Study Title: Portable Endoscopic Camera System Using Modified Action Camera for Endoscopic Sinunasal Examination

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Background and Rationale

Tears are continuously produced from the tear glands in the orbit and the eyelids. Tears are drained at about the same rate of production through a dedicated tear drainage system to the nasal cavity. Nasal examination is an important component of examination for patients presenting with tearing to rule out nasal causes of tear drainage obstruction.

Endoscopic examination of the nose requires the use of bulky system (endoscopic tower) connected to the endoscope lens for light sourcing and image visualization and possible recording. This set up is time consuming to transfer and set up which limits portability and use of this service in many situations as in the inpatient service, emergency room and in busy clinic setting because the endoscopic tower is usually available in one examination lane in oculoplastic clinic.

In this study we aim to test the utility of an alternative compact system consisting of a modified Sony action camera and Epson augmented reality glasses to capture and project the images of the examination in the real-time, respectively. This design would allow more portable use of this examination virtually everywhere in the hospital setting e.g.: in the emergency and inpatient departments as well as in outreach services. In addition, this design can be very helpful for clinical care in underserved communities as well as in developing countries, where traditional endoscopic equipment may not be available or feasible to transport.

To our knowledge, no previous studies have evaluated the use of this technique in endoscopy in general, nor in nasal endoscopic examination. Therefore, this study represents a novel proof-of-concept exploration of a low-cost, portable alternative for nasal endoscopic imaging.

Hypothesis *and/or* Specific Aims *or* Objectives

This study aims to test the utility of this method of examination of the nasal cavity in patients with tearing to rule out endonasal causes of tearing.

Patients with tearing will undergo endoscopic examination with recording using the described system as well as examination and recording with a standard endoscopic system for comparison.

The quality of images of the described method will be compared to the standard endoscopic for resolution, quality and utility by three attendings with experience in endoscopic nasal examination.

The comparison will be for the images captured by the action camera and with the standard tower. The augmented reality glasses are just a means of seeing these pictures in the realtime but the quality of images in the AR glasses are not going to be compared to the standard tower.

Study Design and Procedures

This is a prospective, cross-sectional, non-interventional study designed to evaluate the image quality and clinical utility of a modified portable endoscopic imaging system compared to a standard hospital-based endoscopic tower.

Study Population and Setting

Patients presenting to the ophthalmology or otolaryngology clinics with complaints of tearing and requiring nasal endoscopic examination as part of their standard clinical evaluation will be invited to participate. No investigational or therapeutic procedures will be performed; all imaging will occur during routine endoscopic assessment.

Imaging Procedure

Each participant will undergo two sequential nasal endoscopic examinations during the same clinical visit:

1. Standard Endoscopic Examination: performed using the clinic's standard endoscopic tower system.

2. Modified Sony Action Camera System Examination: performed immediately afterward using the described portable imaging setup.

The following nasal anatomical locations will be imaged with both systems for comparison:

- Inferior meatus
- Inferior concha
- Middle concha
- Middle meatus
- Nasal septum
- Any identifiable nasal pathology (e.g., polyps, ulcers, mucosal thickening)

Each site will be recorded as short video clips and still images for later review and comparison.

Description of the Modified System

The Sony Action Camera was modified to allow direct coupling with a standard rigid nasal endoscope:

1. The native 180° wide-angle lens was replaced with a narrow-field 31° lens, enabling full-frame capture of the endoscopic image without peripheral distortion.

2. The camera housing was adapted by attaching a ¾-inch water pipe end connector, serving as a secure and stable mount for the endoscope eyepiece.

The modified system captures both video and still images. The standard endoscopic tower records video and stills per the clinic's routine workflow to serve as the comparator reference.

Integration of Epson Augmented Reality (AR) Glasses

The Epson augmented glasses will be used to provide real-time, heads-up visualization of the endoscopic feed from the modified camera system.

During the examination, the live endoscopic video stream will be displayed directly in the wearer's field of view through the transparent projection lenses of the AR glasses. This allows the examiner to maintain situational awareness of the patient while simultaneously viewing the nasal anatomy, potentially improving procedural ergonomics and mobility compared to viewing a fixed external monitor.

Use of the Epson AR glasses is limited to the examiner only (not the patient). They are used purely for image visualization and evaluation of workflow feasibility — not for any diagnostic or therapeutic intervention.

User Qualifications and Training

All examinations will be conducted by residency and fellowship trained otolaryngologists and oculoplastic surgeons with expertise in preforming endonasal endoscopic examination.

Before study initiation, all investigators will attend a brief orientation and device training session (~30 minutes) covering assembly of the modified camera, Epson AR glasses, handling and sterilization procedures, and data transmission. No additional certification beyond standard clinical competency in endoscopy is required.

Study Population

Forty adults presenting with sinunasal and lacrimal tearing symptoms suggestive of nasolacrimal drainage obstruction or sinunasal disease in the outpatient ophthalmology or ENT clinic. All recruitment will occur during routine outpatient encounters; no patients will be contacted or identified prior to their scheduled clinical visit.

To determine eligibility, the provider (PI) will access information that is routinely available during standard outpatient care, including name, MRN, age, DOB, diagnosis, and any existing endoscopy orders. Accessing this information is part of the normal clinic workflow and will be used solely to confirm eligibility for this study. This information will not be stored or retained once eligibility is established.

Subjects that meet eligibility will be approached with the proposal to participate in this study on the date of their appointment after the rational of the study, benefits and risks are discussed. Patients who will accept to participate will be asked to sign this study's informed consent form.

Inclusion Criteria

- Adult patients (18 years and older) presenting with tearing suggestive of nasolacrimal drainage obstruction
- Adult patients presenting with sinunasal disease with clinical findings on endonasal examination.
- Adult patients who require a clinically ordered nasal endoscopic exam.

Exclusion Criteria

- Children (Under the age of 18)
- Patients with over secretory tearing.

Risks of the study

There is no more than usual risk of endoscopic nasal examination and the second set of images will require only an additional 3-5 minutes and will not require any additional topical lidocaine spray. The camera and the virtual reality glasses are not in direct contact with the patient. In addition, the camera will be covered by a sterile bag for additional protection of the patient. Another risk to study participants is the potential for loss of confidentiality of study data. Images of the patients will be deidentified and given a study code to protect patients' confidentiality. Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

Benefits of the study

There will be no direct benefits to the study participants; however, knowledge gained from the study could potentially benefit patients in the future who may benefit from this examination portable examination method. This design would allow more portable use of this examination virtually everywhere in the hospital setting e.g.: in the emergency and inpatient departments as well as in outreach services. In addition, this design can be very helpful for clinical care in underserved communities as well as in developing countries.

Data Handling and Recordkeeping

Data Elements and Timing of Collection

Each participant will undergo two sequential nasal endoscopic examinations during a single clinical visit. The standard endoscopic imaging will occur first, followed immediately by imaging using the modified Sony Action Camera system, requiring approximately 3–5 additional minutes.

The following data elements will be obtained for research purposes:

- Endoscopic video clips and still images of nasal anatomical sites (inferior meatus, inferior concha, middle concha, middle meatus, nasal septum, and any visible pathology such as polyps, ulcers, or mucosal thickening).
- A coded study ID (number) used to pair the modified-system recordings with the standard-system recordings for the same nasal side of the same participant.
- Image quality ratings assigned by three attending physicians using a 5-point Likert scale assessing resolution, quality, and clinical utility.
- No other demographic, clinical, or identifiable patient information (e.g., name, MRN, DOB) will be stored. The signed consent form will be retained separately in the sites regulatory binder as required by UAMS institutional policy, but will not be linked to study data.

Data Capture and Storage

Both the standard endoscopic tower and the modified portable system will record media for each specified location.

Source capture:

The modified Sony camera transmits recordings wirelessly to a secure, encrypted UAMS-device.

Standard tower images are stored on the institutional network per routine workflow.

Transfer and storage:

Study media will be exported, de-identified, and stored on a secure UAMS OneDrive folder accessible only to authorized study investigators. During the de-identification process, all direct and indirect identifiers will be removed, including patient name, date of birth, medical record number, encounter number, date of service, and any facial or other uniquely identifying features if present. Each file will be assigned a coded study ID and the link between this coded ID and the participants identity will not be maintained. A temporary linking log containing the study code and direct identifiers will be created for the purposes of confirming eligibility, tracking consent, and ensuring accurate file matching. This linking log will be stored separately

from all study data in a secure, encrypted, access-restricted UAMS One-Drive folder. Access will be limited to only PI and IRB approved study staff. Once all recordings have been verified and permanently de-identified, the link between the coded ID and the participants identity will be destroyed using UAMS-approved deletion methods preventing recovery. Only fully de-identified files will be retained and used for analysis.

De-identification and Coding

Before analysis, all recordings will be permanently de-identified to remove any HIPAA identifiers or metadata. Each image/video set will be assigned a numeric study code solely for matching the modified and standard system images from the same patient and same nasal side. No re-identification will be possible once coding is complete.

Data Evaluation

Three attending physicians experienced in nasal endoscopy will independently grade the anonymized images using a 5-point Likert scale (1 = useless to 5 = excellent). Grading will occur exclusively on coded media files, with no patient identifiers visible at any stage.

Statistical Analysis

All data analysis will be performed by researchers at the Jones Eye Institute (JEI), University of Arkansas for Medical Sciences. Analysts will have access only to de-identified images and coded data, with no links to patient identifiers.

Descriptive statistics (mean, median, and standard deviation) will be used to summarize image-quality scores from both the standard and modified endoscopic systems. Nonparametric tests, including the Wilcoxon signed-rank test, will be applied to compare paired image-quality scores between the two systems to determine whether the modified endoscopic exam performs better, equivalent, or worse than the standard exam. Inter-rater reliability among the three physician graders will be assessed using the Intraclass Correlation Coefficient (ICC).

A total of 40 participants will be enrolled. This sample size provides sufficient power for within-subject comparisons, allowing detection of meaningful differences in image quality while accounting for potential variability across raters and minor data loss.

Sample size justification

A total of 40 participants will be enrolled. This sample size is appropriate for a paired comparison study in which each participant provides image-quality scores for both the modified system and the standard endoscopic system.

The primary analysis will use the Wilcoxon signed-rank test, which is commonly used for paired ordinal data. A formal power analysis for the Wilcoxon test will be completed by a statistician during the final analysis phase. However, based on typical assumptions used for paired nonparametric tests, a sample of 40 paired observations is generally sufficient to detect a small/moderate difference in Image quality with acceptable statistical power (80%) at the standard α=0.05 level.

The sample size also provides a buffer for minor variability in image quality ratings across raters. Overall, enrolling 40 participants is expected to provide sufficient data to compare the two imaging systems.

Data Retention and Disposal

All study data will remain de-identified throughout the research process.

Retention: De-identified image sets and scoring data will be retained in a secure, password-protected UAMS cloud for seven years in accordance with institutional policy for research record retention.

Future use: The research team will not use the collected data for any future research projects.

Destruction: After seven years, data will be permanently destroyed in accordance with UAMS-institutional policy.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the IRB as required.

Participation in this study involves a few minutes of additional time on the patient during their visit. No compensation is going to be offered to the study participants.

The informed consent and HIPAA authorization of each subject, using IRB-approved consent materials, will be obtained before that subject begins any study procedures. All subjects for this study will be provided a consent form on paper describing this study in language understandable to the study population. Consent materials will provide sufficient information for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain what the subjects need to know about the study, including study requirements and study risks and benefits. The consent process will take place during their clinic visit in the exam room. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process.

This consent form must be signed by the subject or legally authorized representative and the person obtaining the consent. The participant will receive a paper copy of the signed consent

form, and the informed consent process will be documented in the research record.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.