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ORIGINAL RESEARCH

Non-Miotic Improvement in Binocular Near Vision with a Topical Compound Formula for Presbyopia Correction

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ABSTRACT

Introduction: The aim of this case series was to examine the association between unaided binocular visual acuity for near vision and pupil change after the instillation of a special topical formulation for presbyopia treatment.
Methods: This was a case series consisting of consecutive participants with presbyopia aged 40–70 years who were tested for visual acuity and pupil diameter before and 2 h after instillation of a formulation of pilocarpine and phenylephrine drops (FOV Tears) for presbyopia. Participants underwent subjective refraction, photopic and scotopic pupil diameter measurement and unaided monocular and binocular visual acuity testing by logMAR for distance and near vision both pre- and post-instillation of eye drops.
Results: The study enrolled 363 subjects (n = 176 women, 48%) with a mean (± standard deviation) age of 50.4 ± 5.8 years. Mean spherical equivalent (SE) changed significantly (− 0.17 Diopters) after instillation of the FOV Tears formulation ($p < 0.001$). Post-instillation of eye drops, the scotopic pupil diameter decreased by 0.97 ± 0.98 mm, and the near visual acuity by logMAR improved significantly by nearly two lines ($p < 0.01$). In the linear regression analyses, age ($p < 0.001$) and SE pre-drop instillation ($p < 0.001$) were associated with unaided binocular visual acuity. The changes in photopic pupil diameter and the scotopic pupil diameter were not associated with unaided binocular visual acuity.
Conclusions: The use of the pilocarpine and phenylephrine formulation (FOV Tears) improved binocular visual acuity for near vision in presbyopic patients, and the effect was independent of pupil change.

Keywords: Presbyopia; Pilocarpine; Phenylephrine; Pupil diameter; Near visual acuity

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Key Summary Points

Why carry out this study?

To examine the association between unaided binocular visual acuity for near vision and pupil change after the instillation of a special topical formulation for presbyopia treatment (FOV Tears).

To assess if FOV Tears with a low pilocarpine concentration produces myopic shifts in distance refraction.

What has been learned from the study?

The use of pilocarpine and phenylephrine in the FOV Tears formulation improved binocular visual acuity for near vision in presbyopic patients.

The effect of FOV Tears was more pronounced in older subjects and in more hyperopic subjects.

Photopic and scotopic pupil change was not associated with the improvement of binocular visual acuity for near vision.

Future research testing these drops for accommodation under laboratory conditions is of paramount importance in presbyopia treatment.

INTRODUCTION

Presbyopia affects more than 40% of the world population aged > 40 years and is the most important cause of near vision disability as only individuals with low myopia can read up close without spectacles in our modern indoor culture [1]. Since Thomas Young [2] performed his first experiments on accommodation, there have been several research breakthroughs on the diagnosis and management of presbyopia. Donders paid great attention to theory, clinical presentation and presbyopia treatment in his pivotal study published in 1864 [3]. The usual treatment for presbyopia has been near addition plus spectacles. Monovision or multifocal contact lenses and corneal refractive surgery with different approaches have also been tested for presbyopia correction. The newest approach is lens extraction and subsequent implantation of multifocal, extended depth of focus or monovision intraocular lenses. However, there are a number of risks associated with surgery [4] compared with other prosthetic or medical options, such as spectacles or pharmacological options. In many cases, presbyopia correction is not addressed for a variety of reasons, such as availability of spectacles, and thus vision remains uncorrected in working age populations, with an associated economic burden [5]. Recent population-based studies around the world have addressed the overall unmet need for presbyopia correction, showing the burden imposed by this common problem [6, 7].

The U.S. Federal Drug Administration has recently approved 1.25% pilocarpine eye drops as a treatment for presbyopia [8]. This new medical option is an addition to the battery of tools, such as spectacles, contact lenses and surgery, which so far have been the most used strategies to correct presbyopia [9]. Pilocarpine is a cholinergic muscarinic receptor agonist that produces miosis and accommodative spasm, thereby increasing the depth of focus and producing myopic shifts in refraction. This drug has been extensively used in ophthalmology for the treatment of glaucoma [10] and accommodative strabismus. Improvements in near vision have been systematically reported in clinical settings by patients who used pilocarpine drops for glaucoma treatment [11].

In recent years, refractive surgeons have shown renewed interest for the medical treatment of residual presbyopia in patients who have undergone refractive procedures to become independent from spectacles or contact lenses [9, 12]. Pilocarpine formulations have been used for presbyopia treatment and found to improve near visual acuity without major adverse side effects [13–15]. In two previous studies, a pilot study [16] and a case series (n = 117 subjects) [13], near uncorrected binocular visual acuity by logMAR (Log of

Minimum Angle of Resolution) was assessed before and 2 h after instillation of diluted pilocarpine (FOV Tears) drops in both eyes. The results of these studies showed that near unaided visual acuity increased by at least one logMAR line in almost 95% of the treated subjects, while the mean increase for the whole sample was almost two logMAR lines.

FOV Tears is an optimized topical formulation of pilocarpine (0.247%) and phenylephrine (0.78%) that counteracts pupil constriction to avoid posterior synechiae and complications under low-light activities [13]. This formulation does not alter the diameter of the photopic pupil, although a 1-mm mean scotopic pupil constriction was found in a previous study [13]. This constriction may increase depth of focus, improving uncorrected near binocular logMAR visual acuity [13]. In the present study our aim was to determine if the change in unaided binocular visual acuity for near vision was associated with change in pupil diameter, with the overall goal to further understand the mechanism of action of this formulation for the treatment of presbyopia. We also aimed to assess if FOV Tears with its low pilocarpine concentration produces myopic shifts in distance refraction.

METHODS

Study Design

This study was designed as a case series of consecutive emmetropic presbyopic participants aged > 40 years who accepted treatment for presbyopia with FOV Tears since year 2020 (data were collected prospectively). The protocol of the study adhered to the tenets of the Declaration of Helsinki of 1964 and it subsequent amendments and was approved by the Ethics Committee of the Vejarano Ophthalmological Foundation in Colombia. Informed consent was obtained from the subjects after explanation of the nature and possible consequences of the study.

Inclusion Criteria and Eye Measurements

Consecutive participants with spherical equivalent (SE) between + 1.00 and − 0.50 Diopters (D) in both eyes, with less than − 1.00 D of astigmatism were included in this study. All participants complained of poor near vision without near correction. Participants with pseudophakia, dry eyes, anisocoria and glaucoma were excluded. A previous study showed no difference in the main outcome measures in subjects with or without previous refractive surgery [17]. Thus, subjects with previous corneal refractive surgery were not excluded from this study.

Participants had a complete ophthalmological exam, including subjective distance refraction (Automated Phoropter, RT-5100; Nidek Co., Ltd., Hiroishi, Japan) after non-cycloplegic autorrefraction (Nidek ARK-530A autorrefractor; Nidek Co., Ltd.). SE was calculated as the spherical value + half the cylindrical value. All measurements were done before and 2 h after instillation of the eye drop formulation in both eyes. This time point was chosen as it is the drug mean peak of action. In a previous study, the effect of FOV Tears was significantly increased at 1 h after instillation, with the mean action peak at 2 h post-instillation [16]. The effect subsequently significantly decreased between 4 and 5 h post-instillation of eye drops. Uncorrected distance visual acuity was measured before and after drop instillation using the Snellen chart with the Nidek Screen SC-1600 system (Nidek Co., Ltd.) at 4 m distance. Unaided near visual acuity was measured with the "New ETDRS chart 2000", at 40 cm (Precision Vision, Woodstock, IL, USA). Visual acuity was measured monocularly and binocularly. Distance and near visual acuity were expressed in logMAR units with 0.1 logMAR unit precision. In all cases, the participants were instructed to begin reading the 1.0 logMAR line, letter by letter and the last line where they could read three letters correctly was recorded as the logMAR visual acuity line. The artificial illumination in the testing room at the sitting place of the subjects was standardized at 950 ± 50 lx with a Lux meter (Digital Lux meter LX-1330B; SMT, Shanghai, China). Change in unaided

binocular visual acuity for near vision was calculated as: (unaided binocular visual acuity for near vision pre-instillation of eye drops − unaided binocular visual acuity for near vision post-instillation of eye drops).

Pupil size was measured before and 2 h after instillation of FOV Tears, both in photopic and scotopic conditions with ± 0.1 mm precision using the Nidek AL Scan biometer with the Nidek eye model (Nidek Co. Ltd). The photopic and the scotopic conditions were established by the infrared Nidek biometer, which takes both measures turning "on" an "off" the internal lights when the patient is in a dark room (with lights off). Thus, the scotopic pupil for this study was measured in the dark. The photopic pupil was measured after 2 s of adaptation to a Scheimpflug light illumination (Nidek standards of 850–950 Lux with a LED light source of 470 nm). Photopic pupil change was calculated as: (photopic pupil pre-instillation of eye drops − photopic pupil post-instillation of eye drops); scotopic pupil change was measured as: (scotopic pupil pre-instillation of eye drops − scotopic pupil post-instillation of eye drops).

Treatment Characteristics

The chemical composition of the Fundacion Oftalmologica Vejarano (FOV) presbyopia drops (FOV Tears) is 0.247% pilocarpine, 0.78% phenylephrine, 0.09% polyethylene glycol, 0.023% nepafenac, 0.034% pheniramine and 0.003% naphazoline. Pilocarpine stimulates the muscarinic receptors; therefore, to avoid an accommodative spasm, an alpha agonist was used to counteract the ciliary body action, to avoid the paralytic and fixed miosis and to avoid redness. A non-steroidal anti-inflammatory drug was also used to increase the time of action and a lubricant was included in the formulation to improve tolerability. The feasibility of FOV drops, in terms of safety and potential efficacy, was examined in a previous study [16].

Statistical Analysis

All data were recorded in an Excel spreadsheet (Microsoft Corp., Redmond, WA, USA) and converted to SPSS file for the analysis (SPSS version 25; SPSS IBM, Armonk, NY, USA). The mean values and standard deviations (SD) were calculated for every parameter. Normality of linear variables was evaluated by the Kolmogorov–Smirnov test. The differences in ocular parameters were compared between pre- and post-treatment. Student *t*-tests for paired data or non-parametric tests were performed to compare means and medians according to the normality of linear variables. Scatterplots and Pearson correlations were used to analyze the relationship between the selected linear variables. The Pearson correlation for SE ($p < 0.001$), visual acuity ($p < 0.001$) or pupil diameter ($p < 0.001$) for the right and left eyes was high in all cases. Thus, value for the right eye were used for all analyses except for binocular visual acuity. As the mean change in pupil diameter had a normal distribution ($p = 0.55$), the subjects were divided into two groups with a mean of approximately 1 mm. The Student *t*-test was performed to compare differences in logMAR uncorrected near visual acuity gained between the two groups. Differences in logMAR gained lines of uncorrected near binocular visual acuity were compared among both groups of photopic pupil change split by the mean value (Student *t*-test). Unaided binocular visual acuity for near vision (dependent variable) was tested for the association with age, sex, SE pre-eye drops, photopic pupil change and scotopic pupil change by multivariable linear regression. The correlation matrix was used to evaluate collinearity. A p value < 0.05 was considered to be statistically significant for the purpose of this study.

RESULTS

This study enrolled 363 emmetropic subjects ($n = 176$ women, 48%) with a mean (± SD) age of 50.4 ± 5.8 years. All subjects were phakic, and 82 subjects (22.6%) had undergone corneal refractive surgery in the past to improve distance vision. Compared to mean SE at pre-instillation of drops, mean SE had changed by a significant amount (− 0.17 D myopic shift) at 2 h post-instillation of eye drops ($p < 0.001$).

Table 1 Eye characteristics of individuals included in the study (n = 363)

Variable	n[a]	Mean ± SD[b]	Range	p[c]
Spherical equivalent pre-instillation (Diopters)	363	0.21 ± 0.35	− 0.50 to 1.00	< 0.001
Spherical equivalent pos-instillation (Diopters)		0.03 ± 0.43	− 1.00 to 1.13	
Unaided visual acuity far vision pre-instillation (logMAR)	362	0.10 ± 0.11	0.0–0.5	< 0.001
Unaided visual acuity far vision post-instillation (logMAR)		0.05 ± 0.08	0.0–0.5	
Unaided binocular visual acuity far vision pre-instillation (logMAR)	363	0.03 ± 0.08	0.0–0.5	< 0.001
Unaided binocular visual acuity far vision post-instillation (logMAR)		0.01 ± 0.04	0.0–0.5	
Unaided visual acuity near vision pre-instillation (logMAR)	362	0.45 ± 0.17	0.0–1.0	< 0.001
Unaided visual acuity near vision post-instillation (logMAR)		0.26 ± 0.15	0.0–1.0	
Unaided binocular visual acuity near vision pre-instillation (logMAR)	363	0.33 ± 0.17	0.0–1.0	< 0.001
Unaided binocular visual acuity near vision post-instillation (logMAR)		0.15 ± 0.12	0.0–1.0	
Photopic pupil pre-instillation (mm)	308	3.30 ± 0.58	2.00–5.10	0.08
Photopic pupil post-instillation (mm)		3.23 ± 0.75	1.70–6.10	
Scotopic pupil pre-instillation (mm)	308	4.99 ± 0.80	2.30–6.90	< 0.001
Scotopic pupil post-instillation (mm)		4.01 ± 0.87	1.90–7.20	

logMAR Log of Minimum Angle of Resolution

[a]n may not add to 363 due to missing data

[b]Mean and standard deviations (SD) of the linear variables under study

[c]p indicates difference between participant characteristics pre- and post-instillation of the eye drops

Table 1 shows the eye characteristics of the subjects included in the study.

The increase in unaided logMAR binocular near visual acuity had a normal distribution (Fig. 1). Unaided near visual acuity increased by almost two lines after drop instillation both monocularly and binocularly (monocular 0.19, biocular 0.18; $p < 0.01$), and binocular near visual acuity increased by at least one logMAR line in 91.5% of the subjects (Fig. 1). A 1.76 ± 0.42 D mean near addition at pre-instillation of drops was not necessary to obtain binocular vision for comfortable near reading after the instillation of the eye drops in most of the participants (91.5%). However, 8.5% of the subjects (n = 31) failed to improve by at least one line of visual acuity.

After instillation of the FOV Tears, the mean (± SD) diameter of the scotopic pupil decreased significantly by 0.97 ± 0.98 mm ($p < 0.001$; Table 1). In 16.8% of subjects there was a mild increase in the diameter of the scotopic pupil at 2 h after drop instillation. Figure 2 shows that there were no significant differences in near visual acuity gain between those subjects with pupils < 1 mm in diameter or those with scotopic pupils ≥ 1 mm in diameter (p = 0.17). The diameter of the photopic pupil decreased by a non-significant amount (0.07 ± 0.69 mm) after the instillation of the FOV Tears (p = 0.08). Photopic pupils increased at least by 0.1 mm in diameter after instillation of FOV Tears in 45.7% of the subjects. Figure 3 shows that non-significant differences in near visual acuity lines gained between photopic pupils with increased (≥ 1 mm) versus decreased (< 1 mm) diameter were found (p = 0.65). There were no significant differences in the change in pupil size (p = 0.77) between both types of eyes. There was a small difference of borderline significance in change

in lines gained for near vision between both eyes (0.01 LogMar; $p = 0.053$).

A positive correlation was found between age of the participants and the change in binocular unaided near visual acuity, with older subjects having a better outcome ($r = 0.15$, $p = 0.005$). A positive correlation was also found between the change in binocular unaided near visual acuity and baseline SE ($r = 0.16$, $p = 0.003$). There was an age-dependent decrease in the scotopic pupil diameter after the instillation. The correlation between pupil diameter and age showed that pupil diameter decreased linearly by 0.3 mm for each 10 years of age ($p < 0.001$). Similarly, the photopic pupil decreased by 0.1 mm in diameter for each 10 years of ageing ($p < 0.01$). The correlation between the change in the scotopic pupil and age of the participants was not significant, with older and younger subjects having a similar amount of change in pupil diameter after the instillation of eye drops ($p = 0.41$).

In linear regression analyses, age ($p < 0.001$) and SE pre-eye drops ($p < 0.001$) were associated with unaided binocular visual acuity (Table 2). The photopic pupil change and scotopic pupil change were not associated with unaided binocular visual acuity.

DISCUSSION

This study describes the effects of the FOV Tears formulation on pupil change in emmetropic patients with presbyopia. Changes in the photopic and scotopic pupil were not associated with the increase in unaided binocular near vision logMAR visual acuity, which may indicate that the mechanism by which the FOV Tears formulation exerts its action is not solely by pupil constriction and that other structures may also be involved, such as the crystalline lens or the ciliary muscle. The results of the present study showed that even without an effective change in the photopic pupil, there was a two-line increase in unaided near vision with instillation of FOV Tears.

Another important finding in this study was the very small and not clinically significant myopic shift of 0.17 (D) in mean distance SE, which shows that there was no relevant spasm of accommodation with the low concentration of pilocarpine in FOV Tears in participants

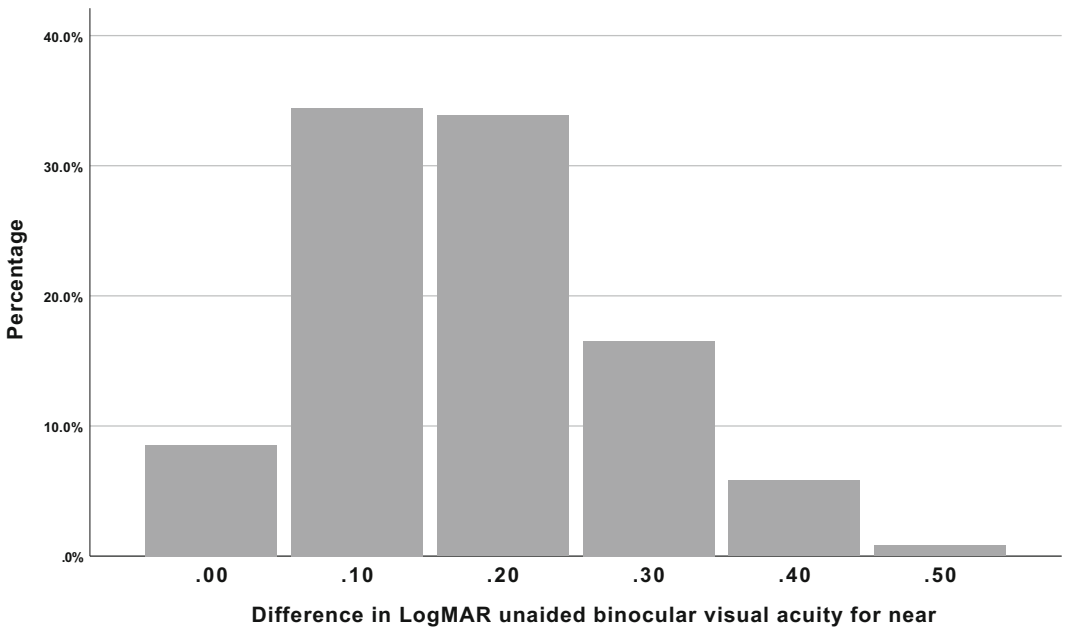

Fig. 1 Histogram showing the distribution of the differences between pre- and post-instillation of drops in unaided binocular visual acuity for near vision (in logMAR). *logMAR* Log of Minimum Angle of Resolution

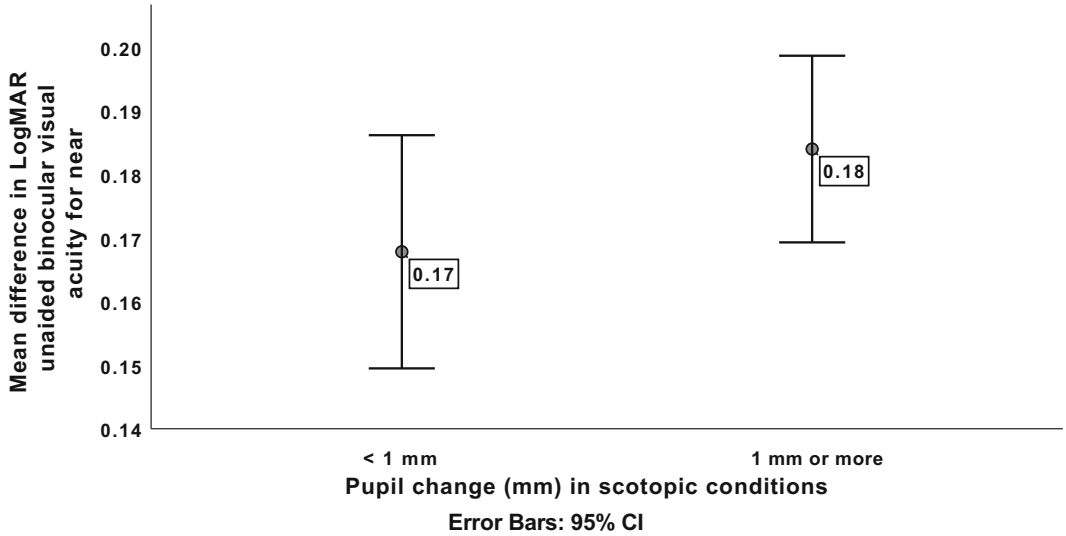

Fig. 2 Mean of difference in LogMar unaided binocular visual acuity changes for near vision by change in pupil diameter under scotopic conditions. Whiskers represent the 95% confidence interval (*CI*)

aged > 40 years. The observed improvement in binocular visual acuity for near vision without a significant concurrent mechanistic change in the size of the photopic pupil or a clinically significant myopic shift needs further research. Future studies on how these drops could enhance near and distance vision independently of pupil size and refractive shift are therefore necessary. Accommodation and the pinhole are important factors to consider. Both accommodation for near vision and presbyopia development [7, 18, 19] include changes in lens stiffness, anterior lens surface curvature, lens thickness, lens position inside the anterior segment and the internal mechanism of accommodation produced by the gradient index [12, 20, 21]. This last mechanism was discovered by Gullstrand and colleagues with their

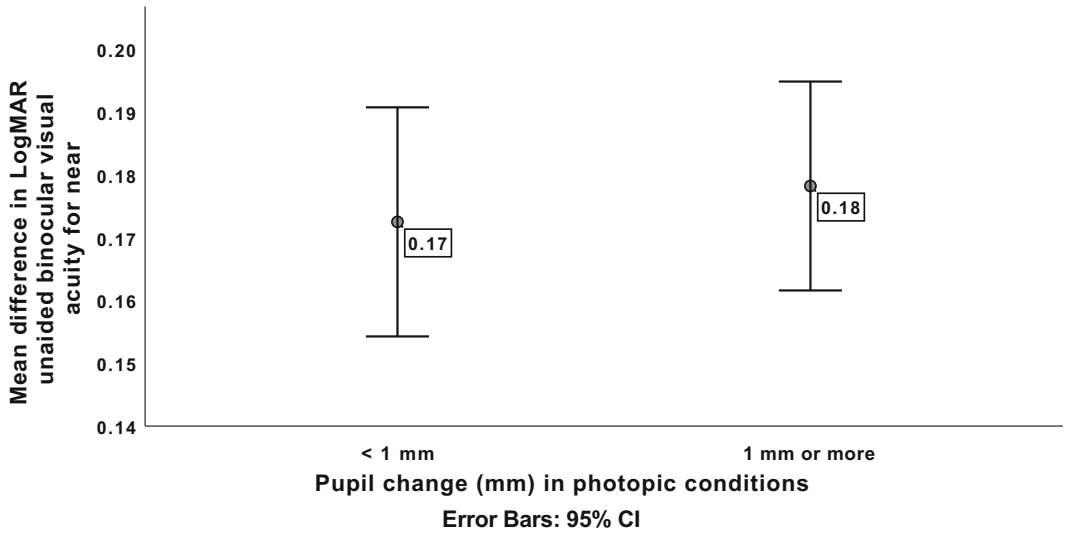

Fig. 3 Mean of difference in LogMar unaided binocular visual acuity changes for near vision by change in pupil diameter under photopic conditions. Whiskers represent 95% CIs

invention of the slit lamp [22]. Measuring changes in these parameters is difficult in clinical practice, with the exception of lens thickness and lens position, measurements of which can be obtained for distance with optical biometry. However, accommodation can be accurately measured under laboratory conditions [23]. Further research is also necessary to gain an understanding of the mechanism of action of these drops with a low concentration of pilocarpine that increase binocular uncorrected near visual acuity. Nevertheless, we cannot exclude the dynamics of practice effects in an optotype acuity task [24] as there was no control or placebo group in the present study.

A recent clinical trial using 1.25% pilocarpine drops and a proprietary vehicle reported the percentage of participants who increased 'distance corrected' near visual acuity by at least two or three lines at 3–8 h after instillation on day 30 of daily use [8]. In that trial, the mean mesopic 'distance corrected' near visual acuity pre-instillation of drops was almost 30 logMAR letters, that is 0.6 logMAR or approximately equivalent to 4 letters on the Jaeger chart [25]. It should be noted that these are the mean values of near uncorrected visual acuity as these are seldom reported. In our study, which included only emmetropic participants, there was no need to use distance correction for near vision as only emmetropic subjects not wearing distance correction were included. It is interesting to note that near vision improved by about two lines following instillation of FOV Tears. This is probably because near tasks in an urban indoor culture require a visual acuity of about 20/40 [26]. Presbyopic symptoms may begin when this threshold is reached and can be alleviated with only a small amount of improvement, namely two improved logMAR lines. Accommodation is a very complex mechanism that has been recently reviewed [27, 28]. The drive for near accommodation is a vegetative automatic reflex initiated by retinal blur perceived at the macular region [29]. The eye is directed to the target of interest by the extra-ocular voluntary striated muscles and simultaneously automatically focused by the mentioned accommodative reflex. Since the study of Sheard using dynamic retinoscopy in 1922 [30], it is well known that near reading tasks in young subjects involve a lag of accommodation [31]. Eyes lag near focus for the expected stimulus target distance. This lag (usually around a value of − 0.75 D) may be the result of printed and visual display letters having big angles of resolution (20/40 visual acuity) [26], and it is probable that the accommodative system lags precision as comfortable near reading can be achieved with lower visual acuity than distance reading.

Table 2 Association of pupil change with unaided binocular visual acuity for near vision (n = 363)

Demographic and eye characteristics	Unaided binocular visual acuity for near vision			
	Unadjusted β (95% CI)	p	Multivariable β (95% CI)	p
Age	0.01 (0.004, 0.01)	< 0.001	0.01 (0.003, 0.01)[a]	< 0.001
Gender (female = 0)	− 0.003 (− 0.03, 0.02)	0.82	− 0.01 (− 0.03, 0.02)[a]	0.49
Spherical equivalent pre-eye drops	0.11 (0.07, 0.14)	< 0.001	0.09 (0.05, 0.13)[a]	< 0.001
Photopic pupil change	0.000 (− 0.02, 0.02)	0.98	0.002 (− 0.02, 0.02)[a]	0.84
Scotopic pupil change	0.01 (− 0.01, 0.02)	0.41	0.01 (− 0.004, 0.02)[b]	0.18

CI confidence intervals

[a]Multivariate model included age, gender, spherical equivalent pre-eye drops and photopic pupil change (n = 308)

[b]Multivariate model included age, gender, spherical equivalent pre-eye drops and scotopic pupil change (n = 308)

The illumination at which the near visual acuity has been measured may be an important limitation of the present study. The photopic conditions selected for this study were based on international standards that suggest high illumination at 500–700 lx for indoor tasks, such as reading [32, 33]. Although, we used high indoor illumination standards, the FOV Tears formulation should also be tested in mesopic conditions, as suggested by the Allergan trial [8]. Distance visual acuity changes from 0.30 logMAR lines at 100 lx to 0.18 logMAR lines when testing at illumination levels of 1000 lx, as in the present study [33]. However, we could find no studies related to changes in mean unaided vision according to room illuminance, so further research is necessary as near unaided visual acuity seems to be sensitive to illumination levels. Interestingly, the Shahroud Eye Cohort Study [7] showed an unaided near visual acuity of 1.07 logMAR units for subjects aged 45–-49 years (approximately 20/200), which is much lower than the mean near unaided value of 0.45 logMAR lines reported in the present study. Differences between studies might depend on the illumination of the testing rooms in both studies, as the illumination of the examination room in the Shahroud Eye Cohort Study was 633 lx [7]. Another important difference between the two studies is that the Shahroud Study is a population-based study and the present study included a clinical sample of participants searching for spectacle independence. A previous study showed that presbyopes can read with a small-pupil diameter of 2–3 mm at maximum or near-maximum speeds with text luminance between 140 and 1.4 cd/m^2 without a significant loss in best focus (distance) vision [34]. Under low-light levels, the image quality is lower with small pupils (1.0–1.5 mm). However, large pupils are most effective at expanding the depth of focus under mesopic light levels [35]. Interestingly, an increase in depth of focus may not be related with the near vision improvement as only pupils < 2 mm can increase the depth of focus of the human eye [36–38].

There is another approach to measuring improvements in near vision, such as near visual activities questionnaires [39]. The literature on these important instruments for presbyopia research has been recently reviewed and their accuracy demonstrated [39]. These short 10-item questionnaires could be systematically used for assessing near vision performance [39], thus showing the changes produced in near vision performance by different treatment options for presbyopia correction. The aim of our group is to implement these instruments in future research with FOV Tears.

Interestingly, the effect of improving reading visual acuity with FOV Tears was more pronounced in older subjects and in more hyperopic subjects. The greater effect in older participants may indicate a possible mechanism of action either at the level of the ciliary muscle or at the level of the internal gradient index, which changes with age [21].

Patients receiving treatment with pilocarpine may be at risk of developing retinal detachment. Further studies with longer follow-up are therefore necessary to access this risk as retinal detachment post-treatment with pilocarpine 1.25% for the treatment of presbyopia was reported in two studies [40, 41]. It is also important to note that the patients who developed retinal detachment had pre-existing retinal pathology, suggesting that the treatment of high-risk patients with pilocarpine should be avoided. Nevertheless, FOV Tears contain a relatively low concentration of pilocarpine (0.247%), and further studies are necessary to ascertain the risk of developing retinal detachment with this lower concentration.

This study has several limitations. The design was a case series, and the follow-up duration was very short; therefore, the long-term effect of this agent in near visual acuity and pupil dynamics is not known. This was a non-randomized study, and a control group was not included. Thus, to reduce bias and allow masking, further randomized clinical trials are important to test the effect of this agent on the pupil diameter. The measurement of near unaided visual acuity should be standardized, as well as the illumination of the reading charts. Further studies should be performed to compare binocular distance-corrected near visual acuity and defocus curves pre- and post-instillation of FOV tears to better understand the factors that

can affect visual performance using this treatment strategy.

CONCLUSIONS

In conclusion, the results of the present study suggest that the changes in the photopic and scotopic pupil were not associated with the improvement of unaided binocular visual acuity for near vision. Future research testing of accommodation under laboratory conditions following instillation of these drops is of paramount importance in presbyopia treatment. Further studies on the effect of treatment should evaluate both near uncorrected visual acuity and near visual activity performance.

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Disclosures. Felipe Vejarano owns the patent for the FOV Tears formulation. Jorge Alió, Rafael Iribarren and Carla Lança have no conflict of interests to declare.

Compliance with Ethics Guidelines. The protocol of the study adhered to the tenets of the Declaration of Helsinki of 1964 and it subsequent amendments and was approved by the Ethics Committee of the Vejarano Ophthalmological Foundation in Colombia. Informed consent was obtained from the subjects after explanation of the nature and possible consequences of the study.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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