works through the principle of indirect decompression, thus avoiding the potentially risks associated with a decompression. The role of ISPDs for the treatment of radicular leg pain and neurogenic claudication has previously been reported.⁴⁻⁸

The BacJac is made up of polyetheretherketone (PEEK), and its nonarticulating design produces wear, which is much less than what is expected in *in vivo* loading.⁹ Polyetheretherketone is thermoplastic with an elastic modulus similar to that of bone, which ensures reduced risk of subsidence.¹⁰ Tests for biocompatibility and biodurability showed no major change in material after aging, and there was no cytotoxic and histopathologic or inflammatory response.¹¹ Another reported advantage of PEEK is that it does not produce artifacts with postoperative imaging, such as MRI. The lower modulus of PEEK is said to reduce the risk of fracture of the spinous process.¹²

We noted a high rate of osteolysis around the implant despite the reported advantages of using PEEK to construct the device. We should also point out that three of the five patients whose X-rays did not show osteolysis were less than 1 year from surgery. It is therefore possible that the rate of osteolysis for the group as a whole at 1 year from surgery will increase. There is clearly an issue

in putting a distraction device that produces compressive forces between bony structures that ordinarily function to withstand tensile forces. Our study does not therefore appear to support the view that the use of PEEK reduces the rate of adjacent spinous process osteolysis although good clinical outcomes were seen despite its presence.

This small prospective study has shown that in selected patients, good early outcomes and patient satisfaction can be achieved with the BacJac. Clearly, longer follow-up studies will be necessary to assess whether these early outcomes are maintained in the long term.

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