Device for intervertebral assisted motion: technique and initial results

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Object. The DIAM is a polyester-encased silicone interspinous dynamic stabilization device that can unload the anterior column and reestablish the functional integrity of the posterior column.

Methods. The DIAM was implanted in 104 patients between May 1, 2001 and October 30, 2001. A retrospective evaluation was performed based on chart review and patient questionnaire at a median follow-up interval of 18.1 months.

There were no implant migrations, infections, or neurological injuries. Of the 20 patients who suffered adverse events, 13 underwent second lumbar spinal operations 0 to 19 months after the initial surgery (in seven the event occurred in a location other than the lumbar spine). The pain level as recorded by the physician showed improvement in 88.5%, no change in 9.6%, aggravation in 0%, and was indeterminate in 1.9%. The questionnaire revealed that at 18 months postoperatively, analgesic usage was decreased in 63.1%, increased in 12.3%, and unchanged in 24.6% of patients, and activities of daily living were improved in 46.2%, decreased in 30.8%, and unchanged in 23.1%. Specific outcomes measures for sitting, standing, physical activity, and psychosocial functioning revealed similar results.

Conclusions. The DIAM implant appears to be a useful and effective alternative in the surgical management of a wide range of lumbar disorders. Patient complications are few and satisfaction is high.

KEY WORDS • lumbar spondylosis • spinal stenosis • dynamic stabilization • neurosurgical implant • intervertebral assisted motion

THE LAST DECADE has seen considerable improvement in instrumented lumbar fusion, with the optimization of hardware and the introduction of minimally invasive techniques. Nevertheless, there remains considerable concern about the complications related to fusion procedures.^{1,3,15} Even with successful arthrodesis, a significant clinical failure rate persists.^{4,6,8}

The clinical uncertainty relating to instrumented lumbar fusion has led to the development of dynamic stabilization techniques. The DIAM implant was developed by the lead author (J.T.). It is a posterior interspinous dynamic stabilization or balancing device. The DIAM is thought to work by reducing loading of the disc, restoring the posterior tension band, realigning the facet joint line, and increasing foraminal height.

Clinical Material and Methods

The DIAM (Cousin-Biotech) is an X-shaped silicone wedge covered in polyester knit. Two securing polyester cords are attached to the wedge. The DIAM comes in four sizes: 8, 10, 12, and 14 mm.

The DIAM has been implanted at three French centers:

Abbreviations used in this paper: ADLs = activities of daily living.

by Dr. Taylor in Nice, Dr. Pupin in Harfleur, and Dr. Delajoux in Paris. In 104 patients a mean of 18 months of follow up was reached, and they are the subject of this retrospective analysis (26 are from Paris, 41 from Nice, and 37 from Harfleur). Employees of the Société TERE0 performed an independent data collection and analysis.

At the Société TERE0 a two-pronged retrospective study was designed. The first prong was to assess whether the DIAM modified the intensity of the pain felt by the patient. The second prong was to measure treatment success as noted by the physician and the patient. Data on adverse events were collected to assess the overall safety of the device.

The sex distribution was 49 (47.1%) women and 55 (52.9%) men. The mean age was 51.2 years, with a median of 50 years (range 25–86 years). The employment rate was 79%, with 25% of patients holding manual labor positions. In 84.6% of patients low-back pain was reported, and 83.7% had radicular pain. The predominant symptom was radicular in 40.4%, in the lower back in 23.1%, and the two symptoms were equal in 36.5%.

In all patients the procedures were performed between May 1, 2001, and October 30, 2001. The data were collected first from the physician medical record on a case report form completed by an employee of the TERE0 company, and second from a patient questionnaire. The

physician record was used to note all references to pain before and after implantation of the device. An independent examiner then categorized the responses into four groups: better, unchanged, worse, or indeterminate. The physician record was further used to extract demographic data, associated disorders, and preoperative, intraoperative, and postoperative clinical data. Adverse events were also recorded.

The patient collection tool was modified from the Dallas Pain Questionnaire, which is self-administered. The visual analog scales in the original self-administered Dallas Pain Questionnaire were modified to create verbal questions with three possible answers: better, worse, or unchanged (the modified Dallas Pain Questionnaire has not been independently verified). Eighteen months after surgery the patients were asked to apply this comparison to the period of time immediately before implantation and 6 months postimplantation. The mean change in pain at 18 months was assessed by asking about their current condition in comparison with their preoperative condition. Questions concerning ADLs were included. The patients were queried about any adverse events to confirm the physician record.

The collected data were entered into a customized database. Statistical analysis was descriptive. Categorical data were noted in percentages and the mean and the median were calculated for continuous data. Participation in the study had no effect on the course of the patient's treatment. The study database was approved by the Commission Nationale de l'Information et des Libertés (National Commission for Information and Freedoms).

Surgical Procedure

The patient is placed prone, as is standard for laminectomies. Fluoroscopic capability is helpful but not required. If a primary decompressive procedure is planned, it is necessary to preserve the spinous processes. There are two methods of implanting the DIAM; the first sacrifices the supraspinous and interspinous ligaments and the second preserves them. The implantation instruments are shown in Fig. 1, the technique is shown in Fig. 2, and selected postoperative imaging is shown in Fig. 3.

In the ligament-sacrificing procedure, after completion of any decompression needed, the supraspinous and interspinous ligaments are removed at the level for DIAM implantation. The interspinous space is then prepared by squaring it off with a rongeur. The space is then distracted and measuring trials are used to determine the size of the DIAM. The implant is inserted and seated with a tamp and mallet. The attached cords are then wrapped around the spinous processes above and below the DIAM implant, tightened, and then crimped. The wound is then irrigated and closed in the standard fashion. No postoperative immobilization is required.

In the ligament-sparing procedure, the supraspinous and interspinous ligaments are preserved during the decompression. The exposure can be unilateral or bilateral. A space is then created between the spinous processes with a Kerrison punch. The distractor is then placed and the space is sized. The appropriately sized DIAM is then folded and deposited. The DIAM cords are removed before insertion, because they are not necessary if the liga-

FIG. 1. Photograph of the DIAM surgical instrumentation. (Used with permission from Medtronic Sofamor Danek, Memphis, TN.)

ments are preserved. The area is then irrigated and closed in the standard fashion. No postoperative immobilization is required.

Results

The mean follow-up duration was 17.7 months, with a median of 18.1 months (range 14.6–20.6 months). Several underlying disorders were represented in the patient group: herniated disc (57.7%), disc disease (40.4%), osteoarthritic foraminal stenosis (35.6%), soft stenosis (5.8%), and bulging disc (1.9%). These rates exceed 100% because a patient could have more than one disease. The location of the diseased segments was as follows: L2–3 (7%), L3–4 (9%), L4–5 (57%), and L5–S1 (27%) (Table 1). Alignment or static issues were identified separately: spondylolisthesis (9.6%), retrospondylolisthesis (7.7%), hyperlordosis with kissing lamina (5.8%), kyphosing disc collapse (4.8%), degenerative scoliosis (3.5%), and facet dysfunction (1%). The location of the static problems was as follows: L1–2 (5%), L2–3 (5%), L3–4 (10%), L4–5 (45%), and L5–S1 (35%). Several patients had potentially aggravating factors: physically demanding work in 16.3%, obesity in 10.8%, and work-related injury in 9%.

The implantation of the DIAM was performed as an isolated procedure nine times (8.6%) and in association with other procedures 95 times (91.4%). The associated procedures were as follows: recalibration (24.1%), foraminotomy (19.3%), discectomy (15.1%), laminectomy and hemilaminectomy (11.4%), “topping off” a fusion (9%), arthroctomy (7.8%), laminoplasty (6%), facetectomy (3.6%), partial ligament excision (1.8%), neurolysis (1.2%), and complete disc curettage (0.6%). The topping off procedure (placing the DIAM above the level of an arthrodesis) was used in one-segment fusions in 73.3%,

FIG. 2. Intraoperative photographs showing insertion techniques. A: Interspace preparation. B: Spreading the interspace. C: Sizing the interspace. D: Folding the DIAM. E: Inserting the DIAM. F: Final position of the device. (Used with permission from Medtronic Sofamor Danek.)

two-segment fusions in 20%, and in three-segment fusions in 6.7% of patients.

The placement of the DIAM was at L1–2 in 1%, L2–3 in 5%, L3–4 in 18%, L4–5 in 62%, and L5–S1 in 14%. The sizes used were 8 mm in 21.4%, 10 mm in 26.8%, 12 mm in 28.6%, and 14 mm in 23.2%. The different sizes were used at all the various levels except at L1–2, where an 8-mm device was used; there was no relationship between position and size. No spine fractures occurred during implantation. Excessive bleeding was noted in 13.5% of cases, and there was one recognized dural tear that was repaired primarily.

The patients were seen for follow-up review and their pain levels were compared with preoperative findings. At the time of the initial follow-up visit, which averaged 66 days postoperatively, with a median interval of 44 days (range 0–213 days), the pain level, as recorded by the physician, was better in 88.5%, unchanged in 9.6%, worse in 0%, and indeterminate in 1.9%.

Twenty patients required another hospitalization after the index procedure. Their reason for repeated hospitalization, the time postoperatively, and the treatment given are noted in Table 2. There were no severe, permanent adverse events or deaths. Nonserious events were noted in 16 patients (15.4%); these phenomena ranged from anxiety to weight gain. Although there were 13 additional lumbar operations, only six represented therapeutic failures. A therapeutic failure was defined as a repeated operation at the original site of the DIAM implantation. Five of the six failures resulted in the implantation of a new

DIAM device. The sixth repeated operation was a laminoplasty with arthrectomy and foraminotomy.

Questionnaires were sent to all patients for whom we had current addresses. Seventy (67%) of 104 questionnaires were returned. The patients who failed to respond did not differ in physician-recorded clinical results from those who did respond. In the 6 months following the procedure, the use of pain medication was less in 50% of patients, more in 18.2%, and the same in 31.8%. At a median of 18.1 months postoperatively the use of pain medication was less in 63.1%, more in 12.3%, and the same in 24.6% (Fig. 4 upper). Persistence of pain was noted in 85.3% of patients at 18 months (back pain 78%, leg pain 72%). Complete pain relief was unusual, occurring only 14.7% of the time.

The change in pain was also analyzed according to ADLs. Difficulty with sitting in the first 6 months and at a median of 18.1 months postoperatively was less in 53.8 and 75%, more in 15.4 and 6.3%, and the same in 30.8 and 18.8% of patients, respectively. Difficulty with standing in the first 6 months and at a median of 18.1 months postoperatively was less in 56.1 and 66.2%, more in 15.2 and 7.7%, and the same in 28.8 and 26.2% of patients, respectively. Difficulty with sleeping in the first 6 months and at a median of 18.1 months postoperatively was less in 63.6 and 70.8%, more in 16.7 and 15.4%, and the same in 19.7 and 13.8% of patients, respectively.

The patients' psychosocial responses were also evaluated again at the same intervals. Difficulty with working due to pain in the first 6 months and at a median of 18.1

FIG. 3. Postoperative imaging of the implanted DIAM. A: Lateral x-ray film. B: Sagittal CT scan. C: Axial CT scan. D: Three-dimensional CT scan. E: Spine model illustrating the device in place. (Used with permission from Medtronic Sofamor Danek.)

months postoperatively was less in 50.8 and 62.7%, more in 20.3 and 16.9%, and the same in 28.8 and 20.3% of patients, respectively. Difficulty with pain affecting interpersonal relationships in the first 6 months and at a median of 18.1 months postoperatively was less in 43.8 and 53.1% and more in 15.6 and 6.3%, respectively, and it was the same in 40.6% of patients at both intervals. Need for others in the first 6 months and at a median of 18.1 months postoperatively was less in 30.3 and 51.6%, more in 33.3 and 12.5%, and the same in 36.4 and 35.9% of patients, respectively. Pain making others irritated, angry, or annoyed with the patient in the first 6 months and at a median of 18.1 months postoperatively was less in 33.3 and 46.6%, more in 11.7 and 10.3%, and the same in 55 and 43.1%, respectively. For ADLs in the first 6 months and at a median of 18.1 months postoperatively, there was less activity in 41.2 and 30.8%, more in 35.3 and 46.2%, and the same in 23.5 and 23.1% of patients, respectively (Fig. 4 lower). Physical activity beyond just ADLs in the first 6 months and at a median of 18.1 months postopera-

TABLE 1
Location of disease in 104 patients who received DIAM implants for dynamic stabilization*

Location	No. of Patients w/ Disease (%)				
	Herniated Disc	Disc Disease	Osteoarthritic Stenosis	Soft Stenosis	All Diseases
L2-3	6 (10.5)	1 (2)	3 (7)		10 (7)
L3-4		5 (11)	9 (22)		14 (9)
L4-5	38 (67)	21 (46)	22 (54)	5 (83)	86 (57)
L5			4 (10)		4 (3)
L5-S1	13 (22.5)	19 (41)	2 (5)	1 (17)	35 (23)
S1			1 (2)		1 (1)

* Some patients had more than one disease. The percentages denote the frequency of disease in the location compared with the number of locations for each disease.

tively was less in 33.3 and 22.2%, more in 34.9 and 54%, and the same in 31.7 and 23.8% of patients, respectively.

Satisfaction with the results of the surgery was also evaluated in the patient questionnaire. Pain relief was reported to have occurred in 83.8%, and pain relief did not occur in 16.2%. The apparent impression of pain relief was better than the results in response to the other more specific functional questions noted earlier. This is probably attributable to a psychological benefit of the DIAM. The impression of a benefit of surgery, or lack thereof, was compared between the physicians and the patients. The impression was found to have a positive concordance in 78%, a negative concordance in 9%, and it was discordant in 13%.

TABLE 2
Adverse events and treatment in 20 patients who were rehospitalized after receiving DIAM implants

Case No.	Adverse Event	Time after DIAM	Treatment
1	lumbar meningocele	7 days	new DIAM implant
2	bilat sciatica recurrence	7 days	replacement pedicle screws
3	hematoma w/drainage	9 days	scar revision
4	paraparesis of femoral nerves	21 days	laminectomy
5	lumbar meningocele	2 mos	new DIAM implant
6	cervicobrachial neuralgia	3 mos	anterior discectomy & fusion
7	recurrent herniated nucleus pulposus	4 mos	discectomy
8	carpal tunnel syndrome	5 mos	neurolysis
9	painful hallux valgus	5 mos	Petersen technique
10	herniated nucleus pulposus	5 mos	new DIAM implant
11	painful hallux valgus	7 mos	Petersen technique
12	thigh pain & paresthesia	7 mos	neurolysis
13	hip necrosis	7 mos	total hip arthroplasty
14	hip necrosis	8 mos	total hip arthroplasty
15	lt buttock pain	11 mos	laminectomy & foraminotomy
16	low-back pain & sciatica	12 mos	new DIAM implant
17	low-back pain & sciatica	12 mos	graft w/ spongy product
18	progressive low-back pain	16 mos	new DIAM implant
19	loosening hip prosthesis	18 mos	total hip replacement
20	rt low-back pain	19 mos	rhizolysis

FIG. 4. *Upper:* Bar graph showing medication usage in 104 patients who underwent DIAM implantation for lumbar disorders. *Lower:* Bar graph showing effects of the implant on ADLs in the same group of patients.

Discussion

Dissatisfaction with the results of fusion has led to the development of alternative treatments for degenerative spinal disease. One area for development has been posterior dynamic stabilization. Several devices have been designed for this purpose. The first published report of such a procedure, which was referred to as a ligamentoplasty, was by Senegas and colleagues.^{10,12} These practitioners used a ligament implant in patients with recurrent herniations of lumbar discs. The results were better with the implant than without. With the ligament implant, 80% of patients had elimination or improvement of back pain and 92.5% had elimination or improvement of leg pain. A second group of 32 patients with claudication evaluated by Senegas using the Lasalle questionnaire showed very good or good results in 88% of patients. Voydeville and Feldmann¹⁴ also looked at two methods of ligamentoplasty in patients with herniated discs or spinal stenosis. In their study, 87 patients were treated with a figure-eight suture and 107 were treated using an interspinous wedge. Pain relief did not differ between the two groups. Recurrence was significantly less ($p < 0.05$) in the group with spinal stenosis treated with an interspinous wedge, and it approached statistical significance in the group with herniated lumbar discs. In a similar system, the Wallis system, a floating flexible wedge that was not fixed to the surrounding bones or tissues was used.¹¹ The preliminary results were favorable.

Experimental support for intraspinal dynamic stabilization such as the DIAM system comes from the work of Minns and Walsh.⁹ They implanted silicone bumpers between the spinous processes in four cadaveric specimens. They tested them biomechanically in various degrees of

flexion and recorded the intradiscal pressures. They reported the following findings:

The implant, which is inserted between the spinous processes, causes substantial compressive forces to be transmitted through the neural arches and reduced intradiscal pressure. In four loaded cadaveric lumbar spines, the use of an implant reduced the intradiscal pressure at all angles of flexion.

The development of the current DIAM system capitalizes on these biomechanical results with a clinically available implant.

A second general method for treating disc degeneration was to create a dynamic posterior stabilization device based on pedicle screw instrumentation. Such a device is the Dynesys system.^{2,13} A series of 83 patients with instability and spinal stenosis, degenerative disc disease, or lumbar herniated nucleus pulposus was followed for a mean of 38 months. The visual analog scale scores fell for back pain (from 7.4 to 3.1) and for leg pain (from 6.9 to 2.4). The Oswestry Disability Index score fell from 55.4 to 22.9%. In a recent article by Grob et al.,⁵ at 2 years postoperatively in 50 consecutively treated patients, of whom 31 returned questionnaires, 52% reported results ranging from "helped a lot" to "helped." These investigators concluded that a substantial number of patients had significant residual back pain. Outcomes after treatment with a second pedicle screw-based system, the Graf system, were reported in 2003.⁷ In this study, 39 patients were followed for a mean of 7 years. These participants were noted to be a highly selected consecutive group with excellent to good results in 64.1%, fair results in 10.2%, worse results in 2.6%; and 23.1% reported no change. The results were better for leg pain than for back pain; 80 and 66.6% of patients with leg and back pain, respectively, reported complete disappearance of pain.

The understanding of the indications for placement of dynamic stabilization technology is in its infancy. In the current cohort of patients, the DIAM was implanted for a variety of indications, and these can be broadly classified into three groups. The first indication is for discogenic disease, either primary or recurrent, with or without discectomy. The second indication is for posterior disease resulting in central stenosis, foraminal stenosis, facet disease, or ligamentous instability leading to no more than a Grade I spondylolisthesis. The third indication is to protect from junction disease by implanting a DIAM above a fresh or existing lumbar fusion. The relative efficacy of the device in these various diseases was not analyzed, and this issue will need to be addressed in future studies.

In our retrospective study of the clinical results of implanting the DIAM prosthesis, several points can be made. The device and implantation procedure appear to be safe and well tolerated by the patients. There were 20 adverse events leading to second surgeries, and of these, 13 required repeated surgery in the lumbar spine. Five events required placing a new DIAM at either the same level (in two cases) or at a different one (in three). Five events involved pathological conditions unrelated to the spine. Three could be considered direct wound complications, including two pseudomeningoceles and one draining wound. The implant procedure itself was technically quite straightforward and should be easily mastered by spine surgeons.

The early clinical results are retrospective and are

affected by all of the associated issues. In particular, the patients were asked to compare their preoperative situation with their status in the 6 months following surgery as well as at a mean of 18.1 months postoperatively. Acknowledging the limitations in gathering the data, we still believed it was important to collect the early results because these would have some bearing on the efficacy of the technique, even if only in the broadest terms. In the majority of patients (85.3%) some pain persisted; however, there was improvement in sitting, standing, and sleeping, and in psychosocial parameters. The efficacy of the procedure was confirmed by the decrease in medication usage, which fell early in 50% of patients and, by the later time period, had improved to 63.1%. It was interesting to note that in all of these areas the improvement was greater at a mean of 18.1 months postoperatively than it was in the first 6 months.

The ADLs were actually decreased in 41.3% of patients in the first 6 months after the procedure, but at a mean of 18.1 months postoperatively the ADLs were increased in 46.2%, decreased in 30.8%, and the same in 23.1%. Physical activity also required time for improvement; it was almost equally better or worse in the first 6 months (34.9% better compared with 33.3% worse), but showing improvement by a mean of 18.1 months postoperatively (54% better compared with 22.2% worse). The perception of improvement was actually better than the actual improvement. We draw this conclusion based on the fact that satisfaction with the procedure was higher than the pain relief seen in the functionality questions. When asked whether the procedure resulted in pain relief, 83.8% answered in the affirmative and only 16.2% answered in the negative. This may represent the psychological benefit of the procedure, consistent with a placebo effect. The results for pain relief were compared between the doctor's record and the patient's questionnaire. There was a positive concordance in 78%, a negative concordance in 9%, and discordance in 13%. The doctor and the patient agreed about the benefit or lack thereof in 87% of cases.

Conclusions

The DIAM is a posterior dynamic stabilization construct that can be implanted safely in the setting of degenerative spinal disorders. There is a positive effect on pain control, medication usage, ADLs, and interpersonal relationships. Patients are generally satisfied with the results.

Disclosure

All authors are consultants for Medtronic Sofamor Danek, which owns distribution rights for the DIAM implant. Dr. Taylor has a direct financial interest in the device.

Acknowledgments

Research and consulting support was received from Cousin Biotech, Werwick-sud, Belgium and Medtronic Sofamor Danek, Memphis, Tennessee. Technical support was provided by Société TERE0, Loos, France.

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Submitted July 11, 2006.

Accepted November 20, 2006.

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