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Novel Tissue Analogue Model for Training Percutaneous Nephrolithotomy

2014 Endourology Society Summer Student Scholarship
Summary Report

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Background

Percutaneous nephrolithotomy (PCNL) was a revolutionary minimally invasive technique for treatment of large kidney stones. Gaining percutaneous access to the kidney is one of the most challenging aspects of the procedure. To facilitate training, Dr. Clayman first introduced the use of a porcine model[1] which demonstrates the importance of simulation from the time that the procedure was first introduced.

Since that time, there have been many simulators designed for training various components of percutaneous renal access. Animal models using chicken and/or porcine tissue [2,3,4] and virtual reality simulators[5] have been reported in the literature.

One component of the PCNL procedure that requires considerable skill is the needle insertion step. Gaining renal access during the PCNL procedure is a challenging task that, if done incorrectly, has the potential to damage the kidney and adjacent structures.[6] The learning curve for the PCNL procedure has been determined by multiple studies and overall it has been shown that competence is achieved in 45-60 procedures and more than 100 cases are needed to achieve 'excellent' results.[7]

The University of Minnesota SimPORTAL designed the C-arm Trainer (CAT) for training the concept of parallax for obtaining access for PCNL.[8] The camera system used for this simulator allows for visualization without the need for fluoroscopy. This is good for training purposes, but increases the design requirements of the model in that the materials used must be translucent to allow for the camera to visualize the needle and calyces filled with dye.

One aspect of the existing PCNL trainer that required investigation and improvement was the amount of force used for needle insertion. Subjective feedback from users revealed that the force required to insert the needle may be too high in the existing model which causes low ease of use and the possibility of negative skill transfer. Accurately replicating the forces used during the actual procedure requires characterization of needle insertion forces in human tissue. This human tissue data can then be used as a guide for the simulator design process of a new prototype model that more accurately represents the needle insertion forces used during the actual PCNL procedure. Needle insertion into soft tissue and synthetic materials has been extensively studied in the fields of medicine and engineering and many tissues have been characterized using various methods.

Objectives

The two main objectives of this project included:

- Characterization of forces encountered by the needle during percutaneous renal access in human cadaveric tissue.
- Creation of simulator prototype model that more accurately replicates needle insertion forces compared to existing version of the SimPORTAL physical simulator model for training PCNL.

Materials and Methods

Force Measurement Device

A force measurement device was designed and built in order to measure needle insertion force with a predetermined displacement (Figure 1). The overall design allowed the device to be portable and included a vertical stage and adjustable horizontal stage as well as 360° lockable rotation platform. The rotational platforms were used to connect the vertical stage to the base and the vertical stage to the

horizontal stage to allow for angle adjustment during the needle placement. Control of the stage displacement was accomplished through a MATLAB GUI and force measurements were obtained using a 10 kg load cell.

Human Tissue

A fresh cadaver was obtained through the University of Minnesota Anatomy Bequest Program and data collection was completed within 72 hours of death. The cadaver was placed in the prone position. A foley catheter was placed and water was used to fill the bladder and create hydronephrosis via retrograde flow. This was necessary for visualization of the renal pelvis on ultrasound as well as to provide confirmation of renal access through flow out of the needle hub.

Before using the force measurement device (Figure 1), we placed "guide" needles to provide a reference for needle positioning and angle (Figure 2). The guide needles were placed by a practicing urologist using ultrasound guidance. Because the device inserts the needle at a fixed starting position and angle, the guide needles were used as a reference so that the needles would be directed into the renal pelvis during each trial without adjustment after the insertion started. Renal access was confirmed by water flow out of the needle hub. The overall set up is shown in Figure 3. Force and displacement of the needle were recorded by the force measurement device as the needle passed through all tissue layers from the skin to renal pelvis.

After the needle insertion, a wire was passed through the needle lumen to mark the needle path for later dissection steps (Figure 2). Each wire was marked with a trial number. Five trials were performed on the left and right for a total of 10 trials.

Following the completion of the needle insertion trials, tissue layers were dissected and distance along the path of needle insertion was measured to allow for the forces obtained during needle insertion to be matched to the tissue layer that was perforated. Figure 4 demonstrates an example of dissection down to transversalis fascia on the left side.

Simulator Model Design

In order to develop a new simulator model, needle insertion data needed to be collected on the synthetic materials. Three different set ups were used to test the synthetic materials.

The first set up involved inserting the needle horizontally into a material block (Figure 5). Many potential materials were tested using this method; however, the two most relevant materials for this project were the clear silicone used in the existing and new version of the PCNL trainer, and a soft silicone that was integrated into the new version of the model.

The second set up was used to test the polyacrylamide copolymer cubes that were used in the new version of the model. The cubes are commercially available and begin as small cubes that grow to a larger volume when placed in water (Figure 6). When fully saturated, the cube edges disappear in water, and the individual cubes cannot be seen (Figure 7). This facilitates the use of the preexisting fluoro-less camera system. The cubes were tested at various ratios of starting material to water in a fixed volume container. The ratio we used was 1 cube:10 mL distilled water. The force measurement device arm was placed vertically and inserted into a container holding the polyacrylamide cubes at a fixed volume (Figure 8). The needle was passed through a small hole made in the plastic wrap covering the top of the container so that that the covering would not contribute to the measured force.

Once the synthetic materials were tested and compared to the human tissue data, specific materials were chosen for the three main layers of the new version of the PCNL model and a prototype model was built. (There were actually four prototypes built, but for simplicity, only the final prototype will be discussed). The model consisted of an outer silicone shell with the calyces (Figure 9) suspended inside (Figure 10). The polyacrylamide cubes were placed in between the shell and calyces and expanded in water to represent tissues between the skin and kidney capsule. The outer part of the shell was covered with a silicone material that was a soft enough durometer to seal back up after the needle was inserted and pulled out. After the new prototype was completed, the third force measurement set up was used to test the new version of the PCNL model as a whole (Figure 11). The needle was inserted through all layers and the forces were recorded.

Results

There were many pieces of data collected throughout this project. However, the data that is most relevant to demonstrating our objective is shown in Figure 12. This figure shows the force of needle insertion plotted against the depth or displacement of needle penetration into the tissue. The data in red represents 10 trials performed on clear silicone material used in the existing version of the PCNL trainer. The data in yellow represents the human tissue, and the data in blue represents the new prototype of the PCNL simulator that was developed during this project. The large peak marked with an asterisk represents the force required to perforate the skin in the cadaver and corresponds to the peak in force when perforating simulated "skin" in the new version of the model.

Discussion

The results of this project provide evidence for the improved accuracy of needle insertion forces in the new version of the PCNL training model. In the existing version of the model, subjective feedback from users aligns with the evidence shown from the force experiments in that, much higher forces are required for the material as compared to the human tissue. In the new version of the model, we were able to simulate a peak in force corresponding to the skin and also when perforating the kidney capsule. These peaks were achieved when the needle moves through the silicone and into the polyacrylamide cubes. As shown in Figure 12, the new version of the model does not have as much of an increase in force when the needle is passing through the polyacrylamide cubes as compared to the human tissue (seen between 3-8 cm). This will be a focus of future work in looking at different types of polyacrylamide hydrogels and also different levels of water saturation of the gels to adjust this parameter.

An additional advantage of using the polyacrylamide cubes is that the needle tracks from previous insertions cannot be seen. This was a challenge in the existing version of the model and using a material that does not show previous attempts is advantageous from both a cost and ease of use perspective.

One worry that we had during the design process was that using water with the polyacrylamide cubes would cause leakage out of the model after needle perforation. However, we found that there is no leakage. Another challenge is the fact that air bubbles are sometimes present in between the polyacrylamide cubes, which slightly disrupts the picture captured by the cameras. This challenge will

be a focus in the future, but may be solved using alternative filling techniques or positioning of the model.

In the future, additional trials need to be completed to discern the forces needed to perforate each individual tissue layer in the cadaveric study. The testing protocol will be revised and the next steps for this research include trying to accurately represent the forces of more tissue layers other than the skin and kidney capsule.

Conclusion

We were able to successfully create a new physical simulator model for training PCNL that more accurately simulates the needle insertion forces encountered in human tissue. Characterization of force data supports this claim and this higher level of accuracy will increase ease of use and decrease the possibility of negative skill transfer.

Figures

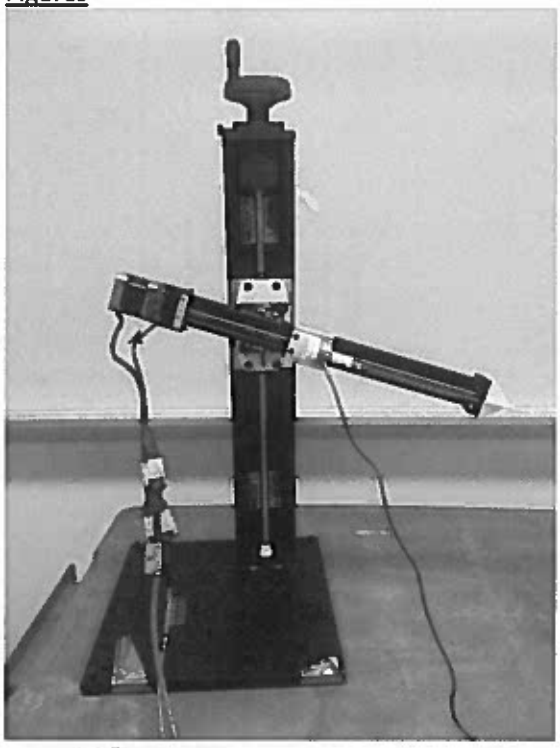

Figure 1. Force measurement device.

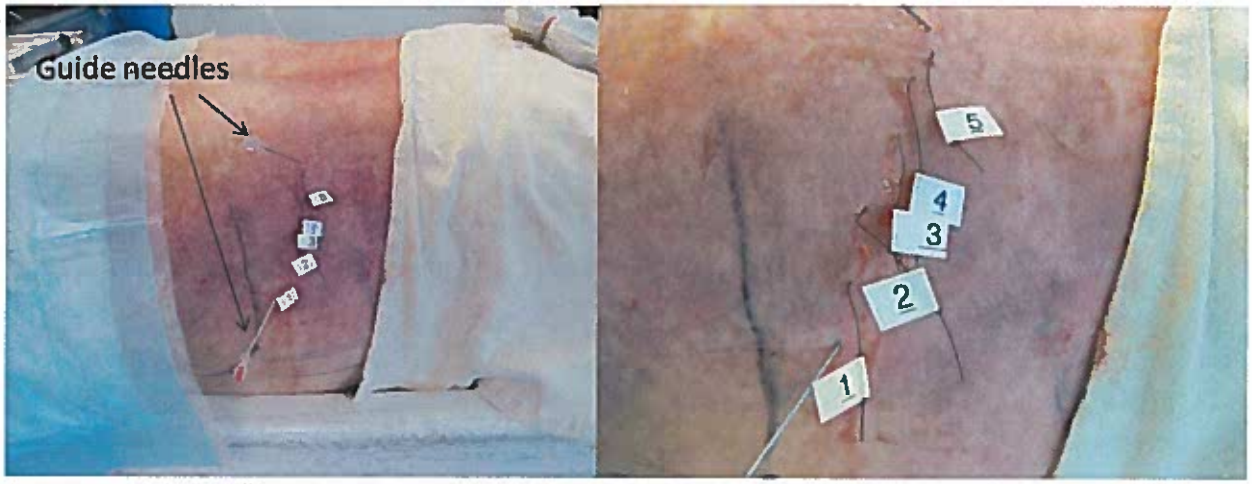

Figure 2. Guide needles and needle insertion trials 1-5 (right side) marked with wires for later dissection.

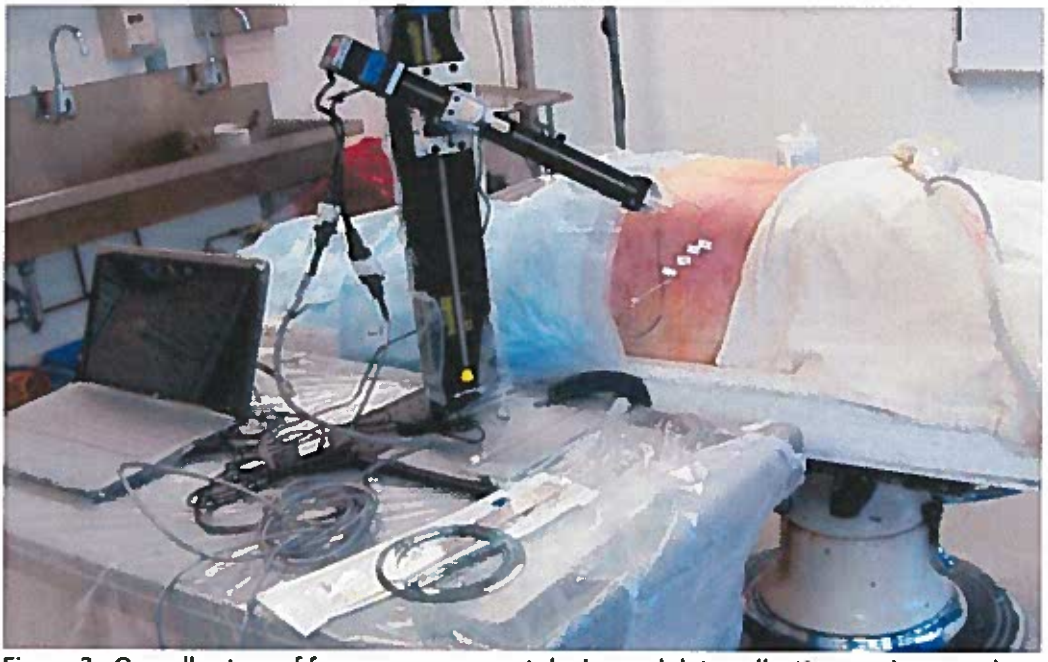
Figure 3. Overall set up of force measurement device and data collection equipment alongside cadaver.

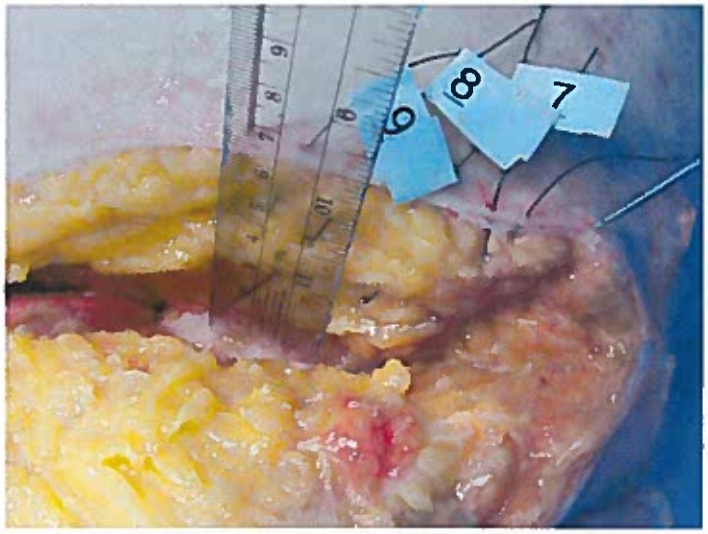

Figure 4. Dissection and measurement down to transversalis fascia for trials 6-10 (left side).

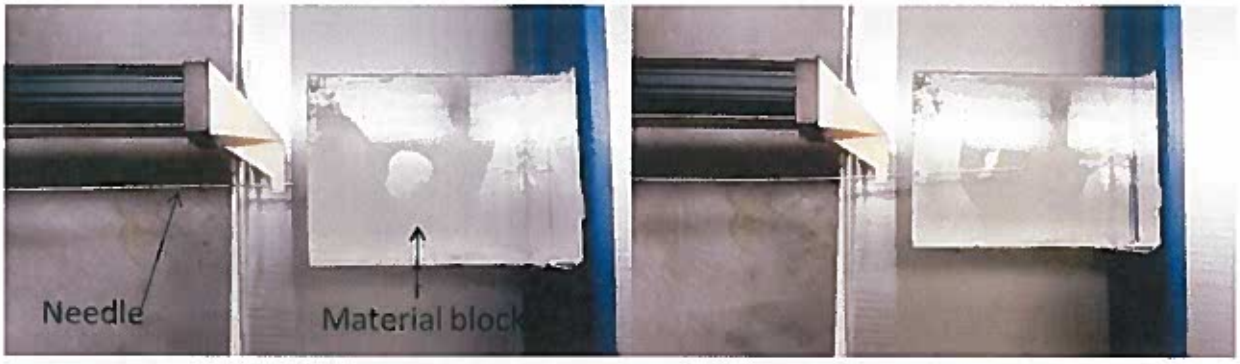

Figure 5. Needle displacement and force measurement into synthetic material block.


Figure 6. Initial, intermediate and final sizes of polyacrylamide cubes after being placed in distilled water.

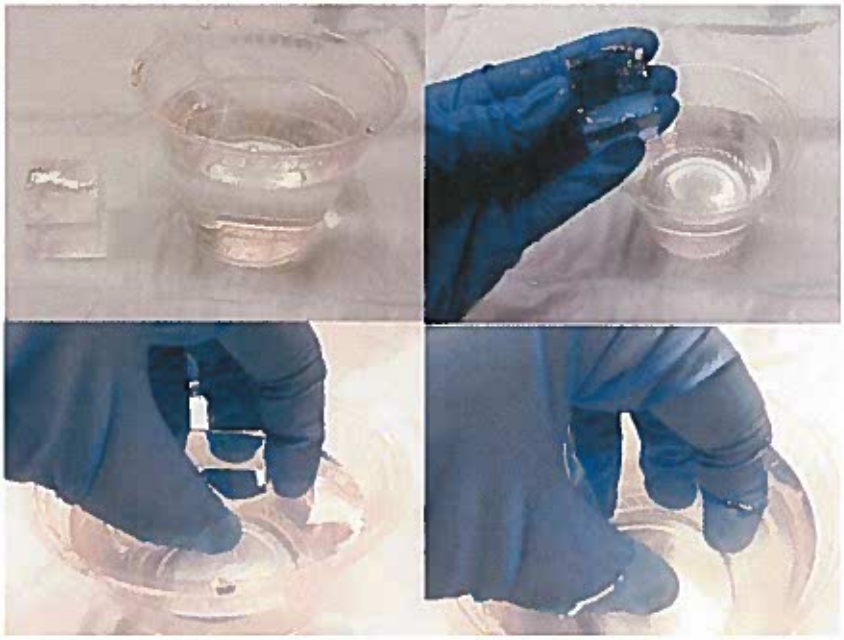

Figure 7. Demonstration of translucency of cube when placed in water.

Figure 8. Needle insertion test set up for polyacrylamide cubes.

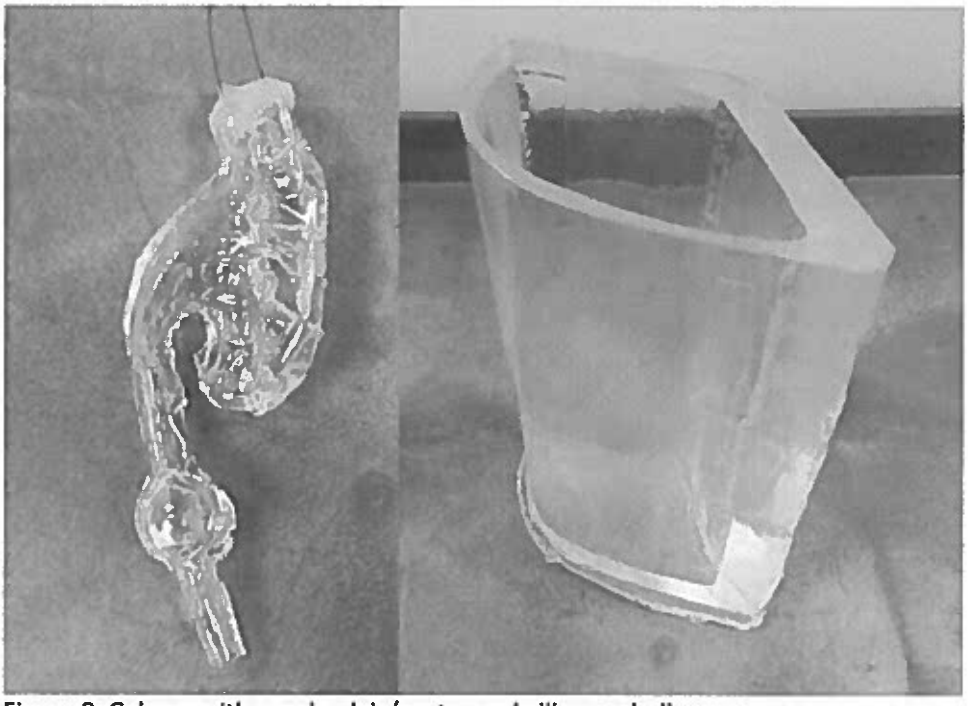

Figure 9. Calyces with renal pelvis/ureter and silicone shell.

Figure 10. Calyces/renal pelvis/ureter suspended within silicone shell by polyacrylamide cubes.

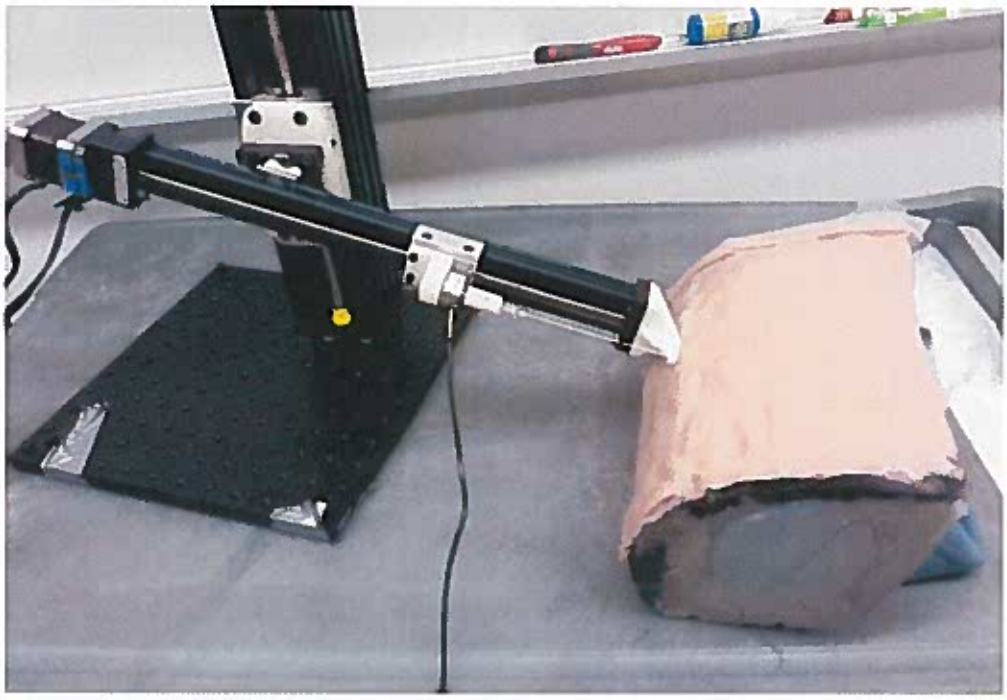

Figure 11. Force measurement set up.

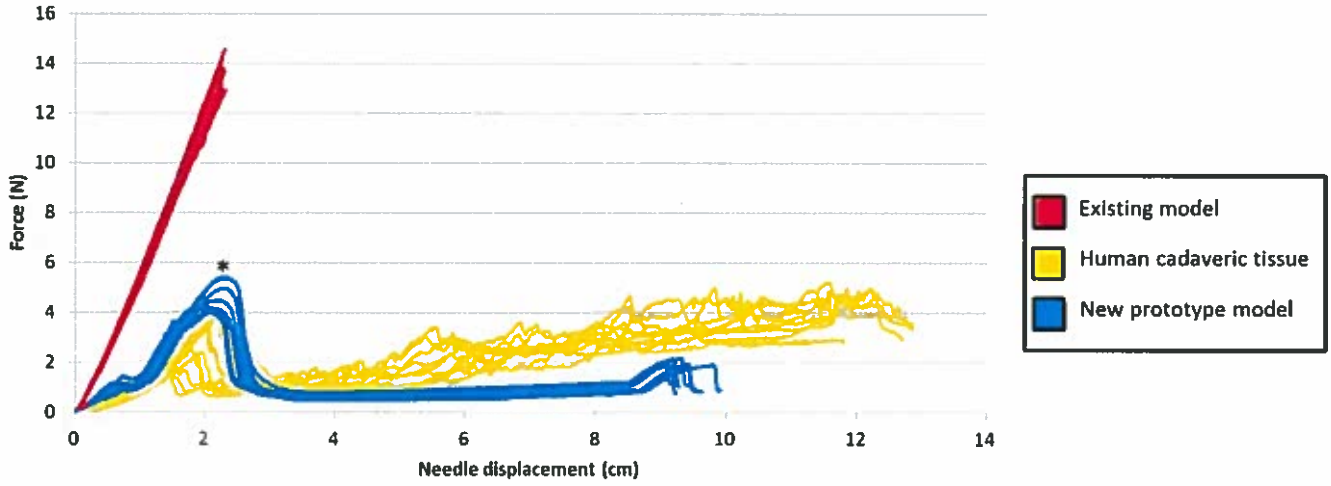

Figure 12. Force vs. needle displacement into synthetic material or human cadaveric tissue.

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