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SUPPLEMENT

# Defining the Ideal Lumbar Total Disc Replacement Patient and Standard of Care

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Lumbar total disc replacement, now in use since 2004, was determined by the panel to be a standard of care for the treatment of symptomatic single-level lumbar degenerative disc disease in the active patient subpopulation as outlined by the investigational device exemption study criteria. The large body of evidence supporting this statement, including surgeons' experiences, was presented and discussed. Consensus statements focusing on decision-making criteria reflected that efficacy, long-term safety, clinical outcomes with validated measures, and cost-effectiveness should form the basis of decision-making by payers. Diagnostic challenges with lumbar degenerative disc disease patients were discussed among the panel, and it was concluded that although variably used among surgeons, reliable tools exist to appropriately diagnose discogenic back pain.
**Key words:** diagnosis, economics, efficacy, fusion, lumbar spine, safety, standard of care, total disc replacement.
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This session of the First Annual Lumbar Total Disc Replacement Summit focused on discussions pertaining to lumbar total disc replacement (TDR) as a standard of care and defining the target population. Topics that were included as part of the initial questionnaire, or discussed in depth at the meeting, included diagnostic challenges, optimizing diagnostic techniques, and the evidence needed for making coverage decisions. Seven consensus statements were developed from this initial session.

Consensus Statements:

1. Reliable tools exist to appropriately diagnose discogenic back pain.
2. Therefore, challenges by payers on clinical treatment decisions should be based on reliable tools.
3. Coverage decisions by payers for lumbar degenerative disc disease (DDD) should be based on comparative effectiveness, long-term safety data (at 5 years) and cost effectiveness.
4. When considering clinical outcomes, validated outcome measures (*e.g.*, VAS, ODI) should be the major determining factor for coverage decisions on treatment of lumbar DDD.
5. In the active patient subpopulation of lumbar DDD patients, as outlined by the IDE selection criteria, TDR should be a standard of care for the treatment of symptomatic single-level lumbar DDD.
6. While some patients with grade 1 spondylolisthesis may be candidates for lumbar TDR, a grade 1 spondylolisthesis is not a requirement for TDR.
7. There are clinical indications for multilevel lumbar TDR or lumbar TDR adjacent to a fusion.

Lumbar TDR is an alternative to spinal fusion in well-selected patients with symptomatic DDD and has now been in use for over 13 years.[1] However, despite the availability of substantial high-level evidence, several of the major health insurance carriers in the US continue to challenge the coverage of single-level lumbar TDR. Insurers denying coverage have cited that lumbar TDR is experimental and investigational, that there is an insufficient level of efficacy and safety evidence in the literature, and/or that there is a lack of long-term studies. Another common reason for denied coverage is that the procedure is not medically necessary. The rationale within these policies now appears outdated considering that extensive research has been published during the time since the first lumbar TDR was approved by the Food and Drug Administration (FDA) in 2004, characterizing the comparative efficacy, safety, and

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**TABLE 1. Regional and Global Recommendations Supporting Lumbar TDR Utilization**

| Organization and/or Region | Summary of Recommendation |
|---|---|
| NASS, US[3] | Recommends coverage for lumbar TDR based on 2 and 5-year data demonstrating TDR is at least equivalent to spinal fusion for discogenic back pain. |
| NICE, UK[4] | Supports use of lumbar TDR based on current safety and efficacy data, with evidence in the review including studies with follow-up to 13 years. |
| HQO, Canada[5] | Supports adoption of lumbar TDR in well-defined patients, with recommendations for a registry to track long-term complications. |
| Europe[6] | Lumbar TDR fully reimbursed in Germany, France, Belgium, Austria, and Demark. Lumbar TDR also reimbursed in UK, Spain and Italy, depending on region and hospitals. |
| MSAC, Australia[2] | Supports ongoing funding of lumbar TDR based on safety, effectiveness, and cost-effectiveness data, with a predicted $0.43 million in cost savings versus fusion. |
| ISASS, global[7] | Recommends universal coverage for single-level lumbar TDR for established selection criteria. Evidence supports that TDR is neither experimental nor investigational. |

*HQO indicates Health Quality Ontario; ISASS, International Society for the Advancement of Spine Surgery; MSAC, Medical Services Advisory Committee; NASS, North American Spine Society; NICE, National Institute for Health and Care Excellence; TDR, total disc replacement.*

cost-effectiveness of lumbar TDR versus fusion and conservative care. Furthermore, the panel acknowledges that reliable tools exist to diagnose discogenic back pain and thus establish the medical necessity of the procedure. Table 1 provides a summary of the various world-renowned health technology assessment agencies and medical associations that have recommended adoption of lumbar TDR as an alternative to spinal fusion.[2–7]

Utilizing the updated body of published evidence, as well as practical experience, the panel of surgeons developed consensus statements pertaining to TDR as a standard of care in the active patient subpopulation with symptomatic single-level lumbar DDD.

## DIAGNOSIS OF LUMBAR DEGENERATIVE DISC DISEASE

DDD is a leading cause of chronic low back pain.[1] A goal of diagnosis is to prove that the disc is the pain generator responsible for the persistent pain. Determination that the patient's chronic pain is discogenic is an indication for lumbar TDR.[8] The literature cites that radiographic evaluation is often the initial diagnostic modality of choice.[8] Additionally, magnetic resonance imaging is an ideal modality for the evaluation of low back pain, with characteristics of lumbar DDD on magnetic resonance imaging being a decrease in disc height, presence or absence of annular tears, signs of disc degeneration, central disc herniation, and endplate changes.[9] Provocation discography is often regarded as the reference standard test for discogenic back pain,[10] however it is currently used on a case-by-case basis only. Although limitations exist with each of these modalities, discogenic back pain often remains a diagnosis of exclusion.

It was evident during panel discussions that diagnostic techniques varied considerably, with no "one size fits all" strategy, but the panel acknowledged that a combination of these techniques is often sufficient for the appropriate diagnosis of discogenic pain. The surgeons reported that they often used a combination of one or more of the following: clinical history, physical examination, initial or advanced imaging, response to diagnostic and therapeutic spinal injections (*e.g.*, nerve root blocks, facet blocks, or lumbar disc blocks), discography, and failure of conservative therapy. These techniques were not discussed in depth at the meeting; rather, the focus was on obtaining consensus on the sufficiency of methods and techniques available.

Diagnostic challenges emphasized by the panel of surgeons included the presence of multilevel cases, confounders of symptoms (*e.g.*, opioid dependence), and need for ruling out other pain generators. Typically, when presented with such challenges, additional testing, such as with the use of discography, was presented as a solution. Coverage of discography was sometimes highlighted as a challenge by some surgeons in certain regions; however, no issues regarding the reliability of the various tools and techniques were raised by the panel. To substantiate that reliable tools exist, panel surgeons referred to clinical trial evidence, which aligns with the notion that reliable tools exist to diagnose discogenic back pain and that patients are being selected appropriately for TDR.[11–14] Reliable tools can therefore help determine the medical necessity of the TDR procedure.

## EVIDENCE AND COVERAGE DECISIONS

Initially, the panel deliberated on factors important in establishing a standard of care; however, the discussion broadened to consider criteria for TDR coverage decisions, with a focus on efficacy and safety. The coverage decision-making process for lumbar DDD can vary across regions and organization types, such as health technology groups, insurers, and government bodies. Each organization has different processes for gathering evidence and variable criteria for assessing and interpreting such evidence to make decisions. From the panel's perspective, the consensus was that coverage decisions by payers for lumbar DDD should be based on the following components:

- Comparative efficacy (or effectiveness)
- Long-term safety
- Cost-effectiveness

**TABLE 2. Long-term Clinical Studies of Lumbar TDR in DDD Patients With 5+ Years Follow-up**

| Study | Study Design | Mean Follow-up (Yrs) | Region |
|---|---|---|---|
| Aesculap 2017[22] | IDE RCT[‡,§,†] | 5 | US |
| Guyer 2016[23] | IDE RCT[¶,§] | 5 | US |
| Skold 2013[24] | RCT[§,†,*] | 5 | Sweden |
| Zigler 2012[11] | IDE RCT[†] | 5 | US |
| Gornet 2010[13] | IDE RCT[*] | 5 | US |
| Guyer 2009[14] | IDE RCT[§] | 5 | US |
| Park 2016[25] | Observational[†] | 10 | Korea |
| Eliasberg 2016[26] | Observational | 5 | US |
| Lu 2015[27] | Observational[§] | 11.8 | China |
| Aghayev 2014[28] | Observational[§,‡,*,†] | 5.5 | Sweden |
| Siepe 2014[29] | Observational[†] | 7.4 | Europe |
| Park 2012[30] | Observational[†] | 6 | Korea |
| David 2007[31] | Observational[§] | 13.2 | France |
| Lemaire 2005[32] | Observational[§] | 11.3 | France |
| Tropiano 2005[33] | Observational[†] | 8.7 | France |

[*] *Maverick.*
[†] *ProDisc-L.*
[‡] *activL.*
[§] *Charité.*
[¶] *Kineflex.*
*IDE indicates Investigational Device Exemption; RCT, randomized controlled trials.*

US insurers typically evaluate the efficacy and safety of lumbar TDR as part of their assessments, but it is sometimes unclear which components drive the efficacy assessments, and whether ''long-term'' is consistently defined across plans. For clinical outcomes, the panel recommends that validated outcomes measures, such as the Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and health-related quality of life (HRQoL) tools (*e.g.*, the SF-36 form) should be the basis for the interpretation of efficacy/effectiveness by decision-makers. Such outcomes are consistently reported across randomized trials of lumbar TDR devices and while subjective, provide clinically meaningful interpretation of patient results. Many observational studies of lumbar TDR also typically report on such validated outcome measures. In brief, several meta-analyses have shown that lumbar TDR improves disability, pain, and patient satisfaction outcomes compared with fusion in lumbar DDD patients over a 2-year period,[15–20] with a recent meta-analysis indicating that these incremental benefits remain at 5 years.[21]

Long-term safety evidence has been a matter of question within US coverage policies, despite several recommendations being made in favor of lumbar TDR from world-renowned organizations. Currently, there are 5 randomized trials[11,13,14,22,23] and one additional non-IDE randomized trial[24] of lumbar TDR with 5-year follow-up data. A 5-year meta-analysis of four randomized trials reported that the rate of reoperation, defined as device-related failures resulting in subsequent surgical interventions, such as revision, removal, or supplemental fixation, was significantly lower with lumbar TDR vs. fusion.[22] Furthermore, there are several observational studies of lumbar TDR, many published within the last 2 years, with long-term follow-up periods ranging from 5 years to 13.2 years (Table 2).[11,13,14,22–33] In summary, these data collectively indicate that there is a reasonably low rate of complications with lumbar TDR in the short and long terms compared to spinal fusion. In a subsequent section, it has been noted that the panel achieved consensus that 5-year data was considered long-term data for lumbar TDR.

While cost effectiveness was not the focus of the discussions, this topic was acknowledged. The cost effectiveness of a health technology is considered a coverage and reimbursement criterion by several stakeholders globally. For example, the Medical Services Advisory Committee (MSAC) in Australia evaluates cost effectiveness and total cost, in addition to comparative safety and clinical effectiveness, to make recommendations for public funding. In DDD, several cost-effectiveness studies evaluated the total costs of TDR compared with the total costs of fusion over 2 years, relative to an effectiveness measure (*e.g.*, narcotics discontinuation, ODI success, quality of life). In general, total costs typically included both upfront index procedure costs and downstream resources and complications, such as reoperations. The MSAC provided a recommendation that supports the ongoing funding of lumbar TDR and predicted $0.43 million of cost savings compared with fusion.[2] Additional economic evaluations of lumbar TDR support the finding that it is cost effective relative to fusion or conservative care.[34,35] In regions such as the US, cost effectiveness is not a formal criterion for funding decisions; however, conduct of such studies is becoming increasingly common in an era of cost containment. Several economic evaluations conducted in the US have reported that there are similar or lower costs

associated with lumbar TDR relative to fusion from a provider and private insurer perspective.[36–39] The economics of lumbar TDR is further discussed in a complementary session publication.

To date, there is a considerable body of evidence evaluating the comparative effectiveness, long-term safety, and economics of lumbar TDR compared with fusion in patients with DDD, and the panel acknowledges this. This evidence permits comprehensive assessments of the value of lumbar TDR in the treatment of lumbar DDD patients.

## TOTAL DISC REPLACEMENT AS STANDARD OF CARE IN SELECTED PATIENTS

Standard of care (SOC) is a concept that cannot be universally defined. In medical terms, an SOC may be referred to as a treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance, although more than one SOC may be appropriate in some situations. In legal terms, SOC can be interpreted as the level at which the average, prudent provider in a given community would practice. It is also how similarly qualified practitioners would have managed the patient's care under the same or similar circumstances.[40]

In discussions with the panel, the notion was that SOC considers both evidence and experience; often the "best option becomes the method that works best in a surgeons hands," and not one that necessarily has the most data. Based on the body of evidence published to date, and the practical experience gained from the panel of clinicians, the consensus of the panel was that lumbar TDR should be *a* SOC for the treatment of symptomatic single-level lumbar DDD in the active patient subpopulation, as outlined by IDE selection criteria. Table 3 provides a summary of common patient selection criteria utilized within the IDE randomized trials for lumbar TDR. Interestingly, 1 of the 17 surgeons disagreed with the proposed statement on SOC because defining an SOC specifically for single-level lumbar DDD was thought to be too restrictive, even though this may be a reasonable starting point.

Aside from implant characteristics, appropriate patient selection is arguably the most important factor in determining TDR treatment success.[41] Careful differential diagnosis to identify the lumbar disc as the primary pain generator is essential. Once a diagnosis of single-level symptomatic lumbar DDD is made, careful attention must be paid to contraindications. Older patients (*i.e.*, > 55 years of age) have a higher risk of TDR contraindications such as spinal stenosis, high-grade spondylolisthesis, and osteopenia.[42] As such, TDR eligibility is higher in the younger patient population, who are typically more active. In relation to this discussion, one panel member quoted that: "the more active a patient is, the more their life will be affected by limited range of motion and future adjacent level disease."

**TABLE 3. General Lumbar TDR Selection Criteria in IDE Trials**

| |
|---|
| No more than a grade 1 spondylolisthesis at the involved level |
| Failed at least 6 months of conservative therapy |
| Symptomatic DDD at one level |
| Level L3 to S1 (or L4 to S1) |
| Skeletally mature patients |

*DDD indicates degenerative disc disease.*

One US coverage policy has mistakenly stipulated that for a patient to qualify for lumbar TDR, the patient must have a grade 1 spondylolisthesis.[43] This is a misinterpretation of the indication criteria. While several of the IDE trial patients did in fact have a grade 1 spondylolisthesis, this is not an indication for TDR. Therefore, the panel provided the consensus that while some patients with grade 1 spondylolisthesis, particularly in the instance where a retrolisthesis is involved, may be candidates for lumbar TDR, a grade 1 spondylolisthesis is not a requirement for TDR. Furthermore, there are instances where patients with a grade 1 spondylolisthesis may not qualify for a TDR. As a follow-up to the Summit, the panel has continued to attempt to address this discrepancy with the relevant payer. The panel felt it important to address this policy to prevent the wrong patients from being treated with lumbar TDR which may result in patient harm.

Although the emphasis of discussions at the First Annual Lumbar Total Disc Replacement Summit were on the responsible indications for lumbar TDR as approved by the FDA, the panel highlighted that there are sometimes clinical indications for multilevel TDR, or disc replacement adjacent to a fusion (*i.e.*, hybrid procedures), although this cannot be promoted. Panel experience has indicated that some of these patient types may benefit from lumbar TDR, such as those with 2-level disease. Further evidence must be gathered and evaluated on these additional patient populations.

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