Original Article

# Fixed-Bearing Posterior-Stabilized Implant versus Constrained Condylar Knee in One-Stage Bilateral Primary Arthroplasty of the Varus Knee: A Randomized Controlled Trial with Minimum 2-year Follow-Up


## Abstract

**Background:** Severe varus deformity of the knee poses a technical challenge in balancing the flexion–extension gaps. The use of a varus–valgus constrained prosthesis is a solution to achieve coronal plane stability. The results of constrained condylar knee (CCK) implants in primary total knee arthroplasty are not well known. This study aims to compare the functional outcomes of posterior-stabilized (PS) and CCK implants for primary arthroplasty of the varus knee. **Materials and Methods:** Twenty patients with bilateral severe osteoarthritis and genu varum of more than 10° were enrolled in this study. One knee was randomly implanted with a fixed-bearing PS implant, whereas the other was implanted with a CCK prosthesis. Pre- and postoperative Knee Society Score (KSS) and Oxford Knee Score (OKS) questionnaires were completed, and knee flexion was measured and compared. **Results:** The patients were followed for 32 months on average (24–36 months). On the KSS and OKS, both the groups improved significantly, but the difference between them was not statistically significant. Postoperative knee flexion was also not different between the two groups. Furthermore, 18 patients could not distinguish the difference between the two prostheses, whereas two patients preferred the PS one. **Conclusion:** We demonstrated that a PS prosthesis can achieve comparable functional results to the CCK one in the short term.


**Keywords:** *Arthroplasty, genu varum, knee, prosthesis, total knee replacement*


**Mohammad Mahdi Sarzaeem, Shahram Sayyadi[1], Ali Pourmojarab, Mohammad Mahdi Omidian, Mohammad Mahdi Bagherian Lemraski, Mojtaba Baroutkoub, Sohrab Salimi[1], Alireza Manafi Rasi**

*Departments of Orthopedic Surgery and Traumatology and [1]Anesthesiology, Imam Hossein Medical Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran*


## Introduction

Total knee arthroplasty (TKA) is the current standard method of treatment for severe painful osteoarthritis (OA) of the knee.[1] Several prosthesis designs have evolved over the years to overcome problems encountered during TKA and lead to a better outcome. Higher constraint prosthesis such as constrained condylar knee (CCK) is one of the answers for coronal malalignment and major deformities during TKA.[2] CCK prostheses have become more popular in recent years as an implant of choice for revision TKA procedures and cases when appropriate soft-tissue balance and limb alignment could not be achieved.[2,3] Although several studies have investigated the use of CCK in performing revision TKAs, little data are available on the use of CCK with or without stems as a primary prosthesis in coronal deformity of the knee.[4] Varus knee is the most common deformity found in TKA candidates, which requires considerable technical precision both before and after surgery.[5] A varus of more than 10° is usually considered severe. During TKA surgery, ligamentous balancing techniques are used to balance flexion and extension gaps in the mechanical alignment surgical technique.[6] Several researchers have advocated various procedures for releasing extremely varus knees, including the removal of medial-sided osteophytes, the release of medial capsule and periosteum, the posterior capsule, membranous venom, the superficial medial collateral ligament (MCL), and the posterior MCL.[6-8] If the medial-sided release is insufficient to produce balanced flexion and extension gaps, one option is the use of a more constrained prosthesis such as CCK or rotating hinge implants.

In the present study, the short-term outcomes of a series of patients with one-stage bilateral primary TKAs and severe varus deformity using the fixed-bearing posterior-stabilized (PS) implant for one



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***Address for correspondence:***
*Dr. Alireza Manafi Rasi, Department of Orthopedic Surgery and Traumatology, Imam Hossein Medical Center, Tehran, Iran.*
*E-mail: drmanafi54@yahoo.com*

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knee and CCK for the other are reported. The study is unique as it assesses the patient's both knees and eliminates the potential pitfalls of case–control matching.

## Materials and Methods

This study is a randomized clinical trial conducted at a tertiary university hospital in Tehran, Iran, from March 2009 to December 2011. We considered a sample size of 57 patients (for sample size power 90 and significance level 0.05) with significant bilateral knee OA and severe (≥10°) varus deformity. The inclusion criteria were bilateral severe OA of the knees and varus deformity of more than 10° in both knees. The exclusion criteria were revision TKA, any severe underlying medical condition precluding surgery, previous major periarticular surgical interventions, valgus deformity of the knee, and chronic osteomyelitis about the knee. A standard standing three-joint alignment X-ray of both lower limbs was obtained and preoperative planning and templating were done accordingly. Initially, the objectives, nature, and process of the study were explained to the patients, and a form of written consent approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences was received from all patients who entered the study. Individuals were also reassured that they could leave the study at any stage of the research that they were reluctant to continue to collaborate; also, their participation in the research would not interfere with their treatment. All surgeries were performed by one senior surgeon (one of the authors) through the southern approach under spinal or general anesthesia using a sterile pneumatic tourniquet with 1 gr of intravenous cefazolin administered half an hour before the surgery as antimicrobial prophylaxis. The implants used were Zimmer® NexGen® PS Fixed-Bearing Knee and NexGen® Legacy® CCK (Zimmer Inc., Warsaw, IN, USA). The femoral cuts were done using an intramedullary guide with an anterior referencing system, whereas the tibial cut was done with an extramedullary one. The femoral component was externally rotated by 3° of the posterior condylar axis. Flexion and extension gaps were gauged using a standard spacer block, all osteophytes were removed, and step-by-step soft-tissue releases were performed using the algorithmic approach proposed by Verdonk *et al*.[9] In this stage, our objective was to find patients who needed complete release of the superficial MCL to achieve a balanced flexion–extension gap in both knees. Therefore, a total of 34 patients that either of their knees achieved flexion–extension gap balance without the need for complete superficial MCL release were removed from the study. Twenty-three patients met the intraoperative criterion and were analyzed. In every patient, one knee was randomly implanted with the PS prosthesis and the other knee with the CCK prosthesis regardless of the preoperative radiographic degree of varus. The randomization process was computer generated. All implants were fixed using 40 g of Hi-Fatigue G Bone Cement (Zimmer Biomet). Patella was not resurfaced in any of the cases. Stability and tracking were checked and confirmed by the surgeon on both sides, and the surgical wound was closed in the standard manner. Drains were not used. Patients began the rehabilitation protocol with active range of motion exercises the next day following surgery, and all received 40000 IU subcutaneous enoxaparin for venous thromboembolism (VTE) prophylaxis once a day for 28 days and no oral antibiotics. Patients had no deep vein thrombosis, infection, or wound-related issues in the early postoperative period.

The patients were followed postoperatively at 1 month and every 3 months thereafter for the 1st year and then every 6 months for a minimum of 2 years. One out of the initial 23 patients relocated and 2 patients failed to complete the follow-up visits, so 20 patients (40 knees) were finally analyzed. A trained evaluator not involved in the study design was responsible for data collection.

Pre- and postoperative Knee Society Score (KSS) [Figure 1], with a maximum of 100 points, and the Oxford Knee Score (OKS) [Figure 2], with a maximum of 60 points, were used to evaluate the functional outcomes of TKA patients. To assess a subjective form of patients' overall satisfaction, they were also questioned at the last follow-up visit that which knee they felt most comfortable with and if they preferred one of the two knees over the other. The range of motion of both knees was also assessed pre- and postoperatively during the physical examination of patients.

### Statistical analysis

The statistical analyses were performed using SPSS software version 25.0 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, version 25.0. Armonk, NY, USA: IBM Corp.). Continuous variables were described using means and standard deviations (SD). To analyze differences, a paired *t*-test was used to assess quantitative factors. A two-tailed $P < 0.05$ was considered to indicate statistical significance.

## Results

A total of twenty patients (16 women and 4 men) aged 63–74 years with one-stage bilateral primary TKAs were followed for at least 2 years. The average duration of follow-up was 32 months, with a range of 24–36 months. The mean preoperative body mass index (BMI) of the patients was 23.4 (ranged 18–29). On the preoperative long leg X-rays, the patients' mean measured varus angle was 18.6°, with the minimum varus of 12°, ranging from 12° to 24°.

The prosthesis survival rate was 100% for both the groups, with no revision procedures required nor any postoperative infections.

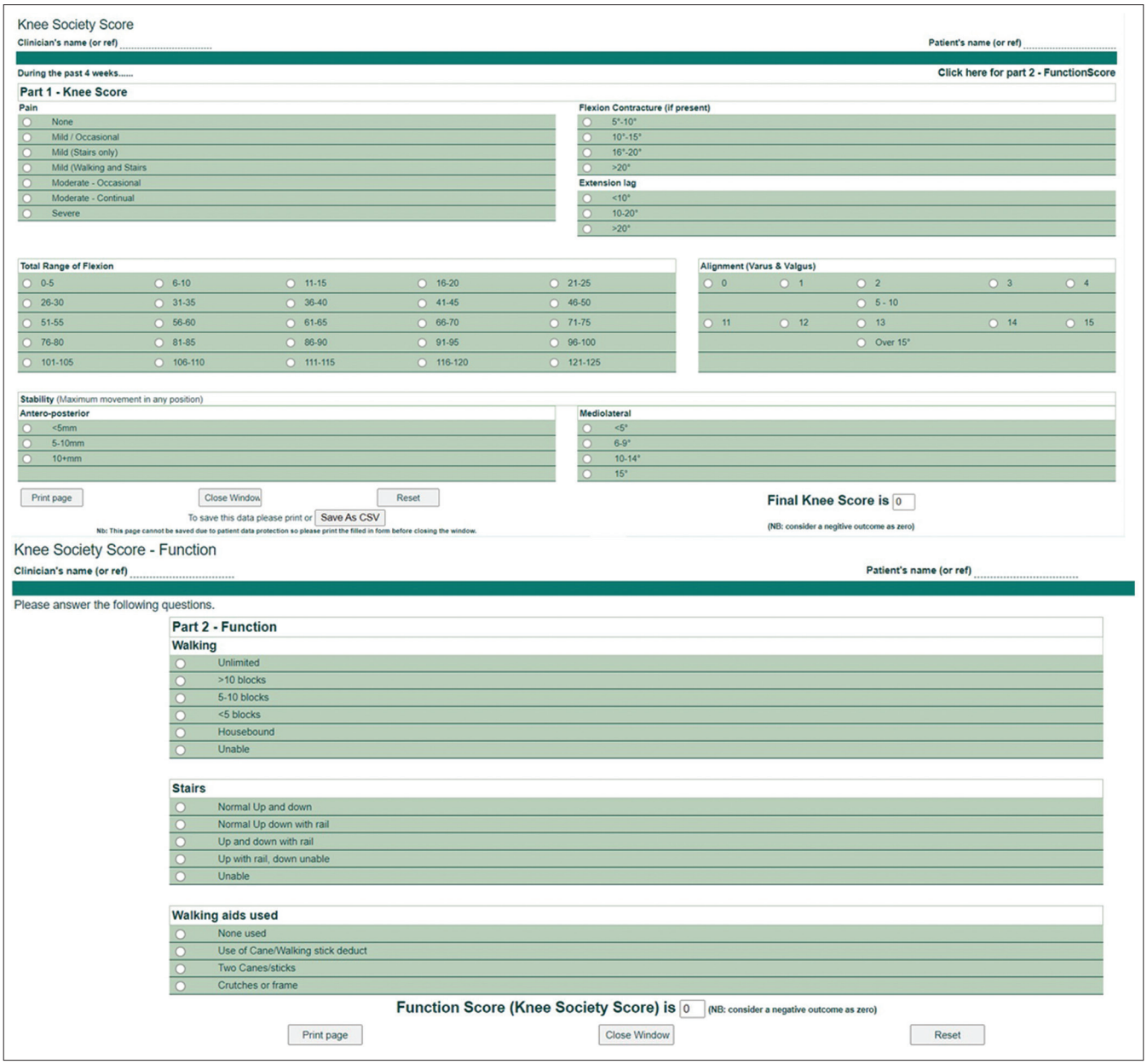


**Figure 1: The Knee Society Score**

**Table 1: Knee Society Score**

| KSS | Mean±SD | | *P* |
|---|---|---|---|
| | Preoperative | Postoperative | |
| Both knees | 49.4±18.2 | 89.8±20.1 | <0.001 |
| PS group | 48.5±14.2 | 87.7±18.2 | <0.001 |
| CCK group | 50.3±20.3 | 91.9±23.2 | <0.001 |

SD: Standard deviation, KSS: Knee Society Score, CCK: Constrained condylar knee, PS: Posterior-stabilized

## Knee Society Score

Preoperatively, the mean (SD) KSS for both knees was 49.4 (18.2), and in the final follow-up, the mean (SD) KSS increased to 89.8 (20.1) for both knees. This increase was statistically significant ($P < 0.001$). The mean (SD) preoperative KSS for the PS prosthesis group was 48.5 (14.2), whereas the mean (SD) preoperative KSS for the CCK prosthesis was 50.3 (20.3). This score increased to 87.7 (18.2) for the PS group and 91.9 (23.2) for the CCK group, respectively, which was significantly different in each group compared to its preoperative scores ($P < 0.001$). However, the difference in postoperative scores between the two prostheses did not reach a significant level ($P = 0.27$ and 0.34, respectively). These results are summarized in Table 1.

## Oxford Knee Score

The mean (SD) OKS for both knees was 23.1 (20.5) points before surgery, and it significantly increased to 42 (19.6) points in the last follow-up ($P < 0.001$). Preoperatively, the mean (SD) OKS was 24.5 (14.9) and 21.8 (19.5) for

the PS and CCK groups, respectively, which increased to 40.9 (18.2) points for the PS group and 43.1 (20.3) points for the CCK group postoperatively. This increase is statistically significant in each group compared to its preoperative scores ($P < 0.001$), although this rate was not significant when comparing the postoperative scores of the two groups ($P = 0.082$ and 0.736, respectively). These results are summarized in Table 2.

### Range of motion

The mean (SD) knee flexion was 90.2° (12.3°) for both knees prior to surgery and increased to 118.3° (16.2°) after the operation. The preoperative mean (SD) knee flexion for the CCK group was 92.2° (18.2°), which increased to 119.1° (19.5°) postoperatively. The mean (SD) knee flexion for the PS group was 88.3° (16.8°) before and 117.6° (18.5°) after surgery. A substantial improvement in knee flexion in both PS and CCK prostheses is noticed compared to each group's preoperative scores ($P < 0.0001$). However, the difference in the postoperative flexion was not significant between the two groups ($P = 0.27$ and $P = 0.26$, respectively). These results are summarized in Table 3.

**Table 2: Oxford Knee Score**

| OKS | Mean±SD | | *P* |
|---|---|---|---|
| | Preoperative | Postoperative | |
| Both knees | 23.1±20.5 | 42±19.6 | <0.001 |
| PS group | 24.5±14.9 | 40.9±18.2 | <0.001 |
| CCK group | 21.8±19.5 | 43.1±20.3 | <0.001 |

OKS: Oxford Knee Score, SD: Standard deviation, CCK: Constrained condylar knee, PS: Posterior-stabilized

**Table 3: Pre and postoperative knee flexion**

| Knee flexion (°) | Mean±SD | | *P* |
|---|---|---|---|
| | Preoperative | Postoperative | |
| Both knees | 90.2±12.3 | 118.3±16.2 | <0.001 |
| PS group | 88.3±16.8 | 117.6±18.5 | <0.001 |
| CCK group | 92.2±18.2 | 119.1±19.5 | <0.001 |

SD: Standard deviation, CCK: Constrained condylar knee, PS: Posterior-stabilized

### Subjective assessment

The patients were blinded to the type of prosthesis used in each knee.

When questioned at the final follow-up visit, the difference between the two knees was not felt by 18 out of the 20 patients. Two patients, however, evaluated the CCK prosthesis as the better knee. None of the patients favored the PS side over the CCK side. This difference was not statistically significant.

## Discussion

The most important finding of our study was that in patients with severe (more than 10°) varus, the functional outcomes of primary TKA using the fixed-bearing PS prosthesis were not substantially different from those of CCK prosthesis.

Knee OA is a major cause of pain and diminished activity in the aging population.[1,2,10] For severe painful knee OA refractory to conservative treatment strategies, total joint arthroplasty remains the preferred method of treatment in selected patients.[11] It is estimated that the number of TKAs performed in the United States will rise to 3.48 million annual cases by over 670% increase by 2030.[1,12] According to the Iranian Joint Registry, the number of primary TKAs conducted in Iran between 1990 and 2002 almost tripled.[13]

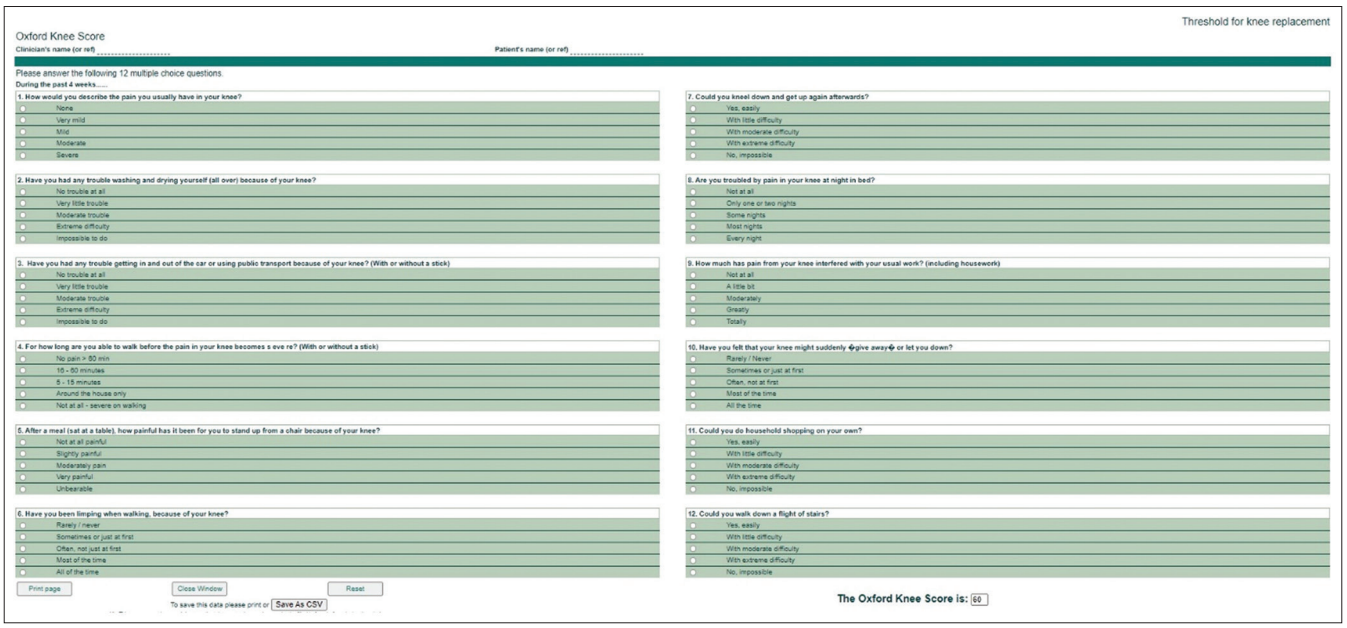


**Figure 2: The Oxford Knee Score**

Although very successful, knee replacement has some drawbacks. The two leading causes of revision total knee surgeries in the United States are infection and mechanical loosening which place a substantial burden on the health system.[14] Improper mechanical balance might be a major cause of early component loosening. In a retrospective study of 8598 arthroplasties, Berend *et al*.[15] declared that a preoperative deformity ≥3° of varus on the tibia was a risk factor for medial-sided collapse. Some authors have reported that the rate of aseptic loosening of the tibial component is substantially higher in patients with severe varus than in patients with less severe preoperative deformity.[16,17] Gap balancing techniques are also more difficult in patients with severe varus deformity. The selection of a more constrained prosthesis system such as CCK is one of the ways of dealing with the problematic primary TKA in severe tibia vara.[18] However, due to the reported higher rates of complications in high constraint systems and more bone cuts,[2] the use of these systems must be limited to cases with clear indications. The problem is that despite the well-established results of CCK prosthesis in revision procedures, the outcomes of primary TKA with CCK are currently not clear.[19] There has yet to be a large-scale clinical trial that compares the outcomes of knee replacement with CCK versus conventional PS/CR prostheses.

In a study by Badawy *et al*.,[19] the revision risk of primary constrained and hinged TKA with unconstrained TKA on 401 cases from the Norwegian Arthroplasty Register was investigated. They reported that when septic revisions are excluded from the results, hinged and CCK implants had similar performance to unconstrained TKA. These findings are consistent with our results, but the functional outcomes were not reported.

In a systematic review by Avino *et al*.,[20] it was concluded that varus–valgus constraint in primary TKA is associated with significant clinical improvement without significant risk of early failure. However, this risk was extended beyond 5 years of follow-up.

Carneiro *et al*.,[1] in a study of 30 primary TKAs with CCK implant, reported 63.3% excellent and 23.3% good results in pain scores with no signs of radiographic lucency and concluded that the CCK implant is an acceptable option for primary TKA.

Czekaj *et al*.[3] studied the outcomes of a low-constraint mobile-bearing knee prosthesis for severe coronal deformities and reported an excellent IKS of 93.8 (±7.4) and function score of 82.4 (±20.2) which is in agreement with the current study.

In 2006, Lachiewicz *et al*.[21] studied the 10-year survival rate and clinical outcomes of CCK knee replacements. A total of 54 knees from 44 patients were examined in this study. The researchers discovered that surgery failed in 2 out of 44 patients, and 12 had excellent results, 24 had good results, 3 had relatively good results, and the remaining 3 cases were weak. According to this study, the Knee Score improved significantly, but the Functional Score did not change significantly. Preoperatively, the average range of motion in the knee was 93°, which increased to 97° postoperatively. Finally, Lachiewicz *et al*. reported a 96% 10-year survival rate for the prosthesis. Most of these results are consistent with our study.

The major drawback of all the previously mentioned studies was the lack of a matched control group that we tried to overcome by performing bilateral one-stage arthroplasties. In this study, we used two different types of prostheses to perform on two knees of a patient with severe bilateral OA and a varus degree of at least 10°. In terms of functional outcome scores (KSS and OKS) and range of motion, both the groups significantly improved compared to the preoperative status. There was no significant difference in scores, knee flexion, and patient preference in the follow-up visits.

The most notable limitation of our study is the limited number of cases which could shadow the clinical importance of the results. Further randomized clinical trials are required for more precise results.

## Conclusion

In this study, we demonstrated that a fixed-bearing PS prosthesis can produce equal functional results in the short term when compared to a CCK prosthesis in cases of severe varus deformity of the knee. The authors advise that a soft-tissue release be performed adequately during TKA surgery on a knee with severe varus deformity and a more constrained implant be reserved only for the cases of severe instability because of the higher cost and the need for more bone removal.

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### Conflicts of interest

There are no conflicts of interest.

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