Real-World Evaluation of an Interspinous Spacer used for the Treatment of Lumbar Spinal Stenosis

Michael F. Esposito1, Richard Ferro2, John Chatas3, Michael Verdolin4, John Hatheway5, Robert Wilson6, Jessica Jameson7, Holly Kaufman8, Lilly Chen8, Roshini Jain8


BACKGROUND

Indirect Decompression Systems (IDS) or Interspinous Spacers are an option in well-selected patients with impaired physical function who experience relief in flexion from symptoms of leg, buttock and/or groin pain due to lumbar spinal stenosis (LSS). A growing body of published clinical evidence has demonstrated excellent long-term clinical benefit with sustained pain relief, improved quality of life and medication reduction up to 5 years post-implant.1-3 Real-world reports demonstrated excellent long-term clinical benefit for patients including leg pain responder rate and pain severity of 75% and 60% respectively at 12 months post-operation.4 Here, we provide real-world outcomes in patients with severe pain who received an Indirect Decompression System (IDS) for LSS related pain and symptoms as part of an ongoing multi-center observational case series.

METHODS

Study Design
Multi-center, observational case-series. Data collected by site personnel only

Study Device
Boston Scientific Superion Indirect Decompression Systems (IDS)

Patients/Sites
41 patients with severe pain (8 or above) at 7 centers who received IDS for their Lumbar Spinal Stenosis (LSS)

RESULTS

Baseline Characteristics (n = 41)

<table>
<thead>
<tr>
<th>Gender - Females (%)</th>
<th>56% (23/41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [Mean (SD)]</td>
<td>69.7 (11.2) yrs. n = 41</td>
</tr>
<tr>
<td>Baseline NRS [Mean (SD)]</td>
<td>9.4 (0.5) n = 41</td>
</tr>
<tr>
<td>Follow-up duration [Mean (SD)]</td>
<td>115.1 (161.8) days n = 41</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Lumbar Spinal Stenosis</td>
</tr>
</tbody>
</table>

Overall Pain Scores (n = 41)

A 5.4-point improvement (9.4 - 4.0, p < 0.0001, n = 41) was reported at last follow up (mean = 115 days) among patients with severe pain at Baseline (8 or more)

Distribution of pain scores at last follow up (n = 41)

41% (17 of 41 patients) reported a pain score of 3 or less at last follow up

90% (37 of 42) of patients reported a clinically significant* improvement in their overall pain at last follow up

*≥ 2-point improvement in pain scores (NRS)

REFERENCES


CONCLUSIONS

Results from this ongoing real-world observational case-series of severe pain patients (8 or more on NRS) who received IDS for the treatment of their LSS symptoms demonstrated at last follow up (mean = 115 days):
• 5.4 pt. improvement in overall pain (9.4 - 4.0, p < 0.0001)
• 90% reported a clinically significant improvement in pain (≥ 2-point improvement)
• 41% reported a pain score of 3 or less

This preliminary evidence supports other reports in the literature.

DISCLOSURES

Holly Kaufman, Lilly Chen and Roshini Jain are employees of Boston Scientific.