

5-year Follow-up of Interlaminar Stabilization Surgery in the ≤ 65 Year Old Patient: More Value, Less Cost

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Background: After conservative treatment has failed, surgical intervention for symptomatic lumbar spinal stenosis (LSS) is common. However, LSS is rarely a discreet issue and often presents with spondylolisthesis, deformity, or other degenerative changes. Although decompression surgery is considered the standard treatment, trends indicate spine fusion surgery has disproportionately increased despite it being the more invasive approach. Interlaminar stabilization (ILS) is an evidence-based and less invasive alternative to fusion that is non-terminal and motion preserving. The purpose of this study was to compare the efficacy of decompression + ILS (D+ILS) to decompression plus posterolateral fusion (D+PLF) in patients aged ≤ 65 years with LSS with or without grade 1 spondylolisthesis.

Methods: A cohort from the original multi-center, randomized controlled Investigational Device Exemption clinical trial was examined with 5-year follow-up. The cohort included 181 patients with 131 in the D+ILS group and 50 in the (D+PLF) group. Intraoperative data, including length of hospital stay (LOS), estimated blood loss (EBL), and operative time were recorded. Pain management surveys and patient-reported outcomes were collected including Oswestry Disability Index (ODI), Short Form Surveys (SF-12), Zurich Claudication Questionnaire (ZCQ), and Visual Analog Scale (VAS) for back and leg pain and were completed preoperatively and out to 60 months postoperatively. Composite Clinical Success (CCS) was defined as a ≥ 15 point improvement of ODI plus the absence of reoperations, neurological deficits, and major device-related complications.

Results: Patient follow-up at 60 months for the D+ILS group and D+PLF groups were 88.2% and 86.7% respectively. Mean length of hospital stay was 1.79 days in the D+ILS group and 3.06 days in the D+PLF group ($p < 0.001$). A statistically significant difference was noted in mean EBL with 112cc for D+ILS and 337.8cc for D+PLF ($p < 0.001$). D+ILS patients experienced a significantly shorter surgery than D+PLF patients with a mean operative time of 96.5 minutes for D+ILS and 153.3 minutes for D+PLF ($p < 0.001$). Radiographic findings show preservation of foraminal height and disc height out to 5 years in D+ILS. At 60 months in the D+ILS group, narcotic and NSAID/ASA/Acetaminophen usage decreased from preoperative values by 17% and 20%, respectively. At 60 months, there was no statistically significant difference in the CCS between treatment groups. There were no differences in patient-reported outcomes.

Discussion: At 5-year follow-up, D+ILS has been shown to be a durable and efficacious treatment option in a younger spinal stenosis population with or without grade 1 spondylolisthesis. Decompression + ILS surgery is significantly less invasive for the patient as measured by shorter operative times, decreased blood loss, and shorter length of stay. As hospital costs are of growing concern, these substantial differences should be strongly considered. As a cohort of a non-inferiority study design, patient-reported outcomes showed no differences between the groups. However, in this younger and more physically active patient population, a safe and effective non-terminal surgery should be considered before more invasive fusion surgery.

Category: 1 - Clinical

Topic: 17 - Thoraco-Lumbar Degenerative

Comparison of Decompression with Interlaminar Stabilization vs. Decompression with Fusion in Patients Requiring Surgical Treatment for Spinal Stenosis with Grade I Spondylolisthesis at 5 Year Follow-Up*C. Dowe¹, A. Breceovich¹, F. Cammisa¹, C. Abjornson¹*¹Hospital for Special Surgery, Spine Research, New York, NY, United States

Background: Multiple studies have supported decompression with fusion over decompression alone for the surgical management of spinal stenosis with spondylolisthesis. More recently, level-1 evidence has supported microsurgical decompression with interlaminar stabilization (D+ILS) as an effective alternative.

Purpose: The purpose of this study was to compare microsurgical decompression with instrumented posterolateral fusion (DF) to D+ILS in patients who require surgical treatment for lumbar spinal stenosis with grade I spondylolisthesis at 5 year follow-up.

Study Design/Setting: This patient cohort was part of a prospective, randomized, multicenter Investigational Device Exemption (IDE) non-inferiority study with a 2:1 randomization ratio which enrolled a total of 322 patients from 21 sites in the United States between 2006 and 2010.

Patient Sample: Of the 322 patients enrolled in the original study, 150 patients were diagnosed with up to Grade 1 spondylolisthesis. Within the cohort, 99 patients enrolled received ILS (coflex[®], New York, New York) and 51 received DF.

Outcome Measures: Efficacy was measured by Composite Clinical Success (CCS) scores. Patients achieved CCS if all four of the following outcomes were met: achieving a ≥ 15 point improvement from baseline Oswestry Disability Index (ODI), no reoperation or epidural injections, no persistent, new, or increasing neurological deficits, and no major device-related complications.

Methods: Data was collected pre-operatively, and then at 6 weeks, 3, 6, 12, 18, 24, 36, 48, and 60 months post-operatively. A patient had to be a success in all four components of CCS to achieve clinical success at the 60 month mark.

Results: Baseline demographic, clinical, or radiographic variables were similar for the two groups. Patient follow-up at 5 years was 88.9% ILS and 76.4% for DF groups. Intraoperatively, ILS patients experienced significantly shorter operative times ($p < 0.0001$), less estimated blood loss ($p < 0.0001$), and shorter length of stay ($p < 0.0001$) than DF patients. There was no difference between groups in patients who underwent a reoperation and/or post-operative epidural injection ($p = 0.71$). The percentage of patients achieving CCS in the D+ILS group was non-inferior to that in the DF group [ILS 44.3% (39/88); DF 53.8% (21/39); $p = 0.48$].

Conclusions: As designed, this study demonstrates non-inferiority of decompression with interlaminar stabilization versus fusion for a validated composite endpoint of safety and efficacy, including patient-reported outcomes for the treatment of spinal stenosis with grade I spondylolisthesis. ILS provides a durable and effective treatment option in a less invasive manner for the patient. For the healthcare system, it is a significantly more cost-effective treatment option at approximately half the operative time and almost 2 days shorter hospital stay. As a non-terminal procedure, ILS offers an opportunity for motion sparing while not limiting options if further surgical intervention is needed in the future.

Category: 1 - Clinical

Topic: 19 - Value and Outcomes in Spine Surgery

Medical Cost Savings for Lumbar Spinal Stenosis Treated with Decompression and Interlaminar Stabilization as an Alternative to FusionV. Bender¹, K. Fitch², T. Engel², S.R. Gollish³¹Optimize Science, Mill Valley, CA, United States, ²Milliman, Inc., New York, NY, United States, ³Jupiter Medical Center, Palm Beach, FL, United States

Background: Lumbar fusion is often performed following decompression in patients with lumbar spinal stenosis (LSS), resulting in significant cost to the healthcare system. Interlaminar stabilization (ILS) is a clinically effective alternative to fusion associated with shorter operative times and a shorter length of hospital stay, both major drivers of cost. We examined the potential economic impact of utilizing ILS instead of fusion for a portion of decompressions requiring stabilization.

Methods: Data regarding the incidence and cost of lumbar decompression and fusion for LSS were gathered from a commercial database (MarketScan 2013, Truven Health Analytics, Ann Arbor, USA). All 2013 costs were trended to 2016 using a 5% annual medical cost trend. We calculated the medical costs including the cost of the initial procedure, 180 day post-surgery recovery and hospitalization, and prescription drugs. In order to estimate the cost of decompression followed by ILS, we added the implant cost to the calculated cost of decompression alone, assuming similar average surgical time, length of stay, and rehabilitation. Using the identified incidence and costs, we then estimated the medical cost impact of replacing 10%, 25%, or 50% of LSS-related spinal fusion surgeries with decompressive surgery followed by an ILS-device (Coflex, Paradigm Spine, New York, USA).

Results: The average cost of LSS-related decompression with fusion was \$88,812. The estimated cost of decompression with ILS was \$33,776, taking into account the cost of decompressive surgery, implants, hospitalization, and prescription drugs. The estimated difference per procedure between decompression with fusion versus decompression with ILS was \$55,037 higher for fusion surgery. The estimated cost savings of replacing 10%, 25%, or 50% of spinal fusions with ILS are \$0.15, \$0.37, and \$0.74 per member per month, respectively. For a commercially insured population of 100,000 members, that would translate to an annual cost savings of \$180,000, \$444,000 and \$888,000, respectively.

Conclusions: Our analysis of the incidence and costs of LSS-related surgery in a commercial insured population estimates that fusion surgery is over \$50,000 more costly per procedure than decompression with interlaminar stabilization. Utilization of interlaminar stabilization as an alternative to fusion in a clinically appropriate portion of LSS patients would favorably impact the total cost of care while preserving clinical outcomes.