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ORIGINAL ARTICLE

Clinical and radiological evaluation of cervical disc arthroplasty with 5-year follow-up: a prospective study of 384 patients

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Abstract

Background Cervical total disc replacement was developed to avoid known complications of cervical fusion. The purpose of this paper was to provide 5-year follow-up results of an ongoing prospective study after implantation of cervical disc prosthesis.

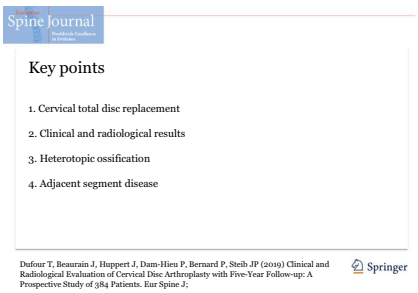
Methods Three hundred and eighty-four patients were treated using Mobi-C cervical disc (Zimmer Biomet, Troyes, France) and included in a prospective multicentre study. Routine clinical and radiological examinations were reported preoperatively and postoperatively with up to 5-year follow-up. Complications and revision surgeries were also explored.

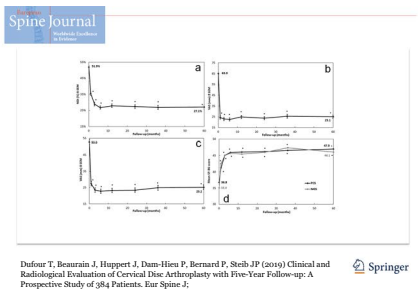
Results Results at 5 years showed significant improvement in all clinical outcomes (NDI, VAS for arm and neck pain, SF-36 PCS and MCS). Motion at index level increased significantly from 6.0° preoperatively to 8.0°, and 72.1% of the implanted segments were still mobile (referring to threshold of ROM > 3°). Proximal and distal adjacent discs showed no significant change in average motion 5 years after surgery compared to baseline. Ossification resulting in complete fusion was observed in 16.4% of the implanted segments. Distal and proximal adjacent disc degeneration occurred in 42.2% and 39.1% of patients, respectively. Complications rate was 8.9%, and 1.5% of the patients had reoperation at the index level. Surgery rate of adjacent discs was 2.9%. An increased percentage of working patients and a decrease in medication consumption were observed. At 5 years, 93.3% patients were satisfied regarding the overall outcome.

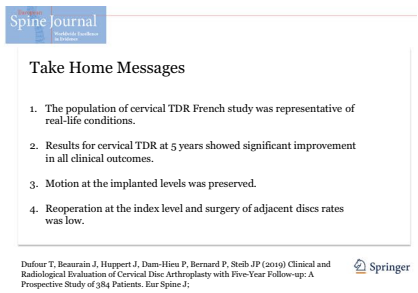
Conclusions In this study, favourable 5-year follow-up clinical and radiological outcomes were observed with a low rate of adjacent level surgery.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.







Keywords Cervical total disc replacement · Mobi-C · Clinical results · Radiological results · Heterotopic ossification · Adjacent segment disease

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Extended author information available on the last page of the article

Introduction

After failure of conservative treatment in patients with cervical degenerative disc disease, anterior cervical discectomy and fusion (ACDF) was the traditional standard surgical procedure [1–3]. Although ACDF typically relieves pain significantly, pseudarthrosis occurs in some patients, and the elimination of motion at the index level in the others may result in adjacent level degeneration [4–6].

Cervical total disc replacement (CTDR) was developed as an alternative treatment, in order to avoid drawbacks of ACDF by replacing the degenerative discs and preserving physiological cervical function [7–9]. A large number of arthroplasty devices have been developed [7, 10]. Previous published studies have established that CTDR provides pain relief and functional improvements similar or superior to those of ACDF with lower rates of adjacent segment degeneration [11–13].

The present study aimed to investigate the efficacy and safety of a cervical disc prosthesis (Mobi-C, Zimmer Biomet, Troyes, France) with 5-year follow-up (FU). The 2-year intermediate results already published [14, 15] demonstrated encouraging clinical and radiological performance and preservation of the status of the adjacent levels.

Materials and methods

Study design

Between November 2004 and August 2009, 384 patients had surgery with the Mobi-C cervical disc prosthesis (Fig. 1) in this observational, prospective and multicentre study involving eight centres in France. The study will be pursued until 10 years of FU is attained.

The indication was degenerative cervical discopathy at one or more levels of the cervical spine leading to chronic and disabling radiculopathy, spondylotic and discogenic myelopathy, or both, resistant to well-conducted medical treatment. Diagnosis was confirmed by imaging (CT, MRI and X-rays).

Exclusion criteria were osteoporosis, non-adherence to the protocol, metabolic bone disease, congenital or post-traumatic deformity, infection, neoplasia, instability of the interbody space or cervical canal stenosis (< 12 mm). Previous cervical spine surgery (including surgery at the index level), work-related injury and learning curve cases were not exclusion criteria.

Outcomes

Each patient was followed up prospectively with preoperative and regular post-operative evaluations for 5 years (1; 3; 6; 12; 24; 36; and 60 months). Clinical outcomes were determined by a self-assessment questionnaire that included the Neck Disability Index (NDI, 0–100%), visual analogue scale (VAS, 0–100 mm) arm and neck pain scores and Medical Outcomes Survey Short Form-36 (SF-36) summarized by the physical (PCS) and mental (MCS) component scores. Standardized questions relating to patient satisfaction, medication consumption and employment status were likewise completed at each FU stage of the investigation. Study did not plan medication guideline for pain neither in HO prevention. Adverse events were monitored and

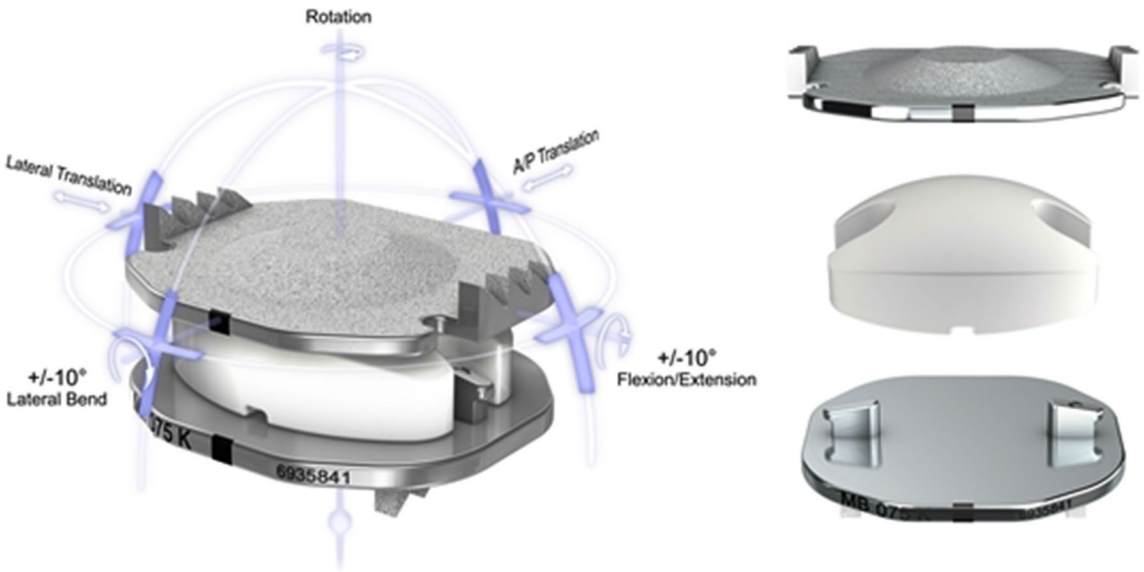

Fig. 1 Mobi-C® cervical disc, level of mobility and components including proximal and distal endplate and central polyethylene core

recorded. Additional surgeries at index or adjacent levels were reported. Dynamic radiographs were obtained at each visit to assess the range of motion (ROM) at index and adjacent levels with the SpineView software (Surgiview, France). The extent of heterotopic ossifications (HO) was graded according to Mehren–McAfee classification [16, 17] by a senior spine surgeon who was blinded to the clinical status. Adjacent segment degeneration was scored, by two investigators, according to Kellgren–Lawrence grading system (grades 0–4) [18] using the figures and legends of the atlas of standard radiographs, in which grade 0 or 1 denotes no or minimal anterior osteophytosis, grade 2 denotes definite anterior osteophytosis with possible narrowing of disc space and some sclerosis of vertebral plates, and grades 3 and 4 indicate moderate narrowing of disc space with definite sclerosis of vertebral plates and osteophytosis or severe narrowing of disc space with sclerosis of vertebral plates and multiple large osteophytes [19].

Statistical analysis

All available data were taken into account. The paired t test was used for comparisons between preoperative and post-operative continuous data. The McNemar's test was used for comparison of categorical data. The significance level was $p < 0.05$. Statistical analyses were conducted using the statistical program R (version 3.3.2; https://www.R-project.org).

Results

Three hundred and eighty-four patients received 535 prostheses and agreed to enroll in the FU phase. Demographic information, preoperative status and surgical data are reported in Table 1. Overall, 85.6% (328/383) of the patients had no previous cervical surgery, and 12.0% (46/383) had a previous fusion at index and/or adjacent and/or distant levels. Taking into account premature withdrawals from the study, at 5 years, the expected number of patients was 371, and FU rate was 80.6% (299/371). Figure 2 illustrates dynamic 5-year post-operative X-rays (flexion/extension) for one- and two-level procedures.

Statistically significant improvements in all clinical outcomes were noted at all FU examinations (Fig. 3). Disability assessed by NDI and VAS for arm and neck pain decreased significantly from baseline to each FU. The mean NDI improvement at 5-year FU was 24.2% (95% CI 21.8% to 26.5%, $p < 0.001$), VAS arm pain improved 38.7 mm (95% CI 34.6–42.8 mm, $p < 0.001$), and VAS neck pain improved 26.6 mm (95% CI 23.0–30.2 mm, $p < 0.001$). SF-36 score from baseline to 5 years improved with increases of 9.7 (95% CI 8.4–11.0, $p < 0.001$) and 10.9 (95% CI 9.1–12.6, $p < 0.001$) for PCS and MCS, respectively.

Table 1 Demographic information, preoperative status and surgical data

	Mean ± SD or *n* or %	Range	*n*
Age (years)	44.8 ± 8.1	23–73	384
Gender	169 males		384
	215 females		
Duration of symptoms	< 1 year: 52.4%		368
	1–4 years: 29.1%		
	> 4 years: 18.5%		
Number of operated level	1 level: 66.9%		384
	2 levels: 28.1%		
	3 levels: 3.6%		
	4 levels: 1.3%		
Operated level	C3–C4: 2.4%		535
	C4–C5: 12.2%		
	C5–C6: 43.7%		
	C6–C7: 40.8%		
	C7–D1: 0.9%		
Operative duration (min)	101.5 ± 41	40–283	372

Mean preoperative and post-operative ROM are presented in Fig. 4. At 5-year FU, motion at the index levels was significantly increased (mean ROM = 8.0° vs. 6.0° preoperatively) and 72.1% of the implanted segments were still mobile, with mobility defined as flexion–extension ROM > 3°. Adjacent discs showed no significant change in ROM compared to baseline and the large majority exhibited only mild or no degeneration. The incidence of adjacent segment degeneration is presented in Table 2. Overall, 39.1% (91/233) and 42.2% (54/128) of proximal and distal adjacent discs, respectively, showed some increase in degeneration 5 years after surgery. Grade 4 HO occurred in 16.4% (48/406) of the implanted segments at 5 years, grade 3 HO in 6.8% (20/406), grade 2 in 39.4% (115/406), grade 1 in 14.4% (42/406) and grade 0 in 22.9% (67/406).

Amongst all the 384 patients enrolled, 34 patients (8.9%) experienced 41 adverse events (device/surgery-related, with/without reoperation) during their FU. There was no expulsion of the device, no device failure and no vertebral body fracture. Reoperation for device removal or repositioning was performed in 1.5% of the patients (6/384). In addition, 11 patients (2.9%) were surgically treated for adjacent disc disease (ADD): four were considered as development of a new symptomatic ADD, and the other seven had already an ADD considered as minor before the index surgery.

With regard to medication consumption, the rate of patients using analgesics decreased significantly from 83.2% (297/357) before surgery to 28.6% (76/266) at 5 years. Professional status was significantly upgraded at 5 years with

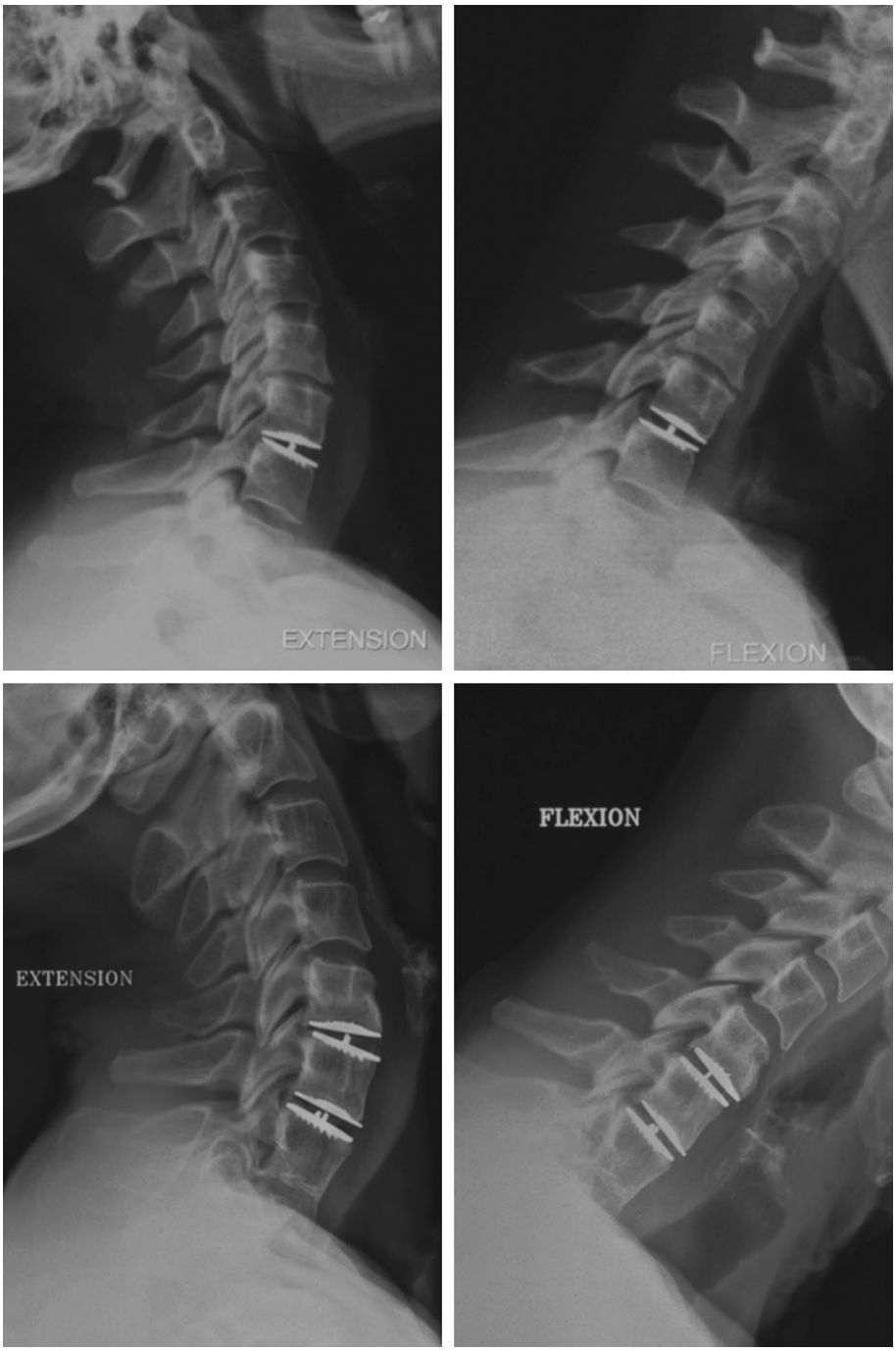

Fig. 2 Dynamic radiographs 5 years after implantation for one- and two-level CTDRs

an increase in working patients, from 35.6% (136/382) preoperatively to 59.3% (166/280), and a decrease in patients on sick leave from 51.8% (198/382) preoperatively to 5.7% (16/280). At 5 years, patient satisfaction regarding cervical and arm pain was 80.4% (225/280) and 75.5% (210/278), respectively, and 93.3% (263/282) answered yes to the question "Would you undergo the procedure again?".

Discussion

The present study was designed to assess both clinical and radiological outcomes of a cervical disc prosthesis. The results of this investigation demonstrated that clinical outcomes have improved at all time points after surgery until final FU, with statistical significance, compared to baseline. Preservation of mobility at index level and a low operation rate for adjacent disc disease were also observed.

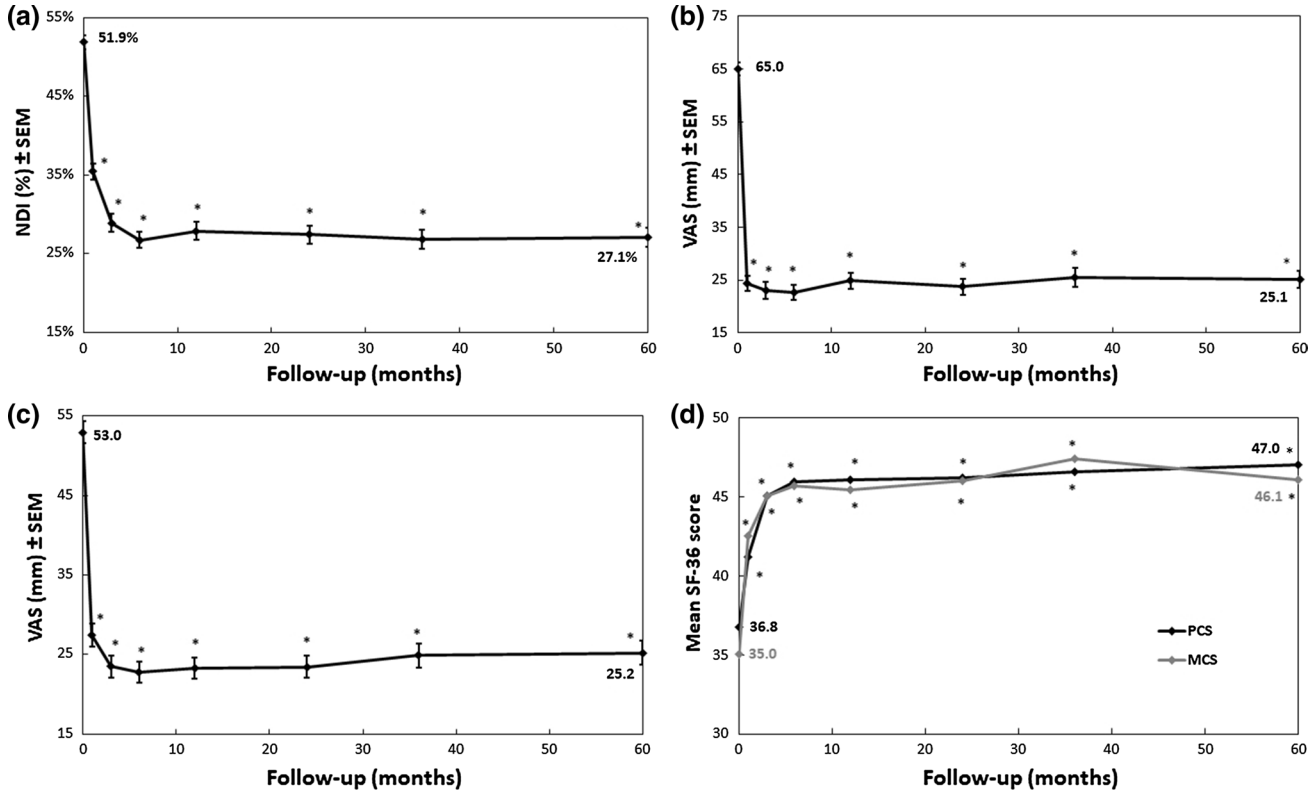

Fig. 3 Clinical outcomes over follow-up. Results are expressed as mean ± SEM. *$p \leq 0.05$ compared to preoperative baseline: **a** Neck Disability Index (NDI, 0–100%). **b** Visual analogue scale (VAS, 0–100 mm) for arm pain. **c** Visual analogue scale (VAS, 0–100 mm) for neck pain. **d** SF-36 PCS and MCS

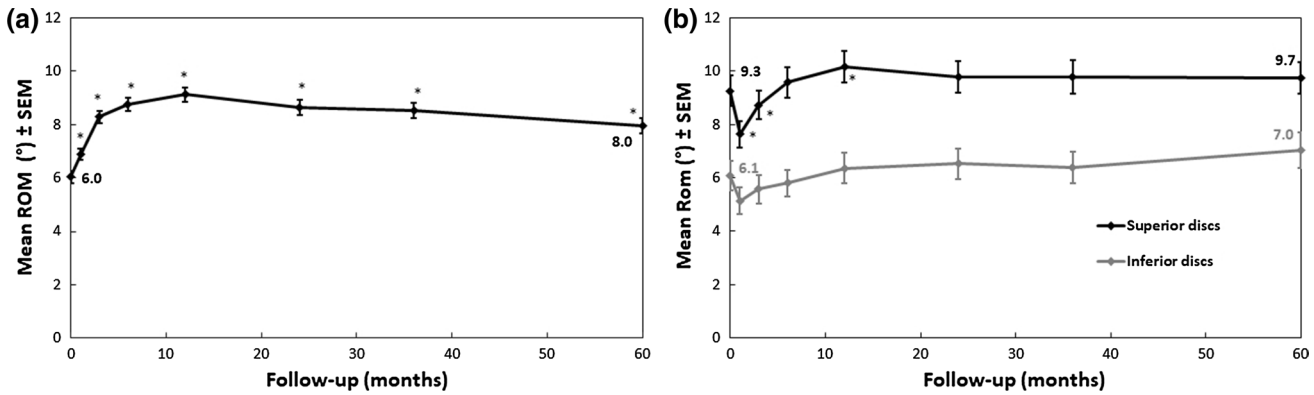

Fig. 4 Radiological outcomes over follow-up. Results are expressed as mean ± SEM. *$p \leq 0.05$ compared to preoperative baseline: **a** ROM at the index level. **b** ROM at adjacent levels

Several studies have been conducted to investigate the effectiveness of CTDR as a viable alternative to ACDF [20–28]. The major advantage of CTDR, aside from pain relief, has been preservation of mobility at index levels and a subsequent low incidence of ADD, a high rate of which after ACDF has long been criticized [29, 30].

With regard to relief of symptoms, the present results at 5-year FU demonstrated statistically significant improvement for NDI, VAS for arm and neck pain and SF-36 results for both PCS and MCS. Similar observations have been reported in a number of studies evaluating the clinical efficacy of CTDR using various prostheses [4, 14, 20–23, 25, 27, 28, 31]. These findings were clearly supported by meta-analysis studies [12, 13].

In response to motion preservation, radiological results showed significant improvement at 5 years with a mean

Table 2 Incidence of adjacent levels degeneration according to Kellgren–Lawrence classification preoperatively and at 5-year (M60) FU

Grade	Proximal adjacent discs		Distal adjacent discs	
	Preop ($n=296$) (%)	M60 ($n=263$) (%)	Preop ($n=201$) (%)	M60 ($n=171$) (%)
Grade 0	55.4	35.0	73.1	50.9
Grade 1	28.7	42.2	14.4	28.7
Grade 2	10.5	14.8	8.0	13.5
Grade 3	4.4	6.5	3.5	6.4
Grade 4	1.0	1.5	1.0	0.6

ROM of 8° and 72.1% of implanted prostheses maintaining mobility above a threshold of 3°. In two prospective, randomized, controlled trials comparing the same device with ACDF, similar mean ROM was reported at 5 years FU (10.2° and 9.3°) [22, 26, 31]. Likewise, this mean ROM was also in accordance with other mid- and long-term studies involving other devices which ranged from 6° to 13° [3, 12, 13, 32]. A threshold of 2° has commonly been used to decide on the mobility of prostheses, possibly explaining why higher rates of mobility have been reported [21].

Occurrence of HO remains a potential drawback of CTDR [17, 33]. In this investigation, the characterization of the different grades showed that HO led to complete fusion (grade 4) in 16.4% of the implanted segments at 5 years. In a meta-analysis of 38 studies, Kong et al. (2017) found that overall prevalence of severe HO (grade 4 HO) was 17.0% (95% CI 12.8–22.2%), and in particular, for studies with 2- to 5-year FU was 22.2% (95% CI 15.5–30.7%) [34]. In a prospective, non-randomized study with long-term FU, grade 4 HO was observed in 16.1% of cases at 5 years and in 26% at 10 years [24]. However, there was lower incidence observed at 5-year FU in an investigational device exemption (IDE) study of the present prosthesis, with HO reported in 8.5% of 1-level patients and 9.7% of two-level patients [22, 26]. This difference may be due to stricter selection criteria in the IDE study.

Both orthopaedic and neurosurgeons were involved in the study. When the study operations were performed, the orthopaedic surgeons of the group were not yet using surgical microscopes. At present, the use of a microscope is recommended, because it improves the efficacy of posterior longitudinal ligament (PLL) release and osteophyte resection. Improved osteophyte resection might decrease the rate of grade 4 HO after CTDR. Distraction might also reduce the incidence of this complication. In ACDF, distraction is beneficial, because it enlarges the foramens and reduces PLL buckling. Over distraction, however, is not recommended for CTDR, because it would lead to stretching of cervical facet joint capsules, a source of neck pain. Finally, large endplates that can be used today, were not available when the present study began. It has been found that proper endplate sizing may be an important factor for mitigating HO [35]. Larger plates in the front might have hindered fusion (grade 4 HO) in some cases by mechanically blocking some of the peripheral bone growth. In any event, grade 4 HO after CTDR is probably no more frequent than pseudarthrosis following ACDF [36], and contrary to pseudarthrosis, clinical outcomes did not deteriorate in patients with grade 4 HO. Outcomes of CTDR patients with grade 4 HO are similar to those of successfully fused ACDF patients.

Motion at adjacent levels showed a slight increase without statistical significance. There was evidence that fusion increased mobility at adjacent levels, with greater effect on proximal levels [29]. In addition, it is open to debate as to whether incidence of adjacent segment degeneration is related to natural degeneration or biomechanical stress as results of adjacent fusion [5, 6, 30]. While Hilibrand et al. reported an annual incidence rate of adjacent segment degeneration of 2.9% after fusion [37], Xia et al. noted 32.8% (95% CI 17.8–47.9%) occurrence of adjacent segment degeneration after cervical spine surgery [38]. The present study showed some further degeneration in 39.1% at the proximal adjacent level and in 42.2% at the distal adjacent level; similar results were observed in the IDE studies [22, 26]. One of the more significant findings to emerge from the present study is the low rate of ADD surgery, performed in only 2.9% of patients at 5 years. This tend to support the protection of adjacent discs from ADD [39, 40]. In the literature, this rate is impacted by the design of the device itself [41] and rate ranged from 4% to as high as 16% after CTDR [21, 38].

There was a low adverse events rate reported in present study during 5 years of FU, with, in addition a low rate of reoperation at the index level. Dejaegher et al. reported in a 10-year follow-up after implantation of another cervical disc prosthesis 186 adverse events recorded for 73 patients, out of 89 included in the study, and 2% rate of reoperation at the index level. It has become common with recent publications to report that CTDRs have significantly lower rates of adverse events and reoperations than ACDF [3, 11, 13, 32].

It should also be noted that medication consumption declined significantly and significant resumption of work was observed at 5-year FU. Despite the fact that cost-effectiveness data are country dependent, cost-effectiveness analyses regarding CTDR and ACDF for the treatment of one- or two-level cervical degenerative disc disease have concluded that both CTDR and ACDF are cost-effective procedures, but that CTDR remained more cost-effective than ACDF [42–44]. Similarly, the present patients have maintained a high level of satisfaction 5 years after surgery.

One limitation of the present study is a potential selection bias arising from the fact that the study was not randomized.

The lack of a control group partially limits the impact of the results. In particular, data on radiographic adjacent segment degeneration are less meaningful without a comparative control group. One limitation of this article is the absence of detail in the population profile stratification (age, multilevel, length of symptoms and comorbidities) that could impact results and bias the comparison with ACDF in the literature. Nonetheless, the present report provides real-world intermediate-term evidence that will hopefully help readers better evaluate how CTDR might contribute to their everyday clinical practice. Furthermore, in the present study, work-related injury cases and patients with previous arthrodesis of the cervical spine were not excluded.

In a meta-analysis comparing non-randomized observational studies with randomized controlled trials in cervical disc arthroplasty, Jee et al. concluded that prospective observational studies can achieve relevant outcomes and conclusions [45]. To go further, Grob et al. suggest not to discredit observational studies as a relevant source of evidence in spine surgery [46]. The present report describes the results of a large, multicentre uncontrolled observational study on cervical disc arthroplasty. Specifically, we have detailed the 5-year patient reported outcomes (NDI, VAS, SF-36 and patient satisfaction), radiographic ROM, adjacent segment degeneration, heterotopic ossification and reoperation rates.

Conclusion

After 5-year FU, results of CTDR in 384 patients demonstrated favourable clinical and radiological outcomes. All clinical outcomes were improved reflecting high patient satisfaction. Radiological evaluation shows that mean mobility of the index levels was maintained with no increase in the ROM at adjacent levels. Surgery for ADD was low compared to literature reports on ACDF and other CTDRs. Moreover, the low adverse events rate and low reoperation rate at the index levels tend to confirm the safety and efficacy of the present CTDR system.

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Compliance with ethical standards

Conflict of interest Each of the authors is an investigator of the multicenter Mobi-C prospective study. Dufour, Beaurain, Huppert, Bernard and Steib are also co-designers of Mobi-C and have received royalties from Zimmer Biomet. Prof. Dam Hieu has no conflict of interest in relation to this study. We have disclosures with other medical companies unrelated to this study. Dr. Dufour is a consultant for the Zeiss microscope company. Pr Steib is a consultant for Clariance and Medtronic. Dr. Bernard is a consultant for OSD.

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