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A PEDIATRIC SUPRACONDYLAR HUMERUS FRACTURE WIRE NAVIGATION SIMULATOR

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ABSTRACT

Trainees in orthopedic surgery are required to receive dedicated laboratory-based surgical skills training in their first year of residency. Simulators are often used in this training. Our group previously developed a hip fracture wire navigation simulator to train and assess skill in placing a K-wire within a femur bone surrogate using synthetic fluoroscopic images to aid in navigation. In this paper, we describe design considerations and challenges in modifying the existing simulator to enable the training of multi-wire pinning of a pediatric supracondylar humerus fracture. The design involves changing the bone of interest from the adult femur to the pediatric humerus, while using the same platform technology. Considerations include ease of use, minimizing motion of the fixed bone, and minimizing materials used. The robustness of the bone mounting was tested by running an experiment using 3D scans and surface deviation analysis to test repeatability of bone placement and its resistance to rotational motion after being placed in the fixture. After the new design was shown to hold the bone rigidly, a pilot study of the new simulator was conducted to confirm that the surgeons and residents consider the simulator experience as being a valid representation of the actual surgical skill.

INTRODUCTION

Orthopedic residents receive dedicated laboratory-based surgical skills training in their first year of residency [1]. Surgical simulators are used by many programs to fulfill these training requirements. Our research group previously developed a simulator to train surgeons on the task of hip fracture wire navigation and demonstrated that training with the simulator can improve surgical performance in a mock operating room [2,3]. Simulator users drill their wire into a foam femur model (Sawbones, Vashon Island, WA) which is housed inside a soft tissue-mimicking shell (Figure 1). Computer generated fluoroscopic images of the anatomy and the wire properly located in space are produced by an integrated camera system and image processing techniques. The simulation includes an automated scoring system to consistently assess the user's performance.

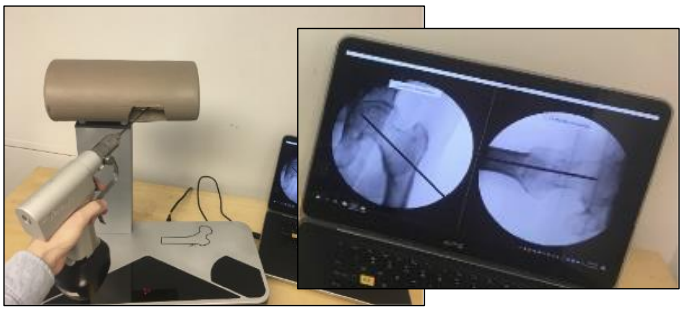

Figure 1: (left) The hip fracture wire navigation simulator in use. The laptop shows simulated fluoroscopic images (magnified in inset to right) presented to the residents as they drill in bone.

Key components of the simulator include the base that houses the stereo pair of cameras, the vertical mast, and the surrogate of the anatomy of interest fixed to the top of the mast. The two cameras in the base create a 3D working envelope where their fields of view intersect. The position of the bone on the mast must allow for all possible wire locations to be within the working envelope of the cameras while in use.

Another surgery that relies heavily on wire navigation skills is the pinning of pediatric supracondylar humerus fractures, the most common pediatric fracture treated surgically. Treatment involves placing three diverging stainless-steel pins across the fracture site. The surgeon tries to maximize the spread of the pins

to achieve superior mechanical stability. There is a concern that the gap between surgeons who can and cannot adequately treat these fractures is increasing [4].

To address the widening gap in skill, our group has adapted the platform of the hip fracture wire navigation simulator to train residents on wire navigation for treating pediatric elbow fractures. After a new module was prototyped, we were interested in how receptive the surgeons were to the new simulator. A pilot experiment was conducted with this new design involving 4 residents and 4 staff surgeons at the University of Iowa. Participants were then surveyed to learn their opinions about the face validity of the simulator (Figure 2). Residents were asked how well the simulator represented the surgical challenges of navigating wires when treating pediatric elbow fractures and responded with an average score of 4.5/5.

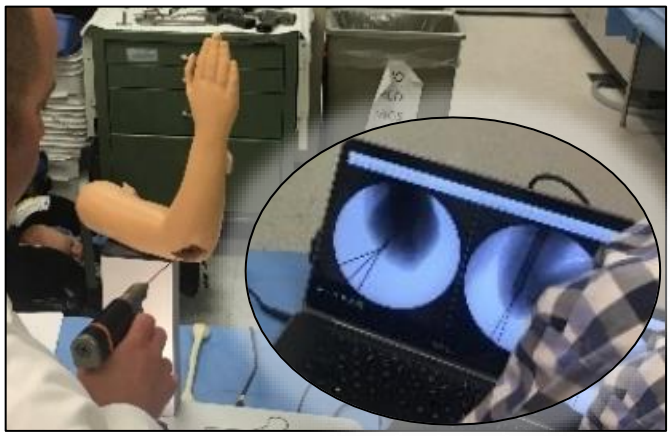

Figure 2: The prototype simulator in use. On the screen of the laptop are the generated corresponding synthetic fluoroscopic images (zoomed in inset image for sake of visualization).

Although this survey confirmed the face validity of the pediatric elbow fracture pinning simulator prototype, there were several concerns with its design. One concern was that swapping out replacement bone surrogates was cumbersome. Another was poor control over the precise placement of each new bone surrogate in the prototype. The final concern was that because of the relative slimness of the pediatric bone surrogate, there was risk for too much deflection of the bone during simulator use, which could cause a mismatch between the actual and system-assumed position of the bone. This paper presents the ensuing design process used to further develop the new module.

METHODS

The design modification involved replacing the vertical mast of the adult hip fracture wire navigation simulator to accommodate a pediatric humerus. There was no change in the way that the mast is affixed to the simulator base or to the simulator elements inside the base. With this design, the procedure being simulated can be varied by simply swapping out different masts.

The original prototype of the pediatric simulator featured a clam shell-like fixture for the entire humerus bone model (Figure 3). The bone was located in space so that all plausible wire positions would fit inside the working envelope of the simulator. Although the design functioned properly, it had several drawbacks. The shell that held the bone in place was 3D printed and designed to have full surface-to-surface contact to secure the bone. The placement of the bone inside this shell was somewhat ambiguous because there were not enough features on the surface of the bone to hold it rigidly in the same position each time a new replacement humerus was introduced. It was also cumbersome to replace the bone after each use, needing to unscrew and re-attach two wingnuts each time. The design used an entire humerus model from Sawbones, when the region of interest is only the distal end, adding unnecessary costs. The last concern was that the fixture design did not fit into the Sawbones soft tissue pediatric arm model used. Extensive design modifications were needed to be able to use this model.

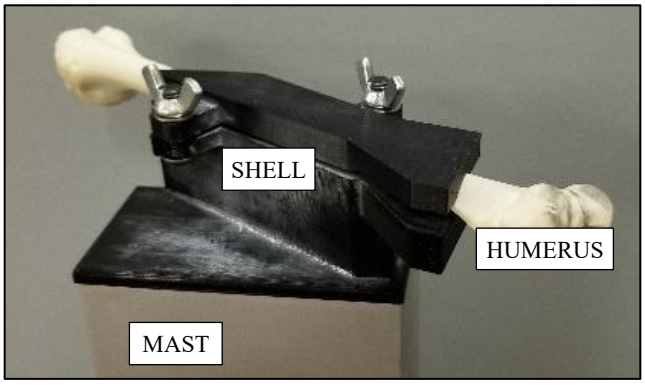

Figure 3: The prototype fixation method.

To ensure simulator calibration, the bone model must be held rigidly and repeatably on the mast of the simulator. An error of greater than 1mm was deemed unacceptable given the degree of precision needed to place a wire on such a small bone anatomy. Errors larger than this would result in an obvious misalignment of the model being displayed to the user on the computer and the physical model. A new mounting system was designed and tested (Figure 4).

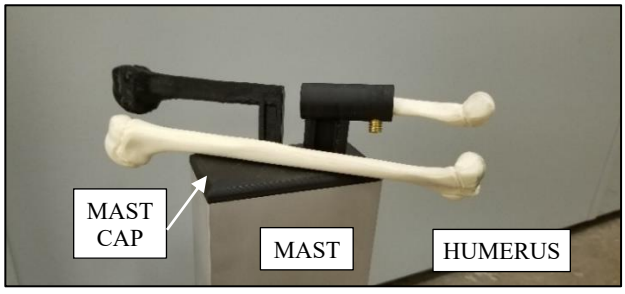

Figure 4: The bone mounting system used in the experiment. A model of the entire pediatric humerus is shown in front of the system for reference.

The goal of this system was to eliminate concerns with the prototype described above while keeping relative motion of the

humerus under 1mm. The repeatability of placement, ease of replacing the bone after each use, fitting of the fixture inside the model soft tissue arm, and minimizing of the materials used were all design considerations. A set screw was implemented to add friction to avoid rotational motion once the bone was placed in the fixture. The proximal third of the humerus was 3D printed to the mast cap and fixation system to give the soft tissue arm more support. The soft tissue arm has a negative space inside to accommodate the pediatric humerus model.

An experiment was conducted to test the rigidity and repeatability of the system. There were two main components to the experiment. The first tested the fixture's ability to resist rotational motion of the bone. This phase involved placing the bone model in the mount and 3D laser scanning it. Then a torque along the long axis of the bone was applied in a clockwise (CW) direction, and the scan was repeated. A second torque was applied in the opposite (counterclockwise (CCW)) direction and the bone scanned again. This procedure was repeated several times with several bone models that were cut to size repeatably on a Tormach 770 PCNC mill to fit the fixture. With the 3D laser scans of the bones, the models were brought into Geomagic Studio 2014 software to conduct a surface deviation analysis between different pairs of bones to find the maximum deviation between points on the two models of interest.

The second phase of the experiment followed a similar procedure to test the repeatability of placement within the fixture. Several bone models were cut to size, placed in the holder and scanned with no applied torques. The same deviation analysis was performed in Geomagic, comparing the change in points of pairs of bone models. Each bone was scanned, removed, replaced in the holder, and scanned again to test the repeatability of itself as well as against other cut bones.

RESULTS

The results of the surface deviation analysis are reported in terms of the mean deviation of points between any two scans and their standard deviation (SD). Figure 5 shows an example of the deviation analysis for a bone with a relatively small amount of positional change.

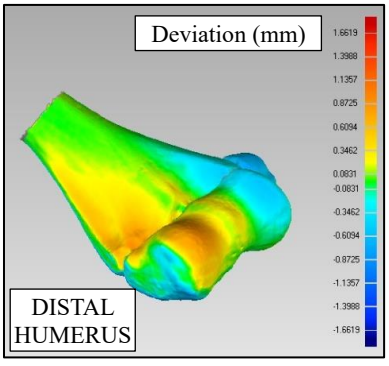

Figure 5: An example of the analysis of surface deviation conducted using 3D laser scans and Geomagic software.

A large change in the mean deviation but small change in SD would suggest that placement of the bone into its holder is not repeatable. A large change in the mean deviation, but small change in SD would suggest a lack of rotational stability within the holder.

Table 1 summarizes the data used to test the rotational stability of the distal humerus holder. The largest SD in the deviation between points on the surfaces of the 3D scanned bones is 0.353mm. If our cutoff is that the mean deviations must be less than the allowed 1mm of movement, this fixation device achieved this goal in terms of its rotational stability.

Table 1: Phase 1 of the experiment testing the rotational stability of the fixation device with torques applied in both CW and CCW directions. The units are in millimeters.

	Original to CW Torque Position		Original to CCW Torque Position		CW Torque to CCW Torque	
	Mean	SD	Mean	SD	Mean	SD
Bone 1	0.018	0.277	0.011	0.138	0.010	0.353
Bone 2	0.001	0.146	0.009	0.200	0.018	0.262

Table 2 summarizes the second phase of the experiment testing the repeatability of the fixture. The mean deviation of the points was relatively small, suggesting that the fixture device can consistently hold the distal humerus. Although the mean deviation of the points was small, the SD of the deviation of the points was relatively large, but it remained under the threshold of 1mm of maximum deviation.

Table 2: Phase 2 of the experiment comparing the relative change between different bones in the fixture with no applied torque. Units are in millimeters. Each bone was scanned twice.

	Bone 1 – Scan 2		Bone 2 – Scan 1		Bone 2 – Scan 2	
	Mean	SD	Mean	SD	Mean	SD
Bone 1 – Scan 1	0.013	0.134	0.035	0.371	0.032	0.368
Bone 1 – Scan 2	-	-	0.000	0.374	0.002	0.373
Bone 2 – Scan 1	-	-	-	-	0.000	0.056

DISCUSSION

This study establishes that the new design provides an accurate and reliable way to hold the small bone model used in the pediatric elbow wire navigation simulation. It has also increased the usability of the simulator by making it simpler to change out bones after use and locking them in place on the mast.

Since the modification of the structure of bone fixation did not change the aesthetic or feel of the bone used in the simulator, the face validity would be deemed unlikely to have changed since the first prototype of the pediatric module. The new design was used by residents in October 2019, and there was a generally positive reaction.

Additional work is underway to make the design yet more user-friendly. This current design requires a hex key to tighten the set screw used to fix the bone. In more recent iterations, a thumb screw was implemented for more ease of use. In future development of new modules for the simulator, the concepts learned in this study can be applied, streamlining new application development.

Other studies are slated to be conducted with this simulator now that the physical design is completed. We are designing an experiment that compares the intra-operative performance of residents who have used the simulator vs. those who have not. This experiment will determine the construct validity of the new simulator by establishing if training on the simulator leads to improved performance in the operating room.

ACKNOWLEDGEMENTS

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REFERENCES

[1] Carpenter JE, et al. (2013). ABOS Surgical Skills Modules for PGY-1 Residents. Retrieved from https://www.abos.org/residency-programs/residency-skills-modules/abos-surgical-skills-modules-for-PGY-1-residents/

[2] Long SA, Thomas G, Karam MD, Anderson DD. (2019). Do Skills Acquired from Training with a Wire Navigation Simulator Transfer to a Mock Operating Room Environment? Clin Orthop Related Research, 477(10):2189–98.

[3] Long S, Thomas GW, Anderson DD. (2016). Designing an Affordable Wire Navigation Surgical Simulator. J Med Devices, 10(3):030921.

[4] Frick SL, Mehlman CT. (2017). The Community Orthopaedic Surgeon Taking Trauma Call: Pediatric Supracondylar Humeral Fracture Pearls and Pitfalls. J Orthop Trauma, 31 Suppl 6:S11-S15.

