ASSESSMENT OF THE OCULOMOTOR RESPONSE IN HUMAN FACTOR ENVIRONMENTS

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Summary

The need to measure the response of the oculomotor system, such as ocular accon accurately and in real-world environments is essential. New instruments l developed over the past 50 years to measure eye focus including the extensively u well validated *Canon R-1*, but in general these have had limitations such as a close view, a poor temporal resolution and the need for extensive instrumentation bulk naturalistic performance of environmental tasks. The use of photoretinoscopy specifically the *PowerRefractor* was examined in this regard due to its remc binocular measurement of accommodation, eye movement and pupil size and its (of-view.

The accuracy of the *PowerRefractor* to measure refractive error was on average s more variable than subjective refraction and previously validated instrumentat *PowerRefractor* was found to be tolerant to eye movements away from the visua could not function with small pupil sizes in brighter illumination. The *Powe* underestimated the lead of accommodation and overestimated the slop accommodative stimulus response curve.

The *PowerRefractor* and the *SRW-5000* were used to measure the oculomotor resp variety of real-world environment: spectacles compared to single vision contact use of multifocal contact lenses by pre-presbyopes (relevant to studies o retardation); and 'accommodating' intraocular lenses. Due to the accuracy concern *PowerRefractor*, a purpose-built photoretinoscope was designed to measure the o response to a monocular head-mounted display.

In conclusion, this thesis has shown the ability of photoretinoscopy to quantify cha oculomotor system. However there are some major limitations to the *PowerRefract* the need for individual calibration for accurate measures of accommodation and ver the relatively large pupil size necessary for measurement.

Key words: ocular accommodation, vergence, pupil size, photoretinoscopy.

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CHAPTER 1

INTRODUCTION

1.1 Definition of Accommodation

Accommodation is the process whereby changes in the dioptric power of the lens occur, so that an in focus retinal image of an object of regard is obtained and maintained at the high-resolution fovea (Ciuffreda, 1998). An emmetrope viewing a distant object focuses the image on the retina with the eye in its weakest dioptric state. To view a closer object clearly, positive power must be added to the emmetrope's refracting system.

1.2 History of Accommodation

The concept of accommodation dates back as far as 100AD (Dubois Poulsin, 1987) with Rufos and Gallen describing the lens as divine (*divinium occulum).* The Greeks conceived that the brain emitted a spirit that transverses the hollow optic nerve, crossed into the lens from where it then emanated in the form of rays to touch the objects to make them seen. It was not until the Middle Ages that this concept was reviewed by the Arabs. Alhazen (cited Dubois Poulsin, 1987) suggested that the rays emanated from the object and converged toward the crystalline lens, but the visual spirit in turn radiated out from the brain conveyed by the optic nerves toward the crystalline lens.

1.3 Mechanics of Accommodation

The concept of lenticular accommodation over axial length changes or corneal curvature changes was first proved by Young (1801) who neutralised the power of his cornea in a water bath and was still able to focus. Helmholtz (1855) was able to confirm this by viewing double Purkinje images. The first Purkinje image reflects from the front of the cornea and the second dimmer one from the back surface, neither of which moved during accommodation. The third Purkinje image reflects from the anterior surface of the capsule and lens and the fourth one from the posterior surface. Helmholtz (1855) showed that the anterior pole of the lens moved forward approximately 0.4 mm with full accommodation and that this major effect was due to the increase in the curvature of the anterior surface of the eye. He also showed a very small, backward movement of the posterior pole of the lens during an increase in curvature of the posterior surface with maximum accommodation. The mechanism of accommodation first suggested by Helmholtz has been supported broadly by many subsequent studies (Stark, 1988, Fincham, 1951, Wyatt, 1988), although later disputed by Schachar (e.g. Schachar and Anderson, 1995).

1.4 Theories of Accommodation

Stark (1988) described the Helmholtzian theory of accommodation as Dual, Indirect and Active. Dual, because it combined both lenticular and extra lenticular elements. The lenticular elements are the capsule and the lens itself, with the ciliary muscle as the extra lenticular elements. The indirect element of the theory applies to the fact that the ciliary muscle does not act directly on to the lens. Instead it acts indirectly by relaxing the tension in the axial portion of the zonule and this axial zonule then releases the lenticular mechanism.

The active part of the theory comes about because when activity occurs in the ciliary muscle, active positive accommodation occurs. With decreased activity or relaxation in the ciliary muscle there results a decreased level or a relaxation of accommodation. The internal elastic force within the zonules flatten the capsule and lens, and thus produces relaxation of accommodation. With the active contraction of the ciliary muscle, tension of the axial zonule is released. This permits the lenticular mechanism to act for itself and produce a more spherical form of the lens. The final dynamics are dependent on the visco-elastic forces of the lens and the elastic forces of the capsule (Weale, 1989).

Schachar, (Schachar *et al.*, 1993, Schachar and Anderson, 1995) has proposed a completely alternative mechanism of accommodation. During ciliary muscle contraction he suggests that there is increased tension in the equatorial lens zonules that pulls the lens equator nearer the sclera with a relaxation of the anterior and posterior lens zonules. These forces result in the lens becoming a spindle shape that is thinnest at the equator and more steeply curved centrally. This causes the power of the lens to increase. Presbyopia is discussed further in Chapter 7 but Schachar (1992) proposed that it occurs as the result of the normal growth of the lens and that the equatorial lens diameter increases with age. No change in the dimensions of the sclera occurs so the distance between the ciliary muscle and the lens will decrease, reducing the tension that the zonules can exert on the lens as the ciliary muscle contracts. This would then cause a reduction of the amplitude of accommodation.

1.5 Components of Accommodation

Heath (1956) was the first to classify the components of accommodation separately into four functional units. These together form a framework for the stimuli of accommodation and the final state of response. The four components are:

1) Reflex Accommodation – is the only component that is directly stimulated by the quality of the retinal image i.e. a reduction in the overall contrast and contrast gradient of the retinal image (Heath, 1956). Reflex accommodation has been shown to act for small amounts of blur (up to 2.00 D) (Fincham, 1951). Beyond this a voluntary effort is required (Ciuffreda and Kruger, 1988). Reflex accommodation is the largest and possibly the most important component of accommodation under both monocular and binocular control (Hung, Ciuffreda and Rosenfield, 1996).

2) Vergence Accommodation - is the accommodation that is induced by fusional vergence. This gives rise to the convergence accommodation/convergence ratio (CA/A).

Rosenfield and Gilmartin, (1988) found this to be ~0.40 dioptres per metre angle in young adults. The amount of CA/A decreases with age (Bruce, Atchison, and Bhoola; 1995, Baker and Gilmartin, 2002). It is measured under open loop conditions i.e. with blur feedback rendered ineffective, using either binocular pinholes or a blur free difference of Gaussian target. These methods prevent the intrusion of blur driven reflex accommodation on the measured response (Ciuffreda, 1998).

3) Proximal Accommodation - is the accommodation due to the influence or knowledge of apparent (or perceived) nearness of an object. It is stimulated by targets located within 3 m of the individual (Rosenfield, Ciuffreda and Hung, 1991). Proximal accommodation is fully manifested when no visual feedback is available with respect to blur and disparity i.e. under open loop conditions (Ciuffreda, 1998). Hung, Ciuffreda and Rosenfield (1996) found that under open loop conditions its contribution can be quite large and can provide between 42.5 to 81.6% of the total near response. However, under normal natural viewing conditions (binocular closed loop) the proximal response becomes quite small, accounting for around 4% of the accommodative level. The authors do, however, suggest that proximity may still play an important role by providing cues for attaining coordinated and harmonious motor responses under specific viewing conditions.

4) Tonic Accommodation - is found in the absence of blur disparity and proximal inputs and is unusual as it is considered to be the result of a lack of stimulus. It was first reported in 1789 (Levene, 1965) by the astronomer Lord Maskelyne who noted that the use of a negative lens facilitated his night observation. It was generally assumed that accommodation relaxed when distant objects are viewed, but an eye receiving no specific stimulus to cause it to focus, tends to adopt and maintain a particular level of accommodation other than zero. This is normally referred to as the resting state or dark focus of the eye. The value of the resting state tends to stay stable for a particular individual (Heron, Smith and Winn, 1981),

but there is variation between individuals even when they are matched for age. This may imply that the nervous system does not act equally in different individuals, even though we generally quote the classic figures for the amplitude of accommodation with age. Charman (1982) suggests that if the sympathetic part of the system is weak then this will reduce the sympathetic section of the stimulus response curve which would reduce the clarity of distance objects whilst increasing the parasympathetic response. Charman then suggested that such an eye would be myopic. If this myopic eye is corrected with the appropriate negative lens then its resting state will lie at a lower dioptric value than that of an emmetropic eye. He also suggests that a relatively strong sympathetic branch results in hypermetropia. This would suggest that if the refractive state of the eye influences the way that the eye accommodates, then the resting position of the eye will also be affected by the degree of ametropia.

It has been found in several studies that accommodation is at its most accurate and visual acuity highest when the stimulus is conjugate with the individual subject's dark focus (Johnson, 1976, Kotulak and Morse, 1994). This occurs even when there is good illumination and would suggest that for optimum performance in any demanding visual task the optical distance of the stimulus should correspond to the dark focus of the individual observer. Accommodative responses have been thought to be a compromise between accurate focusing and the observer's dark focus, the value depending on the distance of the stimulus relative to the observer's dark focus and the relative effectiveness of the accommodative stimulus (Leibowitz and Owens, 1975). However, other studies (e.g. Fisher and Ciuffreda, 1988; Collins, Davis and Atchison, 1994) suggest that tonic accommodation does not serve as a perceptual anchor point or reference state used in interpreting the distance information derived from blur-driven accommodative innervation.

Usually, when the specific stimulus to accommodation is removed, the accommodation system returns rapidly towards its tonic position. However, if the stimulus is removed after extended focusing effort, the decay is much slower as some degree of smooth muscle tone is retained after a sustained period of fixation and this accommodative hysteresis effect can become evident in subsequent tonic accommodation measures (e.g. Ebenholtz, 1983). A similar effect can be observed in the vergence system (e.g. Hung, 1992). Wolf, Ciuffreda and Jacobs (1987) found both tonic accommodation and tonic vergence gradually increased during a reading task, with changes in tonic accommodation occurring more rapidly. Accommodative hysteresis seems to act to reduce the demand for blur-driven accommodative innervation when accommodation must be maintained for a period of time.

Ong and Ciuffreda (1995) reviewed the literature, finding that accommodative hysteresis can occur from as little as 10 minutes of near-work and has a mean magnitude of about 0.40 D, with a range from 0.12 to 1.30 D. Its decay is characterised by an exponential function having a total time course ranging from 30 seconds to a few hours (for longer tasks).

The relationship between tonic accommodation and refractive error was investigated by McBrien and Millodot (1987). It was noted that corrected hyperopes have the highest dioptric value of tonic accommodation and that late onset myopes have the lowest dioptric value. They also found that the time taken to reach a stable tonic position of accommodation was slower in hyperopes compared to emmetropes and myopes. Due to the slow time course of the hysteresis effect and its inhibitory nature, the role of sympathetic innervation is more likely to be associated with sustained periods of accommodation (McBrien and Millodot, 1988). Fisher and Ciuffreda (1989) found that sustained focus at the near-point resulted in a significant increase in tonic accommodation and the apparent distance of the target. Hasebe, Graf and Schor, (2001) noted that they could fatigue the accommodative system in monocular and binocular tasks and in both cases the baseline tonic accommodation was reduced.

1.6 Accommodation Response Curve

When emmetropes or corrected ametropes view a near object, they will exert a level of accommodation less than the stimulus vergence, a phenomenon which is referred to as accommodative "lag". Conversely, for distant objects the response exceeds the stimulus vergence and this error is often termed the accommodative "lead" (e.g. Denieul, 1982). The linear portion of the stimulus-response curve has been shown to be affected by target luminance (Johnson, 1976), spatial frequency (Tucker and Charman, 1987), blurred objects (Heath, 1956), and increased depth of focus (Ward and Charman, 1985), age (Simonelli, 1983) and refractive error (McBrien and Millodot, 1986), although others have suggested that this is not the case (e.g. Ramsdale, 1985). The stimulus response curve is discussed further in chapter 4.

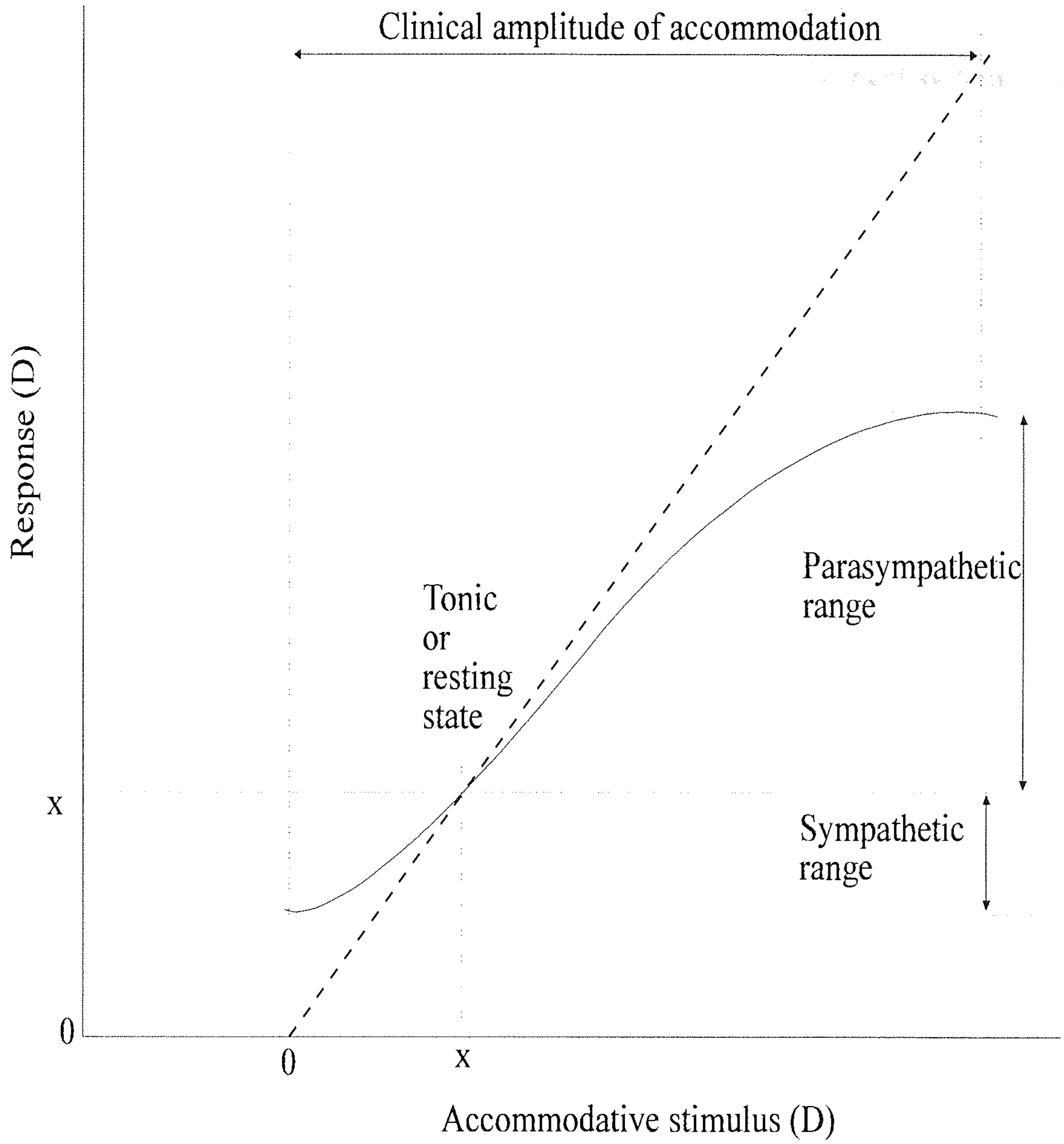


Figure 1.1: Stimulus Response Curve (From Charman, 1982)

1.7 The Pupil and Depth of Focus

Depth of focus is the variation in image distance in a lens or optical system, which can be tolerated without incurring a lack of sharpness in focus. Projected into free space this dioptric interval defines the depth of field of the eye (Ciuffreda, 1998). Depth of focus can be thought of as the tolerance factor for internal system error, i.e. a small amount of retinal defocus is tolerated without producing the effects of blur. One of the classic studies of depth of focus was carried out by Campbell in 1957 and the depth of focus was found to be ±0.3 D for a 3 mm pupil. This is similar to the value found by Charman, (1991). Campbell also ascertained that maximum blur sensitivity was obtained with a wavelength of 550 nm and that depth of focus is reduced with increases in target luminance contrast and pupil size.

1.8 Under Accommodation - The Mandelbaum Effect

The Mandelbaum effect refers to an accommodative response to an intervening surface while attempting to focus a distant object of interest. This was first described by Mandelbaum (1960) who discovered his inability to focus the distant skyline while observing it through a mesh window screen. There are many everyday occurrences such as scratched, dirty or rain splattered car or aeroplane windshields, in which the Mandelbaum effect may present a visual problem or safety hazard (Weintraub, 1987). Aircraft windscreens have been known to be particularly susceptible to scratching (being made of plastic components for safety and strength) and are often significantly distorted (Gomer and Eggleston, 1978). Rainbowing and other optical defects could provide accommodative cues in otherwise clear windscreens. Also, the visual environment of car drivers or pilots has intervening objects, such as A-pillar posts or cockpit pillars, which may bias the observer's visual accommodation response (e.g. Roscoe and Hull, 1982; Chong and Triggs, 1989).

Owens (1979) found the eye tended to focus on the target that was located nearest to the resting/dark focus of accommodation, thus apparently accounting for the Mandelbaum effect. He suggested that minimal fatigue and greater clarity would be obtained for visual displays located at a distance corresponding to this level of accommodation. He concluded that a foveal stimulus at an optical distance near the resting accommodative level might disrupt accommodation for a fixed target at an optically different distance.

Kotulak, Morse and Wiley (1994) described that the knowledge of the distance of the target was an important factor in instrument viewing and in a minority of their study was more important than the optical distance of the object. They also found that subjects whose accommodation is influenced by knowledge of object distance tend to have a more proximal dark focus than those whose accommodation is independent of knowledge of object distance. It was suggested that the Mandelbaum effect, could be cognitive (i.e. known distance) rather than physical.

Over-accommodation has been found to occur with head up displays (e.g. Norman and Ehrlich, 1986; Iavecchia, Iavecchia and Roscoe, 1988) due to a variation on the Mandalbaum effect. This phenomenon has often been termed "mis-accommodation" (e.g. Roscoe 1987a), as the eyes are not accurately focused on objects of interest. Mis-accommodation may also occur with helmet-mounted displays (HMD) and the problem is more pronounced if the user has to mentally process the virtual image (Edgar, Pope and Craig, 1994).

1.9 Accommodation in Children

The stimuli to accommodation in adults have been discussed (see section 1.4). In children, the ability to accommodate and produce a clear retinal image is very important as a consistent blurred image reaching the retina can result in amblyopia developing. Amblyopia is a condition that is usually defined as a non-specific loss of visual acuity of at least two lines that is not caused by pathology or correctable by ordinary refractive means (Millodot, 1993). It is a relatively common condition that occurs in around 2-5 % of the population (Flom and Meumaier, 1966).

Due to the lack of a reliable response, the accommodative level in children has generally been measured in two ways 1. Dynamic retinoscopy and 2. Photoretinoscopy (Table 1.1).

The findings are variable, with Banks (1980) showing that accommodation is similar to that found in adults at 9-10 weeks, whereas Howland, Dobson and Sayles, (1987) suggested that the accommodative response is not fully accurate even at 10 months. One reason for this may be the difference between dynamic retinoscopy and photorefraction. Retinoscopy takes several seconds to perform and during that time accommodation may drift. The end point chosen may be subject to the experimenter's bias, the child may try to focus through the lens itself if it is in placed in front of the eye for too long or the retinoscope beam may induce a change in accommodation towards the dark focus (Currie and Manny, 1997).

Dynamic retinoscopy (Woodhouse *et al.*, 2000) involves the child fixating on a near target, such as a translucent internally illuminated cube with pictures on the outside. The target is placed at set dioptric distances from the child's eye e.g. 10, 6 and 4 dioptres. The point at which a neutral retinoscopy reflex is achieved is then determined, with the reciprocal of the distance relating to the accommodative response to the target. Photoretinoscopy will be discussed in further detail later in this chapter. Table 1.1 shows the main experimental features of the studies, which have been carried out both with dynamic retinoscopy and photoretinoscopy.

As well as measuring accommodation in infants there are several other groups in which reduced accommodation has been implicated. In particular, children with Down Syndrome and cerebral palsy show marked reduction in accommodation compared to normal children of the same age (Leat and Gargon, 1996; Cregg *et al*, 2001). The need to measure accommodation accurately is therefore of great importance, not only because of the possibility of the development of amblyopia, but also due to the educational needs of all children, as most learning is done at near. This is discussed further in Chapter 4.

Author	Method	Findings
Haynes *et al.*, (1965)	Dynamic retinoscopy	~0-1 month –average accommodative response was 5 D for all distances ~1-2 months- some accommodative changes with distance 2-4 months - adult like accommodation
Braddick *et al*(1979)	Photorefraction	~< 9 days: consistent focusing at 75cm ~ 2-3 months: consistent focusing at 1.5 m in 60 – 70% of infants ~ 6-8 months: consistent focusing at 1.5 m in all infants
Brookman (1983)	Dynamic Retinoscopy	~ 2-12 weeks: Slopes of SR curves was 0.6
Howland *et al*(1987)	Dynamic Photoretinoscopy	2-9 months: Slopes of SR curves ranged from 0.54 to 0.66 10 months: appropriate direction of response, but inaccurate responses.
Currie and Manny (1997)	Photoretinoscopy	~1.5 months variable response 3 months responded in correct direction for pattern target but not all accurately

Table 1.1: Studies which have been carried out both with dynamic retinoscopy and photoretinoscopy.

1.10 Photorefraction

Photorefraction is a term used to describe a technique used by a group of instruments that provide an objective measurement of accommodation and refractive error. They have an advantage over many other methods as they can be used remotely, and are therefore useful in measuring accommodation in infants, uncooperative subjects and during human factor tasks, such as driving or flying, involving unrestricted head and eye movements. All photorefractive techniques also have the potential ability to measure both eyes simultaneously.

Howland and Howland first described the technique of photoretinoscopy in 1974. The method estimated the instantaneous refractive state, by photographing the light returning from the subject's eyes, illuminated by a fibre optic light source centred in a camera lens (Figure 1.2). The defocus of the eye determines the spread of the returning light at the camera. The returning light passes through an arrangement of four pie-shaped cylinder lenses aligned along two orthogonal meridians, which are typically plano/+1.50 DS. The 35 mm reflex camera is focused on the patient who is ideally 1-2 m away. When the light is reflected from the subject's eye, it is imaged in a cross pattern where the length of the arms are dependent on the amount of defocus i.e. the refractive error (but not its sign) and their width is dependent on pupil size. Astigmatism causes the cross arms to be different lengths. This has been termed Orthogonal Photorefraction - OP; (Howland *et al.,* 1983) and has been used to measure infant astigmatism (Howland, Atkinson, Braddick and French, 1978) and infant accommodation (Braddick, Atkinson, French and Howland, 1979). Accommodation was measured in the latter study by taking photographs at two different camera-to-subject distances, 0.75 m and 1.5 m (to evaluate focusing ability) and also with the subject focusing on rattles and toys in-between the child and the camera. These measurements were then used to confirm the data from focusing on the camera. The direction of refractive error was subsequently identified using dynamic retinoscopy at a distance of 50 cm.

One difficulty found with orthogonal photorefraction is that when small refractive errors were present there was no image formed on the film, termed the dead zone. The reason for this is ascribed to the vignetting effect of the fibre optic tip, which obstructs some of the rays returning to the camera. An eye was said to be in focus if no star arms were formed.

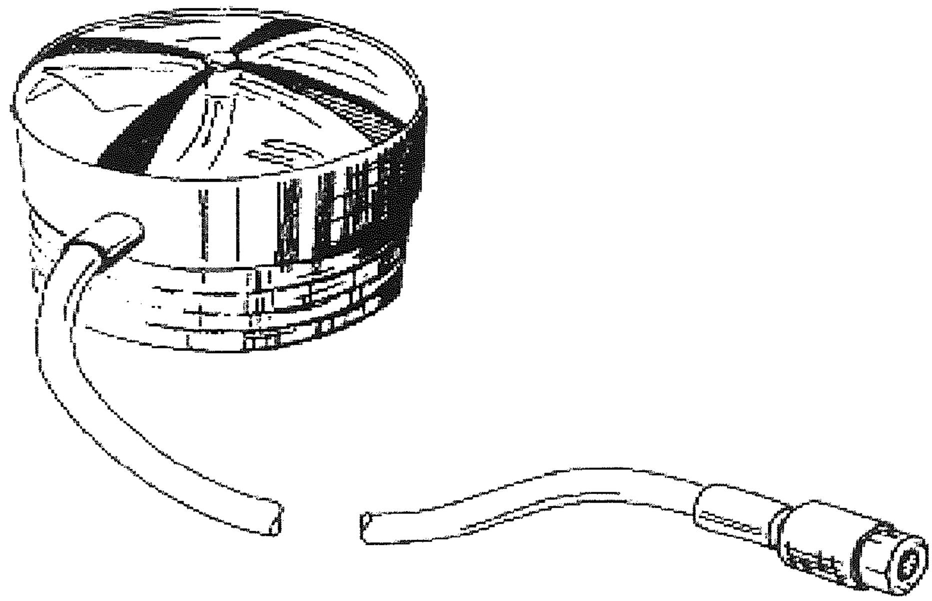


Figure 1.2: Photorefraction attachments for a 35 mm camera. Four 70-degree pie shaped cylinder lens segment surround the fibre optic light guide. From Howland and Howland (1974).

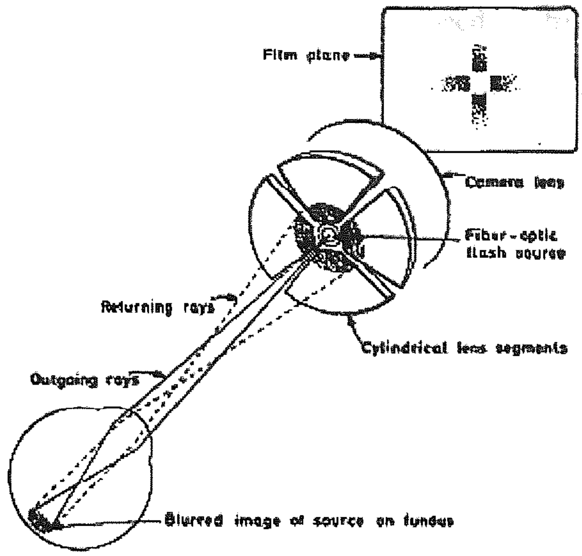


Figure 1.3: Optics of photorefraction. Light from the fibre optic guide is focused on the retina of the subject. The light returning from the retina to the camera falls on the cylinder lens segments and is focused into a cross shaped pattern. The lengths of the cross-shaped pattern, with the lengths of the cross arms being directly proportional to the degree of defocus in the corresponding meridian. From Braddick *et al.*, (1979).

Howland and colleagues (1983) described a modification to Orthogonal Photorefraction, which was termed Isotropic Photorefraction, as the defocus is equal in all directions. In Isotropic Photorefraction there are no cylindrical lens segments surrounding the central fibre optic light. The camera is defocused relative to the subject. This translates the spread of light that is returned to the camera lens into a defocused pupil picture at the film plane. The greater the degree of defocus of the eye relative to the camera, the greater the radius of the blur circle of the defocused pupil at the film plane. For each estimate of refractive state, two defocused pictures of the subject are taken; one focused 0.50 D in front of the pupil plane and one focused 0.50 D behind the pupil plane. The magnitude of the subject's defocus relative to the camera can be determined by the measurement of the size of defocused pupil in either picture. The sign of the subject's defocus relative to the camera can be determined by comparison of the two photographs. A hyperopic focus would produce smaller defocused pupils in the picture focused behind the pupil than in front, whereas a myopic focus would produce smaller defocused pupils in the picture focused in front of pupil. Quantitative estimation of the subjects refractive error can be worked out by using the pupil size, which is determined from a third photograph which is focused at the pupil plane and a ray traced model of the optical system of the camera (Howland *et al.*, 1983). The flash source when reflected by the eye is imaged as an ellipse who's major and minor axes represent the astigmatic meridians of the eyes, (Figure 1.4)

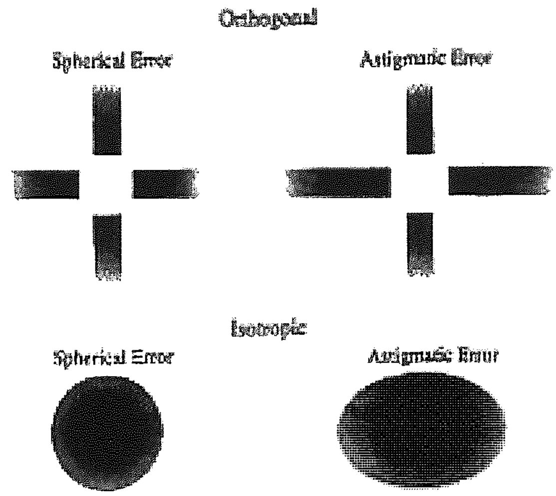


Figure 1.4 This shows the difference in the patterns formed by the pupils in orthogonal and isotropic photorefraction. From Campbell, Bobier and Roorda, (1995).

Isotropic Photorefraction has proved useful in studies on the focusing of infants during preferential looking tests (Dobson *et al.*, 1983) and together with Orthogonal Photorefraction in looking at assessing vision in both normal and handicapped children. (Howland and Sayles, 1983; Howland, Dobson and Sayles, 1987; Hui, Peck and Howland, 1995). Combinations of the techniques have also been used to study the refractive states of the eyes of animals including penguins (Howland and Sivak, 1984), and flying fish (Murphy *et al.*, 1983). A combination of the two techniques is used because the sign of the defocus is difficult to distinguish in orthogonal photorefraction, but easier with isotropic photorefraction.

Murphy and colleagues (1983) used cine film to continuously record the images reflected from the retina in orthogonal photorefraction, allowing a dynamic accommodative trace for animals to be measured. Recording on video later came to be described as dynamic photoretinoscopy and allows accommodative changes to be studied in real time. This was especially important in viewing amphibious mammals that are active above and under water e.g. sea otters (Murphy *et al.,* 1990).

The more recent developments in photoretinoscopy have some similarities to retinoscopy. The camera, which is focused on the pupils, records the pupil illuminated by its fundus reflex (Kaakinen, 1979). When the eye is myopically focused in relation to the camera the pupil reflex is on the opposite side to the illumination (equivalent to the 'against' movement in retinoscopy). Conversely, the pupil appears illuminated on the same side as the light source (usually the inferior portion of the pupil) when the eye is hypermetropically focused in relation to the camera (equivalent to the 'with' retinoscopy reflex)

Using ray tracing, Howland (1985), demonstrated an isotropic arrangement with the illuminating infrared LEDs positioned on a mask, which shielded the lower half of the camera aperture. The appearance of the "crescent" of light in the pupil was a function camera to subject distance (A), eccentricity of the light source to the camera aperture (E), pupil size (R), and the degree of defocus of the subject relative to the camera (D). Specifically, for a crescent to appear in the pupils of a subject:

$$X < 2RA/ (2R+E) \qquad \text{(eqn 1)}$$

Where X is the distance from the subject to the plane of focus of the eyes

The dark fraction or the ratio of the segment height of the dark part of the pupil to the total diameter was shown to be (eqn 2):

$$DF = E/2AR \qquad \text{(eqn 2)}$$

The sensitivity of the measurements increases with the camera to subject distance, A, and the pupil radius, R, and decreases with higher eccentricities, E (eqn 2).

1.11 Eccentric Photorefraction

The concept of eccentric photorefraction was first discussed by Bobier and Braddick (1985). It was described as a technique to measure accommodation and the refractive states along a single meridian of the eye. The method was similar to that described by Howland (1985), but distinctive in that the visible light flash source is eccentric to the optical axis of the camera.

Duckman and Meyer, (1987), compared eccentric photorefraction to retinoscopy, finding it to be an effective method of screening for refractive errors, especially in toddlers and non-verbal subjects, and when used correctly was as accurate as retinoscopy.

A modification to this technique was presented by Schaeffel, Faraks and Howland (1987). To prevent pupillary constriction, infrared light (IR) provided by high out-put light emitting diodes (LED's) were used (Figure 1.5). Therefore, the refraction can be performed while the pupil is at its maximum dilation.

Using ray tracing, it was shown that the amount of defocus (D) can be described by:

$$D = E/2 \times DF \times R$$

where E is the eccentricity from the top of the paper shield, DF is the dark fraction or the ratio of the segment height of the dark part of the pupil to the total pupil diameter, A is the distance of the subject from the camera and R is the radius of the pupil.

Using several IR LEDs positioned at different eccentricities from the camera axis also extended the range of measurement. The linear relationship between eccentricity and defocus was tested at two different distances (A) (0.95 m and 0.56 m) and was found to give a range of ± 8.00 D with a model eye. In the arrangement described there was a sensitivity of about ± 0.3 D at 1.50 m.

The LEDs do not represent point sources of light as the total light emitting area is around 3 mm and a slope is formed on the pupil instead of the crescent shapes, which were formed in eccentric and orthogonal photorefraction. If the eye is focused at the plane of the camera, the returning light is refocused on to the LEDs, so the pupil appears almost dark. If the eye is defocused myopically with respect to the camera the returning light is refocused in a plane between the eye and the camera and subsequently spread out in a cone the angle of which depends on the amount of defocus. The relative position of the reflex in the pupil tells the sign of the refractive error. For an eye myopic relative to the camera, only rays coming from the lower part of the pupil can be detected due to the shield, which covers the lower part of the aperture. For an eye which is focused hyperopically in respect to camera then only the upper part of the pupil will be illuminated.

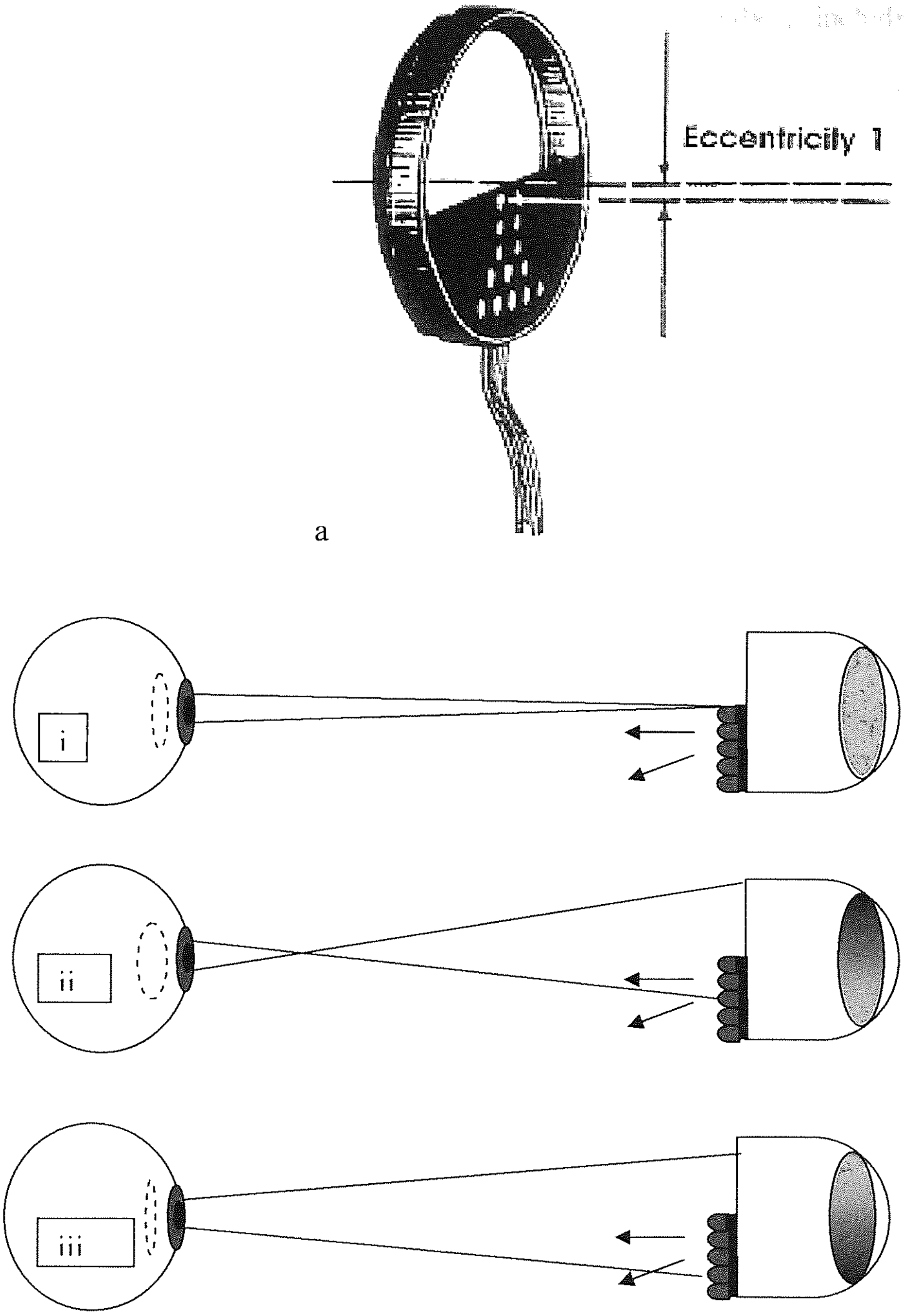


Figure 1.5: (a) Infra red photoretinoscope, which is placed in front of the video camera. The IR LEDs are arranged at five different eccentricities from the edge of the non-reflective black shield, which occludes about half the camera aperture. The number of LEDs for each eccentricity is increasing to compensate for the intensity drop in fundus reflexes created from higher eccentric light source. From Schaeffel, Faraks and Howland, (1987)

(b) Ray diagrams showing photoretinoscopy (i) emmetropic (ii) if the eye is defocused hyperopically then the returning light from the camera is refocused in a plane behind the eye. Only rays emanating from the upper part of the pupil are imaged due to the shield and (iii) if the eye is defocused myopically then the returning light from the camera is refocused in a plane between the eye and the camera. Only rays emanating from the lower part of the pupil are imaged due to the shield.

This technique has also been used for animal studies, including measuring corneal accommodation in chicks and pigeons (Schaeffel and Howland, 1988) and the brown kiwi (Sivak and Howland, 1987). Using infrared light has the advantage that the animal is not aware it is being measured and the pupil size is relatively unaffected making measurement easier.

Different eccentricities give differing degrees of dark focus and the radiation output across the LED is not constant and is maximal along its axis. This means that it is very important that the LEDs are pointing directly at the eye as if they are even slightly displaced the reflex is reduced. In Shaeffel's photoretinoscope, the LEDs were positioned in a triangle, with the apex (one or two LEDs) at the centre of the camera lens and the base (5-6 LEDs) at the camera lens edge.

Also an electronic circuit was set up to allow the LEDs to be flashed in sequence, with adjustable frequency. This allowed a fast change in the dark fraction and gave the impression of apparent motion in the reflex in the pupil. The direction of the motion gives the sign of the defocus and according to the author is useful in measuring small eyes which otherwise would not be able to be refracted e.g. bats and tadpoles. However, the light reflected from the retina was minimal from more eccentrically located LEDs and the additional electronic circuitry and coupled with more complex computer programming led to future versions illuminating the entire triangle of LEDs simultaneously (Schaeffel, Wilhelm and Zrenner, 1993).

The greater the camera to subject distance then the greater the accuracy. However, the further the camera is from the subject's eye then the dimmer the light returned would be and the smaller the camera image which would have the effect of reducing the accuracy. So, therefore, a compromise distance must be used and is usually between 1-1.5 m. Using this technique, the light crescents in the pupil created by the different eccentric light sources add up to an almost linear intensity gradient in the vertical pupil meridian. Image-processing software can be used to determine the slope of the intensity profile. Because the slope changes continuously with refraction, it permits continuous measurement of refractive state in that meridian. The calibration slope appears to vary with pupil size, due to the reflectivity of the retina (Schaeffel, Wilhelm and Zrenner, 1993), although this is discussed in further chapters.

1.12 Measurement of Astigmatism

One difficultly with infrared photoretinoscopy compared to Orthogonal and Isotropic photoretinoscopy is that it is not easy to measure astigmatism, as the LEDs only give an intensity gradient in one meridian. When using Orthogonal Photorefraction the cross arms become proportionally longer in the meridian of the astigmatism compared to the spherical meridian. The cross is also rotated to the direction of the astigmatism. In Isotropic Photorefraction a spherical image is formed if the refractive error is only spherical. If there are spherical and astigmatic errors an elliptical image is formed (Figure 1.4).

Wesemann, Norcia and Allen (1991) examined the theory of eccentric photorefraction with astigmatic eyes. By using complex mathematical equations they worked out that the angular tilt of the dark crescent appearing in the subject's pupil are derived as a function of five different variables, the strength of the sphere, the strength of the cylinder, the axis, the eccentricity of the flash and the distance of the camera away from the subject. The authors noted that one photograph was not enough to screen for astigmatic errors. In particular astigmatism in the vertical or horizontal meridian gives rise to a crescent with a horizontal border, therefore making the crescent formed indistinguishable from one created by a purely spherical error. The solution that they suggested was to take two pictures in two orthogonal orientation of the photorefractor i.e. at 90° to each other.

Several of the techniques have run the camera image through a video processor (Schaeffel, Wilhelm and Zrenner, 1993) and several have gone on to try to develop the technique into a commercial product. Thompson *et al.*, 1996, developed the *Tomey ViVA* Infrared Photorefractor as a method to determine manifest refraction of human subject without cycloplegia at a distance of 1 m. It was found to be accurate, but only over a ±3.00 D range. The instrument had IR LEDs surrounding three sides of the camera and was originally thought to be useful in measuring accommodation, although it does not seem to have been used in any research studies. One reason for this may be that it underestimates cylinder powers by as much as 2 D on a three-dioptre cylinder.

The photoretinoscope developed by Gekler *et al.*, (1997) consisted of a circular arrangement of six individual knife-edge refractors (Figure 1.6). The diameter of the open aperture and the distance of the IR LEDs from the optical axis were optimised to obtain maximally bright fundal reflections in the pupil coupled with a maximal range of measurements. Due to the radial symmetry of the LED arrangement, each of the three meridians is refracted twice from opposite orientations because the entrance pupil of the camera lens and the LED arrangement are not exactly in the same plane, the effective eccentricity of a row of LEDs may be different for different positions of the pupil in the video image. As a result the slope measured in the pupil may differ, depending on the relative position of the eye in the video frame. The problem can be overcome if the refractions obtained from two opposite LEDs are averaged after the sign reversal is taken into account. This would also increase the reliability with two refractions obtained from opposite directions.

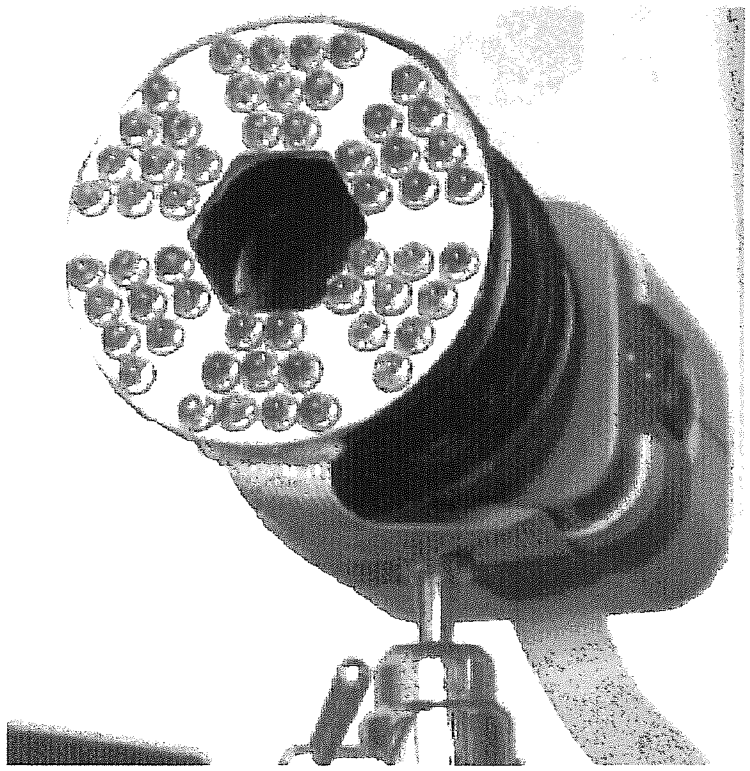


Figure 1.6: Circular Photoretinoscope. From.http://www.uak.medizin.uni-tuebingen.de/frank/flor3.html 22 Jun. 01

Calibration for the instrument was done initially on only eight subjects but the authors concluded that this was an accurate machine that was an improvement on other photorefractors previously produced. Further work was done by Schaeffel, Weiss and Seidel (1999). They expanded the photoretinoscope developed by Gekler *et al.,* (1997) and named it the *PowerRefractor*™. (Figures 1.7 and 1.8). It can quantify the accommodative state of both of the eyes in the vertical power meridian at 25 Hz from 1 m distance, using the horizontal oriented knife-edge of the photoretinoscope. It is also able to measure, pupil size and direction of gaze dynamically. Astigmatism is measured as previously described in static measures, taking approximately 3 s to perform. Schaeffel, Weiss and Seidel (1999) used the *PowerRefractor* to show that using this instrument there is an approximately 0.3 D of under accommodation when reading.

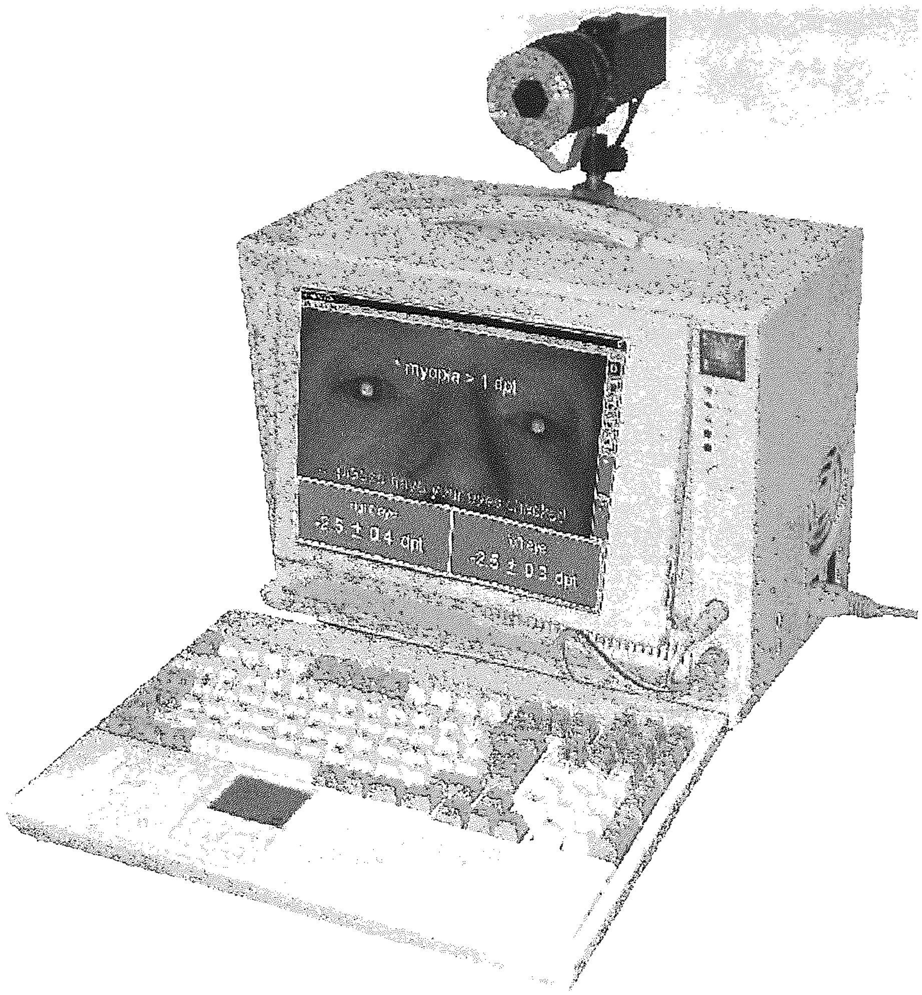


Figure 1.7: The *PowerRefractor* consists of a portable aluminium case, a monochrome camera, a photoretinoscope with driver board and the software. From http://www.uak.medizin.unituebingen.de/frank/techtran.html 22 Jun. 01.

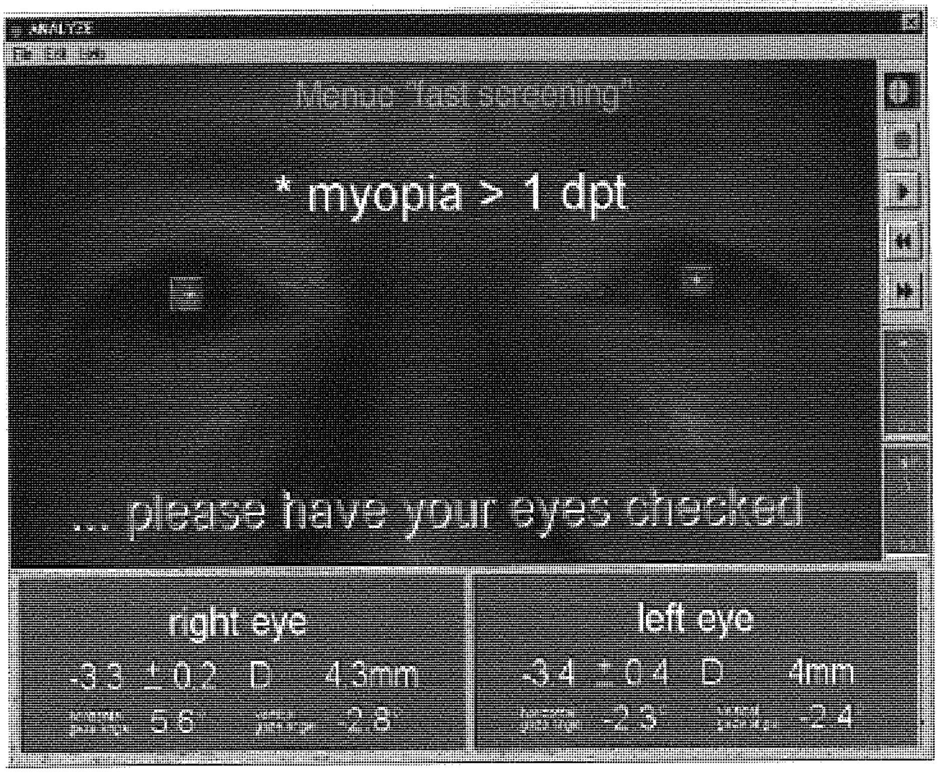


Figure 1.8: Fast screening mode (from http://www.uak.medizin.uni-tuebingen.de/frank/fastscr.gif. 22 Jun. 01.

Choi *et al.*, (2000) further investigated the *PowerRefractor* testing laboratory, clinical and kindergarten populations. Overall the *PowerRefractor* was shown to have a comparable or slightly better reliability than conventional autorefractors, but its main advantages were that it is faster and can measure both eyes at the same time. The authors do not mention any disadvantages to the *PowerRefractor* except its measurement range is smaller than in a traditional autorefractor by about a factor of two.

Gekler *et al.*, (1997) calculated the amount of infrared light emitted from the *PowerRefractor* was approximately 30 times less than the permitted United States standards.

This thesis examines the technique of photorefraction especially the new commercial *PowerRefractor* to assist in determining oculomotor function in human factor applications.

CHAPTER 2

CLINICAL EVALUATION OF THE *POWERREFRACTOR*™: A REMOTE, CONTINUOUS AND BINOCULAR MEASUREMENT SYSTEM OF OCULOMOTOR FUNCTION

Introduction

The oculomotor triad comprising ocular accommodation, vergence and pupil size, is essential to seeing a clear, single, luminance-intensity controlled image of the outside world. Continuous measurement of the oculomotor system is needed to understand further conditions such as ocular neurological effects and their progression, the potential of multifocal intraocular lenses and the efficacy of orthoptic training. Although many techniques have been devised to measure accommodation continuously over the last two decades, photoretinoscopy is unique in enabling the measurement of accommodation, vergence and pupil size in both eyes simultaneously, objectively, remotely (typically the camera is placed 1m from the eyes) and continuously (Wolffsohn, Hunt and Gilmartin, 2002)

The *PowerRefractor* is the first commercially available instrument to use photoretinoscopy and allow continuous measurement of the oculomotor triad. The instrument is marketed principally as an autorefractor, for the objective measurement of refractive error. Autorefractors are mainly used in clinical practice to give an objective measure of the patient's prescription often in place of retinoscopy. They are also used in a modified or converted form in clinical research to measure accommodative responses (e.g. Bruce, Atchison and Bhoola, 1995, Heron, Charman and Grey, 1999). The *PowerRefractor* is distinctive from many other types of commercial auto refractors as it measures the refractive error of both eyes simultaneously by photoretinoscopy and is remote from the patient, having a working distance of 1 m.

Choi and colleagues (2000) attempted to validate the *PowerRefractor*, but there were several limitations to their study: the *PowerRefractor* measures were compared on only 15 subjects to the patient's previous spectacle prescription and not to a current full subjective refraction; subjective refraction was performed on 40 patients, but details of the refraction were not given and the subjects had a variety of ocular pathologies; the author's kindergarten study only compared the results to the *Canon R-1* open-field autorefractor; the intra-session repeatability was not assessed and inter-session repeatability was only measured in the kindergarten group. Therefore, the aim of this study was to assess the validity and repeatability of the *PowerRefractor* in non-cyclopleged adults to both subjective refraction and to a recently validated open-field autorefractor, the *Shin-Nippon SRW-5000.*

Three different techniques of photorefraction have been described: orthogonal (Howland and Howland, 1974); isotropic (Howland *et al.*, 1983); and eccentric (e.g. Bobier and Braddick, 1985, Howland, 1985), but all work on the principle of analysing the vergence of reflected light rays returning to a camera after illuminating a point on the retina.

Howland and Howland described and theoretically analysed the technique of photorefraction in 1974. Their method estimated the instantaneous refractive state, by photographing the light returning from the subject's eyes, illuminated by a fibre optic light source centred in a camera lens. The defocus of the eye determined the spread of the returning light at the 35 mm reflex camera focused on the subject's eyes, typically 1-2 m away. The returning light passed through an arrangement of four pie shaped cylinder lenses aligned along two orthogonal meridians, which were typically plano/+1.50 D. When the light was reflected from the subject's eye, it was imaged in a cross pattern where the length of the arms are dependent on the amount of defocus (refractive error, but not its sign) and their width was dependent on pupil size. When an eye was accurately focused at the camera distance, no star arms were formed. Astigmatism caused the cross arms to be different lengths. The sign of the refractive error could be determined subjectively as a result of chromatic aberration, with a myopic prescription causing the cross arms to have red tipped fringes and a hyperopic prescription having blue tipped fringes. One difficulty found with Orthogonal Photorefraction was that when small refractive errors were present there was no image formed on the film termed the dead zone. The reason for this was ascribed to the vignetting effect of the fibre optic tip, which obstructs some of the rays returning to the camera. This technique was mainly used to study infant accommodation (e.g. Braddick, Atkinson, French and Howland, 1979).

Howland and colleagues (1983) described a modification to Orthogonal Photorefraction, termed Isotropic Photorefraction as the defocus was equal in all directions and the camera was defocused relative to the subject. The spread of light that is returned to the camera lens was translated into a defocused pupil picture at the film plane. The greater the degree of defocus of the eye relative to the camera, the greater the radius of the blur circle of the defocused pupil at the film plane. For each estimate of refractive state, two defocused pictures of the subject were taken; one focussed 0.50 D in front of the pupil plane and one focussed 0.50 D behind the pupil plane. The magnitude of the subject's defocus relative to the camera could be determined by the measurement of the size of defocused pupil in either picture. The sign of the subject's defocus relative to the camera was determined by comparison of the two photographs. A hyperopic focus would produce smaller defocused pupils in the picture focused behind the pupil than in front, whereas a myopic focus would produce smaller defocused pupils in the picture focused in front of the pupil. Quantitative estimation of the subject's refractive error can be determined by using the pupil size, which is determined from a third photograph focused at the pupil plane and a ray traced model of the optical system of the camera (Howland *et al.*, 1983). The flash source when reflected by the eye is imaged as an ellipse that's major and minor axes represent the astigmatic meridians of the eyes.

The concept of eccentric photorefraction was first discussed by Bobier and Braddick (1985). The method was similar to that described by Howland (1985), but distinctive in that the visible light flash source was eccentric to the optical axis of the camera. A formula was devised to estimate refraction from the height of the light crescent. If the eye is defocused myopically with respect to the camera, the returning light is refocused in a plane between the eye and the camera and subsequently spread out in a cone, the angle of which depends on the amount of defocus. Only rays emanating from the lower part of the pupil are imaged due to the shield covering the lower part of the aperture. For an eye focused hyperopically in respect to camera, only the upper part of the pupil will be illuminated. The MTI photoscreener, used in pre-school screening in the USA, uses this principle, but requires the Polaroid of the imaged pupil crescents to be measured individually by a trained observer (Tong *et al.*, 2000). Schaeffel and Howland (1991) tried to digitise this process, but were limited by the processor speed at the time, the dead zone obscuring low prescriptions and the non-linearity of the brightness across the pupil.

The first commercial video refractor using eccentric photorefraction, the *Tomey Viva*, Fortune Optical, Padova, was found to have only reasonable accuracy up to ±3.00 D (Thompson *et al.*, 1996). This may have been due to it using a single light source, resulting in a large deadzone and a non-linear intensity gradient versus refractive error (Wolffsohn, Hunt and Gilmartin, 2002). Non-linearity is improved by using LEDs at more than one eccentricity below the knife edge (Schaeffel, Faraks and Howland, 1987) and measuring the slope of the brightness profile across the pupil rather than just the height of the pupil crescents (Schaeffel *et al.,* 1993). Wesemann, Norcia and Allen (1991) devised equations, which allowed astigmatism to be measured more accurately.

The *PowerRefractor* uses the eccentric technique, with an infrared light source located on the edge of a mask, eccentric to the optical axis of the camera. The resulting light gradient across the pupil is measured in six meridians separated by 60° simultaneous to a pulse of infra-red light emitting diodes (LEDs) mounted on a knife edge perpendicular to each meridian in turn. The gradient of each pair of opposite meridians are averaged to remove the effect of asymmetrical meridians and the sphero-cylindrical refraction calculated, (Gekler *et al.*, 1997 and Wesemann, Norcia and Allen 1991)

The aim of this study was to assess the validity and repeatability of the *PowerRefractor* (Figure 2.1) to measure refractive error in non-cyclopleged adults to both subjective refraction and to a recently validated open-field autorefractor, the *Shin-Nippon SRW-5000.*

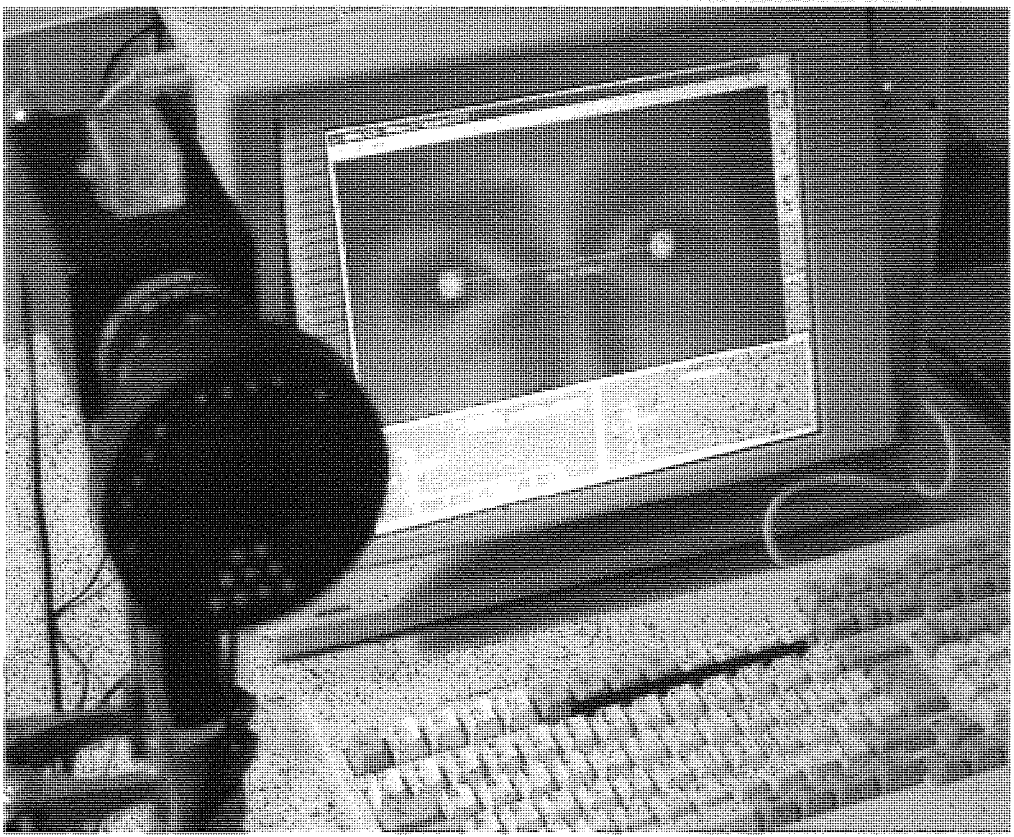


Figure 2.1: The *PowerRefractor* shown in full refraction mode.

Method

One hundred subjects, staff and students of Aston University (40 male and 60 female), with a mean age of 23.8 ± 5.7 years (range from 18 to 45 years, median 22.0 years) participated in the study. Subjects with ocular pathologies and abnormal binocular vision were excluded from the study. Standard subjective refraction, using an endpoint criterion of maximum plus consistent with best vision, was performed on 200 eyes after the purpose of the study was explained and informed consent given. The study had prior approval by the institutional human science ethics committee. All refractions were performed by a United Kingdom trained and registered optometrist, who was masked as to the patient's habitual prescription and the results of the autorefraction. Retinoscopy was performed initially on all subjects followed by cross-cylinder to locate the axis of the cylinder (in 2.5° increments) and its power (in 0.25 D increments). Best sphere, duochrome and binocular balancing (Humphris technique) were used to refine the spherical component power (in 0.25 D increments).

Autorefraction was carried out with the *PowerRefractor* (located 1 m from the subject) in full refraction mode by a second optometrist. Subjects were seated such that both eyes were visible in the instrument monitor and viewed the camera lens (as specified in the manufacturers instructions). A series of 50 readings were taken in quick succession (taking on average 10-12 s) from each eye and the final autorefractor prescription calculated from the average of the last five valid (identified by green colouration) results (power in increments of 0.25 D, cylindrical component axis to <0.1°). The *PowerRefractor* readings were taken under an ambient illumination of 39.6 lux at the eyes which ensured that no readings were rejected because the pupil size was too small (see chapter 3). Measurements of repeatability were obtained by examining the differences between the five readings taken from each eye and by re-measuring the prescription of 100 eyes at a subsequent session at the same time of day, between 7 to 10 days after the first readings were taken. The validity of autorefractors is traditionally assessed by comparing their results to that of subjective refraction (Bullimore, Fusaro and Adams, 1998). This is because they are principally designed to assist ophthalmologists and optometrists to reach the endpoint of subjective refraction as quickly as possible, in a manner similar to that of retinoscopy.

The *PowerRefractor* was also compared to another commercially available autorefractor, the *Shin-Nippon SRW-5000* in a separate cohort of 150 subjects aged from 18 to 37 years (average 20.1 ± 4.2 years, median 19.0 years), 45% of whom were male. The *SRW-5000* is an infrared open view autorefractor found to be valid and repeatable compared to subjective refraction in both adults and children (Mallen *et al.,* 2001, Chat and Edwards, 2001). Subjects were positioned such that the eye under test viewed a Maltese cross at 5 m, so that the instrument was directly aligned with the visual axis of the eye. Five readings were taken in quick succession (power in increments of 0.125 D, cylindrical component axis to 1°). *PowerRefractor* measures were taken by another optometrist, as described above.

STATISTICAL ANALYSIS

As the refractive errors of the two eyes are related, the data from the each eye separately and the pooled data from both eyes were analysed. The bias between measures (the mean difference, standard deviation and 95% confidence limits) were calculated and presented graphically (Bland and Altman, 1986) Comparison between measures were performed using paired 2-tailed t-tests. Assessing the variance in the astigmatic component poses a problem in the conventional clinical notation (Bullimore, Fusaro and Adams, 1998). Therefore the sphere, cylinder and axis component were converted into a vector representation (Thibos, Wheeler and Horner, 1997):

- a spherical lens of power MSE (equal to the mean spherical equivalent = sphere + [cylinder / 2])
- Jackson cross-cylinder at axis 0° with power J_0 (= -[cylinder / 2] cos[2 x axis])
- Jackson cross-cylinder at axis 45° with power J_{45} (= - [cylinder / 2] sin [2 x axis]).

Results

The refractive error of the sample, as represented by the subjective refraction, ranged from -8.75 to +6.00 D mean spherical equivalent (MSE mean ± S.D. = -1.51 ± 2.43 D). The maximum amount of measured astigmatism was –4.50 DC. There was no significant difference (<0.2 D, p>0.05) in the mean refractive components between the right and left eye and therefore the data from the two eyes were combined and averaged in some graphs for the clarity of presentation.

Validity

Prescription component differences between the subjective refraction and the *SRW-5000* compared to the *PowerRefractor* are shown in Table 2.1. The mean difference in components measured by the *PowerRefractor* were in better agreement with non-cycloplegic subjective refraction than the *SRW-5000* autorefractor, but were variable in both cases (Figures 2.2 and 2.3). The dotted lines on the graphs indicate the extent to which the *PowerRefractor* might over or under read compared to the alternative methods examined (i.e. the *PowerRefractor* might read as much as 1.26 D above or 0.94 D below subjective refraction for MSE).

Right Eye

Refractive Component	***PowerRefractor* vs. *Subjective Refraction***		***PowerRefractor* vs. Shin-Nippon *SRW-5000***	
	Mean difference (D)	Significance	Mean difference (D)	Significance
MSE	+0.05 ± 0.63	0.41	-0.20 ± 0.72	<0.001
Sphere	+0.17 ± 0.56	<0.01	-0.14 ± 0.77	<0.05
J_0	+0.09 ± 0.28	<0.01	+0.11 ± 0.31	<0.001
J_{45}	-0.02 ± 0.15	0.15	-0.02 ± 0.18	0.23
Cylinder	-0.24 ± 0.52	<0.001	-0.11 ± 0.58	<0.05

Left eye

Refractive Component	***PowerRefractor* vs. *Subjective Refraction***		***PowerRefractor* vs. Shin-Nippon *SRW-5000***	
	Mean difference (D)	Significance	Mean difference (D)	Significance
MSE	+0.03 ± 0.76	0.67	-0.22 ± 0.75	<0.001
Sphere	+0.15 ± 0.68	<0.05	-0.13 ± 0.77	<0.05
J_0	+0.09 ± 0.32	<0.01	+0.09 ± 0.31	<0.001
J_{45}	+0.02 ± 0.17	0.23	+0.01 ± 0.16	0.30
Cylinder	-0.24 ± 0.60	<0.001	-0.17 ± 0.53	<0.001

Table 2.1: Mean difference (± S.D.) in refractive components between the *PowerRefractor* and non-cycloplegic subjective or *SRW-5000* autorefractor objective refraction.

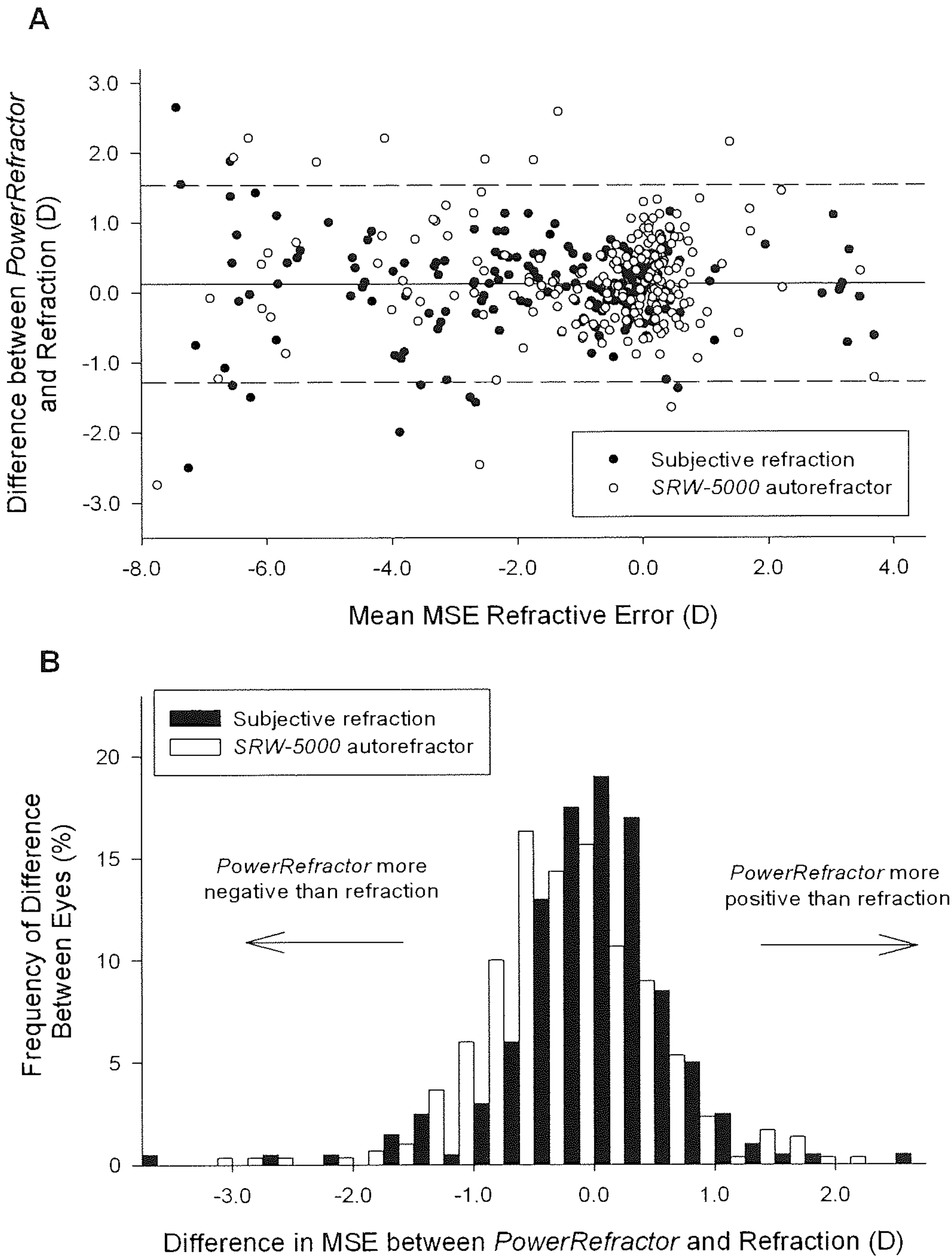


Figure 2.2: **A.** Difference between *PowerRefractor* measures and subjective or *SRW-5000* autorefractor objective MSE refraction. N=200/300 eyes. Solid line shows mean difference and dashed lines ± 95% confidence interval. **B.** Frequency distribution of refractive error difference between the subjective refraction and *SRW5000* compared to the *PowerRefractor* refraction. N=200/300

There appears to be no bias in the accuracy of the *PowerRefractor* with the type or magnitude of refractive error, although there are a few outlying values to the data, principally those with high myopia. Approximately 41% of *PowerRefractor* readings were within ± 0.25 D, and 67% within ± 0.50 D of the MSE as found by subjective refraction and 30% were within ± 0.25D, and 56% within ± 0.50 D of the MSE as found by the *SRW-5000* autorefractor (Figure 2b).

Figure 2.3 shows the difference in the J_0 and J_{45} component of patients' refractions between subjective refraction, *SRW-5000* autorefractor and *PowerRefractor* compared to the mean value. Approximately 53% of *PowerRefractor* measures were within ±0.25 D and 75% within ±0.50 D of the cylindrical component of the prescription found by subjective refraction and 57% were within ±0.25 D and 84% within ±0.50 D of the cylindrical component found by *SRW-5000* autorefraction. The axis of the cylindrical component was less reliable than the spherical and cylindrical power components (Table 2.2 a, b). However, if only cylindrical components ≥0.75D are considered (as these are likely to have more than a 0.1 logMAR effect on distance visual acuity if significantly off axis), the accuracy of cylindrical axis calculated by the *PowerRefractor* is found to be improved.

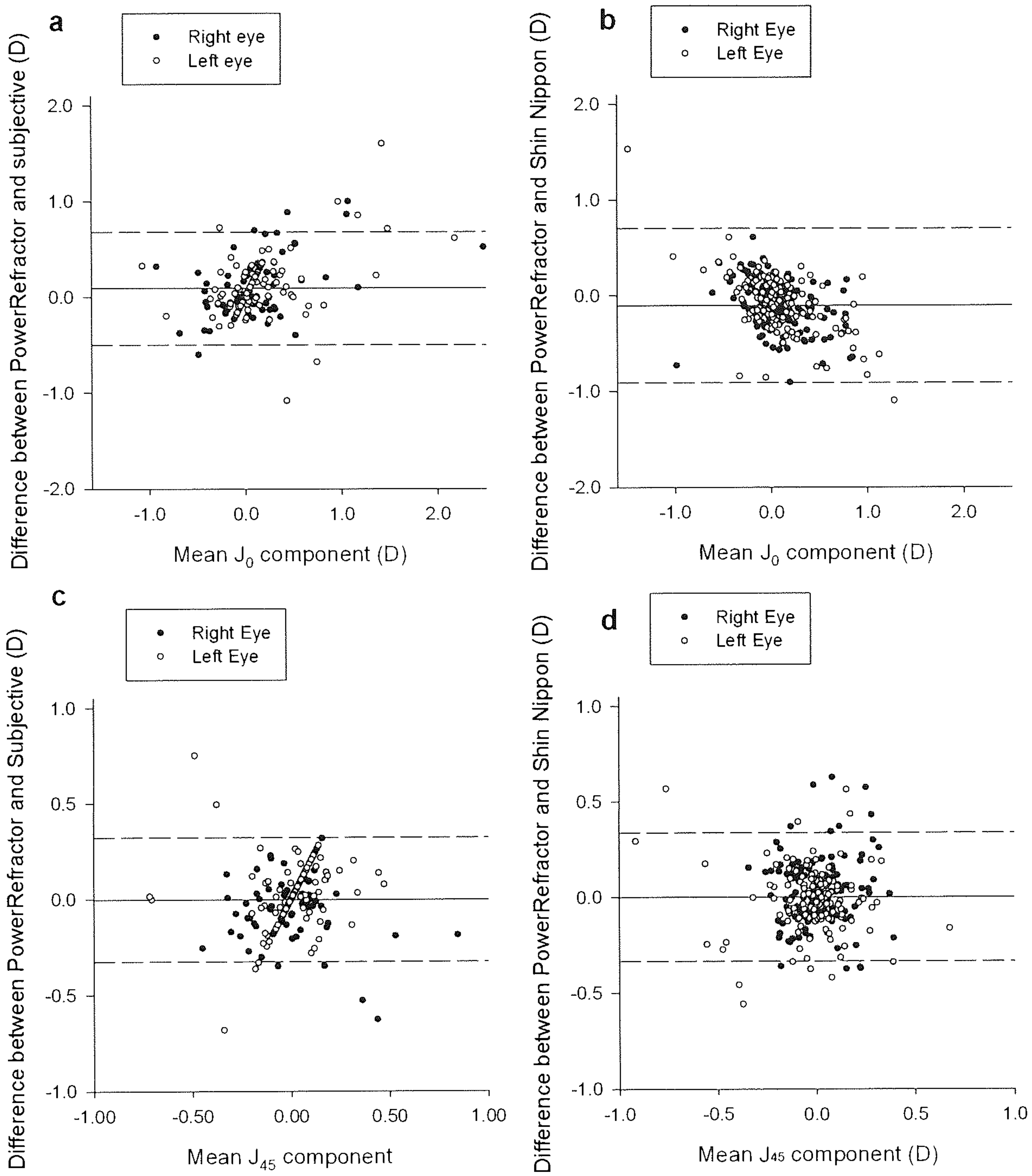


Figure 2.3: Difference between (a) *PowerRefractor* and Subjective measures of the J_0 component, (b) *PowerRefractor* and *SRW-5000* measures of the J_0 component, (c) *PowerRefractor* and Subjective measures of the J_{45} component, and (d) *PowerRefractor* and *SRW-5000* measures of the J_{45} component.

A

Right Subjective

	All prescriptions with a cylindrical component n=74	Prescriptions with a cylindrical component (subjective) ≥ 0.75 D n=30
± 5°	24 (32%)	12 (40%)
± 10°	40 (54%)	20 (67%)
± 15°	48 (65%)	24 (80%)
± 20°	52(70%)	26 (87%)

Left Subjective

	All prescriptions with a cylindrical component n=74	Prescriptions with a cylindrical component (subjective) ≥ 0.75 D n=28
± 5°	21 (28%)	11 (39%)
± 10°	37 (50%)	20 (71%)
± 15°	45 (61%)	21 (75%)
± 20°	55 (74%)	25 (89%)

Pooled Data for Right and Left Eyes

	All prescriptions with a cylindrical component n=148	Prescriptions with a cylindrical component (subjective) ≥ 0.75 D n=58
± 5°	45 (31%)	23 (39%)
± 10°	77 (52%)	40 (68%)
± 15°	93 (62%)	45 (78%)
± 20°	107(72%)	51 (88%)

Table 2.2A: Comparison of the axis of the cylindrical component measured by *PowerRefractor* with non-cycloplegic subjective.

B

Right Shin Nippon *SRW-5000*

	All prescriptions with a cylindrical component n=124	Prescriptions with a cylindrical component (subjective) ≥ 0.75 D n=37
± 5°	28 (23%)	15 (41%)
± 10°	46 (37%)	22 (59%)
± 15°	62 (50%)	27 (73%)
± 20°	70 (56%)	28 (76%)

Left Shin Nippon *SRW-5000*

	All prescriptions with a cylindrical component n=121	Prescriptions with a cylindrical component (subjective) ≥ 0.75 D n=38
± 5°	29 (24%)	14 (37%)
± 10°	48 (40%)	20 (53%)
± 15°	63 (52%)	26 (68%)
± 20°	72 (60%)	28 (74%)

Pooled Data for Right and Left Eyes Shin Nippon *SRW-5000*

	All prescriptions with a cylindrical component n=245	Prescriptions with a cylindrical component (subjective) ≥ 0.75 D n=75
± 5°	57 (23%)	29 (39%)
± 10°	94 (38%)	57 (57%)
± 15°	125 (51%)	53 (71%)
± 20°	142 (58%)	56 (75%)

Table 2.2B: Comparison of the axis of the cylindrical component measured by *SRW-5000* autorefractor objective refraction.

REPEATABILITY

Intersession repeatability (i.e. the standard deviation of differences between 5 measures taken on one occasion) was 0.057 D for the spherical component, 0.067 D for the cylindrical component, 0.067 D for the mean spherical equivalent, 0.040 for the J_0 and 0.029 for the J_{45} component. Table 2.3 presents the mean intrasession differences between the prescription components. These were found to be small, with the majority of the second visit prescriptions falling within ±0.50 D of the initial measurement.

Right Eye

	MSE	*J0*	*J45*	*Sphere*	*Cylinder*
Mean difference	0.06	-0.001	0.003	0.07	-0.01
S.D. of differences	0.36	0.11	0.05	0.36	0.12
Within ±0.25 D (%)	84	-	-	86	92
Within ±0.50 D (%)	96	-	-	96	100
Within ±0.75 D (%)	98	-	-	98	100

Left Eye

	MSE	*J0*	*J45*	*Sphere*	*Cylinder*
Mean difference	0.01	0.01	0.01	0.02	-0.01
S.D. of differences	0.37	0.10	0.06	0.40	0.17
Within ±0.25 D (%)	83	-	-	83	96
Within ±0.50 D (%)	96	-	-	94	100
Within ±0.75 D (%)	98	-	-	98	100

Pooled Data of Right and Left Eyes

	MSE	*J0*	*J45*	*Sphere*	*Cylinder*
Mean difference	0.03	0.01	0.01	0.04	-0.01
S.D. of differences	0.37	0.10	0.06	0.38	0.15
Within ±0.25 D (%)	83	-	-	84	93
Within ±0.50 D (%)	96	-	-	95	100
Within ±0.75 D (%)	98	-	-	98	100

Table 2.3: Difference in refractive component of the *PowerRefractor* found between different sessions.

Discussion

The ability of the *PowerRefractor* to measure continuously from a remote location, binocular parameters of the complete oculomotor triad, could prove to be of great value in optometric and ophthalmological research. Commercial photorefractive devices have been available for a number of years, but only for static measure of refractive error. For example the *MTI photoscreener* is used in pre-school screening in the USA, but requires the *Polaroid*™ of the imaged pupil crescents to be measured individually by a trained observer (Tong *et al.*, 2000). Although on average the *PowerRefractor* prescription was similar to that of subjective refraction, the range of differences was large (up to 3.50 D), with 95% of readings within ±1.12 D (Figure 2.2). This was particularly the case with myopic prescriptions over –4.00 D, confirming the stated accuracy range (-6.00 to +4.00) of the *PowerRefractor* by Choi and colleagues (2000) However, the discrepancy between the *PowerRefractor* prescription and subjective refraction within this range could still be up to 2.50 D. Under-correcting myopia by such a degree would severely reduce a patient's visual acuity and in young children could lead to impaired visual development. Two subjects with a prescription of greater than –10.00 D were assessed outside of the study, for whom the *PowerRefractor* indicated a prescription of only –3.00 to –4.00 D. Compared to the *SRW-5000* autorefractor, the *PowerRefractor* prescription was more negative and again had a wide range of differences. Both autorefractors measure refractive error using image analysis techniques of infra-red light reflected from the fundus, although the *PowerRefractor* measures the light gradient and the *SRW-5000* the reflected image size. Compared to previously validated open-field autorefractors (e.g. the *Canon R-1* and the *SRW-5000*) the *PowerRefractor* is, on average, just as accurate, but approximately 24-42% more variable (RMS values) (Mallen *et al.*, 2001, McBrien and Millodot, 1985).

Inter- and intra-session repeatability of the *PowerRefractor* was found to be small and was similar to previously validated open-field autorefractors. (Mallen *et al.*, 2001, McBrien and Millodot, 1985). This would indicate that the variability is due to the lack of individual calibration (see chapter 9), the poor accommodative stimulus of the camera head LEDs and perhaps the linear range of the change in light gradient across the pupil with refractive error, (Schaeffel, Wilhelm and Zrenner, 1993) rather than stability of the imaging technique. An emmetrope focusing accurately at the camera distance should have a uniformly illuminated pupil. However, chromatic aberration, lead of accommodation, and in children small eye artefacts, all combine to produce focusing error and hence a light gradient across the pupil. As a slope change of +0.50 translates to approximately 1.00 D, small changes in slope can have a significant effect of apparent refraction. In addition, as the camera head is closer than optical infinity, a ≤–1.00 D myope, emmetrope and pre-presbyopic hypermetrope could all appear to have the same refractive error when focusing on the camera head LEDs at 1 m. A more suitable target would be a non-accommodative distant target (such as a spot of light) with +1.00 DS added to the internally generated prescription.

In conclusion, the *PowerRefractor* is a practical and effective autorefractor, which is likely to have a particularly use in the screening of children and patients unable to give a subjective response. The variability, particularly with high myopia is, however, of some concern, with potential under correction of over 1 D in ~7% of cases. The instrument may also be useful in research as it is able to measure remotely accommodation, pupil size and gaze direction in both eyes simultaneously at 25 Hz, providing objective measures of the oculomotor system while subjects binocularly view a natural scene in an unenclosed and unrestricted environment.

CHAPTER 3

TOLERANCE OF THE *POWERREFRACTOR* ™

FOR HUMAN FACTOR APPLICATION

Introduction

Optimal integration of the oculomotor system is critical for an in-focus, single image of appropriate retinal luminance. The visual demands of the modern world include the use of artificial displays such as visual display units (VDUs) and television. Virtual imagery is also becoming increasingly common in military applications such as head-up displays (HUDs) in jet fighters and virtual reality training facilities (Wolffsohn, Edgar and Mc Brien, 2001). The ideal instrument for measuring ocular accommodation in human factors applications would:

- have a wide valid measurement range - without the need for individual calibration
- be open field - allowing binocular, unrestricted viewing is less likely to cause accommodative error from factors such as proximity
- be objective - not requiring a subjective response or interrupting the accommodative response by the presence of the measurement system
- provide absolute measures of accommodation - not presuming that the accommodative response matches the accommodative stimulus demand
- measure accommodation with high temporal resolution - the reaction time of accommodation to predictable stimuli is ~200 ms (Phillips, Shirachi and Stark, 1972).
- be tolerant to eye movements from the optical axis of the instrument, changes in head position and changes in target luminance
- be portable i.e. fit within the constraints of a working environment e.g. the cockpit of a flight simulator.

A review of previous techniques used to measure ocular accommodation over the past 50 years shows many devices capable of quantifying the refractive status of the eye, but few which have the temporal resolution high enough to study the dynamic characteristics of accommodation (e.g. Heron and Winn, 1989). The principal techniques used to provide continuous (temporal resolution of <0.1 s) measurement of accommodation have been:

1) Scheiner's principle (Stanford Research Institute Eyetracker/Optometer (SRI))

Prior to 1955, several attempts were made to measure the dynamics of accommodation by photographing the Purkinje images. However, the third Purkinje image was very dim and the glare of the light source obscured the target (Campbell and Robson, 1959). More successful continuous measures of accommodation were made by Campbell and colleagues (Campbell and Robson, 1959; Campbell and Westheimer, 1960). The filaments of a double slit light source were imaged on the retina with a rotating wheel obscuring each slit in turn at 300 Hz. The separation between the slits varied with refractive error and in continuous mode, the light reflected from the fundus was diverted by a semi-reflective mirror into two photocells. Infra-red radiation (IR) was used to make the instrument objective. Modulation of the signal in phase with the rotation of the disc occurred with eye defocus, with the ratio of light between the photocells indicating the direction of the defocus. No modulation was apparent if the eye was focused on the filament image. Although the temporal resolution was high, calibration assumed that the accommodative response to a dioptric stimulus was accurate, the measurement range was small (~3 D), the pupils needed dilating and precise fixation with the subject's head fixed with a bite bar was necessary. The SRI tracked both eye movement and accommodation in both eyes simultaneously using this technique, but was very expensive and difficult to calibrate (Cornsweet and Crane, 1970; Crane and Steele, 1978). The principle has been used again in a more recent study (Takeda *et al.*, 1999).

2) Intensity of light reflected from the fundus (*Canon R-1*)

The *Autoref R-1* (*Canon*, Lake Success, NY, USA: no longer manufactured) allowed a binocular, open field-of-view through a semi-silvered mirror, that produced valid, reliable and rapid, objective measures of the refractive state of an eye (McBrien and Millodot, 1985). It has been very extensively employed in optometric research over the last two decades. In static mode the *Canon R-1* lens carriage swept along a 5 kHz chopped infra-red measurement beam reflected off the fundus to a photocell, measuring the time to maximum output in each of three meridians (separated by 60 degrees) as this is sufficient to compute a sphero-cylinder prescription (Bennett, 1960; Winn *et al.,* 1989). The value was not calculated from the magnitude of the signals and therefore was unaffected by the pupil size above a threshold diameter (2.9 mm). It measured refractive status in about 200 ms (Pugh and Winn, 1988) and would take a repeat measure in a minimum of about 1 second. Changes in apparent accommodation were <0.25 D with gaze within 3° of the optical axis of the instrument (McBrien and Millodot, 1987).

In continuous mode, the lens carriage was disabled and set manually to the linear portion of the voltage output/time curve. The voltage output from one of the three detectors was sampled continuously to indicate the amount of defocus present (Pugh and Winn, 1988; Davis, Collins and Atchison, 1993). The focusing lens was now stationary, so changes in accommodation affecting the focus of IR radiation on the photocell varied the intensity related output voltage. The waveform amplitude produced varied substantially between subjects, presumably because of individual differences in media characteristics or retinal reflectance's, so universal calibration was not possible. In continuous mode, the output signal amplitude of the *Canon R-1* changes substantially if a subject's pupil size decreases to <3.9 mm during measurement (Winn *et al.*, 1989). The optometer has a range of ±15.0 D sphere, ±7.0 D cylinder in static mode, but only a range of ~3 D in dynamic operation. The *Canon R-1* ceased production a number of years ago and many of the instruments currently in use are reaching the end of their useful lives.

3) Image size of light reflected from the fundus (*Shin-Nippon SRW-5000* and *NVision-K*)

The *Shin-Nippon SRW-5000* Autorefractor is a new infra-red open view auto-refractor which features an ergonomic arrangement similar to that of the *Canon R-1*. The *SRW-5000* calculates refractive error in two stages. A ring target of infra-red radiation is imaged after reflection off the retina. On the initial measurement, a lens is rapidly moved on a motorized track to place the ring approximately in focus. The image size of the ring target is then analysed digitally, on this initial and subsequent measurements, in multiple meridians to calculate the toroidal refractive prescription. The instrument can take static measurements of refractive error in the range of ± 22 D sphere, ±10 D cylinders in steps of 0.12 D for power and 1° for the cylindrical axis. In static mode, the instrument can take up to 45 static prescription readings in 1 minute (image analysis is performed in 0.15 s). The instrument has been found to be highly valid (accurate) compared to subjective refraction and repeatable in both adults (Mallen *et al.*, 2001) and children (Chat and Edwards, 2001), with pupil sizes ≥2.9 mm. The instrument can be converted to give dynamic measurements of accommodation by continuous display of the measurement ring and image analysis of the video output of the instrument. The ring width correlates with refractive error and utilising edge detection techniques a resolution of <0.01 D is achieved at 60 Hz (Wolffsohn *et al.*, 2001). The *Shin-Nippon* NVision-K incorporates keratometry as well as similar autorefractor optics to the *SRW-5000*. The measurement ring is broken into three segments, but in static mode the NVision-K is just as accurate as the *SRW-5000* (Davies *et al.*, 2003). Unfortunately, the keratometry CCD, rather than the autorefractor CCD is connected to the video output and therefore it has not been possible to convert this instrument to continuous recording.

4) Photorefraction (*Tomey* ViVA, *Topcon* PR-1000 and 2000, *PowerRefractor*)

The *PowerRefractor* has been described in detail in chapters 1 and 2, has a wide measurement range and is portable. It is open-field, objective and records absolute measures of accommodation. It measures accommodation with temporal resolution of up to 25 Hz which is well above the resolution required to measure microfluctuations of accommodation (Charman and Heron, 1988). However, its suitability to assess the oculomotor triad in typically unrestricted human factor environments is unknown. This study aimed to assess the *PowerRefractor's* tolerance to eye movements away from the visual axis, to longitudinal shifts in the eye-to-instrument camera distance away from the optimal 1 m specified and to changes in environmental luminance.

Method

Ten subjects aged from 22 to 30 years (average 26.6 ± 2.4 years; 6 male, 4 female), gave informed consent to take part in the study. Each subject underwent a full binocular refraction and was only included in the study if there was no evidence or history of binocular vision anomalies or ocular pathology. All the subjects could attain at least 6/6 visual acuity in each eye. Subjects were made functionally emmetropic with ultra-thin soft contact lenses (*Acuvue*, Johnson & Johnson) to ensure that the accommodative demand to view the task for each subject was virtually identical. The subject's head was positioned on a head and chin rest, 1 m from the *PowerRefractor* which was aligned to image both of the subject's eyes.

Tolerance to Eccentricity of Gaze

Subjects viewed a 90% contrast Maltese cross at 0.99 m (5 cd/m^2), 0.9° above the optical axis of the *PowerRefractor* and 50 readings of accommodation were taken at each horizontal eccentricity, 0°, 5°, 10°, 15°, 20° and 25° to the left of the optical axis of the instrument, in a random order. This was moved in a straight line and not in an arc as even at the most extreme angle, this would make only 0.1 D difference in demand and therefore cannot be expected to significantly influence the results. Vertical eccentricities were not measured.

Tolerance to Longitudinal Shifts in Eyes-to-Instrument Camera Distance

The Maltese cross was repositioned and viewed centrally, with 50 readings of accommodation taken at each 2 cm interval from 0.92 m to 1.20 m *PowerRefractor*-to-eye distance along the optical axis of the *PowerRefractor*, in a random order.

Tolerance to Changes in Environmental Luminance

Finally, the Maltese cross and *PowerRefractor* were repositioned centrally at 1 m, with 50 readings of accommodation taken at each target luminance, ½, 5, 10, 15 and 20 cd/m^2, in a random order. The *PowerRefractor* stored continuous data of accommodation, pupil diameter and eye gaze direction for each eye in a data file, which was then analysed.

This study had been passed by the ethics committee and all participants signed consent forms.

Results

Tolerance to Eccentricity of Gaze

Apparent horizontal pupil size (ANOVA F = 0.98, p = 0.44) and accommodation in the left eye (F = 0.79, p = 0.57) were unaffected by eccentricity of gaze up to 25°. However, in the right eye apparent accommodation was significantly lower at 15° compared to 10°, presumably because of the change in reflectivity of the blind spot compared to the retina (Figure 3.1). Measures were only possible in 5 out of 10 subjects at 25° gaze eccentricity. Pupil size is measured by the instrument measuring the overall diameter and the pupil may appear more oval on eccentric gaze. This may have led to the difficulties in measurement on the most extreme gaze.

Tolerance to Longitudinal Shifts in Eyes-to-Instrument Camera Distance

Apparent pupil size progressively decreased with increasing distance between the eye and the *PowerRefractor* as expected (F = 8.60, $p<0.001$), but apparent accommodation was unaffected (F = 1.25, p = 0.24; Figure 3.2). The *PowerRefractor* was unable to take measures from 4 out of 10 subjects at 0.92 m and 1.20 m from the eye and from 1 out of 10 subjects at 0.94 m, 1.16 m and 1.14 m.

Tolerance to Changes in Environmental Luminance

A change in target luminance affected pupil size (F = 11.00, $p<0.001$), but apparent accommodation remained unaffected (F = 0.17, p = 0.92) (Figure 3.3). However, the *PowerRefractor* was unable to take measures in 2 out of 10 subjects at 15 cd/m^2 and in 9 out of 10 at 20 cd/m^2 which related to pupil sizes $<3.7 \pm 1.0$ mm (S.D.).

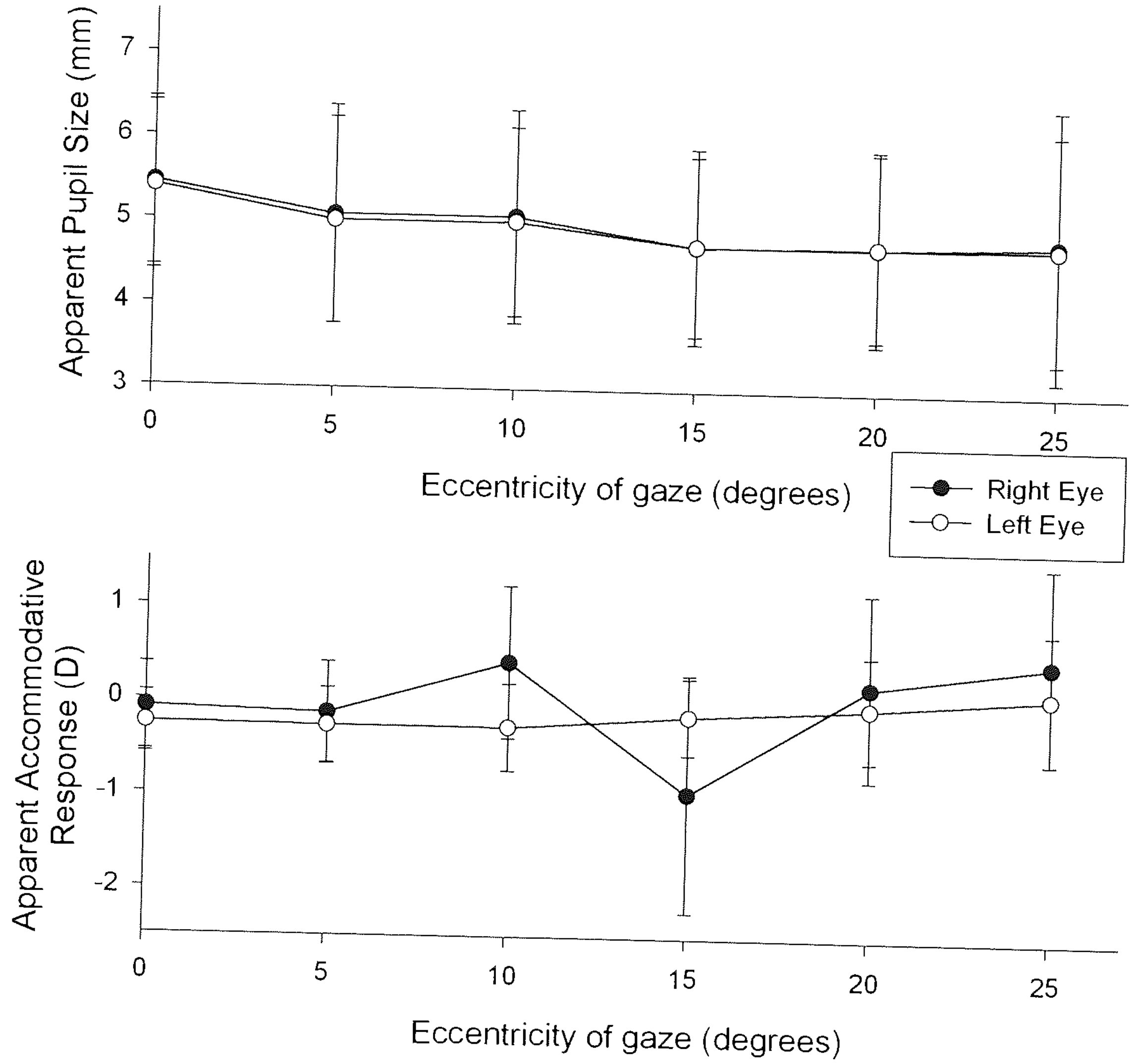


Figure 3.1: Apparent pupil size and ocular accommodation with eccentricity of gaze to the left of the *PowerRefractors* optical axis. n = 10. Error bars = ± 1 S.D.

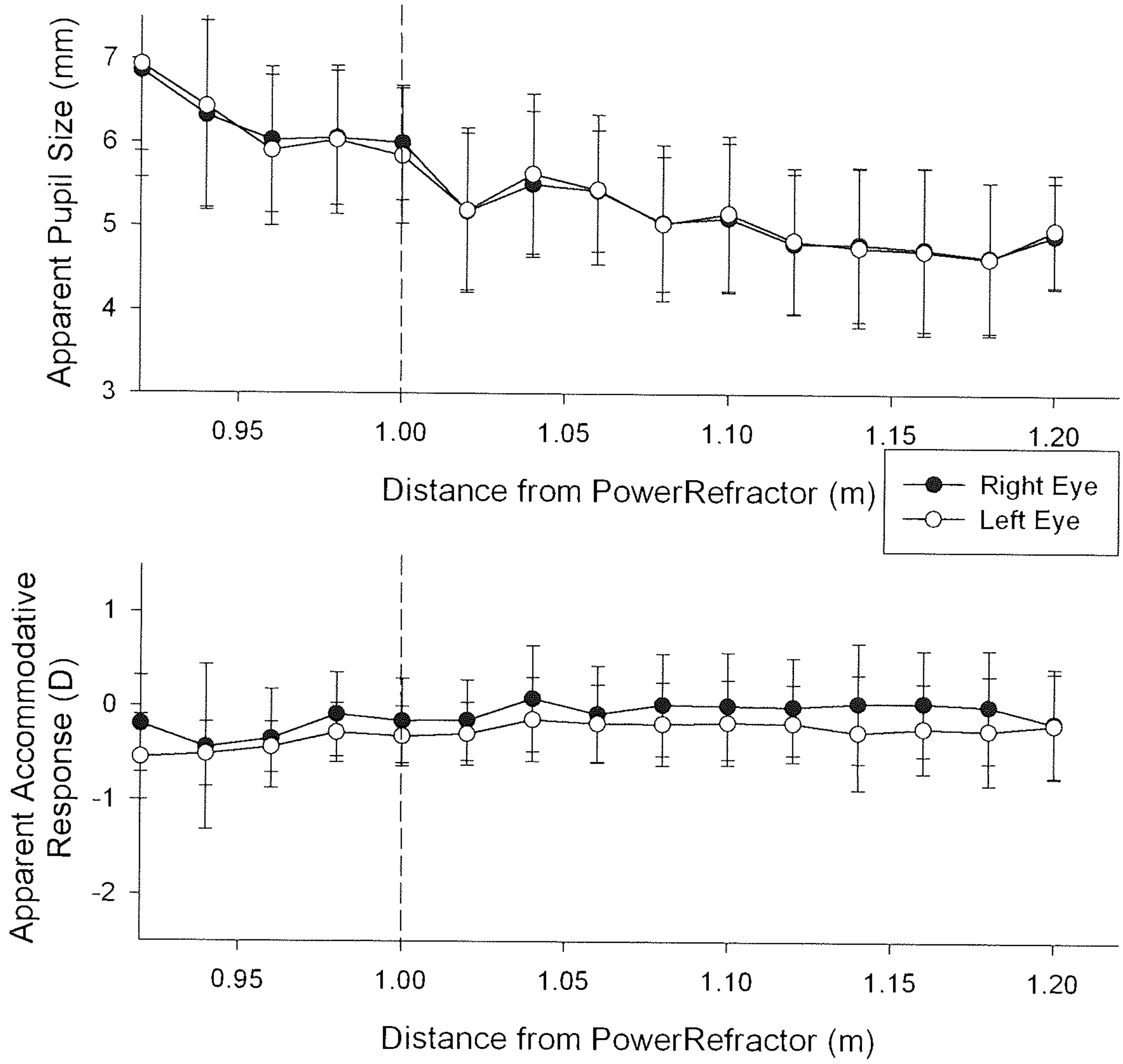


Figure: 3.2: Apparent pupil size and ocular accommodation with *PowerRefractor*-to-eye distance. n = 10. Error bars = ±1 S.D.

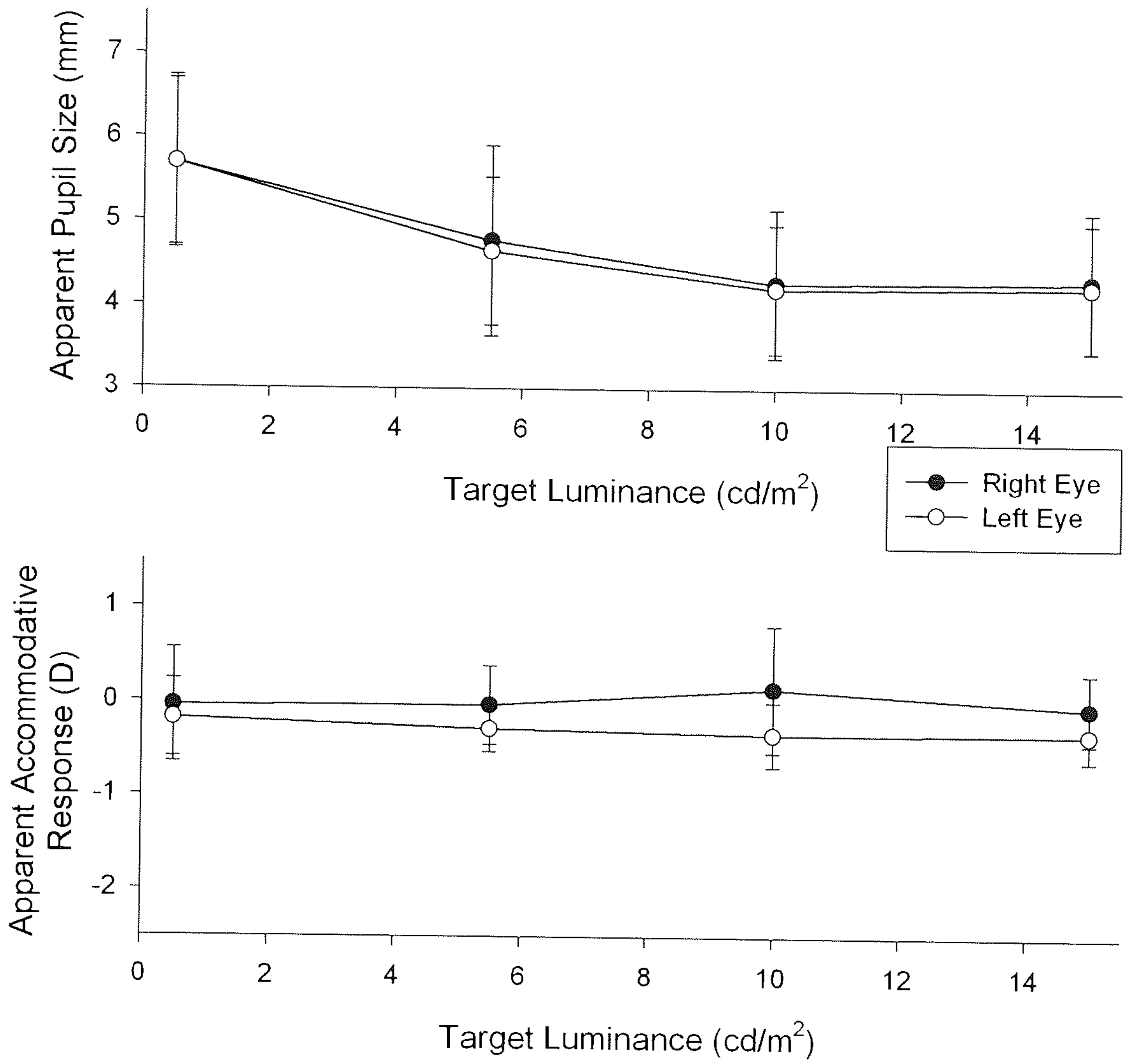


Figure: 3.3: Apparent pupil size and ocular accommodation with target luminance. n = 10. Error bars = ± 1 S.D.

Discussion

Few instruments are able to quantify accurately ocular accommodation in human factors applications. The use of image analysis techniques in newer instruments such as the *SRW-5000* and the *PowerRefractor* allow accurate, objective, absolute measurement of accommodation at a high temporal resolution with a wide valid measurement range, no need for individual calibration and an open field of view. The *SRW-5000* was found to be tolerant to ±0.5 cm longitudinal movement (<0.10 D change) and 25° eccentricity of gaze (<0.50D change; Wolffsohn *et al.*, 2001).

This study has found the *PowerRefractor* to be tolerant to eye movements from the optical axis of the instrument (~0.50 DS change in apparent accommodation with gaze 25° eccentric to the optical axis), longitudinal head movement (<0.25 DS from 2 cm towards and 20cm away from the correct photorefractor-to-eye distance) and changes in background luminance (<0.25 DS from 0.5 to 20 cd/m^2 target luminance). However, the results of individual subjects were more variable and individual assessment of errors to allow for correction factors would be appropriate for small sample studies.

The *PowerRefractor* can be used remotely from the subject who need not be confined by a bite-bar or headrest, as long as they do not move over a longitudinal range of greater than 22 cm and are positioned initially slightly further away than 1m (the middle of the optimal range being 1.09 m from the *PowerRefractor* camera). This may suggest that the fixed focus of the instrument camera (preset by the manufacturer) is not optimal. Whether this varies between instruments is not known and should be assessed by laboratories using this data.

The tolerance to eye movements is much greater than that found with previous instrumentation such as the *Canon R-1*. Twenty-five degrees from fixation in all directions is enough to encompass the visual environment of most human factor applications. However, the blind-spot artefact (an apparent change in accommodation of approximately 1 D) can significantly affect the results and therefore as accommodation is consensual it may be advisable to take the results from the left eye when viewing to the left and from the right eye when viewing to the right. The blind spot will lead to a change in brightness, which as it is not uniform, will effect the slope and therefore the apparent refraction.

Unfortunately pupil size is of concern, with measurement failure common even in moderate light levels (15 cd/m^2 target luminance). This would appear to relate to fundus reflectivity (the image analysis programming requires an intensity differential between the pupil and its surround for the eye to be located) as it occurred with a range of pupil sizes.

In conclusion, the remote, completely open-field of the *PowerRefractor* together with its ability to measure pupil diameter and eye gaze position, as well as ocular accommodation makes it a very useful instrument to quantify the dynamics of the oculomotor system in human factors applications. Pupil size is of concern, however, potentially limiting its use in many environments without modification (of the instrument or environment).

CHAPTER 4

STIMULUS RESPONSE CURVES AS DETERMINED BY THE *POWERREFRACTOR*

Introduction

In chapter 3, the tolerance of the *PowerRefractor* was assessed and shown to be suitable for human factor applications, except for the possible limitation of ambient luminance. However, chapter 2 identified that although the *PowerRefractor* prescription was on average similar to that of subjective refraction, the range of differences was large (up to 3.5 D), with 95% of readings falling within ±1.12 D. If this inaccuracy is related to an individual's characteristics, such as the retinal reflectance, this will have little impact on the results of within-subject experimental designs or where results are compared to a baseline accommodative level. However, if the inaccuracy is due to inherent instrument variability, then this may have serious consequences for the use of the instrument beyond screening of refractive error.

As outlined in the introduction (chapter 1), the accommodative capacity of an individual is best characterised by the stimulus-response curve (e.g. Charman, 1982). The slope of the stimulus response function can be affected by factors such as age (Mordi and Ciuffreda, 1998; Ramsdale and Charman, 1989), luminance (Johnson, 1976) and refractive error (McBrien and Millodot, 1986), it has been shown to be repeatable within an individual (Baker *et al.*, 1998). The mean accommodative response is independent of pupil size (Stark and Atchison, 1997).

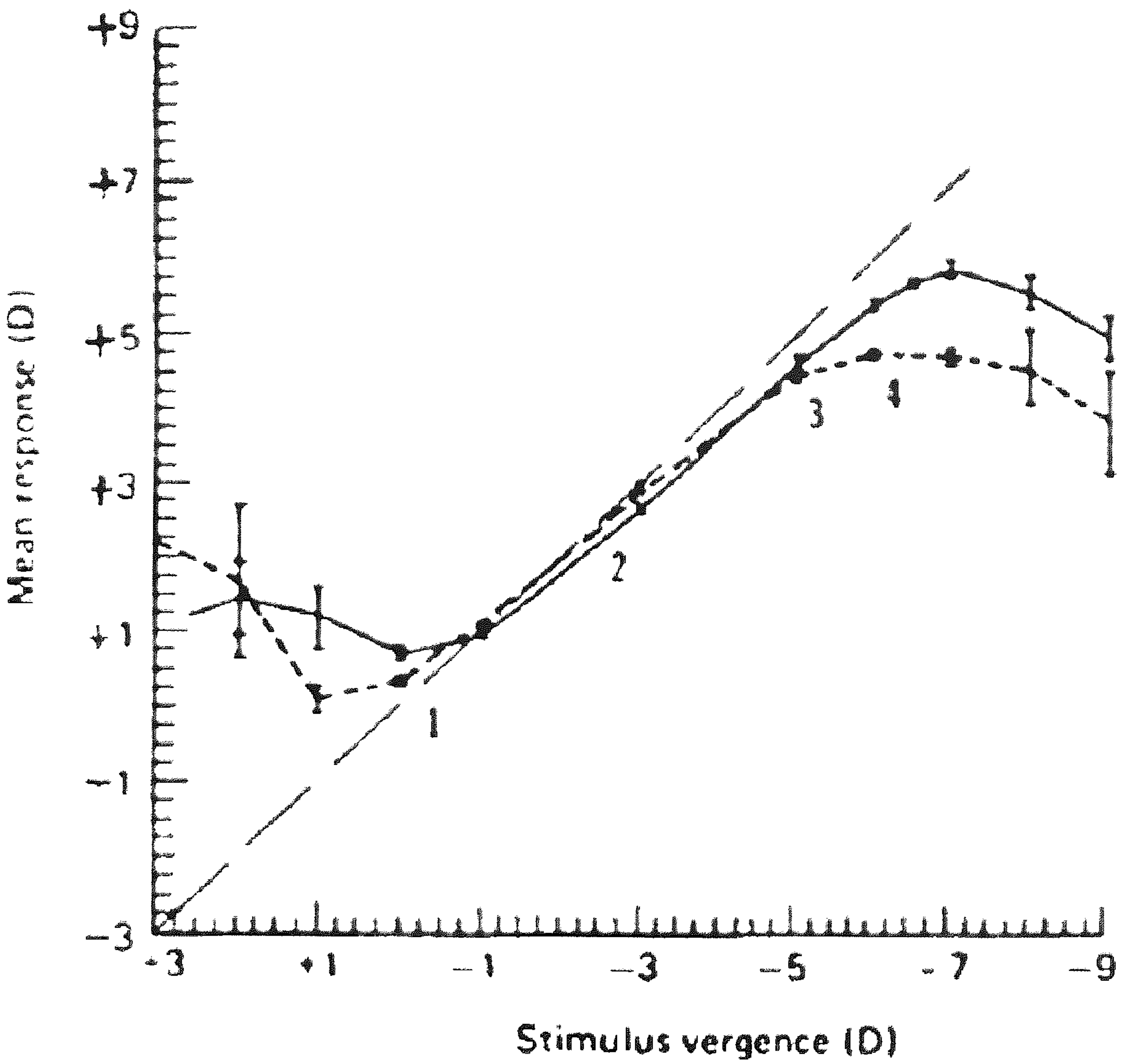


Figure 4.1 Static accommodative stimulus/response for two visually normal subjects. (from Ciuffreda, 1991). The vertical bar represent 2 standard deviations 1= non linear region, 2 = linear region, 3 = non linear transition region, 4 = non linear accommodative amplitude region.

Ciuffreda, 1991 (Figure 4.1) divided the stimulus response curve into four regions include -

1. the initial non linear portion over which the induced accommodative changes are usually less than predicted. This region is strongly influenced by an individual's tonic balance, especially if precautions are not taken with regard to patient instruction. In clinical terms, this lead of accommodation is seen as a minimal change in accommodative response for a target viewed anywhere between optical infinity and a few metres from the individual.

2. the linear manifest zone. In this area the change in accommodative response is usually in proportion to the accommodative stimulus. This typically extends from 1m to 20 cm below the individuals amplitude of accommodation. (Miege and Denieul, 1988)
3. The non linear transitional range of 'soft saturation'. In this portion, further increases in the stimulus produce progressively smaller responses than are found in the linear zone.
4. the non linear latent zone of hard saturation. In this area further increases in the stimulus do not produce any further increase in the response. This is the point where the crystalline lens has reached it maximum level of convexity and can deform no further to any decrease in the zonular tension. This is known clinically as the subjective amplitude of accommodation.

The stimulus response curve can be described by a number of parameters. Even when viewing a distant object, the depth of the focus of the human eye allows clear viewing without the need for the accommodative system to focus at optical infinity. The level adopted is referred to as the lead of accommodation. The tonic accommodation has been taken as the point at which the stimulus response curve crosses the unity (1:1 accommodative demand to response) line (e.g. Charman 1982, Johnson 1976), although this is open to much debate (Rosenfield *et al.*, 1993a). The slope of the response indicates the gain of the system to changes in accommodative demand, but is only linear over a limited region and is rarely 1.0. Therefore, there is an error between the demand and response, increasing with accommodative demand, known as the accommodative lag. Finally the amplitude of accommodation is the maximal range of accommodation. Often only one of these characteristics is quoted, and therefore Chauhan and Charman (1995) developed a single figure index (the Accommodative Error Index (AEI)) that depicts the discrepancy between the ideal accommodation response and the measured response for a number of accommodation stimuli at different distances. Described in its simplest terms it is the mean of the response error divided by the correlation coefficient. It is given as:

$$AEI = \frac{(1-m)\,[(x_1+x_2)/2]-c}{r^2}$$

where: m is the slope of the response

c is the intercept of the response line

r^2 is the correlation coefficient

x_1 is the dioptric equivalent of the farthest stimulus used and

x_2 is the dioptric equivalent of the nearest stimulus used

It only holds for the linear portion of the stimulus response curve. The AEI is expressed in dioptres and accurate accommodation at all distances would be expressed by an accommodative error index of zero. The further the AEI from zero, the greater the accommodative inaccuracy.

The AEI index has been used repeatedly by researchers examining the accommodative accuracy of children with Down syndrome (Woodhouse *et al.*, 2000, Cregg *et al.*, 2002, Bromham *et al.*, 2002). This group has suggested that an AEI of greater than 0.75D, should be considered to be accommodative insufficiency. Woodhouse *et al.*, 2000 compared the AEI of children between 1 to 45 months. The results for 131 developmentally normal children (average age 13.79 ± 9.79 months) as a control and 65 children with Down syndrome (average age 18.33 ± 11.58 months) (Figure 4.2a). Within the control group the majority had an AEI of between 0 and 2.20 D (0 to 95th percentile), however only 32% of the age matched children with Down Syndrome fell within this range. They also showed that as the children with Down Syndrome got older then their accuracy of accommodation became poorer (Figure 4.2b).

Different protocols and instrumentation have been used to obtain the data to plot the stimulus response curves. Ramsdale (1985) used a binocular laser optometer with the patient fixating on letters at different dioptric distances. McBrien and Millodot (1985) used an infra-red autorefractor, the *Canon AutoRef R-1*, with pupils dilated with phenylepherine to allow the measurements to be taken. Gwiazda *et al.*, (1993) used the *Canon R-1* to measure the accommodative responses of children to three different types of stimuli. The first was similar to that of McBrien and Millodot (1985) whereby the patient fixated a target at different dioptric distances (decreasing distance series, DDS); the second involves negative lenses (NLS) being placed in front of the patient viewing a target a 4 m and the third involved positive lenses (PLS) being placed in front of the eye fixating at 0.25 m. Abbott, Schmid and Strang (1998) aimed to replicate the study of Gwiazda *et al.*, (1993) in older patients and found significant difference between the methods e.g. accommodative lags were highest when using the negative lenses. Woodhouse *et al.*, (2000) used Mohindra retinoscopy in studying their subjects.

Therefore, to further assess the suitability of the *PowerRefractor* to quantify the oculomotor response in human factor applications, it is important to compare the accommodative stimulus response curve of individuals as measured by the *PowerRefractor* with an already well validated autorefractor (the *Shin-Nippon SRW-5000*; Chat and Edwards, 2001; Mallen *et al.*, 2001).

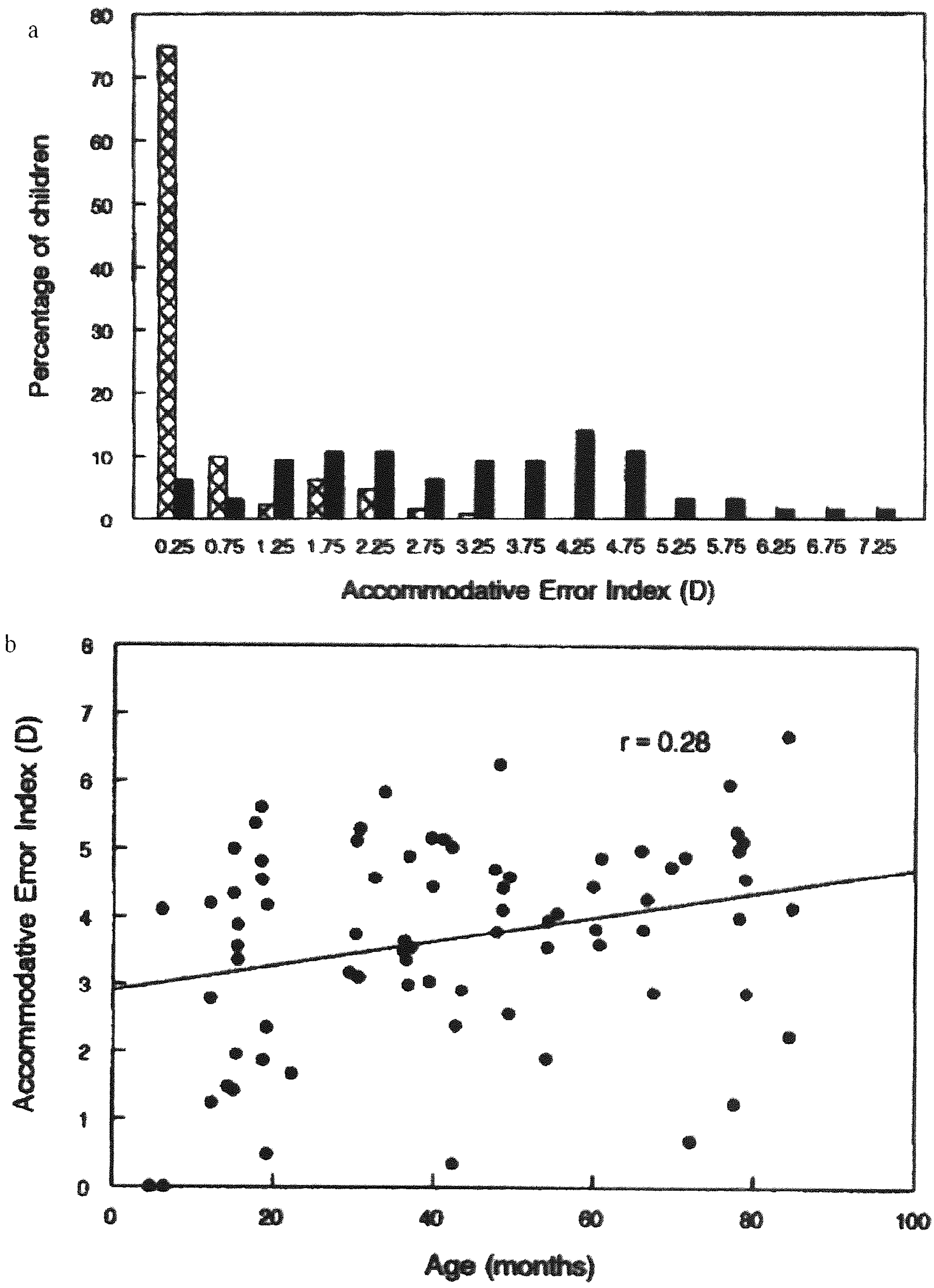


Figure 4.2 (a) AEI for (hatched bars) 131 control children and (filled bars) 65 children with Down syndrome aged 1 -45 months and (b) AEI and age for 77 children with Down syndrome (From Woodhouse *et al.*, 2000).

Method

Thirty subjects aged 18 – 25 (average 21.0 ± 2.2 years: 9 male, 21 female) gave informed consent to take part in the study. Each subject underwent a full binocular refraction using the criteria outlined in Chapter 2 and was only included in the study if there was no evidence or history of binocular vision anomalies or ocular pathology. All the subjects could attain at least 6/6 visual acuity in each eye. The range of mean spherical equivalent refractive error was -7.87D to +3.50 D, measured at 6m. Patients with astigmatism greater than -0.75 D were excluded from the study. Subjects were made functionally emmetropic with ultra-thin soft contact lenses (*Acuvue*, Johnson & Johnson) to ensure that the accommodative demand to view the tasks for each subject was virtually identical.

Accommodative responses were measured using the *PowerRefractor* and the *Shin-Nippon SRW-5000* through undilated pupils in a randomised order. The subject's head was positioned on a head and chin rest. The *PowerRefractor* was positioned 1 m from the subject, aligned with the right eye, but positioned to image both of the subject's eyes. The *SRW-5000* was aligned with the visual axis of the right eye and measured the accommodative response of this eye only, although the subject had a binocular open-field view of the targets. Subjects viewed a static 90% contrast Maltese cross located at 0.17, 0.50, 1.00, 2.00, 3.00, 4.00 and 5.00 D accommodative demand, in real space (matched for angular subtense and luminance), in a random order. Five static readings were taken with both the *PowerRefractor* (full refraction mode) and *SRW-5000* at each distance. All patients were asked to carefully focus on the target and to try to keep it as clear, as if they were reading, whilst the measurements were being taken (Stark and Atchison, 1994).

The illuminance of the room was kept constant at 40 lux at the eyes and the target kept at 5 Cdm-2. This particular luminance was chosen to maintain a pupil size adequate to achieve measurements at all distances with the *PowerRefractor*. The luminance was kept the same for measures taken with the *SRW-5000* so as not to affect the stimulus response curve (Johnson, 1976).

This study had been passed by the ethics committee and all participants signed consent forms.

Statistical Analysis

The results were entered into a spreadsheet, converted into mean spherical equivalents and the slope, its intercept with the 'y' axis, the accommodative lead, r^2 and the AEI was calculated for each subject with both the *PowerRefractor* and *SRW-5000*. Pearson correlation coefficients were calculated using *SPSS* ver11.5.

Results

For each patient two stimulus response curves were plotted, one measured using the *SRW-5000* and one using the *PowerRefractor* (Figure 4.3). To calculate the slope and AEI it was important to determine the linear portion of the stimulus response curve. Therefore, the average r^2 values were compared for 0-5 D, 1-5 D, 0-4 D and 1-4 D (Table 4.1). Although the correlation coefficient was high for all the regions assessed, the highest agreement with a linear slope was found to occur for the 1-5 D region of the stimulus curve and therefore, this region was subsequently used to calculate, and present the slope and AEI values.

Portion of slope	***PowerRefractor***	***Shin Nippon SRW-5000***
0 – 5 D	0.96	0.97
1 – 5 D	0.98	0.98
0 – 4D	0.95	0.95
1 – 4 D	0.97	0.97

Table 4.1: Correlation coefficient (r^2) values for different areas of the stimulus response curve.

Figure 4.4a shows the bias between the slope measures with the *PowerRefractor* and the *SRW-5000* (Bland and Altman, 1986). The mean difference in slope between the two measures was 0.50 ± 0.36 D, showing the *PowerRefractor* stimulus response curve slopes (1.44 ± 0.36 D, range 0.81-2.24 D) are significantly more positive ($p \leq 0.005$) than the equivalent *SRW-5000* slopes (0.94 ± 0.16 D, range 0.59-1.24 D). There is a marked bias in the results, with increasing deviation from zero difference between *PowerRefractor* and *SRW-5000* slopes with increasing average slope.

Figure 4.4b shows the bias between the intercept measures (of the accommodative slope with the "y" axis) with the *PowerRefractor* and *SRW-5000* (Bland and Altman, 1986). The mean difference between the two measures was -1.26 ± 0.98 D, showing the *PowerRefractor* stimulus response curve intercepts (-1.83 ± 0.93 D, range -3.46 D to 0.17) are significantly more negative ($p \leq 0.005$) than the equivalent *SRW-5000* intercepts (-0.57 ± 0.50 D, range -1.30 D to 1.04). There is a marked bias in the results, with increasing deviation from zero difference between *PowerRefractor* and *SRW-5000* intercept with increasing average intercept.

Figure 4.5a shows the bias between the AEI measures with the *PowerRefractor* and the *SRW-5000* (Bland and Altman, 1986). The mean difference between the two measures was 0.24 ± 0.61 D, suggesting that the apparent accommodation measured by the *PowerRefractor* AEI (0.52 ± 0.63 D, range -0.60 to 1.64) was significantly more accurate ($p \leq 0.005$) than the equivalent *SRW-5000* AEI values (0.76 ± 0.52 D, range -0.25 to 1.71 D). There was no apparent bias in the results over the range of average AEI values.

Figure 4.5b shows the bias between the lead of accommodation (taken as the mean spherical equivalent presented by the instruments internal static mode calibration at 0.17 D) as measured by the *PowerRefractor* and the *SRW-5000* (Bland and Altman, 1986). The mean difference between the two measures was 0.67 ± 0.60 D, showing the *PowerRefractor* lead (-0.60± 0.57 D, range -1.90 to 0.28 D) are significantly more negative ($p \leq 0.005$) than the equivalent *SRW-5000* lead values (0.06 ± 0.37 D, range -0.87 to 0.79 D). There was no apparent bias in the results over the range of average lead values.

To allow the results of the two instruments to be compared to previous findings on the change in stimulus response function with refractive error, the slope (Figure 4.6) and lead (Figure 4.7) measured by the *PowerRefractor* and *SRW-5000* were plotted against the mean spherical error of the patients' subjective prescription. The resulting linear equations for accommodative slope and lead are presented in Table 4.2 and Table 4.3 respectively.

Refraction	***PowerRefractor***	***Shin Nippon SRW-5000***
Overall n = 30	y = 0.03*x* + 1.36 $r^2 = 0.10$ p = 0.08	y = 0.02*x* + 0.97 $r^2 = 0.07$ p = 0.15
-3.00 → -8.00 n = 10 see figure 4.2	y = 0.08*x* + 1.93 r^2 =0.10 p = 0.35	y = 0.02*x* + 0.94 $r^2 = 0.03$ p = 0.63
0 → -2.75 n = 10	y = -0.17*x* + 1.22 $r^2 = 0.13$ p = 0.29	y = -0.03*x* + 0.98 $r^2 = 0.02$ p = 0.67
+3.00→ 0 n = 10	y = -0.11*x* + 1.39 $r^2 = 0.19$ p= 0.20	y = -0.02*x* + 0.99 $r^2 = 0.03$ p = 0.63

Table 4.2: Accommodative response slopes for each refractive group. 'y' is the accommodative slope and 'x' is refractive error

Refraction	*PowerRefractor*	*Shin Nippon SRW-5000*
Overall n = 30	$y = 0.01x - 0.47$ $r^2 = 0.004$ $p = 0.73$	$y = 0.02x + 0.10$ $r^2 = 0.01$ $p = 0.54$
-3.00 → -8.00 n = 10	$y = -0.08x - 0.87$ $r^2 = 0.02$ $p = 0.67$	$y = 0.15x - 0.77$ $r^2 = 0.30$ $p = 0.84$
0 → -2.75 n = 10	$y = 0.23x - 0.43$ $r^2 = 0.16$ $p = 0.25$	$y = -0.02x + 0.05$ $r^2 = 0.004$ $p = 0.87$
+3.00 → 0 n = 10	$y = -0.10x - 0.13$ $r^2 = 0.06$ $p = 0.53$	$y = -0.19x + 0.34$ $r^2 = 0.30$ $p = 0.13$

Table 4.3: Accommodative lead for each refractive group. 'y' is the accommodative lead and 'x' is refractive error.

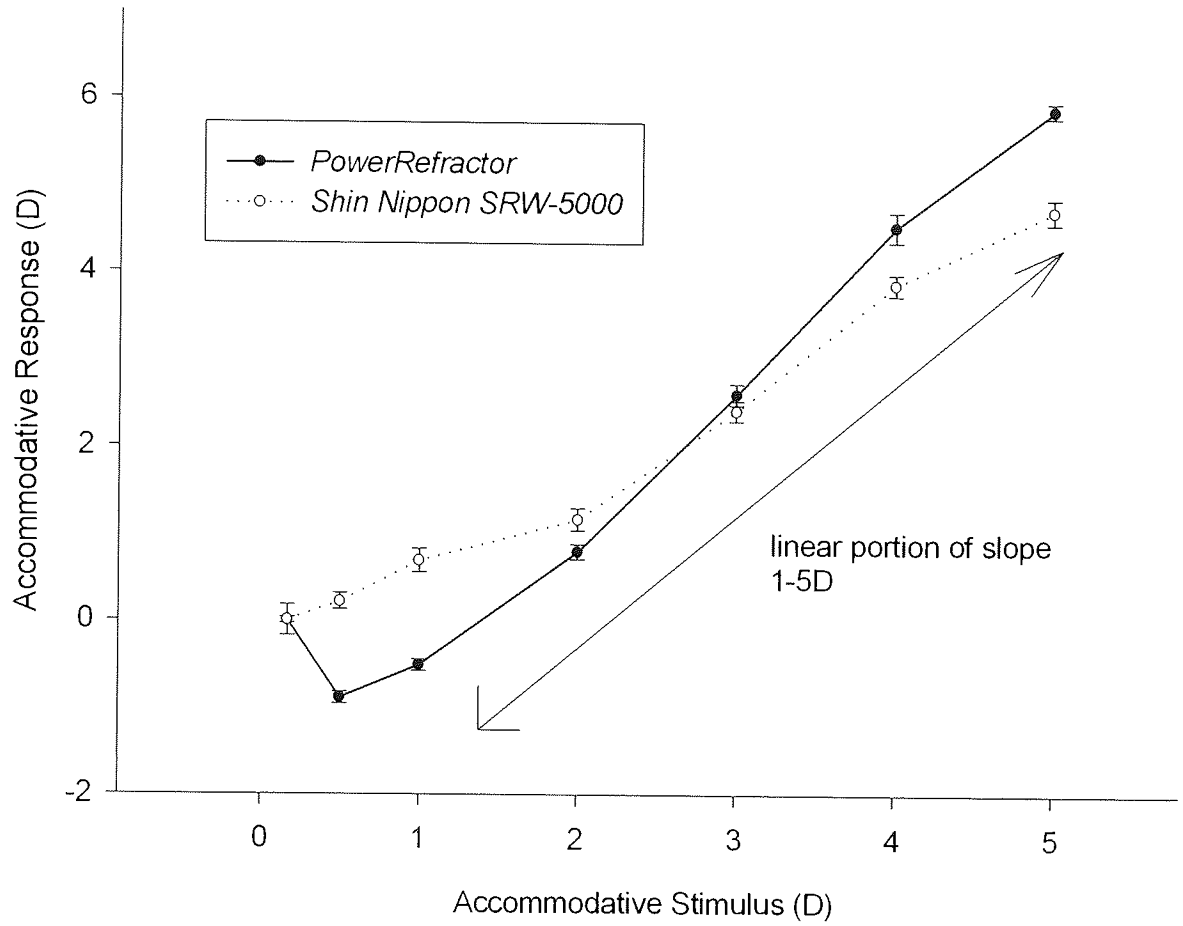


Figure 4.3: Example stimulus response curve (patient 2) showing measures with both the *SRW-5000* and the *PowerRefractor*.

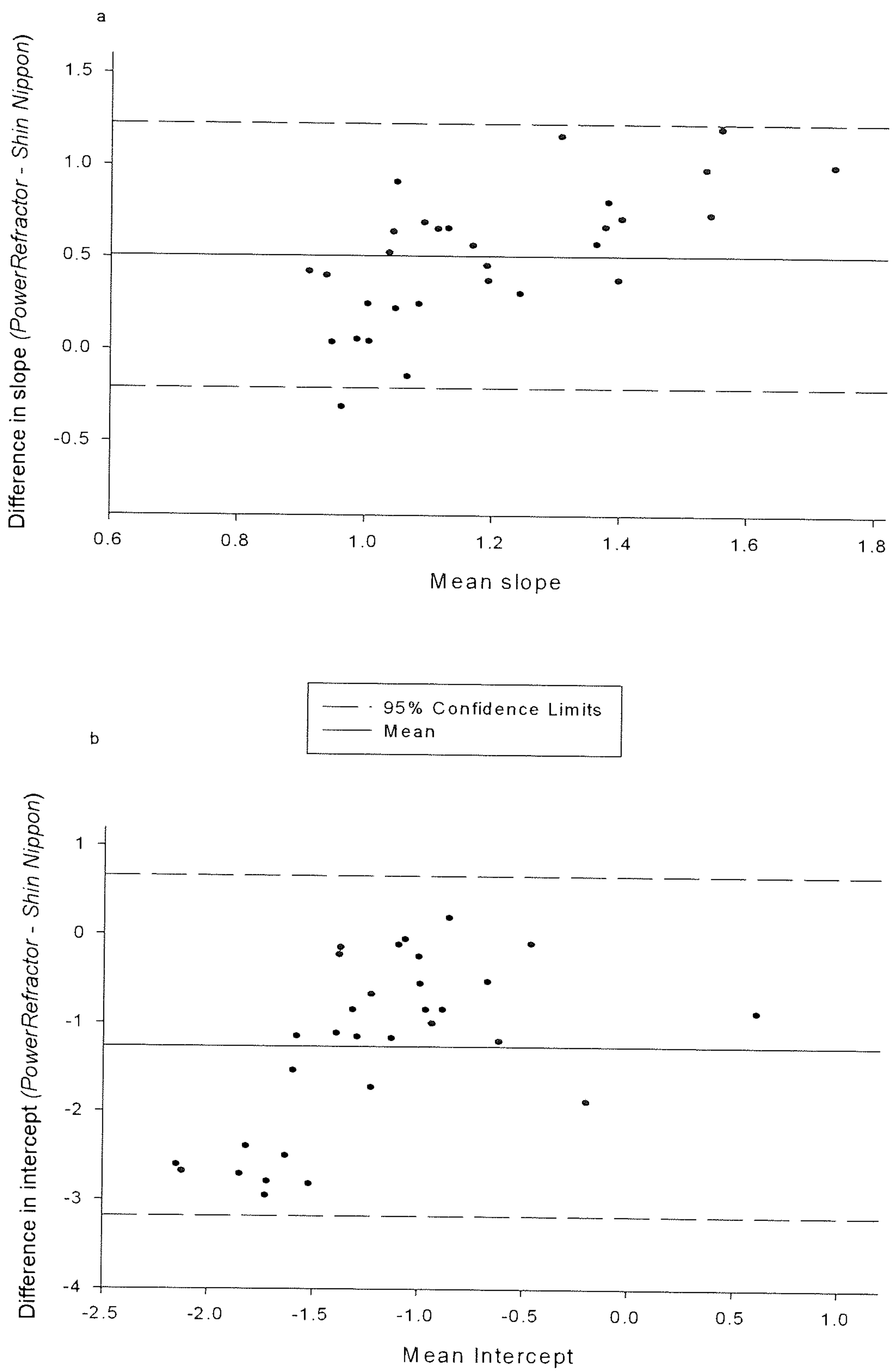


Figure 4.4: (a) Difference in gradient of the stimulus response curve and (b) Difference in intercept of the stimulus response curve as measured by the *SRW-5000* and *PowerRefractor* compared to the mean with contact lenses (1-5 D) n=30.

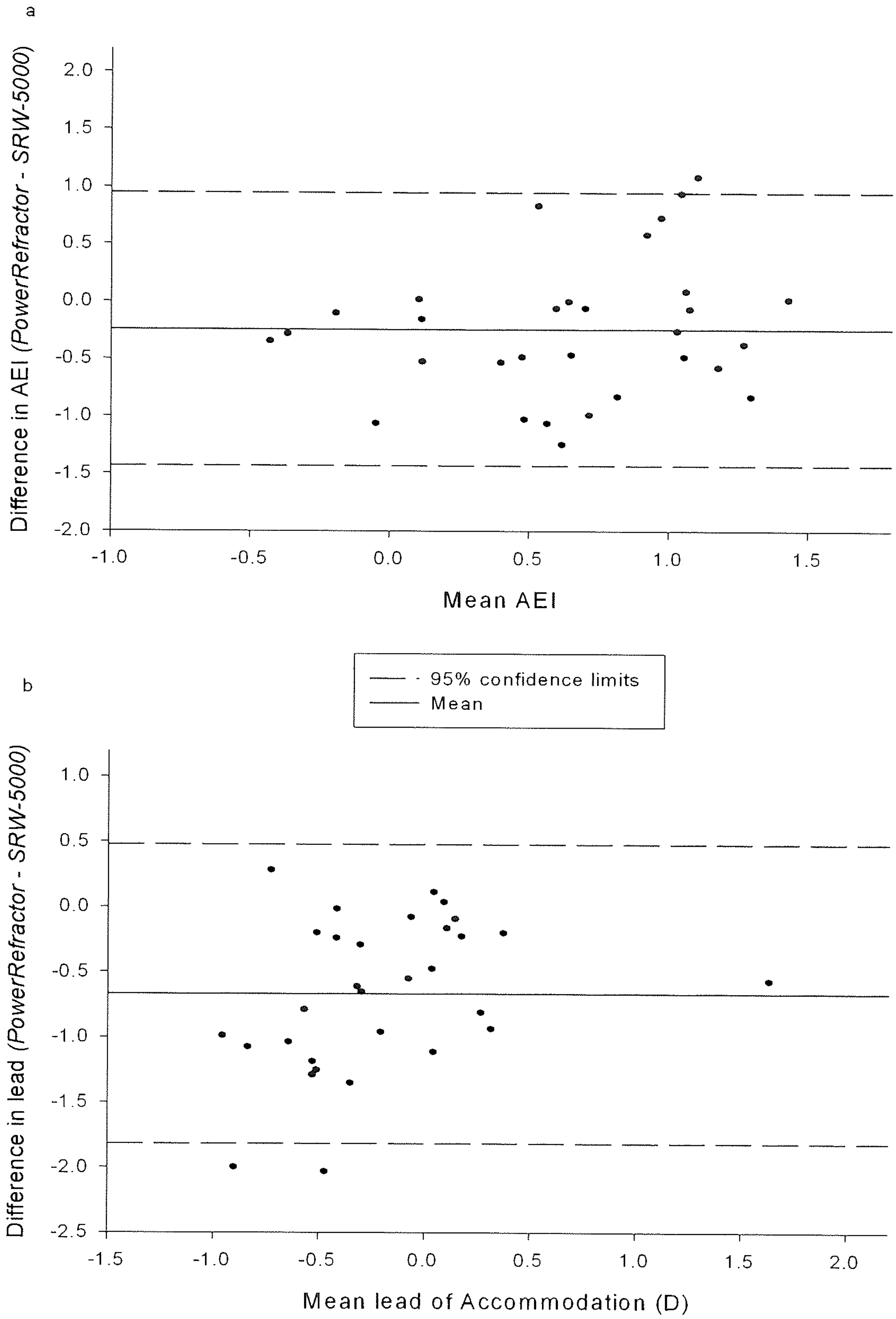


Figure 4.5: (a) Difference in AEI of the stimulus response curve as measured by the *PowerRefractor* and *SRW-5000* compared to the mean n=30 and (b) Difference in lead of accommodation of the stimulus response curve as measured by the *PowerRefractor* and *SRW-5000* compared to the mean n=30

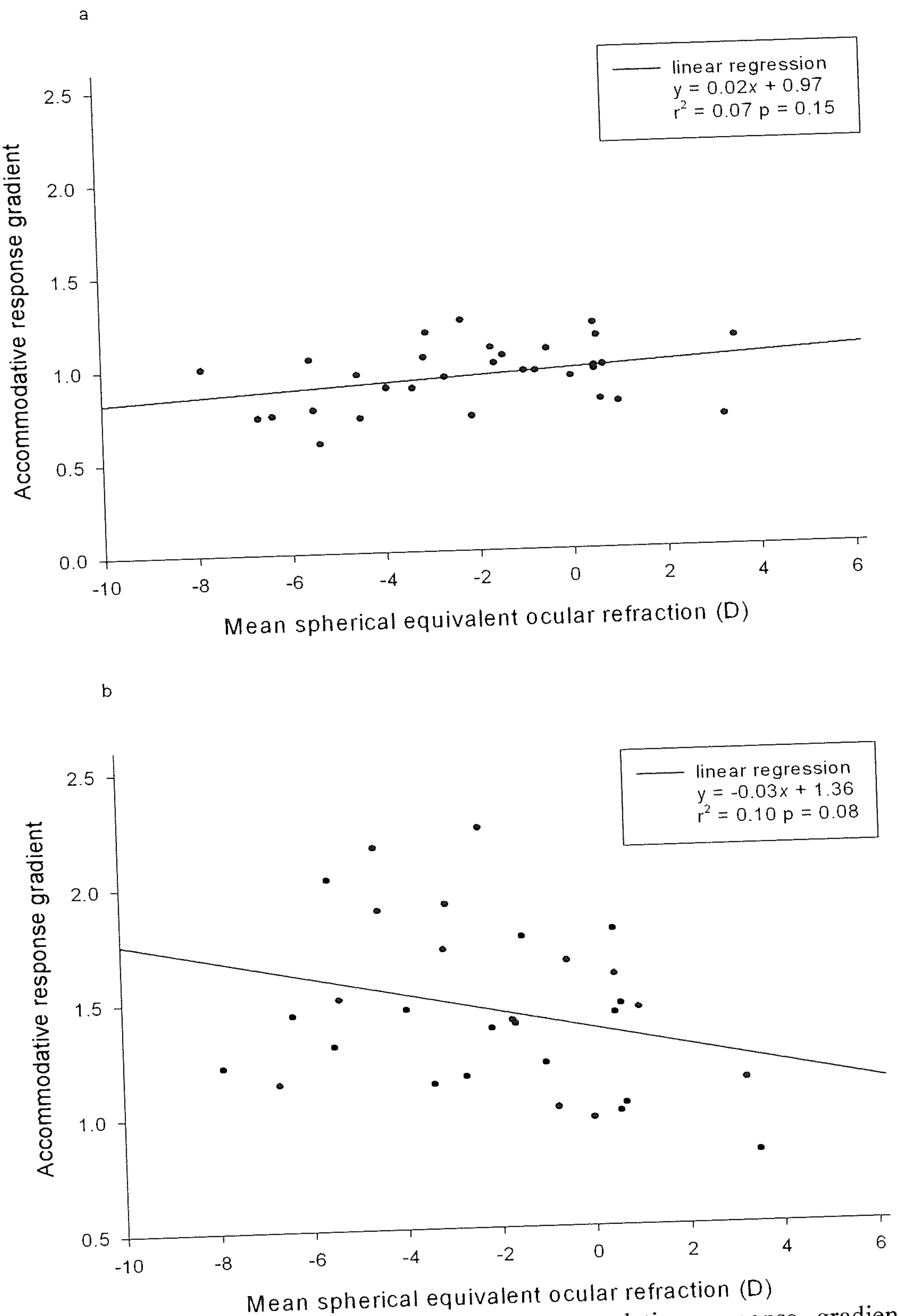
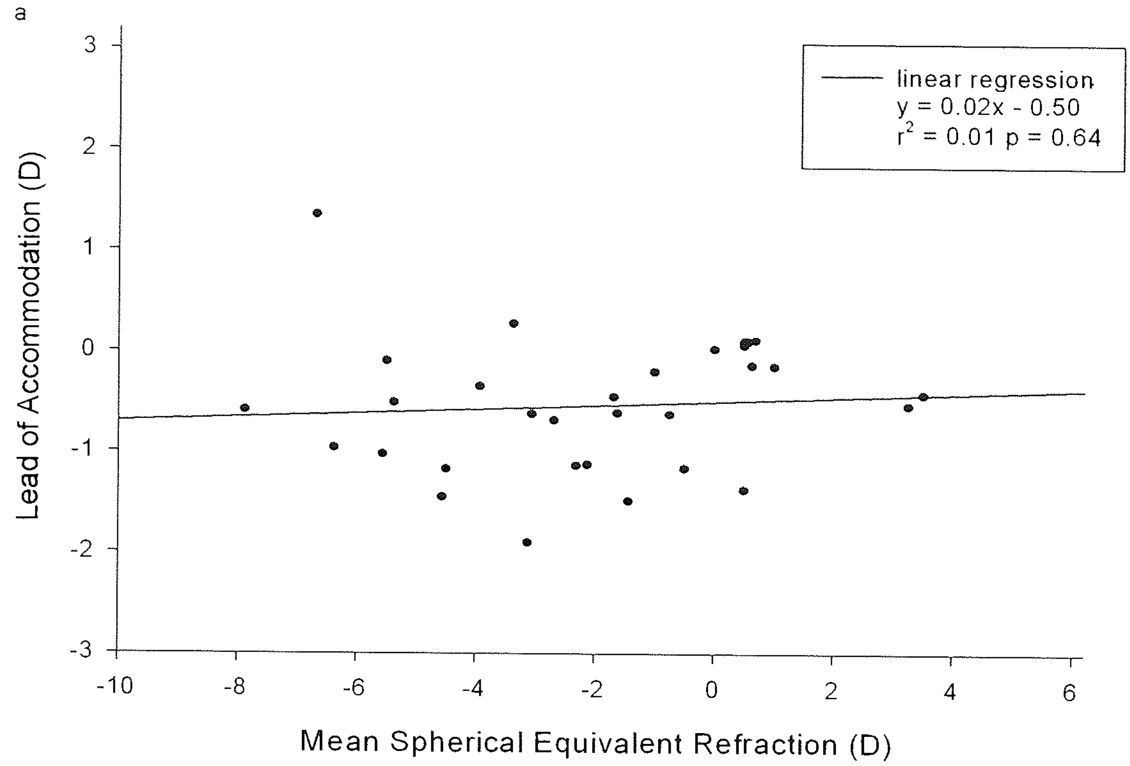


Figure 4.6: (a) Relationship between accommodative response gradient and ocular refraction measured with the *SRW-5000* (b) Relationship between accommodative response gradient and ocular refraction measured with the *PowerRefractor* (1-5 D) n = 30



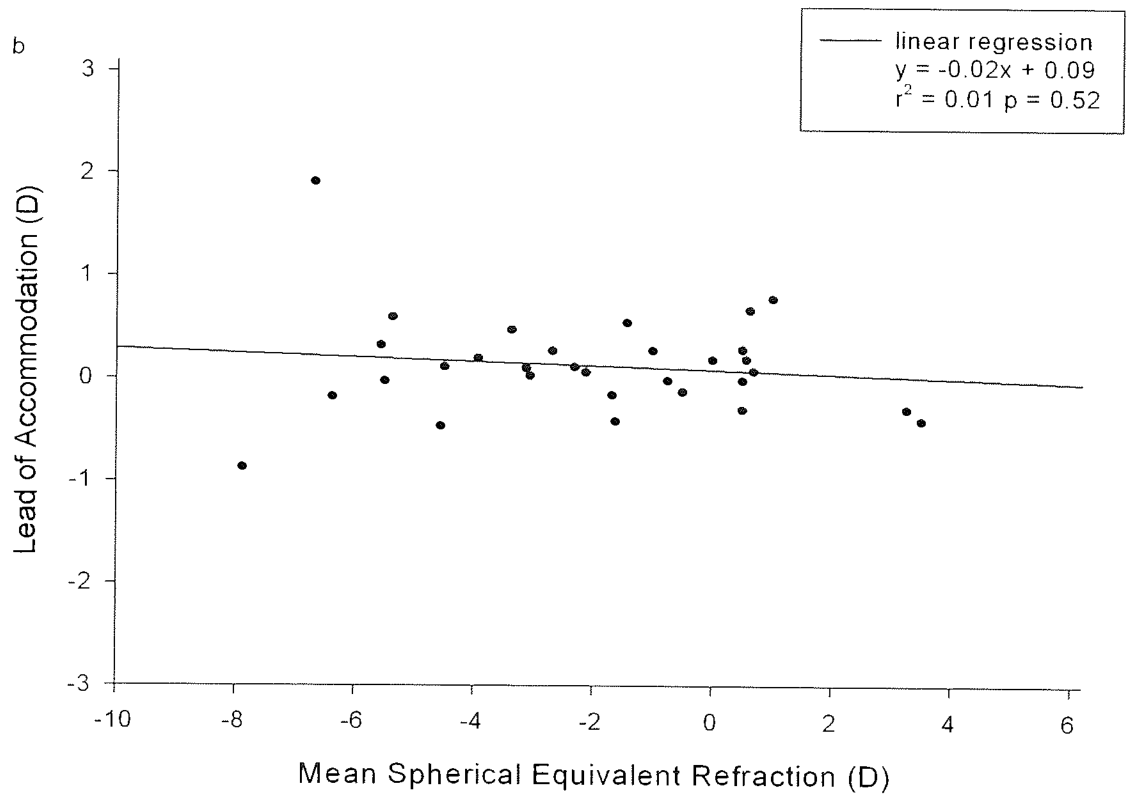


Figure 4.7: (a) Relationship between accommodative lead and ocular refraction measured with the SRW-5000 Nippon (b) Relationship between accommodative lead and ocular refraction measured with the *PowerRefractor* (1-5 D) n = 30

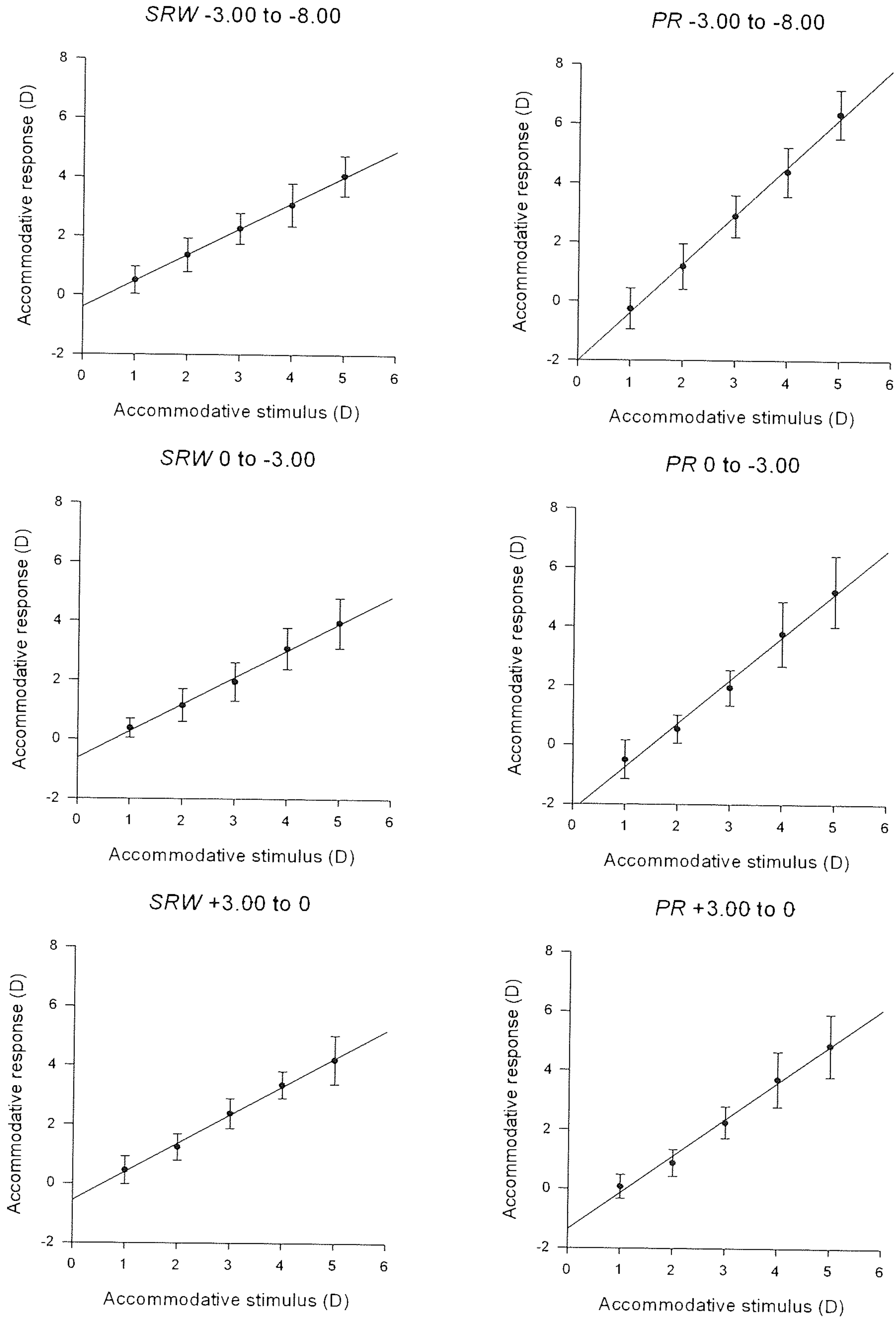


Figure 4.8: Comparison of accommodative response curves for different refractive groups as measured by the *SRW-5000* (*SRW*) and the *PowerRefractor* (*PR*)

Discussion

In general, it is expected that the slope would be within the range of 0.0 to 1.0 (e.g. Abbott, Schmid and Strang, 1998). However, for the results found within this study, 22% of slope measures with the *SRW-5000* and 83% of the *PowerRefractor* were above 1.0. One reason for this may be the difference in the conditions used in previous studies. Ramsdale (1985) and Gwiazda *et al.*, (1993) used spectacle lenses instead of contact lenses to correct their subject. Abbott, Schmid and Strang (1998) and Gwiazda *et al.*, (1993) subjects viewed the targets monocularly, thus removing vergence cues which generally increase the accommodation levels (Fincham, 1951). Only McBrien and Millodot (1985) used the essentially similar experimental conditions as those used within this study. However, one difference is the range over which they calculated the slope of the accommodative response curve (0-5 D compared to 1-5 D within this study). This would flatten the overall slope of the response curve.

A previous study by McBrien and Millodot (1986) showed that there was a strong correlation between individual accommodative response gradients and refractions ($r^2 = 0.25$ and apparent gradient approximately 0.011) with increased accommodative responses slopes noted for hyperopes compared to myopes. This means that hyperopes accommodate more accurately to near targets than myopes. Ramsdale (1985) found no correlation between the response gradient and refraction ($r^2 = 0.10$) and nor did Abbott *et al.*, ($r^2 = 0.00$ and gradient 0.0004). The results of this study from using the *SRW-5000* to compare response gradient with refraction support the results of McBrien and Millodot (1986). The gradient of the linear regression of the results was similar but the correlation of the results was lower in this study ($r^2 = 0.07$, $p = 0.15$). However, the results as measured by the *PowerRefractor* were contrary to previous studies with myopes appearing to accommodate more than hyperopes.

Abbott, Schmid and Strang (1998) using the DDS method, found the accommodative lead error to be +0.51 ± 0.21 D for a stimulus with 0.25 D accommodative demand (using NLS it was +0.62 and PLS was +0.36 D approximately). The accommodative lead found by the *PowerRefractor* was more negative than the DDS value by 1.1 D, with the *SRW-5000* more negative by 0.45 D (measured at the 0.16 D stimulus).

As there was no bias in the difference between the measured subjective refraction and *PowerRefractor* (0.02D/D of refractive error) and *SRW-5000* (-0.02 D/D of refractive error) reading found with refractive error (chapter 2), the difference in accommodative stimulus-response slope with accommodation between the two instruments must be due to a combination of changes in intraocular lens morphology and the measurement technique Although both instruments utilise image analysis of infra-red light reflected from the retina through the pupil, the *SRW-5000* measures only the central 2.9 mm of the pupil (Mallen *et al.*, 2001) where as the *PowerRefractor* measures the light intensity profile across the whole of the pupil. Whilst this causes few problems when the patient is focused for distance (see Chapter 2), it is possible that the aberrations caused by the morphological change of the lens during accommodation could distort the profile of the peripheral reflected light making the eye appear more myopic (over accommodating) than would be expected.

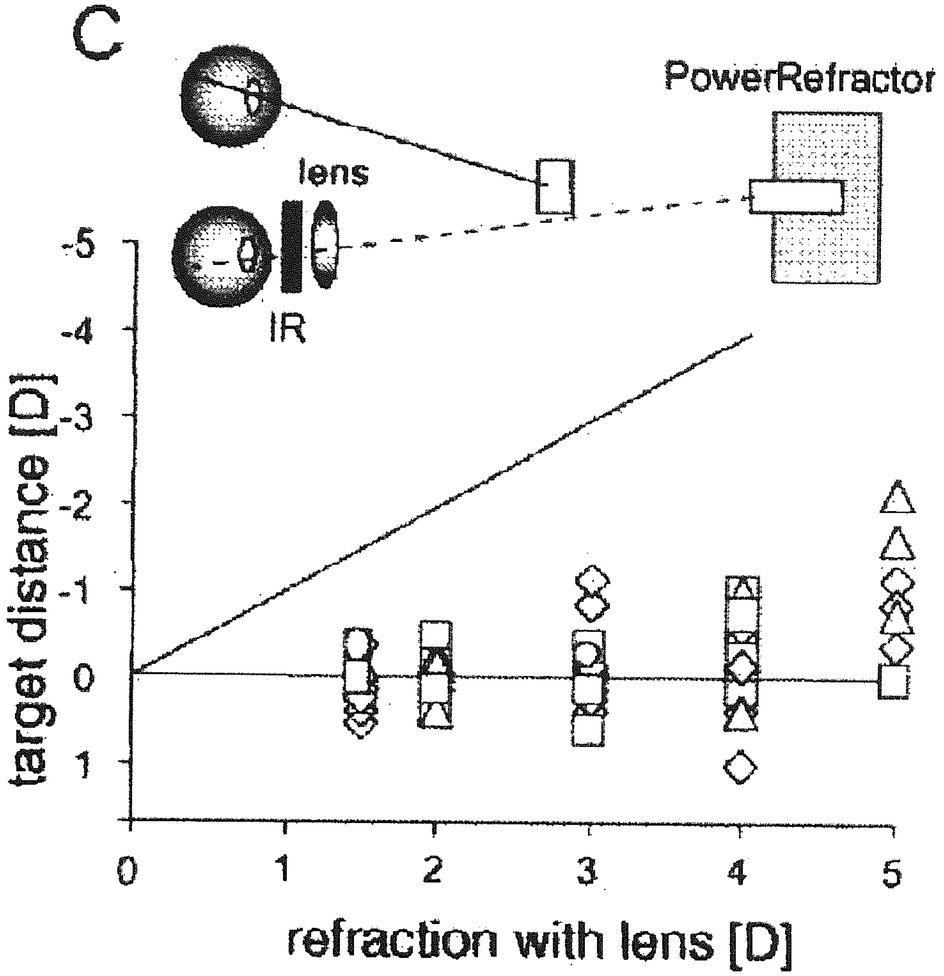


Figure 4.9: Results from calibration of the *PowerRefractor* with ophthalmic lenses (from Seidermann and Schaeffel, 2003).

Seidermann and Schaeffel (2003) checked the calibration of the *PowerRefractor* by asking subjects to read text monocularly at 1.5, 2.0, 3.0, 4.0 and 5.0 D distance. The other eye was covered with an infrared transmitting filter, which precluded vision. A trial lens was held in front of the covered eye based on the reading of the *PowerRefractor*. The hypothesis was that the ophthalmic lens should reduce the measured refractive error back to zero if the measured accommodation was correct. On average this was stated to be the case, however, at the 5D target the *PowerRefractor* still appears to over-read by -1.00 D (on average) and the variation is at least ±0.5 D for 1.5 and 2.0 D of accommodative demand and ±1.0 D for 3.0, 4.0 and 5.0 D of accommodative demand (Figure 4.9). Therefore, any stimulus response curves plotted using these values would be steeper than expected.

This difference in slope impacts on the AEI results. The AEI suggests that the *PowerRefractor* identifies more accurate accommodation than the *SRW-5000.* But the *PowerRefractor* in general gives slopes that are greater than one, resulting in the intercept on the y axis being highly negative. This in turn leads to a negative AEI (not seen in the studies with the children with Down syndrome).

In conclusion, the findings of this study suggest that the *PowerRefractor* may be more suitable to use as a screening tool than as a measure for accommodation responses, especially at high dioptric values, as it would be unclear as to the nature of any changes found. The results found with the *SRW-5000* appear more similar to those previously found in accommodation studies (e.g. McBrien and Millodot, 1986) and therefore this maybe a better method for measuring accommodative responses in human factor applications.

CHAPTER 5

OCULAR MOTOR TRIAD WITH SINGLE VISION CONTACT LENSES COMPARED TO SPECTACLE LENSES

Introduction

Theoretically, the accommodation and vergence demands are different between single vision contact lenses and spectacle lenses. Myopes are required to exert more accommodation and vergence when wearing single vision contact lenses compared to spectacles and conversely hypermetropes are required to exert less accommodation and vergence when wearing single vision contact lenses compared to spectacles. This was first proposed by Alpern in 1949. A number of factors have been proposed to contribute to this effect (Robertson, Ogle and Dyer, 1967; Stone, 1967; Sampson, 1969, 1971) which are discussed further in this chapter.

For myopic patients, spectacles lenses provide a base-in prismatic effect when fixating at near, resulting in a decreased need for convergence. When contact lenses are worn in place of spectacles this effect is lost, so in comparison a greater convergence effort is required. The converse is true for hypermetropic prescriptions in which spectacle lenses present a base-out prism in front of the eyes, increasing the convergence effort required. In addition, the reduced vertex distance of contact lenses compared to spectacle lenses from the eye results in greater effective power of a myopic prescription and a reduced effective power of a hypermetropic prescription when wearing contact lenses compared to spectacle lenses. If this is not compensated for in the prescription fitted, as long as the individual had residual accommodation, they could over-accommodate for a myopic contact lens prescription to maintain a clear image, also resulting in excessive vergence. In contrast, a hypermetrope wearing their spectacle prescription in contact lenses would be able to accommodate less to maintain a clear image, resulting in reduced vergence.

Other factors have been suggested to contribute, such as contact lens movement on the eye causing variable prismatic effects each time the patient blinks, image size blur and peripheral versus central accommodation (Hermann and Johnson, 1966; Robertson, Ogle and Dyer, 1967). It is, however, difficult to ascertain how these factors would result in a characteristic reduction in vergence and accommodation demand for hyperopes and a converse increase in demand for myopes.

Early studies calculated the proposed difference in accommodative and vergence demand between spectacle and contact lenses using geometrical optics (Alpern, 1949; Robertson, Ogle and Dyer, 1967; Stone, 1967). Few studies have attempted to measure these apparent differences in the oculomotor response clinically.

Hermann and Johnson (1966) and Hermann (1971) measured vergence using an electro-oculogram and accommodation was stimulated in the contra lateral unoccluded eye using minus lenses in one esotropic, hypermetropic (+6.75 D) patient and two myopic patients (-5.00 D and -8.00 D). Unfortunately the patients were also dilated to reduce any effect of pupil size changes, but this is likely to have affected the accommodative response. The authors found hypermetropes exert less accommodation and vergence (lower AC/A ratio) when wearing single vision contact lenses compared to spectacles, with the converse finding for myopes. Although the apparent AC/A ratio (measured clinically) is affected, the true AC/A ratio remains relatively unchanged as the accommodation and convergence demand both change in synchrony. Theoretically, the AC/A ratio with spectacles divided by the AC/A ratio with contact lenses equals one minus the spectacle power (in dioptres) multiplied by the spectacle plane from the centre of rotation of the eye minus twice the vertex distance of the spectacles (Stone, 1967).

Robertson, Ogle and Dyer (1967) subjectively measured heterophoria (using a Maddox rod and rotary prisms at distance [4.1 m] and near [0.33 m]), AC/A ratio (using both the change in Maddox rod phoria and fixation disparity with 0.5 D step changes in accommodative demand induced by trial spectacle lenses) and near point of accommodation between spectacles and contact lenses (RGPs). They compensated for the vertex distance of the spectacles compared to contact lenses in terms of power and adjusted the optical centres of spectacle lenses to presume near visual axes to eliminate the effect of prismatic changes. The findings were variable amongst their 28 myopic subjects, but suggested heterophoria and AC/A ratio remain unchanged between wearing spectacle and contact lenses. In contrast to their expected finding due to myopic spectacle minification, the near point of convergence was greater with spectacles than with contact lenses in all subjects and the differences were much greater than those predicted theoretically.

As the differences in oculomotor status between contact lenses and spectacles is an important clinical consideration in early presbyopes and in individuals with binocular vision anomalies, this study objectively and simultaneously looks at the binocular differences in oculomotor triad response (ocular accommodation, vergence and pupil size) over a wide range of refractive error.

Method

Thirty subjects aged 18 – 25 years (average 21.0 ± 2.2 years: 9 male, 21 female) gave informed consent to take part in the study. Each subject underwent a full binocular refraction using the criteria outlined in Chapter 2 and was only included in the study if there was no evidence or history of binocular vision anomalies or ocular pathology. All the subjects could attain at least 6/6 visual acuity in each eye. The range of mean spherical refractive error was -7.87 D to +3.50 D, measured at 6 m. Patients with astigmatism greater than -0.75D were excluded from the study.

Accommodative responses were measured using the *PowerRefractor* and the *Shin Nippon SRW-5000* through undilated pupils in a randomised order. The subject's head was positioned on a head and chin rest. The *PowerRefractor* was positioned 1 m from the subject, aligned with the right eye, but positioned to image both of the subject's eyes. The *SRW-5000* was aligned with the visual axis of the right eye and measured the accommodative response of this eye only, although the subject had a binocular open-field view of the targets. Subjects viewed a static 90% contrast Maltese cross located at several distances (Table 5.1) in real space (matched for angular subtense and luminance), in a random order, both with spectacle lenses (back vertex distance set at 13 mm) or contact lenses (*Acuvue Daily Disposables*, Johnson & Johnson) compensated in power compared to the spectacle lenses for vertex distance, performed in a balanced array.

Target Distance (m)	*Average Vergence (°)*	*Accommodative Demand (D)*
6.00	0.00	0.16
2.00	1.76	0.50
1.00	2.04	1.00
0.50	7.02	2.00
0.33	10.62	3.00
0.25	14.00	4.00
0.20	17.44	5.00

Table 5.1: Target distances and calculated average vergence (presuming an average interpupillary distance of 60 mm) and accommodation demand.

Five static readings were taken with both the *PowerRefractor* (full refraction mode) and *SRW-5000* at each distance. All patients were asked to focus on the target and to try to keep it as clear, as if they were reading, whilst the measurements were being taken (Stark and Atchison 1994). The illuminance of the room was kept constant at 40 lux and the target kept at 5 cdm^{-2}. This particular luminance was chosen to maintain a pupil size adequate to achieve measurements at all distances with the *PowerRefractor*. The luminance was kept the same for the *SRW-5000* measures so as not to affect the stimulus response curve (Johnson, 1976).

Dynamic accommodation was measured from the right eye with both the *Shin-Nippon SRW-5000* (Wolffsohn *et al.*, 2001) and *PowerRefractor* (Hunt *et al.*, 2003). Subjects tracked an oscillating target (90% contrast Maltese cross, size 6/12 equivalent at 50 cm, luminance 40 lux) that moved sinusoidally in real space between 50 cm to 22 cm at a frequency of 0.30Hz.

The *SRW-5000* is able to monitor dynamically the accommodative response with a high resolution and a frequency of up to 50 Hz (Wolffsohn *et al.*, 2001). The data was smoothed by averaging the ten time points either side (approximately 0.2 s) and blinks were removed (Wolffsohn *et al.*, 2003).

This study had been passed by the ethics committee and all participants signed consent forms.

STATISTICAL ANALYSIS

The results were entered into a spreadsheet, converted into mean spherical equivalents and the slope was calculated for each subject with both the *PowerRefractor* and *SRW-5000*. Dynamic traces were plotted, smoothed (running average function, SigmaPlot v6, SPSS) and the amplitude of response and lag between the target and response calculated (averaged across five target cycles). Averaging is essential to smooth out microfluctuations inherent in the measurement. It is more likely to give the true value than taking a measure from an arbitrary point.

Results

For each patient four stimulus response curves were plotted, two measured using the *Shin Nippon SRW-5000* and two using the *PowerRefractor* (spectacles and contact lenses). To calculate the slope it was important to determine the linear portion of the stimulus response curve. Therefore, the average correlation coefficient (r^2) values were compared for 0-5 D, 1-5 D 0-4 D and 1-4 D (Table 5.2). Although the correlation coefficient was high for all the regions assessed, the highest agreement with a linear slope was found to occur for the 1-5 D region of the stimulus curve and therefore this region was subsequently used to calculate and present the slope and AEI values.

PowerRefractor

Portion of slope	Spectacles	Contact lenses
0 – 5 D	0.96	0.96
1 – 5 D	0.97	0.97
0 – 4D	0.95	0.95
1 – 4 D	0.96	0.97

SRW-5000

Portion of slope	Spectacles	Contact lenses
0 – 5 D	0.97	0.97
1 – 5 D	0.98	0.98
0 – 4D	0.96	0.95
1 – 4 D	0.98	0.97

Table 5.2: r^2 values for different areas of the stimulus response curve.

Figures 5.1 and 5.2 show how the relationship between the ratio of the slope of the accommodative stimulus response curve for spectacle divided by the slope for contact lenses varies with refractive error. This allows a comparison of the 'effort' required to accommodate, with values greater than 1.0 indicating greater accommodative effort required when wearing spectacles compared to when wearing contact lenses and vice versa. Slope takes into account all points rather than an individual point and should therefore give a more accurate result overall. When measured by the *PowerRefractor* a significant slope was found between the accommodative effort ratio and refractive error, with hyperopes requiring a greater effort to accommodate with spectacles and myopes finding a greater accommodative effort being required to accommodate with contact lenses (Figure 5.1). However, when the same response is measured with the *SRW-5000* (Figure 5.2) the results do not reach significance ($p = 0.57$).

Figure 5.3 shows the relationship between the ratio of the vergence slopes (change in vergence per dioptre, calculated in the same manner as the accommodative effort ratio) as measured with the *PowerRefractor*. The vergence effort was found to be greater for hyperopes in spectacles and greater for myopes in spectacles ($p<0.01$). The value is lower than the calculated value of 0.16/D possibly due to the effect of accommodation on the near triad. Figure 5.4 shows the relationship between the ratio of the slope of the pupil change for spectacles compared to contact lenses by the *PowerRefractor* (average 0.77 ± 0.68). The rate of pupil change with accommodative demand appears unrelated to refractive error ($p = 0.43$). Figure 5.5 and 5.6 shows the relationship between the ratio (spectacles divided by contact lens slope) lead of accommodation with the *PowerRefractor* (average 0.43 ± 0.79) and the *SRW-5000* (average 0.50 ± 0.83). The lead of accommodation does not seem to be affected by the refractive error ($p=0.99$ and $p=0.17$, respectively).

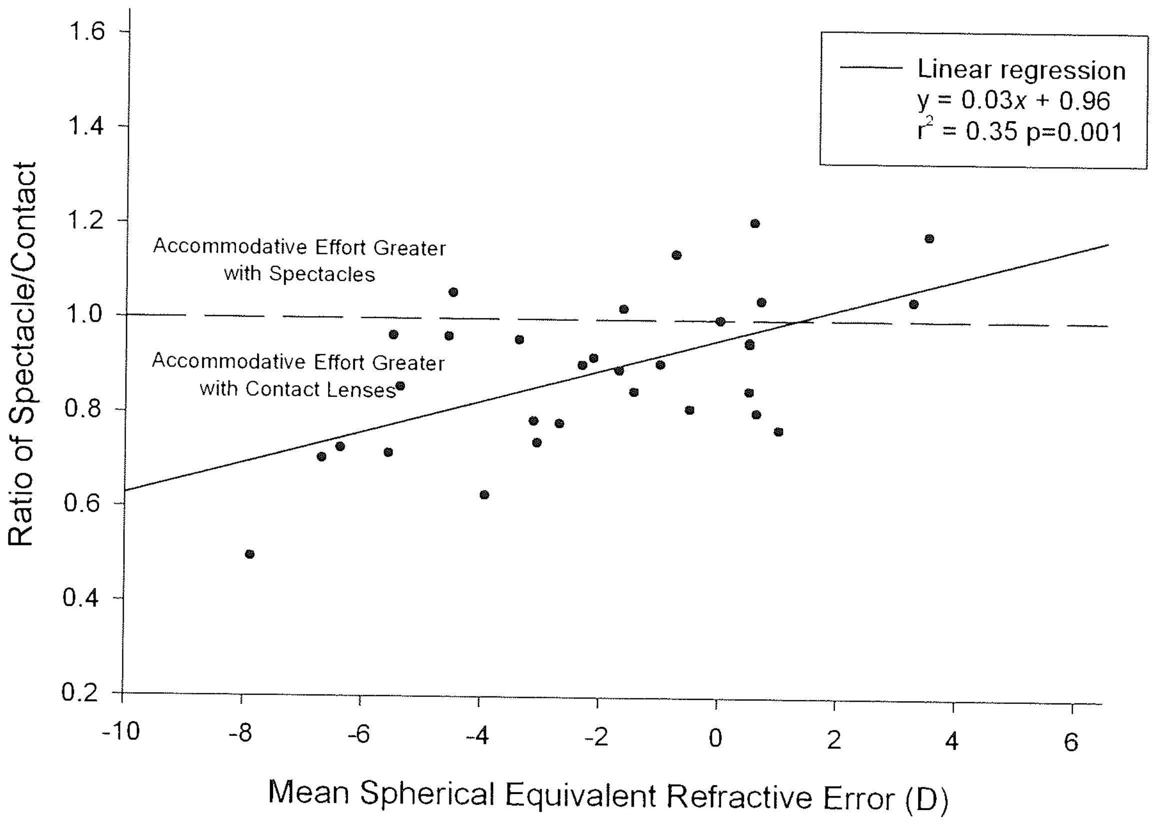
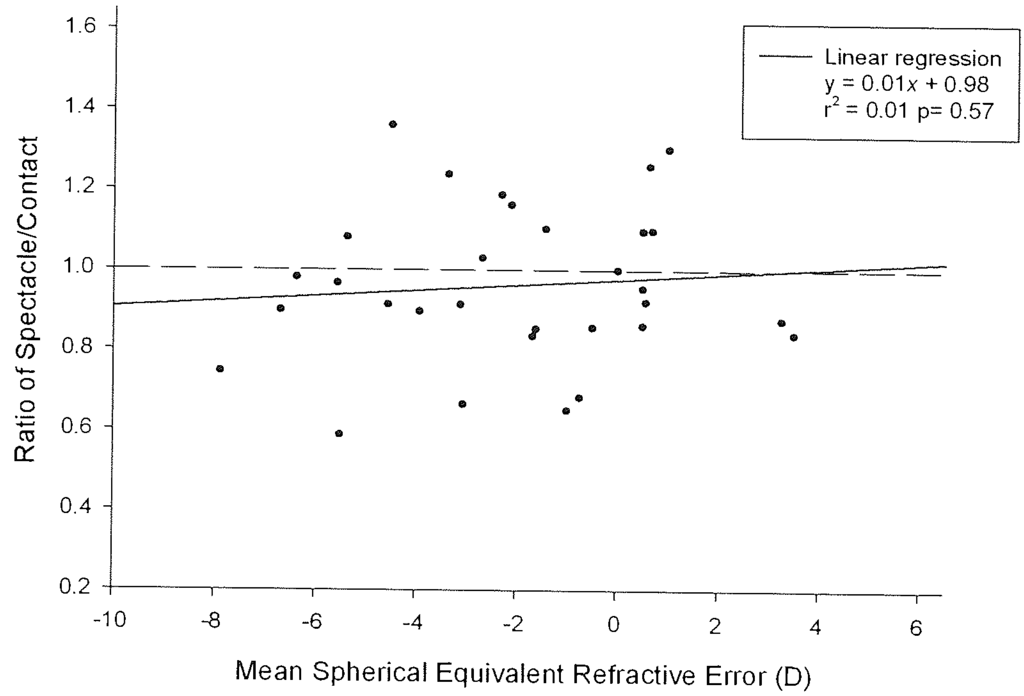


Figure 5.1 Relationship between the ratios of the slope of accommodative response curves for spectacles compared to contact lenses as measured by the *PowerRefractor* (n = 30).



b

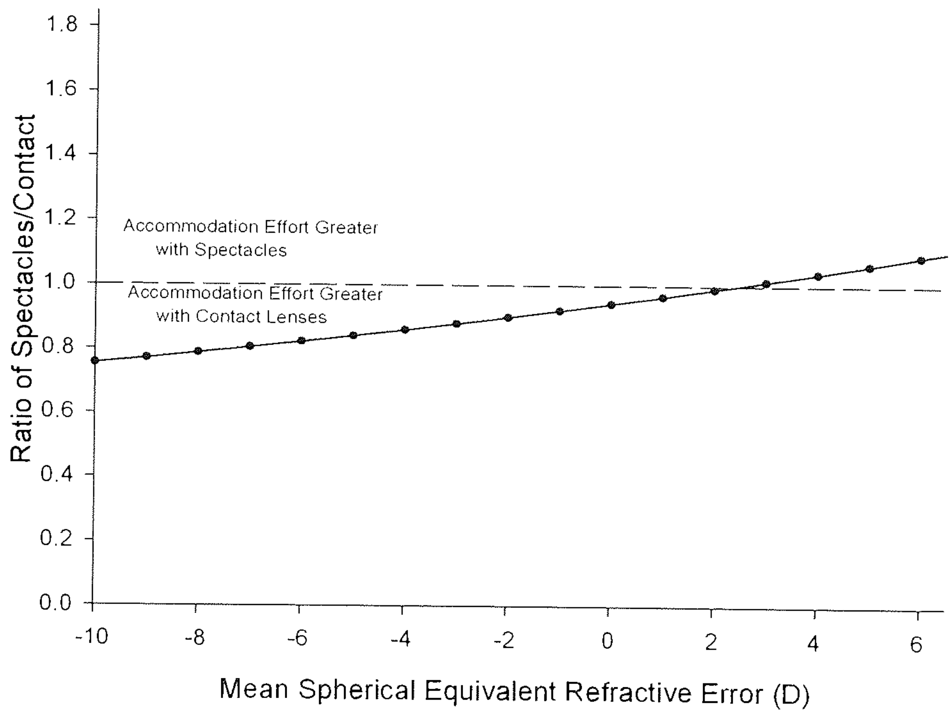


Figure 5.2 Relationship between the ratios of the slope of accommodative response curves for spectacles compared to contact lenses as measured by the *SRW-5000* (n = 30) and (b) calculated relationship between accommodation with spectacles and contact lenses.

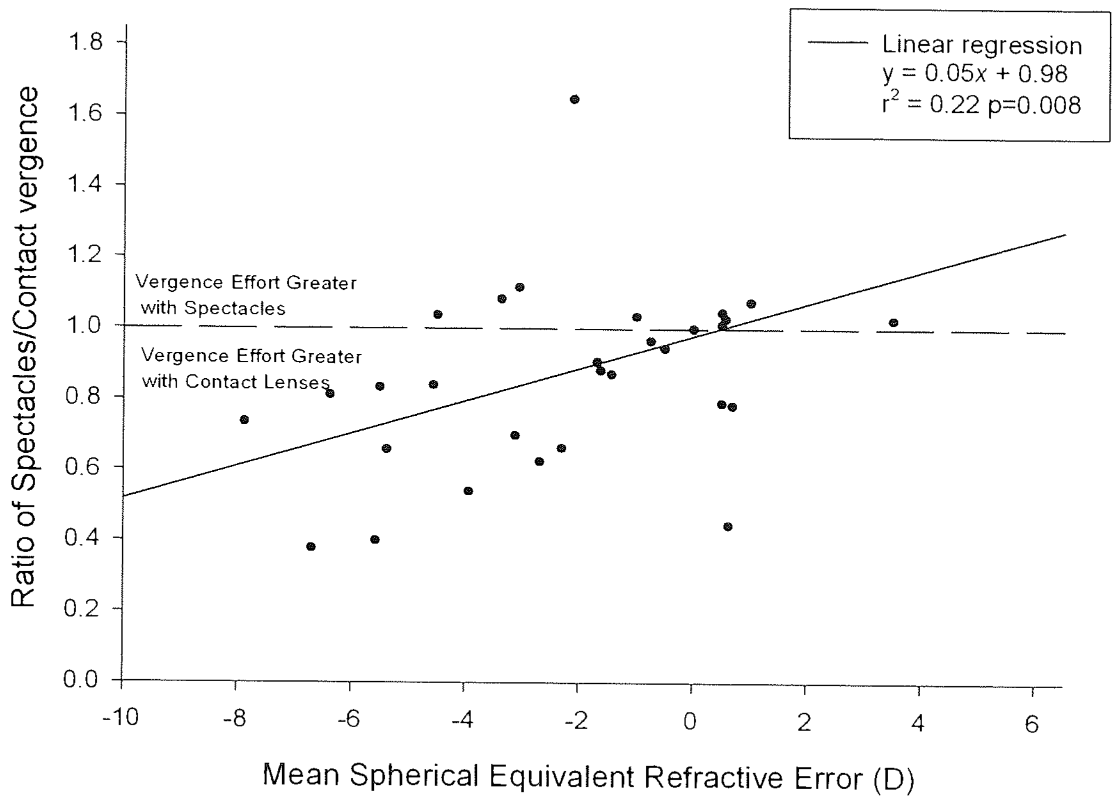


Figure 5.3 Relationship between the ratios of the slope of vergence changes for spectacles compared to contact lenses as measured by the *PowerRefractor* (n = 30)

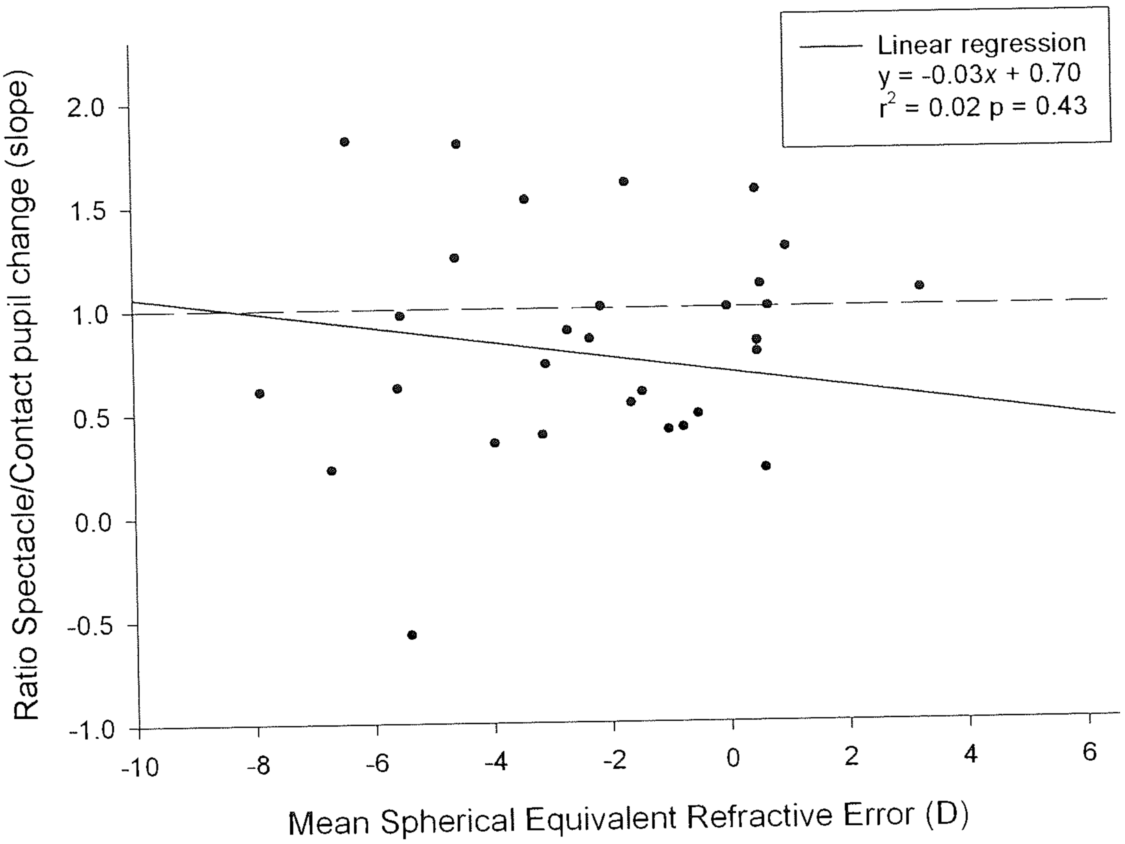


Figure 5.4 Relationship between the ratios of the slope of pupil change for spectacles compared to contact lenses as measured by the *PowerRefractor* (n = 30).

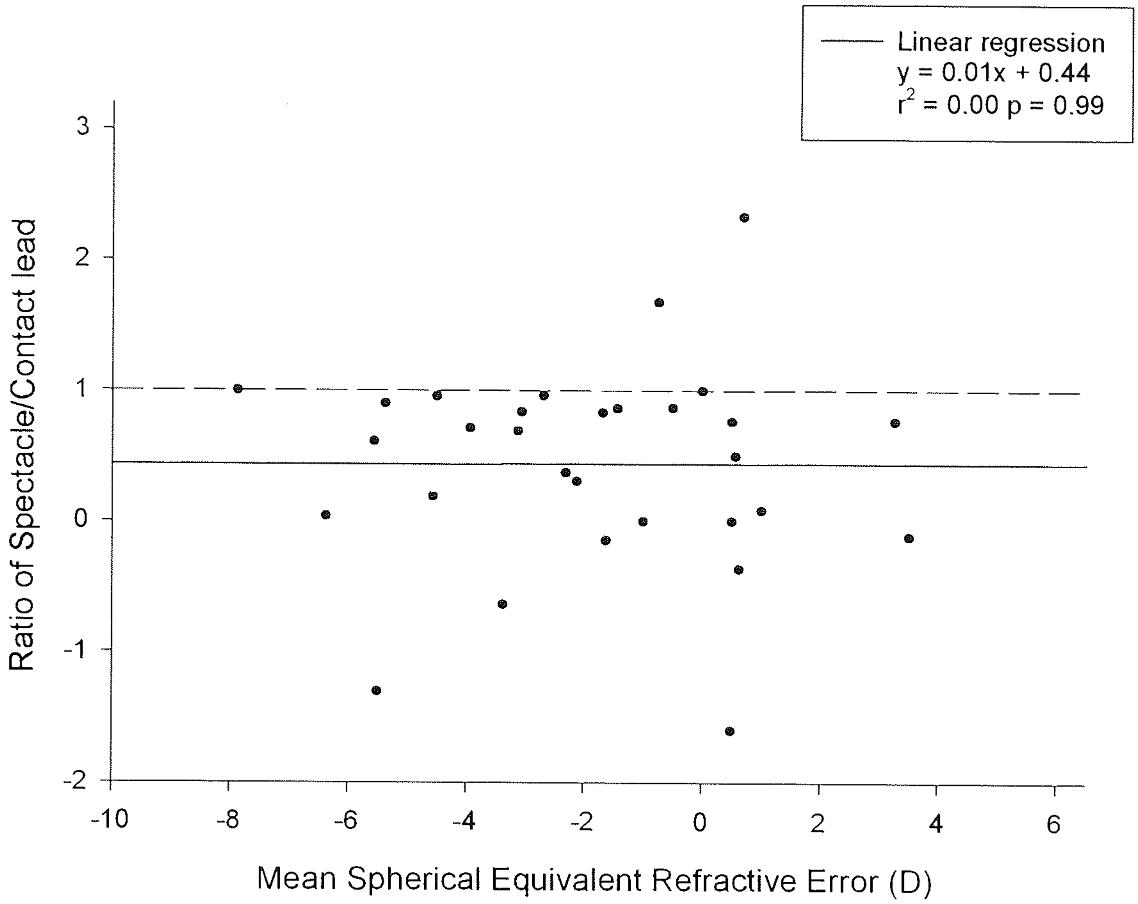


Figure 5.5 Relationship between the ratios of the lead of accommodation for spectacles compared to contact lenses as measured by the *PowerRefractor* (n = 30).

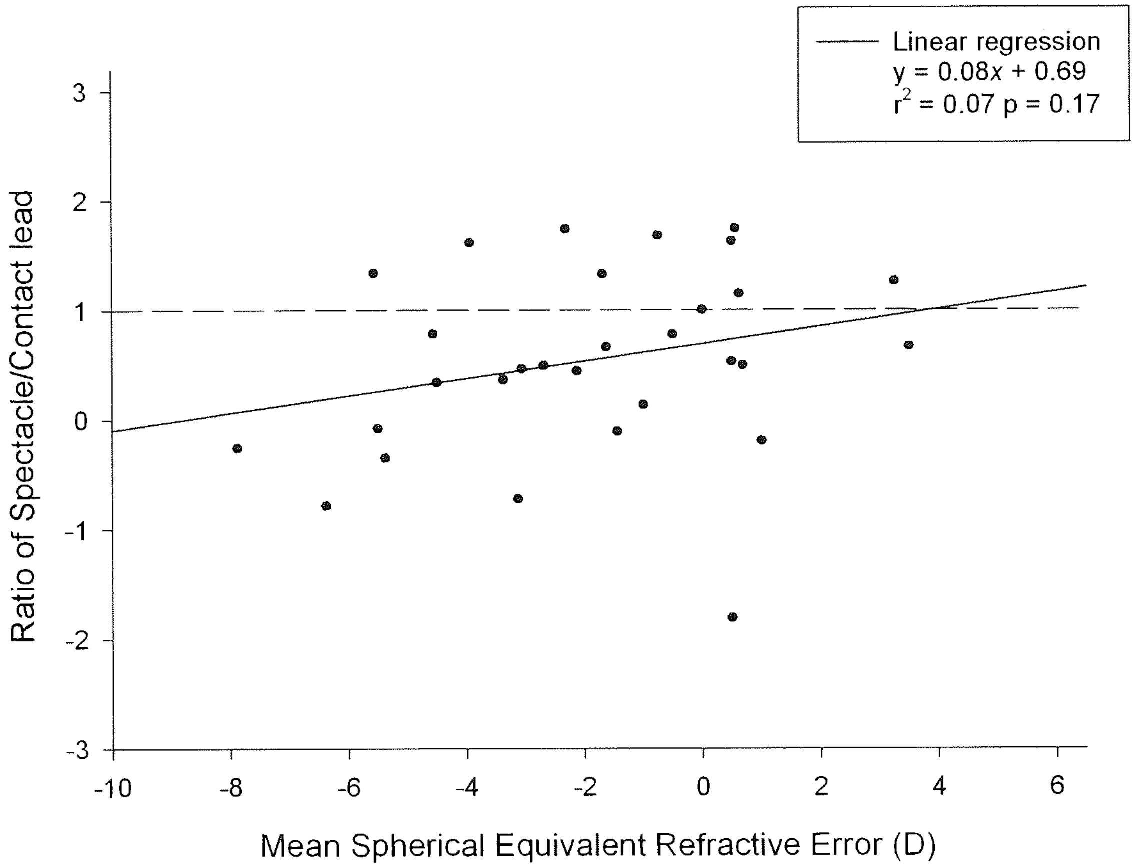


Figure 5.6 Relationship between the ratios of the lead of accommodation for spectacles compared to contact lenses as measured by the *SRW-5000* (n = 30).

When measured dynamically (e.g. Figure 5.7) using the *SRW-5000*, the average change in accommodation over a 2.50 D range with spectacles was 1.70 ± 0.43 D (range 0.81 to 2.53 D) with a time lag of 0.27 ± 0.16 s (range 0.00 to 0.62 s) at the maximal near focus (peak) and 0.26 ± 0.18 s (range 0.00 to 0.67 s) at the maximal distance focus (trough). With contact lenses the change in accommodation was 1.89 ± 0.50 D (range 0.91 to 3.00 D) with a time lag of 0.26 ± 0.17 s (0.00 to 0.79 s) at the maximal near focus and 0.15 ± 0.14 s (range 0.00 to 0.65 s) at the maximal distance focus. There was no significant difference between the amplitude ($p = 0.30$) or the lag ($p = 0.99$) as measured with spectacles and that of contact lenses.

When measured by the *SRW-5000* there was no correlation with refractive error for the change of accommodation ($r = -0.04$, $p = 0.84$), time lag at the maximal near focus point ($r = 0.14$, $p = 0.47$), time lag at the maximal distance focus ($r = 0.36$, $p = 0.06$) for the patient wearing glasses. When wearing contact lenses there was no correlation with refractive error for the change of accommodation ($r = 0.23$, $p = 0.27$), time lag at the maximal near focus point ($r = -0.08$, $p = 0.67$), time lag at the maximal distance focus ($r = -0.12$, $p = 0.55$).

Using the *PowerRefractor's* dynamic recording mode (e.g. Figure 5.8) the average measured change of accommodation over a 2.50 D dynamic range was 4.19 ± 1.20 D (range 1.20 to 6.56 D) with spectacles and 4.39 ± 1.47 D (range 1.47 to 7.88 D) with contact lenses. There was no significant difference between the results with the spectacles and contact lenses ($p = 0.09$). As the *PowerRefractor* could not be time-synchronised with the target, time lag could not be calculated. When measured by the *PowerRefractor* there was no correlation between refractive error and the amplitude of accommodation when wearing spectacles ($r = -0.26$, $p = 0.17$).

The pupil size change was on average 0.57 ± 0.23 mm (range 0.08 to 0.99 mm) with spectacles and 0.59 ± 0.24 mm (range 0.00 to 1.03 mm) with contact lenses over the 2.50 D stimulus range. There was no significant difference between the results with the spectacles and contact lenses (p = 0.34). The pupil achieves its minimum size on average 0.25 ± 0.15 s (range 0.00 to 0.59 s) after the maximum accommodative response and 0.48 ± 0.30 s (range 0.00 to 1.04 s) after the minimum accommodative response when measured with spectacles. When measured with the patient wearing contact lenses, the pupil achieves its minimum size on average 0.30 ± 0.19 s (range 0.00 to 0.85 s) after the maximum accommodative response and 0.52 ± 0.29 s (range 0.00 to 1.18 s) seconds after the minimum accommodative response. There was no significant difference between the pupil compared to accommodative phase at either the minimum (p = 0.30) or the maximum (p = 0.79) accommodative response between spectacles or contact lenses.

There was no correlation with refractive error between change in the pupil size (r = -0.26, p = 0.17) with spectacles (r = -0.11, p = 0.59) or with contact lenses over the 2.50 D stimulus range. There is no correlation with refractive error as to when the pupil achieves its minimum after the maximum accommodative response (r = 0.17, p = 0.39) or maximum size (r = 0.01, p = 0.95) with spectacles. When measured with the patient wearing contact lenses, there was no correlation with refractive error as to when the pupil achieves its minimum after the maximum accommodative response (r = 0.31, p = 0.10) or maximum size (r = 0.01, p = 0.95) with spectacles.

The vergence amplitude (when the eye was on average 15.95 ± 2.78° (range 9.45 to 22.94°) with spectacles and 16.92 ± 2.36° (range 12.15 to 22.94°) with contact lenses. There was no significant difference between the magnitude of vergence exerted when wearing spectacles compared to contact lenses ($p = 0.11$). The peak vergence response as measured with the patient wearing spectacles occurred on average 0.04 ± 0.14 s (range -0.38 to 0.36 s) before the maximal accommodative response. The minimum vergence occurred on average 0.03 ± 0.26 s (range -0.85 to 0.55 s) before the minimum accommodative response. With contact lenses the peak vergence response occurred on average 0.06 ± 0.16 s (range -0.32 to 0.54 s) before the maximal accommodative response. The minimum vergence occurred on average 0.03 ± 0.19 s (range -0.53 to 0.40 s) before the minimum accommodative response. There was no significant difference in phase between vergence and accommodation at either the minimum ($p = 1.00$) or maximum ($p = 0.72$) accommodative response, between spectacles or contact lenses.

There was no significant correlation between refractive error and the total vergence exerted with either spectacles ($r = 0.35$, $p = 0.08$), or contact lenses ($r = -0.19$, $p = 0.33$) or the time to vergence maximum ($r = 0.31$, $p = 0.11$) wearing spectacles or contact lenses ($r = 0.23$, $p = 0.25$).

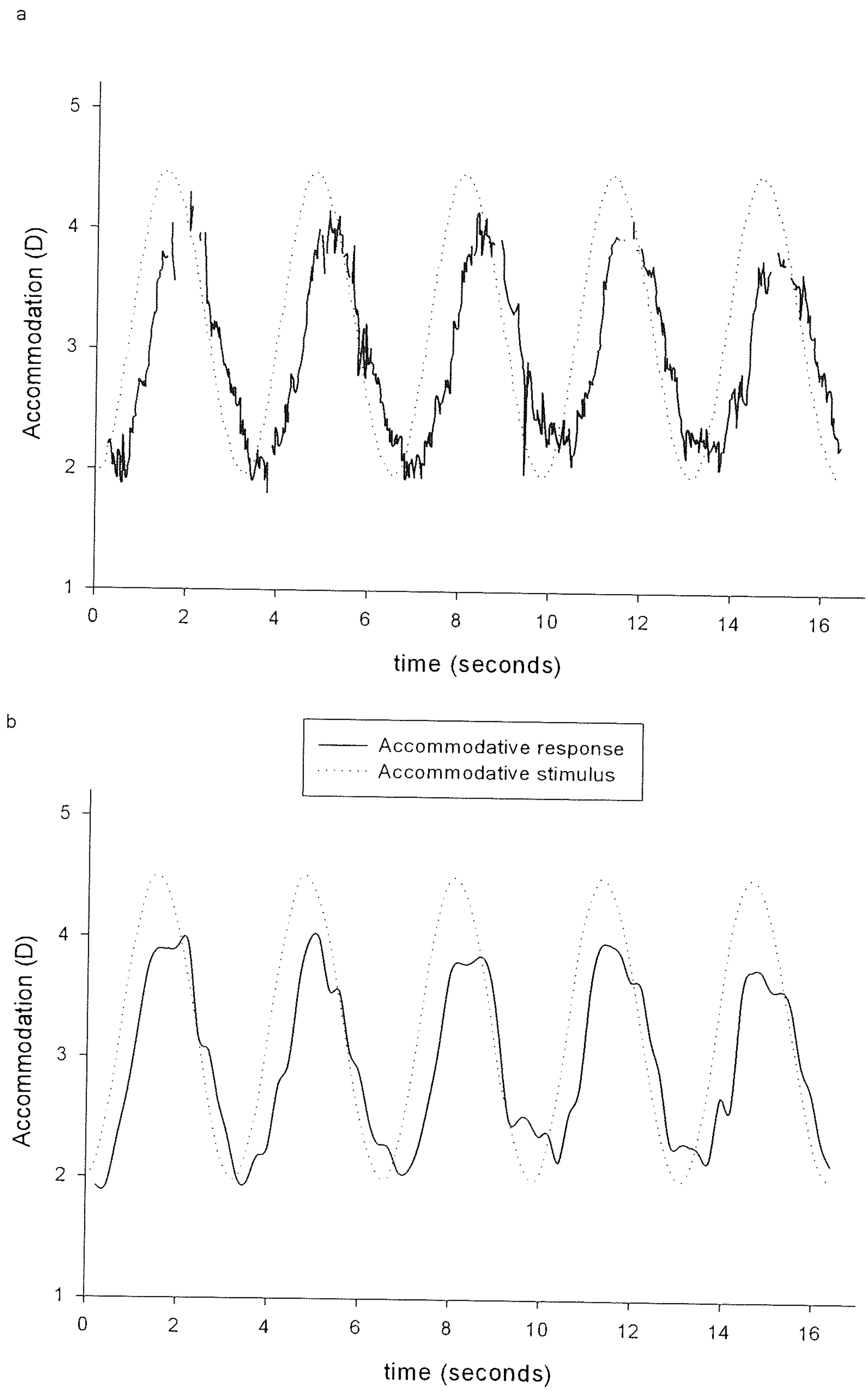


Figure 5.7 (a) Original accommodative response unsmoothed and (b) smoothed (subject 27) with contact lenses as measured with the *SRW-5000*.

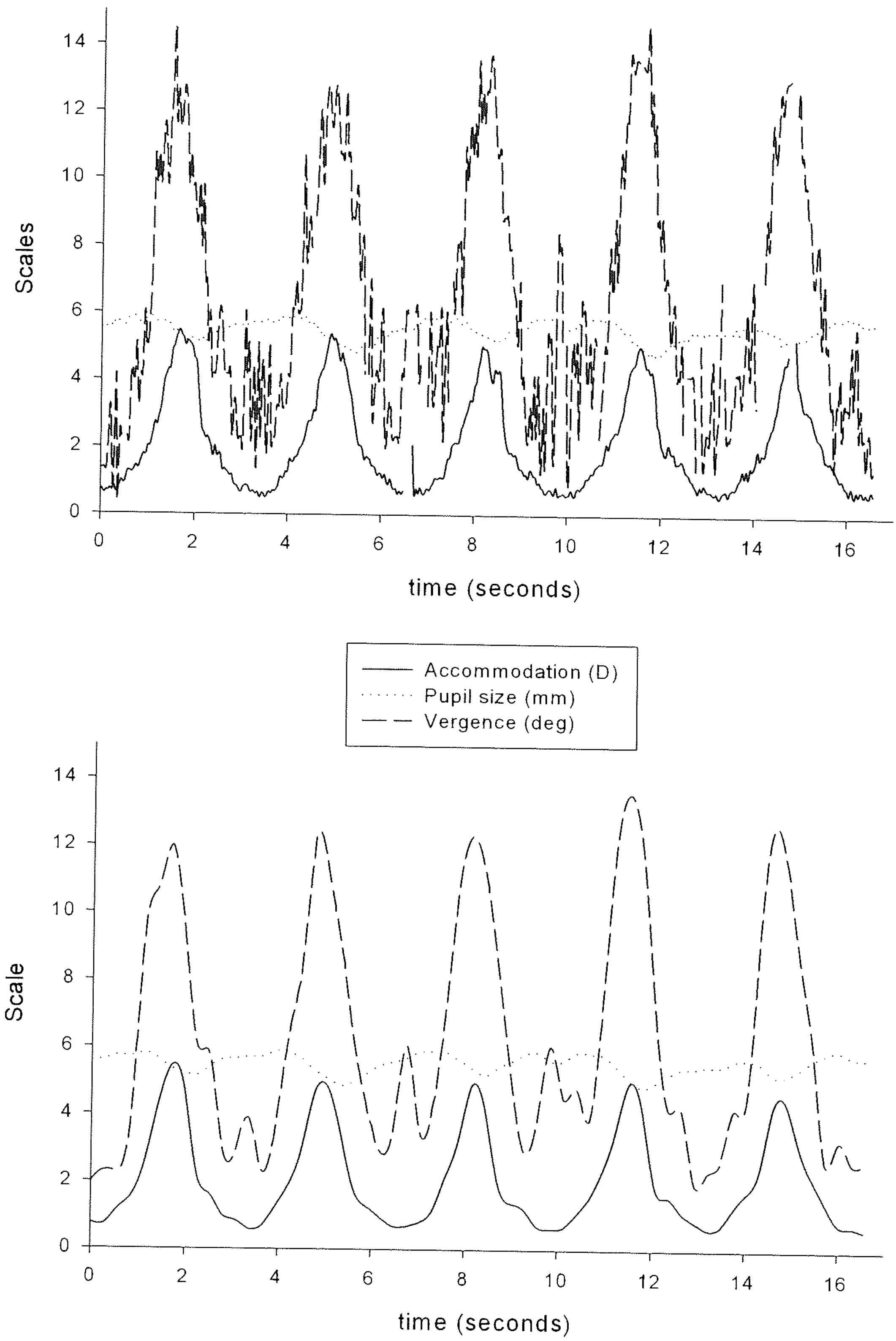


Figure 5.8 (a) Original accommodation, vergence and pupil responses unsmoothed and (b) smoothed (subject 27) with contact lenses as measured with the *PowerRefractor*

Discussion

The results of this study support the theoretical difference in accommodation and vergence demands when wearing single vision contact lenses compared to spectacle lenses (Alpern, 1949; Robertson, Ogle and Dyer, 1967; Stone, 1967; Sampson, 1969, 1971). Myopes were shown to exert more accommodation and vergence when wearing single vision contact lenses compared to spectacles and conversely hypermetropes exert less accommodation and vergence when wearing single vision contact lenses compared to spectacles. Unlike previous clinical studies (Herman and Johnson, 1966; Robertson, Ogle and Dyer, 1967; Herman, 1971), the measures were objective, were taken with natural pupils and measured true accommodation rather than presuming ophthalmic lenses cause their full power to be exerted.

Interestingly, the effect was only significant when measured by the *PowerRefractor* rather than the *SRW-5000*. However, unlike that measured by the *PowerRefractor* the lead of accommodation with the *SRW-5000* appears to follow the same trend, but even a combination of the accommodative lead and response does not reach significance ($p = 0.26$). The tendency of the *PowerRefractor* to overestimate measured accommodation with increased demand has been shown in chapter 4 and this is likely to have enhanced the result found in this study. It is unlikely that the contact lenses had much of an effect on the linearity of the intensity profile across the pupil as they will have an even thickness across the pupil and therefore light will be refracted equally in all parts of the pupil.

No previous studies have dynamically measured the link between accommodation and vergence when wearing contact lenses compared to glasses. Over the 2.5 D range investigated, the range of accommodation (on average 1.7-1.9 D) and time lag (on average

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No previous studies have dynamically measured the link between accommodation and vergence when wearing contact lenses compared to glasses. Over the 2.5 D range investigated, the range of accommodation (on average 1.7-1.9 D) and time lag (on average

0.15-0.25 s) were similar to that previously found (reviewed by Charman and Heron, 2000). The *PowerRefractor* showed average changes of accommodation (4.2 - 4.4 D) rather than the accommodative demand (2.5 D) as was previously shown in chapter 4 The vergence amplitude was on average 16-17° (calculated by Schaeffel's formulae that convergence of the fixation axes = measured convergence * 0.5729 (now degrees) + 2* kappa (deg) + arctan (interpupillary dist/1000) (in mm), *personal communication*, 2002), whereas only 9° would be predicted from the angular change between targets at 22 cm to 50 cm (presuming a 60 mm interpupillary distance), suggesting the *PowerRefractor* over-reads vergence as well as accommodation. Vergence was on average in phase with accommodation, highlighting that they are closely linked, although there was a wide intersubject variation.

As the near triad links accommodation, vergence and pupil size, it might be expected that pupil size changes with accommodative demand differ with refractive error, although the strength of this link for size matched targets has been questioned (Phillips, Winn and Gilmartin, 1992) and no relationship was found in this study as predicted by Robertson, Ogle and Dyer (1967). However, the pupil size did differ with both static and dynamic changes in the accommodative demand and the change lagged behind accommodation and vergence on average by 0.25-0.55 s, suggesting that accommodation and vergence do affect pupil size, even with a constant size target.

The differences in oculomotor status between contact lenses and spectacles are an important clinical consideration in early presbyopes and in individuals with binocular vision anomalies. The findings of this study have particular implications for incipient presbyopic myopes, for example an average -5.00 D myope focusing at 33 cm will exert 3.00 D of accommodation with spectacles and 3.75 D with contact lenses. The discrepancy is greater than that found using monocular ray tracing used in previous studies and can be contributed to vergence effects driving the accommodative system.

In conclusion, this study has objectively and simultaneously measured the binocular differences in oculomotor triad response (ocular accommodation, vergence and pupil size) over a wide range of refractive error, identifying that theoretical calculations are correct in direction, but underestimate the magnitude of the difference between spectacles and contact lenses. This effect is also relevant to the increasing number of people undergoing refractive surgery and should be discussed with the prospective patient in advance of any procedure.

CHAPTER 6

THE PROGRESSIVE ADDITION LENS PARADIGM IN MYOPIA CONTROL: IS THERE A ROLE FOR CONTACT LENSES?

Introduction

Myopia is a refractive condition of the eye in which the images of distant objects are focused in front of the retina when accommodation is relaxed, causing distance vision to be blurred (Millodot, 1993). This is normally corrected by spectacles, contact lenses or, more recently refractive surgery. Animal and human studies have shown that myopia is caused by an increase in the axial component of the eye that is not neutralised by a concomitant change in corneal curvature (Grosvenor and Scott, 1991). However, a common question posed clinically within optometric practice is, is it possible to retard the progression of myopia (Bullimore, 2000)?

There is a wide variation in the figures reported regarding the prevalence of myopia. These variations arise from difference in the population samples and in the methodology utilised (Weale, 2003). Refractive error has a wide range of distribution in newborn infants with myopia being present in approximately 19% of Caucasian infants. In preschool children the emmetropisation process is thought to reduce the prevalence of myopia to 2-3% for Caucasian children. However, by the age of 6 the prevalence of myopia rises to approximately 6% and 25% of Caucasian young adults (reviewed by Logan, 2004). The prevalence of myopia varies considerably with race with 73% of Chinese children aged 15 years having a myopic prescription greater than -0.50D (He *et al.*, 2004). Edwards *et al.*, (2002) report that the prevalence of myopia has increased from approximately 30% to 70% in young Hong Kong adults within a generation and this was regarded as strong evidence for an environmental causal factor. This increase in the prevalence of myopia is a growing public health problem as myopia is associated with conditions such as myopic maculopathy, macular holes, retinal detachment, an increased prevalence to certain types of cataracts and primary open angle glaucoma (Kanski, 1994).

Environment and heredity both seem to play a major role in the development of myopia. Children with myopia are more likely to have parents with myopia, spend significantly more time studying, more time reading and less time playing sports than emmetropic children (Parssinen and Lyyra, 1993, Mutti *et al.*, 2002). Therefore, it has been known for practitioners to prescribe bifocals to children in the hope that these will help decelerate the progression of myopia. The rational was considered to be simple, in that if accommodation is related to the progression of myopia, then bifocals may retard its development by reducing accommodative demand.

Recent studies have suggested there may be another mechanism whereby progressive lenses and bifocals may help alleviate some of the progression of the development of myopia. In young animals, myopia can be induced by preventing the incoming light being sharply focussed on the retina (Smith and Hung, 1999). When Gwiazda *et al.*, (1993) measured the accommodative responses of myopic children, they found that even when accurately corrected, myopes showed a weaker accommodative response to near objects than emmetropic children. This finding was confirmed by O'Leary and Allen (2001) who found that myopes in general had slower accommodative response to positive and negative lenses than emmetropes. However, Nakatsuka and colleagues (2003) found no difference in accommodative accuracy with refractive error in early-onset myopes corrected by spectacles viewing a target binocularly. Fulk, Cyert and Parker (2000) suggested that a reduced accommodative response in children who have myopia that is progressing, may cause a slight retinal blur which could then stimulate faster myopia development, similar to the blur induced myopia found in animals. Bifocals could therefore compensate for the reduced accommodative response and sharpen the image that falls on to the retina, leading to retardation in myopia progression.

The results from randomised trials with bifocal/progressive addition lenses have been equivocal. The Houston Myopia Control Study examined 207 children between 6 and 15 who wore either bifocals with a +1.00 or 2.00 add, or single vision lenses. After the three year follow-up period there was no evidence of a retardation of myopia progression (Grosvenor, 1987). Fulk, Cyert and Parker (2000) conducted a randomised clinical trial investigating the outcome of correcting mildly myopic esophoric children with either single vision lenses (n = 40) or bifocal lenses with a +1.50 add (n = 42). It was noted that over the 30 month trial the average progression for those using single vision lenses was 1.24 D compared to 0.99 D for those using bifocals. However, at the end of the trial the authors still did not feel that prescribing bifocals was of use to all esophoric myopic children. The authors noted that failure of bifocals to prevent the progression of myopia may occur from the incorrect use of the bifocals, with several children found to read over the near segment.

In a clinical trial conducted by Leung and Brown (1999) in Hong Kong, 22 children were assigned to wear progressive lenses (PALs) with +1.50 D addition (P1), 14 to lenses with +2.00 D addition (P2), and 32 in an age-matched single vision control group. The initial myopia level was -3.73 D for the children assigned to +1.50 D additions, -3.67 D for children wearing +2.00 D additions, and -3.67 D for children wearing single vision lenses. The myopia levels changed by -1.23 D for SV, -0.76D for P1 and -0.66 D for P2. This difference was found to be significant. ($p<0.001$). To follow-up the results of this study, Edwards *et al.*, (2002) carried out a 2 year clinical trial where children from Hong Kong between 7 and 10 years wore either single vision correcting lenses (n = 121) or progressive addition lenses (PALs; n = 133). PALs were thought to be more cosmetically acceptable than bifocals and were hoped to improve compliance with the trial. The lens was designed with a short corridor to allow clear intermediate vision, but so that the near vision point of the lens could be reached with minimum eye depression. The near optical point of the PALs in the study was 10mm below the distance optical centre whereas for the normal adult PAL it is 14-16 mm. The +1.50 D addition aimed to reduce, but not prevent the need for accommodation and was a compromise between peripheral distortion and comfort. However, the findings of the study showed no statistical differences between the PALs and single vision group for either myopia or refractive error. There was a statistically significant increase in both axial length and myopia, but there was no difference in the increases that occurred between the two refractive groups.

However, a recent large scale USA study run by the COMET group (Gwiazda *et al.*, 2003) has shown that PALs can significantly retard the progression of myopia in children, on average by 0.06 D/year compared to single vision controls. The trial involved 469 children followed over a three year period, although, the majority of the total treatment effect (0.2 D on average) occurred in the first year of the study. The results provided some support for the role of defocus in the progression of myopia, but again the authors felt that the small magnitude of the effect does not warrant a change in clinical practice.

The role of single vision contact lenses in the retardation of myopia progression have also been investigated, as they have a wider corrected field-of-view and provide cosmetic benefits. However there are several potential complications of contact lens use, especially in children, include allergic conjunctivitis, corneal infiltrates, infective keratitis and contact lens hygiene compliance (Saw *et al.*, 2002).

Although previous studies to control myopia development with contact lenses indicate that rigid gas permeable and PMMA contact lenses slow the progression of myopia in children, the clinical significance in limited due to methodological flaws such as having non-randomised samples (e.g. Kelly, Chatfield and Tustin, 1975) and high drop out rates (e.g. Stone, 1974) (reviewed by Saw *et al.*, 2002). A large scale trial is currently being carried out by the Contact Lens and Myopia Progression (CLAMP) group which is a randomised clinical trial examining the effects of gas permeable contact lenses on myopia progression in children. This group has to date only published limited data on how the trial has been conducted (Walline *et al.*, 2001). However, in a recent randomised clinical trial of rigid contact lenses with 383 Singaporean children aged between 6 to12 years of age over two years, there was no significant differences in the rate of progression of myopia or axial length in children wearing contact lenses compared with those wearing glasses (becoming 1.33 D and 1.28 D more myopic respectively; Katz *et al.*, 2003).

Multifocal and bifocal contact soft contact lenses have the advantage over spectacle lenses that they remain essentially aligned with the visual axis regardless of the direction of gaze. If a reduced requirement for accommodation is linked to the retardation of myopia progression, such lenses may be the obvious correction choice. However, before large scale studies are undertaken, it is important to ascertain whether simultaneous vision contact lenses do reduce the accommodative response of individuals with active accommodation (pre-presbyopes) and that is the aim of this study.

Method

Twenty subjects aged 18 – 25 (average 21.40 ± 3.07 years: 8 male, 12 female) gave informed consent to take part in the study. Each subject underwent a full binocular refraction using the criteria outlined in Chapter 2 and was only included in the study if there was no evidence or history of binocular vision anomalies or ocular pathology. All the subjects could attain at least 6/6 visual acuity in each eye. The range of mean spherical refractive error was -5.50 D to +3.50 D, measured at 6 m. Patients with astigmatism greater than -0.75 D were excluded from the study.

The measurements were made with subjects fully corrected (in random order) by each of Johnson and Johnson *Acuvue* daily disposables (SVCL), UltraVision *Igel Multifocals* (MFCL) and Johnson and Johnson *Acuvue Bifocals* (BFCL) contact lenses. Both MFCL and BFCL had a near addition of +2.50 D. This BFCL only comes in this addition, leading to a working distance of 40cm which is appropriate to young adults. The single vision *Acuvue* is a moulded 58% water content daily disposable contact lens, the *UltraVision Igel Multifocal* is a lathe cut 38% water content, centre near conventional wear lens and the *Acuvue Bifocal* is moulded 58% water content, multi-concentric 'pupil intelligent' disposable contact lens. After insertion of the contact lens, a twenty minute adaptation period was given before assessment of the lens. The lenses were assessed in a single session, in a randomised order.

Subjective AC/A ratios were measured with a Maddox wing, measuring the horizontal heterophoria at 33 cm with plano, +2 D and -2 D trial lenses at a 13mm vertex distance.

Accommodative responses were measured using the *PowerRefractor* and the *Shin Nippon SRW-5000* through undilated pupils in a randomised order. The subject's head was positioned on a head and chin rest. The *PowerRefractor* was positioned 1 m from the subject, aligned with the right eye, but positioned to image both of the subject's eyes. The *SRW-5000* was aligned with the visual axis of the right eye and measured the accommodative response of this eye only, although the subject had a binocular open-field view of the targets. Subjects viewed a static, 90% contrast, Maltese cross located at 0.1, 0.5, 1.0, 2.0 and 3.0 D accommodative demand in free space (matched for angular subtense and luminance), in a random order. Five static readings were taken with both the *PowerRefractor* (full refraction mode) and *SRW-5000* at each distance. All patients were asked to carefully focus on the target and to try to keep it as clear, as if they were reading, whilst the measurements were being taken (Stark and Atchison, 1994). The illuminance of the room was kept constant at 40 lux and the target kept at 5 Cdm-2. This particular luminance was chosen to maintain a pupil size adequate to achieve measurements at all distances with the *PowerRefractor*. The luminance was kept the same for the *SRW-5000* measures so as not to affect the stimulus response curve (Johnson, 1976).

Dynamic accommodation was measured from the right eye with both the *Shin-Nippon SRW-5000* (Wolffsohn *et al.*, 2001) and *PowerRefractor* (Hunt *et al.*, 2003). Subjects tracked an oscillating target (90% contrast Maltese cross, size 6/12 Snellen equivalent,) in real space between 50cm to 22cm at a frequency of 0.30 Hz. The *SRW-5000* is able to monitor dynamically the accommodative response with a high resolution and a frequency of up to 50 Hz (Wolffsohn *et al.*, 2001). The data was smoothed by averaging over 0.4 s time intervals (approximately 20 measurement) and blinks were removed (Wolffsohn *et al.*, 2003). Measurements of vergence and pupil size were recorded from the *PowerRefractor*.

Aberrations across the undilated pupil were quantified using a *Zywave* (*Bausch & Lomb*, Rochester, New York, USA) wavefront-sensing device, which is based on the Hartman-Shack principle. The measured deviation of the 780 nm wavefront (at 70-75 locations within the pupil area) as it passes through the optics of the cornea and intraocular lens is displayed in terms of lower order (i.e. sphere and cylinder, combined to give a 'predicted phoropter refraction' (PPR) term) and high order (i.e. trefoil and coma) aberrations.

STATISTICAL ANALYSIS

The results were entered into a spreadsheet, converted into mean spherical equivalents and the slope and the AEI (Accommodative Error Index, Chauhan and Charman, 1995 as discussed in Chapter 4) were calculated for each subject with both the *PowerRefractor* and *SRW-5000*. Dynamic traces were plotted, smoothed (running average function, SigmaPlot v6, SPSS) and the amplitude of response and lag between the target and response calculated (averaged across five target cycles). One-way within-subject (repeated measures) (ANOVAs) were used to identify oculomotor differences between the three types of lens wear.

Results

When measured with the *SRW-5000* the accommodative response at a static 3.0D demand when corrected by SVCLs was 2.21 ± 0.52 D (range 0.84 to 3.03 and the slope and AEI of the stimulus response curve were 0.95 ± 0.16 (range 0.59 to 1.21) and 0.79 ± 0.46 respectively (range -0.14 to 1.47) (Figure 6.1). When corrected by BFCLs, the accommodative response at 3.0 D demand was 1.71 ± 0.57 D (range 1.03 to 3.15) and the slope and AEI of the stimulus response curve were 0.82 ± 0.18 (range 0.46 to 1.15) and 0.50 ± 0.53 (-0.18 to 1.85) respectively. When corrected by MFCL, the accommodative response at 3.0 D demand was 1.83 ± 0.58 D (range 0.60 to 3.30) and the slope and AEI of the stimulus response curve were 0.81 ± 0.46 (range 0.57 to 1.00) and 0.99 ± 0.77 (range -0.61 to 3.07) respectively. The linear correlation of the accommodative response and demand was high when wearing the SVCL ($r^2 = 0.98 \pm 0.02$, range 0.92 to 1.00), BFCL ($r^2 = 0.96 \pm 0.08$, range 0.62 to 1.00) or MFCL ($r^2 = 0.96 \pm 0.05$, range 0.81 to 1.00). ANOVA showed there was a significant effect of the type of contact lens on the amplitude of accommodation ($F_{(2,38)} = 5.87$, $p = 0.006$) and slope ($F_{(2,38)} = 7.35$, $p = 0.002$) and correlation ($F_{(2,38)} = 5.23$, $p = 0.01$), but no significant effect on the AEI ($F_{(2,38)} = 0.21$, $p = 0.82$) However, power analysis shows that the group size were sufficient to have only a 9% chance of detecting a change at the 5% level of significance.

When measured by the *PowerRefractor* the accommodative response at the 3.0 D static demand when corrected by SVCL was 2.39 ± 0.52 D and the slope and AEI of the stimulus response curve were 1.32 ± 0.28 and 0.83 ± 0.57 respectively (Figure 6.1). When corrected by BFCLs, the accommodative response at 3.0 D demand was 2.22 ± 0.95 D and the slope and AEI of the stimulus response curve were 1.23 ± 0.46 and 0.50 ± 0.62 respectively. When corrected by MFCL, the accommodative response at 3.0 D demand was 2.47 ± 1.00 D and

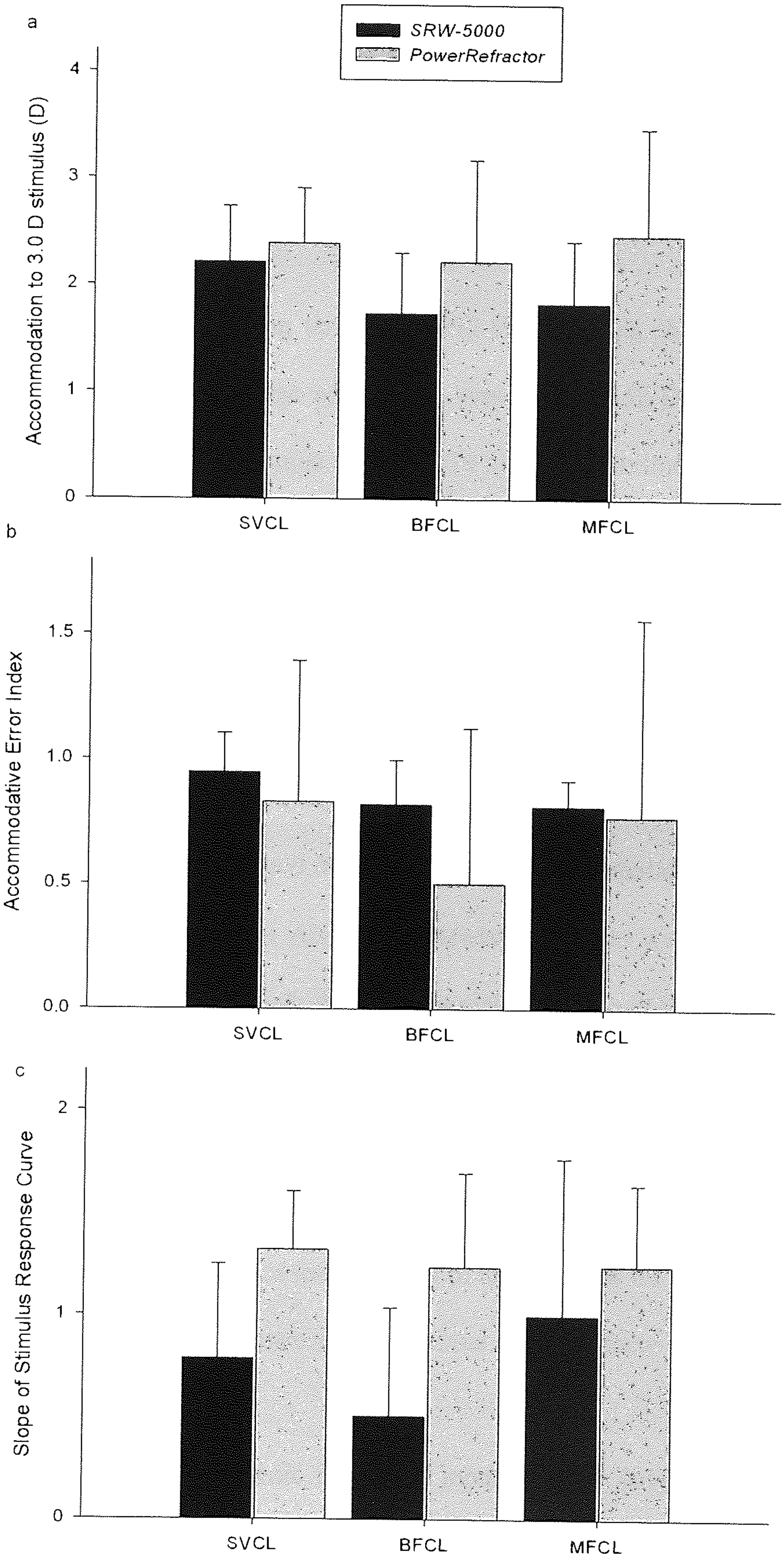


Figure 6.1: Comparison of average (a) accommodation (b) AEI and (c) slope of the stimulus response curve (with SD error bars) as measure by the *SRW- 5000 and the PowerRefractor.*

the slope and AEI of the stimulus response curve were 1.24 ± 0.40 and 0.77 ± 0.78 respectively. The linear correlation of the accommodative response and demand was high when wearing the SVCL ($r^2 = 0.98 \pm 0.02$), BFCL ($r^2 = 0.95 \pm 0.05$) or MFCL ($r^2 = 0.97 \pm 0.11$).

When measured dynamically using the *SRW-5000* (Figure 6.2), the average amplitude of accommodation over a 2.50 D range with SVCL was 1.94 ± 0.52 D (range 1.22 to 3.00 D) with a time lag of 0.27 ± 0.19 s (range 0.00 to 0.79 s) at the maximal near focus (peak) and 0.14 ± 0.16 s (range 0.00 to 0.65 s) at the maximal distance focus (trough). With BFCL the amplitude of accommodation was 1.31 ± 0.58 D (range 0.24 to 2.27 D) with a time lag of 0.21 ± 0.16 s (0.00 to 0.49 s) at the maximal near focus and 0.13 ± 0.11 s (range 0.00 to 0.38 s) at the maximal distance focus. With MFCL the amplitude of accommodation was 1.59 ± 0.53 D (range 0.74 to 2.54 D) with a time lag of 0.22 ± 0.22 s (0.00 to 0.85 s) at the maximal near focus and 0.16 ± 0.15 s (range 0.00 to 0.45 s) at the maximal distance focus. One-way within-subject (repeated measures) ANOVAs showed there was a significant effect of the type of contact lens on the amplitude of accommodation ($F_{(2,38)} = 4.23$, $p = 0.025$), but no significant difference between the SVCLs, BFCLs and MFCLs for time lag at the maximal near focus point ($F_{(2,28)} = 1.96$, $p = 0.16$) or at the maximal distance focus ($F_{(2,38)} = 0.17$, $p = 0.84$). However, power analysis shows that the group size were sufficient to have only a 37% chance of detecting a change at the 5% level of significance for time lag at the maximal near focus point and only a 9% chance at the maximal distance focus point.

Using the *PowerRefractor's* dynamic recording mode (Figure 6.3), the average measured amplitude of accommodation over a 2.50 D dynamic range was 4.00 ± 1.22 D (range 2.01 to 6.62 D) with SVCL, 3.72 ± 1.18 D (range 1.48 to 6.09 D) with BFCL and 4.19 ± 1.56D (range 2.21 to 7.61 D) with MFCL. As the *PowerRefractor* could not be time-synchronised with the target, time lag could not be calculated. One-way within-subject (repeated measures) ANOVAs showed there was no significant effect of the type of contact lens on the amplitude of accommodation ($F_{(2,38)} = 1.41$, $p = 0.26$). However, power analysis shows that the group size were sufficient to have only a 29% chance of detecting a change at the 5% level of significance.

The pupil size change was on average 0.60 ± 0.22 mm (range 0.16 to 1.03 mm) with SVCL, 0.77 ± 0.30 mm (range 0.34 to 1.37 mm) with BFCL and 0.66 ± 0.26 mm (range 0.30 to 1.32 mm) with MFCL over the 2.50 D stimulus range. One-way within-subject (repeated measures) ANOVAs showed there was no significant effect of the type of contact lenses worn on the change in pupil size ($F_{(2,38)} = 3.15$, $p = 0.54$). However, power analysis shows that the group size were sufficient to have only a 57% chance of detecting a change at the 5% level of significance. The pupil achieved its minimum size on average 0.32 ± 0.21 s (range 0.00 to 0.85 s) after the maximum accommodative response and 0.56 ± 0.31 s (range 0.00 to 1.18 s) after the minimum accommodative response when measured with SVCL. When measured with the patient wearing BFCL, the pupil achieved its minimum size on average 0.32 ± 0.17 s (range 0.09 to 0.89 s) after the maximum accommodative response and 0.43 ± 0.15 s (range 0.14 to 0.65 s) after the minimum accommodative response and when measured with the patient wearing MFCL, the pupil achieved its minimum size on average 0.25 ± 0.13 s (range 0.09 to 0.45 s) after the maximum accommodative response and 0.35 ± 0.20 s (range 0.00 to 0.68 s) after the minimum accommodative response. One-way within-subject (repeated measures) ANOVAs showed there was no significant effect with the type of contact lens worn on the change in pupil size at the maximum response ($F_{(2, 38)} = 0.88$, $p = 0.43$) or at the minimum accommodative response ($F_{(2, 38)} = 2.52$, $p = 0.95$). However, power analysis shows that the group size were sufficient to have only a 19% chance of detecting a change at the 5% level of significance for pupil size at the maximum response and only a 47% at the minimum response level.

The vergence amplitude was on average 16.75 ± 2.77° (range 12.15 to 22.94°) with SVCLs, 16.83 ± 3.08° (range 6.06 to 20.78°) with BFCLs and 16.79 ± 2.46° (range 13.74 to 23.51°) with MFCLs. A one-way within-subject (repeated measures) ANOVA showed there was no significant effect of the type of contact lenses worn on the vergence response ($F_{(2, 38)} = 0.91$, $p = 0.41$). However, power analysis shows that the group size were sufficient to have only a 20% chance of detecting a change at the 5% level of significance. The peak vergence response as measured with the patient wearing SVCLs occurred on average 0.05 ± 0.19 s (range -0.32 to 0.54 s) before the maximal accommodative response. The minimum vergence occurred on average 0.01 ± 0.18 s (range -0.31 to 0.40 s) before the minimum accommodative response. With BFCLs the peak vergence response occurred on average 0.13 ± 0.14 s (range -0.40 to 0.13) before the maximal accommodative response. The minimum vergence occurred on average 0.31 ± 0.19 s (range 0.00 to 0.82 s) before the minimum accommodative response. With MFCLs the peak vergence response occurred on average 0.01 ± 0.14 s (range -0.27 to 0.40) before the maximal accommodative response. The minimum vergence occurred on average 0.07 ± 0.18 s (range -0.45 to 0.32 s) before the minimum accommodative response. One-way within-subject (repeated measures) ANOVAs showed there was a significant effect of the type of contact lens on the peak vergence response ($F_{(2,38)} = 4.38$, $p = 0.02$) and at the minimum response ($F_{(2,38)} = 23.88$, $p = 0.0005$). The average measured AC/A ratio of the subjects was 2.91 ± 0.94 (range from 0.75 to 4.00).

Measurement of RMS values was only possible in 17 of the 20 subjects due to the non dilation of the subjects to maximize accommodative responses. The average Zernike RMS value for 6 mm pupil measured when the subject was corrected by SVCL was 0.99 ± 0.55 D (range 0.29 to 2.17) with an average higher order aberration of 0.38 ± 0.12 D (0.15 to 0.64). When corrected by BFCL the average Zernike RMS value for 6mm pupil was 1.31 ± 0.52 D (range 0.53 to 2.36) with an average higher order aberrations of 0.55 ± 0.14 D (0.29 to 0.80) and when measured with the subjects wearing MFCL the average Zernike RMS value for 6mm pupil was 1.31 ± 0.45 D (range 0.61 to 3.86) with an average higher order aberrations of 0.45 ± 0.17 D (0.18 to 0.80). There was no significant effect in the type of contact lens worn on the RMS values measured ($F_{(2, 32)} = 2.07$, $p = 0.14$) (power analysis 40% power although higher order aberrations were significantly greater for bifocal contact lens compared to single vision or multifocal contact lenses ($F_{(2, 32)} = 7.23$, $p = 0.003$).

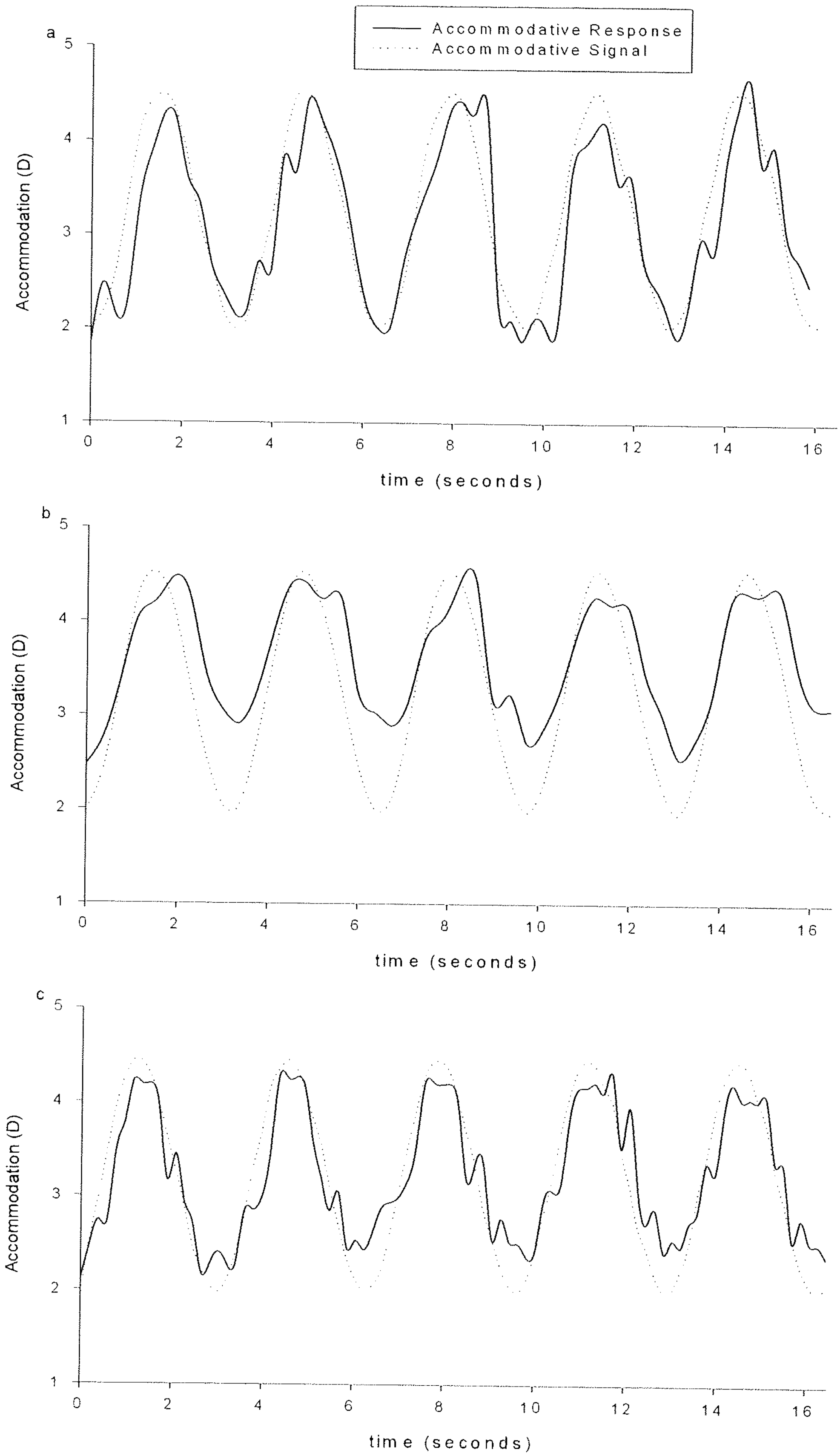


Figure 6.2: Sample smoothed responses for patient 3 for (a) SVCL, (b) BFCL and (c) MFCL measured with the *SRW-5000*.

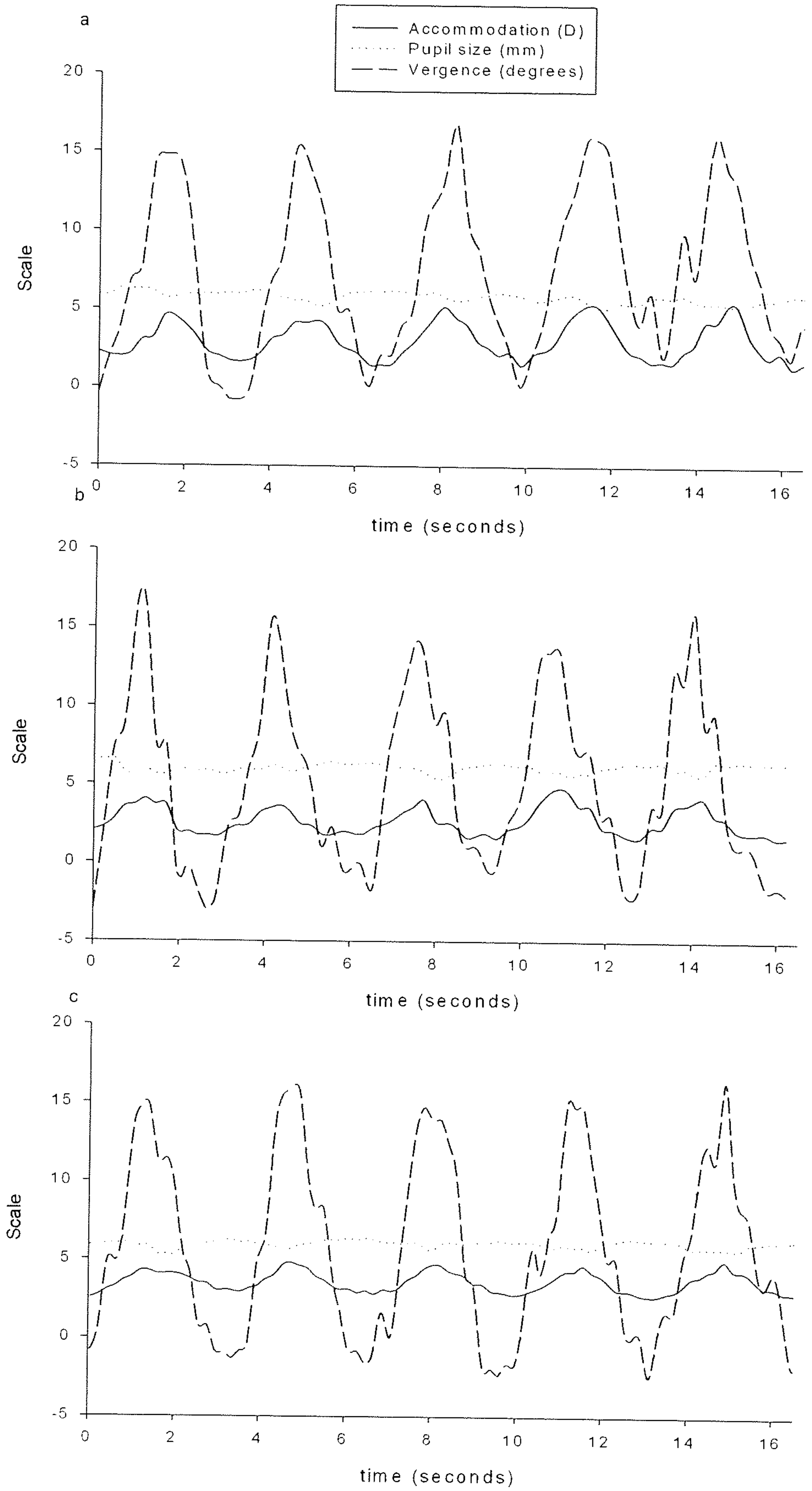


Figure 6.3: Sample smoothed responses for patient 3 for (a) SVCL, (b) BFCL and (c) MFCL measured with the *PowerRefractor*.

Conclusion

Contact lenses have a number of advantages over spectacles in myopia control trials: the near addition remains in the line of sight with eye movement, they are less likely to be removed and are more acceptable cosmetically. The findings of this study indicate that both bifocal and to a lesser extent multifocal contact lenses significantly reduce the need for ocular accommodation by on average 23% and 18% respectively (for a 3 D target, measured by the *SRW-5000*). The effect was similar, a reduction in the exerted accommodation by 33% when wearing BFCLs and 19% when wearing MFCLs, when measured dynamically over the 2.50 D range by the *SRW-5000*), although the time lag behind the target was unaffected. Interestingly, when measured by the *PowerRefractor* the results of accommodation exerted do not achieve significance. Previous chapters (e.g. chapter 4) have shown the increased variability and magnitude of the apparent accommodative response as measured by the *PowerRefractor* compared to the *SRW-5000* and this is likely to have masked the changes between contact lens types identified by the *SRW-5000*. However, the bifocal and multifocal lens designs are likely to have affected the slope of the intensity profile across the pupil and hence the apparent measured *PowerRefractor* accommodation.

As expected, there was no significant effect of the type of contact lenses worn on the change in pupil size or latency of the pupillary response with accommodative demand. Despite an AC/A ratio of approximately 3 prism dioptres per dioptre and a significantly lower accommodative response with BFCLs and MFCLs compared to SVCLs, there was no difference between the different lens types in the magnitude of the vergence response. However, the vergence response seems to have been driven in advance of the accommodation response when wearing BFCLs (by approximately 0.1 to 0.3s). The single near addition nature of a bifocal lens and hence more blurred secondary image (compared to the progressive change in near addition power of a MFCL) may result in an increased drive to the oculomotor vergence mechanism due to the desire to create a clearer image.

There was no significant difference in the RMS values measured when the three types of contact lenses were worn, except for higher order aberrations. These are the aberrations that are third order and higher polynomials and which are not easily corrected with spectacle lenses. Aberrations degrade the retinal image quality, possibly enhancing myopia progression in individuals with significant levels of higher order aberrations. So, although the BFCL and MFCL reduce the amount of accommodation exerted, they appear to increase the level of higher order aberrations by approximately 45% and 18% respectively, which may cause the patient to experience more blur and make them less visually acceptable.

It was not possible to determine how much near addition power the individual was deriving from the BFCL or MFCL as this will depend on the pupil size, lens centration, lens power profile, biometric area over which the instrumentation utilised measures accommodation and subjective tolerance to blur, so the study cannot determine accommodative accuracy. However, as the study used a with-in subject design, it is possible to conclude that BFCLs and MFCLs reduced the accommodative effort exerted by subjects compared to SVCLs, although only by approximately 20-30%. As bifocal contact lenses are no less cosmetically acceptable than multifocal contact lenses and the effect was greater (for the particular lens designs examined), bifocals contact lenses may be the better option for further studies to investigate whether myopia progression can be retarded by reduced accommodative demand (and perhaps improved accommodative accuracy).

CHAPTER 7

OBJECTIVE ACCOMMODATIVE AMPLITUDE AND DYNAMICS WITH THE *1CU* 'ACCOMMODATIVE' INTRAOCULAR LENS

Introduction

Accommodation is the process by which the eye changes focus from distance to near and is produced by a change of shape of the lens from the action of the ciliary muscles on the zonular fibres. It is mainly driven by the parasympathetic innervation of the ciliary smooth muscle, which causes the muscle to slide forward and inwards. This causes a reduction in the diameter of the ciliary collar that leads to a relaxation of the tension of the zonular fibres and a release of the visco-elastic properties of the lens capsule and the lens substance. This results in an axial thickening of the nucleus of the lens, a decrease in the anterior lens radius, a central bulge of the anterior central portion of the lens and an increase in the dioptric power of the lens (Gilmartin, 1995).

Presbyopia is a condition of age, where by the normal age-related reduction in amplitude of accommodation reaches a point when the clarity of vision at near cannot be sustained for long enough to satisfy the individual's requirements (Gilmartin, 1995). The ability to accommodate is essentially lost by the age of 55 years (Ramsdale and Charman, 1989). However, techniques such as impedance cyclography, ultrasound biomicroscopy and magnetic resonance imaging have shown the ciliary body retains much of its contractility throughout life; hence the reduction in amplitude is due to a loss of elasticity of the lens (Swegmark, 1969; Bacskulin *et al.*, 1996; Stenk *et al.*, 1999).

Replacing the natural lens with a multifocal intraocular lens has been described as an effective surgical method to obtain clear vision at both near and distance (Gray and Lyall, 1992; Javitt and Steinert, 2000; Slagsvold, 2000). However, it can lead to a reduction in visual function such as contrast sensitivity (Kamlesh, Dadeya and Kaushik, 2001; Montes-mico and Alio, 2003) and symptoms such as glare (Schmitz *et al.*, 2000). Pseudophakic accommodation would be ideally mimicked by refilling the lens capsule with a visco-elastic substance, similar to that found in the young crystalline lens. However, to-date this effect can only be achieved by an anterior shift in the intraocular lens (Hara *et al.,* 1990; Legeais *et al.*, 1999; Cumming, Slade and Chayer, 2001). Mimicking pseudophakic accommodation by refilling the lens capsule with a visco-elastic substance, similar to that found in the young crystalline lens, has received some attention (Nishi *et al.,* 1993, Young, 2003). However, the principal action of lenses of this type currently on the market (termed 'accommodating' intraocular lenses) is an anterior shift (Hara *et al.,* 1990, Legeais, 1999, Cumming, Slade and Chayet, 2001)

Subjective amplitude of accommodation has been measured in a number of studies (e.g. Nakazawa and Ohtsuki, 1983,1984; Kuchle *et al.*, 2002; Mastropasqua *et al.*, 2003; Langenbucher *et al.*, 2003a,b), being on average 1.33-2.36 D. However, the subjective amplitude accommodation of a single piece conventional intraocular lens is approximately 0.42-1.08 D, due to depth of focus and the optical aberrations of the human visual system (Kuchle *et al.*, 2002; Langenbucher *et al.*, 2003b). A subjective defocusing technique (fogging of a 5 m distance viewing eye in -0.5 D lens steps until visual acuity reduced to 20/50) has indicated an average accommodation of ~1.6 ± 0.5 D with the *1CU* 'accommodating' IOL compared to a single piece conventional intraocular lens of 0.55 ± 0.33 D (Langenbucher *et al.*, 2003a,b).

Attempts to quantify objectively the range of accommodation have included measurement of lens movement, streak retinoscopy, aberrometry and photorefraction (Dick and Kaiser, 2002; Kuchle *et al.*, 2002; Mastropasqua *et al.*, 2003; Langenbucher *et al.*, 2003a,b). Quantification of intraocular lens movement has been performed with ultrasound (Ravalico and Baccara, 1990; Auffarth *et al.*, 2002; Langenbucher *et al.*, 2003a, b), image analysis (Auffarth *et al.*, 2002) and partial coherence interferometry (Auffarth *et al.*, 2002; Kuchle *et al.*, 2002; Findl *et al.*, 2003; Langenbucher *et al.*, 2003a, b) before and after ciliary muscle contraction using pilocarpine or phenylephrine. The movement of the lens on maximal contraction varies greatly between studies and between measurement techniques, being on average between 100 and 1040 μm. Approximate objective accommodative range has then been modelled from this movement.

Streak retinoscopy to static targets (5.00 m compared to 0.35 m) has shown a range of accommodation of on average 1.0-1.2 D for the *1CU* accommodating IOL compared to ~0.2 ± 0.2 D for the single piece conventional IOL control group (Kuchle *et al.*, 2002; Langenbucher *et al.*, 2003b). Dynamic (7 Hz) aberrometry to stepped distance and near targets showed changes in defocus of up to 3.5 D although average data is not presented (Dick and Kaiser, 2002). Photorefraction using the difference in *PowerRefractor* measured with subjects viewing at 5.00 m compared to ~0.35 m showed a mean amplitude of 1.00 ± 0.44 D compared to 0.35 ± 0.26 D for the single piece conventional IOL control group (Langenbucher *et al.*, 2003b).

None of the studies assessing the accommodative facility achieved using an 'accommodative' intraocular lens have quantified the stimulus response curve or the dynamic accommodative response to a moving stimulus (Charman, 2003) and therefore this study aims to measure these features of patients fitted with the *1CU* (Figure 7.1) 'accommodative' intraocular lens. Determining the accommodative stimulus response curve will identify whether the 'pseudophakic' accommodation with an 'accommodative' intraocular lens continues to increase with increasing accommodative demand, asymptotes when accommodative demand exceeds the pseudophakic accommodative range or even decreases with increased target blur past a peak when the pseudophakic accommodative demand and response are matched. The dynamic accommodative response to a moving stimulus will determine whether the pseudophakic accommodative response is similar in dynamic amplitude to the static amplitude and whether the time-course (time lag between the stimulus and response) is similar to that of pre-presbyopic accommodation.

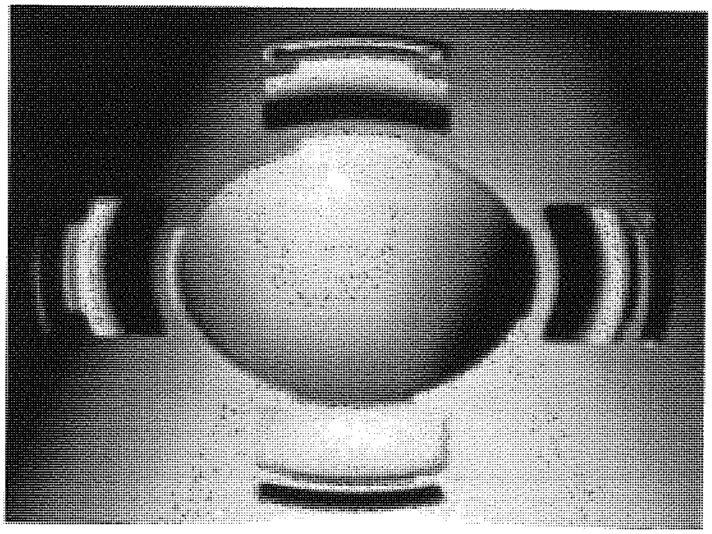


Figure 7.1: The *1CU* intra-ocular lens.

Method

Twelve subjects aged 33-78 years (average 60.7 ± 15.4; 3 male, 9 female) gave informed consent to take part in the study. All had recently (average 127.7 ± 70.9 days; Table 7.1) had phakoemulsification cataract surgery with a one (1) -component-unit (*1CU*) 'accommodative' intra ocular lens (HumanOptics AG, Erlangen, Germany) implanted in one or both eyes (twenty eyes). Each subject underwent a full subjective binocular refraction at 6m as described in Chapter 2.

The HumanOptics *1CU* lens is a single-piece, hydrophilic, acrylic, ultraviolet inhibited intraocular lens with a refractive index of 1.46. It has been shown to result in stable refraction and subjective accommodation over a one year period (Kuchle, 2003) central optic portion, 5.5 mm in diameter, is designed to rest against the post-capsular after the crystalline lens matrix has been removed by phakoemulsification cataract surgery. The optic has a hinged connection to four haptic 'legs', which are thinner near the optic to aid flexibility and allow movement of the optic anteriorly secondary to ciliary muscle contraction.

After retinoscopy and subjective refraction, best-corrected threshold letter acuity was measured distance with high (90%) and low contrast (10% at 3 m), and near threshold word acuity at near (40 cm) with logMAR progression charts (Bailey and Lovie, 1976; Wolffsohn and Cochrane, 2000). Each letter was scored as 0.02 logMAR and guessing was encouraged. Subjects with residual refractive error following surgery were made functionally emmetropic with ultra-thin soft contact lenses (*Acuvue Daily Disposables*, Johnson & Johnson) to ensure that the accommodative demand to view the task for each subject was virtually identical.

Patient	Eye	Age (years)	Gender	Time Since Surgery (days)
sm	R	33	M	184
	L			156
mk	R	41	F	60
	L			90
eh	L	47	F	238
sb	R	50	F	93
fm	R	56	F	149
bp	R	56	F	229
	L			284
af	R	64	F	60
	L			90
bc	R	71	F	116
	L			144
an	R	73	F	49
	L			35
km	R	75	M	140
	L			110
fc	R	78	M	13
jc	R	78	F	172
	L			142

Table 7.1: Demographics of the 12 patients implanted with the *1CU* accommodating intraocular lens.

Accommodative responses were measured using the *PowerRefractor* (Hunt *et al.*, 2003) and the *Shin-Nippon SRW-5000* (Mallen *et al.*, 2001) through undilated pupils in a randomised order. The subject's head was positioned on a head and chin rest. The *PowerRefractor* was positioned 1 m from the subject, aligned with the right eye, but positioned to image both of the subject's eyes. The *SRW-5000* was aligned with the visual axis of the eye under examination and measured the accommodative response of this eye only, although the subject had a binocular open-field view of the targets. Subjects viewed a static 90% contrast Maltese cross located at 0.17, 0.50, 1.00, 1.50, 2.00, 2.50, 3.00 and 4.00 D accommodative demand (6.00, 2.00, 1.00, 0.75, 0.50, 0.40, 0.33, 0.25 m), in real space (matched for angular subtense and luminance), in a random order. Five static readings were taken with both the *PowerRefractor* (full refraction mode) and *SRW-5000* at each distance. All patients were asked to focus on the target and to try to keep it as clear, as if they were reading, whilst the measurements were being taken (Stark and Atchison, 1994). The illuminance of the room was kept constant at 40 lux and the target kept at 5 cd/m^2. This particular luminance was chosen to maintain a pupil size adequate to achieve measurements at all distances with the *PowerRefractor* (Wolffsohn, Hunt and Gilmartin, 2002). The luminance was kept the same for the *SRW-5000* measures so as not to affect the stimulus response curve (Johnson, 1976).

Continuous recording of dynamic accommodation was measured with the *SRW-5000* with the subject viewing a target moving from 0 to 2.50 D at 0.3 Hz through a +5 D Badal lens system. The *SRW-5000* is able to monitor dynamically the accommodative response with a high resolution and a frequency of up to 60 Hz (Wolffsohn *et al.*, 2001). The data was smoothed using by averaging the ten time points either side (approximately 0.2 s) and blinks were removed (Wolffsohn *et al.*, 2003, Figure 7.1). The dynamic amplitude of accommodation and time lag was calculated from the average of five cycles.

Aberrations across the undilated pupil were quantified using a *Zywave* (Bausch & Lomb) wavefront-sensing device, which is based on the Hartman-Shack principle. The measured deviation of the 780 nm wavefront (at 70-75 locations within the pupil area) as it passes through the optics of the cornea and intraocular lens is displayed in terms of lower order (i.e. sphere and cylinder, combined to give a 'predicted phoropter refraction' (PPR) term) and high order (i.e. trefoil and coma) aberrations. Despite the instrument fogging the eye by 1 D to avoid instrument myopia, a significant myopic bias in PPR remains compared to subjective refraction (-1.25 ± 0.81 D), although this increased with pupil dilation (-1.44 ± 0.79 D), suggesting a role for spherical aberration (Hament, Nabar and Nuijts, 2002).

Amplitude of accommodation was measured with an RAF binocular gauge (Clement Clarke/ Haag-Streit, UK). Subjects viewed the N6 (0.75 M units) size letters from distance of 50 cm, which were moved (approximately 5 cm/s) towards the subject until they were no longer resolvable. The target was then moved to 10 cm away from the subject and moved away from the subject until the letters were first resolvable. The reciprocal of the average distance between these two measures was taken as the subjective amplitude of accommodation in dioptres.

This study had been passed by the ethics committee and all participants signed consent forms.

Statistical Analysis

The results were entered into a spreadsheet. Static prescriptions were converted into mean spherical equivalents (MSE) and the slope, its intercept with the 'y' axis, the accommodative lead, the correlation coefficient (r^2) and the AEI was calculated for each subject with both the *PowerRefractor* and *SRW-5000*. Pearson's coefficients were also calculated.

Results

The residual MSE refractive error of the group as represented by the subjective refraction was -0.71 ± 0.44 D. The distribution of residual refractive error is presented in Figure 7.2. The best-corrected distance acuity was on average 0.007 ± 0.16 logMAR for high and 0.13 ± 0.22 logMAR for low contrast letters. The near acuity at 40cm was on average 0.60 ± 0.09 logMAR (Figure 7.3).

The static objective amplitude of accommodation calculated from stimulus response curves measured with the *PowerRefractor* averaged 0.32 ± 0.23 D (range from 0.10 to 0.75 D). When measured by the *SRW-5000*, the static objective amplitude of accommodation averaged 0.72 ± 0.38 D (range from 0.17 to 1.16 D; Figure 7.4). Quadratic curve fitting over the 0.17 to 4.00 D stimulus range showed a stronger agreement with the *SRW-5000* (r^2 = 0.97) than the *PowerRefractor* (r^2 = 0.84).

Linear fitting of the portion of the stimulus response curve normally considered to be linear (1.00-4.00 D; Charman, 1982, Chapter 4) also showed a stronger agreement with the *SRW-5000* (slope 0.18; r^2 = 0.95) than the *PowerRefractor* (slope 0.11, r^2 = 0.77). Examining individual stimulus response curves identifies that there are several different profiles to the graphs. There was a linear increase in accommodative response with increasing stimulus in 4 eyes, an increase followed by decrease in 4 eyes, an increase only at higher levels of stimulus demand in 3 eyes and no apparent increase in accommodative response in 7 eyes. The two eyes of those subjects with bilateral implants usually showed a similar pattern (Figure 7.5).

The average stimulus response vergence slope measured with the *PowerRefractor* in those subjects with binocular implants was 0.74 (r^2 = 0.93; Figure 7.6). The individual stimulus response vergence slopes averaged 1.33 ± 0.95 (r^2 = 0.84 ± 0.16). The pupil size decreased with increasing accommodative stimulus demand (decreasing stimulus distance) by 0.10 ± 0.10 mm/D of accommodative demand (r^2 = 0.84; Figure 7.7).

The average dynamic amplitude of accommodation measured by the *SRW-5000* was 0.71 ± 0.47 D (range 0.31 to 1.56 D) with a lag time behind the target of 0.50 ± 0.48 s (Figure 7.8 and 7.9) There was no significant difference between an individual's static and dynamic amplitude of accommodation (Figure 7.10). There was no significant correlation between the static amplitude of accommodation and demographic characteristics such as age (r = 0.32; p = 0.21), time post operation (r = 0.03; p = 0.91), MSE (r = 0.36; p = 0.16), corrected distance visual acuity (r = 0.22; p = 0.40), corrected near acuity (r = 0.08; p = 0.77), pupil size (r = -0.07; p = 0.80) or time lag (r = 0.08; p = 0.77).

Aberrometry showed a decrease in power (PPR) of the lens-eye combination from the centre of the pupil to the periphery in all subjects, on average -0.38 ± 0.28D/mm (Figure 7.11).

The subjective amplitude of accommodation measured using the RAF rule average 2.24 ± 0.42 D (range from 1.50 to 2.50 D). Pupil size was correlated to the subjective amplitude of accommodation (r = 0.66), with the three eyes with a pupil size >6 mm having an amplitude of 1.5 D, whereas all other eyes had an amplitude of accommodation between 2.0 and 3.0 D. There was no correlation between the power of the implanted *1CU* intraocular lens and the objective static (r^2 = 0.004, p = 0.79) and dynamic (r^2 = 0.002, p = 0.85) amplitude of accommodation, but there was a significant correlation ($r^2 = 0.42$, $p < 0.01$) with the subjective amplitude of accommodation.

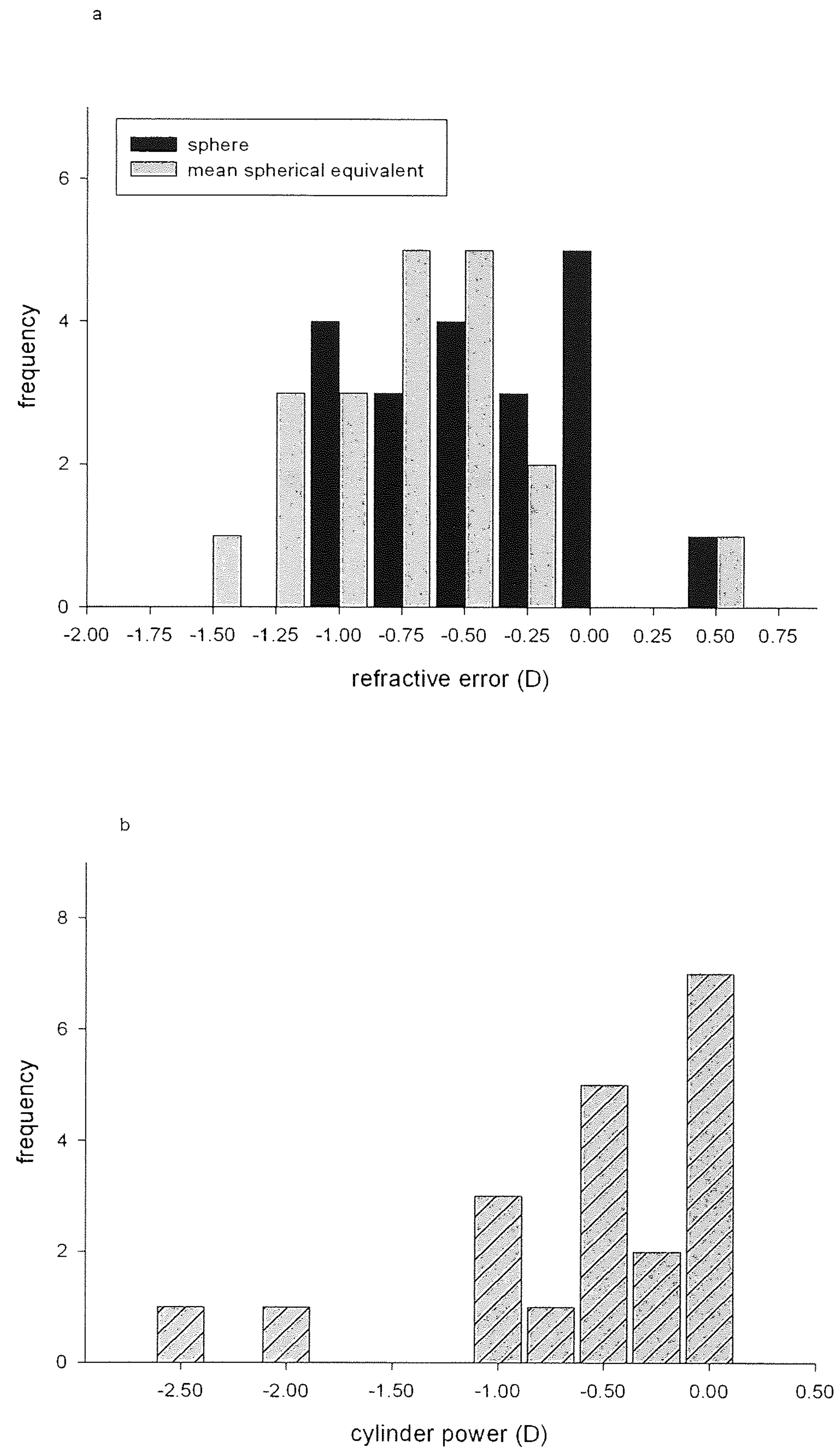


Figure 7.2: (a) Frequency of residual spherical and mean spherical refractive error and (b) percentage cylindrical error following IOL implantation surgery.

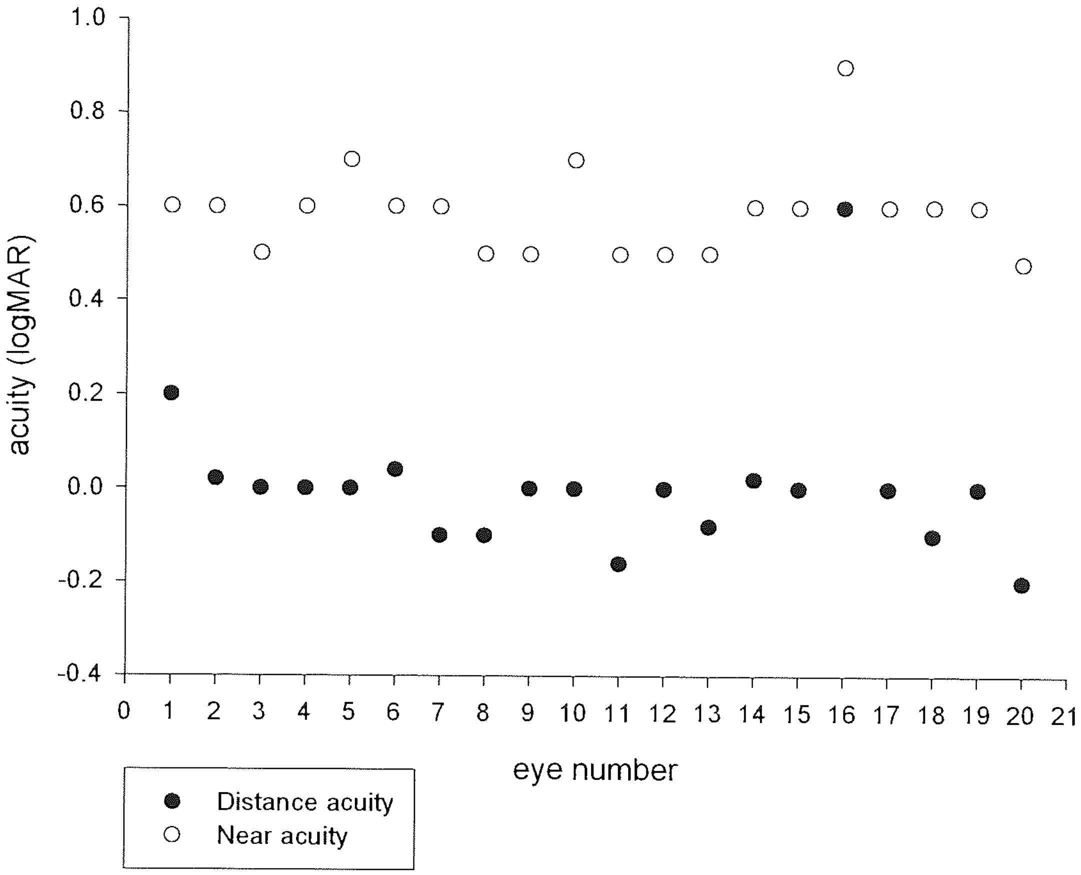


Figure 7.3: High contrast distance and near visual acuity (logMAR) obtained with best distance correction.

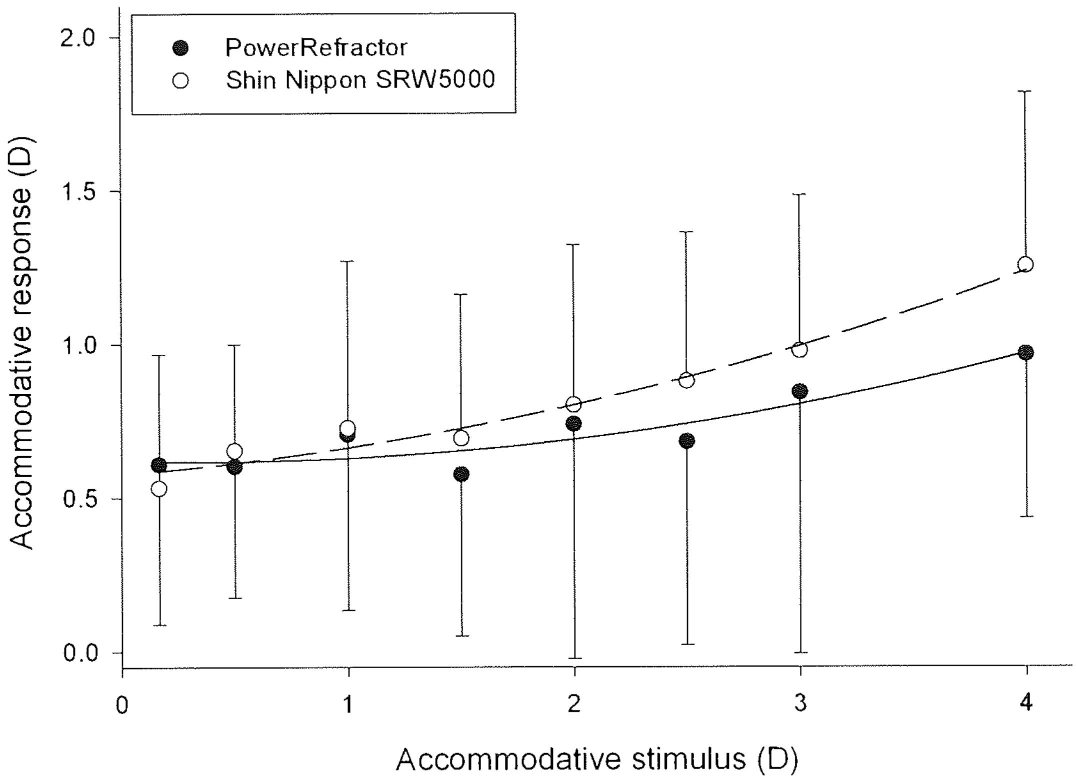


Figure 7.4: Accommodative stimulus response curve as measured with the *PowerRefractor* and with the *SRW-5000* (n = 20). Error bars = 1 S.D.

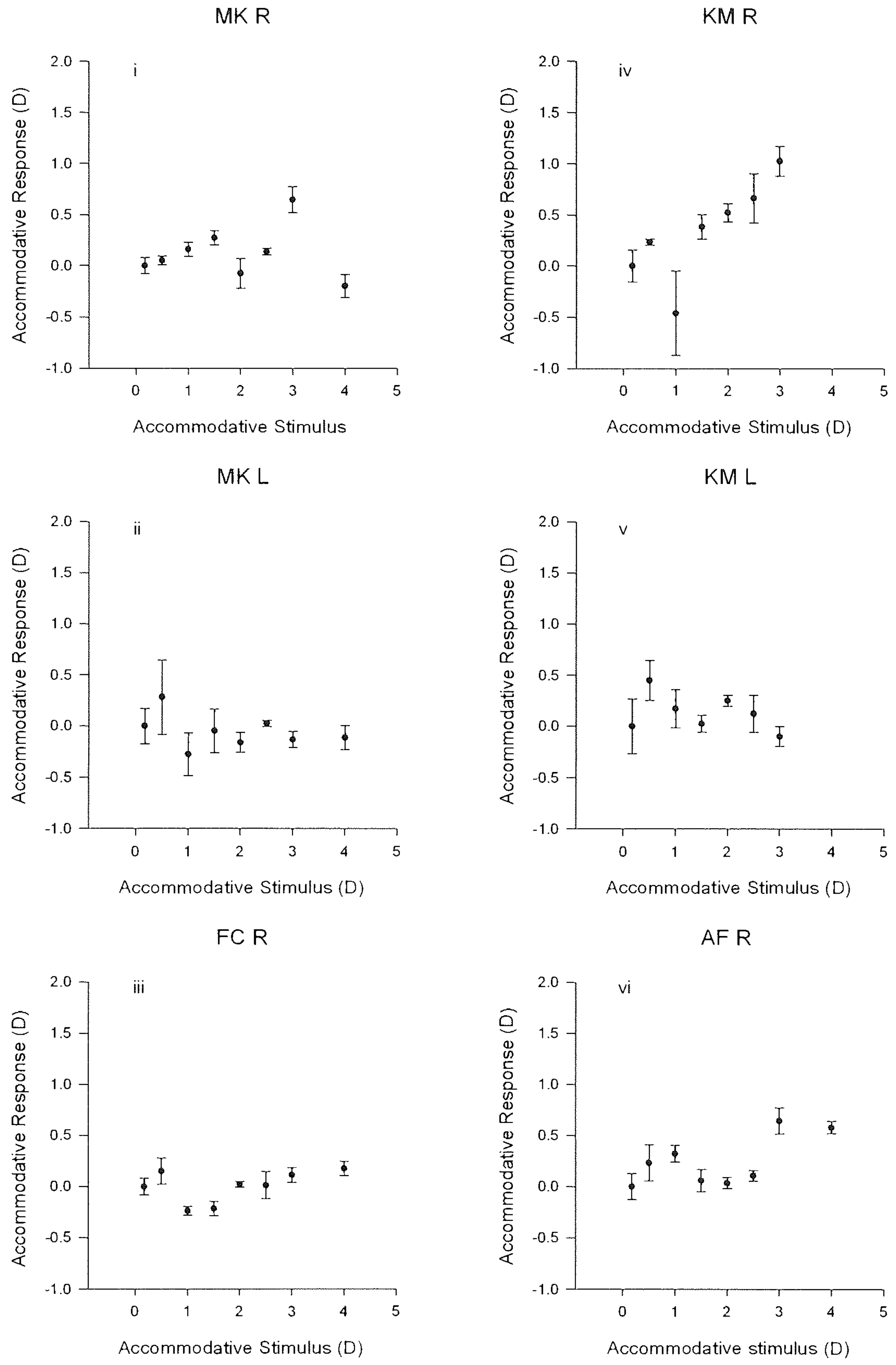


Figure 7.5: Individual stimulus response curves (i – vi)

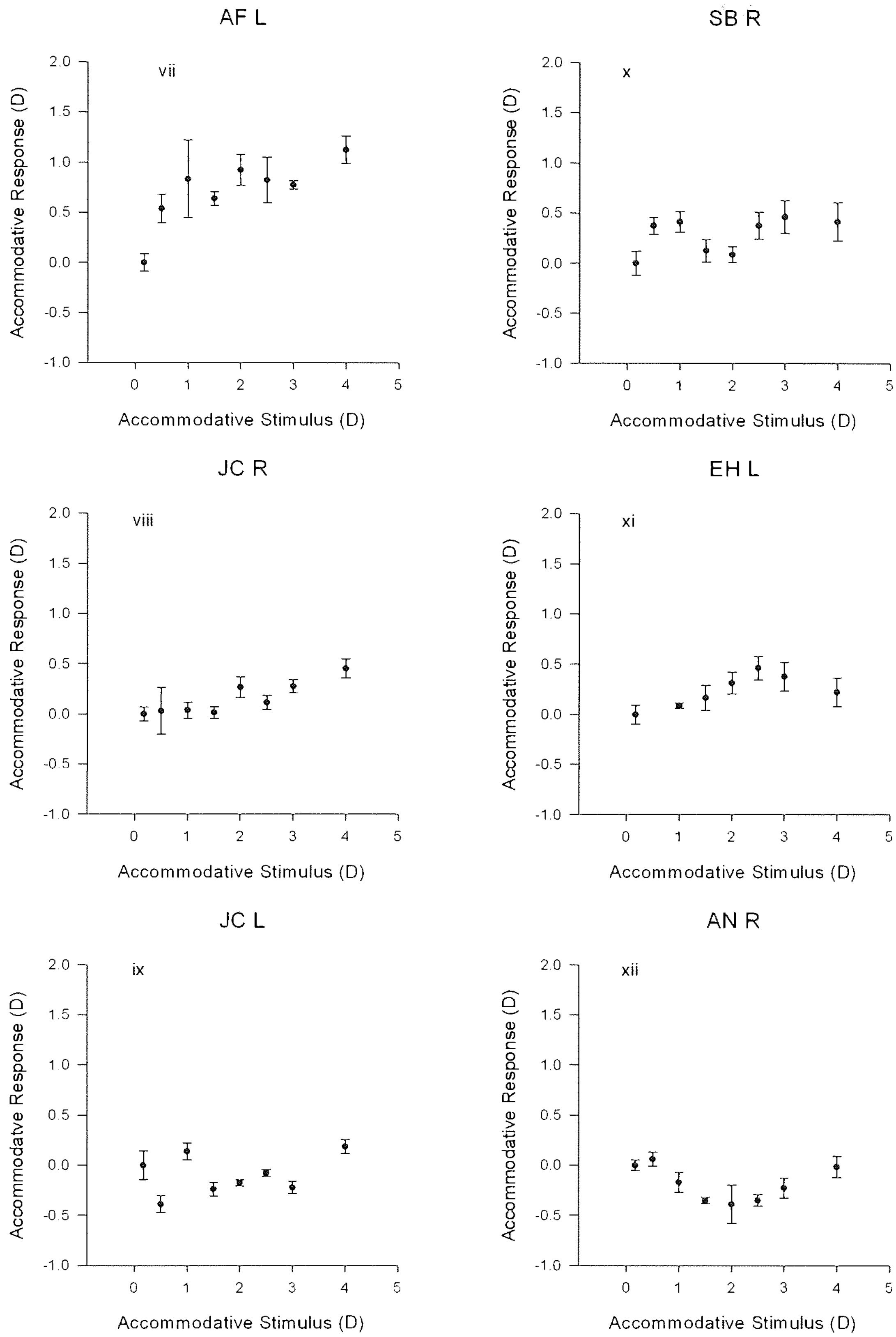


Figure 7.5: Individual stimulus response curves (vii – xii)

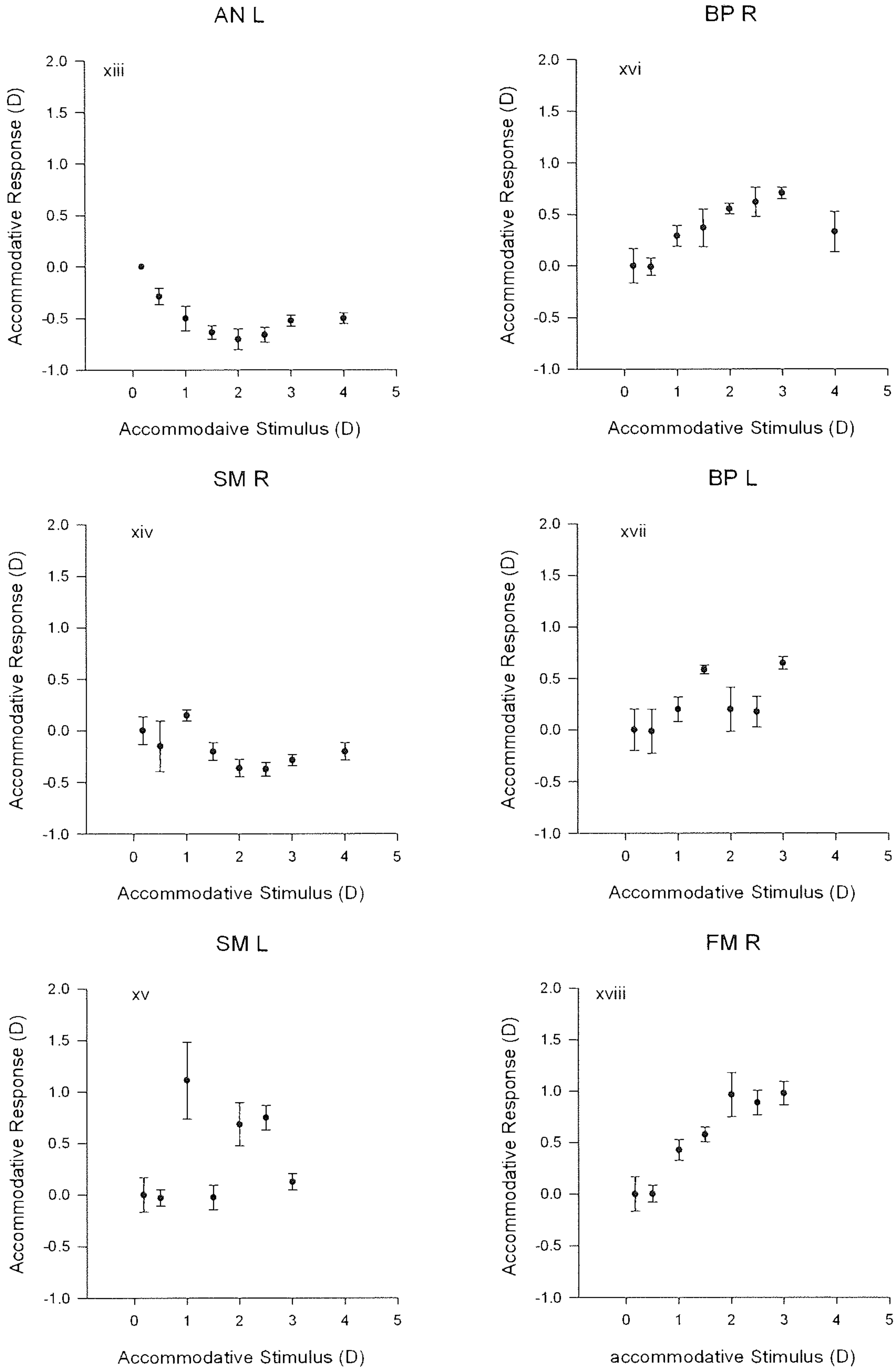


Figure 7.5: Individual stimulus response curves (xii – xvii)

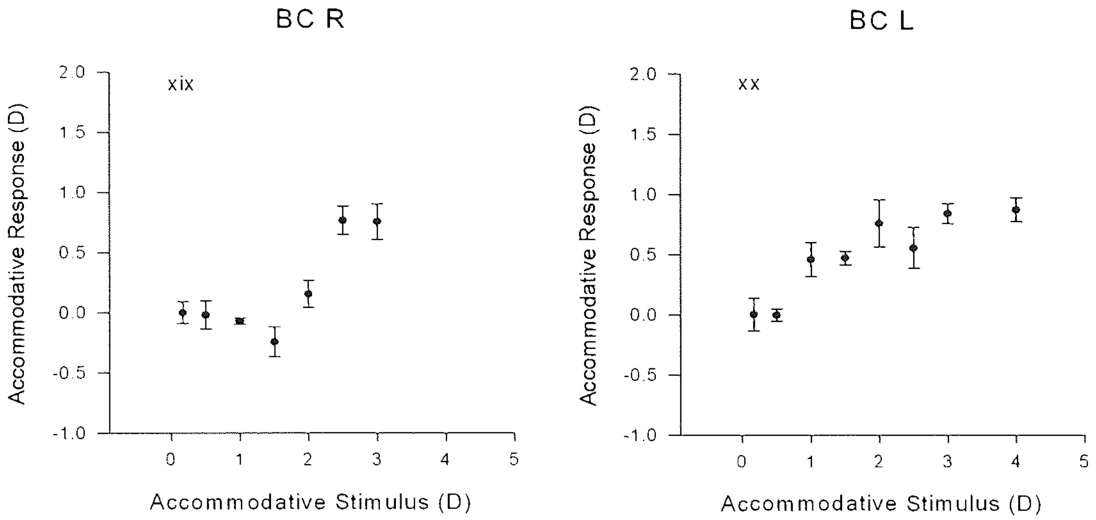


Figure 7.5: Individual stimulus response curves (xix - xx)

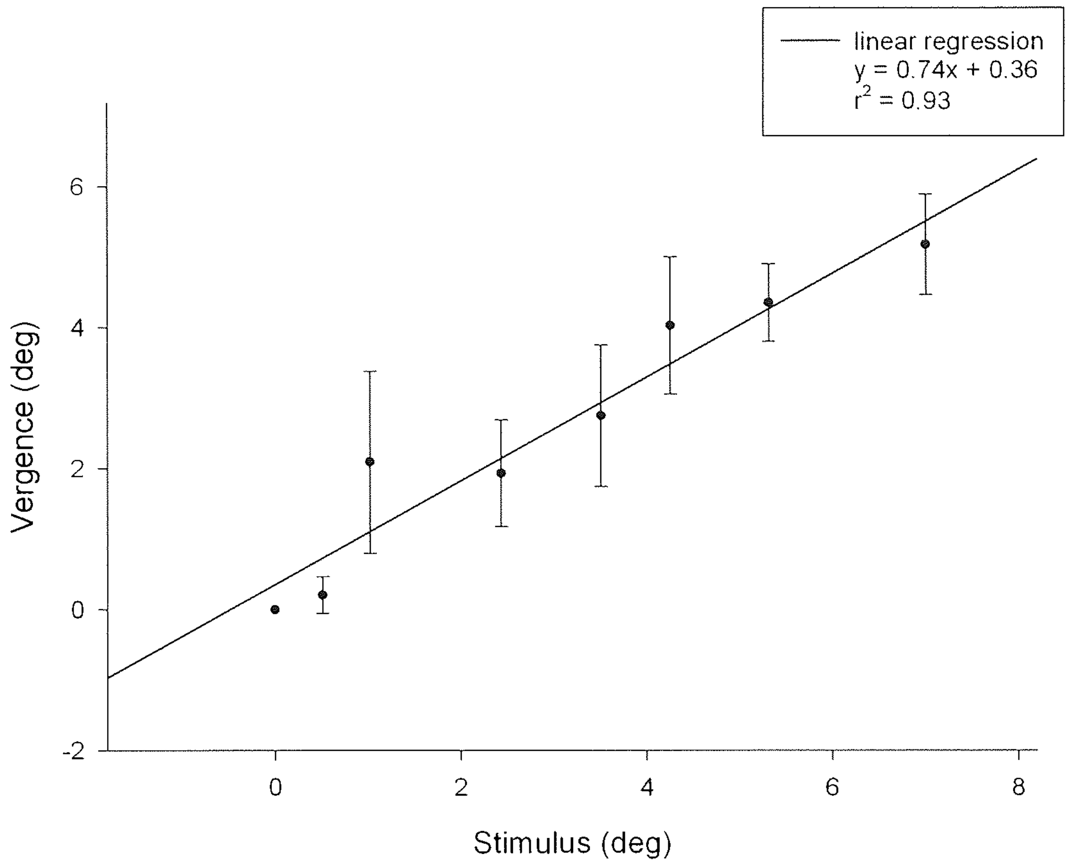


Figure 7.6: Vergence response curve (as measured from the *PowerRefractor*)

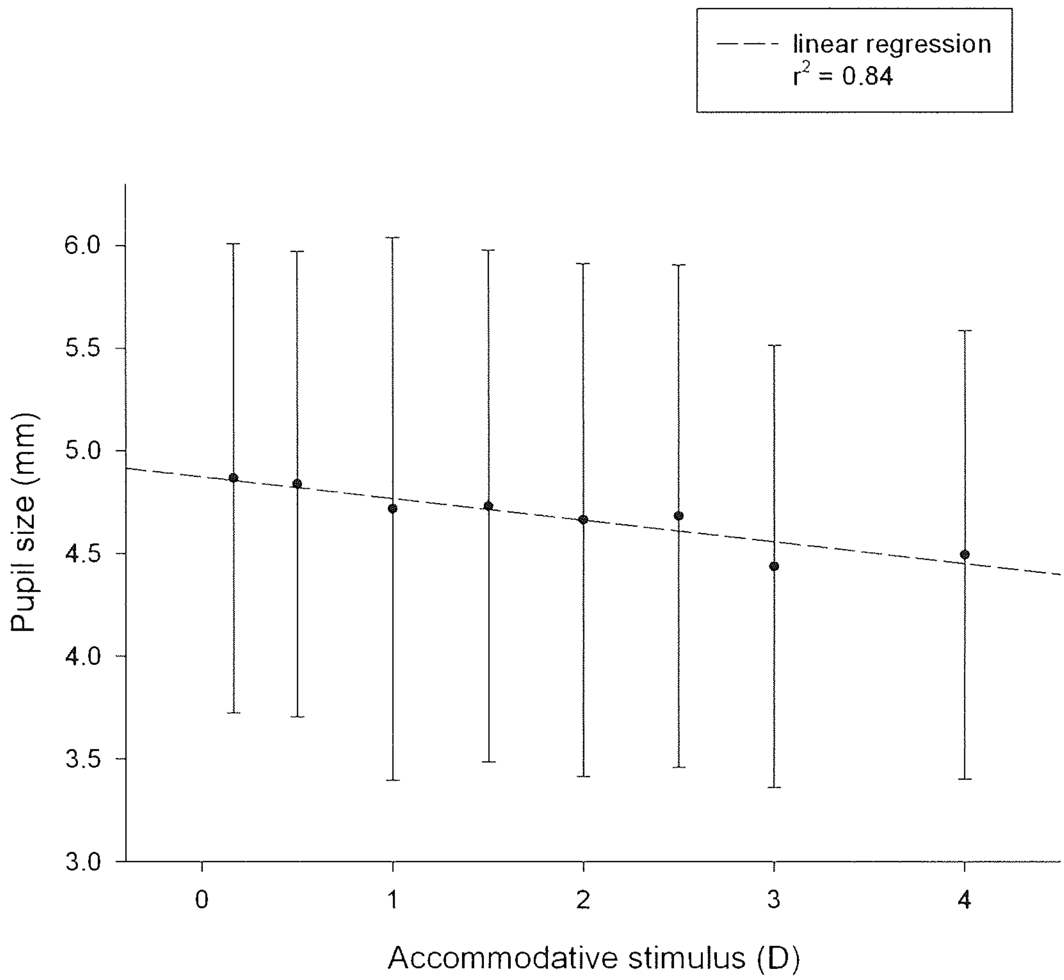


Figure 7.7: Pupil size (mm) compared to accommodative demand (D). n = 20 eyes. Error bars = 1 S.D.

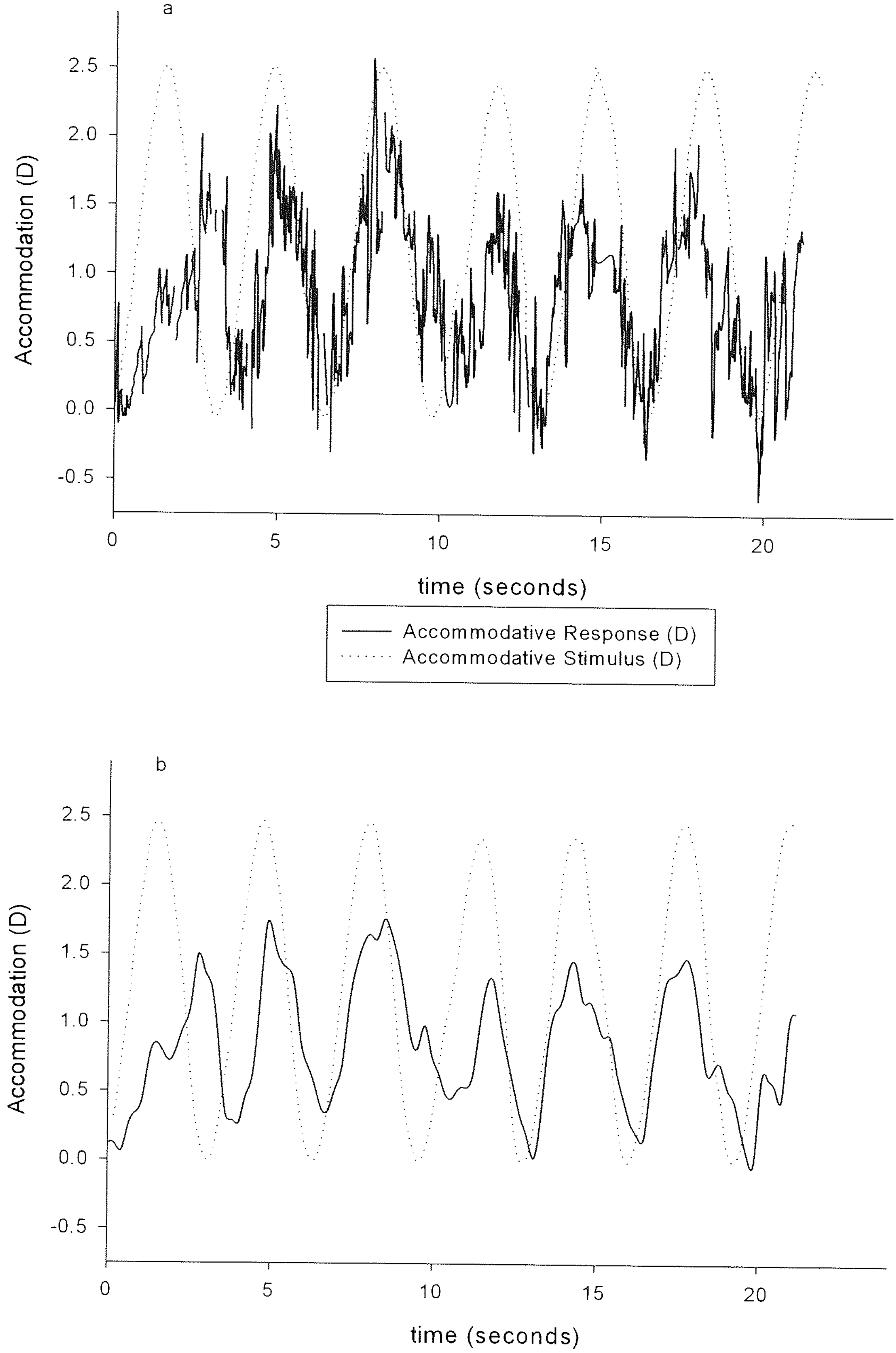


Figure 7.8: (a) Original dynamic accommodation response trace of a patient who was able to track well and who had moderately high dynamic amplitude of accommodation (1.10 ± 0.16) and (b) the same response smoothed.

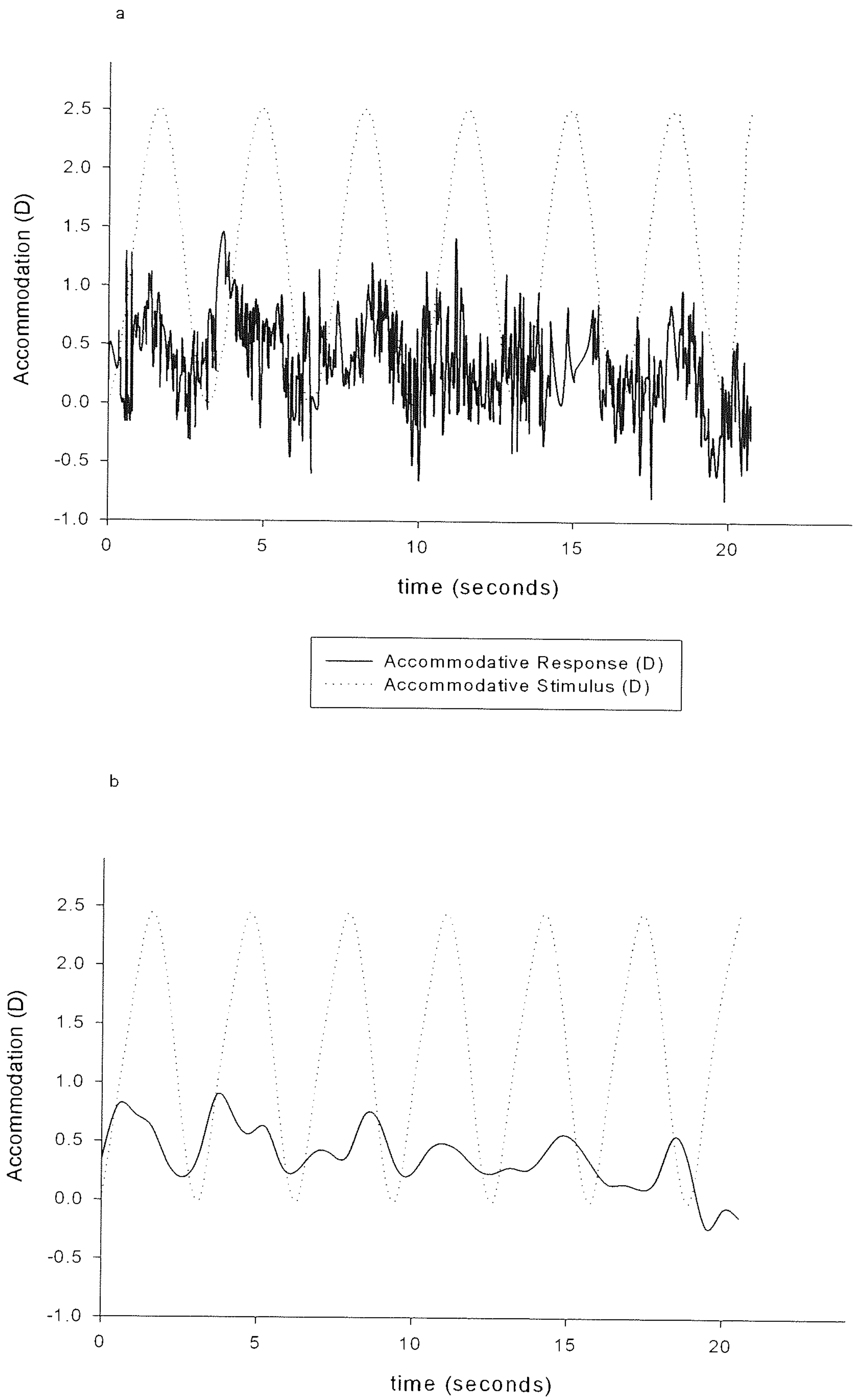


Figure 7.9: (a) Original dynamic accommodation response trace of a patient who was able to track well but who had a lower dynamic amplitude of accommodation (0.44 ± 0.19) and (b) the same response smoothed

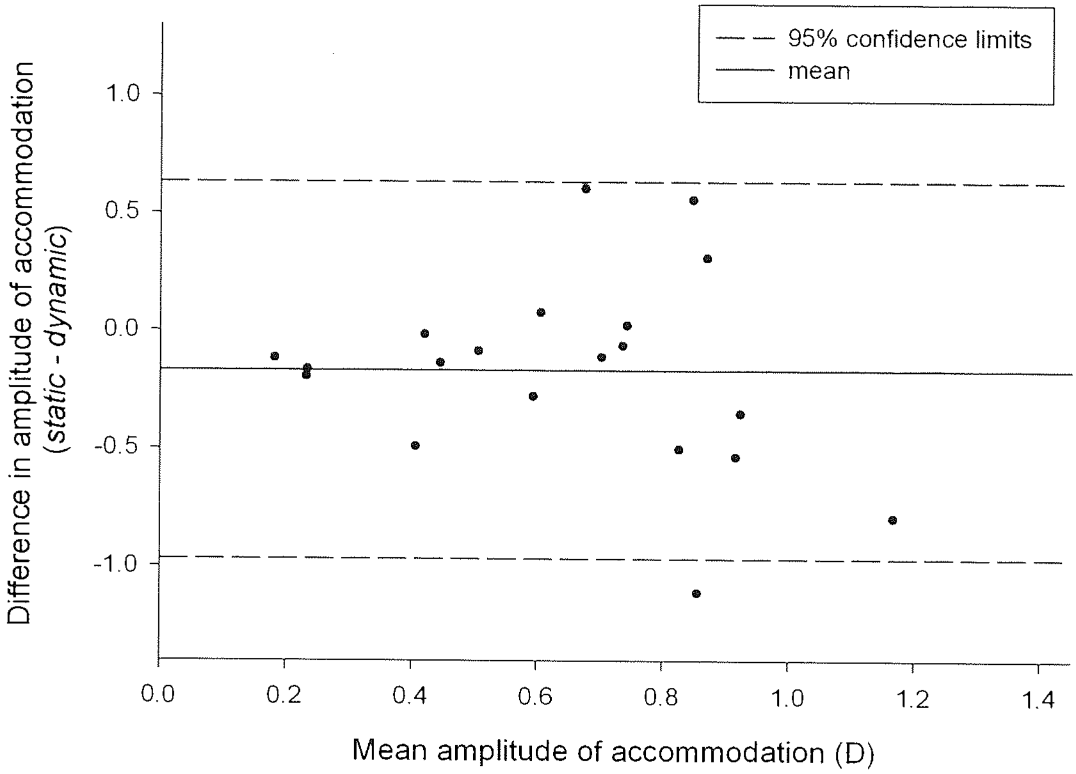
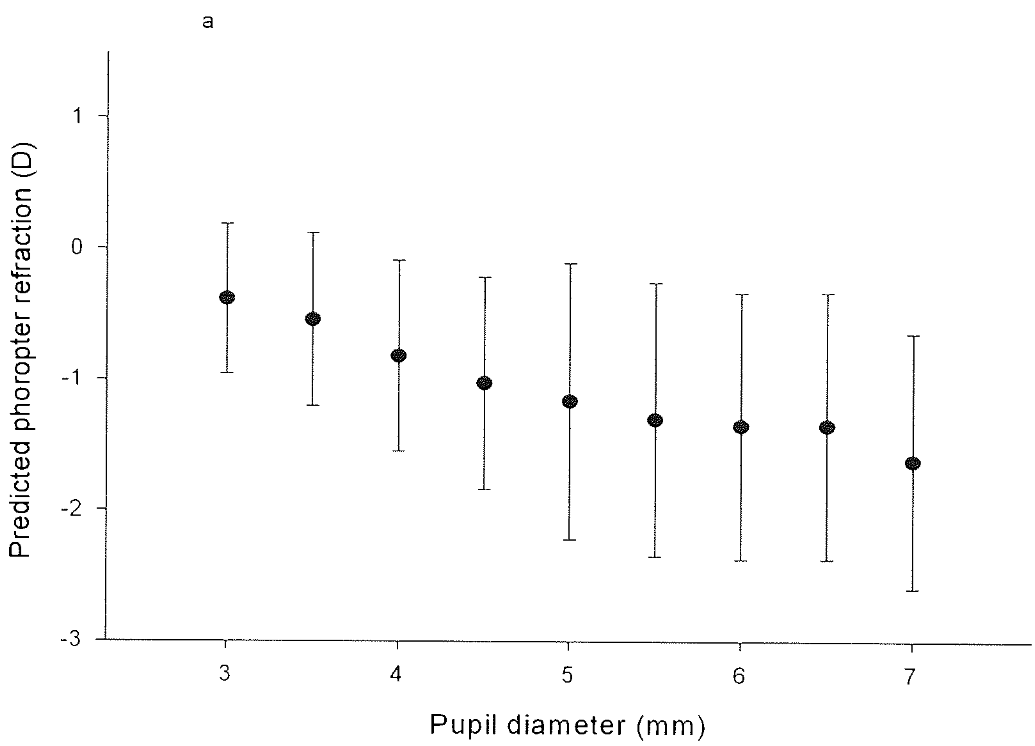


Figure 7.10: Bland – Altman plot for static and dynamic *SRW-5000* amplitude



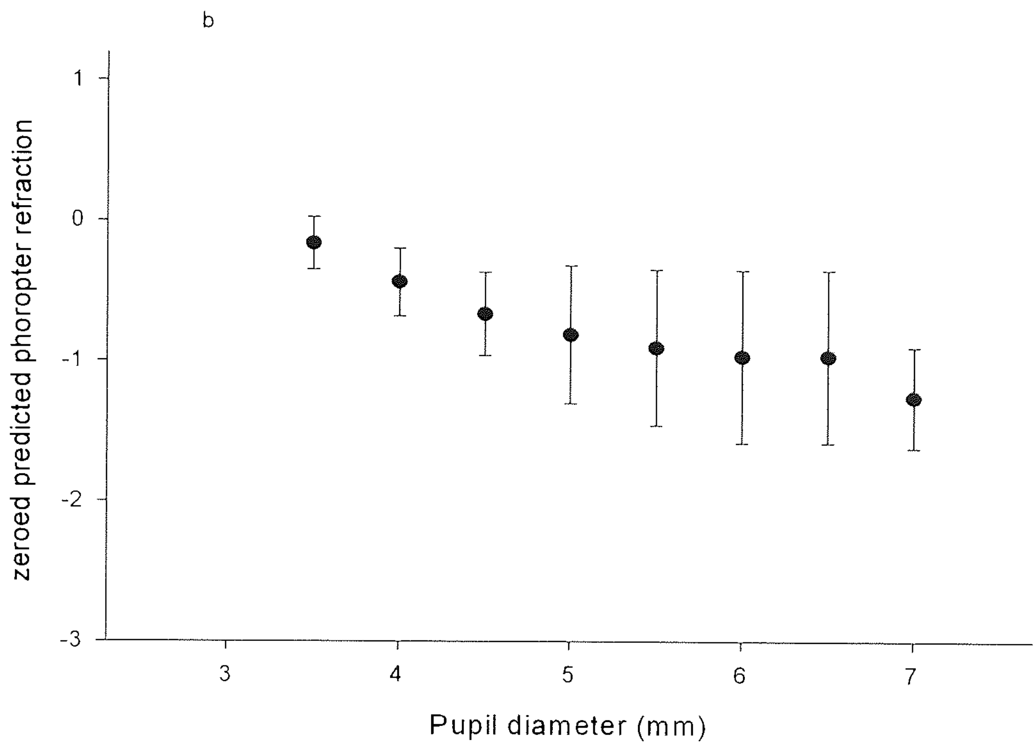


Figure 7.11: (a) Average predicted phoropter refraction against pupil diameter and (b) Zeroed predicted phoropter values against pupil diameter.

Discussion

The anterior shift of an intraocular lens from contractions of the ciliary body with accommodative effort is the closest mimic of the natural accommodative response presently available (Hara *et al.*, 1990; Legeais *et al.*, 1999; Cumming, Slade and Chayer, 2001). The subjective amplitude of accommodation reported by a number of studies, and found in the present study, suggests on average a near point of between 42 and 75 cm which should be enough to allow a comfortable posture while reading (Nakazawa and Ohtsuki, 1983, 1984; Kuchle *et al.*, 2002; Mastropasqua *et al.*, 2003; Langenbucher *et al.*, 2003a, b). However, the anterior shift in intraocular lens is one of a number of factors contributing to the subjective amplitude of accommodation. The near point of accommodation will also be benefited by leaving the patient slightly myopic in correction, as was the case in the population examined.

Quantification of intraocular lens movement has previously been performed before and after ciliary muscle contraction induced by pharmacological agents, rather than accommodation to a target of known demand, and hence the modelled accommodative results are difficult to compare with subjective findings (Ravalico and Baccara, 1990; Auffarth *et al.*, 2002; Kuchie *et al.*, 2002; Findl *et al.*, 2003; Langenbucher *et al.*, 2003a, b). Attempts to quantify objectively the range of accommodation, such as streak retinoscopy and photoretinoscopy, have only examined the difference between two distances (5.00 m and 0.35 m) and presume these relate to the extremes of the accommodative range (Kuchie *et al.*, 2002; Mastropasqua *et al.*, 2003; Langenbucher *et al.*, 2003a,b). Also streak retinoscopy relies on the subjective interpretation of the movement of the light reflex across the pupil and photorefraction accuracy has been questioned (Seidermann and Schaeffel, 2003, Hunt *et al.*, 2003). Photorefraction measured a significantly lower amplitude of accommodation in this study than the well validated *SRW-5000* (Mallen *et al.*, 2001). Unlike the *SRW-5000*, photorefraction refraction examines the light reflex across the whole pupil and therefore will be influenced by lens aberrations and pupil size changes.

Although the average stimulus response curve was linear over the 1.0 to 4.0 D range, individual curves showed considerable variability. Therefore determining the difference between the objective accommodative responses at just two accommodative demands is unlikely to reflect the true accommodative range of an individual. The results also indicate the value of future studies examining the ability of an individual to maintain accommodation at a set accommodative demand, rather than just measuring a static response. As expected individual stimulus response curves were very variable, probably due to the 'fit' of the intraocular lens in the lens capsule, the tonus of the ciliary body, the depth of focus and lens-eye aberrations. The measurement of pseudophakic eyes using the *PowerRefractor* may have been affected by peripheral distortion of the intensity profile across the pupil and hence the apparent slope, but is unlikely to have affected the central measurement annulus of the *SRW-5000*. Unlike the accommodative response, the vergence response of individuals with binocular *ICU* intraocular lens implants was linear, although of reduced amplitude to that expected over a 6.00 m to 0.25 m range (a slope of 0.74 compared to 1.00 predicted). The ability to track a dynamic target was similar to that recorded previously in pre-presbyopes (Wolffsohn *et al.*, 2001), although the amplitude was restricted to that noted by static measurement.

Best-corrected distance acuity was excellent in all cases, with an ability to resolve low contrast letters as good as young healthy individuals (Reeves, Wood and Hill, 1993), unlike that previously found with multifocal intraocular lenses (Kamlesh, Dadeya and Kaushik, 2001; Montes-Micó and Alio, 2003). The aim of the surgeons was to leave the eyes very slightly myopic when choosing the IOL power from the biometry. The near acuity at 40cm was sufficient to read book or newspaper print with relative ease (approximately N5 point or 0.6 M units). The subjective average amplitude of accommodation (2.24 D) could be accounted for by the dynamic objective accommodative range (0.72 D), the subjective amplitude of accommodation found with a single-piece intraocular lens (0.42-1.08 D; Kuchie *et al.*, 2002; Langenbucher *et al.*, 2003b) and the aspheric nature of the lens (-1.75 D from the aberrometry result with a 4.6mm average pupil size). The combination of these factors accounts for more than the subjective accommodative range, suggesting that they may interact rather than be additive. The increased depth of focus of the human eye resulting from the change in pupil size (of on average 0.43 mm) is predicted to be minimal (<0.05D; Atchison, Charman and Woods, 1997).

In conclusion, the objective accommodating effects of the *1CU* lens appear to be limited, although patients are able to track a moving target and achieve adequate acuity and contrast sensitivity for most visual tasks at distance and near. The greater subjective, than objective, amplitude of accommodation is likely to result from the interaction between the depth of focus of the eye and the aspheric nature of the *1CU* intraocular lens.

CHAPTER 8

INDIVIDUAL FACTORS AFFECTING PHOTORETINOSCOPY

Introduction

The experimental evaluation of a monocular head-mounted display (HMD) in chapter 9 could not be assessed by both the Shin Nippon *SRW-5000* and *PowerRefractor* as in the previous chapters, as there was no room for both the HMD and *SRW-5000* combiners and the accuracy of the *PowerRefractor* for measuring the accommodative response had been brought into question (see chapter 4). Therefore it was necessary to use a purpose designed photoretinoscope for remote, binocular assessment of the oculomotor system with improved accuracy.

Since photoretinoscopy was first used in accommodation experiments, the use of individual calibrations for each subject has been an issue. Schaeffel, Wilhelm and Zrenner (1993) were the first to discuss the calibration process. The technique used to determine the change in the slope of the intensity profile across the pupil with a change in refractive error ('conversion factor') was to locate ophthalmic lenses of known powers (between -5 to +5D) in front of the eye to simulate refractive error Figure 8.1. To prevent the eye accommodating to the change in stimulus through the lens, an infrared filter was placed in front of the eyes so that any view through the lenses was obscured, but the photoretinoscope could still image the eye and measure the apparent refractive error using its infrared light source. The authors found the conversion factor to be variable between individuals, but 72% of the variance was found to be accounted for by the fundus reflex brightness (Figure 8.2a). The procedure was repeated on individuals with uncorrected refractive error and found to be similarly related to fundus reflex brightness (Figure 8.2b). From their findings, the authors concluded that it was acceptable to measure refractive error with a photoretinoscope without individual calibration The *PowerRefractor* conversion algorithm to convert the measures of the slope of the intensity profile into refractive error incorporates a factor to account for differences between individuals in the fundus reflex brightness, although this cannot be disclosed for proprietary reasons (personal communication with Dr Frank Schaeffel, 2001). One limitation in the calibration section of their study was the lack of an accommodative stimulus for the eye not under test (occluded), to prevent fluctuations of accommodation due to the absence of a detailed target and the closeness of the visibly opaque, black, filter.

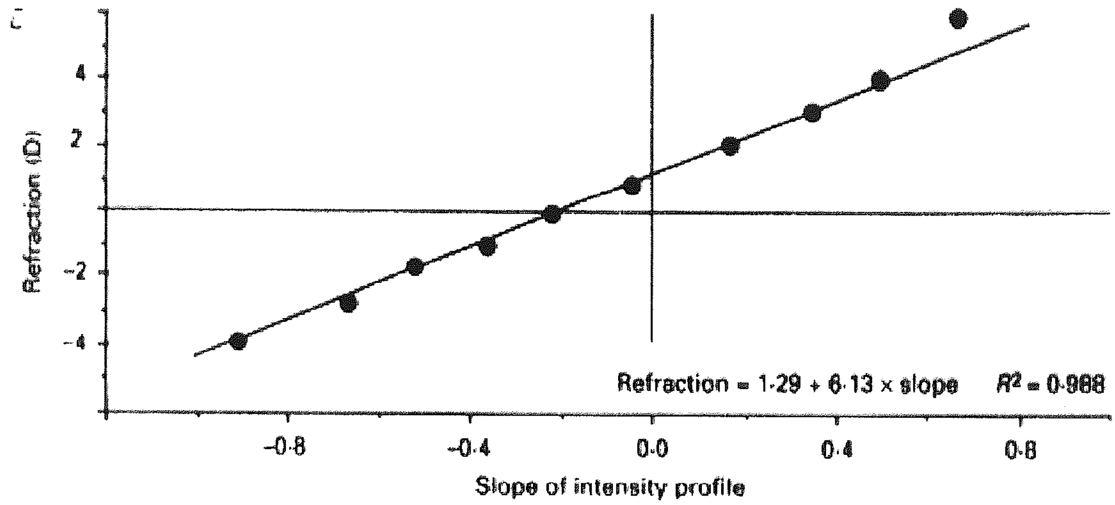


Figure 8.1: Example of the variation in refraction plotted against the slope of the intensity profile (from Schaeffel, Wilhelm and Zrenner, 1993).

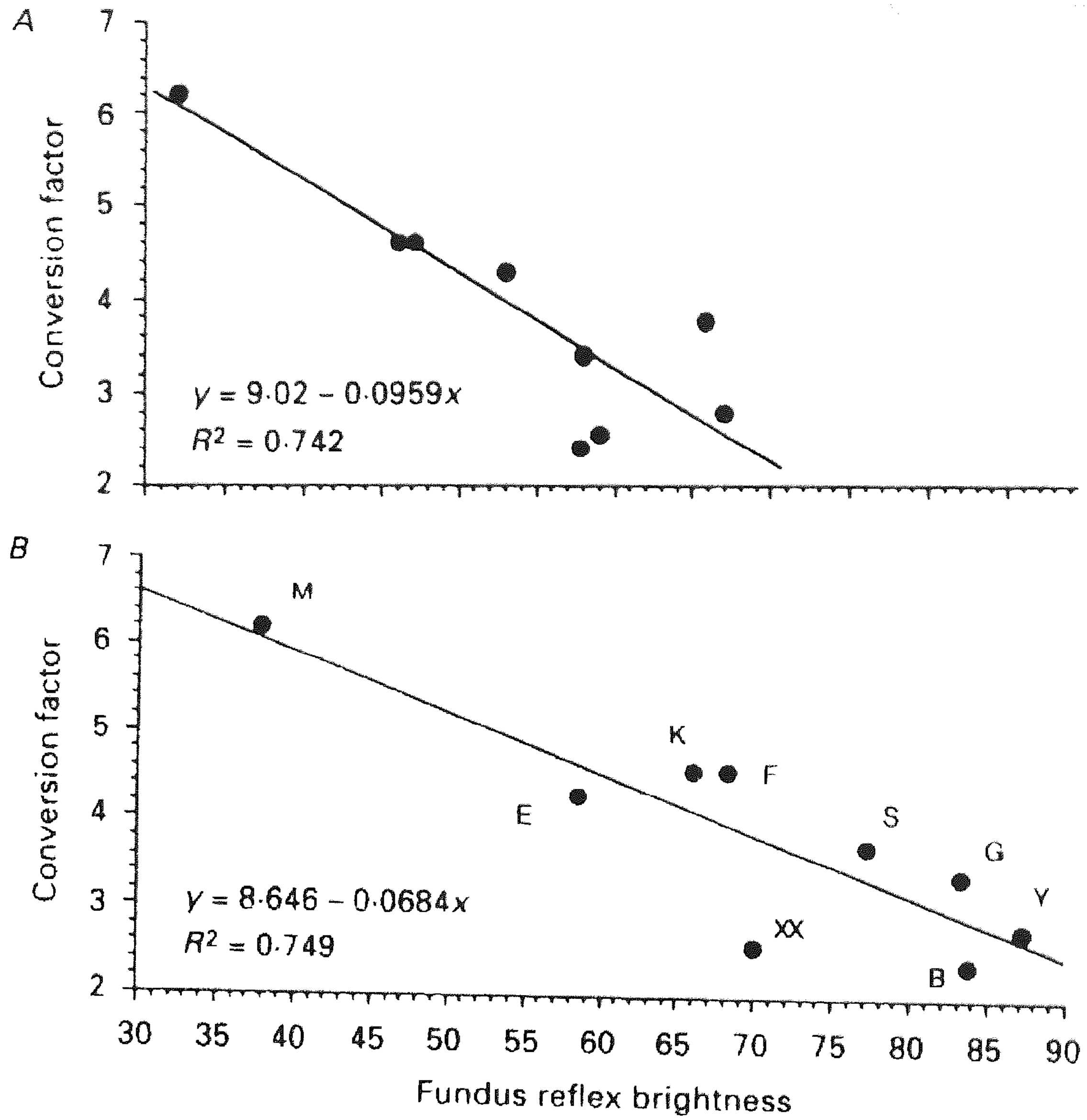


Figure 8.2: Experimental calibration of the change in the slope of the intensity profile per dioptre of refractive error versus fundus reflex brightness with patients (a) fully corrected for their refractive error (n=9) and (b) with uncorrected refractive error (n=9). (From Schaeffel, Wilhelm and Zrenner, 1993).

The *PowerRefractor* has been marketed as a commercial screening device for uncorrected refractive error in children. Because of the time pressures associated with screening, no calibration is recommended, with a pre-set factor incorporated into the programme. However, as seen in chapter 2, there can be large differences in the objective refraction measured with the *PowerRefractor* compared to that found with subjective refraction. It has been suggested by Seidermann and Schaeffel (2003), that part of this difference may be due to the fact that the *PowerRefractor* measures refractive state without cycloplegia or fogging (in fact this is one of its selling points). Furthermore, the authors postulated that it is unlikely that patients focus at their far point during calibration experiments, instead focussing more towards their tonic level (of approximately 1D) when viewing the camera lens and infra-red LEDs at 1m (e.g. Leibowitz and Owens, 1975). The lack of a high contrast target and the low luminance conditions used with the *PowerRefractor* are indeed likely to result in poor accommodative accuracy to the target distance, with previous studies supporting the idea of a drift towards the tonic accommodative level in such conditions (Leibowitz and Owens, 1975). However, the tonic accommodative level varies widely between individuals (e.g.Leibowitz and Owens, 1975, Zadnik *et al.*, 1999). Again the authors concluded that no calibration was needed for refraction screening, but thought calibration may become necessary for precise measurements of accommodation. In their study, Seidermann and Schaeffel (2003) compared refraction measures from the *PowerRefractor* with those of dynamic streak near retinoscopy (Mohindra, 1977). The offset between the *PowerRefractor* and streak near retinoscopy was derived from five subjects and was found to be on average 1.08 D more myopic than the default offset of the *PowerRefractor* over a 0-5 D range.

As identified in chapter 4, Seidermann and Schaeffel (2003) conducted a further test of reliability of the *PowerRefractor* refraction measurements by asking the patient to read text monocularly at 1.5, 2.0, 3.0, 4.0 and 5.0 D distance. The other eye was covered with an infrared transmitting filter, which precluded vision. A trial lens was held in front of the covered eye based on the reading of the *PowerRefractor*. The hypothesis was that the ophthalmic lens should reduce the measured refractive error back to zero if the measured accommodation was correct. On average this was stated to be the case, however, at the 5 D target the *PowerRefractor* still appears to over-read by -1.00 D (on average) and the variation is at least ±0.5 D for 1.5 and 2.0 D of accommodative demand and ±1.0D for 3.0, 4.0 and 5.0 D of accommodative demand (Figure 8.3).

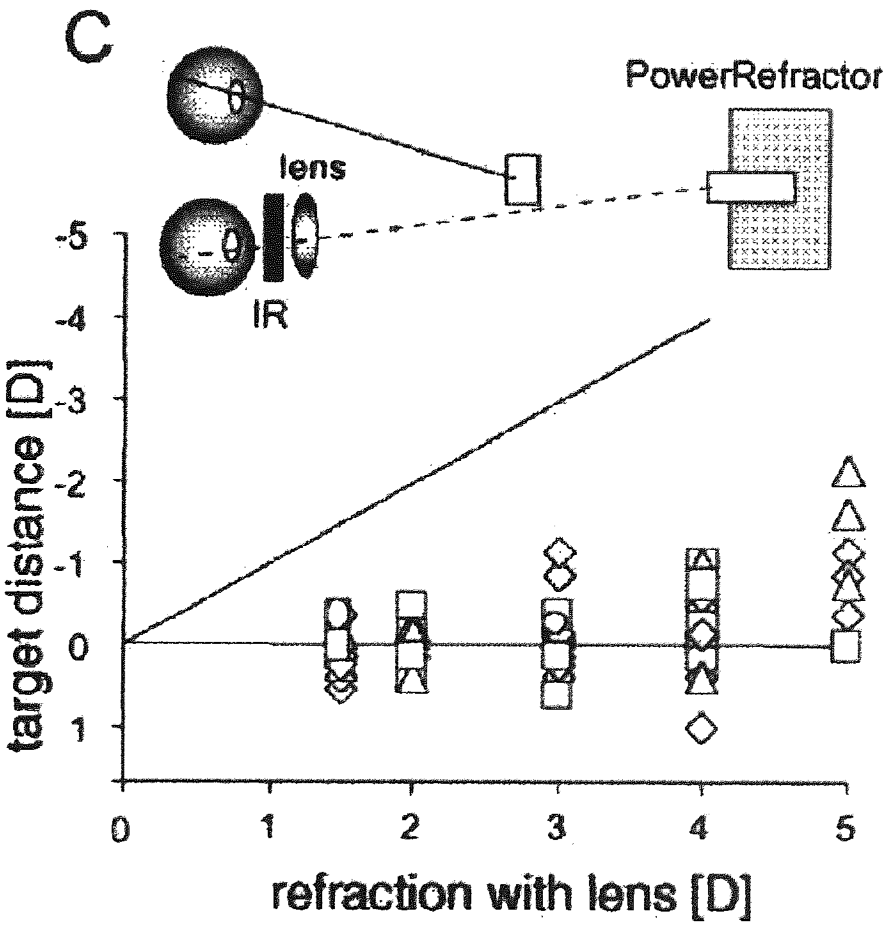


Figure 8.3: Results from calibration of the *PowerRefractor* with ophthalmic lenses (from Seidermann and Schaeffel, 2003).

This study aimed to determine how much of the variation between individuals in the change in the slope of the intensity profile with refractive error/accommodation could be accounted for by patient demographics and eye features, in a large sample.

Method

One hundred subjects, staff and students of Aston University (34 male and 66 female), with a mean age of 22.10 ± 4.25 years (range from 18 to 49 years, median 21.0 years) participated in the study. Subjects with ocular pathologies and abnormal binocular vision were excluded from the study as were those with astigmatism greater than -0.75D. All the subjects could attain at least 6/6 visual acuity in each eye. The range of mean spherical refractive error was -8.50 D to +6.25 D, measured at 6 m (average -1.52 ± 2.59 D). Subjects were made functionally emmetropic with ultra-thin soft contact lenses (*Acuvue*, Johnson & Johnson) to ensure that the accommodative demand to view the task for each subject was virtually identical. Also recorded was the age of onset if the patient had any prescription, the inter-pupillary distance and parent's refraction.

Subjects were seated with their chin on a chin-rest and head positioned against a headrest, 1m away from the photoretinoscope, aligned along their visual axis. A purpose-designed photoretinoscope was used for this study. A cone of infra-red light was projected from 10 LEDs (run at a constant 12 volts) on a mask obscuring the lower half of the video camera lens into the subject's eyes. The pupils were imaged by the video camera (Pulnix 6E, USA) and the image analysed by a purpose designed Labview program (National Instruments), run on a Pentium III 800 MHz PC with a PCI IMAQ-1407 image capture board (National Instruments, USA). The single chip monochrome camera had a resolution of 767x569 pixels (approximately 60 pixels across each pupil) and was gamma corrected. The photoretinoscopy system allowed continuous measurement of accommodation, vergence and pupil size at a rate of up to 50 Hz from both eyes (see Chapter 8). Approximately 50 readings were taken and averaged.

Calibration was achieved by having the subject observe a high contrast (>90%) black Maltese cross on a white background located at 1 m with one eye (maintaining equal accommodative level for both eyes), while the other was covered by an infra-red filter (Lee Wratten 87c). Whereas infra-red light from the photoretinoscope was transmitted by the filter, the eye behind the filter was visually occluded and was therefore unable to accommodate to the lenses placed in front of the filter. Thus calibration to the range of lenses used could be determined without the influence of accommodation. The apparent accommodative level was changed by -1.0, 0.0, +1.0, +2.0, +3.0 and +4.0 D in both the right and left eye in turn and the light intensity profile across the pupil was measured. As well as the slope of the intensity profile (measured 2 pixels nasally compared to the first Purkinje in a single pixel width vertical column, 4 pixels shorter than the pupil diameter), the program also measured retinal reflectance and pupil size. The results were plotted and the gradient of the regression line through the points recorded. Ocular vergence was measured to a resolution of 0.00072 degrees and pupil size to a resolution of 0.00012mm using edge detection techniques to identify the pupil edges to 1/1000th of a pixel.

This study had been passed by the ethics committee and all participants signed consent forms.

Statistical Analysis

Data from the trials were entered into an *Excel* spreadsheet. A hierarchical stepwise regression was performed using *SPSS* v11.5 and the total variance accounted for by the features measured assessed by best-subset linear modelling.

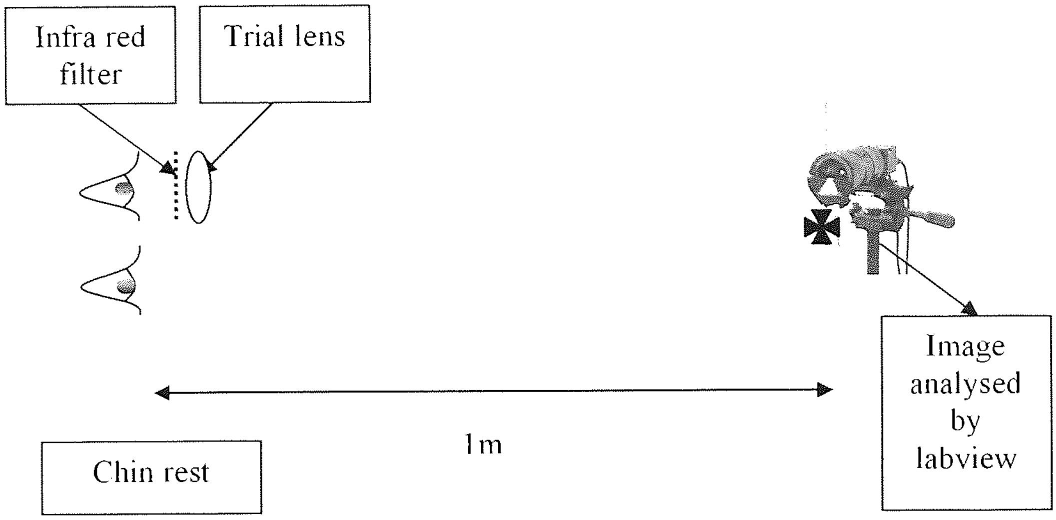
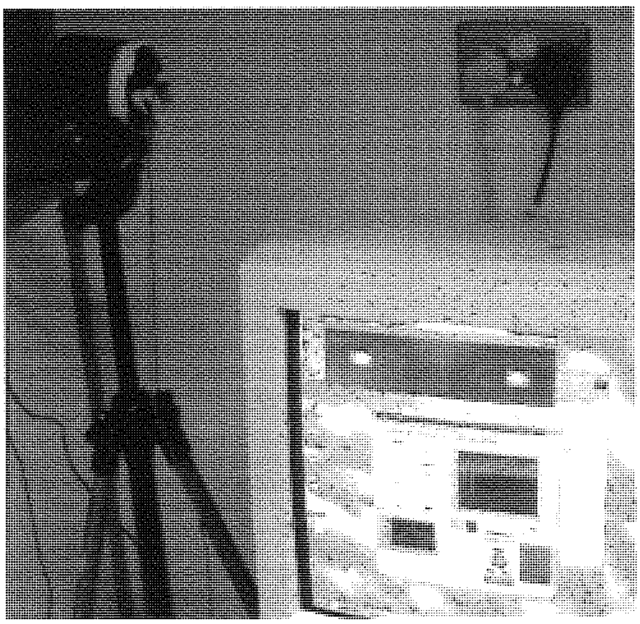


Figure 8.4: Experimental Set Up.



Results

The average correlation of individual subject's change in the slope of the intensity profile with the power of the ophthalmic lenses was 0.96 ± 0.04. The correlation was equally strong between the right and left eye (0.97 ± 0.04 versus 0.96 ± 0.04, p = 0.31). Figure 8.2 shows a typical plot of the slope of the intensity profile with the power of the ophthalmic lenses used.

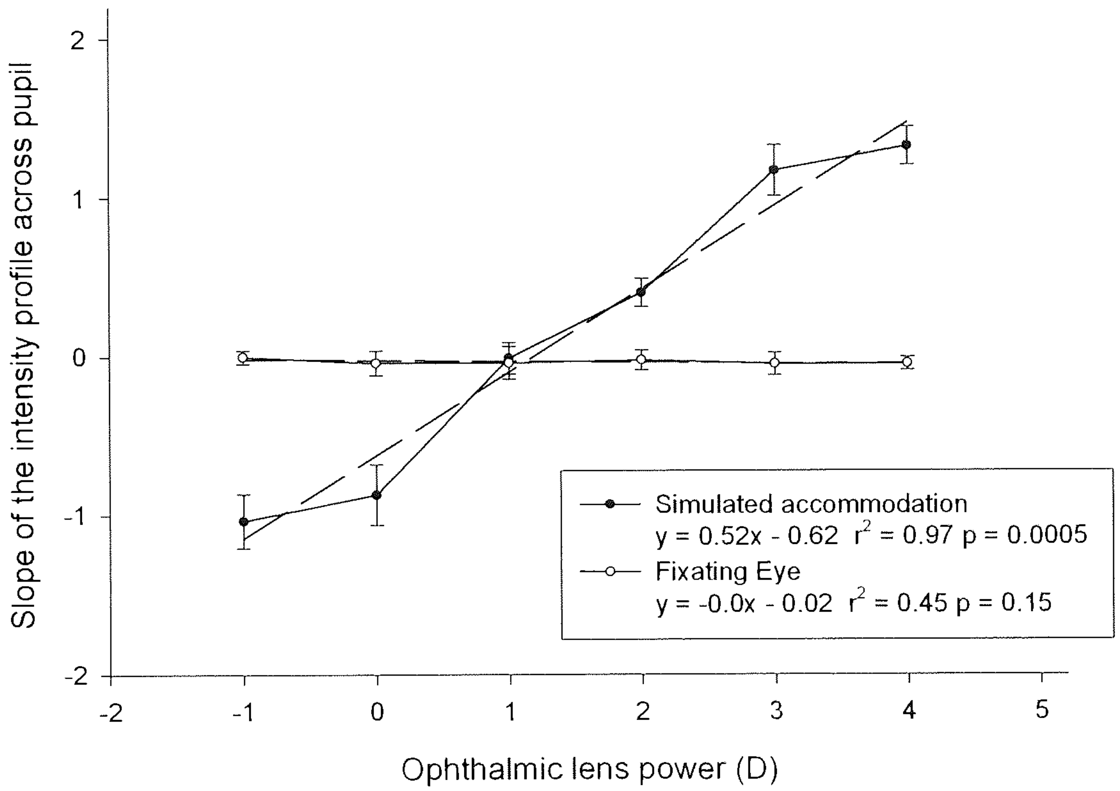


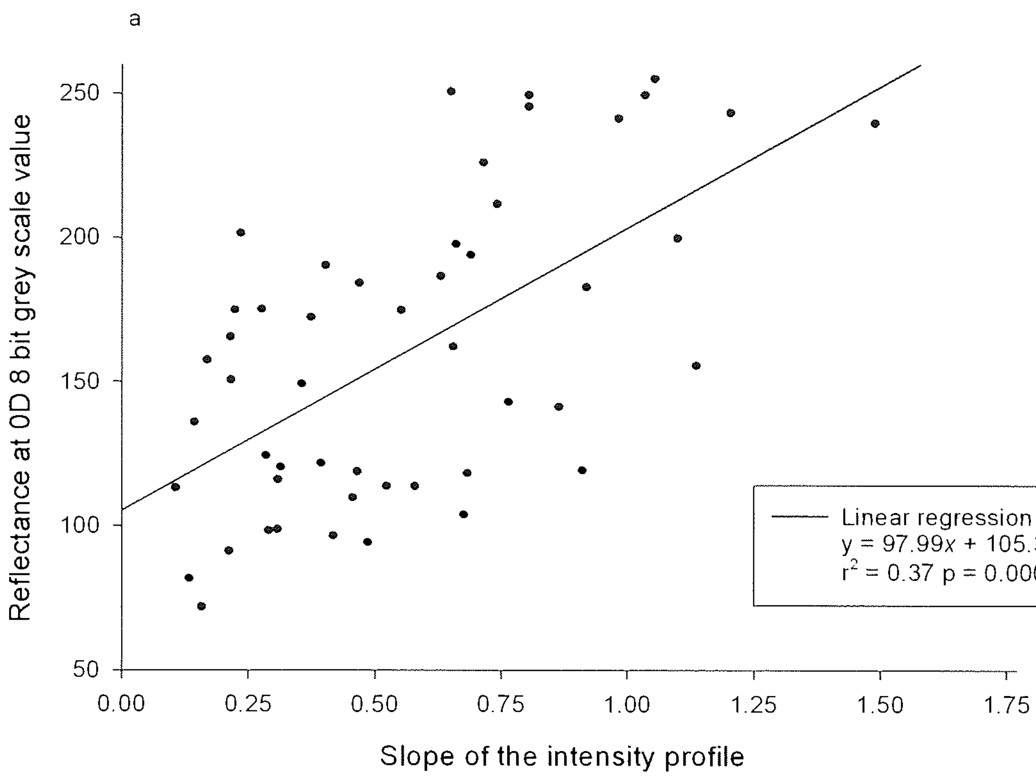
Figure 8.5 The slope of the intensity profile plot against ophthalmic lens power for *Px* 49.

The average change in the slope of the intensity profile was 0.64 ± 0.35 per dioptre of refractive error/accommodation. Again the slope was similar between the right and left eye (0.63 ± 0.33 versus 0.66 ± 0.38, p = 0.24). The slope in the uncovered eye viewing the stationary high contrast target was essentially flat (right 0.02 ± 0.14; left 0.04 ± 0.12).

As the results of the right and left eye were similar and the characteristics of the two eyes of the same subject are known to be related, just the data from the right eye is presented to prevent statistical bias. The regression was calculated for each variable with the slope of the intensity profile and is shown in table 8.1. The relationship between the significant characteristics (pupil size and fundus reflectance) and the slope of the intensity profile is shown in Figure 8.3a and b.

Demographic	Pearson Correlation (r)	Significance (p)
Age	0.16	0.06
Sex	0.12	0.11
Patient prescription	0.04	0.34
Age of onset	0.05	0.30
Inter-pupillary distance	-0.12	0.12
Mother's prescription	0.12	0.13
Father's prescription	-0.01	0.47
Pupil size	0.25	0.01
Slope of pupil change	0.56	0.28
Reflectance	0.62	0.0005

Table 8.1: Regression for each variable with the slope of the intensity profile.



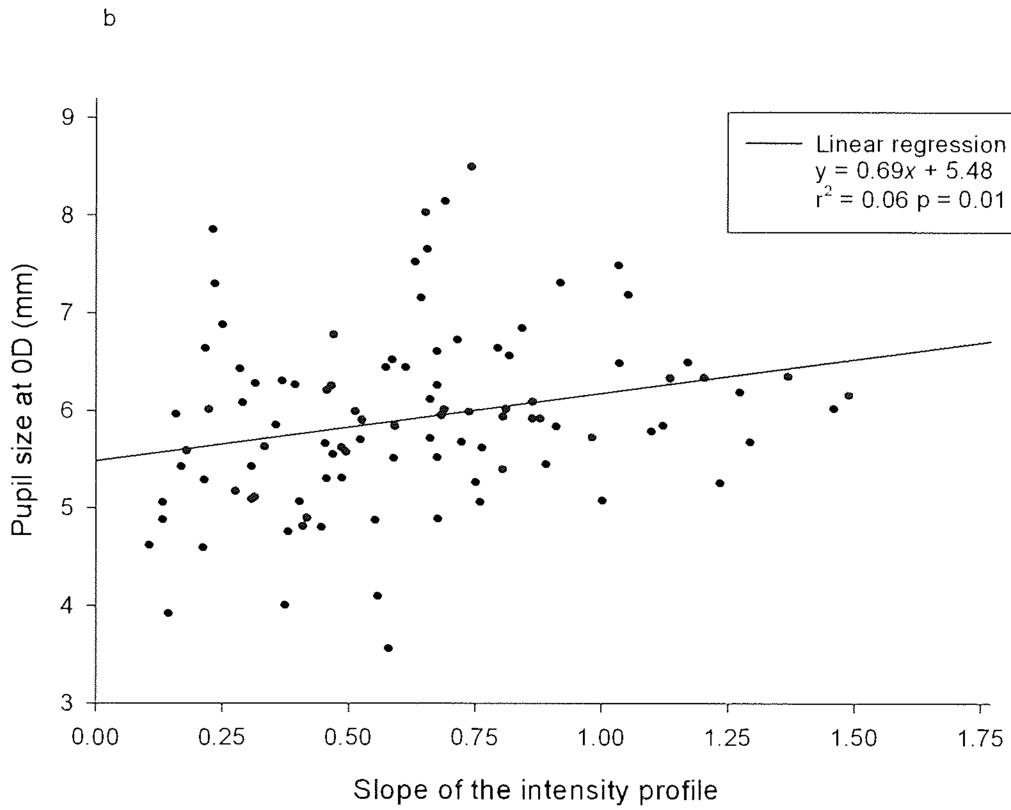


Figure 8.6: (a) Relationship between the slope of the intensity profile and reflectance from the fundus with a 0 D ophthalmic lens held in front of the eye (n=50) and (b) relationship between the slope of the intensity profile and the pupil size at 0 D.(n = 100).

Using a hierarchical multiple regression it was found that the characteristics investigated could account for up to 38% of the variance in the slope of the intensity profile (adjusted R square value = 0.383, F = 8.44, p = 0.171). The only significant variable was the reflectance of the fundus (adjusted R square value = 0.36, Standardised Beta = 0.529, p = 0.0005), with none of the other conditions reaching significance.

Conclusion

A wide range of changes in the slope of the intensity profile with simulated refractive error (slopes) are found in a young adult population. The high correlation between ophthalmic lens power and the change in the slope of the intensity profile, which was similar to that found in previous studies (Schaeffel, Wilhelm and Zrenner 1993), suggests the photoretinoscope was able to measure the luminance profile of the eye. The accommodative target viewed by the eye not under test resulted in no change in luminance profile, identifying that the experimental paradigm was sufficient to simulate accommodation /refractive error without the uncontrolled of changes in ocular accommodation. Therefore the variability in change in the slope of the intensity profile with simulated refractive error must result from individual external factors.

The only significant factor found from the subject characteristics examined in this study was the reflectance from the individual's fundus. Schaeffel, Wilhelm and Zrenner (1993) also found this factor to be significant, but the correlation was much stronger ($r = 0.86$). Retinal reflectance in this study was correlated to the individual's pupil size ($r = 0.47$, $p<0.001$). As the subjects were all under 50 years of age, and the reflectance was unrelated to age ($r = 0.23$, $p = 0.06$), the difference in fundus reflectance is unlikely to be related to media changes. Over the 1 m working distance, the difference in axial length with refractive error was also unlikely to affect fundus reflectance and this is supported by the lack of correlation with refractive error ($r = 0.04$, $p = 0.39$). Retinal pigmentation may be the main factor affecting retinal reflectance, but is unlikely to affect the change in light profile across the pupil. Therefore it is still not apparent how the change is the slope of the intensity profile occurs with simulated refractive error.

Attributing the average slope of the intensity profile change per dioptre with simulated refractive error (slope 0.64) as the value 1.0 D, the compound error over a 5 D range from the difference in this characteristic between individuals (95% confidence interval of 0.69) would be ±5.4 D. Unfortunately factoring the fundus reflectance into the relationship with the slope of the intensity profile found in this study (change per dioptre = ((reflectance–105.33)/97.99)/98 from figure 8.3), increases the error to ± 11.65 D over a 5 D range due to the wide range of fundus reflectance's. The wide variation in results is less than the 95% confidence limits of accommodation responses found with the *PowerRefractor* found in chapter 4 (± 2.32 D), suggesting that the internal compensation for fundus reflectance is decreasing the possible variability by a factor of approximately two. However, the study in this chapter compared to chapter 4 differs in that external ophthalmic lenses were used to simulate accommodation, rather than actual lenticular changes being exerted in response to accommodative demand.

In conclusion, the variation in the slope of the intensity profile change with simulated refractive error is likely to contribute to the inaccuracies of the *PowerRefractor*. It is not possible to fully predict the slope of the intensity profile change with simulated refractive error for an individual without individual calibration. Therefore, in studies utilising between-subject designs or examining individual subject results, individual calibration of photorefraction (including the *PowerRefractor*) is necessary.

CHAPTER 9

USING PHOTORETINOSCOPY TO MEASURE THE BINOCULAR OCULOMOTOR RESPONSE TO MONOCULAR VIRTUAL IMAGE DISPLAYS

Introduction

Helmet mounted displays (HMDs) portray information in the form of a virtual image reflected off an optical combiner, to one eye, which allows the user to view the outside world as well as the displayed information without the need to look at head-down instrumentation. Locating important reference information in this way is designed to allow the user to spend more time head-up and less time head-down searching for information within the cockpit. It also allows enhancement of the outside world scene such as Forward Looking Infra-Red Imagery (FLIR) to be utilised by the user. HMDs have been established in the aeronautical industry to try to overcome the shortfalls of head-up displays (HUDs), which are only visible along a fixed line of sight (e.g. Weintraub and Ensing, 1992; Newman and Haworth 1994). Current HMDs immerse the observer in an artificial environment in which the visual system can be placed under stress from poor illumination and contrast (e.g. Snellen equivalent of about 6/60), a relatively short working distance (typically 25mm; Schor and Task, 1996) and induced prismatic effects (due to decentration of high powered optics) which can lead to visual discomfort (e.g. Mon-Williams, Wann and Rushton, 1993).

The optics of a HUD or HMD will allow its virtual image to be focused at any distance in front of the observer. Aircraft HUDs and HMDs are usually collimated (i.e. focused at optical infinity) as objects of interest are invariably distant and the virtual image is often used to overlay an outside scene to allow landing and manoeuvring in poor visibility and night flying. There is some concern that presenting a virtual image on a combiner may affect the accommodation response (e.g. Roscoe, 1979 and 1987a,b; Iavecchia, Iavecchia and Roscoe, 1988). However, the extent and impact of these problems in aircraft has been much debated (e.g. Weintraub, 1987; Weintraub and Ensing, 1992) and more recently it has been shown that any over-accommodation is minor when using a head-up display collimated at optical infinity

(Wolffsohn *et al.*, 1999). In a featureless cloud environment, the accommodative level drifts to the dark or tonic level of accommodation, but the presence of detailed collimated imagery is enough to maintain the accommodative response in the far distance (Wolffsohn, Edgar and McBrien, 2001).

The accommodative response to monocular displays would appear to be less accurate than to binocular displays (Roscoe, Olzak and Randle, 1976; Roscoe, 1979; Moffit, 1989; Wolffsohn, Edgar and McBrien, 1998), although reaction and response times to targets may not be affected (Heron and Winn, 1989). However, little research has been directed to the oculomotor demands of modern, monocular, virtual image displays. Schor and Task (1996) found that stationary HMD symbology was perceived as located in front of a night vision goggle scene, although the accommodative response remained distant with collimated, monocularly viewed, imagery. Viewing the stationary HMD symbology alone, the accommodative response was found to reflect the distance to which the HMD imagery was focused (over the 0.5 D range examined). No study has investigated either the accommodative response of the eye to which the imagery is not visible or the associated pupil response and vergence components comprising the composite oculomotor response.

Proximal accommodation (Chapter 1), which is produced by knowledge of the apparent nearness of an object of regard, has the potential to contribute a substantial proportion of the total accommodative response (e.g. Rosenfield and Ciuffreda, 1990) and to maintain a sustained response (Rosenfield *et al.*, 1993). However, Wolffsohn and colleagues (1999) found no significant proximal effect (on average <0.1 D) on the introduction of a HUD combiner and Tornado windshield in front of a distant outside world scene. As accommodative accuracy is dependent on the wavelength of target light and phosphor bandwidth, virtual imagery, which tend to be monochromatic, may not induce as accurate an accommodative response as a broader bandwidth display (Charman and Tucker, 1978; Kotulak, Morse and McLean, 1994).

This study aimed to investigate the utility of a remote, objective, high resolution method for *in situ* continuous measurements of accommodation and oculomotor function while using a monocular virtual image display. The oculomotor response to changing the focusing distance of the intervening image and the proximal nature of the combiner were examined.

Methods

Ten subjects aged 19 to 28 years of age (average 25.2 ± 2.8 years) with no ocular pathology or binocular vision defect were selected to take part in the research. Their mean spherical refractive error ranged from +0.75 D to -0.75 D and they were made functionally emmetropic using ultra-thin hydrophilic contact lenses (*Acuvue Daily Disposables*, Johnson and Johnson). They were seated with their chin on a chin-rest and head positioned against a headrest, 1 m away from the photoretinoscope, aligned along their visual axis. Due to the need for increased accuracy compared to that found with the stated universal calibration of the *PowerRefractor*, a purpose designed photoretinoscope was designed for this study.

A cone of infra-red light was projected from a mask obscuring the lower half of the video camera lens into the subject's eyes. The pupils were imaged by the video camera (Pulnix 6E, USA) and the image analysed by a purpose designed Labview program (National Instruments), run on a Pentium III 800MHz PC with a PCI IMAQ-1407 image capture board (National Instruments, USA). The photoretinoscopy system allowed continuous measurement of accommodation, vergence and pupil size at a rate of up to 50 Hz from both eyes simultaneously (Figure 9.1)

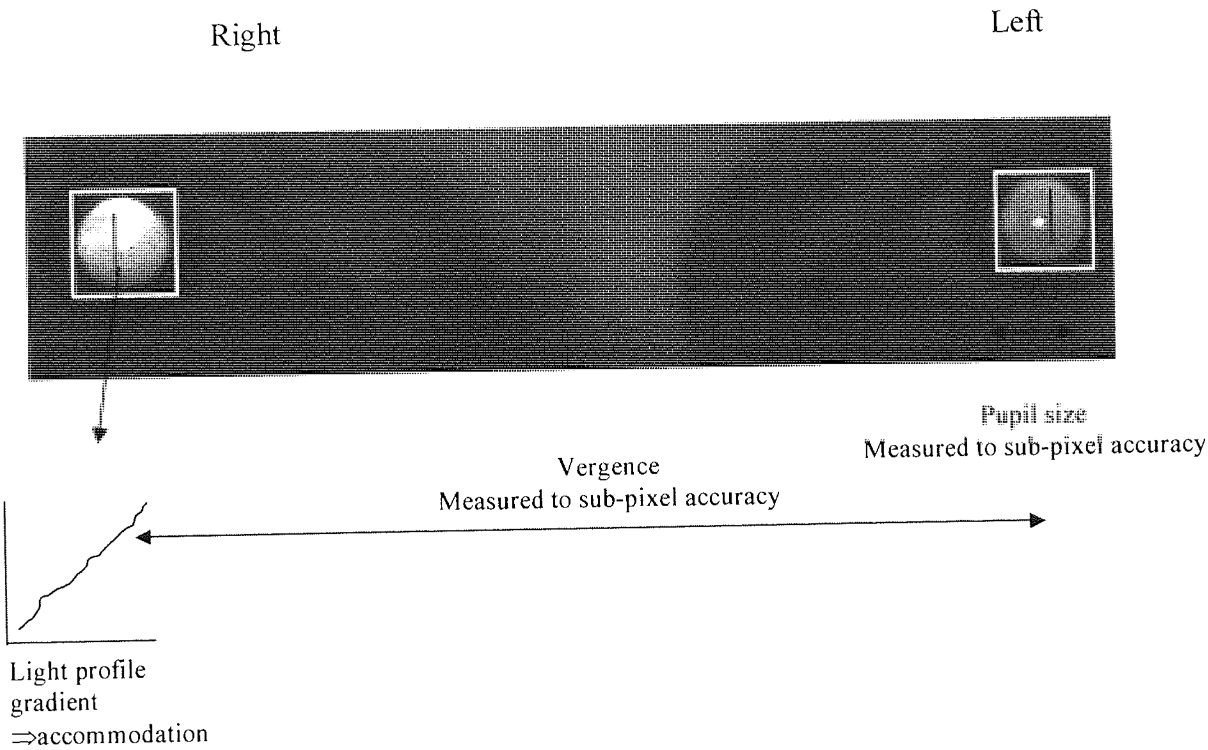


Figure 9.1: Image from the photoretinoscope showing the gradient light intensity profile across the two pupils.

The light intensity profile across the pupil is related to the refractive power of the eye (Howland, 1974; Schaeffel, Wilhelm and Zrenner, 1993; Gekeler *et al.*, 1997). However, calibration of accommodation needs to be performed on each subject as the light intensity gradient across the pupil compared to accommodative level varies between individuals due to the difference in reflectivity of the fundus (Schaeffel, Wilhelm and Zrenner, 1993).

Calibration was achieved by having the subject observe a high contrast (>90%) black on white Maltese cross placed at 1m with one eye (maintaining equal accommodative level for both eyes), while the other was covered by an infra-red filter (Lee Wratten 87c). Whereas infra-red light from the photoretinoscope was transmitted by the filter, the eye behind the filter was visually occluded and was therefore unable to accommodate to the lenses placed in front of the filter. Thus calibration to the range of lenses used could be determined without the influence of accommodation. The apparent accommodative level was changed by -1.0, 0.0, +1.0, +2.0, +3.0 and +4.0 D in each eye in turn and the light intensity profile across the pupil was measured. The results were plotted and the gradient of the regression line through the points recorded. Subjects then viewed the Maltese cross, positioned at 1 m binocularly, with no filters in front of the eyes and a baseline light intensity profile across the two pupils was recorded (assumed to be 1 D of accommodative response). Ocular vergence was measured to a resolution of 0.00072 degrees and pupil size to a resolution of 0.00012 mm using edge detection techniques to identify the pupil edges to 1/1000th of a pixel (Wolffsohn, 2003).

A 50:50 combiner was then positioned in front of the subject's right eye at a distance of 20 cm (Figure 9.2). A virtual image of a miniature (2" x 2") liquid crystal display (LCD) video monitor displaying numbers of resolution 1.14 seconds of arc (equivalent to Snellen acuity of 6/6.8) was viewed by reflection off the combiner (luminance 15 cd/m^2). Both eyes were monitored by the photoretinoscope to measure pupil size, accommodation and ocular vergence while the subject viewed the virtual image with their right eye and the left eye was exposed only to a dark environment. The oculomotor status of the eyes was assessed while the accommodative demand of the virtual image was altered within a Badal optical system to 0 D, 2 D or 4 D (the trials were performed in a randomised array). The accommodative demand of the virtual HMD image was then set to 0 D (optical infinity) and the combiner positioned at 33 cm from the eyes to examine the effect of proximity from the combiner on the oculomotor response.

This study had been passed by the ethics committee and all participants signed consent forms.

Statistical Analysis

Data from the trials (average ± SEM) were entered into an *Excel* spreadsheet. Analysis of variance was used to examine overall effects between groups and Tukey's pairwise multiple comparison tests were used to assess individual group differences (Minitab v9.0). Paired *t-tests* were used to examine specific differences within groups.

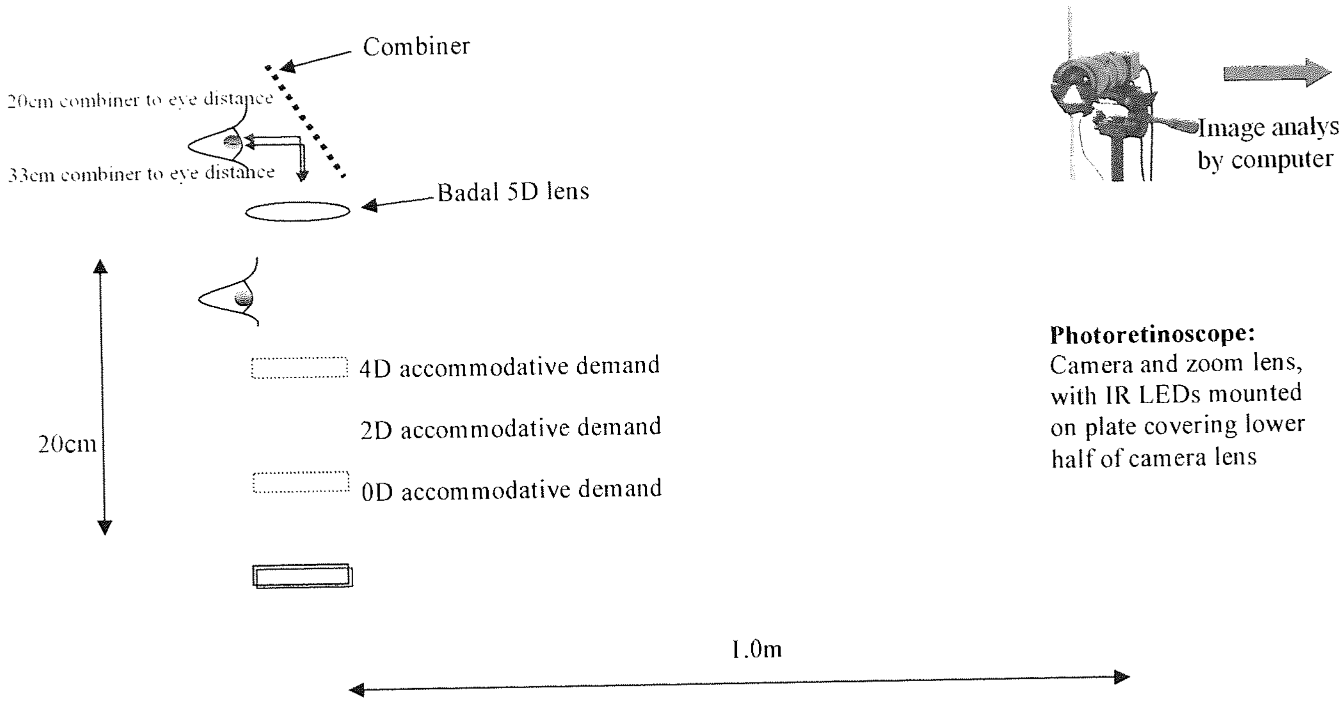


Figure 9.2: Experimental set-up

Results

Accommodative Response

Subjects were found to focus to the accommodative demand of the virtual image (F ANOVA power=32.5, $p<0.001$), with a lead of accommodation of approximately 0.40 D when the image was positioned at optical infinity and a lag of accommodation of approximately 0.30 D when the image demand was 2 D and 0.90 D when the image demand was 4 D (Figure 9.3). The eye to which the virtual image was not visible showed a similar change in accommodation to the accommodative demand of the virtual image ($F=37.7$, $p<0.001$) as that of the eye behind the combiner, with no significant difference between the two eyes ($p>0.05$; Figure 9.3).

When the image was positioned at optical infinity, moving the combiner from 20 cm to 33cm from the eye caused a slight, but significant decrease in the accommodative response (0.46 ± 0.18 D vs. 0.33 ± 0.17 D respectively, $p<0.05$).

Vergence Response

Ocular vergence was found to increase (i.e. the separation between the centres of the pupils decreased) as the accommodative demand of the virtual image presented to the right eye only increased (Figure 9.4). However, the change in separation between the two eyes did not reach significance ($F=1.5$, $p=0.24$). However, power analysis shows that the group size were sufficient to have only a 75% chance of detecting a change at the 5% level of significance.

When the image was positioned at optical infinity, moving the combiner from 20cm to 33cm from the eye had no significant effect on eye vergence ($p = 0.79$).

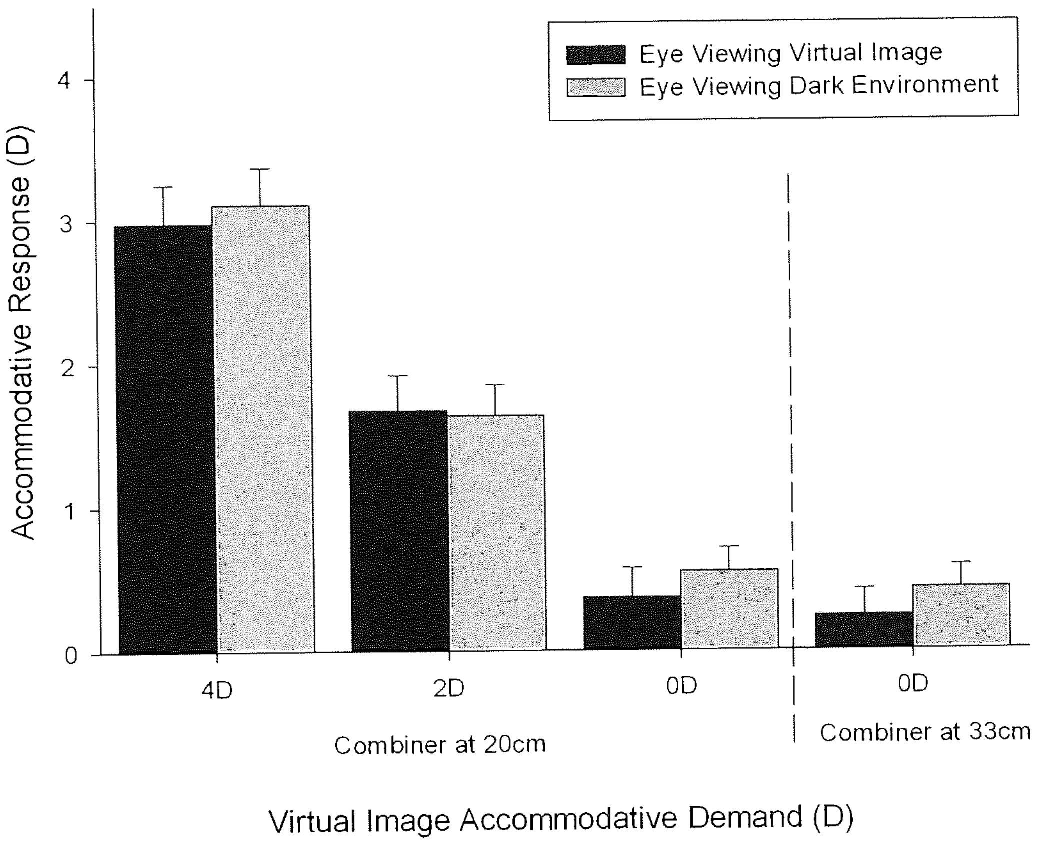


Figure 9.3: Accommodative response of the eye viewing the virtual image and the other eye in a dark environment with the accommodative demand of the virtual image and combiner distance. n=10. Error bars = ±1 SEM

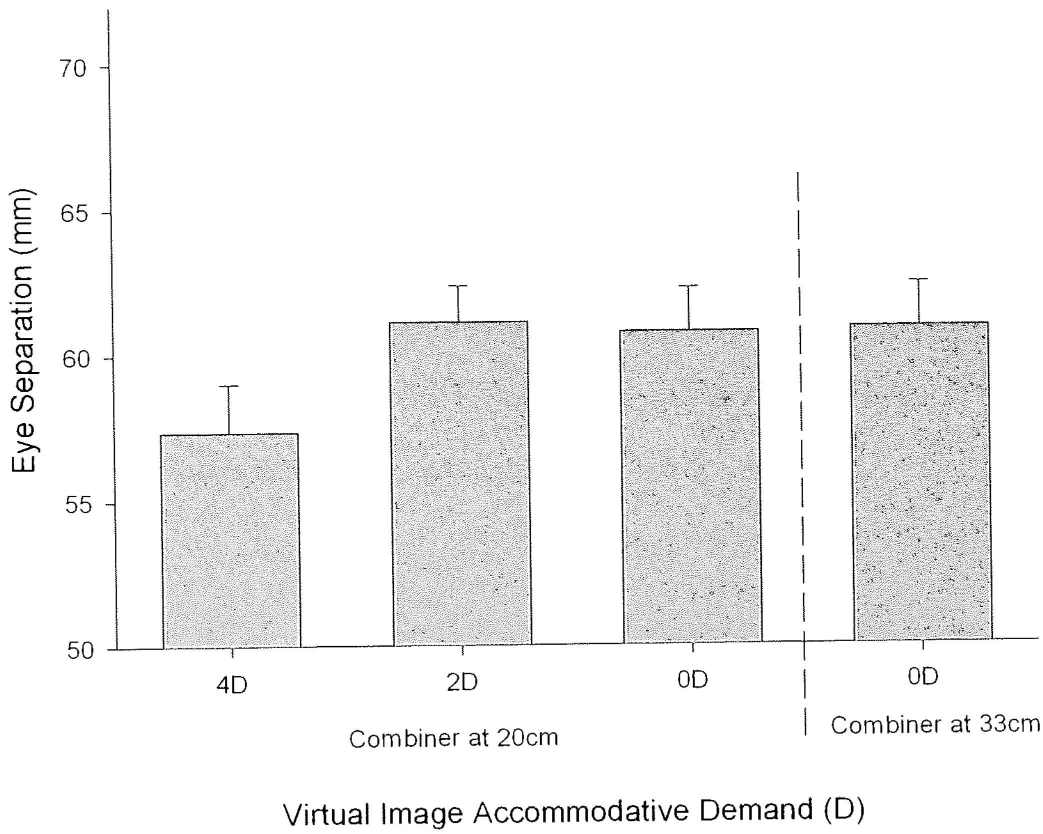


Figure 9.4: Separation between the two eyes with the accommodative demand of the virtual image and combiner distance. n=10. Error bars = ±1 SEM

Pupil Size

There was a contraction in the pupil size of the eye viewing the virtual image with increasing accommodative demand of the image ($F = 6.8$, $p<0.001$; Figure 9.5). The eye to which the virtual image was not visible also contracted with increased accommodative demand ($F = 11.0$, $p<0.001$), with no significant difference between the two eyes ($p>0.05$; Figure 9.5). However, power analysis shows that the group size were sufficient to have only a 75% chance of detecting a change at the 5% level of significance. When the image was positioned at optical infinity, moving the combiner from 20 cm to 33 cm caused a small but significant increase in pupil diameter (6.44 ± 0.20 mm vs. 6.59 ± 0.20 D, $p<0.01$).

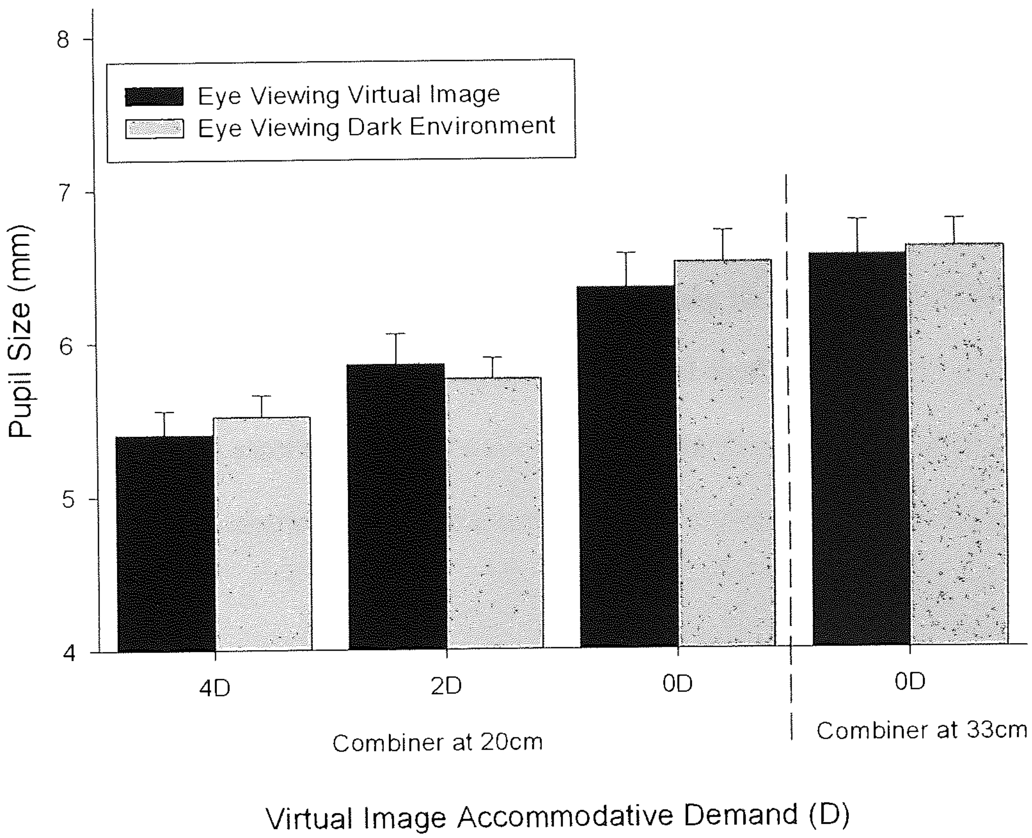


Figure 9.5: Pupil size of the eye viewing the virtual image and the other eye in a dark environment with the accommodative demand of the virtual image and combiner distance. n=10. Error bars = ±1 SEM

Discussion

The study aimed to investigate the use of photoretinoscopy to measure the accommodative response, ocular vergence and pupil diameter simultaneously while subjects viewed monocularly-presented HUD/HMD type images. Photoretinoscopy was shown to be capable of quantifying binocular, *in-situ* oculomotor changes at a resolution of up to 50 Hz (non-interlaced PAL imagery) with a resolution of <0.01 D for accommodation, <0.001 mm for pupil size and <0.001° for ocular vergence.

Photoretinoscopy was applied to a basic, high resolution, virtual image reflected off a combiner in front of one eye while the other eye was exposed to a dark environment with minimal accommodative stimulus. As would be expected, the accommodative response increased to an increase in the accommodative demand of the virtual image with a lead of accommodation below the tonic level and a lag of accommodation above the tonic level (Charman, 1982). The accommodative response of the eye in the dark environment also responded to the accommodative level of the virtual image, despite having no direct view of this image. The difference between the two eyes did not reach statistical significance, although a larger study would be needed to ascertain whether more subtle differences in accommodative function, for example in microfluctuations, are present between the two eyes in such environments.

The reciprocal link between accommodation and vergence resulted in the separation between the two eyes decreasing with increasing accommodative demand of the monocularly viewed HMD image. The reciprocal link between accommodation and vergence is known to break down in the dark (Kotulak and Schor, 1986), but the light of the virtual image seen by one eye only seems to have been enough to maintain the near triad (accommodation, vergence and pupil responses). The near triad synkinesis also resulted in a decrease in pupil size in both eyes as the accommodative demand of the virtual HMD image, visible to only one eye, increased. Again there was no difference in pupil size between the eyes, suggesting that the accommodative demand to one eye was able to drive both pupils equally.

Finally, the effect of target proximity was examined by moving the combiner from 20 cm to 33 cm from the eye while the virtual target was imaged at optical infinity. There was a small, but significant reduction in accommodation and dilation of the pupil indicating the proximity of the combiner was registered by the perceptual system. Further research is needed to examine whether a systematic change in pupil size occurs with changes in the eye to combiner distance, whether the effect is modified by task demand and what effect a combiner at a distance more typical to HMD use (~25 mm) has on oculomotor function.

In summary, this study has shown the ability of a custom designed photoretinoscopy to quantify effectively changes in the binocular oculomotor system. As a remote, relatively inexpensive, binocular system, photoretinoscopy offers the opportunity to better understand the effect of human visual interfaces on the oculomotor visual system.

CHAPTER 10

CONCLUSION

This thesis examines the technique of photorefraction, especially the new commercial *PowerRefractor* and its role in assisting in determining oculomotor function in human factor applications. In reviewing the literature, the need to measure refractive error and, in turn accommodation, accurately and in real-world environments was identified. The theory of accommodation has changed dramatically from the early theories of Rufos and Gallen in 100AD (Dubois Poulsin, 1987) to the more relatively recent work of Helmholtz and Schachar. New instruments have been developed periodically over the past 50 years to measure refractive error and accommodation including the extensively utilised *Canon R-1*, but in general these have had limitations including a closed field-of-view, a poor temporal resolution and the need for extensive instrumentation bulk preventing naturalistic performance of environmental tasks.

A clinical evaluation of the *PowerRefractor* was undertaken on an adult population to assess the accuracy of the instrument, as the ability of the *PowerRefractor* to measure continuously from a remote location, binocular parameters of the complete oculomotor triad, could be of great value in optometric and ophthalmological research. Although for the population examined the average *PowerRefractor* prescription was similar to that found by subjective refraction, the range of differences was large (up to 3.5D), with 95% of readings within ±1.12D. Compared to the *SRW-5000* autorefractor, the *PowerRefractor* prescription was more negative and again had a wide range of differences. Compared to previously validated open-field autorefractors (e.g. the *Canon R-1* and the *SRW-5000*) the *PowerRefractor* is, on average, just as accurate, but approximately 24-42% more variable (Mallen *et al.*, 2001, McBrien and Millodot, 1985).

While the *PowerRefractor* was then seen to be a useful autorefractor and screening device for adults, it was unknown how it would perform under the demanding conditions required for measuring accommodation in human factor applications. It did seem to have many of the necessary criteria required including a wide valid measurement range without the need for individual calibration, an open field-of-view, objective measures and a degree of portability. However, to be useful in unrestricted human factors research, the instrumentation to measure oculomotor function also needs to be tolerant to eye movements and changes in target and ambient luminance. The *PowerRefractor* was found to be tolerant to eye movements which would be essential to any aeronautical or head mounted display research. However, it is severely limited by both the blind spot artefact, that causes an apparent change in accommodation of up to 1 D at approximately 10 – 15° eccentricity, and more significantly was limited to pupil sizes greater than 3 mm. The *PowerRefractor* failed to measure any results for some patients in moderate light levels (15 cd/m^2 target luminance). This is a dilemma in human factor research as it limits the usefulness of the instrument.

If the increased variability of the *PowerRefractor* compared to previous instrumentation was related to an individual's characteristics, such as the retinal reflectance, this would have little impact on the results of within-subject experimental designs or where results are compared to a baseline accommodative level. However, if the inaccuracy was due to inherent instrument variability, then this may have serious consequences for the use of the instrument beyond the screening of refractive error. It was therefore necessary to determine the accuracy of the stimulus response curves calculated with the *PowerRefractor* and to compare them to a well-validated autorefractor, the *SRW-5000*, and the results found in the previous literature. The findings of chapter 4 suggested that the *PowerRefractor* underestimated the lead of accommodation and overestimated the slope of the accommodative stimulus response curve compared to previous validated autorefractors (e.g. McBrien and Millodot, 1986; Mallen *et al.*, 2001)

Chapter 5 examined how the oculomotor triad varies between wearing spectacles compared to contact lenses. Alpern (1949) theorised that the accommodation and vergence demands are different between single vision contact lenses and spectacle lenses, with myopes being required to exert more accommodation and vergence when wearing single vision contact lenses compared to spectacles and the converse being true of hypermetropes. For myopic patients, spectacles lenses provide a base-in prismatic effect when fixating at near, resulting in a decreased need for convergence. When contact lenses are worn in place of spectacles this effect is lost, so in comparison a greater convergence effort is required. As the differences in oculomotor status between contact lenses and spectacles is an important clinical consideration in early presbyopes and in individuals with binocular vision anomalies, chapter 5 objectively and simultaneously measured the binocular differences in the oculomotor triad response (ocular accommodation, vergence and pupil size) over a wide range of refractive error in individuals wearing both single vision spectacles and contact lenses. The measurements were taken with both the *PowerRefractor* and the *SRW-5000* due to the inaccuracies in the former instrument noted in the previous chapter. The study confirmed the theoretical calculations, although the effects were larger than those calculated and identified this feature of oculomotor function to be of particular importance in myopic impending presbyopes who choose to have either contact lenses or LASIK/LASEK surgery.

A similar technique of using both the *PowerRefractor and SRW-5000* was employed for the subsequent studies. Chapter 6 examined the role for contact lenses and the progressive addition lens paradigm in myopia control. The results of previous myopia prevention studies in children, correcting the participants with bifocal and/or varifocal spectacle lenses have been equivocal (Gwiazda, Hyman, Hussein *et al.*, 2003, Parssinen, Hemminki and Klemetti, 1989, Ong, Grice, Held, Thorn, and Gwiazda 1999, Leung and Brown, 1999. One of the reasons for this may have been the non-compliance of the patients with the wearing of the spectacles and use of the appropriate portion of the lenses for all tasks. Contact lenses have many advantages over spectacle lenses in that they are not easily removed and remain in the line of sight at all times. However, before large scale studies can be undertaken, it was important to ascertain whether simultaneous vision contact lenses do reduce the accommodative response of individuals with active accommodation. The study has suggested that accommodative effort exerted by subjects viewing a near target is reduced in pre-presbyopes wearing bifocal or multifocal contact lenses compared to single vision contact lenses, although only by approximately 20-30%. Due to the simultaneous nature of the lenses, accommodative accuracy could not be examined.

Chapter 7 used the *PowerRefractor* and the *SRW-5000* to measure objective the accommodative function of the *1CU* accommodative intraocular lens. None of the previous studies assessing the accommodative facility achieved using an 'accommodative' intraocular lens have quantified the stimulus response curve or the dynamic accommodative response to a moving stimulus and therefore this study aimed to measure the oculomotor function of patients fitted with the *1CU* 'accommodative' intraocular lens. The objective 'accommodating' effects of the *1CU* lens were shown to be limited, although patients were able to track a moving target and achieve adequate acuity for most visual tasks at distance and near. They also subjectively reported being very happy with the result of the operation. The greater subjective, than objective, amplitude of accommodation was likely to have resulted from the interaction between the depth-of-focus of the eye and the aspheric nature of the *1CU* intraocular lens.

One factor that became apparent throughout the previous chapters was the inaccuracy of the *PowerRefractor* measures, particularly at higher accommodative levels, leading to exaggerated readings. Early photorefractive studies suggested the variance in the slope of the intensity profile with changes in refractive error could be accounted for by the reflectance of the individual's fundus, and a correction factor is utilised by the *PowerRefractor* to account for this (Schaeffel, Wilhelm and Zrenner, 1993). Therefore, using a purpose designed photorefractor, the dependence of the slope of the intensity profile change with refractive error was investigated in a large population and compared to demographic factors such as the patient's refractive error, age and pupil size. It was only possible to predict 38% of the variance in the slope of the intensity profile change with simulated refractive error for an individual, accounting for the inaccuracies found in using the *PowerRefractor* without individual calibration. Therefore, in studies utilising between-subject designs or examining individual subject results, individual calibration of the *PowerRefractor* is necessary.

In the final part of the thesis, photoretinoscopy was used to measure the binocular oculomotor response to monocular virtual images of a head-mounted display (HMD). The oculomotor response to changing the focusing distance of the intervening monocular image over a range of 0 to 4 D and the proximal nature of the combiner (at 20 or 33cm) was examined. The accommodative and vergence response increased and the pupil size decreased in both eyes relative to the increasing accommodative demand of the HMD image, despite the virtual image only being visible to one eye. There was a small, but significant reduction in accommodation and dilation of the pupil with increased proximity of the combiner in front of one eye, indicating the proximity of the combiner was registered by the perceptual system.

In conclusion, this thesis has shown the ability of photoretinoscopy to quantify changes in the oculomotor system. However there are some major limitations to the *PowerRefractor*, such as the need for individual calibration for accurate measures of accommodation and vergence, and the relatively large pupil size necessary for measurement.

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Appendix

Ethics Approval, Consent Forms and Supporting Publications

ASTON UNIVERSITY **PROJECT NO..............**

THE SENATE **REG/00/174**

HUMAN SCIENCE ETHICAL COMMITTEE

Application for approval of a research project involving human volunteers

Please read the enclosed guidelines before completing this form - in typescript or black ink - and return the form to: The Secretary of the Human Science Ethical Committee, Registry. If you intend to administer any substance or expose the volunteers to a physical procedure other than simple venepuncture **you must also submit an experimental protocol.**

Project title:

Ocular Motor and Autonomic Function in Human Factor Applications

---

Investigator(s):	Department/address: Telephone:	
Dr James Wolffsohn	Optometry, NRI	0121 359 3611 ext 5160
Professor Bernard Gilmartin	Optometry, NRI	0121 359 3611 ext 5159
Miss Olivia Hunt	Optometry, NRI	0121 359 3611 ext 5175
Mr Leon Davies	Optometry, NRI	0121 359 3611 ext 5100

A
Details of sponsoring/collaborating organisation (if any)

1 Name: British Aerospace, Filton, Bristol and EPSRC

2 Does the sponsoring/collaborating organisation provide insurance? NO

3 If drugs are used, do any require a clinical trials certificate or clinical trials exemption certificate? N/A

*If yes, please provide a copy of the certificate

B
Summary of Project

1 Starting date — 1st November 2002

2 Duration: — 3 years

3 Location: — Aston University, Birmingham (majority) and BAe, Bristol

4 Physical procedures:

Measurement of different ocular parameters using commercially available devices:

I. Oculomotor function (refractive error, eye vergence and pupil size) using standard auto-refractors (*Shin Nippon and PowerRefractor*)
II. Ocular biometry using a non contact partial coherence interferometer (*IOL Master,* Zeiss)
III. Autonomic function using a finger pulse transducer

Subjective Refraction and bionocular vision assessment

Viewing or responding to images on static or moving visual displays

Contact lens fitting of daily disposable lenses (worn for up to 2 hours)

5 Substances to be administered (a substance is anything other than normal food - chemical constituents of food stuffs, ethanol and variation of the diet should be included here) and method of delivery should be specified:

None

6 Psychological assessment:

None

7 Questionnaires: (only to be completed when project contains questionnaire(s) which fall within the types of questionnaire requiring HSEC approval [Guidelines D (3)])

None requiring HSEC approval

C

Subjects

1 Number of volunteers to be used: approximately 500

2 Over what time span? 3 years

3 Age of volunteers: 18-45 years

4 Sex of volunteers: Male and Female

5 Source: Aston University and BAe staff and undergraduate students,

6 Will payments be made to the volunteers and if so, how much will each be paid?

No

7 Are the volunteers' patients or healthy volunteers? (If patients give diagnosis, clinic/responsible practitioner).

The patients are all healthy volunteers.

8 Will any volunteers be excluded and if so, on what grounds?

Volunteers with high astigmatism (>1.50D) will be excluded from the study as this makes it difficult to render then functionally emmetropic with soft contact lenses

9 Is the activity of the volunteer to be restricted in any way either before or after the procedure? (eg diet, driving)

No

10 Consent: Please attach a copy of the consent form you intend to use, detailing how procedures and hazards will be explained.

Attached

D

Risk Assessment: *a thorough Risk Assessment of the project must be undertaken (including for example welfare issues arising from the procedure, and the possible risk of residual effects in volunteers and the consequences thereof).*

1 Please give full details of any hazards, which could affect the health, safety or welfare of any volunteer, or any other person who might be harmed as a result of the experiment.

Contact lens may be inserted into the volunteers' eyes to make them functionally emmetropic. When using contact lenses there is very slight risk of infection, but no know risk exists with short-term use (<1 day). The lenses used will be commercially available daily disposable contact lenses worn for a maximum of 2 hours.

The instruments used are all non-invasive commercially available instruments, which are used in practice. The finger pulse transducer is commonly used in hospital clinics. There are no known risks associated with its use.

2 What levels of risk are associated with these hazards?

Virtually none - see above

3 How do you propose to control the risks associated with these hazards?

Use single use disposable soft contact lenses to eliminate the risk of cross-infection.

4 What criteria have you used to determine whether the risks are acceptable?

Common usage in optometric and medical practice with no reports of adverse effects

5 Is there any precedent for these experiments? If so, please give details with references if possible.

Screening of refractive error and axial length. Ref 01/D

Akselrod, S., Gordon, D., Ubel, F. A., *et al.* Power spectrum analysis of heart rate fluctuation: a quantitative probe of beat-to-beat cardiovascular control. Science. 1981; 213:220-222.

Choi, M; Weiss, S; Schaeffel, F; Seidemann, A; Howland, H.C; Wilhelm, B. and Wilhelm, H. Laboratory, Clinical, and Kindergarten Test of a new Eccentric Infrared Photorefractor. Optometry and Vision Science 2000; 77:537-548.

Collins, M., Davis, B. and Wood, J. Microfluctuations of steady-state accommodation and the cardiopulmonary system. Vision Research. 1995; 35:2491-2502.

Mallen, E.A.H; Wolffsohn, J.S; Gilmartin, B. and Tsujimura, S. Clinical Evaluation of the Shin-Nippon *SRW-5000* autorefraction in Adults. Ophthalmic and Physiological Optics 2001; 21:101-107.

Schaeffel, F; Weiss, S. and Seidel, J. How good is the match between the plane of the text and the focus during reading? Ophthalmic and Physiological Optics 1999; 19:180-92

Schaeffel, F; Wilhelm, H. and Zrenner, E. Inter-individual Variability in the Dynamic of Natural Accommodation in Humans: Relation to Age and Refractive errors. Journal of Physiology 1993; 461:301-320.

6 Has this project been considered/is it being considered by any other Ethical Committee? If so, please give details and decision made.

No

E

STATEMENT BY NAMED INVESTIGATORS, HEAD OF SCHOOL AND (if necessary) RESEARCH SUPERVISOR

I consider that the details given constitute a true summary of the project and that the hazards and potential risks to any volunteer are accurately described. The Principal Investigator is the main point of contact for the Human Sciences Ethical Committee, and accordingly should be a member of academic staff of the University (this implies that supervisors of research students will be the main point of contact)

Principal Investigator or..
date..

Supervisor of Student

Investigator...
date..

Investigator...
date..

Investigator...
date..

Head of School...
date..
(or nominee)

The following should be attached:

* volunteer consent form
* insurance certificate (if available)
* clinical trials certificate or clinical trials exemption certificate (if appropriate)
* experimental protocol

ASTON UNIVERSITY **REG/00/175**

HUMAN SCIENCE ETHICAL COMMITTEE

CONSENT FORM FOR VOLUNTEERS

PROJECT TITLE

Ocular Motor and Autonomic Function in Human Factor Applications

RESEARCH WORKERS, SCHOOL AND SUBJECT AREA RESPONSIBLE

Dr James Wolffsohn, Life and Health Science, Vision Sciences
Professor Bernard Gilmartin, Life and Health Science, Vision Sciences
Miss Olivia Hunt, Life and Health Science, Vision Sciences
Mr Leon Davies, Life and Health Science, Vision Sciences

EXPLANATION OF ANY POSSIBLE HAZARDS AND THE PROCEDURES TO BE USED

1. As part of our ongoing research programme we would be grateful if you would participate in our study into the changes in eye and autonomic system that occur with human factor applications, such as a cognitive task or flying a plane. The tests allow us to measure these effects

2. The procedure uses standard consulting room equipment used widely by optometrists and medical professionals in every day practice, taking only a few minutes. This is not a full eye examination. There are no known hazards involved.

3. If you have a refractive error, you will be fitted with daily-disposable soft contact lenses for up to 2 hours. There are no known adverse effects of such short-term wear.

4. Participation in this study is not a requirement of your university course and you are free to withdraw at any time.

CONFIDENTIALITY OF INFORMATION

The confidentiality of personal information and the anonymity of all volunteers involved in this investigation will be preserved by storage of the data in a locked filing cabinet, and will be accessible only to the investigators

VOLUNTEER'S STATEMENT

I have read and understand the above explanation. I have had the opportunity to discuss it with the investigators and to ask any questions. I agree to take part in the above project and I have been informed that I am free to withdraw at any time.

Signed: ....

Dated: ....

Using Photoretinoscopy to Measure the Binocular Oculomotor Response to Monocular Virtual Image Displays

JS Wolffsohn[1], B Gilmartin[1], OA Hunt[1] & GK Edgar[2]

[1]Neurosciences Research Institute, School of Life and Health Sciences, Aston University, Birmingham, UK

[2]BAE Systems, Sowerby Research Centre, Bristol, UK

Aim: In the real environment, ocular accommodation, vergence and pupil size are linked to allow optimum viewing of the outside world. However, some human interfaces, such as head-mounted aircraft displays, provide visual information to only one eye. Therefore this monocular image, when combined with the eye viewing the normal scene, provides an unnatural binocular visual input. This study investigates the utility of a remote, objective, high resolution method for *in situ* continuous measurements of accommodation and oculomotor function while using a virtual image display.

Method: Ten young subjects took part in the experiment. The technique of photoretinoscopy was utilised to allow ocular accommodation, eye alignment and pupil size to be monitored simultaneously in both eyes. A cone of infra-red light was passed into the eyes from a shield which covered the lower half of a video camera lens. The video camera was placed approximately 1m remote from the subject and the reflection of the infra-red light in the subject's pupils was imaged. The gradient of the light profile has been shown to be correlated to refractive error and the pupil position and size were accurately determined using edge detection image analysis techniques. Initially the change in profile of light intensity across the pupil to lens induced changes in refractive error (-1D, 0D, +1D, 2D, 3D and 4D) was measured as a calibration procedure. Subjects then viewed binocularly a high-contrast (>90%) Maltese cross, positioned at 1m, to provide baseline data. A combiner was positioned 20cm in front of the right eye and accommodative, pupil size and eye position data were collected from both eyes as the subject viewed a target through a Badal system imaged at optical infinity, 2D and 4D. In addition, the combiner was positioned at 33cm in front of the eye while the subject viewed a target imaged at optical infinity to investigate the effect of combiner proximity on the oculomotor response.

Results: As the accommodative demand of the virtual target viewed monocularly increased, the photoretinoscopy devise was able to measure effectively that the accommodative response increased in both eyes, the vergence between the eyes increased and the pupil size of both eyes decreased. Increasing the distance between the combiner and the eye decreased the accommodative response and the pupils dilated.

Conclusion: Photoretinoscopy was shown to be capable of quantifying binocular, *in-situ* oculomotor changes at a resolution of up to 50Hz with a resolution of <0.01D for accommodation, <0.001mm for pupil size and <0.001° for ocular vergence. Photoretinoscopy, therefore, has great potential in improving our understanding of Vision in Vehicles.

Presented - Vision in Vehicles 9, Brisbane, Australia. 19-22 August 2001.

Accommodation and Vergence with Single Vision Contact Lenses Compared to Spectacles

Hunt Olivia A, Wolffsohn James S, García-Resúa Carlos, Gilmartin Bernard Neurosciences Research Institute, Aston University, Birmingham, UK

Background: Theoretically myopes are required to exert more accommodation and vergence when wearing single vision contact lenses compared to glasses and hypermetropes less, but there have been no attempts to quantify the effect clinically.

Method: Thirty subjects (21 female, average age 21.0 ± 2.2 years) with a range of refractive error (-7.87D to +3.50D) viewed in random order, static targets at 0.1, 0.5, 1.0, 2.0, 3.0, 4.0 and 5.0D accommodative demand matched for angular subtense. The subjects were fully corrected with spectacles and daily disposable contact lenses to their full prescription. Accommodation and vergence was monitored objectively with the *PowerRefractor*.

Results: Myopes exerted greater accommodative effort for viewing near targets with contact lenses than glasses and hypermetropes less (r=0.59). Myopes also exerted greater vergence effort for viewing near targets with contact lenses than glasses and hypertropes less (r=0.42).

Conclusion: Theoretical calculations of the accommodative and vergence requirements with glasses compared to contact lenses reflect clinical findings, although there is reasonable variability between individuals.

Presented - BCLA Clinical Conference, Brighton, 6 – 8 June 2003.

Static And Dynamic Measurements of Pseudoaccommodation with *1CU* Intra Ocular Lenses

Author Hunt, Olivia (Neuroscience Research Institute, Aston University)

Coauthor(s) James Wolffsohn (Neuroscience Research Institute, Aston University), Bernard Gilmartin (Neuroscience Research Institute, Aston University), Shehzad Naroo (Neuroscience Research Institute, Aston University), Sunil Shah, Mark Benson, Ian Cunliffe, Alejandro Cerviño (Neuroscience Research Institute, Aston University)

Day Thursday, April 03, 2003

PURPOSE: To measure the accommodative function of patients with HumanOptics *1CU®* (One Component Unit) accommodative intra ocular lenses (IOL). Previous studies have measured only subjective and static accommodation.

METHODS: Twelve subjects, 20 eyes (33 – 78 years, average 60.7 ± 15.4, 3 M, 9 F), with a *1CU* accommodative intra ocular lens recently implanted (average 127.7 ± 70.9 days) in one or both eyes had a full subjective binocular refraction at 6m measuring distance and near acuity. Subjects were made functionally emmetropic with soft contact lenses and accommodative responses were measured using the Shin Nippon *SRW-5000* open-view IR autorefractor. The high contrast static targets (Maltese cross) were matched for angular subtense and viewed in real space in random order monocularly at 0.17, 0.50, 1.00, 1.50, 2.00, 2.50, 3.00 and 4.00D accommodative demand. Continuous recording of dynamic accommodation was measured with the *SRW-5000* (>30 Hz) with the subject viewing a target moving from 0 to 2.50D at 0.3 Hz through a +5D Badal lens system. Wavefront aberrometry measures were made through undilated pupils using the Zywave (Bausch & Lomb).

RESULTS: The best corrected acuity was 0.01 ± 0.16 logMAR at distance and 0.60 ± 0.09 logMAR at near. Subjective amplitude of accommodation was 2.24 ± 0.42D. The static amplitude of accommodation was 0.72 ± 0.12D when measured by the *SRW-5000*. The average dynamic amplitude of accommodation was 0.71 ± 0.47D with a lag of 0.11 ± 1.37 seconds. Aberrometry showed a decrease in power of the lens - eye combination from the centre to the periphery in all subjects, on average -0.38 ± 0.28D/mm.

CONCLUSIONS: The ability to track consistently the accommodative demand of a moving target is of special interest albeit with an objective amplitude of accommodation substantially lower than measured subjectively, a discrepancy we attribute to depth-of-focus effects and the aspheric design of the IOL.

Key Words Accommodation

Presented American Academy of Optometry Conference, Hawaii, April, 2004

Program#/Poster#: 2190

Abstract Title: **Static and dynamic 'accommodation' with *1CU* Intra Ocular Lenses**

Presentation Start: Tuesday, Apr 27, 2004, 9:45 AM -10:00 AM

Location: 114

Reviewing Code: 101 accommodation & presbyopia – VI

Author Block: *S.Mantry*[1,2], *O.Hunt*[3], *J.S. Wolffsohn*[3], *B.Gilmartin*[3], *M.T. Benson*[1], *I.A. Cunliffe*[1], *S.Shah*[1]. [1]Birmingham Midland Eye Centre, Birmingham, United Kingdom; [2]Aston University, Anterior Eye Group, Birmingham, United Kingdom; [3]Aston University, Birmingham, United Kingdom.

Keywords: 717 treatment outcomes of cataract surgery,654 refractive surgery

Purpose: To determine the subjective and objective accommodation of eyes implanted with the *1CU* accommodative intra-ocular lenses (IOL).
Method: Twelve subjects, 20 eyes (33 – 78 years, average 60.7 ± 15.4 years, 3 M, 9 F), with a *1CU* accommodative intra-ocular lens implanted in one or both eyes had a full binocular refraction at 6m and both distance and near acuity was measured with a logMAR chart. Subjects were made functionally emmetropic with soft contact lenses. Subjective amplitude of accommodation was measured with the RAF rule. The objective accommodative stimulus-response curve for static (Maltese Cross) targets (matched for angular subtense) was measured using the *Shin Nippon SRW-5000*. The subjects viewed the targets monocularly, in random order, at 0.17, 0.50, 1.00, 1.50, 2.00, 2.50, 3.00 and 4.00D accommodative demand. Continuous objective recording of dynamic accommodation was measured with the *SRW-5000* with the subject viewing a target moving from 0 to 2.50D at 0.3 Hz through a Badal lens system. Wavefront aberrometry measures were made through undilated pupils using the *Zywave*.
Results: The best corrected acuity was -0.01 ± 0.16logMAR at distance and 0.60 ± 0.09logMAR at near. Subjective amplitude of accommodation was 2.24 ± 0.42D. Objectively the static amplitude of accommodation was 0.72 ± 0.38D, although individual responses varied greatly. The average dynamic amplitude of accommodation was 0.71 ± 0.47D with a lag behind the target of 0.50 ± 0.48s. Aberrometry showed a decrease in power of the lens-eye combination from the centre to the periphery in all subjects, on average -0.38 ± 0.28D/mm.
Conclusion: The objective accommodating effects of the *1CU* lens appear to be limited, although patients are able to track a moving target. The greater subjective amplitude of accommodation is likely to result from the eyes depth of focus of and the aspheric nature of the IOL.

Commercial Relationship: **S. Mantry**, None; **O. Hunt**, None; **J.S. Wolffsohn**, None; **B. Gilmartin**, None; **M.T. Benson**, None; **I.A. Cunliffe**, None; **S. Shah**, None.

Presented ARVO Conference, Fort Lauderdale, Florida, 25 - 28 April, 2004.

The progressive addition lens paradigm in myopia control: is there a role for contact lenses?

Hunt Olivia A, Wolffsohn James S, García-Resúa Carlos, Gilmartin Bernard Neurosciences Research Institute, Aston University, Birmingham, UK

Purpose: Several recent studies have suggested that it may be possible to retard the progression of myopia in children with progressive spectacles. The rationale for their use is that positive power at near reduces accommodative effort (perhaps increasing accommodative accuracy) and consequently reduces the stimulus for growth of the posterior vitreous segment. A logical next step would be to consider progressive contact lenses. Theoretically these should cause the young patient to accommodate less at near than with single vision contact lenses and this is examined in this study.

Method: Twenty subjects (12 female, 8 male, average age 21.40±3.07 years) with a range of mean spherical refractive error (-5.50D to +3.50D) viewed in random order, high contrast static targets (Maltese cross) at 0.1, 0.5, 1.0, 2.0 and 3.0D accommodative demand, matched for angular subtense in free space. The measurements were made with subjects fully corrected (in random order) by each of *Acuvue* daily disposable (SVCL), *UltraVision Igel Multifocal* (PACL) and *Acuvue* bifocal (BICL) contact lenses. Accommodation was monitored objectively with the open view IR *Shin Nippon SRW-5000.* Both PACL and BICL had a near addition of +2.50D. Three indexes of accommodative accuracy were used: response level for a 3D stimulus, accommodative slopes and error indexes derived from accommodative stimulus-response plots.

Results: When corrected by SVCL, the accommodative response at 3.0D demand was 2.21±0.52D and the slope and error index of the stimulus response curve 0.95±0.16 and 0.79±0.46 respectively. However with progressive contact lenses, the response was significantly lower (BICL: response 1.73±0.56 D (P = 0.0003), slope 0.82 ±0.18 (P = 0.009); PACL: response 1.83±0.58 D (P = 0.02), slope 0.82 ±0.11 (P = 0.001).

Conclusion: The results suggest that patients accommodate less with PACL and BICL than with SVCL. If reducing accommodative effort is able to retard the development of myopia, contact lenses may be successful than spectacles as the near addition remains in the line of sight with eye movement and they are less likely to be removed by children. However, significant accommodation is still exerted by pre-presbyopes wearing progressive contact lenses, despite the lack of theoretical need.

Presented - BCLA Clinical Conference, 21 - 23 May, 2004, Birmingham.

'Correction' of Presbyopia with *1CU* Intra-Ocular Lenses

James S. Wolffsohn, Olivia Hunt, Bernard Gilmartin, Shezhad Naroo, Sunil Shah, Mark Benson, Ian Cunliffe, Sanjay Mantry

Purpose. To determine the restoration of subjective and objective accommodation in eyes implanted with the *1CU* accommodative intra-ocular lenses (IOL).
Method. Twelve subjects, 20 eyes (33 – 78 years, average 60.7 ± 15.4 years, 3 M, 9 F), with a *1CU* accommodative intra-ocular lens implanted in one or both eyes had a full binocular refraction and both distance and near acuity measured with a logMAR chart. Subjective amplitude of accommodation was measured with the RAF rule. The objective accommodative stimulus-response curve for static (Maltese Cross) targets (matched for angular subtense) was measured using the *Shin Nippon SRW-5000*. The subjects viewed the targets monocularly, in random order, at 0.17, 0.50, 1.00, 1.50, 2.00, 2.50, 3.00 and 4.00D accommodative demand. Continuous objective recording of dynamic accommodation was measured with the *SRW-5000* with the subject viewing a target moving from 0 to 2.50D at 0.3 Hz through a Badal lens system. Wavefront aberrometry measures were made through undilated pupils using the *Zywave*.
Results. The best corrected acuity was -0.01 ± 0.16logMAR at distance and 0.60 ± 0.09logMAR at near. Subjective amplitude of accommodation was 2.24 ± 0.42D. The objectively measured static amplitude of accommodation was 0.72 ± 0.38D, although individual responses varied greatly. The average dynamic amplitude of accommodation was 0.71 ± 0.47D with a lag behind the target of 0.50 ± 0.48s. Aberrometry showed a decrease in power of the lens-eye combination from the centre to the periphery in all subjects, on average -0.38 ± 0.28D/mm.
Conclusion. The objective accommodating effects of the *1CU* lens appear to be limited, although patients are able to track a moving target. The greater subjective amplitude of accommodation is likely to result from the eyes depth of focus of and the aspheric nature of the IOL.

Presented - BCLA Clinical Conference, 21 - 23 May, 2004, Birmingham.

ASTON UNIVERSITY **PROJECT NO..............**

THE SENATE **REG/00/174**

HUMAN SCIENCE ETHICAL COMMITTEE

Application for approval of a research project involving human volunteers

Please read the enclosed guidelines before completing this form - in typescript or black ink - and return the form to: The Secretary of the Human Science Ethical Committee, Registry. If you intend to administer any substance or expose the volunteers to a physical procedure other than simple venepuncture **you must also submit an experimental protocol.**

Project title:

Ocular Motor and Autonomic Function in Human Factor Applications

---

Investigator(s):	Department/address: Telephone:	
Dr James Wolffsohn	Optometry, NRI	0121 359 3611 ext 5160
Professor Bernard Gilmartin	Optometry, NRI	0121 359 3611 ext 5159
Miss Olivia Hunt	Optometry, NRI	0121 359 3611 ext 5175
Mr Leon Davies	Optometry, NRI	0121 359 3611 ext 5100
....	....	....

A
Details of sponsoring/collaborating organisation (if any)

1 Name: British Aerospace, Filton, Bristol and EPSRC

2 Does the sponsoring/collaborating organisation provide insurance? NO

3 If drugs are used, do any require a clinical trials certificate or clinical trials exemption certificate? N/A

*If yes, please provide a copy of the certificate

B
Summary of Project

1 Starting date — 1st November 2002

2 Duration: — 3 years

3 Location: — Aston University, Birmingham (majority) and BAe, Bristol

5 Physical procedures:

Measurement of different ocular parameters using commercially available devices:

IV. Oculomotor function (refractive error, eye vergence and pupil size) using standard auto-refractors (*Shin Nippon and PowerRefractor*)
V. Ocular biometry using a non contact partial coherence interferometer (*IOL Master,* Zeiss)
VI. Autonomic function using a finger pulse transducer

Subjective Refraction and bionocular vision assessment

Viewing or responding to images on static or moving visual displays

Contact lens fitting of daily disposable lenses (worn for up to 2 hours)

5 Substances to be administered (a substance is anything other than normal food - chemical constituents of food stuffs, ethanol and variation of the diet should be included here) and method of delivery should be specified:

None

6 Psychological assessment:

None

7 Questionnaires: (only to be completed when project contains questionnaire(s) which fall within the types of questionnaire requiring HSEC approval [Guidelines D (3)])

None requiring HSEC approval

C

Subjects

1 Number of volunteers to be used: approximately 500

2 Over what time span? 3 years

3 Age of volunteers: 18-45 years

4 Sex of volunteers: Male and Female

5 Source: Aston University and BAe staff and undergraduate students,

6 Will payments be made to the volunteers and if so, how much will each be paid?

No

7 Are the volunteers' patients or healthy volunteers? (If patients give diagnosis, clinic/responsible practitioner).

The patients are all healthy volunteers.

8 Will any volunteers be excluded and if so, on what grounds?

Volunteers with high astigmatism (>1.50D) will be excluded from the study as this makes it difficult to render then functionally emmetropic with soft contact lenses

9 Is the activity of the volunteer to be restricted in any way either before or after the procedure? (eg diet, driving)

No

11 Consent: Please attach a copy of the consent form you intend to use, detailing how procedures and hazards will be explained.
Attached

D

Risk Assessment: *a thorough Risk Assessment of the project must be undertaken (including for example welfare issues arising from the procedure, and the possible risk of residual effects in volunteers and the consequences thereof).*

1 Please give full details of any hazards, which could affect the health, safety or welfare of any volunteer, or any other person who might be harmed as a result of the experiment.

Contact lens may be inserted into the volunteers' eyes to make them functionally emmetropic. When using contact lenses there is very slight risk of infection, but no know risk exists with short-term use (<1 day). The lenses used will be commercially available daily disposable contact lenses worn for a maximum of 2 hours.

The instruments used are all non-invasive commercially available instruments, which are used in practice. The finger pulse transducer is commonly used in hospital clinics. There are no known risks associated with its use.

2 What levels of risk are associated with these hazards?

Virtually none - see above

3 How do you propose to control the risks associated with these hazards?

Use single use disposable soft contact lenses to eliminate the risk of cross-infection.

4 What criteria have you used to determine whether the risks are acceptable?

Common usage in optometric and medical practice with no reports of adverse effects

5 Is there any precedent for these experiments? If so, please give details with references if possible.

Screening of refractive error and axial length. Ref 01/D

Akselrod, S., Gordon, D., Ubel, F. A., *et al.* Power spectrum analysis of heart rate fluctuation: a quantitative probe of beat-to-beat cardiovascular control. Science. 1981; 213:220-222.

Choi, M; Weiss, S; Schaeffel, F; Seidemann, A; Howland, H.C; Wilhelm, B. and Wilhelm, H. Laboratory, Clinical, and Kindergarten Test of a new Eccentric Infrared Photorefractor. Optometry and Vision Science 2000; 77:537-548.

Collins, M., Davis, B. and Wood, J. Microfluctuations of steady-state accommodation and the cardiopulmonary system. Vision Research. 1995; 35:2491-2502.

Mallen, E.A.H; Wolffsohn, J.S; Gilmartin, B. and Tsujimura, S. Clinical Evaluation of the Shin-Nippon *SRW-5000* autorefraction in Adults. Ophthalmic and Physiological Optics 2001; 21:101-107.

Schaeffel, F; Weiss, S. and Seidel, J. How good is the match between the plane of the text and the focus during reading? Ophthalmic and Physiological Optics 1999; 19:180-92

Schaeffel, F; Wilhelm, H. and Zrenner, E. Inter-individual Variability in the Dynamic of Natural Accommodation in Humans: Relation to Age and Refractive errors. Journal of Physiology 1993; 461:301-320.

6 Has this project been considered/is it being considered by any other Ethical Committee? If so, please give details and decision made.

No

E

STATEMENT BY NAMED INVESTIGATORS, HEAD OF SCHOOL AND (if necessary) RESEARCH SUPERVISOR

I consider that the details given constitute a true summary of the project and that the hazards and potential risks to any volunteer are accurately described. The Principal Investigator is the main point of contact for the Human Sciences Ethical Committee, and accordingly should be a member of academic staff of the University (this implies that supervisors of research students will be the main point of contact)

Principal Investigator or...
date..

Supervisor of Student

Investigator...
date...

Investigator...
date...

Investigator...
date...

Head of School..
date...
(or nominee)

The following should be attached:

* volunteer consent form
* insurance certificate (if available)
* clinical trials certificate or clinical trials exemption certificate (if appropriate)
* experimental protocol

ASTON UNIVERSITY **REG/00/175**

HUMAN SCIENCE ETHICAL COMMITTEE

CONSENT FORM FOR VOLUNTEERS

PROJECT TITLE

Ocular Motor and Autonomic Function in Human Factor Applications

RESEARCH WORKERS, SCHOOL AND SUBJECT AREA RESPONSIBLE

Dr James Wolffsohn, Life and Health Science, Vision Sciences
Professor Bernard Gilmartin, Life and Health Science, Vision Sciences
Miss Olivia Hunt, Life and Health Science, Vision Sciences
Mr Leon Davies, Life and Health Science, Vision Sciences

EXPLANATION OF ANY POSSIBLE HAZARDS AND THE PROCEDURES TO BE USED

5. As part of our ongoing research programme we would be grateful if you would participate in our study into the changes in eye and autonomic system that occur with human factor applications, such as a cognitive task or flying a plane. The tests allow us to measure these effects

6. The procedure uses standard consulting room equipment used widely by optometrists and medical professionals in every day practice, taking only a few minutes. This is not a full eye examination. There are no known hazards involved.

7. If you have a refractive error, you will be fitted with daily-disposable soft contact lenses for up to 2 hours. There are no known adverse effects of such short-term wear.

8. Participation in this study is not a requirement of your university course and you are free to withdraw at any time.

CONFIDENTIALITY OF INFORMATION

The confidentiality of personal information and the anonymity of all volunteers involved in this investigation will be preserved by storage of the data in a locked filing cabinet, and will be accessible only to the investigators

VOLUNTEER'S STATEMENT

I have read and understand the above explanation. I have had the opportunity to discuss it with the investigators and to ask any questions. I agree to take part in the above project and I have been informed that I am free to withdraw at any time.

Signed: ....

Dated: ....