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CLINICAL STUDY

The Cataract National Dataset electronic multicentre audit of 55 567 operations: when should IOLMaster biometric measurements be rechecked?

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Abstract

Purpose **Calculation of intraocular lens (IOL) power for implantation during cataract surgery depends on ocular biometric measurements. The aim of this study was to characterise the normal range of intra- and interindividual variation in axial length (AL) and corneal power (*K*) when IOLMaster measurements were possible and to derive recommendations as to which outlying measurements merit verification before acceptance.**

Methods **The Medisoft electronic patient database contains prospectively collected data conforming to the United Kingdom (UK) Cataract National Dataset on 55 567 cataract operations. From this AL and *K* information on the 32 556 eyes (14 016 paired) of patients older than 25 years, without corneal pathology, history of intraocular surgery and who had all biometric measurements taken with the Zeiss IOLMaster (Carl Zeiss Meditec) were extracted. R 2.8.1 (R Foundation for Statistical Computing) was used for statistical analysis.**

Results **Mean age was 76.4 years and 62.0% were female. Mean (95% confidence interval) values for AL, mean *K* and corneal astigmatism were 23.40 (21.27–26.59) mm, 43.90 (40.94–47.01) D and 1.04 (<2.50) D. Nearly all astigmatism was either with or against the rule. Differences between paired eyes were not statistically significant. 95% individuals had asymmetry of AL and mean *K* <0.70 mm and 0.92 D, respectively.**

Conclusions **On the basis of approximation of the 95% CI above, it is suggested that AL, mean *K* and keratometric astigmatism measurements outside the ranges 21.30–26.60 mm, 41.00–47.00 D and >2.50 D, respectively, and intraindividual asymmetry of AL >0.70 mm or mean *K*>0.90 D should be verified before acceptance.**

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Introduction

Cataract surgery is the most frequently performed operation in the developed world.[1] Nearly all formulae used for calculation of intraocular lens (IOL) power depend on axial length (AL) measurements and require knowledge of corneal power (*K*).[2–6] As a result, accurate and precise measurements are a critical part of preoperative assessment and biometric errors are an important source of ophthalmic error.[7] To minimise such risk the United Kingdom (UK) Royal College of Ophthalmologists (RCOphth) Cataract Surgery Guidelines contain advice as to which outlying biometric measurements merit confirmation.[8] Stating that 96% of AL fall within the range 21.0–25.5 mm and that 98% K-readings lie between 40 and 48 D, the guidelines recommend measurements outside this range should be rechecked. Similarly, the same guidelines suggest that an interocular difference in *K* of

>1.00 D or an AL disparity of >0.3 mm should only be accepted after verification, a recommendation similar to that of Holladay.[2]

Although these guidelines are potentially of very great use, their recommendations are derived from analysis of studies performed in other countries and have not been specifically validated as appropriate for the UK population. The principle aim of this analysis was to address this uncertainty by determining the normal range of biometric variation in the UK cataract surgery population, so enabling the validity of the RCOphth biometry guidelines to be assessed. The secondary goal of this study was to compare biometric measurements between fellow eyes.

Materials and methods

The UK Cataract National Dataset (CND) Electronic Multicentre Audit (EMA) has been described in detail before: it comprises prospectively collected information conforming to the UK CND on 55 567 cataract operations performed at 12 UK National Health Service hospital trusts by 406 surgeons between November 2001 and July 2006.[9]

For reasons of confidentially patients were not originally identified in this database by a unique identifier meaning that paired eyes were not matched. To overcome this limitation, the database was imported into MatLab r2007a (The MathWorks Inc, Natick, MA, USA) and code written to identify eyes with common date of birth, sex, ethnic origin and trust and which had undergone the appropriate order and combination of first and second and left and right eyes. When the free-text field listing the medications used by each potential pair of eyes were compared, there was near perfect agreement of drug names, spellings, order and doses, confirming the validity of this seven-step approach and these combinations were accepted as pairs. In five instances, three eyes appeared to match, so all these eyes were excluded from the paired analysis.

Twelve different keratometers and 17 AL measuring devices were used in the CND EMA. 98% of keratometry measurements were recorded using automated devices with the IOLMaster (Carl Zeiss Meditec, Welwyn Garden City, Hertfordshire, UK) being used in 67.9% of instances. Similarly, the IOLMaster was the device most often used to determine AL and used in 66.0% of cases.

Uniquely, the IOLMaster was the only instrument in this study that used an optical technique, partial coherence interferometry (PCI), to determine AL. Compared with acoustic biometry with a standard 10 MHz ultrasound probe, PCI AL measurements have greater precision (20 μm[10] *vs* 120 μm[11,12]), are negligibly affected by velocity assumptions[13] and consistently measured along the visual axis.[14] In addition, applanation ultrasound measurements are further affected by an inevitable but variable amount of corneal indentation.[15] Given these limitations of ultrasonic AL measurement in general and the specific problem that the type of ultrasound probe (immersion or applanation) was not recorded in the CND EMA, the decision was made to study only those eyes which had all biometric measurements recorded using the IOLMaster.

Data eyes from patients older than 25 years without corneal pathology or a history of intraocular surgery and who had both AL and K measurements with the IOLMaster were identified and their age, past ophthalmic history, AL, maximum and minimum K (K_{max} and K_{min}, respectively) were extracted for inclusion in the present analysis. Mean K (K_{mean}) was defined as $(K_{\mathrm{max}}+K_{\mathrm{min}})/2$ and keratometric astigmatism (K_{delta}) as $K_{\mathrm{max}}-K_{\mathrm{min}}$.

For analysis of AL, K and astigmatism in the entire study population and to compare the sexes, all unpaired eyes were included, but, to avoid correlation bias, only one eye was included from each pair. The paired eye included was selected at random. The subset of matched eyes was used to contrast first and second and left and right eyes using relative differences, so permitting negative values. In addition, asymmetry between paired eyes was calculated in absolute terms using the modulus of the above differences without regard to sign.

Astigmatism was analysed using power vectors.[16] In this system

$$J_0 = (-\mathrm{cylinder}/2)\times \cos(2\times \mathrm{axis})$$

and

$$J_{45} = (-\mathrm{cylinder}/2)\times \sin(2\times \mathrm{axis})$$

J_0 describes the difference in diopteric power between horizontal and vertical axes and is positive when astigmatism is with-the-rule (vertical K steeper) and negative when it is against-the-rule (horizontal K steeper). J_{45} characterises oblique astigmatism being positive if the axis of negative cylinder axis is closer to 45° than 135° and positive if closer to 135° than 45°.

R 2.8.1 (R Foundation for Statistical Computing) statistical software was used.[17] Biometric parameters are not normally distributed so the non-parametric Mann–Whitney U-test was used for statistical comparison. As described, three comparisons were made on the dataset including one eye of each patient (AL, K_{mean} and K_{delta} between males and females) and six analyses were performed on the subset of paired eyes (AL, K_{mean} and K_{delta} between first and second eyes and between left and right eyes). To account for this, a Bonferroni correction was made to the threshold of statistical significance reduced from $P<0.05$ to <0.016 and <0.0083, respectively. Linear regression analysis was used to characterise the change of biometric parameters with age.

Results

A total of 32 556 eyes (58.6%) of 25 548 patients, including 7008 pairs of the 55 567 eyes in the UK CND EMA database met the inclusion criteria. Thus, data from 25 548 unpaired eyes were analysed to determine the normal range of biometric variation, the study's primary objective, and information from 14 016 paired eyes of 7008 subjects used to investigate biometric asymmetry, the study's secondary objective.

Mean patient age was 76.4 (standard deviation (SD) 9.8, range 25–104, median 78.0) years. Patients were 37.8% male, 62.0% female and 0.2% unclassified. 97.3% of patients who had IOLMaster keratometry measurements also had AL measured by IOLMaster.

In Figure 1 the relationship between AL and mean *K* in the study population and the distribution of each parameter against age is plotted. Table 1 lists the median, mean SD 50% and 95% and overall distribution ranges for AL, K_{mean} and K_{delta} in the whole study population and male and female subgroups. Similar information describing the subset of paired eyes and the differences between first and second and left and right eyes is listed in Table 2.

This study found that 92.1% of eyes had AL measurements between 21.0 and 25.5 mm, these limits being equal to 1.5 and 93.6 centiles and 99.0% of eyes had *K* values between 40 and 48 D, the values being equivalent to the 0.5 and 99.5 centiles. A total of 2.8% eyes had an interocular difference in $K>1$ D and 82.5% subjects had AL asymmetry of $\leqslant 0.3$ mm.

As shown in Figure 1, AL moderately correlated with K_{mean} and was described by the relationship

$$K(\mathrm{D}) = 54.11 - 0.44\ (\mathrm{AL\ (mm)}),\ R^2 = 0.14,\ P<0.001$$

Although AL was shorter and K_{mean} steeper in older than younger patients, these correlations were weak and not significant. Specifically,

$$\mathrm{AL\ (mm)} = 25.64 + 0.029\ (\mathrm{age\ (years)}),$$

$$R^2 = 0.04,\ P<0.001$$

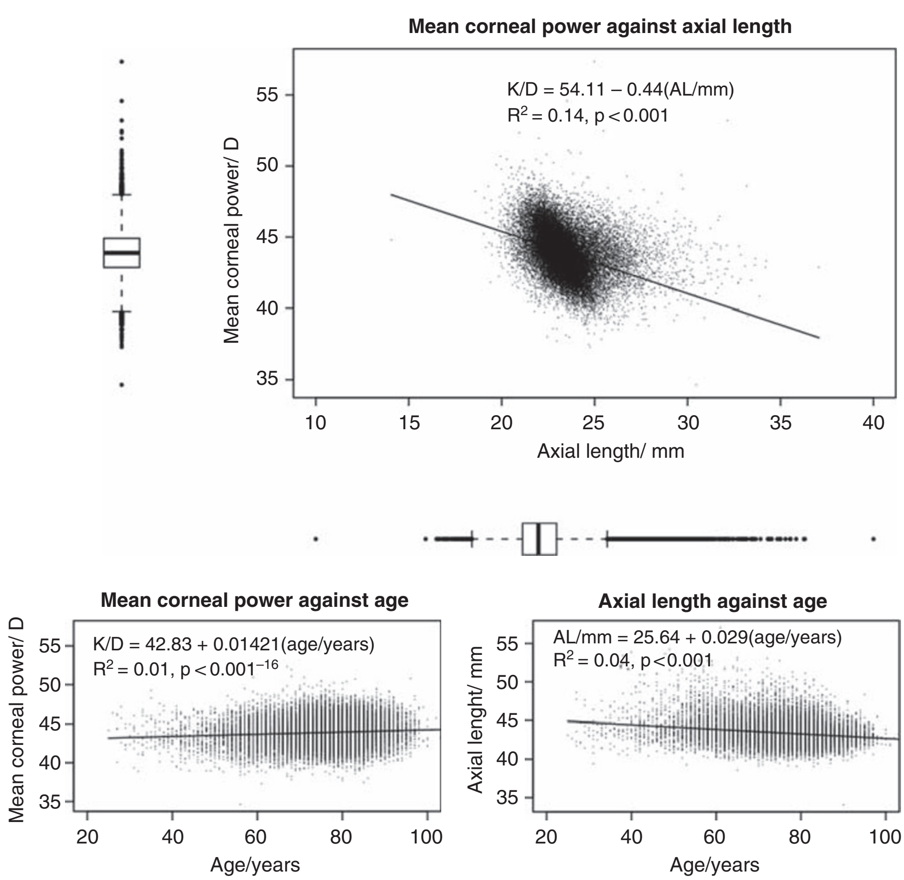

Figure 1 Scatter plot of mean *K* against AL with adjacent box plots for each parameter (top); scatter plot of mean *K* against age (bottom left); scatter plot of AL against age (bottom right).

Table 1 Median, mean, standard deviation (SD) and 50 and 95% distribution ranges of axial length, mean corneal power (K_{mean}) and keratometric astigmatism (K_{delta}) in the 22 458 unpaired eyes studied

	Median	*Mean*	*SD*	*50%*	*95%*	*Range*	P
AL (mm)							
All	23.25	23.40	1.32	22.60–23.98	21.27–26.59	14.06–37.06	
Male	23.63	23.76	1.29	23.00–24.33	21.60–26.78	19.15–34.23	<0.016*
Female	23.02	23.20	1.30	22.41–23.72	21.16–26.45	14.06–37.06	
K_{mean} (D)							
All	43.87	43.90	1.55	42.86–44.92	40.94–47.01	34.64–57.35	
Male	43.41	43.45	1.50	42.43–43.95	40.57–46.84	34.64–53.21	<0.016*
Female	44.15	44.18	1.51	43.16–45.15	41.29–47.21	37.30–57.35	
K_{delta} (D)							
All	0.85	1.04	0.79	0.51–1.34	<2.50	0.00–14.77	
Male	0.81	1.01	0.80	0.49–1.29	<2.46	0.00–14.77	<0.016*
Female	0.87	1.06	0.78	0.52–1.35	<2.51	0.00–11.53	

**P*-values <0.016 are statistically significant.

Table 2 Median, mean, standard deviation (SD) and 50 and 95% limits of the difference in axial length, mean corneal power (K_{mean}) and keratometric astigmatism (K_{delta}) between the 14 016 paired eyes studied

	Median	*Mean*	*SD*	*50%*	*95%*	*Range*	P
AL (mm)							
Absolute	0.12	0.21	0.35	0.05–0.23	<0.70	0.00–9.44	
2nd *vs* 1st	−0.01	−0.03	0.41	−0.14–0.10	−0.92–0.61	−6.23–9.44	<0.0083*
R *vs* L	0.04	0.06	0.40	−0.07–0.17	−0.59–0.85	−7.24–9.44	0.01518
K_{mean} (D)							
Absolute	0.27	0.35	0.35	0.12–0.48	<0.92	0.00–6.1	
2nd *vs* 1st	0.00	0.01	0.49	−0.26–0.28	−0.93–0.92	−6.07–4.39	0.0912
R *vs* L	−0.06	−0.07	0.49	−0.33–0.20	−1.00–0.83	−6.07–3.08	0.01124
K_{delta} (D)							
Absolute	0.35	0.49	0.50	0.16–0.65	<1.38	0.00–10.68	
2nd *vs* 1st	0.00	−0.01	0.70	−0.36–0.35	−1.41–1.34	−10.68–4.51	0.5054
R *vs* L	0.00	0.00	0.70	−0.35–0.36	−1.37–1.41	−10.68–4.97	0.9275

The absolute differences are given as moduli, so are positive, whereas the differences between second and first and right and left eyes are relative values and either positive or negative. **P*-values <0.0083 are statistically significant.

and

$$K_{mean}(D) = 42.83 + 0.01421(\text{age (years)}),$$

$$R^2 = 0.01, P < 0.001$$

In Figure 2, the distribution of axis and power of keratometric astigmatism are shown. There was no correlation between either J_0 or J_{45} and age in either right or left eyes.

Discussion

As detailed in Tables 1 and 2, the absolute values of and interocular differences in AL and K are similar to those reported earlier (Table 3).[26–33] That there were no significant differences between left and right eyes is not unexpected. The finding that males had longer AL and flatter K_{mean} perhaps reflects the difference in stature between the sexes.[34] Although statistically significant, the very small mean difference (−0.03 mm) in AL between second and first eyes is clinically irrelevant.

The 95% biometry limits found here, and so the definition of abnormality, differ from the current recommendations in the RCOphth Cataract Surgery Guidelines. Whereas those guidelines suggest that 96% of AL lie between 21.0 and 25.5 mm and that 98% of eyes have curvature between 40 and 48 D, this study found

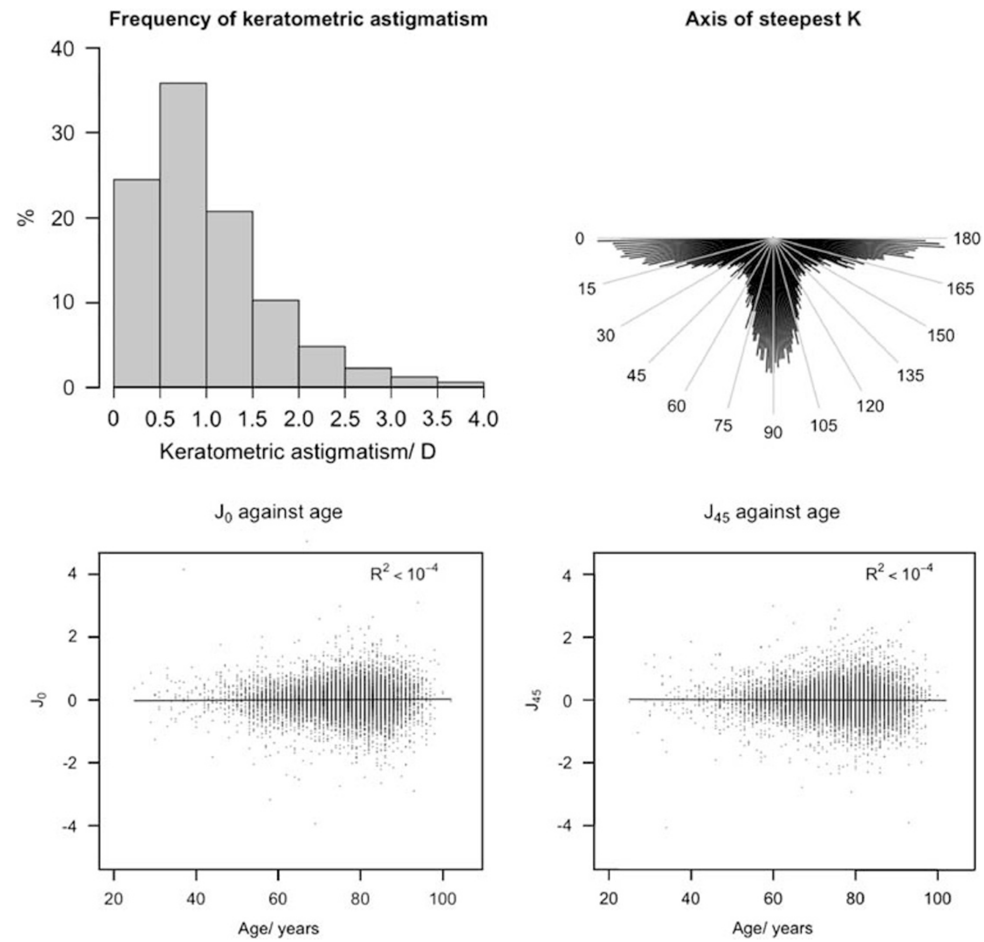

Figure 2 Bar graph showing the prevalence of keratometric astigmatism (top left); polar plot showing the axis of astigmatism (top right) and scatter plots showing the change in J_0 and J_{45} astigmatic power vectors in right eyes with age (bottom left and right, respectively).

that 95% AL were between AL 21.27 and 26.59 mm and 95% K_{mean} between 40.94 and 47.01 D. Likewise, when the RCOphth guidelines advise that >0.3 mm of AL or >1 D of K_{mean} asymmetry is abnormal in this analysis, the 95% limits for these parameters were <0.70 mm and 0.92 D, respectively.

Although most of these differences are relatively small, compared with the Guideline's suggestion that ⩾0.3 mm AL asymmetry is abnormal, the finding here of a mean (±SD) difference of 0.21±0.35 mm is striking. Nonetheless, this discrepancy is consistent with the results of others: Hoffer[25] described intraindividual AL asymmetry of 0.34 (±0.70) mm, Jivrajka found 24% of cataract surgery patients to have AL differences >0.3 mm,[26] Wickremasinghe *et al*[27]measured AL asymmetry of 0.3 (±0.8) mm in Mongolians older than 70 years and Jabbour *et al*[28] described that the SD of AL between fellow eyes was ±0.24 mm.

Although these results do suggest that it would be appropriate to update the RCOphth cataract surgery guidelines, deciding exactly what measurement ranges can be considered normal is complicated by the fact that the parameters are not normally distributed and outlying measurements are common. However, if rounded values approximating to the 95% limits found here were used, requiring 1 in 20 measurements to be checked, then AL measurements outside the range 21.30–26.60 mm and K_{mean} values <41.00 D or >47.00 D should be repeated. Similarly, measurements >0.9 D K_{mean} or >0.70 mm of AL asymmetry should be verified and keratometric astigmatism >2.50 D should be rechecked (Box 1).

For AL, the range of acceptable measurement is significantly greater than currently suggested. It is counterintuitive to think that this increased tolerance will improve biometry outcomes. The apparent paradox can be resolved by the high accuracy and precision of the IOLMaster's non-contact optical measurement technique and the fact that values returned by the instrument are themselves the mean of at least 3 *K* and 5 AL measurements. Indeed, it is possible that increasing the

Table 3 Earlier reported values of AL and *K* variation in cataractous eyes

First author	*Year*	*Number of eyes*	*AL (mm)*	*Mean* K *(D)*	*Delta* K *(D)*	*AL asymmetry (mm)*	*Mean* K *asymmetry (mm)*
This study	2008	32 556	23.41 ± 1.34	43.91 ± 1.55	1.03 ± 0.78	0.21 ± 0.35	0.35 ± 0.35
Jivrajka[18]	2008	750	23.46 ± 1.03			24% > 0.3	
Haigis (cited by[19])	2004	~15 000	23.48 ± 1.67				
Hasemeyer[20]	2003	105	23.26 ± 1.22	43.94 ± 1.65[a]			
Packer[21]	2002	50	23.40				
Norrby[19]	2003	148	23.44 ± 1.33				
Haigis[22]	2000	108	23.37 ± 1.22	43.72 ± 1.81[a]			
Olsen[23]	1995	822	23.47 ± 1.56				
Hoffer[3]	1993	450	23.56 ± 1.24				
Shammas[24]	1987	1000	23.45				
Hoffer[25]	1980	7500	23.65 ± 1.35	43.81 ± 1.60	1.0 ± 1.0	0.34 ± 0.70	0.87 ± 0.83

Unless otherwise specified all values are presented as mean ± standard deviation.
[a]Assuming a keratometric index of 1.3375.

Biometric measurements should be repeated if,

- Axial length is measured as **< 21.30 mm** or **> 26.60 mm**
- Mean corneal power (K) is measured **< 41.00 D** or **> 47.00 D**
- **> 2.50 D** of keratometric astigmatism is apparent

Or if there is a difference between fellow eyes

- in axial length **> 0.70 mm**
- or mean corneal power of **> 0.90 D**.

Box 1 Recommendations for verification of biometry based on the 95% distribution ranges found in this study.

acceptable measurement range might improve patient outcomes by eliminating some of the confusion that can result when multiple biometric reports exist for a single patient.

In contrast to cross-sectional studies of the general population, mostly reporting an increase in K_{mean}, reduction in AL, negative shift in J_0 or similar refractive changes,[29–33,35,36] this study did not find any significant age-related changes. However, being cross-sectional and only including cataractous eyes, the influence of cohort effects and selection bias cannot be excluded, so not much weight can be placed on this.

The validity of these results comes largely from the very large number of eyes included and the fact they were recruited prospectively. Some caution is required, however, because of the uncertain effects of selection bias and, despite the seemingly near perfect pairing process, the fact that fellow eyes were not originally identified in the database so some uncertainty surrounds this process.

Selection bias cannot be quantified but might arise and confound comparison of these results with studies using ultrasound because the IOLMaster is unable to measure AL in all subjects. This is because patient cooperation is required both to position on the IOLMaster and to fixate on an internal target whereas ultrasound AL measurement is possible even in anaesthetised patients. In addition, because the IOLMaster uses an optical double pass measurement technique, media opacities, particularly those that scatter light such as posterior subcapsular cataracts, can render measurement impossible, a factor that does not affect ultrasonic measurements.

Nonetheless, it is believed that this analysis has established the normal range of optical biometric variation in the UK cataract surgery population and that it should enable updated recommendations for measurement verification to be made. Indeed, as the biometric characteristics of the UK cataract surgery population are similar to those of other western populations, (Table 3) it is likely that these recommendations are widely applicable. It is hoped that this information will be of interest to all cataract surgeons.

Summary

What was known before

- Biometry is fundamental for intraocular power calculation before cataract surgery and this is measurements are most commonly performed using the IOLMaster.
- Most earlier studies of biometric variation have been either relatively small, used ultrasound to measure axial length or performed outside the UK.

What this study adds

- This is the largest study of biometric variation to date, all measurements being performed with the IOLMaster on patients in the UK National Health Service.
- The results obtained give an insight into the normal range of biometric variation in the UK and enable recommendations for when outlying measurements should be repeated to be updated.

Conflict of interest

RL Johnston is a Director of Medisoft Limited. The other authors declare no conflict of interest.

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