Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study

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Object. The long-term function of an artificial cervical disc device is critical to its clinical success. The Prestige I Cervical Disc System has been used clinically since June 1998, and long-term results can now begin to be assessed. The authors conducted clinical and radiographic examinations at 3 and 4 years postoperatively to evaluate the long-term performance of the Prestige I device.

Methods. A pilot trial was initiated in which the Prestige I disc was implanted in a cohort of patients with end-stage disease, who often had a history of multiple previous fusion procedures. All patients were followed according to a standardized clinical and radiographic protocol until 2 years postoperatively. Outcome measures included the Short Form-36 (SF-36) and Neck Disability Index (NDI) questionnaires, neurological status, and radiographic status. To evaluate the long-term function of the device, Ethics Committee approval was obtained to assess the patients at 3 and 4 years postoperatively. All patients were contacted, and after signing an additional informed consent document, were reevaluated according to the standardized protocol.

Of the 17 patients in the original cohort, 13 were evaluated at 3 years and 14 were evaluated at 4 years postoperatively. Clinical outcome measures including the NDI and SF-36 showed good improvement, especially when the end-stage nature of the disease is considered. Radiographic analysis showed that the Prestige I disc maintained motion at the treated segment at 3 and 4 years postoperatively.

Conclusions. In this report the authors demonstrate the clinical viability of the Prestige I cervical disc system at long-term postoperative intervals, even in the more severe biomechanical environment of end-stage disease.

KEY WORDS • cervical arthroplasty

Wigfield, et al.,¹⁴ reported the 2-year results of this pilot study of 15 patients with cervical radiculopathy or myelopathy caused by radiologically confirmed cervical disc herniation or posterior vertebral body osteophytes. Fourteen patients had a previous adjacent-level surgical or congenital spinal fusion, usually at two or more levels. In one patient there was radiological evidence of DDD adjacent to the symptomatic treated level. After a standard radical removal of the degenerative disc and osteophytes,^{2,10,11} all patients received the artificial disc prosthesis.

The follow-up findings in the aforementioned study delineated the results at 2 years; it was confirmed that motion was maintained by the prosthesis and that the device was safe and stable. Meticulous attention to surgical technique was essential. In this prospective observational cohort study the authors concluded that the time needed for surgery was comparable to that required for standard fusion after discectomy. One patient, because of persistent neck pain on extension, required removal of the prosthesis and subsequent fusion. It is important to note, however, that the pain persisted after a solid fusion had been achieved at 1 year postoperatively.

Abbreviations used in this paper: DDD = degenerative disc disease; SF-36 = Short Form-36; VAS = visual analog scale.

With increasing interest in cervical disc arthroplasty, it is essential to assess the function of motion-sparing devices at long-term intervals. The predecessor to the Prestige I disc, the Bristol-Cummins disc, began to be used in surgical practice in 1991. The device was implanted in a similar cohort of patients with end-stage disease and the results were subsequently published.³ Of considerable interest is the long-term follow-up study completed in April 2003, which includes the patients originally treated with the Bristol-Cummins device. Twelve of the original 20 patients were evaluated (three had died of causes unrelated to the implant). The mean follow-up duration was 9.1 years postoperatively (range 7–12.7 years). Fourteen artificial joints had been placed in these 12 patients, and 11 joints continued to demonstrate motion.

CLINICAL MATERIAL AND METHODS

Demographic and Follow-Up Summary

The original report included 10 men and five women. Two additional women were subsequently enrolled and are included in this report. The patients' descriptive statistics are detailed in Table 1. The patients ranged in age from 31.9 to 74.5 years. Almost 50% used tobacco and nearly 75% used alcohol. The Prestige I discs were insert-

TABLE 1
*Demographic data in 17 patients
treated with the Prestige I disc**

Factor	Value
age (yrs)	
mean $\pm$ SD	50.1 $\pm$ 11.4
range	31.9–74.5
sex (%)	
male	10 (58.8)
female	7 (41.2)
history of neck op (%)	
yes	9 (60.0)
no	6 (40.0)
tobacco use (%)	
yes	7 (46.7)
no	8 (53.3)
alcohol use (%)	
yes	11 (73.3)
no	4 (26.7)

* SD = standard deviation.

ed between C3–4 and C6–7. There were no cases of dysphonia, dysphagia, wound infections, or device failure in the long-term cohort.

The prosthesis design, mechanical testing methods, patient recruitment policy, surgical technique, and study design were detailed in a previously published report. In addition, the demographic variables and safety of the procedure were documented.¹⁴

This long-term study of the Prestige I disc was completed after Ethics Committee approval was obtained to continue the cohort evaluation at 36 and 48 months. The 36- and 48-month follow-up protocol used the same clinical and radiographic outcome measures as the original one. Flexion/extension x-ray films were obtained to assess motion, and patients underwent a complete neurological examination conducted by the investigator. Additionally, each patient completed outcome questionnaires including the SF-36 General Health Survey, the Neck Disability Index, VAS, and the European Myelopathy Scale. All adverse events were recorded at 36- and 48-month follow-up intervals.

RESULTS

Radiographic Analysis

Flexion/extension x-ray films were available for 11 patients at 36 months and for 12 at 48 months. One patient who required removal of the prosthesis at 12 months with subsequent fusion, as described in the original report, is not included in this follow-up study. A second patient, who suffered progression of myelopathy and subluxation at C6–7 due to advanced DDD below a C4–5 implant, required posterior fusion from C5–7 and demonstrated no motion of the implant after 12 months due to the fusion. At 48 months, 12 patients had a mean angulation of 5.7° and a mean translation of 0.83 mm. As indicated in Table 2, the preoperative mean sagittal angle rotation was 7.5°.

Results on Assessment Questionnaires

Data at 48 months compared with preoperative data from the questionnaires indicated improvement in all

TABLE 2
*Results of radiographic analysis in patients
with artificial cervical discs at long-term follow-up evaluation**

Eval Time	No. of Patients	Sagittal Plane Rotation (°)		Translation (mm)	
		Mean	Range	Mean	Range
preop	13	7.5	1–15	1.5	0–3
6 mos	15	6.4	0–15	0.8	0–2
12 mos	15	5.9	1–10	1.1	1–2
24 mos	14	6.5	1–15	0.9	0–2
36 mos	11	4.9	0–10	1.2	0–2
48 mos	12	5.7	0–12	0.83	0–2

* Eval = evaluation.

aspects of patient function and quality of life, as indicated in Table 3. The patients' employment status remained the same as previously reported, with seven of the 11 still working 4 years postoperatively, in addition to one previously retired patient who has established his own business.

Adverse Events

During the extended follow-up period, no adverse events have been reported on patients' completed questionnaires or on neurological examination. Additionally, there has been no development of adjacent symptomatic or radiological disc disease. No further radiographic studies have been obtained except for the follow-up flexion/extension cervical spine x-ray films.

DISCUSSION

The cause of degenerative symptomatic cervical disc herniation or degeneration with osteophytes developing adjacent to a cervical fusion is controversial. Hilibrand, et al.,^{5,6} showed a rate of adjacent symptomatic disc disease of 2.9% per year and demonstrated that 10 years after fusion up to 25% of patients were symptomatic from adjacent-level disease. We and others have shown that fusion results in increased motion at the adjacent segments.^{4,7,13} Increases in intradiscal pressure in discs adjacent to the fusion level have been demonstrated in in vitro studies.^{8,9,12,15} The increase in adjacent-level motion occurred

TABLE 3
*Percentage improvement on self-administered
assessment questionnaires at 4-year follow-up review
in 14 patients with artificial cervical discs **

Questionnaire	Preop Score	4-Yr Postop Score	% Improvement
VAS			
arm pain	10.2	4.5	55.9
neck pain	10.5	6.0	42.9
NDI score	43.3	30.1	30.5
SF-36			
PCS	32.2	35.9	11.5
MCS	44.1	50.0	13.4
EMS	14.4	14.8	2.8

* EMS = European Myelopathy Scale; MCS = Mental Component Score; NDI = Neck Disability Index; PCS = Physical Component Score.

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in discs that appeared to be radiologically normal before surgery. Cherubino, et al.,¹ reported clinicoradiological and statistical evidence of DDD developing in segments adjacent to fusion. In view of this, a strong argument can be made that fusion does influence the natural history of surgically related DDD at adjacent segments.

In this small prospective study, there has been no evidence of adjacent symptomatic cervical disc degeneration, indicating that the motion-sparing prosthesis is not producing or contributing to adjacent-segment disease. We have shown that there is no increased motion at adjacent levels after implantation of a motion-sparing prosthesis.^{13,14}

CONCLUSIONS

The long-term function of a cervical disc replacement device is essential to its clinical utility. In this limited series we found significant patient improvement from preoperative status in the clinical outcome measures used. The radiographic results demonstrate that the Prestige I device is capable of maintaining function at 4 years postoperatively without development of adjacent-segment disease.

Disclosure

Medtronic Sofamor Danek sponsored the Prestige I clinical trial.

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