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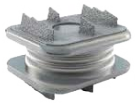
Mobi-C® Cervical Disc Compared to M6-C™ Artificial Cervical Disc

Technology Attributes

Table 1. Design & Biomechanics of Mobi-C and M6-C

Mobi-C Cervical Disc



M6-C Artificial Cervical Disc

Motion Technology: Mobile Bearing Core	Motion Technology: Deformable Core
Technology Attributes • Mobile core adapts to the patient's natural movement through a 3-piece design intended to allow independent and coupled motion • Domed surface designed to articulate angularly with the superior endplate • Flat bottom designed to translate up to 1 mm and rotate on the inferior endplate	**Technology Attributes** • Incorporates an artificial nucleus (polycarbonate urethane) and a woven fiber annulus (polyethylene) designed to provide the same motion as a natural disc
Fixation Technology • Bone sparing lateral teeth designed to maintain integrity of endplates • Plasma sprayed titanium and hydroxyapatite coating and an anatomical dome on the superior endplate	**Fixation Technology** • 3 keels (2 mm high) on each endplate • Titanium plasma spray coating on the endplates
Range of Motion • Flexion/Extension: up to ±10° • Lateral bending: up to ±10° • Core rotation: up to ±8° • Core translation: ±1 mm/axis	**Range of Motion** 6 degrees of mobility • Flexion/Extension • Lateral bending • Axial rotation • Translation (A/P, lateral, vertical)

Clinical Analysis

Both Mobi-C and M6-C have independent studies with 2-year clinical data showing non-inferiority to ACDF at 1-level,[1,2] though there were notable differences between the studies in regards to patient inclusion criteria (Table 2) and reported outcomes (Tables 3 & 4).

Table 2. Notable Differences in the Inclusion/Exclusion Criteria of the 1-Level Mobi-C IDE Study and the 1-Level M6-C SSED Study[1,2]

	Mobi-C	M6-C
Age	18-75 years	18-75 years
Disc Height	≥3 mm	≥4 mm
Severity of Facet Joint Arthrosis	Excluded radiographically confirmed sever facet joint disease or degeneration	Excluded symptomatic facet arthrosis
DEXA Bone Mineral Density Score Cut-Off for Inclusion	T-score ≥ -1.5	T-score > -2.5
Smoking Status	Excluded >1 pack/day	Did not exclude based on smoking status
Diabetic Status	Did not exclude diabetics	Excluded insulin-dependent diabetics
VAS Inclusion Required	Neck and/or arm pain VAS ≥ 30 on 0-100 mm scale	Neck or arm pain VAS ≥ 4 on 0-10 cm scale
Prior Cervical Spine Surgery	No prior spine surgery at the operative level, and no prior cervical fusion procedure at any level	No previous anterior cervical spine surgery, and no previous posterior cervical spine surgery that destabilizes the cervical spine
NSAID Use	Requested that patients refrain from prophylactic use of NSAIDs until 3 months postop	Allowed use of NSAIDs for 6 weeks postoperatively to improve HO

In the FDA IDE study of Mobi-C, 2-year follow-up showed Mobi-C to be non-inferior to ACDF at 1-level (Table 3).[1] In the 1-level arm of this prospective, randomized, controlled trial, Mobi-C had a 2-year success rate of 73.7%, compared to 65.3% for ACDF. Compared to ACDF, Mobi-C supported greater improvements in NDI, SF-12, and VAS scores, as well as reduced rates of secondary surgeries and clinically relevant adjacent segment disease (ASD), defined as at least one increase in Kellgren-Lawrence grade from baseline. At 2 years postop, radiographs showed Mobi-C to support improved mean ROM both flexion-extension (10.8°±6.5°) and lateral bending (5.4°±3.1°). Data collection from the Mobi-C IDE study has continued since the initial 2-year data was published, with 7-year data continuing to support the safety and efficacy of Mobi-C.[5]

Table 3. 2-Year Results of 1-Level Mobi-C[1,13]

	Mobi-C	ACDF
Follow-up	94.3%	92.0%
Success	No serious device- or device procedure-related AEs; no supplemental surgical procedure at the index level; maintenance or improvement of neurological function compared to baseline; and ≥15 point improvement in NDI (on 100-point scale)	
Definition		
Success Rate	73.7%	65.3%
	Mobi-C is non-inferior to ACDF at 1-level	
Progression of ASD		
Superior	15.0%	26.1%
Inferior	8.3%	21.0%
Clinically Relevant ASD		
Superior	9.1%	14.4%
Inferior	2.7%	11.1%
Heterotopic Ossification		
Grade 3	9.5%	-
Grade 4	5.9%	-
Grade 3/4 Combined	15.4%	-
Secondary Surgery		
Index level	1.2%	6.2%
Adjacent level	1.1%	3.7%
NDI Score		
Pre-op	53.4	54.1
2-Year	16.3	19.9
NDI Improvement	37.1	34.2
Range of Motion (ROM)		
Flexion-Extension	10.7	-
Lateral Bending	5.4	-

While direct clinical comparison between Mobi-C and M6-C can't be made due to the lack of a head-to-head clinical study, the study design and data reporting in the M6-C Summary of Safety and Effectiveness (SSED)[2] leave something to be desired. The study was non-randomized, with site-specific treatment groups, meaning that no surgeons in the study performed both cervical total disc replacement (TDR) and ACDF. The ACDF control in the study was comprised of two cohorts – one was treated concurrently with the TDR treatment group at different centers, while the other consisted of historical ACDF control patients from a previous cervical disc study. Due to differences in data collection and outcome measures between the concurrent and historical patients, some data from the control cohorts could not be pooled via a validated method. This prevented direct comparison of certain outcomes (SF-12/SF-36, Odom's Criteria, and Patient Satisfaction) between M6-C and ACDF. When direct comparisons were possible, the M6-C cohort had higher success rates, greater mean NDI score improvement, and lower rates of secondary surgery than the ACDF cohort.

Table 4. 2-Year Results of 1-Level M6-C[2]

	M6-C	ACDF
Follow-up	95.0%	87.7%
Success	No study failure due to secondary surgical interventions at the index level; absence of major complications defined as radiographic failure, neurologic failure, or failure by AE; and NDI score improvement of ≥15/50 points in subjects with a baseline score ≥30/50 points, or a 50% improvement in subjects with a baseline score <30/50 points	
Definition		
Success Rate	86.8%	79.3%
	M6-C is non-inferior to ACDF at 1-level	
Progression of ASD		
Superior	NR	NR
Inferior	NR	NR
Clinically Relevant ASD		
Superior	NR	NR
Inferior	NR	NR
Heterotopic Ossification		
Grade 3	10.7%	-
Grade 4	0.7%	-
Grade 3/4 Combined	11.3%	-
Secondary Surgery		
Index level	1.9%	4.8%
Adjacent level	3.1%	2.1%
NDI Score		
Pre-op	54.8	51.9
2-Year	12.1	17.9
NDI Improvement	42.7	34.0
Range of Motion (ROM)		
Flexion-Extension	8.8	-
Lateral Bending	6.9	-

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