Evaluation of the results of anterior cruciate ligament reconstruction using adjustable femoral cortical suspensory fixation device

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Background
The anterior cruciate ligament (ACL) injury is considered the most common ligamentous injury in the knee. As a result, reconstruction of the torn ACL becomes a common surgical procedure for orthopedic surgeons, especially those who are interested in sports medicine.
Objective
This study aims to evaluate the results of ACL reconstruction (ACLR) using adjustable-loop fixation device for the femur and an interference screw for the tibia. Evaluation will be done using Lysholm knee score and the international knee documentation committee (IKDC) score, and by the assessment of the femoral tunnel diameter changes after a follow-up period of 12 months.
Methods
Twenty patients in whom the torn ACL had been reconstructed arthroscopically using transportal technique with an ipsilateral hamstring tendon. All ACLR operations were done by the same surgeon in the orthopedic department at Fayoum university hospital and Abu-Qir insurance hospital during March 2021, and the follow-up period started in April 2021 and ended in April 2022 with an overall follow-up period of 12 months. An adjustable femoral cortical suspensory fixation device was used and the tibial fixation was done using an interference screw. Postoperatively, all patients were evaluated objectively using the anterior drawer test, Lachman test, and pivot-shift test. The subjective evaluation was performed using Lysholm knee score and the IKDC score. To evaluate femoral tunnel changes, a computer tomography (CT) scan was done at four different levels immediately postoperative and after 12 months postoperative.
Results
The selected patients were homogenous at baseline regarding age, Sex, dominance, and disease duration. As regards preoperative examination, the Anterior drawer test and the Lachman test were positive in all patients (100%), while the Pivot-shift test was positive in only 9 patients (45%), but positive in all patients (100%) after anesthesia. After 12 months post-surgery, all patients were reexamined again using the same tests and we found that all tests were negative in all patients. Patients were subjectively evaluated using both Lysholm Knee Score and IKDC score. Preoperatively, the patients' Lysholm score ranged from (49%–74%) with Mean equals (62.3 ± 8.71), and the final Lysholm score after 12 months ranged from (85%–100%) with Mean equals (97.2 ± 4.09). The patients' IKDC score preoperatively ranged from (20.6%–85%) with Mean equals (56.33 ± 17.03), and the final IKDC score after 12 months ranged from (96.5%–100%) with Mean equals (99.5 ± 1.09). So, there was a statistically significant improvement in the objective and subjective clinical outcome measures. As regards the femoral tunnel diameter changes, we noticed that there was some widening in accordance with F1 (5.46%±1.06), F2 (8.39%±0.67), F3 (7.12%±0.93), and F4 (7.23%±0.82), but there was no correlation between femoral tunnel diameter changes and the IKDC score changes nor the overall improvement in functional outcomes.
Conclusion
In transportal ACLR, the use of adjustable-loop fixation device on the femoral side, may lead to favorable clinical and radiological results regardless of femoral tunnel widening.

Keywords:
ACL reconstruction, adjustable-loop device, femoral tunnel widening

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Introduction

ACL is a complex structure whose orientation, construct, and biology are directly related to its function. It has an important role in carrying loads throughout the entire knee motion and so it plays an important role in knee stability and proprioception [1]. The goal of any ACLR is to restore normal knee stability to approximate normal knee kinematics. The fact that so many different methods have been described for the ACLR indicates that the ideal solution to this problem has not yet been found [2]. The autograft arthroscopic single-bundle is the 'gold standard' technique for ACLR. The femoral tunnel placement can be created through either the transportal or the transtibial technique. Given that the most common cause of ACLR failure has been the non-anatomical femoral tunnel placement, the use of the transportal technique for drilling the femoral tunnel was suggested to place the graft in a more anatomical position [3,4].

Graft fixation is an important factor in ACLR, especially in the first two months of healing. Therefore, the fixation must be strong enough to resist in vivo forces during this period. Methods of graft fixation at the femoral side can be classified into *Cortical suspensory fixation* (e.g., EndoButton – TightRope), *Cross pins fixation* (e.g., RigidFix – TransFix), or *Aperture fixation* (e.g., Interference screw). Cortical suspensory devices are available in two varieties, *Fixed-Loop devices* (e.g., EndoButton) and *Adjustable-Loop devices* (e.g., TightRope).

Fixed-Loop device is the 1st generation suspensory fixation with a fixed-length loop. The length of the loop is fixed but it is stiffer and slippage-free which seems to have created a more favorable biomechanical environment [5,6].

Adjustable-Loop device is the 2nd generation suspensory fixation device with an adjustable-length loop which is reduced after flipping by tightening the rope. It allows full-length filling of the graft part of the femoral tunnel and some degree of final tightening to tension the graft even after placement of the graft [5,6].

Many authors reported that one of the pitfalls of the suspensory system is the progressive widening of the femoral tunnel. In fact, it has been reported that suspensory fixation results in an increased rate of tunnel widening (TW) compared with aperture fixation [7]. It is determined by biological and mechanical factors, such as the micro motions of the graft in the tunnel, including the longitudinal (bungee-cord effect) and the transverse (windshield–wiper effect), which in turn may lead to bone TW [8]. Some authors also believe that the tensioning sutures at the button end reduce the loop length and tension on the graft strands in the same direction of graft advancement into the tunnel. This allows optimal graft-to-tunnel fill, reducing graft motion, and optimizing graft-to-bone healing [9].

This study aimed to evaluate the results of arthroscopic ACLR using the femoral adjustable cortical suspensory device and to know if the femoral TW phenomenon could affect the objective and subjective outcomes using CT-scan after a follow-up period of 12 months.

Methods

Participants

In this study, 20 patients with torn ACL were prospectively enrolled. They had their ACL reconstructed using ipsilateral Semitendinosus and Gracilis (ST/G) through the transportal technique. All ACLR operations were done by the same surgeon in the orthopedic department at Fayoum university hospital and Abu-Qir insurance hospital during March 2021, and the follow-up period started actually in April 2021 and ended in April 2022 with an overall follow-up period of 12 months. The inclusion criteria were any patient whose age was between (18–40 years) with symptomatic torn ACL complaining of knee instability especially active patients who wish to continue participating in sports, patients working in heavy labor who need a stable knee, and patients experiencing instability with activities of daily life. The exclusion criteria were any combined ligamentous injury, previous ACLR, and clinical or radiological evidence of mal-alignment or advanced knee osteoarthritis. All patients agreed to participate in this study and signed an informed consent form. The study protocol was approved by the Local Ethics and Experimental Research Committee.

Surgical technique

Surgery was performed arthroscopically using anterolateral (AL), anteromedial (AM), and accessory anteromedial (AAM) portals. Either spinal or general anesthesia was performed according to patient preference. We prescribed prophylactic antibiotics both pre- and post-operatively. Patients were placed in a supine position with the affected knee flexed at the end of the table allowing knee flexion up to 120°. The injured extremity was prepared and draped in the usual sterile fashion after the application of a tourniquet above the operative site with the use of a lateral post to allow for valgus force application on the operated knee. Complete diagnostic arthroscopy was performed to confirm the ACL tear and to address any meniscal injuries. Semitendinosus and Gracilis tendons were harvested through a small incision made over the Pes anserine and were doubled over a single strand of Ethibond. Each end of the strand was whip-stitched using #2 Vicryl. The diameters of the grafts were measured and the femoral tunnels were drilled accordingly. While the knee was at 120° of hyperflexion, a guidewire was advanced through the AAM portal and exited the femur near its midline as regards the lateral view of the femur. The intra-osseous distance was measured and a reamer the same size as the graft was passed over the guidewire and the femoral tunnel was drilled to a depth equal to the amount of the graft planned to be inside the bone tunnel. The average depth that was drilled ranged from 25 mm–30 mm. While viewing through the AL portal and the knee at 70°–90° of flexion, a director ACL tip aimer set at a 55° angle was inserted through the AM or AAM portal into the knee joint. The tibial tunnel was drilled and reamed according to the graft size. A passing suture attached to the guidewire was introduced through the AM portal then, it was retrieved through the tibial tunnel with a grasping instrument. The two limbs of #2 Vicryl were passed through the *Adjustable-Loop device* strands attached to the graft and then, retrieved through the lateral femoral cortex. For graft advancement inside the femoral tunnel, the button was pulled through the femur until it exits the lateral cortex to achieve fixation and flip. After flipping, we adjusted the length of the suspensory device and advance the graft till complete encroachment of the graft inside the tunnel. After knee cycling and while the knee was extended, an interference screw one size larger than the graft was applied while maintaining the tension of the tibial end of the graft.

Follow-up and rehabilitation

After ACLR, patients were encouraged to use cold therapy for 48 h and to bear weight as tolerated with the use of crutches. Patients were instructed to keep their legs propped up to 1–2 pillows. The pillows were placed under their foot or calf muscle 4 – 6 times a day for the first week after surgery and not behind their knee. All patients were followed up after 2 weeks for removal of stitches, 6 weeks, 3 months, 6 months, and up to 1 year. An accelerated rehabilitation program was followed and applied with an emphasis on full extension and active quadriceps isometric exercises immediately postoperative. Full weight-bearing was allowed as soon as it was tolerated. Unrestricted return to sports or activity was allowed between 6 – 9 months after surgery.

Clinical evaluation

An objective assessment of stability was performed through the execution of the Anterior drawer test, the Lachman test, and the Pivot-shift test. Subjective evaluation was performed using the Lysholm Knee Score and IKDC score. All patients were assessed at a 12-month follow-up visit by an operator who was different from the surgeon.

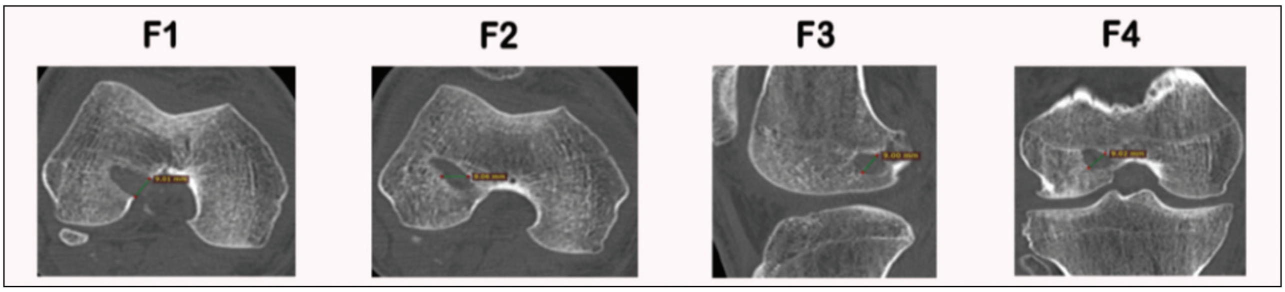
Radiological evaluation

All patients underwent CT examination with Toshiba Computerized Tomography (MX 8000 16 layers; GE Light Speed 16-layers) immediately after surgery, and 12 months postoperatively to study and evaluate the changes that happened in the femoral tunnel diameter according to the CT protocol described by *Ferretti et al.* [10]. The scan was performed considering a section that included the area of the femoral tunnel in addition to 2 cm of additional margin. Measurements were taken at four different levels and all of the diameters were calculated in millimeters by using the software 'RadiAnt DICOM Viewer version no. 19007'. Specifically, image acquisitions were obtained through a volumetric mode; a volume was scanned, and the raw data sets were subsequently manipulated, thus allowing post-process reformation along all of the axes (perpendicular, horizontal, and oblique). All of the measurements were performed by an expert radiologist who was blinded. Four scans determined the tunnel diameter (Figs 1 and 2): [F1] femoral tunnel at the notch, axial image; [F2] femoral tunnel at the middle third, axial image; [F3] femoral tunnel in the middle point, on the sagittal image; [F4] femoral tunnel in the middle point, on coronal image.

Sample size

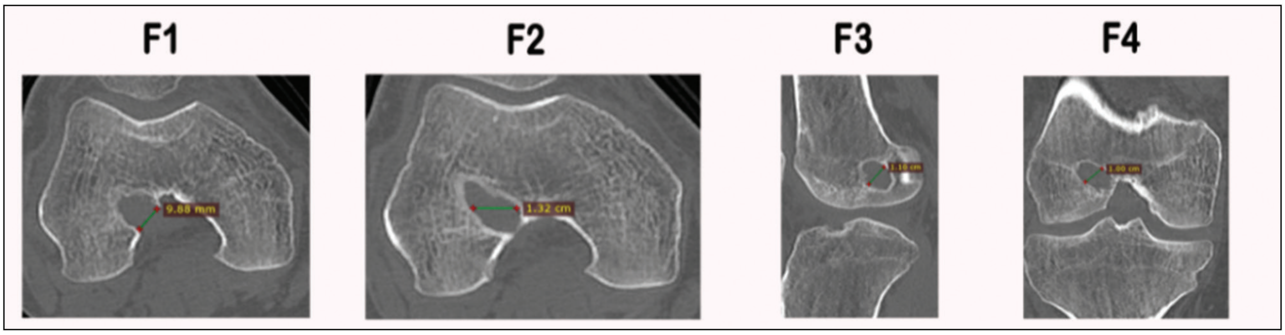
Power analysis was performed a priori in accordance with the femoral tunnel enlargement values from the CT scans. Assuming a two-tailed α value of 0.05 (sensitivity 95%), a β value of 0.20 (study power: 80%), and an effect size value of 0.80, we determined that at least 20 patients were required for the study.

Figure 1



Postoperative CT showing femoral tunnel at [F1, F2, F3, and F4].

Figure 2



Follow-up CT after 12 months showing femoral tunnel at [F1, F2, F3, and F4].

Statistical analysis

Statistical analysis was done using the 'SPSS software package version 20.0. Quantitative data were expressed as mean±standard deviation (SD). Qualitative data were expressed as frequency and percentage. The following tests were done: Independent-samples t-test of significance was used when comparing two means; *P* value ≤0.05 was considered significant.

Results

The demographic data of the patients regarding Sex, age, affected side, meniscal injury, time-lapse from injury to surgery, and mechanism of injury are illustrated in (Table 1).

Table 1 Baseline patient characteristics

Sex	
Male	20 (100%)
Female	0 (0%)
Age (years)	
≤30 years	14 (70%)
>30 years	6 (30%)
Affected Side	
Right	12 (60%)
Left	8 (40%)
Meniscal injury	
Free	9 (45%)
Medial	10 (50%)
Lateral	1 (5%)
Time Lapse from injury to surgery	
≤8 months	15 (75%)
>8 months	5 (25%)
Mechanism of injury	
Contact	13 (65%)
Non-contact	6 (30%)
Traffic	1 (5%)

As regard preoperative examination, the Anterior drawer test and Lachman test were positive in all patients (100%), while the Pivot-shift test was positive in only 9 patients (45%), but positive in all patients (100%) after anesthesia. After 12 months post-surgery, all patients were reexamined again using the same tests and we found that all tests were negative in all patients, which is considered an excellent functional outcome.

Patients were subjectively evaluated using both Lysholm knee score and IKDC score. As regard Lysholm knee score, the result is illustrated in (Table 2). Preoperatively, the patients' Lysholm score ranged from (49%–74%) with Mean equals (62.3 ± 8.71), and the final Lysholm score after 12 months ranged from (85%–100%) with Mean equals (97.2 ± 4.09) which is considered an excellent result.

As regard the evaluation using the IKDC score, the patients' IKDC score preoperatively ranged from (20.6%–85%) with Mean equals (56.33 ± 17.03), and the final IKDC score after 12 months ranged from (96.5%–100%) with Mean equals (99.5 ± 1.09) which is considered an excellent result. According to the IKDC score results, patients were considered as unsatisfactory (Poor and Fair) results, and as satisfactory (Good and Excellent) results. When comparing the IKDC score before and after surgery as shown in (Table 3), we noticed a statistically significant improvement in the subjective clinical outcome measures (*P* value ≤0.05).

CT scan was done on the patients to assess the femoral tunnel changes as illustrated in (Table 4). After comparing the measurements of the femoral tunnel diameter immediately postoperative and 12 months post-surgery, we noticed that there was some widening in accordance with **F1** (5.46%±1.06), **F2** (8.39%±0.67), **F3** (7.12%±0.93), and **F4** (7.23%±0.82).

After analysis of the postoperative femoral TW values in accordance with the postoperative total IKDC score, there was no correlation between the femoral tunnel diameter changes and the IKDC score changes (Table 5). So, although we noticed some widening in the femoral tunnel diameter, this widening did not affect the overall improvement in the functional outcomes.

Table 2 Distribution of the studied cases according to lysholm knee score

	Preoperative (*n*=20)	Postoperative (*n*=20)
	%	%
Limp		
(5)	40	100
(3)	60	-
Using Crutches		
(5)	100	100
Locking		
(15)	30	100
(10)	55	-
(6)	10	-
(2)	5	-
Giving way		
(25)	0	90
(20)	35	5
(15)	15	5
(10)	30	-
(5)	20	-
Pain		
(25)	0	75
(20)	20	20
(15)	20	5
(10)	55	-
(5)	5	-
Swelling		
(10)	30	90
(6)	60	10
(2)	10	-
Climbing stairs		
(10)	15	100
(6)	80	-
(2)	5	-
Squatting		
(5)	30	80
(4)	35	20
(2)	35	-
Min. – Max.	49%–74%	85%–100%
Mean±SD	62.30%±8.71	97.15%±4.09

Discussion

There are multiple options for the femoral fixation of a soft tissue graft in ACLR. Devices for femoral fixation can be divided according to their underlying mechanisms: *Compression* (producing compressive loads to the longitudinal axis of the graft), *Expansion* (producing a bulging of the graft), or *Suspension* (suspending the graft into the femoral tunnel). More recently, suspensory devices have gained increasing interest; they adopt a suspension mechanism and are fixed more or less far away from the knee joint.

Table 4 Femoral TW values in accordance with CT scans

CT scan	Immediate postoperative	12 months postoperative
F1 mm (SD)		
Mean±SD.	9.16 ± 0.23	9.66 ± 0.27
Change	**↑ 0.50±0.10**	
% of change	**↑ 5.46%±1.06**	
F2 mm (SD)		
Mean±SD.	9.24 ± 0.26	10.02 ± 0.29
Change	**↑ 0.78±0.06**	
% of change	**↑ 8.39%±0.67**	
F3 mm (SD)		
Mean±SD.	9.28 ± 0.24	9.94 ± 0.27
Change	**↑ 0.66±0.09**	
% of change	**↑ 7.12%±0.93**	
F4 mm (SD)		
Mean±SD.	9.28 ± 0.22	9.95 ± 0.25
Change	**↑ 0.67±0.08**	
% of change	**↑ 7.23%±0.82**	

Table 5 Correlation between IKDC score change and femoral tunnel diameter change

Femoral tunnel diameter changes	IKDC score changes	
	r_s	*P*
F1 (Axial, Notch)	0.494	0.027*
F2 (Axial, M/3)	-0.291	0.214
F3 (Sagittal, M/2)	-0.136	0.568
F4 (Coronal, M/2)	-0.290	0.216

r_s: Spearman coefficient.
*Statistically significant at *P*≤0.05.

Table 3 Distribution of the studied cases according to IKDC score

	Preoperative (*n*=20) Number (%)	Postoperative (*n*=20) Number (%)	*P*
IKDC Score			
Unsatisfactory	17 (85%)	0 (0)	^{MCN}p<0.001*
Satisfactory	3 (15%)	20 (100%)	
Poor (<60%)	11 (55%)	0 (0)	^{MH}p<0.001*
Fair (60%–75%)	6 (30%)	0 (0)	
Good (75%– 90%)	3 (15%)	0 (0%)	
Excellent (>90%)	0 (0)	20 (100%)	
Min. – Max.	20.60–85.0	96.50–100.0	^{t}p<0.001*
Mean±SD.	56.33 ± 17.03	99.59 ± 1.09	
Median	56.30	100.0	

MCN, McNemar test; **MH,** Marginal Homogeneity Test; **p:** *P*-value for comparing pre and postoperative results; **t:** t-paired test.
*Statistically significant at *P*≤0.05.

Examples of cortical suspension devices are buttons and they are subclassified into fixed-loop and adjustable-loop devices [10]. Most of the studies in the literature evaluated the suspensory fixation device from the biomechanical point of view with few studies evaluating the functional outcomes.

In our study, the most important finding was that the suspensory fixation device provided satisfactory outcomes in terms of knee stability and functional recovery and also, there was some widening in the femoral tunnel diameter, however, this widening had no significant effect on the final overall functional outcomes. The patients have been followed up to 12 months and were subjectively evaluated using both the Lysholm knee score and IKDC score. As regard Lysholm knee score, the scores improved from (49%–74%) preoperatively to (85%–100%) at the end of the follow-up period, while IKDC scores improved from (20.6%–85%) preoperatively to (96.5%–100%) at the end of the follow-up period which is considered an excellent result.

Hardik *et al.* [11] evaluated the outcomes of arthroscopic ACLR in a prospective study of 62 patients with ACL deficient knees using a fixed suspensory device and adjustable suspensory device for femoral side graft fixation. Functional assessment was performed with Lysholm score and IKDC score before and after surgery. The postoperative Lysholm score in the fixed-loop group and adjustable loop group was 94.23% and 94.32% respectively. The IKDC score in the fixed group and the adjustable group was 92.03% and 92.16% respectively. These results are nearly the same as our end results.

Tunnel enlargement after ACLR is not yet fully understood, although it is the main focus of many studies. Many authors showed that tunnel enlargement is more evident in the femoral tunnel than in the tibial tunnel. In our study, we noticed that there was some femoral TW in accordance with F1 (5.46%±1.06), F2 (8.39%±0.67), F3 (7.12%±0.93), and F4 (7.23%±0.82), but there was no correlation between femoral tunnel diameter changes and the IKDC score changes nor the overall improvement in functional outcomes.

Femoral TW can be determined by biological and biomechanical factors [7]. Biological factors are first related to an immune response causing the resorption of the interference screw and secondly to osteonecrosis due to hyperthermia after tunnel drilling. Biomechanical factors related to micromotion of the graft tissue in the tunnel, including the longitudinal (bungee-cord effect) and the transverse (windshield–wiper effect) graft motions within the bone tunnel, which in turn may lead to bone tunnel dilation. The longer the distance between the fixation point and the joint surface, the longer the intra-canalar graft portion without fixation, and hence the greater the TW proximal to the joint surface [8]. A possible hypothesis comes from a recent study on KSSTA, in which have been evaluated biomechanical factors, morphology, and immunohistochemistry in the murine model that underwent ACLR. It shows that peri-implant bone resorption is a time-depending process, sustained by metalloprotease and CD68+ cells within 6 weeks [12].

Nowadays radiological imaging upgrades can combine morphology and metabolism of ligaments like in PET-MRI, and some studies suggest that biological rearrangement, after ACLR, continues up to 24 months postoperatively [13]. However, in literature, there are many attempts to modify TW, either from the biological side, with the controversial use of PRP [14], preserving ACL remnant [15], hybrid graft [16], alendronate [17], manual drilling to reduce terminal stress on the bone [18];or either from the biomechanical side, improving tunnel position [19] and fixation systems stiffness. All these studies are conducted on little patient cohorts or animal models; therefore, we should continue research to well-understand the biological factors combined with the biomechanical element that causes the TW phenomenon.

In the literature, there are different radiological protocols for the study of femoral tunnel enlargement, including radiographs and magnetic resonance [20]; however, we chose a protocol with a CT examination because it appears to be the most accurate method, as demonstrated by Marchant *et al.* [21] and Rathnayaka [22]. The decision to choose a follow-up period of 12 months was because this was the period in which most femoral TW occurred. Peyrache *et al.* [23] reported 16% tunnel dilation 3 months after surgery with no diameter change for up to 2 years and a reduction of 7% over 3 years. Webster *et al.* [24] showed that the enlargement of the femoral tunnel is more evident in the 4 months following surgery without any change in diameter for up to 2 years after the surgery. Finally, in recent work in MR, Weber [25] shows that there is a progressive increase in femoral tunnel diameter from the 6th to the 24th week after surgery, continuing to increase up to 12 months after surgery and reducing slightly after 24 months post-surgery. We performed a single measurement after 12 months that should be indicative of the maximum postoperative enlargement.

In our opinion, a long-term study is recommended to validate the results and conclude more information about femoral tunnel diameter changes and if there will be a regression in the femoral TW noticed in our study.

Conclusion

Based on this study, we can conclude that using the adjustable suspensory fixation device for single-bundle transportal ACLR produces favorable functional results and that femoral TW has no effect on the final clinical and functional outcomes.

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Nil.

Conflicts of interest

All authors declare that they have no conflicts of interest.

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