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Standardised Patient Methodology to Assess Refractive Error Reproducibility

Rakhee Shah[1,2], David F Edgar[2], Ronald Rabbetts[3], Deacon E Harle[4], Bruce JW Evans[1,2]

1 The Neville Chappell Research Clinic, The Institute of Optometry, 56-62 Newington Causeway, London SE1 6DS

2 Henry Wellcome Laboratories for Vision Sciences, Department of Optometry and Visual Science, City University, Northampton Square, London EC1V 0HB

3 Practising Optometrist, Rabbetts Sight Care, 31 Fratton Road, Portsmouth, Hants. PO1 5AB

4 Principal Optometrist and OPwSI (Ophthalmology), Osborne Harle and Associates, 1-3 Martin Hardie Way, Tonbridge, Kent TN10 4AE

Correspondence to: Rakhee Shah, The Institute of Optometry, 56-62 Newington Causeway, London. SE1 6DS

Tel: 0044 - (0)2074074183 Fax: 0044- (0)2074038007

Email: rakhee19@gmail.com

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Abstract

Background: Standardised patient (SP) methodology is the gold standard for evaluating clinical practice. This approach was used to investigate the content of typical optometric eyecare in England and the reproducibility of refractive error measurement using prescriptions obtained by three SPs.

Methods: The three SPs were independently examined by 3-4 expert optometric clinicians to obtain 'benchmark' estimates of refractive error. 102 community optometrists consented to be visited by three SPs who were trained to provide accurate responses during the examinations. The spectacle prescriptions obtained by the SPs were analysed for spherical equivalent refraction, spherical power and cylindrical power using astigmatic decomposition.

Results: The spherical equivalent refractions were found to be within ±0.25D of the benchmark on average 81% of the time and within ±0.50D 97% of the time. The spherical power was within ±0.25D 90% of the time and within ±0.50D 98% of the time. The cylindrical power agreed within ±0.25D 93% of the time and within ±0.50D 100% of the time. Based on reproducibility limits data obtained for all six eyes, any two optometrists would differ in their estimation of spherical equivalent refraction by no more than 0.75D in 95% of repeated measures. The astigmatic data (C_0 and C_{45}) show that optometrists will differ in their estimation of the C_0 component by between 0.25D and 0.61D and for the C_{45} component by between 0.22D and 0.47D in 95% of repeated measures.

Conclusion: The agreement between our data and the results of other similar studies support the conclusions that subjective refractive findings are reproducible to approximately ±0.75D when performed by multiple optometrists in patients of different age groups and levels of ametropia. Standardised patients are an effective way of measuring reproducibility

of refractive error and should be considered for further comparative analysis in different age groups and different levels of ametropia.

Introduction

Background

Optometrists are primary healthcare specialists trained to examine the eyes to detect defects in vision, signs of injury, ocular diseases or abnormality and problems with general health.[1] From the above statement we could say a typical eye examination has two "core" components: the evaluation of the health status of the eye and the evaluation of vision and visual function.

During optometrists' training great emphasis is placed on the "routine eye examination" as most optometrists spend the greater part of their working day carrying out routine examinations. The term "routine examination" can be used to describe the various procedures required during a full eye examination in order to properly assess both the visual status of a patient (and be able to prescribe an appropriate optical correction) and the ocular health. In the USA, one of the goals of optometric 'comprehensive adult eye and vision examinations' is to 'evaluate the functional status of the eyes and visual system'.[2] In the UK, guidance on what a routine eye examination may include is published in the College of Optometrists' Code of Ethics and Guidance for professional conduct. For the routine eye examination this states:[3]

"The optometrist has a duty to carry out whatever tests are necessary to determine the patient's needs for vision care as to both sight and health. The exact format and content will be determined by both the practitioner's professional judgement and the minimum legal requirements."

The legal requirements are defined in the Sight Testing (Examination and Prescription) (No 2) Regulations issued in 1989, following measures contained in the Health and Medicines

Act 1989. As discussed above, professional guidelines exist within optometry[3] and these are clearly valuable as they provide a plan for standards of professional practice. Over recent years, substantial attention has been paid to improving the consistency of clinical care within optometry, the diagnosis of ocular diseases and the appropriate referral of patients, yet far less attention has been given to improving the consistency of prescribing spectacles. Since the core function of optometrists is the prescribing of refractive correction, it is remarkable that there is a lack of evidence based research on reproducibility of refractive error testing and criteria for prescribing a refractive correction. There have been attempts to gain an insight into the clinical activities of optometrists through questionnaires, most notably in the UK by surveys administered by the College of Optometrists.[4;5] These are useful, but there is likely to be a bias, with human nature causing replies to indicate higher standards of practice than may actually pertain. A literature review to gain an insight into methods of measuring clinical care revealed that during direct observation the practitioner is likely to give better than normal levels of quality of care.[6] This literature review[7] also revealed little evidence based research on reproducibility of refractive error testing using unannounced standardised patients presenting for an eye examination.

From an international perspective, the determination of refractive error is a core function of optometrists and the reproducibility of refractive error measurements is therefore of relevance to optometrists worldwide. The content of typical optometric eyecare and the reproducibility of refractive error testing in England were investigated using a methodology new to optometry (standardised patients). This approach has been found in a recent review to be the gold standard methodology for the evaluation of clinical care.[7]

Standardised patients

During most optometric clinical consultations only two people are present: the practitioner and the patient. So, an appropriate method for determining what a practitioner does is to ask

the patient, in particular a patient who has been trained to be an expert observer. There are numerous descriptors of the roles played by individuals during such simulated encounters. The term 'standardised patient' (SP) is a well-accepted term in the literature.[7]

The generic term, simulated patient encounter, describes practitioners' examination of people who are simulating real patients. SPs are not the only method that has been used to investigate clinical practice and standards, but unannounced SPs with completed standardised patient checklists as a record of the encounter have been regarded as the gold standard for quality measurement in clinical practice.[8-15]In order to measure everyday clinical practice, it is important for the SPs to be unannounced: the practitioner must not identify the patient as an SP so that the practitioner performs their normal standard of examination. We believe that our work is the first to use SPs in an optometric or ophthalmological setting.

Refraction and Refractive Error

The General Optical Council's revised competencies for registration as an optometrist in the UK state that: trainee optometrists should have the ability to refract a range of patients with common optometric problems by objective and subjective means. S/he should also be able to make appropriate prescribing and management decisions based on refractive and ocular motor status.[16] In the USA, the code of ethics of the American Optometric Association states that it is the duty of all optometrists to keep their patients' eye, vision and general health paramount at all times.[17] Typically, a clinical evaluation of refractive error comprises two different approaches: objective refraction (which requires minimal participation from the patient) and subjective refraction (based on the patient's feedback on different trial lenses). These procedures are fully described in optometric textbooks.[18;19]

An accurate refraction may also be a valuable diagnostic indication of ocular disease, for example an episodic variation in refractive error could be indicative of uncontrolled

diabetes[20] or lenticular changes. Hence the results of the subjective refraction are important both to the optometrist and to the patient, because most patients judge all aspects of the eyecare they have been provided based on the clarity and comfort of their prescription.[20] In view of this, it is surprising that there is lack of evidence based research on reproducibility of refractive error testing.

In the USA, most States require an optometrist to issue a copy of the ophthalmic lens prescription if requested by the patient at no additional charge.[21] In the UK, primary eyecare examinations are carried out almost exclusively (> 95%) by optometrists[22] and are governed by the archaically-named Opticians Act (1989). This states that practitioners should issue a prescription to the patient immediately following their examination.

Reproducibility of Refractive Error

The consistency, repeatability and reproducibility of refractive error measurements is important in both clinical patient management decisions as well as research applications.[23] It is important to know whether a small difference from one consultation to another constitutes a real change in refractive error.[23] In the context of refractive error findings, the term “repeatability” is used when several refractive measures of a subjective refraction are obtained by one examiner or instrument on the same subject under the same conditions. “Reproducibility” on the other hand is when several measures of a subjective refraction have been obtained by different practitioners and the agreement between their findings assessed.

Validity (a term related to reliability) is an assessment of whether a given method of measurement accurately measures what it aims to measure.[23] In order to be able to assess the validity of a result there must be an assumed standard against which the result can be compared. In the area of refraction the standard is subjective refraction, because it yields spectacle lens values most likely to be accepted by patients[23] and is the gold standard

against which all refraction devices are compared. To date there have been no refraction methods with both the level of validity and the practicality of application to replace conventional subjective refraction as the standard method of refraction.[23]

There have been various attempts to gain an insight into reproducibility of refractive findings,[24-27] albeit using students as subjects and two[24;25;27;28] or three[23;26] practitioners as refractionists.[21;24] The levels of agreement between examiners in some of these studies are shown in Table 1. In all of the studies listed in Table 1, apart from the recent study by MacKenzie, the practitioners were aware that the results of their refractive findings were being assessed to investigate their reproducibility.

Table 1: A summary of previous studies of reproducibility of refractive error assessments.

Study	Setting	Percentage agreement		95% limits of agreement	95% reproducibility limit
		≤±0.25	≤±0.50		
Sloane et al.[26]					
Spherical Equivalent	2 Ophthalmologists and 1 Optometrist refracted 21 young myopic subjects aged 14-18	73%	97%		
Sphere		79%	90%		
Cylinder Power		81%	99%		
French and Jennings.[26]					
Spherical Equivalent	17 first year optometry students refracted each other	73%			
Sphere		68%			
Cylinder Power		85%			
Perrigin et al.[26]					
Spherical Equivalent	3 examiners refracted 32 students	86%	98%		
Sphere		93%	99%		
Cylinder Power		93%	99%		
Bullimore et al.- subjective refraction[25]					
Spherical Equivalent	2 examiners refracted 86 subjects aged between 11 and 60 years			-0.90 to +0.65D	
Astigmatic-J_0				-0.37 to +0.39D	
Astigmatic-J_{45}				±0.31D	
MacKenzie[29]					
Spherical Equivalent	40 optometrists refracted one subject			±0.55D	0.78D
Astigmatic-J_0				±0.17D	0.24D
Astigmatic-J_{45}				±0.17D	0.24D

MacKenzie investigated the reproducibility of refractive error for an asymptomatic 29 year old patient using forty registered optometrists. This study concluded that refractions performed by multiple optometrists on a single eye will differ in the spherical equivalent refraction by over 0.78D on average not more than once in 20 refractions.[29] It should be noted that MacKenzie calculated both the limits of agreement and the reproducibility limits for the components of refractive error, and it is useful to describe the difference between these two variables. The 95% limits of agreement (e.g., Bland & Altman 1986, Bullimore 1998) give the range of measurements within which 95% of optometrists' readings lie. The reproducibility limit is a variable described by the ISO (1994)[30] and in our context is the maximum expected difference in measures of refractive state obtained by any two optometrists. Mathematically, the 95% limits of agreement are calculated as the mean ±1.96 (SD), whereas the reproducibility limit is calculated as 1.96 (SD) ($\sqrt{2}$). MacKenzie gives both the limits of agreement (based on residuals) and the reproducibility limit in his paper, and these are included in Table 1.

Methods

A random selection of 111 optometrists working within 1.5 hours travel from central London was recruited. During the early stages of the study design, it was anticipated that each actor would visit 100 consenting practitioners. A greater number of consenting optometrists than required was recruited to allow for optometrists who may withdraw or change their place of work during the study. Prior to commencing the visits, the actors were given a list stating the names of all consenting practitioners. The actors were therefore able to select, from this list, the practitioners they would visit during the course of the study. 100 consenting practitioners were visited by the SPs in the first and second patient scenarios and 102 consenting practitioners by the third SP for a routine eye examination, each representing a different patient scenario (i.e., different ages, races, presenting symptoms, and clinical features). The

methodology detailing the development of the case scenarios and case specific checklists, and the sample selection of participating practitioners is described in papers relevant to each scenario as part of this series.[31-33] These papers discuss all the other components of the eye examinations, but only briefly summarise the refractive error data. In view of the importance of the reproducibility of refractive error the present paper explores this topic in more detail.

Prior consent was obtained from all practitioners participating in the study. In research of this type the practitioner is the research subject. In accordance with the tenets of the Declaration of Helsinki,[34] research participants should have the right to safeguard their integrity and the right to abstain from participation. Informed consent[10;13-15;35-38] from each participant was a prerequisite for that optometrist to be included in the research described below. As a result, the SP only visited optometrists who had given prior consent to participate in the research. These optometrists did not know when the visit occurred and the visit was unannounced.

The requirement for informed consent inevitably reduces the participation rate. To encourage as high a participation rate as possible, two levels of anonymity were offered, and we believe this to be an innovation in SP research. The rationale behind this decision is that preliminary discussions with several practising optometrists revealed two main reasons why it was felt that practitioners might decline to participate. First, some practitioners may be anxious that the research would discover shortcomings in their clinical practice which might lead to criticism from colleagues or even disciplinary proceedings. To alleviate such concerns, optometrists were offered an option of full anonymity where only the actor knew the practitioner's name. The second reason why some practitioners may decline to participate is because there was no perceived benefit for the practitioner. To address this objection a partial anonymity option was offered, which allowed the practitioners to receive feedback that could improve their standard of practice. With this option the researchers and actor, but no-one else, knew the practitioner's identity and the practitioner received feedback

about the content of their eye examination compared with the recommendations of a panel of experts.

Although the optometrists were likely to be expecting visits from SPs, several steps were taken in an effort to ensure that the SPs remained undetected. Optometrists were only included if they reported examining at least three new patients a week, and no SP visits took place within a month of the optometrist recruitment. Also, no optometrists were recruited who were personally known to a SP. Participating optometrists were advised at the outset that the SPs would present unannounced for the eye examinations and would carry a digital audio recorder during the visits to allow accurate completion of the checklists. The confidential nature of these recordings was emphasised during the course of the study. The audio recordings were checked to ensure that the checklists were accurately completed.

SP Training

During the course of the research project each practitioner was visited by three different SPs, representing different patient scenarios. Two of these three SPs were played by professional actors with no prior expert knowledge of eyecare. These two SPs underwent intensive one-to-one training on the different aspects of an eye examination prior to visiting consenting optometrists. This involved use of a document created by the researchers entitled “The journey through an eye examination” which describes an eye examination in lay terms. The actors observed and received several eye examinations (some whilst being observed) from different optometrists at the Institute of Optometry, London. The actors were trained to remember and record details of each clinical encounter. In particular the actors made a note of the method used for objective assessment of refractive error (autorefraction or retinoscopy), whether a subjective refraction was performed, the technique used by the practitioner to assess any astigmatism (fan and block or cross cylinder) and whether an intermediate and reading addition (if applicable) were established. During the training, the

actors were advised of the importance of giving accurate and consistent responses throughout the visits.

The SP used for the first patient scenario (young myope) was one of the researchers (RS), who is an optometrist with previous acting experience. She received extensive training to ensure that she could remember and accurately record details of the clinical encounter and to ensure that her acting skills were adequate to avoid her being detected as an actor by participating practitioners. For example, care was taken to ensure that this SP avoided using any technical language that would raise the suspicion of the optometrist. Given that the SP used for this scenario is an experienced optometrist, she was advised to make a note of whether a monocular or binocular refraction was performed and whether binocular balancing was carried out.

Some eye examinations during the training were video recorded to allow for quality control later in the study when it was felt that it would be helpful to remind the SPs of certain tests. The SPs were also given a copy of a video of one of their training eye examinations on a CD. At the end of the training period the actors signed confidentiality agreements which stated that any information gathered during the eye examinations was confidential and would be used solely for the completion of the checklist provided.

Each actor was monitored for quality control after every 20-25 visits by attending the Institute of Optometry for an eye examination by a member of staff. This eye examination was video recorded and the actor completed a checklist in the usual way. The checklist was compared with the video recording for inaccuracies, so that any further instruction could be given if required. The researcher also listened to the recording of every SP visit (for practitioners opting for the partial anonymity option) to ensure the actors were consistent in their responses.

A pre-designed checklist was completed by the actors immediately after each examination to provide objective feedback on each consultation. The checklists were designed using information from evidence based reviews, clinical guidelines and the views of three expert panels. All the results relating to the standardised patient visits are discussed in the papers relevant to each scenario.[31-33] The aim of this paper is to provide a detailed analysis of the refractive findings obtained during the visits for all three standardised patients.

During training the SPs were advised that, in England, it is a requirement for a practitioner to issue a signed, written copy of the spectacle prescription at the end of every examination.[39] If the practitioner visited did not immediately issue a copy of the prescription, the SP was advised to ask for a copy of the prescription before leaving the practice. The spectacle prescriptions obtained for each SP were used to calculate the variability of the refractive findings. The refractive findings for each SP were transformed into their components using astigmatic decomposition calculations (discussed in detail below) and the results were used to calculate the frequency distributions of the refractive findings.

Case Scenarios

In the first of the three scenarios, the SP presented for a private eye examination as a 20 year-old student complaining of headaches (first ever headache 4 weeks ago, resembling a migraine). This SP was a myope and presented for the examinations “to see if her glasses were OK”, reporting that her last check-up was about two years ago. The second SP presented as a 44 year-old patient of African racial origin for a private eye examination having experienced recent difficulty with her near vision. The third SP presented for a private eye examination as a 59 year-old patient, with recent onset flashing lights (over the last week) in one eye in the dark.

Refractive Error Analysis

Refractive errors were analysed using both the raw data and the components following astigmatic decomposition calculations,[40] which use the cylindrical components of the astigmatic error, rather than the cross-cylinder components used by Thibos and colleagues.[41] Humphrey's principle of astigmatic decomposition represents the cylindrical power C as a combination of two obliquely crossed cylinders, C_0 at axis 0° and C_{45} at 45°, and has been suggested as a method which allows the statistical analysis of optical prescriptions,[42] because all cylinders are put on a common basis.

A given prescription of Sphere S, Cylinder C and Axis θ can be used to calculate:

$$C_0 = C\cos 2\theta$$

$$C_{45} = C\sin 2\theta$$

and it follows that:

$$C=\sqrt{(C_0^2+C_{45}^2)}$$

The spherical equivalent power M is the algebraic mean of the two principal powers S and (S+C) such that:

$$M = S + (C/2)$$

For any given optical prescription, the total sphero-cylindrical power can be represented by a single scalar quantity (u)[43;44] as:

$$u=\sqrt{(M^2+C_0^2+C_{45}^2)}$$

On the basis that an astigmatic error causes approximately half the blur that would be caused by a spherical refractive error of the same dioptric amount, the influence of astigmatism can be reduced[44] by using:

$$v=\sqrt{(M^2+{}^1/_4C_0^2+{}^1/_4C_{45}^2)}$$

This equation gives identical results to

$$v = \sqrt{(M^2 + J_0^2 + J_{45}^2)}$$

where J_0 and J_{45} are the Thibos cross cylinder components.[41]

Because, by chance, the three SPs all had very low or no astigmatic errors, only the results of the raw data analysis are presented here. If there had been significant astigmatism, then the difference between each optometrist's prescription and the benchmark refraction may be evaluated in terms of the scalar value of the sphero-cylindrical difference between the two results.

Anisometropia can be investigated by calculating the difference in spherical equivalents (M) between the two eyes and/or by calculating the difference in scalar values (v) between the two eyes. Both these approaches were adopted for the second scenario. For the first and third scenarios, the anisometropia was calculated using the spherical equivalent.

The equivalent sphere (M), C_0 and C_{45} values for each prescription were used to calculate 95% reproducibility limits. As described in the introduction, the reproducibility limit is the value within which the absolute difference between two test results obtained under reproducibility conditions may be expected to lie with a probability of 95%.[29] It can also be interpreted as the maximum expected difference in measures of refractive state collected by any two optometrists. The 95% reproducibility limit is calculated by multiplying the absolute value of the 95% limit of agreement by the square root of two [$1.96(\sqrt{2})$ (S.D.)].

It is well known that the distribution of refractive errors in the population is not, strictly speaking, normally distributed but has a leptokurtotic distribution.[45-48] However, for the purposes of the present paper, which evaluates approximately 100 practitioners' measurements of one person's refractive error (for each scenario), the distribution of their results is likely to be a close enough approximation to a normal distribution for parametric

statistics to be appropriate, a procedure in line with the approach taken by most other workers in the field.[49;50] Therefore, parametric statistics have been used to describe and analyse our refractive error data. In particular, the 95% limits of agreement (the range within which 95% of measurements would fall) is calculated using parametric assumptions (1.96xSD), rather than using ranking methods, in line with previous work on reproducibility of refractive error.[29]

During the SP training, the actors were each examined by 3-4 staff clinicians at the Institute of Optometry, who were masked to each other's results. These clinicians all had several years experience in primary and specialist eyecare clinics and are involved in optometric education. For each actor, the mean of these expert refractive findings was taken as a 'benchmark' refractive error.

Results

The means and ranges of the refractive findings obtained by the staff clinicians at the Institute of Optometry that were taken as 'benchmark' estimates of the refractive errors of the SPs are given in Table 2. In the subsequent analysis of the refractive findings obtained by optometrists during the SP visits comparisons were made with these 'benchmark' results. The mean cylinder power and cylinder axis were calculated using astigmatic decomposition.

Comparing astigmatic prescriptions is complicated by the different axes found by practitioners, therefore to facilitate the analysis the C_o and C_{45} Humphrey decomposition components were derived. Anisometropia was considered a continuous variable and was calculated as the absolute difference in M, the spherical equivalent of each eye. Anisometropia was also calculated as the difference in scalar values between each eye for scenario 2. The results for each SP are discussed separately below.

Table 2: The mean refractive findings (benchmark) for the three standardised patients obtained from eye examinations carried out at the Institute of Optometry. The standardised patients' visual acuities are also presented.

	Mean Sphere (D)	Mean Cylinder (DC)	Mean Axis	Visual Acuity
Scenario 1				
Right	-3.94 (range -3.75 to -4.00)	-0.13 (range 0.00 to -0.25)	180° (zero range)	6/5
Left	-3.94 (range -3.75 to -4.00)	-0.25 (zero range)	57° (range 50° to 60°)	6/5
Scenario 2				
Right	2.00 (range+1.75 to +2.25)	-0.15 (range 0.00 to -0.25)	180° (range 4° to 175°)	6/5
Left	3.80 (range+3.75 to +4.25)	-0.29 (range -0.25 to -0.50)	180° (range 165° to 180°)	6/6-
Near-Right	3.00 (range+2.75 to +3.25)	-0.15 (range 0.00 to -0.25)	180° (range 4° to 175°)	N5
Near-Left	4.80 (range+4.50 to +5.25)	-0.29 (range -0.25 to -0.50)	180° (range 165° to 180°)	N5
Scenario 3				
Right	0.06 (range 0.00 to 0.25)	-0.12 (range 0.00 to -0.25)	180° (range 175° to 180°)	6/5
Left	0.12 (range 0.00 to 0.25)	-0.12 (range 0.00 to -0.25)	56° (range 50° to 60°)	6/5
Intermediate-Right	1.56 (range+1.25 to +2.00)	-0.12 (range 0.00 to -0.25)	180° (range 175° to 180°)	N6
Intermediate-Left	1.62 (range+1.50 to +2.00)	-0.12 (range 0.00 to -0.25)	56° (range 50° to 60°)	N6
Near-Right	2.32 (range+2.00 to +2.75)	-0.12 (range 0.00 to -0.25)	180° (range 175° to 180°)	N5
Near-Left	2.37 (range+2.00 to +2.75)	-0.12 (range 0.00 to -0.25)	56° (range 50° to 60°)	N5

The approximately 100 spectacle prescriptions obtained by each of the three SPs were used initially to calculate the mean equivalent sphere and the mean ± 2SDs (Table 3).

Table 3: Descriptive statistics of the spectacle prescriptions (expressed as equivalent spheres) obtained for the standardised patients

	Mean	Mean ± 2SDs
Scenario 1		
Right Equivalent Sphere	-4.06D (S.D.=0.20D)	(-4.46D to -3.66D)
Left Equivalent Sphere	-4.01D (S.D.=0.20D)	(-4.41D to -3.61D)
Scenario 2		
Right Equivalent Sphere	2.05D (S.D.=0.25D)	(1.55D to 2.55D)
Left Equivalent Sphere	3.65D (S.D.=0.27D)	(3.11D to 4.19D)
Near Right Equivalent Sphere	2.96D (S.D.=0.32D)	(2.32D to 3.60D)
Near Left Equivalent Sphere	4.56D (S.D.=0.39D)	(3.78D to 5.34D)

Scenario 3		
Right Equivalent Sphere	0.09D (S.D.=0.16D)	(-0.23D to 0.41D)
Left Equivalent Sphere	0.01D (S.D.=0.15D)	(-0.29D to 0.31D)
Intermediate Right Equivalent Sphere	1.63D (S.D.=0.23D)	(1.17D to 2.09D)
Intermediate Left Equivalent Sphere	1.55D (S.D.=0.24D)	(1.07D to 2.03D)
Near Right Equivalent Sphere	2.12D (S.D.=0.23D)	(1.66D to 2.58D)
Near Left Equivalent Sphere	2.03D (S.D.=0.25D)	(1.53D to 2.53D)

As seen from the benchmark findings in Table 2, all three SPs had minimal astigmatism in each eye. The number of practitioners who found astigmatism ranging from 0.25-1.00DC is illustrated in Figure 1.

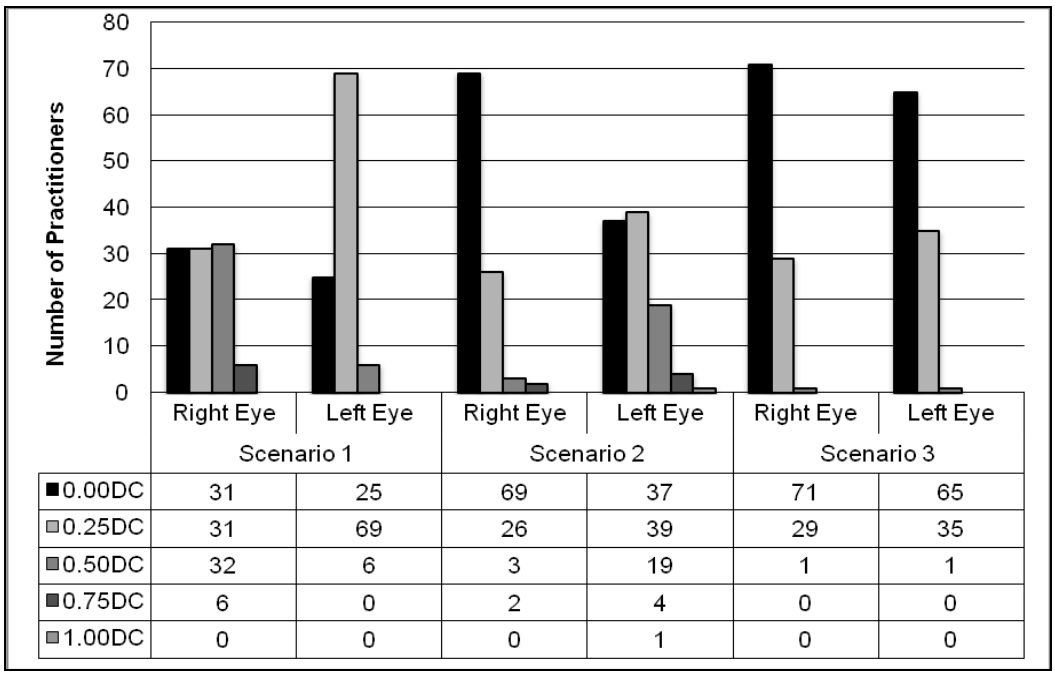

Figure 1: The number of practitioners who found various degrees of astigmatism for the right and left eyes for the three standardised patients.

The reproducibility of the measurement of refractive error between practitioners is an important factor when making clinical management decisions. Table 4 highlights the percentage of practitioners who were in agreement within ±0.25D, ±0.50D, ±0.75D, and ±1.00D of the 'benchmark' refractions for spherical equivalent power, spherical and cylindrical power.

Table 4: Percentage agreement for refractive error between different practitioners

	Percentage Agreement							
	≤±0.25		≤±0.50		≤±0.75		≤±1.00	
	RE	LE	RE	LE	RE	LE	RE	LE
Scenario 1								
Spherical Equivalent	92%	83%	97%	97%	100%	100%		
Sphere	94%	93%	100%	99%		100%		
Cylinder Power	94%	100%	100%					
Scenario 2								
Spherical Equivalent	58%	63%	92%	93%	98%	98%	100%	100%
Sphere	91%	68%	97%	94%	100%	100%		
Cylinder Power	98%	63%	100%	100%				
Near Spherical Equivalent	58%	65%	93%	83%	99%	91%	100%	100%
Scenario 3								
Spherical Equivalent	94%	98%	100%	100%				
Sphere	92%	99%	100%	100%				
Cylinder Power	100%	100%						
Intermediate Spherical Equivalent	45%	66%	97%	98%	100%	100%		
Near Spherical Equivalent	73%	70%	97%	94%	100%	100%		

The 95% limits of agreement and 95% reproducibility limits for spherical equivalent and astigmatic data for the three standardised patients are highlighted in Table 5. The 95% limits of agreement and 95% reproducibility limits for intermediate and near spherical equivalents for the second and third patient scenarios have also been included.

Table 5: The 95% limits of agreement and 95% reproducibility limits for the spherical equivalent, C_0 and C_{45} components, and for the intermediate and near spherical equivalents for prescriptions obtained from the three standardised patients

	95% Limits of Agreement	95% Reproducibility Limits	95% Limits of Agreement	95% Reproducibility Limits
	Right Eye		Left Eye	
Scenario 1				
Spherical Equivalent	-4.06D ± 0.39	0.55D	-4.01D ± 0.39	0.55D
C_0	-0.20D ± 0.43	0.61D	0.06D ± 0.22	0.30D
C_{45}	-0.14D ± 0.33	0.47D	-0.17D ± 0.25	0.36D
Scenario 2				
Spherical Equivalent	2.05D ± 0.49	0.69D	3.65D ± 0.53	0.75D
C_0	0.00D ± 0.25	0.36D	-0.17D ± 0.43	0.61D
C_{45}	-0.05D ± 0.25	0.36D	0.09D ± 0.27	0.39D
Near Spherical Equivalent	2.96D ± 0.63	0.89D	4.56D ± 0.76	1.08D
Scenario 3				
Spherical Equivalent	0.09D ± 0.31	0.44D	0.01D ± 0.29	0.42D
C_0	-0.01D ± 0.25	0.36D	0.04D ± 0.18	0.25D
C_{45}	-0.03D ± 0.16	0.22D	-0.08D ± 0.22	0.30D
Intermediate Spherical Equivalent	1.63D ± 0.45	0.64D	1.55D ± 0.47	0.67D
Near Spherical Equivalent	2.12D ± 0.45	0.64D	2.03D ± 0.49	0.69D

Scenario 1

All the practitioners visited by the SP for this scenario carried out lensometry (spectacle lens BVP measurement using a focimeter), either personally or delegated, of the patient's existing spectacles. 59% carried out an objective assessment of the refractive error. 23% used an autorefractor (personally or delegated), 30% carried out retinoscopy and an additional 6% used both methods. All the optometrists performed subjective testing of the spherical element of the refractive error and 94% checked subjectively for the cylindrical element. 14% of practitioners carried out a binocular refraction.[51] Of the 86% that carried out a monocular refraction, 36% binocularly balanced the prescription. In total, 50% of practitioners binocularly balanced this young adult patient and 75% checked the patient's near visual acuity. Four percent checked the intermediate visual acuity. Thirty six percent of

practitioners checked the patient's accommodation, and 35 of these checked both accommodation and near vision.

53% of the sample recommended an update of the current spectacles and 99% issued a prescription. As noted in Table 3, the mean spherical equivalent for the right eye was -4.06D and -4.01D for the left eye. The mean astigmatic refractive error (calculated using astigmatic decomposition) for the right eye was -0.24DC (range: 0 to 0.75D) and -0.17DC (range: 0 to 0.50D) for the left eye. For the right eye, the mean C_0 was -0.20D (S.D. =0.22D; 95%CI for the mean -0.25D to -0.16D) and the mean C_{45} was -0.14D (S.D. =0.17D; -0.17D to -0.10D). For the left eye, the mean C_0 was 0.06D (S.D. =0.11D; 0.04D to 0.08D) and the mean C_{45} was -0.17D (S.D. =0.13D; -0.19D to -0.14D). The average inter-eye difference using spherical equivalents was 0.12D (range: 0 to 0.38D).

Scenario 2

All of the optometrists visited by the SP in this scenario carried out lensometry, either personally or delegated, of the patient's existing spectacles. 83% carried out an objective assessment of the refractive error. 23% used an autorefractor (personally or delegated), 48% carried out retinoscopy and 12% used both methods. All the optometrists performed subjective testing of the spherical element of the refractive error and 76% checked subjectively for the cylindrical element. The patient presented as a project manager (87% asked this), and 77% of the optometrists asked the patient about the nature of the visual tasks regularly undertaken (e.g., computer use). The SP presented for the eye examinations with a single vision hypermetropic prescription. 74% of optometrists established a prescription for near vision and 45% of these also established a prescription for intermediate vision. None of the optometrists prescribed a different addition for intermediate vision hence it was concluded that the same addition was prescribed for both intermediate and near

vision. All optometrists checked the SP's near visual acuity and 62% her intermediate visual acuity. About half of the optometrists visited checked the range of clear near vision.

Seven optometrists advised the SP on visual hygiene when using the computer. The patient was advised to take regular breaks when using the computer for long periods of time. Only one optometrist explained the need for a reading correction due to the onset of presbyopia. Sixty-nine percent recommended an update of the current spectacles.

The mean spherical equivalent for the right eye (Table 3) was 2.05D and 3.65D for the left eye. The mean astigmatic refractive error (calculated using astigmatic decomposition) for the right eye was 0.05DC (range: 0 to 0.75DC) and 0.19DC (range: 0 to 1.00DC) for the left eye. For the right eye, the mean C_0 was 0.00D (S.D. =0.13D; 95%CI for the mean -0.03 to 0.03) and the mean C_{45} was -0.05D (S.D. =0.13D; -0.07 to -0.02). For the left eye, the mean C_0 was -0.17D (S.D. =0.22D; -0.22 to -0.13) and the mean C_{45} was 0.09D (S.D. =0.14D; 0.07 to 0.12).

The mean inter-eye difference (Anisometropia variable, AV) using the spherical equivalent was 1.60D (SD 0.33, 95%CI for the mean 1.53 to 1.66), with a range of values for AV of 0.75 to 2.50D, and mean ± 2SDs 0.94 to 2.26. The distribution of the anisometropia variable using the spherical equivalent is shown in Figure 2.

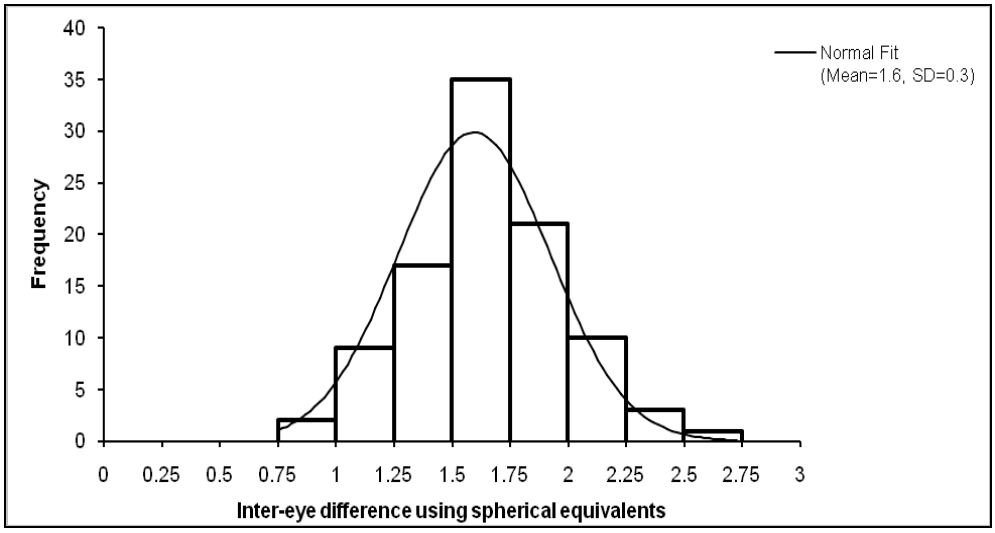

Figure 2: The distribution of the anisometropia variable. This is the difference between the right and left equivalent spheres for 98 spectacle prescriptions for the standardised patient in scenario 2.

A limitation of using spherical equivalents is that these deal with astigmatism in an overly simplistic way and do not, for example, take account of the fact that oblique astigmatism causes a greater degree of blur than with- or against-the-rule astigmatism. This is particularly likely to cause problems when comparing the refractive error of two eyes, as in calculating anisometropia. Although this limitation is not likely to be a major source of error with our patients who have low astigmatism, the effect of astigmatism on the calculation of anisometropia in SP 2 was checked by using a vector representation of astigmatism.[44] Using this approach, the mean inter-eye difference can be evaluated using scalar values (v, as defined by Rabbetts[44]) and was also 1.60D (range: 0.75-2.49D, mean ± 2SDs 0.96 to 2.23).

The average near reading addition was 0.92DS (range: 0.25-1.50DS, mean ± 2SDs 0.32 to 1.52). In view of the fact that the near addition prescribed is highly dependent on the subjective “distance” prescription found, the means and means ± 2SDs for the right and left near spherical equivalents were calculated (Table 3).

Scenario 3

Eighty three per cent of optometrists visited carried out an objective assessment of the refractive error. 25% used an autorefractor (personally or delegated), 47% carried out retinoscopy and 11% used both methods. 99% of optometrists carried out subjective testing of the spherical element of the refractive error and 86% checked subjectively for the cylindrical element. The patient presented as a music teacher (74% asked this), and 67% of optometrists asked the patient about the types of visual tasks he performs (e.g., use of intermediate vision). The SP presented for the eye examinations with single vision near spectacles and intermediate non-prescribed spherical eyeglasses. 99% of optometrists established a prescription for near vision and 56% of these also established a prescription for intermediate vision. All of these 56% of optometrists prescribed a different addition for intermediate vision to that prescribed as the near addition. All of the optometrists who prescribed a reading addition checked the SP's near visual acuity but only 13% checked his intermediate visual acuity.

Thirty-nine percent of the sample recommended an update of the current spectacles and 92% issued a prescription. The mean spherical equivalent (Table 3) for the right eye was 0.09D and 0.01D for the left eye. The average of the astigmatic refractive error (calculated using astigmatic decomposition) from the right eye was -0.08DC (range: 0 to 0.50D) and -0.10DC (range: 0 to 0.50D) for the left eye. For the right eye, the mean C_0 was -0.01D (S.D. =0.13D; 95%CI for the mean -0.03 to 0.02) and the mean C_{45} was -0.03D (S.D. =0.08D; -0.04 to -0.01). For the left eye, the mean C_0 was 0.04D (S.D. =0.09D; 0.02 to 0.06) and the mean C_{45} was -0.08D (S.D. =0.11D; -0.10 to -0.06).

The average inter-eye difference was 0.14 (range: 0-0.63, mean ± 2SDs -0.12 to 0.40) using equivalent spheres. The average intermediate addition was 1.53DS (range: 1.00-2.00DS,

mean ± 2SDs 1.13 to 1.93) and average near reading addition was 2.02DS (range: 1.50-2.50DS, mean ± 2SDs 1.62 to 2.42).

Discussion

The spherical equivalent refractions obtained for the three SPs in our study were within ±0.25D on average 81% of the time, within ±0.50D 97% of the time, within ±0.75D 99% of the time and within ±1.00D 100% of the time. The spherical powers for the prescriptions obtained were found to be within ±0.25D 90% of the time, within ±0.50D 98% of the time and within ±0.75D 100% of the time. The cylindrical powers were within ±0.25D 93% of the time and within ±0.50D 100% of the time.

Our findings are comparable with other studies that have investigated the reproducibility of refractive errors (Table 1). The results for agreement for cylindrical powers in our study should be interpreted with caution since the astigmatic corrections were minimal for all three SPs. MacKenzie concluded that whereas a single optometrist may be able to perform refractions with a precision of ±0.25D, refractions performed by different optometrists on age and ametropia-matched subjects may differ in their spherical equivalent component by 0.75D or more;[29] conclusions in close agreement with those from the current study.

The mean ± 2SD ranges for the spherical equivalent refraction (Table 3) show that for our 100 practitioners visited by the first SP, 95% of the refractive errors determined lie within an 0.80D (approximately 0.75D) range for the right and left eyes. In the case of practitioners visited by the second SP, 95% of the refractive errors lie within a 1.00D range for the right eye and a 1.08D (approximately 1.00D) range for the left eye, and for the third patient scenario 95% of the refractive errors lie within a 0.64D (approximately 0.75D) range for the right eye and 0.60D (approximately 0.50D) for the left eye.

Based on the reproducibility limit data obtained for all six eyes from the standardised patients, we can conclude that any two optometrists will differ in their estimation of distance spherical equivalent refraction on a single eye by no more than 0.75D in 95% of repeated measures. Similarly, the astigmatic data (C_0 and C_{45}) show that optometrists will differ in their estimation of the C_0 component by between 0.25D and 0.61D and for the C_{45} component by between 0.22D and 0.47D in 95% of repeated measures (Table 5). Two optometrists will differ by no more than 0.67D in 95% of repeated measures in their estimation of intermediate spherical equivalent and by no more than 1.08D in 95% of repeated measures for near spherical equivalent refractions.

MacKenzie investigated the reproducibility of sphero-cylinder prescriptions provided by 40 optometrists and concluded that refractions performed by multiple optometrists on a single eye will differ in their spherical equivalent component by over 0.78D on average not more than once in 20 refractions.[29] The same study also concluded that optometrists will differ in their estimation of the J_0 and J_{45} components of astigmatism (which are half the magnitude of the C_0 and C_{45} components)[42] of refraction by no more than 0.24D (approximately 0.50D cylinder) in 95% of repeated measures.[29] The agreement between our data and the results of the study by MacKenzie (2008) for both spherical equivalent and astigmatism support our conclusion that subjective refractive findings are reproducible to approximately ±0.75D when performed by multiple optometrists in patients of different age groups and levels of ametropia.

Based on the limits of agreement given by Bullimore et al. we have calculated their reproducibility limits for spherical equivalent refraction to be 1.10D, and for the J_0 and J_{45} components of astigmatism to be 0.54D (approximately 1.00D cylinder). However, their study design (based on the examination of 86 subjects by two examiners) was markedly different from the current study and from that of MacKenzie, so comparisons should be made with caution.[25;29]

Rosenfield and Chiu investigated the repeatability of clinical refractions by one examiner on 12 subjects on five separate occasions.[52] It should be noted that this study assessed repeatability (repeated measures by the same observer) which would be expected to be less variable than the reproducibility (different observers) assessed in the current study. Although astigmatic decompensation was not used in Rosenfield and Chiu's statistical analysis, the findings of their study revealed that the 95% limits of agreement for spherical equivalent refraction were ±0.29D, ±0.27D for sphere, and ±0.16D for cylinder power.[52] The equivalent parameter for reproducibility used in the present study (columns 2 and 4 in Table 5) has approximately twice the variability reported by Rosenfield and Chiu under repeatability conditions.

The presence of anisometropia later in life does not necessarily imply that there was a significant refractive difference between the eyes in infancy, when the development of vision is at its most rapid and critical stage.[42] In the second scenario, the benchmark eye examinations found a mean inter-eye difference using spherical equivalents of 1.73D (range: 1.38 to 2.13D). The mean inter-eye difference from the 98 spectacle prescriptions obtained was 1.60D (range: 0.75-2.50D, mean ± 2SDs 0.94 to 2.26). These results support the different prescribing philosophies adopted by optometrists for anisometropic patients. Some optometrists prescribe the full anisometropia findings obtained following subjective refraction; some prescribe a balance lens to the worse eye, due to the fear of a non-tolerance if the full subjective refraction was prescribed, and the remaining practitioners give a compromise prescription. In the case of optometrists who prescribe a balance lens or a compromise prescription, there is bound to be a difference between the subjective findings and the final prescription issued. In cases where a spectacle prescription is being prescribed for the first time, a compromise correction may be accepted more readily by the patient. However, the SP in the second case scenario presented for the eye examinations wearing spectacles with a spherical equivalent inter-eye difference of 1.25D. In view of this, it is

interesting to note that the range of inter-eye difference prescribed by the optometrists visited varied from 0.75D to 2.50D.

A greater proportion of optometrists performed an objective assessment of refractive error for the SPs in the second and third scenarios (83%) compared to the first scenario (59%). It is noteworthy that in each scenario a greater proportion of optometrists performed retinoscopy compared with autorefraction. The preference for retinoscopy as the method of objective refraction was less marked in scenario 1 (retinoscopy 36%; auto-refraction 29%) than in scenarios 2 and 3 (retinoscopy 60% and 58% respectively; auto-refraction 35% and 36% respectively).

Subjective refraction is the benchmark against which all refractive devices are measured.[29] Only one practitioner in this study did not perform a subjective refraction, and this applied solely to SP 3. This SP presented with symptoms suggestive of a posterior vitreous detachment and it may be that this practitioner felt that the determination of refractive error was not a priority for this patient.

All three SPs had relatively small amounts of astigmatism or no astigmatism in their current spectacles. The SPs in the first and second scenarios both had no cylindrical correction in the right eye and -0.25DC in the left eye in their current spectacles. The SP in the third scenario presented for the eye examinations with no distance correction and used non-prescribed spherical eyeglasses for near and intermediate work. It is noteworthy that 25 practitioners visited by the SP in scenario two, six practitioners in scenario one and 14 practitioners in scenario three did not subjectively check for a cylindrical element to the prescription. These practitioners may take the view that if a patient is not wearing a cylinder in their current prescription and is achieving good visual acuity without the cylinder then it is not necessary to include a cylinder in any new prescription.[53]

The steps used to determine the final subjective result may vary from patient to patient as the reproducibility of refractive error is a function of both age and refractive state. For patients who have higher degrees of spherical ametropia and/or astigmatism, small differences in vertex distance are likely to influence the measurement of refractive error. This in turn can influence the reproducibility of refractive error by different practitioners. One of the main difficulties when performing a subjective refraction is that, by definition, the practitioner is relying exclusively on subjective responses from the patient, and patient responses are highly influenced by the question asked by the optometrist.

Whilst several studies have provided an insight into the reproducibility of refractive error, the majority of the findings of these studies are based on small samples of practitioners (two, three or a maximum of five) and in some cases students were used as subjects[23;26] rather than "real" patients. These studies, despite the use of only two or three practitioners, found clinically significant differences in results despite similarities in the education and training of these practitioners. Whilst our study was markedly different from those quoted above, in that prescriptions obtained from 100 eye examinations on three different patients were used, it must be stressed that the three standardised patients are not representative of the general population.

In a study of this nature where the actors had several eye examinations with different practitioners, the differences in subjective refraction findings could be explained by: (1) changes in the patients' subjective state between examinations, (2) a change in the patients' subjective response as a result of factors such as "eyelid squinting" or misunderstanding instructions, (3) the examiners using different refracting procedures or different endpoint criteria, (4) some practitioners failing to completely relax the patients' accommodation.[26] It is difficult to control all of these factors although, in response to point one above, all of the visits were completed within a three month period, hence it is unlikely that the patients' subjective state will have changed between the examinations. By monitoring the patient for

quality control after every 20-25 visits, variations in refractive findings due to factor (2) above can be kept to a minimum.

In addition to patient symptoms, several factors need to be taken into consideration when deciding whether or not to prescribe a refractive error or recommend a change in optical prescription. These include the patient's previous ocular history, age, occupation, hobbies and their current spectacle prescription. In many patients we can assume that the power of new spectacles should be the final subjective result although this is not always the case. The standardised patients in our study cases presented for the eye examinations wearing their current spectacles hence the practitioners visited were not masked from their previous prescriptions. The mean benchmark prescriptions noted above were within ±0.25D (sphere and cylindrical power) of their current spectacle prescriptions for all three standardised patients. It is interesting to note that 53% of practitioners visited by the SP in the first scenario, 69% in scenario 2 and 93% in scenario 3 advised the patient to update their spectacles. This latter figure is particularly surprising because the standardised patient in the third scenario was not experiencing any difficulties with his distance or near vision. It could be argued that in the case of the SP in scenario 2, a small change in the hypermetropic prescription would help alleviate the difficulties experienced whilst reading at near.

This study inevitably has limitations. The participation rate expressed as the proportion of optometrists who could be contacted and those who agreed to participate was 27%. Optometrists who volunteered to participate in a study of this nature may be more confident of their skills and may have performed better than those who declined participation.[38] Hence, our results may overestimate performance although we believe that the option of full anonymity will have helped to allay possible concerns about the research highlighting poor practitioner performance.

The data analysed in this study were the prescriptions issued to the SPs at the end of each examination. It is improbable that these prescriptions were identical to the final subjective findings in every case because optometrists may modify their final subjective for various reasons when prescribing. Variations between the final subjective results and the prescriptions given to the SP are unlikely to be a major issue in Scenarios 1 and 3, but may have increased the variability of refractive data for the anisometropic SP in scenario 2. In all three scenarios some optometrists may have found an 0.25 cylinder subjectively, but decided not to prescribe this correction, a decision based on the absence of a cylinder in the SP's current spectacles and the excellent levels of visual acuity achieved with a spherical correction.

The patients in this research did not have very high spherical refractive errors, had minimal astigmatism, and in terms of the determination of their refractive error could be classified as fairly straightforward, although one patient did have a significant degree of anisometropia. It is recommended that future research could usefully use the methods outlined here to determine the reproducibility of optometric measurements for more complex refractive errors. A potential limitation of the present study is that optometrists were not masked to the SPs' current spectacle prescription hence it would be interesting if, in future work, some SPs were to attend without bringing their current spectacles.

A potential limitation is the possibility of practitioners detecting the SP during their visit. In some previous SP studies, practitioners were taken out of their normal practice settings and were aware the patient was a standardised patient, but this was not the case in the present research. In the initial information that was sent to participating practitioners we asked them to inform the researchers if they detected any of the SPs during their visits. None reported identifying the SPs, and nothing that took place during any of the eye examinations led the SPs to suspect that they had been detected.

Conclusion

The data presented here agree with the results of other similar studies leading to the conclusion that subjective refractive findings are reproducible when performed by multiple optometrists in patients of different age groups and levels of ametropia. Standardised patient (SP) encounters are an effective way of measuring reproducibility of refractive error within optometry and should be considered for further comparative analysis of refractive errors for different age groups and different levels of ametropia.

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