

Symposia Synopsis

Artificial intervertebral discs and beyond: a North American Spine Society Annual Meeting symposium

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Editors note:

Beginning with this issue, Synopses of Symposia presented at the North American Spine Society Annual Meeting will appear episodically in *The Spine Journal*. The initial synopsis arose from the 2001 Annual Meeting and was edited by Robert Winter, MD, from material submitted by the authors. It is the goal of *The Spine Journal* to allow readers early access to new materials that may not have been previously published or discussed widely in peer-reviewed journals.

Abstract

Abstract (R.B. Winter, MD)

Background content: This is a synopsis of a symposium presented to the North American Spine Society Annual Meeting in Seattle, WA, 2001.

Purpose: To bring to the reader who may not have attended the symposium a distillation of the material presented on this frontier of spinal surgery.

Methods: Panel presentation.

Results: The proposed indication for artificial disc replacement is a degenerated but contained disc, painful to the point of major life-style interruption, refractory to at least 1 year of nonoperative treatment, preferably at a single lumbar level and without infection, listhesis or major facet joint disease or spinal stenosis. Total disc replacements have been developed and used mostly in Europe. Disc nucleus replacements have also been developed. No disc replacement has been approved for general use in North America as yet. The US Food and Drug Administration is conducting investigational device exemption studies at this time.

Conclusions: Artificial disc replacement is not a new concept, the first attempts having been done in the early 1950s. During the past 15 years, considerable advance has been made with large numbers of patients, mostly in Europe, having surgery with either total disc prostheses or disc nucleus replacements. Only with truly scientific studies using patient randomization, pre- and postsurgery outcome analyses by unbiased independent observers and statistical analysis by independent experts will the real value of these devices be realized. © 2002 Elsevier Science Inc. All rights reserved

Introduction (S. Blumenthal, MD)

There has been much interest in artificial discs for many years, and the potential for clinically effective disc replacement is now becoming a reality. There have been more than 60 patents for artificial discs issued in the United States. There are two major types of lumbar intervertebral discs at this point: total disc replacement and disc nucleus replacement. Other emerging technologies include the potential for facet joint resurfacing or replacement and cervical intervertebral disc replacement. The topics presented during the symposium included the history of artificial discs, biome-

chanical testing, clinical utility in terms of indications and contraindications, as well as specific reports and details on artificial disc designs. Therapeutic modalities for which the artificial disc may be an alternative have included medications, chiropractic, physical therapy, intradiscal electrothermal therapy (IDET) or other intradiscal treatments, various forms of discectomy, interbody fusion, posterolateral fusion and combined anterior/posterior fusion. The goal for any surgical treatment must be improving the outcomes of our patients while decreasing complications. Potential advantages of disc replacement are the avoidance of bone graft

harvest morbidity, cost effectiveness in terms of decreased operative time, hospital stay and recovery time and the avoidance of postoperative orthoses. Theoretical advantages include more physiologic load sharing with adjacent segments, thus potentially decreasing the need for subsequent intervention for adjacent segment breakdown. The ultimate optimum design characteristic for disc replacements will be predicted by biomechanical studies but ultimately determined by the results of clinical studies over time.

History of disc replacement (R. Garcia, MD)

The first published study on disc replacement was in 1955 by David Cleveland [1]. He injected methylmethacrylate into the disc spaces of 14 patients at the time of discectomy. This procedure yielded “acceptable” results. Cleveland developed his concept of disc replacement in the 1950s after visiting James Gardner, who had replaced hundreds of damaged lumbar discs with Lucite pegs. In 1957, Wallace Hamby presented his results of disc replacement with methylmethacrylate at the American Association of Neurological Surgeons [2]. He compared discectomy alone with discectomy with methylmethacrylate and found no difference in terms of hospital stay, return to work, back pain or maintenance of disc height 1 year after surgery. In 2001, Hamburger et al. [3] published a study of injection of methylmethacrylate at the time of anterior cervical discectomy and fusion with a mean follow-up of 12 years. This procedure yielded 77% “good and excellent” results.

In addition to injecting cement into the disc spaces, other concepts for disc replacement were being explored in the 1960s and 1970s. In 1959, Paul Harmon devised Vitalium spheres and implanted these in 13 patients between 1959 and 1961 through an anterior retroperitoneal approach [4]. He never published these results. Nachemson [5] in 1962 reported on a study involving the injection of silicone rubber implants into the disc space. In 1964, Reitz and Joubert [6] in South Africa reported on their results after implanting 19 steel ball prostheses in the cervical spines of patients after discectomy. Fernström [7] in Sweden also implanted stainless steel spheres in the cervical as well as the lumbar spine after discectomy. In 1966, he published his results on more than 100 patients. He concluded that the results obtained with this form of disc arthroplasty were better than discectomy alone and similar to the results of discectomy and fusion. Although this procedure produced acceptable clinical results, it was ultimately abandoned because of subsidence of the steel balls into the vertebral end plates. In 1977, Schulman’s [8] study of posteriorly placed polyurethane in 83 patients, with 62 followed for 5 years, reported improved results in those with radiculopathy. In 1978, Fassio and Genestie [9] replaced lumbar discs with silicone prostheses. Numerous other mechanical disc designs were introduced in the 1970s and 1980s [10–13]. Many of these discs never made it to clinical applications or were abandoned after very limited clinical use. During the 1980s and 1990s, the most

commonly used total disc replacements, the SB Charité (Link; Hamburg, Germany) and the ProDisc (Spine Solutions, New York, New York), were developed and introduced, as well as the use of hydrogel for disc nucleus replacements [14,15]. These three devices will be discussed in more detail.

Indications and contraindications for disc replacement (R. Guyer, MD)

Although the indications for and contraindications to disc replacement are evolving, certain statements can be made at this point. Although the mechanical goals of motion preservation versus motion elimination with fusion are diametrically opposed, the clinical goals of decreased pain and increased function remain intact. The question is, can the same disease, that being symptomatic lumbar degenerative disease, be treated effectively using interventions with the opposite technical goals? The answer, however, does appear to be heading in an affirmative direction. The general indications for total disc replacement are similar to those established in the fusion literature, including back and leg pain unresponsive to appropriate attempts at nonoperative treatment. Nonoperative treatment includes but certainly is not limited to medication, various forms of physical therapy, activity modification and pain management. Radiographically, we see disc degeneration with varying degrees of disc space collapse that is thought to be symptomatic. This can include the very early stages of degenerative disc disease manifested as annular tear pathology. Other indications include postlaminotomy/discotomy syndromes, and some European investigators have suggested that transition segment disease next to an established fusion may be an indication as well. Disc replacement is not used to treat significant spinal deformity or primary radiculopathy. It should be avoided in patients with osteoporosis or instability, and certainly anything greater than a Grade I spondylolisthesis is a contraindication. Patients with significant canal stenosis or neural compressive disease, or pain related to significant scarring from previous surgery should not be treated by disc replacement. Although facet joint ankylosis is an absolute contraindication, the extent of facet joint involvement needs to be considered in treating anterior column disease. As with any elective spine surgery, avoidance of disc replacement in patients with significant psychosocial issues is advised. The indications for isolated nucleus replacement are not as well defined at this time. They may include use after standard discectomy or possibly in discogenic pain syndromes with minimal disc deterioration. Posterior element reconstruction has been suggested in patients with facet joint pain alone and possibly in combination with disc replacement.

SB Charité III disc prosthesis (J-P LeMaire, MD)

The artificial disc with the longest record of use and greatest number of cases worldwide is the SB III Charité prosthesis. Data for a series of patients with more than 10-year follow-up was presented. He performed 85 cases of which 78

were available for review with a mean follow-up of 11 years. These included 34 men and 44 women with a mean age of 50 years. In this group, 20% were heavy laborers and 40% had had previous surgery. Included were 37 single-level, 40 two-level and 1 three-level cases. Using a modified Stauffer and Coventry outcome rating scale (16), including return to work and quality of work recovery, he reported “good to excellent” results in greater than 90% of his study group. He indicated that a positive concordant discography improved his selection criteria and subsequent patient outcomes.

Bony Ingrowth into Coated Endplates (P. McAfee, MD)

The SB Charité III disc prosthesis, available in Europe, has a hydroxyapatite coating to encourage bony ingrowth to aide in anchoring the device. During the symposium, McAfee et al. reported the results of a study investigating the degree of bony ingrowth with this device in a nonhuman primate model. In a worst-case scenario with immediate postoperative activity in a very active baboon population, both macro- and microevaluation found increased trabecular contact of implant surfaces in the total disc model compared with historical reports of femoral stem, tibial plateau and acetabular components.

ProDisc disc prosthesis (R. Bertagnoli, MD)

Dr. Thierry Marnay in France, who began implanting the device in early 1990, invented the ProDisc prosthesis. Data for 58 of 64 patients with 7 to 11 years of follow-up were available for analysis. The mean age of the patients was 46 years, ranging from 25 to 65 years, and 53% were men. Two-level disc replacement was performed in 33% of the patients. All patients underwent disc replacement for symptomatic disc degeneration, and 66% had previously undergone spine surgery, primarily discectomy. With respect to clinical outcome, 64% of patients were completely satisfied, and 29% were satisfied. Back pain, as assessed from visual analog scales ranging from 0 to 10, improved from a preoperative mean of 8.6 to a postoperative mean of 3.2. Leg pain followed a similar pattern, improving from 7.1 to 2.1. There was no difference in results when comparing one-level versus two-level replacements. Complications in the series were two cases of retrograde ejaculation, one hematoma and wound infection and two uneventful vascular problems. There were no cases of device failure.

Prosthetic disc nucleus PDN (R. Salib, MD)

Preliminary clinical studies of the prosthetic disc nucleus (PDN, Raymedica, Bloomington, MN) were done between 1996 and 1998 and included 65 patients with a success rate of 75%. There were, however, 16 explants and/or revisions, resulting in a reoperation rate of 25%. The prosthetic disc nucleus is a hydrogel device designed to imbibe fluid and expand the inside of the nuclear space. The pellet is encased in a polyethylene jacket that functions to restrain and maintain the

device shape when subjected to hydration and loading in the spine. This device can be implanted either anteriorly or posteriorly. After initial modifications, a Phase 3 trial began outside of the United States in 1999 and continued through 2001. An additional 407 patients were implanted in whom there has been a 12% reoperation rate. The clinical success rate was 88%. A Food and Drug Administration investigational device exemption trial is being initiated.

Other disc prostheses (H. Yuan, MD and C. Lee, MD)

Evaluations of several other disc prosthesis designs are under way, including the New Jersey Total Disc Prosthesis, the Aquarelle Prosthesis (Stryker-Howmedlea, Rutherford, NJ) and the NewCleus (Sulzer Spinetech, Minneapolis, MN). These devices are in various phases of early evaluation, including biomechanical testing and evaluation in non-human primate models. A few of these devices have been implanted in a small number of patients outside of North America, and the patients are being followed at this time.

Facet joint replacement (S. Hochschuler, MD)

Disc degeneration, particularly once it has progressed to a severe state, affects the posterior elements. As disc replacement technology is becoming more widespread, exciting technology is emerging for the treatment of facet joint problems as well. Various patents for facet joint replacement or augmentation exist, as well as for posterior ligament augmentation. Whether these will be used as stand-alone devices or in combination with either nucleus or total disc replacements, indications and trials will be forthcoming to determine if they are valuable adjuncts to disc arthroplasty.

Cervical disc replacement (V. Bryan, MD)

Devices for replacement of cervical discs are beginning to emerge. The first mechanical cervical disc has recently been introduced. There has been limited experience with this device outside of the United States, and a clinical investigational device exemption trial is commencing.

Discussion (S. Blumenthal, MD)

In summary, a new era of spinal reconstructive surgery is beginning. Two of the total disc prostheses, the SB Charité and the ProDisc, have been used for more than 10 years in Europe yielding encouraging results. These two devices are currently undergoing evaluation in the United States in FDA investigational device exemption studies. In addition to the prosthetic disc nucleus device, which has been implanted in a large group of patients, several other disc nucleus replacement devices are being evaluated. We are also seeing the early development of cervical disc replacements as well as new treatments for posterior element degeneration.

tive conditions. Considering these new developments and the advances being made in the area of basic science concerning disc tissue and tissue engineering, I am sure that we are seeing just the tip of the iceberg in terms of new therapies for the treatment of disc-related pain.

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One Hundred Fifty Years Ago in Spine . . .

In 1852, Antonius Mathijssen of Brabant published, in Dutch, the first account of use of plaster of Paris as it has been used since for rigid bandaging [1]. His description has been translated into English by Bick [2]. Twenty-five years after his publication, Sayre published his textbook detailing applications of

the use of plaster of Paris for correction and stabilization of spinal deformity [3].

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