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G. Gioia
D. Mandelli
F. Randelli

The Charité III Artificial Disc lumbar disc prosthesis: assessment of medium-term results

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G. Gioia • D. Mandelli
Department of Orthopaedics and Traumatology
IRCCS, San Raffaele Hospital
Milan, Italy

F. Randelli (✉)
Department of Orthopaedics and Traumatology II
IRCCS, Policlinico San Donato
San Donato Milanese (MI), Italy
E-mail: filippo.randelli@fastwebnet.it

Abstract The intervertebral disc prosthesis seems to have gained its place in spinal surgery. The first 45 disc replacements (36 patients) performed at our institution have been followed for 5–9 years with standard radiography, CT, MRI and clinical evaluation. Two prostheses failed and needed further surgery. The mean Oswestry Disability Index score dropped from 44% to 9% and the pain score recorded on a visual analogic scale (VAS) dropped from 8 to 1.4. 92% of patients had excellent or good results and gave a positive answer to the question "Would you be ready to sustain again this same surgical procedure?" In 4 cases, a tendency towards prosthesis subsidence was observed. With time, 6 patients showed periprosthetic calcifications. One patient developed retrograde ejaculation. In conclusion, intervertebral disc prosthesis is a well established procedure that achieves good mid-term results, but doubts still remain about the long-term outcome. Care about right indication, eventual complications and assessment of long-term results are key points for the future of this procedure.

Key words Intervertebral disc prosthesis • Spine • Degenerative disc disease

Introduction

During the past 20 years, the treatment for chronic low back pain and degenerative disc disease, not responding to conservative therapy, has been mainly based on fusion surgery, but in the meantime the use of lumbar disc prostheses in a few selected series has been tested [1]. The aim of this kind of prosthetic implant is the preservation of disc function. It allows spinal segment mobility and reduces, at least theoretically, the reasonable concern of a medium- to long-term effect of overload on adjacent levels seen in fusion surgery, which still represents the standard treatment for degenerative disc disease worldwide. After a long period of scepticism, disc replacement gained the interest of spinal surgeons, as proven by many scientific papers published in the past few years [1–5].

The use of a disc prosthesis is not at all a new concept, since the first cases were already reported in the literature in the second half of the 1980s [2–5]. In the United States, this kind of prosthetic replacement was introduced only a few years ago. The Charité Artificial Disc (DePuy Spine, Raynham, MA, USA) was recently assessed in a comparative randomised trial vs. cage interbody [6, 7]. Prosthetic replacement of intervertebral disc is indicated in symptomatic disc disease as a cause of chronic low back pain or lumbar nerve root pain not due to compressive disc herniation. The ideal candidate should be an individual younger than 50 years (even though some clinicians have recently extended this age limit [8, 9]) with good bone quality. The pathology should be limited to only one or two discs. A totally different indication is represented by disc disease occurring after surgical removal of a disc hernia, if the zygapophyses have been respected and spared

during the previous surgery. Special attention should be paid to the psychological condition of the patient to be scheduled for prosthetic replacement, although this is a consideration of paramount importance in all individuals suffering from low back pain who are to be operated on. Absolute contraindications to the use of a disc prosthesis are migrated or extruded disc herniation, spinal canal stenosis, spondylolysis with or without concomitant spondylolisthesis, and osteoporosis. Our experience with the Charité prosthesis started in 1998. The mean follow-up is over 6 years and offers the opportunity of assessing our medium-term results, which is in fact the objective of the present paper.

Materials and methods

Since June 1998, we implanted the Charité III Artificial Disc prosthesis (DePuy Spine, Raynham, MA, USA) in 56 patients. The prosthesis is composed of two cobalt chromium endplates with a non-constrained polyethylene sliding core. The endplates come in different angles to ensure proper segmental lordosis. The polyethylene core comes in different sizes to restore proper disc height and ideal segment tension. We report here the results obtained in the first group of 36 patients operated before October 2002 with a mean follow-up of 6.9 years (range, 5–9 years). All patients, 13 men and 23 women of a mean age of 39.5 years at time of surgery (range, 32–49 years), underwent prosthetic disc replacement performed by the same surgical team. The mean duration of symptoms before surgery was 19 months (range, 15–24). Patients were complaining of chronic low back pain with irradiation of pain to one or both lower limbs, but without signs of nerve root compression due to disc hernia. We implanted a total of 45 artificial discs. The L5-S1 level disc was substituted in 15 patients, the L4-L5 disc was substituted in 11 patients and the L3-L4 disc in 2. Double disc replacement was done in 7 patients, and in one subject three disc levels were replaced.

Pre-operatively, all patients filled in the self-assessment Oswestry disability index (ODI) [10, 11] form and scored pain on a visual analogic scale (VAS). All patients also underwent pre-operative imaging with standard as well as dynamic X-rays, lumbar computed tomography (CT) and magnetic resonance imaging (MRI). The standard radiographic examination was used to exclude any possible deformity in the investigated segments, while the dynamic X-ray study was used to confirm the absence of overt instabilities. CT allowed us to exclude any pathologic process involving the posterior joint facets while with MRI we evaluated the state of hydration of the pathologic disc and of the adjacent levels. Provocative discography was performed in 28 patients.

Postoperatively, patients underwent standard and dynamic radiography of the lumbar spine, filled in the ODI form and scored pain on VAS at 1, 3, 6 and 12 months, and then at 2-year intervals. The postoperative standard X-ray study aimed to verify the correct positioning and proper sizing of the artificial disc and to detect any possible loosening or subsidence as well as the development of any periprosthetic ectopic ossification [12]. The dynamic X-ray study allowed us to verify the correct functional performance of the replaced segment in flexion and extension. Radiographs of the lumbar spine in anteroposterior (AP) and lateral views were taken to check the correct position of the implants. The outcome was defined as satisfactory when the artificial discs were positioned 2 mm off the midline (in AP projection) and 1 mm from the ideal lateral position (2 mm dorsally to the midline of the vertebral body in the lateral projection). The outcome was defined as moderately decentered in case of a 5-mm difference in the two planes, and poor when the difference was greater than 5 mm. The function of the segment was studied by means of dynamic X-ray studies carried out along the angles between the intersection of the lines drawn from the prosthetic endplates in flexion and extension.

Surgical technique and postoperative care

All artificial discs were implanted through the anterior retroperitoneal approach [13, 14]. All patients underwent antithrombotic prophylactic treatment with low-molecular-weight heparin for seven days after surgery. Fibrinogen and fibrin dimer levels were determined during the first three postoperative days to monitor coagulation profiles and detect thromboembolic events. Standing posture was allowed on postoperative day one. All patients were instructed to wear a semi-rigid brace for 4 postoperative weeks. Normal daily activities, including sports, were allowed starting two months after surgery.

Statistical methods

Pre-operative ODI and VAS were compared with ODI and VAS obtained at last follow-up (6.9 years, range 5–9). A 95% Confidential Interval were desumed for each group of datas (ODI pre-op, VAS pre-op, ODI at last control and VAS at last control).

A Student's t test for paired samples were employed to asses if follow-up ODI and VAS results were significantly different respect to pre-operative datas.

Results

The mean duration of surgery was 70 minutes (range, 60–90) for one-level prosthetic replacement and 110 minutes (range, 90–140) for two-level surgery. Blood loss was 120 ml and 250 ml, respectively. Mean haemoglobin loss in the postoperative period was 1.67 g/dl (range, 1.30–3.5). All patients regained standing posture on postoperative day one. Mean hospital stay was 5 days (range, 3–9). All subjects went back to work by the third month

after surgery, two of them with lighter workloads. At present, the mean follow-up period is 6.9 years (range, 5–9).

The mean preoperative Oswestry disability index (ODI) was 44% (95% CI, 39.3%–48.7%), while the present value is 9% (95% CI, 5.4%–12.2%), with a statistically significant reduction according to Student's *t* test for paired samples ($p<0.0001$) (Fig. 1). The mean VAS pain score went from 8.0 preoperatively (95% CI, 7.5–8.3) to 1.4 postoperatively (95% CI, 0.9–1.9) with a statistically significant reduction according to Student's *t* test for paired samples ($p<0.0001$). When asked to evaluate their surgery, 72% of patients rated the outcome of their prosthetic substitution as excellent, 20% reported a good result, 4% had an inadequate outcome and 4% had a poor result. Radiographs of one patient with an excellent outcome are shown in Figure 2. Thirtythree patients (92%) gave a positive answer to the question "Would you be ready to sustain again this same surgical procedure?" No difference was noticed between patients with one or two operated levels. In two patients, the prosthetic replacement was considered a failure: in one case conversion was needed to posterior stabilisation, while a second patient had to undergo removal of the implant and subsequent circumferential bone fusion in a different institution.

The position of the artificial disc was considered good in 61% of cases, moderately de-centered in 31% and poor in 9%.

Six implants were considered to be undersized. In 4 of these cases, we observed a tendency towards prosthesis subsidence (Fig. 3).

Starting from the fourth postoperative year, we noticed the appearance of periprosthetic bone formation, in accordance with previous reports [15, 16]. The 6 patients

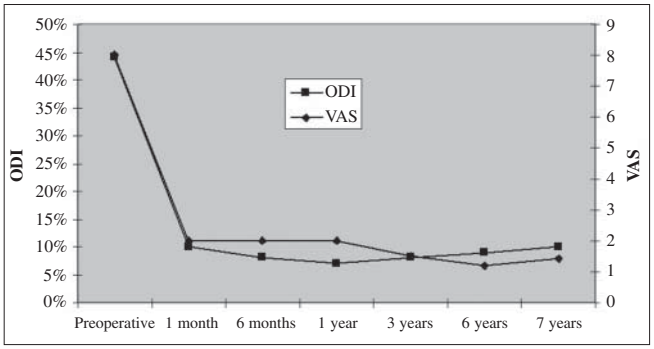

Fig. 1 Oswestry disability index (ODI) and VAS pain scores for 36 patients who underwent lumbar disc replacement

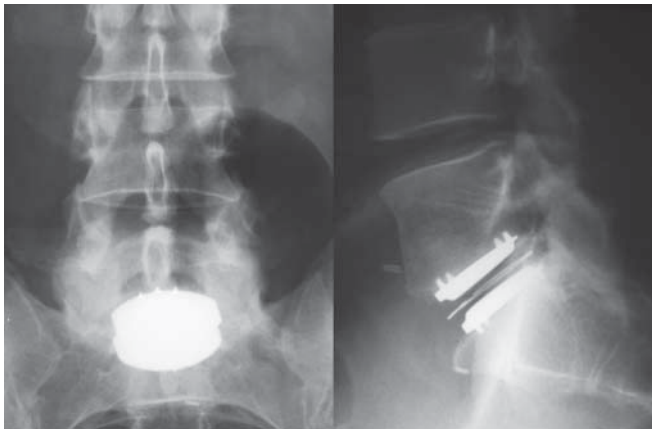

Fig. 2 Standard AP and lateral views of a patient with excellent outcome at the 6-year follow-up

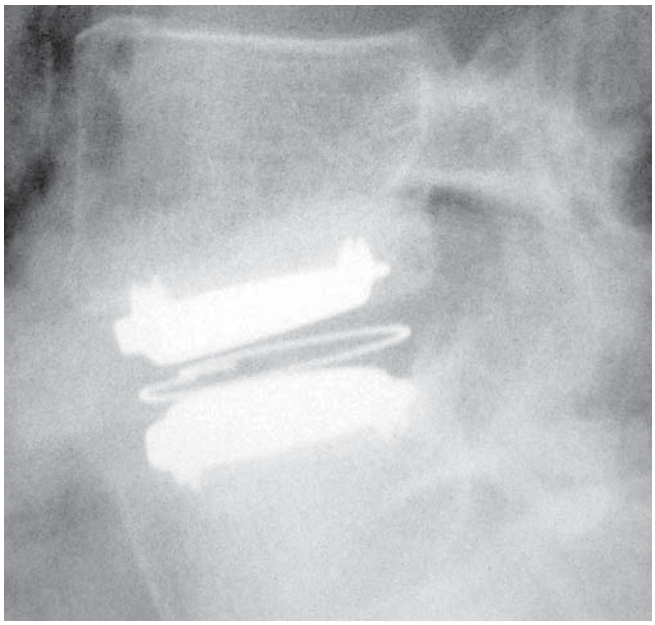

Fig. 3 A case of prosthetic disc plate subsidence

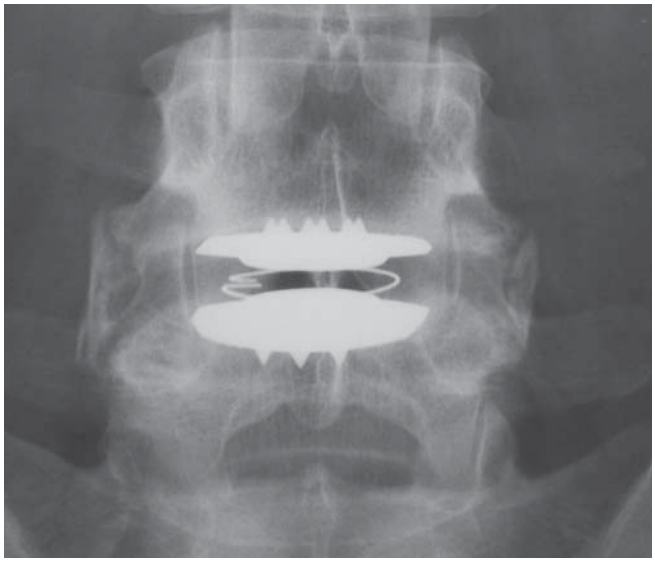

Fig. 4 Periprosthetic calcifications

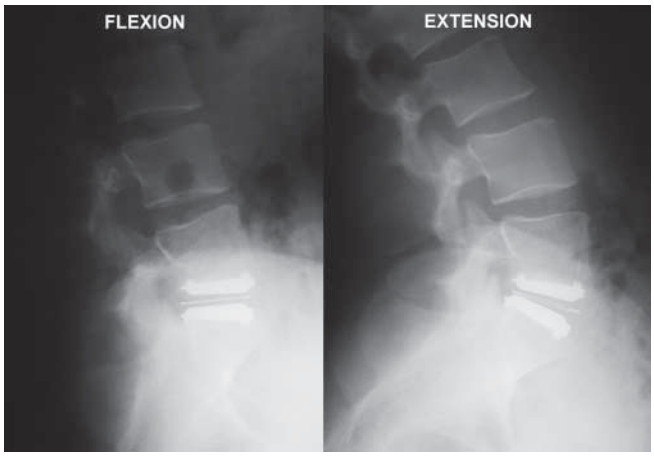

Fig. 5 Dynamic radiographs at the 6-year follow-up show segment excursions

with undersized implants and one with a normal sized implant showed periprosthetic calcifications (Fig. 4). As is also true for hip arthroplasty, such periprosthetic calcifications following disc replacement tend not to cause ankylosis, except when they are extremely severe and bulky. The presence of periprosthetic ossifications did not affect the clinical results in any noticeable way during the follow-up period.

Motion of the operated spinal segment indicated a median prosthetic function of 10.3° for L4-L5 levels and 8° for L5-S1 and L3-L4 levels (Fig. 5).

There were surgical complications in 3 cases. One case of left iliac vein injury occurred during L4-L5 disc replacement, and was sutured uneventfully. One case of pre-sacral nerve injury led a man to have retrograde ejaculation [17]; this patient was unsatisfied and was lost at follow-up. One case of artificial disc malposition with excessive posterior subsidence required immediate revision surgery because of sciatic compression.

One patient experienced scrotal edema on the third postoperative day; this resolved uneventfully. This happened to the first patient, in whom a suction drainage was not applied. Three cases of ileus occurred on day two after surgery and resolved spontaneously within 48 hours.

In the years following disc replacement, two patients underwent bone fusion surgery due to their progressively deteriorating conditions. After 5 years, posterior bone fusion was performed in one woman at the same level previously operated on, because of persistent nerve root pain. Though the entity of pain was less than in the preoperative phase, the clinical condition is not however completely resolved. This particular case was a prosthetic disc replacement carried out on a patient who previously had surgical removal of a disc herniation that lead to discopathy. A second patient underwent revision surgery in another institution where the implant was removed and circumferential bone fusion was performed, four years after disc replacement. This patient was the one with posterior subsidence of the implant that had already been revised by us in the immediate postoperative period for root impingement.

Discussion

Disc replacement allows good and almost immediate clinical results in most cases. Since we immediately appreciated the theoretical advantages of the artificial disc, we initiated our experience with the prosthetic replacement of intervertebral discs in 1998, thanks to cooperation with W. Zeegers who, at the time, had experience in this field [5]. The limited invasiveness of the procedure, in his hands, led us not to delay any longer and to try to perform our first implants. We started to use the Charité Artificial Disc which, at the time, was the only available disc implant. This study reveals that prosthetic replacement of the intervertebral disc provides good clinical results in over 90% of cases of low back pain consequent to degenerative disc disease and not responding to conservative management. Our results are in agreement with most previous studies [4, 6, 7, 16–18].

The Charité III Artificial Disc is the disc implant with the longest follow-up and it was approved by the US Food and Drug Administration (FDA) in October 2004. Similarly good clinical results have been also reported with other prostheses, now on the market, although these have shorter follow-up periods [19–20]. These outcomes confirm the hypothesis that in degenerative disc disease, the first and foremost origin of pain lies within the disc itself and that its removal leads to the remission of symptoms [21]. Furthermore, disc replacement allows dynamic stabilization of the involved spinal segment reducing, theoretically, future adjacent level degenerative disease. This surgical procedure, however, is limited so far to a small number of patients for precise reasons: the uncertain life expectancy of the implant, the limited surgical indications, the need to verify the integrity of the zygapophyses before surgery (the artificial disc substitutes only one of the 3 joints that make up this vertebral functional unit), and the difficulties encountered in the anterior surgical approach required to position this prosthetic disc.

Our clinical results, obtained with correct indications, are encouraging. The rapid resolution of symptoms in almost all patients (92% excellent and good results) was achieved almost immediately and appears to be long-lasting. The surgical procedure was well tolerated and postoperative recovery was fast. As observed in the recent trial

in the USA [6, 7] that compared outcomes in patients treated with Charité Artificial Disc replacement to these who received bone fusion by means of interbody cages, implanted with the same anterior approach, there was a greater level of satisfaction and a shorter hospital stay in patients who underwent prosthetic replacement.

Faced with excellent clinical results in terms of subjective resolution of pain reported by patients, some problems have emerged, in our series, regarding implant function 4–5 years after surgery. The trend towards subsidence of the endplates basically involves only those undersized implants and, in our experience, we only observed it in 4 cases: proper respect of the subchondral bone during its preparation, careful preoperative assessment of bone quality, the new prosthetic design of the Charité III Artificial Disc coupled to the selection of the largest possible implant size are the only tools the surgeon has to limit such phenomenon.

As for periprosthetic bone formation [15, 16], we cannot tell whether such proliferation is due to the surgical technique or to some other factor. In our experience, this event was only observed in patients with small prostheses, that sometimes were employed because of the surgical difficulties encountered in creating space anteriorly. Furthermore, particularly severe disc alterations seem to promote the development of calcified deposits, most probably due to the greater surgical effort required in these cases in preparation of the endplates. Today, we definitely prefer to avoid the prosthetic replacement of extremely tight discopathies.

The analysis of the available short- to medium-term results indicates that a possible increase in the interest for disc substitution is likely to occur. Results seem to be better than those for bone fusion, with even a faster recovery [6, 7, 18]. Complications related to anterior surgery, e.g. retrograde ejaculation, must be well expressed by the surgeon and clearly accepted by the patient. On the other hand, analysis of long-term results – even though there is just one report [15] – does not seem to highlight major advantages in favour of the artificial disc, therefore confining it back to the limited role already played in the two past decades. A 60% rate of spontaneous ankylosis was reported at 15–17 years [15]. Moreover, in the same study, the still functional implants seemed to have the worst clinical results. This obviously contributes to further call in question the doubts of the sceptic ones. If it is true that the Charité prosthesis has some limitations in the long run [15, 20], it is however also true that it provides excellent short- and medium-term results: in this respect we could consider the life expectancy of the artificial disc to be similar to that of other joint replacement implants that are presently used. The difference between disc replacement and other joints lies in the fact that while a loosened hip prosthesis must be revised, the artificial disc seems to stabilize itself even though it looses its function: this might be considered a faiure from the conceptual point of view but can, at the same time, be accepted from the clinical perspective. This finding needs to be studied more in depth by large clinical trials comparing the different designs that are now available on the market. However, the artificial disc demands a rigorous surgical technique which requires great skills by the surgeon, but it helps eliminate the most common problems encountered in bone fusion: nonunion and pain at the donor site where the bone graft was harvested, malpositioning and implant failure that – considering the rapidly increasing use of this surgical procedure – is actually occurring at an increasing frequency which definitely raises some perplexities.

This prosthesis seems, however, to be implanted by surgeons who are unbiased and involved in the matter. They tend to rely on the implant design and characteristics and operate on properly informed and willing patients who, after accepting the good results so far obtained, should also be ready to equally accept the long-term uncertainties [22].

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