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Evaluation of an open-field autorefractor's ability to measure refraction and hence potential to assess objective accommodation in pseudophakes

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ABSTRACT

Background: To evaluate the accuracy of an open-field autorefractor compared to subjective refraction in pseudophakes and hence its ability to assess objective eye focus with intraocular lenses (IOL).

Methods: Objective refraction was measured at 6m using the Shin-Nippon NVision-K 5001/Grand Seiko WR-5100K open-field autorefractor (5 repeats) and by subjective refraction on 141 eyes implanted with a spherical (Softec1 n=53), an aspheric (SoftecHD n=37) or an accommodating (1CU n=22; Tetraflex n=29) IOL. Autorefractor was repeated 2 months later.

Results: The autorefractor prescription was similar (average difference: $0.09 \pm 0.53D$; $p=0.19$) to that found by subjective refraction, with ~71% within $\pm 0.50D$. The horizontal cylindrical components were similar (difference: $0.00 \pm 0.39D$; $p=0.96$), although the oblique (J_{45}) autorefractor cylindrical vector was slightly more negative (by $-0.06 \pm 0.25D$; $p=0.06$) than the subjective refraction. The results were similar for each of the IOL designs except for the spherical IOL, where the mean spherical equivalent difference between autorefractor and subjective was more hypermetropic than the Tetraflex accommodating IOL ($F=2.77$, $p=0.04$). Intra-session repeatability was $<0.55 D$ (95% confidence interval) and inter-session repeatability $<0.50D$ in $\geq 85\%$.

Conclusions: The autorefractor gives valid and repeatable measures of pseudophakic eye refraction and hence objective accommodation.

INTRODUCTION

Objective measurement of the myopic shift that occurs with the effort to focus at near due to alterations in crystalline lens surface curvatures or intraocular lens position, refractive indices or surface curvatures, has become of increased interest to better understand accommodation and attempts to develop 'accommodating' IOLs. Subjective amplitude-of-accommodation and the ability to read near-print of a certain size gives an indication of 'accommodating' IOL visual function performance, but are influenced by factors such as pupil size, ocular aberrations and an individual's tolerance to blur.[1] Objective accommodation in 'accommodating' IOL evaluation studies has been assessed by dynamic/streak retinoscopy, lens movement (assessed by ultrasound or partial coherence interferometry) to a pharmacologically induced ciliary muscle contraction or a contralateral physiological accommodative target, autorefraction or aberrometry [2]. Retinoscopy relies on the subjective responses of skilled examiner and often requires additional lenses in front of the eye to quantify the results. IOL movement from pharmacological ciliary muscle contraction appears to give the maximum possible accommodative response, although pharmacologically-induced accommodation does not relate well to natural physiological eye focus [3]. Although the accommodative response is usually similar in both phakic eyes [4] allowing contralateral stimulation of accommodation to be effective, this cannot be presumed in the pseudophakic eye, where it will be influenced by factors such as IOL size, IOL position, remaining lens capsule elasticity and any capsular fibrosis.

Autorefractors have the advantage of being non-contact, allowing physiological accommodative stimulation of the eye being assessed and are objective and do not affect the patients view of the target through the use of infra-red light [5]. However, many are not open-field, potentially resulting in proximal accommodation (also known as instrument-myopia) [6], and none have been validated against subjective refraction on a pseudophakic

population. Although open-field autorefractors have been extensively validated on a phakic population [7-11], IOL materials are generally of higher refractive index than the crystalline lens and, therefore, more disparate from that of the aqueous humour, thus potentially increasing the prevalence of surface reflections. These reflections could hinder the autorefractor image analysis and hence distort the measurement [12]. Win-Hall and Glasser verified the calibration of the WR-5100K (Grand Seiko Co., Ltd, Hiroshima, Japan) autorefractor (also marketed as the NVision-K autorefractor by Shin-Nippon, Commerce Inc., Tokyo, Japan) and iTrace aberrometer using soft contact lenses in 10 pseudophakes [13], but only on patients implanted with a spherical IOL and not against subjective refraction. As such, this study was designed to assess the accuracy of the open-field NVision-K / WR-5100K autorefractor against subjective refraction in patients implanted with spherical, aspheric and 'accommodating' IOLs.

METHODS

Informed consent was obtained from the subjects prior to inclusion in the study following explanation of the nature and possible consequences of the study. The research followed the tenets of the Declaration of Helsinki and was approved by the Solihull Local Research Ethics Committee. The inclusion criteria were patients who had undergone routine cataract surgery to remove a lenticular opacity affecting the visual function of the patient, and had been implanted without complication with an IOL at least 3 months previously (maximum 6 months). One-hundred and forty one eyes were assessed, following implantation with one of four IOLs (Table 1).

Table 1: Implanted IOLs and demographics of patients assessed.

IOL	Design	Material (refractive index)	Patient Number	Age \pm SD (years)	Gender
Softec1 (Lenstec)	Spherical	Acrylic (1.46)	53	76.8 \pm 10.5	13M, 40F
SoftecHD (Lenstec)	Aspheric	Acrylic (1.46)	37	78.6 \pm 11.0	7M, 30F
1CU (HumanOptics)	Hinge optic 'accommodating'	Acrylic (1.46)	22	71.8 \pm 11.2	11M, 11F
Tetraflex (Lenstec)	Vitreous movement and ciliary swelling 'accommodating'	Acrylic (1.46)	29	68.4 \pm 13.9	11M, 18F

The validity of autorefractors is traditionally assessed by comparing their results to those of subjective refraction, which although more variable than objective measures,[14] provides an endpoint of optimum subjective acceptance. Consequently, all subjects underwent a routine 6 metre, non-cycloplegic, refraction performed by one of three qualified optometrists who was masked from the subjects' habitual prescription and the results of the autorefraction.

Retinoscopy was performed on all subjects followed by cross-cylinder to determine both the axis (in 2.5° increments) and power (in 0.25 D increments) of the cylinder component. Best sphere and binocular balancing was used to refine the spherical component of the prescription (in 0.25 D increments), adopting an endpoint criterion of maximum plus consistent with optimum visual acuity.

The assessed autorefractor was the Shin-Nippon NVision-K 5001 (also branded as the Grand Seiko WR-5100K as described earlier) as part of a family of open-field instruments used extensively in accommodative research. These have been validated previously in children and adults and some versions have been converted to allow dynamic measurement of ocular accommodation [7,8,11,15,16]. The absence of an internal fixation target or enclosed viewing reduces the risk of proximal accommodation. Refractive error is calculated in two stages. An infra-red light target is imaged after reflection off the retina, permitting refraction measurements from pupils as small as 2.3 mm. Initially, a lens is moved rapidly on a motorized track to place the target approximately in focus. The image is then analysed digitally to calculate the toroidal refractive prescription over a range of ± 22.00 D sphere, ± 10.00 D cylinder in steps of 0.12 D for power (with adjustable vertex distance).

Autorefraction was performed while the subjects viewed a high contrast Maltese-cross at optical infinity within a Badal optical system. The instrument was aligned with the visual axis of the eye and five consecutive readings were taken. The measures were repeated 2 months after the first.

Statistical analysis

If both eyes had been implanted, only the data from the right eye was used. Due to the inherent problems of analysing cylindrical components in their conventional form,[17] sphere, cylinder and axis were converted into a vector representation:[18] a spherical lens of power MSE (equal to the mean spherical equivalent = sphere + [cylinder / 2]); a Jackson cross-cylinder at axis 0° with power J_0 (= -[cylinder / 2] cos[2 x axis]); and a Jackson cross-cylinder at axis 45° with power J_{45} (= -[cylinder / 2] sin[2 x axis]). The MSE power is typically used to assess changes in refraction with accommodation.[2] These biases between measures (the mean difference, its standard deviation and 95% confidence intervals) were calculated as suggested by Bland and Altman.[19] The differences between the NVision-K / WR-5100K autorefractor prescription were calculated with paired t-tests and between intraocular lenses with analysis of variance. Intra-session repeatability was obtained by averaging the 95% confidence intervals between the five readings taken for each individual. Inter-session repeatability measurements were calculated from the difference between the original results and the measures taken 2 months later.

RESULTS

The residual refractive error of the sample, as represented by subjective refraction, ranged from -3.31 to $+2.88$ D, mean spherical equivalent (mean = 0.32 ± 1.08 D). The maximum amount of astigmatism was -6.12 DC.

Validity

The NVision-K / WR-5100K autorefractor prescription was similar (mean difference: $+0.09 \pm 0.53$ D, mean spherical equivalent; $p = 0.19$) to that found by subjective refraction. There was little bias in the accuracy of the mean autorefractor prescription with respect to the sign or magnitude of the refractive error (Figure 1). Approximately 42% of autorefractor measures were within ± 0.25 D and 71% within ± 0.50 D of the spherical component of the prescription determined by subjective refraction (Figure 2).

The autorefractor horizontal cylindrical component was similar (mean difference: 0.00 ± 0.39 D, $p = 0.96$) to that found by subjective refraction and there was no apparent bias with respect to the sign or magnitude (Figure 3). However, the oblique (J_{45}) autorefractor cylindrical vector was slightly more negative (by -0.06 ± 0.25 D, $p = 0.06$) than the subjective refraction and was biased towards the sign of the cylindrical power (i.e. more negative difference between autorefractor and subjective refraction for more negative oblique cylindrical vectors; Figure 3).

The validity of the autorefractor measurements with each of the IOL designs is presented in Table 2. Implantation of the Softec1 resulted in a significantly more hypermetropic difference between autorefractor reading and the subjective refraction mean spherical equivalent than the Tetraflex IOL ($F = 72.77$, $p = 0.04$). However, there was no difference in the accuracy of

the autorefractor compared to subjective refraction with either of the cylindrical vectors (J_0 : $F = 2.01$, $p = 0.12$; J_{45} : $F = 2.16$, $p = 0.10$).

Table 2: Difference between autorefractor readings and subjective refraction with each of the implanted IOL designs. Mean \pm 1 S.D. [range]

	Mean Spherical Equivalent (D)	Cylindrical Vector J_0 (D)	Cylindrical Vector J_{45} (D)
Softec1	+0.16 \pm 0.58 [-1.81 to 1.75]	+0.08 \pm 0.38 [-0.50 to 2.14]	+0.01 \pm 0.21 [-0.43 to 0.61]
SoftecHD	+0.20 \pm 0.51 [-1.06 to 1.13]	0.00 \pm 0.36 [-0.80 to 0.89]	-0.13 \pm 0.30 [-0.87 to 0.55]
1CU	-0.07 \pm 0.47 [-0.76 to 0.81]	-0.06 \pm 0.41 [-1.06 to 0.70]	-0.08 \pm 0.19 [-0.67 to 0.36]
Tetraflex	-0.11 \pm 0.44 [-0.88 to 1.31]	-0.13 \pm 0.40 [-1.53 to 0.39]	-0.10 \pm 0.28 [-1.07 to 0.30]

-----Insert Figures 1-3 about here-----

Repeatability

The average intra-session repeatability (95% confidence interval of 5 readings) was 0.54 D for the mean spherical equivalent, 0.48 D for the J_0 vector and 0.29 D for the J_{45} component of the prescription. The difference between the average autorefractor measurements for each subject (inter-session repeatability -repeated measurement separated by 2 months) was -0.14 ± 0.87 D (average \pm 95% confidence interval) with 85% within 0.50 D for the mean spherical equivalent (Figure 1), -0.01 ± 0.51 D with 96% within 0.50 D for the J_0 vector and -0.03 ± 0.59 D with 96% within 0.50 D for the J_{45} component of the prescription. Repeatability was similar between the IOL designs ($p > 0.05$).

DISCUSSION

Objective measurement of ocular refraction is key to understanding accommodation and assessing 'accommodating' IOLs. While the use of a wavefront sensor to achieve this is attractive due to their ability to assess the distortion of light across the whole pupil and ability to assess higher order as well as spherical and astigmatic changes in optical power, no open-field, commercially available devices are widely available. Autorefractors, due to their design to assess refractive error through even small pupils, generally measure from limited locations around a small annulus centred on the visual axis, making them susceptible to failure in detection of localised changes in lens power.[20] However, autorefractors are less expensive than aberrometers and commonly available in clinic practice. Furthermore, some are open-field, allowing the rapid assessment of the oculomotor response to observed targets. Autorefractors are, therefore, ideally placed for the objective measurement of ocular accommodation.

This study assessed the accuracy against subjective refraction of an open-field autorefractor already used in IOL studies to provide objective measurement of accommodation [2,20]. Despite concerns that IOLs materials could cause reflections that could complicate the autorefractor and aberrometer analysis [12], the findings build on a calibration study on spherical IOLs [13], showing that the Shin-Nippon NVision-K 5001 / Grand Seiko WR-5100K can provide repeatable results that are similar to subjective refraction in pseudophakes implanted with spherical, aspheric and 'accommodating' IOLs. There is no 'gold standard' against which an autorefractor can be assessed on patients implanted with accommodating IOLs attempting to focus at different distances to compare the results. This study has shown that the autorefractor can accurately measure the optical power of the eye over a range of different refractive powers (mean spherical equivalent -3.8 to +2.9D as assessed by subjective refraction) and hence patients changing their eye focus over this range would be

accurately detected. This has been indicated in our previous studies when the autorefractor has been able to detect static optical changes in accommodating IOL power over a 4.0D stimulus response curve and even in dynamically tracing the accommodative response of eyes following a target moving towards and away from them.[2,20]

Interestingly, in contrast to the small myopic shift in the spherical and aspheric IOLs, the 'accommodating' IOLs both gave more hypermetropic results than the subjective refraction, perhaps due to flexure of the haptics or optic as has recently been shown.[20] It might have been predicted that the aspheric IOL would have resulted in a more myopic bias compared to subjective refraction compared to the other IOLs due to its power profile change across the lens, but within the autorefractors assessment of power around an annulus of 1.5 mm radius from the visual axis,[7,8] this was not evident.

This study confirms autorefraction as a simple and valid method of assessing objective 'accommodation' without the limitations of corneal contact, pharmacological stimulation,[3] and presumed contralateral stimulation of accommodation in pseudophakes. Hence future studies of IOLs claiming an 'accommodative' ability can include an assessment of objective changes of focus as well as perceived patient benefits and subjective range of focus, allowing a better understanding of their mechanism of action.

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Competing Interests: None declared

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FIGURE LEGENDS

Figure 1: The average mean spherical equivalent compared to the difference for the autorefractor versus subjective refraction (black) and the autorefractor repeated on 2 occasions separated by 2 months (grey). Dashed line indicates 95% confidence interval.

Figure 2: Histogram of the difference in mean spherical equivalent between the autorefractor and subjective refraction.

Figure 3: The average versus the difference between the autorefractor and subjective refraction (black) and the autorefractor repeated on 2 occasions separated by 2 months (grey) for cylindrical J_0 vector (square) and J_{45} vector (triangle) component. Dashed line indicates 95% confidence interval.





