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SHORT-TERM RESULTS OF A PROSPECTIVE STUDY COMPARING INTERBODY FUSION AND DISC ARTHROPLASTY IN PATIENTS WITH CERVICAL DEGENERATIVE DISC DISEASE

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Abstract

The total disc replacement is an alternative to anterior cervical discectomy and fusion in patients with degenerative disc disease. We report short-term results of a prospective clinical trial comparing arthroplasty with Prestige® LP disc prosthesis and interbody fusion with cage in patients with 1- or 2-level cervical radiculopathy. Primary end point for this study was the composite overall success which comprises effectiveness and safety measures. Secondary end points were pain and functional scores, preservation of motion or success of fusion, adverse events and subsequent surgical interventions. A total of 96 patients were enrolled in the trial. Statistically significant superiority of the disc arthroplasty was not achieved but better improvements and less adverse events were observed up to 6 months after surgery, compared to the fusion procedure. The results support the conclusion that the Prestige® LP device is at least as safe and effective as the current standard of care for patients with cervical radiculopathy.

Key words: cervical spine, degenerative disc disease, interbody fusion, disc arthroplasty

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Introduction. Anterior cervical decompression and fusion (ACDF) has been a widely-used procedure for treatment of radiculopathy due to degenerative disc disease since its introduction in 1958 independently by Cloward [4] and Smith and Robinson [13]. Nowadays, artificial substitutes instead of bone grafts are used to promote interbody fusion. However, arthrodesis of a motion segment leads to strain on adjacent spinal levels with accelerated disc degeneration. Annual incidence of 2.9% symptomatic adjacent level disease after ACDF is reported by Hilibrand et al. [10]. The cervical total disc replacement (CTDR) preserves the segmental motion which may prevent these undesired consequences. A number of clinical trials with various disc prostheses have shown that this alternative approach is safe and reliable [2, 6, 8, 12, 16].

We report short-term results of a clinical study comparing interbody fusion with disc arthroplasty for the treatment of degenerative disc disease in patients with cervical radiculopathy.

Materials and methods. ***Study design and subjects.*** A prospective clinical study was conducted to assess the safety and effectiveness of CTDR in comparison to ACDF. Patient selection criteria were based on previously published clinical trials [5, 9, 11]. All subjects were between 18 and 70 years of age with 1- or 2-level symptomatic degenerative disc disease of the subaxial cervical spine (C3-C7) and intractable radiculopathy. In all patients, the neck disability index (NDI) scores were $\geq$ 30 and the Visual Analog Scale (VAS) scores were $\geq$2. Exclusion criteria were segmental instability or absence of motion; severe deformity or facet joint arthrosis; marked reduction of disc space height; severe myelopathy; cervical spine anomaly; neurological or psychiatric disorders; previous cervical spine surgery; disease or long-term medication that affects bone quality. Data were collected before and at 1.5, 3 and 6 months after surgery.

Surgical technique. Anterior approach to the cervical spine was performed to all patients as it is described in detail elsewhere [4, 13]. The intervertebral disc is removed along with the cartilaginous endplates as well as marginal bone spurs and herniated disc fragments to decompress the affected neural structures. Implants for ACDF or CTDR are selected according to the individual anatomy with care not to overdistract the segment. Their appropriate position is verified with fluoroscopy.

Implants. The Prestige® LP (Medtronic Sofamor Danek) artificial cervical disc is a titanium alloy device comprising two articulating components. A ball-in-trough articulation design is intended to replicate a physiological motion pattern. The Cornerstone® SR (Medtronic Sofamor Danek) polyether ether ketone cage is a ring-shape interbody bone graft substitute used to promote fusion.

Outcome assessment. Pain and function were assessed using the NDI and numerical VAS for neck and arm pain [14, 15]. Sagittal plane range of motion was measured on lateral radiographs in flexion and extension. Adverse events and

symptomatic adjacent level disease were documented. The primary end point for the study was the overall success, which is a composite index comprising all of the following effectiveness and safety measures: a ≥15-point improvement in the NDI scores, maintenance or improvement in the neurologic status, no serious adverse events related to the implant or surgical procedure and no subsequent surgery [9, 11].

Statistical analysis. The study hypothesis was that the overall success rates of the CTDR groups were not inferior to that of the corresponding ACDF groups. Fisher's exact test was used to compare measures between the treatment groups. Paired t-test was performed to compare the average improvement from baseline for the patient's self-assessment data.

Results. From January 2009 to December 2011, 96 patients with 1- or 2-level symptomatic cervical radiculopathy were surgically treated in the Clinic of Neurosurgery at St Ivan Rilski University Hospital, Sofia, Bulgaria. Interbody fusion was performed in 73 subjects and 106 cages were implanted. Another 23 patients received 28 disc prostheses. Four groups of patients were formed: 1-level ACDF 1-level CTDR, 2-level ACDF and 2-level CTDR. Demographic and clinical characteristics are shown on Table 1.

Statistically significant reductions ($P < 0.01$) in the NDI and VAS neck and arm pain scores were observed for all groups at each follow-up point (Fig. 1*A*, *B*

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Patient demographic and clinical information. N – number; BMI – body mass index; SD – standard deviation

	ACDF		CTDR		Total
	1-level	2-level	1-level	2-level	
Patients, N (%)	40 (41.7%)	33 (34.4%)	18 (18.7%)	5 (5.2%)	96
Gender, male/female	18/22	13/20	9/9	4/1	44/52
Age, years ± SD	41.7 ± 9.2	50.3 ± 8.6	40.2 ± 9.8	44.9 ± 9.8	44.5 ± 9.6
BMI. kg/m^2±SD	23.9 ± 4.3	26.2 ± 4.8	26.0 ± 3.9	26.0 ± 3.8	25.3 ± 4.4
Smokers, N (%)	22 (55.0%)	21 (63.6%)	11 (61.1%)	3 (60.0%)	57 (59.4%)
Levels treated, N	40	66	18	10	134
C3/C4	6	2	1	0	9 (6.7%)
C4/C5	1	14	0	3	18 (13.4%)
C5/C6	21	32	14	4	71 (53.0%)
C6/C7	12	18	3	3	36 (26.9%)
Operative time, min	148 ± 33	211 ± 41	165 ± 30	222 ± 42	–
Bracing, days	52.9 ± 18.9	61.8 ± 25.7	20.9 ± 20.9	20.4 ± 28.7	–
Follow-up, N (%)					
1.5 months	37 (92.5%)	30 (90.9%)	17 (94.4%)	5 (100%)	89 (92.7%)
3 months	35 (87.5%)	29 (87.9%)	16 (88.9%)	4 (80.0%)	84 (88.0%)
6 months	34 (85.0%)	28 (84.8%)	15 (83.3%)	4 (80.0%)	81 (84.4%)

and C). This result is most pronounced 6 months after surgery. Patients with CTDR had greater score improvements at all intervals than those with ACDF, although the differences are not statistically significant.

The time needed to brace the neck was significantly less ($P < 0.05$) in patients with disc arthroplasty (Table 1). However, the choice and duration of an external orthosis was left to the attending surgeons. The mean range of motion at the treated level was $9.3° \pm 3.4°$ before and $8.7° \pm 3.6°$ after surgery in the CTDR patients. Fusion was successful in 92.2% of cases with the corresponding procedure.

Serious adverse events related to the surgical procedure during the 6-month follow-up period were dural tear in two patients, one laryngeal nerve and one oculosympathetic palsy. Cage subsidence was detected in one patient with 1-level and in two with 2-level ACDF. Implant-related complications in the CTDR groups were not observed. Three serious adverse events unrelated to the procedure or implants were observed: vasovagal reaction during intubation, laceration of

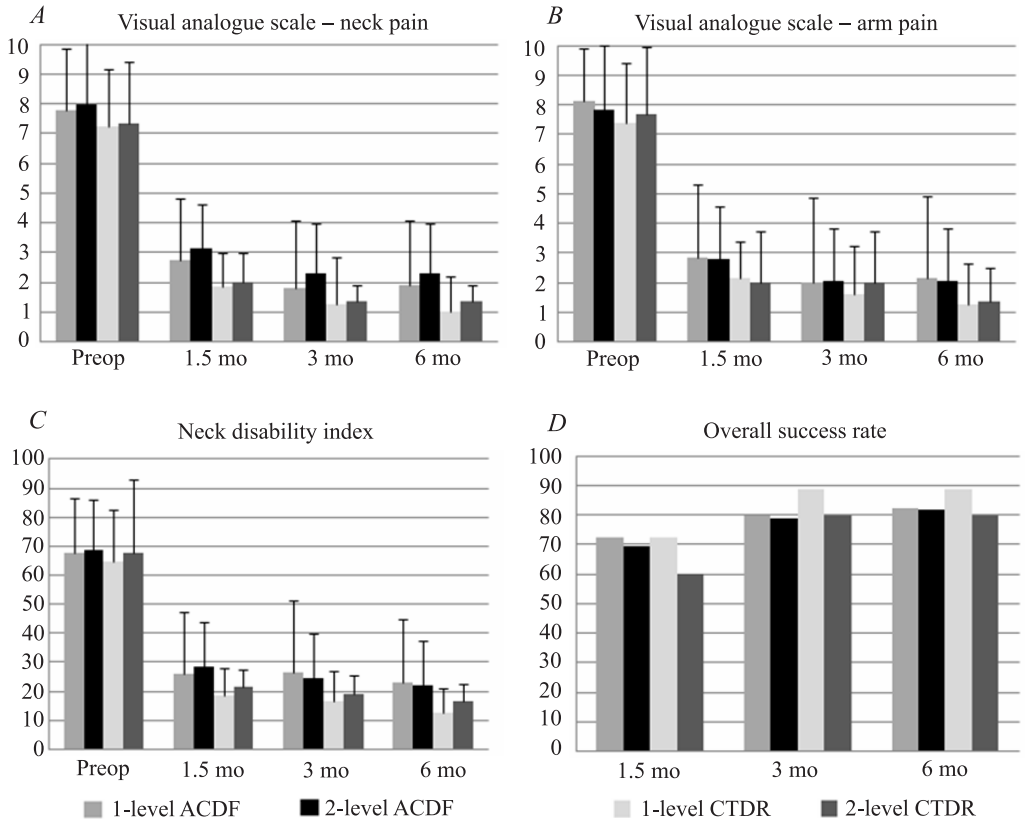

Fig. 1. Functional outcome and overall success rate assessment at 1.5, 3 and 6 months after surgery. *A*) VAS neck pain score; *B*) VAS arm pain score; *C*) NDI score; *D*) Overall success rate

urethra in a male subject during catheterization and postoperative acute erosive gastritis.

Within the study period, secondary surgical procedures at the index level were not performed. However, subsequent operative interventions for adjacent segment degeneration were done in two patients with previous 1-level ACDF and in one with 1-level CTDR. Three more patients with previous 2-level ACDF had symptomatic adjacent level disease. All of them improved with non-operative treatment.

At 6 months, overall success was achieved in 88.9% of the patients in the 1-level and 80.0% of those with 2-level CTDR (Fig. 1*D*). In the ACDF groups this composite measure was 82.5% and 81.8% for 1- and 2-level, respectively.

Discussion. ACDF is well-tolerated and successful procedure which serves as a standard for treatment of cervical radiculopathy. Improvement of fusion rates, reducing bone harvesting morbidity, restoring disc space height and sagittal plane balance were taken into consideration by the surgeons for years. Present spinal implants solve most of these problems and improve clinical outcomes [1, 3].

Although ACDF is beneficial to the treated level, it causes biomechanical stress and increased motion to the adjacent spinal segments [7]. This results in acceleration of the degenerative disease at those intervertebral discs [10]. Thus CTDR and motion preservation after neural decompression may be an alternative to fusion. We found close range of motion of the investigational prosthesis to the preoperative values.

In our study, the disc arthroplasty demonstrated better improvements in the primary and secondary end points up to 6 months after surgery compared to the fusion procedure, even though the results did not reach statistically significant superiority. The degree of clinical improvement is similar to that of large prospective randomized controlled trials investigating other devices [2, 6, 8, 12, 16].

Conclusions. In this study, evidence is provided to support the conclusion that the Prestige® LP device for disc arthroplasty is at least as safe and effective as the current standard of care for patients with cervical radiculopathy. As with any other cervical disc prosthesis, a long-term follow-up will be needed to find out clear advantages of disc arthroplasty over fusion procedures.

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