



The Prestige cervical disc replacement

Vincent C. Traynelis, MD*

Department of Neurosurgery, The University of Iowa Hospitals and Clinics, 200 Hawkins Drive, Iowa City, IA 52242, USA

Abstract

BACKGROUND CONTEXT: Anterior cervical discectomy and arthrodesis is the preferred treatment for a large number of patients with symptomatic cervical spondylosis. This management strategy is successful for the majority of patients, and the short-term results are very good. There is the potential to further improve patient outcome and the long-term success rate.

PURPOSE: The purpose of this report is to review the rationale for cervical arthroplasty and describe the development of the Prestige cervical disc replacement (Medtronic Sofamor Danek, Inc., Memphis, TN).

STUDY DESIGN/SETTING: This report reviews the literature concerning the need for cervical arthroplasty and details the basic and clinical work on the Prestige cervical disc replacement.

METHODS: The key publications concerning the shortcomings of cervical arthrodesis and the clinical and basic studies on the Prestige cervical disc implant are discussed. New long-term clinical data on the Prestige device are reported.

RESULTS: Cervical arthrodesis perturbs normal cervical spinal biomechanics and appears to be associated with accelerated degeneration of the adjacent segments. The Prestige cervical disc replacement is successful in preserving normal spinal motion, both experimentally and clinically. The device is durable, and the clinical outcomes have been excellent.

CONCLUSIONS: The Prestige cervical disc replacement is an effective means of reconstructing the cervical spine after anterior discectomy. It preserves normal motion and may decrease the incidence of adjacent segment disease. © 2004 Elsevier Inc. All rights reserved.

Keywords:

Arthroplasty; Cervical disc degeneration; Cervical fusion; Spinal biomechanics

Introduction

Degeneration of the cervical spinal intervertebral discs is part of the normal aging process. The changes usually occur gradually and frequently do not produce significant symptoms; however, in some individuals, cervical spondylosis results in compression of a nerve root and/or the spinal cord. Symptomatic neural compression can be successfully addressed with a surgical intervention. Anterior cervical decompression and fusion, first described over 50 years ago, has become the surgical procedure of choice for these patients [1–3]. This operative technique allows the surgeon to

safely eliminate the most common causes of cervical neural compression, and the development of a solid arthrodesis provides long-term stability, which halts the degenerative process at the treated segment. Single-level fusions do not seem to significantly alter the global mobility of the cervical spine, but motion is adversely affected when multilevel treatments are necessary. Furthermore, although fusion is beneficial to the diseased level, it is probably detrimental to the remaining motion segments, and there is mounting evidence that cervical arthrodesis increases the stress on the nonoperated discs and therefore adversely impacts the rate of disc degeneration [4–10].

Hilibrand et al. [9] provide perhaps the greatest insight to this problem. These investigators studied 374 patients and found that symptomatic adjacent segment disease occurred at a relatively constant rate of 2.9% during the decade after the surgical fusion. Although a portion of these patients probably had progression of their disease resulting from the natural history of spondylosis, Goffin et al. [8] showed that the rate of radiographic adjacent segment disease was identical whether the fusion was performed for degenerative disease or trauma. This key work indicates that the development

FDA device/drug status: investigational/not approved (Prestige artificial disc).

Author VCT acknowledges a financial relationship (consultant for Medtronic Sofamor Danek), which may indirectly relate to the subject of this manuscript.

* Corresponding author. The University of Iowa Hospitals and Clinics, Department of Neurosurgery, 200 Hawkins Drive, Iowa City, IA 52242, USA. Tel.: (319) 356-2774; fax: (319) 353-6605.

E-mail address: vincent-traynelis@uiowa.edu (V.C. Traynelis)

of adjacent segment disease is most likely related to the arthrodesis. Cummins attempted to address the shortcoming of cervical arthrodesis 15 years ago [11]. His pioneering efforts in the development of a metal-on-metal cervical artificial disc laid the foundation on which the Prestige (Medtronic Sofamor Danek, Inc., Memphis, TN) was built. The original Cummins design has been modified, and multiple improvements have been added. This article will trace the history of the development of the Prestige Artificial Cervical Disc and review the major studies that have been performed with this device.

Bristol/Cummins disc

Cummins began to develop an artificial cervical disc in collaboration with the Department of Medical Engineering at Frenchay Hospital in 1989. After 2 years of multiple modifications and prototype evaluations, the device was approved for human implantation [11]. The Cummins disc was designed to be implanted within the intervertebral space, and it was constructed of Type 316 stainless steel. This artificial cervical disc occupied 11 mm of the interspace, and the anterior face of each of the two components was 14 mm long. It was secured to the vertebral bodies above and below the treated level with screws. Several different screw designs were employed throughout the years during which the Cummins/Bristol disc was implanted.

Between February 1991 and August 1996, 22 joints were implanted in 20 patients. These patients were considered to have “end-stage” disease. Each of them lacked motion over a significant number of levels because of either congenital block vertebrae or prior surgical fusions. Eighteen patients were reexamined in 1996, and motion at the level of the disc implant was noted in 16. The two patients without motion were noted to have marked distraction of the facet joints at the treated level, which was secondary to the relatively large size of the intervertebral portion of the implant. Overdistraction of the segment almost certainly contributed to the loss of motion. A single implant was removed because of a manufacturing error that resulted in an improper ball and socket interface. Although minor screw backout or breakage occurred in some cases, no implant failed. Patients with radiculopathy improved, and those with myelopathy either improved or were stabilized.

Prestige I

The second generation of the Cummins/Bristol cervical disc, the Prestige I (Medtronic Sofamor Danek, Inc., Memphis, TN), was developed in 1998 [12]. The major design change was the conversion of the socket portion of the articulation to a trough. This allowed for anterior-posterior translation to be coupled with flexion/extension motion as it is in the normal human condition. The screws were standardized, and a locking cap prevented backout. The disc

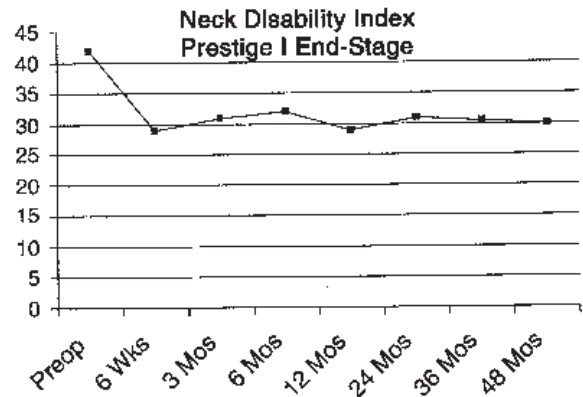


Fig. 1. Improvement in the Neck Disability Index in patients with end-stage disease treated with a Prestige I cervical disc replacement was noted at the first postoperative check, and the improvement persisted over the 4-year period of the study.

was produced in accordance with the strict standards necessary for all spinal implants.

The Prestige I was evaluated prospectively in a cohort of 17 patients, each of whom required a surgical intervention in a segment adjacent to a previous fusion. The patients were assessed for 4 years after placement of the device. Throughout the study, the Prestige I effectively maintained motion. The mean sagittal rotation (flexion/extension) preoperatively was 7.5 degrees. At 24 months, all joints were mobile; there was an average of 6.5 degrees flexion/extension motion. Anteroposterior translation was also preserved. There was no backout of the screws, and none of the joints failed. Assessment at 4 years after surgery demonstrated a positive result in the Neck Disability Index (NDI), visual analog scales (VAS) for neck and arm pain, the European Myelopathy Scale, neurological status and the Short Form (SF)-36 mental and physical component scores (Fig. 1).

Two Prestige I implants required removal. In the first case, the authors surmised that the amount of bone resected during the initial procedure was excessive, which probably resulted in overloading of the facets, leading to a chronic pain syndrome. No significant tissue reaction was noted at

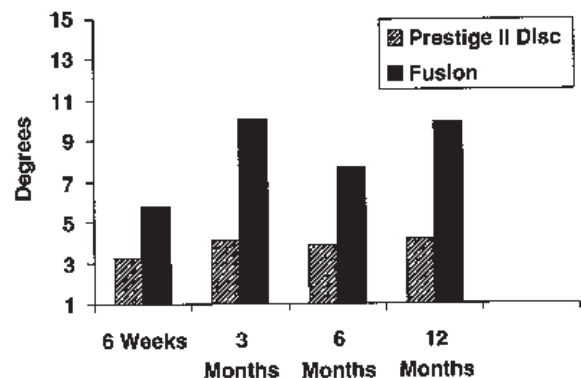


Fig. 2. Mean flexion/extension motion at levels adjacent to a Prestige II implant and an arthrodesis.

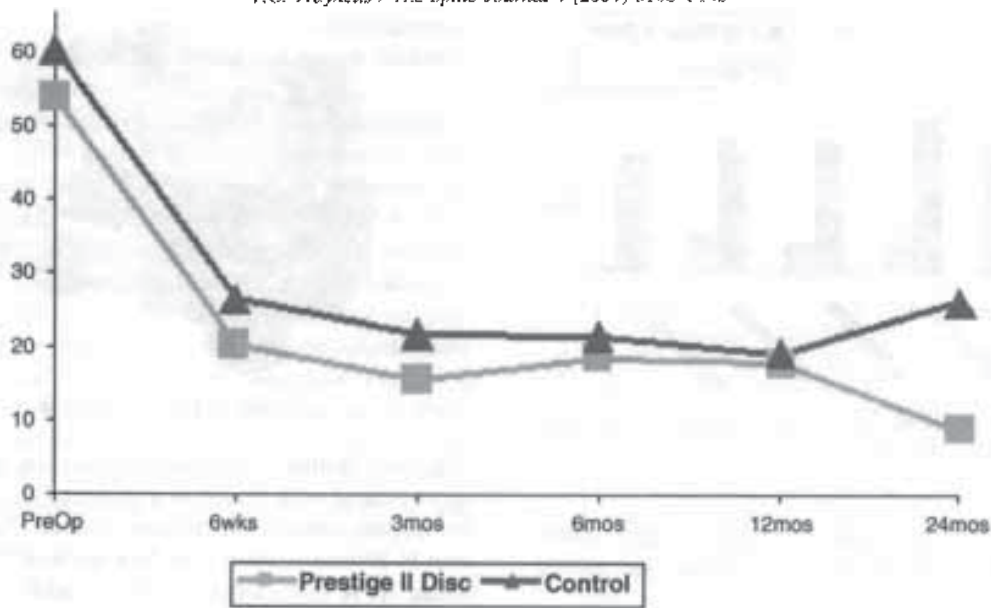


Fig. 3. Neck Disability Scores for patients treated with either a Prestige artificial disc or an arthrodesis (control).

the time of joint removal. Evaluation of the implant showed minimal wearing of the articular surfaces. The second removal was required to treat a preexisting adjacent segment condition. The surgeon elected to remove the fully functional Prestige I implant approximately 3.5 years after surgery in order to place an anterior cervical plate across the adjacent level. Again, no significant tissue reaction or wear debris was noted.

Wigfield et al. [13] assessed the motion of the segments adjacent to levels reconstructed with either the Prestige I or an autologous bone graft. Twelve patients received the Prestige I, and 13 were treated with an arthrodesis. The

adjacent segments were assessed with a magnetic resonance imaging scan preoperatively and scored in terms of the degree of degenerative change present. Preoperative sagittal angular motion was also measured in these segments. There was no difference in these parameters between the two treatment groups. Flexion/extension motion was measured again at 6 and 12 months after surgery. A slight reduction in the motion at the adjacent segments was noted in the patients who received the Prestige I. Overall cervical motion was maintained in these individuals, however, because of the mobility preserved at the operative level. Arthrodesis resulted in a significant increase in sagittal plane rotation at

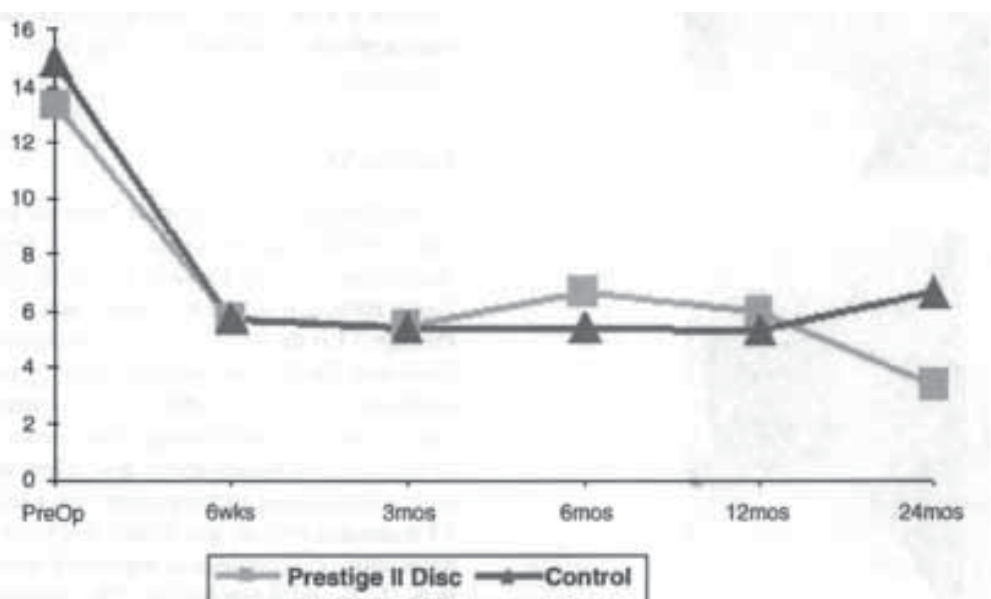


Fig. 4. Neck pain frequency and intensity as measured by the visual analog scale for patients treated with either a Prestige artificial disc or an arthrodesis (control).

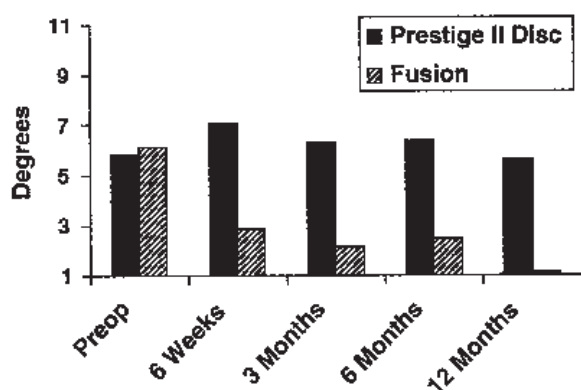


Fig. 5. Sagittal plane rotation measured in degrees for patients treated with either a Prestige artificial disc or a fusion.

the adjacent levels 1 year after the fusion surgery. There was a statistically significant difference between two groups (Fig. 2).

Prestige II

The Prestige II (Medtronic Sofamor Danek, Inc., Memphis, TN) was designed in 1999. A key improvement over the Prestige I was a more anatomic end-plate design, which was roughened to promote bony ingrowth. The Prestige II was



Fig. 6. (Top) Flexion and (Bottom) extension views of a Prestige ST implant.

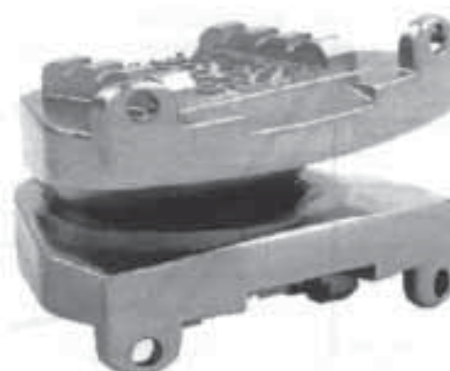


Fig. 7. The Prestige STLP.

important in that it was the first cervical artificial disc to be compared with fusion in a prospective randomized trial comprising patients with primary disease (Robertson J, Porchet F, Brotchi J, Nelson R, McCombe P, Traynelis V, Lubansu A: A multicenter trial of an artificial cervical joint for primary disc surgery, presented at the Society for Spinal Arthroplasty, Montpellier, France, May 2002). This study randomized patients in a 1:1 fashion to compare decompression and placement of the Prestige II device to decompression and uninstrumented arthrodesis with autograft. The inclusion criteria admitted subjects with cervical degenerative disc disease defined as intractable radiculopathy and/or myelopathy resulting from a herniated disc or osteophyte formation. Patients could have only a single level of symptomatic disease and could not have had previous cervical spinal surgery. Twenty-seven patients were randomized to each arm, and the demographic profile of these two groups was identical. The 2-year data demonstrate that the arthroplasty patients had a greater improvement than those in the arthrodesis cohort in the NDI, VAS, and the mental and physical component scores of the SF-36 (Figs. 3 and 4). Segmental cervical motion was maintained across the operated segments in all patients (Fig. 5).

Prestige ST

The Prestige ST (Medtronic Sofamor Danek, Inc., Memphis, TN) became available in 2002 (Fig. 6). The major change between the Prestige II and the Prestige ST was a 2-mm reduction in the height of each anterior flange. The Prestige ST is the device currently being implanted in the US Food and Drug Administration Investigational Device Exemption study. The Prestige ST is constructed of stainless steel. It has two articulating components that are attached to the vertebral bodies above and below the disc prosthesis with a constrained locking screw mechanism. The Prestige ST maintains the ball and trough design, which provides for replication of physiological segmental motion. It is available in 6-, 7-, 8- and 9-mm heights. The implants have a constant width of 17.8 mm, and there are two choices of depth: 12 and 14 mm. The surfaces that contact the end plates are grit

blasted to promote bony ingrowth. The 2.5-mm thick anterior flange compares very favorably with the standard thickness of many cervical plates.

Extensive wear testing consisting of 10 million cycles in flexion and extension and 5 million of a coupled axial rotation and lateral bending motion has been performed on the Prestige ST. The total material lost was 0.37 to 0.42 mm³/million cycles. This compares very favorably with the 5 mm³/million cycles of debris generated by a cobalt-chromium (Co-Cr) total hip prosthesis and even more so with the 43 to 135 mm³ of material lost in a Co-Cr on polyethylene total hip prosthesis. The previously mentioned explanted Prestige I (constructed with the same materials as the Prestige ST) validates the bench top testing. Currently, the Prestige ST is being evaluated in an Food and Drug Administration Investigational Device Exemption study in the United States.

Prestige STLP

The most recent version of the Prestige implant is the Prestige STLP (Medtronic Sofamor Danek, Inc., Memphis, TN). This artificial cervical disc radically differs from its predecessors in that acute fixation is achieved by a set of rails that are placed on the intervertebral contact surface (Fig. 7). This not only eliminates the anterior profile of the device but also simplifies implantation and allows for unrestricted multilevel implantation. The Prestige STLP is currently available outside of the United States.

Conclusion

Total cervical disc replacements preserve normal motion at adjacent segments and in doing so will hopefully decrease the incidence of adjacent segment degeneration. The Prestige STLP was born 15 years ago in the form of the Cummins/Bristol cervical disc prosthesis. Its design incorporates multiple advances and enhancements, which have been developed over many years. It physiologically reconstructs

the cervical spine by providing solid axial load-bearing support while allowing for normal physiological cervical spinal motion.

References

- [1] Cloward RB. The treatment of ruptured intervertebral discs by vertebral body fusion. *Ann Surg* 1952;136:987.
- [2] Cloward RB. The anterior approach for removal of ruptured cervical disks. *J Neurosurg* 1958;15:602–17.
- [3] Smith GW, Robinson RA. The treatment of certain cervical-spine disorders by anterior removal of the intervertebral disc and interbody fusion. *J Bone Joint Surg (Am)* 1958;40:607–24.
- [4] Baba H, Furusawa N, Imura S, Kawahara N, Tsuchiya H, Tomita K. Late radiographic findings after anterior cervical fusion for spondylotic myeloradiculopathy. *Spine* 1993;18:2167–73.
- [5] Cherubino P, Benazzo F, Borromeo U, Perle S. Degenerative arthritis of the adjacent spinal joints following anterior cervical spinal fusion: clinicoradiologic and statistical correlations. *Ital J Orthop Traumatol* 1990;16:533–43.
- [6] Clements DH, O'Leary PF. Anterior cervical discectomy and fusion. *Spine* 1990;15:1023–5.
- [7] Döhler JR, Kahn MR, Hughes SP. Instability of the cervical spine after anterior interbody fusion. A study on its incidence and clinical significance in 21 patients. *Arch Orthop Trauma Surg* 1985;104:247–50.
- [8] Gollin J, van Loon J, Van Calenbergh F, Plets C. Long-term results after anterior cervical fusion and osteosynthetic stabilization for fractures and/or dislocations of the cervical spine. *J Spinal Disord* 1995;8:500–8.
- [9] Hillbrand AS, Carlson GD, Palumbo MA, Jones FK, Boldman HH. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg (Am)* 1999;81:519–28.
- [10] Pospiech J, Stolke D, Wilke HJ, Claes LE. Intradiscal pressure recordings in the cervical spine. *Neurosurgery* 1999;44:379–85.
- [11] Cummins BH, Robertson JT, Gill SS. Surgical experience with an implanted artificial cervical joint. *J Neurosurg* 1998;88:943–8.
- [12] Wigfield CC, Gill SS, Nelson RJ, Metcalf NH, Robertson JT. The new Frenchay artificial cervical joint. Results from a two-year pilot study. *Spine* 2002;27:2446–52.
- [13] Wigfield C, Gill S, Nelson R, Langdon I, Metcalf N, Robertson J. Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. *J Neurosurg* 2002;96(Spine 1):17–21.