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MOTION PRESERVING SPINE SURGERY (C KEPLER, SECTION EDITOR)

Lumbar disc replacement surgery—successes and obstacles to widespread adoption

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Abstract
Purpose of review Lumbar disc replacement has been a surgical alternative to fusion surgery for the treatment of lumbar degenerative disc disease (DDD) for many years. Despite enthusiasm after the approval of the first devices, implantation rates have remained low, especially in the USA. The goal of this review is to provide a general overview of lumbar disc replacement in order to comprehend the successes and obstacles to widespread adoption.
Recent findings Although a large amount of evidence-based data including satisfactory long-term results is available, implantation rates in the USA have not increased in the last decade. Possible explanations for this include strict indications for use, challenging surgical techniques, lack of device selection, fear of late complications or revision surgeries, and reimbursement issues.
Summary Recent publications can address some of the past concerns, but there still remain obstacles to widespread adoption. Upcoming data on long-term outcome, implant durability and possible very late complications will determine the future of lumbar disc replacement surgery.

Keywords Degenerative disc disease · Lumbar spine · Fusion · Total disc replacement · Widespread adoption

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Introduction

Low back pain (LBP) is a major health complaint throughout the world with an annual prevalence of 38%. As our population is aging, the number of individuals suffering from LPB is likely to increase considerably in the coming decades [1]. LBP is associated with a substantial socioeconomic burden with resulting costs exceeding $100 billion per year in the USA [2]. The etiology of LBP is multifactorial including DDD, facet arthropathy, disc herniation, spondylolysis, and spondylolisthesis. Isolating a single cause of LBP is difficult since these conditions often co-exist. However, in order to successfully select optimal surgical interventions, accurate identification of the primary pain generator is critical [3•, 4].

For a long time, treatment options for patients with progressively symptomatic DDD were limited to either conservative treatment or fusion of the affected level [3•]. The goal of lumbar fusion is to eliminate movement at degenerated joints and to restore stability [5]. From 2000 to 2009, surgical treatment for lumbar DDD increased 2.4-fold in the USA [6]. Despite the rising rates of fusion surgeries in particular, these procedures have several potential issues, such as failure to achieve a solid fusion mass (pseudarthrosis), adjacent segment degeneration (ASD) and complications at the bone donor site (usually the iliac crest) [7–9]. Radiographic signs of degeneration of disc spaces adjacent to the site of a lumbar fusion may be the result of increased biomechanical stress and/or the natural history of lumbar spondylosis [10, 11].

The shortcomings of arthrodesis and the success of arthroplasty in other orthopedic subspecialties motivated spine surgeons to establish lumbar total disc replacement (TDR) as an alternative to lumbar fusion [9, 12]. Theoretically, TDR is an ideal treatment option because it restores disc height and relieves pain without restricting motion at the diseased spinal level, which may reduce reoperation

rates due to ASD. Furthermore, it may allow for earlier patient mobilization since usually there is no need for a brace compared to fusion [9].

History

The first lumbar disc prosthesis was implanted by the Swedish Ulf Fernstrom in the late 1950s. He used an anterior approach to implant an artificial disc in the form of a steel ball [12]. The procedure involved excision of the degenerated nucleus that was postulated to produce chemical factors that caused pain. Implantation of the steel ball was intended to maintain disc space height and motion. Although initial results were promising, long-term failure of the device was attributed to excessive compressive load concentration with subsidence into the subchondral bone [12, 13].

Using ideas derived from total knee and hip prosthesis, articulating disc replacement designs began to emerge. In the early 1980s, Schellnack and Buttner-Janz initiated the first prosthesis designed to be commercially distributed as a TDR: the SB Charité. The implant was comprised of a sliding core of ultra-high molecular weight polyethylene (UHMWPE) between two metallic end plates. The original device (SB Charité I) consisted of small, shell-like end plates. In the course of time, stress concentrations along this small surface area resulted in subsidence into the vertebral body in several cases. Thereafter, successive models of the SB Charité were used instead [12–14].

In the late 1980s, Marnay developed the ProDisc. In contrast to the Charité, there was only a single articulating interface between the polyethylene core fixed to the inferior end plate and a superior metallic end plate [13]. Since then, other designs of lumbar artificial discs including the Maverick, FlexiCore, and activL artificial disc have come onto the market.

Biomechanics

The articular surfaces of the TDR devices are designed to meet several biomechanical requirements including toleration of load without breaking, reduction of friction and wear, and conservation of range of motion (ROM) over a long period of time. In order to evaluate the devices, wear and motion tests are performed under varying loads and movements [15]. It is assumed that the spine undergoes approximately 100 million flexion cycles during a lifetime. Ten million cycles should be the minimal life length of an implant, but 30 million cycles is considered optimal. Consequently, implant durability can represent a severe demand for device components [16].

Articular surfaces of TDR devices are made up of combinations of metal alloy (including titanium, stainless steel, cobalt, and chromium), polymer composites and ceramic [17]. Metal-on-polyethylene interfaces raise concern of creep, cold flow, and wear debris issues. Polyethylene wear debris and the biological sequelae have been shown to cause osteolysis and aseptic loosening in total hip and knee replacements. Given the use of similar materials in TDR, the same debris and device component issues may be of concern [18, 19]. In contrast, metal-on-metal interfaces are associated with dramatically lower wear rates. Although reports of systemic metal deposition after hip arthroplasty exist, it is uncertain if this mechanism also applies to the relatively avascular and nonsynovial spinal disc space [20]. In a recent study, serum ion levels in TDR patients were well below the recommended threshold levels that warrant closer monitoring for hip replacement patients (Medicines and Healthcare Products Regulatory Agency) [21•].

The two main TDR design concepts include relatively constrained (e.g., Maverick, ProDisc, activL) and unconstrained (e.g., Charité) implants. By allowing translation, unconstrained implants reduce stress concentration at specific points on the bearing surfaces. However, since unconstrained devices rely on surrounding structures to provide restraint to extremes of ROM, this may lead to greater stress on the facet joints. Unconstrained devices have a mobile axis of rotation, and may compensate for small errors in device placement [20, 22]. Semi-constrained disc implants may be able to share a bigger part of the load and could protect the facet joints from early degeneration. Since these devices have a fixed axis of rotation, they seem to be less forgiving and need exact anatomic placement [20, 23].

Most of the current available TDR devices are designed to imitate the biomechanics of an intact lumbar motion segment, but not mimic the physiological characteristics of the natural disc. Attempts to simulate the natural disc by the use of elastic-type disc prostheses like the AcroFlex lumbar disc replacement resulted in poor clinical outcomes with no further justified use [17, 24]. Also, nucleus disc replacement techniques have been developed in the last few years, but discussion of these devices is beyond the scope of this review.

Selection criteria for lumbar TDR

As with any surgery, it is important to determine proper patient selection criteria. To understand the specific indications for lumbar TDR, the differences between fusion and arthroplasty need to be highlighted. First, fusion is intended to eliminate motion and thereby pain from any lumbar pain generator including the disc, facet joints, and surrounding structures. Since arthroplasty preserves motion and solely addresses the disc space, it can only relieve pain generated from the disc, but no other sources (e.g., facet joints) [17]. When considering TDR, facet anatomy is assessed preoperatively. In this regard,

patients with a high pelvic incidence (more than 65°) are prone to present arthritic changes at the facet joints. Since motion may be limited after surgery due to the hypertrophic facet joints, these patients are not good candidates for TDR. Second, TDR is not intended to stabilize the spinal column and should not be used in patients with a translational deformity such as spondylolisthesis. Third, a motion maintaining or restoring TDR procedure is not appropriate in patients with impaired motion due to segmental autofusion (e.g., ankylosing spondylitis). Lastly, disc arthroplasty also requires stable fixation to the bone. Patients with poor bone quality might develop fixation failure and vertebral body fracture [17, 25].

Taking the aforementioned points into account, lumbar TDR might be considered a viable treatment option in patients suffering from painful DDD unresponsive to more than 6 months of nonoperative care with diagnostic studies confirming the disc as the likely pain generator, and without significant facet joint degeneration, deformities, instabilities or osteopenia/osteoporosis [26].

Surgical technique

The patient is positioned in the supine position with the legs apart (so-called da Vinci position), which allows the surgeon to stand between the patient's legs and to work directly anterior to the disc space. When approaching L4–L5 or above, an oximeter on the left hallux should monitor for ischemia due to short-term compression of the left iliac artery by retractors. Before the start of the procedure, it has to be verified that clear AP and lateral radiographs of the index level can be obtained [15, 27].

Lumbar TDR is typically performed through an anterior approach. A left retroperitoneal approach is recommended in all levels with the exception of L5–S1. The basis for the left side preference is the anatomic location of the great vessels. The aorta (on the left) is not only easy to identify but also has a more resilient wall in comparison with the inferior vena cava (on the right). However, to access L5–S1, especially in males, a right-sided approach is preferred to avoid injury to the superior hypogastric plexus (located in the left anterior part of the promontory) and resulting retrograde ejaculation. Another benefit of accessing L5–S1 from the right side is that a virgin left-sided retroperitoneal plane is preserved if the patient has to undergo a second anterior approach to a more cephalad lumbar disc in the future [12, 27].

Vessels are the biggest obstacle when accessing the disc, with L4–5 usually being the most challenging.

Access to general and vascular surgeons ("access surgeon") in case of visceral or vascular injury, especially in revision surgeries, is required [27, 28]. Special attention should always be given to the ascending lumbar vein, which should be ligated if necessary.

The disc is excised and the cartilaginous end plates removed. Special attention should be given to preserve the integrity of the bony end plates upon which the prosthesis will rest in order to help prevent subsidence [27, 29]. Ideally, the TDR device should be implanted posteriorly in order to place the center of rotation of the device in a favorable biomechanical position. Initial fixation is reached through teeth (Charité, activL) or a keel (ProDisc-L) on the implant endplates, which may be enhanced afterwards by osseointegration facilitated by the surface coating of the device [27, 30].

Successes and obstacles to widespread adoption

Although early outcomes of the first approved lumbar TDRs garnered enthusiasm, utilization rates have remained low over the last decade. The reasons for this trend might include historical shortcomings, biomechanical concerns regarding wear debris and device failure, strict indications for use, and challenging surgical techniques with a long learning curve. Also, the fear of late complications, revision surgeries, conflicting data from published meta-analysis, lack of TDR selection, and reimbursement issues are other plausible reasons [31–33].

Over the last few years, there have been reports of long-term results with follow-up times of 5 to greater than 10 years [32, 34•, 35•, 36]. According to these studies, lumbar TDR surgery was a safe procedure with overall low complication and revision rates, significant improvement in health-related quality of life (HRQOL) scores, and high rates of successful outcomes. Moreover, there are reports that mobility is preserved in the majority of cases and TDR seems to have a protective effect against adjacent-level disease. This shows favorable TDR outcomes in well-selected patients.

However, meta-analyses of randomized controlled trials (RCTs), representing the highest level of evidence, have been published to compare lumbar TDR with fusion for lumbar DDD [37–41]. The findings of these meta-analyses are conflicting and thereby result in uncertainty for decision makers. In 2016, a systematic review of these overlapping meta-analyses was published in order to evaluate these studies and provide decision-makers with treatment recommendations based on the best available evidence. Among the five included meta-analyses, the Cochrane review by Jacobs et al. [38] was found to be the best available evidence on the comparison of lumbar TDR and fusion for lumbar DDD [42•].

This Cochrane review included seven RCTs [43–49] involving a total of 1474 patients. Six of the studies compared lumbar TDR with fusion, one study [47] compared lumbar TDR to nonsurgical treatment. In these studies four different discs including the Charité, Maverick, ProDisc-L, and Flexicore were used. With the exception of one study, the follow-up period of the studies was 2 years. Subjects undergoing disc replacement surgery showed a mean improvement

in their back pain visual analog scale (VAS) of 5.2 mm (of 100 mm) higher compared with fusion. Also, the improvement of the Oswestry Disability Index (ODI) score at 2 years was 4.27 points greater than in the fusion group. The authors concluded that although statistically significant, the differences did not appear clinically significant. TDR was shown to be at least equivalent to fusion in the short term, but because complications might occur in the longer term, the authors suggested that the spine community be cautious about adopting TDR on a large scale [38].

Although Jacobs et al. provide the best currently available evidence, it has to be recognized that this study was published in 2012 and the latest RCT evaluated was from 2011. Furthermore, the primary studies had a follow-up of 2 years, and thereby, longer-term results could not be assessed [42•]. Additionally, some of the included studies have been criticized because of commercial sponsorship (manufacturers of the TDR device) and the use of inappropriate control groups [38].

Longer term studies and evidence are lacking on clinical outcomes, complications, and ASD rates. Many patients have undergone a TDR at an early age and there are concerns about the evolution of these implants in an aging population. Major concerns in this patient population include implant durability, prosthesis migration, or dislocation. In such cases, revision surgery with disc removal followed by interbody fusion is performed. Revision surgery for TDR is complex and challenging, since abdominal adhesions increase the risk of vascular or visceral complications. Additionally, there have been reports of patients with persistent back pain, despite optimal device position. Especially in these cases, the indication for revision surgery is not clear. Furthermore, there are no specific guidelines regarding surgical approach and the question of device removal. Alahmadi et al. reported poor outcomes after revision surgery even when a good fusion is obtained. For this reason, a high threshold level has been recommended before performing a salvage fusion [50].

Until recently, there were only two FDA-approved lumbar TDRs on the US market: the Charité Artificial Disc (DePuy spine, Inc., Raynham, MA) approved in 2004 and the ProDisc Lumbar Disc Replacement (SYNTHES Spine, Inc., West Chester, PA) following 2 years later. In June 2015, the activL Artificial Disc (Aesculap Implant Systems, LLC) received Food and Drug Administration (FDA) approval [33]. For the purpose of this review, recently published data on these three selected devices is summarized.

Charité artificial disc

The first prospective, randomized FDA IDE trial comparing lumbar TDR with the Charité to anterior lumbar interbody fusion (ALIF) was conducted by Blumenthal et al. and showed that the use of the Charité artificial disc was safe and clinically equivalent to ALIF in the short term [44]. Favorable long-term data (including good clinical outcome, high return to work rate, and low rates of adjacent-level disease) with follow-up of at least 10 years were reported by David and Lemaire et al. [51, 52].

In 2015, Lu et al. reported their 11-year minimum outcomes of 32 patients implanted with the Charité artificial disc. In this study, satisfactory clinical and radiologic outcomes were maintained for a mean follow-up of 11.8 years. The authors reported a clinical success rate as defined by the FDA (≥ 15-point improvement in ODI, freedom from device failure or serious device-related adverse events, maintenance/improvement in neurological status) of 87.5% and a return to work rate of 75.9%. No device failure or major complications were noted. At the final follow-up, heterotopic ossification was detected in 71.4% and prosthesis subsidence occurred in three patients (9.4%) [34•].

In a 2016 published study by Guyer et al., 5-year outcomes of two lumbar TDR devices were compared. This RCT included 190 patients receiving Charité and 204 patients receiving Kineflex-L. During the 5-year follow-up, no significant differences were noted between the two groups. Patients in both the Charité and Kineflex-L group experienced significant clinical improvements measured by ODI and VAS scores. Radiographic analysis showed that the segmental ROM in both groups initially decreased at 3 months, increased until 24 months and remained stable thereafter. The reoperation rate in both groups was approximately 11% [21•].

ProDisc lumbar disc replacement

Zigler et al. reported the 5-year results of the prospective, randomized, multicenter FDA IDE study of the ProDisc-L. In this study, 236 patients were randomized either to single-level TDR or circumferential fusion. Although patients in both groups maintained significant improvement in their ODI scoes at the 5-year follow-up compared to their preoperative values, TDR patients were more satisfied than fusion patients. The percentage of patients indicating they would have surgery again was 82.5% in TDR patients and 68% in fusion patients. Furthermore, the reoperation rate at the index level was higher in the fusion group compared to the ProDisc-L group (12 vs 8%) [53].

Zigler et al. also reported on 5-year adjacent-level degenerative changes. Adjacent-level degeneration was defined by radiologic signs including disc height loss, endplate sclerosis, osteophytes, and spondylolisthesis. Comparing adjacent levels preoperatively and at 5 years after the index surgery, circumferential fusion patients were more than three times likely to experience changes in adjacent-level degeneration than the TDR patients [54].

In a 2014 published prospective case series, Siepe et al. report their 5- to 10-year outcomes after ProDisc II implantation. The study cohort consisted of 181 patients with a mean follow-up of 7.4 years, ranging from 5.0 to 10.8 years. There was significant improvement in ODI and VAS scores at all post-operative follow-up time points ($p < 0.0001$). The authors report that more than 86% of patients were highly satisfied or satisfied, whereas approximately 14% of patients were not satisfied. The complication rate was 14.4% and the overall reoperation rate was 16%. Single-level TDRs demonstrated lower complications (11.9 vs 27.6%; $p = 0.03$) and greater satisfaction rates compared to two-level cases. In consideration of their reported acceptable complication and reoperation rates, the authors concluded that fear of excessive late complications following ProDisc II implantation are not justified [32].

Park et al. [35•] conducted a retrospective analysis to evaluate successful long-term outcomes following lumbar TDR using the ProDisc II. With a mean follow-up duration of 10 years, lumbar TDR using the ProDisc II demonstrated an overall clinical success rate of 66.7% and a subjective satisfaction rate of 72.9%. The study population of 54 patients was divided into two groups. The first group consisted of patients who met the ideal indication for TDR, defined as DDD without other accompanying spinal disorders. The second group consisted of patients who presented with combined spinal disorders including spondylolisthesis, retrolisthesis, facet joint arthritis, and lateral recess stenosis. Although the authors acknowledged not knowing why lumbar TDR rather than fusion surgery was performed for the second group, they mentioned that the indication for TDR was broader at the time the surgeries were performed. All clinical results of the group with accompanying spinal disorders were inferior to those of the group who met the ideal indication for TDR. The authors concluded that strict patient selection is critical for successful outcomes in lumbar TDR [35•].

activL artificial disc

In 2015, Garcia et al. reported the two-year outcomes of the activL multicenter randomized controlled IDE clinical trial. Patients with symptomatic single-level DDD and a history of at least 6 months of nonsurgical management were allocated to treatment with activL ($n = 218$) or FDA-approved control devices, consisting of ProDisc-L or Charité ($n = 106$). The overall treatment success rate (defined as ODI improvement of ≥15 points, no neurological deterioration, maintenance or improvement in ROM at index level, no reoperation, or major device-related complication) at 2 years with activL was superior to the controls ($p = 0.02$). Also, the radiographic success rate, which was defined as maintenance/improvement in range of motion, was significantly higher in the acitvL group (59 vs 43%). Serious adverse events related to the device were less common in patients treated with activL vs controls (12 vs 19%). The authors concluded that the single-level use of the activL TDR is safe and effective for the treatment of symptomatic lumbar DDD through 2 years and performs superior to FDA-approved controls. Long-term treatment durability of the activL Artificial Disc is still unknown and requires further investigation [3•, 33].

Conclusion

A substantial amount of data on lumbar TDR reporting good clinical results has been published over the past few years. In review of the literature, most authors agree that patient selection is one of the most important factors affecting TDR outcomes. Especially for young patients suffering from DDD without any significant facet joint degeneration, deformity, instability, or osteopenia/osteoporosis, lumbar TDR might be a suitable alternative to lumbar fusion. Nonetheless, concerns regarding long-term outcome, implant durability, and possible very late complications might still impede the widespread adoption of lumbar TDR.

Compliance with ethical standards

Conflict of interest Stephan N. Salzmann, Nicolas Plais and Jennifer Shue declare that they have no conflict of interest. Federico P. Girardi reports grants from MiMedx, personal fees from Paradigm Spine, LLC, personal fees from HealthPoint Capital, LP, personal fees from Spineart USA, personal fees and other from Centinel Spine, grants from Spinal Kinetics, personal fees from Scient'x USA, personal fees from Pharmawrite, LLC, personal fees from DePuy Spine, personal fees from OrthoDevelopment Corp, personal fees from Gerson Lehrman Group, Inc., personal fees from Lanx, Inc., grants from Aesculap Implant Systems, other from Paradigm Spine, other from LifeSpine, other from Pioneer Surgical Technology, Inc., and other from Small Bone Innovations, outside the submitted work.

Human and animal rights and informed consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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