

Cervical fusion, arthroplasty outcomes similar at one year

IDE trial results showed treatment with artificial discs or fusion led to pain relief and less neck disability.

by Susan M. Rapp

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CHICAGO — Implanting an artificial cervical disc may be better in the long run than anterior cervical disc arthrodesis for treating patients with single-level cervical disc disease. The reason: The artificial disc may not be as detrimental to the motion segments adjacent to the treated disc.



In a prospective randomized controlled trial of the Prestige artificial disc, an investigational device exemption study approved by the Food and Drug Administration (FDA), Kenneth Burkus, MD, compared outcomes in patients he treated with the two techniques. He presented results of 22 patients who had the Prestige disc implanted and 20 patients who underwent anterior discectomy and interbody fusion at the North American Spine Society 19th Annual Meeting.

"Throughout the study, the Prestige implant effectively maintained motion. At last follow-up, all joints were mobile," said Burkus, an orthopedic surgeon at the Hughston Clinic in Columbus, Ga.

The Prestige device is manufactured by Medtronic Sofamor Danek of Memphis, Tenn., but has not been approved by the FDA for use in the United States.

Anterior approach

Burkus followed all 42 patients preoperatively through 12 months postop and analyzed the data for their procedures. Among the outcome measures they used were tests for neurological status, the Visual Analog Scale for pain, the neck disability index, the SF-36 score, and dynamic flexion and extension radiographs of the treated discs.

Both patient groups had highly similar demographic scores.

He used an anterior surgical approach for all patients, treating the C5-C6 level most frequently. The dis-

ectomy/fusion patients who formed the control group received cortical allograft, some local bone graft and a cervical plate. The anterior technique to implant the artificial disc was



This patient's preoperative radiographs showed signs of symptomatic single-level cervical disc disease at C5-C6.

straightforward and similar to that used on the fusion patients, Burkus said.

"This study is designed to show clinical equivalence of the treatments, with maintenance of motion in the investigational disc replacement group," Burkus said.

He performed postoperative clinical and radiographic evaluations when patients were discharged from the hospital, and at one and one-half, three, six and 12 months postop.



He underwent total disc replacement as part of a prospective randomized controlled clinical trial. This postoperative lateral radiograph shows the implanted Prestige cervical disc used to treat his disc disease.

Patients in both groups improved significantly according to all outcome measures.

"Statistical analysis showed no statistically significant differences

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