

Synthes, Medtronic, DePuy attempt to overcome technological, reimbursement hurdles currently limiting adoption of ADRs

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- Lack of evidence to support idea of adjacent disc degeneration prevention
- No long-term benefit over spinal fusion
- ADR may see uptake/reimbursement for younger patients

Artificial disc replacement (ADR) is seeing limited adoption due to reimbursement hurdles and technological shortcomings, orthopedic spine surgeons said.

Several companies are attempting to leverage quicker patient recovery and potential cost savings to push for reimbursement, which may increase adoption in younger patients or patients with chronic lower back pain, experts added.

Despite of the current ADR environment, a myriad of companies are still investing in newer generation ADRs such as Nuvasive (NASDAQ:NUVA), SpineCore, SpinalMotion, and AxioMed. The three approved artificial discs in the US include the Charite by DePuy (NYSE:JNJ), the ProDisc by Synthes (VTX:SYST), and the Prestige by Medtronic (NYSE:MDT).

The current ADR technology seems to be non-inferior to standard of care but could provide cost savings in the cervical spine setting, experts noted.

ADR is a surgical procedure in which degenerated intervertebral discs in the spine are replaced with artificial devices. The procedure is used to treat chronic, severe low back pain and cervical pain resulting from degenerative disc disease. ADR originally generated significant interest in the spine world as an alternative to spinal fusion procedures. The technology has been used in Europe for more than 15 years, but the first disc was only recently approved in the US in 2004. Insurance companies in the US still consider ADR to be experimental.

One of the main value propositions of the artificial disc was that it could prevent degeneration of discs on adjacent levels, but this has not been clearly demonstrated by studies to date, said Dr Rayshad Oshtory, an orthopedic surgeon at the Post Street Surgery Center in San Francisco. Studies indicate that the degree of degeneration of adjacent levels when using ADR is identical to fusion procedures, suggesting that the degeneration process is likely due to the natural progression of the disease rather than fusion.

The real value of the artificial disc is that patients can heal faster and return to work sooner, said Dr Richard Guyer, co-founder of the Texas Back Institute and associate clinical professor of orthopedics at the University of Texas Southwestern. He noted that the overall societal cost may be lower as suggested by some studies, and many more studies are being planned to demonstrate a cost benefit, he added.

The environment for disc reimbursement was extremely poor several years ago, but some insurance companies are now "softening a little bit," Guyer noted. He specified that he has had some luck with certain branches of Cigna (NYSE:CI) and Blue Cross Blue Shield on a case-by-case basis. Guyer added that recently a patient of his was also able to receive reimbursement from a self-insured company, managed by United Healthcare.

Workers Compensation reimburses disc replacement due to the value of quicker recovery, Guyer added.

"The technology is good and we are going to see advancement. We will likely generate better data as time goes on," Guyer said.

The ideal ADR patient is one who has had a prior discectomy but still has subsequent chronic back pain, according to Guyer. About 20% of the patients who currently undergo spinal fusion would be ideal candidates for ADR, he estimated. For patients with pure lower chronic back pain, the percentage is much higher, he added.

Reimbursement has been a significant issue and insurance companies have constantly turned down coverage for patients who would have been great candidates, explained Dr Marco Rodriguez, an orthopedic spine surgeon in South Carolina. He noted that he would use the disc for patients within the age range of 30-50 because they can quickly return to work. He added that ADR would be ideal for about 10-20% of the patients in that age range.

"[ADR] technology is not bad but has not blown anyone away," said Dr Alexander Vaccaro, professor and attending surgeon in the department of orthopedic surgery and neurosurgery at Thomas Jefferson University Hospital. From an insurance company's standpoint, the technology is non-inferior to current approaches, so it would not make sense for them to pay more for use in the lumbar spine, he said. However, the technology is cheaper in cervical spine, he noted.

Many companies are trying to enter this space, maybe because they do not want to be left out, but the ones with products already on the market are not seeing much traction, said Vaccaro.

When compared to spinal fusion, current ADR technology does not fare much better in the long-term, said Dr Michael Lospinuso, chief of spinal surgery at Meridian Health System.

Yet companies such as Nuvasive continue to invest in a newer generation of ADRs and there is some optimism from a reimbursement standpoint, said Guyer.

Medtronic, Synthes, and DePuy did not respond to request for a comment.

Michael Lambert, CFO of Nuvasive, said in an interview that the company recently filed a PMA with the FDA for its cervical disc product, PCM, and also had its 100-day PMA meeting. The company plans to start training its sales force next year and is preparing for a full commercial launch of PCM sometime in 2012. Lambert added that Nuvasive is also developing a lateral artificial disc, for which the company is currently enrolling patients in a study that should

Johnson & Johnson
Medtronic, Inc.
Nuvasive, Inc.
Synthes GmbH

Company

Spinal Motion

Intelligence Type(s)

Product Development

Topic

Medical Devices

Intelligence Grade

Strong evidence

Sub-sectors

Medical equipment and services

Country

USA

complete enrollment in 2011, he said.

by Viral Gandhi

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