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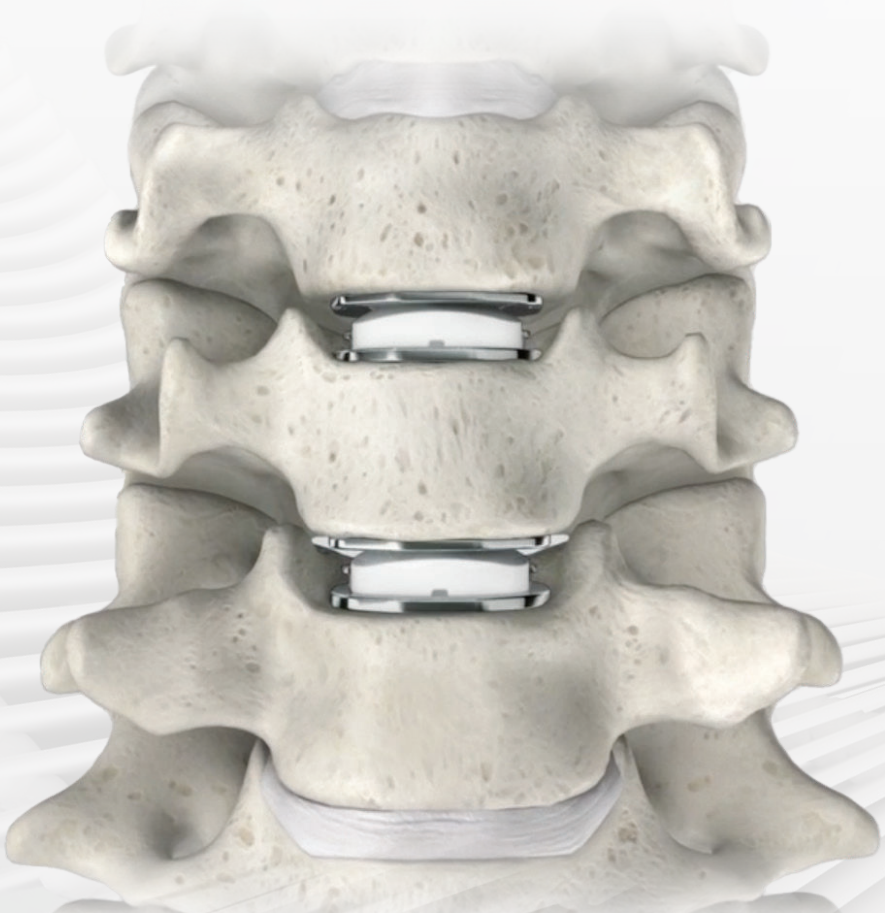
Ten-Year Outcomes of 1- and 2-Level Mobi-C® Patients

Mobi-C®
Cervical Disc



Extended Follow-Up from the Mobi-C IDE Study

The following presentation summarizes the key results of the Mobi-C 10-year study that was recently published in Neurosurgery.[1] Upon completion of the 7-year FDA Investigational Device Exemption (IDE) study of the Mobi-C Cervical Disc, follow-up continued on a subset of patients from nine high-enrolling centers.

All patients in the study had undergone cervical disc arthroplasty (CDA) with Mobi-C for the treatment of degenerative disc disease (DDD) with radiculopathy or myeloradiculopathy at one or two contiguous levels from C3-C7 (Fig. 1).

Clinical and radiographic outcomes of 187 Mobi-C patients were collected through ten years postoperatively to assess the long-term safety and effectiveness of Mobi-C. The 10-year outcomes of the Mobi-C patients were assessed without comparisons to ACDF, as follow-up of the ACDF control group from the IDE study was completed after seven years of follow-up.[2] The aim of this analysis was to determine whether the statistically significant improvement observed in both 1- and 2-level Mobi-C patients from baseline to seven years postoperatively was maintained out to ten years.

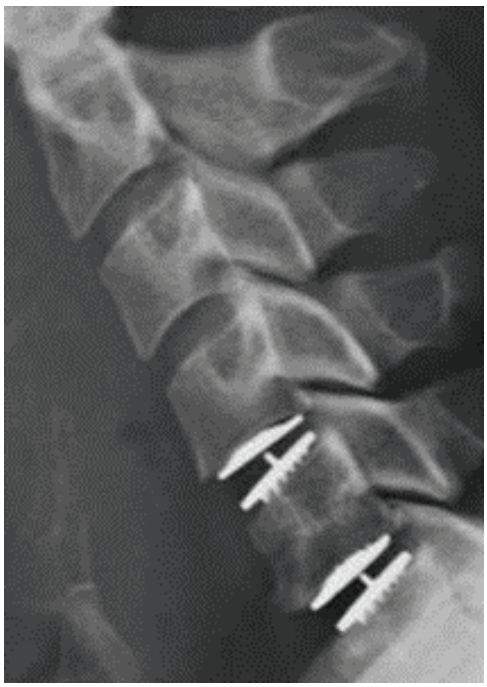


Figure 1. Two-level Mobi-C.

Key Findings

- At ten years, all patient-reported outcomes were equivalent to or improved from seven years.
- Between 7-year and 10-year follow-up:
  - C2-C7 range of motion (ROM) and sagittal alignment were maintained.
  - Segmental ROM in flexion/extension and lateral bending was maintained in both 1-level and 2-level constructs.
  - Clinically relevant radiographic adjacent segment pathology (rASP) did not differ significantly in either 1-level or 2-level patients.
  - Incidence of motion-restricting heterotopic ossification (HO) did not differ significantly in either 1-level or 2-level patients.
  - No subsequent surgery at an adjacent level after seven years.

Mobi-C continues to be a safe and effective treatment for 1- and 2-level cervical disc degeneration.

References:
1. Kim K, Hoffman G, Bae H, et al. Ten-Year Outcomes of 1- and 2-Level Cervical Disc Arthroplasty From the Mobi-C Investigational Device Exemption Clinical Trial. Neurosurgery. 2021;88(3):497-505. 2. Radcliff K, Davis RJ, Hisey MS, et al. Long-term evaluation of cervical disc arthroplasty with the Mobi-C Cervical Disc: a randomized, prospective, multicenter clinical trial with seven-year follow-up. Int J Spine Surg 2017;11(4):244-262.

10-Year Mobi-C Results

Radiographic outcomes from 7-year to 10-year follow-up:

- Segmental and global ROM and sagittal balance were maintained (Table 1);
- Clinically relevant (grade 3/4) rASP was not significantly different (Fig. 2), with a 10-year incidence of 21.3% in 1-level patients and 10.2% in 2-level patients;
- The incidence of motion-restricting HO at ten years was not significantly different from that at seven years for 1-level (30.7% vs. 29.6%) or 2-level (41.7% vs. 39.2%) patients.

Table 1. Segmental and global ROM (degrees) in Mobi-C patients through ten years.

	Flexion/Extension			Lateral Bending			Global ROM (C2-C6 flexion/extension)	
	2-Level Superior	2-Level Inferior	1-Level	2-Level Superior	2-Level Inferior	1-Level	2-Level	1-Level
Preop	8.9	6.8	8.9	8.9	8.9	8.9	8.9	8.9
7 Years	9.4	6.8	9.4	9.4	9.4	9.4	9.4	9.4
10 Years	9.5	6.9	9.5	9.5	9.5	9.5	9.5	9.5
P-value*	0.91	0.97	0.59	0.99	0.99	0.90	0.99	0.19

*10 years vs. 7 years

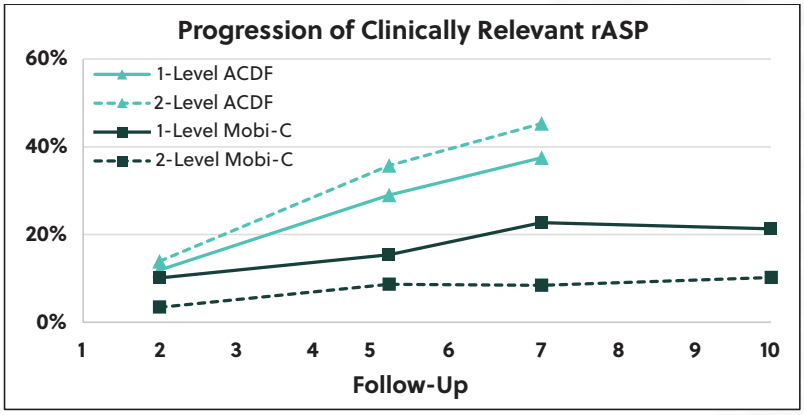


Figure 2. Progression of clinically relevant rASP throughout follow-up. ACDF reporting ends at seven years due to completion of the FDA IDE study.

Safety outcomes between 7-year and 10-year follow-up:

- There were two index level surgeries and no adjacent level surgeries reported after seven years.
- The cumulative incidence of subsequent surgery at 10-year follow-up was 4.3% (11/257) at an adjacent level and 5.1% (13/257) at the index level.
- Seven device-related adverse events (AEs) were reported in five patients (HO = 5, subsidence = 2), but none were classified as serious (i.e., requiring hospitalization or reoperation). Only one patient required an intervention (facet joint injections) due to a device-related AE.

Clinical Outcomes

There was no significant difference (p>0.05) between 1- and 2-level outcomes at ten years. Therefore, the following refer to analysis of 1- and 2-level patients combined (Table 2):

- At ten years, Mobi-C patients continued to have significant improvement in neck disability index (NDI), neck and arm pain, and neurologic function compared to baseline.
- Furthermore, NDI and pain outcomes at ten years were significantly improved from seven years, although these improvements were less than the minimum clinically important difference (MCID) for NDI (15/100) and pain (10/100).
- Maintenance or improvement of neurologic function from baseline did not differ significantly between 7-year (86%) and 10-year (86.3%) follow-up (p=0.60).
- Overall patient satisfaction remained very high at ten years, with the majority of Mobi-C patients reporting they were "very satisfied" (ten years: 88.8% vs. seven years: 88.0%; p=0.26).

Table 2. Clinical outcomes of 1- and 2-level Mobi-C implants.

Outcome	Baseline	7 Years	10 Years	Baseline vs. 10-Year p-value	7-Year vs. 10-Year p-value
NDI	54.4	19.3	15.1	<0.0001*	0.003*
Neck Pain	72.1	20.3	13.3	<0.0001*	0.002*
Arm Pain	69.9	15.5	11.3	<0.0001*	0.037*
SF-12 Physical	32.9	45.7	47.5	<0.0001*	0.13
SF-12 Mental	41.6	51.0	51.5<	0.0001*	0.91

*Denotes a statistically significant difference

Conclusion

Two key advantages of CDA over ACDF are preservation of segmental ROM and reduced incidence of ASP following surgery. Due to the elimination of motion at the treated segment(s), and subsequently increased load and stress on untreated adjacent levels, ACDF can lead to the onset or acceleration of pathologies in adjacent segments. CDA with Mobi-C, on the other hand, has been shown to preserve motion while providing mechanical stability and relief of pain.

Given the emphasis on motion preservation when deciding between CDA and ACDF, two of the biggest concerns following CDA are postoperative development of rASP and motion-restricting HO. While a publication directly comparing the 10-year outcomes of Mobi-C and ACDF is expected later in 2022, the present study showed minimal progression of both rASP and HO between 7- and 10-year follow-up in both 1- and 2-level Mobi-C patients, and no adjacent level surgeries were reported after seven years. ROM and sagittal alignment were also maintained at ten years when compared to early postoperative baseline, and patients continued to have significant improvement in clinical and patient-reported outcomes compared to pre-op. Overall results through ten years were comparable to 7-year outcomes, demonstrating that CDA with Mobi-C continues to be a safe and effective surgical treatment for patients with 1- or 2-level cervical degenerative disc disease.

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