Robotic-Assisted Unicompartmental Knee Arthroplasty Reduces Components' Positioning Differences among High- and Low-Volume Surgeons

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Abstract

Robotic-assisted medial unicompartmental knee arthroplasty (mUKA) has been introduced to improve accuracy in implant positioning and limb alignment, overcoming the reported high failure rates of conventional UKA. Indeed, mUKA is a technically challenging procedure strongly related to surgeons' skills and expertise. The purpose of this study was to evaluate the likelihood of robotic-assisted surgery in reducing the variability of coronal and sagittal component positioning between high- and low-volume surgeons. We evaluated a prospective cohort of 161 robotic mUKA implanted between May 2018 and December 2019 at two high-volume robotic centers. Patients were divided into two groups: patients operated by "high-volume" (group A) or "low-volume" (group B) surgeons. We recorded intraoperative lower-limb alignment, component positioning, and surgical timing. Postoperatively, every patient underwent a radiographical protocol to assess coronal and sagittal femoral/tibial component alignment. Range of motion and other clinical outcomes were assessed pre- and 12 months postoperatively by using oxford knee score, forgotten joint score, and visual analog scale. Of 161 recruited knees, 149 (A: 101; B: 48) were available for radiographic analysis at 1 month, and clinical evaluation at 12 months. No clinical difference neither difference in mechanical alignment nor coronal/sagittal component positioning were found ($p > 0.05$). A significant difference was recorded in surgical timing (A: 57 minutes; B: 86 minutes; $p < 0.05$). No superficial or deep infections or other major complications have been developed during the follow-up. Robotics surgery in mUKA confirmed its value in improving the reproducibility of such technical procedure, with satisfactory clinical outcomes. Moreover, it almost eliminates any possible differences in component positioning, and lower limb alignment among low-and high- volume knee surgeons.

Keywords

- medial unicompartmental knee arthroplasty
- robotic-assisted surgery
- MAKOplasty
- component positioning
- high- and low-volume surgeons

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Medial unicompartmental knee arthroplasty (mUKA) is a grounded successful treatment for patients with an isolated end-stage disease affecting the medial compartment of the knee joint.[1] It is already well established that, in those patients suitable for a mUKA, this procedure has some advantages compared with total knee arthroplasty (TKA) including shorter operating time, better restoration of native kinematics preserving the natural knee (preservation of bone stock as well as decrement in periarticular soft-tissue trauma), lower overall complication rate, and improved both short-term clinical outcome and patient satisfaction.[2–4] However, many national arthroplasty registries show that the durability of mUKA in terms of long-term implant survivorship and revision rates is comparable to TKA.[5–8] mUKA is a technically demanding procedure and failures mostly derived by suboptimal/malposition of the components and limb malalignment, and osteoarthritis progression of the previously unaffected knee compartments.[9,10] Recent studies report lower survivorship rates of those implants performed in low-volume centers compared with high-volume centers,[11,12] meaning that, despite an accurate patient selection and preoperative planning, the mUKA realized only based on the surgeons' skills and expertise still remains an operator-dependent procedure.

Over recent years, the advent of new technologies and in particular the robotic-assisted surgery have been introduced to minimize those surgical variables leading to early failure, and improving the reliability upon limb alignment,[13,14] implant positioning,[9,15,16] and soft tissue balancing.[17]

The latest literature has been mainly focusing on analyzing the survival rate of the robotic mUKA, but to date, we can only expect short-term results because of the relatively recent introduction of the robotics in this field. Therefore, we might have been expected to find high survival rate at the short-term follow-up,[18] which is not so different from the short-term results derived by conventional UKA or TKA.[19,20]

We focused our prospective cohort study on the assessment of correct lower limb alignment and component positioning performed both by high-volume surgeons (group A) and low-volume surgeons (group B).

The purpose of this study was to answer the question if robotic-assisted surgery could minimize the difference among high- and low-volume surgeons in performing such technical surgical procedure. This could have major effects in the analysis of future prospective long-term survivorship studies reducing the bias related to the variability of implant positioning. An affirmative answer to our question could mean that robotics, despite the initial costs, may decrease the burden of revision disease reducing the overall costs to the health care system even if mUKA is done in low-volume centers or by low-volume surgeons.

Materials and Methods

We report a prospective cohort study about component alignment in robotic mUKA comparing two groups of patients operated by "high-volume" (group A) or "low-volume" (group B) surgeons between May 2018 and October 2019 at two high-volume centers for robotic surgery. Each patient was operated by a surgeon with at least 5 years of experience in this field. The same operating surgeon performed also the clinical evaluation and gave the indication for surgery. According to the number of mUKA performed early by the surgeon, patients were allocated in two groups: the "high-volume group" for those patients operated by a surgeon performing more that 30 robotic UKA every year (group A) and the "low-volume group" for those patients operated by a surgeon performing equal or less than five robotic UKA every year (group B). Patients' allocation and demographic data were reported in ►**Table 1**. Finally, 157 consecutive patients (161 knees) treated with robotic-assisted mUKA due to medial osteoarthritis of the knee were included in this study. Indication for mUKA was similar for both groups and was isolated medial osteoarthritis (Kellgren-Lawrence grade III–IV),[21] osteonecrosis of the medial condyle, reducible deformity, and stability in sagittal plane. Contraindications were patients with lateral or patellar osteoarthritis, inflammatory arthritis, ligament insufficiency or fixed flexion or varus deformity >10 degrees, patients operated by surgeons with less than 5 years of experience and with a yearly surgical volume between 6 and 30 mUKA.

The study and follow-up, respecting the criteria of the Declaration of Helsinki, have been approved by our institutional review boards. The institutional review boards accepted the proposal of the study, and all selected patients were properly informed before surgery about the treatment and follow-up visits after discharge.

Table 1 Patients' allocation and demographic data

	High volume	Low volume	*p*-Value
Number of mUKA	108	53	NA
Number of surgeons	3	12	NA
Mean operation for surgeon (min–max)	36 (32–39)	4.4 (2–5)	NA
Age (y)	67 ± 7.3	65 ± 8.4	0.556
BMI (kg/m^2)	25.6 ± 4.2	24.3 ± 4.3	0.639
Gender ratio (M:F)	48:60	25:28	NA
Side ratio (L:R)	51:57	23:30	NA

Abbreviations: BMI, body mass index; mUKA, medial unicompartmental knee arthroplasty; NA, not applicable.

Surgical Technique

All patients received a preoperative CT and a three-dimensional computer model of the knee is realized to plan the implant position and bone resection to restore the joint anatomy. Patients were placed supine, pneumatic tourniquet was applied on the upper thigh, inflated during the bone cut, and released after the cement had set to allow hemostasis before wound closure. The whole series of mUKA was performed by using the MAKOplasty robotic instrumentation kit (MAKO Surgical Corp, Stryker). A mini-parapatellar approach was performed in all

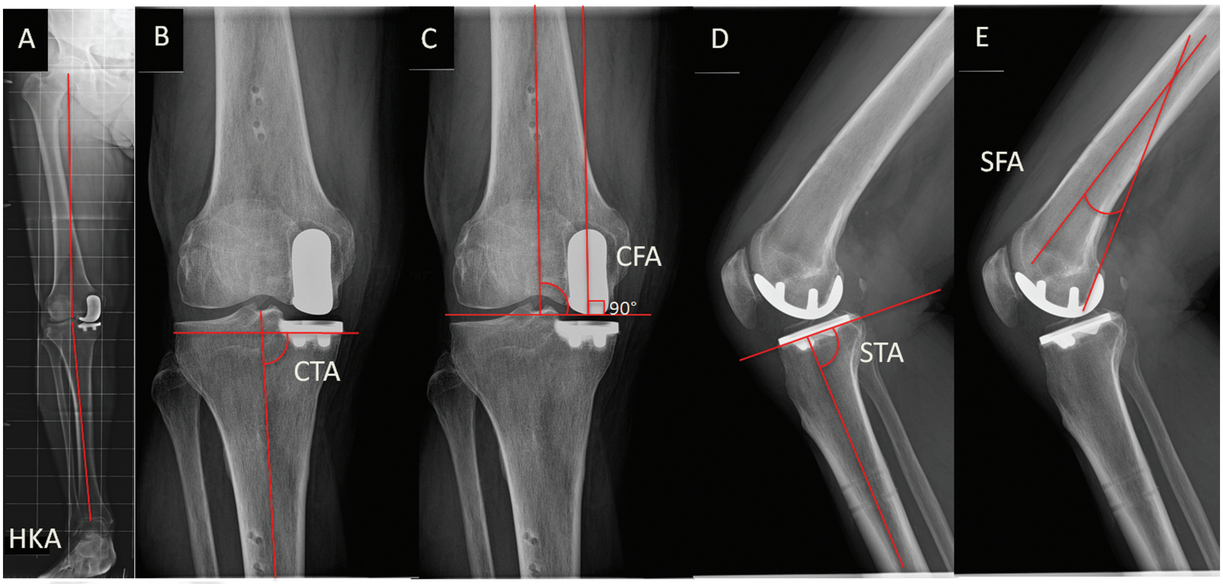

Fig. 1 (A) Hip-knee-ankle angle; (B) coronal tibial component angle; (C) coronal femoral component angle (D) sagittal tibial component angle; and (E) sagittal femoral component angle.

cases with a subvastus extension when required. Anatomical landmarks were recorded by using optical motion capture system to match the three-dimensional CT models with the landmarks (The Crisis software MAKO Surgical Corp, Stryker). Joint balancing and tracking of the virtual component were then performed, and component position was fine-tuned to obtain proper soft tissue balance. After all adjustments were completed, the robotic arm was used to perform tibial and femoral resection through a high speed-burr that haptically guides and controls the cuts. Then trial components were put in place, and a new calibration was made to check if there were any differences between the previous accepted planning. Consequently, the components (MCK Restoris Knee, Stryker) were cemented after a proper pulse lavage and drying up of the joint. No drainage was used, and the skin was closed in a conventional manner. Details of the MAKO mUKA surgical technique are already described elsewhere.[22]

All patient received the same deep venous thrombosis prophylaxis with low molecular weight heparin once a day (started 12 hours before surgery) and wore class I compressive socks from the day 1 after surgery. Preoperative antibiotic prophylaxis was provided by 2 g of cefazolin 30 minutes before the tourniquet was on and then 1 g every 8 hours for 24 hours postoperatively. Tranexamic acid intravenous infusion (1 mg/kg) was administrated 30 minutes preoperatively and at the time of wound closure.

Radiographic Analysis

Pre- and postoperative weight-bearing radiographs (anteroposterior, lateral, and full-length hip-to-ankle films) were taken 1 month after the surgery in the specialist outpatient clinic. The coronal hip-to-ankle radiographs were taken with the patient standing and the knee in full extension and both malleoli placed 20 cm apart with the toes pointing forward according to the rule described by Moreland et al.[23]

The pre- and postoperative mechanical axis of the lower limb, femoral and tibial component alignment in coronal plane (varus/valgus), and sagittal plane (flexion/extension) were measured by using a specialized software (Carestream Health, Rochester, NY; ►**Fig. 1**). Data were recorded to an accuracy of 0.1 degree. All measurements were independently done by two observers, and the results were analyzed for interobserver variability. The hip-knee-ankle angle (HKA) was measured on the coronal hip-to-ankle radiographs as the angle formed between a line from the center of the femoral head and the center of the knee and a line from the center of the knee and the center of the talus (positive numbers indicating varus alignment and negative numbers indicating valgus alignment).

On the antero-posterior knee radiographs we measured: the coronal femoral component angle as the medial angle formed by a perpendicular line to the major axis of the femoral component and the mechanical axis of the femur, and the coronal tibial component angle coronal tibial component angle as the medial angle formed by tibial component and the mechanical axis of the tibia.

On the lateral knee radiographs, we measured the sagittal femoral component angle as the angle formed by the intersection of posterior femoral resection and the line of the mechanical axis of the femur, and the sagittal tibial component angle as the posterior angle formed at the intersection between a line tangent to the tibial component and a line of the mechanical axis of the tibia.

Clinical Evaluation

Clinical outcomes were assessed postoperatively at 12 months of follow-up by using the Oxford Knee Score (OKS), the forgotten joint score, the visual analog scale (VAS), measuring the range of motion, and recording any complication reported during the postoperative period.

Table 2 Preoperative clinical evaluations' comparison between high- and low-volume surgeons

	High volume	Low volume	*p*-Value
Range of motion (degrees)	112	115	0.523
Mechanical alignment (degrees)	7.3	6.8	0.089
Oxford knee score	20.5	21.3	0.876
Visual analog scale	45.7	52.7	0.565

Abbreviation: SD, standard deviation.

Both groups were comparable for preoperative data as showed in ►**Table 2**.

Statistical Analysis

Statistical analysis was performed by using SPSS statistics software (IBM, Armonk, NY). Normally, distributed continuous variables were compared by using Student's *t*-test taking *p*-values of less than 0.05 as statistically significant with a 95% confidence interval. Continuous variables without normal distribution were analyzed by using the "Mann–Whitney" test. Chi-square test was used to compare categorical variables.

The "intraclass correlation coefficient" (ICC) was used to calculate interobserver variability in measuring angles on X-rays. An ICC between 0.75 and 1.00 was considered as excellent (almost no variability in between the two observers' measurements) with a 95% of confidence interval.

Results

Of 161 recruited knees, 149 (48 knees operated by a low-volume surgeon and 101 knees by a high-volume surgeon) were available for radiographic analysis 1 month after surgery, and their data were analyzed in this study. The same patients were available at 12 months of follow-up for clinical evaluation.

No difference ($p > 0.05$) was reported in mechanical alignment and component position in coronal and sagittal plane between the two groups as show in ►**Table 3**. There were no clinical differences ($p > 0.05$) between the two groups at 12 months of follow-up in OKS, FJS, VAS, and ROM as show in ►**Table 4**. The ICC between the two observers were 0.89 and 0.92 for group A and B, respectively.

Surgical timing among the two groups was statistically significant longer for the low-volume group (group A: 57 minutes, range = 39–93 minutes; group B: 86 minutes, range = 62–135 minutes; $p < 0.05$). No arthroplasty failures were recorded and so no revision surgery was performed in the follow-up period. No superficial or deep infections have been developed during the 12 months of follow-up. Two patients in the high-volume group and one in the low-volume group suffered by superficial wound infection and treated successfully with antibiotics. No other major complication was recorded during the follow-up time.

Table 3 Results of mechanical alignment and component position in coronal and sagittal plane between the two groups (high- and low-volume surgeons)

	High volume (Mean ± SD) (degrees)	Low volume (Mean ± SD) (degrees)	*p*-Value
Mechanical alignment	175.9 ± 2.2	175.5 ± 2.3	0.101
Coronal femoral angle	90.1 ± 1.5	90.3 ± 1.5	0.252
Coronal tibial angle	88.6 ± 1.3	88.9 ± 1.3	0.812
Sagittal femoral angle	17.8 ± 1.8	17.6 ± 1.6	0.229
Sagittal tibial angle	83.4 ± 2.5	84.0 ± 2.4	0.598

Abbreviation: SD, standard deviation.

Discussion

The main finding of the present study was that robotic MAKO assisted surgery virtually reduce any possible variability in components positioning and lower limb alignment among high- and low-volume surgeons, with the only difference concerning the overall surgical timing.

Early failure/revision rates still remain the main concern during the decision-making whether or not to choose in between UKA and TKA.[5–8,24] Apart from differences in failure modalities between mobile or fixed UKA implants, the majority of failures (such as bearing dislocations or aseptic loosening or polyethylene wear or progression of osteoarthritic disease in the other knee compartments) are attributable to component malalignment/malposition strictly connected to surgical technical problems.[10,25–28] An ideal/optimal implant coronal alignment is considered to be 0 degrees, whereas an angle between 3 and 7 degrees is considered as ideal posterior slope.[29,30] It seems quite obvious that overcorrection will end up in overloading of the lateral compartment, accelerating the progression of osteoarthritis.[31] In the same way, undercorrection is associated

Table 4 Clinical results among high- and low-volume surgeons

	High volume	Low volume	*p*-Value
Oxford knee score (0–48)	41.5	39.9	0.897
Forgotten joint score	56.5	54.7	0.538
Visual analog scale (0–100)	3.5	5.5	0.745
Range of motion (degrees)	126	129	0.457
Time of surgery (min) (min–max)	57 (39–93)	86 (62–135)	<0.05

with higher polyethylene wear.[32] It is interesting to notice that Diezi et al[33] showed how important is to take into consideration not only the general limb alignment, but also the relative mismatch malposition of the femoral and tibial component. They reported that an alteration of the coronal (varus/valgus) femorotibial contact angle could increase local stress around three to four times and thus lead to failure. Moreover, to underline the importance of malposition and malalignment, Chattelard et al,[15] in their retrospective multicentre study of 559 mUKA, reported as ≥5 degrees of residual mechanical varus or >6 degrees tibiofemoral components divergence, as well as a greater than 2 mm change in joint space height, a greater than 3 degrees change in tibial component obliquity and a slope value greater than 5 degrees or a change in slope greater than 2 degrees, were factors strongly associated with decreased prosthesis survival. Based on those previous outcome studies, we agreed with Gulati et al and Ridgeway et al to define the range of prosthesis-tibial angle of 87 to 93 degrees as being optimal.[34,35]

Those studies confirm that mUKA is highly sensible to technical parameters; therefore, it could mean that the surgeon might be the main factor for implant failure. Data from national registries show that those surgeons who perform 1 to 2 UKA/year have a yearly failure rate of 4%, while increasing the surgeon performances decrees the revision rate (~10 UKA/year amounts to 2% revision rate; ~30 UKA/year amounts to 1% revision rate).[36] However, therein lies a dilemma; as reported by Murray et al,[37] a surgeon should raise his/her usage of UKA at approximately 20% to reduce the failure rate at the same level of those following TKA. But how could a surgeon do that if not broadening the indications for mUKA? The fact is that enrolling more patients is not the same as enrolling the proper patient candidate to this specific surgery, and it will eventually end up in incorrect patient's selection and consequently higher incidence of early failures.[38] The other solution could be to focus on the surgical procedure reducing the possible intraoperatively technical error of surgeons. Nowadays, new smart technologies such as patient specific instrumentation, computer-assisted surgery, and robotic-assisted surgery have been introduced to improve the accuracy of implant positioning and limb alignment in mUKA.

The present study was designed to evaluate the importance that robotic-assisted surgery could have in the future to reduce surgical errors while performing such a technical procedure regardless of surgeon experience. As far as we know, this is the first prospective in vivo study in which we compared postoperative component positioning and limb alignment among two different group of surgeons, the ones performing more than 30 mUKA annually (high-volume surgeons) and the ones performing ≤5 mUKA/year (low-volume surgeon). There are other studies already published in literature that focus on evaluating component positioning irrespectively of surgeons' experience,[39,40] but those are mainly in vitro (saw bone/cadaveric) studies. Karia et al[40] performed a research on saw-bone to assess the accuracy with which inexperienced UKA surgeons implant the components using robotic assistance compared with conventional instrumentation. They also assessed the effect of repetition has on component positioning accuracy (rotational and translational errors) in both groups. They found that robotic assistance enabled surgeons to achieve precision and accuracy when positioning UKA components, irrespective of their experience. Moreover, they reported that the conventional group's positioning remained inaccurate even with repeated attempts although procedure time improved. In the same way, in our study, we found that the use of robotic MAKO assisted surgery virtually reduce any possible variations in components positioning and lower limb alignment. Even at the postoperative radiographic control, we reported no variability in all the parameters examined (►**Table 3**).

Lonner et al,[16] in their retrospective study, evaluated radiographically (standard radiographs) the tibial components' positioning (both sagittal and coronal view) in two groups of patients, one treated with conventional UKA (27 knees) and one with robotic MAKO assisted mUKA (31 knees). They reported a statistically significant difference in the slope (3.9 vs. 1.9 degrees) and varus (3.8 vs. 1.8 degrees) accuracy positioning. Furthermore, Bell et al[41] were the first to describe both the femoral and tibial component positioning at a CT scan control in three different axial planes (coronal, sagittal, and axial), comparing a group of 58 conventional UKA with 62 robotic-assisted MAKO UKA. In their randomized prospective control study, they found lower median errors in all component parameters taken into account (tibia: sagittal = 7.98 vs. 1.64 degrees, coronal = 3.71 vs. 2.58 degrees, axial = 7.95 vs. 2.97 degrees; femur: sagittal = 6.87 vs. 3.35 degrees, coronal = 5.09 vs. 2.09 degrees, axial = 5.78 vs. 2.70 degrees).

Based on our findings, the only difference we recorded in between Group A and Group B was related to the overall surgical timing. Low-volume surgeons (Group B) performed the surgeries with a statistically signified increase on surgical timing compared with high-volume surgeons (group A: 57 minutes, range = 39–93 minutes; group B: 86 minutes, range = 62–135 minutes; $p < 0.05$). The same findings have been recently confirmed by Vermue et al regarding the use of robotic-assisted surgery in total knee arthroplasty.[42] The authors reported that the robotic-assisted TKA learning curve for surgical timing was significantly affected by the surgical profile (high vs. medium vs. low volume), while the precision of implant positioning and gap balancing showed no learning curve.

This study has several limitations. First, we reported only 12 months of follow-up, but the purpose of the research was to be a prospective cohort study evaluating some technical and radiographical results of a surgical procedure and not to evaluate its survivorship. Therefore, survival rates analysis was beyond the purpose of this study. However, because of the robotics has come out just recently in this field of orthopedics, mid- and long-term outcomes are lacking. Recently, Pearl et al[18] published a study about short-term survivorship and patient satisfaction of robotic-assisted mUKA. In their multicentric prospective study, at a mean follow-up of 2.5 years, they found high survivorship and high satisfaction rate of robotic-assisted mUKA. They also performed a worst-case scenario analyses that show how those results are almost the same that we can expect from conventional mUKA, meaning that we should not jump to any conclusions till we have longer follow-up studies. Second, we performed every robotic surgery using a single brand semiautonomous system (MAKO, Stryker) that need a preoperative CT scan mapping. It carries two major disadvantages: one is that it adds costs to the overall costs of the robotic procedure and the second is the problem related to the potential radiation risk. Ponzio and Lonner[35] reported that this preoperative long-leg CT scan exposes the patient to a mean radiation dose of 4.8 mSv that is almost the same of approximately 48 chest X-rays. Fortunately, other semiautomatic image-free robotic systems have been recently introduced on the market, and new lower-emission CT technologies have already been under construction.

Cost implementations are perhaps the major deterrent of this technology. It has already reported by Peersman et al[44] that, including the possibility of two revision procedures, conventional UKA yields clear advantages in terms of costs compared with TKA. Recently, a similar state-transition Markov model comparing cost-effectiveness of robotic-assisted UKA versus TKA was developed by Moschetti et al.[45] As it could be expected, they found that robotic-assisted UKA costs more than conventional UKA, but at the same time, it offers slightly better results at the short-term follow-up (0.06 additional quality-adjusted life-years), meaning that there is only an average increase of $47.180 per quality-adjusted life-years. They also reported that this system is cost-effective only for high-volume UKA centers and not for low- and medium-volume arthroplasty Centers (94 UKA per years was found to be the minimum number of performed arthroplasties at a single center to be cost-effective). Finally, Swank et al[46] showed that the overall incremental expenses for robotic-assisted TKA could be retrieved within 2 years when performed in high-volume centers.

Conclusion

Based on our study and on the recent literature, we first confirmed the utility of robotics to improve reproducibility in mUKA, but also demonstrated that it almost eliminates any possible difference in component positioning, and lower limb alignment among high- and low-volume surgeons in performing such a technically complex surgical procedure. Unfortunately, whether or not those results could determine a real decrease in failure rates of mUKA it is far to be demonstrated and will need further long-term study.

Note

The study and follow-up, respecting the criteria of the Declaration of Helsinki, have been approved by the institutional review board of Azienda Ospedaliera Universitaria Careggi Department of Surgery and Translational Medicine. The Institutional Review Board accepted the proposal of the study, and all selected patients were properly informed before surgery about the treatment and follow-up visits after discharge. All patients accepted to have their data been published on a journal.

Authors' Contributions

M.I. and F.M. are the two authors who made both the conception and the design of the work as well as they drafted the first version of the work. Each author has made substantial contributions to the design of the work as well as to the acquisition, analysis, and interpretation of data. All authors have also substantively revised the work and have approved the submitted version (and any substantially modified version that involves the author's contribution to the study), and they have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Conflict of Interest

None declared.

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