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 perio

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Abbreviations used in this paper: ADL = activities of daily living; ADR = artificial disc replacement; AP = anteroposterior; CT = computerized tomography; LBP = low-back pain; MR = magnetic resonance; ODI = Oswestry Disability Index; PLL = posterior longitudinal ligament; VAS = visual analog scale.

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Figures and Tables

Abstract

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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-yea 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.

KEYWORDS: total disc replacement; ProDisc; lumbar discogenic pain; low-back pain; elderly.

Introduction

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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 be proposed as an alternative to lumbar fusion in the treatment of certain cases of lumbar spondylosis when significant facet joint degeneration is absent. Artificial dis 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 nc 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

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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, osteoperosis defined as a T-score greater thar −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 erosiv 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 joint 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 wit 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 th 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 diseas 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 marke 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 retractir 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 posteric cortex of the superior and inferior vertebral bodies and elevating the insertion of the PLL. At the conclusion of the discectomy and implantation, the two halves of the anterior anulus fibrosus were reapproximated.

Lateral fluoroscopy was used to determine appropriate size with regard to disc height and AP diameter (trialing). The adequate central/midline location of prosthes 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 th 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[8] 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 ar 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 and 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 nc 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.

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FIG. 1. Imaging studies obtained in a patient who underwent three-level ADR: postoperative radiographs *(left)* and preoperative MR images (*center* and *right*).

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. Given the size and observational nature of the 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) combinec with careful exploratory data analysis.

Results

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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 duratior 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 tw 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 postoperatively; 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.

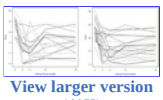

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FIG. 2. Graphs showing raw VAS *(left)* and ODI *(right)* scores for each of the 22 elderly patients.

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 (pre-surgery–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 postoperatively. 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.

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TABLE 1 *Summary of raw ODI and VAS clinical outcome data**

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.

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TABLE 2 *Summary of clinical outcome data in patients older than 60 years of age**

Click to view table

TABLE 3 *Incidence of medication usage before and 24 months after surgery**

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 hetero-topic 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 c abnormal vascular anatomy. No vascular complications occurred in relation to surgery.

Discussion

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The treatment of chronic discogenic LBP in patients older than 60 years of age is challenging and controversial. The diagnostic challenges associated with LBP ar 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 scoliotic deformities, osteoporotic fractures, and the possibility of metastatic or marrow malignancy.[13] 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[2] wrote that "age changes are observed in the arterioles, capillaries, and venules found in the nutrient canals or spaces the bone adjacent to the cartilage or disc. The calcification of the articular cartilage and vascular changes seen in the older vertebrae . . . impede the passage of nutrients from the blood to the disc proper."

Bressler, et al.,[6] 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. Stoll, et al.,[19] 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 Dynesys instrumentation (Zimmer Corp., Warsaw, IN) (without fusion); postoperatively, status had improved. In another study conducted to evaluate the use 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.[23] The results of dynamic posterior stabilization and rigid versus semirigid instrumentation with fusion were recently compared in three groups with degenerative spinal stenosis.[12] The authors found no clear-cut advantage for any one type of instrumentation in terms of fusion rate 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 i spinal stenosis and isolated lumbar disc herniation. An and colleagues[1] 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.[15,17,18,21]

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 bo single-and multilevel lumbar disc disease.[3–5] Our overall complication rate, however, in the older age group was higher, and it reflected two cases of foot drop and case of loss of pro-prioception 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 face joint degeneration and spinal stenosis. If necessary, myelography should be performed to exclude advanced cases of spinal stenosis. Circumferential spinal stenosi 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 lordot 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 w use 5 to 10 ml of bone cement in the relevant vertebral bodies following implant placement but during the same operative session. After implementing this procedural modification, no cases of implant subsidence have occurred.

Conclusions

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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.

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