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Artificial disc: preliminary results of a prospective study in the United States

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Abstract Artificial discs have been used in Europe for many years with good results. This technology has recently been available in the United States on a limited, investigational basis. The purpose of this study is to review the preliminary results of one center's experience using the SB Charité III disc replacement. The study group consisted of the series of our first consecutive 56 patients who received the Link SB Charité III artificial disc. There were 25 men and 31 women, with a mean age of 39.9 years. All patients had single-level symptomatic disc disruption at L4-5 or L5-S1. The discs were implanted using the same approach as used for mini-open anterior lumbar interbody fusion procedures. The primary data recorded included visual analog scales (VAS) assessing pain and the Oswestry Disability Questionnaire. Data were collected pre-operatively and at 6 weeks, 3 months,

6 months, and 12 months post-operatively. Peri-operative data as well as complications were recorded. At the time of this preliminary study, 22 patients have reached the 12-month post-operative follow-up period. There was a significant improvement in the VAS and Oswestry scores at the 6-week follow-up period. These improvements were maintained throughout the 12-month follow-up period. The preliminary results of this prospective study indicate that the artificial disc yields significant improvement that is maintained during a 12-month follow-up. Data from more patients and with longer follow-up are needed to determine whether these results can be maintained in the long term.

Keywords Artificial disc · Spinal arthroplasty · Prospective study · Lumbar spine

Introduction

In some areas of orthopedics, implants are commonly used that restore or closely mimic the normal motion of joints. The need for such in spine has long been recognized. There is a great desire to restore the motion of the spinal segment rather than fusing it, which is currently the primary operative treatment for several painful spinal conditions. The first attempts at disc replacement were prompted by a desire to fill the disc space after a discectomy had been performed. This was done to restore the disc height and help avoid problems related to further de-

generation of the operated segment. The concept of total disc replacement evolved much later, and is now generally thought of as a replacement for spinal fusion. While total disc replacement and interbody fusion are used to treat the same symptomatic pathology, an artificial disc is used to mimic the loading and motion characteristics of the normal intervertebral disc. Not only does this allow more normal motion of the spine, but it avoids the potential problem of pseudoarthrosis and does not put additional demands on the adjacent segments, particularly with bending. With time, the additional load may lead to breakdown of the disc adjacent to the fusion, requiring further treatment.

Total disc replacements have been used in Europe for more than a decade. The first total disc replacement to emerge into widespread use was the SB Charité (Waldermar Link). The first and second developmental designs of this device were implanted in the mid-1980s, only at the Charité Clinic in East Berlin of the former East Germany, and were not commercially available. With these designs, there were problems with implant migration, damage to a vertebral body, and compression of the implant [1]. The SB Charité III, a third design of the artificial disc, was made commercially available in 1987 and remains in use worldwide today. There have been several studies reporting the clinical results when using this device. Although the outcome measures in the various studies differ, the rate of good to excellent outcome ranges from 63% to 75% [2, 3, 6, 8, 9]. The purpose of this study was to describe our preliminary results using the artificial disc in a prospective study with rigid inclusion criteria.

Materials and methods

The data for this study are from one center participating in the FDA (Food and Drug Administration) regulated IDE (investigational device exemption) study being performed to investigate the safety and efficacy of devices prior to their being available for general use. The large-scale IDE study is a prospective, randomized, multicenter study, with an enrollment goal of approximately 300 patients. Patients are randomized to receive either the artificial disc or BAK threaded fusion cages (Sulzer SpineTech). This was selected as a comparison group, since interbody fusion is currently the primary treatment available for disc-related pain unresponsive to non-operative treatment. The randomization is weighted with a 2:1 ratio of artificial disc to fusion cages. Also, each surgeon performed artificial disc operations prior to the randomization, to gain experience with the operative technique. Approval to conduct the study was given by the FDA, and by each participating center's Institutional Review Board (IRB). Due to the relatively small number of BAK patients at our facility, this report is limited to our experience with the artificial disc. Future reports will include comparative data with the fusion group.

Study inclusion criteria are:

1. Age of 18–60 years
2. Symptomatic single-level degenerative disc disease at the L4-5 or L5-S1 level confirmed by plain radiographs, magnetic resonance imaging (MRI), and provocative discography
3. Oswestry score of at least 30, and a pain score on the visual analog scale (VAS) of at least 40
4. Failure to achieve pain relief after at least 6 months of non-operative care
5. Primary complaints of back pain with or without pseudoradicular pain passing into the lower extremities, and
6. Being willing and able to give written informed consent

Exclusion criteria are:

1. Objective evidence of nerve root compression
2. Straight leg raise producing pain below the knee
3. Spinal fracture, bone disease, spondylolysis, spondylolisthesis, scoliosis, spinal tumor, or severe facet joint arthrosis, and
4. Being more than one standard deviation greater than normal body weight

Data were collected prior to surgery, peri-operatively, and at 6 weeks, 3 months, 6 months, and 12 months post-operatively (24-month data are currently being collected). Outcome data were collected, in-

cluding the visual analog scale (VAS) assessing pain and the Oswestry Disability Questionnaire [5].

This study is based on the consecutive series of our center's first 56 patients who received the SB Charité III prosthesis. The group consisted of 25 men and 31 women. The mean age was 39.9 years, ranging from 19 to 59 years. The prosthesis was used at the L5-S1 level in 44 patients and at the L4-5 level in the remaining 12 patients. Twenty-two patients have reached the 12-month follow-up period.

Operative technique

The approach to the spine for disc replacement surgery is very similar to the mini-open approach we have used for anterior lumbar interbody fusion for many years. The three surgeons participating in this study all had extensive experience with anterior lumbar interbody fusion prior to implanting an artificial disc. In order to achieve proper prosthetic placement, patient positioning is critical. Fluoroscopic imaging is used to ensure that the spinous process is vertical and the pedicles are perpendicular to the spinous process. A general surgeon performs the procedure to gain access to the spine. The incision is approximately 4–5 cm in length. After the general surgeon has achieved access to the spine, disc tissue is removed from the disc space. The spreader instrument is used to distract the disc space. The endplate size is selected with the goal of covering as much of the vertebral body endplate as possible. This aids in avoiding subsidence. Endplate gauges, which are the same sizes as the prosthetic endplates, but without anchoring teeth, are used to determine the desired size of the implant to be used. The obliquities of the prosthetic endplates are selected so that the inner surfaces of the plates are parallel. In some cases, it is necessary to smooth the vertebral body endplates slightly to allow more contact area with the prosthesis. However, care should be taken to avoid damage to the endplates. Ideal positioning of the device is in the center of the disc space when viewed on the anteroposterior image. The ideal position of the device in the lateral view is approximately 2 mm posterior to the sagittal midline of the vertebral body. One must check to confirm that the prosthetic endplates are placed in the insertion device correctly: that is, with the more narrow edge of the prosthesis passing into the posterior section of the disc space, and the thicker, oblique edge being located in the anterior portion of the disc space. It is helpful to use a "breakable" operating table. During the prosthesis implantation, the table should be cracked open to allow easier introduction of the device. The spreading and insertion forceps, loaded with the prosthetic endplates, are maneuvered into the disc space. After assessing the location of the endplates with regard to their location in the lateral view, the forceps are opened and adjusted using a set of spacers. The height of the polyethylene core to be used is determined by using trial cores. After the appropriate size is determined, a core is placed in the core insertion instrument and positioned between the prosthetic endplates. The forceps are gradually released, lowering onto the core. The core insertion instrument is removed and the core position is confirmed with imaging. The forceps are then removed. A final image is obtained to verify correct placement of the endplates and core. The wound is closed in the same fashion as after open anterior fusion.

Patients are discharged from the hospital with a home exercise program. They are encouraged to be cautiously active. They are instructed to walk a few blocks up the street several times a day. Then they are to progress to several miles. After the first few weeks following surgery, patients begin participation in a rehabilitation program incorporating conditioning, motion, and strengthening.

Results

The mean operative blood loss during the disc implantation procedures was 134.3 cc. The mean operative time

Fig. 1 The mean VAS scores pre-operatively and at the various time periods post-operatively

Fig. 2 The mean Oswestry scores pre-operatively and at the various time periods post-operatively

was 78.7 min, ranging from 45 to 165 min. Operative time decreased with the number of cases performed.

As presented in Fig. 1, there was a 52.7% improvement in the mean VAS pain score at the time of the 6-week follow-up. This improvement was statistically significant ($P < 0.05$; paired t -test) and was maintained throughout the 12-month follow-up period. A similar pattern was noted in the Oswestry disability scores (Fig. 2). There was a 39.6% improvement in Oswestry disability scores at the 6-week follow-up, with slightly more improvement between the 6-week and 3-month follow-up periods. The improvements from the pre-operative values were statistically significant ($P < 0.05$; paired t -test). In our series, there have been no cases of device fracture or dislocation.

Case report

This patient was a 46-year-old man who presented with a 15-month history of back pain following a severe automobile accident. He did not complain of lower extremity pain. He worked at an Internet business. He had undergone a course of physical therapy and epidural steroid injections that failed to give him adequate pain relief. His physical examination was negative for nerve root compression. Review of his MRI examination showed a degenerated

Fig. 3 Magnetic resonance image showing degeneration of the L5-S1 space and a high-intensity zone

L5-S1 disc with a high-intensity zone posteriorly (Fig. 3). Presented in Fig. 4 are the discogram and the computed tomography (CT)/discogram of the L5-S1 level, showing significant posterior spread of the contrast. The injection provoked pain concordant with the patient's back pain. The artificial disc study was described to the patient and he consented to participate. The operative time was 96 min and the estimated blood loss was 200 cc. Pre-operatively, the patient was working only part time. Post-operatively, he returned to work full time. His pre-operative VAS score was 58 (of 100) and his Oswestry score was 46%. By the 3-month follow-up, both scores had dropped to less than 10. The patient's flexion and extension radiographs made at 12-month follow-up are shown in Fig. 5B, and demonstrate motion at the operated segment.

Discussion

The results of this study are encouraging and support the artificial disc as a viable treatment option. However, it should be noted that these are the preliminary results on a subgroup of patients participating in a multicenter study. Two-year follow-up data are being collected at all the centers as patients reach that follow-up point. After all the data have been collected, a comparison with the fusion group can be made. The current study is the first prospective report in the literature on a consecutive series of patients undergoing disc replacement. The study design allowed us to make comparisons between the patients' pre-operative and post-operative conditions using standardized

Fig. 4 The pre-operative discogram (A) and computed tomography/discogram (B) demonstrating significant spread of the contrast posteriorly at the L5-S1 disc level

Fig. 5A,B Flexion and extension radiographs made at the patient's 1-year follow-up appointment. There is clear motion at the level with the disc prosthesis

outcome assessments. Significant improvements were seen in these measures at the time of 6-week post-operative follow-up. These improvements were maintained during the 12-month follow-up period. These results support those from earlier retrospective European studies reporting favorable outcomes [2, 3, 6, 8, 9].

The European experience with total disc replacement has provided valuable knowledge concerning the ideal device size and placement, as well as refining the insertion technique for the device. Also, the data supporting early participation in active rehabilitation [2] have been valuable in designing our rehabilitation program for disc replacement patients. Although the indications and approach to the spine are very similar to those used for anterior interbody fusion, the need to restrict motion following surgery is not needed. Instead, patients are taught to engage in gentle bending motions soon after the spinal arthroplasty procedure.

There have been very few reports in the literature for other designs of artificial discs. Enker et al. reported their experience with a disc composed of two titanium endplates with a rubber core fused between them [4]. They implanted the device in six patients. Four of the six patients had satisfactory results, one device failed, and one other patient had no pain relief after surgery. This device was abandoned due to concerns about possible carcinogenic materials in the rubber. A new version of this disc is currently undergoing testing. The ProDisc (Spinal Solutions) has been used in Europe for approximately 10 years. It is composed of two titanium endplates with a fixed polyethylene core between them. The inferior surface of the core is flat, and its edges fit into ridges on the inferior device endplate. Motion occurs by articulation of only the upper plate on the convex superior surface of the constrained core. There has been little published on the results of this device. Marnay reported 8- to 10-year follow-

up results on a group of 44 patients who received this prosthesis [7]. A good/excellent result was noted in 78% of these patients.

In our own experience, as well as that reported in the long-term follow-up studies from Europe, the artificial disc designs that allow motion by articulation of bi-convex surfaces have not had technical failures [2, 3, 6, 7, 8, 9]. No problems with wear debris have been identified in clinical or biomechanical studies [1, 2, 3, 6, 7, 8, 9].

Traditional factors dealing with patient selection and surgical skills remain true for disc replacement. Surgery should only be considered after the patient has failed an appropriate course of non-operative treatment including medication, activity modification, and active rehabilitation. Patients with poor psychological profiles are poor candidates for disc replacement. Surgeons must be trained appropriately in the indications and contraindications for disc replacement. Also, surgeons must undergo appropri-

ate training in the operative technique and use of the instrumentation.

The results of this study support the European experience that disc replacement surgery is a promising treatment. Patients on whom this report was based will be followed for a longer period of time. Also, these data will be combined with those from the other centers participating in the multicenter trial. The final results from that large-scale study will provide more information about the performance of the disc compared to spinal fusion.

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