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Functional Pedicle Based Posterior Dynamic Stabilization System (DSS®) - First ResultsR. Bertagnoli¹¹ProSpine, Straubing, Germany

Introduction: Pedicle based posterior dynamic stabilization systems are designed to stop degenerative processes and control intersegmental motion. Optimal biomechanical control is achieved when the center of rotation is close to the natural point, when facet joints are unloaded, hyper mobility in extension/flexion is avoided, shock absorption is provided and rotational movements are limited in spondylolisthesis. The motion remains in the neutral zone. Stiffness parameters were determined in a finite element model and combined with clinical and safety aspects for the final design (Wilke et.al Spine 34 (3) 255-261 (2009). Indications are patients degenerative disc disease at one or more levels including grade 1 spondylolisthesis. This modular system (Paradigm Spine GmbH) uses flexible spacers (DSS motion) and rigid spacers (DSS Fusion) to combine fusion with stabilization to protect adjacent levels (topping off) or stabilize existing total disc prostheses. If a later fusion should become necessary only the spacer is exchanged.

Material and methods: The purpose of this prospective, consecutive controlled study of 94 patients is to investigate the safety and efficacy the DSS® system. Employed parameters were VAS and ODI. Patients are assessed pre and postoperatively 3, 6, 12, 24 and 36 month.

Results: 53 males (mean age 51 range 29 - 71) and 41 female patients (mean age 54 range 33 - 88) received single or multi level surgeries between Th9 and S1. In a total of 39 motion cases the single level (stand alone or in combination with a previous total disc replacement in the same or neighboring segment) L4/L5 was the most frequent (70%). There are 6 two level, 1 four and 2 five level cases. For 12 fusion cases in the single level (alone or in combination with TDR) L5/S1 is most frequent (66,6%) followed by L4/L5. There are 2 two level cases and 1 three level.

43 Patients received hybrid multilevel implantations (fusion combined with motion or vice versa) including 6 in combination with TDR. The most frequent two level construct (n=15) was L3-L5 (61,5%) followed by L2-L4 and in three level constructs (n=15) L3/S1 (40%) followed by L2-L5 (33%). In four level cases (n=8) L2-S1 predominates (75%); there are 3 five level and each 1 7 and 8 level cases. VAS, NDI values decreased significantly at 3 month postoperative and were maintained throughout the follow up.

VAS scores decreased from a mean score of $6.8 \pm 1,2$ baseline to $4,1 \pm 2,4$ at 3 months; $4,0 \pm 2,2$ at 6 months; $4,1 \pm 2,3$ at 1 yr ; $3,9 \pm 3,1$ at 2 yrs. and $4,0 \pm 3,3$ at 3 yrs. ODI scores (in %) were reduced from $52,2 \pm 17,5$ baseline to $44,2 \pm 17,6$ at 3 months, $46,4 \pm 16,8$ at 6 months; $42,4 \pm 17,2$ at 1 yr; $43,2 \pm 15,3$ at 2yrs and $37,2 \pm 15,7$ at 3 yrs.

Conclusion: Apart from ease of implantation and the modularity of the system there are indications that other products with different biomechanics show differences in clinically relevant parameters. These results of the small patient group needs to be completed by long term data.