Original Article

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An Investigation for Etiologies of Revisional Surgeries after Placement of Device for Intervertebral Assisted Motion: A Case Series Study

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Objective: Interspinous process devices are widely used for the treatment of lumbar spinal stenosis. This retrospective study aimed to investigate the etiology of revision surgery after placement of a Device for Intervertebral Assisted Motion (DIAM).

Methods: Surgical indications and complications before revision surgery were reviewed from the medical records of patients who underwent revision spinal instrumentation placement surgery in our hospital. Pain scores were evaluated before and after revision surgery.

Results: Forty-four patients were included, with a mean age of 58.80 (± 13.12) years and a majority (79.5%) of females. Complications occurred in the ten patients implanted with one DIAM, including infection, instability, or stenosis in 3/10 (30%); not preventing adjacent segment disease in 6/10 (60%); and DIAM-involved instability in 1/10 (10%). The remaining 34 cases with multiple DIAM implants experienced DIAM-involved instability with stenosis (34/34, 100%).

Conclusions: The contraindications of DIAM include multiple interspinal process devices, cases with pars fracture or unstable spine, and implanted in L5-S1 site.

Key words: interspinous process device (IPD), Device for Intervertebral Assisted Motion (DIAM), adjacent segment disease (ASD)

Introduction

An interspinous process device (IPD) is one kind of non-fusion device widely used for the treatment of lumbar neurogenic disease caused by lumbar spinal stenosis. Multiple studies have illustrated the short-term clinical outcomes of surgeries with IPD device,[1-6] including pain relief,[1,5] safety,[1-3] and good decompression efficacy.[1-6] Among IPDs, the Device for Intervertebral Assisted Motion (DIAM™, Medtronic, Ltd., USA) has shown good results in biochemical tests and clinical outcomes. Spinal stabilization by DIAM purportedly provides flexible support of the

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lumbar spine while treating spinal degeneration.[5,6] Taylor et al.[6] also suggested three indications for DIAM device placement, including (1) discogenic disease, either primary or recurrent, with or without discectomy; (2) posterior spinal disease resulting in central stenosis, foraminal stenosis, facet disease, or ligamentous instability leading to no more than a Grade I spondylolisthesis; and (3) to protect from junction disease by implanting a DIAM above a fresh or existing lumbar fusion.

Although the DIAM placement is generally acceptable, increasing complications and precautions are reported.[7,8] The long-term complications of DIAM and other IPDs include higher rates of reoperation and revision surgery, and higher cost-effectiveness.[3,7-14] Studies have reported a reoperation rate of 4.7% – 8.5%, and a mean time to reoperation ranged from 13.4 months to 6.5 years after DIAM placement.[15,16] The wide range of reoperation duration suggests that avoiding risk factors may prolong the use of DIAM. This retrospective observational study aimed to investigate the etiology of revision surgery after the initial DIAM placement.

Patients and Methods

Participants

Patients who could tolerate symptoms using conservative treatment with medication, physical therapy, or even injection prolotherapy were excluded from this study as they were not considered candidates for revision surgery. Forty-four patients who underwent revision spinal surgery due to intolerable pain and sciatica after receiving DIAM from 2016 to 2018 in our hospital were included in this study. Patients underwent dynamic X-rays and magnetic resonance imaging (MRI) examination of the lumbar spine before the revision surgery. Patient data were reviewed from medical records, including clinical characteristics and complications. Outcome indicators included the Visual Analog Scale (VAS) pain score, the bone healing status assessed by X-ray images, and the clinical outcomes after revision surgery. This study was conducted in accordance with the Declaration of Helsinki and reviewed by the ethics committee of our hospital, and the requirement for informed consent was waived.

Surgical methods

Patients who remained symptomatic following at least three months of conservative treatment were referred for revision surgery. All the patients received revision surgery with spinal instrumentation with or without cages interbody fusion, depending on joint space narrowing. Three cases with suspected infection were converted to internal fixation after removal of the DIAM and debridement. The signs of infection were not severe, and the surgical field was thoroughly cleaned after removal of the DIAM. Six failed topping off cases underwent extended spinal instrumentation fusion with at least two more upper levels of fixation. The remaining 34 cases with multiple DIAMs received multiple levels of fusion, depending on the pre-operative imaging evaluation.

X-ray and magnetic resonance imaging images

The X-ray and MRI images were obtained according to standard procedures to determine the segmental instability. Spinal segments with more than 4 mm of translation and a dynamic angle of $> 10^{\circ}$ were considered unstable. MRI images of the lumbar spine were used to assess spinal stenosis and facet joint instability.

Statistical analysis

Categorical data are presented as n (%), and continuous data are presented as mean ± standard deviation. The association between the DIAM number and complications was assessed using Fisher's exact test. A two-sided $p < 0.05$

was considered statistically significant. Statistical analyses were performed using the statistical software package SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

This study included 44 patients who underwent revision surgery after DIAM implantation. Most patients underwent the first DIAM placement operation in another hospital. Therefore, we were unable to obtain their original medical records and it was difficult to determine when those patients underwent their first DIAM implantation. The six topping-off DIAM procedures were performed in our hospital approximately 5 to 15 years ago. The demographic characteristics are summarized in Table 1. The mean age of the patients was 58.80 ± 13.12 years, and 79.5% of patients were female. Our results showed that 19 (43.2%) and 15 (34.1%) cases had 3 and 2 DIAMs, respectively, and only 10 cases (22.7%) had 1 DIAM. The most prevalent complication was multiple DIAM-involved instability with stenosis (77.3%).

Table 1. Patient characteristics.

Term	Total population (N = 44)
Age	58.80 ± 13.12
Gender	
Female	35 (79.5%)
Male	9 (20.5%)
Level	
L1-2	2 (4.5%)
L2-3	3 (6.8%)
L2-3-4-5	7 (15.9%)
L3-4	2 (4.5)
L3-4-5	14 (31.8%)
L3-4-5-S1	11 (25.0%)
L4-5	2 (4.5%)
L4-5-S1	2 (4.5%)
L5-S1	1 (2.3%)
DIAM number	
1	10 (22.7%)
2	15 (34.1%)
3	19 (43.2%)
Complication	
DIAM alone with infection	2 (4.5%)
DIAM alone with instability	3 (6.8%)
Not preventing ASD	6 (13.6%)
Inadequate decompression	30 (68.2%)
Multiple DIAM-involved instability with stenosis	34 (77.3%)

ASD: adjacent segment disease; DIAM: Device for Intervertebral Assisted Motion.

The association between the DIAM number and the reported complications is presented in Table 2. Among patients with only one DIAM, three (30.0%) had infection, instability, or stenosis; 6 (60.0%) were not able to prevent adjacent segment disease (ASD), and 1 (10%) had DIAM-involved instability with stenosis. However, multiple DIAM-involved instabilities with stenosis were observed in all patients who received 2 (15, 100%) or 3 (19, 100%) DIAMs ($p < 0.001$).

Persistent low back pain and intractable sciatica was the main complaint of most patients. The X-ray and MRI images of two patients with low back pain and residual stenosis are shown in Figures 1 and 2. The Figure 1 case had an L1, 2 compression fracture, which underwent vertebroplasty first. Upper back pain was improved after the vertebroplasty but the lower back region pain and severe sciatica persisted. Figure 3 shows the X-ray image of a patient who un-

Table 2. Association between the DIAM number and complications.

	DIAM number (n = 44)			*p*-value
	1 (n = 10)	2 (n = 15)	3 (n = 19)	
Complication				**< 0.001**
DIAM alone with infection, instability, or stenosis	3 (30.0%)	0 (0.0%)	0 (0.0%)	
Not preventing ASD	6 (60.0%)	0 (0.0%)	0 (0.0%)	
DIAM-involved instability with stenosis	1 (10.0%)	15 (100.0%)	19 (100.0%)	

ASD: adjacent segment disease; DIAM: Device for Intervertebral Assisted Motion.

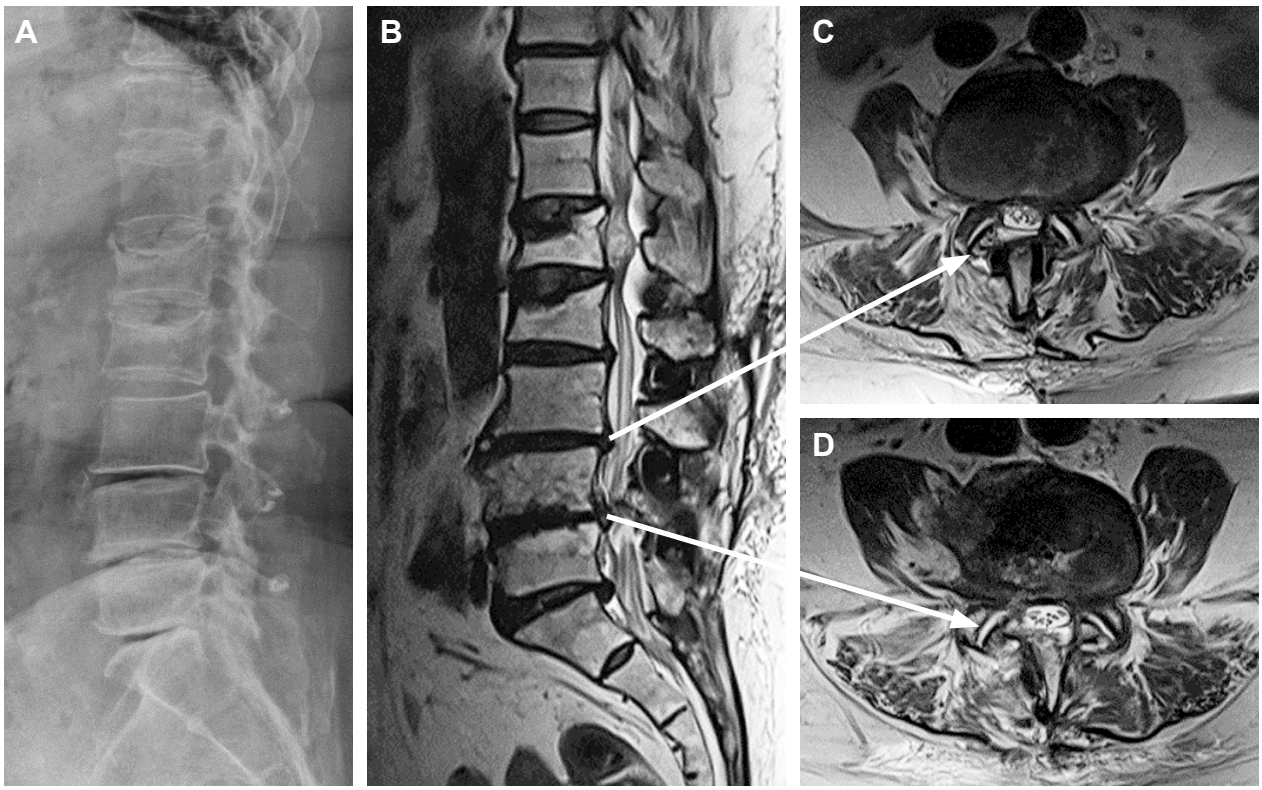

Fig. 1 A case with persistent back pain and lower leg numbness caused by multiple DIAMs. (A) X-ray and (B) MRI images in the sagittal plane. (C and D) MRI images in the axial plane. DIAM: Device for Intervertebral Assisted Motion; MRI: Magnetic resonance imaging.

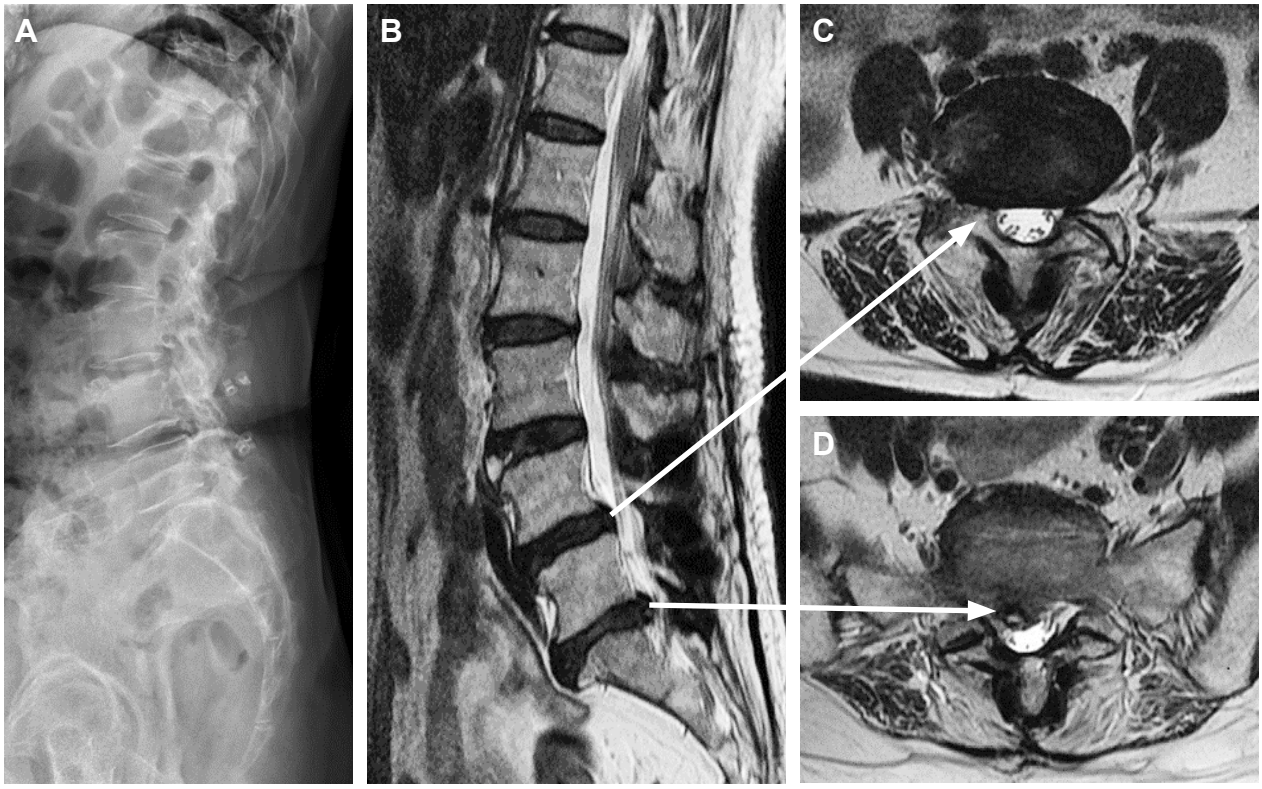

Fig. 2 A case with severe back pain with right leg sciatica caused by the DIAM device. (A) X-ray and (B) MRI images in the sagittal plane. (C and D) MRI images in the axial plane. MRI: Magnetic resonance imaging.

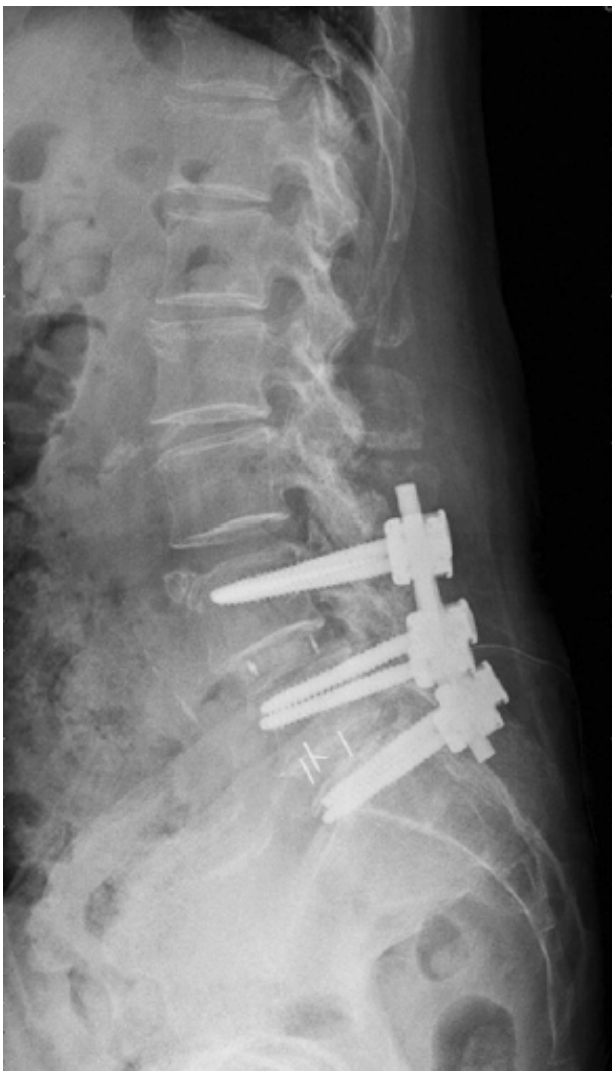

Fig. 3 A case who underwent revision surgery and internal fixation for L4-5-S1 with stainless steel after nerve decompression.

derwent revision surgery and internal fixation for L4-5-S1 with stainless steel and anterior interbody fusion with cages after nerve decompression and removal of the DIAM device. A foreign body reaction (Fig. 4) caused by the DIAM device was observed in some cases. All the cultures showed negative findings. The preoperative VAS pain scores were approximately 6 – 10, and those at the one-year follow-up improved 1 – 4. Most patients were reportedly satisfied 1 – 3 years after the revision surgery.

Discussion

In patients with a relatively unstable spine who receive spinal decompression surgery and DIAM alone, greater spinal instability is noted. DIAM is not a fusion device, but it can used in relatively stable spine cases. A reduction in ASD after multilevel spinal fusion with proximal DIAM implantation has been reported. Placement of a DIAM to top off a multilevel fusion construct significantly reduced the occurrence of radiographic ASD compared with that following only an instrumented fusion construct.[17,18] However, as the follow-up time increases, DIAM's effectiveness in preventing ASD becomes less effective, and more patients require revision surgery to treat junctional level instability. We suggest DIAM placement in patients with a disc space of < 1/2 and with no arthritis in the facet joint; otherwise, DIAM's effect in preventing ASD is not obvious.

Double IPD treatment resulted in a high complication rate, and double DIAM placement resulted in a high frequency of spinal process fractures. Moreover, in three f the surgeries, IPD was contraindicated.[8] However, this study

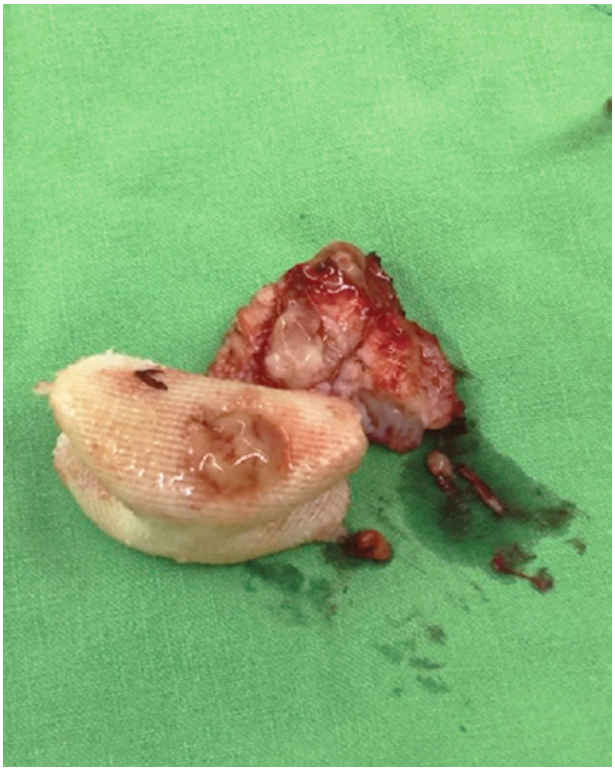

Fig. 4 A case with a foreign body reaction caused by the DIAM device. DIAM: Device for Intervertebral Assisted Motion.

found that most revision cases in our hospital received at least two DIAMs, which caused persistent back pain, lower leg numbness, and spinal instability leading to neural tube stenosis (Fig. 1). These cases usually required further revision surgery to remove the previous implanted DIAMs, fully decompress, and fuse with the implant.

Among the patients who received revision surgery, most of those with inadequate decompression received multiple DIAM implantations and visited our hospital due to neurological symptoms of the lower limb, such as back pain with leg sciatica (Fig. 2). The MRI results of these patients showed spinal stenosis and facet joint widening. However, it could not be determined whether the symptoms were caused by insufficient decompression during the operation or an unstable spine (multiple diameters). Besides, these kinds of revision surgery are not difficult to perform because adhesions are found only in lamina decompression, in the virgin site near the nerve root. As long as facetectomy is performed, adequate decompression can be achieved (Fig. 3).

The entire intervertebral process ligament should not be destroyed during DIAM implantation. Hence, it is suggested to make a tunnel at the bottom of the intervertebral process ligament near the dura, then implant the DIAM through the hole. In most revision cases in our hospital, the majority of the intervertebral process ligaments have been destroyed. Although fibrotic tissue growth is noted, it causes spinal instability.

Implantation of DIAM is not preferred in the L5-S1 space[2,16,19,20] as the spine process of S1 is too small to appropriately support the DIAM. In eleven of the revision surgery patients, DIAM was implanted in L5-S1, and obviously, instability was noted. Accordingly, in elderly patients with poor bone quality with osteoporosis, the spinal process is very fragile and cannot withstand the opening force of DIAM, so any accident can cause a fracture of the spinal process. Most patients in this study were older than 70 (N = 30) years, and 14 patients are aged over 80 years. These elderly patients with osteoporosis are relatively contraindicated for DIAM. As DIAM is a foreign body, it can cause infection. Long-term rubbing by the dura may cause granulomas and infection[21] (Fig. 4).

To prevent the complications mentioned above, DIAM implantation is inappropriate to patients with pars fracture cases, unstable spine, and multiple implants, and is prohibited for the L5-S1 site. Inappropriate indications, incomplete decompression, or instability after DIAM implantation will result in a failed surgery and require revision surgery.

This study has several limitations. First, it is a retrospective study with all the inherent limitations. Second, it is a single-center study with a limited sample size. Finally, the time interval between the initial and revision surgeries is uncertain because most patients received their first DIAM placement surgery in other hospitals.

Conclusions

The indications of DIAM are disc herniation, spinal stenosis, black disc disease, and fusion after ASD (topping off). The borderline indication includes stable degenerative spondylolisthesis (Grade 1) without osteoporotic cases. The contraindications of DIAM are the use of multiple interspinal process devices, inappropriate to pars fracture cases, unstable spine, and prohibited use for L5-S1 site.

Author Contributions

Shang-Won Yu: Conception and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; critical revision of the manuscript; final approval of the manuscript; guarantor of integrity of the entire study; definition of intellectual content; literature research; clinical studies; obtaining

funding; administrative, technical or material support. Yu-Hsien Kao: Conception and design; critical revision of the manuscript; final approval of the manuscript; guarantor of integrity of the entire study; supervision. Shih-Chieh Yang: Conception and design; analysis and interpretation of data; critical revision of the manuscript; final approval of the manuscript; guarantor of integrity of the entire study; statistical analysis. Ching-Hou Ma: Definition of intellectual content; literature research; administrative, technical or material support; supervision. Chin-Hsien Wu: Final approval of the manuscript; guarantor of integrity of the entire study; supervision. Yuan-Kun Tu: Definition of intellectual content; clinical studies; obtaining funding; administrative, technical or material support.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of E-Da Hospital (protocol code: EMRP-110-046 and date of approval: 2021/05/27).

Informed Consent Statement

Patient consent was waived due to a retrospective study design. It was approved by the Institutional Review Board of E-Da Hospital.

Data Availability Statement

The raw data can be available by request to the corresponding author.

Conflicts of Interest

The authors declare no conflict of interest.

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