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# We Need to Talk about Lumbar Total Disc Replacement

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## ABSTRACT

**Background:** Replacement of a diseased lumbar intervertebral disc with an artificial device, a procedure known as lumbar total disc replacement (LTDR), has been practiced since the 1980s.

**Methods:** Comprehensive review of published literature germane to LTDR, but comment is restricted to high-quality evidence reporting implantation of lumbar artificial discs that have been commercially available for at least 15 years at the time of writing and which continue to be commercially available.

**Results:** LTDR is shown to be a noninferior (and sometimes superior) alternative to lumbar fusion in patients with discogenic low back pain and/or radicular pain attributable to lumbar disc degenerative disease (LDDD). Further, LTDR is a motion-preserving procedure, and evidence is emerging that it may also result in risk reduction for subsequent development and/or progression of adjacent segment disease.

**Conclusions:** In spite of the substantial logistical challenges to the safe introduction of LTDR to a health care facility, the procedure continues to gain acceptance, albeit slowly.

**Clinical Relevance:** Patients with LDDD who are considering an offer of spinal surgery can only provide valid and informed consent if they have been made aware of all reasonable surgical and nonsurgical options that may benefit them. Accordingly, and in those cases in which LTDR may have a role to play, patients under consideration for other forms of spinal surgery should be informed that this valid procedure exists.

TDR

Keywords: lumbar artificial disc replacement, lumbar total disc replacement, lumbar disc arthroplasty, lumbar disc degenerative disease, lumbar fusion, lumbar discectomy, informed consent

## INTRODUCTION

The most satisfactory definition for lumbar degenerative disc disease (LDDD) is "a condition where a damaged lumbar vertebral disc causes chronic pain in the lumbar region and/or leg (sciatica)," and the underlying disc changes include annular fissure, degeneration of the nucleus pulposus, and herniation.[1] Annular fissures (AFs) are separations of annular fibers from their attachment to the vertebral bone and are classed as concentric, radial, or transverse.[1] Nuclear degeneration (ND) manifests in a wide array of changes, including (but not restricted to) desiccation, fibrosis, and narrowing of the disc space.[2–5] A disc is described as herniated if there is localized displacement of disc material beyond the limits of the intervertebral disc space, and disc herniation (DH) is classified as protrusion or extrusion.[1] Of note, the presence of disc tissue extending beyond the edges of the ring apophyses, throughout the circumference of the disc, is referred to as bulging and is not considered a form of herniation.[6] It is important to appreciate that AFs, ND, and DH are radiologically evident in 39% to 76%, 48% to 85%, and 27% to 67% of asymptomatic patients, respectively.[7]

LDDD can present with low back pain (LBP), sciatica, or both. LBP attributable to LDDD is described as discogenic, is principally midline and immediate paraspinous in the lumbar area, and is aggravated by sitting and flexion.[8] Discogenic back pain is primarily mechanical in nature and is the result of internal disruption (ND and AFs), leading to the inability of the nucleus pulposus to properly bear the compression load and consequential and inappropriate diversion of this load to the posterior annulus.[9–11] However, there may also be a chemical component to discogenic LBP, as inflammatory agents contained in degraded matrix materials can stimulate and facilitate nociception.[12]

The term *sciatica* (or lumbar radiculopathy) refers to pain that radiates from the buttock down along the course of the sciatic nerve,[13] and neuroradiologic studies report that 87% of cases are associated with lumbar DH,[14] the remainder

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being either of extraspinal or of unknown origin.[15] The sciatic nerve is the largest nerve in the human body,[16] and disturbances anywhere along its course can give rise to symptoms; in the case of DH, mechanical compression (distortion) of the nerve root below the affected disk is the putative cause,[16] although the chemical impact of inflammatory cytokines may also contribute to symptoms.[17] Sciatica attributable to DH is typically aggravated by any Valsalva maneuver and is not always accompanied by LBP.[16] Weakness and muscle wasting of the affected limb is seen in less than half of cases, and foot drop is rare,[16] reflecting the view that sensory fibers of the sciatic nerve may be more sensitive to compression than its motor fibers[18] because the dorsal roots of spinal nerves that subserve nociception are unmyelinated and of small diameter (C group peripheral nerves), whereas motor function is subserved by fibers that are myelinated and of large diameter (A group peripheral nerves).[19] Most clinical tests devised to ascertain whether the reported sciatica is attributable to lumbar DH are a variation of the straight-leg raising test, which is sensitive (90%) but not specific.[20] A few days after the onset of symptoms, electromyography and nerve conduction studies reveal a topographic distribution of muscular denervation corresponding to a nerve root, thereby confirming a radiculopathy.[16]

In the majority of cases, sciatica resolves spontaneously within 3 months of onset.[16,21] Recovery may be facilitated with physical therapy aimed at enhancing control of the transversus abdominis and multifidus muscles, thereby stabilizing the spine, although the value of such regimes is difficult to measure.[16] Epidural injections of glucocorticoids are associated with short-term decrease in leg pain but not with a decrease in need for subsequent surgery.[22–24] Attempts to identify clinical and psychological variables of prognostic value in patients with sciatica have been unrewarding.[25] For example, of four studies considering the predictive value of duration of symptoms, only one[21] reported a longer duration to be associated with a poor outcome in cases of conservatively treated sciatica.[25] Notwithstanding the favorable natural history of symptoms in most cases, a substantial proportion of patients with recalcitrant and disabling sciatica are offered spinal surgery with a view to more effectively and more rapidly alleviating symptoms,[26] and this approach is reasonably premised on the observation that only surgery has been shown to benefit pain relief and a composite of condition-specific outcomes in the short, medium, and long term.[27,28] Nevertheless, it should be acknowledged that many patients will continue to experience mild to moderate symptoms 5 years after surgery.[29]

In the absence of DH, it is difficult to comment on the natural history of LDDD because of the lack of correlation between evident disease and symptoms,[30–32] with the inevitable consequence that prospective studies are limited to a subgroup of symptomatic patients. Furthermore, LDDD and its progression are not a mere function of age, because genetic background[33–35] and environmental factors (ie, mechanical, such as compressive loading, shear stress, and vibration)[12] profoundly influence the risk for the condition and its progression, and any correlation is further confounded by the observation that the presence of LDDD at a given level appears to be self-initiating and self-propagating at the same[36–38] and at adjacent[39] levels. Notwithstanding the imperfect association between age and LDDD, a relationship does exist,[40] reflected in and attributable to an age-related decline in the water[41,42] and macromolecule[43] content of intervertebral discs; accordingly, LDDD should be viewed as a chronic and progressive condition.

Disc herniation is the result of ND in the presence of AF,[44] and sciatica attributable to DH can improve substantially with a nonsurgical approach, resulting in a good or excellent outcome in 85% to 90% of cases.[45–47] Indeed, a recent and systematic review reports that magnetic resonance imaging–confirmed spontaneous regression of lumbar DH occurs in 96%, 79%, and 41% of sequestered, extruded, and protruded cases, respectively.[48] However, the relationship between clinical improvement and radiologic evidence of spontaneous resorption of herniated disc material is less clear.[47]

Beyond the self-initiating and self-propagating nature of LDDD at the same and adjacent levels, LDDD also appears to cause vertebral body changes[49] and osteoarthritis of the facet joints.[50] Furthermore, nerve root enhancement on contrast-enhanced magnetic resonance imaging, indicative of peridural fibrosis,[51,52] is evident in many unoperated cases of disc herniation,[53–56] but the prognostic value of this finding is doubtful.[25,57,58]

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## SURGICAL OPTION IN PATIENTS WITH LUMBAR DISC DEGENERATIVE DISEASE

Appropriately selected patients are offered surgery in cases of LDDD, and there are three surgical approaches available: 1) disectomy, 2) fusion procedures, and 3) lumbar total disc replacement.

### Discectomy

Discectomy, including microdiscectomy, endoscopic microdiscectomy, and laminectomy/laminotomy with discectomy, is offered to patients with lumbar DH with severe and persistent sciatica and/or neurological sequelae, and it is aimed at relieving nerve root compression or irritation caused by herniated disc material.[59] In an analysis of 30 809 patients who had undergone this procedure for this surgical indication, 78% reported good/excellent results at a mean follow-up of 6.1 years.[60] However, 1 large trial (n = 283) with low risk of bias revealed that although surgery did result in faster pain relief when compared with prolonged conservative treatment in patients who were symptomatic for 6 to 12 weeks, there was no difference after 1 year.[61] Although these findings were consistent with the 2-year results of the Spine Patient Outcomes Research Trial (SPORT; n = 501),[62] the 8-year results did report that surgery (in this case, open discectomy) was superior to nonoperative treatment in relieving symptoms and improving function.[63] However, the impact, positive or adverse, of discectomy on the natural course of LDDD remains unclear.[64] Further, repeat discectomy in cases of recurrent lumbar DH is less successful than primary discectomy in unoperated patients with lumbar DH,[57] especially if there is evidence of epidural fibrosis in the operative field.[65]

### Fusion Procedures

Fusion (arthrodesis) may be indicated in cases of discogenic pain caused by LDDD or in cases in which recurrent DH is causing mechanical back pain or sciatica; it is premised on the rationale that it reduces the nociceptive load by wide removal of the disrupted disc material and the stabilization of the affected motion disc segment(s).[66] The value of lumbar spine fusion for discogenic low back pain in cases of LDDD remains controversial and contested, with some reviews and meta-analyses being unable to conclude that surgery is superior to the conservative approach,[67] whereas others advocate the procedure.[68] In cases of recurrent disc herniations, there is little evidence in support of lumbar fusion for patients with evidence of instability or chronic LBP.[69] Although argument continues with respect to the quantification of risk of adjacent segment disease (ASD) following lumbar fusion, there is a consensus that this procedure is indeed associated with increased risk of pathology of adjacent segments.[70]

## LUMBAR TOTAL DISC REPLACEMENT

### Premise and Rationale

The intervertebral disc is an avascular structure, the principle function of which is to confer limited mobility on the spine and to act as a shock absorber. Lumbar total disc replacement (LTDR), which involves removing the patient's disc and replacing it with a lumbar artificial disc (LAD), was developed with a view to avoiding undesirable sequelae of lumbar arthrodesis (principally, motion sacrifice and ASD, but also a plethora of other fusion-related complications).[71] Put simply, the objective of LTDR is to remove the diseased disc that is causing pain while minimizing the risk of ASD and restoring normal motion in the postoperative patient (by sparing the physiological motion, maintaining an ideal sagittal balance, and stabilizing the lumbar spine in good curvature).

In brief, the rationale for LTDR is sound.

### History

#### *1960–1988*

The first LAD, consisting of a steel ball, was implanted in 1960, and the procedure was ultimately complicated by late postoperative subsidence.[72] Throughout the 1980s, small, observational (uncontrolled) series of LTDRs using the SB Charite LAD reported encouraging outcomes.[73–77] During this period, there were a total of 4 publications on the subject of LTDR[72–74,77]; of these, only the first case report was published in the English language.[72]

#### *1989–1998*

In 1990, Marnay implanted the first ProDisc I model of LAD,[71] and this design was subject to successive refinements, culminating in the launch of the ProDisc II in 1999.[78] Throughout the 1990s, using either an SB Charite model[79–83] or a ProDisc (I and/or II),[78,84] small and observational (uncon-

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trolled) series of LTDRs continued to indicate successful outcomes; however, poor results were reported following implantation of an alternative design.[85] In this period, there were 6 peer-reviewed articles reporting surgical outcomes,[79–83,85] 1 clinical review,[76] and 4 nonclinical biomechanical reports on the subject of LTDR.[86–88]

### *1999–2008*

The encouraging results at the end of the 1990s, albeit emanating from low-level evidence, went some way toward providing proof of principle in the concept of LTDR. As a consequence, uptake of the procedure by spinal surgeons (and investment by medical device companies in innovation in LAD design) flourished, reflected in 102 peer-reviewed articles reporting surgical outcomes,[78,89–189] 63 clinical reviews (including correspondence to journals),[190–252] 46 nonclinical biomaterial and biomechanical reports,[253–298] and the advent of 5 new LADs[99,118,165,176,299,300] to the market between 1999 and 2008.

### *2009–2017*

In spite of its complex and technically demanding nature, and because of the promising short- and mid-term results, spinal surgical centers continue to adopt LTDR, but slowly. Indeed, between 2009 and the time of writing (November 2017), a steady growth of the peer-reviewed literature on the subject of LTDR is reflected in a further 178 peer-reviewed articles reporting surgical outcomes,[301–479] 110 clinical reviews (including correspondence to journals),[66,398,480–558] 94 nonclinical biomaterial and biomechanical reports,* and the advent of 10 new LADs.†

## LADS: BIOMECHANICAL AND BIOMATERIAL CONSIDERATIONS

Given that meaningful discussion is predicated on meaningful research and its clinical applicability, reported herein are outcomes following implantation of only those LADs that have been and remain commercially available for at least 15 years at the time of writing *and* that have been investigated by Level 1 evidence (systematic review of randomized controlled trials [RCTs; Level 1a] or an individual RCT with a narrow confidence interval [Level 1b])[651] *and* have a minimum follow-up of five years. Devices not meeting these criteria are not systematically reviewed but, where relevant, will be discussed where their use has yielded insights into the challenges inherent in LTDR.

In order to be effective, a prosthetic intervertebral disc must have a solid nondestructive interface with the adjacent vertebral bodies, provide mobility, and resist wear.[648] LADs may be classed as articulating or nonarticulating, the former relying on a mechanical interface and the latter consisting of a deformable elastomeric core.[629]

### Articulating LADs

Typically, articulating LADS are classed according to back motion limitation in mobility and are therefore described as nonconstrained or semiconstrained.[71] A nonconstrained LAD has no specific limitation in its mobility, whereas a semiconstrained LAD may allow partial translation or no translation. The more constrained an LAD, the greater the risk of adverse sequelae following less-than-perfect primary placement of the device[75]; the less constrained an LAD, the greater the mechanical stresses imposed on the posterior joints.[94]

The ProDisc-L (Synthes Spine, West Chester, Pennsylvania) is the only LAD to fulfill our aforementioned and a priori criteria for critique[341,343]; this LAD is of a semiconstrained design that prevents pure translation, the latter restriction aimed at protecting the facets from excessive shear loading.[94] The device is based on a ball-and-socket principle and consists of two cobalt chrome alloy endplates and an ultra–high-molecular-weight polyethylene (UHMWPE) inlay; the endplates have central keels and small spikes for initial fixation on the vertebral bodies.[135]

### Nonarticulating LADs

The failure of articulating LADs to replicate the elasticity of the native disc has prompted the development of compressible yet nonarticulating devices aimed at more closely emulating the shock absorptive and flexural stiffness properties of the natural nondiseased intervertebral disc.[629] Challenges inherent in the development of such devices include the identification of materials that are biocompatible (given that the potential for periprosthetic tissue reaction would presumably be increased because such reactions relate to the number of particles generated[649]), that are resistant

*References 284, 319, 348, 377, 559–649.

†References 306, 313, 318, 324, 391, 402, 441, 562, 582, 643, 650.

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to wear and tear(s), and that provide sufficient adhesion to the vertebral bodies.[402] In any case, our aforementioned and a priori criteria for meaningful comment preclude such LADs being reviewed here.[629]

## Clinical Outcomes

The first LAD to be used on a large scale was the SB Charite (DePuy, Inc, Raynham, Massachusetts), and there is ample Level 1 evidence of its implantation resulting in superior[108,129,155,416] or noninferior‡ outcomes when compared with fusion in cases of LDDD, whereas there is no published Level 1 evidence of LTDR being inferior to its lumbar interbody fusion (LIF) comparator using this LAD. Studies (typically observational) representing lesser levels of evidence have also reported favorable outcomes of LTDR using this LAD.§ Series|| and case reports[97,112,149,161,409,456] of adverse events in association with use of the SB Charite are also plentiful. By 2007, more than 15 000 Charite LADs had been implanted.[161] In 2009, DePuy merged with Synthes (the manufacturer of ProDisc-L), whereupon the new entity (DePuy Synthes, part of the Johnson & Johnson Family of Companies) discontinued the SB Charite LAD in favor of the ProDisc-L LAD (see below).

Indeed, and for a range of LADs, there is a growing body of Level 1 evidence demonstrating superiority# or noninferiority[498,503,529,544,553] of LTDR when compared with fusion in the management of LDDD (with follow-up ranging from 1 to 4 years), whereas no comparative studies/meta-analyses conclude in favor of fusion over LTDR. Beyond comparisons between LIF and LTDR, many favorable (typically observational) reports of LTDR using a variety of LADs, but representing lower levels of evidence and/or a follow-up of less than 5 years, have also been published.** Poor outcomes have also been published,[334] as have case reports†† and series‡‡ of adverse events following implantation of these various LADs.

There has been (to our knowledge) only 1 study comparing outcomes following LTDR with outcomes following conservative rehabilitative therapy, in which 173 patients with LBP attributable to LDDD (of note, radicular pain was an exclusion criterion) were randomized to surgery (using the ProDisc II; n = 86) or to a nonsurgical approach consisting of supervised physical exercise in combination with cognitive support (n = 87).[461,652] Although the prespecified minimally important clinical differences were not achieved at 2 years, LBP and physical disability did exhibit a significantly greater improvement (reflected in the Oswestry score) among patients who had undergone LTDR than among patients managed conservatively.[437,461] At 8 years' follow-up, the findings continued to favor surgery over multidisciplinary rehabiliation.[468]

In an attempt to ensure clinical relevance and validity, and in keeping with the a priori criteria (ie, attention directed toward LTDR following implantation of LAD[s] that have been investigated through high-quality evidence and that have been [and remain] commercially available for at least fifteen years at the time of writing, thereby facilitating comment on long-term sequelae of this procedure using a given device), a discussion largely restricted to LTDR using the ProDisc-L now ensues.

A prospective, randomized, multicenter US Food and Drug Administration (FDA) investigational device exemption (IDE) study compared outcomes following LTDR using the ProDisc-L (n = 161) with outcomes following circumferential fusion (control group, n = 75) for the treatment of back and/or radicular pain attributable to 1-level LDDD. At 2 years, the LTDR group fared significantly better than the control group in terms of the Oswestry Disability Index, visual analogue pain assessment, patient satisfaction, and FDA-defined overall success; furthermore, radiographic flexion-extension range of movement (ROM) analysis revealed greater motion at 24 months than preoperatively in 89% of patients who had undergone LTDR.[119] This was also the case for patients who had undergone 2-level LTDR.[376] The observed superiority of LTDR over fusion was demonstrated in spite of the investigation not being designed to

‡*References 102, 103, 151, 154, 175, 418.*

§*References 98, 123, 141, 143, 160, 163, 170, 177, 179–181, 312, 386, 464.*

||*References 113, 115, 121, 126, 128, 138, 157, 172, 173, 319, 322, 345, 387, 392, 400, 410, 414, 443, 450, 460.*

#*References 78, 251, 306, 327, 375, 406, 408, 453, 485, 492, 504.*

***References 79–83, 95, 99, 100, 106, 111, 117, 120, 127, 133–135, 139, 144, 145, 147, 148, 152, 153, 156, 158, 159, 165, 166, 178, 182, 183, 187, 301, 305, 308–311, 313–315, 317, 318, 321, 323, 324, 326, 329, 331, 335, 347, 349, 352, 353, 356, 358–362, 364, 367–370, 372, 373, 381–384, 388–391, 393, 394, 402, 405–408, 411–413, 417, 420, 422–428, 430–432, 436–438, 440–442, 444, 446, 449, 452, 454, 455, 459, 460, 465, 467, 469, 471, 475.*

††*References 328, 344, 365, 439, 447, 448, 465.*

‡‡*References 118, 330, 354, 380, 419, 421, 460.*

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show a difference between the surgical techniques (ie, the study was only powered to demonstrate/refute noninferiority of LTDR when compared with the surgical standard of care [fusion]). At 5 years, observed improvements in outcome measures were maintained, the segmental ROM remained within the normal range following LTDR, and secondary surgical procedures had been required at the index level in 8% and 12% of LTDR and fusion patients, respectively.[343] Moreover, incidence of adjacent-level degeneration was evident in a significantly lower proportion of patients following LTDR (6.7%) than following fusion (23.8%),[341] and outcomes were comparable for patients who had undergone 1-level or 2-level LTDR.[332]

Since publication of that RCT, amelioration of symptoms and improvements in Oswestry Disability Index have consistently been reported in prospective studies of LTDR using the ProDisc-L investigating outcomes (and variables that might influence those outcomes), and examples include the following: good pain relief and functional improvement in the absence of device-related complications (n = 104; minimum follow-up of 2 years)[139]; demonstrable pain relief following the procedure at 2 years' follow-up, with some regression at 5 years' follow-up (but remaining significantly improved from preoperative pain levels; n = 36; minimum follow-up of 5 years)[369]; use of this procedure to treat symptomatic ASD following remote fusion (n = 20; minimum follow-up of 2 years)[92]; outcomes not adversely impacted by smoking (n = 104; minimum follow-up of 2 years;)[91]; outcomes not adversely affected by patient age greater than 60 years (n = 22; minimum follow-up of 2 years)[93]; successful outcomes achieved following bisegmental and tri-segmental implantation of this LAD (n = 25; minimum follow-up of 2years)[94]; improvement of physical capability following the procedure (n = 18; minimum follow-up of 1 year)[358]; results at 18 months' follow-up that were excellent (n = 11; 61%) or good (n = 3; 16%) in 14 of 18 patients (77%) and results at 6.5 years' follow-up that were excellent (n = 10; 55%) or good (n = 2; 11%) in 12 of 18 patients (66%).[364]

With respect to the consequences of LTDR for sagittal balance and lumbar spine movement following LTDR (using 1 of 3 models of LAD, including the ProDisc-L [n = 10], and where the device was confirmed radiologically to be centered), the following observations were made: an increase in disc height; no significant change in range of motion at the index level; no impact on pelvic incidence, pelvic tilt, or sacral slope; and an increase in L1-S1 lordosis (although 94% of subjects remained in the physiologic range).[132] In a prospective study of 42 patients who underwent ProDisc-L implantation at either L4-L5 or L5-S1, a mean increase in disc height was observed of 6.8 mm anteriorly and 3.5 mm posteriorly, and mean range of movement decreased from 7° to 5.7°; however, there was a positive relationship between postoperative disc height and ROM, prompting the investigators to suggest that patients with greater preoperative disc collapse are more likely to benefit from LTDR in terms of this outcome measure.[164] In a study of 12 patients (15 ProDisc-L LADs), implantation of 4 to 5 tantalum beads into the vertebrae adjacent to the surgical level at the time of surgery enabled radiostereometric analysis and revealed an average ROM at 12 months of 6.3° and 3° in the sagittal plane and on lateral bending, respectively; these post-LTDR ROMs, although less than normative values for ROM in these planes, are superior to observed ROMs (0° to 4°) following fusion.[167] In another study involving 200 patients (155 undergoing LTDR using the ProDisc-L and 45 undergoing fusion, and followed for at least 24 months), total lumbar ROM increased by 6.3° in those who had undergone LTDR at the L4-L5 level, and segmental analyses revealed that patients exhibited slight loss of relative contribution to total lumbar motion from the operative level but that this was compensated for by the caudal adjacent level (although no increase in total lumbar ROM was observed following LTDR in patients in whom the LAD was implanted at the L5-S1 level); in contrast, loss of relative ROM contribution from the operative level was observed following fusion (and was redistributed among multiple cranial adjacent levels, but primarily by the first cranial level).[406] In a prospective study of 40 patients scheduled for monosegmental or bisegmental LTDR using the ProDisc-L (comprising 45 LADs),[451] absolute segmental ROM and total lumbar ROM was assessed preoperatively and again 3 years postoperatively. No significant change was observed in either of these outcome measures (mean preoperative measures of absolute segmental ROM and total lumbar ROM were 6.9° and 34.9°, respectively, compared with mean postoperative measures of 7.3° and 35.8°, respectively; these results reflected an increase, a

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decrease, and no change in the former in 40%, 35%, and 25% of patients, respectively, and an increase, a decrease, and no change in the latter in 40%, 30%, and 30% of patients, respectively), while a compromised clinical outcome was observed in association with decreased total lumbar ROM. Segmental translation (mean ± SD: 0.83 mm ± 0.78 mm) at 24 months' follow-up has been demonstrated in a study of 35 LTDR patients in which the ProDisc-L was used, and the observed segmental translation was related to segmental ROM, to global lumbar ROM, and to observed change in the height of the functional spine unit.[429]

Some years ago, the International Society for the Advancement of Spine Surgery (ISASS) selected a panel of physicians and charged that panel with the task of educating patients, physicians, medical providers, reviewers, adjustors, case managers, insurers, and others on the subject of LTDR solely on the basis of best evidence-based scientific research. In 2015, this ISASS panel issued a policy statement concluding that single-level LTDR represents a proven technique and a well-tested technology that must be accepted for the benefit of patients and that single-level LTDR should lead to better outcomes and fewer complications than fusion surgery, with the additional putative benefit of exerting a protective effect on adjacent levels.[483] With respect to the ProDisc-L, the ISASS panel notes that patients suffering from persistent back pain and/or radicular pain attributable to LDDD are suitable candidates for LTDR using this LAD.[483]

Finally, it should also be noted that there is evidence that patients with LDDD have a greater likelihood of being totally pain free following LTDR (using 1 of 3 LADs, including the ProDisc-L) than following fusion.[513]

## COMPLICATIONS OF LTDR (USING THE PRODISC-L)

The complications of LTDR are classed as spinal or nonspinal.

### Nonspinal Complications of LTDR

The nonspinal complications of LTDR are classed as intraoperative (injury to ureter, nerves,[378] or large vessels[71,433]) or postoperative (infection,[404] retrograde ejaculation, wound problems, hematoma,[71] formation of retroperitoneal lymphocele[401]) and are common to all LTDR procedures that adopt an anterior lumbar surgical approach, irrespective of the LAD used. Although a less-invasive lateral approach[313,420] or a laparoscopic approach[430] for LTDR may impact the risk of the aforementioned and other complications, these innovations do not fulfill our a priori criteria for meaningful comment.

### Spinal Complications of LTDR

The spinal complications of LTDR are classed as those attributable to LAD malposition or those that can occur in the presence of (persistently) optimal LAD anchorage.

#### *Spinal LTDR Complications Attributable to LAD Malposition*

Malposition of the implanted LAD may be the result of suboptimal placement at the time of the procedure or the result of postoperative migration or subsidence.

*Suboptimal Anchorage of the LAD at the Time of Surgery*. LTDR is a technically challenging procedure, and it is unsurprising that implantation of the first generation of LADs (the SB Charite) was associated with a steep learning curve,[171] that suboptimal placement was seen in 60% of cases,[345] and that ideal placement of the LAD was associated with better clinical and functional outcomes.[345] The critical importance of primary anchorage has been reported for other LADs.[331,349,458]

A study of 201 cases with 5-10 years' follow-up in which the ProDisc II (the predecessor of ProDisc-L) was implanted by surgeons who were new to the procedure reported good results.[323] Nevertheless, in a series of 41 LTDR patients in which the ProDisc II was used, progression of facet degeneration at the index level was seen in 29.3% of cases and was related to malposition of the LAD on the frontal plane.[182]

With respect to the ProDisc-L, patients who suffered adverse events related to LTDR in an IDE RCT comprising 151 participants were significantly less satisfied than patients who did not suffer such adverse events at 24 months, emphasizing the importance of surgical precision and ease.[397] In 1 cohort of 44 patients undergoing LTDR using the ProDisc-L, operating time decreased with increasing experience, but ultimate clinical and functional

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outcomes were not compromised by undergoing the procedure with a less-experienced surgeon.[436]

In summary, ideal placement of the ProDisc-L (or any LAD) is a prerequisite for optimal outcomes; accordingly, there is an argument for acknowledged exclusion of cases with less-than-perfect primary anchorage when the rationale and/or long-term outcomes of LTDR are under investigation but inclusion when the real-world implications of performing this procedure are under investigation.

*Migration/Subsidence of the Implanted LAD in the Postoperative Period*. In a series of 52 patients who underwent LTDR using the ProDisc II, radiographs were independently analyzed 3 days postoperatively and again between 6 and 24 months postoperatively, and no cases of migration were observed.[184] However, in a series of 18 patients (19 LADs) in whom removal of a ProDisc-L was indicated on clinical grounds, migration and endplate subsidence of the prosthesis were evident in 3 (15%) and 4 (21%) cases, respectively; further, polyethylene dislodgement was evident in a further 3 (15%) cases.[348] To our knowledge, however, there are no data on the incidence of LAD migration and subsidence following ideal placement at the time of surgery.

### Spinal LTDR Complications Unrelated to LAD Malposition

*Periprosthetic Wear Debris*. Beyond device-related problems arising from LAD malposition, biological responses to periprosthetic wear debris can also give rise to spinal complications following LTDR.

The ProDisc-L LAD consists of 2 cobalt-chromium metallic endplates, which are fixed to the adjacent vertebral bodies and which articulate against a core made up of ultra–high-molecular-weight polyethylene (UHMWPE); hence, this LAD is classed as metal-on-polyethylene.[319] However, wear of the UHMWPE core has been observed in several models of metal-on-polyethylene LAD, with consequential and adverse implications for clinical outcomes.[319] Such periprosthetic tissue reactions were first described in 2009, when polyethylene particles were detected in 15 of 16 tissue samples taken from patients undergoing revision surgery for intractable pain following implantation of the SB Charite LAD (also a metal-on-polyethylene LAD) and the concentration of these particles was positively related to the periprosthetic tissue reaction.[414] The observed periprosthetic tissue reactions following LTDR (using the SB Charite LAD) are not dissimilar to those observed following total hip replacement and total knee replacement and can occasionally result in osteolyis, subsidence, migration, and fusion.[126,172,377,588] Of note, severe rim impingement of the implanted LAD is associated with increased production of biologically relevant UHMWPE particles, at least with the SB Charite LAD.[572]

With respect to the ProDisc-L, kinematic studies suggest that the osteolytic potential of wear particles associated with its use is lower than for total hip replacement as a consequence of lower wear rates.[568,646] However, posterior component impingement is seen in a considerable proportion of patients with ProDisc-L prostheses, especially following L4-L5 and bisegmental implantations, and this may be a risk factor for periprosthetic reactions in some patients.[162] Although the ProDisc-L has not been associated with numerous reports of adverse clinical outcomes attributable to periprosthetic tissue reaction, 1 series of 8 cases of this LAD being retrieved from seven patients has been reported, in which revision surgery was indicated for recalcitrant back pain (and osteolysis was evident in two cases) and subsequent periprosthetic tissue analysis revealed UHMWPE particles; however, the authors noted a 99% reduction in the particle numbers when compared with their own earlier studies of retrieved SB Charite LADs and concluded that wear resistance of contemporaneous LADs has improved greatly when compared with historical LADs.[319]

*Concerns Germane to Facet Arthrosis*. LTDR necessarily compromises the anterior longitudinal ligament and the annulus fibrosus (and sometimes the posterior longitudinal ligament), giving rise to concerns regarding the possibility of rotational instability.[443] One 10- to 14-year follow-up of 5 patients implanted with the SB Charite at one level revealed mobility in torsion identical to that of 6 volunteers (although normal kinematics were not restored in patients who had undergone bisegmental LTDR),[136] indicating that compensatory and active stabilizing elements play a beneficial role in vivo (thereby explaining the disparity with in vitro predictions from cadaveric studies[607] and finite models[623]). Indeed, it appears from a series of 10

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patients who underwent LTDR that the most important determinant of postoperative index-level and adjacent-level vertebral rotation in the sagittal plane is, in fact, preoperative ROM,[305] and this observation represents an unappreciated confounding factor for interpretation of nonclinical biomechanical and kinematic studies germane to this procedure.

Concerns regarding spinal instability following LTDR have profound implications for the facet joints of the posterior spine, which are true synovial joints found at every spinal level (except C1-C2) and which represent 2 of the 3 articulations between adjacent vertebrae, the third articulation being the intervertebral disc.[653] Accordingly, the total motion of the spine is a composite of the motion of the individual motion segments (or "3-joint complexes"), and the purpose of the bilateral facet joints (together with the disc) is to transfer loads and guide and constrain motions in the spine[534]; in this latter regard, and more specifically, an important function of the facet joints is to aid in the inhibition of rotation and excess motion in order to keep the vertebrae aligned.[648] In most cases, the disc is the primary load-bearing structure of any given motion segment, carrying up to 33% of total load borne by that segment, and this load is increased and decreased during spinal extension and flexion, respectively.[654] In cases of narrowed and functionally incompetent intervertebral discs, less body weight is supported by the disc and forces are consequentially transmitted across the facet joints,[654] reflected in the observation that up to 70% of an axial load can be borne by the facet joints in cases of severe LDDD (thus predisposing to facet arthrosis).[655]

Biomechanical studies have suggested that LTDR using ball-and-socket–type LADs (such as the ProDisc-L) results in increased facet loading at the surgical level,[624] especially following L4-L5 and L5-S1 LAD implantation,[590] and these observed increases in facet loading are more evident during lateral bending and axial rotation; and that posterior placement of the prosthesis provides a more physiologic load transfer to the vertebral body.[294,584,634] Although such devices may also increase ROM under axial load, they seem to maintain the helical axis of motion with similar facet contact forces to the intact spine.[635,637] Moreover, the degree of LAD constraint affects postimplantation kinematics and load transfer, such that a semiconstrained LAD (eg, ProDisc II, ProDisc-L, Maverick) results in the facets being partially unloaded when compared with unconstrained LADs (such as the SB Charite).[253] Further, a small study comparing paradoxical and coupled motions following LTDR (using the ProDisc-L; n = 10) and lumbar discectomy (n = 8) revealed similar postoperative overall sagittal ROM and coupled motion for the 2 procedures, but significantly greater paradoxical motion was seen at the L4-L5 level[109] (with possible adverse implication for facet degeneration) following LTDR.[147] Ultimately, in situ function of the ProDisc-L will be determined by how well it is incorporated into the mechanical environment within the disc space in vivo, which, in turn, will be determined by other spinal structures (such as ligaments, articular facets, vertebrae, and muscular stabilizers); violation of this mechanical environment could adversely impact LTDR patients, but, frustratingly, such violation also confounds biomechanical and kinematic studies.[639]

Clinical concerns regarding facet arthrosis following LTDR were first published in 2007, when a degradation of index-level facet joints were seen in 36% and 32% of patients implanted with SB Charite and ProDisc II LADs, respectively, in a series of 61 patients followed up for a minimum of 3 years.[187] These results were replicated in a series of 32 patients (41 ProDisc II LADs) with a minimum follow-up of 2 years, in which progression of index-level facet degeneration was observed in 29% of cases, although it was noted that risk of such progression was related to malposition of the prosthesis on the frontal plane and/or to 2-level LTDR.[182] In a retrospective study of 29 patients requiring revision surgery 16 to 84 months following LTDR using 1 of 3 LADs (SB Charite, n = 26; ProDisc II, n = 2; Acroflex, n = 1) because of intractable pain, 5 (17%) had facet fractures on computed tomography scan, 29 (100%) exhibited distraction or compression of the facets, 7 (25%) had endplate fracture-related subsidence (of less than 4 mm in 6 of these 7 cases), and 100% of the 8 patients who underwent pre-revision diagnostic facet injections reported at least partial and temporary relief of persistent leg pain (suggesting that clinically meaningful facet arthrosis was a major contributor to the need for revision).[450] In a prospective study of 93 patients (108 LADs) implanted with the ProDisc II and with an average follow-up of 53 months and a minimum follow-up

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of 24 months, progression of facet joint degeneration was evident in 20% of index-level facet joints but was significantly more common following LTDR at the lumbosacral junction than following surgery above this level.[446] In a prospective study of 116 patients, index-level facet arthrosis appeared or deteriorated in 20 of 59 patients (34%) who were randomized to LTDR using the ProDisc II compared with 2 of 57 patients (4%) who were randomized to conservative rehabilitative therapy, although the development or progression of facet arthrosis did not relate to clinical outcome in either group (at least by the time of the final [24-month postoperative] follow-up).[346] Interestingly, no facet changes were evident on independently assessed computed tomographic images secured 3 days postoperatively and again 6 to 24 months postoperatively in a series of 52 patients implanted with the ProDisc II in which the prosthesis was well-centered and where no migration had occurred.[184]

With respect to the ProDisc-L, Shin et al.[429] reported mean (± SD) segmental translation of 0.49 (± 49) mm and of 0.83 (± 0.78) mm at 1 month and 24 months, respectively, in a series of 35 consecutive patients, but they noted that the observed segmental translation was not associated with progressive facet arthrosis. It should be appreciated, however, that (adjacent) segment translation appears to be worse following lumbar fusion than after LTDR.[124,367]

With respect to clinical data germane to facet arthrosis following LTDR using the ProDisc-L, a retrospective study of 42 patients (51 LADs) followed for at least 3 years classed surgical levels as exhibiting postoperative and radiologically apparent progressive facet arthrosis (PFA; n = 19; 37%) or not exhibiting PFA (n = 32; 63%), and analysis revealed that preoperative facet tropism (asymmetry in both facet joint angles[656]) of greater than 5° was the only preoperatively identifiable determinant of PFA.[337] Of note, the clinical implications of PFA following LTDR using the ProDisc-L were not discussed in the aforementioned series,[337] which remains (to our knowledge) the only publication describing postimplantation facet arthrosis using this LAD, thus emphasizing the need for incidence data in this respect.

In brief, therefore, LDDD is a risk factor for facet arthrosis,[655] as are each of the surgical procedures aimed at alleviating symptoms attributable to this condition, including lumbar interbody fusion,[657] lumbar discectomy,[658,659] and LTDR.

*Heterotopic Ossification*. Heterotopic ossification (HO), which refers to the presence of bone in a soft tissue where bone does not normally exist, has been described following LTDR and is categorized as Class 0 (no HO), Class I (island of bone not within the margins of the disc and not interfering with motion), Class II (bone within the margins of the disc and interfering with ROM), Class III (the range of motion of the vertebral end plates is blocked by the formation of HO and/or postoperative osteophytes on fexion-extension of lateral bending photographs), or Class IV (bony ankyloses).[189] In a series of 65 patients (82 LADs) implanted with either the ProDisc (model not specified; 91.5%) or SB Charite (8.5%), HO was evident in 25 segments (30.5%) and was graded as Class I, II, and III in 9.8%, 14.6%, and 6.1% of segments, respectively (there were no cases of Class IV HO). In terms of ROM, visual analog scale (VAS), and Oswestry Disability Index, there was no difference between Class I and II (or, indeed, between patients with these classes of HO and patients without HO).[392] Patients with Class III HO were also statistically comparable with those without HO in terms of VAS and Oswestry Disability Index, but the former did exhibit significantly less segmental ROM than the latter.[392]

The observation of HO following LTDR in two singular case reports has prompted some commentators to hypothesize that use of keel-based LADs (such as the ProDisc II and its successor, the ProDisc-L) is more likely to result in this postoperative event.[374,399] Beyond a reduction in ROM, HO following LTDR can also be associated with radicular pain[307] and (rarely) with osteolysis (see below).[660]

*Osteolysis*. Osteolysis (a mode of degradation, which involves the destruction of bone[648]) can occur following orthopedic arthroplasty at the interface between bone and implant.[661] In the case of LTDR, this process is primarily driven by micromotion of the implant and the body's response to wear debris,[649] because debris particles disrupt bone homeostasis through an inflammatory process and consequential maturation of osteoclasts, thus increasing bone resorption.[661] Commentators have suggested that the low prevalence of osteolysis

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following LTDR (when compared with, say, total hip replacement) is attributable to the small ROM of LADs.[662]

With respect to the ProDisc-L, a series of 2 patients suffering postimplantation osteolysis has been reported in which retrieved implants and periprosthetic tissue reactions were studied and where osteolytic cysts were evident in adjacent vertebrae.[660] In the patient who had undergone hybrid LTDR, HO and tissue necrosis due to wear-induced inflammation was observed; in the patient who had undergone nonhybrid LTDR, inflammation was noted in tissue regions with metal and polyethylene wear debris, and the LAD exhibited signs of impingement; these findings suggest that wear debris and inflammation contribute to osteolysis following LTDR, but the authors also noted the rarity of this complication following the procedure.[660] Furthermore, there is reason to believe that the observed reduction of UHMWPE particle numbers in the case of the contemporary ProDisc-L will favorably impact the small risk of post-implantation osteolysis using this LAD.[319]

*Vertebral Body-Splitting Fractures*. Vertebral body-splitting fractures are rare following single-level LTDR using the ProDisc-L, the published literature consisting of a series of 2 Asian women (and therefore in which small vertebral bodies may have played a role) in whom no adverse long-term effects were evident as a result of this complication.[140] However, vertebral body-splitting fractures are more commonly seen following multilevel LTDR using the ProDisc-L and can be associated with sclerotic fracture margins, although the risk of this event can be reduced by modifying the surgical technique.[357]

## BENEFITS OF LTDR

The benefits of LTDR may be classed as those corollary to amelioration of symptomatology and those that are corollary to biomechanical and kinematic considerations.

### Benefits Corollary to Amelioration of Symptomatology

The aforementioned discussion has demonstrated that single-level LTDR is noninferior (or superior) to LIF for the treatment of recalcitrant and symptomatic LDDD presenting with LBP and/or radiculopathy. Given that chronic pain is causal to depression,[663] social isolation,[664] and work disability,[665] and since improved physical capability (in a way that is subjectively appreciated) is reported following implantation of the ProDisc-L,[358] it is unsurprising that successful LTDR has a profound and positive impact on a patient's quality of life by alleviating these psychosocial consequences of LDDD. Indeed, sex life and sexual function in men and women with symptomatic LDDD has been observed to improve following LTDR in a way that is commensurate with reduction in LBP, but this is not the case for men following LIF.[408]

### Benefits Corollary to Biomechanical and Kinematic Considerations

#### *Background*

A review of in vivo kinematic studies confirms a reduction in overall lumbar ROM (and reports instability at the rostral adjacent level in circa 30% of patients) following lumbar arthrodesis.[532] The risk of ASD-indicated surgery following arthrodesis varies from 7% at two years[453] to 16.5% at five years,[666] and may be as high as 36% ten years postarthrodesis.[666]

In contrast with arthrodesis, LTDR aims to replicate the complex biomechanical function of the motion segment in a way that improves quality of motion and does not provoke problems in the adjacent segments.[633] Specifically, LTDR seeks to offer a physiological preservation of motion at the treated motion segment, the putative corollary of which is avoidance of hypermobility and therefore consequential unloading of adjacent segments and, therefore, a reduced risk of ASD.[297,298,667–669]

#### *Design Features of the ProDisc-L (and Its Predecessor, ProDisc II) Germane to Biomechanical and Kinematic Considerations of LTDR*

The SB Charite, which is an unconstrained LAD[595] that is not keel based, was the most widely implanted device in LTDR surgery until circa 2009. The ProDisc-L LAD (and its predecessor, the ProDisc II) is a semiconstrained device composed of 2 cobalt-chromium-molybdenum endplates covered with a titanium plasma spray coating to promote bony ongrowth into the surface of the implant. The articulating surface is composed of a UHMWPE inlay contacting metal, and a keel at each endplate guides correct intraoperative orienta-

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tion of the LAD and is necessary to primary and long-term fixation.[357]

### *In Vitro Studies*

In vitro studies investigating adjacent segment biomechanics following LTDR versus arthrodesis are confounded by limitations of current in vitro methodology; for example, testing protocols for flexibility or stiffness under different loading scenarios (eg, pure moment or eccentric load) are premised on erroneous assumptions regarding postoperative motion behavior by the patient.[628] Notwithstanding and with full appreciation of these limitations, insights have been gained by cadaveric study and warrant mention.

A human cadaveric biomechanical study demonstrated that the degree of implant constraint influences facet/implant surgery and that an unconstrained LAD (with 5 degrees of freedom; SB Charite) at L5-S1 results in increased facet loading that is not seen following implantation of a semi-constrained LAD (with 3 degrees of freedom; ProDisc II) at the same level.[253] Moreover, when subjected to anterior-posterior shear, the semiconstrained ProDisc-L is more robust to in vitro wear rates than the unconstrained SB Charite.[585] Further cadaveric study on the impact of the device keel on vertebral compression properties following implantation of the ProDisc-L demonstrated that the keel introduces a reduction in stiffness to the implant-endplate interface.[638] Moreover, another cadaveric biomechanical study has demonstrated that ROM of operated and adjacent motion segments is preserved following implantation of the ProDisc-L at L4-L5, that the kinematics of adjacent segments was unaffected by implantation of this LAD, and that the procedure did not result in significant altered disc pressures in adjacent motion segments.[606] Finally, a cadaveric study has also compared arthrodesis with LTDR (using the ProDisc-L) in terms of flexion-extension, bilateral lateral bending, and bilateral torsion; the study also compared the results with an intact spine and demonstrated only minimal adjacent-level effects following 1- and 2-level LTDR constructs, whereas 1- and 2-level fusions resulted in increased adjacent-level effects in each of the motions tested.[298]

Finite element analyses comparing arthrodesis to LTDR (using the ProDisc II) at the L3-L4 level, using a validated 5-level intact model as a reference, revealed high ROM, annulus stress, and facet pressure at adjacent levels (especially at L2-L3) following arthrodesis, whereas adjacent level instability was not evident following LTDR, indicating that development and progression of ASD is more likely following arthrodesis than following LTDR.[623]

With respect to LTDR versus discectomy (rather than the usual comparator [arthrodesis]), a cadaveric biomechanical study (n = 7) compared L3-L4 facet loading under conditions simulating L4-L5 LTDR, L4-L5 discectomy, and a healthy L4-L5 intervertebral disc and reported significantly greater stress on the L3-L4 facets following L4-L5 discectomy (when compared with normal disc integrity at L4-L5) but no increase in L3-L4 facet loading following L4-L5 LTDR (when compared with normal disc integrity at L4-L5), suggesting that lumbar discectomy may indeed contribute to ASD and that LTDR may confer benefits in this respect over lumbar discectomy.[267] Indeed, another cadaveric biomechanical study evaluated compressive load in the proximal adjacent segment under various loading scenarios in 3 models (an intact sample, a discectomy sample, and a postimplantation LTDR sample) and reported significantly greater compressive loading in the proximal segment in the discectomy sample when compared with the intact model but no difference between compressive load in the proximal segment in the post-LTDR model versus the intact model, again suggesting that discectomy does indeed represent a greater risk for ASD than LTDR.[642] The results of these studies are consistent with the those of another cadaveric study (n = 10) that demonstrated that lumbar LTDR at L4-L5 maintained adjacent-level intradiscal and facet force pressures (under variable loading conditions) at values of intact spines, whereas each of these pressures were increased after arthrodesis at L4-L5 (and intradiscal pressures [but not facet force pressures] were also increased following discectomy at L4-L5).[587]

### *Clinical Studies*

The in vivo postoperative impact on intervertebral mobility of a mobile-core LAD (where the core is free to translate in the transverse plane during flexion-extension and lateral bending, thus allowing a moving axis of rotation and enabling the adjacent vertebrae to rotate without necessary accompanying translation) has been compared with that of a fixed-core design (where motion is allowed by a ball-and-

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socket configuration and where, therefore, the amount of intervertebral translation occurring with rotation is dependent on the radius of the core's curvature; the ProDisc-L), in which it was observed that ROM and motion distribution at implant level were not different between the two LAD designs (ie, a fixed-core design, such as the ProDisc-L, does not sacrifice ROM and yet does not run the risk of possible adverse effects of a mobile-core LAD on facet loading and segmental mobility).[383]

A prospective study of 116 patients who were randomized to LTDR using ProDisc II (n = 59) or conservative rehabilitative therapy (n = 57) and who were followed for a minimum of 2 years afforded a unique opportunity to comment upon ASD as a function of the natural history of LDDD versus ASD following implantation of a LAD, whereupon it was noted that ASD occurred with statistically comparable frequencies in the 2 arms of the study.[346]

Auerbach et al.[406] analyzed radiographic results 24 months following surgery in a prospective, multicenter RCT comparing single-level LTDR using the ProDisc-L (n = 155) with arthrodesis (n = 45) and reported significant improvement and no change in total lumbar ROM following LTDR at L4-L5 and L5-S1, respectively. Further, LTDR resulted in a significantly greater contribution by the operated level to postoperative total lumbar ROM (L4-L5, –2.5%; L5-S1, –5.1%) than did arthrodesis (–16.8%). Moreover, the relative contribution by the first cranial adjacent segment to total lumbar ROM increased by 12.1% following arthrodesis at L5-S1, whereas the respective figure was –1.2% following LTDR. Finally, a significantly increased ROM (6%) at the first adjacent caudal segment following LTDR was observed, but this was not the case following fusion (3%). In brief, therefore, LTDR using the ProDisc-L results in slight loss of relative contribution by the operated level to total lumbar ROM, which was compensated (at least after L4-L5 surgery) by the caudal adjacent segment level; in contrast, a far greater loss of contribution to total ROM by the operative level following arthrodesis was demonstrated, and this loss was redistributed among multiple cranial adjacent levels (especially the first cranial adjacent level), indicating that fusion represents greater risk for development and progression of ASD.[406]

In a retrospective review at a single center, further ASD-indicated surgery was required in 20 of 1000 (2%) consecutive patients who had undergone LTDR (at a mean postimplantation interval of 28.3 [range 0.5-85] months); of note, some of these patients had been operated within a randomized clinical trial of LTDR versus fusion, affording this surgical center access to 67 arthrodesis procedures for comparison purposes. Of these, 3 (4.5%) required reoperation to address ASD (at a mean postimplantation interval of 59.43 [range 40-96] months).[355] Further, upon review of the pre-LTDR magnetic resonance imaging scans (images were available for 14 of the 20 patients requiring surgery for ASD following LTDR), in no case had ASD progressed following implantation of the LAD.[355]

In 2008, a systematic review reported radiographically evident ASD in 314 of 926 patients (34%) and 31 of 313 patients (9%) following arthrodesis and LTDR, respectively; symptomatic ASD was reported in 173 of 1216 patients (14%) and 7 of 595 patients (1%) following arthrodesis and LTDR, respectively; these findings prompted a Class C recommendation in favor of LTDR over arthrodesis in an attempt to reduce risk of ASD following surgery for LDDD.[251]

Another systematic review of all cohort studies and randomized, controlled trials germane to ASD following LTDR versus fusion was conducted by Wang et al.[504] in 2012, in which the overall strength of the evidence for each key question was rated using the Grades of Recommendation Assessment, Development and Evaluation (GRADE). It was reported that (on the basis of moderate evidence) patients who undergo fusion are nearly 6 times more likely to require surgical treatment for ASD (pooled risk from 2 RCTs: 7%) than patients who undergo LTDR (pooled risk from 2 RCTs: 1.2%), but that the limited evidence precluded a definitive statement.[504]

In conclusion, the rationale that LTDR is associated with lower risk of ASD development and progression than arthrodesis is biomechanically and kinematically sound, and it is underpinned and supported by all available in vitro studies. Clinical results also indicate that LTDR is superior to arthrodesis in terms of postoperative ASD development and progression. Although the superiority of LTDR over fusion in terms of ASD risk cannot be said to be definitively proven, patients with symptomatic LDDD considering management options should be informed that the increased risk of ASD development and progression following arthrodesis

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is definitively proven; they should also be informed that development and progression of ASD is also seen following lumbar discectomy and as a consequence of the natural history of LDDD.

## CONTRAINDICATIONS AND INDICATIONS FOR LTDR

### Contraindications

Exclusion criteria for participation in the initial prospective, randomized, multicenter, IDE clinical trial comparing LTDR (using the ProDisc-L) with arthrodesis, published in 2007, were chosen with a view to maximizing comparability of the 2 procedures and minimizing the risk of confounding; they were never intended for adoption as contraindications for the procedure.[119] Informed by subsequent study and technological developments, and in order to accommodate case-by-case decision making in a real-world setting, the contraindications for LTDR are necessarily less stringent than the exclusion criteria of the initial IDE trial.

For example, LDDD at more than 1 level represented an exclusion criterion for the initial trial, but it has since been shown that 2-level LTDR using the ProDisc-L results in outcomes comparable to those of 1-level LTDR using this LAD.[332] Also, osteopenia (defined by specific dual energy X-ray absorptiometry bone density measures) was an exclusion criterion in the initial trial,[483] but subsequent technological advances in vertebral body augmentation now allows greater flexibility in the threshold measures of bone density formerly deemed a contraindication for this procedure.[93,600]

### Indications

In spite of widespread misconceptions, it is important to emphasize that LBP (with or without coexisting radicular pain) attributable to LDDD is not the sole indication for LTDR, and that patients with radicular pain (with or without coexisting LBP) attributable to LDDD should also be considered for this procedure (where symptoms persist beyond a trial of no less than 6 months' conservative treatment).[361,483,533]

Recurrent herniation is not uncommon following primary discectomy for lumbar DH,[368] and given that prior discectomy compromises the outcome of subsequent arthrodesis[416] and also subsequent repeat discectomy[670] but does not compromise the outcome of subsequent LTDR,[416] the indications for LTDR have been extended to include recurrent DH following primary discectomy.[368]

### Financial Implications of LTDR

Work disability is a major personal, financial, and public health burden,[671] and annual productivity losses attributable to LBP have been estimated at $28 billion in the United States alone,[672] reflecting the observation that LBP affects 600 million people and is the leading cause of disability worldwide.[673]

In the early years of LAD implantation and soon after the first device received FDA approval (October 2004), the Nationwide Inpatient Sample was used to analyze the revision burden following LTDR (11.2% of 7172) and fusion (5.5% of 62 731) for the years 2005 and 2006. The analysis found that the revision burden for LTDR fell well within the revision burden range for hip and knee replacement surgeries and noted that these latter procedures are generally considered cost effective.[398] In 2007, a cost-minimization model was employed to assess the financial implications of LTDR (using the SB Charite) versus 3 different techniques of lumbar fusion; the conclusion was that LTDR is likely to be more cost effective than arthrodesis (or, at worst, equivalent to arthrodesis).[252]

An in-depth financial analysis of 10 randomly selected patients from each arm of the ProDisc-L IDE RCT concluded that the hospital costs associated with LTDR are similar to transforaminal interbody fusion and to anterior spinal fusion (after excluding costs associated with recombinant human bone morphogenetic protein-2) but are significantly less than posterior spinal fusion.[199]

In a cohort of 53 prospectively studied patients undergoing 1- or 2-level LTDR using the ProDisc-L and 17 patients undergoing circumferential fusion for 1- or 2-level LDDD, in-depth analysis encompassing a wide range of financial parameters (eg, operating time, cost of implants, surgical and anaesthetic fees, hospital charges, length of stay, etc) revealed that patients undergoing 1-level ProDisc-L LTDR represented a significantly smaller financial burden than those undergoing 1-level arthrodesis (while charges were comparable for the 2 procedures for patients undergoing 2-level surgery).[104]

A cost comparison of patients undergoing 3-level LTDR (using the ProDisc-L; $n = 21$) versus 3-level arthrodesis ($n = 22$) revealed significantly lower costs in association with LTDR, and this was

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attributable to a mean of 3 fewer hospital days for patients implanted with an LAD.[449]

A randomized, controlled health economic study with 2 years' follow-up, using a design that factors in the cost to the individual and to society (eg, return to work, number of sick days, gain in quality-adjusted life years, etc), compared patients undergoing single-level LTDR (n = 80) using a variety of LADs (ProDisc-L, n = 28; SB Charite, n = 26; Maverick, n = 26) versus lumbar fusion (n = 72); the study concluded that LTDR is the more cost effective of the 2 surgical approaches.[445]

Another study compared 50 562 lumbar fusion procedures with 2415 LTDR procedures in terms of the need for reoperation and reported that LTDR was associated with significantly less risk of subsequent lumbar surgery in the first postoperative year (2.94% versus 4.01%), although no significant differences were observed between the 2 surgical approaches at 3-year and 5-year follow-up.[304]

Finally, analysis of Medicare Benefits Schedule claims data in Australia was used to compare the cost effectiveness of LTDR versus lumbar fusion and concluded that, overall, LTDR represented a cost-saving procedure when arthrodesis is the comparator.[500]

In summary, therefore, it appears that LTDR is more cost effective than its typical comparator (arthrodesis) from the perspective of patients, of society, and of health care providers.

## UPTAKE BY SPINAL SURGEONS

An offer of LTDR to patients with LDDD has become more likely in recent years,[445] but the anticipated rapid and widespread adoption of this procedure by spinal surgeons did not follow its FDA approval in 2004.[556]

For example, a retrospective analysis of the Nationwide Inpatient Sample between 2000 and 2009 revealed that surgical treatment for LDDD had increased 2.4-fold in the United States during this period, and this was reflected in an increase in all fusion procedures but not in LTDR.[488] Indeed, 911 LTDR procedures were performed in the United States in 2005 (a period commencing 3 months after FDA approval), and this had declined to 653 LTDR procedures by 2008.[510] At that time, these observations seemed to reflect the views of United States–based spinal surgeons; for example, of 133 surveyed spinal surgeons, 64% said they were less likely to perform LTDR than they would have been 1 year previously (although 42% of them had performed LTDR in the past), whereas 81% were more likely to perform cervical total disc replacement than they had been 1 year previously (although only 30% of them had ever performed this latter procedure).[527] However, the initial poor uptake of LTDR by spinal surgeons should be interpreted with full appreciation that less than 1% of those surveyed at the 2009 Annual Meeting of the American Orthopaedic Association said that they would opt for (any) surgical treatment if they personally and hypothetically suffered from chronic LBP attributable to LDDD, and, at that time, 77% of respondents persisted in the (now untenable[9]) view that the intervertebral disc is not the major cause of low back pain.[521] Moreover, in 2011, one retrospective study misleadingly reported that only 14.9% of patients with LDDD requiring surgery would be eligible for LTDR if all the exclusion criteria for the IDE trial (including diabetes mellitus and history of chronic disease) were to be (inappropriately) deemed contraindications for the procedure, but that this figure rose to 25.8% when only absolute contraindications were applied (the study still controversially deemed, for example, LDDD affecting more than 1 level as a contraindication).[551]

However, dampening enthusiasm for LTDR plateaued in or around 2009, and we are now in a period of slow but steady growth of the procedure, reflected in the publication of 178 surgical series since that time. In brief, LTDR has survived a difficult introduction to the spinal surgical community, is not being discarded by that community, and is now gaining acceptance by that community.

Notwithstanding the observations that LTDR is proven to be noninferior (or superior) to lumbar fusion, that the risk of postsurgical ASD development and/or progression appears to be less following LTDR when compared with arthrodesis, and that LTDR is more cost effective than lumbar fusion, the slow growth of LTDR is unsurprising because of the challenges inherent in the safe introduction of this procedure to a health care facility. These challenges can be classed as financial, logistical, and regulatory, and they are inextricably interdependent.

The logistical challenges in any attempt to safely introduce LTDR to a facility include, but are not restricted to, the following: flexibility in relation to access to intensive care facilities; the perceived need by some spinal surgical centers for a vascular

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surgeon to perform some of the surgery, or at least to be on standby[445]; the need for at least 2 spinal surgeons trained in LTDR to be available for cross-cover and to work together in a noncompetitive environment of collegiality; training of theater and ward staff; and development of a streamlined process in terms of preoperative and postoperative care. Of course, each of these logistical challenges has financial implications for the proposed surgeons and the proposed health care facility (see below) and are not unrelated to regulatory issues (see below).

Any endeavor to safely introduce LTDR to a facility has financial implications, and these can be classed as those relating to the patient, those relating to the facility, and those relating to surgical and medical staff. Clearly, where an insurance-dominated health care system does not provide financial cover for the subscriber's preferred treatment option of a proven noninferior procedure, demand for the procedure will be low (and this, in turn, will have implications for surgical volume and corollary adverse implications for retention of appropriate spinal surgical skills[674]). And if the eligibility criteria for supporting the procedure are too restrictive and fail to reflect advances since the initial trials that have confirmed noninferiority of LTDR when compared with fusion, patient demand and surgical skills are adversely affected.[510] In this scenario, surgeons may find themselves in the unenviable position of doing the bidding of the insurance companies (ie, acting as a rationing device). The financial implications for the surgeon also need to be addressed, as remuneration of a surgeon's time represents the basis of any relationship between a health insurance company and a service provider; again, nonremuneration of the surgeon in respect of LTDR may compel the surgeon to discontinue the LTDR service, again with adverse implications for patients and skills. Finally, a health care facility has running costs and also needs to be appropriately remunerated for LTDR, a procedure which has been shown to be noninferior and more cost effective than spinal fusion. Financial uncertainties surrounding any attempt to safely introduce LTDR will inevitably prevent the health care facility from committing resources to the proposed new service. Further, these financial uncertainties are, at least in part, related to regulatory issues.

The regulatory issues surrounding the safe introduction of LTDR can be classed as those relating to FDA (or equivalent) approval, those relating to eligibility criteria for financial support laid down by the health insurance companies, and those relating to professional standards of medical, paramedical, and nursing staff. FDA approval for LTDR is for single-level surgery only, because the IDE trial was designed and powered to test whether single-level LTDR was noninferior to spinal fusion[510] (notwithstanding the observation that 2-level and 1-level LTDR are equivalent [in the same IDE trial] in terms of clinical outcomes[332]). In spite of a growing body of subsequent studies that indicate that several of the exclusion criteria of the original IDE trial should not be deemed contraindications to LTDR, many health insurance companies nevertheless inappropriately adopted these trial-specific exclusion criteria as eligibility criteria for financial support for LTDR, and they continue to do so (again, with adverse consequences for demand by patients for the procedure and its uptake by surgeons).[510] Finally, the regulatory demands on surgeons and paramedical and nursing staff are exacting, and, in a litigious environment, medico-legal considerations discourage personnel from conducting a procedure that might not fulfill all eligibility criteria (even nonclinical criteria and irrespective of the perceived [in]appropriateness of such criteria[675]).[676]

The problems are best exemplified by the hypothetical surgeon who wants to introduce this noninferior and cost-effective procedure to his/her practice. First, the surgeon trains (or retrains) in a center of excellence for LTDR because of the unfamiliar nature of the procedure, and he or she ensures that a committed and competent colleague does likewise (and that someone looks after their practices in the interim, and that their mortgages are also paid). Of course, before committing to this sabbatical period of training, the spinal surgeon has secured (in writing) a commitment from the local health insurance companies to support LTDR in a nonrestrictive fashion (so that demand will ensure sufficient volume to maintain surgical proficiency and also so that the health care facility will be in a position to commit to this expansion of services) in a way that is not contingent upon the FDA altering the nature of its approval for single-level LTDR only (alternatively, or in addition, the surgeon has persuaded the FDA to alter the nature of its approval for LADs).

Clearly, this is breathtakingly difficult.

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The delivery of health care in much of the English-speaking world is insurance based, and therefore, in essence, neoconservative in outlook (ie, "Faster, better, cheaper"). This system of health care provision does not lend itself to the introduction of innovative surgical procedures; accordingly, many patients from English-speaking countries find themselves compelled to travel to other jurisdictions if they want to avail of LTDR and other technologies.[677]

## FUTURE PERSPECTIVES AND CHALLENGES

Notwithstanding the fact that one can now make an evidence-based assertion that LTDR is (at least) noninferior to lumbar fusion for many patients with LDDD, there remains a need to study and publish the long-term sequelae of this procedure. For example, what are the cumulative risks of device-related complications such as migration, subsidence, and biological reactions to UHMWPE particles after, say, 10 or 15 years? Equally, what is the risk of ASD 10 or 15 years after the procedure, and how does this risk compare with lumbar discectomy (LD), lumbar fusion, and the natural history of LDDD? Does LTDR mitigate against nonspinal sequelae of LDDD (such as osteoarthritis of the knee[678])?

The longest follow-up of LTDR was published in 2006, in a series of 53 patients with an average follow-up of 17 years and where first-generation LADs (now discontinued) were implemented, and where spontaneous ankylosis was seen in association with 32 of 63 LTDRs (60%), necessitating a secondary surgical procedure in 5 patients (9%).[138] Data germane to the ProDisc-L in terms of these observations and other outcomes and in the context of comparable periods of follow-up should be available, and these should be published.

With respect to future study, expansion of indications for LTDR need to be investigated. Specifically, an RCT of LTDR versus repeat lumbar discectomy in cases of recurrent disc herniation following primary LD is warranted (because primary LD adversely impacts outcomes of repeat LD[670] but does not adversely impact outcomes of LTDR[416]). Furthermore, future studies should attempt to identify preoperative prognostic indicators for LTDR versus its comparator and should factor in familiarity of the operating surgeons with each procedure into analyses.

It is widely acknowledged that the spinal surgical community is poorly served by the literature in respect of the management of low back pain.[679] Nevertheless, there is ample evidence to assert that LTDR is noninferior (and possibly superior) to lumbar fusion in patients with recalcitrant symptoms of back and/or radicular pain attributable to LDDD. The challenge rests on making this procedure more accessible to patients, to surgeons, and to health care facilities, and therefore addressing the logistic, financial, and regulatory issues that hamper the safe introduction of LTDR to a facility. It is incumbent upon spinal surgeons to work, together, to this end.

Rational debate surrounding LTDR is as legitimate as it is healthy. Advocates for the procedure point out that it is (at least) noninferior to spinal fusion for appropriately selected patients, that motion is not sacrificed, and that it may confer protections against subsequent development or progression of ASD, and they point to the published literature in support of this position.[483] Hesitation in introducing LTDR to a health care facility is, however, equally justified, given the aforementioned difficulties in doing so safely.

Spurious arguments against LTDR have, however, occasionally been articulated and are seen by some as a contrivance to disparage a procedure that has been tried, tested, and shown to be an evidence-based, motion-preserving, and noninferior alternative to spinal fusion for many patients with LDDD.[483]

Examples of specious arguments (and their respective rebuttals, *in parenthesis and italics*) include the following:

- "LTDR is a novel or experimental procedure." (*LTDR has been performed since the late 1980s and has been FDA approved since 2004.*)
- "LDDD is a benign disease and doesn't warrant the risks of LTDR." (*Any condition causing pain, depression, and social isolation cannot be labeled "benign"; in any case, only a patient can subjectively grade severity of disease and how it impacts his/her quality of life.*)
- "Longer-term data are needed." (*Longer-term data on LTDR are indeed required, and such data continue to emerge; however, the current lack of such data should not preclude disclosure of the existence and proven benefits of a noninferior procedure, just as lack of long-term data did not preclude patients from having access*

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*to total hip and knee replacements in the 1990s. Finally, the longer-term data we have on spinal fusion, in terms of ASD and in terms of reoperation, hardly represent a defense of spinal fusion.*)

- "LTDR is only indicated in cases of discogenic back pain." (*This is not true; LTDR is indicated in cases of LBP and/or radicular pain attributable to LDDD.*)
- "Well, personally, I don't believe in the procedure." (*No doctor should feel under pressure to advocate a procedure he/she doesn't believe in; however, the failure to disclose and discuss the existence of a noninferior procedure could be ethically and legally problematic.*)
- "It's simply too risky." (*The risks inherent in LTDR and spinal fusion need to be thoroughly explained, and patients should also understand that the natural course of LDDD is not necessarily benign and that adverse sequelae related to persistent and chronified pain [depression, social isolation, sexual dysfunction, etc] and to disease progression [ASD, scoliosis, osteoarthritis of the knee, etc] can occur; in the absence of full disclosure, ethical and legal issues may arise.*)

In brief, it rests on the patient (and not the doctor) to make an informed and personalized decision regarding the risks and benefits of LTDR in his/her case, and the patient's ability to do so depends on a patient-centered disclosure by the doctor.

## ETHICAL AND MEDICO-LEGAL IMPLICATIONS OF LTDR FOR THE SPINAL SURGEON

The ethical and legal requirements for informed consent prior to a proposed procedure derives from the concept of personal (patient) autonomy.[680] The competent patient can only make a voluntary, uncoerced, and informed decision to proceed following disclosure (by the treatment provider) and understanding (by the patient) of the risks and benefits of the proposed surgery *and* of alternative approaches. In other words, patient-centered medicine[681] cannot be practiced in the absence of shared decision making and patient-centered disclosure.[682] This is particularly true for spinal surgery,[683] especially given the concern expressed regarding the Internet as a source of information germane to LTDR.[526] Accordingly, a spinal surgeon who proposes lumbar fusion to a patient with LDDD but who fails to disclose and discuss an existing alternative and noninferior procedure (such as LTDR) is not fulfilling his/her duty of care to that patient and, as a result, is exposed professionally and legally. It is important also that there is documentary evidence of the spinal surgeon's full disclosure, given that weaknesses in the consenting procedure are major contributors to successful claims against doctors[684] and given that most postoperative patients don't recall any preoperative discussion regarding alternative treatment options.[685]

Examples of grievances that a dissatisfied postfusion patient might allege in the absence of full and documented preoperative disclosure regarding LTDR include the uninformed nature of the consent procedure and a consequential lack of awareness of an alternative operation that is proven to be noninferior and motion preserving and that may prevent progression of ASD. Clearly, and in the event of an arthrodesis-specific complication, the patient can allege that this adverse event would not have occurred if he/she had been allowed to opt for LTDR.

Grievances may not be restricted to dissatisfied postfusion patients and may be voiced by patients with LDDD who declined an offer of spinal fusion but who were never informed of LTDR. In this scenario, allegations could include that the decision to decline surgery was uninformed and made on the basis of a lack of awareness of a motion-preserving and noninferior alternative to arthrodesis. Further, the concept of pain chronification[686] and the progressive nature of LDDD should be explained to the patient in a timely manner, as undue delay could compromise the clinical outcome of LTDR[417] and because a patient may wish to minimize his/her risk of ASD development or progression on the basis of LTDR's putative protective effect in this regard.

Finally, and given the confrontational nature of litigation, a litigant could contend (by innuendo or otherwise) that the failure of the spinal surgeon to disclose the noninferior alternative was financially motivated.

Ultimately, the right to control one's own life and decide what happens to one's own body are well-established legal and ethical principles. Choosing to undergo or forego medical or surgical treatment

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requires the patient (not the doctor) to balance the potential risks and benefits of different approaches so the patient (not the doctor) can make an informed choice about what happens to his or her body.

After all, some of us are doctors, but we are all patients.

## CONCLUSION

LTDR is a noninferior alternative to lumbar fusion for many patients with LBP and/or radicular pain attributable to LDDD. Irrespective of whether spinal surgeons are advocates of LTDR, if they are to advocate for their patients, they must disclose the existence and discuss the concept of this procedure to patients who might benefit from it.

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