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Original Research Article

One eye at a time: feasibility of unilateral 0.5% pilocarpine therapy in presbyopia management

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ABSTRACT

Background: The objective of the study was to evaluate the feasibility, efficacy, and patient tolerance of unilateral instillation of 0.5% pilocarpine for near vision improvement in presbyopic individuals.
Methods: This prospective interventional study included 130 eyes of 65 presbyopic individuals. A single drop of 0.5% pilocarpine was instilled in one eye of each participant once daily. Distance corrected near visual acuity was assessed uniocularly and binocularly on the 7th and 15th day following initiation of treatment. Subjective improvement in near vision was recorded using patient feedback on comfort and functional near tasks. Binocular vision, stereopsis, and patient- reported outcomes regarding reading comfort, glare, headache, and overall satisfaction were documented at each visit. After completion of 15 days, the same protocol was repeated in the fellow eye of the patient, following a unilateral sequential treatment approach. Statistical analysis was performed using paired t-test and Wilcoxon signed-rank test, as appropriate.
Results: The results demonstrated a clear and progressive improvement in near visual acuity over the two-week period with unilateral administration of 0.5% pilocarpine. Subjective assessment revealed improved reading ease and reduced dependance on near correction in the majority of participants. The treatment was well tolerated. Reported ocular side effects were mild and transient, including brow ache and mild dimming of vision, with no serious adverse effects recorded.
Conclusions: Unilateral administration of 0.5% pilocarpine is an effective and safe strategy for presbyopia management, providing meaningful binocular visual function. Sequential unilateral treatment may offer a practical, patient-friendly non-surgical option for presbyopia management.

Keywords: Presbyopia, Pilocarpine, Miosis, Near vision, Unilateral administration, Binocular vision, Visual acuity, Pharmacological management

INTRODUCTION

Presbyopia is an age-related, progressive loss of accommodation that typically becomes clinically significant after the age of 40 years and affects nearly all individuals by the fifth decade of life.[1-3] It represents one of the most common causes of near vision impairment worldwide and has a substantial impact on quality of life, occupational performance, and daily activities.[4-7] With increasing life expectancy and prolonged digital service usage, the global burden of presbyopia continues to rise, making the development of effective, safe, and patient-friendly treatment strategies increasingly important.[8-12]

Traditionally, presbyopia has been managed with optical correction in the form of reading glasses, bifocals, progressive additional lenses or contact lens.[13,14] While effective, these options are often associated with inconvenience, reduced patient satisfaction, dependency on external aids, and suboptimal visual performance in certain occupational settings.[15-18] Surgical approaches such as corneal inlays, laser refractive procedures, and lens- based surgeries have been explored, but these interventions are invasive, costly, and may be associated with irreversible visual side effects, limiting their acceptance among patients with early or moderate presbyopia.[19-21]

In recent years, there has been renewed interest in pharmacological treatment of presbyopia, aimed at temporarily enhancing near vision without permanent anatomical alteration.[22-24] The primary goal is to improve near vision by enhancing the eye's depth of focus or stimulating residual accommodative ability. Among the most studied agents is pilocarpine, a muscarinic agonist that acts on M3 receptors in the iris sphincter and ciliary muscle.[25,26] Pilocarpine, a parasympathomimetic agent, induces pupillary miosis and increases depth of focus, thereby improving near visual acuity. Additionally, pilocarpine contracts the ciliary muscle, allowing the lens to adopt a more convex shape and improve accommodation in younger presbyopic patients with residual flexibility of the lens.[27,28]

Pilocarpine has been used in ophthalmology for over a century, primarily for the management of glaucoma, laser procedures, and intraoperative miosis. However, its use for presbyopia is relatively new. The approval of 1.25% pilocarpine drops (Vuity) by the U.S Food and Drug Administration (FDA) in 2021 marked a significant milestone in this field.[28] More recently, a lower concentration formulation (0.4% pilocarpine, Qlosi) has received the FDA approval aiming to reduce side effects such as diminution in far vision, headaches, and ocular discomfort.[29]

Low- concentration pilocarpine formulations have gained attention due to their ability to provide functional near vision improvement while minimizing adverse effects such as excessive miosis, accommodative spasm, brow ache, and reduced distance vision. Several studies have demonstrated the efficacy of bilateral pilocarpine use in improving near vision; however, concerns remain regarding binocular distance blur, reduced contrast sensitivity, and patient intolerance when both eyes are treated.

Unilateral (monocular) pharmacological therapy represents a potentially advantageous alternative strategy. By instilling pilocarpine in only one eye, near vision may be enhanced through a pinhole effect while preserving distance vision and binocular visual function through the untreated eye. This approach mimics the principles of modified monovision while avoiding permanent refractive changes. Despite its theoretical benefits, unilateral use of pilocarpine for presbyopia has been relatively underexplored in clinical practice, particularly in real-world observational settings.

Most existing studies on pharmacological presbyopia management have focused on bilateral dosing and higher concentrations of pilocarpine.[30-32] Additionally, many trials have been conducted under highly controlled experimental conditions, which may not accurately reflect routine clinical practice. There remains a paucity of data evaluating the feasibility, tolerability, and real - world applicability of unilateral low-dose pilocarpine in a broader presbyopic population.

The present study was therefore undertaken at assess the feasibility of unilateral pharmacological management of presbyopia using 0.5% pilocarpine drops in patients over 40 years of age. The choice of a lower concentration and once-daily dosing was made to minimize potential side effects while maintaining therapeutic benefit. Unlike previous studies, this investigation emphasizes a prospective observational design, focuses specifically on monocular treatment, and evaluates outcomes in a real-world clinical setting. By prioritizing feasibility, tolerability, and practical applicability over efficacy alone, this study seeks to address an important gap in current presbyopia research. Through this approach, the study aims to determine whether unilateral low- dose pilocarpine can serve as a practical, minimally invasive, and patient-acceptable option for presbyopia management, and to provide foundational data may guide future controlled trials and clinical decision making.

METHODS

This prospective observational clinical study was conducted at Command Hospital (EC), Kolkata to evaluate the feasibility of unilateral pharmacological treatment of presbyopia using topical 0.5% pilocarpine eye drops. The study adhered to the tenets of the Declaration of Helsinki, as revised in 2013 (Fortaleza, Brazil).[33] Institutional Ethics Committee approval was obtained before the commencement of the study, and written informed consent was obtained from all participants prior to enrollment.

Patients presenting with symptoms of presbyopia were screened for eligibility. Individuals aged 40 years and above were included. The study was conducted from January 2025 to June 2025 which included follow- up period. All participants underwent a comprehensive ophthalmic evaluation before initiation of therapy. Inclusion criteria comprised symptoms attributable to presbyopia, including difficulty with near tasks and best corrected of 6/12 or better in both eyes. Exclusion criteria included a history of glaucoma, uveitis, angle closure disease, visually significant cataract, retinal or optic nerve pathology, prior ocular surgery or trauma, known hypersensitivity to pilocarpine, concurrent use of other

miotic agents or medications affecting accommodation and ocular surface disease requiring topical therapy.

Baseline assessment included uncorrected and best – corrected distance visual acuity (DVA), near visual acuity (NVA) measured using a standardized near vision chart at a fixed working distance, objective and subjective refraction, slit-lamp biomicroscopy, pupillary assessment under photopic conditions, intraocular pressure (IOP) measurement by applanation tonometry, and dilated fundus examination. Distant visual acuity was assessed using the Snellen chart and recorded in logarithm of the minimum angle of resolution (logMAR) units. Subjective difficulty with near tasks was recorded using a structured patient-reported questionnaire assessing reading comfort, clarity of near vision, and dependence on near spectacles.

Near vision values (both monocular and binocular) is noted at a distance of 30 cm using hand held N-notation near vision chart at first visit. Patient is given a bottle of fortified drops of 0.5% Pilocarpine drops (Prepared by diluting commercially available 2% pilocarpine eye drop with carboxymethyl cellulose (CMC) eye drop) and asked to daily put a single drop unilaterally in one eye in morning at a time once daily (Figure 1 A-F). The eye selected for treatment was based on patient preference or clinician discretion, with preference given to the non-dominant eye when applicable.

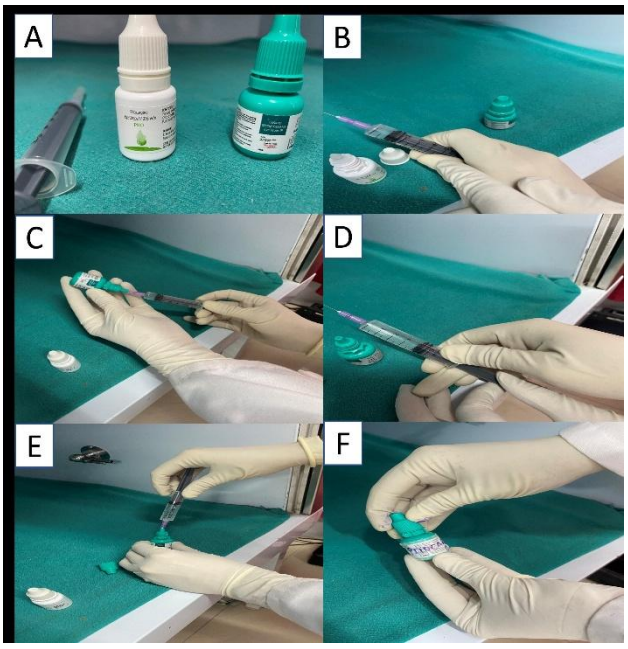

Figure 1: (A and B) Aseptic withdrawal of 1 ml of commercially available 2 % pilocarpine into a sterile syringe during preparation of low-dose pilocarpine; (C and D) dilution step: 3 ml of CMC eye drops added to 1 ml of 2% pilocarpine, yielding a total volume of 4 ml of 0.5% pilocarpine solution; (E and F) final preparation: the remaining CMC eye drops discarded, and 4 ml of 0.5% pilocarpine transferred into the CMC bottle and appropriately labeled.

Near vision was noted (both monocularly and binocularly) on 7th day & 15th day.

Subjective improvements in near vision was also noted (score 1, 2 and 3 respectively for improvement seen in reading newspaper, reading mobile messages and reading small letter of drug labels). After 15 days same process is repeated in other eye of the patient. Ocular side effects were noted at each visit (scores of 0, 1, 2, 3 and 4 respectively for- no side effects, pain/stinging sensation in the eye, brow ache, red eye and acute loss of vision).

Patients were instructed to instill one drop once daily, preferably in the morning, and were counseled regarding possible transient adverse effects such as brow ache, mild ocular discomfort, headache, or transient distance blur.

Patients were evaluated at predetermined follow-up visits after initiation of therapy. At each visit, near visual acuity of the treated eye was assessed using patient – reported outcomes related to ease of near tasks, duration of comfortable reading, and reduction in spectacle dependence. Secondary outcome measures included assessment of ocular and visual side effects such as headache, brow ache, conjunctival congestion, excessive miosis, dimming of vision under low illumination, reduction in distance vision, and overall visual discomfort. Intraocular pressure measurement and slit lamp examination were repeated at each follow-up visit to monitor safety and tolerability. Treatment was discontinued in patients who developed significant intolerance or clinically relevant adverse effects.

Statistical analysis was performed using standard statistical software. Continuous variables were expressed as mean±standard deviation (SD), while categorical variables were expressed as frequencies and percentages. For continuous near visual acuity measurements comparisons between follow-up visits (day 7 and day 15) were performed using the paired t-test.

Ordinal outcomes, including improvement in near vision expressed as number of lines gained and near vision categories (N- notation), were analyzed using the Wilcoxon signed- rank test. Subjective improvement in near vision and reported adverse effects were analyzed descriptively. A p value less than 0.05 was considered statistically significant.

Ethics approval

All procedures performed in studies involving human participants were in accordance with the local ethical committee (Command Hospital Eastern Command, Kolkata with reference no 282) and with the 1964 Helsiniki Declaration and its amendments or comparable ethical standards. This manuscript did not involve any kind of animal research.

RESULTS

A total of 65 patients (130 eyes) with symptoms of presbyopia were included in this prospective observational study. Of these, 46 patients (70.8%) were male and 19 patients (29.2%) were female (Table 1). The majority of participants belonged to the younger presbyopic age group, with 57 patients aged between 40 and 49 years, followed by 6 patients in the 50- 59 years age group and 2 patients in the 60-69 year age group (Table 1).

Table 1: Clinicodemographic profile of the study population (n=65).

Features	No of patients (N)	Percentage (%)
Age (years)		
Range	40-65	
Mean±SD	48±17.67	
40-49	57	87.7
50-59	06	9.2
60-69	02	3.1
Gender		
Male	46	70.8
Female	19	29.2
Refractive status		
Emmetrope	55	84.61
Hypermetropia	06	9.2
Myopia	04	6.15
Baseline DVA (logMAR) Mean±SD		0.12±0.10
Baseline DVA (Snellen)		6/6-6/12
Baseline NVA (N-notation)		
Uniocular near visual acuity Mean±SD (approx.)		N16±7.5
Binocular near visual acuity Mean±SD (approx.)		N14±4.5
Baseline intraocular pressure		
Range		14-18
Mean±SD		16.0±1.2
Systemic comorbidities		
Diabetes mellitus	04	6.2
Hypertension	06	9.2
Diabetes and hypertension	02	3.1
Thyroid disorder	04	6.2
None	49	75.3
Ocular comorbidities		None

Baseline assessment confirmed preserved distance visual acuity and normal intraocular pressure in all participants, ensuring a stable ocular status prior to intervention. A small proportion of participants had common systemic comorbidities; however, none had associated ocular pathology that could confound outcomes (Table 1).

Baseline near visual acuity was reduced, as expected in presbyopia, and was consistently better under binocular testing compared with uniocular assessment, reflecting a binocular summation.

Table 2: Uniocular near vision improvement after unilateral 0.5% pilocarpine at day 7 and day 15 (n=130 eyes).

Line of improvement	Day 7 N (%)	Day 15 N (%)
0 line	12 (9.2)	3 (2.3)
1 line	43 (33.1)	37 (28.5)
2 lines	43 (33.1)	41 (31.5)
3 lines	24 (18.5)	38 (29.2)
4 lines	8 (6.1)	11 (8.5)
≥ 1 line improvement	118(90.8)	127 (97.7)
Statistical test Wilcoxon signed-rank test		P<0.001

P value <0.05 was considered statistically significant.

Table 3: Uniocular near visual acuity after unilateral 0.5% pilocarpine at day 7 and day 15 (n=130 eyes).

Near visual acuity	Day 7 N (%)	Day 15 N (%)
N6	23 (17.7)	36 (27.7)
N8	51 (39.2)	55 (42.3)
N10	28 (21.5)	24 (18.5)
N12	23 (17.7)	11 (8.5)
N18	05 (3.8)	04 (3.1)
N8 or better	74 (56.9)	91 (70.0)
Statistical test Paired t-test		P<0.001

P value <0.05 was considered statistically significant.

Objective assessment of near visual acuity demonstrated significant improvement in uniocular near vision following unilateral instillation of 0.5% pilocarpine eye drops. At day 7, improvement of at least one line was observed in 90.8% of eyes, with the majority achieving one to two lines of gain. By day 15, 97.7% of eyes demonstrated at least one line improvement, with a notable shift toward higher line gains, including three and four lines of improvement. The progression in uniocular near visual acuity between day 7 and 15 was statistically significant (Wilcoxon signed – rank test, p<0.001) (Table 2). In addition to line-based improvement, uniocular near visual acuity showed a clinically meaningful enhancement, with the proportion of eyes achieving N8 or better increasing from 56.9% at day 7 to 70.0% at day 15, reflecting sustained functional near vision improvement with continued therapy (Table 3).

Binocular near vision demonstrated measurable improvement following unilateral administration of 0.5% pilocarpine. At day 7, 89.2% of patients showed an improvement of at least one line, with the majority achieving one to two lines of gain. By day 15, binocular near vision improvement of at least one line was observed in 95.4% of patients, with a marked increase in

the proportion achieving three or more lines of improvement. The improvement in binocular vision near visual acuity from day 7 to day 15 was statistically significant (Wilcoxon signed- rank test, p<0.001) (Table 4). Binocular near visual acuity consistently outperformed uniocular outcomes, suggesting a beneficial binocular summation effect (Table 5).

Table 4: Binocular near vision improvement after unilateral 0.5% pilocarpine at day 7 and day 15 (n=130 eyes).

Line of improvement	Day 7 N (%)	Day 15 N (%)
0 line	14 (10.8)	6 (4.6)
1 line	55 (42.3)	46 (35.4)
2 lines	38 (29.2)	39 (30.0)
3 lines	20 (15.4)	35 (26.9)
4 lines	3(2.3)	4 (3.1)
≥ 1 line improvement	116 (89.2)	124 (95.5)
Statistical test Wilcoxon signed- rank test		P<0.001

P value <0.05 was considered statistically significant.

Table 5: Binocular near visual acuity after unilateral 0.5% pilocarpine at day 7 and day 15 (n=130 eyes).

Near visual acuity	Day 7 N (%)	Day 15 N (%)
N6	25 (19.2)	42 (32.3)
N8	55 (42.3)	52 (40)
N10	26 (20)	22 (16.9)
N12	20 (15.4)	11 (8.5)
N18	04 (3.1)	03 (2.3)
N8 or better	80 (61.5)	94 (72.3)
Statistical test Paired t-test		P<0.001

P value <0.05 was considered statistically significant.

Both uniocular and binocular near visual acuity improved progressively from day 7 to day 15 following unilateral pilocarpine administration. At both time points, binocular assessment demonstrated statistically superior near vision compared to uniocular testing, consistent with a binocular summation effect (day 7: p=0.048; Day 15: p=0.041) (Table 6).

Subjective assessment revealed a high level of patient-perceived benefit following unilateral administration of 0.5% pilocarpine. The majority of participants reported improved ease of performing routine near-vision tasks, particularly activities involving digital devices and reading printed material at day 7. A smaller proportion noted improvement in discerning fine print such as drug labels, while only a negligible number of patients reported no subjective benefit. These findings indicate that unilateral pilocarpine therapy provides meaningful functional improvement in day-to-day near-vision activities. This subjective improvement persisted for 15 days, with several patients reporting increased duration of comfortable near work (Figure 2).

The proportion of patients reporting subjective improvement increased slightly at the 15- day visit compared to 7 days, suggesting adaption to monocular pharmacological treatment. Subjective outcomes correlated well with objective near visual acuity improvement, although a small subset of patients with minimal objective change still reported subjective visual comfort.

Binocular near vision improved in most patients despite unilateral treatment, indicating preservation of binocular visual function. No patient reported disabling binocular visual disturbance or intolerance related to monocular miosis. Distance vision under binocular conditions remained largely unaffected.

Unilateral instillation of 0.5% pilocarpine was well tolerated by the majority of participants. Most patients did not report any adverse events, while a small proportion experienced mild and transient symptoms, predominantly brow ache and occasional mild ocular discomfort. These symptoms were self -limiting and did not require discontinuation of treatment (Figure 3).

Table 6: Comparison of uniocular and binocular near visual acuity at day 7 and day 15 after unilateral 0.5% pilocarpine (n=130 eyes).

Near visual acuity	Uniocular day 7 N (%)	Binocular day 7 N (%)	Uniocular day 15 N (%)	Binocular day 15 N (%)
N6	23 (17.7)	25 (19.2)	36(27.7)	42 (32.3)
N8	51 (39.2)	55 (42.3)	55 (42.3)	52 (50.0)
N10	28 (21.5)	26 (20.0)	24 (18.5)	22 (16.9)
N12	23 (17.7)	20 (15.4)	11(8.5)	11(8.5)
N18	5 (3.8)	4 (3.1)	4(3.1)	3 (2.3)
N8 or better	74 (56.9)	80 (61.5)	91 (70.0)	94 (72.3)
Statistical test: Wilcoxon signed-rank test				
Day 7 (Uniocular vs Binocular): p=0.048				
Day 15 (Uniocular vs Binocular): p=0.041				

P value <0.05 was considered statistically significant.

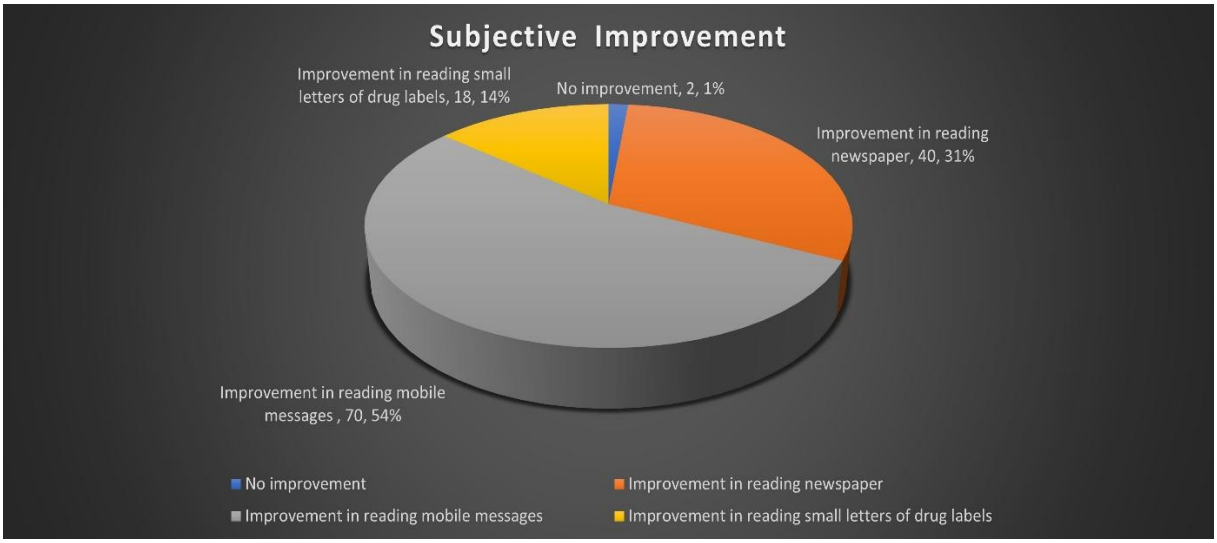

Figure 2: Subjective improvement in near-vision activities following unilateral low-dose pilocarpine therapy.

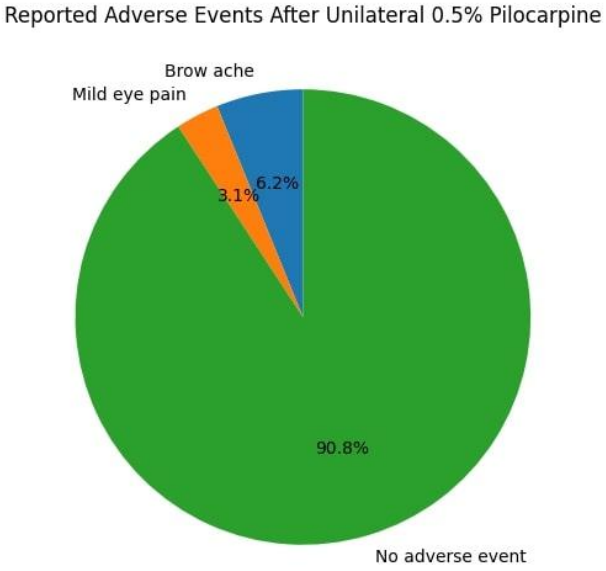

Figure 3: Adverse effects reported after unilateral pilocarpine use.

No patient developed significant reduction in distance vision, clinically significant anisocoria- related symptoms, or dimming of vision severe enough to affect daily activities. Intraocular pressure remained stable throughout the follow-up period, and no serious ocular adverse events were noted.

The absence of significant influence from age or gender, except for marginally higher binocular gains in females at 15 days, suggests that this regimen could be universally effective in early presbyopic patients.

DISCUSSION

Presbyopia is a universal, age-related visual disorder that reduces near focusing ability due to progressive loss of accommodation. Traditionally, its correction relies on optical means such as reading glasses, bifocals, multifocal contact lenses, or surgical options like multifocal and accommodating intraocular lenses.[34] However, the advent of pharmacological therapy has renewed interest in non-invasive approaches that restore near vision through modulation of pupillary dynamics and depth of focus rather than structural lens changes.[13-15]

The present prospective observational study evaluated the feasibility of unilateral pharmacological management of presbyopia using topical 0.5% pilocarpine eye drops in patients over 40 years. The choice of unilateral instillation aimed to mimic monovision by enhancing near focus in one eye while preserving distance clarity in the fellow eye. The lower concentration of pilocarpine (0.5%) was chosen to minimize side effects commonly associated with higher concentrations in glaucoma. The findings demonstrate that unilateral low-dose pilocarpine can result in meaningful objective and subjective improvement in near vision, both uniocularly and binocularly, while maintaining an acceptable safety profile. Importantly, near vision improvement was observed as early as 7 days and was sustained at 15 days, suggesting a rapid onset and stability of effect.

At baseline, most participants required N18 or poorer near vision, reflecting functional presbyopia. By the 7th day, more than half the eyes improved to N8 or better, and by 15 days, nearly 70% of eyes achieved N8 or better, both uniocularly and binocularly. Binocular near vision consistently outperformed uniocular measures, suggesting binocular summation and neural adaptation to the induced anisometropia.

These results mirror those of the GEMINI-1 Phase 3 trial, which evaluated pilocarpine 1.25% (Vuity, Allergan) and reported that approximately 30–40% of participants gained three lines or more in near vision without losing distance acuity at 30 days.[28] Our findings demonstrate

comparable visual gains with a lower concentration (0.5%), likely due to reduced ciliary fatigue and improved tolerability.

The improvement over two weeks indicates not only the pharmacologic effect of miosis but also a progressive neural adaptation, where the brain adjusts to optimize binocular function. Similar trends have been observed in studies using bilateral pilocarpine or carbachol-brimonidine combinations, where the peak effect develops within the first week and stabilizes thereafter.

Recent years have witnessed growing interest in pharmacological treatment of presbyopia as a reversible, non- invasive alternative to optical or surgical correction.[16-18] Most published studies evaluating pilocarpine for presbyopia have focused on bilateral instillation, proprietary formulations, or higher drug concentrations.[24-28,34-36] These studies have generally reported improvement in near vision but have also highlighted concerns related to reduced distance vision, dimming in low-light conditions, and patient intolerance associated with bilateral miosis. In contrast, the present study specifically explored unilateral instillation, aiming to preserve binocular distance vision while providing functional near vision improvement through increased depth of focus in the treated eye.

The observed improvement in near vision lines in the majority of patients in this study is consistent with prior reports demonstrating the miotic effect of pilocarpine as the primary mechanism for near vision enhancement. However, unlike many interventional trials that primarily emphasize efficacy under controlled conditions, the present study focused on feasibility in a real – world clinical setting, which is a key distinction. The sustained improvement at both 7 and 15 days suggests that unilateral pilocarpine is not only effective but also practical for short-term use in symptomatic presbyopic patients.

An important findings of this study is the improvement in binocular near vision despite unilateral treatment consistent with the concept that binocular depth of focus increases as one pupil constricts while the fellow eye compensates for illumination and stereopsis.

This supports the concept that monocular pharmacological miosis can enhance near vision without significantly disrupting binocular visual function. This approach resembles modified monovision but avoids permanent refractive or surgical alteration, making it particularly appealing for patients with early or mild presbyopia who are reluctant to adopt spectacles or undergo invasive procedures.

Subjective improvement reported by patients correlated well with objective near vision gains, highlighting the clinical relevance of unilateral pilocarpine therapy. Notably, some patients reported subjective benefit even in the presence of modest objective improvement, underscoring the importance of patient-perceived visual comfort and functional vision in presbyopia management. This finding aligns with previous studies emphasizing that patient satisfaction does not always directly correlate with measured acuity alone.

With respect to safety, topical 0.5% pilocarpine was generally well tolerated. Reported side effects were mild, transient, and self- limiting, most commonly including brow ache, headache, and mild ocular discomfort. No serious adverse effects, significant reduction in distance vision, or clinically relevant changes in intraocular pressure were observed. These findings are consistent with existing literature on low-dose pilocarpine use and further support the safety of unilateral administration.

Several pharmacological agents have been investigated for presbyopia correction, including pilocarpine, carbachol, aceclidine, and combination drops with brimonidine or oxymetazoline.[37,38] Among these, pilocarpine remains the most widely studied due to its established safety record.

The GEMINI-1 and GEMINI-2 multicentric randomized trials using 1.25% pilocarpine once daily demonstrated efficacy lasting up to six hours post-instillation with transient side effects such as headache and dim vision. Subsequent real-world studies have suggested that lower concentrations may extend tolerability while maintaining near vision gains.[28,35]

Our study adds to this body of evidence by showing that even 0.5% pilocarpine, when administered unilaterally, can achieve similar benefits with fewer adverse events. To our knowledge, published data on unilateral low-dose pilocarpine therapy remain scarce, making this study a novel exploration of a pragmatic and patient-friendly regimen.

The novelty of this study lies in its exclusive evaluation of unilateral 0.5% pilocarpine in a prospective observational design, focusing on feasibility rather than efficacy alone. Unlike many previous studies that employed bilateral dosing or proprietary combinations, this study reflects routine clinical practice, assessing real-world patient tolerance, acceptance, and functional outcomes. Additionally, the assessment of both uniocular and binocular near vision at multiple points provides valuable insight into the functional implications of unilateral pharmacological therapy.

The strengths of this study include its prospective design, inclusion of both objective and subjective outcome measures, and evaluation of near vision under uniocular and binocular conditions. The focus on feasibility and safety in a real- world setting enhances the external validity of the findings. Furthermore, the use of a readily available low-cost formulation of pilocarpine increases

the potential applicability of this treatment approach, particularly in resource- limited settings.

The study has certain limitations. The observational design and absence of a control group limit the ability to draw definitive conclusions regrading comparative efficacy. The follow-up period was relatively short, precluding assessment of long- term tolerability, sustained efficacy, or adaptation effects. Although no persistent pupillary abnormalities or clinically significant adverse effects were observed during the study period, the potential for permanent pupillary changes with prolonged use of 0.5% pilocarpine cannot be excluded. Chronic parasympathomimetic stimulation may theoretically result in sustained alterations in pupil dynamics or iris sphincter function, although evidence regarding the risk with low-dose pilocarpine remains limited. Additionally, objective measurements of contrast sensitivity and night vision were not included, which may provide further insight into functional visual outcomes. Therefore, larger prospective studies with longer follow-up are warranted to validate these findings and to evaluate the long-term safety, durability of efficacy, and risk of permanent pupillary changes associated with chronic unilateral 0.5% pilocarpine therapy for presbyopia.

Despite these limitations, the findings of this study suggest that unilateral low-dose pilocarpine represents a feasible, safe, and patient-acceptable pharmacological option for presbyopia management. This approach may be particularly beneficial for patients seeking temporary or reversible near vision enhancement without compromising distance vision or undergoing invasive procedures.

CONCLUSION

This prospective observational study indicates that unilateral administration of 0.5% pilocarpine eye drops appears to be a feasible and well-tolerated pharmacological option for presbyopia in individuals over 40 years. The treatment resulted in early and sustained improvement in near vision with minimal, transient side effects and preservation of binocular visual function. The findings support the concept that pharmacological modulation of pupil size and ciliary tone can serve as a viable non-surgical alternative in presbyopia management. With further refinement and long-term validation, low-dose pilocarpine therapy may represent a new frontier in individualized presbyopia correction, bridging the gap between optical aids and surgical interventions.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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