Review Article

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Lumbar Artificial Disc Replacement: A Review

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Abstract

This study reviewed the literature on the treatment of symptomatic lumbar degenerative disc disease with artificial disc replacement which has the advantage of motion preservation. This technique is evolving with continuous modifications in the prosthesis design and needs a long term follow- up of clinical outcomes. The indications and contraindications of the procedure are being defined and the initial results are comparable to the lumbar fusion with preservation of motion.

Keywords: Artificial Disc; Disc Degeneration; Lumbar**.**

Introduction

Degenerative disc disease (DDD) is defined by both the biologic and mechanical degradations of the intervertebral disc that subsequently lead to pain. DDD has been touted as the leading cause of pain and dysfunction worldwide. The prevalence of DDD is roughly described in proportion to age such that 40% of people 40 years of age have DDD, increasing to 80% among those 80 years of age or older. Various types of non surgical and surgical treatment modalities are available for relieving the pain and disability caused by DDD. In up to 20% of patients with DDD, conservative therapy may be unsuccessful in whom surgery should be considered. Surgical fusion is considered as the surgical Gold standard for Lumbar DDD but the surgical management of chronic low back pain due to DDD is still controversial. After 100 years of fusing vertebrae together, spine surgeons can now treat back pain by restoring "natural motion" to the lumbar spine with an artificial disc. Lumbar disc arthroplasty is a surgical procedure on the lumbar spine that involves complete removal of the damaged or diseased lumbar intervertebral disc and implantation of an artificial disc. The procedure may be done as an alternative to lumbar spinal fusion and is intended to reduce pain yet retain the movement at the site of surgery and restore inter-vertebral disc height and alignment of spine.

Historical Aspects

Initial attempts at artificial disc surgery date back to the 1950s, The first published study on disc replacement was in 1955 by David Cleveland [1] who injected methylmethacrylate into the disc spaces of 14 patients at the time of iscectomy. Then Fernström (1966) implanted stainless steel balls into the disc spaces in more than 100 patients and found that results obtained with this form of disc arthroplasty were better than Discectomy alone and similar to the results of discectomy and fusion [2]. Although this procedure produced acceptable clinical results, it was ultimately abandoned because of subsidence of the steel balls into the vertebral end plates. In 1978, Fassio and Genestie [3] replaced lumbar discs with

silicone prostheses. More-recent innovations include efforts by Schellnac and Búttner-Janz in the 1980s with the introduction of the Charité SB disc (DePuy Spine). The first artificial disc prosthesis was approved by the FDA in October 2004, followed then in 2006 by the ProDisc-L (Synthes Spine Inc, Paoli, PA).

Concept of Motion Preservation

The potential advantages of disc arthroplasty include motion preservation maintaining the stability, avoidance of progression of adjacent segment degeneration, reconstitution of the disc height and spinal alignment, maintenance of mechanical characteristics. This avoids the disadvantages of fusion related complications such as pseudarthrosis, instrumentation and post-operative immobilization. In some cases, it is thought that pain relief may be greater with motion preservation than by fusion. The current approaches to spinal arthroplasty use principles and materials similar to those used in diarthrodial joint arthroplasties.

Bio-Mechanics

The intervertebral motion segment is a three-joint complex consisting of the disc and the superior and inferior facets. In the normal motion segment, the three joints act together to provide physiologic motion. Excessive motion in physiologic directions or motion in nonphysiologic planes such as pure AP translation is resisted by bony anatomy and soft tissues.

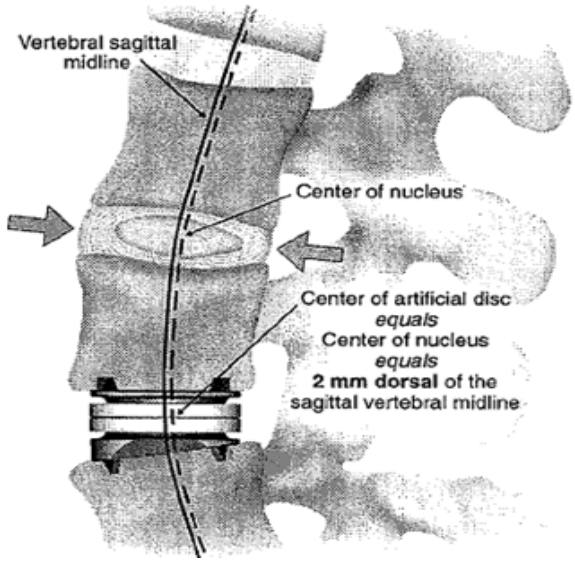


Fig. 1: Lumbar motion segments showing location IAR in normal disc and artificial disc

Constraint in TDR designs has implications in ROM (kinematics) and facet preservation. When the function of the intervertebral disc is compromised, excessive loads may be transmitted to the posterior elements. The long-term clinical success of TDR may hinge upon the ability of the implant to protect the posterior elements from excessive loads. Intervertebral kinematics and shear loading patterns will likely affect long term facet preservation.

The normal flexion-extension IAR of a lumbar motion segment differs between different levels in the spine and migrates during intervertebral motion. In general, the IAR lies slightly posterior to the midline of the vertebral body on sagittal imaging and slightly below the superior endplate of the inferior vertebra. L5–S1 is a notable exception because the IAR lies within the disc space instead of below the suoerior endplate [4]. The precise location of the implant IAR relative to the physiologic IAR of any given motion segment is determined by the combination of implant design and by the surgeon's placement of the implant.

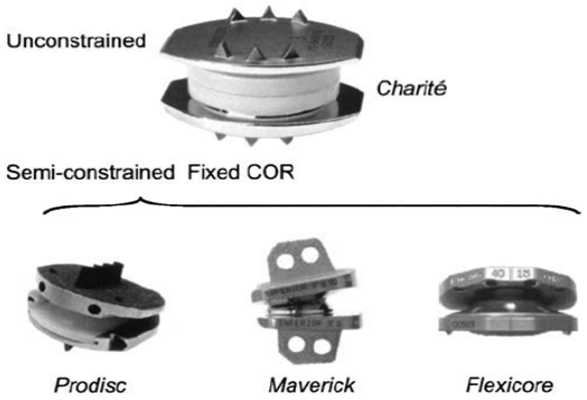


Fig. 2: Total disc replacement implant designs

Indications and Contraindications

The current FDA approved indications for lumbar ADR are as follow:

Indications

- 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.

- ODI ≥ 30 and VAS pain score of ≥ 40 .

Extended Indications

- Postlaminotomy/discotomy syndromes with discogenic axial back pain.
- Symptomatic adjacent segment disease next to an established fusion.

Contraindications: [5]

- Previous thoracic or lumbar fusion.
- Multilevel degenerative disc disease.
- Facet joint arthrosis.
- Noncontained herniated nucleus pulposus · Spondylolisthesis ≥ 3 mm
- Scoliosis ≥ 11°
- Osteoporosis.
- Patients with significant canal stenosis ≤ 8 mm or neural compressive disease.
- Pain related to significant scarring from previous surgery.
- Metabolic bone disease.
- Morbid obesity (BMI _ 40 or weight _ 100 lb over ideal body weight.
- Rheumatoid arthritis or other autoimmune spondyloarthropathies.
- Systemic disease including but limited to AIDS, HIV, hepatitis.
- Active malignancy.

⊙ Chronic severe disabling discogenic low back pain isolated to one or two levels that has failed a minimum of 6 months of nonoperative therapy in patient who has stable spine with no significant canal stenosis and facetal arthrosis. [6,7,8].

Surgical Technique

Preoperative Imaging

- All patients have to be assessed for the pattern of vascular anatomy in the lumbar region with respect to level of bifurcation of great vessels, accessory or anomalous vessels. This can be done by either CT angiogram or MRI.
- Measurement of disc height, segmental lordosis, sizing and templating of the prosthesis size is mandatory as a pre-operative preparation. A CT scan will be very useful in taking the accurate measurements.

Pre-Operative Preparation

- Lumbar disc replacement is done by approaching the involved disc anteriorly either by retroperitoneal or Trans peritoneal approach. As the approach is Trans abdominal, bowel preparation is essential pre-operatively. The patient is advised to take only liquids starting from 24 hours prior to planned surgery time. Oral laxative is given on the night prior to surgery and patient has to be informed about frequent bowels in the early morning.

Patient Positioning

- The patient is placed in the supine position, with the upper and lower limbs abducted. This so-called Da Vinci position or French position requires a special table with movable leg holders. A radiolucent table is required in all cases. The lumbar spine should be kept in a neutral position in the sagittal plane to minimize tension on the retroperitoneal vessels and excessive axial loading of the posterior elements of the spine as occurs in hyperlordosis.

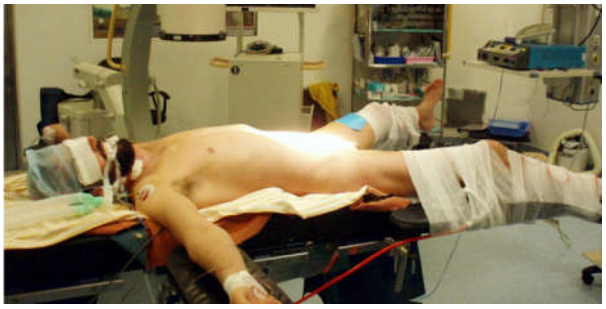


Fig. 3: Da vinci or French position of the patient for ADR.

Approach

- Anterior approach is used commonly as a standard approach to implant the artificial disc. Either transverse or left paramedian incision is taken to depending on the level of intervertebral disc to be replaced. Fluoroscopy is used to mark the incision accurately so that it is centered over the index level.
- The disc can be approached by either retroperitoneal or transperitonial route. The retroperitoneal approach is preferred in most

cases. Transperitoneal approach is reserved for patients in whom the retroperitoneal approach is difficult or contraindicated, such as those who have had previous open abdominal surgery, obese patients, and patients who have had revision anterior retroperitoneal surgery.

- The retroperitoneal plane lies deep to the rectus sheath. Blunt dissection with sponge sticks is used to dissect within the retroperitoneal plane leading to the lateral edge of the psoas muscle. At this point, the plane of dissection continues anterior to the psoas. Typically, the ureter is swept medially with the peritoneum. The iliac vessels are identified and protected. For an L4-L5 or L3-L4 disc replacement, the vessels are mobilized from the left to the right to expose the anterior aspect of the annulus. In order to mobilize the iliac vein safely, it is necessary to ligate and transect the left iliac anastomosis lying on the left side of the L5 vertebral body. As the vessels are mobilized to the right, if the tension on the vessels above the L4-L5 disc space is excessive, ligation of the L4 segmental vessels is necessary. At L3-L4, mobilization of the aorta and vena cava is achieved by ligation of the L3 and/or L4 segmental vessels.

Disc Preparation

- Once the disc space is exposed and the operating field is secured by a self-retaining retractors. The midline is marked by fluoroscopy .
- Discectomy and End-Plate Preparation is begun with anterior anulectomy is performed with a scalpel or with monopolar electrocautery at the junction of the annulus and end plate. A large Cobb elevator is used to separate the cartilaginous end plate from the osseous end plate. The disc is sub totally resected centrally leaving the lateral aspect of the annulus intact.

Disc distraction

Mobilization of the motion segment is a critical step in the procedure. This allows appropriate posterior placement of the implant and increases the implant range of motion. The distraction device is used to successively open the lateral and posterior aspects of the disc space. There should be parallel distraction of the end plates, not preferential opening of just the anterior column. If the posterior part of the disc space does not distract adequately, it is necessary to release the posterior longitudinal ligament and posterior osteophytes with use of distraction, curets, and a Kerrison rongeur.

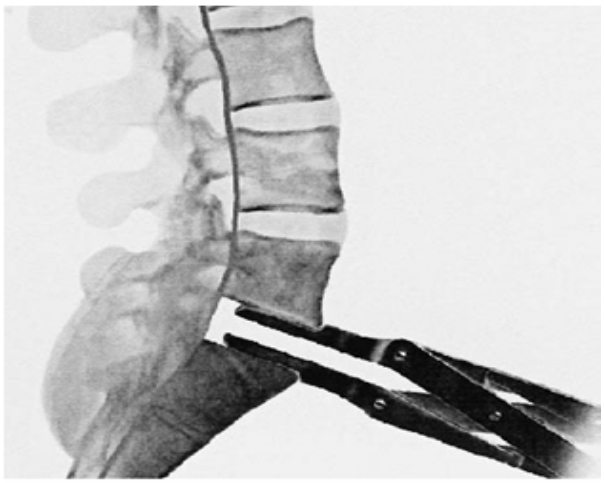


Fig. 4: Distraction device opening up the disc space after final preparation

Trial Implant Insertion

- Once appropriate disc-space mobilization is achieved, trial implants are used to determine the Proper implant size. In general, the largest implant that can be safely inserted is chosen to maximize end-plate coverage. In contrast to implant height selection in anterior arthrodesis, it is generally not advisable to insert the tallest implant that will fit into the disc space because it places the soft tissues in maximum tension will decrease the postoperative range of motion. Posterior placement of the implants is biomechanically ideal. This places the center of rotation of the implant in a physiologic position posterior to the midline of the disc space in the sagittal plane and allows the implant to rest on the stronger peripheral zone of the posterior end plate.

Keel Cut Preparation

- The chisel, guided into position by the trial implant, is used to prepare slots in the end plates to match the implant keels. Ideal placement of the chisel cuts will lead to the ideal final mediolateral position of the implant. The cuts must be symmetrical and should be oriented parallel to the disc space on the lateral fluoroscopic views.

Prosthesis Implantation

- The prosthesis is implanted parallel to end plate under C-arm guidance. Any deviation will lead to malalignment and subsequent subsidence or displacement. Ideally the centre of the prosthesis

should be about 0-3 mm posterior to midline of the vertebral body. This position simulates the anatomical instantaneous axis of rotation. The implant should be 3 mm short of posterior edge of the vertebral body. In AP view, the prosthesis should be within 0-3 mm of lateral borders of the spinous process.

Complications

Approach Related Complications

- Transperitonial approach is related with high rate of paralytic ileus, small bowel obstruction and retrograde ejaculation and therefore retroperitoneal approach is preferred. Inadvertent peritoneal opening can happen in retroperitoneal approach and ileus is known to occur in this approach also.
- Injury to inferior venacava or iliac veins can occur during exposure or prosthesis implantation. Therefore careful blunt retraction is essential and anatomical variations should be kept in mind. Deep iliac vein thrombosis and pelvic phlebitis can occur following retraction.
- Retrograde ejaculation sometimes transient but can be permanent can occur in males due to anterior approach. Also manipulation of the sympathetic plexus can cause sympathetic disturbances in the affected lower limb due to which patients may feel warmth in one limb as compared to other.
- Injury to left ureter is common in retroperitoneal approach specially when there is revision surgery.
- There are chances of hematoma formation in the pelvic cavity if hemostasis is not proper and also increased risk of infection. Abdominal hernias can occur if the rectus sheath was not closed properly.

Implant-Specific Issues

- Malpositioning of the prosthesis is a known complication which affects the biomechanics of the motion segment and can result in failure of the prosthesis. An anteriorly placed prosthesis can cause over loading of the facets and result in aggravated degeneration. It also increases the risk of dislocation. A prosthesis placed too much posteriorly can result in canal stenosis and compress the neural elements. A prosthesis placed at a lordotic angle of >15 degrees has the risk of anterior dislocation.
- Right sizing of the prosthesis pre-operatively is very important because a smaller prosthesis is has more chances of subsidence, loosening and dislocation. The vertebral body consists of a strong apophyseal ring in the periphery and a cartilaginous end plate in the center. The ideal implant should provide largest endplate coverage and should sit in most anatomical position. Large size prosthesis may be difficult to impact and any forceful impaction may fracture the body or prosthesis may enter the neural canal.

Long Term Complications

- Subsidence of implant can happen because of under sizing of implant, malpositioning or intra-operative violation of the endplate.
- Heterotrophic ossification is seen in some patients after lumbar ADR. The exact incidence is not known but varies from 1.4% to >15% [9]. The clinical significance of heterotrophic ossification on restricting the movement at involved motion segment is difficult to predict as there can be good range of motion within the physiological range even in presence of heterotrophic ossification.
- Infection of the prosthesis is a serious complication which occurs rarely but causes devastating consequences. Patients with peritoneal and bowel injury intra-operatively are more prone for infection. Patients with urinary tract infections, pelvic inflammatory diseases and immune suppression are more prone for infections.

Literature Review

Charité

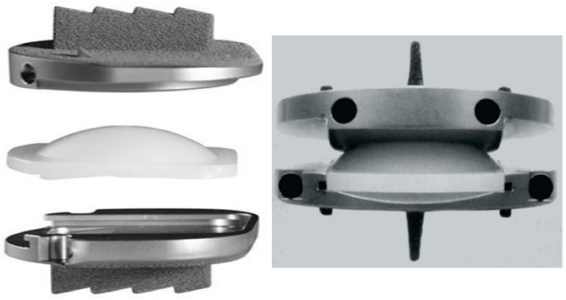
Fig. 5: Charite' lumbar disc prosthesis

- Lemaire et al reported the results of a prospective study of 105 patients with chronic low back pain treated by the SB Charite´ III prosthesis at one or two levels. At an average follow-up of 51 months, 79% had excellent results and 87% had returned to work. Fifty-five patients had minimum 10-year follow-up, 79% of whom continued to work.
- Blumenthal et al and Hochschuler et al reported on 56 patients with chronic low back pain treated by the SB Charite´ III disc replacement. The mean VAS improved 52% from baseline and the Oswestry 40% [10].
- Studied Fiftythree patients (63 TDRs) retrospectively who underwent Lumbar ADR with Charite'.

Who are available for long-term follow-up of 17 years. Implantation of Charite´ TDR resulted in a high rate (60%) of spontaneous ankylosis after an average follow-up of 17 years. There was no significant difference in the clinical outcome between the three types of prostheses. Although no adjacent segment degeneration was observed in the few functional implants (17%), these patients were significantly less satisfied with the long-term outcome of the surgery than the patients with spontaneously ankylosed motion segments or fusion after implant failure. Although the Charite´ TDR nowadays is an approved implant, the evidence that long-term results of TDR implantation in DDD are as good as or even better than fusion results is still missing.

Prodisc-L

- Jack Zigler et al. Results of the Prospective,



A B

Fig. 6: ProDisc-L prosthesis: A- components. B: Assembled prosthesis

Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc-L Total Disc Replacement Versus Circumferential Fusion for the Treatment of 1-Level Degenerative Disc Disease . SPINE 2007. Volume 32, Number 11, pp 1155–1162. Two hundred eighty-six (286) patients were treated on protocol and the results of Lumbar ADR with Prodisc-L were compared to anterior fusion done between 2001-2003. ProDisc-L has been found to be safe and efficacious. In properly chosen patients, ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria.

- Tropiano et al evaluated 53 patients with single or multiple level disease at 1-year follow-up.51 Oswestry disability scores improved from 56% to 14% and VAS from 7.4 to 1.3. Results improved over time, and there were no differences between single- and multi-level cases. The reoperation rate was 6% secondary to vertebral fracture, implant apposition, and persistent radiculopathy.
- Delamarter et al reported early results in 53 patients of a randomized trial of the PRODISC II to fusion. At 6 months, no differences between interbody fusion and VAS were observed. However, the disc replacement patients did have better pain relief and function at 6 and 12 weeks.

Maverick

Fig. 7: Maverick metal on metal prosthesis

- LeHuec et al reported on early results on a prospective series of 30 patients that had received the Maveric prosthesis following at least 1 year of failed conservative treatment for chronic back pain at L4–L5 or L5–S1.52 . Clinical success as defined by Oswestry score improvement was 82% and 86% at 6 months and 1 year, respectively. VAS scores improved from a preoperative mean of 7.5 to a postoperative mean of 3.0. The mean SF36 score improved from 40 to 72 at the 1-year follow-up. No implant required removal or surgical revision.

Conclusion

Lumbar artificial disc replacement theoretically has the dual advantage of treating the discogenic low back pain with preservation of mobility at the involved motion segment. The success rate of Lumbar ADR in the short term follow-up is more than 70% in majority of the studies. The key factors in success of lumbar ADR are proper selection of patients for surgery and precise surgical technique. This procedure involves approach related and implant related complications which can be devastating in some patients leading to serious morbidity and sometimes mortality. Also the revision surgery in failed cases involves more complications and the results of revision are not clearly known. Therefore careful patient selection and intense surgical training is necessary for the success of this procedure.

The long term results of Lumbar ADR are lacking and many queries remain unanswered which include longevity of the implant, polyethylene wear, behavior of surrounding tissues, Preservation mobility of the motion segment and its effect on adjacent segment degeneration are yet to be studied. Therefore the initial success with lumbar disc arthroplasty with results comparable to fusion have to be constantly monitored before embarking the procedure as a standard technique for lumbar degenerative disc disease.

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