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# VISUAL PERFORMANCE IN MYOPIC PATIENTS WEARING DAILY-DISPOSABLE MULTIFOCAL SOFT CONTACT LENSES

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Doctor of Optometry

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September 2019

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**SUMMARY:**

The ageing population will become one of the biggest issues affecting Singapore in the near future. Ophthalmic practitioners will need to be ready to deal with an increased prevalence of glaucoma, cataract, age related maculopathy and even presbyopia. As presbyopes lose their ability to accommodate at near vision, visual aids such as progressive lenses, bifocal lenses, reading glasses, monovision contact lenses and multifocal contact lenses are prescribed to help them with reading difficulties and improve their daily lives. Interestingly, an international survey in 2011 revealed zero percent soft multifocal contact lenses was prescribed in Singapore for presbyopia correction. Although there are improvements in multifocal lens design and material, no new research being conducted to investigate the presbyopic lens fitting status in Singapore. Nonetheless, recent studies have shown an increased in multifocal contact lenses prescribing trends, perhaps reflecting not just the availability of newer multifocal contact lenses, but also improvement in practitioners' confidence and knowledge in multifocal contact lenses. However, in spite of the available guides on choosing multifocal contact lenses, there is no comprehensive way to help the practitioner in selecting the best option for an individual. As such, 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.

A survey was conducted to understand the Singaporean practitioners' attitude towards soft multifocal lenses and its prescribing trend. In this survey, an increase in the rate of soft multifocal contact lens fitting was observed, the perception of the unavailability of an 'ideal' multifocal contact lens, and increased chair time in fitting soft multifocal contact lenses were identified as significant barriers. However, enablers such as the increased in practitioners' motivation, confidence and proactiveness in fitting soft multifocal contact lenses were gathered.

Additionally, this study aimed to compare the relative performance of three daily-replacement soft contact lenses for presbyopic correction in an optometric practice population in Singapore. The three daily-disposable multifocal contact lenses included in this study were 1-day Acuvue® Moist Brand Multifocal Contact Lenses for Presbyopia (Johnson & Johnson Vision Care, Jacksonville, FL), Clariti 1-day Multifocal (Cooper Vision, NY) and Dailies AquaComfort Plus Multifocal (Alcon, Fort worth, TX). In this crossover study design, 35 presbyopic participants with myopia were fitted in a random order with three different types of multifocal contact lens. After 1 month, visual performance was quantified by high contrast distance, intermediate and near visual acuity, defocus curve under photopic and mesopic conditions, reading speed, Near Activity Visual Questionnaire rating and Photographic questionnaire for Photic Phenomena. The results showed comparable levels of binocular distance, intermediate and near visual acuity achieved with the three different types of multifocal contact lens at 1-month follow up. However, a better distance acuity at distance under mesopic condition for AquaComfortPlus. In terms of subjective participant lens preference, nine participants (26%) preferred Moist multifocal, 16 participants (46%) preferred Clariti multifocal and 10 participants (28%) preferred AquaComfortPlus multifocal. However, lens preference was not related to demographic factors relating to age, gender, refractive error and the magnitude of reading addition or physiological characteristic such as pupil size. In terms of the performance of participants with their preferred lens when observing the defocus curve under mesopic condition, it emerged that there was an interaction between lens types and acuity at different levels of defocus. From this, it seems that lens preference may perhaps be driven by a change in visual experience that only manifested in low illumination conditions, suggesting it may be important to conduct objective measure such as visual acuity under mesopic condition when fitting modern-day multifocal contact lenses.

It remains a hope for the future that new clinical tests or more diverse lens designs would be valuable to help the practitioner to improve the chances of first time success when fitting a multifocal contact lens for presbyopic correction.

Key words: multifocal, presbyopia, accommodation, visual acuity, soft contact lenses

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## LIST OF ABBREVIATIONS

Moist multifocal	1-day Acuvue® Moist Brand Multifocal Contact Lenses for Presbyopia
Clariti multifocal	clariti™ 1 day multifocal
Aqua ComfortPlus multifocal	Dailies Aqua ComfortPlus multifocal
MF CL	multifocal contact lenses
BF CL	bifocal contact lenses
PAL	progressive addition lens
VA	visual acuity
BDVA	binocular distance visual acuity
BIVA	binocular intermediate visual acuity
BNVA	binocular near visual acuity
Add	addition
QoL	Quality of Life
SD	Standard deviation
NAVQ	Near Acuity Visual Questionnaire
A	Appendix

## 1. Introduction

### 1.1 Presbyopia

Presbyopia has been defined in a number of different ways. The generally understood definition amongst laypeople is that it is the loss of near vision that occurs with age. Amongst clinicians, it is more precisely understood as an age-related visual impairment owing to the loss in the accommodative capacity of the eyes. This age-related loss of amplitude of accommodation that results in an inability to focus at near vision has been noted to commence at about the fourth decade of life (1) and completed as early as 50 years of age (2), though it is believed to be extremely prevalent and universal in individuals above the age of 65 (3). Ultimately, the clinical consequences of presbyopia is that without optical correction, the accommodative reserve becomes insufficient to meet the patient's near focus demands.

Other definitions are used clinically in order to diagnose presbyopia and it includes a classification termed functional presbyopia, which is defined as needing a significant add power to the presenting distance refraction correction to achieve a near visual acuity criterion (4). This is separate from the standard objective presbyopia, defined as needing a significant optical correction added to the best distance optical correction to improve near vision to a near visual acuity criterion (4). Distinctly, both of these definitions does not include accommodation as part of the criterion. Therefore, could lead to an epidemiological consequence where people with low to moderate uncorrected myopia will never develop functional presbyopia but are likely to develop objective presbyopia and a young hyperope would be diagnosed as a "functional presbyope" if a near prescription aids his or her near vision.

#### 1.1.1 Prevalence of presbyopia

The prevalence of presbyopia in the developing countries is not well known, as most refractive error studies in these countries have been limited to distance vision (5). Previous population-based studies on the prevalence of presbyopia in China have reported a prevalence for persons aged 40 years and above in a rural area was 67.3% (6) and persons aged 35 years and above in an urban population was 25.2% (7). Reflecting the urban-rural and socioeconomic distribution status in southern India, the Andhra Pradesh Eye Disease Study (8) recruited participants of 30



years of age and above from one urban and three rural areas and found an average prevalence of presbyopia was 55.3%. The Shahroud Eye Cohort Study (9), which represented a mean socioeconomic status of Iran, reported the prevalence of presbyopia between 40 to 64 years of age population was 58.15%. In another study of a rural African population, a high prevalence of presbyopia of 61.7% was reported in people aged 40 years and older (10). Notably, it is difficult to draw conclusions about the prevalence of presbyopia in the general population, as there is no universally accepted definition of presbyopia and standardised measuring technique, such as the end point chosen and the distance at which near vision is to be tested (5). Additionally, there are limited presbyopia studies that have used population-based approach. Nonetheless, presbyopia was estimated to affect 1.4 billion individuals worldwide in 2000 and 1.8 billion people in 2015 (11). The number of people affected by presbyopia will continue to increase to an estimate of 2.1 billion by 2030, as a result of population growth and an aging population (11). Although presbyopia is not a blinding condition, it has been increasingly recognised as an important public health issue as it can have multiple effects on the overall near visual function, quality of life (QoL), functional dependence and social functioning. It was reported that in 2011, presbyopia posed a significant burden on worldwide productivity with an estimated potential loss of US\$11.023 billion (12). Indeed, previous population-based studies have reported only a third of patients with presbyopia were currently using spectacles (5, 13). Duarte et al. (14) estimated prevalence of presbyopia of 55% in Brazil and in those who had near vision spectacles, 30% were found with ineffective corrections. Additionally, a Ugandan study reported an uncorrected presbyopia prevalence of 48% in those presenting with visual impairment (15). Nirmalan et al. (8) and Marmamula et al. (16) found patients with uncorrected presbyopia accounted for 70% and 81% respectively in southern India and these higher prevalence of uncorrected presbyopia have been demonstrated to be related to rural domiciles (17). Recently, a Singapore study reported that 33.9% presbyopic individual had uncorrected presbyopia and they experienced a significant decrement in vision-based tasks (18). Though this rate seems toward the lower end of spectrum, but for a modernised urban society with ready access to eye care and optical services, it is high compared to other western nations with similar levels of development, such as in Australia, where the burden of uncorrected presbyopia was reported to be 16% (19). Therefore, this highlights the need for patient education, specifically for the presbyopic group in Singapore, with the aims of reducing the high prevalence of non-corrected presbyopia observed and improving the use of presbyopic vision corrections.

### 1.1.2 Factors affecting the age-of-onset of presbyopia

Presbyopia is widely regarded as a multifactorial process (13). Age is the major risk factor for the onset of presbyopia although the condition may occur prematurely as the result of ocular accommodative ability, refractive condition, type of correction and the general health of the person.

The amplitude of accommodation in normal human eye have received considerable attention especially in the area of age and the development of presbyopia. With regard to the accommodative amplitude function, studies have shown a linear aged-related decline in the maximum amplitude (20-22), ranging from approximately 0.2 to 0.45 D per year (21, 23, 24). Edwards et al. (25) reported that Chinese people in Hong Kong have lower amplitudes of accommodation compared to Caucasians, and observed that presbyopia would occur between the ages of 36 and 40 years if presbyopia is considered to commence when the amplitude of accommodation declines to less than 5 D. Another study assessed a group of South-Eastern Asian and found that the onset of presbyopia begins at the age of 35 years (26). However, no ethnicity influences in the age at onset and progression of presbyopia was reported between Hispanic and non-Hispanic patients (27). A meta-analysis of the relationship between sex and presbyopia by Hickenbotham et al. (28) reported that though there was no significant sex difference in accommodative amplitudes, females were of a greater risk for presbyopia than males of equivalent age and they were more likely being diagnosed with presbyopia. Pointer et al. (29) based on the prescription by eye doctor and compared the add power amongst females and males and observed a greater prevalence of presbyopia amongst females and presbyopia affected women earlier than men (8, 29). Also, studies of presbyopia showed females require higher add powers than men of similar age (9, 28), perhaps due to the higher prevalence of hyperopia in females as reported by Kempen et al. (30). Considering refractive error, higher incidence of presbyopes in hyperopes might be expected, as they employ their accommodation earlier and more frequently, thus susceptible to presbyopia (7). However, Koretz et al. (21) and Miranda et al. (31) reported significantly greater subjective accommodative amplitudes for women than men of the same age. They also observed lower levels of presbyopia amongst women despite not to a level of statistical significance. Interestingly, other study has suggested environmental components such as task performed and viewing distances were the cause of earlier onset of presbyopia in women, rather than the gender-specific physiological differences in accommodative amplitudes (28). In addition, previous studies have also considered those

factors that may accelerate the lens aging process and thus leading to differences in the onset of presbyopia. One such contributory factor was 'geographical'. Miranda et al. (32) showed that in regions where exposure to sunlight is greater, presbyopia begins earlier in life. The authors also observed solar radiation of near ultraviolet (310-400 nm) concomitant with corresponding high average temperatures accelerate lens aging. Indeed, Mid-Europeans are said to become presbyopic at an earlier age than Scandinavians (33).

With regard to lifestyle, study has evaluated the difference in age of onset and progression of presbyopia between smokers and non-smokers and found that the onset of presbyopia was earlier in the smoking group (34). Though the exact mechanism by which smoking causes presbyopia to develop earlier has not been clearly understood, it has been clinically verified that cigarette smoking can substantially increase the oxidative stress in the lens, which may further accelerates the development of cataract (35). Concerning the effect of disease, studies (36-38) have reported of lower amplitudes of accommodation in diabetes patients compared with healthy people. Braun et al. (39) demonstrated that increased duration of diabetes and older age are important risk factors associated with low accommodative amplitude. Similarly, Leffler et al. (40) reported significant association between reading addition and duration of diabetes in patients over the age of 40 years and estimated reading addition increased 0.06 D per year of diabetes duration. Studies have also assessed amplitude of accommodation in HIV-positive patients. Westcott et al. (41) has identified accommodative failure in a significant proportion of HIV-positive patients aged between 26 and 35 years and more recently, Mathebula et al. (42) reported a significantly reduced amplitude of accommodation in 58 (age range 20-39 years) HIV and AIDS patients on antiretroviral drugs. It is unknown whether the amplitude of accommodation reduction occurred due to an ongoing injury to the eye and visual system by the HIV or prior to antiretroviral therapy, but the authors highlighted that this group of patients might experience presbyopia earlier in life.

There are wide varieties of primary, secondary, and tertiary factors that can be attributable to the onset of presbyopia, however, common risk factors are described in Table 1.

Age	<ul style="list-style-type: none"> <li>▪ Presbyopia in the Chinese race occurs between the ages of 36 and 40 years (Edwards et al., 1993).</li> <li>▪ Onset of presbyopia in Southeastern Asian begins at the age of 35 years (Ong, 1981).</li> <li>▪ Africa, Central America and India, an earlier onset of presbyopia in the fourth decade (Wharton &amp; Yorton, 1986; Nwosu, 1998; Nirmalan et al., 2006).</li> <li>▪ Hispanic and non-Hispanic - no difference in age of onset (Carnevali &amp; Srithaphanh, 2005).</li> </ul>
Gender	<ul style="list-style-type: none"> <li>▪ More near corrections in females (Pointer, 1995).</li> <li>▪ Higher prevalence amongst women than men (Patel et al., 2007).</li> <li>▪ Women had more severe presbyopia than men (Patel et al., 2007).</li> <li>▪ Earlier onset in females (short stature, menopause) (Hickenbotham et al., 2012).</li> </ul>
Refractive error and mode of correction	<ul style="list-style-type: none"> <li>▪ Hyperopia - additional accommodative demand (if uncorrected) (Pointer, 1995).</li> <li>▪ Hyperopia - employ their accommodation earlier and more frequently thus susceptible to presbyopia (Kempen et al., 2004).</li> <li>▪ Myopia - higher amplitude of accommodation, presbyopia would manifest later in the myopic patients (McBrien &amp; Millodot, 1986).</li> <li>▪ More accommodative and vergence effort is required by myopes when they change from spectacles to contact lenses, thus prone to presbyopia earlier (Hunt et al., 2006).</li> </ul>
Occupation	<ul style="list-style-type: none"> <li>▪ Individuals in occupations involving detailed close work may be expected to note onset of presbyopia sooner than later (Duarte et al., 2003; Wong et al., 2001).</li> </ul>
Ocular disease or trauma	<ul style="list-style-type: none"> <li>▪ Structural injury or removal of lens, zonules, or ciliary muscle (Slataper, 1950).</li> </ul>
Systemic disease	<ul style="list-style-type: none"> <li>▪ Diabetes and the duration of diabetes (Adnan et al., 2014).</li> <li>▪ Multiple sclerosis (impaired innervation); vascular insufficiency; myasthenia gravis; anaemia; influenza; measles; tuberculosis, sarcoidosis; polycythaemia; leukaemia; tumours; HIV (Westcott et al., 2001).</li> </ul>
Drugs	<ul style="list-style-type: none"> <li>▪ Reduced amplitude of accommodation is a side effect of both non- prescription and prescription drugs such as chronic alcohol consumption (Campbell et al., 2001).</li> <li>▪ prescription and nonprescription drugs which have anticholinergic activity (Chlorpromazine, hydrochlorothiazide, antianxiety agents, antidepressants, antipsychotics, antispasmodics, antihistamines, diuretics) will cause blurred vision and inability to accommodate will impair near vision (Feinberg, 1993).</li> </ul>
Iatrogenic factors	<ul style="list-style-type: none"> <li>▪ Full scatter photocoagulation was associated with transient reduction in accommodative amplitude (Braun et al., 1995).</li> <li>▪ Intraocular surgery (Braun et al., 1995).</li> </ul>
Geographical factors	<ul style="list-style-type: none"> <li>▪ Proximity to the equator with higher average annual temperatures, earlier onset of presbyopia (Weale, 2003)</li> <li>▪ Higher ambient temperatures were associated with earlier onset of presbyopia (Miranda, 1979).</li> <li>▪ Higher exposure to UV radiation (Hickenbotham et al., 2012).</li> </ul>
Other	<ul style="list-style-type: none"> <li>▪ Poor nutrition and dietary habits (Emerole et al., 2014)</li> <li>▪ Hair dye is potentially toxic to the human lens, some individuals were reported to develop early presbyopia (Jain et al., 1979).</li> </ul>

Table 1: Risk factors in presbyopia.

## 1.2 Correction of presbyopia with contact lenses

Different fitting strategies and contact lens designs can be used when using contact lenses to correct presbyopia. The main ones are discussed below.

### 1.2.1 Distance-powered contact lens wear and near-reading spectacles

Typically, this option consists of single-vision contact lens to correct the distance refractive errors and plus power reading glasses to provide the required near addition. Such combination is perhaps the simplest and least expensive option for existing contact lens wearers (43).

Although such combination provides optimum vision at distance and near, it is inconvenient, as it requires frequent application and removal of the reading glasses when performing near tasks. In fact, this option will not satisfy nor address the needs for patient who does not wish to wear spectacles. However, it remains a popular method employed in practice (44).

### 1.2.2 Undercorrect distance vision

Another option is to slightly undercorrect the contact lens distance power binocularly. Such combination is particularly useful and effective on early or emerging patients with mid-to higher-range of myopia (45). This strategy creates only subtle decrease in distance acuity and reduces symptoms of presbyopia and the accommodative effort stimulated by full contact lens distance correction. However, it may be necessary to provide distance spectacles to improve vision especially driving at night. Notably, this option may not be appropriate for patients with hyperopia as additional accommodative demand is required if uncorrected (29).

### 1.2.3 Monovision

The basic principle for monovision is to fit the dominant eye with a contact lens to correct the distance vision, while the other non-dominant eye corrected for near vision. A satisfactory vision can be achieved over a range of dioptric distances if interocular suppression occurs and the difference between the two refractive states is appropriately selected. This may seem overly simplistic, but in practice, suppression and comfortable binocular vision do not appear to be

possible for all patients (46). As might be expected, the loss of stereoacuity is usually noticeable for new wearers or patients with higher near additions. Jain et al. (47) reported that stereopsis was reduced from 87 to 124 seconds of arc with monovision. However, vision and task-related performances under supra-threshold photopic condition were found to be comparable between monovision with add below +2.50 D and patients fitted with balanced binocular corrections. As expected, inferior performances with monovision were observed at low level of contrast and illumination (48-52).

#### 1.2.4 Bifocal and multifocal contact lenses

The options for presbyopic designs in contact lens wearers are much improved these days, due to the availability of different refractive and diffractive optical designs. These designs can be summarised in Figure 1. Bifocal and multifocal contact lenses can be simultaneous-image or alternating-image designs. With the exception of alternating design, all the lenses depend upon the principle of simultaneous design. Some designs are available in both soft and corneal lenses but some designs are unique to one type of contact lens.



Figure 1: Presbyopic contact lens designs. The red, green and yellow areas represent areas for distance, near and intermediate vision respectively. Image source: Charman WN. (53)

#### 1.2.4.1 Simultaneous design

In general, simultaneous design requires the lens to be stable and is associated with some form of image degradation and visual compromise. This is because objects at distance and near are imaged simultaneously on the retina, producing one focused and one blurred image that overlaps on the same retinal elements. The visual system thus needs to be able to select the clearer image and ignore the out-of-focus image. The result of this superposition of in- and out-of-focus images is reduction in image contrast and quality, especially in smaller details (53). Nonetheless, the binocular summation will otherwise improve image contrast, acuity and visual performance of binocular vision compared to that of monocular vision. However, such summation is thought to occur when optical disparity is less than 1.00 D (54). Other factors that may impact lens performance are pupil size, lens design and centration of optics relative to the pupils, such as if the optics are decentered with respect to visual axis, asymmetrical aberration will be induced causing “shadowing” effect (53).

##### 1.2.4.1.1 Aspherical design

The focal power of aspheric design lenses changes progressively from the geometric centre of the lens towards the periphery area of the optic zone, with the refractive power spreading in a concentric manner around the lens. Such progression of power are best described as ‘multifocal’ (Figure 2).



Figure 2: Power profiles of zonal aspheric design. Image source: Bakaraju and colleagues (55)

With the different powers associated with different regions of the lens, the overall on-eye performance will vary somewhat with the change in pupil size, leading to variations in distance-

and near -image contrast. However, this could be minimised if lens design takes pupil size variation into account. Using a fixed or variable eccentricity of a continuous aspherical surface to produce power distribution, the aspheric design lenses can be further subdivided into centre-near design (power distribution is most plus centrally and it incorporates controlled amount of negative spherical aberration) and centre-distance design (power distribution is most minus centrally and it incorporates controlled amount of positive spherical aberration) (Figure 3). Notably, the induced spherical aberration in these contact lenses can result in the degraded of the best image on the retina, however, it is outweighed by the yield of an extension in depth of focus (i.e. increased vergence range) (55), over which there is no apparent deterioration in the retinal image quality (Figure 4) (56).

Although both centre-distance design and centre-near design are available in rigid and soft materials, modern aspheric multifocals are mostly of the centre-near front-surface aspheric designs.



Figure 3: A: Centre-near design (power distribution is most plus centrally). B: Centre-distance design (power distribution is most negative centrally). Image source: Meyer and colleague (54).





Figure 4: Distribution of focus and image quality in multifocal contact lenses compared to monofocal contact lenses. Image source: Perez-Prados and colleagues (56).

#### 1.2.4.1.1.1 Front-surface aspheric designs

Front-surface soft aspherical design generate negative spherical aberration, resulting in a decreasing plus power from the geometric centre of the lens. This essentially creates a centre-near design. The aspheric curve is calculated to increase the overall spherical aberrations of the eye-lens optical system, thus increasing in depth of focus. This increase in depth of focus is effective in correcting presbyopia of up to +1.50 D (54). As presbyopia increases, more complex surface geometry of varying eccentricity and greater lens asphericity are required to stabilise distance and near power zones. Notably, each individual has a distinct ocular spherical aberration. Naturally, eyes with greater positive spherical aberration will effectively work against the negative spherical aberration generated by a centre-near aspheric design, resulting in less multifocal addition effect. Hence, such patients will require higher reading addition power than their subjective refraction addition power to improve their near vision. Consequently, the interaction between lens design and ocular aberrations causes the variation in visual

performance of a particular lens design and may explain in part why the same lens of this type performs differently on different eyes (57). In like manner, changing to a different lens design may improve performance, as different centre-near aspheric soft lenses do have different optical power distributions on their surfaces (Figure 5). Example of brands of multifocal contact lenses that utilize front-surface aspheric design are PureVision Multi-Focal (Bausch + Lomb, Rochester, NY), SofLens MultiFocal (Bausch + Lomb, Rochester, NY), Focus Dailies Progressive (Alcon, Fort worth, TX) and Air Optix Aqua Multifocal (Alcon, Fort worth, TX).



Figure 5: Dioptric power map of two centre-near aspheric multifocal contact lenses of similar prescription, (red indicates high power, blue indicates lower power). Image source: Meyer and colleague (54).

#### 1.2.4.1.1.2 Back-surface aspheric designs

Back-surface aspheric surfaces that generate the reading addition are mostly found in rigid lens designs (54). It generates positive spherical aberration, resulting in an increasing positive power from the geometric centre of the lens towards the peripheral. Example of brands of multifocal contact lenses that utilize the back-surface design aspheric technology include the Conforma VFL 3 Multifocal (Conforma Laboratories Inc., Norfolk, VA) and the Boston MultiVision (Bausch + Lomb, Rochester, NY). For back-surface aspheric design, the greater the back surface rate of flattening (eccentricity), the higher in the reading power produced in relation to the distance power. However, the higher reading power could adversely affect the distance vision, especially under low contrast and low illumination conditions. It is important to note that with rigid lenses, the higher the back surface eccentricity, the more significant departure from patient's corneal topography resulting in decentred lens fit. Hence, a sufficiently steep lens fitting is required to allow better lens centration.

It is important to note that for back-surface centre-distance aspheric soft lenses designs, there is a limited amount of positive spherical aberration can be generated and therefore, they are better suited for early presbyopia (of up to +1.25 D) (54).

#### 1.2.4.1.2 Zonal aspherical and spherical designs

The multifocal zonal aspheric designs use a combination of aspheric and concentric annular ring lens designs. It combines aspheric front curves with concentric back curves to produce balance simultaneous vision, which approaches the natural range of focus of young, non-presbyopic patients (58). A range of reading addition power is available and for each of the add power, normal physiological change in pupil size with age as well as illumination change have been guided the lens design in the optimisation of power profile and zone distribution (Figure 6).



Figure 6: The power profile and zone distribution for each of the add powers. Image source: Meyer and colleague (54).

Another approach with zonal design is the centre-distance and centre-near designs (Figure 7). This could take the form of either aspherical, spherical or both, with unique power zones to produce complementary inverse geometry lenses. Regardless of reading addition power, the power zones are fixed. The centre-distance lens is usually trialled on the dominant eye and the centre-near on the non-dominant eye. This approach is essentially using the modified monovision approach although each lens is a multifocal. Caution should be taken not to exceed level of disparity between lenses as this could prevent summation for acceptable binocular vision, especially for older wearers. Example of brands of multifocal contact lenses that utilize zonal design include Frequency 55 Multifocal (Cooper Vision, NY) and Proclear® Multifocal (Cooper Vision, NY).



Figure 7: Multizone concentric modified monovision design. Image source: <https://coopervision.com/only-biofinity-multifocal>.

#### 1.2.4.1.3 Diffractive designs

Diffractive designs are the only simultaneous vision lenses that exhibit true equality of near and distance powers (43). It functions by focusing image at distance and near through refraction and diffraction respectively (Figure 8). This design is described to be pupil independent, as equal amount of light traverse through both distance and near zone of the lens (43). However, diffractive contact lenses designs are not currently commercially available for presbyopic correction (59).



Figure 8: A central zone focuses images at distance by refraction of light and near through diffraction principles created by the zone echelettes. Image source: Perez-Prados and colleagues (56).

#### 1.2.4.2 Alternating image (translating) designs

The translating designs have two power segments with the distance correction on top and the near correction below (Figure 9), set out in the similar way to bifocal spectacle lenses. During primary gaze, the distance segment is positioned over the pupil for distance viewing and when reading, gaze is directed downwards and the near segment translates upwards to allow near vision correction. Owing to the challenges of soft lens translating effectively, the vast majority of alternating image designs are available in rigid materials.

The position of these segments and lens translation are the key to the optical performance success of this design. The lower lid plays a major role in positioning and stabilising the lens, while upper lid plays the role in lens translation. However, it is challenging to fit patient with larger pupil size, as the line of separation between the segments has to be fitted lower to avoid the pupil margin and coincidentally, requires greater translation to achieve pupil coverage over the lower segment for near viewing. Although in recent years more alternating designs have become available in both soft and hard materials, they are still not widely accepted and fitted. One example is the Acuvue Bifocal (Johnson & Johnson Vision Care, Jacksonville, FL), a center-distance, concentric design that uses alternating distance and near zones.



Figure 9: Alternating Image (Translating) Design. Image source: <https://www.allaboutvision.com/contacts/bifocals.htm>

In summary, the significant improvements in the optical performance and patient satisfaction with front surface aspheric have formed a part of growth in presbyopic contact lenses correction with multifocal contact lenses (54).

### 1.3 Clinical Techniques used to assess the visual performance of soft multifocal contact lenses

In clinical practice, evaluation techniques on soft multifocal contact lenses could include visual functions, adverse effects and subjective benefits.

#### 1.3.1 Visual function

##### 1.3.1.1 Visual acuity and defocus curve

Visual acuity (VA) is a broad term covering the ability of the visual system to detect spatial changes. In clinical settings, it means the visual ability to resolve separate points and recognise shapes. Standard high contrast VA is the most commonly used in clinical practice for providing quantitative assessment of visual function, with near VA and near vision adequacy are the most clinical evaluations of presbyopic corrections (60). However, only arbitrary near distances are assessed, such as 40 cm for near and 100 cm for intermediate regardless of patients habitual or comfortable working distance (61). Hence, a measure of subjective VA across a range of distances (distance to near) is needed to better understand the performance of a multifocal contact lens.

Most studies concerning multifocal visual performance have used logMAR-principle letter chart, such as the Bailey-Lovie chart (62) and the Early Treatment Diabetic Retinopathy Study (ETDRS) (63). In comparison to Snellen acuity, LogMAR letter charts use logarithmic scale, incorporating equal numbers of similarly legible letters per line and uniformity between-letter and between-row spacing. These essentially create equal test task at each size level on the chart (reducing the risk of guessing) and eliminate truncation due to irregular geometric progression between lines. Key factors for measuring VA include testing distance and illuminance/luminance of the target letters (64). There has been an increase use of computerised software, tablet technology and display screens to measure VA. Black et al. (65) reported that LogMAR letter charts displayed on an iPad tablet with an antiglare screen were in agreement with standard clinical tests of VA in adults with normal vision. Equivalent repeatability between high-contrast VA measurements using electronic ETDRS and printed ETDRS charts (ETDRS) (63) have been demonstrated in both adults (66, 67) and children. Similarly, Shan et al. (68) reported comparable repeatability VA measurements in both adults and children made with the printed and computerised crowded Kay picture cards. While these platforms bring numerous benefits

such as improve data recording accuracy, reduce testing times and better control of letter chart luminance and optotypes, there is a need to further explore the display screen types as these may influence display quality, visual performance, visual fatigue and reaction time (69).

Defocus curve is widely used to evaluate the expected level of vision at different distances achieved in multifocal performance. The principle is based on the change in effective vergence, by adding plus and minus lenses in a phoropter to check the patient's VA, rather than moving the test chart to various distances. A typical example of a defocus curve is shown in Figure 10. The results from defocus curve measurements describe the dioptric range over which patients can maintain a specific VA. This level of VA can be expressed as relative or absolute (Figure 10). Relative level of VA defines VA cut-off relative to the best-attained level of VA (relative criterion), while an absolute level of VA determines the limits of VA independent of best-attained VA (absolute criterion). In other words, relative criterion refers to a range of object vergences that is associated with the best level of VA while absolute criterion refers to the range of object vergences through which VA is considered adequate.

One of the challenges of defocus curve is the inconsistency in the approaches taken in the evolution of defocus curve between studies. The relative criterion has been proposed by Gupta et al. (70) in the assessment of accommodating intraocular lenses (IOLs) and was adopted in other study assessing the performance of accommodating IOLs (71). However, for absolute criterion, a limit of 0.3 logMAR VA is commonly adopted in multifocal IOL studies. Incidentally, the 0.3 logMAR matches the level of driving standard VA in Europe (72). Amidst the different adoption of methods, Buckhurst and colleagues (73) analysed the metrics for defocus curve and concluded that neither the relative nor absolute criterion methods was sensitive to differentiate between multifocal designs. For the differentiation of presbyopia-correcting designs, they suggested to use the area-of-focus (under defocus curve) metric in addition to direct comparison of VA at every level of optical defocus. Additionally, to derive a defocus curve, a wide variety in methods has been proposed in past trials, such as lens power range used (73-75), non-randomization (76) and randomization letter sequences and lens presentation (77,78). Subsequently, Gupta et al. (79) demonstrated that the presentation of lens or LogMAR test chart letter sequences during measurements is important, as these minimise learning effect and adaptation bias. Later, step size of 0.50 D was found to be the optimal for measuring defocus curve as compared to greater step, though longer length of time in test examination, plotting and

data evaluation are required (80). Thus far, defocus curve have mostly used in the study of IOLs' performance. Although it is a useful strategy to measure the effectiveness of presbyopia correcting options, relatively few studies have reported on defocus curve and multifocal contact lenses.



Figure 10: A typical schematic representation of a defocus curve showing the absolute and relative range-of-defocus and 3 area-of-focus defocus metrics for simultaneous multifocal optical devices, such as multifocal contact lenses. The upper dash line depicts the absolute criterion and the lower dash line depicts the relative criterion. The black arrows depict the depth-of-focus metrics for either criterion. The left-hand-zone under the curve represents the near-area metrics (25 cm and 50 cm), the central zone under the curve represents the intermediate (INT) area metric (between 50 cm and 2 m) and the right-hand zone under the curve represents the distance (DIST) area metric (80). Image source: Wolffsohn et al. (80)

#### 1.3.1.2 Functional Reading Ability - Reading Speed and Critical Print Size

Reading is one of the most common skills and the ability to read is vital. For most people, reading is a key function in everyday life. Therefore, any visual loss that affects reading ability will have considerable impact on a patient's quality of life and reading ability has often presented as the primary reason for eye-related problems referrals (81). Reading is a highly complex task and process. Efficient reading involves visual sensory, sufficient extent of visual field, eye movements, higher cognition of comprehension and endurance (82). It has been shown that routine clinical measurements of distance and near letter VA are poor predictors for the actual reading performance and provide no information about the degree of disability to carry out near tasks (83, 84). Therefore, near visual performance can be assessed through functional reading ability and several reports have indeed proposed the use of functional reading speed and critical print size (CPS) to evaluate visual performance of patients with presbyopic corrections (61, 85, 86).



In functional reading ability assessment, the commonly evaluated metrics include reading acuity, maximum reading speed (MRS) and CPS. Reading acuity corresponds to the smallest print that can just be read. This measure indicates the absolute limit on reading small print. Compare to letter acuity, reading acuity is a more functional-relevant measure of vision in a normal reading task. Reading speed is a measure of reading performance. The number of words read correctly divided by the time taken to read each sentence usually determines reading speed, in words per minute (wpm). MRS is the best reading performance that can be attained when print size is not a limiting factor (87). It was reported that reading speed remains constant over large print sizes, resulting in a plateau on a plot of reading speed against print size (88). The measurements over this plateau is defined as MRS (Figure 11). CPS is determined by the smallest letter size that can be read at the maximum speed and it is correspondence to the minimum magnification required for best reading.



Figure 11: A hypothetical example of MRS and CPS. Dashed line is the maximum reading speed. Image source: Alabulkadar (89)

Reading ability can be measured with several commercially available charts and reading tests, such as the Minnesota low-vision reading test (MNRead) chart (Lighthouse International, NY, US) (90), and the Radner chart (Precision Vision; La Salle, IL, US) (91). Reading test charts were mainly designed for use in low vision clinical examinations, rehabilitation and vision research. However, increasingly they are used to evaluate functional reading ability for patients with presbyopic corrections, such as presbyopia-correcting IOLs, multifocal contact lenses, monovision and varifocal spectacles. In comparing the design of MNRead and Radner charts, both are very similar and can be applied to all patients regardless of the level of vision. Both charts adopted a logarithmic progression of print sizes. Although the typefaces of MNRead and Radner are different, research evidence on the legibility of typefaces in low vision patients yield

inconclusive results (92). The MNRead has been calibrated for horizontal crowding, but in decreasing the adverse effect of crowding, such as line width and increased letter spacing has limited effect on reading speed (93). Another difference is that Radner is more standardised in terms of syntactical and geometric structure (number of syllabus, characters position and word length) compared to MNRead. It is still unclear if the highly standardised Radner will lead to better reliable results as there are no direct comparison studies between MNread and Radner available, but in standardised reading tests, print size should be the only parameter affecting performance (94). This also means all test sentences should have equal difficulties and requires same reading time when presenting in the same print size. Hence, the highest comparability of sentences is preferred (94).

Notably, despite the development and refinement of tradition functional reading test charts, they are still paper-based, where limited versions to overcome learning effects and susceptible to light and oxidation degradation. The paper-based test is usually slow with tedious manipulation of test procedures, such as sentence unveiling and the need to manual time recording, graph plotting and data analysis (95). “Glitches” in experimenter’s reaction time in timing each sentence, pauses, false start and time taken to self-correct reading errors will lessen the accuracy and repeatability of the measurements (81). As such, the mobile app reading speed test developed by Kingsnorth et al. (95) can provides an alternative for quick and efficient reading test. This mobile app reading speed test is based on mobile computing platform, using programming language for Apple iPad 3 and utilises the already validated English Radner test sentences (90), each consists of structurally standardised 14 words, starting from 1.0 logMAR to -0.1 logMAR in 0.1 logMAR steps. Using a mobile reading speed app can provide portability, convenience, graph plotting and automation in data analysis (Figure 12). At the end of the test, final determination of LogRAD (Reading Acuity Determination) score is the LogRAD for the smallest print size read and this will be presented on the screen. Additionally, the CPS and MRS can be calculated automatically by the machine’s software. Other advantages of mobile app reading speed test include rapid testing and timing measurements. The mobile app reading speed test has been reported to show a high inter-chart and test-retest reliability and while the results are not interchangeable with paper-based charts, the mobile app reading speed test has the potential to capture functional visual ability in research studies and clinical practice (95).



Figure 12: A typical results from Radner Reading Apps.

### 1.3.2 Glare

Visual performance also includes glare sensitivity. Glare can be described as having difficulty seeing in the presence of bright light, such as direct or indirect sunlight or artificial light such as car headlamps at night. Glare is caused by brightness within the patient's visual field that is significantly greater than the luminance to which the eyes are adapted, leading to irritation, discomfort, and decreased visual performance (96). This form of visual dysfunction and its corresponding complaint may increase in conditions such as multifocal contact lens wear (97). Studies have shown that even though VA may appear to be normal, it could be greatly affected when glare happens (98). Increased sensitivity to glare in patients wearing multifocal rigid gas permeable, soft bifocals, monovision and varifocal spectacles has been reported, albeit good binocular contrast sensitivity and low and high contrast acuity (99).

In the case of 'glare or 'photic phenomena', there are few tested systems of analysis (100). They mainly consist of psychophysical assessments that attempt to reproduce a patient's symptoms or questionnaire-based assessments. Psychophysical assessments commonly involve the assessment of the extent of the loss of VA that occurs with the introduction of a bright light source. Previous studies (101) have shown an increasing reduction of VA in the

presence of glare with increasing age. Others have included the measurement of the retinal blur circle or halo, using instruments often referred to as halometers. These devices measure the size of a photopic scotoma created by a central glare source (102). Early methods for the assessment of halos involved drawing the outline of the halo created from a candle (103) and recent studies have used computer programmed halometers in measuring the size of glare area by randomly presented letters moving towards the glare source (78, 104). Notably, psychophysical assessments would have difficulty in reproducing all types of photic phenomena caused by multifactorial aetiology in the examination room (100) and questionnaire assessments in determining if patients suffer from wide range of glare are subjected to interpretation errors and response biases (105). Hence, the severity of glare cannot be graded just purely based on the description of the patient. To avoid these problems, the forced choice Photographic questionnaire for Photic Phenomena was chosen in this study in the assessment of glare. The forced choice Photographic questionnaire for Photic Phenomena (Figure 13) was developed using a combination of established principles in health management and clinical and theoretical evidence of patients' actual visual experiences. Digital photographs from various natural settings were chosen to represent the most common environments in which these glare symptoms took place (100).

The forced choice Photographic questionnaire for Photic Phenomena has eight images in total. To determine if patients suffer from any photic phenomena, they are to point out any particular image(s) representing the problems they experience and the stages of severity (a grading scale of four levels of severity) (Figure 14). Grade 1 image denotes 'just visible' glare phenomenon, which will assigned a score of 1, whilst Grade 4 representing 'maximum glare' which will be assigned a score of 4. The final photic phenomenon image score will be simply adding the scores of each photic phenomenon (100). This system was tested for repeatability and reliability where no significant difference was found in the mean score of 22 participants tested 2-6 weeks apart ( $p = 0.32$ ,  $r = 0.96$ ) and between examiners ( $p = 0.64$ ,  $r = 0.95$ ). Thus, the authors suggested satisfactory level of repeatability and reliability in the forced choice Photographic questionnaire for Photic Phenomena assessment (100).

Relatively few studies have considered the effect of induced glare of presbyopes wearing different modalities of multifocal contact lenses. Although excellent VA is now achievable, the

drive for broader aspects of visual function assessments has now increased, as good VA does not necessarily predict problems encountered in everyday life, such as glare.



Figure 13: Types of photic phenomena. First row (left to right): Ripple effect; Stream of light; Central flash. Second row: (left to right): Day haloes, starburst, flare; Night haloes, starburst, flare; Bright arc. Third row: (left to right): Dark arc; Peripheral arc effect.



Figure 14: Forced choice Photographic Images for Photic Phenomena. Four photographs depicting a grading scale of four levels of severity. Grade 1 image denotes just visible glare phenomenon, whilst Grade 4 representing maximum glare.

### 1.3.3 Subjective benefits - patient's subjective reported outcomes

Early performance assessments of multifocal contact lenses seem to provide little information about their performance later on during wear (61). In an attempt to assess patient's satisfaction and their QoL, subjective reported visual satisfaction has previously been used in comparative studies of different presbyopia-correcting technologies, methods of providing correction and wearing modalities (61, 106, 107). However, the majority of these studies used questionnaires that have not been developed specifically for patients who wear contact lenses. Nonetheless, Woods and colleagues (106) have reported a significant better performance with multifocal correction compared to monovision for subjective ratings in the real world situations (walking, task orientation, changing focus and watching television), albeit a better objective performance with monovision in the consulting room. Others have found no association between reduction in subjective visual satisfaction (ghosting, halos, visual quality, visual fluctuation and facial recognition) with VA reductions in soft multifocal contact lens wear (3). Notably, the National Eye Institute Refractive Error Quality of Life Instrument (NEI-RQL) questionnaire has been used in the study of QoL issues related to multifocal contact lenses and monovision (108). The ability of NEI-RQL questionnaire to discriminate between different modes of contact lens wear have also been reported (109, 110). Therefore, subjective visual evaluation appears to assess the impact of contact lens correction on the patient as a whole than the traditional visual acuity tests, thus may present as a better indicator on lens performance. In addition, incorporating real-world tests to establish realistic performance assessment of presbyopic contact lens corrections may have good predictive power in long-term wearing success.

Visual Functioning Questionnaire (VF-11) is another questionnaire used to assess vision-specific functioning. It aims to determine the impact of compromised vision on visual functioning by assessing the level of difficulty in performing daily activities. These activities include: reading small print, reading newspapers, recognizing people, seeing stairs, seeing street or shop signs, filling out lottery forms, playing games (cards or mah-jong), cooking, watching television and driving during the day and night. VF-11 (Rasch analysis), has been adapted, validated, and used previously to suit the local cultural context in Asian population and the 11-item VF-11 questionnaire is a modified version of the 14-item Visual Functioning (VF-14) questionnaire (111). Nine of the VF-11 scale items were rated on a numeric scale ranging from 0 (no difficulty) to 4 (unable to perform activity). The remaining two driving items had three response options (1, no difficulty; 2, a little difficulty; 3, a great difficulty).

Buckhurst and colleagues developed the Near Ability Vision Questionnaire (NAVQ) (112). It is the only Rasch analysis designed and validated questionnaire for the assessment of vision related QoL with presbyopic corrections. NAVQ has been found able to discriminate between those with having near vision problems from those who do not. For performance comparison, the authors recommended to use NAVQ in conjunction with standardized objective measurements, as subjective evaluations of patient-perceived effects and vision related QoL are important considerations in the assessment of presbyopia correction. In the same way, Gupta et al. (113) also emphasized the importance of incorporating vision related QoL assessment in the field of presbyopia correction. They have suggested patient's satisfaction and visual symptoms could only be established from patient's objective point of view. Currently, subjective reported visual satisfaction assessments of near visual function in the field of presbyopic lens corrections has not been extensively explored (85).

#### 1.4 Conclusion

With the aging population, the average age of contact lens wearer is increasing (114), contributing to an undoubtedly a huge potential for growth in presbyopic contact lens market (53). Recently, there seems to be a widespread introduction of daily-disposable wearing mode of multifocal contact lenses (115-118). Therefore, it is important to examine the visual performance achieved with these type of daily-disposable multifocal contact lenses, as disposability are becoming increasingly popular in the contact lenses market. However, it has been reported that practitioners are still under prescribing multifocal contact lenses (44). It has also been reported that the success rate of prescribing multifocal contact lenses ranging from 67 to 83 per cent after three month of wear to 30 to 40 per cent in longer term cases (56, 119). Thus, evaluation of the current range of lens design would enable practitioners to successfully fit and yield higher satisfactory results in presbyopic patients. It is clear that multifocal contact lens prescribing is at best static in Singapore (120, 121). This may be attributed to factors such as perceived multifocal contact lens disadvantages such as 'ghosting', increased 'chair time' and special skills required to fit multifocal contact lens (44, 122). In addition, there remain some challenges in positioning multiple focal elements to optimise visual performance over the full near-to-distance range, despite great efforts and improvements have been made to overcome these problems by manufacturers (44). In recent times, manufacturers have released a great

variety of soft simultaneous image lens design to meet different patient needs (56), along with techniques of measuring both subjective visual performance and objective quality of vision (Table 6 in Chapter 3), but their fitting is still unsatisfactory in some cases (56). Previous investigations conducted on visual performance of multifocal contact lenses have reported mixed findings and few studies have compared the performance and/or patient satisfaction across two or more different daily-disposable multifocal lens designs (123).

Despite the information reported by the annual international contact lens prescribing trend surveys (44, 114), there is still limited information on multifocal contact lens prescribing trends in Singapore. Thus, this thesis sought to understand the current multifocal contact lens prescribing trends in Singapore and the attitudes of Singapore contact lens practitioners towards prescribing of multifocal contact lenses (Chapter 2). Additionally, this thesis aimed to compare the objective and subjective visual performance of the three commercially available daily-disposable multifocal contact lenses (Chapter 3), which, to our knowledge, have yet to be evaluated in a large number of participants with a range of visual performance metrics. Also, a series of visual assessments, including the traditional acuity based measures and subjective responses were assessed to determine their influence on lens preference (Chapter 4), as the most suitable clinical metrics for estimating predictability of the most suitable multifocal lens that will work best for a particular presbyope has not been sufficiently studied.



## 2. Practitioner's attitude towards fitting multifocal soft contact lenses in Singapore.

### 2.1 Introduction

An aging population, whereby older individuals account for a larger proportion of the total population, was a key demographic outcome of population trends during the twentieth century. This trend will certainly be the distinctive social transformations of the twenty-first century and will affect virtually all developed or developing countries over the medium-term (124).

The rapid ageing of populations will also be one of the biggest issues affecting Singapore (125). In Singapore, reflecting this ageing population, the median age of the resident population went up from 29.8 years in 1990 to 40.8 years in 2018 (Figure 15) and Singapore resident aged the 45 and older grew to 43.6 per cent in 2018 (126). As presbyopes lose their ability to accommodate at near vision, visual aids such as progressive lenses, bifocal lenses, reading glasses, monovision contact lenses and multifocal contact lenses are prescribed to help them with reading difficulties and improve their daily lives (4). Thus, such increased in the proportion of presbyopic Singaporean people in turn highlights an outstanding opportunity for contact lens practitioners to provide contact lenses as a means of correcting presbyopia.



Figure 15: Age distribution of Singapore resident population. Image source: Department of Statistics, Ministry of Trade & Industry, Republic of Singapore, Population Trends 2018 (126).

With the advancement of technology, multifocal contact lenses have improved tremendously throughout the years. Such technological advancements of lens materials and designs will generate significant impact on patient satisfaction and contact lens market (124). Studies have reported the latest generation of multifocal contact lenses as a good option for presbyopic correction (56, 75, 77, 99). Indeed, several countries have reported of increased prescribing trend of multifocal contact lens. Morgan et al. (127) evaluated the contact lens prescribing trends in the United Kingdom (UK) over a 10-year period and reported that multifocal soft contact lenses were more frequently fitted than monovision lenses. In 2008, Efron et al. (128) observed a general increase in daily-disposable soft multifocal contact lens prescribing trend in UK, owing to an increase in its availability.

In the United States (US), similar multifocal contact lens prescribing trend was reported from 2002 to 2014, with a predisposition towards prescribing soft multifocal contact lenses (12.3%) for presbyopic correction, compared to soft monovision lenses (5%) (129). Likewise, a study in Canada reported a significant increase in the usage of multifocal contact lenses from 13% in 2000 to 19.8% in 2015. In addition, the demographic analysis in the study showed an apparent peak in the of 45-49 years old age group, suggesting 'younger' presbyopic patients were being fitted with multifocal contact lenses in Canada (130). These increased in prescribing trends perhaps reflecting not just the availability of newer design of multifocal contact lenses, but also improvement in practitioners' confidence and knowledge in multifocal contact lenses fitting. As one would expect, multifocal contact lenses should thus be the preferred choice of correcting presbyopia as compared to other presbyopic contact lens correction options. However, some eye care practitioners often maintain beliefs that multifocal contact lenses fitting requires more chair time and offer lower chance of success as compared to monovision lenses, resulted in the reluctance of fitting multifocal contact lenses (43, 106).

Woods et al. (131) in 2002 investigated contact lens prescribing trends in the Australian's states and territories. The authors reported that despite having 20% of patients aged older than 45 years old, only 2.6% and 4.7% of all soft contact lenses prescribed were multifocal contact lenses in Queensland and Victoria respectively. A 10-year study in Australia reported similar trend whereby only 5% out of the 20% of soft contact lenses patients over 45 years old were fitted with soft multifocal contact lenses. Considering significant innovations in multifocal contact lenses design over the span of 10 years, these had limited impact on multifocal lens prescribing (124). Over in Hong Kong, Charm et al. (132) evaluated the attitude of practitioners towards

prescribing different types of contact lenses and reported that amongst the presbyopic contact lens patients, 17% were fitted with bifocals, 27% with monovision lenses and 56% had reading glasses worn over single-vision contact lenses.

Morgan et al. (127) highlighted the unpopularity of multifocal contact lenses and observed a combination of barriers, ranging from the lack of technical knowledge, fitting skills and confidence of practitioners and the absence of availability of 'ideal' multifocal contact lenses. Other barriers include the complexity and time involvement in achieving acceptable fitting and providing the wearers good visual performance. Additionally, perceived high cost of multifocal contact lenses has been recognised as one key factor for lower percentage of multifocal contact lens fitting (122). Poor awareness of multifocal contact lenses design and the lack of training amongst practitioners are also some of the underlying reasons for this phenomenon (133, 134). In the hope of improving the fitting rate of multifocal contact lenses, Charm et al. (132) proposed to look into factors such as attitude, differences in training and confidence amongst practitioners. The authors suggested and encouraged supplementary education to keep practitioners updated, as well as to educate them on the fitting of different lens designs. Additionally, practitioners should also change their perception on the performances of multifocal contact lenses and they should not be deterred by their previous experience of failure rates in fitting.

Thite et al. (122) investigated the barriers in multifocal contact lens dispensing in Mumbai, India. The primary barriers found were practitioner's view of increased chair time with multifocal contact lens fitting, limited power range of multifocal contact lenses and the lack of availability of trial lenses. It was also reported that about 62% practitioners surveyed showed least and neutral response in the level of motivation toward dispensing of multifocal contact lenses. Additionally, when comparing years of experience of the practitioners surveyed, those practitioners with more experience (>8.5 years of practice experience) were the least likely to dispense multifocal contact lenses. This group of practitioners also hold the belief that high cost of multifocal contact lenses could be a deterrent for their presbyopic patients. Interestingly, graduate optometrists (completed a degree program or higher in optometry) associated multifocal contact lens dispensing with poor business proposition. Perhaps this may indicate business value propositions of graduates vary across different education and training levels.

In 2011, Morgan and colleagues conducted a global survey of contact lens prescribing for presbyopia (44). They reported that only 37% of presbyopic patients (over 45 years of age) were prescribed with multifocal contact lenses. Prominently in this study, the authors reported that in Singapore, the number of practitioners fitted multifocal contact lenses and monovision lenses was close to zero, thus demonstrated the significance under-prescribing of contact lenses for the correction of presbyopia in this country. The authors further highlighted a general lack of training in presbyopic contact lens fitting and the inadequacy of clinical and laboratory research in this field. Nonetheless, recent international contact lens prescribing surveys indicated about half of all presbyopic patient has now been fitted with multifocal contact lenses (Figure 16). The successful fitting of such lenses has doubled over the past decade (55), presumably reflecting newer and better products and the increase in demand for such lenses in the marketplace (121). With the improving trend in vision for multifocal contact lenses, it is important to investigate practitioners' attitudes towards fitting and recommending multifocal contact lenses, as the demand is set to increase (52). Although major investment has been devoted in developing and promoting new soft multifocal lens materials and designs, it is clear that multifocal contact lens prescribing rate is at best remain relatively the same in Singapore from 2012 to 2017 (120, 121). Therefore, it is important to investigate specifically the practitioner attitudes to soft multifocal contact lenses and its prescribing trend.

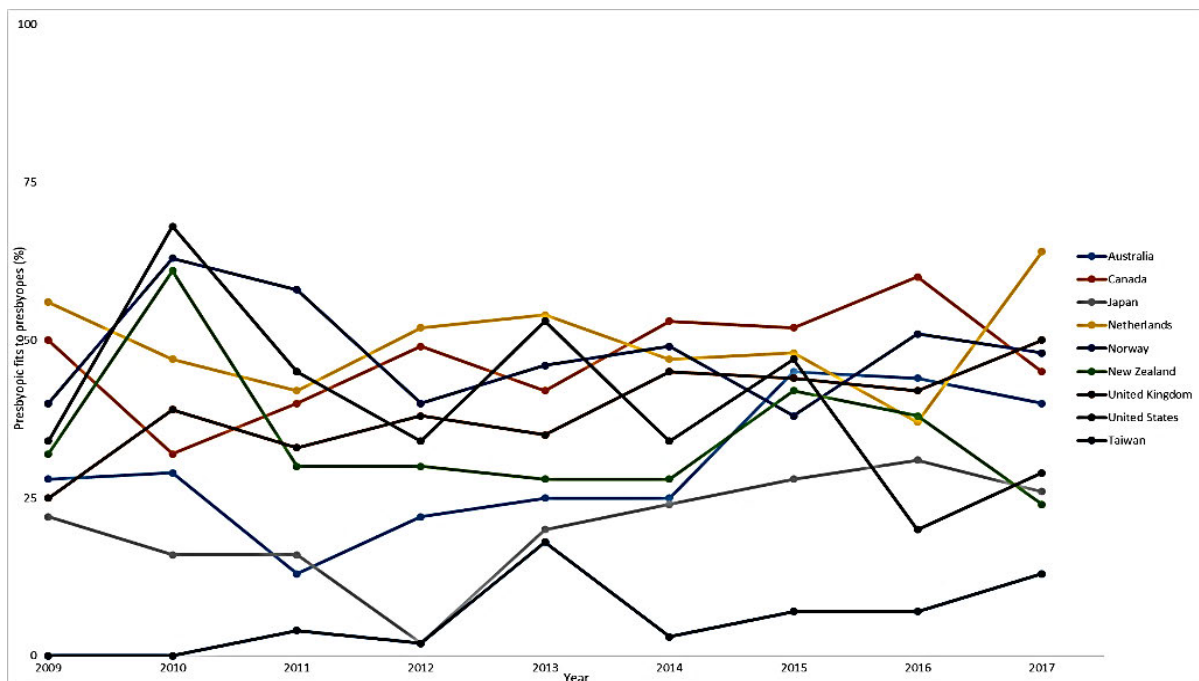


Figure 16: Multifocal & monovision contact lenses fits as a proportion of all soft contact lens fits to presbyopes (those over 45 years of age) in nine nations between 2009 & 2017 (121).

## 2.2 Method

### 2.2.1 Study population and sampling procedures

The study was approved by the Singapore Polytechnic Ethics Review Committee and was conducted in accordance with the tenets of the Declaration of Helsinki.

All optometrists providing eye care services are required to be registered with the Singapore Optometrists & Opticians Board from 1 Jan 2008. The required number of returned questionnaires was established using Cochran's formula for categorical variables (135). With an estimated total number of optometrists (with full registration) in Singapore at the time of study was 706 (136), and given a 5% level of accepted risk and 5% margin of error, and the desired sample size was 249. The number of drawn sample size was calculated to be about 623, based on the assumption of 40% response rate (135), thus, the final drawn size was rounded up to 650.

Simple random sampling was accomplished using a computer random number generator. First, the sampling frame was organised. A listing of all optometrists (with full registration) was located on the Ministry of Health (Singapore), Optometrist and Opticians Board website. A Microsoft Excel® 2016 spreadsheet (Microsoft Corp, USA) with column headings optometrist's full name, work address, and random number identification was created for all optometrists. The sample was drawn for this list by placing the function code =RAND() into the random number cells. The RAND function in Excel is one function specially designed for generating random numbers. It returns a random decimal number between 0 and 1. After number assignment, they were sort in ascending order (lowest to highest). The first 650 names beginning with the lowest random number were selected.

### 2.2.2 Questionnaire Development

A questionnaire was chosen as the method of research for this study as it is useful in describing the characteristics of a large population and both qualitative and quantitative responses can be obtained through this method (137). A structured questionnaire (Appendix A1) to determine the usage and dispensing of soft multifocal contact lenses and practitioners' attitude towards fitting

soft multifocal contact lenses was developed for this study. Selection of domains and items to be included in the study was collected based upon substantive and theoretical relevance of factors related to multifocal contact lens prescribing; a search on general contact lens prescribing trend literature (120, 127, 129, 138), contact lens correction for presbyopia literature (44, 139), including those related to dispensing multifocal contact lenses (122, 132, 140-142) and invited responses from focus group. The participants of the focus group were chosen and invited through word-of-mouth based on their job title/same role (Optometrist/contact lens practitioner). The focus group consisted of 5 eye care practitioners (ECPs) who regularly dispensed multifocal contact lenses (on average minimum two or more patients per month) and 5 ECPs who did not or occasionally dispensed multifocal contact lenses (on an average one or less patient per month) (122). One focus group discussion was conducted for designing the research questionnaires. During the focus group discussion, the process began with identifying the main aim and defining the key research objectives of the study. Based upon the research objectives, a list of questions was prepared as guidance for discussion. Fifteen questions were identified in 3 different domains: demographic variables, contact lens fitting characteristic and practitioners' views and opinions on fitting soft multifocal contact lenses. In this process, all the discussions points covering these 3 domains were rated from being most common and relevant to the survey. All the highly rated points were studied and incorporated into the final questionnaire. Revisions to the question wording and design were made as needed to keep the question format as regular as possible, but different content areas required different question syntax. Three style of questions were chosen: incidence (e.g., How many presbyopic patients do you fit contact lens per month?), occurrence (e.g., for soft contact lens correction of presbyopia, the type I mostly recommend is...) and agree-disagree assessment (e.g., Fitting soft multifocal contact lenses is complex and time consuming). For the agree-disagree assessment, a 5-point response scale was chosen over a 4-point scale, a 7-point scale and a visual analogue scale, as it has been shown to be more useful and easier to complete (143). However, no formal construct-validity testing was performed for this survey.

The questionnaire was written in English and consisted of 3 sections. The first section was to collect demographic information from the study population such as practitioners' years of experience, practice type and location (region) in Singapore. The second section consisted of questions about practitioners' contact lens fitting characteristics. For the types of soft contact lenses correction of presbyopia, practitioners were asked to indicate the single primary aspect of mode of correction and choice of modality of soft contact lens correction of presbyopia. The

third section consisted of questions related to specifically the practitioners' views and opinions on fitting soft multifocal contact lenses including questions on the attitude, confidence and motivation of the practitioner in fitting soft multifocal contact lenses. These questions were presented in different statements and employ a 5-point ordinal scale, with responses from 'Strongly disagree', 'Disagree', 'Neither agree nor disagree', 'Agree' and 'Strongly agree'. The responses of the practitioner were rated based on their level of agreement to the statements in the survey. An additional open-ended question was included at the end of the survey to understand why the practitioner was or was not regularly recommending and dispensing soft multifocal contact lenses.

It was reported that qualitative data are more realistic, subjective and contain richer information than those provided by quantitative method. However, quantitative data are more structured and more often quantifiable (137). In this study, the questionnaire collected both quantitative and qualitative data. The frequency data are expected to provide some understanding to the presbyopic contact lenses correction trend in Singapore and the qualitative data answers to support the clinical reasoning of practitioners by providing useful information on the dispensing of soft multifocal contact lenses. Thus, the reasons for combining qualitative and quantitative data help to address different research questions and clarify the basis of the results.

### 2.2.3 Questionnaire Administration

The survey, consisted of three-page questionnaire (Appendix A1), were distributed through mails with explanation prior to enrolment was sent to the 650 randomly selected optometrists. In each mail, an introduction letter (Appendix A2), a survey form and stamped reply envelope were included. The introduction letter included the purpose of the survey, also stating that the survey was voluntary. The survey was then anonymously returned in the postage paid envelope. The participants in the survey did not received monetary reimbursement for their participation.

### 2.2.4 Data Analysis

Information from returned survey forms was manually entered into a Microsoft Excel® spreadsheet. Statistical analyses were performed with the aid of Minitab (Minitab 17 Statistical

Software (2010). State College, PA: Minitab, Inc. [www.minitab.com](http://www.minitab.com)). Descriptive statistics were employed to define demographic information (years of experience, type and location of practice) of practitioners in relation to the soft multifocal contact lens prescribing attitudes and characteristics. Practitioners completing the form described themselves as working in one of the four optometry practice types, data from only the two of these practice types were compared (i.e. independent and chain stores) due to the relative paucity of data from the other two practice setting type (i.e. Private Clinic/Hospital and institution). The free text responses were elicited from open-ended question to understand why the practitioner was or was not regularly recommending and dispensing soft multifocal contact lenses. These brief statements were grouped, coded based on key word searches and manually entered into a Microsoft Excel® spreadsheet.

For categorical variables, proportions and frequency count were calculated. For continuous variables, means and standard deviations were computed. Group comparisons of categorical variables were made using the Pearson's chi-square tests and continuous variables using two-sample t-test. p value <0.05 was considered to be statistically significant.

## 2.3 Results

### 2.3.1 Practitioner demographics

Two hundred and sixty eight (41.2%) optometrists out of 650 completed the survey. The mean experience of the practitioners surveyed was  $7.7 \pm 6.9$  years with a positively skewed distribution (Figure 17). There were 177 (66%) practitioners with experience up to 8 years and 91 (34%) with experience >8 years being surveyed ( $p < 0.00$ ). The majority of the practices represented were independent store (61.6%), retail chain stores (36.2%) and 2.2% from the institutions (Table 2).



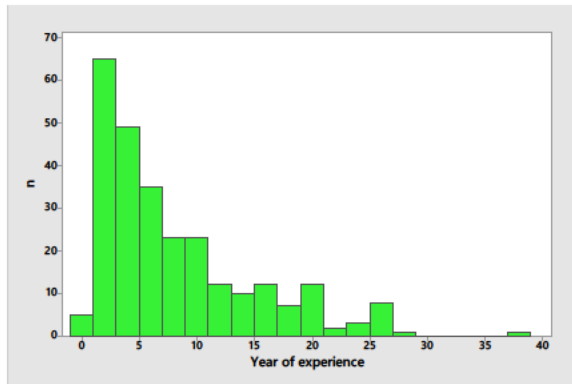


Figure 17: Years of experience distribution of practitioner surveyed in this study

Figure 18 shows the proportion of location of practice (Central vs Outside Central) and proportion of principal work place (Institution vs Chain Store vs Independent Practice) of practitioners survey in this study. No significant relationship found between the principal work place and the location of practice of the practitioners ( $p = 0.542$ ). Although it was observed that practitioners surveyed in the central area generally had more years of experience (number of years an optometrist has been in practice) than the practitioners outside central area, this was not statistically significant ( $p = 0.216$ ). Similarly, though practitioners that practiced in academic institutions were found to be the most experienced, followed by independent practices and chain stores ( $p = 0.363$ ), it was also not statistically significant.

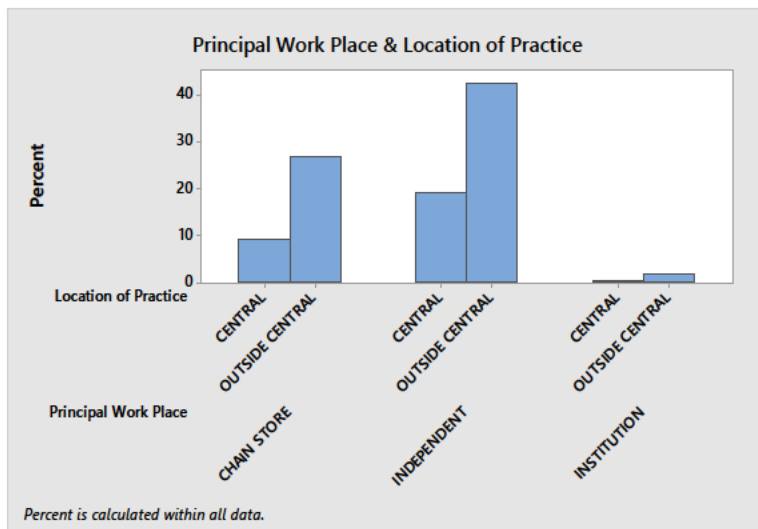


Figure 18: Proportion of Location of Practice (Central vs Outside Central) and Proportion of Principal Work Place (Institution vs Chain Store vs Independent Practice)

Practitioners/ Practices (n=268)	Classification	n	%	Number of soft multifocal contact lenses fit per month (Mean $\pm$ standard deviation)
Job description	Optometrist	268	100	
Years of practice*	experience up to 8 years	177 <sup>a</sup> (3.52 $\pm$ 2.11)	66.0	3.9 $\pm$ 6.2
	experience > 8 years	91 <sup>a</sup> (15.69 $\pm$ 5.71)	34.0	3.7 $\pm$ 4.0
Type of Practice	Independent	165	61.6	3.4 $\pm$ 5.5
	Chain Store	97	36.2	4.8 $\pm$ 5.5
	Private Clinic/Hospital	-	-	-
	Academic Institution	6	2.2	0.8 $\pm$ 1.2
Practice location	Central Region	77	28.7	3.5 $\pm$ 3.7
	Outside Central Region	191	71.3	4.0 $\pm$ 6.1

Table 2: Demographic details of practices and practitioners.

<sup>a</sup> Mean  $\pm$  standard deviation of number of years of experience

\*Significant between practitioners' years of experience; p <0.00

### 2.3.2 Contact lens fitting rate and prescribing trends

On average, the total number of contact lens fits per month was 33, of which, an average of 7 were presbyopic contact lens fits with 3 were soft multifocal contact lens fits. Multifocal contact lenses (71.3%) were indicated by practitioners as their first choice for soft contact lens correction of presbyopia, followed by monovision lenses (20.5%), single vision near spectacles to wear over contact lens (7.5%) and the remaining bifocal contact lenses (BFCL) (Figure 19). For soft contact lenses correction of presbyopia, the practitioners mostly recommended daily-disposables (65.7%) over the monthly disposables (32.8%) (Figure 20). As for the modality of contact lens wear, practitioners mostly recommended daily wear (77.5%), followed by occasional wear (18.8%) and the remaining extended wear.

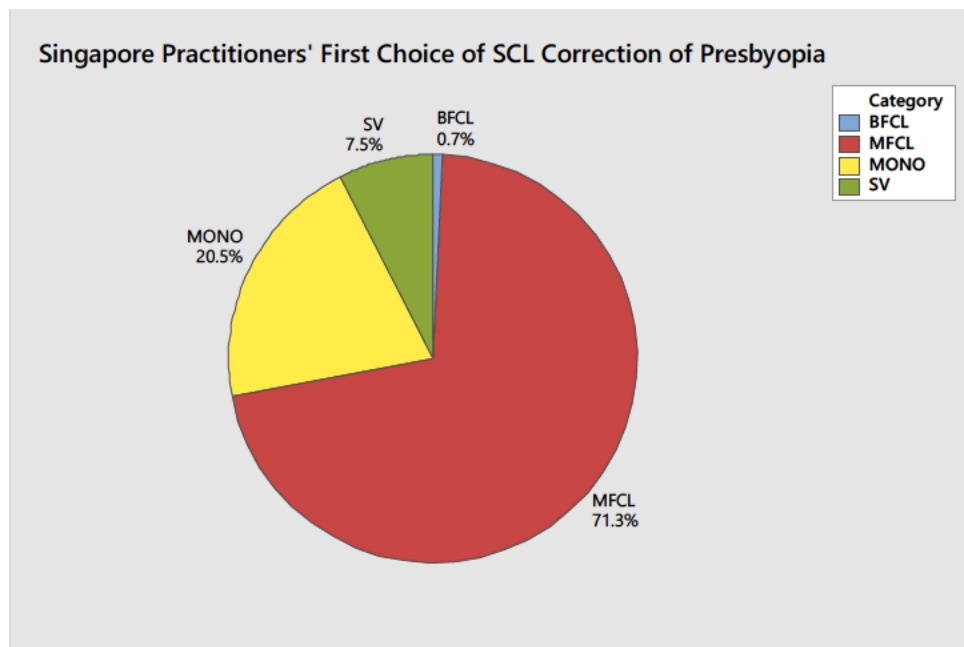


Figure 19: Singapore Practitioners' first choice of soft contact lens correction of presbyopia

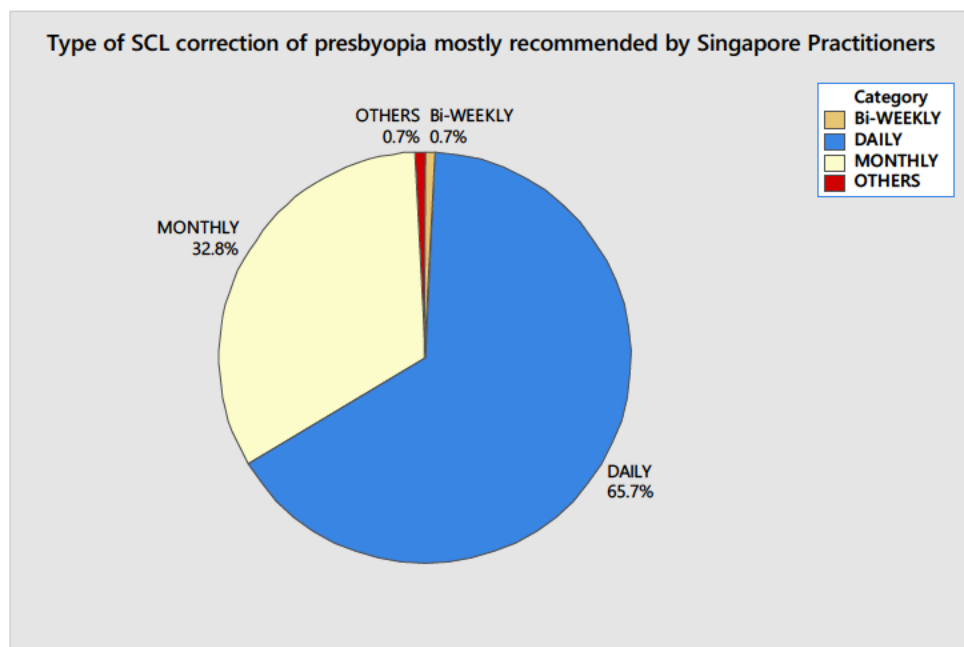


Figure 20: Type of soft contact lens correction of presbyopia mostly recommended by Singapore Practitioners.

The soft multifocal contact lens fitting rate was found to be similar in both practitioners with experience up to 8 years and with experience >8 years ( $p = 0.69$ ). There was also no difference

in the fitting of soft multifocal contact lenses in the central and outside central area of Singapore ( $p = 0.42$ ). No significant difference in proportion of soft multifocal contact lens dispensing for chain store practice, independent practitioner and academic institution ( $p = 0.07$ ).

When it comes to the first choice of soft presbyopic contact lens correction, both the practitioners with experience up to 8 years and with experience  $>8$  years would recommend multifocal contact lenses, followed by monovision lens, single vision spectacles for near to wear over distance contact lenses and BFCL ( $p = 0.057$ ). Additionally, Singaporean practitioners regardless of years of practice experience have the tendency to recommend daily-disposable soft contact lenses ( $p=0.092$ ) and as daily wear modality ( $p=0.063$ ) for their presbyopic patients.

### 2.3.3 Practitioners' attitude

The most common barriers in prescribing of soft multifocal contact lenses from practitioners' perspective were lack of 'ideal' multifocal contact lenses (47%) and soft multifocal contact lens fitting was time consuming and complex (35%). Forty six percent of practitioners had identified the need of technical and skills training in soft multifocal contact lens fitting. On the other hand, the majority of practitioners reported high awareness of the availability of multifocal contact lenses (88%). They were confident in the prescribing of soft multifocal contact lenses (81%), motivated in the fitting of soft multifocal contact lenses (71%) and frequently recommending soft multifocal contact lenses as an option for presbyopia correction (66%) (Figure 21).

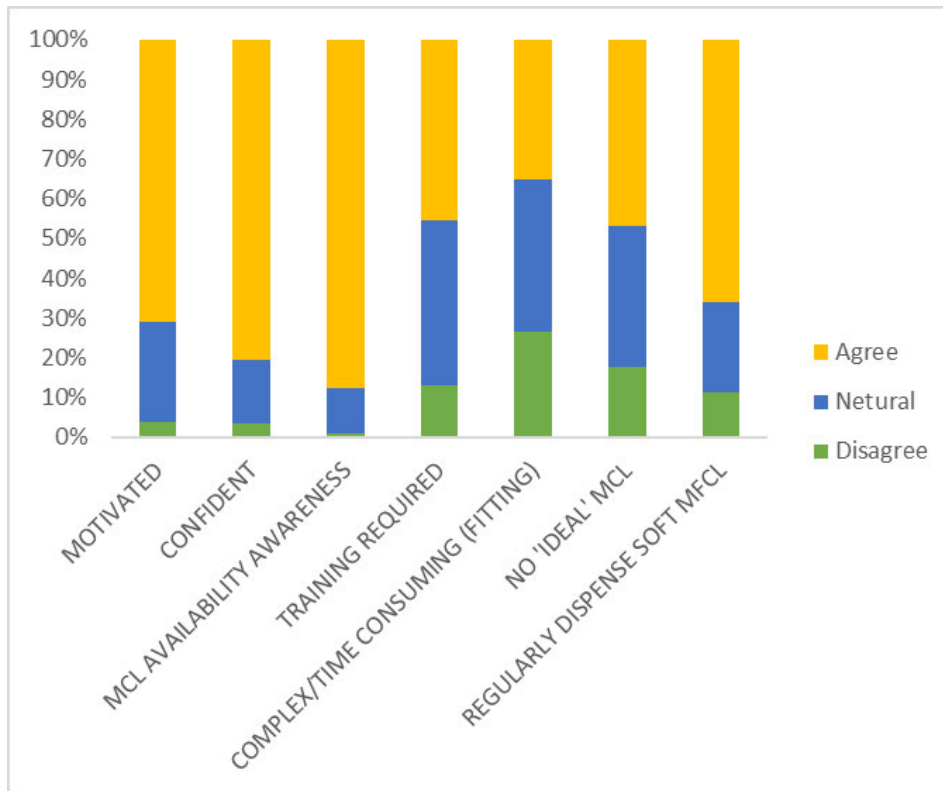


Figure 21: Responses from survey regarding attitudes towards prescribing soft multifocal contact lenses.

#### 2.3.3.1 Attitudes of experienced ( > 8 years ) and non-experienced (up to 8 years) practitioners

Attitudes of experienced and non-experienced practitioners were analysed to identify the possible attitudes that could affect the prescribing rate amongst the practitioners. Table 3 shows the results of Chi-square test for the relationship between the responses to the questions and the years of experience of the practitioners. It was found that significantly, more experienced practitioners reported that there is a lack of 'ideal' soft multifocal contact lenses in the Singapore market ( $p = 0.030$ ) and had the tendency to agree that fitting soft multifocal contact lenses is complex and time consuming ( $p = 0.075$ ) as compared to the non-experienced practitioners. In contrast, non-experienced practitioners would tend to agree that they would regularly recommend and dispense soft multifocal contact lenses ( $p = 0.350$ ). However, regardless of practitioner's experience, majority reported confident in prescribing soft multifocal contact lenses and were aware of the availability of all soft multifocal contact lenses in Singapore. Similarly, no

evidence found between practitioner's experience and his/her motivation in fitting soft multifocal contact lenses and the need of special skills and technical training.

Practitioners' Attitudes	Experience up to 8 years			Experience > 8 years			
	Agree	Neutral	Disagree	Agree	Neutral	Disagree	
I am motivated to fit multifocal contact lenses	72%	25%	3%	69%	26%	5%	Pearson Chi-Square = 0.271 p-Value = 0.873
I am confident in prescribing soft multifocal contact lenses	82%	14%	4%	78%	20%	2%	Pearson Chi-Square = 1.864 p-Value = 0.394
I am aware of the availability of all soft multifocal contact lenses in Singapore	86%	12%	2%	90%	10%	0%	Pearson Chi-Square = 1.844 p-Value = 0.398
I need special technical and skills training for soft multifocal contact lenses fitting	46%	43%	11%	45%	37%	18%	Pearson Chi-Square = 2.712 p-Value = 0.258
Fitting soft multifocal contact lenses is complex and time consuming	31%	43%	26%	43%	30%	27%	Pearson Chi-Square = 5.182 p-Value = 0.075
Currently there is an absence of availability of an 'ideal' soft multifocal contact lenses	41%	39%	20%	58%	29%	13%	Pearson Chi-Square = 7.019 <i>*p-Value = 0.030</i>
I do regularly recommend and dispense soft multifocal contact lenses	69%	20%	11%	60%	28%	12%	Pearson Chi-Square = 2.097 p-Value = 0.350

Table 3: Tabulated Chi-square results between responses of practitioners with up to 8 years and > 8 years of experience.

### 2.3.3.2 Attitudes of regular and non-regular soft multifocal contact lenses fitters

Of the 268 practitioners, 139 (51.9%) were considered as regularly dispensed soft multifocal contact lenses (on average of three or more patients per month) and 129 (48.1%) were non-regular soft multifocal contact lenses dispensers (on average two or less patients per month). Table 4 shows the results of Chi-square test for the relationship between the responses of regular and non-regular soft multifocal contact lenses fitters. It was found that practitioners who regularly dispensed soft multifocal contact lenses were significantly highly motivated ( $p = 0.000$ ) and were more confident in prescribing soft multifocal contact lenses ( $p = 0.003$ ) as compared to non-regular soft multifocal contact lenses dispensers. These enablers significantly influenced

the regular dispensers in recommending soft multifocal contact lenses frequently ( $p = 0.000$ ). Although the regular dispensers were more aware of the availability of all soft multifocal contact lenses in Singapore ( $p = 0.350$ ) and considered fitting soft multifocal contact lenses was not complex nor time-consuming ( $p = 0.257$ ), they were found to be statistically insignificant. Interestingly, despite majority of the non-regular soft multifocal contact lenses dispensers were aware of the availability of all soft multifocal contact lenses and confident in fitting these lenses, only about half of them were frequently recommending multifocal contact lenses and motivated to fit multifocal contact lenses (Table 4).

Practitioners' Attitudes	Non regularly dispensed soft multifocal contact lenses			Regularly dispensed soft multifocal contact lenses			
	Agree	Neutral	Disagree	Agree	Neutral	Disagree	
I am motivated to fit multifocal contact lenses	58%	38%	4%	85%	12%	3%	Pearson Chi-Square = 26.035 * $p$ -Value = 0.000
I am confident in prescribing soft multifocal contact lenses	73%	22%	5%	89%	9%	2%	Pearson Chi-Square = 11.724 * $p$ -Value = 0.003
I am aware of the availability of all soft multifocal contact lenses in Singapore	85%	14%	1%	91%	8%	1%	Pearson Chi-Square = 2.101 $p$ -Value = 0.350
I need special technical and skills training for soft multifocal contact lenses fitting	40%	45%	15%	51%	38%	11%	Pearson Chi-Square = 3.374 $p$ -Value = 0.185
Fitting soft multifocal contact lenses is complex and time consuming	39%	37%	24%	30%	40%	30%	Pearson Chi-Square = 2.716 $p$ -Value = 0.257
Currently there is an absence of availability of an 'ideal' soft multifocal contact lenses	48%	35%	17%	46%	36%	18%	Pearson Chi-Square = 0.251 $p$ -Value = 0.882
I do regularly recommend and dispense soft multifocal contact lenses	50%	32%	18%	84%	12%	4%	Pearson Chi-Square = 35.390 * $p$ -Value = 0.000

Table 4: Tabulated Chi-square results between responses of regular and non-regular soft multifocal contact lenses fitters.

### 2.3.3.3 Attitudes of practitioners working in retail chain stores and independent practices

Attitudes of practitioners working in retail chain stores and independent practices were analysed to identify the possible behaviours that could affect the prescribing pattern amongst the practitioners. In this part of the analysis, we include only the responses from practitioners in

stand-alone practice and retail chain stores. Table 5 shows the results of Chi-square test for the relationship between the responses to the questions and the principal workplace of the practitioners.

Practitioners from retail chain stores were significantly more motivated to fit soft multifocal contact lenses as compared to the stand-alone practitioners ( $p = 0.006$ ). It was found that significantly more stand-alone practitioners would agree that there was no 'ideal' soft multifocal contact lenses available in the market ( $p = 0.024$ ) and they also reported the need for special technical and skills training in soft multifocal contact lens fitting ( $p = 0.023$ ). However, no relationship could be found between the practitioners' confidence in fitting soft multifocal contact lenses and the principal work place of practitioners.

Practitioners' Attitudes	Independent			Chain Store			
	Agree	Neutral	Disagree	Agree	Neutral	Disagree	
I am motivated to fit multifocal contact lenses	65%	29%	6%	80%	20%	0%	Pearson Chi-Square = 10.132 <b>*p-Value = 0.006</b>
I am confident in prescribing soft multifocal contact lenses	81%	16%	3%	81%	16%	3%	Pearson Chi-Square = 0.061 p-Value = 0.970
I am aware of the availability of all soft multifocal contact lenses in Singapore	88%	10%	2%	88%	12%	0%	Pearson Chi-Square = 2.000 p-Value = 0.368
I need special technical and skills training for soft multifocal contact lenses fitting	45%	38%	17%	44%	50%	6%	Pearson Chi-Square = 7.555 <b>*p-Value = 0.023</b>
Fitting soft multifocal contact lenses is complex and time consuming	34%	35%	31%	37%	43%	20%	Pearson Chi-Square = 4.168 p-Value = 0.124
Currently there is an absence of availability of an 'ideal' soft multifocal contact lenses	49%	30%	21%	42%	45%	13%	Pearson Chi-Square = 7.495 <b>*p-Value = 0.024</b>
I do regularly recommend and dispense soft multifocal contact lenses	64%	23%	13%	70%	24%	6%	Pearson Chi-Square = 3.281 p-Value = 0.194

Table 5: Tabulated Chi-square results between responses of practitioners and the principal workplace.



#### 2.3.3.4 Free text responses generated from open-ended question

The last 'open ended' question in the survey concerned the reason for whether practitioner routinely recommending and dispensing soft multifocal contact lenses for the correction of presbyopia. A significant proportion of practitioners that regularly recommend and dispense soft multifocal contact lenses (30%) cited convenience benefits for their patients as the major factor. This group of practitioners also cited soft multifocal contact lenses could provide as an additional contact lens option for correcting presbyopia. They also observed an increasing demand for soft multifocal contact lenses due to aging population. Other factors that influenced the practitioners' regularity in recommending and dispensing of soft multifocal contact lenses included improvement in patient's QoL, visual needs and ability to achieve good distance and near vision with multifocal contact lenses. On the contrary, a significant proportion of practitioners that were not regularly recommending and dispensing soft multifocal contact lenses cited low demand (26%) and unpredictable performance of soft multifocal contact lenses. They also cited poor vision as primary reason for abandonment from soft multifocal contact lenses (15%). Others reasons reported included limited soft multifocal contact lenses parameters, increased chair time in fitting multifocal contact lenses and poor business proposition.

#### 2.4 Discussion

We investigated the soft multifocal contact lens prescribing trends in Singapore based on the observations and opinions collected from a group of registered optometrist through a questionnaire. The response rate of this study compared favourably to previous studies using similar administration of mail survey (132, 144). From the data collected, the respondents' mean years of experience was 7.7 years (range from 0.33 to 37 years), with 66% of respondents with up to 8 years of experience and 34% of respondents with > 8 years of experience. This implies that the average years of practice is skewed towards the younger practitioners as compared to the older ones. The predominance of younger practitioners amongst optometrists in Singapore is well established (136), half of the optometrists are between 20 to 29 years old, while only 9% of them are between 50 to 59 years and 3% of them are 60 years and above.

Increased in successful fits with soft multifocal contact lenses have been reported over the years, reflecting of a high proportion of presbyopes are now fitted with soft multifocal contact lenses. In an early study, Morgan et al. (121) reported that about 50% of all soft presbyopic lens fitting were soft multifocal contact lenses. Indeed, this study revealed that approximately 50% of presbyopic lenses fitted in Singapore were soft multifocal contact lenses, showing similar extent of contact lens fitting to presbyopes. This result contrasted with the early survey published in 2011 (44) reported that almost zero multifocal contact lenses was prescribed in Singapore for presbyopia correction. This was perhaps consistent with the limited availability of multifocal contact lenses during the period of survey (in 2011). Morgan et al. (44) similarly pointed out that limited market availability during a study period may lead to the low rate of fitting in soft multifocal contact lenses. The high rate of fitting soft multifocal contact lenses found in this study reflects the fact that about four brands of soft multifocal contact lenses were available throughout this survey period (145). This overall increased rate of prescribing multifocal contact lenses also indicates a high level of acceptance of modern generation multifocal contact lenses amongst practitioners who engage in presbyopic contact lens fitting. Similar increase in soft multifocal contact lens fitting rate can also be observed in the other countries such as the UK (127, 128) and the US (129).

Our data showed that across different contact lens modality, a significant higher in the usage of daily-disposable (representing 66% of soft contact lens correction of presbyopia). However, an international survey of daily-disposable contact lens prescribing indicated a low proportion of 4% for daily-disposable lens fits worldwide (118). Nonetheless, the authors highlighted the difference between nations with respect to the extent of daily-disposable contact lens fitting and its significant positive association to the purchasing power parity (PPP) per capita gross domestic product (GDP). Countries such as Japan, Norway and UK were indicated as 'high daily-disposable lens prescribing group' in the study. Thus, the high usage of daily-disposable for presbyopia correction in Singapore may be attributed by its 'high' PPP per capita GDP. Interestingly, when considering the total monthly household income and Singapore residents households by area (central and outside central area) in this study, the total monthly household income does not appear to have effect on the daily soft multifocal contact lens fitting rate, though the median total monthly household income for central and outside central area was reported to be \$27,800 and \$46,650 respectively (146).

In this study, practitioners identified the perspective of unavailability of an ideal multifocal contact lens and increased chair time in fitting soft multifocal contact lenses as the primary barriers. Similar to this study, Morgan et al. (44) described that psychological factor such as an absence of an ideal multifocal contact lens may lead to practitioners' incongruent perception of compromised visual performance and results in decreased patients' satisfactory. The absence of a 'perfect' multifocal contact lens may also imply practitioner dissatisfaction with the current multifocal designs and may withdraw multifocal contact lenses as an option for correcting presbyopia (139). Thite et al. (122) examined the attitudes amongst practitioners towards multifocal contact lens dispensing in India and found that increased chair time was one of the significant barrier practitioners faced when fitting multifocal contact lenses. Increased chair time in fitting and follow up with multifocal lens wearers has led to the possibility of not choosing this system for the patient (147). Indeed, fitting multifocal contact lenses is more involved and time consuming as compared to conventional spherical or toric lens fitting, with multiple tedious lens trials and additional tests such as to determine the dominant eye may need to be undertaken (140). However, practitioners should not be deterred by the increased chair time of seemingly complex fitting, as it has scarcely been reported that increased chair time has led to an increase dropout rate of soft multifocal contact lenses wearer. Notably, the chair time required to achieve successful fitting can be reduced with the newer multifocal contact lenses designs (148), along with the provision of continuing educational programmes for practitioners, in order to enhance their skills and boost their confidence in fitting multifocal contact lenses (122). Indeed, a significant proportion of practitioners surveyed in this study highlighted the need of special technical and skills training for soft multifocal contact lenses fitting. Psychological factors such as lack of product awareness, fitting skills, technical knowledge and expertise may have a significant negative impact on the prescribing of multifocal contact lenses. Thus, such barrier can be overcome by accelerated professional education in presbyopia contact lens fitting (44). Additionally, level of motivation and confidence amongst practitioners have been reported as primary barriers in fitting multifocal contact lenses (44). Similarly, Thite et al. (122) reported a significantly large proportion of the practitioners indicated low level of motivation towards dispensing multifocal contact lenses. While these factors were also featured in this study, they were not found to be the significant barriers. A high proportion of practitioners surveyed in this study claimed that they were motivated and confident to fit and dispense soft multifocal contact lenses and had the knowledge about multifocal contact lenses availability in the Singapore market. In addition, a high proportion of them (66%) also agreed that they were active in recommending and dispensing of soft multifocal contact lenses. These positive attitudes

perhaps are the main drivers towards dispensing of multifocal contact lenses. Leveraging on these attitudes is certainly very important as it could positively influence the dispensing rate of multifocal contact lenses (122). In fact, our findings demonstrated practitioners who regularly dispensed soft multifocal contact lenses were significantly more motivated and confident. They were also actively dispensing this lens type as compared to non-regular soft multifocal contact lenses dispensers. These elements may inevitably improve professional satisfaction, which has been identified as a main motivator in practitioners who regularly dispensed multifocal contact lenses (122).

Although soft multifocal contact lens fitting rate was found to be similar in both experienced practitioners with experience up to 8 years and with experience >8 years, this study did not show any significant difference in motivation between more-experienced and less-experienced practitioners. This differs from Thite et al. (122) study where experienced practitioners (> 8.5 years) in Mumbai, India were observed to be significantly least motivated at dispensing multifocal contact lenses. However, a significantly higher proportion of more-experienced practitioners in Singapore agreed with the non-existence of a 'perfect' soft multifocal contact lens than less-experienced practitioners. According to Morgan et al. (44), practitioners thus may perceive possible patient dissatisfaction with the current available presbyopic contact lens options, leading to patients losing faith in the prescribing practitioner.

It has been shown that multifocal contact lens fitting behaviours are influenced by optometric practice setting (140). However, little is known of the influence of optometric practice setting in Singapore on the practitioner attitudes in dispensing soft multifocal contact lenses. In Singapore, we arbitrarily define independent practices as those owned by an individual that operate out of one location, while chain store practices defined as those operate out of more than two locations. Singapore practitioners at chain store practices were found to be significantly more motivated in fitting multifocal contact lenses compared to those practicing at independent practices. Contrary to our findings, Morgan et al. (140) reported of a higher proportion of multifocal lens fits in independent optometry practices. This could be due to the study was conducted in the UK and differences in the criteria used for definition of practice setting, where independent practices were defined as operate out of fewer than 15 locations. Further to this, our findings showed a significant higher proportion of fits of daily-disposable multifocal soft contact lenses in both the independent practices and retail chain stores. Prominently, practice efficiencies offered by daily-disposable lenses, such as relatively easy in

fitting and lens supply which can be immediately dispensed from the stock (140), may have influence chain store practices, as these may provide the most favourable business and commercial operational model.

Significantly, Singapore practitioners at independent practices indicated the need of more special skills and technical training in soft multifocal contact lens fitting. Indeed, practitioners' level of training has an influence on soft multifocal contact lens fitting rate (44, 133, 134), and inadequacy in knowledge has been suggested as a factor for low prescribing rate of presbyopic lens fits (132). Hence, more continuing education in presbyopic contact lens fitting should be provided to enhance practitioner fitting skills and their understanding of multifocal contact lens performance. With better knowledge and skillsets, practitioner will be more confident and in turn, will have a positive impact on the dispensing rate of soft multifocal contact lens (122).

Overall, practitioners in Singapore were proactive in their recommendation of soft multifocal contact lenses to patients. The most commonly cited reasons for actively recommending soft multifocal contact lenses were the convenience of multifocal lens system offered for the patient and they were able to provide the patient with uncompromised good vision and stereopsis. Indeed, the freedom, convenience and the benefit of contact lenses compared to spectacles in the correction of presbyopia have been well discussed (53, 54, 44, 149). Additionally, modern soft multifocal contact lenses have been shown to provide excellent visual acuity while preserving stereopsis. (49, 52, 86, 150). Hence, it is important to understand these enablers and perhaps make practitioners aware of them through professional education programme. These enablers may be the prerequisite factors that contribute to the success of multifocal contact lens dispensing. On the other hand, the most cited reason for not regularly recommending and dispensing of soft multifocal contact lenses was low consumer demand. Contrary to this, multiple worldwide patterns of fitting contact lenses for the correction of presbyopia have indicated tremendous potential demand in the presbyopic market (44, 54, 122, 139, 151). Instead of relying on practitioner's understanding, perhaps it is important to increase presbyopic patients' awareness of the availability and advantages of multifocal contact lenses. Concurrently, training on proper patient selection to the practitioners has been identified as an enabler for presbyopic lens fitting success and must thus be encouraged (43, 122).

The analysis of this study is similar to previous studies comparing the relationship between practitioners' attitudes, fitting and dispensing of contact lenses (122, 152). Nevertheless, this study did not correct for multiple comparisons while analysing the data and potentially can increase the likelihood of Type I errors. Thus, these findings are far from conclusive but they do provide some important insights. However, a number of procedures have been developed to deal with multiplicity but there is continuing controversy regarding if and when these procedures should be used (153). The current study examines the responses based on a sample of practitioner population in Singapore. Notably, to avoid data interpretation errors, Rothman. (154) recommended a preference of not making adjustments for multiple comparisons, when the data obtained are not random numbers but of actual observations. In addition, post hoc tests has been reported to be ineffective substitute for an experiment designed specifically to make planned comparisons (155).

Other limitations of this study include survey participants were invited to complete a paper survey, which was delivered by mail. Incorrect addresses or delays in postal delivery may have excluded some practitioners from participating in this survey. This study collected responses from the practitioners only. There is a risk of bias since practitioners who completed and returned the questionnaire were voluntary and may be those with an interest or bias or with strong opinions towards presbyopic contact lens practice, thus may not be representative of the population of contact lens practitioners. This is reflected in the positive response to the statement that they regularly dispensed soft multifocal contact lenses, where 88.8% of the surveyed practitioners showed neutral or agreement. In the survey, practitioners were asked to report their approximate frequency of contact lens fittings. The data provided by each practitioner are only estimates and is solely dependent on individual practitioner's reliability in reporting them. Possible incorrect in reporting may have influenced the accuracy of the results. Moreover, part of the survey was designed to assess practitioner's attitudes and there was the chances for misinterpretation and expansion of scope of the questions.

This study collected responses from the practitioners only and did not directly reach out to the patients. Studies have shown the primary reasons for discontinuation of contact lens wear in the presbyopic population was due to patient's dissatisfaction with vision and discomfort (156). Other factors such as differences in rate of progression, onset of presbyopia in different race and nationality, the effects of aging and eye diseases in the patients such as dry eyes, astigmatism and cataract can further contribute as limitations to practitioners when fitting

multifocal contact lenses (119). In that respect, in order to fully study factors influence practitioners attitudes toward soft multifocal contact lens prescribing, it is important to obtain information regarding presbyopic contact lens wearers' attitudes to multifocal contact lenses. Additionally, to conduct a detailed eye examination amongst the presbyopic contact lens wearers to exert influence on practitioners attitudes toward soft multifocal contact lens prescribing.

## 2.5 Conclusion

Due to the increase in availability of soft multifocal contact lenses in Singapore, there was an increase in the rate of soft multifocal contact lens fitting (114). Practitioners' perception of the unavailability of an 'ideal' multifocal contact lenses and increased chair time in fitting soft multifocal contact lenses were observed as primary barriers. Additionally, the need for training of contact lens practitioners in soft multifocal contact lenses was identified. Along with barriers, enablers such as the increased in practitioners' motivation, confidence and proactiveness in fitting soft multifocal contact lenses were gathered. Daily-disposable multifocal contact lenses and daily wear modality were the most popular choices amongst Singaporean practitioner. A clear shift in trend that more practitioners would prefer multifocal contact lenses over monovision as their first choice of correction for presbyopia was observed. To improve multifocal contact lens fitting rate, accelerated educational training programmes in presbyopic contact lens fitting should be provided to the practitioners. This will help in increasing the confidence and motivation level amongst practitioners in the dispensing of multifocal contact lenses. Presbyopic correction is currently one of the most demanded areas of contact lens practices. This survey gathered valuable new information about the attitudes of fitting and dispensing soft multifocal contact lenses to presbyopes in Singapore. Additionally, the information help to understand the motivators and barriers to soft multifocal contact lens fitting and may help to support future planning strategies to improve the proportion of contact lenses prescribing for presbyopia.

### 3. Visual performance in myopic participants wearing daily-disposable multifocal soft contact lenses

#### 3.1 Introduction

The global population of older people is set to increase and according to the Singapore Department of Statistics, the median age of Singapore's population has increased over recent years to 40.8 years and Singapore residents aged 45 and older grew to 43.6 per cent in 2018 (126). The shift in population age structure does imply an increase in the presbyopic population and present with great potential and opportunity to increase the number of patients who can benefit from contact lenses.

Better health and increased vitality during the middle adult years have altered the range of activities undertaken by presbyopic population and their attitudes towards physical appearance have substantially changed over the last two to three decades (56, 61). No longer is 'old-age' assumed a time of inactivity and inability to enjoy life. The change in attitude towards appearance and range of lifestyle activities have made visual correction options that are burden-free and convenient more appealing. Thus, it is unsurprised to note that a huge disparity exists between the presbyopic patients whom desire to be less dependent on spectacles and the actual contact lens wearers in this population (43).

Presbyopia can be corrected using spectacles, contact lenses and even surgery. Common types of ophthalmic lens to correct presbyopia are the bifocal and progressive-addition lens (PAL) (53). For bifocals, a distinct separation of top of the lens for distance prescription while the lower portion is used for near vision, thereby making it convenient for users. On the other hand, PALs provide a smooth transition of lens power, to allow clear and comfortable vision at all distances. This is in contrast to the sudden image jump and absence of an intermediate zone in bifocals (157). However, the downside to PAL would be the presence of distortion at the edge of the lenses and an adaptation period that is required especially for first time wearers (53).

Contact lens correction for presbyopia has been clearly recognized for more than 50 years (158). Perhaps one of the simplest solution for existing contact lens wearers is to have single-vision contact lens to correct the distance refractive errors and plus power reading glasses to provide for the required near addition. Such combination seems to be the easiest to fit and



considerably the least expensive (43). Although it is inconvenient with frequent application and removal of reading spectacles when performing intermediate or near tasks, it provides optimum vision at distance and near. This was demonstrated in a crossover study by Madrid-Costa and colleagues (77), where they reported that binocular distance visual acuity (BDVA) and binocular near visual acuity (BNVA) were significantly better in patients wearing distance soft contact lenses combined with reading spectacles compared to multifocal contact lens. However, this finding was described as 'not clinically meaningful', as the difference found was in the order of 1 to 2 letters of logMAR VA (78). Other studies (150) have also reported an insignificant difference in the near stereoacuity between patients wearing distance soft contact lenses combined with reading spectacles and those wearing multifocal contact lenses.

Monovision is another method for correcting presbyopia, where one eye is focussed for distance vision and the other for near (47). In contact lens practice, monovision is achieved with a single-vision contact lens worn in one eye for distance prescription to correct distance vision and the contra-lateral eye with the near prescription to correct near vision. In practical, presbyopic patients usually can accept up to 1.5 D addition correction in the eye for near vision, as interocular differences resulted from higher addition seems to present unacceptable suppression problem (159). Previous studies in VA with monovision yield contradictory findings, whereby both superior (160), inferior (99) and no significant differences (106) as compared to multifocal contact lenses were reported. However, poor stereopsis is often reported in monovision modality (75, 86, 108). But interestingly, it has been reported that most patients did not seem to notice the reduction in such stereoacuity (47). Others have proposed that the age of patients may influence the stereoacuity outcomes, as no significant difference in stereopsis was found in emerging and low addition prebyopoes patients with monovision compared to multifocal contact lenses (106).

Perhaps the loss of stereoacuity is particularly more noticeable in a new wearers (161) and this usually lead to the complaint of poorer distance vision. Notably, difficulty in 'night driving vision' due to glare was reported in 80% of patients with monovision (43) and more importantly, other studies have reported of increased risk of tipping and gait related accidents in contact lenses wearers with monovision correction (162). Nevertheless, monovision still account for about 10% of the worldwide market as a treatment option for correction of presbyopia (121).

To address the shortcomings of monovision, continuous improvements in the optical designs of simultaneous vision multifocal contact lens have led to improve performance, in terms of better vision and binocularity (150). Soft multifocal contact lenses are broadly categorised based on simultaneous vision design, as discussed in section 1.2.4.1. In multifocality, when viewing a distant or near object, all the images will form on the retina simultaneously, where focused image will superimpose with the defocused images formed from the other parts of the multifocal contact lens (53, 74). Thus for simultaneous vision multifocal contact lens to work, the brain must be able to discriminate the desired focused images. Ideally, patients must be able to suppress blurred images that falls on the retina, as well as having good blur tolerance (43). Previous clinical studies conducted on visual performance of multifocal contact lenses measurable in clinical settings include VA, contrast sensitivity, optical aberrations, stereoacuity, accommodative functions and subjective ratings measured from real world situations (such as driving and watching television) (99, 106, 163-165). Table 6 shows a summary of in-vivo clinical studies conducted on multifocal contact lenses in the last decade.

In a crossover study, Richdale and colleagues (108) assessed the visual performance and satisfaction (using the NEI-RQL) of presbyopes using multifocal contact lenses (SofLens Multifocal Contact Lenses; Bausch + Lomb, Rochester, NY) and monovision lens (SofLens59; Bausch + Lomb, Rochester, NY). Both the high and low contrast BDVA and BNVA were found to be comparable, however, 76% of participants reported that they preferred multifocal contact lenses to monovision. Fernandes et al. (52) also reported comparable high and low contrast BDVA and BNVA of silicone hydrogel multifocal contact lens (Biofinity® multifocal; CooperVision, NY) and monovision lens (single-vision Biofinity; CooperVision, NY) correction. However, they found significant improvement in the near VA of the dominant eye and the distance vision of the non-dominant eye in the multifocal contact lens correction after an adaptation of 15 days wear. This demonstrates that there is an adaptation to multifocality overtime. On the contrary, Woods et al. (49) reported a significant better in both the high and low contrast BDVA and BNVA with monovision compared to multifocal contact lenses (Air Optix Aqua Multifocal Contact Lenses; Alcon, Fort Worth, TX) in a group of participants with a medium level of reading-addition power. Similarly, Gupta et al. (86) reported that patients with monovision lens (single-vision PureVision Contact Lenses; Bausch & Lomb, Rochester, NY) had significant better BDVA and BNVA than patients with both low and high addition multifocal contact lenses (PureVision Multi-Focal Contact Lenses; Bausch & Lomb, Rochester, NY).

Other studies have investigated the visual performance of different brands of multifocal contact lenses. In a study that recruited 45 presbyopic participants, Guillon et al. (166) recorded better BNVA and BNVA for Acuvue bifocal lenses (Johnson & Johnson Vision Care, Jacksonville, FL) compared to Focus Progressive (CIBA Vision, Duluth, GA) under four test conditions: high luminance high and low contrast, low luminance high and low contrast. Another study involving 6 participants with Focus Progressive (CIBA Vision, Duluth, GA), low addition PureVision Multi-Focal Contact Lenses (Bausch & Lomb, Rochester, NY) and high addition PureVision Multi-Focal Contact Lenses (Bausch & Lomb, Rochester, NY) yield no significant differences in distance VA and Pelli-Robson contrast sensitivity tests between these three types of multifocal contact lenses (165). However, a previous study of Madrid-Costa et al. (74) reported better BDVA and BNVA under mesopic conditions with low addition PureVision Multi-Focal Contact Lenses compared to ACUVUE OASYS® for Presbyopia (Johnson & Johnson Vision Care, Jacksonville, FL). In another study based on the visual performance results of 10 participants aged 40-45 years, Vasudevan et al. (167) reported that both the high and low contrast distance and near VA, accommodative response, contrast sensitivity function and optical aberrations were not significantly different between three multifocal lens designs with low addition power; Acuvue Oasys for Presbyopia multifocal (Johnson & Johnson Vision Care, Jacksonville, FL), Air Optix Aqua Multifocal Contact Lenses and the Biofinity multifocal contact lens. Notably, the study was conducted in 10 participants and adopted a very limited adaption period, whereby all the fittings were within the same visit.

Although modern soft multifocal contact lenses seem able to provide excellent VA while preserving stereopsis, previous investigations conducted on visual performance of soft multifocal contact lens designs show conflicting findings with high variability within results of different lens designs (Table 6) (75). Factors such as unique technology, lens design and material of different lens brands, refractive error, changes in pupil sizes, lighting levels and patient lifestyle, can have influence on the visual performance and acceptance of soft multifocal contact lenses (167). Furthermore, previous multifocal contact lens research has focused on comparing monovision contact lens correction with presbyopic contact lens designs (49, 52, 75) in a limited number of participants (74, 168), short lens adaptation time (same day or minimum lens wear period) before performance measurements and assessment (61, 167) or using limited visual performance metrics (99, 166) (Table 6). In addition, few studies (52, 108) have reported on the visual performance comparing different lens brand in monthly replacement modality.

Recently, Efron et al. (118) reported the continued upward popularity trend in daily-disposable modality. Over the last few years, there has been a marked increase in the availability of daily-disposable multifocal contact lens options from major manufacturers. In 2012, the annual Contact Lenses and Solutions Summary listed only one daily-disposable multifocal contact lens available within the United States, but this has expanded to eight lens types with a range of parameters and add power options (145, 169). Notably, one study have compared the visual performance of daily-disposable multifocal soft contact lenses with relatively limited visual performance metrics and short adaptation (123). Hence, this study aimed to comprehensive assess and compare the relative performance of three daily-disposable multifocal soft contact lens designs currently available in the market. The results may assist clinicians in choosing one lens brand over the other, depending on the lens features and patient's needs and requirements.

Study	N	Age, Yr	Design	Lenses	Measurements
Sha et al., 2018	72	40-73	1 week Crossover	1-Day Acuvue moist MF, BioTrue ONEday for Presbyopia, Dailies AquaComfort Plus MF	High & low contrast VA, stereopsis, Subjective Questions
Wahl et al., 2018	16	23-28	No adaptation Crossover	Biofinity SV, Biofinity MF, Spectacles,	CSF, Glare
Sanchez et al., 2018	20	18-30	No adaptation Crossover	Pure Vision 2 for presbyopia, Biofinity MF, Monovision	VA, Steropsis, CS
Tilia et al., 2017	52	45-70	No adaptation Crossover	Prototype MF, Air Optix Aqua MF	VA, CS, Stereopsis, Ghosting Scale, Subjective Questions
Diec et al., 2017	46	47-57	5-7 days Crossover	Acuvue Oasys for Presbyopia, Air Optix Aqua MF	VA, Stereopsis, Subjective Questions
Novillo-Díaz et al., 2017	150	40-65	3 months N=50	Methafilcon IV, Biofinity MF, Air Optix Aqua MF	Number of dropouts, Risk of discontinuation, QOL, Anxiety level
Sha et al., 2016	20	45-70	1 hour Crossover	Lotrafilcom B, Acuvue Oasys for Presbyopia, Air Optix Aqua MF	VA, CS, Stereopsis, Subjective Questions, Lens fit assessment
Sivardeen et al., 2016	35	42-65	4 weeks Crossover	Air Optix Aqua MF, Pure Vision 2 for presbyopia, Biofinity MF, Monovision	Lifestyle, Personality, VA, Defocus, Stereopsis, Halometry, Pupil Size & Decentration, Ocular Aberration, Reading metrics (RS, CPS), NAVQ, Ocular physiology
Woods et al., 2015	49	43-66	2 weeks Crossover	Air Optix Aqua MF, Monovision	VA, Stereopsis, Subjective Questions

Garcia-Lazaro et al., 2015	28	40-46	1 month Crossover	Air Optix Aqua MF, PureVision MF, Acuvue Oasys for Presbyopia, Monovision	VA, CS, + Glare
Pinero et al., 2015	16	43-58	2 weks Crossover	Duette MF, Air Optix Aqua MF, Biofinity MF	VA, CS, Ocular Aberration
Woods et al., 2015	49	43-66	2 wks Crossover	Air Optix Aqua MF, Monovision	VA, Stereopsis, , Subjective Questions
Fernandes et al., 2013	20	45-57	15 days Crossover	Biofinity MF vs Biofinity MF	VA, NVA, CSF, stereopsis
Plainis et al., 2013	12	22-29	No adaptation Crossover	Air Optix Aqua MF: low, medium, high ADD	VA, defocus, artificial pupil, Aberrometry
Madrid-Costa et al., 2013	20	42-48	1mth Crossover	PureVision: low ADD vs Acuvue Oasys for Presbyopia	VA, NVA, CSF, defocus, Photopic/mesopic
Vasudevan et al., 2013	19	40-45	No adaptation Crossover	Acuvue Oasys for Presbyopia, Air Optix Aqua MF, Biofinity MF	VA, NVA, CSF, Range of near vision, Defocus
Madrid-Costa et al., 2012	20	45-65	1mth Crossover	Proclear MF toric vs Proclear toric with reading spectacles	VA, NVA, CSF +glare, Defocus, stereopsis, photopic/mesopic,
Llorente-Guillemot et al., 2012	20	41-60	1mth Crossover	PureVision MF high vs spectacles	VA, CSF+ glare, photopic/mesopic
Ferrer - Blasco et al., 2011	25	50-60	1mth Crossover	Proclear MF vs distance CL+ spectacles	VA, NVA, stereopsis
Legra et al., 2010	4	20-37	Non-dispensing	No correction vs Proclear MF,	VA, CSF, TFF
Chu et al., 2010	11	45-64	No adaptation Crossover	PALs, BF spectacles, MF CLs	Driving metrics
Chu et al., 2009	20	47-67	No adaptation Crossover	PALs, BF spectacles, MF CLs	Driving metrics
Gupta et al., 2009	97	30-88	Non-dispensing	IOLs, PALs, PureVision MF, Monovision	BNVA, Reading metrics (RA, CPS, RS)
Woods et al., 2009	25	39-49	1 wk Crossover	Habitual, Focus MF, Monovision, distance CLs	VA, CSF, stereopsis, reading speed, Subjective Questions
Chu et al., 2009	255	45-70	Survey	Habitual (No Correction, BF, PAL, Monovision, MF)	Survey
Papas et al., 2009	88	40-60	4 day Crossover	Acuvue BF, Focus MF, ProclearMF, Soflens MF	VA, IVA, NVA, photopic / mesopic, stereopsis, reading speed, Subjective Questions
Gupta et al., 2009	20	49-67	1 mth Crossover	PureVision MF vs Monovision	VA, IVA, NVA, CSF, reading speed, defocus, stereopsis

Sanders et al., 2008	25	No Recorded	Non-dispensing	Proclear MF	VA at 4M (high & low contrast), pupil size
Richdale et al., 2006	38	41-64	N=19	Soflens MF vs Monovision	VA, NVA, CSF, stereopsis
Pujol et al., 2003	6	29-45	No adaptation Crossover	Aspheric MF vs multicurve MF	MTFs at D, I & N
Patel et al., 2002	10	Not disclosed	Non-dispensing	Progressive MF	Aberrations, pupil size
Guillon et al., 2002	45	41-68	No adaptation Crossover	Acuvue BF vs Focus MF	VA, NVA, CSF, photopic/mesopic
Soni et al., 2003	30	40-65	1week Crossover	Acuvue BF vs 2x exp diffractive/refractive MF	VA, CSF, Subjective Questions

Table 6: Studies comparing contact lenses for presbyopia from 2003 onwards.

### 3.2 Method

This clinical study was designed as a single-blinded (subject-masked), randomised, crossover, dispensing trial which participants wore three types of daily-disposable multifocal lens correction, each for a period of 1 month, in a randomised order. The study duration for each subject was 3 months. The study was approved by the Singapore Polytechnic Ethics Review Committee and by Aston University Ethics Committee and was conducted in accordance with the tenets of the Declaration of Helsinki.

#### 3.2.1 Participants and Recruitment

Participants aged 40 years or older who reported using a presbyopic refractive correction were recruited at the Singapore Polytechnic Optometry Centre in Singapore, responded to a notice for research participants from September 2016 to December 2017. Inclusion criteria were myopic adults 40 years of age and above with best corrected distance and near VA of at least 0.10 logMAR or better in each eye. Participants were screened to exclude those with spectacle astigmatism of >0.75 D, anisometropia (> 0.75 D mean spherical equivalent), heterotropia, amblyopia in either eye (unilateral amblyopia was defined as a  $\geq 2$ -line difference in best VA, when < logMAR 0.18 in the worse eye; bilateral amblyopia was defined as best VA in both eyes < logMAR 0.3), positive history of ocular, systemic diseases and ocular surgery. Informed consent was obtained from all participants after explanation of the nature and possible consequences of the study. Every subject was assigned a code number so that the

anonymization of the collected demographic data was ensured. Before inclusion in the study, all participants had a complete eye examination, including screening for ocular and systemic disease, refraction, VA, binocular examination and comprehensive slit lamp biomicroscopy.

### 3.2.2 Contact Lenses

At the time of this study, there were only three different daily-disposable multifocal soft contact lenses with two or more add powers from three different manufacturers available in Singapore market. Thus, the three different soft multifocal contact lenses used for the investigations were 1-day Acuvue® Moist Brand Multifocal Contact Lenses for Presbyopia (Johnson & Johnson Vision Care, Inc., Jacksonville, FL) Clariti 1-day Multifocal (Cooper Vision, NY) and Dailies AquaComfort Plus Multifocal (Alcon, Fort worth, TX) (Figure 22). The summary of the main characteristics of the three types of contact lens fitted is shown in Appendix A5.



Figure 22: Three different models of daily-disposable multifocal contact lens used in the study. Left, Moist multifocal (Johnson & Johnson Medical Limited (03/06/2019); retrieved from <https://www.jnjvisioncare.co.uk/multifocal>). Centre, Clariti multifocal (CooperVision, Inc (2019); retrieved from <https://coopervision.com/practitioner/ecpviewpoints/product-spotlight/keep-eyes-healthier-through-the-ages-with-clariti-1day-multifocal>). Right, AquaComfortPlus multifocal (Alcon Vision LLC (2019); retrieved from <https://www.myalcon.com/professional/contact-lenses/dailies/aquacomfort-plus-multifocal-technology>

### 3.2.2.1 1-day Acuvue® Moist Brand Multifocal Contact Lenses for Presbyopia

1-day Acuvue® Moist Brand Multifocal Contact Lenses for Presbyopia (Moist multifocal) lens system consists of three variations on a centre-near aspheric design, providing three levels of add power indicated as Low, Mid and High. It uses INTUISIGHT technology for pupil optimization for presbyopic eye and according to the company information, it is the only multifocal contact lens that closely matches the optical design to the pupil size according to the add and refractive range (Figure 23). It also has a unique hybrid asphere/sphere back curve for precision centering to align the optical design over the pupil for most corneal shapes (Figure 24) (170).



Figure 23: Left, Pupil Optimized Design by Moist multifocal. Right, Fixed Optical Designs by other brands. Image source: AcuvueProfessional.com



Figure 24: Precise Fit by Moist multifocal. Image source: AcuvueProfessional.com

### 3.2.2.2 Clariti 1-day Multifocal

Clariti 1-day Multifocal (Clariti multifocal) from CooperVision is made with silicone hydrogel. The lens system consists of two variations of a aspheric centre-near, progressive intermediate and peripheral distance design (Figure 25), providing two levels of add power indicated as Low and



High. Clariti multifocal feature unique WetLoc™ technology. The WetLoc™ process creates a lens that naturally attracts and binds water molecules to the lens surface, so the eyes can stay moist and comfortable throughout the day (171).



Figure 25: Clariti 1-day Multifocal with smooth power transitions across the optical centre. Image source: <https://coopervision.co.uk/practitioner/contact-lenses/clariti-1-day-multifocal>

### 3.2.2.3 Dailies Aqua ComfortPlus multifocal

The Dailies Aqua ComfortPlus multifocal (AquaComfortPlus multifocal) lens system consists of three variations of an aspheric design, providing three levels of add power indicated as Low, Med and High. It features a unique Precision Profile Design (Figure 26) that provides a smooth transition from centre-near to intermediate and distant, which creates a more evenly controlled rate of change (74). The power gradient also designed to provide consistent add power across the entire power range, which gives the same effective add power at -3.00 D as at +3.00D (159). It also has an aspheric back surface designed for optimal centration and fitting.



Figure 26: AuqaComfortPlus multifocal unique Precision Design. Image source: <https://airoptix.myalcon.com/contact-lenses/air-optix/products/air-optix-aqua-multifocal/>

### 3.2.3 Assignment of Contact Lenses

After a full eye examination, participants were randomly assigned to be initially fitted with either Moist multifocal, Clariti multifocal or AquaComfortPlus multifocal. Randomization was carried out using block randomization. It was carried out separately in each block to the three study lenses numbered L1 (Moist multifocal) , L2 (Clariti multifocal) and L3 (AquaComfortPlus multifocal). A ranking method was used to assign study lenses to the each plots (RAND function in Microsoft Excel® 2016 spreadsheet). The random numbers generated were assigned to each ‘treatment’ within each block. The rank of those numbers within each block then designated the plot. An example of this procedure is demonstrated in Table 7.

Block	Treatment:	<b>L1</b>	<b>L2</b>	<b>L3</b>
<b>I</b>	Random number	0.077	0.264	0.663
	Rank (plot no.)	<b>1</b>	<b>2</b>	<b>3</b>
<b>II</b>	Random number	0.731	0.408	0.593
	Rank (plot no.)	<b>3</b>	<b>1</b>	<b>2</b>
<b>III</b>	Random number	0.914	0.830	0.377
	Rank (plot no.)	<b>3</b>	<b>2</b>	<b>1</b>
<b>IV</b>	Random number	0.335	0.740	0.000
	Rank (plot no.)	<b>2</b>	<b>3</b>	<b>1</b>

Table 7: Random numbers were assigned to each treatment within each block.

Contact lenses were power matched to the participant’s prescription and all fittings were performed following the manufacturers’ guidelines (Appendix A7, A8, A9). After lens insertion, a setting time of 15 minutes was allowed before a standard lens fit assessment of centration, coverage, movement to confirm the participant had a comfortable wear, followed by determining the final powers for the most optimized visual outcomes. Ocular dominance (sensory) was determined using the fogging techniques, where the dominant eye was the one in which the participant reported the greatest uncomfortable blurred visual perception with a +1.50D lens under binocular conditions (172, 173). The participant’s pupil size was measured using a commercial wavefront aberrometer (COAS, Wavefront Sciences Inc, New Mexico, USA).

Participants were instructed the appropriate lens insertion and removal prior to the dispensing of lenses. Each participant was masked to the lens brand they had been prescribed and were

asked to wear the contact lenses for a minimum of 4 hours per day and a minimum of 4 days per week (118), for 4 weeks. The participants were also informed to wear the lenses for at least 3 hours before turning up on the day of their follow-up visits. After 4 weeks of contact lens wear, each participant returned for an assessment of visual function. As the lenses were assessed after a month's wear, there is therefore unlikely to have any potential residual effect on the previous lens wear, thus, there was no washout period between each lens (75).

### 3.2.4 Study Visits and Assessments

An examiner performed all the visits scheduled in the protocol. The examiner conducted the follow-up visits in which BDVA was measured using a 6 m computerized ETDRS chart (Opto SMARTCHART; Opto Group Pte Ltd, Adelaide, Australia). Both binocular intermediate VA (BIVA) and BNVA were measured using a 1 m ETDRS chart (Precision Vision, QNET BV, Amsterdam, The Netherlands) and 40 cm ETDRS chart (Good-Lite, QNET BV, Amsterdam, The Netherlands ) respectively. Reading speed and CPS were evaluated with a mobile app reading speed test developed by Kingsnorth et al.(95). The mobile app was installed in an iPad 3 and screen luminance was set to 200 milli-candela (95). Using the mobile app under photopic (85 cd/m<sup>2</sup>) lighting condition, participants were positioned at 40cm from the screen and in the field of view of the tablet computer's front facing camera. Once started, the mobile app would present the Radner reading sentences one at a time in 0.1 logMAR steps, starting from 1.0 logMAR and finishing when participant pressed the "Cannot Read" button or -0.1 logMAR was reached. The tablet would simultaneously start the stopwatch to measure the reading duration between the text had first been presented to the time when the participant pressed the 'Read' button on the screen. At the end of the test, final determination of LogRAD for the smallest print size read will be presented on the screen and the MRS and CPS (derived from the reading speed data as the acuity at which the reading speed dropped below the 95% confidence interval; see section 1.3.1.2) can be calculated automatically by the machine's software. The forced choice Photographic questionnaire for Photoc Phenomena (Aslam Glare test; Aston EyeTech Ltd, Birmingham, UK) mobile app was also installed in an iPad 3 and used to quantify glare phenomenon (see section 1.3.2) (100). The front board of the forced choice Photographic questionnaire for Photoc Phenomena has eight images in total (see Figure 13). The first three images depict daylight glare from sun causing excessively bright light, stream of light and ripple effect. The next three images depict starburst effect in daylight, halo effect in nighttime and light

arc effect in daylight. A final set of two images depict dark and light arc effects in daylight. Participants were presented with the front board images with a set of standardized instruction (100): 'Some people can get problems in their vision with light effects or glare at the different times in different places and these are pictures of the problems some people have', and if participant pointed out a particular image representing the problem they experience, a separate chart depicting the photopic phenomena in four sequential stages of severity (see Figure 14) would be presented and followed by: 'Some patients only get this problem in the mild form and some will get very severe forms. How bad, on this scale would you say you were?'. These statements were repeated if necessary until the participant pointed at a specific photographic image. The final photic phenomenon image score will be simply adding the scores of each photic phenomenon (100). Subjective evaluation of near visual ability was assessed using the validated Near Ability Vision Questionnaire (NAVQ; see section 1.3.3) (109) (Appendix A9). Participants were also asked to rate their near vision satisfaction on a 6-point scale (0 been completely satisfied and 5 being completely unsatisfied). Additionally, the VF-11(178) (Appendix A10) was used to determine the impact of near visual ability on visual functioning (see section 1.3.3). Binocular defocus curve was measured over the range of +1.00 to -4.00DS in 0.50 DS step with randomized letter sequences and lens presentation (70) under both photopic (85 cd/m<sup>2</sup>) and mesopic (3 cd/m<sup>2</sup>) lighting conditions (74, 175). At each 4 week visit, slit lamp biomicroscopy was performed to examine anterior eye health before been randomly assigned to the next lens type.

### 3.2.5 Data Analysis

The data were entered into a Microsoft Excel® 2016 spreadsheet (Microsoft Corp, USA) and analysed using Minitab (Minitab 17 Statistical Software (2010). State College, PA: Minitab, Inc. [www.minitab.com](http://www.minitab.com)). Binocular data were included in the analysis of all parameters except pupil size data were grouped as ocular dominant or non-dominant. Mean  $\pm$  standard deviation are reported in the text and tables.

CPS, photic phenomenon image scores and VF-11 scores were not normally distributed (Kolmogorov-Smirnov test,  $p < 0.05$ ). Therefore, the CPS (set at the smallest logRAD that could be read at maximum reading speed), photic phenomenon image scores and VF-11 (Rasch) scores differences for each soft multifocal contact lens fitted were compared with nonparametric

rank analysis of variance (Independent samples Kruskal-Wallis distribution comparison test). VA, reading speed, defocus curve acuities, NAVQ (Rasch) scores and pupil parameters were found to be normally distributed (Kolmogorov-Smirnov test,  $p > 0.05$ ), therefore, parametric repeated-measures ANOVA was conducted. For defocus curve, in addition to the direct comparison method of analysis involves statistical comparison of the visual acuity at each defocus level, the depth-of-focus method of analysis describes the dioptric range over which participants can sustain an absolute level of VA [i.e., a cut-off of +0.30 log MAR (73)] were calculated for the 3 area-of-focus: distance area ( $\pm 0.50$  D), intermediate (between 50cm [-2.00 D] and 2 m [-0.50 D]), and near area (between 25 cm [-4.00 D] and 50 cm [-2.00 D]). A one-way repeated-measures ANOVA was used to determine if there was any statistically significant difference in the area-of-focus between the lenses. Pupil size data were analysed according to ocular dominance; ANOVA was used to compare BDVA and BNVA values of the dominant and non-dominant eyes respectively. A minimum of 27 participants were estimated to be required to demonstrate a statistical significant for repeated-measures ANOVA analysis between three types of lenses to detect  $0.1 \pm 0.1$  logMAR difference in VA at a significant level of 5% and power of 90% (Minitab 17 Statistical Software 2010). A total number of 35 participants were recruited, accounting for about 20% dropout rate (175).

### 3.3 Results

#### 3.3.1 Participant Demographic

A total of 35 participants were enrolled in the study and all the 35 participants completed testing all the three study lenses. The participants comprising of 26 females (74%) and 9 males (26%), of average age  $47.6 \pm 4.4$  (range 41 to 59 years). Spectacle refraction of the participants was  $-3.57 \pm 1.38$  DS with  $1.60 \pm 0.39$  D near addition. The mean subjective refraction BDVA was  $-0.08 \pm 0.05$  and BNVA was  $-0.02 \pm 0.08$ . The mean photopic pupil diameter in the dominant eye was  $3.56 \pm 0.68$  mm and  $3.50 \pm 0.75$  mm in the non-dominant eye ( $F = 0.15$ ,  $p = 0.703$ ). While the mean mesopic pupil diameter in the dominant eye was  $4.85 \pm 0.74$  mm and  $4.90 \pm 0.74$  mm in the non-dominant eye ( $F = 0.02$ ,  $p = 0.881$ ).

Four of the cohort (11%) were neophytes, 30 (86%) were previous single vision soft spherical contact lens wearers and one participant (3%) had previously worn presbyopic contact lenses;

however, none had previously worn the contact lenses trailed in the present study. The participants' habitual correction and other demographic data are shown in Table 8. The distribution of the participants' reading additions relative to their age is shown in Figure 27.

	Mean and SD
Sphere	-3.57 ± 1.38 (range -7.00 to -1.50)
Cylinder	-0.36 ± 0.29 (range -0.75 to Plano)
BDVA (logMAR)	-0.08 ± 0.05 (range -0.20 to 0.02)
Reading addition (D)	1.60 ± 0.39 (range 0.75 to 2.25)
BNVA (logMAR)	-0.02 ± 0.08 (range -0.20 to 0.10)
Photopic Pupil size: Ocular Dominant (mm)	3.56 ± 0.68 (range 2.38 to 4.96)
Photopic Pupil size: Ocular Non Dominant (mm)	3.50 ± 0.75 (range 2.22 to 5.03)
Mesopic Pupil size: Ocular Dominant (mm)	4.85 ± 0.74 (range 3.21 to 6.25)
Mesopic Pupil size: Ocular Non Dominant (mm)	4.88 ± 0.74 (range 3.08 to 6.07)
Habitual correction	
SVD	n = 11
PAL	n = 19
SCL (Distance ) + Reading SPX	n = 1
SCL (Monovision)	n = 3
SMCL (Monthly disposable)	n = 1

Table 8: Summary of the main participant characteristics.

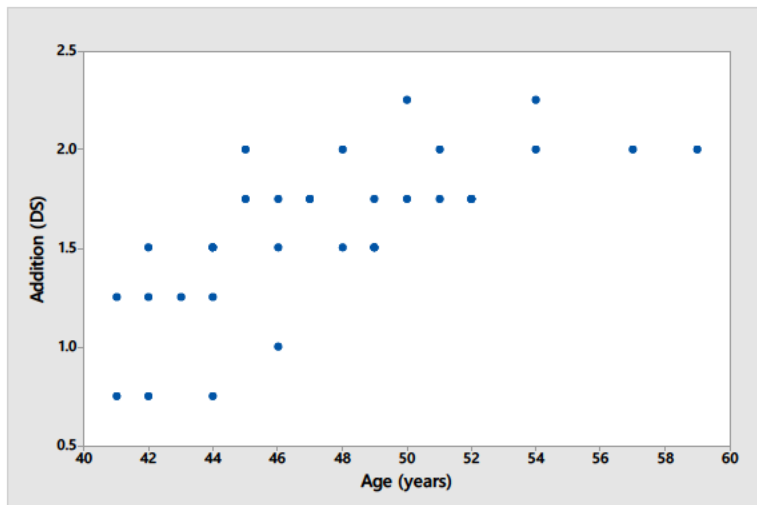


Figure 27: The distribution of the participants' reading additions relative to their age.

### 3.3.2 Visual Acuity

For Moist Multifocal, 4 participants (11%) were fitted with low add OU (add power range, +0.75 to +1.25 D), 28 participants (80%) were fitted with mid add OU (add power range, +1.50 to +1.75 D), 1 participant (3%) was fitted with high add OU (add power range, +2.00 to +2.50 D) and 2 participants (6%) were fitted with mixed add (mid add in one eye and high add on the other). For the Clariti Multifocal, 34 participants (97%) were fitted with low add OU (add power range, add  $\leq$  2.25 D) and 1 participant (3%) was fitted with mixed add (low add in one eye and high add on the other). For AquaComfort Plus Multifocal, 4 participants (11%) were fitted with low add OU (add power range, add  $\leq$  +1.25 D), 30 participants (86%) were fitted with mid add OU (add power range, +1.50 to +2.00 D) and 1 participant (3%) was fitted with high add OU (add power range, +2.25 to +2.50 D). There were no significant ocular findings and no participants were discontinued because of inadequate contact lens fitting, contact lens and ocular health complications. All VA outcomes comparing the three types of multifocal contact lens are summarised in Table 9. There were no statistically significant differences found in the level of binocular distance, intermediate and near VA achieved with the three different types of multifocal contact lens at 1-month follow up.

Mean (SD)	1-Day Acuvue Moist Multifocal	Clariti 1Day Multifocal	Dailies AquaComfort Plus Multifocal	p-value
BDVA LogMAR	-0.05 (0.07)	-0.06 (0.07)	-0.04 (0.06)	0.43
BIVA LogMAR	-0.10 (0.08)	-0.10 (0.09)	-0.09 (0.08)	0.72
BNVA LogMar	0.03 (0.10)	0.02 (0.09)	0.00 (0.07)	0.29

Table 9: A comparative analysis of the visual outcomes obtained with the three types of multifocal contact lens evaluated (mean ( $\pm$ SD) logMAR acuity) at 1-month follow up.

### 3.3.3 Pupil Size

There was no correlation found between pupil diameters of dominant eye with BDVA amongst the three types of multifocal contact lens (Figure 28). Similarly, no interaction between pupil diameters of non-dominant eye with BNVA amongst the three types of multifocal contact lens, though it was observed that participants wearing Clariti multifocal and AquaComfortPlus multifocal showed a trend of toward better near vision with smaller pupil size of non-dominant eye and correlation of ocular non-dominant with binocular near visual acuity at 1-month follow-up visit (Table 10).

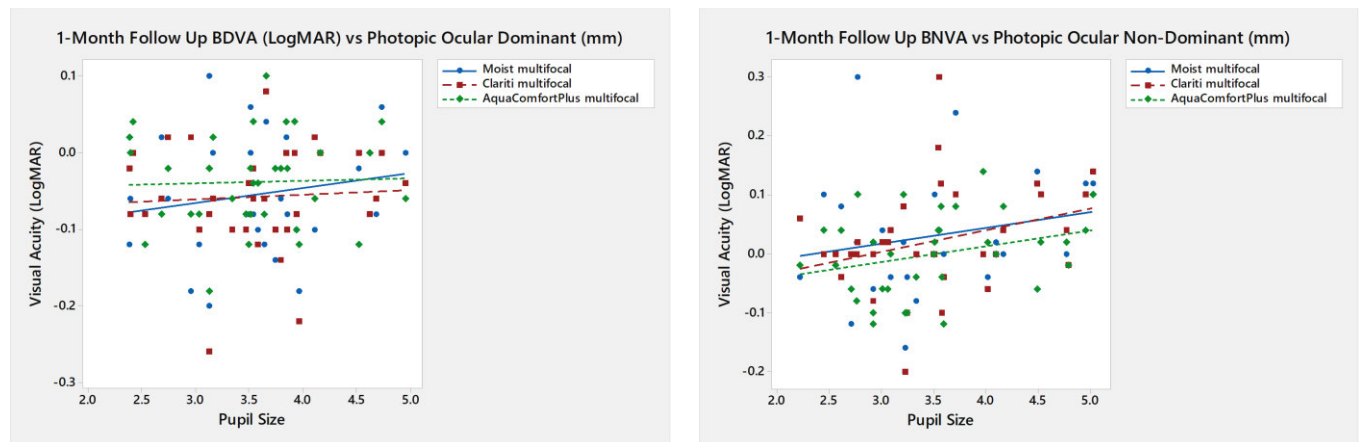


Figure 28: Correlation of ocular dominant with binocular distance visual acuity (left) and correlation of ocular non-dominant with binocular near visual acuity (right) at 1-month follow-up visit.



Ocular Dominant (PHOTOPIC)		Ocular Non-Dominant (PHOTOPIC)	
	Pearson correlation P-Value		Pearson correlation P-Value
BDVA_Moist Multifocal	0.186 0.284	BNVA_Moist Multifocal	0.208 0.229
BDVA_Clariti Multifocal	0.062 0.724	BNVA_Clariti Multifocal	0.305 0.075
BDVA_AquaComfortPlus Multifocal	0.035 0.845	BNVA_AquaComfortPlus Multifocal	0.292 0.089

Table 10: shows the Pearson correlation and p-value of ocular dominant with binocular distance visual acuity.

### 3.3.4 Defocus Curve

Under photopic condition, the results obtained with the absolute depth-of-focus analysis method revealed that all three types of multifocal contact lenses had similar distance, intermediate and near visual range of focus ( $p = 0.949$ ,  $p = 0.990$ ,  $p = 0.742$ ) (Table 11). Additionally, the results of the direct comparison method revealed no statistically significant differences between multifocal contact lenses in the binocular logMAR VA achieved, showing all the lens type worked similarly (Figure 29). Notably, the highest near-visual peaks were 0.04 logMAR at a defocus level of -2.00 D (50 cm) in AquaComfort Plus multifocal and 0.08 logMAR at a defocus level of -2.00 D (50 cm) in both Moist multifocal and Clariti multifocal.

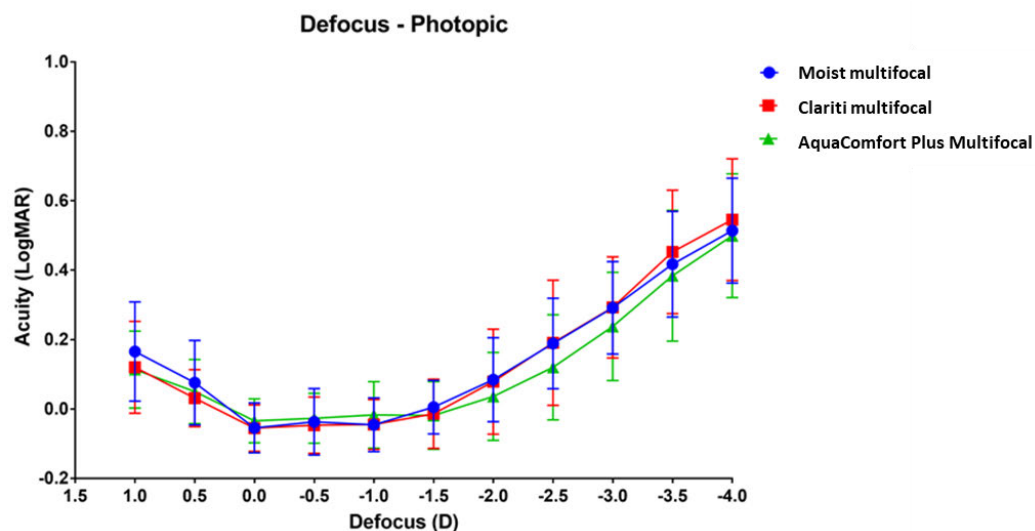


Figure 29: Defocus curve under photopic condition for Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal. Y-axis shows visual acuity and X-axis vergence. Error bars represent standard deviation of the means.

The mean defocus curves achieved with the acuity at different levels of defocus of the three different types of multifocal contact lens under mesopic condition is shown in Figure 30. Under mesopic condition, the results obtained with the absolute depth-of-focus analysis method revealed that all three types of multifocal contact lenses had similar distance and intermediate visual range of focus ( $p = 0.993$ ,  $p = 0.876$ ) (Table 11). The vision across the near visual range of focus for the three types of multifocal contact lenses in the current study was omitted as they had exceeded the absolute criterion with a limit of 0.3 logMAR (73). Additionally, the results of the direct comparison method showed an interaction between lens type and acuity at +1.00 D and +0.50 D level of defocus. At +1.00 D, Clariti multifocal and AquaComfortPlus multifocal outperformed 1-Day Moist multifocal ( $p = 0.01$ ). At +0.50 D, AquaComfort Plus Multifocal was found to outperformed 1-Day Acuvue Moist Multifocal ( $p = 0.03$ ). There was no statistically significant differences between lens types at any level of defocus at 0.00 D and -4.00 D.

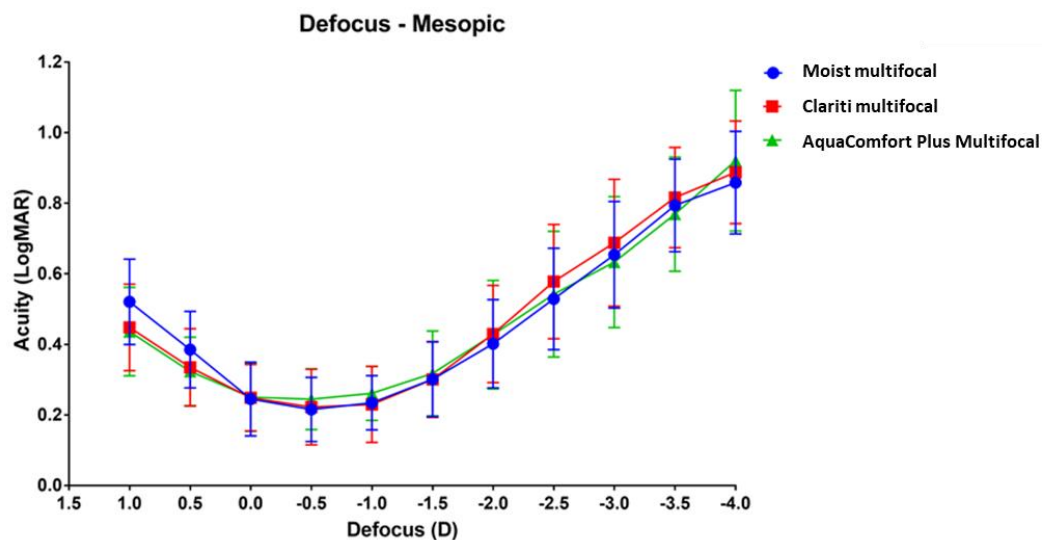


Figure 30: Defocus curve under mesopic condition for Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal. Y-axis shows visual acuity and X-axis vergence. Error bars represent standard deviation of the means.

Area of focus (LogMAR*m <sup>-1</sup> )	1-DayAcuvue Moist Multifocal	Clariti 1Day Multifocal	Dailies AquaComfort Plus Multifocal	p-value
<b>Photopic</b>				
Distance area	0.32 ± 0.05	0.33 ± 0.04	0.31 ± 0.04	P = 0.949
Intermediate area	0.46 ± 0.05	0.47 ± 0.06	0.47 ± 0.06	P = 0.990
Near area	0.22 ± 0.09	0.25 ± 0.11	0.26 ± 0.10	P = 0.742
<b>Mesopic</b>				
Distance area	0.05 ± 0.04	0.04 ± 0.04	0.04 ± 0.04	P = 0.993
Intermediate area	0.08 ± 0.05	0.09 ± 0.06	0.07 ± 0.06	P = 0.876
Near area	-	-	-	-

Table 11: Statistical comparisons for the distance, intermediate and near area of focus metrics (logMAR\*m-1) using absolute (at +0.30 logMAR) (73) depth-of-focus criteria at 1-month follow-up visit.

### 3.3.5 Reading Speed and Critical Print Size

Table 12 shows a comparative analysis of the reading speed and critical print size obtained with the three types of multifocal contact lens evaluated. Reading speed did not differ between lens types at 1-month follow up visit ( $F = 0.21$ ,  $p = 0.807$ ). Similarly, there were no interaction between critical print size and lens types at 1-month follow up visit ( $F = 0.09$ ,  $p = 0.916$ ).

Mean (SD)	1-Day Acuvue Moist Multifocal	Clariti 1Day Multifocal	Dailies AquaComfort Plus Multifocal	p-value
Maximum reading speed, black text, white background (words per min)	135.22 (29.03)	135.27 (27.26)	139.12 (29.30)	0.807 (ANOVA)
Critical print size, black text, white background (LogMAR)	0.20 (0.12)	0.20 (0.12)	0.19 (0.12)	0.916 (Kruskal-Wallis)

Table 12: Comparison of MRS, CPS with each presbyopic contact lenses (mean ± SD) evaluated at each visit and the statistical significance of the variance.

### 3.3.6 Glare

A comparative analysis of the photic phenomenon image score obtained with the three types of multifocal contact lens evaluated can be seen in Table 13. A Kruskal-Wallis H test was conducted to determine if photic phenomenon image score was different for the three different types of multifocal contact lenses. The test shows that there was no statistically significant difference in participants' vision in getting problems with light effect or glare at different times and in different places between the three types of multifocal contact lens ( $H = 0.15$  ,  $p = 0.92$ ).

Group	Mean (SD)
1-Day Acuvue Moist Multifocal	0.457 $\pm$ 0.780
Clariti 1Day Multifocal	0.400 $\pm$ 0.775
Dailies AquaComfort Plus Multifocal	0.429 $\pm$ 0.815

Table 13: Mean photic phenomenon image score for each type of multifocal contact lenses. Score of 1 denotes just visible glare phenomenon whilst score of 4 representing maximum glare.

### 3.3.7 Subjective Evaluation of Near Visual Ability

The descriptive data of the overall subjective satisfaction of near visual ability between the three types of multifocal contact lens is shown in Figure 31. There was not interaction found between the subjective satisfaction ratings of the satisfied group and the unsatisfied group for each of the presbyopic correction (Table 14) ( $p = 0.398$ ).

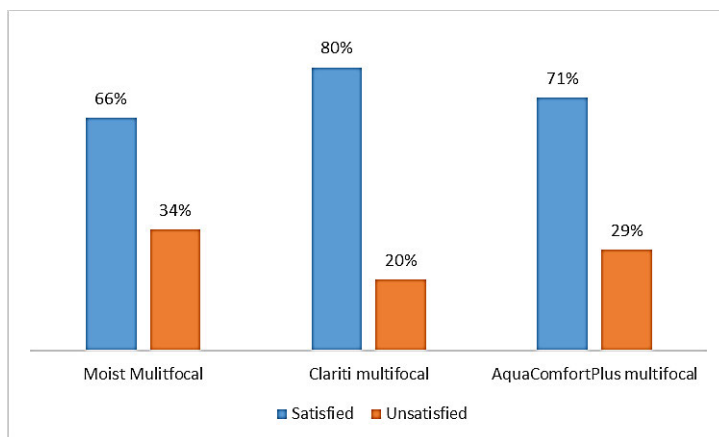


Figure 31: The overall subjective satisfaction ratings (descriptive data) of near visual ability between the three types of multifocal contact lens.

Group	N	Sum of Ranks
1-Day Acuvue Moist Multifocal	35	74.0
Clariti 1Day Multifocal	35	63.5
Dailies AquaComfort Plus Multifocal	35	72.5
<i>Chi-Square 1.84</i>		
<i>p-value 0.398</i>		

Table 14: Friedman's test analysis of overall satisfaction ratings of near visual ability between the three types of multifocal contact lens.

The NAVQ rating of near performance (Table 15) also did not differed between lens types ( $F = 0.31$ ,  $p = 0.731$ ), thus indicating no difference in the near visual related quality of life score amongst the three types of multifocal contact lens.

Type of multifocal contact lenses	Mean NAVQ Score (SD) (Logits)
1-Day Acuvue Moist Multifocal	31.84 (20.24)
Clariti 1Day Multifocal	30.07 (22.59)
Dailies AquaComfort Plus Multifocal	34.14 (21.78)
<i>NAVQ = Near Activity Visual Questionnaire</i>	

Table 15: Mean NAVQ score out of 100 for each type of multifocal contact lenses.

### 3.3.8 VF-11

A Kruskal-Wallis H test was conducted to determine if vision-specific functioning score was different for the three different types of multifocal contact lenses (Table 16). The test shows that there was no statistically significant difference in the level of difficulty in performing daily activities due to the participants' vision with the three different types of multifocal contact lenses ( $H = 0.64$ ,  $p = 0.726$ ).

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<u>Type of multifocal contact lenses</u>	<u>Mean VF-11 Score (SD) (Logits)</u>
1-Day Acuvue Moist Multifocal	-2.10 (0.85)
Clariti 1Day Multifocal	-2.18 (0.80)
Dailies AquaComfort Plus Multifocal	-2.27 (0.74)

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Table 16: Mean VF-11 score for each type of multifocal contact lenses.

### 3.4 Discussion

To the knowledge of the author, the current study is the first single-masked, randomized, crossover trial reports on the relative difference in visual performance after full time wear of three different daily-disposable multifocal contact lens designs in a group of myopic presbyopes.

Our results showed all three types of multifocal contact lens provide good results in terms of VA at distance, intermediate and near. There were no significant differences in the VA at distance, intermediate and near, despite the different in the power profiles of multifocal contact lenses used in this study (Figure 32). Kim et al. (115) have reported that Moist multifocal has a gradual changes in power between the near and distance zones, however, there is no distinct relative plus power to the distance prescription in the low addition lens for Moist multifocal.

AquaComfortPlus multifocal also has a gradual change in power between the near and distance zones and having similar amount of central relative plus powers in all the available addition powers. On the other hand, Clariti multifocal has a gradation zones with stepped power change profile, with a stepped powers in the intermediate zone starting from 1.2 to 2.4 mm semi-diameter (115). In general, for any of the multifocal contact lens type, visual compromises will increase with the lens addition power. (176, 177). In this study, our participants were mostly early to moderate presbyopic and they were fitted with low-add and mid-add lens design. With considerable amount of residual accommodation in the early to moderate presbyopia group, a lens with lower add power will be sufficient to provide good reading performance without sacrificing distance and intermediate vision (115). This may explain the comparable good results in terms of VA obtained with all three types of multifocal lenses. Similar to our results, Vasudevan and colleagues (167) reported that there was no significant difference in high contrast near visual acuity in a group of early presbyopic participants fitted with low-add multifocal lens designs. This could be attributed to the fact that multifocal contact lenses have

optical designs that enable them to provide an increased depth of focus in presbyopic patients (167), which might result in a decreased in accommodative stimulus and lowering accommodative response, in turn helping early to moderate presbyopic patients with insufficient amplitude of accommodation to perform near task. Additionally, good visual acuity and visual quality have been found achievable with low add powers under photopic visual conditions, such as under the standard clinical testing environment in this study (178). Further, our study lenses necessitated the evaluation of binocular acuity, and this may have contributed to good visual acuities obtained (179), as the perceptual process of image enhancement termed binocular summation has been shown to be able to compensate the degradation of the retinal imaged (180, 181) attributed by loss of contrast in simultaneous multifocal lenses (182).

Regarding pupil size, there were no significant differences between pupil diameters of dominant eye with BDVA and pupil diameters of non-dominant eye with BNVA amongst the three different multifocal contact lens designs studied. Studies (183, 184) have showed that laterality of ocular dominance and laterality of distance/near correction had no effect on binocular visual acuity. Also, Sivardeen et al. (75) has shown no correlation between pupil parameters, ocular dominance and total optical aberrations when multifocal contact lenses were in situ. The authors explained that despite the differences in multifocal contact lens designs, any overall differences in visual performance might be masked by the inherent aberrations of human eye and the restriction of the pupil annulus.



Figure 32: Absolute refractive power profiles of the three different models of daily-disposable multifocal contact lens used in the study. Left, Moist multifocal. Centre, Clariti multifocal. Right, AquaComfortPlus multifocal. Image source: Kim et al. (115)

In this study, the area-of-focus metric, which provides the overview of the visual range separately for distance, intermediate and near, was evaluated using absolute depth-of-focus analysis method (73). There was no significant difference in the visual range of focus for the three types of multifocal contact lens. However, for the direct comparison of the VA at every level of defocus under photopic condition, an optimum VA result of  $-0.06 \pm 0.07$  logMAR was obtained at 0.00 D defocus (equivalent to distance-vision viewing) for Clariti multifocal. No distinct peak in the distance vision was present for either Moist multifocal or AquaComfortPlus multifocal, although the range of clear vision (0.08 logMAR or better) extended from +0.50 D to -0.50 D defocus, with no sharp drop of acuity in the distance zone. Similar results of optimum distance vision were observed in a previous study of PureVision Multifocal and Acuvue Oasys for Presbyopia (74). However, unlike to our findings, these two centre-near multifocal contact lenses exhibited distinct distance vision peaks. This might be partly due to difference in the studied lens designs (74). PureVision Multifocal has bi-aspheric design, leading to different rates of power change for the central and peripheral portions, with notable abrupt discontinuity in the profile in the PureVision Multifocal higher add (185), and for Acuvue Oasys for Presbyopia, there is a distinct profile pattern with alternating distance and near zones. Nonetheless, similar to other studies (75, 86), our results showed no evidence of second peak at -2.50 D (equivalent to near viewing at 40 cm), commonly observed in multifocal intraocular lens designs (73, 104). This disparity may have contributed by the difference in the refractive design of multifocal intraocular lens, the relative position of multifocal intraocular lens from the ocular nodal point compared to the contact lenses or the relatively high addition of multifocal intraocular lens (73, 75).

In the current study, the mean intermediate VA at defocus level -1.00 D (equivalent to 100 cm from the eye) under photopic condition was about -0.02 LogMAR and better in the three types of multifocal contact lens. This is in agreement with study by Gupta and colleagues (86), where they have showed simultaneous multifocal contact lenses provide better intermediate vision compared to monovision. However, under mesopic condition, this study found an interaction between lens types and acuities only at the level of defocus for subjective range of clear vision at distance. This indicate the lens types work differently from one another for distance under mesopic condition, with AquaComfortPlus multifocal outperformed Clariti multifocal and Moist multifocal. This might be explained by the relative refractive power profiles analysis, which AquaComfortPlus multifocal showed the most negative spherical aberration as compared to Moist multifocal and Clariti multifocal. Perhaps, this increased in negative spherical aberration



for minus powers contributed to the visual performance enhancement in study participants with myopia (115).

In this study, CPS was found to be similar between the three types of multifocal contact lens under investigation, suggesting reading acuity threshold and comfortable reading letter size achieved amongst these lenses were similar. MRS was also found to be insignificant between the three types of multifocal contact lenses. This is perhaps expected, as by definition, CPS is determined by the smallest letter size that can be read by patient at the maximum speed. These results do agree with findings of other studies comparing presbyopic contact lens corrections (75, 85). Notably, an assessment of reading performance is not solely an assessment of visual resolution but it is also a highly complex task and involves nonvisual process such as visual sensory, higher cognition of comprehension and endurance (85).

Earlier studies have identified glare as a main issue for presbyopes when driving at night (99). Indeed, Chu and colleagues (186) reported that multifocal contact lens wearers were the least satisfied with their vision at night time and more likely to be troubled by glare when driving at night. However, in this study, getting problems with glare or light effect at different times and in different places did not differ between all the types of multifocal contact lens under investigation. This might be explained by the design of power gradient of these lenses, which gradually change from centre to the edge of optical zone, thus providing smooth transition between distance and near refractive correction. Distinctly, even the high add power profiles of Moist multifocal and AquaComfortPlus multifocal show hardly any distinct transitions point between the near and distance powers within the optical zone (115). Although there was plateaus between step-cased reductions of power in Clariti multifocal lenses across the optic diameter (115), these steps did not seem to cause glare symptoms, indicating such plateaus were probably too narrow to have an impact on visual performance. Nevertheless, studies of multifocal lens design consists of abrupt concentric aspheric distance and near zones has been shown to create the largest halo around a light source, thus potential susceptible to glare symptoms compared to lens design with smooth transition between distance and near refractive correction (75). Such understanding may influence practitioner's lens choice, in particular for patients who complained of glare or dysphotopsia under low illumination environment or during night time with their currently worn lens design.

Despite the differences in power profile designs between the three types of multifocal contact lenses under investigation, there was no significant difference in the subjective perception of near vision ability (NAVQ) or satisfaction of near vision ability or the level of difficulty in performing daily activities (VF-11). This may reflect the lack of significant difference in near acuity and the subjective range of clear vision for near, which indicate that there was no considerable difference in general visual function at near. Also, considering each type of multifocal contact lens has its own advantages and disadvantages, coupled with wide range of participants' visual needs and expectations, but when considered collectively, this may balance out for each type of lens leading to a similar average perception (86).

Studies have shown that the preference of multifocal contact lens has been largely rated on the quality of near reading vision as opposed to the quality of distance vision (149). In addition, positive correlation between overall visual satisfaction and near VA has been demonstrated (187). Indeed, the priority of this study was to determine the performance of each lens types at near under standard clinical setting. Along with this, high contrast visual acuity at distance and intermediate, the amount of glare experienced and the level of difficulty in performing daily activities were also quantified to assess the impact each lens type had at distance in myopic presbyopes. On that account, the results are reflecting only a subset of the range of parameters available in these lens types. Future comparative visual performance studies of these presbyopic lens types should include emmetropic and hyperopic patients and with a full range of lens powers. However, the very recent report on Moist multifocal and AquaComfort Plus multifocal by Sha and colleagues (123) shows no significant differences in binocular high contrast VA at varying distances (6, 2, and 1 m and 70, 50, and 40 cm), despite 24% and 21% of study participants was non-myopic and had an addition of +2.00 D or greater respectively. Hence, for future studies, it will be important to analyse the visual performances of these presbyopic lens types stratified by low, medium or high presbyopes and power range (such as plus and minus), as the power profile consistency has been found to be variable across the power range for each lens type (115).

Other limitations include the lack of comparisons to a spectacle correction measure of vision for the same participants. This study also do not have monocular acuity measures and hence no measures of acuity differences between the eyes. Any differences in acuity between the eyes could be expected to have different impact on measures of vision and visual function for the different contact lens types. However, in this study, all lenses were fitted following

manufacturers' fitting guide aims to maintain binocularity as much as possible to avoid a monovision or modified-monovision scenario. Additionally, to further discriminate lens design and to correlate design features with visual performance, next stage studies should also include assessments of quality of distance, intermediate and near vision such as ghosting and their visual experience such as visual fluctuation.

### 3.5 Conclusion

The results of this study suggest that the three types of simultaneous vision aspherical centre-near daily-disposable multifocal contact lens provide comparable visual performance and range of clear vision in myopic patients with presbyopia, but a better distance acuity at distance under mesopic condition for AquaComfortPlus. Under photopic condition, these multifocal contact lenses preserve good VA for distance, intermediate and near and practitioners should consider trying one of these multifocal contact lenses for those presbyopic patients wishing to achieve spectacle-free vision correction.

#### 4. The utility of clinical tests to predict success with multifocal contact lenses.

##### 4.1 Introduction

Progressing aging of the world population has contributed to a growing presbyopic contact lens market (138). The industry and contact lens practitioners continue to encounter challenges when it comes to providing satisfactory procedures to correct presbyopia and to optimise the visual performance over the full near-to-distance range under all possible illumination conditions. Recent widespread of daily-disposable lenses may have helped to make soft contact lenses more attractive (118) and offered presbyopes a versatile vision correction option, yet the majority of the presbyopic contact lens patients are still being fitted with non presbyopic corrections (44). Studies (44,140) have reported that psychological factors such as lack of technical fitting skills, practitioners' confidence in presbyopic lens performance and fear of failing to obtain a satisfactory result in a shortest possible time could be the primary barriers in fitting presbyopic lens. Furthermore, the evidence for routine clinical tests performed such as visual acuity to determine success when fitting multifocal contact lenses remains less robust compared to spherical or toric contact lens designs (61, 106, 188). Hence, this poses great challenges to practitioner who usually relies on initial optometric consulting room test results to determine the likelihood of success or failure with the lens. Therefore, the utility of other predictors, clinical or non-clinical, would be valuable to help the practitioner in the initial selection of an optimum presbyopic lens and thus increased practitioner confidence, reduce chair time and contact lens wearers' dropout rate.

Most manufacturers of presbyopic contact lenses have advocated the use of their recommended fitting guide or fitting tips as the initial process for presbyopic lens fit, promising higher performance and acceptance success. However, these fitting guides mostly include contact lens fit data such as patient's spectacle prescription, near addition power or ocular dominance. Additional data such as pupil size is usually not required. In fact, most lens designs are labelled as pupil independent, but most of the current multifocal contact lenses are based on concentric distance and near zones, requiring a minimum pupil diameter to work (185, 189). Additionally, the varying power of simultaneous-image lens design when placed over the pupil may alter aberrations and affect visual performance (115, 190). Hence, the routine contact lens fit data including pupil size may influence the preference and performance of multifocal contact lenses.

Subjective responses to a range of visual experiences such as vision satisfaction, clarity, glare, ghosting, satisfaction with vision for driving at night and overall satisfaction with lenses have been used in the attempt to determine whether these data could serve as useful indicators of longer-term behaviour and performance of presbyopic contact lens wear. Indeed, good repeatability for assessment of subject responses in primary care setting has been reported when used to assess visual quality (191). In a previous study by Papas et al. (61) with four types of multifocal soft contact lens, it was observed that after an adaptation of 4 days of lens wear, participants expressed a significant degree of overall dissatisfaction with the contact lenses, despite the visual acuity did not change during the adaptation period. Similarly, Deic et al. (188) reported a significant declined in overall subjective vision satisfaction in the performance of multifocal contact lenses in a group of presbyopes, though majority of acuity-based measurements remained constant between fitting and follow-up visits. Likewise, despite monovision has been found to provide better performance in the consulting room in terms of both the high-and low-contrast near vision tests, multifocal presbyopic correction was indicated as the preferred choice amongst patients for 'real-world' tasks such as watching television, driving at night and changing focus (106). These results suggest that subjective responses perhaps are more useful indicators of the success of presbyopic contact lens options, as compared to the initial consulting room acuity testing.

The present study compared the objective and subjective (patient-reported) outcomes for a group of presbyopic participants following 1-month wear of three commercially available daily-disposable multifocal soft contact lenses in Singapore. The main aim of this study was to determine if lens preference was influenced by the visual performance metrics, based on inter-subject (individual with a particular design compared to other participants) and intra-subject (individual with similar lens type compared to other lens design). In addition, it was aimed to determine whether the initial acuity based measurements at fitting could predict the performance of these contact lenses in myopic presbyopes after 1 month of lens wear.

#### 4.2 Method

This is a single-masked randomised crossover dispending trial consisting of three 1-month phases, one for each of the daily-disposable multifocal soft contact lens brands.

#### 4.2.1. Participants

As described in section 3.2.1, 35 presbyopic participants (74% females) were recruited in this study based on the inclusion and exclusion criteria outlined.

#### 4.2.2. Contact Lenses

As described in section 3.2.2, after a full eye examination, participants were randomly assigned and fitted with either 1-day Acuvue® Moist Brand Multifocal Contact Lenses for Presbyopia (Johnson & Johnson Vision Care, Jacksonville, FL), Clariti 1-day Multifocal (Cooper Vision, NY) or Dailies AquaComfort Plus Multifocal (Alcon, Fort worth, TX) contact lenses. Lenses were fitted according to each manufacturer's fitting guide (Appendix A2, A3, A4).

#### 4.2.3. Assessment of visual function

Contact lenses were power matched to the participant's prescription. After lens insertion, a setting time of 15 minutes was allowed before a standard lens fit assessment of centration, coverage, movement to confirm participant had a comfortable wear, followed by determining the final powers for the most optimized visual outcomes. Ocular dominance (sensory) was determined using the fogging techniques, where the dominant eye was the one in which the participant reported the greatest uncomfortable blurred visual perception with a +1.50D lens under binocular conditions (172, 173).

Participants were informed to wear the lenses for at least three hours before turning up on the day of their follow-up visits. After 4 weeks of contact lens wear, each participant returned for an assessment of visual function, which are described in section 3.2.4. Participants were also asked to report the average number of days lenses were worn for each week and the average number of hour of daily wearing time. Additionally, after the completion of the study and trialling the three types of contact lens, participants were asked to choose their preferred lens type (i.e. "no preference" was not an option). The study protocol followed the tenets of the Declaration of Helsinki, informed consent was obtained from all participants after explanation of the nature and possible consequences of the study, and the participants were free to withdraw at any time without prejudice in any way.

#### 4.2.4 Data analysis

Binocular data were included in the analysis of all parameters except pupil size data were grouped as ocular dominant or non-dominant. Mean  $\pm$  standard deviation are reported in the text and tables. The cohort was divided according to overall lens preference. Comparisons between contact lens preference to other lens types trialed (intra-subject) and to participants who preferred other lens types (inter-subject) to determine whether lens preference was influenced by visual performance.

The analysis of this current study is similar to previous study comparing the relationship between lens preference and visual performance (78). The decision concerning the degree of freedom was subsequently based on the advice and research results by Armstrong et al. (192), indicating that the likelihood of having a more precision in the estimation of a particular effect (of a factor and interaction) if the error term is at least 15 degree of freedom. Hence, the repeated measures design of the current study were calculated to have achieve sufficient degree of freedom to be powered for the analysis of all metrics in 35 participants recruited, even when split by fewer participants preferring some of the lens type. Data analyses were conducted using Minitab (Minitab 17 Statistical Software (2010). State College, PA, USA: Minitab, Inc. [www.minitab.com](http://www.minitab.com)). CPS, glare score and VF-11 score were not normally distributed (Kolmogorov-Smirnov test,  $p < 0.05$ ); therefore, nonparametric rank analysis of variance (Independent samples Kruskal-Wallis distribution comparison test) were conducted. High contrast BDVA, BIVA and BNVA, reading speed, photopic and mesopic defocus curve acuities, NAVQ scores and pupil parameters were found to be normally distributed (Kolmogorov-Smirnov test,  $p > 0.05$ ), therefore, parametric repeated-measures ANOVA was conducted. For defocus curve, in addition to the direct comparison method of analysis involves statistical comparison of the visual acuity at each defocus level, the depth-of-focus method of analysis describes the dioptric range over which participants can sustain an absolute level of VA [i.e. a cut-off of +0.30 log MAR (73)] were calculated for the 3 area-of-focus: distance area ( $\pm 0.50$  D), intermediate (between 50cm [-2.00 D] and 2 m [-0.50 D]), and near area (between 25 cm [-4.00 D] and 50 cm [-2.00 D]). A one-way repeated-measures ANOVA was used to determine if there was any statistically significant difference in the area-of-focus between contact lens preferences.

### 4.3 Results

A total of 35 participants were enrolled, trialled and completed the study with reported achieving an average of about 8 hours wearing time each wearing day (Table 17). There were no contact lens related adverse events seen during the study period.

Frequency of wear	Moist multifocal	Clariti multifocal	Dailies AquaComfort Plus Multifocal	p
Days per week	4.7 ± 1.0	4.8 ± 1.1	4.9 ± 1.2	0.845
Hours per day	8.6 ± 3.2	8.3 ± 3.0	8.2 ± 3.5	0.821

Table 17: Frequency of wear reported by participants for the three types of multifocal contact lens.

#### 4.3.1 Dispensing compared with assessment visits

Table 18 shows comparisons between individual type of multifocal contact lens at dispensing visit and 1-month follow up, BIVA and BNVA were one letter worse 1-month follow up with Moist Multifocal and Clariti Multifocal respectively, but these differences were not statistically significant. For any other variables, the differences in acuity between contact lens types comparing between dispensing visit and 1-month follow up were less than one letter and no significant differences were observed.

	Dispensing Visit	1-Month Visit	p-value
BDVA LogMAR			
1-Day Acuvue Moist Multifocal	-0.06 (0.06)	-0.05 (0.07)	0.82
Clariti 1Day Multifocal	-0.07 (0.07)	-0.06 (0.07)	0.40
Dailies AquaComfort Plus Multifocal	-0.05 (0.06)	-0.04 (0.06)	0.22
BIVA LogMAR			
1-Day Acuvue Moist Multifocal	-0.12 (0.07)	-0.10 (0.08)	0.20
Clariti 1Day Multifocal	-0.11 (0.10)	-0.10 (0.09)	0.88
Dailies AquaComfort Plus Multifocal	-0.01 (0.08)	0.00 (0.07)	0.11
BNVA LogMAR			
1-Day Acuvue Moist Multifocal	0.02 (0.06)	0.03 (0.10)	0.38
Clariti 1Day Multifocal	0.00 (0.09)	0.02 (0.09)	0.68
Dailies AquaComfort Plus Multifocal	-0.01 (0.08)	0.00 (0.07)	0.74

Table 18: Comparisons between individual type of multifocal contact lens at dispensing visit and 1-month follow up (mean (±SD) logMAR acuity).



Table 19 shows comparisons between individual type of multifocal contact lens at dispensing visit and 1-month follow up for reading metrics. Similarly, there was no statistically significant change in maximum reading speed and CPS over the 1-month period for all three types of multifocal contact lens, although a trend to better level of reading acuity (two letters better) 1-month follow up with Clariti multifocal.

	Dispensing Visit	1-Month Visit	p-value
Maximum reading speed, black text, white background (words per min)			
1-Day Acuvue Moist Multifocal	135.91 (26.90)	135.22 (29.03)	0.76 (ANOVA)
Clariti 1Day Multifocal	137.72 (26.26)	135.27 (27.26)	0.38 (ANOVA)
Dailies AquaComfort Plus Multifocal	138.48 (27.23)	139.12 (29.30)	0.83 (ANOVA)
Critical print size, black text, white background (LogMAR)			
1-Day Acuvue Moist Multifocal	0.20 (0.11)	0.20 (0.12)	0.874 (Kruskal-Wallis)
Clariti 1Day Multifocal	0.25 (0.11)	0.20 (0.12)	0.056 (Kruskal-Wallis)
Dailies AquaComfort Plus Multifocal	0.23 (0.10)	0.19 (0.12)	0.100 (Kruskal-Wallis)

Table 19: Comparison of MRS, CPS with between individual type of multifocal contact lens at dispensing visit and 1-month follow up (mean  $\pm$ SD).

#### 4.3.2 Prediction of preference based on baseline data

At the end of study, nine participants (26%) preferred Moist multifocal, 16 participants (46%) preferred Clariti multifocal and 10 participants (28%) preferred AquaComfortPlus multifocal.

##### 4.3.2.1 Demographic

There were no difference in contact lens preference based on age ( $p = 0.238$ ), gender ( $p = 0.678$ ), refractive error ( $p = 0.151$ ) and the magnitude of reading addition ( $p = 0.138$ ) (Table 20).

Factor	Moist multifocal n = 9	Clariti multifocal n = 16	AquaComfortPlus multifocal n = 10	p
Age (years)	46.0 ± 4.4	49.0 ± 5.0	46.9 ± 3.3	0.238 (ANOVA)
Female: male (%)	67:33	81:19	70:30	0.678 (Chi-sq)
Refraction: spherical equivalent (dioptries)	-3.14 ± 0.33	-4.19 ± 0.34	-3.59 ± 0.49	0.151 (Kruskal-Wallis)
Reading addition (dioptries)	1.39 ± 0.20	1.73 ± 0.053	1.55 ± 0.10	0.138 (Kruskal-Wallis)

Table 20: Demographic factors of participants preferring Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal.

#### 4.3.2.2 Pupil size

Multifocal contact lens preference was not dependent on pupil size (Moist multifocal;  $3.43 \pm 0.39$  mm, Clariti multifocal;  $3.71 \pm 0.78$  mm, AquaComfortPlus multifocal;  $3.32 \pm 0.75$  mm,  $F=1.05$ ,  $p=0.360$ ) or ocular dominance ( $F=1.08$ ,  $p=0.379$ ) (Table 21). There was also no significant difference in the pupil size of the dominant eye compared to the non-dominant eye ( $F=0.15$ ,  $p=0.703$ ).

#### 4.3.3 Subjective and objective variables and contact lens preference, based on inter-subject (individual with a particular design compared to other participants) and intra-subject (individual with similar lens type compared to other lens design).

##### 4.3.3.1 Visual Acuity

The objective vision results of both between participants (inter- subject; participants who preferred one lens type compared to the remaining participants who did not prefer the lens) and within participants (intra-subject; participants who preferred one lens type compared to their results attained wearing the other lens types) are presented in Table 21. Visual acuity after 4 weeks of wear was not related to intra-subject and inter-subject contact lens preference, although there were trends where participants who preferred AquaComfortPlus multifocal achieved better BNVA compared to the remaining cohort attained wearing AquaComfortPlus multifocal.

#### 4.3.3.2 Pupil size

Pupil size in the dominant and non-dominant were not statistically different in participants preferring one type compared to the participants who did not prefer the lens (inter-subject-Table 21).

	VA (logMAR)			Pupil size (mm)	
	BDVA	BIVA	BNVA	Dominant	Non-dominant
<b>Moist multifocal</b>					
Preferred n = 9	-0.06 ± 0.09	-0.12 ± 0.07	0.01 ± 0.14	3.63 ± 0.28	3.38 ± 0.42
Non-preferred n = 26	-0.04 ± 0.04	-0.09 ± 0.09	0.04 ± 0.08	3.54 ± 0.78	3.54 ± 0.84
Significance of inter-subject differences	0.682	0.326	0.563	0.590	0.488
Significance of intra-subject differences	0.930	0.404	0.856	-	-
<b>Clariti multifocal</b>					
Preferred n = 16	-0.04 ± 0.04	-0.08 ± 0.07	0.03 ± 0.06	3.71 ± 0.79	3.71 ± 0.83
Non-preferred n = 19	-0.07 ± 0.08	-0.12 ± 0.11	0.01 ± 0.11	3.44 ± 0.57	3.32 ± 0.65
Significance of inter-subject differences	0.094	0.249	0.506	0.275	0.135
Significance of intra-subject differences	0.789	0.896	0.874	-	-
<b>AquaComfortPlus multifocal</b>					
Preferred n = 10	-0.05 ± 0.05	-0.11 ± 0.08	-0.03 ± 0.06	3.27 ± 0.71	3.26 ± 0.82
Non-preferred n = 25	-0.03 ± 0.07	-0.08 ± 0.08	0.01 ± 0.07	3.68 ± 0.65	3.59 ± 0.72
Significance of inter-subject differences	0.310	0.292	0.066	0.134	0.278
Significance of intra-subject differences	0.748	1.000	0.065	-	-

Table 21: Mean ± standard deviation BDVA, BIVA, BNVA and pupil size in the dominant and non-dominant eye of participant preferring Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal.

#### 4.3.3.3 Reading metrics

No significant inter-subject difference in MRS was observed between participants who preferred Moist multifocal (145.3 ± 40.2 wpm versus 131.7 ± 24.1 wpm,  $p = 0.360$ ) or Clariti multifocal (130.3 ± 23.9 wpm versus 139.5 ± 29.8 wpm,  $p = 0.319$ ) or AquaComfortPlus multifocal (137.1 ± 29.8 wpm versus 139.9 ± 29.7 wpm,  $p = 0.799$ ), when compared to the rest of the cohort who did not preferred each particular lens type. Similarly, CPS was not statistically different in participants who preferred Clariti multifocal (0.21 ± 0.1 logMAR versus 0.18 ± 0.13 logMAR,  $p = 0.643$ ), AquaComfortPlus multifocal (0.16 ± 0.11 logMAR versus 0.2 ± 0.12 logMAR,  $p = 0.401$ ) and Moist multifocal (0.14 ± 0.17 logMAR versus 0.22 ± 0.10 logMAR,  $p = 0.070$ ) when compared to the remaining cohort who did not prefer each particular lens type (inter-subject).

Regarding the intra-subject differences, the MRS and CPS of participants who preferred Moist multifocal (MRS  $p = 0.970$ ; CPS  $P = 0.440$ ), or Clariti multifocal (MRS  $p = 0.786$ ; CPS  $P =$

0.630) or AquaComfortPlus multifocal (MRS  $p = 0.890$ ; CPS  $P = 0.159$ ) was not significantly different to the results attained wearing the other types of contact lens types.

#### 4.3.3.4 Defocus curve

In this study, the area-of-focus metric, which provides the overview of the visual range separately for distance, intermediate and near, was evaluated using absolute depth-of-focus analysis method (73). Table 22 shows the results of the distance area, intermediate area and near area under photopic and mesopic conditions.

Under photopic condition, no significant difference in the visual range of focus between participants who preferred Moist multifocal compared to those who preferred other lens types for the distance area, intermediate area and near area ( $p = 0.884$ ,  $p = 0.621$ ,  $p = 0.890$ ; inter-subject) and there was no interaction in the direct comparison of the VA at every level of defocus. Similarly, there was no significant difference in the visual range of focus between participants who preferred Clariti multifocal and those who preferred other lens types for the distance area, intermediate area and near area ( $p = 0.286$ ,  $p = 0.555$ ,  $p = 0.598$ ; inter-subject) and no interaction found in the direct comparison of the visual acuity at each defocus level. For participants who preferred AquaComfortPlus multifocal, there was also no significant difference in the distance area, intermediate area and near area compared to those who preferred other lens types ( $p = 0.827$ ,  $p = 0.419$ ,  $p = 0.657$ ; inter-subject). However, the direct comparison of the visual acuity at each defocus level revealed that those preferred Clariti multifocal had a significant worse visual acuity compared to those who preferred other lens types at level of defocus of  $+0.50$  D,  $-0.50$  D and  $-1.00$  D, whilst the differences were found to be within 1 line of letter and thus were not considered clinically relevant.

Under mesopic condition, the absolute depth-of-focus analysis method revealed no significant difference in the visual range profile between participants who preferred Moist multifocal compared to those who preferred other lens types for the distance area and intermediate area ( $p = 0.673$ ,  $p = 0.585$ ; inter-subject). There was no significant difference in the distance and intermediate area between participants who preferred Clariti multifocal ( $p = 0.635$ ,  $p = 0.616$ ; inter-subject) and AquaComfortPlus multifocal ( $p = 0.557$ ,  $p = 0.367$ ; inter-subject) compared to the remaining cohort who did not prefer each particular lens type. The vision across the near

visual range of focus for the three types of multifocal contact lenses in the current study was omitted as they had exceeded the absolute criterion with a limit of 0.3 logMAR visual acuity (refer to section 1.3.1.1). As for the direct comparison of the VA at every level of defocus, there was a significant better visual acuity for those preferred Moist multifocal compared to those who preferred other lens types at the level of -0.50 D defocus. However, the difference was within one line of letter and was not considered clinically relevant. Conversely, at the level of -0.50 D defocus, there was a significant worse visual acuity for those preferred Clariti multifocal compared to those who preferred other lens types. However, the difference was also within one line of letter and was not considered clinically significant. Additionally, at the level of -1.50D defocus, there was a significant better visual acuity for those preferred AquaComfortPlus multifocal compared to those who preferred other lens types and the difference was one line of letter and was considered clinically relevant.

	Photopic			Mesopic		
	Distance area	Intermediate area	Near area	Distance area	Intermediate area	Near area
<b>Moist multifocal</b>						
Preferred n = 9	0.42 ± 0.06	0.50 ± 0.06	0.12 ± 0.06	0.06 0.03	0.08 0.05	-
Non-preferred n = 26	0.40 ± 0.07	0.45 ± 0.05	0.11 ± 0.06	0.03 0.04	0.05 0.03	-
Significance of inter-subject differences	0.884	0.621	0.890	0.673	0.585	-
<b>Clariti multifocal</b>						
Preferred n = 16	0.40 ± 0.05	0.44 ± 0.05	0.14 ± 0.06	0.03 ± 0.04	0.03 ± 0.05	-
Non-preferred n = 19	0.48 ± 0.06	0.50 ± 0.07	0.09 ± 0.09	0.05 ± 0.04	0.06 ± 0.04	-
Significance of inter-subject differences	0.286	0.555	0.598	0.635	0.616	-
<b>AquaComfortPlus multifocal</b>						
Preferred n = 10	0.44 0.04	0.53 0.05	0.22 0.08	0.06 0.04	0.07 0.04	-
Non-preferred n = 25	0.41 0.06	0.44 0.06	0.16 0.07	0.03 0.04	0.02 0.03	-
Significance of inter-subject differences	0.827	0.419	0.657	0.557	0.367	-

Table 22: Mean ± standard deviation of distance, intermediate and near area-of focus metrics (logMAR\*m<sup>-1</sup>) using absolute (at +0.30 logMAR) depth-of-focus criteria of participant preferring Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal.

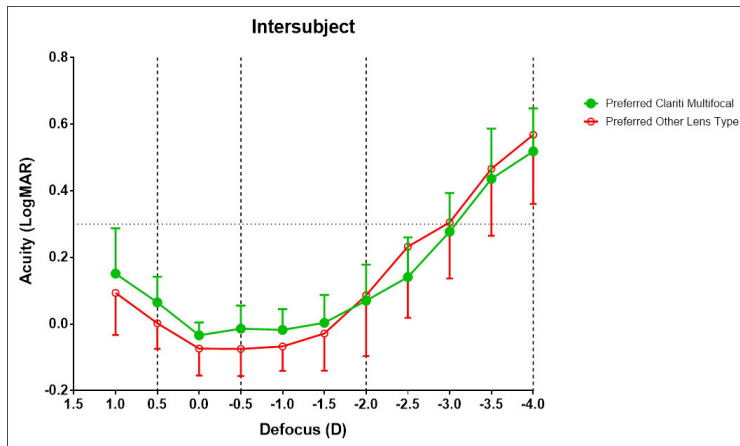


Figure 33: Mean binocular defocus curve profile measured of participants who preferred Clarity multifocal (n=16) compared to the participants who did not prefer Clarity multifocal (n=19) under photopic condition.

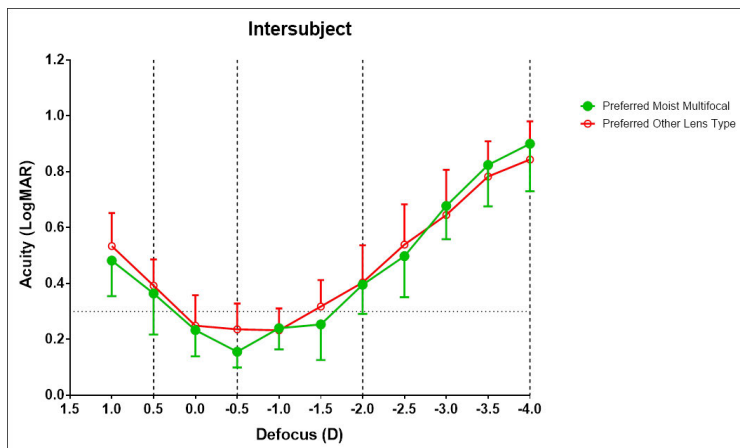


Figure 34: Mean binocular defocus curve profile measured of participants who preferred Moist multifocal (n=9) compared to the participants who did not prefer Moist multifocal (n=26) under mesopic condition.

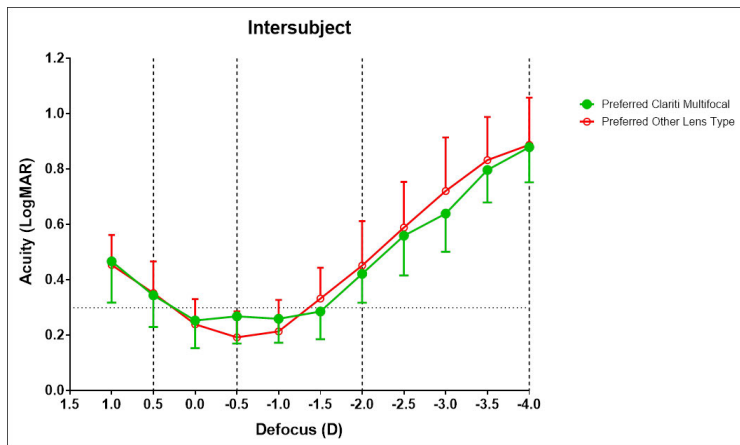


Figure 35: Mean binocular defocus curve profile measured of participants who preferred Clarity multifocal (n=16) compared to the participants who did not prefer Clarity multifocal (n=19) under mesopic condition.

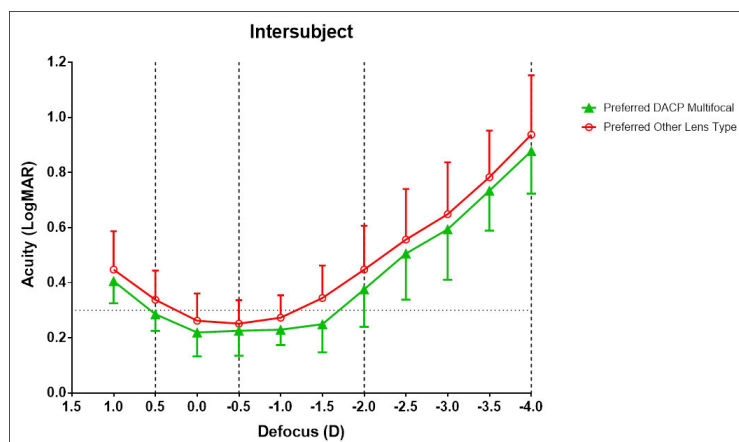


Figure 36: Mean binocular defocus curve profile measured of participants who preferred AquaComfortPlus multifocal (n=10) compared to the participants who did not prefer AquaComfortPlus multifocal (n=25) under mesopic condition.

#### 4.3.3.5 NAVQ

There was no difference in NAVQ rating ( $24.8 \pm 17.8$  versus  $34.3 \pm 20.8$ ,  $p = 0.204$ ) of near performance between participants who preferred Moist multifocal to those who did not (inter-subject). Similarly, NAVQ ratings were unable to discriminate between participants who preferred Clariti multifocal ( $31.5 \pm 19.2$  versus  $28.9 \pm 25.6$ ,  $p = 0.734$ ) and AquaComfortPlus multifocal ( $27.7 \pm 19.0$  versus  $36.7 \pm 22.7$ ,  $p = 0.247$ ) to those who did not (Table 23).

Considering intra-subject differences, NAVQ rating of near performance observed a nonsignificant interaction amongst participants who preferred Moist multifocal ( $P = 0.682$ ) or Clariti multifocal ( $p = 0.252$ ) or AquaComfortPlus multifocal ( $p = 0.686$ ) when compared to their results attained wearing the other lens types (Table 23).

Additionally, no difference in the overall subjective self-reported satisfaction with near vision ability between participants who preferred Moist multifocal ( $p = 0.364$ ), Clariti multifocal ( $p = 0.865$ ) and AquaComfortPlus multifocal ( $p = 0.124$ ) to those who did not respectively (inter-subject). Likewise, no interaction was found in the overall self-reported satisfaction with near vision ability in participants who preferred one lens type compared to the results when the same participants wore the other lens types (intra-subject) (Moist multifocal,  $p = 0.562$  ; Clariti multifocal,  $p = 0.262$  ; AquaComfortPlus multifocal,  $p = 0.222$ ) (Table 23).

#### 4.3.3.6 The forced choice Photographic questionnaire for Photic phenomenon

The forced choice Photographic questionnaire for Photic phenomenon image score was not significantly dependent on the preference of Moist multifocal ( $p = 0.199$ ) or Clariti multifocal ( $p = 0.562$ ) or AquaComfortPlus multifocal ( $p = 0.401$ ) when comparing individual participant to the rest of the cohort (inter-subject). Similarly, no significant intra-subject differences emerged based on the photic phenomenon image score obtained while each participant wore their preferred lens type when compared to the results attained wearing the other lens types (Moist multifocal,  $p = 0.959$  ; Clariti multifocal,  $p = 0.702$  ; AquaComfortPlus multifocal,  $p = 0.725$ ) (Table 23)

#### 4.3.3.7 VF-11

Inter-subject vision-specific functioning score comparison revealed no significant differences between participants who preferred one lens type to the participants who preferred other lens types (Moist multifocal,  $p = 0.266$ ; Clariti multifocal,  $p = 0.436$ ; AquaComfortPlus multifocal,  $p = 0.827$ ). Likewise, no interaction was found in vision-specific functioning score in participants who preferred one lens type compared to the results when the same participants wore the other lens types (intra-subject) (Moist multifocal,  $p = 0.328$ ; Clariti multifocal,  $p = 0.205$ ; AquaComfortPlus multifocal,  $p = 0.692$ ).



	MRS (wpm)	CPS (LogMAR)	NAVQ (Logits)	The forced choice Photographic questionnaire for Photic phenomenon Score	VF11 (Logits)
<b>Moist multifocal</b>					
Preferred n = 9	145.3 ± 40.2	0.14 ± 0.17	24.8 ± 17.8	0.11 ± 0.33	-2.39 ± 0.69
Non-preferred n = 26	131.7 ± 24.1	0.22 ± 0.10	34.3 ± 20.8	0.55 ± 0.86	-2.01 ± 0.89
Significance of inter-subject differences	0.360	0.070	0.204	0.199	0.266
Significance of intra-subject differences	0.970	0.440	0.682	0.959	0.328
<b>Clariti multifocal</b>					
Preferred n = 16	130.3 ± 23.9	0.21 ± 0.10	31.5 ± 19.2	0.31 ± 0.70	-2.00 ± 0.84
Non-preferred n = 19	139.5 ± 29.8	0.18 ± 0.13	28.9 ± 25.6	0.47 ± 0.84	-2.19 ± 0.88
Significance of inter-subject differences	0.319	0.643	0.734	0.562	0.436
Significance of intra-subject differences	0.786	0.630	0.252	0.702	0.205
<b>AquaComfortPlus multifocal</b>					
Preferred n = 10	137.1 ± 29.8	0.16 ± 0.11	27.7 ± 19.0	0.60 ± 0.84	-2.01 ± 1.02
Non-preferred n = 25	139.9 ± 29.7	0.20 ± 0.12	36.7 ± 22.7	0.36 ± 0.81	-2.14 ± 0.80
Significance of inter-subject differences	0.799	0.401	0.247	0.401	0.827
Significance of intra-subject differences	0.890	0.159	0.686	0.725	0.692

Table 23: Mean ± standard deviation MRS, CPS, NAVQ score, The forced choice Photographic questionnaire for Photic phenomenon Score and VF11 of participant preferring Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal.

#### 4.4 Discussion

To the knowledge of the author, the current study is the first single-masked randomised cross-over trial to examine whether it is possible to predict fitting success of three commercially available daily-disposable multifocal soft contact lenses, using a range of clinical tests and subjective questionnaires.

From the clinician's perspective, an ideal clinical measure to assess visual performance in multifocal contact lenses would be the one that could produce identical result in both during the early stage of wear and later in the adaptation period (61). Such a clinical evaluation would then provide a full detailed of the multifocal contact lens wearer's visual performance, thus furnish as an effective and reliable success factor or failure risk judgement. In the current study, no differences in the measurements of BDVA, BINA and BNVA were found between the dispensing and 1-month follow-up visits. This confirms previous work (61, 188) that reported visual acuity measurements over time are usually consistent between dispensing visit and follow-up assessments and do not change over adaptation period. However, studies have shown discrepancy in visual acuity with adaptation in multifocal lenses; Papas et al. (61) reported a decreased in high contrast near acuity in low illumination over the first 4 days of wear. Fernades et al. (52) reported an improvement of distance high contrast VA after a short-term 15 days of

multifocal contact lens wear. Therefore, the lack of consistency as to whether visual acuity achieved in multifocal contact lenses with adaptation suggests that when viewing at fitting alone, acuity-based measurements may not be the best predictor with multifocal contact lenses (188). Additionally, in the current study, there were no relations between photopic distance, intermediate and near acuity metrics in each preference group compared with the preferred and non-preferred lens types. Woods et al. (106) without analyzing the objective changes over 2 weeks of wear, highlighted that from the subjective perspective, multifocal lens was the preferred choice for overall lens satisfaction and real-world tasks rating such as driving and watching television compared to monovision correction. Sivardeen and colleagues (78) assessed presbyopic contact lens preference over 4 weeks of wear and reported that patients who preferred PureVision 2 for Presbyopia and Biofinity multifocal had a better photopic low contrast visual acuity and photopic high contrast distance visual acuity respectively. It would thus seem that performance at low contrast and the quality of photopic visual acuity at distance might be important factors for lens success. However, Sheedy and colleagues (193) in a 8 weeks presbyopic contact lens wear study observed improvements in task performance but not visual acuity metrics. As such, there is still question about the usefulness of the quality of high contrast visual acuity when multifocal contact lenses were worn in determining lens success. Nonetheless, it is unlikely that majority of distance, intermediate and near viewings for patients would have comprised of objects with similar demand as a 6/6 line. In addition, most modern multifocal contact lenses are able to offer reasonable quality of image and visual acuity, due to the increased depth of focus produced by the gradual change in power across the lens (115, 185, 194), further indicating poor predictive value of visual acuity metrics in lens preference.

Near visual function is most commonly assessed by measurement of best corrected near visual acuity. However, reading metrics such as MRS and CPS may offer a more real-world near visual function assessment in patients (85). In the current study, MRS and CPS did not change for the three types of multifocal contact lens over the adaptation period of one month. There seems to be a trend but clinically unimportant improvement of about 2 letter in CPS for Clarity multifocal after 1 month of wear. Further, MRS, CPS and assessment of vision related QoL using NAVQ rating were also found to be independent of overall lens preference. This is similar to a study by Sivardeen et al. (78) which found no relationship between lens preference and reading metrics and NAVQ rating. Analogously, other has also shown no relationship between multifocal lens designs and QoL questionnaire scores (using the NEI-RQL-42) (195). Additionally, Papas et al. (61) found no significant difference in MRS and CPS across study

visits (assessed with different contrast reading charts) but reported a decreased in subjective near vision quality in patients with presbyopic contact lenses. This indicates the limitation of the conventional chart based assessment in clinical setting for multifocal contact lenses and appear to be insensitive to a change in subjectively perceived visual quality. Therefore, reading metrics such as MPS, CPS and subjective NAVQ rating are deemed insensitive to detect change and predict performance in multifocal contact lenses fitting, thus suggesting other factors that were not measured in the current study may be important for overall participant satisfaction. One of such factor could be the image clarity. Sivardeen et al. (78) observed higher subjective image clarity rating of an iPhone 4s apps navigation screen in patients who preferred Biofinity multifocal contact lens design as compared to those who did not, indicating image quality rating at near may drive lens preference.

Aging and the range of pupil sizes (196-199) have been reported to have significant impact on the visual performance of multifocal contact lenses, as they influence the area of contact lens optic exposed in situ. However, pupil size was found to be independent of overall lens preference in the current study. Sivardeen et al. (78) reported of similar finding and additionally, the authors reported that neither pupil centration (when the lens in situ) nor the pupil de-centration relative to the optical axis influenced presbyopic contact lenses preference. Therefore, pupil metrics seemed to be a poor indicator for multifocal contact lens success. Nonetheless, it is interesting to note the inadequacy of in-office pupillary measurements (200), as it has been suggested that real pupillary diameters should be considered in relation to visual tasks in real life condition, since pupil diameter is a dynamic parameter that depends on working distance, age and lighting levels (195). A similar argument applies for pupil measurement using aberrometer, as this technique objectively measure pupil size in real time and patient required to fixate on the illuminated target and thus may not be indicative of the typical pupil size if an individual (78).

Regarding defocus curve, the area-of-focus metric analysis provides an overview of the visual range separately for distance, intermediate and near (73). In this study, the range of clear focus at distance area, intermediate area and near area were insensitive to differences between lens preferences. However, the direct comparison of the VA at each defocus level measured under photopic condition demonstrated an unexpected finding that those who preferred Clariti multifocal showed a minimal worsening of vision (within one line of letter) at level of defocus of +0.50 D, -0.50 D and -1.00 D (distance and intermediate) compared to those who did not prefer

the lens. However, there were no differences in age and effect of refractive error and reading addition as identified. Likewise, there was no difference in the level of difficulty in performing daily activities between those preferred Clariti multifocal to those who did not, as assessed by the vision-specific functioning ratings (VF-11). Hence, it would seem that range of distance and intermediate vision under photopic condition does not drive lens preference. Similarly, study (78) has reported no relation between preference of presbyopic lens types and vision across a range of distances. However, it has been reported that patients with a better range of vision at intermediate and (occasionally) near distances in multifocal contact lens wear tend to have higher satisfaction with their overall vision (201).

Under mesopic condition, there was an interaction between lens types and acuity at different levels of defocus. Generally, participants who preferred Moist multifocal had a significant better visual acuity at the 2 m distance compared to those who did not prefer the lens. Those preferred AquaComfortPlus multifocal had a significant better vision at the 67 cm compared to those who did not prefer the lens. However, those who preferred Clariti multifocal had a worse vision at the 2 m distance compared to those who did not the lens. Again, these were not due to how the participants preferring one type of multifocal lens performed, nor ocular dominance, pupil size, glare or in the level of difficulty in performing daily activities. Nevertheless, differences were more apparent when observing the defocus curve under mesopic condition. From this, it seems that in most cases, participants preferring one type of multifocal contact lens in the current study experienced a degree of change over the range of distance or intermediate, that may not be have been apparent under photopic situation. Notably, Papas and colleague (61) observed a significant difference in high contrast distance and near acuity under low illumination condition in multifocal contact lenses. Sivardeen et al. (75) also observed a significantly difference in high and low contrast visual acuity between a centre-near aspherical design multifocal contact lens compared with other lens types under mesopic condition but not under photopic condition. Additionally, study comparing soft multifocal contact lenses with single vision contact lenses reported that the differences in distance visual acuity were more apparent under low-contrast conditions as compared to high-contrast situations (201). Thus, lens preference may perhaps be driven by a change in visual experience that only manifested in low illumination conditions, suggesting it may be important to conduct objective measure such as visual acuity under mesopic condition when fitting modern-day multifocal contact lenses.

Further, the data also suggests a visual acuity measurement at slightly greater distance at near may be important in driving lens preference. In predicting patient success with multifocal contact lenses, Sha and colleagues (201) recommended to measure visual acuity at slightly greater distance instead of the common 40 cm, as better visual acuity at intermediate was a factor that influenced patients' willingness to purchase presbyopic contact lenses. In addition, a study has reported comparable subjective performance for intermediate visual tasks for multifocal lenses and monovision (201). Notably, these studies involved early-presbyopes with residual amplitude of accommodation, allowing accommodative ability in viewing objects at the intermediate distance. In the current study, most participants were fitted with low-add and med-add lens designs and this would be different in patients with advanced presbyopia, which with increasing reading add power and differences in the recommended multifocal contact lenses fitting philosophy would cause a change in depth of focus and refractive disparity between eyes. Nonetheless, Papas and colleagues (61) found the range of clear vision at near was the only useful objective measurement at dispensing visit. They explained that "truncation of the spatial region" in which visual task can be comfortably executed would influence the outcome of visual satisfaction. This highlights the importance of measuring visual acuity across a range, such as the intermediate and near range.

Studies (61, 106, 188) have advocated the use of subjective measurements to assist practitioners in gauging patients' satisfaction and predicting success in multifocal contact lens wear. These measurements include subjective rating of overall satisfaction with lenses (106), vision and lens comfort questionnaires (61) and take home questionnaires comprised vision clarity and stability (188). In the current study, not significant difference was found between lens preferences and the overall self-reported satisfaction with near vision ability rating. Additionally, when considering the subjective assessment of participants' vision-specific functioning rating (VF-11), contact lens preference was not dependent on the level of difficulty in performing daily activities, such as reading small print, reading newspapers, seeing stairs, seeing street or shop signs and driving during the day and night. These correspond with the lack of relationship between lens preference and MRS, CPS, NAVQ rating, the forced choice Photographic questionnaire for Photopic Phenomena rating or photopic and mesopic range of vision across distance, intermediate and near recorded clinically. Concerning driving, it has been indicated as one of the most challenging activities to perform whilst wearing multifocal contact lenses (56, 186). A study (106) has found significant higher satisfaction with vision for daytime and night driving with multifocal contact lenses over monovision, whilst others (78, 188) reported of lack of

differences between predicting lens preference and night driving or subjective halos size. Additionally, there was also a lack of relationship between subjective take home questionnaires rating for driving during the day and night time between visits (133). Notably, there were research methodology differences, in terms of the type of subjective questionnaires and method of scoring. We recognise that in the current study, other visual experience such as personal lifestyles, vision quality, vision stability or fluctuation, ghosting or lens comfort were not measured and measuring these metrics may have been more influential in the decision of lens preference (52, 61, 78, 188). Though studies have reported that visual quality and overall satisfaction reductions in multifocal contact lens adaptation (52, 61), recent studies (50, 195) have indicated better visual performance results and less multifocal contact lens wear discontinuation rate, presumably due to newer aspherical centre-near multifocal lens designs. However, future studies should include subjective assessment related to specific tasks and activities (186, 195) that are in actual visual conditions and real daily life activities (49) to better assess patient's experience, overall satisfaction and predict multifocal contact lens preference. Additionally, other patient's comments such as the reasons for the lens preference need to be taken into consideration in order to identify or detect possible indicators that drive lens preference (49).

It is difficult to make strict comparisons between studies because factors that both direct and indirect influence visual function and experience are not controlled across all studies, in terms of methodology used to measure visual acuity, reading addition, refractive error groups, level of illumination in clinical setting and other parameters. Furthermore, there were differences in the used of questionnaires (albeit rarely validated) to acquire subjective semi-qualitative responses. Moreover, visual performance is also affected by the age or power of reading addition (106), ocular aging and multifocal contact lenses' power profile and design (51). Nevertheless, the lack of difference between predicting multifocal contact lens preference and visual function in the current study maybe due to the mechanism of neural adaptation, in which a brief 2 to 3 days of short adaptation period followed by improvement in the perceived image quality has been shown to occur in simultaneous vision corrections (188, 202). Hence, the ability to learn how to use reduced visual acuity to perform complex tasks may be a possible explanation for the improved task performance over time in multifocal contact lens wearers (193). Also, the information here should be considered as preliminary, as maybe confounded by the limitation of unequal and limited number of participants subdivided by lens type and lens preference.

Although there was no statistically significant in the preference between the three types of aspherical centre-near multifocal contact lens in the current study, the fact that they provide satisfactory visual acuity after 4 weeks of wear provides the support for clinician to consider multifocal modality as first choice of presbyopic corrections. Additionally, distance performance of similar lens design has been shown to match that of a single vision contact lens (201). Nevertheless, measurement such as the level of defocus at distance under photopic and low illumination conditions might be considered as useful indicator for Clariti multifocal, and level of defocus at distance and intermediate under low illumination might be considered useful indicator for Moist multifocal and AquaComfortPlus multifocal respectively. Additionally, allowing patients at least over 4 days of lens wear before proceeding to assess visual performance appears to be a better clinical strategy than relying solely on the objective vision tests during the fitting or dispensing day to determine success (61).

#### 4.5 Conclusion

In conclusion, contact lens visual performance, self-reported satisfaction with near vision ability and vision-specific functioning provided poor indication of the preferred lens type between Moist multifocal, Clariti multifocal and AquaComfortPlus multifocal after 4 weeks of wear. This may be due to a combination of the minimal differences between the current multifocal contact lens designs and the mechanism of neural adaptation. Although findings from other studies have indicated no change in visual acuity between multifocal contact lens fitting visits and follow-up visits, this was not supported by subjective preference or ratings. Hence, in addition to the assessments during early lens adaptation days to obtain a picture of multifocal contact lens performance, subjective responses together with level of defocus at distance and intermediate under low illumination appear to be useful indicators for each individual status.

## 5. Conclusion.

### 5.1 General conclusion.

As identified in Chapter 1, over the past decade, the world has seen a prominent increase in the trend of multifocal contact lens fitting. However, surveys on worldwide contact lens prescribing trends by Morgan and colleagues (44) showed some practitioners are still reluctant to fit lenses of such modality. Low prescribing rate of multifocal contact lenses has been linked to factors such as perceived complexity of multifocal lens designs, greater perceptual compromises with multifocal contact lenses, chair time involved if multiple fittings and re-fittings are required and unavailability of a 'perfect' MFCL that can provide good comfort and optical imagery over a wide range of focal distances (44).

In 2011, presbyopic lens fitting in Singapore was found to be of 0% and the practitioners' attitude were one of the factors to be blamed for the low fitting rate (44). Although there are improvements in multifocal lens design, material, and an increase in the availability of the daily-disposable wearing mode (145), no new research is being conducted to investigate the presbyopic lens fitting status in Singapore. In addition, there is still no clarity on the factors governing the prescribing and dispensing of multifocal contact lenses in Singapore.

Studies have reported continuous improvements in the optical designs of simultaneous vision multifocal contact lens and these have led to improved performance, in terms of better vision and binocularity (150). However, simultaneous vision presbyopic contact lenses with concentric and aspheric power profiles are frequently associated with worse visual acuity under photopic and mesopic conditions when compared to single-vision contact lenses and spectacles lenses (160, 203). In addition, the optical profile of multifocal lens designs will differ in response to changes in pupil size and lighting levels (115, 200). Thus, clinical measurements of these aspects of lens performance may be able to differentiate lens performance and preference.

Considering the aforementioned, this study was undertaken to examine specifically Singapore practitioners' attitudes towards soft multifocal contact lenses and its prescribing trend. Additionally, a randomised, single-blind, cross-over trial was conducted to comprehensively compare vision, reading metrics and defocus curve of three types of modern daily-disposable



multifocal soft contact lens designs (Chapter 3), and to determine which baseline measure(s) best predicted lens preference for each individual patients (Chapter 4).

Chapter 2 surveyed a cohort of optometrists across Singapore to understand soft multifocal contact lens prescribing trend and practitioner attitudes in soft multifocal contact lenses fitting. Increased in successful fits with soft multifocal contact lenses have been reported over the years, reflecting of a high proportion of presbyopes are now fitted with soft multifocal contact lenses (114). Indeed, it was observed that there was an increase in the rate of soft multifocal contact lens fitting in Singapore, presumably due to the recent increase in availability of soft multifocal contact lenses. In addition, when prescribing presbyopic correction, daily-disposables and daily wear modality were the most popular choices amongst Singaporean practitioners. Although enablers such as the increased in practitioners' motivation and proactiveness in fitting soft multifocal contact lenses were gathered, Singapore practitioners' perception of the unavailability of an 'ideal' multifocal contact lenses and increased chair time in fitting soft multifocal contact lenses were observed as primary barriers. This survey gathered valuable new information about the attitudes of fitting and dispensing soft multifocal contact lenses to presbyopes in Singapore and may further support future planning strategies to improve the proportion of contact lenses prescribing for presbyopia. Additionally, Singapore practitioners indicated of the need of more special skills and technical training in soft multifocal contact lens fitting. Indeed, practitioners' level of training has an influence on soft multifocal contact lens fitting rate (44, 133, 134). The above-mentioned reasons supported the premise of this thesis in gaining better understanding of the performance offered by modern daily-disposable multifocal soft contact lenses (Chapter 3) and to investigate the most informative indicators for making a better prediction of which brand will work best for individual patients (Chapter 4).

In chapter 3, a comparison of the performance of three commercially available daily-disposable multifocal soft contact lenses was made in 35 participants and the results evaluated. This chapter examined the combination of factors that may influence participant's' visual performance with multifocal contact lenses, which include the design characteristics of the lens (power profiles), ocular changes (pupil size), the visual environment of the participant (the illumination level as well as potential dysphotopsia) and visual tasks (range of clear vision and reading performance). Despite the differences in power profiles between the three types of multifocal contact lens under investigation, there were no significant differences in the visual acuity at distance, intermediate and near. The three types of multifocal contact lens have shown

to provide good results in terms of VA at distance, intermediate and near. This could be attributed to the fact that multifocal contact lenses have optical designs that enable them to provide an increased depth of focus in presbyopic patients (167) that helped early to moderate presbyope in performing near task. Notably, in this study, our participants were mostly early to moderate presbyopic and they were fitted with low-add and mid-add lens design. However, under mesopic condition, defocus curve indicated AquaComfortPlus multifocal outperformed Clariti multifocal and Moist multifocal in terms of the subjective range of vision for distance. This might be explained by the difference in the relative refractive power profiles, where AquaComfortPlus multifocal showed the most negative spherical aberration or perhaps due to a complex interaction of the total optical biometry of the eye (which include corneal and lenticular aberrations) when AquaComfortPlus multifocal were fitted. However, these were not assessed in the study. Generally, there was no considerable difference in general visual function between these lenses, as indicated by the lack of significant differences in reading performance, subjective perception of near vision ability, photic phenomena and the level of difficulty in performing daily activities. Perhaps each type of multifocal contact lens has its own advantages and disadvantages, coupled with wide range of participant's' visual needs, lifestyle or expectations may have 'balance out' for each type of lens, leading to a similar average perception when considered collectively (204).

Chapter 4 described if lens preference is related to objective visual performance measured and subjective (participant-reported) outcomes with the lenses. In this trial, Clariti multifocal was the most preferred contact lens chosen by the participants. AquaComfortPlus multifocal was the second most accepted option followed by Moist multifocal. The success of the Clariti multifocal lens may be attributed to perhaps a deliberate manipulation of its power profile, which has variable amounts of spherical aberrations depending on lens power (there is an increase in negative spherical aberration in lens with higher minus power) (115). Clinical performance measured using defocus curve under mesopic condition showed participants who preferred Moist multifocal had a significant better visual acuity at the 2 m distance compared to those who did not prefer the lens, and those preferred AquaComfortPlus multifocal had a significant better vision at the 67 cm compared to those who did not prefer the lens. These perhaps suggesting a change in visual experience over the range of distance or intermediate manifested under mesopic condition may play a role in driven lens preference. However, the analysis of other the routine clinical performance measured and subjective questionnaires in predicting lens preference were generally disappointing. Lens preference was not driven by how the

participants preferring one type of multifocal lens performed, nor ocular dominance, pupil size, glare, self-reported satisfaction with near vision ability rating or in the level of difficulty in performing daily activities such as reading small print and driving during the day and night.

In the current study, the three types of multifocal contact lens were found to provide satisfactory visual acuity after 4 weeks of wear. Previous study has shown distance performance of similar aspherical centre-near design was able to match that of a single vision contact lens (201). This perhaps provides the support for clinician to consider multifocal modality as their first choice of presbyopic corrections.

## 5.2 Evaluation of experimental work: suggestions for improvement and plans for future research.

Chapter 2 collected responses from the practitioners to report their approximate frequency of contact lens fittings and as with any anonymous survey study, limitations are encountered due to the possibility of subject misreporting and may have influenced the accuracy of the results. Moreover, part of the survey was designed to assess practitioner's attitudes and there was the chances for misinterpretation and expansion of scope of the questions. In addition, mail questionnaires was employed as the survey approach methodology. This method has been shown to achieve lower response rates than interview methods such as telephone (205). In general, response rates should be maximized in order to minimize the magnitude of any non-response bias and high response rates help to maintain the representativeness of a sample.

As identified early in Chapter 3 and 4, quantifying the interaction of the optical aberrations of the contact lens and the eye, in the presence of dynamic elements such as tear film and accommodative system (167, 185, 190) and capturing of monocular as well as binocular data could be used for further exploration and aid the examination of this population. It should be also noted that media changes may influence presbyopic contact lens performance and acceptance (74).

According to the Singapore Department of Statistics, the Singapore population in 2017 for the age group of 40-69 years was 840,907 for the number of males and 867,715 for the number of females. Clearly, the ratio of male to female in this study' cohort (Chapter 3) of participants was

not representative of the Singapore population in numbers, however, it may be reflective of the ratio of gender that wears contact lenses. Similarly, the study cohort by age group was also not representative of the Singapore residents by age group, where the number of age 40-49 was 227,051, age 50-59 was 159,621 and age 60-69 was 106,871. In addition, this was a single centre trial, with participants were all from one practice and the analysis of this study was restricted to residents of Singapore with myopia, due to the fact that almost half of Singaporeans aged 40 years and above have some degree of myopia (206). It is not known if the data can be extrapolated to the general population and patient with hypermetropia; future studies of a large multi-centre are needed to include a wider range and variety of potential contact lens wearing presbyopes. Nevertheless, it can be speculated that refractive error and multifocal contact lens visual performance are poor predictors of lens preference as have been suggested for soft multifocal contact lenses (80, 126).

It should be recognised that measurements of multifocal contact lens performance in 'consulting room' are usually performed under controlled conditions and in optimally illuminated environments. This environment is not representative of the everyday life visual conditions experienced by patient. For this reason, future study should include subjective ratings centred on specific task-orientated performances at various distances to better estimate their adaptation to 'real-world', such as viewing street signs, faces, hand held electronic devices, computers, reading magazines and driving. Studies (59, 106) have shown investigating visual satisfaction for habitual tasks with multifocal contact lenses could provide valuable information for practitioners to decide between different contact lens designs, as well as offering a better prediction of long term wearing success with multifocal contact lenses.

In the study, there were no control on the wear time assigned to each of the individual type of lens; however, each participant serves as his or her own control, thereby eliminating individual participant differences. Notably, some participants may be able to memorize the information presented as some of the tests were repeated during study visits, such as the English Radner test sentences which reading speed was measured for each participants every 4 weeks and on 6 occasions.

Responding to a questionnaire item is itself a complex cognitive process. Participants must interpret the question, retrieve relevant information from memory, making a judgment and finally putting and editing into the required response format. Although the nature of the study and the

questionnaires were thoroughly explained in detail to all participating participants, there is still a possibility that not all questions were answered as intended, due to different interpretation of questions by participants. On top of that, participants may mark an unintended response on the scale for the question. Additionally, the authors have not control over individual's expression of 'satisfaction' and 'dissatisfaction', as it was reported that even when patient were corrected to visual acuity of 6/9, they may still have complaints and 'unsatisfied' about their vision and correction (108).

We have confined this study to only the commercially available lens designs and the results derived have been only based on the three types of simultaneous vision daily-disposable multifocal soft contact lenses. In future study, possible trends in visual performance that will be able to differentiate between patients can be analysed using different modality, lens design such as the extended depth-of-focus design or a non-symmetrical design and optical principle such as the modified monovision with multifocal contact lenses, instead of a simultaneous refractive model used in this study. In this study, optical feature of the multifocal lens was an area investigated, it would be interesting to assess patient's visual experience, and tolerance with each contact lens in future studies as they may provide additional information concerning these contact lenses.

### 5.3 Concluding summary.

This thesis reports on the survey of multifocal soft contact lens prescribing trends in Singapore. The overall increased rate of prescribing multifocal contact lenses with the high usage of daily-disposable for presbyopia correction in Singapore reflect the fact that practitioners having a high level of acceptance of modern generation multifocal contact lenses. This thesis also reports on a single-blind randomised crossover trial and aimed to comprehensively compare the vision and visual performance of the three types of daily-disposable multifocal lens correction. After the 1-month wear, all the lenses performed similarly for the acuity measurements and subjective variables. The routine clinical tests from baseline measurements to visual functioning factors were unable to predict lens preference when comparing the preferred to the non-preferred lens, even though there were differences in lens preference between the lenses and better performance was observed with some tests. It is likely that other visual experience such as

personal lifestyles, vision quality, vision stability or fluctuation, ghosting or lens comfort may have been more influential in the decision of lens preference.

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## Appendices

### A1: Questionnaires to survey the attitude contact lens practitioners towards prescribing of multifocal contact lenses.

1

To survey the attitude contact lens practitioners towards prescribing of soft multifocal contact lenses.

If you do not fit contact lenses, please pass this questionnaires to a colleague who does.

What is your job description?	How many years have you been .....	The type of practice you work in.....	The location of practice you work in.....
<input type="checkbox"/> Optometrist <input type="checkbox"/> Contact Lens Practitioner	qualified: _____ fitting Contact Lenses: _____	<input type="checkbox"/> Independent <input type="checkbox"/> Chain Store <input type="checkbox"/> Private Clinic/Hospital <input type="checkbox"/> Other (please specify) _____	<input type="checkbox"/> Central Region <input type="checkbox"/> Outside Central Region

Q1. How many patients do you see per month?

.....

Q2. How many patients do you fit contact lens per month?

.....

Q3. (a) How many presbyopic patients do you fit contact lens per month?

.....

(b) Of these, how many are soft multifocal contact lenses (MFCL)?

.....

Q4. How many soft MFCL aftercare you do per month?

.....

Q5.	For soft contact lenses correction of presbyopia , my first choice would be to fit:  (Choose ONE only) <input type="checkbox"/> Single vision spectacles for near to wear over contact lenses <input type="checkbox"/> Monovision with contact lenses <input type="checkbox"/> Bifocal contact lenses <input type="checkbox"/> Multifocal contact lenses
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Q6.	For soft contact lenses correction of presbyopia , the type I mostly recommend is:  (Choose ONE only) <input type="checkbox"/> Daily Disposable <input type="checkbox"/> Bi-weekly Disposable <input type="checkbox"/> Monthly Disposable <input type="checkbox"/> Others
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Q7.	<p>For soft contact lenses correction of presbyopia, the modality I mostly recommend is:</p> <p style="text-align: center;">(Choose ONE only)</p> <p><input type="checkbox"/> Daily Wear</p> <p><input type="checkbox"/> Extended Wear</p> <p><input type="checkbox"/> Occasional Wear</p>
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In the following questions, please choose and circle the most appropriate answer.

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Q8.	I am motivated to fit MFCL.	0	1	2	3	4
Q9.	I am confident in prescribing soft MFCL.	0	1	2	3	4
Q10.	I am aware of the availability of all soft MFCL in Singapore.	0	1	2	3	4
Q11.	I need special technical and skills training for soft MFCL fitting.	0	1	2	3	4
Q12.	Fitting soft MFCL is complex and time consuming.	0	1	2	3	4
Q13.	Currently there is an absence of availability of an 'ideal' soft MFCL.	0	1	2	3	4
Q14.	I do regularly recommend and dispense soft MFCL.	0	1	2	3	4

Q15. State the MAIN reason for Q14.

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--- END OF SURVEY ---

Thank you very much for your valuable inputs and time.

When completed, please return this survey form in the pre-paid envelope provided to:

School of Chemical & Life Sciences  
Singapore Polytechnic  
W115, 500 Dover Road  
Singapore 139651  
Attn: Mr. Danny Sim





A2: An introductory letter to invite practitioner to participate in the survey.

Date: 20 May 2016

Singapore Polytechnic Optometry Centre,  
School of Chemical & Life Sciences  
Singapore Polytechnic

Dear Eye Care Practitioner,

We are conducting a survey to understand the practitioner attitude towards prescribing of soft multifocal contact lenses (MFCL).

We would like to invite you to complete ALL the Questions in this brief survey. Completion of the survey is expected to take 5-10 minutes. The questions are quite general.

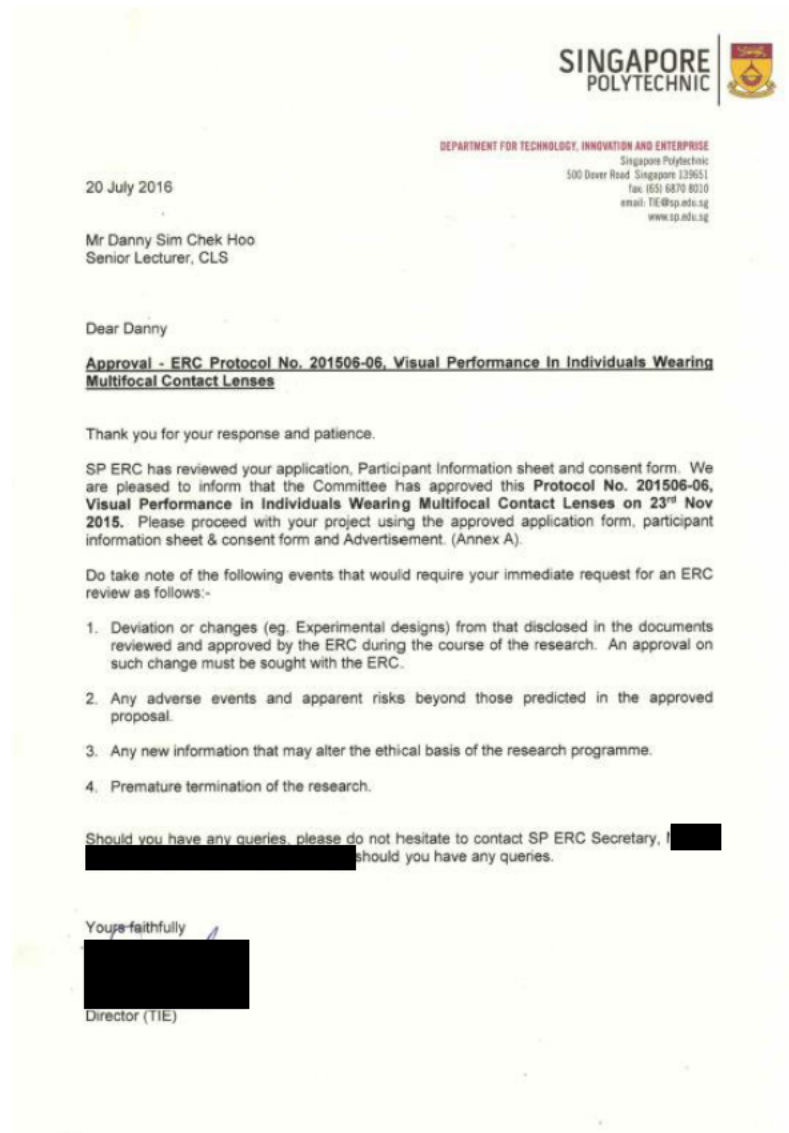
Participation in this survey is voluntary.

When completed, please send the survey form in the stamped addressed envelope provided by 31<sup>st</sup> December 2016 to:

School of Chemical & Life Sciences  
Singapore Polytechnic  
W115, 500 Dover Road  
Singapore 139651  
Attn: Mr Danny Sim

Thank you very much for your valuable inputs and time.

### A3: Singapore Polytechnic Ethics Committee acceptance of project.



## A4: Aston University Ethics Committee acceptance of project.



Aston University  
Aston Triangle  
Birmingham  
B4 7ET  
0121 204 3000

Date: 22/03/18

Life and Health Sciences

Dear Danny Sim Chek Hoo ( Supervisor: Dr Shehzad Naroo)

Study title:	<i>Visual Performance in Myopic Individual Wearing Daily Disposable Multifocal Lenses</i>
REC REF:	Ethics application 1277

### Confirmation of Ethical Opinion

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

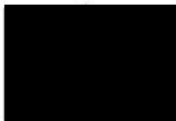
### Approved documents

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

Document	Version	Date
PhD Ethics Application 1277	-	
06-2015_erc_application_form_v4 - visual_performance_in_individuals	-	29/11/17
06-2015_erc_participant_is_cf_v4-visual_performance_in_individuals_wear	-	29/11/17
cls_wsh_2015-206	-	29/11/17
cls_wsh_2015-307	-	29/11/17
singapore_erc_letter_of_approval		29/11/17
study_rational_and_protocol_visual_performance_in_myopic_individual_wea		29/11/17
Participant Information Sheets and Consent Forms_002	2	30/01/18



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

Yours sincerely



Chair of the University Research Ethics Committee

## A5: Participant Information Sheets and Consent form

<p><small>If you do not understand any parts of this form they will be explained to you by a member of the research team</small> Participant initials: _____ Research team member's initials: _____</p> <p> Aston University Version Number and Date: 002, 30 January 2018</p> <p><b><u>PARTICIPANT INFORMATION SHEET</u></b> <b><u>Title of the Study: Visual Performance in Myopic Individual Wearing Daily Disposable Multifocal Lenses</u></b></p> <p><b><u>Invitation</u></b> You are being invited to participate in a research study. Before you decide to participate, it is important for you to understand why the study is being done and what it will involve. Please take the time to read the following information carefully, and discuss with friends and family, if you wish. Please feel free to ask us about anything that is not clear.  This Participant Information Sheet describes the purpose of this study. It explains what will happen to you if you decide to participate and provides detailed information about the conduct of the study.</p> <p><b><u>What is the purpose of the study?</u></b> The purpose of this research is to compare the visual performance of three different daily disposable soft multifocal contact lenses.</p> <p><b><u>Why have I been chosen?</u></b> You have been invited because you are over 40 years of age and have lost your ability to naturally focus on near objects but your eyes are otherwise healthy.</p> <p><b><u>What will happen to me if I take part?</u></b> After the study has been explained to you and you have agreed to take part, you will be expected to wear study contact lenses and see your study optometrist for follow-up visits. There will be a total of 4 study visits. Each visit will last about 1-1.5 hours.</p>	<p><small>If you do not understand any parts of this form they will be explained to you by a member of the research team</small> Participant initials: _____ Research team member's initials: _____</p> <p> Aston University Version Number and Date: 002, 30 January 2018</p> <p><b><u>PARTICIPANT INFORMATION SHEET</u></b> <b><u>Title of the Study: Visual Performance in Myopic Individual Wearing Daily Disposable Multifocal Lenses</u></b></p> <p><b><u>Invitation</u></b> You are being invited to participate in a research study. Before you decide to participate, it is important for you to understand why the study is being done and what it will involve. Please take the time to read the following information carefully, and discuss with friends and family, if you wish. Please feel free to ask us about anything that is not clear.  This Participant Information Sheet describes the purpose of this study. It explains what will happen to you if you decide to participate and provides detailed information about the conduct of the study.</p> <p><b><u>What is the purpose of the study?</u></b> The purpose of this research is to compare the visual performance of three different daily disposable soft multifocal contact lenses.</p> <p><b><u>Why have I been chosen?</u></b> You have been invited because you are over 40 years of age and have lost your ability to naturally focus on near objects but your eyes are otherwise healthy.</p> <p><b><u>What will happen to me if I take part?</u></b> After the study has been explained to you and you have agreed to take part, you will be expected to wear study contact lenses and see your study optometrist for follow-up visits. There will be a total of 4 study visits. Each visit will last about 1-1.5 hours.</p>
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<p><i>If you do not understand any parts of this form they will be explained to you by a member of the research team</i>  Participant initials: _____ Research team member's initials: _____</p> <p><b>Baseline Screening Visit / Visit 1:</b></p> <p>At the first visit, after you have signed the consent form, eye measurements will be taken to ensure that you are eligible to take part in the study. These will include questions about your general health and contact lens history, vision check, measures of your eyes and a check of the health of your eyes. If suitable, a pair of soft multifocal contact lenses (study lens A) will be placed in your eyes to check how the contact lens fits and how well you see with the multifocal contact lenses at far distance and near distance.</p> <p>When you first put the contact lenses on the eyes, you will probably feel the lenses and tear for a while. The tears will subside and you will feel more comfortable after that.</p> <p>You will be supplied with sufficient quantity of contact lenses (study lens A) and will be asked to wear these lenses for one month.</p> <p>You will also be taught how to properly apply and remove lenses.</p> <p><b>Visit 2:</b></p> <p>You will be asked to come to Visit 2 wearing the study lens A. At this visit, study measurements will be taken including vision for distance and near, and subjective responses (i.e how you feel about wearing the study lens A and your near visual function).</p> <p>Your eyes will be examined and if determined to remain healthy, a pair of multifocal contact lenses (study lens B) will be placed in your eyes to check how the contact lens fits and how well you see with the multifocal contact lenses at far distance and near distance.</p> <p>You will be supplied with sufficient quantity of contact lenses (study lens B) and will be asked to wear these lenses for one month.</p> <p>You will also be taught how to properly apply and remove lenses.</p> <p><b>Visit 3:</b></p> <p>You will be asked to come to Visit 3 wearing the study lens B. At this visit, study measurements will be taken including vision for distance and near, and subjective responses (i.e how you feel about wearing the study lens B and your near visual function).</p>	<p><i>If you do not understand any parts of this form they will be explained to you by a member of the research team</i>  Participant initials: _____ Research team member's initials: _____</p> <p>Your eyes will be examined and if determined to remain healthy, a pair of multifocal contact lenses (study lens C) will be placed in your eyes to check how the contact lens fits and how well you see with the multifocal contact lenses at far distance and near distance.</p> <p>You will be supplied with sufficient quantity of contact lenses (study lens C) and will be asked to wear these lenses for one month.</p> <p>You will also be taught how to properly apply and remove lenses.</p> <p><b>Visit 4 / Exit visit:</b></p> <p>You will be asked to come to Visit 4 wearing the study lens C. At this visit, study measurements will be taken including vision for distance and near, and subjective responses (i.e how you feel about wearing the study lens C and your near visual function).</p> <p><b>Are there any potential risks in taking part in the study?</b></p> <p>The risks associated with taking part in this study are very small. The overall safety profile of the investigational contact lenses for presbyopia is anticipated to be similar to that for currently available single vision soft contact lenses. Hydrogel and silicone hydrogel contact lenses are non-toxic and biocompatible for on-eye use. As part of the study we will use Fluorescein 1.0% eye drops. This is a staining agents used to aid external examination of your eye. When applied to the eye, they may sting for a few moments. Due to their colouring (orange/ yellow) they may cause the vision to take on a coloured appearance for a few minutes. If the eyelids and the skin around the eyes become coloured by the stain then this can be removed with cold water.</p> <p>It is important to follow instructions on how to use the contact lenses as well as handling of the study contact lenses. Failure to follow study optometrist instructions may increase the risk of developing eye problems.</p> <p>It is expected that you will adapt to using the study contact lenses. The study optometrist will check your eyes and ensure that the contact lenses prescribed work best for you. There may be slight blurriness of vision due to the design of the multifocal contact lenses.</p> <p>You may experience one or more of the following symptoms: eye pain, feeling something in the eye, unusual secretions, eye redness, sensitivity to light, eyes burn, sting or itch, watery eyes, blurred vision, seeing rainbows and halos around objects, uncomfortable lens and eye dryness. Remove your study lenses immediately and tell your study optometrist if you experience any of these</p>
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<p><i>If you do not understand any parts of this form they will be explained to you by a member of the research team</i>  Participant initials: _____ Research team member's initials: _____</p> <p>symptoms or feel something wrong with your lenses or your eyes. Please talk to your study optometrist about your concerns.</p> <p>(Study optometrist: Danny Chek Hoo Sim, phone number [REDACTED])</p> <p>If you experience discomfort as a direct result of your participation in this research, you must contact the study optometrist immediately. If necessary the study optometrist will refer you to a medical practitioner.</p> <p>If you require more information about possible risks and disadvantages please ask.</p> <p><b><u>What should you do if your sight is affected when wearing the lenses?</u></b></p> <p>The vision with multifocal contact lenses compared to eye glasses or spherical contact lenses may be less sharp or different. You may notice these symptoms more under dim light, foggy or rainy conditions, or with very bright lights. You may experience headache while wearing contact lenses or eye glasses and may need more time to adapt to them.</p> <p>If you experience any of the above symptoms or discomforts, immediately remove the study lenses and contact your study optometrist.</p> <p><b><u>Do I have to take part?</u></b></p> <p>No, your participation in this study is voluntary and you are entitled to refuse. Your decision of refusal will not affect your employment or in the case of a student it will not affect your relationship with the Singapore Polytechnic.</p> <p>If you decide to take part in this study you will be asked to sign a Consent Form. You will be given a copy of this and an information sheet to keep. If you change your mind you are free to withdraw at any time and without giving any explanation.</p> <p><b><u>Expenses and payments:</u></b></p> <p>Yes, you will receive S\$40.00 per scheduled visit as compensation for your time, travel and participation.</p>	<p><i>If you do not understand any parts of this form they will be explained to you by a member of the research team</i>  Participant initials: _____ Research team member's initials: _____</p> <p><b><u>Will my taking part in this study be kept confidential?</u></b></p> <p>Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Our procedures for handling, processing, storage and destruction of your data are compliant with the Singapore Personal Data Protection Act 2012. You have the right to view the data we have on record about you and to correct any errors. Additionally, the study datasets will be coded, stored or handled in anonymous form and will not link to personal identifiers.</p> <p><b><u>What will happen to the results of the research study?</u></b></p> <p>It is intended that the results of the research will be presented at scientific meetings, and published in relevant clinical and academic journals. The study will also be written into the Doctor of Optometry thesis of Danny Chek Hoo Sim. You will not be identified in any report or publication.</p> <p><b><u>Who is organising and funding the research?</u></b></p> <p>The Diploma in Optometry, School of Chemical &amp; Life Sciences, Singapore Polytechnic is organising this study.</p> <p><b><u>Who has reviewed the study?</u></b></p> <p>This study was reviewed and given a favourable opinion by the Aston University Research Ethics Committee.</p>
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If you do not understand any parts of this form they will be explained to you by a member of the research team  
Participant initials: \_\_\_\_\_ Research team member's initials: \_\_\_\_\_

**Who do I Contact if I have concerns about the study or I need Further Information?**

If you have a concern about any aspect of this study or would like more information, you should in the first instance speak with the principal investigator or another member of the research team and they should be able to answer your questions.

Mr Danny Chek Hoo Sim
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If you do not understand any parts of this form they will be explained to you by a member of the research team  
Participant initials: \_\_\_\_\_ Research team member's initials: \_\_\_\_\_

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

If the researchers cannot address any concerns that you have about the conduct of the study and wish to make a complaint, then you should contact the Aston University Director of Governance:

Mr John Walter
Director of Governance
Aston University
Birmingham, B4 7ET
Tel: [REDACTED]
Email: [REDACTED]

A6: The summary of the main characteristics of the three types of contact lens fitted in this study.

Characteristics	Moist multifocal	Clariti multifocal	AquaComfortPlus multifocal
			
Unique Technology	INTUISIGHT™ technology	WetLoc™ process	Precision Profile Design
Material	Etafilcon A	Somofilcon A	Nelfilcon A
Design	Aspheric centre-near	Center-near	Aspheric centre-near
Dk/t (Fatt)	25.5	86	26
Water content (%)	58	56	69
Modulus (MPa)	0.31	0.50	0.89
Refractive Index	1.40	1.4003	1.38
Specific gravity	0.98	1.17	-
Centre thickness (-3.00) (mm)	0.084 mm	0.07mm	0.10
Base curve (mm)	8.4	8.6	8.7
Diameter (mm)	14.3 mm	14.1	14.0
Power (D)	+6.00D to -9.00D (0.25D steps)	+5.00D to -6.00D (0.25D steps)	+6.00D to -10.00D (0.25D steps)
Addition	Low, medium and high	Low and high	Low, medium and high



A7: 1-Day Acuvue Moist multifocal fitting guide.



A8: Clariti 1 Day multifocal fitting guide.



A9: Dailies AquaComfort Plus multifocal fitting guide.



A10 : Near Ability Vision Questionnaire (NAVQ)



## A11: The Modified VF-11 Items Used in the Study

### Visual Functioning Questionnaire (VF11)

Type of Correction: (Please Tick ONE Option ONLY)

Spectacles:

Contact Lenses:

☐ Single Vision

☐ Distance CL + Reading Specs

☐ Bifocals

☐ Monovision

☐ Varifocals

☐ Multifocals

How much difficulty do you have in :	No Difficulty	A Little Difficulty	Moderate Difficulty	Great Difficulty	Unable to do the activity
1. Reading small print in the telephone book even with glasses?	0	1	2	3	4
2. Reading newspaper-size print even with glasses?	0	1	2	3	4
3. Recognizing friends when you meet them while shopping even with glasses?	0	1	2	3	4
4. Seeing stairs even with glasses?	0	1	2	3	4
5. Reading street signs or shop signs even with glasses?	0	1	2	3	4
6. Filling out 4-D or Toto forms even with glasses?	0	1	2	3	4
7. Playing games—chess or cards—even with glasses?	0	1	2	3	4
8. Cooking even with glasses?	0	1	2	3	4
9. Watching television even with glasses?	0	1	2	3	4
	No Difficulty	A Little Difficulty	Great Difficulty		
10. Driving during the day because of vision?	1	2	3		
11. Driving at night because of vision?	1	2	3		