

# Total Disk Replacement May Rival Spinal Fusion

BY MITCHEL L. ZOLER  
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PHILADELPHIA — Spinal disk replacement was at least as effective as conventional spinal fusion for treating patients with degenerative disk disease in results from several manufacturer-sponsored studies reported at the annual meeting of the North American Spine Society.

Although total disk replacement with a prosthesis is still in development—and so far initial studies have shown it to be no better than spinal fusion—experts believe it has several potential advantages.

“We’re hoping for better long-term results, especially in patients with two-level disk degeneration,” said Dr. Cameron B. Huckell, an orthopedic surgeon at the State University of New York at Buffalo. “We know that the results [of spinal fusion] drop off with time.”

Patients also may return to work faster after disk replacement. “An initial study at our center showed that arthroplasty patients went back to work in half the time, compared with fusion patients,” said Dr. Richard D. Guyer of the University of Texas Southwestern, Dallas. “The economic issues will be significant,” he added.

“Many studies show similar results, but they were, by design, noninferiority trials,” said Anthony M. Petrizzo, D.O., an orthopedic surgeon at New York University. “The structure of noninferiority trials is to combine all the data, and then you’ll have an answer. When the numbers are so similar, as with fusion and disk replacement, you need a very large number of patients to detect a difference, and we don’t have that yet.”

And there is also the view that both types of repair will play a role. “Some patients will need fusion, but for most patients arthroplasty will be better in the long run,” predicted Dr. James J. Yue, an orthopedic surgeon at Yale University in New Haven, Conn.

Two studies reported at the meeting compared cervical-disk replacement with spinal fusion. One study randomized 22 patients to single-level, anterior, cervical discectomy and fusion with allograft bone and anterior plating, and 24 patients to single-level disk replacement using the ProDisc-C prosthesis. Synthes Spine is developing the ProDisc-C for cervical disk replacement and the ProDisc-L for lumbar disk replacement, and the company sponsored the studies with these devices.

Patients were followed for 2 years, and assessed periodically during follow-up by the neck disability index, short-form 36, a visual analog scale, and range of motion.

By most of these measures, spinal fusion and arthroplasty showed no significant differences in outcomes. Disk replacement showed a significantly better improvement in neck disability index compared with fusion after 12 months, but this advantage disappeared during later follow-up, Michael E. Janssen, D.O., and associates reported in a poster at the meeting.

The arthroplasty patients had less arm pain than the fusion patients after 3, 6, and 12 months. Patient satisfaction was significantly higher in the arthroplasty group 6 months after surgery, and no one in that group had a serious adverse reaction or device-related issues. Patients who had disk replacement had improved mobility and range of motion after surgery, said Dr. Janssen, an orthopedic surgeon at the University of Colorado in Denver.

The second cervical study included 21 patients and had a similar design. After up to 2 years of follow-up, the 11 patients treated by cervical disk replacement had very similar outcomes to the 10 patients treated by fusion, Dr. Petrizzo and his associates reported in a poster.

Two comparisons of lumbar-disk replacement with spinal fusion also had a similar design. In one study, 16 patients with two-level degenerative disk disease



This patient, a police officer with two cervical disk herniations, underwent a two-level ProDisc-C replacement, recovered fully, and returned to work after 4 weeks.



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were randomized to total disk arthroplasty with the ProDisc-L, and 8 patients were randomized to circumferential spinal fusion. Another 12 patients with two-level disease were treated with arthroplasty on a nonrandomized basis.

After an average follow-up of 18 months, pain and function were similar in the two groups, who were assessed using a visual analog scale of pain, the Oswestry disability index, short-form 36, and range of motion tests. The Oswestry score fell from 70 at baseline to 43 in the arthroplasty patients, and from 64 to 36 in the fusion patients, Dr. Petrizzo and his associates reported in a second poster.

The second study compared patients with single-level lumbar-disk disease; 9 patients were randomized to fusion and 18 to arthroplasty with a ProDisc-L. An additional 38 patients were treated by arthro-

plasty on a nonrandomized basis.

During an average follow-up of 1 year, periodic assessments by the same measures used in the two-level study showed no significant differences in response between the two groups, Dr. Petrizzo said during an oral presentation at the meeting.

A fifth study reviewed 22 patients aged 60 or older who received a ProDisc-L to repair lumbar disk disease. Seventeen patients had single-level disease, 4 had two-level disease, and 1 had three-level disease.

After an average follow-up of more than 34 months, the patients had significant improvements in their Oswestry disability index and pain scores, Dr. Yue said. The rate of patient satisfaction was 91%. One patient developed a partial foot drop and recovered; another developed complete foot drop and did not recover. Two other patients had partial implant subsidence. ■

## MRI Reveals the Structural Abnormalities of Whiplash Injury

BY DOUG BRUNK  
San Diego Bureau

SAN DIEGO — High-resolution MRI is a useful tool to assess ligaments and membranes in the upper cervical spine and classify structural abnormalities in grades of severity, results from a controlled study of 92 whiplash injury patients have demonstrated.

The finding is important because the structural basis of whiplash injury is unknown, Jostein Krakenes, Ph.D., said at the annual meeting of the Cervical Spine Research Society.

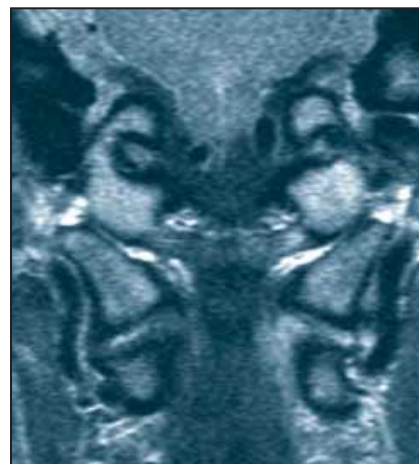
“Structural changes can be graded with reasonable reliability [using MRI],” he said.

For the prospective study, 92 patients with whiplash injuries sustained after frontal or rear-end automobile collisions 2-9 years previously and 30 uninjured



Increased signal intensity on MRI, as pictured above, suggests damage to the alar ligaments in whiplash injury patients, according to Dr. Jostein Krakenes.

controls underwent high-resolution MRI of the craniovertebral junction in three orthogonal planes, said Dr. Krakenes of Haukeland University Hospital, Bergen, Norway. The investigators included only patients with



PHOTOS COURTESY DR. JOSTEIN KRAKENES

persistent neck pain, tenderness in neck muscles and other soft tissues by palpation, and decreased range of neck motion 3 months after the whiplash injury.

Three radiologists blinded to the clinical information inter-

preted the images twice at 3-month intervals.

He explained that on MRI normal alar ligaments and membranes show low signal intensity and appear dark. Increased signal intensity within ligaments, meanwhile, is regarded as injury.

A high signal in one-third or less of the cross-section was defined as grade 1, a high signal in one-

third to two-thirds of the cross-section was grade 2, and a high signal in two-thirds or more of the cross-section was grade 3.

Of the 394 ligaments and membranes evaluated, 117 (30%) were grade 2 or 3 lesions in the

whiplash group. Among the 140 ligaments and membranes evaluated in the control group, only 7 (5%) had grade 2 lesions and none had grade 3 lesions.

Most of the damage in the whiplash group patients with grade 2 or 3 lesions was localized to the alar ligaments, said Dr. Krakenes. Most of the high grade changes seen in controls were localized to the transverse ligaments.

When the investigators assessed inter- and intraobserver agreement, highest reliability was found for the atlanto-occipital membrane and lowest for the transverse ligament.

He concluded that increasing neck disability index with increased MRI grading “indicates that craniovertebral ligament lesions may explain some of the impairment of the whiplash associated disorder.” ■