Lumbar disc replacement

Dr. Harshwardhan Hegde, MS (Ortho)
Dr. Mandeep Singh, D (Ortho)
Dr. Anurag Awasthi, D (Ortho)
Dr. Gurinder Bedi, MS (Ortho), DNB (Ortho), FRCS (Ortho)

Low back pain (LBP) remains a constant source of trouble for many patients. The incidence has steadily risen through the years. Most of the Orthopedic clinics are full of people coming in for treatment of low back pain. Broadly speaking the classification of back pain can be mechanical or neurological. While neurological problem can often be solved with decompression of the spinal canal or neural canal, the issues with mechanical causes remain rather complex. In the 1990s, physicians and surgeons caring for people with disabling mechanical back pain became increasingly interested in isolating the disc as the source of pain. Advances in diagnostic imaging studies, such as the MRI scan and discography, now allow for a more definitive diagnosis to be made of discogenic pain which can be collectively labeled as degenerative disc disease (DDD).

No consensus is available on how to treat this problem. Surgical intervention is recommended when conservative treatment fails to alleviate the symptoms. Arthrodesis of the painful segment remains the gold standard for surgical intervention in managing this pathology, combined with decompression if the patient has radicular symptoms also.

The use of an artificial disc to replace a damaged spinal disc that is generating chronic back pain has been practiced in a number of European countries for many years and is currently in various phases of development and clinical trials in the U.S. Some of the discs are already in the 3rd versions of their designs and some have been taken off the market.

This study looks at a cohort of patients who have had total disc replacement (TDR) under our care from March 2006 to April 2010. We present our results of 50 patients with degenerative disease who have had this surgery done and have been followed up for a minimum period of 5 months.

METHODS & MATERIALS

Patient Selection
We recommended this surgery to patients who were relatively on the younger side (<50 years) preferably, and who had symptoms unresponsive to non-operative intervention which were longstanding (at least 12 months’ duration). Low back pain was the predominant symptom in all the cases, in patients with radiation LBP was at least 80% of manifest symptoms. All patients were evaluated clinically and radiologically with flexion-extension radiographs and MRI scans. Patients with facet arthropathy (radiological), radicular symptoms showing narrowed lateral canal or central canal, those with spinal deformities and people with gross instability were excluded from the study.

We included patients with:
- Degenerative disc disease with loss of disc height and dehydration
- Extensive Modic changes of the disc space noted on MRI scan
- Intensive annular pathology including high intensity zones and annular disruption
- Degenerative disc disease with annular pathology and bulge including disc fragment protrusion with containment within the annulus
- Previous discectomy patients

Implant
We have used 3 implants which are currently approved and are widely used i.e. Charite III (Depuy), Prodisc L (Spine Solutions/Synthes) and Maverick (Medtronic, Sofamor Danek). The decision to use these discs was based mainly on their availability as these implants are quite costly, not widely used in our country hence not readily available.

Surgical Protocol
All of the disks were implanted with the patients lying supine via a left anterior retroperitoneal approach. A low-transverse incision was used to replace L5-S1 disks, and a low-midline incision was used to implant L4-L5 disks. Degenerated L5-S1 discs were approached at the bifurcation between the iliac vessels, and L4-L5 discs were approached on the left side of the aorta by retracting the iliac artery and vein to the right. The hypogastric plexus is identified and protected by retracting to the left side.

Preparation of the disc space and implant insertion: A complete discectomy that includes excision of the posterior annulus is followed by distraction of the disc space using a specially designed spreader. The end plate cartilage was removed down to bleeding bone but the mechanical integrity of the osseous end plates was carefully preserved. Care was taken to ensure that posterior corners were cleared as meticulously as able to ensure posterior disc placement. Optimum sizing of the implant is performed using trial implants, followed by implantation of the end-plate assembly. Care is taken to position the prosthesis in the midline in the coronal plane and posteriorly in the sagittal plane using fluoroscopy (C-arm). Gradual distraction of the endplates to accommodate the polyethylene inlay is performed (depending on implant). Once the inlay gets snap-locked into the inferior endplate, the distractor is removed and the wound is closed in a routine manner.

E-mail: Gbedi24@aol.com
RESULTS

Fifty patients with total disc replacement surgery since 2006 till April 2010 were evaluated. There were 40 males and 10 females with average age of the patient 39.08 (range 26–61 years). Total number of discs implanted was 57. The operations were performed in monosegment in 43 patients and bisegment in 7 patients.

Ten patients were operated at L4-5 level, 33 patients were operated at L5-S1 level and 7 patients were operated at both L4-5 and L5-S1 level.

The indications were as follows:

<table>
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<th>Indication</th>
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<tr>
<td>Degenerated disc disease</td>
<td>30</td>
</tr>
<tr>
<td>Degenerated disc disease with NPP (disc protrusion)</td>
<td>16</td>
</tr>
<tr>
<td>Previous failed surgery</td>
<td>4</td>
</tr>
</tbody>
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As mentioned, all patients had received nonoperative treatment for at least 12 months which included medication, physiotherapy, and orthotics. Eight patients had been given previous steroid injections (epidural, nerve root blocks). As a lot of our practice is tertiary referrals including international patients, we are unsure about the quality of the treatment given earlier. These patients however took the replacement options readily when offered.

MRI showed decreased signal intensity at the affected disc site on T2 weighted images. Almost all patients showed some Modic changes in the adjacent vertebra. Median disc herniation was seen in 10 and paramedian herniation was seen in 6 patients. DEXA bone densitometry was done in elderly patients to rule out osteoporosis.

Mean operative time was 109 minutes (range, 96–200 minutes), and mean hospital stay was 4 days (range, 3–7 days). We took the help of our general surgery colleagues for exposure of the desired vertebral level. Average volume of blood lost during the surgery was 250 ml.

None of the patients required blood transfusion and were all mobilized the very next day. Most of the patients stayed in hospital only for 3 days and are normally not in much pain even compared to our other posterior approach spinal surgery patients. Some of the patients did notice some odd sensation in the lateral aspect of the thigh and gluteal area postoperatively which could be ascribed to facetal joint stretching.

Three weeks after surgery, patients began gentle physiotherapy. No orthosis were used postoperatively, and patients advanced according to tolerance to unrestricted activities beginning 1 month after surgery.

EVALUATION

As a routine we did a pre-operative evaluation of the patients with Oxford Disability Index (ODI) and also visual analog scale (VAS). On follow-up patients were again evaluated with these scores. The last scores reported by these patients were used in the analysis of these patients. Radiographs were also taken on follow-up to check for any displacement of prosthesis or loss of movement (Figures 1 and 2).

All employed patients returned to their previous occupation. The mean VAS (Graph 1) and mean ODI (Graph 2) values before the procedure differed significantly from the corresponding mean values at each time point assessed during follow-up. VAS scores showed a pre-operative mean of 8.6 (range 7–10), and postoperative means of 2.6 (range 1–8). Mean ODI improved from a value of 73.3 (range 40–100) preoperatively to 35.0 (range 12–60).

Complications

<table>
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<tr>
<th>Complication</th>
<th>Number</th>
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<tbody>
<tr>
<td>Paralytic ileus</td>
<td>5</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Infection (superficial)</td>
<td>2</td>
</tr>
<tr>
<td>Intra-op vascular injury</td>
<td>1</td>
</tr>
<tr>
<td>Retrograde ejaculation</td>
<td>1</td>
</tr>
<tr>
<td>Implant malposition (minor)</td>
<td>3</td>
</tr>
<tr>
<td>Delayed wound healing</td>
<td>1</td>
</tr>
<tr>
<td>Groin and testicular pain</td>
<td>1</td>
</tr>
</tbody>
</table>

There was no postoperative neurodeficit in any of the patients. There was difficulty in mobilizing vessels in one of the
patients at L4-5 level which caused damage to the iliac vein. The rupture was repaired but the patient had swelling lasting for about 5 months before it subsided.

Low back pain and leg pain were almost completely resolved in all cases within 3 months postoperatively; gabapentin was used for 3 months in 4 patients that reported mild leg pain. None of the cases required continuous analgesia.

Follow-up radiological examination did not demonstrate any radiolucent zones or sclerotic lines around the implants. Periannular ossification or mechanic failure did not develop in any case. Subsidence, loosening, failure or dislocation in metal or polyethylene components of the implant and heterotopic ossification was not observed although 3 patients had suboptimally-placed implants (not posterior enough).

**DISCUSSION**

The Implant

There has been considerable interest in development of an ideal disc replacement and many manufacturers have their own versions; some of them having been changed a few times already. The lumbar artificial disc replacement comes in a variety of sizes and angles. There are *constrained* and *unconstrained* designs. The constrained devices provide a fixed center of rotation and are not much in use. The unconstrained design allows the center of the implant to move forward and back slightly during lumbar motion. The surgeon can also choose an implant with the correct angle for each patient in order to build in the right amount of lordosis. Another artificial disc replacement design is a ball-and-socket articulation to allow for normal translation of motion at that segment.

The Charité was approved by the FDA (treatment of single-level disease at the L4-5 or L5-S1 levels) in October 2004 and the Prodisc-L was approved in August 2006. The Maverick and Flexicore lumbar discs have completed their randomized enrollments and are currently in continued access non-randomized modes. Other lumbar devices currently in clinical trials in the US are Flexicore (SpineCore) and Kineflex (SpinalMotion).

There are some differences between the 3 implants we used and the philosophy of their designs although the surgical technique remains largely the same. There is no study however to confirm the superiority of one over the other.

The Charité Artificial Disc (Figure 3) has two metal alloy endplates and its unique sliding core. This offers the theoretical advantage of allowing the spacer to shift dynamically within
the disc space during spinal motion, moving posteriorly with flexion and anteriorly in lumbar extension. The polyethylene spacer can move or slide with modest constraint between the metal plates. The metal plates attach to the bone by three small pegs in front and three small pegs in back.

**The Maverick** (Figure 4) is a two-piece metal-on-metal design that incorporates a more posterior center of rotation. It was introduced in USA in 2003 and is currently being utilized much more extensively in Europe where large clinical series are now being studied. This prosthesis is a semi-constrained ball-and-socket, metal-on-metal device with a posterior center of rotation which matches that of the disc segment. The first implantation of Maverick prosthesis was in January 2002. It has an Anterior and Oblique version especially for the L4-L5 level for ease of insertion, allowing up to 30° angle of insertion.

**The ProDisc II** (Figure 5) consists of 3 components: 2 cobalt-chromium end plates and a convex polyethylene core that acts as a bearing surface and shock absorber. The polyethylene core is secured to the caudal end plate by a modular locking system, leaving 2 moving parts. Each endplate has a central anchoring keel and 2 spikes to provide immediate stability and is coated with a titanium plasmapore surface to enable bone ingrowth for secondary stability. Specially designed instrumentation is used to create a midline groove in the vertebral end plates for implant insertion and to lock the polyethylene core into the caudal end plate. The device is modular and can be adjusted to the local anatomy, enabling surgeons to customize implants to each patient. There are 2 endplate sizes (medium and large), 3 heights (10, 12, and 14 mm), and 2 lordosis angles (6° and 11°). The range of motion is 13° flexion, 7° extension and 10° lateral bending. Axial rotation is relatively free and is restrained by the facet joints and surrounding soft-tissue tension, particularly that afforded by the remaining lateral annular fibers. The prosthesis does not translate and this may protect the facet joints from antero-posterior shear stress.

Concerns regarding the long-term effects of spine fusion on the entire spine have led to the search for a more physiological solution. It is theorized that just as hip and knee arthroplasty revolutionized the treatment of degenerative disease in those joints, the development of the artificial disc may similarly affect the treatment of spinal spondylosis. It is believed but yet not proven that by reconstructing the normal biomechanics of the lumbar spine, the complications associated with spine fusion will be prevented.

Disc replacement surgery is done to stop the symptoms of degenerative disc disease. Discs wear out or degenerate as a natural part of aging and from stress and strain on the spine. Eventually, the problem disc collapses, which causes the vertebra above to sink toward the one below. This loss of disc height affects nearby structures—especially the facet joints.

When the disc collapses it no longer supports its share of the load in the spine. The normal facet joints take about 3–25% of segmental load but a degenerative joint takes about 47% of load. The facet joints of the spine begin to support more of the force that is transmitted between each vertebra. This increases the wear and tear on the articular cartilage that covers the surface of the joints. Shrinking disc height also reduces the size of the neural foramina. The arthritis also results in further development of osteophytes into the canal which can cause foraminal or lateral canal stenosis.

Replacing the damaged disc can restore the normal intervertebral space. Enlarging the disc space relieves pressure on the facet joints and can dilate the neural foramina. Another benefit of the artificial disc replacement is that it mimics a healthy disc.
Natural motion is preserved in the spine where the new disc is implanted. And it helps maintain stability in the spinal joints above and below it.

The rationale for spinal fusion is that it eliminates painful nonphysiological motion across the destabilized or degenerated segment and preserves sagittal balance, and it also can restore normal disk space height if combined with interbody spacers. Fusion alters the normal biomechanics of the spine, transmitting forces to adjacent vertebral levels. The increased forces in the neighboring segments accelerate disk degeneration, facet arthropathy, and osteophyte formation, leading to recurrent back pain and symptomatic spinal stenosis at levels adjacent to the fusion site.\textsuperscript{3,4} Spine fusion also is associated with other complications including alteration of muscular synergy, loss of spinal mobility, graft collapse resulting in suboptimal sagittal balance, and complications associated with the hardware implanted to achieve immediate stability and the harvesting of iliac bone that may be necessary for bone fusion.\textsuperscript{5,6}

The problems with spine fusion surgery hence are: \textbf{First}, the rate of successful fusion is about 80%. While complete fusion of the segments is not always necessary for pain relief, it is concerning that we cannot always find a way for bone to grow across the damaged disc space. \textbf{Second}, fusing a spinal disc space decreases the motion of the back, and may lead to symptoms of stiffness. \textbf{Finally}, because of the stiffness when the fusion is performed, the segments of spine above and below the fusion are subjected to increased stresses. Patients who have a fusion at one level are more likely to develop problems at adjacent discs above or below later on.

Good to excellent results have been reported in 50–100% of patients following anterior interbody or posterior spine fusion. However, spinal fusion is not a benign treatment. In a long-term study (\texttextsuperscript{>}20 years) by Lehmann et al.,\textsuperscript{7} results of lumbar fusion demonstrated that approximately half of the patients suffered recurrent symptoms requiring medication years after the original procedure. At their last follow-up visit, approximately 15% of patients reported undergoing additional surgery during the study period.

Total disc replacement has numerous potential advantages, including the avoidance of pseudarthrosis, postoperative bracing, and the development of junctional degeneration. Theoretically disc replacement should unload the facet joints and can actually delay any arthritic changes in them.\textsuperscript{8} Because candidates for total disc replacement are often young, a successful disc replacement prosthesis must ensure decades of high loading without mechanical failure.\textsuperscript{9} Two separate randomized prospective FDA regulated studies with short-term follow-up in which total disc arthroplasty was compared with interbody fusion demonstrated statistically equivalent results on the basis of validated outcome measures.\textsuperscript{10,11} However even in these prospective Investigational Device Exemption clinical trial, regulated by the U.S. FDA\textsuperscript{10} at 24 months, a greater proportion of patients in the artificial disc group than in the fusion group expressed satisfaction with treatment (73.7% vs 53.1%; \textit{P}=0.0011) and would opt for the same treatment again (\textit{P}<0.05). Rates of reoperation were 5.4% vs 9.1%, respectively. Various studies in the past have reported beneficiary results for TDR.\textsuperscript{9,12,13} Studies with longer follow-up have provided conflicting information with some demonstrating overwhelming success\textsuperscript{9} and others demonstrating multiple complications and less than desirable outcome.\textsuperscript{14}

Disc replacement however remains an operation which is rapidly coming of age. All patients however are not suitable for this surgery and the relative contraindications for artificial lumbar disc include:

\begin{itemize}
  \item Multilevel pathology with indeterminate source of pain
  \item Lumbar scoliosis with apical degenerative disc disease
  \item Translational instability syndromes including spondylolisthesis and spondylolysis
  \item Previous infection, tumor or vertebral body dimorphism
  \item Presence of stenosis and subarticular disease and severe facet joint pathology
  \item Persistent epidural fibrosis
  \item Patients with a body mass index \textgreater{}34 should be counseled extensively to try and achieve a body mass index \textless{}30 prior to implantation
  \item Poor bone mineral density
\end{itemize}

Other authors have suggested doing DEXA scan and provocative discography for all the patients pre-operatively. We did a DEXA scan in the slightly elderly age group only (beyond 50 years). The value of discography remains questionable although we did have to do it on 2 occasions where the second level was doubtful. Previous studies showed a high rate of false-positive and false-negative results equally.\textsuperscript{15,23}

Though disc replacement is a promising technology, it is reasonable to consider that it is not a panacea for all kinds of spinal disorders. The indications for disc replacement are narrow enough to estimate that only 5% of consecutive patients selected for lumbar surgery in fact met with the selection criterion for total disc replacement.\textsuperscript{16}

\textbf{Complications}

The approach related complications essentially include potential injury to the major vascular and visceral structures. Because of a reported 2.8\% incidence of laceration to major abdominal vessels in patients operated on by experienced access-surgeons,\textsuperscript{17} the recommendation is to use a general surgeon for exposure of the desired level. The exposure to L5-S1 disc is relatively simple and can be approached by creating space at the division of aorta and inferior vena cava into common iliac vessels and ligating the middle sacral vessels. The approach to L4-5 disc needs extensive mobilization of the aorta and inferior vena cava to the right side after ligation of the segmental vessels at L4 and iliolumbar vein at L5. The iliolumbar vein drains into the left common iliac vein and has a very variable course. Its course has to be traced carefully and the vein needs ligation to avoid any traction-related injury. Regular pre-operative vascular studies such as Computer Tomography—angiography to better understand the local vascular anatomy have been suggested, but we do not think them to be necessary. Other approach related complications include abdominal wall and retroperitoneal hematomas deep vein thrombosis, retrograde ejaculation (inadvertent injury to superior hypogastric plexus) and distal embolization by atheromatous plaques.\textsuperscript{16}
Initial implant-related complications were a result of faulty design and involved subsidence and breakage of the prosthesis. With the present designs, isolated incidents of anterior prosthetic migration and dissociation of the SB Charité as well as Prodisc II polyethylene core have been noted. Revision surgery in the form of removal of prosthesis and spinal fusion as well as repositioning of the core has been performed to rescue the situation. Vertebral body fracture has been noted during insertion of prosthesis or in the postoperative period. Prosthesis malposition in the medio-lateral plane can be unforgiving and lead to lateral subsidence and eccentric facet loading. Anterior malpositioning is detrimental as it can reduce the prosthetic range of motion apart from increasing the loading on the facet joints. Implant subsidence can affect outcomes in several ways and is related to the size of the prosthesis in proportion to that of the endplate as well as bone mineral density. Residual back and leg pain have been reported and could be a result of inappropriate patient selection or surgeon-related factors. These patients variably had pre-existent disc degeneration at other levels, facet arthritis at the same level pre and post surgery, postoperative disc degeneration at adjacent levels, previous back surgeries in the form of nucleotomies, laminectomies, etc. Surgeon related factors include asymmetrical insertion of prosthesis, wrong patient selection and extension of indications.

Polyethylene wear debris, a major concern that is linked to osteolysis and implant-loosening in hip and knee replacements has been reported in isolated cases in disc replacement in long-term studies using the SB Charité prosthesis. None of the current designs have been reported to show this radiologically in the literature. Metal-on-metal disc have however shown high levels of ions in the blood. Adjacent segment degeneration following total disc replacement at short-term interval (2 years) has ranged from 0% to 5%, but there is possibility of higher incidence developing later. The issue of adjacent level degeneration assumes importance as the implanted disc is expected to share some part of load-bearing by replicating the ‘shock-absorber’ function of the intervertebral disc, apart from allowing mobility. However, the present generation prostheses do not permit axial compression at the implanted level and it is probable that the load-bearing task (shock-absorption capacity) of the implanted level may be transferred onto the adjacent segments. Heterotopic ossification which might paradoxically fuse the segment, has been documented in a few studies, and strategies need to be developed to address the same. Most of the recent literature is reporting reasonably good outcome especially in the short term and much shorter rehabilitation even compared to spinal fusion. Our study is too short term to draw any firm conclusion from but technically as a procedure, we did not have any real issues. Most of the patients did very well and their return to function was quite quick.

We do not have direct access to many of them in follow-up so we could not do serial radiographs to visualize any loss of movement or ossification around the replaced disc. The scoring system however would indicate that they are doing well. We have not had any request or felt the need to revise any of our replacements. Our series with individual disc is small to draw any definite conclusions regarding distinct advantages of one over the other but as regards ease of insertion, patient comfort, return of lordosis and overall satisfaction, the Maverick disc seems to be more likely to work in the long term.

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REFERENCES

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