

Position Paper on Artificial Lumbar Disc

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I. Purpose

The purpose of this document is to provide a review of the relevant literature concerning the use of artificial discs in the treatment of lumbar spinal conditions. Primary emphasis is directed toward basic information about the disc, indications and contraindications to use of the disc, and outcomes published in peer-reviewed journals. This information should assist MCOs and providers in authorization decisions if this procedure is requested for the treatment of injured workers in Ohio.

II. Background

Currently the most common surgical approach to debilitating lumbar degenerative disc disease is lumbar fusion with or without instrumentation. The problem with any fusion procedure is the loss of motion allowed by the intervertebral disc space that is fused. With loss of spinal motion at that disc space it is theorized that the adjacent vertebral discs receive additional mechanical stress which accelerates the degeneration of these adjacent intervertebral disc spaces leading to more problems including the potential for additional surgery at the adjacent disc levels. To avoid this dilemma, a desired solution would be replacement of the degenerated disc with an artificial disc that allows normal or nearly normal biomechanical function at the disc space, reduces or at least not increase mechanical stress on the adjacent disc spaces, maintains normal disc height, not create inflammatory problems, and relieves the pain experienced by the patient due to the degenerative disc disease.

Four artificial disc designs have been designed and FDA investigational studies are being conducted on three designs. These include the ProDisc by Spine Solutions, Inc.; the FlexiCore artificial disc by SpineCore; and the Maverick artificial disc by Medtronic. The Charite artificial disc by DePuy Spine has completed FDA investigational studies and the artificial disc has been approved for marketing in the United States.¹ This paper will focus on the Charite artificial disc since it has been approved for use, over 6500 have been implanted worldwide, and there have been several reports of its use from Europe.

III. Charite Artificial Disc

The initial model of this artificial disc was developed in 1982 at Charite Hospital in Berlin by Schellnack and Buttner-Janzen. The disc was called the "SB Charite I". The first implantation of the disc was performed at Charite Hospital in 1984. Due to axial migrations of the disc, the disc was modified in 1985 with the metal endplates enlarged with bilateral wings to improve the support. This model of the disc was known as the "SB Charite II". The SB Charite I and II were limited to use at only Charite Hospital in the German Democratic Republic and never commercially available. Due to fractures in

the SB Charite II endplates and insufficient instrumentation, the developers contacted Waldemar Link, Inc. to assist in further development and production.

In 1987 the SB Charite III disc was produced and made available commercially. This model consists of two endplates made of cobalt-chromium-molybdenum (Co-Cr-Mo) alloy which forms an articulating bearing surface with a central ultrahigh molecular weight polyethylene central core. Each endplate has three ventral and three dorsal fixation teeth that are implanted into the inferior and superior vertebral endplates. The surface of the endplate abutting the central core is concave allowing stability and translation of the mobile central core which has a convex shape. The endplates are produced in four sizes with four different lordotic endplate angles to create the appropriate amount of lordosis. The central core has five sizes with 1 mm increments from 7.5 mm to 11.5 mm.²

IV. European Clinical Studies

Lemaire reported on his outcomes of 107 patients who had received a total of 147 prostheses followed for at least 10 years after placement of the SB Charite III artificial disc.³ According to the authors, biomechanical studies reportedly had indicated that the SB Charite III disc closely replicates movement in a normal disc. Studies in the laboratory and in vivo had demonstrated polyethylene thickness loss well under one millimeter and no significant evidence of wear after 10 years. In terms of the clinical outcomes, 100 patients were available for reexamination. Six patients reportedly moved and one patient had died of lung cancer. Using a modified Beaujon score that considered an excellent result (no pain, no medication, resumption of activity in the same job after three months) and a good result (intermittent and infrequent lumbar pain not requiring major or prolonged medication, resumption of activity in the same job after more than three months or in a less strenuous job after fewer than 3 months), 90% of patients reportedly showed excellent or good results after more than 10 years. Eighty percent of 95 patients (5 retired at age 60) had resumed occupational activities in the same job. Five patients required a secondary fusion. X-rays showed non luxation of the prosthesis. Range of motion showed average mobility for flexion-extension of 10.3° and “lateral inclination” was 5.4°. Only 5 individuals developed symptomatic posterior joint arthritis. Nine complications were reported that included two neurological complications, one vascular, three cases of phlebitis, and two patients had a moderate post-traumatic depression of the lower plate of the prosthesis. Of the neurological complications, one patient developed L5 paralysis on the second postoperative day with recovery three months later after a second surgery. Another patient had sexual difficulties that spontaneously recovered after one year. There were no complications due to sepsis or inflammatory granuloma. Three patients developed peri-prosthetic ossification which was anterior in 2 cases and laterally in one case that resulted in complete fixation of the prosthesis.

Zeegers et. al. reported their two year results in 50 patients who had received a total of 75 SB Charite III artificial discs.⁴ Of the 50 patients, four were lost to follow-up. Patients were classified as having a good, fair, or poor result based on relief of pain, return to employment, physical activities, and use of analgesics. Seventy percent reportedly had a good or fair result. While only age less than 45 years was the only factor that had a statistically significant better result, patients without previous surgery and without other

lumbar degenerative characteristics tended to have better outcomes. Sixty-five percent of patients had improvement of pain. Eighty-one percent returned to some work and 43% returned to their original work. Thirty-eight of forty-six (83%) reportedly “did not regret their surgery”. The range of motion of the prosthesis determined by lateral flexion and extension x-rays was 9°. Of those evaluated at two years, no patient had a migration of the prosthesis more than 2 mm. Twelve of the 50 patients required re-operation with seven due to complications. The authors reported no problems due to the material or the prosthesis. According to these authors, indications for artificial disc replacement are severe discopathies and directly related morbidity such as degenerative disc disease, postnucleotomy situations, isolated disc resorption, and lateral recess stenosis because of diminished disc height. Contraindications include spondylolisthesis, spinal stenosis, altered posterior elements, infection, metabolic bone diseases like osteoporosis and osteomalacia, severe scarring after previous surgery and insufficient motivation of the patient.

Twenty-seven patients who presented to a tertiary spine center in the Netherlands since 1995 with complications after undergoing SB Charite III artificial disc insertion at other facilities in the Netherlands was reported by van Ooij, et. al.⁵ Of the 27 patients, 26 had received surgery at one institution and belonged to a series of approximately 500 patients (26/500) who had undergone disc replacement. The mean interval from surgery to presentation was 53 months and the mean follow-up post disc replacement surgery was 91 months. Twenty-two had a single level artificial disc insertion, four had prosthesis inserted at two levels and one patient had artificial disc inserted at three levels. Three patients had an artificial disc inserted at L4-5 after having had a prior anterior fusion at L5-S1. Three others had a percutaneous nucleotomy performed at the same level and a posterior undercutting facetectomy had been performed in two patients. One patient had herniated disc surgery performed before disc prosthesis insertion. Twelve patients had reported an initial good result which ranged from one month to 10 years. Fourteen patients reported no benefit at all. One patient had anterior dislocation of the prosthesis at L5-S1 within one week post insertion which required replacement with a cage and fusion. She was evaluated two years post fusion because of disabling back pain and was noted to have a nonunion of the fusion. Other early complications included an anterior dislocation of the prosthesis after three months requiring removal, four patients experienced abdominal wall or retroperitoneal hematomas, one male had retrograde ejaculation and erectile dysfunction, and another male had erectile dysfunction without retrograde ejaculation. Of late complications, degenerative disc disease at another level was noted on 12 patients (in 7 patients degenerative disc disease was present prior to surgery). Facet joint arthrosis at the same or adjacent level was seen in 11 patients. Subsidence of the prosthesis was noted in 18 patients and the authors indicated the prosthesis was too small in 10 cases. One patient had anterior subluxation of the polyethylene core blocking the segment in extension. The individual underwent a posterior fusion with good results for four years. After four years the individual developed back pain due to new degeneration of the disc above. Two patients had anterior migration of the disc prosthesis at L4-L5 compressing the great vessels in one patient. Both patients ultimately required posterior fusion. One patient who was 13 years post disc replacement at L4-5 and above a L5-S1 fusion has radiographic signs of wear. The authors concluded that there was still concern on the long-term safety of the artificial disc and procedure particularly given the young age of the patients at the time of insertion of the artificial discs.

V. Studies performed in United States

Reports in the United States are results from randomized clinical trials performed at several sites following the same protocol as part of the FDA regulated IDE (investigation device exemption) study for the SB Charite III artificial discs. These articles compare results of artificial disc replacement using the SB Charite III disc to lumbar fusion using BAK cages. The studies were designed so that participants were assigned to receive either the artificial disc or fusion using BAK cages. Probability of receiving the disc versus the BAK cages was 2:1.

Study inclusion criteria were:

- a. patient age between 18 and 60 years,
- b. Symptomatic single-level degenerative disc disease at the L4-L5 or L5-S1 level confirmed by plain radiographs, magnetic resonance imaging (MRI), and provocative discography,
- c. Oswestry Disability Index score of at least 30 and a pain score on visual analog scale (VAS) of at least 40 out of 100,
- d. Failure to achieve pain relief after at least 6 months of non-operative care,
- e. Primary complaints of back pain with or without pseudoradicular pain passing into the lower extremities, and
- f. Being willing and able to give written informed consent.

Exclusion criteria are:

- a. Prior history of attempted fusion procedure anywhere in the thoracolumbar spine,
- b. Objective evidence of nerve root compression,
- c. Straight leg raise producing pain below the knee,
- d. Spinal fracture, bone disease, spondylolysis, spondylolisthesis, scoliosis, spinal tumor, or severe facet joint arthrosis, and
- e. Being more than one standard deviation greater than normal body weight

Using this study protocol, Hochschuler et. al. reported on the preliminary outcomes of 56 patients who had received the SB Charite III prosthesis. They reported a 52.7% reduction in the VAS pain score at 6 weeks post-operative as compared to the pre-operative baseline score. This improvement was maintained over the twelve month reporting period. Similar improvement was noted in the Oswestry disability scores. They reported no cases of device problems or dislocations. The authors noted the importance of appropriate training of the surgeons and proper patient selection.⁶

McAfee et. al., using essentially the same inclusion and exclusion criteria described above reported their one to three year outcomes comparing 41 patients who underwent SB Charite disc replacement to 19 patients that underwent BAK interbody fusion using autograft. No patients required any additional spinal reconstructive procedures and there was no dislodgement of the prosthesis, loosening of the prosthesis, or cases of significant subsidence defined as erosion of the prosthesis into the vertebral body. The authors reported improvement of the preoperative to post operative VAS pain score and Oswestry Disability Index scores for both the artificial disc and BAK fusion that were comparable to results for lumbar decompression for spinal stenosis. They report one case of each of the following complications: postoperative small bowel obstruction, significant postoperative heterotopic ossification, 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 the disc replacement. The authors state that the most important parameter for achieving a good result is patient selection.⁷

As part of this multicenter study, Guyer et. al., reported on the two year follow-up from 144 patients enrolled in the two previously cited studies. One hundred patients were randomly selected to receive the Charite artificial disc and 44 underwent anterior lumbar interbody fusion using BAK Cages. Outcome measures include the VAS and Oswestry Disability Index plus questions regarding patient satisfaction and patient opting to have the same surgery again. These measures were obtained at 6 weeks, three months, 6 months, 12 months, and 24 months post operatively and compared to preoperative baseline values. At 24 months the Oswestry scores improved 53.6% compared to baseline in the Charite artificial disc group and improved 53.7% in the BAK fusion group. Comparing the preoperative baseline to the 24 month score, the VAS score improved 57.7% in the Charite group and 60.4% in the BAK fusion group. Over 70% of patients receiving the Charite artificial disc were satisfied and approximately 90% were satisfied or somewhat satisfied. Approximately 65% of patients in the BAK fusion group were satisfied and nearly 95% were either satisfied or somewhat satisfied. Approximately 65% of the Charite group and 55% of the BAK fusion group responded that they would definitely choose the same treatment again. The authors report that three patients required an additional posterior spinal fusion for persistent pain. There were no cases of prosthetic dislodgement, significant subsidence, prosthetic loosening, or late infections. They report six cases of transient neurological deficit including paresthesias and L5 weakness which resolved.⁸

Geisler et. al., reported on the FDA IDE multicenter trials of the Charite artificial disc at 14 centers using the same protocol and criteria as above.⁹ The study was comprised of 304 individuals with 205 randomly selected to receive the Charite Artificial Disc and 99 selected to receive BAK fusion. Both the VAS score and the Oswestry Disability Index were improved at 24 months in comparison to the baseline for both groups. In the Charite group, the VAS score had a mean decrease of 57.5% and the BAK fusion group decreased by 49.4%. The Oswestry scores showed a mean change of -24.8 in the Charite group and -22 in the BAK fusion group. In the Charite group, 62% of patients had a 25% improvement of their Oswestry score compared to 49% of the BAK fusion group. The VAS score improved by at least 20 points in 65% of patients in the Charite group and 56% of patients in the BAK fusion group. Mean flexion-extension range of motion measured at 24 months was $7.4 \pm 5.28^\circ$ (mean \pm standard deviation) compared to $1.1 \pm 0.87^\circ$ in the BAK group. Neurological Adverse Events (NAE) were monitored according to IDE protocol and classified as major, minor, or other neurological events. Major NAE occurred in 4.9% of the Charite group and 4.0% of the BAK fusion group. Major NAE included burning or dysesthetic leg pain, motor deficit in the index level, and nerve root injury which occurred in only one patient. Minor NAE was numbness in the index level and numbness in sacral nerve distribution. Minor NAE were reported to have occurred in 9.8% of patients in the Charite group and 8.1% of patients in the BAK fusion group. Other NAE included numbness in peripheral nerve or nonindex level, positive Waddell signs, reflex change, and mechanical signs (straight leg raise). Overall, NAE occurred in 16.6% of patients in the Charite group and 17.2% in the BAK fusion group. The authors concluded that the disc was safe and effective and clinical outcomes at two years are equivalent to one-level BAK fusion outcomes. They recommend use of the Charite artificial disc in properly selected patients and by trained surgeons to achieve good clinical and functional outcomes.

VI. FDA Approval

On October 26, 2004 The Center for Devices and Radiological Health of the Food and Drug Administration (FDA) approved the Charite Artificial Disc for marketing by DePuy Spine, Inc. According to the approval, the device “is indicated for spinal arthroplasty in skeletally mature patient with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. Patients receiving the Charite Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the Charite Artificial Disc.”¹⁰

VII. Recommendation

The Charite artificial disc has been approved by the FDA. Case series reports from Europe and recent clinical control trials in the United States have demonstrated preliminary outcomes equal to or better than lumbar fusion for the treatment of debilitating degenerative disc disease. Outcomes measured to date include reduction in the post operative VAS score and Oswestry Disability Index in comparison to preoperative measurements, low complication rate that is less than that for fusion, and limited problems related to the artificial disc itself. It should be noted that the European studies inclusion and exclusion criteria were not as strict as those in the United States studies. One European study of complications showed a complication rate of roughly 5% (26/500). Therefore, additional studies are necessary to identify long-term complications and effectiveness of the procedure.

The literature to date documents little evidence of problems related to product malfunction or dislocation in comparison to accepted spinal fusion techniques. Various authors have stressed the importance of proper patient selection, experienced surgeons, and inserting the proper size prosthesis to avoid prosthesis-related problems. Studies indicate that range of motion for the artificial disc is maintained as is the disc space height. There have been no reported problems with wear debris or reactions to the components of the disc. Disability time appears to be reduced and a higher percentage of recipients have returned to work.

Limitations to the studies include the fact that studies at least in the United States have had strict patient selection procedures, surgery performed by a limited number of surgeons, and duration of follow-up of only a few years. The duration of follow-up may not be sufficient for the identification of significant problems which may develop in individuals who undergo artificial disc replacement. With widespread use it can be assumed that patient selection may not be as strict as in the reported studies and the complication rate may also increase. It is unknown how many if any of the disc replacements were paid by workers' compensation. However, it can be assumed that outcomes in workers' compensation patients may not be as good as that reported in the literature to date.

Studies are already being conducted regarding replacement of cervical discs and use of other lumbar discs¹¹ and the European literature describes use of the discs at more than one lumbar level and in patients who would not meet the FDA approved criteria.

According to the Ohio Supreme Court in *Miller v. Industrial Commission of Ohio*, authorization of any medical service must be reasonably related to the work-related injury, reasonably necessary and appropriate, and reasonably cost effective.¹² The reported cost of the Charite artificial disc is \$10,600 versus \$4,800 for BAK cage.¹³ The operative procedure is similar to a fusion which would be the alternative procedure. Though the above costs are not the reimbursed amounts, given the expense of spine fusions, the reported results to date comparable to spinal fusion, and the potential for better outcome with less duration of disability, it is difficult to deny authorization of the procedure due to cost effectiveness as long as the treatment is reasonably related to the appropriate injury and all criteria for authorization are met.

In summary, it appears that the Charite artificial disc can be considered as an alternative to tradition lumbar fusion procedures.

VIII. Indications/Contraindications

Indications provided by the FDA should be strictly followed in any authorizations. These include the following:

- Skeletally mature individuals with degenerative disc disease at one level (either L4-L5 or L5-S1);
- Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies;
- There should be no more than 3 mm of spondylolisthesis at the involved level;
- The patient should have failed at least six months of conservative treatment prior to implantation of the artificial disc.

In addition to the above FDA indications, the following criteria are commonly found in the literature and are recommended:

- Age 18 to 60 years;
- Degenerative disc disease defined as discogenic back pain with degeneration of the disc as confirmed 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; and/or
 - Scarring thickening of annulus fibrosis with osteophytes indicating osteoarthritis
- Radiographic studies (usually computed tomography or magnetic resonance imaging) supporting the diagnosis of degenerative disc disease. Findings include vacuum disc sign, high-intensity zone signal, Modic changes, degenerative cyst formation, and marginal vertebral body osteophyte formation;
- Discogram performed by an independent radiologist or anesthesiologist demonstrating concordant pain reproduction and that includes at least one control level that was not painful and did not reproduce the patient's symptoms;

- Nonradicular leg pain or back pain in the absence of nerve root compression (i.e., pain resulting from disc herniation) as determined by MRI or CT without lateral recess stenosis. (The only exception is that in carefully selected cases neuroforaminal stenosis could be corrected by the artificial disc restoring the intervertebral disc height and increasing the neuroforaminal height);
- Oswestry Disability Index score of more than 30
- Visual analog Scale (VAS) score of greater than 40 (of 100) assessing pain.

Contraindications or exclusion criteria generally include:

- Previous attempted lumbar fusion procedure anywhere in the thoracolumbar spine;
- Patients with bone abnormality such as osteoporosis or osteopenia;
- Objective evidence of nerve root compression;
- Straight leg raise producing pain below the knee;
- Spinal fracture, spondylolysis, spondylolisthesis, scoliosis, spinal tumor, or severe facet joint arthrosis;
- Patient being more than one standard deviation greater than normal body weight;
- Patient with significant psychosocial symptoms.

Patients who have had prior discectomy, IDET, or chemonucleolysis may be appropriate for artificial disc replacement if there is no leg pain below the knee and enough of the posterior facets are present to prevent overdistraction of the facet joints.

IX. Appropriate ICD-9 Codes

Since authorization of treatment must be directed toward treatment of the allowed conditions, it is recommended that claims have an allowed diagnosis of degenerative disc disease (ICD-9 Code 722.52 Lumbar or lumbosacral intervertebral disc degeneration). Since the procedure is limited to the L4-5 or L5-S1 disc, other ICD-9 Codes in 722.5 which include thoracic intervertebral disc are not appropriate.

Each BWC-affiliated MCO is responsible for the medical management including authorization of services for individuals whose workers' compensation claim the MCO is managing. Final authorization decisions regarding the Charite artificial disc is at the discretion of the MCO medically managing the specific claim.

¹ Geisler FH, Blumenthal SL, et. al.: “Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charite intervertebral disc” *Journal of Neurosurgery (Spine 2)* 1:143-154, 2004.

² Link, HD: “History, design and biomechanics of the LINK SB Charite artificial disc” *European Spine Journal* 11 (Suppl. 2):S98-S105, 2002.

³ Lemaire JP: “SB CHARITE intervertebral disc prosthesis: biomechanical, clinical and radiological correlations with a series of 100 cases over a follow-up of more than 10 years” *Rachis* 14:271-285, 2002.

⁴ Zeegers, WS, Bohnen LM, et. al.: “Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients” *European Spine Journal* 8:210-217, 1999.

⁵ Van Ooij A, Oner FC, and Verbout AJ: “Complications of Artificial Disc Replacement” *Journal of Spinal Disorders & Techniques* 1:369-383, 2003.

⁶ Hockschuler SH, Ohnmeiss DD, et. al.: “Artificial disc: preliminary results of a prospective study in the United States” *European Spine Journal* 11 (Suppl. 2):S106-S110, 2002.

⁷ McAfee PC, Fedder IL, et. al.: “Experimental Design of Total Disk Replacement – Experience with a Prospective Randomized Study of the SB Charite” *Spine* 28:S153-S162, 2003.

⁸ Guyer RD, McAfee PC, et. al.: “Prospective randomized study of the Charite artificial disc: data from two investigational centers” *The Spine Journal* 4:252S-259S, 2004.

⁹ Geisler FH, Blumenthal SL, et. al.: “Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charite intervertebral disc” *Journal of Neurosurgery (Spine 2)* 1:143-154, 2004.

¹⁰ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=4861> verified Jan 3, 2005.

¹¹ Anderson PA and Rouleau JP: “Intervertebral Disc Arthroplasty” *Spine* 29:2779-2786, 2004.

¹² *State ex rel. Miller v. Industrial Commission*, 71 Ohio St. 3d 229, 643 N.E.2d 113, Ohio 1994.

¹³ <http://www.spine-health.com/print/PRO/medicine/struggle001.html> Verified Jan 6, 2005.