**SUPPLEMENTAL DIGITAL CONTENT**

**Table, Supplemental Digital Content 1, Main study eligibility criteria**

|  |
| --- |
| **Key Inclusion Criteria** |
| * Skeletally mature adults aged 18 to 60 years * Radiographic evidence of lumbar DDD, based on identification of any of the following characteristics by MRI scan:   + instability (≥3mm translation or ≥5° angulation)   + osteophyte formation of facet joints or vertebral endplates   + decreased disc height (>2mm compared to the adjacent level)   + scarring/thickening of ligamentum flavum, annulus fibrosis, or facet joint capsule   + herniated nucleus pulposus   + facet joint degeneration   + vacuum phenomenon * Single-level symptomatic disease at L4/L5 or L5/S1 * Minimum of 6 months of unsuccessful conservative treatment * Minimum Oswestry Disability Index score of 40/100 * Minimum VAS back pain score of 40/100 mm * Surgical candidate for an anterior approach to the lumbar spine |
| **Key Exclusion Criteria** |
| * Previous surgery at any lumbar level, other than IDET, percutaneous nucleoplasty, microdiscectomy, hemilaminectomy, or laminotomy * Chronic radiculopathy, defined as unremitting pain with a predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least 1 year * Anatomically unsuitable for TDR based on preoperative radiographic assessment * Index level disc height < 3 mm * Myelopathy * Previous compression or burst fracture at index level * Sequestered herniated nucleus pulposus with migration * Mid-sagittal stenosis <8mm (by MRI) * Spondylolysis. * Lumbar scoliosis (>11 degrees sagittal plane deformity) * Spinal tumor * Active systemic infection or infection at the site of surgery * Facet ankylosis or severe facet degeneration * Continuing steroid use or prior use for more than 2 months * Pregnancy or planning to become pregnant within the next 2 years * Morbid obesity (BMI >35) * Osteoporosis, osteopenia, or metabolic bone disease * History of rheumatoid arthritis, lupus, or other autoimmune disorder * Ankylosing spondylitis * Abdominal pathology that would preclude the abdominal surgical approach |

**Table, Supplemental Digital Content 2, Patient characteristics and outcomes in Control group**

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **ProDisc-L**  **(n=64)** | **Charité**  **(n=41)** |
| **Demographics** |  |  |
| Age, years | 41±9 | 40±9 |
| Male gender, n (%) | 32 (50) | 20 (49) |
| Body mass index, kg/m2 | 27±5 | 27±4 |
| **Medical history, n (%)** |  |  |
| Current narcotic use | 57 (89) | 39 (95) |
| Smoking history | 31 (48) | 12 (29) |
| Previous lumbar surgery | 18 (28) | 12 (29) |
| **Main outcomes** |  |  |
| ODI success | 43 (67) | 26 (63) |
| Neurological success | 48 (75) | 32 (78) |
| Radiographic success | 28 (44) | 16 (39) |
| Device success | 54 (84) | 35 (85) |
| Freedom from serious device-related AEs | 48 (75) | 26 (63) |

One patient (ProDisc-L) excluded from Control group comparisons due to implant failure.

**Figure, Supplemental Digital Content 1, CONSORT flow diagram.**



ITT: intent-to-treat; SDRE: serious device-related event