Two Year Outcomes of Prospective Randomized Trial Comparing Lumbar Decompression With or Without Interlaminar Stabilization

An Interim Analysis including 184 patients

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The Degenerative Cascade of Spinal Stenosis

Is Decompression Alone Enough?

Is Decompression and Interlaminar Stabilization too much?

Who has better outcomes?

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The Purpose of the Trial

• To compare clinical and functional outcomes of patients with moderate to severe lumbar spinal stenosis
• Two prospectively randomized groups
  1. Decompression alone (DA)
  2. Decompression and Interlaminar Stabilization (ILS)
Methods

• Prospective randomized controlled level 1 study with 1:1 randomization
• Moderate to severe lumbar spinal stenosis, 1 or 2 contiguous levels, L1 to L 5 with VAS back pain scores > 50 mm, 6 sites in Germany
• 184 patients randomized, 97 Decompression alone (DA), 87 Interlaminar Stabilization ILS with minimum of 2 year f/u
• Responder analysis based on CCS at 24 months
• CCS required freedom of reop or injections (ESIs)
• CCS also with ODI, ZCQ, treadmill test, and VAS pain
Treadmill testing/Success criteria

- Treadmill success required improvement in walking time $\geq 8\text{ min}$ or for 15 min
- ZCQ success required $\geq 2$ of 3 ZCQ components
- VAS back and leg success required $\geq 20\text{ mm}$ improvement
- Narcotic use was used as an additional CCS component
- $>15$ point ODI improvement used as a primary endpoint
Results

• At m24, 17 patients (19.5%) ILS and 31 (32%) DA had either an event (reop. or ESI, p=.056)
• For ILS, first event failure was reop. 15/17, 12/31 for DA
• Among event free subjects, 82.5% ILS and 87.5% DA achieved ZCQ success
• Overall CCS 63.5% for ILS and 53.2% for DA, p=.078
• ILS had less narcotic use 13.3% ILS vs 25.3% DA, p=.075
• Using no narcotics for/with CCS, 58.1% ILS vs 43% DA, p=.06
• Treadmill tests, narcotic use, VAS back pain, ZCQ, ODI all favor ILS
• Safety profiles comparable for both groups
Time to Reoperation or Epidural Steroid Injection

Survival Estimates
With Number of Subjects at Risk

Logrank p=0.1024

Days Post Index Surgery

GROUPS  1: Coflex  2: Control
No Narcotic Use at m24 and incremental CCS Adding No Narcotic Use

Percentage achieving success:

- No Narcotic Use: 88.9%
- CCS-ODI-No Narc: 74.2%
- Endpoint: 50.0%
- ILS & DA: p=0.044
- DA: p=0.049

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No New or Worsening, Persistent Neurological Deficit and Incremental CCS Adding Neuro Endpoint

This endpoint evaluates individual sub test and determines whether or not there is a new or worsening motor or sensory deficit not present at baseline that is present at month 12 and still present at month 24.
Improvement in Functional Treadmill Test at Mo. 24 in patients with No Reop. and No ESI

Sig. Improvement in max walking distance >= 8 min, or to the point of walking for 15 min.

Percentage achieving success

- ILS & DA: 82.5%
- DA: 66.7%
- 55.9%

p = 0.049

Sig. improvement in max. walking distance >=8min, or to the point of walking for 15 min.
Improvement in Functional Treadmill Test Incremental CCS with m24 Narcotic Use

Percentage achieving success

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<thead>
<tr>
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<th>ILS &amp; DA</th>
<th>DA</th>
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<tbody>
<tr>
<td>CCS-Treadmill</td>
<td>55.9%</td>
<td>34.4%</td>
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<tr>
<td>CCS-Treadmill-No Narc.</td>
<td>52.5%</td>
<td>31.2%</td>
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p=0.017
Conclusions

- Decompression and ILS for moderate to severe spinal stenosis resulted in measurably and significantly better functional outcomes, lower treatment failure rates, and less use of narcotics compared to decompression alone using responder analysis based on CCS and other important clinical measurements of improvement.

At m24, for moderate to severe spinal stenosis, **DA is beneficial, decompression + ILS is better**

Disclosures:
- Grant/ research support: This RCT was financially supported by Paradigm Spine.
- Consultants: Michael Rauschmann, Joerg Franke, Steffen Sola are consultants for Paradigm Spine.