# Use of Ocular Point of Care Ultrasound in Diagnosing Retinal Detachment in the Emergency Department: A Prospective Study.

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LOMA LINDA UNIVERSITY
School of Medicine

1. PROTOCOL INFORMATION
*Title: Use of Ocular Point of Care Ultrasound in Diagnosing Retinal Detachment in the Emergency Department: A Prospective Study.*
*Funding Source: Emergency Medicine*
*Phase of Study: initial*
*Version Date of Protocol: version 1*

2. PRINCIPAL INVESTIGATOR'S INFORMATION
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3. STUDY PERSONNEL
P*atients will be enrolled and data will be collected by an IRB trained Loma Linda emergency medicine advanced practice provider or physicians and Loma Linda student research assistants*

4. STUDY INFORMATION
*Location(s) of Research Activity: Loma Linda Emergency Department*
*Expected Start/Stop Dates of Research:July 2017-July 2018*
*Type of Research: Other- Ultrasound diagnostic*

5. INCLUSION / EXCLUSION CRITERIA
*Inclusion criteria: Participants may include any patient that is greater than 18 years old with any complaint of vision loss, flashers, floaters and/or any other patient whom the emergency physician feels requires an evaluation for mac on retinal detachment, mac off retinal detachment, vitreous hemorrhage, and or vitreous detachment. Patients that meet this eligibility criterion must also be receiving a consult by a LLU ophthalmology physician in order to obtain comparative time values and accuracy for ED physician diagnosis versus ophthalmologist diagnosis.*

*Exclusion criteria: Exclusion Criteria includes any ocular trauma, any concern for ruptured globe, or any other extraneous reason determined by the treating ED physician. Excluded patients also include: pregnant women, patients < 18 years of age, and patients not receiving an ophthalmology consult. We will be excluding pregnant women in order to minimize the exposure to ultrasonography for expectant*

*mothers. We will be excluding patients <18 years of age because it is unlikely that the data from these patients will significantly contribute to our investigation.*

6. SUBJECT RECRUITMENT & SCREENING

*Number of Subjects: estimated 250-300 across all sites in conjunction with USC, UCI, UCLA*
*Subject Age Range: 18+*
*Subject Gender: males and females both*
*Racial/Ethnic Distribution: any*
*Target Study Population: Adults non pregnant patients with painless vision loss*
*Recruitment Method Info: Potential patients will be identified by screening the ED tracking board and by asking physicians working in the department if they have any patients who will be evaluated for a possible retinal detachment.*

7. INFORMED CONSENT PROCESS

*The study will take place in the Emergency Department of LLUMC. The patient study population will include adult patients presenting to the emergency department with ocular complaints that lead to a physician's suspicion of retinal detachment. A treating attending physician or resident will evaluate the patient as per standard of care. If there is a concern for retinal detachment, the treating physician will order an ophthalmology consult.*
*IRB trained resident physicians or attending physicians of the Loma Linda emergency department will identify and approach patients regarding the study and obtain a signed informed consent if the patient agrees to participate. No medical records will need to be accessed for the purposes of this screening. If the patient declines to be enrolled in the study, treatment will proceed as per standard of care determined by the treating physician. In the cases where the physician treating the patient approaches the patient about being enrolled in this study, it will be made clear to the patient that his/her decision to be enrolled or not will in no way affect their quality of care in the ED by that physician. Only patients who require an ophthalmology consult to diagnose retinal detachment, as part of their normal ED care, will be enrolled. No x-rays, CTs, or formal ultrasounds will be performed solely for the purpose of this study. If a patient agrees to be enrolled in the study, he/she will sign a written informed consent form and a HIPAA form prior to the ultrasound procedure being performed.*
*The time of ophthalmology consult will be recorded. Next an emergency department physician will perform the ocular ultrasound and make a diagnosis based upon their findings. Images will be archived and stored in a locked hard drive stored in a locked office. Agreeing to participate will allow the study team to collect data from the ultrasound exam and authorize access to the subject's medical record for the purposes of research only. Information accessed from the medical record includes the duration of symptoms, height and weight, age, and the outcomes of standard testing. The final discharge diagnosis from the ophthalmology consult will be reviewed as well.*

*8.* STUDY DESIGN

a. *Background or rationale for this study: This is a prospective, cross-sectional study to assess the utility of Point of Care Ultrasound (POCUS) in the diagnosis of ocular complaints in the emergency department with specific focus on the accuracy of diagnosis when compared to that of a blinded ophthalmologist. Ocular complaints represent between 2% and 3% of ED visits (Walker et al, 2011). This percentage may include vision-threatening diagnoses including*

*retinal detachment, which can occur in 3-4% of patients presenting with ocular complaints (Alotaibi et al, 2011). However, the equipment and expertise required to adequately assess for conditions such as retinal detachment are limited in busy EDs due to the time consuming and challenging nature of the examination. Incorporating the use of an ultrasound could provide a more available, focused, and timely assessment.*

b. Objectives. *To determine the accuracy of ocular ultrasound in diagnosing retinal detachment compared to gold standard of ophthalmology examination.*

c. Procedures involved (Research Interventions): *Ocular Ultrasound*

d. Alternative procedures, if any, that are not included in the study but might be advantageous to the subject. *none*

e. If any deception is required for validity of this study, explain why this is necessary and how subject(s) will be debriefed. *n/a*

f. Concise review of literature that supports the rationale, objectives, and methodology of the proposed study: *Ocular POCUS has been utilized by ophthalmologists for decades and has been described as a tool for identifying retinal detachment since 1969 (Lizzi et al, 2004; Coleman et al, 1969; Vrablik et al, 2014). The ophthalmology team at LLU Medical Center evaluates patients using a focused ocular exam with a fundoscope and ocular dilation. The emergency department team has access to one fundoscope for ocular examination; incorporating the use of an ultrasound could provide a more available, focused, and timely assessment. A recently published meta-analysis identified only 3 small prospective trials in the Emergency Department that were determined to be at low risk of bias (Vrablik, 2014). The first study conducted by Blaivas et al in 2002 demonstrated an impressive 100% sensitivity and 100% specificity of ocular POCUS identification of retinal detachment in 61 subjects. In this study all attending physicians and residents received only 1 hour of hands-on instruction and 1 hour of lecture prior to study participation (Blaivas et al, 2002). A second study conducted in 2010 by Yoonessi et al demonstrated a sensitivity of 100% and specificity of 83% in detecting retinal detachment by ocular POCUS in 48 subjects after only a 20-minute ocular ultrasound lecture (Yoonessi et al, 2010). Shinar et al conducted the final study in 2011, which demonstrated a sensitivity of 97% and specificity of 92% in detecting retinal detachment by ocular POCUS in 92 subjects (Shinar et al., 2011). These studies suggest that ocular POCUS is an accurate diagnostic tool for identifying retinal detachment in the ED and may require minimal ED physician training. However, these studies are limited in their sample size. We intend to expand upon this prior research by enrolling more patients in addition to comparing the accuracy of ocular POCUS diagnosis to a blinded ophthalmologist. In secondary outcome measures we will compare the overall time to diagnosis of the Emergency Physician performing ocular POCUS to the time to diagnosis of the consulting ophthalmologist. Many additional studies have identified multiple other diagnostic utilities for ocular ultrasound. While accurate assessment of the optic disc can provide critical information regarding the patient's intracranial pressure, and be invaluable in diagnosis and treatment for patients, an accurate evaluation by fundoscopic examination is challenging at best and often impossible for those without specific expertise. Utilizing ultrasound to assess both retrobulbar optic nerve sheath and optic disc swelling as an indicator of increased intracranial pressure may prove as an*

*accurate alternative. This may lead to earlier ED detection of increased intracranial pressure that may be caused by a variety of pathologies including inflammatory diseases, infection, infiltrative conditions, and microvascular infarction, such as occurs with malignant hypertension (Blaivas, 2003; Tayal et al, 2007; Kimberly et al, 2008; Geeraerts et al, 2008, Teismann et al, 2013). Other case reports recently suggest the potential utilization of ultrasound to identify optic neuritis and as risk stratification for identifying orbital cellulitis (Kang et al, 2014). Therefore, continuing to expand the research of ocular POCUS in the ED could lead to a multitude of uses for the evaluation of ocular complaints that may improve the accuracy and speed to diagnosis at a lower cost with a non-invasive diagnostic tool.*

## 9. DATA COLLECTION

*Potential study subjects will be identified by participating researchers by a complaint of painless vision loss and treating physician's clinical suspicion of retinal detachment for which an ophthalmology consult is ordered. If a patient meets criteria for the study, then a research team member will approach each patient who meets criteria for possible enrollment. The patient will be given a Consent Form to read and any questions answered by the enrolling and/or treating physician. If he or she agrees to participate in the study, the patient will sign a HIPAA Authorization Form and Consent Form prior to enrollment. The emergency physician will evaluate the patient as per standard of care. Inclusive criteria for this study denotes that patients must be receiving an ophthalmology consult as per standard of care. The time of ophthalmology consult will be recorded. The ocular point of care ultrasound will then be performed on the patient while a research team member (including research assistant students) records required information on a data collection form. The ultrasound that will be performed will be for research purposes in the majority of cases. The treating physician may perform an ocular ultrasound on the patient as part of the treatment plan, per physician preference. In this case, the patient will still need to consent to the use of their ultrasound data for research. The physician performing the ultrasound will place the probe over the patient's closed eye. The physician will perform two exams, a static exam and a kinetic exam. In the static exam the physician will as the patient to keep their eyes forward while they scan longitudinal and transverse in long and short axis (all in normal gain). Then for the kinetic exam, the physician will use normal gain to visualize the ocular nerve in longitudinal axis, then the physician will over gain for the same visualization. The PHI recorded will be the medical record number, name of the patient, and date and time of treatment. Only the lead researcher and co-researchers will have access to the medical record number for reviewing ultrasound reports and disposition reports, as indicated on the attached Data Collection Sheet. The final diagnosis of the ophthalmologist will be accessed through the use of the medical record number. The time it was entered in the chart will be used as the time parameter for which we use as the ophthalmologist consult time. Patient privacy will be protected during this study as the patient information will be coded and replaced with a study number that will be used during the study. This information will be kept in a locked area and separate from the study files, only authorized members of the study team will have access to patient identifiable data. Subject identifiable information will be destroyed once the data is no longer needed. Regarding training, ED residents will receive supplemental lecture and hands-on training in ocular ultrasound. The purpose of this supplemental training will be to familiarize residents with performing an ocular ultrasound. The training itself will not be evaluated in practice for research purposes.*

*Only the lead researcher and co-researchers will be using the medical record number for accessing patient information and reports.*

10. LABELING & STORAGE OF DATA & SPECIMENS

*Patient's private health information will be kept confidential and enrollment in the study will include a patient study number. The master patient identification key will be kept in a locked office accessible only to researchers. Patient's ultrasound images will be stored on a password encrypted drive which will be locked in an office accessible only by Lead Researcher.*

11. DATA ANALYSIS

*The data will be screened for normality, missing data, outliers, and skewness. Descriptive statistics will be conducted on the data, including all study related variables. Correlation matrices and path analyses will be presented to examine the mediating role. Effect sizes for all of these statistics will be reported to establish practical significance.*

12. RISK AND INJURY

*Patients deemed eligible for the study will be subjected to bedside ocular ultrasound via modalities described above, which require specific movements of the ultrasound probe as well as changing settings on the machine itself. As such, patients will only be exposed to ultrasound gel and ultrasound probes emitting high-frequency sound waves, which poses a minimal risk of infection, no radiation exposure, and is generally well-tolerated by patients. Patients will have a small plastic patch known as a Tegaderm applied to their closed eyelid prior to application of ultrasound gel, to further reduce the very low risk of infection or irritation from the gel. This is routine practice and is well tolerated by patients. At any point, study subjects may decide to refuse consent for the study.*

13. BENEFIT(S)

*Patients will not be personally compensated but the performance of ultrasound may aid in diagnosis of ocular complaints or identification of ocular pathology.*

14. COMPENSATION

*There will be no compensation for patients or researchers.*

15. CONFIDENTIALITY

*Patient privacy will be protected during this study as the patient information will be coded and replaced with a study number that will be used during the study. This information will be kept in a locked area and separate from the study files, only authorized members of the study team will have access to patient identifiable data. The patient's images will be held on a password encrypted external hard drive which will be stored in a locked office.*

16. LITERATURE REVIEW


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