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Disc Prosthesis for Degenerative Disease and Axial Instability—CHARITÉ™ Artificial Disc

Richard D. Guyer, MD, and Gregory Elders, MD

Spine surgery has entered into a new stage of stabilization with motion preservation and spinal arthroplasty. The Charité Artificial Disc Replacement, one of the first examples, has been developed and refined from 1982 to the present. In a randomized prospective controlled study with single level fusion it was found to be safe and effective and was approved by the FDA in October 2004. To date over 11,000 implantations have been carried out worldwide. This is a demanding procedure that requires strict adherence to proper patient selection, proper implant sizing, and proper implantation technique. While short term follow up is encouraging, long term follow up will answer questions of adjacent segment disease, implant wear, and longevity issues.
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Spine surgery has entered into a new stage of evolution, that of stabilization with motion preservation and spinal arthroplasty. Although spinal arthroplasty devices have been utilized by surgeons in Europe and around the world for over two decades, due to the United States' more restrictive regulatory process concerning medical devices, these technologies have only now, with the recent FDA approval of the CHARITÉ™ Artificial Disc prosthesis, become available in the US.

Traditionally, spinal fusion has been used to treat the abnormal motion and pain associated with degenerative spinal pathology, and in truth, has been an effective treatment method for stabilizing pathologic spinal segments. Unfortunately, with elimination of motion at the diseased segment(s), the natural kinematics of the global spine are altered in a detrimental fashion. The majority of these changes occur at the segments adjacent to the fused levels. Cunningham and coworkers,[1] using a cadaveric model, demonstrated that fusion of just a single lumbar segment increases the range of motion in adjacent segments. This altered motion has been suggested to result in adjacent-level disc disease or "transition syndrome." This consequence has been supported by clinical experience as well. Gillet[2] reported a 20% rate of adjacent-level disc disease requiring surgical intervention in his series of lumbar fusion patients, and Ghiselli and coworkers[3] concluded that the predicted rate of adjacent-level complications requiring reoperation in lumbar fusion at 10 years following the index surgery is 36.1%. In addition to adjacent segment degeneration, spinal fusion is associated with a number of other complications including symptomatic pseudarthrosis, hardware failure in instrumented cases, graft collapse, autograft harvest site pain, loss of normal sagittal balance, and lost motion across the fused segment(s).

Artificial disc replacement is said to prevent many of these complications by preserving more natural spinal kinematics. Just as the orthopedic management of degenerative conditions involving the large joints of the upper and lower extremities has evolved from joint fusion to joint replacement, disc replacement may offer patients improved clinical outcomes through preservation of normal range-of-motion and physiologic function.

The goals of spinal arthroplasty include relief of pain, restoration of "normal" anatomy [ie, disc height and neural foraminal patency], and preservation of segmental mobility at the affected level. Various methods for achieving these goals have been proposed, but the most clinically successful technique with the present technologies is that of total disc replacement.

Experience

In 1982, Karen Buttner-Janz and Kurt Schellnack[4,5] of Charité Hospital in East Germany introduced the original

Texas Back Institute, Plano, Texas.
Address reprint requests to Richard D. Guyer, MD, Texas Back Institute, 6020 West Parker Road, Suite #200, Plano, Texas 75093. E-mail: rguyer@texasback.com

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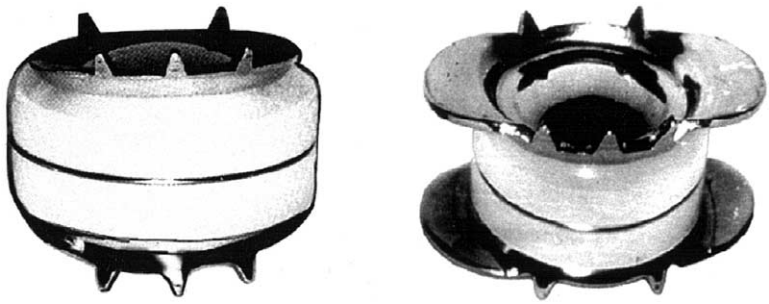

Figure 1 SB CHARITÉ I (left) and SB CHARITÉ II (right) models.

version of the SB CHARITÉ total disc prosthesis (Fig. 1). The design of the implant was based on principles borrowed from peripheral joint replacement technologies. It consisted of an ultrahigh molecular weight polyethylene core articulating with adjacent stainless steel endplates. Unfortunately, the original design of this implant was plagued by problems with endplate subsidence, prompting the inventors to revise that design in 1985. This version of the implant had larger endplate contact area with laterally located endplate extensions intended to prevent subsidence (Fig. 1). Unfortunately, although endplate subsidence was less frequently a problem, the new version implants were prone to breakage of the metal endplates. Both of the original two models of the device were manufactured solely for use at the Charité Hospital and neither was ever made commercially available.

It was at this point that the designers enlisted the aid of the Link Corporation to design the third version of the CHARITÉ prosthesis, which included the positive qualities of the previous designs without their inherent weaknesses. The Link SB CHARITÉ III was designed in 1987 and acquired by DePuy Spine in June 2003, at which time it was renamed CHARITÉ Artificial Disc. It remains the currently used design (Fig. 2). It has improved metallurgic qualities using casted CoCrMo alloy endplates. Six teeth per endplate secure the device to the vertebral endplates. The implant is modular in regards to its components, allowing the surgeon to fit the prosthesis optimally to each patient's unique anatomy. Four endplate footprint sizes are available. Lordosis is fixed into the endplates at 0°, 5°, 7.5°, or 10°. The endplate lordosis can be individually selected to provide optimal lordotic angulation. Finally, five sizes of UHMWPE Sliding Cores are available, ranging from 7.5 to 11.5 mm in 1.0-mm increments. This allows the surgeon to individualize the disc height to each patient's native anatomy.

To improve osseo-integration at the implant–bone interface, a porous ingrowth coating has become available outside the US. McAfee and coworkers[6] recently demonstrated an average 47.9% porous ingrowth using hydroxyapatite coating in a nonhuman primate model. This option is expected to be available in the US by the end of 2005.

Clinical Results

Over 11,000 CHARITÉ Artificial Disc procedures have been performed worldwide. The first US implantation was in March of 2000. Unfortunately, there remains a relative paucity of published reports available in the English language with good clinical follow-up.[5,7-13]

In 1988, Buttner-Janz and coworkers[5] reported their early results with 76 CHARITÉ prostheses implanted in their first 62 patients. Mean follow-up was 15 months (up to 3 years). Unfortunately, they did not specify the number of each version of the prosthesis implanted (SB CHARITÉ I, II, or III). However, since the SB III prosthesis had only recently been introduced, one would think that the majority of prostheses implanted were the earlier designs (ie, SB I or II). Fifty-four percent of patients rated themselves as being "highly satisfied" with their results and an additional 29% were "better than before the operation." Only 2% were "worse than before the operation" and 15% of patients had no change from their preoperative state. Postoperative range-of-motion at the operative level averaged 5° at 2 years compared with 9° preoperatively. What was significant, however, was a 39% rate of complications that were directly related to the components of the earlier implant designs, including postoperative intracorporeal migration, ventral dislocation, and endplate fissuring and breakage. Despite the high rate of implant-related complications, the results were encouraging enough to spur further prosthesis design improvements and clinical testing.

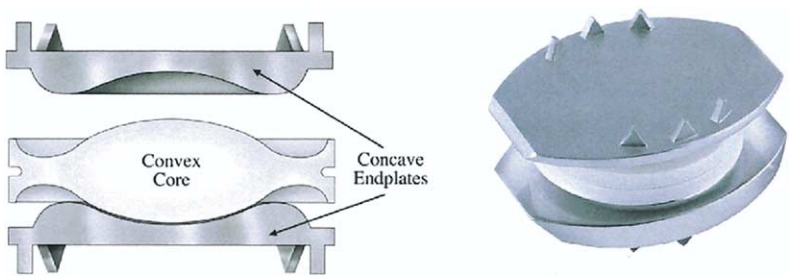

Figure 2 CHARITÉ Artificial Disc components. (Color version of figure is available online.)