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Development and Validation of a Gaze-based Training for Endoscopic Kidney Stone Surgery

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1.0 Background

This project aims to develop an augmented reality (AR) tool to enhance skill acquisition for endoscopic kidney stone surgery. Of the 100,000 patients who undergo an endoscopic kidney stone treatment annually in the United States, 25% will require a repeat stone surgery within 20 months of their index surgery [1, 2, 3, 4]. The repeat stone surgery rate is almost completely driven by postoperative residual stone fragments, which lead to ureteral obstruction causing pain, urinary tract infection, and kidney injury [5, 6, 7]. One significant factor that contributes to residual stone fragments is limited visualization of the entire collecting system - a skill directly associated with surgeon experience [8]. This leads to novice surgeons having a much higher recurrence rate than experienced ones. As the incidence of kidney stone disease continues to increase (prevalence of 10%, incidence of 1116 per 100,000), improved endoscopic surgical training is required to improve outcomes of stone surgeries and minimize complications by improving stone-free rate [9, 4].

Currently, skill assessment during endoscopic stone surgery is limited. There are no objective metrics for endoscopic surgery to assess skill. The only feedback trainees get is in the form of verbal communication from expert surgeons, usually after the conclusion of surgery. Thus, most feedback is synoptic and limited in facilitating skill acquisition [10]. Operative time and patient safety concerns restrict the amount of active, real-time feedback given during a case for skill acquisition. Endoscopic kidney stone surgery is uniquely challenging given the small depth and field of view of current endoscopes, which complicate the complete visualization of the entire collecting system. Navigation of the collecting system relies on mentally mapping preoperative imaging to the endoscopic surgical field. Success in mapping relies on hand-eye coordination, memory, and spatial reasoning, which are gained through practice. Thus, there is a need for tools that facilitate endoscopic surgical skill acquisition.

The overarching hypothesis for this research is that we can improve surgical skill acquisition and outcomes for endoscopic kidney stone surgery by integrating eye gaze sharing during procedures. Eye gaze guidance has been shown to lead to better skill acquisition in virtual reality surgical tasks compared with motion guidance alone [11]. The proposed system would provide real-time education for trainees during endoscopic stone surgery such as through head-mounted displays (i.e., the Microsoft Hololens 2). We have previously demonstrated eye gaze sharing in phantoms. By implementing this system in the operating room (OR), we would be able to instill durable skill acquisition in trainees.

2.0 Rationale and Specific Aims

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The aims of this study are to:

1. Evaluate skill level during endoscopic stone surgery using optical tracking.
2. Evaluate skill acquisition during endoscopic stone surgery using optical tracking.

3.0 Animal Studies and Previous Human Studies

We have previously demonstrated an eye tracking method during endoscopic kidney stone surgery using the Microsoft HoloLens 2 (Microsoft Corporation, Redmond, WA) [27]. Our method of eye tracking is independent of head motion or surgeon movement. We evaluated the method in a task-directed study in phantoms, comparing six trainees and four expert surgeons. Surgeons are categorized as expert (fellowship-trained endourologist, average case volume of > 100 ureteroscopy per year) or trainees (< 100 ureteroscopy per year). Specifically, we asked each participant to localize fiducial kidney stones in three phantoms. We evaluated and compared eye tracking metrics between experts and trainees. We found statistically significant differences in multiple parameters, including gaze path, fixation number and time, and gaze area. Specifically, expert surgeons completed the task in 52s compared to 318 s for trainees ($p < 0.01$), experts' gaze traveled 7.32 m during that time compared to 19.92 m for trainees ($p < 0.01$), and the total area covered by experts' gaze was 1045 cm2 compared to 1433 cm2 for trainees ($p < 0.01$). This suggests that experienced surgeons have more deliberate eye movements overall when exploring surgical anatomy, while trainees have to visually examine more of the displayed anatomy to complete a task (Fig. 1).

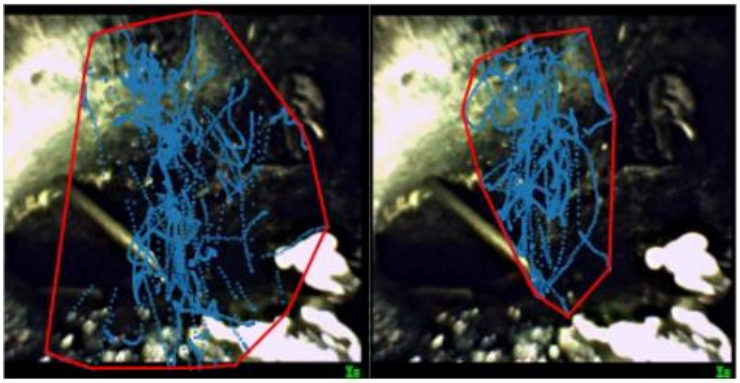

Fig 1: Trace of gaze over an entire stone identification trial for trainee and expert overlaid on a screenshot. Trainees' gaze explores a much larger area whereas experts' gaze is more focused.

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4.0 Inclusion/Exclusion Criteria

For expert surgeons

Exclusion Criteria

1. If the expert surgeon does not wish to participate.

Inclusion criteria

1. Any board-certified urologist who would like to participate

For residents

Exclusion Criteria

1. Medical students, fellows or other non-urologic residents
2. Urology residents who wish to not participate

Inclusion Criteria

1. Any urology resident

For Patients

Exclusion Criteria

1.Pediatric patients (<18 years old).

2. Anatomy or medical history that precludes ureteroscopy
3. Kidney stones >2cm in the longest diameter

Inclusion Criteria

1.Patients who are candidates for kidney stone surgery with ureteroscopy

5.0 Enrollment

We will identify all urology residents who are undergoing surgical training at VUMC. All residents will perform perioperative and operative duties as per standard of care and training at our facility as determined by the American College of Graduate Medical Education (ACGME). The identified resident information will be shared with investigators using standard secure file transfer according to protocol. Expert surgeons will be identified as any board certified urology faculty at VUMC. Identifying information (name, DOB, etc) will be saved in encrypted,

password protected files. We plan on enrolling 10 residents in this initial study for evaluation of the technology and workflow. Patients undergoing ureteroscopy will be informed of the study.

6.0 Study Procedures

We will recruit ten urology residents who will prospectively be randomized into the control and experimental groups and measure their performance intraoperatively during stone localization. Specifically, each trainee will be tasked with stone localization as is standard of care during ten endoscopic stone surgery under the guidance of an expert surgeon. Ten expert surgeons will also be recruited. All trainees and experts will wear HoloLens 2s to track their eye gaze. The trainees and experts in the control group's HoloLenses will not show any augmentation, but trainees in the control group will receive verbal feedback from an expert surgeon as is standard procedure. In the experimental group, the trainees' HoloLenses will project the experts eye gaze (in the form of a virtual pointer) in addition to verbal feedback from the expert surgeon. Each trainee will perform stone localization in six separate patients with either solely verbal (control group) or verbal and gaze guidance to test skill acquisition (expert group). Then, the trainees will perform stone identification in four additional patients without guidance. After localization, the remainder of the case will continue as is standard of care. After the first six patients, each trainee in both groups will perform the same visualization task on four new patients with only verbal guidance. Quantitative metrics: We will measure the total percentage eye gaze area seen during all ten surgeries to assess skill acquisition. Additionally, we will measure if there is a significant difference between the performance of each group in the last four surgeries. We will also evaluate differences in the NASA Task Load Index for the surgeons. Statistical Evaluation and Sample Size: A t-test will evaluate the hypothesis that surgeons eye gaze area decreases with exposure to the eye gaze sharing system. With an estimated average of 70% decrease, each surgeon must complete 10 cases to measure a 15% improvement in gaze area with a statistical significance of 0.05 and a power of 0.8.

7.0 Risks of Investigational Agents/Devices

As the surgery itself will proceed as standard of care, there is little risk residents. The greatest risk would be a privacy breach which will be mitigated by securely storing identifying information and promptly destroying it once it is no longer

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needed. There are no foreseen risks to patients as surgery is to proceed as is standard of care. No patient data will be recorded.

8.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

No adverse events are anticipated. However, unanticipated problems will be reported to the IRB by the PI within 5 business days of the discovery.

9.0 Study Withdrawal/Discontinuation

Subjects will be withdrawn from the study if access is unobtainable in a retrograde fashion. Subjects may withdraw from the study at any time.

10.0 Privacy/Confidentiality Issues

Data will be collected and stored within REDCap (Research Electronic Data Capture). Only key study personal listed as the principal investigator, study coordinator research- clinical roles and REDCap data manager will have access to the research information. The investigator and study coordinator at each site will have access to the medical record numbers and unique study identification numbers for each of their participants. Only the study coordinator and research-clinical roles will have access to the surgeon survey responses; the principal investigator and those listed as sub-investigators will not have access to this data prior to data analysis. Eye gaze data will be de- identified when stored in an encrypted drive and will be accessible only by key study personnel. Consent forms will be obtained per REB requirements and will be secured in a password protected-electronic study binder or paper study binder, stored in a locked office. Responses to surgeon questionnaires will be collected via REDCap. At the completion of the study, study data will be downloaded from REDCap to be stored on the study binder.

11.0 Follow-up and Record Retention

It is anticipated the data collection will take 12 months to complete, and another 12 months to analyze the data. All identifiers will be destroyed 4 years after the study initiation, or 2 years after data collection is complete, whichever is sooner.

12.0 Funding

National Institute of Health 1R211EB035783 (pending review): Development and Validation of Gaze-based Training for Endoscopic Kidney Stone Surgery

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