Journal of Spinal Disorders & Techniques
Vol. 16, No. 4, pp. 424–433

SB Charité Disc Replacement

Report of 60 Prospective Randomized Cases in a U.S. Center

Paul C. McAfee, Ira L. Fedder, Samer Saiedy, Erin M. Shucosky, and Bryan W. Cunningham

Spine *and Scoliosis Center, St. Joseph's Hospital, Baltimore, Maryland*

Summary: Sixty patients with one-level discogenic pain confirmed by plain radiography, magnetic resonance imaging, and provocative discography for degenerative disc disease were randomized: one-third BAK anterior interbody fusion and two-thirds anterior SB Charité artificial disc replacement. The mean age was 40.3 years (range 21–56 years). Nineteen cases were at L4–L5 and 41 cases were at L5–S1. Nineteen cases had BAK anterior interbody fusion and 41 cases were randomized as SB Charité disc replacement. The length of surgery was mean 88.4 minutes (range 54–137 minutes) for both groups. The estimated blood loss was mean 289.5 mL (range 50–1800 mL). The length of hospital stay was a mean of 3.03 days (range 2–6 days). Oswestry Disability Index scores for the SB Charité disc (aggregate study group) were 50.0 ± 14.3 preoperatively and 25.0 ± 20.1 at 1–3 years' follow-up ($P < 0.001$). This is the first study that shows improvement of functional outcome measures in a prospective randomized design with disc arthroplasty treating primarily mechanical back pain and achieving comparable successful results to lumbar fusion—interbody fusion cage and BMP or interbody autograft and pedicle screw instrumentation. **Key Words:** degenerative disc disease, SB Charité disc, artificial disc

INTRODUCTION

The lumbar artificial disc is an alternative to arthrodesis. Its purpose is to restore the basic motion of the intervertebral segment and to protect the adjacent levels against unphysiologic loading.

MATERIALS AND METHODS

The indications for the clinical application of the SB CharitC (DePay-Acromed-Johnson and Johnson, Raghnam, MA) artificial disc replacement in this study were any patient between the ages of 18 and 60 years, optimally below age 60, with symptomatic degenerative disc disease or lumbar spondylosis objectively documented by computed tomography (CT) or magnetic resonance imaging (MRI). Some specific radiographic findings included vacuum disc sign, high intensity zone signal, Modic changes, degenerative cyst formation, and marginal vertebra1 body osteophyte formation. All patients were studied with a provocative discogram performed by an independent *radiologist or* anesthesiologist who was not part of the surgical team. To be positive, the discogram had to demonstrate concordant pain reproduction and use at least one control level that was not painful and did not reproduce the patient's symptoms. Degenerative disc disease was defined as discogenic back pain with degeneration of the disc as confinned by history and radiographic studies with one or more of the following factors: contained herniated nucleus pulposus, paucity of facet joint degeneration changes, decrease of intervertebral disc height of at least *4* mm, or scarring/thickening of annulus fibrosis with osteophytes indicating osteoarthritis. In this prospective IDE study, only single intervertebral level disc disease at either L4–L5 or L5–S1 was included, although in Europe and throughout the world, multiple vertebral levels are routinely treated. Patients with radicular leg pain

Received January 15, 2003; accepted April 22, 2003.
Address correspondence and reprint requests to Dr. Paul C. McAfee, Scoliosis and Spine Center, O'Dea Medical Bldg. 104, 7505 Osler Dr., Towson, MD 21204 E-mail: mack8132@aol.com

and neurogenic claudication were excluded: nonradiculas leg pain or back pain in the absence of nerve root compression (ie, due to disc herniation) as determined by MRI or CT scan without lateral recess stenosis. The only exception to this is that in carefully selected cases, neurofo-raminal stenosis could be corrected by the SB Charité restoring the intervertebral disc height and increasing the neuroforaniinal height.

In all 60 cases, an independent nurse practitioner or physician's assistant interviewed the patient and administered an objective, quantitative pain scale to document the patient's level of pain and functional disability. The Oswestry Scale and Visual Analog Scale were both used for this prospective study. The SB Charité disc replacement was used for end-stage-type disc disease and symptoms rather than a primary treatment. All patients exhausted and failed a minimum of 6 months of conservative, nonoperative treatments. These included physical therapy, facet joint injections, epidural steroids, acupuncture, back school, behavior modification, ultrasound, anti-inflammatory medications, analgesic medications, muscle relaxants, lumbosacral stabilization therapy, orthotic management, and other nonoperative attempts at reducing the mechanical back disability.

Patients were excluded if they had undergone a previous attempted fusion procedure anywhere in the thoracolumbar spine. Patients were excluded with osteopenia and high-risk patients in this category such as women status post oophorectomy had to undergo DEXA scans to demonstrate an absence of osteopenia. Other exclusion criteria were 1) objective evidence of nerve root compression; 2) straight leg raise producing pain below the knee; 3) spinal fracture, spondylolysis, spondylolisthesis, scoliosis, spinal tumor, or severe facet joint arthrosis: or 4) being >1 SD greater than normal body weight.

An ideal candidate for an artificial disc replacement is illustrated in Figure 1.

Patients with prior discectomy, IDET, or chemonucleolysis were included in this study if there was no leg pain below the knee, and they proved to be excellent candidates for the procedure. Enough of the posterior facets needed to be present to prevent overdistraction. If complete bilateral facetectomies had been performed during the previous surgery, then the patient was excluded, as facet joints are required for rotational stability.

Patients satisfying the above criteria were enrolled in this study according to a prospective randomized design: two-thirds chance for SB Charité disc replacement and one-third chance for anterior interbody BAK interbody fusion using autograft.' The first five cases to fulfill the above entrance criteria all underwent SB Charité disc replacement as "training" cases so that the remainder of the patients in the randomized design would not be affected by a learning curve or bias pertaining to the surgeon's technical expertise. At this site, there was no selection bias introduced by storing up or "cherry-picking" patients to be used as the first five training cases—the first five consecutive patients fulfilling the inclusion criteria listed above were treated by the SB Charité disc replacement. This practice would negatively influence the IDE Food and Drug Administration study because the training cases will be excluded from the IDE analysis.

All 60 consecutive patients underwent randomization according to a random number generator and had appropriate surgical consent regarding randomization and institutional review board approval at St. Joseph's Hospital (Towson, MD, U.S.A.). Regardless of the treatment arm, BAK interbody autograft fusion or SB Charité disc replacement, the surgical approaches were identical: anterior retroperitoneal.

Surgical Technique

The surgical technique for the SB CharitC has been previously reported by this investigative group,' including a full-length textbook.[3] It is worth summarizing several key points, however. First, a complete, rather than a "reamed channel" or partial discectomy, is required.[4] The lateral circumferential attachments of the annulus fibrosis are preserved. Second, the midline of the spinal column is marked by placing a screw or skeletal marker in the vertebral body above the index disc. This needs to be confirmed radiographically by anteroposterior C-arm fluoroscopy immediately after the surgical approach, prior to discectomy. Third, parallel distraction and restoration of the normal intervertebral disc height is accomplished with the use of the central spreader and twisting distracting chisels of graded widths from 7.5 to 9.5 mm (Fig. 2). Fourth, good coverage of the cross-sectional area of the vertebral end plates is optimized by trying different sizing templates and checking the fit intraoperatively with fluoroscopy. This helps prevent postoperative subsidence. Fifth, and most important, the optimal position in the frontal plane is in the midline, but on the lateral image (ie, midsagittal plane), it is 2 mm posterior to the midline. This position reproduces the physiologic instantaneous axis of rotation (IAR), throughout the flexion-extension arc, of the normal disc, as experimentally mapped out by Gertzbein et al.[5]

RESULTS

There were a total of 60 patients enrolled in this prospective, consecutive study: 30 men and 30 women. Nineteen patients underwent BAK as part of the surgical control group and 41 patients underwent SB CharitC disc

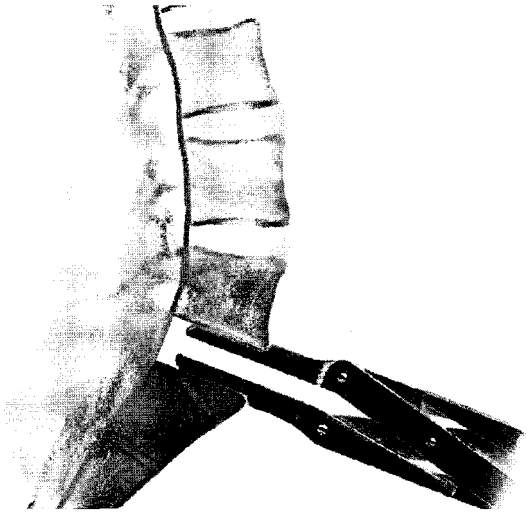


FIGURE 2. This is a lateral schematic representation of one of the critical steps in the surgical preparation of the intervertebral disc space. After a complete discectomy preserving the majority of the annulus fibrosis, the Link central spreading instrument is used *to* restore the intervertebral disc height by stretching the posterior longitudinal ligament. Notice that there is parallel distraction of the end plates, not preferential opening of just the anterior column, unlike many other disc replacement techniques.

replacement. The mean age was 40.3 years (range 21–56 years). The cases were distributed according to surgical level: 19 cases at L4–L5 (Fig. 3) and 41 cases at L5–S1 (Fig. 4).

Although it is difficult to measure and compare the technical difficulty and morbidity of the two treatment groups, the surgical anterior retroperitoneal approaches were identical with the exception that the control group patients also underwent iliac bone graft harvesting. Due to the sensitive nature of this innovative study, the combined total demographic parameters for the control group and SB CharitC group will be reported together—this is a requirement of the sponsor. The parameters for the BAK group were comparable with those reported by Kuslich et al.[6] The length of surgery was a mean of 88.4 minutes (range 57–137 minutes) for both groups. The estimated blood loss was a mean of 289.5 mL (range 50–1800 mL) for the total of 60 patients. The length of hospital stay was a mean of 3.03 days (range 2–6 days) for the total of 60 patients.

The clinical follow-up ranged from 1 to 3 years. There were no patients lost to follow-up. There were no patients requiring additional spinal reconstructive procedures within the follow-up interval thus far. There we no dislodgement of the prostheses, no cases of significant subsidence, no evidence of prosthetic loosening, no late infections—but the minimum follow-up period was only 1 year.

Objective Outcome Measures

The preoperative and postoperative Visual Analog Scale (Fig. 5A) and Oswestry Disability Index (Fig. 5B) objective measures of functional outcome are shown in

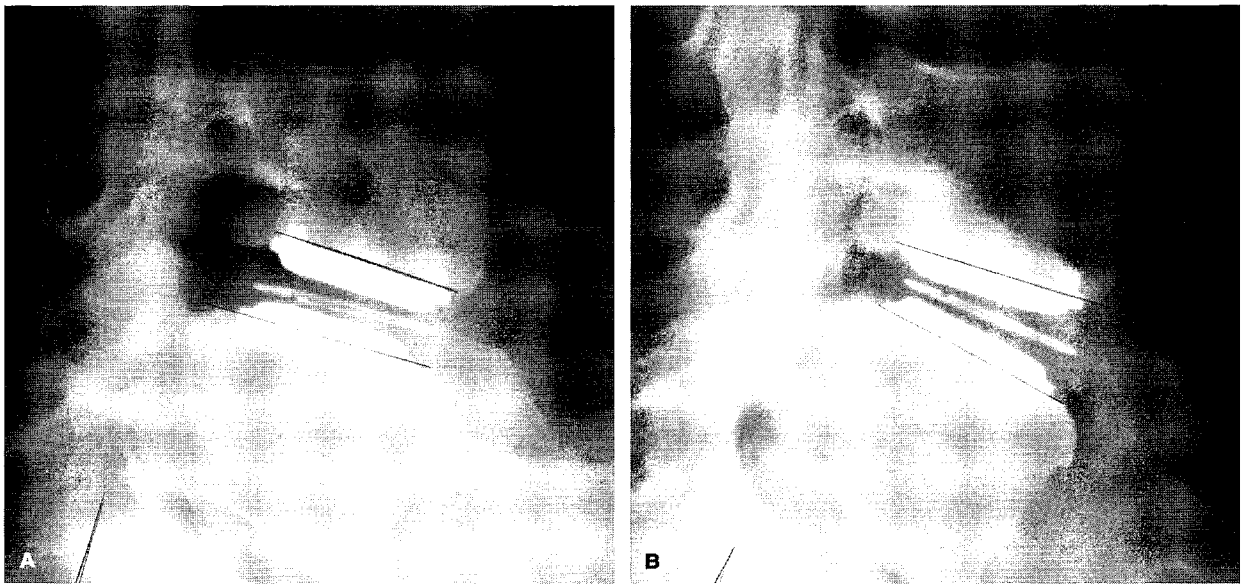


FIGURE 3. This 48-year-old man underwent SB Charite prosthetic insertion at L4–L5. A, The lateral radiograph at 2 years' follow-up shows 2° flexion orientation of the end plates. He improved from a preoperative Visual Analog Scale score of 99 to 8. His Oswestry Disability Index score improved from 76 to 20. B, The lateral radiograph in extension shows 11.5" of end plate angulation, demonstrating a total of (11.5" − [−2°]) = 13.5" of flexion-extension motion. At 2.5 years postoperatively, the patient is working full, 8-hour shifts, 48 hours per week at Bethlehem Steel Corporation, performing repetitive overhead lifting of 80 lbs.

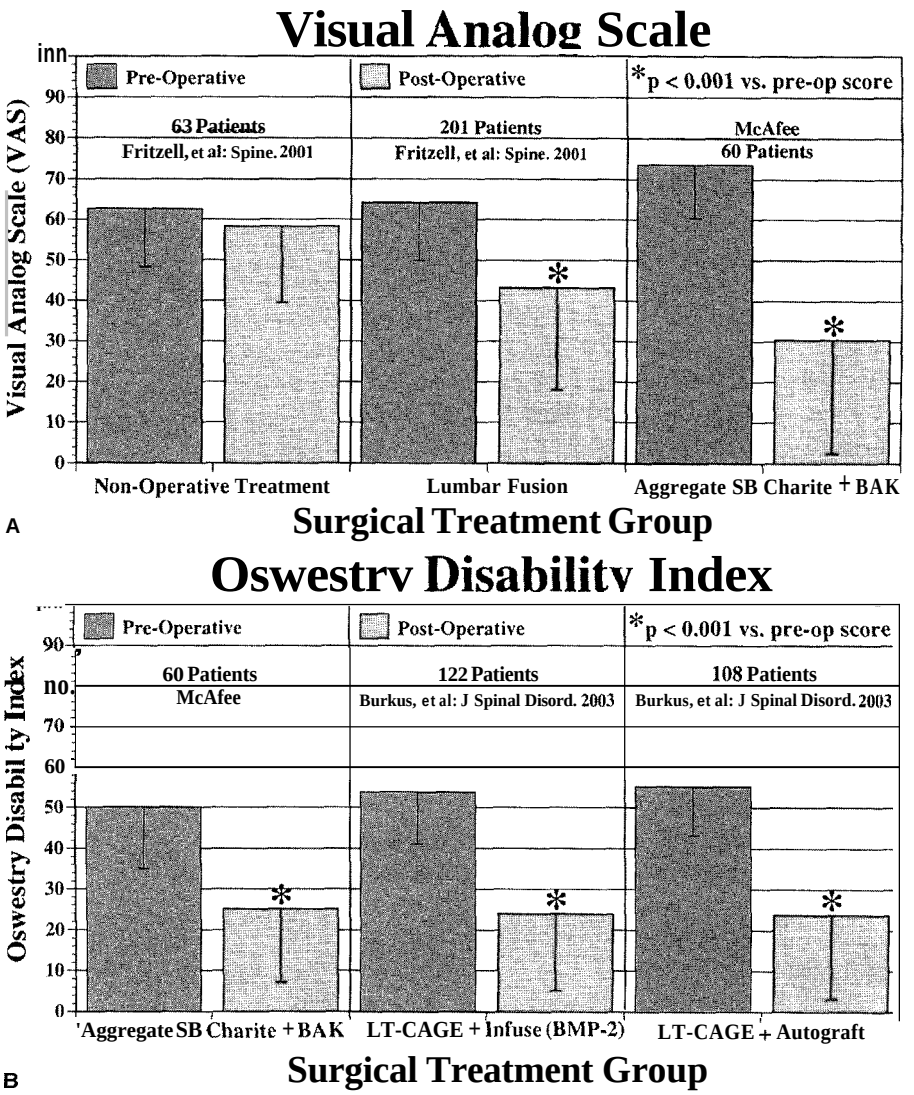


FIGURE 5. Visual Analog Scale measurement (A) and the Oswestry Disability Index (B) show the total objective outcome measures preoperatively and postoperatively. There were 19 patients randomized for BAK instrumentation with fusion and 41 patients randomized for SB Charite instrumentation. A, For comparison, the corresponding measures for a nonoperative treatment group (n = 63) and a lumbar fusion group (n = 201) from Fritzell et al[7] are graphed. The Visual Analog Scale improvement in the aggregate group (n = 60) showed highly significant improvement following SB Charite disc replacement ($P < 0.001$). B, The Oswestry Disability Index also showed highly significant improvement following SB Charite disc replacement ($P < 0.001$) (aggregate group). A group of patients with INFUSE (BMP-2) and autogenous iliac bone graft undergoing interbody fusion with the lumbar, tapered cage is graphed for comparison.'?It is comforting to see that even in this preliminary series with an innovative technique such as disc arthroplasty, including the so-called "learning curve," results are achieved that are comparable with those using third-generation cage techniaues.

Figure 5. The Visual Analog Scale objective scores are compared with those reported by Fritzell et al[7] in the 2001 Volvo Award winning classic study. The Visual Analog Scale scores before and after treatment are tabulated for nonoperative treatment (n = 63) and lumbar interbody fusion (n = 201). The Visual Analog Scale score for the aggregate SB CharitC group was 73.5 ± 14.9 preoperatively and improved to 30.4 ± 29.4 postoperatively ($P < 0.001$).

The Oswestry Disability Index from the aggregate group of 60 patients before and after surgery are compared with INFUSE (BMP-2) (Medtronic Sofamor-Danck, Memphis, TN) and autologous iliac bone graft combined with anterior interbody fusion using a lordotic tapered cage.'

The Oswestry Disability Index for the aggregate SB Charité disc replacement group was 50.0 ± 14.3, preoperatively and 25.0 ± 20.1 at 1–3 years' follow-up ($P < 0.001$).

These improvements in outcomes were highly significant ($P < 0.001$). This compares favorably with series of comparisons with pain improvement following prospective randomized trials of interbody fusion cages with BMP-2,[8–10] which used a threshold of a 15-point improvement in the Oswestry Disability Index as a definition of success. They reported 78% of patients as being successful using this criterion. We could not use a control group using BMP as BMP was investigational at the start of this study. For individual patients within the total aggregate group—42 of 60 patients or 70%—demonstrated improvement of >15-point improvement in the Oswestry Disability Index, which is very similar. Overall, this series of 60 consecutive patients randomized between the BAK and the SB CharitC, as a group, showed a 25-point improvement in the Oswestry scale.

Unfortunately, the studies of BMP did not use the Visual Analog Scale so as a benchmark, we used the com-

tion of polyethylene wear particulate, less cold flow, and less tangential stress at the metal-bone interfaces.[17]

Metal-on-metal bearing surfaces show particulate with increased systemic distribution of smaller particulate and remain class III as opposed to safer class II total hip devices. There is also a 0.5% reported incidence of hypersensitivity. Ceramic-on-ceramic total hip prostheses possess theoretical advantages over CoCr UHMWPE with regard to wear rates. Unfortunately, the brittleness of the material has led to partial or total component fracture especially in cases of component impingement. The practical demonstration of this is the fact that Zirconia femoral heads were recalled after >80 cases of catastrophic ceramic fracture, occurring with a totally constrained application in the hip joint, which has a fixed, one-point center of rotation.

Mobile-Bearing Design Versus Fixed IAR

Gertzbein et al[5] have described the physiologic pattern of motion in the normal-functioning intervertebral disc as an ellipse rather than a single point. The ellipsoid is toward the posterior aspect of the disc space in the same location nearly reproduced by the SB CharitC artificial disc. Cunningham et al[18] have used a pure moment 6 degrees of freedom unconstrained biomechanical testing method with image analysis to calculate the variable IAR for the SB CharitC prosthesis, and it is consistent with the characterization of Panjabi.[17] The center of the normal intervertebral disc displaces posteriorly with spinal flexion. This is possible only without impingement of the zygapophyseal joints if there is an intermediate mobile core between the two prosthetic end plates.[17]

Clinical results of total knee replacements have the longest survival with the lowest incidence of osteolysis if they have a mobile bearing design analogous to the SB CharitC. Buechel et al[19] reported *282* patients with the New Jersey Low Contact Stress Total Knee Replacement surviving a minimum of 10 years. Survivorship of patients who underwent cementless rotating platform knee replacements with endpoints of revision for any reason or a poor clinical knee score was 98.3% at 18 years. The concept of an intermediate bearing of UHMWPE has been borne out in total knee replacements and disc replacements over 10 years.

Lemaire[15] has a series of 100 patients followed over 10 years after SB Charité; good results remained in >80% of all cases. Poor results were attributed to incorrect indications in four cases: one with posterior facet arthritis, thoracolumbar kyphosis superior to the implant site in one case, and extensive postoperative fibrosis in two cases. Five patients retired, and 82% returned to work; *72.7%* have continued the same level activity (91.3% in the sedentary group, 66.6% in the light labor group, 83% in the heavy labor group). Nine percent had a reduced level of activity (19% in the light labor group, 16.6% in the heavy labor group). Nine percent did not return to work *(8.7%* in the sedentary group, 14.3% in the light labor group). After 10 years, there were no significant changes of the work status of the patients, and the variations in relative gain were not significant.

Porous Ingrowth Surface of Prosthesis

Loosening is the number one concern, and complication of total joint replacements in the appendicular skeleton. The worldwide available version of the SB CharitC prosthesis utilizes two plasma-sprayed layers of titanium electrochemically coated with calcium phosphate (CaP) to decrease postoperative prosthesis migration and loosening. The calcium phosphate coating is electrochemically bonded to the implant surface at room temperature and serves to optimize mineralized anchorage at the vertebral end plates. The resulting electrochemical Cap-contoured surface is stronger than prostheses using plasma spray HA coating. Szmukler-Moncler et al[20] compared the osteointegration of electrochemically bonded CaP- versus plasma-sprayed hydroxyapatite (HA)–coated prosthesis in a porcine model. It was not only stronger, but the bioactive calcium phosphate coating demonstrated improved bone apposition: $73 \pm 6.2\%$ electrochemically bonded CaP versus $49.8 \pm 16.4\%$ plasma-sprayed HA ($P = 0.009$). This unique implant coating is partially bioabsorbable. It starts out as CaP. Only during the process of mineralization do the more easily soluble aspects of this compound transform into the less easily soluble HA. This represents a prestage of bone mineral HA and supports the natural healing process. The bioactive CaP coating is present only until osseointegration progresses into the underlying titanium coating. The mineral component is absorbed by >99% by 6 weeks postoperatively.

McAfee et al[21] investigated the biomechanical, histochemical, and biological ingrowth characteristics of the most widely used total disc prosthesis: the calcium phosphate-coated SB Charite' (DePay-Acromed-Johnson and Johnson, Raghnam, MA). Seven mature baboons (n = 7; *Pupio cynocephalus)* underwent L5–L6 total disc replacement through an anterior transperitoneal approach. Six months postoperatively, plain film radiographic analysis showed no lucencies or loosening of any prosthetic vertebral end plate. Gross histopathologic analysis of the CaP-coated SB prosthesis demonstrated excellent ingrowth at the level of the implant-bone interface, without evidence of fibrous tissue or synovium formation. Histochemical assays showed no accumulation of particulate

Comparison of Spinal Decompression with "Back Pain" Procedures

The number one parameter responsible for achieving a good result with the SB Charité disc replacement is patient selection. In the past, the most successful spinal procedures were the decompression of the cauda equina in relief of neurogenic claudication in lumbar spinal stenosis (the 90–95% success range), whereas surgical procedures, namely, spinal fusions, proved successful only 50% of the time if patients presented primarily with low back pain. The comparison of the Oswestry Disability Index and Visual Analog Scale outcome measures reported in this study shows a quantum improvement in the care of select patients with mechanical, discogenic lumbar pain. This is the first study showing improvement of functional outcome measures in a prospective randomized design of a disc arthroplasty treating primarily mechanical back pain that can achieve comparable results to Yukawa et al[24] in the treatment of lumbar pain for spinal stenosis.

REFERENCES

1. McAfee PC. Symposium: a critical discrepancy—a criteria of successful arthrodesis following interbody spinal fusions. *Spine.* 2001; 26:320–334.
2. McAfee PC. Artificial disc prosthesis: the Link SB Charité. In: Kaech DL, Jinkins JR, eds. *Spinal Restabilization Procedures.* Amsterdam: Elsevier Science B.V.; 2002:299–310.
3. Buttner-Janz K, Hochschuler SH, McAfee PC. *The Artificial Disk.* New York Springer-Verlag; 2001.
4. McAfee PC, Lee GA, Fedder IL, et al. Anterior BAK instrumentation and fusion: complete versus partial diskectomy. *Clin Orthop.* 2002;389:55–63.
5. Gertzbein SD, Seligman J, Holtby R, et al. Centrode characteristics of the lumbar spine as a function of segmental instability. *Clin Orthop.* 1986;208:48–51.
6. Kuslich SD, Ulstrom CL, Griffith SL, et al. The Bagby and Kuslich method of lumbar interbody fusion. History, techniques, and 2-year follow up results of a United States prospective, multicenter trial. *Spine.* 1998;23:1267–1278.
7. Fritzell P, Hagg O, Wessberg P, et al. 2001 Volvo Award Winner in Clinical Studies: lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine.* 2001;26: 2521–2534.
8. Burkus JK, Heim SE, Gornet MF, et al. Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical using the LT-cage lumbar tapered fusion device. *J Spinal Di* 2003;16:113–122.
9. McKay B, Sandu HS. Use of recombinant human bone mo genic protein-2 in spinal fusion applications. *Spine.* 200 S66–S85.
10. Zdeblick TA, Heim SE, Kleeman TJ, et al. Laparoscopic appı with tapered metal cages: rhBMP-2 vs. autograft. *NASS.* 200 200.
11. McAfee PC, Cunningham BW, Devine JD, et al. Classificatic heterotopic ossification (HO) in artificial disk replacement. *Spi* 2002;2: 94 **S.**
12. Zeegers WS, Bohen LMLJ, Laaper M, et al. Artificial disc rep ment with the modular type SB Charité III. 2 year results i prospectively studied patients. *Eur Spine J.* 1999;8:210–217.
13. Cinotti G, David T, Postacchini F. Results of the disc prosthesis a minimum follow up period of 2 years. *Spine.* 1996;8:995–1(
14. Griffith SL, Shelokov AP, Buttner-Janz K, et al. A multicenter rospective study of the clinical results of the Link SB CharitC i vertebral prosthesis. The initial European experience. *Spine.* 1 19:1842–1849.
15. Lemaire JP, Shalli W, Laveste F, et al. Intervertebral disc prosth Results and prospects for the year 2000. *Clin Orthop.* 1997; 64–76.
16. Devaine PA, Robinson EJ, Bourne RB, et al. Measurement of p ethylene wear in acetabular components inserted with and wit cement. *J Bane Joint Surg* (Am). 1997;79:682–689.
17. White AA and Panjabi MM. *Clinical Biomechanics of the Spine* 112–115. JB Lippincott Co. 1990 2nd Ed.
18. Cunningham BW, Orbegoso CM, Dmitriev AE, et al. The effec titanium particulate on the development and maintenance of a terolateral spinal arthrodesis: an in vivo rabbit model. *Spine* 2(27:1971–1981.
19. Buechel FF Sr, Buechel FF Jr, Pappas MJ, et al. Twenty-year ev ation of meninscal bearing and rotating platform knee replaceme *Clin Orthop.* 2001;388:41–50.
20. Szmukler-Moncler S, Perin S, Ahossi V, et al. Evaluation BONIT, a fully resorbable CaP coating obtained by electrocbem deposition, after 6 weeks of heating. A pilot study in the pig max In: Davidovitch A, Mah J. *Biological Mechanisms of Tooth Ei tion, Resorption arid Replacements by Implants.* Boston, MA: H vard Society for the Advancement of Orthodontics 1998:481–4
21. McAfee PC, Cunningham BW, Orbegoso CM, et al. Analysis porous ingrowth in intervertebral disc prostheses. **A** non-human mate model. *Spine.* 2003;28:332–340.
22. Cunningham BW, Lowery GL, Gonzales V, et al. An analysis of Acroflex lumbar disk prosthesis. A non-human primate model. I ceedings of the North American Spine Society, November 3, 2C Seattle, WA, U.S.A., pp 74–75.
23. Cunningham BW, Orbegoso CM, Dmitriev AE, et al. The effec spinal instrumentation particulate wear debris: an in vivo rab model and applied clinical study of retrieved instrumentation car *Spine J.* 2002;2:69S–70S.
24. Yukawa Y, Lenke LG, Tenhula J, et al. et al. **A** comprehensive stu of patients with surgically treated lumbar spinal stenosis with n rogenic claudication. *J Bone Joint Surg (Am).* 2002;84:1954–19

wear debris (no titanium, UHMWPE, cobalt chrome) or cytokines (tumor necrosis factor-α, prostaglandin E„ interleukin [IL] 1, IL-2, or IL-6)[18,22,23] Total end plate area showed the mean ingrowth of 47.9 ± 9.12 and the total range from 35.5% to 58.8% ingrowth. The porous ingrowth, percentage pore ingrowth coverage at the bone-metal interface was more favorable for the CaP/Ti-coated total disc replacement compared with that reported for standard porous-coated cementless total joint components in the appendicular skeleton (range 10–30%). The reason for the improved degree of porous ingrowth in total disc replacement prostheses is probably due to ligamentotaxis causing sustained compression across the metal-bone interface and the uniqueness of the coating (Fig. 6).

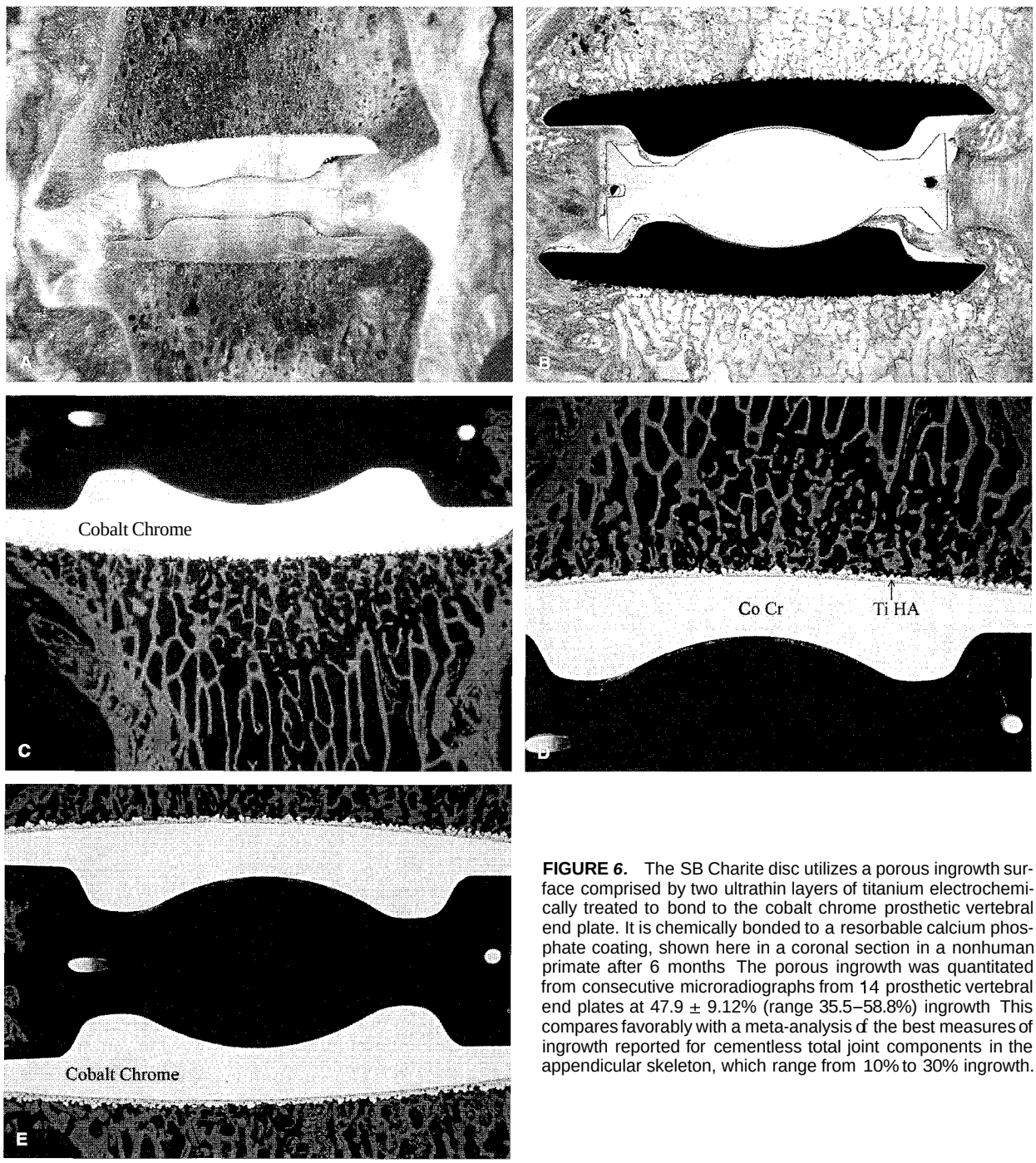


FIGURE 6. The SB Charite disc utilizes a porous ingrowth surface comprised by two ultrathin layers of titanium electrochemically treated to bond to the cobalt chrome prosthetic vertebral end plate. It is chemically bonded to a resorbable calcium phosphate coating, shown here in a coronal section in a nonhuman primate after 6 months The porous ingrowth was quantitated from consecutive microradiographs from 14 prosthetic vertebral end plates at 47.9 ± 9.12% (range 35.5–58.8%) ingrowth This compares favorably with a meta-analysis of the best measures of ingrowth reported for cementless total joint components in the appendicular skeleton, which range from 10% to 30% ingrowth.

parison of Fritzell et al.[7] A direct comparison of our results with those reported in prospective Food and Drug Administration IDE studies on the BAK cage, the Ray cage, and the Brantigan cage is not possible as these studies used a modified Prolo scale for functional outcome measurement. Keep in mind that in the perspective of the overall IDE, this follow-up is a mean, rather than a minimum, of 2 years, that this is only 1 of 15 investigative sites, and, of course, that in the final analysis the results from stand-alone BAK will be partitioned out. With the pendulum of clinical favor and published reports becoming negative with stand-alone BAK cages, the final analysis might be expected to be more favorable with SB Charité disc replacement when analyzed alone.

Complications (for Combined 60 Patients = 19 BAK + 41 SB CharitC)

To date, no implants have been explanted. There was one death by unrelated to the spinal procedure. There was one case of postoperative small bowel obstruction of uncertain etiology. At the conclusion of what was thought to be an uneventful procedure, the left ureter, left and right iliac vessels, peritoneum, and visceral structures were specifically examined as part of our routine. There was nothing abnormal noticed by either the access vascular surgeon or the spinal surgeon. Four days postoperatively, the patient was admitted with a small bowel obstruction. Emergent exploratory laparotomy revealed adhesions of the greater omentum. Postoperatively, there was no deep wound infection or long-term sequelae. The surgeons, in retrospect, thought that the sustained retraction of the bowel by a self-retaining Thompson retractor contributed to this condition so its use was subsequently curtailed. The patient is >2 years' follow-up, asymptomatic, and working in the defense industry full time.

There was one case of significant postoperative heterotopic ossification, and this was specifically looked for in a prospective radiographic evaluation and the subject of another report.[11] This was a class 2 type of heterotopic ossification, which means there was ectopic bone within the disc space but that it did not affect motion. In fact, the patient demonstrated 16" of differential motion at the operative level, L4–L5, on flexion-extension radiographs 2 years postoperatively.

One case each of the following occurred in the total cohort of 60 cases: retrograde ejaculation, depression, adynamic ileus requiring a nasogastric tube, adynamic ileus spontaneously resolving without a nasogastric tube, urinary tract infection, epididymitis, lateral epicondylitis, and degenerative changes at the vertebral level above.

DISCUSSION

The SB Charité disc arthroplasty has five ur
tures that should be emphasized as not all dis
ment prostheses are the same: 1) the biomater
high-molecular-weight polyethylene (UHMW
5834/2; ASTM 648)–cast CoCrMo alloy (ISO
ASTM F75-82) articulating bearing surface (r
metal on metal or ceramic on ceramic)"; 2)
bearing design rather than a ball-and-socket de
the TiCaP porous ingrowth surface; 4) com
molded sheet polyethylene standard gamma i
sterilized versus highly cross-linked polyethyle
the maximum preservation of vertebral body bor
opposed to cutting a groove into the middle of
bral body and insertion of a fin possibly requir
pectomy for revision.

The first commercially available version c
Charité prosthesis was designed by Buttner
Schellnack and manufactured out of cobalt-ch
UHMWPE by Waldemar Link GmbH & Co. in
Germany, in 1987.[3] This predates any other cob:
disc replacement by >10 years. Over 5000 Link
theses have been implanted worldwide[12–15]; t
largest experience by any other disc prosthe
world was <800 cases.

Bearing Surface

The SB CharitC articulating surface is cobc
alloy and high-density polyethylene that has
since 1987. The calculated wear rate of thi
UHMWPE is <0.152 mm/year,[16] and the
UHMWPE core recommended for clinical use i
More favorable wear particulate and incidence i
sis has been described with highly cro
UHMWPE, cross-linked either with radiatio
peroxidase. The early wear rates in simulatc
newer configuration of UHMWPE are impro
mm/year); however, the highly cross-linked va
greater chance of plastic deformation due to i
crystallinity, ultimate tensile strength, and m
tantly the reduction of tensile elongation at frac
flow of UHMWPE is less of a concern wi
Charité than any other prosthesis because the
of the lordotic end plates can be chosen to ensu
biconvex UHMWPE bearing surfaces articulat
concave parallel inner surfaces of the metal e
The two CoCrMo end plates can be adjusted
from 0°, 2.5°, 5°, 7.5°, or 10°. There is greater
ity of both end plates' lordotic angulation tha
other modular prosthesis: 0–20° total angulatio
sis in 2.5" increments. The result is less tribolog

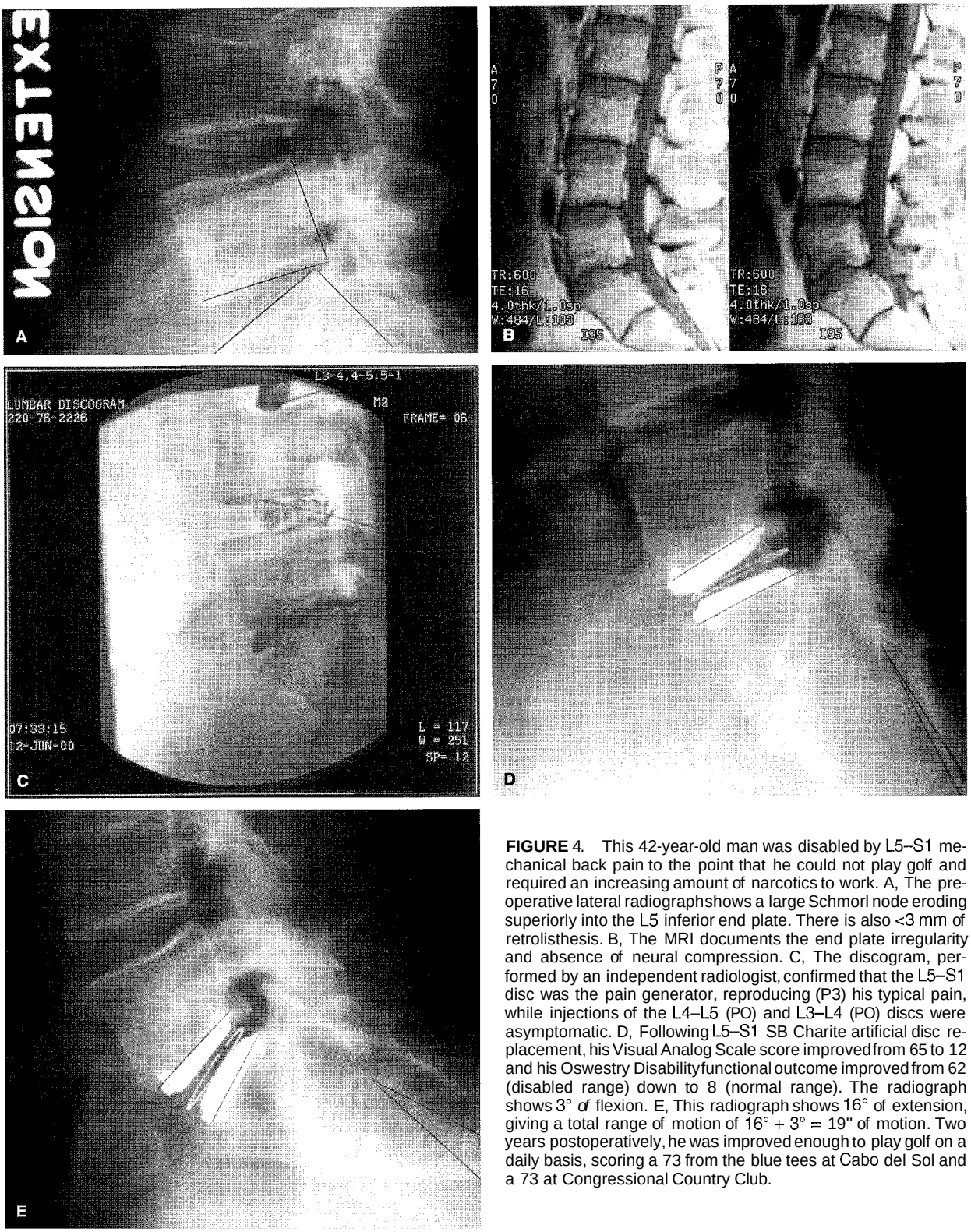
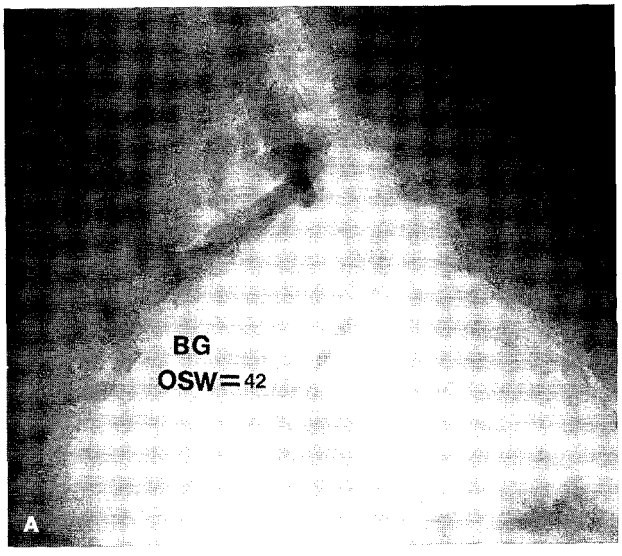
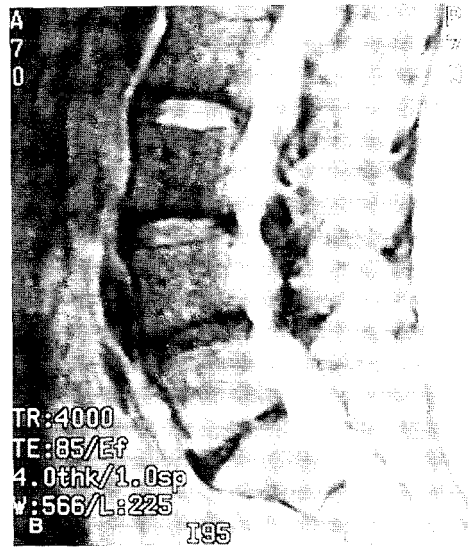
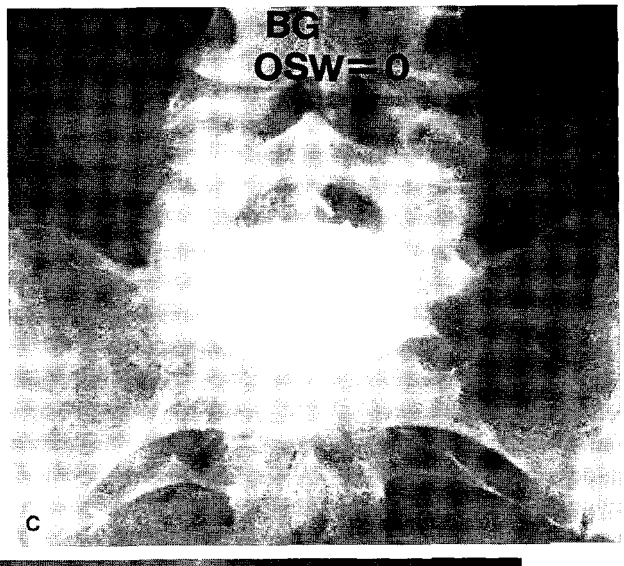
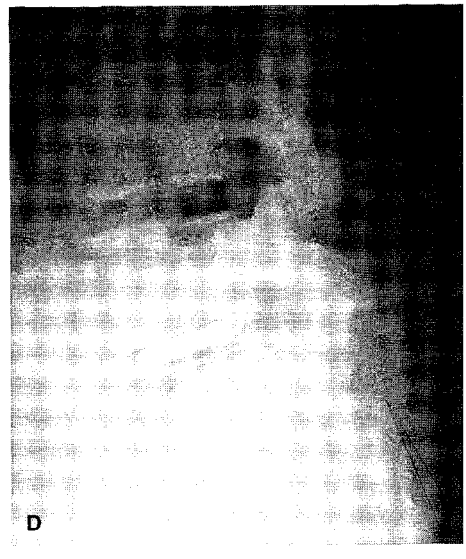


FIGURE 4. This 42-year-old man was disabled by L5–S1 mechanical back pain to the point that he could not play golf and required an increasing amount of narcotics to work. A, The preoperative lateral radiograph shows a large Schmorl node eroding superiorly into the L5 inferior end plate. There is also <3 mm of retrolisthesis. B, The MRI documents the end plate irregularity and absence of neural compression. C, The discogram, performed by an independent radiologist, confirmed that the L5–S1 disc was the pain generator, reproducing (P3) his typical pain, while injections of the L4–L5 (PO) and L3–L4 (PO) discs were asymptomatic. D, Following L5–S1 SB Charite artificial disc replacement, his Visual Analog Scale score improved from 65 to 12 and his Oswestry Disability functional outcome improved from 62 (disabled range) down to 8 (normal range). The radiograph shows 3° of flexion. E, This radiograph shows 16° of extension, giving a total range of motion of 16° + 3° = 19" of motion. Two years postoperatively, he was improved enough to play golf on a daily basis, scoring a 73 from the blue tees at Cabo del Sol and a 73 at Congressional Country Club.









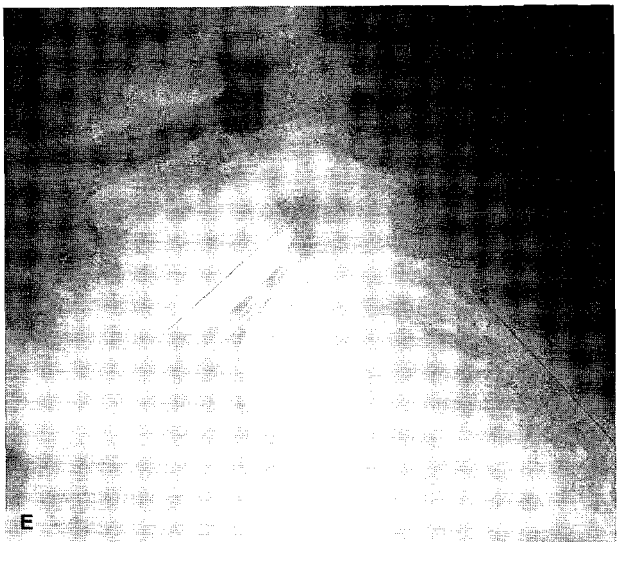


FIGURE 1. An ideal candidate for an SB Charite artificial disc r placement is presented. A 33-year-old woman has had two prior fail laminectomies, at L5–S1. She persisted with mechanical back pa (90%) and posterior thigh pain (10%). The discogram at L5–S1 repr duced severe concordant pain, whereas injections at L4–L5 and L L4 were negative. She was unable to walk or work due to disabli back pain, Oswestry score was 42, and she was requiring an increa ing amount of narcotic analgesics to get through the day. A, The late radiograph shows extreme L5–S1 disc space narrowing, but the pc terior elements were normal by CT scan. There was also a vacuu disc sign at L5–S1. B, The T2-weighted MR image discloses Moc type II degenerative changes throughout the adjacent vertebral bc ies, representing bone marrow edema and reactive changes. T TI-weighted MR image ruled out any significant nerve root compre sive pathology. C, After undergoing a successful L5–S1 SB Char prosthesis procedure, her Oswestry score was 0, she was asymptoi atic, and she was able to walk throughout Disneyworld with her thr children 2 months postoperatively. *D,* The lateral radiograph demc strates 9" of flexion 2 years postoperatively. **E,** The correspondi lateral radiograph in extension shows 24°, meaning a total flexic extension arc of 15" (24" − 9" = 15") in a previously collapsed di space. This patient had an excellent clinical and radiographic resu