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Dynamic stabilization in lumbar spinal stenosis with COFLEX[®] interspinous implant - an update*R. Bertagnoli¹*¹ProSpine, Straubing, Germany

Introduction: Treatment of spinal stenosis may cause instability of the segment. To unload disc and facets posterior stabilisation it is preferred over a fusion concept. With an interspinous device a 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. Primary indication is a moderate to severe 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[®] interspinous implant.

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

170 Patients were assessed pre-operatively and post-operatively at 3 month, 6 month then yearly.

Results: The mean age of the 91 males was 66 yrs. (35- 84) and of the 79 females 67 yrs (44-86). 122 single levels of surgery included L2/L3 (4%), L3/L4 (22,2%), L4/L5 (71,4%) and L5/S1 (2,4%). 48 multilevel implantations are L2/L3 - L3/L4 (26,7%), L3/L4 - L4/L5 (67,3%); L4/L5-L5/S1 (2%); L4/L5-L5/L6 (2%) and one 3-level from L2 - L5 (2%). VAS, ODI and SF 36 values decreased significantly postoperatively and were maintained throughout the follow up. VAS scores decreased from a mean score of $6,9 \pm 2,3$ baseline to $4,2 \pm 2,4$ at 3 months; $4,3 \pm 2,8$ at 6 months; $4,4 \pm 2,7$ at 12 months; $5,2 \pm 2,8$ at 24 months; $4,0 \pm 3,1$ at 36 months and $4,3 \pm 3,3$ at 48 months. ODI scores (in %) were reduced from $50,6 \pm 17,8$ baseline to $34,8 \pm 18,9$ at 3 months, $34,8 \pm 19,7$ at 6 months; $33,8 \pm 17,2$ at 12 months; $38,2 \pm 18,7$ at 24 months; $33,7 \pm 19,5$ at 36 months and $27,6 \pm 22,7$ at 48 month post-operative. The SF 36 physical / mental component and total was baseline P $28,9 \pm 6,8$ M $27,9 \pm 9,5$ T $65,8 \pm 16,6$ and improved at 3 months P $36,8 \pm 10,7$ M $32,1 \pm 11,7$ T $80,6 \pm 16,4$; 6 months P $36,1 \pm 9,3$ M $29,2 \pm 9,2$ T $79,5 \pm 18,2$; 12 months P $35,2 \pm 10,4$ M $31,6 \pm 9,2$ T $79,6 \pm 17,3$; 24 months P $33,8 \pm 9,2$ M $30,8 \pm 9,1$ T $77,7 \pm 17,9$; 36 months P $35,7 \pm 10,4$ M $31 \pm 7,6$ T $79,3 \pm 21$ and 48 months P $38 \pm 11,5$ M $32,3 \pm 9$ T $86,3 \pm 18,2$. 87%, respectively 83% of the patients were completely satisfied or at least satisfied with the result of the surgery 12, 24 months post-operative and no one reported to be unsatisfied at 36 and 48 month. There was no implant failure.

Conclusions: The Coflex[®] implant offers a simple surgical treatment strategy with a low risk potential. Results show good improvement of clinical relevant parameters and a high degree of patient satisfaction. Longer term data collection is impaired due to high age of patients.