

The CHARITÉ Artificial Disc: Design History, FDA IDE Study Results, and Surgical Technique

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INTRODUCTION

Lumbar fusion serves to eliminate abnormal motion and instability at symptomatic degenerated levels, subsequently reducing or eliminating low back pain in patients with degenerative disc disease (DDD). Reported clinical outcomes for these procedures vary widely. A meta-analysis of lumbar fusion procedures performed by Geisler et al.¹⁰ demonstrated the elimination of lumbar segmental motion that resulted in a significant reduction in pain and subsequent improvement in disability level.

Fusion is successful in many cases because the abnormal motion itself is the root cause of pain. When the segment is fused, it no longer moves and cannot, therefore, cause pain. Fusion, however, can result in stress and increased motion in the segments adjacent to the fused level, as demonstrated by Cunningham et al.⁶ This may initiate and/or accelerate the degenerative disease process in adjacent segments. Reported rates of adjacent-level disease requiring reoperation after lumbar fusion range from 20 to 35%.^{11,12} The inherent problem with surgical arthrodesis of the degenerative lumbar segment is that it merely masks the true disease process by eliminating the intervertebral motion and its normal physiological function.

RATIONALE FOR AN ARTIFICIAL DISC

Fusion is designed to eliminate the normal motion of one or more lumbar segments. In using lumbar artificial disc technology, the restoration and maintenance of normal physiological motion are provided rather than the alternative, the elimination of motion. The premise of lumbar artificial disc technology is threefold: 1) correct abnormal motion; 2) restore and maintain motion, intervertebral lumbar segmental space height, lordosis, and instantaneous axis of rotation; 3) reduce and/or eliminate pain and improve functional ability. If these goals are achieved, it stands to reason that the segments adjacent to the dynamically stable segment would not be subject to abnormal loads and motions, and, therefore,

deceleration or elimination of adjacent level disc disease and transition syndrome will follow.

DESIGN HISTORY OF THE CHARITÉ ARTIFICIAL DISC

The CHARITÉ Artificial Disc (DePuy Spine, Raynham, MA) was designed to duplicate the kinematics and dynamics of a normal lumbar motion segment while restoring disc space height and motion segment flexibility.^{4,15} The prosthesis was designed by Büttner-Janzen and Schellnack in the early 1980s. The first two designs, SB CHARITÉ I and SB CHARITÉ II, were implanted in a small number of patients in East Berlin and were never made commercially available.¹⁵ These early designs included stainless steel endplates, which were prone to breaking and subsidence. The third-generation and current design was first marketed by Waldemar Link outside the United States in 1987. DePuy Spine acquired the product rights to the CHARITÉ Artificial Disc in 2004.

The CHARITÉ Artificial Disc is comprised of two CoCrMo endplates and a free-floating ultra high molecular weight polyethylene core. The primary attachment of the plates is made possible by six “teeth” on the inferior and superior endplates, which are forcefully implanted into the cranial and caudal vertebral endplates. Layers of plasma-sprayed porous titanium and calcium phosphate were added to the CHARITÉ disc distributed outside the United States since 1998. The disc, with this enhancement, was introduced to the United States market in April 2006 (*Fig. 24.1*). This coating provides for potential osseous ongrowth and long-term stability of the prosthesis after implantation.¹⁸

The prosthesis endplates are currently available in seven footprint geometrical configurations (including three wide footprints) adaptable to the size of the vertebral endplates, each with four available angles (0, 5, 7.5, and 10 degrees). This allows for built-in lordosis with variations of 0 to 20 degrees.

The unconstrained design of the CHARITÉ Artificial Disc allows the mobile sliding core to translate dynamically within the disc space during normal spinal motion, moving posteriorly in flexion and anteriorly in lumbar extension (*Fig.*



FIGURE 24.1 The CHARITÉ Artificial Disc is comprised of two CoCrMo plates and an ultra high molecular weight polyethylene mobile sliding core. The surface of the plates is sprayed with titanium calcium phosphate, which provides for bony ongrowth and stability of the prosthesis.

24.2). The mobile core performs in a similar fashion to the mobile knee bearing in many of the contemporary knee implant designs. This could be considered a second generation device or an advanced-type design over a fixed core device, much like the mobile core in the knee is considered an advanced design over fixed bearings. The CHARITÉ design provides not only unloading of the posterior facet structures during this normal replication of motion, but also allows forgiveness for slight off center positioning of the implant.¹⁷

Finite element analysis supports the concept of an unconstrained device unloading the facet joints. In a two-level three-dimensional nonlinear finite element model, Moumene and Geisler²¹ described the effect of CHARITÉ disc replacement on the facet joints at the operative level (L4–L5) compared with to a fixed core design. The model demonstrated increased facet loading of 161% greater load in

axial rotation, 24% more in flexion/extension, and 35% more in lateral bending with a fixed-core device versus the CHARITÉ Artificial Disc.

In a cadaveric model, Cunningham et al.⁶ demonstrated that the center of rotation for the CHARITÉ prosthesis closely mimics that of a normal lumbar disc at the level of implantation and at the superior adjacent level. Fusion, however, greatly distorted the center of rotation at the level of implantation and at the superior adjacent level. In addition, compared with a normal intact segment, the CHARITÉ device did not adversely affect the range of motion at adjacent levels while fusion caused a “marked increase” in adjacent level motion. The coupled translation with angulation was noted in the normal spine and reproduced at the level with the CHARITÉ artificial disc. This increased range of motion and subsequent forces and stress at the adjacent level is hypothesized to be a major contributing factor to accelerating adjacent level degenerative changes.

CLINICAL HISTORY OF THE CHARITÉ ARTIFICIAL DISC

To date, there have been more than 15,000 CHARITÉ prostheses implanted worldwide.¹⁹ Most of this experience is outside of the United States and prior to Food and Drug Administration (FDA) approval of the CHARITÉ Artificial Disc in October 2004. The early experience with the CHARITÉ prosthesis is mixed,^{5,13,22,24,25} largely due to limited sizing, rudimentary instrumentation, and underdeveloped patient indications.^{2,16} The challenges of the early experience were a necessary step in refining the indications and techniques for lumbar disc replacement in preparation of the FDA Investigational Device Exemptions (IDE) study. Lemaire et al.¹⁴ described excellent clinical and radiographic results in 10 patients with a minimum 10-year follow-up period after disc replacement with the CHARITÉ Artificial Disc. They reported excellent or good clinical outcomes in 90% of patients, with a mean range of motion in flexion/extension of 10.3 degrees. The return to work rate was 92%. There was a



FIGURE 24.2 The unconstrained design of the CHARITÉ Artificial Disc allows the mobile sliding core to translate dynamically within the disc space during normal spinal motion, moving posteriorly in flexion and anteriorly in lumbar extension.

2% incidence of adjacent-level disease requiring reoperation, and a 5% incidence of posterior revision with no anterior revision procedures. Scott-Young²³ described good clinical outcomes and a very low revision rate of 2.7% in 182 patients with 2–5 year follow-up.

THE FDA MULTICENTER TRIAL OF THE CHARITÉ ARTIFICIAL DISC

The FDA IDE trial of the CHARITÉ Artificial Disc was the first prospective, randomized, controlled, multicenter study of two very different surgical treatments for DDD in the spine in patients failing non-operative care. The study was performed at 14 centers across the United States. The primary

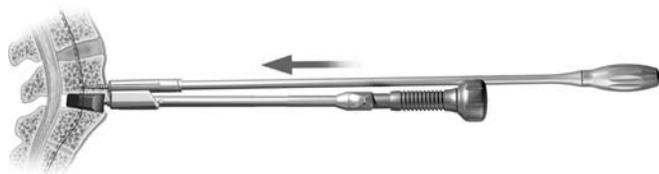


FIGURE 24.3 After identification of the midline with fluoroscopic assistance, a midline marker is placed into the superior vertebral body to key off of for implantation of the prosthesis.

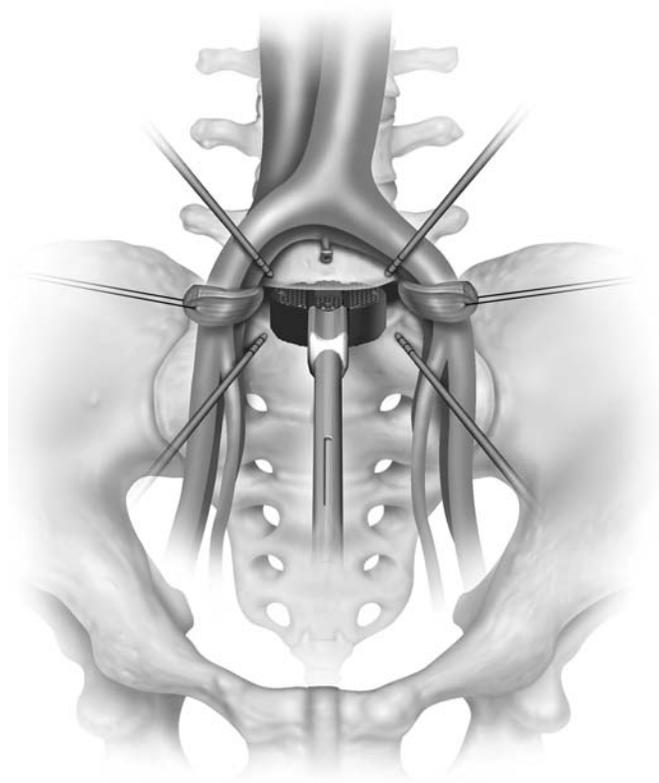


FIGURE 24.4 Trials are inserted into the prepared disc space which are used to assess the endplate footprint size and proper lordotic angle.

inclusion criteria included single-level DDD at L4–L5 or L5–S1 confirmed by magnetic resonance imaging (MRI) scans and provocative discography, age 18 to 60 years, Oswestry Disability Index (ODI) score of 30 or greater, back pain Visual Analog Score (VAS)-rated score of 40 or greater, with no radicular component (referred leg pain was permitted), and failed non-operative treatment of at least 6 months duration. The primary exclusion criteria included previous thoracic or lumbar fusion, multilevel DDD, facet joint arthrosis, non-contained herniated nucleus pulposus, osteoporosis, spondylolisthesis slip greater than 3 mm, scoliosis greater than 11 degrees, and midsagittal stenosis less than 8 mm.

Local institutional review board approval was obtained at each site. The study protocol indicated that participants at each site were to perform five non-randomized cases before beginning the randomization arm; 71 non-randomized cases were performed to implant the CHARITÉ device. Enrollment in the randomized arm of the study began in May 2000 and concluded in April 2002. Patients were then randomized into a CHARITÉ group or the control group of anterior lumbar interbody fusion with BAK cages (Zimmer, Warsaw, IN) filled with autograft. Two hundred and five patients were randomized to the CHARITÉ group and 99 were enrolled in the control group, a 2:1 randomization. The 2:1 randomization is preferred in non-inferiority studies to assess potentially rate-adverse events. Demographic features were not significantly different between the two groups with respect to age or sex. There was no intergroup difference with respect to levels treated: L4–L5, 61 patients (29.8%) in the CHARITÉ group and 32 patients (32.3%) in the BAK group; L5–S1, 144 patients (70.3%) in the CHARITÉ group and 67 patients (67.7%) in the BAK group.

Clinical results of the study were described in detail by Blumenthal et al.³ and radiographic results by McAfee et al.¹⁷ Overall and key adverse event rates were similar between the groups with no significant differences. Geisler et al.¹⁰ previously reported no significant difference between the groups with respect to neurological adverse events and specifically major neurological adverse events. Clinically, mean ODI and VAS scores were significantly lower in the CHARITÉ group ($P < 0.05$) at all time points, except at 24 months at which time the mean scores in the CHARITÉ group were numerically, but not statistically, lower. Blumenthal et al.^{2,3} used the student's *t*-test, as pre-specified in the study protocol, which assumes a normal distribution of data. However, a recent analysis by Geisler⁹ demonstrated that the use of a non-parametric test (Wilcoxon Rank Sum) is more appropriate for this data analysis because the distributions of the ODI and VAS scores in both groups at 2 years did not exhibit a normal (bell-curve) distribution. Using the non-parametric test, mean ODI and VAS scores in the CHARITÉ group were significantly lower than the mean scores in the control

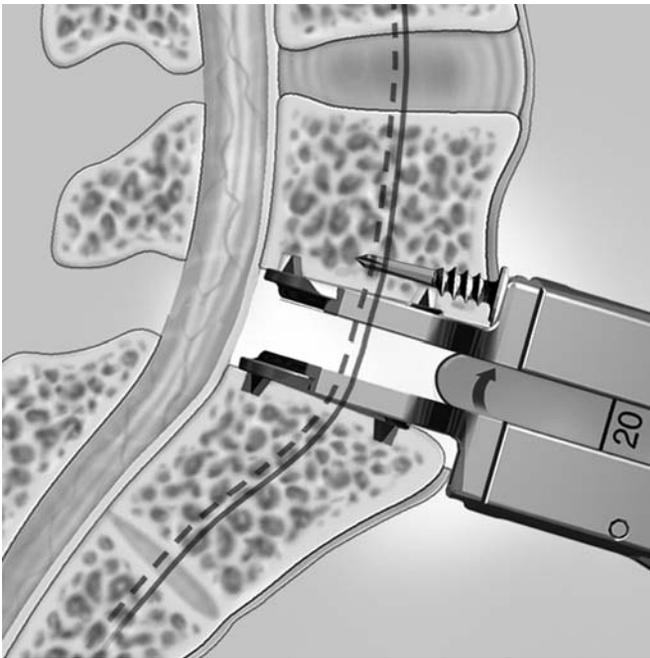


FIGURE 24.5 Lateral view of the metal prosthesis endplates impacted into the vertebral endplates.

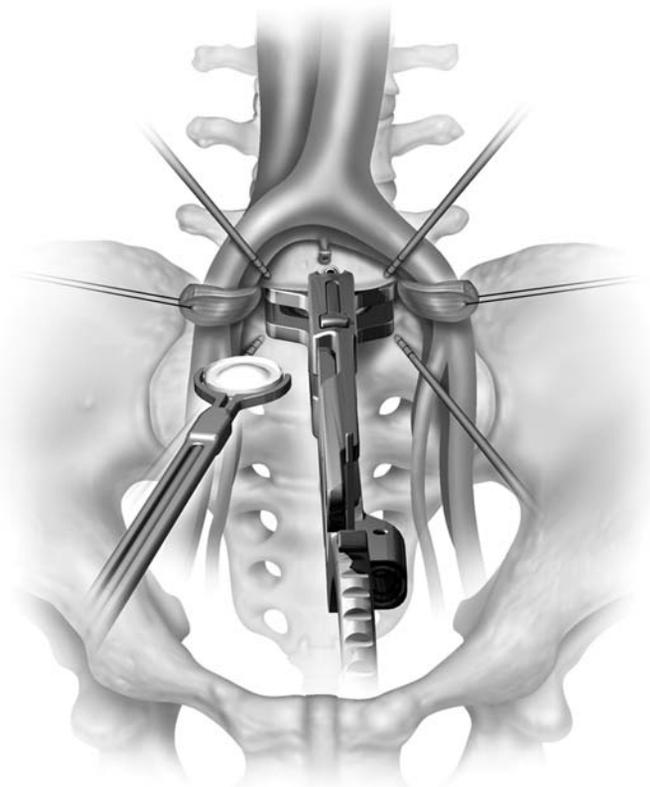


FIGURE 24.6 Once the metal endplates have been placed, trial cores are used to size the distracted space and the final core is placed.

group at all time points, including the 24 month follow-up ($P < 0.05$). In addition, both groups demonstrated highly significant ($P < 0.001$) improvement in VAS and ODI scores versus the baseline condition at all time points. This new analysis demonstrates that total disc replacement with the CHARITÉ Artificial Disc in indicated patients results in superior clinical outcomes as measured by ODI and VAS questionnaires.

The radiographic analysis described by McAfee et al.¹⁷ demonstrated restoration and maintenance of flexion/extension range of motion in the CHARITÉ group with a mean range of motion of 7.5 degrees versus a baseline value of 6.6 degrees. McAfee et al. also reported significantly better restoration of disc space height and significantly less subsidence in the CHARITÉ group compared with the control group. Finally, ideal surgical placement of the prosthesis correlated with good clinical outcome. McAfee noted, “The zone of ideal placement of the CHARITÉ Artificial Disc is large and forgiving in both planes (± 10 mm).”

SURGICAL TECHNIQUE

A highly detailed surgical technique was described by Geisler⁸ in 2005. All surgeries in the IDE study were performed via an anterior retroperitoneal approach, with the assistance of a general or vascular surgeon at the majority of study sites.

After the direct anterior approach to either L4–L5 or L5–S1 is completed, the anterior longitudinal ligament is dissected to fit the width of the disc implant. A complete discectomy is performed, with care taken not to disturb the osseous endplates, although all of the cartilaginous endplates are removed. The discectomy is enlarged to expose the vertebral body circumferential rim of cortical bone. Posterior osteophytes are removed using a 0.25-inch chisel or a Kerrison punch.

A spreader is then placed into the disc space to produce parallel distraction, which is accomplished using a paint paddle-type instrument placed within the spreader. The posterior ligament is stretched and/or ripped to some extent, increasing the posterior height of the disc space. This posterior distraction of the disc space returns the collapsed posterior facets to near normal position. Once the disc space has been distracted, additional disc material that was contained within the buckled ligament within the neural canal is often delivered into the disc space. This is then removed using a Kerrison or biopsy punch. In approximately two-thirds of the patients, some epidural bleeding or significant bone bleeding along the posterior edge occurs during disc space distraction. This is easily managed by placing strips of Avitene in the disc space and compressing them down against the remaining posterior longitudinal ligament area by using a standard sponge. After allowing it to sit for 2 to 3 minutes, the sponge can be removed, leaving the thin layer of Avitene in place.

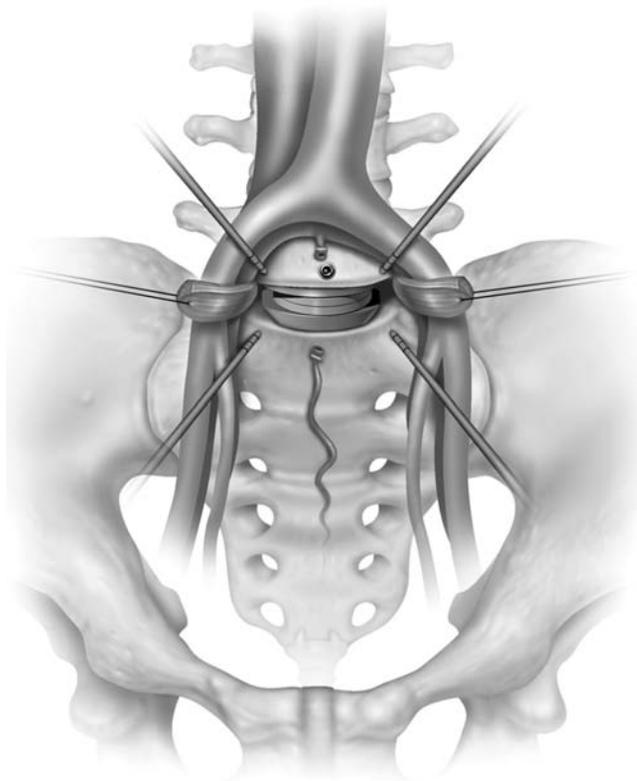


FIGURE 24.7 Visual verification is required in the anterior plane to ascertain that the implant is recessed below the anterior cortical margin.

This is easier to accomplish during the initial discectomy rather than after the metal endplates and core have been inserted. A broach is then used to scratch the vertebral bony endplates at the location where the teeth on the CHARITÉ endplates will impact.

After identification of the midline with fluoroscopic assistance, a midline marker is placed into the superior vertebral body to key off of (*Fig. 24.3*). Various trials are then inserted into the disc space, which are used to assess the endplate footprint size, and proper lordotic angle (*Fig. 24.4*).

Under fluoroscopic control, the metal endplates of the prosthesis are inserted and tapped into position. The metal endplates of the implant are impacted into the disc space (*Fig. 24.5*), positioned posteriorly within it, and then parallel distraction is performed. During this expansion, it is essential that only the very lateral edges of the implant are touched with the distraction instrumentation to avoid scratching the inside of the cupped metal endplates as this would result in a very significant increase in the amount of plastic wear. Once the metal endplates have been placed, trial cores are used to size the distracted space and the final core is placed (*Fig. 24.6*). The correct position of the plastic core is verified to ensure that it articulates with the cups and distraction is then fully removed.

Anteroposterior and lateral fluoroscopy is used to aid in positioning the device and to provide final radiological verification. Visual verification is required in the anterior plane to ascertain that the implant is recessed below the anterior cortical margin (*Fig. 24.7*). A bone tamp is used on the sides of the metal endplates of the implant to make minor adjustments and also to impact the anterior cleats into the cortical bone of the vertebral body. The optimal device placement is 2 mm dorsal in the sagittal vertebral body midline and in the midline in the anteroposterior view with the metal endplates on the circumferential cortical bone (*Fig. 24.8*).

REVISION STRATEGIES

If revision is necessary, the primary revision strategy is posterior instrumented fusion. This will lock down the pros-

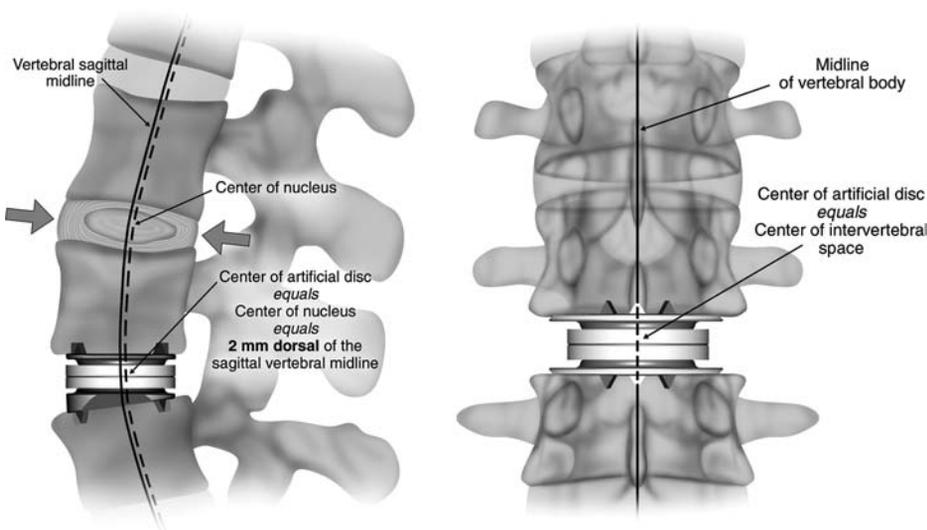


FIGURE 24.8 The optimal device placement is 2 mm dorsal in the sagittal vertebral body midline and in the midline in the anteroposterior view with the metal endplates on the circumferential cortical bone.

thesis and will act as an anterior spacer. An anterior revision is generally required for an expelled or migrated prosthesis that threatens vascular or neurological structures. The primary benefit of a non-keeled device, such as the CHARITÉ prosthesis, is that it can be revised anteriorly, leaving the anatomy intact for a new prosthesis⁷ or conversion to interbody fusion. With keeled designs, a partial vertebrectomy or corpectomy may be necessary during revision and revision to a new prosthesis is not possible.¹ Revision rates, reasons for revision, and procedures undertaken in the IDE study were detailed in a recent study by McAfee et al.¹⁹ In addition, a 200-page monograph of revision strategies for a number of lumbar artificial disc prostheses, including the CHARITÉ Artificial Disc, published in 2005, is also available for review.²⁰

CONCLUSION

Lumbar disc replacement with the CHARITÉ Artificial Disc is a promising treatment modality for axial lumbar pain and preserving joint motion in selected patients. The 2-year clinical outcomes after a single level discogenic degenerative disc disease seem superior to historical fusion results. Additional research will be done in the coming years to determine whether or not topping off a lumbar fusion will help prevent adjacent level disease, whether or not this device can be used below a scoliosis when the degenerative changes occur, and whether or not multi-level disease will have the same good clinical response as single-level treatment.

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