incidence of subsequent lumbar spine re-operation, which included revision lumbar disc arthroplasty, anterior lumbar fusion, posterior lumbar fusion, lateral lumbar fusion and laminectomy without fusion. Univariate and multivariate analyses were used to identify demographic risk factors for subsequent re-operation.

RESULTS: A total of 1,372 patients underwent an inpatient lumbar disc arthroplasty procedure between January 2005 and September 2013. Over the study duration, a decreasing number of inpatient lumbar disc arthroplasty procedures were performed in New York State (m=30 cases/year, p<0.001). Subsequent lumbar spine re-operation after an index lumbar disc arthroplasty procedure occurred in 17.6% of patients, with an 8.8% re-operation rate by two years. The most common lumbar re-operation was lumbar laminectomy and/or discectomy (8.5%). Overall, 14.2% of patients underwent subsequent lumbar fusion, specifically, lateral fusion (7.5%), posterior fusion (5.1%), and/or anterior fusion (3.6%). Compared to those patients who did not undergo subsequent lumbar surgery, those who did undergo a re-operation were more likely to have diabetes mellitus (OR=2.35, 95% CI 1.17-4.73, p=0.016). There was no statistical difference between the two cohorts in age (<40 or >40), sex, race, insurance, comorbidity score, tobacco use or lumbar diagnosis for the index lumbar disc arthroplasty procedure.

CONCLUSIONS: We identified a 17.6% incidence of subsequent lumbar spine surgery after inpatient lumbar disc arthroplasty, and an 8.8% re-operation rate at two years. Over the study duration, 14.2% underwent a subsequent lumbar fusion procedure. Diabetes mellitus was the only patient demographic factor to significantly influence the odds of lumbar spine re-operation. Inpatient lumbar disc arthroplasty procedures declined over the study duration in New York State. Further investigation is needed to evaluate if these findings correlate with the newest generation of lumbar disc arthroplasty designs.

FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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78. The current incidence of adjacent segment pathology following cervical disc arthroplasty (CDA) or anterior cervical discectomy and fusion (ACDF): a systematic review and meta-analysis of randomized clinical trials

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BACKGROUND CONTEXT: The introduction of CDA has provided a biomechanically sound alternative to ACDF, helping to preserve motion and potentially reduce adjacent segment pathology. To date, studies have shown conflicting results on the true impact of ACDF and CDA on adjacent levels.

PURPOSE: To assess rates of radiographic adjacent segment degeneration (ASDeg) and symptomatic adjacent segment disease (ASDis), as well as reoperation rates due to adjacent segment pathology in patients who have undergone anterior cervical discectomy and fusion (ACDF) vs cervical disc arthroplasty (CDA).

STUDY DESIGN/SETTING: Meta-analysis of randomized controlled trials (RCTs).

PATIENT SAMPLE: A total of 18 studies were included in the final analysis, comprising 4,082 total patients with 1,854 patients who underwent ACDF and 2,454 who underwent CDA.

OUTCOME MEASURES: The pooled outcomes of interest included: adjacent segment degeneration, adjacent segment disease and reoperation for adjacent segment pathology. Adjacent segment degeneration was defined as changes on plain radiographs or magnetic resonance imaging (MRI) at segments adjacent to a previously operated level. Adjacent segment disease or symptomatic adjacent segment pathology was defined by persistent neck pain and new-onset radiculopathy/myelopathy. Symptomatic adjacent segment pathology requiring additional surgical intervention was categorized as reoperation due to adjacent segment pathology.

METHODS: A comprehensive search of RCTs was performed in PubMed from 2012 to 2019. Relevant studies included were assessed for quality using the Cochrane Beck Review Group guidelines. Rates of ASDeg, ASDis, and reoperation due to adjacent segment pathology were extracted and included in the final analysis.

RESULTS: Overall, ACDFs compared to CDAs had higher rates of radiographic adjacent segment degeneration (45.26% vs 31.91%), symptomatic ASDis (16.21% vs 10.96%), and reoperation (8.53% vs 5.26%, respectively; all p<0.05). In these single-level studies, there was a significant difference between ACDF and CDA in terms of symptomatic ASDis (13.57% vs 6.11%, p: 0.015), but not radiographic ASDeg (43.76% vs 38.40%, p: 0.397) or reoperation rates (7.11% vs 3.03%, p: 0.082). Among studies comparing 1- to 3-level fusion/arthroplasty, no significant difference between ACDF and CDA was noted in terms of ASDeg (36.97% vs 21.41%, p: 0.054), ASDis (22.82% vs 23.11%, p: 0.960), or reoperation rates (10.91% vs 8.98%, p: 0.126).

CONCLUSIONS: Currently, CDA has lower rates of adjacent segment degeneration, disease, and reoperation rates compared to ACDF in those with at least 2 years follow-up. CDA may be a viable alternative to ACDF; however, further long-term studies are warranted to ensure consistency and establish longevity of our findings.

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79. Secondary surgery rate and five-year outcomes of hybrid TDR/ACDF vs multilevel ACDF

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BACKGROUND CONTEXT: Cervical total disc replacement, TDR, is increasingly accepted as a surgical treatment option for patients who have failed conservative care of single-level conditions. However, coverage for multilevel disease, which is more common, is usually restricted to fusion surgery. Multilevel conditions are more challenging as some levels have soft disc conditions favoring TDR and other levels have bony stenosis and facet overgrowth favoring fusion (ACDF). The purpose of this study was to compare off-label hybrid TDR/ACDF to multilevel ACDF for multilevel cervical disease.

PURPOSE: Comparison of off-label hybrid TDR/ACDF to multilevel ACDF for multilevel cervical degenerative conditions.

STUDY DESIGN/SETTING: Two cohort prospective study.

PATIENT SAMPLE: Consecutive patients who had cervical hybrid procedure with minimum 5-yr follow-up. Historical prospectively analyzed multilevel ACDF control cohort that could have had hybrid if insurance would have approved.

OUTCOME MEASURES: Neck and arm pain VAS, Pain Drawing, disability outcomes, self-report of success.

METHODS: Consecutive Hybrid TDR/ACDF patients, n=83, who had minimum of 5 years follow-up were compared to controls. The Hybrid group had the TDR placed at the level were the primary condition was (soft) disc-related whereas the ACDF was performed at the level(s) where the primary condition was bony stenosis or spondylotic. The control group was evaluated prospectively and those with central stenosis were eliminated as they were not satisfactory hybrid candidates. Secondary surgeries were also analyzed for all cohorts. Within the hybrid cohort, 2/3 had a hybrid construct at their index surgery and 1/3 had TDR adjacent to a prior ACDF.

RESULTS: There were no demographical differences between the two cohorts. Both hybrid TDR/ACDF and multilevel ACDF groups had similar preoperative pain and disability and, within both cohorts, had significantly improved outcomes after surgery. Between groups, there were no

differences in outcomes for any of the measures over the 5+ year follow-up. Narcotic medication usage decreased; from 75% preop in the hybrid group to 19% at 3-5 years postop. Secondary surgeries found that over 5 years, adjacent level surgery was in 6 (7%) and 11(14%) patients in the Hybrid and the multilevel ACDF groups respectively. Pseudarthrosis repair was 6% vs 7% in the hybrid and multilevel ACDF cohorts respectively. The study appears valid in that our single-level TDR vs ACDF results were similar to that reported in multiple prior studies and found slightly better outcomes for single-level cervical TDR relative to ACDF.
CONCLUSIONS: Hybrid TDR/ACDF, used off-label, gives comparable outcomes to multilevel ACDF patients at medium-term follow-up. Secondary surgeries due to adjacent segment disease were half as frequent in the Hybrid cohort. A hybrid procedure is a viable treatment option for patients with multilevel cervical disease.
FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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80. FDA trial of decompression and paraspinous tension band for degenerative spondylolisthesis: 12 months follow-up in 93 subjects

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BACKGROUND CONTEXT: Degenerative spondylolisthesis (DS) with lumbar spinal stenosis (LSS) is commonly treated with decompression and fusion. The LimiFlex paraspinous tension band (PTB) is an investigational stabilization device for patients with DS and LSS.
PURPOSE: The purpose of this study is to assess the operative safety and short-term outcomes of decompression and PTB compared to transforaminal lumbar interbody fusion (TLIF) for patients with DS and LSS.
STUDY DESIGN/SETTING: Multicenter prospective concurrently controlled study.
PATIENT SAMPLE: Patients undergoing treatment (decompression and PTB or TLIF stabilization) of Grade I Meyerding lumbar degenerative spondylolisthesis.
OUTCOME MEASURES: Patient demographics, patient reported ODI, VAS leg, and VAS back, and procedural, discharge, and short-term clinical outcomes up to 12 months postoperatively.
METHODS: Patients with single-level Grade 1 DS with LSS were enrolled in the multicenter, FDA-IDE study comparing decompression with PTB and decompression with TLIF. Perioperative and patient-reported clinical outcomes were recorded at baseline and 6-week, 3-month, 6-month and 12-month follow-up. All patients who reached 12-month follow-up were included in this interim analysis. Summary statistics are reported, as well as paired t-tests to assess within-group changes.
RESULTS: A total of 93 patients (58 PTB, 35 TLIF) reached 12-month follow-up. Characteristics of PTB vs TLIF groups, respectively were: age 64.9±8.1, 64.1±7.4 yrs; BMI 28.7±4.9, 29.2±5.8; current smokers 2%, 3%. Perioperative outcomes for PTB vs TLIF were: operative time 110±29, 172±58 minutes; EBL 42±26, 241±155 mL; LOS 0.6±1.5, 3.3±1.7 nights. A significant reduction from baseline to 12 months for mean VAS-leg/hip (79.4±10.4 to 19.8±27.5), VAS-back (67.5±22.9 to 17.7±25.1) and ODI (53.1±13.1 to 12.6±16.0) was reported for PTB patients (all $p<0.01$) with 91% achieving 15-point ODI improvement. TLIF patients demonstrated similar improvements for VAS-leg (79.6±13.7 to 29.3±29.2), VAS-back (73.3±18.3 to 20.5±24.1), and ODI (52.4±12.6 to 17.2±18.2) (all $p<0.01$), with 83% achieving 15-point ODI improvement. During the 12-month follow-up, 2 PTB (3.4%) and 3 TLIF (8.6%) subjects had reoperations.
CONCLUSIONS: These preliminary results suggest that decompression with PTB stabilization for spondylolisthesis can be accomplished safely without a significant increase in complications during the perioperative and short-term follow-up periods. Similarly, statistically significant improvements in patient-reported outcomes were demonstrated in each group. As groups were not propensity matched, further investigation to include quantitative comparison between groups with long-term follow-up is needed to confirm these results.
FDA DEVICE/DRUG STATUS: LimiFlex Paraspinous Tension Band (Investigational/Not approved).

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81. Seven-year results of a randomized controlled IDE trial for lumbar artificial discs in single-level degenerative disc

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BACKGROUND CONTEXT: The activL artificial disc received Food and Drug Administration approval in 2015 based on 2-year follow-up data.
PURPOSE: To compare the 7-year safety and efficacy of the activL® artificial disc with ProDisc-L total disc replacement (TDR) in the treatment of patients with symptomatic single-level lumbar degenerative disc disease (DDD).
STUDY DESIGN/SETTING: Prospective, randomized, multicenter IDE.
PATIENT SAMPLE: A total of 206 patients who underwent single-level lumbar arthroplasty with either Activ L or Prodisc L.
OUTCOME MEASURES: ODI, SF-36, VAS, complications, re-operations.
METHODS: Eligible patients presented with symptomatic, single-level, lumbar DDD who failed ≥6 months of nonsurgical management. At entry, 283 patients were randomly allocated to treatment with activL (n=218) or ProDisc-L (n=65) TDR. At 7-years follow-up, a total of 206 patients (activL: 160, ProDisc-L: 46) were available for analysis.
RESULTS: The activL group was non-inferior compared to the ProDisc-L group in the primary composite end point at 7 years (p=0.0369). Relative to baseline, significant reductions in visual analog scale (VAS) back/leg pain severity as well as improvements in Oswestry Disability Index (ODI) and SF36 Questionnaire were observed in both treatment groups at 7 years. The activL group showed significantly better range of motion for flexion-extension (FE) rotation, disc height/angle and higher proportion of patients without heterotopic ossification, compared with ProDisc-L. Freedom from a serious adverse event through 7 years was 62% in activL patients and 43% in ProDisc-L patients (log-rank p=0.011). Significant reduction in narcotic usage compared to baseline were observed in both treatment groups over time, with 0% of TDR patients using narcotics at 7 years. Freedom from reoperation was high for TDR patients at 95%. Patients who experienced improvements in radiographic (FE rotation, FE