Aim 5: Training and Test Scenarios

Jun 23rd, 2018

1 Scenario for Training and Testing

The surgical sub-step of cutting the urethra during Robot-Assisted Radical Prostatectomy (RARP) procecdure was selected for generation of simulation scenario. The required surgical-steps during RARP procedure includes: (i) Dropping the bladder, (ii) Dividing the neck of the bladder, (iii) Exposing the posterior lateral, (iv) Cutting the urethra, and (v) Anastomosis. Although the approach in performing the surgery might vary between surgeons, e.g. whether they perform a transperitonial or an extraperitonial approach, in this project, we simulate only cutting the urethra, which is constant across different variations in terms of requirements, tools and approach.

Urethra dissection is performed by cutting the urethra close to the apex of the prostate, typically with cold scissors to avoid damaging the nearby nerves and structures. Before urethra cutting, cold cutting scissors are used to dissect around it. Occasionally, the puboprostatic ligament (PPL) is cauterized to block bleeding at the side. Otherwise, cautery is minimized as much as possible in this process as the monopolar current can spread to almost 5-7 mm, which might damage the nearby nerve bundles. The challenge in arriving at the site of the urethra cutting is in carefully dissecting around it. Around the urethra, there is a large vascular complex (called the Dorsal Venous Complex or Santorini's Plexus) and the PPL, which the surgeon carefully approaches. As the surgeon dissects through this area, he will be able to recognize the different tissue qualities (muscles, ligaments, veins) until he reaches the urethra and identify the best approach to tackle the dissection.

In preparation before cutting the urethra, it has to be first isolated from the surrounding tissue. The first rule of isolating the urethra is to not skeletonize it: trying to create a perfectly round tube, which will de-vascularize it and remove all the supporting tissue and will potentially cause tearing during the anastomosis process. A surgeon also has to minimize cautery around the urethra as much as possible, to not damage the surrounding tissues and nerves.

Cutting the urethra is an iterative process of cutting, assessing tissue behaviour, and cutting again. The following are the detailed steps observed from prostatectomy videos and described by interviewed surgeons:

1. Create the initial cut

2. Move the tools away
3. Assess the cut and the tissue behaviour
4. Mentally plan the next cut
5. Continue cutting
6. Repeat steps 2 - 5, until Foley's catheter is visible
7. Retract Foley's catheter
8. Circumferentially repeat steps 2 - 5, until done

Observing tissue behaviour: in this step, the surgeon is assessing how the tissue behaves as he proceeds with the cutting. This is due to the different types of layers the urethra is made of. For instance, the muscle layer retracts differently from the mucosa layer.

Through our interviews with surgeons, we also identified a list of risky approaches that some surgeons follow but are not recommended for training surgeons. Ideally, the following scenarios should not be allowed in simulations:

- Cauterizing the urethra: the only cautery that should happen around that area is at the puboprostatic ligament, which has vessels that could bleed otherwise with cold cutting.
- Large cuts: taking a large step can be risky as a large cut can reach to the rectum and puncture it.
- Not using a catheter at the site: having a catheter provides the surgeon with a visual cue of where he reaches around the urethra. Not having a catheter might not be ideal for a novice surgeon.
- Stretching the urethra before cutting: this will provide a good length for the surgeon but will risk skeletonizing and traumatizing the tissues around the urethra.
- Placing the scissors behind the urethra for a better orientation: also, could run at a risk of reaching the rectum behind the urethra.

2 Metrics for Performance Evaluation

There are two major metrics to evaluate a proper cut of the urethra during prostatectomy: the location of the cut and the shape of the cut. In this iteration, we provide the user with an indication of the ideal cutting location, as shown in the sketch in Figure 1, and focus on evaluating only the shape of the cut.

2.1 Location of the Cut

Once the surgeon has reached to the urethra (after going through the different structures towards it), he will see on the pelvic wall the dorsal vein complex, the pubo-prostatic ligaments on each side, and then he will see a tubular structure and the prostate that has been disconnected from the pelvic wall to a certain degree. The surgeon needs to consider a number of factors when determining the location of the cut, including positive tissue margins, staying clear on the sphincters to maintain continence, and the appropriate length of urethra stump to ensure optimum anastomosis with least tissue tension. Other factors depend on the status, location, and aggressiveness of the cancer: the further away from the apex and the less aggressive the cancer is, the closer to the prostate the cut should be located. The staging of the cancer can be defined based on the biopsies taken before the surgery. In general, the location also depends on a surgeon's own judgment from pre-op biopsy and associated Gleason score and cannot be accurately measured or quantified in centimeters as a general rule.

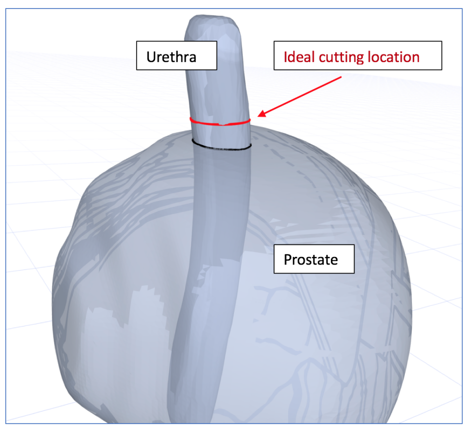


Figure 1: A sketch of the interface showing the user the intended location of cutting

2.2 Shape of the Cut

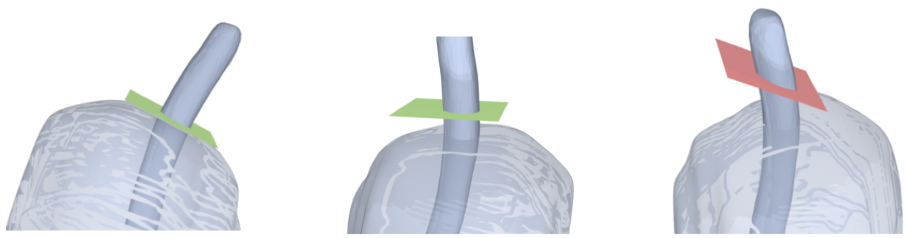
An ideal shape of the cut is evaluated by three metrics as descibed in following sub-sections

2.2.1 Cutting in One Plane

This means that the cut should be symmetrical. I.e. it is only performed in one plane. The plane should be parallel to the plane of the prostate surface. The simulation software should be able to calculate the cutting plane the surgeon is performing and approximate it to one flat plane parallel to the surface of the prostate for a cut to be correctly performed.

Figure 2a shows the plane of the surface of the prostate. An ideal cut should be performed in a plane parallel to this plane, as shown in Figure 2b. Since the training simulation will display the location of the ideal cut, as shown in Figure 1, a surgeon using this simulation will have a visual cue of the angle of the plane. Figure 2 shows the ideal cutting plane location and orientation with respect to the plane of the prostate surface.

Figure 3 show a visual representation of performing a non-uniform asymmetrical cut and how it maps to multiple planes.



(a) The prostate's surface plane

(b) The cutting location should be above the apex of the prostate and in one plane parallel to the prostate's surface plane

(c) Cutting the urethra should not be performed in a plane not in parallel to the prostate

Figure 2: The ideal location and orientation of the cutting plane

(a) An example of a non-uniform cut performed in multiple planes

(b) Cutting the urethra should not be performed in multiple planes

Figure 3: Cutting in multiple planes

2.2.2 One Initial Opening

As a good practice for a clean cut, the surgeon should should perform the task starting from only one initial cut in the urethra and should not create multiple initial cuts.

2.2.3 Cut in Small Steps

Another good practice for a clean cut is cutting only a few millimeters at a time. The minimum and maximum size of a single cutting step is to be defined empirically through test runs and evaluations with surgeons during the formative validity tests.

3 Graphical User Interface

A graphical user interface is needed to communicate the score of the surgeon based on his or her performance in completing the cutting task and to inform the surgeon of ways to improve the performance. In this section, we present the three main screens of this simulator:

1. Pre-simulation: to inform the surgeon of the scoring mechanism
2. Simulation: to display feedback on the surgeon's performance in real-time
3. Post-simulation: to provide an overview of the surgeon's performance and the total score

The simulation starts with a total score of 100. The score decreases as the surgeon performs any of the following errors:

1. (-10) The surgeon cuts outside the target line and ends up with an asymmetrical cut
2. (-10 per initial cut) The surgeon creates more than one initial cut
3. (-5 per large cut) The surgeon cuts larger than the accepted threshold per cut
4. (-1 per collision) The surgeon unnecessarily collides the tool with the tissue
5. (-2 each time) The surgeon's tool leaves the surgical scene

3.1 Graphical User Interface: Pre-Simulation

This graphical user interface, presented as a mockup in Figure 4, visually presents to the surgeon instructions to correctly perform the cutting task. The first instruction (starting from the top left) is to follow the line displayed over the urethra for the ideal cutting location. The second is related to the metric presented in section 2.2.1. The third is related to the metric presented in section 2.2.2. The fourth is related to the metric presented in section 2.2.3. The fifth and sixth are recommended practices in surgery to avoid collisions with tissues and to keep the tool within the field of view.

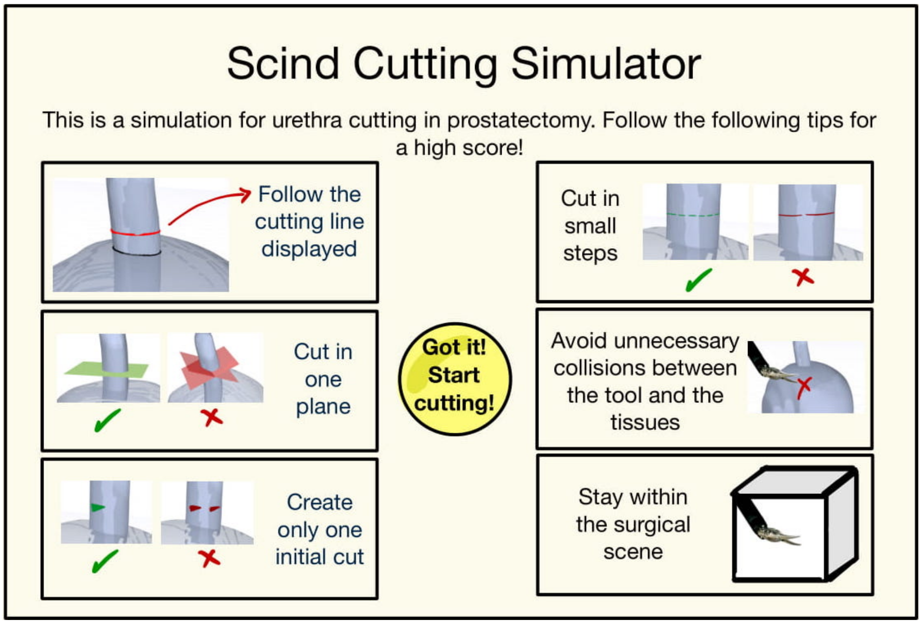


Figure 4: A mockup of the pre-training screen

3.2 Graphical User Interface: During Simulation

This graphical user interface, presented in all its possible scenarios as multiple mockups in Figure 5, shows the graphical representations of communicating an error to the surgeon. In the default case, the surgeon's simulator screen has little to no information displayed other than the surgical scene and the time elapsed since the start of the cutting task. In case of creating an asymmetrical cut (related to section 2.2.1), the deviation is highlighted in red for the surgeon to visualize the cutting error and deviate back to the correct track. In case of creating multiple initial cuts (related to section 2.2.2), the location of any other cut made other than the first one is highlighted in red. In all other error cases, a message will be displayed to the surgeon.

Note that all error visualizations and messages disappear within a few seconds to minimize distractions from the main task and to optimize the focus of the surgeon on cutting.

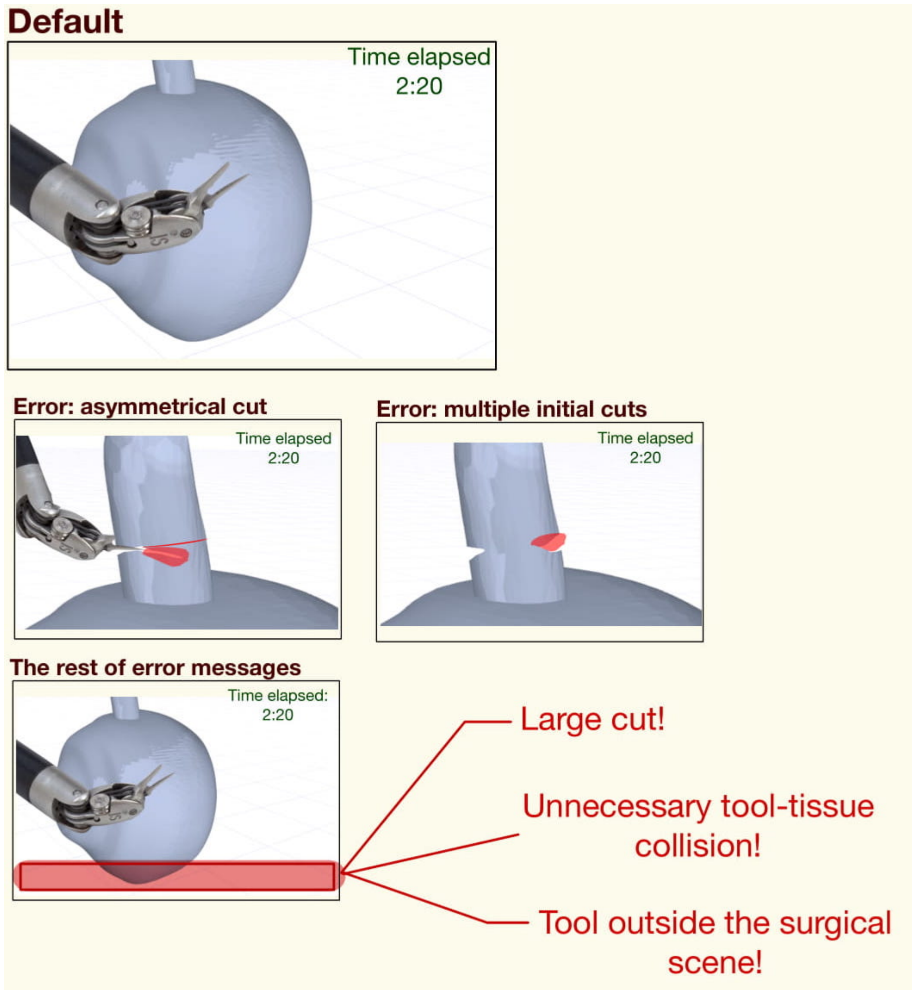


Figure 5: A mockup of the training screen and the different possible scenarios

3.3 Graphical User Interface: Post-Simulation

This graphical user interface, displayed upon the completion of the cutting task, displays to the surgeon the total score as well as a breakdown of the errors performed during the task. An example is presented in the mockup in Figure 6. In this example, the surgeon has scored a total of 76%, with an asymmetrical cut, two instances of large cuts, and four unnecessary collisions between the tool and the tissue. The interface also displays to the user options to repeat the task or exit the simulation.

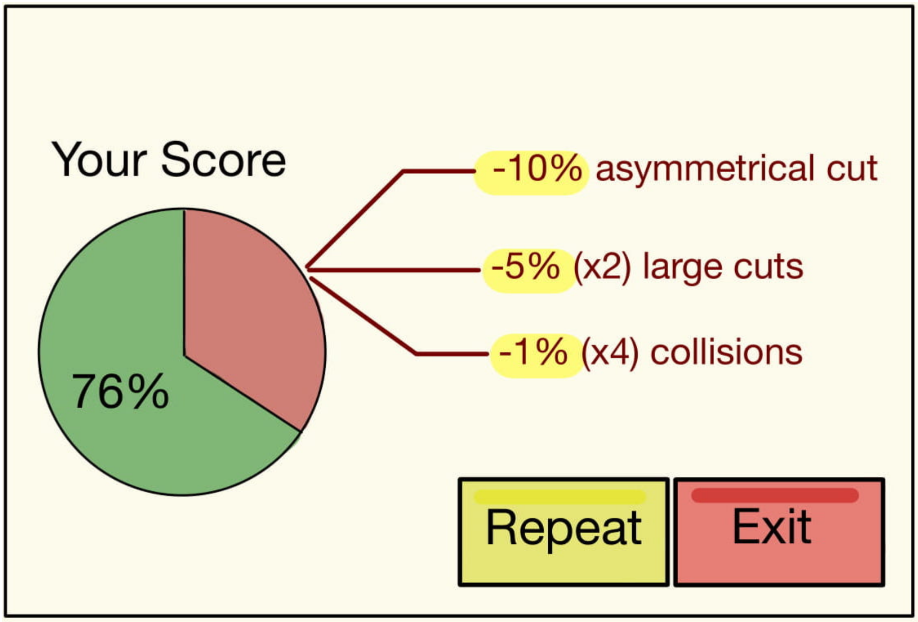


Figure 6: A mockup of an example of results screen

4 Evaluation Protocol

The validity tests we are performing at this stage of research are carried in a form of a formative usability study. A formative usability study is an iterative process of multiple usability testing approaches to evaluate the system being developed and assess the integration of features to ensure detecting and eliminating usability issues early before the final design is produced.

Formative evaluation focuses on qualitative results collected from a variety of evaluators, including the design and development team, experts in the field, and target users. In the case of our simulation interface, participants in formative evaluations include the research team, expert surgeons, surgery training professionals, medical doctors with a background in prostatectomy, and surgeons-in-training. These methods are tailored to focus on the face, content and construct parameters of the simulator.

The data collected from the described formative usability testing methods is primarily qualitative. This data can be later categorized into areas of improvement and used to enhance the simulator for running the next iterations of formative evaluation tests. This qualitative data describes the state of each of the heuristics for face, content and construct validity and list usability issues to be resolved and areas of improvement.

We are conducting two formative evaluation tests: heuristics evaluation and think-aloud evaluation, as described in following sub-sections.

4.1 Heuristics Evaluation

Heuristics evaluation is a formative evaluation method for finding the highest number of usability issues before the final design is produced. A list of heuristics is generated and tested through using the system of interest by a group of evaluators.

4.1.1 Study participants (evaluators)

The participants (or evaluators) in this method are not the target users, but usability experts and domain experts. A diverse group of evaluators ensures finding different types of and more usability issues. In the case of this project, this includes expert surgeons (whom this project is not targeted for, but can provide insights on the usability of the interface), the research team, and medical doctors with a background in prostatectomy.

4.1.2 Study Structure

In heuristics evaluation, evaluators participate in two sessions: individual and group. In the individual session, the evaluator performs the cutting task and discusses a number of heuristics with the test moderator or the main usability researcher. In the group session, evaluators discuss their individual findings and propose solutions to these problems. The following is the detailed structure of each session.

Individual Evaluation Session A session for where the evaluator individually completes and discusses the cutting task with the test moderator.

1. Introduction (standardized with all evaluators)
   - (a) Provide an overview of the project and the heuristics evaluation method
   - (b) Describe the current state and capabilities of the system
   - (c) Describe (and demo, if necessary) the cutting task
2. Allow the evaluator to freely use and explore the interface
3. Guide the evaluator through the task, while discussing the heuristics
4. Record the usability problems encountered or reported by the evaluator

Group Debriefing Session After individually testing with all the evaluators, organize a group meeting, list all the problems encountered with all evaluators, and discuss possible solutions.

4.1.3 Cutting Task Heuristics

1. Face Validity:
   (a) The cutting mechanism represents a real world cutting task in a prostatectomy surgery
   (b) The device is a sufficiently accurate representation of a real robotic system
   (c) The hand controllers are effective for working in the simulated environment
   (d) The user interface is efficient and minimalistic
2. Content Validity:
   (a) The cutting task is effective for teaching the cutting skill for our target users
   (b) The scoring system effectively communicates the user's performance on the cutting exercise
   (c) The scoring system effectively guides the user to improve the performance on the simulator
   (d) The scoring system is effectively communicated to the user and messages are presented in plain language
   (e) Learning the system is feasible by first-time users with minimal supervision/training
3. Construct Validity:
   (a) The system is able to distinguish between an experienced and a novice user based on errors
      i. Number of times the cutting tool damages the tissue with unnecessary touches/cuts
      ii. Number of times the cutting tool goes outside the defined boundary
   (b) The system is able to distinguish between an experienced and a novice user based on shape of cut
      i. An interpolated plane of the overall cut (with a threshold for error tolerance)
      ii. The number of centimeters per small cut
      iii. The number of initial cuts
   (c) The system is able to distinguish between an experienced and a novice user based on general statistics
      i. Time taken to complete the test

4.2 Think-aloud Evaluation

Contrary to heuristics, the think-aloud method is performed with target users. In this method, the only data collected from the user is their thinking process throughout using the simulation and while completing the cutting task. Also, contrary to heuristics, the test moderator does not interfere or discuss the interface with the participant. Similar to heuristics, task completion is performed individually. This method is performed in three simple steps:

1. Recruit representative participants (target users)
2. Ask the participants to complete the cutting task and describe their mental process as they complete the task
3. Meanwhile, the test moderator records the session and takes note of the interaction

We are recruiting roughly 5 participants (target users of the simulator: surgeons and medical students) to participate in the think-aloud evaluation technique. Following the session, the participant will fill a qualitative evaluation form including Likert-scale questions relating to face and content validity and discuss the interface informally with the researchers.