W. S. Zeegers
L. M. L. J. Bohnen
M. Laaper
M. J. A. Verhaegen

Artificial disc replacement with the modular type SB Charité III: 2-year results in 50 prospectively studied patients

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W. S. Zeegers · L. M. L. J. Bohnen
M. Laaper · M. J. A. Verhaegen
Department of Orthopaedics,
Maasland Hospital, Sittard,
The Netherlands

L. M. L. J. Bohnen (✉)
Oude Rijksweg Noord 30,
NL-6114 JE Susteren, The Netherlands

Abstract The Modular Type SB Charité disc prosthesis has been developed as a device for artificial disc replacement (ADR) in patients with symptomatic discopathies. Here, we report on our first series of 50 (out of 350) patients, who had a satisfactory clinical result in 70% of cases (2 years' follow-up). Subgroup analysis revealed that patients with an isolated discopathy without previous spinal operations or other pathology at the same or other spinal level benefitted more from the surgery. However, this technique was associated with some problems: a 13% rate of permanent side-effects and/or complications was observed caused by the anterior approach. Four percent were related to poor implantation

technique. There were no problems related to the material of the prosthesis. Twelve patients needed re-operation, but this was beneficial in only three of them. In one patient we had to convert to an interbody fusion. We conclude that in patients with severe isolated symptomatic discopathies that are resistant to conservative treatment, a mobile disc prosthesis is worth considering as a real alternative to a spondylodesis. However, accurate patient selection is imperative. With these criteria we were encouraged by our results to continue the implantation of this artificial disc.

Key words Lumbar spine · Discopathy · Disc prosthesis · Outcome · Complications

Introduction

Spinal fusion has been used as a treatment of chronic disabling low back pain not responding to conservative treatment. Results of spinal fusion, however, are often unpredictable [13,14]. Complications of spinal fusion, such as bone graft donor site pain, prolonged period of postoperative recuperation, pseudarthrosis, spinal stenosis, and spondylolysis acquisita have been reviewed by Lee et al. [13, 14]. In addition, Lee lists several complications that can affect adjacent unfused segments, such as disc herniation, accelerated degeneration, spinal stenosis, spondylolysis, facet joint arthritis, and instability. In this context, preservation of segmental mobility is perceived favourably [11]. Artificial disc replacement (ADR) has been devel-

oped as a technique to preserve segmental motion after surgical treatment of a symptomatic discopathy [11]. ADR has the advantage of reduced force on the adjacent segments, and facilitates postoperative mobilisation. Büttner-Janz et al. [2, 3, 5] evaluated several designs of ADR: The prosthesis with a metal ball of Fernström showed penetration of the metal ball into the vertebral body in most cases, which is due to the high local mechanical load at the contact areas. However, Fernström [9] found better clinical results in patients with this spherical endoprosthesis after evacuation of the disc than in those without this implant, at a follow-up of 0.5–2.5 years. MacKenzie [16] also used this technique in patients with disabling symptomatic discopathy and discal prolapse. He too reported encouraging clinical results at that time (1972), which also encouraged the consideration of artificial disc replacement.

Fig. 1 Anteroposterior view of Modular Type SB Charité III disc prosthesis at L4-L5, consisting of two cover plates (cobalt-chromium alloy), which are fixed without cement, as well as a moveable polyethylene sliding core between the plates

Fig. 2 Lateral view of Modular Type SB Charité III disc prosthesis at L4-L5. The choice of endplates is determined by the disc that is being replaced. Oblique models are used at L5-S1 and the plane-parallel are used at levels above L5-S1

Correction of decreased disc space height has been thought to be important, because diminished disc space height has been linked to several problems, including narrowing of the intervertebral foramen, change of kinetic centre, overload of facet joints, disturbance of the structures with hypermobility, and overload at insertions of ligaments [22, 23]. The design of the Link SB Charité disc prosthesis was based on the concepts of ADR developed by Büttner-Janz and Schellnack [2–5] and it has been tested clinically. Its development and composition have been extensively described by Büttner-Janz and Schellnack [2] and Griffith et al. [11]. The prosthesis underwent several major modifications in design (structure and manufacturing) from type I to type II and finally to type III (Figs. 1, 2), because of prosthetic failure (model and material problems) and subsidence in clinical use [2, 5]. There is paucity of published literature on clinical results with ADR. Therefore, we want to present our first experiences and preliminary results of our learning curve with a 2-year postoperative follow-up of our prospective study.

Materials and methods

Fifty patients with medically refractory lumbar discopathies underwent placement of a Modular Type SB Charité III disc prosthesis at the Maasland Hospital, Sittard (the Netherlands), between June 1989 and June 1991. All patients were operated by the main author. All patients were studied prospectively, and were evaluated after a postoperative period of 2 years. Four patients were lost to follow-up. The patients were interviewed and examined before operation and at regular periods afterwards. Other data were abstracted from the patients' case files and radiographs. Seventy-five disc prostheses were inserted in 50 patients. Of these, seven prostheses were placed at another level in patients already having received one or two disc prostheses. One prosthesis insertion was con-

verted into an interbody fusion because of malposition. Twenty-nine patients had a prosthesis inserted at one level, 18 at two levels, and 3 patients had three prostheses inserted (Table 1). The mean age at the operation was 43 years (24–59 years). Thirty women and 20 men were operated. Mean duration of history of low back complaints was 10 years (range 1–35 years).

Patients with predominant symptoms or deficits in the legs that could be related to involvement of the nerve roots were excluded. The radiographic features for each operated level were diverse: 40 discopathies (DP), 29 post-discectomy discopathies, and 6 discopathies with possible signs of disc protrusion at CT imaging but without any clinical radicular symptoms. All patients had failed conservative management. Twenty of 50 patients were involved in heavy physical labour. Fifty-four percent (27/50) of all patients had undergone previous surgery (Table 2). Special attention was paid to possible confounding factors, such as discitis, spondylolysis/spondylolisthesis, transitional vertebra, or conservative treatment of former disc herniation. We used standard anteroposterior (50/50), lateral (50/50) and flexion/extension radiographic views (40/50) often supported by CT (37/50), discography (36/50) and MRI (2/50). Special attention was paid to preoperative characteristics of degeneration at the same or other lumbar levels. According to our own criteria, we divided these into 'no', 'minor' or 'definite' characteristics of other lumbar degeneration (Table 3). We used criteria derived from those of Stauffer and Coventry [20] to assess the clinical response to surgery. The patients were classified as having a 'good', 'fair' or 'poor' clinical result, based on relief of pain, re-

Table 1 Operated levels of 50 patients^a

Level	n
L5-S1	8
L4-L5	16
L4-S1	12
L3-S1	3
L3-L4	5
L3-L5	5
L5-S1 + L3-L4	1

^aOne level with a prosthesis (in malposition) is not mentioned in this Table, because it had already been converted into an interbody fusion at the time of this follow-up study

Table 2 Previous lumbar surgery including the levels of a disc prosthesis ($n = 27/50$ patients, 54%)

Surgical procedure	No. of patients
Percutaneous microdiscectomy	11
Laminectomy and/or discectomy:	8
+ percutaneous microdiscectomy	1
+ chemonucleolysis	2
+ chemonucleolysis + percutaneous microdiscectomy	1
Spinal fusion:	2
+ percutaneous microdiscectomy	1
+ denervation of facet joint	1

Table 3 Criteria used for classification of preoperative lumbar degeneration apart from discopathies to be operated

<i>Group A:</i> No other characteristics of (lumbar) degeneration
<i>Group B:</i> Minor characteristics of other degeneration: (with a maximum of 3 of these)
B1 – Spondylosis: osteophytes, slight sclerosis or cysts
B2 – Segmental hyperflexion, hyperextension, or pinching
B3 – Shift > 3 mm during flexion and extension
B4 – Minor arthritis of facet joints
B5 – Herniation on CT (without radicular symptoms)
B6 – Minor narrowing of intervertebral foramen or disc space height of other level
<i>Group C:</i> Definite signs of other lumbar degeneration:
C1 – More than 3 group B characteristics
C2 – Evident degeneration of another disc
C3 – Evident degeneration of facet joints
C4 – Vacuum phenomenon

turn to employment, physical activities and consumption of analgesics. A good or fair result was defined as a positive clinical result. The assessment of the technical results was based on position and angulation of the prosthesis. The position of the prosthesis was assessed by normal AP and lateral radiographs. Attention was paid to the position of the prosthesis in the transversal intervertebral disc space (central, asymmetric, or malposition) and to the eventual angulation of the prosthesis to the neighbouring borders of the vertebral bodies (acceptable, borderline, or wrong). Technical results were classified into 'good', 'fair' or 'poor' according to our own criteria for position and angulation (Table 4). We used the method of Farfan to measure the disc space height [8].

Technique of operation

Griffith et al. [11] have described the technical surgical details of this disc prosthesis. The three-piece disc prosthesis consists of two cover plates of cobalt-chromium alloy, implanted without cement, as well as a moveable polyethylene sliding core between the plates (Figs. 1, 2). The size of the artificial disc is determined by the diameter of the endplates of the intervertebral body. Typically, the oblique models are used at the L5-S1 level and the plane-parallel models are used at levels above L5-S1. Each geometric configuration of artificial endplate is manufactured in three sizes. The anterior retroperitoneal approach was used as described for interbody fusion [17]. The size of the prosthesis is measured after cleaning of

Table 4 Criteria for classification of technical results

Good technical result

Central position: the centre of the prosthesis is located at a distance of less than 1/8 of the (anteroposterior and lateral) diameters from the centre of the disc space.

Angulation of endplates of the prosthesis is less than 15° to the transversal vertebral plane.

Fair technical results

Asymmetric position: position is not central, but the prosthesis is inside the side-lines of the disc space.

Angulation between plates of the prosthesis and the transversal vertebral plane is between 15° and 30°.

Poor technical result

The prosthesis is partially outside the side-lines of the disc space.

Angulation is more than 30°

Oversized prosthesis

The maximum diameter of the prosthesis exceeds the minimal diameter of the endplates of the vertebra.

Undersized prosthesis

In the sagittal or frontal plane, the diameter of the prosthesis is less than 2/3 of the vertebral body diameter.

the intervertebral space. The selected metal endplates are introduced by gently tapping on the introducer only. The polyethylene sliding core is placed between the plates after distraction of the bodies has been performed. The height of the core is dependent on the degree of distraction. Teeth in the coverplates and release of distraction prevent sliding during removal of the introducer.

Peri-operative and postoperative period

The patients receive peri-operative antibiotics and no urinary catheter. Oral fluid in the first days are dependent on abdominal recovery. Early mobilisation is encouraged without restriction directly after the operation. A supporting belt is optional.

Results

Clinical results

Seventy percent of the patients had a positive clinical result (32/46). Four patients were lost to follow-up, despite repeated summonses.

Factors in clinical outcome

There were no significant differences in clinical outcome for the following factors: Central versus asymmetric position of the prosthesis; one versus two prostheses in the same patient; pure discopathy versus post-discectomy discopathy; duration of history, less versus more than 5 years; and good versus fair technical result. Previous surgery no longer showed a difference in clinical outcome by 2 years after the operation, in contrast to 1 year postoperatively.

The following factors showed a non-significant tendency toward better outcome: Patients without previous surgery and without other lumbar degenerative characteristics or other possible (roentgenographic) pathology (our 'ideal candidate') demonstrated better clinical results (81% vs the others 66%). This difference was statistically significant at 1 year after surgery. Patients without complications did better than those with (82% vs 62%), and finally, patients without re-operations after a disc prosthesis did better than those with (79% vs 53%).

The following factor was associated with a statistically significant better outcome: Age under 45 years showed better clinical results. All factor significance was tested by Chi-square at the $P < 0.05$ level.

Reduction of pain

Sixty-five percent (30/46) showed improvement of low back pain. Four patients did not have preoperative leg pain. Sixty-four percent (27/42) reported improvement of leg pain at 2 years after surgery.

Return to work

All working activities at home and during leisure and employed labour time are included. Three patients did not work at all before surgery. In four patients no information is available about their work at the 2-year follow-up. Eighty-one percent returned to some work (35/43), and 43% returned to their original work.

Analgesics

Fifteen out of 34 patients were able to decrease their analgesic intake.

Patient satisfaction

Here, 83% (38/46) did not regret their surgery at all. The most frequent argument for regret was a disappointing clinical result (6/8).

Peri-operative and postoperative period

Generally, all patients underwent (supine) bedrest averaging 4 days (0–45 days) followed by a mean time to mobilisation of another 7 days (1–45 days). The total hospital stay averaged 10 days (3–90 days), according to the protocol of the period between June 1989 and June 1991. A supporting belt was provided to half of the patients for an average period of 12 weeks (0.5 week–1 year).

Technical results

Thirty-eight out of 50 patients had complete roentgenographic documentation 2 years postoperatively. According

to our own criteria (Table 4), 74% (28/38) showed a good technical result, and 24% (9/38) showed a fair positioning, although clinically well accepted. Two out of 50 patients showed a malpositioning by the surgeon. One of these 2 patients (who had a double prosthesis) needed a spondylodesis after removal of the malpositioned prosthesis. This finally resulted in a positive clinical result. The other patient with a malposition and some slip was lost to follow-up despite repeated summonses.

Eighteen percent of all prostheses showed an asymmetric position, that clinically could be accepted. The majority of implants were located fairly centrally. Two percent of all prostheses were positioned rather steeply, but all were less than 30° to the transversal plane. No endplates were oversized, but 23% were undersized.

According to the disc space height quotient of Farfan [8], 14% of all levels with a prosthesis showed a decrease in height ($> 25\%$), 2 years after surgery. There was no significant migration (> 2 mm) of the prostheses in our patients who attended the 2-year evaluation. Unfortunately, the above-mentioned patient with a malposition and some slip of the prosthesis did not attend follow-up. The range of motion of the prosthesis (ROM) between flexion and extension (on lateral radiographs) averaged 9° (range 2°–17°) 2 years postoperatively, which equalled the preoperative ROM, namely 9° (range 2°–20°).

Re-operations

Twelve patients (24%) out of the 50 patients needed re-operations. Seven re-operations were related to complications,

Table 5 Types of re-operation ($n = 24$) in 12 patients

Procedure	<i>n</i>
<i>A. Re-operations at the segment with a prosthesis</i>	6
Dorsal release:	4
+ ligamentoplasty (Graf)	(1)
+ arthrodesis of facet joints	(1)
+ lateral decompression + block of facet joints	(1)
+ facetectomy	(1)
Dorsal fusion after partial removal of facet joint, with prosthesis in situ	2
<i>B. Re-operations at other levels</i>	11
Percutaneous nucleotomy	2
Disc prosthesis	7
Discectomy	1
Dorsal release	1
<i>C. Re-operations related to complications (3 patients)</i>	7
Release of haematoma	2
Unsuccessful effort to reposition prosthesis	1 ^a
Conversion of prosthesis (malposition) into fusion	1 ^a
Vascular surgery (aorta)	3 ^a

^aSame patient

11 concerned other segments, while 6 reoperations were performed at the level of the disc prosthesis (Table 5).

All operations at the level of the prosthesis, apart from salvage of complications, were performed to improve pain control (Table 5 A). Pain control was also the indication for additional operative treatment at other levels (Table 5 B). Re-operation was beneficial in only three patients.

Re-operation for complications (seven, in only three patients) included release of haematoma (two times), with the others being in our first and only patient to undergo removal of the prosthesis, which resulted in severe difficulties (Table 5 C).

Complications and side-effects

We also paid attention to subjective complaints (pain, disturbances in sensation, cramps, etc. (Table 6). During this postoperative period, side-effects or complications at or after the first implantation operation were reported 52 times by 30 patients. Only 16% of these were permanent. Only 2/52 were clearly related to the implantation technique,

Table 6 Complications and side-effects 2 years after surgery, including re-operations

	Temporary (n = 44)	Permanent (n = 8)
<i>Neurological (n = 10)</i>		
Dysaesthesia of legs	4	3
Paresis/muscle weakness	1	–
Cramps in legs	2	–
<i>Wound, haematoma (n = 17)</i>		
Painful/numb scar	5	–
Haematoma	12	–
<i>Abdominal problems (n = 3)</i>		
Retroperitoneal haematoma	1	–
Visceral dysfunction	1	–
Abdominal pain	1	–
<i>New or progression of old pain (n = 5)</i>		
Low back or leg pain	5	–
<i>Vegetative dysfunctions (n = 8)</i>		
Sympathectomy effect	3	4
Disturbance of miction	1	–
<i>Vascular problems (n = 1)</i>		
Aortal lesion (at removal of prosthesis)	1	–
<i>General complications (n = 5)</i>		
Infection of urinary tract	4	–
Impotence, retrograde ejaculation	1	–
Deep venous thrombosis	1	–
<i>Prosthesis (n = 2)</i>		
Malposition of prosthesis	1	1

while there were no problems related to the material of the prosthesis itself.

Discussion

Clinical results

Enker et al. [7] tried to compare their clinical results using the Acroflex ADR with the series described by Büttner-Janz et al. [5], who used the SB Charité ADR and found 83% satisfactory clinical results at an average period of 15 months (max 3 years) after surgery. Enker et al. [7] pointed out that differences in age and surgical indications and a failure to differentiate the results of patients undergoing primary from those undergoing revision surgery did not allow a valid comparison between the two studies. A comparison of our results with the SB Charité type III ADR and the experiences of the multicentre study with the SB Charité types I, II and III ADR [11], shows similar improvements in back pain. Wittig et al. [23] described their experiences with the SB Charité type III ADR and found good or satisfactory clinical results in 77% of their patients at a follow-up of 3–18 months. In contrast to Cinotti et al. [6], we did not find a significant difference in clinical outcome depending on whether patients had received an ADR at one or at more segments. We showed that patients without previous surgery had better clinical results 1 year postoperatively, but that this difference faded away 1 year later. Similarly, no difference according to previous surgery was reported by Büttner-Janz et al. [5]. Our patients who had no previous surgery and no other degeneration or spinal disorder (apart from the symptomatic discopathy) – our ‘ideal candidates’ – showed a positive clinical result in 80% at 2-year follow-up. Total return to original working activities was rather limited (43% 2 years after the operation). Similar disappointing results were reported by Griffith et al. [11]. Fourteen patients had a poor clinical outcome 2 years after the operation. Other degenerative pathology at the same or other lumbar level was found in six of those 14 patients. Another patient became pain free after psychiatric treatment. So far, there is no satisfactory explanation for the poor outcome of the other patients. Cinotti et al. [6] reported better clinical outcome after ADR for patients with no previous back surgery. We can confirm this finding only at 1 year after surgery, and we should also note that in our series of 50 operated patients, 54% had undergone previous spinal surgery. A critical review of our good and poor clinical results makes clear how difficult it is to find the real origin of low back pain. We identified discopathy as a possible cause of their pain syndrome when a preoperative provocative discogram caused identical pain. Despite this selection, there remain some patients whose poor clinical results cannot be explained by complications or other pathology. This illustrates that reasons for low back pain can be ob-

score. It needs to be emphasized that chronic pain behaviour is also related to psychosocial factors. Psychosocial screening in this field will be absolutely necessary.

What, then, makes a patient a candidate for a disc prosthesis? Logically, this would be a patient with proven discogenic low back pain, without any other (organic or psychological) cause for their complaints. Therefore, we looked at our patients without any previous spinal surgery or other organic disease in the lower back, and we found good 2-year results in 80% of this selected subgroup of patients (called our 'ideal candidates').

Indications and contra-indications

Several indications and contra-indications for ADR have been previously reported, but are not unanimously accepted. An ADR is primarily designed for severe discopathies and directly related morbidity: disc degeneration [7, 11], postnucleotomy situations [5, 7, 11], isolated disc resorption [7], and lateral recess stenosis because of diminished disc height [7]. For disc degeneration at one or more levels, some authors [7, 22] point to the importance of ADR in case of juxtafusion degeneration. Wittig et al. [22] report that adjacent to a spondylodesis, increased damage can be expected because of loss of function of the fused spine. A mobile prosthesis at the adjacent level, instead of an extra fused level of an adjacent discopathy, can be a solution for additional detrimental stresses on other levels. In contrast, others [10, 12] do not confirm these ideas in their studies on spinal fusion. For painful back syndromes after discectomy we agree with Enker et al. [7], that these theoretically can be good indications, provided that there is no recurrent disc herniation, no instability and no damaged posterior elements. Lateral recess stenosis due to disc degeneration and loss of disc space height might respond to disc space height restoration by ADR but should be considered a *relative indication* [7]. Enker et al. [7] point to the potential importance of the condition of the posterior elements in assessing results of a disc prosthesis, because the posterior elements play a role not only in a (partly) load-carrying capacity and in resisting shear forces, but the facet joints also play a role in the kinematic functioning of the motion segment. Enker et al. therefore, suggest that ADR could be indicated in the face of intact posterior elements, to allow the ADR to serve as a load-sharing device in concert with the posterior elements [7].

There are more definite *contra-indications*, including spondylolisthesis, spinal stenosis, altered posterior elements, infection, metabolic bone diseases like osteoporosis and osteomalacia, severe scarring after previous surgery and insufficient motivation of the patient. Spondylolisthesis should be a contra-indication because of the risk of dislocation [11]. In spinal stenosis, the encroachment will not be released by ADR. Altered posterior elements, like

prior decompressive laminectomy, prior posterior fusion efforts [22] or degenerative facet joints [3, 22] are also reported as contra-indicative. We think that here, a fusion in the long run will provide more stability than an ADR with the possibilities of slip or wear. Previous and latent infections have also been mentioned as contra-indications [3, 22]. Several authors [3, 11, 22] have concluded that ADR should be avoided in metabolic bone diseases such as osteoporosis and osteomalacia, because of subsidence. Wittig et al. [23] add severe scarring (at the same or other level) after spinal surgery to the list of contra-indications, because in their experience this problem is not solved by the distraction provided by the prosthesis. Some authors also report insufficient compliance or motivation of the patient [3, 22].

Segmental mobility by ADR

Our series shows maintenance of segmental mobility in patients with ADR. This was also shown in other clinical studies [6, 15], as well as in a cadaver study with this prosthesis [1].

Size and position of the prosthesis

From a mechanical point of view, the prosthesis as a load-bearing device should be placed centrally in the intervertebral disc space. Wittig et al. [23] describe that the centre of the implanted prosthesis did not exactly coincide with the natural axes for sagittal movements. However, like Büttner-Janz et al. [4], they did not find a relationship between the horizontal position and postoperative consequences. Similarly, we did not find significant differences in clinical results between centrally and asymmetrically located prostheses. Wittig et al. [23] focus on the problematic cranio-caudad tilt of the prosthesis, because this not only can diminish the range of motion but also, unfortunately, can relocate more compression forces from the weight-bearing disc prosthesis to the facet joints. Further kinematic studies will be needed to address this anticipated detrimental effect on motion and load sharing.

Complications and re-operations

We reported several complications. Some of them have been reported before. We had complications both due to the operation and to poor implantation technique. Büttner-Janz et al. [5] mentioned a low number of general complications, as did Griffith et al. [11] in 1994, related to the anterior surgical approach.

Two of our patients required evacuation of an anterior abdominal wall haematoma. Frymoyer [10] mentions a 1–2% chance of sexual impotence in male patients by us-

ing the anterior approach for the two lower levels, particularly the L5-S1 level. We had one patient with temporary sexual problems (retrograde ejaculation). We did not encounter any infections of the prosthesis in our series. We observed complications due to poor implantation technique in only two patients. Büttner-Janz et al. [5] mentioned 10 times intracorporal migration and 2 times ventral dislocation in 67 endoprostheses. They state [2, 4, 5] that migration or slipping can probably be reduced by using the largest area of contact between the endplates and the prosthesis. Apart from a doubtful difference in position (< 2 mm) in the transversal plane, no significant migration in this plane or slip could be seen in our patients who attended the 2-year follow-up. Some of the complication-related re-operations will be due to a learning curve that every physician will go through when learning a new technique [11]. The rate of complications caused directly by the implantation of the disc prosthesis was, according to Griffith [11], 6.5% of the patients (4.3% of all prostheses implanted). This compares to 4% in our series (due to malpositioning, but not due to the material). From our first and only patient with revision of the prosthesis in this series we learned about its difficulties and dangers (Table 5C).

Comparing complications of a disc prosthesis and those of an anterior interbody fusion is very difficult. Despite the same surgical approach, specific complications and re-operations are associated with each type of implant, like dislocation of the prosthesis or complications of spinal fusion (outlined in the Introduction). Studies differ not only in indications, patient selection and follow-up, but also in the assessment of side-effects or complications. Some studies mention postoperative transient hypotonic ileus, but do not count it as a significant complication [20, 21]. This also can be the case for bladder dysfunction [21]. We did pay attention to these minor problems, including altered

sensation or muscle strength, scarring, haematomas, vegetative changes and abdominal problems. In this way, we found that 15% of our patients had side-effects or complications of a more permanent character. Interbody fusion studies have reported complication rates of 6–25% of their patients [17, 19–21], while permanent problems are reported here as 0–25% [17, 19, 20]. Twenty-four percent of our patients were reoperated: 29% (7/24) for complications, and the rest for improving pain control. Anterior interbody studies have shown reoperation rates of 6–20%, with 12–100% of these being performed for complications or non-unions [19–21]. The only effort for revision in our present study resulted in damage to the large vessels. Vascular damage to the large vessels is also reported in 1–4% in some studies of anterior interbody spondylodesis [17, 21], while other studies did not report this problem [19, 20]. Larger studies with a much longer follow-up are needed to learn the true indications for ADR. In this limited group of 50 patients with severe low back pain, of whom 54% had undergone previous failed spinal surgery, we report satisfactory clinical results (70%). From our total population of more than 350 operated patients with a disc prosthesis, this study concerns only our first 50 successive patients. It is important to realise that this study includes our learning curve for technique, criteria and patient selection. Therefore, we need a long-term follow-up of a larger group of patients with optimal (radiographic and psychological) selection criteria. Finally, important questions like migration, collapse, kinematics and wear of the prosthesis can only be studied satisfactorily in a long-term follow-up study.

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