Treatment of spinal stenosis with coflex - an interspinous dynamic device - results of a follow-up study of 154 patients.

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Objective

Spinal stenosis is a known disease of the facet joints. We consider this as the main indication for implanting the dynamic interspinous coflex™ device (Paradigm Spine GmbH, Germany) after decompression of the neural structures. Due to the implantation technique, the implant is positioned close to the anatomical centre of rotation (COR) and reaches the level of the facet joints. Therefore the range of motion of the facet joints can be controlled, the joint is slightly distracted, the foraminal height is restored and due to the metallic stiffness the height will be maintained. Using this procedure, in addition to the effect of decompression the low back pain is relieved.

Material and methods

Our follow-up study was part of an international multi centre data-collection for an IDE-study in the United states to determine the safety and efficacy of the coflex™-implant, a funtionally dynamic interspinous implant (U-shaped titanium) (Fig.1 and 2). From February 2002 until November 2004 we treated 240 patients in our hospital with this procedure. 206 (86%) patients could be evaluated, 154 of them operated due to spinal stenosis (64 (42%) male, 90 (58%) female; 66 patients (43%) age 40-65, 88 (57%) age > 65): 96 (62%) presented with stenosis only, 42 (27%) presented with a combination of stenosis and spondylolisthesis, in 16 patients (11%) a stenosis and an additional scoliosis was found. Median follow-up 14.5 months. At the time of follow-up all patients had questionnaires, x-ray taken (Fig.3) and clinical examination.

Fig. 1: coflex™, a funtionally dynamic interspinous implant (U-shaped titanium; Paradigm Spine GmbH, Germany)

Results

We found preoperatively 92/154 (60%) patients with moderate or severe low back pain (LBP). Postoperatively, in this group the LBP in 66 (72%) patients did improve, 37 (40%) even showed no low back pain anymore. Mean preoperative walking distance was < 1000m in 137 (89%) patients, postoperatively 134 (87%) patients could walk >1000m. According to the questionnaires, 141 (92%) patients were satisfied or very satisfied, only 13 patients (8%) were not satisfied. Long-term follow-up did not show a decrease of patients satisfaction. 146 patients (95%) stated that they would undergo this surgery again. Immediate postoperative complications occured in 5 patients (3%), namely 2 seromas, 1 worsening of existing motoric deficite, 2 worsenings of existing sensory deficite. 2 patients had the coflex™ removed (not device related) and we saw only 1 migrated coflex™ (5mm, no clinical signs). We found no broken or deformed coflex™. 3 patients needed fusion within 12 months postoperatively, 1 patient presented with recurrent disc herniation and in 1 case we saw a disc herniation on a new level.

Discussion

The study confirmed the known positive effect of decompression of neural structures on claudication and leg pain. In addition, the moderate and/or severe LBP could be relieved in 72% of the patients. The decreased preoperative walking distance, partly due to LBP, partly due to claudication, improved significantly. Also, the patient satisfaction was extremely high (92%) and the majority (95%) would undergo surgery again. Therefore, we think that the decompression with additional coflex™ implantation can not only improve the claudication but also the accompanying low back pain. The rate of complications in our study was very low.

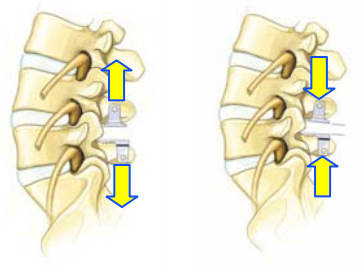

Fig. 2: Dynamic function of coflex™ in flexion/extension

Conclusion

The treatment with coflex™ as a method of dynamic stabilisation after neural decompression allows to reduce low back pain without fusion. We could demonstrate that the implantation of coflex™ is safe and effective. Further prospective studies will be needed and are planned.

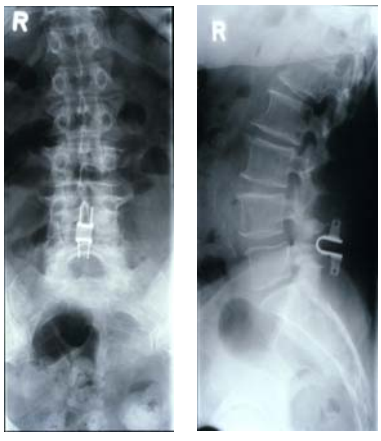

Fig. 3: coflex™ 12mm L4/5 after decompression (x-ray, ap and lateral)