

Prospective, Randomized Trial of Metal-on-Metal Artificial Lumbar Disc Replacement

Initial Results for Treatment of Discogenic Pain

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Study Design. This study presents data on 67 patients from 2 study sites involved in the multicenter, prospective, randomized, controlled investigational device exemption study of FlexiCore artificial disc replacement *versus* fusion with a 2-year follow-up.

Objective. To compare the outcomes achieved with the FlexiCore disc replacement *versus* standard circumferential fusion for the treatment of discogenic pain due to single level degenerative disc disease (DDD).

Summary of Background Data. The FlexiCore Intervertebral Disc (Stryker Spine, Allendale, NJ) is a metal-on-metal artificial lumbar disc replacement device currently being studied for the treatment of DDD under an investigational device exemption protocol approved by the United States Food and Drug Administration. Artificial disc replacement in the spine is designed to preserve motion at the intervertebral segment and subsequently reduce adjacent segment degeneration. This is the first study to compare a metal-on-metal artificial lumbar disc replacement with circumferential fusion. Here we report the 2-year follow-up results.

Methods. Forty-four patients were treated with the FlexiCore and 23 patients were treated with fusion. The FlexiCore treatment group consisted of 23 men and 21 women, with an average age of 36 and an average body mass index of 28. Thirty-two of the FlexiCore surgeries were performed at L5–S1, and 12 were performed at L4–L5. The control treatment group consisted of 10 men and 13 women, with an average age of 41 and an average body mass index of 28. Seventeen of the control surgeries were performed at L5–S1, 5 were performed at L4–L5, and 1 was a 2-level fusion performed at L4–L5 and L5–S1. Prospective data were collected before surgery and after surgery at 6 weeks, and at 3, 6, 12, and 24 months. Disability and pain were assessed using the Oswestry Disability Index and the Visual Analog Scale. Range of motion was determined by independent radiologic assessment of flexion/extension and lateral bending radiographs.

Results. The mean Oswestry Disability Index scores were 62 (FlexiCore) and 58 (control) before surgery, 36 (FlexiCore) and 50 (control) at 6 weeks, and 6 (FlexiCore)

and 12 (control) at 2 years. The mean Visual Analog Scale scores were 86 (FlexiCore) and 82 (control) before surgery, 32 (FlexiCore) and 43 (control) at 6 weeks, and 16 (FlexiCore) and 20 (control) at 2 years. The FlexiCore group's angular rotation averaged 2.8° before surgery and 3.8° at 6 weeks after surgery. The group's lateral bending averaged 4.7° before surgery and 4.2° at 6 weeks after surgery. The average operative time (skin to skin) was 82 minutes for the FlexiCore group *versus* 179 minutes for the control group ($P < 0.001$). The average estimated blood loss was 97 mL for the FlexiCore group *versus* 179 mL for the control group ($P < 0.02$). The average hospital stay was 2 days for the FlexiCore group *versus* 3 days for the control group ($P < 0.005$).

Conclusion. These initial results from 2 study sites demonstrate that the FlexiCore compares very favorably to circumferential fusion for the treatment of lumbar DDD unresponsive to conservative treatment. These results are not intended to represent the overall study results.

Key words: lumbar, artificial disc replacement, metal-on-metal disc replacement. **Spine 2008;33:123–131**

Low back pain is the most commonly encountered complaint in a primary care physician's practice, with lumbar disc degeneration being one of the likeliest etiologies. In fact, degenerative disc disease (DDD) has been touted as the leading cause of pain and dysfunction in the United States, and its socioeconomic impact, with an estimated 50 billion dollars in annual health care costs, has deeply affected the country's medical resources and productivity as a society today.¹ DDD results from changes both in the nucleus pulposus and the annulus fibrosus. The number of viable cells in the nucleus pulposus declines as people age. Also the concentration of proteoglycans and water decreases. Additionally, proteoglycans begin to fragment and the composition of the nucleus pulposus becomes progressively more fibrotic. The outer annulus undergoes myxomatous degeneration with loss of normal collagen fiber organization, leading to increased incidence of fissures and cracks.² Ultimately, disc space height is compromised. Disc degeneration is accompanied by both small vessel proliferation and nerve fiber invasion into the vertebral endplates and peripheral regions of the disc. These structural and mechanical changes are believed to be contributing factors to a patient's back pain. DDD is defined by both the biologic and mechanical degradations of the intervertebral disc that subsequently lead to pain. Degeneration of the disc is confirmed clinically by patient history, physical examination, and radiographic studies. Discography is a useful procedure that can help elucidate which level or levels are involved. Under fluoroscopic guidance, dye is in-

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The device(s)/drug(s) that is/are the subject of this manuscript is/are being evaluated as part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol for treatment of single level discogenic pain in the lumbar spine.

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serted into the disc space, increasing the intradiscal pressure, and provoking a patient's typical pain if the disc is the pain generator.

Once the diagnosis of DDD is made, conservative methods such as nonsteroidal anti-inflammatory drugs and a structured physical therapy regimen are employed (for at least 6 months) as the first steps in management. Treatments such as ultrasound, acupuncture, spinal manipulation (chiropractor), muscle relaxants, traction, and shoe orthotics may be used alternatively or additionally, to attempt to alleviate the discomfort. For patients who have failed nonoperative treatment and continue to experience incapacitating axial back pain that severely limits their activities of daily living, the standard of care for DDD in the lumbar spine has been spinal fusion. Reports in the literature, however, demonstrate that spinal fusion alters the biomechanical stresses at the affected level, which may contribute to adjacent level degeneration.^{3,4} Lumbar artificial discs have recently been proposed as an attractive alternative to arthrodesis because they restore or maintain the basic motion of the intervertebral segment, thereby eliminating a potential cause of adjacent segment degeneration.

The FlexiCore Intervertebral Disc (Stryker Spine, Allendale, NJ) is a metal-on-metal intervertebral disc composed of a retained ball and socket device positioned between 2 base plates (Figure 1). The device is designed to preserve motion at the intervertebral segment.

Materials and Methods

The authors participated in a prospective, randomized, controlled, multicenter investigational device exemption study to compare the safety and effectiveness of the FlexiCore to circumferential spinal fusion in the treatment of discogenic pain secondary to DDD at a single level in the lumbosacral spine (L1-S1) that has failed to respond to conservative treatment. The entire study cohort includes 401 patients randomized to either the FlexiCore group or the fusion group (control) using a ratio of 2:1. This report describes the initial results of the 76 patients enrolled by the authors at 2 study sites.



Figure 1. FlexiCore metal on metal artificial disc.

The study inclusion criteria were that the patient must be skeletally mature, be between 18 and 60 years of age, and have DDD at a single level between L1 and S1. To confirm the diagnosis of DDD, the patient had to report a greater percentage of axial pain than radicular pain, and had to have an magnetic resonance imaging, computed tomography (CT) myelography, or lateral flexion/extension films demonstrating either (1) translational instability defined as greater than or equal to 3 mm, (2) angular instability defined as greater than or equal to 5°, or (3) disc height decreased by greater than 2 mm compared to adjacent disc height. Preoperative discography was not required in the design of this study; however, the senior authors (R.C.S. and M.H.) used this modality exclusively for the diagnosis of DDD before any surgical intervention (SI).

Before enrollment, patients were consented and administered objective, quantitative questionnaires to document levels of pain and functional disability. The Oswestry Low Back Pain Scale [Oswestry Disability Index (ODI)] and Visual Analog Scale (VAS) questionnaires were used to determine preoperative and postoperative function and pain levels. To be included in the study, a patient had to report VAS and ODI scores of at least 40 on a 0 to 100 scale. In addition, the patient must have completed and failed at least 6 months of conservative treatment.

Patients were excluded if they had previous bilateral lumbar decompression or a unilateral decompression in which greater than 50% of the facet had been resected, microdiscectomy if a facet fracture was suspected, or any lumbar fusion. Patients having any of the following conditions were also excluded: spondylolysis or isthmic spondylolisthesis at the level to be treated or at an adjacent level, moderate to severe spinal stenosis, lumbar scoliosis greater than 10°, confirmed facet joint arthritic changes at the level to be treated or at an adjacent level, or significant motion segment instability. Other exclusion criteria were Paget disease, osteopenia (including osteoporosis or osteomalacia), or any other metabolic bone disease; long-term use of corticosteroids; rheumatoid arthritis, active hepatitis, acquired immune deficiency syndrome, ARC, human immunodeficiency virus; active malignancy within the last 15 years; cervical myelopathy; or body mass index (BMI) greater than 40.

Seventy-six patients were enrolled by the authors at 2 study sites. Fifty were assigned to the FlexiCore group, and 26 were assigned to the control group. Four patients withdrew from the FlexiCore group and 5 patients withdrew from the control group before index surgery. Of the 67 remaining patients, 45 were assigned to the FlexiCore group, and 22 were assigned to the control group. One patient who was randomized to the FlexiCore group instead received a fusion. Therefore, 44 patients were treated with the FlexiCore and 23 patients were treated with fusion. The FlexiCore treatment group consisted of 23 men and 21 women, with an average age of 36 and an average BMI of 28. Seven members (16%) of this group were smokers. Thirty-two of the FlexiCore surgeries were performed at L5-S1, and 12 were performed at L4-L5. The control treatment group consisted of 10 men and 13 women, with an average age of 41 and an average BMI of 28. Four members (17%) of this group were smokers. Seventeen of the control surgeries were performed at L5-S1, 5 were performed at L4-L5, and one was a 2-level fusion performed at L4-L5 and L5-S1.

Each patient in the fusion treatment group received a circumferential fusion using a femoral ring allograft, posterior pedicle screw instrumentation, and autogenous iliac crest bone

graft, except for 1 patient who received an anterior lumbar interbody fusion with LT cages. Two separate approaches were involved in the circumferential fusion control group. For the anterior lumbar interbody fusion, the patient was placed supine on the operating room table. A mini-open rectus sparing retroperitoneal approach was used through a transverse skin incision. All were approached from the left side. The transverse skin incision measured 5 cm in length and the anterior rectus sheath was divided vertically. Dissection was carried medially to retract the hemi-rectus laterally, thus preserving its neurovascular status. The peritoneal sac was mobilized by blunt dissection off the abdominal wall and retracted past midline. The bifurcation of the great vessels was identified and any soft tissue elements overlying the disc space were bluntly mobilized. Appropriate vessels are then identified, ligated, and divided. Then, the great vessels are mobilized to allow access to the entire disc space. The entire anulus and anterior longitudinal ligament were incised sharply and the disc was removed using Cobb elevators, rongeurs, and a sharp curette. The cartilaginous endplate was removed entirely and the subchondral bone was preserved. Sequential distraction of the disc space was performed and the femoral ring allograft was impacted into the distracted disc space resting on the strong peripheral subchondral bone. After closure of the anterior incision, the patient was then placed prone on the operating table. Posterior iliac crest bone graft was harvested through a separate incision overlying the posterior superior iliac spine. This was a vertical incision measuring approximately 4 cm. By making a small vertical incision over the posterior superior iliac spine, the cluneal nerves were avoided. The outer table of the iliac crest was exposed and cancellous bone was harvested after removing the outer table of the iliac crest. Lastly, a standard posterior midline lumbosacral incision was then made to expose the spine. The entrance to the pedicle was found using anatomic landmarks and radiographic guidance. A high-speed burr gained entry to the pedicle and then a pedicle probe was used to cannulate the pedicle followed by a tap and the screw. The transverse processes were decorticated with a high-speed burr and the cancellous autograft was packed into the intertransverse interval. The rods were attached to the screws and proper position confirmed with radiographs. The wounds were then closed in the standard, layered fashion.

Study patients were assessed before surgery and at the following postoperative intervals: 6 weeks, 3 months, 6 months, 12 months, and 24 months. Improvements in function and pain were assessed by the patients using the ODI and VAS questionnaires. Range of motion (ROM) was assessed for the FlexiCore group by comparing preoperative and postoperative radiographs. Finally, data on operative time, estimated blood loss (EBL), and length of hospital stay (LOS) were collected.

FlexiCore Surgical Technique

Proper patient positioning is essential. The patient is placed supine on the operating room table with the arms abducted 90° and with adequate padding under the elbows to protect the ulnar nerves. A mini-open rectus-sparing retroperitoneal approach to the anterior aspect of the lumbar spine is accomplished through a transverse bikini incision. The assistance of a vascular surgeon is useful for the safe dissection of the anterior aspect of the lumbar spine. A spinal needle is inserted into the disc space and the level is verified on anterior-posterior and lateral radiographs. The midline is marked. A scalpel is used to create a window in the anulus that approximates the size of the

FlexiCore implant. Cobb elevators, curettes, and pituitary rongeurs assist in clearing away all disc material to the level of the posterior longitudinal ligament. A Kerrison punch can then be used to remove any posterior osteophytes or excess soft tissue as these may inhibit the correct positioning of the prosthesis. The posterior longitudinal ligament is sacrificed, using a Kerrison punch so that the disc space can be adequately distracted in a parallel fashion. A series of distracting spacers is inserted to restore the disc height. Restoring the disc height will also assist in removal of fragments of disc or soft tissue that may not be visible when the disc is collapsed. Insertion of these distractors must be done carefully so as not to cause an iatrogenic vertebral endplate fracture or nerve-root traction injury because of excessive stretching. Endplate preparation is performed with a large sharp curette; removing all cartilaginous but retaining the strong subchondral endplate. A static distractor that mimics the implant shape is inserted to restore annular tension. Disc height and insertion depth are confirmed by repeat lateral radiography and the inferior baseplate of the static distractor should lie flush with the superior endplate of the inferior vertebral body. The size of the static distractor will be a guide to the size of the disc that is to be used. Next, a dynamic distractor is inserted to further stretch the disc space an additional 1.5 to 2 mm to prevent damage to the endplates by the spike or dome portion of the prosthesis. Parallel jaw distractors help to maintain the disc height and assist the surgeon in introducing the artificial disc. An inserter/impactor can then be used to implant the prosthesis with proper placement guided by ramps. The FlexiCore should be positioned so that the cephalad baseplate dome is matched with the concavity contour of the inferior vertebral endplate of the cephalad vertebra and the posterior aspect of the implant is within 2 to 3 mm of the posterior margin of the disc space. Removal of the ramps from the inserter helps to seat the implant into the vertebral endplates so that the spikes are imbedded in the endplates and the titanium plasma spray is closely approximated to the endplates to facilitate bony on-



Figure 2. Lateral radiograph of a FlexiCore disc.

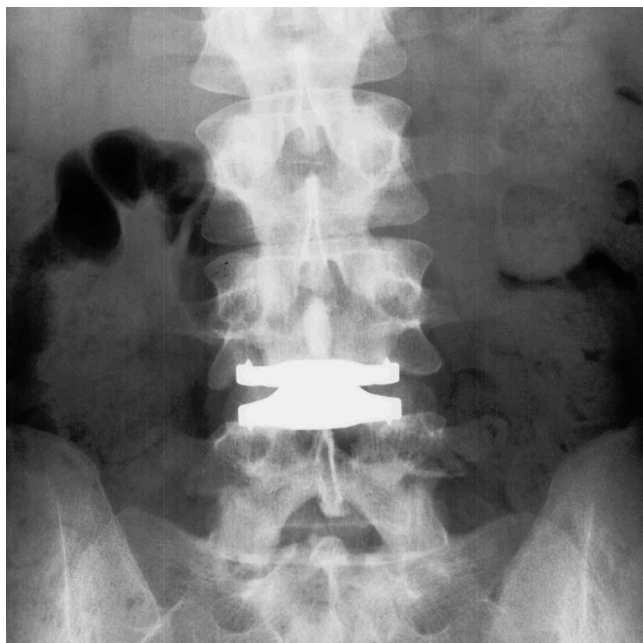


Figure 3. AP radiograph of FlexiCore disc.

growth. The position of the FlexiCore is then checked radiographically in both the anteroposterior and lateral planes (Figures 2, 3). Note that there is no intraoperative implant assembly required. Once the prosthesis is correctly positioned and adequately seated, the anterior wound is closed in layers in the usual manner and a sterile dressing is applied.

Results

The operative time, EBL, and the LOS were compared between the FlexiCore group and the control group using an unpaired *t* test for statistical analysis. The average operative time was 82 minutes for the FlexiCore group and 179 minutes for the control group ($P < 0.001$) (Figure 4). The average EBL was 97 mL for the FlexiCore group and 179 mL for the control group, which was a

Blood Loss (BL)

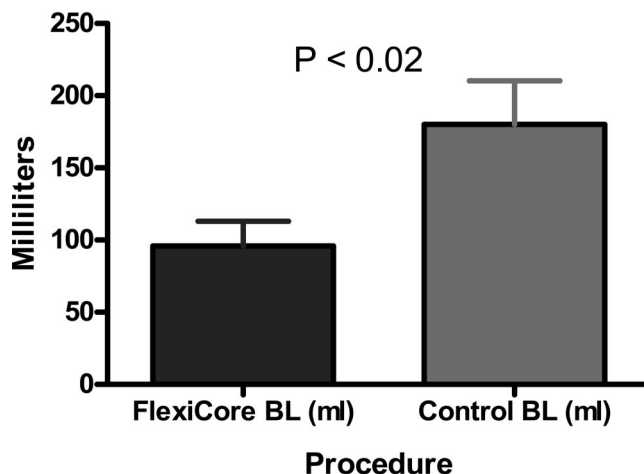


Figure 5. Estimated blood loss (EBL) of FlexiCore versus control group and associated *P*.

statistically significant difference ($P < 0.02$) (Figure 5). The LOS was 1 day shorter in the FlexiCore group (2 days) than in the control group (3 days) ($P < 0.005$) (Figure 6).

Outcome Measures

The ODI was first compiled in 1976 by John O'Brien and came into publication around 1980 by Fairbank *et al.*⁵ Since that time, it has become one of the most popular and relied-on outcome measures for daily functional changes associated with low back disability. According to a recent review article written by Fairbank *et al* in *Spine*⁶ the ODI is a valid and vigorous measure of condition specific disability that has the power to detect meaningful changes in disability status. Thus, it was used both before surgery and at the specified postoperative intervals to follow each patient's progress in the FlexiCore study. The average ODI before surgery was 62 for

Operating Time (OT)

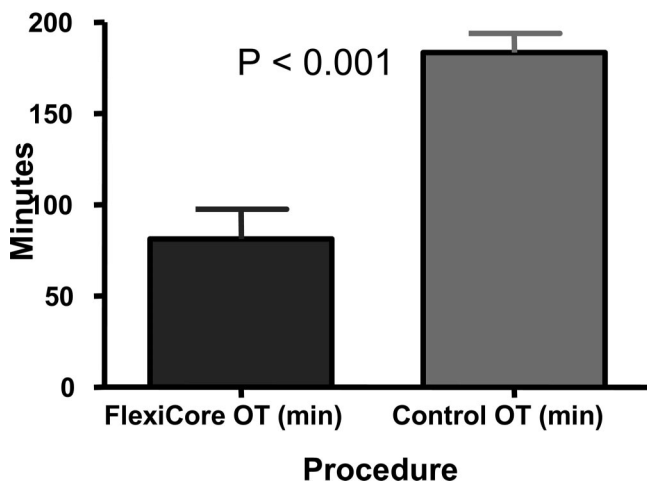


Figure 4. Operative time of FlexiCore versus control group and associated *P*.

Length of Stay (LOS)

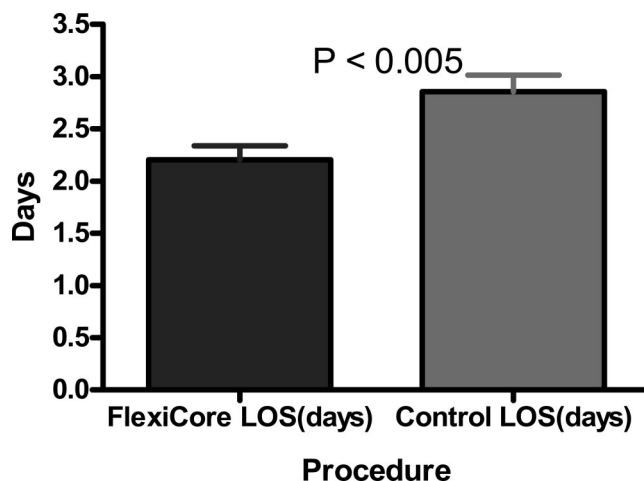


Figure 6. Length of Stay (LOS) for FlexiCore versus control group and associated *P*.

Oswestry Comparison

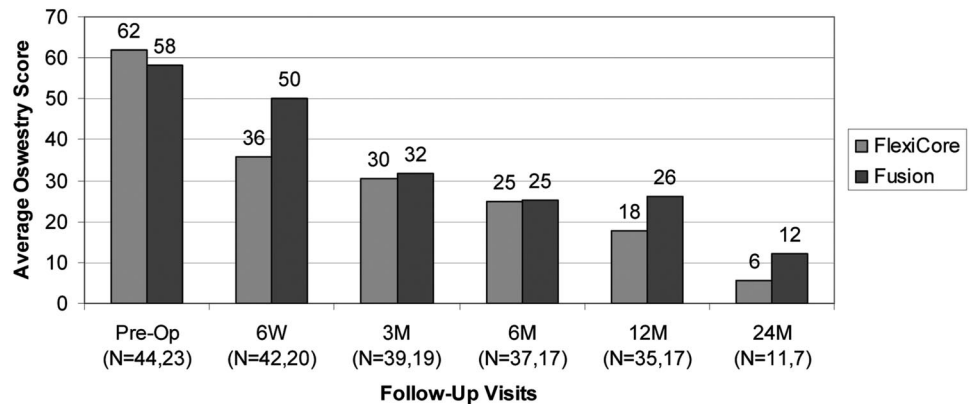


Figure 7. Oswestry Disability Index (ODI) of FlexiCore versus control before surgery and at follow-up visits.

the FlexiCore group and 58 for the control group. At the follow-up intervals, the average ODI scores were 36 (FlexiCore) and 50 (control) at 6 weeks, 30 (FlexiCore) and 32 (control) at 3 months, 25 (FlexiCore) and 25 (control) at 6 months, 18 (FlexiCore) and 26 (control) at 12 months, and 6 (FlexiCore) and 12 (control) at 24 months (Figure 7).

The VAS has been used extensively by physicians to quantify the severity of pain that a patient is experiencing. For this study, as can be seen in Figure 8, the preoperative average VAS was 86 for the FlexiCore group, and 82 for the control group. At the follow-up intervals, the average VAS scores were 36 (FlexiCore) and 43 (control) at 6 weeks; 39 (FlexiCore) and 33 (control) at 3 months, 33 (FlexiCore) and 26 (control) at 6 months, 24 (FlexiCore) and 32 (control) at 12 months, and 16 (FlexiCore) and 20 (control) at 24 months (Figure 8).

Radiographic Outcome Measure

Radiographic evaluation (AP, Lateral, Flexion-Extension, and Lateral Bending) was performed before surgery to evaluate the ROM at the involved disc space. After surgery, repeat radiographic evaluation was performed on all of the FlexiCore recipients by comparing postoperative and preoperative films. Each radiograph was evaluated by an independent core lab and the ROM for the

disc segment was recorded. Three types of motion were recorded before surgery and at the 6-week follow-up appointment: (1) translational motion (on Flexion-Extension radiographs), (2) angular rotation (Flexion-Extension radiographs), and (3) lateral bending (Lateral Bending radiographs). The angular rotation for the FlexiCore recipients was 2.8° before surgery, and 3.8° after surgery (at the 6-week follow-up appointment). Lateral bending for the FlexiCore recipients averaged 4.7° before surgery and 4.2° after surgery (at the 6-week follow-up appointment). Routine films were also taken in the fusion group to assess the status of the hardware.

Complications

Adverse events were recorded for each study subject, and were classified as serious adverse events (SAEs) if they were life threatening, required hospitalization, or required medical intervention to preclude permanent impairment. SAEs were further classified as either requiring SI or not requiring SI. This paper discusses only the SAEs that required SI (Table 1), with other SAEs listed in Table 2. For the FlexiCore group, there were 8 patients who experienced an SAE requiring SI. One patient developed a wound infection that required 3 irrigation and debridements (2% incidence). One patient developed a retroperitoneal hematoma that required surgical evacuation.

VAS Comparison

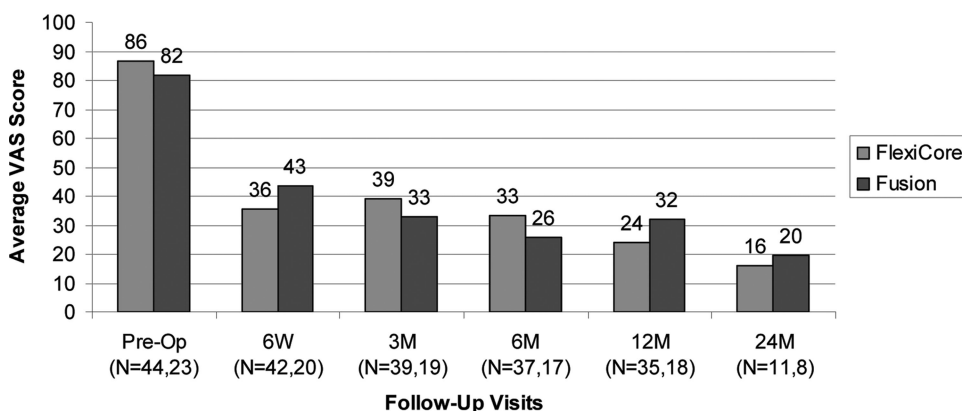


Figure 8. Visual Analog Pain Scale (VAS) for FlexiCore versus control before surgery and at follow-up visits.

Table 1. SAE Requiring Surgical Intervention (SI)

Complication	Fusion	FlexiCore
Wound infection (requiring SI)	3 (14)*	1 (2)*
Low back pain requiring removal of hardware	5 (22)	0 (0)
Low back pain requiring subsequent fusion procedure	0	1 (2)
Radicular leg pain	0	2 (5)
Retroperitoneal hematoma	0	1 (2)
Vertebral end plate fracture	0	1 (2)
Hardware migration	0	1 (2)
Vascular injury	0	1 (2)

Values in parenthesis indicate percentage values.

*Data includes 1 patient in each group requiring repeat irrigation and debridement.

One patient, who underwent L4–L5 FlexiCore insertion, required removal of a bony fragment through a laminotomy because of an L4 vertebral body endplate fracture that caused severe buttock and leg pain. This was noted on radiographs and CT at an early follow-up appointment (2 weeks) and can be seen in Figure 9. Subsequent selective nerve root sleeve injection relieved the pain and the patient underwent hemilaminotomy to remove the bony fragment (Figure 10). The patient had complete relief of pain after fragment removal. Two patients developed leg pain after the index arthroplasty procedure. One patient developed this pain 2 months after the index procedure, and the other occurred 15 months after the index procedure. Selective nerve root injection confirmed an L4 radiculopathy (at the level above the FlexiCore implant) in both patients and each underwent microlumbar discectomy with hemilaminotomy, which resolved their problems. Disc migration was seen in 1 subject and this was noted at the 2-month follow-up appointment. The patient presented with complaints of bilateral hip pain with extension exercises in physical therapy, and on routine radiographs the FlexiCore was found to be approximately 2 mm proud of the anterior disc space. The subject was revised 4 months after the index procedure to a larger FlexiCore prosthesis and had resolution of symptoms. Vascular injury was encountered once and it involved injury to the left ilio-lumbar vein. It was noted when exposing the anterior portion of the lumbar spine in preparation for disc identification, and the vessel was repaired during the index procedure with 5–0 prolene suture. Lastly, 1 patient continued to have significant low back discomfort a few months after FlexiCore implantation. An epidural provided short-term relief. Subsequently, under fluoroscopic guidance, an injection of

Table 2. Other SAEs Not Requiring Surgical Intervention

Complication	Fusion	FlexiCore
Stridor/hypoxia	0	1 (2)
Tachyarrhythmia	0	1 (2)
Pulmonary embolism	1 (2)	0
Extraperitoneal seroma	1 (2)	0

Values in parenthesis indicate percentage values.

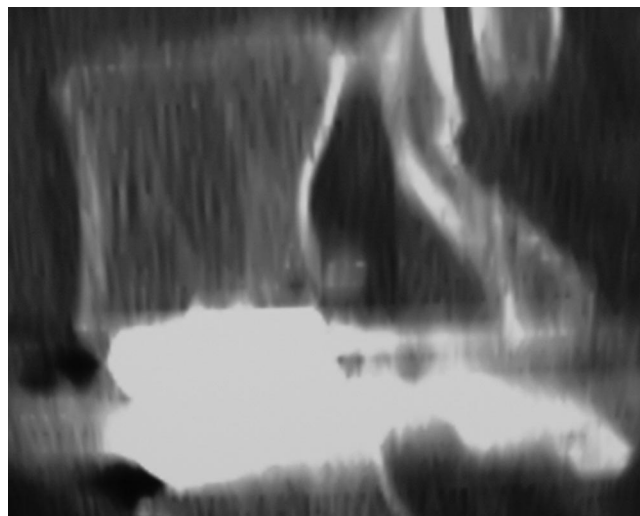


Figure 9. CT reconstruction of lumbar spine after FlexiCore disc insertion showing vertebral endplate bony fragment.

marcaine into the FlexiCore disc space provided approximately 75% relief of pain. Thus, it was determined that the motion segment continued to be the pain generator, and an instrumented posterior fusion was performed 15 months after the index procedure at the same level as the artificial disc. The patient's symptoms gradually improved.

For the circumferential fusion group, 2 patients developed 3 wound infections (14% incidence) with 1 patient requiring a repeat irrigation and debridement 10 weeks after the index procedure. Five patients required removal of hardware. One required removal due to a deep wound infection. The other 4 required SI because of painful hardware. In all the cases, a CT scan confirmed a solid fusion, and on removal of the posterior hardware the pain gradually resolved (See Table 1).

SAEs not requiring SI included stridor/hypoxia, tachyarrhythmia, nonfatal pulmonary embolism, and extraperitoneal seroma. These are listed in Table 2.

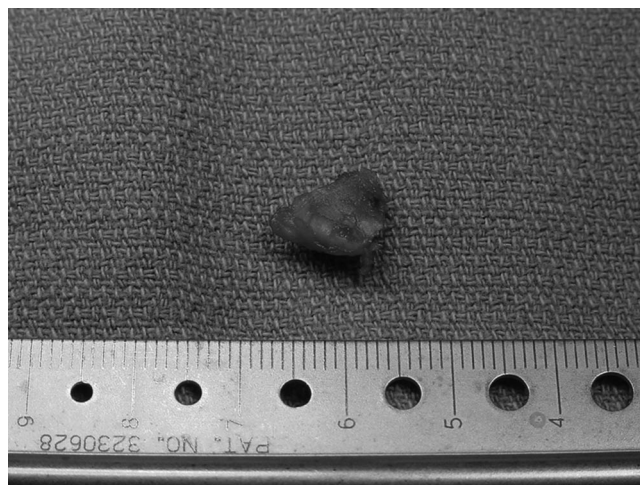


Figure 10. Bony fragment removed surgically after CT confirmed vertebral body endplate fracture.

The clinical literature reports the results and complications of lumbar disc arthroplasty from 2 main prototypes, namely, the ProDisc I and II (Synthes Spine, Paoli, PA) and the SB CHARITÉ III (Depuy Spine, Raynham, MA). The SB CHARITÉ was originally developed in Berlin, Germany, and its success was limited by device-related complications. Improvements were made which eventually lead to the production of the SB CHARITÉ III, about which there have been numerous publications written because of the vast experience with this prosthesis. Briefly, the CHARITÉ artificial disc is composed of 2 cobalt-chromium alloy endplates with “teeth” for bony attachment and a sliding ultra-high molecular weight polyethylene core. In an initial series by Griffith *et al*,⁷ out of 139 artificial discs implanted, complications were reported in 6.5% with a reoperation rate of 3%. Cinotti *et al* retrospectively reviewed 56 SB CHARITÉ III artificial discs with a minimum follow-up of 24 months and found that 9 cases required reoperation. Seven were revised to posterolateral fusion without removing the disc and 2 underwent disc removal (1 converted to anterior/posterior fusion and the other disc replaced with smaller size after dislocation in the early postoperative period).⁸ Several other cases of disc migration have been recorded using the SB CHARITÉ III. David revealed 2 patients in a series of 163 prostheses that required fusion because of disc migration⁹ and Caspi *et al* had similar results with 2 discs showing evidence of migration in the early postoperative period.¹⁰ A study published by van Ooij *et al* in 2003¹¹ chronicled their experience over 8 years with the SB CHARITÉ. They found prosthesis migration and frank dislocation to be a rare complication. Their series highlighted the following main causes of dissatisfaction at a mean of 53-month follow-up: (1) facet joint arthrosis at the same level, (2) degeneration of facet joints and discs at neighboring levels, and (3) subsidence of the prosthesis. Guyer *et al*¹² in a prospective, randomized study reported on 100 implanted SB CHARITÉ prostheses and stated that they had no cases of dislodgement, subsidence, loosening, or late infection. McAfee *et al*¹³ and Blumenthal *et al*¹⁴ also report no device-related complications.

The ProDisc was first examined by Marnay¹⁵ who published a long-term follow-up (7–11 years) of 93 implanted artificial discs and reported no evidence of migration or disc subsidence. Similar results were confirmed by Bertagnoli and Kumar.¹⁶ As technology advanced, the ProDisc II attempted to improve on the original ProDisc design by incorporating a modular polyethylene inlay. Zigler *et al* recently evaluated the ProDisc II in 35 patients and reported only one significant adverse event, the dislodgement of the polyethylene liner.¹⁷ Tropiano *et al*,¹⁸ in a series of 68 prostheses with a minimum of 12-month follow-up, revealed a total complication rate of 9% with 6% requiring repeat SI. One complication included a vertebral body endplate fracture in the early postoperative period that required explantation and revision to fusion, and 2 other compli-

cations were because of “symptomatic” component malpositioning, necessitating implant revision. Delamarter *et al*, in his series of 35 ProDisc II prostheses, reported no evidence of disc migration or component failure after a minimum of 6 months follow-up.¹⁹

The FlexiCore study group had a reoperation rate (defined as surgery to remove or replace the FlexiCore device, or to supplement with additional hardware) of 4.5% (2 of 44) and a low rate of other SAEs, which compares well with these other published series and with the FlexiCore study’s control group.

■ Discussion

The gold standard of treatment for DDD causing mechanical back pain in the lumbar spine unresponsive to nonoperative treatment has been fusion. Clinical studies, however, suggest that the altered biomechanical stresses created by fusion contribute to adjacent level degeneration. Recently in the United States, the artificial disc prosthesis has become an attractive option. Its aim is to attempt restoration and preservation of normal spinal biomechanics while withstanding the loads applied by the human body. By restoring normal segmental motion of the spine, the hope is to reduce or even eliminate adjacent level degeneration. Eck *et al* reviewed biomechanical and radiologic studies after lumbar fusion to examine adjacent segment degeneration after lumbar fusion.²⁰ Their evidence showed that true fusion did, in fact, alter the biomechanics at junctional levels, creating increased forces, mobility, and intradiscal pressure in adjacent segments. The altered biomechanics then lead to the Modic changes in the adjacent disc as seen by magnetic resonance imaging and the symptomatic changes as noted by the patients. Gillet reviewed a series of 106 lumbar spinal fusions with a total of 2- to 15-year follow-up and showed a 20% reoperation rate due to this adjacent segment degeneration.²¹ Ghiselli *et al* had similar results with long-term follow-up of lumbar fusion. In a series of 215 fusions and follow up of over 6 years, there was a 27.4% reoperation rate due to adjacent level disease.²² However, the segments close to the fusion are not the only ones susceptible to degeneration. A report by Schlegel *et al*³ with a patient population of 58 and an average symptom-free period of 13.1 years, found that segments adjacent to the adjacent level of fusion itself were just as likely to break down and cause symptoms possibly requiring revision surgery.

The results of this study correlate well with previously published articles in that the artificial disc compares favorably with fusion for the treatment of DDD. The ODI and the VAS scores changed significantly in both groups over the 24-month follow-up period. At the 6-week follow-up appointment, there was a greater improvement in both the VAS and ODI in the FlexiCore group *versus* the control group. The 3- and 6-month follow-up VAS and ODI scores were very similar in the 2 groups, however, at the 12-month and 24-month mark there seemed to be a further decline of the VAS and ODI in the FlexiCore

group when compared to the stable scores found in the fusion group. Radiographically, the FlexiCore artificial disc also performed well. Preoperative and postoperative comparisons were made and showed relative preservation of motion at the intervertebral segment.

There are multiple studies in the literature comparing the results of other models of artificial discs (*i.e.*, CHARITÉ, ProDisc), but this study is the first to compare the FlexiCore artificial disc with a control group. The control group in this study underwent circumferential fusion, which has been proven superior to anterior or posterior fusion alone. The FlexiCore prosthesis is a metal-on-metal intervertebral disc composed of a retained ball and socket device positioned between 2 cobalt-chromium alloy base plates with a titanium plasma spray surface specifically designed to facilitate bony on-growth of the vertebral endplate. The implant features a fixed center of rotation with a semiconstrained motion in axial rotation. Its metal-on-metal design proposes reduced wear and creep seen in polyethylene implants. Its components were recently evaluated in *Spine J* in 2004 by Valdevit and Errico²³ in a biomechanics study evaluating the durability of this specific artificial disc while performing failure testing of critical components and fatigue experiments in overloaded conditions. Through a series of complex testing, their conclusion was that the mechanical characteristics and performance of the FlexiCore disc exceeded the needs of a physiologic environment.

In our study, there were no frank dislocations and only 1 patient had evidence of disc migration at follow-up. This was corrected by removal of the migrated disc and replacement with a larger sized prosthesis. The infection rate was higher in the fusion group; however, the importance of this difference is difficult to ascertain because of the small sample size in the control group. There were no cases of retrograde ejaculation in either our FlexiCore group or our control group; however, the literature reports a rate of 2% to 7% incidence with the anterior approach.²⁴

One of the limitations of this study is the small number of patients enrolled. As evidenced by the infection rate (14% in the control *vs.* 2% in the FlexiCore), differences in incidence rates can be exaggerated because of a small patient number. In addition, as was pointed out by Dr. Herkowitz in a recent publication in *J Bone Joint Surg*, 2006 comparing the CHARITÉ artificial disc to lumbar interbody fusion, they had an 18% incidence of persistent iliac crest pain after surgery and the ODI and the VAS cannot discriminate between pain that is residual from the iliac crest *versus* the lumbar spine. Thus, the ODI and VAS may be artificially higher in the fusion group when compared to the artificial disc group.²⁵ Also, patients' perceived outcomes may bias their outcome measure results if they expected to receive an artificial disc when in fact they were randomized to the fusion arm.

A recent report by Bertagnoli *et al* reveals their 2-year minimum follow-up data on insertion of the ProDisc arthroplasty at the site of adjacent segment degeneration after lumbar fusion. Their analysis indicates that the artificial disc was efficacious for the treatment of juxtalevel degeneration secondary to fusion and they had no device related complications.²⁶ This may represent a future direction for total disc arthroplasty.

■ Conclusion

The results for this study show that artificial disc replacement with the FlexiCore metal-on-metal intervertebral disc prosthesis compares favorably and may be a viable alternative to the gold standard of fusion for the treatment of DDD. The FlexiCore device delivered improvements in pain and function similar to fusion, while preserving motion at the intervertebral segment. It is theorized that the FlexiCore device, by preserving spinal biomechanics, may reduce the incidence of adjacent segment degeneration. Surgeon familiarity with the procedure as well as meticulous patient selection by comprehensive preoperative work-up is essential to obtain a good result, which ultimately is to relieve pain and maintain a patient's functional capabilities.

■ Key Points

- Low back pain is a very common disorder among the adult population.
- The goal of artificial disc replacement is to preserve motion and to prevent adjacent segment degeneration.
- Outcome measures such as VAS and ODI display favorable results in the artificial disc replacement group.
- Patient selection is of utmost importance for good clinical results.

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