ISASS Policy Statement – Lumbar Artificial Disc

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ISASS Policy Statement – Lumbar Artificial Disc

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Purpose

The primary goal of this Policy Statement is to educate patients, physicians, medical providers, reviewers, adjustors, case managers, insurers, and all others involved or affected by insurance coverage decisions regarding lumbar disc replacement surgery.

Procedures

This Policy Statement was developed by a panel of physicians selected by the Board of Directors of ISASS for their expertise and experience with lumbar TDR. The panel's recommendation was entirely based on the best evidence-based scientific research available regarding the safety and effectiveness of lumbar TDR.

KEYWORDS: LUMBAR ARTIFICIAL DISC, LUMBAR ARTHROPLASTY, LUMBAR DISC REPLACEMENT
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Background

Most of the major health insurance carriers in the US, including UnitedHealth, Aetna, Humana, and most Blue Cross Blue Shield affiliates, do not provide coverage for single level lumbar TDR even in patients meeting strict selection criteria. As a result, millions of Americans with chronic and debilitating lumbar degenerative disc disease who might reasonably benefit from a lumbar TDR are denied access to this technology based solely on their insurance carriers coverage policy.

The most common explanation for denying coverage for lumbar TDR is that the technology is considered "experimental and investigational." Some carriers indicate that "the long-term clinical outcome of lumbar disc replacement is unclear. The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the disc may occur and that, in some cases, revision surgery may be needed." Statements like this are disingenuous, choosing to ignore the long-term outcomes from well-controlled Level 1 studies demonstrating decreased adjacent segment degeneration, minimal component wear issues, and lower revision rates than fusion.

Rationale

A common definition of an experimental technique is one that is new and untested.

A common definition of an investigational technique is one that is not approved and under investigation in clinical trials.

Evaluation of peer reviewed published literature and publicly-debated scientific presentations provides extensive evidence that lumbar disc replacement is neither experimental nor investigational. It has been extensively tested and has received FDA approval after careful and lengthy evaluation of multicenter Level 1 data. Lumbar TDR is not new. The idea of replacing damaged or degenerated lumbar discs started in the 1950's.[1,2]

Over the last several decades, multiple attempts have been made to replace painful lumbar disc with implants that maintain motion at the operative level. The Charite artificial disc, developed in Berlin in the 1980s by Drs. Karin Buttner-Janz and Kurt Schellnack was first implanted in the US in 2000 to start a multicenter prospective randomized IDE study. Since 2000, tens of thousands of patients have been treated in the US and worldwide with an increasing inventory of lumbar disc implants. Although some critics speculated that the widespread availability of lumbar TDR would lead to large failure rates and

high levels of revision, a detailed and unbiased review of the published literature demonstrates otherwise. Most clinicians and scientists agree that the majority of complications associated with lumbar TDR implantation are related to errors in patient selection, deviating from well established inclusion and exclusion criteria (Table 1, Table 2).

In 2005 Blumenthal et al[3] published the result of the first prospective, randomized trial comparing lumbar disc replacement with the Charite to ALIF. The study represented the initial US experience with lumbar disc replacement. 375 patients were enrolled in 14 sites across the US. The authors reported lower levels of pain and disability at all follow up intervals between 6 weeks to 24 months. In addition, the disc replacement group reported higher patient satisfaction, and shorter hospital stay compared to the fusion group. The complication rates in both groups were similar for both groups, but the re-operation

Table 1. Inclusion and Exclusion Criteria for ProDisc-L (from the FDA SS&E labelling document).

Inclusion	Exclusion
• Degenerative Disc Disease (DDD) in one vertebral level between L3 and S1. Diagnosis of DDD requires back and/or leg (radicular pain); and radiographic confirmation of any 1 of the following by CT, MRI, discography, plain film, myelography and/or flexion/extension films: ◦ Instability (≥3mm translation or ≥5° angulation; ◦ Decreased disc height >2mm; ◦ Scarring/thickening of annulus fibrosis; ◦ Herniated nucleus pulposus; or ◦ Vacuum phenomenon • Age between 18 and 60 years • Failed at least 6 months of conservative treatment • Oswestry Low Back Pain Disability Questionnaire score of at least 20/50 (40%) (Interpreted as moderate/severe disability) • Psychosocially, mentally and physically able to fully comply with this protocol including adhering to follow-up schedule and • Signed inform consent	• No more than 1 vertebral level may have DDD, and all diseased levels must be treated • Patients with involved vertebral endplates dimensionally smaller than 34.5 mm in the medial-lateral and/or 27 mm in the anterior-posterior directions • Known allergy to titanium, polyethylene, cobalt, chromium or molybdenum • Prior fusion surgery at any vertebral level • Clinically compromised vertebral bodies at the affected level due to current or past trauma • Radiographic confirmation of facet joint disease or degeneration • Lytic spondylolisthesis or spinal stenosis • Degenerative spondylolisthesis of grade > 1 • Back or leg pain of unknown etiology • Osteopenia or osteoporosis: A screening questionnaire for osteoporosis, SCORE (Simple Calculated Osteoporosis Risk Estimation), will be used to screen patients to determine if a DEXA scan is required. If DEXA is required, exclusion will be defined as a DEXA bone density measured T score < -2.5. • Paget's disease, osteomalacia or anything other metabolic bone disease (excluding osteoporosis which is addressed above) • Morbid obesity defined as a body mass index > 40 or a weight more than 100 lbs. over ideal body weight • Pregnant or interested in becoming pregnant in the next 3 years • Active infection – systemic or local • Taking medication or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids) • Rheumatoid arthritis or other autoimmune disease • Systemic disease including AIDS, HIV, Hepatitis • Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer) unless he/she has been treated with curative intent and there has been no clinical signs or symptoms of the malignancy for at least 5 years

Table 2.Indications and Contraindications for ProDisc-L.

Indications for Use	Contraindications
The ProDisc-L Total Disc Replacement is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade 1 spondylolisthesis at the involved level. Patients receiving the ProDisc-L Total Disc Replacement should have failed at least six months of conservative treatment prior to implantation of the ProDisc-L Total Disc Replacement.	The ProDisc-L Total Disc Replacement should not be implanted in patients with the following conditions: • Active systemic infection or infection localized to the site of implantation • Osteopenia or osteoporosis defined as DEXA bone density measured T-score < -1.0 • Bony lumbar spinal stenosis • Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium) • Isolated radicular compression syndromes, especially due to disc herniation • Pars defect • Involved vertebral endplate that is dimensionally smaller than 34.5 mm in the medial-lateral and/or 27mm in the anterior-posterior directions • Clinically compromised vertebral bodies at the affected level due to current or past trauma • Lytic spondylolisthesis or degenerative spondylolisthesis of grade > 1

rate was significantly lower in the lumbar TDR group compared to the fusion group (5.4% vs. 9.1%).

In 2009, Guyer et al[4], published the 5 year follow up results of the Charite IDE trial. One hundred and thirty-three randomized patients were evaluated at a minimum of 5 years post index operation. The authors reported that the Charite group had a statistically higher success rate than the ALIF group (58% vs 51%; p=0.0359). Although there were no significant differences between the 2 groups in terms of ODI, VAS, or SF-36, patient satisfaction and employment status were higher in the Charite group. The re-operation rate at the index level was 8% for the Charite group and 16% for the fusion group. The authors concluded that although there were no statistically significant differences between the 2 groups in clinical outcomes, the Charite group demonstrated higher patient satisfaction, higher employment status, and lower re-operation rates, while maintaining motion at the operative level.

Longer term follow-ups at 10 years have been reported in Europe, demonstrating durability of lumbar arthroplasty. Lemaire et al[5] reported on 100 Charite patients with minimum 10 year follow-up. Clinically, 62% had an excellent outcome, 28% had a good outcome, and only 10% had a poor outcome. Of the 95 patients eligible to return to work, 91.5% did so. These outcomes compare favorably with results described in the literature for fusion for lumbar DDD.

David et al[6] reported on 106 Charite patients with mean follow-up of 13.2 years. Clinical outcomes and the rate of return to work were excellent overall. The rate of adjacent level disease requiring operation (2.8%) compared very favorably with rates of up to 30% in patients treated with fusion.

In a more recent publication, Zigler et al[7] reported the results of the 5 year follow up of the ProDisc-L study. Of the 236 original cohort of patients, 82% were available for follow up at a minimum of 5 years post-op. Although both groups demonstrated significant improvements in ODI compared to pre op values, the percentage of patients indicating they would have the surgery again was higher in the ProDisc-L group compared to the fusion group (82% vs. 68%). In addition, the re-operation at the index level was lower for the ProDisc group versus the fusion group (8% vs. 12%). The authors concluded that although fusion and disc replacement are reasonable alternatives for well selected patients, patients undergoing lumbar disc replacement have higher patient satisfaction and avoid the segmental stiffness associated with fusion.

As a companion article Zigler et al[8] also reported on radiographic adjacent level degeneration as measured by independent radiologic analysis. Comparison of adjacent levels preoperatively and 5 years after surgery demonstrated a threefold increase in adjacent level degeneration in patients who randomized to single level 360 fusion over those who randomized to a ProDisc-L implant. Reoperation rates at the adjacent level were twice as high in the post-fusion patients at 5 years.

Although only ProDisc-L is currently FDA approved in the US for commercial use in the lumbar spine, there are several prospective studies published on the clinical and radiographic outcomes of other lumbar arthroplasty implants in the FDA pipeline. Several lumbar implants are used outside the US (OUS) with thousands of patients implanted, but have not yet gone through an IDE approval for sale in the US.

Gornet et al[9] published results of the IDE trial using the Maverick metal on metal implant. The study was the largest prospective, randomized trial comparing lumbar TDR to ALIF with a metal cage and BMP. 577 patients were included in this study, including 405 in the TDR group and 172 in the ALIF group. The disc replacement group reported statistically superior outcomes ($p<0.05$) at all post-operative evaluations in ODI, back pain, and SF-36. Operative times and blood loss were higher in the Maverick group, whereas device related adverse events were lower in the Maverick group. The authors concluded that they had demonstrated statistical superiority of the Maverick arthroplasty versus fusion on key clinical outcomes including improved physical function, reduced pain, and earlier return to work. Maverick is implanted only OUS. Metal on metal arthroplasty devices are under intense scrutiny by the FDA as well as by the surgeon community. New MOM designs are likely to face an even more strenuous regu-

latory path in the future.

Sasso et al[10] published their results on a metal on metal implant. The study included prospective data from 2 sites in a multicenter trial comparing lumbar TDR with the FlexiCore implant versus circumferential fusion. 67 patients were included in this prospective randomized trial. Operative time, blood loss, and hospital stay were statistically significantly lower in the FlexiCore group. The authors concluded that the FlexiCore compared very favorably to circumferential fusion for the treatment of lumbar DDD unresponsive to conservative treatment. This implant did not complete the FDA approval process.

In addition to US studies regarding patients enrolled in IDE trials, there are several published European studies comparing lumbar TDR to fusion. Skold et al[11] reported results of a prospective randomized studies comparing lumbar TDR to fusion. Of the 152 patients included in this study, 80 were randomized to TDR while 72 were assigned to the fusion group. 99% of the patients were available for follow up at 5 years post-op. At follow up the percentage of patients who were totally pain-free was significantly higher in the TDR group versus the fusion group (38% vs 15%; $p<0.003$). The authors also reported better improvement in VAS and ODI in the lumbar TDR group, with no difference in complications or reoperations.

Although not a randomized study, Siepe et al[12] reported their prospective outcomes 5 to 10 years after lumbar TDR with the ProDisc-L implant. The authors reported on 181 patients at an average follow up of 7.4 years. The authors reported significant improvements in VAS and ODI at all postoperative follow up stages ($p<0.0001$), and concluded that their results demonstrated satisfactory and maintained mid- to long-term clinical results after a mean follow-up of 7.4 years. The authors stated that the fears of excessive late complications or reoperations following TDR procedures cannot be substantiated with the present data.

Conclusions

Science in general, and particularly clinical medicine, has evolved from anecdotal and retrospective investigations to more objective, rigorous, and prospective scientific investigation. In the face of strong Level I prospective randomized multicenter studies with long-term follow-up, it is inexcusable that treatment guidelines be directed by personal opinions and business-based decisions. Treatment guidelines should be based on these tested and proven therapeutic algorithms.

Our interpretation and understanding of the efficacy and safety of clinical interventions can only be dictated by well-established evidenced based guidelines.

Scientifically proven techniques and technologies must be accepted for the benefit of appropriate patients. One of the best values of these multiple IDE studies has been to identify the patients who would predictably benefit from lumbar arthroplasty. IDE study inclusion and exclusion criteria should provide an easy avenue for insurance payors to define the patients they can approve for lumbar disc replacement, since the outcomes for these patients should be predictable.

Based on a thorough review of the best available evidence-based scientific literature the International Society for the Advancement of Spine Surgery concludes that lumbar TDR is not new, experimental, or investigational. It is a well-tested technology which should predictably lead to better outcomes and less complications than fusion surgery, as well as a protective effect on adjacent levels.

There is sufficient evidence-based scientific evidence to support the safety and efficacy of single level lumbar TDR for patients meeting well established selection criteria. ISASS would support patient authorization guidelines that mirror the selection criteria from the IDE studies, as long as the device is implanted by a trained experienced spine surgeon.

There are now several long-term prospective and retrospective studies available on lumbar TDR which provide objective evidence regarding their safety and effectiveness. Data from prospective randomized clinical trials have reported consistently low rates of re-operations, and extremely low levels of particulate

wear debris complications. A list of relevant research is available below.

Based on sound analysis of the scientific literature, the International Society for the Advancement of Spine Surgery recommends universal coverage for single level lumbar TDR in patients meeting the established selection criteria.

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Disclosures

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