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**„The ProDisc C Prothesis: clinical and radiological
experience one year after surgery“**

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The ProDisc C Prosthesis: clinical and radiological experience one year after surgery

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Introduction

To date anterior cervical discectomy and fusion (ACDF) may be considered to be the standard procedure for treatment of degenerative disc disease of the cervical spine^{1,2}. However, there is evidence, that ACDF may result in progressive degeneration of the adjacent segments^{3,4}. To avoid this, there have been numerous attempts to develop test and use artificial cervical discs^{5,6}. These will be influenced by the function of such an implant that has been designed to preserve segmental motion. If this is true, the implant should preserve segmental motion for a long time. The objective of the current study was to investigate segmental motion following implantation of a cervical spine disc prosthesis versus segmental motion of a segment having received ACDF with bone graft and an anterior titan plate, 12 months after surgery.

Methods

This is a prospective randomised and controlled study, approved by the local ethical committee of Saarland (Germany), n 119/04.

45 patients (26 male, 19 female, mean age 43 Years (yrs), (Standard deviation (SD) 9 yrs) suffering from symptomatic degenerative disc disease, not responding to a trial of conservative treatment and or progressive radicular deficits were included between April 2004 and Mai 2005. The cervical spine fusion Cage, named Solis consists of Poly –Ether –Ether –Ketone (PEEK). The prosthesis implant is a metal polyethylene ball-in-socket design.

Roentgen Stereometric Analysis (RSA) is known to provide highly accurate three-dimensional in vivo measurements⁷.

Mann-Whitney-test and Wilcoxon-test for unpaired values were used to determine a statistical difference of residual intervertebral translations before and after prosthesis as well as ACDF in the three axis of motion ($p < 0.05$). The segmental motion was calculated using a vector of X, Y, and Z axis.

Results

Mean value and standard deviation (XYZ Vector) for segmental motion after disc prosthesis implantation one week postoperative was 2.2 (1.2), decreasing to 1.2 (0.37) after 3, 0.8 (0.35) after 6, 0.63 (0.34) after 12 weeks, after 24 weeks 0.8 (0.41) and 0.8 (0.41) after 48 weeks. There was a significant decrease in motion six weeks ($p < 0.05$), when compared to the value obtained after one week. However 12, 24 and 48 weeks postoperatively there were no significance when compared to six week value ($p > 0.05$). Data for each axis are contained in figure 1, 2, 3.

The medial-lateral, proximal-distal, and posterior-anterior translation did not differ between 12 and 48 weeks postoperatively .

Results from radiographic study: Control group

Mean value and standard deviation (XYZ Vector) for segmental motion after ACDF one week postoperative was 0.65 (2.0), decreasing to 0.25 (0.4) after 3, 0.24 (0.37) after 6, 0.16 (0.35) after 12, 0.1 (0.4) and 0.1 (0.4) after 24 weeks. There was a non significant decrease in motion three and six weeks postoperatively compared to one week ($p > 0.05$). However 12, 24 and 48 weeks postoperatively there

were a significant decrease in motion when compared to the value obtained after one week ($p < 0.05$). Data for each axis are contained in figure 1, 2, 3.

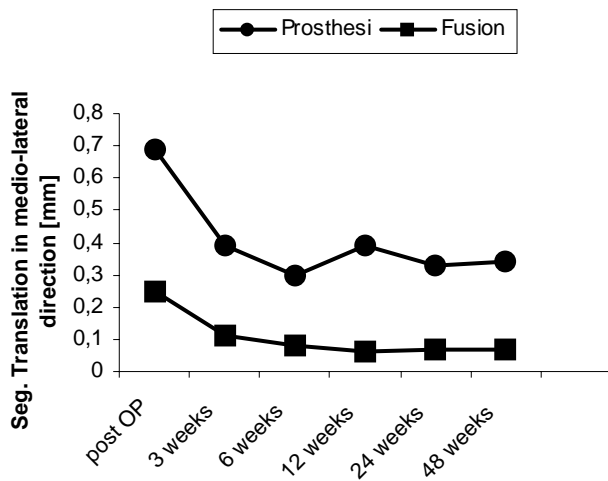


Figure 1 Segmental translation in medio-lateral direction (Mean value and standard) for each follow-up examination. The micro-motion of a segment receiving prosthesis is more pronounced when compared to fusion group. However, segmental motion decreases in both groups over the time.

Discussion

Within the current study, we found, that cervical spine segmental motion decreases over time in the presence of both disc prosthesis or fusion device. However, the loss of segmental motion is significantly higher in the fusion group.

Conclusion

Cervical spine segmental motion decreases over time in the presence of both disc prosthesis or fusion device. However, the loss segmental motion is significantly higher in the fusion group, when looked 3, 6, 12, 24 and 48 weeks after surgery. We observed significant pain reduction in neck and arm

postoperatively, with out significant difference between both groups

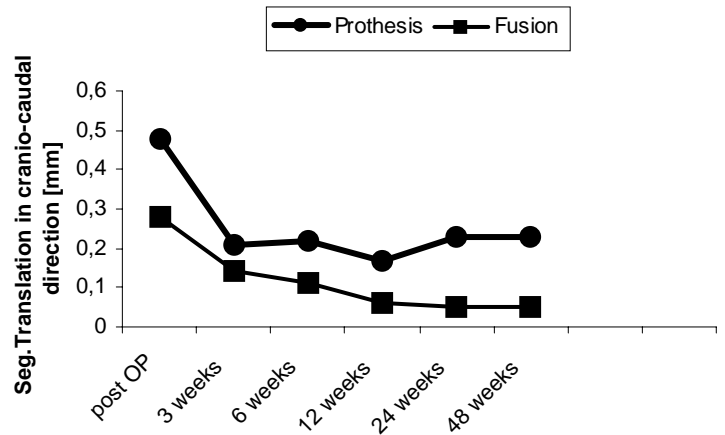


Figure 2 Segmental translation in cranio-caudal direction (Mean value and standard) for each follow-up examination. The micro-motion of a segment receiving prosthesis is more pronounced when compared to fusion group.

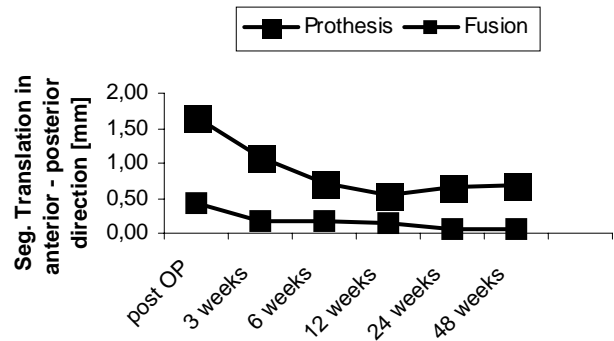


Figure 3 Segmental translation in anterior-posterior direction (Mean value and standard deviation) for each follow-up examination. Examination. The micro-motion of a segment receiving prosthesis is more pronounced when compared to fusion group.

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