Original Article

Fistula laser closure versus lay open and primary sphincter repair versus staged rerouting operation in management of trans-sphincteric perianal fistula: A prospective randomized controlled trial

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ABSTRACT

Background: Peri-anal fistula is one of the prevalent anal diseases. Controlling the infection and preserving faecal continence are the primary objectives of therapy. Surgeons frequently employ fistulotomy, primary sphincter repair, phased rerouting procedures, and fistula tract laser closure (FiLaC), a recent sphincter-preserving technique also used to treat peri-anal fistulas.

Aim: To assess outcome and efficacy of FiLaC versus lay open and primary sphincter repair versus staged rerouting operation in management of trans-sphincteric perianal fistula.

Patients and Methods: This was a prospective randomized controlled trial that was conducted at Ain Shams University Hospitals. It included 45 patients diagnosed with transsphincteric perianal fistula. The study period was 18 months, including 6 months duration for follow-up. Study began in August 2022.

Results: Our results showed that FiLaCgroup has higher recurrence rate compared with other two groups at 3 and 6 months follow-up. Although in terms of postoperative pain (visual analog scale (VAS) score) There was a highly statistically significant difference between the three study groups (*P=0.001*). As FiLaC group showed a low postoperative VAS score when compared with the other two groups. Together with operative time and postoperative hospital stay, results showed that FiLaC group was superior in comparison to the other two groups (*P=0.001*). Otherwise concerning the postoperative bleeding, wound infection, Healing, and WEXNER score, there was no statistically significant difference detected between the three study groups were (*P>0.05*).

Conclusion: Lay open with phased rerouting and primary sphincter repair had a reduced recurrence rate and a greater success rate. However, in terms of operating time, hospital stay following surgery, VAS score, and WEXNER score, FiLaC was better. All studied approaches were safe and effective in treating trans-sphincteric perianal fistula.

Key Words: Filac, perianal fistula, rerouting, sphincter repair.

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INTRODUCTION

An epithelial-lined trackway that connects the anal canal to the perianal skin is called a fistula-in-ano. The most frequent cause of perianal fistula is an anorectal abscess. An obstruction of the anal gland leads to infection and the development of an anorectal abscess. Trans-sphincteric perianal fistula can occur when the fistula passes through the sphincters because of its close relationship to the sphincter complex[1].

Inflammatory and granulation tissue are characteristics of an anal fistula, which then forms an epithelialized connection between the anal canal and the exterior peri-anal region. Because of the ongoing cell turnover, the fistula tract is constantly filled with debris, which obstructs healing[2].

The relationship between the fistula and the anal sphincters determines its classification. Despite being benign, the illness can give the sufferer ongoing anxiety and stress, affecting his quality of life. The major objectives of therapy are to control the infection and preserve faecal continence[1].

Fistulotomy or fistulectomy (primary or staged, with or without sphincteroplasty), endorectal advancement flap, ano-cutaneous advancement flap, fistula plug, fibrin glue, electrocauterization or fistula track laser closure (FiLaC), ligation of inter-sphincteric fistula tract, and

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setons (temporary draining, cutting) are surgical options for definitive management[3].

The purpose of this study is to evaluate the results and effectiveness of lay open primary sphincter repair versus phased rerouting surgery and FiLaC in the treatment of trans-sphincteric perianal fistula.

PATIENTS AND METHODS:

This was a prospective randomized controlled trial that was conducted at Ain Shams University Hospitals. It included 45 patients diagnosed with transsphincteric perianal fistula divided into three groups each group consists of 15 patients and randomized through a closed envelope technique. Group I underwent laser closure of perianal fistula (FiLaC) procedure. Group II patients underwent a lay open and primary sphincter repair. Group III patients underwent staged rerouting.

The study lasted 18 months from August 2022 to January 2024 at Ain Shams University clinics and was compared according to operative time, postoperative pain, hospital stay, wound healing, fecal incontinence, and recurrence of symptoms.

This study included both male and female patients aged greater than 18 years old and diagnosed with trans-sphincteric fistula by clinical per-rectal examination, MRI and (EUA: Examination Under Anesthesia).

Otherwise, patients diagnosed with trans-sphincteric perianal fistula secondary to any other pathology, rather than infection as malignancy, diverticulitis, trauma, and patients with a history of inflammatory bowel disease as Crohn's, ulcerative colitis and tuberculosis were excluded from this study. Patients with other current anorectal disease as abscess, impaired anal sphincter function or fecal incontinence and patients with history of previous anal surgeries were also excluded.

All patients were subjected to clinical assessment, full detailed medical and surgical history were assessed and history of anal symptoms as pain, bleeding, discharge or pruritis ani. Inspection for any prolapsed tissue, active bleeding, fissures, or hemorrhoids was done. MRI in the anorectal region, (PR: PerRectal) examination to exclude any masses, and assessment of the continence by (Wexner: is a name not abbreviation so no expansion) score were done. Routine preoperative labs; (complete blood count, Coagulation profile, liver and renal functions, viral markers) were done for all patients.

The protocol and all related documentation were approved for ethical and research purposes by the Council of Surgery Department, Ain Shams University, before the start of the study and in compliance with local regulations. Additionally, the Research Committee (REC) of the Faculty of Medicine at Ain Shams University (ASU) approved the study protocol after presenting the permission form, case-record data form, and patient information leaflet.

Operative details

All operations were done, or directly supervised by the same anorectal surgery team. Operations were performed under spinal or general anesthesia. All operations were done in the lithotomy position. The site of the operation was prepared and draped.

Group I (FiLaC): After identifying the internal and exterior fistula apertures, as well as the fistula tract, curettage and saline rinsing of the tract was done. The LASER probe was introduced via the internal aperture after being placed into the external opening and extended into the fistula tract. The probe's tip was then retracted only few mm from the interior entrance. The LASER was used at a 100J energy level and the probe was permitted to proceed into the fistula tract on its own during application and was manually removed when its route was impeded. Any untreated parts of the fistula tract were eliminated by gently withdrawing the probe a few millimeters and then moving it back toward the internal entrance. The LASER probe was withdrawn after every three shots, and the tip was cleaned using gauze dipped in hydrogen peroxide to avoid carbonization. The LASER was turned off when the probe's tip was a few millimeters from the exterior entrance. Excision of the fistula's internal opening is followed by direct closure with 3/0 vicryl suture. Interrupted, absorbable sutures (vicryl 3/0) were used to seal the wound loosely (Fig. 1).

Group II (Fistulotomy with primary sphincter repair): Following the identification of the internal opening and the probing of the tract, the external and internal sphincters were cut to complete the whole lay open from the outer opening to the inner opening. A curette was used to remove the granulation tissues inside the fistula tract after the peripheral portion of the tract was excised. To repair the sphincter muscle, the inner orifice, including the mucosal surface, was excised. Three to four interrupted 2–0 (PDS: Polydioxanone Suture) sutures were used to gather the anal sphincter stumps together and seal the entire fistula tract gap within the muscles. The submucosa and mucosa of the anal canal were then closed with 3–0 vicryl sutures, and the outer part of the wound was left open to allow for adequate drainage (Figs. 2 and 3).

Group III, (staged rerouting): Diathermy was used to coring out the fistulous tract at the beginning of the first stage. At the point when the track passed through the external sphincter, dissection came to an end. The track was then drawn to the intersphincteric space after being separated from the external sphincter by muscle splitting. A few interrupted stitches completely covered the external sphincter opening. The distal portion of the transposed track

was removed and a seton was added if it was too lengthy. Once the first stage wound had fully healed, the second step was carried out. After probing, the intersphincteric fistula was opened. This required the internal sphincter's lowest fibres to split. For appropriate drainage and healing, the track was curetted, and a short cutback was made (Fig. 4).

Urine retention, hemorrhage, abscess development, wound infection, and early incontinence were among the problems that were monitored during the postoperative period. Following surgery, patients got a single intravenous dosage of a third-generation cephalosporin and a week's worth of oral antibiotics. Following the procedure, liquid food intake was initiated in the evening. Bulk laxatives were then taken for at least two weeks, followed by a soft diet for two days.

On the second postoperative day, all patients had their wounds dressed. Before surgery, all patients were given instructions on how to complete the visual analog scale (VAS) interview, which ranges from 0 to 10. A VAS (VAS: 0 for no pain and 10 for greatest pain experienced) was used to quantify the severity of postoperative pain every 8 h for the first 24 h and during weekly follow-up visits. After that, it was recorded at regular intervals.

Monitoring the patients and following them up was done every week for the first 2 weeks, and subsequently every 2 weeks until full recovery. Monthly visits were then scheduled every two months for a total of 6 months of follow-up to identify delayed complications, such recurrence or faecal incontinence. The same skilled surgical team was assigned for all follow-up visits of the patients.

Fig. 1: Laser probe application.

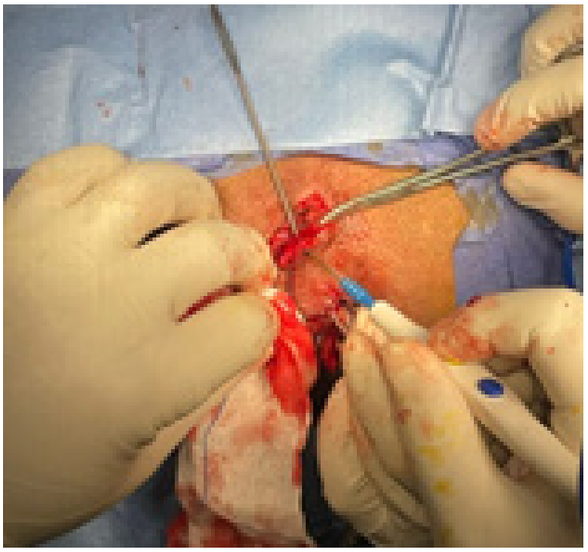

Fig. 2: Identification of internal opening and probing of the tract.

Fig. 3: Sphincterotomy, Edges of sphincter being held for primary repair.

Fig. 4: Seton application.

Statistical analysis

In our study we included 45 patients with perianal fistula who met the inclusion criteria and managed either by FiLaC, lay open and primary sphincter repair or by staged rerouting.

Among FiLaC group, there was no statistically significant difference between the three study groups as regard age *P=0.64*.

As regards the mean operative time, there was a highly statistically significant difference between the three study groups. As in FiLaC group, the mean operative time was 25.9±6.6min. While in the sphincterotomy group was 41.2±6.7min. However, among Staged group was 32.2±4.7min. *P=0.001* (Table 1, Fig. 5).

Regarding postoperative hospital stay, there was a highly statistically significant difference between the three study groups. As the mean postoperative hospital stay was 1±0 among FiLaCgroup. While among sphincterotomy group was 1.9±0.8. However, the staged group was 1.6±0.7. *P=0.001* (Table 1).

Concerning the postoperative bleeding, wound infection, and healing at 1 month follow-up, no statistically significant difference was detected between the three study groups were (*P>0.05*) (Table 1).

As for FiLaC group results showed 6.7% postoperative bleeding, 6.7% wound infection, and 93.3% of cases showed proper wound healing. While in the sphincterotomy group postoperative bleeding, wound infection and healing at 1 month was 13.3, 13.3, and 86.7% of cases, respectively. However, in staged group postoperative bleeding was present among 6.7%, wound infection 6.7%, and healing at 1 month was 86.7% of cases (Table 1).

About postoperative pain (VAS score) there was a highly statistically significant difference between the three study groups were (*P=0.001*). Although at 1, 3, and 6 months follow-up, there was no statistically significant difference between the three study groups (Table 2).

As for FiLaC group results showed a mean postoperative (VAS) score of 2.9±0.59 with median equal to 3. While, sphincterotomy group the mean postoperative pain score (VAS) was 6.0±1.2 with a median equal to 6. However, in staged group the mean postoperative pain (VAS score) was 5.67±0.9 with median equal to 6 (Table 1, Fig. 6).

Among FiLaC group, the mean VAS at 1-, 3-, and 6-month follow-up was 3.6±1.5, 1.1±1.3, 0.53±0.52, respectively, with a median equal to 4, 1, and 1, respectively (Table 2).

While, in the sphincterotomy group the mean VAS at 1-, 3-, and 6-month follow-up was 4.6±1.6, 1.4±1.4, 0.93±0.7, respectively, with a median equal to 4, 1, and 1, respectively (Table 2).

Among staged group the mean VAS at 1-, 3-, and 6-month follow-up was 4.2±1.2, 1.3±1.1, 0.8±0.77, respectively, with a median equal to 4, 1, and 1, respectively (Table 2).

As regards VAS score at 1, 3, and 6 months follow-up, there was no statistically significant difference between the three study groups (Table 2).

Concerning WEXNER score, there was no statistically significant difference between the three study groups at 1, 3, and 6 months follow-up (Table 3).

As for FiLaC group, the mean WEXNER at 1-, 3-, and 6-month follow-up was 0±0, respectively, with a median equal to 0. While in sphincterotomy group the mean WEXNER at 1-, 3-, and 6-month follow-up was 0.4±1.25, respectively, with a median equal to 0. Among the staged group the mean WEXNER at 1-, 3-, and 6-month follow-up was 0.53±1.41, 0.67±1.4, and 0.4±1.2, respectively, with a median equal to 0 (Table 3).

Regarding the recurrence rate results showed relatively higher recurrence in the FiLaC group compared with the other two groups at 3 and 6 months follow-up. As for FiLaC group, Recurrence was 26.7% at 3 month follow-up, and at 6 months it was 26.7%. While among sphincterotomy group recurrence was 13.3% at 3 months and 13.3% at 6 month follow-up. Regards the staged group Recurrence was 0% at 3 month follow-up, and at 6 months it was 13.3%. (9) (Table 4).

Table 1: Comparison between outcomes of the three study groups

	Group							
	Filac		Sphinctrotomy		Staged			
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	*P*	Significance
Operative time	25.93±6.76	25.00	41.20±6.74	40.00	32.27±4.71	33.00	0.001*	HS[a]
Postoperative pain (VAS score)	2.9±0.5	3.0	6.0±1.28	6.0	5.6±0.9	6.0	0.001‡	HS[b]
Postoperative hospital stay	1.00±.00	1.00	1.93±.80	2.00	1.60±.74	1.00	0.001*	HS[a]

	N (%)	*N* (%)	*N* (%)		
Postoperative bleeding					
Negative	14 (93.3)	13 (86.7)	14 (93.3)	1.0**	NS
Positive	1 (6.7)	2 (13.3)	1 (6.7)		
Wound infection					
Negative	15 (100.0)	13 (86.7)	14 (93.3)	0.76**	NS
Positive	0	2 (13.3)	1 (6.7)		
Healing at 1 month FU					
Delayed	1 (6.7)	2 (13.3)	2 (13.3)	1.0**	NS
Healed	14 (93.3)	13 (86.7)	13 (86.7)		

*ANOVA test.
‡Kruskal–Wallis test.
**Chi square test.
aFiLaC versus Sphinctrotomy (HS), FiLaC versus Staged (S), Sphinctrotomy versus Staged (NS) by Post hoc test.
bFiLaC versus Sphinctrotomy (HS), FiLaC versus Staged (HS), Sphinctrotomy versus Staged (NS) by Post hoc test.

Table 2: Comparison between the three study groups as regard VAS score at follow-up

	Group							
	FiLaC		Sphinctrotomy		Staged			
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	*P*	Significance
VAS at 1 month FU	3.60±1.55	4.00	4.67±1.63	4.00	4.20±1.26	4.00	0.23*	NS
VAS at 3-month FU	1.13±1.30	1.00	1.47±1.46	1.00	1.33±1.18	1.00	0.77*	NS
VAS at 6-month FU	0.53±0.52	1.00	0.93±0.70	1.00	0.80±0.77	1.00	0.30*	NS

*Kruskal–Wallis Test.

Table 3: Comparison between the three study groups as regard WEXNER at follow-up

	Group							
	FiLaC		Sphinctrotomy		Staged			
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	*P*	Significance
WEXNER at 1 month FU	0.0±0.0	0.0	0.47±1.25	0.0	0.53±1.41	0.0	0.34*	NS
WEXNER at 3 month FU	0.0±0.0	0.0	0.47±1.25	0.0	0.67±1.40	0.0	0.21*	NS
WEXNER at 6 month FU	0.0±0.0	0.0	0.47±1.25	0.0	0.47±1.25	0.0	0.34*	NS

*Kruskal–Wallis Test.

Table 4: Comparison between the three study groups as regard Recurrence at follow-up

	Group				
	FiLaC *N* (%)	Sphinctrotomy *N* (%)	Staged *N* (%)	*P*	Significance
Recurrence at 3-month FU					
Negative	11 (73.3)	13 (86.7)	15 (100.0)	0.141*	NS
Positive	4 (26.7)	2 (13.3)	0		
Recurrence at 6-month FU					
Negative	11 (73.3)	13 (86.7)	13 (86.7)	0.697*	NS
Positive	4 (26.7)	2 (13.3)	2 (13.3)		

*Fisher exact test.

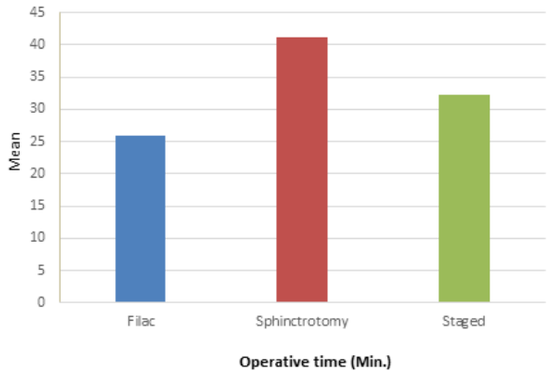

Fig. 5: Comparison between the three study groups as regard operative time.

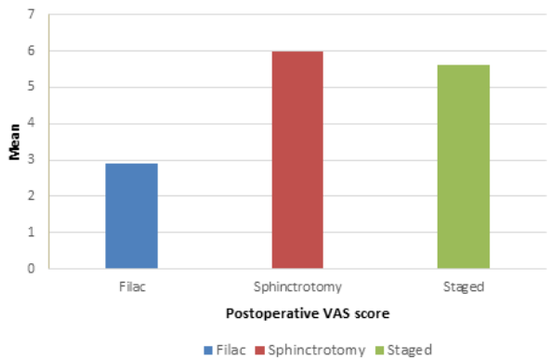

Fig. 6: Comparison between the three study groups as regard postoperative visual analog scale score.

DISCUSSION

Having variable patterns and multiple degrees of complexity, a perianal fistula have always been a challenge for surgical professionals, as it is known for its high rate of complications postoperatively that are usually presented as recurrence and affection of anal sphincter function that could occur with considerable number of operations[4].

FiLaC was designed mainly to treat complex peri-anal fistula being a novel minimally-invasive procedure characterized by sphincter preservation. The Laser effect on the fistula tract is limited to the luminal aspect of the tract without further impact of sphincter mechanism[4].

One of the techniques used to treat complicated peri-anal fistulas is fistulotomy and sphincter reconstruction, which removes infection and restores the sphincter muscle's anatomical integrity[5,6].

Despite having sufficiently good healing rates, it may be linked to issues such as faecal incontinence, especially in cases of significant peri-anal fistulas[7,8].

Rerouting operation was first described by Mann and Clifton. The procedure aimed at converting transsphincteric fistulae into intersphincteric or submucous fistulae, which can then be laid open safely with minimal, or without, sphincter division[9].

The FiLaC procedure was found to be superior when comparing the mean procedural duration and post-operative hospital stay between the three studied groups. This was in line with the findings of Giamundo *et al*.[10], who reported that the average procedural time for a FiLaC procedure was around 20min (range: 6–30min). This was a much lower operative length than the 25.9+/-6.7min duration seen in our study. Given the types of fistulas they examined and the fact that they did not close the inner entrance of the fistula tract while taking into account the laser's shrinking impact, this might be the consequence of a technical discrepancy. In line with our findings regarding postoperative hospital stay, Almahfooz[11] also reported recently that the median length of FiLaC surgery was 18min (range: 10–32min), and that patients stayed in the hospital for no more than one day after the procedure.

Regarding early post-operative complications our follow-up revealed that FiLaC operation resulted in very favorable outcomes and lower pain presented by lower mean VAS score compared with the two other. However, by the third month of follow-up VAS score gradually decreased with time and finished in very low, insignificant scores in all three groups which is consistent with Giamundo *et al*.[10] who stated that morbidity following FiLaC according to their study presented as temporary pain in eight patients out of 45 (18%) patients and the median VAS score for postoperative pain recorded 3.0 in early postoperative period which is close to our results which showed mean VAS score for FiLaC group 3.6 at 1 month follow-up. Also, Marref *et al*.[12] found the postoperative follow-up of the patients showed insignificant complications with minimal pain (VAS <3).

Over the course of the 6-month follow-up, we discovered that the recurrence rates were comparatively higher in the FiLaC group than in the other two groups. Four out of 15 patients, or 26.7% of the total, experienced recurrence after 6 months, which is in line with the Giamundo *et al*. study[10], which found that the recurrence rate was 28.6%, or 10 out of 35 patients, who had FiLaC. In 2015, they conducted a second trial with 45 patients who were monitored for a longer duration; nevertheless, no significant changes were seen.

Regarding group 2 (lay open and primary spincter repair) our results showed 2 out of 15 patients showed recurrence after 6 months, and 13 patients completely healed which represents 13.3% recurrence

rate after 6 months follow-up. This is slighty higher than recurrence rates reported by Arroyo *et al*.[13] They reported that 8.6% of patients with complicated perianal fistulas who had sphincterotomy and primary sphincter repair experienced recurrences; the average follow-up duration was 81 months. In a recent study, Litta *et al*.[14] examined 203 patients with perianal fistulas; the mean follow-up period was 56 months, and the recurrence rate was 7%. Depending on the kind, complexity of the fistula, and length of follow-up, the recurrence rates following fistulotomy and primary sphincter reconstruction vary greatly in the literature for years, ranging from 0 to 16%.

Meanwhile, in group 3 (staged rerouting) our study results showed 2 out of 15 patients showed recurrence after 6 months, representing 13.3% of patients, which is consistent with the worldwide recurrence rate which varies from 0 to 16% according to Vial *et al*.[15].

Regarding fecal incontinence in patients within our study, outcomes were pretty good involving very little impaction in the three groups particularly in the group of FiLaC which showed no fecal incontinence among this group. This finding was fairly consistent with Wilhelm[16] who mentioned that there were minor incontinences (soiling) following FiLaC procedure which persisted for 6 months before it was finally managed, on the other hand Marref *et al*.[12] and Giamundo *et al*.,[10] did not encounter any new incontinence cases or deterioration of previously existed incontinence during follow-up of their patients.

Regarding the rates of incontinence following fistulotomy and primary repair our results showed 2 out of 15 patients showed incontinence within 6 months follow-up representing 13.3% of patients. A great variability within the literature was found (from 3.6 to 21.7%), this variability depends on form and degree of complexity of the treated fistula within these studies[5–13,15,17–19]. Ratto *et al*.[5,17] performed two studies on a large sample of patients, in which close values of incontinence rates were detected (11.6 and 12.4%). Also, Aguilar-Martínez *et al*.[18] reported that 11.2% of their patients had some deterioration of anal continence by the end of follow-up period.

While on evaluation of incontinence rates in group 3 (staged rerouting) we found that 3 out of 15 patients showed symptoms of incontinence within 3 months follow-up with improvement of symptoms of one patient on the 6 months follow-up to show a final result of 2 out of 15 patients with persistent symptoms of incontinence after 6 month follow-up representing 13.3% which is accepted in comparison with the average rate of incontinence following staged operation reported in literature which is 12% (range 0–67%) according to Ritchie *et al*.[19].

It is fair to mention that results of our study might have been affected by some limitations as, its relatively small numbers of patients in the study sample and to a lesser extent the short follow-up period of only 6 months may also be a factor that could limit outcome data, but we also should mention that it is quite challenging to follow-up a large number of patients for a very long period after surgery without losing contact with patients during follow-ups particularly if the patients had a complete recovery, further studies which could overcome these limitations may be of great value and is highly recommended.

CONCLUSION

Lay open with phased rerouting and primary sphincter repair had a reduced recurrence rate and a greater success rate. However, in terms of operating time, hospital stay following surgery, VAS score, and WEXNER score, FiLaC was better. All studied approaches were safe and effective in treating trans-sphincteric perianal fistula.

CONFLICT OF INTEREST

There are no conflicts of interest.

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