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Original article

Efficacy and safety of Micropulse® transscleral cyclophotocoagulation in glaucoma☆

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ABSTRACT

Objective: To report the results using Micropulse® transscleral cyclophotocoagulation (Iridex) in the treatment of glaucoma.

Methods: Retrospective study in adult patients with glaucoma with at least 6 months of follow-up, and only one session of Micropulse®. The same surgical technique was used in all cases. The only laser parameter that could vary was the total treatment duration (in seconds). The remaining parameters were fixed at 2 Watts of power and 0.5 ms (31.3%) of active cycle.

Results: A total of 22 eyes of 17 patients with glaucoma of various types and stages were included (mainly congenital and pseudoexfoliation). The mean follow-up time was 7.9 months. The total treatment duration varied from 100 to 180 s.

Definition of success: 5 mmHg < Intraocular pressure (IOP) < 21 mmHg and a reduction of ≥20% of the baseline value and no addition of oral carbonic anhydrase inhibitors, and no re-operation.

The overall success rate was 72.7% in the first month, 54% at 4 months, 41% at 6 months, and 27.3% at final follow-up. Patients with longer treatment durations (180 s) achieved better results. The mean reduction in IOP in successful eyes was 36% (from 26.3 to 16.7 mmHg, SD 4.58, $p = 0.028$). No complications were reported.

Conclusions: In a heterogeneous population of glaucoma (mostly congenital and pseudoexfoliation types), a low success rate (27.3%) was obtained in the medium-term with a single session of Micropulse®.

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Eficacia y seguridad de la ciclofotocoagulación transescleral con micropulsos en el tratamiento del glaucoma

Palabras clave:
Glaucoma
Ciclofotocoagulación
Láser diodo infrarrojo
Micropulse®

RESUMEN

Propósito: Comunicar nuestros resultados con la ciclofotocoagulación transescleral con el láser diodo Micropulse® (Iridex) en el tratamiento del glaucoma.

Métodos: Estudio retrospectivo en pacientes adultos con glaucoma con al menos 6 meses de seguimiento y solo una sesión de Micropulse®. Se utilizó la misma técnica quirúrgica, el único parámetro de láser que podía variar fue el tiempo total de tratamiento (en segundos). Los parámetros restantes se mantuvieron fijos en 2 W de potencia y 0,5 ms (31,3%) de ciclo activo.

Resultados: Se obtuvo un total de 22 ojos de 17 pacientes con glaucoma de diversos tipos y estadios (en su mayoría congénitos y pseudoexfoliativos). El tiempo medio de seguimiento fue 7,9 meses. La duración total del tratamiento varió de 100 a 180 segundos.

Definición de éxito: 5 mm Hg < presión intraocular (PIO) < 21 mm Hg, y una reducción ≥ 20% del valor basal y no adición de inhibidores orales de la anhidrasa carbónica y no reoperación.

La tasa de éxito global fue del 72,7% en el primer mes, del 54% a los 4 meses, del 41% a los 6 meses y del 27,3% en el seguimiento final. Los pacientes tratados con duraciones de tratamiento más prolongadas (180 s) lograron mejores resultados. La reducción promedio de la PIO en ojos exitosos fue del 36% (de 26,3 a 16,7 mm Hg, DE: 4,58, p = 0,028). No se informaron complicaciones.

Conclusiones: En una población heterogénea de glaucoma (principalmente de tipo congénito y pseudoexfoliativo) obtuvimos una baja tasa de éxito (27,3%) en el mediano plazo con una sola sesión de Micropulse®.

Introduction

Glaucoma is one of the main causes of irreversible blindness around the world.[1] When hypotensor medical treatment or treating the trabecular mesh with laser are not enough to control the disease, conventional surgical procedures are generally considered, including filtrating surgery or valve implants. Unfortunately, conventional techniques involve a high incidence of complications with bearing degrees of severity (34% for valves and 36% for trabeculectomy at 5 years).[2]

Frequently, when the above surgical options are exhausted, diode laser cyclophotocoagulation could be an option.[3] It has been proposed that this technique diminishes intraocular pressure (IOP) due to the combination of 2 mechanisms: on the one hand, photodestruction of the ciliary body pigment epithelium and on the other increased aqueous humor drainage through the uveoscleral pathway.[4]

Diode laser at a wavelength of 810 nm is more selective for tissues containing melanin (pigment epithelium).[3,5] Despite said selectivity, nonpigmented adjacent tissue also suffer collateral damages due to absorbing some energy directly from the laser[5] in addition to the indirect heat energy from the adjacent pigment epithelium. Said energy does not have any pathway for dissipation and therefore photocoagulation of adjacent tissue becomes inevitable.[6] This technique frequently gives rise to severe complications including hypotony, *phthisis bulbi*, chronic inflammation and diminished visual acuity.[7–10]

To overcome said complications, a modified transscleral cyclophotocoagulation technique has been developed. Transscleral cyclophotocoagulation with Micropulse® infrared diode laser (IRIDEX Corp., Mountain View, CA) utilizes diode laser micro-pulses in repetitive active laser (ON) cycles combined with inactive cycles (OFF).[11] The mechanism of action of this technique is not yet fully elucidated. Clinic and experimental studies suggest that the OFF periods restrict the accumulation of heat energy in tissues adjacent to the pigment epithelium and enable thermal dissipation before reaching coagulation temperatures, thus reducing collateral damage.[11–13]

It has been proposed that Micropulse® is equally effective but safer than continuous wave cyclophotocoagulation.[9]

The present paper presents the results of a cohort in Latin America that includes the first case treated with this technique in the region.[14]

Methods

An observational retrospective study with glaucoma patients having different subtypes and stages, mostly with difficult management (such as congenital and pseudoexfoliative glaucoma). In addition, said patients were not good candidates for conventional glaucoma surgery due to systemic or ocular reasons. The study subjects were treated consecutively with Micropulse® during the 2016–2017 period.

The study included all adult patients with at least 6 months follow-up and a single Micropulse® session (Table 1). All

procedures were conducted in accordance with the ethical standards of the institutional and/or national research committees and complying with the stipulations of the 1964 Helsinki declaration and subsequent amendments or with comparable ethical standards. For this type of study, i.e., retrospective review of clinical records, formal consent is not required.

Due to the scarcity of bibliography on the ideal parameters for said technique, each surgeon decided to treat patients applying fixed parameters regardless of the individual characteristics or disease stage. The only variable that changed between surgeons was the overall duration of treatments: surgeon 1 applied 100 s to all patients, while surgeon 2 applied 160 s and surgeon 3 180 s. Even though this was their first experience with Micropulse®, said 3 surgeons were acquainted with a very similar previous technique, i.e., continuous wave conventional cyclophotocoagulation. Therefore, even though the learning curve effect was probably very low it cannot be discarded.

Surgical technique

A micro-pulsed infrared diode laser having a wavelength of 810 nm was utilized. Each laser cycle had a total duration of 1.6 ms, comprised by 0.5 ms (31.3%) of active laser (ON) and 1.1 ms (68.7%) of inactive laser (OFF). Laser power remained fixed at 2 Watts (W) in all cases.

Patients were administered peribulbar blockage with a short duration anesthetic (2% lidocaine) and/or slight systemic sedation. Treatment was applied over 360 degrees, avoiding the 3 and 9 o'clock angles.

The probe includes a notch that is oriented toward the central cornea, and its base is close to the conjunctival limbus. Distance can vary slightly depending on individual anatomy of each patient (for example, in buphthalmic eyes the probe is placed more posteriorly).

The probe moves slowly and uniformly clockwise and counterclockwise over each hemisphere in several brush-like strokes. A lubricant gel or artificial tears are applied to facilitate probe movement. The procedure can begin in the upper or lower half of 180 degrees.

Definition of success

Success criteria were defined as per the guidelines of the World Glaucoma Association[15]: (1) IOP between 5 mmHg and 21 mmHg; (2) ≥20% reduction of baseline IOP in post-surgery months 1, 4, 6 and at the end of follow-up; (3) no post-treatment addition of oral carbonic anhydrase inhibitors; and (4) without re-intervention for glaucoma within the follow-up period.

Statistical analysis

The following parameters were registered for each patient: age, sex, ethnicity, type of glaucoma, post-surgery complications, pre-and postoperative IOP and number of glaucoma medicaments at month 1, 4, 6 and at the end of the follow-up. Additional glaucoma surgeries for patients who did not respond to the Micropulse® treatments were also registered.

Pre-and postoperative IOP, and the number of glaucoma medicaments for successful eyes, were compared with the range test with the Wilcoxon sign. The results per glaucoma type and overall treatment time were secondarily analyzed. The IBM SPSS® Statistics 23.0 application was utilized, taking $p < 0.05$ for statistical significance.

Table 1 – Summary of patients included in the study.

Patient	Eye	Age	Sex	Glaucoma type	Excavation	Previous glaucoma surgery
1	LE	77	F	Post-keratoplasty	0.7	Cataract, keratoplasty
2	LE	30	F	Mixed mechanism	0.8	–
3	RE	49	M	Aphakic	0.9	Cataract, TBC
4	RE	22	M	Post-keratoplasty	0.3	Valve
5	RE	11	F	Aphakic	0.8	Cataract
6	RE	71	M	Pseudoexfoliative	0.9	Cataract, EPNP
7	RE	36	F	Aphakic	0.7	Cataract, TBC, endophotocoagulation
8	LE	29	M	Mixed mechanism	0.9	Cataract, valve
9	RE	50	M	Congenital	0.9	Cataract, 2 valves
	LE			Congenital	0.9	Cataract, TBC, valve
10	RE	22	M	Congenital	0.9	TBC, valve
	LE			Congenital	1	TBC, 2 valves
11	RE	79	F	Pseudoexfoliative	0.9	Cataract, TBC
	LE			Pseudoexfoliative	0.9	Cataract, TBC
12	RE	75	M	Open angle	1	Cataract, TBC
	LE			Open angle	1	Cataract, TBC
13	RE	24	F	Congenital	1	Cataract, TBC
	LE			Congenital	1	Cataract, TBC
14	RE	29	M	Congenital	0.9	TBC, valve
15	RE	42	F	Juvenile	0.9	TBC, 2 valves
16	LE	69	F	Pseudoexfoliative	0.7	–
17	LE	45	M	Pseudoexfoliative	0.9	SLT 180° inferiores

NPDS: nonpenetrating deep sclerotomy; SLT: selective laser trabeculoplasty; TBC: trabeculectomy.

Table 2 – Demographic data.

Number of eyes (number of patients)	22 (17)
Mean age (SD)	46.2
Median (range)	39 (11–79)
Females, n (%)	8 (47)
Race, n (%)	
Hispanic	17 (100)
Previous glaucoma procedures (%)	20 (91)

Table 3 – Distribution of glaucoma types.

Glaucoma type	*n* (%)
Congenital	7 (32)
Pseudoexfoliative	5 (23)
Aphakic	3 (14)
Open angle	2 (9)
Post-keratoplasty	2 (9)
Juvenile	1 (5)
Mixed mechanism	2 (9)

Results

Overall, 22 eyes of 17 patients were treated with Micropulse®. The mean age of treated patients was 44.7 years (SD 22.2; range 11–79) and 8 patients (47%) were female. Predominance diagnostics were congenital glaucoma ($n = 7$; 32%) and pseudoexfoliative glaucoma ($n = 5$; 23%). Twenty-one eyes (95%) were in treatment with a mean of 3.43 (SD 1.03) anti-glaucoma topical medicaments prior to the intervention. The remaining eye did not receive topical treatment due to intolerance. Eight of said eyes (36%) were administered oral acetazolamide prior to treatment. The majority of eyes had undergone previous ocular surgery ($n = 20$; 91%) (Tables 1–4).

The mean follow-up time was 7.9 months (SD 2.34; range 6–14).

At month 1, the overall success rate was 72.7%. At month 4, 54.5% (12/22). At month 6, 41% (9/22). At the end of the follow-up (7.9 months), 27.3% (6/22 eyes) (Fig. 1).

Results per glaucoma type

Glaucoma types were grouped in congenital ($n = 7$), pseudoexfoliative ($n = 5$), while the rest of cases were grouped as miscellaneous ($n = 10$).

At the end of the follow-up, 2 of the 7 eyes with congenital glaucoma (28.6%) and 2 of the 5 eyes with pseudoexfoliative glaucoma (40%) were successful. As for the rest of eyes (miscellaneous glaucoma), 2 were successful (20%).

Table 4 – Previous glaucoma procedures.

	n (%)
Total number of eyes	20/22 (91)
Trabeculectomy	13 (36)
Cataract surgery	7 (35)
Valve implant	8 (24)
Endophotocoagulation	1 (2)
Nonpenetrating deep sclerectomy	1 (2)
Selective laser trabeculoplasty	1 (2)

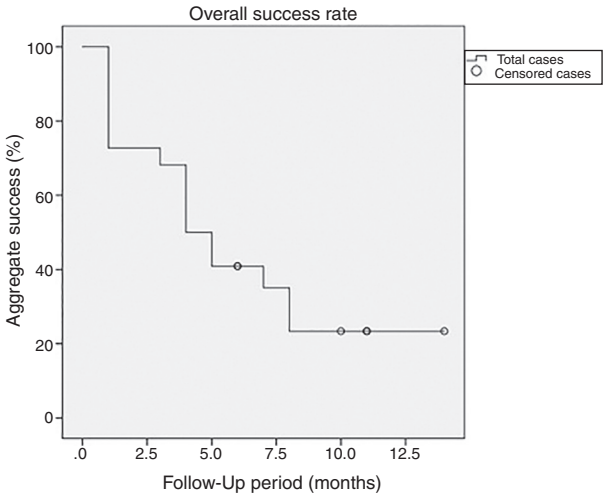

Fig. 1 – Overall success rate.

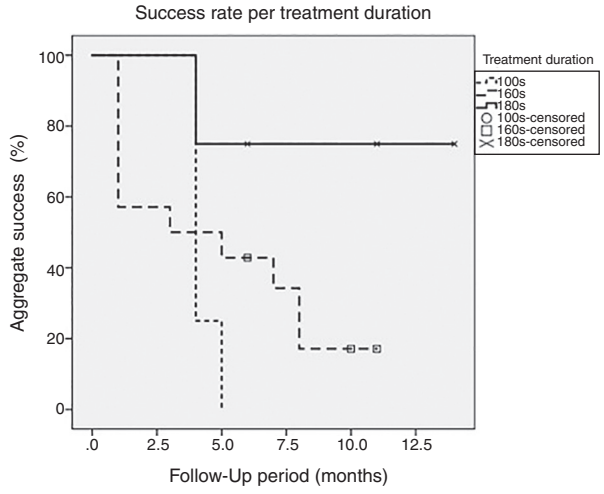

Fig. 2 – Success rate grouped by treatment duration variable.

Mean IOP reduction in successful cases of each group was 38%, 46% and 33%, respectively.

Results per overall treatment duration

At the end of the treatment none of the patients treated with 100 s (4 cases) was successful, while those treated with 160 s 3/14 (21.4%) were successful and those treated with 180 s 3/4 (75%) were successful (Fig. 2 and Table 5).

At the final follow-up, for all the eyes that fulfilled the success criteria (6/22 eyes), overall baseline IOP reduction was 36% (9.7 mmHg, SD 4.59); from 26.3 mmHg (SD 6.34) preoperative to 16.7 mmHg (SD 3) postoperative, $p = 0.028$ (Fig. 3).

In successful eyes with 160 s treatment, the mean IOP reduction was 37.7% (8.67 mmHg). In successful eyes with 180 s treatment, the mean IOP reduction was 34.3% (10.7 mmHg). All patients in the 100-s group failed after 4–5 months. Until that time they had achieved a mean baseline IOP reduction of 19 mmHg (46.4%). According to surgeon criteria, all these

Table 5 – Results.

Patient	Eye	Glaucoma type	Follow-up time (months)	Total treatment duration (s)	Pretreatment IOP (mmHg)	Result	Post-treatment IOP in successful eyes (mmHg)	Pretreatment medication	Medication at follow-up end	Post-Micropulse® glaucoma surgeries	Micropulse® complications
1	LE	Post-keratoplasty	6	100	39	Failure	–	2 + Actz	3 + Actz	Valve	None
2	LE	Mixed mechanism	7	100	50	Failure	–	Actz	–	Micropulse®	None
3	RE	Aphakic	6	100	34	Failure	–	4 + Actz	–	Micropulse®	None
4	RE	Post-keratoplasty	6	100	36	Failure	–	4 + Actz	–	Micropulse®	None
5	RE	Aphakic	8	160	25	Failure	–	3	4	Valve	None
6	RE	Pseudoexfoliative	6	160	30	Failure	–	2 + Actz	–	Express shunt®	None
7	RE	Aphakic	11	160	26	Success	14	3	3	–	None
8	LE	Mixed mechanism	6	160	20	Success	16	4	4	–	None
9	RE	Congenital	10	160	23	Success	13	4	4	–	None
	LE	Congenital	9	160	14	Failure	–	4	–	Express shunt®	None
10	RE	Congenital	6	160	31	Failure	–	4	4	CWTSCPC	None
	LE	Congenital	7	160	22	Failure	–	4	4	Micropulse®	None
11	RE	Pseudoexfoliative	7	160	17	Failure	–	4	4	CWTSCPC	None
	LE	Pseudoexfoliative	7	160	14	Failure	–	4	4	CWTSCPC	None
12	RE	Open angle	8	160	16	Failure	–	4 + Actz	4 + Actz	CWTSCPC	None
	LE	Open angle	7	160	28	Failure	–	4 + Actz	4 + Actz	CWTSCPC	None
13	RE	Congenital	8	160	13	Failure	–	4	4	CWTSCPC	None
	LE	Congenital	8	160	10	Failure	–	4	4	CWTSCPC	None
14	RE	Congenital	14	180	28	Success	19	1		–	None
15	RE	Juvenile	12	180	24	Failure	–	4 + Actz		–	None
16	OS	Pseudoexfoliative	11	180	38	Success	21	1		–	None
17	OS	Pseudoexfoliative	6	180	38	Success	20	4 + Actz		–	None

CWTSCPC: continuous wave transscleral cyclophotocoagulation.

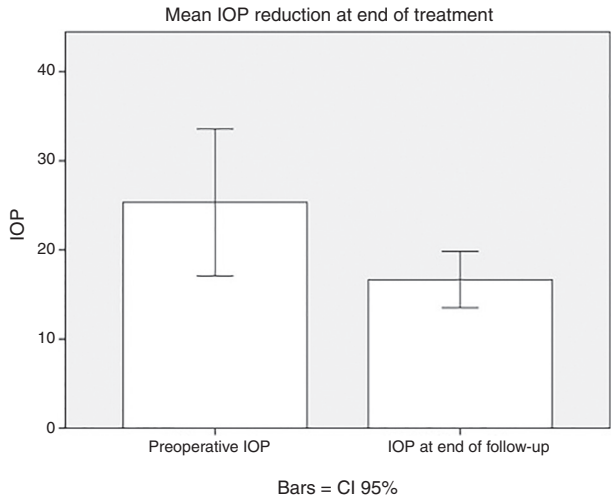

Fig. 3 – IOP prior to intervention and at end of follow-up in eyes fulfilling success criteria.

patients were administered a second Micropulse® 100-s session immediately after failure. At month 6 (final follow-up), IOP remained high in 2 out of 4 patients (33 and 36 mmHg), despite retreatment. In contrast, IOP diminished to 15 and 19 mmHg in the other 2 patients during the same period (baseline IOP: 34 and 36 mmHg, respectively). It should be noted that surgical/laser retreatment was considered to be a failure in this study.

Differences in the number of hypotensor medicaments before and after treatment were not recorded (Table 5). Similarly, Emanuel et al. did not find statistically significant differences in a cohort of refractory glaucoma after 12 months follow-up ($p = 0.085$).[16]

The procedure was adequately tolerated and at the date of writing no complications arose in any of the patients.

At the end of the follow-up, 16 of the 22 eyes treated with Micropulse® had not fulfilled the success criteria and were registered as failures. Mean failure time was 6.13 months (SD 1.93). All of these cases required additional surgery/laser treatment. Seven patients received conventional transscleral cyclophotocoagulation, 5 were retreated with Micropulse®, 2 received the Express® implants, one valve implant and one trabeculectomy.

Discussion

Micropulse® (Iridex) is a relatively recent technique that irradiates a micro-pulsed infrared diode laser beam during the active (ON) cycle with a duration of 0.5 ms (31.3%). The active cycle is followed by inactive (OFF) cycles with a duration of 1.1 ms (68.7%).[11] Therefore, it has been proposed that non-pigmented surrounding tissue receive less thermal energy and have more time to dissipate it during the inactive period, thus remaining under the coagulation threshold.[11] Aquino et al. have suggested that this mechanism accounts for the lower complications rate when compared to continuous wave conventional cyclophotocoagulation.[9] The experience of the present authors demonstrates that Micropulse® is a safe procedure as none of the cases exhibited complications.

The overall success rate in the midterm and the mean baseline IOP reduction were lower in the present study when compared to those reported by other authors.[9,11,16–18] This lower success rate, both overall and for each type of glaucoma could be to some extent attributable to the fact that the predominant glaucoma types of the present study were difficult to manage (congenital and pseudoexfoliative). It is important to emphasize that the predecessor of the present technique, i.e., conventional cyclophotocoagulation, was historically reserved for a heterogeneous group of patients cared for in daily clinic practice who share the antecedents of failure with conventional surgeries (trabeculectomy or valves). This includes special cases that are not eligible for conventional surgeries due to unacceptably high risk. As the present study describes the initial experience with this new surgical technique, derived from conventional cyclophotocoagulation, it can be expected that the authors decided to treat a heterogeneous group of patients who would otherwise have received conventional cyclophotocoagulation. The objective of the authors is to report the results in a group of patients that is frequently seen by glaucoma subspecialists in daily practice.

Additional reasons diminish the value of comparing the present results with the higher success rates of other studies. The authors have identified differences in the definition of success criteria described in the articles. In a prospective study, Tan et al.,[11] obtained in 40 eyes a success rate of 80% at 16.3 ± 4.5 months follow-up. In contrast with the present study, retreatment with Micropulse® was not considered as a failure. In addition, cases fulfilling only one of the following 2 IOP criteria: (1) IOP < 21 mmHg; or (2) ≥30% baseline IOP reduction were also taken as successful. Laser power was established at 2 W and the overall treatment duration was 100 s (100 s for each session administered to retreatment patients). No complications were reported. The less rigorous success criteria enabled the inclusion of 5 eyes with laser retreatment and 13 eyes that fulfilled only one IOP criterion. In another prospective study ($n = 48$) with 18 months follow-up, Aquino et al.[9] compared the efficacy and safety of Micropulse® against conventional cyclophotocoagulation. Laser power was also set at 2 W and the overall duration of treatment was 100 s. Mean baseline IOP reduction was 45% in both groups. Up to 3 laser sessions were administered. This higher IOP reduction obtained with up to 3 laser sessions in some cases makes comparisons with the present study less reliable.

More recently, Kuchar et al.[18] and Emanuel et al.[16] also reported higher success rates in their respective studies. The former reported a success rate of 73.7% (14/19) after one laser session with variable treatment durations (100–240 s). However, the mean follow-up period was only 60.3 days. It must be noted that with the same follow-up time, the success rates of the present study were very similar but diminished significantly in subsequent checkups (Fig. 1). The second study applied a more aggressive approach with a mean treatment duration of 319 s and mean power of 1.9 W. Interestingly, this extended treatment duration produced a sustained IOP reduction of approximately 40% during at least 12 months.

However, complications also increased to 54% (45/84). The present study observed a tendency toward improved results in patients treated for longer periods (180 s), which is a middle point between the treatment durations utilized by the above mentioned authors. It should be pointed out that due to limitations such as the sample size the authors were not able to assess the statistical significance of this tendency. In fact, a critical point of this technique is defining the optimal parameters of the laser and the duration of the treatment to strike the best balance between effectiveness and safety. The present data raise the question about whether the treatment duration variable could play a role in this balance.

Conclusions

In a heterogeneous glaucoma population with a majority of congenital and pseudoexfoliative glaucoma, the present study has observed poor general results for a single session treatment with Micropulse® in the medium term. No complications were reported in any of the cases. In addition, better results were observed with longer treatment duration (180 s), although the statistical significance of this tendency could not be analyzed. Prospective studies with a larger sample size and longer follow-up periods are required to evaluate the efficacy and safety of Micropulse® in the long-term.

Conflict of interests

Dr. Lerner received travel expenses from Iridex in the past year and Dr. Noecker is a paid Iridex consultant. The rest of authors declare the absence of any conflict of interests.

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