Title: Long-Term Follow-Up of One- and Two-Level Cervical Disc Arthroplasty: Outcomes from the First 128 Patients With 10-Year Follow-Up in a U.S. Multi-Center Study.

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Introduction

Short-and mid-term studies have demonstrated the effectiveness of cervical disc arthroplasty (CDA) for treatment of cervical disc degeneration.

The purpose of this study is to examine the 10-year outcomes of a multicenter experience with CDA for one- and two-level pathology.
Methods

• Prospective, randomized, FDA IDE clinical trial of the Mobi-C cervical disc at one or two contiguous levels.

• Primary inclusion criteria were cervical degenerative disc at one or two contiguous levels and no prior cervical operations.

• Outcome measures included NDI, VAS neck and arm pain, neurologic status, patient satisfaction, secondary surgical procedures and adverse events. Range of motion was obtained from radiographs analyzed by independent radiologists.

• Follow-up was extended to 10 years for consenting patients at seven high-enrolling centers in the original IDE study. This preliminary analysis looks at the first 128 (approximately 50%) patients with 10-year follow-up. There were no significant differences in demographics or preoperative patient-reported outcomes between these patients and the original FDA cohort.
Results

Ten-year follow-up was obtained from 128 patients at 7 centers. Patient characteristics and preoperative outcomes were similar to the 413 CDA patients in the original FDA cohort.

Ten years after CDA, patients showed significant improvement from baseline NDI, VAS neck and arm pain, and neurologic function. Outcomes were not significantly different from results at seven years for NDI at one (14.2 vs. 17.5; p=0.27) or two levels (15.5 vs. 17.9; p=0.17).

Comparable results were seen for neck and arm pain, and segmental range of motion. Neurologic deterioration at 10 years was 12% vs. 13% at seven years (p=0.80). At 10 years, 91.3% of patients were “very satisfied” with the outcome of disc replacement surgery.

Between seven and 10 years, one patient (0.8%) had a subsequent surgery at a non-adjacent cervical level, and there were no reports of device-related adverse events.
Patient reported outcomes

Neck Pain

Follow-up (years)

VAS Pain Score

Preop 5 years 7 years 10 years

1 Level 2 Level

p = 0.17 p = 0.17

Neck Pain

VAS Score

1 Level 2 Level

p = 0.17 p = 0.17
Patient reported outcomes

NDI

Follow-up (years)

NDI (%)

0 1 2 3 4 5 6 7 8 9 10

1 Level

2 Level

P values from ANOVA comparing 10-year vs. 7-year results.

Patient reported outcomes

Arm Pain

Follow-up (years)

VAS Pain Score

0 10 20 30 40 50 60 70 80

1 Level

2 Level

p = 0.27

p = 0.14

p = 0.89

p = 0.99
Neurologic deterioration

Deterioration defined as worse motor, sensory, or reflex assessment compared to baseline.

\[ p = 0.80 \]

\[
\begin{array}{ccccccc}
\text{Follow-up (years)} & 1 & 2 & 3 & 4 & 5 & 7 & 10 \\
\% Patients & 12.5 & 15.4 & 12.3 & 14.6 & 12.9 & 13.0 & 12.0 \\
\end{array}
\]

Neurological Deterioration: Sensory

Deterioration defined as worse light touch or pin prick assessment compared to baseline.

\[ p = 0.19 \]

\[
\begin{array}{ccccccc}
\text{Follow-up (years)} & 1 & 2 & 3 & 4 & 5 & 7 & 10 \\
\% Patients & 4.5 & 3.4 & 7.0 & 7.3 & 7.0 & 6.1 & 2.6 \\
\end{array}
\]

Neurological Deterioration: Motor

Deterioration defined as worse motor assessment compared to baseline.

\[ p = 0.78 \]

\[
\begin{array}{ccccccc}
\text{Follow-up (years)} & 1 & 2 & 3 & 4 & 5 & 7 & 10 \\
\% Patients & 0.0 & 0.9 & 0.9 & 1.8 & 0.9 & 4.4 & 5.1 \\
\end{array}
\]

Neurological Deterioration: Reflex

Deterioration defined as worse reflex assessment compared to baseline.

\[ p = 0.97 \]

\[
\begin{array}{ccccccc}
\text{Follow-up (years)} & 1 & 2 & 3 & 4 & 5 & 7 & 10 \\
\% Patients & 9.1 & 12.1 & 7.1 & 10.1 & 7.0 & 7.0 & 6.9 \\
\end{array}
\]

Range of Motion

Range of Motion: 1-Level

\[
\begin{array}{cccccccc}
\text{Follow-up (years)} & 0 & 1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 10 \\
\end{array}
\]

Range of Motion: 2-Level Superior

\[
\begin{array}{cccccccc}
\text{Follow-up (years)} & 0 & 1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 10 \\
\end{array}
\]

Range of Motion: 2-Level Inferior

\[
\begin{array}{cccccccc}
\text{Follow-up (years)} & 0 & 1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 10 \\
\end{array}
\]
Discussion

• Longer follow up of CDA Investigational Device Exemption (IDE) studies have shown favorable results for CDA.

• However, all the IDE studies had strict inclusion and exclusion criteria. Therefore, the surgeons still need to be careful about the patient selection.
Conclusions

• Ten years after CDA, both one- and two-level patients maintained segmental range of motion.
• CDA patients continued to have significant improvement from baseline NDI, VAS neck and arm pain, and neurologic function.
• Demonstrated continued maintenance of postoperative outcomes of cervical arthroplasty out to 10 years.
• There were no reports of device-related adverse events or subsequent surgery between the 7- and 10-year follow-up.
• These preliminary results demonstrate that total disc arthroplasty with Mobi-C continues to be a safe and effective surgical treatment for patients with one- or two-level cervical degenerative disc disease up to 10 years after implant.