

**Phenylephrine Versus Eyelid Taping for Muller's Muscle-Conjunctival
Resection (MMCR) Evaluation**

NCT05890027

06/24/2025

1) **Protocol Title**

Phenylephrine Versus Upper Eyelid Taping For Muller's Muscle-Conjunctival Resection Evaluation

2) **Objectives**

In this study, we will be assessing whether Phenylephrine 2.5% ophthalmic solution eye drops better demonstrate surgical need when compared to traditional upper eyelid taping in patients with ptosis under evaluation for Muller's muscle-conjunctival resection.

3) **Background**

Prior research has quantified the loss of superior visual field (SVF) and degree of impairment attributed to ptosis^{18, 19, 23, 29}. Loss of vision due to ptosis can lead to difficulty performing activities of daily living, and surgical intervention has been demonstrated to significantly improve quality of life^{2, 4, 10, 11, 25}. The goal of surgical repair is to improve vision by elevating the upper eyelid margin in those with ptosis¹. Various procedures can be performed to accomplish this including external levator resection, Muller's muscle and conjunctival resection or frontalis suspension^{1,2,5,10}. To assess whether the patient's ptosis is affecting their peripheral vision, SVF testing is routinely performed on the ptotic eye first at baseline, then after manual taping of the upper eyelid^{1,6,11,12}. Taping serves to predict visual improvement after surgical intervention. Baseline visual field testing is performed with the eyelid and brow in the resting position, and patients must be documented as having a baseline superior visual field of 30 degrees or less from fixation. Then, to qualify for insurance reimbursement, patients must demonstrate an improvement of at least 12 degrees over baseline with eyelid and brow elevation^{1,6,7,27,30}.

In a recent study, less than half of patients evaluated with ptosis alone met insurance criteria for visual field improvement after eyelid taping as compared to those with dermatochalasis or brow ptosis, who met criteria in all cases after taping²¹. This prompted the question of whether manual taping accurately mimics surgical outcomes in patients with ptosis only. Unlike with dermatochalasis (excess skin) or brow ptosis (drooping eyebrow), ptosis (drooping eyelid) requires direct taping of the eyelid which can be challenging²⁰. In addition, direct taping of the eyelid can lead to difficulty with closing the eyes and subsequent dry eyes, which can blur vision. Prior research has demonstrated the difficulties associated with manual upper eyelid taping, and alternative taping techniques have been proposed²⁰.

This study will evaluate whether Phenylephrine 2.5% ophthalmic solution can more accurately measure ptosis severity as compared to manual upper eyelid taping in the assessment for and reimbursement of surgical repair. Phenylephrine is an alpha-adrenergic agonist and works to elevate the

upper eyelid through stimulation and contraction of Mullers muscle^{3,5, 9, 13, 17}. Phenylephrine eye drops have long been used in patients with ptosis to demonstrate surgical need, predict intervention outcomes, and as a tool in planning surgical procedures^{5, 8, 13, 14, 22, 24, 26}. In particular, the so-called “Phenylephrine Test” has been used by clinicians to assess patient eligibility for conjunctival Mullers muscle resections^{2, 5, 13, 16}. To our knowledge, this is the first study to directly compare Phenylephrine ophthalmic solution to traditional eyelid taping as an effective tool in the assessment and reimbursement for surgical ptosis repair.

4) Inclusion and Exclusion Criteria

Inclusion:

- Individuals diagnosed with ptosis undergoing conjunctival Muller's muscle resection evaluation.
- Individuals with a baseline MRD1 of less than 2.5.
- Individuals who can tolerate and have no hypersensitivity to phenylephrine 2.5% ophthalmic solution.
- Individuals who can tolerate eye-drop medications.
- Individuals who are physically able to take a tangent screen visual field test.
- Age: Adults who can comprehend the instructions and procedures (+ 18 years old).

Exclusion:

- This study will not incorporate any of the following at-risk populations: adults unable to consent, individuals who are not yet adults, pregnant women, prisoners.
- This study will not include participants who refuse to consent.
- This study will not include participants who are too tired or unable to take a tangent screen visual field test (see Risk to Subjects).
- This study will not include individuals who may not be able to tolerate phenylephrine 2.5% ophthalmic solution.
 - o Specifically, those with a past medical history of bradycardia, hypotension, autonomic dysfunction, or severe cardiovascular disease²⁸
- This study will not include individuals who consume drugs contraindicated in phenylephrine use:
 - o Ergot Derivatives (Vasoconstrictive CYP3A4 Substrates)
 - o Iobenguane Radiopharmaceutical Products
 - o Kratom
 - o Lisuride
 - o Monoamine Oxidase Inhibitors

5) Procedures Involved

- **Study design:**

- Study Type: Single arm sequential
 - Proposed Enrollment: 30 eyes
- **Date range for patient recruitment and data collection:**
 - February 2024 –August 2024
 - Data per eye will be collected in one session lasting up to 60-minutes either before or during the patient's clinical appointment
- **Source record:**
 - Secure data collection form in Box
- **Data collected:**
 - Measured values in three conditions (baseline, upper eyelid taped, post-phenylephrine 2.5% ophthalmic solution):
 - MRD1
 - Tangent screen visual field
 - Patient information: (obtained via participant interview or electronic medical record review and recorded in secure Box spreadsheet):
 - Age
 - Visual acuity test results
 - Insurance coverage
 - Do you wear contact lenses?
 - Have you suffered any recent ocular trauma?
 - Have you undergone any recent ocular surgeries?
 - Have you been diagnosed with any cardiovascular conditions or undergone any cardiovascular procedures?
 - Have you been diagnosed with a neurologic condition (e.g., 3rd Cranial Nerve Palsy, Horner Syndrome)?
 - Have you been diagnosed with an autoimmune condition (e.g., Myasthenia Gravis)?
 - Has your clinical condition (ptosis) affected your ability to complete activities of daily living (e.g., driving, cooking, cleaning, dressing)?
 - Post-study questionnaire (obtained once the participant has completed all three study conditions and recorded in secure Box spreadsheet):
 - On a scale of 1-5 (1 – very poor, 5 – excellent), how was your experience with upper eyelid taping?
 - Please elaborate (comments will be recorded)
 - On a scale of 1-5 (1 – very poor, 5 – excellent), how was your experience using the Phenylephrine 2.5% eye drops?
 - Please elaborate (comments will be recorded)
- **Outcome Measures:**
 - Comparison of efficacy of taped lid and adding phenylephrine through Visual Acuity, Measured by using a tangent screen visual field test, up to 1 hour.
 - Comparison of efficacy of taped lid and adding phenylephrine through MRD 1, Measured by MRD1:distance between upper lid

margin and corneal light reflex measured in mm by transparent ruler, up to 1 hour.

- **Photography:**

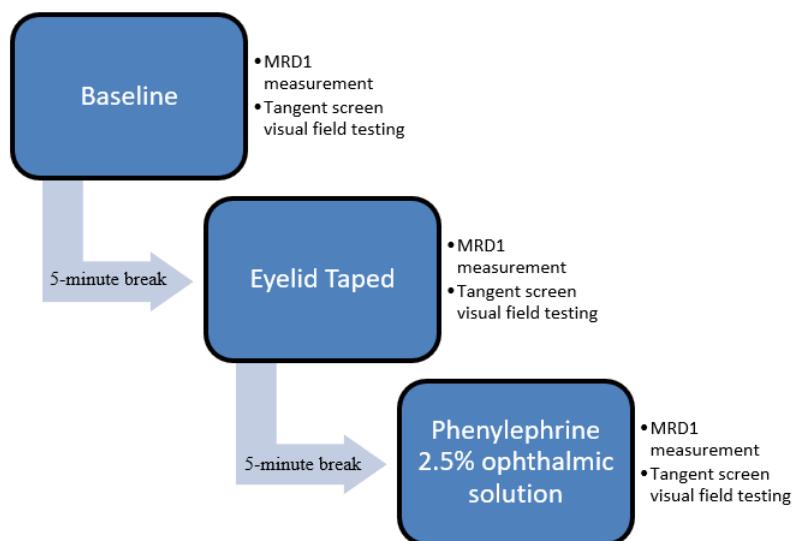
- Photographs will be taken prior to testing, with the eyelids taped prior to visual field testing, and with phenylephrine eye drops applied prior to visual field testing. These photographs are standard of practice when submitting documentation to insurance.
- The participant may decline the publishing of these photographs and still be included in the study.

- **Patient recruitment and consent:**

- Patients will be recruited from the waiting area and during clinic visits at the ophthalmic plastic surgery department at the Bascom Palmer Eye Institute.
- Patients will be given verbal and written information about the study and all questions will be answered to ensure comprehension and willingness to participate.
- Patients will sign the physical study consent form prior to the study (Appendix II). A copy of this consent form will be provided to the participant upon request.

- **Research procedure:**

- The researcher will evaluate the MRD1 (Margin to Reflex Distance, specifically the distance in millimeters from the light reflex at the center of the eye to the center of the upper eyelid), then the participant will undergo superior visual field testing using the tangent screen method.
- These two measures will be evaluated with the ptotic eye in three distinct conditions, all patients will be measured in all three conditions, as outlined in the following diagram:



- First, MRD1 and superior visual field will be analyzed at baseline with no manual taping or eye drops in the ptotic eye.

- Next, the evaluation will occur with the ptotic upper eyelid manually lifted and taped.
- Lastly, the upper eyelid will be released, and one drop of phenylephrine 2.5% ophthalmic solution will be placed in the conjunctival fornix of the ptotic eye by the research coordinator as the participant looks downward. The analysis will begin 10 minutes after drop instillation to ensure maximum eyelid elevation³.
- Participants will be provided with breaks in between each of the three conditions as needed.
- The entire study should take no more than 60 minutes.
 - There are numerous tests that can be used to assess visual field including Tangent screen, Goldmann perimetry, and Humphrey visual field. Tangent screen has been found to be the fastest modality of the three. In one study, testing duration of both eyes with the eyelids in the natural and taped positions took on average 12:10 by Goldmann perimetry and 18:50 by Humphrey visual field⁵. In contrast, tangent screen testing was found to take an average of 6:23 to evaluate both eyes in both conditions¹.
- There will be no additional testing or follow-up once the above research procedure has been completed.

6) **Data and Specimen Banking**

This section is not applicable. This research is not banking data or specimens for future use.

7) **Data Management**

The data will be collected and stored in Box, a secure and HIPAA-compliant cloud storage platform. Any paper records will be kept under lock and key in the PI's office. The records kept in the PI's office will not be linked to the patient's name and will be de-identified according to HIPAA requirements. The key that links the study numbers to the patient identifiers will be kept separately under lock and key. Only study team members, members of the patient's clinical care team members and people in departments or on committees responsible for overseeing the research will have access to the data collected.

Statistical procedures will include paired t-test comparing MRD1 values between control and phenylephrine, and McNemar's test to evaluate the proportion of eyes that meet insurance criteria between taping and phenylephrine. Spearman correlation analysis will be used to assess any correlation between changes in MRD1 and VF performance after phenylephrine. Additionally, a paired t-test will compare patient satisfaction scores after taping and phenylephrine.

8) **Risks to Subjects**

- **Privacy**

- We anticipate that this study will entail minimal psychological/social stress related to privacy and confidentiality. Investigators will minimize the risk of loss of confidentiality by identifying data collection forms by code only, and by only releasing non-identifying information in summary format. Personal information will be protected to the fullest extent allowed according to federal regulations.
- **Adverse Events & Serious Adverse Events**
 - An **adverse event** will be defined as any event that may harm the subject or require the subject to seek medical attention, and a **serious adverse event** will be defined as adverse events that require the subject to seek medical attention and may be life threatening.
 - **Adverse Events**
 - Adverse events include falls during or immediately after taking the visual field test. Individuals without a fall risk will be chosen for the study. In addition, they will be given clear instructions and training to prevent falls.
 - This protocol calls for three iterations of tangent screen visual field testing which requires focus and can lead to patient fatigue. Prolonged, uninterrupted superior visual field testing will be avoided, and breaks of 5 minutes will be afforded to the patient between tests as needed.
 - **Serious Adverse Events**
 - A serious fall during or immediately after taking a visual test constitutes a serious adverse event. The same precautions as mentioned above will be taken to prevent this.
 - Phenylephrine can potentially cause nausea, vomiting, headache, and can lead to exacerbations of underlying cardiovascular disease²⁸. However, the amount of phenylephrine available systemically following ophthalmic application is generally less in comparison to oral or IV doses. Additionally, this study will not include patients with serious underlying cardiovascular disease.
 - Phenylephrine can also cause blurring of vision impacting activities of daily living such as driving¹⁵. To minimize risk, study team members will set expectations about the testing procedure and associated risks (including cautioning against driving or operating machinery immediately following dosing) prior to testing in the clinic.
 - Risks of Muller's Muscle-Conjunctival Resection may include over-exposure of the eye, an asymmetry between eyes, inward or outward-turning eyelid, eyelash loss, infection, bleeding, or changes in vision.

9) Potential Benefits to Subjects

- The study will ultimately provide information for future patients by gaining a better understanding of whether phenylephrine 2.5% ophthalmic

solution can be used as a more effective criteria for surgical ptosis repair evaluation.

10) Vulnerable Populations

n/a

11) Setting

Data collection and recruitment will occur at the ophthalmic plastic surgery clinic at the Bascom Palmer Eye Institute. Data analysis will take place at the University of Miami.

12) Resources Available

- **Sara T. Wester, MD** – Principal Investigator. Professor of Clinical Ophthalmology and specialist in Ophthalmic Plastic and Reconstructive Surgery qualified to evaluate visual field quality and outcomes. Dr. Wester will be supervising and collaborating with the research team on all aspects of this study.
- **Naomi Gutkind, MD** – Resident physician at the Bascom Palmer Eye Institute, qualified to evaluate visual field quality and outcomes. Dr. Gutkind will be involved in supervising and collaborating with the research team on all aspects of this study.
- **Lynn A. Leveille, MS** – An MD candidate at the University of Miami Miller School of Medicine and registered nurse, Ms. Leveille will be involved in the coordination of key research personnel, study design, patient consent, data collection, data analysis, interpretation of results, data safety and confidentiality, and dissemination of findings.
- **Annika J. Patel, BS** - An MD candidate at the University of Miami Miller School of Medicine, Ms. Patel will be involved in study design, data analysis, interpretation of results, data safety, confidentiality, and dissemination of findings.
- **Chrisfouad R. Alabiad, MD** - Professor of Clinical Ophthalmology and Assistant Dean for Student Affairs at the University of Miami Miller School of Medicine. Dr. Alabiad specializes in Ophthalmic Plastic and Reconstructive Surgery at the Bascom Palmer Eye Institute and is qualified to evaluate visual field quality and outcomes. Dr. Alabiad will be collaborating with the research team on all aspects of this study.
- **Wendy W Lee, MD** - Professor of Clinical Ophthalmology. Dr. Lee specializes in Ophthalmic Plastic and Reconstructive Surgery at the Bascom Palmer Eye Institute and is qualified to evaluate visual field quality and outcomes. Dr. Lee will be collaborating with the research team on all aspects of this study.
- **Andrew Rong, MD** - Assistant Professor of Clinical Ophthalmology. Dr. Rong specializes in Ophthalmic Plastic and Reconstructive Surgery at the Bascom Palmer Eye Institute and is qualified to evaluate visual field quality and outcomes. Dr. Rong will be collaborating with the research team on all aspects of this study.

- University of Miami Miller School of Medicine (UMMSOM) – UMMSOM is a private institution with a mission to perform research that will advance the science and practice of medicine. Through this commitment to research, UMMSOM is the number one NIH-funded institution in Florida.
- Bascom Palmer Eye Institute (BPEI) – BPEI serves as the department of ophthalmology for UMMSM. BPEI has consistently been ranked as the top eye hospital in the country as published in the U.S. News & World Report.

13) Prior Approvals

No prior approvals were obtained.

14) Recruitment Methods

Patients who are seen in the ophthalmic plastic surgery clinic at BPEI will be asked to participate in this study. Study team members will review medical records of patients seen at BPEI from 2/1/2023-2/29/2024 to identify eligible participants prior to their next visit. The PI or one of the study team members will introduce the study to potential participants. The participants will be selected according to the established clinic schedule to ensure equal access to study participation. Participants will be recruited at the time of their visit to the outpatient clinic. No recruitment advertisement or materials will be used. No payments or other incentives will be offered to participants.

15) Confidentiality

Each study participant will be issued a participant ID. All information will be stored at UM by participant ID for each participant. All data will be stored on the encrypted UM data systems. A shared directory with limited access only by those working on the study has been created. Any information in paper copy will be kept in a locked file cabinet. Before analysis, observations from chart reviews will be stripped of personal identifiers and stored indefinitely at the UM for possible future analysis. All data will be inspected for quality assurance prior to analysis

All study personnel will be certified to conduct human subjects' research by the University of Miami Institutional Review Board.

Choose the statements below that are applicable to this research:

15(a). Data will be collected from the EMR or subjects at UHealth or JHS.
 Research Subjects will sign a HIPAA Authorization before the research will collect this data.
 Research Subjects will not sign a HIPAA Authorization for this data collection and the research is requesting a waiver of HIPAA authorization from the IRB. (Complete Section 17 below)

15(b). Data collected:

- Will not include Protected Health information or Personally Identifiable Information
- Will include Protected Health information or Personally Identifiable Information

15(c). How will the research store the data?

- On a University of Miami electronic device (e.g. encrypted, password-protected computer)
- On a cloud-based storage system that is approved by the University of Miami
- Other, specify: [Click here to enter text.](#)

Select one of the following:

- The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that **does not include any** indirect or direct identifiers (listed in the instructions for Section 15 of this protocol), and the recorded data will not be linked to the individual's' identity.

OR

- The Principal investigator (and/or Study Team members) will record (e.g., write down, abstract) the data collected in a manner that does not include any direct identifiers (see list in the instructions for Section 15 of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to each study subject and link the code to the study subject's identity. The link to each subject's identity and/ or other identifiable information will be maintained on a document separate from the research data.

Biospecimens

- Not applicable. No biospecimens will be collected

15d. Jackson Health System additional requirement

- This section is not applicable because the research is not collecting health information from JHS under a waiver of authorization (without obtaining a HIPAA authorization from the participant)

16) **Provisions to Protect the Privacy Interests of Subjects**

This study will entail minimal psychological/social stress related to privacy and confidentiality. Investigators will minimize the risk of loss of confidentiality by identifying data collection forms by code only, and by only releasing non-identifying information in summary format. Personal information will be protected to the fullest extent allowed according to federal regulations.

17) **Waiver of Authorization for Use and Disclosure of Protected Health Information (HIPAA)**

Waiver of Authorization for access to medical record for subject identification/recruitment.

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

I confirm

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

I confirm

18) **Consent Process**

All informed consent documents will be in English (with HIPAA authorization forms in English, Spanish, and Creole). The consenting process will be conducted with the individual in a private room to protect the privacy of the subjects.

Professional translation services will be utilized as needed. There is no time limit for obtaining informed consent. The participants will be given as much time as they need to ask questions and come to a decision. Participants are encouraged to discuss their involvement with friends and family members prior to signing the consent form. The investigator may give the participant a copy of the consent form for review before discussing the study at the site. The consent will be obtained during a standard care visit. The participant will sign a hard copy of the consent form to be saved by the study team. A copy of the consent form will be provided to the participant upon request.

All questions will be answered fully before the subject is enrolled into the study, however, if questions arise after enrollment the PI's number is listed on the consent and the study coordinator will give the participants their information so that they may be contacted at any time. Prospective participants will be explained that this study is completely voluntary, and they do not have to participate. Their medical care will remain the same whether they participate in the study or not. The information should be communicated in a manner and language that is clear and understandable, be communicated in an organized fashion, and allow for questions the subject may have. If the site/investigator is unsure the participant understands due to a language or hearing impairment, the participant will not be enrolled.

Non-English-Speaking Subjects

HIPAA authorization forms will be available in English, Spanish, and Creole. If/when a subject to be enrolled speaks a language other than English, a translator and a witness will be present to orally translate the consent form completely, and

they will be provided a written consent in their language of choice, if available, so the participant is aware of their rights before they sign, if they chose to do so. If an informed consent form or translator is not available in the patient's desired language, the patient will not be enrolled in the study.

Adults Unable to Consent

Adults unable to consent will be excluded from the proposed study.

19) Process to Document Consent in Writing

We will obtain informed consent by providing participants with a physical copy of the consent documentation, going over the consent details with them and having them sign the consent form in person. We will provide a copy of the physical consent form upon participant request. The informed consent document will also include information regarding who they can call if they have questions regarding their participation in the study.

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