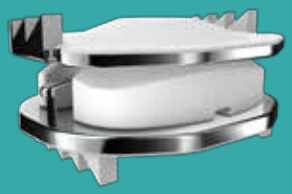
Mobi-C®
CERVICAL DISC

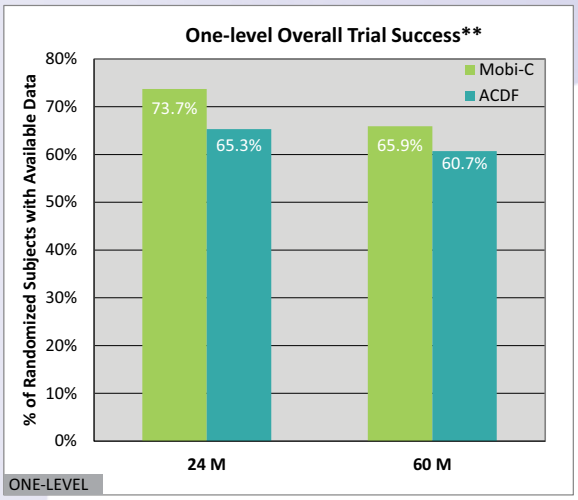


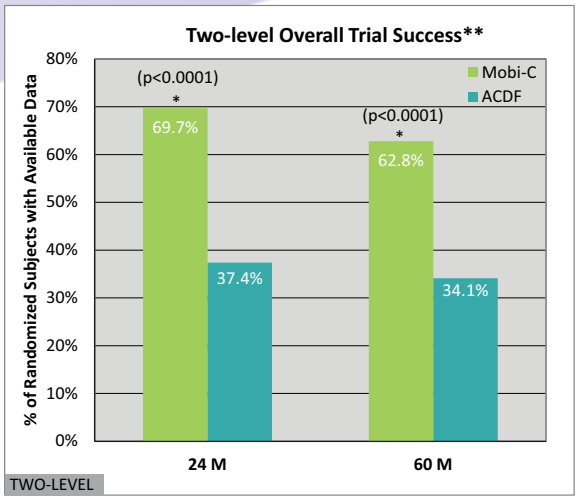
Statistical Superiority in Overall Trial Success Compared to Fusion for Two-Level Disc Replacement

MOBI-C CLINICAL TRIAL

The Mobi-C Cervical Disc (Mobi-C) Investigational Device Exemption (IDE), a multi-centered, prospective, randomized and controlled clinical trial, examined Mobi-C compared to the control, anterior discectomy and fusion (ACDF). ACDF patients received allograft bone and an anterior cervical plate.

To be considered an overall trial success, subjects had to be successful in all 5 components which included: no neurologic deterioration, neck disability index improvement, no device-related adverse events, no radiologic failure, and no subsequent surgeries at the treated level(s).





* Fisher's Exact text used to compare frequencies between the treatments.
**Overall trial success based on IDE defined primary endpoint.

KEY RESULTS AT 60 MONTHS: TWO-LEVEL STUDY

SUBSEQUENT SURGERIES

- Mobi-C subjects required fewer subsequent surgeries at the operated levels (3.8%) compared to ACDF subjects (16.2%).

RETURN TO WORK

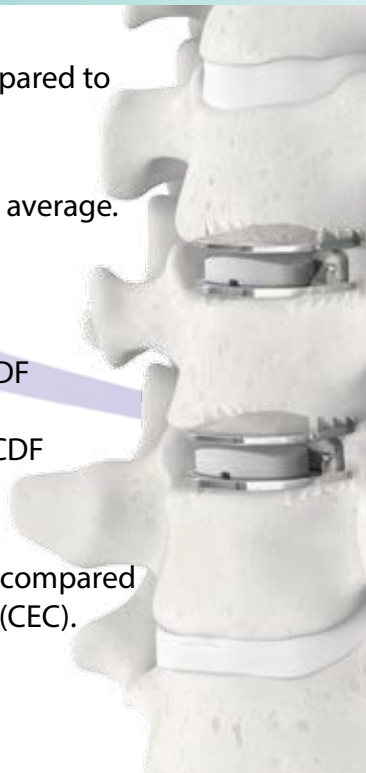
- Randomized Mobi-C subjects returned to work 20.9 days sooner than ACDF subjects on average.

ADJACENT LEVEL DEGENERATION

- Randomized Mobi-C subjects developed lower rates of adjacent level degeneration compared to ACDF:
  - At the inferior adjacent level, 77.5% of Mobi-C subjects compared to 44.9% of ACDF subjects showed no negative radiographic changes ($p<0.0001$).
  - At the superior adjacent level, 67.4% of Mobi-C subjects compared to 29.2% of ACDF subjects showed no negative radiographic changes ($p<0.0001$).

ADVERSE EVENTS

- Randomized Mobi-C subjects experienced fewer device-related adverse events (19.1%) compared to ACDF subjects (36.2%), as determined by an independent Clinical Events Committee (CEC).



LDR

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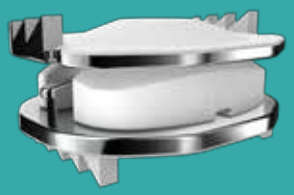
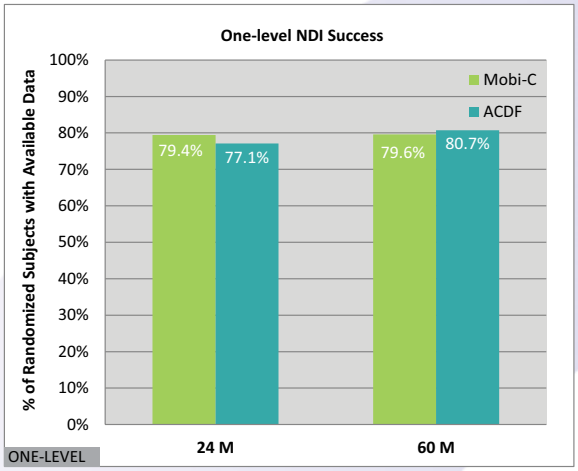
CERVICAL DISC

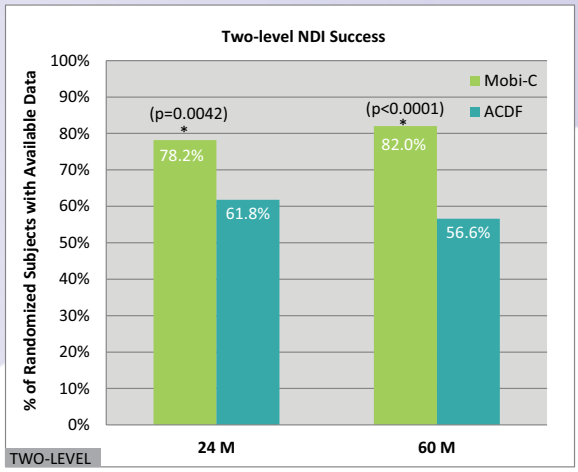


FDA APPROVED IN 2013

MORE THAN 30,000 IMPLANTED GLOBALLY SINCE 2004

NECK DISABILITY INDEX (NDI) SUCCESS**



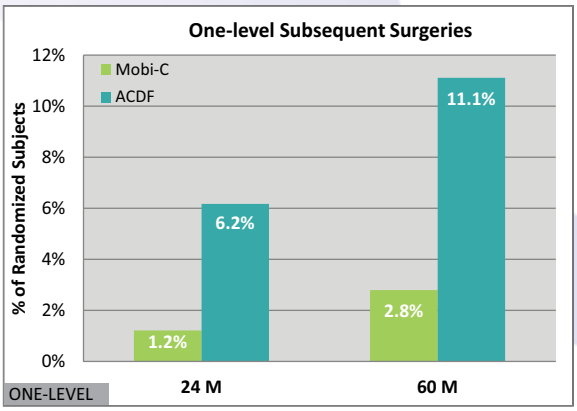


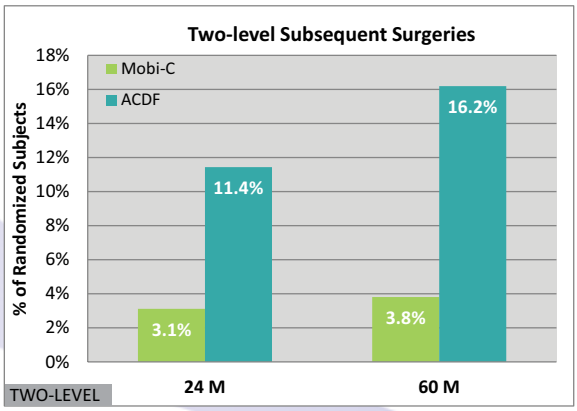
* Fisher's Exact text used to compare frequencies between the treatments.

Mobi-C subject NDI success rates were higher than ACDF at all timepoints in the study for both one and two levels.

**NDI success is defined as ≥15 point improvement in subjects with a baseline NDI of ≥30 points, or ≥50% improvement in subjects with a baseline NDI <30 points.

SUBSEQUENT SURGERIES AT THE TREATED LEVEL(S)





Mobi-C subjects required fewer subsequent surgeries at the operated level(s) compared to ACDF for both one and two levels.

INDICATIONS

The Mobi-C Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height compared to adjacent levels. The Mobi-C Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C Cervical Disc.

Visit www.cervicaldisc.com for complete clinical study results and to find a trained Mobi-C surgeon in your area.

MB B 10 REV B 10.2015