

Topical Management of Presbyopia Today and Tomorrow

Mark Schaeffer, OD

1

Financial Disclosures - Mark Schaeffer, OD

I Have Received Honoraria From:

- Alcon - Consultant, Speaker
- Allergan - Consultant, Speaker
- Bausch + Lomb - Consultant, Speaker
- CooperVision- Consultant
- Horizon Pharmaceuticals- Consulnat
- ScienceBased Health - Consultant
- Sight Sciences - Consultant
- Tarsus Pharmaceutical - Consultant

• Founder, Dr. MES Consulting
 • Founding Member, Intrepid Eye Society



2

Presbyopia

- Age-related farsightedness. A gradual, age-related loss of the eye's ability to see objects up close. Caused by the diminished elasticity of the crystalline lens.
- "Presby-" in Greek translates to "old"
- How many times a day do you see a patient with presbyopia?
 - How many times per day do you say the word "presbyopia"

3




Presbyopia

Does anyone really want to look like this in the real world?

4


PRESBYOPIA:

INEVITABLE AND AFFECTING MORE PEOPLE THAN EVER




How many people are affected globally?

~ 1.8 billion¹



How many Americans are presbyopes?

128 million^{2,4,*}




How many people buy their readers at the drugstore?

30.9 million⁵

*Determined based on U.S. Census data.

5

How does this affect our patients?




Journal of Optometry

ORIGINAL ARTICLE

Presbyopic correction use and its impact on quality of vision symptoms

Alfred Janssen¹, Colin Wickham^{1,2}, James L. Hoffbauer^{1,3}



Acta Ophthalmologica

Review Article

Review of the impact of presbyopia on quality of life in the developing and developed world

Praveen D. Gupta¹, William C. Roberts², Edward B. Rosen³, Susanna A. Tomasek⁴ and Graham A. Nisbet⁵

6

Presbyopia by the Research

- 90% are frustrated or irritated by Presbyopia
- Research at Harvard: People who feel old tend to age faster
- Research at Yale: People who think aging is declining tend to develop cardiovascular and memory problems
- Average adults spend >11 hours EVERY DAY watching, reading, and interacting with media!

7

How much screen time are you getting?

8

How has this affected you?

If you have presbyopia?
If you treat presbyopia?

9


Treatments - 2021

Glasses <ul style="list-style-type: none"> Progressive ADD Lens Bifocal lenses Computer Progressive ADD Lens Single Vision Near Rx Over-the-Counter Readers 	Surgical <ul style="list-style-type: none"> Excimer Laser Monovision Modified Monovision Multifocal ablation Femtosecond laser inlays IOLs Extended Depth of Focus Accommodating Light Adjustable Femtosecond laser-induced shape change
Contact Lenses <ul style="list-style-type: none"> Multifocal contact lenses Monovision Distance with Readers over the top Hybrid lenses GP / Scleral Lenses 	

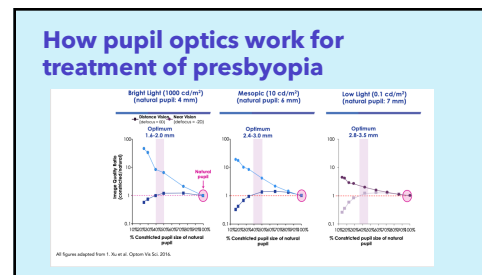
10

So what changed?

VUITY FDA APPROVED OCTOBER 2021



11



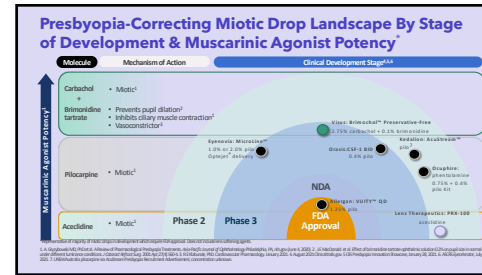
12

Pharmacologic Treatments for Presbyopia

Typical Drops in Development/Approved	Active Ingredient(s)	Mechanism of Action
Vuity™ (Atropine) - FDA Approved (2022)	Atropine	Miotic
BRIMONIDINE™ (Vias Therapeutics)	Carbachol + Brimonidine tartrate	Carbachol: Miotic Brimonidine: Myotic Prevents pupil dilation, inhibits contraction of ciliary muscle, increases permeability of carbachol's "pore" pathway
CSF-1 (Orasis)	Pilocarpine	Miotic
PRX-100 Liquid Vision (LENZ Therapeutics)	Acedidine	Miotic
MicroLine OptiJet™ (Eyenovia)	Pilocarpine	Miotic
AcuDress™ (Kodan)	Pilocarpine	Miotic
Near® and Pilocarpine Combination (KOD Ophthalmics)	Phenylephrine, naphazoline and pilocarpine	Miotic: Both pilocarpine and phenylephrine (myotic products) Vasoconstricts small muscles (phenylephrine/myotic product)

1. S. Gopal et al. Ocular and Systemic Pharmacokinetics of Brimonidine and Topical Atropine: Topical Administration in Rabbit Cornea and Systemic Administration in Rabbit Cornea and Topical Atropine in Rabbit Cornea. *Journal of Ophthalmology*. 2020;18(11):115-124. 2. Allergan patent application No. 10,228,000 (2018.01.11). 3. Ocular and Systemic Pharmacokinetics of Brimonidine and Topical Atropine in Rabbit Cornea and Systemic Administration in Rabbit Cornea. *Journal of Ophthalmology*. 2020;18(11):115-124. 4. Eyovia: Phenylephrine Myotic Ophthalmic Solution Provides Long-Lasting Pupil Modulation And Improves Visual Acuity. <https://www.eyovia.com/press-releases/eyovia-phenylephrine-myotic-ophthalmic-solution-provides-long-lasting-pupil-modulation-and-improves-visual-acuity>

13



14

Vuity

- Allergan
- Pilocarpine 1.25% with pHast technology
- GEMINI-1 and GEMINI-2 studies
 - ~40% of patients had 3 line increase in near VA in mesopic (40 lux) conditions
 - Statistically significant improvement at 6 hours at near in GEMINI-1 trials
 - 9 out of 10 patients achieved better than 20/40 at near on Day 30, Hour 1
- VIRGO studies
 - Investigating bid dosing for Pilocarpine 1.25%
 - Expected possible FDA filing 2022

15

Future options

- Orasis Pharmaceuticals
 - CSF-1: Parasympathomimetic miotic
 - Pilocarpine 0.4% dosed bid OU
 - 2 hours apart
- Phase 3 trials completed (NEAR-1, NEAR-2)
 - 40% achieved 3 line or greater increase at near 1 hour post-dose 1
 - 50% achieved 3 line or greater increase at near 1 hour post-dose 2
- On Day 15:
 - Statistically significant improvement as quickly as 20 minutes
 - Up to 8 hours post-dose 1
- Expected 2023

16

Future options

- Eyenovia: MicroLine
 - Topical spray 1.0% or 2.0% pilocarpine
 - Optejet dispenser
 - 1/5 volume of eyedropper
 - Dosed as needed
 - 3-4 hours of improved near vision
 - VISION-1 completed 2021
 - Endpoints met for 3-line improvement in near vision in low light conditions at 2 hours post treatment
 - VISION-2: Second Phase 3 registration study trial

17

Future options

- LENZ: LNZ100 / LNZ101
 - Acedidine 1.75%
 - Acedidine + Brimonidine
 - Potential for longer duration
 - Benefits of eye whitening
 - Targets iris sphincter muscle with limited or reduced action on ciliary muscle
 - Decreased risk of myopic shift due to lack of ciliary muscle involvement
 - Finished phase 2B trials
 - Improved at least 2 / 3 lines of improvement within 30 minutes (81% / 53% respectively)
 - Showed up to 7 hours duration
 - Based on Acedidine only
 - Beginning Phase 3 in 2H2022

18

Future options

- Visus Pharmaceuticals (Brimochol)
 - Brimonidine and Carbochol
 - Miotic (Carbachol) and sympatholytic alpha-2 agonist to prevent pupil dilation (brimonidine)
 - Brimonidine potentially reducing commonly associated side effects of miotics
- Phase 2b trials completed, beginning Phase 3 trials

19

Future options


- Novartis Pharmaceuticals
 - UNR844 (Lipoic acid choline ester)
 - Breaking disulfide bonds that form within crystalline lens
 - Helps restore lens elasticity
 - Enrolling Phase 2 trial / experimental concentration phase

20

Future options

- Ocuphire Pharmaceuticals
 - 0.75% Nyxol (Phentolamine- alpha 1 / 2 antagonist)
 - Iris dilator muscle inhibition
 - 24+ hour durability
 - Phase 2 trials
 - Looking at addition of low-dose pilocarpine (0.4%) for adjunctive drop

21



Adding drops into our treatment pattern
 WHAT ARE YOU DOING TO IMPLEMENT THIS INTO YOUR PRACTICE?

22

Considerations to make

- What is my current workflow with presbyopic patients?
- How to integrate new technologies with current refractive solutions
- Performing dilated fundus examinations
- Managing expectations of the patient / the staff / doctor
- Managing and educating on side effects
- In-office trial or in-office visit? How to bill and code for this visit since it is not medical

23

Working through your workflow

- What does the patient journey/experience look like in your office?
 - New patients and established patients
- Is there enough time for you to counsel your patients regarding all the new treatments available?
 - In-office trial vs bringing the patient back for a presbyopia consult
- When does the patient visit the optical?
 - Helps experience if doing in-office trial

24


Dilated fundus examinations

Any miotic drop will have retinal detachment in the product insert as a listed possible side effect

Safe practice would be dilated fundus examinations on all presbyopic patients

25

Managing expectations



EXPECTATIONS FOR THE PATIENT



EXPECTATIONS FOR THE STAFF



EXPECTATIONS FOR THE DOCTOR

26




Who to Consider as a Candidate?

- There is no "magic" candidate
- Better expectation setting = higher success
- Patients who are looking for other options
- Present to all patients, not all will accept

27





Getting over objections



- Patient Buy-In
- Staff Buy-In
- Optical dispensary sales objections

28

The presbyopia consult

-  Service fee to consult patients on new treatment option
-  We charge for contact lens evaluations which use our expertise, check visual acuities, and give proper education regarding a medical device
-  Includes follow-up visits to assess vision on return visit as well as dilated examination to rule out any retinal changes
-  Can be done as telehealth (on follow-up visits) after in-office portion completed

29

Managing expectations 2: The sequel

What to avoid to be successful


No Plan of Action

Not discussing all the options available with the patient

Not establishing what success looks like to the patient before prescribing options

30

Bringing it All Together



- Set the tone
- Prescribe the best treatment for the patient
- Be the expert
- Flex that knowledge
- Use the "Why"

31

Thank you!
mark@drmesconsulting.com

32