Is coflex-F implant an alternative to pedicle screw fixation in a lumbar device fusion?

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Objective: In a prospective study, the clinical data of patients, who underwent surgical treatment with interbody fusion and coflex-F stabilization, are collected. The focus of this study is to see if this implant can give as much stability as the pedicle screw in order to have a proper fusion result in intercorporal distraction using cages in TLIF, PLIF or ALIF. Coflex-F as an adjunct to lumbar interbody fusion bridges, the gap.

Methods: Lumbar interbody fusion in TLIF, PLIF or ALIF Technique is performed with the goal of restoring the lordosis through cages, implanting of coflex-F which is thicker (2.1 mm versus 1.5 mm) than coflex. This along with the screws adds additional stability, rigidity and stiffness to the posterior spine thereby facilitating fusion. Secure anchorage is achieved through screw and sleeve fixation. Coflex-F was implanted at the L1-L5 level for one segment. The purpose is to achieve stabilization and to promote fusion in patients with DDD. The patient is placed in the prone position on a surgical frame avoiding hyperlordosis of the spinal segments to be operated upon. Any facet distraction has to be avoided. Patients data was collected pre-op, 3-, 6- and 12 months post-op with VAS- and ODI-Scores Questionnaires as well as evaluating post-op x-ray findings.

Results: The clinical data was collected in 5 spine centers in Germany. For the prospective study, we had total number of n=71 patients; female=36; male=35. The average age was 60 years (34–86). The treated segments included L1-L5 (n=54), L4/5 (72%) (n=14), L3/4 (18%) (n=7), L2/3 (9%), n=1 L1/2 (1%). Data about VAS- and ODI-Score were collected pre-operatively, 3, 6 and 12 months post-op. There was an improvement of the pain level in more than 50% patient satisfaction 12 months post-op was more than 60%. Complications consisted of wing breakage n=1 (1.75%) and n=2 (3.51%) required additional stabilization.

Conclusions: Interspinous stabilization with coflex-F is an ideal adjunct to fusion in cases of DDD with or without mild instability. This implant allows for segmental stabilization in combination with interbody fusion cages and bridges, the gap between stand-alone anterior solutions and 360-fusions using pedicle screw fixation. It can be applied in a less invasive tissue sparing procedure, thereby, significantly reducing iatrogenic damage and resulting in shorter rehabilitation for patients: Further advantages include less blood lost, smaller skin incision, protection of neurological structures and shorter operating times due to the simple surgical technique. The results are comparable to the fusion with cage and pedicle screw.