Comparison of Decompression with Interlaminar Stabilization vs. Decompression with in Patients Requiring 2 Levels of Surgical Treatment for Spinal Stenosis

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Background

Current Accepted Treatment Options for Lumbar Spinal Stenosis

Non-Surgical Conservative Care
- Epidural Steroid Injections
- Pain medications
- Physical Therapy

Symptoms persist >12 weeks\(^1\)

Surgical Treatment Options
- Decompression Alone
- Decompression with Fusion

Studies have looked at surgical treatment options in general cohorts of stenosis patients, but have not specifically examined the longevity of multi-level surgical treatments

\(^1\)Weinstein, *NEJM*, 2008
Interlaminar stabilization (ILS)

- Hypothesis: ILS is a viable alternative to decompression with fusion for treating two levels of spinal stenosis
  - Example: coflex® (Paradigm Spine, NY, NY) ILS device achieved FDA PMA approval, for up to a Grade I spondylolisthesis, in 2012
  - U-shaped device, fixed between lamina after decompression
  - Goals:
    - Unload facet joints
    - Stabilize the motion segment
    - Maintain the neurological decompression & foraminal height
    - Preserve some motion

Until now, the two-level experience of ILS compared to instrumented fusion has not yet been formally analyzed or described
Methods: Patient Population

Enrollment

Total patients enrolled/randomized: n = 322

- Single Level
  - Patients requiring treatment at single level: n = 206
    - ILS
      - Patients who received ILS: n = 77
    - Fusion
      - Patients who received fusion: n = 39

- Two Levels
  - Patients requiring treatment at 2 levels: n = 116
    - Month 60 CCS
      - Total patients analyzed for CCS: n = 69
        - Patients excluded from analysis: n = 8
      - Total patients analyzed for CCS: n = 33
        - Patients excluded from analysis: n = 6

88% 5 year follow up
### Results: Composite Clinical Success

#### Month 60 Overall Efficacy: Two Level Procedures

<table>
<thead>
<tr>
<th>Status pre-op compared with Month 60</th>
<th>Decompression + ILS</th>
<th>Decompression + fusion</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement of ≥15 points in ODI at Month 60 compared to baseline</td>
<td>86.7%</td>
<td>92.9%</td>
<td>0.532</td>
</tr>
<tr>
<td>No reoperation or epidural steroid injection (Up to Day 1825)</td>
<td>68.8%</td>
<td>51.3%</td>
<td>0.065</td>
</tr>
<tr>
<td>No reoperations, revisions, removals, or supplemental fixation</td>
<td>87.0%</td>
<td>74.4%</td>
<td>0.088</td>
</tr>
<tr>
<td>No epidural injection at any lumbar level up to and including the Month 60 visit</td>
<td>80.5%</td>
<td>69.2%</td>
<td>0.174</td>
</tr>
<tr>
<td>No persistent new or increasing sensory or motor deficit at 60 months</td>
<td>96.5%</td>
<td>96.2%</td>
<td>0.939</td>
</tr>
<tr>
<td>No persistent new or increasing sensory deficit</td>
<td>98.3%</td>
<td>100.0%</td>
<td>0.493</td>
</tr>
<tr>
<td>No persistent new or increasing motor deficit</td>
<td>98.2%</td>
<td>96.2%</td>
<td>0.564</td>
</tr>
<tr>
<td>No major device-related complications</td>
<td>97.4%</td>
<td>94.9%</td>
<td>0.480</td>
</tr>
<tr>
<td>Composite Clinical Success (Month 60 CCS-FDA)</td>
<td>55.1%</td>
<td>36.4%</td>
<td>0.077</td>
</tr>
</tbody>
</table>

<sup>1</sup>Chi-Square test
## Reoperation Categories

<table>
<thead>
<tr>
<th>Reoperation Category</th>
<th>D+ILS (N=77) n (%)</th>
<th>D+Fusion (N=39) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound/surgery related</td>
<td>3 (3.9%)</td>
<td>1 (2.6%)</td>
</tr>
<tr>
<td>Under treatment</td>
<td>2 (2.6%)</td>
<td>2 (5.1%)</td>
</tr>
<tr>
<td>Device related issue</td>
<td>2 (2.6%)</td>
<td>2 (5.1%)</td>
</tr>
<tr>
<td><strong>Device ineffective</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>A. Early (≤2 years post-op)</strong></td>
<td>2 (2.6%)</td>
<td>1 (2.6%)</td>
</tr>
<tr>
<td><strong>B. Late (&gt;2 years post-op)</strong></td>
<td>1 (1.3%)</td>
<td>4 (10.3%)</td>
</tr>
<tr>
<td>Trauma</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>10 (13.0%)</td>
<td>10 (25.7%)</td>
</tr>
</tbody>
</table>
Results: ODI

*Significant difference between ILS and fusion groups: two sample pooled t-test p-value = 0.023
† Significant difference between ILS baseline and follow-up: within-group paired t-test
◊ Significant difference between fusion baseline and follow-up: within-group paired t-test
Results: Mean VAS Leg Pain for Most Symptomatic Leg

*Significant difference between ILS and fusion groups: two sample pooled t-test p-value = 0.035
† Significant difference between ILS baseline and follow-up: within-group paired t-test
◊ Significant difference between fusion baseline and follow-up: within-group paired t-test
Conclusions

- This is the first analysis that specifically focuses on the sustainability of two-level fusion vs. ILS treatments.
- At 5 years post-op, patients who received ILS at two levels performed as well, if not better, than patients who received fusion at two levels.
  - As demonstrated by Composite Clinical Success and secondary outcome measures.
- The reoperation rate for fusion patients was twice the rate for ILS patients:
  - 25.7% fusion vs. 13.0% ILS.
- With regard to late-term (>2 years post-op) device sustainability:
  - 10.3% fusion late device ineffective vs. 1.3% of ILS late device ineffective.
- ILS has been found to be a durable and sustainable option for treating two levels of spinal stenosis.
Thank you!
References

Disclosures

Research support was provided by Paradigm Spine, LLC (NY, NY, USA)