RESEARCH PROTOCOL

Protocol Title: Pilot Study: Feasibility and Usability of a Head-Mounted Spatial Computing Device for Intraoperative Visualization during Intraocular Surgery

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1. ABSTRACT

1.1 Study Overview

This prospective, observational, single-arm feasibility and usability study will assess the use of Apple Vision Pro (AVP) as an adjunct intraoperative visualization tool during ophthalmic surgery, including cataract, anterior segment, and retina procedures. The AVP is a commercially available mixed-reality headset that will be worn by attending surgeons to display the surgical microscope camera feed, preoperative imaging, intraoperative images, electronic health record (EHR) data, and facilitate real-time communication with other surgeons. The device functions solely as an adjunctive visualization interface and does not acquire images, alter microscope function, modify surgical technique, or affect patient care. Standard operating room monitors, and microscope displays will remain active and serve as the primary reference for all critical surgical steps.

1.2 Study Objectives

Primary Objective:
To evaluate the feasibility and usability of Apple Vision Pro as an adjunct visualization and information display tool during ophthalmic surgery.

Secondary Objectives:
- To explore effects on surgeon comfort, perceived workload, and workflow integration
- To document any device-related technical issues or safety concerns
- To assess surgeon acceptance and satisfaction using validated usability measures

1.3 Study Design and Duration

Design: Prospective, observational, single-arm feasibility study

Estimated Enrollment: 40-70 surgical cases

Study Duration:
- Enrollment Period: 1-2 months following IRB approval
- Total Study Duration: Approximately 12 months from IRB approval
- Individual Participant Duration: Day of surgery only, with no additional follow-up visits beyond standard clinical care

2. BACKGROUND AND RATIONALE

2.1 Scientific Background

Mixed-reality and spatial-computing headsets are increasingly being explored in the operating room to display real-time imaging, patient vitals, and surgical overlays. Early feasibility reports across minimally invasive general surgery and other specialties have demonstrated the potential for these technologies to enhance surgical visualization and workflow integration[1][2].

A recent pilot study in oculoplastic surgery evaluated surgeons wearing Apple Vision Pro during eyelid malposition procedures and found high ratings for usability, integration with workflow, and freedom of movement, with System Usability Scale scores exceeding 85 out of 100[3]. Ongoing investigations are exploring the use of AVP for ophthalmic and cataract surgery to provide immersive three-dimensional visualization and potentially improve surgical precision and ergonomics[3][4][5].

2.2 Rationale and Knowledge Gap

Despite emerging interest in spatial computing technology for ophthalmic surgery, limited data exist on intraoperative ergonomics, workflow integration, and surgeon experience when using AVP specifically during ophthalmic microsurgery. The unique demands of ophthalmic procedures including fine motor precision, reliance on high-magnification microscopy, and critical depth perception necessitate systematic evaluation of head-mounted display technology in this context.

This study will systematically capture usability metrics, assess potential task interference, and document any device-related adverse events during actual surgical procedures. The findings will inform future integration of mixed-reality technology into ophthalmic surgical practice and provide foundational data for larger-scale trials.

2.3 Risk Classification

This study presents a head-mounted spatial computing display as a Non-Significant Risk (NSR) device study based on the following considerations:

- The device does not constitute a life-supporting or life-sustaining device
- The AVP does not directly contact the patient
- The device functions solely as an alternative visualization interface and does not acquire images, alter microscope function, modify surgical technique, or independently affect patient care
- Standard-of-care visualization equipment remains available and serves as the primary reference throughout all procedures
- Failure of the AVP is unlikely to pose a serious risk to subjects since standard-of-care visualization is concurrently available at all times

3. STUDY OBJECTIVES AND ENDPOINTS

3.1 Primary Objective

To evaluate the feasibility and usability of the Apple Vision Pro as an adjunct visualization and information display tool during ophthalmic surgery.

3.2 Secondary Objectives

1. To explore the effects of AVP use on surgeon comfort and perceived workload during ophthalmic procedures
2. To assess workflow integration and acceptance by surgical teams
3. To document the frequency and nature of any device-related technical issues
4. To identify any safety concerns associated with intraoperative AVP use
5. To collect preliminary data on surgeon satisfaction and willingness to adopt the technology

3.3 Primary Endpoints

1. Usability: Mean scores on the XR Usability Questionnaire (XR-UQ) adapted for AVP and digital microscopy
2. Feasibility: Proportion of cases in which the AVP was successfully used throughout the entire procedure without premature removal due to technical or ergonomic issues

3.4 Secondary Endpoints

1. Mean scores on study-specific Likert scale items assessing ease of integration, discomfort, interference with tasks, perceived depth perception, and ergonomics
2. Frequency and description of technical issues reported by surgeons
3. Proportion of cases with intraoperative complications potentially related to device use
4. Operative time compared to institutional averages for similar procedures
5. Qualitative feedback from open-ended questionnaire responses regarding surgeon experience and recommendations for improvement

4. INVESTIGATIONAL DEVICE

4.1 Device Description

Apple Vision Pro (AVP): is a commercially available mixed-reality spatial computing headset manufactured by Apple Inc. The device features:
- High-resolution micro-OLED displays for immersive visual content
- Advanced spatial audio
- Eye tracking and hand gesture controls

- Ability to display multiple virtual screens in the user's field of view
- VisionOS operating system (version will be documented at study initiation)

NGENUITY 3D Visualization System: is an FDA-cleared digital ophthalmic surgical microscope manufactured by Alcon. It is used as standard of care to visualize the operative eye during intraocular surgery and provides high-definition digital imaging of the surgical field via bilateral microscope mounted CMOS cameras.

4.2 Intended Use in This Study

The Apple Vision Pro will be worn by the attending surgeon during ophthalmic surgical procedures. The device will be used to display:

1. Surgical microscope camera feed: Real-time video output from the NGENUITY digital microscope
2. Preoperative imaging: Relevant diagnostic images (e.g., biometry, optical coherence tomography, corneal topography, fundus photographs)
3. Electronic health record (EHR) data: Cloud-based patient information including surgical plan, lens specifications, and relevant medical history
4. Real-time communication: Video conferencing capability to consult with other surgeons during the procedure if needed

4.3 Regulatory Status

The Apple Vision Pro is a commercially available general-purpose consumer device and is not specifically cleared by the FDA as a surgical navigation system or medical device. In this protocol, the AVP is used solely as a visualization adjunct to display information that would otherwise be available on standard operating room monitors or microscope oculars.

The NGENUITY digital microscope is an FDA-cleared (510(k) clearance) Class II medical device indicated for use in ophthalmic surgical procedures.

The AVP does not:
- Acquire or process medical images independently
- Modify the function of the surgical microscope
- Alter surgical technique or patient care pathways
- Deliver therapy or directly contact the patient

4.4 Justification for Non-Significant Risk (NSR) Classification

This study presents the Apple Vision Pro as a Non-Significant Risk device based on 21 CFR 812.3(m) because:

1. The device is not implanted

2. The device does not directly contact the patient
3. The device is not used to support or sustain life
4. The device does not present a potential for serious risk to the health, safety, or welfare of subjects because:
  - It serves only as an alternative display interface for information already available through standard equipment
  - Standard-of-care visualization equipment remains the primary reference throughout all procedures
  - Surgeons are instructed to immediately remove the headset if any interference with visualization, comfort, or safety occurs
  - All operating room staff are educated about the device and empowered to voice safety concerns

5. STUDY POPULATION

5.1 Number of Subjects

Target Enrollment: 40-70 surgical cases at seven study sites

5.2 Inclusion Criteria

Patient Participants:

1. Age equal to greater than 18 years
2. Undergoing clinically indicated and elective ophthalmic surgery (including but not limited to cataract extraction with intraocular lens implantation, anterior segment procedures, or retinal surgery) at a study site listed above
3. Able and willing to provide written informed consent prior to participation
4. English or Spanish speaking, or able to provide consent with assistance of a legally authorized representative

Surgeon Participants:

1. Attending ophthalmic surgeon credentialed to perform ophthalmic surgery at a participating study site
2. Willing to wear the Apple Vision Pro during surgical procedures
3. Willing to complete usability questionnaires following surgical cases
4. Willing to provide written informed consent for participation in research-related activities

5.3 Exclusion Criteria

For Patient Participants:

1. Prisoners or incarcerated individuals
2. Inability to provide informed consent and no legally authorized representative available
3. Cognitive impairment or language barriers that prevent the patient from understanding the informed consent process in the absence of a legally authorized representative
4. Procedures in which the attending surgeon judges that any additional operating room equipment poses unacceptable risk to the patient
5. Complex ocular pathology that could interfere with surgical visualization or increase procedural risk, including but not limited to:
   - Significant lenticular zonule instability
   - Previous complex ophthalmic surgery (e.g., prior vitrectomy, prior glaucoma surgery, prior corneal transplant)
   - Corneal scarring, significant opacity, or edema that limits visualization
   - Active ocular surface infection or significant inflammation
   - Dense cataract (grade 4+ nuclear sclerosis or posterior subcapsular cataract)
   - Pupil diameter <5mm after dilation
6. Emergency or urgent surgical procedures
7. Subjects who lack the capacity or are consider vulnerable to consent for themselves
8. Pregnancy

For Surgeon Participants:

1. Ophthalmology fellows, residents, or medical students (even if performing procedures under attending supervision)
2. Surgeons who have not completed training on AVP use and sterility protocols specific to this study
3. Surgeons with medical conditions that contraindicate use of head-mounted displays (e.g., history of severe motion sickness, active vertigo, severe claustrophobia)

5.4 Rationale for Inclusion/Exclusion Criteria

Inclusion criteria ensure that participants are appropriate candidates for elective ophthalmic surgery and can provide informed consent. Exclusion of complex cases minimizes confounding factors and ensures that the pilot study focuses on routine surgical scenarios where baseline risk is low and any device-related interference can be more easily identified. Restriction to attending surgeons ensures adequate surgical expertise and decision-making authority to immediately discontinue device use if safety concerns arise.

8. DATA MANAGEMENT AND STATISTICAL ANALYSIS

8.1 Data Collection and Management

Data Sources

1. Surgeon Questionnaires:
   - XR Usability Questionnaire (XR-UQ)
   - Study-specific Likert-like scale items
   - Open-ended qualitative responses

2. Clinical Data Abstraction:
   - Patient demographics
   - Diagnosis and procedure type
   - Operative time
   - Intraoperative and postoperative complications
   - Device removal events

Data Handling Procedures

1. Study ID Assignment: Each surgical case will be assigned a unique study identification number at the time of enrollment. A separate, password-protected linkage file connecting study IDs to medical record numbers will be maintained on secure institutional servers with access limited to authorized research personnel.

2. Data Entry: Surgeon questionnaire responses will be entered into a secure, HIPAA-compliant electronic database (e.g., REDCap or equivalent institutional system). Clinical data abstracted from medical records will be entered using the study ID only, with no direct identifiers.

3. Data Storage: All electronic data will be stored on secure, encrypted, password-protected institutional servers with automatic backup. Physical documents (e.g., signed consent forms) will be stored in locked file cabinets in a secure office accessible only to research personnel.

4. Access Control: Access to identifiable data will be limited to the Principal Investigator and designated research coordinators who have completed human subjects protection training. De-identified datasets for analysis will be accessible to biostatisticians and co-investigators as needed.

5. Data Retention: All study data will be retained for a minimum of seven years following study completion, or longer if required by institutional policy or regulatory requirements. After the retention period, data will be securely destroyed (e.g., shredding of physical documents, secure deletion of electronic files).

Video and Image Data (If Applicable)

If intraoperative video or images are collected:

- Explicit consent for video recording will be obtained separately
- De-identification will be performed whenever possible (cropping faces, obscuring visible identifiers)
- Files will be stored on encrypted institutional servers of the operating surgeon
- Use will be limited to research analysis and educational purposes explicitly described in the consent form, no videos or pictures will be required as part of this study.
- Sharing outside the research team will require additional consent or IRB approval

8.2 Sample Size Justification

Target Enrollment: 40-70 surgical cases

Rationale:
This is a pilot feasibility study with descriptive objectives rather than hypothesis-driven outcome comparisons. The sample size is not based on statistical power calculations but rather on practical considerations:

1. Usability Assessment: A sample of 40-70 cases will provide stable estimates of mean usability scores and identify the range of user experiences with adequate precision for a pilot study.

2. Feasibility Endpoints: This sample size will allow detection of device removal or technical issues if they occur with any meaningful frequency (e.g., >1% of cases).

3. Multi-Site Representation: With 11 participating sites and multiple surgeons, 40-70 cases will provide sufficient diversity of surgical scenarios and user perspectives to inform future study design.

4. Practical Considerations: The enrollment period of 1-2 months is realistic given surgical volumes at participating sites, and the sample size is sufficient to complete enrollment within the projected timeline.

8.3 Statistical Analysis Plan

Descriptive Statistics

1. Usability Scores:
  - Calculate mean, median, standard deviation, and range for XR-UQ total scores and subscale scores
  - Calculate mean, median, and standard deviation for each study-specific Likert-scale item
  - Present frequency distributions (e.g., percentage responding "agree" or "strongly agree")

2. Feasibility Metrics:

- Calculate proportion of cases in which the AVP was used throughout the entire procedure without premature removal
- Calculate proportion of cases with any reported technical issues
- Describe frequency and nature of technical problems (e.g., display lag, connectivity issues, discomfort)

3. Safety and Complications:
- Calculate proportion of cases with any intraoperative complications
- Calculate proportion of cases with complications potentially related to AVP use (as determined by PI review)
- Describe all adverse events in detail

4. Operative Time:
- Calculate mean and median operative time, stratified by procedure type
- Compare to historical institutional averages using descriptive statistics (formal statistical testing is exploratory and not powered)

5. Surgeon Characteristics:
- Describe number of participating surgeons, cases per surgeon, and range of experience levels

Missing Data

Cases with incomplete questionnaire data will be included in analyses using available data (i.e., pairwise deletion for specific items). Sensitivity analyses may be conducted to assess the impact of missing data on primary findings. If >10% of cases have substantial missing data, the pattern of missingness will be investigated and described.

Software

Statistical analyses will be performed using standard software packages (e.g., SPSS, SAS, R, or Stata). Qualitative analysis may be facilitated using qualitative data analysis software (e.g., NVivo, Atlas.ti).

8.4 Data and Safety Monitoring

Ongoing Safety Monitoring

The Principal Investigator will:
1. Review all adverse events within 48 hours of occurrence
2. Review cumulative usability and safety data monthly during the enrollment period

3. Immediately suspend enrollment if a serious adverse event potentially related to AVP use occurs or if a pattern of safety concerns emerges

Stopping Rules

The study will be suspended or terminated if any of the following occur:
1. A serious adverse event (e.g., unplanned vitrectomy, lens dislocation, retinal tear) is judged by the PI to be probably or definitely related to AVP use
2. A pattern of minor complications or near-miss events potentially related to AVP use emerges (e.g., >10% of cases with device-related issues that prompt concern)
3. More than 30% of cases result in premature removal of the AVP due to safety or usability concerns
4. Institutional or regulatory authorities identify concerns with the study protocol or conduct

Reporting to the IRB

All adverse events, unanticipated problems involving risks to subjects or others, and protocol deviations will be reported to the IRB in accordance with institutional policies and federal regulations (45 CFR 46 and 21 CFR 812). Serious adverse events will be reported within the timeframe specified by the IRB (typically within 24-48 hours).