

Single-piece Foldable Intraocular Lenses versus Three-piece Intraocular Lenses in the Sulcus following Posterior Capsular Rupture in a Philippine Tertiary Hospital

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ABSTRACT

Objective. Successful intraocular lens (IOL) placement in cataract surgery is synonymous with the IOL being placed in the capsular bag. When the capsular bag is violated, the ciliary sulcus becomes an option to approximate an in-the-bag position. Studies report that single-piece foldable acrylic (SPA) IOLs are a poor choice for the sulcus. This study aimed to report the visual outcomes and complications of sulcus placement of single-piece intraocular lenses and three-piece intraocular lenses, and compare the design and characteristics to the occurrences of complications.

Methods. The medical records of patients were retrospectively reviewed in a single center from 2016-2019.

Results. A total of 245 eyes from 237 patients were included in the study with a mean age of 61 years and male predominance. Majority of sulcus implantation occurred during phacoemulsification (87%). Around 82% (n=202) were implanted with single-piece IOLs and 18% (n=43) were three-piece IOLs. Best corrected distance visual acuity (BCDVA) was 20/20 after six months for both groups. Comparison between two groups showed no superiority with each other. Complications notable were elevated intraocular pressure, corneal edema, loss of IOL centration, and pigment dispersion. Smaller optic diameter and overall length predispose to higher probabilities of loss of centration. Pliability, hydrophobicity/hydrophilicity, and material do not correlate with postoperative complications. There were significantly higher numbers of pigment dispersions in IOLs with square-edged design.

Conclusions. In conclusion, visual outcomes remain equally excellent for both single-piece and three-piece groups. In contrast, there were more notable complications in single-piece group. Loss of centration tends to occur more with mean optic diameters lower than or equal to 5.50 mm and an overall length of less than 12.50 mm or lower. While appropriate for the capsular bag, square-edged designs were found to be inappropriate for the sulcus. The retrospective design does not allow strong inferences hence caution should be taken in correlating results.

Keywords: single-piece, three-piece, Philippines, intraocular implant, cataract surgery, sulcus implantation



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INTRODUCTION

Successful intraocular lens (IOL) placement in cataract surgery is synonymous with the IOL being placed in the capsular bag. An IOL is an artificially manufactured lens that is meant as a substitute to the natural lens once it is removed by cataract surgery.^{1,2} For best visual outcomes, the IOL is placed safely inside the lens capsule after removal of the nucleus in lens extraction surgery, well-centered to the pupillary axis, and the IOL-capsular complex is adequately supported by lens zonules.^{1,2} This “in-the-bag” placement of an IOL approximates an optimal surgical and refractive outcome. However, complications are unavoidable and may arise in a routine lens extraction surgery.³ There are situations that when the posterior capsular bag becomes violated such as in posterior capsular rupture. When remains intact, the ciliary sulcus may be a safe alternative to place an intraocular lens. This becomes an option since sulcus placement is almost synonymous to in-the-bag placement because of the near proximity of the sulcus with the bag.^{1,2}

The currently recommended intraocular lens placed in the sulcus is either a one-piece polymethylmethacrylate (PMMA) lens, or a three-piece intraocular lens with posteriorly angulation and thin looped haptics, and these variations in their designs result to lesser complications.⁴⁻⁶ Various haptic designs continuously evolve through time in terms of position stability of IOL to obtain a consistent position to minimize any undesirable postoperative refractive error.^{1,2,4,6} On the other hand, numerous studies¹⁻¹³ discouraged the use of single-piece IOLs in the sulcus. Several studies contraindicated placement of these IOLs because of their square-edged optic design, thick haptics, and unpolished side walls which cause friction to the iris surface.^{6,13} The broader haptics and sharp edges cause chaffing of the posterior iris and eventually results a pigment dispersion syndrome.¹⁴ Pigment dispersion syndrome becomes a clinical dilemma when the pigments block the trabecular meshwork subsequently resulting to glaucoma when left untreated.¹⁴

The complications of a single-piece IOL are a highly-publicized information. Many independent studies are available discussing the outcomes and complications associated with it; however, because the surgeries associated with implanting a sulcus intraocular lens are an intraoperative and unforeseen dilemma, most reviews available in literature were retrospective and employed smaller sample sizes. A conclusive correlation about the complications of sulcus placement of single-piece intraocular lenses and its design and characteristics is difficult to elicit. Despite being retrospective, this study employed a 4-year review of all outcomes of sulcus placement of single-piece IOLs in a tertiary hospital in the Philippines to employ a larger sample population.

OBJECTIVES

This study determined and compared the visual outcomes and complications of sulcus placement of single-piece and three-piece intraocular lenses in a tertiary hospital in the Philippines. Specific parameters of an intraocular lens [i.e., rigidity and flexibility, square-edged design, hydrophobic or hydrophilic, and material, whether acrylic or polymethylmethacrylate (PMMA)] were identified and correlated. These parameters were retrieved from the attached paper descriptions of the intraocular lenses. This study described the demographics of the patients who underwent IOL sulcus placement based on age, gender, laterality, and type of lens extraction performed (i.e., phacoemulsification, extracapsular cataract extraction), with or without anterior vitrectomy done. Intraocular lens dimensions such as overall length, optic diameter, and central thickness were also recorded. Postoperative complications [i.e., increased intraocular pressure (IOP) with or without the need for glaucoma co-management, decentered intraocular lens, corneal edema, corneal decompensation, retinal detachment, pigment dispersion and others] were identified.

METHODS

This study was a retrospective, comparative chart review study employing retrieval of 245 eyes from 237 patients with IOL sulcus placement (either single-piece or three-piece) from January 1, 2016 to December 31, 2019. All methods were carried out in accordance with relevant guidelines and regulations. Our study was approved by the University of the Philippines – Manila Ethics Review Board (UPM-REB) prior to the conduct of the study. Informed consent was waived by the institutional review board/ethics committee due to its retrospective chart review conduct.

All eyes which underwent intraocular lens implantation in the sulcus, either of same sitting (primary) or staged procedure (secondary) were included. Excluded were eyes with preexisting retinal pathology, glaucoma, corneal pathology, and optic nerve pathology. Pediatric patients (age less than 18 years), less than two months of follow up, and incomplete medical records were also excluded.

Primary outcomes were best corrected visual acuity at day 1, 1st month, 3rd month, and 6th month postoperatively, and the postoperative complications.

Clinicodemographic profile of the subjects of the study and characteristics of the intraocular lens implanted to the subjects were described. Continuous numerical variables were summarized as mean and standard deviation, if the data was normally distributed as assessed by Shapiro-Wilk test of normality, and, median and interquartile range (IQR) if otherwise. Discrete numerical variables were summarized as median and IQR. Categorical variables were summarized as count and proportion. Prevalence of the different postoperative complications was presented as percentage.

Comparison of the cumulative incidence of the different postoperative complications were assessed by chi-square test or Fisher exact test of homogeneity, as appropriate. Comparison of the IOL design and characteristics between those with different postoperative complications versus without, including pigment dispersion syndrome were assessed by Mann-Whitney U test. Assumptions of both repeated-measures ANOVA and Friedman test were not met by the dataset, hence comparison of the BCVA between single-piece and three-piece IOL across different time-points were done graphically using box plots. Since this is a retrospective study, control of confounders is limited to stratification in the data analyses (e.g., analyses were run according to IOL type, outcomes).

RESULTS

Data were collected from a total sampling and complete enumeration of 245 eyes which satisfied inclusion criteria. For the patient characteristics (Table 1), results showed a mean age of 61 years old with more males than females. Follow-up period was 6 ± 2.42 months. For the surgical characteristics, majority of the sulcus implantation occurred during phacoemulsification primarily on the same sitting setup. Anterior vitrectomy was done in 97% (n=238) of the total eyes and posterior vitrectomy was done in 21% (n=52) of total eyes. Vitreous loss was recorded in 238 eyes (97%).

Majority of the sulcus implanted IOLs were single-piece where predominantly were foldable, acrylic, hydrophobic, and had a square-edged design (Table 2). In terms of intraocular lens dimensions, namely the central thickness or the optic thickness, optic diameter and overall length, lenses had a mean central thickness of 0.45 mm, optic diameter of 6 mm and overall diameter of 12.5 mm. The three-piece IOLs were found to be relatively thicker in the central portion of the optic (0.45 mm) compared to single-piece IOLs (0.43 mm).

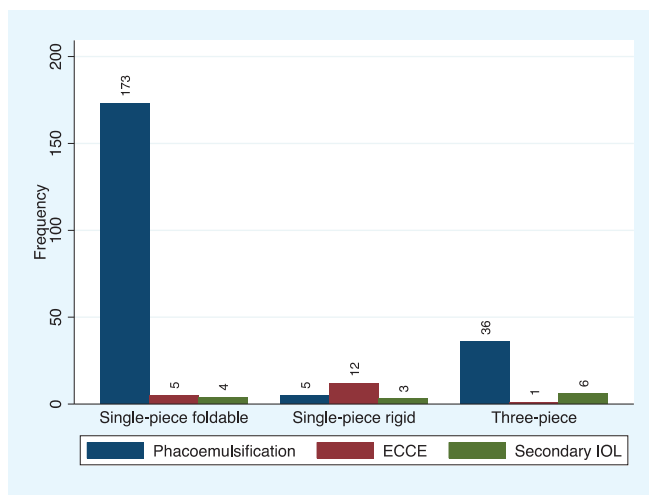


Figure 1. Type of IOL used for each procedure.

Conversely, the single-piece IOLs were smaller in terms of average optic diameter and overall diameter as compared to three-piece IOLs.

Single-piece foldable and three-piece IOLs were implanted predominantly during phacoemulsification (Figure 1). Single-piece rigid IOLs were implanted more in ECCEs.

Best corrected distance visual acuity (BCDVA) was presented as logarithm of the minimal angle of resolution or logMAR units. Preoperative BCDVA was on the average 0.69 logMAR units (20/100) for single-piece group, and 0.62 logMAR units (20/83) for three-piece group. Post-

Table 1. Clinicodemographic Profile and Characteristics of the IOL Implanted in the Subjects of the Study

Demographics	N / Median	% / IQR
Age group		
19-40	11	4.49%
41-60	89	36.33%
>60	145	59.18%
Sex		
Male	133	54.29%
Female	112	45.71%
Laterality		
Left	126	51.43%
Right	119	48.57%
Lens extraction procedure		
Phacoemulsification	214	87.35%
Extracapsular cataract extraction	18	7.35%
Secondary IOL	13	5.31%
Anterior vitrectomy performed	238	97.14%
Posterior vitrectomy performed	52	21.22%
IOL implantation timing		
Primary	213	86.94%
Secondary (staged procedure)	32	13.06%

Table 2. Characteristics of IOL that were Implanted in the Sulcus

Intraocular Lens	n / Median	% / IQR
Three-piece	43	17.55%
Single-piece	202	43.00%
Pliability		
Foldable	182	90.10%
Rigid	20	9.90%
Material		
Acrylic	181	90.05%
Polymethacrylate	20	9.95%
Undisclosed	1	0.41%
Square-edged design		
Hydrophobicity/Hydrophilicity	110	54.46%
Hydrophobic	110	54.46%
Hydrophilic	92	45.54%
Central thickness	0.45	0.07
Optic diameter	6	0
Overall diameter	12.5	0.5

operatively, there was an improving trend of visual outcomes for both three-piece and single-piece groups through time (Table 3). Comparing the visual outcomes of the two groups per period in time, both single-piece and three-piece groups demonstrated no superiority over the other.

Different postoperative complications were recorded: presence and severity of anterior chamber inflammation, elevated intraocular pressures that may or may not have progressed to glaucoma, corneal edema, loss of centration, pigment dispersion syndrome, and retinal detachments.

Postoperative anterior chamber inflammation was classified to either transient (occurring less than two weeks), or persistent (more than two weeks). Both groups demonstrated only mild and transient postoperative inflammations. Around 16 eyes (7.08%) had persistent inflammation. From these 16 eyes, 13 eyes resolved after four weeks of topical steroids, while three eyes, all from single-piece group, had chronic inflammation refractory to topical steroids and warranted uveitis specialist co-management. The cumulative

incidences of postoperative inflammation between single-piece and three-piece IOLs showed no sufficient evidence to conclude that there is a significant difference between the two groups (Table 4).

Elevated intraocular pressure was more noted in the three-piece group (30.23%, n=13) compared to the single-piece group. From the 56 eyes which had elevated IOP, 37 eyes required treatment: 29 eyes from single-piece group; eight eyes from three-piece group. Most common medications prescribed to address the elevated IOP were timolol (63%), acetazolamide (21%), and brimonidine (19%). Twenty-two eyes required control treatment with only one topical medication, 12 eyes with two medications, two eyes with three medications, and one eye with four medications. Mean IOP elevations of 23 mmHg and 21 mmHg for single-piece and three-piece, respectively. Twelve eyes warranted a glaucoma specialist co-management: 10 from the single-piece group, two from the three-piece group. Three eyes (all from the single-piece group) progressed to glaucoma where two were

Table 3. Comparison of Best Corrected Distance Visual Acuity (BCDVA) in logMAR Units between Single-piece and Three-piece IOL across Different Time Points (n=245 eyes)

IOL Group	Log MAR, median (IQR)				
	Preoperative	Postoperative day 1	Postoperative month 1	Postoperative month 3	Postoperative month 6
Single-piece	0.6989 (1.1645)	0.544 (0.824)	0.176 (0.457)	0.0969 (0.301)	0.0969 (0.301)
Three-piece	0.62145 (0.16505)	0.544 (0.8239)	0.301 (0.4471)	0.0969 (0.301)	0 (0.176)

Table 4. Comparison of the Cumulative Incidence of Postoperative Complications between Single-piece and Three-piece IOL

Postoperative complications	Overall	Single-piece		Three-piece		p-value
	n (%) / Median (IQR)	n / Median	% / IQR	n / Median	% / IQR	
Inflammation						
Chronicity						1.000
Transient	210 (92.92%)	173	92.51%	37	94.87%	
Persistent	16 (7.08%)	14	7.49%	2	5.13%	
Increased intraocular pressure						
Duration, days	56 (22.86%)	43	21.29%	13	30.23%	0.205
Onset	30 (29)	30	29	30	29	0.944
Early	47 (83.93%)	39	90.70%	8	61.54%	0.024
Late	9 (16.07%)	4	9.30%	5	38.46%	
Chronicity						0.315
Transient	24 (42.86%)	20	46.51%	4	30.77%	
Chronic	32 (57.14%)	23	53.49%	9	69.23%	
Need for glaucoma co-management	12 (21.43%)	10	23.26%	2	15.38%	0.711
Number of glaucoma medications	1 (2)	1	2	1	2	1.000
Corneal edema						
Duration, days	89 (36.33%)	74	36.63%	15	34.88%	0.828
Chronicity	7 (23)	7	23	7	23	0.237
Transient	52 (58.43%)	41	55.41%	11	73.33%	0.199
Chronic	37 (41.57%)	33	44.59%	4	26.67%	
Intraocular lens decentration						
Onset, days	19 (7.76%)	17	8.42%	2	4.65%	0.541
	15 (58)	7	28	60	60	0.304
Retinal detachment						
Onset, days	4 (1.63%)	3	1.49%	1	2.33%	0.540
	5.5 (5.5)	5	4	12	0	0.500
Pigment dispersion syndrome						
	15 (6.12%)	13	6.44%	2	4.65%	1.000

Table 5. Comparison of IOL Characteristics with Presence of Loss of IOL Centration

	Single-piece Group		Three-piece Group		p-value
	n / Median	% / IQR	n / Median	% / IQR	
Central thickness	0.43	0.02	0.45	0.07	0.1285
Optic diameter	5.90	0.25	6.00	0.00	0.0232
Overall length	12.5	0.25	12.75	0.50	0.0093

Table 6. Comparison of IOL Characteristics with Presence and Absence of Complications in General and Presence of Pigment Dispersion

IOL Characteristics	Overall complications	With pigment dispersion	Without complications	p-value
Rigidity				0.199
Foldable	121/132 (91.67%)	12/15 (80.00%)	61/71 (85.92%)	
Rigid	11/132 (8.33%)	3/15 (20.00%)	10/71 (14.08%)	
Material				0.897
Acrylic	121/163 (74.23%)	13/15 (86.67%)	60/80 (75.00%)	
PMMA	42/163 (25.77%)	2/15 (13.33%)	60/20 (25.00%)	
Hydrophobicity				0.248
Hydrophilic	85/163 (52.15%)	10/15 (66.67%)	48/80 (60.00%)	
Hydrophobic	78/163 (47.85%)	5/15 (33.33%)	32/80 (40.00%)	
Square-edge				0.047
Yes	78/163 (47.85%)	9/15 (60.00%)	32/80 (40.00%)	
No	85/163 (52.15%)	6/15 (40.00%)	48/80 (60.00%)	

open angle glaucoma, and one was a secondary angle closure glaucoma. One open angle glaucoma case required filtering surgery. Elevated IOP had a mean 30 days of duration. Elevated IOP was categorized into the following: either early (defined as onset of elevated IOP within two weeks) or late (onset was beyond two weeks); transient (duration within four weeks regardless of management), or chronic (more than four weeks). In terms of onset, a significantly higher proportion of early onset increase in IOP was recorded in single-piece group, and a significantly higher incidence of late onset increase in IOP in three-piece group than in single-piece group (p -value = 0.02). With regard to chronicity, there were more chronically increased IOP in three-piece group than in single-piece group, but this was insignificant.

A total of 89 eyes had corneal edema postoperatively with an average duration of seven days. Fifty-seven (64.04%) from which were observed, and no medications were given. Thirty-two (35.96%) eyes received sodium chloride as initial treatment, and no patients deteriorated to corneal decompensation until their last recorded follow-ups. Most corneal edemas occurred transiently ($n=52$, 58.43%), operationally defined as within two weeks, with spontaneous resolution, where mostly not needing sodium chloride treatment. Chronic corneal edema, or more than two weeks of edema, was reported higher in single-piece group ($n=33$, 44.59%). However, there was no sufficient evidence to conclude that there is a significant difference in the cumulative incidence of postoperative corneal edema between single-piece and three-piece groups.

A total of 19 eyes (7.76%) lost centration as observed postoperatively with a mean onset of 15 days. For loss of centration, this study subdivided loss of centration to decentration, subluxation, and dislocation. Decentration is loss of centration where IOL is retained in the ciliary sulcus, but the geometric center is not in the visual axis. Subluxation is partial displacement out of the ciliary sulcus (i.e., haptic may be incarcerated in anterior chamber or iris), but a retained part is confined within the anterior segment (i.e., incarcerated in the iris). Dislocation is complete displacement out of the ciliary sulcus (i.e., entire IOL in the anterior chamber, IOL dropped in the posterior segment).⁹ There were more losses of intraocular lens centration with single-piece group ($n=17$, 8.42%) than the three-piece group ($n=2$, 4.65%). In the single-piece group, two eyes had decentrations, four had subluxations, and nine had dislocations into the retina. There were two decentrations and one subluxation in three-piece group. No dislocations were recorded. Those with loss of centration have significantly lower median overall length (12.5 mm) and optic diameters (5.9 mm) than those without loss of centration (Table 5).

Four (1.63%) eyes were noted with retinal detachment at a mean onset of 5.5 days. All eyes with retinal detachment were predisposed to IOL explant prior to the retinal detachment.

Fifteen eyes (6.12%) had pigment dispersion: 13 from single-piece group and 2 from three-piece group. No patients were diagnosed with pigment dispersion glaucoma. These numbers were correlated to the characteristics of intraocular lenses: rigidity, material, hydrophobicity/hydrophilicity,

and square-edged design (Table 6). Pigment dispersion syndrome positively correlated with the square-edged design of an intraocular lens ($p=0.047$). Although there were higher numbers of occurrences of pigment dispersion in foldable, acrylic, and hydrophilic IOLs, these were not statistically significant.

DISCUSSION

There is no debate in current available literature regarding the visual outcomes of implanting a single-piece IOL in the sulcus. Visual acuity remained excellent for those with stable sulcus IOLs because it maintained the advantages of a small incision surgery with good postoperative visual results.⁹ Additionally, the near proximity of the sulcus with the bag provides a good option should the posterior capsule gets compromised.^{2,4,6} Similar papers showed a good visual outcome for majority of eyes implanted with sulcus single-piece IOL with at least 20/40 or better in all eyes.^{2,7,11}

With regard to postoperative complications, several studies reported numerous complications associated with single-piece acrylic (SPA) intraocular lenses.^{1,2,4,6,10} There is growing evidence of chronic complications related to their use in the ciliary sulcus.^{1,2,4,6,7,10} Many of these eyes ultimately required surgical intervention, including lens exchange, pars plana vitrectomy, and trabeculectomy to address complications. Varying degrees of inflammation and corneal edema were anticipated as these also correlate with the complexity of the surgery. Many have proposed mechanisms with the elevated intraocular pressures.¹⁴ There is a multitude of etiologies that could predispose to an elevated intraocular pressure that may or may not lead to glaucoma in such cases, namely, pupillary block mechanism, pigment dispersion leading to blockage of trabecular meshwork, inadvertent intraoperative trauma to trabecular meshwork.^{14,15} Loss of centration and pigment dispersion syndrome directly correlate with the design, characteristics, and parameters of the IOL itself.¹⁵

The currently recommended intraocular lenses to be placed in the sulcus are the three-piece intraocular lens or a single-piece PMMA rigid intraocular lens.^{4,6} This was primarily because three-piece IOLs and single-piece PMMA rigid IOLs are designed to be more stable in sulcus because of their large optic diameters and long haptics which are crucial to maintain stability in the sulcus. At the present time, designs of intraocular lenses continue to evolve, and the optic diameters and overall lengths of single-piece IOLs already approximate that of three-piece. In this 4-year retrospective study, the investigators were still able to include in the data a few older designs where some of the mean optic diameters measured at the minimum 5.50 mm and overall lengths at less than 12.50 mm. Correlating these measurements with the occurrences of postoperative complications, a mean optic diameter lower than or equal to 5.50 mm and an overall length of less than 12.50 mm or lower equate to significantly

higher probabilities of loss of centration (Table 5). Based on measurements in living eyes using ultrasound biomicroscopy (UBM), sulcus-to-sulcus approximately measures 12.5 mm.¹² Thus, any length lower than 12.5 mm, while ideal for in-the-bag fixation, is already undersized for the ciliary sulcus. Implanting sizes under the minimum could cause either loss of centration or IOL tilt. Moreover, a study conducted by Renieri et al. performed ultrasound biomicroscopy (UBM) in these eyes where they significantly found IOL tilt for those clinically stable sulcus IOLs.⁷ Additionally, studies reported that single-piece IOLs have minimal to no posterior angulation^{2,4,6} and the optic may more likely prolapse anteriorly, increasing the risk for dislocation.

Some published literature point to the square-edged optic design, thick haptics, and unpolished side walls of single-piece acrylic IOLs being the cause of friction at the edges of the lens resulting to pigment dispersion syndrome.¹⁴ The thicker optic of single-piece IOLs predisposes more to a pupillary block mechanism. At the same time, the adherent surface of the acrylic IOL and the bulkier single-piece haptics promote iris chafing, increasing the risk for pigment dispersion syndrome, uveitis-glaucoma-hyphema (UGH) syndrome, iridocyclitis, and increased IOP. This coincides with more numbers of persistent anterior chamber inflammation in single-piece IOLs than three-piece IOLs seen in this study.

The retrospective design of this study does not allow strong inferences; however, our results may be useful for comparison scenarios. This study had no control over the standardization of the surgical protocol, the follow-up appointments, and the number of surgeons who performed the procedure. Since this study was performed in a tertiary training hospital, the procedures were done by residents-in-training guided by consultants, further confounding variability in the management as well as the results. Retrospective studies are prone to recall and misclassification bias. Considering all of the abovementioned, this may have affected the majority of the parameters showing statistical insignificance despite the large volume of patients included in the study. The authors conducted the data analyses in a manner avoiding these biases. Knowledge on the outcomes and complications of SPA IOLs derived from this study should be taken with caution.

CONCLUSION

In conclusion, visual outcomes remain excellent for both single-piece and three-piece groups. In contrast, there were more notable complications in single-piece group. Loss of centration tends to occur more with mean optic diameters lower than or equal to 5.50 mm and an overall length of 12.50 mm or lower. While appropriate for the capsular bag, square-edged designs were found to be inappropriate for the sulcus. The retrospective design does not allow strong inferences hence caution should be taken in correlating results.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

All authors declared no conflicts of interest.

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