Is Lumbar TDR Able to Restore and Maintain Segmental ROM in L5/S1 in a Mid-term Period of 3 Years?

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Introduction: Lumbar DDD is supposed to change characteristics of segmental alignment and motion pattern. These changes may lead to facet irritations or ALD. Diverse IDE trials have revealed general benefit and safety of lumbar arthroplasty. However, especially for L5/S1, there have been multiple discussions on the effect and benefit of TDR in mid- and long-term follow-up regarding alignment and segmental ROM of the index-level and a potential protection of adjacent levels.

Purpose: This clinical investigation was performed to proof, if new designs of lumbar disc prosthesis are able to restore Lordosis and ROM in L5/S1 over a mid-term period of 3 years.

Methods: Patients from 2 centers, enrolled in a prospective multi-center study have been evaluated over a period of 3 years. All patients have been presented with DDD in lumbar level L5/S1. Enrolled patients did follow the inclusion and exclusion criteria and specific indication patterns. Patients were treated with a new type of lumbar disc prosthesis (activ L) with limited translation which give surgical possibility of a new offset technology in anterior-posterior dimension. Data were collected prospectively. Radiographs were analyzed by an independent core-lab (frictionless GmbH) using computer-aided measurements. Segmental alignment is measured in the sagittal plane from neutral films between the superior endplates of superior & inferior vertebrae in units of degrees. ROM is measured in the sagittal plane from maximum flexion and extension films in units of degrees and Average Disc Height (ADH) as mean value between Anterior Disc Space Height and Posterior Disc Height (distances between anterior (posterior) edge of inferior endplate of the superior vertebrae and the corresponding edge of the inferior vertebra). Device Loosening was defined as more then 50% radiolucency of at least one metal component.

Results: Segmental Lordosis was restored from 20,2° +/- 10,3° to 29,3° +/- 6,6° (p = 0,001). Publications [Stagnata and Gelb] showed values of 21+/−6 and 24+/−7 for un-symptomatic volunteers. ROM could be improved from 6,0° +/- 3,3° to 10,5° +/- 7,0° with an increase of 4,5° (75%). For other types of prosthesis lower post-op values for the L5/S1 ROM have been demonstrated. Healthy volunteers show a mean ROM for L5/S1 of approx. 14° [Hayes, Percey]. The average disc height could be restored from 4,5mm +/- 2,3mm to 11,6mm +/- 1,4mm, with an increase of 7,1mm (158%). There was no device loosening and no device breakage.

Discussion/conclusion: Function and clinical outcome of TDR are highly related to restoration of lordotic alignment, ROM and disc space height to approx. physiological values. Especially lordotization and ROM seems to have an influence not only for short-term results of the index-level, but also for long-term-results and potential complications as facet joint degeneration and adjacent level disc degeneration in the long-term run. Our data suggests that TDR with activ L is able to restore disc space height, lordotic alignment and ROM to approx. physiological values. Especially the post-OP ROM values of activ L in L5/S1 showed very good results with 11,3°, which is much more then reported from other types of prosthesis.