Interspinous/Interlaminar implants are the way to go for degenerative spondy

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History
- 1954 - Knowles device - Included frequent rotation and loosening, so was no longer used.
- 1986 – Wallis system by Abbot Spine
- 1990’s – Multiple devices became available in Europe

Interspinous Motion Devices
- All class 3 medical devices, so IDE was required for approval.
- Indicated for lumbar spinal stenosis and up to grade 1 spondy.
  - 2012 – Coflex (Paradigm Spine) approved in US
  - 2015 – Superion (Vertiflex) approved in US
- Coflex IDE was conducted against a decompression and fusion control.
Interspinous Fixation Devices

- Multiple devices are on the market – approved via 510k, so control data was not required.
  - Southern Spine – Stabilink
  - Alphatec Spine - Bridgepoint
  - Zimmer/Biomet - Aspen
  - LDR - Interbridge

Coflex – 5 year IDE data

**ODI**

![Graph showing ODI scores over time for Coflex and Fusion Control](image)

* Statistically significant compared to pre-operative value within each treatment. Error bars represent standard deviation.

**VAS Back**

![Graph showing VAS Back scores over time for Coflex and Fusion Control](image)

* Statistically significant compared to pre-operative value within each treatment. Error bars represent standard deviation.
Coflex – 5 year IDE data
Reoperations

<table>
<thead>
<tr>
<th>Time</th>
<th>Coflex%</th>
<th>Fusion%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1 yrs</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td>1 - 2 yrs</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>2 - 3 yrs</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>3 - 4 yrs</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4 - 5 yrs</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Coflex – German Study

- RCT with 1:1 randomization
  - Control is open microsurgical decompression alone
  - 225 patients (110 Coflex, 115 Control)
  - Single and multi-level treatment
- Outcomes
  - ODI and VAS back/leg were significantly improved in both groups, but not different
  - Risk of secondary intervention was 1.75 (95% CI 0.99 to 3.09) times higher among control compared to Coflex (p=0.055)

Other studies

- Roder et al (2015) – Short term results show lumbar decompression with Coflex compared to decompression alone is safe and effective
  - SWISSpine registry study
- Lonne et al (2015) - Minimally invasive decompression and X-Stop has similar outcomes, both improved significantly. X-Stop had a higher risk of secondary surgery, but decompression had more severe complications.
  - Prospective, multicenter RCT
- Wu et al (2014) – PLoS review paper. Spacers are associated with higher reoperation and higher cost, but all clinical outcomes were statistically similar when pooled.
Thank You!