

Pharmacologic Treatment of Presbyopia FOV Tears

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"To have a Pharmaceutical therapy that could effectively reduce dependence on bifocals or reading glasses is truly a GROUNDBREAKING approach in the treatment of presbyopia"

Richard Lindstrom, MD

Which could be the Features of an Ideal Pharmaceutical and Topical Therapy

- Binocular use (Not Monovision)
- Truly accommodative not pseudoaccommodative
- Improves near vision and intermediate
- Improves distance vision or at least doesn't alter it
- Dynamic pupil in different light conditions
- Mild and controlled dynamic miosis that also could diminish glare (Dynamic Pseudoaccommodation)
- Not extreme and fix miosis that decrease contrast sensitivity
- Non toxic with the epithelium
- Non toxic with endothelial cells
- Improves lacrimal film or at least doesn't alter it
- Doesn't burn and neither red eye
- Doesn't produce inflammation or ocular hypertension
- Doesn't cause alteration in macula (CME)
- Avoids the physiological deterioration of accommodation with age

Even in this century doesn't exist a non-invasive treatment for presbyopia, only surgical treatments, because of this, since 2010 I was thinking in this kind treatment, but for the group of patients who were emetropes, because for the ametropic patients always they had have a solution; my thought always was to make a substance that increase accommodation avoiding any spasmodic result or similar to monovision, always trying to keep the stereopsis, and in this idea in mind, I started to mix some amount of many well known FDA approved substances, those kept the far vision and in some cases even improve it and of course improve the near vision but in a physiological way, this mean increasing accommodation when the eye need it and release it when doesn't or when you see for far [1].

With the finished product, I designed a prospective observational study in September 2012 to assess the efficacy and safety, performed under a clinical protocol, the protocol was approved by the Clinic's Ethics Committee, with patient's signed informed consent, also a manual form to fill and digital data base and also filed a patent (Published - 10 Countries) with a reputable US law firm (Knobbe-Martens-Olson and Bear).

The study features:

- **20 Patients** - 40 eyes with Spherical defect from +2.00 D to -1,50 D with average of +0.26 D with less of 1.50 diop of astigmatism and spherical equivalent from +1.25 D to -1.87 D with average of -0.03 D and defocus from 0.12 D to 2.75 D with average of 0.73 D.
- **9 Emmetropes** with spherical defect from +1.00 D to -0,50 D with average of +0.33 D with less of 1.00 diop of astigmatism and spherical equivalent from +0.75 d to -0.62 d with average of +0.14 d and defocus from 0.25 d to 1.37 d with average of 0.69 d.
- **5 Post LASIK in their youth** with spherical defect from +2.00 d to -0,75 d with average of +0.30 d with less of 1.50 diop of astigmatism and spherical equivalent from +1.25 d to -1.00 d with average of -0.04 d and defocus from 0.12 d to 2.75 d with average of 0.76 d.
- **6 Post PresbV LASIK** (Vejarano Method) with spherical defect from +1.50 d to -1,50 d with average of +0.10 d with less of 1.00 diop of astigmatism and spherical equivalent from +0.25 d to -1.87 d with average of -0.29 d and defocus from 0.25 d to 1.87 d with average of 0.75 d.
- **Total Average in Age** 49, 65 with range between 41 to 57; in emmetropes average 49, 44 with range between 44 to 55; in post lasik average 46 with range between 41 to 50; in post presbv lasik average 53 with range between 48 to 57.
- Only 1 drop in each eye (Not Monovision)
- Measurements was taken Previously, ½, 1, 2, 3, 4, 5

Hours post the application and 1 Week and 1 Month later.

The subjective test were:

- UCVA monocular and binocular for far and near
- BCVA monocular and binocular for far and near
(No lost lines of vision and for near some 20/15)
- BCFVA-near vision monocular and binocular
- Refraction for Far and Near

Using the Snellen Chart for Far and the Hand-held Rosebaum chart with Jaeger notation for Near with always the same luminosity (440 to 445 LUX).

The objective test were:

- Pupil Size Photopic with the Pentacam machine and Scotopic with the nidek autorefractor and in some patients both with the Nidek AL Scan
- Endothelial cell count with the Konan Specular Biomicroscopy
- IOP (Intraocular Pressure) with both Goldmann applanation Tonometer and the Pascal Dynamic Contour Tonometer

- Keratometry with the Nidek Autokeratorefractor
- Pachymetry with Pentacam machine and Konan Biomicroscopy
- ACD (Anterior Chamber Depth) with Pentacam Machine and in some patients with Nidek AL Scan
- Schirmer test for the lacrimal film and in some with hd analyzer machine.

The subjective results showed near UCVA improved by about 2 to 3 lines in each eye and binocularly from a baseline mean of about J3.5 to about J1.5. Mean UCVA at far was 20/25 at baseline, and except for a slight decrease after 1 hour, was improved by an average of about 1 line in each eye at all follow-up measurements. Binocularly, UCVA at far increased by 1 line on average, and no patient had a loss in binocular UCVA at far.

Whereas other presbyopia drops improve near vision by causing an extreme miosis or a myopic shift [1-4] that can reduce far vision, refractive measurements in this study showed there was a maximum myopic shift of just 0.5 D that occurred only at 1 hour post-treatment.

To test if the results depend of Pseudoaccommodation or real accommodation the Pupil diameter was also measured and found to be mildly affected by the topical treatment ("dynamic miosis"). Moreover, the measurements showed that the treatment seemed to mitigate significant pupil enlargement under scotopic conditions as well as significant contraction in photopic conditions ("dynamic Pseudoaccommodation").

To prove the accommodation action was taken many subjective and objective measurements, as Defocus Curve, iTrace [5] and HD analyzer [6], all of them showed 0,75 diopters of increase in accommodative amplitude comparing pre and 2 hours post drops and an amount of 1,25 to 1,75 diopters in accommodative range and impressively 20/25 or better in all of the patients for intermediate vision.

Also based in the accommodation theory, if accommodation occurs, then the anterior chamber decrease, the anterior surface of the lens get steep and also increase the lens thickness by the anterior and posterior displacement of the capsules caused by the reciprocal zonular action of the anterior and posterior fibers.

At the scheimpflug images the change average was -55 microns that generates around of 2,54 diopters of accommodation [7,8], and at the OCT anterior segment images was -70 microns, which is equivalent to 1,90 diopters [9,10].

About safety, there was no change in Endothelial cell count and also I notice a decrease in the IOP both Goldmann and Pascal tonometers in an average of -0,75 mm of Hg (-4,86%) and -0,59 mm of Hg (-2,50%) respectively; also the lacrimal film keep intact measured by HD Analyzer; the previous patterns they were equal and in some patients improved, in some of them also took the OCT lacrimal meniscus and at least kept the same too, neither macular edema by OCT or increase in Pachymetry, neither impairment in contrast sensitivity.

With continuous used I notice improving in accommodation accompanied of independence of near correction based in a satisfaction survey, the results in 2 months of continuous use are: Improve in Global vision, increasing in independence of near glasses wear to almost reach a total independence in most of the patients, and increase in global satisfaction with the treatment with decreasing of any of discomfort.

Measured at 1 month of use 100% 20/40 or better; 80% 20/30 or better for uncorrected near vision.

In summary

- Improves 2 - 3 lines for near and 1 for Far Vision and gives extraordinary for Intermediate (20/25 or better).
- Increase 0,75 Diopters in Accommodation Amplitude

- In Total gives 1,75 Diopters of Accommodation, improving with time of use.
- Action proved mostly Accommodative with a new concept of dynamic pseudoaccommodation
- Non toxic for the epithelium, endothelial cells, lacrimal film, macula neither trabecular meshwork.
- The Continues use, improves near vision in 2 lines (improves physiological deterioration of Accommodation with age) and decrease 1 mm of Hg in IOP.

It is truly a improved physiological accommodation.

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