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Original Research Article

Efficacy and safety of 1% pilocarpine eye drops in the treatment of presbyopia: A clinical evaluation

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Abstract

Background: Presbyopia is an age-related loss of near focusing ability due to reduced lens elasticity and ciliary muscle function, affecting over 1.8 billion people globally. While spectacles remain the primary correction method, they are often inconvenient. Surgical options exist but have limitations. Pilocarpine, a miotic agent, improves near vision by inducing miosis and enhancing depth of focus. Recently FDA-approved for presbyopia, its long-term safety and efficacy remain under study. This research evaluates the effectiveness and tolerability of 1% pilocarpine eye drops as a non-invasive alternative for presbyopia management.

Aim & Objective: Our primary objective of the study was to evaluate effect and safety of 1% pilocarpine among presbyopic subjects.

Materials and Methods: The present prospective study was conducted in the Department of Ophthalmology at tertiary care center among 100 subjects coming for evaluation of presbyopia. Between the duration of February 2023 to March 2024. Subjects were asked to instil 1% pilocarpine eye drop in each eye, one drop once daily in the morning for 30 days. The patient was followed up at 1 week, 2 weeks, 30 days and 60 days.

Results: In the present study the average age of participants was 46.34 ± 4.79 years with a higher prevalence among males (54%). The chief complaints among subjects were diminution of vision (56%), headache (40%), and watering (33%) Our results showed a significant improvement in near vision after 30 days of pilocarpine use, with many subjects achieving functional vision without additional correction. More than half of the participants (55.91%) exhibited marked improvement, often eliminating the need for reading glasses. A reduction of 26.21 cells/mm2 was noted from baseline data but was not statistically significant. While the treatment was generally well-tolerated, a small percentage (7%) of subjects experienced mild side effects, such as eye pain, irritation, and increased lacrimation. All of then voluntarily discontinued participation from study.

Conclusion: 1% pilocarpine eye drops show promising results in reducing presbyopic correction needs and may be an effective therapeutic option for presbyopia. Though individual responses may vary, warranting further research with larger sample sizes and longer follow-up periods.

Keywords: Presbyopia, Pilocarpine eye drops, Visual acuity, Pupil diameter, Refractive errors.

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1. Introduction

The human eye achieves visual clarity by refracting light to precisely concentrate it onto the retina. The inability of an optical component of the eye to focus the optical image is known as a refractive error. Presbyopia is not a refractive error but it does affect near visual acuity. When the lens loses its usual accommodating capacity, it results in presbyopia and eyes are unable to concentrate on things that are closer than arm's length.¹

Presbyopia is an age-related impairment of near vision characterised by a gradual decrease in the eye's

accommodation. It is hypothesized that the weakening of the ciliary muscles or a loss of lens elasticity preventing focal point change are the two main factors involved in the development of presbyopia. Oxidized protein sulphydryl groups within lens fibre cells from intraprotein crosslinks may cause the loss of lens elasticity, which over time leads to a reduction in accommodative amplitude. Blurred vision and the inability to see clear details at a near working distance are the hallmarks of presbyopia.²

Presbyopia starts to become functionally apparent at around 40 years old and affects individuals for a considerable

*Corresponding author: Nazia Jamal Email: jamalnazia@gmail.com part of their working lives. If left uncorrected or undercorrected, presbyopia could result in productivity losses. The adoption of digital technology has made better near vision a necessity due to the exponential increase in the use of screens for work and leisure. Age-related loss of accommodation causes presbyopic subjects to experience additional visual stress and productivity losses, often leaving their intermediate and near vision under or uncorrected.²

Presbyopia, either uncorrected or under-corrected, can affect many aspects of quality of life, including reading difficulties (inability to read fine print, need for increased lighting, diplopia, epiphora, headache, fatigue, or asthenopia) and other activities (threading a needle or seeing fine details on proximal objects). Premature crystalline lens breakdown brought on by UV radiation exposure can lead to the early onset of presbyopia and hypermetropia.³

One of the leading causes of vision impairment worldwide is uncorrected presbyopia.⁴ Global estimates indicate that there are around 1.8 billion persons suffering from presbyopia, with a 95% confidence interval ranging from 1.7 to 2.0 billion. Among these, a total of 826 million individuals experienced near vision impairment due to the absence or insufficient usage of vision correction methods.⁵ By 2030, the global population of individuals with presbyopia is projected to reach 2.1 billion.⁶ Presbyopia has a significant impact on both the well-being of individuals and the whole economy of the country, particularly in low- and middle-income countries such as India. Therefore, it is crucial to address presbyopia to achieve sustainable development goals that aim to promote health and well-being for everyone.⁷

The treatment and correction of presbyopia remain difficult due to the absence of pharmaceuticals or techniques that can achieve flawless vision at all distances without any associated risks. At present, there are multiple choices available for treating presbyopia, including optical correction using bifocal or progressive spectacles, mono-focal or multifocal contact lenses, corneal or intraocular surgical procedures, and pharmaceutical treatment. Spectacles, whether monofocal, bifocal, or multifocal lenses, are frequently used for optical correction due to their convenient availability and non-invasive nature. Nevertheless, numerous patients perceive eyewear as uncomfortable. Monovision contact lenses can impair stereopsis due to their use of only one eye for near tasks. Depth perception is compromised when there is a discrepancy in the focusing ability of both eyes. While multifocal contact lenses can serve as a substitute for glasses, they might also lead to discomfort or difficulty for certain patients, especially those who are inexperienced with wearing contact lenses. Contact lenses are also associated with a potential risk of severe ocular surface infections.

There is a growing interest in surgical options, namely corneal or intraocular procedures, due to their utilisation of cutting-edge technologies. Corneal surgery, including procedures like corneal monovision, corneal inlays, collagen shrinking, or multifocal LASIK, was a common approach for correcting presbyopia. They have shown efficacy in enhancing close-range eyesight; yet, there are drawbacks, including compromised mid-range or long-range eyesight, diminished ability to perceive contrasts, dysphotopsia, or regression in refractive correction. Consequently, certain patients still necessitate the use of spectacles following the surgeries. In addition to corneal surgeries, we employed intraocular lenses (IOLs), such as monovision IOLs or multifocal IOLs, to address presbyopia. However, these IOLs have drawbacks such as dysphotopsia or reduced intermediate vision.⁸

Presbyopia can be currently corrected with the use of reading glasses or laser surgery. Currently, there are no viable substitutes for glasses or laser treatment. Several obstacles hinder the administration of topical ocular medicines, including anatomical and physiological barriers, noncompliance and undesirable side effects. Topical eye drops often cause side effects such as eye discomfort, irritation, redness, inflammation, and blurred vision. The negative effects may arise from either the therapeutic substance itself or one of the ingredients present in the vehicle of the eye drop.

Scientists are presently studying several novel pharmacological compounds to cure presbyopia, utilising two primary modes of action. The initial category of medications is pupillary miotics, which induce a pinhole effect and enhance the depth of field. The parasympathetic system regulates the degree of contraction of the ciliary muscle and iris, which is necessary for altering the shape and position of the lens. Both structures exhibit activation of muscarinic receptors in response to system stimulation. Muscarinic agonists induce contraction of the ciliary muscle and an increase in lens thickness. Inducing miosis enhances the depth of focus and generates pseudo-accommodation. Eye drop pilocarpine 1% is a prominent muscarinic agonist employed in clinical trials. Pilocarpine induces both constriction of the pupil (miosis) and contraction of the ciliary body. These effects aid in the adjustment of the eye's focus and potentially stimulate increased tear production by enhancing the secretion of fluid from the lacrimal glands. The eye drop affects the ciliary muscle, resulting in physiological adjustment and dynamic pseudo-accommodation.9 The US FDA approved 1.25% pilocarpine hydrochloride ophthalmic solution (AGN-190584) in November 2021. This eye drop is intended for the treatment of presbyopia. This eye drop treatment for presbyopia has become the first to get FDA approval in the United States.8

1.1. Research gap and rationale for the study

Despite advancements in pharmacological interventions for presbyopia, treatment options remain limited to corrective lenses, surgical approaches, and emerging miotic agents. Among these, 1% pilocarpine eye drops have shown promise in improving near vision by inducing miosis and increasing depth of focus.

However, several gaps persist in the existing literature

- Limited long-term safety data: While pilocarpine has been studied in higher concentrations, its chronic use in lower doses for presbyopia remains insufficiently explored, particularly concerning ocular surface changes, accommodative function, and retinal effects.
- 2. Efficacy across different age groups and Refractive Profiles: Most studies have not comprehensively analysed its effectiveness in individuals with varying presbyopic severity, ametropia, or lens status (phakic vs. pseudophakic eyes).
- 3. Optimal dosing and patient tolerance: The balance between efficacy and adverse effects (e.g., headache, dim vision, or ciliary spasm) needs further evaluation to determine the ideal concentration and frequency.
- 4. Comparative effectiveness with other miotic agents: There is a scarcity of direct comparative studies between 1% pilocarpine and newer pharmacologic alternatives, limiting its positioning in clinical practice.

Given these gaps, this study aims to provide robust clinical data on the efficacy, safety, and patient tolerability of 1% pilocarpine in the treatment of presbyopia, thereby contributing to a more evidence-based approach for its adoption in routine ophthalmic practice.

2. Materials and Methods

The present prospective study was conducted in the outpatient department of ophthalmology at CSSH Subharti Medical College among 100 subjects. The study aimed to evaluate the effect and safety of 1% pilocarpine eye drops among presbyopia affected individuals.

2.1. Study design

Prospective study.

2.2. Place of study

Netaji Subash Chandra Bose Subharti Medical College, Meerut.

2.3. Duration of study

14 months.

2.4. Sample size

A sample size of 100 cases of presbyopia in the age group 35-55 years was taken and followed for 2 months.

An informed written consent was obtained from all the participants before enrolment.

The ethical clearance was taken ethical committee Subharti Medical College. Relevant preliminary details of the patients were taken in the Performa.

2.5. Inclusion criteria

- 1. Age group of 35-55 years including both male and female.
- 2. Individuals have to be in general good health, emmetropes (defined as uncorrected distant VA 6/9 or better) with presbyopia in each eye.
- 3. Photopic, high-contrast uncorrected distance visual acuity (UDVA) of 6/9 or better in each eye at the screening and baseline visit.
- 4. High-contrast uncorrected near visual acuity (UNVA) of 20/40 (N8) to 20/200 (N36) in each eye at the screening and baseline visits.
- 5. Spectacle correction of magnitude +1.00 to +2.50 reading resulting in mesopic high-contrast UNVA of 20/20 (N6) or better in each eye.
- 6. Mesopic pupil diameter <8.0 mm and photopic pupil diameter >3.0 mm.

2.6. Exclusion criteria

- 1. Intraocular pressure <10 mmHg and >21 mmHg.
- 2. Individuals with corneal abnormalities.
- 3. Individuals with a history of any intra-ocular surgery including cataract surgery.
- 4. Individuals with angle closure glaucoma.
- 5. Abnormal pupil shape, anisocoria >1mm between pupils under mesopic conditions.
- 6. History of migraine, headaches requiring treatment
- 7. Any concurrent use of topical ophthalmic medications during the study.

2.7. Methodology

- 1. Detailed clinical history (regarding their Diabetes Mellitus and hypertension status or any other systemic illness) along with a thorough ophthalmic examination was done during the OPD visit.
- VA was tested with the Snellen chart (uncorrected distance visual acuity-UDVA) and Jaeger's chart (uncorrected near visual acuity-UNVA and corrected near visual acuity-CNVA) then the refractive status of the patient was assessed.
- Near point of convergence (NPC) and near point of accommodation (NPA) calculated by Royal Air Force (RAF) rule.
- 4. Assessment of Pupillary diameter in photopic and mesopic. Pupil size measurement with a pupilometer involves positioning the device close to the eye, aligned with the visual axis, to capture accurate readings in both mesopic (low light) and photopic (bright light) conditions. The pupilometer uses infrared light to avoid triggering pupil constriction

- 5. Tonometry by non-contact tonometer (NCT) or Schiotz tonometer to rule out glaucoma.
- Thorough slit lamp examination to exclude anterior segment abnormality.
- Dilated fundoscopy with an indirect ophthalmoscope was done to rule out retinal pathology or degeneration.
- 8. Emmetropes with presbyopia were asked to instil 1% pilocarpine eye drop in each eye, one drop once daily in the morning for 30 days. The patient was followed up at 1 week, 2 weeks, 30 days and 60 days.
- 9. At each visit UNVA, UDVA, CNVA, NPC, NPA and pupillary diameter in mesopic condition documented.
- 10. Any side effects like headache along with floaters or flashes documented.

2.8. Data assessment

The software SPSS 26.0 version was used for data analysis. A percentage was used to display qualitative data. The mean and standard deviation of quantitative data were used as representations. A 0.05 value is considered significant in our analysis.

3. Results

In the present study, we enrolled 100 subjects who were affected by presbyopia and visited the Department of Ophthalmology at Subharti Medical College, Meerut. We observed the effect and safety of 1% pilocarpine eye drops among these patients. Among 100 subjects, 7 participants withdrew from the trial after one week due to adverse effects caused by the use of 1% pilocarpine eye drops. (Eye pain and irritation, increased lacrimation and conjunctival hyperaemia).

A total of 100 presbyopic subjects were enrolled in the study. **Table 1**, Among 100 subjects, 46% were females whereas 54% were males enrolled in the study.

Table 1: Gender distribution

Gender	Frequency	Percent	
Female	46	46.0	
Male	54	54.0	
Total	100	100.0	

The age distribution of the participants is detailed in **Table 2**. The presbyopic subjects were categorised into four age groups: $1) \le 40$ years (14%), 2) 41-45 years (36%), 3) 46-50 years (27%) and 4) 51-55 years (23%), with the highest proportion of subjects (36%) in the 41-45 years age group. Overall, mean age of the study was 46.34 ± 4.79 years.

Figure 1 presents the distribution of various occupations among the study participants. The most common occupational category was teachers (25%), followed by laborers (16%) and homemakers (18%). A significant proportion of participants were businesspersons (14%) and

farmers (13%), while clerks (10%), workers (12%), and drivers (8%) constituted the remaining portion of the study population.

Table 2: Age group distribution

	Frequency	Percent
≤ 40	14	14.0
41-45	36	36.0
46-50	27	27.0
51-55	23	23.0
Total	100	100.0

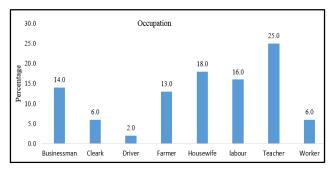


Figure 1: Occupation

Table 3, Out of 100 patients, 56% had Diminution of Vision, 31% had watering and 40% had headache as chief complaints during the study observations.

Table 3: Chief complaint

	Percent
Diminution of Vision	56.0
Headache	40.0
Watering	33.0

3.1. Effect of 1% pilocarpine on near vision

Table 4, Administration of 1% pilocarpine eye drops demonstrated significant improvement in uncorrected near visual acuity (UNVA), while uncorrected distance visual acuity (UDVA) remained unchanged. The UNVA data indicates a progressive improvement in near vision over time. At Day 0 and Day 7, 14 subjects had N8 vision, 61 had N10, and 25 had N12. However, by Day 14, there was a noticeable shift, with more subjects improving to N8 (19 subjects) and fewer remaining at N12 (18 subjects). By Day 30, the improvement was substantial, with 49 subjects achieving N8 vision, a significant reduction in N12 cases (only 8 subjects), and a corresponding shift from N10 to N8. This trend continued through Day 60, where 49 subjects retained N8 vision, only 4 remained at N12, and the proportion in N10 slightly increased from 36 to 40.

UDVA	Day0	Day7	Day14	Day 30	Day60
6/6	100	100	93	93	93
UNVA	Day0	Day7	Day14	Day 30	Day60
N8	14	14	19	49	49
N10	61	61	56	36	40
N12	25	25	18	8	4

Table 4: Uncorrected distance visual acuity (UDVA) and Uncorrected near visual acuity (UNVA)

Table 5: Effect of 1% pilocarpine on presbyopic correction and reading ability

Initial Presbyopic Correction (D)	Number of Subjects	Subject able to read without glasses	Symptoms (Headache/Watering)	Percentage able to read without glasses
0.75	14	14	No	100
1	25	24	No	96
1.25	29	13	No	44.83
1.5	25	1	No	55.91

Table 5, in subjects with mild presbyopia, particularly those with 0.75 D and 1.00 D correction, pilocarpine demonstrated excellent efficacy, enabling nearly all participants to read without presbyopic glasses. Specifically, all 14 subjects with 0.75 D presbyopia and 24 out of 25 subjects with 1.00 D presbyopia achieved presbyopic spectacle-free near vision, resulting in success rates of 100% and 96%, respectively. This indicates that pilocarpine is highly effective in early presbyopia, where only a slight improvement in depth of focus is required to restore functional near vision.

However, the efficacy declined in subjects with moderate presbyopia. Among those with 1.25 D, only 13 out of 29 subjects (44.83%) could read without presbyopic glasses, while in the 1.50 D group, 14 out of 25 subjects (55.91%) achieved presbyopic spectacle independence. This suggests that while pilocarpine-induced miosis and depth of focus enhancement provide some benefit, they may not be sufficient in more advanced presbyopia, accommodative loss is more pronounced. Interestingly, the success rate at 1.50 D was slightly higher than at 1.25 D, which may reflect individual variability in response to the drug.

In the present study, we observed that pupil diameter decreases from Day 0 to Day 30 was 1.16 mm after applied of 1% pilocarpine eye drops, enhancing depth of focus (**Figure 2**). This pharmacologically induced miosis mimicked the physiological changes seen in aging but in a controlled manner, improving near vision without significantly impacting distance vision.

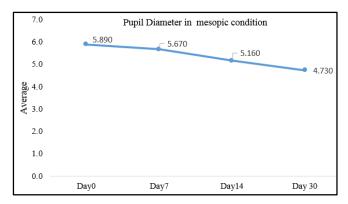


Figure 2: Pupil diameter in mesopic condition

However, age-related changes in pupil dynamics also played a role in the baseline measurements. The younger age group (≤40 years) tends to have a larger baseline pupil diameter and a slightly more prolonged reduction pattern. The older age groups (51-55 years) exhibit a more consistent and possibly stronger miotic response, stabilizing at smaller pupil sizes by Day 30.

These findings align with the understanding that pupillary constriction can improve near vision in presbyopic individuals, making 1% pilocarpine an effective non-invasive alternative for presbyopia correction. However, the long-term impact on age-related pupil function requires further study.

4. Discussion

Presbyopia is a widespread condition caused by natural changes in the protein of the eye's crystalline lens that occurs with age. ^{10,11} Presbyopic individuals are defined as those who cannot read the N8 optotype with distance adjustment, or who can read at least one extra line with the use of a plus lens. ¹² The Markoulli et al. study reported that around 1.8 billion individuals worldwide were affected by presbyopia in 2015. It is expected that the prevalence of presbyopia will increase to 2.1 billion by 2030 as a result of population dynamics. ¹³

A study conducted at a hospital in Kano, Nigeria, revealed that 83% of individuals above the age of 35 suffer from presbyopia, a finding that aligns with our study. Treatment of presbyopia could be done as follows: 1) Spectacles, 2) Contact lenses, 3) Surgical approaches 4) Pharmaceuticals 5) Ciliary muscle electrostimulation.

In the present study, we aimed to evaluate the effect and safety of 1% pilocarpine eye drops in presbyopia affected subjects. We enrolled 100 presbyopic subjects based on the inclusion and exclusion criteria of the study. Among them, 7 participants voluntarily withdrew from the study after one week of use of 1% pilocarpine eye drops due adverse effects.

4.1. Age

In the present study, the overall mean age was 46.34 ± 4.79 years. Kannarr S. et al. observed that the overall mean age of the study was 50.4 ± 3.3 years. ¹⁴ This result was similar to the studies from Central America and Africa. ¹⁵ According to Khurana DA et al., the overall mean age of the study was 48.18 ± 6.57 years. ¹⁶ Abramson DH. et al. observed that the overall mean age of the study was 69 years which was much higher than the present study finding. ¹⁵

4.2. Gender

In the present study, 46% of females and 54% of males were enrolled during the study observation. In Renna et al. study, they found that males had a higher presbyopia rate than females. ¹⁷ Vargas V. et al. also found the same findings with the present study results as male predominance with 55%. ¹⁸ Khurana DA et al. and Majumder M. et al. observed that the gender predilection was in contrast to our study findings. ^{16,19} Kannarr S. et al. found that 61.4% of all subjects were females whereas 38.6% were males. ¹⁴

4.3. Chief complaints

In the present study, presbyopia-affected subjects had the following complaints: Diminution of vision (56%), Headache (40%) and Watering (33%). Majumder M. et al reported in all enrolled subjects, 51.6% had Diminution of vision, 11.75% had headache, 21.05% had eyeache, 29.25% had blurring of vision and 7.83% had watering. ¹⁹ 8.77% had headache problems observed by Kannar S. et al. ¹⁴

4.4. Occupation

In our study, 30% were labourers, 18% were housewives, 25% were teachers, 14% were businessmen and 13% were farmers requiring presbyopic correction. Patients with higher education are more likely to be involved with near work, both in professional and nonprofessional aspects of their lives. Therefore, they are more likely to complain of presbyopia. Mukuria M et al. had a contrary observation of more severe presbyopia among those who were less literate. According to Malhotra S. et al. study, 48.5% were homemakers, 45.8% were unemployed population, 36.8% were labourers and 28.9% were office workers.

4.5. Pupil diameter

In the present study, we observed that the decrease in pupil diameter from Day 0 to Day 30 was 1.16 mm after the instillation of 1% pilocarpine eyedrops. The mechanism of action of Pilocarpine, for the treatment of presbyopia, is through enhancing both depth of focus and accommodation.22-24 The pupil constricted administration of pilocarpine as compared to baseline in all subjects. Ruggeri M. et al. also observed that 1.56 mm decrease in pupil diameter after 1% pilocarpine eyedrops.⁹ Waring GO et al. also demonstrated decrease in size of pupil from from 3.5 mm to 1.5mm which supports of our study.²⁵ Pilocarpine contracts iris sphincter muscles and ciliary muscles by binding to and activating muscarinic M3 receptors.^{26,27} Contraction of the iris sphincter causes pupil constriction, creating a pinhole effect that increases both the depth of focus and the ability to focus on near objects. 24,28

4.6. Presbyopic correction

In our study, after 30 days of using 1% pilocarpine eye drops, the following outcomes were observed among the subjects. All 14 subjects with initial presbyopic correction of +0.75 D had improvement in UCNV to N6 and does not required near glasses. Similarly, 25 subjects who had initial presbyopic correction of +1.00 D, 24 had improvement in presbyopic symptoms and 29 subjects who had initial presbyopic correction of +1.25 D, 13 had improvement to N8 and required some degree of presbyopic correction. 25 subjects who had initial presbyopic correction of +1.50 D, only 1 had improvement of symptoms but required some degree of correction. These 55.91% subjects were able to read without glasses. Notably, these subjects were relieved of their initial symptoms of headache or watering. Socea S et al. observed ≥ 2-line improvement in binocular uncorrected near visual acuity (UNVA) from the baseline and concluded that pilocarpine could be an alternative to reading glasses and surgery similar to our present study. Lievens CW et al. [32] study showed significant improvements of more ≥3-line in UNVA, vision-related reading skills and the level of satisfaction achieved with pilocarpine which supports our study findings and Kannarr S et al.14 also observed an improvement of at least three lines in subject's vision which had similar observations corroborating with the present study.

4.7. Side effect

The present study revealed that 3% of subjects had eye pain, 2% experienced eye irritation and 2% developed increased lacrimation and Conjunctival Hyperaemia as side effects that either appeared or persisted following administration of 1% pilocarpine eye drops after 1 week of follow-up. These subjects were voluntarily withdrew from study and discontinued the use of pilocarpine eyedrop. Waring GO et al. also reported some ocular side effects after the instillation of 1% pilocarpine eye drops. ²⁵ During their study, they found

that 14.1% of participants had headaches, 4.3% of participants had visual impairment, 2.5% of participants had Conjunctival Hyperaemia, 2.5% of participants had visual blur, and 2.5% of participants had eye irritation. 2.5% of participants had eye pain, 2.5% participants had increased lacrimation, 2.5% participants had nausea and 0.6% participants developed punctate keratitis. Price Jr FW et al found headache 2.4% and punctate keratitis 2.4% with 1% concentration of pilocarpine.³⁰ While the study sheds valuable light on pilocarpine's potential as a presbyopia treatment, a note of caution is warranted. Including contraindications, such as its unsuitability for patients with certain eye conditions like iritis or narrow-angle glaucoma, would guide safe application.

4.8. Strengths of study

- 1. Pilocarpine directly targets the eye muscles, offering a specific, non-invasive therapeutic approach that is likely to be safe and accessible.
- 2. Standardized, objective measurement tools are used, making results quantifiable and reliable.
- 3. Focus on a controlled 1% concentration allows for better assessment of both safety and effectiveness.
- 4. Addresses the unmet need for non-surgical presbyopia treatments.

4.9. Limitations of study

- Potential lack of long-term follow-up, which may overlook chronic side effects or diminishing effectiveness.
- Generalizability may be limited due to variability in individual responses, influenced by factors like age or severity of presbyopia.
- 3. Side effects such as headache and visual disturbances could affect participant adherence.
- 4. Noticeable miotic effect might lead to a placebo effect.
- 5. Reliance on self-reported vision improvement introduces potential bias.
- Single-dose focus limits exploration of a doseresponse relationship, which could better inform optimal treatment strategies.

5. Conclusion

This study highlights the widespread prevalence of presbyopia, a common age-related condition affecting the crystalline lens of the eye, with significant implications for quality of life worldwide. Our investigation, focused on the efficacy and safety of 1% pilocarpine eye drops for treating presbyopia, enrolled 100 subjects who were thoroughly assessed for various demographic and clinical parameters. It offer a convenient, non-invasive option to improve near vision in presbyopia by enhancing depth of focus through pupil constriction. However, its temporary effects, need for frequent dosing, and common side effects, such as eye pain and lacrimation, limit its broader applicability. Additionally,

contraindications in certain eye conditions and the potential for ocular fatigue with long-term use warrant careful patient selection. Balancing these benefits and limitations is essential to maximize pilocarpine's potential as a presbyopia treatment. Based on the observed outcomes, it can be concluded that 1% pilocarpine eye drops shows promising results in reducing the need for presbyopic correction in individuals with varying degrees of initial presbyopia.

6. Source of Funding

None.

7. Conflict of Interest

None.

8. Ethical

Ethical No. SMC/UECM/2023/541/264.

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