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Functional Dynamic Stabilization in Lumbar Spinal Stenosis with COFLEX® Interspineous Implant - 4 Year Results

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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.