Lumbar Total Disc Replacement: Charité Artificial Disc ™

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INTRODUCTION

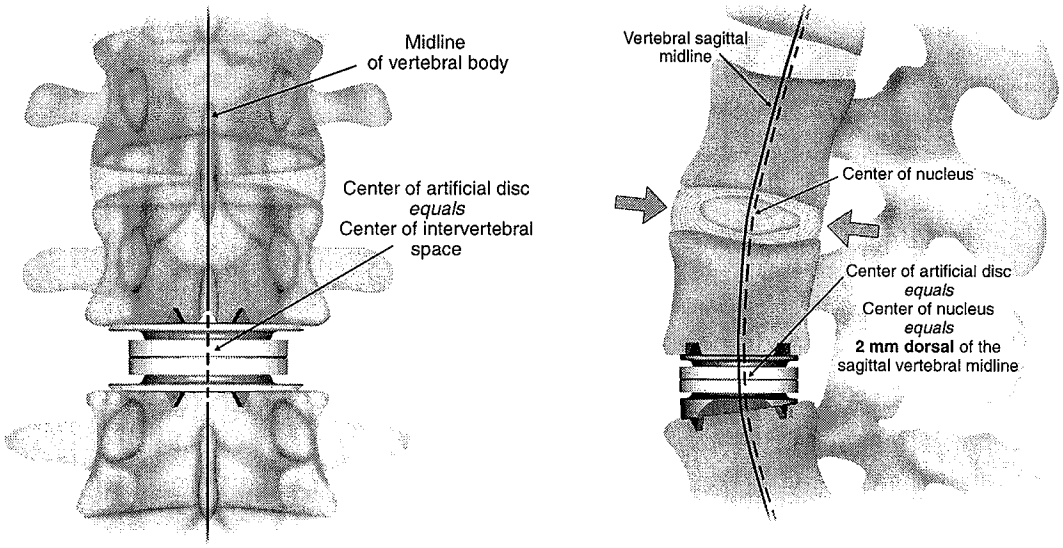
In an effort to preserve segmental lumbar motion and to prevent adjacent segment disease, there has been a growing enthusiasm in the use of intervertebral disc prosthesis as an alternative to segmental lumbar fusion. To date, over 100-disc prosthesis have been designed, but only10 prosthesis have been approved and implanted in human. The Charité Artificial Disc™ has had the longest clinical follow-up with more than 5000 implantations in over 30 countries and reported >10-year satisfactory results [3,4,6,7,10,11,16].

The development of the SB Charité™ prosthesis began in the early 1980's by Kurt Schellnack and Karin Büttner-Janz at Charité Hospital in Berlin, Germany. The artificial disc prosthesis was designed as an unconstrained three-component implant made from two metal endplates with an interposed polyethylene-sliding core. Since the world's first human implantation in 1984, three generations of the lumbar SB Charité™ prosthesis have been introduced. In Type I SB Charité™, the endplates were stainless steel, 1 mm thick, and round. Initially, 11 fixation teeth, each 2 mm long, were used at the periphery, which was later revised to three anterior and two posterior teeth. These implants, placed in 13 patients, were complicated by subsidence into the vertebral body due to high concentrated stress in the small surface area of contact between the metal endplate and the vertebra. This led to enlargement of the endplates with the Type II SB Charité™ and placement of 44 implants in 36 patients (1985-1987). However, Type II implants experienced high rates of fatigue failure at the junction of the lateral wing and the center of the implant. This failure was attributed to the implant material (non-forged stainless steel) and the lack of congruity between the vertebral endplate and the metal endplate. Type I and Type II SB Charité™ were implanted in 49 patients at the Charité Hospital. In 1987, Waldemar LINK GmbH & Co revised the endplate design and material and manufactured the Type III SB Charité™ or the LINK® SB Charité™ in Hamburg, Germany. The implant has recently adopted a new name, Charité Artificial Disc™, after it was purchased by DePuy Spine (Johnson & Johnson, Raynham, MA). The endplates are made of chrome-cobalt-molybdenum (CoCrMo) alloy with a convexity to better match the concavity of the vertebral endplates. A bioactive coating, TiCaP™, for bony on-growth has been available worldwide since 1998 except in the United States. The unconstrained sliding-core is a bi-convex polyethylene that is interposed between the inner concavities of the endplates with a radiopaque wire for radiographic visualization. Endplate fixation is obtained with three fixation teeth anteriorly and three posteriorly, each measuring 2.5 mm in height. Currently, five implant sizes (1 through 5), four sliding core sizes (7.5, 8.5, 9.5, 10.5, 11.5), and oblique endplates (0°, 5°, 7.5°, 10°) are available to allow variety of surgical options in restoring segmental lordosis and to achieve parallel alignment of the inner metal endplates.

SPINE BIOMECHANICS AND ARTIFICIAL DISC REPLACEMENT

The lumbar spine involves very complex kinematics with an intricate interplay between the disc, posterior facets, and ligaments. White and Panjabi as well as other investigators [5, 15] have extensively studied the characteristics of lumbar motion and have defined segmental range of motion, coupling patterns, and Instant Axis of Rotation (IAR). The position of the IAR has been described as not being a constant point and moving posteriorly with extension and anteriorly with flexion. Anterior translation of the cephalad vertebrae is coupled with flexion which is an important element of segmental lumbar motion as it removes stress from

the posterior facet joints [5]. The Charité Artificial Disc™ was designed to recreate the physiologic coupling pattern as well as the variable IAR of the lumbar spine [1,10]. The floating sliding core of the unconstrained three-component prosthesis replicates the physiologic coupling action as it translates anteriorly with flexion and posteriorly with extension. An accurate prosthesis placement, within 0-3 mm posterior to the midline of the vertebral body, is required to simulate the lumbar kinematics as described by Panjabi [15] (see figures below).



INDICATIONS

As with any other surgical intervention, patient selection and proper indication is the most important factor in predicting good surgical outcome. Unlike degenerated peripheral joints in which pain is generated as a result of movement of two destroyed cartilaginous surfaces, pain generator in lumbar degenerative disease is more complex and less understood. Only patients with pure discogenic back pain secondary to degenerative disc disease are candidates for lumbar total disc replacement. Therefore, it is critical to obtain a detailed clinical history, physical examination, and adequate imaging studies to diagnose discogenic back pain and to utilize diagnostic provocative discography to confirm this entity if needed. Posterior facets should be carefully evaluated on physical exam and on the imaging studies such as MRI and CT scans. If posterior facet disease is suspected, diagnostic injection may be used to rule out this condition as the contributing source of pain as these patients do not benefit from total disc replacement. The following outline of indication and contra-indications was set forth by the U.S. IDE (Investigational Device Exemption) trial for the Charité Artificial Disc™ that was initiated in 1999. The randomized study with two-year follow-up is now completed and recently the FDA has approved use of this device. Currently, multiple-level Charité ™ TDR is performed outside of U.S. It is anticipated that with FDA approval multi-level TDR will be performed in the U.S.A. The present FDA approved guidelines follow the I.D.E. study and are as follows:

- Age 18-60 years;
- Single level disease at L4/L5 or L5/S1;
- Symptomatic Degenerative Disc Disease (DDD) with objective evidence of lumbar DDD by CT or MRI. Provocative discogram may also be used as a confirmatory test. Degenerative disc disease is defined as discogenic back pain with degeneration of the

disc as confirmed by history and radiographic studies with one or more of the following:

  - Contained herniated nucleus pulposus;
  - Paucity of facet joint degeneration;
  - Decrease of intervertebral disc height of at least 4 mm and/or:
  - Scarring/thickening of the annulus fibrosis with osteophytes indicating osteoarthritis.

- Leg pain and/or back pain in the absence of nerve root compression as determined by MRI or CT scan, without prolapse or narrowing of lateral recess;
- At least 6 months of failed conservative management.

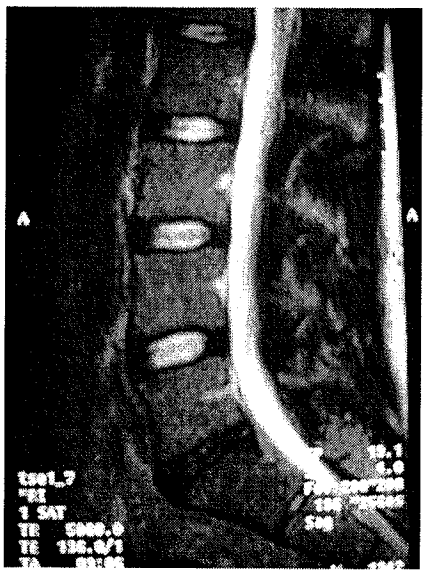
CONTRAINDICATION

- Previous thoracic or lumbar fusion;
- Previous spine surgery at the affected level except prior discectomy, non-destabilizing laminectomy/otomy without facetectomy, or nucleolysis;
- Osteoporosis or metabolic bone disease. Osteoporosis is defined as bone mineral density of more than 1 standard deviation below the norm for matched age group
- Single or bilateral radicular leg pain on strait leg test (pain radiating past the knee into lower extremity) in the presence of a documented disc herniation;
- Lumbar scoliosis (>11 degrees of coronal deformity);
- Mid-sagittal stenosis of <8 mm, as measured by CT or MRI;
- Lateral recess stenosis;
- Segmental instability defined as more than 3 mm of motion in flexion and extension;
- Spondylolysis;
- Spondylolesthesis >3mm;
- Lumbar spinal stenosis, central and lateral recess;
- Morbid obesity (body mass index over 40% or more than 100 lbs over ideal body weight);
- Spinal neoplasm;
- Active systemic or local infection;
- Facet joint arthrosis;
- Pregnancy;
- History of chronic steroid use;
- Arachnoiditis;
- Metal allergy;
- Autoimmune disorders;
- Psychosocial disorder (Waddel score >3);
- Previous retro-peritoneal or >3 intra-abdominal operations.

Case Examples

1. A 28 year-old disabled actor presented with intractable low back pain recalcitrant to 2 years of non-operative management including anti-inflammatory medications, physical therapy, acupuncture, and steroid injections. He complained of morning stiffness and pain, especially with changing posture and minimal bilateral buttocks pain. Patient reported an Oswestry Disability Index (ODI) of 85 and Visual Analog Scale (VAS) of 8. MRI scan of the lumbar spine revealed degenerated and collapsed disc space at L5-S1 (see image on next page). Provocative discogram revealed a positive concordant pain with relief after infusion of anesthetics. He was diagnosed with discogenic low back pain based on his history, MRI, and confirmatory

provocative discography. MRI axial views of the L5-S1 revealed normal morphology of the posterior facets without any degeneration. This patient was felt to be an ideal candidate for total disc replacement as it would preserve segmental motion and potentially decrease the risk of adjacent segment disease. After an uncomplicated surgery, patient's ODI and VAS score decreased to 20 and 3 at 6 weeks, respectively, and maintained at 2 years of follow-up.



2. A 35 year-old male referred to our institution for evaluation as a potential candidate for lumbar total disc replacement. He complained of worsening low back pain with associated bilateral leg pain for the past three years and failed non-operative management. Lumbar x-rays and MRI revealed degenerative disc disease at L5-S1 with normal adjacent levels. However, there was also evidence of pars fracture with grade I spondylolesthesis at L5-S1 that was confirmed with a CT scan. Lumbar TDR was not offered to this patient, as pars fracture with spondylolisthesis is a contra-indication to this operation, as it would render the operated segment unstable. He underwent an uncomplicated lumbar interbody fusion and decompression with significant improvement of his symptoms.

PREOPERATIVE PLANNING

Access Surgeon
Typically an experienced vascular or a general surgeon performs the retroperitoneal approach at our institution. This is one of the most critical parts of the operation with potentially disastrous complications (Please refer to complications section). Safe mobilization of the iliac vessels and adequate exposure of the intervertebral disc space can enhance the accuracy of the device placement as well as minimizing vascular complication during the implantation. Preoperative imaging with MRI and CT scan can help in identifying the vascular anatomy as it relates to the spinal segment receiving the artificial disc. Calcifications of the vessels are important to identify as well as any inflammatory process or protruding osteophytes at the disc level.

Radiographic Measurements
Pre-operative AP and lateral x-rays (including flexion and extension views) are obtained to evaluate segmental stability and motion as well as identifying transitional vertebrae, which may lead to incorrect localization intra-operatively. Radiographs need to be carefully examined to rule out occult spondylolysis. Oblique views and/or CT scans are obtained for further evaluation as needed. Posterior disc height at non-degenerated adjacent levels (generally one or two levels above the diseased level) must also be assessed to get an idea of normal disc height and the limit of maximum intra-operative distraction.

Operating Room Preparation
A radiolucent table that enables the use of an intra-operative C-arm image intensifier must be used. The lower lumbar spine should be adequately visualized in both AP and lateral views for safe and proper prosthetic placement. Furthermore, the operating table should allow flextion/extention of the lower spine intra-operatively. Lumbar extension may be needed (especially at L4/5 level) to perform adequate discectomy in a completely collapsed

disc space as well during the anterior implant insertion. We use the Skytron 3100 operating table, which is equipped with a kidney rest that can be raised to increase lumbar lordosis when needed. We also prefer bringing the c-arm before prepping the patient to ensure adequate visualization of the disc space. The kidney rest is partially raised directly under the disc space to allow anterior opening of the disc, which will facilitate insertion of the prosthesis.

OPERATIVE TECHNIQUE

Positioning

The patient is placed supine on an operating table and general endotracheal anesthesia is induced by the anesthesiologist. Prophylactic antibiotic is administered intravenously 30 minutes before the incision time. SSEP/ EMG as well as bilateral TEDs and SCDs are used in all cases. EMG abnormalities sometimes occur with left iliac vessel retraction in L4-5 cases secondary to ischemia. These potentials are also useful in assessing potential nerve irritation or injury from displaced osteophytes, which may occur during the endplate preparation or impaction phase of the procedure. Before the skin is prepared, the C-arm is brought in, and the desired level is visualized on AP/lateral views and the planned incision is marked.

Surgical Approach

After the abdomen is prepared and draped in the usual fashion, a transverse or vertical skin incision is made and a retroperitoneal dissection is performed to expose the desired level. The anterior rectus sheath is incised longitudinally and the rectus muscle on the left is retracted from the midline. The posterior rectus sheath and transversalis fascia are incised longitudinally. The transversalis fascia can be separated from the underlying peritoneal lining by finger dissection below the arcuate line, which is the inferior extent of the transversalis fascia. Using this technique, blunt dissection is used to dissect the peritoneum from left to right until the midline vascular structures and spine is identified by palpation. For exposure of an interspace above the aorta/vena cava bifurcation (e.g. L4-L5), left-to-right dissection is performed and the vasculature is retracted to the right side after ligating segmental vessels. For the exposure of an interspace below the bifurcation (e.g. L5-S1), left and right iliac vessels are retracted to their respective sides. Avoidance of monopolar cauterization and use of gentle dissection with sweeping of tissues away from the spine will minimize the chance of sympathetic plexus injury which can lead to retrograde ejaculation in the male patient. For retraction, we prefer the use of the Omnitract ™, which utilizes renal blades of varying depths and anchors to the operating table for fixed retraction. Depending on the surgeon preference, alternative retraction techniques can be used, such as Wiley retractors for hand held retraction or anchorage of four instruments (such as sharp Homan's retractors) in the upper and lower vertebral bodies. It is important to obtain wide exposure and to visualize the width of the intervertebral space and up to the mid body of the level above and below the operating disc space. The iliac vessels must be retracted with the retractor blades out of the operating field. The left iliac vein has the tendency to creep under the blade and enter the field, which increases the risk of vascular injury. The surgeon must be cognizant of the location of the vessels and their safety throughout the case. Compared to anterior spinal fusion techniques, a greater side-to-side exposure is required for artificial disc replacement to allow for placement of larger size implants. Larger surface area coverage of the vertebral endplate is optimal for long-term success and in decreasing endplate subsidence.

Prosthetic Implantation

Identification of the center of the vertebral body in coronal view

A spinal needle is placed in the middle of the disc and its location is verified under an AP view of an image intensifier. Adjustments are made accordingly followed by placement of 3.5 mm fully threaded cancelous screw, 12 mm in length, in the cephalad vertebrae body, about 5 mm above the anterior lip. The screw is tapped gently with a mallet and then advanced.

Anterior annulotomy

A long handled 10-blade is used to perform the anterior annulotomy. An H-type incision is made by making the first cut in the center of the disc from rostral to caudal direction. Once the bony surface is reached, the blade is turned side ways and the superior/inferior annular attachments are incised bilaterally. The incision is taken laterally as far as the width of the anterior vertebral body and an annular open book flap is created on both sides. A suture is placed at two ends of the flap and taken outside the wound secured with hemostats.

Complete discectomy

Cobb elevators, currettes, pituitary rongeurs, and kerrisons are used to perform a complete discectomy in a standard fashion. The kidney rest can be raised to open-up the anterior disc space especially at the L4-5 level. Unlike spinal fusion surgery, disc material must be removed to the posterior annulus as well as removing any posterior osteophytes which may block the insertion of the prosthesis. The posterior aspect of the prosthesis will sit on the hard cortical bone of the posterior ring apophysis so it is imperative that posterior disc material be removed for easier insertion. Endplate preparation is also done using curettes to flatten any irregularities in the bony endplate. Osteotomy using osteotomes is not performed as it creates bleeding and can result in heterotopic bone formation as described by other authors [11].

Parallel Disc distraction

The central spreading distractor is placed in the disc space using lateral fluoroscopy and gentle distraction is applied. Posterior distraction should not exceed the normal posterior disc height of the levels above. In a severely collapsed disc space, the posterior longitudinal ligament as well as the posterior annulus may tear and a pop may be heard. Occasionally, posterior epidural venous bleeding is encountered for which hemostatic sponges are packed in the posterior disc space and left undisturbed for 3-5 minutes. Next, calibrated T handled calibrated spreaders are introduced into to center of the endplate in a parallel fashion and then turned 90 degrees with the dominant hand as the contra-lateral hand places constant distraction force on the central distracting device. Distracting is started with size 7.5 mm and increased to 8.5 mm and then 9.5 mm, if a 9.5 mm polyethylene core is to be implanted.

Endplate templating

Different sized "lollipop" trials are used to determine implant size and lateral fluoroscopy is used to ensure ~ 80% endplate coverage, the ability to place the implant in the ideal anatomical position, (with the center of the implant being 0-3 mm posterior to the mid vertebral body) and stopping 2-3 mm short of the posterior vertebral border.

Broaching

Broaching is performed with a grooved driver placed in the center of the body and driven posteriorly using a mallet. The anterior and posterior teeth of this instrument correspond to the teeth on the prosthesis. Lateral x-ray is taken to make certain that the instrument can be driven just short of the posterior edge of the inferior vertebral

vertebral border. This generally insures that the final implant will be inserted with appropriate predistraction of the interspace.

Angled Trial Endplates
After adding appropriate augmentations to the superior and inferior endplates to obtain parallel to slightly divergent endplates, trial endplates are inserted and lateral fluoroscopy is taken. The endplates are configured to place an increased angle trial at the lower level so that the core can be placed in a position more parallel to the horizontal. Generally, there should not be a difference of more than 5 mm between the angled prosthesis placed at the superior endplate compared the inferior endplate device with the larger device placed at the inferior endplate. Calibrated spreaders can be inserted once again followed be insertion of the trial core instrument.

Prosthesis implantation
The prosthesis is correctly placed on the driver and implanted using a mallet under lateral C-arm fluoroscopy. It is important to align the implant parallel to the endplate during placement. Any deviation from parallelism can cause violation of the upper or the lower endplate, which can lead to improper implant placement and subsequent subsidence. Once the posterior tip of the prosthesis passes the middle of the vertebral body, the kidney rest is lowered to allow the disc space to return to its natural position. Ideally, the center of the prosthesis should be about 0-3 mm posterior to the midline of the vertebral body. This position most accurately simulates the anatomical Instantaneous Axis of Rotation. As the implant is driven posteriorly, the posterior teeth will hit the posterior apophyseal ring, or the posterior lip of the vertebral body, and it will come to a stop. Aggressive impaction should be avoided at this point, as it may cause fracture of the posterior apophyseal ring. If there is difficulty inserting the implant, the implant should be removed and the broach reinserted and tapped to the posterior edge of the inferior vertebral body to ensure appropriate distraction.

Sliding Core Insertion
The implant is distracted enough to insert the polyethylene core in the center of the implant followed by release of the distraction. Penfield four is used to ensure the core rotates freely followed by removal of the driver.

Final Implant Positioning
The lateral x-ray should show the implant with the center 1-3 mm posterior to the middle of the vertebra and short of the posterior edge of the vertebral body about 3 mm. An AP view is then obtained before to check midline alignment. The prosthesis needs to be within 0-3 mm of the lateral borders of the spinous process. If the implant is off midline by more than 3 mm, the implant should be removed and repositioned unless technical difficulties are encountered. Next, the upper and lower teeth are driven further into the endplate using an impactor.

Annular closure
Although it has not shown to have any biomechanical advantage, anterior annular closure is performed using a number one absorbable suture. The center marking screw is taken out using a screwdriver and the void is filled with small amount of bone wax to obtain hemostasis.

The wound is copiously irrigated followed by closure of the rectus fascia, subcutaneous fascia, and the skin using absorbable sutures.

IMMEDIATE POSTOPERATIVE PERIOD

Pain Management
Ketorolac (Toradol) 30 mg IV is given every 8 hours for total of three doses with the first dose given at the end of the case. Alternatively, a Cox-2 inhibitor can be given with a sip of water in the preoperative holding area before surgery. This has the advantage of avoiding platelet aggregation effects and decreasing GI side effects compared to Toradol. Oral opioid analgesic combinations are used on p.r.n. bases with intravenous opioid agonist, such as morphine sulfate or hydromorphone, for breakthrough pain only. We avoid using Pain Controlled Administration (PCA) as it delays postoperative bowel recovery and rehabilitation. Patients are discharged on oral opioid analgesic combinations on p.r.n basis as well as an daily oral non-steroidal anti-inflammatory medication for daily for 4 weeks.

Diet
With presence of bowel sounds, sips of liquid are started 6 hours after surgery and advanced to liquid diet on the 1st postoperative day as tolerated. Patients can be discharged home on postoperative day 1 on liquid diet with clear instructions on how to advance diet at home.

Activity
Patients are allowed to sit up, get out of bed and ambulate with assistance.

REHABILITATION

The postoperative rehabilitation program for patients with the Charité Artificial Disc™ is as follows:

- *<3 weeks:* Lumbar flexion and cardiovascular exercises are permitted during this immediate postoperative period with restriction on rotation and lumbar extension.
- *3-6 weeks:* Lumbar rotation can be started.
- *6-12 weeks:* Lumbar extension can be performed at this point unless the initial implant placement is in >10 degrees of divergent for which extension should be restricted for 12 weeks. With time, there is increased scar formation over the anterior annulus, which provides a blockage to anterior implant dislocation. Anterior abdominal exercises as well as truncal stabilization can begin during this period.
- *>12 weeks:* Return to sports must be individualized and determined by the treating surgeon. Contact sports and high impact activities that would place a large stress on the endplates should be avoided.

RESULTS

In 1997, Lemaire et al reported on their clinical experience with the lumbar Charité Artificial Disc™ in France. Total of 105 cases, with a mean follow-up of 51 months, were reviewed which showed 79% of the patients with an excellent results and 87% return to work. Factors leading to failure were listed as posterior facer arthritis, osteoporosis, structural deformities, and secondary facet pain.

The U.S. prospective randomized FDA trial on the Charité Artificial Disc™ IDE study for one level lumbar disc disease with a minimum of two-year follow-up was completed in December of 2003. 375 patients were enrolled in fifteen investigational U.S. sites with a 2:1 randomization of Charité:BAK after completion of 71 training cases (5 training case/site). One third of patients were randomized with the BAK anterior interbody fusion device (n=99) and two thirds of patients with the Charité Artificial Disc™ (n=205). Postoperative follow-up was performed at 3 months, 6 months, 12 months, and 24 months. Data was collected on 276 patients (71 training cases and 205 randomized) who received the artificial disc and 99

BAK cases. Minimum follow up period was 2 years with 91% of patients returning at two years. Mean surgery time was significantly improved in the randomized group (110.8 minutes) compared to the initial training group (141.9 minutes), $p< 0.001$. Mean operative time and blood loss was similar for both the BAK and Artificial Disc group. The length of stay was less in the artificial disc group (3.7 vs. 4.3 days). VAS pain scores and ODI improved significantly in both groups with the Charité group experiencing a significantly greater improvement at 6 week, 3 months, 6 months and 1 year. Patient satisfaction was 93% with the Charité prosthesis compared to 81% satisfaction for the BAK spinal fusion procedure at one year following the procedure. At the end of 24 months, 13% of BAK fusions were very dissatisfied with the procedure compared to only 2% of the disc replacement patients. Asked if they would choose the same treatment, at 24 months following the procedure, 82% of the Charité artificial disc group said yes and only 65% of the fusion cases would have the procedure repeated. There was a higher rate of complications in the training group compared to the randomized group and a lower complication rate in the groups with greater than 10 case experience. Operative time was also less in the high enrolling sites (3.5 days for high enrolling sites compared to 4.5 days for the low enrolling sites). Major complications (vessel injury, implant displacement or neurological injury) were less than 1 % in both BAK and Charité groups.

We evaluated our single-site experience with the Charité Artificial Disc™ on 40 consecutive patients with minimum of 6 months follow-up (range: 6-24 months). The first 13 patients were part of the 2:1 Charité: BAK FDA randomized trial and the following 27 patients were part of the continued access non-randomized Investigational Drug Exemption (IDE) group. There were 18 males and 22 females with the prosthesis placed at L4-5 in 14 patients and at L5-S1 in 26 patients. VAS and ODI scores were recorded for all patients preoperatively and postoperatively at 6 weeks, 3, 6,12, and 24 months. The mean preoperative VAS of 73.2 (S.D. 14.5) was improved to 39.2 (S.D. 26.4) at 6 weeks post-operatively ($p<0.001$, paired T-test) and was maintained at 3, 6 months and for those patients reaching 12 months ($p<0.001$) and 24 months ($p<0.001$) of follow-up. The mean preoperative ODI score was 53.4 (S.D. 13.4) and improved to 37.6 (S.D. 18.6, $p<0.001$, paired T-test) at 6 weeks and sustained at 3, 6, 12, and 24-month follow-up visits. There was no statistical difference in outcome when L4-L5 was compared with L5-S1. Four patients in this series experienced complications. Two patients had their implants removed after one was dislocated and the other anteriorly displaced. The prosthesis dislocation occurred in a patient who was non-compliant with postoperative rehabilitation protocol and performed hyperextension exercise one week after surgery. An anterior displacement occurred in one patient with no inciting event on postoperative day 12. This complication was attributed to the steep sacral inclination. Both patients underwent a repeat anterior retroperitoneal approach and removal of the prosthesis followed by anterior interbody fusion and posterior spinal fusion with instrumentation. Two additional patients underwent posterior spinal fusion and instrumentation due to continued low back pain with the device in-situ at 6 months and 20 months post-operatively.

COMPLICATIONS

Surgical Approach Related Complications

The most important factor in minimizing complications is to have an experienced vascular or a general surgeon, who is familiar with anterior lumbar exposures, perform the surgical approach. However, minor as well as major complications can still occur during both the surgical approach and the implantation. Therefore, extreme diligence and attention to detail throughout the entire procedure cannot be overemphasized. Although both transperitoneal and retroperitoneal approaches may be utilized, most surgeons prefer the latter approach

due to its lower morbidity. With the transperitoneal approach, there is higher risk of post-operative ileus, small bowel obstruction, and retrograde ejaculations.

With the retroperitoneal approach, inadvertent peritoneal tissue penetration may occur which can be safely sutured closed. Post-operative ileus can still occur even without peritoneal tissue violation. It has been our experience that the use of PCA dramatically slows down the bowel recovery and therefore we have abandoned its use for these procedures.

Vena cava and/or left iliac vein injury can occur during surgical dissection as well as implantation. Although this is not a common complication when an experienced access surgeon performs the approach, these injuries can cause sever morbidity and even mortality. Therefore, protection of the vessels with blunt retractors after dissection is very important. The surgeon must be cognizant of the location and the safety of the vessels through out the entire procedure. Left iliac deep vein venous thrombosis and pelvic phlebitis can occur from prolonged retraction. Although this is a rare complication, some surgeons place a pulse oximeter on the left toe to monitor the blood flow.

With the anterior lumbar approach, male patients have a small risk of post-operative retrograde ejaculation that is often transient but may be permanent. Due to the close proximity of the sympathetic plexus, manipulation or retraction of the chain may also cause the sympathetic effect. This could cause sensation of a warmer left leg compared to the contra lateral side. With retroperitoneal approach, careful dissection, and judicious use of monopolar electrocautery, the risk of these complications is minimized. At our institution, we have not experienced this complication in the 70 patients who have undergone the lumbar total disc replacement.

Left ureter injury can occur during retroperitoneal approach with a higher risk during revision surgery. Urethral stent may be beneficial in presence of scar tissue and can be performed by an urologist.

Adhering to strict sterile technique and maintenance of hemostasis, respectively, can minimize the risk of infection and deep hematoma. Careful closure of the rectus fascia can prevent abdominal hernias.

Immediate Complications of Implantation

During central distraction and restoration of the disc height and lordosis, the following complications may be encountered. Epidural venous bleeding can occur, especially with distraction of a collapsed disc space, which can be controlled by packing hemostatic sponges in the posterior disc space and left undisturbed for 3-5 minutes.
Post-operative radicular pain can result from stretching the exiting nerve root during distraction of a previously posterior lumbar surgery with perineuronal scarring or overdistraction. This is often transient and resolved with conservative management. Overdistraction can be avoided by restoring the posterior disc height to its normal level as judged by the adjacent segments with a normal disc height. Although restoration of the disc height can offload the impacted posterior facets when maintained after placement of the prosthesis, intraoperative overdistraction with central spreader can also theoretically disrupt the posterior facet capsule and act as a source of pain postoperatively.

Malpositioning of the implant in the coronal as well as sagittal plane should be avoided as it may affect the patient outcome. The ideal lateral placement is the center of the prosthesis 0-3 mm posterior to the center of the vertebral body in the sagittal plane. This position closely simulates the anatomic IAR (Figure 2a). In the coronoal plane, the implant should

also be placed in the center of the vertebral body Radiographically, the middle tooth of the implant in the AP view should be within 0-3 mm of the spinous process (Figure 2b). In our reviewed series of 40 patients with minimum of 6-month follow-up, there was a negative correlation between ideal AP positioning and patient satisfaction if the AP alignment was outside the 3 mm range.

It is important to remember that the vertebral body consists of dense cortical apophyseal ring at the periphery and cartilaginous endplate in the center. Therefore, the posterior apophyseal ring acts as a safety stop preventing the prosthesis from entering the canal during implantation. As the implant is impacted in the disc space under lateral fluoroscopy, the posterior teeth of the prosthesis will come in contact with the dense cortical posterior apophyseal ring and high level of resistance is felt. If a large implant is chosen with >90% lateral endplate coverage, it becomes harder to drive the prosthesis in the ideal position and aggressive attempts at driving the prosthesis further posterior can cause fracture of the posterior apophyseal ring into the canal. Therefore it is important to choose the right size implant during templating that provides the largest endplate coverage and that it can also be placed in the ideal anatomical position, keeping in mind that the implant has to stop 2-3 mm short of the posterior vertebral border.

Anterior implant subluxation or dislocation is often the result of poor implant placement and patient's non-compliance with postoperative activity restrictions such as hyperextension, or large lumbosacral angle. Placing the implant with >15° of divergence or segmental lordosis increased the risk of dislocation and should be avoided. This position allows minimal implant extension, which can lead to a dislocation if a patient continues lumbar extension beyond this limit. This can be avoided by placing oblique or augmented endplates to obtain parallel endplates. Vertical endplate is also a risk factor for implant dislocation, which can due to a large lumbosacral angle or poor implant placement by violating the endplate during placement. Currently, we routinely use inferior endplate augmentation at L5-S1 to decrease the anterior disc height and obtain parallelism. Anterior dislocation in the immediate postoperative period can be taken back to surgery for revision easier than with late dislocation due to lack of well-formed scar tissue.

Long-Term Complications of Implantation

Subsidence of the prosthesis into the vertebral body can occur as a result of asymmetric implantation, under sizing of the implant and intra-operative endplate violation. This complication may cause persistent activity related back pain and may require a posterior spinal fusion. With use of lateral fluoroscopy during implantation, endplate violation can be avoided by ensuring that the prosthesis is getting inserted parallel to the endplates. This is sometimes hard to accomplish at L5-S1 with presence of large lumbosacral angle where the surgeon's hand needs to be lowered caudally significantly. The inferior retractors may also abut against the hand and their positions may need to be adjusted.

Although some authors have reported partial or total heterotopic ossification surrounding the prosthesis rendering in immobile [12], 6% incidence has been reported at 2 years (with no bridging of osteophytes) in the U.S prospective randomized trial. Even though etiology of heterotopic ossification is multi-factorial, osseous bleeding from osteotomies may be a contributing factor to heterotopic ossification formation. We do not perform endplate osteotomies, as some surgeons do, to obtain greater area of contact between the implant and the endplate. Non-steroidal anti-inflammatory medication is routinely prescribed in the postoperative time period to decrease pain and minimize heterotopic bone formation.

Infection of the implant, which has not been reported in the U.S, randomized Charité study, can be very difficult to treat and its management would be similar to any other

intervertebral body fusion device. Clearly, as with management of a late implant dislocation, anterior approach to the disc space is most challenging aspect of the re-operations. In Europe. the anterolateral approach is utilized at L4-5 and an osteoligamentous flap is raised under the iliac vessels to avoid difficult dissection of the vessels from the anterior disc space.

Persistent low back pain can be secondary to poor patient selection, inaccurate diagnosis, and poor implant placement. Posterior spinal fusion with instrumentation can be performed as a salvage operation for those patients with posterior facet pathology or persistent pain of unknown etiology.

CONCLUSION

In the past, low back pain secondary to degenerative disc disease was treated non-operatively as surgical treatment often led to unsatisfactory results. With advances in technology in the past two decades, spinal arthrodesis is used by many spine surgeons for patients in whom non-operative management has failed. However, several investigators have raised concern regarding long-term effect of lumbar fusion (>10-15 years) as it may place more stress on the adjacent levels causing early degeneration [8,9,11,16]. Moreover, the attractive idea of preserving lumbar motion and at the same time treating discogenic back pain has sparked a great enthusiasm among many investigators to design disc implants that most closely simulates the normal biomechanics of the lumbar disc [1,10].

The Charité Artificial Disc™ preserves segmental motion as well as the Instant Axis of Rotation of the lumbar spine. The unconstrained three-component feature of the implant allows restoration of the functional sagittal lordosis and balance. To date, many European studies as well as early U.S. clinical results have showed >70% satisfactory results with the use of this device [3,4,6,7,10,11,16]. The most important factors in obtaining good results are proper surgical indication, as the single most critical factor, followed by accurate implant placement.

Although the early clinical results of lumbar total disc replacements are promising, long-term results with adequate follow-up are needed to adequately assess the efficacy of lumbar disc replacement in selected patients with discogenic low back pain. Additionally, long-term issues such as polyethylene wear and its behavior on the surrounding structures, longevity of the implant, the effect of motion sparing device on the adjacent as well as on the same segment, and the results of revision surgeries for failed implants will be better defined in the future [2,14]. Before embarking on the use of the prosthesis, the reader is advised to stay up to date with the literature on lumbar total disc replacement out-come studies, as with use of any other new investigational device, in order to offer patients the most sensible treatment option at any time period.

Figure Legends

Figure 1. Charité Artificial Disc™
Figure 2 a-b. Correct positioning of the implant is important in reproducing functional biomechanics.
Figure 3. 28 year-old male with low back pain. MRI scan of lumbar spine demonstrates **a.** L5-S1 disc collapse and desiccation on sagittal view. **b.** Normal facet morphology with no hypertrophy on the axial view.

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