

**The use of portable electronic vision  
enhancement systems by the visually  
impaired (the p-EVES study)**

A thesis submitted to the University of  
Manchester for the degree of Masters of  
Philosophy in the Faculty of Life Sciences

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## Abstract

The p-EVES study was designed to assess the effectiveness of portable electronic vision enhancement systems (p-EVES) compared with conventional optical aids for near vision tasks in patients with low vision. The author of this thesis was the clinician researcher on the study and this thesis presents selected data from the study.

A literature review explores the epidemiology of low vision, the impact that having low vision can have on the patient and the current systems for service provision in the UK. Optical and electronic magnifiers are considered, and their advantages and disadvantages reviewed.

A focus group was held at the beginning of the p-EVES study in order to choose the devices to be used in the study. A total of 16 devices were evaluated, and four devices were selected for the study.

Recruitment and the initial assessment of p-EVES participants were undertaken by the clinician researcher. The California Central Visual Fields Test (CCVFT) has not been widely used to measure central scotoma, but it allowed binocular scotomas to be evaluated. A grading system was designed, and 92% of participants were found to have a central scotoma. The grading system showed significant correlations with visual acuity and contrast sensitivity measurements and no significant correlation with maximum reading speed.

Participants needed instruction in how to use the p-EVES devices at home so task-based practice was undertaken. It was found that this took between 5 and 30 minutes per participant. A difficulties questionnaire administered one week following prescription of p-EVES found that only 2 individuals were having technical difficulties using the device. . A maximum variation sampling method was used to select 27 participants for interview.

Previous guidance on prescribing p-EVES devices was derived from clinical experience. The difficulties questionnaire and the interview transcripts now allow the presentation of some evidence-based guidelines for prescribing p-EVES.

## **Declaration**

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## **Chapter 1 Visual Impairment and its Rehabilitation**

### **1.1 The p-EVES Study:**

The data presented in this thesis was collected during the p-EVES study. This study was designed to investigate the effectiveness and acceptability of a new type of portable electronic vision enhancement system (p-EVES) compared with traditional optical magnifiers for near vision tasks in patients with low vision. The initial idea behind the study arose from positive anecdotal evidence from patients who had access to a p-EVES device through the Welsh Low Vision Service (now called Low Vision Service Wales). If the results show evidence of effectiveness of p-EVES and that we should be prescribing them to patients, this information could potentially be used to support the supply of p-EVES in the National Health Service (NHS) in England in the future.

The study was conducted at Manchester Royal Eye Hospital (MREH) and the patients were recruited from the MREH low vision clinic. The study team consisted of a lead investigator, expert advisors on the subject, a study researcher, a clinician researcher, statisticians, health economists, a qualitative methods expert and a service user. The p-EVES study was registered with the clinical trials register and the ethics application was approved by National Research Ethics Service (NRES). The funding from the study came from the National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) programme.

The design of the study was a two-arm, randomised cross-over study. Participants were randomised into one of two groups. Group one received the interventions in the order AB and group 2 received the interventions in the order BA. A is a two month period where the patients use their existing magnifiers and the p-EVES device and B is a two month period where they only use their existing magnifiers. Another approach would have been to recruit patients with no previous experience of using optical or electronic magnifiers and then assign them randomly to either an optical or a p-EVES device. However, this would have meant it was likely that these

would only be patients who were new to rehabilitation with potentially only 'mild' visual loss so the number of tasks that they were having difficulty with may be few at this stage, (Taylor et al, 2014)

A flow chart illustrating the different steps and tests involved in the p-EVES study is shown in figure 1.1.

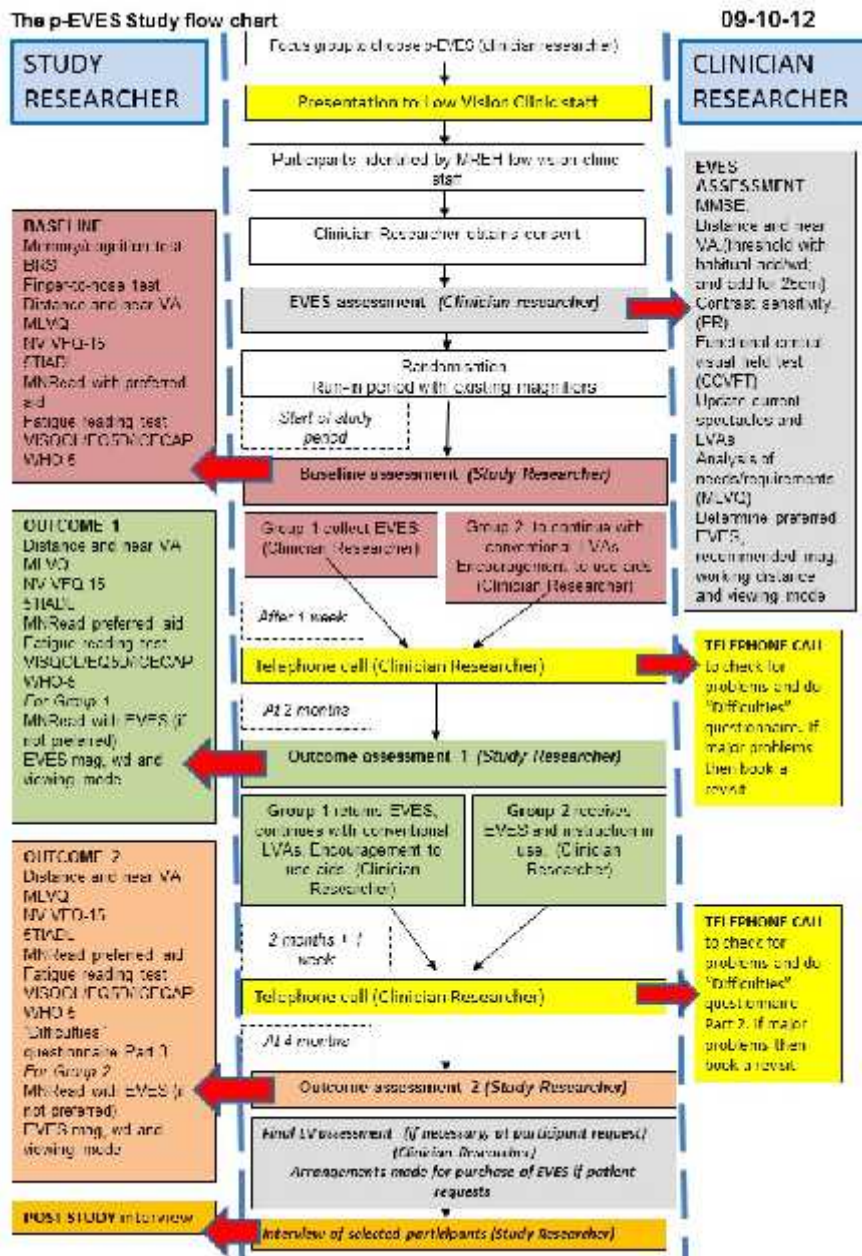


Figure 1.1: A flow chart of the p-EVES study design. The areas involving the clinician researcher are clearly marked.

The methodology paper for the p-EVES study by Taylor et al (2014) is in appendix 1.

Some examples of p-EVES are shown below (Figure 1.2)



Figure 1.2: Three examples of p-EVES devices: Minimax by Reinecker; Compact+ by Optelec, i-loview 7 by Humanware.

### 1.2 Aims of thesis:

The overall aim of the p-EVES study is to use both quantitative and qualitative data to compare the effectiveness and acceptability of p-EVES devices in patients with low vision. The aim of this thesis is to present the aspects of the p-EVES study that the author (clinician researcher) was directly involved in. A literature review will aim to review all relevant publications relating to the need for this study to be undertaken. The process behind choosing the p-EVES devices that went on to be used in the main study will be explained and the ways in which participants were instructed to use the devices and then followed up will be evaluated. The experience gained by the author during the p-EVES study allows some prescribing guidelines to be presented. Finally, a test used during the p-EVES study to detect the presence of a central scotoma will be evaluated as this has not been previously evaluated.

### 1.3 Search methodology:

Literature was identified by searching the following databases: Web of Science, EMBASE and PubMed. Additional literature was identified via hand searching of relevant reviews and by asking experts in the field for their advice on relevant studies to include. Examples of search terms used included 'activity limitation low

vision', 'electronic low vision aids', field of view with magnifiers', quality of life questionnaires low vision'.

#### 1.4 Low Vision:

The term low vision indicates a reduction in visual acuity, which even with full refractive error correction, still results in a lower visual performance on a standardised clinical vision test than would be expected for a patient of that age (Dickinson 1998).

The World Health Organisation (WHO) has defined 'low vision' as "visual acuity less than 6/18 and equal to or better than 3/60 in the better eye with best correction" or "one who has impairment of visual functioning even after treatment and/or standard refractive correction, and has a visual acuity of less than 6/18 to light perception, or a visual field less than 10 degrees from the point of fixation, but who uses, or is potentially able to use, vision for the planning and/or execution of a task for which vision is essential." (World Health Organization and International Agency for the Prevention of Blindness. 2004).

Dandona and Dandona (2006) debated some of the potential issues with the current definitions provided by the WHO and proposed that modifications be made to them to improve their utilisation and implementation worldwide. One of their main concerns was the use of 'best corrected visual acuity' to classify low vision. They suggested that if this was changed to a person's 'presenting visual acuity', then this would account for uncorrected refractive error as a cause of visual impairment, which in turn would increase the total of number of people worldwide with low vision by approximately 38%.

In the current tenth version of the ICD, specific categories are provided to define the types of visual functioning (Colenbrander 2010) and these are shown in table 1.1.

Table 1.1: 'Classification of severity of visual impairment'  
(ICD10 Version:2010)

CATEGORY OF VISUAL LOSS	DESCRIPTION		MAXIMUM VISUAL ACUITY	MINIMUM VISUAL ACUITY	MAXIMUM VISUAL FIELD*	MINIMUM VISUAL FIELD*	
0	Normal and mild visual impairment		6/6	6/18			
1	Visual impairment	Low Vision	Moderate visual impairment	<6/18	6/60		
2			Severe visual impairment	<6/60	3/60		
3		Blind	blind	<3/60	1/60	≤10° around central fixation	>5° around central fixation
4			blind	<1/60	light perception	≤5° around central fixation	
5			blind	no light perception			
9	undetermined		cannot be measured				

#### 1.4.1 Epidemiology of low vision

The WHO estimated that in 2010 there were approximately 246 million people worldwide with low vision based on their classification (VA<6/18 - 3/60 with best correction). They also state that low vision is not distributed evenly throughout the globe. Over 90% of the world's visually impaired population are in the developing countries (Global data on visual impairments. 2010).

It was found by the WHO that of the world's 'blind' people, 58% of these are in Asia, with an approximate further 20 million defined as being severely visually impaired also being from this continent (Lim, 2006). Dandona et al (2001) estimated that in 2000, the number of people considered as 'blind' in India was 18.7 million, and if there was no change in trend, it was predicted that the number of 'blind' people would increase to 31.6 million by 2020.

Records of the number of 'blind' people in Britain have been kept since 1851, (Bunce et al 2010). In 2008, a review by Bosanquet and Mehta estimated that in the UK, there are approximately 2 million people who are visually impaired. These

people are mostly over 65 years old. Evans et al (2002) measured the prevalence of visual impairment in patients aged 75 and over. They used Medical Research Council assessment data for patients in 106 general practices between 1994 and 1999 and in total, were able to analyse visual acuity data from 14,600 people. Using their results along with mid 2001 population estimates for the UK, they estimated that at the time of the analysis (2001), there were approximately 506,000 people living with low vision (defined as <math>6/18-3/60</math>) and approximately 103,000 'blind' people in the UK over the age of 75. There are also approximately 44,000 young people (ages 0-25) including 25,000 who are children (aged 0-16) who are affected by visual impairment in the UK, (Bosanquet and Mehta, 2008).

#### 1.4.1.1 Registration

After the Blind Persons Act in 1920, patients in England and Wales could be certified as being 'blind' by any medical practitioner and the details of these individuals were kept on a register. From the mid-1930s patients had to be registered by an ophthalmologist who had to complete a series of forms called BD8 forms. The National Assistance Act in 1948 started the current system of registration where local authorities, who were required to establish registers of 'blind' or 'partially sighted' people, had to administer the statutory services for these low vision patients (Tate et al, 2005).

The BD8 forms then became Certificate of Visual Impairment (CVI) forms in November 2003 and the categories re-named as 'Severely Sight Impaired' (SSI) or 'Sight Impaired' (SI) respectively (Bunce et al, 2010).

The CVI guidelines for registration state that a patient must have a binocular visual acuity of worse than 6/60 to be certified as SI, (Department of Health, 2013). In Australia and the USA, patients with binocular visual acuity of worse than 6/60 are classed as 'legally blind'. It has been argued that this terminology is confusing as this may still leave the patient with significant amounts of residual vision, therefore the terms 'low vision' or 'visual impairment' are recommended as more appropriate for use worldwide (Colenbrander 2010).

In the UK, the CVI is completed by a patient's consultant and must also be signed by the patient. Above, it has been referenced that there are approximately 2 million people who are visually impaired; however, there are approximately 360,000 people who are registered as SI or SSI. There are a number of potential reasons for this discrepancy. Firstly, the 2 million figure is an estimated figure and is based on sight loss meaning a VA of  $<6/12$  in the better seeing eye. It also includes those people with uncorrected refractive error and those who are waiting for cataract surgery where the vision loss could be reversed. Secondly, there will be a group of people who fall under the WHO's definition of low vision but do not fall into the CVI definition of sight impaired i.e. those whose binocular visual acuity is between  $6/18$ - $6/60$ . Having said that, people who fall into this visual acuity range can be registered if they have a significant visual field defect. Thirdly, evidence has shown that there is a significant amount of 'under-registering'. Barry and Murray (2005) conducted a study at the Birmingham and Midland Eye Centre for three months in 2003 to investigate the reasons behind under-registration. Broadly speaking they found that 45% of patients who would have met the eligibility criteria for registration, were not registered. Generally, this study attributed the under-registration to a lack of training of ophthalmologists, however it is important to note that this was a single institution study so cannot be taken to reflect the UK as a whole.

#### 1.4.1.2 Gender Distribution

In a study looking into certification for sight impairment in England and Wales, Bunce and Wormald (2006) found that in their patient sample, out of those aged over 65, 64% of those registered as 'blind' were female and 67% of those registered as 'partially sighted' were also female. However, in the working population, they found that gender was more equally split with 55% of those registered as 'blind' being male and 51% of those registered as 'partially sighted' being male. It is important, however, to bear in mind the increased life expectancy for females in the developed world, which may account for the larger number of female registrations in the over 65 category.

In order to gain a better understanding of the global burden of 'blindness' by gender, Abou-Gareeb et al (2001) conducted a meta-analysis of many population-based studies. The findings were that, overall, women accounted for 64.5% of all the world's 'blind' people. This excess of visual impairment in women was more apparent among the elderly population. They concluded that this was likely to be due to a number of factors that are different in the developing world compared with the developed world. For example, in some developing countries there is a different rate of utilisation of services and due to a lower socioeconomic status of females, they tend to have more barriers to receiving treatment. This concept was confirmed in a study by Mganga et al (2011), which commented that the accessibility to eye care services by elderly women is a significant problem in many areas of Africa.

#### 1.4.1.3 Age Distribution

The WHO state that visual impairment is not uniformly distributed across all age groups and this finding is confirmed in many studies from across the world.

In Australia, more than one study has shown an exponential increase of 'low vision' and 'blindness' with increasing age. Taylor et al (2005) combined data sets from two of these studies (Table 1.2).

Table 1.2: *'Estimated age distribution of people with low vision and blindness in Australia, 2004'* PVA= presenting visual acuity

Adapted from Taylor et al. (2005)

Age Group (years)	Prevalence of Low Vision (PVA < 6/12)	Prevalence of Blindness (PVA < 6/60)
40-49	0.67%	0
50-59	2.28%	0.09%
60-69	4.51%	0.29%
70-79	11.41%	0.68%



80-89	28.75%	4.12%
90+	39.49%	16.94%

These results clearly show the large increase in visual impairment with age.

A similar result was found in the study by The Eye Diseases Research Group (2004). In the United States both 'low vision' and 'blindness' increased markedly with age for all races/ethnicities and it was found that there was a rapid increase in 'blindness' over the age of 85 years. This result is confirmed to be the same in the Canadian population also (Maberly et al, 2006).

The health and social care information centre (HSCIC) reported on the number of people registered as 'blind' and 'partially sighted' and these figures are shown in table 1.3.

Table 1.3: *Blindness and partial sight in England; summary age distribution of certifications; March 2014*

	Number of People
<b>Blind</b>	
0-64 years	41,425
65 years and above	101,960
All ages	143385
<b>Partially Sighted</b>	
0-64 years	38,870
65 years and above	108,845
All ages	147,715

Global studies into the prevalence of low vision across the different age groups tend to classify 'older' people as over 50 years. It is widely agreed that in this age group, the prevalence of low vision is significantly higher than in the lower age groups (Resnikoff et al, 2004).

Many of these studies agree that due to an ageing population, the prevalence of visual impairment will greatly increase over the coming years (The Eye Diseases Research Group 2004; Frick et al, 2007; Taylor et al, 2005).

#### 1.4.1.4 Aetiology

More than 90% of all visually impaired people live in the developing world (Cunningham, 2001). Therefore, the main causes of visual impairment found in global studies mostly reflect diseases seen in developing countries.

The most common cause of global 'blindness' is cataract and there are almost 21 million people estimated to be classified as 'blind' (using the WHO classification) due to this disease (Ackland 2012).

Other causes of global blindness include trachoma, onchocerciasis, glaucoma, diabetic retinopathy and age-related macular degeneration (ARMD) (Reskinoff and Keys 2012). Over the past three decades, there have been some changes in the reported causes of visual impairment across the world, (Figure 1.3).

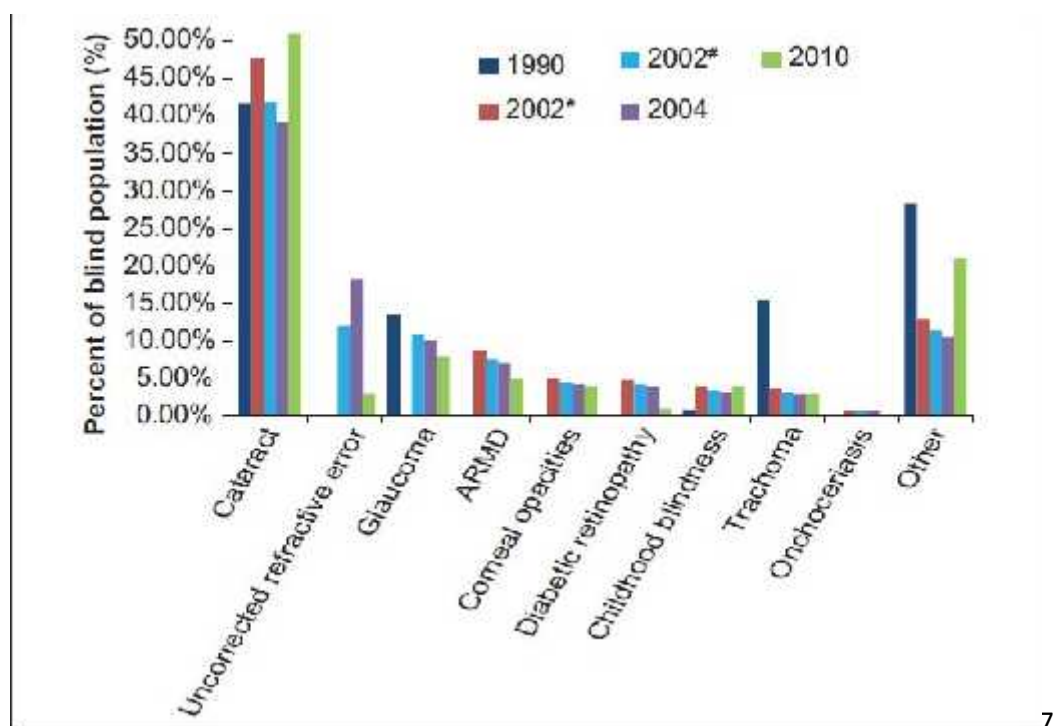


Figure 1.3: *'Global causes of blindness as a percentage of total blindness: 1990–2010\* (\*excluding refractive error, #Including refractive error)'*, Resnikoff and Keys, (2012)

Early studies did not include uncorrected refractive error as a cause of visual impairment (VI). This definition of VI incorporates the WHO's definition of 'low vision' and 'blindness'. This cause of VI was only taken into account from 2002 onwards, which caused an overall apparent rise in the prevalence of global visual impairment from 2.59%- 4.13%. However, since 2002, the number of visually impaired people due to uncorrected refractive error has decreased markedly (Resnikoff and Keys 2012). Pascolini and Mariotti (2011) found that uncorrected refractive error is a much more prevalent cause of 'low vision' than of 'blindness'.

In developed countries such as the United Kingdom, Australia and the United States, the leading causes of visual impairment are AMD, glaucoma and diabetic retinopathy (Taylor et al, 2005).

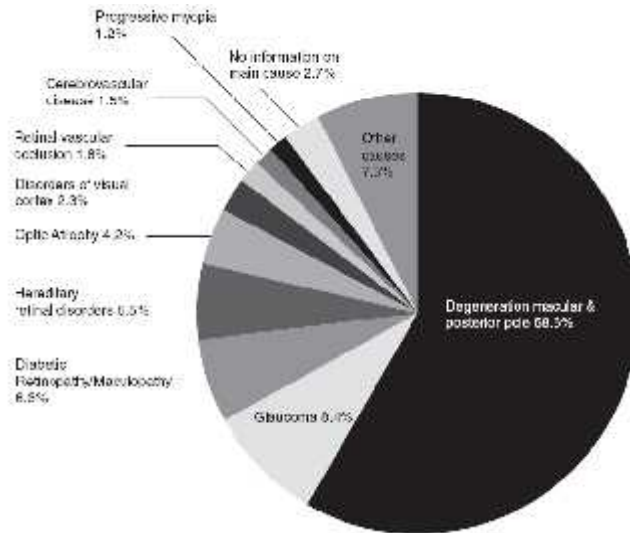


Figure 1.4: *Main causes of SSI in England and Wales: April 2007-March 2008.* Bunce et al (2010)

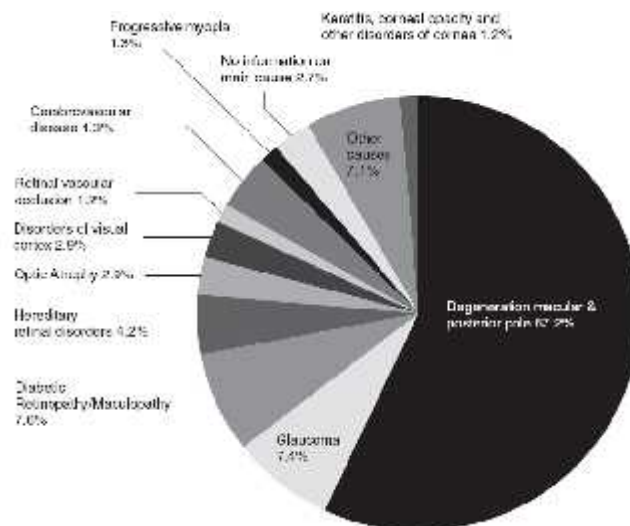


Figure 1.5: *Main causes of SI in England and Wales: April 2007-March 2008.* Bunce et al (2010)

Bunce et al (2010) found that the leading cause for certification in England and Wales is AMD. This disease accounted for 58.6% of all 'blind' registrations and 57.2% of all 'partial sight' registrations during their study (Figure 1.4 and 1.5). Glaucoma and diabetic retinopathy were found to be the next most commonly recorded ocular disorders. Since 1990-1991 the age specific incidence of all three diseases has increased, most markedly in relation to diabetic retinopathy where in the over 65s the numbers have more than doubled. Liew et al (2014) looked at the leading causes of blindness certifications in England and Wales, specifically in the working population (classed as ages 16-64). A comparison was made between data from years 1999-2000 and years 2009-2010. It was found that for the first time in at least five decades, diabetic retinopathy/maculopathy is no longer the leading cause of certifiable blindness in England and Wales among the working population. Hereditary retinal disorders have taken over as the leading cause of blindness.

#### 1.4.2 Impact of Low Vision

According to the WHO's international classification of functioning disability and health (ICF), 'Impairment' is defined as 'a problem in body function or structure such as a significant deviation or loss'. In ophthalmology, generally various tests are performed on a patient with low vision in order to 'grade' the scale of their visual impairment. These tests include measurements of visual acuity, contrast sensitivity and near vision amongst others. However, simply knowing how the eye functions is not a full indication of how the individual functions as a whole. Other areas need to be considered such as mobility, employment and social issues; all which will identify the level of help the person needs (Knudtson et al, 2005; Colenbrander 2010).

The primary aim of Network 1000 was to establish what issues visually impaired people in the UK face in their everyday lives. A total of 30% of people reported that they could not see any size of print without a magnifier and 52% said that they could manage the headlines in the newspaper only. The majority could recognise shapes and sizes of furniture in a room, however only 10% of people could recognise a friend from across the road.

#### 1.4.2.1 Impact on quality of life (QoL)

As AMD is the leading cause of low vision in the developed world, Brown et al (2005) looked into the relationship between the disease and quality of life of the patients with this condition. WHO defines (QoL) as 'an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns'. In Brown et al's study, a standardised questionnaire was created by the authors to assess health related QoL. It was found that mild AMD causes a 17% decline in a patient's health-related QoL, similar to the decline found with the human immunodeficiency virus (HIV). In severe AMD, the QoL of the average patient is reduced by 63%, similar to that found in patients who have been left bedridden after a severe stroke. Mitchell and Bradley (2004) designed an 'individualised questionnaire' for measuring the impact of macular disease on a patient's QoL. The questionnaire was called the MacDQoL. It was based on 'domains', such as work, hobbies, motivation and finances and the majority of the domains used were validated by a focus group of members of the macular society. The study findings were that macular disease has a substantial negative impact on QoL.

#### 1.4.2.2 Activity limitation and participation restriction

Advanced AMD, is associated with painless, progressive, central visual impairment, (Lim 2012). The disease causes difficulty with tasks requiring central vision, such as writing, reading, recognising faces and driving, (Brown et al, 2005). Lamoureux et al (2008) investigated participation in daily living in patients with low vision caused by AMD using the Impact of Visual Impairment questionnaire (IVI). The mean age of their patients was 83.5 years. They did find that, although not normally acknowledged as a primary issue caused by AMD, mobility and activities related to a patient's independence, specifically 'going shopping' ranked as a main concern. A study into the impact of diabetic retinopathy on participation on daily living found that the activities with the most significant restriction of participation were reading, mobility, work and leisure. The participants in this study, for whom the average age was 67.5 years, also completed the IVI questionnaire (Lamoureux et al, 2004). The

IVI is a 32-item questionnaire, designed to provide a measurement of impact of visual impairment on restriction of participation of daily living. This questionnaire is divided into five main sections; leisure, household, mobility and emotional and was found by Weih et al (2002) to be a practical and simple to administer tool that could be implemented in the low vision setting to evaluate the impact of a patient's visual impairment and to assess their needs.

West et al (2002) investigated the relationship between measurements of visual acuity and contrast sensitivity, and performance of everyday tasks. In this study, patients undertook performance based tests in three categories; mobility, daily living tasks which include a visual component and visually complex tasks, such as facial recognition. It was concluded that both visual acuity and contrast sensitivity were significantly related to performance on all tasks except for stair ascent/descent tasks where contrast sensitivity was the lone predictor of performance. Legood et al (2002) found that older people who have a sight problem are 1.7 times more likely to have a fall than a sighted older person and they are 90% more likely to have multiple falls.

Another area covered by the Network 1000 survey was employment. In the sample, 20% of the working age population were unemployed and 22% were on long-term sick leave. 12% retired from work earlier than deemed normal. Out of those not working, whilst still considered as working age, 27% of people reported that they stopped work due to the onset or deterioration of their visual impairment. It was also found that those who were registered SSI were significantly more likely to be out of work than those registered SI. Out of those patients who did not want to work, most reported that this position was down to their visual impairment and/or their general health. 23% of the patients out of work were in receipt of income support.

#### 1.4.2.3 Psychological impact of low vision

In the Network 1000 survey, patients with visual impairment also presented with other disabilities. A total of 28% were registered as disabled and 70% reported long-term health issues including arthritis and heart problems. 43% of patients also

reported that they had a hearing impairment, 36% of whom were in the younger age group (18-29). In the interviews some patients reported that their visual impairment made it difficult to manage their other health conditions. A study by Hernandez Trillo and Dickinson (2012) looked at the contribution of non-visual and psychosocial factors on QoL in people with low vision using QoL questionnaires. In this study it was concluded that physical and mental health, along with other non-visual factors were found to be stronger QoL predictors than visual factors such as contrast sensitivity and visual acuity.

A reduction in performance in ADL is likely to cause depression and depression is likely to reduce ADL, making the relationship between functional loss and depression more complex. Evans et al (2007) conducted a study into depression in older people with low vision. They found that there is a definite link between depression and visual impairment in the older age groups. After controlling for certain functional factors including the ability to perform activities of daily living (ADL), it was found that visually impaired people were 25% more likely to suffer from depression than normally sighted individuals. Brody et al (2001) looked at the prevalence of depression in people with AMD and the relationship with depression within this population. They found that in the elderly population with advanced AMD, depression is a significant problem. Schilling and Wahl (2011) also studied people with AMD and the impact of the visual impairment on Adaptation to age-related Vision Loss (AVL). They found that the impact of vision loss on AVL was mediated by a patient's functional ability. Bookwala and Lawson (2011) looked at poor vision in older adults and depressive symptoms using the Activity Restriction Model. This model hypothesises that in later life, stressors can directly impact on depressive symptoms and also there can be an indirect impact from a restriction in routine every day functioning. They found that the model was an 'excellent fit' for the depressed effect and poor vision in later life. A direct impact of subjective poor vision on depressive symptoms was seen and indirectly, on social isolation and physical restriction, leading to depressive symptoms. When looking at the level of adjustment to visual loss in a cross-sectional study of adults, Tabrett and Latham (2012) found that personality traits, such as neuroticism and consciousness, can



impact on the ability of a person to adjust to their visual loss, more so than factors such as onset and severity.

There has been some evidence to show that there is a link between visual impairment and suicide (Lam et al, 2008). However this was found to be an indirect link, associated with other health problems. No statistically significant direct link was found in Lam's study. A review of various qualitative studies looking into the link between vision loss in later life and emotional wellbeing revealed that the loss of independence was reported as the most challenging aspect of sight loss. This loss of independence was linked to frustration when not being able to perform simple tasks and a feeling of loss or bereavement (Nyman et al, 2012). A recent review of the literature on the subject of depression in people with visual impairment due to AMD has suggested that people with activity restriction are at the greatest risk of depression. It was suggested that an integrated approach to managing depressive symptoms in older adults with visual impairment was the best way forward, (Casten and Rovner 2013).

### 1.5 The role of magnifiers in visual rehabilitation

In the terminology of the ICF the aim of visual rehabilitation is primarily to remove the activity limitation experienced by the individual. In most cases it is important that the individual retains their independence and self-sufficiency, and is able to perform the task autonomously. Strategies to allow this will typically use vision enhancement (magnification, contrast or lighting) or sensory substitution (auditory or tactile replacement of the visual element of the task).

Magnification is defined as 'the ratio of the enlarged retinal image size to the unmagnified image size under standard viewing conditions'. There are four different ways in which magnification can be produced: decreasing the viewing distance; increasing the size of the object (eg. large or giant print books); transverse magnification (such as an electronic or flat-field magnifier); and angular magnification (eg using a telescope). Plus lens magnifiers (whether spectacle-mounted, hand-held or stand-mounted) create magnification by allowing a close

viewing distance without the need for accommodation, so long as the object is at the focal point of the magnifying system.

For many people with low vision, reading can become a very difficult or even impossible task, (Fine et al, 1996). Magnifiers are however well suited to this task: from fluent reading of a novel or newspaper to spot reading, such as finding nutritional information on a food packet (Bowers et al. 2007).

### 1.5.1 Optical magnifiers

Optical magnifiers may be hand-held, stand-mounted or spectacle-mounted, (Figures 1.5-1.7). Plus lens magnifiers are available in a wide range of dioptric powers, many devices have their own light source and can be battery powered or re-chargeable from mains electricity (Virgili and Acosta, 2009). As the dioptric power of the magnifying lens increases, the viewing distance of the desired target decreases, making these magnifiers useful mainly for tasks that require near resolution acuity. Among the most frequently used optical magnifiers are stand magnifiers due to their ease of use, portability and relatively low expense, (Fine et al, 1996). In Moorfields Eye Hospital, over the past thirty years, the most commonly prescribed low vision aids (LVAs) have been non-illuminated hand magnifiers, illuminated stand magnifiers (figure 1.6) illuminated hand magnifiers (figure 1.7). Between 1973 and 2003 the number of prescribed illuminated hand magnifiers has increased (Crossland and Silver 2005). Where reading matter is distant, telescopes can be used and these can be hand-held or spectacle mounted (figure 1.8), (Virgili and Acosta 2009). However, when looking at the uses of LVAs in a population of veterans, Watson et al (1997) found that the main reasons for using their telescopes were travel, television, lawn and garden and identifying faces. Reading was not identified as a task that was performed with either type of telescope. If spectacle-mounted telescopes are useful only for stationary tasks that do not require mobility and orientation, (Christoforidis et al, 2011).

The main disadvantage of optical magnifying systems is that they are limited to a maximum magnification of approximately 20x, and 10x-12x usually being the highest powers used practically within a low vision setting. 20x in a plus lens system

would require a lens with a dioptric power of +80.00 and a working distance of only 1.25cm. This system would have considerable aberrations and a considerably restricted field of view (Dickinson 1998).



Figure 1.6: *Illuminated stand magnifier.*



Figure 1.7: *Illuminated hand magnifier.*



Figure 1.8: *Spectacle mounted telescope*

### 1.5.2 Electronic magnifiers

Transverse magnification can be created using a television camera to create a magnified image on a monitor screen. These systems can be termed closed-circuit televisions (CCTVs) due to the direct cable link between the imaging and viewing systems (figure 1.9). However, a more appropriate label would be 'electronic visual enhancement systems' or EVES, as this indicates the provision of 'features', as opposed to simply a 'surveillance' system, (Peterson et al, 2003).

EVES are generally prescribed to patients with moderate to severe visual impairment, as they enable higher magnifications than optical magnifiers. Other advantages of EVES include contrast enhancement, reduction of aberrations and a more natural working distance, which in turn leads to better posture and the potential for binocular viewing. If the patient's underlying ocular pathology worsens, the variable magnification of these devices can allow their continued use. However, EVES are more expensive than optical aids and many are not portable, (Burggraaff et al, 2010; Harper et al, 1999; Wolffsohn and Peterson 2003).

Broadly speaking, EVES can be classified by type into four sub-groups; stand-mounted (or desktop mounted), mouse-based, handheld and head-mounted, although the latter are not currently available. These classifications do not cover the concept of 'p-EVES' devices. Originally, EVES were a desktop-mounted design where the 'task' (eg a newspaper) is placed under a camera and manipulated in a regular pattern using an X-Y platform, (Dickinson 1998). In the 1980s 'mouse' style EVES devices were described. These featured a 'rolling' camera, mounted in a case that can be moved over the object of interest. They require connection to a television set or a computer. The newest models of these have a large depth of focus, allowing curved surfaces to be viewed and they encompass some of the features of the traditional fixed camera EVES such as variable magnification (although limited) and contrast reversal, (Wolffsohn and Peterson 2003).

The invention of miniature solid-state electronics has enabled smaller, more portable EVES (p-EVES) to be produced. P-EVES devices consist of a camera and small display screen built into the same hand-held device and have their own light source.



Figure 1.9: Desktop mounted CCTV

### 1.6 Current Provision of magnifiers in the UK

The UK has a multi-disciplinary approach to low vision services, which are mostly multi-agency and are comprised of various professionals, including optometrists, rehabilitation officers, social workers, ophthalmologists, orthoptists, nurses etc. Dickinson et al (2011) looked into low vision service provision in England. They profiled the services against the standards set out by the Low Vision Service Census Group (1999) and the NHS recommended standards for low vision services (2007). These standards were put in place to respond to the needs of those in the community with visual impairment. There were several different approaches evaluated. These included an integrated service, optometrist led hospital services, orthoptist and nurse led hospital services and social service low vision provision. It was found that all of the models for low vision services did use a multidisciplinary

approach but that all had their strengths and their weaknesses. It was commented upon that one of the strengths of all forms of low vision service evaluated was that there were robust referrals between the different professionals within the services.

Patients can be seen within the National Health Service (NHS) in Low Vision clinics for rehabilitation. The patients do not need to be certified as SI/SSI in order to gain access to this service or to the social services for an assessment of need. Ryan and Margrain (2010) reviewed whether the current registration criteria is fit for purpose and in doing so found that a large number of patients who are not registered but do have some sight loss are using rehabilitation services.

A number of patients with low vision may be independent, motivated individuals with the ability to access self-help information that may meet many of their rehabilitation needs. However, large, growing proportions of visually impaired people in the UK are elderly and may have other disabilities, as well as living alone. For these patients, access to rehabilitation services is vital.

Ryan and Margrain (2010) looked at the type and location of these services across the UK. They found that the distribution of services was geographically unequal and that in some locations, services were scarce. Currently, most low vision work is undertaken in the hospital eye service (65%). The study identifies the need for more provision of services in the community. Many of the patients attending hospital clinics would have their optical requirements met by the provision of a relatively simple optical device, which could be provided by optometrists in the community. One of the main problems in setting up these services in the community is that the local optical committee has to negotiate with commissioners to be able to provide the low vision aids free of charge, as they are able to in the hospital low vision service.

LVAs can be provided on permanent loan to patients within the NHS system, otherwise they are available to buy from the suppliers, some opticians and various other organisations. The LVAs available for loan are limited to the majority of optical aids; electronic aids are not usually provided as part of this service currently.

The Welsh National Assembly has identified this geographical 'lottery' in the way low vision services are spread out and introduced a nationwide low vision service in 2004. The Low Vision Service Wales is located in community based optometric practices throughout Wales. Patients are seen by accredited optometrists and dispensing opticians who work closely with social services, ophthalmologists, schools etc. and LVAs are provided on a loan basis, (Margrain et al, 2005).

## 1.7 The difficulties of using magnifiers

### 1.7.1 Field of View

LVAs provided for reading tasks to people who have low vision enable them to read smaller print than they would be able to see without the use of the aid. However, the introduction of a magnifier does restrict the field of view available for reading. In the case of optical magnifiers, the restricted field is caused by the physical aperture of the magnifying lens, which is restricted by aberrations (aspheric design of equivalent magnification would have a larger diameter). The stronger the magnification, the smaller the field of view that is available and the smaller the eye-to-magnifier distance. In the case of electronic magnifiers, however, the field of view is not restricted by aberrations and depends on the size of the screen used.

Field of view is one of the four main requirements for reading. Legge et al (1985) reported that for scanned texts, a window of at least 4 characters wide is essential for an observer, with normal or low vision, to maintain their maximum reading speed. As the field of view decreases, the reading rate slows.

Brinker and Bruggeman (1996) investigated the impact of field of view with CCTVs on reading speed and found that the reading speeds of patients increased significantly when the width and height of the viewing window increased. They found a similar result to Fine et al in that the reading rate continued to increase in an almost linear fashion up until their maximum window width of 12 characters. To support this result, they investigated 'normal' subjects using a lower magnification, which afforded a window of up to 24 characters. It was demonstrated that reading

rate still increased beyond a width of 12 characters then levelled off at 24 characters.

Another study that looked into window width on CCTVs was conducted by Beckmann and Legge (1996). It was found that when reading text on a CCTV, normally sighted patients required a window width that was three times greater to achieve 85% of maximum reading speed for manually reading stationary text compared with controlled 'drifting' text. They found less of a relationship with their low vision subjects at a window width requirement of two times greater.

Lovie-Kitchin and Woo (1988) also looked at reading speeds with CCTVs. They tested 18 'normal' subjects and 10 low vision subjects using various different field sizes and magnifications on a CCTV. They found that in low vision subjects who have naturally slower reading speeds, the reading speed can increase with higher magnifications despite the smaller field of view. Alternatively, subjects with faster reading speeds would benefit from minimum magnification, giving maximum field of view.

Dickinson and Fotinakis (2000) observed the reading speeds of normally sighted subjects when using hand magnifiers to read two different sizes of text, 10-point and 18-point. A reduction in reading speed with hand-magnifiers was found, even at low magnification levels. One given explanation for this is that the introduction of a magnifier creates a smaller field of view, which causes saccadic eye movements to change; this matter will be discussed further in section 1.6.2. Although reading speed tends to increase as the field of view increases, this study found that there has to be a substantial decrease in the field of view (2 characters) before the decrease in reading speed becomes statistically significant.

Cohen and Waiss (1991 (a) and (b)), conducted two studies looking at reading speeds with four different types of optical magnifiers. The initial study (a) aimed to investigate the reading speeds of 60 'normal' observers with each of these devices. The magnifiers were types of spectacle-mounted, hand-held, stand and tele-microscopic near devices. The field of view of each device was kept the same for each patient using it. The results showed that there were significant differences in



reading speed, depending on the type of device used. The reading speed seemed to directly correlate with the field of view size given by each magnifier, with spectacle-mounted giving the largest field of view and the fastest reading speed and the stand magnifier giving the smallest field of view and the slowest reading speed. In order to investigate this further, Cohen and Waiss carried out a further study (1991) where the same magnifiers were used but all were controlled for their field of view, giving approximately 20 characters. The findings were that despite major differences in their form or usage, the reading speeds were the same for the three of themagnifiers. The tele-microscope was the only device to have a slower reading speed in comparison.

In an experiment by Fine et al (1996), it was found that reading rates continue to increase up to a field of view of 13 characters. In this study, patients with both normal and low vision read short passages using a fibre-optic stand magnifier. This type of magnifier allowed the field of view available to be varied and fields of 3,5,9 and 13 degrees were used while patients were timed reading aloud. It was suggested by the authors that the difference in the results of this experiment and Legge et al's experiment were due to the lack of page navigation required when reading from a controlled display whereas when reading with stand magnifiers, there are no limits on where the device can be moved, making the window size more important. When using a CCTV, the reader must control the display and navigate their way from one line to the next. This is done, however, by using an x-y table which helps to keep the vertical alignment. This x-y table can be fitted with stops and its resistance can be altered to control movement. Arguably this is not the same as the amount of navigation required when using an optical magnifier.

The results from all of these studies indicate that the field of view of an LVA is one of the main variables responsible for reducing reading rate. Therefore, a main advantage of electronic magnifiers compared with optical magnifiers is that the field of view can be increased by simply increasing the size of the display screen.

### 1.7.2 Eye movements when reading

It is to be expected that the introduction of magnifiers would interrupt the normal eye movements when reading, 'Normal' eye movements are covered in more detail in chapter 2. When studying the effect of magnifiers on the reading process, Neve (1989) found that if the width of the line is larger than the width of the magnifier, a horizontal movement of the magnifier must be made and the eye movements must be tuned to magnifier movements. The movement of the magnifier to the right causes an apparent movement of the stimulus to the left, which disturbs the reading process. This effect is particularly observed when the reader must locate the next line. In this case, the leftward movement of the magnifier causes an apparent shift of the image to the right and disturbs the reader's ability to locate the left margin, hence the next line.

This was studied in greater detail by Dickinson and Fotinakis (2000). This study aimed to investigate the changes in reading eye movements of normally sighted subjects with hand-magnifiers. The normal 'staircase' pattern of eye movements was found in control conditions where no magnifier was used. Upon the introduction of hand magnifiers, the patterns of eye movements were noted to change. Instead of the usual fixation pauses, smooth leftward eye movements were observed, creating a 'saw-tooth' pattern (Figure 1.5). This result confirmed the findings of Neve (1989) that the rightward movement of the magnifier causes this leftward shift of the reading material which has to be traced by the eyes. The eyes fixate on a point in the text, and then trace the leftward movement for a time equivalent to the fixation pause in normal reading. Following this a saccade is then made to the next fixation. A 'reverse' saw-tooth pattern can occur when the reader must find the next line.

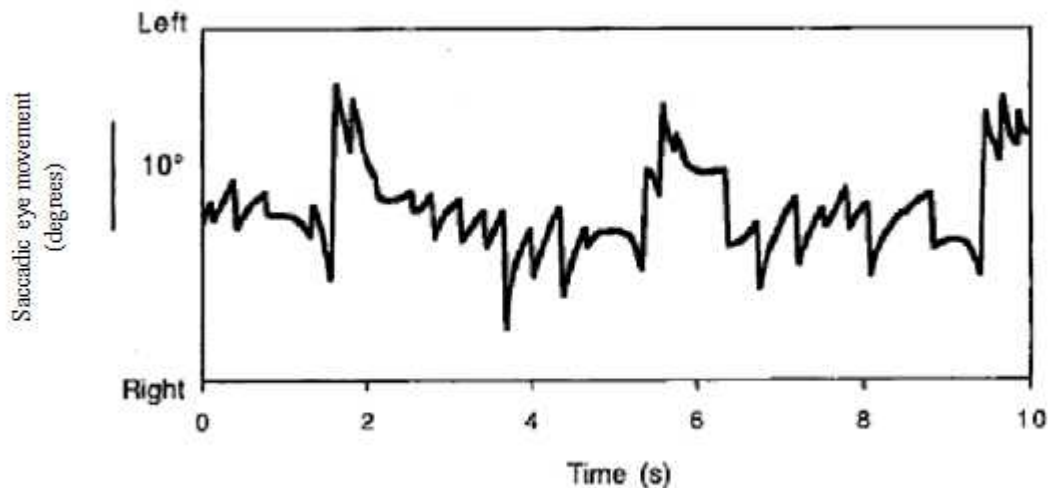


Figure 1.9: *Example of a 'saw-tooth' eye movement pattern when reading with a magnifier. Bowers et al (2001).*

It was observed that as subjects' heads were not restrained during this study, there is a possibility that fast head movements in the direction of reading were occurring along with the saccades. In order to investigate the effect of head movements on the results, three subjects repeated the experiment with their heads restrained. The forward saccades were found to be larger than in 'natural' conditions leading to the conclusion that head movement can cause some of the movement of the image across the retina in reading.

It is clear from the results of these studies that the interruption of eye movements must cause a decrease in reading speed when using a magnifier.

Bowers et al (2007) investigated the potential page navigation problems when reading with an optical magnifier. The navigation movements necessary to read text were divided into two phases; the forward phase, during which the line is read and the magnifier is moved leftwards; and the retrace phase when the magnifier is moved from the end of a line to the start of another. The patients in this study tended to use a straight or diagonal downward movement during the forward phase. When retracing, most patients used a downward diagonal movement to find the next line, very few used a straight or upwards movement. When page navigation strategies are taught to patients on prescription of their optical

magnifier, some practitioners teach the patient to retrace in a straight line back along the line they have just read and then move down onto the next line. However, in Bowers et al's study, the patients were not taught these specific retrace strategies.

When using CCTVs, it has been reported that the most common retrace movement has been found to be a straight line and then simply dropping down onto the next line. This approach is probably the simplest method when using an x-y table (Beckmann and Legge 1996).

### 1.7.3 Reading performance with magnifiers

In patients of all ages with 'normal' vision, reading speed decreases without loss of comprehension when the magnification increases or the number of visible characters is reduced. With increased magnification, most low vision patients show an initial increase in their reading speed, followed by a plateau or decrease with further magnification increases (Wolffsohn and Peterson 2003). Erlich (1987) studied CCTV use in patients with AMD and Retinitis Pigmentosa (RP). He also had a 'normal' control group. It was found that in patients with AMD, reading speed is highly correlated with magnification of EVES device, whereas in RP the same applies only in reverse contrast.

There have been a number of studies comparing the reading speeds when using optical aids vs EVES devices. Goodrich et al (1980) investigated veteran patients with low vision who had been using a CCTV for at least two years. Fifty percent also used optical aids and these subjects were used to compare reading speed and durations for the two different devices. The mean optical aid reading speed was 84.67 wpm and the mean CCTV reading speed was 82.38; which shows no statistical difference. Patients in this study were also asked to estimate their reading durations for each device and these results were statistically different. The mean duration estimated for an optical aid was 34.48 minutes and was 105.26 minutes for a CCTV. Stelmack et al (1991) also found that reading duration was longer with CCTVs than with optical magnifiers. Their patients reported being able to use a CCTV for 29 minutes, their optical aids for 13 minutes and their spectacles for 11

minutes. This study also investigated reading speed with CCTVs vs optical aids and it was found that the reading speed with CCTVs is greater than that with optical aids (59 wpm vs 30 wpm).

Peterson et al (2003) did not measure reading duration but did look at other performance variables for near reading tasks, comparing the subject's own optical magnifier with various commercially available EVES devices. This study concluded that compared with optical aids, EVES allow smaller print sizes to be read and at a faster reading speed. However, locating the next column of print was significantly faster with the subject's own optical magnifier than any of the EVES devices, which the authors put down to the significant learning effect when undertaking commonly performed tasks. Goodrich and Kirby (2001) agreed that electronic devices give a better reading speed than optical aids. In their study, both a hand-held and a stand-mounted electronic device gave a mean reading speed of 76 wpm, whereas the optical aids gave a mean reading speed of 64 wpm. Goodrich et al also looked at comparisons in reading duration for the different devices. Their results agreed with other studies (Goodrich et al 1980 and Stelmack et al, 1991) that the reading duration with the electronic magnifiers was significantly longer at 36 minutes than with optical magnifiers, 23 minutes.

Nguyen et al (2009) investigated the impact of prescription of appropriate magnifiers (including optical magnifiers and CCTVs) on reading speed in patients with AMD. Reading ability was achieved in 94% of patients after the issue of appropriate devices compared with only 16% beforehand. In this study, no reading ability corresponded to a reading speed of <30 wpm. In almost all patients, reading speed was less than 30 wpm prior to the provision of magnification, giving virtually no reading ability. In comparison, the reading speed improved to a mean of 72 wpm with the appropriate aid, allowing patients to comfortably read the desired newspaper print. It must be noted, however, that patients in this study who were classed as having 'severe visual impairment' showed significantly less improvement in reading speed than patients with better visual acuity.

Ortiz et al (1999) compared two electronic LVAs, a CCTV and a head-mounted video magnifier called Low Vision Enhancement System (LVES). Mean reading speed for news articles was 61 wpm for the LVES and 67 wpm for the CCTV, the authors postulated that the two devices were comparable for reading speed. However, as previously referenced, the range of magnifications of the LVES was poor in comparison to that of the CCTVs and two patients struggled to read the 10 point font with LVES, whereas they had no difficulty with the CCTV.

### 1.8 How effective is rehabilitation?

There are a number of ways to assess the effectiveness of a low vision rehabilitation programme or service. Effectiveness, in the context of the following studies, is the degree to which the intervention or programme is successful in producing a desired outcome. One way to assess effectiveness is to measure changes in visual function before and after the intervention. Margrain (2002), collected data over a 6 month period in the low vision clinics at Cardiff University. The patients were new referrals and before intervention 23% of them could read N8 (standard newspaper print size). Following the prescription of appropriate low vision aids, 88% could read N8 or smaller. Nilsson and Nilsson (1986) studied 120 patients with advanced AMD for an average of 5 years, a period over which they had access to low vision rehabilitation including optical magnifiers with methods of training in their use and training in utilization of remaining vision. They found that the number of participants able to read newspaper print rose from 0.8% to 92.5%. Similarly, Nilsson (1986) looked at a different aetiology; diabetic retinopathy. As in the previous study the 79 patients were exposed to a similar rehabilitation programme and were followed for 3.6 years. When taking into account progression of retinopathy, the final near and distance VAs were still significantly better following prescription of low vision aids compared with baseline measurements.

Another approach to evaluating the effectiveness of a low vision rehabilitation programme is to use questionnaires, for example to assess quality of life. In 2010, Court et al conducted a study with the aim of comparing a new community based low vision service (CLVS) and the already established hospital low vision service

(HLVS). The primary outcome measure of this study was the seven-item National Eye Institute Visual Function Questionnaire (NEI-VFQ). In this questionnaire the patient is asked to rate a specific difficulty from 1-5, number 5 indicating a higher disability. The seven-item version targets seven areas of a patient's visual disability that low vision services are known to be able to do something about (Stelmack et al, 2002). 488 patients were recruited (HLVS n=145; CLVS n=343) and were given a pre-service questionnaire before their initial appointment and then a post-service questionnaire 3 months afterwards. The study found that both HLVS and CLVS produced a significant reduction in self-reported visual disability, as measured with the seven-item NEI-VQF. Ryan et al (2013) then carried out an observational study of the then established Welsh Low Vision Rehabilitation Service. They recruited 342 patients with the aim to determine whether the same reduction in self-reported visual disability at 3 months seen in the study by Court et al, was also seen at 18 months. The results showed that the patients did have significantly reduced self-reported visual disability at 18 months; however this difference was not as significant as the reduction at 3 months. It was discussed that this may be due to a general reduction in baseline function over time. In the UK, Pearce et al (2010) used the Mass of Activity Inventory (MAI) questionnaire to assess the effect of adding further low vision device training. Participants were randomised so that some received a further appointment to assess their handling of the device and the some were 'controls' who did not receive a further appointment. The questionnaire was completed prior to the participants' first assessment and then at one and three months following the initial LVA. There was no further improvement seen for those who had the extra appointment compared to those who did not.

In America, Stelmack et al's LOVIT study (2008) had the objective of assessing the effectiveness of a low vision programme in a multicentre randomised controlled trial. In this study, the Veterans Affairs Low-Vision Visual Functioning (LV VFQ-48) questionnaire was used to assess changes in patient's reading ability from baseline to four months after taking part in an outpatient low vision programme. The participants were enrolled either into a treatment or a control group. The programme included a low vision assessment, counselling, prescription of LVAs and

six-weekly sessions with a low vision therapist. The results showed that the treatment group in this study showed significant improvements in all aspects of visual function compared with the controls.

Reeves et al (2004) conducted a study to compare the effectiveness of three different low vision intervention models for patients with AMD. Intervention A was an enhanced low vision rehabilitation model (ELVR), which included a supplementary home based visit; B was a conventional (hospital based) low vision rehabilitation model (CLVR). A third model (C) acted as a control intervention which had a home visit like ELVR but this visit did not contain any supplementary rehabilitation (CELVR). The primary outcome measure in this study was vision specific QoL (VCM1). This is a ten-item questionnaire that contains questions related to the way patients feel about their visual impairment and the impact that the impairment has on their lives. The research found no evidence to suggest that ELVR was beneficial over CLVR. Another result from the study was that there was a lack of improvement in the outcomes in the CLVR model over time, this could lead to questions over the effectiveness of CLVR; however as suggested in the paper, this comparison is not controlled for and does not measure how QoL would potentially deteriorate over time if there had been no CLVR.

#### 1.8.1 Perceived Usefulness of magnifiers

Throughout the world, reading is deemed to be one of the most highly valued activities in human culture. So much so that many international bodies use literacy rates as one of their primary indicators for social and economic development (National Research Council 2002). Legge et al (1985) defined low vision as the inability to read a newspaper at a reading distance of 40cm with full refractive correction in place.

The purpose of low vision rehabilitation is to ensure patients can continue or resume their usual daily living tasks. Difficulty with reading is one of the most commonly reported complaints; therefore it is one of the main goals of a typical patient with low vision (Dickinson 1998). More specifically, in a study by Elliot et al (1997), it was found that 75% of their patients rated reading as their primary aim



and 21% as their secondary aim. Reading may be specifically important as a recreational activity in the elderly generation where they may be subject to forms of physical disability. This age group also tend to spend more of their time at home compared with other age groups, therefore reading would serve as an activity to keep them occupied whilst indoors. Hearing impairment increases with age and for these patients, hearing loss has been suggested to be compensated for by reading ability (Lott et al, 2001).

There have been several studies that look at the usefulness of different types of low vision aids. For many of these studies, usefulness is a secondary outcome and the ways in which it is assessed differs between the studies. It is assessed mainly by the use of questionnaires following prescription of devices and relates to how a patient rates the impact of the prescription of a device on their ability to perform tasks and activities of daily living. Table 1.4 details the studies to be discussed below.

Author	Title	Location	Brief Description	Results
Goodrich et al (1976)	A Preliminary Report on Experienced CCTV Users	Western Blind Rehabilitation Centre (WBRC). California. US	Follow up study of 27 veterans to describe the use and usefulness of CCTVs. Quantitative and Qualitative data taken at home visit.	19/26 patients ranked CCTV most useful magnifier
Shuttleworth et al (1995)	How effective is and intergrated approach to low vision rehabilitation? Two year follow up results from south Devon	South Devon Low Vision Service, Torbay Hospital	Questionnaire posted to 125 patients 1 year and 2 years after they attended LV clinic. To assess effectiveness of integrated approach to LV rehabilitation. Also assessed usefulness of LVA(s) prescribed.	At year 1, 77% of respondents commented favourably on 'usefulness' of LVA

Watson et al (1997)	National survey of the impact of low vision device use among veterans	Blind Rehabilitation Centres and Visual Impairment Centres to Optimise Remaining Sight (VICTORS), USA	2 year study of veterans' use of LVAs. 200 participants completed telephone surveys 12-24 months after device prescription.	85.4% LVAs still in use.
Watson et al (1997)	Veteran's use of low vision devices for reading	Blind Rehabilitation Centres and Visual Impairment Centres to Optimise Remaining Sight (VICTORS), USA	As above-further investigations into LVA usage for reading. Analysis of 3 types of LVA for 'helpfulness' of aids.	Video magnifiers were found to be the most helpful device for longer durations of reading.
Harper et al (1999)	Evaluating the outcomes of low vision rehabilitation	Manchester Royal Eye Hospital Low Vision clinic patients	56 subjects, all with diagnosed AMD. Manchester Low Vision Questionnaire used to predict 'usage rates' of LVAs.	87% patients used LVA on regular basis, 67% at least once a day. 70-77% rated helpfulness of LVA in ADLs 'extremely' or 'quite a bit' helpful
Dougherty et al (2011)	Abandonment of Low-Vision Devices in an Outpatient Population	Multicentre. 4 clinical sites, 3 colleges of optometry, one university ophthalmology clinic, US.	Telephone surveys on 88 patients with low vision 1 year after prescription of LVAs. Main outcome measure was abandonment of LVA.	Out of 88 patients, 19 had abandoned at least one LVA.
Decarlo et al. (2012)	Use of Prescribed Optical Devices in Age-Related Macular Degeneration	University of Alabama at Birmingham Center for Low Vision Rehabilitation	Enrolment period May 2008- Jan 2011. 199 patients. Evaluated perceived usefulness and frequency of use of	Magnifiers were reported to be moderately-to-extremely useful by >80%

			prescribed optical devices. Also determined tasks that patients were using their LVA for.	of participants.
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Three studies looked only at the usefulness of optical magnifiers. Harper et al (1999) looked at device usage rates in AMD patients and found that 87% of the subjects reported using their devices on a regular basis with 67% reporting that they use a device at least once a day. When asked to rate their primary optical device, 52% of subjects rated it as 'extremely important' and 55% agreed with the statement 'I would be lost without my low vision aid(s)' A more recent study investigating device 'usage' was conducted by DeCarlo et al (2012). Magnifiers were reported to be moderately-to-extremely useful by >80% of participants.

Shuttleworth et al (1995) looked at usefulness of magnifiers as a secondary aim in their study. A questionnaire was posted to low vision patients 1 year and 2 years following prescription of the device. At 1 year, 77% (n=125) of patients commented positively on the usefulness of the LVA originally supplied and only 9% said they did not use the aid. After 2 years, 3 more patients stopped using their LVAs. 18 of the respondents bought their own additional LVAs from other sources, of these patients, 89% used their LVA more than twice a day. The study does not specify whether these 'additional' magnifiers include electronic devices, so we do not know whether this contributes to the high recorded usage rates.

Three of the studies included electronic magnifiers. A study by Dougherty et al (2011) used telephone surveys to evaluate usage of LVAs in a sample of 88 patients. The main outcome measure of this study was 'abandonment' of LVA (>3 months of no use). The results showed that out of the 88 patients, 19 had abandoned at least one device. Reasons for the abandonment of each device were varied, however the main reasons given were; the device is ineffective for the required task or, another device was more effective for the required task (some patients had more than one device). Unfortunately, this study did not specify any results for which type of device was least likely to be abandoned. In Goodrich et al's (1976) study, 73% of

patients ranked the CCTV as their most useful magnifier over their optical magnifiers and the activities carried out with the CCTV ranged from stamp collecting to artwork, meaning these devices can be incorporated into a person's daily life and used for both professional and recreational means. This was a small sample of patients (n=26) compared with Watson et al's (1997) study. In this study 200 veterans were surveyed by telephone following the prescription of magnifying devices including video magnifiers. They were generally able to use the video magnifiers for longer durations of reading (30 minutes) compared to stand or hand-held devices (a few minutes). They were also asked to rate the 'helpfulness' of their devices. This was assessed using the following question: 'How helpful would you say your LVA has been for the task of reading?' Video magnifiers were found to be their most helpful device for longer durations of reading with >80% ranking their video magnifier as 'extremely helpful'. This is compared with ~50% ranking their optical aids as 'extremely helpful'. No participants in this study had discontinued use of their video magnifiers at the time of the telephone survey.

The literature suggests that the majority of patients tend to find their devices useful, whether optical or electronic, however, when measured, the degree of 'usefulness' tends to be rated by patients as higher overall when using electronic devices compared with optical devices. Possible reasons for this could be related to disadvantages of optical aids reported in Watson et al (1997)'s study such as magnification not being strong enough and disliking the optical design. There is no available information about the usefulness of p-EVES devices at present.

### 1.9: Conclusions of literature review

In the UK, there are an estimated 2 million people with low vision, most of whom have access to low vision clinics where optical magnifiers can be prescribed on permanent loan. There is a lack of literature about the newer p-EVES devices on the market and anecdotal, clinical experience suggests that these are popular amongst patients and clinicians. This, combined with the success of the supply of p-EVES through the Low Vision Service Wales, justifies the need for more research into the effectiveness of p-EVES for near vision tasks in a low vision population.

## **Chapter 2: Selecting and prescribing the p-EVES devices to be used in the study**

### **2.1 Identifying suitable p-EVES devices for inclusion in the study**

One of the main events that prompted the need for the p-EVES study was the successful supply of p-EVES devices through the Low Vision Service Wales. This came about when children were interviewed in a focus group setting and they expressed that the designs of their optical magnifiers were 'distasteful' compared with p-EVES, which were preferred due to their more stylish designs and magnification capabilities (Dyment 2009). The Welsh Council for the Blind conducted further focus groups where p-EVES were identified as the preferred aids over optical magnifiers. The participants identified which were their preferred devices and which were less practical. Once the chosen devices had gone to tender, one device was selected for provision through the Welsh Low Vision Service, now called Low Vision Service Wales. Due to the success of the focus group approach in the Low Vision Service Wales, it seemed appropriate that a similar method be taken to select the p-EVES to be used in the p-EVES study.

In order to ensure that the focus group had access to some of the most recent p-EVES on the market, the focus group took place once recruitment was ready to begin. An internet search was undertaken by both the chief investigator and the clinician researcher in January 2013 to identify all the p-EVES on the market at that time. Between the two researchers, 37 devices were identified and then their features looked at more closely. A list of devices identified can be found in appendix 2. Many of these devices had fixed magnification and/or contrast, so these were eliminated from the search in favour of devices with variable magnification and contrast settings. Other devices did not have a UK distributor, so these were also removed from the list.

The screen sizes ranged from 2.8 inches to 7 inches, a feature that was to be discussed and determined at the focus group, therefore this range was reflected in our final list of devices.

Once the list had been compiled, letters were written to the p-EVES manufacturers to request one or more of the identified models for the focus group, and then 20 for the main study if their device was selected as a result of the focus group.

Six of the companies agreed to this, and these are listed in Table 2.1 with the p-EVES models they supplied.

Table 2.1: *List of the p-EVES devices supplied for the focus group*

Optelec	Compact Mini
	Compact+
	Compact 4HD
	Compact 5HD
	Compact 7HD
Bierley	Maggie MD
Reineker (UK distributor=Optima)	Mano
	Minimax
Schweizer (UK distributor=Optelec)	eMag 34
	eMag 43
	eMag 70
Ai-squared (UK distributor=Humanware)	i-loview
	i-loview 7
Humanware	Smartview Versa
Associated Optical	Mobilux Digital
	Smartlux Digital

It had been decided within the study team that a number (3 or 4) of devices would be taken forward into the main study. This meant that the participants, with the help of the clinician researcher, would be able to select the p-EVES device that they felt would best meet their requirements.

### 2.1.1 Focus Group

A focus group is a group of individuals who are selected within research projects to discuss the research topic. The discussions usually take a semi-structured format

and contain both open and closed questions to keep the conversation flowing whilst arriving at essential decisions (Kitzinger 1995). The advantages of a focus group approach include the fact that people respond not only to the questions posed by the researcher but also to the comments made by other focus group participants. This approach is also more cost and time effective than conducting individual one-on-one interviews. Disadvantages compared with one-to-one interviews include participants not being completely open with their opinions in front of people they have not met before, and potentially one person dominating the discussion (Halcomb 2007). Also they can be harder to control compared with an individual interview approach, (Stelmeijer et al, 2014). The aim of a focus group is to gather a range of public opinions on a set topic. This approach in the p-EVES study meant that the p-EVES could be presented to a small sample of subjects, with a mix of ages and gender, to promote discussion and ultimately have the patients choose the most appropriate devices to be used in the study.

The p-EVES study was funded by the National Institute for Health Research (NIHR in its Research for Patient Benefit (RfPB) programme. This programme was inspired by patients and it is, therefore, important that Patient and Public Involvement (PPI) can be demonstrated through the studies it funds. The focus group was one way that PPI has been demonstrated in the p-EVES study. This approach means that the public can be involved in the research directly, rather than it just being 'about' or 'for' them.

## Methods

In choosing the focus group participants it was important that they would be people who were willing to speak in front of a group to give their opinions, and a mixture of those with and without p-EVES experience was also desirable. The p-EVES study co-investigator from the Macular Society supplied a list of eight potentially willing participants who fitted the above criteria. The participants were aware that if they were involved in the focus group then it was not appropriate for them to then be a participant in the p-EVES study. Based on this, one patient decided to decline to be involved in the focus group and then later became a p-



EVES study participant. Seven patients initially accepted and then due to one illness on the day, the final focus group number was six participants.

The focus group cohort is shown in table 2.2.

Table 2.2: *Focus group participants*

Participant #	Gender	Age	Diagnosis
1	Female	81	Macular hole/Age related macular degeneration
2	Male	77	Age related macular degeneration
3	Male	56	Stargardts disease
4	Female	68	High Myopia
5	Female	46	Choroidopathy
6	Female	83	Age related macular degeneration

The focus group was carried out on 19<sup>th</sup> February 2013 and took place for two hours, split into two sections. The first hour involved the participants trying out the p-EVES devices. Newspaper and magazine print was provided to try out reading with each device. Writing materials were also provided. The aim of the first hour was to make sure that each participant was able to try each device for enough time to use all the buttons/features. The facilitators were on hand to answer any questions and to help with the controls. At this stage, the participants were working alone and occasionally communicated with each other, however it was encouraged that specific opinions regarding the devices were saved for the group discussion in the second section. The devices were labelled with numbers, one purpose of this was to keep the session organised, and the other was for the participants to rank the 16 devices in order of preference. For the second hour the participants sat around a table with the facilitators and this part of the session was audio-recorded.

Some 'rules' were read aloud to the group before commencing the discussion. These encouraged participants to speak one at a time and to speak loudly and clearly for the recording. For the group discussion, the devices had been arranged into four rough groups of four, detailed in table 2.3. This was in order to help keep the discussion flowing and simple.

Table 2.3: *p-EVES groupings for focus group*

Group 1- 'smaller devices'	Maggie MD	3.0"
	eMag 34	3.4"
	Compact Mini	3.5"
	Minimax	2.8"
Group 2- 'medium sized devices with handle option'	Mobilux Digital	3.4"
	Smartview Versa	4.3"
	Compact+	4.3"
	eMag 43	4.3"
Group 3- 'medium sized devices with stand option'	Mano	3.5"
	Smartlux Digital	5.0"
	i-loview	4.3"
	Compact 4HD	4.3"
Group 4- 'larger devices'	Compact5HD	5.0"
	Compact 7HD	7.0"
	eMag 70	7.0"
	i-loview 7	7.0"

For each device, the group gave their opinions one at a time. Each participant was called upon using first names and both negative and positive opinions were encouraged. Facilitators encouraged discussion about certain features of each device, when they had not been mentioned and occasionally the facilitators had to move the discussions along where repetition was occurring to ensure that equal time was spent discussing each device. A pre-written script was available to keep the facilitators on track and consisted of both open-ended and then closed questions. For example, the first question would be 'What did you like about the device?' and then it was followed by questions such as 'Did you have an opinion on the size of the buttons?'. The script can be found in appendix 3. The original ranking system was found to be confusing for patients so at the end of the discussions for each group of devices, each participant was asked to name their favourite device of

that group. Also, once all the devices had been discussed, the participants were asked to each name their favourite three devices of the sixteen.

The focus group recording was transcribed so that results could be interpreted. Following this, the transcript was reviewed by members of the p-EVES study group and the results were discussed in order to decide upon the devices to be used within the p-EVES study.

Results of focus group:

Interestingly the participants of the focus group rarely mentioned the image clarity or magnification of the devices and they tended to concentrate on their practicalities, such as size and weight. The 7 inch devices were very popular, specifically the Compact 7HD by Optelec, however it was felt by the group overall that these were too large in size to be considered 'portable'. The "smaller" group were seen as devices that could be taken shopping but unsuitable for leisure reading tasks. One option going forward into the p-EVES study would have been to select the most popular device in each of the four groups. This would reflect the different types of devices on the current market and would mean that in the main study we would be investigating how a p-EVES device compares with an optical aid for a specific task. However, this would mean steering away from the original p-EVES study plan. The original idea behind the p-EVES study was to select one versatile p-EVES device to potentially replace all of a patient's optical near vision magnifiers. On this premise, it was decided to restrict the device choices to the 'medium' sized devices favoured by the focus group participants.

The four devices selected were: the eMAG 43 by Schweizer, the Compact+ by Optelec, the Compact 4HD by Optelec and the Mobilux Digital by Eschenbach. The specifications of these are in appendix 4.

## **Chapter 3: Recruitment and Assessment of Participants for the p-EVES Study**

### **3.1 Recruitment**

Recruitment for the p-EVES study took place between April 2013 and October 2014. The participants were recruited from the low vision clinics at Manchester Royal Eye Hospital by the optometrists. The optometrists used a specially designed recruitment sheet to identify suitable patients based on the inclusion/exclusion criteria (table 3.1). Once a patient had been identified as eligible for the study, they were approached by the clinician researcher, either in the clinic or over the telephone, and given participant information. This information was given either in large print or audio format. The patients were given a minimum of one week to consider the information and were then contacted to book them in for an initial assessment for the study.

Table 3.1: *Inclusion/exclusion criteria for p-EVES study*

<b>Inclusion Criteria:</b>
Adult (Over 18 years old)
Visual Acuity (VA) of 0.70logMAR (6/30 Snellen) or worse and/or log contrast sensitivity of 1.20 or worse (in the better eye)
Stable ocular pathology (no change in VA > 2 lines in previous 6 months)
Currently have an optical low vision aid only (i.e. not tried p-EVES before)
Adequate hearing (adequate to respond to verbal instruction)
Habitual language is English (because the reading tests are in English)
<b>Exclusion Criteria:</b>
A physical disability preventing the participant from operating the p-EVES
A score of <19 on the mini mental state examination (MMSE Blind)

### **3.2 Initial Assessment**

Once a patient had been recruited into the p-EVES study, they had an initial assessment with the clinician researcher. During this assessment, the inclusion/exclusion criteria of the p-EVES study were confirmed and some demographic and baseline data was taken from each participant. This included their registration status, their diagnosis, their living situation (e.g., lives alone), their employment status and their ethnicity. Their binocular distance visual acuity was measured, along with their habitual near visual acuity and their near visual acuity

with a reading addition for 25cm. Contrast sensitivity was measured binocularly using the Peli Robson chart and the Central California Visual Fields Test (CCVFT) was completed to assess for the presence of central scotoma. Two questionnaires were completed at the initial assessment. One was the Mini Mental State Examination (MMSE) (Reisches and Geiselman 1997). The 'blind' version of this test was used to ensure that the participants will have no difficulty complying with the demands of the study. A score of 19 (out of 22) or less would indicate that the participants would have difficulty with this. The Manchester Low Vision Questionnaire (MLVQ) was the second questionnaire completed (Harper et al, 1999). This evaluated the participant's current use of their optical magnifiers, for example the frequency and duration of use and the tasks that they are being used for. At this stage, before the participants were consented into the study, any changes to their current optical magnifiers were made to ensure they were the optimal magnifiers for near vision tasks. Once the participants had officially begun the p-EVES study, it would not be appropriate to alter the magnifiers as this could interfere with the main study results.

At this initial assessment the participants were introduced to the four p-EVES devices and they, with guidance from the clinician researcher, selected their preferred device to be used in the study. This process was relatively informal as the patients were shown the p-EVES in a random order and compared them on a reading chart. For some patients the decision was made quite quickly with some devices being eliminated straight away due to initial handling issues. Others spent some time with each device before making a decision. In order to avoid guiding the participant's choice of p-EVES, they were not given much help beyond pointing out the features on each device. This was to prevent the personal opinions of the clinician researcher, regarding which of the four devices were favourable, from influencing the participants in any way.

The specifications of the four p-EVES in the study were similar with regards to the colour/contrast options available and the size of the screen (ranging from 3.5-4.3 inches). However the magnification range, design (handle/stand) and controls

(position/size/colour of buttons) of the devices did vary. It was usually these latter features that caused a participant to choose one device over another.

At the beginning of intervention A, the participants were given a more structured ‘task based practice’ session with their chosen device to ensure that they were able to use it comfortably before taking it home to use for the two months. Usually, the device chosen in the initial assessment was the one used by the participant in the study. However, some participants did request to change their device at the level of task based practice to another one having thought about it after their initial assessment. The different elements of the ‘task based practice’ will be covered in detail in chapter 4.

### 3.3 Assessing the presence of central scotoma

#### 3.3.1 The importance of a central scotoma for reading ability

Whittaker and Lovie-Kitchin, (1993) conducted a review of various research studies into the psychophysics of reading to investigate what visual requirements a patient has in order to achieve certain reading rates. They concluded that the requirements for successful reading can be described under 4 main headings ; (1) acuity reserve: the ratio of the size of the stimulus to a patient’s acuity threshold; (2) contrast reserve: the ratio of stimulus contrast to the patient’s contrast threshold; (3) field of view, and (4) central scotoma size.

Table 3.1: *The four main visual requirements for reading (Whittaker and Lovie-Kitchin, 1993)*

Visual Requirement	Reading Rates (WPM)			
	Spot	Fluent	High Fluor	Optimum
	40 WPM	80 WPM	160 WPM	
	Class level: fifth grade level			
	44 WPM	88 WPM	174 WPM	
Contrast reserve	3:1	4:1	10:1	>30:1
Field of view (characters)	1	2-5	4-6	4-6
	with scrolled text			
	2	5	12	16-20
	with stationary text			
Acuity reserve	1:1	1.5:1	3:1	6-18:1
Eccentricity of fixation (distance from fovea)	>15°	<11°	<2°	0°
Scotoma diameter	>30°	22°	4°	None

A scotoma is an area of the retina that has a reduction in light sensitivity compared with that of normally sighted subjects. Scotomas can be characterised by their retinal location, for example central scotomas are foveal involving. They can also be characterised by their density, and/or their area. Dense scotomas (or absolute scotomas) are delineated by a retinal area that is insensitive to very bright stimuli, where relative scotomas are identified when bright stimuli are detected, but using dimmer stimuli reveals areas of loss (Fletcher et al, 1999; Fletcher et al, 2012). Macular disease is the main cause of central scotoma. Geographic atrophy is a form of advanced age-related macular degeneration and it can create an absolute scotoma that corresponds well to the borders of the lesion, (Sunness et al, 1996). The ability to perceive objects falling in this area is either lost or seriously compromised. This results in reading difficulties being one of the most commonly reported problems for patients with AMD, (Harvey and Walker, 2014). The visual system will often choose a preferred retinal eccentric area where the central scotoma affects the whole fovea, such that one or more preferred retinal loci (PRL) develop. Crossland et al (2005) defined a PRL as 'a discrete retinal area that contains the centre of a target image for >20% of a fixation interval'. The PRL is able to perform visual tasks in the absence of the fovea such as directing eye movements and recognising objects, (Schuchard 2005).

Difficulties reading with central scotoma are caused by deficits of the peripheral visual system, such as sensory, oculomotor and perceptual deficits, (Seiple et al, 2005). Normal eye movements in reading consist of a series of saccades and fixations. Each successive saccade will bring the fovea to a new point in the text and the fovea will then pause briefly on this area while it gathers information (fixation). The average saccade lasts 7-9 letter spaces and a preselected landing place for a saccade comes from parafoveal information gathered during the last fixation pause. Usually this place is central, or slightly left of centre in the word, (Bullimore and Bailey 1995). This sequence of saccades and pauses creates a 'staircase' pattern. The time taken to read text will increase if the saccades are shorter, the fixations are more frequent, and the fixations are constant in duration. Legge et al (1997)

looked at the 'visual span' in normal vision. Their definition of visual span for reading is 'the number of characters recognised at a glance'. More specifically, 'on either side of the point of fixation within which characters of a given size can be recognised'. Perceptual span has a slightly different definition. Rayner et al (2010) defines perceptual span as 'the region of effective vision during eye fixations in reading'; so this has more to do with the functional demands of reading.

In PRL, saccades are automatically redirected so that information that would normally be fixated by the fovea will be fixated by a more eccentric part of the retina, (Whittaker et al, 1988). Legge et al (1997) investigated the relationship between eye movements and the shrinking visual span, the number of characters recognised on each glance, experienced by patients with low vision. The experiment revealed that at low contrast, the number of characters recognised at first glance decreases. This leads to an increase in the number of saccades and fixation length, resulting in slower reading. Bullimore and Bailey (1995) also found that in age-related maculopathy, such as AMD, reading speed is reduced due to a reduction in the number of letters being read per fixation. Seiple et al (2005) conducted a study where patients with AMD underwent training in practicing their eye movements. Their reading speeds in words per minute (wpm) were measured before and after the 8 week training. The average reading speed increased by 24 wpm from before to after training, this was found to be statistically significant. The study concluded that improving eye movement control has a positive effect on reading ability in those patients with AMD. Rubin and Turano's study (1994) however, had concluded that inefficient eye movement only account for part of the decreased reading rates in patients with central field loss. The method used in this study was sequential presentation of words in the same location within the visual field. Reading performance using rapid serial visual presentation (RSVP) was measured and compared with static text presentation in subjects with central scotoma and in 'normal' subjects. They found that RSVP speeds were 1.5x faster for subjects with central scotomas and 2.1x faster for those with no central scotoma than the static text presentation. After converting the reading speeds to word duration, it was found that subjects with central scotomas required longer word durations than



those without central scotomas. They proposed that an additional factor to be investigated would be the limited rate at which the eccentric retina can perform the pattern decoding tasks that are required for reading.

Sensory losses in the peripheral retina can contribute to difficulties with reading. Seiple et al (2004) found in their research that visual acuity, contrast sensitivity and temporal sensitivity for letter recognition decrease as a function of retinal eccentricity in all retinal meridians. However, these deficiencies may be compensated for by the use of magnifying aids (Seiple et al, 2005).

Field loss is suggested to interact with character size in affecting reading function however clinical experience tends to show that patients with central field defects would benefit from magnified character size, whereas those with small islands of central vision may achieve optimal reading performance with intermediate character sizes (Legge et al, 1985).

For those with low vision and central field loss, e.g. due to AMD, the maximum reading speed has been shown to be slower than those with other causes of low vision. Calbrese et al (2010), investigated the suggestion that crowding has an effect on the reading speed in patients with absolute macular scotomas as the magnitude of crowding in the eccentric retina has been found to be greater. They looked at the effect of interline spacing on the maximal reading speeds in patients with absolute macular scotoma. It was found that increasing interline spacing and therefore reducing crowding was only beneficial for very slow readers, which they classed as <20 wpm, for spot reading. Generally, vertical crowding did not appear to be a major factor in determining maximal reading speed in this group of patients.

Scotoma size has been investigated in various studies. Fine and Rubin (1998) found that the amount of text, or number of letters, lost from the view of a reader is more significant in reducing reading rate than the physical size of the scotoma. As part of a larger study, Sunness et al (1996) investigated the impact of the size of geography atrophy on reading speeds. It was found that the maximum reading speed correlated highly with the size of the atrophic area. Ergun et al (2003) investigated the effect of scotoma size on reading speed in patients with subfoveal occult with

no classic choroidal neovascularisation (CNV) in AMD. The scotomas were measured using the microperimetry programme 2.01 of the Rodenstock scanning laser ophthalmoscope. They found that absolute scotoma size (mean size 1.299 mm<sup>2</sup>) correlated significantly with reading capacity and speed in this group of patients. Relative scotomas (mean size 8.943mm<sup>2</sup>) showed no such correlation.

Eccentric viewing is the use of non-foveal preferred retinal loci (PRL) for viewing. In other words, patients who have a central scotoma use an intact part of the peripheral retina for fixation, instead of a damaged fovea. Crossland et al (2005) investigated PRL development in a cohort of patients with macular disease. The patients all had bilateral central scotomas and had suffered from visual loss in the better eye in the 2 weeks leading up to recruitment. Patient's scotomas were assessed at baseline and then at 4 more visits up to 12 months. All of the recruited patients developed a PRL within 6 months.

Generally, patients use a PRL to the left of their visual field scotoma. It is thought that patients tend toward this PRL because they read from left to right. This PRL will allow them to monitor where their fixation is landed relative to the word read before it, i.e. to the left (Nilsson et al, 2003; Guez et al, 2003)

Jeong and Moon investigated the clinical effect of eccentric viewing in patients with low vision, specifically those with a central scotoma. They concluded that training can significantly increase the efficiency of remaining vision and also improve the degree of patient satisfaction. Once the patients in this study had received their training, their reading speed doubled. There was no significant improvement in the visual acuity for reading or for distance, however the author comments that the reading speed is a more important parameter, as this is a more demanding task than simply identifying an optotype. This study used direct ophthalmoscopy to locate the patient's PRL. A fifty degree fundus photograph was taken and the Humphrey Field Analyser II along with Goldmann kinetic perimetry was used to study the location and sensitivity of the PRL. On the other hand, Nilsson et al (2003) used scanning laser ophthalmoscopy (SLO) to investigate eccentric viewing training in their study population. They found that 90% of their patients who had severe

AMD could use a TRL (trained retinal locus), which is a method of eccentric viewing that uses a favourable locus, above or below their retinal lesion after 5-6 hours of formal training using the SLO. In these patients, reading speeds increased from 9 wpm average before training to 68 wpm following training. To complement the results found by Nilsson et al, Nugyen et al (2009) suggested that in patients who have absolute central scotoma, the combination of an LVA with eccentric viewing training could increase reading speed significantly. Both studies showed the effectiveness of eccentric viewing training in a low vision population. Jeong and Moon's method was inexpensive and convenient, however it did not offer the precision achieved with the SLO technique as the PRL was located by passively moving the fixation target. However, the SLO is too expensive to allow practical application in low vision rehabilitation generally and is not commercially available. The more recent method of choice for measuring central scotomas in a research or clinical setting is using the microperimeter for example the Nidek MP1, (Markowitz and Reyes 2013). Previous to the availability of this equipment, it was traditional to use a central automated visual field or an amsler grid to assess a patient's central field. The disadvantages of microperimetry include, like the SLO, the high cost and limited availability of the equipment. In the context of the p-EVES study, the presence of a central scotoma was to be tested for its value in predicting successful use of p-EVES. If it was found to be useful, then a test was required which could be easily be made available in clinical practice. It was also necessary to determine the scotoma binocularly, since this was how the p-EVES device would be used by participants. The limitations of the Amsler grid have been reported previously (Crossland and Rubin, 2007) so the Central California Visual Field Test (CCVFT) was chosen to be used in the p-EVES study at the initial assessment for each participant. In addition to its use within the main study, the availability of these data gave an opportunity in this thesis to investigate the relationship of central scotoma to distance and near VA, contrast sensitivity and reading speed.

### 3.2 Methods

The literature about the California Central Visual Field Test (CCVFT) is limited thus far but the manufacturer's website describes it as an inexpensive tool for assessing a patient's central scotomas in the central 20 degrees of visual field.

Generally, the CCVFT is a practical, inexpensive and simple tool for scotoma assessment clinically. It allows a patient to appreciate their scotoma, which may aid in them in finding and understanding their PRL.

The test was administered binocularly to give a functional field as used by the patient. The same room and lighting conditions were used for all 100 participants. The manufacturer's instructions provided with the testing equipment were followed and these are provided in appendix 7.

To give a brief overview of the technique used; the fixation target was placed between the patient and the practitioner, facing the patient. The patient was asked to fixate on the dot in the middle of the circles throughout the test and any eccentric viewing was recorded. Short flashes of stimuli were presented within the three circles in a random order and the patient was asked to tap on the table whenever they saw the stimulus. Once all areas had been tested, isopter lines were drawn to illustrate the scotoma found.

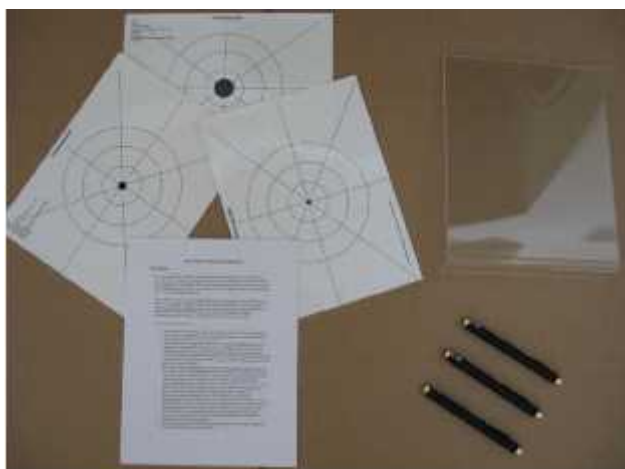


Figure 3.1: *Equipment used in CCVFT testing*

In order to analyse the results found with the CCVFT, a simple ‘grading’ system was formulated. It was decided that with any defect, no matter how small, if it can be plotted then it can be deemed as clinically significant. The dimmest laser pointer was not able to be detected at any point by most of the participants so this was not factored into the grading. The grades decided upon are shown in the table below.

Table 3.2: CCVFT grading method used in p-EVES study

0	no defect anywhere on chart
1	only a defect (with either laser 2 or laser 3) outside 2 <sup>nd</sup> ring
2	a defect with laser 2 outside 1 <sup>st</sup> ring
3	a defect with laser 3 outside 1 <sup>st</sup> ring
4	a defect with laser 2 inside 1 <sup>st</sup> ring
5	a defect with laser 3 inside 1 <sup>st</sup> ring

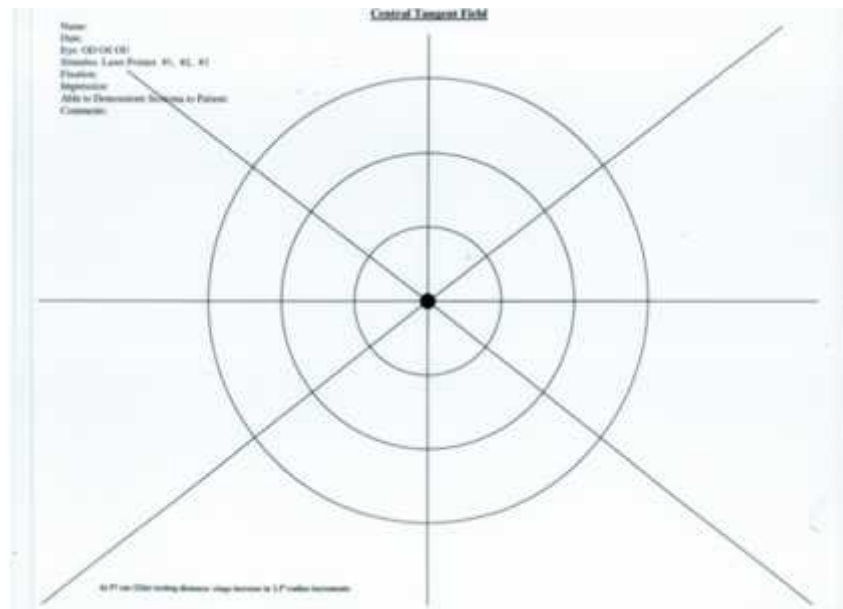


Figure 3.2: Example of CCVFT recording sheet for smallest fixation spot

For the first 20 p-EVES participants, an amsler grid test was also carried out to look for any differences in the practical elements of carrying out the two tests and the results obtained.

For the first 20 p-EVES participants, an Amsler Grid test was also carried out to look for any differences in the practical elements of carrying out the two tests and the results obtained. The test was administered binocularly to aid comparison between the two techniques. The standard black-on-white Amsler was used and the participants used their habitual reading correction and working distance to perform the test.

Using other p-EVES study baseline data, such as maximum reading speed in words per minute, relationships between this data and the gradings could be evaluated using ANOVA.

### 3.3 Results

Table 3.3: *Number of participants in each CCVFT grading*

Grade	Number of participants (%)
0	8
1	12
2	25
3	21
4	17
5	17

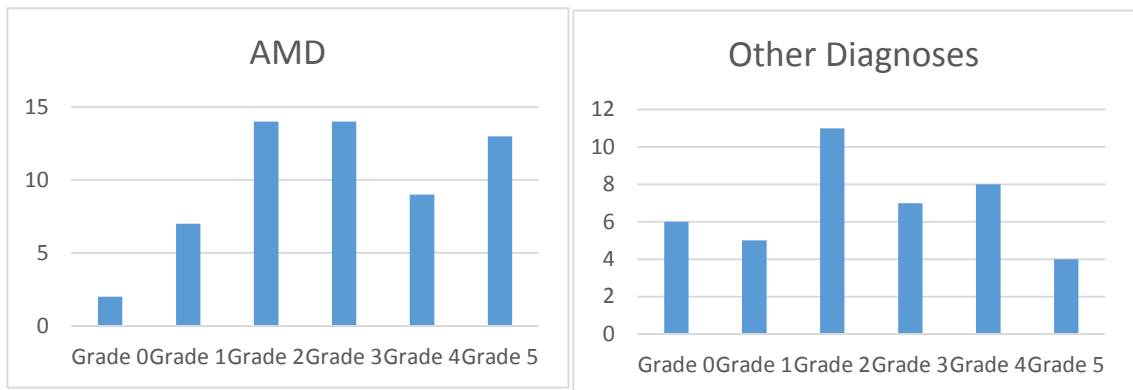


Figure 3.3: *CCVFT grading by diagnosis (a) % of those with AMD; (b) % of those with other diagnoses*

The majority of p-EVES participants had a diagnosis of AMD, either dry or wet. The CCVFT grading for these participants is shown above (Figure 3.3). The remaining participants had a variety of different diagnoses including myopic degeneration, glaucoma, congenital nystagmus and uveitis. The CCVFT grading for these participants have been plotted on the same graph because the numbers of participants with each diagnosis were low.

The majority of the participants were able to complete the CCVFT with one set of instructions read aloud to them at the beginning of the test. However in the case of 12% of participants, the test had to be stopped and the patient reinstructed when it was clear they hadn't fully understood the original instructions. After completing the first few assessments it was generally found that when administering the CCVFT, the fixation spot size used was often larger than the one suggested in the guidelines for use based on the patient's binocular distance VA. Fixation was documented as either central or eccentric and then stable or unstable by the examiner, based on their own observations.

In terms of fixation stability, 40% of participants were deemed to be fixating eccentrically by the examiner and 60% fixating centrally. 68% were able to maintain stable fixation whether centrally or eccentrically.

The Amsler Grid test was performed on the first 20 p-EVES participants, along with the CCVFT. Out of the 20 participants, 12 reported no scotoma with Amsler, despite in some cases a Grade 3 or 4 scotoma being found with the CCVFT. 3 reported that they could not see the grid at all. The remaining 5 did report a scotoma and were able to point to it on the grid.

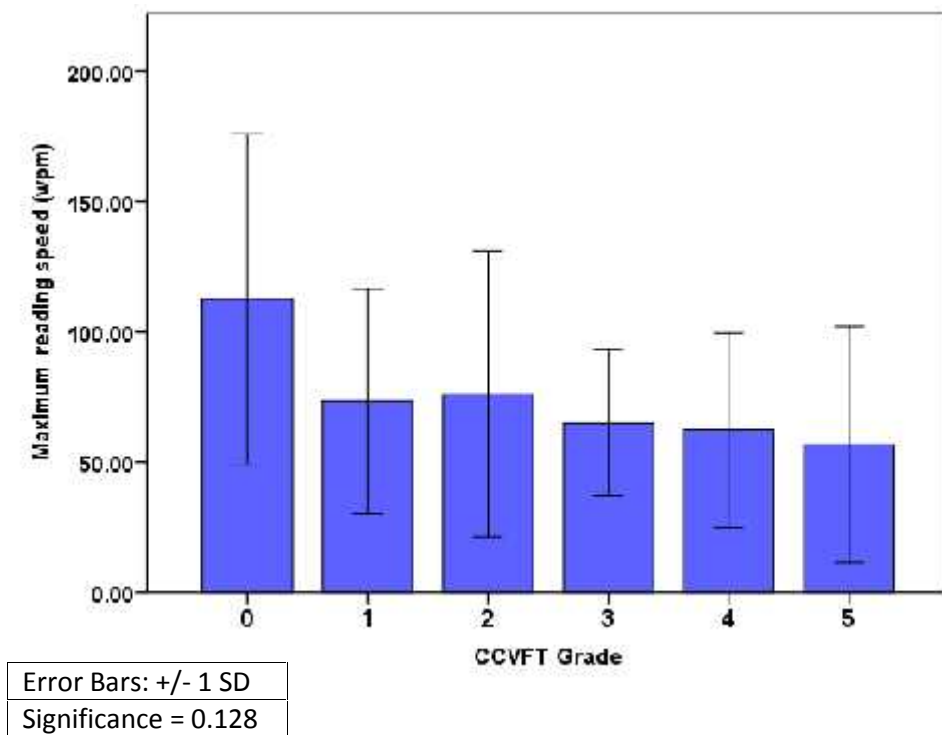


Figure 3.4: Bar graph showing the maximum reading speed of p-EVES participants for each CCVFT grade



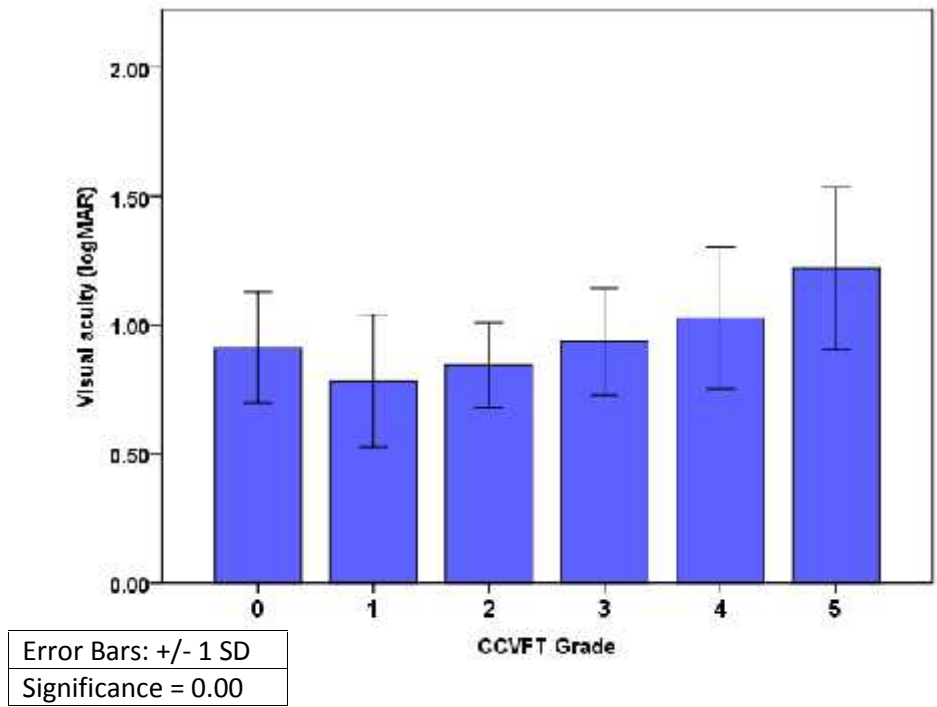


Figure 3.5 Bar graph showing the relationship between binocular logMAR VA and CCVFT grade

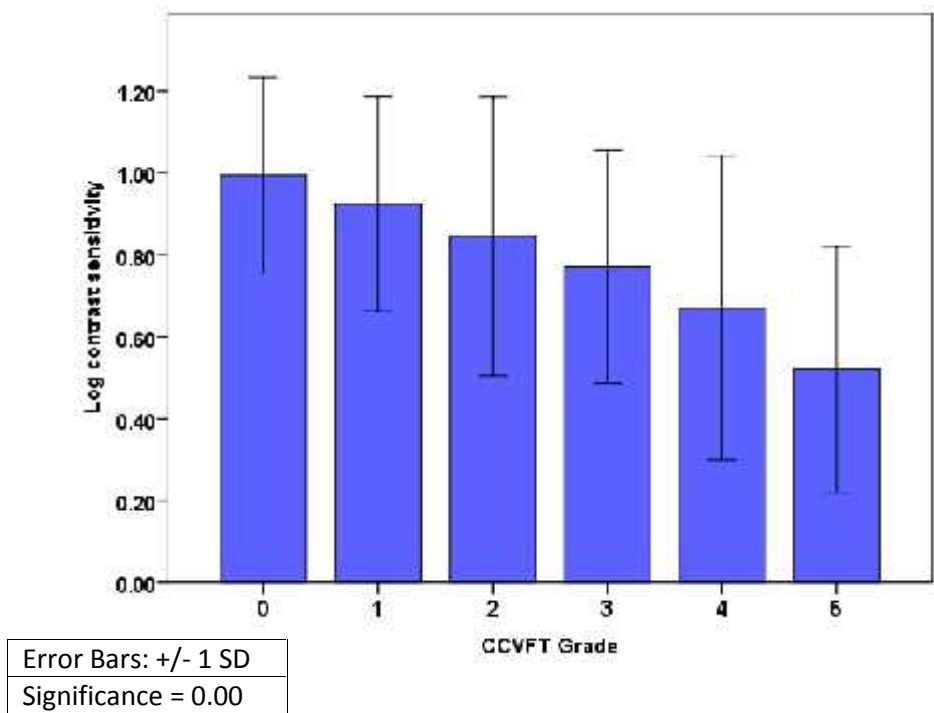


Figure 3.6 Bar graph showing the relationship between Pelli Robson contrast sensitivity and CCVFT grade

### 3.4 Discussion

Central scotoma measurement can be a useful part of a low vision assessment in gaining an understanding as to why a patient may be having certain difficulties such as reduced reading speed. It also allows practitioners to make patients aware of their central scotoma. Fletcher et al (2012) indicated that low vision practitioners cannot depend on their patients to report the presence of central scotoma but that some awareness of it can improve accuracy when reading. The CCVFT is a simple way of demonstrating a patient's central scotoma to them at the time of assessment.

Scherlen et al (2011) compared the CCVFT with the Nidek MP1. They found that the CCVFT is a faster, cheaper and more portable technique. MP1 was found to be a more precise measurement of absolute scotoma and allows better control of fixation stability.

The Amsler Grid has a similar advantage as the CCVFT compared with the microperimeter in that it is also a simple, cheap and quick method of measuring a patient's central scotoma. The CCVFT takes slightly longer and more practice to perform the test effectively; however it seems to be a more sensitive test for detecting central scotomas and demonstrating them to patients.

One of the limitations found when administering the CCVFT was the difficulty of accurately determining the participant's fixation stability whilst trying to concentrate on administering the stimuli. Where microperimeters are able to provide estimates of fixation stability based on preliminary algorithms, during the CCVFT the clinician administering the test has to examine the patient's fixation themselves and make a comment on it on the record. This sort of gross assessment may vary from clinician to clinician and lead to variability.

It is difficult to determine how useful laser pointer number 1 (the dimmest stimuli) will be in a clinical setting. The 100 participants in this study were recruited from the low vision clinic at MREH so this should be a fair representation of the types of patient who may undergo this type of test in a clinical setting. Since almost none of

our participants were able to perceive laser pointer 1 at any location in the central field, it is unlikely that this stimuli will be useful in a clinical setting. Laser 2 is the next brightest stimuli and laser 3 is the brightest. When formulating the grading for the CCVFT it was determined that the location of any scotoma from the centre of fixation was more relevant than the density of the scotoma, i.e. relative or absolute.

Looking at the relationship between CCVFT grade and maximum reading speed in wpm, there is no significant correlation between the two. Looking at the distribution on the graph (figure 3.4), it appears that it is the presence of a scotoma alone that seems to reduce reading speed, not the grade of the scotoma itself.

Looking at binocular visual acuity, a significant pattern was seen when comparing average VA with CCVFT grades (figure 3.5). The graph suggests that a poorer visual acuity does correlate with increasing CCVFT grade. Similarly, the CCVFT grade also shows a significant correlation with contrast sensitivity baseline measurements, in that the poorer the contrast sensitivity, the higher the grade of scotoma as measured by the CCVFT (figure 3.6).

A limitation of the grading system used is the fact that the scotomas can vary in size significantly but still fall under the same grade. For example, shown below (figure 3.7) are two CCVFT plots that are given a grade of 3 but the scotoma sizes are significantly different. They do, however, spare the central 5 degrees around fixation, which could be more useful to the patient when reading.

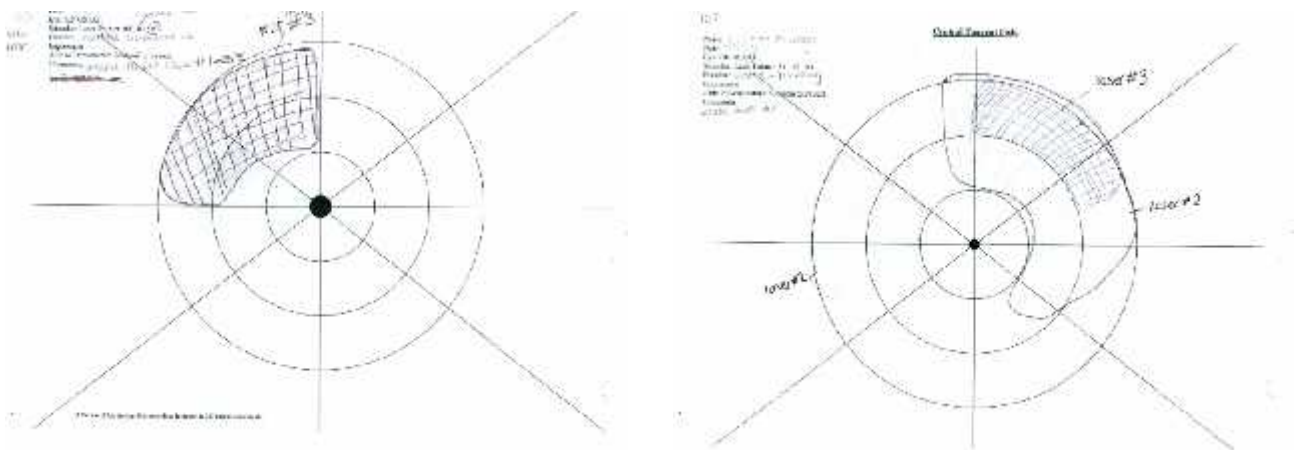


Figure 3.7: 'Grade 3' CCVFT Plots

Previously, it was discussed that the location of a patient's PRL to the left or the right of fixation has a considerable impact on reading speed. This grading system allows a small scotoma slightly above fixation to be graded the same as a relatively larger scotoma to the right of fixation as shown below in figure 3.8.

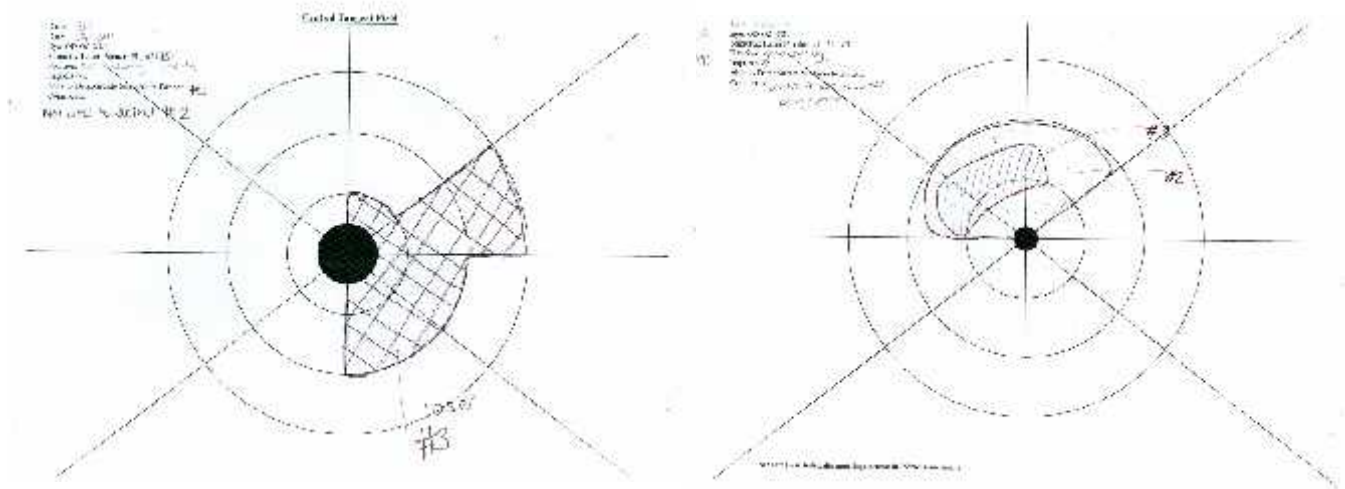


Figure 3.8: *Two Grade 5 CCVFT plots*

Going forward, it may be more appropriate to use more specific 'sub-grades' to include the exact position of the scotoma relative to fixation i.e. right or left; also to grade the scotoma area. Some basic training in the use of the CCVFT may be beneficial in decreasing inter-practitioner variability and further research into its repeatability would be useful. Overall, the CCVFT is a very good tool for demonstrating a central scotoma to a patient, so in a clinical setting may be very useful; however, more work will need to be done to determine an effective grading scale for the test if the test is to be carried out in a research setting.

## **Chapter 4 Training in the use of electronic vision aids and its effectiveness**

### **4.1 Introduction**

The aim of this chapter is to look at the need for and type of training that should be provided when prescribing a p-EVES device to a patient. It also reviews the success of the difficulties questionnaire as a follow up tool. Raw MLVQ study data has been accessed and is presented with the aim of comparing the uses of p-EVES devices compared with optical devices.

When a patient with low vision is prescribed a low vision aid of any type, they will inevitably need some information regarding how it works so that they can leave their low vision assessment and be able to use the aid in their daily life. The amount of information they need will depend on the complexity of the device and the ability of the patient to take the information on board and remember it when they get home. This information can be provided in the form of basic instructions or more extensive training upon the prescription of a device. A general definition of instruction would be that it is similar to the information that is given in a manual for a household appliance. In the low vision setting however, this information would be given verbally and the practitioner should check that the patient has understood the instructions given. These instructions would cover how to set the device up and how to operate all the different functions of the device. For example, telling a patient what each button does and where it is on the device. Training, on the other hand, could be defined as a more 'hands-on' approach. Burggraaff et al (2012) defined training as a protocol including instructions regarding working distance and posture, exercises in reading, writing and looking at pictures or photographs and addressing hobbies and interests. This training can be delivered within a programme which can be weeks or months long. If the need for instruction or training with a device is not met, the patient may get the aid home and find that they are unable to operate it and may find themselves giving up on the aid altogether due to the frustration of not understanding how it works.

Nugyen et al (2009) carried out a retrospective study to consider the effect of the prescription of low vision devices on reading ability. It was found that the reading

ability of a large population increased without the need for specific training, other than brief instructions on the handling of devices. However, this study does not differentiate between the results for patients using optical aids and those using CCTVs.

Looking more specifically at EVES devices, Goodrich et al (1977) suggested that training for 50 minutes a day over a ten day period increased reading speed and duration of reading with a CCTV. However, this study used performance based measures only and no qualitative information was gathered. The participants in this study underwent the usual training delivered in the Blind Rehabilitation Programme of the Veteran's Administration during these sessions. Mehr (1973) described this programme in more detail. The patients receive instructions in the use of the CCTV and then advice is given on their orientation to the device and they attempt specific tasks such as reading a newspaper or writing out a cheque. Based on the original definitions set up at the beginning of this chapter, this is certainly 'training'. Goodrich and Kirby (2001), however, found that reading performance with both optical magnifiers and EVES devices does not improve beyond five hour long sessions of training. The electronic devices in this study, however, were a mixture of hand-held mouse-based electronic aids and CCTVs. These results are contradictory to those obtained by Goodrich et al (1977). The exact details of the training programme in the Goodrich and Kirby (2001) study were not given but the five hour long training sessions may not have been on consecutive days like in the Goodrich (1977) study. Therefore, some of the improvement over the five sessions may have been due to practice between the sessions.

Culham et al (2009) found that extensive training with EVES devices is not necessary for a user to manage alone. In this study four different devices were looked at: three different types of head mounted EVES and one table mounted EVES. 95% of patients reported that they had little or no difficulty with setting up and handling the EVES and 33% of patients claimed that they did not require the instructions in order to fully operate the device. However, these patients only had exposure to the devices for a week prior to obtaining results so they may not have had enough time to use the p-EVES device within their normal routine. A week may not have been

long enough to have chance to forget any of the instructions they were given and they may have been using the device more intensively as it would still be a novelty. The participants in this study were given 'basic training' in how to use the devices. Unfortunately the authors do not go into detail as to whether this included just basic instructions or some more extensive training. Based on the definitions given earlier, however, training is usually given within a programme and more than one session, which was not administered in this study.

Burggraaff et al (2012 (a) and (b)) conducted an RCT investigating the effects of training in the use of CCTVs to look at two outcome measures. The first was reading performance and the second; quality of life, depression and adaptation to vision loss. Reading performance improved significantly upon introduction of the CCTV but did not appear to be influenced by training or practice. The majority of patients received basic instruction in simple technical skills from the suppliers when they delivered the device and these instructions were reported as helpful. Therefore, a combination of supplier technical training and effective prescription of CCTVs by low vision practitioners may be all that is required to improve a patient's reading performance (reading acuity, speed and number of errors). In the RCT the baseline questionnaire evaluated quality of life before prescription of the CCTV, whereas at follow up, quality of life was assessed for patients who did and did not receive training in the use of the device. A large improvement in vision-related quality of life was found from baseline to follow up, however little effect was seen from training in the use of the device. On the other hand, health related quality of life did seem to improve with CCTV training. The authors comment that an effective way to proceed in low vision practice would be to contact patients who have received a CCTV and make sure that they are comfortable with operating the device. Training could then be given to those who express some difficulty. The results from this RCT suggest that one out of four/five patients may express difficulty and require further training.

## 4.2 Methods

Based on the evidence that extensive training to use electronic low vision aids does not have a significant effect on reading performance and that further training need only be given to patients who express difficulty using a device, the following steps were used in the p-EVES study: The participants received task based practice, which is a form of 'instruction' in how to use the device. A difficulties questionnaire was then conducted over the telephone so that those participants experiencing difficulty using the device could be identified.

### 4.2.1 Task Based Practice

At the beginning of intervention A, participants needed some form of instruction to use the p-EVES to ensure they were confident in how to operate all the features for the two month period. A list of tasks were put together for the participants to perform with the p-EVES.

To demonstrate the magnification and contrast settings, a newspaper and a magazine were used. Participants were asked to change the magnification and contrast to their preferred setting and then asked to read a segment aloud.

The next task was allocated to show the participant how to write using the device. A crossword puzzle was used to demonstrate this. And the participant was asked to randomly write letters in some of the boxes whilst using the device.

A brightly coloured food packet was used to demonstrate the full colour option on the device. Due to the varying contrasts on the food packet, using the enhanced contrast features meant some of the writing disappeared. The full colour option allows all information to be visible.

To demonstrate the snapshot feature on the device, three herb jars were placed away from the participant, in a line as if they were on a supermarket shelf. The participant was then encouraged to hold the p-EVES up to the items and take a snapshot of an individual jar. The participant was then shown how to delete the image that they had taken.



The time taken for each participant to complete task based practice was recorded.

#### 4.2.2 Difficulties Questionnaire

Following a patient collecting a device it was important that there was some follow up to ensure that there were no technical problems with it. One week following collection a phone call was made, if the participant was not available, the phone call was attempted the following week and repeated until the participant was reached. A specific script was followed as closely as possible to keep the content of all the phone calls similar. The script was written prior to the start of the p\_EVES study and the choice of questions was informed by the focus groups held by the low vision service Wales (covered in Chapter 2), and by the clinical experience of the p-EVES study team. The questionnaire is attached in appendix 5.

The questionnaire was completed 1-2 weeks after both interventions A and B to ensure both groups were receiving the same encouragement.

The questionnaire had to take place in this short time frame because if the patient was having technical difficulties with the device they needed to be booked in as soon as possible to be re-instructed with task based practice.

#### 4.2.3 Interviews

The purpose of the interviews was to obtain some qualitative data to support the research findings. The participants to be interviewed were chosen randomly by maximum variation sampling in order to target a mix of participants with varying demographics and visual status. The aim was to continue to interview participants until data saturation: that is, until no new themes emerged from the interviews. One third of the participants of the p-EVES study were interviewed at the end of the final visit. The interviews were conducted by the study researcher and recorded. They were later transcribed and were coded and analysed by the study researcher. For the purposes of this thesis, the transcripts of the interviews were available and enabled two specific areas to be investigated. Firstly the responses given about the p-EVES by participants in the interviews could be compared to those given in the difficulties questionnaires to see if this would be an effective method of following

patients up if p-EVES are to be made available within NHS clinics. Secondly they could be used to support prescribing guidelines for p-EVES. In this thesis the data from the transcripts is used both quantitatively (by numerically comparing responses) and qualitatively (by the inclusion of selected quotes).

#### 4.2.4 MLVQ

In order to explore any significant differences between the usages of optical and p-EVES devices, the raw MLVQ data from the main study was accessed. The MLVQ was performed at the end of each two monthly intervention, i.e. after the participants had access only to their optical aids for two months and also after they had access to their p-EVES device for the other two months. The main areas looked at were where were the devices used, how often they were used and the average duration for which they were used. The responses given by each participant were entered into an excel spread sheet and were used to create bar graphs to illustrate the differences between how optical and p-EVES devices were used by the participants of the study.

### 4.3 Results – task based practice/relationship between difficulties questionnaire and interviews

#### 4.3.1 Task Based Practice

A total of 93 participants underwent the practice. The range of time taken for the p-EVES participants to complete task based practice was 5-30 minutes. The average time taken was 15 minutes.

Table 3.1: Average time taken to complete task based practice

p-EVES device	Number of participants	Average time taken to complete task based practice (minutes)
Compact 4HD	35	17.3 (SD=6.57)
Compact+	5	9.0(SD=4.47)
eMAG 43	47	14.1(SD=5.48)
Mobilux Digital	6	14.4(SD=4.47)

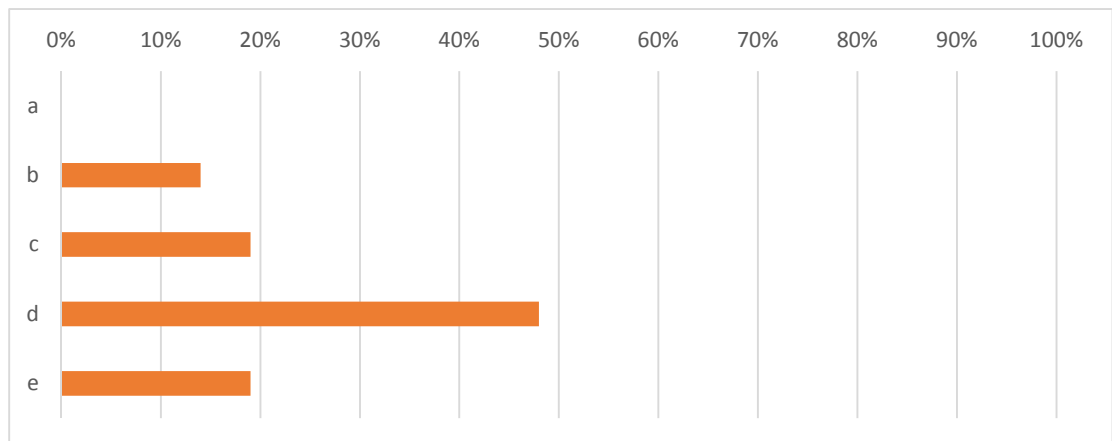
Of the 93 participants who went through the task based practice there was only one who had any difficulty with the tasks. This participant found it impossible to perform the writing task and it had to be abandoned.

In the end of study interviews, when asked about training and how much participants felt was necessary for people to get used to the device, the majority agreed that the task-based practice they received was sufficient; px 130 *'I don't think they need it (training). I mean, it's just a case of showing them. There's your on off button, there's your different contrasts and there's your zoom. It'll take 5 or 10 minutes to show somebody that'*; px 123 *'To go through charging it up to going through all the symbolism and how to work it I'd say between 15 and 20 minutes'*. Other participants felt it may need to be a longer appointment as they forgot about some of the features that were shown in task-based practice; px 116 *'Yes , 2 or 3 hours at least, because you can't just pick something up and you say to them, well, you press this button or you press that button. I mean you told me this takes photographs, I'd never have known'*; px 139 *'Perhaps a couple of hours. You've got to take into account, as I say, I'm talking about elderly people, people in my age bracket, whether they are up to date with technology'*.

### 4.3.2 Difficulties Questionnaires

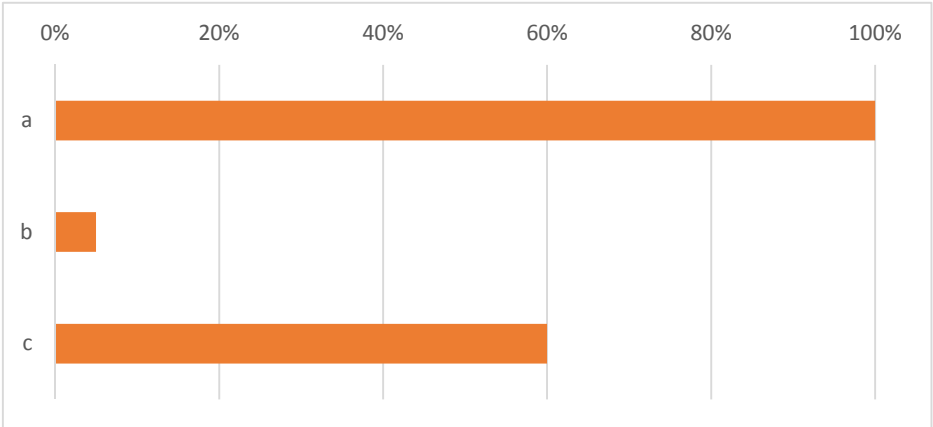
Presented below are the difficulties questionnaire responses for all participants in the intervention where they only used their optical aids.

<b>Q1 How many times have you used your magnifier(s) each day on average? (One chosen category per person)</b>		
(a)Not using	n=0	0%
(b)1-2	n=12	14%
(c)2-5	n=18	19%
(d)5-10	n=45	48%
(e)>10	n=18	19%



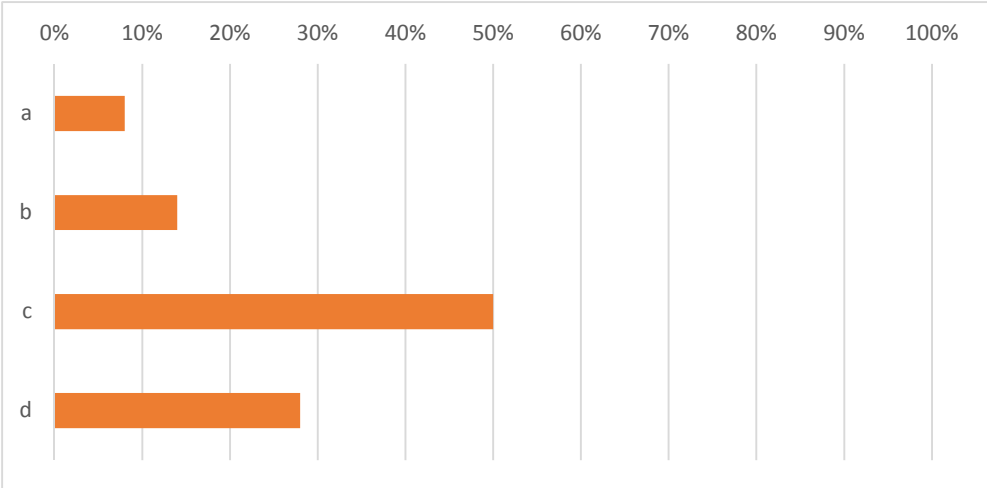
**Q2 Where have you used it? (Multiple chosen categories per person)**

(a) In home	n=93	100%
(b) In work	n=5	5%
(c) Outside the home	n=56	60%



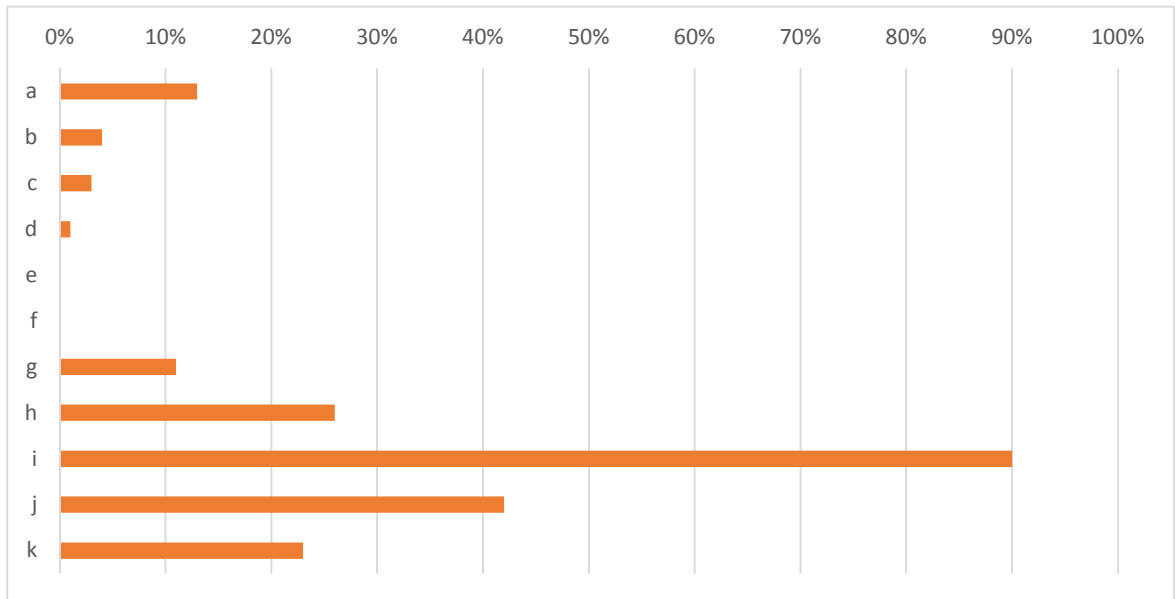
**Q3 How easy have you found it/them to use? (One chosen category per person)**

(a) very difficult	n=7	8%
(b) relatively difficult	n=13	14%
(c) relatively easy	n=47	50%
(d) very easy	n=26	28%



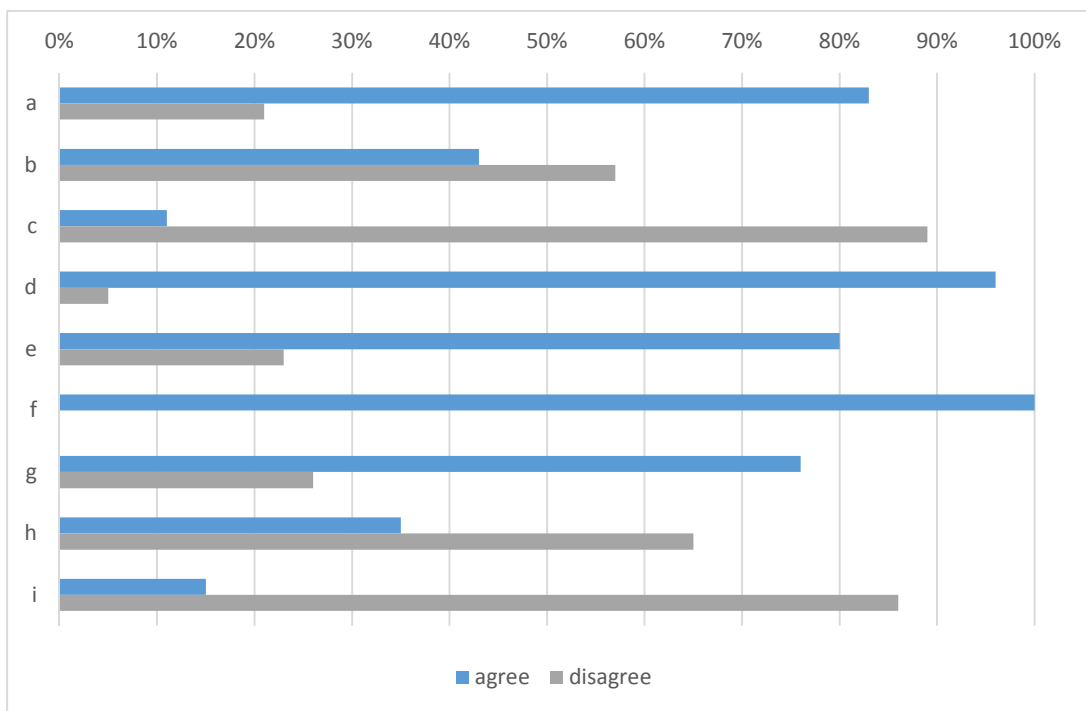
**Q4 Do you experience any of the following difficulties with the device/your magnifiers: (Multiple chosen categories per person)**

(a) Appearance looks odd/self-conscious about using it	n=12	13%
(b) Worried about loss/breakage/damage	n=4	4%
(c) Weight	n=3	3%
(d) Difficult to hold/poor grip or handle	n=1	1%
(e) Technical problems	n=0	0%
(f) Difficult to operate/switches or controls poorly positioned	n=0	0%
(g) Too bright/not bright enough	n=10	11%
(h) Doesn't help vision enough	n=24	26%
(i) Too small a screen/field of view	n=84	90%
(j) Apparent movement/smearing of the image	n=39	42%
(k) Eyes felt uncomfortable/headaches	n=21	23%



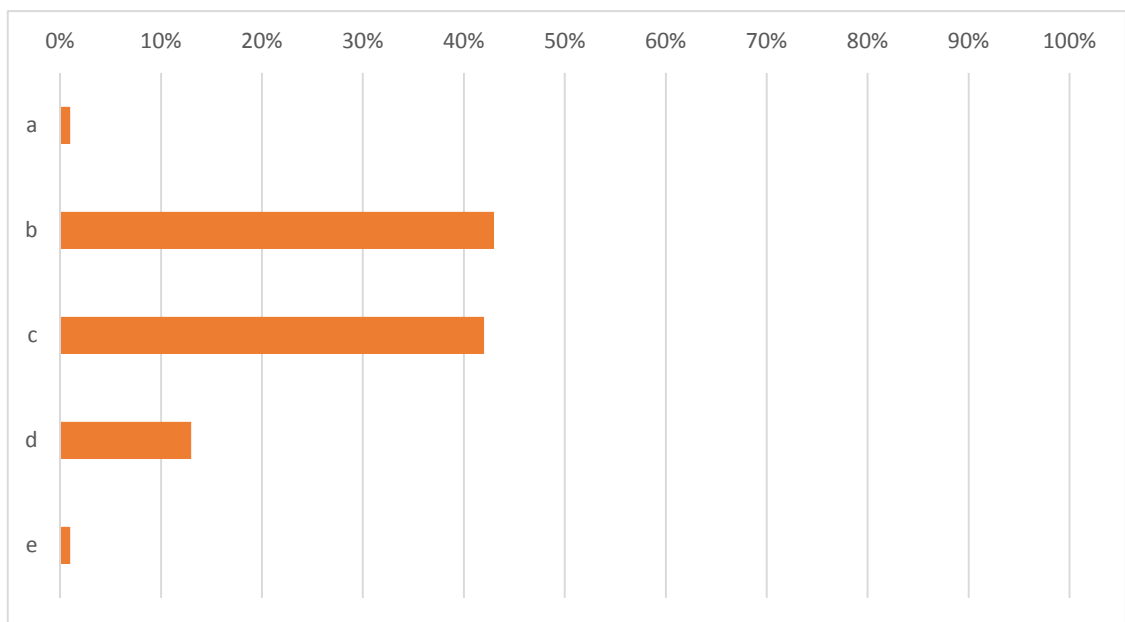
**Q5 Do you agree or disagree with any of these descriptions for the device/your magnifiers? (Multiple chosen categories per person)**

	Agree		disagree	
	n	%	n	%
(a) Good magnification (for your vision)	n=77	83%	n=18	21%
(b) Good contrast	n=40	43%	n=53	57%
(c) Good field of view/screen size	n=10	11%	n=83	89%
(d) Easy to operate	n=89	96%	n=5	5%
(e) Suitable for the task you need to do	n=74	80%	n=21	23%
(f) Easy to understand how to use it	n=93	100%	n=0	0%
(g) Good size to carry around	n=71	76%	n=24	24%
(h) Attractive appearance	n=33	35%	n=60	65%
(i) Doesn't look like a magnifier	n=14	15%	n=80	86%



Presented below are the difficulties questionnaire responses for all participants in the intervention where they had their p-EVES device.

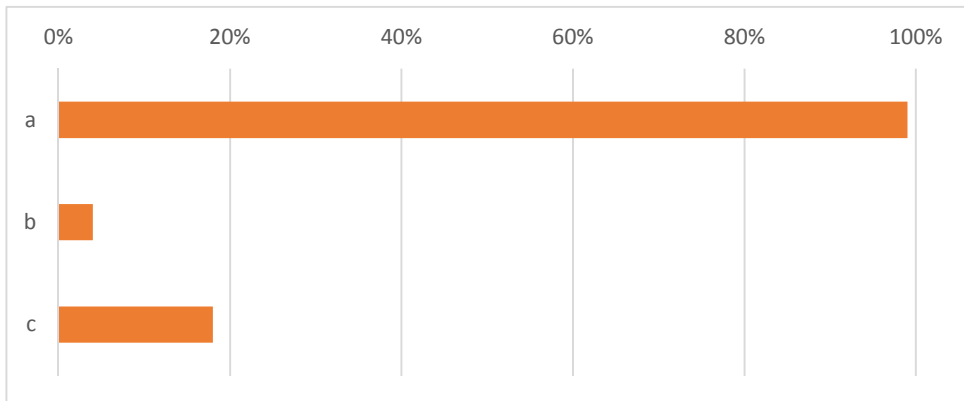
<b>Q1 How many times have you used your magnifier(s) each day on average? (One chosen category per person)</b>		
(a)Not using	n=1	1%
(b)1-2	n=40	43%
(c)2-5	n=39	42%
(d)5-10	n=12	13%
(e)>10	n=1	1%





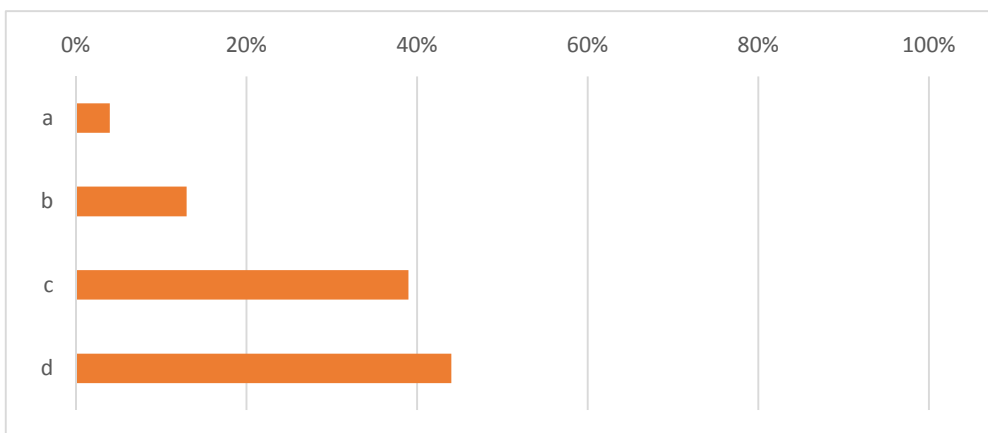
**Q2 Where have you used it? (Multiple chosen categories per person)**

(a) In home	n=92	99%
(b) In work	n=4	4%
(c) Outside the home	n=17	17%



**Q3 How easy have you found it/them to use? (One chosen category per person)**

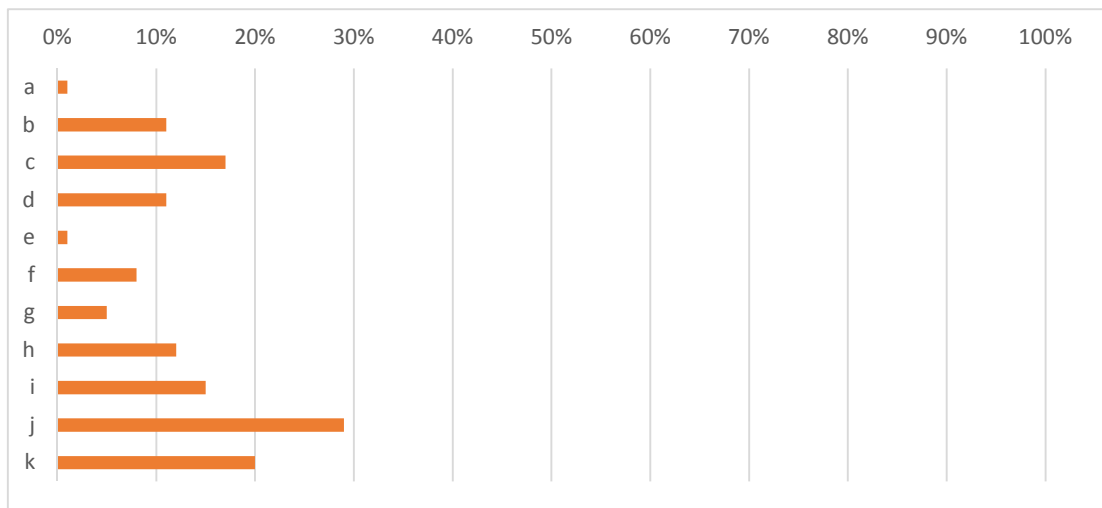
(a) very difficult	n=4	4%
(b) relatively difficult	n=12	13%
(c) relatively easy	n=36	39%
(d) very easy	n=41	44%



**Q4 Do you experience any of the following difficulties with the device/your**

**magnifiers: (Multiple chosen categories per person)**

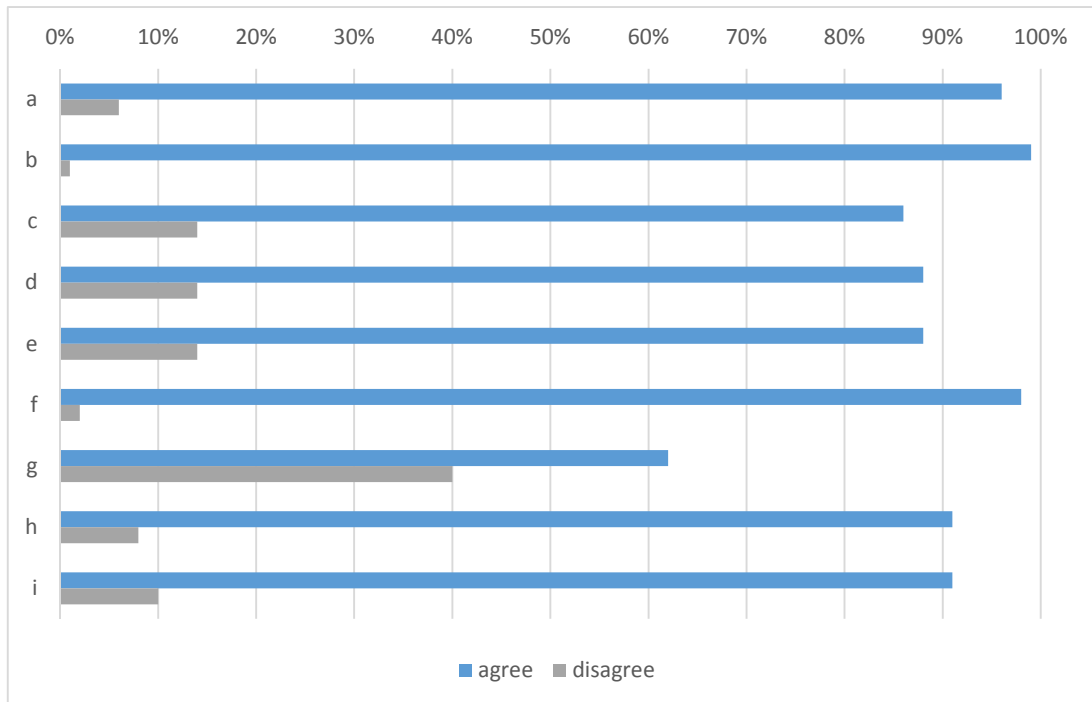
(a) Appearance looks odd/self-conscious about using it	n=1	1%
(b) Worried about loss/breakage/damage	n=10	11%
(c) Weight	n=16	17%
(d) Difficult to hold/poor grip or handle	n=10	11%
(e) Technical problems	n=2	2%
(f) Difficult to operate/switches or controls poorly positioned	n=7	8%
(g) Too bright/not bright enough	n=5	5%
(h) Doesn't help vision enough	n=11	12%
(i) Too small a screen/field of view	n=14	15%
(j) Apparent movement/smearing of the image	n=27	29%
(k) Eyes felt uncomfortable/headaches	n=19	20%



In reference to Q4 (e), only two participants were identified as having technical difficulties on the difficulties questionnaire and they were brought back for reinstruction. One was due to a technical fault with the charger and this was replaced by the suppliers. The other was due to difficulties using the on/off switch on the Compact 4HD and this issue was not possible to ascertain over the phone.

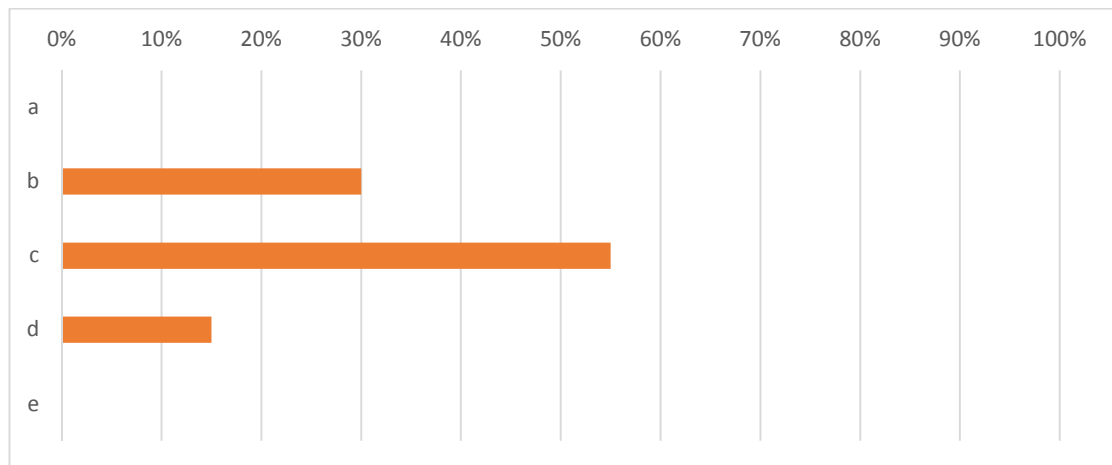
**Q5 Do you agree or disagree with any of these descriptions for the device/your magnifiers? (Multiple chosen categories per person)**

	Agree		disagree	
	n	%	n	%
(a) Good magnification (for your vision)	n=89	96%	n=6	6%
(b) Good contrast	n=92	99%	n=1	1%
(c) Good field of view/screen size	n=80	86%	n=13	14%
(d) Easy to operate	n=82	88%	n=13	14%
(e) Suitable for the task you need to do	n=82	88%	n=13	14%
(f) Easy to understand how to use it	n=91	98%	n=2	2%
(g) Good size to carry around	n=58	62%	n=37	40%
(h) Attractive appearance	n=85	91%	n=7	8%
(i) Doesn't look like a magnifier	n=85	91%	n=9	10%



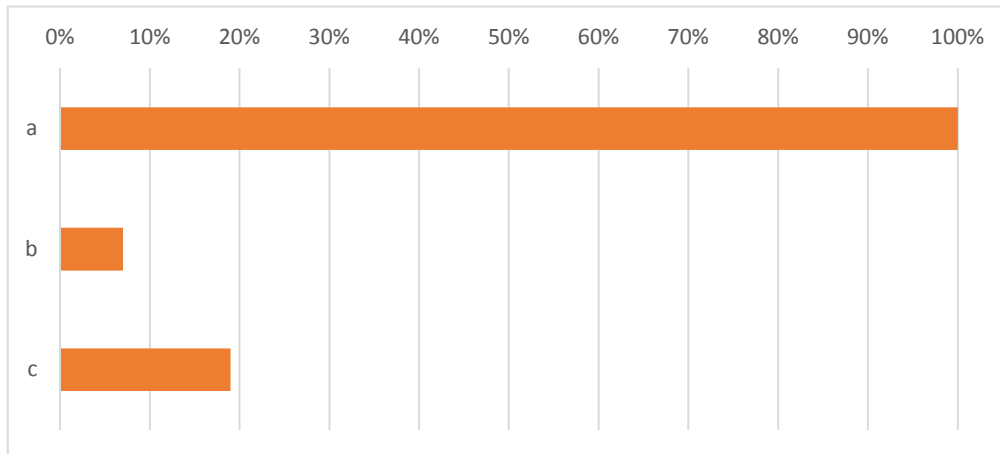
The following graphs are difficulties questionnaire responses collated only from the group of participants who went on to be interviewed. Only the p-EVES devices responses are recorded.

<b>Q1 How many times have you used your magnifier(s) each day on average? (One chosen category per person)</b>		
(a)Not using	n=0	0%
(b)1-2	n=8	30%
(c)2-5	n=15	55%
(d)5-10	n=4	15%
(e)>10	n=0	0%



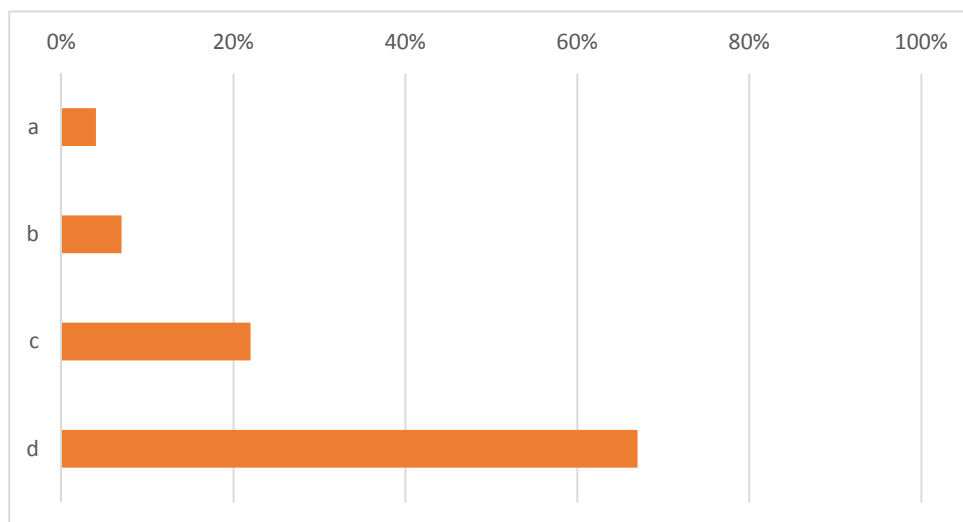
**Q2 Where have you used it? (Multiple chosen categories per person)**

(a) In home	n=27	100%
(b) In work	n=2	7%
(c) Outside the home	n=5	19%



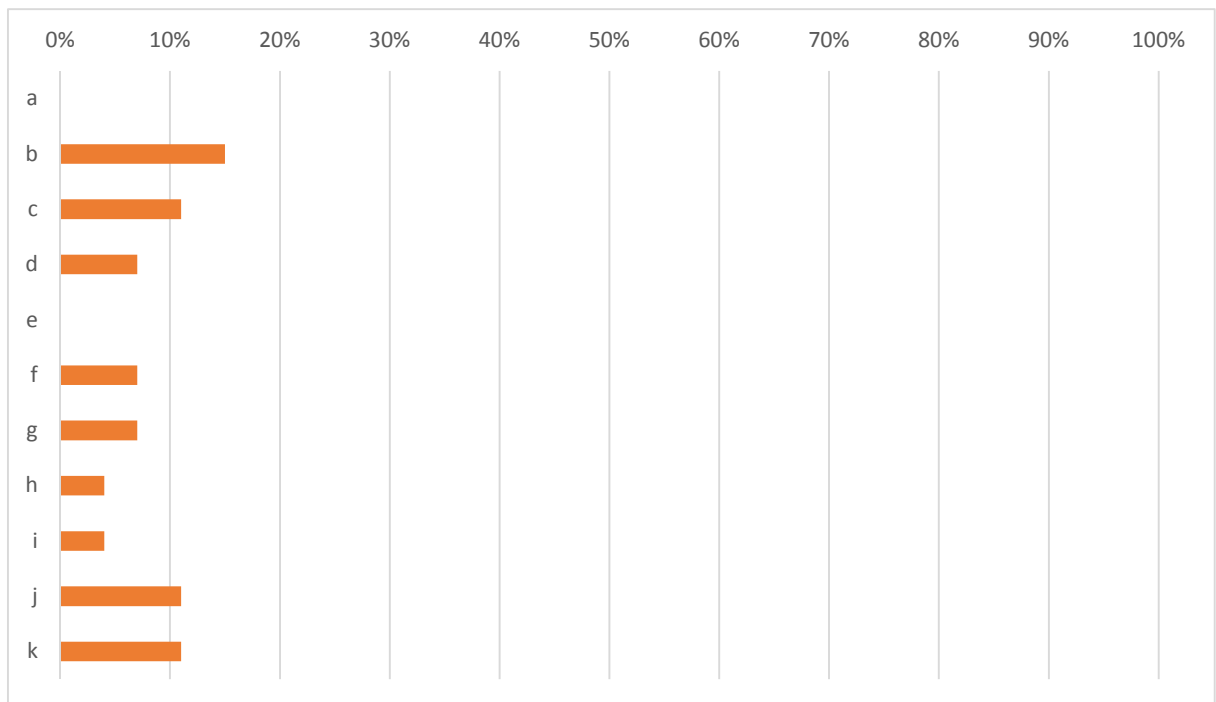
**Q3 How easy have you found it/them to use? (One chosen category per person)**

(a) very difficult	n=1	4%
(b) relatively difficult	n=2	7%
(c) relatively easy	n=6	22%
(d) very easy	n=18	67%



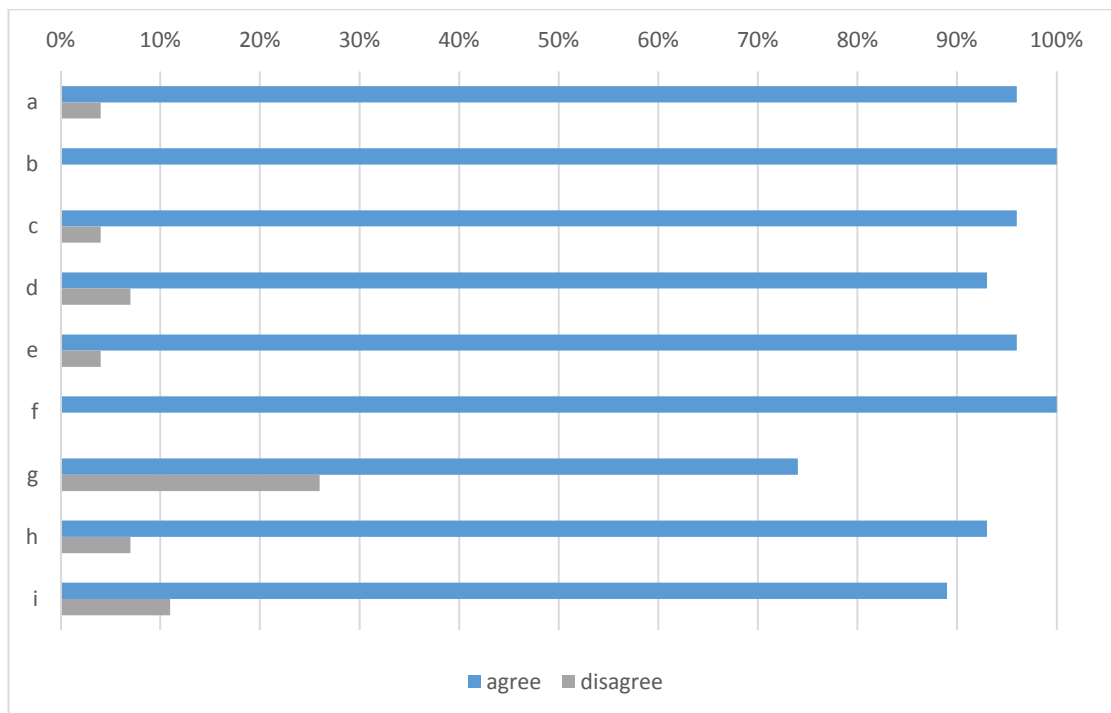
**Q4 Do you experience any of the following difficulties with the device/your magnifiers: (Multiple chosen categories per person)**

(a) Appearance looks odd/self-conscious about using it	n=0	0%
(b) Worried about loss/breakage/damage	n=4	15%
(c) Weight	n=3	11%
(d) Difficult to hold/poor grip or handle	n=2	7%
(e) Technical problems	n=0	0%
(f) Difficult to operate/switches or controls poorly positioned	n=2	7%
(g) Too bright/not bright enough	n=2	7%
(h) Doesn't help vision enough	n=1	4%
(i) Too small a screen/field of view	n=1	4%
(j) Apparent movement/smearing of the image	n=3	11%
(k) Eyes felt uncomfortable/headaches	n=3	11%



**Q5 Do you agree or disagree with any of these descriptions for the device/your magnifiers? (Multiple chosen categories per person)**

	Agree		disagree	
	n	%	n	%
(a) Good magnification (for your vision)	n=26	96%	n=1	4%
(b) Good contrast	n=27	100%	n=0	0%
(c) Good field of view/screen size	n=26	96%	n=1	4%
(d) Easy to operate	n=25	93%	n=2	7%
(e) Suitable for the task you need to do	n=26	96%	n=1	4%
(f) Easy to understand how to use it	n=27	100%	n=0	0%
(g) Good size to carry around	n=20	74%	n=7	26%
(h) Attractive appearance	n=25	93%	n=2	7%
(i) Doesn't look like a magnifier	n=24	89%	n=3	11%



Below are some quotes from the patient interviews that relate to the most reported difficulties in this group.

**Interview quotes relating to Question 4 (b)-participants who were worried about loss/breakage or damage.**

(b) px 117 *'well it wasn't mine and I didn't want to bash it about';*

px 138 *'never, I was frightened of losing it';*

px 129 *'Well that was on loan, I didn't want to drop it.'*

**Interview quotes relating to Question 5 (g)-participants who did not agree that the device was a good size to carry around**

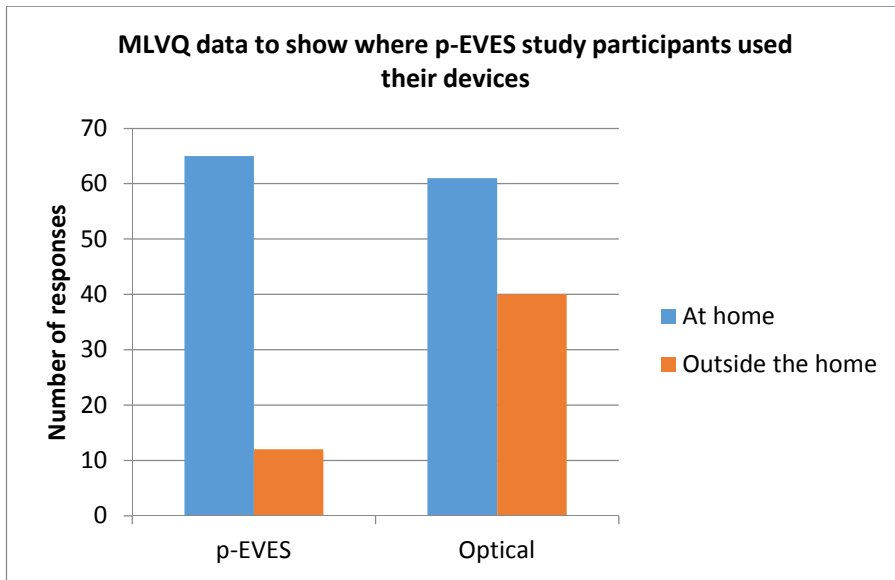
(g) px 123 *'I wouldn't take the electronic one out. I just found it too big',*

px 106 *'it's the portability issue of it... that's probably the negative';*

px 128 *'I found it very heavy and cumbersome to use for shopping'*



### 4.3.3 MLVQ results



p-EVES	
Chi-square	68.768
Degrees of freedom	1
p-value	0

Optical	
Chi-square	11.366
Degrees of freedom	1
p-value	0.00074801

Figure 4.1: Bar graph to show the locations in which p-EVES study participants used their devices-taken from the MLVQ with chi-squared statistics.

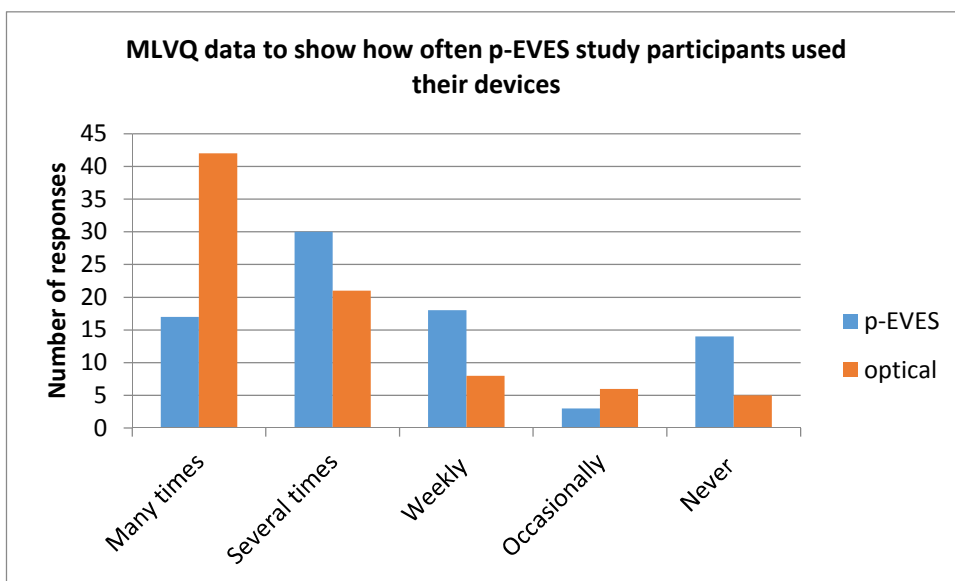


Figure 4.2: Bar graph to show how often p-EVES study participants used their devices-taken from the MLVQ.

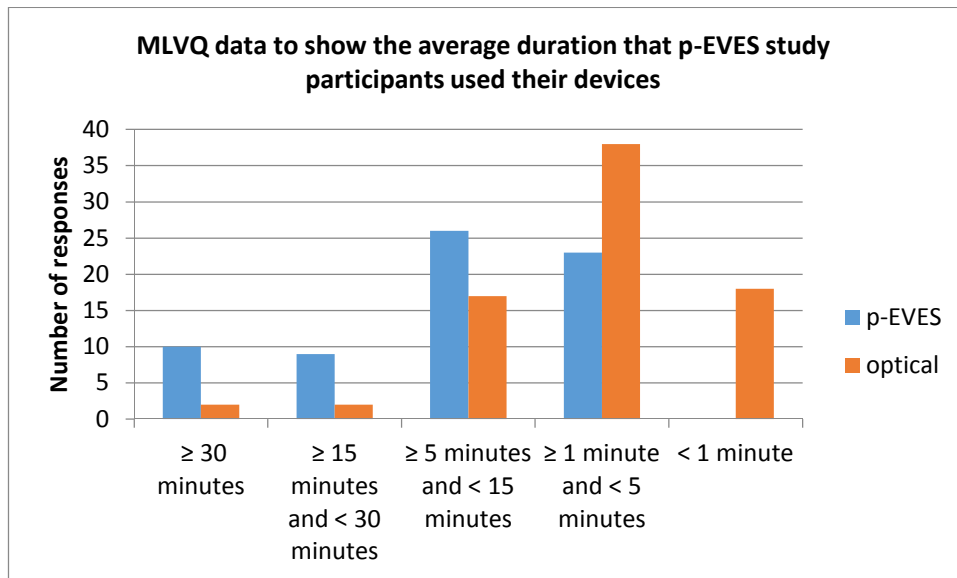


Figure 4.3: Bar graph to show the average duration that p-EVES study participants used their devices-taken from the MLVQ.

#### 4.4 Discussion

The results from the task-based practice and difficulties questionnaires from 1-2 weeks post prescription of the p-EVES have been evaluated and compared with the opinions given by the participants during the interviews after 4 months in the study.

Fifteen minutes was the average time taken for completing task-based practice. This small amount of time could be quite easily incorporated into a low vision assessment. The maximum time taken was only 30 minutes which could also potentially work as an ‘add-on’ to a low vision assessment. Going forward, if p-EVES were to be supplied by the NHS, the time taken to complete task based practice would become relevant when assessing the cost effectiveness of incorporating this into the low vision service. There was some variation between the lengths of time taken to perform task based practice for each of the four different devices. Due to having such small numbers of the compact+ and mobilux digital devices chosen, compared with the larger numbers of participants choosing the compact 4HD and the eMag43, this difference was not significant statistically.

The one participant who struggled to use the p-EVES to write during task based practice later became a drop out because they were having little success using the p-EVES at home. The difficulties questionnaire for this participant did not pick up any technical difficulties needing reinstruction, however the participant did express that they were not satisfied with the device. It may be that when prescribing p-EVES, if a patient struggles performing any elements of the task-based practice with a device, they should be rebooked to try on another day with a longer appointment time or at this point, it could be deemed appropriate to change the device based on the difficulties the patient is having with it. It may also be a sign of a lack of motivation to use the p-EVES, in which case it may not be suitable to prescribe at all or it may be sensible to bring the patient back in a few months when their motivation may have improved.

Looking at the responses given by participants when using p-EVES compared with those given when they were using just their optical aid there are some clear differences. Most participants reported that they used their primary optical aid 5-10 times a day and when using p-EVES the usage was slightly less at 1-5 times. It has to be considered that when the participants were given the p-EVES device to take home for two months, they also had access to their optical aids, so they may be using both. This could be the reason for the lower reported usage of the p-EVES compared with the optical aids when used alone; px 128 'I'd go in there and have a read what I had to read there or if I was in the lounge I'd use the electronic one'. When they were asked how easy the devices were to use, those using p-EVES mainly answered 'very easy' and the majority of those using the optical aids answered 'relatively easy'. The main reason that contributed to this difference could be the field of view of the optical device as this was reported as a difficulty by a significant number of participants (78%) and this was also confirmed as an issue by some participants in the interviews; px 113 'the thing about them is that they only cover a small area, even the bigger one and if you move it you can lose the thread of what you're reading'. In the p-EVES questionnaire, field of view was still reported as a difficulty but only by 13% of participants. The main difficulty reported with p-EVES was 'apparent movement/smearing of the image', however this was

only reported by 25% of participants. It is clear from the results of the difficulties questionnaire that at 1-2 weeks after prescription, patients report very strongly that the field of view is an issue with optical aids but there are very few other difficulties found with this type of low vision aid. There were a few different difficulties reported with the p-EVES including movement/smearing of the image, eyes feeling uncomfortable/headaches, field of view and the weight of the device. The number of participants who reported these issues, however, was low.

Question 2 was to ascertain where participants were using the devices. With both the optical and the p-EVES devices, participants mainly used them at home. However the main difference between the two was that 53% of participants were using their optical aid outside the home and only 15% were using the p-EVES in this way. This may be related to portability of the devices. Having said this, when asking the participants if they thought the devices were a good size to carry around 53% felt that their p-EVES was portable. It may be that 1-2 weeks is too short a period of time with a device to gain a representative idea of what patients will use it for long term. Other reasons for not taking the p-EVES out and about could be the cosmetic appearance of the device, the weight of it or the worry over losing or breaking the device. These reasons, however, did not come across as important in the difficulties questionnaires.

The p-EVES difficulties questionnaires for just those participants interviewed at the end of the study have also been recorded in the results. Looking at these results and the responses given in the interviews, some conclusions can be drawn. The main difficulty reported by this group was that they were worried about losing or breaking the device. As part of the study the p-EVES did not belong to the participant but could be purchased after the study was over at a discounted rate. In the interviews it did appear that participants were worried about taking the p-EVES out with them due to the device not officially belonging to them. Some of these participants said they would have been inclined to take the device out with them if it had been their own. Participants who were nervous to take it out mostly commented that they would have if it belonged to them; px 117 Q: 'But if you had one, do you think you would take it out and about?' A: 'Yes, I would, yes'. However,

there were several participants who did feel that the device was too big to carry around at the stage of the difficulties questionnaire.

The majority of interviewed participants found the p-EVES 'very easy' to use and reported few difficulties at 1-2 weeks. This was reflected in the interviews where the same participants were still reporting a positive overall opinion of the device. The one participant who reported that the device was 'very difficult' to use, still reported this at the end of the study; px 159 'I'd say I was disappointed with the electronic one because of the amount of time to set up and start getting it into place'.

It does appear from these results that the difficulties questionnaire at 1-2 weeks after prescription of a p-EVES is a useful tool for predicting how well patients are likely to get on with the device long term. If a patient reports a technical problem, it is essential to book another appointment to address these issues. However, even with patients who do not report technical difficulties but are reporting other difficulties, it may help to see them again for a reminder of all of the features and to offer some encouragement. For example, those participants who answer that they are struggling with 'apparent movement/smearing of the image' or say the device is 'difficult to operate' may just need a reminder of how to set up their preferred settings or which buttons control what feature. The questionnaire is, therefore, also a good tool for identifying patients who may need some further instruction or encouragement. In order to be used in a clinical setting, it would benefit from some amendments. Firstly, there is some repetition in question 5 as participants took 'easy to operate' and 'easy to understand how to use it' as the same question twice generally. Also, there are a few questions relating to the appearance of the device and this did not seem to be an issue for the p-EVES study participants overall. Therefore, this could be omitted from the questionnaire completely. One feature that was introduced in task based practice but not included in the difficulties questionnaire was the snap-shot/camera option on each device. A few of the interviewed participants did find this feature useful and others forgot it existed at all. It would be beneficial to incorporate this into the questionnaire going forward. Forgetting about features, like the snap-shot, may depend on whether patients get

the opportunity to use the device fairly soon after taking it home or whether they have a gap, for example if they go on holiday and don't take their p-EVES with them. The manufacturer's instructions were included with the p-EVES devices in the study, however these can often be extensive and complicated for a patient with low vision. An alternative could be to write some simplified instructions for each device in an accessible format.

The task-based practice was sufficient for most participants in the p-EVES study but there were a few who felt they could have benefitted from longer training with the device. It is important to assess motivation before prescribing a p-EVES to take home and those who are identified to require more encouragement/training may need a supplementary appointment before they take the device away.

Looking at the MLVQ data, figure 4.1 suggests that while some people use their p-EVES device outside the home, the majority of p-EVES users use the device in the home only. This reflects the responses in the difficulties questionnaires. The reasons for not taking the p-EVES device out may relate to the weight/size of the device. It also may be due to participants being aware that the device did not officially belong to them and being concerned that they may lose or break the device in this study setting. Therefore this may not be an issue if these devices were to be prescribed within the NHS. It is important to note that in the study, the p-EVES users still had access to their optical aids and may have felt that the optical aids were more convenient to use while outside the home.

With regards to the frequency of device use, figure 4.2 shows that the optical aids are being used more frequently throughout the day than the p-EVES devices. Then when looking at figure 4.3, the duration of use of optical aids is clearly shorter than that of p-EVES devices, suggesting that optical aids are used in short spurts many times throughout the day i.e. for spot/survival reading. In contrast, the p-EVES devices seem to be used less frequently overall than the optical aids, however when looking at the durations, p-EVES are reported as being used for longer periods of time, i.e. for leisure reading.

#### 4.5 Study limitations:

One potential limitation of this study is that the clinician researcher had a lot of involvement with the participants. This relationship could mean that the participants may feel that they want to tell the researcher what they think they want to hear, for example in the difficulties questionnaires, they may not want to admit to having certain difficulties due to the fact that the researcher has taught them how to use the device initially. A possible source of bias is that as the study progressed, the clinician researcher became more experienced in doing the task based practice and gained knowledge from participants in what sort of problems they were having. This could have led to modifications in the explanations used in task based practice in order to prevent the same difficulties being reported again.

## **Chapter 5 Guidelines for prescribing p-EVES**

The experience gained in this study may help to inform future prescribing decisions of p-EVES.

### **5.1 Device purchase**

The first area to consider is which participants in the p-EVES study went on to purchase their p-EVES device, as an analysis of this may help inform some prescribing decisions.

The manufacturers of the devices used within the p-EVES study offered a discount to those participants wishing to purchase their device at the end of the study period. The discount was between 25-30% off the retail price, depending on the device. Out of the 82 participants who completed the p-EVES study, 28 (34%) went on to purchase their device. Table 4.1 shows how this was distributed among the different devices.

Table 5.1: *The numbers of p-EVES study participants who purchased their device.*

p-EVES device	Number who bought their device after the study
Compact 4HD	13
Compact+	0
eMAG 43	15
Mobilux Digital	0

In order to determine whether there were any significant factors that predicted whether a participant was likely to go on to purchase a device or not, an analysis was undertaken. First of all, the variables to be analysed were chosen. They are shown in table 5.2 along with codes used for inputting the data into SPSS..



Table 5.2: *The definitions of the codes used in the SPSS analysis*

Codes for variables used in analysis	Meanings of codes
Age	Age of participant
Livesalone	Does the patient live alone?
distanceva	Distance VA at baseline
Nearva	Near VA at baseline
Cs	Contrast Sensitivity
readingspeed	Reading speed in wpm
ccvft	California Central Visual Field Test grade (covered in chapter 5)
acorn	'ACORN' grading. ACORN is a classification system that allows the population to be segmented into certain socio-economic 'groups'
highestpower	The highest power of the participant's optical aids
lowestpower	The lowest power of the participant's optical aids
havestand	Does the participant have a stand magnifier?
MLVQgradeduration	The duration of use of the p-EVES graded from the MLVQ
Isitgrade4	If the duration of use is grade 4

SPSS was used to perform a multiple logistic regression to see whether any of the variables above are predictive of whether a participant purchased a device or not. Block 0 of the SPSS output, where the explanatory variables are not included in the analysis, gives an overall correct prediction value of 66%, meaning that the model guesses whether a participant bought or did not buy their device correctly 66% of the time. Once the explanatory variables are entered into the model (Block 1), this increases to 83% of the time.

Table 5.3: *Variables not in the equation from SPSS output Block 0*

	Score	df	Sig
age	9.690	1	.002
livesalone	.170	1	.680
distanceva	4.688	1	.030
nearva	.569	1	.451
Cs	.118	1	.731
readingspeed	.983	1	.321
ccvft	.410	1	.522
acorn	1.850	1	.174
highest power	3.235	1	.072
lowest power	1.920	1	.166
havestand	.581	1	.446
MLVQgradeduration	10.460	1	.001
Isitgrade4	6.343	1	.012
Overall statistics	33.625	13	.001

Table 5.3 shows the variables not used in the equation and the p-values in the last column show that the MLVQgradeduration variable has the most statistical significance, prior to inclusion of the variables into the model.

Forward stepwise regression was used and this included three steps.

'MLVQgradeduration' was added to the model first, followed by 'age', then followed by 'livesalone'. No further variables were used as they did not improve the model.

The significant predictive variables found by this analysis are the duration of use of the p-EVES, the age of the participant and whether they live alone.

The analysis found that when a participant reported a longer duration of use with their p-EVES device on the MLVQ; the more likely they were to purchase a device. This is unsurprising as an ability to use the device for longer, indicates that it could be used for leisure reading over just spot/survival reading. It also suggests a person is comfortable when using the device, for example they may have a better posture or working distance, in order for them to have a longer duration of use. These positive experiences of p-EVES devices may lead patients into feeling that a device like this would be worth investing in. Participant number 110 went on to buy his device once the study had finished. When interviewed it was apparent that he was able to use it for a long period of time. This is illustrated in table 5.4.

Table 5.4: *Excerpt from interview with participant 110*

Study researcher's question:	Participant's answer:
<b><i>'Right. So how long could you use the electronic device for, before your eyes got tired?'</i></b>	<i>'Well, using the black on white, I can normally use it for the full length of the unit working.'</i>
<b><i>'Right, and would that be for sort of leisure reading?'</i></b>	<i>'Yeah. Yeah.'</i>
<b><i>'So how long should that be?'</i></b>	<i>'Oh well, up to two hours.'</i>

The analysis also showed that the likelihood of purchasing a device increases with increasing age. There are a few possible explanations for this relationship. One possibility would be if older people have more money saved than younger people, enabling them to make this purchase after only approximately four months' notice. This claim is unable to be proven by any data available in the study, although the socio-economic data taken from ACORN showed no significant relationship with who did and did not go on to purchase a device; meaning there was no predictive factor found when looking at who was deemed likely to be able to afford the devices and who was not.

Another reason that could explain the relationship between age and purchasing the device is that older people may be less likely to have access to other technology that can enlarge print compared with a younger person, for example iPad's and kindles. They may be more likely to have physical print to read than a younger person. This was commented on by one of the younger participants in the p-EVES study (age 23) and this is shown in table 5.5.

Table 5.5: *Excerpt from interview with a 23 year old p-EVES study participant*

Study researcher's question:	Participant's answer:
<b><i>'Right. So how long could you use the electronic device for, before your eyes got tired?'</i></b>	<i>'Well, using the black on white, I can normally use it for the full length of the unit working.'</i>
<b><i>'Right, and would that be for sort of leisure reading?'</i></b>	<i>'Yeah. Yeah.'</i>
<b><i>'So how long should that be?'</i></b>	<i>'Oh well, up to two hours.'</i>

The relationship found with 'livesalone' was that participants who lived alone were less likely to purchase a p-EVES device than those who lived with a spouse or relative. A possible explanation for this was seen in the study by Watson et al (1997) where the factor 'presence of a helper' was the only demographic variable that was found to be statistically significant in whether a veteran continued to use their device. In this case it was found to be 1.9x more likely that a veteran would

continue to use their LVA if a helper was present. Therefore, in the p-EVES study, if a participant lived with another person, this person may have helped or encouraged them to use the device in the first few days or weeks, enabling the participant to be motivated in its use, possibly more so than someone who lives alone.

The interviews conducted at the end of the study visits on one third of the p-EVES study patients have been used in conjunction with personal experience to discuss prescribing guidelines for p-EVES . Some of the parameters discussed below were part of the p-EVES study inclusion criteria and others arose out of the findings during the study when prescribing the p-EVES.

### 5.2. Contrast sensitivity

It has been shown that a twofold decrease in contrast sensitivity is associated with a threefold to fivefold likelihood that patients will self-report difficulties with reading (West et al, 2002). Whittaker and Lovie-Kitchin (1993) suggested that contrast reserve is one of the main requirements for reading and for text to be read fluently, it needs to be presented at several times higher contrast than a patient's contrast threshold. A study by Crossland and Rubin (2012) used self-reported visual function data and found a relationship between reduced contrast sensitivity and difficulty reading newsprint. It was suggested that it would be helpful to these patients if text could be made available in a format that can be viewed on an LED computer.

Contrast sensitivity was a baseline measurement taken from all participants of the p-EVES study. The inclusion criteria stated: Log Contrast Sensitivity of 1.20 or worse. The range of contrast sensitivity measurements at the baseline assessment was from 1.20 to 0.00 log units (no letters visible at 1m). Of those interviewed, the lowest contrast sensitivity measurement was 0.45 log units and the interviews given by these participants gave mixed responses. Four of them gave very positive reviews of the p-EVES, two of which went on to buy the device at the end of the study. Two others with the same CS measurement, however, had very little success with the device.

All of the devices had various colour/contrast options detailed in appendix 5.

When participants were initially selecting their preferred device, the most popular option was the white on a black background. Every participant preferred an enhanced contrast option for reading print, not full colour. However, for reading print on packets/tins where there are various different colours of print and backgrounds, the full colour option was more effective as some of the enhanced options made some of the writing disappear; px 159: 'colours, it seemed to go like if you put it on to, say, a soup, and it would just go all like fuzzy'.

Overall the interviewed participants did not seem to mention contrast of the device as a main consideration unless prompted, magnification and layout of the device came across as the more important features. When prompted, however, the participants preferred the full colour, enhanced black on white or white on black; px 128: 'The colours I didn't find, I didn't like the colours. I liked the black and white more than anything'; px 130: 'I tried to use all the contrasts, every one on the electronic, but it just didn't...the normal one (full colour) just came to effect all the time'. There were a small number of patients, however, who did mention that the different colours were useful; px 139: 'being able to use a different set of colours was quite nice for a change. Restful to your eyes to use a different background'; px 116: 'I like my blue and yellow and the black and yellow, because I find it stands out better than say ordinary writing on white paper'.

Contrast sensitivity was an inclusion criteria for the p-EVES study, however based on the interviews and anecdotally it did not seem to have much influence over which device was chosen or whether participants got on with the device overall. It does not need to be heavily considered when prescribing p-EVES.

### 5.3 Visual Acuity

The inclusion criteria for visual acuity (VA) stated 'V/A of 6/30 (0.7 LogMAR) or worse (in the better eye)' The binocular VAs of p-EVES patients ranged from 0.30logMAR (eligible based on contrast sensitivity) to 1.68logMAR. The average VA of the participants who opted for the compact 4HD was 0.94logMAR which is identical to that of the eMAG 43 group. Looking at either end of the VA scales there

were no obvious patterns with who found p-EVES useful and who did not. The participants who had vision on the lower end of the scale ie 1.30logMAR or less found the tactile elements of the devices more important. Two of them returned the devices and dropped out due to difficulty operating the devices. Others in this category, however, had very positive experiences with the p-EVES and two actually purchased a device after they finished the study. Another measurement that was taken at baseline was near VA. Near VA measurements ranged from 0.40M to 6.3M. One area that was looked at was the relationship between near VA and the magnification chosen.

The magnification options of the p-EVES devices chosen for the study are detailed in appendix 5.

Looking at those participants with near VA measurements of 1.0m (newspaper print size) or better, there were some who found the p-EVES devices useful for very small print but a couple of them commented that the minimum setting was still too magnified for them; px 132: 'the three magnification settings were very good. Although for me I would say it was probably too powerful'; px 138: 'I really need one, which maybe gives a smaller print, and therefore a greater width coverage'. The two participants interviewed with the most reduced near VA measurement of 6.3m both had very successful experiences with the p-EVES device. Px 130 felt that it improved his working distance which made him feel more comfortable using the device in public: 'because I can look from a distance and not go right up to it, and that's the embarrassing part I don't like'. The other participant, px 128, found the high magnification settings on her compact 4HD better compared with her optical magnifier and also referred to the more comfortable working distance: 'well it made everything easier didn't it , you know, without the complications of screwing your face up at everything and holding it up to your eye'.

Near VA would have been a more appropriate inclusion criteria for the p-EVES study instead of distance VA and should be a consideration when prescribing p-EVES devices. A near VA measurement of 1.0m or worse would be an appropriate guideline when choosing to prescribe p-EVES.

#### 5.4 Age

The inclusion criteria in the p-EVES study that referred to age was 'Adult (over 18 years)'. The average age of the participants in the p-EVES study was 71. As mentioned earlier, 85% of participants chose either the Compact 4HD or the eMAG 43. The average ages for each device were very similar. For the Compact 4HD the average age was 72 and 73 for the eMAG 43. The Compact 4HD is mounted on a tilted stand for use at a desk or table. This feature was popular among some of the participants who spent little time away from their homes. This is because the majority of the time that the p-EVES device was in use, there will have been access to a flat surface to work from and this creates a more comfortable reading posture, 'it's tilted so that you read it without hanging over the top of ....With it being tilted it's a lot easier'. One of the disadvantages of this device is that, away from its stand, it has to be positioned very accurately to focus on an object which can be difficult for elderly patients. There is no handle on the device which makes positioning more difficult. If a patient is not planning on using the device anywhere but at home, the compact 4HD or a similar device may be appropriate. In the same light, some of the larger devices such as the compact 7HD may also be appropriate for these patients, as portability will not be such an important feature. The higher expense of these devices may be an issue for some patients however. Although the average age of the patients choosing the eMAG was the same as that of the compact 4HD, the majority of the patients who were employed or in full time education opted for the eMAG 43. One of the youngest participants (aged 34) saw the benefits of the eMAG 43 but felt that it was too bulky and would have preferred a smaller device that would fit in the pocket.

Based on the above information, the age of the patient was an appropriate inclusion criteria for the p-EVES study as there was no upper limit, however 'appropriate activity goals' would be a more useful guideline for prescribing p-EVES.

#### 5.5 Dexterity/handling

The patients who had problems with dexterity found the location of the buttons very important. The eMAG 43 was found to be quite easy to use due to the location



of the buttons all being on the front of the device and them being tactile. They were also different colours which some participants found helpful; px 113: 'the fact that they were different colours helped'. It was more difficult to instruct patients in the use of the compact 4HD. The reason for this was that the buttons were in different locations on the device and required different amounts of pressure to operate them. For example, the on/off button required a 3 second press to operate it, which confused some people and was the reason for having to bring one patient back for re-instruction. When removing the device from its stand, many patients found that they would accidentally catch one of the buttons, either the snap shot or the on/off, which would then cause confusion; px 128: 'I didn't like where the camera button was.....was just awkward'.

There were only 4 patients out of the 100 who opted for the compact+. Two of these patients were interviewed although one didn't really use it at all once they had got it home. One participant commented that it was 'time consuming' trying to set up the device. Anecdotally it did take longer for patients to understand how to operate the magnification settings compared with other devices and a few patients dismissed the device very quickly as they struggled to locate the on/off switch.

When choosing a device from the original four, 7 participants opted for the mobilux digital. Often, the reason for this was due to the similarity between this and their optical magnifiers as it has a fixed handle. It was not a popular device overall but one participant did find it useful but would have preferred it to be a more portable design; px 130: 'I just liked it, but unfortunately it was too bulky with the handle on it'.

When prescribing a p-EVES, dexterity should be considered when choosing what type of device to recommend. Ideally it should be one with the buttons all on the front of the device and easy to press. Poor dexterity is not a contra-indication for demonstrating a p-EVES device.

### 5.6 Motivation/Encouragement

Patients need to be motivated to use the p-EVES in the first place as some devices take longer than others to get used to how to operate them and unmotivated patients may just give up; px 148: 'I couldn't do it at all so I never bothered any more, but that's just me'. As previously mentioned, the compact + and compact 4HD caused some problems for a few patients due to the layout and usability of the buttons, therefore patients need to be motivated in order to get used to operating devices like these. There were a few patients who would have struggled if it was not for family members offering encouragement, so this is something that should be considered when prescribing these devices. For example, one patient lived alone and her son visited at least weekly and charged the device for her. Also px 120 was poorly during her time with the device and a family member re-instructed her when she had forgotten how to use some of the buttons. This particular participant went on to purchase her device at the end of the study. When considering prescribing these devices it could be useful to ascertain how much the patient sees family members or friends to ascertain how much encouragement they are likely to receive. This would be made easier if they attended the clinic with family or friends in the first place. If they did not, booking them in another time when they can attend with someone else may help. When issuing these devices it could be useful to give patients a contact number to call if they feel that they have 'forgotten' how to use some of the features or if they feel that they simply need a 'refresher'.

In summary, when prescribing p-EVES devices to patients, the following parameters should be considered; Near VA, dexterity, appropriate activity goals and motivation/encouragement, these are summarised in table 5.6.

Table 5.6: *Guidelines for prescribing p-EVES*

Guidelines for prescribing p-EVES	
Near VA	Consider when near VA is 1.0m or worse
Appropriate activity goals	Consider for those whose goal is to read, choose a device that suits the patient's needs i.e. if they are planning on only reading at home, ok to issue a 'bulky' devices with a tilted stand but for someone planning on taking the device to the shops, will need a smaller, more portable device.
Motivation/encouragement	Consider for those who have motivation to learn to use the device and plan on using it regularly (so they do not forget the layout). If the patient has family/friends who are encouraging, this may help the patient in using the device at home.
Dexterity	Ideally it should be one with the buttons all on the front of the device and easy to press. Poor dexterity is not a contra-indication for demonstrating a p-EVES device.

### Conclusions and future work

This thesis has summarised the involvement of the clinician researcher in the p-EVES study. Anecdotal evidence showed that p-EVES devices are popular amongst patients and clinicians, however the literature on this type of low vision aid is limited. The main p-EVES study looked at a comparison between p-EVES and optical magnifiers, using both quantitative and qualitative data. This thesis, on the other hand, uses the experiences during the study to discuss how to prescribe these devices and which types of patients to prescribe them to. Task based practice is an effective way of instructing patients to use a p-EVES device and a follow up by telephone call will allow any issues with operating the device to be addressed promptly. Guidelines for prescribing the devices have been recommended. The CCVFT allows clinicians to plot a patient's central scotoma, however more work into analysing the plots would need to be done to make it an effective test in a research setting.

This year, the main p-EVES study results will be published and a prescribing paper is also being written currently. Positive results will enable a bid to be made to commissioners of services to introduce p-EVES into NHS low vision clinics across the UK.

## References:

- Abou-Gareeb, I et al. 2001. Gender and blindness: a meta-analysis of population-based prevalence surveys. *Ophthalmic Epidemiology*, 8(1), pp. 39-56.
- Ackland, P. 2012. The accomplishments of the global initiative VISION 2020: The Right to Sight and the focus for the next 8 years of the campaign. *British Journal of Ophthalmology*, 60(5), pp. 380-386.
- Attebo, K et al. 1996. Visual acuity and the causes of visual loss in Australia. The Blue Mountains Eye Study. *Ophthalmology* 103(3), pp. 357-364.
- Barry, RJ and Murray PI. 2005. Unregistered visual impairment: is registration a failing system? *British Journal of Ophthalmology*, 89(8).
- Beckmann, PJ and Legge, GE. 1996. Psychophysics of reading--XIV. The page navigation problem in using magnifiers. *Vision research*, 36(22), pp. 3723-3733.
- Bookwala, J and Lawson, B. 2011. Poor Vision, Functioning, and Depressive Symptoms: A Test of the Activity Restriction Model. *Gerontologist*, 51(6), pp. 798-808.
- Bosanquet, N and Mehta P. 2008. © RNIB and The Guide Dogs for the Blind Association.
- Bouma, H et al. 1982. Is large print easy to read? *Annual Progress Report*, 17, pp. 84-90.
- Bowers, A et al. 2007. Reading with optical magnifiers: page navigation strategies and difficulties. *Optometry and Vision Science* 84(1), pp. 9-20.
- Bowers, A et al. 2001. Eye movements and reading with large print and optical magnifiers in macular disease. *Optometry and Vision Science*, 78(5), pp. 325-334.
- Bowers, A et al. 2001. Illumination and reading performance in age-related macular degeneration. *Clinical and experimental optometry*, 84(3), 139-147.
- Brinker, BPLM and Bruggeman H. 1996. Visual requirements for reading: The importance of a large field of view in reading with a magnifier. *Journal of Videology* (1), pp. 27-38.
- Brody, BL et al. 2001. Depression, Visual Acuity, Comorbidity, and Disability Associated with Age-related Macular Degeneration. *Ophthalmology*, 108(10), pp. 1893-900.
- Brown, MM et al. 2005. Age-related macular degeneration: economic burden and value-based medicine analysis. *Canadian journal of ophthalmology*, 40(3), pp. 277-287.
- Bullimore, MA and Bailey, IL. 1995. Reading and eye movements in age-related maculopathy. *Optometry and vision science*, 72(2), pp. 125-138.
- Bunce, C et al. 2010. Causes of blind and partial sight certifications in England and Wales: April 2007–March 2008. *Eye* 24(11), pp. 1692-1699.
- Bunce, C and Wormald, R. 2006. Leading causes of certification for blindness and partial sight in England & Wales. *BMC Public Health* 6(58).

- Burggraaff, MC et al. 2012. (a) Randomized Controlled Trial on the Effects of Training in the Use of Closed-Circuit Television on Reading Performance. *Investigative Ophthalmology and Visual Science* 53(4), pp. 2142-2150.
- Burggraaff, MC et al. 2012. (b) Randomized Controlled Trial on the Effects of CCTV Training on Quality of Life, Depression, and Adaptation to Vision Loss. *Investigative Ophthalmology and Visual Science* 53(7), pp. 3645-3652.
- Calbrese, A et al. 2010. Small Effect of Interline Spacing on Maximal Reading Speed in Low-Vision Patients with Central Field Loss Irrespective of Scotoma Size. *Investigative Ophthalmology and Visual Science*, 51(2), pp. 1247-54.
- Casten, RJ and Rovner, BW. 2013. Update on depression and age-related macular degeneration. *Current opinion in ophthalmology*, 24(3), pp. 239-43.
- Christoforidis, JB et al. 2011. Age related macular degeneration and visual disability. *Current Drug Targets*, 12(2), pp. 221-233.
- Cohen, JM and Waiss, B. 1991. (a) Comparison of reading speed in normal observers through different forms of equivalent power low vision devices. *Optometry and vision science*, 68(2), pp. 127-131.
- Cohen, JM and Waiss, B. 1991. (b) Reading speed through different equivalent power low vision devices with identical field of view. *Optometry and vision science*, 68(10), pp. 795-797.
- Colenbrander, A. 2010. Assessment of functional vision and its rehabilitation. *Acta Ophthalmologica* 88(2), pp. 163-173.
- Court, H et al. 2011. How effective is the new community-based Welsh low vision service? *British Journal of Ophthalmology*, 95(2), pp. 178-184.
- Crossland, MD and Rubin, G. 2012. Text Accessibility by People with Reduced Contrast Sensitivity. *Optometry and Vision Science* 89(9), pp. 1276-1281.
- Crossland, MD and Rubin, G. 2007. The Amsler chart: absence of evidence is not evidence of absence. *British Journal of Ophthalmology*, 91(3), pp. 391-393.
- Crossland, MD and Silver, JH. 2005. Thirty years in an urban low vision clinic: changes in prescribing habits of low vision practitioners. *Optometry and Vision Science*, 82(7), pp. 617-622.
- Crossland, MD et al, 2005. Preferred retinal locus development in patients with macular disease. *Ophthalmology*, 112(9), pp. 1579-85.
- Culham, LE et al. 2009. Users' subjective evaluation of electronic vision enhancement systems. *Ophthalmic and Physiological Optics*, 29(2), pp. 138-149.
- Culham, LE et al. 2004. Clinical performance of electronic, head-mounted, low-vision devices. *Ophthalmic and Physiological Optics*, 24(4), pp. 281-290.
- Cunningham, E. 2001. World blindness—no end in sight. *British Journal of Ophthalmology*, 85(3), pp. 253.
- Dandona, L and Dandona R. 2006. Revision of visual impairment definitions in the International Statistical Classification of Diseases. *BMC Medicine* 4:7 doi:10.1186/1741-7015-4-7.

- Dandona, L et al. 2001. Estimation of blindness in India from 2000 through 2020: implications for the blindness control policy. *The national medical journal of India* 14(6), pp. 327-334.
- Decarlo, DK et al. 2012. Use of prescribed optical devices in age-related macular degeneration. *Optometry and vision science*, 89(9), pp. 1336-42.
- Department of health. 2013. Certificate of Visual Impairment: Explanatory notes for consultant ophthalmologists and hospital eye clinic staff. *Website* <https://www.gov.uk/> [accessed 04/04/2015]
- Dickinson, CM and Fotinakis, V. 2000. The Limitations Imposed on Reading by Low Vision Aids. *Optometry and Vision Science* 77(7), pp. 364-372.
- Dickinson, C. 1998. *Low Vision: Principles and Practice*. Oxford: Butterworth-Heinemann.
- Dickinson, C et al. 2011. A profile of low vision services in England: the Low Vision Service Model Evaluation (LOVSME) project. *Eye*, 25(7), pp. 829-31.
- Douglas, G et al. 2006. Network 1000. *RNIB website*, [Accessed: 28/02/2013].
- Dymont, Sophie. *Reading With Confidence: A Report On The Provision Of Electronic Pocket Magnifiers For Children With Sight Problems In Wales..* 1st ed. Cardiff: Wales Council for the Blind, 2009. Print.
- Ergun, E et al, 2003. Scotoma Size and Reading Speed in Patients with Subfoveal Occult Choroidal Neovascularization in Age-related Macular Degeneration. *Ophthalmology*, 110(1), pp. 65-9.

Erlich,D.1987. A comparative study in the use of closed-circuit television reading machines and optical aids by patients with retinitis pigmentosa and maculopathy. *Ophthalmic and physiological optics*, 7(3),pp. 293-302.

- Evans, JR. 2002. Prevalence of visual impairment in people aged 75 years and older in Britain: results from the MRC trial of assessment and management of older people in the community. *British Journal of Ophthalmology*, 86(7), pp. 795-800.
- Evans, JR et al. 2007. Depression and anxiety in visually impaired older people. *Ophthalmology*, 114(2), pp. 283-288.
- Fine, EM and Rubin, GS. 1998. Reading with central field loss: number of letters masked is more important than the size of the mask in degrees. *Vision Research*, 39(4), pp. 747-56.
- Fine, EM et al. 1996. The necessary field of view to read with an optimal stand magnifier. *Journal of the American Optometric Association* 67(7), pp. 382-389.
- Finger, RP et al. 2012. Blindness and Visual Impairment in Germany: A Slight Fall in Prevalence. *Deutsches Arzteblatt International*, 109(27-28), pp.484-489.
- Fletcher, DC et al. 1999. Relative locations of macular scotomas near the PRL: effect on low vision reading. *Journal of rehabilitation research and development*, 38(4), pp. 356-364.

- Fletcher, DC et al. 2012. Patient Awareness of Binocular Central Scotoma in Age-Related Macular Degeneration. *Optometry and vision science*, 89(9), pp. 1395-8.
- Frick, KD et al. 2007. Economic Impact of Visual Impairment and Blindness in the United States. *Archives of Ophthalmology* 125(4), pp. 544-550.
- Frick, KD and Kymes, SM. 2006. The calculation and use of economic burden data. *British Journal of Ophthalmology*, 90(3), pp. 255-257.
- Global data on visual impairments 2010. Available at: <http://www.who.int/blindness/GLOBALDATAFINALforweb.pdf?ua=1> [Accessed 01/03/2016].
- Goodrich, GL and Kirby, J. 2001. A comparison of patient reading performance and preference: optical devices, handheld CCTV (Innoventions Magni-Cam), or stand-mounted CCTV (Optelec Clearview or TSI Genie). *Optometry*, 72(8), pp. 519-528.
- Goodrich, GL et al. 1980. Parameters in the use of CCTV's and optical aids. *American journal of optometry and physiological optics*, 57(12), pp. 881-892.
- Goodrich, GL et al. 1976. A preliminary report on experienced closed-circuit television users. *American journal of optometry and physiological optics*, 53(1), pp. 7-15.
- Guez, JE et al, 1993. Is there a systematic location for the pseudo-fovea in patients with central scotoma. *Vision research*, 33(9), pp. 1271-9.
- Halcomb, E J et al. Literature Review: Considerations In Undertaking Focus Group Research With Culturally And Linguistically Diverse Groups. *J Clin Nurs* 16.6 (2007): 1000-1011.
- Harper, R et al. 1999. Evaluating the outcomes of low vision rehabilitation. *Ophthalmic and Physiological Optics*, 19(1), pp. 3-11
- Harper, R et al. 1999. Head mounted video magnification devices for low vision rehabilitation: a comparison with existing technology. *British Journal of Ophthalmology*, 83(4), pp. 495-500.
- Haymes, SA and Lee, J. 2006. Effects of task lighting on visual function in age-related macular degeneration. *Ophthalmic and Physiological Optics*, 26(2), pp. 169-179.
- Hernandez Trillo, A and Dickinson CM. The Impact of Visual and Nonvisual Factors on Quality of Life and Adaptation in Adults with Visual Impairment. *Investigative Ophthalmology and Visual Science*, 53(7), pp. 4234-41.
- ICD Version: 2010. Available at: <http://apps.who.int/classifications/icd10/browse/2010/en#/H53-H54> [Accessed: 12/01/2013].
- Jeong, JH and Moon, NJ. 2001. A Study of Eccentric Viewing Training for Low Vision Rehabilitation. *Korean Journal of Ophthalmology* 25(6), pp. 409-416.
- Kitzinger, J. 1995. Qualitative research. Introducing focus groups. *British Journal of Ophthalmology* 311(7000), pp. 299-302.
- Knudtson, MD et al. 2005. Age-Related Eye Disease, Quality of Life, and Functional Activity. *Archives of Ophthalmology* 123(6), pp. 807-814.



- Lam, BL et al. 2008. Reported Visual Impairment and Risk of Suicide. *Archives of Ophthalmology* 126(7), pp. 975-980.
- Lamoureux, EL et al. 2004. The Impact of Diabetic Retinopathy on Participation in Daily Living. *Archives of Ophthalmology*, 122(1), pp. 84-88.
- Lamoureux, EL et al. 2008. Assessing Participation in Daily Living and the Effectiveness of Rehabilitation in Age Related Macular Degeneration Patients Using the Impact of Vision Impairment Scale. *Ophthalmic Epidemiology*, 15(2), pp. 105-113.
- Leat, SJ and Woodhouse, JM. 1993. Reading performance with low vision aids: relationship with contrast sensitivity. *Ophthalmic and physiological optics*, 13(1), pp. 9-16.
- Legge, GE et al. 1985. Psychophysics of Reading II. Low Vision. *Vision research* 25(2), pp. 253-266.
- Legge, GE. 1991. Glenn A. Fry Award Lecture 1990: three perspectives on low vision reading. *Optometry and vision science*, 68(10), pp. 763-769.
- Legge, GE et al. 1992. Psychophysics of reading. Clinical predictors of low-vision reading speed. *Investigative Ophthalmology and Visual Science*, 33(3), pp. 677-687.
- Legge, GE et al. 1997. Psychophysics of reading—XVI. The visual span in normal and low vision. *Vision research*, 37(14), pp. 1999-2010.
- Lee, S et al 2005. Preference of low-vision devices in the Hong Kong low-vision population. *International Congress Series*, Vol 1282, pp. 196-200.
- Legood, R et al. 2002. Are we blind to injuries in the visually impaired? A review of the literature. *Injury prevention*, 8(2), pp. 155-160.
- Liew G, et al. 2014. A comparison of the causes of blindness certifications in England and Wales in working age adults. *BMJ open*, 4(2).  
(16–64 years), 1999–2000 with 2009–2010
- Lim, LS et al. 2012. Age-related macular degeneration. *Lancet*, 379(9827), pp. 1728-1738.
- Lim, K. 2006. Vision 2020 and Prevention of Blindness: Is it Relevant or Achievable in the Modern Era? *Annals of the Academy of Medicine, Singapore* 35(3), pp. 215-222.
- Lott, LA et al. 2001. Reading performance in older adults with good acuity. *Optometry and vision science*, 78(5), pp. 316-324.
- Lovie-Kitchin, J et al. 2000. Oral and silent reading performance with macular degeneration. *Ophthalmic and physiological optics*, 20(5), pp. 360-370.
- Lovie-Kitchin, JE and Woo, GC. 1988. Effect of magnification and field of view on reading speed using a CCTV. *Ophthalmic and Physiological Optics*, 8(2), pp. 139-145.
- Maberley, DAL et al. 2006. The prevalence of low vision and blindness in Canada. *Eye* 20(3), pp. 341-346.
- Margrain, TH. 2000. Helping blind and partially sighted people to read: the effectiveness of low vision aids. *British journal of ophthalmology*, 84(8), pp. 919-921
- Margrain, TH et al. 2005. A revolution in Welsh low vision service provision. *British journal of ophthalmology*, 89(8), pp. 933-934.

- Markowitz, SN and Reyes, SV. 2013. Microperimetry and clinical practice: an evidence-based review. *Canadian journal of ophthalmology*, 48(5), pp. 350-7.
- Mehr, EB et al. 1973. Experience with closed circuit television in the blind rehabilitation program of the Veterans Administration. *American journal of optometry and archives of American academy of optometry*, 50(6), pp. 458-69.
- Mganga, H et al. 2011. Overcoming Gender Inequity in Prevention of Blindness and Visual Impairment in Africa. *Middle East African journal of ophthalmology*, 18(2), pp. 98-101.
- Minassian, DC. 2011. Modelling the prevalence of age-related macular degeneration (2010e2020) in the UK: expected impact of anti-vascular endothelial growth factor (VEGF) therapy. *British journal of ophthalmology*, 95(10), pp. 1433-1436.
- Mitchell, J and Bradley, C. 2004. Design of an individualised measure of the impact of macular disease on quality of life (the MacDQoL). *Quality of life research*, 13(6), pp. 1163-75.
- National Research Council. 2002. Visual impairments: Determining Eligibility for Social Security Benefits. Washington D.C., National Academy Press.
- Neve, JJ. (1989). On the use of hand-held magnifiers during reading. *Optometry and vision science*, 66(7), pp. 440-449.
- Nguyen, NX et al. 2009. Improvement of reading speed after providing of low vision aids in patients with age-related macular degeneration. *Acta Ophthalmologica* 87(8), pp. 849-843.
- Nilsson, UL. 1986. Visual rehabilitation of patients with advanced diabetic retinopathy. A follow-up study at the Low Vision Clinic, Department of Ophthalmology, University of Linköping. *Documenta Ophthalmologica Advances in ophthalmology*, 62(4), pp. 368-382.
- Nilsson, UL and Nilsson, SE. 1986. Rehabilitation of the visually handicapped with advanced macular degeneration. A follow-up study at the Low Vision Clinic, Department of Ophthalmology, University of Linköping. *Documenta Ophthalmologica Advances in ophthalmology*, 62(4), pp. 345-367.
- Nyman, SR et al. 2012. Emotional well-being and adjustment to vision loss in later life: a meta-synthesis of qualitative studies. *Disability and rehabilitation*, 34(12), pp. 971-981.
- Ortiz, A et al. 1999. Reading with a head-mounted video magnifier. *Optometry and vision science*, 76(11), pp. 755-763.
- Pascolini, D and Mariotti, SP. 2011. Global estimates of visual impairment: 2010. *British Journal of Ophthalmology*, 96(5), pp. 614-618.
- Pearce, E et al. 2011. The efficacy of low vision device training in a hospital-based low vision clinic. *British journal of ophthalmology*, 95(1), pp. 105-8.
- Peterson, RC et al. 2003. Benefits of Electronic Vision Enhancement Systems (EVES) for the Visually Impaired. *American Journal of Ophthalmology* 136(6), pp. 1129-1135.

- Rayner, K et al. (1978). Eye Movements and Integrating Information across Saccades. *Journal of Experimental Psychology: Human Perception and Performance*, 4(4), pp. 529-44.
- Rayner, K et al (2010). Eye movements, the perceptual span, and reading speed. *Psychonomic bulletin and review*, 17(6), pp. 834-839.
- Reeves, BC et al. 2004. Enhanced low vision rehabilitation for people with age-related macular degeneration: a randomised controlled trial. *British Journal of Ophthalmology*, 88(11), pp. 1443-9.
- Reischies, FM and Geiselmann, B. 1997. Age-related cognitive decline and vision impairment affecting the detection of dementia syndrome in old age. *British Journal of psychiatry*, 171, pp. 449-51.
- Resnikoff, S and Keys, TU. 2012. Future trends in global blindness. *British Journal of Ophthalmology*, 60(5), pp. 387-395.
- Resnikoff, S et al. 2004. Global data on visual impairment in the year 2002. *Bulletin of the World Health Organisation*, 82(11), pp. 844-851.
- Royal National Institute of Blind People, (2009) Cost Oversight. *Campaign report 29*, RNIB.
- Rubin, GS and Legge, GE. 1989. Psychophysics of reading. VI—The role of contrast in low vision. *Vision Research*, 29(1), pp. 79-91.
- Rubin, GS and Turano, K. 1994. Low Vision Reading with Sequential Word Presentation. *Vision Research*, 34(13), pp. 1723-1733.
- Ryan, B and Margrain, TH. 2010. Registration for people with sight impairment: fit for purpose? *British Journal of Ophthalmology* 94(12), pp. 1692-1693.
- Schuchard, RA. 2005. Preferred retinal loci and macular scotoma characteristics in patients with age-related macular degeneration. *Canadian journal of ophthalmology*, 40(3), pp. 303-312.
- Schilling, OK et al. 2001. The Adaptation Dynamics of Chronic Functional Impairment: What We Can Learn From Older Adults With Vision Loss. *Psychology and ageing*, 26(1), pp. 203-13.
- Seiple, W et al, 2004. Multidimensional visual field maps: relationships among local psychophysical and local electrophysiological measures. *Journal of rehabilitation research and development*, 41(3A), pp. 359-72.
- Seiple, W et al, 2005. Eye-Movement Training for Reading in Patients with Age-Related Macular Degeneration. *Investigative Ophthalmology and Visual Science*, 46(8), pp. 2886-96.
- Shuttleworth, GN et al. 1995. How effective is an integrated approach to low vision rehabilitation? Two year follow up results from south Devon. *British Journal of Ophthalmology*, 79(8), pp. 719-23.
- Stalmeijer, RE et al. 2014. Using focus groups in medical education research: AMEE Guide No. 91. *Medical Teacher*, 36(11), pp. 923-39.
- Stelmack, J et al. 1991. Reading performance of geriatric patients post exudative maculopathy. *Journal of the American optometric association*, 62(1), pp. 53-57.

- Stelmack, J et al. 2002. Measuring Low-Vision Rehabilitation Outcomes with the NEI VFQ-25. *Investigative Ophthalmology and Visual Science*, 43(9), pp. 2859-68.
- Stelmack, J et al. 2012. The Effectiveness of Low-Vision Rehabilitation in 2 Cohorts Derived From the Veterans Affairs Low-Vision Intervention Trial. *Archives of Ophthalmology*, 130(9), pp.1162-8.
- Stelmack, J et al. 2008. Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT). *Archives of ophthalmology*, 126(5), pp. 608-17.
- Sunness, JS et al. 1996. Fixation Patterns and Reading Rates in Eyes with Central Scotomas from Advanced Atrophic Age-related Macular Degeneration and Stargardt Disease, *Ophthalmology*, 103(9), pp. 1458-1466.
- Tabrett, DR and Latham, K. 2012. Adjustment to Vision Loss in a Mixed Sample of Adults with Established Visual Impairment. *Investigative ophthalmology and vision science*, 53(11), pp. 7227-34.
- Tate, R et al. 2005. The prevalence of visual impairment in the UK; A review of the literature. RNIB report (Online) [Accessed 16/01/2013].
- Taylor, J et al. 2014 The p-EVES study design and methodology: a randomised controlled trial to compare portable electronic vision enhancement systems (p-EVES) to optical magnifiers for near vision activities in visual impairment, *Ophthalmic and Physiological Optics*, 34(5), pp. 558-72.
- Taylor, HR et al. 2005. Vision loss in Australia. *The Medical journal of Australia*, 182(11), pp. 565-568.
- The Eye Diseases Prevalence Research Group. (2004). Causes and Prevalence of Visual Impairment among Adults in the United States. *Archives of Ophthalmology*, 122(4), pp. 477-485.
- Virgili, G and Acosta, R. 2009. Reading aids for adults with low vision. *Cochrane database of systematic reviews* (4), CD003303.
- Watson, GR et al. 1997. Veteran's use of low vision devices for reading. *Optometry and vision science*, 74(5), pp. 260-265.
- Watson, GR et al. 1997. National survey of the impact of low vision device use among veterans. *Optometry and vision science*, 74(5), pp. 249-259
- Weih, LM et al. 2002. Assessment of the Impact of Vision Impairment. *Investigative Ophthalmology and Visual Science*, 43(4), pp. 927-935.
- West, SK et al. 2002. How Does Visual Impairment Affect Performance on Tasks of Everyday Life? *Archives of Ophthalmology* 120(6), pp. 744-780.
- Whittaker, SG et al. 1988. Eccentric Fixation with Macular Scotoma. *Investigative ophthalmology and visual science*, 29(2), pp. 268-278.
- Whittaker, SG and Lovie-Kitchin, J. 1993. Visual requirements for reading. *Optometry and vision science*, 70(1), pp. 54-65.
- Wolffsohn, JS and Peterson, RC. 2003. A review of current knowledge on Electronic Vision Enhancement Systems for the visually impaired. *Ophthalmic and Physiological Optics* 23(1), pp. 35-42.

- World Health Organization and International Agency for the Prevention of Blindness. 2004. *3.5.4 Low vision* (Online). Available at: [http://www.who.int/ncd/vision2020\\_actionplan/contents/3.5.4.htm](http://www.who.int/ncd/vision2020_actionplan/contents/3.5.4.htm). [Accessed: 12/01/2013].

## Appendix 1: p-EVES study methodology paper

Taylor et al (2014)



### The p-EVES study design and methodology: a randomised controlled trial to compare portable electronic vision enhancement systems (p-EVES) to optical magnifiers for near vision activities in visual impairment

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**Keywords:** cost effectiveness, effectiveness, electronic magnifiers, vision enhancement, visual impairment

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#### Abstract

**Purpose:** To describe the study design and methodology for the p-EVES study, a trial designed to determine the effectiveness, cost-effectiveness and acceptability of portable Electronic Vision Enhancement System (p-EVES) devices and conventional optical low vision aids (LVAs) for near tasks in people with low vision.

**Method:** The p-EVES study is a prospective two-arm randomised cross-over trial to test the hypothesis that, in comparison to optical LVAs, p-EVES can be used for longer duration; used for a wider range of tasks than a single optical LVA and/or enable users to do tasks that they were not able to do with optical LVAs; allow faster performance of instrumental activities of daily living and allow faster reading. A total of 100 adult participants with visual impairment are currently being recruited from Manchester Royal Eye Hospital and randomised into either Group 1 (receiving the two interventions A and B in the order AB), or Group 2 (receiving the two interventions in the order BA). Intervention A is a 2-month period with conventional optical LVAs and a p-EVES device, and intervention B is a 2-month period with conventional optical LVAs only.

**Results:** The study adopts a mixed methods approach encompassing a broad range of outcome measures. The results will be obtained from the following primary outcome measures: Manchester Low Vision Questionnaire, capturing device 'usage' data (which devices are used, number of times, for what purposes, and for how long) and the MNRRead test, measuring threshold print size, critical print size, and acuity reserve in addition to reading speed at high ( $\approx 90\%$ ) contrast. Results will also be obtained from a series of secondary outcome measures which include assessment of timed instrumental activities of daily living and a 'near vision' visual functioning questionnaire. A companion qualitative study will permit comparison of results on how, where, and under what circumstances, p-EVES devices and LVAs are used in daily life. A health economic evaluation will provide results on: the incremental cost-effectiveness of p-EVES compared to optical magnifiers; cost-effectiveness; and cost-utility.

**Conclusion:** The evidence base in low vision rehabilitation is modest and further high quality clinical trials are required to inform decisions on healthcare provision. The p-EVES study findings are anticipated to contribute to this broader evidence requirement, with the methodological issues evident here being relevant to other trials within the field.

## Introduction

Over 1 million people in the United Kingdom (UK) live with untreatable visual impairment (VI), many of them are elderly and the numbers at risk of VI will inevitably rise with the ageing of the population.<sup>1</sup> The UK Vision Strategy<sup>2</sup> recognises the importance of delivering support, and achieving independence, for people with VI. A major difficulty reported by individuals with VI is their inability to carry out simple tasks, especially those involving reading. It is known that these difficulties are a major cause of depression in an older population.<sup>3,4</sup> vision loss, disability and depression can be a 'single syndrome, with each element amplifying and perpetuating the adverse effects of the others'.<sup>5</sup>

In the UK, National Health Service (NHS) low vision clinics, typically based in hospital ophthalmology departments, provide assessment of people with VI and dispense optical magnifiers free of charge on permanent loan to try and ameliorate the restrictions in activities experienced by those with sight loss. These magnifiers have the limitations of a small field of view and very short working distances and often require the patient to view monocularly which some people find difficult and uncomfortable. In addition, several different optical devices are often needed if the patient wants to perform a variety of different tasks. An alternative approach to optical magnifiers has been the development of *electronic vision enhancement systems* (EVES) for visual tasks (for a review see Wolfsohn & Peterson<sup>6</sup>). Early EVES devices were expensive and bulky and therefore had limited acceptance, even current systems (such as CCTVs) are not widely used in the UK because they are not provided through the NHS. More recently, technological advances have led to the development of moderately priced *portable-electronic vision enhancement systems* (p-EVES) which offer potential benefits in comparison to optical magnifiers. For example p-EVES devices can be used more naturally (binocular viewing and habitual working distance) and also incorporate many features not seen in optical magnifiers (e.g. variable magnification, different contrast settings and freeze frame facility). In addition, p-EVES devices may be psychologically more acceptable to some patients, since they resemble other high-tech hand-held devices such as mobile phones/computers. In contrast, their greater complexity may make

them unsuitable for patients with poor cognitive abilities or limited manual dexterity. These p-EVES devices are currently on the market to buy privately, but are not provided through the NHS in England. If p-EVES devices are more successful than optical magnifiers in allowing patients to carry out activities of daily living, they could be expected to support increased independence, quality of life and wellbeing. The ability of a person with VI to remain independent could lead to a decrease in formal social care costs, in addition to reducing the indirect cost of assistance from family and friends.

A number of trials comparing different low vision aids (LVAs) have been published (for a systematic review see Virgili *et al.*<sup>7</sup>). Previous comparisons of electronic and optical magnifying devices have been reported, but they have not used the most current p-EVES designs now available.<sup>8-11</sup> These studies have provided only limited evidence that electronic devices can outperform optical LVAs. For example, Culham *et al.*<sup>10</sup> compared performance of four different head-mounted EVES to conventional optical LVAs in a group of patients with VI secondary to macular disease. For individual patients and particular tasks, some EVES provided better performance, however, reading speed and time taken to perform certain everyday tasks tended to be better with optical LVAs. In a related study the same research group found that the majority of patients questioned rated EVES devices as either 'the same' or 'better' at providing near magnification than their habitual (optical) LVAs.<sup>12</sup> This later study highlighted how the subjective impressions of LVA users can supplement clinical measures of performance to provide a more complete description of LVA success. Peterson *et al.*<sup>11</sup> compared performance with a stand-mounted EVES, a 'mouse' EVES with monitor or head-mounted display, and optical LVAs during reading and practical tasks. Results were variable but in general EVES provided faster reading speeds, but optical LVAs tended to provide faster performance of tasks that required location of the object of interest.

In Wales, approximately one third of all optometrists are accredited to provide the *Low Vision Service Wales* and supply LVAs in a National Health Service from their community practices. For the past few years this has included one modern p-EVES device (the Optelec Compact+). Anecdotal reports from patients and practitioners suggest that these

devices are popular and successful, and research suggests that the p-EVES device is among the most popular devices supplied through the scheme.<sup>13</sup>

### Trial objective

The aim of the study is to compare the effectiveness, cost-effectiveness and acceptability of modern p-EVES devices to conventional optical magnifiers for near vision tasks. The current study represents the first randomised controlled trial (RCT) that directly compares the latest p-EVES designs (which were not available to previous studies) to current optical LVAs, with fully-adapted patients with VI, and incorporates a comprehensive range of outcome measures in order to evaluate whether this new technology offers real benefits in comparison to current optical magnifiers.

### Trial development

The stimulus for the study was the widespread positive reaction and comments such as '...this (p-EVES) is my lifeline... this is absolutely magic' from patients during the first year that the p-EVES devices were available through the Low Vision Service Wales, and the possibility of extending this supply to the rest of the UK if these anecdotal reports were supported by evidence from a robust trial. If it is found that p-EVES devices can offer a clinically significant advantage for near vision activities for particular patients, when compared to their existing optical magnifiers, this would provide evidence that would help inform any future recommendations by the National Institute for Health and Care Excellence (NICE), or decisions by commissioners of services, regarding the supply of p-EVES devices within the NHS. Despite the (currently) greater cost of an individual p-EVES in comparison to most optical devices (from ~£200 upwards, compared to an average of approximately £50) there is also a potential saving to providers of low vision services in that the p-EVES may do the job of, and replace, several optical magnifiers. In addition, the current trend is for the cost of optical devices to be increasing, while the cost of electronic devices is decreasing. In the wider economic context, the ability of the patient to carry out more tasks independently could reduce the burden on formal and informal care networks.

Over recent years there has been increasing recognition of the important contribution that public involvement can make to research.<sup>14</sup> The experiences of service users and carers are likely to provide a valuable perspective that may help shape a research project and help ensure that its aims are important and relevant to the public. A key feature of this study is the contribution of service users, and this began with the design of the research. A pre-study focus

group which included device users ( $n = 3$ ), family members ( $n = 3$ ), and professionals ( $n = 2$ ) from the *Low Vision Service Wales and Social Services* was conducted. In addition, one-to-one telephone interviews were carried out with members ( $n = 3$ ) of the Stockport group of the Macular Society who had purchased p-EVES devices privately and could compare them to the optical devices provided through the NHS. With the aim of refining the intervention, a script was created which included specific questions about whether training was needed to use the aid, and the length of time it took to become familiar with it typical responses included 'fairly simple', 'really easy to use', and 'it really is straightforward'. Users were also asked what they thought would be the best research outcome measure: what would show how good this device was? The versatility of the device was a common theme with comments such as 'there are so many things you can do with it', 'I've used them all (different magnification levels) at various times...from 3 to 18...I've used the full range' and 'this is one magnifier that does everything'.

It was planned that the p-EVES devices to be used in the trial would only be selected when recruitment was imminent, in order that the latest devices would be available. Another pre-study focus group of individuals with VI ( $n = 6$ ) was recruited with help from the Macular Society, including working age and older patients, as well as those with and without previous experience with p-EVES devices. Within a single session, participants had access to 16 current, modern p-EVES devices from five different suppliers. The p-EVES devices available had a range of screen sizes and magnification and contrast settings. Participants were given time with various reading and writing materials to identify their preferred p-EVES device(s). Participants were asked to score each device, and take part in a general discussion which used prompting questions to explore device characteristics and usability. The discussion was audio-recorded and transcribed. Four devices (with screen sizes from 2.8" to 3.5") were reported by users as offering too small a field of view for leisure reading and three larger devices (screen sizes 5" to 7") were felt to be too large to regularly carry and use outside the home or office. Weight, button size and configuration, and handle design were other features rated as important by users, but image quality was not mentioned. On the basis of the device scores and comments from the discussion, and considering the premise of the study that a single p-EVES device had the potential to support both leisure and survival reading and therefore be more versatile than an optical magnifier, the four highest scoring suitable p-EVES devices were chosen for the trial.

The four devices chosen were the Optelec Compact+, Optelec Compact 4HD, Schweizer eMag43, and Eschenbach Mobilux Digital. These devices are shown in Figure 1 and





**Figure 1.** The four p-EVES devices selected for use in the p-EVES study: Optelec Compact+ (upper left), Optelec Compact 4HD (upper right), Schweizer eMag43 (lower left), Eschenbach Mobilar Digital (lower right).

the manufacturer’s specifications of these devices are given in Table 1.

**Trial design**

The p-EVES study is a single-site study being conducted at Manchester Royal Eye Hospital (MREH), UK. An overview of the p-EVES study design is shown in Figure 2. Experienced optical aid users are recruited to a prospective two-arm cross-over RCT with a 1:1 randomisation to the two

study arms. Participants are randomised to Group 1 or Group 2. Group 1 receives the two interventions A and B in the order AB, while Group 2 receives the two interventions in the order BA. Intervention A is a 2 month period with conventional optical magnifiers and a p-EVES device, and Intervention B is a 2 month period with conventional optical magnifiers only. Individuals are allowed to retain their existing optical LVAs when they are provided with the p-EVES, since some optical aids (e.g. distance telescopes) couldn’t be replaced by a p-EVES device, and it would have

**Table 1.** Characteristics of the p-EVES devices used in the study (manufacturers specifications)

p-EVES device	Screen size	Magnification range	Contrast settings	Contrast enhancement	Camera facility	Handle
Optelec Compact+	4.3"	3 fixed settings: x5/x 7.5/x10	Full Colour, Black on White, White on Black, Yellow on Black, Yellow on Blue	Yes	Yes	Yes (Foldout)
Optelec Compact 4HD	4.3"	Continuous Zoom: x1.7 to x2	Full Colour, Black on White, White on Black, Yellow on Black, Yellow on Blue	Yes	Yes	No
Schweizer eMag43	4.3"	3 fixed settings (dependant on handle position): x5/x 7.5/x10 When flat on surface with handle IN and either x2/x3/x4 or x7/x10.5/x14 with handle OUT (depending on working distance)	Full Colour, Black on White, White on Black, Yellow on Black, Yellow on Blue	Yes	Yes	Yes (Foldout)
Eschenbach Mobilar Digital	3.5"	3 fixed settings: x3/x 4.5/x6	Full Colour, Black on White, White on Black, Black on Yellow, Yellow on Black	Yes	Yes	Yes (Fixed)

Table 2. Measurements taken at each of the study visits

Variables		p-EVES assessment	Baseline (Study visit 1)	Study visit at end of optical aid period (Study visit 2 or 3)	Study visit at end of p-EVES and optical aid period (Study visit 2 or 3)
Inclusion/exclusion criteria	MMSE (Blind)	✓			
	Contractility	✓			
	Distance VA (LogMAR)	✓	✓	✓	✓
To assist in selecting p-EVES	Threshold near	✓			
	Word acuity				
Primary outcome measure (1)	MLVQ (Part 1)	✓	✓	✓	✓
	MLVQ (Part 2)	✓	✓	✓	✓
Predictive measures	Central visual field (CCVFT)	✓			
	ACE-II		✓		
	Brief Resilience Scale		✓		
Primary outcome measure (2)	Finger-to-nose test		✓		
	MNRead High contrast (90%)		✓ With optical LVA	✓ With optical LVA	✓ With preferred LVA Repeated with p-EVES if optical LVA preferred
Secondary outcome measures	MNRead Reduced contrast (50%)		✓ With optical LVA	✓ With optical LVA	✓ With preferred LVA Repeated with p-EVES if optical LVA preferred
	IRIST		✓ With optical LVA	✓ With optical LVA	✓ With p-EVES
Secondary outcomes measures (health economic)	S-TADL		✓ With optical LVA (if required)	✓ With optical LVA (if required)	✓ With preferred LVA (if required)
	NV-VQ-15		✓	✓	✓
	WHO-5		✓	✓	✓
	EQ-5D-5L		✓	✓	✓
	ICRCA-A		✓	✓	✓
	VisQoL		✓	✓	✓

The refractive correction and the participant's optical LVAs are updated if necessary. It is well known that magnification can be less effective in the presence of a central scotoma, therefore the presence of a central scotoma may be predictive of unsuccessful use of a p-EVES device. Viewing with the p-EVES is binocular, and therefore the California Central Visual Field Test (CCVFT)<sup>13</sup> is used to determine the presence of a binocular scotoma, and the location of any preferred retinal locus used.<sup>16</sup>

An analysis of needs assessment is performed using the Manchester Low Vision Questionnaire (MLVQ).<sup>17</sup> This is a two-part questionnaire designed to evaluate low vision rehabilitation. Part 1 captures task specific data (which tasks LVAs are used for and how helpful LVAs are in allowing tasks to be performed) and Part 2 determines LVA usage (frequency of use, length of continuous use, and ease of use). Part 1 is used to evaluate the needs of the participant so that the most appropriate LVAs can be provided.

Participants have the opportunity to look at the four different p-EVES devices in the study and choose the one which best matches their requirements with guidance from the clinician researcher (based on the responses to the MLVQ questionnaire). Instruction on use of the selected p-EVES device is given but no formal training is provided (equivalent to the typical situation with NHS hospital provision of optical LVAs). The clinician researcher demonstrates optimal magnification, working distance and viewing mode (contrast) settings for the selected p-EVES device. The p-EVES assessments are expected to take approximately 1 h.

The participant has a task-based practice session immediately following study visits 1 and 2 (i.e. at the start of each of the 2-month trial periods). The purpose of the practice session is to remind the participant of the instructions for magnifier use to ensure they have a basic knowledge of how to use the current LVAs, and to provide general encouragement

to keep using the LVAs when necessary. The clinician researcher gives guidance on how to turn the magnifier on/off, what the controls do, how to recharge the device (p-EVES) or change batteries (optical magnifiers), and the optimal posture/working distance of the current device(s). At each practice session the participant attempts five tasks with their current magnifier(s) (p-EVES when in that trial phase, optical otherwise) to ensure that they are using the devices correctly. The five tasks are (1) to fill in one answer (answer given) in a crossword puzzle (2) to read one entry from a television guide magazine (glossy paper) (3) to read the first sentence from a newspaper article (matte paper) (4) to read cooking instructions on a packet of food (5) to use the camera facility to identify the name of a book that is out of reach. Due to the absence of a camera facility with optical magnifiers, the final task (5) is completed with p-EVES only (when in that phase of the study), when participants only have optical magnifiers, only the first four tasks are completed.

The clinician researcher telephones participants at 1 week after the start of each arm of the study. The purpose of this phone call is to identify any major problems with the participant's current LVAs. For consistency and to avoid bias this step occurs in both arms of the study. The clinician researcher follows a script and administers a difficulties questionnaire (whether in group 1 or group 2) that covers how often the magnifier is used, where the magnifier is used, how easy/difficult the magnifier is to use, and asks specifically about a range of possible difficulties with the LVAs. If the clinician researcher identifies clear problems (i.e. the device is not working properly or the participant does not know how to operate it) the participant is booked in for a visit with the clinician researcher for replacement of the aid and/or re-instruction to ensure the device is working properly and the participant has a basic knowledge of its operation.

At the end of their involvement in the study, the participant will be offered the opportunity to purchase the p-EVES device if they wish (at a discounted price), and the number who take up this offer will be recorded.

### Predictive measures

It is possible that certain individuals are more likely to benefit from the use of a p-EVES device than others. This benefit may relate to their visual status, which is therefore determined during the initial p-EVES assessment. In addition, there are three further non-visual measures completed at baseline (study visit 1) which may help provide potential predictive or prognostic measures for successful p-EVES use. These are Addenbrooke's Cognitive Examination (ACE-III),<sup>18</sup> The Brief Resilience Scale,<sup>19</sup> and the Finger-to-Nose Test.<sup>20</sup>

The ACE-III<sup>18</sup> is a questionnaire designed to assess cognitive function within five domains: attention, memory, verbal fluency, language and visuo-spatial abilities. The maximum score is 100 with higher scores indicating better cognitive functioning. In this study the sections which require the subject to interpret visual information were omitted (some of the language domain and the entire visuo-spatial domain), reducing the maximum possible score to 65. The ACE-III is included because it may be argued that a specific level of cognitive ability is required in order to benefit from the p-EVES devices, since they have a more complex range of controls than optical devices.

The Brief Resilience Scale<sup>19</sup> is a questionnaire which assesses the ability to 'bounce back' or recover from stress. This scale will be used to test the hypothesis that someone with high resilience would be more willing to try a novel device, and make the effort to become familiar with it, and therefore be more successful.

The Finger-to-Nose Test is used to measure upper limb motor coordination requiring a series of fast, accurate, repeated movements of the arm for good performance. The participant is asked to place the index finger of the dominant hand on their nose and then extend the arm to touch a target at the distance of the fully extended arm, and they then touch the nose again (this is one cycle). This has been shown to be a good measure of manual dexterity which is appropriate for a visually impaired individual.<sup>20</sup> Participants are timed while performing three complete cycles as quickly and accurately as possible, and the final result is the mean time of three tests. Characteristics of the movements such as dysmetria (imprecision in making a movement) or tremor are not recorded. The hypothesis is that a certain level of manual dexterity may be required for optimal use of LVAs, and this dexterity may need to be greater for p-EVES devices, because of the variety of controls to be used.

### Outcome measures

A number of outcome measures are carried out at all three study visits: at baseline and at the end of each of the two phases, in each arm of the trial (see Table 2). There are two primary outcome measures (MNRead and MLWQ) and a series of secondary outcome measures.

#### Primary outcome measures

The hypothesis is that, in comparison to optical magnifiers, the p-EVES devices will:

1. Allow faster reading.

A primary outcome measure will be the maximum reading speed measured with high contrast ( $\approx 90\%$ ) MNRead Acuity Charts (Minnesota Laboratory for Low-Vision Research, <http://gandalf.psych.umn.edu/groups/>

gellab/MNREAD/) using the p-EVES device, compared to the preferred optical magnifier.

Previous studies<sup>21,22</sup> suggest that magnifying aids provide significant improvement in reading speed although these studies combine optical and electronic magnifiers. In a comparison of electronic and optical aids, Goodrich and Kirby<sup>9</sup> found a 12 words per minute difference in reading speed. The reading speed (and duration) was significantly greater with the electronic LVAs in comparison to the optical LVAs.

2. Be preferred (used more often) than a single optical magnifier.

The MLVQ (Part 2) rates frequency of use of each LVA used (on a scale of 0–4). The primary outcome would be a significant increase in usage of the p-EVES device compared to the preferred optical magnifier (optical magnifier used most frequently).

#### Secondary outcome measures

All of the selected p-EVES devices contain a 'contrast enhancement' feature that is not available with the optical magnifiers. To investigate whether the contrast enhancement features of the p-EVES devices offer a measurable improvement in reading performance in reduced contrast conditions, reduced contrast ( $\approx 50\%$ ) versions of the MNRead charts have been custom made for the study. These charts will be used to compare reading speed with p-EVES devices to optical magnifiers. However, when measuring reading speed with the MNRead charts using the p-EVES device, participants are not given any instruction on what contrast setting to use. Therefore, the measurement is partly dependent on the participant's ability to be able to recall these features and use the p-EVES device to its full potential.

The International Reading Speed Texts (IReST) is a standardised test used for measuring reading speed over extended paragraphs.<sup>23,24</sup> It is included in this study because it was designed to offer a more realistic assessment of 'leisure reading' ability. In leisure reading, the ability to read for longer durations is considered to be important, since it suggests the device is more comfortable (or not so tiring) to use. There is evidence suggesting that electronic magnifiers (although the type was not specified) have been rated as the most successful and used for the longest durations.<sup>25</sup> Conversely, for spot reading, using the device for a shorter time might be a possible advantage of the p-EVES device (i.e. being able to accomplish tasks more quickly than when using optical magnifiers). Therefore, whether longer duration of LVA use is a positive result (i.e. allowing less tiring use) or a negative result (i.e. taking longer to do things) is dependent on the task the participant is doing. The MLVQ captures data on the average and longest dura-

tion that participants have used their LVAs for. For those participants who at baseline use an optical magnifier to 'read books and newspapers', the MLVQ (Part 1) will be used to determine whether (1) they subsequently prefer to use a p-EVES for this task, and, if so, (from MLVQ Part 2) (2) what is the longest time they can read with the p-EVES (graded on a scale of 0–4).

The MLVQ will also be used to investigate whether a single p-EVES device is used for a wider range of tasks than a single optical magnifier (i.e. is more versatile and could therefore potentially replace a number of different devices) and/or enable users to do tasks that they were not able to do with optical LVAs. MLVQ (Part 1) will be used to determine the number of different tasks which are reported to be performed with the p-EVES device in comparison to the preferred optical magnifier, and the number of tasks which cannot be performed, or can only be performed with assistance, with the p-EVES device in comparison to optical magnifiers.

Five timed instrumental activities of daily living (5-TIADLs) have been adapted from the 5-TIADLs designed by Owsley et al.<sup>26,27</sup> to determine whether the p-EVES would be spontaneously chosen by the subject to carry out the task, and whether this allowed faster and/or more accurate performance of key everyday tasks. The five tasks used are: finding a number in a telephone book, writing a phrase within a designated space on a piece of paper, reading ingredients on a can of food, finding items from a selection of items on a shelf and reading information on a medicine bottle. Each task uses actual everyday objects (as opposed to simulated or pictured stimuli). Details of the 5-TIADL test are provided in Supporting Information. It should be noted that although the 'task based practice' given to each participant involves similar tasks, none of them are the same as in the 5-TIADL test. The performance of each TIADL is assessed in terms of both speed and accuracy. Speed is assessed as time taken to perform the task (measured on a stop-watch to the nearest 0.1 s) and accuracy is assessed using a 5-point grading scale. At the start of each task all the participant's current LVAs (optical and p-EVES, if applicable) are placed on the table in front of the participant within easy reach, and the p-EVES devices are turned on. For the 5-TIADL tasks, the participant is allowed to choose which device to use (or to choose to do the task without an aid) for each individual task, and this choice is recorded.

To investigate the perceived difficulty in carrying out a wider range of activities than it is practical to test directly, a 15 item questionnaire was devised (NV-VFQ-15) based on selecting appropriate 'near vision' items from the VFQ-48 questionnaire, which has been shown to be sensitive to rehabilitation.<sup>28</sup> The NV-VFQ-15 results will be scored using previously published algorithms.<sup>29</sup>

### Administration of outcome measures

Each of the three study visits is expected to last approximately 1.5 h including breaks as necessary to avoid fatigue. All of the questionnaires are administered verbally, face-to-face: a standard script is used for any instruments that had no instructions provided. All measurements are performed according to instructions provided with the clinical test (unless otherwise stated), at a table in a clinical consulting room with localised lighting providing even daylight illuminance of  $\approx 1500$  Lux. Several tests are conducted three (or 4) times during the course of the study (see Table 2). Therefore three (or 4) versions of the tests were selected from those available (if a commercial test), and three different versions of each of the 5-TIADL tasks have been developed for repeat measures during the trial. The choice of which versions of the tests to use for each visit was included in the randomisation procedures.

All of the reading tasks (MNRead high and reduced contrast, and IReST) are audio recorded for later analysis (in terms of accuracy and timing) using audio editing software (Wavepad Sound Editor v5.00, NCH Software, [www.nch.com.au/wavepad](http://www.nch.com.au/wavepad)). At study visit 1 (baseline) MNRead will be measured at high and reduced contrast with the preferred optical magnifier. At subsequent study visits MNRead (high and reduced contrast) is measured with the participant's preferred LVA (optical magnifier or p-EVES device). If this is the optical magnifier, then the MNRead measurements are repeated with the p-EVES device. If the preferred LVA is the p-EVES device the measurements are not repeated with the optical magnifier. Each measurement during the study is taken with a different MNRead chart. Participants used the viewing distance that was appropriate for their selected magnifying device. Use of a device meant that it was not possible to use the standard method of revealing each sentence and measuring the time taken from that point.<sup>30</sup> The time taken was therefore that to actually speak the words in each case (analysed from the audio recordings of the reading tasks).

The IReST test is done three times in total for each participant in the study (1  $\times$  at each of the three visits) using a different paragraph of text at each visit. At the baseline study visit 1 IReST is measured with an optical magnifier. At subsequent study visits IReST is measured with the p-EVES device when the participant is in that arm of the study, and with the optical magnifier otherwise.

Magnification, contrast setting and field of view will be recorded when the p-EVES device is used for a particular task.

### Health economic evaluation

The incremental cost-effectiveness of the p-EVES devices will be compared to optical magnifiers. This evaluation will

involve considering the cost of the two interventions (including both the devices themselves and the professional time required to prescribe and dispense them), and also reporting the minutes per hours of carer time freed up through use of p-EVES devices as compared to conventional optical LVAs (determined using national carer/value of unpaid time rates). The data gathered from the MLVQ can be used to evaluate whether any changes in the ability to carry out everyday tasks with the p-EVES will in turn free up carer time. Then a cost-effectiveness analysis can be conducted using difficulty in carrying out near vision tasks (as determined by the 15-item NV-VFQ-15) as the measure of effect.

For p-EVES devices to be funded through the NHS system, positive guidance from NICE will be required based on an improvement in the health-related quality of life (increase in QALY). The EQ-5D<sup>31</sup> is a questionnaire used to measure health-related quality of life and is the measure recommended by NICE in its Technical Guidance.<sup>32,33</sup> A cost-utility analysis using EQ-5D as the measure of utility will be conducted to generate a cost per QALY and Cost Effectiveness Acceptability Curve (CEAC)<sup>34</sup> for comparison with the NICE ceiling of £10 000–£30 000 in the UK.<sup>35</sup> It has been suggested that the EQ-5D is unresponsive to vision-related problems.<sup>36</sup> This is particularly likely to be the case in the current study which compares two interventions (rather than considering the comparison between an intervention and a no-intervention control). This study will therefore attempt to determine which measure of utility is the most appropriate for assessing QALY change in respect to LVA technology for people with visual impairment. The ICECAP-A,<sup>36</sup> Vision Quality of Life Index (VisQoL)<sup>33,37</sup> and WHO-5 Wellbeing Index (1998 Version)<sup>38</sup> are therefore included as alternative outcome measures which are potentially more sensitive to quality of life changes in patients undergoing visual rehabilitation. The ICECAP-A is a 5-item questionnaire designed as a measure of capability for use in economic evaluation.<sup>36,39</sup> It is potentially more sensitive in settings with patients experiencing sight loss as it is a measure of capability rather than physical functioning. The VisQoL is a questionnaire designed to specifically assess the impact of visual impairment on quality of life<sup>33,37</sup> and the WHO-5 is a five-item questionnaire used to assess depression.<sup>38</sup> A secondary cost-consequence analysis will be conducted using the EQ-5D, ICECAP-A, WHO-5 and VisQoL to examine which measure is most appropriate for assessing outcomes for the purpose of economic evaluation. It is hoped that in addition to providing a preliminary assessment of cost-effectiveness in this study, this will also act as a feasibility study of a range of outcome measures, and that this will inform future long-term studies.

### Administration of outcome measures

Each of the three study visits is expected to last approximately 1.5 h including breaks as necessary to avoid fatigue. All of the questionnaires are administered verbally, face-to-face; a standard script is used for any instruments that had no instructions provided. All measurements are performed according to instructions provided with the clinical test (unless otherwise stated), at a table in a clinical consulting room with localised lighting providing even daylight illuminance of  $\approx 1500$  lux. Several tests are conducted three (or 4) times during the course of the study (see Table 2). Therefore three (or 4) versions of the tests were selected from those available (if a commercial test), and three different versions of each of the 5-TIADL tasks have been developed for repeat measures during the trial. The choice of which versions of the tests to use for each visit was included in the randomisation procedures.

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The IReST test is done three times in total for each participant in the study (1  $\times$  at each of the three visits) using a different paragraph of text at each visit. At the baseline study visit 1 IReST is measured with an optical magnifier. At subsequent study visits IReST is measured with the p-EVES device when the participant is in that arm of the study, and with the optical magnifier otherwise.

Magnification, contrast setting and field of view will be recorded when the p-EVES device is used for a particular task.

### Health economic evaluation

The incremental cost-effectiveness of the p-EVES devices will be compared to optical magnifiers. This evaluation will

involve considering the cost of the two interventions (including both the devices themselves and the professional time required to prescribe and dispense them), and also reporting the minutes per hours of carer time freed up through use of p-EVES devices as compared to conventional optical LVAs (determined using national carer/value of unpaid time rates). The data gathered from the MLVQ can be used to evaluate whether any changes in the ability to carry out everyday tasks with the p-EVES will in turn free up carer time. Then a cost-effectiveness analysis can be conducted using difficulty in carrying out near vision tasks (as determined by the 15-item NV-VPQ-15) as the measure of effect.

For p-EVES devices to be funded through the NHS system, positive guidance from NICE will be required based on an improvement in the health-related quality of life (increase in QALY). The EQ-5D<sup>31</sup> is a questionnaire used to measure health-related quality of life and is the measure recommended by NICE in its Technical Guidance.<sup>32,33</sup> A cost-utility analysis using EQ-5D as the measure of utility will be conducted to generate a cost per QALY and Cost Effectiveness Acceptability Curve (CEAC)<sup>34</sup> for comparison with the NICE ceiling of £20 000–£30 000 in the UK.<sup>35</sup> It has been suggested that the EQ-5D is unresponsive to vision-related problems.<sup>36</sup> This is particularly likely to be the case in the current study which compares two interventions (rather than considering the comparison between an intervention and a no-intervention control). This study will therefore attempt to determine which measure of utility is the most appropriate for assessing QALY change in respect to LVA technology for people with visual impairment. The ICECAP-A,<sup>36</sup> Vision Quality of Life Index (VisQoL)<sup>35,37</sup> and WHO-5 Wellbeing Index (1998 Version)<sup>38</sup> are therefore included as alternative outcome measures which are potentially more sensitive to quality of life changes in patients undergoing visual rehabilitation. The ICECAP-A is a 5-item questionnaire designed as a measure of capability for use in economic evaluation.<sup>36,39</sup> It is potentially more sensitive in settings with patients experiencing sight loss as it is a measure of capability rather than physical functioning. The VisQoL is a questionnaire designed to specifically assess the impact of visual impairment on quality of life<sup>35,37</sup> and the WHO-5 is a five-item questionnaire used to assess depression.<sup>38</sup> A secondary cost-consequence analysis will be conducted using the EQ-5D, ICECAP-A, WHO-5 and VisQoL to examine which measure is most appropriate for assessing outcomes for the purpose of economic evaluation. It is hoped that in addition to providing a preliminary assessment of cost-effectiveness in this study, this will also act as a feasibility study of a range of outcome measures, and that this will inform future long-term studies.

period. Participants are randomised to the two arms of the trial (group 1 and group 2) in a 1:1 ratio. Within each study arm there are two binary stratification variables, age (<60, ≥60 years) and visual acuity (<1.3 LogMAR, ≥1.3 LogMAR). Once allocated to trial arm, a subsequent randomisation of the six possible test orders for the three different versions of the tests (e.g. 5-TIADL version 1/2/3) is randomly provided for each participant. Following the p-EVES assessment visit, the clinician researcher forwards the details of the participant to an independent trial administrator who enters the data on to the randomisation system. The data entered in to the system consists of a unique participant study reference number, date of birth, age at recruitment, visual acuity, and confirmation that eligibility criteria are met and consent has been obtained. The system then randomises the participant to group 1 or group 2 and allocates the test versions which will be used for that participant at each study visit. This information is emailed to the administrator who then notifies the group allocation to the clinician researcher and the test order allocation to the study researcher separately. This means that the study researcher is masked to the group allocation of the participant when the baseline assessment is carried out. The reason that randomisation process needed to be carried out before the baseline study visit was so that the test order was known in order for the baseline measurements to be taken.

#### Data input, storage and quality control

The data from each of the study visits are manually inputted to spread-sheets by the study researcher (visit 1/2/3 data) and the clinician researcher (p-EVES assessment data) and stored on a secure server for subsequent data analysis. Following the data entry process, 10% of data will be selected at random using a random number generator and double entered to check the accuracy of the data entry. This step will require manually cross-checking the entries in the spread-sheets with the original study visit source documents. In addition, to reduce the possibility of bias, 10% of the audio recordings for IRaST and MNRread measurements will be randomly selected and re-analysed by a second researcher masked to the participant group, the timing of the study visit and the device used for the measurements. These data will be double entered to check the accuracy of the original analysis.

#### Data analysis

For the quantitative primary and secondary outcome measures two models for the AB/BA crossover design will be used. The basic model will use the CROS *t*-test.<sup>46,47</sup> This model accounts for the participant, period and treatment factors. This analysis will then be extended using the analysis of variance approach for the crossover design. This

model includes the participant, period and treatment factors in the model and also allows baseline covariates to be included as needed. During analysis of the secondary outcome measures Bonferroni correction to the *p*-value to adjust for multiple comparisons will be used.

#### Ethical approval and trial registration

The study protocol received National Research Ethics Service (NRES) approval on behalf of the Central Manchester and Manchester Children's University (CMMU) Hospitals NHS Trust (approval number 12/NW/0.803). The project was also approved by the CMMU Trust Research and Development Office and The University of Manchester Research Ethics Committee. The p-EVES study is registered with clinicaltrials.gov (Identifier: NCT01701700), adheres to the CONSORT guidelines (<http://www.consort-statement.org>), and conforms to the tenets of the Declaration of Helsinki.

#### Discussion

At present there is a limited evidence base in the field of low vision rehabilitation on which to base decisions about health service commissioning and healthcare delivery. Over recent years, technological advances have led to the development of modern p-EVES devices. While p-EVES devices have received positive patient feedback through the Welsh low vision service (Low Vision Service Wales), more research is required to fully establish their clinical benefit and the exact role they can play within low vision service provision. The p-EVES study represents the first RCT that directly compares the latest p-EVES designs to current optical LVAs. In due course, the results of this clinical trial should provide evidence that will help facilitate evidence based provision of low vision care.

A strength of this study is the contribution of service users to identifying the importance of the topic, and assisting in the design of the study to help ensure the research is relevant to those with VI. Letters of support were also provided by patient organisations when research funding was being sought. There has also been considerable support from the manufacturers of the p-EVES devices, and they are keen to gain insights into what users want from these LVAs, and how their devices can be improved.

There were a number of ways in which a RCT to compare optical magnifiers and p-EVES devices could have been designed. An alternative would have been to recruit patients with VI without previous experience of any type of magnifying aid, and randomly assign them to receive an 'optical' or 'p-EVES' device. However, patients new to rehabilitation would be likely to have relatively mild visual loss and possibly a limited range of tasks with which they

were finding difficulty at that stage. Furthermore, many such patients would be likely to have accessed devices from the local community ahead of any formal NHS clinic evaluation, with few patients being truly without any experience of devices. Another possibility which was considered was to recruit experienced optical aid users, and randomise to a 'real' or 'sham' p-EVES device. Discussions were carried out with manufacturers to assess whether a realistic 'sham' device could be created. The most plausible would have been a device which offered a display with 1.6x magnification, but the high and variable contrast image, which is independent of external illumination, may in itself have been beneficial to some participants.

The study design chosen for the trial does have limitations. For example, it may bias against the p-EVES since participants will already be familiar with optical aids, and may be reluctant to change; alternatively previous LVA experience may assist in p-EVES device handling. Also, with the cross-over trial design used it is not possible to mask either participants or researchers to the fact that the p-EVES device is being used, introducing the possibility of bias. However, the intervention is delivered by the clinician researcher whilst outcomes are measured by a different individual (the study researcher). The study researcher is not aware of any of the findings of the clinician researcher. So, for example, only the clinician researcher knows how well or how poorly the subject reacted to the p-EVES when it was first demonstrated and what problems and difficulties have been reported during the follow-up telephone calls. In addition, the audio recording procedure allows for masked re-analysis of the reading speed data (ReST and MNRead).

There is a risk with a single-site trial within a specialist centre that the results may not be directly applicable to a more general population with VI. Similarly, the assessment, prescribing, and practice sessions within a tightly controlled RCT may not be directly transferable to clinical practice and the real world implementation in a healthcare setting outside a trial. However, the trial is being conducted in a typical hospital-based LV service and it is hoped that the profile of patients recruited to the trial will be representative of the population with VI, and therefore the results of the trial will be generally applicable.

A recent systematic review of the effectiveness of low vision service provision identified the use of 47 different outcome measures in the studies evaluated.<sup>48</sup> This review highlights the current lack of consensus on the best outcome measures to use in the evaluation of low vision rehabilitation programs. In the absence of a preferred methodology for such a study, one strength of the current design is the range of outcome measures, each of which is designed to explore a different aspect of the intervention. It is hoped that this approach will give an insight into which

outcome measures are most informative, so that this information can be used when planning subsequent studies. The use of mixed methods also allows exploration of contradictory or unusual findings; for example, to explore why a device allows a better measured performance but is not popular with users.

The primary outcome measure is reading speed, but this is being measured in several different ways in order to fully determine its significance. The MNRead was chosen as the primary outcome measure because it could be applied to all participants, regardless of their level of vision, and with the minimum of non-visual influence. However the ReST may give a more realistic measurement of leisure reading ability, in that it can highlight difficulties with the standard print size, potential fatigue with the longer paragraphs and page navigation issues such as identifying the start of lines. It was not appropriate to use a 'leisure reading' measure as a sole primary outcome however, because many individuals with VI use audiobooks and/or talking newspapers for these tasks.

Whilst MNRead may give an indication of 'spot-reading' ability, it is important to assess how this is incorporated into everyday activities; therefore 5-TIADL tasks are included in the study. These tasks also involve reading, but this time as applied to a practical task where use of any magnifying device may be difficult to combine with the positioning, posture and handling requirements of the activity. Similarly, the NV-VPQ-15 will also provide a measure of the difficulties experienced when applying magnifying aids in everyday circumstances.

Whilst there is no standard way in which qualitative methods are used in an RCT, it is recognised that their inclusion can have many advantages.<sup>49</sup> In this study, planned individual interviews will provide a more complete picture of the participant's experiences during the trial. It gives the opportunity to explore user reactions such as 'it changed my life' and '...it's given him his life back...he was very low-spirited' (from the pre-study focus group) which can be difficult to capture using quantitative outcome measures alone. The more general discussion around participants' experiences of visual impairment and rehabilitation may also generate further research questions for future studies.

The 2-month period using the device was based on the reports of users in the pre-study focus groups that the p-EVES devices were simple to use and that it only required a few days to become comfortable with using them, and that 2 months was sufficient time to evaluate how the devices could be used in their everyday lives. A 2 month period also means that the overall study can be completed within a relatively short time, and that results can be promptly disseminated into practice. However, this limited time period means that it is not possible to investigate



whether supplying a p-EVES device changes the pattern of a patient's visits to the low vision clinic, or the number of magnifier changes which they require. It is also less likely that information can be provided regarding the long-term reliability of the p-EVES (e.g. do batteries stop recharging, or screens develop faults). The relatively short study period does however mean that manufacturers can be given useful information to develop new devices in a timely fashion.

The results from this trial may help community practitioners (that can currently provide p-EVES devices privately) decide on the best options for their patients. In addition, if findings are positive and p-EVES are found to be effective and cost-effective, it may be that p-EVES could be made available through existing hospital and community NHS funded low vision clinics. The precedent of the Low Vision Service Wales has provided evidence that this funding is feasible in one region of the UK, the manufacturers can make devices available in bulk, and practitioners already possess most of the necessary skills to implement the intervention. The potential therefore exists for the results to be translated into changes in service delivery within a short period of time, if any clinical benefit is established.

No NICE guidance currently exist regarding low vision devices. However, the new Evaluation Pathway Programme for Medical Technologies' aims to 'identify new or innovative technologies that may offer advantages to patients and/or to the National Health Service'. A notification of p-EVES to NICE was made by a manufacturer in summer 2011. The findings of this research will be reported to NICE to inform any future decisions made on whether p-EVES devices should be included in the armory of devices available through the NHS to help support those with visual impairment. In addition, information from this trial may provide information useful to the commissioners of services aiming to meet the requirements of the Joint Strategic Needs Assessment for Eye Care and Sight Loss Services.<sup>20</sup>

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The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

### References

1. World Health Organisation. *Global trends in the magnitude of visual impairment and blindness*. 2014. <http://www.who.int/blindness/causes/trends/en>, accessed 14/3/14.
2. UK Vision Strategy. *Outcome 2 2014*. <http://www.vision2020uk.org.uk/UKVisionStrategy/page.asp?section=258&sectionTitle=Outcome+2>, accessed 18/4/14.
3. Evans JR, Fletcher AE & Wormald RPL. Depression and anxiety in visually impaired older people. *Ophthalmology* 2007; 114: 283–288.
4. Fiske A, Wetherell JL & Gatz M. Depression in older adults. *Annu Rev Clin Psychol* 2009; 5: 363–389.
5. Rovner BW, Catten RJ, Hegel MT, Massof RW, Leiby BE & Tasman WS. Improving function in age-related macular degeneration – design and methods of a randomised clinical trial. *Contemp Clin Trials* 2011; 32: 196–203.
6. Wolffsohn JS & Peterson RC. A review of current knowledge on Electronic Vision Enhancement Systems for the visually impaired. *Ophthalmic Physiol Opt* 2003; 23: 35–42.
7. Vigliani G, Acosta R, Grover LL, Bentley SA & Giacomelli G. Reading aids for adults with low vision. *Cochrane Database Syst Rev* 2013, Art.No.: CD003303.
8. Ehrlich D. A comparative study in the use of closed-circuit television reading machines and optical aids by patients with retinitis pigmentosa and maculopathy. *Ophthalmic Physiol Opt* 1987; 7: 293–302.
9. Goodrich GL & Kirby J. A comparison of patient performance and preference: optical devices, handheld CCTV (Innovations Magni-Cam) or stand-mounted CCTV (Optelec Clearview or TSI Genie). *Optometry* 2003; 72: 519–528.
10. Cullham LE, Chabra A & Rubin GS. Clinical performance of electronic, head-mounted, low vision devices. *Ophthalmic Physiol Opt* 2004; 24: 281–290.
11. Peterson RC, Wolffsohn JW, Rubinstein M & Lowe J. Benefits of electronic vision enhancement systems (EVES) for the visually impaired. *Am J Ophthalmol* 2003; 136: 1129–1135.
12. Cullham LE, Chabra A & Rubin GS. Users' subjective evaluation of electronic vision enhancement systems. *Ophthalmic Physiol Opt* 2009; 29: 138–148.
13. Charlton M, Jenkins DR, Rhodes C, Martin-Smith T & Ryan B. The Welsh low vision service—a summary. *Optom Pract* 2001; 12: 29–38.
14. INVOLVE. *Guiding Notes for Researchers Involving the Public in NHS, Public Health and Social Care Research*.

- INVOLVE. Banleigh, 2012. <http://www.invo.org.uk/wp-content/uploads/2012/04/INVOLVEbriefingNotesApr2012.pdf>, accessed 18/4/14.
15. California Central Visual Field Test. <http://www.mattngly-lowvision.com/content.cfm?n=mpfl>, accessed 18/4/14.
  16. Cole RJ. Modifications to the Fletcher Central Field Test for patients with low vision. *J Vis Impair Blind* 2008; 102: 659.
  17. Harper R, Doordyn K, Reeves B & Sater L. Evaluating the outcomes of low vision rehabilitation. *Ophthalmic Physiol Opt* 1999; 19: 3–11.
  18. Addenbrooke's Cognitive Examination (ACE) III. 2012. <http://neura.edu.au/sites/neura.edu.au/files/page-download/ACE-III%20Administration%20%28UK%29.pdf>, accessed 14/4/14.
  19. Smith BW, Dalen J, Wiggins K, Tooley E, Christopher F & Bernard J. The Brief Resilience Scale: assessing the ability to bounce back. *Int J Behav Med* 2008; 15: 194–200.
  20. Dickinson CM & Shim M. The influence of manual dexterity on reading speed with a hand-held magnifier. *Invest Ophthalmol Vis Sci* 2007; 48: 4368–4374.
  21. Nguyen NX & Trauzettel-Klosinski S. Effectiveness of magnifying low vision aids in patients with age-related macular degeneration. *Neuro-ophthalmology* 2009; 33: 115–119.
  22. Nguyen NX, Weismann M & Trauzettel-Klosinski S. Improvement of reading speed after providing of low vision aids in patients with age-related macular degeneration. *Acta Ophthalmol* 2009; 87: 849–853.
  23. Hahn GA, Penka D, Gehrlich C et al. New standardized tests for assessing reading performance in four European languages. *Br J Ophthalmol* 2006; 90: 480–484.
  24. Trauzettel-Klosinski S, Dietz K & the IReST Study Group. Standardized assessment of reading performance: the new International Reading Speed Texts IReST. *Invest Ophthalmol Vis Sci* 2012; 53: 5452–5461.
  25. Watson GR, de l'Aunne W, Long S, Maino J & Stelmack J. Veterans' use of low vision devices for reading. *Optom Vis Sci* 1997; 74: 260–265.
  26. Owley C, McGwin G, Sloane ME, Salvey BT & Wells J. Timed instrumental activities of daily living tasks: relationship to visual function in older adults. *Optom Vis Sci* 2001; 78: 350–359.
  27. Owley C, Sloane M, McGwin G & Ball K. Timed instrumental activities of daily living tasks: relationship to cognitive function and everyday performance assessments in older adults. *Gerontology* 2002; 48: 254–265.
  28. Stelmack JA, Tang XC, Reda DJ, Rinne S, Mancil RM & Massof RW. Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT). *Arch Ophthalmol* 2008; 126: 608–617.
  29. Stelmack JA & Massof RW. Using the VA LV VFQ-48 and LV VFQ-20 in low vision rehabilitation. *Optom Vis Sci* 2007; 84: 705–709.
  30. Ahn SJ, Legge GE & Luebker A. Printed cards for measuring low-vision reading speed. *Vision Res* 1995; 35: 1939–1944.
  31. EQ-5D. <http://www.euroqol.org>, accessed 14/4/14.
  32. National Institute for Health and Clinical Excellence. Guide to the Methods of Technical Appraisal. National Institute for Health and Clinical Excellence: London, 2008.
  33. National Institute for Health and Care Excellence. Guide to the Methods of Technology Appraisal. National Institute for Health and Care Excellence: London, 2013. <http://publications.nice.org.uk/guide-to-the-methods-of-technology-appraisal-2013-pmg9>, accessed 14/3/14.
  34. Fenwick E, O'Brien B & Briggs A. Cost-effectiveness acceptability curves – facts, fallacies and frequently asked questions. *Health Econ* 2004; 13: 405–415.
  35. Misajon R, Hawthorne G, Richardson J et al. Vision and quality of life: the development of a utility measure. *Invest Ophthalmol Vis Sci* 2005; 46: 4007–4015.
  36. Al-Janabi H, Flynn T & Coast J. Development of a self-report measure of capability wellbeing for adults: the ICE-CAP-A. *Qual Life Res* 2012; 21: 167–176.
  37. Peacock S, Misajon R, Lezzi A, Richardson J, Hawthorne G & Keefe J. Vision and quality of life: development of methods for the VisQoL vision-related utility instrument. *Ophthalmic Epidemiol* 2008; 15: 218–223.
  38. Bonignone M, Barkow K, Jensen F & Heun R. Validity of the five-item WHO Well-being Index (WHO-5) in an elderly population. *Eur Arch Psychiatry Clin Neurosci* 2001; 251(Suppl. 2): 27–31.
  39. Coast J, Peters TJ, Natarajan L, Spurgeon K & Flynn T. An assessment of the construct validity of the descriptive system for the ICECAP capability measure for older people. *Qual Life Res* 2008; 17: 967–976.
  40. Campbell M, Fitzpatrick R, Haines A et al. Framework for the design and evaluation of complex interventions to improve health. *BMJ* 2000; 321: 694–696.
  41. Hernandez-Trillo A. *The impact of psychological factors on adaptation and quality of life with visual impairment*. 2011. PhD Thesis, University of Manchester.
  42. Smith HJ, Dickinson CM, Cache I, Reeves BC & Harper RA. A randomized controlled trial to determine the effectiveness of prism relocation spectacles for patients with age-related macular degeneration. *Arch Ophthalmol* 2005; 123: 1042–1050.
  43. Glaser BK & Strauss AL. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Aldine Publishing Company: Chicago, IL, 1967.
  44. Westerman SJ & Davies DR. Acquisition and application of new technology skills: the influence of age. *Occup Med* 2000; 50: 478–482.
  45. Russell D, Hoare ZSI, Whitaker RH, Whitaker CJ & Russell IT. Generalised method for adaptive randomisation in clinical trials. *Stat Med* 2011; 30: 922–934.
  46. Senn S. *Cross-Over Trials in Clinical Research*, 2nd edn. Wiley: New York, 2002.
  47. Senn SJ. The AB/BA crossover: how to perform the two-stage analysis if you can't be persuaded that you shouldn't. In: *Liber Amicorum Roel van Strik* (Hansen B & De Ridder

- M, editors), Erasmus University, Rotterdam, The Netherlands, 1996; pp. 98–100.
48. Binns AM, Bunce C, Dickinson C *et al*. How effective is low vision service provision? A systematic review *Surv Ophthalmol* 2012; 57: 34–65.
  49. Lewin S, Glenton C, & Oxman AD. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *BMJ* 2009; 339: b3496.
  50. UK Vision Strategy. *Commissioning guide for eye care and sight loss services*. 2014. <http://www.commissioningforeye.org.uk/com.nho.me.asp?section=175&sectionTitle=Health+and+Wellbeing+Boards>, accessed 14/3/14.
  51. Reischies FM & Geiselman B. Age-related cognitive decline and vision impairment affecting the detection of dementia syndrome in old age. *Br J Psychol* 1997; 171: 449–451.

### Supporting Information

Additional Supporting Information may be found in the online version of this article

**Table S1.** 5-TIADL Tasks.

**Table S2.** Scale for grading accuracy of 5-TIADL tasks.

**Appendix 2: List of p-EVES devices initially identified as on the market.**

Amigo	Enhanced Vision
Pebble	
Pebble Mini	
Assist Vision Slider	Assist Vision
Aukay	Aumed
Eye-C	
Snow	Zoomax
Capture	
Compact Mini	Optelec
Compact +	
Compact 4HD	
Compact 5HD	
Compact 7HD	
Crystal	Ash Technologies
Crystal Plus	
Crystal XL	
Quicklook 2GO	
Quicklook Zoom	
e-mag 34	Schweizer
e-mag 43	
e-mag 70	
Mano	Reinecker
Minimax	
i-loview	Ai-squared
i-loview more	
Smartview mobile	Humanware
Smartview versa	
Smartview versa +	
Boost	Ablenet aids
Ruby	Freedom Scientific
Sapphire	
Looky	Rehan Electronics
Looky +	
Explore	Bierley
Maggie Pro	
Maggie MD	
Shoppa	
Strix	Freedom Vision Inc

### **Appendix 3: Script for focus group**

#### **Focus Group 19/02/2013**

##### **Script**

1<sup>st</sup> device:

What did you like the most about this device?

What did you like the least about this device?

Talking points:

- Layout/design of device
- Image quality
- Writing with the device
- Portability
- Reading matte paper vs reading glossy paper

**(Complete the above questions for each device)**

More general:

- Name your favourite three devices from today's session in rank order (favourite first).

**Appendix 4: Manufacturers specifications from their websites for the main study p-EVES devices**

**Compact 4HD**



- manufacturer = optelec
- screen size = 4.3 inches
- magnification = 1.7x – 12x
- Consists of two parts- viewer and detachable stand
- High contrast semi colours for easier reading
- 3 hours rechargeable battery
- Snapshot feature

**Compact +**



- manufacturer = optelec
- screen size = 4.3 inches
- magnification = 5x, 7.5x and 10x
- 5 high contrast viewing options
- 3 hours rechargeable battery
- Snapshot feature

eMAG 43



manufacturer = schweizer

screen size = 4.3 inches

magnification = 2x – 14x in three steps

5 high contrast viewing options

3 hours rechargeable battery

Snapshot feature

Mobilux Digital



screen size = 4.3 inches

magnification = 3x, 4x and 6x

5 high contrast viewing options

3 hours rechargeable battery

Snapshot feature

**Appendix 5: Difficulties Questionnaire**

**Difficulties Questionnaire**

**Px Number:**

**Magnifier:**

**Date:**

**How many times have you used your magnifier(s) each day on average?**

Not using      1-2      2-5      5-10      >10

**Where have you used it?**

In home      In work      Outside the home

**How easy have you found it/them to use?**

Very difficult      relatively difficult      relatively easy      very easy

**Do you experience any of the following difficulties with the device/your magnifiers:**

Appearance looks odd/self-conscious about using it

Worried about loss/breakage/damage

Weight

Difficult to hold/poor grip or handle

Technical problems (device not working or didn't know how to operate it) **BOOK A VISIT FOR REPLACEMENT OF AID/ RE-INSTRUCTION**

Difficult to operate/switches or controls poorly positioned

Too bright/not bright enough

Doesn't help vision enough

Too small a screen/field of view

Apparent movement/smearing of the image

Eyes felt uncomfortable/headaches

Any others?



**Do you agree or disagree with any of these descriptions for the device/your magnifiers?**

Good magnification (for your vision)

Good contrast

Good field of view/screen size

Easy to operate

Suitable for the task you need to do

Easy to understand how to use it

Good size to carry around

Attractive appearance

Doesn't look like a magnifier

**Any other comments?**

**Appendix 6: Contrast and magnification features of the p-EVES devices in the main study**

p-EVES	Manufacturer's Magnification Settings	Colour/Contrast options
Compact+	Fixed settings 5x,7.5x and 10x	Full colour, white on black, black on white, yellow on black, yellow on blue.
Compact 4HD	Continuous zoom 1.7x-12x	Full colour, white on black, black on white, yellow on black, yellow on blue.
eMAG 43	Various settings dependent on location of handle and working distance. Range from 2x-14x	Full colour, white on black, black on white, yellow on black, yellow on blue.
Mobilux Digital	Fixed settings 3x, 4.5x and 6x.	Full colour, white on black, black on white, black on yellow, yellow on black

## **Appendix 7: CCVFT manufacturer's instructions**

### **Indications for Using the California Central Visual Field Test**

Suspected central field defects:

Macular disease including age-related macular degeneration and diabetic retinopathy (ischemic maculopathy and post focal laser photocoagulation).

Optic neuropathies, including glaucoma.

Difficulty with word and letter misidentification in spite of adequate magnification.

Difficulty with page navigation (losing place, skipping lines, rereading text, etc.).

Slow reading that may be caused by scotomas.

Need for education of patient in location of scotomas and compensatory eye movements to avoid scotomas.

### **Instructions for Administering the California Central Visual Field Test**

When the plastic holder is used, insert one of the three tangent field testing forms in the plastic holder (3 laminated original tangent forms are included – please copy them for testing and recording purposes). Choose the form with the smallest central fixation black dot that the patient can comfortably perceive (generally the small dot to 20/200, medium dot to 20/400 and the large dot for acuities worse than 20/400). Make a second copy of the form for use as a recording form.

Place the plastic holder on a table or surface between the patient and the examiner, with the form facing the patient. The distance from the test form to the patient eyes should be 57cm (22 inches), which will allow the visual field designations on the form to be accurate.

Instruct the patient to strictly maintain their best possible fixation/attention on the black central fixation dot. Patients will either see the central dot with their fovea if they have no appreciable dense scotoma and may therefore hold fixation in a steady fashion, or if they have a dense central scotoma, they may search for the central dot with a peripheral retinal locus (PRL) and once they settle on a view, it may be very difficult for them to hold it steady without prior fixation training. Continue to encourage them to maintain that view and fixation. It is worth noting this viewing posture for future training and education. It is important for the patient to see the target and not guess where the center is and prompt them frequently if fixation is very unsteady. If they cannot see the target it would be better to choose the next larger fixation spot.

The examiner should flash stimuli onto the back of the testing form. Flashes should be of very brief duration (longer duration stimuli will have an increased chance of allowing a scotoma to be moved and smeared across a larger retinal area). It may aid to keep the laser pointer steady by holding it in two hands or resting it against your forehead. When the patient sees a stimulus, they should tap on the table or use a clicker to indicate that it was seen. The laser pointers have a slightly audible click when flashing stimuli, hence an occasional presentation of a stimulus that does not show on the testing form, altering the rhythm/intervals of the stimulus presentation, and presenting laser flashes at random locations on the testing form will help prevent the patient from responding to the click instead of what is seen or anticipating the next stimulus flashed.

The field test stimuli can be administered in any order deemed appropriate for the particular patient's situation: (1) For example, some patients with profound visual impairment with very large scotomas as from disciform macular degeneration, may be best introduced to the test by presenting the largest brightest spot first and then additional testing can be done after the position of the dense scotomas is established. This approach could also be used for patients with profound contrast sensitivity loss but with only moderate vision loss, which may be seen in advanced atrophic macular degeneration or advanced glaucoma; (2) another example would be for patients with minimal impairment, where it may be most efficient to start with the dimmest stimuli and if all presentations are seen by the patient, then it can be assumed they will also be able to see the brighter stimuli.

Whatever presentation order is used:

Be sure to record which laser pointer was used for the area of scotoma indicated on the report. Laser Pointer #1 (dimmiest - white colored pointer with 1mm cap hole with dark density filter), Laser Pointer #2 (mid level - matte silver colored pointer with 1mm cap hole with medium density filter) or Laser Pointer #3 (brightest - black colored pointer with 3mm cap hole with no filter).

With the dimmer spot sizes, the examiner can produce three isopters and identify more subtle scotomas. With detailed testing using several isopters, it may be appropriate to bill a higher level visual field CPT test code on insurance billing.

The laser light can be seen by both the patient and examiner (as well as family or other people observing from behind the examiner). This allows the examiner to see if the patient's fixation is steady, and to correct any wandering eye movements during the testing. It may be helpful to provide prompts to the patient when necessary to "look at the black dot in the center of the paper" (the patient may try to look for the laser light before presentation). The scotoma pattern can be approximated on the testing/recording form. This will not be as precise as an SLO with eye tracking but is a very good estimate of scotomas.

The test may be administered either monocularly or binocularly. Testing the patient who has vision in both eyes in a binocular manner has some advantages over monocular testing. This provides very helpful information about the patient's central field as they are using it in activities of daily living. (We perform most activities with both eyes open). The central fields recorded monocularly, and the binocularly are often uniquely different, and when combined with observing the patient's fixation, a great deal can be learned about the patient's compensatory techniques. This is an advantage over the monocular testing of the SLO.

Test especially carefully in the 5 degree area to the right and left of fixation. This is the critical field used for reading.

Draw crude isopter lines on the recording form according to the pattern of response the patient gives. Make sure isopter lines are drawn as if the patient was looking at them. Areas where the stimulus was not appreciated with Laser Pointer #3 can be labeled dense scotomas ("DS") - see Recording Example #1 (page 7). Areas where the stimulus was not appreciated with Laser Pointer #1 or #2 (but was appreciated with Laser Pointer #3) can be labeled relative scotomas ("RS") - see Recording Example #2 (page 8).

Do not ignore any missed stimuli - they are likely significant. The same area of the testing form may alternately test positive and negative for appreciation of the stimulus due to unavoidable movement of the eye.

Sustained (kinetic) stimuli are very slowly extinguished by the visual system and not generally useful for the initial evaluation. But...once scotomas have been identified by the flashing technique, kinetic stimuli can sometimes be useful to outline the margins of very large scotomas. Present the stimulus inside the large scotoma and move it out toward seeing areas. As the patient indicates the stimulus being perceived, the margins of large scotomas can be identified.

Remember that scotomas move with movement of the eyes. Since fixation is frequently unsteady and the eyes move, using arrows on the recording sheet to indicate observed shifts in areas of misses can be helpful when developing strategies during scotoma training.

This test has been useful for identifying central islands of vision surrounded by ring scotomas. Feedback to patients on the presence of these ring scotomas is very useful.

Central islands are common and if the patient is missing everywhere on the test page and appear to be fixating centrally, carefully explore the central 5 degrees as they may have a central island from AMD with geographic atrophy or a very small central field from RP or glaucoma. If it is a poor functioning central island a brighter stimulus may need to be used. Once a central island is found, search for more peripheral areas of remaining vision that may be present in situations of a ring scotoma. See Recording Example #3 (page 9).

The test distance is 57 cm and therefore a near addition correction of approximately +1.75D would be expected, however when considering the reduced visual acuity of low vision patients, the blur induced by wearing the habitual distance correction should not interfere with viewing the target. Also, viewing above the bifocal segment will maintain a comfortable and straight ahead line of sight throughout testing. Care should be taken to not view through the top edge of the bifocal, as this can cause a double image of the laser spot.

It is important to recognize that patient detection of the laser spot on the test page is significantly impacted by room lighting. Brighter lighting will decrease contrast and reduce visibility of the stimulus, and decreased lighting will increase contrast and increase visibility of the stimulus. This effect can be used by the examiner to enhance or decrease the patient's detection of the spot.