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Measuring hip fracture fixation guide wire placement for performance assessment in simulation and the operating room

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MEASURING HIP FRACTURE FIXATION GUIDE WIRE PLACEMENT FOR PERFORMANCE ASSESSMENT IN SIMULATION AND THE OPERATING ROOM

by

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

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ABSTRACT

The purpose of this study was to define a more accurate way of assessing guide wire navigation performance, which is a crucial first step in fixing an intertrochanteric femoral fracture. This study introduces a new measurement technique called the trajectory accuracy metric (TAM) to quantify the placement of a guide wire with respect to an ideal trajectory. A total of seventy-two cases were collected in which a Post Graduate Year 1 (PGY1) resident was instructed to place a guide wire through the neck and head of a synthetic femur as close to a center-center position as possible. Each resident was guided by the use of fluoroscopic anteroposterior (AP) and lateral images. A simple geometrical model of a femur was used to define an ideal wire trajectory in which the wire was inserted at a neck-shaft angle (NSA) of 130° and placed centrally through the femoral neck. 3D models of the femur and wire were created for each case, and the wire trajectory was compared with respect to ideal by calculating TAM, which is the average distance between the two wires. The average TAM across all cases was 8.62mm, with a minimum value of 3.35mm and a maximum value of 24.17mm. Since this is a novel measurement, further studies should be done to evaluate its reliability and validity. Additionally, more wire trajectories should be incorporated into this measurement because successful placement of a guide wire is not restricted to one correct trajectory.

Another application of assessing guide wire navigation performance can be applied to a surgical simulation study, in particular, if skills obtained during surgical simulation carry over to a setting that closely resembled the OR. A cross-over experimental design was used for two groups, and metrics used to determine improvement included tip-apex distance (TAD), procedural time, number of fluoroscopic

shots requested, additional breaches of the lateral cortex, and number of entries into the joint space. Twenty-four PGY1 residents participated in this study and were told to minimize all metrics, especially TAD. Significant improvements were seen in procedural time and the number of fluoroscopic images requested. In the future, including additional participants may demonstrate a more prominent transfer of skill.

Furthermore, the variability of TAD was explored. This is an important metric as a TAD of over 25mm is widely viewed as being a predictor of screw cut-out. Since TAD is very subjective, a new technique of TAD measurement was introduced to incorporate a 3D apex location on the femoral head. This measurement was found to significantly decrease the amount of both interobserver and intraobserver variability. Further work needs to be done to determine the most accurate way of assessing TAD as a reliable predictor of screw cut-out.

PUBLIC ABSTRACT

One of the most crucial aspects of training first-year surgeons is ensuring that they acquire surgical skills prior to entering the operating room (OR). This study attempts to define a more accurate method of assessing and measuring surgical skills when fixing a hip fracture with a guide wire. The measuring system currently used today, which is widely described as a fairly accurate predictor of fracture fixation failure, can be quite subjective and prone to inaccuracies. This study introduces an alternative method of measurement that quantifies the deviation of guide wire trajectory from an ideal path. We believe that this method is helpful for surgeons to understand the importance of guide wire trajectory, and its application can be extended to both surgical simulation and the OR.

Additionally, this study introduces a preliminary experiment that examines the transfer of surgical skills from a hip fracture simulator to a setting that closely resembles the OR. Surgical simulators can be of great benefit to first year surgeons as they look to improve their surgical skills. Surgeons must learn to balance their time appropriately due to the presence of fluoroscopy, which emits radiation, while placing the implant in a satisfactory position. Significant improvements were found in procedural time and the number of fluoroscopic images requested in an OR setting after thirty minutes of simulator use. It is possible that the surgeons were not given enough time to practice on the simulator, so a new experimental design and more subjects will hopefully show more significant improvements after simulator intervention.

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CHAPTER 1 – INTRODUCTION

1.1 Overview

Surgical skills training is of utmost importance for the education and guidance of first-year orthopaedic residents. One of the most commonly used surgical techniques involves the navigation of a guide wire through bone. The surgeon must use fluoroscopy to generate 2D images of the bone; however, one of the most challenging aspects of a surgery is mentally reconstructing these 2D images to create a 3D model of the fracture and implant. This important skill can pose issues for younger residents.

This study focuses on guide wire navigation to treat an intertrochanteric femoral fracture. When treating this fracture, navigating the guide wire through the femur using anteroposterior (AP) and lateral images is the first and most important step because it creates a path for the implant. Despite the importance of this procedure, there is currently no accurate and reliable way of measuring its success.

This study also introduces a preliminary experiment involving skills obtained from surgical simulation. Due to recent strict regulation of residents' hours, less time is being spent in the operating room (OR). This can pose a problem for residents looking to acquire valuable experience and training because they may not receive as many opportunities to observe or participate in surgical procedures. Like any skill, surgical skill develops with exposure and practice, and decreasing time in the OR can result in resident inexperience and lack of confidence. Surgical simulation may be a solution to combat this problem. While it is somewhat underappreciated, it has obvious benefits which should sway more institutions to implement it into their curriculum. Residents are able to use simulators in their spare time to practice surgical skills in which they may not yet feel comfortable performing on a patient. Simulators are a safe alternative, and they do not interfere with the mandated resident work week.

1.2 Objective

This study is attempting to define a more accurate method of assessing guide wire navigation skills when fixing an intertrochanteric femoral fracture. Currently, tip-apex distance (TAD) is a widely accepted measurement to evaluate success of guide wire placement. AP and lateral fluoroscopic images are used to obtain a manual measurement, and a TAD of less than 25mm is regarded as the gold standard to prevent lag screw cut-out. However, TAD may not be the most accurate measurement due to its subjective nature, loosely defined measurement technique, and discrepancy based on the presence of internal or external rotation.

Assessing guide wire trajectory along the femoral neck and head may instead be a useful tool to evaluate the success of guide wire placement, but to our knowledge, it has not yet been explored. This study introduces the trajectory accuracy metric (TAM), a computer-based method to quantify guide wire trajectory with respect to a pre-defined ideal wire trajectory. Due to its automated nature, there is much less subjectivity and ambiguity as compared to TAD, the conventional method of assessing wire navigation performance.

A preliminary experiment involving first-year orthopaedic residents has also been introduced to investigate if guide wire navigation skills obtained during surgical simulation would carry over to a setting that closely resembled the OR. Important parameters to assess improvement include TAD, number of fluoroscopy shots requested by the surgeon, time taken to complete the procedure, number of lateral cortex breaches, and number of entries into the joint space. Of these metrics, TAD is commonly regarded as the most important. A new method to evaluate TAD was also introduced to define the apex as a singular point in an attempt to decrease the amount of both interobserver and intraobserver variability.

1.3 Hypothesis

TAM, a new method to quantify guide wire trajectory, has been introduced in this study. It is hypothesized to be a more accurate and valuable assessment of guide wire navigation success to visualize and quantify deviation from a center-center position. Furthermore, it will provide residents with another metric upon which they can improve.

It has been hypothesized that residents will improve their guide wire navigation performance in an OR setting from trial to trial, but their most significant improvements will occur immediately after simulator intervention. Their improvements will be reflected in a decreased time taken to complete the procedure and decreased number of fluoroscopic images requested. It has also been hypothesized that defining an apex on the femoral head will decrease the amount of interobserver and intraobserver variability in measuring TAD compared to the conventional measurement technique introduced by Baumgaertner [1].

CHAPTER 2 – TRAJECTORY ACCURACY METRIC (TAM) TO ASSESS GUIDE WIRE NAVIGATION

2.1 Introduction

The 250,000 proximal femoral fractures reported per year in the US are projected to increase to 500,000 by the year 2040 [2]. Intertrochanteric hip fractures, which are particularly deadly and expensive, account for as much as 50% of all proximal femoral fractures [3, 4]. Intertrochanteric fractures are often treated with dynamic hip screws (DHS). The first step in surgically placing a DHS is precisely placing a surgical guide wire through the femoral neck and into the apex of the femoral head, creating a path for the cannulated screw to follow. Surgeons use fluoroscopic images to navigate the guide wire through the femur. Although minimizing the duration of surgery and the number of fluoroscopic images used is important, surgeons strive to balance these factors with accurately placing the guide wire, because poor wire placement is a predictor of implant failure [5]. Inexperienced residents are also challenged to interpret 2D AP and lateral fluoroscopic images in order to mentally reconstruct a 3D understanding of the wire position relative to the bony anatomy [6, 7].

DHS failure rates as high as 16-23% have been reported [1, 2]. The most common form of failure is screw cut-out, in which the neck-shaft angle collapses into varus, causing the screw to penetrate the femoral head and possibly enter the joint space [7-11]. Cut-out may be attributed to an age-related decrease in bone density, poor reduction, instability, and poor fracture fixation [12, 13]. The best way to avoid cut-out is through an accurate placement of the screw within the femoral head [8].

The tip-apex distance (TAD) was introduced by Baumgaertner et al. to roughly measure the placement of the lag screw within the femoral head from AP and lateral radiographs [1]. The radiographs are first calibrated for magnification using the known diameter of the screw. Next, a best-fit ellipse is drawn to match the subchondral bone of the femoral head. A line is drawn between the two points where this ellipse intersects the cortical boundaries of the femoral neck. The perpendicular bisector of this line is extended upward through the femoral head, and the location where it intersects the ellipse defines the apex [9]. In both the AP and lateral radiographs, the distance between the tip of the screw and the apex is measured, and then these two values are summed to produce the TAD.

A low TAD value is achieved when the guide wire is placed centrally and deep on both the AP and lateral radiographs (center-center position). The repeatability of TAD measurement is highly dependent upon accurate placement of the fluoroscope when acquiring images, and previous studies have shown the TAD to be especially sensitive to internal and external rotation of the femur [1, 14]. The interobserver variability of TAD measurements has been reported to be as high as 10% [1]. Baumgaertner et al.'s key finding in their clinical study was that screw cut out was substantially more likely when the TAD was greater than 25mm, and large TADs should therefore be avoided. However, this gold standard has been the subject of controversy and may not be the most accurate method of measuring guide wire placement. Studies have shown that cut-out can occur despite a TAD of less than 25mm, and therefore other recommendations of acceptable TADs have been suggested [11, 15, 16].

Despite the widespread clinical use of TAD, understandable given the ease with which it can be measured, one of its biggest limitations is an inability to measure wire trajectory. Wires placed with the same TAD can have vastly different trajectories;

therefore, an acceptable TAD may not necessarily correlate with a good wire trajectory. Identifying a way to quantify guide wire trajectory with respect to a pre-defined desired trajectory would provide a beneficial metric to use in combination with TAD. To our knowledge, there have been no prior studies explicitly exploring guide wire trajectory measurement.

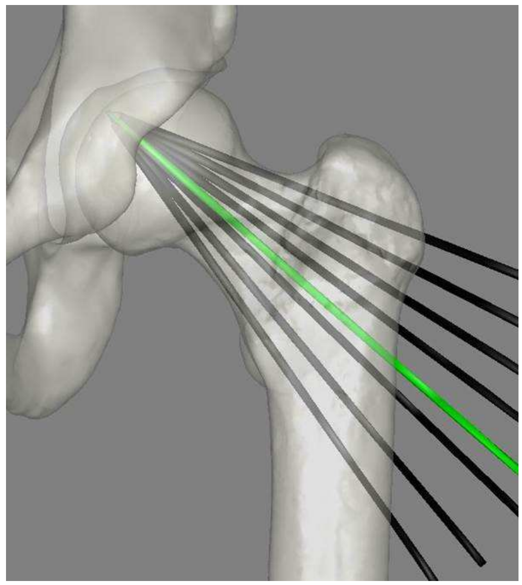


Figure 1. Guide wires with the same TAD but varying trajectories. The green wire is in a center-center position.

The purpose of this study was to introduce a new measure of wire placement called the trajectory accuracy metric (TAM) that quantifies the deviation of a wire from a desired trajectory. We hypothesized that the TAD and TAM are independent measures of wire placement, and that the TAM is a more reliable measure of wire placement than the TAD. A study of wire navigation performance was then used to characterize the relative values of the TAD and TAM in application.

2.2 Methods

2.2.1 Introduction

The TAM is measured from two fluoroscopic views of a wire in a bone. For present purposes, the geometry of a synthetic femur bone was used. A specified linear path through the bone defines the desired placement. The actual wire placement is obtained by deducing its 3D position from the fluoroscopic images. The TAM is defined as the average distance between the desired and the actual wire placement.

2.2.2 Defining the Ideal Wire Trajectory

The general anatomy of the synthetic femur was represented using simple geometric models. A cylindrical shaft, cylindrical neck, and spherical head were created in Creo Parametric (PTC, Needham, MA). These geometric models were appropriately sized and aligned to match a laser-scanned STL model of the synthetic femur. The cylindrical neck and shaft were aligned at a 130° neck-shaft angle to represent a commonly used DHS angle. The spherical head was oriented based on best fit to account for femoral head offset. The ideal wire trajectory was then defined to lie along the axis of the cylindrical neck and extending to the opposite surface of the spherical head. The point at which the wire trajectory intersected the femoral head was defined as the apex.

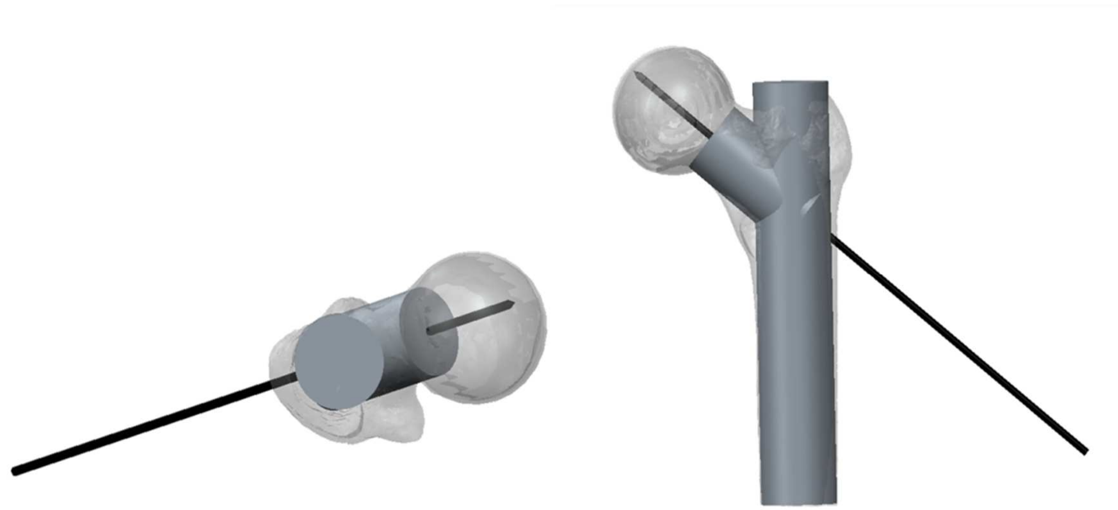


Figure 2. Assembly consisting of femur, 3.2mm wire, cylindrical shaft, cylindrical neck, and spherical head. The wire and cylindrical neck were aligned at a 130° NSA.

2.2.3 Femoral and Wire Transformations

MATLAB (MathWorks, Natick, MA) was used to identify the 3D location of the femur and placed wire. A manual series of [x, y, z] translations and rotations was implemented to closely match the STL femoral model to its fluoroscopic orientation on both the AP and lateral views. The obtained coordinates were run through a CMA-ES (Covariance Matrix Adaptation Evolution Strategy) optimizer to achieve a more accurate fit. The trial wire vector relative to the femur was identified, and its position was triangulated from the two orthogonal views. An optimizer was not used on the wire due to its lack of complex geometry.

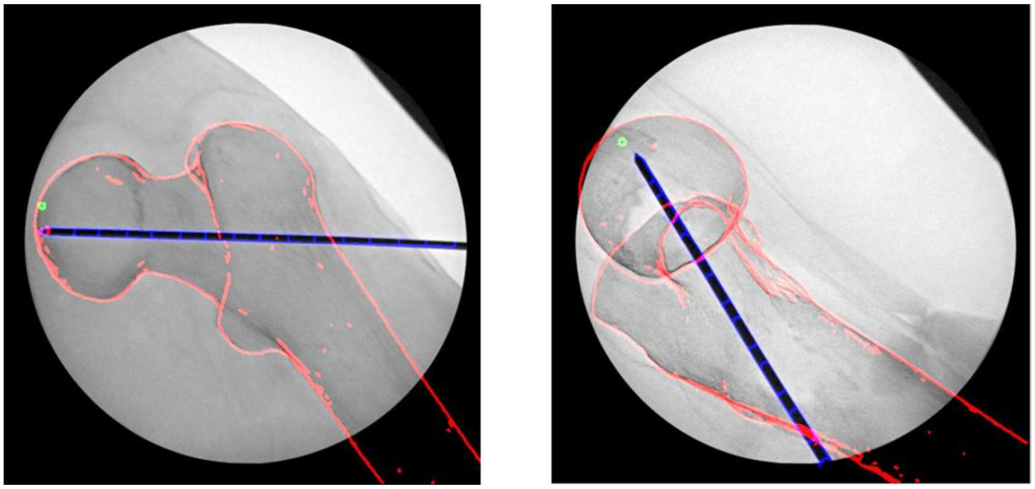


Figure 3. Fluoroscopy images in which the femur and wire have been overlaid with their respective STL models. The green circle represents the apex.

2.2.4 Measuring the TAM

TAM, the average distance between the placed wire and ideal wire trajectory, was calculated in MATLAB. The coordinates of the wire tip and entry into the lateral cortex were identified for both wires. The distance between the two wires was calculated along the length of the placed wire in increments of 0.05mm. To obtain the TAM, the total distance was summed and normalized to account for differences of wire depth into the femoral head.

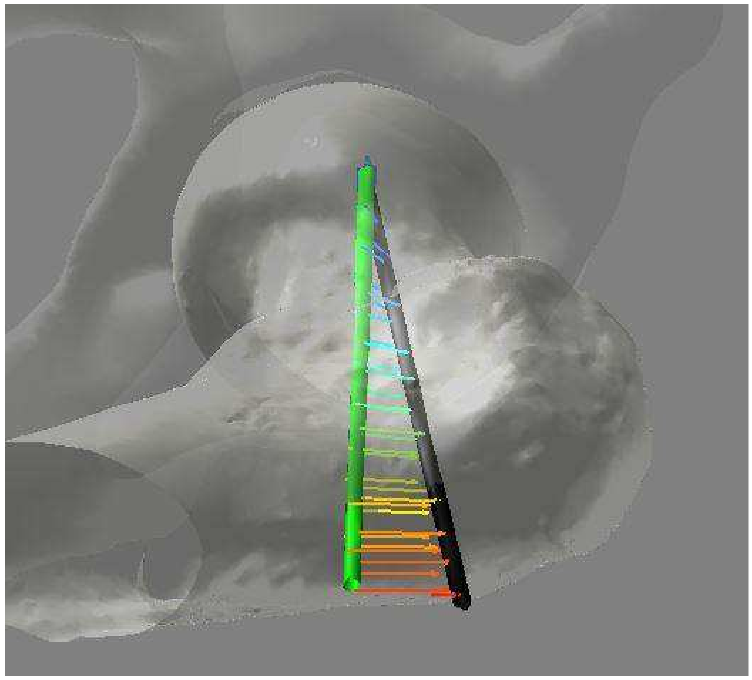


Figure 4. Representation of the TAM calculation between the ideal wire and the trial wire. The ideal wire is green, and the color of the direction arrows indicates the distance from the trial wire (dark blue = 0mm, red > 20mm).

2.2.5 Participants

A group of 24 first-year orthopaedic residents participated in this study, which had been previously reviewed by our Institutional Review Board. Each resident was tasked with inserting a guide wire into a radiopaque synthetic femur encased within a soft tissue sleeve (Sawbones, Vashon Island, WA). Residents were instructed to place the wire as close to center-center as possible to minimize the TAD without piercing the far cortex of the femoral head. A C-arm fluoroscopic system was used to obtain AP and lateral images to assist in placing the wire. Each resident completed this exercise three times with a thirty minute break between trials. The final AP and lateral fluoroscopy images from each trial were saved. TAD was measured on each image in Osirix (Pixmeo, Bernex, Switzerland) using the method described by Johnson et al. [9].

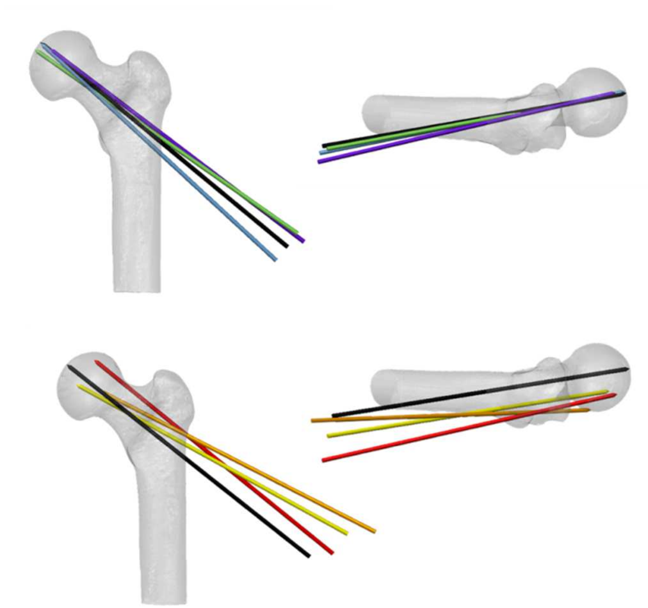
2.2.6 Data Analysis

To determine if TAM and TAD were independent measurements, a Student's t-test was performed in SAS. Statistical significance was defined as $p<0.05$.

2.3 Results

The average TAD for all cases was 21.92mm, with a minimum of 10.16mm and a maximum of 49.60mm. The average TAD for a single resident over their three trials ranged from 11.03mm to 35.68mm. TAD standard deviations of a single resident averaged 5.73mm, with a range of 0.26 to 8.82mm.

The average TAM across all seventy-two cases was 8.62mm, with a minimum of 3.35mm and a maximum of 24.17mm. The range of the average TAM for a single resident was 4.75mm to 15.88mm. TAM standard deviations of a single resident averaged 2.13mm, with a range of 0.26 mm to 8.82 mm.



	TAM	TAD
green	3.35 mm	10.68 mm
blue	3.60 mm	17.67 mm
purple	4.15 mm	24.83 mm
yellow	15.75 mm	32.80 mm
orange	23.79 mm	49.60 mm
red	24.17 mm	30.36 mm

Figure 5. AP and lateral views of three cases with the lowest and highest TAMs and their corresponding TAD measurements.

Table 1. TAM and TAD measurements across each resident's three trials. The three minimum TAD and TAM values are highlighted in yellow, and the three maximum TAD and TAM values are in red. Both measurements are expressed in units of mm.

Subject Number	Trial 1		Trial 2		Trial 3		Average TAM	TAM Standard Deviation	Average TAD	TAD Standard Deviation
	TAM	TAD	TAM	TAD	TAM	TAD				
1	6.74	22.57	24.17	30.36	13.10	22.19	14.67	8.82	25.04	4.61
2	8.58	21.27	4.15	24.83	5.83	26.31	6.19	2.24	24.14	2.59
3	3.35	10.68	6.63	12.24	4.25	10.16	4.75	1.69	11.03	1.08
4	7.28	22.88	7.26	19.08	8.20	15.64	7.58	0.54	19.20	3.62
5	6.51	14.82	6.16	14.12	5.65	21.00	6.11	0.43	16.65	3.79
6	8.82	13.60	8.61	17.78	8.31	22.06	8.58	0.25	17.81	4.23
7	11.33	33.65	7.12	33.61	9.59	21.07	9.35	2.12	29.44	7.25
8	8.11	24.64	15.75	32.80	23.79	49.60	15.88	7.84	35.68	12.73
9	12.18	28.21	9.32	20.63	9.64	20.68	10.38	1.57	23.17	4.37
10	8.17	26.94	7.30	14.69	11.42	26.30	8.96	2.17	22.64	6.90
11	11.17	37.49	9.88	16.22	6.19	14.91	9.08	2.59	22.87	12.68
12	7.74	22.30	7.67	13.68	5.06	15.88	6.83	1.53	17.28	4.48
13	7.64	22.33	7.71	25.00	8.64	12.35	8.00	0.56	19.89	6.67
14	6.67	15.94	4.62	16.38	5.64	20.65	5.64	1.02	17.66	2.60
15	5.93	13.10	8.77	13.08	6.82	18.85	7.17	1.45	15.01	3.32
16	9.76	40.84	6.13	22.33	7.03	27.64	7.64	1.89	30.27	9.53
17	9.52	29.87	9.78	41.64	10.96	31.18	10.09	0.77	34.23	6.45
18	5.85	20.21	6.35	15.82	8.60	15.11	6.93	1.47	17.05	2.77
19	13.06	28.91	11.24	25.96	9.52	15.63	11.27	1.77	23.50	6.97
20	9.33	24.49	5.34	11.65	8.24	14.69	7.64	2.06	16.94	6.71
21	6.92	20.53	7.45	34.89	10.95	19.85	8.44	2.19	25.09	8.50
22	13.60	22.52	6.91	17.69	6.20	19.73	8.90	4.08	19.98	2.42
23	9.61	23.91	7.30	29.11	7.08	16.42	8.00	1.40	23.15	6.38
24	8.11	25.46	3.60	17.67	4.80	11.74	5.51	2.34	18.29	6.88

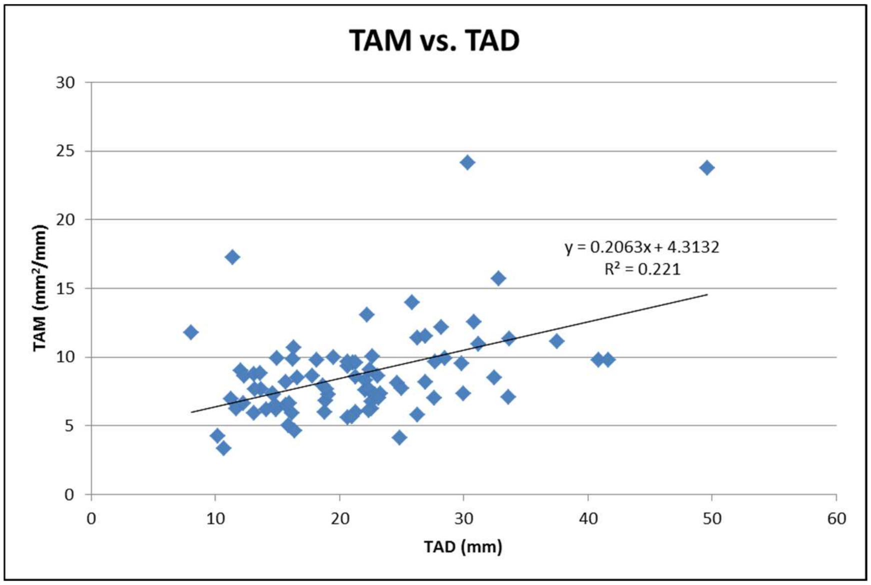


Figure 6. Scatter plot of TAM vs. TAD. The R^2 value is 0.3422, indicating a weak correlation.

A Student's t-test was conducted to determine whether there was a significant difference between TAD and TAM. Significant results were found ($p < 0.0001$), indicating these two measures are independent.

2.4 Discussion

To our knowledge, this is the first instance of exploring guide wire trajectory measurement. An ideal wire trajectory was defined by using a simplified geometrical model and placing the wire at a 130° neck-shaft angle. 3D models were created to represent the femoral and wire positioning on the obtained fluoroscopic images. The ideal wire trajectory was then introduced to these models to calculate TAM, a measurement that was developed to assist with the quantification of guide wire trajectory with respect to an ideal wire position. This value provides an average distance measurement between the trial wire and the ideal wire.

To determine whether TAD and TAM were independent measurements, a Student's t-test was conducted. Significant results were found ($p<0.0001$), indicating that there is a difference between these two measures. Obtaining a low TAD does not necessarily correlate with a low TAM, which was evident in a few select cases.

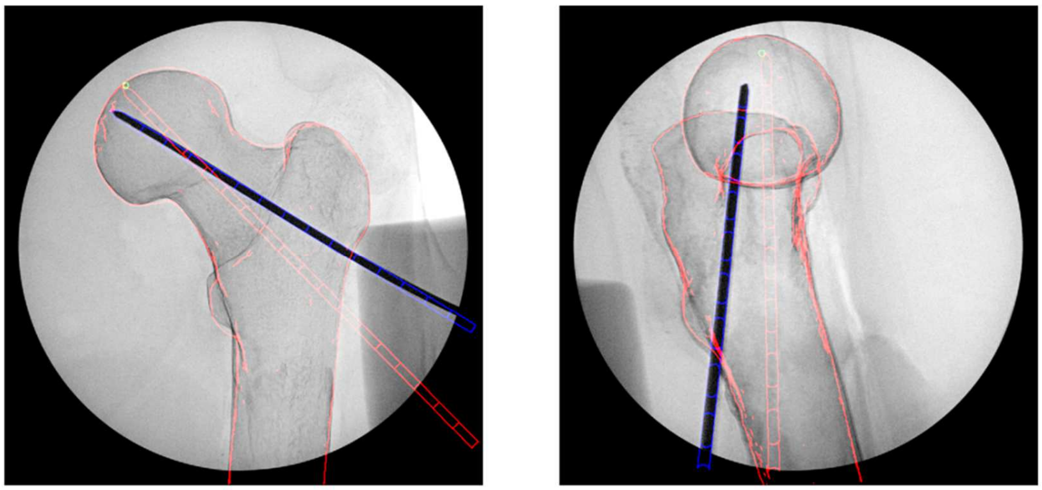


Figure 7. Example of a case with a relatively large TAM (13.60mm) and acceptable TAD (22.52mm). The TAD was within the threshold of 25mm; however, the chosen trajectory came very close to perforating the femoral neck.

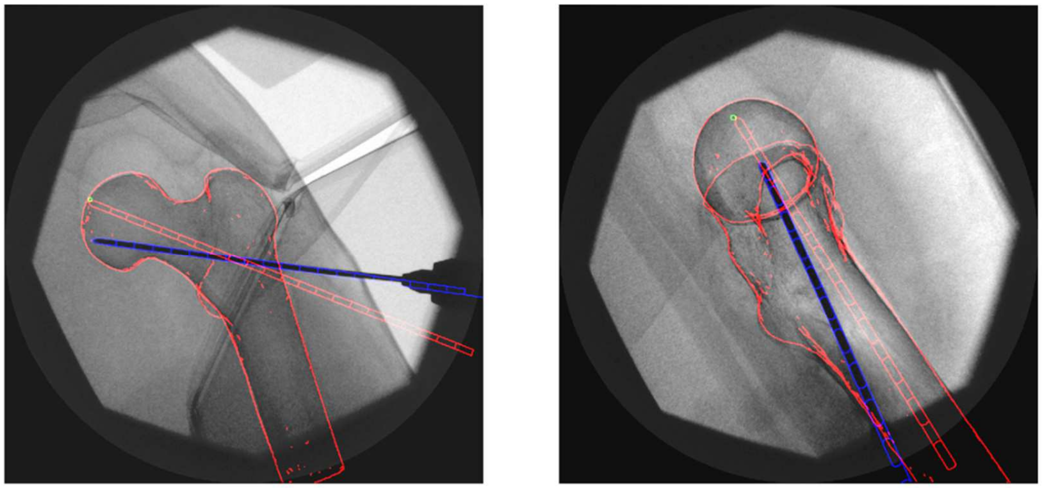


Figure 8. Example of a case with a small TAM (9.78mm) and a large TAD (41.64mm). Since the wire is placed inferiorly and the lateral image is not in an ideal orientation, this results in a large TAD when using the method described by Johnson et al. [9].

Unlike TAD measurements, TAM is not dependent on obtaining an ideal fluoroscopy image with limited internal or external rotation. Since the femur has such a unique geometry, its position can be easily identified on the fluoroscopy image prior to optimization using a series of [x y z] translations and rotations. Interobserver and intraobserver reliability in placing the bone would be a way to ensure the optimizer is providing consistent results. The wire can be placed at the correct location when using both the AP and lateral images, but there is currently no optimization procedure for locating the wire due to its lack of unique geometry. This is the only source of subjectivity throughout the process since TAM is an automated measurement.

Even though a simplified geometrical model was used to define one ideal wire trajectory, it is important to recognize that many trajectories can be used to achieve a TAD of 0mm. Surgeon preference can play a role in defining an ideal wire trajectory. For example, surgeons may want to implant a 135° DHS or prefer a low-center wire placement. Additional studies should be conducted to account for other ideal wire trajectories, even those that deviate from a 130° neck-shaft angle at a center-center position.

There are a number of limitations to this study. First, the wire was not run through an optimizer due to its simple geometry, rendering it unable for MATLAB to assess its depth in the image. In the future, MATLAB code can be used to combine the AP and lateral image to identify the location of the bone and wire in space. Furthermore, this study was restricted by only defining one ideal wire trajectory. A multitude of wire trajectories can be used to obtain a low TAD, so incorporating more wire trajectories into this measuring technique would be beneficial.

There is a lot of potential in expanding this research. Simulators that teach this skill could incorporate TAM, which would be provided as feedback to residents as they are progressing through the simulation. This could be a useful piece of information as residents are learning new surgical skills. Since TAM is quantitative, residents will likely look to improve their TAM as they continue to practice guide wire placement, similar to improving TAD. Furthermore, TAM can be compared between beginners and experts to determine if experience plays a role in minimizing TAM.

In conclusion, this study introduced TAM, a new method of measuring guide wire trajectory, which may be a valuable tool for practicing residents to visualize and quantify the location of the guide wire in respect to the center-center position of the femur. TAM and TAD were found to be independent measurements of guide wire navigation. Further studies need to be conducted to determine and incorporate other ideal wire trajectories and to validate this method of measurement.

CHAPTER 3 – SIMULATOR AND C-ARM EXPERIMENT

3.1 Introduction

Intertrochanteric fracture fixation is a common surgery and is therefore an important skill for surgeons to master. The first step of this surgery involves drilling a guide wire through the femoral neck and head to create a path for the cannulated screw, and obtaining an acceptable TAD is crucial to reduce the risk of complications or screw cut-out. Despite the importance of this surgery, there has been a downward trend in the number of surgeries performed by surgical residents. Surgeons are spending less time in the OR, and this directly results in decreased surgical experience and competence. Due to this trend, more institutions are gravitating toward the benefit of surgical simulation. Simulation enables surgeons to acquire skill outside of the OR and allows them to practice in a low-pressure situation, providing them with time to think through the process and reflect on their surgical technique [7]. Simulation is also thought to improve a surgeon's accuracy, which is important when aiming for a low TAD and a minimal number of wire insertions all while avoiding drilling the wire into the joint space [17-19]. Additionally, some simulators mimic the surgery without the use of fluoroscopy, which is advantageous in limiting radiation exposure to the surgeon.

This preliminary study explores whether guide wire navigation skills obtained during simulator use will transfer over to a similar, fluoroscopy-based experiment. It has been hypothesized that surgical skills will improve from trial to trial on the fluoroscopy-based experiment. However, the most significant improvements, in particular time and number of fluoroscopy shots requested, will occur immediately after simulator intervention. Furthermore, a new method of measuring TAD has been introduced to incorporate a 3D apex location, and it has been hypothesized that this method will decrease the variability of both interobserver and intraobserver measurements as compared to the standard measurement method.

3.2 Methods

3.2.1 Mock OR Exercise

Twenty-four PGY1 orthopaedic residents from the MOSS Consortium participated in this study. A task to assess guide wire placement in the fixation of a reduced intertrochanteric fracture was developed as a pre-test, mid-test, and post-test to determine improvements throughout the course of the experiment. This exercise was done in a setting that closely resembled the OR to observe if the skill of placing a guide wire would carry over to a similar, intermediate step prior to progressing in the OR.

Synthetic, radiopaque left femurs were placed inside a soft tissue sleeve to represent a supine patient's thigh (Sawbones). This construct was anchored to an adjustable, radiolucent table using ratchet cables. The surgeons were told to treat this exercise as if they were operating on a patient, and they were allowed to palpate the soft tissue sleeve to identify anatomical features. This exercise utilized a fluoroscopic C-arm operated by a radiology technician. The surgeon was able to request AP and lateral fluoroscopic images throughout the procedure; however, they were not allowed to instruct the radiology technician to move the C-arm in any other way. Surgeons used a drill (Stryker, Kalamazoo, MI) and a custom-threaded 3.2mm diameter guide wire. They were not permitted to use any other surgical devices to place the guide wire, such as an angle guide, and were instructed to place the guide wire as close to center-center as possible to obtain a low TAD. The synthetic femur was replaced after every trial to prevent surgeons from using a previously drilled hole.

Figure 9. Set-up of the mock OR experiment.

3.2.2 Surgical Simulator

A low-cost, radiation-free simulator was developed for surgeons to practice their guide wire insertion skills in a safe and stress-free learning environment. It uses a camera and image processing to display a virtual depiction of the position of the wire, which has been custom-etched with a binary pattern, in relation to the femur. A custom-made soft tissue sleeve (Sawbones) encompasses the synthetic femur, and it contains a slit to mimic an incision and provide a starting point for the practicing surgeon. The surgeon can request either an AP or lateral shot, which is subsequently displayed on the adjacent laptop. For beginners, there is a training mode available containing feedback for improving their performance, such as suggesting to drop their wrist to account for femoral anteversion, and a green shaded area of acceptable wire positions for the surgeon to understand that there are a multitude of correct trajectories to minimize TAD. In this experiment, the simulator was training surgeons to insert the wire at a NSA of 130° to minimize TAD. The laptop display, regardless of beginner or expert training mode, provides the surgeon with metrics including TAD, time, and number of shots requested. The metrics are updated with every shot taken. Once the surgeon is finished with the procedure, these parameters are aggregated into a final score.

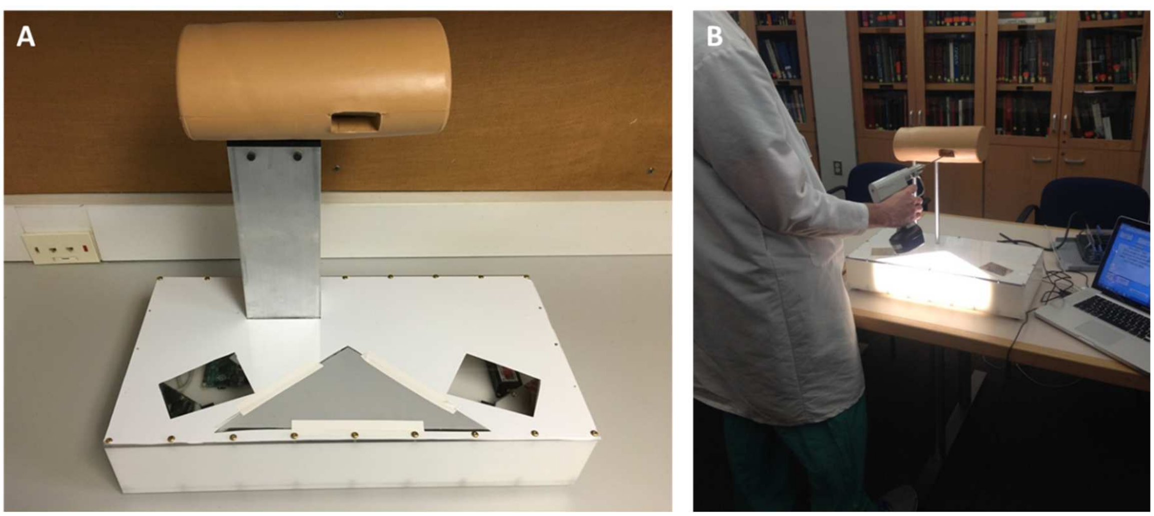


Figure 10. Fluoroscopy-free simulator. A: The hardware is contained in the white box, and the femur is encompassed by the soft tissue sleeve. B: Resident using the simulator.

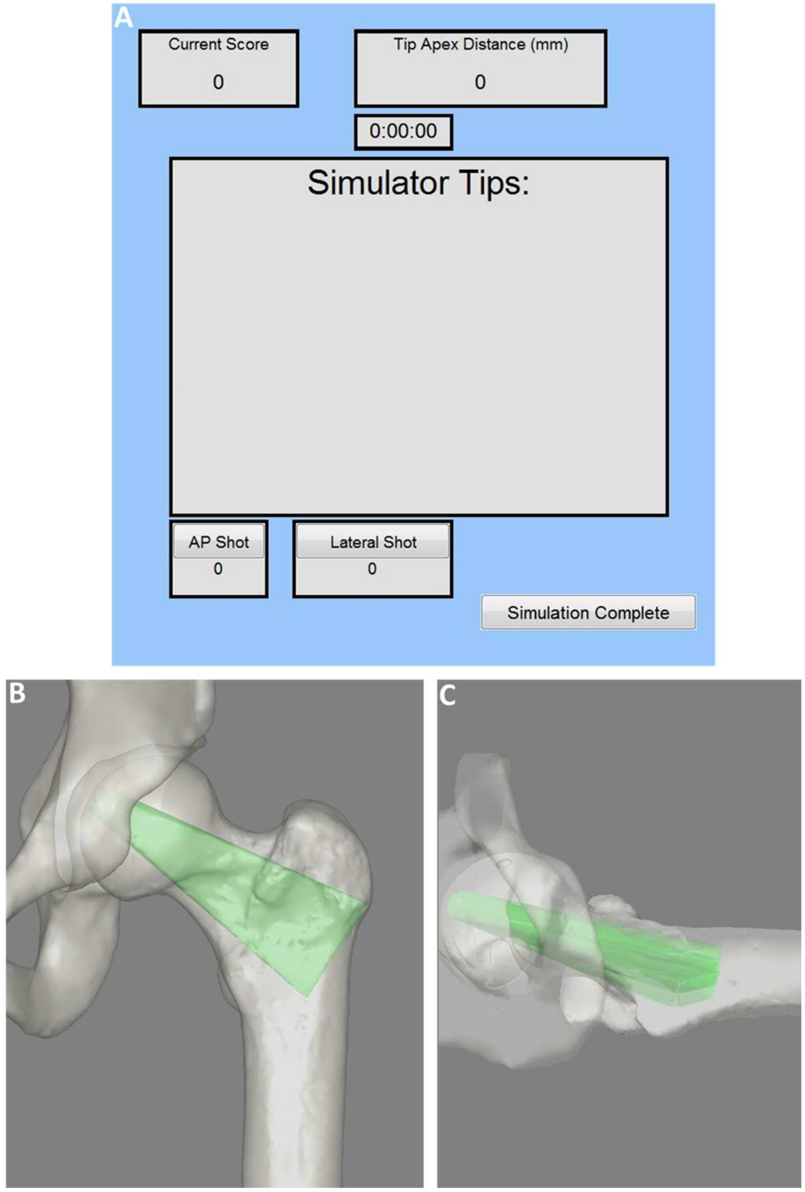


Figure 11. Output images of the simulator, which are displayed on an adjacent laptop. A: Screenshot of the feedback provided to the surgeon. B: AP image display. C: Lateral image display.

3.2.3 Experimental Design

Prior to the experiment, the surgeons were given a brief introduction of the exercise. They were told the most important metric was TAD; however, they should also try to minimize all other metrics while placing the wire in a center-center position. Each surgeon completed a total of three trials in the mock OR (15 minutes each to allow ample time to place one guide wire) and one training bout with the simulator (30 minutes to provide enough time for at least 4 trials). Surgeons would first complete a pre-test in the mock OR (Trial 1) to provide a baseline of their skill. A cross-over experimental design was implemented in which half of the surgeons were randomly assigned to use the simulator between Trials 1 and 2, and the other half used the simulator between Trials 2 and 3. Finally, each surgeon completed a post-test (Trial 3). All images obtained from the mock OR and the simulator were saved for analysis. A paired t-test was used to analyze the data in SAS to determine if significant improvements occurred over the resident's three trials or immediately after simulator use.

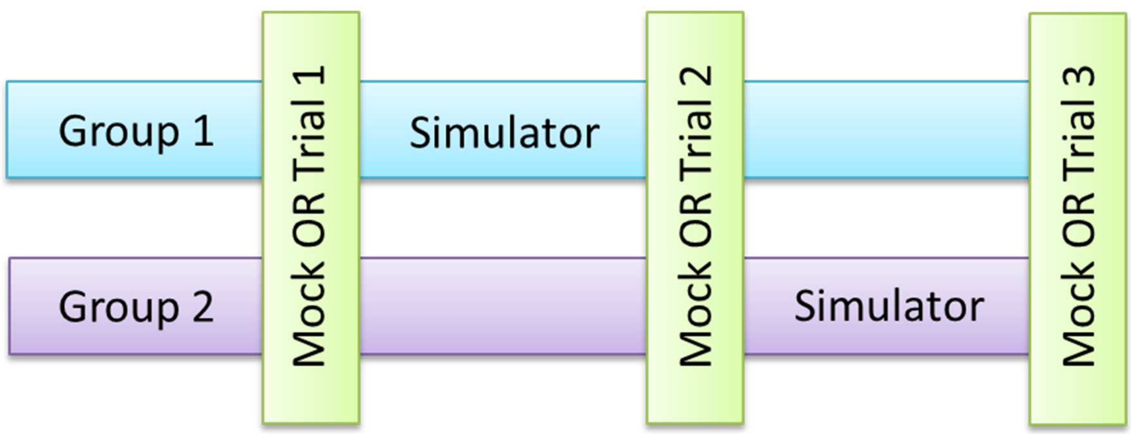


Figure 12. Cross-over experimental design for the mock OR and simulator exercises.

3.2.4 Defining the Apex

The apex was defined using the methodology described in Section 2.2.2. In addition to creating an apex at a 130° NSA, an additional apex was created at a 122°

NSA to observe how TAD measurement varies when the apex is defined in a different location.

3.2.5 Femoral and Wire Transformations

MATLAB was used to manually position the femur, wire, and 130° NSA apex STL models to match the orientation on the fluoroscopy images, as described in Section 2.2.3. Once the optimized coordinates were found, the image was saved as a DICOM. The 122° NSA apex model was then loaded into MATLAB, using the same optimized coordinates of the bone and wire. The resulting image was also saved as a DICOM.

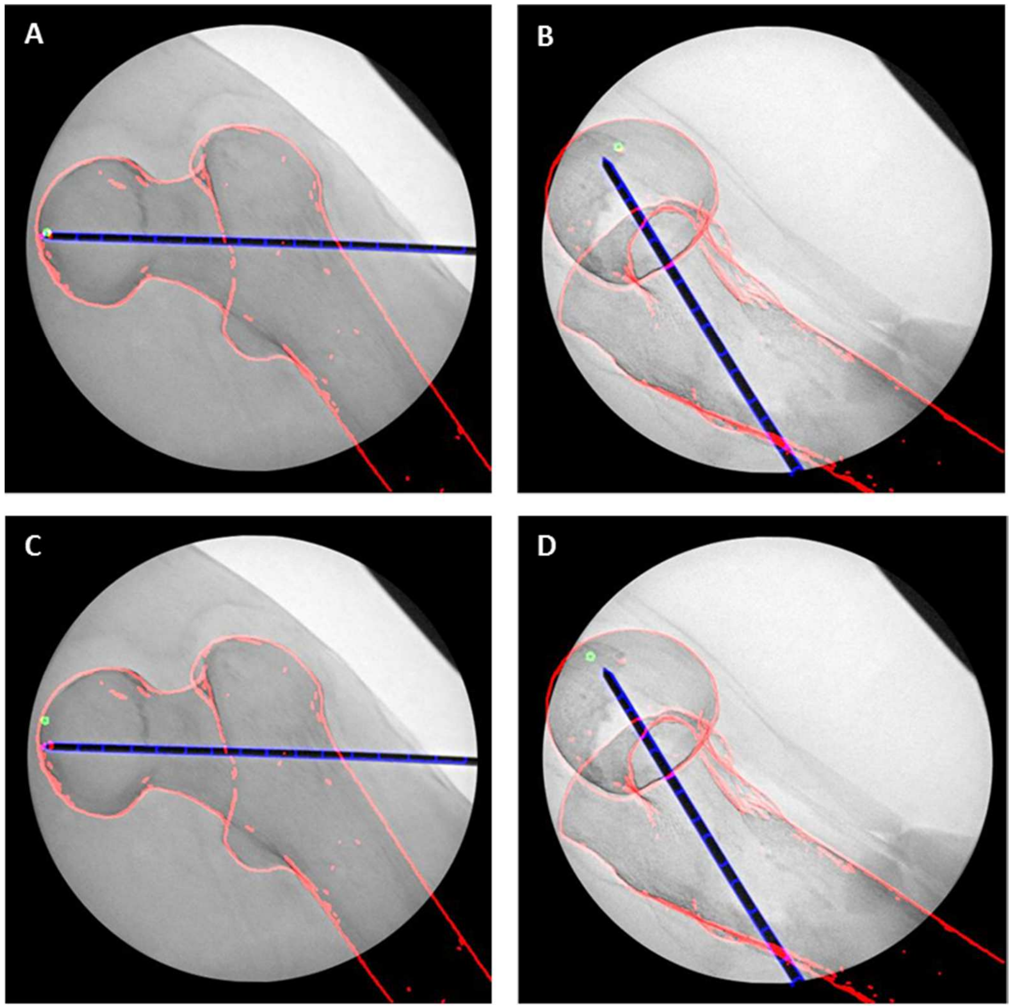


Figure 13. Fluoroscopy images overlaid with the femur, wire, and apex STL models. The green circle represents the apex. A and B: AP and lateral images with the apex placed at a 122° NSA. C and D: AP and lateral images with the apex placed at a 130° NSA.

3.2.6 Measuring TAD

Osirix (Pixmeo, Bernex, Switzerland) was used to obtain TAD measurements. For each trial, two individuals independently measured three different apex placements: using the method described by Johnson et al. [9], a straight-line distance with the apex at 122°, and a straight-line distance with the apex at 130°. A straight-line distance involves first calibrating the image and then simply drawing a line from the tip of the wire to the center of the apex. Both individuals were given a brief overview of the correct measuring technique for each method. The individuals measured each apex placement twice, and these measurements were taken one week apart. For each form of measurement, the intraobserver variance was assessed by taking the difference between the two measurements. The interobserver variance was evaluated by taking the difference between the minimum and maximum measurements. The obtained TAD measurements were analyzed in SPSS using the intraclass correlation coefficient (ICC).

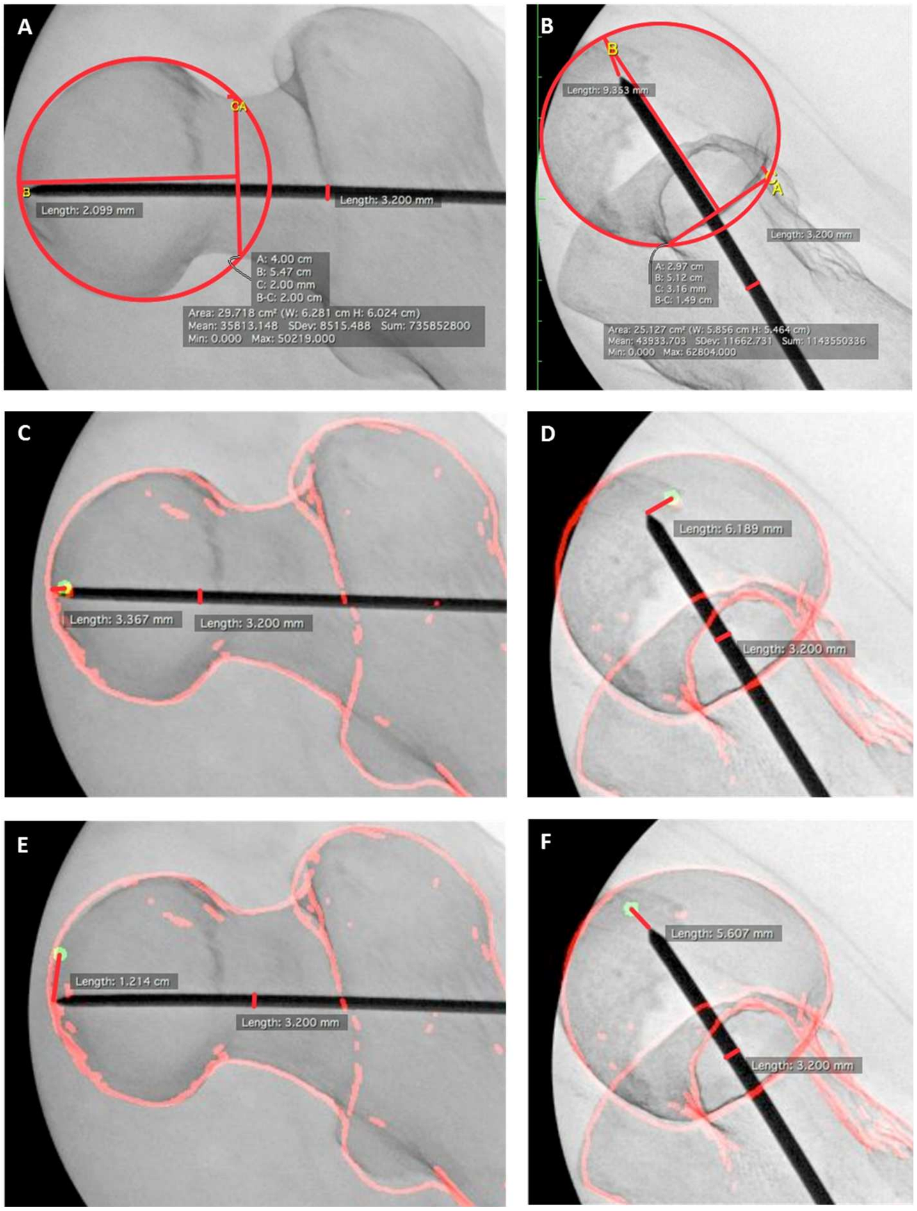


Figure 14. TAD measurements in Osirix. A and B: Using the technique described in Johnson et al. C and D: Apex at 122°. E and F: Apex at 130°.

3.3 Results

3.3.1 Mock OR Experiment

Statistically significant improvements in time and number of shots requested were found among all residents (Groups 1 and 2 combined) when comparing Trials 1 and 3 (p

< 0.05). Group 2 also demonstrated significant improvements in time. When comparing results before and after simulator intervention, significance was seen among all residents in the number of shots requested. Improvements in time were trending toward significance (p = 0.069).

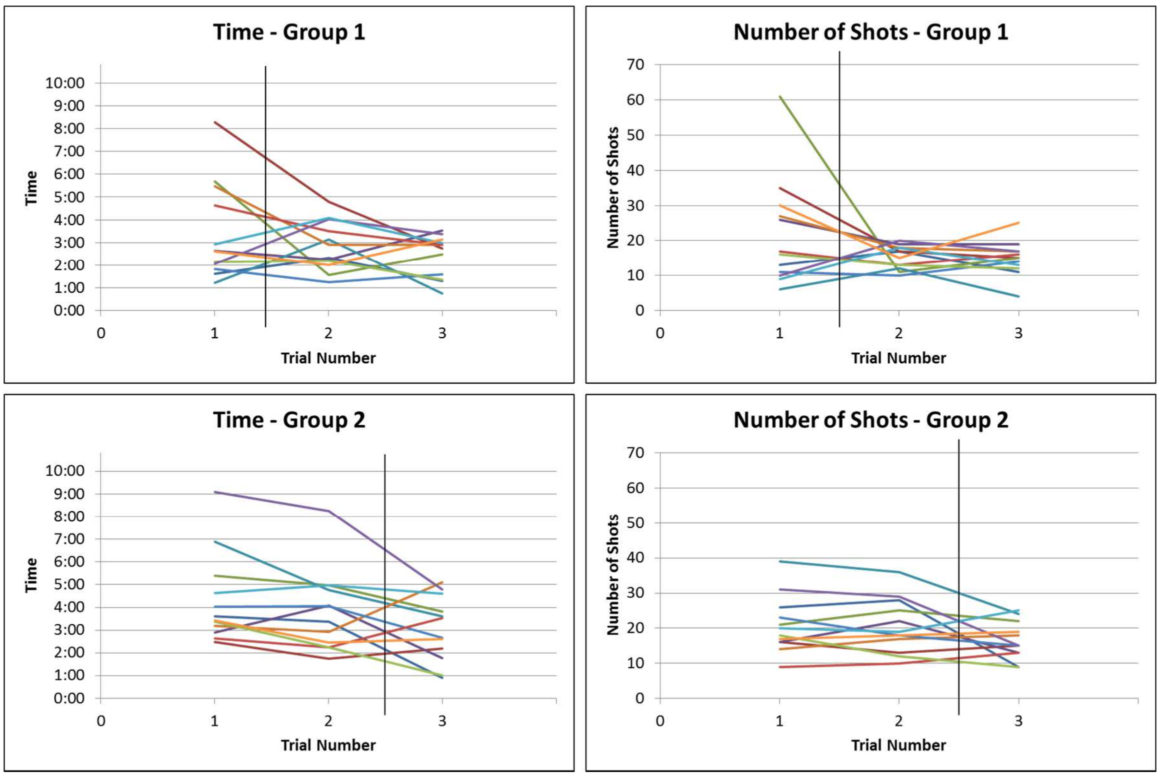


Figure 15. Time and number of shots requested during three trials of the mock OR experiment. The vertical line represents simulator intervention.

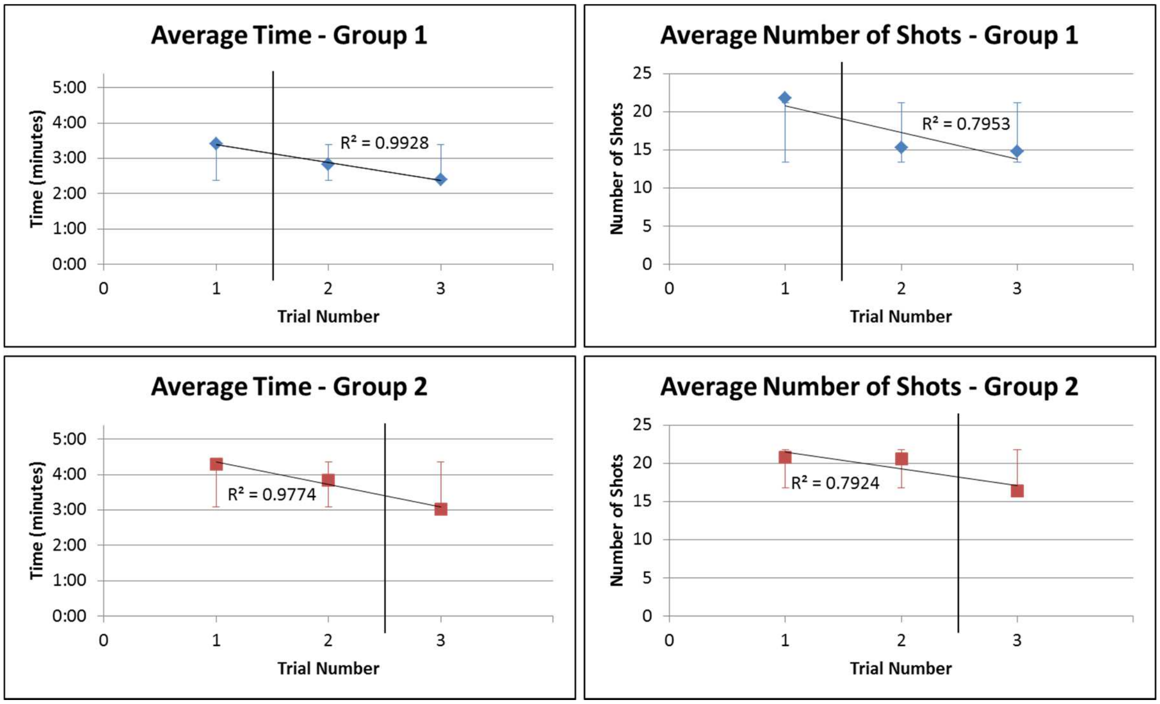


Figure 16. Average time and number of shots requested for each group throughout the mock OR experiment. The vertical line represents simulator intervention. Error bars of one standard deviation are displayed.

Table 2. P-values obtained from a paired t-test in SAS. Statistical significance is denoted in yellow ($p < 0.05$).

	P-values for Trials 1-3			P-values for Pre vs. Post Simulation		
	Group 1	**Group 2**	**Groups 1 and 2**	**Group 1**	**Group 2**	**Groups 1 and 2**
Time	0.094	0.031	0.0049	0.33	0.12	0.069
Shots	0.12	0.091	0.023	0.20	0.088	0.048
TAD (standard)	0.11	0.40	0.12	0.69	0.86	0.67
TAM	0.99	0.98	0.98	0.89	0.40	0.60

3.3.2 TAM and TAD

No distinguishable trends could be seen from the TAM or TAD data. There was no significance in either group when comparing the TAM or TAD over all three trials or when comparing trials before and after simulator intervention.

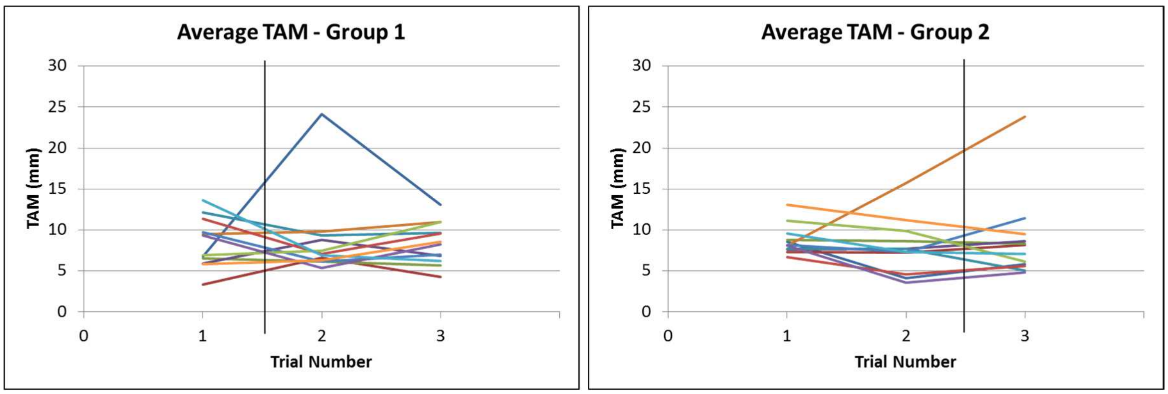


Figure 17. Average TAM measurements for each trial of the mock OR experiment.

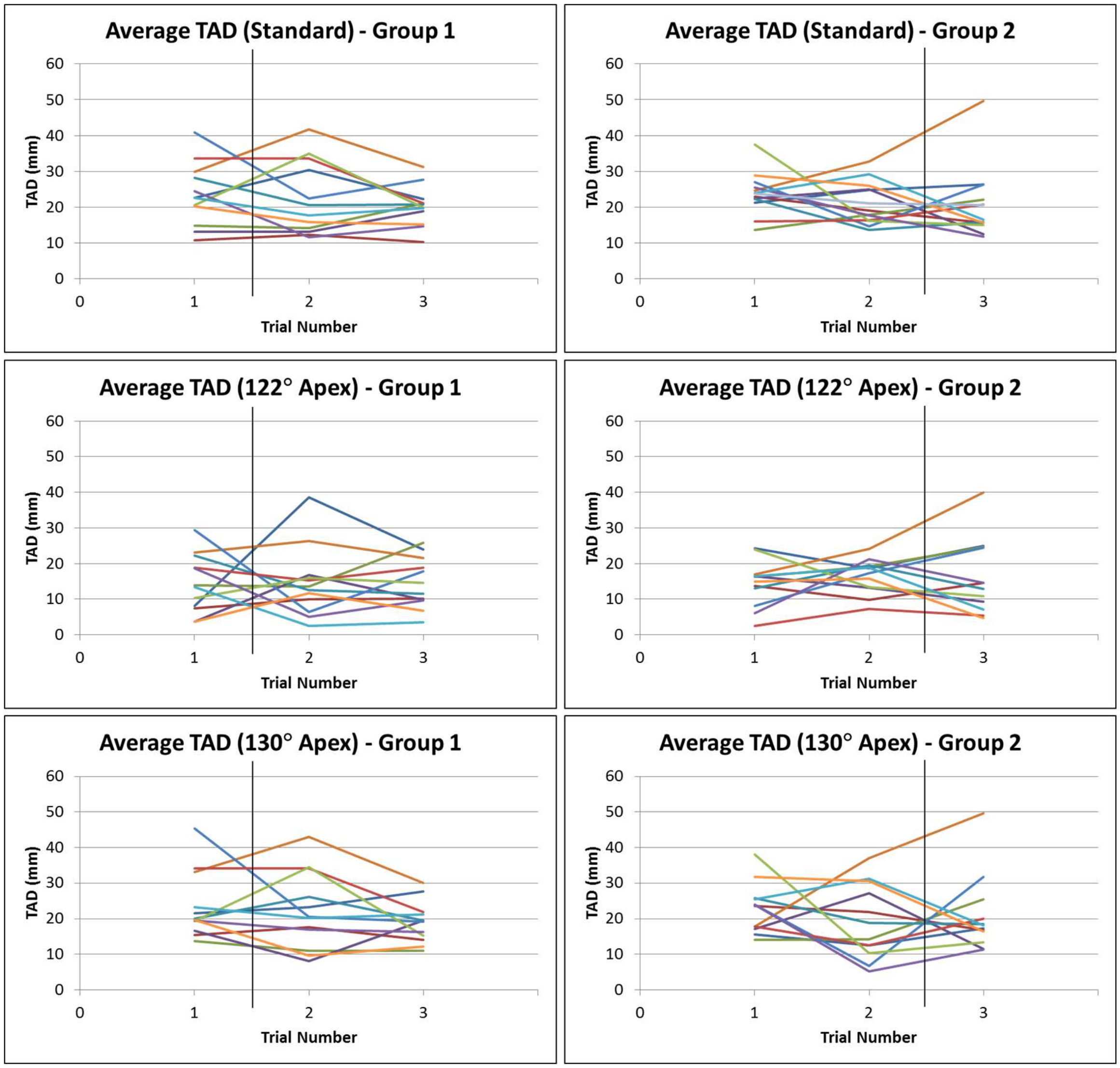


Figure 18. TAD measurements taken after each trial of the mock OR experiment.

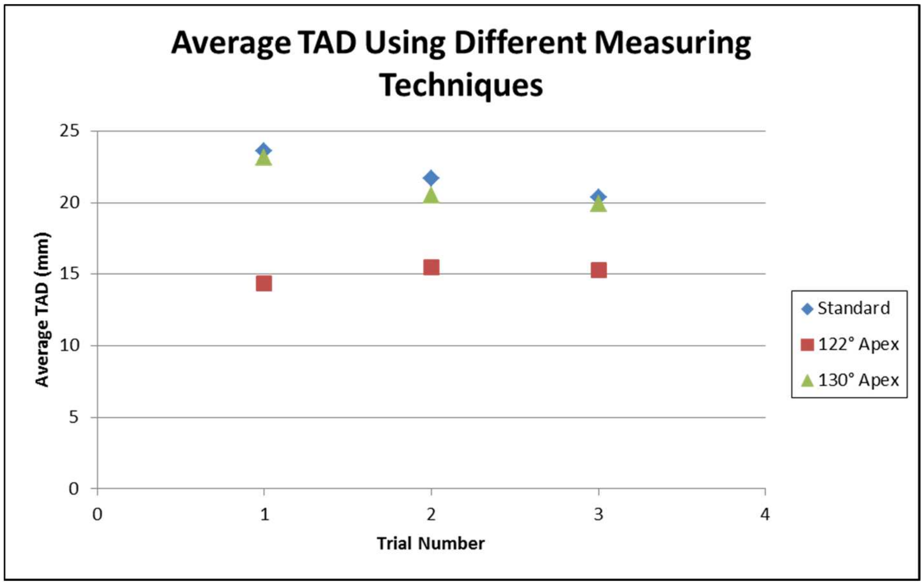


Figure 19. Chart depicting the average TAD measurement by trial based on the measuring technique used.

The standard method of measuring TAD was found to have a wider range of values for each individual case, therefore causing greater variability between both intraobserver and interobserver measurements. Once the apex was defined at a fixed location (either at 122° or 130°), the results were less variable. Additionally, ICC was used to assess intraobserver variability, and the value increased with the presence of a defined apex which indicates better reliability.

Table 3. Intraobserver differences in TAD measurements. All measurements are in mm.

		Standard	**122° Apex**	**130° Apex**
Individual 1	**Avg Difference**	1.51	0.50	0.65
	Min Difference	0.08	0.00	0.01
	Max Difference	10.04	2.52	3.91
Individual 2	**Avg Difference**	1.20	0.53	0.61
	Min Difference	0.03	0.02	0.02
	Max Difference	4.66	3.39	2.30

Table 4. Interobserver differences in TAD measurements. All measurements are in mm.

	Standard	122° Apex	130° Apex
Avg Difference	2.81	1.07	1.31
Min Difference	0.76	0.15	0.17
Max Difference	10.36	3.61	3.91

Table 5. Single ICC to analyze intraobserver reliability.

	Standard	122° Apex	130° Apex
Individual 1	0.968	0.995	0.993
Individual 2	0.981	0.993	0.996

3.4 Discussion

The goal of this preliminary study was to determine if skills obtained during guide wire navigation practice on a radiation-free simulator would translate over to a setting that utilized a C-arm and closely resembled the OR. A cross-over experimental design was used in which half of the residents would use the simulator between Trials 1 and 2 of the mock OR exercise (Group 1) and the other half would use the simulator between Trials 2 and 3 (Group 2). When comparing Trials 1 and 3, significant improvements in time and the number of shots requested were found among all residents. Significant improvements were also found in the number of shots when comparing trials immediately before and after simulator intervention. Although time was not found to be significant, it was approaching a significant result ($p = 0.069$).

Neither group demonstrated significant improvements in TAD or TAM throughout the experiment. This could be due to the fact that recommendations for TAD simply define the gold standard as less than 25mm [1]. There is currently no evidence that even smaller TAD measurements are correlated to decreased risks of screw cut-out.

Some residents may have recognized that they were within the threshold of an acceptable TAD and chose to stop advancing the guide wire to avoid perforating the femoral head and being exposed to unnecessary radiation. Residents were instructed to place the wire at a center-center position but were not told to insert the wire at a 130° trajectory to minimize their TAM, which may explain the lack of significant results for TAM.

Despite the presence of specific guidelines to measure TAD, it is a fairly subjective measurement that can be prone to inaccuracies. In fact, Baumgaertner reported the interobserver variability to be as high as 10% [1]. In this study, different forms of measurement and apex locations yielded different TADs, demonstrating that TAD is quite dependent on the specific measuring technique and location of the apex. While defining a specific apex location on the bone decreased the variability for both interobserver and intraobserver measurements, some variability still remained. ICC was calculated to determine the amount of intraobserver reliability. On average, ICC increased and approached a value of one when the apex was defined, indicating a near-perfect reliability. This does not account for possible intraobserver error, but since each rater was given a brief overview of correct measuring technique prior to obtaining TAD measurements, this should not be an issue. The variability between the three different measuring techniques was large, meaning that additional testing needs to be done to further validate this technique of measuring TAD and verify which measurement best predicts screw cut-out. Furthermore, since the introduced methods involve a 3D apex location, a new gold standard may need to be identified. This study did not explore if TAD changes with the orientation of the femur, which would be a valuable piece of information as this research progresses forward.

The amount of time spent with the simulator was a large limitation in this study. Some residents showed obvious improvement after using the simulator; however, this may have simply been transient since they had no further exposure to the simulator after the experiment. On the contrary, some residents did not show improvement throughout the course of the experiment. If residents were able to practice on the simulator daily for a period of two weeks, a more significant trend toward improvement of all metrics may have been visible over time. A retention test could also be implemented to determine if skills obtained from the simulator were retained. Even though minimizing TAD was stressed as being the most important metric, some residents tried to "game" the system and instead tried to achieve the best time. This caused them to place less emphasis on TAD, and in turn, may have skewed the results. An additional limitation was the number of residents that participated in the experiment. Adding more subjects to the study will hopefully display a more prominent trend in the results.

The fluoroscopy images obtained during this experiment, especially the lateral, were not in an ideal orientation. The lateral shot gave a false impression of the femoral head border, causing some residents to accidentally drill into the joint space. The residents were not permitted to instruct the radiology technician to move the C-arm in any way except switching between AP and lateral shots because the exercise was purely meant to test guide wire insertion skill. The images used in this experiment may have also had an effect on the resulting TAD measurement when using the method described by Johnson et al. [9]. A linear relationship had been previously reported between the amount of internal or external rotation and the resulting TAD, and the rotation present in the fluoroscopy images may have caused an overestimation of TAD [14]. Although the fluoroscopy shots may not have been ideal, it was still a valuable exercise because surgeons often times have to work with the shot they are given in the OR.

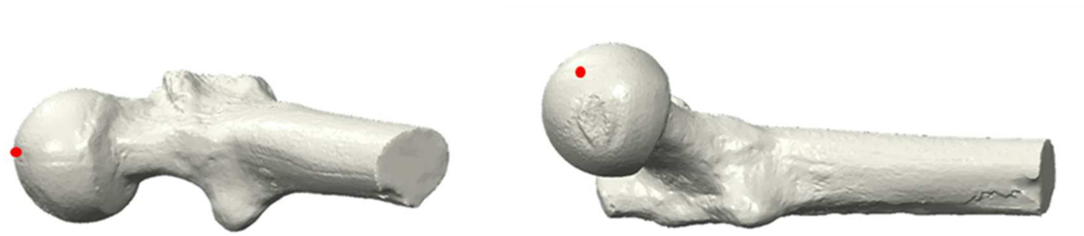


Figure 20. Ideal lateral (left) vs. obtained lateral (right). The apex is shown in red.

Some significance was found with carryover of surgical skills, most notably in the procedural time and number of shots requested. However, no significant improvements were seen in TAD or TAM. More subjects and a refined experimental design will hopefully demonstrate more significant improvements in the mock OR experiment after simulator use.

CHAPTER 4 – EXPANSION OF RESEARCH INTO SIMULATOR AND OR

4.1 Introduction

The research of defining a new method to quantify guide wire trajectory and locate the apex on the femoral head can potentially be expanded into both the simulator and OR, providing surgeons with valuable information that can assist them in their practice. Additionally, its application has the possibility to expand past intertrochanteric fractures to other fractures that utilize the skill of guide wire navigation.

4.2 Simulator Applications

Adding guide wire trajectory feedback into the simulator would be of extreme benefit for residents as they are practicing guide wire navigation. In addition to metrics that are displayed on the laptop and updated after each fluoroscopy shot, an ideal wire trajectory could be shown relative to the chosen trajectory. A color map could be incorporated to display the distance from ideal at different points along the wire, and TAM can be displayed on the screen and updated with each subsequent shot. This may help the resident obtain a better understanding of how their chosen trajectory deviates from an ideal trajectory.

Since there are a variety of wire trajectories that can be used to successfully place the guide wire, the simulator can prompt the user by asking for the trajectory in which they are aiming. For example, the simulator could provide the option of a low-center trajectory or a trajectory at a 135° NSA. A training mode could first display the ideal wire trajectory for the user to learn how to place the wire correctly, and this feedback could be taken away as the simulation becomes more advanced. Additionally, changes could be made to the current shaded region that indicate acceptable wire placement. A range of trajectories that represent a TAD of less than 25mm and are contained within the femoral neck can be defined, and the shaded region can be updated to only include trajectories that fall within this criteria.

4.3 OR Applications

Expanding these methods into the OR, particularly redefining the femoral head apex, may prove to be very beneficial for surgeons. Since the current method of measuring TAD may be prone to inaccuracies, surgeons could use this approach to identify a specific 3D apex location, thus leading to a more accurate and less variable TAD measurement to assess the risk of screw cut-out. Furthermore, they could use these tools to create 3D models of both the bone and implant. This could be an important learning instrument as they are able to visualize a computer-generated model with the capability of comparing and quantifying implant placement to their intended wire trajectory.

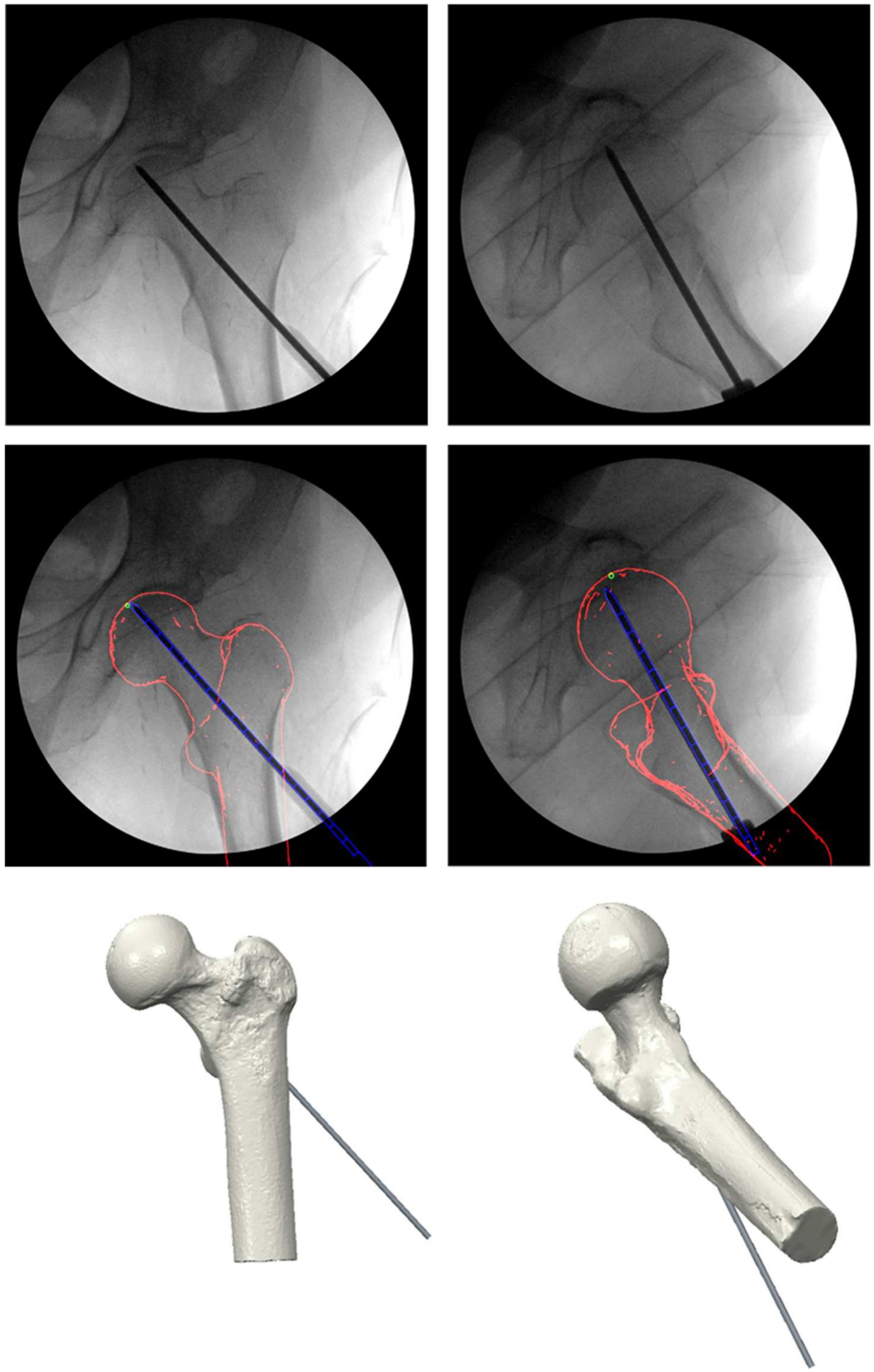


Figure 21. AP and lateral views of femur and wire alignment in an OR case.

Despite the application of these techniques into the OR, there are a few limitations. One of the biggest limitations is the fact that each individual's femur is a slightly different shape. The Sawbones femoral model is simply a representation of one femur – it does not account for individual differences in femoral geometry. This can cause variability when trying to fit the idealized femoral model to the fluoroscopy image obtained in the OR. Additionally, the intensity of bone on the fluoroscopy image is not as prominent as that of the synthetic femur, so it can be difficult to observe its outline. The presence of surgical instrumentation in these images can make this task even more difficult. Due to the lack of contrast, the MATLAB code used to identify and enhance the edges of the image also has a difficult time detecting the periphery of the femur, resulting in a weak outline. Furthermore, the models of OR cases would include a fracture, which is something that was not addressed in this study. It was assumed that the intertrochanteric fracture was successfully reduced, but this is not always the case in the OR. More work needs to be done to determine how to best model these fractures and how the ideal wire trajectory and TAM changes with each case.

In regards to the C-arm experiment, more participants and a refined experimental design are necessary to determine whether there is a significant transfer of skill after using the simulator. Once this is concluded, this experiment can be expanded to determine if skill obtained from the simulator transfers over to the OR.

These techniques can be expanded beyond intertrochanteric fractures since guide wire navigation is a universal skill. Other measurement techniques of different fractures, analogous to TAD for femoral fracture fixation, can apply the approach of 3D location placement to obtain a less variable measurement. Similarly, other fracture fixation procedures that utilize guide wires will most likely benefit from quantifying wire trajectory for surgeons to gain an understanding of how their chosen trajectory deviates from ideal.

CHAPTER 5 – CONCLUSION

The aim of this study was to define new techniques of guide wire navigation performance in the fixation of intertrochanteric femoral fractures. To our knowledge, there have been no prior studies that explore the significance of guide wire trajectory or attempt to quantify it. A new method called TAM has been introduced to quantify the average distance of a guide wire trajectory from an ideal trajectory. The ideal trajectory was defined by using simple geometry to model the femur, and it was placed in a center-center position through the femoral neck and at a 130° NSA. We believe that this is a useful and novel measurement, especially for residents looking to improve their wire navigation skills without having to rely on a variable measurement such as TAD. Further studies should be completed to incorporate other ideal wire trajectories into the calculation and validate this method.

A preliminary study was developed to determine if surgical skills obtained by means of a simulator could carry over to a scenario that closely resembled the OR. When comparing Trials 1 and 3 of the mock OR experiment, statistical significance was found in both the time and number of shots requested. Significant improvements were also found in the number of shots taken prior to and immediately following simulator intervention. No significance was found in TAD or TAM. The next step in this study is to improve the experimental design in hopes that deliberate practice with the simulator over a given amount of time will correlate with a significant improvement in metrics including procedural time, number of shots requested, TAD, and TAM.

This study also examined the current method of TAD measurement, which can be subjective and variable. A new technique of defining the apex was introduced to obtain a more accurate measurement, and this was found to decrease both the amount of interobserver and intraobserver variability compared to the standard measurement of TAD. However, the measured TAD was found to be dependent on the location of the apex. Further studies should be done to determine the exact location of the apex, and a new value may need to be redefined as the gold standard to avoid screw cut-out.

We believe that these techniques have the potential to be important learning tools to incorporate into the simulator and in the OR. If TAM was incorporated into the simulator, residents would be able to quantify guide wire trajectory with respect to ideal as it progresses upward through the femoral neck and into the femoral head, which could supplement their guide wire navigation skills. Using a new and less variable method of measuring TAD can be utilized in the OR as a predictor of screw cut-out; however, further studies need to be done to determine the most accurate placement of the apex. Furthermore, guide wire trajectories can be used by surgeons to analyze and critique their guide wire placement after surgery. Similar to TAD, there may even be a specific guide wire trajectory that is a predictor of screw cut-out, so this is definitely an area that warrants more exploration.

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