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Indications for Lumbar Total Disc Replacement: Selecting the Right Patient with the Right Indication for the Right Total Disc

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Abstract

Summary of Background Data

As with any surgery, care should be taken to determine patient selection criteria for lumbar TDR based on safety and optimizing outcome. These goals may initially be addressed by analyzing biomechanical implant function and early clinical experience, ongoing evaluation is needed to refine indications.

Objective

The purpose of this work was to synthesize information published on general indications for lumbar TDR. A secondary objective was to determine if indications vary for different TDR designs.

Methods

A comprehensive literature search was conducted to identify lumbar TDR articles. Articles were reviewed and patient selection criteria and indications were synthesized.

Results

With respect to safety, there was good agreement in the literature to exclude patients with osteopenia/osteoporosis or fracture. Risk of injury to vascular structures due to the anterior approach was often addressed by excluding patients with previous abdominal surgery in the area of disc pathology or increased age. The literature was very consistent on the primary indication for TDR being painful disc degeneration unresponsive to at least 6 months of nonoperative care. Literature investigating the impact of previous spine surgery was mixed; however, prior surgery was not necessarily a contra-indication, provided the patient otherwise met selection criteria. The literature was mixed on setting a minimum preoperative disc height as a selection criterion. There were no publications investigating whether some patients are better/worse candidates for specific TDR designs. Based on the literature a proposal for patient selection criteria is offered.

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Conclusions

Several TDR indications and contra-indications are widely accepted. No literature addresses particular TDR design being preferable for some patients. As with any spine surgery, ongoing evaluation of TDR outcomes will likely lead to more detailed general and device design specific indications.

keywords: *total disc replacement, lumbar spine, indications, comprehensive literature overview*
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Introduction

Some surgeons believe in strict adherence to a relatively short list of indications for total disc replacement (TDR). Singh et al.[1] proposed that if TDR use follows the pattern of pedicle screws and cylindrical cages, rapid growth will be followed by expanded indications, resulting in inconsistent clinical outcomes and increased complications, leading to curtailed use. If TDR is used in 'properly indicated patients', this rise and fall in use may be avoided. The appropriate indication for surgery is critical for success.[2] The first purpose of this review is to evaluate information regarding *general indications for TDR*. The second purpose is to develop an overview for determining *specific indications for different TDRs*.

Indications for Lumbar Fusion

Lumbar fusion is used to treat pain attributed to abnormal motion or mechanical insufficiency produced by degenerative change.[3] Often compressed nerves are released simultaneously to reduce back and leg pain. In the last 40 years, indications for fusion have remained largely constant. Described indications include: degenerative disc disease (DDD), isthmic spondylolisthesis, unstable spinal stenosis, degenerative spondylolisthesis, degenerative scoliosis, segmental instability, disc-related back pain, failed previous surgery, and post-facetectomy syndrome.[3,4] Bambakidis et.al.[4] define radiographic instability of a motion segment as translational motion of >3 mm in levels above L5-S1 or 5 mm at L5-S1, or motion segment angulation of >10° on lateral flexion/extension radiographs.

General Indications for Lumbar TDR

Some fusion indications have been found to be appropriate for lumbar TDR, as demonstrated in randomized Food and Drug Administration Investigational Device Exemption (FDA IDE) studies with up to five-year follow-up.[5,6] Wong et al.[7] proposed that the ideal TDR patient is likely earlier in the Kirkaldy-Willis degenerative cascade than a fusion patient. The primary indication for lumbar TDR is symptomatic DDD.[7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29] In defining general indications, data needed includes patient history, pain and disability, clinical and image findings, diagnostic procedures, and psychosocial factors. TDR indications/contraindications literature is summarized below.

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Patient data and medical history

Many contraindications are related to personal and medical characteristics (Table 1). Age ranges in different studies included: 18-60 years;[9,16,18,21,26,28,29,30,31,32,33,34,35] 18-70 years;[36,37] 20-55 years;[38] 20-60 years;[19] and, 30-55 years.[13] One study investigated a population over 60 years old and recommended TDR for patients with adequate bone quality and without circumferential spinal stenosis.[39]

TDRs were implanted after failed nonoperative therapy for a minimum of 6 months,[8,9,13,16,18,19,25,26,28,29,32,33,34,35,36,37,40,41,42] although nonoperative therapy duration varied from 338 to 9 months.[30]

Several studies included patients with prior surgery, such as microdiscectomy or percutaneous nucleotomy.[12,16,17,24,26,40,42,43] Others allowed patients with failed disc excision,[11] failed spine surgery,[26] prior fusion with adjacent segment disease (ASD),[12,41,44,45] and below a previous long fusion for scoliosis.[46] Bertagnoli et al.[30,44] found no differences in outcomes for patients with prior posterior discectomy or laminectomy vs. those with no previous surgery for both single- and multi-level TDR. Leahy et al.[14] found no statistically significant differences in outcomes for patients with no previous lumbar surgery vs. those with a previous discectomy. Geisler et al.[47] studied patients from the Charité IDE trial with and without prior back surgery. There were no significant differences in Oswestry Disability Index (ODI) and visual analog scales (VAS) pain scores. At 2-year follow-up, both groups had similar levels of satisfaction and return-to-work. Tropiano et al.[26] found satisfactory results in 90% of patients with previous surgery. Zeegers et al.[43] found that previous surgery was not related to outcome at 2-year follow-up, in contrast to 1-year results. Siepe et al.[24] found no significant differences between DDD and DDD post-discectomy groups. Pre-existing leg pain did not deteriorate after disc replacement. Others suggest a negative impact of previous spine surgery on outcomes. Gornet et al.[36] described exclusion criteria as prior posterior lumbar surgery with significant morbidity, but discectomy, laminotomy/laminectomy, and intradiscal procedures were not excluded. Blondel et al.[48] found that patients with previous surgery at the TDR level had the poorest outcomes. ODI scores were significantly higher for patients with postdiscectomy syndrome. Radicular pain VAS scores were significantly higher for patients with recurrent disc herniation. Tropiano et al.[25,26] reported patients with failed back surgery experienced notable radicular pain after ProDisc implantation, possibly due to epidural fibrosis resulting in nerve root traction after intervertebral distraction.

Pain and disability

TDR indications are generally back and/or leg pain with no nerve root compression[9,28,30,49] or back pain with/without leg pain.[13,16,29,34,35,36,38,40,42] These symptoms can be quantified using patient self-assessments. For potential TDR patients, indications have been described as preoperative VAS back pain scores of at least 40[9,18,34,35,37] or 50[38] of 100. Preoperative ODI score >30%[9,18,19,33,35,36,38] or 40%[29,32,37] have been required.

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Clinical findings

There is no specific literature about clinical examination prior to TDR. In case of CT scan or MRI findings of central canal and/or the lateral recess stenosis, clinical evaluation should focus on nerve compression.

Imaging

X-ray, CT, or MRI findings are used to further define indications for TDR. X-rays are used primarily to assess bony anatomy and alignment, and used to exclude diagnoses such as scoliosis, spondylolisthesis, and fractures.[50] CTs are also used to exclude other diagnoses. CT may be used to assess the spinal canal, vertebral bony anatomy and posterior joints, and may be more effective than X-rays for identifying osteophytes or endplate sclerosis. MRI can be used to evaluate the spinal canal, space for neural structures, bony alignment and facet joints, and provides direct assessment of neural and disc structures.[50]

The role of preoperative disc height has been investigated. Suggested indications for TDR included an intervertebral disc height of >4 mm, with or without scarring, and thickening of annulus fibrosis with osteophytes indicating osteoarthritis.[16,31] However, Bertagnoli et al.[30] showed that preoperative disc height did not effect outcomes, while Siepe et al.[22] found that patients with more advanced DDD and reduced disc height had superior satisfaction rates. They found TDR was a viable treatment for advanced DDD, but reduced ROM should be expected.

Some variations in indications include mono-segmental DDD with or without Modic changes,[24] DDD and contained disc herniation,[24] segmental instability due to DDD,[12,45] isolated disc resorption,[12] abnormal discs related to genetic inability to form normal collagen,[12] stenosis where fusion is indicated,[12,45] low-grade spondylolisthesis,[12,45] and degenerative rotational scoliolis.[44] Jehan et al.[46] allowed previous long fusion for scoliosis. Siepe et al.[24] compared clinical outcomes in TDR patients with DDD, DDD+disc herniation, DDD post-discectomy, and DDD+Modic changes. All groups improved, with the best results achieved for DDD+disc herniation. Modic changes did not significantly influence outcome.

Radiographic measures including sacral tilt, pelvic tilt, pelvic incidence, and global lordosis are used to characterize sagittal balance. While some studies found that DDD patients generally do not have abnormal sagittal balance,[51,52] others reported improved balance post-TDR.[53,54]

Invasive diagnostic procedures

Provocative discography has been described as the single most important diagnostic tool for DDD.[50] It is recommended for patients who failed nonoperative treatment and whose X-rays and MRI show now other obvious pathologies.[56] Berg et al.[58] found that the surgical decision changed in 71% of patients based on information gained from discography.

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Facet joint injections are important to determine if pain is facet mediated, in which case TDR may be contra-indicated. Compromised outcomes were associated with more severe, multilevel degenerative disease including facet arthritis.[32]

Bone quality

Vertebral body fracture can occur during TDR placement or postoperatively. This can be a serious complication. Another risk is device subsidence into the vertebral body, resulting in pain and/or compromised biomechanical TDR function. In a cadaveric study, Lee[59] investigated bone mineral density (BMD) assessed by CT. He suggested BMD not be <-1.5 standard deviations below the mean value for young adults. For values of -2.0 to -1.5, he advised caution, and TDR be avoided in patients with T-scores <-2. Some studies used osteoporosis as an exclusion criteria,[29] other used osteopenia.[9,21] Currently, it seems general consensus is to exclude patients with DEXA T-scores <-1.0, the World Health Organization definition of osteopenia.[60]

Psychosocial and psychological factors

Psychosocial factors have more impact on back pain disability than biomedical or biomechanical factors.[61] Most clearly linked to back pain are depression, anxiety, distress, self-perceived poor health, and sexual and/or physical abuse.[61] Depression, anxiety, psychosis, bipolar disorder, and narcotic abuse, can significantly affect surgical outcomes.[62] Patients with both medical and psychosocial risk factors had the poorest outcomes.[62] TDR inclusion criteria require that patients are mentally, emotionally, and physically able to understand the procedure, grant informed consent, and comply with postoperative care instructions.

Levels operated

Siepe et al.[23] found that ProDisc at L4-L5 resulted in better outcomes and higher patient satisfaction than use at L5-S1; however, L5-S1 patients had lower complication and reoperation rates. Some studies evaluated single-level TDR only at L4-L5 or L5-S1,[9,18,21,22,28,33,35,36] others included two-level TDR from L3 to S1,[8,10,11,13,15,17,29,31,32,37,41] and some included three-level[26] and four-level[12,44] TDR. Tropiano et al.[25,26] found TDR could be used successfully at 2 or 3 contiguous levels. Zigler et al.[64] found no differences in 1-vs. 2-level outcomes, with both groups improving significantly. Siepe et al.[23] reported better outcomes for single-level than for 2-level procedures, associated with greater complication and reoperation rates. Siepe et al.[24] found bisegmental TDR results deteriorated at 12 and 24 months compared with the monosegmental outcomes. Patient satisfaction rates were 85.7% for mono- and 64.3% for bi-segmental TDR. Chin[31] found more favorable results in patients with isolated disc disease compared with multi-level disease.

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TDR contraindications

In studies reviewing large series of fusion cases to determine how many would have been TDR candidates, the figure was <10%.[7,,31] Numerous contraindications to TDR are cited in the literature (Table 1). Chin et al.[31] and Huang et al.[65] considered contraindications to fall under two broad categories: 1) Painful conditions not caused by the disc, and 2) Conditions that may compromise long-term device functionality.

Table 1. Contraindications to TDR Cited in Clinical Studies

Anatomical / inherent / degenerative / mechanical	**Subsidence / dislocation risk**
Pars defects[37]	Osteoporosis[7,9,19,21,25,26,33,34,36,43,8,29,30,37,38,44,49,65,79,80]
Fracture at L4, L5 or S1[9] or compromised vertebral body[7,16,24,29,35,38,79,81]	Endocrine or metabolic disorder known to affect osteogenesis[36]
Disc height < 3mm[10], <4mm[7]	Metabolic bone disease[7,9,19,21,24,29,37,43,49,81]
End stage disc resorption and collapse[19]	Osteopenia[7,9,12,16,19,21,26,31,37,49,82]
Facet ankylosis[7]	Osteopathy[7]
Facet joint arthrosis/ degeneration[7,8,9,10,11,12,14,15,16,17,19,21,24,25,26,29,30,31,33,34,35,37,38,41,44,49,65, 78,79,80,81, 82,83]	Paget disease[7,21]
Retrolisthesis[7]	Chronic steroid use[9,19,21,29,37,49,83]
Posterior element insufficiency[7,21,24,26,36,43,65]	
Postsurgical deficiency of posterior elements [25,31] or prior posterior lumbar surgery with significant morbidity[36]	**Pathology not, or possibly not, treatable by TDR**
Scoliosis [7,9,12,13,16,21,24, 31,33,34,35,36,37,40,49,65,81,84] or major deformity[15,19,25,26,29,37,38,41,4482]	Nerve root compression[7,16,35]
Irregular vertebral body endplate shape[7,24,29,81]	Positive straight leg raise[9]
Spondylosis[7,9,16,21,24,30,31,35,37,43,49,65,81,82]	Radicular pain symptomology[7,15,19,29,37,43,81,82]
Spondylolisthesis[7,9,11,13,15,16,19,24,29,30,31,33,34,35,36,37,38,41,43,44,49, 65,78,80,81,82,83]	Straight leg raise producing pain below knee[16,35,37]
Isthmic spondylolysis / olisthesis[19,21,38]	Noncontained herniated nucleus pulposus[7,9,12,16,1925,31,33,34,49,65,82]
Lumbosacral joint anomalies[81]	Scarring from previous surgery[43]
Instability[14,21,24,37,40,81]	Arachnoiditis[7,9,12,19,49]
Prior decompressive laminectomy[12]	Stenosis[7,9,12,1319,21,24,25,29,30,31,33,34,36,37,38,41,43,44,49,65,78,81,82]
Previous fusion[7,9,11,15,16,19,21,29,30,33,34,36,37,38,44,49,79]	Multilevel degeneration beyond 1 or 2 levels specified for TDR[9,19,29,33,34,36,37,38,49]
Pseudoarthrosis[7,12,31,65]	Previous spinal surgery at affected level – except for discectomy, laminotomy/ectomy, without accompanying facetotomy, or intradiscal procedures at the level to be treated[9,13,24,36,49,81]
	Fibromyalgia[7]
Possibly reaction on implant material	Cervical myelopathy[21]
History of hypersensitivity to protein pharmaceuticals or collagen[36]	

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History of implant rejection[19]	**General**
Metal allergy[7,9,19,24,29,30,34,36,37,44,49,79,81]	Infection[7,8,9,19,24,26,29,30,34,36,37,38,41,43,44,49,81]
History of anaphylaxis[36]	Active hepatitis[21]
	Active malignancy[19,21,29,34,36,37]
Anterior approach related	3 or more Waddell signs[13]
Obesity – definition varied with study[7-9,13,15,16,19,21,29,30,34,35,37,44,49]	Autoimmune disorder[7,9,19,21,29,34,36,37,49,83]
Vascular anatomy that is aberrant[7]	Pregnancy[7,19?9,26,29,30,34,38,41,44,49,79]
Vascular calcification[7]	Psychosocial disorder[7,36?8,9,12,13,19,37,38,49,80]
Previous abdominal surgery[7,26,37]	Osteomyelitis[7]
Abdominal wall hernia[12]	Spondylodiscitis[7]
Previous iliofemoral phlebitis[12]	Chronic disease of a major organ – cardiac failure, hepatitis, diabetes[7,26]
Abdominal pain profile[19]	Neuromuscular disease[30,44]
Previous vascular surgery[7]	Ankylosing spondylitis[7]
Prior retroperitoneal radiation[7,12,19]	Spinal tumor[7,9,16,19,24,35,37,38,41,49,81]
Prior surgery at the involved level[7,19,36,37,41,81]	
	Other
	Previous exposure to any or all bone morphogenetic proteins (human or animal)[36]

Discussion

There are several widely described general TDR indications including painful DDD unresponsive to >6 months of nonoperative care, no significant facet joint degeneration, no osteopenia/osteoporosis, and lack of conditions that may compromise outcome and/or interfere with proper TDR functioning such as severe instability. They are mainly base on FDA-study-related parameters and surgeons' experiences. To date, there is nothing published about potentially different indications for different TDR types with regard to design or materials.

TDR Design and Material

Lemaire et al.[2] proposed that "disc prosthesis is indicated particularly in situations where restoration of a center of rotation and redefinition of segmental kinematics are required." But TDR designs simulate different disc functions. Inherent in current designs are disc height restoration, intervertebral angle, and varying degrees of motion and stability.

TDR designs include functional two- and three-component ball and socket variations with gliding surfaces and 1-piece designs consisting of multiple components bonded together or one compact component (Table 2). These designs inherently have different biomechanical characteristics, leading to advantages and disadvantages. Spherical ball and socket designs provide axial rotational without limitation, but with risk of damaging

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surrounding anatomy, namely facet joints. This design does not provide load sharing in axial compression. Nevertheless spherical ball and socket discs with polyethylene have minimal elastic features with potential positive influence on axial load distribution at the vertebral endplates. Spherical ball and socket discs are generally metal-on-metal, metal-on-polyethylene, or PEEK-on-PEEK. Patients with metal-on-metal devices may have increased metallic ion levels from the implant,[66,67,68] a phenomenon much more documented in hip implants.[71,72,73] One TDR study found some of the serum ion levels to be greater than reported for hip replacements;[66] while other studies found the levels to be similar for hip replacement[67] and below levels determined high enough to merit monitoring of hip replacement patients68 as described by the Medicines and Healthcare Products Regulatory Agency[69] or in more recent literature.[70] Some metal-on-polyethylene designs may become impinged on one area of the core[74] or on an area of the metal plates.[75,76] Deformation and failure of polyethylene cores have occurred, often when devices were inaccurately placed or when inappropriate prosthetic components were used.

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Table 2. TDRs: Design and Materials.

Name of TDR	Design	Material
Functional three-component		
Charité Artificial Disc (DePuy Spine) [A]	3 component ball and socket, 2 equal articulating surfaces	CoCr – UHMWPE – CoCr
InMotion (DePuy Spine) [A]	3 component ball and socket, 2 equal articulating surfaces (further development of Charité Artificial Disc)	CoCr – UHMWPE – CoCr
Kineflex-L (Spinal Motion, Inc.) [I]	3 component ball and socket, 2 equal articulating surfaces	CoCr – CoCr – CrCo
Activ L (Aesculap / BBraun) [I]	3 component ball and socket, 2 equal articulating surfaces	CoCr – UHMWPE - CoCr
Dynardi (Zimmer) [NA]	3 component ball and socket, 2 equal articulating surfaces	CoCr – Sulene PE - CoCr
Mobidisc (LDR Spine)[I]	3 component with 2 articulating surfaces: 1 ball and socket superior surface and 1 flat inferior surface	CoCr – UHMWPE – CoCr
Orbit (Globus Medical)[NA]	3 component with 2 articulating surfaces: 1 ball and socket superior surface and 1 cylindrical inferior surface (for extension/flexion)	PEEK – PEEK - PEEK
Functional two-component		
ProDisc-L (DePuy Synthes) [A]	3 component ball and socket, 1 articulating surface, core affixed to caudal plate	CoCr – UHMWPE-CoCr
Maverick (Medtronic)[I]	2 component ball and socket, 1 articulating surface	CoCr – CoCr
Flexicore (Stryker) [I]	2 component ball and socket, 1 articulating surface, internal stiff stop of axial rotation	CoCr – CoCr
XL TDR (NuVasive) [I]	2 component ball and socket, 1 articulating surface	CoCr - CoCr
Functional one-component		
Freedom (AxioMed) [I]	1-piece bonded viscoelastic, no articulating surface	Ti – SPCU - Ti
M6-L (Spinal Kinetics, Inc.)[NA]	1-piece viscoelastic, with movable core - not bonded to plates	Ti - PCU core - Ti, UHMWPE fiber annulus, PCU sheath
Cadisc-L (Ranier)[NA]	1-piece bonded viscoelastic, no articulating surface	PCU with graduated modulus
LP-ESP (FH Orthopedics) [NA]	1-piece viscoelastic, no articulating surface	Ti plates, silicone core filled with microvoids, surrounded by PCU
Physio-L (K2M) [NA]	1-piece viscoelastic, no articulating surface	Ti – PCU – Ti multidurometer core

CoCr = cobalt chrome; PCU = polycarbonate urethane; SPCU = silicone polycarbonate urethane; Ti = titanium alloy; UHMWPE = ultra high molecular weight polyethylene

FDA status: [A] Approved; [I] Investigational; [NA] Not approved, not involved in IDE trial at this time

One-piece discs consist of combinations of metal and polymers or graduated modulus elastomers, where simultaneous injection of polymers with different moduli (stiffness) provides a dual modulus disc with a graduated modulus region. Designs with one or more components implanted as one piece can potentially provide performance characteristics most like those of a healthy disc because they are viscoelastic.[77] They can simulate a disc to a large extent, but with equal and reduced[19,77] ROM in every direction due to the homogeneous material. The natural intervertebral disc needs dampening properties for producing motion, because it does not have typical joint surfaces.

To date, there is no research addressing whether a particular TDR design may be better for some patients than for others. Kinematic studies may be needed to determine if motion pattern or other characteristics afforded by a particular design may best address specific needs of an individual patient.

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Specific Indications for Lumbar TDR

There is no guide to "determine the right patient with the right indication for the right TDR." More is known about the "right patient" than the "right total disc," nearly nothing about the "right TDR type." Bertagnoli et al.[78] correlated surgical outcome with indications and categorized prime, good, borderline, and poor indications based on combinations of the number of levels operated, disc space height, and the condition of facet joints and adjacent segments. The authors always used the same disc in these different patient groups, as no viscoelastic disc was marketed at the time.

Compared to discs with spherical ball and socket gliding surfaces (Table 2), viscoelastic discs may be judged on their design expanding TDR indications. But there are differences between various viscoelastic discs and between different ball and socket discs. Thus it is impossible to propose specific indications for *all* ball and socket discs and for *all* viscoelastic discs.

It is desired to determine the "right TDR" for each patient, but no clinical TDR guide exists. In comparison to spherical ball and socket discs (Table 3) advantages of viscoelastic discs are related to more stable biomechanical properties.

Table 3. Functional Properties of Ball and Socket vs. Viscoelastic TDRs.

Characteristic Compared to Natural Disc	Metal-on-Metal	Metal-on-Poly	Viscoelastic one-Piece
1. Restoration of normal/adjacent Disc Height	(+)	(+)	(+)
2. Restoration of Disc Angle	(+)	(+)	(+)
3. Mimics Quantity of Motion (ROM)	-	-	(-)
4. Mimics Quality of Motion (stiffness, COR, NZ)	-	-	(-)
5. Stability (Passive Restraint)	-	-	(+)
6. Shock Damping	-	(-)	+

1. & 2. Restoration of normal disc height and disc angle depends on the assortment of available implants in relation to patient's disc height and disc angle variations. The disc height is most stable in the long run in metal-on-metal discs, followed by metal-on-poly implants. Most viscoelastic one-piece discs can better sustain the disc angle than functional 2- or 3-component discs.

3. No disc has physiological ROM to the different directions (sagittal, frontal, transversal plane). Spherical ball and socket discs imply always hypermobility.

4. There is no disc with complete qualitative physiological features.

5. Stability is not to separate from quantity and quality of motion. The intervertebral motion has much more resistance in viscoelastic discs.

6. Damping function is the pre-condition for any motion in viscoelastic one-piece discs. Material Poly has a low degree of elasticity.

Devices providing suitable ROM and stability may be appropriate for patients with a wide set of TDR indications. Huang et al.[65] suggested contraindications may vary between different implant designs, specifically related to constraint, noting that constrained designs may be more suitable for patients with instability such as spondylolisthesis or post-facetectomy instability, or patients with mild facet arthrosis. Some 1-piece viscoelastic discs have limited ROM which may not protect adjacent levels.

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Many questions must be answered before having specific indications for the "right total disc," including:

1. Is there osteoporosis/osteopenia?

2. Is there structural or degenerative scoliosis?

3. Is there a loss of lordotic angle in the segment or the lumbar spine as a whole?

4. Is there central stenosis?

5. Is there foraminal stenosis?

6. Is there a pars defect?

7. Is there anterolisthesis?

8. Is there retrolisthesis?

9. Is there lateral olisthesis?

10. How unstable is the segment?

11. How much height has the disc lost compared to a healthy adjacent disc?

12. Are Modic changes present?

13. Are facet joints normal?

14. Are there osteophytes and where?

15. At what point is the disc in the degenerative cascade?

16. Is there calcification of abdominal vessels?

17. How do observations equate with symptoms and signs?

18. Are there further absolute or relative contraindications?

Indication Guide for Lumbar TDR

The literature review was assimilated into an overview on TDR patient selection. The target of this study was to improve the surgeon's decision making for the "right patient" with the "right indication," and the "right TDR." The proposals in Table 4 are not yet the final version, but a step toward being more precise in selection for TDR. Functional three- and two-component ball and socket discs have gliding areas not providing physiological ROM in all directions. In the future those TDRs will probably be replaced by implants with real physiological ROM, which 1-piece devices do not have. Table 4 is not intended to be comprehensive, but rather to identify what else should be evaluated when decision making is not clear.

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Table 4. Proposed overview how to determine types of TDR in relation to patient selection criteria.

	Preoperative factor	Functional three component spherical ball and socket disc	Functional two component spherical ball and socket disc	One-piece viscoelastic disc with movable core	Compact (stiff) one-piece viscoelastic disc
Patient Selection Criteria					
Patient data and medical history	Age	20-40	20-40	30-50	40- >60 (precondition >50 y: sclerosis of endplates)
	Back pain	yes	yes	yes	yes
	Leg pain	yes	yes	yes	yes, no>50 y
	Duration of non-surgical treatment	20-30 y: 9 months 30-40 y: 6 months	20-30 y: 9 months 30-40 y: 6 months	30-40 y: 6 months 40-50 y: 5 months	40-50 yrs: 5 months 50-60 yrs: 4 months >60: 3 months
	Prior surgery	no (besides nucleotomy/ discectomy without destabilizing bone resection)	no (besides nucleotomy/ discecomy without destabilizing bone resection)	no (besides nucleotomy/ discectomy without destabilizing bone resection)	yes (without facet-resection or laminectomy)
Pain and disability	VAS	> 50/100	> 50/100	> 40/100	> 40/100
	ODI	≥ 40/100	≥ 40/100	≥ 40/100	≥ 40/100
Clinical findings	No severe nerve stretching findings	no severe nerve stretching findings	no severe nerve stretching findings	no severe nerve stretching findings	No severe nerve stretching findings
Radiographic findings	Maximal reduced disc height compared to upper healthy disc	1/2	1/2	1/2	2/3
	Osteochondrosis	yes	yes	yes	yes
	Degenerative spondylolisthesis	no	no	no	Yes< 3mm
	Isthmic spondylolisthesis	no	no	no	no
	Degenerative scoliosis	no	no	minimal	yes
	Bony stenosis of spinal canal	no	no	no	no
	Facet arthritis grades[85]	up to grade II	up to grade II	up to grade II	up to grade III
	Facetectomy	no	no	no	no
MRI	Nucleus pulposus prolapse at disc level with nerve root irritation (= anterior discectomy possible)	yes	yes	yes	yes
	Modic changes	yes	yes	yes	yes
Invasive diagnostic procedures	Facet joint injection	no reduced pain	no reduced pain	no reduced pain	< 50% reduced pain
	Specific pain at discography	yes	yes	yes	yes
	Reduced leg pain at periradicular injection	+/-	+/-	+/-	+/-

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Bone quality	DEXA	T>-1.0	T>-1.0	T>-1.0	T>-1.0
Psychosocial / psychological factors	Result of test(s)	negative	negative	negative	negative
Surgical experience	Possible number of levels	1	1-2	1-2	> 2

Final remarks

The ideal TDR candidate may be an individual between 35 and 45 years old, with back pain severe enough to impact activities of daily living and/or work. Symptomatic DDD with or without radicular pain is the primary indication for TDR. Indications for TDR are based on patients' clinical problems, on several image findings, and other information. Three examples:

- Low back pain (DDD) caused by osteochondrosis
- Sciatica associated with degenerative spondylolisthesis <3 mm
- Sciatica after nucleotomy

In summary, we believe TDR candidates should have failed sufficient nonoperative treatment, have no structural anatomic abnormalities, have BMD T score >-1.0, no significant psychological issues, and diagnostic studies confirming the disc as the pain generator. All major contraindications should be absent. There are few viscoelastic discs, but they may offer advantages over current ball and socket devices; more outcome data is needed to determine if they expand TDR indications. Three- and two-component discs with physiological ROM are not yet developed.

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Disclosures

Rick Guyer, MD is a consultant for DePuy Spine and K2M.

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