Does High Mobility Affect Patient Outcomes After Arthroplasty with the Mobi-C® Cervical Disc?

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Introduction

As the cervical disc arthroplasty (CDA) market continues to grow and surgeons appreciate the clinical benefits of CDA, they look to offer such benefits to a wider range of patients. It has been postulated (Patwardhan 2019) that patients with preoperative high mobility may have an increased rate of clinical failure. Particular attention has been paid to the range of motion (ROM) afforded by each disc, with some suggesting that artificial discs with an unconstrained design, such as the Mobi-C implant, may lead to high segmental mobility or translation at the operative level.

Concerns about segmental ROM considered beyond typical mobility arise from its potential to lead to facet joint wear and accelerated degeneration (Kerferd 2017), a well-known cause of neck pain (Manchikanti 2002). Excessive mobility may be demonstrated radiographically as antero- or retrolisthesis in flexion or extension. Despite these concerns, there are very few reports of segmental high mobility with artificial cervical discs, and no reports associating high mobility with poor clinical outcomes.

Design Rationale of the Mobi-C Cervical Disc

The Mobi-C Cervical Disc was designed to complement the natural anatomy and motion of the cervical spine. With an anatomy-mimicking convex superior endplate and a mobile core intended to move with the spine, Mobi-C allows 5 independent degrees of freedom: 2 translational and 3 rotational (Fig. 1), facilitating both independent and coupled motions similar to the natural motion of the cervical spine. The Mobi-C design allows for flexion-extension and axial rotation limited only by the patient's anatomy. Mechanical stops limit core translation to ±1 mm in both the sagittal and coronal planes, preventing segmental instability as defined above. The instantaneous axis of rotation (IAR) is allowed to move in response to the patient's anatomy, rather than being fixed in space as in a fixed core device.

Clinical Study of Mobi-C

The clinical safety and effectiveness of Mobi-C was investigated through an FDA Investigational Device Exemption (IDE) study (Radcliff 2017). The IDE study was a prospective, randomized, multicenter clinical trial of patients with a diagnosis of degenerative disc disease with radiculopathy or myeloradiculopathy at either one or two contiguous levels from C3 to C7. Patients who met the criteria of White et al. (1975) for cervical segmental instability were excluded. The study was divided into separate one-level and two-level treatment arms that were conducted in tandem. A total of 413 patients underwent CDA with Mobi-C between April 2006 and March 2008, with 179 patients treated at one level and 234 patients treated at two levels. Radiographic outcomes were assessed by an independent team of radiologists. Measurements obtained included flexion-extension ROM. Patient-reported clinical outcomes included the neck disability index (NDI) and the visual analog scale (VAS) for neck pain. All subsequent surgeries were documented in detail and adverse events (AEs) were assessed by a committee of non-investigator surgeons who were blinded to treatment whenever possible.

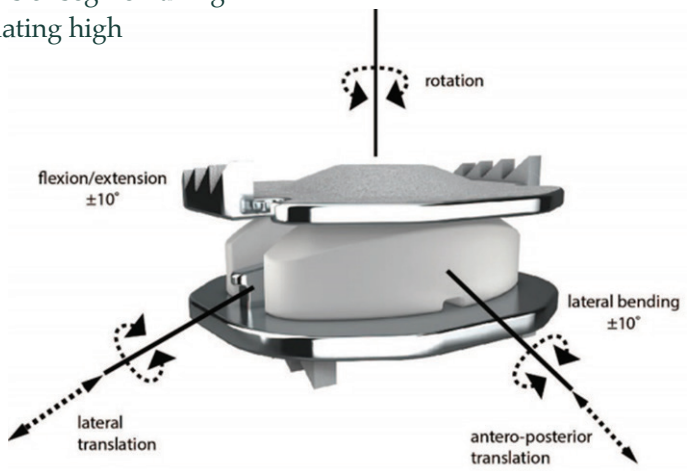

Fig. 1 *The Mobi-C Cervical Disc*

Evaluating the Presence and Effect of High Mobility in Mobi-C IDE Patients

What is considered "High Mobility" in Mobi-C patients?

While there is no consensus on the definition of cervical hypermobility, segmental ROM in healthy adults can serve as a reference benchmark. In an early biomechanical study, White et al. (1975) proposed the following criteria for segmental instability of the cervical spine: translation greater than 3.5 mm, or a difference of >11° in angular motion between the evaluated and adjacent levels. White & Panjabi (1990) later performed extensive biomechanical testing of normal cadaveric spines to determine normal ROM at each level of the spine, and presented their findings in the textbook *Clinical Biomechanics of the Spine.*

To assess the effect of higher postoperative cervical ROM on patient outcomes, "high mobility" Mobi-C patients were defined using the following criteria of White et al. (1975) and White & Panjabi (1990):

- Radiographic instability defined as translation greater than 3.5 mm; or
- A difference of >11° in angular motion between the operated and adjacent levels; or
- High ROM at the operated level(s), defined as flexion/extension (F/E) greater than normal ROM:
  - C3-C4: 15°
  - C4-C5: 20°
  - C5-C6: 20°
  - C6-C7: 17°

Preoperative Mobility

When compared to reference ranges for the normal cervical spine, the mean preoperative F/E ROM of Mobi-C study patients was lower, and all operated segments fell with the normal ROM range (Table 1) (internal data on file). Many study patients had diminished ROM prior to surgery due to disc degeneration and may have been further inhibited by neck pain. Almost 10% of eventual Mobi-C patients had ROM of less than 2° at one or both operated segments. Only nine patients (2.2%) had what could be considered high mobility at an index level, defined as ROM higher than the reference normal value. Four of these did not exhibit evidence of high mobility at any postoperative visit, suggesting that preoperative high mobility does not correspond to postoperative high mobility.

Table 1 *Preoperative ROM in the Mobi-C IDE study compared to normal ROM for the cervical spine.*

	Mobi-C IDE Study Flexion/Extension (°)				Reference Normal Flexion/Extension (°)*	
Level	N	Mean	Std Dev	Range	Mean	Range
C3-C4	3	6.0	6.4	0.3 - 12.9	15	7 – 26
C4-C5	73	11.2	5.2	0.3 - 24.9	20	13 – 29
C5-C6	328	8.6	4.6	0.3 - 21.7	20	13 – 29
C6-C7	220	6.8	3.9	0 - 21.4	17	6 - 26

*White & Panjabi (1990).

Postoperative Mobility

In the IDE study, mean ROM increased in the first year after placement of the Mobi-C. In a small percentage of patients, ROM increased to a level considered to be high mobility at one or more follow-up visits (Table 2).

Table 2 *Mobi-C patients with high mobility postop*

Patient Cohort	% (n)
High mobility at any follow-up visit	19.9% (82/413)
High mobility at 2+ follow-up visits	15.0% (62/413)
High mobility at majority of follow-up	9.0% (37/413)
1-Level	8.9% (16/179)
2-Level	9.0% (21/234)

Postoperatively, less than 20% (82 patients) had at least one radiographic occurrence of high mobility at the operated level, and 15% (62 patients) had more than one postoperative occurrence of high mobility (Table 2). Thirty-seven (9%) patients had high mobility in the majority of postoperative follow-ups. High mobility occurred most frequently after 12 months (Fig. 2), and was more prevalent in the upper segments of the cervical spine (Fig. 3).

High Mobility by Follow-Up Visit

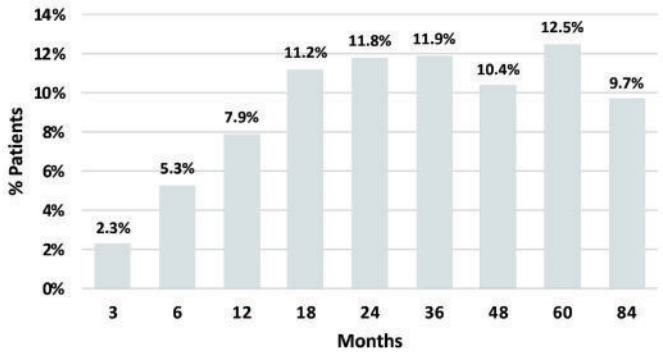

Fig. 2 *Distribution of subjects with high mobility at each follow-up visit.*

High Mobility by Level

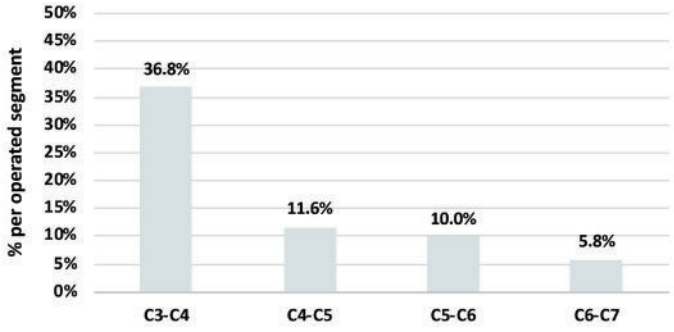

Fig. 3 *Occurrence of high mobility by level.*

Outcomes

Patient Reported Outcomes

When patients with normal and high mobility were compared, there were no differences in NDI (Figure 4) or neck pain (Figure 5). The differences between normal and high mobility patients were not statistically significant ($p>0.05$) at any time point, and were less than the minimal clinically important difference (MCID) for NDI (15/100) and pain (10/100).

NDI

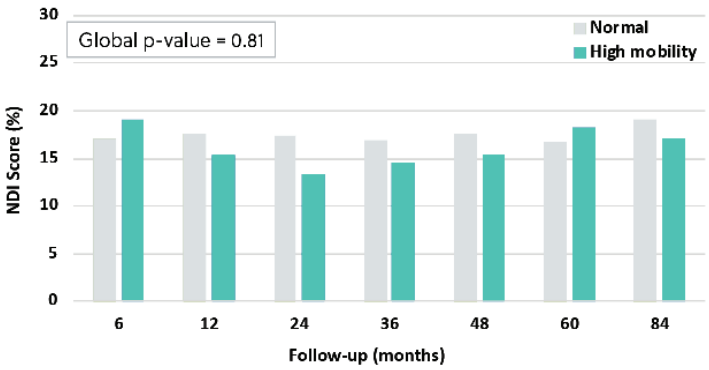

Fig. 4 *Mean NDI in the presence of normal and high mobility at each follow-up. There was no significant difference ($p>0.05$) at any time point.*

Neck Pain

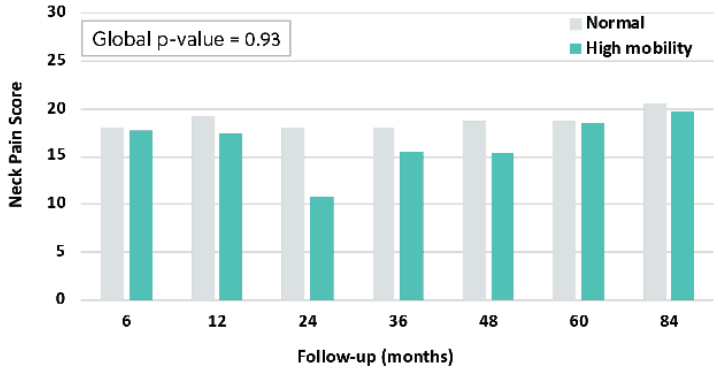

Fig. 5 *Mean neck pain in the presence of normal and high mobility at each follow-up. There was no significant different ($p>0.05$) at any time point.*

Subsequent Surgery

Facet joint degeneration, which can lead to neck pain, was not evaluated in the IDE study. However, revision surgery at the index level due to neck pain may be a proxy for index level facet joint degeneration. If we consider subsequent surgery of the operated level, only four patients in the entire cohort (<1%) had a subsequent surgery at the index level due to recurrent or ongoing neck pain. One of these patients (1/37, 2.7%) was in the high mobility group and three (3/376, 0.8%) were in the normal mobility group ($p=0.31$). **There is no statistical correlation between high mobility and reoperation for neck pain.**

Adverse Events

"Hypermobility" was reported as an adverse event in two subjects throughout the study. Both of these patients had anterolisthesis observed on radiographs in the first 6 months after surgery. **Radiographs also showed that, though there was a listhesis, the Mobi-C had demonstrated ROM at every postoperative visit.** These patients were included in the normal ROM group in the previous analysis. This suggests that high mobility was not the mechanism contributing to anterolisthesis in these patients. Neither event was serious, nor did either patient have an associated AE or subsequent surgery.

CONCLUSION

As the cervical disc market continues to grow and surgeons seek to better understand which patients are the best candidates for CDA, postoperative mobility has become a topic of interest. There is no accepted clinical standard for assessing high mobility, but published reference values of normal cervical mobility can be used to determine higher than normal ROM. Using these reference values, analysis of postoperative radiographs in the Mobi-C IDE study cohort found that only 9% of Mobi-C patients had consistently high mobility.

Although placement of the Mobi-C can allow for high mobility in some patients, high mobility patients did not have worse clinical or radiographic outcomes when compared to Mobi-C patients with normal ROM, and there was no clear evidence of adverse events or surgical intervention associated with high mobility. Subgroup analysis of the Mobi-C IDE data set confirms that, within certain indications, adverse clinical outcomes were not associated with high ROM. More research is necessary to suggest which patients may do better with CDA versus fusion.

KEY TAKEAWAYS

- There are no established criteria for classifying high segmental mobility, but reference values have been published that can be used to assess higher than normal ROM.
- Preoperatively, 2% of Mobi-C patients had radiographic evidence of high ROM.
- At 12 months and beyond, high mobility occurred in 7.9% – 12.5% of patients at any given follow-up.
- About 9% of patients showed consistent evidence of high mobility at a majority of postoperative visits.
- High mobility did not correspond to poor outcomes in the Mobi-C IDE cohort.
- There was no significant difference in NDI or neck pain between high and normal ROM.
- There was no risk of adverse events associated with high mobility.
- Revision surgery at the index level due to neck pain was rare, and occurred at similar rates in patients with normal or high ROM.

References:

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