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Functional Dynamic Stabilization in Lumbar Spinal Stenosis with COFLEX® Interspineous Implant - Min. 3-year Results
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Introduction: A decompression procedure to treat a spinal stenosis may cause instability of the segment. For posterior stabilisation it is preferred to use a non fusion concept to avoid adjacent level degeneration with a minimally invasive surgery. 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.

Material and methods: The purpose of this study is to collect long term clinically relevant parameters for patients treated with the Coflex® (Paradigm Spine) interspinous implant.
Pre- and post-operative disability and pain scores have been obtained using Oswestry and Visual Analog Pain Scores (VAS) and the raw total obtained from SF36 mental and physical component scale.
Patients were assessed pre-operatively and post-operatively at 3 month, 6 month, 12, 24 and 36 month.

Results: Up to now (date of submission of abstract) 143 patients (182 devices) were treated with the device. Indication is a spinal canal stenosis with or without hypertrophic facet joints.
The mean age of the patients was 65 years (35-87) in the examined 3 year 117 patient group. Levels of surgery included 14 L2/L3, 50 L3/L4, 78 L4/L5, 2 L5/S1 and 2 L5/L6. Multilevel: 1 L2/L3 - L3/L4, 3 L3/L4 - L4/L5 and one 3-level from L2 - L5. Visual analog pain scores decreased from a mean score of 7.9 pre-operative to 4.5 (improvement of 43%) at twelve months post-operative and 5.1 at 24 month (improvement of 35%) and 5.4 at 36 month. Oswestry disability scores were reduced from 54% pre-operative to 48% at 12 months, 34.2% at 24 month 48% at 36 month post-operative.
Preoperative SF36 raw total values were 64.1 and improved at the 12 month interval to 78.5 and was maintained at 78.4 for the 24 month interval and 76,8 at 36 month.
88%, respectively 87% of the patients were completely satisfied or at least satisfied with the result of the surgery 12, 24 and 36 months post-operative.
In two cases reinstrumentation to a fusion was necessary.

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.