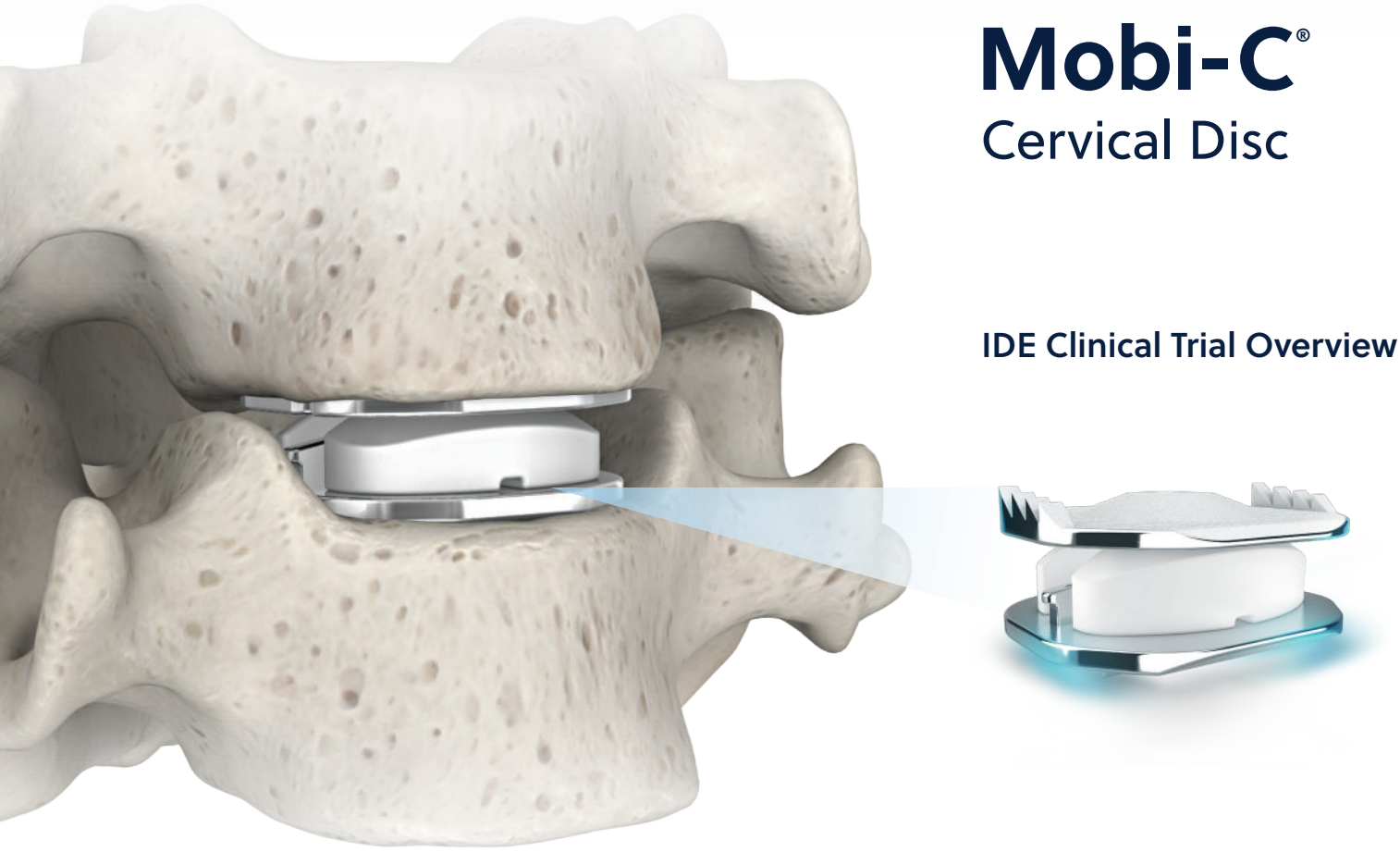
Comparison of Mobi-C to Anterior Cervical Discectomy and Fusion at One Level



Mobi-C®
Cervical Disc

IDE Clinical Trial Overview

ZimVie

ANATOMICAL DESIGN THAT FITS THE NATURAL VERTEBRAL ANATOMY

ZimVie

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KEY TRIAL RESULTS

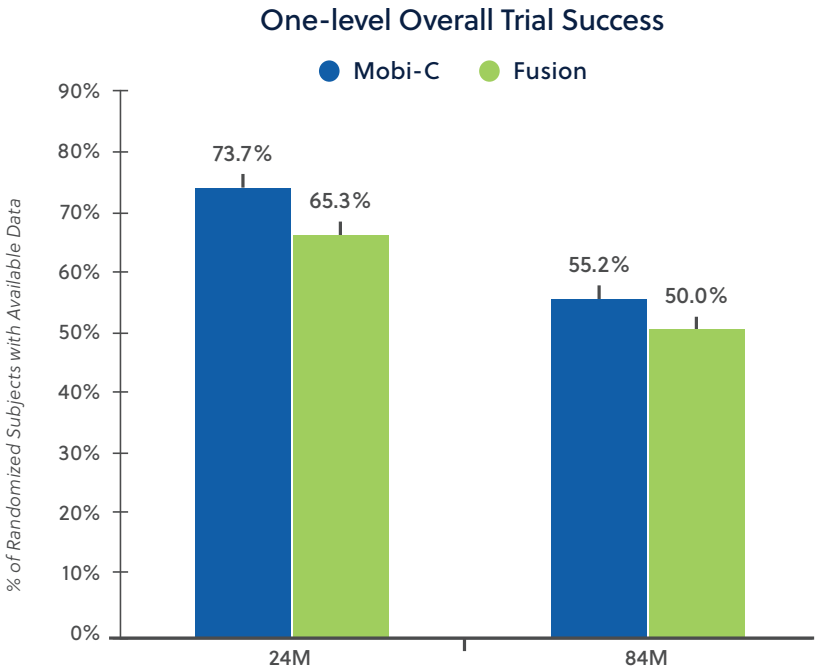
FEATURING PATENTED MOBILE BEARING TECHNOLOGY

Mobi-C demonstrated:

Non-inferiority in overall trial success

compared to ACDF at 84 months.

Results



At 84 months

- Nominally fewer subsequent surgeries at the index levels compared to ACDF.
- Lower average rates of adverse events determined to be major complications compared to ACDF.
- Lower average rates of adjacent level degeneration compared to ACDF.
- A mean ROM in F/E of 10.2° at the index level.

A mean return to work time 7.5 days sooner than ACDF.

Mobi-C is a safe and effective surgical option at one-level in the cervical spine from C3-C7 in indicated subjects.

NOTE: Please refer to ZimVie.com for complete study results.

OVERALL TRIAL SUCCESS: THE COMPOSITE ENDPOINT

Success Criteria

The Mobi-C IDE trial was a multi-center, prospective, and randomized controlled trial. Mobi-C, the investigational treatment, was compared to the control, anterior cervical discectomy and fusion (ACDF). The one-level trial included 245 randomized subjects, 164 Mobi-C and 81 ACDF subjects (a 2 to 1 ratio, respectively).

Trial success was based on a composite endpoint. A subject was considered a success at 84 months if all of the following criteria were met:

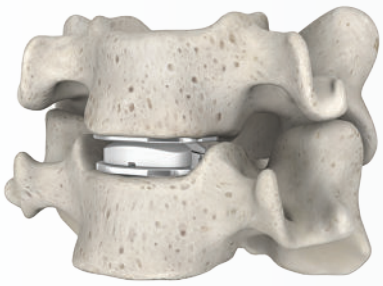
- Sufficient NDI improvement (≥ 15 points in subjects with baseline ≥ 30 points, or ≥ 50% improvement in subjects with baseline < 30 points)
- No subsequent surgery at the treated level
- No major complications defined as:
  - No radiographic failure
  - No neurologic deterioration
  - No adverse event determined to be a major complication

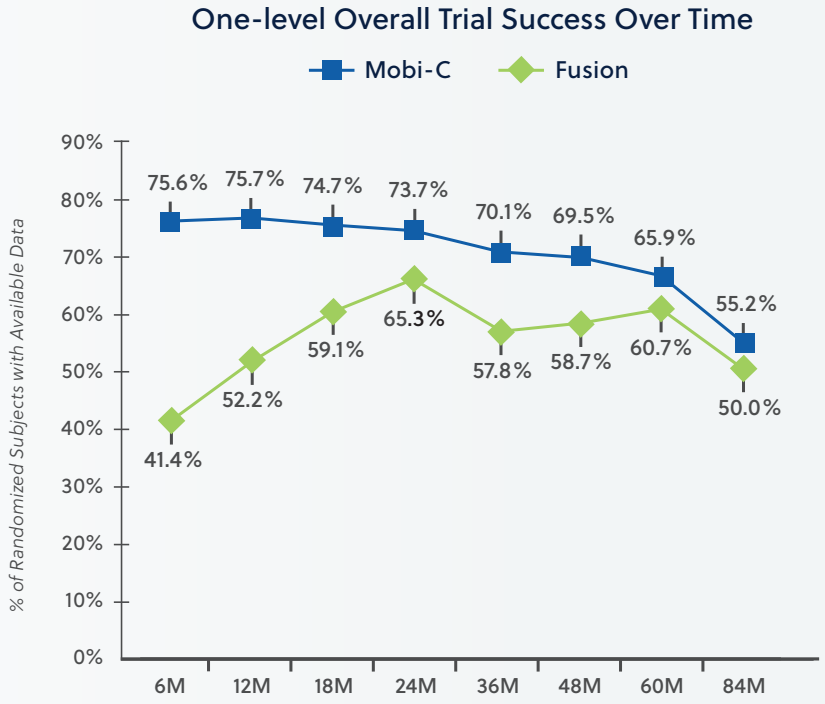
Results

Mobi-C established non-inferiority to ACDF at one-level.

Of all composite endpoint criteria, Mobi-C and ACDF subjects were most likely to fail the NDI success standard (23.5% and 22.2% of randomized subjects, respectively).

As shown in the chart, Mobi-C showed nominally higher success rates than ACDF at all timepoints.





COMPOSITE ENDPOINT COMPONENTS

NECK DISABILITY INDEX (NDI)

Success Criteria

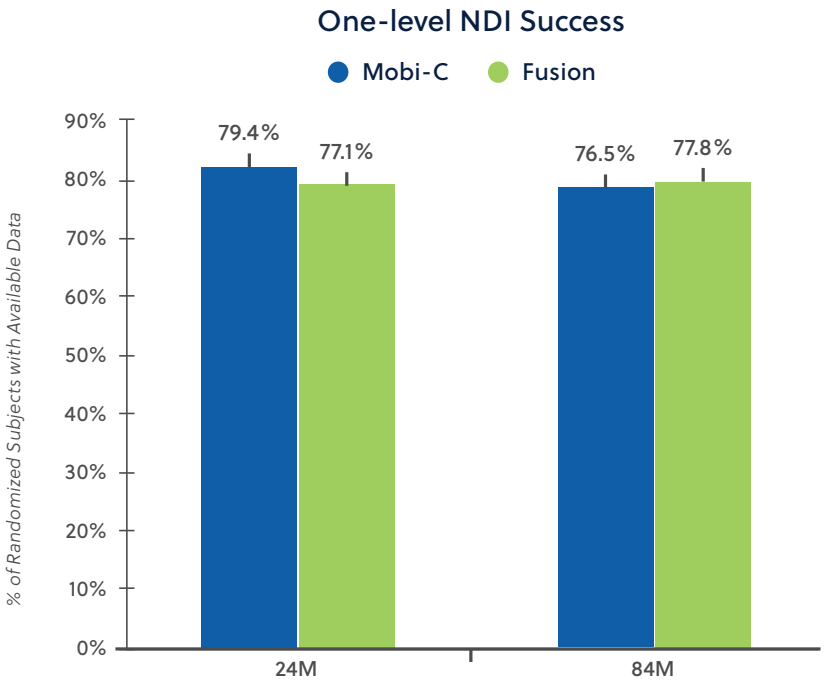
NDI is measured using a subject answered questionnaire, which assesses the effect of pain on daily life.

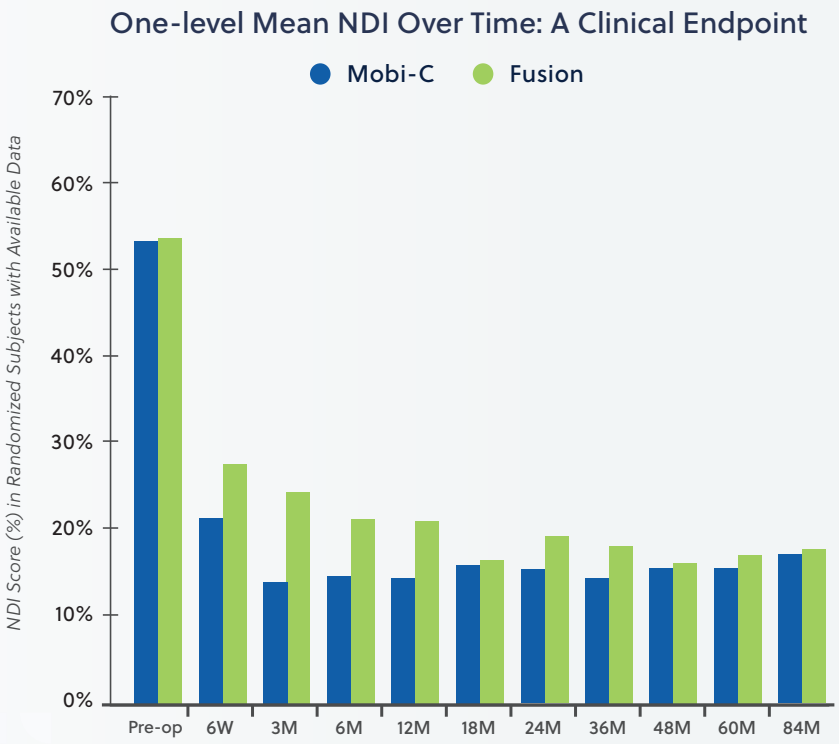
Each of the 10 assessed criteria[§] receives a score from 0 to 5; the highest score (50 points) represents the most disabled. The final score can be converted to a percentage.

[§] **NOTE**: NDI assessed criteria includes: pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation.

If baseline NDI:	NDI score improvement at 84 months must be:
≥ 30 points out of 50 points	≥ 15 points out of 50 points
< 30 points out of 50 points	≥ 50% improvement

Results





COMPOSITE ENDPOINT COMPONENTS *(continued)*

SUBSEQUENT SURGERIES AT THE TREATED LEVEL

Success Criteria

The subject was considered a success in terms of subsequent surgery if none of the following were necessary at the treated levels: removal, revision, reoperation, or supplemental fixation.

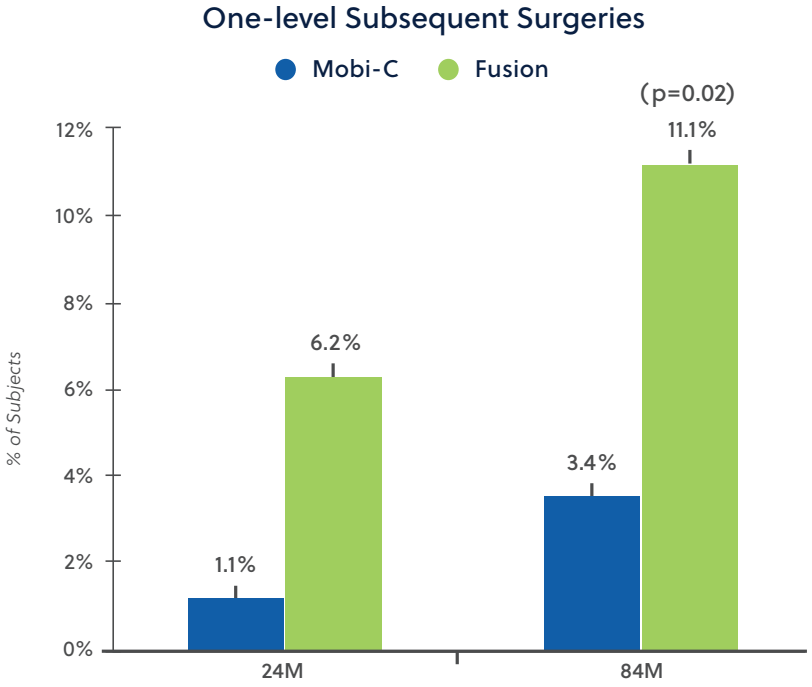
Results

Mobi-C had fewer subsequent surgeries on average compared to ACDF through 84 months.

As shown in the chart:

Mobi-C had fewer subsequent surgeries on average

compared to ACDF through 84 months.



NOTE: See page 18 for details on subsequent surgical interventions.

NEUROLOGIC STATUS

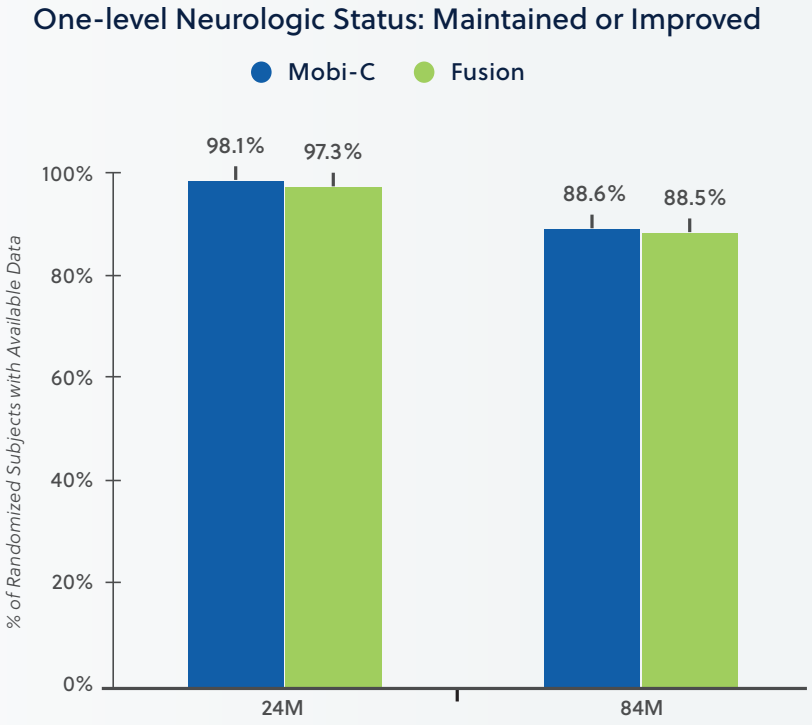
Success Criteria

Neurologic status was measured using motor, sensory-light touch, sensory-pin prick, and reflex assessments.

The surgery was considered a success if neurological status was maintained or improved.

Results

As expected, both treatment groups demonstrated similar percentages of subjects with stable or improved neurologic status at 84 months.



COMPOSITE ENDPOINT COMPONENTS *(continued)*

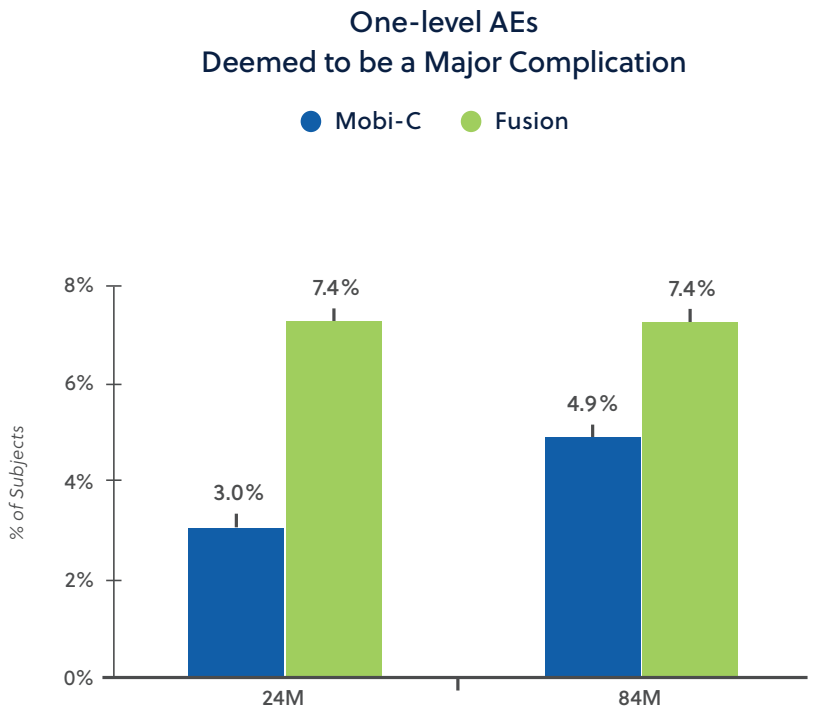
Results

ADVERSE EVENTS DETERMINED TO BE MAJOR COMPLICATIONS

Success Criteria

The Clinical Events Committee (CEC) independently determined if an adverse event (AE) was a major complication.

If so, the subject was considered a study failure.



COMMONLY REPORTED ADVERSE EVENTS

NOTE: Adverse event data includes the Mobi-C non-randomized training cases.

Commonly Reported AEs Through Month 84	Mobi-C	ACDF
Neck pain	55.3%	54.3%
Arm pain	39.1%	30.9%
Neck and arm pain	5.6%	8.6%
Headache	33.5%	35.8%
Back pain	34.6%	33.3%
Neurological - neck	26.8%	29.6%
Neurological - upper extremity sensory	49.7%	51.9%
Shoulder pain	30.2%	28.4%
Dysphagia	12.3%	21.0%
Dysphonia	1.7%	4.9%
Surgical wound infection	3.4%	1.2%
Nonunion (ACDF only)	–	6.2%
Heterotopic ossification at index levels (Mobi-C only)	6.1%	–
Unanticipated adverse device effect	0.0%	0.0%

SECONDARY ENDPOINTS

ADJACENT SEGMENT DEGENERATION

Success Criteria

Adjacent segment degeneration was assessed at the spinal segment immediately above and below the treated levels.

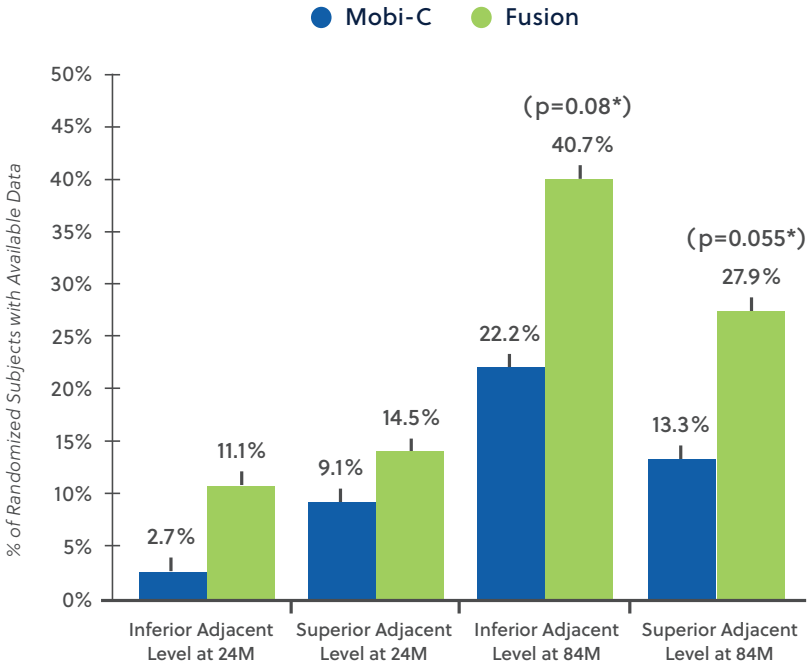
An independent core lab assessed degeneration using the Kellgren-Lawrence five point grading scale.*

An adjacent segment was counted as having degenerated if the segment worsened by 1 grade or more.

*NOTE: The Kellgren-Lawrence scale looks at radiographs for evidence of disc degenerative changes, including the absence or presence of osteophytes, disc narrowing, and endplate sclerosis. The five grades are: none (0), minimal (1), definite (2), moderate (3), or severe (4).

Results

Clinically Relevant§ Adjacent Segment Degeneration at One-level

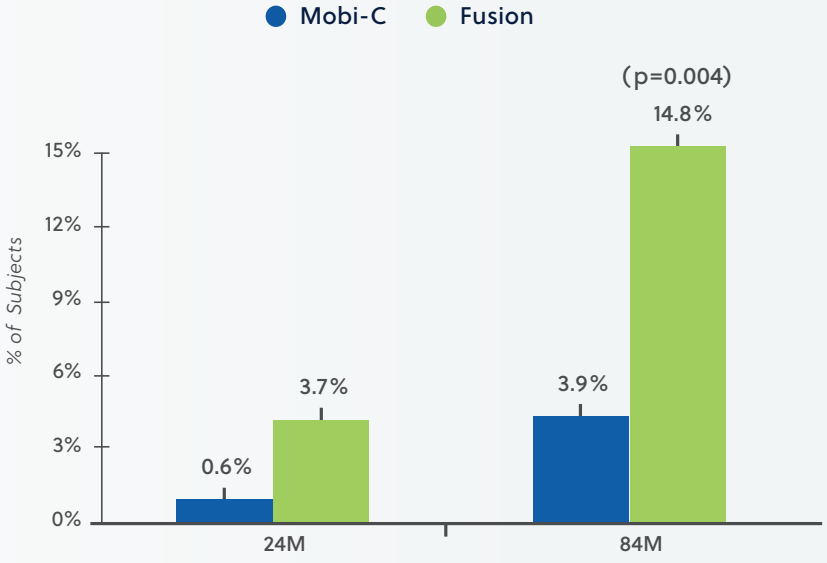


§NOTE: Grades 0, I, or II were defined as not being clinically relevant, while grades III or IV were defined as clinically relevant.

ADJACENT SEGMENT SURGERIES

Results

One-level Adjacent Segment Surgeries



SECONDARY ENDPOINTS
(continued)

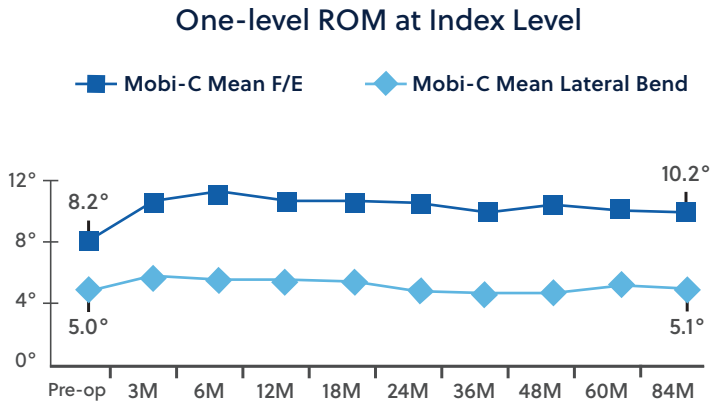
RADIOGRAPHIC FUSION RESULTS FOR THE ACDF SUBJECTS

		Fusion Status
IDE Study	6M	42/69 (60.9%)
	12M	58/70 (82.9%)
	24M	67/75 (89.3%)
	36M	57/63 (90.5%)
	48M	58/62 (93.5%)
PAS Study	60M	56/60 (93.3%)
	84M	47/49 (95.9%)

RANGE OF MOTION (ROM) RESULTS FOR THE MOBI-C SUBJECTS

Results

Randomized Mobi-C subjects demonstrated mean ROM at the index level of 10.2° for flexion-extension and 5.1° for lateral bending.†



†**NOTE**: Percent of randomized subjects with available data.

SUBJECT SATISFACTION

Success Measurement

Question	Possible Answers
1. How satisfied are you with the surgical treatment you received?	Very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied
2. Would you recommend the same treatment to a friend with the same condition?	Definitely yes, probably yes, probably no, or definitely no

Results*

Mobi-C	ACDF
Very Satisfied at 84M	
90.9%	77.8%
Definitely Yes at 84M	
89.4%	77.8%

***NOTE:** Randomized subjects with available data.

CLINICAL ENDPOINTS

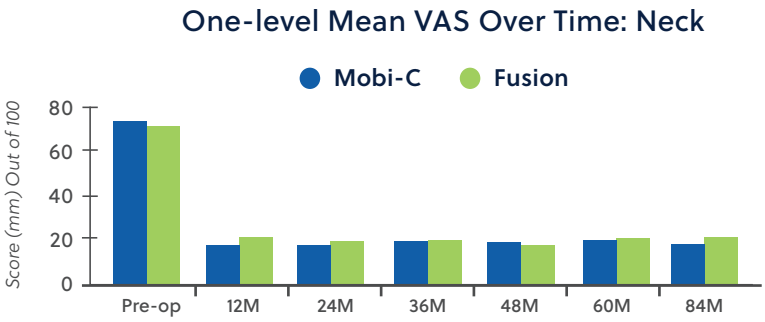
VISUAL ANALOG SCALE (VAS)

Success Criteria

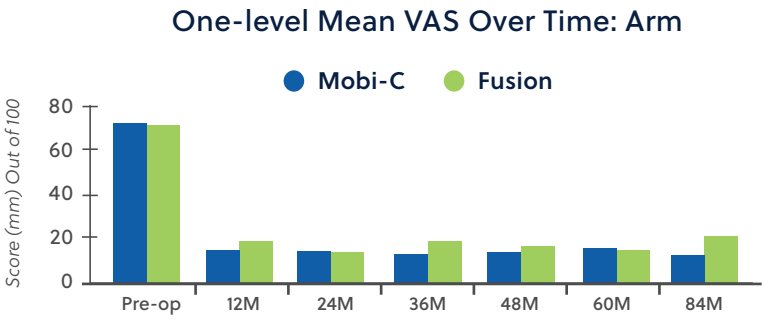
Subjects were asked to separately rate their neck, and left and right arm pain. The VAS score is measured on a 100 mm line with 'No Pain' on the left and 'Worst Possible Pain' on the right. The subject marks a point on the line that best represents his or her pain.

The distance is then measured in millimeters from 'No Pain' on the left to the subject's mark to create the VAS score.

Results[§]: Neck



Results[§‡]: Arm



[§]**NOTE:** Randomized subjects with available data.

[‡]**NOTE**: The combined arm score was based on the most symptomatic arm at baseline carried forward.

RETURN TO WORK

Success Measurement

The number of days from surgery until the subject was able to return to work was counted.

Results

Return to Work	Randomized Mobi-C	Randomized ACDF
Mean time (days)	29.3	36.8

HETEROTOPIC OSSIFICATION

Success Criteria

Mobi-C radiographs were assessed for heterotopic ossification using a classification system adapted from McAfee and Mehren.* HO was assessed by two independent radiologists with a third radiologist adjudicating in instances of disagreement.

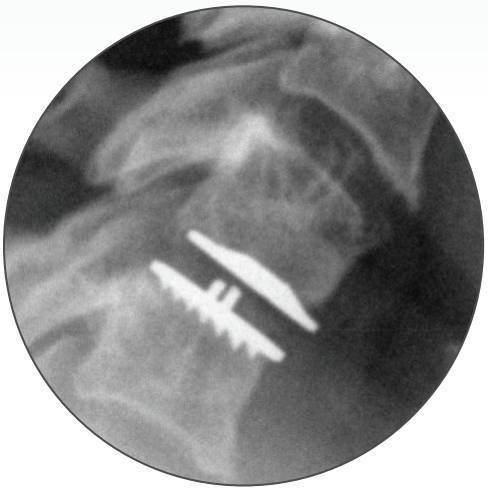
*__NOTE__: Grades 0, I, or II were defined as not being clinically relevant, while grades III or IV were defined as clinically relevant.

Results

HO at 84 Months *(Randomized subjects with available data)*		
Not Clinically Relevant	Grade 0/I/II	71.3%
Clinically Relevant	Grade III/IV	28.7%

NOTE: Although use of NSAIDs was not part of the post-operative regimen, 21.3% of randomized Mobi-C subjects reported use of NSAIDs between discharge to week 6 and 25.6% between week 6 and month 3.

CONCLUSION



Mobi-C demonstrated:

At 84 months

Nominally fewer subsequent surgeries at the index level compared to ACDF.

Lower average rates of adverse events determined to be major complications compared to ACDF.

Lower average rates of adjacent level degeneration compared to ACDF.

A mean **ROM in F/E of 10.2°** at the index level.

A mean return to work time 7.5 days sooner than ACDF.

> THIS CLINICAL TRIAL ESTABLISHED THAT MOBI-C AT ONE-LEVEL IS NON-INFERIOR TO ACDF AT 84 MONTHS FOR OVERALL TRIAL SUCCESS.

Conclusion:

Mobi-C is a safe and effective

surgical option at one-level in the cervical spine from C3-C7 in indicated subjects.

NOTE: Please refer to ZimVie.com for complete study results.

APPENDIX

TRIAL DESIGN

The Mobi-C IDE trial was a multi-center, prospective, and randomized controlled trial. The trial tested Mobi-C for non-inferiority to the current standard of care, ACDF.

The primary trial endpoint analysis was based upon 24 month results. The IDE trial consisted of one-level and two-level treatment arms conducted simultaneously under the same FDA-approved protocol. *(This document focuses on the one-level treatment arm.)*

Investigational Treatment:

- Anterior discectomy followed by insertion of Mobi-C at one-level.

Control Treatment:

- Anterior discectomy followed by insertion of allograft bone at one-level and an anterior cervical plate. *(DePuy Spine Slim-Loc® or the Medtronic Atlantis® or Atlantis Vision®).*

Randomization Scheme:

- 2 to 1 ratio, Mobi-C to ACDF respectively

245 Randomized Subjects:

- 164 Mobi-C
- 81 ACDF

The trial allowed for 1 nonrandomized training case per site and resulted in 15 nonrandomized Mobi-C subjects in the one-level arm.

24 Investigative Sites

Post-operative follow-up for the IDE trial:

- 6 weeks, 3 months, 6 months, 12 months, 18 months, 24 months, 36 months, and 48 months

Post-operative follow-up for the Post-Approval Studies:

- 60 months and 84 months

SUBJECT ACCOUNTING

Subject Accounting (One-level)	Randomized Mobi-C	Randomized ACDF
Subjects Treated	164	81
Subjects with Data at 84 Months	121	52
Expected Number of Subjects at 84 Months	151	70
Follow-up Rate at 84 Months	80.1% of randomized Mobi-C and 74.3% ACDF subjects presented some data at 84 months.	

SUBJECT DEMOGRAPHICS

Demographics were similar for both treatment groups. A breakdown of the data for all randomized subjects is provided in the table below for comparison.

Demographics at Baseline (One-level)	Randomized Mobi-C	Randomized ACDF	P-value
Male	47.6%	44.4%	0.6843*
Female	52.4%	55.6%	
Mean age (years)	43.3	44.0	0.5657**
Mean BMI (kg/M²)	27.3	27.4	0.8460**
Ethnicity - Hispanic or Latino - Not Hispanic or Latino	 1.8% 98.2%	 2.5% 97.5%	0.6667*
Race - Caucasian - Black/African American - Asian - American Indian/ Alaskan Native - Other	 92.7% 2.4% 1.8% 1.2% 1.2%	 85.2% 12.3% 1.2% 1.2% 0.0%	0.0710*
Work status - Able to work	 65.9%	 56.8%	0.3264*
Driving Status - Able to drive	 94.5%	 97.5%	0.5035*
Smoke more than one pack per day - Yes - No	 0% 100%	 0% 100%	>0.9999*

*Fisher's Exact test used to compare treatments.
** An unpaired test used to compare treatment groups.

SURGERY DATA

Surgery Data (One-level)	Randomized Mobi-C	Randomized ACDF
Mean Est. Blood Loss (mls)	45.0	48.1
Mean Length of Hospital Stay (days)	2.0	2.1
Mean Operative Time (hrs)	1.5	1.3
Levels Treated (One-level)		
C3-C4	0.6%	4.9%
C4-C5	6.7%	2.5%
C5-C6	56.1%	56.8%
C6-C7	36.6%	35.8%

INCLUSION CRITERIA

Enrollment in the one level Mobi-C study arm was limited to subjects who met the following inclusion criteria.

1. Age 18-69 years.
2. Diagnosis of radiculopathy or myeloradiculopathy of the cervical spine, with pain, paresthesias or paralysis in a specific nerve root distribution C3 through C7, including at least one of the following:
   - Neck and/or arm pain (at least 30 mm on the 100 mm visual analogue scale [VAS] scale).
   - Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale.
   - Abnormal sensation including hyperesthesia or hypoesthesia; and/or
   - Abnormal reflexes.
3. Symptomatic at one-level from C3 to C7.
4. Radiographically determined pathology at the level to be treated correlating to primary symptoms including at least one of the following:
   - Decreased disc height on radiography, computed tomography (CT), or magnetic resonance imaging (MRI) in comparison to a normal adjacent disc.
   - Degenerative spondylosis on CT or MRI.
   - Disc herniation on CT or MRI.
5. NDI Score of ≥ 15/50 or ≥ 30%.
6. Unresponsive to nonoperative, conservative treatment (rest, heat, electrotherapy, physical therapy, chiropractic care and/or analgesics) for:
   - Approximately six weeks from radiculopathy or myeloradiculopathy symptom onset; or
   - Have the presence of progressive symptoms or signs of nerve root/spinal cord compression despite continued nonoperative conservative treatment.
7. Appropriate for treatment using an anterior surgical approach, including having no prior surgery at the operative level and no prior cervical fusion procedure at any level.
8. Reported to be medically cleared for surgery.
9. Reported to be physically and mentally able and willing to comply with the Protocol, including the ability to read and complete required forms and willing and able to adhere to the scheduled follow-up visits and requirements of the Protocol.
10. Written informed consent provided by subject or subject's legally authorized representative.
11. Willingness to discontinue all use of non-steroidal anti-inflammatory drugs (NSAIDs) from one week before surgery until 3 months after surgery.

EXCLUSION CRITERIA

Subjects were **NOT** permitted to enroll in the Mobi-C study if they met any of the following exclusion criteria.

1. Reported to have an active systemic infection or infection at the operative site.
2. Reported to have a history of or anticipated treatment for active systemic infection, including HIV or Hepatitis C.
3. More than one immobile vertebral level between C1 to C7 from any cause including but not limited to congenital abnormalities and osteoarthritic "spontaneous" fusions.
4. Previous trauma to the C3 to C7 levels resulting in significant bony or discoligamentous cervical spine injury.
5. Reported to have had any prior spine surgery at the operative level.
6. Reported to have had a prior cervical fusion procedure at any level.
7. Axial neck pain in the absence of other symptoms of radiculopathy or myeloradiculopathy justifying the need for surgical intervention.
8. Disc height less than 3 mm as measured from the center of the disc in a neutral position and disc height less than 20% of the anterior-posterior width of the inferior vertebral body.
9. Radiographic confirmation of severe facet joint disease or degeneration.
10. Reported to have an increased risk of osteoporosis/osteopenia. This was defined as a T-score less than (worse than) -1.5 on a previous or required Hologic Sahara or dual energy X-ray absorptiometry (DEXA) scan.

    All subjects that met one or more of the following were to undergo a Hologic Sahara or DEXA scan as part of the study enrollment procedures:

    - Females 50 years and older;
    - Females who were post-menopausal or post-hysterectomy with oophorectomy;
    - Subjects taking bisphosphonate medication for the treatment of osteoporosis; and/or
    - Subjects with history of chronic use of high dose steroids. High dose steroid use is defined as part of Exclusion Criterion #22.

    All females less than 50 years of age, and all males, who had not had a Hologic Sahara or DEXA scan within six months of surgery, were screened for osteoporosis using the Simple Calculated Osteoporosis Risk Estimation (SCORE) questionnaire.

    Subjects whose screening suggests increased risk (SCORE greater than 6) were to undergo a Hologic Sahara or DEXA scan as part of the study enrollment procedures.

EXCLUSION CRITERIA *(continued)*

11. Reported to have Paget's disease, osteomalacia or any other metabolic bone disease other than osteoporosis, (which is addressed on the previous page).
12. Reported active malignancy that included a history of any invasive malignancy (except non-melanoma skin cancer), unless the subject had been treated with curative intent and there had been no clinical signs or symptoms of the malignancy for at least five years.
13. Symptomatic DDD or significant cervical spondylosis at more than two-levels.
14. Spondylolysis.
15. Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by:
    - Translation ≥ 3.5 mm, and/or
    - Greater than 11° angular difference to that of either adjacent level.
16. Known allergy to cobalt, chromium, molybdenum or polyethylene.
17. Segmental angulation of greater than 11° at treatment or adjacent levels.
18. Reported pregnancy or nursing at time of enrollment, or with plans to become pregnant within the next three years.
19. Reported to have rheumatoid arthritis, lupus, or other autoimmune disease that affect the musculoskeletal system.
20. Congenital bony and/or spinal cord abnormalities that affect spinal stability.
21. Reported to have diseases or conditions that would preclude accurate clinical evaluation (e.g. neuromuscular disorders).
22. Reported concomitant conditions requiring daily, high-dose oral and/or inhaled steroids. High dose steroid use is defined as:
    - Daily, chronic use of oral steroids of 5 mg/day or greater.
    - Daily, chronic use of inhaled corticosteroids (at least twice per day).
    - Use of short-term (less than 10 days) oral steroids at a daily dose greater than 40 mg within one month of the study procedure.
23. Reported to have current or recent history of substance abuse (alcoholism and/or narcotic addiction) requiring intervention.
24. Clinically Severe Obesity, as defined by National Institutes of Health (NIH) Clinical Guidelines Body Mass Index (BMI > 40).
25. Reported use of any other investigational drug or medical device within the last 30 days prior to surgery.
26. Evidence of symptomatic moderate to severe facet joint degeneration or disease where the investigator felt this was a major contributor to the subject's pain as diagnosed by injection and imaging.

EXCLUSION CRITERIA *(continued)*

27. Reported to be taking medications known to potentially interfere with bone/soft tissue healing (e.g., high-dose oral and/or inhaled steroids, immunosuppressant medication, chemotherapeutic agents).
28. Reported to have pending personal litigation relating to spinal injury (worker's compensation was not an exclusion).
29. Reported to have a current history of heavy smoking (more than one pack of cigarettes per day).
30. Anticipated or potential relocation greater than 50 miles that may interfere with completion of follow-up examinations.
31. Reported to have mental illness or belonged to a vulnerable population, as determined by the investigator (e.g., prisoner or developmentally disabled), that would compromise ability to provide informed consent or compliance with follow-up requirements.
32. Reported to have an uncontrolled seizure disorder.
33. Reported to have taken epidural steroids within 14 days prior to surgery.

COMMONLY REPORTED ADVERSE EVENTS

Commonly Reported AEs Through Month 84	Mobi-C	ACDF
Neck pain	55.3%	54.3%
Arm pain	39.1%	30.9%
Neck and arm pain	5.6%	8.6%
Headache	33.5%	35.8%
Back pain	34.6%	33.3%
Neurological - neck	26.8%	29.6%
Neurological - upper extremity sensory	49.7%	51.9%
Shoulder pain	30.2%	28.4%
Dysphagia	12.3%	21.0%
Dysphonia	1.7%	4.9%
Surgical wound infection	3.4%	1.2%
Nonunion (ACDF only)	–	6.2%
Heterotopic ossification at index levels (Mobi-C only)	6.1%	–
Unanticipated adverse device effect	0.0%	0.0%

NOTE: Adverse event data includes the Mobi-C non-randomized training cases.

APPENDIX *(continued)*

SUBSEQUENT SURGICAL INTERVENTIONS AT THE INDEX LEVEL – PROCEDURE DETAILS

Treatment Group	Associated AE(s)	Subsequent Surgical Intervention Detail
Mobi-C (n=164)	**Right C4-C5 radiculopathies**	Reoperation - laparoscopic right C4-C5 cervical laminectomy
	Radiculopathy and spondylosis	Removal of device and conversion to ACDF at index level
	Recurrent neck pain	Removal of device and conversion to ACDF at the index level and one additional level
	Device malpositioning	Removal of device and conversion to ACDF at the index level
	Cervical discogenic pain	Removal of device and conversion to ACDF at the index level and at the adjacent level below
	C5-C6 neck pain and post-laminectomy syndrome	Removal of device and conversion to ACDF at the index level

Treatment Group	Associated AE(s)	Subsequent Surgical Intervention Detail
ACDF (n=81)	**Foraminal stenosis and pseudoarthrosis at the index level**	Supplemental fixation in the form of posterior instrumentation at index level
	Failure of fusion	Removal of ACDF hardware and repeat ACDF at the index level
	Misplaced screw	Removal of ACDF hardware and addition of ACDF at the adjacent level below
	Pseudarthrosis at the index level and herniated disc at the adjacent level above	Removal of ACDF hardware and repeat ACDF at the index level and addition of ACDF at the adjacent level above and addition of ACDF two levels above (three level ACDF)
	Pseudarthrosis at the index level and radiculopathy	Supplemental fixation in the form of posterior fusion instrumentation at the index level
	Pseudoarthrosis at the index level	Supplemental fixation in the form of posterior fusion instrumentation at the index level
	Herniated discs at adjacent levels	Removal of ACDF hardware and fusion at inferior adjacent levels
	Stenosis - cervical spine	Removal of ACDF hardware and addition of ACDF at the adjacent level above
	Radial postero-lateral fissuring at adjacent level	Removal of ACDF hardware and total disc arthroplasty (ProDisc) at adjacent level

APPENDIX *(continued)*

INDICATIONS

Visit ZimVie.com for complete clinical study results including indications, contraindications, warnings, precautions, and risks.

The Mobi-C® Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level 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 Prosthesis 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 Prosthesis.

Disclaimer

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations.

Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications contraindications, precautions, warnings and adverse effects.

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The clinical data presented is from use of the Mobi-C US implant design which has minor design differences compared to the Mobi-C in other countries.

For more information visit ZimVie.com

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