Lumbar total disc arthroplasty in patients older than 60 years of age: a prospective study of the ProDisc prosthesis with 2-year minimum follow-up period

RUDOLF BERTAGNOLI, M.D., JAMES J. YUE, M.D., REGINA NANNIEVA, A.B., ANDREA FENK-MAYER, M.D., DANIEL S. HUSTED, M.D., RAHUL V. SHAH, M.D., AND JOHN W. EMERSON, PH.D.

Department of Orthopaedic Surgery, Spine Center, St. Elizabeth Klinikum, Straubing, Germany; and Department of Orthopaedic Surgery and Rehabilitation, and Yale University School of Medicine, New Haven, Connecticut

Object. The authors conducted a prospective longitudinal study to obtain outcome (minimum follow-up period 2 years) regarding the safety and efficacy of single-level lumbar disc (ProDisc prosthesis) replacement in patients 60 years of age or older.

Methods. This prospective analysis involved 22 patients treated in whom the lumbar ProDisc prosthesis was used for total disc arthroplasty. All patients presented with disabling discogenic low-back pain (LBP) with or without radicular pain. The involved segments ranged from L-2 to S-1. Patients in whom there was no evidence of radiographic circumferential spinal stenosis and with minimal or no facet joint degeneration were included. Patients were assessed preoperatively and outcome was evaluated postoperatively at 3, 6, 12, and 24 months by administration of standardized tests (the visual analog scale [VAS], Oswestry Disability Index [ODI], and patient satisfaction). Secondary parameters included analysis of pre- and postoperative radiographic results of disc height at the affected level, adjacent-level disc height and motion, and complications.

Twenty-two (100%) fulfilled all follow-up criteria. The median age of all patients was 63 years (range 61–71 years). There were 17 single-level cases, four two-level cases, and one three-level case. Statistical improvements in VAS, ODI, and patient satisfaction scores were observed at 3 months postoperatively. These improvements were maintained at 24-month follow-up examination. Patient satisfaction rates were 94% at 24 months (compared with 95% reported in a previously reported ProDisc study). Radicular pain also decreased significantly. Patients in whom bone mineral density was decreased underwent same-session vertebroplasty following implantation of the ProDisc device(s).

There were two cases involving neurological deterioration: unilateral foot drop and loss of proprioception and vibration in one patient and unilateral foot drop in another patient. Both deficits occurred in patients in whom there was evidence preoperatively of circumferential spinal stenosis. There were two cases of implant subsidence and no thromboembolic phenomena.

Conclusions. Significant improvements in patient satisfaction and ODI scores were observed by 3 months postoperatively and these improvements were maintained at the 2-year follow-up examination. Although the authors’ early results indicate that the use of ProDisc lumbar total disc arthroplasty in patients older than 60 years of age reduces chronic LBP and improves clinical functional outcomes, they recommend the judicious use of artificial disc replacement in this age group. Until further findings are reported, the authors cautiously recommend the use of artificial disc replacement in the treatment of chronic discogenic LBP in patients older than age 60 years in whom bone quality is adequate in the absence of circumferential spinal stenosis.

Key Words • total disc replacement • ProDisc • lumbar discogenic pain • low-back pain • elderly

Individuals in their seventh decade compose the fastest growing population in the US and Canada. Although LBP, particularly chronic LBP, is one of the most common maladies in these countries, a paucity of data exist in the English-language literature on this topic.6 Artificial disc replacement in the lumbar spine has been proposed as an alternative to lumbar fusion in the treatment of certain cases of lumbar spondylosis when significant facet joint degeneration is absent. Artificial disc replacement has been studied almost exclusively in younger patients.3–5,7–9, 20,22 Although chronic LBP occurs commonly in the older age group, there has been no prospective study to examine the use of ADR in this population.6,10,14–16 The goal of the present study was to assess the efficacy of ADR in the treatment of discogenic LBP in patients older than 60 years of age.

Clinical Material and Methods

Patient Evaluation

Data were compiled prospectively for lumbar ProDisc (Synthes, Paoli, PA) procedures performed in patients...
60 years of age or older, between March 2000 and January 2003. Disabling discogenic LBP was present with or without radicular symptoms due to L1–S1 degenerative disc disease evidenced on MR imaging, CT scanning, and discography. We included only patients for whom complete 2-year follow-up data were available.

Exclusionary criteria included the following: patients with spinal stenosis in the presence of neurogenic claudication, osteoporosis defined as a T-score greater than −2.5, a history of fusion surgery, chronic infections, metal allergies, inadequate vertebral endplate size, pregnancy, Workers’ compensation recipients, spinal litigation, body mass index greater than 35, and/or any isthmic or degenerative spondylolisthesis greater than Grade One. Conservative treatment had failed in all cases for a minimum 9-month course. Patients with significant facet joint arthrosis defined as bridging osteophytes and/or cystic changes with irregular and erosive changes were excluded from ADR surgery. Surgery was performed after a complete radiographic assessment (including AP, lateral, flexion–extension, and lateral bending radiographs), CT scanning, and MR imaging discography/CT scans were obtained in all patients to evaluate discogenic sources of pain and the degree of facet degenerative changes. For inclusion in the study, discography needs to be negative. Patients with evidence of intraarticular facet joint degeneration, specifically evidence of joint space narrowing with or without cystic changes, were excluded from the study. Patients in whom there were minimal extraarticular facet joint changes (calcifications) were not excluded. Positive discography was defined as concordant pain with at least a rating of six out of 10 and an abnormal discography CT scan contrast pattern (that is, anular tear or disc extrusion). Patients with T-scores on bone mineral density testing less than or equal to −2.5 were excluded.

All procedures were performed by the senior author (R.B.) at a single tertiary care Level-1 institution. Five percent of our patients suffered preoperatively for discogenic LBP alone, without radicular and/or neurogenic symptoms. Ninety-five percent of the patients experienced either intermittent (25%) or persistent (75%) leg pain as well as chronic LBP.

Bias as to outcome was avoided by using primary outcome measurements determined by patient responses to questionnaires. Secondary parameters requiring measurements such as disc height of the affected level, adjacent-level disc height, and motion were performed by a trained technician. The data were collected and compiled by an independent technician. After the aforementioned data were compiled, they were analyzed by an independent examiner who had no interaction with the patients or involvement with the surgical procedures at any time during this study.

Surgical Technique

The surgical approach was uniformly undertaken with the patient in a supine position on a fluoroscopic imaging table, with his/her legs and arms abducted, and the surgeon working between the patient’s legs. An approach surgeon was not utilized. Fluoroscopy was obtained in AP and lateral planes to determine level of diseased disc and obliquity of lordosis prior to incision. A transverse incision for the L5–S1 segment 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 a left-sided median retroperitoneal approach for all other levels, was then performed by the senior author, exposing the level of disease. Discectomy was conducted by incising the anterior anulus fibrosus into two halves and retracting these halves laterally by using suture. A complete discectomy was undertaken with strict preservation of the osseous endplate. The PLL was preserved when possible. In cases involving difficult intervertebral mobilization or disc material herniation, the PLL was removed by applying a curved curette against the pos-
Lumbar arthroplasty in the elderly

The results were based on the distance measurements of the adjacent levels, angulation measurements, andL lateral fluoroscopy was used to determine appropriate size with regard to disc height and AP diameter (trialing). The adequate central/midline location of the prosthesis was confirmed using AP fluoroscopy prior to making keel cuts. After the midline was determined, keel cuts were made using the keel cutting chisel guided over the prosthesis trial. The endplates were then distracted and the polyethylene artificial disc was inserted. Thereafter, AP and lateral fluoroscopy was conducted to confirm appropriate prosthesis positioning and size.

Outcome Measurement

Patients were assessed preoperatively and postoperatively at 3, 6, 12, and 24 months. The primary functional outcomes were disability and pain based on the ODI and the VAS for back pain only. The VAS for leg pain was not used. Additional clinical parameters included analysis of pre- 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 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 > once per day, requires medication, and results in changes in ADL employment). Medication usage was rated as 1) none; 2) occasional (once a day); and 3) regular (> once a day). Back pain and leg pain were rated as 1) no pain; 2) occasional leg pain requiring no medications; and 3) persistent leg pain that either required or did not require medication use.

Radiographic Neuroimaging Assessment

Preoperative and postoperative radiographs (AP, lateral, flexion–extension, and lateral bending) were obtained in all patients (Fig. 1). Detailed measurements of intervertebral disc heights of the affected and adjacent levels, angular intervertebral disc motion, and subsidence were made using digitized images and appropriate computer software (Medimage Software; Vepro Computersysteme GmbH, Pfungstadt, Germany). Measurements were acquired three times and a mean score was obtained for angular and length measurements. These angular and length measurements were undertaken by a single reviewer. Two separate reviewers (the attending spine surgeon not involved in surgery and the attending radiologist) reviewed all pertinent radiographs for device-related loosening, dislodgment, and/or subsidence.

Statistical Analysis

The following two primary research questions are of interest: 1) whether there was a significant improvement in status from presurgery to 3 months postsurgery (proximal effect); and 2) whether there was enduring improvement from 3 months to 2 years postsurgery. For the purposes of this study, we limited our analysis to several simple tests (t-tests with the continuous VAS and ODI scores, and nonparametric sign tests with back and leg pain scores) combined with careful exploratory data analysis.

Results

Demographic Data

Follow-up criteria were fulfilled in all 22 cases. The median age for both sexes was 63 years (range 61–71 years). There were 17 single-level cases, four two-level cases, and one three-level case. The median follow-up duration was 34.6 months (range 24–56 months). There were nine men and 13 women. The median duration of pain preoperatively was 95 months (range 6–475 months). Three patients had undergone prior lumbar surgery at the same site of ADR (one laminectomy and two discectomy procedures). The median blood loss was 100 ml (range 30–600 ml). The median operative time was 140 minutes (range 60–250 minutes). The mean T-score for all patients was −1.79 (range −0.08 to −2.33).

Clinical Outcomes

The images in Fig. 1 show individual patient measurements for the continuous variables, ODI, and VAS scores. Only one patient reported an unchanged VAS score from presurgery to 24 months postsurgery; only a small improvement in the ODI score was documented in this patient as well. In all other cases some improvement in VAS score was observed in the interval between presurgery and 24 months after surgery, and in only one patient was there a slight decrease in the ODI score. This patient was also the only case in which an immediate decrease in ODI score was not observed in the interval between preoperative examination and by 3 months after surgery. Clinical outcomes did not change significantly during the 3- to 24-month interval. The mean trend is represented by the line segments connecting the points in the center of the clusters in Fig. 2. It appears that the immediate benefits from surgery (evidenced at the 3-month follow-up examination) were maintained, on average, but further improvements occurred only in selected individuals, not on average.

Table 1 provides a summary of these results, including the mean presurgery, and 3-, 6-, 12-, and 24-month postsurgery scores, as well as two measures of improvements (presurgery–3 months and 3–24 months). Although the improvements in the preoperative to 3-month postoperative interval score were statistically significant in both measures (p values < 0.00001), a comparison of these results with those of other studies is of greater interest. Changes in ODI and VAS score from 3 months to 24 months were insignificant, consistent with the hypothesis that gains achieved at 3 months were sustained at 24 months postsurgically. Finally, it is interesting to note that in 10 of the 22 patients a 50% reduction in ODI score was apparent at 24 months, and in 15 of the 22 patients the reduction was greater than 20%. Similarly, 18 of 22 experienced at least a 20% reduction in VAS-measured pain at 24 months, whereas in 13 of 22 a minimum 50% reduction in VAS-measured pain was documented at 24 months.

Back pain, leg pain, and satisfaction scores were ordinal
(1, completely satisfied; 2, satisfied; and 3, not satisfied). Tables 2 and 3 offer summaries of the mean score at each follow-up interval, although no measure of patient satisfaction was available at baseline. A delay in reduction of back pain is evident; improvements at 3 months were rare, with only three patients experiencing any improvement over baseline status. All but one patient reported reduced LBP at 6 months after ADR, with the improvements sustained, on average, through 24 months. In contrast, leg pain improved immediately at the 3-month follow-up examination. Examination of the individual leg pain scores showed that the leg pain measurements exhibited far more variability (and fewer clear trends by individual) than any of the other scores. In the 19 patients whose baseline pain was severe (Grade 3), pain improved to the minimal level (Grade 1 in eight to Grade 2 in 10), and remained severe in only one.

Radiographic Outcomes

The mean preoperative height of the affected discs was 4 mm, whereas postoperatively the height increased to a median of 14 mm (p < 0.001). Motion at the affected disc level was increased from 3° preoperatively to 12° postoperatively (p < 0.004). The adjacent-level disc heights were not significantly changed. There were two cases in which subsidence of the prosthesis occurred. There were no cases of loosening, dislocation, or failure of the device’s metallic or polyethylene components. No case of heterotopic ossification was observed.

Summary of Complications

Device-Related Complications. In this study, there were no cases of loosening, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurological injuries caused by the implant components, and/or infection. As we mentioned, two cases of implant subsidence occurred, both within the first 8 weeks of the index surgery. Both complications occurred early in our series, in patients with T-scores ranging from −1.76 to −2. In one case subsidence occurred in the inferior endplate of L-4 in a single-segment (L3–4) ADR. In the second case subsidence occurred after a three-level (L3–S1) ADR (Fig. 1 left). The T-scores for each patient in whom subsidence occurred were −2 and −1.76, respectively.

Approach-Related Complications. There were no approach-related complications.

Neurological Changes. We observed two postoperative cases of unilateral foot drop. One patient had undergone L4–5 ADR and the other L3–S1 ADR. In both cases, there was preoperative evidence of circumferential spinal stenosis (Fig. 1 center and right), defined as the concurrent presence of significant PLL hypertrophy and concurrent subarticular stenosis resulting in the loss of approximately 30% of normal canal diameter documented on axial MR imaging. In the latter case of foot drop, the patient also experienced loss of proprioception and vibration sensation bilaterally and required a posterior decompressive procedure following ADR surgery; postoperatively the patient regained ambulatory status with the assistance of a single cane. In the former case the patient recovered anti-gravity strength (Grade 3/5) without requiring any other surgical intervention. In the latter case, the patient only recovered Grade 1/5 motor strength. Our overall complication rate was 18.2%.

Vascular Status/Complications. Vascular status was assessed based on clinical history, examination, and plain CT scanning findings. An exclusion criterion had been vascular insufficiency either clinically or radiologically (for example, arterial aneurysm or circumferential calcification). None of the patients enrolled in the study were excluded based on abnormal vascular anatomy. No vascular complications occurred in relation to surgery.
Surgical challenges include osteoporotic fractures, and the possibility of metastatic or marginal malignancy. The surgical outcomes of discogenic back pain in patients older than 60 years of age are those whose focus is spinal stenosis and isolated lumbar disc herniation. An and colleagues examined lumbar degenerative processes in patients older than 60 years of age. They reported good and excellent results in 92% of their treated patients was 70.8% in those with stenosis, 66.6% in those with stenosis and herniated disc, and 63.6% in those with lateral recess stenosis. Similar findings have been documented in several other studies. Ms, Ms, Ms, Ms, Ms.

The clinical outcomes achieved in the present study are similar to our clinical findings in previous studies in which we evaluated ADR in younger patients with both single- and multilevel lumbar disc disease. Our overall complication rate, however, in the older age group was higher, and it reflected two cases of foot drop and a case of loss of proprioception and vibration sensation, which required permanent cane-assisted ambulation.

We recommend strict adherence to traditional inclusion and exclusion criteria for ADR and that CT scans be obtained in all cases to assess for the presence of facet joint degeneration and spinal stenosis. If necessary, myelography should be performed to exclude advanced cases of spinal stenosis. Circumferential spinal stenosis at the affected level should be considered a relative contraindication to ADR because of the potential of decreasing the spinal canal volume as a result of the lordotic enhancement. If ADR is to be used in this instance, we recommend first undertaking a posterior decompressive laminectomy and later an ADR or posterior decompression and fusion. Building on our early experience with two cases of subsidence, we now routinely perform open prophylactic vertebroplasty in which we use 5 to 10 ml of bone cement in the relevant vertebral bodies following implant placement but during the procedure of the X-Stop prosthesis (St. Francis Medical Technologies, San Francisco, CA) for spinal stenosis at 1 year, the authors reported better results in prosthesis-treated patients than in those who did not undergo surgery. The results of dynamic posterior stabilization and rigid versus semirigid instrumentation with fusion were recently compared in three groups with degenerative spinal stenosis. The authors found no clear-cut advantage for any one type of instrumentation in terms of fusion rates and clinical outcome.

The only other studies in the literature in which investigators examine lumbar degenerative processes in patients older than 60 years of age are those whose focus is spinal stenosis and isolated lumbar disc herniation. An and colleagues evaluated lumbar disc herniations in patients who ranged in age from 50 to 78 years (mean age 56 years). They reported good and excellent results in 92% of their patients following discectomy. In terms of the treatment of spinal stenosis, Javid and Hadar evaluated patients whose mean age was 61.3 years and concluded that after a 1- to 11-year follow-up period the success rate in laminectomy-treated patients was 70.8% in those with stenosis, 66.6% in those with stenosis and herniated disc, and 63.6% in those with lateral recess stenosis. Similar findings have been documented in several other studies.

Discussion

The treatment of chronic discogenic LBP in patients older than 60 years of age is challenging and controversial. The diagnostic challenges associated with LBP are amplified in the older patient population because of the frequent concomitant presence of pain generators such as advancing facet joint degeneration, chronic spinous process impingement, degenerative sciotic deformities, osteoporotic fractures, and the possibility of metastatic or marginal malignancy.12 Surgical challenges include osteoporotic bone density, chronic disc height loss, foraminal stenosis/ pseudoradiculopathy, subarticular stenosis, and facet joint degeneration. Anterior surgical approaches may be complicated by vascular calcification and arterial insufficiency.

In terms of metabolism, Bernick and Cailliet wrote that “age changes are observed in the arterioles, capillaries, and venules found in the nutrient canals or spaces of the bone adjacent to the cartilage or disc. The calcification of the articular cartilage and vascular changes seen in the older vertebrates . . . impede the passage of nutrients from the blood to the disc proper.”

Bressler, et al., eloquently demonstrated that evidence-based data in the literature is lacking in terms of the treatment of LBP in patients older than 65 years of age. In their metaanalysis, none of the 12 studies that met relevancy criteria was prospective and all were based on questionnaires except for two in which the authors also included physical examinations. In none of these studies did the investigators evaluate the effect of surgical outcomes or compare surgical and nonsurgical outcomes.

We are unaware of any studies in the English-language literature in which the focus was to evaluate retrospectively or prospectively any surgical technique in the treatment of discogenic back pain in patients older than 60 years of age. Stoil, et al., evaluated 83 patients (mean age 58.2 years) with several diagnoses including 20 cases of degenerative discogenic back pain. The outcomes of the pool patient population were measured before and after the placement of Dynsys instrumentation (Zimmer Corp., Warsaw, IN) (without fusion); postoperatively, status had improved. In another study conducted to evaluate the use

| TABLE 2 | Summary of clinical outcome data in patients older than 60 years of age* |
|---------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Outcome Variable | Preop | 3 | 6 | 12 | 24 |
| patient satisfaction (%) | NA | 94 | 95 | 90 | 94 |
| satisfied | NA | 61 | 57 | 60 | 80 |
| completely satisfied | NA | 33 | 38 | 30 | 14 |
| back pain (%) | overall | 100 | 90 | 62 | 79 | 57 |
| intermittent | 9 | 14 | 57 | 74 | 52 |
| persistent | 91 | 76 | 5 | 5 | 5 |
| leg pain (%) | overall | 95 | 47 | 43 | 50 | 47 |
| intermittent | 25 | 33 | 24 | 40 | 28 |
| persistent | 70 | 14 | 19 | 10 | 19 |

* NA = not applicable.

| TABLE 3 | Incidence of medication usage before and 24 months after surgery* |
|---------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Usage | NSAIDs | Narcotics | Tramadol |
| Preop | Postop | Preop | Postop | Preop | Postop |
| never | 10 | 46 | 85 | 100 | 60 | 50 |
| occasionally | 25 | 38 | 5 | 0 | 0 | 15 |
| regularly | 65 | 15 | 10 | 0 | 40 | 0 |

* Values are presented as percentages. Abbreviation: NSAIDs = nonsteroidal antiinflammatory drugs.
same operative session. After implementing this procedural modification, no cases of implant subsidence have occurred.

Conclusions
In conclusion, although our early results indicate that the use of ProDisc lumbar total disc arthroplasty in patients older than 60 years of age reduces chronic LBP and increases clinical functional outcomes, we recommend the judicious use of ADR in this age group. Until further studies become available, we cautiously recommend the use of ADR in the treatment of chronic discogenic LBP in patients older than 60 years of age who have adequate bone quality in the absence of circumferential spinal stenosis.

References
Approximately 185,000 spinal fusion procedures are performed annually in the US to treat various clinical conditions including trauma, spondylolisthesis, deformity correction, spinal stenosis, discogenic back pain, and adjacent-level disc disease following remote fusion. The incidence and pathobiomechanics of adjacent-level disc disease have been extensively reported and studied. The clinical outcomes following adjacent-level fusion surgery have been reported to be excellent in a small subset of patients.

Lumbar ADR has been proposed as an alternative to lumbar fusion in the treatment of certain cases of lumbar spondylosis in the absence of significant facet joint degeneration. To the best of our knowledge, the use of ADR in the treatment of adjacent-segment degeneration following remote fusion has not been prospectively studied. The goal of the present study was to assess the efficacy of ProDisc ADR in the treatment of adjacent-segment degeneration following remote lumbar fusion.

Clinical Material and Methods

Patient Population

There were nine men and nine women. The median age for both sexes was 50 years (range 35–67 years). The median preoperative duration of pain was 104 months (mean 70, range 6–400 months).

Patient Evaluation

After institutional review board approval, prospective data were compiled for lumbar ProDisc procedures per-
formed at symptomatic levels adjacent to segments previously treated with lumbar fusion between December 2000 and December 2002. Patients ranging in age from 18 to 70 years were eligible for enrollment in this study. Patients suffered from disabling low-back pain with or without radicular symptoms resulting from L1–S1 DDD that was confirmed on MR imaging, CT scanning, and discography. Only cases with a minimum of 2-year follow-up data were included for analysis. All surgeries were performed by a single surgeon at a single center.

Exclusionary criteria included the following: spinal stenosis, osteoporosis, chronic infections, metal allergies, pregnancy, facet joint arthrosis, inadequate vertebral end-plate size, Workers’ compensation, spinal litigation, body mass index greater than 35, and/or any isthmic or degenerative spondylolisthesis greater than Grade 1. In all cases a minimum 9-month course of conservative treatment had failed. This conservative management included physical therapy, medication usage, and appropriate interventional pain management.

Magnetic resonance images had been obtained in all patients at the time of their initial fusion surgeries. All of these MR imaging studies, as well as repeated studies acquired within 6 months of the index ADR surgery, were analyzed for the presence of DDD at the adjacent levels. In our cohort of patients, there was no evidence of adjacent-level DDD at the time of fusion surgery.

Surgery was performed after a complete radiographic/neuroimaging assessment in all patients including AP lateral flexion-extension, lateral bending radiography, CT, and MR imaging. All patients underwent discography/CT scanning to evaluate discogenic sources of pain and the degree of facet joint degenerative changes. Patients with evidence of intraarticular facet degeneration, specifically that of joint space narrowing with or without cystic changes, were excluded from the study. Patients in whom we observed minimal extraarticular facet joint changes (calcifications) were not excluded. Positive discography was defined as concordant pain with at least a VAS score of 6 of 10 and an abnormal postdiscography CT scan contrast pattern (that is, anular tear, disc extrusion). All procedures were performed by the senior author at a single tertiary care Level-1 institution. Twenty-five percent of our patients experienced only discogenic low-back pain without radicular and/or neurogenic symptoms; 75% had either intermittent (25%) or persistent (50%) leg pain as well.

An outcome bias was avoided by using primary outcome measurements determined by patient responses to questionnaires. Secondary parameters requiring measurements such as disc height of the affected level, adjacent-level disc height, and motion were performed by a trained technician. The data were collected and compiled by an independent technician. After the aforementioned data had been compiled, they were analyzed by an independent examiner who had no interaction with the patients or involvement with the surgical procedures at any time during this study.

Surgical Technique

The surgical approach was consistent in all cases as follows. The patient was placed supine on a fluoroscopic imaging table, with his/her legs and arms abducted, and with the surgeon working between the patient’s legs. Fluoroscopy images were obtained in the AP and lateral planes to determine the level of diseased disc and obliquity of lordosis prior to incision. A transverse incision in cases for L5–S1 treatment, or a 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, or a left-sided median retroperitoneal approach for all other levels, was then undertaken by the senior author to expose the level of disease.

Using lateral fluoroscopy, trialing was performed to make the assessment of appropriate size of the artificial disc with regard to height and AP diameter. Adequate central/midline location of prosthesis was confirmed on AP fluoroscopy prior to the making of keel cuts. After the midline was determined, keel cuts were made using the keel.

---

Fig. 1. Preoperative radiographs (upper left and right) obtained in a patient who had undergone a prior L3–5 fusion and preoperative MR images (lower left and right) revealing adjacent-level degeneration at L1–2 and L2–3.
Lumbar arthroplasty for adjacent-segment degeneration

cutting chisel guided over the prosthesis trial. The endplates were then distracted, and the polyethylene implant was inserted. Anteroposterior and lateral fluoroscopy was performed to confirm the appropriate prosthesis positioning and size. No other procedures were performed at that time of the index procedure.

Outcome Measurement

Patients were assessed preoperatively and 3, 6, 12, and 24 months postoperatively. The primary functional measures were disability (the ODI) and pain (the VAS). Additional clinical parameters included analysis of pre- and postoperative patient satisfaction, general back pain, radicular pain, medication usage, and complications. Patient satisfaction was rated as completely satisfied (pain absent at all times and unimpaired employment and ADL), satisfied (slight pain that requires no medication and that occurs no more than once per day, minimal impairment in employment or ADL); and 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 (≥ once per day; 2), and regular (> once per day; 3).

Radiographic Assessment

Postoperative radiographs (standing AP, lateral, flexion-extension, and lateral bending films) were obtained at 3, 6, 12, and 24 months in all patients (Figs. 1 and 2). The patient represented in Fig. 1 underwent preoperative discography that revealed positive findings at L1–2 and L2–3. 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 using digitized images and appropriate computer software (Medimage Software; Vepro Computersysteme GmbH, Pfungstadl, Germany). To measure the angular motion, the Cobb method was calculated using the prosthetic endplates as references. Measurements were performed three times by a single reviewer, and a mean score was obtained for angular and length measurements. Two separate reviewers (the attending spine surgeon not involved in surgery and an attending radiologist) reviewed all pertinent radiographs for signs of device-related loosening, dislodgment, and/or subsidence.

Statistical Analysis

Two primary research questions are of interest: 1) whether significant improvement occurred between baseline and the 3-month postsurgery examination (proximal effect); and 2) whether improvement was maintained from 3 months to 2 years postsurgery. Because of the size and observational nature of the study, we limited our analysis to several simple tests (t-tests for the continuous VAS and ODI scores, and nonparametric sign tests for back and leg pain scores) combined with careful exploratory data analysis.

Results

Demographic Data

Eighteen of 20 patients fulfilled all follow-up criteria. Two patients could not be examined postoperatively because they moved. Questionnaires regarding ODI, VAS, satisfaction, medication usage, and back pain rating were sent to these two patients. No adverse events occurred nor were additional procedures necessary in these patients. The median follow-up period was 27 months (range 24–48 months). The mean interval between the prior fusion surgery and ProDisc ADR was 4.5 years (median 3 years, standard deviation 51.8 months, range 6–216 months).

Fifty-six percent of the patients had undergone prior two-level (eight cases [44%]) or three-level (two cases [11%]) fusion (Table 1). The remaining 45% of patients had undergone single-level fusion. In one case, a ProDisc was placed into a prior nonunion and an additional level of ADR was performed. In our study, 16 patients underwent one-level ADR and two patients underwent two-level ADR. Two patients had previously undergone ALIF. In these two patients, a standard retroperitoneal exposure was performed. The median blood loss was 100 ml (range 40–300 ml). One patient required a blood transfusion.

The median operative time was 152 minutes (range 70–280 minutes). The duration of hospital stays ranged from 6 to 14 days (mean 12 days). Note that surgeries were performed at a German facility where hospital stays are regulated according to diagnosis and German national patients are required to stay in the hospital based on diagnosis codes for at least 10 days following ADR surgery.

Clinical Outcomes

The graphs in Fig. 3 show individual patient measurements for the continuous variables, ODI and VAS. An improvement in VAS-documented pain failed to occur in only two patients between the baseline and 24-month measurements, and some improvement in ODI scores were observed in both. Furthermore, one of these two patients was the only patient who did not report an immediate reduction in VAS score by 3 months (there was no change in this patient’s VAS score during this period). In all patients, an immediate improvement in ODI scores was documented at
3 months, and all demonstrated some improvement at the 24-month examination compared with the presurgery examination. In only three patients did ODI scores not continue to improve between 3 and 24 months. The mean trend is represented by the line segments connecting the points in the center of the clusters in Fig. 3. Decreases in medication usage were also noted at 24 months compared with preoperative values (Table 4).

Table 2 provides a summary of the ODI and VAS scores, including the means and standard errors of the means presurgery and at 3, 6, 12, and 24 months postsurgery, as well as two measures of improvements (presurgery–3 months and 3–24 months). The improvements observed during the interval between pretreatment and 3 months posttreatment were statistically significant in both measures (in each case, \( p < 0.0001 \)).

Although 3- to 24-month follow-up ODI improvements were of statistical significance (\( p = 0.002 \)), the corresponding improvement in VAS score was not significant; however, the improvements in VAS score achieved at the 3-month examination appear to be well sustained to 24 months. Finally, it is interesting to note that in 11 of the 20 patients a reduction in ODI score greater than 50% was present at 24 months, and in 17 the reduction was greater than 20%. Similarly, in 16 of 20 more than a 20% reduction in VAS score was documented, whereas in 12 at least a 50% reduction in VAS score was observed at the 24-month examination. Two patients with initial improvements in VAS and ODI scores experienced a return of some pain and disability at 6 months. Both of these patients had previously undergone posterior instrumented PLF and removal of previous instrumentation was required. After the hardware was removed, disability and pain improved.

Back pain, leg pain, and satisfaction scores were ordinal (completely satisfied [1], satisfied [2], unsatisfied [3]; Table 3). Figure 4 shows a graphic representation of the mean score at each follow-up interval, although no measure of patient satisfaction was available at baseline. A delayed onset in reduction of back pain was evident; improvement at 3 months was rare, with only three patients experiencing any improvement compared with their baseline status. In contrast, improvement in leg pain appeared immediately, but with little continued improvement on average throughout the follow-up period. In fact, examination of individual leg pain scores showed that the leg pain measurements were far more variable (and fewer clear trends by individual) than any of the other measures considered. It is interesting to note that of the four patients with moderate baseline back pain (pain Grade 2), none claimed any im-

![Fig. 3. Raw VAS (left) and ODI (right) scores obtained in each of the 20 patients.](image-url)
improvement (to a grade of 1) at 24 months and one reported increased back pain (to a grade of 3); the other three reported no change (Grade 2). Of the 16 patients who presented with severe pain (Grade 3), pain in eight decreased to the lowest level (Grade 1), it improved somewhat in five (to a grade of 2), and it continued to be severe in three patients. Preoperatively, 23% of the patients worked part time and 13% worked full time; these rates increased to 38 and 27%, respectively. Thirty-five percent of the patients remained unemployed postoperatively.

**Radiographic Analysis**

The median preoperative affected posterior disc height was 3.7 mm; postoperatively, it increased 11 mm (p < 0.001). Motion of the affected discs was increased on average from 3’ preoperatively to 6’ postoperatively (p < 0.004). The adjacent-level disc height was not significantly changed. There were no cases of hardware subsidence, loosening, dislocation, or failure of metallic or polyethylene components.

**Summary of Complications**

**Device-Related Complications.** We observed no device-related complications. There were no cases of hardware loosening, subsidence, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurological injuries caused by the implant components, and/or infection.

**Approach-Related Complications.** There were no approach-related complications.

**Other.** A single patient experienced delayed-onset elevated liver function parameters and jaundice. The cause was thought to be secondary to a transfusion reaction. No viral origin was identified, and recovery was spontaneous.

**Discussion**

Adjacent-level disc degeneration following lumbar fusion has been well documented and little controversy exists as to the additional disability resulting from this proximate degenerative process.7,11,12,18,20,24 Ghiselli, et al.,11 have reported the incidence of postoperative adjacent-segment degeneration (defined by instability) to be 16.5% at 5 years and 36.1% at 10 years.11 Although Chen, et al.,1 reported a 94.9% fusion rate in patients with adjacent-level degeneration, their combined excellent and good clinical rate was only 76.4%. The optimal treatment method for adjacent-segment degeneration, thus, has yet to be defined. Although renewed pain is often a clinical indicator of symptomatic adjacent-segment degeneration, the disease process at the adjacent segment can often be distinct from the initial triggering process at the proximate level of disease.25 Schlegel, et al.,25 conducted a longitudinal study in 58 patients with symptomatic abnormalities adjacent to previously fused segments. The patients were symptom free for a mean of 13 years. Although spinal stenosis was the most common diagnosis, adjacent-segment abnormalities also included prolapsed disc and listhesis. Interestingly, the authors also found that 58% of the levels contiguous with the adjacent levels were also abnormal. Therefore, diagnos-

![Graph demonstrating the mean back and leg pain scores and patient satisfaction at each follow-up interval.](image-url)


In early in vitro biomechanical studies, Lee and Langrana found that posterior fusion produced the greatest stress on adjacent motion segments. In a clinical study, Lee further characterized adjacent-level disease including facet joint degeneration, disc degeneration, acquired spondyloyis, and spinal stenosis. In in vitro studies conducted by Weinhofer, et al., and others, increased intradiscal pressure has also been demonstrated in adjacent-level discs. Finite analysis demonstrated that fusion increased stress on the vertebral endplate and anulus fibrosus, suggesting that adjacent-level disease may begin with damage to these two motion segment components. Similar stresses were found in finite analysis of cervical fusion. Histo logical analysis of adjacent-level specimens obtained in a canine model implicated the facet joints in the degenerative process. Due to the varying clinical presentations and degrees of adjacent-segment degeneration, a single optimal treatment modality will not likely be found; however, as illustrated in our early findings, ADR appears to offer an effective option for those patients with adjacent-segment degeneration in the setting of primarily axial back pain with or without radicular symptoms, in the absence of facet joint degeneration. Compared with our analysis of multilevel ADR in which we observed a 93.4% clinical success rate, the use of ADR to treat adjacent-segment degeneration appears to offer a reasonable alternative. Although a randomized prospective comparison of ADR and fusion may theoretically yield superior Level-1 data, analysis of our data provides initial feasibility and clinical support for the use of ADR as a treatment alternative. We concede that long-term follow-up evaluation will be necessary before ADR can be considered a general recommendation for the treatment of adjacent-segment degeneration.

We recommend strict adherence to traditional inclusion and exclusion criteria for ADR and that all patients undergo CT scanning to assess for facet joint degeneration. The presence of facet joint impingement secondary to posterior fixation used for prior fusion should be excluded. The pain-inducing hardware should be removed prior to ADR. If necessary, myelography should be undertaken to exclude advanced cases of spinal stenosis. Circumferential spinal stenosis present at the adjacent-level segment should be considered a relative contraindication to ADR because of the potential of decreasing the spinal canal volume as a result of the lordotic enhancement.

### References

14. Hochschuler SH, Ohnmeiss DD, Guyer RD, Blumenthal SL:

---

### TABLE 4

**Summary of medication usage stratified by regularity of consumption**

<table>
<thead>
<tr>
<th>Drug Usage</th>
<th>NSAIDs (%)</th>
<th>Narcotics (%)</th>
<th>Tramadol (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preop 24 mos</td>
<td>Preop 24 mos</td>
<td>Preop 24 mos</td>
</tr>
<tr>
<td>never</td>
<td>31.2</td>
<td>64.2</td>
<td>68.7</td>
</tr>
<tr>
<td></td>
<td>92.8</td>
<td>37.5</td>
<td>42.8</td>
</tr>
<tr>
<td>occasionally</td>
<td>0</td>
<td>14.2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>7.1</td>
<td>0</td>
<td>14.3</td>
</tr>
<tr>
<td>regularly</td>
<td>68.8</td>
<td>20.0</td>
<td>31.2</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>62.5</td>
<td>42.8</td>
</tr>
</tbody>
</table>

* NSAIDs = nonsteroidal anti-inflammatory drugs.
Lumbar arthroplasty for adjacent-segment degeneration


Manuscript received March 16, 2005. Accepted in final form November 1, 2005.
Address reprint requests to: James J. Yue, M.D., Department of Orthopaedic Surgery and Rehabilitation, Yale University School of Medicine, 800 Howard Avenue, P.O. Box 208071, New Haven, Connecticut 06520. email: james.yue@yale.edu.