ARTICLE

Comparison of an upgraded optical biometer with 2 validated optical biometers

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Purpose: The Revo NX is a new optical biometer, based on spectral-domain optical coherence tomography and able to obtain high-definition scans of both the anterior and posterior segment of the eye. A previous study found that its measurements of axial length (AL) were not interchangeable with those provided by a validated optical biometer; so, the manufacturer updated the instrument to improve agreement of AL values. This study aimed to prospectively compare the measurements by the updated Revo NX (version 9.5.0, biometry module) with those by 2 validated devices, the IOLMaster 700 and Lenstar LS-900.

Setting: Optopol Technologies, Zawiercie, Poland.

Design: Prospective evaluation of diagnostic test.

Methods: Comparison between the devices was performed using repeated measures analysis of variance (ANOVA) with Bonferroni posttest, correlation coefficients, and the Bland-Altman method.

Results: The investigation evaluated the results of 63 patients. For AL, anterior chamber depth (ACD), and lens thickness (LT), the differences were not clinically significant because they were less than 0.01 mm. Repeated measures ANOVA, however, detected a statistically significant difference for AL (P < .0001) and central corneal thickness (P < .0001) but not for ACD (P = .0630) or LT (P = .2667). The results obtained with all 3 biometers manifested a high level of agreement in the Bland-Altman analysis and very strong correlation.

Conclusions: The measurements by the updated Revo NX had high agreement with the other optical biometers; a clear improvement was detected than the previous analysis between the original Revo NX (version 8.0.3) and the Lenstar LS-900.

J Cataract Refract Surg 2021; 47:859–864 Copyright © 2021 Published by Wolters Kluwer on behalf of ASCRS and ESCRS

Optical biometry is known to be the gold standard for preoperative biometry. The most recent generation of optical biometers use swept-source optical coherence tomography (SS-OCT), which has been implemented in the IOLMaster 700 (Carl Zeiss Meditec AG), Anterion (Heidelberg Engineering GmbH), Argos (Movu, Inc.), and the OA-2000 (Tomey Corp.).[1–3] Although these devices use SS-OCT and obtain excellent anterior segment images, they are not able to provide detailed diagnostic scans of the posterior segment, which could be useful in clinical practice.[4]

We recently reported that a new anterior and posterior segment spectral-domain OCT biometer (Revo NX, software version 8.0.3; Optopol Technologies) provides repeatable and reproducible measurements of axial length (AL), anterior chamber depth (ACD, measured from epithelium to lens), lens thickness (LT), and central corneal thickness (CCT).[5] However, these measurements were found not to be interchangeable with those provided by a validated biometer (Lenstar LS-900 software version 1.1.1; Haag-Streit AG). Subsequently, the manufacturer modified the biometer by improving its calibration to obtain better agreement with the measurements provided by the other competing devices. The aim of this study was to compare the ocular measurements obtained with Revo NX (after improved calibration) with those achieved by IOLMaster 700 and Lenstar LS-900.

METHODS

This study adhered to the tenets of the Declaration of Helsinki, and the protocol was approved by the local bioethical committee. All participants signed informed consent forms after acknowledging the purpose of the study. Patients were recruited from healthy volunteers and were examined at the Research and Development Unit, Optopol Technologies, Zawiercie, Poland. Patients with eye diseases, including cataract, macular disorders,

Submitted: June 23, 2020 | Final revision submitted: November 20, 2020 | Accepted: November 23, 2020

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The contribution of IRCCS–GB Bietti Foundation was supported by the Italian Ministry of Health and Fondazione Roma.

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0886-3350/$ - see frontmatter
https://doi.org/10.1097/j.jcrs.0000000000000541

Table 1. Mean and Ranges of the 3 Biometers.

	Revo NX		IOLMaster 700		LENSTAR LS-900	
Parameter	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range
AL (mm)	23.79 ± 0.73	22.33, 25.70	23.78 ± 0.72	22.36, 25.65	23.80 ± 0.72	22.36, 25.67
ACD (mm)	3.31 ± 0.31	2.67, 4.03	3.31 ± 0.32	2.66, 4.02	3.30 ± 0.31	2.66, 4.04
LT (mm)	4.20 ± 0.37	3.50, 5.23	4.20 ± 0.38	3.52, 5.22	4.20 ± 0.37	3.53, 5.21
CCT (μm)	559.2 ± 31.7	499, 662	563.6 ± 32.6	508, 668	555.4 ± 31.9	499, 660

ACD = anterior chamber depth (corneal epithelium to lens); AL = axial length; CCT = central corneal thickness; LT = lens thickness

trauma, inflammation, or having undergone previous intraocular surgery were excluded.

Instruments

Three devices were used to obtain ocular distances: 2 validated biometers, the IOLMaster 700 (software version 1.80.10.61129) and Lenstar LS-900 (software version 1.1.1), whose measurements have been reported to be in good agreement, and the new OCT (Revo NX, biometry module, software version 9.5.0).[1] The Revo NX is an anterior–posterior segment spectral-domain OCT; a superluminescent diode laser (wavelength 830 nm) is the light source in this device. It has an axial resolution of 5 μm, transverse resolution of 12 μm, and scan depth of 2.4 mm. Because Revo NX is an OCT device, it does not give keratometric information. Although a corneal tomography module was later released for Revo NX, it needs to be purchased separately; at the moment, results for corneal tomography cannot be combined with OCT biometry to provide intraocular lens (IOL) power calculations within the software. Thus, keratometric values were not compared among devices.

The IOLMaster 700 is a SS-OCT biometer using the wavelength of 1055 nm. The Lenstar LS-900 uses optical low-coherence reflectometry with a superluminescent diode laser (820 nm). With Lenstar, aqueous depth measurements (distance from the corneal endothelium to the anterior lens surface) were obtained; to calculate ACD, aqueous depth was added to CCT, to enable comparison between the devices.

Measurement Technique

The measurements were performed between 8 AM and 4 PM by a single examiner. For each patient, the examinations were obtained with all 3 devices in random order. Only results for the right eye were included in the analysis. Because the repeatability and reproducibility of Revo NX was confirmed in earlier studies, single measurements were taken with all the 3 devices.[5,6]

Statistical Analysis

Statistical calculations were conducted with the MedCalc (software version 18.11.3, MedCalc Software bvba) and Instat (software version 3.10, GraphPad); the results are presented as the mean ± SD. Comparison between the devices was performed using repeated measures analysis of variance (ANOVA) with Bonferroni posttest (because the data were normally distributed in the Kolmogorov-Smirnov test), correlation coefficients, and the method by Bland and Altman, who suggest plotting the differences between the measurements (y axis) against their mean (x axis).[7] The Bland-Altman plots were adjusted to enable comparison between several devices as recommended elsewhere.[8] The 95% limits of agreements were defined as the mean ± 1.96 SD of the differences between the 2 measurement techniques. A P value less than 0.05 was considered statistically significant.

Sample size calculation was performed using the PS program (version 3.1.6) for power and sample size calculations.[9] A sample size of 54 eyes per group was estimated to detect a difference in AL of 0.01 mm, based on a standard deviation of difference between IOLMaster 700 and Lenstar of 0.02 mm, a power of 95% at a significant level of 5%.

RESULTS

The investigation was conducted in March 2019 and involved 64 patients. In 1 patient, the lens type was mistakenly selected as a pseudophakic poly(methyl

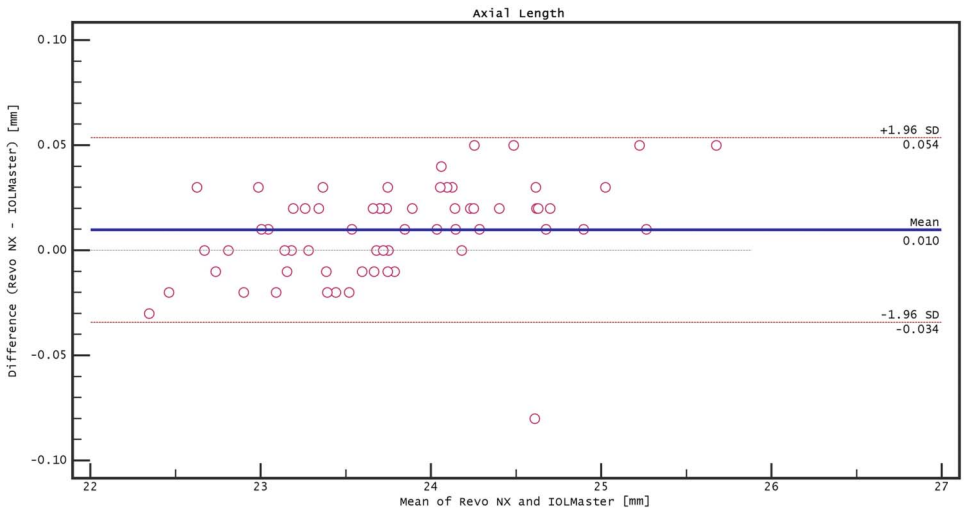

Figure 1. Bland-Altman plot of agreement in axial length measurements between Revo NX and IOLMaster 700.

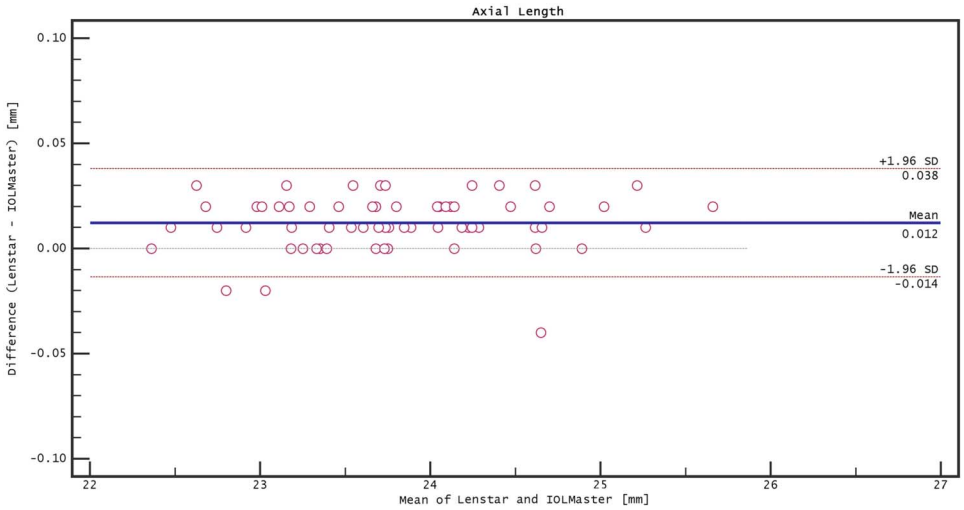

Figure 2. Bland-Altman plot of agreement in axial length measurements between LENSTAR LS-900 and IOLMaster 700.

methacrylate) IOL, and this could not be changed at a later stage; thus, the eye distances were incorrectly interpreted by the IOLMaster and excluded. Accordingly, the results of 63 patients were included in the study. The mean patient age was 35.5 ± 0.7 years (range 21 to 65 years), and there were 17 women (27%). The mean spherical equivalent refraction was 0.12 ± 1.46 (range −3.0 to +5.5 diopters [D]). The mean flat keratometry reading was 42.37 ± 1.24 D, whereas the mean steep keratometry value was 43.34 ± 1.31 D, as measured by the Lenstar.

The mean and ranges of the results obtained with the 3 analyzed biometers are presented in Table 1. The Bland-Altman plots showed minor differences in AL between Revo NX and IOLMaster and between Revo NX and IOL Master; the mountain demonstrated high agreement between all 3 devices (Figures 1 to 3). For AL, ACD, and LT, the differences were not clinically significant because they were all less than 0.01 mm. Repeated measures ANOVA, however, detected a statistically significant difference for AL ($P < .0001$); Bonferroni posttest analysis revealed that the difference was not statistically significant between Revo NX and Lenstar LS-900, whereas it was statistically significant between Revo NX and IOLMaster 700 ($P < .001$) and between IOLMaster 700 and Lenstar LS-900 ($P < .001$). No statistically significant differences were obtained between the 3 devices for ACD ($P = .0630$) and LT ($P = .2667$).

Regarding CCT, the mean value was slightly higher with the IOLMaster 700 than that with the other devices. The mean CCT measurements by the Revo NX were in the middle between those provided by the other 2 instruments. Repeated measures ANOVA detected a statistically significant difference ($P < .0001$) among the 3 devices, and Bonferroni posttest confirmed such a difference between each pair of biometers.

As reported by Table 2, all measured parameters were highly correlated (r value >0.95). Excellent agreement was found for AL, ACD, and LT; CCT measurements revealed a still good but slightly worse agreement, especially between the Lenstar LS-900 and the other 2 devices (Figures 4 to 6).

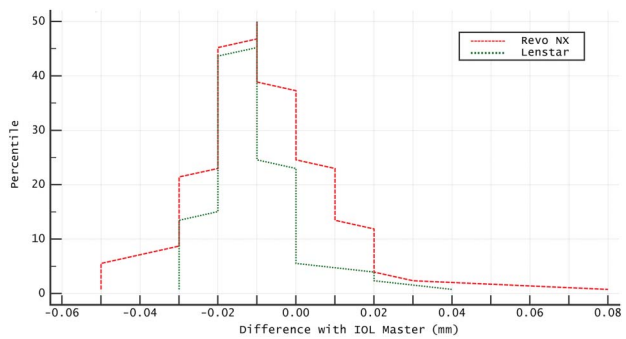

Figure 3. Mountain plot presenting the distribution of the difference in axial length between Revo NX, LENSTAR LS-900, and IOLMaster 700 measurements.

DISCUSSION

This study showed that measurements by the updated Revo NX can be considered interchangeable with those provided by 2 validated optical biometers using 2 different modalities, the IOLMaster 700 and the Lenstar LS-90. This is an improvement over the previous version, which overestimated AL by 0.11 mm in comparison with the Lenstar LS-900. Also another study reported lower differences between Revo NX and the IOLMaster in ocular biometry.[6] The precision of all of the instruments is 0.01 mm for AL measurements, and we aimed to detect such a difference between the devices. According to Olsen, a 0.10 mm inaccuracy in AL estimation corresponds to a postoperative error of 0.27 D in the spectacle plane for an eye with normal dimensions.[10] Thus, an accuracy of at least 0.10 mm was deemed to be required in biometry before cataract surgery.[10] However, with the advances in optical biometry and

Table 2. Differences Between Revo NX, LENSTAR LS-900 and IOLMaster 700.

Parameter	Device	Mean difference ±SD	95% LoA	*r* value	*P* value (posttest analysis)	*P* value
AL (mm)	Revo NX–IOLMaster 700	0.0097 ± 0.0224	−0.0343, 0.0536	0.9996	.0310	<.001
	Revo NX—LENSTAR LS-900	−0.0025 ± 0.0235	−0.0486, 0.0435	0.9995	1.000	
	LENSTAR LS-900–IOLMaster 700	0.0122 ± 0.0131	−0.0135. 0.0380	0.9998	.0001	
ACD (mm)	Revo NX–IOLMaster 700	−0.0048 ± 0.0309	−0.0558. 0.0653	0.9957	1.000	.0630
	Revo NX—LENSTAR LS-900	0.0098 ± 0.0365	−0.0617. 0.0813	0.9932	.1189	
	LENSTAR LS-900–IOLMaster 700	−0.0051 ± 0.0307	−0.0653. 0.0551	0.9958	.7987	
LT (mm)	Revo NX–IOLMaster 700	−0.0011 ± 0.0468	−0.0929, 0.0907	0.9923	1.000	.2667
	Revo NX—LENSTAR LS-900	−0.0087 ± 0.0537	−0.1141, 0.0966	0.9894	.6374	
	LENSTAR LS-900–IOLMaster 700	0.0076 ± 0.0362	−0.0633, 0.0785	0.9961	.7319	
CCT (μm)	Revo NX–IOLMaster 700	−4.4 ± 4.5	−13.2, 4.4	0.9906	<.0001	<.0001
	Revo NX—LENSTAR LS-900	3.8 ± 8.5	−12.8, 20.5	0.9645	.0016	
	LENSTAR LS-900–IOLMaster 700	−8.2 ± 8.4	−24.7, 8.3	0.9662	<.0001	

ACD = anterior chamber depth (corneal epithelium to lens); AL = axial length; CCT = central corneal thickness; LT = lens thickness

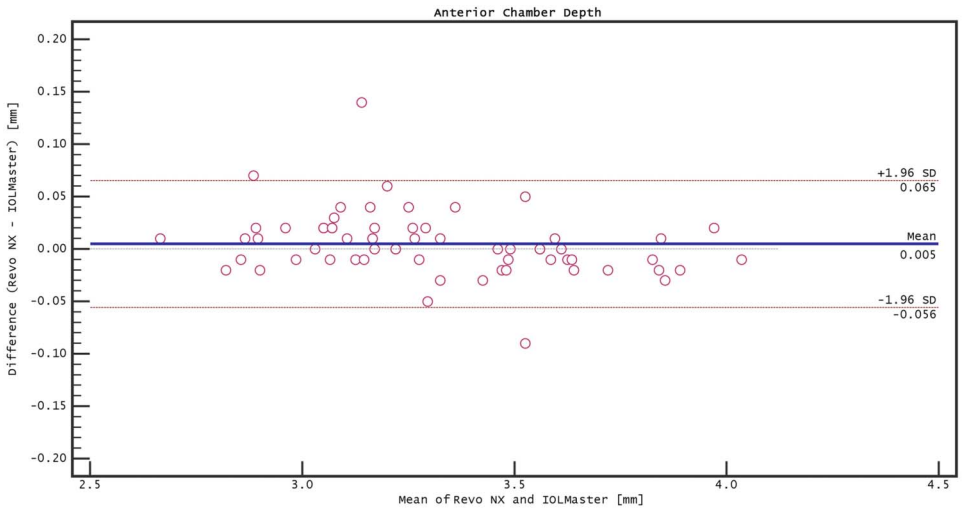

Figure 4. Bland-Altman plot of agreement in anterior chamber depth measurements between Revo NX and IOLMaster 700.

increasing patient expectations, even greater precision would be required. The difference in mean AL is now lower than 0.01 mm than those of both devices, a value that has no clinical meaning, especially when integrated with high level of agreement (Bland-Altman plots) and high correlation. The statistically significant difference

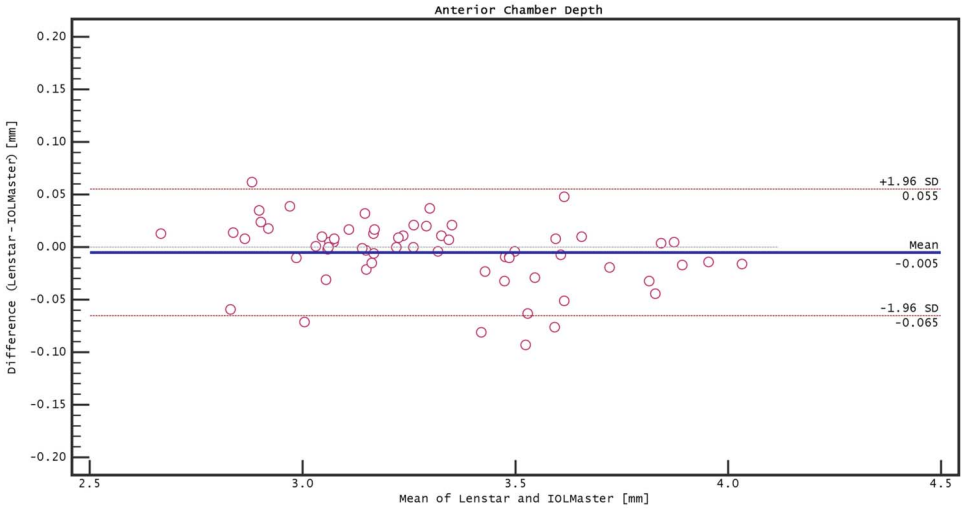

Figure 5. Bland-Altman plot of agreement in anterior chamber depth measurements between LENSTAR LS-900 and IOLMaster 700.

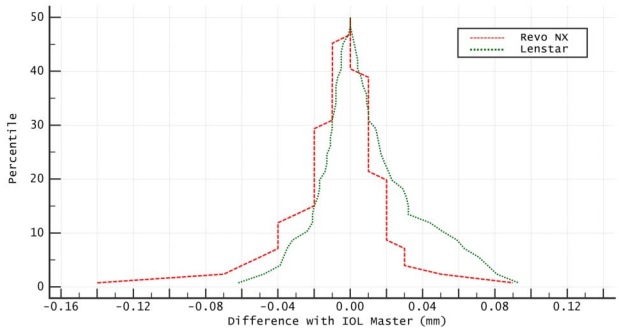

Figure 6. Mountain plot presenting the distribution of the difference in anterior chamber depth between Revo NX, LENSTAR LS-900, and IOLMaster 700 measurements.

in AL between the Revo NX and the IOLMaster 700 is not surprising because similar statistically significant differences have been previously found between the IOLMaster 500 and the Lenstar LS-900 and between the IOLMaster 700 and the Lenstar LS-900.[1,11] In all these cases, the differences were not judged to be clinically significant because they were within 0.03 mm. Moreover, some recent studies have shown that, even when using calibrated optical biometers, the mean difference in AL measurements between the IOLMaster and the Lenstar LS 900/OA-2000 might reach 0.05 mm.[12,13]

The estimation of postoperative ACD remains truly empirical in content, and an accurate prediction of ACD remains more important in short eyes than that in long eyes.[14] Nevertheless, in a theoretical model by Engren and Behndig, an error in preoperative ACD estimation of 1.00 mm would result in a refractive shift of as much as 0.32 D postoepratively.[15] The differences in ACD and LT improved than that of our previous report and lost any statistical significance when compared with those of the Lenstar LS-900 and the IOLMaster 700. The interchangeability of not only AL but also ACD and LT is of utmost importance for IOL power calculation because it minimizes the differences of optimized constants for IOL power calculation and, therefore, enables surgeons to achieve better refractive outcomes in patients undergoing cataract surgery.

The relative differences in CCT were slightly greater than for the other measured ocular distances but still not clinically significant. The highest range of the 95% limits of agreement (from −12.8 to 20.5 μm) was observed between the Revo NX and the Lenstar LS-900.

This study has some limitations that require further investigations. First, the keratometry values of the Revo NX were not yet implemented and available and, thus, could not be assessed. Second, we analyzed only healthy subjects. Third, we did not enroll long eyes (>26 mm). In conclusion, we observed that the measurements in normal eyes by the updated Revo NX had high agreement with those from validated optical biometers; a clear improvement was detected than that of the previous analysis between the Revo NX and the LENSTAR LS-900.

WHAT WAS KNOWN

- Optical methods are considered to be the gold standard for preoperative biometry.
- Our previous study has shown that optical biometry can be used in a new anterior and posterior segment spectral-domain optical coherence tomography device, providing repeatable and reproducible measurements of axial length (AL), anterior chamber depth (ACD), lens thickness, and central corneal thickness.
- The results have shown a strong correlation with a validated optical biometer; however AL and ACD measurements cannot be considered interchangeable.

WHAT THIS PAPER ADDS

- The updated Revo NX (version 9.5.0) optical biometer has high agreement with the other accepted optical biometers.
- We have observed an improvement than the previous analysis between the original Revo NX (version 8.0.3) and the Lenstar LS-900: there was no statistically significant difference in ACD and lens thickness, whereas the difference in AL and central corneal thickness was clinically irrelevant.

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Disclosures: *Dr. Kanclerz reports nonfinancial support from Visim and Optopol Technologies. Dr. Hoffer licenses the registered trademark name Hoffer to ensure accurate programming of his formulas to Carl Zeiss Meditec AG (IOLMasters), Haag-Streit AG (LENSTAR/EyeStar), Heidelberg Engineering GmbH (Anterion), OCULUS Optikgeräte GmbH (Pentacam AXL), Optopol Technology (Revo NX), Movu, Inc. (Argos), NIDEK Co., Ltd. (AL-Scan), Tomey Corp. (OA-2000), Topcon EU/VisiaImaging (Aladdin), Ziemer Ophthalmic Systems AG (Galilei G6), and all A-scan biometer manufacturers but not Alcon Laboratories, Inc. (Verion). Ms. Przewłócka has nothing to disclose. Dr. Savini is a consultant to CSO and has received personal fees from Alcon Laboratories, Inc., OCULUS Optikgeräte GmbH, and Carl Zeiss Meditec AG. The authors have no financial interests.*

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