

Selection of NEW Disc Arthroplasty Studies Published in 2015

| | Clinical Study | Years of Follow-Up | # of Patients | Type of Study | Conclusions | Journal | Publication Date | Authors |
|---|--|---------------------|--|--|--|---|------------------|---|
| 1 | Disc Arthroplasty: Mobi-C vs anterior discectomy and fusion | 4-years | 330 | Prospective, randomized, multi-center | Four-year results from this study continue to support TDR as a safe, effective, and statistically superior alternative to ACDF for the treatment of degenerative disc disease at 2 contiguous cervical levels | Journal of Neurosurgery | January 2015 | Reginald Davis Pierce Nunley Kee Kim Michael Hisey Robert Jackson Hyun Bae Gregory Hoffman Steven Gaede Guy Danielson Charles Gordon Marcus Stone |
| 2 | Disc Arthroplasty: Cervical Total Disc | 4-Years | 164 one-level TDR 225 two-level TDR Total: 389 | Prospective, randomized, multi-center, FDA IDE study | A 4-year post hoc comparison of 1- and 2-level TDR patients concurrently enrolled in a 24-center, Food and Drug Administration Investigation Device Exemption clinical trial indicated no statistical differences between groups in clinical outcomes, overall complication rates, and subsequent surgery rates. | SPINE | June 2015 | Hyun Bae Kee Kim Pierce Dalton Robert Jackson Michael Hisey Reginald Davis Gregory Hoffman Steven Gaede Guy Danielson Daniel Peterson John Stokes Ali Araghi |
| 3 | Disc Arthroplasty: Long Term Outcomes PCM Cervical Disc Arthroplasty | 5-years and 7-years | 293 at 5 years 110 at 7 years | Prospective, randomized, controlled, multi-center, FDA IDE study | The long-term results show good clinical outcomes after ACDF and PCM arthroplasty. PCM patients showed greater improvement in neck disability index and neck pain scores with a lower rate of radiographical adjacent-level degeneration and a trend toward fewer secondary surgical procedures. These data support PCM arthroplasty to be a viable and sustainable alternative to ACDF. | SPINE | May 2015 | Frank Phillips Fred Geisler Kye Gilder Christopher Reah Kelli Howell Paul McAfee |
| 4 | Disc Arthroplasty: Discover Artificial Disc vs. ACDF | 2-year | 153 | Randomized, controlled multi-center study | Both groups improved significantly after surgery. NDI changed from 63.1 to 39.8 in an intention-to-treat analysis. No statistically significant difference between the ADR and the ACDF groups could be demonstrated with NDI values of 39.1 and 40.1, respectively. | The Spine Journal | June 2015 | Martin Skeppholm Lars Lindgren Thomas Henriques Ludek Vavrouch Hakan Lofgren Claes Olerud |
| 5 | Disc Arthroplasty: ProDisc-C Total Disc Replacement vs. AFDF | 7-years | 209 | Prospective, randomized, controlled, multi-center, FDA IDE study | Total disc arthroplasty with ProDisc-C is a safe and effective surgical treatment of single-level symptomatic cervical degenerative disc disease. Clinical outcomes after total disc arthroplasty with ProDisc-C were similar to those after ACDF. Patients treated with ProDisc-C had a lower probability of subsequent surgery, suggesting that total disc arthroplasty provides durable results and has the potential to slow the rate of adjacent-level disease. | The Journal of Bone & Joint Surgery | November 2015 | Michael Janssen Jack Zigler Jeffrey Spivak Rick Delamarter Bruce Darden Branko Kopjar |
| 6 | Disc Arthroplasty: ProDisc-L Disc Replacement | 4-years | 108 | Retrospective review, single site | The procedure led to a statistically significant improvement in the functional scores. The motion of the upper disc segment was 9° (0°–19°) in flexion/extension and 5.5° (2°–12°) in lateral bending. It was 6.2° (0°–14°) and 1.9° (0°–7°) at the lower disc segment. The range of motion was similar in L3/L4 and L4/L5, but was less in L5/S1. Lack of mobility was not correlated with alterations in the functional outcome. The complication rate was 18%. | Orthopaedics & Traumatology: Surgery & Research | February 2015 | S. Trincat G. Edgard-Rosa G. Geneste T. Marnay |
| 7 | Disc Arthroplasty: XL TDR Lumbar Disc Replacement | 3-years | 64 | Prospective, randomized, controlled, multi-center, FDA IDE study | The results following XL TDR show good clinical and radiographic outcomes out to 3 years postoperative, with clinically significant improvements in pain, function, and general health, few complications, and high patient satisfaction. | European Spine Journal | March 2015 | Antoine Tohmeh William Smith |

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| 8 | Disc Arthroplasty: Costs of Cervical Disc Replacement vs ACDF | na | 6,635 ACDF patients, 327 CDA patients | Retrospective matched cohort analysis | Patients who underwent CDA for single-level degenerative disease had lower readmission rates, lower reoperation rates and reduced index and total costs than those treated with acdf. CDA was effective in reducing the monthly cost of care compared with ACDF | SPINE | April 2015 | Kris Radcliff Jack Zigler Jeff Zigler |
| 9 | Disc Arthroplasty: Cervical Total Disc Replacement Is Superior to ACDF | na | 4,516 | Meta-analysis of 19 randomized controlled clinical trials | Cervical total disc replacement presented favorable functional outcomes, fewer adverse events, and fewer secondary surgical procedures. The efficacy and safety of cervical total disc replacement are superior to those of fusion. Longer-term, multicenter studies are required for a better evaluation of the long-term efficacy and safety of the two procedures. | PLOS One | March 2015 | Zhang Liang Tao Zhou Li Li Chen |
| 10 | Disc Arthroplasty: Comparison of TDR With Lumbar Fusion | 2-year | 363 | Meta-analysis of 6 randomized controlled clinical trials | The present meta-analysis of RCTs reveals that in a long-term follow-up (2 years) TDR shows significant superiority for the treatment of lumbar DDD compared with fusion. However, due to the number of eligible studies in this meta-analysis which are still not enough, more high quality RCTs with long-term follow-up (at least 2 years) are further needed to confirm the clinical benefits with the use of tDR in treatment of lumbar DDD> | Journal of the College of Physicians and Surgeons Pakistan | 2015 | Nie Chen, Wang Zeng |
| 11 | Disc Arthroplasty: An 11-year follow-up of the Charité III lumbar disc replacement | 11-year | 32 | Retrospective analysis, single site | Twenty-eight patients (87.5%) had a successful outcome, as defined by the FDA. Reoperation was performed in 2 patients for adjacent segment degeneration and pedicle fracture. Both VAS and ODI scores showed significant improvement compared to baseline. | European Spine Journal | April 2015 | Hai, Lu, Kong, Wang, Zang, Kang, Meng, Wang |
| 12 | Disc Arthroplasty: Retrospective study on Effectiveness of Activ L Total Disc | 28 months | 30 | Retrospective case series with radiographic follow-up | At the final follow-up, the success rate was 86.7%. Visual analogue scale score for low back pain and leg pain, and Oswestry Disability Index scores significantly improved after surgery. | SPINE | April 2015 | Lu, Kong Hai, Wang Zang, Kang Meng, Wang |
| Source: RRY Publications, LLC and public documents | | | | | | | | |