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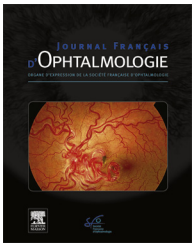

ORIGINAL ARTICLE

Changes of ocular biometry in eyes with posterior chamber phakic intraocular lens implantation

Modifications de la biométrie oculaire dans les yeux avec implantation de lentille intraoculaire phaque de chambre postérieure

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Anterior chamber depth;
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Intraocular lens calculation;
Myopia;
Ocular biometry;
Phakic intraocular lens

Summary
Objective. — To evaluate changes in biometric variables and intraocular lens (IOL) calculation results after posterior chamber phakic IOL (PCPIOL) implantation.
Methods. — This retrospective, observational study included 65 eyes of 38 patients who underwent PCPIOL (EVO Visian ICL) implantation for correction of myopia. Prior to and a minimum of one year (mean 14.9 months) after EVO Visian ICL implantation, biometric variables and IOL calculation results were compared. Optical biometry, including anterior chamber depth, axial length, flat, steep, and mean keratometry values and IOL calculation results for the Holladay 2, Hoffer Q, Haigis, and SRK/T formulas were measured using the IOLMaster 700 SWEPT Source OCT biometer.
Main results. — The mean anterior chamber depth decreased from 3.70 ± 0.22 mm to 3.34 ± 0.39 mm, the mean axial length increased from 26.61 ± 1.61 mm to 26.71 ± 1.66 mm, and the mean flat keratometry changed from 42.82 ± 1.86 D to 42.73 ± 1.83 D. These changes were statistically significant. The mean IOL power calculation also revealed a statistically significant decrease with all four formulas (ranging from 0.19 D to 0.30 D) after PCPIOL implantation.

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Conclusions. — Biometric variables and IOL calculation results showed statistically significant changes one year after EVO Visian ICL implantations. However, IOL power calculations yielded a decrease of less than 0.50 D, inducing much less refractive deviation in the spectacle plane; and the change was primarily related to an increase in AL measurements. IOL power calculations in eyes with EVO Visian ICL in situ provided satisfactory and reliable results.

MOTS CLÉS
Biométrie oculaire ;
Calcul de lentille intraoculaire ;
Lentille collamer implantable ;
Lentille intraoculaire phaque ;
Longueur axiale ;
Myopie ;
Profondeur de la chambre antérieure

Résumé
Objectif. — Évaluer les changements des variables biométriques et les résultats du calcul des lentilles intraoculaires (LIOs) après l'implantation d'une LIO phaque de chambre postérieure (LIOPCP).
Méthodes. — Cette étude observationnelle rétrospective a inclus 65 yeux de 38 patients ayant subi une implantation LIOPCP (EVO Visian ICL) pour la correction de la myopie. Avant et au moins un an (en moyenne 14,9 mois) après l'implantation d'EVO Visian ICL, les variables biométriques et les résultats des calculs de l'LIO ont été comparés. La biométrie optique, y compris la profondeur de la chambre antérieure, la longueur axiale, les valeurs de kératométrie plate, raide et moyenne (K), et les résultats des calculs LIO des formules Holladay 2, Hoffer Q, Haigis et SRK/T ont été mesurés à l'aide du biomètre IOLMaster 700 SWEPT Source OCT.
Principaux résultats. — La profondeur de la chambre antérieure moyenne a diminué de $3{,}70 \pm 0{,}22$ mm à $3{,}34 \pm 0{,}39$ mm, la longueur axiale moyenne a augmenté de $26{,}61 \pm 1{,}61$ mm à $26{,}71 \pm 1{,}66$ mm et le K plat moyen a changé de $42{,}82 \pm 1{,}86$ D à $42{,}73 \pm 1{,}83$ D. Ces changements ont été statistiquement significatif. Le calcul de la puissance moyenne de l'LIO a également révélé une diminution statistiquement significative dans les quatre formules (allant de 0,19 D à 0,30 D) après l'implantation du LIOPCP.
Conclusion. — Les variables biométriques et les résultats des calculs LIO ont montré des changements statistiquement significatifs après un an d'implantation d'EVO Visian ICL. Cependant, les résultats de puissance de la LIO ont donné une diminution inférieure à 0,50 D, induisant un décalage de réfraction beaucoup plus petit sur le plan des lunettes et le changement était principalement lié à une augmentation de la longueur axiale. Les calculs de puissance de LIO dans les yeux implantés avec ICL Visian ont fourni des résultats satisfaisants et fiables.

Introduction

Implantable collamer lens (ICL) is a posterior chamber phakic intraocular lens (PCPIOL). Although laser refractive surgery constitutes most of the refractive procedures in the world, PCPIOL implantation has become a widespread procedure in eyes that are not candidates for laser refractive procedures due to unsuitable corneal parameters and/or high refractive errors. PCPIOL can correct myopic errors up to −18.00 Diopters (D), hyperopia up to 10.00 D, and astigmatism up to 6.00 D. PCPIOL can be explanted or exchanged. As several studies reported good efficacy and safety, the popularity and the number of implantations increased [1—4].

All PCPIOL implanted eyes will eventually require crystalline lens extraction and intraocular lens (IOL) implantation in the future because of three main reasons. Firstly, cataracts can be induced by PCPIOL implantation. An anterior subcapsular cataract may arise because of the low vault (the distance between the posterior surface of the PCPIOL and anterior surface of the natural, crystalline lens) after PCPIOL implantation [5—8]. The mechanical contact of PCPIOL with the crystalline lens, and inadequate aqueous circulation which were more common with the older models, V4 and V4b, were the proposed mechanisms for the development of anterior subcapsular cataracts. These models did not have a central hole. The more accurate determination of the PCPIOL size and the V4c model PCPIOL with a central hole, which is already on the market since 2011, caused this undesired effect to decrease considerably [9—15]. Secondly, the aging and other cataract reasons seen in the normal population such as systemic diseases, trauma, steroid use may also induce cataracts in PCPIOL implanted eyes. Moreover, because the majority of these eyes have high myopia, they are expected to develop cataracts earlier. Thirdly, other than the cataract development, when these patients reach the presbyopic age, they may request crystalline lens extraction and premium IOL implantation for presbyopic correction. In all these cases, obtaining the most accurate biometry has crucial importance in achieving the best refractive outcomes.

The study aimed to understand how PCPIOL affected biometric variables and IOL calculation formulas. We evaluated the changes in the anterior chamber depth (ACD), axial length (AL), keratometric readings, and IOL power

calculations with Holladay 2, Hoffer Q, Haigis, and SRK-T formulas after PCPIOL implantation by using Zeiss IOLMaster 700 SWEPT Source Optical Coherence Tomography (OCT) biometer (Carl Zeiss Meditec AG, Jena, Germany).

Patients and methods

This retrospective, observational study included patients which underwent EVO Visian ICL (ICL Model V4c, STAAR Surgical, Nidau, Switzerland) implantation for myopia between January 2017 and June 2018. The study was conducted under the Declaration of Helsinki and approved by Institutional Review Board. Written informed consent was obtained from all participating individuals.

Myopic eyes with or without astigmatism who were not suitable for corneal refractive surgery were included in the study. For EVO Visian ICL implantation, patients older than 21 years old and with stable refraction were selected. Exclusion criteria were ACD lower than 2.8 mm, endothelial cell count (ECC) lower than 2500 cells/mm^2, presence of any ocular and systemic diseases, and history of any ocular surgery.

All patients underwent a routine, full ophthalmic examination. Uncorrected distance visual acuity and corrected distance visual acuity (CDVA) were measured with the Snellen chart. ECC measurements were made by SP 3000P specular microscope (Topcon Corporation, Tokyo, Japan). The Online Calculator and Ordering System (OCOS) from STAAR Surgical was used to calculate the PCPIOL power. Orbscan (Bausch & Lomb, Rochester, New York, USA) and Pentacam (Oculus Optikgeräte, Wetzlar, Germany) were the devices to assess corneal topography, pachymetry, horizontal white to white (WTW) distance, and ACD measurements from the corneal endothelium.

ACD, AL, keratometry (K) readings as flat K (K1) and steep K (K2) were measured by using the IOLMaster 700 SWEPT Source OCT biometer (Carl Zeiss Meditec AG, Jena, Germany), and IOL calculations were made with the same device in phakic mode. The measurements with good signal quality (checked by the quality check mode of the device) were taken by the same experienced operator. Holladay 2, Hoffer Q, Haigis, and SRK/T formulas were used to calculate the IOL power for the AcrySof® IQ Aspheric Natural IOL (Model SN60WF, Alcon Laboratories, Inc. Fort Worth, TX, USA). Optical biometry lens constants which were set for this IOL were ACD of +5.601 for Holladay 2; pACD of +5.64 for Hoffer Q; a0 of −0.769, a1 of +0.234, a2 of +0.217 for Haigis suite, and A-constant of 119.00 for SRK/T.

Surgeries were performed by the same surgeon (EC) under topical anesthesia. Firstly, two corneal side port incisions and after injection of 1.0% cohesive ophthalmic viscosurgical device (OVS), a temporal clear corneal incision with 2.8 mm width were created. A cartridge was used for PCPIOL injection into the eye. Following placement of PCPIOL haptics into the sulcus in the correct axis, irrigation of OVS was performed utilizing Irrigation/Aspiration (I/A) handpiece with I/A mode Centurion Vision System (Alcon Laboratories, Inc. Fort Worth, TX, USA) phacoemulsification machine. Incisions were closed by hydration after providing miosis by injecting intracameral carbachol. Slit-lamp examination and measurement of intraocular pressure were performed within the first hours of the operation day, and oral acetazolamide tablets were given as needed. Antibiotic and corticosteroid eye drops were used four times a day postoperatively. Patients were followed on 1st day and after one week, one month, three months, and every year in the postoperative period. The vault was measured by Visante optical coherence tomography (Carl Zeiss Meditec AG, Germany).

Number Cruncher Statistical System (NCSS, 2007) was used for the statistical analysis and the interpretation of the data. Descriptive statistical methods were reported as the mean, standard deviation, median, frequency, ratio, minimum and maximum to evaluate the study data. The compatibility of the quantitative data to normal distribution was analyzed with Kolmogorov-Smirnov, Shapiro-Wilk test, and the graphical evaluations. Paired Sample *t*-test for normally distributed variables and Wilcoxon Signed Ranks test for not normally distributed variables were applied for analyses differences for the comparison of the results across the pre-and the post-operation. *P* values of less than 0.05 were considered statistically significant.

Results

The study consisted of 65 eyes of 38 patients who underwent EVO Visian ICL implantation to correct myopia. Twenty-two (57.9%) of patients were female and 16 (42.1%) of patients were male. The mean age of the patients was 28.29 ± 4.79 years (ranging from 21 to 37 years). Both eyes of 27 patients and one eye of 11 patients (33 eyes were right, 32 eyes were left) were included in the study. Eight of the single eye patients had undergone laser refractive surgery, two, phacoemulsification respectively in the other eyes. One eye of the single eye patients had the low quality measurements and was excluded from the study. The mean duration of follow-ups was 14.9 months (ranged from 12 to 18 months).

Improvements in both refraction and CDVA were statistically significant after PCPIOL implantation (Table 1).

AL increased, and ACD decreased significantly after the operation (Table 2). Regarding K values, while flat K (K1) and

Table 1 Preoperative and postoperative refraction and corrected distance visual acuity.

(*n* = 65)		Preop	Postop	*p*
Refraction (SE) (D)	*Mean* ± *SD*	−9.81 ± 4.14	−0.27 ± 0.47	0.001**
CDVA (Snellen Equivalent)	*Mean* ± *SD*	6/7.98 ± 6/3.05	6/6.33 ± 6/1.01	0.001**

SE: spherical equivalent; CDVA: corrected distance visual acuity; SD: standard deviation; ***p*<*0.01*.

Table 2 Preoperative and postoperative axial length, anterior chamber depth, keratometry, and postoperative vault values.

($n = 65$)		Preoperative	Postoperative	p
AL (mm)	*Min.—Max. (Median)*	22.7—30.2 (26.5)	22.7—30.4 (26.6)	0.001[a]
	Mean ± SD	26.61 ± 1.61	26.71 ± 1.66	
ACD (mm)	*Min.—Max. (Median)*	3.3—4.2 (3.7)	2.7—4.1 (3.3)	0.001[a]
	Mean ± SD	3.70 ± 0.22	3.34 ± 0.39	
K1 (D)	*Min.—Max. (Median)*	35.5—47.7 (42.8)	35.7—47.7 (42.7)	0.012[b]
	Mean ± SD	42.82 ± 1.86	42.73 ± 1.83	
K2 (D)	*Min.—Max. (Median)*	36.8—49.3 (45.6)	36.9—49.4 (45.5)	0.615
	Mean ± SD	45.08 ± 2.11	45.06 ± 2.10	
K AVE (D)	*Min.—Max. (Median)*	36.1—48.3 (44.2)	36.3—48.5 (44)	0.045[b]
	Mean ± SD	43.92 ± 1.93	43.86 ± 1.90	
VAULT (mm)	*Min.—Max. (Median)*	N/A	0.1—0.9 (0.5)	
	Mean ± SD		0.49 ± 0.17	

Paired Samples t Test: [a]$p < 0.01$; [b]$p < 0.05$.
AL: axial length; ACD: anterior chamber depth; K1: flat keratometry; K2: steep keratometry; K AVE: average keratometry; mm: milimeter; D: diopter; SD: standard deviation.

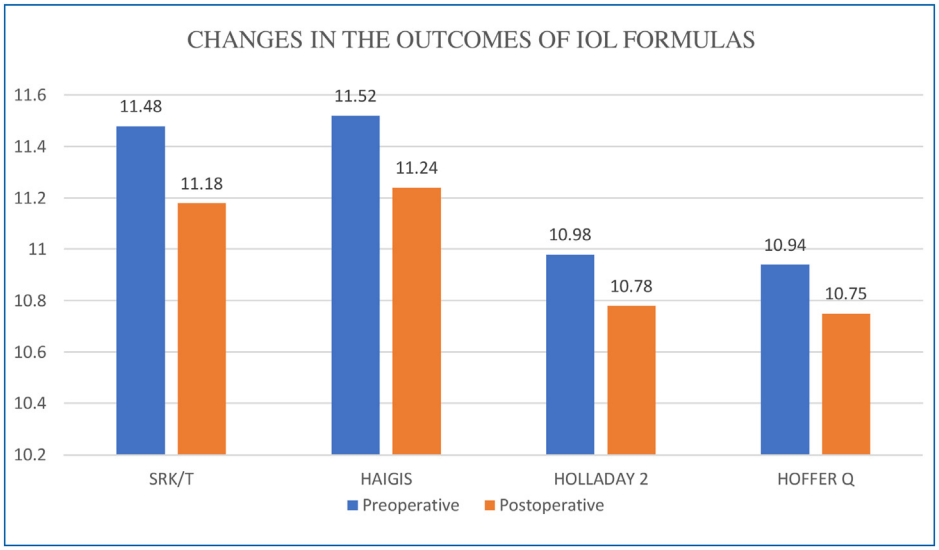

Figure 1. The outcomes of IOL formulas after ICL implantation demonstrated a statistically significant decrease. The highest difference was 0.30 D with SRK/T followed by 0.28 D of Haigis, 0.20 D of Holladay 2 and 0.19 D of Hoffer Q, respectively.

average K (K AVE) decreased significantly postoperatively, there was no significant change in steep K (K2) (Table 2).

The calculated IOL power demonstrated a statistically significant decrease ($p < 0.01$) in all formulas, ranging from 0.19 D to 0.30 D (Fig. 1).

No complications were observed intraoperatively and postoperatively.

Discussion

To our knowledge, our study is the first to compare biometric variables and four IOL calculation formulas before and after PCPIOL implantation in the substantial number of eyes and at least one year (the mean 14.9 months) follow-up by using IOLMaster 700 SWEPT Source OCT optical biometry. We found a statistically significant increase of 0.1 mm in AL after PCPIOL implantation. AL changes reported by previous studies varied from 0.016 mm to 0.12 mm increase after phakic IOL (pIOL) implantation (Table 3) [16—20]. The longest follow-up duration in these studies was three months, and the device used for measurements was IOLMaster 500 partial coherence interferometry and/or A-Scan ultrasound biometry. Differently, the mean duration of follow-up in our study was 14.9 months (ranged from 12 to 18 months) and we used IOLMaster 700 SWEPT Source OCT for biometric measurements. An ICL has a low refractive index (1.442) and very little thickness. Moreover, according to the manufacturer, IOLMaster devices use an equivalent refractive index of the entire eye. The longer follow-up duration in our study may be another factor inducing the higher axial length difference than the studies with 1 or 3 months follow-up duration. Some studies point out axial elongation in myopic adults. Saka et al. investigated axial length changes in myopic adults by

Table 3 Studies reporting axial length change after phakic IOL implantations.

Study	*n* (eyes)	Phakic IOL Type	Measuring Device	AL Change	Length of Follow-up
Pitault et al., [16]	25	PRL, ICL, Artisan	IOLMaster	**0.016 mm**	3 months
Shin et al., [17]	40	Artisan	A-Scan	-0.03 ± 0.15 mm	3 months
			IOLMaster	0.12 ± 0.07 mm	
	36	Artiflex	A-Scan	0.09 ± 0.16 mm	3 months
			IOLMaster	0.07 ± 0.10 mm	
Seok et al., [18]	141	ICL	A-Scan	0.05 mm	1 month
Lee et al., [19]	45	ICL, Artiflex	IOLMaster	0.01 mm	1 month
Amro et al., [20]	24	ICL	IOLMaster	0.01 mm	3 months

AL: axial length.

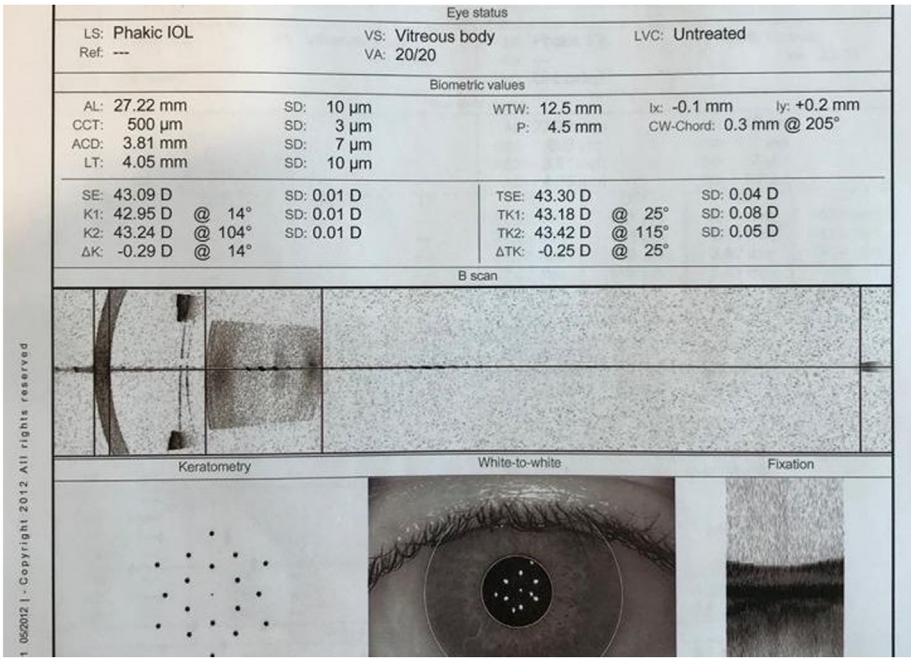

Figure 2. B-scan image of an eye with EVO Visian ICL and measurements of ocular biometric parameters in IOLMaster 700 Swept source optical coherence tomography.

measuring with IOLMaster and demonstrated that the mean axial length increased significantly from 29.35 ± 1.80 mm to 29.48 ± 1.85 mm in 2 years, a mean increase of 0.13 mm with a range of -0.12 to 1.10 mm [21]. In another study done by Meier et al., the authors reported that the mean axial length increased from 29.06 ± 1.96 mm to 29.92 ± 2.47 mm, eight years after pIOL implantation [22]. Our finding related to AL is consistent with these previous studies.

ACD decrease was another statistically significant finding in our study. Several studies done with different measuring devices reported a decrease in ACD. Yan et al. reported a significant decrease in ACD after two years of PCPIOL V4c implantation by using pentacam [23]. Elmohamady et al. evaluated the changes of the anterior chamber of the eye after PCPIOL implantation in high myopia similarly by pentacam and showed ACD decrease [24]. The authors based this finding on the false measurement of ACD as a distance between the posterior corneal surface and the anterior surface of the ICL. Ju et al. investigated ACD after PCPIOL implantation, using anterior segment OCT, and revealed a statistically significant reduction in mean ACD from 3.28 ± 0.14 mm to 2.45 ± 0.22 mm, three months after the implantation in their study [25]. A study done with IOLMaster 500 also showed a significant decrease in ACD, and the authors interpreted this change as a result of the light reflections from the pIOL [20]. We revised B-scan measurements to check if IOLMaster 700 SWEPT source OCT could differentiate the anterior surface of the PCPIOL from the anterior capsule of the natural lens in ACD measurements. We saw no confusion in ACD measurements and the device measured ACD correctly in PCPIOL in situ eyes (Fig. 2).

Average K and flat K values demonstrated changes with the differences of -0.06 D and -0.09 D respectively in our study. Even if these changes showed statistical significance,

they were too small to express clinical significance. They were probably surgically induced. The steep K value was the only variable that did not show any significant change. In the study done by Amro et al., the authors stated flat K alteration from 42.48 ± 1.56 D to 42.31 ± 1.66 D after PCPIOL implantation similarly to our study, but they found these outcomes statistically insignificant [20]. Likewise, Elmohamady et al. reported a flat K decrease after PCPIOL implantation from 43.28 ± 1.11 D preoperatively to 42.74 ± 1.39 D after a one-year follow-up in the study which comprised 34 eyes [24].

The question of how PCPIOL affected the outcomes of IOL power calculation formulas was one of the main concerns in our study. We found statistically significant decreases in the outcomes of IOL calculation formulas; Holladay 2, Hoffer Q, Haigis, and SRK/T postoperatively. Comparably, Lee et al. evaluated the outcomes of SRK/T and Haigis formulas after PCPIOL implantation and stated that postoperative IOL powers predicted by the SRK/T (−0.03D, $p = 0.023$) and Haigis formulae (−0.06D, $p = 0.001$) were significantly lower than the preoperative values although the differences were too small to influence IOL power selection [19]. In the aforementioned study, Amro et al. reported a statistically insignificant increase in outcomes of IOL calculations with SRK/T, Hoffer Q, Holladay 1, Haigis, and Barrett Universal formulas [20]. The maximum change was 0.15 D of Hoffer Q formula in their study comprised of 24 eyes [20]. In the study evaluating outcomes of IOL power calculation in pIOL in situ before PCPIOL explantation, cataract extraction and IOL implantation, the authors reported that while the mean target spherical equivalent (SE) was −1.38 ± 1.53 D before cataract extraction, and IOL implantation, the mean achieved SE was −1.18 ± 1.73 D postoperatively [22]. The outcomes of this study support our findings demonstrating lower IOL power outcomes after pIOL implantation.

The limitation of our study may be its retrospective design. Studies with longer follow-up may be designed prospectively. **Furthermore, the studies comparing the target and the achieved refraction after cataract extraction in pIOL implanted eyes by calculating IOL powers in pIOL*in situ*will provide valuable data for better prediction of IOL power.**

In conclusion, we showed statistically significant changes in biometric variables. As the time interval between pIOL implantation and cataract extraction increases, it is expected that biometric variables such as AL can change. However, IOL power calculations in EVO Visian ICL in situ eyes also showed less than 0.50 D change, which causes very little refractive shift in the spectacle plane. Therefore, we believe that IOL power calculation in EVO Visian ICL *in situ* eyes provides reliable and satisfactory results.

No previous publication or presentation.

Authors' contributions

BK contributed to the design and writing of the study, acquisition, analysis and interpretation of the data. EC contributed to the conception, design and writing of the study, acquisition, analysis and interpretation of the data. All authors made the critical revision of the article, read and approved the submitted manuscript.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Istanbul Rumeli University (Approval number: 2020/12-02a).

Written informed consent was obtained from all participating individuals.

Consent for publication

Not applicable.

Availability of data and materials

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

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Disclosure of interest

The authors declare that they have no competing interest.

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