Rudolf Bertagnoli
Selva Kumar

Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications

Received: 18 February 2002
Accepted: 17 April 2002
Published online: 6 September 2002
© Springer-Verlag 2002

Abstract In this prospective study, a total of 134 prosthetic discs were replaced in 108 patients undergoing total disc replacement surgeries for degenerative disc disease. It was the aim of this study to correlate the clinical findings and the outcome of our patients treated with Prodisc II prostheses for various indications and to formulate indication criteria for disc replacement surgeries. The discs were implanted at L5/S1 in 61 patients, L5/L6 in 3 patients, L4/L5 in 31 patients, L3/L4 in 7 patients, and L2/L3 in 3 patients. There were 12 patients with two-level implants: from L4 to S1 in 11 of them and from L2 to L5 in the remaining one. Two patients also had three-level implants, from L3 to S1. Follow-up evaluation included plain radiographs, physical evaluation, and subjective evaluation by the patient using the Oswestry scale, the visual analog pain scale, and the SF-36V2 well-being questionnaire. The evalu-

ation exercise showed that 90.8% of patients had excellent results, 7.4% had good results and 1.8% had fair results, with no poor results seen. Postoperatively, the average vertebral motion was increased in all patients at the operated level. Progression of disc degeneration at the adjacent levels was noted in ten patients. The average time to resuming activities of daily living unaided was 2.3 weeks. No implant failures or complications due to surgery were encountered in this study. Total prosthesis disc replacement for degenerative disc disease was found to be a good treatment modality, provided proper patient selection and criteria are adhered to. We were able to formulate indication criteria based on this.

Keywords Total prosthetic disc replacement · Disc arthroplasty · Degenerative disc disease · Lumbar spine

R. Bertagnoli (✉) · S. Kumar
Klinikum St. Elisabeth,
Kay 2a, 94315, Straubing, Germany
e-mail: bertagnoli@ogp.de,
Tel.: +49-9421-7101816,
Fax: +49-9421-530475

Introduction

Chronic back pain and degenerative disc disease are among the most common ailments affecting the population worldwide. Seventy to eighty percent [28] of the population of the Western world experiences low-back pain at one time or another. Although many of these complaints can be treated conservatively, there have been a growing number of cases that have failed conservative management, and treatment for these cases usually entails surgical intervention. There are numerous surgical options

available for degenerative disc disease, ranging from standard discectomies (open or microsurgical) to percutaneous nucleotomies, chemical and thermal nucleolysis and spinal fusion modalities. Although they may give symptomatic relief initially, long-term reviews of these treatment modalities have shown them to be less favorable [11, 13, 14]. Even the fusion modalities that were once thought to be the answer to these problems have, in the long term, proved to have their own pertinent problems in the forms of accelerated degeneration of the adjacent lumbar segments, pseudoarthrosis, spinal stenosis and low-back pain, to name a few [4, 16, 21, 24]. It is

these problems, coupled with the need for a better treatment modality, that have brought about the idea of a total prosthetic replacement as a treatment for degenerative disc disease.

Though a few studies involving clinical trials have been done [6, 10, 15, 30], they have all included very few study subjects, and none gives a clear picture as regards indications for such operative treatments. It was hence the aim of this study to correlate the clinical findings and outcomes of our patients treated with full prosthetic disc replacement with the various indications, to formulate an indication pattern as a guideline for full prosthetic disc replacement surgeries.

Materials and methods

A total of 134 discs were replaced in 108 patients, operated by a single surgeon, and all patients were available for evaluation. The follow-up period ranged from 3 months to 2 years.

There were 58 men and 50 women, with an average age of 41.5 years (range 34–65 years). Preoperative diagnosis included disc degeneration (vertical instability) in 67 patients, failed disc surgery syndrome in 35, and 6 patients were diagnosed with transition zone syndrome (TZS). The operated levels were L5/S1 (61 patients), L5/L6 (3 patients), L4/L5 (31 patients), L3/L4 (7 patients), L2/L3 (3 patients), L4/L5 and L5/S1 (10 patients), L2/L3 and L4/L5 (1 patient), and L3/L4, L4/L5 and L5/S1 (2 patients).

All patients were evaluated with plain radiographs, which were standardized, and also with magnetic resonance imaging (MRI), which showed disc degeneration at one or more levels and the status of the facet joints. Plain radiographs were also used to assess the spinal range of motion on flexion and extension at the operated levels and the adjacent levels, and status of the implant. The preoperative status of the discs and facet joints at the adjacent levels was evaluated. Clinical evaluation included physical examination, which included spinal range of movements, motor strength, peripheral nerve assessment and patients' subjective response to the Oswestry questionnaire, the SF-36V2 well-being questionnaire and the visual analog pain scale (VAS). On follow-up, patients' response to pain sensation, their need of analgesics and duration of analgesic use were also recorded. All patients undergoing surgery had previously been treated with conservative management for a minimum period of 6 months, and all had shown a positive preoperative response to discography. All operations were performed using an anterior approach, approaching the disc space retroperitoneally whenever possible. The patients were all positioned supine in the "French position". As is our practice, all operations were performed using less invasive techniques. Postoperatively, all patients underwent physiotherapy within 1 week of operation. They were also required to wear a lumbar corset for a maximum of 3 months.

Severe osteoporosis, physiological dysfunction, history of previous disc infection, severe posterior element pathologies, fracture of the vertebra, and tumor were deemed to be contraindications, and formed the basis for exclusion criteria.

Statistical analysis was performed using the *t*-test and chi-squared test.

Results

From the analysis obtained preoperatively and during the follow-up period, the overall clinical outcome was deemed to be excellent in 98 patients (90.8%), good in 8 patients

Fig. 1 Clinical outcome: overall results

Fig. 2 Average patient satisfaction with outcome correlated with "prime", "good", and "borderline" indications

(7.4%), fair in 2 patients (1.8%), and poor in none (0%). Of the two patients who had fair results, both had advanced disc degeneration also involving the adjacent levels and secondary osteoarthritis of the facet joints.

Postoperatively, nine patients had residual leg pain or back pain including facet joint pain. There were 45 patients who required analgesics for more than 2 weeks, 12 of whom required regular analgesics for a period ranging from 6 months to 1 year, and 33 patients required analgesics only occasionally. Immediate postoperative complications were noted in only one patient, in the form of systemic septicemia, which resolved with a course of antibiotics. This was not, however, related to the surgery. The patients were able to resume their activities of daily living unaided after an average of 2.3 weeks (range 1.5–3.2 weeks) ($P < 0.001$).

Table 1 Indication criteria of categories for full disc replacement (OA osteoarthritic)

Indications	Disc levels	Accompanying features
Prime	Single level	>4 mm remaining disc height No OA changes to facet joints No adjacent level degeneration Intact posterior elements
Good	Single level/ double level	>4 mm remaining disc height No primary OA changes to facet joints Minimum degeneration of adjacent discs Minimum posterior segment instability, e.g. post microdiscectomy
Borderline	Single/double/ triple level	<4 mm remaining disc height Primary OA changes to facet joints Minimum adjacent level degeneration Minimum posterior segment instability Adjacent to fusions
Poor	Single/double/ triple level	Gross degeneration of the spine Secondary OA changes to the facet joints <4 mm disc height remaining at the adjacent levels Posterior segment instability

There were 54 patients who were on follow-up for more than 1 year, 35 of whom were able to resume work at the same level as prior to surgery, 17 were able to resume work at a lower level than prior to surgery, and 2 patients were unable to return to work due to residual back or leg pain ($P>0.005$). The average range of vertebral motion at the L5/S1 operated levels was 9° (range 2° – 13°), at the L4/L5 levels it was 10° (range 9° – 13°), at L3/L4 it was 10° (range 8° – 15°) and at L2/L3 it was 12° (range 9° – 15°). The average range of vertebral motion at the adjacent segments compared to the preoperative range of motion was: decreased range 5° (range 3° – 8°) (6 patients), increased range 6° (range 3° – 8°) (86 patients), and it was unchanged in 16 patients. Analysis also showed that, postoperatively, all patients had an increase in the average range of motion at the operated levels. Twelve of those who showed no change in the average range of motion at the adjacent levels had presented with advanced degenerative disc disease prior to surgery, and four had

secondary changes of the facet joints in addition to advanced degenerative disc disease prior to surgery. In these patients, the average preoperative range of motion at the operated segment was 4° (range 2° – 6°), and postoperatively, the range of motion averaged 7° (range 5° – 10°). Progression of disc degeneration at the adjacent levels was noted in five patients (4.6%); at L5/S1 levels in three of them and at L4/L5 levels in two ($P=0.003$). It was also noted that all the patients who had progression of disc degeneration had presented with an anterior disc height of less than 7 mm prior to surgery. We correlated the outcome of the surgery with the indications (number of degenerate discs and the accompanying features), and then categorised the indications from “prime”, which correlated with the best outcomes, to “borderline” and “poor”, which were associated with the least satisfactory results (Fig. 1, Fig. 2, Table 1).

The average level of patient satisfaction with outcome in the prime category was 98% (range 96%–99%); it was

Fig. 3 Case 1 (prime indication): a 44-year-old woman with vertical instability and severe low-back pain, who had previously undergone unsuccessful conservative treatment

Fig. 4 Case 2 (good indication): a 30-year-old man with radicular symptoms at L4, L5, and severe low-back pain. He had previously undergone unsuccessful percutaneous nucleotomy treatment at L5/S1, as well as unsuccessful conservative treatment

Fig. 5 Case 3 (borderline indication): 53-year-old man with vertical segmental instabilities at L3-S1, radicular symptoms at L4, L5, and severe low-back pain. He had previously undergone unsuccessful conservative treatment

93% in the good category (range 89%–97%) and 83% in the borderline category (range 79%–88%).

Radiographic evaluation during follow-up did not show any implant loosening or subsidence of the prosthesis, nor was there any structural failure of the implants, such as rupture of the plate or expulsion of the polyethylene. Examples of cases in various categories are given in Fig. 3, Fig. 4 and Fig. 5.

Discussion

This prospective study was carried out in order to analyze the effectiveness of a prosthetic disc replacement in degenerative discs of various indications and stages of degeneration, so as to formulate indication criteria for total disc replacement surgeries for degenerative disc disease.

Since the early work of Fernström in the late 1960s, who explored the possibility of replacing the diseased intervertebral disc with a prosthetic device, much work has been done in this field in terms of research and development of designs [1, 3, 9, 17, 20, 22]. Early clinical trials

on humans [5, 6, 8, 10, 15, 26, 29] have shown varying degrees of optimism. Nevertheless, the need for a better treatment modality has been emphasized by studies showing the unwarranted sequelae of present treatment modalities, especially those following spinal fusion [4, 16, 21]. It has been postulated that an ideally performed total disc replacement would eliminate untoward results of disc surgery, such as instability pain, stenosis, pseudoarthrosis, accelerated degeneration of the adjacent segment and spondylosis, to name a few that may be encountered in other treatment modalities [23, 25, 27, 30]. In addition, it has also been postulated that such a device may have a protective role on the facet joints, as suggested by Hedman et al. [17]. Overcoming the long-term unwarranted outcomes, while at the same time restoring the lumbar motion segment would be most welcome.

In 1991, in his series using the SB Charité artificial disc prosthesis, Zippel reported 54% very good results, 29% improved, 15% unchanged and 2% poor results. Further studies done by Zippel and also by Fernström have all failed to address the status of the posterior elements, particularly the facet joints [12, 30]. This is an important

point, not to be overlooked when performing a total disc replacement, especially when the posterior elements have been shown to carry at least 18% of the compressive loads and resist one-third of the shear forces of the functional motion segment. As the facet joints also serve the kinematics function of guiding segmental spinal motion, better results would naturally be obtained in cases that have less facet joint degeneration or before secondary osteoarthritic changes of the facets are noted. In the same context, preserving the posterior longitudinal ligament is also desired, as this adds to the load sharing device in concert with the posterior elements [2, 7, 18]. From the results obtained in our series, we concur with the study by Kilkardy-Willis [19], that the best results of a prosthetic disc replacement are obtained in patients with disc degeneration before secondary changes in the facet joints are seen, otherwise progression of the degenerative process of the facet joints leads to instability. Though advanced disc degeneration may pose a challenge in total disc replacement, we have found that in such cases alone, resection of the posterior longitudinal ligament facilitates the mobilization of the segment. The analysis of our results, with varying follow-up periods and scenarios, has shed some light on the indications for a total disc replacement with a prosthesis in degenerative disc disease. This has helped us in formulating an indication criterion for total disc replacement surgeries, which we have subdivided into four categories (Table 1).

In accordance with this, the contraindications for a total disc replacement surgery would be: osteoporosis or other osteopathy that results in a reduced load-bearing capacity of the vertebral body endplates, and generally all severe dorsal pathologies, e.g. spondylolisthesis or hyper-

trophic facet joints with secondary spinal stenosis, fractures, infection and tumors. Using these basic guidelines, we believe that a more favorable outcome may be obtained for total disc replacement surgeries, putting emphasis on better patient selection and indications.

Conclusion

In conclusion, from the overall favorable results obtained in our series, we strongly believe that total disc replacement with a prosthetic disc is a good treatment option for degenerative disc disease of the spine, provided the proper criteria are adhered to in patient selection. The early results presented here, which were obtained under study conditions, though lacking in the duration of follow-up of for a portion of the patients, nevertheless allow a great deal of optimism regarding this mode of therapy. However, it should be emphasized that not all patients with degenerative disc disease will be ideal candidates for disc replacement. As we encountered in our series, the best results were seen in the prime and good indications. The overall outcome of disc replacement surgeries may be compromised by the inclusion of patients with borderline and poor indications. Hence, great emphasis should be placed on the indications, especially for surgeons who are new to such operations. It is also pertinent to continue to critically judge and closely follow the progress of this treatment modality, in order to ascertain whether the good short-term results are also demonstrated in the long term. More prospective multicenter studies would be helpful in order to better evaluate the outcome of total disc replacement surgeries for degenerative disc disease.

References

- Aharinejad S, Bertagnoli R, Wicke K, Schneider B (1990) Morphometric analysis of vertebra and intervertebral discs as a basis of disc replacement. *Am J Anat* 189:69–76
- Bertagnoli R (1992) Ergebnisse der dorsoventralen stabilisierungsverfahren beim Postnucleotomiesyndrom und bieausgeprägten osteochondrotischen Veränderungen im Lumbalbereich. In: Matzen KA (ed) *Wirbelsäulen Chirurgie*, vol II. Thieme, Stuttgart, pp 234–248
- Bertagnoli R (2001) Continuum of care in degenerative disc disease. *Back Up* 1:4–8
- Brodsky AE (1976) Post-laminectomy and post-fusion stenosis of the lumbar spine. *Clin Orthop* 115:130
- Büttner-Janz K, Schellnack K, Zippel H, Conrad P (1988) Experience and results with the SB-Charité lumbar intervertebral endoprosthesis. *Z Klin Med* 43:1785–1789
- Cinotti G, David T, Postacchini F (1996) Results of disc prosthesis after a minimum follow-up of 2 years. *Spine* 21:995–1000
- Cryon BW, Hutton WC (1980) Artificial tropism and stability of the lumbar spine. *Spine* 5:168–172
- David T (1993) Lumbar disc prosthesis: surgical technique, indications and clinical results in 22 patients with a minimum of 12 months follow-up. *Eur Spine J* 1:254–259
- Eljkelkamp MF, Dankelaar Van CC, Veldhuizen AG, Horn Van J R, Huyghe JM, Verkerke GJ (2000) Requirements for an artificial intervertebral disc. *Int J Artif Organs* 24:311–321
- Enker P, Steffee A, Mcmillin C, Kessler L, Biscup R, Miller S (1993) Artificial disc replacement. Preliminary report with a 3-year minimum follow-up. *Spine* 18:1061–1070
- Etsuro Y, Kasuhiro C, Yoshiaki T, Kiyoshi H (2001) Long-term study of standard discectomy for lumbar disc herniation. A follow-up study of more than 10 years. *Spine* 26:652–657
- Fernström U (1996) Arthroplasty with intercorporeal endoprosthesis in herniated disc and painful disc. *Acta Chir Scand* 357 [Suppl]:154–159
- Feymore JW, Hanley EN Jr, Howe J, Kuhlmann D, Matteri RE (1979) A comparison on radiographic findings in fusion and non-fusion patients 10 or more years following lumbar discal surgery. *Spine* 4:435–440
- George AL, Konstantinos S, Paul GK, George S, Dimitrios SK, George H (1999) Seven to 20-year outcome of lumbar discectomy. *Spine* 24:2313–2317

-
15. Griffith FL, Shelokof AP, Buttner-Janz K, LeMrie JP, Zeegers WS (1994) A multicenter retrospective study of the clinical results of the link SB Charité intervertebral prosthesis. *Spine* 19: 1842–1849
 16. Harris RI, Wiley JJ (1963) Acquired spondylolysis as a sequel to spine fusion. *J Bone Joint Surg Am* 45:1159
 17. Hedman TP, Kostuik JP, Fernie GR, Hellier WG (1991) Design of an intervertebral disc prosthesis. *Spine* 16 [Suppl 1]:256–260
 18. King AL, Prasad P, Ewing CL (1975) Mechanism of spinal injury due to cephalocaudal acceleration. *Orthop Clin North Am* 6:19–31
 19. Kirkaldy-Willis WH, Burton CV (1992) *Managing low back pain*, 3rd edn. Churchill Livingstone, New York, pp 105–119
 20. Langrana LA, Lee CK, Yang SW (1991) Finite element modeling of the synthetic intervertebral disc. *Spine* 16 [Suppl 6]:245–252
 21. Lee CK (1988) Accelerated degeneration of the segment adjacent to a lumbar fusion. *Spine* 13:375–377
 22. Lee CK, Langrana LA, Parsons JR, Zimmerman MC (1991) Development of a prosthetic intervertebral disc. *Spine* 16 [Suppl 6]:253–255
 23. Lee CK, Parsons JR, Langrana LA, Zimmerman MC (1992) Relative efficacy of the artificial disc versus spinal fusion. In: Weinstein JN (ed) *Clinical efficacy and outcome in the diagnosis and treatment of low back pain*. Raven Press, New York, pp 237–244
 24. Lehman TR, Spratt KF, Tozzi JE, et al (1987) Long-term follow-up of lumbar fusion patients. *Spine* 12:97–104
 25. Ray CD (1992) The artificial disc: introduction, history and socioeconomics. In: Weinstein JN (ed) *Clinical efficacy and outcome in the diagnosis and treatment of low back pain*. Raven Press, New York, pp 205–226
 26. Sott AT, Harrison DJ (2000) Increasing age does not affect good outcome after lumbar disc replacement. *Int Orthop* 24:50–53
 27. Steffee AD (1992) The Steffee artificial disc. In: Weinstein JN (ed) *Clinical efficacy and the outcome in the diagnosis and treatment of low back pain*. Raven Press, New York, pp 245–258
 28. Vijay KG, Nishima K, Weinstein JN, King YL (1986) Mechanical properties of the lumbar spinal motion segments as affected by partial disc removal. *Spine* 11:1008–1012
 29. Zeegers WS, Bohnen LM, Laaper M, Veerhaegen MJ (1999) Artificial disc replacement with modular type SB Charité. III. 2-year results in 50 prospectively studied patients. *Eur Spine J* 8:375–377
 30. Zippel H (1991) ‘Charité modular’: conception, experience and results. In: Weinstein JN, Mayer HM, Weigel K (eds) *The artificial disc*. Springer, Berlin Heidelberg New York, pp 69–78