

338

Pedicle Based Posterior Dynamic Stabilization System (DSS®)*R. Bertagnoli¹*¹ProSpine, 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 with 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 87 patients is to investigate the safety and efficacy the DSS® system used in motion and hybrid constructs. Fusion only patients (n=18) are not evaluated. Employed parameters were VAS and ODI. Patients are assessed pre and postoperatively 3, 6, 12, 24 and 36 month.

Results: The mean age of 49 males was 53 yrs. (29 - 75) and of the 38 females 55 yrs. (33 - 83). Patients received single or multi level surgeries between Th09 and S1. In a total of 44 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 (76,5 %). There are 6 two level, 2 three and 1 five level cases.

43 Patients received hybrid multilevel implantations including combinations with TDR. The most frequent two level construct (n=15) was L3-L5 (60%) followed by L4-S1 and in three level constructs (n=15) L2-L5 (40%) equals L3/S1 (40%). In four level cases (n=10) L2-S1 predominates (80%); there are 2 five level and each 1 7 and 8 level cases. VAS, ODI values decreased significantly at 3 month postoperative and were maintained throughout the follow up.

VAS scores decreased from a mean score of $6.4 \pm 1,8$ baseline to $4,1 \pm 2,1$ at 3 months; $4,9 \pm 2,5$ at 6 months; $4,8 \pm 2,2$ at 1 yr ; $4,7 \pm 3,1$ at 2 yrs., $5,7 \pm 3,0$ at 3 yrs. ODI scores (in %) were reduced from $52,2 \pm 17,5$ baseline to $43,6 \pm 15$ at 3 months, $44,8 \pm 14,8$ at 6 months; $42,4 \pm 17,2$ at 1 yr; $43,2 \pm 15,3$ at 2 yrs and $46,5 \pm 21,6$ at 3 yrs. 4 year data not representative yet due to small sample.

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. The combination of the system with TDR offers new possibilities to stabilize these prostheses if necessary. These results of the patient sample are further completed by long term observation.