Mechanical Characteristics of Male Urethral Catheterization: Simulator and Cadaveric Donor Study

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Dedication

This work is dedicated to my family and friends.
Abstract

Catheter-associated urinary tract infections (CAUTI) is among the most common hospital acquired infection [1], while medical students placing catheters could increase CAUTI risk four times [2]. Therefore, a better understanding of the catheter insertion mechanical characteristics is needed to develop more realistic simulators for accurate clinical training. A custom-made Catheter Insertion Force Assessment Tool (+/- 0.25N absolute accuracy) and Position Acquisition System were used in male urethral catheterization studies on benchtop simulators (n=4) and cadaveric donors (n=5) to quantitatively examine the insertion force and 3D motion. Displacement-dependent effects resembling tissue stiffness appeared to dominate the force profile over rate-dependent effects such as viscous friction. In cadaveric studies, the average prostate region force was found to be higher than non-prostate region force. Average catheterization forces in simulators (8.1N) were roughly 45 percent higher than in donors (5.6N) when considering all data per insertion segment falling within 98 percentiles to diminish outlier effects.
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Chapter 1

Introduction

1.1 Motivation

Urethral catheterization is a routine medical procedure that facilitates direct drainage of the urinary bladder [4]. It is one of the most common procedures performed in healthcare settings. Between 15 to 25 percent of hospitalized patients receive urinary catheters during their hospital stay [5].

Catheter-associated urinary tract infections (CAUTI) is the most commonly reported hospital acquired infection [1]. More than 30 percent of the acute care hospital infections are CAUTI and around 450,000 cases of CAUTI happens in the U.S. per year, of which results in around 13,000 deaths [6]. It also costs increased healthcare burden. Hospitals spend around 760 USD per CAUTI and more than 340 million dollars are attributable to CAUTI in the U.S. each year [6].

In addition, urinary catheter-associated trauma is also common, as it occurs in 3.2 per 1000 male catheterizations [7]. It could cause further complications such as continuous pain, urethral stricture and gross hematuria, and 25 percent of these patients might require surgical intervention [8].

Noticeably, inexperienced healthcare provider placing urinary catheters could cause a 4-fold increased risk of CAUTI [2]. Therefore, proper instruction and accurate simulation during early clinical training is needed to reduce CAUTI rates. In order to develop more realistic simulators, a better understanding of the mechanical characteristics of the insertion procedure is required.
1.2 State of the Art and Prior Work

Patient and environmental factors have been well studied in terms of contributing to an increased CAUTI risk. However, only one study assessed healthcare providers from a force perspective.

A recent study [9] has found health providers with greater than 25 years’ experience exerted distinctly lower insertion force than less experienced health providers. However, the results were subjectively self-reported rather than quantitatively measured.

To our knowledge, there is no research that has directly investigated the mechanical characteristics of urinary catheter insertion objectively; as there are no available devices to measure required forces and motions.

1.3 Objectives and Scope

The objectives of this work are to:

- Design tooling to quantitatively measure insertion force and motion.
- Demonstrate feasibility of clinically meaningful data acquisition on bench-top simulators and cadaveric donors.
- Better understand the mechanical characteristics of catheter insertion.
  - Aim 1: Investigate whether insertion force is dominated by friction force (positive force - speed relationship) or tissue ‘spring’ force (positive force – trajectory length per push relationship).
  - Aim 2: Compare prostate region and non-prostate region force profiles for cadaveric donors.
  - Aim 3: Compare insertion characteristics between simulators and donors in terms of insertion force, procedure time, speed, trajectory length per push.

The scope of this research project is only limited to male urethral catheterization in benchtop simulators and post mortem human cadaveric specimens.
1.4 Organization

• Chapter 1: Introduction: background and objectives.

• Chapter 2: Hardware and software development: tools used in the experiment.

• Chapter 3: Experiment: protocol used for the simulator study and cadaveric donor study.

• Chapter 4: Analysis and results.

• Chapter 5: Discussion and conclusion.
Chapter 2

Hardware and Software Development

2.1 Force Assessment Tool

The design and use of a custom-made Catheter Insertion Force Assessment Tool (referred to as Force Assessment Tool throughout this thesis) was described in prior work [10]. This section includes the design requirements, hardware development, software development, design iterations, and system calibration of this tool in further detail.

2.1.1 Design Requirements

The design requirements of the Force Assessment Tool are shown in Table 2.1.

Table 2.1: Design Requirements for the Force Assessment Tool.

<table>
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<td>Quantitatively measure force during insertion</td>
</tr>
<tr>
<td>Easy to use, does not greatly impede typical insertion motion</td>
</tr>
<tr>
<td>Wireless data transmission</td>
</tr>
<tr>
<td>External power</td>
</tr>
<tr>
<td>Compatible with sterile drape cover</td>
</tr>
</tbody>
</table>
2.1.2 Hardware Development

The one degree-of-freedom (DOF) Force Assessment Tool consisted of two 780g load cells (Phidgets Inc., Calgary AB, Canada) to capture the insertion force selectively, as shown in Figure 2.1. A spring-assisted clip was designed to provide force for the jaws to stay open, as shown in Figure 2.1b. The purpose of this is to have the user close the clip and clamp on the catheter during the insertion procedure, as shown in Figure 2.1c. This allowed the user hand motion to better mimic the hand motion in the actual insertion procedure. The load cells were secured in the clip using off-the-shelf nylon screws and nuts (McMaster-Carr, Elmhurst, IL). These screws and nuts were chosen for its light weight property. One jaw had a V-shape groove to accommodate all sizes of catheters. The other jaw was designed to be flat for the sterile drape compatibility.

The handle housed the electronic components, including two load cell HX711 amplifiers (SparkFun Electronics, Inc., Niwot, CO), a Teensy 3.2 microcontroller (PJRC, Sherwood OR, USA), and a Bluetooth modem (SparkFun Electronics, Inc., Niwot, CO) for wireless data transmission to a recording computer, as shown in Figure 2.1a.

All custom mechanical parts (jaws, clip and housing) were 3D printed.
2.1.3 Software Development

The force data acquisition process is shown in Figure 2.2. Arduino code was developed to transmit the load cell data to an excel data sheet. A Parallax Data Acquisition tool (PLX-DAQ) software add-in for Microsoft Excel was used in the excel data sheet. This add-in allowed the Teensy 3.2 microcontrollers to connect to the load cells, so that the serial port of the recording computer could send data directly into Excel. An example snapshot of the user interface during force data collection is shown in Figure 2.3. The data output includes: time in milliseconds, the analog output from load cell one, the analog output from load cell two, and the calibrated force output. Detailed
explanation of the calibration is outlined in Chapter 2.1.5.

Figure 2.2: Force data acquisition process.

Figure 2.3: User interface for PLX-DAQ.

2.1.4 Design Iterations

This subsection includes multiple design iterations for the Force Assessment Tool: spring-assisted c-clamp, spring-assisted clip, and the final iterations.
Spring-assisted C-clamp

Spring-assisted c-clamp was the first iteration of the *Force Assessment Tool*, as shown in Figure 2.4. The design was comprised of two subsystems: the c-clamp portion, shown in Figure 2.4a, and the handle portion, shown in Figure 2.4b. The catheter could be clamped down with the force provided by the spring, as shown in the right of Figure 2.4a. Only one load cell was used for this iteration. However, the final prototype was hard to use and it did not mimic natural push motion. The user needed to push the lower portion of the c-clamp very hard to release the catheter, and then pulled the tool back on the catheter. A different design of the tool was created to accommodate this issue.

(a) Clamping portion of the device. Left: CAD model. Right: As prototyped.

(b) Handle of portion of the device. Left: Overall handle. Right: Eletronics housing.

*Figure 2.4: Spring-assisted c-clamp.*
Spring-assisted Clip

Spring-assisted clip, as shown in Figure 2.5, was developed to overcome the awkward user hand motion issue mentioned above. Two load cells were used in this design. The v-shape jaw design was selected to better lock the catheter in place. The groves in the jaws allow them to be overlapped and grip on all sizes of catheters. Spring-assisted clip iteration one, shown in the left of Figure 2.5, required users to set the hands on the portion of the clip that was closer to the housing. This was uncomfortable for users with large hands, thus spring-assisted clip iteration two was designed, shown in the right of Figure 2.5. The clip of iteration two had an added portion right above the load cells for the user’s thumb and index finger to sit on.

![Figure 2.5: Spring-assisted Clip iteration one (left) and two (right).](image)

Final Iterations

Final iteration of the Force Assessment Tool (Figure 2.1) was accomplished for the experiment (Chapter 3). The new iteration had a v-shape jaw and a flat jaw. Since the experiment included a cadaveric study, which required a drape to be covered on the tool for repeated use, the jaws were redesigned for better catheter gripping purposes.
For future human study, the research project would be continued with a different iteration of the tool, as shown in Figure 2.6. A sterile drape was required by the hospital regulatory bodies to cover the tool. Therefore, the jaws, clip and housing components were filleted to minimize risk of the tool cutting through the sterile drape. This change was not implemented in the experiment outlined in Chapter 3 but remains an option for future studies.

Figure 2.6: Final design iteration with updated jaws, clip and housing.

2.1.5 System Calibration

Calibration Protocol

The load cells were calibrated with the jaws and clips on, using different calibration weights, as shown in Figure 2.7. A rubber band was tied around the clip so that the clip remained closed. No rubber band was tied around the load cells. A c-clamp was used to secure the device. A series of five different weights was put on the closed jaws separately. The force readings from each weight were recorded then averaged. A linear correlation graph was plotted to find the relationship between used weights and load cell readings. This relationship was then used as an input in the Arduino code. A sample calibration curve is shown in Figure 2.8. The Force Assessment Tool was calibrated each time before use.
Accuracy Testing

When moving the Force Assessment Tool in space, the load cells would pick up signals due to its gravity. This signal was characterized, and the result is shown in Figure 2.9. The Force Assessment Tool was moved around in space extensively and the force signal was recorded over approximately 15 seconds. The maximum force value during the characterization testing was 0.25N. Therefore, the accuracy of the Force Assessment Tool was determined to be +/- 0.25N based on this characterized worse unwanted signal.
2.2 Position Acquisition System

The Position Acquisition System was developed by Amer Safdari, a biomedical engineering graduate student who also worked on this research project.

In summary, the Position Acquisition System was comprised of OpenCV ArUco markers from [12], as shown in Figure 2.10, and a GoPro camera (GoPro Inc., San Mateo, CA). The OpenCV ArUco markers were used to measure the 3 dimensional position and orientation of the tool during the insertion procedure. This was done with resources from the open computer-vision (OpenCV) library [13]. Videos of the insertion were first taken and the 3 dimensional position and orientation of the tool could then be extracted.

The accuracy of the Position Acquisition System was characterized and the report was accepted through Design of Medical Devices Conference, as shown in Appendix A.4.1. The accuracy of the system was found to be 3mm in the planar directions.

Figure 2.9: Result from force accuracy testing.

Figure 2.10: OpenCV ArUco markers.
Chapter 3

Experiment

This chapter outlines the male catheterization experiment protocol.

3.1 Experiment Strategy

The experiments were comprised of two sections: simulator study and cadaveric study. The goals of the experiments were to:

- Obtain insertion force and position profile
- Compare insertion force and position profile between simulators and cadaveric donors

With these goals in mind, the experiments were designed with the following parameters controlled:

- Insertion Procedure Personnel
- Amount of Lubrication Applied
- Catheter Size and Type

The general setup for the experiments is shown in Figure 3.1. A GoPro camera, component of the Position Acquisition System, was placed in front of a recording computer, the Force Assessment Tool and the study subject, simulator or cadaver. A USB
caber was used to connected the recording computer and the Force Assessment Tool for powering the Force Assessment Tool rather than using the external battery. The Force Assessment Tool was covered with sterile drape and an OpenCV ArUco marker was placed on the sterile drape, facing the GoPro camera.

Figure 3.1: General setup of the experiment.

3.2 Simulator Study

3.2.1 Simulator Models

Two different types of male catheterization benchtop simulators were used in this study, as shown in Figure 3.2. The model from Life/form® (Figure 3.2a) had a harder touch than the model from Remedy Simulation Group® (Figure 3.2b), thus these models were labeled as simulator hard and simulator soft, respectively.
3.2.2 Experiment Protocol

All insertion procedures were completed by Michael Tradewell, a fourth year medical student from University of Minnesota - Twin Cities Medical School. He is also the coauthor of our prior work [10]. The same amount of lube (single packet of PDI® Lubricating Jelly, 5ml) was used during each insertion procedure. A 16Fr Lubri-Sil catheter from BARD® SureStep Foley Tray System was used repeatedly, and the lube on the catheter was cleaned off between testing different models. To apply the lube to the catheter, the catheter tip was dipped into the lube package. Both hard and soft models were tested twice on different dates (11/26/2018 and 12/18/2018). This was done to ensure the lube dried out before the catheter was tested again, and minimize the effects of leftover lubrication. A sample testing view captured by the GoPro camera is shown in Figure 3.3.
3.3 Cadaveric Study

3.3.1 Cadaveric Donors

Access to donors was granted through the University of Minnesota’s Anatomy Bequest Whole Body Donation Program. All insertion procedures were also completed by Michael Tradewell.

Three separate cadaveric studies were performed on 10/30/2018, 11/26/2018 and 12/18/2018. Eight male donors were accessed in total. The insertion process was successfully completed in five out of eight donors. The insertion process was incomplete for the other three donors possibly due to collapsed urethra. No complete data was collected for these three donors.

Table 3.1: Donor Information

<table>
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<th>Age</th>
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<th>Related Medical History</th>
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<tr>
<td>1</td>
<td>92</td>
<td>11</td>
<td>Benign Prostatic Hyperplasia</td>
</tr>
<tr>
<td>2</td>
<td>76</td>
<td>16</td>
<td>Benign Prostatic Hyperplasia, Bladder Outlet Obstruction</td>
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<table>
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<tr>
<th>Donor</th>
<th>Age</th>
<th>Days since Death</th>
<th>Related Medical History</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>72</td>
<td>25</td>
<td>N/A</td>
</tr>
<tr>
<td>4</td>
<td>29</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>5</td>
<td>31</td>
<td>10</td>
<td>N/A</td>
</tr>
</tbody>
</table>

3.3.2 Experiment Protocol

A 16Fr Lubri-Sil catheter from BARD® SureStep Foley Tray System was used repeatedly per study and the lube on the catheter was cleaned off between different donors. The only exception was donor two, where a 16Fr coude catheter from BARD® was used. This catheter was chosen due to donor two’s medical history, including benign prostatic hyperplasia (BPH) and bladder outlet obstruction (BOO). To apply lube to the catheter, the catheter tip was dipped into the same brand of lube packet (single packet of PDI® Lubricating Jelly, 5ml). A sample testing view captured by the GoPro camera is shown in Figure 3.4. Two OpenCV ArUco markers were used: one placed on the Force Assessment Tool and one placed on the medical professional’s non inserting hand. This was done to capture the motion of both hands during the procedure. For the scope of this study, only data of the insertion hand was be analyzed.
Figure 3.4: Cadaveric study setup.
Chapter 4

Analysis and Results

This chapter outlines the analysis process after raw force and position data collection and the experiment results.

4.1 Analysis Strategy

In order to have a better understanding of the catheter insertion mechanical characteristics, raw force data collected from the Force Assessment Tool and raw position data collected from the Position Acquisition System were post-processed. The properties of interest could be summarized as following based on the objectives of this research project [1,3]:

- Insertion Force Profile
- Insertion Position Profile
- Insertion Speed Profile

The following analysis procedure was created to process the raw data and capture the properties of interest.

4.2 Analysis Procedure

The overall analysis procedure followed the outline shown in Figure 4.1.
Figure 4.1: Analysis procedure for the cadaveric donor and simulator data sets.

**Force Data**

The raw force data was first imported from excel to MATLAB for analysis. A power spectrum analysis was done as shown in Figure 4.2 in order to determine the cutoff frequency for a digital filter. Based on Figure 4.2, a cutoff frequency of 10Hz was chosen. A second-order low pass Butterworth filter was then applied to the force data to eliminate the high frequency noise. This type of filter was chosen for its maximum pass band flatness so that the signal would not be distorted too much.
Figure 4.2: A single-sided power spectrum was done with unfiltered force data from donor four.

A time-sync process then was done to the filtered force data. During data collection, force data was displaced on the recording computer screen, which was captured in the video. The start of force collection was identified when force data showed up on the computer screen. The time difference between the start of the video and the start of force collection was manually calculated.

After time-syncing the force data with the video data, an interpolation process was done so that the force data would have the same data length as video frames, as shown in Figure 4.3.
Figure 4.3: Pre-interpolation and post-interpolation force data from donor four.

A segmentation process then was done to determine the push force for every insertion motion. The push force segments were identified by an algorithm in which only segments cut force if the force increases, as shown in Figure 4.4.
Finally, the segmented push force was offset to start at zero in order to find the incremental force. This was done by subtracting the initial value from the array of segmented push forces.

**Position Data**

Similarly, position data was imported in MATLAB, then filtered with a second-order low pass Butterworth filter. A power spectrum analysis was done and the cutoff frequency was determined to be 1 Hz. After filtering, position data was segmented using the same algorithm as the force data. Position data per push was then offset-corrected and integrated to get the trajectory length per push. Only position data in X and Y direction were used due to the accuracy of Z direction being distinctly lower than the other two directions. Y axis roughly points up, X axis roughly points superiorly, i.e. towards the donor’s head.
Speed Data

In order to get the speed profile of the insertion motion, position data was taken with Holoborodko low-noise derivatives\cite{14}. This method was chosen for its noise suppression ability. The derivatives, representing velocity data, were filtered with the same Butterworth filter as the position data. Magnitude of velocity data in X and Y direction was then calculated. Velocity data in Z direction was not used due to lack of accuracy. After that, speed data was segmented based on the time points of segmented force data.

Single Push Segmentation

Force, position and speed data were segmented for both simulator and donor sets of data. A prostate and a non-prostate push were identified by the medical student operator (Michael Tradewell) for the cadaveric data respectively. This was done by watching the recorded videos post—procedure. A single push that resembled the clinical catheterization the most from simulators was identified as well.

Post-Hoc Statistical Tests

A post-hoc two sample t-test was done for force data between simulators and cadaveric donors at a statistical significance level of $p \leq 0.05$.

4.3 Results

The force data were processed for donors one to five, simulator hard 1, simulator hard 2, simulator soft 1 and simulator soft 2. The speed and position data did not include simulator hard 2 and simulator soft 2 due to technical difficulties with the video files of these two samples.

4.3.1 Force - Speed Relationship

The absolute insertion force and speed profile for all cadaveric sets are shown in Figure 4.5. The insertion force was higher during the last couple pushes for all cadaveric donor sets. The insertion speed was higher during the middle pushes for donor three, four and five. No specific pattern was found for donor one and two.
Figure 4.5: Segmented absolute insertion force versus insertion speed in the XY plane for all cadaveric data sets.
The absolute insertion force and speed profile for all simulator sets are shown in Figure 4.6. There were multiple force spikes throughout the procedure but they did not occur with specific patterns. The insertion speed did not experience large variations among all pushes.

Figure 4.6: Segmented absolute insertion force versus insertion speed in the XY plane for all simulator data sets.

The relationship between incremental force and speed is shown in Figure 4.7 for all cadaveric sets. No obvious specific patterns were observed for donor one, two and three. For donor four and five, certain pushes appear to have a similar pattern: with force increasing, speed decreased, then increased and finally decreased again.
Figure 4.7: Incremental push force versus speed in the XY plane for all cadaveric sets.
For simulator sets, similar patterns were found in comparison to donor four and five, as shown in Figure 4.8.

Looking at Figure 4.9, simulator data appear clustered largely around the lower left corner of the graph while cadaver data were more spread out and had a larger speed range. No obvious overall force-speed pattern could be observed from this figure.
4.3.2 Force - Trajectory Length Relationship

The absolute force and trajectory length change profile for all cadaveric sets are shown in Figure 4.10. The trajectory length per push was higher during a couple early middle pushes for donor three, four and five. No obvious pattern was found for cadaver one and two. Relatively lower trajectory length per push were found during the last couple pushes for donor two, three, four and five. No strong, obvious positive correlation between larger forces and longer trajectory length could be found.
Figure 4.10: Segmented push force and push trajectory length for all cadaveric data sets.
The absolute force and trajectory length profile for all simulator sets are shown in Figure 4.11. The trajectory length profile did not follow a specific pattern among all pushes. However, positive correlation between larger forces and longer trajectory length could be observed from the graph.

Figure 4.11: Segmented push force and push trajectory length for all simulator data sets.

Based on Figure 4.12, for all cadaveric sets, the incremental insertion force increased with the trajectory length per push. Higher force appeared to be associated with relatively shorter push. The force-trajectory data was overall very spread out, indicating a large range of trajectory length per push.
Figure 4.12: Incremental push force versus incremental push trajectory length for all pushes from all cadaveric data sets.
A positive incremental force - trajectory length correlation was also found in the simulator sets as shown in Figure 4.13. Comparing to Figure 4.12, the simulator data was less spread out. This could also be identified based on Figure 4.14.

Figure 4.13: Incremental push force versus incremental push trajectory length for all pushes from all simulator data sets.
Figure 4.14: Incremental force versus incremental trajectory length per push for all data sets (cool colors: simulator, warm colors: human cadaveric donors).

4.3.3 Cadaver versus Simulator Insertion

The soft and hard simulator models appeared more grouped together for analysis due to similar behavior for force and trajectory length were found between the two models.

Figure 4.15 shows that simulators resulted in typically higher average absolute insertion force and incremental insertion force than cadaveric donors. The standard deviation for simulator data was also smaller. Simulators also resulted in a longer average procedure time, according to Figure 4.17.

A single push was identified in each data set as the most representative push during each procedure. For cadaveric sets, a single push was identified as the non-prostate push and another push was identified as the prostate push. The results from cadaveric donor sets are shown in Figure 4.18. The results from simulator sets are shown in Figure 4.19. All the single pushes from simulators and non-prostate pushes from donors were compiled to form Figure 4.20. All the pushes had low value of maximum incremental force.
Figure 4.15: (a) Maximum absolute insertion force (b) maximum incremental insertion force for all cadaveric and simulator sets.

Figure 4.16: Maximum incremental insertion force (98 percentile) for all cadaveric and simulator sets.
Figure 4.17: Maximum length of procedure time for all cadaveric and simulator sets.
Figure 4.18: Incremental push force versus incremental push trajectory length for a single push from all cadaveric sets.
Figure 4.19: Incremental push force versus incremental push trajectory length for a single push pushes from all simulator sets.

Figure 4.20: Incremented force versus incremented trajectory length for a single push from all cadaver and simulator study sets.
Statistical Tests

The results of post-hoc two sample t-test appear below. It was found that the maximum incremental insertion force (98 percentile) for simulators and cadaveric donors were statistically significant different at 0.05 significance level (roughly 5.6N for cadaveric runs vs 8.1N for simulator runs on average).

Table 4.1: Simulator vs Donor mean insertion force difference (results of the Post-hoc two sample t-test).

<table>
<thead>
<tr>
<th></th>
<th>Donor - Simulator Maximum Incremental Insertion Force Difference (98 Percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-Value</td>
<td>0.0037</td>
</tr>
<tr>
<td>Confidence Interval</td>
<td>[-3.3368,-0.9546]</td>
</tr>
</tbody>
</table>

4.3.4 Cadaveric Donor Study: Prostate versus Non-prostate Region

The results from Figure 4.18 were compiled to form Figure 4.21. As shown in Figure 4.21, the prostate pushes all had relatively higher force than the non-prostate pushes. Despite the trajectory length change varied for both prostate pushes and non-prostate pushes, the force for non-prostate pushes remained in the same range among all donors. Looking at Figure 4.22, the prostate pushes had higher average maximum incremental force and larger standard deviation than the non-prostate pushes. Compare to the average and maximum peak incremental force from simulators, the group of non-prostate force was lower. The group of prostate force and average peak incremental force from simulators were around the same. The group of maximum peak incremental force from simulators was higher than all the rest of the groups.
Figure 4.21: Force - trajectory length relationship for prostate push versus non-prostate push in all cadaveric sets.

Figure 4.22: Maximum increment force for prostate push from cadavers, non-prostate push from cadavers, average and maximum peak incremental force from simulators.
4.3.5 Cadaveric Donor Study Summary

The summary of all donor information and the related results is shown in Table 4.2. BPH stands for benign prostate hyperplasia. BOO stands for bladder outlet obstruction. No positive correlation was found between BPH and high insertion force. No positive correlation was found between BOO and high insertion force either.

Table 4.2: Donor Information.

<table>
<thead>
<tr>
<th>Donor</th>
<th>Age</th>
<th>Catheter Used</th>
<th>Days since Death</th>
<th>Related Medical History</th>
<th>Max Prostate Force (N)</th>
<th>Max Absolute Force (N)</th>
<th>Max Incremental Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>92</td>
<td>Silicone</td>
<td>11</td>
<td>BPH</td>
<td>7.527*</td>
<td>5.622*</td>
<td>7.527*</td>
</tr>
<tr>
<td>2</td>
<td>76</td>
<td>Coude</td>
<td>16</td>
<td>BPH, BOO</td>
<td>3.880</td>
<td>6.759</td>
<td>5.993</td>
</tr>
<tr>
<td>3</td>
<td>72</td>
<td>Silicone</td>
<td>25</td>
<td>N/A</td>
<td>4.640</td>
<td>11.01**</td>
<td>10.19**</td>
</tr>
<tr>
<td>4</td>
<td>29</td>
<td>Silicone</td>
<td>12</td>
<td>N/A</td>
<td>4.328</td>
<td>4.499</td>
<td>4.897</td>
</tr>
<tr>
<td>5</td>
<td>31</td>
<td>Silicone</td>
<td>10</td>
<td>N/A</td>
<td>3.624</td>
<td>5.840</td>
<td>5.960</td>
</tr>
</tbody>
</table>
Chapter 5

Conclusion and Discussion

5.1 Discussion

5.1.1 Force - Speed Relationship

Force - speed relationship was of interest to elucidate important parameters underlying typical friction effects, as shown in Figure 5.1.

![Figure 5.1: Classic force - speed relationship in terms of friction force.](image)

Figure 5.1: Classic force - speed relationship in terms of friction force.
A hypothesis of the force-speed relationship was made before the study based on the graph: the insertion force versus speed would be highly dependent on the viscous friction segment. However, from both the simulator and cadaveric donor data sets, it was found that the force did increase with pushing as expected, but speed did not seem to follow a specific pattern during the push events. It could be concluded that the force did not have a strong linear correlation with speed and no other obvious rate-dependent friction model structure was observed.

From Figure 4.9, noted that the simulator data sets had a much more clustered behavior than the cadaveric donor sets. This was possibly because the simulator required shorter pushes to prevent the catheter from buckling during insertion, thus the speed was comparatively low and more clustered. The buckling effect could be due to that a higher force was experienced during the insertion which impeded the catheter’s advancement. Or it could be a result from the inconvenience of using the Force Assessment Tool. However since higher speed was found during the cadaveric data, it was more likely that the buckling effect was from exerting a higher force.

5.1.2 Force - Trajectory Length Relationship

As shown in Figure 4.14, force increased with the increase of trajectory length. This may be because a substantial portion of the force actually was from pushing the tissue away rather than from the friction force. The level of force possibly depended more on the diameter and shape of the urethra. This could also explain why the simulator data were less spread out — possibly due to less variations in the urethra diameter.

5.1.3 Cadaveric Donor versus Simulator Insertion

It was found that the simulators resulted in shorter pushes (Figure 4.14), higher absolute and incremental average maximum force per push (Figure 4.15), and longer procedure time (Figure 4.17) than the cadaveric donors. There was also less variations in force and no specific increase or decrease pattern throughout the insertion profile, thus no prostate or non-prostate region could be distinguished.

On the other hand, from the cadaveric data sets, relatively short and long push were both experienced. The absolute and incremental average maximum force per push
(Figure 4.15) was typically lower but with greater apparent variability. There was an overall shorter procedure time. The force had a pattern over time and was higher during the last couple pushes. A prostate region and a non-prostate region could be distinguished based on the force pattern over time, but not force values, as shown in Figure 4.10. This also reinforced the conclusion drawn from former section that the force actually was from pushing the tissue away.

Interestingly, force level remained around the same in the cadaveric sets even though the trajectory length changed significantly, as shown in Figure 4.10. This was possibly due to the distal portion of the urethral being rather open, thus increasing the push length did not necessarily increase the force.

5.1.4 Cadaver: Prostate versus Non-prostate Region

As shown in Figure 4.22, the prostate push had higher average force than non-prostate push. Note that the level of prostate push force varied substantially. A reason to explain this was that the prostate push was manually identified after the procedure was done, which could have caused uncertainty.

5.1.5 Cadaveric Donor Study Summary

No positive correlation was found between BPH and high insertion force. No positive correlation was found between BOO and high insertion force either. Looking at the force data from donor one (marked with *) as shown in Table 4.2, the maximum incremental force was higher than the maximum absolute force. This was due to the negative force during the procedure, potentially because the user did not release the clamp fully and dragged the load cells on the catheter. Looking at the force data in donor three (marked with **), these force values were abnormally high. This could possibly be explained by the user pushing the load cells too far and eventually touched the glans penis.

5.2 Limitations

There were several limitations in this study:

1. Limited Sample Size: Very limited sample sizes from Simulators (N=2), human
donors (N=5) and clinician operators (N=1) was used. This was only a feasibility study and an exploratory analysis of initial data. The generalizability of such results is highly uncertain or limited.

2. Segmentation Method: The segmentation method could not segment out the true push force if there were multiple spikes during one push. A better segmentation method is needed in order to limit the error encountered here. However, around 90 percent of the data had single spike, so this method was deemed acceptable.

3. Tooling Accuracy: The Force Assessment Tool had an accuracy of +/- 0.25N and this caused around 3 percent error. The Position Acquisition System had an accuracy of +/- 3mm and this caused around 7 percent error. This was large but did not change the positive relationship between force and trajectory length per push.

4. Prostate Identification: Prostate push identification was done after the procedure by watching the videos. It would be better to identify it during the procedure, as the identification was based on the feeling of the healthcare provider’s insertion hand. A more direct approach of identifying it during the procedure would be preferred in handling this. However, the visual cue from the video, according to the user, was sufficient to identify the prostate pushes with confident.

5. Manual Time - Sync: The force data and the position data was manually time-sync and prone to human errors (0.01s resolution). In order to validate that the time-sync process was completed correctly, a combined video was made with both the procedure and time-sync data was made per data set in the analysis process, thus this method was acceptable.

6. Limited to Cadaveric and Simulated Tissues: These results, observations, or conclusions may not generalize to realistic in vivo human settings. They offer little or no insight to true in vivo behavior. However, this work provides initial evidence that the system is valid and capable of measuring reasonable differences in the range of typical human anatomy. These initial, limited results better warrant a follow up study in typical human patient participants.
5.3 Conclusion

The following conclusions could be drawn from this study:

1. There was a positive force - trajectory length relationship and this indicated the dominant force arose from tissue stiffness or elasticity responses caused by pushing the tissue away rather than rate-dependent effects like friction.

2. Simulators resulted in a typically higher average maximum insertion force than cadaveric donors and exhibited less anatomical variability (like a distinctive prostate effect) than cadaveric tissues.

3. In cadaveric donors, average prostate push force was found to be higher than average non-prostate push force.

5.4 Future Work

Although the study was useful to understand the catheter insertion mechanical response characteristics, aspects of the Force Assessment Tool could be improved further. An improvement could be made to the Force Assessment Tool and the Position Acquisition System to better time — sync the force data and the position data. So far the time — sync was manually done and this was prone to human errors. Another improvement of the experimental protocol would be identifying the prostate during insertion procedure rather than later by watching the videos. Future work would include collecting data in human studies and comparing the results to the simulator and cadaveric data presented in this thesis.
References


Appendix A

Appendix

This appendix defines terms in a glossary, and contains a table of acronyms and their meaning.

A.1 Glossary

- **Force Assessment Tool** – A custom-designed tool used to measure the insertion force during male catheterization.

- **Position Acquisition System** – A custom-designed system used to acquire 3D position during male catheterization.

- **PLXDAQ** – Parallax Data Acquisition tool (PLX-DAQ) software add-in for Microsoft Excel [11].

- **OpenCV Aruco Markers** – Markers used to track 3D position during male catheterization [12].

- **Benign Prostate Hyperplasia** – Age-associated prostate gland enlargement that could cause difficulty to urinate.

- **Bladder Outlet Obstruction** – A blockage at the base of the bladded which reduces or stops the flow of urine into the urethra.
• **Stribeck curve** – A concept in the field of tribology which shows that friction in fluid-lubricated contacts is a non-linear function of the contact load, lubricant viscosity and the lubricant speed.

### A.2 Acronyms

Table A.1: Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAUTI</td>
<td>Catheter-Associated Urinary Tract Infection</td>
</tr>
<tr>
<td>DOF</td>
<td>Degree of Freedom</td>
</tr>
<tr>
<td>BPH</td>
<td>Benign Prostate Hyperplasia</td>
</tr>
<tr>
<td>BOO</td>
<td>Bladder Outlet Obstruction</td>
</tr>
<tr>
<td>OpenCV</td>
<td>Open Source Computer Vison</td>
</tr>
<tr>
<td>PLXDAQ</td>
<td>Parallax Data Acquisition tool</td>
</tr>
</tbody>
</table>

### A.3 List of Figures

A.3.1 Donor 1
Figure A.1: Absolute insertion force versus insertion speed in the XY plane for donor one.

A.3.2 Donor 2
Figure A.2: Absolute insertion force versus insertion speed in the XY plane for donor two.

A.3.3 Donor 3
Figure A.3: Absolute insertion force versus insertion speed in the XY plane for donor three.

A.3.4 Donor 4
Figure A.4: Absolute insertion force versus insertion speed in the XY plane for donor four.

A.3.5 Donor 5
Figure A.5: Absolute insertion force versus insertion speed in the XY plane for donor five.
A.3.6 Simulator Hard 1

Figure A.6: Absolute insertion force versus insertion speed in the XY plane for simulator hard one.
A.3.7 Simulator Soft 1

![Graph](image)

Figure A.7: Absolute insertion force versus insertion speed in the XY plane for simulator soft one.

A.4 Papers Accepted

A.4.1 2019 Design of Medical Device Conference

Accepted
ABSTRACT
Catheter associated urinary tract infection (CAUTI) is among the most common nonpayment hospital acquired conditions and contributes a significant health care burden. Inexperienced health care providers placing indwelling urinary catheters are associated with an increased risk of CAUTI, thus more realistic simulators are needed during early training and it requires the mechanical dynamics of the procedure to be well understood. A custom insertion force assessment device, along with a video recording system (OpenCV ArUco markers and a GoPro camera), were used to collect the insertion force and motion data on fresh cadaver specimens. In addition, evaluation of the video system accuracy was done to understand the boundaries of the procedure’s target workspace. During our experiments, we found that typical urinary catheter insertion force range for male catheterization is around 3–6 Newtons and the video system can achieve an accuracy of +/- 3 mm in the plane of the camera, and +/- 10-25 mm along its axis depending on the distance.

INTRODUCTION
Catheter associated urinary tract infections (CAUTI) are the most commonly reported hospital acquired infection. CAUTI cause increased hospital cost and patient morbidity [1]. While a great deal is known about patient and environmental factors that contribute to an increased CAUTI risk, only recently have studies began assessing providers who are placing indwelling catheters. Most notably, inexperienced health care providers placing indwelling urinary catheters are associated with a 4-fold increased risk of CAUTI [2]. One potential avenue to reduce CAUTI rates is to provide proper instruction, objective assessment, and accurate simulation during early clinical training or remedial testing.

Realistic simulators may better facilitate skill transfer into practice settings but this requires accurate knowledge of the mechanical responses of tissues to clinician motions such as friction or force magnitudes. This should span both typical and atypical anatomy as well as tissue responses resulting from proper motions and improper motions that lead to injury or potentially CAUTI’s. Urinary insertion force has been subjectively self-reported by healthcare providers after completing a procedure [3]. To our knowledge, no research that has investigated the mechanics of urinary catheter insertion objectively and there is no readily-available device to measure required forces and motions. The objective of this work is to i) introduce a design to practically capture motion and force of typical urinary catheterization, ii) determine the accuracy of this inexpensive motion capture method, and iii) demonstrate feasibility of clinically meaningful data acquisition on fresh human cadaveric specimens.

1 Contact author: timk@umn.edu.
METHODS

The mechanical dynamics tracking platform in this work leverages our prior work [4] which describes a catheter insertion force assessment tool. In short, this inexpensive device is comprised of a 3D-printed handle instrumented with two 780 g load cells (Phidgets Inc., Calgary AB, Canada) and two HX711 load cell amplifiers (SparkFun Electronics, Inc., Niwot, CO) to measure the insertion force. A Teensy 3.2 microcontroller (PJRC, Sherwood OR, USA), and bluetooth modem (SparkFun Electronics, Inc., Niwot, CO) served as a means to communicate data back to the host PC.

ArUco markers [5] were used to measure the 3 dimensional motion of the operator during the procedure with the open computer-vision (OpenCV) library [6]. Video capture of the markers was facilitated by a GoPro Hero7 Black camera (GoPro Inc., San Mateo, CA) set to record 1080p footage at 240 FPS (1920x1080 pixels used in post-processing herein). The procedure in the ArUco library documentation was used to calibrate our camera and obtain intrinsic and distortion parameters [7].

The accuracy of the ArUco markers and video system was assessed in the a target workspace enclosing typical hand motion for urinary catheter insertion [Fig. 2, 3]. The “closest” configuration was roughly 270 mm away from the camera, and the displacement between the two successive configurations were known to be 140 and 290 mm respectively. At each configuration, the camera was set to record the ArUco markers for 3–5 seconds. The videos were then processed by OpenCV routines and the ArUco library, and the position data imported into MATLAB.

At each frame, the centroid of all the detected ArUco markers was computed which served as a reference point. The ground truth positions in the plane of the paper (hereby referred to as the xy plane) were measured via a caliper and compared to the output of the computer vision algorithm.

To validate our device and tracking system for feasibility in a patient setting, data were collected on two male human cadavers prior to being fixtured. Access to cadavers was granted through 2 Copyright © 2019 by ASME
the University of Minnesota’s Anatomy Bequest Whole Body Donation Program. The device was used to place both a Foley, and a Coude urinary catheter while subject to computer vision tracking. The procedure was conducted by medical student and co-author, Michael Tradewell.

FIGURE 4: A, B) PHOTO OF CATHETER INSERTION FORCE ASSESSMENT TOOL. C) PERFORMING CATHETERIZATION ON UNFIXED CADAVERIC SPECIMEN WITH DEVICE AND TRACKING PLATFORM

RESULTS

FIGURE 5: BOX PLOT OF ROOT MEAN SQUARED ERROR IN THE XY PLANE FROM TRACKING EXPERIMENT

FIGURE 6: Z DISPLACEMENT ERROR FROM TRACKING EXPERIMENT IN ALL 3 CONFIGURATIONS.
FIGURE 7: DEPICTS THE RELATIVE ACCURACY IN THE XY PLANE. THE BLACK X’S REPRESENT THE GROUND TRUTH POSITION OF EACH MARKER, AND THE RED DOTS ARE THE MEASUREMENTS OUTPUT BY THE COMPUTER VISION TRACKING ALGORITHM. THIS IS SHOWN FOR ALL 3 CONFIGURATIONS.

FIGURE 8: POLAR PLOTS PRESENTING A MAGNIFIED VIEW OF FIG. 7. ALL RED DOTS ARE DATA POINTS REFERENCED WITH RESPECT TO THEIR TRUE POSITION (BLACK X).
FIGURE 9 3D TRAJECTORY CAPTURED DURING A SINGLE STROKE OF INSERTION IN THE CADAVERIC STUDY. VECTORS ALONG THE TRAJECTORY ARE REPRESENTATIVE OF THE VELOCITY. THE COLORBAR ILLUSTRATES THE FORCES EXPERIENCED ALONG THE TRAJECTORY.
The ArUco computer vision algorithms for marker tracking proved to be quite accurate. In the xy plane, we observed a typical RMS error of roughly 3 mm [Fig. 5]. In the z-axis (along the axis of the camera), larger errors were recorded — on the order of 10 - 25 mm depending on the distance away [Fig. 6]. Larger errors along the axis of a camera relative to in-plane errors are well documented in computer vision literature, aligning well with the results presented here. Additionally, as expected there is a trend between increasing distance, and increasing error across both in-plane and out of plane measurements.

In the context of our application in urinary catheter insertion, the device primarily moves along a single plane. Thus proper camera positioning can sidestep the penalty in accuracy incurred by motion in the z-axis. This affords us roughly millimeter level accuracy when tracking motion during catheterization, while being inexpensive and easy to implement.

During the cadaver study, it was found that typical urinary insertion force was about 3 - 6 Newtons. Largest force was found to be at the end of the single “push-event” during the catheter insertion. To better quantify the friction force during the insertion motion, the relationship between the insertion force and velocity would be further examined in the future.

This work demonstrates successful, practical motion and insertion force collection on urinary catheter placement in clinically realistic settings. Future work will seek in vivo data from consenting patients.

REFERENCES


In the context of our application in urinary catheter inser-
A.5  Papers in Review

A.5.1  2019 American Urological Association Abstract

IN REVIEW
Dynamics of Foley Catheter Insertion: A Cadaver Study

Xiaoyin Ling, Michael B Tradewell, Amer Safdari, Timothy M Kowalewski

Presenting Author: Michael B Tradewell

Introduction and Objective

Catheter associated urinary tract infection (CAUTI) is among the most common non-payment hospital acquired conditions. Foley catheter placement has been shown to impact CAUTI rates. Notably, medical student placers are associated with a 4-fold higher CAUTI rate. Little is known about the dynamics of urinary catheter insertion. Our objective is to characterize the mechanics of Foley catheter insertion to aid the creation of accurate training modules and simulators.

Methods

The mechanics of Foley catheter insertion were characterized with two unfixed male cadavers (access through University of Minnesota Medical School Anatomy Bequest Program). Both had a history of benign prostatic hyperplasia and no known history of urologic operations. A 16 Fr silicone Foley catheter was passed into the bladder of the first cadaver without difficulty. A 16 Fr Coude catheter was used for second cadaver due to bladder outlet obstruction. Custom designed instrumentation, with a calibrated +/- 0.002N accuracy, was used to measure the insertion force, Figure 1. OpenCV ArUco markers were used to capture the 3D insertion motion with a GoPro camera.

Results

The duration of the two catheterizations were 27.3 and 25 seconds for cadaver one and two, respectively. Each peak of the force curve was associated with a push-event, Figure 2A. It took 13 and 10 push-events to ‘hub’ the Foley in each case; the average insertion forces were 2.29 and 3.68 Newtons and the maximum insertion forces were 5.05 and 6.75 Newtons. Push-events were measured to be roughly 5 cm/s on average throughout the procedure. Figure 2B depicts a typical 3D insertion trajectory.

Conclusions

The coupled force measurements and computer vision motion capture gives a first-of-its-kind full mechanic assessment of urinary catheter insertion. The Coude catheter seemed to be associated with a higher insertion force. With future efforts, we plan to replicate this work in living patients to compare to these cadaveric results and to inform the creation of accurate training modules and simulators.
Figure 1. Illustration of instrumented catheterization procedure.

Figure 2. A) Insertion force and speed plotted against time. B) 3D dynamics of a single push event.
A.6 Published Work
ABSTRACT 15

A CATHETER INSERTION FORCE ASSESSMENT TOOL: DESIGN AND PRECLINICAL RESULTS

Xiaoyin Ling1, Michael Tradewell2, Robert M. Sweet3, and Timothy M. Kowalewski1

University of Minnesota, Department of Mechanical Engineering1 or Biomedical Engineering2
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Introduction: Urethral catheterization is among the most common procedures performed in healthcare settings. There is no standardized approach to Foley catheter insertion and iatrogenic urethral injury is thought to occur in 3.2 per 1000 male catheterizations [PMID27654098]. Furthermore, traumatic insertion contributes to catheter associated urinary tract infections (CAUTI) [PMID20156062]. Incorrect catheter insertion force profiles may be a measurable proxy for insertion trauma. A recent study found providers with greater than 25 years’ experience exert significantly less insertion force than their less experienced colleagues [PMID19254403], unfortunately subjective self-reporting rather than quantitative measurements were used. We present the design and preclinical results of a low-cost device intentionally designed to quantitatively measure urinary catheter insertion force in situ.

Methods: The one degree-of-freedom catheter insertion force assessment tool utilizes two 780g load cells to selectively capture the insertion force. The clip, a spring-assisted design, provides force for the jaws to close and clamp on the catheter. The load cells are calibrated with the jaws and clips on, using different calibration weights. The handle houses the electronic components, including two load cell amplifier HX711 with Teensy 3.1 board, and Bluetooth modem for the wireless data transmission. A silicone benchtop model [Male Catheterization Model from vendor Life/form®] and a 14Fr plastic Foley catheter [Self - Cath® from Coloplast] are utilized for the data collection.

Results: A picture of the assessment tool design and build appear in Figure 1 with a cost of $84 and calibrated accuracy of +/- 0.2g. The device successfully collected insertion force-time data at 115.2 kHz with the silicone model as the data shown in Figure 2. Each peak value is associated with a push of the insertion process.

Conclusion: We present the design of an inexpensive catheter insertion force measurement device for scientific research purposes, which could be developed into a training tool in the future. These data demonstrate the ability of our device to measure the typical dynamic range of forces on a Foley catheter during insertion in a benchtop model. Next, we will record measurements in more simulators, cadavers and patients to validate and improve simulators and standardized insertion protocols. In the future, the design could be updated to account for the sterilization standard required for a clinical study.

Figure 1: The device and its components as (a) designed, (b) built, and (c) used.

Figure 2: The insertion force measurements for a full insertion cycle. (a) With lube on the entire catheter, the maximum force is around 2.5N. (b) With lube on only the tip of the catheter, the maximum force is around 7N.