STUDY PROTOCOL

Study Title:
A Feasibility Trial of a Novel Robotic System for Retrograde Intrarenal Surgery
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Principal Investigator: Professor Chi Fai NG, Tzu Leung Ho Professor of Urology, Department of Surgery, The Chinese University of Hong Kong

Co-Investigators:
Dr Alex Liu, Assistant Professor, Department of Surgery, The Chinese University of Hong Kong
Dr Peter KF Chiu, Associate Professor, Department of Surgery, The Chinese University of Hong Kong
Dr Steffi Yuen, Associate Consultant, Department of Surgery, NTEC

Institute Affiliation:
SH Ho Urology Centre, Department of Surgery, Faculty of Medicine,
The Chinese University of Hong Kong, HKSAR

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Synopsis

Title	**A Feasibility Trial of a Novel Robotic System for Retrograde Intrarenal Surgery**
Protocol version & date of last version of protocol	Version: v1.1 Date: 2 Sep 2025
Objectives, and methodology	Study Objective To evaluate the feasibility and safety of a novel robotic system (TaloStone T1000) for retrograde intrarenal surgery (RIRS) Methodology A proof of concept, prospective, single centre study that follows stage 1 (Idea) guidelines of the IDEAL (Idea, Development, Exploration, Assessment, Long-term Study) framework. Subjects Ten patients with renal stone(s) suitable for RIRS who fulfil the inclusion and exclusion criteria will be recruited Intervention RIRS will be performed with the TaloStone T1000 system Study Outcome Measures Primary outcome: rate of successful RIRS using the system (feasibility) Secondary outcomes: stone clearance, intra-operative time, complication rate, feedback questionnaires
Country(-ies) of study	Hong Kong
Centres	Prince of Wales Hospital North District Hospital

I. Introduction

Retrograde intrarenal surgery (RIRS) has become a preferred method for the diagnosis and treatment of urological diseases, such as kidney stone removal [1]. However, the complex urinary and limited visibility of existing endoscope lead to inefficient manipulation of flexible ureteroscopes [2]. Besides, conventional flexible ureteroscopy requires repetitive manual manipulation, which often results in surgeon fatigue, mucosa injury from respiratory motion, and variable stone clearance rates, particularly in complex calyceal anatomies.

Our research topics focus on the development of an novel robotic system for RIRS, currently dubbed "TaloStone T1000". The robotic system platform consists of a surgeon control console, a multi-functional video cart, and patient-side robotic arm with fiber-optic-sensorized flexible ureteroscopy as shown in Fig. 1. The surgeon console with optimized design of ergonomics is equipped with haptic master devices for smooth and precise control of the robotic arm to manipulate the flexible ureteroscope as well as instruments, e.g., stone baskets and laser fibers [3]. The system also supports seamless integration of multiple modalities, including pre-operative CT scans, intra-operative endoscopic videos, and fiber-optic sensing [4]. Besides, our self-developed flexible ureteroscope is embedded with fiber optic sensors for real-time shape sensing, force estimation, and simultaneous intrarenal pressure control and temperature monitoring [5]. Shape sensing enables precise navigation of the ureteroscope within the renal collecting system, and force estimation provides accurate feedback of tip contact interaction to the master devices on the surgeon control [6].

Moreover, AI algorithms are incorporated to assist in diagnostics and higher level of supervised surgical autonomy, thereby improving safety and efficiency [7][8]. We developed AI-powered diagnostics for stone sensing, laser fiber recognition, depth awareness, and CT-to-endoscopy localization [9][10]. Based on the sensing results from AI-powered diagnostics, we proposed a supervised framework that can automate repetitive procedures throughout in-sheath and ureter navigation, laser approaching, and laser trajectory planning [11][12][13]. The entire operation is under supervision of the surgeon, who can use one trigger on the master device or footswitch to enable or disable the supervised autonmated features. The foot pedal of laser device remains to trigger laser emission by the surgeon for stone fragmentation, dusting, and pop-corning. The basic safety and essential performance of both hardware and software in the robotic system were developed under clinical standards and medical device regulations.

To date, a total of two cadaveric studies have been conducted using the robotic system. In August 2024, we performed the first cadaver study of the robotic system at Prince of Wales Hospital (PWH), where user study of ergonomic manners and tele-operation control of stone treatment was investigated. The second cadaver study, focusing on the AI-powered features of the robotic system, was completed at PWH in June 2025. Synthetic renal stones of around 3mm were retrogradely inserted to the renal collecting systems, with successful fragmentation via the robotic RIRS system using Holmium:YAG laser. Over 10 doctors from PWH and the Chinese University of Hong Kong, participated in the cadaver studies. The current system response, motion speed of the robotic system, and operations with ergonomic control console can satisfy

the requirements of the doctors. In addition to the cadaver studies, we have conducted a set of laboratory testing and experiments, validating its robustness and stability of the system.

Following our success in cadaveric trials, we planned to further validate of the feasibility of the use of the system in clinical cases. In this study, we aim to evaluate the robotic system's safety and feasibility in RIRS in a stage 1, proof of concept study that follows the concepts outlined in the IDEAL framework (Idea, Development, Exploration, Assessment, Long-term Study).

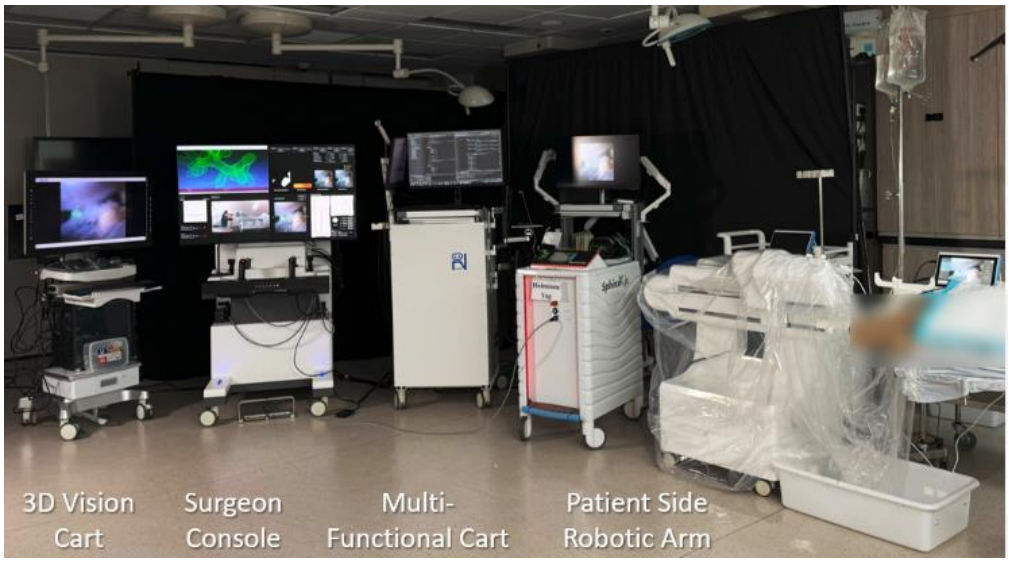

Fig. 1 TaloStone T1000 for RIRS.

II. Methods

Aim

The aim of this study is to evaluate the feasibility and safety of performing RIRS using the TaloStone T1000 system.

Study Design

This is a prospective, single-arm study that will be conducted by investigators from The Chinese University of Hong Kong/Prince of Wales Hospital in the period from November 2025 to June 2026. The investigators are experts in endo-urological surgery and robot-assisted surgery. The study design follows the guidelines for stage 1 of the IDEAL framework [14], [15]. The study will be carried out in accordance with the Declaration of Helsinki of the World Medical Association and the International Conference on Harmonization – Good Clinical Practice.
The study information will be provided to subjects during a preoperative consultation by the investigators and the research staff. Subjects will be provided with approved informed consent explaining the study procedure, risks, assessments, and required compliance; and will be given

ample time to make their decision regarding participation in the study.

Perioperative data and outcomes from all cases of those participating in the study will be reviewed by an independent Data and Safety Monitoring Committee (consisting two senior urologists not involved in this study) for safety and identification of serious perioperative complications (within 30 days after the surgery) as interim to safeguard study subjects. The Committee will make periodic recommendations to the study team on whether to continue, modify, or prematurely terminate the study. Any adverse events will also be immediately reported to the Clinical Research Ethics Committee of the hospital.

Reporting of this stage 1 study will follow the IDEAL Reporting Guidelines. [16].

Subjects

The details of the selection criteria are as follows:

Inclusion criteria
1) Adult patients >18 years old
2) Renal stone(s) less than 2cm in maximal length
3) Clinically indicated for RIRS
4) Willingness to participate as demonstrated by giving informed consent

Exclusion criteria
1) Patients with no preoperative CT imaging available
2) Patients who are not recommended to receive RIRS
3) Severe concomitant illness that drastically shortens life expectancy or increases risk of therapeutic intervention
4) Untreated active infection
5) Un-corrected coagulopathy
6) Presence of another malignancy or distant metastasis
7) Emergency surgery
8) Vulnerable population (e.g. mentally disabled, pregnant)

Preparation and Training:

1) Patients who satisfy all the inclusion and exclusion criteria, and agree and sign the consent form, will be recruited to participate in the study.
2) A user guide with detailed workflows will be provided to all the surgeons and clinical staff to familiarize them with the robotic procedure. The assistant surgeon should have a training on the use of and setting up the robot before surgery.

Pre-operative procedure:

1) The robot will be covered by a sterilized cover to avoid direct contact with the patient. The flexible ureteroscopes and instruments are sterilized and/or disposable.

2) Multiple ureteroscopes and sheaths will be prepared to accommodate variations in urinary tract size and length among patients.
3) The robotic system together with the monitoring devices will be taken into the operating room. The clinical staff and engineering staff will set up all devices for the RIRS in operating room.
4) The system cables among the surgeon control console, multi-functional video cart, and patient-side robotic arm will be connected.
5) Connect the VIDEO IN interfaces (HDMI, SDI) on the surgeon console and multi-functional video cart with cables from the video processor of flexible ureteroscope to project the video stream; if necessary, connect the VIDEO OUT interfaces to the default monitors and other devices in the operating room.
6) Emergency buttons will be provided on both surgeon console and patient-side robotic arm.
7) Set up cameras for data recording.

Intra-operation Procedure:

1) The patient will receive the operation under spinal or general anaesthesia
2) The patient will be positioned in the lithotomy position
3) The surgeon or the assistant surgeon will insert a cystoscope to cannulate the ureteric orifice and advance a 0.035" Terumo guidewire. Fluroscopy will be used to confirm guidewire position.
4) Ureteric access sheath will then be railroaded along the guidewire, under fluoroscopic guidance
5) At the same time, the patient-side robotic arm will be mobilized into the operating area, at the end of the operating bed. The surgeon control console and multi-functional video cart will be placed at appropriate places accordingly.
6) Press the "Power" buttons to power on the surgeon control console, multi-functional video cart, and patient-side robotic arm, respectively. Then they will light up and start the initialization procedures.
7) The surgeon can press the "Up" and/or "Down" buttons on the surgeon console to adjust its height and operating work space. Handedness of master devices and motion speed of each joint can be customized.
8) The assistant surgeon installs the single use flexible ureteroscope and instrument onto the patient-side robotic arm with quick-connect mechanism, where a control panel will be provided to indicate the operation procedures.
9) After the ureter inside the ureter/kidney, the system runs tele-operation control mode. The surgeon manipulates the master devices on the surgeon console to control the motion of ureteroscope as well as instrument during the surgery. The surgeon can trigger foot pedal of laser device for stone fragmentation, dusting, and pop-corning.
10) AI-powered in-sheath and ureter navigation, laser approaching, and laser trajectory planning can be activated by triggering the button on the master device or another footswitch.
11) During the surgery, the information of the robot status (e.g., control mode, torque, speed, position, etc.) can be displayed on the monitors of both surgeon console and patient-side robotic arm. The clinical staff can monitor the robot status through the monitor, and the engineering staff can monitor the whole system.

12) In case of an emergency, the engineering staff or the clinical staff will activate the emergency stop button to lock the robot to ensure safety.
13) Experimental data (such as surgery time, robot position, control commands) will be recorded simultaneously.
14) When the RIRS is completed, the flexible ureteroscope and sheath will be removed, and the robot will be pushed away from the working area.
15) A double-J stent will be inserted through the guidewire, with position confirmed by fluoroscopy and cystoscopy. The guidewire and cystoscopy will then be removed.
16) 2-way Foley catheter will be inserted with the operation finished.

Post-operation Procedures:

1) Routine clinical care will be offered to the patient, with admission to the urology wards after recovery.
2) The surgeon and clinical staff will be interviewed after the surgery is completed.

III. Plan of investigation and analysis

Study Outcome Measures

Primary Outcome Measures

Successful RIRS by the robotic system, i.e. without conversion to conventional manual RIRS

Secondary Outcome Measures

1) Stone free rate
   - by non contrast computer tomography (NCCT) performed within 1 month of surgery
   - without residual stone fragments, or residual stone fragments <2mm)
2) Operative time
   - total operative time (time from start of operation to the end of operation)
   - console time (from start of control of robotic system to end of control of robotic system)
   - robotic control time (defined as time spent manipulating the control for navigation)
   - robotic set-up time (from the moment the robot is pushed into the operating room to the moment the flexible ureteroscope is attached to the robot)
   - procedure time (total operative time - The robot set-up time)
   - lasing time
3) Total laser energy used
4) Total radiation dose during operation
5) Surgeon radiation exposure
   - by radiation dosimeter
6) Length of hospital stay
7) Post-operative pain
   - by visual analogue scale, from 0-10 with 10 being the most pain
8) Post-operative complications during 30 days after discharge
9) Surgeon questionnaires
   - Subject-administered questionnaire incorporating Subjective Mental Effort Questionnaire (SMEQ). Please refer to Appendix 1.

- System Usability Scale (SUS), which studies the usability [18]. Please refer to Appendix 2.
- NASA Task Load Index (NASA-TLX). Please refer to Appendix 3.
- Stimulator Sickness Questionnaire (SSQ). Please refer to Appendix 4.
- Likert scale for ergonomic and comfort outcomes. Please refer to Appendix 5.

Data Collection and Follow-up

Enrolled subjects will be assessed at baseline, during hospitalization, and follow-up clinic visits. The postoperative follow-up will be in the week 30 days (+ 7 days) after surgery, and then subsequent follow-up will depend on the surgeons usual standard protocol. Demographic and baseline characteristics of the subjects, as well as data about the primary and secondary endpoints, will be recorded by an independent research assistant.

Statistical Analysis

The chi-squared test (or Fisher's exact test when appropriate), Student's t-test, and Mann-Whitney U test will be used to compare categorical, parametric, and non-parametric data, respectively. Longitudinal changes in mean quality of life or incontinence scores over time will be analyzed by the repeated measures analysis of variance test with post hoc pairwise comparisons using Bonferroni correction. A 2-sided P value <0.05 is considered to be statistically significant.

Sample Size Estimation

As there is very limited clinical research and published data on the feasibility and safety of the TaloStone T1000, it is not possible to calculate an accurate sample size. We plan to recruit at least 15 subjects to determine initial descriptive data for the primary endpoint, in order to perform a sample size calculation for a larger trial.

Clinical Implications

The prospective study will provide important information on the feasibility, safety, and effectiveness of the TaloStone T1000 system in performing RIRS. A positive study showing at least similar safety and outcomes compared with historic conventional RIRS will provide supporting evidence for continuing development of this new technology.

IV. Safety Measures

The known risks of this study are due to RIRS related risks, and potential injury due to improper operation of the robotic system. To ensure safety and minimize these risks, several approaches will be applied. Firstly, experienced surgeons and theatre staff with years of experience in conventional RIRS will be involved in this study. The surgeons and theatre staff will be all trained and familiar with the manipulation of the robot. Secondly, the researchers will monitor the whole surgery. Thirdly, the robot is equipped with safety mechanisms. Given there were no inadvertent injuries in the pre-clinical studies, the risk of injury related to the robot is minimal.

Additionally, we have further enhanced safety in the following ways:

(1) Patient-Side Robot:
The patient-side robot is outside the patient with only a flexible ureteroscope inside the body, which is soft with compliance to the tissue, reducing damage to the ureter and kidney.

(2) Safety standards:
The robot complies with the electrical safety standards specified in IEC 60601-1, i.e., Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance.

(3) Device check:
Prior to surgery, the assistant surgeon will confirm the status of the robot, including mechanics, range of motion, and other parameters.

(4) Force limitations:
All robot joints are limited in output force by limiting the current of the motors. The values of the limiting currents for each joint were collected by laboratory experiments. Thus, when subjected to a load much greater than expected (e.g., when the robot collides with the patient), the robot will stop working, reducing the damage to the patient.

(5) Motion range limitations:
The robot has two levels of motion range limit. First, we set the robot's motion boundary in the software, so that when the robot approaches the motion boundary, it slows down and stops. Second, each joint of the robot is equipped with mechanical limits to ensure that the robot does not exceed the given motion range even under extreme conditions.

(6) Emergency protection:
In an emergency, the surgeon or assistant surgeon can press the emergency stop switch, and the robot will stop working, after which the flexible ureteroscope can be manually removed from the robot with no damage to the patient.

Engineers will be on standby to evacuate the robot, allowing the assistant surgeon to perform manual flexible ureteroscopy

(7) Contamination prevention:
The flexible ureteroscope manipulated inside the patient is sterile, single-use, and disposable. The robot will be covered by a sterilized cover to avoid direct contact with the patient.

V. Quality Control and Assurance

All the staff involved in the study will have completed their required Collaborative IRB Training Initiative (CITI) in the protection of human research subjects and Good Clinical Practice training.

The medical staff to be involved in the study will be trained to access the full functionality of the robotic system that follow the prescribed protocol procedures individually or a group consisting of engineering staff for guidance. The trained medical staff are able to independently function the

robot (excluding unforeseeable malfunctioning situations) for surgery operations without the help of the engineering staff.

The engineering staff to participate in the study will be trained to be familiar with the set-up in operating theater and conduct briefing of the procedures with the medical staff in a group format. The trained engineering staff are able to support the medical staff to follow the surgical workflow during surgery and take assistive actions for safety guarantee under any malfunctioning situations of the system.

VI. Ethical Considerations and Adverse Events Reporting

This study will be conducted in compliance with the protocol approved by the Institutional Review Board, the relevant federal regulations, and IRB policies and procedures. The study will be carried out in accordance with the Declaration of Helsinki of the World Medical Association and the International Conference on Harmonization – Good Clinical Practice. No deviation from the protocol will be implemented without the prior review and approval of the IRB, except where it may be necessary to eliminate an immediate hazard to a research subject. In such a case, the deviation will be reported to the IRB according to its policies and procedures.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of all subjects will be sought using the IRB-approved consent form. Before a subject undergoes any study procedure, an informed consent discussion will be conducted and written informed consent obtained with a consent form signed by the subject or legally acceptable surrogate if applicable. An investigator-designated research professional will obtain written informed consent from subjects.

The project staff will ensure that the participants' anonymity is maintained. In electronic databases, participants will be de-identified with pseudo-patient numbers. All documents will be stored securely and only accessible by project staff and authorized personnel. The study will comply with the Data Protection Act, which requires that data be anonymized as promptly as possible.

Personal data will be retained for 5 years after the conclusion of the study. At the end of this storage period, all data will be destroyed, ensuring no identifiable personal information remains.

VII. Data Management

Source data are all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from robotic system, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, CT-scans, x-rays, subject files, and

records kept at the pharmacy, at the laboratories, and at medical-technical departments involved in the clinical trial.

Several digital video cameras will be used to record videos of the overall surgery procedure. The participating surgeons and assistant surgeons will be asked to complete the feedback questionnaire form at the end of the surgery. These files will be saved to encrypted hard disk for further analysis.

VIII. Financing and Insurance

Clinical trial insurance will be arranged from CUHK Clinical Research Management Office (CRMO). The anticipated risks of this intervention are not expected to exceed those associated with the standard of care. The participants will be continually monitored if they suffer from any adverse event, till resolution of the event. All patients who experience an adverse event (AE) will be evaluated at appropriate time intervals until the event resolves or stabilizes. At the conclusion of the study, the investigator will assess unresolved AE and determine if additional follow-up is warranted based on clinical assessment. The information supplied by the participants is not anticipated to impact the clinical management of their conditions. The subjects will not receive any financial compensation for their involvement in the study.

IX. Publication Policy

The investigators intend to disseminate the study's outcomes to regional, national, and international scientific peer groups. This includes publication in professional journals, as well as presentation at regional, national, and international meetings. Authorship, accountability, and acknowledgment will follow the guidelines outlined by the International Committee of Medical Editors. Additional authors may include other investigators, usually members of departmental research staff or inter-departmental collaborators and/or site investigators. The principal investigator or other protocol team members may present data at scientific meetings.

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Appendix 1: Subject-administered questionnaire incorporating SMEQ

1. Overall, this RIRS surgery was

Very Easy	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	Very Difficult

2. I was satisfied with the ease of completing this surgery with the robotic system.

Strongly Disagree	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	Strongly Agree

3. How successful were you in controlling the flexible ureteroscope motion through surgeon console?

Very Low	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	Very High

4. I agree that the robotic system has improved the efficiency of the surgery.

Strongly Disagree	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	Strongly Agree

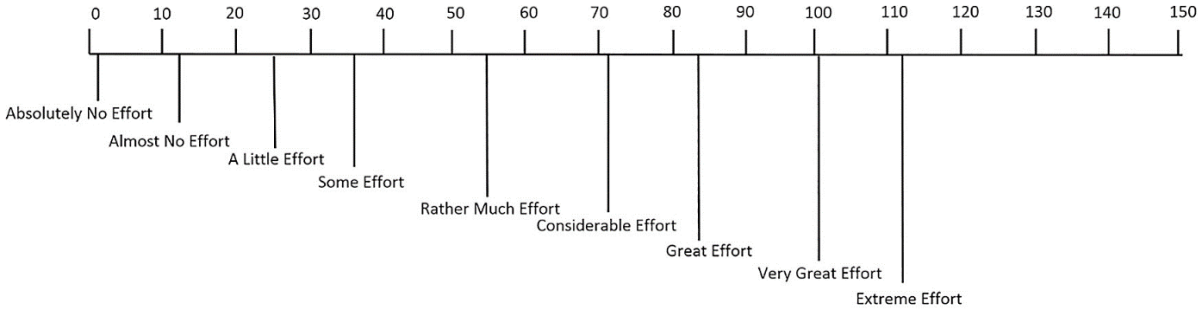
5. How interested are you in using this system to help you perform a RIRS?

Very Low	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	Very High

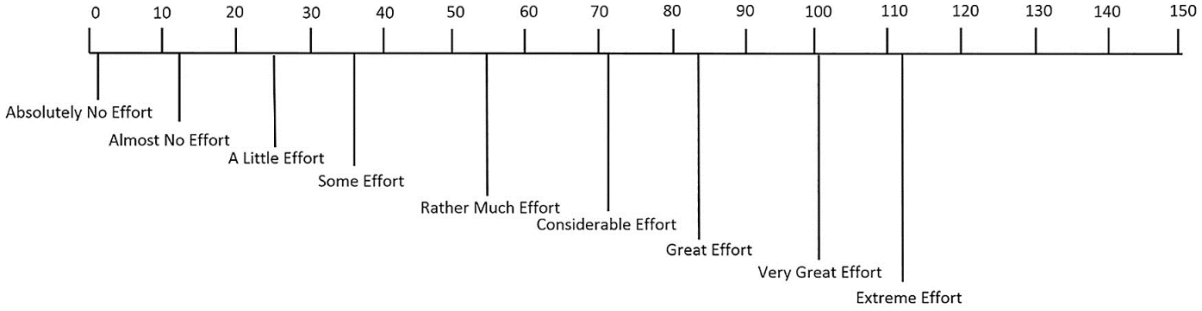
6. I agree that the AI and robotics technologies can be transferred to other surgeries and improve efficiency as well.

Strongly Disagree	○ 0	○ 1	○ 2	○ 3	○ 4	○ 5	Strongly Agree

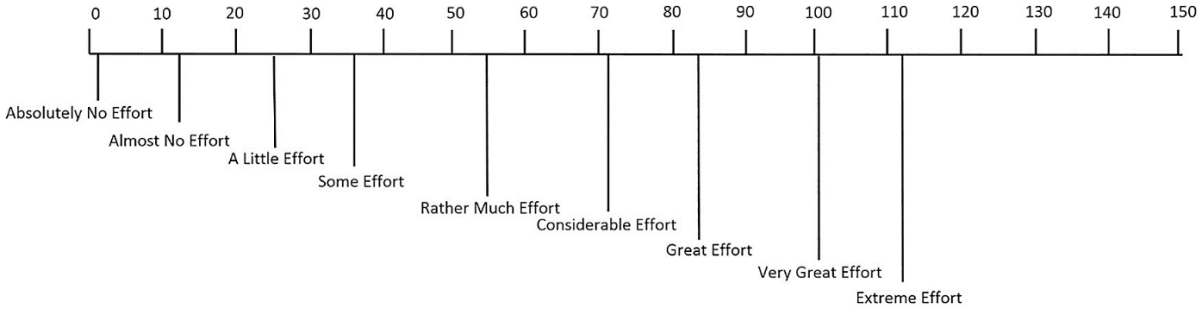
7. How much effort do you spend to manually control the flexible ureteroscope?



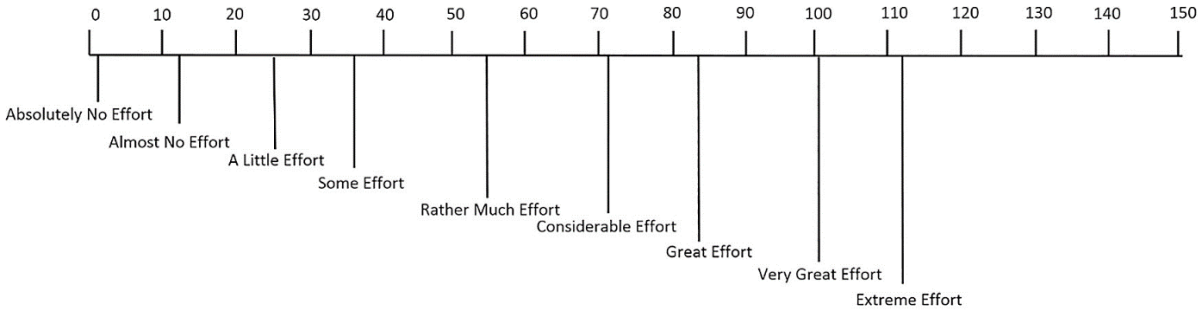
8. How much effort do you spend to control the flexible ureteroscope through the surgeon console?



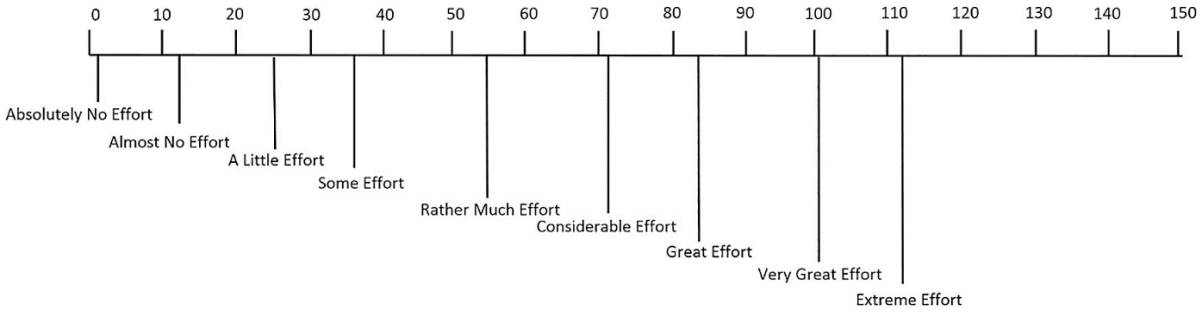
9. How much effort do you spend to control the flexible ureteroscope through the supervised autonomy?



10. How much effort do you think it takes to learn how to use surgeon console and supervised autonomy to control the flexible ureteroscope?



11. How much effort do you spend to control the flexible ureteroscope into extreme position with the robotic system?



12. What are the major limitations of our robotic system?

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13. Do you have any other feedback about the experiments (preference, suggestions etc.)?

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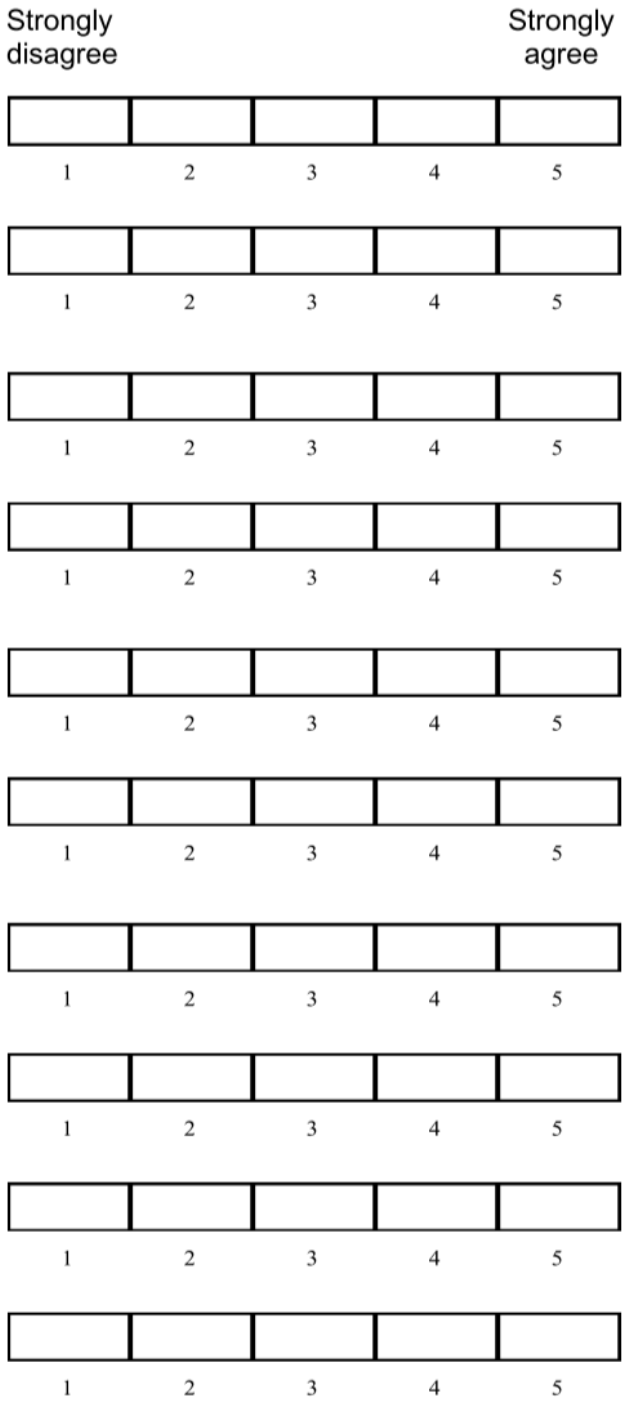
Appendix 2: System Usability Scale



Appendix 3. NASA Task Load Index (NASA-TLX)

1. Mental Demand: How mentally demanding was the task? (Rate 1 = Very Low, 10 = Very High)

2. Physical Demand: How physically demanding was the task? (Rate 1 = Very Low, 10 = Very High)

3. Temporal Demand: How hurried or rushed was the task? (Rate 1 = Very Low, 10 = Very High)

4. Performance: How successful were you in accomplishing what you were asked to do? (Rate 1 = Very Low, 10 = Very High)

5. Effort: How hard did you have to work to accomplish your level of performance? (Rate 1 = Very Low, 10 = Very High)

6. Frustration: How insecure, discouraged, irritated, stressed, and annoyed were you? (Rate 1 = Very Low, 10 = Very High)

Appendix 4. Simulator Sickness Questionnaire (SSQ)

Please indicate the severity of each symptom experienced during or after the procedure using the following scale:
0 = None | 1 = Slight | 2 = Moderate | 3 = Severe

1. General discomfort
2. Fatigue
3. Headache
4. Eye strain
5. Difficulty focusing
6. Increased salivation
7. Sweating
8. Nausea
9. Difficulty concentrating
10. Fullness of head
11. Blurred vision
12. Dizziness with eyes open
13. Dizziness with eyes closed
14. Vertigo (feeling of spinning)
15. Stomach awareness
16. Burping

Appendix 5. Likert Scales on Ergonomics and Comfort

1. I experienced minimal discomfort or fatigue during the procedure. (1 = Strongly Disagree, 5 = Strongly Agree)

2. The system interface allowed for natural and intuitive movement. (1 = Strongly Disagree, 5 = Strongly Agree)

3. I did not experience eye strain or visual fatigue. (1 = Strongly Disagree, 5 = Strongly Agree)

4. My posture and positioning were comfortable throughout the procedure. (1 = Strongly Disagree, 5 = Strongly Agree)