A comparison of the mydriatic effect between an experimental mixture of 5.0% phenylphrine and 0.5% tropicamide to the standard protocol of one drop of 2.5% phenylephrine and one of drop of 1.0% tropicamide

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A COMPARISON OF THE MYDRIATIC EFFECT BETWEEN AN EXPERIMENTAL MIXTURE OF 5.0% PHENYLEPHRINE AND 0.5% TROPICAMIDE TO THE STANDARD PROTOCOL OF ONE DROP OF 2.5% PHENYLEPHRINE AND ONE DROP OF 1.0% TROPICAMIDE

BY

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A thesis submitted to the faculty of the College of Optometry Pacific University Forest Grove, Oregon for the degree of Doctor of Optometry May 1998

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Brandi Nelson currently attends Pacific University College of Optometry where she will earn her Doctorate of Optometry Degree in May 1999. While attending Pacific University she was second year class president, and chair for the college of Optometry's Multiple Sclerosis Walk team. In addition, she held the position of liason for the Association of Schools of Optometry, ASCO, during the 1996-97 academic year. She is a member of the American Optometric Association, American Optometric Student Association, American Optometric Association- Political Action Committee, and Phi Theta Upsilon.

Brandi received her Bachelor of Science degree at the University of Wyoming in May 1995. She plans to return to the Rocky Mountain area to practice primary care optometry.

TRISHA C. ROGERS:
Trisha Rogers currently attends Pacific University College of Optometry where she will earn her Doctorate of Optometry Degree in May 1999. While attending Pacific University she was active in Amigo's, and provided free vision care on a Amigo's trip to Jamaica in the spring of 1997. She was a four year member of Beta Sigma Kappa International Optometric Honor Society, and held the position of treasurer for the organization during her third year. Trisha is also a member of American Optometric Association, American Optometric Student Association, American Optometric Association- Political Action Committee, and Phi Theta Upsilon.

Trisha received a Bachelor of Visual Science Degree from Pacific University in December 1996. Prior to admission to the College of Optometry, Trisha attended Northwest College in Powell, WY where she received an Associate of Science Degree in May 1993. She then attended Pacific University for two years. Her future plans are to practice primary care optometry in Arizona.
INTRODUCTION

Evaluating the ocular health of every patient is the standard of care in the optometric profession. Part of this standard is performing binocular indirect ophthalmoscopy and high plus ophthalmoscopy to evaluate the entire posterior segment with stereoscopic views. In order to achieve an adequate pupil diameter for viewing the structures of the fundus, diagnostic pharmaceutical agents are needed. The typical protocol is one drop of anesthetic followed by one drop of 2.5% phenylephrine and one drop of 1.0% tropicamide, with five minute intervals between each drop. This study will compare the above standard protocol to an experimental one drop mixture of 5% phenylephrine and 0.5% tropicamide.

Phenylephrine is a direct acting alpha-adrenergic agonist which contracts the iris dilator muscle. It causes little to no effect on the ciliary muscle, thus resulting in mydriasis with no cycloplegia. In ophthalmic solutions, concentrations of 2.5% and 10% are commercially available. Studies have shown that the dose-response curves for phenylephrine indicate increasing mydriasis with concentrations up to 5%. Concentrations above 5% show little additional effect in mydriasis. Maximum dilation occurs within 45 to 60 minutes depending on the concentration and number of drops used. Pre-dilation size of the pupil usually returns in 4 to 6 hours. When topical anesthetic precedes the instillation of phenylephrine the mydriatic effect is greater in amplitude, more rapid in onset, and longer lasting. (p439 B&J) Systemic adverse effects of phenylephrine include systemic hypertension, ventricular arrhythmia, tachycardia, and reflex bradycardia. However, the Bergerud and Saccomanno study evaluating the mydriatic effect of this same experimental mixture of 5% phenylephrine and 0.5% tropicamide, showed no statistically significant increase in pulse or blood pressure following its instillation.

Tropicamide is an indirect acting anti-cholinergic agent. Tropicamide aids in mydriasis by relaxing the iris sphincter. It is the preferred anti-cholinergic agent due to its ability to give an effective
dilation in a short amount of time. Maximum dilation occurs in 15 to 30 minutes with a duration of 4 to 6 hours. Its cycloplegic effects reaches its peak between 30 to 45 minutes, but quickly diminishes. Dose response curves show that tropicamide gives equal mydriatic effect in concentrations from 0.25% to 1.0%. It has also been shown that there is no significant difference in mydriatic latency, time difference between drop instillation and dilation, between 1.0% and 0.5% solutions. Tropicamide is known as a safe mydriatic agent virtually free of systemic side effects. Together, phenylephrine and tropicamide have a compound effect in dilating the pupil.

There are general considerations when applying topical ophthalmic drugs. One is the ability of the eye to retain approximately 10 microliters of fluid. Since the average dropper tip delivers 25 to 50 microliters per drop, the value of more than one drop is questionable. A second factor is the interval missing between drop instillations. To insure that the first drop is not flushed away by the second, or that the second drop is not diluted by the first, it is standard to wait five minutes between instillations. Due to the above factors, we feel that the experimental one drop mixture of 5.0% phenylephrine and 0.5% tropicamide will be clinically effective and less time consuming in reaching mydriasis.

In May of 1997, the Bergerud and Saccomanno determined the onset, peak, and duration of the experimental mydriatic solution. Results from that study showed a statistically significant increase in pupil diameter within ten minutes of instillation. The purpose of our study is to directly compare the onset and peak dilation between the experimental mixture and the standard protocol.
SUBJECTS AND METHODS

The experimental mixture was prepared by Lloyd Center Pharmacy of Portland, OR. This is the same pharmacy that prepared the mixture for the Bergerud and Saccomanno study. The topical mydriatic combination product was prepared by combining one part of 1.0% tropicamide (supplied by Professional Compounding Centers of America) and one part 10.0% phenylephrine (powder form supplied by Spectrum Chemical). The resultant preparation consisted of 0.5% tropicamide and 5.0% phenylephrine as active ingredients with benzalkonium chloride 0.01% as the preservative. Purified water and 0.4% hydroxypropylmethylcellulose were used as the vehicle; dibasic and monobasic sodium phosphate as buffers; and edetate disodium as the chelating agent. The solution was osmotically corrected with potassium chloride and sodium chloride. The pH of the solution was 5.1 and the viscosity was 1.3 to 1.5 centipoise. The combination was supplied in standard eye dropper bottles with a drop size equal to 33 microliters. The solutions were stored at room temperature in amber bags to protect against ultraviolet radiation.2

Pupil diameters were measured using an Essiler PRC pupillometer by Sola. The pupillometers were set at infinity and readings were taken monocularly. Subjects were instructed to look at the center fixation light. The measurements were then performed by lining up the vertical mire with one edge of the pupil, recording that number, and then lining up the same mire with the other edge of the pupil, and recording that measurement. The pupil size was determined by taking the difference between the two measurements. Prior to measuring subjects, each examiner took 10 measurements on one individual to determine intra-examiner reliability. These measurements were then analyzed for accuracy. put results here.

Data collected for the purpose of this study was taken from 16 subjects (32 eyes) in February of 1998. The subjects ranged in age from 22 to 40, with a mean age of 27. The group consisted of 11 males and 5 females. Subjects were grouped into a "blue" category
(consisting of blue, grey, or green irides) or a “brown” category (consisting of brown or hazel irides). Seven subjects fell into the “blue” group and nine into the “brown” group.

Prior to drop instillation each subject was asked a detailed case history. They were screened for medical history of hypertension, heart conditions, lung conditions, pregnancy, thyroid problems, diabetes, medications, and allergies. Each also had a slit lamp examination in which anterior chamber angles were measured with the Van Herick Method. All subjects met the criterion of having at least a grade three angle. Intraocular pressures were then measured by Goldmann applanation tonometry and all subjects were below 21mm Hg.

This study was conducted in a masked fashion. Those performing pupil size measurements did not know if subjects had received the experimental or standard drops. The subjects were randomly split into two different groups. One group received the experimental drop and the other received the standard two drop regimen. One drop of proparacaine was instilled in each subject’s eyes, followed by one minute of punctal occlusion. Those in the standard group then received one drop of 1.0% tropicamide followed by one minute of punctal occlusion. After that one minute, they received one drop of 2.5% phenylephrine again followed by one minute of punctal occlusion. The experimental group received one drop of the mixture and followed with one minute of punctal occlusion. After this punctal occlusion, the time was noted and each subject went into the testing room where the pupils would be measured every ten minutes for the next 70-90 minutes.

Variables such as overhead lighting and room conditions were kept constant for each subject’s pupil readings by having the subject sit in the same place for each measurement. Each tester was assigned eight subjects on whom to measure the pupil diameter. All subjects participating in an associated study were measured for a period of 70 minutes. All others were measured for 90 minutes.

Seven days later the same subjects returned and the experimental and standard groups were switched. Each subject followed the same group protocol as the week prior. To keep
measurements constant the subjects were assigned the same seat and pupil examiner.
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We would like to acknowledge Lloyd Center Pharmacy, Portland, OR for preparing the combination product used in this study.