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Orthop Clin N Am 36 (2005) 301 – 313

ORTHOPEDIC
CLINICS
OF NORTH AMERICA

Clinical Results of ProDisc-II Lumbar Total Disc Replacement: Report from the United States Clinical Trial

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Chronic low back pain from degenerative disc disease is endemic in our society. The surgical treatment of this problem can often be frustrating. Fusion of the painful degenerative segment is often associated with mediocre results, prolonged recovery time, significant postoperative morbidity, and future degeneration at the adjacent levels. Lumbar disc replacement has been shown to be a promising alternative in the treatment of low back pain and may eliminate the stigmas associated with fusion. The long track record of lumbar disc replacements in Europe combined with the recently completed United States Investigational Device Exemption (US IDE) pivotal clinical trials have provided encouraging results for this motion-preservation technology compared with spinal fusion. Interest in disc replacement has risen rapidly in the last few years in the United States, but the concept itself is not new. It represents the latest development in the spectrum of nonfusion surgical technologies for spinal reconstruction.

Despite the controversy surrounding surgical fusion of the painful degenerating functional spinal unit, for lack of a better alternative it has de facto become the "gold standard" procedure for intractable cases that fail nonoperative treatment. The specter of potential complications and poor outcomes from fusion has however driven a major effort to develop numerous motion-preserving anterior or posterior spinal column reconstruction techniques. Conceptually, the logical progression of intervention for a degenerative spinal segment should be as depicted in Fig. 1, with examples of currently available state-of-the-art implants at each stage. Each subsequent intervention can be considered a salvage procedure for the previous procedure. Dynamic neutralization and nucleus replacement may be performed individually or in combination. These devices are still considered experimental pending the completion of clinical trials. A spinal fusion, the present gold standard, is still available as the end-stage salvage procedure.

The ProDisc implant

Thierry Marnay created the first ProDisc-I prosthetic disc in 1989 at Montpellier, France. The first human implantation was in 1990. To his credit, after implanting 93 implants in almost 70 patients, Marnay stopped to evaluate the long-term outcomes of his implant. Finally, in 2001 and 2005 he published his results after an 8- to 10-year follow-up [1–3]. All implants remained intact without any migration or subsidence. Range of motion of the spinal segments was maintained. Back and leg pain were significantly reduced, and almost 93% of the patients were satisfied and would have the surgery again. The promising results from his experience paved the way for the pivotal clinical trials recently completed in the United States.

The first generation ProDisc-I had titanium endplates and a double keel. In 1999, it was changed to cobalt chrome endplates with a single keel (ProDisc-II, Fig. 2). The single serrated keel over each endplate, two small lateral pegs, along with the plasma-sprayed ingrowth surface give the implant

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doi:10.1016/j.ocl.2005.03.004

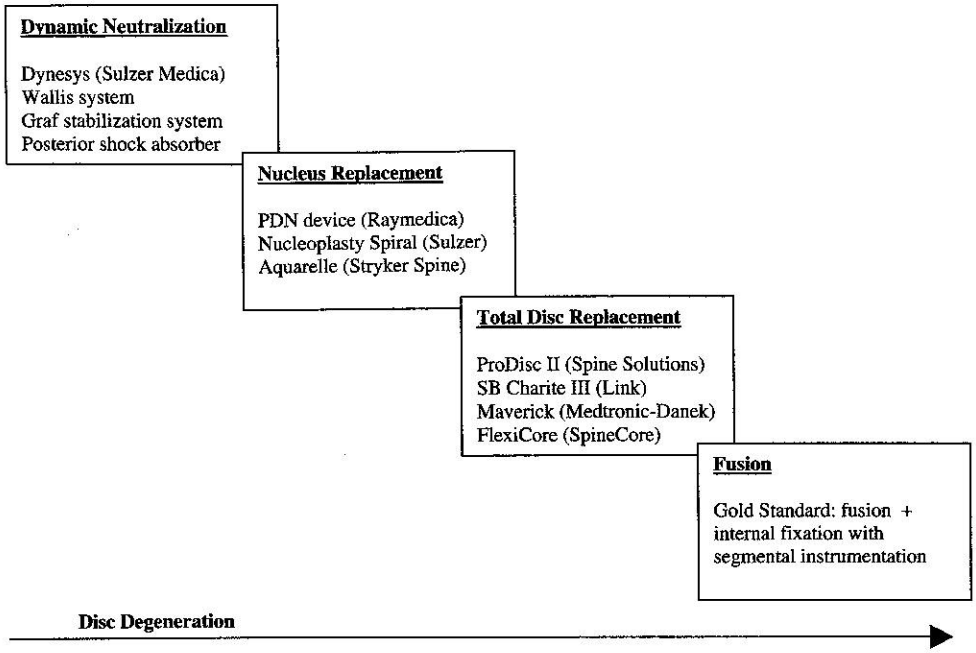

Fig. 1. Options in surgical treatment of degenerative disc disease.

immediate stability. The insert is made of ultra-high molecular weight polyethylene, which snap-locks to the bottom endplate and thus has only one articulating convex side. The device is semiconstrained, allowing it to "load-share" with collateral structures such as the facet joints, ligaments, tendons, and muscles, especially in shear. This places more load at the device-bone interface but protects the facet joints. Axial rotation is unconstrained, and the axis of rotation of the cephalad endplate is angled posteriorly in the neutral position due to the intradiscal lordosis of the prosthesis, consistent with the physiologic axis of rotation [4].

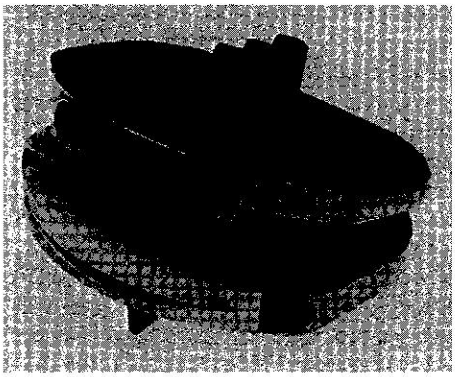

Fig. 2. The ProDisc-II (Synthes, Paoli, PA).

At the time of article submission, more than 5000 ProDisc-II prostheses have been implanted worldwide since 1999 [5]. A body of literature on the outcomes of these procedures already exists and is listed in Table 1. In general, results have been favorable, with outcomes consistently in the 90% good to excellent results, and with significant decreases in pain and disability scores. Functionally speaking, in the experience at our institute, the disc replacement patients had significantly greater segmental range of motion compared with the controlled fusion group at up to 24 months. [6,7] Bertagnoli and Kumar [8] reported an average range of motion of 10 degrees at L3-L4, L4-L5 and 9 degrees at L5-S1 at 1 year after ProDisc placement. Tropiano et al [9] reported a 10 degree range of motion at L4-L5 and 8 degree range of motion L5-S1 after a mean of 1.4 years of follow-up. Huang et al [10] reported that at a mean of 8.7 years, the ProDisc prostheses had a mean measurable motion of 4 degrees at L3-L4, 4.5 degrees at L4-L5, and 3.2 degrees at L5-S1 without any radiographic evidence of loosening or osteolysis. Equally important, only nine of 34 (26%) junctional levels above the prostheses demonstrated transitional degeneration at a mean of 8.7 years, none of them requiring surgery. In a comparable follow-up period, Cauchoix and David [11] reported transitional changes in 79% of patients 10 years after fusion surgery. For a follow-up ranging from

Table 1
ProDisc outcome studies

Study
Marnay [1]
Mayer and Wiechert [19]
Marnay [2]
Bertagnoli and Kumar [8]
Delamarter et al [6]
Zigler et al [14]
Tropiano et al [9]
Bae et al [7]

Abbreviations: ODS, Oswe

2 to15 years, Gillet [12
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United States pivotal

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Table 1
ProDisc outcome studies

Study	Number of patients (N)	Mean follow-up in years	Results (% good/excellent)
Marnay [1]	64	7–11	93%
Mayer and Wiechert [19]	34	0.5	83%
Marnay [2]	>200	2	Favorable early results
Bertagnoli and Kumar [8]	108	Up to 2	99%
Delamarter et al [6]	35	0.5	Significantly lower VAS, ODS
Zigler et al [14]	49	0.4	Significantly lower VAS, ODS
Tropiano et al [9]	53	1.4	94%
Bae et al [7]	56	1.5–2	Significantly lower VAS, ODS

Abbreviations: ODS, Oswestry Disability Score; VAS, Visual Analog Score.

2 to15 years, Gillet [12] reported transitional degeneration in 32% after 1-level fusion, but severe enough for 11% to need further surgery.

There are few published reports of device or insert subluxation, dislocation, migration, or subsidence. This is likely due to the uniconvex articular surface of the polyethylene insert, fixation of the insert to the lower endplate, and the larger serrated keels on the endplates. The insert locks onto the lower metal endplate. The surgeon needs to make sure it is snapped on flush, for an error in this step, though uncommon, can risk it coming loose. Mayer et al [13] described one patient in a series of 34 patients who underwent reoperation to replace an insert that wasn't locked into place properly. Similarly, Zigler et al [14] describe one case out of 28 where the insert was not locked in properly. Tropiano et al [9] described two cases of malposition of the implant at time of surgery in a series of 53, with three patients needing reoperation.

United States pivotal clinical trial

Currently, 19 US sites are participating in a large-scale, prospective, randomized study comparing clinical outcomes between patients receiving circumferential fusions and the ProDisc-II total disc replacement for one- and two-level degenerative disc disease in the lumbosacral spine L3-S1 vertebral segments. This study is a US Food and Drug Administration (FDA) Investigational Device Exemption multicenter, prospective, randomized study to investigate the safety and efficacy of this ProDisc-II implant. The current enrollment goal was 500 patients, which has been surpassed with surgeries falling under "continued access" or "compassionate use" arrangements with the FDA. Such arrangements have been allowed because of the promising early clinical results achieved by patients receiving the artificial discs. This is an interim comparative analysis and description of the first 78 randomized patients at 2 years after ProDisc total disc replacement or anterior/posterior fusion from one site participating in the FDA-regulated IDE study (ProDisc investigational device exemption #G010133, Synthes, NY).

Design

Approval to conduct the study was given by the FDA and by our participating center's Institutional Review Board (IRB). Patients with predominantly back pain and one or two levels of lumbar degenerative disc disease were considered for the study. Patients were evaluated with plain radiographs, MRI, and occasionally discogram/CT scans. Meticulous inclusion and exclusion criteria were applied and are listed in Table 2. After all criteria were met, the patient was randomized to either anterior-posterior fusion with femoral allograft in the front and autologous iliac crest bone graft with instrumentation in the back, or total disc replacement through an anterior retroperitoneal approach. The randomization was performed such that two out of three patients would receive the prosthetic disc and one out of three would receive circumferential fusion. The circumferential fusion was the current standard of care for up to two-level degenerative disc disease. Patients were blinded to the treatment until after the surgical procedure was performed.

Surgical technique for the ProDisc-II

The ProDisc-II is implanted via an anterior approach to the lumbar spine. In our institute, we use the anterior retroperitoneal approach with a mini-incision less than 6 cm for one-level cases and about 8 cm for two-levels. Intraoperative fluoroscopy is used throughout the operation to verify the placement of the prosthesis. Once exposure is obtained, an anteroposterior (AP) view confirms the level and identifies the midline, which is then marked with the

Table 2
Criteria for patient enrollment in the USA ProDisc-II clinical trial

Inclusion criteria	Exclusion criteria
Degenerative disc disease in one or two adjacent levels between L3-S1	More than two levels of degenerative disc disease
	Endplate dimensions less than 34.5 mm medial-lateral or 27 mm anteroposterior
Back and/or leg pain	Known metal and/or polyethylene allergies
Failure of at least 6 months of conservative therapy	Prior lumbar fusion surgery
Oswestry score >20/50 (>40%)	Clinically compromised vertebral bodies due to prior trauma
Ability to comply with protocol and follow-up	Clinically significant degenerative facet disease
Ability to give informed consent	Lytic spondylolisthesis and/or clinically significant stenosis
Radiographic evidence of disc degeneration includes	Degenerative spondylolisthesis >grade I
1. Decrease in disc height by at least 2 mm	Back or leg pain of unknown etiology
2. Instability indicated by >3 mm translation or >5 degrees of angulation, but less than grade I slip	Objective diagnosis of osteoporosis (DEXA scan)
	Presence of metabolic bone disease (eg, Paget's, osteomalacia)
3. Annular thickening and disc desiccation on MRI	Morbid obesity (Body Mass Index >40)
4. Herniated nucleus pulposus	Pregnancy or expected pregnancy within 3 years
5. Vacuum phenomenon	Active infection
	Medications that retard healing (eg, steroids)
	Autoimmune diseases (eg, rheumatoid arthritis)
	Systemic diseases (eg, AIDS, HIV, hepatitis)
	Active malignancy

cautery. A complete diskectomy is then performed. Cartilage is removed from the vertebral endplates. If herniated disc material is identified on the preoperative MRI, this may be removed through the anterior approach. In some cases, the posterior longitudinal ligament may have contracted, preventing re-expansion of the disc space, so this must be released from the posterior vertebral body with a forward-angled curette. Once the normal anatomic height has been restored with distraction under fluoroscopy, a trial is placed to help select the proper disc size, angle, and height. A sagittal groove is then cut in the vertebral endplates in the exact midline, using a chisel placed over the trial. This groove will accept the central keel of the implant. The trial is removed, and the final implant is then securely impacted into place with an insertion tool. The insertion tool allows distraction of the disc space for placement of the UHMWPE liner, which is snap-fit into position. After the insertion instrument is removed, gross inspection is made to ensure the UHMWPE liner is properly flush against the inferior endplate (Fig. 3), and final fluoroscopic views are taken to confirm correct position of the prosthesis (Fig. 4).

Surgical technique for circumferential fusion

The same anterior approach is used for the anterior diskectomy and fusion. The endplates are also prepared in the same manner, except a femoral ring allograft is placed in the intervertebral space instead of the prosthesis. A standard technique is used for the posterior pedicle screw instrumentation and fusion. The iliac crest bone graft is taken through a separate incision.

Outcome instruments

Patients were asked to complete the standardized Oswestry Disability Index questionnaires [15,16] and to rate their pain on the Visual Analog Scale (VAS) before surgery and at each follow-up clinic visit (6 weeks, 3 months, 6 months, 12 months,

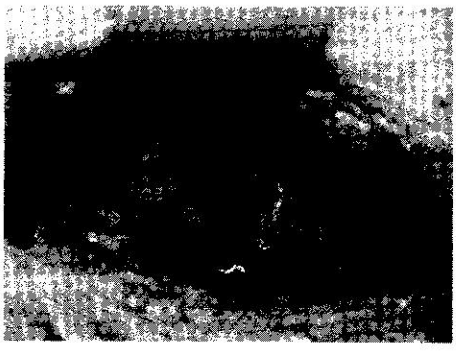

Fig. 3. The polyethylene insert must be flush and locked against the inferior plate.

Fig. 4. Final in

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Radiographs

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For fusion patients, or
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Table 3
Characteristics of random

Subject characteristics
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One-level surgery
Two-level surgery

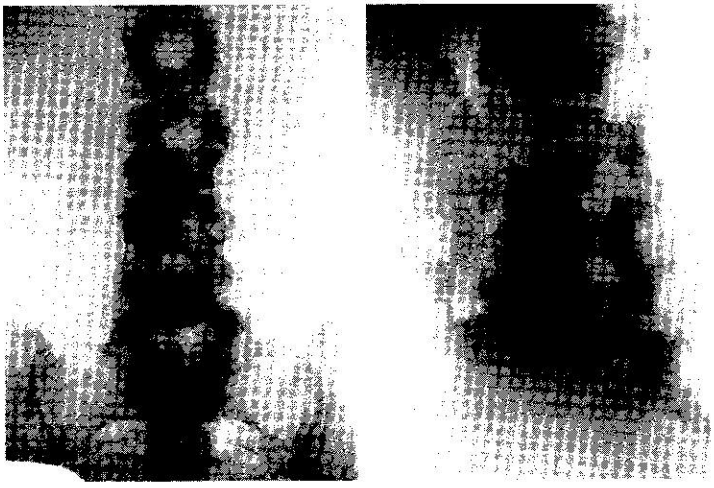


Fig. 4. Final intraoperative fluoroscopic views are inspected to confirm correct positions of prostheses.

18 months, and 24 months). On the follow-up assessments, each patient was requested to remember the pain felt before surgery and asked, "Remembering the pain you felt before surgery, would you have this surgery again?" Additionally, a 10-cm line visual scale (similar to the VAS) was presented to the patient with the instruction to "indicate the amount of satisfaction you feel with your treatment." Investigator-initiated structured queries were on types of recreational activity, ambulatory status, and medications taken for pain.

Radiographs

Flexion, extension, anteroposterior, lateral, and lateral side-to-side bending radiographs (six views total) were taken before surgery and after surgery at 6 weeks, 3, 6, 12, 18, 24 months, and annually thereafter for the artificial disc replacement patients. For fusion patients, only AP and lateral films were taken at 6 weeks and 3 months. At the 6-month and all subsequent postoperative visits, all six radiographs were taken for them as well.

Statistical analysis

Outcomes, range of motion, and demographics were analyzed statistically. Outcome measures and motion data were analyzed by using mixed designs analysis of variance (ANOVA) with repeated measures for assessment interval and a grouping effect for treatment modality (SAS, GLM procedures). Student t-tests and χ^2 were used for simple comparisons across treatments. To determine specific effects, post hoc pair-wise statistical comparisons were made with Student t-tests (group) or paired t-tests (interval within subjects). Angular range of motion was measured at L3-L4, L4-L5, and L5-S1 segments in flexion-extension, and right and left lateral bending. Analysis of variance equations were computed on degrees of motion data including a grouping effect for treatment and within effect for assessment interval,

Table 3
Characteristics of randomized patients treated with artificial discs versus those treated with fusion

	Treatment		
Subject characteristics	Disc replacement (n = 56)	Fusion (n = 22)	P value
Gender (% male)	57%	45%	not significant
Age (average years and range)	39.7 (19–59)	44.2 (25–59)	not significant
Smoking currently	11%	23%	not significant
Worker's compensation cases	33%	39%	not significant
One-level surgery	21	5	
Two-level surgery	35	17	

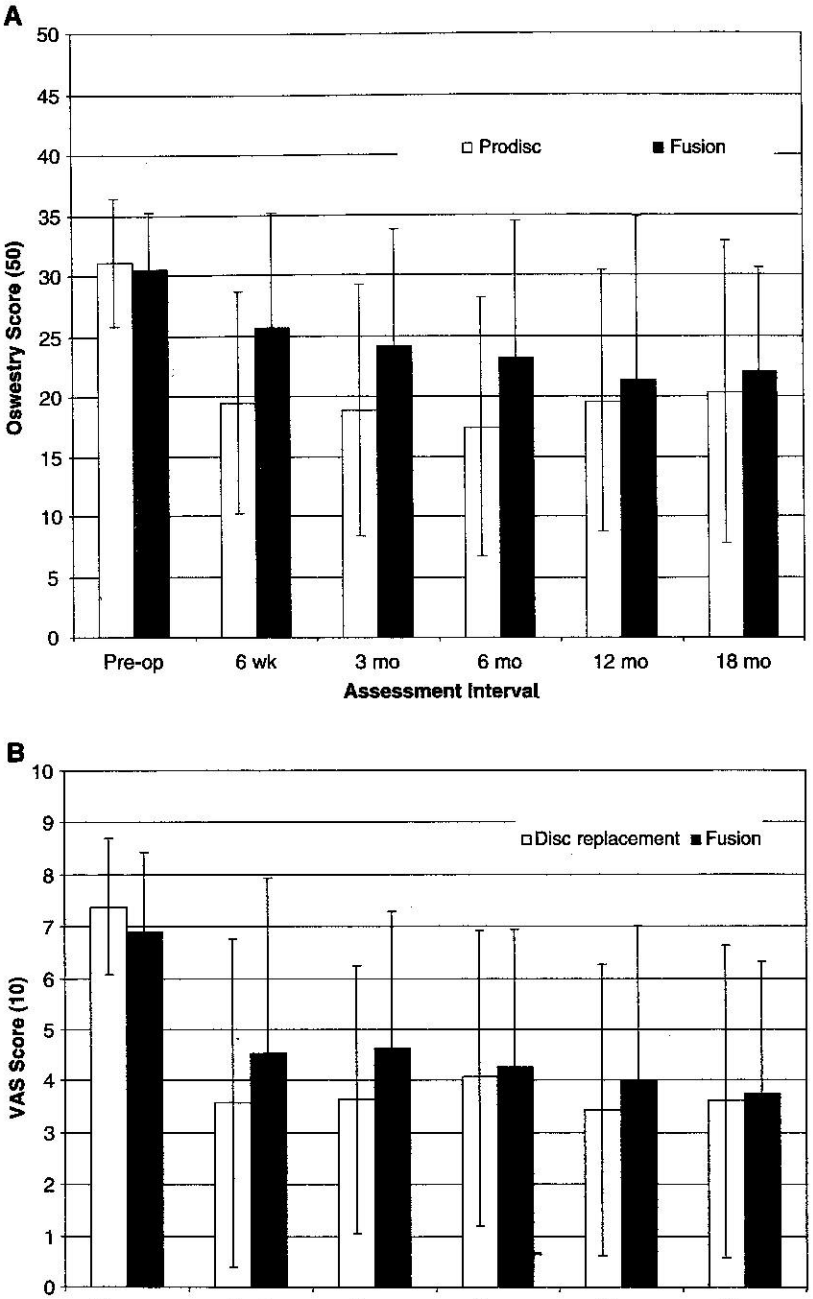
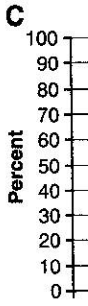


Fig. 5. (*A*) Mean and standard deviations of disability as measured by the Oswestry Questionnaire for patients treated with artificial disc compared with those treated with a fusion procedure. (*B*) Mean and standard deviations of pain as measured by the Visual Analog Scale (10-cm line) for patients treated with artificial disc compared with those treated with a fusion procedure. (*C*) A significantly higher percentage of patients were satisfied with their artificial disc replacement surgeries compared with fusion patients.



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Outcome measures

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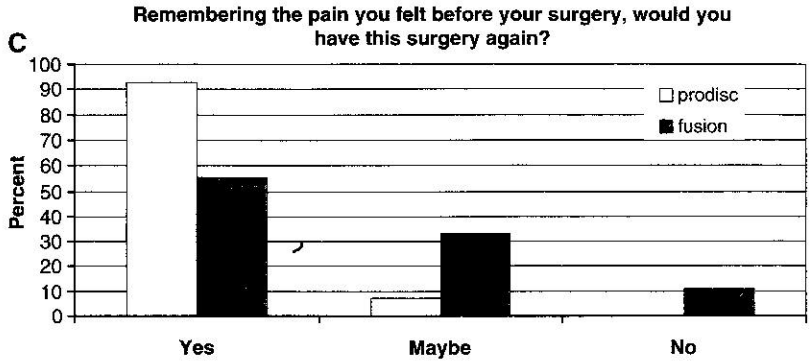

Fig. 5 (*continued*).

separately for each treated segment (L3-L4, L4-L5, and L5-S1).

Results

Data from the first 78 randomized patients (56 ProDisc-II and 22 fusion) with 18- to 24-month follow-up were available for interim analysis. The average age, gender, narcotic use, smoking history, worker's compensation percentage, and duration of back pain before surgery was similar between patients treated with artificial disc replacement (DR) and those treated with a spinal fusion (F), presented in Table 3. Of the 26 patients that were treated for one-level disc disease, there were 21 patients who had disc replacement procedures and five patients who had fusion procedures. Of the 52 patients treated who had two-level disease, 35 patients had disc replacement and 17 patients had fusion procedures. There were no instances of implant migration, breakage, or mechanical failure, nor was any revision surgery required.

Outcome measures

Preoperative values on the VAS and Oswestry Disability Index (ODI) were not significantly different among patients randomized to disc replacement or fusion. After treatment, the disc replacement patients had significantly better results at 6 weeks (VAS) and 3 months (VAS, ODI) compared with fusion patients. By 6 months, although both treatment groups showed significant improvement compared with preoperative values, there was no longer a significant difference between the two groups. From 6 months out to 2 years, the disc replacement patients continued to show more improvement than fusion patients, but the difference was not significant. At the longest follow-up, both groups were significantly improved from their preoperative state (Fig. 5A–C).

Patients who received a disc replacement had a significant decrease in pain as measured by the VAS as early as 6 weeks after surgery ($P<0.05$). At 3-month, 6-month, 12-month, 18-month, and 24-month intervals, this significant reduction in pain was maintained at about a 50% decrease from preoperative levels (all P values <0.05). Fusion patients also showed significant improvement in VAS scores postoperatively versus preoperatively ($P<0.05$). A direct comparison between the groups of patients revealed disc replacement treated patients had significantly less pain than fusion treated patients at 3 months ($P<0.05$).

The patients treated with the disc replacement also reported quicker increase in functional ability than those who underwent spinal fusion (Table 4). Disability was significantly reduced from preoperative reports (ODI) for disc replacement patients by as early as 3 months ($P<0.001$). It took fusion patients generally 6 months before a significant improvement was observed ($P<0.01$). Disc replacement patients had significantly more reduction in early pain and disability. At 6 months and later up to 2 years,

Table 4
Average recovery rates of disc replacement patients

	Treatment	
Functional status	One-level disc replacement	Two-level disc
Hospital stay	2 days	3 days
Return to work	2 weeks	2–3 weeks
Recreational sports	3 months	3 months

disc replacement and fusion patients had similar scores on both the VAS and ODI. At final follow-up, 93% of the patients reported that they were "satisfied" or "entirely satisfied" with the procedure.

Estimated motion from flexion-extension radiographs

Range of motion data are presented separately for treated vertebral segments L4-L5 (Fig. 6A) and for L5-S1 (Fig. 6B). Flexion-extension angular differences measured from radiographs yielded a measure of estimated range of motion. Motion for the disc replacement and fusion-treated segments are presented for preoperative and postoperative intervals (6 months and 12 months). Flexion-extension radiographs were not obtained after surgery for fusion patients until the 6-month follow-up visit.

An analysis of sagittal angular motion revealed an increase in motion from preoperative to the 6-month postoperative period for the L4-L5 vertebral segment

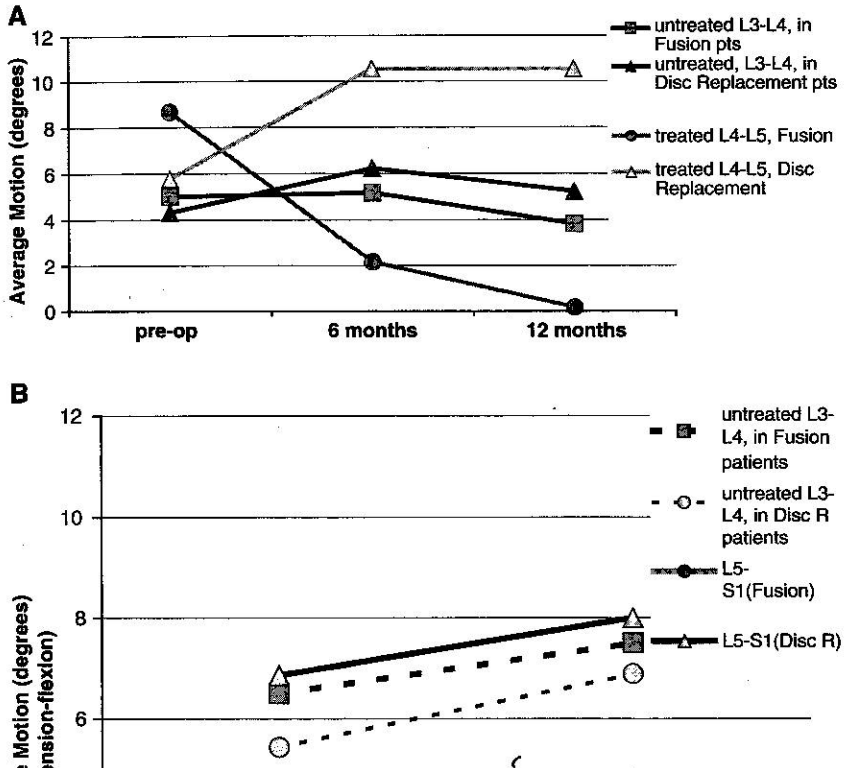

Fig. 6. (*A*) Means for motion at the L4-L5 segment and the L3-L4 segment for patients treated at the L4-L5 segment with artificial disc versus fusion. Motion was determined from flexion-extension angular measurements. (*B*) Means for motion at the L5-S1 segment and the L3-L4 segment for patients treated at the L4-L5 segment with artificial disc versus fusion. Motion was determined from flexion-extension angular measurements (1–2 year data are available but were still being measured from radiographs at time of this printing).

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Discussion

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For an evaluation of consistency in the methodology used to compute motion from radiographic measurements, data from the untreated L3-L4 segments were evaluated separately in each group. There was no significant difference in angular motion at the untreated L3-L4 level measured before surgery and after surgery at 6 months and 12 months for patients in the disc replacement or fusion group. Fig. 6A presents L3-L4 data for patients treated at L4-L5, and Fig. 6B presents L3-L4 data for patients treated at L5-S1 (no significant difference).

Discussion

Demonstration of superiority or at least equivalency to the current standard of care is a prerequisite for new treatments in degenerative disc disease to be accepted in practice. Although lumbar spinal fusion has led to some improvement in symptoms compared with nonsurgical care, unfortunately many patients continue to have pain and functional limitations. Smith et al [17] showed a 68% clinical improvement at 5 years in 25 patients suffering from low back pain and who had positive discograms but refused surgical intervention. One of the most acclaimed recent studies on fusion for low back pain revealed that 60% to 68% of patients rated themselves "better" or "much better" at 2 years after surgery, and 12% to 16% were "worse" [18]. VAS scores decreased from 6 to 4 on average, and leg pain decreased from 4 to 3. Overall Fritzell et al [18] showed that lumbar fusion reduced back pain by 33% compared with 7% with nonsurgical treatment. In this study, disability according to the ODI was reduced by 25% compared with 6% in the nonsurgical patients.

In comparison with published results from lumbar spinal fusion for chronic low back pain, the initial European study on the ProDisc prosthesis showed more promise. A retrospective study of the original ProDisc-I, with 7 to 11 years of follow-up on 61 patients was conducted [1]. One third of these patients had two-level ProDisc-I implantation. There were no cases of subsidence or migration, and no implants had to be removed or revised. Overall, 92.7% of the patients reported that they were "satisfied" or "entirely satisfied" with the procedure. The average VAS for back pain went from 8.5 to 3.0 from pre-op to post-op. VAS for leg pain went from 7.0 pre-op to 2.0 post-op.

The excellent European results with the ProDisc devices with the lack of any catastrophic failures or device-related issues have paved the way for the FDA pivotal clinical trials currently underway in the United States. The interim results presented here are derived from the subset of all patients with 18 to 24 months of follow-up at a single institution. Although this analysis is limited to one site in the US trial and represents a mid-term report, it does provide prospective information on how randomized patients recover after prosthetic disc replacement versus fusion procedures in the postoperative period up to 2 years. Disc replacement patients display less pain on the VAS at the early postoperative period up to 6 months and have significantly improved functional status (lower ODI) at up to 6 months compared with fusion patients.

The early superiority of disc replacement over fusion may be partially explained by the decreased postsurgical morbidity in the disc replacement group. Disc replacement patients have only an anterior procedure and thus do not have to recover from the additional posterior approach and harvesting of iliac crest bone graft necessary for spinal fusion. Circumferential spinal fusion (as opposed to anterior only) was chosen as the "standard of care" controls because the ProDisc-II is unique among the proposed artificial disc designs in the market today in that it can be used for two-level degenerative disc disease. Standalone anterior spinal fusion is not the standard of care for multilevel degenerative disc disease.

Fusion patients did not report a significant increase in functional status and decrease in pain until the 6-month period. At the 6-month assessment, they had similar VAS and ODI scores to the disc replacement patients, showing a marked improvement from 3 to 6 months. Compared with their pre-op status, the spinal fusion patients also had dramatic improvement in their VAS and ODI scores by 6 months. This may be due to consolidation of the fusion. However, this may also be partially explained by a selection bias, because all patients in this study have to meet strict selection criteria before qualifying for the study (Table 2).

The issue of motion preservation was critically evaluated from pre-op to 24 months in both disc replacement and fusion patients. All patients in this motion analysis were treated at either the L4-L5 or L5-S1 level, or both. At the L5-S1 level, an increase in sagittal motion in the disc replacement patients was observed compared with fusion patients. However, this difference was not significantly different. This may be in part due to the fact that this level is naturally the least mobile in the lumbar spine, and therefore differences in motion are small and harder to detect with a relatively small sample size. The L5-S1 level is also the most difficult to visualize accurately on a lateral radiograph due to the shadow of the sacral ala on this projection.

At the L4-L5 level, the sagittal motion data suggests that the disc replacement not only preserves motion, but can also increase or restore motion, at least in the follow-up period presented. Theoretically, by maintaining range of motion, a protective effect is imparted against future degeneration at the adjacent segments. In the future, it will be important not only to evaluate whether or not there is motion but also to qualify the type of motion that occurs across the spinal segment, as this may play a role in facet displacement and loading. Each prosthetic design will have its own motion parameters, with differing constraints and kinematics in bending, rotation, and translation. All disc replacements may maintain motion and protect the adjacent level, but the local effect at the facets may be the differentiating factor. Only long-term follow-up will reveal whether a significant effect is observed at the level adjacent to a disc replacement, and whether facet arthrosis can be prevented or will be exacerbated depending on the prosthesis design. Other issues that may exist with disc arthroplasty such as infection, wear particles, subsidence, implant failure, and longevity have not been a factor at this interim stage of the study.

Summary

In the musculoskeletal arena, low back pain is a veritable epidemic in our society today. The treatment for this common ailment, both nonoperative and operative, can often be frustrating. The current surgical standard of care, spinal fusion, is often associated with mediocre results, long recovery time, significant postoperative morbidity, and future adjacent segment degeneration. Artificial disc replacement has proven to be a promising alternative to other surgical treatments of chronic low back pain and may obviate the stigmas associated with spinal fusion. The US IDE Pivotal Clinical Trial, which has recently completed enrollment at selected clinical sites, will provide valuable information comparing this new technology to the current mainstay treatment of spinal fusion. The intermediate-term results from our site demonstrate that the objective of decreasing postoperative morbidity and improving recovery has been met. Patients who received the disc replacement as opposed to fusion had a significant improvement in pain and functional status in the early postoperative period. Over the intermediate-term, the prosthetic disc does serve to preserve motion at the surgical level(s). The more important benefit of protection of adjacent levels can only be assessed with completion of the multi-center study and long-term follow-up.

Case studies

Case 1

A 38-year-old man presented with severe back and buttock pain after discectomy at L4-5 in 1997. After the discectomy, he initially experienced some relief of his leg pain and then had progressively worsening back and buttock pain. He had a prolonged course of physical therapy, analgesic medication, and multiple epidural injections, all of which only gave him temporary mild relief. On examination, he had significant mechanical pain with flexion, extension, and side bending. Radiographs and MRI revealed moderate disc degeneration at L4-5, and minimal degeneration at L3-4 and L5-S1 (Fig. 7A, B). A discogram revealed concordant pain at L4-5 only. The patient underwent a one-level L4-5 anterior disc replacement with ProDisc-II. Clinically, the patient reported great improvement in his back pain, and was able to return to active duty as a police officer. The lateral flexion and extension radiographs on his 2-year follow-up reveal preservation of motion at L4-5 (Fig. 7C).

Case 2

A 45-year-old woman presented with intractable low back pain of at least 5 years duration. She works as a park ranger in an Alaskan national park, and her symptoms were significantly hindering her work. Her pain radiated to bilateral buttocks but no further. She had failed the gamut of nonoperative treatment, including physical therapy with multiple modalities,

Fig. 7. Case 1 preoperat
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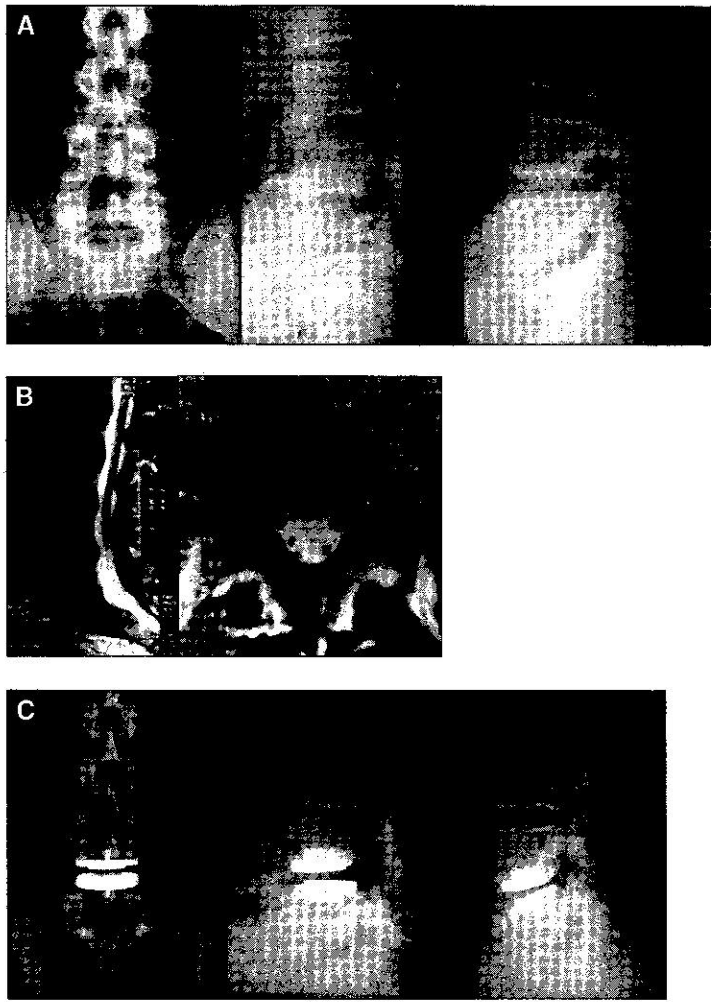

Fig. 7. Case 1 preoperative radiographs (*A*), and MRI (*B*), and postoperative anteroposterior and flexion extension radiographs (*C*).

epidural steroid injections, facet blocks, and radiofrequency ablation of her facet joint nerves. She was on Celebrex and multiple hydrocodone pills a day for pain control. Her radiographs and MRI revealed degenerated discs at L3-4 and L4-5 (Fig. 8A, B). Discograms were concordantly positive at L3-4 and L4-5. She had markedly asymmetric collapse of the disc spaces at the two affected levels, resulting in local scoliotic deformity. She successfully underwent a two-level artificial disc replacement with the ProDisc-II (Fig. 8C). By 6 months postoperatively she related outstanding pain relief and continues to do well 18 months out. She went back to work as a park ranger, was swimming, and was off all narcotic pain medications.

Case 3

A 37-year-old woman presented with an approximately 20-year history of low back pain that had been progressively deteriorating over the last several years. She denied any radiation of her pain. She was a multi-sport athlete in high school when her troubles began. She had tried exhaustive nonoperative measures for her back. She had seen chiropractors, physical therapists, taken multiple nonsteroidal anti-inflammatory pills and strong narcotic pain pills, and received acupuncture to no avail. The pain was keeping her from even her normal activities of daily living at this point. Plain radiographs revealed mild degenerative changes with anterior spurring at L3-4

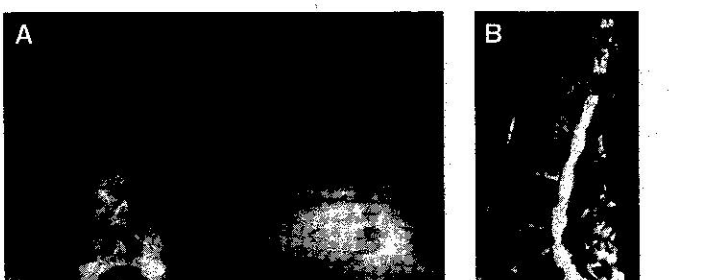

Fig. 8. Case 2 preoperative radiographs (*A*), and MRI (*B*), and postoperative anteroposterior and flexion extension radiographs (*C*). Note the dynamic correction of local scoliotic deformity at L3-5 due to asymmetric disc collapse.

Fig. 9. Case 3 preoperative radiographs (*A*), MRI (*B*), and CT discogram (*C*), and postoperative anteroposterior and lateral radiographs (*D*).

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and L4-5, but severe degenerative changes at L5-S1 with collapse of disc space (Fig. 9A). The MRI revealed desiccated discs at L3-4, L4-5, and L5-S1 (Fig. 9B). Discogram CT revealed internal disc disruption at all three levels and positive concordant pain at all three levels as well (Fig. 9C). A single or two-level fusion would not have addressed all her sources of pain and would have left a compromised disc to bear supraphysiologic loads adjacent to the lever arm of the fusion construct. Her young age also made a three-level fusion a poor surgical choice due to the risk of adjacent segment disease and her desire for an active lifestyle. Therefore a special request was made to the FDA to gain permission for the compassionate use of a three-level artificial disc replacement surgery with the ProDisc-II. This was approved and the patient successfully underwent surgery (Fig. 9D). She is approximately 6 months after surgery and doing very well. She is in an independent walking program and weaning herself off of all narcotics. She is currently on two to three hydrocodone pills a day and weaning off.

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