

Complications of Artificial Disc Replacement

A Report of 27 Patients with the SB Charité Disc

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Summary: Disc prosthesis surgery is rapidly becoming an option in treating patients with symptomatic degenerative disc disease. Only short-term and midterm results are described in the literature. Most operated patients belong to the age group of 30–50 years. In these active patients, complications can be expected to increase with longer follow-up, similar to total joint replacements in the extremities. Reported here is a series of 27 patients from another institution, who presented with unsatisfactory results or complications after SB Charité disc replacement. The objective of this work was to describe the possible short- and long-term unsatisfactory results of disc prosthesis surgery. Twenty-seven patients were seen in a tertiary university referral center with persisting back and leg complaints after having received a Charité disc prosthesis. All patients were operated on in a neighboring hospital. Most patients were operated on at the L4–L5 and /or the L5–S1 vertebral levels. The patients were evaluated with plain radiography, some with flexion-extension x-rays, and most of them with computed tomography scans. The group consisted of 15 women and 12 men. Their mean age was 40 years (range 30–67 years) at the time of operation. The patients presented to us a mean of 53 months (range 11–127 months) following disc replacement surgery. In two patients, an early removal of a prosthesis was required and in two patients a late removal. In 11 patients, a second spinal reconstructive salvage procedure was performed. Mean follow-up for 26 patients with mid- and long-term evaluation was 91 months (range 15–157 months). Early complications were the following: In one patient, an anterior luxation of the prosthesis after 1 week necessitated removal and cage insertion, which failed to unite. In another patient with prostheses at L4–L5 and L5–S1, the prosthesis at L5–S1 dislocated anteriorly after 3 months and was removed after 12 months. Abdominal wall hematoma occurred in four cases. Retrograde ejaculation with loss of libido was seen in one case and erection weakness in another case. A temporary benefit was experienced by 12 patients, while 14 patients reported no benefit at all. Main causes of persistent complaints were degeneration at another level in 14, subsidence of the prosthesis in 16, and facet joint arthrosis in 11. A combination of pathologies was often present. Slow anterior migration was present in two cases, with compression on the iliac vessels in one case. Polyethylene wear was obvious in one patient 12 years after operation. In eight cases, posterior fusion with pedicle screws was required. In two cases, the prosthesis was removed and the segment was circumferentially fused. These procedures resulted in suboptimal long-term results. In this relatively small group of patients operated on with a Charité disc prosthesis, most problems arose from degeneration of other lumbar discs, facet joint arthrosis at the same or other levels, and subsidence of the prosthesis. It is to be expected that many more patients will be seen with late problems some years after this operation as the survivorship will decrease with time. **Key Words:** disc replacement, SB Charité disc prosthesis, degenerative disc disease, artificial disc replacement, complications.

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INTRODUCTION

An intervertebral disc prosthesis is intended to restore normal function of a spinal motion segment by replacing a degenerated intervertebral disc in the lower lumbar or

cervical spine. The stability of the operated segment must be maintained or improved by the method. Theoretically, this procedure has many advantages over spinal fusion. In spinal fusion, motion is eliminated and overload of neighboring discs causing early degeneration is often seen, although usually appearing only after 10–15 years.^{1–5} Moreover, this adjacent segment degeneration also depends on the extent of the fusion.

In agreement with Hedman et al,⁶ a disc prosthesis with articulating properties should have the following features:

It should have long endurance and should preferably last for the rest of the life of the recipient. This is due to the specific risks of the anterior surgical approach being much greater in revisions due to scarring. Since the great vessels are located anterior to the discs at levels above L5–S1 and the bifurcation of the aorta and vena cava mostly lies directly superior to the L5–S1 disc, vascular complications are the most feared. They have been reported in several studies concerning anterior lumbar surgery.^{7–9} In males, the neural prevertebral plexus is at risk. If injured, retrograde ejaculation, loss of libido, and even impotence can result.¹⁰ Damage to the ureter has also been described.¹¹

The materials of which the prosthesis is composed are of critical importance to prevent premature disintegration. Otherwise, revision or removal of the prosthesis is the consequence. Since patients with disc degeneration as an indication for a disc prosthesis implantation are relatively young (under 50 years, osteoporosis is a contra-indication), the life span of the prosthesis should be approximately 40 years. This precludes, as Hedman et al stated, the use of high molecular weight polyethylene.

The prosthesis should generate a normal or near-normal movement compared with the pattern of the sound spinal motion segment. In the lumbar spine, the range of motion is highest for flexion-extension, with a center of rotation located in the posterior part of the disc, according to White and Panjabi.¹² Besides, there is some lateroflexion and axial rotation. In the case of a disc prosthesis, the center of rotation should be located posteriorly too, with a simultaneous constraint for axial rotation. If not, overloading of the corresponding facet joints and degeneration of these joints will result.

The fixation of the prosthesis to the bone of the vertebral body is very important. Immediate as well as long-term fixation is desired to prevent migration or subsidence. The central part of the endplate is generally too weak to support the prosthesis. Subsidence and loosening can be the result. Consequently, the prosthesis should be placed on the rim of the endplate without intrusion of the spinal canal or compression of exiting nerve roots or

great vessels. Screw fixation may be sufficient for the first weeks but can be expected to toggle loose. Pegs and spikes may be adequate only for the short term, because they fail under tensile loading. Porous coated and macrot textured surfaces could attain better primary stability and allow direct ingrowth of bone into these surfaces, but in the spine, there is little knowledge about this phenomenon.^{13,14}

Given these prerequisites, it appears almost impossible to manufacture a disc prosthesis that possesses all these characteristics. Consequently, many designs have been proposed with frequent “improvements,” as was recently described by Szpalski et al.¹⁵ The SB Charité III disc prosthesis (Waldemar Link GMBH & Co., Hamburg, Germany) has been used clinically for at least 20 years. The Prodisc prosthesis (Aesculap AG & Co., Tuttlingen, Germany) has a follow-up of 7–11 years in the first operated group of patients.¹⁶ Long-term follow-up (10–20 years) should now become available but has not yet been published in peer-reviewed literature.

We report on 27 patients seen at the University Hospital Maastricht, the Netherlands, a tertiary university referral center for spine patients. All patients except one belonged to a series of approximately 500 patients operated on at a single institution in the Netherlands.

MATERIAL AND METHODS

In the last 8 years, from 1995 up till now, 27 patients with persisting back and leg problems, with a history of implantation of an SB Charité disc prosthesis of the lower lumbar spine, were seen at our outpatient department. Fifteen patients were female with an average age at the time of the index operation of 41 years (31–67 years), and 12 patients were male with an average age of 38 years (30–47 years). The mean interval from surgery to presentation in our clinic was 53 months (11–127 months). For 26 patients with the prosthesis in situ for a relatively long period, the mean follow-up was 91 months (15–157 months). Most patients had the prosthesis inserted in a single level: 14 at level L4–L5, 6 at L5–S1, 1 at L2–L3, and 1 at L3–L4. Four patients received a disc prosthesis at both levels L4–L5 and L5–S1 and one patient even at three levels (L3–L4, L4–L5, L5–S1). In three patients, the disc prosthesis implantation at L4–L5 was preceded by an anterior fusion of L5–S1. Preceding the disc replacement, a percutaneous nucleotomy of the same level was performed in another three patients and a posterior undercutting facetectomy in two patients. One patient had herniated disc surgery performed before the disc prosthesis insertion.

We lack information concerning the pain level and

functional status prior to the disc replacement, but all patients told us that they preoperatively suffered serious and constant back pain and leg pain for considerable time periods. All preoperative x-ray films were collected and showed degenerative discs in all cases. These were confirmed to be painful at preoperative discography in all patients.

RESULTS

In Table 1, the data on the 27 patients are summarized. The table is constructed according to the year of operation.

A good initial result of the operation was reported by 12 patients, ranging from 1 month to 10 years. No benefit at all was experienced by 14 patients.

Early Complications

The following early complications were stated by the patients: In one patient (case 18), the prosthesis at L5–S1 dislocated anteriorly within 1 week postoperatively. It had subsequently been replaced by a carbon-fiber cage, filled with bone. She visited our outpatient clinic 2 years later with persistent disabling back pain, which was caused by a nonunion at this level and disc degeneration at one level higher. Despite a posterior pedicle screw instrumented arthrodesis at L4–S1, she continued to experience pain. In case 6, the prosthesis at L5–S1 dislocated anteriorly after 3 months. The prosthesis was removed after 12 months. The L4–L5 prosthesis remained in situ. Other early complications were abdominal wall or retroperitoneal hematomas in four patients, in one male patient retrograde ejaculation, libido loss, and erectile dysfunction, and in another man erectile dysfunction without retrograde ejaculation.

Late Complications

Case 18 is obviously not included in the late results series, so 26 patients remain in this group. The clinical picture of most of the patients was of a very disabling nature. They complained of incapacitating back and leg pain, which was most severe during sitting, standing, and at night. Turning in bed at night especially provoked much pain, disturbing sleep severely. Typically, walking was the least disturbed. Physical examination nearly always showed very restricted and painful flexion-extension movements but less disturbed lateroflexion and rotation movements. In a few patients, however, hardly any limitation of the spine movements was noted. X-ray investigation and, in most patients, computed tomography (CT) scanning has been performed to determine the problems related to the disc prosthesis and to find the source of the

persistent pain. Usually, we did not order flexion-extension radiographs because of the very small clinical excursions and severe pain caused by motion in the majority. In a few patients, we ordered magnetic resonance imaging (MRI) investigations to assess the quality of the adjacent discs. In almost every patient, abnormalities were seen on x-ray and/or CT scan and/or MRI investigation, which were thought to be related to the complaints.

Degenerative disc disease at another level, already obvious on the x-ray films before the operation or developed after the operation, was seen in 12 patients. In seven patients, it was clear that before the disc prosthesis surgery, nonoperated adjacent levels were also degenerated but were apparently judged to be nonsymptomatic by the primary surgeon after a discography. On these discograms, which all patients had before the operation, several of them had a multilevel disc disease; inconsequently, not all degenerated levels were operated (Fig. 1). We also saw seven patients with one- or two-level disc degeneration, who developed adjacent-level degeneration at previously sound levels after disc prosthesis surgery, probably giving rise to new symptoms. In one patient (case 7), initially satisfied because of 8 years of pain relief, the level of the prosthesis fused spontaneously and subsequently new symptoms developed, probably due to disc degeneration two levels higher (Fig. 2).

Facet joint arthrosis, whether at the same level as the disc prosthesis or at a neighboring level, was definitely seen in 11 patients. The arthrosis could be well visualized on CT scan examination. Some patients had a grinding sensation in their back on flexion-extension movements. Especially, extension was painful. In our center, we performed eight times a posterior instrumented fusion. In all these patients, a hypertrophic facet joint arthrosis was present, sometimes reaching huge dimensions (Fig. 3C). It could not be discerned whether this arthrosis was already present before the operation, but it is the opinion of the operating author that the arthrosis was related to a very abnormal movement pattern of the segment with the disc prosthesis. In a few patients, adjacent levels were also affected by facet joint arthrosis. Often, the facet joint arthrosis was present in subsided prostheses (Figs. 3A–C), but also in patients with nonsubsided prostheses in good position, this arthrosis was recognized.

Subsidence of the prosthesis was present in 18 patients and was supposed to be a main source of persistent complaints. The subsidence took place in different regions of the vertebral body and showed varying severity. It was judged from the plain x-rays and CT scans that the prosthesis was definitely too small in 10 cases and of adequate width and depth in 8. The subsidence could be in the anterior, posterior, or lateral part of the vertebral body. Despite this subsidence of one or both metallic plates, the

TABLE 1.

No.	Name	Sex	Age	Operation	Previous operations	Level of disc prosthesis	Duration of pain relief	Early complications
1	J.P.	M	44	1989		L4-5	1 year	Haematoma abdominal wall
2	M. S-U	F	42	1989	Anterior fusion L5-S1 1984	L4-5	No pain relief	Haematoma abdomen
3	C.W.	M	44	1990 2x 1991	Percutaneous nucleotomy L4-5 and L3-4	L4-5/L5-S1/L3-4	No pain relief	
4	E. a.d. B	F	39	1991		L4-5	10 years almost total pain relief	
5	A. B-H	F	36	1991	Percutaneous nucleotomy L3-4 1991	L3-4	No pain relief	
6	A. L-O	F	39	1992	HNP OK 2x 1963	L4-5/L5-S1	2-3 years after last operation somewhat less pain, also less activity.	
7	B.B.	M	39	1992	Anterior fusion L5-S1 1961	L5-5	8 years good pain relief	
8	A.K.	M	37	1992		L4-5	8 years	
9	J.F	M	33	1992		L4-5; L5-S1 intra operatively not possible due to abnormal great vessels.	No relief of pain	Retrograde ejaculation, loss of libido and erectile function. Hypoaesthesia scrotum and groin. Abdominal herniation operated 1993
10	J.v.O	M	41	1993	Posterior release 2x 1990	L4-5/L5-S1	Some relief of pain for 9 years; was bedridden before operation	
11	S.G.	F	44	1993		L2-3 (4 lumbar vertebrae)	No pain relief	asymmetrical insertion
12	J.S.	M	42	1995	Anterior fusion L5-S1 1963	L4-5	1½ year good pain relief	Haematoma abdominal wall and retroperitoneally
13	H.T-v. B	F	39	1995		L5-S1	No pain relief. More pain after operation	

TABLE 1.

Late complications	Re-operation	Neighboring levels degenerative		CT or MRI scan or discography	Clinical symptoms at F-U
		Preoperatively	Postoperatively		
Lateral subsidence		uncertain	3 levels above prosthesis degenerative scoliosis T12-L4 10°	CT facetdegeneration L5-S1	Continuous backpain and leg weakness
Subsidence; presumed wear prosthesis				CT cysts, sclerosis and fragmentation of bone around prosthesis	Continuous backpain and right legpain
Lateral subsidence L4-5/L5-S1. Gross subsidence L3-4	Dorsal release and facetectomy 1992. Posterior fusion L4-5-S1 1996			Not performed	Continuous pain in back and both legs. Weak left leg
Slow anterior migration Pressure on great vessels	Removal of prosthesis. Anterior + posterior fusion L4-5 2002			CT anterior migration. Pressure on great vessels	Backpain and pain right leg After reoperation 2002 almost total pain relief
Subsidence	Posterior fusion L3-4 after percutaneous fixation 2000			Not performed	After fusion 50% less backpain and left leg pain. Also bad functioning left total knee prosthesis
Dislocation of prosthesis L5-S1. Removal and fusion L5-S1; Anterior position of nucleus and some subsidence L4-5. Spontaneous fusion L4-5. Disc degeneration L2-3	Removal dislocated prosthesis; fusion L5-S1 1993. Posterior release 1993		Some degeneration levels L2-3 and L3-4.		Continuous back and right leg pain.
Gross subsidence; kyphotic posture	Posterior fusion L4-5 2001		T12-L1 L1-2 possibly also L3-4	MRI: degeneration L2-3 with bulging. No HNP	Lumbar pain + right leg pain After fusion persistent kyphotic posture and S1 joint pain.
Prosthesis laterally positioned, too small. Subsidence laterally	Refuses fusion L4-5-S1.	L5-S1	Severe degeneration L5-S1		Continuous pain in back and both legs and tingling.
Some subsidence L4-5>L5-S1			Slight degeneration L3-4	Discography L3-4 and L2-3 normal	Continuous pain in back and left leg with tingling.
Gross subsidence disc prosthesis. Severe disc degeneration L3-4 and L4-S1	Posterior fusion with pedicle screw system L3-4 1997. On waiting list for fusion L2-S1.	T10-11 T11-12 L3-4	L4-S1 T10-11 T11-12		Continuous pain in back and left leg.
Anterior subluxation polyethylene core; segment L4-5 fixed in lordosis.	Posterior fusion L4-5 1997. Facet joint degeneration.		L2-3		After fusion 1997 good diminution of symptoms. Relapse of symptoms 2000. Disc degeneration L2-3.
Slight subsidence L5 plate. Breakage of the metal wire around polyethylene core				CT uncertain facetartrosis L5-S1. No reaction on facetjoint injections.	Almost continuous backpain and both legs with tingling.

TABLE 1. Continued

No.	Name	Sex	Age	Operation	Previous operations	Level of disc prosthesis	Duration of pain relief	Early complications
14	G.d.K-S	F	33	1995		L4-5	1 month some pain relief	
15	J.v.d. H-K	F	41	1995		L4-5	No pain relief	
16	T.L-J	F	42	1995		L4-5 L5-S1	No pain relief	
17	H.N.	F	67	1996		L5-S1	No pain relief, Leg pain more severe after operation.	Abdominal haemaloma
18	N.B-v. E	F	31	1996		L5-S1	Not applicable	Anterior luxation of the prosthesis
19	M.v G-B	F	34	1997		L5-S1	8 weeks	
20	G.D.	M	38	1997		L4-5	No pain relief. Worsening of complaints	
21	P.E.	M	30	1997		L5-S1	8 months	
22	H.N.	M	38	1998		L4-5	4 years partial pain relief	Erection Weakness Coldness left leg
23	C.P.	F	48	1999	HNP 2 x 1995-1996	L4-5 L5-S1	2 months	

TABLE 1. Continued

Late complications	Re-operation	Neighboring levels degenerative		CT or MRI scan or discography	Clinical symptoms at F-U
		Pre-operatively	Postoperatively		
Subsidence; facetjoint artrosis L4-5/L5-S1	Posterior release 1997. Posterior fusion L4-5-S1 1998. Refusion with removal of osteosynthesis 1999.			1997 CT scan Facetjoint artrosis L4-5	After refusion persistent backpain and right leg pain
Subsidence; degeneration L3-4 and L5-S1	Posterior fusion refused.	Probably facetjoint artrosis L5-S1	Severe facetjoint artrosis L4-L5, L5-S1. Less severe facetjoint artrosis L3-4 + some spinal stenosis.	Facetjoint artrosis 3 levels on CT scan, some spinal stenosis on CT-myelogram at L3-4	Continuous backpain and both legs; crepitations in the back. Alcohol addiction
Slow anterior and lateral migration prosthesis L4-5. Severe degeneration L3-4	Posterior release L5-S1 1996. Posterior fusion L2-S1 recently performed.		Severe degeneration L3-4 with lateral shift and rotation	CT facetjoint artrosis L3-4 L4-5 and L5-S1 MRI black disc L2-3, degenerated disc L3-4.	Continuous pain in back and right leg and tingling.
Subsidence	Posterior release 1997 Removal of prosthesis after 1 week; Insertion of a Brantigan cage.	All other lumbar segments. L3-4 L4-5	All other lumbar segments L3-4 L4-5	MRI 1997 degeneration L3-4/L4-5. Discography L3-4 not painful with slight degeneration. L4-5 painful.	Continuous back- and legpain, less with walking. After posterior pedicle screw fixation and fusion L4-S1 complaints only by more strenuous activity (6-4-2000). Recently pseudartrosis operation L4-5.
Facetjoint artrosis; some subsidence	Posterior release L5-S1 1998. Posterior fusion L5-S1, 2002			CT facetjoint artrosis confirmed at operation	Before reoperation 2002 almost continuous back and left legpain
Subsidence; prosthesis too small. Almost spontaneous fusion.				CT scan: No obvious facetartrosis. No motion on flexion/extension X-rays.	Continuous backpain and cold right foot.
Slight subsidence; oblique insertion, facet joint artrosis	Posterior fusion L5-S1 2001. Removal of screws due to sterile effusion 2002. Pseudartrosis of fusion L5-S1.			CT before fusion facetjoint artrosis, confirmed at operation.	After last operation backpain after more strenuous activity. Jehovah's witness.
some subsidence; hyperlordosis operated segment				CT myelography no herniated disc or spinal stenosis	Persistent upper legpain 80% reduction of backpain
Breakage of metal wire around polyethylene core L4-5, L5-S1. Diminution of height of the polyethylene core.	Posterior release L4-5, L5-S1, 3 months after disc prosthesis operation. Prosthesis L4-5 repositioned more anterior.		L2-3 L3-4 some disc degeneration.	CT 2002 facets L4-5/L5-S1 without obvious artrosis. Extensive laminectomy L4-5. Discography degeneration + pain L3-4.	Continuous back and left legpain with hypoesthesia left leg.

TABLE 1. Continued

No.	Name	Sex	Age	Operation	Previous operations	Level of disc prosthesis	Duration of pain relief	Early complications
24	L.H.	M	41	1999		L5-S1	No relief	
25	J.T.	M	40	2000	Percutaneous nucleotomy L4-5 1992 Posterior release L4-5 1994	L4-5	Some relief 8 months	
26	J.W-S	F	42	2000		L4-5	No pain relief. More pain than before operation.	
27	Z. H-S	F	45	2001		L4-5	8 months some pain relief	

polyethylene core was radiographically never dislocated out of the metal plates.

In one patient (case 12), the polyethylene core was subluxated anteriorly, and this L4–L5 segment above a formerly fused L5–S1 segment was blocked in extension; nevertheless, the metallic plates remained in perfect position. A posterior fusion was performed with an initially good result, but new complaints were noted 4 years later, thought to be due to a new degeneration of the disc at L2–L3.

In two patients, a slow anterior migration of the disc prosthesis at L4–L5 had been seen, which resulted in compression on the great vessels in one patient (case 4; Fig. 4). This patient was satisfied for almost 10 years and then began to experience pain again. The prosthesis was removed and proved to be loose in fibrotic tissue and adherent to the great vessels. It did not show macroscopic signs of wear. The resulting big defect between and within the vertebral bodies was reconstructed by us with a large tricortical iliac crest graft. Subsequently, a posterior pedicle screw instrumentation and fusion were performed. A pronounced arthrosis of the facet joints was present. With a follow-up of 7 months, the fusion is well healed and the patient is momentarily satisfied. In the other patient, a posterior fusion was recently performed (case 16; Fig. 1).

In one patient (case 2) with the prosthesis in situ for >13

years, the prosthesis at L4–L5 above a previous L5–S1 fusion shows radiologic signs of wear. The prosthesis is subsided into L4, surrounded by extensive sclerosis. CT scanning revealed fragmentation of surrounding bone and cyst formation. This phenomenon appears analogous to polyethylene wear effects around hip prostheses or in silicone synovitis. The patient, although severely handicapped, refuses further operations at the moment (Fig. 5).

In two patients (cases 13 and 23), we observed breakage of the metal wire around the polyethylene core. The cause of this abnormality is obscure, but our interpretation is that it could be related to cold flow of the polyethylene, giving rise to flattening of the core. The patients were operated on in 1995 and 1999, respectively.

In three patients, we observed hyperlordosis of the operated segment, resulting in an opening of the facet joints in the superior part and a compression in the inferior part of the joints. This could be a cause of later facet joint arthrosis.

DISCUSSION

A good surgical solution for symptomatic disc and/or facet joint degeneration is yet to be found. Arthrodesis of a painful motion segment has given mixed results in the literature, although it has been proven to be superior to conservative treatment after short-term follow-up.^{2,17} Pre-

TABLE 1. Continued

Late complications	Re-operation	Neighboring levels degenerative		CT or MRI scan or discography	Clinical symptoms at F-U
		Pre-operatively	Postoperatively		
Gross subsidence. After removal prosthesis and fusion retrograde ejaculation and abdominal herniation.	Posterior release 2000 Removal of prosthesis and cage insertion and posterior instrumentation 2001.		Probably degeneration L4-5	Before removal of prosthesis on CT scan facetartrosis L5-S1.	After removal of prosthesis and fusion persistent back and right leg pain.
Radiculopathy due to percutaneous nucleotomy; subsidence posteriorly of the L5 plate.		L3-4 old osteochondrosis L5-S1 some degeneration	The same as preoperative	CT facetjoints L4-5 artrotic	Continuous backpain and bilateral legpain. Crepitations in the back.
Overdistraction of segment L4-5. Fixed position L4-5 in hyperlordosis.		L5-S1 also degenerative but not painful on discography	L5-S1	CT scan some facet joint narrowing L4-5 right side. Flex/ext no movement in the disc prosthesis.	Continuous back and bilateral legpain. Spinal fusion L4-5-S1 offered.
Prosthesis inserted with too much distraction. Fixed hyperlordosis.		MRI preoperatively also black discs L3-4 and L5-S1.	The same as preoperatively.	CT: facetjoint artrosis L4-5 with distraction upper part and compression distal part of the joints. Also facetjoint degeneration L5-S1 right side	Back and lower leg pain, after longer walking and sitting.

sumably, adjacent segment degeneration affects the long-term results and may be responsible for unsatisfactory clinical outcomes. For this reason and because of easier postoperative rehabilitation, disc arthroplasty appears to

be an attractive alternative to arthrodesis, especially in younger patients. Although theoretically appealing, there are currently insufficient data to assess the performance of intervertebral disc arthroplasty adequately. Introduction of

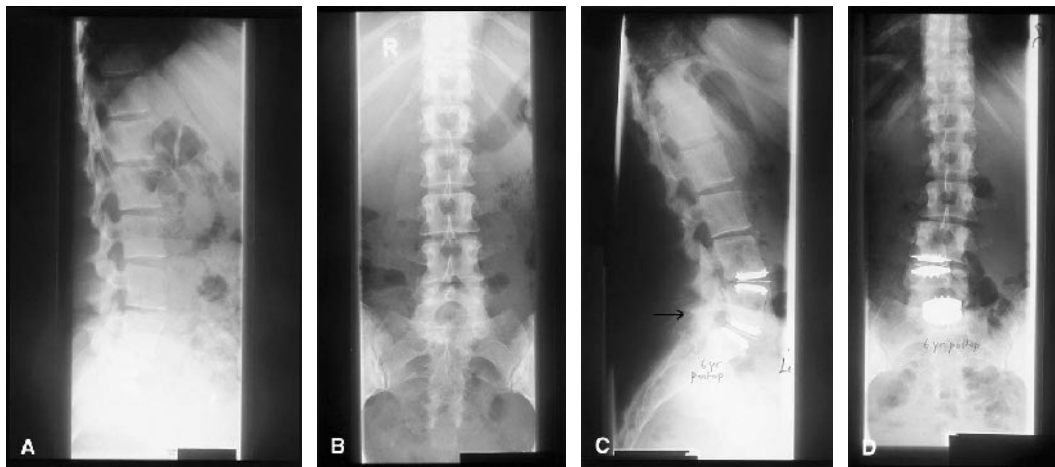


FIGURE 1. Case 16. A, Lateral radiograph of the lumbar spine preoperatively. There is obvious narrowing of discs L4–L5 and L5–S1. Disc L3–L4 discographically showed some degeneration but was not symptomatic. Disc L2–L3 discographically was not degenerated. B, Anteroposterior radiograph of the lumbar spine preoperatively. An almost straight spine and some obliqueness of L4 on L5 are seen. C, Lateral radiograph of the lumbar spine 6 years postoperatively. Note the anterior position of disc prosthesis at L4–L5. There is some subsidence of the metal plates at L4 and L5 posteriorly. Narrowing of L3–L4 disc is seen. D, Anteroposterior radiograph of the lumbar spine 6 years postoperatively. Left lateral position of disc prosthesis at L4–L5, also due to rotation of L4 on L5 and L5 on S1, is seen, along with narrowing of disc space L3–L4 and shift of L3 on L4 to the right.



FIGURE 2. Case 7. Anteroposterior and lateral radiograph of the lumbar spine 8 years after disc replacement at L4–L5. Spontaneous fusion of disc prosthesis level L4–L5 is seen. Also note previous anterior fusion L5–S1 and degenerative disc L2–L3.

this new technology has not followed the principles of scientific prudence, and despite almost 20 years of clinical application, there is doubt concerning the safety and efficacy of the method.

Since the beginning of the 1980s, the intervertebral SB Charité disc prosthesis type has been under development. Büttner-Janzen et al^{18–21} reported about the technique in 1987, 1988, 1989, and 1990. Only short-term results were published, with limited numbers of patients. In the 1988 publication, 83% of 62 patients with 76 implanted prostheses with a mean follow-up of only 15 months were satisfied. In two patients, the prosthesis had migrated, necessitating removal; in another two patients, anterior subluxation of 50% of the prosthesis occurred, although the clinical result was still good.

A multicenter retrospective study of 93 patients with 139 SB Charité III prostheses with only 11.5 months' mean follow-up was published in 1994 by Griffith et al.²² In 92.5% of the patients, back pain was present before the operation; only 19.8% had complete resolution of their symptoms. In 65.5%, the back pain decreased. The resolution of leg complaints was in 41% and 48% of the patients for the left and right leg, respectively. It seems from these figures that a significant number of patients were not

fully relieved of their back and/or leg pain. The reoperation rate of the Charité III prosthesis was low, only 3 patients in 93 patients, but the follow-up was short.

Cinotti et al²³ published a series of 46 patients with at least 2 years' follow-up with an average of 3.2 years. In 63%, a satisfactory result was noted. The results were somewhat better in patients with one-level operation and without previous back surgery. The main reason for unsatisfactory results, according to the authors, was a wrong indication.

The series of Lemaire et al²⁴ of 105 patients with a mean follow-up of 51 months shows that 79% of the patients had an excellent result, with return to work in 87% (in 27% to less demanding work). They stated that the double-joint mechanism allows restoration of the basic rotation and translation motions, so that the facet joints should not be overstressed. However, late osteoarthritic changes of the facet joints are recognized as one of the reasons for an unsatisfactory outcome.

Zeegers et al²⁵ reported on the first 50 of 350 patients, with a follow-up evaluation of all patients after 2 years. In 70%, a satisfactory clinical result was achieved. Four patients were lost to follow-up, and it is not clear from the text whether these patients were regarded as failures. Permanent sequelae and complications were seen in 13%, and 12 patients (24%) needed a reoperation, which benefited only 3 of them. One patient had to undergo three reoperations because of a lesion of the aorta. The end result of this patient is not mentioned. There was an asymmetric position of the prosthesis in 18%.

Short- and more recently medium long-term results for the Charité prosthesis and for the Prodisc prosthesis were reported by David^{26–28} and Marnay,^{16,29} respectively. David reported 79% excellent and good results in 142 reviewed patients of 147 patients operated on before 1997. Ten patients had a posterior fusion for facet joint arthrosis and malpositioning, and 11 patients had partial or total ossifications. One prosthesis was removed with fusion, and two prostheses migrated and were fused. This series can be no judgment of long-term results, since most patients were operated on <10 years ago.

Marnay reported on 93 prostheses implanted in 64 patients between 1990 and 1993. No implants were removed, and all implants were stable without migration or subsidence. In five patients, a posterior fusion was performed. The results were good or excellent in 93% of the patients, and only 7% was dissatisfied, with a follow-up of 7–10 years. No mention is made in the abstract of how many patients were lost to follow-up. In both these series, a nonbiased observer was not involved in the investigation.

Sott³⁰ described good results also in patients older than 45 years (his oldest patient was 61 years old; the mean age of 14 patients with 15 Charité prostheses was 48 years).

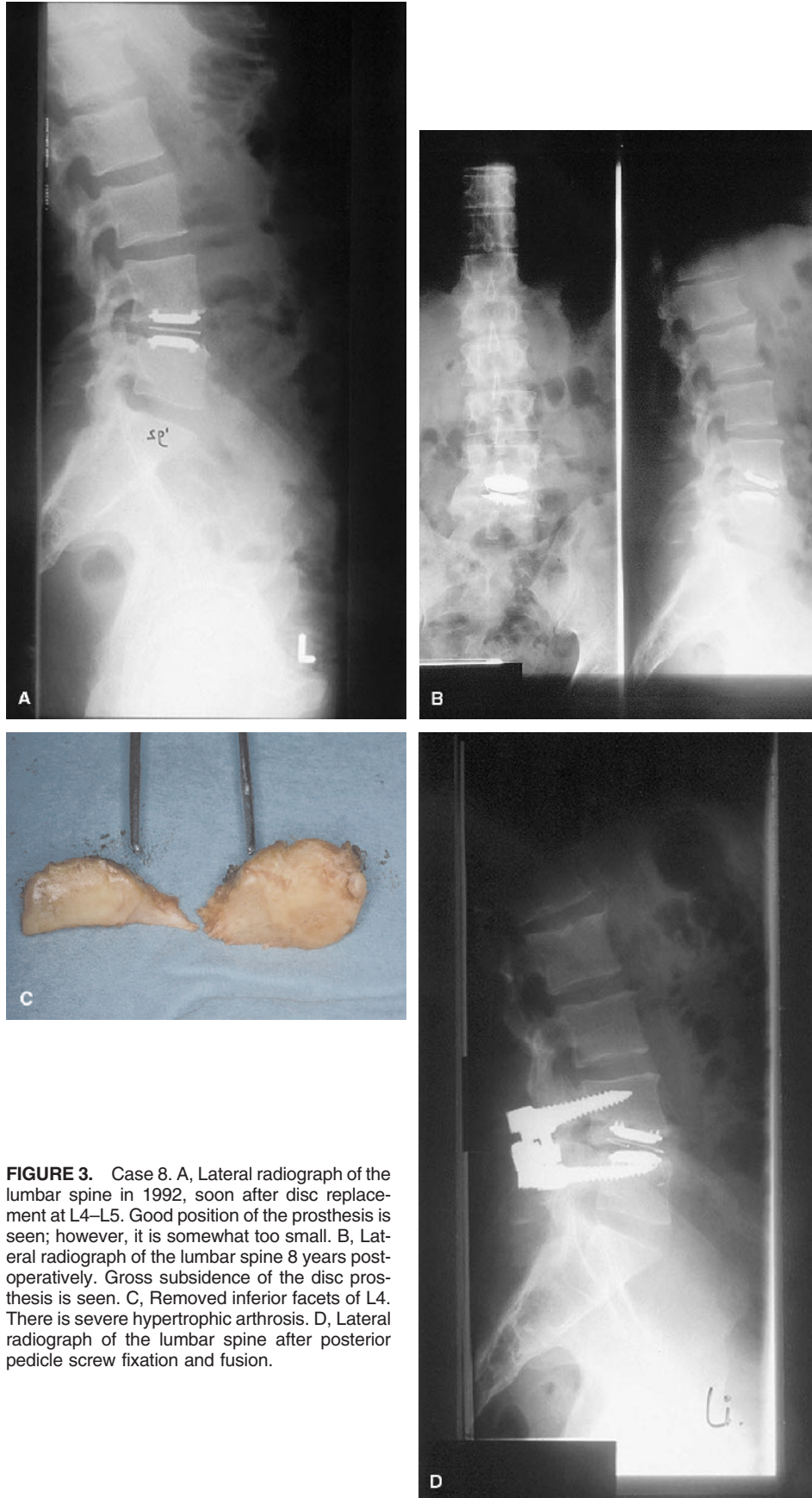


FIGURE 3. Case 8. A, Lateral radiograph of the lumbar spine in 1992, soon after disc replacement at L4–L5. Good position of the prosthesis is seen; however, it is somewhat too small. B, Lateral radiograph of the lumbar spine 8 years post-operatively. Gross subsidence of the disc prosthesis is seen. C, Removed inferior facets of L4. There is severe hypertrophic arthrosis. D, Lateral radiograph of the lumbar spine after posterior pedicle screw fixation and fusion.

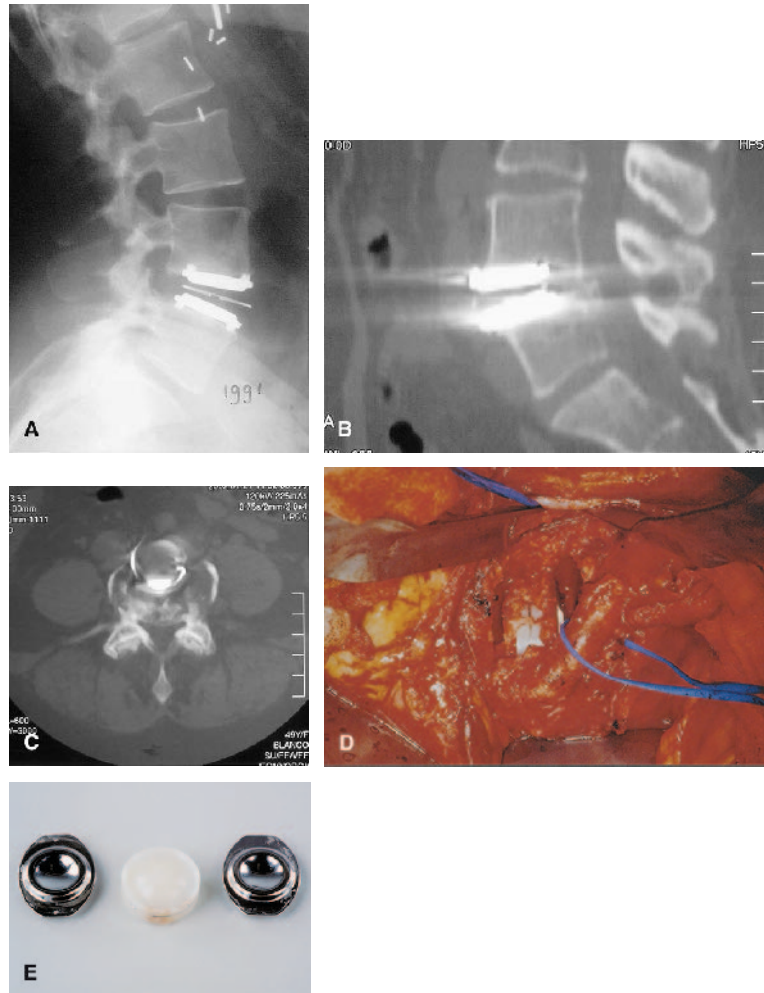


FIGURE 4. Case 4. A, Lateral radiograph of the lumbar spine in 1991. Disc prosthesis at L4–L5 is in good position, although somewhat anterior. B, CT scan with lateral scannogram in 2001. Anterior subluxation of the disc prosthesis at L4–L5 is seen, lying against the major vessels. C, CT scan in 2001 at the level of the core of the disc prosthesis. Pressure on the great vessels is seen. Note also the facet joint arthrosis. D, Intraoperative view at removal of the disc prosthesis. The proximal plate is already removed. The prosthesis was loose, lying in connective tissue and adherent to the major vessels. Vessel loops around the ureter (proximal) and common iliac artery (distal) are seen. E, Removed disc prosthesis. There are no obvious signs of wear.

Facet joint arthrosis and advanced osteoporosis, however, must be ruled out.³⁰

In the United States, two prospective randomized clinical trials are underway, comparing Charité and Prodisc disc prosthesis surgery with BAK cage fusions.³¹ The short-term results (<2-year follow-up) are promising. However, the final judgment of these prostheses must be made after ≥ 10 years, as is the case for every joint prosthesis, especially since the age of the operated patients is in the range of 30–50 years.

In the operative treatment of degenerative disc disease of the lumbar spine, the concept of preserving motion instead of fusing one or multiple segments is very attractive. It has been applied before, beginning with Fernström.^{32,33} Some later designs proved to be unsuccessful³⁴ or have been described only in preclinical papers.³⁵

Several problems in reaching the goal of painless functioning of the lumbar spine with one or more disc prostheses in situ must be recognized.^{36,37} First, the indication for operation is an issue of much debate. Most spine surgeons will acknowledge that pain can be derived from

degenerative disc or facet joint disease, analogous to degenerative disease of all other joints in the human body. In the lumbar spine, however, these comparable degenerative disorders occur in people without any related symptoms. Also, social and psychological factors can play an important role in the clinical presentation. These factors will be of great importance in the final result of every operative or conservative intervention undertaken for this specific pain. Furthermore, it is frequently very difficult to relate the pain to the radiologic abnormalities. Discography is very much debated and has been proven to be unreliable in some studies, described by Krismer.¹⁷ If degeneration is obvious on conventional x-rays or MRI but not symptomatic on discography, nonsymptomatic levels can become symptomatic some time after fusion or other interventions, but also spontaneously. It is not proven up till now that after replacement with an artificial disc of only the symptomatic disc(s), the nonsymptomatic degenerative discs will remain nonsymptomatic.

The intervertebral disc prosthesis is often compared with a hip or knee prosthesis. This comparison has sig-

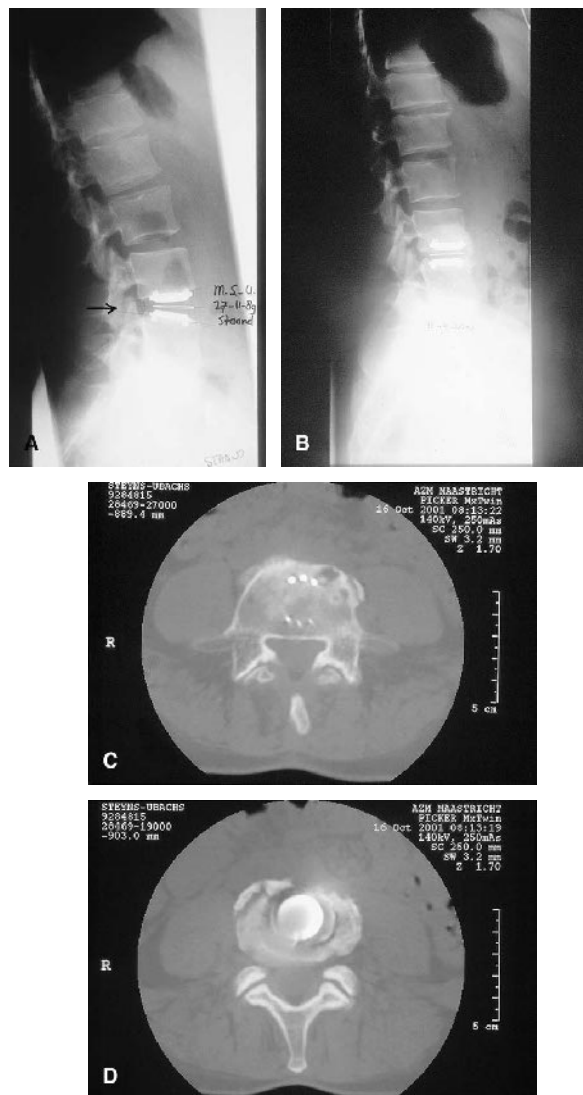


FIGURE 5. Case 2. A, Lateral radiograph of the lumbar spine in 1989. Good position of the disc prosthesis above an old anterior fusion at L5–S1. Some opening up of the proximal part of the facet joints at L4–L5 is seen. B, Lateral radiograph of the lumbar spine in 2001. Gross subsidence of the disc prosthesis, extensive sclerosis in the vertebral bodies L4 and L5, and ossification of the anterior ligament are seen. There are presumed loss of height of the polyethylene core and loss of lordosis in segment L4–L5. C, CT scan in 2001 at the level of the spikes of the metal plate L4. Cyst formation and scattered sclerosis in the vertebral body L4 are seen. D, CT scan in 2001 at the level of the polyethylene core shows fragmentation of bone and ossification around the core.

nificant limitations. A spinal motion segment is composed of one intervertebral disc and two posterior facet joints. The kinematics of the spine with its multiple motion segments is totally different from that of a unicompartamental hip or knee joint.

While the facet joints are true synovial joints, the intervertebral disc is a synchondrosis rather than a real joint. Degenerative disc disease is supposed to be the main

cause of the symptoms, but this is only speculative. It could well be that the facet joints play a role in the pain syndrome of most of these patients. Obviously, replacing only the intervertebral disc will then not be sufficient to relieve the complaints.

In our patient group, we saw numerous patients with very severe arthrosis of the facet joints years after the disc replacement. They had developed this arthrosis with grossly subsided prostheses; but also when there was a perfect position of the prosthesis in the intervertebral space, this arthrosis could be present. It seems very unlikely that the Charité or other models of disc prosthesis mimic the normal intervertebral movement pattern so closely that normal facet joint movements and loading are possible. Even Lemaire et al²⁴ had some concerns in this matter. The center of rotation for flexion-extension movements in physiologically normal-functioning segments is positioned posteriorly in the disc space.¹² With the Charité and also the Prodisc prosthesis, this center is centrally or slightly anteriorly positioned, depending on the accuracy of insertion. It is logical to assume that normal intervertebral motion is not possible with such a prosthesis.

A normal intervertebral disc has a shock-absorbing function. The current prostheses, made from metal and polyethylene or from metal alone (the recently developed Maverick prosthesis, Waldemar Link GmbH & Co. Barkhausenweg 10, D-2000 Hamburg 63, Germany), have little shock-absorbing capacity, and this should be a matter of concern. Hardly anything is written about this aspect in the literature.

The spine is composed of multiple segments, closely related to each other, forming a chain of joints. Fusing one segment imposes greater stresses on other segments, and the more there are fused, the greater the stresses imposed on the remaining segments; premature degeneration is then likely to develop. The proponents of disc prostheses state that because of preserving motion, less stress will be imposed on the neighboring segments. This hypothesis obviously needs further proof, since no reports specifically dealing with this matter have been published. It is hoped that the randomized trials now underway in the USA comparing disc prosthesis surgery with cage fusion will give an answer to this question. In our series, we saw seven patients demonstrating degeneration at levels other than the operated one(s), not present before the disc replacement. This can be the result of the degenerative disease itself, spreading to multiple levels of the spine, but could also be the result of stresses on the adjacent levels, generated from the level of the nonphysiologically functioning disc prosthesis. Many questions still exist concerning the biomechanics of a disc prosthesis.^{14,38} It is our strong impression that the implants now available are not acting as normal intervertebral discs in this respect.

The fixation of a disc prosthesis onto the vertebral endplates is a matter of concern. Hedman et al⁶ state that press-fit-type fixation components with spikes, pegs, and posts are inadequate after tensile loading and may be effective only for the relatively short term. We saw many subsided disc prostheses, sinking anteriorly, posteriorly, or laterally in the vertebral bone. It is known that the central endplate is relatively weak and that only the outer rim of the endplates contains stronger bone. This implies that the metal plates must be large enough to rest on the peripheral rim of the endplates. Several patients had too small a prosthesis inserted, with resulting subsidence. Our data do not allow us to compare subsidence rates between those with optimal coverage and those with smaller coverage. A disadvantage of larger plates is that they have more risk for compression on the exiting nerve roots dorsolaterally and on the great vessels ventrally. Texturing of the plates, as has been performed recently in the Charité prosthesis and which is already the case in the Prodisc, can be of help in reducing subsidence or migration. Only longer follow-up will identify how well this works.

The insertion of these prostheses requires an anterior retroperitoneal or transperitoneal route (for L5–S1), preferably with minimal invasiveness.^{39–41} The great vessels must be mobilized for a good insertion of the prosthesis in the L4–L5 disc and cranially, to a lesser extent for L5–S1. The dimensions of the plates of the prosthesis determine the extension of the dissection and mobilization of the vessels. This poses bleeding and thromboembolic risks for the great vessels. Indeed, this has been reported.^{7–9} Also, early or late anterior migration can cause vascular compression. We saw anterior migration in three of our patients with anterior subluxation and pressure on the major vessels in one of these patients. Additionally, an aortic lesion is described in the work of Zeegers et al.²⁵

In males, a fair risk is present for developing temporary or permanent retrograde ejaculation or other sexual disturbances. This risk has been reported in from 2% to 7%¹⁰; it occurred in two patients of our group, in one patient primarily and in the other after removal of the prosthesis (patients 9 and 24).

The final question is: What is the fate of the prosthesis after ≥ 10 years? This is a valid question, since the operated patients are of a relative young age. All the patients we saw, with one exception, were between 30 and 50 years at the time of the primary operation. As was stated, a disc prosthesis should survive for at least 40 years. It is very questionable if the lifetime of the designs now available will be that long. Little is known about the long-term behavior of biomaterials such as polyethylene, polyolefin rubber (present in the AcroFlex prosthesis), and metals in the spine.^{13,40,43} One can argue that ≥ 10 years of pain-free functioning is a good result for a patient with severe

pain. However, revision of the prosthesis must be fairly easy if malfunctioning and wear and tear of the prosthesis occur. This is the crux of the current disc prostheses. Revision can be very dangerous because of the adherence to the great vessels and the nerve plexus. The other solution, a posterior fusion without removing the disc prosthesis, was performed eight times in our group. The results were disappointing in most patients up till now. The reason for this finding is unclear. One of the reasons could be a constant pain source of the remaining disc prosthesis, as is possible after a posterior or posterolateral solid fusion without removal of the painful disc at the same level.

CONCLUSION

No reports with long-term follow-up (10–15 years and longer) have been published yet. The authors saw a group of disabled patients, operated on for degenerative disc disease with a Charité disc prosthesis 1–13 years previously. Their recurrent or persistent back and leg pain was caused mainly by disc degeneration on neighboring levels, facet joint arthrosis at the same or neighboring levels, hyperlordosis of the operated segment, subsidence and migration, and, in one case, presumed polyethylene wear. It is argued that the metal-polyethylene implants now available are biomechanically of questionable quality, have problems with fixation, and will probably fail in a substantial percentage of patients after ≥ 10 years. Removal of the prosthesis is dangerous, and posterior fusion without removing the prosthesis will give suboptimal results. The implants must be considered as experimental devices, and only long-term results from scientifically proven investigations and performed by unbiased observers will tell the orthopaedic community about whether disc prosthesis implantation is an acceptable orthopaedic surgical procedure.

KEY POINTS

A group of 27 patients with unsatisfactory results after insertion of a Charité disc prosthesis was seen in a tertiary referral center.

The main causes of the unsatisfactory results were degeneration of facet joints on the same level, degeneration of facet joints and discs at neighboring levels, as well as subsidence and migration of the prosthesis. In one patient, signs of polyethylene breakdown were seen.

It is argued that the current designs are problematic regarding their biomechanics and that the fixation of the prosthesis on the vertebral endplates is a problem.

Long-term follow-up studies have not yet become available; until these long-term results are known, the insertion of these disc prostheses should be viewed as experimental.

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