Introduction: A decompression procedure to treat a spinal stenosis may cause instability of the segment. To avoid adjacent level posterior stabilisation it is preferred as a non fusion concept. With an interspineous device flexible stabilization is achieved while preserving the intervertebral disc and vertebral structures. It prevents a compression of neuronal space on extension and reduces load on the facet joints. If the ligament band is degenerated the affected segment is also stabilized for rotational movements. Indication is a spinal canal stenosis with or without hypertrophic facet joints.

Material and methods: The purpose of this study is to collect long term clinically relevant parameters for patients treated with the Coflex® implant.

Pre- and post-operative data has been obtained using Visual Analog Pain Scores (VAS), Oswestry disability index (ODI) and the SF36.

153 Patients were assessed pre-operatively and post-operatively at 3 month, 6 month, 12, 24, 36 and 48 month.

Results: The mean age of the 77 males was 65 yrs. (35- 84) and of the 76 females 67 yrs (44-86). 112 single levels of surgery included L2/L3 (4.4%), L3/L4 (23.2%), L4/L5 (70.6%) and L5/S1 (1.8%). 41 multilevel implantations are L2/L3 - L3/L4 (21.9%), L3/L4 - L4/L5 (70.9%); L4/L5-L5/S1 (2.4%); L4/L5-L5/L6 (2.4%) and one 3-level from L2 - L5 (2.4%). VAS, NDI and SF 36 values decreased significantly postoperatively and were maintained throughout the follow up. VAS scores decreased from a mean score of 7.2 ± 2.1 baseline to 4.4 ± 2.3 at 3 months; 4.3 ± 2.8 at 6 months; 4.3 ± 2.7 at 12 months; 4.5 ± 2.7 at 24 month; 3.6 ± 2.5 at 36 month and 4.0 ± 3.4 at . ODI scores (in %) reduced from 51.2 ± 16.6 baseline to 36.2 ± 18.1 at 3 months, 34.5 ± 20 at 6 months; 34.6 ± 19.9 at 12 months; 36.5 ± 19 at 24 months; 34.1 ± 21 at 36 month and 28.4 ± 22.7 at 48 month post-operative. The SF 36 physical / mental component and total was baseline P 46.8 ± 22.0 M 27.5 ± 9.4 T 64.8 ± 16.5 and improved at 3 month P 36.2 ± 11.0 M 31.9 ± 11.7 T 79.7 ± 17.2; 6 month P 36.7 ± 9.4 M 30.6 ± 12.8 T 79.6 ± 18.5; 12 month P 34.9 ± 10.4 M 22 ± 9.4 T 79.4 ± 17.7; 24month P 35.6 ± 10.0 M 30.5 ± 9.4 T 79.5 ± 18.6; 36 month P 35.6 ± 9.1 M 31.3 ± 7.7 T 79.5 ± 19.7 and 48 month P 32.7 ± 12.2 M 29.1 ± 8.7 T 86.6 ± 18.4. 88%, respectively 82% of the patients were completely satisfied or at least satisfied with the result of the surgery 12, 24 months post-operative an no one reported to be unsatisfied at 36 and 48 month. Three cases required a revision.

Conclusions: The Coflex® implant offers a simple surgical treatment strategy with a low risk potential. First results show good improvement of clinical relevant parameters and a high degree of patient satisfaction. The investigation in this group of patients is continued to collect more long term data.