**Clinical: Prosthesis**

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**ProDisc®-C Nova Total Disc Replacement - First Results**

*R. Bertagnoli*

†ProSpine, Straubing, Germany

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**Introduction:** Cervical total disc replacement (TDR) is intended to address discogenic pain, restore disc height, and preserve functional motion between two vertebral bodies in patients with symptomatic cervical disc disease. Thus, TDR may prevent subsequent adjacent disc degeneration. The ProDisc®-C Nova (Synthes Gmbh) TDR, is the next-generation ProDisc®-C. It has an updated keel design, better enabling multi-level implantation, and updated materials to allow for improved MRI imaging. The purpose of this study was to evaluate the preliminary clinical results of the ProDisc®-C Nova TDR.

**Methods:** Beginning in 2009, a prospective, controlled, consecutive case series of 60 patients have received cervical arthroplasty using the ProDisc®-C Nova TDR (132 devices). To date, patients have been assessed pre-operatively and post-operatively at 3, 6 months and 12 months. Evaluations included the Neck Disability Index (NDI), Visual Analog Scales (VAS), satisfaction and SF-36 patient self-assessments, physical and neurological exams, and radiographic evaluation.

**Results:** 28 were males with a 51 yrs. average ranging from 36 - 84 yrs. and 32 were females 52 yrs. average ranging from 36 - 69 yrs.). Of the 60 patients, 23.3% underwent single-level (C3/C4 = 1; C4/C5 = 2; C5/C6 = 7; C6/C7 4); 41.6% two-level (C3-C5 = 6; C4-C6 = 7; C5-C7 10; C3/C4+C5/C7 = 1; C4/C5 +C6/C7 =1); 26.6% three-level (C3-6= 1; C4-C7 = 13; C3-C5+C6/C7= 1; C3/C4 + C6 Th1 ) and 8.3% four-level surgery (C3 - C7 = 4; C3/C4+C5-C7+Th1/Th2=1).

At 3 months, the mean NDI score improved significantly and maintained this improvement out to 12 months (baseline: 44.7 ± 20.3 %; 3 months: 27.9 ± 18.9 %; 6 months: 34.0 ± 21.7 %; 12 months: 35.7 ± 22.6 %). Similarly, the average VAS pain intensity score showed significant improvement at 3 months, from baseline, and maintained improvement out to 12 months (baseline: 6.0 ± 3.0mm; 3 months: 3.1 ± 2.7mm; 6 months: 3.1 ± 2; 12 months: 4.4 ± 3.2 ). The SF 36 physical / mental component and total was baseline P 39 ± 9.2 M 25.9 ± 10.8 T 81.3 ± 18.7; 3 month P 42.6 ± 10.8 M 26.1 ± 9.1 T 83.8 ± 17.2; 6 month P 42.4 ± 14.6 M 30.3 ± 8.7 T 91.3 ± 21.7 and at 12 month P 41 ± 12,11 M 31,3 ± 4.4 T 88,6 ± 15.6;

At 3 month all patients were satisfied or very satisfied at 6 months 8.1% of patients reported being unsatisfied and at 12 month none of the patient swas unsatisfied with their surgery. Radiographic evaluation demonstrated that functional range of motion was being maintained. One patient required a re-operation due to subsidence, because of an infection, at 6 months.

**Conclusions:** Since the majority of the affected patients require multi-level surgery, the design of the ProDisc®-C Nova is optimal for these cases, and allows for superior imaging. The early results of this study provide evidence that ProDisc®-C Nova is a safe and efficacious TDR surgical treatment for patients with disabling disc disease in both single and multi cervical vertebral levels. Longer follow up is required to confirm these findings.