COUSIN SURGERY

CERVICALE



C DISC

Clinical Studies

Comparison of post-operative quality of life and cervical kinematics following replacement with C Disc prosthesis & Mobi-C prosthesis [1]

2 year follow-up

Study design

Comparative prospective study evaluating the clinical and radiographic outcomes of total cervical disc replacement.
The new C DISC prosthesis, designed with a dual-radius core reproducing physiological cervical kinematics, was compared to the reference prosthesis Mobi-C.

The objective

The objective was to compare the clinical and radiographic outcomes of the C DISC and Mobi-C cervical prostheses, particularly regarding:

- Reduction of cervical and brachial pain
- Improvement in function and quality of life
- Preservation of range of motion at the operated level

Methods

Two matched cohorts, for a total of 77 patients, were included in the study:

29 patients implanted with C DISC
48 patients implanted with Mobi-C
Patients underwent surgery on one or two cervical levels. Clinical evaluation was performed preoperatively and then at 6 weeks, 6 months, 1 year, and 2 years postoperatively.

Results

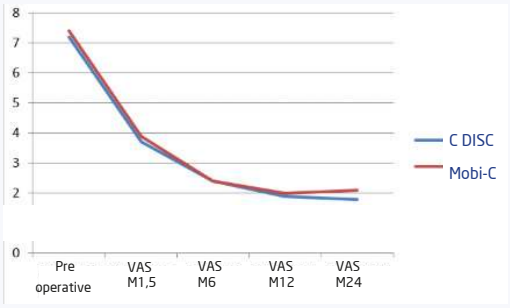
Cervical and brachial pain

A significant reduction in pain (measured using the VAS - Visual Analog Scale) was observed in both groups at 2 years ($p < 0.00001$):

Cervical pain (VAS):

7,2 ➡ 1,8 in the C DISC group

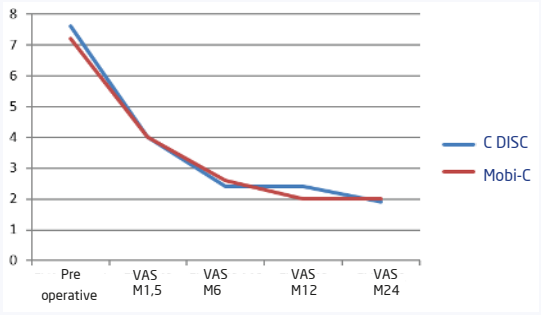
7,4 ➡ 2,1 in the Mobi-C group



Brachial pain (VAS):

7,6 ➡ 1,9 in the C DISC group

7,2 ➡ 2,0 in the Mobi-C group

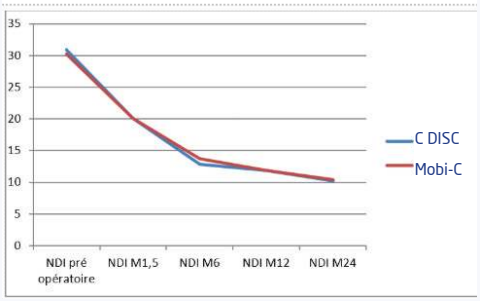


Neck Disability Index (NDI) : Neck Disability Index

The NDI score showed improvement in both groups, with no significant difference between the preoperative and 2-year postoperative cervical disability scores ($p = 0.00001$):

30,9 ➡ 10,2 in the C DISC group

30,2 ➡ 10,4 in the Mobi-C group



Quality of life (SF-12)

Quality of life scores (PCS: Physical Component Summary and MCS: Mental Component Summary) significantly improved at 2 years in both groups ($p < 0.001$).

C DISC
PCS : 37,8 ➡ 47,1

MCS : 35,0 ➡ 47,5

Mobi-C
PCS : 36,9 ➡ 47,5

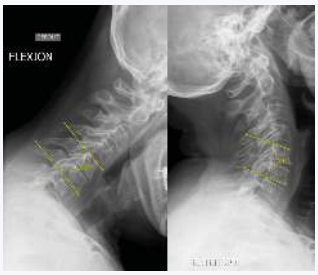
MCS : 34,4 ➡ 47,8

Radiographic results at 2 years

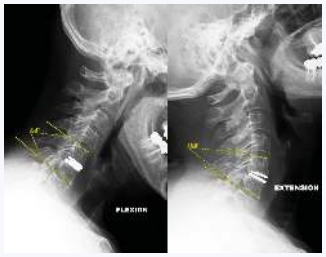
The mean preoperative global cervical lordosis (C2-C7) was -8.5° in the C DISC group and -10.8° in the Mobi-C group.
At 2 years, a significant increase was observed in both groups ($p < 0.05$), reaching -16.1° and -21.1°, respectively.

Flexion/extension range of motion (ROM) at the operated level significantly increased in both groups at 2 years ($p < 0.05$):

C DISC 8,2° ➡ 11,1°



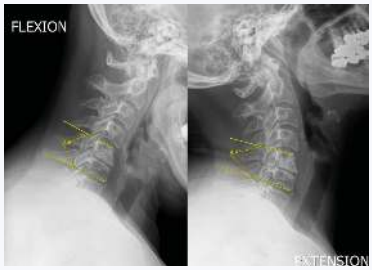
Preoperative ROM C DISC



Postoperative C DISC

Higher ROM values were observed in the Mobi-C group, with 3.4° greater extension compared to C DISC.

Mobi-C 8,5° ➡ 13,7°



Preoperative ROM Mobi-C



Postoperative ROM Mobi-C

C DISC demonstrated significant improvement in pain, function, and quality of life at 2 years. Compared with Mobi-C, flexion-extension ROM was lower, consistent with the biomechanical principle of the C DISC prosthesis, designed to restore controlled mobility while reducing stress on the posterior facet joints.

(1) Etude :

Comparison of quality of life and kinematics after cervical disc replacement with two non-constrained prostheses N. Giordano-Orsini1, Y.P. Charles1, Y. Ntilikina1, N. Tuzin2, F. Lavaste3, J.-P. Steib1 Hôpitaux Universitaires de Strasbourg, France

PMCF Strasbourg Study: 2-Year Follow-Up Results

7 year follow-up

Design of the study

The C DISC study is a post-market clinical follow-up (PMCF) study designed to evaluate the safety and performance of the implant after CE marking.

It is an observational, ambispective, non-interventional, single-center long-term study (7 years) currently ongoing.

Methodology

Patients are evaluated preoperatively, at the time of surgery, and during several postoperative follow-up visits at:
1-3 months, 6 months, 1 year, 2 years, 5 years et 7 years. Patients underwent surgery on one, two, three, or more cervical levels.

Objectives

Primary objectives

› Performance

To demonstrate the effectiveness of the C DISC prosthesis in reducing patient disability at 2 years after implantation through improvement of the NDI (Neck Disability Index) score.

› Safety

To evaluate the safety of the C DISC prosthesis through the rate of surgical reinterventions (removal, revision, supplemental fixation, or additional surgery) at the treated levels within 7 years following implantation.

Secondary objectives

Secondary objectives assess the long-term clinical and functional performance of the device as well as its safety, including:
Evolution of disability, cervical and brachial pain, Quality of life and patient satisfaction, Cervical mobility and stability, Sagittal balance ,Adjacent segment degeneration, Medication consumption, Professional and sports activity status, Surgical reinterventions, Adverse events Heterotopic ossification, Potential device failures

Intermediate Results

Improvement in Neck Disability (NDI)

The mean NDI score improved from 54.5% ± 20.2 (Severe Disability) to 33.6% ± 20.8 (Moderate Disability) at 2 years.
Improvement was observed regardless of the number of treated levels (1 to ≥3 levels) and appeared as early as 1 to 3 months after surgery.

Pain reduction

A significant reduction in cervical and brachial pain was observed at 2 years:

› Cervical pain (VAS): 67.1 mm ± 24.9 ➡ 30.5 mm ± 24.8

Upper limb pain: approximately 50% reduction

Improvement in Quality of Life

SF-36 scores showed significant improvement at 2 years:

Physical score: 37,5 ±14.4 ➡ 54,5 ± 23.4

Mental score: 37,5 ➡57,8

Radiological Results (ROM - Range of Motion)

Radiographic analyses showed that:

The C DISC prosthesis is associated with a slight increase in cervical lordosis, a transient decrease in overall mobility followed by recovery at 6 months, and an increase in mobility at the operated level remaining stable over time.

Cervical lordosis (C2-C7)

-11.90° ±9.3 ➡-14.5°± 9.5 (post-op)

Global mobility (C2-C7)

41.7° ± 13.8 ➡35.3°±11.8 (post-op) ➡ 41.0° ± 11.4 (2 years)

Segmental mobility (C5-C6)

11.3° ±5.6 ➡ 12.6°± 5.6 (pre-op, 2 years)

Heterotopic Ossification

The incidence remained low:

3 patients (2.8%) with complete fusion of the treated segment.

Safety

Among the 107 patients followed, no reinterventions were performed either at the treated level or at adjacent levels.

No implant migration, subsidence, or implant failure was reported at this stage.

Very low rate of Serious Adverse Events (SAEs):
2 SAEs unrelated to the device (1.9%)
1 event probably related to the procedure (0.9%): excised scar granuloma

Conclusion

- Both clinical studies demonstrated significant improvement in 2-year outcomes (cervical VAS: 7.2 to 1.8; brachial VAS: 7.6 to 1.9; NDI: 30.9 to 10.2), associated with improved quality of life.
- Global cervical mobility transiently decreased immediately after surgery, then recovered to values close to preoperative levels at 6 months and remained stable over time. Increased mobility was observed at the operated level within the framework of controlled mobility related to the biomechanical characteristics of the prosthesis.
- No reintervention, migration, or implant failure was reported at 2 years, with a low incidence of adverse events.

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