Original Article

Comparison of *in vivo* kinematic and radiological parameters of three cervical disc prostheses

ABSTRACT

Introduction: Cervical total disc replacement (CTDR) is an alternative to anterior cervical discectomy and fusion for select patients that may preserve range of motion and reduce adjacent segment disease. Various CTDR prostheses are available; however, comparative data are limited. This study aimed to compare the short-term kinematic and radiological parameters of the M6-C, Mobi-C, and the CP-ESP prostheses.

Methods: This retrospective cohort study included patients treated with CTDR between March 2005 and October 2020 at a single institution. Patients were included if their follow-up assessment included lateral erect and flexion/extension radiographs. The primary outcome assessed at 3-months postoperatively was range of motion, measured by the difference in functional spinal unit angle between flexion and extension.

Results: A total of 131 CTDR levels (120 patients, 46.2 ± 10.1 years, 57% male) were included. Prostheses implanted included the M6-C ($n = 52$), Mobi-C ($n = 54$), and CP-ESP ($n = 25$). Range of motion varied significantly (8.2° ± 4.4 vs. 10.9° ± 4.7° vs. 6.1° ± 2.7 , $P < 0.001$). On *post hoc* analysis, the Mobi-C prosthesis demonstrated a significantly greater range of motion than either the M6-C prosthesis ($P = 0.003$) or CP-ESP ($P < 0.001$).

Conclusion: Although the optimal range of motion for CTDR has not been established, short-term differences in the range of motion may guide the selection of CTDR prosthesis. Further studies with longer follow-up and consideration of clinical outcome measures are necessary.

Keywords: Cervical total disc replacement, CP-ESP, disc arthroplasty, M6-C, Mobi-C, total disc replacement

INTRODUCTION

Cervical total disc replacement (CTDR) has emerged as an effective alternative to anterior cervical discectomy and fusion (ACDF) for some patients with cervical degenerative disc disease resulting in radiculopathy or myelopathy.[1] Although ACDF has traditionally been the procedure of choice, the resultant loss of mobility may result in compensatory changes in adjacent segments and accelerated degenerative pathology, so-called adjacent segment disease (ASD).[2,3] In contrast, CTDR aims to relieve the symptoms and preserve physiological mobility of the cervical spine.[4,5] Biomechanical evidence suggests that CTDR may result in decreased adjacent level stress,[6-8] and clinical studies have demonstrated decreased radiographic evidence of ASD compared to ACDF.[9] The relationship between radiographic and clinical ASD is incompletely understood,[10] but there is also growing evidence that CTDR may also decrease the incidence of further surgery at adjacent levels.[11-13]

There are numerous cervical arthroplasty prostheses available, utilizing a variety of different design principles.[1] The three commonly used prostheses in Australia include the Mobi-C (LDR Spine USA, Austrin, TX, USA), M6-C (Spinal Kinetics, Sunnyvale, CA, USA) and the recently developed CP-ESP (FH Orthopedics, Mulhouse, France). Each of these

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devices has been investigated individually, but there is a lack of comparative evidence.[13-16] This study aims to define and compare the short-term *in vivo* biomechanical and radiological properties of these three CTDR prostheses.

MATERIALS AND METHODS

A retrospective cohort study was conducted on patients derived from a prospectively maintained database. All patients were treated at a tertiary hospital by a single senior spine surgeon. Ethics approval was received from the Institutional Review Board of the authors' affiliated institution. All patients provided consent for the release of their medical data.

Population

This study included consecutive adult patients who underwent CTDR between March 2005 and August 2020 who satisfied the exclusion criteria [Table 1] and had adequate 3-month follow-up including lateral flexion/extension radiographs of the cervical spine [Figure 1]. This study included no restrictions on the number of cervical levels treated or the existence of previous surgery at other cervical spine levels. The indication for surgery was symptomatic radiculopathy and/or myelopathy secondary to cervical degenerative disc disease, which did not respond to conservative treatments for at least 3 months. Three types of CTDR procedure were included in this study: Single-level CTDR, multi-level CTDR, and hybrid surgery (combined CTDR and ACD). Each CTDR operative level was treated as an independent observation.

Radiographic assessment

Biomechanical measurements were recorded based on lateral flexion/extension views of standing radiographs, using Cobb angle measurement tools inbuilt into radiological analysis software (InteleRad, Canada). Range of motion was assessed by measuring the difference in functional spinal unit (FSU) angle in flexion and extension. The FSU angle was defined by the angle formed between lines subtended from the superior endplate of the rostral vertebral body and the inferior endplate of the caudal vertebral body [Figure 2]. A lordotic angle was defined to be a positive value. The anterior and posterior disc height of each operated level was also measured on an erect lateral radiograph and defined as the distance between the inferior endplate of the cranial vertebral body and the superior endplate of the caudal vertebral body at the anterior and posterior limits of the disc space, respectively [Figure 2].

Table 1: Exclusion criteria

Pregnancy
Concurrent malignancy
Metabolic bone disease
Osteoporosis
Ossification of the posterior longitudinal ligament
History of cervical surgery at the diseased segment
Posttraumatic cervical deformity
Previous cervical spine deformity
Active infection
Known allergy to any component of the prosthesis
Signs of segmental instability on radiographs
Loss of disk height >50%

Surgical approach

A standard right-sided anterior approach to the cervical spine was utilized in all cases, as previously described.[17] After dissection, a Caspar distractor (A-Spine ASIA, Taiwan) was used to distract the disc space at the operative level and a discectomy was performed. The endplates were prepared for prosthesis insertion. A template prosthesis was used to confirm sizing, and then, the appropriate prosthesis was inserted with intraoperative radiography utilized throughout the procedure. The types of implants used during the trial period included the Mobi-C (LDR Spine USA, Austrin, TX, USA), M6-C (Spinal Kinetics, Sunnyvale, CA, USA), and the CP-ESP (FH Orthopedics, Mulhouse, France). The implant used was based upon the preference of the patient and surgeon during a preoperative discussion, with consideration to the range of implants available at the time and individual patient factors. The patient received a soft collar and routine anti-inflammatory medication for 2 weeks postoperatively.

Statistical assessment

Statistical analysis was performed using the SPSS software version 26 (IBM; Armonk, New York, USA). $P < 0.05$ was considered statistically significant. Parametric continuous data were expressed as mean ± standard deviation and categorical data were expressed as percentages. Parametric continuous variables were compared across the three prostheses using Welch's or standard one-way analyses of variance, depending upon whether the assumption of homogeneity of variances was violated or not. *Post hoc* testing was performed using either the GamesHowell test or the TukeyKramer test, depending upon whether the assumption of homogeneity of variances was violated or not. The categorical variables were compared across the three prostheses using the Chi-squared test or Fisher's exact testing as appropriate.

RESULTS

Characteristics of study population

A total of 131 CTDR levels were included in this study (120 patients, 46.2 ± 10.1 years, 57% male). Baseline characteristics are summarized in Table 2. Prostheses implanted included M6-C ($n = 52$), Mobi-C ($n = 54$), and CP-ESP ($n = 25$). Prostheses were implanted mostly in

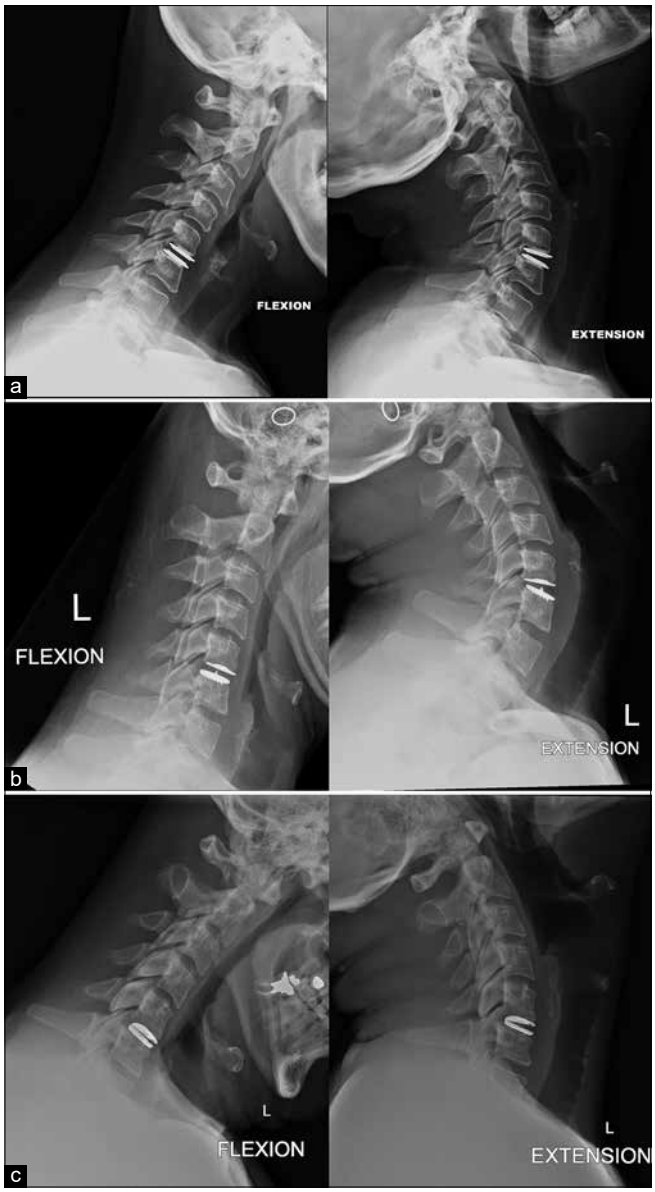

Figure 1: Lateral radiographs demonstrating flexion (left) and extension (right) for a range of patients with a C5/6 single level total disc replacement who received (a) M6-C prosthesis, (b) Mobi-C prosthesis, and (c) CP-ESP prosthesis

single-level CTDR procedures (56%), and less commonly in multi-level CTDR procedures (12%) or hybrid procedures (31%). All multi-level CTDR procedures included only two spinal levels while hybrid procedures included both two-level (83%) and three-level (17%) procedures. The most common spinal segments for CTDR prostheses in this study were C5/6 (52%) and C6/7 (26%).

Range of motion

The range of motion for each implanted prosthesis at 3-month follow-up is summarized in Table 3. Across the three prostheses tested: M6-C, Mobi-C, and CP-ESP, range of motion varied significantly (8.2° ± 4.4° vs. 10.9° ± 4.7° vs. 6.1° ± 2.7°, $P < 0.001$). *Post hoc* analysis with the GamesHowell test revealed a significantly greater range of motion for the Mobi-C prosthesis compared to either the M6-C ($P = 0.003$) or the CP-ESP ($P < 0.001$). Range of motion data for the two most common surgical levels, C5/6 and C6/7, are also presented in Table 3. The comparison of prostheses implanted at C5/6 revealed significant variation between the three prostheses ($P < 0.001$) and a significantly greater range of motion for the Mobi-C prosthesis compared to the CP-ESP on *post hoc* testing with the TukeyKramer test ($P < 0.001$). Other pairwise comparisons at C5/6 were not significant. Range of motion at C6/7 did not vary significantly across prostheses ($P > 0.05$).

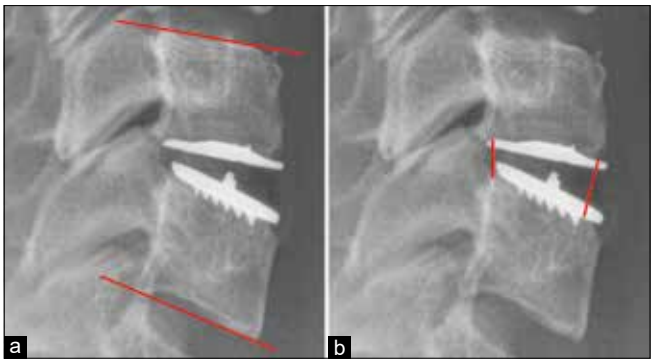

Figure 2: Radiological assessment methods: (a) Functional spinal unit angle, measured on flexion/extension lateral radiographs extension angle using Cobb angle measured tool and defined by the angle formed by lines subtended from the superior endplate of the rostral vertebral body and inferior endplate of the caudal vertebral body; (b) anterior and posterior disc heights, measured on an erect lateral radiograph and defined as the distance between the inferior endplate of the cranial vertebral body and the superior endplate of the caudal vertebral body at the anterior and posterior limit of the disc space, respectively

Disc height

The anterior and posterior disc heights achieved at 3-month follow-up are summarized in Table 4. Across the three prostheses tested: M6-C, Mobi-C, and CP-ESP, significant variation was detected in both anterior disc height (9.5 ± 1.4 mm vs. 8.5 ± 1.3 mm vs. 8.4 ± 0.9, $P = 0.002$) and posterior disc height (6.1 ± 1.1 mm vs. 5.4 ± 1.4 mm vs. 4.8 ± 1.6 mm $P = 0.001$). *Post hoc* comparisons with the GamesHowell test revealed that the M6-C prosthesis produced significantly greater anterior disc height at 3 months than the Mobi-C ($P = 0.002$) or CP-ESP prostheses ($P = 0.007$). Similarly, *post hoc* testing the TukeyKramer test revealed that the M6-C produced greater posterior disc height at 3 months than the Mobi-C ($P = 0.023$) or CP-ESP ($P < 0.001$).

DISCUSSION

This study assessed the short-term kinematic and radiological outcomes following CTDR with three commonly used

prostheses: The M6-C, Mobi-C, and CP-ESP prostheses. This is the first study to provide comparative data between the CP-ESP and other prostheses. This study found significant variation between prostheses with respect to the range of motion at 3 months, with the Mobi-C demonstrating a greater ROM than either the M6-C or CP-ESP.

It is hypothesized that the preservation of physiological ROM following CTDR may reduce the risk of ASD compared to ACDF.[1] There is a growing body of evidence in support of this hypothesis, with previous biomechanical studies demonstrating reduced adjacent level intradiscal pressure and facet joint forces at adjacent levels after CTDR compared to ACDF[6-8] This has also been supported by clinical evidence, with most randomized controlled trials reporting significantly less ASD after CTDR compared to ACDF, in a recent systematic review and meta-analysis.[18] However, the relationship between postoperative range of motion at the operated segment and the clinical outcome has not been clearly established. This study found that the Mobi-C prosthesis produced a greater range of motion than the other studied prostheses. This finding aligns with previously published data. One previous comparative study of the M6-C and Mobi-C prostheses found that the Mobi-C resulted in significantly greater extension compared to the M6-C.[19] Similarly, a biomechanical study in 16 fresh-frozen human cervical spine specimens reported that implantation of a C5/6 Mobi-C prosthesis resulted in significantly greater segmental ROM compared to preoperative values (16.8° ± 3.7° vs. 13.8° ± 4.2°, $P < 0.05$), whereas the M6-C prosthesis did not result in a change from preoperative values.[20]

For healthy young adults, the normative mean ROM for a subaxial cervical motion segment varies between 10.2° and 19.7°.[21-23] According to previous normative studies, the mean ROM was observed to be between 14.6°–19.7° at C5/6, and 12.3°–15.8° at C6/7.[21-23] In contrast to these normative studies, the ROM for each prosthesis in this study appear to be lower, with mean ROM varying between 5.9°–11.7° at C5/6, and 6.2°–10.7° at C6/7. However, comparison with historical controls is difficult as differences in ROM could be accounted for by many factors, such as age,[24,25] joint pathologies,[26] postural abnormalities,[24] and gender[25] as well as inter-rater variability in ROM measurement.

While the optimal ROM following CTDR is not yet clear, supra-physiological mobility [Figure 3] may worsen clinical outcome and increase the risk of ASD or facet joint degenerative changes. It has been postulated that excessive prothesis mobility may put increased demand on the spinal musculature to stabilize the spine, increasing strain on spinal components and contributing to pain.[27] It is possible that the ROM results of this study may inform surgeon or patient preference for a particular implant, but further studies with longer-term follow-up and consideration of clinical outcomes are required to determine the best available prosthesis. The

Table 2: Characteristics of the study population

Characteristic	Value
Total (*n*)	131
Age, mean±SD (*n*=131)	46.2±10.1
Male gender (n=131), *n* (%)	74 (57)
Smoker (*n*=114), *n* (%)	16 (14)
Diabetes (*n*=114), *n* (%)	1 (1)
BMI, mean±SD (*n*=59)	26.6±4.4
Procedure performed (*n*=131), *n* (%)	
Single-level CTDR	74 (56)
Multi-level CTDR	16 (12)
Hybrid procedure	41 (31)
CTDR spinal level (*n*=131), *n* (%)	
C3/4	3 (2)
C4/5	26 (20)
C5/6	68 (52)
C6/7	34 (26)
Prosthesis (*n*=131), *n* (%)	
M6-C	52 (40)
Mobi-C	54 (41)
CP-ESP	25 (19)

SD – Standard deviation, BMI – Body mass index, CTDR – Cervical total disc replacement

Table 3: Range of motion for cervical total disc replacement prostheses at 3 months follow-up

Prosthesis	M6-C	Mobi-C	CP-ESP	*P*
All levels range of motion, mean degrees±SD	8.2±4.4 (*n*=52)	10.9±4.7 (*n*=54)	6.1±2.7 (*n*=25)	<0.001[a]
C5/6 range of motion, mean degrees±SD	9.2±4.6 (*n*=28)	11.7±4.6 (*n*=28)	5.9±2.3 (*n*=12)	<0.001[b]
C6/7 range of motion, mean degrees±SD	8.3±4.0 (*n*=9)	10.7±4.0 (*n*=18)	6.2±2.7 (*n*=6)	0.051[b]

[a]Welch's ANOVA, [b]Standard ANOVA. SD – Standard deviation, ANOVA – Analyses of variance

Table 4: Anterior and posterior disc height for cervical total disc replacement prostheses at 3 months follow-up

Prosthesis	M6-C	Mobi-C	CP-ESP	*P*
Anterior disc height, mean mm±SD	9.5±1.4 (*n*=35)	8.5±1.3 (*n*=52)	8.4±0.9 (*n*=22)	0.002[a]
Posterior disc height, mean mm±SD	6.1±1.1 (*n*=38)	5.4±1.4 (*n*=53)	4.8±1.6 (*n*=22)	0.001[b]

[a]Welch's ANOVA, [b]Standard ANOVA. SD – Standard deviation, ANOVA – Analyses of variance

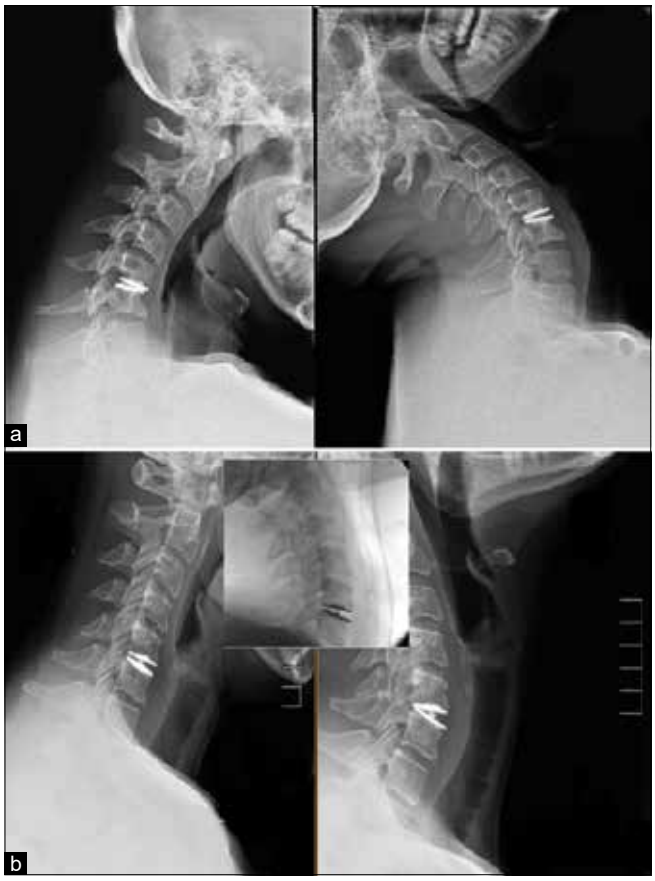

Figure 3: Lateral radiographs demonstrating hypermobility in flexion (left) and extension (right) at the operated level in patients who received (a) M6-C prosthesis and (b) Mobi-C prosthesis. No cases of hypermobility of the CP-ESP prosthesis were identified during the trial period

limited published comparative data did not find a significant difference in clinical outcomes measures between the Mobi-C and M6-C prostheses.[17]

The prostheses used in this current study vary in their design principles and materials and this may have contributed to the ROM data observed. Both the M6-C and the CP-ESP employ endplate sandwiched viscoelastic designs which are able to provide six degrees of freedom and combined motions due to deformation of their viscoelastic components.[28] The M6-C is a mobile bumper viscoelastic device, featuring a compressible polycarbonate urethane polymer that mimics the nucleus pulposus and a polyethylene weave annulus that is intended to prevent tissue ingrowth and contain wear debris and is welded to titanium endplates.[29] The CP-ESP is a monoblock viscoelastic device featuring a polycarbonate urethane core fixed to titanium endplates.[15] There are theoretical advantages and disadvantages to each design: The M6-C has no stress peak at the interface of the core and endplate as these components are unbonded, while the CP-ESP, which has no motion at the core-endplate interface has a corresponding reduced risk of wear debris.[28] In contrast, the Mobi-C is a "ball and socket" prosthesis with a mobile core of polyethylene articulating with superior and inferior cobalt chromium molybdenum alloy endplates.[20,30] The mobile core has a spherical articulation with the superior endplate and a planar articulation with the inferior endplate. The contrast in design between the viscoelastic prostheses (M6-C and CP-ESP), which provide increasing resistance to motion at the extremes of ROM, and the "ball and socket" prosthesis (Mobi-C) may partially explain the observed difference in range of motion.

Similarly, the variation in anterior and posterior disc height observed in this study may also be related to the design of the individual prostheses and the surgical technique necessary for their implantation. The Mobi-C and CP-ESP implants have an anatomical shape, with a flat inferior endplate and a domed superior endplate, and therefore, minimal endplate preparation is necessary for their implantation. The M6-C prosthesis has a wedge-shaped design with flat inferior and superior endplates and significant endplate preparation is necessary to provide space for implantation. In addition, the smallest height available for the M6-C prosthesis is 6 mm, while the height of a natural disc may vary between 3.5 and 6.1 mm.[31-33] As such, the height of the prosthesis and the need for significant tissue removal during endplate preparation likely contributed to the greater anterior and posterior disc height observed for the M6-C prosthesis. It has been postulated that excessive anterior/posterior disc height (over-distraction) may result in worsened clinical outcomes through stretching of facet joints.[28,34] However, previous comparative studies of the M6-C and Mobi-C prostheses did not report significantly different clinical outcomes.[17]

Data comparing different CTDR prostheses is limited and does not show significant clinical differences between prostheses.[17,19] However, each of the prostheses included in this study has demonstrated clinical efficacy in previous trials. The M6-C demonstrated positive clinical outcome results and no serious adverse effects in an early study of 36 one-level CTDR patients.[16] More recently, the M6-C has received Food and Drug Administration (FDA) approval for single-level CTDR based upon its positive clinical and safety profile in a US FDA Investigational Device Exemption (FDA IDE) trial that assessed 160 patients who received M6-C prostheses against an ACDF control group.[35] A postapproval study is ongoing. The Mobi-C prosthesis has demonstrated clinical efficacy for both single-level and two-level CTDR in multiple FDA IDE trials.[11,13,36,37] In addition, a prospective uncontrolled study conducted in France reported favorable outcomes for both single-level and multi-level CTDR.[38] The CP-ESP has been investigated in one previous study with

a biomechanical component and a clinical component of 71 implanted protheses with 12 months follow-up.[15] This study concluded that the CP-ESP demonstrated encouraging clinical results but recognized that further long-term clinical evaluation was required.

The present study has several limitations that require consideration. Only ROM and anterior and posterior disc height were measured. There are several kinematic parameters not addressed by the current study, including centers of rotation, lateral flexion and vertebral body translation. In addition, clinical data such as Visual Analog Scale scores or other patient-reported outcomes were not assessed. Further studies are necessary to more complete compare the kinematic and clinical properties of these prostheses. In addition, the short follow-up period another limitation as ROM and disc height has been demonstrated to change over time.[9,15] Finally, the single surgeon single-institution study design and relatively young cohort may influence the external validity of these results.

CONCLUSION

At 3 months follow-up, significant variation was noted in the range of motion across the three prostheses tested. The Mobi-C prosthesis demonstrated a significantly greater range of motion than the M6-C or CP-ESP. Short-term differences in ROM may guide the selection of CTDR protheses for various age groups and pathologies, although further research is required to determine the optimal ROM after CTDR.

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Conflicts of interest
There are no conflicts of interest.

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