FDA approves second lumbar artificial disc

Synthes Spine’s ProDisc in August became the second lumbar artificial disc to receive Food and Drug Administration (FDA) approval. The first was Charité by DePuy Spine, approved in 2004.

The ProDisc should be better accepted. Data show it is easier to implant, with less of a learning curve than Charité. And outcomes look strong compared to traditional spinal fusion.

Both OR time and blood loss are significantly less with ProDisc than traditional fusion. Outcomes for pain and return to work were also favorable, according to new data presented by the clinical researchers led by Rick Delamarter, MD, at the North American Spine Society meeting in September in Seattle (chart). They say theirs is the first randomized investigational study to show statistically superior outcomes for an artificial disc compared with fusion.

“I think because of this, ProDisc will be better accepted with a better chance of reimbursement from CMS,” says Robin Young, editor and publisher of Orthopedics This Week, referring to the Centers for Medicare and Medicaid Services.

Julie Blatnik, RN, BSN, CNOR, director of the spine care program for St Paul, Minn-based HealthEast Care System, who is familiar with the training for both Charité and ProDisc, says it appears that the ProDisc technique is easier, and it uses about one-third as many instruments as the Charité.

Charité, meanwhile, has met bumps in the road. Surgeons have been slow to adopt it, and many insurers do not cover it. Some 5,000 Charité disc replacements have been performed, compared to about 200,000 spinal fusions performed each year.

FDA to follow outcomes

The FDA will follow outcomes of the ProDisc closely. Synthes must conduct a 5-year study to assess the long-term safety and effectiveness of the disc in the 286 patients who participated in the preapproval clinical trials. The company also must evaluate overall success, complete an annual analysis, and report any major adverse

ProDisc-L versus spinal fusion

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<th>ProDisc</th>
<th>Fusion</th>
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<tr>
<td>Operative time</td>
<td>121 min</td>
<td>229 min</td>
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<tr>
<td>Blood loss</td>
<td>204 cc</td>
<td>465 cc</td>
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<tr>
<td>Hospital stay</td>
<td>3.5 days</td>
<td>4.4 days</td>
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<td>Disability scores</td>
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<td>Pain scores</td>
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<td>Complication rate</td>
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events, such as implant breakage, subsidence, or expulsion from the disc space. The FDA say results of the study and analyses will be reflected in supplementary labeling for the disc. The conditions are similar to those for the Charité disc.

**Disc design**

The ProDisc was designed by a French spine surgeon, Thierry Marnay, MD, and has had more than 15 years of clinical follow-up in Europe. The disc consists of 3 parts (photo):

- a metal (cobalt-chrome alloy) endplate that is anchored to the bottom surface of the vertebral body
- a second endplate that is anchored to the top surface of the vertebral body
- a plastic (ultra-high molecular weight polyethylene) inlay that fits between the 2 endplates.

The artificial disc replaces the damaged disc. The endplates and inlay help restore the natural distance between the vertebrae. The top endplate slides over the domed part of the inlay, allowing movement at the implant level and alleviating pain associated with movement.

**Indications**

The FDA’s approval letter to Switzerland-based Synthes states the ProDisc is indicated for use in patients who:

- are skeletally mature
- have no more than Grade 1 spondylolisthesis at the involved level
- have degenerative disc disease at 1 level in the lumbar spine (L3-S1)
- have pain caused by a degenerated disc confirmed by the patient’s history and radiographic tests, such as MRI
- have had no relief from pain after at least 6 months of conservative treatment.

**Surgeon training**

Like the Charité, the ProDisc is implanted anteriorly through an incision in the abdomen. A general surgeon exposes the spine, and a spine surgeon removes the damaged disc to create a space between the 2 vertebrae to implant the artificial disc. The procedure generally takes about 1 to 2 hours.

Initially, only 120 to 150 surgeons will be invited to the training for the ProDisc, including those who participated in the clinical trials. But Synthes plans to start training for other surgeons to learn the procedure, according to one of the investigators, Jack Zigler, MD.

There will be 2 structured courses that include didactic instruction, case reviews, skills labs, cadaver spine insertion, and live surgical demonstration. Individual proctoring will also be available.

HealthEast, an early adopter of the Charité disc, expects to perform its first ProDisc procedures in December or January. Two surgeons will be attending some of the first ProDisc training courses, Blatnik says. Both have been using the Charité disc. One says he has been pleased with its results in his carefully selected patients, though he was skeptical at first, she says.

HealthEast surgeons have performed about 15 Charité procedures, with 3 being multilevel. The system has 17 orthopedic and neuro surgeons.

**Reimbursement**

Because of HealthEast’s work with its surgeons and insurers, Blatnik says that its Charité cases have been reimbursed at a level that is at least as good as its fusion cases in terms of the percentage of charges that are reimbursed. The list price of the Charité is $11,500. The price for the ProDisc is expected to be $9,898 with no discounts. (Synthes has not made its price public.) Blatnik says Synthes has said that initially it will deliver the disc individually for cases so it can monitor patient selection and make sure only surgeons who have had the training will be performing the case. Synthes did not respond to OR Manager’s request for comment.

Blatnik says she is gradually seeing more acceptance of the artificial disc by insurers, but the region’s Blue Cross & Blue Shield plan has not approved reimbursement.
for it. The Blue Cross & Blue Shield Association’s Technology Evaluation Center issued an assessment in 2005 that found the artificial disc did not meet its criteria. Blues’ plans in each area make their own coverage decisions.

Medicare covers the procedure under DRG 499 and 500 (back and neck procedures except spinal fusion), with a payment of between $4,700 and $7,200, much less than the cost of the Charité device alone. After initially saying it would cover the procedure, Medicare reversed its position in May 2006, allowing coverage for the Charité disc for patients under 60 at the discretion of local Medicare medical directors; coverage is excluded for patients 60 and over.

Blatnik notes that HealthEast surgeons are very careful in their patient selection, making sure the patient is an appropriate candidate and that the procedure will be covered by insurance.

**What’s next?**

FDA approval of the first artificial cervical disc, likely the Prestige from Medtronic Sofamor Danek, is expected early in 2007.

“The cervical disc will be received enthusiastically and should have a higher rate of acceptance than the lumbar disc,” Young says. It’s also less expensive.

—Judith M. Mathias, RN, MA
—Pat Patterson

**References**


