SPINE Volume 30, Number 19, pp 000–000

The Treatment of Disabling Multilevel Lumbar Discogenic Low Back Pain With Total Disc Arthroplasty Utilizing the ProDisc Prosthesis

A Prospective Study With 2-Year Minimum Follow-up

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Summary of Background Data. The treatment of debilitating multilevel discogenic low back pain has been controversial and varied. The purpose of this study is to assess the efficacy and safety of the ProDisc implant in patients with disabling multilevel discogenic low back pain.

Methods. A prospective analysis was performed on 25 patients (63 prostheses) treated with multilevel lumbar ProDisc total disc arthroplasty. Minimum follow-up was 2 years. Patients 18 to 60 years of age with disabling discogenic low back pain and minimal radicular pain secondary to multiple level lumbar spondylosis from L1 to S1 were included. Preoperative and postoperative disability and pain scores were measured using Oswestry and visual analog scores. Preoperative and postoperative neurologic, radiographic, and pain medication assessments were also performed at similar postoperative intervals.

Results. A total of 29 patients (72 prostheses) were enrolled in the prospective analysis. Twenty-five patients (63 prostheses) fulfilled all follow-up criteria and are included for final analysis. Fifteen bisegmental and 10 trisegmental level cases were performed. Visual analog pain, Oswestry, and patient satisfaction scores were significantly reduced at the 3-month as well as at 48-month follow-up. Radiographic analysis revealed an affected disc height increases from 5 mm to 12 mm ($P < 0.05$) and affected disc motions from 3° to 7° ($P < 0.05$). No change in adjacent level disc heights was seen.

Complications included a single case of subsidence of the inferior endplate of the L4–L5 segment in a bisegmental L4–L5/L5–S1 case. We also report a delayed case of anterior extrusion of a polyethylene component in a patient who had sustained a fall of a bicycle.

Conclusions. Our preliminary data on multisegmental ProDisc lumbar total disc arthroplasty appear to be a safe and efficacious treatment method for debilitating lumbar spondylosis without significant facet arthropathy. In our select (non-Workers Compensation and/or medical legal) cohort of patients, we demonstrate a patient satisfaction rate of 93%. Careful and appropriate patient selection is essential in ensuring optimal surgical outcomes.

Key word: lumbar degenerative disc disease. **Spine 2005;30:000–000**

Multilevel lumbar disc disease (MLDD), either traumatic or degenerative, is one of most common causes of chronic, disabling low back pain. The economic, social, and psychological consequences of this disabling condition are quite devastating and have been well documented. The pathogenesis and etiology of MLDD are complex and controversial. Most often individuals with MLDD have experienced repetitive external trauma and may have undergone a discectomies for disabling radicular symptoms and subsequently developed incapacitating low back pain both at the affected levels and adjacent levels. Other factors such as hereditary factors, smoking habits, and obesity/poor physical conditioning may also be mitigating factors in the pathogenesis of MLDD.[1] Operative intervention is only considered when nonoperative measures have been exhausted and disability and pain are still present.

A moderate amount of experience has been accumulated with various forms of spinal arthrodesis such as posterolateral fusion with or without instrumentation, posterior interbody fusion, anterior interbody fusion, and combined anterior/posterior fusion for the treatment of single or bisegmental chronic discogenic low back pain.[2–8] Results have been noted to vary with respect to age, smoking status, Workers' Compensation, and others.[9] Prospective studies have revealed no differences in fusion and patient satisfaction rates among these different fusion methods and average approximately 75%.[8,10–13] Downsides of spinal arthrodesis include symptomatic pseudarthrosis, adjacent level degenerative changes (36.1% at 10 years) of discs and facet joints, instrumentation pain, symptomatic arthrodesis, and graft site morbidity.[14]

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Acknowledgment date: April 30, 2004. First revision date: August 31, 2004. Second revision date: October 25, 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.

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In this light, 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. Few prospective studies with a minimum of 2-year follow-up have been published on the results of lumbar disc prosthesis.[15,16] Moreover, these studies are based on 1) surgeries done by multiple surgeons and 2) nonindependent evaluation of the study data. To the best of our knowledge, there has been no long-term prospective literature on the use of the ProDisc lumbar prosthesis in the treatment of multilevel lumbar degenerative disc disease.

The goal of the present prospective study is to evaluate changes in functional and disability outcomes in a prospective cohort of patients that have received the ProDisc lumbar disc replacement for multilevel level degenerative disc disease with minimum follow-up of 2 years and to evaluate any unknown contraindications and/or complications of this treatment modality.

■ Materials and Methods

Patient Evaluation. Prospective data were compiled for multilevel ProDisc procedures from March 2000 to December 2001. Institutional review board approval for use of the ProDisc technique was applied for and granted before commencement of this project. Patients 18 to 60 years of age with disabling and recalcitrant discogenic low back pain and minimal radicular pain secondary to multilevel lumbar disc disease from L1 to S1 as confirmed on magnetic resonance imaging and discogram/CT were included. All eligible patients who satisfied our inclusion/exclusion criteria were evaluated for participation in this study. Seventy percent of the patients entered in the study had greater than 50% disc height loss and advanced lumbar spondylosis at least 2 levels between L1–S1, and had at least one prior surgical procedure excluding fusion (Figure 1). Thirty percent of our patients had less than 50% disc height loss. Only patients with complete 2-year follow-up data were included for analysis. F1

Exclusionary criteria included: patients with spinal stenosis, osteoporosis, prior fusion surgery, chronic infections, metal allergies, pregnancy, facet arthrosis, inadequate vertebral endplate size, neuromuscular disease, pregnancy, Workers' 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 including anteroposterior (AP)/lateral/flexion/extension radiographs, computerized tomography in the axial, sagittal, and coronal planes, MRI, and/or discography. Discography was used in each case. Positive discography was defined as concordant pain ≥6 of 10. Negative controls were used in all discograms. Discograms were followed by postdiscography CT scans. Levels that did not meet appropriate pain levels on discography and/or did not show clear evidence of circumferential injury did not receive ADR surgery. AQ: 3

All procedures were performed by the senior author at a single institution. 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 blinded to the hypothesis of the primary investigator. The data were collected and compiled by an independent technician who had no financial or material relationships with the device manufacturer, blinded to the hypothesis of the primary investigators. After the above data had been compiled, it was analyzed by an independent examiner who had no financial or material relationships with the device manufacturer and 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 left sided median retroperitoneal approach for all levels was then performed by the senior author exposing the level of disease. Exposure was assisted with the use of a specialized anterior spinal retractor

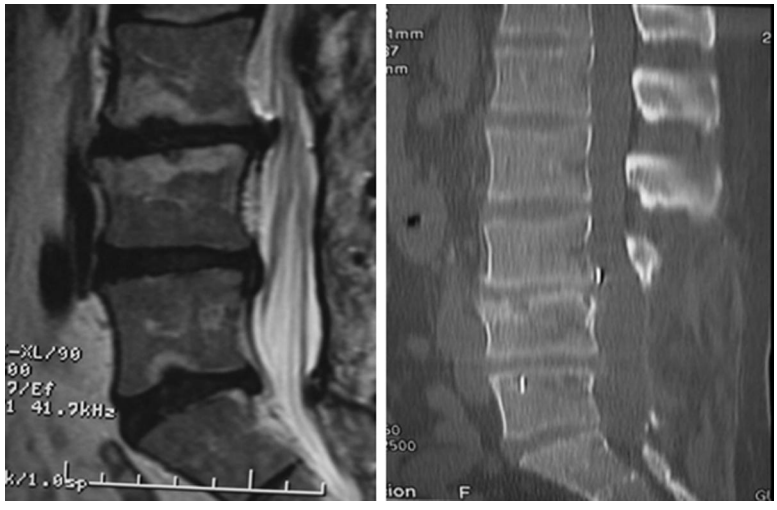

Figure 1. Preoperative imaging of a 37-year-old patient status post-multilevel laminectomy at age 20 with multilevel lumbar spondylosis.

system, SynFrame (Synthes Spine, Paoli, PA). A complete anterior discectomy was performed beginning at the most caudal affected disc. 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 placement of the most caudal implant, dissection to the next most affected cephalad disc was performed and the above steps (discectomy, trailing, chiseling, and final implant placement) were repeated until all affected discs had been replaced (Figure 2). F2

Outcome Measurement. Patients were assessed before surgery and after surgery at 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[17] 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: 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, and 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 none (1), occasional (less than 1 time per day) (2), and regular (greater than 1 time per day) (3).

Radiographic Assessment. Preoperative and postoperative radiographs were obtained in all patients including standing anteroposterior, 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.

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 months postsurgery (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.

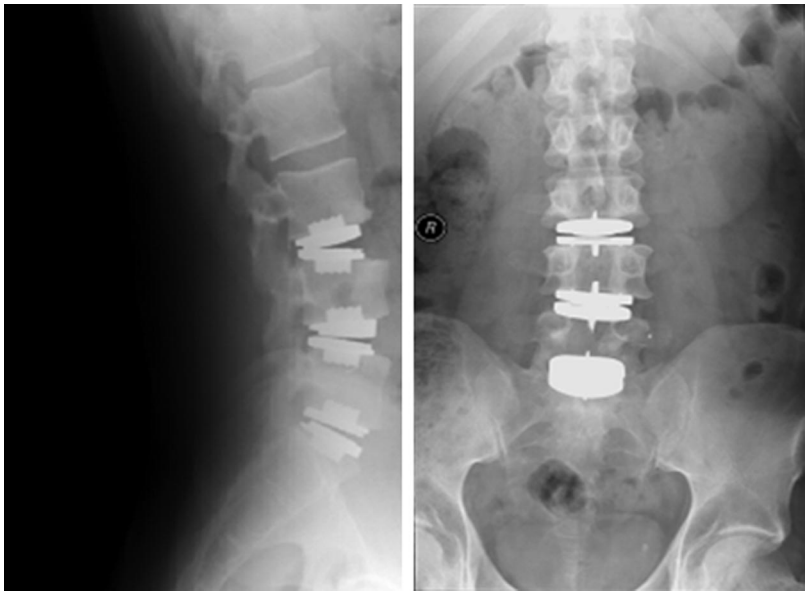

Figure 2. Postoperative radiographs

Table 1. Age and Gender Data

	Male	Female	Total
No.	15	10	25
Mean age (yr)	49.6	47.7	
Median age (yr)	51	50.5	
Range age (yr)	30–60	34–60	

■ Results

Demographic

T1 The demographic results are summarized in Table 1. A total of 25 of a possible 29 patients fulfilled all follow-up criteria. Four patients were lost to follow-up due to the fact that their permanent addresses were outside of Germany. Although early clinical data could be obtained in these patients, a complete set of radiographic data were missing. The median follow-up time was 31 months (range, 25–41 months). There were 15 male and 10 female patients. The median age for both gender groups was 51 years (range, 30–60 years). The average duration of pain before surgery was 70 months (median, 76 months; range, 9–210 months). Sixty-eight percent (n = 17) of patients had prior posterior surgery at the affected levels. Two thirds of these prior surgeries were laminoforaminotomies and one third were laminectomies. Median time between prior and ProDisc surgery was 6.2 years (range, 6 months to 24 years). Twenty-four percent of patients were smokers. There were 15 double segmental, 10 triple segmental. These included eight L4–L5, L5–S1, 10 L3–L4, L4–L5, L5–S1, five L3–L4, L4–L5, one L2–L3, L4–L5, one L3–L4, L5–S1.

The average operative time for a 2-level surgery was 135 minutes and for a three-level 184 minutes. Average blood loss for a 2-level surgery was 275 mL and 350 mL for a 3-level surgery. Patients were encouraged to ambulate on the day of surgery but no later than postoperative day 1. Discharge criteria (ambulation, oral intake, and voiding) were achieved at an average time of 3.5 days postop.

Clinical Outcomes

T2–6 Clinical outcomes are summarized in Tables 2 to 6. Preoperative Oswestry disability scores decreased from 65% to 21% at 2-year follow-up ($P < 0.001$). Similarly, preoperative visual analog scores decreased from 8.3 to 2.1 at 2-year follow-up ($P < 0.001$). Statistically significant decreases in the Oswestry ($P < 0.001$) and visual analog scores ($P < 0.001$) occurred at 3 months, and these improvements were maintained from the 3-month follow up to the 2-year follow-up period ($P < 0.001$ for Oswestry and $P < 0.05$ for VAS). Patient satisfaction levels were 96% satisfied or completely satisfied at 3-month follow-up and 92% satisfied or completely satisfied at 2-year follow-up ($P = 0.32$) No patient reported no or occasional back pain before surgery, which changed to 88% of all patients reporting no back pain or occasional back pain at 2-year follow-up. This statistically significant improvement ($P < 0.001$) in back pain occurred by 3 months ($P < 0.001$), but this did not significantly change from 3 months to the 2-year follow-up ($P = 0.28$).

Forty-eight percent of all patients before surgery reported no or occasional radicular pain. This increased to 100% at 2-year follow-up ($P < 0.05$). This increase occurred by 3 months ($P < 0.05$) but did not significantly increase from 3 months to the 2-year follow-up ($P = 0.31$). Medication usage including nonsteroidal antiinflammatories, narcotics, and morphine derivatives (Tramadol) was decreased significantly compared with preoperative usage rates. Employment patterns following surgery revealed a fivefold increase in full-time, a twofold increase in part-time employment, and a fourfold decrease in the number of patients who were not working (Figure 3). F3

With regards to patients who had previous surgery and in those who had not had surgery, within the limits of our statistical analysis due to the limited number of patients, there was no difference in clinical outcome scoring. The rates of satisfied and unstatisfied patients in patients with and without surgery were 92.4%, 7.6% and 94.6% and 5.4% respectively. Both patients who AQ: 4 remained dissatisfied with their outcomes had had prior surgery and were in bisegmental cases. One patient was a smoker and one was not. In 1 case, the patient had a subsidence of the inferior endplate of the L4–L5 segment in a L4–L5/L5–S1 procedure. This patient's symptoms did not warrant revision either symptomatically or radiographically. Statistical analysis of 2-level *versus* 3-level cases was not performed because of a lack of sufficient numbers of patients for such a comparison.

Table 2. Clinical Outcomes

	Oswestry (%)	VAS
Preop	65.0 (42–92)	8.3 (6–10)
3 mos	28.9 (4–64)	3.2 (0.2–7.8)
6 mos	22.6 (0–60)	2.2 (0–8.7)
12 mos	20.4 (0–54)	2.5 (0–6.5)
24 mos	21.6 (0–48)	2.1 (0–6)

Values are median (range).

Table 3. Patient Satisfaction (%)

	3 Mos	6 Mos	12 Mos	24 Mos
Completely satisfied	60	71	79	75
Satisfied	36	21	13	17
Unsatisfied	4	8	8	8

Table 4. Back Pain (%)

	Preop	3 Mos	6 Mos	12 Mos	24 Mos
No pain	0	38	44	48	56
Episodic pain	8	62	52	40	36
Regular pain	92	0	4	12	8

Table 5. Radicular Pain (%)

	Preop	3 Mos	6 Mos	12 Mos	24 Mos
No pain	20	48	71	81	67
Episodic pain	28	44	29	19	33
Regular pain	52	8	0	0	0

Radiographic Analysis

The median preoperative height of the affected discs was 5.4 mm. Ninety-four percent of patients had at least 75% disc height loss compared with adjacent normal levels. After surgery, disc heights were on average increased to 11.7 mm (SD 1.34) ($P < 0.001$). Motion of the affected discs in flexion and extension was increased from 2° before surgery to 7° after surgery (SD 4.11, $P < 0.001$). The heights of the adjacent level discs were not significantly changed ($P = 0.74$). No correlation was determined to exist between clinical outcome and pelvic incidence, tilt or sacral slope.

Results of Patients With <2-Year Follow-up

Of the 4 patients who were lost to follow-up, we have 1-year data on 3 patients and 3-month data on 1 patient. The patients with 1-year follow-up had an average Oswestry score of 24%, VAS of 3.4, and there were no unsatisfied patients. Three of four were smokers and 3 were male. There were no complications in any of the patients with less than 2-year follow-up.

Complications

Device-Related Complications. We report 1 case of partial implant subsidence. In a bisegmental case at L4–L5 and L5–S1, we noted subsidence of the inferior component of the L4–L5 prosthesis (Figure 4). This subsidence occurred in a 36-year-old man with no prior history of osteoporosis. The subsidence was noted on a postoperative radiograph 3 days following the index surgical procedure. Repeat radiographs were obtained biweekly for 1 month and monthly for 6 months. After the initial subsidence, no increase in subsidence was noted and the patient returned to normal activity without pain at approximately 5 months after surgery. We have had one other similar subsidence case, after ending the collection of our index cohort of patients for the present study, in a 44-year-old female patient who at 1.2 years follow-up continues to have intermittent pain but has declined further stabilization surgery.

We also report a single case of anterior extrusion of a polyethylene component in a patient who underwent a 2-level replacement at L4–L5 and L5–S1. This was identified at the 2-year follow-up visit after the patient had sustained a fall off a bicycle. This complication was treated with removal of the entire prosthesis and an anterior fusion with a femoral ring allograft and Pyramid plate (Danek, Memphis TN). Fusion was elected due to the presence of an anterolisthesis of L5 on S1, which had developed following the fall.

No other cases of loosening, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurologic injuries were caused by the implant components and/or infection.

Approach-Related Complications. A subcutaneous sterile inflammatory suture reaction was identified and the suture was debrided and the skin closed primarily. We also report 1 case of temporary retrograde ejaculation that recovered spontaneously at 5.5 months after surgery. No cases of vascular injury, ureteral injury, or other neurologic injury occurred.

Table 6. Medication Usage (%)

	NSAIDs		Narcotics		Tramadol	
	Preop	24 Mos	Preop	24 Mos	Preop	24 Mos
None	28	68	56	96	40	92
Episodic	12	16	12	0	4	8
Regular	60	16	32	4	56	0

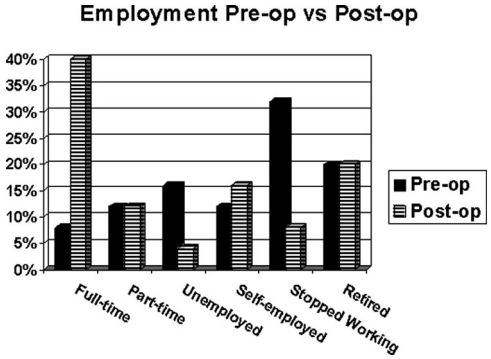

Figure 3. Employment trends following single-level ProDisc surgery.

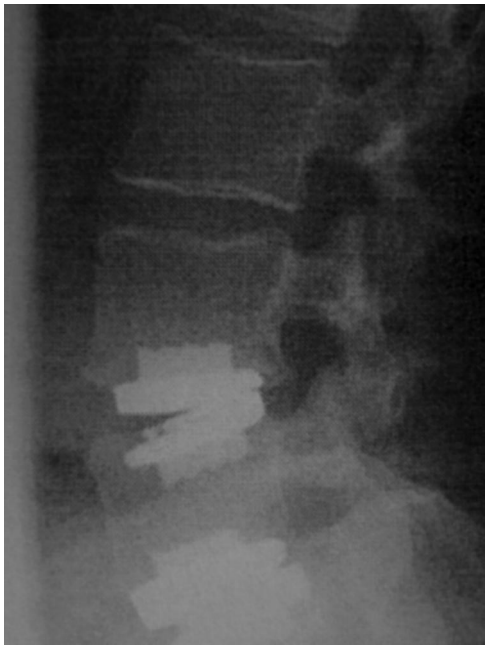

Figure 4. Case of subsidence of inferior component of L4–L5 replacement level in a bisegmental patient.

■ Discussion

MLDD is a common finding in many asymptomatic as well as symptomatic individuals. The origin of symptomatic *versus* asymptomatic MLDD is a matter of controversy. Although a thorough discussion of the etiology, pathogenesis, and classification of MLDD falls outside the immediate purpose of this study, we think that MLDD arises as a result of a multifactorial combination of traumatic, genetic/hereditary, social (tobacco), physical (obesity), and senescence factors.[1] There are also different radiographic appearances on MRI in which all the degenerative segments appear to be equally degenerative; whereas in other instances, one observes a cascade of changes with more severe changes seen at the caudal levels and less effected levels evident more cranially (Figure 5). F5

We have made no attempt in this article to classify MLDD in terms of these different factors and radiographic appearances; however, we think that there can exist a cascade effect in which one disc, termed the proximate disc, becomes dysfunctional and degenerative and this proximate disc contributes to adjacent level degeneration. In most instances, this proximate disc is usually located more caudally. This particular type of MLDD we term proximate MLDD (Figure 5). Although we have seen profoundly positive results in a great number of our patients, we have observed especially gratifying results in those patients with proximate MLDD.

The use of total disc arthroplasty for debilitating discogenic low back pain has been under investigation for over approximately 20 years.[15,18–32] 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. The authors, granted, are not aware of a prospective analysis of multilevel disc fusion surgery for MLDD and therefore cannot offer a substantial comparison to ADR surgery.

Similar to other motion oriented anatomic structures, spinal segments are required to fulfill certain motion activities to allow for normal physiologic function. In addition, spinal segments must also be stable enough to provide protection of the spinal elements. Studies have reported that, following lumbosacral fusion, there can be an initiation or acceleration of the degeneration of the discs at the adjacent levels.[14,33–36] Others have reported that the exaggerated motions and forces at the adjacent level can result in an acquired spondylolysis.[37–39]

Recently, in 1990, the first 64 ProDisc implant surgeries were performed in France by Dr. Thierry Marnay.[40] These initial patients were retrospectively reviewed and had a 92.7% clinical success rate at 7- to 10-year follow-up with no implant failures. Sixty-six percent of these patients had single-level implants. None of these implants required surgical revision. Marnay's implant (ProDisc I) implanted in these initial patients had a double keel construct in comparison to the single keel (ProDisc II) as employed in the present study. All other components are identical between the two models.

A number of studies in the English and German literature have investigated the use of other lumbar disc arthroplasty techniques.[15,16,24,25,28–30,32,41,42] 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. Cinotti *et al* retrospectively reviewed 46 patients (36 single) using the SB Charite III implant. Overall clinical success rate was 69% in isolated disc replacement.[21] Patients who had had no previous surgery before disc arthroplasty had a 77% clinical success rate. The clinical outcomes in this study were attributed to poor patient selection and not implant deficits. Griffith *et al* reported on a retrospective, multicenter, multisurgeon study involving 93 patients (50 single and 43 multilevel) using the SB Charite III implant.[25] Statistically significant clinical outcome improvements in back and leg pain, strength, and range of motion were achieved. Device-related complications including migration, failure, and dislocation occurred in 6.5% of patients. Hochschuler *et al* reported 1-year pro-

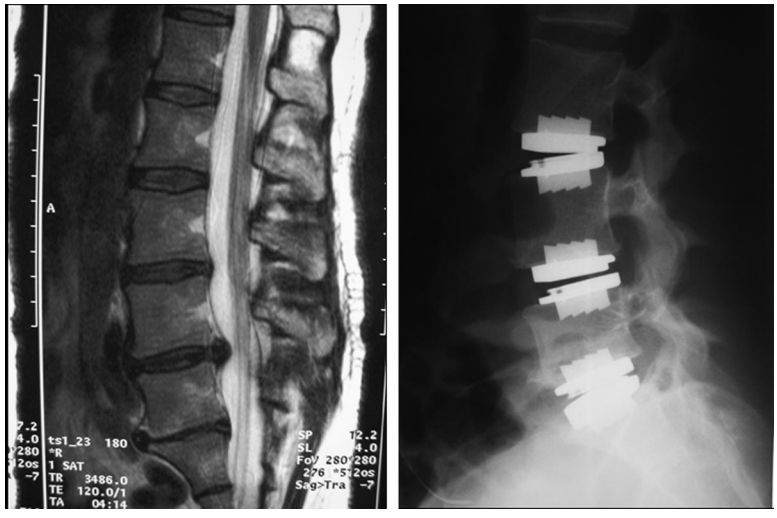

Figure 5. Example of cascade appearance of "proximate MLDD."

spective data using the SB Charite III prosthesis and reported improvements in clinical outcome and no device-related complications 22 single-level patients.

In the German literature, Buttner-Janz *et al* retrospectively analyzed 20 postnucleotomy patients who were subsequently treated at a later date with the SB Charite III prosthesis.[43] They report complete clinical success in approximately 25% of patients and partial satisfaction in an additional 70% of patients with follow-up ranging from 6 months to 13 years. Hopf *et al* prospectively reported on 24 monosegmental patients at a follow-up of 14.7 months.[16] They included in their exclusion criteria patients older than 45 and patients with previous surgery.

In the present study, we present 2-year nonrandomized multilevel prospective data on the ProDisc lumbar implant. Design deficits in our study include the lack of a nonoperative control group and/or a randomized 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 2-year follow-up revealed a 93% 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. Our results complement other recent data on the ProDisc implant.[40,44,45]

We found no difference in outcomes in patients who had had prior surgery and in those who had no previous surgery. 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 pseudo-articulations 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 which we believe also play a significant role. These factors include both implant design and biologic factors such as an ingrowth surface, 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.

Our total enrollment of all patients using the ProDisc prosthesis is approximately 600, including single and multisegmental diseased patients. We have performed a total of 75 double segmental and 37 triple segmental cases inclusive of the patients we have reported in this series. We have found very similar outcome results in these subsequent patients. We have expanded our clinical indications to include patients over 60, prior fusion patients with adjacent level disease, and in some patients with degenerative rotational scoliosis. We have also performed a single quadruple segmental replacement which at 15 months after surgery is performing without complications both clinically and radiographically. Results in these expanded populations appear very similar to those obtained in our monosegmental and multisegmental patients and will be forthcoming.

Multisegmental ProDisc lumbar total disc arthroplasty is a safe and efficacious treatment method for debilitating lumbar spondylosis without significant facet arthropathy. Ideal candidates often, but not always, exhibit a "proximate" pattern of degeneration. In our analysis, statistically significant improvement in patient satisfaction and disability scores occurred after surgery in 93% of patients at 2-year follow-up. Multilevel ProDisc lumbar surgery appears to afford immediate implant stability and functional mobility allowing for early return to activities of daily living and employment. This stability appears to be evident in both primary surgical procedures and in patients who have had posterior decompressive procedures performed. Contraindications to multilevel disc arthroplasty include obesity, osteoporosis, significant loss of articular facet cartilage, isthmic spondylolisthesis, or degenerative spondylolisthesis greater than Grade 1, nondegenerative scoliosis, and presumably MRI changes that do not correlate with discography.

Clinical indications for surgery are chronic debilitating low back pain with or without radicular pain. Careful and appropriate patient selection is essential in ensuring optimal surgical outcomes. Preservation of endplate integrity is paramount to a successful outcome, especially on the superior endplate of L5 in patients undergoing L4 to S1 disc arthroplasty. Careful evaluation of bone density and consideration for concomitant vertebroplasty in selective cases may be necessary and warrant future studies. Avoidance of excessive postoperative external bodily trauma should maintained at all times after surgery. AQ: 6

■ Key Points

- Severe and recalcitrant multilevel discogenic low back pain can be effectively treated with ProDisc lumbar arthroplasty.
- Careful preoperative evaluation and experienced and meticulous operative technique are essential.
- Prior posterior laminectomy and/or discectomy are not contraindications to ProDisc lumbar surgery.
- High-energy trauma or injury many lead to device failure and/or dislodgement.

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