SPINE Volume 30, Number 19, pp 2230–2236

The Treatment of Disabling Single-Level Lumbar Discogenic Low Back Pain With Total Disc Arthroplasty Utilizing the Prodisc Prosthesis

A Prospective Study With 2-Year Minimum Follow-up

Rudolf Bertagnoli, MD,* James J. Yue, MD,† Rahul V. Shah, MD,† Regina Nanieva, BA,‡ Frank Pfeiffer, MD,‡ Andrea Fenk-Mayer, MD,‡ Trace Kershaw, PhD,§ and Daniel S. Husted, MD†

Study Design. Prospective, longitudinal minimum 2-year follow-up.

Objective. To assess the efficacy and safety of the Prodisc implant in patients with disabling single-level discogenic low back pain (LBP).

Summary of Background Data. The treatment of debilitating discogenic LBP has been controversial and varied. To date, a longitudinal prospective study of the treatment of single-level incapacitating discogenic LBP using the Prodisc total disc arthroplasty technique has not been described.

Methods. A prospective analysis was performed on 118 patients treated with single-level lumbar Prodisc total disc arthroplasty. Patients 18 to 60 years of age with disabling and recalcitrant discogenic LBP with or without radicular pain secondary to single-level discogenic LBP from L3 to S1 were included. Patients were assessed before surgery, and outcome measurements were after surgery administered at 3, 6, 12, and 24 months.

Results. A total of 104 patients (88%) fulfilled all follow-up criteria. The median age of all patients was 47 years (range, 36–60 years). Statistical improvements in VAS, Oswestry, and patient satisfaction scores occurred 3 months postoperatively. These improvements were maintained at the 24-month follow-up. Radicular pain also decreased significantly. Full-time and part-time work rates increased from 10% to 35% and 3% to 24%, respectively. No additional fusion surgeries were necessary either at the affected or unaffected levels. Radiographic analysis revealed an affected disc height increase from 4 mm to 13 mm ($P < 0.001$) and an affected disc motion from 3° to 7° ($P < 0.004$).

Conclusions. Single-level Prodisc lumbar total disc arthroplasty is a safe and efficacious treatment method for debilitating lumbar discogenic LBP. Significant improvements in patient satisfaction and disability scores occurred after surgery by 3 months and were maintained at the 2-year follow-up. No device-related complications occurred. Patients with severe to moderate disc height loss as well as those with symptomatic posterior anular defects with minimal disc height loss achieve functional gains and significant pain relief. Careful and appropriate patient selection is essential in ensuring optimal surgical outcomes.

Key words: low back pain, discogenic back pain, disc replacement, disc arthroplasty, Prodisc. **Spine 2005;30: 2230–2236**

A moderate amount of experience has been accumulated with various forms of spinal surgery, in particular arthrodesis procedures, for the treatment of chronic discogenic low back pain.[1–7] Prospective studies have revealed fusion rates and patient satisfaction scores of approximately 75%.[7–11] Results have been noted to vary with respect to age, smoking status, Worker's Compensation, and others.[12] Consequently, artificial disc replacement has been proposed as a substitute for spinal fusion with the aim of treating back pain while preserving vertebral motion at the operated levels and protecting adjacent levels from undergoing degenerative changes.

Few prospective studies have been published on the results of lumbar total disc replacement.[13,14] Moreover, these studies are based on 1) short-term follow-up periods; 2) surgeries done by multiple surgeons; and 3) non-independent evaluation of the study data. To the best of our knowledge, there has been no long-term prospective literature on the Prodisc lumbar prosthesis specifically focused on single-level lumbar disease. The goals of the present prospective study are: 1) to evaluate changes in functional and disability outcomes in a prospective cohort of patients that have received the Prodisc lumbar disc replacement for single-level degenerative disc disease with minimum follow-up of 2 years; 2) to further elucidate the indications for lumbar disc replacement; and 3) to evaluate any unknown contraindications and/or complications of this treatment modality.

Although a review of some of the alternative forms of treatment will be discussed in later sections, due to the preliminary and empiric nature of our study, a compar-

From the *St. Elizabeth Klinikum, Spine Center, Straubing, Germany; †Department of Orthopaedic Surgery and Rehabilitation, Yale University, New Haven, CT; ‡Department of Orthopaedic Surgery, Spine Center, St. Elizabeth Klinikum, Straubing, Germany; and §School of Public Health, Yale University, New Haven, CT.

Acknowledgment date: December 16, 2003. First revision date: March 5, 2004. Second revision date: July 5, 2004. Third revision date: October 13, 2004. Acceptance date: November 1, 2004.

The device(s)/drug(s) that is/are the subject of this manuscript is/are not FDA-approved for this indication and is/are not commercially available in the United States.

No funds were received in support of this work. Although one or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript, benefits will be directed solely to a research fund, foundation, educational institution, or other nonprofit organization which the author(s) has/have been associated.

Address correspondence and reprint requests to James J. Yue, MD, Yale University School of Medicine, Department of Orthopaedic Surgery and Rehabilitation, 800 Howard Avenue, P.O. Box 208071, New Haven, CT 06520; E-mail: james.yue@yale.edu

ison or superiority/inferiority analysis is not a main objective of our present study. Such a report will be presented in forthcoming analyses at 10- and 15-year follow-up periods when such relative comparisons are a more pertinent objective.

■ Methods

Patient Evaluation. Prospective data were compiled for single-level Prodisc procedures from March 2000 to December 2001. Patients 18 to 60 years of age were entered into this study. These patients demonstrated disabling discogenic low back pain with or without radicular symptoms resulting from degenerative disc disease from L3 to S1 as confirmed on magnetic resonance imaging, computed tomography, and, when indicated, discography. Only patients with complete 2-year follow-up data were included for analysis.

Exclusionary criteria included: patients with spinal stenosis, osteoporosis, prior fusion surgery, chronic infections, metal allergies, pregnancy, facet arthrosis, inadequate vertebral endplate size, more than one level of spondylosis, neuromuscular disease, pregnancy, Worker's Compensation, spinal litigation, body mass index greater than 35, and/or any isthmic or degenerative spondylolisthesis greater than Grade 1. All patients had failed conservative treatment for a minimum of 9 months.

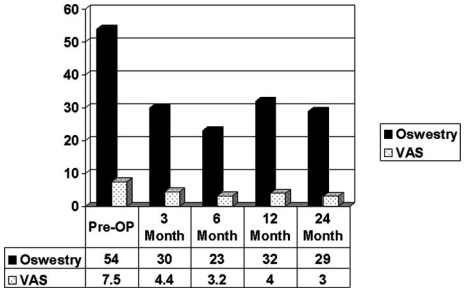
Surgery was performed after a complete radiographic assessment had been performed in all patients including anteroposterior (AP), lateral/flexion, extension/lateral bending radiographs, computerized tomography, and magnetic resonance imaging. All patients received CT scans to evaluate in particular the degree of facet degenerative changes. Patients with evidence of intra-articular facet degeneration, specifically evidence of joint space narrowing with or without cystic changes, were excluded from the study. Patients with minimal extra-articular facet changes (calcifications) were not excluded. Discography was used only in patients with questionable multilevel spondylosis findings on magnetic resonance imaging and/or in the setting of minimal disc height loss and a question of a chronically symptomatic anular tear. Positive discography was defined as concordant pain with at least a rating of 6 out of 10 and an abnormal postdiscography CT scan contrast pattern (*i.e.*, anular tear, disc extrusion). All procedures were performed by the senior author (R.B.) at a single tertiary care Level 1 institution (St. Elizabeth's Klinikum, Straubing, Germany). Bias as to outcome was avoided with the use of primary outcome measurements determined by patient responses to questionnaires. Secondary parameters requiring measurements such as disc height of affected level, adjacent level disc height, and motion were performed by a trained technician. The data were collected and compiled by an independent technician (R.N.). After the above data had been compiled, it was analyzed by an independent examiner (J.J.Y.) who had no interaction with the patients or involvement with the surgical procedures at anytime during this study.

Surgical Technique. The surgical approach was consistent, with the patient in a supine position on a fluoroscopic imaging table with legs and arms abducted with the surgeon working between the patient's legs. Fluoroscopy was obtained in AP and lateral plane to determine level of diseased disc and obliquity of lordosis before incision. A transverse incision for L5–S1, or longitudinal incision for all other levels, was then made at the marked level of diseased disc. A standard right sided median retroperitoneal approach to L5–S1, and left-sided median retroperitoneal approach for all other levels, was then performed by the senior author exposing the level of disease. The access portion of the surgery was performed by the primary surgeon (R.B.) in each case. No additional access surgical assistance (*i.e.*, vascular, urological, general surgery) was used. Exposure was assisted with the use of a specialized anterior spinal retractor system, SynFrame (Synthes Spine, Paoli, PA). A complete single-level anterior discectomy was performed. When indicated, the posterior longitudinal ligament was released in order to remove extruded disc material and/or to obtain appropriate intervertebral disc height. Only the cartilaginous portion of the vertebral endplate was removed. Preparation of the endplates was performed by using standard and ring curettes and endplate elevators. A burr was used only when endplate leveling could not be achieved with appropriate curettes.

Trialing was performed to make the assessment of appropriate size with regards to height and AP diameter using assistance of lateral fluoroscopy. Adequate central/midline location of prosthesis was confirmed using AP fluoroscopy before administration of keel cuts. After the midline was determined, keel cuts were made using the keel cutting chisel guided over the prosthesis trial. The chisel and trial were then removed, and the appropriate-sized final prosthetic endplates were inserted to an adequate depth under lateral fluoroscopic control. The endplates were then distracted and the polyethylene implant was inserted. Following this, AP and lateral fluoroscopy confirmed appropriate prosthesis positioning and size. No other procedures were performed at the time of the index procedure.

Outcome Measurement. Patients were assessed before surgery and after surgery 3, 6, 12, and 24 months. The primary functional outcomes assessed before and after surgery were disability and pain scores using the Oswestry Disability Index[15] and the visual analog score. Additional clinical parameters included analysis of preoperative and postoperative patient satisfaction, general back pain, radicular pain, medication usage, and complications. Patient satisfaction was rated as follows: 1, completely satisfied (pain absent at all times and unimpaired employment and activities of daily living [ADL]); 2, satisfied (slight pain that requires no medication and that occurs no more than once per day, minimal impairment in employment or ADL); or 3, unsatisfied (pain that occurs more than one time per day, requires medication and results in changes in ADL and employment). Back pain, radicular pain, and medication usage were rated as follows: 1, none; 2, occasional (less than 1 time per day); and 3, regular (greater than 1 time per day).

Radiographic Assessment. Preoperative and postoperative radiographs were obtained in all patients including standing AP, lateral, flexion and extension, and lateral bending films. Detailed measurements of intervertebral disc heights of affected and adjacent levels, angular intervertebral disc motion, subsidence, pelvic tilt and incidence, and sacral slope were obtained by using digitized images and appropriate computer software (Medimage Software, Vepro Computersysteme GmbH, Pfungstadl, Germany). Measurements were performed three times, and an average score was obtained for angular and length measurements. These angular and length measurements were performed by a single reviewer. Two separate reviewers (attending spinal surgeon not involved in surgery and attending radiologist) reviewed all pertinent radiographs for device-related loosening, dislodgement, and/or subsidence.



	Pre-OP	3 Month	6 Month	12 Month	24 Month
Oswestry	54	30	23	32	29
VAS	7.5	4.4	3.2	4	3

Figure 1. Oswestry (%) and VAS scores.

Statistical Analysis. To assess changes over time, repeated measures general linear models (GLM) were conducted for the continuous variables (Oswestry and VAS) and generalized estimating equations (GEE) were conducted for patient satisfaction and back pain. Three research questions were of primary interest for this study: 1) whether there was a significant change from presurgery to 3-month post surgery (proximal effect), 2) whether that change was sustained 2 years postsurgery (distal effect), and 3) whether there was continued change from 3 months to 2 years postsurgery. Therefore, three planned contrasts were conducted within the GLM and GEE analyses: 1) comparing scores from presurgery to 3 months postsurgery, 2) comparing presurgery to 24 months postsurgery, and 3) comparing 3 months postsurgery to 24 months postsurgery. Preoperative patient satisfaction scores were not made. Therefore, overall time effect was used to assess whether there were overall changes from the 3- to 24-month follow-up.

■ Results

Demographic

A total of 104 of a possible 118 patients fulfilled all follow-up criteria. Seven patients could not be examined after surgery because their permanent addresses were outside of Germany. Questionnaires (Oswestry, VAS, patient satisfaction, medication usage, and back pain rating) were sent to these 7 patients. No adverse events or additional procedures were necessary in these patients. Two patients did not comply with appropriate follow-up visits and 1 patient's preoperative data were lost. The median follow-up time was 31 months (range, 24–45 months). There were 47 males and 57 females. The median age for both gender groups was 47.5. The median duration of pain before surgery was 104 months (median, 70 months; range, 6–400 months). Fifty-seven percent of patients had prior posterior surgery at the affected levels. Thirty-one percent of patients were smokers. The predominant level of surgery was L5–S1 (80). The remaining levels were L4–L5 (17) and L3–L4 (7). Five cases were performed in patients that had either a missing rib at T12 or a lumbarized S1 vertebra. A total of 62 patients (58%) had prior partial nucleotomy surgery. Forty-five patients had no previous surgery. The median operative time was 81 minutes (range, 52–135 minutes). Median blood loss was 100 mL (range, 50–200 mL).

Table 2. Back Pain (%)

	Preop	3 Mos	6 Mos	12 Mos	24 Mos
No pain	0	21.3	22.8	28.7	32.0
Occasional pain	15.3	67.0	62.4	59.4	59.2
Regular pain	84.6	11.6	14.8	11.9	9.0

Clinical Outcomes

Clinical outcomes are summarized in Figure 1 and Tables 1 to 4. Preoperative Oswestry disability scores decreased from 53% to 29% at the 2-year follow-up. Results of the planned contrasts using repeated measures GLM analysis showed significant decrease in Oswestry disability scores from preoperative to 3-month follow-up, $F(1,103) = 132.80$, $P < 0.001$, $\eta^2 = 0.56$. That change was sustained at the 2-year follow-up, $F(1,103) = 113.71$, $\eta^2 = 0.53$, $P < 0.001$. However, there was no significant change from 3-month to 2-year follow-up, $F(1,103) = 0.71$, $P = 0.79$, $\eta^2 = 0.00$, indicating that the decrease in disability score occurred primarily by 3 months after surgery. Overall, VAS decreased from 7.6 to 3 at the 2-year follow-up. Similarly, preoperative visual analog scores showed significant decreases compared with the 3-month follow-up, $F(1,103) = 222.64$, $P < 0.001$, $\eta^2 = 0.68$. That change was sustained at 2-year follow-up, $F(1,103) = 161.361$, $\eta^2 = 0.61$, $P < 0.001$.

Patient satisfaction levels were 93.2% satisfied or completely satisfied at the 3-month follow-up and 96.0% satisfied or completely satisfied at the 2-year follow-up. However, there was no significant change in patient satisfaction from 3-month to 24-month follow-up using GEE analyses, $\chi^2(1) = 3.49$, $P = 0.07$. Ninety-one percent of all patients reported no back pain or occasional back pain at the 2-year follow-up. GEE analyses with planned contrasts showed a significant decrease in constant back pain from preoperation to the 3-month follow-up, $\chi^2(1) = 61.63$, $P < 0.001$. This decrease was sustained at the 2-year follow-up, $\chi^2(1) = 40.87$, $P < 0.001$. However, there was no significant change from the 3-month to 2-year follow-up, $\chi^2(1) = 0.10$, $P = 0.76$. Therefore, decreases in constant pain occurred by 3 months postoperation and did not significantly change from 3 months to 24 months after surgery.

Table 1. Patient Satisfaction (%)

	3 Mos	6 Mos	12 Mos	24 Mos
Completely satisfied	59.2	57.8	55.4	58.3
Satisfied	34.0	27.4	32.8	38.5
Unsatisfied	4.8	14.7	11.9	3.1

Table 3. Radicular Pain (%)

	Preop	3 Mos	6 Mos	12 Mos	24 Mos
No pain	11.9	53.6	60.4	45.2	62.6
Occasional pain	45.5	36.1	28.6	41.6	29.5
Regular pain	42.6	10.3	11.0	13.2	8.8

Table 4. Medication Usage (%)

	NSAIDs		Narcotics		Tramadol	
	Preop	24 Mos	Preop	24 Mos	Preop	24 Mos
None	5.8	59.0	83.0	90.0	74.0	79.0
Occasional pain	23.7	12.0	0	0.1	4.9	7.8
Regular pain	49.5	28.7	15.8	8.9	21.0	12.8

Before surgery, 42.6% of patients had either regular or intermittent leg pain. At the 2-year follow-up, 8.8% of patients reported regular leg pain. Medication usage, including nonsteroidal anti-inflammatories, narcotics, and morphine derivatives (Tramadol), was decreased significantly compared with preoperative usage rates. Employment patterns following surgery revealed a threefold increase in full-time, a fourfold increase in part-time employment, and a fivefold decrease in the number of patients who were not working for more than 6 months.

With regards to patients who had previous surgery and in those who had not had surgery, there was no difference in clinical outcome scoring. Indeed, all 3 patients who remained dissatisfied with their outcomes were in patients who had had no prior surgery.

Radiographic Analysis

The median preoperative height of the affected discs was 4 mm. Four fifths of patients had at least 75% disc height loss compared with adjacent normal levels (Figure 2A). One fifth (21 patients) had minimal to moderate disc height loss but had a concomitant chronic and severely symptomatic posterior anular tear with associated disc material extrusion as evidenced on discography (Figure 2B). An example of a postoperative radiograph is illustrated in Figure 3.

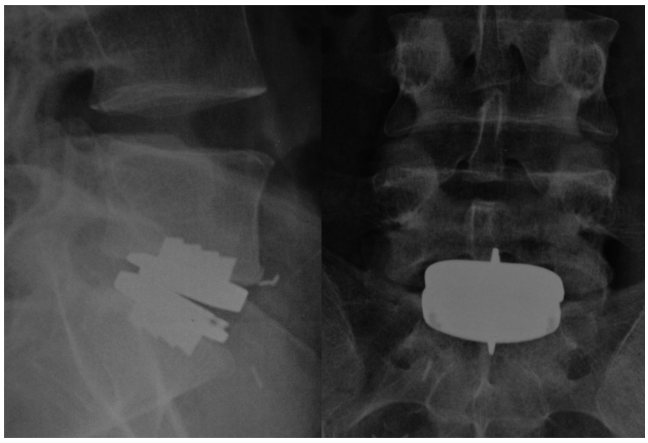


Figure 3. Postoperative radiographs.

After surgery, disc heights were increased to a median height of 13 mm ($P < 0.001$). Motion of the affected discs was increased from 3° before surgery to 7° after surgery ($P < 0.004$). The heights of the adjacent level discs were not significantly changed. No correlation was determined to exist between clinical outcome and pelvic incidence, tilt, or sacral slope (Figure 4). There were no cases of subsidence, loosening, dislocation, or failure of metallic or polyethylene components.

Complications

Device-Related Complications. We report no device-related complications. In this study, there were no cases

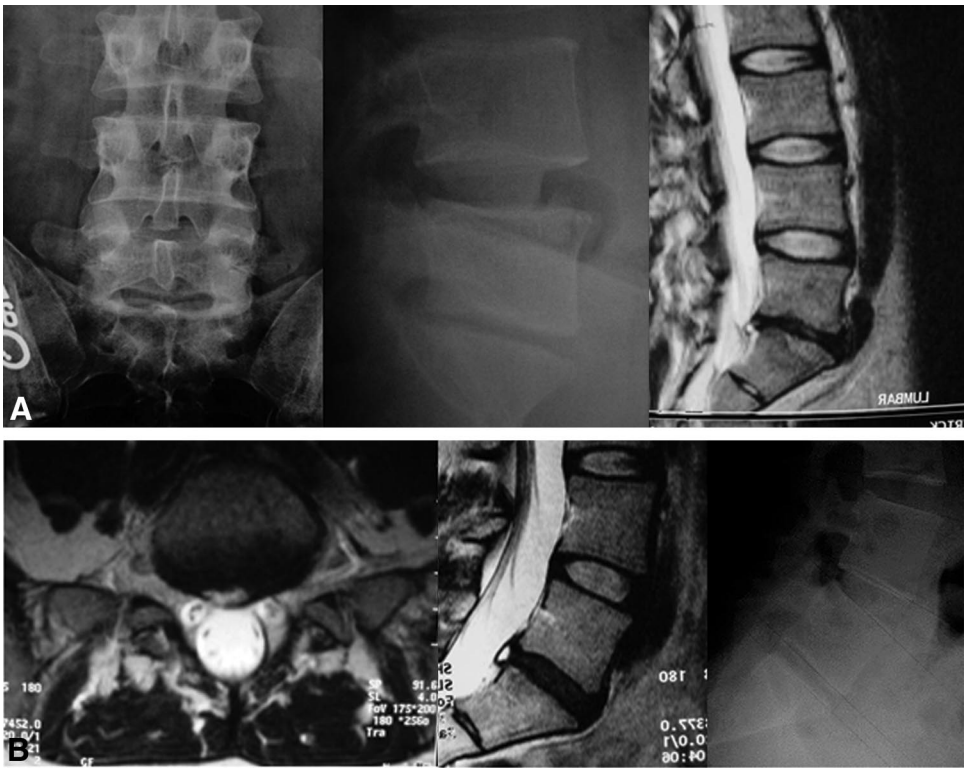


Figure 2. **A**, Preoperative imaging of patient with severe disc height loss (see Figure 3 for postoperative radiographs). **B**, Preoperative imaging of patient with minimal disc height loss and chronic herniated inflammatory granulation tissue.

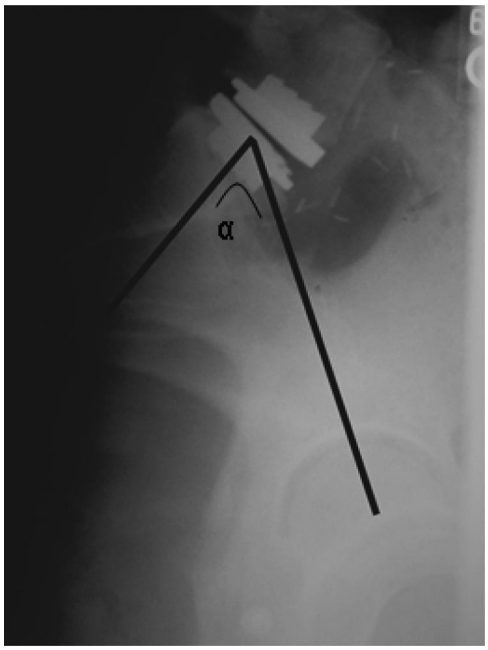


Figure 4. Pelvic inclination (PI) measurement. PI had no effect on clinical or radiographic outcomes.

of loosening, subsidence, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurologic injuries caused by the implant components, and/or infection

Approach-Related Complications. Two cases of retroperitoneal hematomas and a single subcutaneous hematoma were diagnosed in the perioperative period. The 2 cases of retroperitoneal hematomas were diagnosed early in our series using abdominal ultrasound. General surgical patient on-call coverage performed decompressions in both cases. Symptoms before drainage were limited to lower abdominal pain only. After these 2 early cases, no other retroperitoneal hematomas were identified and no other secondary procedures were performed on any patients. The subcutaneous hematoma was evacuated percutaneously. We also report 1 case of retrograde ejaculation that recovered spontaneously at 6.5 months after surgery. No cases of vascular injury, ureteral injury, or neurologic injury occurred.

A single patient had persistent leg pain following application of an L5–S1 implant that required posterior exploration and decompression. Posterior foraminal exploration revealed posterior subarticular stenosis. The patient continued to be unsatisfied with her outcome at 32 months post index procedure.

■ Discussion

The treatment of chronic and debilitating low back pain associated with degenerative changes of intervertebral discs has been the focus of many treatment regimens, including nonoperative[16,17] as well as operative (nonfusion and fusion) methods.[4,6,7,10,18–27] Fritzell *et al*[18] in 2001 published Level 1 controlled and randomized data comparing nonoperative *versus* operative (fusion) treatment methods and concluded that "lumbar fusion in a well-informed and selected group of patients with severe CLBP can diminish pain and decrease disability more efficiently than commonly used nonsurgical treatment." Specifically, back pain was reduced by 33% *versus* 7% in the fusion *versus* nonoperative treatment groups. Oswestry scores were reduced by 25% in the fusion group *versus* 6% in the nonoperative group. Sixty-three percent of the fusion patients rated themselves as either much better or better *versus* only 29% in the nonoperative group. Thirty-six percent of patients in the fusion group returned to work *versus* only 13% in the nonoperative group.

In comparison, our preliminary data using the ProDisc ADR surgery reveals a median reduction in pain measured by VAS of 41%, a median reduction in Oswestry disability scores of 24%, satisfaction rates of 96% at the 2-year follow-up, and a return to work rate of up to 50%. We think that our data compare favorably with the fusion and nonoperative treatment groups as presented by Fritzell *et al*[18] as well as other published study cohorts.[7,9]

The use of total disc arthroplasty for debilitating discogenic low back pain has been under investigation for more than approximately 20 years.[13,28–42] The impetus behind spinal disc arthroplasty technology has been largely driven by the unsatisfactory outcomes following spinal fusion both at affected levels and also at adjacent levels. Studies have reported that following lumbosacral fusion there can be an initiation or acceleration of the degeneration of the discs at the adjacent levels.[23,43–45] Others have reported that the exaggerated motions and forces at the adjacent level can result in an acquired spondylolysis.[46–48]

A number of studies in the English and German literature have investigated the use of other lumbar disc arthroplasty techniques.[13,14,34,35,38–40,42,49,50] The majority of these studies are retrospective, concurrently analyze both single and multilevel cases, involve multiple surgeons and centers, have less than 2-year follow-up, and/or do not have an independent evaluator. In the present study, we present 2-year prospective data on the Prodisc lumbar implant. Design deficits in our study include the lack of a nonoperative control group and/or a randomized or historical study population. Pertinent strengths include: prospective analysis, single surgeon/single center procedures, independent data collection and input, as well as independent data evaluation.

Our clinical outcomes both in the immediate 3-month postoperative period and at the 2-year follow-up revealed a 96% rate of satisfaction or complete satisfaction. We think that these excellent results are a direct result not only due to the qualities of the implant, but moreover, of careful patient selection by an experienced low back surgeon. We found no difference in outcomes in patients who had had prior surgery and in those who had no previous surgery. In addition, the degree of preoperative disc height loss did not negatively or positively affect the clinical or radiographic outcomes in our patients.

Although we used strict inclusion and exclusion criteria, the predominant indication for disc replacement was unremitting, chronic discogenic back pain producing extensive and detrimental lifestyle, economic, and in some cases devastating psychological effects. Care should be used to assess patients for the presence of facet arthropathy, sacralized or lumbarized vertebrae or other congenital variants, and in those patients with pseudoarticulations of the L5 transverse process with the ilium. Although we think that the presurgical evaluation of the patient is one of, if not, the most critical factors for successful lumbar disc arthroplasty, there are other important factors we think also play a significant role. These factors include both implant design and biologic factors, which are also integral to achieving clinical success. The Prodisc implant appears to offer immediate postoperative implant stability because of its keel configuration both in patients who have had prior surgery and in those who have not.

Although we report 2-year follow-up data, we emphasize the need for longer follow-up studies. We view our data as primarily preliminary in nature and will be reporting our long-term data at 10 and 15 years. The authors emphasize that the genuine value of our present study will be obtained in these later studies. However, as empirical and preliminary data, our outcomes are comparable with present-day fusion and nonoperative standards and, we believe, are an encouraging milestone in the evolution of care of individuals with severe lumbar discogenic low back pain.

■ Conclusion

We recommend single-level Prodisc arthroplasty as a safe and efficacious treatment modality in patients with debilitating discogenic low back pain. We emphasize that prior experience with anterior approaches to the lumbar spine and complete anterior discectomy and mobilization of intervertebral disc spaces are essential to assure satisfactory outcomes. Prior posterior discectomy or laminectomy does not appear to affect outcomes. Patients with moderate or severe disc height loss can benefit from this procedure. In addition, patients with minimal disc height loss associated with chronic inflammatory granulation tissue also benefit. Preoperative pelvic incidence values have neither a positive or negative effect on outcomes.

■ Key Points

- Single-level lumbar discogenic back pain is effectively treated with Prodisc lumbar disc replacement.
- Pain is substantially decreased and function is improved following lumbar disc replacement.
- Prior posterior nonfusion surgery is not a contraindication to lumbar disc replacement.

References

1. Sarwat AM, O'Brien JP, Renton P, et al. The use of allograft (and avoidance of autograft) in anterior lumbar interbody fusion: a critical analysis. *Eur Spine J* 2001;10:237–41.
2. Liljenqvist U, O'Brien JP, Renton P, et al. Lumbosacral fusion using a femoro-cortical allograft ring [in German]. *Z Orthop Ihre Grenzgeb* 1998; 136:358–63.
3. Liljenqvist U, O'Brien JP, Renton P. Simultaneous combined anterior and posterior lumbar fusion with femoral cortical allograft. *Eur Spine J* 1998;7: 125–31.
4. Nachemson A, Zdeblick TA, O'Brien JP. Lumbar disc disease with discogenic pain: what surgical treatment is most effective? *Spine* 1996;21:1835–8.
5. Kozak JA, O'Brien JP. Simultaneous combined anterior and posterior fusion: an independent analysis of a treatment for the disabled low-back pain patient. *Spine* 1990;15:322–8.
6. O'Brien JP. The role of fusion for chronic low back pain. *Orthop Clin North Am* 1983;14:639–47.
7. Gibson A, Grant I, Waddel G. The Cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis. *Spine* 1999;24: 1820–32.
8. Schofferman J. A prospective randomized comparison of 270 degrees fusions to 360 degrees fusions (circumferential fusions). *Spine* 2001;26:E207–12.
9. Fritzell P. Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish lumbar spine study group. *Spine* 2002;27:1131–41.
10. France JC, Lauerman WC, et al. A randomized prospective study of posterolateral lumbar fusion: outcomes with and without pedicle screw instrumentation. *Spine* 1999;24:553–60.
11. Thomsen KCF, Eiskjaer SP, Hansen ES, et al. The effect of pedicle screw instrumentation on functional outcome and fusion rates in posterolateral fusion: a prospective randomized study. *Spine* 1997;22:2813–22.
12. Daniel JW, Fairbank JC, Vale PT, et al. Low back pain in the steel industry: a clinical, economic and occupational analysis at a North Wales integrated steelworks of the British Steel Corporation. *J Soc Occup Med* 1980;30: 49–56.
13. Hochschuler SH, Ohnmeiss DD, Guyer RD, et al. Artificial disc: preliminary results of a prospective study in the United States. *Eur Spine J* 2002;11(suppl 2):106–10.
14. Hopf C, Heeckt H, Beske C. Disc replacement with the SB Charite endoprosthesis: experience, preliminary results and comments after 35 prospectively performed operations [in German]. *Z Orthop Ihre Grenzgeb* 2002;140: 485–91.
15. Fairbank JC, Couper J, Davies JB, et al. The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980;66:271–3.
16. Smedley J, Inskip H, Cooper C, et al. Natural history of back pain: a longitudinal study in nurses. *Spine* 1998;23:2422–6.
17. Yelland M, Del Mar C, Pirozzo S, et al. Prolotherapy injections for chronic low back pain: a systematic review. *Spine* 2004;29:2126–33.
18. Fritzell P, Hagg O, Wessberg P, et al. 2001 Volvo Award Winner in Clinical Studies. Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine* 2001;26:2521–32; discussion 32–4.
19. Inoue S, Watanabe T, Hirose A, et al. Anterior discectomy and interbody fusion for lumbar disc herniation: a review of 350 cases. *Clin Orthop* 1984; 183:22–31.
20. Hagg O, Fritzell P, Nordwall A. Characteristics of patients with chronic low back pain selected for surgery: a comparison with the general population reported from the Swedish lumbar spine study. *Spine* 2002;27:1223–31.
21. Hagg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J* 2003;12: 12–20.
22. Watkins RG, O'Brien JP, Draugelis R, et al. Comparisons of preoperative and postoperative MMPI data in chronic back patients. *Spine* 1986;11: 385–90.
23. Lehman TR, Tozzi JE, et al. Long-term follow-up of lower lumbar fusion patients. *Spine* 1987;12:97–104.
24. Slosar PJ, Reynolds JB, Schofferman J, et al. Patient satisfaction after circumferential lumbar fusion. *Spine* 2000;25:722–6.
25. Turner JA, Herron L et al. Patient outcomes after lumbar spinal fusion. *JAMA* 1992;268:907–11.
26. Hagg O, Fritzell P, Ekselius L, et al. Predictors of outcome in fusion surgery for chronic low back pain: a report from the Swedish Lumbar Spine Study. *Eur Spine J* 2003;12:22–33.
27. Ghiselli G, Wang J, Bhatia N, et al. Adjacent segment degeneration in the lumbar spine. *J Bone Joint Surg Am* 2004;86:1497–503.

28. Bao QB, McCullen GM, Higham PA, et al. The artificial disc: theory, design and materials. *Biomaterials* 1996;17:1157–67.
29. Bao QB, Yuan HA. New technologies in spine: nucleus replacement. *Spine* 2002;27:1245–7.
30. Buttner-Janz K, Schellnack K, Zippel H. Biomechanics of the SB Charite lumbar intervertebral disc endoprosthesis. *Int Orthop* 1989;13:173–6.
31. Cinotti G, David T, Postacchini F. Results of disc prosthesis after a minimum follow-up period of 2 years. *Spine* 1996;21:995–1000.
32. Cunningham BW, Lowery GL, Serhan HA, et al. Total disc replacement arthroplasty using the AcroFlex lumbar disc: a non-human primate model. *Eur Spine J* 2002;11(suppl):115–23.
33. de Kleuver M, Oner FC, Jacobs WC. Total disc replacement for chronic low back pain: background and a systematic review of the literature. *Eur Spine J* 2003;12:108–16.
34. Enker P, Steffee A, McMillin C, et al. Artificial disc replacement: preliminary report with a 3-year minimum follow-up. *Spine* 1993;18:1061–70.
35. Griffith SL, Shelokov AP, Buttner-Janz K, et al. A multicenter retrospective study of the clinical results of the LINK SB Charite intervertebral prosthesis: the initial European experience. *Spine* 1994;19:1842–9.
36. Hedman TP, Kostuik JP, Fernie GR, et al. Design of an intervertebral disc prosthesis. *Spine* 1991;16(suppl):256–60.
37. Kotani Y, Abumi K, Shikinami Y, et al. Artificial intervertebral disc replacement using bioactive three-dimensional fabric: design, development, and preliminary animal study. *Spine* 2002;27:929–35; discussion 35–6.
38. LeMaire JP, Skalli W, Lavaste F, et al. Intervertebral disc prosthesis: results and prospects for the year 2000. *Clin Orthop* 1997;337:64–76.
39. Link HD. History, design, and biomechanics of the LINK SB Charite artificial disc. *Eur Spine J* 2002;11(suppl):98–105.
40. Szpalski M, Gunzburg R, Mayer M. Spine arthroplasty: a historical review. *Eur Spine J* 2002;11(suppl 2):65–84.
41. Urbaniak JR, Bright DS, Hopkins JE. Replacement of intervertebral discs in chimpanzees by silicone-Dacron implants: a preliminary report. *J Biomed Mater Res* 1973;7:165–86.
42. Zeegers WS, Bohnen LM, Laaper M, et al. Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients. *Eur Spine J* 1999;8:210–7.
43. Esses SI, Crawford MJ, Dreyzin V. Kinematic evaluation of the lumbar fusion techniques. *Spine* 1996;21:676–84.
44. Hsu ZJ, White A, Reynolds J, et al. Deterioration of the motion segments adjacent to lumbar spine fusion. *North American Spine Society Meeting*, Colorado Springs, CO, 1998.
45. Lee CK. Accelerated degeneration of the segment adjacent to a lumbar fusion. *Spine* 1988;13:375–7.
46. Harris WJ. Acquired spondylolysis as a sequel to spinal fusion. *J Bone Joint Surg Br* 1963;45:1159–70.
47. Blaiser MR. Acquired spondylolysis after posterolateral spinal fusion. *J Pediatr Orthop* 1987;7:215–7.
48. Brunet WJ. Acquired spondylolysis after spinal fusion. *J Bone Joint Surg Br* 1984;66:720–4.
49. Kostuik JP. Alternatives to spinal fusion. *Orthop Clin North Am* 1998;29:701–15.
50. Mayer HM, Korge A. Non-fusion technology in degenerative lumbar spinal disorders: facts, questions, challenges. *Eur Spine J* 2002;11(suppl):85–91.