DETERMINING WHICH FACTORS INFLUENCE THE OPTIMUM MULTIFOCAL CONTACT LENS CORRECTION FOR PRESBYOPIA

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Summary:

Presbyopia is a consequence of ageing and is therefore increasing in prevalence due to an increase in the ageing population. Of the many methods available to manage presbyopia, the use of contact lenses is indeed a tried and tested reversible option for those wishing to be spectacle free. Contact lens options to correct presbyopia include multifocal contact lenses and monovision. Several options have been available for many years with available guides to help choose multifocal contact lenses. However there is no comprehensive way to help the practitioner selecting the best option for an individual. An examination of the simplest way of predicting the most suitable multifocal lens for a patient will only enhance and add to the current evidence available.

The purpose of the study was to determine the current use of presbyopic correction modalities in an optometric practice population in the UK and to evaluate and compare the optical performance of four silicone hydrogel soft multifocal contact lenses and to compare multifocal performance with contact lens monovision. The presbyopic practice cohort principal forms of refractive correction were distance spectacles (with near and intermediate vision provided by a variety of other forms of correction), varifocal spectacles and unaided distance with reading spectacles, with few patients wearing contact lenses as their primary correction modality. The results of the multifocal contact lens randomised controlled trial showed that there were only minor differences in corneal physiology between the lens options. Visual acuity differences were observed for distance targets, but only for low contrast letters and under mesopic lighting conditions. At closer distances between 20cm and 67cm, the defocus curves demonstrated that there were significant differences in acuity between lens designs ($p < 0.001$) and there was an interaction between the lens design and the level of defocus ($p < 0.001$). None of the lenses showed a clear near addition, perhaps due to their more aspheric rather than zoned design. As expected, stereoacuity was reduced with monovision compared with the multifocal contact lens designs, although there were some differences between the multifocal lens designs ($p < 0.05$). Reading speed did not differ between lens designs ($F = 1.082$, $p = 0.368$), whereas there was a significant difference in critical print size ($F = 7.543$, $p < 0.001$). Glare was quantified with a novel halometer and halo size was found to significantly differ between lenses ($F = 4.101$, $p = 0.004$). The rating of iPhone image clarity was significantly different between presbyopic corrections ($p = 0.002$) as was the Near Acuity Visual Questionnaire (NAVQ) rating of near performance ($F = 3.730$, $p = 0.007$). The pupil size did not alter with contact lens design ($F = 1.614$, $p = 0.175$), but was larger in the dominant eye ($F = 5.489$, $p = 0.025$). Pupil decentration relative to the optical axis did not alter with contact lens design ($F = 0.777$, $p = 0.542$), but was also greater in the dominant eye ($F = 9.917$, $p = 0.003$). It was interesting to note that there was no difference in spherical aberrations induced between the contact lens designs ($p > 0.05$), with eye dominance ($p > 0.05$) or optical component (ocular, corneal or internal: $p > 0.05$).

In terms of subjective patient lens preference, 10 patients preferred monovision, 12 Biofinity multifocal lens, 7 Purevision 2 for Presbyopia, 4 AirOptix multifocal and 2 Oasys multifocal contact lenses. However, there were no differences in demographic factors relating to lifestyle or personality, or physiological characteristics such as pupil size or ocular aberrations as measured at baseline, which would allow a practitioner to identify which lens modality the patient would prefer. In terms of the performance of patients with their preferred lens, it emerged that Biofinity multifocal lens preferring patients had a better high contrast acuity under photopic conditions, maintained their reading speed at smaller print sizes and subjectively rated iPhone clarity as better with this lens compared with the other lens designs trialled. Patients who preferred monovision had a lower acuity across a range of distances and a larger area of glare than those patients preferring other lens designs that was unexplained by the clinical metrics measured. However, it seemed that a complex interaction of aberrations may drive lens preference. New clinical tests or more diverse lens designs which may allow practitioners to prescribe patients the presbyopic contact lens option that will work best for them first time remains a hope for the future.

Key words: multifocal; monovision; presbyopia; accommodation; contact lenses.

Dedications

This doctorate is dedicated to my Mum, Dad, my wife Riffath and my three daughters, Shaakirah, Raheema, and Aleeyah.

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LIST OF ABBREVIATIONS

AirOptix	Air Optix AQUA multifocal
Bioinfinity	Biofinity multifocal
Oasys	Acuvue OASYS for Presbyopia
Purevision 2	PureVision 2 for Presbyopia
Purevision	PureVision multifocal
Monovision	Biofinity single vision
MF	Multifocal contact lenses
MV	Monovision
VA	Visual acuity
NVA	Near Visual Acuity
CSF	Contrast sensitivity function
IVA	Intermediate visual acuity
D	Distance
I	Intermediate
N	Near
ADD	Addition
Binoc	Binocular
Spex	Spectacles
mth	Month
wk	Week
hr	Hour
min	Minutes
Yr	Year
2X exp	Two experimental
vs	compared to
SV	Single vision spectacle lenses
BIF	Bifocal spectacle lenses
PAL	Progressive spectacle lenses
QOL	Quality of Life
QoV	Quality of Vision
Qs	Questionnaire
GP	Rigid gas permeable
BF	Bifocal contact lenses
MTF	Modulation transfer function
SD	Standard deviation
NAVQ	Near Acuity Visual Questionnaire

CLs	Contact lenses
CL	Contact lens
CLAOJ	The CLAO Journal
OVS	Optometry & Vision Science
CXO	Clinical and Experimental Optometry
OPO	Ophthalmic & Physiological Optics
CLAE	Contact Lens & Anterior Eye
IOVS	Investigative Ophthalmology & Visual Science
Eye CL	Eye & Contact Lens: Scientific & Clinical Practice
J. Mod Opt	Journal of Modern Optics
Optometry	Optometry-Journal of the American Optometric Association
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CHAPTER 1:

1. INTRODUCTION

There has been a steady continuous increase in the presbyopic population in Europe. There has been an increase of 2.3% from 1998 to 2009 in the 50 to 65 years age group with 18.9% of the European population in the same age interval (Eurostats, 2010).

Contact lens correction for presbyopia offers a wide range of options including monovision, translating or simultaneous vision contact lenses. Multifocal contact lens and monovision wearing success has been explored from different perspectives: objective retinal image quality analysis (Gispets et al., 2002), psychophysical measures of visual quality (Ueda and Inagaki, 2007; Sanders et al., 2008) and subjective visual satisfaction (Papas et al., 2009; Back et al., 1989; Sheedy et al., 1991; Situ et al., 2003; Richdale et al., 2006; Gupta et al., 2009).

This thesis will examine attempts to correct the decrease in the focus of the eye with age using contact lenses. These lenses have been marketed for many years, with changes in design aimed to improve the range of clear focus, while minimising adverse effects such as a loss of contrast sensitivity and glare symptoms. However, as will be identified, there is little comparison between these designs worn by the same individuals, nor have factors been identified relating to a patient which predict which design is likely to work best for them.

The current use of presbyopic corrections by patients from an optometric practice was examined and how this related to their vision-related quality of life.

A cross-over and double masked study was designed in order to evaluate visual satisfaction and wearing success with 4 types of simultaneous image multifocal contact lenses: Acuvue for Presbyopia (Johnson & Johnson Visioncare, Jacksonville, FL, USA), Biofinity multifocal (Cooper Vision, Pleasanton, CA, US), PureVision 2 for Presbyopia (Bausch & Lomb, Rochester, NY, USA), AirOptix (AO) multifocal (Alcon, Fort Worth, TX, USA) and monovision - Biofinity single vision (Cooper Vision, Pleasanton, CA, USA). In this way different centre-distance and centre-near multifocal lenses could be compared with each other and monovision correction. A comprehensive battery of tests was conducted while the patient was wearing each lens. The patient was also instructed to give a preference from all 5 modes of correction and this along with optimal visual performance with the different contact lenses for presbyopia was related back to baseline measures to determine whether this could have been predicted.

1.1. ACCOMMODATION

Accommodation is the ability to alter the dioptric power of the eye by changes in anatomical structures in order to produce a retinal image of objects at various distances. Many theories have been proposed to explain this phenomenon but its exact mechanism has not yet been determined. The exact mechanism of accommodation and its disruption with age has been a matter of debate for several centuries (Fincham, 1937). Donders and Helmholtz describe the underlying mechanisms (Helmholtz, 1909; Donders, 1864): The view of Donders relates to the hypothesis that the ciliary muscle contraction force decreases with age causing presbyopia; while the opposing Helmholtz theory considers the resistance to the deformation of the stiffer crystalline lens due to lenticular sclerosis as the cause for presbyopia.

Recent research has confirmed that many other aspects of the lenticular structures also undergo changes with age, in addition to those previously described. This includes changes in the ciliary body shape and size (Strenk et al., 1999; Strenk et al., 2006), anterior translation of the zonular insertion onto the lens (Farnsworth and Shyne, 1979), changes in the thickness of the capsule, loss of elasticity (Krag and Anreassen, 2003; Krag et al., 1997) and continued growth in the size, mass and volume of the lenticular structure (Glasser and Campbell, 1998). Although there has been a recent discussion of alternative theories of accommodation and its changes with age; however, there is credible evidence against each of them, and the consensus of research still supports the Helmholtz theory (Glasser, 2003; Glasser and Campbell, 1998; Heys et al., 2004).

1.1.1. Helmholtz Theory of Accommodation

The more widely accepted theory of accommodation is that of Helmholtz (Helmholtz, 1855), assumes that the zonules supporting the crystalline lens are under maximal tension when the lens is at minimum optical power.

The Helmholtz theory proposes that the anterior, posterior and the equatorial zonules exert tension simultaneously. This theory states that the optical power of the crystalline lens is increased by relaxation of the tension on these zonules, while an increase in zonular tension causes a decrease in optical power. However, this theory does not explain the peripheral surface flattening and reduction in spherical aberration that have been reported to occur during accommodation (Fincham, 1937).

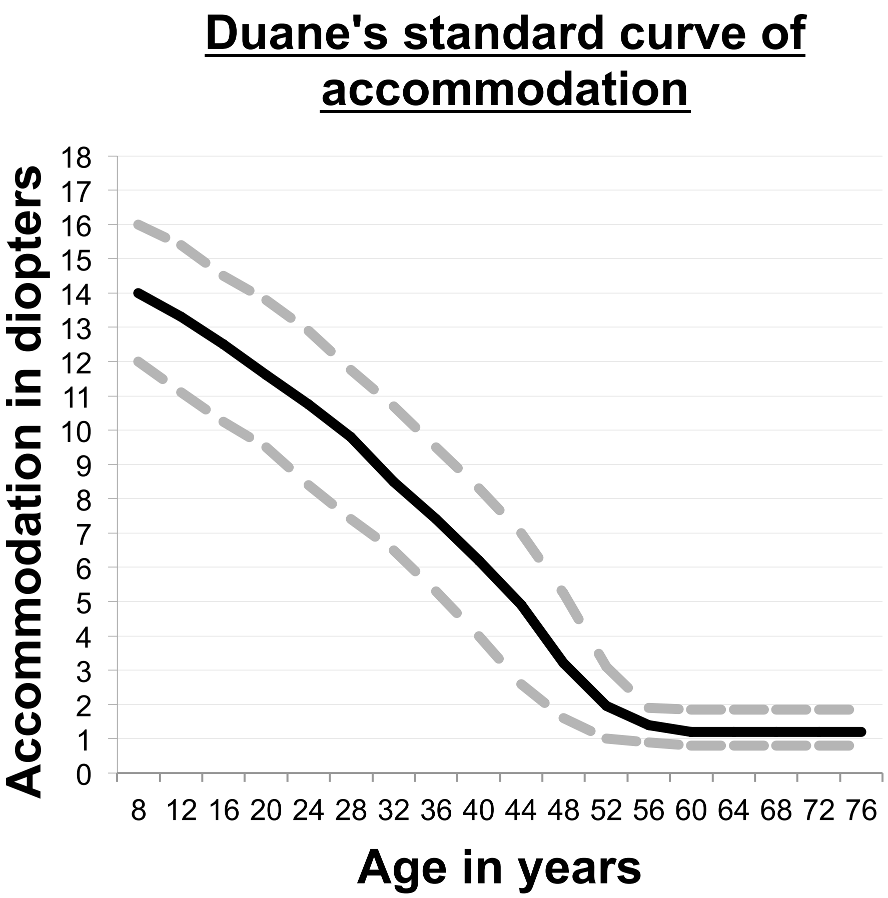

Figure 1.1: Duane's standard curve of accommodation in dioptres in relation to age in years. Mean (solid black line) and 95% confidence interval (dashed grey line) (Adapted from Duane, 1922).

1.1.2. Tscherning Theory of Accommodation

In 1894, the Danish ophthalmologist Marius Hans Erik Tscherning published his own theory of accommodation (Texier et al., 1987), which differed from

Helmholtz's theory in two basic ways:

1). When the ciliary muscle contracts, the zonules - instead of relaxing - tightens. As a result the anterior face of the crystalline lens increases its curvature to form a central lenticonus, and there is flattening of the periphery.

2). Contraction of the pupil during accommodation covers the flattened lens periphery, reducing spherical aberration (Koke, 1942).

Tscherning's theory resulted immediately in a great deal of controversy that still persists to this day (Schachar et al., 1993).

1.1.3. Gullstrand Theory of accommodation

In the first half of the 20th century, Allvar Gullstrand, a Swedish ophthalmologist proposed that a third of accommodation was due to the lens fibres themselves increasing their refractive index in the centre of the lens. If this theory was plausible, presbyopia would result from the failure of this refractive index change. However this and other new theories were not widely accepted (Atchison, 1995; Martin et al., 2005).

1.1.4. Catenary

D. Jackson Coleman proposed that the lens, zonules and anterior vitreous form a diaphragm between the anterior and vitreous chambers of the eye (Schachar and Fygenson, 2007). Ciliary muscle contraction initiates a pressure gradient between the vitreous and aqueous compartments that support the anterior lens shape in the reproducible state of a steep radius of curvature in the centre of the lens with slight flattening of the peripheral anterior lens i.e. the shape, in cross section, of a catenary. The anterior capsule and the zonules form a hammock shaped surface that is totally reproducible depending on the diameter of the ciliary body. The ciliary body thus directs the shape but does not need to support an equatorial traction force to flatten the lens (Schachar and Fygenson, 2007).

1.1.5. Schachar Theory of Accommodation

The Schachar theory of accommodation assumes that the equatorial zonules are under minimum tension when the lens is at minimum optical power (Schachar, 1992; Schachar and Anderson, 1995). The equatorial zonules apply increasing tension to the lens during accommodation. This increased equatorial zonular tension expands the equatorial diameter of the lens, alters the surface curvatures of the lens and, thereby, increases the central optical power of the lens (Glasser and Kaufman, 1999). The Schachar theory proposes that during the accommodative process increasing tension is exerted exclusively by the equatorial zonules. The anterior and posterior zonules act like the supportive ligaments of skeletal joints and are stabilizing components, which are tense during distance vision and relax during accommodation. This causes the central surfaces of the crystalline lens to steepen, the central thickness of the lens to increase and the peripheral surfaces of the lens to flatten. This results in increasing the central optical power of the lens and reducing spherical aberration (Abolmaali et al., 2007). As a result of the increased equatorial zonular tension on the lens during accommodation, the stress on the lens capsule is increased and the lens remains stable and unaffected by gravity (Schachar and Fygenson, 2007). As the equatorial diameter of the lens continuously increases throughout life, zonular tension simultaneously declines. This results in a reduction in baseline ciliary muscle length that is associated with both lens growth and increasing age. Since the ciliary muscle, like all muscles, has a length-tension relationship, the maximum force the ciliary muscle can apply decreases, as its length shortens with increasing age. This explains the decline in the accommodative amplitude that results in presbyopia (Schachar and Fygenson, 2007).

Various studies have failed to support Schachar's theory of accommodation and also studies of scleral expansion surgery have not reported any valuable restoration of accommodation (Glasser and Kaufman, 1999; Mathews, 1999).

In any experimental investigation of lens change with accommodation, it is difficult to observe the entire accommodative system. Biomicroscopic studies on living eyes provide the best images of curvature change, but the presence of the iris blocks the view of the equator where the force is applied (Brown, 1974; Koretz et al., 1997; Koretz et al., 1984). In vitro studies that have tried to simulate the process of accommodation provide similarly limited information about the ciliary muscle action (Pierscionek, 1993; 1995b). Magnetic resonance imaging (MRI) permits a view of the whole lens and the ciliary muscle without optical distortions (Koretz et al., 2004; Strenk et al., 1999). MRI methods have been used to show that lens thickness increases and lens diameter decreases with accommodation consistent with the Helmholtz theory although this study represented a small sample size (Jones et al., 2007). It is more difficult to control for vergence movements when the eye accommodates and MRI has a lower resolution and magnification compared with biomicroscopic imaging. In addition, the properties and processes of the eye are subject to change, both short term, with the dynamics of the system, and long term, as the system ages. It is possible that an element of both the theories postulated by Helmholtz and Schachar (see Figure 1.2) are correct depending on the biometry of the system, the material properties, and the direction and strength of forces (Pierscionek et al., 2005).

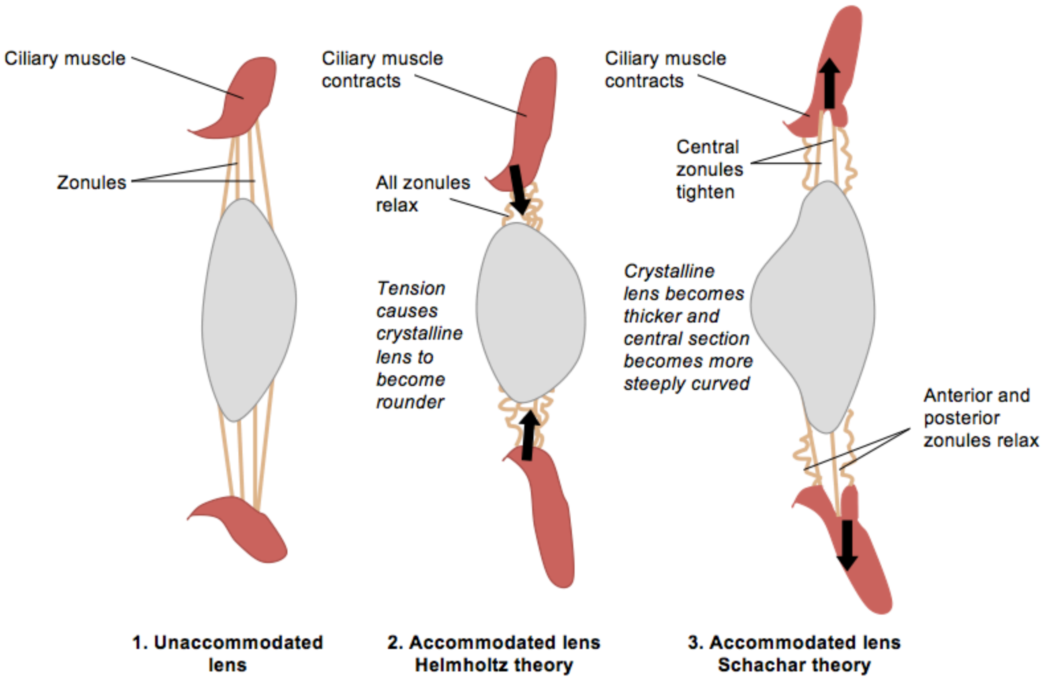

Figure 1.2: Shows a schematic representation of the difference between Helmholtz and Schachar theories (adapted from University of Waikato, 2012. www.sciencelearn.org.nz).

1.2. PRESBYOPIA

Presbyopia is undoubtedly as old as the advent of man. Aristotle referred to those affected by the condition as “presbyters,” a Greek term for the elderly. Hence presbyopia is derived from presbys meaning “old man” or “elder,” and the Neolatin suffix –opia, meaning “sightedness.” Cicero, Nepos, and Suetonius also referred to the condition (Harper, 2010). No standard definition of presbyopia exists, however a person may be considered presbyopic when near vision clarity is insufficient for their requirements (Gilmartin, 1995), usually corresponding to accommodative amplitude below 3 Dioptres (Weale, 2000).

The English friar Roger Bacon writing around 1250AD, drawing on the earlier work of Alhazen and other authors, seems to be the first European author both to state the problem that older people experience with near vision and also to provide a possible solution of seeing through the medium of crystal or glass or transparent substance (Charman, 2014). At about the same time an unknown European craftsman conceived the idea of mounting two positive lenses in a suitable frame to create the first reading spectacles for presbyopia (Charman, 2014). In the past some writers have attempted to attribute the invention of spectacles to particular named individuals such as Alessandro Della Spina, a monk who died at Pisa in 1313 but this is still a matter for debate (The College of Optometrists, 2015). Using spectacles for presbyopia made the acquisition of knowledge possible through reading and other near pursuits throughout life for intellectuals and those requiring near vision, contributing to the scientific, artistic, and social advancement of the Renaissance (Harper, 2010).

In the 1520s, Francesco Maurolico, an Italian monk, believed a flattening of the convex crystalline lens, a theory also described by Descartes and others, caused presbyopia. Henry W. Pemberton, an English physician used the term accommodation in his dissertation of 1719 agreeing with Descartes and Maurolico that it resulted from changes in crystalline lens curvature (Harper, 2010). Benjamin Franklin was reportedly behind the manufacture of the first pair of bifocals in 1784 (Callina and Reynolds, 2006). The ciliary muscle was first described in the middle of the 19th century and in 1853, Hermann von Helmholtz, published “A Theory Of Accommodation.” He observed that for seeing near objects, the contraction of the ciliary muscle allows a relaxation of the zonular fibres and consequently, a bulging of the crystalline lens because of its own elasticity, the process described as accommodation (Harper, 2010). However, research into a fuller understanding of the process and causes of presbyopia remain on going.

1.3. PREVALENCE AND FACTORS AFFECTING THE AGE-OF-ONSET OF PRESBYOPIA

There is little information on the prevalence of presbyopia in the developing countries as most studies on refractive error in these countries have been limited to distance vision (Weale, 2003). More information regarding its prevalence is available in the USA, where 76.5 million persons were born during the 19 years following World War 2 (1946 to 1964) known as the baby boomers generation (Durrie, 2006). This generation is now over the age of forty, and include many existing or soon to be presbyopes.

Over all, more than 2.0 out of 6.5 billion people are over 40 years of age around the world. However, only 1.04 billion were estimated to have presbyopia in 2005 (Holden et al., 2008). The proportion of over 60 years has risen from eight per cent in 1950 to 11 per cent in 2009 and it is estimated to be 22 per cent in 2050 (Morgan et al., 2011). Clearly as the global population ages, the prevalence of presbyopia will increase. The number of presbyopes worldwide is expected to reach 2.3 billion by the year 2020. McDonnell and colleagues (2003) have found presbyopia to be associated with very low, vision-targeted, health-related quality of life compared with younger, emmetropic subjects (McDonnell et al., 2003). Recently, Holden and co-authors (2008) have evaluated the personal and community burdens of uncorrected presbyopia (Holden et al., 2008). They estimated that globally about 1 billion people have presbyopia. Of these, nearly 410 million were prevented from performing near tasks in the way they required suggesting that presbyopia precipitates a considerable economic burden on individuals, their family and eventually their nation.

Presbyopia is widely regarded as a multifactorial process (Weale, 2003). Age is the major risk factor for the development of presbyopia, although the condition may occur prematurely in the presence of congenital, traumatic, inflammatory, vascular, neoplastic and degenerative diseases, toxins and side effects of drugs. (Table 1.1: Pointer, 1995; Slataper, 1950; Jain et al., 1979; Jain et al., 1982; Miranda, 1979; Miranda, 1980; Stevens and Bergmanson, 1989; Hunter and Shipp, 1997). However, it has been argued that studies examining the factors affecting presbyopia are prone to the effects of confounding variables (Bourne, 2007). Previous studies have correlated geographical variations such as latitude and ambient temperature with the age of onset of presbyopia. Higher ambient temperatures were associated with earlier onset of presbyopia (Weale, 2003; Miranda, 1979). Edwards and colleagues (1993) have confirmed that Hong Kong Chinese people have lower amplitudes of accommodation than Caucasians. According to the authors if presbyopia is considered to commence when the amplitude of accommodation declines to less than 5D, then presbyopia in the Chinese race occurs between the ages of 36 and 40 years. The fact that as early as in the second decade of life the amplitude of accommodation in Chinese is lower than that of Caucasians, suggests that reduced amplitude of accommodation may at least in part be due to factors other than long term environmental effects. These findings are similar to those in studies from Central America and Africa that have reported an age of onset of presbyopia early in the fourth decade rather than in the fifth (Wharton and Yorton, 1986; Nwosu, 1998). A study on the Hispanic population suggested no significant statistical difference in the age of onset and progression of presbyopia between the Hispanic and non-Hispanic patients (Carnevali and Srithaphanh, 2005). Nirmalan and colleagues (2006) performed a multivariate study and confirmed that presbyopia occurred earlier in the female sex (Nirmalan et al., 2006). However, Hickenbotham and colleagues (2012) suggest that the earlier onset of presbyopia in women was not due to a physiological difference in accommodation but rather due to other sex differences, such as tasks performed and viewing distances.

In terms of the effect of disease, Braun and colleagues (1995) demonstrated that diabetes and duration of diabetes, with increasing age, are important risk factors for reduced accommodative amplitude. An apparent transient decrease in accommodative amplitude following scatter photocoagulation occurs which should be considered when assessing the accommodative needs of patients with diabetes and when discussing its side effects (Braun et al., 1995). Amplitudes of accommodation were significantly smaller in the HIV-positive group between 26 and 35 years (Westcott et al., 2001). Toxins also seem to have an effect as Jain and colleagues (1979) found lenticular changes in 89% of the 200 hair dye users compared to 23% in the control group with an additional 7% developing early presbyopia and concluded that hair dye is potentially toxic to human lens, an observation confirmed on animal experiments.

Factors that have a potential to cause partial or complete loss of accommodation can precipitate presbyopia at an age earlier than usual. Examples are hyperopic refractive error, trauma involving crystalline lens, ciliary muscles and/or zonular fibres, drug side effects, poor nutrition and other systemic diseases (Kleinstein, 1987).

Table1.1: Factors affecting the onset of presbyopia based on current academic evidence.

Age	• Onset in Chinese 36-40yrs (Edwards et al., 1993). • Central Americans and Africans - fourth decade (Wharton and Yorton, 1986; Nwosu, 1998). • Hispanic and non-Hispanic - no difference in age of onset (Carnevali and Srithaphanh, 2005).
Hyperopia	• Additional accommodative demand (if uncorrected). • Hence presbyopia evident earlier (Pointer, 1995)
Occupation	• Closer and greater near vision demands especially in poor lighting will result in the need for presbyopic correction earlier (Hickenbotham et al., 2012).
Gender	• More near corrections in females (Pointer, 1995). • Earlier onset in females (short stature, menopause) (Hickenbotham et al., 2012).
Ocular disease or trauma	• Removal or damage to lens, zonules, or ciliary muscle (Slataper, 1950).
Systemic disease	• Diabetes and the duration of diabetes (Braun et al., 1995). • Multiple sclerosis (impaired innervation); cardiovascular accidents (impaired accommodative innervation); vascular insufficiency; myasthenia gravis; anaemia; influenza; measles; HIV positive; tuberculosis, sarcoidosis; polycythaemia; leukaemia tumours (Westcott et al., 2001).
Drugs	• Decreased accommodation is a side effect of both non-prescription and prescription drugs e.g. alcohol intake (Campbell et al., 2001), • Chlorpromazine, hydrochlorothiazide, antianxiety agents, antidepressants, antipsychotics, antispasmodics, antihistamines, diuretics (Feinberg, 1993; Thaler, 1979).
Iatrogenic factors	• Scatter (panretinal) laser photocoagulation (Braun et al., 1995). • Intraocular surgery.
Geographic factors	• Proximity to the equator (higher average annual temperatures, earlier onset (Weale, 2003). • Greater exposure to ultraviolet radiation (Hickenbotham et al., 2012).
Prescription and mode of correction	• Myopes require greater accommodation and convergence when moving from spectacles to contact lenses, bringing on presbyopia earlier as does changing a hypermetrope from contact lenses to spectacles (Hunt et al., 2006).
Other	• Poor nutrition, decompression sickness, lenticular changes caused by hair dye (Jain et al., 1979).

1.4. CORRECTION OF PRESBYOPIA WITH CONTACT LENSES.

The first soft bifocal contact lenses was available in the United States in the late 1980s (Soni et al., 2003), and has advanced in the last 30 years with visual acuity varying dependent on the design of the lens, lighting and contrast (Sheedy et al., 1991; Fischer et al., 2000; Guillon et al., 2002).

This thesis aims to understand the optical performance of multifocal contact lenses and therefore other options such as surgical or spectacles methods of correcting presbyopia are beyond the scope of this thesis. There are three basic principles involved in the contact lens mode of presbyopia correction, namely monovision, alternating image bifocals and simultaneous image multifocal contact lenses. The desire of presbyopic individuals to achieve adequate vision at all distances without the use of spectacles while retaining comfort and convenience, has led to the development of a wide range of multifocal designs. Contact lenses intended specifically for presbyopia have a wide variety of optical designs. Translating or alternating designs contain the distance and near correction in spatially distinct portions of the lens, and rely on changes in vertical eye-positioning relative to the lens to ensure that the gaze is directed through the optical portion, appropriate for a given task (Morgan et al., 2011). Such designs, which are much more common for rigid than for soft lenses, depend on a variety of factors for precise and reliable translation (Robboy and Erickson, 1987) and tend to require greater precision in fitting (Borish, 1988).

Regardless of form, all other contact lens designs are based on the principle of simultaneous vision (Charman, 2014) wherein only a portion of the light rays received at each foveal retinal locus will have vergence appropriate for the dioptric distance of the current point of regard, while the remaining rays have greater or lesser vergence (Young et al., 1990).

Simultaneous image lenses include designs that use a series of grooves forming a diffractive phase grating to create the reading addition although these are not available commercially (Cohen, 1993); concentric designs that have a centre-surround arrangement for the two lens powers necessary for the bifocal optics (Evans and Thompson, 1991); and aspheric designs that involve continuous change in power from the lens axis to the peripheral portion of the central optical zone, thereby creating a multifocal effect. Variations on these basic categories include centre-surround designs where the distance and near portions are repeated in successive zones, multiple designs where there are multiple transition zones with differing degrees of aspheric change intervening between the distance and near portions of the lens, or where the asphericity is confined to a very small portion of the lens (Charman, 2014). Some manufacturers promote different designs for each eye to increase the range of clear focus combinations available to patients. Other lens types that utilize simultaneous images for the relief of presbyopia include rigid gas permeable (RGP), hybrid multifocals (RGP surrounded by a soft “skirt”) and sclerals.

The following subsections describe each method briefly, followed by a discussion of their overall optical and visual performance characteristics.

1.4.1. Monovision

Westsmith, in late 1950’s, proposed a technique of fitting presbyopes with contact lenses, where one eye was corrected for distance and the other eye was prescribed for near, referred to as ‘monovision’. It is the most commonly employed technique by clinicians treating presbyopic patients who desire to wear contact lenses (Jain et al., 1996; Gauthier et al., 1992). However, some practitioners dislike it as it departs from the clinical goal of providing a binocular balanced correction for distance, intermediate and near objects simultaneously.

The dominant eye is fitted with the distance lens and the non-dominant eye with the near lens with the near add power for the monovision correction selected based on the near spectacle addition and the subject’s age. The dominance can be identified in various methods such as the pointing method or the sensory dominance method (Evans, 2007).

Monovision contact lens wear has been examined in several studies (Situ et al., 2003; Richdale et al., 2006; Gupta et al., 2009; Freeman and Charman, 2007; Woods et al., 2009; Fernandes et al., 2013). Regardless of the near add prescribed, all agree that stereopsis is reduced (Gupta et al., 2009; Fernandes et al., 2013), although the magnitude of this reduction seems to be less with Random dot tests (Papas et al., 2009) than stereograms (Gupta et al., 2009). Reading performance has rarely been evaluated in these studies, but Gupta and colleagues (2009)) showed that monovision performed better than a center-near aspheric simultaneous vision multifocal contact lenses of the same material for distance and near vision and the multifocal PureVision provided better stereoacuity and near range of clear vision with little differences in contrast sensitive function (CSF) which was supported by a study by Ferrer-Blasco and Madrid-Costa (2011).

A study by Josephson and Caffery (1987) found that 80% of presbyopic contact lenses wearers reported driving difficulties at night-time with monovision and multifocal contact lenses (aspheric bifocal) and Back and co-authors (1992) also found that patients wearing bifocal contact lenses experienced more haloes than wearers of monovision. Schor and colleagues (1987) found that monovision wearers at lower levels of illumination reported haloes and that the haloes reduced with increasing illumination. In addition, 17% of monovision wearers were not satisfied with monovision for driving and this level of dissatisfaction was greater at night-time due to distance vision blur and ghosting around lights (Collins et al., 1994).

The author is only aware of one objective measurement of driving performance with monovision conducted by Wood and colleagues (1998) with thirteen monovision wearers on the open road under daytime conditions. No adverse effects on sign recognition, mirror checks, lane-keeping deviations, and driving time and speed estimation were found with monovision.

Enhanced monovision occurs when one eye is given a single vision lens for the distance that is most important for the patient, and the other eye is given a multifocal lens (Franklin, 2005). Modified monovision occurs when multifocal lenses are fitted to each eye, but one is biased towards distance vision and the other towards near vision (Franklin, 2005).

The recent studies described above confirmed that the multifocal option offers similar or superior patient satisfaction by providing better stereoacuity and near range of clear vision (Gupta et al., 2009; Ferrer-Blasco and Madrid-Costa, 2010; 2011) as patient preference over monovision (Richdale et al., 2006; Situ et al., 2003).

However, these studies generally focused on comparing monovision to a single presbyopic contact lens design (Richdale et al., 2006; Gupta et al., 2009), examine limited numbers of patients (Llorente-Guillemot et al., 2012; Madrid-Costa et al., 2012) and do not fully adapt patients to lens wear before performance measurements are assessed (Chu et al., 2010; Chu et al., 2009;

Papas et al., 2009).

A comparison of monovision correction and Hydrocurve bifocal contact lenses correction found that 80% preferred the bifocal correction (Josephson and Caffery, 1987). Monovision was compared with diffractive optics bifocal lens and monovision gave better low contrast acuity and bifocal gave better stereoacuity (Papas et al., 1990). Kirschen and co-authors (1999) compared the interocular difference in visual acuity between monovision and Acuvue bifocals finding a significant decrease in the interocular difference in visual acuity at distance and near with the bifocals.

1.4.2. Alternating/Translating Designs

The translating designs employs a principle in which the main portion of the lens has a distance correction while another section has near correction. Translating images has resulted in the highest success rate of any contact lens presbyopic correction due to the quality of vision achieved at both distances (Kirman and Kirman, 1988; Remba, 1988). Non-symmetric designs have required the incorporation of prism ballast to allow the lens to be stably positioned at or near the lower lid such that the lens can be nudged superiorly with downward gaze. Theoretically the carrier portion of the correcting contact lens is pushed up by the lower lid upon down gaze, resulting in lens decentration (Bennett, 2010). The corrective lenses move when the gaze is directed from distance to near, or from near to distance, to provide a constant focused image. This requires smooth lens translation to provide the eye with distance and near segments as required. Whilst this type of correction philosophy is promising as it avoids pupil sharing of optical zones at all times, the translation of the contact lenses is difficult to control and near vision cannot be obtained for all directions of gaze.

Newer segmented translating designs are available with the ability to provide intermediate correction while the introduction of a hybrid design provides an option when a RGP results in either poor centration or excessive subjective awareness (Bennett, 2010).

Bifocal RGP contact lenses provide superior visual performance than a simultaneous image bifocal lens when comparing near visual acuities (Ueda and Inagaki, 2007).

1.4.3. Simultaneous Designs

The simultaneous images mode of presbyopic contact lens correction includes diffractive and concentric bifocals as well as aspheric multifocal designs. These lenses do not require translation, as they position the distance, intermediate (if multifocal) and near optical portion over the pupil at all times. Consequently, both the in- and out- of-focus images are simultaneously present on the retina leaving the brain to organize and adapt to the complex light distribution (a form of selected suppression).

1.4.3.1. Refractive

Concentric or annular contact lenses are designed with a central zone, which provides either distance or near power, surrounded by a peripheral annulus allowing for either near or distance vision, respectively (Gispets et al., 2011). Their performance is affected by pupil size and lens position relative to the optical axis of the eye. As described above, the major problem of this modality is that the in-focus image of the distant, intermediate or near object is always accompanied by a superimposed out-of-focus image formed by the remainder of the lens.

Simultaneous vision contact lenses project the image set at distance and near onto the retinal plane. When viewing a distant object there is a focused image of the distant object and an out-of-focus image of the same distant object on the retina and when viewing a near object, an out-of-focus image of the near object and an out-of-focus image of the same object is formed on the retina.

A comparison of a multifocal lens with a distance contact lens and a reading spectacle concluded that Proclear multifocal lenses provided good distance and near visual acuity preserving stereopsis (Ferrer-Blasco et al., 2010; Ferrer-Blasco et al., 2011). This was replicated with a Proclear toric multifocal with single vision toric with reading spectacles suggesting that the astigmatic corrected presbyopic option provides an optimal distance and near vision quality without compromising the stereopsis (Madrid-Costa et al., 2012).

To the authors knowledge there has been very limited studies incorporating more than two multifocal lenses (Table 1.4). The only exception is a study by

Papas and co-authors (2009) that compared 4 multifocal lenses conducting a wide range of visual tests. However, there were limitations in the adaptation period being only 4 days, the range of clear focus was not quantified, the assessment of glare was non-objective and there was limited reported comparison between lenses.

1.4.3.2. Aspheric

Aspheric optics can be added to a contact lens to create simultaneous images across a range of vergences to encompass both near and distance targets.

Few studies have evaluated an aspheric multifocal profile. A centre-near aspheric multifocal contact lens design was found to be worse than monovision correction of the same material for distance and near visual acuity (Gupta et al., 2009). In contrast, Richdale and colleagues (2006) and Fernandes and co-authors (2013) found an aspheric multifocal performed better than monovision when they used a centre-distance design for the dominant eye and a centre near design for the non-dominant eye. A centre-distance multifocal aspheric contact lenses (Proclear MF) has also been shown to provide good distance and near visual acuity preserving stereopsis (Ferrer-Blasco and Madrid-Costa, 2011). However, it is not just the aberration profile of the lens that dictates visual function, but the combination of this with the aberrations of the individual’s eyes (Plainis et al., 2013). Due to these studies the investigation of the pupil centration and aberrometry were performed in this experiment.

1.4.3.3. Diffractive

Diffractive designs have multiple echelettes that focus distant images by refraction and near images by diffraction of light. While they are considered to be truly pupil-independent, the design of diffractive contact lenses involves a loss in image contrast caused by the fraction of light that goes into higher diffraction orders (Young et al., 1990). To obtain the additional optical power required for near, the back surface has a stepped profile of circular gratings incorporated into the lens. The conventional distant image formed by refraction is termed as ‘zero-order’, while the resultant near image formed by refraction at both surfaces and diffraction at the second is referred to as ‘first-order’. One key advantage of this modality is pupil independence while the large wavelength dependency of diffraction pattern is its major disadvantage however. These lenses were actively marketed during late 80's and early 90's of the last century (Harris et al., 1992), however cost made them commercially unviable and diffractive optics are not used in any current contact lens designs.

Table 1.2. summarises clinical, in-vivo studies conducted on presbyopic contact lenses in the last decade. Most examine 25 or less subjects aged 45 years and older, where some have recruited younger subjects who are unlikely to be fully presbyopic but will have reduced amplitude of accommodation. They range from non-dispensing studies where the lenses are evaluated on initial trial with no adaptation period to assessing the visual function of cohorts of habitual wearers, although the latter offers no direct comparison between lens designs. However most adopt a 1-month crossover design where lens designs can be compared in the same subjects after a period of adaptation.

Table 1.2: summarises clinical, in-vivo studies conducted on presbyopic contact lenses in the last decade (see Abbreviations page 9).

Research Study	N°	Age (Yr)	Design	Lenses	Measurements
Fernandes et al., OVS 2013	20	45-57	15 days Crossover	Biofinity MF vs Biofinity MV	VA, NVA, CSF, stereopsis
García-Lázaro et al., CXO 2013	22	50-64	Contralateral Crossover	Purevision MF vs Pinhole	VA, NVA, CSF, defocus, Photopic/mesopic, stereopsis
Plainis et al., OPO 2013	12	22-29	No adaptation Crossover	Air Optix Aqua MF: low, medium, high ADD	VA, defocus, artificial pupil, Aberrometry
Cummings et al., CLAE 2012	100	49+/-6.3yrs	1wk Crossover	Lotrofilcon B and Comfilcon A MF	Binoc VA, IVA, NVA
Madrid-Costa et al., OPO 2013	20	42-48	1mth Crossover	PureVision: low ADD vs Acuvue Oasys for Presbyopia	VA, NVA, CSF, defocus, Photopic/mesopic
Madrid-Costa et al., OVS 2012	20	45-65	1mth Crossover	Proclear MF toric vs Proclear toric with reading spex	VA, NVA, CSF +glare, Defocus, photopic/mesopic, stereopsis
Llorente-Guillemot et al., CXO 2012	20	41-60	1mth Crossover	PureVision MF high vs spex	VA, CSF+ glare, photopic/mesopic
Ferrer - Blasco et al., CXO 2011	25	50-60	1mth Crossover	Proclear MF vs dist CL and spex	VA, NVA, stereopsis
Ferrer - Blasco et al., OVS 2010	25	50-60	1mth Crossover	Proclear MF vs dist CL +spex	VA, NVA, stereopsis
Chu et al., IOVS 2010	11	45-64	No adaptation Crossover	PALs, BF spex, MF CLs	Driving metrics
Chu et al., OVS 2009	20	47-67	No adaptation Crossover	PALs, BF spex, MF CLs	Driving metrics
Woods et al., Eye CL 2009	25	38-50	1 wk Crossover	Focus MF, Monovision, Habitual, dist CLs	VA, CSF, stereopsis, reading speed, Qs
Chu et al., Eye CL 2009	255		Survey	Habitual	Survey
Papas et al., Eye CL 2009	88	40-60	4 day Crossover	Acuvue BF, Focus MF, Proclear MF, Soflens MF	VA, IVA, NVA, photopic / mesopic, stereopsis, reading speed, Qs
Gupta et al., OVS 2009	20	49-67	1 mth Crossover	PureVision MF vs Monovision	VA, IVA, NVA, CSF, reading speed, defocus, stereopsis
Freeman & Charman, CL&AE 2007	8	63+/-4	1 hr	Diffractive bifocal vs Monovision	VA, NVA, CSF, stereopsis
Ueda & Inagaki, Eye CL 2007	16		30min Crossover	GP BF vs soft BF	VA, NVA, Photopic/mesopic, Qs
Rajagopalan et al., J Mod Opt 2007	26	42-65	N=8 adapted	GP monovision, Acuvue BF, GP MF, varifocals	CSF
Rajagopalan et al., OVS 2006	32	51+/-6	N=8 adapted	GP monovision, Acuvue BF, GP MF, varifocals	CSF, +/-glare, near task performance
Richdale et al., OVS 2006	38	41-64	N=19 1mth	Soflens MF vs Monovision	VA, NVA, CSF, stereopsis
Ardaya et al., Optometry 2004	20	<45yr	Non-dispense	Acuvue BF +1.00, +1.50, +2.00, +2.50	VA, CSF
Pujol et al., OPO 2003	6	29-45		Aspheric MF vs multicurve MF	MTFs at D, I & N
Situ et al., Eye CL 2003	40		6 months	Monovision to Acuvue BF	VA, CSF
Soni et al., OVS 2003	30	40-65	1wk Crossover	Acuvue BF vs 2x exp diffractive/refractive MF	VA, CSF, Qs
Patel et al., CLAO J 2002	10		Non-dispensing	Progressive MF	Aberrations, pupil size
Guillon et al., CLAOJ 2002	45	41-68	No adaptation Crossover	Acuvue BF vs Focus MF	VA, NVA, CSF, photopic/mesopic

1.5. NEURAL ADAPTATION TO MULTIFOCAL CORRECTION

Multifocal lenses project images from far, near and potentially intermediate distances simultaneously on the retina. Neural adaptation involves the brain learning to use these different images. As the visual cortex contains no prewired circuitry to digest information from multifocal lenses, the brain requires a period of adjustment known as neural adaptation which involves suppressing near vision when viewing distant objects and restricting distance vision when focusing up close (Webster et al., 2002). Without a neural template to single out and convey the dominant percept into awareness, a period of neural adaptation is needed for the brain to put in place the neural tracks and with time the halos and the image distraction slowly decrease and disappear (Blake, 1989). While a period of adaptation with multifocal contact lenses has been suggested in order to obtain optimal visual performance (Papas et al., 2009), its duration has not been quantified.

For example, correcting the aberrations of keratoconics does not lead to the gain in visual acuity predicted (Sabesan and Yoon, 2009) perhaps due to long established neural adaptation (Sabesan and Yoon, 2010). However, it is not clear whether this would be similar to re-adaptation to vision through a less optically aberrated optic such as multifocal contact lens. Adaptation to astigmatism seems to occur, in relatively young subjects, in a matter of minutes, although the adaptation is orientation dependent (Sawides et al., 2010) and adaptation long-term memory and binocular interactive effects may occur (Yehezkel et al., 2010). However, the effect of age on ability and rate of adaptation is not clear.

1.6. TECHNIQUES USED TO ASSESS PRESBYOPIC VISUAL FUNCTION

1.6.1. Visual acuity

Visual acuity (VA) is the most commonly measured visual function and is a measure of the finest detail that can be seen (spatial resolution). Although large population-based studies have shown a decrease in VA with age (Foran et al., 2003; Klein et al., 1991) and this decline has been shown to accelerate with increased age, in early presbyopia distance VA is similar to that in early childhood (Foran et al., 2003; Haegerstrom-Portnoy, 2005). To overcome many of the shortcomings of the traditional Snellen chart, Bailey and Lovie (Bailey and Lovie, 1976) proposed a new design for visual acuity charts. This design uses 10 letters of approximately equal legibility, five to a line, spaced such that the separation between lines and between letters gives similar 'crowding' effects at all levels. This avoids the major objection to Snellen charts that the task varies at different levels (lines on chart or distances from the chart). As the letter size varies on a logarithmic scale, visual acuity can be scored according to the logMAR system. By this system, each letter correct scores -0.02 logMAR units and each correct line of five letters scores -0.1 logMAR units. The patient must read until no correct responses are made on a line and are encouraged to guess when uncertain (Kitchin and Bailey, 1981).

1.6.2. Contrast sensitivity

Contrast sensitivity better represents vision in a natural environment consisting of a diversity of contrasts, textures, borders and spatial frequencies hence contrast sensitivity is considered to be a more comprehensive measure representing visual function in real world conditions than visual acuity (Elliott, 1987), as contrast thresholds are measured for different spatial frequencies. Therefore a more complete assessment of visual capability is provided by measurement of the human contrast sensitivity function by assessing both spatial resolution and contrast sensitivity (Woods and Wood, 1995).

The Pelli-Robson chart to measure contrast sensitivity, has been used in many studies (Pelli et al., 1988). The studies show that there is little change in contrast sensitivity throughout adulthood until approximately 60 to 65 years of age (Haegerstrom-Portnoy et al., 1999), thereafter declining 0.1 log contrast sensitivity per decade (Rubin et al., 1997). Mean log contrast sensitivity was approximately 1.8 to 1.9 log contrast sensitivity in the 20's age group and around 1.8 log contrast sensitivity in the 60's age group (Elliott and Bullimore, 1993; Elliott et al., 1990).

The human visual system is able to adapt to a change in illumination by more than a factor of 10^{11} using a combination of two types of photoreceptors: rods and cones (Stockman and Sharpe, 2006). Photopic conditions are when the rod photoreceptors have been fully saturated and only the cone photoreceptors can deliver an interpretable signal (Stockman and Sharpe, 2006). Mesopic vision is more complex and depends on the outputs of both the rods and the cones. Furthermore there are differences in the properties of the post-receptoral pathways subserving the rod and cone signals before they merge (Stockman and Sharpe, 2006). A common definition of photopic conditions is a luminance level greater than 10 cd/m^2 (Uvijls et al., 2001) and by using mesopic levels referred to by Rosen to levels of illumination between 0.05 and 50 cd/m^2 (Rosen, 2002).

The level of road lighting at night is found to be in the mesopic region, between 0.5 and 10 cd/m^2 (Charman, 1996; He et al., 1997), hence measuring the performance of presbyopic correction in mesopic lighting conditions is important.

Low contrast acuity charts conventionally have grey letters on a white background. The typical difference between high (90 per cent) and low contrast (10 per cent) acuities in normal patients is just over two lines (Brown and Lovie-Kitchin, 1989).

It has been suggested that testing under low luminance conditions is more sensitive to changes in vision (Guillon et al., 1988). Greater differences between single vision (Guillon et al., 1988) and bifocal contact lens designs have been noted with low luminance-low contrast acuity tests than with conventional high luminance-high contrast tests.

As these lenses are designed to provide good vision at distance and near conditions, the visual response needs to be evaluated under both conditions. There have been few reports of an assessment of visual performance with multifocal contact lenses as a function of the illumination level (see Table 1.4).

1.6.3. Stereopsis

The ability to detect the relative depth of objects using binocular disparity is referred to as stereopsis and is important in undertaking many activities of daily living (Norman et al., 2008). The magnitude of the stereoacuity reduction with age is dependent upon the stereoscopic tests used (Ferrer-Blasco and Madrid-Costa, 2011). Most of the research on presbyopic contact lenses that has been conducted including the measurement of stereoacuity has used the Random dot method (Gupta et al., 2009; Woods et al., 2009; Richdale et al., 2006; Table 1.4). Random dot stereograms are devoid of any monocular clues, and the patient has no way of guessing what the stereofigure is and where it is located on the test plate (Blakemore and Julesz, 1971).

1.6.4. Near acuity charts

Several reading charts or reading card tests have been developed to measure reading performance, such as the Sloan M Cards, the Bailey Charts, the MNread, and the Radner Reading Charts (RRCs) (Sloan and Brown, 1963; Bailey and Lovie, 1980; Mansfield et al., 1993; Ahn et al., 1995; Radner et al., 1998). Gupta and colleagues (2009) demonstrated that results from reading charts using lowercase, capital letters or words all strongly correlated with each other, although the measured values differed. Reading metrics did not correlate with near visual acuity and therefore provide useful additional information.

Both the Radner (Radner et al., 1998) and Minnesota Near reading charts (MNRead; Lighthouse International, New York, USA) have superseded previous reading charts such as the Pepper Visual Skills for Reading Test (Baldasare et al., 1986). The popularity of these charts can be attributed to their ease of implementation and the standardization of the text used for each line of writing (Stelmack et al., 1987). Recently, the strict principles of the RRCs (Radner et al., 1998) were used to develop a Dutch-language version of these charts (Maaijwee et al., 2007), as well as versions in English, Spanish (Alió et al., 2008), Swedish and Hungarian (Burggraaff et al., 2010). Other language versions are in print or in progress (Radner et al., 2008).

There is a difference in sentence standardization between the MNread Acuity chart and RRCs. The sentences of the MNRead Chart have 3 lines and 60 characters, but their number (10-14 words), length, and position of words vary greatly, and reading speed calculation assumes that this represents 10 words of a supposed average English word length of 6 characters (Stifter et al., 2004). Radner reading charts in contrast are highly comparable in the number of words used (14 words), word length, position of words, lexical difficulty and syntactical complexity, and statistically selected the most similar ones. In this way the sentence optotypes vary minimally, geometric proportions are kept at a constant at all distances to achieve accurate and standardized measurements of reading acuity and reading speeds at every viewing distance. The RRC is advantageous over a MNRead as the MNRead uses sentences that are similar in number of lines and number of characters, but not in length and position of words (Maaijwee et al., 2008).

The RRC showed a high inter-chart and test-retest reliability and was used in our tests (Maaijwee et al., 2008). Stifter and colleagues demonstrated that the Radner Reading charts provide highly reproducible measurements of reading acuity and speed in individuals with no moderate or substantial visual impairment (Stifter et al., 1989).

Reading speed is a commonly used test when evaluating low vision attributable to macular disease. This form of assessment has grown in popularity for the assessment of presbyopic correcting IOLs (Sanders and Sanders, 2010; Packer et al., 2010). There is no consensus for the methods used to evaluate the results after testing. The common metrics of critical print size, reading acuity, and maximum reading speed are used, but the methods used to derive these values are rarely stated. Other approaches to the evaluation include the direct comparison of reading speed at each spatial frequency and recording of the spatial frequency at which reading speed is reduced below 80 words per minute.

Measurement of reading ability provides greater detail regarding visual ability in non-clinical situations. Spot or survival reading: approximately 40 words per minute (WPM), occurs when the size of print approaches the threshold visual acuity. Fluent reading: approximately 160 WPM occurs when the print size is large enough to provide an optimal reading speed (Whittaker and Lovie-Kitchin, 1993).

The original MNRead was developed for the assessment of low vision patients using the drifting text method: this measures dynamic reading speed by moving sentences across a computer screen at increasing speeds (Legge et al., 1989). In comparison, the static text method presents stationary sentences and examines the time taken to read these sentences. The two methods produce similar results, however, the drifting text method is relatively difficult to administer (Rice et al., 2005). Therefore a static printed text version of the MNRead was developed; the current printed card format uses a regular 0.1 LogMAR progression with print sizes ranging from 1.30 to -0.60 LogMAR. There are 60 characters and 10 words per sentence. Each subject starts at the largest print size and is encouraged to read each paragraph at the fastest speed that is comfortable to them. The time taken to read each paragraph is recorded. This continues until the patient can no longer resolve the print (Mansfield et al., 1993).

The Radner reading test was developed as a static printed reading acuity chart with standardized sentence construction. Each sentence contains three lines, fourteen words and eighty-two to eighty-four characters; the first and second line has five words and the third line has four words. The construction of the sentences has been standardised to ensure that syllables, nouns and verbs are positioned across each sentence consistently. The reading speed measurements attained with the Radner reading test correlate well with long text paragraphs and the measurements of reading speed are highly repeatable. Reading acuity is expressed as the smallest distinguishable print size and is expressed in logRADs.

There is a smallest print size below which reading speed begins to decline sharply, termed the critical print size (CPS). The CPS typically lies in the range from about 0.15° to 0.3° depending on the individual, stimulus factors such as font (Mansfield et al., 1996) and the methods for measuring reading speed or for estimating the CPS. Critical print size is the smallest character size for which reading is possible at maximum speed.

Reading speed is calculated using the formula below and from this the maximum reading speed (MRS) and critical print size can be calculated (Radner et al., 1998). Reading speed in words per minute is equal to 840/t where t is the time taken to read each paragraph

Each paragraph consists of 20 syllables, and equates to 0.1 logRAD. To calculate reading acuity the number of paragraphs read is counted along with the number of errors. Any incorrectly identified syllables are accounted for with each having a value of 0.005 logRAD (Maaijwee et al., 2008). The following equation defines the reading acuity:

Reading acuity (logRAD) = 1 - (s x 0.1) – (es x 0.005) (Maaijwee et al., 2008).
s is the number of paragraphs read.
es are the number of incorrectly identified syllables.

1.6.5. Defocus curves

Defocus curves are a novel approach to reporting multifocal performance. Defocus curves assess VA over a range of optical defocus, thus indirectly assessing VA across a range of distances. The technique and subsequent analysis to evaluate defocus curves have been inconsistent in past trials. Gupta and colleagues (2007) concluded that the lens sequence or the presentation of letters of a LogMAR chart need to be randomized between presentations to reduce the memorization effect; a recommendation rarely practiced.

The results of defocus curve measurements are commonly expressed as the range of focus levels where a specific visual acuity can be maintained. Gupta and colleagues (2008) proposed a specific level of acuity criteria for the assessment of accommodative IOLs, with the aim of quantifying the range of clear focus. This criterion was adopted in a study assessing the Opal-A accommodative IOL (Cleary et al., 2010a). Previously no criteria have been set for the assessment of multifocal intraocular lenses and the methods used to evaluate defocus curves vary between studies (Petermeier and Szurman, 2007; Toto et al., 2007). However, for comparing different presbyopia-correcting technologies, Buckhurst and colleagues (2012) proposed an area under the standardized defocus curve metric.

The optimum step size for measuring the defocus curve was found to be 0.50D as faster methods of capturing defocus curves by using a greater step between the metric measurements appeared to distort the results and was not valid (Wolffsohn et al., 2013).

1.6.6. Clinical grading scale

Grading scales vary in the number of “steps” and conditions of interest and can be descriptive (Woods, 1989), artistically rendered (Efron, 1998), photographic (McMonnies and Chapman-Davies, 1987) or computer generated (Chong et al., 2000). Even with the use of a grading scale, there is a wide discrepancy between observers grading the same image and on repeat grading by the same observer (Efron, 1998; Efron et al., 2001). Interpolating between grading images (such as to one tenth of a unit) increases discrimination and sensitivity (Twelker and Bailey, 2000) but relies on a linear incremental increase in severity between grades. However computerized image analysis techniques using edge detection (Fieguth and Simpson, 2002) and colour extraction (Simpson et al., 1998) image analysis techniques are highly repeatable and offer the potential for more sensitive grading than subjective grading scales (Wolffsohn, 2004).

1.6.7. Dysphotopsia

Rigid gas permeable multifocals (RGP), soft bifocals, monovision, and varifocal spectacles have good binocular contrast sensitivity, satisfactory binocular low and high contrast acuity but increased sensitivity to glare (Rajagopalan et al., 2006).

The impairment of visual function resulting from the presence of a bright light source in the field of vision describes glare disability (Babizhayev, 2003). It is commonly assessed by determining the extent of the loss of visual acuity that occurs with the introduction of a bright light source. The difference in the number of letters read between the no glare condition and glare conditions has been referred to as the disability glare index (Bailey and Bullimore, 1991). A linear increase in the reduction in VA in the presence of glare with increasing age has been reported by previous studies (Bailey and Bullimore, 1991; Rubin et al., 1997).

To measure the surrounding retinal blur circle or halo, several instruments often referred to as halometers (see Figure 1.3 and 1.4) have been created. These devices measure the size of a photopic scotoma created by a central glare source. Early methods for the assessment of halos involved drawing the outline of the halo created from a candle at a set distance (Elliot, 1924). The first halometer, described in the literature, consisted of a tungsten lamp mounted on a wooden box with a slide rule radiating away from the light. Subjects were required to move the slide rule to the outer rim of the halo to provide a measure of the photopic scotoma surrounding the light source (Elliot, 1924). Sheppard and colleagues recently used a halometer to measure the size of the area of glare for each patient under mesopic ($5cd/m^2$) conditions using randomly presented letters moving towards the glare source (Sheppard et al., 2013).

Visual challenges frequently confronted by those wearing different modes of presbyopic corrections include ghost images and haloes, often exacerbated during dim light levels when pupil size increases. Relatively few studies have considered these effects in comparative clinical vision (Back et al., 1992; Fisher et al., 2000). Sources of ghosting are expected to be primarily from the junctions between distant and near zones and decentration of the optics relative to the entrance pupil of the eye (Charman and Walsh, 1986; Tucker et al., 1986). Haloes are caused by the superimposition of the in- and out-of-focus images from the inappropriate portion of the remainder of correcting lens and gives rise to excessive flare and loss of contrast (Charman and Saunders, 1990).

It has been found that concentric bifocals induce more distractive ghosting at near than either diffractive bifocals or monovision correction. Both concentric and diffractive bifocals produce larger haloes than the monovision correction of presbyopic correction (Back et al., 1992). Glare with night driving has been reported to be of significant concern to elderly drivers (Chu et al., 2009).

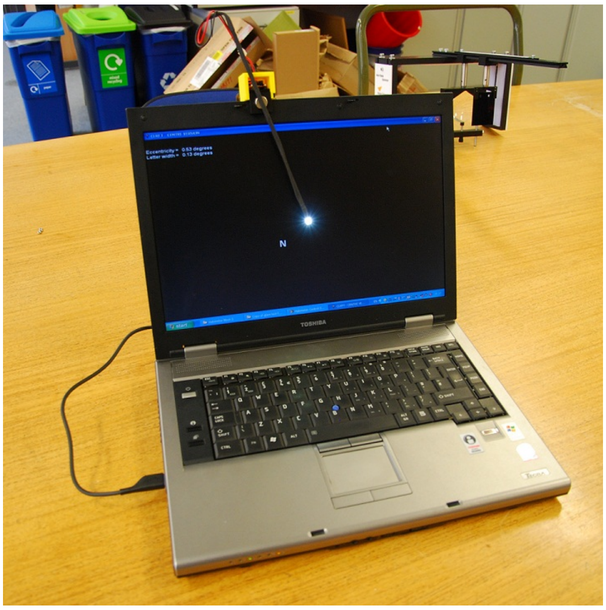

Figure 1.3: BD Halometer program with the light source arm, which was attached to the edge of the computer screen.

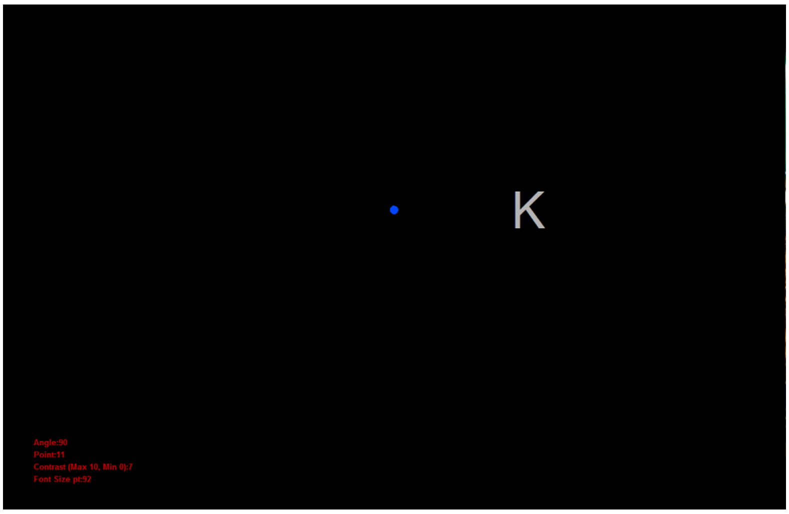

Figure 1.4: Letter displayed on the screen of the halometer – non-serif Arial bold and approximates to the 5x4 letters stipulated by the British Standard BS 4274.

1.6.8. Aberrometry

Ideal optical system is stygmatic, which means that object point is imaged by the optical system into the image point without deformation. The optical system of the eye is not ideal as it has aberrations. Aberrations limit and determine visual quality. Wavefront aberrometers measure monochromatic low and high order aberrations. Wavefront aberrations are described by Zernike polynomials (Mocko et al., 2012).

The majority of aberrometers are based on the Hartmann-Shack Principle (Liang et al., 2009) which is an objective, parallel, double-pass method using backward projection: A Hartman-Shack device uses a narrow laser beam that is sent along the ocular line of sight into the eye, where it reflects on the retina. This reflection serves as secondary source that illuminates the pupil area from behind. The outgoing light is then guided through a set of relay lenses that splits up the wavefront into a number of apertures individually focussed on a charged coupled device camera. Due to the focal shift, the resulting spot pattern shows spot displacements compared with the reference positions. In this way, the wavefront slopes are determined for the entire pupil at the same instance. The number of lenses in the matrix limits the spatial resolution of this system, and the focal distance of the lenses limits its sensitivity. The problem of this system is its limited dynamic range.

In a study carried out by Liang and colleagues (2009), 3 Hartmann-Shack aberrometers were compared and important discrepancies were found in high order aberration measurements (Rozema et al., 2006), emphasising the importance of randomised crossover designs using the same instrument when comparing multifocal lens designs. They capture whole eye aberrations so the combined effect of contact lens optics and eyes inherent optics can be assessed together, as this is what determines how well simultaneous image designs actually work for an individual. Additional measures that can be captured by aberrometers include pupillometry, pupil displacement from the optical axis and if a Placido disc system is incorporated around the measurement head, corneal topography can be used to derive corneal aberrations which, subtracted from whole eye aberrations quantified by the wavefront sensor, allows internal ocular aberrations to be elicited.

1.6.9. Patient reported outcomes

The performance of multifocal contact lens designs has ben explored objectively and subjectively. This approach is useful however the best ways to assess these lenses are when they are worn in specially demanding visual tasks, which entails during work or at home. For this reason, it was thought that a questionnaire investigating visual satisfaction would provide valuable information for practitioners to decide between different contact lens designs as well as presenting a better prediction of long term wearing success.

Subjective visual satisfaction and wearing success have been previously studied in different contact lens designs and wearing modalities with Papas and co-workers exploring the subjective visual satisfaction to variables such as ghosting, appearance of halos, lens comfort, vision quality, vision fluctuation, facial recognition and overall satisfaction (Papas et al., 2009). Richdale and colleagues (2006) measured patient satisfaction with Bausch and Lomb SofLens and monovision using the quality of life survey - National Eye Institute Refractive Error Quality of life instrument (NEI-RQL).

Although there are several questionnaires used to assess patients' views on their vision with presbyopic lens corrections these are generally not validated and do not collect information on lifestyle and dysphotopsia. The only validated questionnaire to assess vision related quality of life (QOL) with presbyopic corrections is the Near Ability Vision Questionnaire (NAVQ) developed by Buckhurst and colleagues (2012), with which it was demonstrated that progressive addition spectacle lenses outperform most other forms of presbyopic correction including multifocal contact lenses and monovision, although only one design of lens was evaluated.

1.7. CONCLUSION

With an increase in the ageing population worldwide and a consequent rise in the number of presbyopes, the demand for contact lenses to correct presbyopia will inevitably increase. Evaluation of the current range of lens design and fitting would enable practitioners to successfully fit a higher percentage of presbyopes. According to Morgan and colleagues (2011), practitioners are still under prescribing multifocal contact lenses.

The problem of positioning multiple focal elements to deliver effective near vision, without degrading distance performance or vice versa, remains a challenging one, and lens designers have made great efforts to overcome these problems. In recent times vast strides have been made in multifocal contact lens design along with techniques of measuring visual performance and both subjective and objective quality of vision. Few studies have compared visual performance and/or patient acceptance across two or more different bifocal or multifocal lens designs and those that have, provided limited comparison. New designs have been introduced as well as a move to silicone-hydrogel materials. Currently the ability for a practitioner to predict which multifocal design works best for a particular presbyope has not been extensively explored. As this will be dependent on the combination of the lens and the optical aberrations of the eye, it is unlikely that any design could work universally.

Hence, this thesis examines what forms of correction patients are currently using to manage their presbyopia (Chapter 2), a double-blind randomised cross-over trial that comprehensively compares vision, visual performance and dysphotopsia with modern multifocal soft contact lenses designs (Chapter 3) as well as determining which baseline measures and lifestyle factors help to predict which lens works best in individual patients (Chapter 4).

CHAPTER 2:
PRINCIPAL MODES OF REFRACTIVE CORRECTION FOR PRESBYOPIA IN A CLINICAL PRACTICE AND RESULTING QUALITY OF VISION.

2.1. INTRODUCTION

Two hundred and eighty five million people worldwide are visually impaired with uncorrected refractive error (Bastawrous et al., 2013). Holden and co-authors (2008) using multiple population-based surveys estimated around 1.04 billion people globally have presbyopia. The median age has shifted from 34.1 years in 1971 to 38.6 years in 2004 and it is projected to increase to 42.9 years in 2031 (Morgan and Efron, 2009).

Clearly the greatest potential growth in the contact lens market today involves the presbyopic patient (Bennett, 2010). There is an interest in multifocal contact lenses and once aware of the availability of the presbyopic correction, 21 out of 33 presbyopic patients agreed to be fitted with contact lenses, provided the practitioner is proactive in recommending them (Jones et al., 1996). Worldwide, the presbyopic population is under represented in the contact lens market with less than 40% of contact lens wearers older than 45 years of age being prescribed a presbyopic correction (Morgan and Efron, 2009; Morgan et al., 2011). Multifocal soft lenses have been prescribed more frequently than monovision corrections since 1996 (Morgan and Efron, 2006). More recent figures suggest worldwide that around 29% of presbyopes are fitted with multifocal lenses and 8% with monovision, although these figures and the percentage fitted with contact lenses for presbyopia varies considerably between nations (Morgan et al., 2011). Females were almost three times more likely to be prescribed a presbyopic contact lens correction compared to men, maybe due to their attitude towards cosmesis generally including contact lenses (Morgan and Efron, 2006; 2009).

The traditional non-surgical methods to correct presbyopia are single-vision distance and near, bifocals, and progressive spectacles lens together with contact lens modalities as discussed in the previous chapter (Morgan et al., 2010; Evans, 2007; Bennett, 2010). The desirability of restoring presbyopes with clear vision in all distances involves both fixed and variable focus lens systems, and surgical methods which modify the optics of the cornea, replacing the crystalline lens with different fixed optics, or attempting to at least partially restore active accommodation (Charman, 2014).

Inadequate near vision correction due to presbyopia can have a negative effect on daily living, career opportunities and self-esteem (Lu et al., 2011). Research undertaken reports that functional presbyopia results in difficulty with near tasks in 53% of Indians (Nirmalan et al., 2006), 58% Brazilians (Duarte et al., 2003) and 70% of rural Tanzanians (Patel et al., 2006). Previous epidemiology research has focused almost exclusively on distance rather than on near visual loss (Memon, 1992). In the developed world, inadequate near vision correction can still occur, with a Finnish study finding 6.1% of subjects had difficulty in reading while 1.5% of those could not read newsprint at all (Laitinen et al., 2005).

There are limited scientific reports on the usage of refractive correction in presbyopes. Bastawrous and colleagues (2013) studied the prevalence of refractive error and the spectacle coverage in patients over 50 years old and found that the myopia was more common than hyperopia (affecting 59.5% compared to 27.4%). Market reports generally do not differentiate presbyopes from pre-presbyopes, but demonstrate that the use of corrective eyewear in the UK is very common and has not changed greatly from 2011 (62% in 2011 to 69% in 2013). More women than men wear both glasses (72% versus 66%) and contact lenses (16% versus 11%), with 74% of people in the UK either wearing corrective eyewear or having had laser eye surgery (The College of Optometrists, 2013).

An indicator of satisfaction from the use of visual correction is vision-related quality-of-life (QOL) among patients. Two different individuals may have the same visual function, but with different perception of their QOL. Research has shown that QOL changes with the presence of eye disease (Alió et al., 2005), refractive surgery (Sakimoto et al., 2006), spectacles and contact lenses (Lohmann et al., 1993). Many vision-related questionnaires have been developed, but most combine assessment of quality of vision with questions on other traits such as visual disability (Schein, 2000). The disadvantage is that due to the combining of traits the meaning of the measurement can become unclear (Pesudovs et al., 2007) and it is incorrectly assumed that the scores of each question can be averaged which implies all of the item ratings follow a linear scale (Townsend and Ashby, 1984). Other questionnaires have been designed to specifically examine one type of refractive correction such as the Freedom from Glasses Value Scale (FGVS) for post refractive surgery (Lévy et al., 2010) and the Self-Perceived Quality of Vision Questionnaire for intraocular lenses (Harman et al., 2008), but their sensitivity cannot be presumed across all refraction correction modalities.

There are several questionnaires that have been developed specifically for evaluating QOL in patients with refractive errors (Pesudovs et al., 2004; Jones-Jordan et al., 2010; Vitale et al., 2000; Queirós et al., 2012).

The National Eye Institute Refractive Error Quality of Life-42 (NEI RQL-42) contains 4 questions that relate specifically to near vision, the remaining questions relate to vision throughout daily life (Queirós et al., 2012). Independent analysis revealed that NEI RQL-42 is able to discriminate between different methods of refractive correction (Nichols et al., 2003; Baylock et al., 2008). The questionnaire uses Likert summary scoring and by presenting a summed score assumes that the equal distances between response choices represent equal distances in the dimension measured and the items represent equal difficulty (Pesudovs, 2006). Item response models such as Rasch analysis overcome these issues by transforming Likert interval data into linear form through the probability relationship between item difficulty and person ability (Wright and Lionacre, 1989; Pesudovs, 2006; Norquist et al., 2004; McAlinden et al., 2010). Hence, the Quality of Life Impact of Refractive Correction questionnaire (QIRC) was developed using Rasch analysis targeted at pre-presbyopic healthy adults requiring refractive correction. Presbyopes were not included as they will encounter different issues to pre-presbyopes in reference to using refractive corrections to allow clear vision at different distances and the prevalence of ocular disease increases with age (Pesudovs et al., 2004).

An alternative to the QIRC is the Quality of Vision (QoV) assessment tool developed consisting of a Rasch tested, linear scaled, 30-item instrument (10 items rated in terms of symptom frequency, severity and whether bothersome) providing a QoV score (McAlinden et al., 2010). QoV is a subset of QOL focusing purely on visual impairment rather than combining aspects of visual disability and the impact on social function. While this questionnaire has also not been tested previously on a presbyopic population, it is more detailed than the QIRC and included questions relating to dysphotopsia which is a known problem with presbyopic corrections (Josephson and Caffery, 1987), so was felt to be appropriate for the population to be examined in this study. The Near Activity Visual Questionnaire (NAVQ) is the only Rasch analysis designed questionnaire specifically designed to quantify the subjective perception of near visual function with spectacles and contact lenses use or following refractive surgery (Buckhurst et al., 2012), but does not address distance vision and therefore was utilized in subsequent chapters alongside visual measurements.

Technology has advanced the range of options for the correction of presbyopia with excellent clinical outcomes reported (McAlinden and Moore, 2011; Buckhurst et al., 2012). While distinct visual corrections for presbyopia have been examined such as multifocal contact lens and intraocular lens designs (Woodward et al., 2009; Zhang et al., 2011), how individual patients utilize different forms of presbyopic correction is not known or whether some combinations outperform others in terms of vision-related QOL. Therefore the purpose of this study was to determine the use of presbyopic corrections in patients attending an optometric practice and to compare this with vision-related QOL.

2.2. METHOD

Two hundred and seventy-one sequential patients with healthy eyes who reported using a presbyopic refractive correction, attending a Community Optometric Practice based in Surrey, between September 2014 and January 2015 were enrolled in the study. All were happy to give informed consent and to complete the short questionnaire.

The vision-related QOL was assessed by patient's completing the Quality of Vision (QoV) questionnaire developed by McAlinden and colleagues (2010) along with further information as to the percentage of time that they wore different forms of refractive correction (see Appendix A11; A12).

The patients were asked to look at the QoV photographs which simulate the visual symptoms of Glare, Haloes, Starbusts, Hazy vision, Blurred vision, Distortion and Double vision (see Appendix A11) and to familiarise themselves with the interpretation of each symptom. The patient was required to rate how often they experience each symptom (frequency), how severely they experience the symptom (severity), and how bothered they were by the symptom (bothersome) during their full waking hours (Skiadaresi et al., 2012). The response was based on how they felt in the past week.

The QoV was scaled according to item difficulty by the use of Rasch analysis in collaboration with the questionnaire's creator. As the QoV has a question relating to blur, but without the distance specified, the question was repeated for far, intermediate and near vision and the analysis performed with each of these questions included in turn and with their average score to assess the impact of this element of the questionnaire design on the vision-related QOL.

2.3. RESULTS

Of the 271 patients that completed the study, 46.9% were male. 8.5% were under 45 years, 22.9% 45-50 years, 21.4% 51-55 years, 12.2% 56-60 years, 12.2% 61-65 years, 5.9% 66-70 years and 16.9% over the age of 70 years old. Nine (3.3%) had had corneal refractive surgery (distance vision correcting), 19 (7.0%) standard cataract surgery and 3 (1.1%) cataract surgery with a multifocal or focusing intraocular lens implanted (but all still used presbyopic refractive correction so were not excluded from subsequent analysis).

43.2% reported their visual tasks were mainly distance, 35.1% mainly intermediate and 21.8% mainly near. 53.5% drove often, 24.4% occasionally, 4.4% rarely and 17.7% never. The percentage of patients that used the different forms of non-permanent refractive correction is presented in Table 2.1, along with the average percentage of the time for those that used it. Hence 28.4 ± 36.3% of the time patient wore no correction.

Table 2.1: Percentage use and time of each form of refractive correction. N=271.

	Use (%)	Time (%)	
		Average	SD
Distance spectacles	33.6	44.7	36.2
Near/Reading spectacles	47.2	29.2	26.6
Bifocal spectacles	4.4	65.1	41.1
Varifocal spectacles	37.6	84	28.5
Distance contact lenses	7.4	48.9	37.6
Multifocal contact lenses	5.5	52.9	39.9
Monovision contact lenses	4.4	40.2	41.9

As the QoV scores were highly correlated (r > 0.97, p, 0.001) in frequency, severity and bothersome scores regardless of whether the blur question was targeted to far, intermediate or near vision, an average of these blur distances was used for all subsequent analysis.

Cluster analysis was used to identify the core wearing pattern approaches of the patients. Splitting the patients into 3 groups identified one (n=74) whose primary usage was distance vision spectacles (50% of the time on average) with distance contact lenses (12%) near spectacles (10%), bifocal spectacles (9%) and multifocal contact lenses (8%) being the other main forms of correction. The second group (n=91) primarily used varifocal spectacles (93% of the time on average). The final group (n=106) were unaided most of the time (67%), with reading spectacles used for near vision (27% of the time). Splitting the patients into 4 groups adds a group of just 9 patients from this cohort who principally use multifocal contact lenses (81% of the time), with varifocal spectacles the rest of the time (13%), but this group was too small for further analysis.

There was a difference in age distribution across the three groups with the varifocal group tending towards an older profile and the distance vision spectacle dependent group having a younger profile (Kruskal-Wallis Chi-Square 11.344, p = 0.003). There was no significant difference in gender balance (Kruskal-Wallis Chi-Square 1.389, p = 0.239), reported principal distance of viewing (Kruskal-Wallis Chi-Square 0.827, p = 0.661) or how often they drive (Kruskal-Wallis Chi-Square 4.076, p = 0.130) between the groups. Despite Rasch correction, QoV was found not to be normally distributed for frequency (Kolmogorov-Smirnov Z 4.801, p < 0.001), severity (Z = 5.336, p < 0.001) or how bothersome (Z = 6.651, p < 0.001) symptoms were. Therefore non-parametric independent samples Kruskal-Wallis tests were used to analyse QoV between the identified groups.

Frequency of symptoms varied across groups (p = 0.001) with those unaided most of the time having less symptoms (QoV 7.7 ± 11.3) than those that principally wore varifocals (QoV 16.2 ± 17.8; p = 0.001) or those that principally wore distance spectacles (15.6 ± 16.9; p = 0.001). Severity of symptoms varied across groups (p = 0.007) with those unaided most of the time having less symptoms (QoV 6.3 ± 9.5) than those that principally wore varifocals (QoV 12.0 ± 14.4; p = 0.008) or those that principally wore distance spectacles (QoV 12.0

± 13.8; p = 0.006). How bothersome symptoms were varied across groups as well (p = 0.013) with those unaided most of the time (QoV 4.6 ± 9.9) having less symptoms that those that principally wore varifocals (QoV 10.6 ± 15.7; p = 0.003), but were similar to those that principally wore distance spectacles (QoV 8.6 ± 14.6; p = 0.072; Figure 2.1).

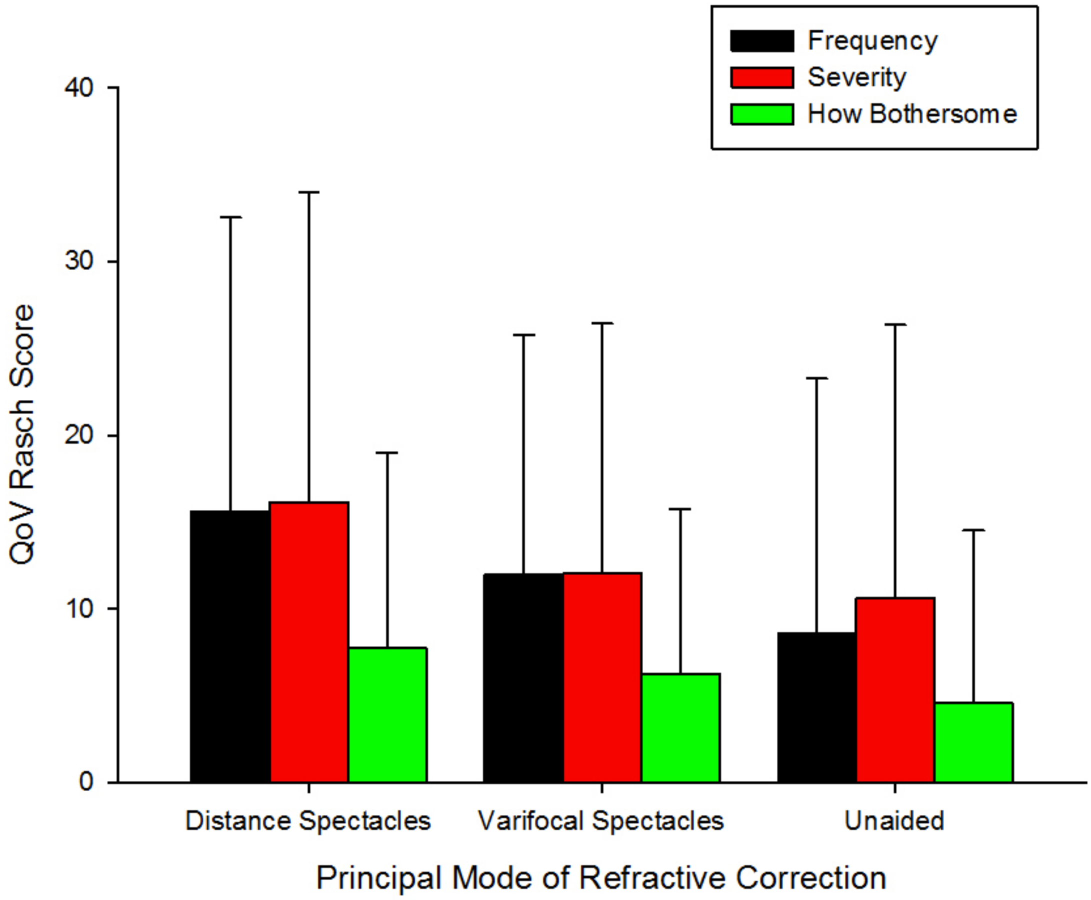

Figure 2.1: QoV ratings for frequency, severity and how bothersome for each of the three principal modes of refractive correction identified in the cohort. N=271. Error bars = 1 S.D.

2.4. DISCUSSION

Over one billion people in the world are presbyopic (Holden et al., 2008), with a continuing shift to an increasing average age. Despite the potential expansion in the contact lens market resulting from this population growth (Bennett, 2010) and the interest in this modality of refractive correction (Jones et al., 1996), the presbyopic population is under represented in the contact lens market (Morgan and Efron, 2009; Morgan et al., 2011). As identified in the introduction (section 2.1) there are limited scientific reports on the usage of refractive correction in presbyopes. This study examined a large cohort of presbyopic patients across the age span associated with the loss of a functional range of accommodation. While this was from a single practice in one location in the world, this provides an insight as to how patients combine refractive corrections to manage their lifestyle requirements for clear vision at different focal distances. The gender distribution of our sample is similar to that reported by the Office for National Statistics for the UK population (Office for National Statistics, Northern Ireland Statistics and Research Agency, National Records of Scotland, 2011). Few had a surgical solution for refractive correction and most of these were not aimed at correcting presbyopia.

Approximately two-fifths of patients reported their visual tasks were mainly distance, one-third mainly intermediate and two-fifths mainly near. The requirement for intermediate seems larger than one might expect, but the exact distance range this refers to is not defined and the growing use of tablets and smart phones has potentially inflated this category. Most of the cohorts were still driving, with around two-fifths reporting rarely or never driving. Restriction of driving activity is known to increase with age, although visual quality is not a reported influencing factor (Asse et al., 2014).

The combinations of refractive corrections used by individual patients varied greatly as expected. Cluster analysis was able to identify 3 substantial groups (the smallest representing 27%) in this cohort, with the primary form of correction being: distance vision spectacles with a second form of correction to provide clear near vision; varifocal spectacles who rarely used any other form of refractive correction; and those who were unaided most of the time, using reading spectacles for near vision. With the low uptake of multifocal contact lenses and drop off in the usage of contact lenses with age (Morgan and Efron, 2009; Morgan et al., 2011), it was perhaps expected not to find a substantial group of patients (<5%) using this form of principal correction for presbyopia. This supports the focus of this thesis in better understanding the performance offered by modern multifocal contact lenses and monovision (Chapter 3) and how to predict which design will work best for individual patients (Chapter 4).

The group that primarily used distance vision spectacle were younger as expected, as their residual accommodation would be higher, allowing a wider range of clear focus without additional correction (Wolffsohn et al., 2011). It also follows that those primarily using varifocal spectacles had an older age profile, with those who were mainly unaided using reading glasses about one-third of the time presumably being emmetropes or those of low distance refractive error that is less age specific. However, the group demographics in terms of gender, and lifestyle in terms of the reported principal distance of viewing or how often they drove, was similar in profile between groups.

Vision-related QOL is a potentially useful measure to assess how well these approached to refractive correction are serving the visual needs of patients. While inadequate near vision correction due to presbyopia is reported to have a negative effect on daily living, career opportunities and self esteem (Lu et al., 2011), quality of vision with different forms of refractive correction has not been assessed previously. In this cohort, the principal form of refractive correction influenced the frequency, severity and how bothersome the symptoms affecting the quality of vision. Those who did not need a refractive correction most of the time had better quality of vision that those using either varifocals of distance spectacles with other forms of near and intermediate correction. Hence despite the optical quality of modern spectacles, their use still appears to impact quality of vision, which highlights the need for further research and development on the refractive correction of presbyopia.

2.5. CONCLUSION

Vision-related QOL can be used to measure and assess how well refractive corrections are serving the visual needs of presbyopic patients. The presbyopic practice cohort principal forms of refractive correction were distance spectacles (with near and intermediate vision provided by a variety of other forms of correction), varifocal spectacles and unaided distance with reading spectacles, with few patients wearing contact lenses as their primary correction modality.

Those who did not require a refractive correction for most of the time had better quality of vision than those using either varifocals or distance spectacles with other forms of near and intermediate correction.

Clearly, modern spectacle lenses still have an impact on the quality of vision drawing attention to need for further investigation into the refractive correction of presbyopia.

CHAPTER 3:

COMPARISON OF THE PERFORMANCE OF THE MULTIFOCAL CONTACT LENSES.

3.1. INTRODUCTION

As highlighted in the introduction (section 1.4.6; table 1.2) there has been a growing body of research comparing presbyopic contact lens designs over the past decade. These were summarized in table 1.2. However, these studies generally focused on comparing monovision to a single presbyopic contact lens design (Richdale et al., 2006; Gupta et al., 2009), examine limited numbers of patients (Llorente-Guillemot et al., 2012; Madrid-Costa et al., 2012), do not allow patients to fully adapt to lens wear before performance measurements are assessed- only a 15 minutes were given for the lenses to settle (Chu et al., 2010; Chu et al., 2009), and 4 days of lens wear for adaptation to occur before performance assessments (Papas et al., 2009) or use limited visual performance metrics to compare between the lens designs (Situ et al., 2003; Rajogopalan et al., 2007). None of these studies have examined the impact of the lenses on ocular physiology (such as hyperaemia and corneal staining), which could contribute to poor visual performance due to degradation of the tear film if the eye is adversely affected. In addition, the manufacturers revise lens designs every few years as they seek to enhance their market share and as they also introduce new lens materials. The aim of this study was to comprehensively examine the relative performance of a range of current multifocal contact lens designs compared to monovision in a double masked, randomized controlled trial.

3.2. METHOD

3.2.1. Patients

Thirty-five presbyopic patients (27 females and 8 males) of mean age 54.3 ± 6.2 years (range 42 to 65 years) were recruited from the patient database of a community optometric practice in the South West of London. The cohort enrolled in this study provided the demographics that were expected in terms of age and distribution of reading adds. Initially 41 subjects were recruited with 6 subjects who withdrew from the study due to personal reasons. Most (n = 28) were previous contact lens wearers and two had worn presbyopic contact lenses previously but not any of the designs to be tested. The inclusion criteria for participation included: age 42 years or above; being able and willing to adhere to any study instructions and complete all specified evaluation; astigmatism less than or equal to 0.75D; monocular corrected distance visual acuity in each eye better than 0.00 logMAR; normal binocularity in the form of no marked amblyopia (greater than 0.1 logMAR difference between the eyes, tropia or anisometropia (greater than 1.00D mean spherical equivalent between the eyes). Patients were excluded if there was evidence of a history of: anterior segment pathology; previous intraocular or corneal surgery; lens opacities or cataract; corneal abnormalities (including endothelial dystrophy, guttata, recurrent corneal erosion, etc); history of chronic dry eye disease; any fundus pathology (such as macular degeneration or retinal detachment); or systemic or topical medication known to influence visual function measures.

3.2.2. Contact Lenses

All the patients were assigned to be fitted randomly with one of four different silicone hydrogel multifocal or monovision contact lenses:

Air Optix AQUA (AO) multifocal (Alcon, Fort Worth, TX, USA) low-, medium-, and high- add lenses (centre-near aspheric/bi-aspheric designs).

PureVision 2 for Presbyopia (PV 2) multifocal (Bausch & Lomb, Rochester, NY, USA) low- and high- add lenses (center-near aspheric/bi-aspheric designs).

Acuvue OASYS for Presbyopia (Vistakon, Division of Johnson & Johnson Vision Care, Jacksonville, FL, USA). low-, medium-, and high- add lenses (several concentric aspheric distance/centre-near zones).

Biofinity multifocal (CooperVision, Fairport, NY, USA) +1.50, +2.00 and +2.50 D add lenses. The lenses were of the ‘‘D’’ design in which the ‘‘distance’’ correction is at the lens centre (center-distance) or the ‘‘N’’ design in which the ‘‘near’’ correction is at the lens centre (centre-near).

Monovision with Biofinity single vision lenses (CooperVision, Fairport, NY, USA).

The power profile of these lenses as recently published by (Plainis et al., 2013) indicate that the increase in power at the centre of the low-add Purevision lens is “an instrumental artifact”, and the powers for the “low-add” Purevision multifocal and Air Optix (AO) lenses exhibit smooth, continuous parabolic profiles. These low-add lenses have a negative spherical aberration (i.e. centre-near); the paraxial focus is used for near vision (Plainis et al., 2013). The changes in the power as a function of lens zonal radius for AO med and AO high addition lenses cannot be fitted by a single second-order function. These lenses have a bi-aspheric design, leading to different rates of power change for the central and peripheral parts. There is a sharp discontinuity in the profile for the PV high lens although the central and peripheral zones can be linked to another parabolic function. The Oasys and Biofinity multifocals have more complex power profiles. The Oasys exhibits a series of concentric zones separated by abrupt discontinuities. The centre of the lens is of lower positive power. The width of the zones depends on the add; the zone widths are broader in the "higher add". Biofinity multifocal, as the manufacturers claims, appears to have a constant power over the central circular region of radius 1.5mm, although this power is slightly positive compared to the stated value. Within the annular zone, from 1.5mm to 2.1mm, the positive power increases approximately linearly and the gradient increases with the nominal add power. The outer zones of the lens show a slow, linear, positive increase in power with a gradient, which is almost independent of the nominal, add power. The variation in power across the multifocal lenses produces enhanced depth of focus. The through focus nature of the image, which influences the distance correction and the reading addition will vary with several factors, including lens centration, the wearer's pupil diameter, and ocular aberrations, particularly spherical aberration; visual performance with some designs may show greater sensitivity to these factors.

The patient remained masked as to which lens design or monovision they had been prescribed and were provided with the lenses in an unmarked case for each eye by the unmasked practitioner. The fitting of each lens was strictly according to each respective lens manufacturer's guidelines. Fittings were evaluated 20 minutes after lens insertion following confirmation of good fit and centration. Previous research showed that contact lens movement on blink with the patient looking up was more diagnostic of overall lens movement as well as being easier to observe than movement on blink in primary gaze (Wolffsohn et al., 2009) and that only horizontal lag is diagnostic of overall lens movement (Wolffsohn et al., 2009). The importance of the push-up test in evaluating soft contact lens movement and adequate fit has been previously highlighted (Young, 1996) and was assessed in the fit evaluation (Wolffsohn et al., 2009). The decision on whether contact lenses should be trialled on the eye is based on clinical judgement, and may depend on the lens material and thickness. However, it would not be normal to accept more than two 'minus' grading in movement on blink, lag and push-up, or limbal incursion. Comfort must also be acceptable to the patient and acuity good and stable, with the prescription checked by over-refraction.

All the subjects were instructed to lens insertion, removal, and cleaning techniques as required and were provided with a supply of preservative free multipurpose solutions or one-step peroxide consistent with their previous cleansing regime. Once the fitting procedure was complete at a single initial visit, the subjects were asked to trial the contact lenses for 4 weeks to allow for adaptation (Sheedy et al., 1993). Most of the research on multifocal contact lenses has used trial lenses for 4 weeks (Madrid-Costa et al., 2012; Gupta et al., 2009; Ferrer-Blasco and Madrid-Costa, 2011). The patients were advised to wear the lenses each day as long as was possible up to a maximum of 12 hours per day. On completion of the 4 weeks of contact lens wear, the patient returned for assessment of visual function and optics before being prescribed the next lens type in randomized order.

3.2.2.1. Contact Lens Fitting Protocols

A full spherical-cylindrical refraction was performed on each patient with an end point of the maximum plus power without compromising the best distance visual acuity, ensured by utilizing the Humphrey's binocular balancing technique. The reading addition was estimated based on the patient's age (the amplitude of accommodation changes with age are predictable) (Woo and Sivak, 1979) and refined based on their subjective responses to viewing a near chart at 40cm (Madrid-Costa et al., 2012). The distance refraction was converted to a mean spherical equivalent and adjusted for back vertex distance. Sensory eye dominance was deduced using three successive consistent trials of the "+1.50D blur test", with the dominant eye identified as that with the introduction of a +1.50D lens had the least impact on vision (Pointer, 2012). Eye dominance test capitalizes on binocular rivalry by assessing the predominance of one monocular stimulus over another when the two eyes receive dissimilar stimulation (Handa et al., 2004). The lens power chosen was based on the mean spherical equivalent refined with ±0.25D flippers for the distance lens in the dominant eye and based on the manufacturer's guidelines (or distance power with the near addition added for monovision) for the near lens design in the non-dominant eye (Appendix A1, A2, A3, A4). The lenses were assessed after 20 minutes to ensure adequate centration, coverage and movement. For the monovision trial, the dominant eye was fitted with the distance lens, and the non-dominant eye with the near lens, the former being identified using sensory dominance test as described earlier. The near add power was based on the near spectacle addition which was added to the distance lens of the dominant eye.

3.2.3. Assessment of Ocular Surface Physiology and Visual Function

A second masked researcher conducted the assessment of all the visual function. Assessments with each contact lens presbyopia correction option took place at the same time ± 1 hour for each individual patient and at least 3 hours after lens insertion to minimise any solution induced staining effects. Slit lamp biomicroscopy was performed to evaluate bulbar, limbal and the palpebral hyperaemia (with lid eversion) and the corneal staining (with fluorescein) graded using the Efron grading scale in 0.5 steps (see section 1.6.6). Binocular high (95%) and low (12.5%) contrast distance visual acuity was measured using a computerized logarithm of the minimum angle of resolution (logMAR) chart (David Thomson Chart 2000, IOO Marketing, London, UK) at 6m under both photopic (85 cd/m2) and mesopic (5 cd/m2) lighting conditions (see section 1.6.1; 1.6.2). Stereoacuity was assessed binocularly at 40cm using the TNO random dot stereogram test (Lameris Ootech B.V., NC Nieuwegein, Holland; see section 1.6.3). Reading speed was evaluated with a computerized tablet Radner Test mobile app (Stifter et al., 2004; see section 1.6.4). Critical print size was derived from the reading speed data as the acuity at which the reading speed dropped below the 95% confidence interval (see section 1.6.4). A defocus curve was measured over the range of +1.50DS to -5.00DS in 0.50DS steps, with randomized letter sequences and randomized lens presentation order to reduce memory effects (Gupta et al., 2007; section 1.6.5). The glare induced by the contact lenses was assessed by halometry using a computerized chart to determine the distance from a glare source that letter targets were obscured in 8 meridians (Sheppard et al., 2013; see section 1.6.7). Subjective evaluation of near visual ability was assessed with a standardized questionnaire (the NAVQ; Buckhurst et al., 2012; see section 1.6.9) and patients rated their quality of vision on a 10-point scale (10 being excellent) when viewing an iPhone 4S held at their habitual working distance (fixed for each lens type) under 85 cd/m2 lighting conditions. A diary was also kept in which patients rated their satisfaction with vision on a 10 point scale at near, intermediate, far distance (5m) and far distance (5-15m) as well as the amount of light scatter they were experiencing, and they recorded the number of hours they had worn the lens (see section 1.6.9; Appendix A9). This was repeated on days 1, 7, 14 and 28 of each lens wearing period and recorded on a data collection sheet (Figure 2.1). Finally the optical aberrations of the patient's eyes wearing the contact lenses were measured using a wavefront analyzer (KR-1W, Topcon Tokyo, Japan; see Figure 3.1) with a Placido disc assessment of corneal aberration, Hartmann-Shack lenslet array analysis of total aberrations and calculation of internal aberrations from the difference between these (Pisella, 2012; see section 1.6.8). The aberrometer (see Figure 3.1) also measured the pupil size with the in-build camera and calculated the distance between the centre of the optical profile and the centre of the pupil.

The study followed the tenets of the Declaration of Helsinki and informed consent was obtained from all participants after explanation of the nature, procedures, and consequences of this study. The Audiology and Optometry Research Ethics Committee of Aston University approved the study and subjects were free to withdraw at any time without obligation.

Figure 3.1: The KR-1W Wavefront analyser. Topcon Great Britain Ltd, Berkshire, and U.K kindly provided the above image.

3.2.4. Data analysis

Failure to correctly recognize plate IV on the TNO stereopsis test was allocated a score of 540 minutes of arc, one step between plates below plate IV. Only right eyes were analyzed except for aberrations and pupil size, where the analyzed eyes were grouped as ocular dominant or non-dominant. Physiological, acuity, stereopsis and iPhone rating measures were found to be not normally distributed (Kolmogorov-Smirnov test $p < 0.05$) therefore non-parametric rank analysis of variance was conducted. Defocus curve acuities, reading speed, critical print size, halo size, NAVQ scores, pupil parameters and aberrations were found to be normally distributed (Kolmogorov-Smirnov test $p > 0.05$) therefore parametric repeated measures analysis of variance was conducted (Armstrong et al., 2011).

As the analysis involved repeated measures, more traditional sample size metrics potentially underestimate the study power such as Ridgman's approximate formula (cited in Armstrong et al., 2000):

$$R = (2C\sqrt{2}/\sqrt{r})$$

Where r is the percentage difference detectable in an experiment i.e. the difference between a treatment and a control mean expressed as the percentage of the mean of the whole experiment, C is the coefficient of variation (the SD as a percentage of the mean) and r is the number of replicate patients in each group. To estimate the number of patients required in a given experiment to have a high probability of detecting a particular percent difference between the means R with a coefficient of variation of the experimental material C, then the equation can be rearranged as follows:

$$r = (2C\sqrt{2}/R)\ 2$$ (Armstrong et al., 2000)

Hence Armstrong and colleagues advise at least 15 degrees of freedom for repeated measure type statistics (Armstrong et al., 2000), which was achieved in all metrics with the 35 subjects recruited, even when split by lens preference (see Chapters 4).

3.3. RESULTS

3.3.1. Physiology

Limbal hyperaemia ($p = 0.068$) and fluorescein staining ($p = 0.557$) was similar between the multifocal lens designs (Figure 3.2). However, bulbar hyperaemia differed (p = 0.020) between lens types, being greater with the Purevision 2 and monovision than with the other multifocals ($p < 0.05$) as did palpebral redness/roughness (p = 0.012), being greater in the Purevision 2 design than the other multifocals ($p < 0.05$) and greater with monovision that the Biofinity (p = 0.031).

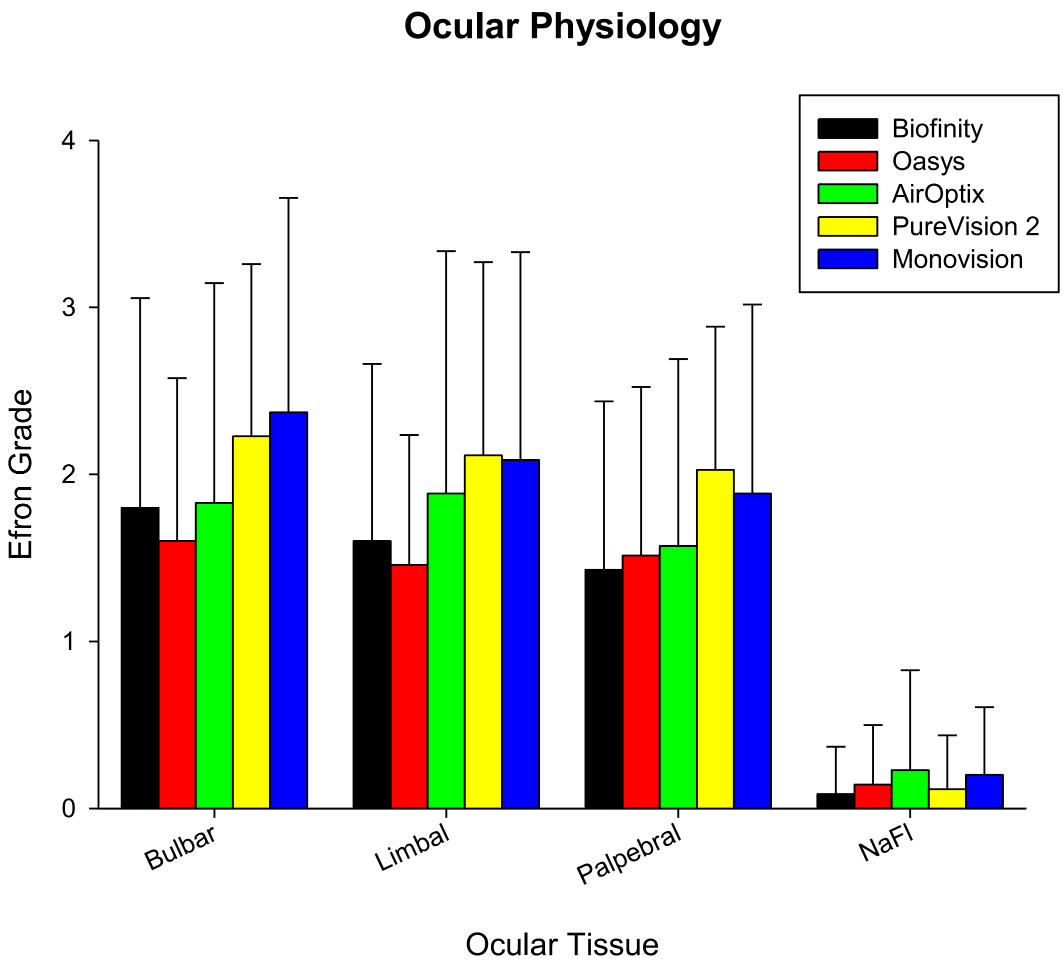

Figure 3.2: Ocular physiology in the form of bulbar, limbal and palpebral hyperaemia along with corneal fluorescein staining graded using the Efron scale for each presbyopic contact lens correction. N = 35. Error bars = 1 S.D.

3.3.2. Acuity

Binocular best distance corrected visual acuity under photopic conditions was similar (p = 0.102) between lens designs (Figure 3.3). However at 12.5% contrast differences were evident (p = 0.009), with monovision distance photopic acuity outperforming the Oasys ($p = 0.002$) design. Acuity under mesopic conditions also differed with lens design at high ($p < 0.001$) and low ($p = 0.012$) contrasts. At both contrasts monovision outperformed Oasys ($p < 0.002$) and AirOptix ($p < 0.01$). In addition, at high contrast mesopic viewing, Oasys performed worse than Biofinity ($p = 0.003$) and Purevision 2 ($p = 0.040$) and AirOptix performed worse than Biofinity ($p = 0.001$).

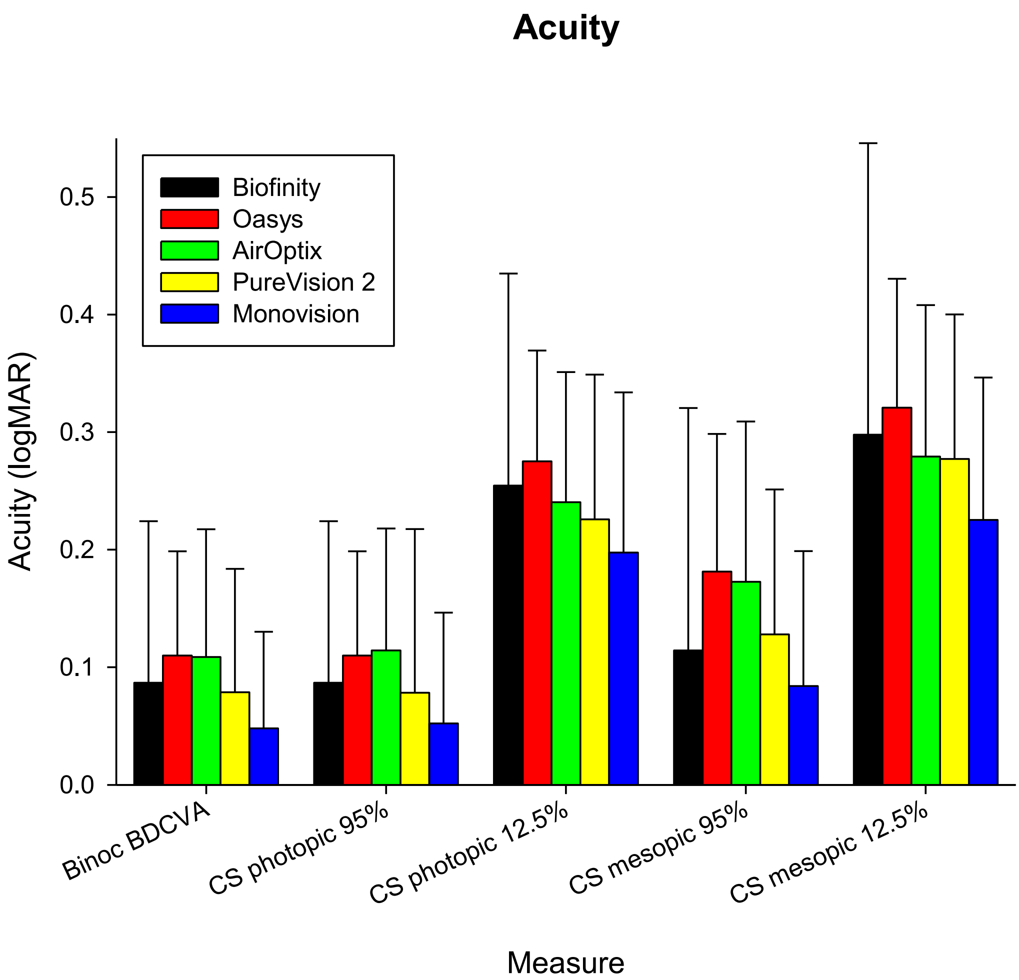

Figure 3.3: The logMAR visual acuity for Biofinity, Oasys, AirOptix, PureVision 2 and Monovision in binocular vision, photopic and mesopic conditions. In the photopic and mesopic environment the contrast sensitivity was either 12.5% or 95%. N =35. Error bars = 1 S.D.

3.3.3. Stereopsis

Stereopsis differed between lens designs ($p < 0.001$) with monovision (339.4 ± 137.0 seconds of arc) performing worse than Biofinity (220.9 ± 118.4 seconds of arc; $p < 0.001$) and Purevision 2 (254.6 ± 108.3 seconds of arc; $p = 0.007$). The AirOptix (313.3 ± 162.3 seconds of arc) performed worse than the Biofinity ($p < 0.001$) and Purevision 2 ($p = 0.037$) and the Biofinity also outperformed the Oasys (290.0 ± 152.9 seconds of arc; $p = 0.007$).

3.3.4. Defocus Curves

There was a significant difference in acuity between the different levels of blur as expected ($p < 0.001$) with vision reducing for positive lens blur, but at a slower rate for negative blur, showing the multifocal lenses increased the range of clear focus. There was also a significant difference between lens designs ($p < 0.001$), although there was no second trough of good vision indicating the lenses were not bifocal in action. However, there was an interaction between lens design and acuity at different levels of defocus ($p < 0.001$) showing the designs worked differently from one another (Figure 3.4). For +0.50D and +1.00D monovision outperformed Oasys ($p < 0.05$). There was no difference between lens designs at 0.00D and -0.50D. At -1.00D Purevision 2 outperformed Oasys ($p =0.006$), which was also the case at -1.50D ($p = 0.25$) as did monovision ($p = 0.007$). Other than at -3.50D and -5.00D, monovision outperforms Oasys ($p < 0.05$) and AirOptix ($p < 0.05$), with Biofinity outperforming Oasys at -2.00D ($p = 0.041$) and AirOptix from -2.50D ($p < 0.05$).

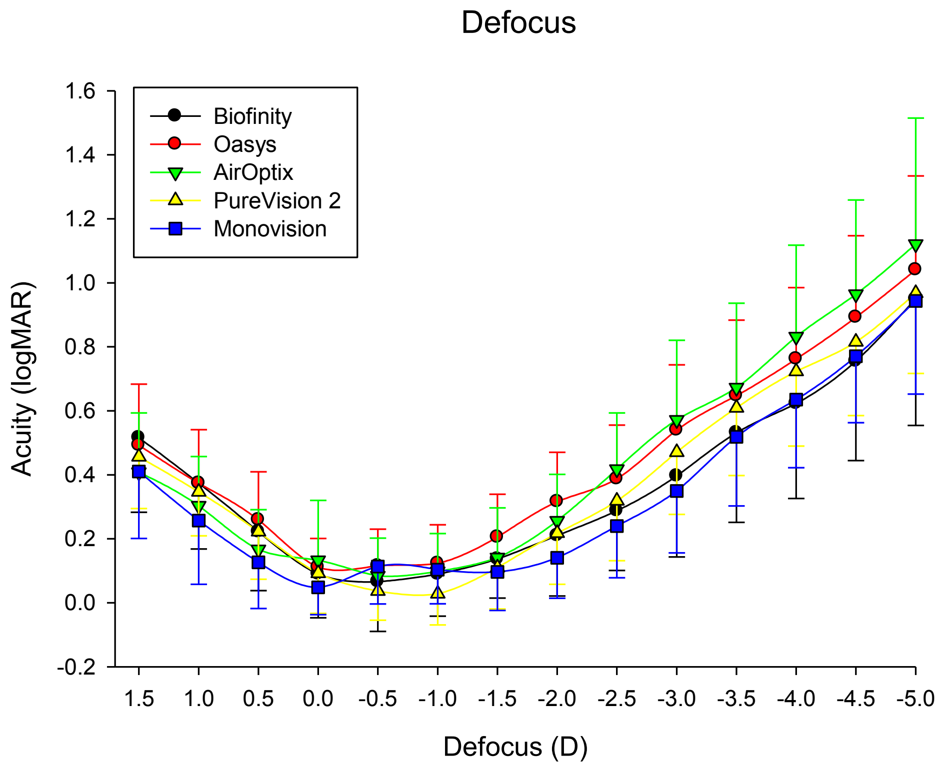

Figure 3.4: A graph showing the visual acuity (logMAR) as a function of the lens defocus (D) for the Biofinity, Oasys, AirOptix, Purevision 2 multifocal contact lenses and Monovision. N=35. Error bars =1 S.D.

3.3.5. Reading

Reading speed did not differ between lens designs (F = 1.082, p = 0.368; Table 3.1). Critical print size significantly differed between lens designs (F = 7.543, p < 0.001), with Oasys worse than Biofinity (p = 0.004) and monovision (p = 0.002; Table 3.1).

3.3.6. Glare

Halo size, significantly differed between lenses (F = 4.101, p = 0.004) and between orientations (F = 14.984, p < 0.001), but there was no interaction between them (F = 0.841, p = 0.703), with AirOptix causing a larger halo than Purevision 2 at 0° and 45° (p < 0.05; Figure 3.5), but with no differences with the Biofinity, Oasys and monovision designs.

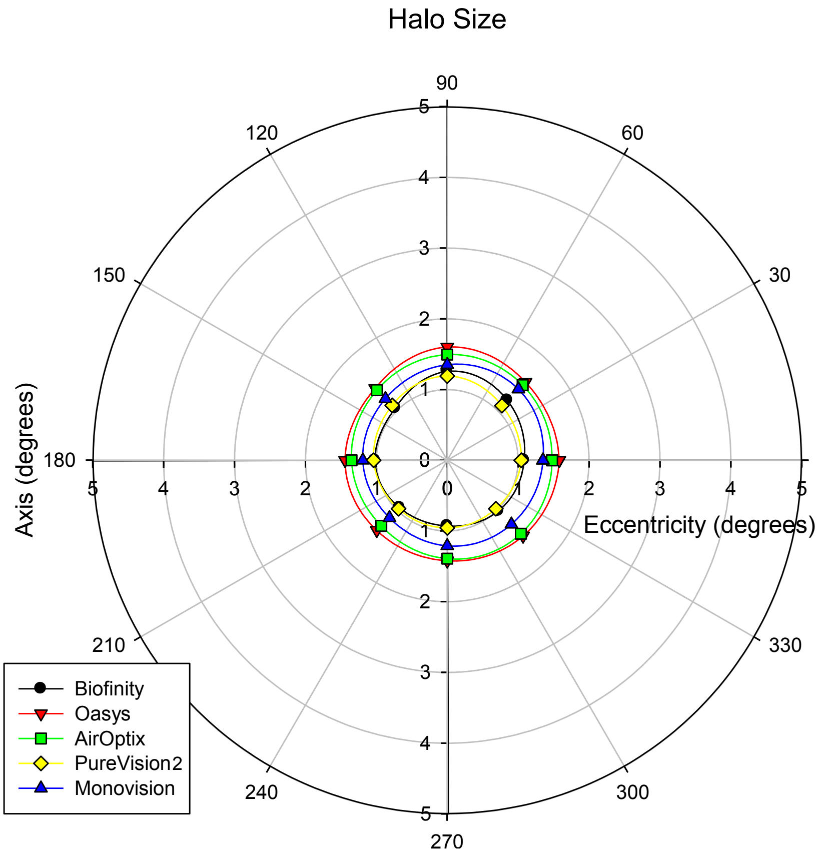

Figure 3.5: Binocular results of the Halometer for each multifocal type and monovision. The polar plots show the map of the extent of scotoma in the 8 meridians tested. N = 35.

3.3.7. Subjective Rating

The iPhone was held at a distance on average of 39.4 ± 6.4 cm (range 28 to 53 cm) and this was kept constant across all iPhone assessments. The rating of iPhone image clarity was significantly different between presbyopic corrections (Related-samples Friedman's 2-way Analysis of Variance = 0.002) with the Biofinity and monovision outperforming ($p < 0.05$) Oasys and AirOptix, but not Purevision 2 (Table 3.1). NAVQ rating of near performance also differed between lens designs ($F = 3.730$, $p = 0.007$) with the Biofinity resulting in a significantly better quality of life score than the Oasys, but there was no difference from the AirOptix, Purevision 2 and monovision presbyopic corrections (Table 3.1).

Table 3.1: Comparison of reading speed, critical print size, iPhone rating, NAVQ score, pupil size and pupil decentration with multifocal or monovision contact lenses (average ± standard deviation). N = 35.

	Biofinity	Oasys	AirOptix	Purevision 2	Monovision
Reading Speed (wpm)	154.6 ± 22.1	158.1 ± 21.2	157.1 ± 20.0	155.4 ± 20.5	160.1 ± 23.0
Critical Print Size (logMAR)	0.23 ± 0.16	0.37 ± 0.15	0.29 ± 0.17	0.30 ± 0.16	0.22 ± 0.17
iPhone rating (/10)	7.5 ± 2.3	6.2 ± 2.6	5.8 ± 2.6	6.6 ± 2.5	7.4 ± 2.0
NAVQ (/100)	39.8 ± 17.1	53.7 ± 18.4	51.3 ± 25.7	41.9 ± 23.2	44.3 ± 18.5
Pupil Size Dominant Eye (mm)	4.7 ± 1.0	5.1 ± 1.1	4.8 ± 1.0	5.1 ± 0.8	5.0 ± 0.9
Pupil Size Non-Dominant Eye (mm)	4.7 ± 1.0	4.9 ± 1.1	4.6 ± 1.0	5.0 ± 0.8	5.0 ± 1.0
Pupil Decentration Dominant Eye (mm)	0.4 ± 0.2	0.4 ± 0.1	0.4 ± 0.2	0.4 ± 0.2	0.3 ± 0.2
Pupil Decentration Non-Dominant Eye (mm)	0.3 ± 0.2	0.3 ± 0.2	0.4 ± 0.2	0.3 ± 0.2	0.3 ± 0.2

3.3.8. Pupil Size / Centration

The pupil size did not alter with contact lens design ($F = 1.614$, $p = 0.175$), but was larger in the dominant eye (4.95 ± 0.96 mm vs. 4.83 ± 0.97 mm; $F = 5.489$, $p = 0.025$), although there was no interaction between these factors ($F = 1.537$; $p = 0.195$). Pupil decentration relative to the optical axis did not alter with contact lens design ($F = 0.777$, $p = 0.542$), but was greater in the dominant eye (0.40 ± 0.19 mm vs. 0.34 ± 0.17 mm; $F = 9.917$, $p = 0.003$), although there was no interaction between these factors ($F = 2.275$; $p = 0.065$). Pupil size was poorly correlated with decentration in both dominant and non-dominant eyes ($r < 0.10$).

3.3.9. Aberrations

The patients acted as their own control as they wore all of the lenses thus natural pupil size was used for all evaluations. There was no difference in higher order aberrations induced between the contact lens designs ($F = 0.855$, $p = 0.493$), with eye dominance ($F = 3.621$, $p = 0.066$) or optical component (ocular, corneal or internal $F = 1.594$, $p = 0.211$) or any interaction between them ($p > 0.05$). There was no difference in spherical aberrations induced between the contact lens designs ($F = 0.318$, $p = 0.865$), with eye dominance ($F = 0.307$, $p = 0.583$) or optical component ($F = 0.636$, $p = 0.532$) or any interaction between them ($p > 0.05$).

3.4. DISCUSSION

This study is the first double blind, randomized controlled trial with contact lenses crossover to examine the relative difference in visual performance, ocular physiology and optics between modern silicone-hydrogel contact lenses for presbyopia compared to monovision. As highlighted in the introduction, whilst previous studies have examined visual performance differences between presbyopic lens designs, the tests used and comparisons made have been limited. None have examined differences in indicators of ocular physiology such as bulbar, limbal and palpebral hyperaemia along with corneal fluorescein staining. It is not surprising that the regular presence of contact lenses can cause changes in ocular physiology. While it might be expected that all silicone hydrogel contact lenses have a limited impact on ocular physiology as studies have shown they result in less redness than traditional hydrogel contact lenses (Brennan et al., 2002), both bulbar and palpebral hyperaemia differed between lens types. As the thickness profile of the contact lenses will differ depending on the optical power design, this could impact on oxygen transmission and tear dynamics, resulting in physiological changes, but why this impacted on only some of the physiological indicators and not others is not clear. The Biofinity lens seems to have had the least impact and as the only centre-distance design (Plainis et al., 2013), this might suggest that a thinner profile in the centre of the lens is beneficial to ocular physiology.

The monovision outperformed all the multifocal contact lenses on trial in both the mesopic and photopic conditions. When comparing results of acuity obtained between studies, the type of chart and the scoring method used may have a significant effect on the results obtained and is an important consideration. Previous studies have shown that in simultaneous vision the retinal images in both multifocal contact lenses and intraocular lenses reduces the contrast sensitivity under photopic and mesopic conditions compared with single vision lenses or monovision (Gupta et al., 2009; Madrid-Costa et al., 2010). This is due to the splitting of the incoming light into two or more foci (Montés-Micó et al., 2004). Consistent with previous studies with simultaneous vision multifocal intraocular lenses we observed that the patients wearing simultaneous multifocal contact lenses had worse contrast sensitivity under mesopic conditions (Ferrer-Blasco et al., 2008; Baylock et al., 2008).

The results will be different to that of other previous studies such as Gupta and colleagues (2009) who used only a centre-near aspheric multifocal lens in the dominant and non-dominant eyes. In contrast Fernandes and his colleagues (2013) used only a multifocal contact lens that combines different spherical and aspheric optics for the dominant and non-dominant eyes. The minimal variations observed in this study at distance vision even compared with monovision may be explained by the fact that there was an equal effect of an increase in retinal blur due to the superimposed images of the multifocal lenses and the central blur suppression scotoma observed by the monovision lens.

Stereoacuity was better with the multifocals compared with monovision contact lenses. Previous studies have demonstrated a range of stereoacuity from 40-sec arc to 400-sec arc with multifocal contact lenses depending on the type of lens, add power, and the test of stereoacuity used. Most studies have consistently found better stereoacuity with multifocal contact lenses than with monovision (Richdale et al., 2006; Gupta et al., 2009). The variation of stereoacuity may be the result of the near blur found with the multifocal contact lens and the modified monovision format (one high add and one low) as the fitting strategy proposed by the manufacturers of both Air Optix and Oasys resulted to a certain degree of '"modified monovision." The effects of monocular blur (e.g. monovision) on stereoacuity are known to be greater than the effects of binocular blur (e.g. superimposed retinal images in multifocal lenses) and therefore the stereoacuity of monovision is less than multifocal contact lenses (Goodwin and Romano, 1985; Fernandes et al., 2013). Multifocal optics with one lens biased to distance viewing and the other lens biased toward near viewing minimally affects stereoacuity as also concluded by Ferrer-Blasco and Madrid-Costa (2011). The stereoacuity observed in this study would differ depending on which stereotest was used. Some studies measure stereoacuity with multifocal contact lenses using Stereo (Titmus) Fly test (Stereo Optical, Chicago, IL) which is susceptible to monocular cues to depth and can therefore overestimate the actual level of stereopsis. In this study, the TNO random dot stereogram test was used as it is free from any monocular depth cues and requires outlines to be generated cortically, which can be more difficult with age resulting in worse values of stereoacuity.

The subjective range of clear vision for distance, near and intermediate, assessed by the defocus curves was not found to be greater with the multifocal contact lens than with monovision contact lenses or to differentiate between multifocal designs. The defocus curve showed a peak of optimum distance VA at zero defocus, vision remained optimum up to around +1.00D of positive defocus and the introduction of negative lenses resulted in a continuous worsening of the vision for all the contact lenses used for all defocus steps. The results do not show the traditionally expected near vision peak around +2.00D to +3.50D seen with most multifocal intraocular lens designs (Buckhurst et al., 2012). However, they closely match the defocus curves presented by Gupta and colleagues (2009) using the same robust defocus curve measurement technique, which gives the results more credibility. The difference probably results from contact lenses being further from the nodal point of the eye than the intraocular lens, being more mobile with every blink and with the optical profiles being more blended and aspheric refractive only designs (Plainis et al., 2013). AirOptix performed better at the distance VA, potentially resulting from its bi-aspheric front and back surface design.

Reading speed did not differ between all the lens designs under investigation. However, critical print size, the smallest text size at which the subject's reading speed remains unaffected, significantly differed between lens designs. Gupta and his colleagues (2009) found a similarity in CPS between monovision and the original Purevision multifocal design and concluded that the acuity threshold is affected by retinal blur and not the comfortable reading print size (Gupta et al., 2009). The difference between the original and new optical design of the Purevision 2 is described by the designers as more add power across the centre portion of the lens, wider intermediate zone where add power gradually transitions to an accurate distance power, optimized for a more natural experience (www.bausch.com, 2015).

Halo size did significantly differ between each lens design and between orientations with Purevision 2 creating the smallest halo. Earlier studies have identified that glare when night driving is a major issue for presbyopes (Rajagopalan et al., 2006). The results indicate that Purevision 2 was the least affected by a glare source. The difference in the power profiles of the multifocal lenses may explain this. Purevision 2 unlike some of the other two-zone bifocal design lenses, with a central circular region having one power and the surrounding outer ring with a constant power, has a more complex design with a power gradient increasing or decreasing gradually from the centre to the edge of the optical zone. Due to there being no specific distance or near zone, the lens has less of an abrupt change from the different zones thereby the performance varies differently with the pupil diameter and with its centration.

The rating of iPhone image clarity was significantly different between presbyopic corrections with the Biofinity and monovision outperforming Oasys and AirOptix, but not Purevision 2. This will provide an indicator of performance of individuals during their daily activities when using hand-held devices. NAVQ rating of near performance also differed between each lens designs with the Biofinity resulting in a significantly better quality of life score than the Oasys but there was no difference from the AirOptix, Purevision 2 and monovision presbyopic corrections. This finding is supportive of the use of the NAVQ questionnaire as a tool to differentiate between the overall ratings of satisfaction for near vision with presbyopic lenses. The Biofinity presumably performed in this way due to availability of the 'D" lens strongly biased in favour of distance vision and “N” design lens being strongly biased towards near vision (Plainis et al., 2013). The “D” lenses have a central distance zone, an intermediate annular zone of gradually increasing power for intermediate vision, and an outer “near” zone. The “N” design lenses have a broadly similar design producing a centre-near design lens.

The pupil size did not alter with contact lens design but was larger in the dominant eye. Pupil decentration relative to the optical axis did not alter with contact lens design, but was also greater in the dominant eye. Hence decentration of the lens relative to the pupil seems to be dictated by the anatomy of the individual rather than being influenced by the lens thickness profile. Pupil size was poorly correlated with decentration in both dominant and non-dominant eyes so these two aspects do not seem linked. Larger pupils increase the amount of light reaching the retina, but decrease the eyes natural depth of focus, so it is not clear how pupil size and decentration contribute to eye dominance. The performance of simultaneous multifocal contact lenses is dependent on pupil size and centration (Zandvoort et al., 1993; Bullimore and Jacobs, 1993). Good lens centration and limited movement of lens are important for a positive visual outcome with all the presbyopic contact lens options. Decentration changes the retinal image producing oblique astigmatism (Charman and Walsh, 1986) and is generally more pronounced for distance vision and for larger pupil diameters (Charman and Walsh, 1988). Since centre-near designs provide greater power in the lens centre due to the negative spherical aberration present, smaller pupils will enhance near visual acuity especially when high addition lenses are used, but will compromise distance vision.

There was no difference in higher order aberrations including spherical aberrations induced between the contact lens designs with eye dominance or optical component (ocular, corneal or internal). These findings suggest that all the current presbyopic contact lenses appear to have been designed with a similar combination of aberrations, which might in part explain why performance with these lens designs is largely similar. The results of this study should be relevant to the general population as the manufacturers’ guidelines were followed (although this resulted in modified monovision in many cases). The sample of patients were mainly female which reflects the imbalance in patients opting to wear contact lenses, although there are no known remarkable differences in related visual performance with gender (Richdale et al., 2006).

3.5. CONCLUSION

The visual performance of patients wearing multifocal contact lenses depends on two important factors: the characteristics of the lens (i.e. the optical design of its refractive surfaces) and the visual conditions for the patient (i.e. distance or near vision and the illumination level, because the latter affects both the ocular pupil size and neural performance) (Plainis et al., 2013).

This chapter has examined the first of these aspects, finding that despite the differences in optical design between presbyopic contact lenses (Plainis et al., 2013), once in the eye, the combination of the individual's optical aberrations and that of the lenses resulted in similar aberration profiles. This could explain the largely similar visual performance of the lenses. The generally equal performance of monovision probably resulted from the manufacturer's guidelines that were followed, which tend towards modified monovision fitting. This chapter looked at the objective measurements and the next chapter will examine how the patients felt with each lens using a lifestyle questionnaire to assess subjective response.

CHAPTER 4:
PREDICTING SUCCESS WITH PRESBYOPIC MULTIFOCAL DESIGNS.

4.1. INTRODUCTION

An ageing population is leading to an increased prevalence of presbyopia and with the new presbyopes being described as being more active, contact lenses provide an ideal vision correction modality (Gifford et al., 2013). The ability to make a prediction of the likelihood of success or failure of a particular design of multifocal contact lens or monovision will increase practitioner confidence in recommending and fitting, as the ratio of successful to non-successful wearers will increase with increased ability to make this prediction. This would promote the aspiration of patients to wear presbyopic contact lens correction, as patients would be less likely to drop out of the modality before a successful solution for their lifestyle, expectations and ocular optics is found. The decreased chair time also has potential cost savings to the practitioner and a reduction in the dropout rate should increase practice revenue. According to Morgan and colleagues (2011), 37 per cent of presbyopic contact lenses fitted to the over 45 years age group are being fitted with a distance prescription only and are likely to be relying on intermittent use of supplementary reading spectacles for close work (Morgan et al., 2011). Vision-related QOL is a potentially useful measure to assess how well these refractive corrections are serving the visual needs of presbyopic patients. The presbyopic practice cohort principal forms of refractive correction were distance spectacles (with near and intermediate vision provided by a variety of other forms of correction), varifocal spectacles and unaided distance with reading spectacles, with few patients wearing contact lenses as their primary correction modality.

So far the research conducted suggest it is unwise to rely on initial consulting room tests to predict success with multifocal contact lens options (Woods et al., 2009; Papas et al., 2009). Papas and colleagues (2009) examined 4 multifocal lens designs at dispensing and after 4 days and identified that performance changed over this time in an unpredictable manner. However, they did not compare preference between the lenses or visual function after adaptation to baseline measures to see whether this could have been predicted. Although adaptation to new contact lens multifocal optics has not been studied in detail, only 4 days would appear to be a relatively short period of time. Woods and colleagues (2009) examined one multifocal contact lens to monovision and distance vision worn over a one-week period. They used a less comprehensive battery to evaluate visual function, but concluded “that making a prediction of “success or not” based on consulting room acuity tests alone is probably “unwise” because monovision outperformed the multifocal in clinical testing whereas this was reversed in the “real-world” test.

The differences between individuals that might be expected to impact patient preference are activities performed, personality, pupil size and ocular aberrations. Pupil size may affect the proportion of distance, near and intermediate focus optics in front of the pupil aperture (Zandvoort et al., 1993), affecting visual quality and the lens design that works best for the particular individual. Some patients, such as those undertaking low contrast tasks, may prefer centre-distance to centre-near designs. Plainis and colleagues (2013) investigated the effect of pupil size and spherical aberration on the visual performance of centre-near, aspheric multifocal contact lenses. They found that both near VA and depth of focus improve with the multifocal contact lenses, the effect being more pronounced for small pupils, and binocular rather than monocular vision. They concluded that both ocular spherical aberration and the aberration profiles provided by the multifocal lenses affect their functionality. It is not just the optical design of the contact lenses that are of relevance, but the combination of these with the inherent aberrations of the eye. In addition, pupil decentration will cause changes in coma (Lopez-Gil et al., 2002) which if sufficiently increased could degrade image quality (Fernandez-Sanchez et al., 2008); hence pupil decentration differences between designs may influence preferences. Little has been published on the associations between multifocal contact lens induced aberrations and measured visual function. However, Martin and Roorda (2003) have shown that visual quality with bifocal soft lenses can be predicted based on contact lens induced ocular aberrations by investigating the variability of the patient’s response due to the interaction of the ocular aberrations and the aberrations produced by changes in defocus of the multizone bifocal contact lens. Variation in the subjective tolerance such as to blur (Woods et al., 2010) and anxiety towards lens wear (Laretzaki et al., 2011) have been observed, due to optical factors such as pupil size (Bakaraju et al., 2012), high-order aberrations (Bakaraju et al., 2010), binocular summation (Plainis et al., 2011) and personality characteristics.

Visual performance has been predicted by taking optical measurements into account (Woods et al., 1994). For example, Legras and Rouger (2008a) succeeded in predicting the contrast sensitivity visual benefit of correcting higher order aberrations of 25 subjects. Legras and colleagues (2010) were able to predict the through-focus visual performances (i.e. visual acuity and contrast sensitivity) of two multifocal contact lens designs. There are studies using adaptive optics to examine the effect of multifocal optics on clinical performance (limited to visual acuity and contrast sensitivity), which have also assessed subjective rating (Legras et al., 2010; Martin and Roorda, 2003; Legras and Rouger, 2008a). These studies have noted that there is a difference between the results of clinical measurements and the level of satisfaction experienced by patients.

Hence this study examines whether patient preference for a particular contact lens presbyopic correction option could be predicted from the activities they want to perform, their personality, pupil size and inherent ocular aberrations. In addition, the visual function achieved with the preferred presbyopic correction option is compared to the other contact lens options to determine what aspects of visual function might dictate this preference.

4.2. METHOD

4.2.1. Patients

As described in section 3.2.1, thirty-five presbyopic patient (27 females and 8 males) of mean age 54.3 ± 6.2 years (range 42 to 65 years) took part in this study based on the inclusion and exclusion criteria outlined.

4.2.2. Contact Lenses

All the patients were randomly assigned to be fitted with one of four different silicone hydrogel multifocal or monovision contact lenses:
Air Optix AQUA (AO) multifocal (Alcon, Fort Worth, Texas, USA) low-, medium-, and high- add lenses (centre-near aspheric/bi-aspheric designs).
PureVision 2 for Presbyopia (PV 2) multifocal (Bausch & Lomb, Rochester, New York, USA) low- and high-add lenses (centre-near aspheric/ bi-aspheric designs).
Acuvue OASYS for Presbyopia (Vistakon, Division of Johnson & Johnson Vision Care, Jacksonville, Florida, USA) low-, medium-, and high-add lenses (several concentric aspheric distance/centre-near zones).
Biofinity multifocal (Cooper Vision, Fairport, New York, USA) + 1.50, +2.00 and

+2.50 D add lenses. The lenses were of the ‘‘D’’ design, in which the ‘‘distance’’ correction is at the lens centre (centre-distance) or the ‘‘N’’ design is also available, in which the ‘‘near’’ correction is at the lens centre (centre-near).
Monovision with Biofinity single vision lenses (Cooper Vision, Fairport, New York, USA).

The patient remained masked as to which lens design or monovision they had been prescribed, and were provided with the contact lenses in an unmarked case by the unmasked practitioner. The fitting of each lens was strictly according to each respective lens manufacturer’s guidelines (see Appendix A1; A2; A3; A4). All the subjects were instructed on lens insertion, removal, and cleaning techniques as required and were provided with a supply of preservative free multipurpose solutions or one-step peroxide consistent with their previous cleansing regime. All the patients except one used the preservative free multipurpose solutions, but as they used this for all lenses this will have caused no bias in the lens comparison. Once the fitting procedure was complete at a single initial visit, the subjects were asked to trial the contact lenses for 4 weeks to allow for adaptation (Sheedy et al., 1993). Most of the research conducted on multifocal contact lenses, have trialled the lenses for a period of 4 weeks (Madrid-Costa et al., 2012; Gupta et al., 2009; Ferrer-Blasco and Madrid-Costa, 2011), as this seems to be sufficient for the patient to adapt (see section 1.4; Table 1.2). On completion of the 4 weeks of contact lens wear, the patient returned for assessment of visual function and optics by a masked clinician before being prescribed the next lens type in a randomized order.

Measurements of visual function with each lens are described in chapter 3. Optical aberrations of the patient’s eyes (not wearing the contact lenses) were measured using a wavefront analyzer (KR-1W, Topcon Tokyo, Japan) with a Placido disc assessment of corneal aberration, Hartmann-Shack lenslet array analysis of total aberrations and calculation of internal aberrations from the difference between these (Pisella, 2012). The aberrometer also measured the pupil size with the in-build camera and calculated the distance between the centre of the optical profile and the centre of the pupil.

The study followed the tenets of the Declaration of Helsinki and informed consent was obtained from all participants after explanation of the nature, procedures, and consequences of this study. The Audiology and Optometry Research Ethics Committee of Aston University approved the study and subjects were free to withdraw at any time without obligation.

4.2.3. Assessment of Lifestyle and Personality

A lifestyle questionnaire was completed prior to the contact lenses being fitted (see Appendix A10). As there is no validated questionnaire for lifestyle analysis with respect to presbyopic corrections, the questions were adapted from a range of previous multifocal contact lens and refractive error studies (Nichols et al., 2003; Richdale et al., 2006; Woods et al., 2009). A self-administered questionnaire assigned to assess how refractive errors affect daily life was developed and validated as reliable in 2003 (Nichols et al., 2003). Du Toit and colleagues in 1998 used Cattell's 16 Personality Factor (16 PF) test, to examine those patients who would continue with monovision, finding only one aspect, "superego strength," was relevant. Hence personality was assessed subjectively by asking the patient to represent his/her view of his/her personality in a linear scale from 0-10 where 0 represented easy going and 10 represented a perfectionist. This was felt to be an important aspect to measure, as the personality of a patient will determine a willingness to accept a compromise in vision (Bennett, 2008).

4.2.4. Presbyopic Contact Lens Preference

After the completion of the study, patients were asked to choose their preferred presbyopic correction from the 5 lens modalities (i.e. “no preference” was not an option).

4.2.5. Data Analysis

Lifestyle characteristics were found to be not normally distributed (Kolmogorov-Smirnov test $p < 0.05$) therefore non-parametric rank analysis of variance (Independent samples Kruskal-Wallis distribution comparison Test) was conducted. Pupil parameters and aberrations as well as age, PC working distance and near addition power were found to be normally distributed (Kolmogorov-Smirnov test $p > 0.05$) therefore parametric repeated measures analysis of variance was conducted.

As outlined in chapter 3, failure to correctly recognize plate IV on the TNO stereopsis test was allocated a score of 540 minutes of arc, one step between plates below plate IV. Right eyes only were analyzed except for aberrations and pupil size, where the eyes were analyzed grouped as ocular dominant or non-dominant. As two of the lenses (Acuvue OASYS and AirOptix Aqua) had less than 5 patients who selected them, these were excluded from the analysis. For those patients who selected the Biofinity multifocal, Purevision 2 for Presbyopia multifocal and monovision, the measurements with their preferred lens were compared with those patients who did not prefer that lens. In addition, those patients preferring each of the Biofinity multifocal, Purevision 2 for Presbyopia multifocal and monovision lens options, had their measurement with their preferred lens compared with the measurement with the lenses they did not prefer. As pupil parameters and aberrations were found to be normally distributed (Kolmogorov-Smirnov test $p > 0.05$), parametric t-tests or repeated measures analysis of variance was conducted. For the other metrics, Friedman non-parametric testing was employed.

4.3. RESULTS – PREDICTION OF PREFERENCE FROM BASELINE INFORMATION

Ten patients preferred monovision correction, 12 Biofinity, 7 Purevision, 4 AirOptix and 2 Oasys.

4.3.1. Lifestyle Activities

The activities reported as performed on a regular basis are presented in Figure 4.1. The importance of near tasks and intermediate tasks were rated as “important” to subjects (median grade) and they were estimated to be conducted 4.1 ± 2.1 hours and 5.6 ± 2.3 hours a day respectively. Books were reported to be held at chest level (median) and their computer screen working distance was estimated to be on average 55 ± 15cm. Night driving was reported to be undertaken occasionally (median).

There was a significant difference in contact lens preference with age ($F = 4.046$, $p = 0.010$), with those preferring AirOptix (62.8 ± 3.9 years) being significantly older than those preferring Biofinity (52.8 ± 4.6 years; p = 0.025) or monovision (51.0 ± 6.7 years; p = 0.007), but not near addition power (F = 0.137, p = 0.967) or computer working distance (1.927, p = 0.132). In the lifestyle characteristics that were relevant to over 80% of patients (Figure 4.1), there was no difference in contact lens preference based on distribution of gender (p = 0.756), eye dominance (p = 0.802), glasses usage (p = 0.117), newspaper/book reading frequency (p = 0.629), day (p = 0.285) and night time driving frequency (p = 0.858), computer use hours (p = 0.702), cooking (p = 382), shopping (p = 0.899), mobile phone usage n (p = 0.983), paperwork (p = 0.194), movie (p = 0.415), importance of near (p = 0.287) and intermediate (p = 0.346) work, hours of near (p = 0.535) and intermediate (p = 0.759) work per day and distance of book reading (p=0.350).

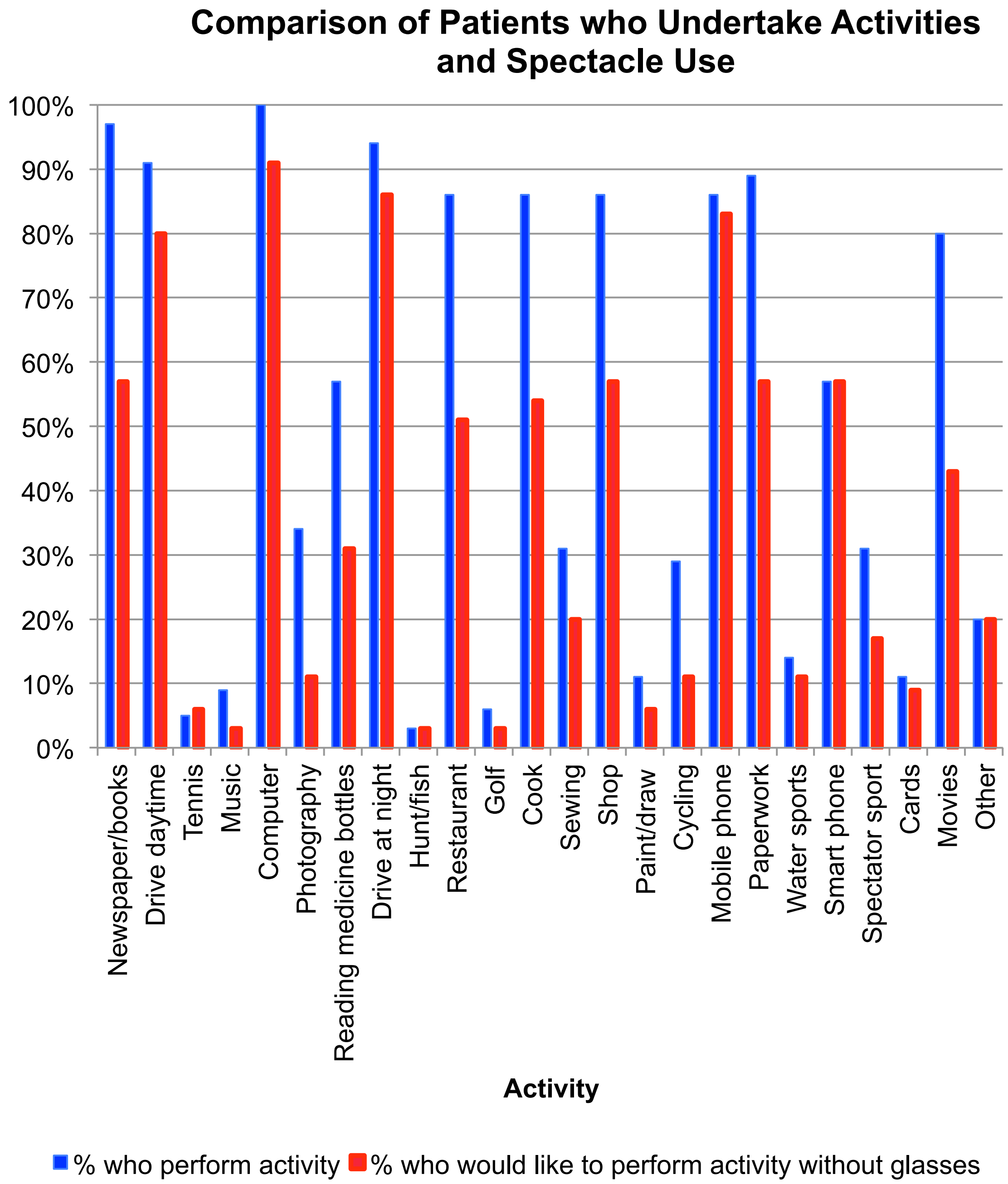

Figure 4.1: Lifestyle activities of the patients involved in the study presenting the percentages of the patients who perform each activity and the percentage of patients who would like to perform the activity without glasses.

4.3.2. Personality

The majority of patients scored a personality score of 6 indicating most of the patients were erring on being more of a perfectionist with >60% reporting a personality score of 6 or more (Figure 4.2). There was no significant difference in personality between those patients preferring one presbyopic contact lens design compared to another (F = 1.182, p = 0.323).

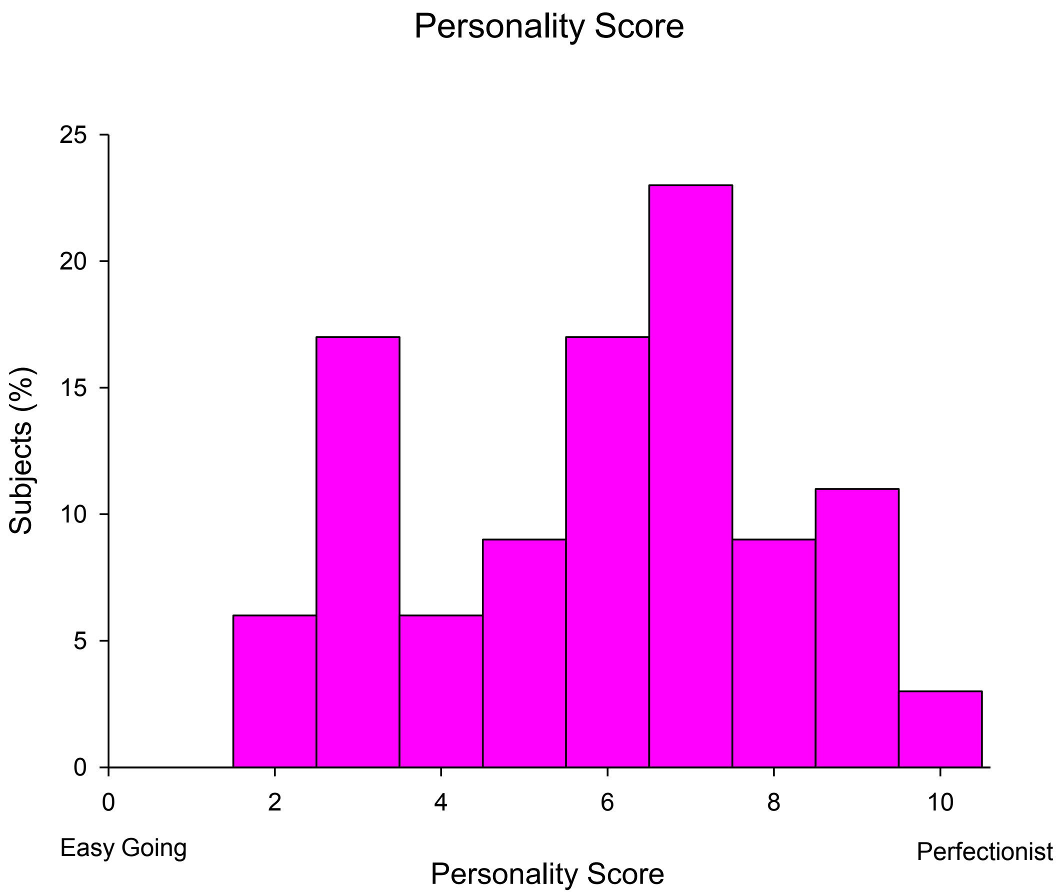

Figure 4.2: The percentage of patients in the study who subjectively assessed their personality out of a score of 0 to 10 (where 0 is easy going and 10 is a perfectionist). N=35.

4.3.3. Pupil

There was no difference in pupil size between those patients preferring one presbyopic contact lens design compared to another (F = 0.910, p = 0.471) and no interaction with ocular dominance (F = 1.174, p = 0.342) although as found with contact lenses (see section 2.2.3), the pupil size of the eye deemed to be dominant was larger (5.27 ± 0.99 mm vs. 5.08 ± 1.01 mm; $F = 4.206$, $p = 0.049$). Again there was no difference in pupil decentration relative to the optical axis between those patients who preferred one presbyopic contact lens design compared over another ($F = 0.641$, $p = 0.638$) and no interaction with ocular dominance ($F = 0.435$, $p = 0.782$).

4.3.4. Aberrations

There was no difference in pre-contact lens fitting aberrations between patients who preferred one type of optical design to another (Table 4.1).

Table 4.1: Analysis of variance between aberrations prior to contact lens wear compared between patients who preferred each of the presbyopic contact lens corrections. N = 35.

Aberrations	Overall		With eye dominance		With optical component	
	F	P	F	P	F	P
Astigmatism	1.535	0.217	1.416	0.253	1.196	0.317
Higher Order Aberrations	0.703	0.596	1.266	0.305	0.591	0.782
3rd Order Aberrations	0.673	0.616	1.267	0.305	0.601	0.774
4th Order Aberrations	0.882	0.486	1.199	0.332	0.907	0.517
Trefoil	0.689	0.605	1.203	0.33	0.939	0.492
Coma	0.598	0.667	1.308	0.29	0.746	0.651
Tetrafoil	1.001	0.423	1.717	0.172	1.38	0.224
2nd Order Astigmatism	1.04	0.403	0.88	0.488	0.887	0.533
Spherical	1.225	0.321	0.415	0.797	0.919	0.508

4.4. RESULTS – RELATIONSHIP OF PREFERENCE COMPARED TO VISUAL FUNCTION WITH PRESBYOPIC CONTACT LENS OPTIONS

For those patients who selected the Biofinity multifocal, Purevision 2 for Presbyopia multifocal and monovision which had sufficient group sizes, visual function measurement were compared:

With their preferred lens vs. those patients who did not prefer that lens.
With their preferred lens vs. the other lenses these patients trialed but did not prefer.

4.4.1. Physiology

Bulbar hyperaemia ($p > 0.05$), limbal hyperaemia ($p > 0.05$), palpebral redness and roughness ($p > 0.05$) and fluorescein staining ($p > 0.05$) were not statistically different in those who preferred one multifocal lens design or monovision compared with those who did not choose this option (Table 4.2). This was also the case for the multifocal lens designs or monovision not preferred by that patient group (Table 4.2).

Table 4.2: Bulbar hyperaemia, limbal hyperaemia, palpebral redness and roughness and fluorescein staining grading (Efron scale) compared between those patients preferring a multifocal lens design or monovision compared with those patients who preferred the other designs trialled (other patients) and to the multifocal designs or monovision not preferred by this group (not preferred). N = 35.

	Bulbar Hyperaemia	Limbal Hyperaemia	Palpebral Hyperaemia	Corneal Staining
	Biofinity Multifocal			
Preferred lens n=12	2.2 ± 0.8	1.8 ± 0.7	1.6 ± 0.8	0.0 ± 0.0
Other patients n=23	1.6 ± 1.4	1.5 ± 1.2	1.3 ± 1.1	0.1 ± 0.3
Significance	0.217	0.356	0.520	0.202
Significance with lenses not preferred n=12	0.206	0.733	0.273	0.368
	Purevision 2 Multifocal			
Preferred n=7	1.6 ± 1.0	1.6 ± 1.0	1.7 ± 0.8	0.1 ± 0.4
Other patients n=28	2.4 ± 1.0	2.3 ± 1.2	2.1 ± 0.9	0.1 ± 0.3
Significance	0.058	0.169	0.285	0.789
Significance with lenses not preferred n=7	0.293	0.387	0.080	0.368
	Monovision			
Preferred n=10	2.7 ± 1.1	2.3 ± 0.9	2.2 ± 1.0	0.3 ± 0.5
Other patients n=25	2.2 ± 1.4	2.0 ± 1.4	1.8 ± 1.2	0.2 ± 0.4
Significance	0.346	0.528	0.306	0.364
Significance with lenses not preferred n=10	0.074	0.061	0.195	0.174

4.4.2. Acuity and Stereopsis

BDCVA ($p > 0.05$), stereoacuity ($p > 0.05$), high or low contrast acuity under mesopic conditions ($p > 0.05$) and high contrast acuity under photopic conditions ($p > 0.05$) were not statistically different in those preferring one multifocal lens design or monovision compared with those who did not choose this option (Table 4.3). However, patients who preferred the Purevision 2 multifocal achieved better low contrast acuity under photopic conditions than subjects who preferred the other lens designs or monovision. There was generally no difference in the acuity metrics for each preference group between their performance with the preferred and non-preferred lens designs or monovision except for high contrast acuity under photopic conditions in which case those who preferred the Biofinity had better acuity (0.04 ± 0.11logMAR) than with the Purevision 2 lens design (0.07 ± 0.09logMAR) or monovision (0.07 ± 0.09logMAR; Table 4.3). For stereoacuity, the statistical differences arose from poorer stereoacuity with monovision compared with the multifocal lens designs as expected (Table 4.3).

Table 4.3: Binocular best distance corrected visual acuity (BDCVA), acuity at high (95%) and low (12.5%) contrast under photopic and mesopic conditions and stereopsis were compared between those patients who preferred a multifocal lens design or monovision and compared with those patients who preferred the other designs trialled (other patients) and to the multifocal designs or monovision not preferred by this group (not preferred). N = 35.

	Binocular BDCVA (logMAR)	Photopic CS 95% (logMAR)	Photopic CS 12.5% (logMAR)	Mesopic CS 95% (logMAR)	Mesopic CS 12.5% (logMAR)	Near Stereopsis (min/arc)
	Biofinity Multifocal					
Preferred n=12	0.04 ± 0.11	0.04 ± 0.11	0.18 ± 0.11	0.06 ± 0.13	0.23 ± 0.16	200.0 ± 141.5
Other patients n=23	0.11 ± 0.15	0.11 ± 0.15	0.29 ± 0.20	0.15 ± 0.23	0.33 ± 0.28	231.7 ± 106.2
Significance	0.179	0.077	0.179	0.248	0.224	0.460
Significance with lenses not preferred n=12	0.494	0.024	0.521	0.132	0.182	0.029
	Purevision 2 Multifocal					
Preferred n=7	0.07 ± 0.15	0.07 ± 0.10	0.12 ± 0.14	0.09 ± 0.14	0.22 ± 0.12	252.9 ± 91.4
Other patients n=28	0.08 ± 0.09	0.08 ± 0.15	0.25 ± 0.11	0.14 ± 0.12	0.29 ± 0.12	255.0 ± 113.6
Significance	0.777	0.887	0.007	0.352	0.196	0.963
Significance with lenses not preferred n=7	0.595	0.067	0.311	0.459	0.495	0.038
	Monovision					
Preferred n=10	0.05 ± 0.10	0.06 ± 0.09	0.22 ± 0.11	0.10 ± 0.15	0.23 ± 0.16	309.0 ± 131.2
Other patients n=25	0.05 ± 0.08	0.05 ± 0.10	0.19 ± 0.15	0.08 ± 0.10	0.22 ± 0.11	351.6 ± 140.0
Significance	0.999	0.855	0.615	0.566	0.887	0.414
Significance with lenses not preferred n=10	0.245	0.567	0.469	0.255	0.704	0.050

4.4.3. Defocus Curves

With the Biofinity multifocal there was no difference in defocus curve between those who preferred this lens design and those who did not ($F = 1.246$, $p = 0.272$) nor was there an interaction with the level of defocus ($F = 0.475$, $p = 0.915$). With the Purevision 2 multifocal there also was no difference in defocus curve between those preferring this lens design and those who did not ($F = 0.259$, $p = 0.720$) nor was there an interaction with the level of defocus ($F = 0.471$, $p = 0.940$). However, with monovision there was a difference in defocus curve between those who preferred this lens modality and those who did not ($F = 4.102$, $p = 0.001$) and there was an interaction with the level of defocus ($F = 2.127$, $p = 0.012$; Figure 4.3).

For the Biofinity multifocal there was no difference in defocus curve for those preferring this lens design between this lens and the other multifocal designs and monovision ($F = 1.418$, $p = 0.280$) nor an interaction with the level of defocus ($F = 1.254$, $p = 0.200$). For the Purevision 2 multifocal there was also no difference in defocus curve for those preferring this lens design between this lens and the other multifocal design and monovision ($F = 2.719$, $p = 0.088$) nor an interaction with the level of defocus ($F = 1.312$, $p = 0.147$). Finally for monovision there was no difference in defocus curve for those preferring this lens modality, between this lens wear modality and the two multifocal designs ($F = 0.426$, $p = 0.659$) nor an interaction with the level of defocus ($F = 1.428$, $p = 0.088$).

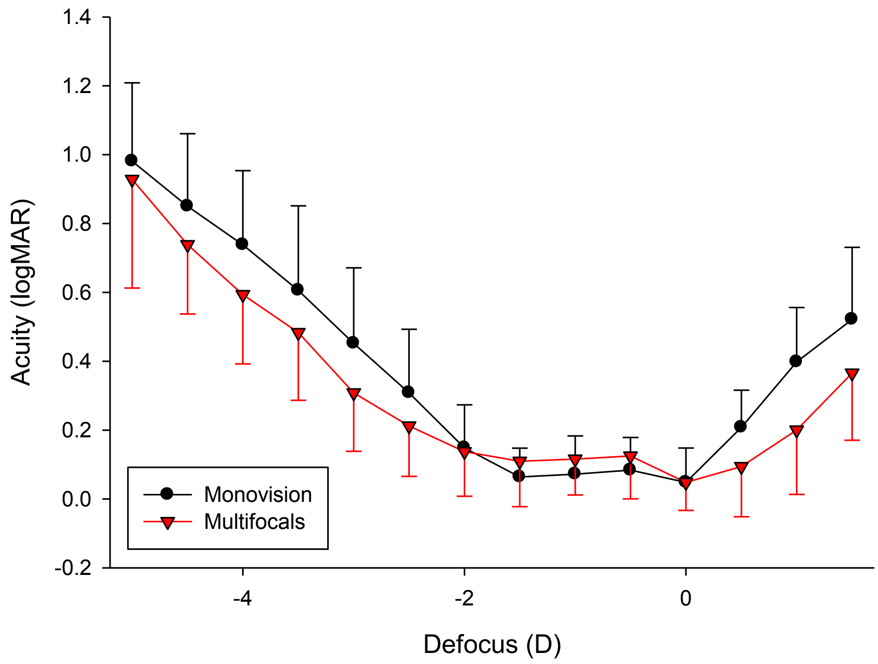

Figure 4.3: Defocus curve of those preferring monovision (n = 10) compared with those who did not (n = 25) showing a negative difference and an interaction with the level of defocus. Error bars = 1 S.D.

4.4.4. Reading

With the Biofinity multifocal, there was no difference in reading speed between those preferring this lens design and those who did not (155.3 ± 17.8 vs. 154.3 ± 24.4; p = 0.897), whereas the critical print size of those preferring this lens design was significantly better than those who did not (0.13 ± 0.11 vs. 0.28 ± 0.15; p = 0.004). For the Purevision 2 multifocal, there was no difference in reading speed between those preferring this lens design and those who did not (147.0 ± 17.7 vs. 157.5 ± 20.9; p = 0.231) and the critical print size of those preferring this lens design was similar to those who did not (0.30 ± 0.12 vs. 0.30 ± 0.18; p = 0.999). For monovision, there was no difference in reading speed between those preferring this lens modality and those who did not (159.1 ± 20.3 vs. 160.5 ± 24.4; p = 0.877) and the critical print size of those preferring this lens design was similar to those who did not (0.22 ± 0.14 vs. 0.22 ± 0.18; p = 0.951).

With the Biofinity multifocal, there was no difference in reading speed (p = 0.867) or critical print size (p = 0.891) for those preferring this lens design, between this lens and the other multifocal design or monovision. With the Purevision 2 multifocal, there was also no difference in reading speed (p = 0.717) or critical print size (p = 0.074) for those preferring this lens design between this lens and the other multifocal design or monovision. For monovision, there was no difference in reading speed (p = 0.202) or critical print size (p = 0.272) for those preferring this lens modality between this lens modality and the two other multifocal designs.

4.4.5. Glare

With the Biofinity multifocal there was no difference in halo size between those preferring this lens design and those who did not (F = 0.817, p = 0.373) nor an interaction with the angle of eccentricity (F = 0.707, p = 0.666). With the Purevision 2 multifocal there also was no difference in halo size between those preferring this lens design and those who did not (F = 0.312, p = 0.580) nor an interaction with the angle of eccentricity (F = 0.795, p = 0.592). However, with monovision although there was a difference in halo size between those preferring this lens modality and those who did not (F = 1.556, p = 0.221), there was an interaction with the angle of eccentricity (F = 2.761, p = 0.011).

With the Biofinity multifocal there was no difference in glare for those preferring this lens design, between this lens and the other multifocal design and monovision (F = 0.195 p = 0.824) and no interaction with orientation of light scatter (F = 1.117, p = 0.347). With the Purevision 2 multifocal there was also no difference in glare for those preferring this lens design between this lens and the other multifocal design and monovision (F = 2.186, p = 0.155) and no interaction with the orientation of light scatter (F = 0.894, p = 0.568). Finally with monovision there was no difference in glare for those preferring this lens modality between this lens wear modality and the two multifocal designs (F = 1.490, p = 0.252) and no interaction with the orientation of light scatter (F = 1.589, p = 0.091).

4.4.6. Subjective Rating

With the Biofinity multifocal there was no difference in NAVQ rating of near performance (34.0 ± 16.7 vs. 42.9 ± 16.8; p = 0.146) or iPhone image clarity

(7.8 ± 1.7 vs. 7.3 ± 2.6; p = 0.496) between those preferring this lens design and those who did not, nor in the distance at which the iPhone was held (39.6 ± 7.5 vs. 39.3 ± 5.9; p = 0.890). For the Purevision 2 multifocal there was no difference in NAVQ rating of near performance (36.2 ± 16.3 vs. 43.3 ± 24.7; p = 0.477) or iPhone image clarity (7.6 ± 2.5 vs. 6.4 ± 2.5; p = 0.273) between those preferring this lens design and those who did not, nor in the distance at which the iPhone was held (39.9 ± 7.1 vs. 39.3 ± 6.3; p = 0.826). With monovision there was no difference in NAVQ rating of near performance (39.9 ± 16.5 vs. 46.0 ± 19.3; p = 0.387) or iPhone image clarity (8.0 ± 1.5 vs. 7.1 ± 2.2; p = 0.256) between those preferring this lens modality and those who did not, nor in the distance at which the iPhone was held (38.5 ± 4.7 vs. 39.7 ± 7.0; p = 0.617).

With the Biofinity multifocal, there was also no difference in NAVQ rating of near performance (p = 0.534) for those preferring this lens design between this lens and the other multifocal design or monovision, but iPhone image clarity was worse with monovision when compared with the Biofinity multifocal (p = 0.025). With the Purevision 2 multifocal, there was also no difference in NAVQ rating of near performance (p = 0.873) or iPhone image clarity (p = 0.276) for those preferring this lens design between this lens and the other multifocal design or monovision. For monovision, there was no difference in NAVQ rating of near performance (p = 0.272) or iPhone image quality (p = 0.459) for those preferring this lens modality, between this lens modality and the two other multifocal designs.

4.4.7. Pupil Size / Centration

Pupil size and centration in the dominant and non-dominant eye were not statistically different (p > 0.05) in those preferring one multifocal lens design or monovision compared with those preferring one multifocal lens design or monovision compared with those who did not choose this option (Table 4.4). This was also the case for the multifocal lens designs or monovision not preferred by the same patient group (Table 4.4).

Table 4.4: A comparison of pupil size and centration in the dominant and non-dominant eye in those patients preferring a multifocal lens design or monovision compared with those patients preferring the other designs trialled (other patients) and with the multifocal designs or monovision not preferred by this group (not preferred). N = 35.

	Pupil Size		**Pupil Centration**	
	Dominant	*Non-Dominant*	*Dominant*	*Non-Dominant*
	Biofinity Multifocal			
Preferred n=12	4.6 ± 0.9	4.6 ± 0.9	0.4 ± 0.2	0.3 ± 0.1
Other patients n=23	4.7 ± 1.1	4.7 ± 1.1	0.4 ± 0.2	0.3 ± 0.2
Significance	0.779	0.897	0.786	0.960
Significance with lenses not preferred n=12	0.717	0.999	0.178	0.529
	Purevision 2 Multifocal			
Preferred n=7	5.3 ± 1.0	5.1 ± 1.0	0.5 ± 0.1	0.3 ± 0.2
Other patients n=28	5.1 ± 0.8	4.9 ± 0.8	0.4 ± 0.2	0.3 ± 0.2
Significance	0.537	0.641	0.632	0.684
Significance with lenses not preferred n=7	0.867	0.368	0.867	0.867
	Monovision			
Preferred n=10	5.0 ± 1.0	5.0 ± 1.3	0.4 ± 0.2	0.4 ± 0.1
Other patients n=25	5.1 ± 0.9	4.9 ± 0.9	0.3 ± 0.2	0.3 ± 0.2
Significance	0.773	0.800	0.244	0.184
Significance with lenses not preferred n=10	0.926	0.905	0.670	0.301

4.4.8. Aberrations

With the Biofinity multifocal there was no difference in aberrations between those who preferred this lens design and those who did not (F = 0.100, p = 0.754) and no interaction with eye dominance (F = 0.414, p = 0.524), ocular component (cornea, lens or whole eye: F = 0.531, p = 0.591), but there was an interaction with difference in aberrations (F = 2.618, p = 0.009). For the Purevision 2 multifocal there was also no difference in aberrations between those preferring this lens design and those who did not (F = 0.171, p = 0.682), no interaction with eye dominance (F = 0.402, p = 0.531), ocular component (cornea, lens or whole eye: F = 1.022, p = 0.366), but there was an interaction with difference in aberrations (F = 2.042, p = 0.042). For monovision there was no difference in aberrations between those preferring this lens modality and those who did not (F = 0.046, p = 0.831) and no interaction with eye dominance (F = 0.061, p = 0.807), ocular component (cornea, lens or whole eye: F = 0.138, p = 0.872), nor was there an interaction with difference in aberrations (F = 1.421, p = 0.188).

With the Biofinity multifocal there was no difference in aberrations for those preferring this lens design between this lens and the other multifocal design and monovision (F = 0.333, p = 0.721) and no interaction with lens structure (F = 0.684, p = 0.607) or ocular structure (F = 1.287, p = 0.296), but there was an interaction with ocular dominance (F = 5.124, p = 0.015) and ocular aberrations (3.733, p < 0.001). With the Purevision 2 multifocal there was also no difference in aberrations for those preferring this lens design between this lens and the other multifocal design and monovision (F = 0.226, p = 0.816) and no interaction with eye dominance (F = 0.081, p = 0.922), ocular structure (cornea, lens, whole eye: F = 1.341, p = 0.284), but there was an interaction with ocular aberrations (F = 2.723, p < 0.001). Finally with monovision there was no difference in aberrations for those preferring this lens modality, between this lens wear modality and the two multifocal designs (F = 0.246, p = 0.784) and no interaction with ocular dominance (F = 1.309, p = 0.295), ocular structure (F = 0.954, p = 0.445), but there was an interaction with ocular aberrations (F = 2.810, p = 0.009).

4.5. DISCUSSION

Subjective visual satisfaction and success with wearing different contact lens designs have been studied previously (Gupta et al., 2009; Richdale at al., 2006; Situ et al., 2003; Papas et al., 2009; Gispets et al., 2011). A number of studies report a subjective preference for multifocal options (Situ et al., 2003; Richdale et al., 2006). Papas and colleagues (2009) found a reduction in subjective visual satisfaction due to visual quality, visual fluctuation, facial recognition, halos, ghosting and overall satisfaction with the four multifocal lenses they used in their study. Fernandes and co-authors also confirmed this later in 2013.

The performances of simultaneous vision multifocal contact lenses are dependent on pupil size and centration (Zandvoort et al., 1993) and objective assessment of these features have been proposed to aid the understanding of the performance and preference of the multifocal lenses and monovision. Brenner suggested that subjective results are the key to assessing the success of these lenses (Brenner, 1994). It is thought that the quality of reading vision is more important than that of distance vision when deciding on the preference of a multifocal lens (Hutnik & O'Hagan, 1997). Therefore the subjective view of near vision is more significant.

The different refractive designs may help explain the difference in performance. The centre part of the Purevision lens used by Gupta and co-authors (2009) was covered by the near power for both eyes. In contrast Fernandes and colleagues (2013), used this scenario in the non-dominant eye with the dominant eye having a central spherical zone for clear distance vision, which may explain the Biofinity presbyopic contact lens design performing so highly in the results. Furthermore, the asymmetric nature of Biofinity multifocal limits the distance vision in the non-dominant eye and the near vision in the dominant eye, which corresponds to the parameter of the lens where the central spherical area for near is 1.7mm and for the distance area is 2.7mm (Fernandes et al., 2013). The aspheric nature of the front surface of Biofinity single vision lens may have contributed to monovision performing better than conventional spherical lenses although there was a significant preference for this correction. More than two distinct power profiles with higher add powers may help reduce the inconvenience of changing lens powers, as reading needs increase and can help keep patients for longer in multifocal contact lenses.

Plainis and colleagues (2013) noted that the new breed of multifocal lenses have no clearly defined “distance” and “near” powers but a gradual variation in power across the lens surface resulting in an increased depth of focus producing a reasonable quality of image and visual acuity (Hickenbotham et al., 2012). The through-focus nature of the image will vary dependant on the pupil diameter and within the depth of focus, the best focus will change with the spatial frequency spectrum of the target viewed (Charman and Saunders, 1990). The net effect of the add is not the same as the depth of focus since a non-zero depth of focus exists even in a single vision lens. The effect of the add is the increase in the depth of focus that would be achieved over that of the single vision lens (Yi et al., 2011). The aberrations of the eye, especially the spherical aberration, can influence the power profiles of the contact lens worn. The spherical aberration of the eye varies with the individual (Plainis et al., 2005) and generally increases with age (Atchison and Markwell, 2008). With centre-near lenses e.g. AirOptix and Purevision the overall spherical aberration is reduced due to the “add effect” for the lenses being not additive unlike when a normal soft lens is worn in the eye (Dietze and Cox, 2003). The wide range of spherical aberrations measured for different individuals explains the range of preferences for the lenses (Plainis et al., 2013). The eyes natural aberrations will be reduced by the contact lenses depending on their design.

Subjective ratings may appear routine but they are a means of formalizing parts of a history taking. Papas and Schultz looked into these subjective responses with the results suggesting that vision rating can be repeatable, provided that the overall visual standard is fairly good (Papas and Schultz, 1997). In fact, Papas and colleagues suggest that although there may be good reasons for measuring and recording acuity, a legal requirement as recommended by the College of Optometrists (The College of Optometrists Members handbook), its importance in multifocal assessment appears to be limited (Papas et al., 2009).

The use of the computer, reading newspapers and books, driving both at night and daytime and using a mobile phone were the main activities the patients regularly performed and also wished to continue without wearing any glasses. The real time assessment of vision using an iPhone to collect subjective data proved to be important as most of the patients used the mobile phone and wished to be spectacle free when using this hand held device. Gispets and colleagues (2011) investigated task orientated visual satisfaction with two different designs of multifocal lenses used in this study. They observed that

visual satisfaction decreased for tasks involving visual demands for near and distance vision rather than for intermediate vision.
In the lifestyle characteristics that were relevant to over 80% of patients, there were no differences in contact lens preference based on distribution of gender, eye dominance, glasses usage, newspaper/book reading frequency, day and night time driving frequency, computer use, cooking, shopping, the use of the mobile phone, paperwork, watching films, importance of near and intermediate work, hours performing near and intermediate work per day and distance of book reading. There was a significant difference in contact lens preference related to age, with those preferring AirOptix being significantly older than those preferring Biofinity or monovision, but not related to near addition power or PC working distance. This was unexpected as the ocular spherical aberrations increases in multifocal contact lenses with increasing add powers (Bakaraju et al., 2010). Personality was also found not to impact lens preference. The lack of factors affecting lens preference may be due to the similar optical aberrations induced, not creating a large enough advantage for a particular lens optical design in a particular visual environment. This hypothesis was recently supported by the analysis of the subjective visual and task performance with a questionnaire that was completed by Fernandes and colleagues in 2013. Despite the differences observed between the Biofinity multifocal and the monovision lens types there was no significant difference in the subjective perception of the visual performance between the lens types used. Alternatively, the same size, split by lens preference, may not have been large enough to detect small differences in the baseline features measured in the patients.

Best corrected visual acuity, stereoacuity, high or low contrast acuity under mesopic conditions and high contrast acuity under photopic conditions were not statistically different in those preferring one multifocal lens design or monovision compared with those who did not choose this option. It is hard to explain the one difference that was statistically significant, where patients who preferred the Purevision 2 multifocal achieved better low contrast acuity under photopic conditions than subjects preferring the other lens designs or monovision.

More importantly, there were generally no differences in the acuity metrics for each preference group between their performance with the preferred and non-preferred lens designs or monovision. However, the better high contrast acuity under photopic conditions achieved with the Biofinity multifocal by patients who preferred this lens design compared with the Purevision 2 lens design or monovision could have driven this lens preference. Except for this case, acuity measurements, regardless of lighting and contrast conditions do not seem to drive lens preference.

It was quite an unexpected finding that those who preferred monovision were not the patients who had better vision across a range of distances than those who preferred a multifocal lens design, but in fact the converse. This was not to do with a difference in age as identified. It was also not to do with how the patients preferring monovision performed with multifocal contact lens designs, where there was found to be no difference. Hence it would seem that visual acuity across a range of distances does not drive lens preference. Likewise, functional vision as assessed by reading speed did not drive lens preference, although those patients who preferred one of the multifocal lens designs (the Biofinity multifocal) maintained their reading speed at lower print sizes (critical print size) compared with patients who did not prefer this lens design, which may have contributed to this preference. However, those patients preferring the Biofinity had an equally good critical print size with the other lens modalities trialled in this study.

As with defocus curves, it was quite unexpected that the people who preferred monovision were not the patients that had a smaller glare spread than those who preferred a multifocal lens design, but in fact the converse. Again, this was not to do with a difference in age. It was also not to do with how the patients preferring monovision performed with multifocal contact lens designs, where there was found to be no difference. Hence it would seem that glare does not drive lens preference.

Subjectively, there was no difference in NAVQ rating of near performance or iPhone image clarity between those patients preferring a particular lens design and those who did not, nor in the distance at which the iPhone was held. However, once again those preferring the Biofinity multifocal contact lens design rated image clarity of an iPhone to be better with this design compared to those patients wearing monovision, perhaps partly driving their preference for this design.

Pupil size and centration in the dominant and non-dominant eye were not statistically different in those preferring one multifocal lens design or monovision compared with those preferring one multifocal lens design or monovision compared with those who did not choose this option and this was also the case for the multifocal lens designs or monovision not preferred by that patient group. However, while for aberrations this was also true, there were complex interactions between the aberrations that may have influenced lens preference. These must have been the aberrations of the contact lens in combination with the individual's eyes, as the aberrations of the patient's eyes alone were not found to be a predictive factor in lens preference.

4.6. CONCLUSION

A multifocal design was the most preferred contact lens chosen by the patients in the trial. Monovision was the second most accepted presbyopic option. The simultaneous multifocal contact lens can potentially provide a better balance of real world visual function due to minimal binocular interference than monovision. It is possible the success of Biofinity multifocals may be attributed to the presence of four power profiles and a distinctive lens for each dominant and non-dominant eye. The aspheric nature of the Biofinity single vision lens used in the monovision form may also have contributed to the preference observed. However two distinct power profiles with higher add powers may help reduce the inconvenience of changing lens powers, as reading needs increase and can help keep patients in multifocal contact lenses for longer.

As expected, with an increase in age of the patient there was an increased preference for a multifocal contact lens rather than monovision. The multifocal with greater power profiles and additions performed better with increasing age of patient.

The presbyopic patient appears to be more closely associated with being more of a perfectionist (see Figure 4.2) and it is important that this meticulous nature of the patient is taken into account in fitting multifocal and monovision corrections. The findings of this chapter suggest that presbyopic patients wishing to be spectacle independent should consider either monovision or multifocal contact lens options with a greater choice of addition powers and permutations.

The results were disappointing in terms of what drives predictability of current presbyopic contact lens designs. Hence whether subjective preference is related to objectively measured visual performance with the lenses, or whether current clinical tests are not sufficient to determine subjectively rated performance was assessed.

Several patterns seem to have become apparent through this analysis of how people who preferred a lens type performed with this lens type compared to other patients and with themselves wearing different lens designs. The Biofinity lens preferring patients had a better high contrast acuity under photopic conditions, maintained their reading speed at smaller print sizes and subjectively rated iPhone clarity as better with this lens compared with the other lens designs trialled. The number of subjects preferring the Biofinity lens was the largest, but the statistical power was sufficient to detect differences in all the evaluations undertaken. Patients who preferred monovision had a lower acuity across a range of distances and a larger area of glare than those patients preferring other lens designs. This cannot be explained by the metrics measured in this study, but may relate to physiological differences in this group, such as a less stable tear film or more subtle media opacities. Multifocal contact lenses by their very nature have a more complex optical profile than single vision lenses (Plainis et al., 2013) which will lead to a more varied thickness profile that could disrupt the tear film in those with a naturally less stable tear layer. Early media opacities might drive patients to prefer monovision, hence the larger amount of glare measured in this group compared with other subjects, due to the clarity of image achieved monocularly being better than when wearing multifocals, which was not assessed in this study. Finally it would seem that a complex interaction of aberrations may drive lens preference.

CHAPTER 5:
CONCLUSION.

5.1. GENERAL CONCLUSION

As identified in the introduction to this thesis (Chapter 1) the increase in the ageing population worldwide leading to a rise in the number of presbyopes, would inevitably result in an increased demand for contact lenses to correct presbyopia. Surveys such as those conducted by Morgan and colleagues (2011) across the world over a number of years have confirmed that practitioners are still under prescribing multifocal contact lenses. These studies also identify that the number of patients using contact lens drops with the increase in patient age, which may be due to factors such as poorer tear film (Kopf et al., 2008), but may also be partly related to the onset of presbyopia and the need for a specific refractive correction for objects of interest over a wide range of focal distances. In attempting to deliver reasonable visual acuity across a range of distances, simultaneous image contact lens designs such as concentric and aspheric power profiles, adversely affect contrast sensitivity and glare (Llorente-Guillemot et al., 2012). Hence clinical measurements of these aspects of lens performance may also differentiate lens preference. In addition, the optical profile of most multifocal lens designs will differ depending on the lens centration relative to the pupil and with pupil size, which are also factors that might influence lens design preference (Zandvoort et al., 1993; Bullimore and Jacobs, 1993). Monovision is another alternative way to overcome presbyopic loss with a range of clear focus, but is known to impact stereoacuity (Gupta et al., 2009).

As there is currently no evidence to predict which presbyopic contact lens design will work best with a particular patient (Woods et al., 2009), it is likely that the onset of presbyopia is causing contact lens drop-outs as even if the practitioner attempts to fit a presbyopic contact lens this option may not necessarily be optimal and may result in the patient seeking other forms of refractive correction. This certainly seems to be the case with contact lens drop out in general, as evidenced by the large numbers of patients who after dropping out of lens wear, if refitted subsequently are successfully refitted with a more appropriate lens design (Young et al., 2002). Taking the forementioned research into consideration, this study was undertaken, the aim of which was to conduct a double-blind randomised cross-over trial to comprehensively compare vision, visual performance and dysphotopsia with modern multifocal soft contact lens designs as well as determine which baseline measures and lifestyle factors help to predict the best lens for each individual patient.

Chapter two examined a large cohort of presbyopic patients across the age span associated with the loss of a functional range of accommodation. While this was from a single practice in one location in the world, this provides an insight as to how patients combine refractive corrections to manage their lifestyle requirements for clear vision at different focal distances. The combinations of refractive corrections used by individual patients varied greatly as expected. Cluster analysis was able to identify 3 substantial groups in this cohort, with the primary form of correction being: distance vision spectacles with a second form of correction to provide clear near vision; varifocal spectacles who rarely used any other form of refractive correction; and those who were unaided most of the time, using reading spectacles for near vision. The lack of a substantial group of patients using contact lenses as their primary form of refractive correction for presbyopia supported the premise of this thesis in better understanding the performance offered by modern multifocal contact lenses and monovision (Chapter 3) and how to predict which design will work best for individual patients (Chapter 4).

In chapter three, a comparison of the performance of 4 multifocal contact lens designs was made compared to monovision in 35 patients and the results evaluated. The visual performance of patients using multifocal contact lenses depends on many important factors: the characteristics of the lens (i.e. the optical design of its refractive surfaces), the optical biometry of the eye they are fitted on (lenticular and corneal aberrations, lens centration relative to these optical components and the pupil) and the visual environment of the patient (i.e. the illumination level, because the latter affects both the ocular pupil size and neural performance as well as potential dysphotopsia and target contrast). This chapter examined the combination of these factors, finding that despite the differences in optical design between presbyopic contact lenses, once on the eye, the combination of the individual's optical aberrations and that of the lenses resulted in similar aberration profiles. This could explain the largely similar visual performance of the lenses. The generally equal performance with monovision probably resulted from the manufacturer's guidelines that were followed, which tend towards modified monovision fitting.

The next chapter four, described if subjective preference is related to objectively measured visual performance with the lenses, or whether current clinical tests are not sufficient to determine subjectively rated performance. We investigated if clinical performance measured by using currently available clinical tests predicts preference. Several patterns became apparent through this analysis revealing how people who preferred a lens type performed with this lens type compared with other patients and with themselves wearing different lens designs. The Biofinity lens preferring patients had a better high contrast acuity under photopic conditions, maintained their reading speed at smaller print sizes and subjectively rated iPhone clarity as better with this lens compared with the other lens designs trialled. The number of subjects who preferred the Biofinity multifocal lens was the largest, but the statistical power was sufficient to detect differences in all the evaluations undertaken. Patients who preferred monovision had a lower acuity across a range of distances and a larger area of glare than those who preferred other lens designs. This cannot be explained by the metrics measure in this study, but may relate to physiological differences in this group, such as a less stable tear film or more subtle media opacities (neither of which were assessed). Multifocal contact lenses by nature have a more complex optical profile than single vision lenses (Plainis et al., 2013) which will lead to a more varied thickness profile that could disrupt the tear film in those with a naturally less stable tear layer. Early media opacities might drive patients to prefer monovision, due to the greater amount of glare measured in this group compared with other subjects, resulting in the clarity of image achieved monocularly being better compared with wearing multifocals, which was also not assessed in this study. Finally it would seem that a complex interaction of aberrations may drive lens preference.

The final chapter examined lens preference and whether this depended on visual conditions as dictated by the patient's lifestyle, personality factors which might link to expectations and the optics of the eye and whether it could be predicted from clinical baseline measures.

A multifocal design was the most preferred contact lens chosen by the patients in the trial. Monovision was the second most accepted presbyopic option. The simultaneous multifocal contact lens can potentially provide a better balance of real world visual function due to minimal binocular interference compared to monovision. It is possible the success of the Biofinity multifocal may be attributed to the presence of four power profiles and a distinctive lens for the dominant and non-dominant eye. The aspheric nature of the Biofinity single vision lens used in the monovision form may also have contributed to the preference observed, as this would have provided some multifocality as evidenced in the defocus curve data.

Although the factors influencing the visual performance of the presbyopic lenses are multifactorial there are three important factors determining the preference of the multifocal and monovision lenses: the practitioner, the patient and the design of the contact lens. The presbyopic patients in this study tend to rate themselves as having more of a perfectionist personality (see Figure 4.2.) and it is important that this meticulous nature of the patient is taken into account in fitting multifocal and monovision corrections. The findings as seen in this chapter suggest that presbyopic patients wishing to be spectacle independent should consider either monovision or multifocal contact lens options with a greater choice of addition powers and permutations.

The results of this study were disappointing in terms of what factors drives the predictability of the success of current presbyopic contact lens designs. The next chapter four, described if subjective preference is related to objectively measured visual performance with the lenses, or whether current clinical tests are not sufficient to determine subjectively rated performance. We investigated if clinical performance measured by using currently available clinical tests predicts preference. Several patterns became apparent through this analysis revealing how people who preferred a lens type performed with this lens type compared with other patients and with themselves wearing different lens designs. The Biofinity lens preferring patients had a better high contrast acuity under photopic conditions, maintained their reading speed at smaller print sizes and subjectively rated iPhone clarity as better with this lens compared with the other lens designs trialled. The number of subjects who preferred the Biofinity multifocal lens was the largest, but the statistical power was sufficient to detect differences in all the evaluations undertaken. Patients who preferred monovision had a lower acuity across a range of distances and a larger area of glare than those who preferred other lens designs. This cannot be explained by the metrics measure in this study, but may relate to physiological differences in this group, such as a less stable tear film or more subtle media opacities (neither of which were assessed). Multifocal contact lenses by nature have a more complex optical profile than single vision lenses (Plainis et al., 2013) which will lead to a more varied thickness profile that could disrupt the tear film in those with a naturally less stable tear layer. Early media opacities might drive patients to prefer monovision, due to the greater amount of glare measured in this group compared with other subjects, resulting in the clarity of image achieved monocularly being better compared with wearing multifocals, which was also not assessed in this study. Finally it would seem that a complex interaction of aberrations may drive lens preference.

5.2. EVALUATION OF EXPERIMENTAL WORK: SUGGESTIONS FOR IMPROVEMENT AND PLANS FOR FUTURE RESEARCH

As already identified, quantifying media changes, tear quality and capturing monocular as well as binocular data may have aided the examination of this population. Multifocal contact lenses have also been shown to cause slight visual field depressions when analysed with an automated visual field (Madrid-Costa et al., 2012). This is an area that was not investigated and one, which is worth exploring in future research work to add to measuring the multifocal lenses using defocus curves.

According to the Office for National Statistics (ONS) the UK population in 2011(Office for National Statistics, Northern Ireland Statistics and Research Agency, National Records of Scotland, 2011) for the age group 40-70 years was 11,723,000 for the number of males and 12,080,000 for the number of females. Clearly the ratio of male to female in our cohort of patients was not representative of the UK population in numbers, although the cohort involved in the survey in Chapter 2 reflected the national population of presbyopes. In future studies a more accurate representation of the population would be beneficial. In addition our patients were all from one practice, so a multicentre study might better represent the wide range of potential contact lens wearing presbyopes.

There is always a possibility that patients do not understand a question or questions in a questionnaire or inadvertently mark an unintended response on the scale for the question. The nature of the study and the questionnaire were explained in detail to all participating patients, and they were all willing participants. However, the author cannot be sure that all questions were answered as the patient intended. Some patients may have been able to subconsciously memorize some of the repeated tests. For example, contrast sensitivity was frequently measured binocularly, in mesopic and photopic conditions for each patient, every 4 weeks on 5 different occasions. The author had no control on the wear time of the assigned lenses but patients were their own control so they were likely to be similar for any individual subject. Aberrations were measured with infrared light and not visible light, therefore a potential limitation exists.

This study has been confined to only the commercially available designs and the results derived have been based on this. Future investigations may be possible using a diffractive design or a non-symmetrical design instead of a simultaneous refractive model to differentiate between patients. The optical features of the multifocal lens was an area that was investigated, however, in future research, one would like to look solely either at the fit or comfort of the multifocal lenses or both together.

5.3. CONCLUDING STATEMENT AND HAVE THE AIMS OF THE EXPERIMENT BEEN ACHIEVED

This thesis reports on a survey of existing use of refractive correction in presbyopes and a double blind randomised crossover trial that comprehensively compared vision, visual performance and dysphotopsia with modern multifocal soft contact lenses designs. The latter showed that current optical designs perform similarly when combined with the optics of the human eye and limited by the pupil aperture. While there are different preferences between them, this cannot be well predicted by current clinical tests from baseline measures and lifestyle factors. However, the performance in the preferred lens is better for some tests than the lenses not chosen. It is likely that more diverse optical designs such as diffractive and simultaneous optics may support different lifestyles better in future presbyopic contact lens designs.

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APPENDICES

A1: Acuvue Oasys for Presbyopia fitting table. (www.jnjvisioncare.co.ukcontact-lens//all-acuvue-brand-contact-lens/multifocals/acuvue-oasys-for-presbyopia).

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A2: PureVision 2 for Presbyopia fitting table. (www.bausch.com: How to fit PureVision 2 For Presbyopia 2013).

A3: Air Optix Aqua multifocal fitting table.
(https://www.myalcon.com Professional fitting and information guide).

A4: Biofinity multifocal fitting table.
(www.biofinitymultifocal.eu/en/fitting-guide 2015 Biofinitymultifocal lens fitting guidelines).

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A5: Colour coded power maps for multifocal contact lenses AO multifocal (Alcon), Purevision multifocal (PV, Bausch and Lomb), Acuvue Oasys for Presbyopia (Vistakon, Johnson and Johnson) and Biofinity multifocal (BF, Coopervision). Horizontal scale indicates distance (mm) and vertical scale optical power (D). Taken from Plainis et al., 2013 with kind permission of the author.

A6: Currently marketed daily disposable multifocal soft contact lens designs (www.sauflon.co.uk/eye-care-professionals/products/clariti-1day-multifocall; www.coopervision.co.uk/contact-lenses-proclear-multifocals; www.dailiesplus.co.uk/products/dailies-aquacomfort-multifocalshtml).

	CLARITI ONE DAY MULTIFOCAL	PROCLEAR ONE DAY MULTIFOCAL	AQUACOMFORT PLUS MULTIFOCAL
Power:	+5.00D to -6.00D (0.25D steps)	+6.00D to -6.00D (0.25D steps) -6.00 to -10.00 (0.50D steps)	+6.00D to -6.00D (0.25D steps) -6.50D to -10.00D (0.50D steps)
Add Powers:	LOW up to +2.25D HIGH +2.25D to +3.00D	Designed with a single power profile. Add up to +2.50D	LO, MED, HI
DK/t: (@-3.00D)	86	28	26
Material: Water content:	Filcon II 3 56%	Omalfilcon A 60%	Nelfilcon A 69%
Design:	Aspheric back surface CN	Aspheric CN (approximate max add +0.75D	Aqua release Aspheric CN
Base Curve:	8.6mm	8.7mm	8.7mm
Diameter:	14.1mm	14.2mm	14.00mm
Centre Thickness: (@-3.00D)	0.07mm	0.09mm	0.10mm
Modulus:	0.5MPa	0.4MPa	05MPa
Replacement Schedule:	Daily	Daily	Daily
Visibility Tint:	Handling tint	Light blue	Light blue
U.V. Blocking:	Yes UVA/UVB	None	None

A7: Currently marketed monthly disposable multifocal soft contact lens designs (http;//www.myalcon.com; http://www.bausch.com; http://www.jnjvisioncare.co.uk; http;//www.biofinitymultifocal; http;//www.sauflon.co.uk).

	ACUVUE OASYS FOR PRESBYOPIA	AIR OPTIX AQUA MULTIFOCAL	BIOFINITY MULTIFOCAL	PUREVISION 2 FOR PRESBYOPIA	CLARITI MULTIFOCAL
Power:	Plus 6.00D to Minus 9.00D (0.25D steps)	Plus 6.00D to Minus 10.00D (0.25D steps)	Plus 6.00D to Minus 8.00D (0.50D after Minus 6.00D)	Plus 6.00D to Minus 10.00D (0.25D steps)	Plus 8.00D to Minus 8.00D (0.50D after Minus 6.00D)
Add Powers:	LOW +0.75 to +1.25 ADD MID +1.50 to +1.75 ADD HIGH +2.00 to +2.50 ADD	LOW up to +1.25 MED +1.50 to +2.00 HIGH +2.25 to +2.50	+1.00, +1.50 +2.00, +2.50 D Lens N Lens	LOW +0.75D to +1.50D ADD HIGH +1.75D to +2.50D ADD	LOW: up to +2.25D HIGH: +2.25D to +3.00D
DK/t: (@-3.00D)	147	138	142	130	86
Material: Water content:	Senofilcon 38% water content	Lotrafilcon B 33% water content plasma polymerisation	Comfilcon A 48% water content	Balafilcon A 36% water content	Filcon II3 56% water content
Design:	Zonal Aspheric Design	Precision Transition bi-aspheric front & back surface aspheric	Centre distance and centre near with progressive intermediate zone	Centre-near aspheric optics	Centre near and peripheral distant with smooth progression of intermediate vision
Base Curve:	8.4mm	8.7mm	8.6mm	8.6mm	8.7mm
Diameter:	14.3mm	14.2mm	14.0mm	14.0mm	14.2mm
Centre Thickness: (@-3.00D)	0.07mm	0.08mm	0.08mm	0.07mm	0.07mm
Modulus:	0.69Mpa	1.00MPa	0.75MPa	1.06 MPa	0.5MPa
Replacement Schedule:	2 weekly replacement	Monthly replacement	Monthly replacement	Monthly replacement	Monthly replacement
Visibility tint:	Blue	Blue	Sofblue	Light blue	None
U.V. Blocking:	Class 1 99.1%UVB 96.1%UVA	None	None	None	UVA & UVB

A8: The Near Activity Visual Questionnaire (NAVQ).

THE NEAR ACTIVITY VISUAL QUESTIONNAIRE (NAVQ)

Name: ______________________ DOB: ___/___/____ Gender: Male/Female Date: ____________

Please answer ALL questions for the situation IF/WHEN YOU DO THE DESCRIBED ACTIVITY WITHOUT EXTRA READING SPECTACLES.

Circle the relevant option.

If you do not do the described activity or you have stopped for reasons that are not related to your vision then please circle the 'N/A' option.

How much difficulty do you have:	N/A or stopped for non-visual reasons	No Difficulty	A little difficulty	Moderate difficulty	Extreme Difficulty
1. Reading small print, such as: newspaper articles, items on a menu, telephone directories?	x	0	1	2	3
2. Reading labels/ instructions/ ingredients/ prices such as on: medicine bottles, food packaging?	x	0	1	2	3
3. Reading your post/ mail, such as: electric bill, greeting cards, bank statements, letters from friends & family?	x	0	1	2	3
4. Writing and reading your own writing, such as: greeting cards, notes, letters, filling in forms, checks, signing your name?	x	0	1	2	3
5. Seeing the display & keyboard on a computer or calculator?	x	0	1	2	3
6. Seeing the display & keyboard on a mobile or fixed telephone?	x	0	1	2	3
7. Seeing objects close to you and engaging in your hobbies, such as: playing card games, gardening, seeing photographs?	x	0	1	2	3
8. Seeing objects close to you in poor or dim light?	x	0	1	2	3
9. Maintaining focus for prolonged near work?	x	0	1	2	3
10. Conducting near work without spectacles?	x	0	1	2	3

OVERALL	Completely Satisfied	Very Satisfied	Moderately Satisfied	A little satisfied	Completely Unsatisfied
How satisfied are you with your near vision?	0	1	2	3	4

A9: Patient recording sheet for contact lenses.

DAY 1

1. How satisfied are you with your vision with these contact lenses?

- At near: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At intermediate: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5-15m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*

2. How much glare/ light scatter do these lenses cause, such as when driving at night: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
3. How many hours on average a day have you worn the lenses? ____________

DAY 7

1. How satisfied are you with your vision with these contact lenses?

- At near: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At intermediate: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5-15m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*

2. How much glare/ light scatter do these lenses cause, such as when driving at night: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
3. How many hours on average a day have you worn the lenses? ____________

DAY 14

1. How satisfied are you with your vision with these contact lenses?

- At near: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At intermediate: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5-15m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*

2. How much glare/ light scatter do these lenses cause, such as when driving at night: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
3. How many hours on average a day have you worn the lenses? ____________

ON NEXT APPOINTMENT

1. How satisfied are you with your vision with these contact lenses?

- At near: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At intermediate: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
- At far distance of 5-15m: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*

2. How much glare/ light scatter do these lenses cause, such as when driving at night: *Not at all 0☐1☐2☐3☐4☐5☐6☐7☐8☐9☐10☐ Very*
3. How many hours on average a day have you worn the lenses? ____________

A10: The Lifestyle Survey completed by all patients recruited in the study.

Name: ________________________________ **Date:** ______________

We recognize that your eyes are very important to you. We would like to know how *you* use your eyes on a daily basis. Along with your eye exam, this info will assist us in recommending the best options for your eyes and your personal ***Lifestyle Vision***.

• Do you wear glasses now? ____ No If Yes: ____ All the time ____ Sometimes ____ Only for far distance ____ Only for near tasks such as reading ____ Only for the intermediate distance tasks such as computer

What is your occupation? ________________________

Check the following activities you do on a regular basis:

Read Newspapers/Books ☐
Drive – Daytime ☐
Play Tennis ☐
Play a Musical Instrument ☐
Use the Computer ☐
Photography ☐
Read Medicine Bottles ☐
Drive – Nighttime ☐
Hunt or Fish ☐
Dine in Restaurants ☐
Golf ☐
Cook ☐
Needlepoint/Sew ☐
Shop ☐
Paint/Draw ☐
Bicycle Use Cell Phone ☐
Paperwork / Writing ☐
Participate in Water Sports ☐
Use iPhone/Blackberry ☐
Watch Spectator Sports ☐
Play Cards/Dominos ☐
Watch Movies in Theatre ☐

Underline **the above activities you would like to do *without glasses*, if possible.**

- How important is it for you to do near tasks such as reading without glasses? ____Very important ____ Important ____ Not important
- How important is it for you to do intermediate distance tasks such as view a computer screen without glasses? ____Very important ____ Important ____ Not important
- Roughly how far away would you do intermediate tasks such as view a computer screen?
- How many hours per day do you: do near tasks such as reading? ______ do intermediate distance tasks such as using the computer? ______
- Where do you hold your book when reading? ____ Close to your face ____ Chest level ____ In your lap
- How do you feel about wearing glasses? ____
- If it were possible to go without glasses most of the time, would you like that? ____No ____Yes
- Do you drive at night? ___ No If Yes: ___ Occasionally ___ Nightly ____ As profession (truck, cab, etc.)
- What occupational, recreational, or other activities do you currently engage in that are not listed above? ____
- Please place an "X" on the following scale to describe your personality as best you can:

Easy going |____|____|____|____|____|____|____|____|____|____| Perfectionist

A11: Quality of Vision Pictures illustrating the symptoms described in the Survey used in Chapter 2.

Look at the pictures illustrated below and familiarise yourself with the following symptoms:

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A 12: Survey used in Chapter 2 including the QoV questionnaire.

This survey should only take 5 minutes to complete and examines quality of vision with the type of refractive correction(s) you use.

1. What percentage of the time do you correct your vision using:

Distance spectacles (%)	
Near/Reading spectacles (%)	
Bifocal spectacles (%)	
Varifocal spectacles (%)	
Distance contact lenses (%)	
Multifocal contact lenses (%)	
Monovision contact lenses (%)	

2. Have you had previous Ocular Surgery:

	Yes	No
Corneal refractive surgery / LASIK?		
Standard cataract surgery?		
Multifocal or focusing implant cataract surgery?		

How often do you experience:

	Never	Occasionally	Quite Often	Very Often
Glare				
Haloes				
Starbursts				
Hazy vision				
Blurred vision (distance objects)				
Blurred vision (intermediate objects)				
Blurred vision (near objects)				
Distortion				
Double or multiple images				
Fluctuations in your vision				
Focusing difficulties				
Difficulty in judging distance of depth perception				

How severe is your:

	Not at all	Mild	Moderate	Severe
Glare				
Haloes				
Starbursts				
Hazy vision				
Blurred vision (distance objects)				
Blurred vision (intermediate objects)				
Blurred vision (near objects)				
Distortion				
Double or multiple images				
Fluctuations in your vision				
Focusing difficulties				
Difficulty in judging distance of depth perception				

How bothersome is your:

	Not at all	Mild	Moderate	Severe
Glare				
Haloes				
Starbursts				
Hazy vision				
Blurred vision (distance objects)				
Blurred vision (intermediate objects)				
Blurred vision (near objects)				
Distortion				
Double or multiple images				
Fluctuations in your vision				
Focusing difficulties				
Difficulty in judging distance of depth perception				

Demographics

AGE

Under 45	
45-50	
51-55	
56-60	
61-65	
66-70	
Over 70	

GENDER

Male	
Female	
Other	

VISUAL TASKS

Mainly distance	
Mainly intermediate	
Mainly near	

DRIVING

Often	
Occasionally	
Rarely	
Never	

A13: Aston University Ethics Committee acceptance of amendment to project.

Aston University Ethics Committee
Aston University
Aston Triangle
Birmingham
B4 7ET
Telephone +44 (0)121 204 3000
Fax +44 (0)121 204 3696

Chairperson: Ms Nichola Seare

Secretary: Mr John Walter

21st November 2012

Professor James Wolffsohn

School of Life and Health Sciences

Dear James

Study Title: 'Determining what factors influence the optimum multifocal contact lens presbyopia correction'

REC Reference: Ethics Application 409

Protocol Number:

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The project is approved until the completion date specified on the form (December 31 2015) provided it is commenced within two years of the date of this letter and you are required to notify the Committee when the project is completed.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
University Ethics Application Form	One	16/08/2012
Risk Elimination and Control Form	One	16/08/2012
The Near Activity Visual Questionnaire (NAVQ)	One	16/08/2012
Patient Information Sheet	One	16/08/2012
Consent Form	One	16/08/2012
Patient Information Sheet	Two	25/09/2012
Research Protocol	One	25/09/2012

Patient Information Sheet	Three	20/11/2012

Statement of compliance

The Committee operates in accordance with the Aston University Ethics policy and procedures:

http://www1.aston.ac.uk/registry/for-staff/regsandpolicies/ethics-policy-and-procedures/

Reporting Requirements

The details of the investigation will be placed on file. You should notify the Secretary of the University Ethics Committee of any adverse events which occur in connection with this study and/or which may alter its ethical consideration, and/or any difficulties experienced by the volunteer subjects.

If you intend to make any future protocol amendments these must be approved by the Ethics Committee prior to implementation. You should also seek approval for any extension of the approved completion date.

Membership

The members of the University Ethics Committee present at the meeting are listed below:

- Dr Carolyn Rowe, Lecturer in Politics, Aston University
- Ms Nichola Seare, AHRIC Director, Aston University
- Mr John Walter, Director of Governance, Aston University

REC reference: **Ethics Application 409**	
Please quote this number on all correspondence	

With the Committee's best wishes for the success of the project

Yours sincerely

J.G. Walter

Secretary of the Ethics Committee

Email: j.g.walter@aston.ac.uk

A14: Consent Form Consent form for experimental participants at Specsavers Opticians, New Malden, Surrey.

Personal Identification Number for this study: ___________

CONSENT FORM

Title of Project: **Determining What Factors Influence The Optimum Multifocal Contact Lens Presbyopia Correction**

Research Venue: Specsavers Opticians, 72 High Street, New Malden, Surrey KT34ET

Name of Principal Investigator: Mr. Ahmed Sivardeen
Supervisor: Prof. James Wolffsohn

Please initial box

1. I confirm that I have read and understand the information sheet dated .... for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary, the study tests are not part of any medical treatment or negate the need for regular eye examination and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. ☐

3. I agree to take part in the above study. ☐

_________________________ _________________
Name of Research Participant Signature Date

_________________________ _________________
Name of Person taking Consent Signature Date

1 copy for research participant; 1 copy for Aston University

A15: Patient Information Sheet

Aston University
Life & Health Sciences

PATIENT INFORMATION SHEET

Supervisor: Prof. James Wolffsohn

Mr. Ahmed Sivardeen,

Mr. Alan Barlin,
Mr. Sebastian Swillo,
Specsavers Opticians, 72 High Street, New Malden, Surrey, KT3 4ET

Project Title: Determining what factors influence the optimum multifocal contact lens presbyopia correction.

Invitation:
You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?
The purpose of the study is to determine what factors influence the optical performance of 4 silicone hydrogel (lenses that let lots of oxygen to the eye) soft multifocal (so you can see at distance and near) contact lenses and compare this with monovision (where you have one eye focused at distance and the other at near). The measurements we take of your vision will then allow us to determine which lenses best suit different eyes.

Why have I been chosen?
You have been chosen as you are interested in wearing multifocal contact lenses on a regular basis and you need glasses for near vision.

What will happen to me if I take part?

The location of the study will be at New Malden Specsavers Opticians, 72 High Street, New Malden. The duration of the study will be approximately 3 months. By volunteering to participate you will be giving anybody in the research team consent to analyse your results and compare them to other participants involved in the project. You will wear 4 different designs of multifocal contact lenses for 4 weeks each. You will also wear a distance lens in other eye and a near in the other for 4 weeks in the form of monovision. After each 4 weeks use of each lens, your eyes will be examined using a standard dye to ensure that no damage has occurred, you will fill in a short vision questionnaire, your vision and reading will be checked, your ability to assess depth will be measured and the effect of glare quantified. Furthermore at a later date after the fitting of the contact lenses, measurements will be made of the optics of the eyes with each of the different types of lens.

Are there any potential risks in taking part in the study?

Contact lens wear do pose a very slight risk to the eyes, especially if they are not cared for properly. However, you will be seen more often than normal and the lenses are the best available for having a minimal impact on the eye. There is a risk of breaching privacy and confidentiality in relation to the patient records. This risk will be minimized by keeping your data anonymous at all times. Mr. Ahmed Sivardeen will have access to your records. He will be responsible for putting your results onto a database and maintaining your privacy and confidentiality. Other members of the research team will only be given access to the database after your identity has been removed.

Do I have to take part?

No, you do not have to participate if you do not wish to do so. This information sheet is yours to keep and you will be asked to sign the enclosed consent form. You are free to withdraw at any time from the project. No sanctions will be taken against any patient who refuses to participate in or withdraws from this project. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Expenses and payments:

There are no expenses or payments for participation in this project. The contact lenses will be provided free of charge and there will be no charge for the professional service that is involved during the project.

Will my taking part in this study be kept confidential?

Yes, your participation in the study will be fully confidential. There will be no way to link any research data to any individual participant. Only Mr. Ahmed Sivardeen will have full access to the data used. He will maintain utmost confidentiality regarding the data assembled. Documentation of the results and procedures will be confidentially stored separately from the Specsavers Opticians computer system.

What will happen to the results of the research study?

We aim to publish the results of this project. However, there will be no reference to any individual's performance in any publication. Details of any publication will be conveyed to each participants.

Who is organising and funding the research?

Mr.Ahmed Sivardeen will be organising the research. There is no funding for this research project.

Who has reviewed the study?

The research has been reviewed by Aston University's Ethics Committee.

Who do I contact if something goes wrong or I

Aston University

Information on this page has been removed for data protection purposes

Who do I contact if I wish to make a complaint about the way in which the research is conducted.

If you have any concerns about the way in which the study has been conducted, then you should contact Secretary of the University Research Ethics Committee: j.g.walter@aston.ac.uk or telephone 0121 204 4665.