

Subjective and Objective Evaluation of Two Different Multifocal Contact Lenses: Randomize Clinical Trial

İki Farklı Multifokal Kontakt Lensinin Objektif ve Subjektif Değerlendirilmesi: Randomize Klinik Çalışma

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ABSTRACT Objective: The aim of this research is to evaluate 2 different soft multifocal contact lenses (MFCL) that were used in daily and monthly presbyopia rehabilitation in terms of visual acuity and patient satisfaction. **Material and Methods:** Balafilcon A and Etafilcon A were applied to 62 patients. Visual acuity was evaluated in appropriate photopic conditions with logMAR at 6 m for distance and with Jaeger chart at 30 cm for near. Treatment and routine follow-up letter contrast sensitivity (CS) tests were recorded. A questionnaire was filled by patients regarding their contact lens satisfaction separately for near, intermediate and distance vision that includes questions about ghosting, visual clarity, and overall image satisfaction. The average was calculated after scoring of these between 0-10. **Results:** Visual acuities were obtained: For the participants who used Balafilcon A is 0.053 (± 0.02), and in near vision Jaeger chart 1.03 (± 0.4); for the participants who used Etafilcon A is 0.053 (± 0.01) in distance visual acuity and in near vision Jaeger chart 1.23 (± 0.45). While there was no significant difference in near and distance vision between the 2 lenses, the CS increased in both lenses. However, this increase was lesser than the detected increment in glasses. The near, intermediate and distance patient satisfaction were similar in all lenses. **Conclusion:** A visual rehabilitation that satisfies MFCL applied patients can be achieved by considering the design of the lens according to the need for distance or near vision.

ÖZET Amaç: Bu araştırmanın amacı, günlük ve aylık presbiyopi rehabilitasyonunda kullanılan 2 farklı yumuşak multifokal kontakt lensi (MFKL) görme keskinliği ve hasta memnuniyeti açısından değerlendirilmesidir. **Gereç ve Yöntemler:** Altmış iki hastaya Balafilcon A ve Etafilcon A uygulandı. Görme keskinliği, mesafe için 6 m'de logMAR ve yakın için 30 cm'de Jaeger çizelgesi ile uygun fotopik koşullarda değerlendirildi. Tedavi ve rutin takipte, kontrast duyarlılık [contrast sensitivity (CS)] testleri kaydedildi. Hastalar tarafından yakın, orta ve uzak görüş için ayrı ayrı kontakt lens memnuniyetleri ile ilgili olarak gölgelenme, görsel netlik ve genel görüntü memnuniyeti ile ilgili soruları içeren bir anket dolduruldu. Bunların 0-10 arasında puanlanmasından sonra ortalama hesaplandı. **Bulgular:** Balafilcon A kullanan katılımcılar için 0,053 ($\pm 0,02$) ve yakın görüş için Jaeger eşeli ile 1,03 ($\pm 0,4$); Etafilcon A kullanan katılımcılar için uzak görme keskinliği 0,053 ($\pm 0,01$) ve yakın görüş için Jaeger eşeli ile 1,23 ($\pm 0,45$) görme keskinlikleri elde edildi. İki mercek arasında yakın ve uzak görüş açısından önemli bir fark olmazken; CS, her iki mercekte de arttı. Ancak bu artış, gözlüklerde tespit edilen artıştan daha azdı. Yakın, orta ve uzak hasta memnuniyeti tüm lenslerde benzerdi. **Sonuç:** MFKL uygulanan hastaları tatmin edecek bir görsel rehabilitasyon, lensin uzak veya yakın görme ihtiyacına göre tasarımı dikkate alınarak sağlanabilir.

Keywords: Presbyopia; soft contact lens; patient satisfaction

Anahtar Kelimeler: Presbiyopi; yumuşak kontakt lens; hasta memnuniyeti

Recently, since the elderly population has been increasing rapidly, the importance of presbyopia treatments has been growing day by day.^{1,2} The most standard and affordable method of presbyopia reha-

bilitation is the usage of glasses. Together with standard monofocal near glasses, bifocal and multifocal glasses after a short adaptation period has been also a rehabilitation preference.³ However, individuals

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might not prefer to use glasses due to their cause to discomfort in sports activities and cosmetic appearance, or patients are uncomfortable wearing glasses. Therefore, patients have tended to use contact lenses for near vision.

Different contact lens types and techniques can also be applied for correcting presbyopia in both present and new contact lens users. For distance vision, these are contact lenses together with reading glasses for near; bifocal or multifocal contact lenses (MFCL); monovision applications. Even if it has been decided according to the patient's requirements, MFCL were substantially comfortable for appropriate patients.⁴ Retractive laser surgery, conductive keratoplasty and corneal ring segments have been surgical procedures. Scleral expansion procedures can be applied to rehabilitate presbyopia by placing a polymethylmethacrylate ring in the sclera on the ciliary muscles.⁵ Monovision intraocular lens (IOL) application or multifocal IOL applications such as Trifocal or EdoFF have been alternative surgery choices.⁶

Among these, there is monovision contact lens application in which the vision of one eye, which is an old but effective contact lens application, is corrected with a contact lens and the number is adjusted to provide sufficient near vision in the other eye and sufficient distance and near vision is provided. However, MFCL have been gaining interest as a new aspect due to the difficulty in the suppression of one eye and deterioration of 3D vision in monovision.^{7,8} MFCL can be rigid or soft. Soft MFCL can provide alternating or simultaneous vision. Although both lenses in our study had simultaneous vision MFCL, Etafilcon A and Balafilcon A were aspherical center near (CN).⁴ Simultaneous vision designs has been aiming to provide clear vision simultaneously at 2 or more distances by expanding the depth of focus of the lens-eye system through lenses with multiple powers at the same time.⁹ MFCL that were adopted into our lives with the innovations of the technology have reactive zones with different diopter power and they provide vision in the different distance with the same lens.

Visual performance of MFCL; changes in pupil size, natural optical aberrations, ambient illumination levels and the size of astigmatism are affected by

many factors. Each lens manufacturer produces a unique lens design and material that sets it apart from its competitors. However, in practice, there is usually not enough time to try the same patient on several different brands. In our study, we aimed to create a preliminary idea by evaluating the satisfaction of multifocal contact lens wearers in different designs.

MATERIAL AND METHODS

This study was a prospective, randomized clinical trial that was conducted at University of Health Science Ulucanlar Eye Training and Research Hospital, Cornea Contact Lens Unit, Ankara, Turkey. Study protocols and informed consents were reviewed and the study followed the tenets of the Declaration of Helsinki. Ankara Training and Research Hospital Health Ethics Committee of Clinical Research accepted the research protocol (no: 93471371-514.10, date: 05/11/2020).

This observational, cross-sectional study included 124 eyes of 62 individuals. The subjects were separated into 2 groups. Group 1 included 62 eyes of 31 patients who used Balafilcon A (Pure vision multifocal) with reusable-monthly. Group 2 included 62 eyes of 31 patients who used Etafilcon A (1-Day Moist Acuvue daily) with daily disposable. All patients were over 40 years, $\leq \pm 0.75$ D astigmatism and vision correctable to at least 0.5 or better in each eye with contact lenses. Sensory eye dominance was assessed using the alternate blur method.¹⁰

Exclusion criteria were a history of any other ocular disease or dry eye, ocular surgery, atopy or any systemic diseases (e.g. diabetes mellitus, rheumatological diseases) which were affected ocular surface and refraction.

Etafilcon A is an aspheric centre near design hydrogel lens which is CN MFCL and the optic zone is smaller for hypermetropic corrections and larger for myopic ones and is available in three add powers. Balafilcon A is an anterior near-centre aspheric design with a rear spherical surface. In this lens, there is a relatively slow progressive radial power change.¹¹

After complete ophthalmological examinations for all cases, contact lenses were applied according to refractive status of patients. The selected initial power

was based on the spherical equivalent of the distance spectacle prescription adjusted for vertex distance as needed in both lenses. Multifocal contact lens application was performed randomly to the patients.

According to the fitting protocol of Etafilcon A (1-Day Acuvue Moist Daily) MFCL; if the spectacle add was +1.50 D or less, the low add was used on both eyes for the multifocal lens. If the add was between +1.75 D and +2.25 D, the low add was used on the dominant eye, and the high add was used on the nondominant eye. If the add was +2.50 D or greater, the high add was used on both eyes. In the Balafilcon A (Purevision monthly multifocal lenses, distance distance vision was assessed the same protocol and at near distance, if the spectacle add was +1.50 D or less, the low add was used on both eyes for the multifocal lens. If the add was +1.75 D to +2.50 D, the high add was used on both eyes. The properties of both contact lenses are given in [Table 1](#).

The contact lenses were assessed for proper centration, limbal coverage, and adequate movement (0.25-0.50 mm) under the biomicroscopic examination. Snellen charts from 6 m for distance visual acuity, Jagger cards from 50 cm for intermediate distance visual acuity and Jagger cards from 30 cm for near vision were assessed with contact lenses.

All patients have undergone control examination 6 months later but we have evaluated the results of the sixty months in the current study. In control, ex-

amination included distance visual acuity with logMAR (Smart System 2 2020 Visual Acuity System; M&S Technologies), middle distance and near visual acuity with Jagger cards and questionnaire evaluation, a Hamilton-Veale chart for contrast sensitivity (CS) examination.

Distance visual acuity was measured with the logMAR (logarithm of the minimum angle of resolution, Smart System 2 2020 Visual Acuity System; M&S Technologies).

Treatment and routine follow-up letter CS tests were recorded. CS was evaluated with a Hamilton-Veale chart with uncorrected visual acuity, corrected with spectacles and with contact lens. This test was modelled on the Pelli-Robson CS and uses a card with 16 pairs of letters over 8 lines. The patient was asked to read the letters and the value was recorded as log CS [$\log (l/c)$]. The contrast range was from 0 to 2.25 log units.

Patients filled out a questionnaire about the performance of their contact lenses. Variables were graded on a 1-10 numeric rating scale in 1-point steps. We modified and used the questionnaire Sha which have been used in a previous study by asking patients to evaluate their near, intermediate, and distance vision and give a value between 0-10 for visual quality, ghosting, vision clarity and overall image satisfaction for each distance. We obtained an average value within each distance.⁷

TABLE 1: Contact lens properties.

	Balafilcon A	Etafilcon A
Water content (%)	36	58
Oxygen transmissibility Dk/T (cm/sec)	110	21.4
Oxygen permeability Dk (cm ² /sec)	99	25.5
Diameter (mm)	14.0	14.3
Base curve (mm)	8.60	8.40
Power range (D)	+6.0-(-10)	+6.0-(-9.0)
Near addition (D)	2 adds; low (<+1.50 D) High (1.75-2.50 D)	3 adds; low (+0.75 to +1.25 D), med (+1.50 to +1.75 D), high (+2.00 D to +2.50 D)
Wear modality	Reusable-Monthly	Daily disposable
Lens design	Center near, aspheric	Center near, aspheric
Manufacturer	Bausch & Lomb	Johnson & Johnson
Refractive index	1.42	1.40

D: Dominant; N: Non-dominant; D: Dioptre; Dk: Oxygen permability; Dk/t: Oxygen transmissibility.

TABLE 2: Visual acuity and contrast sensitivity distribution.

	Etafilcon A	Balafilcon A	
Distance vision average (SD)	0.057 (±0.01)	0.053 (±0.02)	p>0.05*
Near vision average (SD)	1.23 (±0.45)	1.03 (±0.4)	p>0.05+
Contrast sensitivity (uncorrected)	0.76 (0.00-1.15)	0.70 (0.00-1.03)	p>0.05*
Contrast sensitivity (with spectacles)	1.46 (1.15-1.95)	1.44 (1.00-1.95)	p>0.05*
Contrast sensitivity (with contact lens)	1.43 (0.75-1.95)	1.38 (0.69-1.79)	p>0.05*

*Mann-Whitney U test; +Crosstabulation; SD: Standard deviation.

STATISTICAL ANALYSIS

All statistical analyses were performed using IBM SPSS for Windows version 15.0 (SPSS, Chicago, IL, USA). The number of people required to be included in the study according to the Student t-test by taking the effect size (Cohen-d)=0.8, with Type 1 error=0.05, power=0.85, is 60 in total, 30 people in each group.

Shapiro-Wilk's test was used to assess the assumption of normality. Normally distributed continuous variables were expressed as mean±standard deviation while the continuous variables that do not have normal distribution were expressed as median (25.percentile-75.percentile), (minimum-maximum). Comparisons of normally distributed continuous variables between groups were performed using student's t-test while for non-normally distributed continuous variables, differences between groups were tested using Mann-Whitney U test. Lastly, associations between categorical variables were determined by chi-square analysis and Fisher exact test. A two-sided p value<0.05 was considered statistically significant.

RESULTS

It was planned to include 35 patients for both 2 contact lens groups, however, 4 patients in both groups gave up using the contact lenses due to they couldn't adapt, and had not come to visit for the control. As a result, 31 patients have been enrolled per contact lens group. The findings on 6th-month controls were evaluated from the patients who were using contact lens which were prescribed regularly for 6 months. The mean age was 49.3 (42-58) years in the patients who have used Etafilcon A; 50.5 (43-59) years in the pa-

tients who have used Balafilcon A; no significant difference was observed between these groups (p>0.05). The female/male ratio of Balafilcon A users were 67.7/32.3; this ratio of Etafilcon A users were 48.4/51.6. The right eye has been found dominant in all users of contact lens and the dominant lens was applied to the right eye. As it can be seen in Table 2, any significant differences haven't been demonstrated for distance, intermediate and near visual acuities.

Mean logMAR CS was 0.76 (0.00-1.15) for uncorrected, 1.46 (1.15-and 1.95) with near spectacles and 1.43 (0.75-1.95) with contact lens for Etafilcon A. The mean logMAR CS of Balafilcon A was 0.70 (0.00-1.03) for uncorrected, 1.44 (1.00-1.95) with near spectacles and 1.38 (0.69-1.79) with contact lens. Significantly higher CS levels were recorded after using for both contact lenses compared to uncorrected values. There was no significant difference between the 2 lenses with the increase in CS and spectacles corrections (p>0.05). Visual acuities of the patients, their contrast sensitivities, and their distribution based on contact lens types were demonstrated in Table 2.

As a result of the evaluation of satisfaction questionnaires, satisfaction scores based on contact lens

TABLE 3: The results of satisfaction questionnaire according to the contact lens types.

	Near Mean (SD)	Intermediate Mean (SD)	Distance Mean (SD)
Etafilcon A	8.26 (±0.8)	8.52 (±0.7)	7.94 (±0.96)
Balafilcon A	8.35 (±0.6)	8.58 (±0.5)	7.89 (±0.9)
	p=0.8*	p=0.9*	p=0.8*

*Mann-Whitney U test; SD: Standard deviation.

type were given in Table 3. There was statistically significant high satisfaction in all users. Although any significant difference hasn't been detected between the 2 lens types regarding the satisfaction of the vision in the near, intermediate and distance, as a result of Mann-Whitney U test ($p=0.4$) (Table 3).

DISCUSSION

In this research, we have evaluated the visual acuity, CS in near sight, and subjective satisfaction of the enrolled patients in terms of 2 different type of MFCL: Which are CN designed daily disposable Etafilcon A and monthly Balafilcon A. High visual satisfaction has been obtained in all distances for both types of contact lens after 6 months of usage with an increase in CS and distance and near visual acuities between contact lenses.

No statistically significant difference was examined between near and intermediate and distance in 2 lenses. The areas which have different refractive indexes due to the movement of the lens on the eye trying to focus during the intermediate and near vision can lead to glare and halo formations. However, it was reported that 76% of the presbyopia patients have been still preferred multifocal soft contact lenses over monovision.^{12,13} Neuronal adaptation has developed over time in different retinal images which occur simultaneously even if the development mechanism hasn't been known fully. According to a hypothesis about the adaptation have assumed that brain suppresses the blurry component of the simultaneous image.^{14,15} With considering this adaptation, we have evaluated the patients who used the lenses for a long-time.

Visual acuity for both lens groups was >0.04 which was obtained with logMAR. There was no difference in distance visual acuity. The visual acuity values for the near vision obtained with the Jaeger chart were with Etafilcon A was 1.23 and with Comfilcon A was 1.03. Even if no statistically significant difference was detected, much better near vision was obtained with Etafilcon A. In addition, Sha et al. have demonstrated in their research on 3 different CN MFCL that Etafilcon A has created much better near vision among others.¹⁶ We have made a questionnaire for the lens users regarding glare, visual clarity, and full image satisfaction while subjective vision per-

formance of the contact lenses was evaluating. When the evaluation was performed in separately for near, intermediate and distance; values as higher than 8/10 were revealed in both of the MFCL for near, intermediate and distance vision. However, there wasn't any significant difference between the 2 lenses. CN feature of many MFCL has been preferred by companies to support the near vision of the patients. In our research, this effect was provided with Etafilcon A which achieves relatively much better near vision. Gupta et al. have obtained worse quality of vision regarding simultaneous MFCL with CN feature on monovision compare to our research.¹⁷ However, the number of participants was a limiting factor in their research. Moreover, an increment of the distance and near vision also with maintaining stereopsis was observed at both Proclear MFCL (similar feature with Biofinity) and Purevision MFCL (CN-simultaneous) in the research of Ferrer-Blasco's.^{17,18} Furthermore, Fernandes et al. have discovered better vision in multizonal MFCL. They suggested that near vision in the dominant eye and distance vision in the non-dominant eye normally have been maintained by lenses adjusted as center of the 1.7 mm in N lens and 2.3 mm of the D lens.¹⁹

When we have evaluated the CS test performed with Hamilton-Veale cards for both lens groups before the refraction examination, after correcting the refraction with glasses, and after using contact lens, there was an increase of CS for both contact lenses and the glasses after the correction of the refraction. However, the CS obtained with glasses was detected as higher. Therefore, it was demonstrated that monovision solutions were higher in CS due to glare and light separation occurs in multifocals.¹⁷ The lower CS in lenses compared to glasses was an expected result based on multifocality since a similar decrease in CS has been demonstrated in a variety of studies.²⁰⁻²² The included MFCL users already found the lens adequate for saving the day and preferred the lens as it provides wider vision compared to multifocal glasses and leads to lesser distortion. As it has been seen in our research, similarly to the literature the reason for not using MFCL was its inadequate vision quality.^{23,24}

All lens users were evaluated in a long term in this research. Other studies have shown that the early

period performance of a lens can be misleading due to the patients' need for adaptation time.^{25,26} Since we have exceeded this time length, the evaluation of the users regarding image performance could be considered highly important.

While the presence of patients for near vision in each additional group in this study has guided us, it was also limiting us due to the scarcity of the patient number. More clear and detailed results can be observed by increasing the number of participants and classifying the different groups from our point of view.

CONCLUSION

To the best of our knowledge, this study is in terms of making a comparison between 2 CN MFCL by the subjective and objective data. In conclusion, there was no statistically significant difference in both MFCL in terms of CS. As a result of these findings, we suggest for the patients who prioritize their need for distance vision are suitable both of 2 lenses and for those who prioritize their need for near vision is Etafilcon A. We have been thinking that this will provide visual comfort and patient satisfaction in the long term. A thorough investigation of each patient's routine life in terms of visual demand and working distance can be helpful when choosing lens design to increase patients' visual satisfaction and use success. While the limitations of our study sample probably

prevented its higher level of wearing success, as is often the case with contact lens research, the findings of this study may contribute to a complex issue such as exploring future multifocal lens designs, multifocal contact lens fitting and selection.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Burcu Kazancı, Fatma Çorak Eroğlu, Dilay Özek; **Design:** Burcu Kazancı, Fatma Çorak Eroğlu, Dilay Özek; **Control/Supervision:** Burcu Kazancı; **Data Collection and/or Processing:** Burcu Kazancı, Fatma Çorak Eroğlu; **Analysis and/or Interpretation:** Burcu Kazancı, Fatma Çorak Eroğlu, Serhat Hayme, Dilay Özek; **Literature Review:** Burcu Kazancı, Fatma Çorak Eroğlu, Dilay Özek; **Writing the Article:** Burcu Kazancı, Fatma Çorak Eroğlu, Serhat Hayme, Dilay Özek; **Critical Review:** Burcu Kazancı, Fatma Çorak Eroğlu, Dilay Özek; **References and Fundings:** Burcu Kazancı, Fatma Çorak Eroğlu; **Materials:** Burcu Kazancı.

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