

Few early complications seen with new expandable disc device

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NEW YORK — European orthopaedic surgeons conducting a prospective nonrandomized multicenter study of an expandable lumbar disc arthroplasty system found one-year results were comparable to early results with some of the first lumbar total disc arthroplasty devices used.

The most promising characteristic of the expandable Dascor implant studied was its ability to restore and maintain the patient's disc height to 8.5 mm, according to investigator Jean-Charles Le Huec, MD, of Bordeaux, France. He reported the initial results at the Spine Arthroplasty Society Global Symposium on Motion Preservation Technology, [here](#).

The Dascor implant [Disc Dynamics; Eden Prairie, U.S.A.] also effectively relieved patients' back and leg pain based on Visual Analog Scale (VAS) results.

“This is the first report of an expandable disc arthroplasty using a minimally invasive approach respecting the anatomy and the shape of the disc, [with] perfect adaptability to the endplate. The results are similar to total disc replacement (TDR), but there is less complication related to the implant,” Le Huec said.

Minimally invasive surgery

The Dascor implant consists of a polyurethane balloon filled with a polyurethane that cures in situ. It replaces the lumbar nucleus pulposus.

With the patient lying supine or in a lateral decubitus position, the surgeon performs a discectomy using specially designed straight and curved instruments and disc rongeurs, which preserve the annulus. He then implants the device at L5-S1 or L4-L5 through an anterior mini-open, visually assisted technique by inserting the balloon and using dye to check if enough disc space is available to fill it sufficiently.

Finally, the surgeon checks the balloon's position with AP and oblique radiographs taken with a C-arm and inserts a catheter, through which the polymer material is injected. After the balloon is filled, he cuts the catheter prior to closure.

The surgery lasts about 75 minutes, with an average blood loss of 72.0 cc.

Investigators are studying the Dascor arthroplasty system's safety and performance characteristics. They plan to follow 50 patients for two years.

Strict indications

Investigators followed the first 17 patients to receive the Dascor implant for one year postoperatively. The patients met the following indications:

- (1) age ranging from 20 to 70 years old;
- (2) diagnosis of lumbar degenerative disc disease (DDD) based on history and clinical examination;
- (3) dark disc diagnosis on lumbar MRI;
- (4) positive discogram at the affected level;
- (5) minimum back pain score of 5 on a 10-point VAS scale; and
- (6) Oswestry Low Back Disability Index (ODI) score greater than 40%.

In addition, patients could have only one lumbar level affected by DDD. Patients also had to have failed at least six months of nonoperative care and be willing to complete two years of follow-up, Le Huec explained.

The 17 patients (nine men and eight women) in the initial series had a mean age of 38 years and a mean body mass index of 25. They underwent the surgery at centers in France or Germany and completed the one-year follow-up.

In vitro, in vivo studies

In vitro studies into the device's safety revealed that "there was no significant difference with the control group, and the in vivo study ... [found] there was no local toxicity and no adverse events," Le Huec said. Lumbar cadaver testing at L4-L5 showed that although disc height was lost after the discectomy, "when you put the balloon inside the disc, you restore the disc height as normal," he said.

Researchers also studied Dascor's ability to handle peak loads to 1200 N. "There is no peak stress on the endplate, which is very important to try to avoid Modic changes after implantation. And, we have exactly the same results with the same load in flexion and extension," Le Huec said.

Mean preoperative Oswestry Disability Index scores of 52 dropped to 21. Results were also favorable based on the VAS scores, which changed from 7.3 preop to 3.3 at one year. Leg pain VAS scores improved from 5 to 1.6. Patients reduced their analgesic medication use significantly during the first postoperative year.

Complications resolved

"There have been no unanticipated or device-related adverse events reported," Le Huec said. However, 13 adverse events (none device-related)

occurred in 10 patients, 11 of which were mild. He theorized that these were related to the surgery, and all of them resolved within six weeks. A painful psoas hematoma that developed in one of the patients took two months to resolve. There was one unrelated late infection.

Developers are working on a posterior surgical approach for implanting the Dascor prosthesis, Le Huec said. This kind of alternative is needed because it would have “wider indications than the anterior approach. ... The anterior insertion of Dascor is safe and effective.”

For more information:

Le Huec J-C, Halm H, Ahrens M, et al. Multi-center clinical evaluation of nucleus replacement with the Dascor disc arthroplasty system: One-year follow-up results. Presented at the Spine Arthroplasty Society Global Symposium on Motion Preservation Technology. May 4-7, 2005. New York.

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