


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

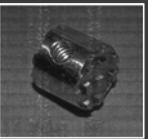


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History

- 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.
 - 2005 – XSTOP (Medtronic) approved in US (launched in 2008 and removed from market in 2015)
 - 2012 – Coflex (Paradigm Spine) approved in US
 - 2015 – Superior (Vertiflex) approved in US 2015
- Coflex IDE was conducted against a decompression and fusion control.



Interspinous Fixation Devices

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

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Coflex – 5 year IDE data ODI

The chart displays ODI scores for two groups: Coflex (white bars) and Fusion Control (black bars). The y-axis represents the ODI Score from 0 to 100. The x-axis shows time points: Pre-op, Week 6, Month 3, Month 6, Month 12, Month 18, Month 24, Month 36, Month 48, and Month 60. Both groups start with a high ODI score at Pre-op (~75). The Fusion Control group shows a steady decline to ~25 by 60 months. The Coflex group shows a sharp drop at Week 6 (~35) and remains significantly lower than the Fusion Control group at all subsequent time points. Error bars represent standard deviation, and asterisks indicate statistical significance.

Time Point	Coflex™	Fusion Control
Pre-op	75	75
Week 6	35	60
Month 3	30	55
Month 6	28	50
Month 12	25	45
Month 18	25	45
Month 24	25	45
Month 36	25	45
Month 48	25	45
Month 60	25	45

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

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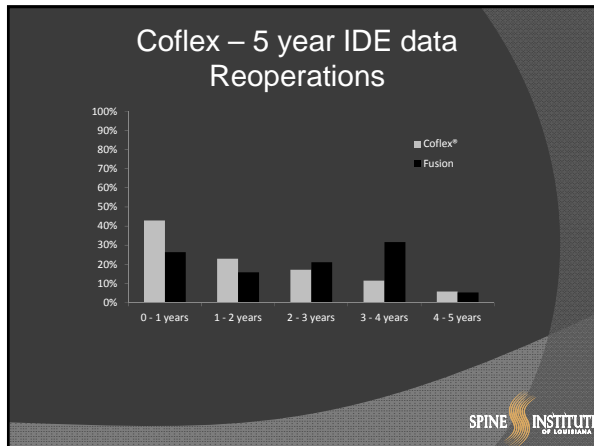
Coflex – 5 year IDE data VAS Back

The chart displays VAS Back scores for two groups: Coflex (white bars) and Fusion Control (black bars). The y-axis represents the VAS Back score from 0 to 100. The x-axis shows time points: Pre-op, Week 6, Month 3, Month 6, Month 12, Month 18, Month 24, Month 36, Month 48, and Month 60. Both groups start with a high VAS Back score at Pre-op (~85). The Fusion Control group shows a steady decline to ~30 by 60 months. The Coflex group shows a sharp drop at Week 6 (~35) and remains significantly lower than the Fusion Control group at all subsequent time points. Error bars represent standard deviation, and asterisks indicate statistical significance.

Time Point	Coflex™	Fusion Control
Pre-op	85	85
Week 6	35	70
Month 3	30	65
Month 6	28	60
Month 12	25	55
Month 18	25	55
Month 24	25	55
Month 36	25	55
Month 48	25	55
Month 60	25	55

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

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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)

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Other studies

- Roder, et al (2015) – Short term results show lumbar decompression with Coflex compared to decompression alone is safe and effective
 - SWISSspine 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.

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