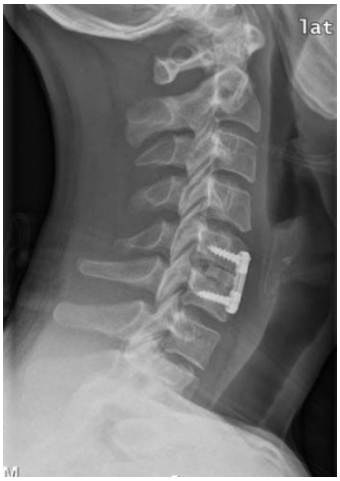
Cervical Total Disc Replacement With Mobi-C Is a Safe and Effective Alternative to Cervical Fusion, Long-Term Study Shows

Written by Kristin Della Volpe *(/author/43738/della-volpe)*

Cervical total disc replacement with the Mobi-C device demonstrated similar safety and efficacy to anterior cervical discectomy and fusion (ACDF), in a 5-year prospective, randomized, controlled study published in the *International Journal of Spine Surgery*.



(http://www.spineuniverse.com/sites/default/files/imagecache/gallery-large/wysiwyg_imageupload/3998/2016/04/04/cervical_anterior_discectomy_fusion_postop_lateral_xray.jpg)

"It is important for surgeons, non-surgeons, and patients to know that there is an alternative to cervical fusion with results that are at least as good and with lower rates of degeneration of the levels next to the treated level," said lead author Michael S. Hisey, MD (http://www.spineuniverse.com/author/46030/hisey) , who is an Orthopaedic Surgeon at Texas Back Institute in Denton, Texas. "This results in lower rates of needing additional surgery for these adjacent levels," Dr. Hisey said.

"Also important is that the artificial discs tended to have lower complication rates and lower need for additional surgery at the treated level," Dr. Hisey explained.

Investigational Device Exemption Trial

The study was conducted as part of a U.S. Food and Drug Administration (FDA) regulated Investigational Device Exemption (IDE) trial. A total of 245 patients at 23 centers were randomized (2:1 ratio) to receive cervical total disc replacement (TDR) with the Mobi-C Cervical Disc Prosthesis or ACDF with anterior plate and allograft. At 5-years, follow-up data was available for 85.5% of the TDR group and 78.9% of the ACDF group.

The primary outcome was a composite success criterion involving the following:

- Minimum 30/100 point improvement in NDI scores compared to baseline
- No device-related subsequent surgery
- No adverse events classified as possibly or probably device-related
- No neurologic deterioration
- No intraoperative changes in treatment if randomized to Mobi-C

Total Disc Replacement Found Noninferior to Cervical Fusion
A similar proportion of patients in both groups met the composite success criterion (61.9% and 52.2% of the TDR and ACDF groups, respectively), demonstrating that TDR was statistically noninferior to ACDF. In addition, similar improvements were found in the following outcome assessments: Neck Disability Index (NDI), visual analog scales (VAS) assessing neck and arm pain, and Short Form-12 (SF-12) health survey.

Significantly fewer patients in the TDR group required a subsequent device-related surgery compared with the ACDF group (3.0% vs 11.1%; $P<0.05$), or had an adjacent segment degeneration at the superior level (37.1% vs 54.7%; $P<0.03$). Patients in the TDR group maintained segmental range of motion at the treated level throughout the 5-year study, the authors noted.

In addition, the groups showed similar rates of device-related adverse events (5.5% and 3.7%, respectively) and neurological deterioration (4.3% and 6.2%, respectively). Furthermore, both groups showed high rates of patient satisfaction, with 92.0% of TDR patients and 83.9% of ACDF patients being very satisfied with their treatment at 60 months.

Choosing Patients for Cervical Total Disc Replacement
“All patients who are candidates for cervical artificial disc are candidates for fusion, but it doesn’t go the other way,” Dr. Hisey said. “Not all patients who are candidates for a fusion will do well with a Mobi-C.”

“When I have a patient with a cervical disc herniation or degeneration requiring surgery, I often start by deciding whether they are a candidate for a Mobi-C,” Dr. Hisey told SpineUniverse. “If they have cervical radiculopathy or myeloradiculopathy at one or two levels, this may be the best treatment for them. Patients with severe degeneration, chronic myelopathy, or deformity are not ideal candidates for a Mobi-C, but may do very well with a fusion.”

“In addition, patients are not candidates for Mobi-C if they have significant osteoporosis, significant facet degeneration, more than two levels requiring treatment, ongoing infection, or compression of the neural elements requiring removal of a significant amount of the endplate to achieve decompression. It turns out that somewhere between 30% and 50% of patients who are candidates for a fusion are good candidates for a Mobi-C.”

Study May Improve Insurance Coverage of the Mobi-C
“In general, the Mobi-C is not more expensive than fusion surgery, but insurers have still been slow to embrace this new technology,” Dr. Hisey said. “This is rapidly changing, and hopefully the publication of the 5-year results will tip the balance in favor of approval.”

“Because the Mobi-C does not accelerate the degeneration of adjacent levels the way fusion does, surgeons can sometimes offer their patients a smaller operation—maybe a one-level artificial disc, when a two-level fusion would be recommended," Dr. Hisey said. “This is because fusion of a level that is not currently causing symptoms is sometimes recommended if it is next to a symptomatic level to prevent the need for surgery on this level down the road.”

Commentary

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I would like to congratulate the authors on this interesting article on the 5-year results of the single-level Mobi-C artificial cervical disc replacement versus an ACDF control group from a prospective, randomized Investigational Device Exemption (IDE) study. All the patients in the study had radiculopathy or myelopathy at a single level that was refractory

to nonsurgical treatment. I would expect either ACDF or disc replacement would enable a surgeon to perform a successful decompression and to alleviate neck and arm pain. Not surprisingly, both groups of patients improved significantly compared to baseline. One key message of this study is that both procedures are safe and effective in improving neck and arm pain in appropriately selected patients.

When comparing procedures, there were no significant, persistent, long-term differences between groups in neck pain or arm pain. I would not expect to see such differences since both groups of patients have had their nerve compression relieved. There was some evidence of greater improvement in early pain in the disc replacement group that did not persist 5 years.

Comparing groups, there was a difference in the incidence of secondary surgery due to device-related adverse events and adjacent segment degeneration. There were fewer secondary surgeries in the disc replacement group. For that reason, the artificial disc replacement group had a higher overall study success rate.

Strengths of the study include the large number of patients and the long-term follow-up. Additionally, these results are consistent with the other studies in the literature that show a lower secondary surgery rate with artificial disc replacement.

At five years, however, there was a significant difference in secondary surgery rates for device-related adverse events and adjacent segment disease. Although the rates of secondary surgery have been a subject of controversy, this prospective study with high rates of follow-up provides a valuable insight into the failure rates of current ACDF plating. There is little literature on the management of fractured ACDF plates or screw prominence. I suspect that within an IDE study, ACDF patients with prominent screws or plate fracture are managed proactively.

One weakness of the study is the reliance on the FDA derived-composite success endpoint. Although this endpoint is universally used among the disc replacement IDE studies, it is somewhat arbitrary. Further study is necessary to determine whether the composite success endpoint correlates to clinically important thresholds.

My colleagues and I recently published the 5-year results of the two-level cervical disc replacement.[1] We found similar improvements in all patients versus baseline. We also found that the disc replacement patients had on average lower rates of secondary surgery and a higher overall composite success rate. Other recent papers have determined that 2-level cervical disc replacement is cost effective relative to ACDF.

It is important to realize that the results of these studies reflect the outcomes of a select group of patients who met inclusion and exclusion criteria. Further study is necessary to determine if there are specific patients who benefit more from either ACDF or disc replacement. Also, we need further information on the outcome of disc replacement in patients outside of IDE study conditions. However, for appropriately selected patients, cervical total disc replacement with Mobi-C appears to be a better long-term option than ACDF, as the former procedure is associated with a lower rate of secondary surgery.

Reference

1. Radcliff K, Coric D, Albert T. Replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. *J Neurosurg Spine.* 2016 March 25:1-12. [Epub ahead of print]

Disclosure: *Michael Hisey reports fees from faculty for Mobi-C training.*

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