

Total Disc Replacement

FOR THE CERVICAL SPINE

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HIP AND KNEE JOINT REPLACEMENT SURGERY OR ARTHROPLASTY HAS BECOME ROUTINE SINCE ITS INCEPTION IN THE EARLY 1960S WITH A HIGH DEGREE OF PATIENT SATISFACTION.

OTHER JOINT REPLACEMENT procedures eventually followed including shoulder, elbow, ankle and other smaller joints of the hand. Large volumes of these procedures are performed at both hospital and outpatient centers to correct painful arthritic conditions of the joints. Until recently however, arthroplasty of the spine (or artificial disc replacement), has not been a viable option in the United States.

The main challenge facing surgeons and engineers was the development of a suitable replacement for the intervertebral discs. Spinal disc replacements needed to have the ability to mimic a very complex range of movement and be safe to implant. Additionally, they had to be reliable and long lasting. Over the course of prior decades, dramatic improvements have been made in the development of the artificial disc. There are now several artificial disc replacements available for both the cervical and lumbar spine, and they are currently being offered to appropriate candidates in the United States.

Neck pain and arm pain can have a severe and sometimes even devastating effect on a patient's quality of life. Symptoms may result from compression of the spinal nerves, spinal cord or from the disc itself. Typically, if standard conservative treatments are ineffective or the patient becomes unable to perform activities of daily living due to progression of pain or neurological symptoms, surgical intervention is indicated. Anterior cervical discectomy and fusion is currently considered definitive treatment for symptomatic cervical degenerative disc disease. Some disadvantages may include loss of flexibility, alteration of biomechanics, and the development of adjacent segment disc degeneration. Although the majority of patients will have good



to excellent results from cervical fusions, over time, symptomatic disc problems surrounding the fusion may occur.

Disc replacement in the cervical spine is a relatively new alternative treatment option for cervical disc disease and injury in certain patients and may possibly reduce the known shortcomings of fusion. Artificial disc replacement allows for motion preservation and near normal distribution of stress of the adjacent spine, possibly reducing damage to nearby discs and joints.

Recovery from cervical artificial disc replacement can be very rapid and bracing is generally not necessary. A typical patient may be released to most activities (including high-impact activities) after the wound is healed. Imaging studies are generally performed postoperatively to ensure that the range of motion has been preserved and that there are no implant complications. Subsequently, X-rays are taken much less frequently because physicians are not waiting for "fusion" to occur.

The two cervical artificial discs that have been approved for use in the United States include the Prestige Cervical Disc System (Medtronic) and the ProDisc-C (Synthes Spine, Inc.). Both were



approved for usage in 2007. They are both indicated in the reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease, radiculopathy and/or myelopathy. The Prestige disc features a metal on metal articulation while the Prodisc-C has a polyethylene spacer. The two implants have both demonstrated safety, durability and excellent clinical results in U.S. trials.

Medtronic's Prestige Cervical Disc System has been studied rigorously. In a Level 1, multicenter prospective randomized controlled 32-site study that involved 541 patients (2002-2004), a comparison was done between cervical disc replacement and anterior fusion (ACDF). Patients in the study had to be at least 18 years of age with documented cervical degenerative conditions/symptoms with associated neurologic involvement and had to fail at least six weeks of nonsurgical treatment. At the 12- and 24-month follow-up points, the disc replacement group reported more improvement in their neck pain and a greater ability to go about their daily activities than the fusion group. Sagittal (front and back) angular motion was maintained from 7.55° preoperatively to 7.59° at 12 and 24 months postoperatively.

Patients undergoing disc replacement had median return to work that was 16 days faster than the fusion group. There were no implant failures or migrations. Fewer patients in the replacement group required secondary surgical procedures. The most significant overall theme from this study was that the cervical fusion patients had excellent clinical results but the replacement patients did even better.

The ProDisc-C total disc replacement also underwent rigorous testing as part of FDA-regulated IDE clinical study. The prospective, randomized trial (13 centers) of 209 patients with symptomatic cervical disc disease at a single level from C3-C7 were randomized to receive either a total disc replacement or standard ACDF. Disc replacement patients demonstrated a significant improvement in pain and disability and required fewer re-operations than ACDF patients. Patients receiving disc replacement demonstrated a mean range of motion of 9.4° at the 24-month follow up, clearly demonstrating excellent motion-preservation.

With a continued increase in the number of artificial cervical disc replacements performed, indications have continued to expand. Many patients who have disc disease adjacent to a



previous fusion may become excellent candidates for cervical total disc replacement. The U.S. studies along with longer-term European experience demonstrate a role for cervical disc replacement in select patients. Currently, there are patients who travel overseas at significant expense seeking motion-preservation implants because multilevel total disc replacements occur in Europe but have not yet received FDA approval in the United States.

For FDA-approved single-level cervical artificial disc replacement, insurance acceptance has been slow. However, the success of disc replacement in selected cases and its cost-effectiveness may lead this procedure to eventually become an accepted standard of care for the treatment of symptomatic cervical disc disease.

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