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Perceptions Of Comfort And Vison In Center Distance Multifocal Contact Lenses In Non-Presbyopic Adults

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PERCEPTIONS OF COMFORT AND VISON IN CENTER DISTANCE MULTIFOCAL CONTACT LENSES IN NON-PRESBYOPIC ADULTS

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ABSTRACT

Purpose: The aim of this study was to assess the subjective performance of four different multifocal contact lenses (MFCLs) amongst a population of adults excluding presbyopes.

Methods: Forty-three subjects were fit with up to four different lenses (Biofinity "D" MFCL, NaturalVue MFCL, MiSight 1 Day contact lens, & Intelliwave MFCL). Information about vision and comfort were gathered using subjective assessments. Pupil size data were gathered as secondary outcome measurements.

Results: There were no significant differences in ghosting, haloes, and visual clarity between larger and smaller pupils. All MFCLs had reduced overall visual clarity compared to habitual correction except for Biofinity. There was a significant difference between lenses regarding vision clarity, stability, and comfort.

Conclusions: Our study shows that there are differences between MFCLs in regard to vision and comfort. The lenses that ranked higher for vision and comfort were also most likely to be purchased. Pupil size did not appear to have a effect on visual performance between the MFCLs. Given these findings, practitioners should base their treatments on objective findings and the patients' subjective experience to increase successful fittings.

Keywords: multifocal contact lenses, myopia control, quality of vision, surveys

DEDICATION

This is dedicated to my biggest supporter and my best friend, Kyle. It was only by God's grace that I was able to finish this challenging project, but you continued to point me to the Father whenever I felt discouraged, disappointed, overwhelmed, or lazy. There isn't anyone in this world like you.

I love you.

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TABLE OF CONTENTS

Page

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

History of Contact Lenses

The first soft contact lens was created in 1961 in Czechoslovakia by Otto Wichterle.[1] The patent was sold to Bausch and Lomb in 1965, and in 1971 the first commercially available soft contact lens, SofLens, was mass produced (https://www.bausch.com/about-bausch-lomb/history-heritage/, 2023). It has been found that people prefer contact lens wear over other modalities of refractive error correction because of cosmesis, freedom from glasses, and because wearing contacts can allow for a more active lifestyle, among a few of the many reasons.[2, 3] However, because of the optical design of monofocal contact lenses, as patients age and begin to lose the ability to accommodate, monofocal contact lenses become inadequate to fully correct vision at all distances. Other options for fully correcting vision for presbyopes include bifocal spectacles or progressive addition lenses, wearing reading glasses over distance contact lenses, or utilizing monovision, where one eye is corrected for distance vision and the other eye is corrected for near vision with a contact lens. Multifocal contact lenses were originally created so that patients could still enjoy the benefits of contact lenses while also having their refractive error corrected at all distances. One of the earliest multifocal contact lens designs seen are translating gas permeable lenses consisting of a distance prescription in the top half and near prescription in the bottom half of the lens. Vertical eye movements and proper positioning on the lower eyelid cause the primary line-of-sight to translate between the two optical zones.[4] Bausch + Lomb along with Wesley

Jessen were the first to launch a bifocal soft contact lens in the US in 1981 (https://www.bausch.com/about-bausch-lomb/history-heritage/, 2023). Three years later, they launched the first simultaneous vision multifocal called the PA1.[5]

Contact Lens Types

Multifocal contact lenses are optically different than standard monofocal contact lenses. Multifocal contact lenses allow light from near, intermediate, and distant object planes to be simultaneously in focus on the retina.[6] Monofocal contact lenses differ from multifocal contact lenses in design because the power of the lens is based on distance correction only. Meaning that to focus on object planes closer than optical infinity, one must use natural accommodation to add more plus power to the optical system. Accommodation occurs when the ciliary body in the eye contracts, causing lens zonules to relax tension force on the crystalline lens in the eye.[7, 8] Reducing tension on the lens increases the radius of curvature of both the front and back surfaces of the lens, effectively adding more plus power to the optical system and focusing light rays from near objects onto the retina.[8]

Multifocal Contact Lenses

Since their inception, multifocal contact lenses have gained popularity around the world. In 2015, approximately 1.8 billion people had presbyopia. The global unmet need for presbyopia correction at that time was 45%.[9] Of those patients with presbyopia correction, only 16% wore contacts (2011) and of those, less than 33% wore multifocal contact lenses.[10] Morgan et al. investigated global prescribing trends from 2000 to 2020

and found that the percentage of multifocal contact lenses fit worldwide has increased in people over 45 years old.[11] A report published by a global research and marketing company entitled "Contact Lenses Market - Global Outlook and Forecast 2022 – 2027" found that multifocal contact lenses are predicted to "grow at the highest compound annual growth rate" compared to other contact lens designs.[12, 13] The average age of contact lens wearers has also increased, which Sha et al. believes highlights a growing market for presbyopic (or multifocal) contact lenses.[14] It was found that a higher percentage of presbyopic females wear multifocal contact lenses compared to their male counterparts.[11]

Multifocal Contact Lens Design

Two popular soft multifocal contact lens designs are the aspheric design and the concentric ring design. Aspheric designed contact lenses where the distance prescription is localized centrally (known as center-distance lenses) use positive spherical aberrations to increase the depth of focus, while contact lenses with the reading prescriptions localized centrally (known as center-near lenses) use negative spherical aberrations.[15] Aspheric lenses have a gradual power change that extends from the center of the contact lens to the periphery.[16] Concentric ring designed multifocal lenses differ because they have discrete, alternating zones of near and distance prescription power. These types of multifocal contact lenses can have either the distance or reading prescription localized to the center of the lens. The third type of commercially available multifocal contact lens is the extended depth-of-focus (EDOF) designed lens. NaturalVue multifocal contact lens (Visioneering Technologies, Inc.) and Mylo (Mark'ennovy Personalize Care SL,

Majadahonda, Madrid, Spain) are the only commercially available EDOF lenses on the market today (2022). The Mylo EDOF lens was originally designed at the Brien Holden Vision Institute in Sydney, Australia.[17] Their EDOF technology manipulates higher order aberrations to increase the depth of focus. According to developers, these lenses produce a non-monotonic, aperiodic, refractive power variation across the optic zone diameter.[16, 17] The Mylo lens creators used an EDOF design principle that resulted in improved retinal image quality for points on, and anterior, to the retina while points posterior to the retina had reduced retinal image quality.[18] The Mylo lens also produces an EDOF design up to +1.75D, compared to NaturalVue MFCL which claims to cover add requirements up to +3.00D.[18, 19] Though NaturalVue is marketed as center distance, studies have shown that this lens has no discrete distance zone in the center, but rather there is an increase in plus power immediately starting from the center of the lens.[19] Studies that have investigated the power profiles of such lenses demonstrate that this EDOF lens reaches the maximum plus power prescription at around 2.7 mm before switching to a steep decrease in plus power from 2.7 mm to 3 mm. The power at the 3 mm radius is maintained to the edge of the optic zone for low myopic prescriptions. However, it was shown that for higher myopic prescriptions, the plus power continued to decrease to the edge of the optic zone, meaning that in some lenses, the peripheral optic zone had more minus power than the center of the optic zone. The same study found that low distance minus prescriptions have the greatest maximum add power while higher distance minus prescriptions have the least maximum add power.[19]

Multifocal Contact Lenses and Myopia Control

Multifocal contact lenses were originally designed for presbyopic patients who wanted options outside of wearing spectacles. Rueff et al. did a study on presbyopic opinions on contact lenses and found that presbyopic patients are just as motivated to wear contact lens correction as patients without presbyopia.[16] Since the development of multifocal contact lenses, new indications have emerged such as myopia management. Recent research conducted by Smith et al. confirms the leading theory that myopic defocus in the periphery of the eye can control central refractive error progression depending on the eccentricity.[20] The study used 26 young monkeys as test subjects and tracked how lenses with varying annular designs affected emmetropization over 128 days on average. It was determined that myopic defocus had a more pronounced effect on slowing axial length growth of the eye when the signals were more proximal to the fovea compared to more distal signals.[20] Several earlier animal studies had used chicks to demonstrate that competing myopic defocus signals were able to influence both refractive error and axial length during development of the eye.[21, 22] The lenses used had either high plus (+5D) or minus power (-5D) concentrated in either the center or periphery, with varying central zone diameters. This study found that the greatest impact to growth and refractive error occurred when myopic defocus was induced in the periphery of the eye.[21] These consistent findings between the different animal models laid the foundation for clinical trials in humans.

In 2011, the DIMENZ (Dual-focus Inhibition of Myopia Evaluation in New Zealand) study utilized the novel concept of simultaneous constant myopic defocus with clear central vision in developing human eyes (whereas other studies had attempted either

constant myopic defocus with at least one eye having poor distance acuity or myopic defocus at distance only).[23] The study consisted of forty children each wearing a center-distance, +2.00D add multifocal lens on one eye and a single-vision soft contact lens on the contralateral eye. After ten months of full-time wear, the study participants switched which eye was assigned to the multifocal lens, and continued wear for another ten months. The DIMENZ study found that there was a significant difference between axial length growth and spherical refractive error between eyes with the treatment lens on compared to eyes with the control lens on. That same year, Sankuridurg et al. conducted a larger study that also investigated if reducing peripheral hyperopic defocus could slow the progression of myopia in children. Their study showed that multifocal contact lenses were able to reduce the amount of peripheral hyperopic defocus in myopic eyes, compared to spectacle lenses. They reached similar conclusions as the DIMENZ study – there was a reduction in axial length and reduction in myopia progression in eyes wearing multifocal contact lenses.[24]

The Defocus Incorporated Soft Contact (DISC) study reported 46% myopia progression in children using multifocal contact lenses with a +2.50 add, compared to single-vision groups, further proving the efficacy of multifocal lenses in slowing myopia progression.[25] This study was also key in demonstrating that the amount of time spent wearing the treatment lens could impact the amount of myopia progression over time. To be effective, the multifocal lenses had to be worn for at least five hours per day, with increasing duration of wear correlating to decreasing progression of myopia.[25] The Bifocal Lenses in Nearsighted Kids (BLINK) study, conducted over a timespan of 3 years, was able to determine that the magnitude of the add power within the lens can

affect the rate of progression. The +2.50 multifocal contact lens being tested was effective at slowing myopia progression whereas the +1.50D multifocal contact lens was not.[26] It appears that there is also an upper limit between the correlation of myopia control efficacy and add power since lenses ranging from +8.00D to +20.00D of add power are not more effective than lenses with +2.00D of add power.

After the BLINK study report was published, an abstract was presented that challenged the idea that the peripheral myopic defocus between the two lens types used within the BLINK study was the sole cause of the slowed myopia progression.[27] Analysis of the BLINK study determined that only about 15% of the reduction in axial length was due to peripheral myopic defocus. The implications of this study are that although +2.50 add multifocal contact lenses are more efficacious than +1.50 add lenses, peripheral myopic defocus may not fully explain the mechanism of action.[27] A study by Spors et al. found an association between increased higher order aberrations and decreased myopia progression. Specifically, spherical aberrations and coma were found to be greater in multifocal contact lenses with higher add powers.[28]

Although the mechanism of action remains to be fully understood, it is widely accepted that multifocal contact lenses are an effective treatment option in slowing the progression of myopia. Center-distance multifocal contact lenses are typically used for myopia control over the center-near design primarily because these lenses have been shown to be effective at producing myopic defocus in the peripheral retina. However, research is varying about the efficacy of center-near designed lenses at producing myopic defocus and slowing the progression of myopia.[29-31] It has been shown that center-near multifocal lenses are able to produce peripheral myopic defocus, albeit to a lesser extent.

While the difference between how much myopic defocus is produced is not significant (except for at 30 degrees of eccentricity), center-near designs are typically less-tolerated by pre-presbyopes visually.[30] A different study that tested three center-distance multifocal lenses and 1 center-near multifocal contact lens found that the center-near lens caused peripheral hyperopic defocus compared to the other lenses.[29]

Other Multifocal Contact Lens Indications

Prior to 2019, multifocal contact lenses (MFCLs) were off-label for myopia control treatment. Currently, only two contact lenses are indicated specifically for myopia control in the United States - Abiliti™ and MiSight™ (2022). Only MiSight has been FDA approved for the slowing of the progression of myopia in children. Another off-label use for MFCLs may be treating binocular vision problems. A case study conducted by Zaunbrecher and Dattolo found that some non-presbyopic patients who suffer from headaches and accommodative infacility or insufficiency may benefit from multifocal contact lenses. Their small, retrospective study saw improvement in objective measurements such as NRA/PRA, push-up amps, and near vergences, and reduced symptoms of frequent headaches, visual acuity fluctuations, and inability to translate from near to far (Zaunbrecher AC, Dattolo JA, AOA Abstract, 2019). Many studies have reported little to no change in accommodative effort using multifocal contact lenses,[32-34] but Tarrant et al. found that MFCLs had the potential to transform accommodative lag into accommodative lead in some myopic patients.[35]

The Future of Multifocal Contact Lenses

Based on a search of recent patent literature, MFCL designs may continue to evolve in the near future.[36, 37] One proposed design uses Fresnel-like prism to shift the focal points of peripheral light rays anteriorly in front of the retina.[37, 38] Another novel design would involve creating small regions of add power off-axis creating islands of myopic defocus.[37, 39] As discussed earlier, multifocal contact lenses overall have continued to improve in design, function, and performance over time.

Side Effects of Multifocal Contact Lenses

While the benefits of multifocal contact lenses are exciting to consider, it is important to address the unique challenges that come with this type of soft contact lens. In the last decade, much research has been done to investigate MFCL performance, including testing high contrast visual acuity, low contrast visual acuity, light aberrations, and subjective performance.[14, 40-45] Studies have shown that high contrast visual acuity is usually comparable to single vision contact lenses, but low contrast acuity is reduced in multifocal contact lenses.[14, 41] Furthermore, a study by Rae et al. showed that negative spherical aberrations in single vision contact lenses resulted in better high and low contrast visual acuities. [44, 46] Since center-distance multifocal contact lenses utilize positive spherical aberrations, this likely contributes to the reported decline of low contrast visual acuity. However, the DIMENZ study found that children who wore a dual focus contact lens on one eye did not show a statistically significant difference between

visual acuity or contrast sensitivity (using the Pelli-Robson chart) compared to the other eye wearing a single vision distance lens.[23, 41]

Another commonly reported side effect of multifocal contact lens usage is glare.[14] A study by Gregory et al. found that induced glare did not result in a lower visual acuity compared to single vision contact lenses, however patients may still subjectively report it as an issue.[41] One study investigated the effect of MFCL design on the sensitivity of glare and contrast. Biofinity center-near and center-distance designs were compared to single vision lenses (spectacles and contact lenses). Results from the study found that center-distance MFCLs had higher amounts of glare ($p<0.001$) and contrast sensitivity was reduced under glare conditions. Contrast sensitivity was reduced in both glare and non-glare conditions for the center-near designed MFCL, but there was no significant amount of glare produced by the lens itself. In fact, subjects reported that center-near MFCL glare was comparable to that of single vision contact lenses and lenses in a trial frame.[47]

Ghosting and haloes may also be a significant negative side effect of multifocal contact lenses, due to the various prescription powers located within the optic zone of the lens.[14, 48] Fedtke et al. discovered that the increase in even and/or odd higher order aberrations caused an increase in ghosting symptoms with several types of multifocal contact lenses. Factors like decentration, add power, pupil size, and lens design have been shown to correlate with the amount of ghosting.[44] Kollbaum et al. completed a study that focused on ghosting as a side effect of multifocal contact lenses. The study aimed to determine if aspects of ghosting could be effectively rated; then, a validated questionnaire created in the first part of the study was used to assess the ability to perceive ghosting. It was found that the four attributes of ghosting (direction, intensity, offset, and blur) can be

quantified with high accuracy. This study also found that the perception of ghost images with MFCLs is strongly associated with how displaced and how clear the ghost image is. They concluded that higher add powers in lenses may cause noticeable ghosting for patients if the lens in significantly decentered, according to Prentice's Rule.[49] Because the design of MFCLs is so different from single vision contact lenses, and because these lenses can cause a unique set of visual complications, practitioners are tasked to assess performance in alternative manners.

Objective and Subjective Performance Evaluation

In clinical settings, contact lens performance is typically assessed objectively, with the clinician measuring high contrast visual acuity to determine if the patient's vision is acceptable or not. Other objective measurements that may be helpful with multifocal contact lenses include low contrast visual acuity and contrast sensitivity testing, to a limited extent. However, due to visual complications such as ghosting, glare, and haloes, it's been suggested that subjective assessments may be more sensitive and accurate when evaluating the performance of a multifocal contact lens.[42, 50] One study found that over a period of 4 days, high-contrast visual acuity did not significantly change among a group of subjects wearing MFCLs, but there was a decreased quality of vision when asked about factors such as ghosting, haloes, and visual fluctuation. The study noted how the objective, chart-based assessments did not appear to be sensitive enough to detect subjective changes in performance. They concluded that subjective responses are one of the most helpful indicators of the individual's status, while traditional acuity-based methods are generally unhelpful.[48] Studies by Dr. Rueff et al.

dive into why there may be discrepancies between subjective and objective assessments. Their work brings to light the fact that ocular findings don't always correlate with patient reported symptoms, especially when it comes to discomfort. One study found that in the absence of ocular surface disruptions, some patients can experience visual discomfort and it can be difficult to differentiate the two.[16] Therefore, specific subjective assessments can be a valuable tool to help measure contact lens performance. Clinicians may simply choose to ask about visual symptoms while gathering a history of present illness from the patient, or may choose to utilize a questionnaire, many of which have been validated.

A few examples of vision-related questionnaires are the National Eye Institute Visual Function Questionnaire (NEI-VFQ), Orthokeratology Contact Lens QoL questionnaire (OCL-QoL), National Eye Institute Refractive Error Quality of Life questionnaire (NEI-RQL), Contact Lens Dry Eye Questionnaire (CLDEQ-8), and Contact Lens Impact on Quality of Life (CLIQ) questionnaire. Questionnaire administration has become more acceptable as the standard of care as healthcare shifts from being more doctor-focused to being more patient-focused.[51] Visual quality can also be quantified using numeric rating scales (i.e. 0 -100), visual analog scales, and Likert scales, which all have similar capabilities in the presence of minimal spherical defocus.[49] A study by Kollbaum et al. created a validated survey assessing ghosting and found that there was overall agreement between the validated questionnaire and a 0-100 numeric rating scale.[49] Clinically, this suggests that creating simple surveys using scales can be a great tool for eyecare practitioners to use, even in the absence of access to validated surveys. Subjective assessments are easy to administer, sensitive to detecting visual performance,

readily available, patient-centered, and clinically useful. For these reasons, questionnaires were used as primary outcome measures in the following study.

Contact Lens Comfort

Aside from vision, it is also important for practitioners to address comfort in contact lens wearers. In 2013, contact lens discomfort was defined by the International Workshop of Contact Lens Discomfort as a condition characterized by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation of contact lens wear".[52, 53] This group also began their report by acknowledging that the underlying cause of contact lens discomfort is multifactorial and difficult to attribute to one specific parameter. Understanding comfort is important to help prevent contact lens dropout.

Pucker et al. found that neophyte contact lens wearers are more likely to drop out due to unsatisfactory vision while established contact lens wearers drop out due to unsatisfactory comfort.[54] Therefore, comfort and vision are equal motivators for contact lens dropout.[16] Although there can be an economical benefit to reducing contact lens dropout in patients, in some areas of optometry (like myopia management), a patient choosing to continue or discontinue contact lens wear can be the difference between success and failure of treatment. Lam et al. found that myopia progression is inversely proportional to CL wear time.[55] Therefore, comfort is a key factor to take note of when assessing contact lenses of any modality. Discomfort is thought to be associated with ocular surface findings or contact lens parameters such as lens material or oxygen

transmissibility. Discomfort has also been associated with contact lens solution and replacement schedule.[53] One study by Rueff et al. suggests that differences between comfort scores or preferences may be due to optical differences of a MFCL compared to single vision soft contact lenses.[16] The study that this idea was derived from looked at the Bausch and Lomb Ultra spherical soft contact lens and Bausch and Lomb Ultra for Presbyopia, a center-near aspheric MFCL. They found that even though the base curve, diameter, and material for each lens was the same, subjects had different perceptions of vision and comfort. This may imply that the reduced visual quality of some multifocal lenses is perceived as reduced "visual comfort" by some groups and can affect patient responses when asked about the blanket term "comfort".

The first step in the contact lens discomfort sequence includes the patient having physical awareness and visual disturbance.[56] The next steps include reduced comfortable wear time, reduced total wear time, temporary discontinuation, and finally permanent drop-out.[56] While the study did show that there was a difference in comfort between multifocal contact lenses and single vision contact lenses, it is unclear whether the design of the multifocal (aspheric, extended depth of focus, concentric rings) affects the amount of comfort perceived. A larger crossover study was later conducted that fit 84 pre-presbyopic contact lens wearers in both single vision and multifocal contact lenses. There were no differences in comfort scores between the lens types, however, younger patient had more symptomatic scores when comparing multifocal contact lenses to single vision contact lenses.[57] This suggests that age may also contribute to comfort while wearing multifocal contact lenses. Contact lens comfort may have temporal variations, suggested by research by Woods, Bentley, and Fonn.[58] Contact lens discomfort is a multi-faceted

problem with no singular, underlying etiology. Research continues to develop with the goal of reducing discomfort among all contact lens wearers.

Study Aims and Outcomes

The aim of this study was to measure quality of vision and ocular comfort in non-presbyopic, adult subjects who wore up to 4 different commercially available multifocal contact lenses (MFCL) applicable to myopia management. What made this study different from other studies that compare MFCLs were the lenses chosen, the number of lenses compared, and the age group of the study population. Young adults were evaluated instead of children because adults are able to provide descriptive feedback more easily. However, presbyopic participants were excluded from this study in order to more closely mimic the accommodative ability found in children. While the current literature shows that research has been done to compare two or three lens types within a study, very few studies directly compare four different lenses that are commercially available. All of the lenses used in this study were center-distance design, in order to better translate the results into myopia control application. The lenses chosen in this study incorporated every current multifocal lens design: aspheric, concentric rings, and EDOF. The lenses also span from 1 day disposable to quarterly disposable. This study differs from similar studies in that it primarily utilizes subjective performance assessments to measure outcomes compared to objective assessments.

METHODS

Overview

This study was conducted in accordance with the tenets of the Declaration of Helsinki. Written informed consent was acquired from all subjects prior to study participation and the study was approved by the Institutional Review Board of the University of Alabama at Birmingham. This was a single-site, randomized, partially double-masked crossover trial. Up to 60 subjects were recruited, ages 18 to 35, from Birmingham, Alabama, and the surrounding areas via word of mouth, postcards, email, social media postings (Facebook), flyers, and UAB Eyecare clinic records. Each subject was fit binocularly with up to 4 different contact lenses, depending on refractive error limitations and contact lens fit.

Contact Lenses

The four available lenses were Biofinity "D" center-distance multifocal with +2.50 add power (comfilcon A, CooperVision, San Ramon, CA), NaturalVue Multifocal contact lens (etafilcon A, Visioneering Technologies, Alpharetta, GA), MiSight 1 Day (omafilcon A, CooperVision, San Ramon, CA), and Intelliwave Pro (efrofilcon A, Art Optical Contact Lens, Walker, MI). The Biofinity D multifocal is indicated for daily wear and monthly replacement. It has a 48% water content and spherical lens parameters ranging from +6.00 D to -12.25 D of refractive error correction. It has a toric multifocal option correcting up to -5.75 D of cylinder power. The NaturalVue Multifocal contact lens is indicated for daily wear and replacement. It has 58% water content and spherical

lens parameters ranging from +4.00 D to -10.00 D of refractive error correction. The lens is described as center-distance but does not have a discrete “add power” zone; instead, it uses extended depth-of-focus technology to induce up to +3.00 D of add power. The MiSight 1 Day multifocal has a daily disposal replacement schedule. It has a 60% water content and spherical lens parameters ranging from -0.50D to -7.00D of refractive error correction. There is currently no toric lens option. The multifocal is described as has having dual-focus concentric ring design with alternating distance correction (in the center of the optic zone) and +2.00D of add power. The Intelliwave Pro multifocal is indicated for daily wear (up to all waking hours) and monthly replacement (up to 6 months). It has a 74% water content and spherical lens parameters ranging from -20.00 D to +20.00 D of refractive error correction (with less than -0.75D of cylinder power). The toric multifocal lenses correct astigmatism of up to 4.00 D in power. The multifocal comes in either center near or center distance design that contributes up to +4.00D of add power. For this study, +2.50D of add power was used. Intelliwave Pro incorporates freeform stabilization which uses peripheral balance zones that interact with the lid for better positioning. These lenses also use aberration control and deliver enhanced contrast sensitivity, according to the manufacturer. This particular lens claims to have a “multi-aspheric front surface” which allows for simultaneous clear vision at all distances. See Table 1 for a full list of contact lens parameters. Each of the four contact lenses were fit binocularly in random order over the course of up to 6 study visits. Subjects and examiners were masked to all contact lens brands except for MiSight and NaturalVue, the two daily disposable lenses.

Eligibility

The subjects were required to be within 18 – 35 years of age (inclusive) and have previous soft contact lens wear experience, have vision correctable to 20/30 or better, and have refractive error between +6.00 D and -20.00D. Exclusion criteria for the study included history of ocular surgery or severe ocular trauma, active infection or inflammation, keratoconus, retinal abnormalities, strabismus, reduced amplitude of accommodation (according to Hofstetter's formula), greater than 8 prism diopters of exophoria at near,[59] less than 30 degrees of local stereoacuity, or pregnant or nursing women. Subjects with any condition or situation which the examiner believed might put the subject at risk or confound study results were excluded from the study.

Baseline Visit

After potential subjects were screened, subjects were invited to the baseline visit where the informed consent document was distributed and signed. All subjects were asked to wear their glasses at the baseline visit. High-contrast visual acuity (HCVA) of left and right eyes were measured at 20 feet using the Bailey-Lovie Chart. Near visual acuities were recorded in bright lighting using a near card held at 40 cm. Acuities were recorded in Logarithm of the Minimum Angle of Resolution (LogMAR) format. Subjects filled out the Vision Quality Survey using Research Electronic Data Capture (REDCap) software.[60, 61] Subjects answered the questions at the baseline visit based on their current form of refractive error correction. Pupil size was measured under photopic lighting conditions and mesopic lighting conditions using an optometric millimeter ruler to the nearest 1 mm. Illuminance was recorded using a Lux Meter (Dr. Meter, Hong Kong). A secondary pupil size measurement was taken using the Grand Seiko WR-5100K

autorefractor. The autorefractor was used to obtain an estimate of each subject's prescription; then, the prescription was refined subjectively using a phoropter. Binocular vision testing included the unilateral and alternating cover test at distance and near (40 cm) as well as using a stereo acuity card to test stereopsis. Amplitude of accommodation of each eye was measured using the push-up method three times per eye and averaging the results. A slit lamp biomicroscope was used to document normal or abnormal anterior segment findings. Up to four pairs of contact lenses were ordered per subject, based on what each subject qualified for, and a follow-up visit was scheduled. Qualification was determined by each person's refractive error and the available parameters for each contact lens brand. Subjects with ≥ 0.75 D of cylinder power in their vertexed contact lens prescription in at least one eye were fit into MFCL brands that allowed for toric correction (Biofinity and Intelliwave). Subjects with hyperopia were fit into MFCL brands that allowed for hyperopic correction (NaturalVue, Biofinity, and Intelliwave). Subjects with ≤ 0.50 D of cylinder power in their vertexed contact lens prescription were fit into a spherical contact lens determined by calculating the spherical equivalent; those subjects were eligible to be fit in all four lenses unless they were hyperopic (ineligible for MiSight) or had a prescription that was outside of the parameters listed in Table 1. SAS (Cary, NC) code was used to generate a random order of contact lens wear for each subject.

Visit Two

Each subject returned within 2 weeks from the initial baseline visit. At this visit, high-contrast visual acuity of left and right eyes was measured at 20 feet using the Bailey-Lovie Chart for each of the four lenses (as eligible). Near visual acuities were

recorded (left and right eyes respectively) in bright lighting using a near card held at 40 cm. Acuities were recorded in LogMAR format. Stereoacuity (seconds of arc, RANDOT, Stereo Optical, Chicago, IL), distance and near cover test, and biomicroscopic examination were performed while the subjects wore each of the lenses. The lenses and order that the lenses were to be worn were deidentified, randomized and double-masked to the subject and investigator. The subject was given Lens 1 to take home and instructed to wear the lenses for 5 consecutive days for at least 8 hours per day. Each subject was also properly educated on contact lens hygiene and maintenance.

Follow Up Visits

The next follow up visit was scheduled on the subject's last day of contact lens wear, and all measurements from visit two were repeated (high contrast visual acuity, cover test, stereopsis, biomicroscopic examination). Additionally, the subjects were asked to complete the Vision Quality Survey using REDCap software, based on their experience wearing the lens for the past 5 days. The second lens was distributed at the conclusion of this visit and the subject given the same instructions described above for how and when to wear the lens and return for the next visit. This was repeated until the subject had worn all lenses that they were qualified for. At the subject's last visit, in addition to the previous testing described, the subject was given a contact lens brand comparison survey that compared each lens worn to the other lenses. After the survey was completed the subjects were released from the study (Figure 1). Subjects were compensated for each visit that was completed.

Subjective Questionnaire

The Vision Quality Survey was composed of several questions that addressed a wide range of visual scenarios. Each survey question utilized a 1-10 interval in 1-unit steps. Comfort was assessed by asking about overall ocular comfort and comfort at the end of the day yesterday just before contact lens removal (1 = uncomfortable, 10 = comfortable). Common side effects of MFCLs were addressed by asking about overall ghosting during the daytime and nighttime (1 = none, 10 = severe), haloes during the nighttime (1 = not bothersome, 10 = bothersome), and vision stability during the daytime and nighttime (1 = very stable, 10 = very unstable). Vision quality was assessed by asking about driving vision during the daytime, nighttime, and overall (1 = blurred, 10 = clear). Vision quality was also assessed by asking about clarity of vision while viewing far away objects and near objects (1 = blurred, 10 = clear). Subjects were also asked to assess overall vision satisfaction (1 = not satisfied, 10 = satisfied). The Contact Lens Brand Comparison Survey was completed at the end of the study, and all subjects were presented with 9, forced-choice questions that assessed MFCL preference. The questions queried which contact lens felt the most and least comfortable to wear all day, which contact lens provided the best vision when looking at near and far objects respectively, which contact lens provided the best vision at all distances overall, which contact lens provided the best nighttime vision, which contact lens provided the best daytime vision, which contact lens was the subject most likely to purchase, and which contact lens was the subject least likely to purchase.

Statistical Analysis

Data were collected with Research Electronic Data Capture (REDCap) and exported for analysis into Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA). STATA/IC 17 (StataCorp LLC; College Station, TX, USA) was used to calculate all statistical analyses. Descriptive statistics are presented as medians and interquartile ranges (IQRs) and analyzed with non-parametric statistics given that the sample was small and not normally distributed. Categorical variables were summarized as percentages. The Kruskal-Wallace test was used to determine if differences existed between refractive error classification, multifocal contact lens type, or pupil sizes. The Wilcoxan rank-sum (Mann-Whitney U) test was used to compare subjects with and without astigmatism. Statistical significance was set at a $p < 0.05$.

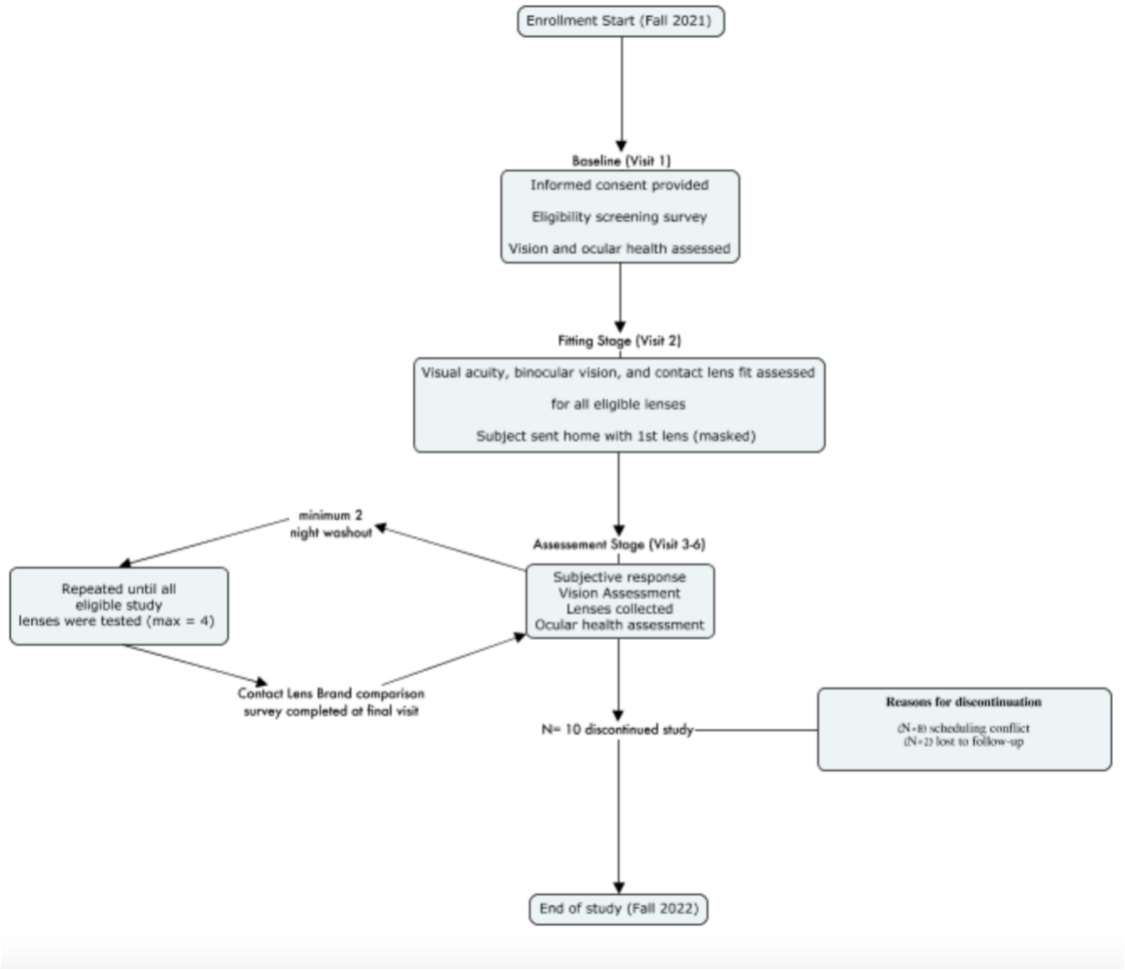

Figure 1. Participant flow chart.

Table 1. Contact lens parameters. Contact lens parameters of the four different center-distance, commercially available contact lenses used in the study. Refractive error = RE.

	Biofinity MF	**MiSight**	**NaturalVue**	**Intelliwave PRO**
# of subjects eligible based on RE	43	28	28	43
# of subjects successfully fit	40	19	28	38
Company	CooperVision	CooperVision	Visioneering Technologies	Art Optical
Material	Comfilcon A	Omafilcon A	Etafilcon A	Efrofilcon A
Water Content	48%	60%	58%	74%
Base Curve (mm)	8.6	8.7	8.3	7.8 – 9.5
Diameter (mm)	14.0	14.2	14.5	13.0 – 15.0
Sphere Power (D)	+6.00 to -10.00 (0.50D steps after -6.00D)	-0.50 to -7.00 (0.50D steps after -6.00)	+4.00 to -12.25	+20.00 to -20.00
Toric Option Available?	Yes	No	No	Yes
Addition Power (D)	+2.50	+2.00	Up to +3.00	Up to +4.00
Oxygen Permeability (Dk)	128	33	28	60
Oxygen Transmissibility (Dk/t)	160	~32	25.5	~20; variable
Modulus (MPa)	0.75	0.30	0.31	0.35
Design	Aspheric	Concentric rings	Extended depth-of-focus	Multi-aspheric front surface

RESULTS

Demographics and Dropout

Fifty-three subjects (n=53), ages 18 to 35, began the study while forty-three subjects (n=43) completed the study in its entirety. Sixteen out of the forty-three subjects successfully wore all four contact lenses, 9/43 wore 3 different contact lenses, 17/43 wore two different contact lenses, and 1 subject wore only one of the four contact lenses. Of the 43 that completed the study, 41 subjects completed the exit survey. Subject demographics are shown in Figure 2., including age, sex, refractive error (spherical equivalent, right eye), and race. The most common reason for discontinuing the study was related to scheduling (n=8). Additionally, two (n=2) subjects were lost to follow-up and thereby unable to compete the study. Of those who completed the study, 74% were female. Ten percent of study participants identified as Hispanic, 53% as white, 33% as Asian, and 15% as African American. Subjects who were classified as having low to moderate myopia, defined as refractive error with a spherical equivalent of less than 6 diopters of myopia, made up 70% of the study population. Subjects with high myopia, defined as refractive error with a spherical equivalent of 6 diopters or more of myopia, made up 25% of the study population.62 Subjects with hyperopia made up 5% of the study population. The refractive error cut-off values referred to the spectacle prescription and were not based on the vertexed contact lens prescription. About 30% of the study participants had clinically significant astigmatism, defined as being -0.75 or more

diopters in either eye. This value was derived based on the lowest amount of cylinder power manufactured in contact lenses, and findings by Gaib and Vasudevan that reported no significant difference in visual quality between patients with low amounts of cylinder.63 All study participants had a history of contact lens wear, while 18% of subjects did not habitually wear contact lenses at the time of the study.

Contact Lens Qualifications

Biofinity multifocal and Intelliwave were the most inclusive lenses, with 93% and 88% of subjects able to be successfully fit in each lens, respectively. Sixty-five percent of participants were able to wear NaturalVue multifocal lenses and 44% were able to wear MiSight lenses. The study participants who wore the MiSight lenses were the least diverse in refractive error type, as no hyperopic participants wore this lens, and only 16% of participants with clinically significant astigmatism were able to wear this lens. Intelliwave and Biofinity had the most diverse refractive profile range, as all subjects with clinically significant astigmatism and all hyperopic participants were able to wear both lenses. Sixteen percent of participants with clinically significant astigmatism and all hyperopic participants were able to wear the NaturalVue lens. Overall, most study participants reported good vision, comfort, and minimal visual side effects secondary to aberrations when using their habitual correction (spectacles, spherical soft contact lenses, and toric soft contact lenses).

Effect of Pupil Size

Pupil sizes in ambient lighting (Lux meter values ranging from 222 to 285 lux) ranged from 3 millimeters to 6 millimeters. The average pupil size in this lighting was 4.4 millimeters. Pupil size in dim lighting (Lux meter values ranging from 22 to 55 lux) ranged from 4.5 millimeters to 8 millimeters. The average pupil size in this lighting was 6.0 millimeters. When the study population was divided into those with larger pupils (greater than or equal to 6 mm in dim lighting) and those with smaller pupils (less than 6 mm in dim lighting), there was no statistically significant differences found between the two groups in terms of clarity of vision at distance, clarity of vision at near, overall ghosting during the daytime, overall ghosting during the nighttime, and haloes during the nighttime (See Figure 3). There were 19 subjects in the smaller pupil group. Seventeen out of the nineteen patients had a pupil size of 5.5 millimeters. Two of the nineteen patients had a pupil size of 4.5 millimeters. There were 22 subjects in the larger pupil group. Twelve of the twenty-two subjects had a pupil size of 6 millimeters. Ten of the twenty-two subjects had a pupil size of 7 millimeters. One subject had a pupil size of 6.5 millimeters and one subject had a pupil size of 8 millimeters (See Figure 3).

Comparison to Habitual Correction

When subjects were asked to assess overall clarity of vision, all multifocal lenses were ranked as less clear compared to habitual correction (median [IQR] of 9.0 [1.0]) except for Biofinity (median [IQR] of 9.0 [2.0]) ($p=0.0001$). However, when subjects were specifically asked to assess clarity of vision at near and clarity of vision at distance,

all multifocal contact lenses were perceived to be less clear than the habitual correction (median [IQR] of 9.0 [2.0]) (p=0.0001). On average, there was no ghosting either during the daytime or nighttime reported for habitual correction, compared to the MFCLs used in this study, where all had at least some measure of ghosting reported as a side effect (p=0.0001). The median ranking for overall vision stability, where 1 was "very stable" and 10 was "unstable", was less favorable in all MFCLs compared to habitual correction (2.0 [3.0]) (p=0.0001). Haloes during the nighttime (1 is "not bothersome" and 10 is "bothersome") were ranked to be more bothersome for all MFCLs compared to habitual correction (median [IQR] is 2.0 [2.0]) (p=0.0039). Of the four MFCLs, none had an overall higher visual satisfaction (1 is "not satisfied" and 10 is "satisfied") ranking compared to the habitual correction (median [IQR] is 9.0 [2.0]) (p=0.0001). When subjects were asked to assess overall ocular comfort, each subject's habitual correction and NaturalVue had median ratings of 9.0 [2.0] and 9.0 [3.0] respectively (p=0.0001). When subjects were asked to assess comfort at the end of the day, just before contact lens removal, NaturalVue had a median rating of 9.0 [5.0], followed by Biofinity (8.0 [4.0]), each subject's habitual correction (8.0 [5.0]), MiSight (4.0 [5.0]), and Intelliwave (3.0 [7.0]) (p=0.0001).

Perception of Visual Quality

The results from the contact lens survey showed that there was a statistically significant ($p < 0.05$) difference between lenses regarding questions about clarity of vision and vision stability. Clarity of vision at distance was rated most favorably for MiSight

with a median [IQR] rating of 8.0 [3.0], followed by Intelliwave with 7.0 [3.0], NaturalVue with 5.0 [3.5], and lastly Biofinity with 4.0 [4.0] ($p = 0.0019$). Clarity of vision at near was highest for Biofinity, with a rating of 9.0 [2.0], followed by NaturalVue with a rating of 8.0 [3.5], and lastly MiSight (7.0 [3.0]) and Intelliwave (7.0 [4.0]) ($p = 0.0234$).

Overall vision clarity was ranked highest for Biofinity, with a rating of 9.0 [2.0], followed by MiSight with a rating of 8.0 [3.0], then Intelliwave 7.0 [3.0], and finally NaturalVue 6.0 [2.0]. When asked about clarity of vision at near, there was a statistically significant difference between subjects with low/moderate myopia (8.0 [3.0]), high myopia (9.0 [3.0]), and hyperopia (9.0 [4.0]). The survey questions used a 1 – 10 scale where "1" was most blurry and "10" was most clear. There was no statistically significant difference in how the survey questions were answered between those participants with clinically significant astigmatism and those without. When overall vision stability was analyzed, participants were asked to rank each lens on a 1 – 10 scale where "1" was very stable and "10" was unstable. Biofinity was ranked most favorably with a median rating of 3.0 [3.0]. MiSight had a median rating of 4.0 [5.0]. NaturalVue, with a median rating of 5.5 [3.0], and Intelliwave, with a median rating of 5.0 [5.0] were ranked the lowest. There were no statistically significant differences between lenses for questions regarding daytime ghosting, nighttime ghosting, haloes during the nighttime, or overall vision satisfaction.

Perception of Comfort

There was a significant difference ($p = 0.0009$) between MFCL types when subjects were asked to assess overall ocular comfort (1 = uncomfortable, 10 = comfortable). Intelliwave had a median rating of 5.0 [5.0], followed by Biofinity and MiSight with a median rating of 8.0 [3.0], and NaturalVue with a median rating of 9.0 [3.0]. There was a significant difference ($p = 0.0001$) between MFCL types when subjects were asked to assess comfort at the end of the day, just before contact lens removal (1 = uncomfortable, 10 = comfortable). Intelliwave had a median rating of 3.0 [7.0], followed by MiSight with a median rating of 4.0 [5.0]. Biofinity had a median rating of 8.0 [4.0] and NaturalVue had a median rating of 9.0 [5.0]. There was a significant difference ($p = 0.03$) between refractive error types when subjects were asked to assess comfort at the end of the day, just before contact lens removal. Subjects with low to moderate myopia reported a median rating of 6.5 [6.0]. Subjects with high myopia reported a median rating of 8.0 [5.0]. Subjects with hyperopia reported a median rating of 9.5 [1.0]. There was no statistically significant difference in ocular comfort or comfort at the end of the day between subjects with clinically significant astigmatism and those without. Tables 2 and 3 further detail the comfort and vision results.

Brand Comparison Survey Results

Of the 43 participants who completed the study, 41 finished the Contact Lens Brand Comparison exit survey (n=41). When asked about comfort, 37% of respondents said that Biofinity was the most comfortable, followed by MiSight (27%), NaturalVue

(22%), and Intelliwave (17%). Fifty-nine percent of the respondents said that Intelliwave was the least comfortable followed by Biofinity (32%), NaturalVue (7%), and MiSight (2%). When asked about best distance vision, 46% of subjects preferred Biofinity, followed by Intelliwave and MiSight (27% for both). NaturalVue was not preferred by any subject for this question. When asked about best near vision, 51% of subjects chose Biofinity, followed by MiSight (29%) and Intelliwave (20%). NaturalVue was not preferred by any subject for this question. When asked about best vision at all distances overall, Biofinity was preferred by 49% of subjects, followed by MiSight (29%) and Intelliwave (22%). When asked about best daytime vision, 49% of subjects preferred Biofinity, followed by MiSight (29%) and Intelliwave (22%). When asked about best nighttime vision, 49% of subjects preferred Biofinity, followed by MiSight (27%) and Intelliwave (24%). NaturalVue was not preferred by any subjects for any of these questions. When subjects were asked which contact lens they were most likely to purchase, 54% responded with Biofinity, followed by MiSight (27%), followed by Intelliwave (20%). When subjects were asked which contact lens they were least likely to purchase, 54% chose Intelliwave, 44% chose Biofinity, and 2% chose MiSight. No subjects chose NaturalVue as most likely or least likely to purchase. See Figures 6 and 7 for brand comparison survey results.

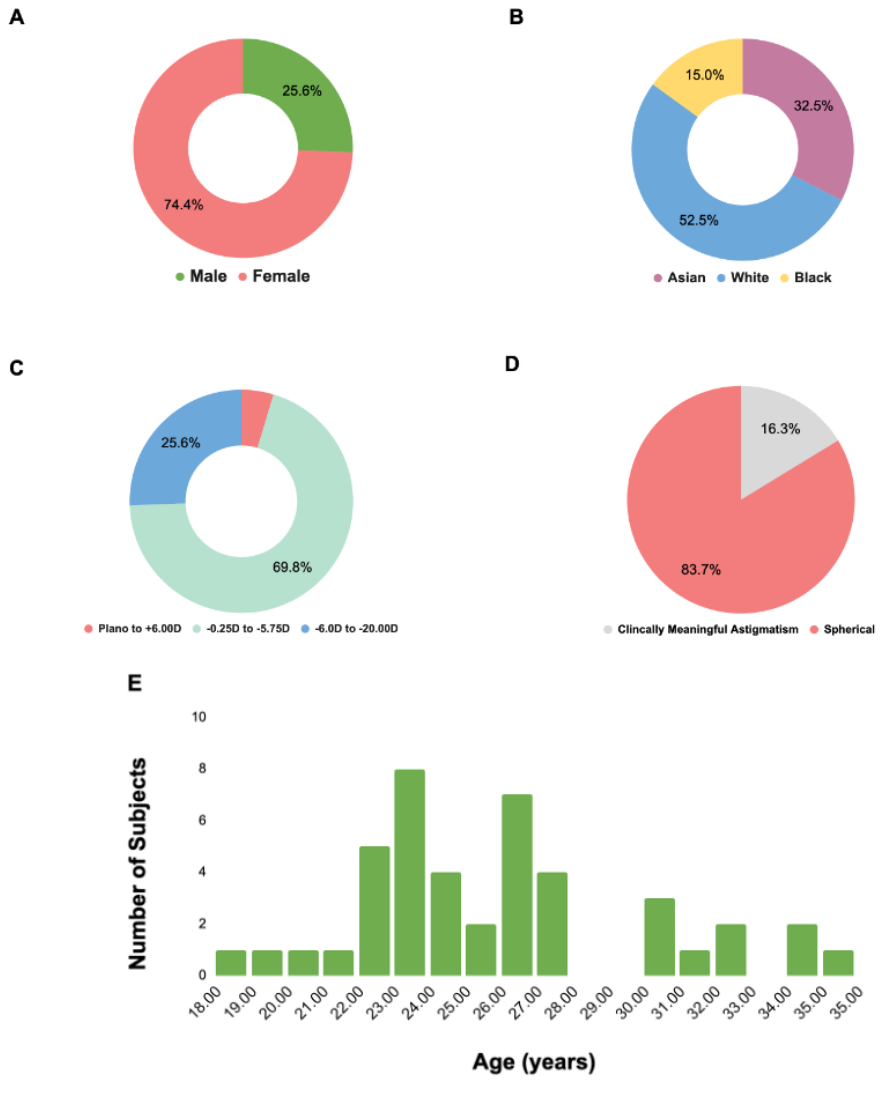

Figure 2. Demographic data of study participants. (A) Sex of participants. (B) Race of participants. (C) Refractive error of participants divided into those with hyperopia, low to moderate myopia, and high myopia. (D) Refractive error of participants divided into those with clinically meaningful astigmatism and those without astigmatism. (E) Age distribution within the study population.

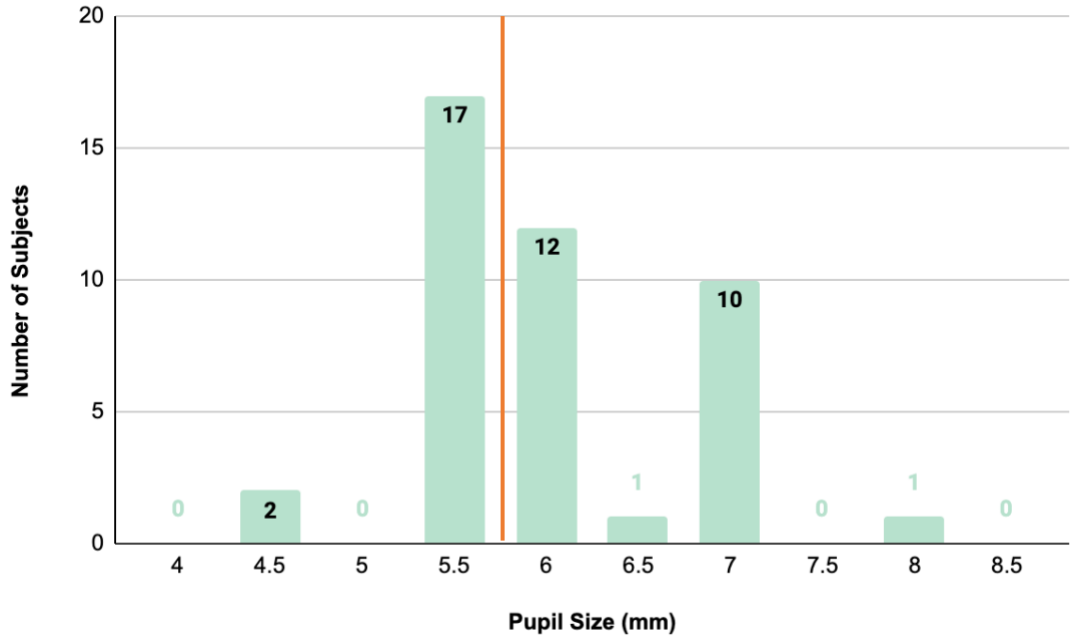

Figure 3. Distribution of pupil sizes within the study population. This chart displays the various pupil sizes in dim lighting within the study population and how many subjects accounted for each pupil size. The orange line represents the separation between large and small pupils with the subjects to the left of the line having "smaller pupils" and those to the right of the line having "larger pupils" within the study. Twenty-nine out of 43 subjects had a pupil size of either 5.5 or 6 mm.

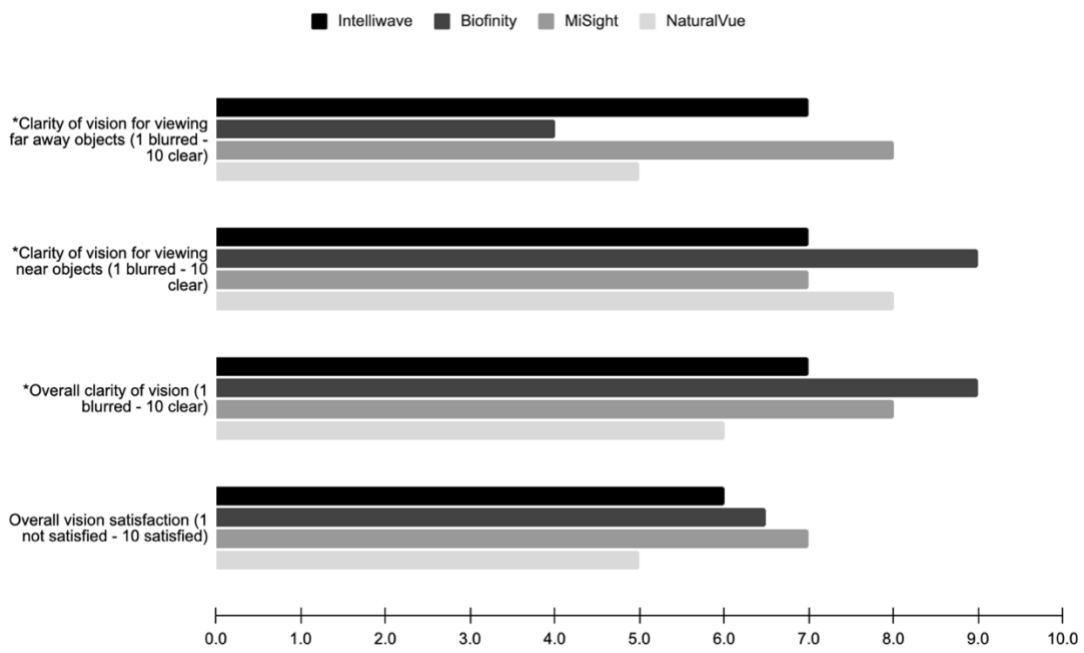

Figure 4. Vision Quality Survey. This chart displays four of the eight analyzed questions derived from the vision quality survey, with the first 3 questions having statistically significant differences between the four contact lenses. The scale on the x-axis ranges from 1 to 10, with "1" representing the most unfavorable experience and "10" representing the most favorable experience.

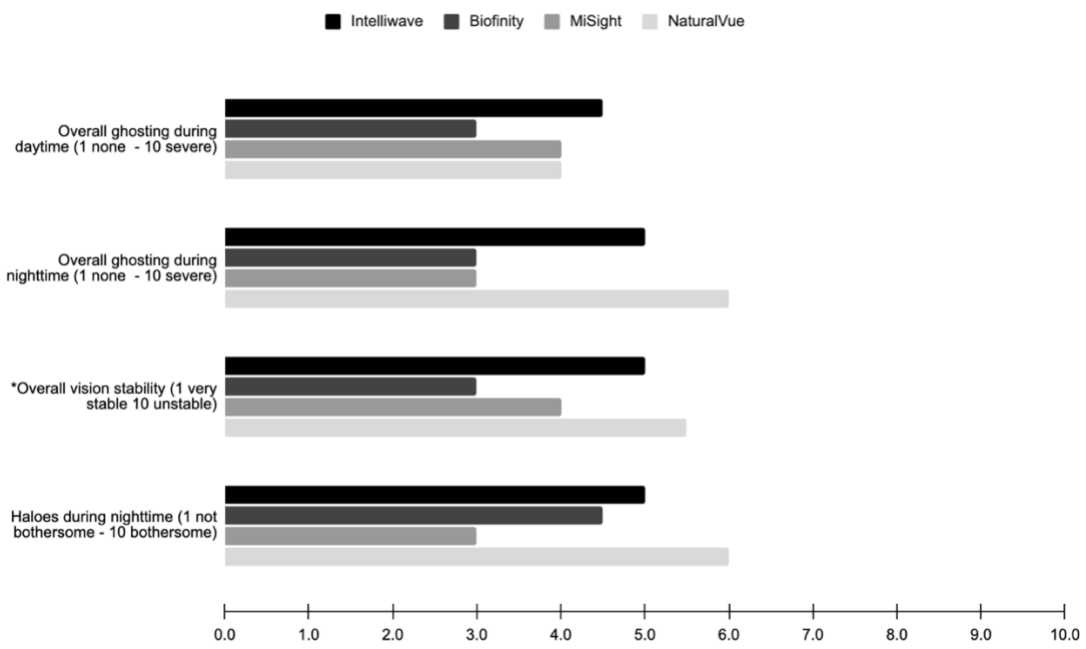

Figure 5. Vision Quality Survey with inverted scale. This chart displays four of the eight analyzed questions derived from the vision quality survey, with the third question having statistically significant differences between the four contact lenses. The scale on the x-axis ranges from 1 to 10, with "1" representing the most favorable experience and "10" representing the most unfavorable experience.

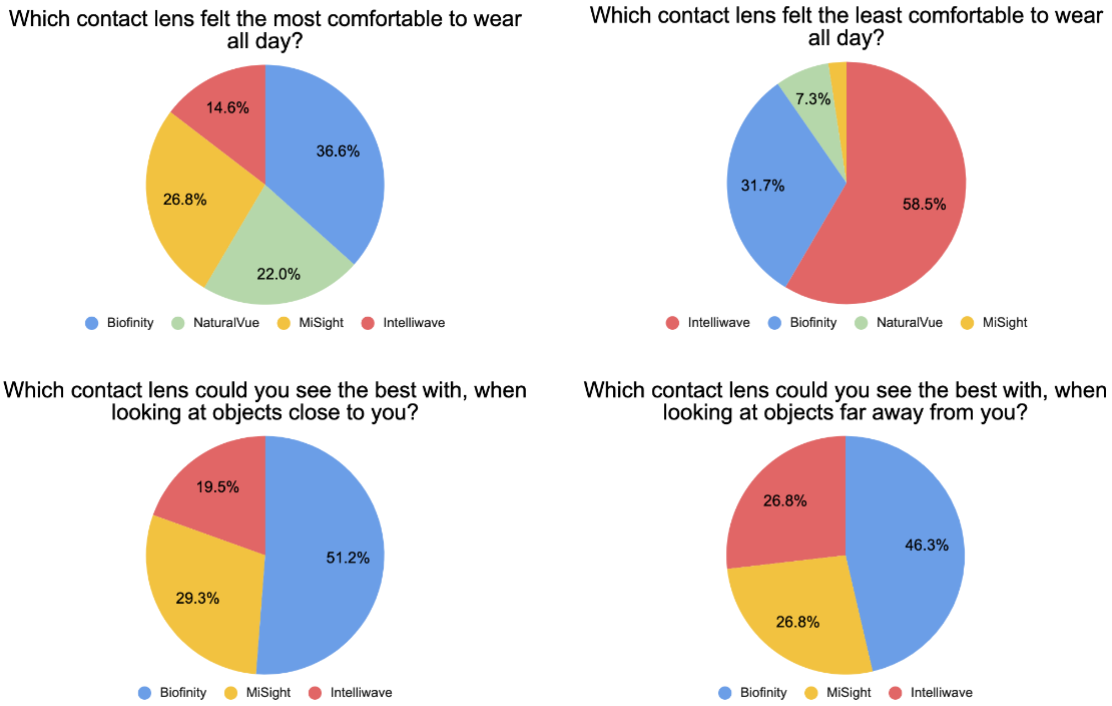

Figure 6. Brand comparison survey results. Shown in the figure are four of the nine questions of the brand comparison survey and the percentage of respondents who chose each lens for each question.

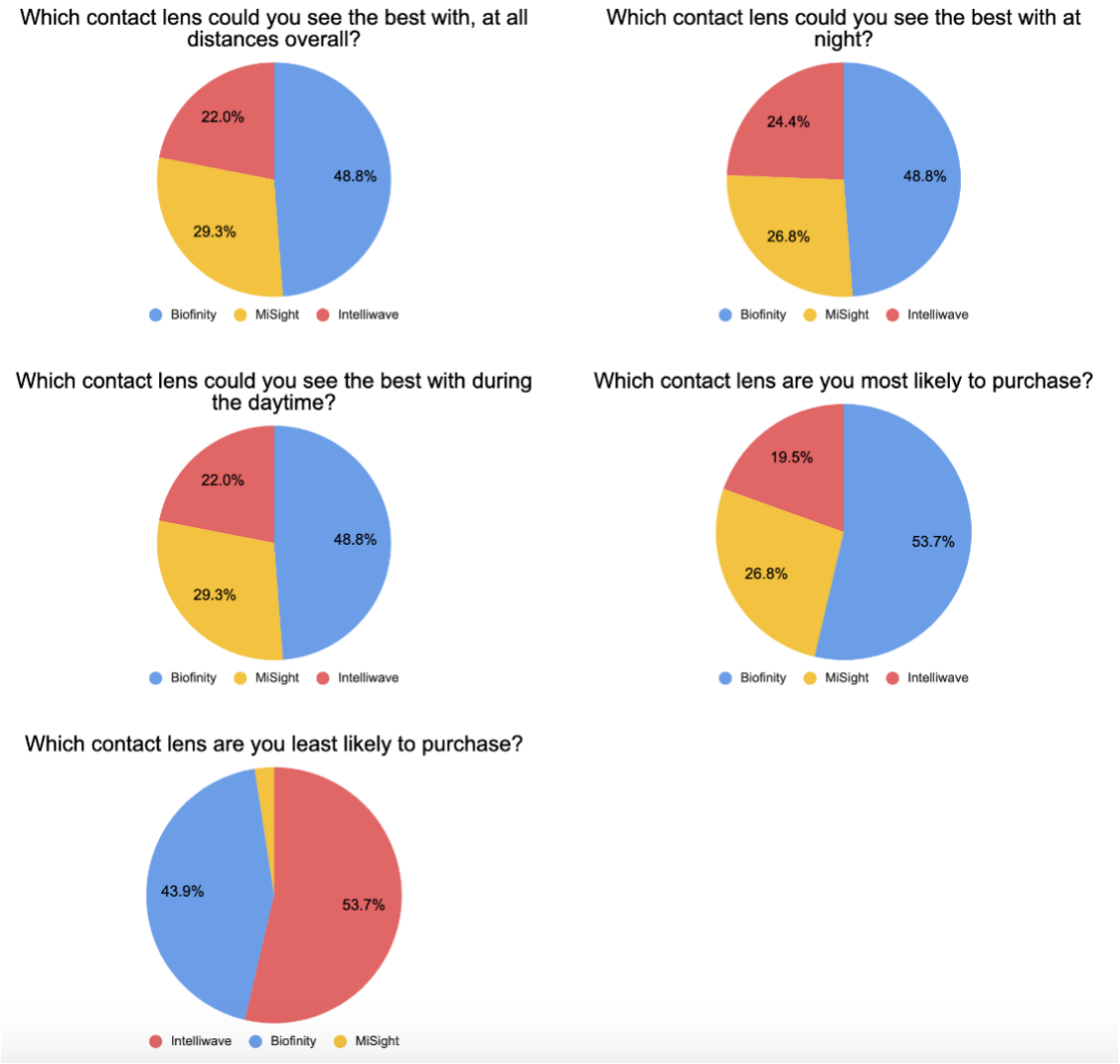

Figure 7. Brand comparison survey results (con't). Shown in the figure are five of the nine questions of the brand comparison survey and the percentage of respondents who chose each lens for each question.

Table 2. Vision quality survey results. Comparison of quality of vision and comfort factors between four multifocal contact lenses using medians and interquartile ranges. Significant results ($p \leq 0.05$) are bolded. Survey scales are ranked from 1 (most unfavorable) to 10 (most favorable).

Subjective Variable	Biofinity	Intelliwave	NaturalVue	MiSight	P-value
Contact Lens Comfort *(1 uncomfortable - 10 comfortable)*					
Comfort at the end of day yesterday just before contact lenses removal	8.0 ± 4.0	3.0 ± 7.0	9.0 ± 5.0	4.0 ± 5.0	**p=0.0001**
Overall Ocular Comfort	8.0 ± 3.0	5.0 ± 5.0	9.0 ± 3.0	8.0 ± 3.0	**p=0.0009**
Clarity of Vision *(1 blurred - 10 clear)*					
Clarity of vision for viewing far away object	4.0 ± 4.0	7.0 ± 3.0	5.0 ± 3.5	8.0 ± 3.0	**p=0.0019**
Clarity of vision for viewing near objects	9.0 ± 2.0	7.0 ± 4.0	8.0 ± 3.5	7.0 ± 3.0	**p=0.0234**
Overall clarity of vision	9.0 ± 2.0	7.0 ± 3.0	6.0 ± 2.0	8.0 ± 3.0	**p=0.0001**
Overall vision satisfaction *(1 not satisfied – 10 satisfied)*	6.5 ± 3.0	6.0 ± 5.0	5.0 ± 3.0	7.0 ± 4.0	p=0.1703

Table 3. Vision quality survey results with inverted scale. Comparison of quality of vision and comfort factors between four multifocal contact lenses using medians and interquartile ranges. Significant results ($p \leq 0.05$) are bolded. Survey scales are ranked from 1 (most favorable) to 10 (most unfavorable).

Subjective Variable	Biofinity	Intelliwave	NaturalVue	MiSight	P-value
Vision Stability *(1 very stable - 10 very unstable)*					
Overall vision stability	3.0 ± 3.0	5.0 ± 5.0	5.5 ± 3.0	4.0 ± 5.0	**p=0.3757**
Haloes *(1 not bothersome - 10 very bothersome)*					
Haloes during nighttime	4.5 ± 5.5	5.0 ± 6.0	6.0 ± 6.5	3.0 ± 4.0	p=0.3317
Ghosting *(1 none - 10 severe)*					
Overall ghosting during the nighttime	3.0 ± 4.0	4.5 ± 4.0	6.0 ± 5.0	3.0 ± 4.0	p=0.3972
Overall ghosting during the daytime	3.0 ± 3.5	4.5 ± 4.0	4.0 ± 4.5	4.0 ± 3.0	p=0.6112

Table 4. **Vision quality survey results between different refractive error groups.** Shown in the table are medians [interquartile ranges] for subjects with hyperopia, high myopia (greater than or equal to -6.00 D), and low to moderate myopia. Both results are statistically significant. Survey scales are ranked from 1 (most unfavorable) to 10 (most favorable).

	Low to moderate myopia	High Myopia	Hyperopia	P-values
End-of-day comfort	6.5[6]	8.0[5]	9.5[1]	0.0361
clarity of vision, near	8.0[3]	9.0[3]	9.0[4]	0.0350

DISCUSSION

Visual Performance of Different Multifocal Contact Lenses

The results of this study found that there are measurable differences in visual performance between center-distance MFCLs. Biofinity MFCL was ranked the lowest in terms of distance vision, but ranked highest for near vision clarity, overall clarity, and vision stability. The reduced visual acuity at distance for this particular lens has been reported before.[41, 64] Gregory et al. reports that when fitting the Biofinity center distance MFCL, 58% of the lenses need additional minus power on top of the vertexed contact lens power to achieve good distance vision.

MiSight was ranked highest in terms of distance vision clarity but was one of the lowest for near vision clarity. MiSight was also ranked second highest for vision stability. When Sha et al. compared MiSight to Proclear MFCL center distance and two other prototypical EDOF multifocal contact lenses, MiSight had the lowest ranking for overall vision stability, albeit not statistically significant.[42] MiSight was also ranked lowest for overall lack of ghosting and haloes in that study. However, our study did not find a significant difference between the four contact lenses when assessing ghosting and haloes. Fedtke et al. compared MiSight to Air Optix Aqua single vision lens and found that the central refractive component of the lens measured significantly more minus at distance and significantly less minus at near, corresponding with the subjective clarity of vision results of the current study.[44] NaturalVue was ranked lowest for overall vision clarity, vision stability, and was not ranked most favorably for any statistically significant question.

Research by Gregory et al. showed that NaturalVue had similar objective vision compared to center distance concentric ring and aspheric center distance MFCLs.[41] The results of the present study don't appear to directly support or contradict findings by Gregory et al. It is possible that the MiSight lens ranked highest for distance visual clarity because it had the smallest add power (+2.00 D) of the four studied lenses (Biofinity and Intelliwave had +2.50 add power and NaturalVue had up to +3.00 add power).

Intelliwave was ranked lowest for near vision clarity, vision stability, and was not ranked most favorably for any statistically significant question. There is limited literature on the subjective performance of Intelliwave center distance MFCL so no comparisons can be made between the results of this study and other research. It could be that the design of the lens may contribute to the poor near vision since it is the only lens with a multi-aspheric front surface design.

Based on the results, having clinically significant astigmatism did not have an effect on how each subject ranked vision or comfort for each lens. The study did show that refractive error had an effect on clarity of vision at near for all MFCLs but had no statistically significant effect on other aspects of visual performance and comfort. In this case, near vision clarity was rated highest for subjects with high myopia (6 diopters or greater) and subjects with hyperopia. Interestingly, this survey found that comfort and the end of the day just before contact lens removal was rated highest for subjects with high myopia and hyperopia as well. While no conclusions can be drawn, this result should prompt further investigation into how subjective near vision clarity can affect comfort at the end of the day.

Comfort of Multifocal Contact Lenses

Our results seem to agree with work conducted by Rueff et al., that found that MFCLs may induce discomfort symptoms in non-presbyopes, as most MFCLs trialed were ranked less favorably than each subject's habitual correction in every vision and comfort question.[16] An outlier in this case was Biofinity MFCL, which did not rank lower than habitual correction for 'overall clarity of vision" among the study population. Of the four MFCLs, there was a clear difference in discomfort where over half of the subjects reported that Intelliwave was the most uncomfortable. The results were more evenly distributed when subjects were asked which lens was most comfortable, with Biofinity having a little more than one-quarter of subjects preferring this lens. These results suggest that how a question is worded can produce a different range and distribution of answers. NaturalVue was ranked most favorably for "overall comfort" and "comfort at the end of the day just before removing lenses" compared to the other MFCLs. It was also ranked just as high as habitual correction for "overall comfort" and higher than habitual correction for "comfort at the end of the day before removal". The cause of these ratings is unclear. One possible explanation could be the replacement schedule allowing for the greatest amount of comfort. However, MiSight was another daily disposable MFCL used in this study and it was not ranked consistently high for both overall comfort and comfort at the end of the day. A study by Sapkota found no significant difference between daily versus monthly wear contact lens modalities.[65] Another explanation could be that the material, etafilcon A, is a more comfortable material. Johnson and Johnson Vision Care utilized etafilcon A, a hydrogel material, over 35 years ago when they launched the first frequent disposable and daily disposable lenses in the global market.[66] The original ACUVUE lens was made of etafilcon A and the current 1-Day Acuvue Moist uses

etafilcon A. A study by Sha et al. compared a prototypical EDOF daily disposable lens to the daily disposable Acuvue Moist MFCL and measured subjective performance of comfort on a 1-10 scale.[67] There was no difference in reported comfort, which the study reported was likely due to similar lens materials and similar lens wearing modality.[67] In another study, there was no significant difference in comfort when 1-Day Acuvue Moist (etafilcon A) was compared to BioTrue ONEday for Presbyopia (nesofilcon A) and Dailies AquaComfort Plus Multifocal (nelfilcon A).[68] The other lens materials used in the present study were comfilcon A (Biofinity MFCL, silicone-hydrogel), omafilcon A (MiSight & Proclear, hydrogel), and efrofilcon A (Intelliwave & C–VUE Advanced Definitive, silicone-hydrogel). A study by Lazon de la Jara et al. found that there are not statistically significant differences in comfort between silicone hydrogels and hydrogels.[66] Other studies corroborate these findings.[69, 70] It is possible that the design of the NaturalVue MFCL could be contributing to the comfort, since the power profile of the lens is significantly different from the other lenses used in this study. Intelliwave was ranked the lowest for comfort within this study. Little research on comfort has been done on efrofilcon A, the material Intelliwave is made out of, to establish its level of comfort.[71] The results between the two surveys were consistent in that Intelliwave was ranked lowest for comfort on a numeric 1-10 scale and ranked most uncomfortable when asked to pick between 3 other lenses. This agreement between surveys prompts a stronger conclusion to be made about how comfortable the lens is within this sample population. However, there was no agreement between the surveys for the most comfortable lens – one survey reported that NaturalVue was ranked highest numerically for comfort while the other reported that Biofinity was perceived as most comfortable when asked to pick between 3 other lenses. Further research should be conducted to see if the comfort results

are repeatable and to establish the underlying cause.

Ghosting Effect

In this study, each subject's perception of ghosting was not found to be significantly different when different MFCLs were compared. Fedtke et al. theorized that the presence of ghosting might be affected by the pupil size, add power, lens design, or lens decentration.[44] This study did not find any significant differences between the MFCLs despite the different lens designs, MFCLs were perceived significantly different compared to each subject's habitual correction. Furthermore, subjects with larger pupils in dim light, categorized as greater than 6mm, did not report a significant difference in ghosting compared to subjects with smaller pupils in dim light. This disproves a hypothesis for this study, that larger pupils would experience significantly more ghosting than smaller pupils. A study by Talens-Estarellas et al. found that when 80-90% of the pupil was covered by the central optic zone of a center distance multifocal lens, their subjects had better distance visual acuities compared to when only 60% of the pupil was covered. When 90-100% of the pupil was covered with the central optic zone, certain levels of contrast sensitivity improved compared to when 60-70% of the pupil was covered.[72] These results suggest that smaller pupils would have better objective visual performance. Although subjective assessments have been found to be more sensitive than objective assessments in predicting patient satisfaction of MFCLs, it seems reasonable to hypothesize that having smaller mesopic pupil sizes would reduce symptoms such as glare and ghosting, since light entering the eye would travel through fewer zones of alternating power.[67] One reason the results of this study may not support this hypothesis is due to the small study size. Another reason may be how large and small pupil size was

designated. The 2 groups were formed by finding the average pupil size of the study population in dim light (6 millimeters) and dividing the group into those with equal to or larger than average pupils and those with smaller than average pupils. As seen by the distribution of pupil sizes in Figure 3, the majority (29/43) of subjects had pupil sizes of either 5.5 or 6 mm. It is highly unlikely that a difference of 0.5 mm is enough to note significant variations in ghosting, haloes, and clarity of vision. Therefore, it likely that the two groups compared did not have enough separation between pupil sizes to determine if the side effect profile of multifocal contact lenses varies between pupil sizes. It's been shown that age and refractive error are related to pupil size.[80] Because the age distribution of the study subjects was primarily between 22 years and 30 years old, and the majority (95%) of the study subjects had myopia, it is reasonable to expect that the spread of pupil sizes would be condensed to a small range of sizes. Future studies should ensure that there is a broad spectrum of pupil sizes to better assess how it can impact visual performance. Currently, mesopic pupil size seems to vary between populations and there is no established normative value across all ages, ethnicities, and sexes.[73, 74] It would be beneficial to have a universally agreed upon average for pupil size for different age ranges, to help establish categories of pupil sizes.

Brand Comparisons

The forced-choice brand comparison survey revealed that about half of the subjects were most likely to purchase Biofinity and about half were least likely to purchase Intelliwave. No subjects chose NaturalVue as most or least likely to purchase. There were several questions where NaturalVue was not chosen by any subject (i.e. best near, distance, and overall vision, best daytime vision, best nighttime vision). This could

imply that NaturalVue had very few strong effects on visual performance, either positively or negatively, within this study population. This result is interesting in light of results published by Gregory et al., which found that NaturalVue had comparable vision compared to other more common MFCL designs.[41] Their study compared NaturalVue to Biofinity center distance MFCL in non-presbyopes and found similarity between distance acuity, near acuity, and reading speed, despite the difference in lens designs. Based on their findings, it would be reasonable to expect that some subjects would choose NaturalVue as a preferred lens for visual needs but that was not the case in this study.

Limitations

This study had some limitations to the design. It is possible to assume that there may have been some subjects who were confused by the change in scale for certain questions. For instance, when subjects were asked to assess overall vision satisfaction, "1" was not satisfied and "10" was satisfied. However, when they were asked to assess vision stability, "1" was very stable and "10" was unstable. This could have led to inaccurate data being reported, if a participant thought they were ranking a lens favorably, but instead were ranking it poorly, or vice versa. Upon analyzing the baseline data, only 1/ 43 subjects appeared to have reversed the scale. To prevent this in the future, it would be beneficial to keep the scales more consistent (i.e.1 being least favorable and 10 being most favorable) for all survey questions.

Another limitation to the study was that the questionnaires were not validated. However, the questionnaires were based off of similar surveys used to analyze visual performance.[17, 42, 43, 68, 75, 76] Questions were used that pertained to commonly reported side effects of MFCLs and visual tasks that would affect an individual's quality of life.

Developing a custom survey that had questions pertaining specifically to multifocal contact lenses made the study more efficient. One value in using validated questionnaires is to track for clinically meaningful changes over time. Since the purpose of this study was not to track changes, but to answer specific questions about vision and comfort, the questionnaire made for this study was the most logical and useful outcome measure.

Lastly, the responses were gathered from each subject after 1 week of wearing the contact lenses. The benefit of this amount of time is that it mimics the clinical experience, where patients are given a short period of time to trial contact lenses before returning to make the appropriate changes. The disadvantage of assessing lenses after 1 week of wear is that the perception of vision and comfort may change with longer wear time. One study by Sapkota et al. showed that the comfort scores of contact lenses increased from month 1 to month 2 across a variety of lens materials, although the results were not statistically significant ($p>0.05$).[65]

Future Studies

Given that significant differences were found within the small population of this pilot study, it would be worthwhile for future research to investigate how comfort and vision are impacted by different types of MFCLs in a larger population. As MFCL research continues to develop, it would be beneficial to have a validated questionnaire specifically designed to assess MFCL visual performance and comfort. Lastly, this study was conducted with the intent that the findings could be useful to practitioners treating children with myopia progression. Visual performance and quality of life factors are starting to become metrics used in myopia management research.[77] With this is mind, future studies should directly examine children's perception of vision and comfort

wearing MFCLs used in myopia management.

CONCLUSIONS

This study found that there are measurable differences in visual performance and comfort between different center distance MFCLs. All of the MFCLs demonstrated worse subjective performance in terms of vision and comfort compared to habitual correction, which agrees with previous studies.[42-44] This study also agrees with findings from other studies that show there is value and utility in using subjective questionnaires to assess contact lens performance.[51, 75, 78, 79] The lenses that ranked highest in regards to comfort and vision were also ranked most likely to be purchased. Pupil size did not make a significant difference in this study when factors like clarity, ghosting, and haloes were measured. Both hyperopes and high myopes had more favorable rankings for end-of-day comfort and near vision clarity than low-to-moderate myopes.

It can be difficult for practitioners to select a multifocal contact lens for a patient, especially when it comes to myopia management. There has been little guidance in the literature about the comfort and subjective performance of many of the lenses used to slow the progression of myopia in children. The results from this study can give practitioners insight into how a lens performs, so that treatment with contact lenses can be tailored to each individual patient. Since good subjective performance of a lens can lead to increased wear time and more effective treatment, the results of this study and similar studies can lead to successful, evidence-based treatment for myopia control and normal multifocal contact lens fittings.

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APPENDIX A

IRB APPROVAL FORM

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 |
irb@uab.edu

APPROVAL LETTER

TO: Pucker, Andrew D

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)
IORG Registration # IRB00012550 (IRB 03)

DATE: 29-May-2022

RE: IRB-300004545
IRB-300004545-013
Optimizing Multifocal Soft Contact Lens Fitting for Myopia Management

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The IRB reviewed and approved the Revision/Amendment submitted on 16-May-2022 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	1, 4, 7,
Determination:	Approved
Approval Date:	29-May-2022
Expiration Date:	28-May-2025

Although annual continuing review is not required for this project, the principal investigator is still responsible for (1) obtaining IRB approval for any modifications before implementing those changes except when necessary to eliminate apparent immediate hazards to the subject, and (2) submitting reportable problems to the IRB. Please see the IRB Guidebook for more information on these topics.

The following apply to this project related to informed consent and/or assent:

- Waiver of 24 Hour Waiting Period
- Waiver (Partial) of HIPAA

Documents Included in Review:

- REVISION/AMENDMENT EFORM

To access stamped consent/assent forms (full and expedited protocols only) and/or other approved documents:
1. Open your protocol in IRAP.
2. On the Submissions page, open the submission corresponding to this approval letter. NOTE: The Determination for the submission will be "Approved."
3. In the list of documents, select and download the desired approved documents. The stamped consent/assent form(s) will be listed with a category of Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)