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Creation of a High-Fidelity, Low-Cost, Intraosseous Line Placement Task Trainer via 3D Printing --Manuscript Draft--

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Corresponding Author:	Alicia Schiller University of Nebraska Medical Center Omaha, Nebraska UNITED STATES		
Corresponding Author's Institution:	University of Nebraska Medical Center		
Corresponding Author E-Mail:	alicia.schiller@unmc.edu		
Order of Authors:	Nicholas Markin		
	Nathan Goergen		
	Priscila Armijo		
	Alicia Schiller		
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TITLE:

Creation of a High-Fidelity, Low-Cost, Intraosseous Line Placement Task Trainer via 3D Printing

AUTHORS AND AFFILIATIONS:

Nicholas W. Markin, Nate S. Goergen, Priscila Rodrigues Armijo, Alicia M. Schiller

University of Nebraska Medical Center, Omaha, NE 68198, USA

Email addresses of co-authors:

9 Nicholas W. Markin (nmarkin@unmc.edu)

Nate S. Goergen (nathan.goergen@unmc.edu)Priscila Rodrigues Armijo (p.rodriguesarmijo@unmc.edu

13 Corresponding author:

14 Alicia M. Schiller (alicia.schiller@unmc.edu)

SUMMARY:

We describe a procedure to process computed tomography (CT) scans into high-fidelity, reclaimable, and low-cost procedural task trainers. The CT scan identification processes, export, segmentation, modeling, and 3D printing are all described, along with the issues and lessons learned in the process.

ABSTRACT:

The description of procedural task trainers includes their use as a training tool to hone technical skills through repetition and rehearsal of procedures in a safe environment before ultimately performing the procedure on a patient. Many procedural task trainers available to date suffer from several drawbacks, including unrealistic anatomy and the tendency to develop user-created 'landmarks' after the trainer tissue undergoes repeated manipulations, potentially leading to inappropriate psychomotor skill development. To ameliorate these drawbacks, a process was created to produce a high-fidelity procedural task trainer, created from anatomy obtained from computed tomography (CT) scans, that utilize ubiquitous three-dimensional (3D) printing technology and off-the-shelf commodity supplies.

This method includes creating a 3D printed tissue mold capturing the tissue structure surrounding the skeletal element of interest to encase the bony skeletal structure suspended within the tissue, which is also 3D printed. A tissue medium mixture, which approximates tissue in both high-fidelity geometry and tissue density, is then poured into a mold and allowed to set. After a task trainer has been used to practice a procedure, such as intraosseous line placement, the tissue media, molds, and bones are reclaimable and may be reused to create a fresh task trainer, free of puncture sites and manipulation defects, for use in subsequent training sessions.

INTRODUCTION:

Patient care competency of procedural skills is a critical component for developing trainees in civilian and military healthcare^{1,2} environments. Procedural skills development is particularly

important for procedure-intensive specialties such as anesthesiology³ and front-line medical personnel. Task trainers may be used to rehearse numerous procedures with skill levels ranging from those of a first-year medical student or medical technician to a senior resident or fellow. While many medical procedures require significant training to complete, the task presented here—placement of an interosseous (IO) line—is straightforward and requires less technical skill. Successful placement of an IO line can be accomplished after a relatively short period of training. The use of simulation during medical training, which includes the use of task trainers, is recognized as a tool to gain technical procedural skills through the repetition and the rehearsal of a clinical procedure in a safe, low-stress environment, before ultimately performing the procedure on patients^{2,4,5}.

Understandably so, simulation training in medical education environments has become widely accepted and appears to be a mainstay, despite the paucity of data regarding any impact on patient outcomes^{6,7}. Additionally, recent publications demonstrate that simulation improves team performance and patient outcomes as the result of improved team dynamics and decision-making. Still, there is little data to suggest that simulation improves the time or success rate to perform critical, life-saving procedures^{8,9} suggesting that simulation is complex and multifaceted in the education of health care providers. In patients where standard intravenous access is not possible or indicated, IO line placement may be used to achieve vascular access quickly, requiring minimal skill. Timely and successful performance of this procedure is critical, particularly in the perioperative environment or a trauma scenario¹⁰⁻¹². Because IO line placement is an infrequently performed procedure in the perioperative area and can be a life-saving procedure, training in a non-clinical environment is critical. An anatomically accurate task trainer specific to IO line placement is an ideal tool for offering predictable training frequency and skills development for this procedure.

Although widely used, currently available commercial task trainers suffer from several significant drawbacks. First, task trainers that allow for multiple attempts of a procedure are costly, not only for the initial purchase of the task trainer but also for replenishing the replaceable parts such as silicone skin patches. The result is often infrequently replaced parts, leaving prominent landmarks that provide the trainee a suboptimal training experience; patients will not come premarked where one should do the procedure. Another drawback is that the high cost of traditional task trainers can result in limited access by users when the devices are 'locked up' in protected storage locations to prevent loss or damage to the devices. The result is requiring more rigorously and less available scheduled practice time, limiting their use can certainly make unscheduled training difficult. Finally, most trainers are considered low-fidelity^{5,13,14} and use only representative anatomy, potentially leading to inappropriate psychomotor skills development or training scars. Low-fidelity trainers also make the thorough assessment of skill acquisition, mastery, and degradation very difficult as training on a low-fidelity device may not adequately mimic the actual real-world procedure.

Representative anatomy also impedes the proper evaluation of the acquisition and mastery of psychomotor skills. Moreover, assessing the transfer of psychomotor skills between simulated medical environments to patient care becomes nearly impossible if some of the psychomotor

skills are not reflected in the clinical task. This results in the prevention of consensus on the ability of medical simulation and training to affect patient outcomes. To overcome the challenges of cost, anatomical accuracy, and access, we have developed a low-cost, high-fidelity IO line task trainer. The task trainer is designed from an actual patient's CT scan, resulting in accurate anatomy (Figure 1). The materials used are ubiquitous and easy to obtain, with components that are relatively easy to reclaim. Compared to many other commercially available trainers, the modest cost of the task trainer design described here dramatically reduces the desire to sequester the trainers in a less accessible, protected location and makes multiple repetitions without leading landmarks possible.

PROTOCOL:

NOTE: The University of Nebraska Medical Center Institutional Review Board determined that our study did not constitute human subject research. The local IRB obtained ethical approval and waiver of informed consent. Complete anonymization of imaging data was done before analysis per the hospital de-identification protocol.

1. Data

1.1. Obtain a CT scan capturing the anatomy of interest for the planned task trainer. Be careful to take into consideration the working volume limitations of the 3D printer used and required landmarks for procedural steps.

1.2. If the scan is obtained in a Digital Imaging and Communications in Medicine format (DICOM), convert to a Neuroimaging Informatics Technology Initiative (NiFTi)¹⁵ format (.nii).

2. Segmentation

116 2.1. Use 3D Slicer software (http://www.slicer.org) to segment the CT images. Import the NIfTi
 117 file from Step 1.2 into 3D Slicer.

119 2.2. Select the **Segment Editor** module to generate the segments needed to model the trainer.

121 2.2.1. Add one segment for the 1) Bone and 2) Tissue components of the task trainer.

NOTE: Development of some trainers, such as those used to train chest tube insertion, may require additional segments.

2.2.2. Select segment 1) Bone. Using the **Threshold** Effect, change the intensity range until the
 defined "window" range identifies the Bone component of interest.

NOTE: For bone segments the usual range is between 100 and 175 HU (Hounsfield Units) to the available maximum value and for tissue, which is typically –256 HU to the available maximum.

2.2.3. Use the **Threshold** function to highlight the 1) Bone component and apply it to the scan using the **Apply** command.

2.2.4. Use the **Scissors** function to remove any areas of the scan not needed to create the task trainer. Use care to ensure that the bone marrow space remains hollow for IO trainers.

NOTE: This step is the first reduction of the segment of interest to the desired dimensions of the trainer. The build volume limitations of the 3D printer to be used should be considered here; however the segment may be further reduced in section 3.

142 2.3. Repeat steps 2.2.1–2.2.4 for the 2) Tissue component.

144 2.4. Using the **Segmentations** module; export each component as an STL file.

3. 3D Modeling

148 3.1. Use AutoDesk Meshmixer to crop the 3D segments further and reduce the resolution of 149 each segment, in terms of the number of geometric elements, for optimal performance within 150 Fusion360.

3.1.1. Confirm that imported STL files have the correct triangle normal orientation. Ensure the normals of each triangle point in the direction of the outer surface of the mesh. If the triangle orientation is incorrect, flip the triangle normal by performing the Select | Modify | Select All function and then the Select | Edit | Flip Normals function.

3.1.2. Eliminate unwanted structures (e.g., unwanted segments of tissue or vasculature captured by the CT due to the use of contrast) of the imported STL Segments, and refine the models needed to create the task trainer. To refine the model by removing unwanted structures within the segments that may have been inadvertently included within the threshold range of the exported segment, use the **Select** operation, select the triangles on the undesired structures, then **Edit | Discard**.

3.1.3. Following 3.1.2, use the **Edit | Plane Cut** tool to crop the model to fit within the confines of the 3D printer build volume. To reduce the computational overhead incurred due to excessive geometric resolution, reduce the number of triangles used to define the model to allow for optimal performance in Fusion360. Click on **Select**, double-click anywhere on the mesh to select the entire mesh, then **Edit | Reduce**. For **Reduce Target**, reduce to a Triangle Budget of under approximately 10,000 faces.

NOTE: The printer currently used by the authors has a maximum build volume of 250 x 210 x 210 mm; thus the model was cut to a maximum long-axis length of 220–230 mm to allow the mold to fit within the printer's build volume. The printer's build volume should dictate the long-axis length by making the model approximately 20–30 mm shorter. The geometry can easily be

reduced to ~10K triangles without loss of clinically relevant detail to develop high-fidelity task trainers.

3.1.4. Eliminate or reduce holes and surface irregularities using the **Select** tool. Once the triangles of the mesh around the defect are selected, use the command **Select | Edit | Erase&Fill** to improve surface holes and irregularities. Export and save the finished models using the STL file type.

NOTE: The outer surface of the target bone for the interosseous line task trainers requires complete closing; otherwise, the melted tissue media will enter the marrow space and degrade the task trainer performance.

3.2. Use AutoDesk Fusion360, and import the bone and tissue models by adding the .STL files
 into the workspace as a mesh using the Insert | Insert Mesh command.

3.2.1. Convert the imported meshes into BRep solids by disabling the Fusion360 timeline and reducing the number of triangles in the target mesh to <10,000. Select the imported **Mesh Body** and right-click. Choose the **Mesh to BRep** option. After the meshes have been converted to BReps solids, resume the Fusion360 timeline.

195 3.2.2. Modify the solid to create the Task Trainer's mold by splitting the rectangular solid along the long axis of the Tissue BRep.

NOTE: The mold is created around the Tissue BRep by using the sketch feature to build a cube or rectangular solid that encompasses the Tissue solid. The mold size should be modified to meet the maximum build volume of the selected 3D printer. As the mold is split in two, the longest dimension printed may not be the final mold's largest dimension as they are joined.

3.2.3. Select 2–3 locations for support pins, and place the pre-designed assembly group components to fix the task trainer's bones. Make sure that the locations selected for the support pins have an ample support structure in the bone around the head of the pin.

NOTE: The bone around the pin head selected does not need to be perfectly uniform as the assembly group also contains a solid cylindrical support structure, which will be fused with the bone. This structure adequately supports the head of the pin and preserves correct anatomic placement of the bones within the tissue media.

3.2.4. Import and position a bone plug onto the open marrow space of the Bone BRep to prevent tissue media from entering the marrow space, and keep the simulated bone marrow from draining out.

3.2.5. Generate an opening (typically 4–6 cm in diameter) through the molds in the space represented by the Tissue BRep solid to permit pouring the liquid tissue media into the mold.

3.2.6. Once the components of the pre-designed assembly groups are positioned to fix the bones in space, perform **Boolean Combine** functions to either add or cut the various assembly groups into the models.

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3.2.6.1. Perform a mirror of the objects before step 3.2.6 to make the task trainer for the ipsilateral side. Repeat steps 3.2.3–3.2.5 before 3.2.6.

3.2.7. Export the final components for printing. Select the desired body within the workspace and generate an STL file via **right-click | Save As STL**.

4. 3D Printing

4.1. Using Simplify 3D, position the STL file on the bed of the 3D printer so that the slicing program may generate the GCODE required to print the item. Print the components with Polylactic Acid (PLA) 3D printer media filament using a 0.4 mm nozzle at a hot end temperature of 210 °C. Make sure that the settings utilize 4 top and bottom layers and 3 perimeter shells.

4.2. Orient the bones vertically to minimize the required support material within the marrow cavity. Print using a raft, 0.2 mm layer height, 20% infill, and full support material (from the print bed and within the print). When printing the tissue molds, orient the mold components with the tissue surface facing up. Print the tissue molds without a raft, 0.3 mm layer height, 15% infill, and full support material.

4.3. Arrange the support pins and other components to minimize support material—print all pin support parts with a raft, 0.2 mm layer height, and 20% infill. Print the threaded components without support material at a reduced speed, to maximize the fidelity of the thread structures.

4.4. Once each component's parameters are selected, prepare and export the GCODE file generated by Simplify 3D to an SD card. Using a Prusa i3 MK3, select the saved GCODE file from the SD card and print with 1.75mm PLA 3D printer media filament.

5. Assembly

252 5.1. Prepare the tissue medium.

NOTE: The trainee's current level of skill mastery may dictate whether opaque or transparent tissue medium is required. Transparent medium allows the trainee to visually track their progress during IO insertion and more easily identify bony landmarks, while opaque medium better simulates actual clinical experience.

5.1.1. Measure the following components to be used to create the tissue media, and set aside (these quantities may be scaled as needed) 260 g of unflavored gelatin; if required, 140 g of finely ground psyllium husk fiber, orange-flavored, sugar-free (omit this step to create a transparent medium); 42 g of 4% w/v chlorhexidine; 70 g of a 6% sodium hypochlorite solution.

NOTE: Psyllium husk fiber may be used to make an opaque medium. This component should be added immediately after the gelatin if an opaque medium is desired¹⁶.

5.1.2. Heat 1000 mL of water (tap is acceptable) to 85 °C. Add the water to a mixing container several times larger than the volume of ingredients, such as an 18.9 L bucket.

5.1.2.1. While vigorously mixing the tissue medium solution, add the gelatin, psyllium husk fiber, chlorhexidine solution, and sodium hypochlorite solution to the water, in order, and wait before adding the next ingredient after the previous one is incorporated.

NOTE: Do not add psyllium husk fiber if making transparent medium. It is usual for bubbles in the mixture to form when sodium hypochlorite solution is added.

5.1.3. Heat the mixture in a 71 °C water bath for a minimum of 4 h to allow the bubbles to dissipate from the solution. Place the mixing container in the hot water bath directly, or transfer the mixture to a separate container, such as plastic storage bags.

5.1.4. Prepare the tissue medium for pouring into the assembled mold. Ensure that the mixture is homogeneous and fluid. Maintain the temperature of the mixture at 46 °C.

NOTE: If the tissue medium is not immediately needed, it may be stored at 4 °C or -20 °C within a storage container until needed.

5.2. Prepare the simulated bone marrow solution.

NOTE: The simulated bone marrow solution may be prepared in advance and stored in a covered container at room temperature until ready for use.

5.2.1. Measure and thoroughly mix 100 g of cool water (tap is fine); 100 g of ultrasound gel; and 5 mL of red food coloring (optional, used to improve simulation). Ensure that the final product is thick but fluid enough to transfer quickly.

5.3. Secure the bone to the bottom of the mold, and assemble the mold.

5.3.1. Spray each side of the mold's inner surfaces with a non-silicone-based releasing agent, such as non-stick cooking spray. Secure the bone using the support pins to maintain the correct position within the tissue space. Secure the bones/pins to the bottom of the mold.

5.3.2. Align the top of the mold to the bottom portion, and secure the two halves of the mold together. Verify the bone plug is in position to prevent tissue medium entering the marrow space during pouring.

- 5.4. Position the mold such that the opening is facing up, and pour the 46 °C tissue medium into the mold's cavity. Remedy any leakage of the tissue medium from the mold using an inverted air duster canister by directly spraying the warm tissue medium with the canister to cool it quickly. Transfer the filled mold to a 4 °C refrigerator for a minimum of 6 h, or until the tissue medium has set.
- 5.5. Disassemble the mold, and remove the task trainer and the support pins. Remove the bone plug, fill the marrow space with simulated 'bone marrow' created in 5.2, and replace the bone plug. Place the task trainers in a plastic storage bag, and store the assembly at either 4 °C or -20 °C until needed for training.

317 **6. Task training**

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- 319 6.1. Remove the task trainer from storage and allow it to reach room temperature. If not 320 already in place, add simulated bone marrow material from step 5.2 per instruction in 5.5.
- NOTE: Allowing the trainer to warm to room temperature improves the simulation experience.
- 6.2. Perform training on the task trainers. Instruct the trainees to place IO needles (Figure 2A), and aspirate simulated bone marrow (Figure 2B) as per the IO line placement's usual steps.
- 6.3. Following training, disassemble the task trainers to reclaim tissue, the medium, and the bones.
- NOTE: After manipulation, the bones of the IO trainer will have holes created by insertion of the IO line canula. These holes may be either filled with PLA using a handheld 3D printer pen, or alternately the bones may be discarded.
- 334 6.4. Reassemble and reuse reclaimed materials for subsequent training as per section 5.
 335 Alternatively, melt the tissue medium down, reclaim per 5.1.4, and store at either 4 °C or -20 °C,
 336 if not immediately needed.

REPRESENTATIVE RESULTS:

- Following the protocol, the modeling of the task trainer utilized a CT scan of a de-identified patient. Segmentation of the CT images utilized 3D Slicer software and Auto Meshmixer for 3D modeling. For 3D printing, both 3D Simplify and the Prusa i3 MK3 were used (**Figure 1**). Subsequently, we completed the assembly of the 3D-printed parts, prepared the tissue media mixture, and poured the media mixture into the assembled task trainer mold. Following a training period with the task trainer, the tissue medium was reclaimed and reused in the assembly of fresh task trainers.
- The CT scan of a patient's left knee joint used for the 3D modeling comprised 6–7 cm of tibia and fibula bones below the knee, 2–3 cm of femur bone above the knee, and the patella. During this protocol's execution, the artifacts seen in the CT scan resulting from the overlap between

different anatomical segments were manually discarded in Meshmixer after exporting each segment to STLs and performing the 'flip normals' operation. The left tibial bone and tissue STL meshes were modified to reduce the marrow cavity surface's anatomical complexity. Supporting structures were generated to fix the femur, tibia, fibula, and patella to one another. A supporting "brace structure" was added into the Fusion 360 to help booster the thin fibula structure of the bone to the tibia, thus preventing this bone from breaking off.

The mold structure consisted of a rectangular solid, separated into a top and bottom structure, and a 2.5 mm channel to hold the silicone foam cord on the tissue segment's outline perimeter. Supporting pin structures, alignment pin channels, and the bone plug receiver were added to the bone and mold structures by importing their applicable structures into the model (**Figure 3**). The mold was designed such that two 41 mm Supporting Pin Assembly groups would be sufficient to properly support and suspend the bone structures within the tissue cavity. An opening made to expose the tissue cavity facilitated pouring of the tissue medium by cutting a cylindrical body structure from the mold structure's front.

After finalizing the mold and bone structures in Fusion 360, the following four .STL segments were created by exporting the model: 1) Bones, 2) Bottom mold box, 3) Top mold box, and 4) model hardware (2 x 41 mm Supporting Pins, 2x Supporting Pin Bottoms, and 1x Bone Plug). Next, four STL segments were imported into Simplify 3D, and the representative GCODE files were generated for these segments for printing using a 0.4 mm nozzle and 0.3 mm layer height at a 100 mm/s print rate. **Table 1** lists print times and PLA filament material requirement estimates using the settings previously mentioned when all segments were printed on Original Prusa MK3 printers. Rapid incorporation of the tissue medium (gelatin) components is essential to achieve a consistent and homogenous final product. The amount of tissue medium used varies depending on the model of task trainer assembled. An example of the design and actual volumes of tissue medium used in the tibial IO insertion Task Trainer model is shown in **Table 2**.

To de-mold the task trainer, the compression devices were loosened, the mold top and bottom were separated, and the 2 x 41 mm support pins were rotated and removed from the bones. The bone marrow cavity was then filled with simulated marrow solution, and a bone plug was securely inserted. The final task trainer was then imaged with a CT scan for the measurement of anatomical landmarks and segments. The results demonstrate a high-fidelity task trainer IO line placement (**Figure 4**). The newly molded task trainer was then placed in a zip lock bag, returned to the refrigerator, and stored for use in a future training session.

Transparent and opaque task trainers were assembled (**Figure 5**) for IO line placement training sessions. A total of 40 task trainers (20 tibia and 20 humeri) were used during a half-day training of IO line placement offered to the Department of Anesthesiology at our Institution. Both faculty and trainees attended this training. Each attendee had 15 min of hands-on interaction with both task trainers (tibia and humerus) and the equipment necessary to perform the IO line placement. Preliminary data on the task trainers' advantages and disadvantages and task trainer improvements were collected immediately afterward.

Advantages identified by attendees specific to the use of the task trainer included: a) high level of anatomical similarity, b) ability to find anatomical landmarks, c) tactile sensation resembling tissue, d) reproducibility of the practiced procedure, e) ability to aspirate bone marrow to provide task completion feedback, and f) appropriate tactile feedback when drilling into the bone. The ability to reclaim and reuse the task trainer, and the low-cost of the trainer were important features identified by attendees. Further, faculty and trainees suggested adding a skin or fabric layer to more closely resemble the skin's tactile feedback and increasing the limb length. After the training, the tissue medium was reclaimed and reused (**Figure 1**).

FIGURE AND TABLE LEGENDS:

Figure 1: Flow chart depicting the process to create an intraosseous line placement task trainer.

Figure 2: Intraosseous line placement with a tibial task trainer performed using a trainer with opaque tissue medium. (A) Drilling into the bone with a commercially available IO placement drill. (B) Aspiration of marrow upon successful placement of the IO line. Abbreviation: IO = intraosseous.

Figure 3: 3D-designed and 3D printed components that compose the tibial task trainer. (A) 3D designed tibia; (B) 3D printed tibia; (C) 3D designed mold and of the tissue surrounding the tibia and pins; (D) 3D printed mold of the tissue surrounding the tibia and pins.

Figure 4: Opaque and transparent tissue media allows for customization of training. (A) and (C) represent a humerus and tibial task trainer made with opaque tissue medium. (B) and (D) represent a humerus and tibial task trainer made with transparent medium. Note the visibility of skeletal structures with transparent tissue medium.

Figure 5: Anatomical distances are similar between CT scan data used to create the task trainer and from the fully assembled IO line placement humerus task trainer. (A) Bone thickness (mm), (B) skin depth (mm), and (C) the tendon groove (mm) from the CT scan data are anatomically similar to the (D) Bone thickness (mm), (E) skin depth (mm), and (F) tendon groove in CT scan of the fully assembled humerus task trainers. Abbreviations: CT = computed tomography; IO = intraosseous.

Table 1: List of time and cost of each component required.

Table 2: Tissue media volumes.

DISCUSSION:

In this protocol we detail a 3D task trainer's development process to train the infrequently performed and life-saving procedure of IO line placement. This self-guided protocol uses 3D printing to produce the bulk of the model structures, while the remainder of the components used to assemble the task trainer are ubiquitous, easily obtainable, and non-toxic materials that may be reclaimed and reused. The 3D task trainer is low-cost and requires minimum expertise to create and assemble. We have successfully used our 3D IO line placement task trainer in UNMC

Department of Anesthesiology training sessions, which included a demonstration and hands-on practice by faculty and trainees in attendance. The feasibility data collected during the training indicated that attendees agreed that the task trainers had a high degree of anatomical fidelity to actual patient anatomy, and they were further satisfied with the tactile feedback of the device.

Critical steps in the production of a task trainer have been divided into two sections: 3D design and fabrication; task trainer assembly. When creating the 3D models used to form the task trainers, adequate segmentation was critical. Without adherence to anatomic accuracy, the final product may not be correct. Threshold segmentation requires attention to the task trainer's area of interest to ensure that surface detail is present to give the models the correct shape and thickness. Tibia and humerus thickness are particularly important to provide sufficient tactile feedback during simulated IO line placement. The process for segmenting tissue and bone components can be incredibly time-consuming as CT scans often use iodinated contrast agents, which have overlapping HU ranges with those of bone. Thus, anatomical structures permeated with iodinated contrast may be inappropriately included within bone segments.

Appropriate preparation and storage of the tissue media are critical. Adherence to temperatures stipulated within the protocol is necessary to prevent damage to the 3D printed structures and ensure maximum tissue media longevity. Notably, the tissue media must remain cold or frozen and covered in plastic when not being used to prevent microbial growth and dehydration. The availability and accuracy of patient's CT scans can impose limitations on creating the IO line task trainer. There appear to be limits on the generation of models regarding the requirements for 3D printing. During the 3D printing process layers of thermoplastic are deposited on top of prior layers or support material. Some models and proposed trainers produced by this process can exceed the size limits of a 3D printer and require modification of the printer size or components to allow printing that retains the trainer's critical aspects (such as the marrow space for IO models). Other formats suitable for task trainer creation include magnetic resonance imaging. However, the imaging modality displays different data types, requiring modifications to this protocol.

This IO line placement task trainer has several innovative features, including a reduced cost compared to other task trainers, and the ability to customize the task trainer to different anatomic sites (humerus and tibia) and various anatomies, including male or female, and high and low body mass index. Further, the tissue media mixture can be prepared in different opacities, allowing for varying levels of visualization of skeletal structures or landmarks, if desired. Given its anatomical accuracy and reusable nature of its subcomponents, this task trainer provides unique medical procedure training and simulation research opportunities, including the transference of procedural skills from a simulation or training environment to a testing or clinical environment. The high-fidelity and low-cost attributes of this task trainer make it an excellent choice for evaluating procedural skill acquisition and degradation in healthcare trainees and providers. Further, the superior anatomical fidelity of the trainer grants opportunities to evaluate the impact of ergonomics on training scars and degradation of trainer structure, which is a rapidly emerging topic of interest in this field¹⁷. Overall, this tool's use may promote a better understanding of best practices in medical simulation¹⁸.

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DISCLOSURES:

487 The authors have nothing to disclose.

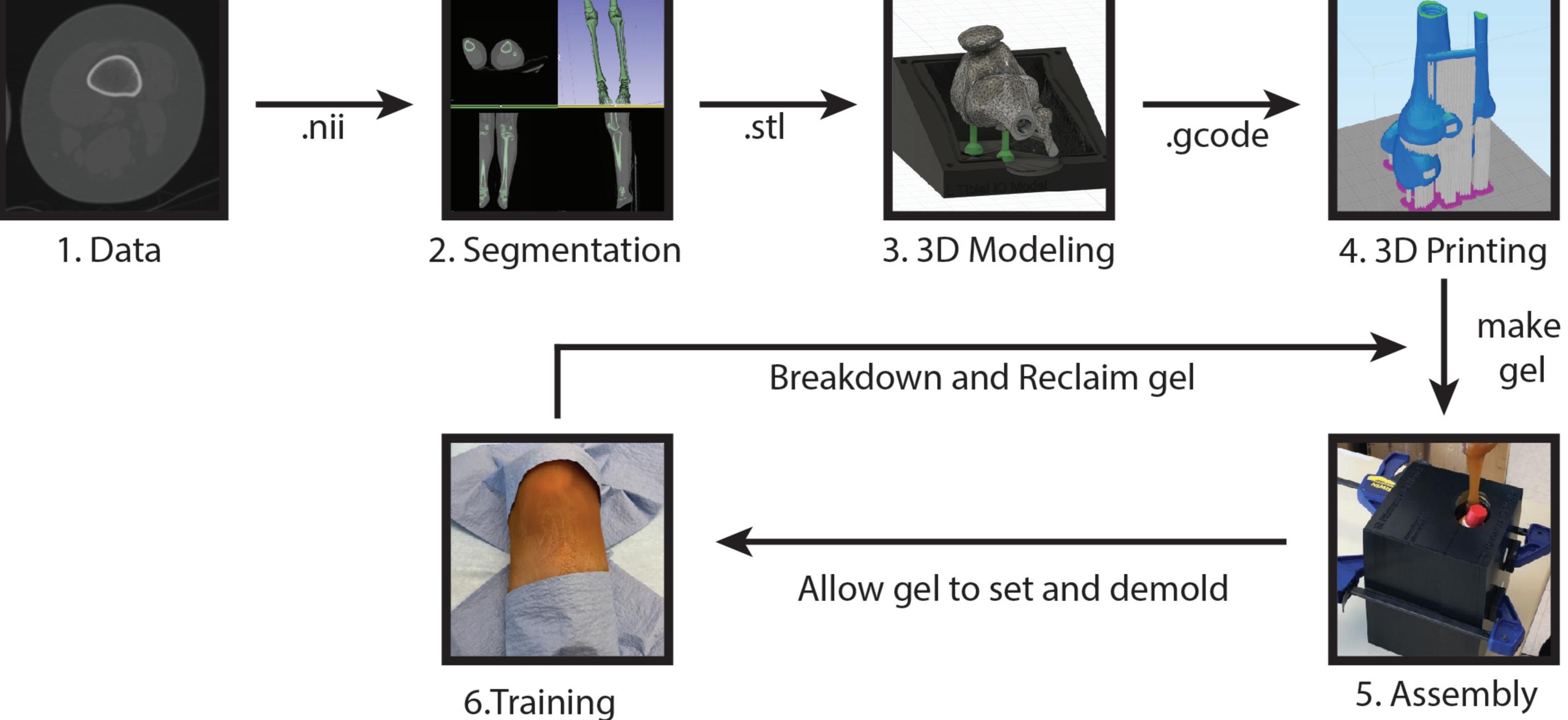
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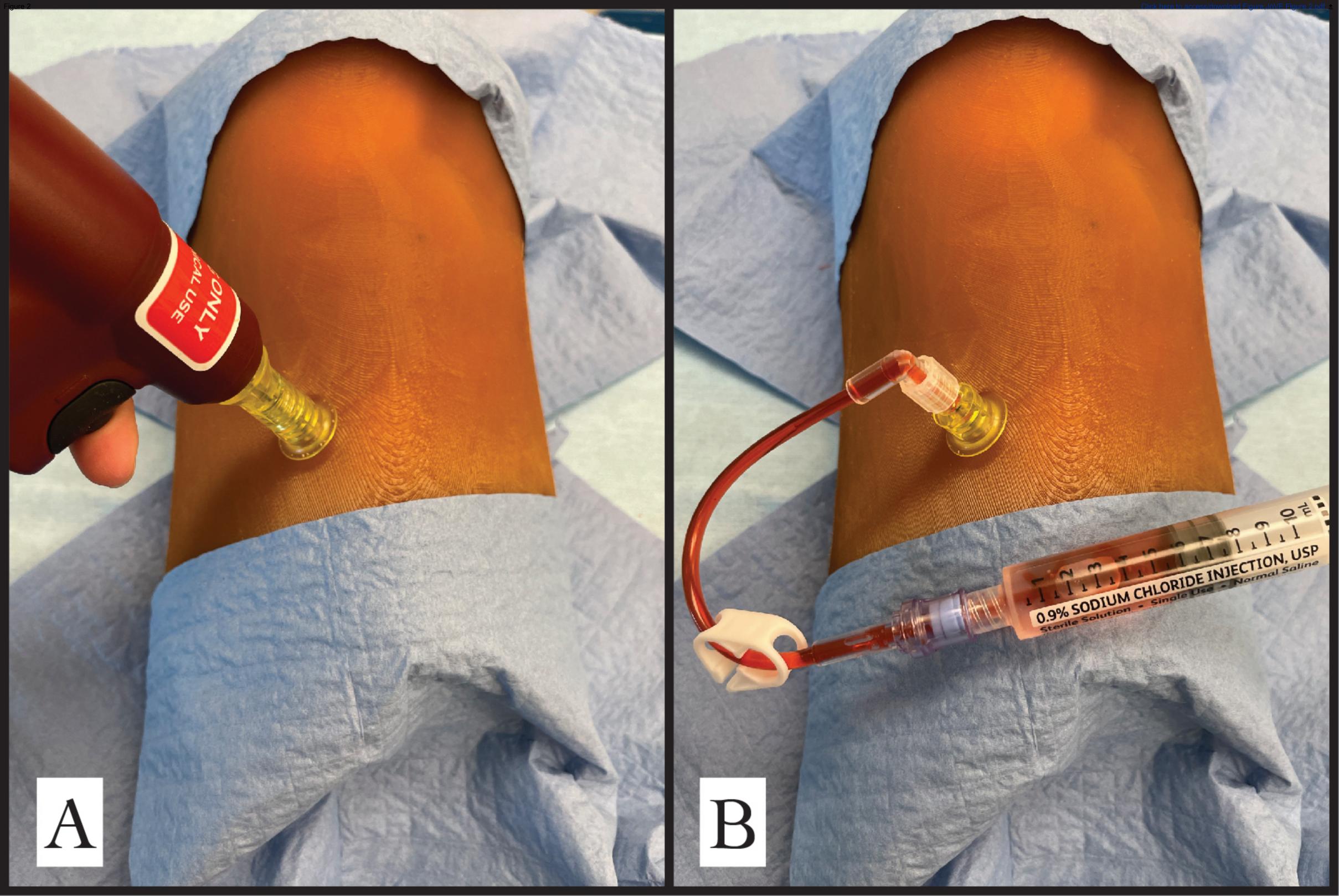
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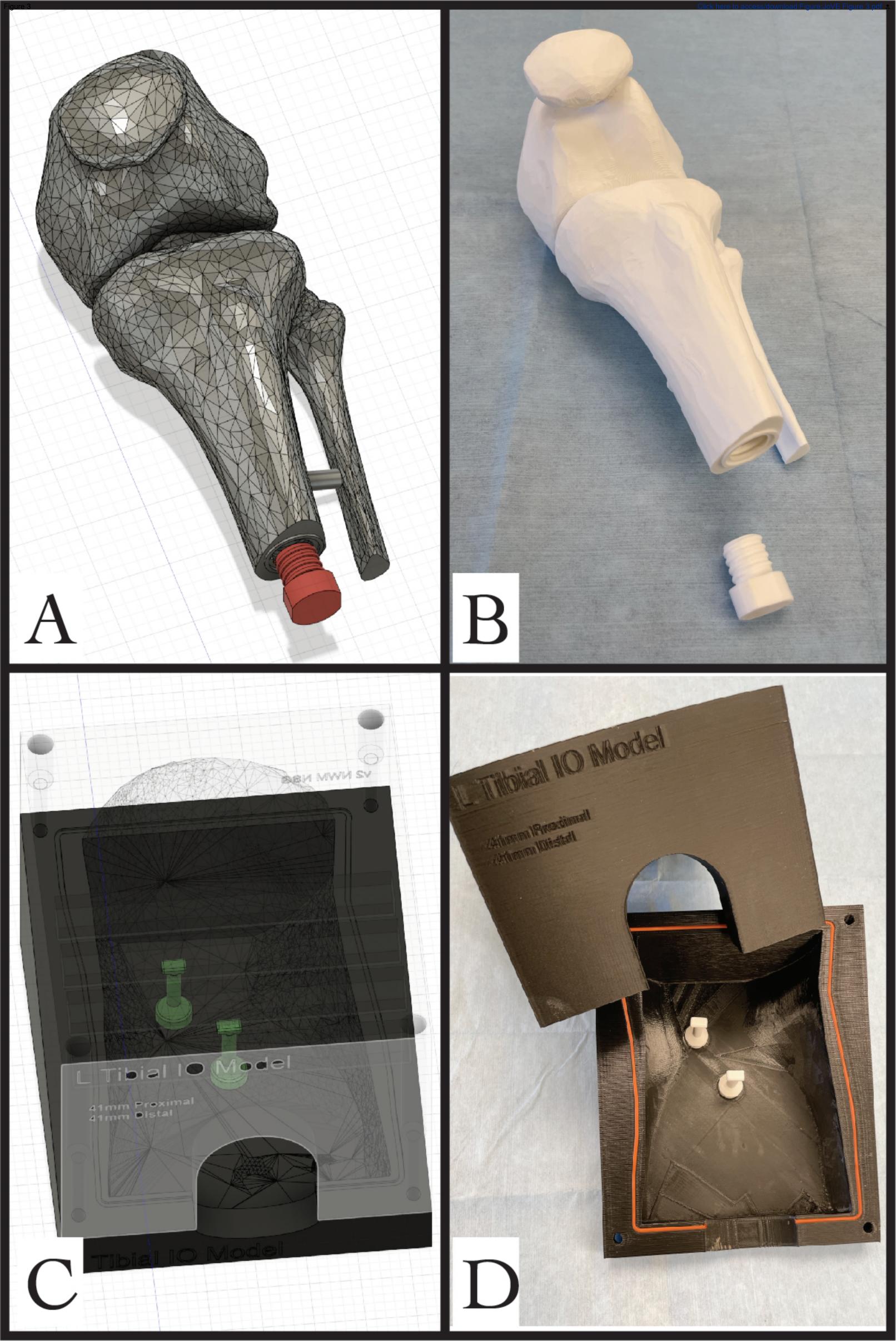
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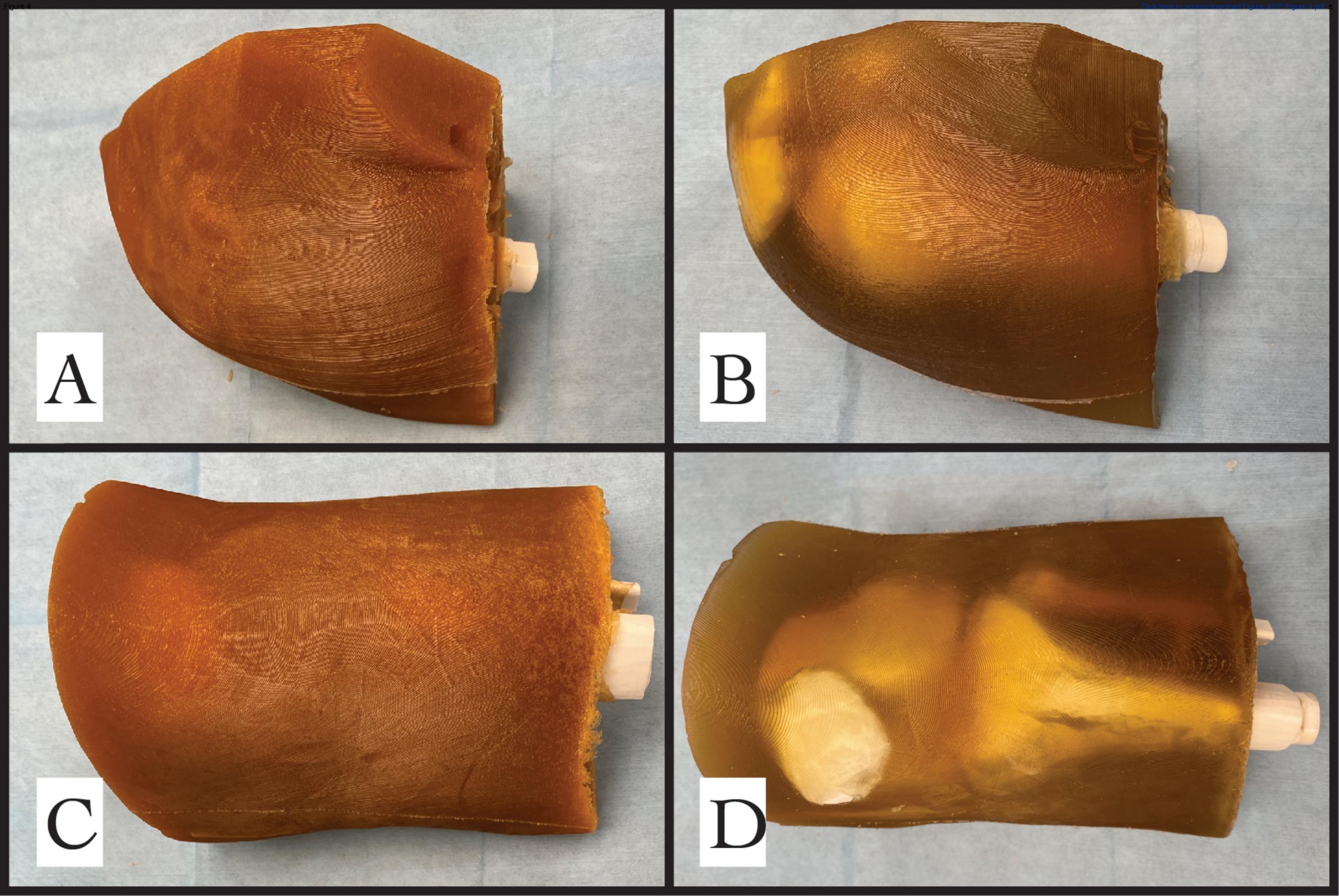
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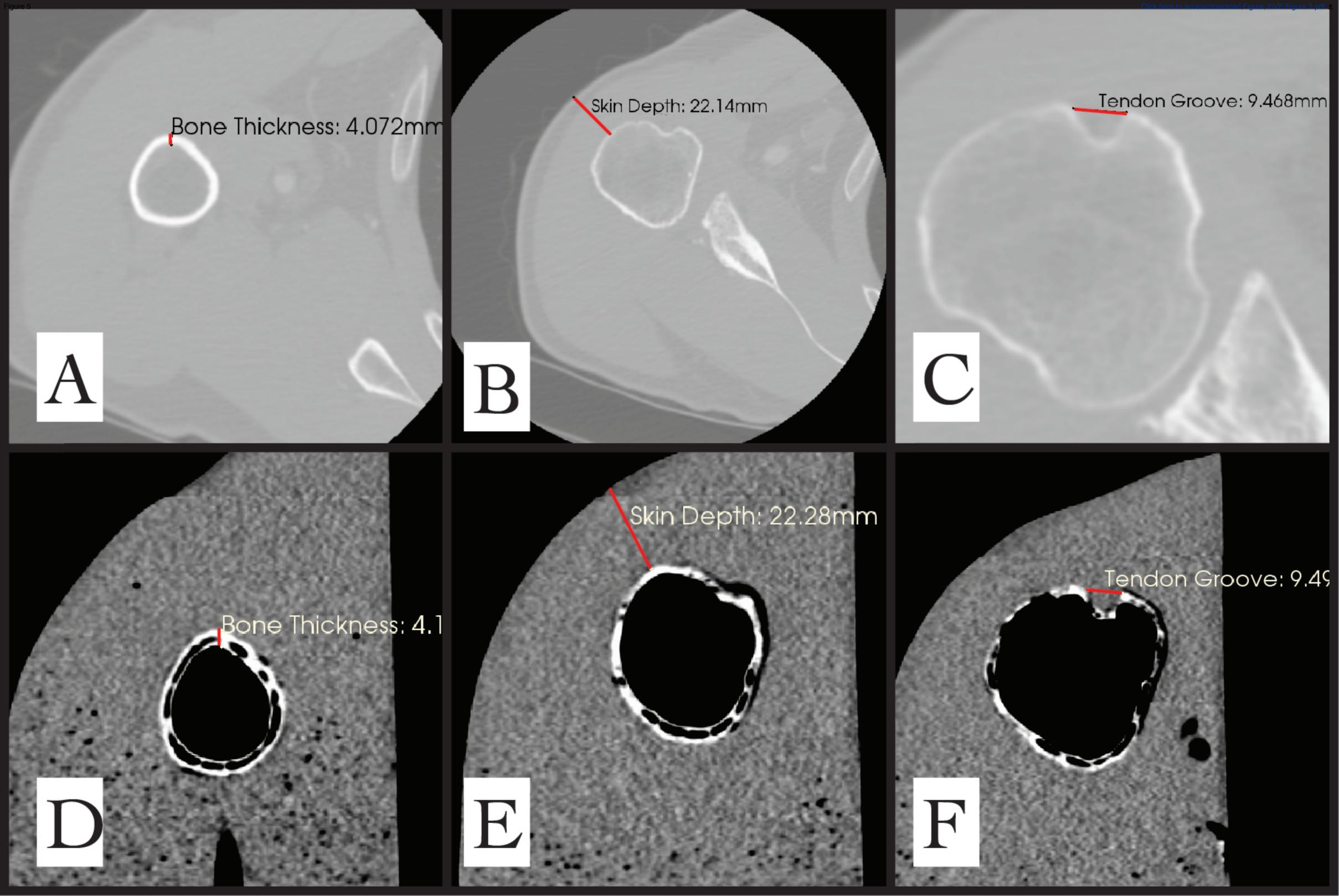


5. Assembly









Structure	Approximate Print Time (h)	PLA Filament requirements (estimated, in g)	Material Cost (Dollars)
Вох Тор	32	800	16.00
Box Bottom	17	450	9.00
Bones	9	200	4.00
Hardware	2	16	0.32

Structure	Volume (L)	Estimated Cost
Tissue Cavity	2.06 L	n/a
Bone Structure	0.313 L	n/a
Tissue Cavity – Bone Structure	1.747 L	\$35 (reclaimable)
Marrow Cavity	0.075 L	\$0.25

Name of Material/ Equipment	Company	Catalog Number	Comments/Description
3D printer filament, poly-lactic acid (PLA),	N/A /		
1.75 mm	Hatchbox		Base for 3D printing molds, bone structures, and bone / mold hardware
3D printer, Original Prusa i3 MK3	Prusa		To print molds, bone structures, and bone / mold hardware
bleach, household (6% sodium hypochlorite)	Clorox		Animicrobial additive for tissue media
bolts, 1/4", flat / countersunk or round head	l,		
various lengths	N/A		Hardware used to hold mold casing halves together during casting
Bucket, 5 gallon, plastic	N/A		To hold tissue media during media preparation
chlorhexidine, 4% solution w/v			Animicrobial additive for tissue media
drill, household 3/8' chuck	N/A		To stir tissue media during media preparation
food coloring, red (optional)	N/A		Coloring additive for simulated bone marrow
gelatin, unflavored	Knox		Base for tissue media
hex nuts, 1/4"	N/A		Hardware used to hold mold casing halves together during casting
Non-stick cooking spray	N/A		Mold releasing agent
plastic bags, ziplock	Ziplock		To store tissue media
psyllium husk fiber, finely ground, orange	Procter &		
flavored, sugar free (optional)	Gamble	Metamucil	Opacity / Echogenicity additive for tissue media
screwdriver, flat / Phillips (matching bolt			
hardware)	N/A		To tighten mold casing hardware
silicone gasket cord stock, 3mm, round,			
various lengths	N/A		Gasket media for mold casings
spray adhesive, Super 77 (optional)	3M		Agent used to improve bed adhesion during 3D printing
stirring paddle / rod			To stir tissue media during media preparation
turkey baster, household, ## mL	N/A		To inject simulated bone marrow into bone marrow cavity
ultrasound gel			Base for simulated bone marrow
water, tap			Used in both tissue media and simulated bone marrow

Dear Dr. lyer,

Thank you for the opportunity to submit a revised draft of our manuscript, JoVE62434, "Creation of an Anatomically Correct, Low-Cost, Intraosseous Line Placement Task Trainer. We appreciate the time and effort you and the reviewers have dedicated to providing valuable and constructive feedback. We have been able to incorporate changes into the manuscript to address the reviewers' concerns. Please see below for a point-by-point response the reviewer's comments and suggestions.

Editorial comments:

Changes to be made by the Author(s):

1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues.

Thank you. We have thoroughly proofread and corrected grammatical errors.

2. Justify all the text, maintain a 0-inch left indent throughout the text and indicate new paragraphs using single-line spacing.

This had been done.

3. For in-text formatting, corresponding reference numbers should appear as numbered superscripts after the appropriate statement(s). Also, multiple references should be cited serially (e.g. "1,3,5" instead of "5, 1,3").

This has been done.

- 4. Use "mL" instead of "ml", "oC" instead of "C /degrees-centigrade". Include a single space between the quantity and its unit e.g.: "4 g" instead of "4g"," 0.3 mm" instead of "0.3mm", etc. This had been done.
- 5. Please check the usage of the psyllium husk. The step indicates that it is optional, but the protocol uses it. It would be clearer if the protocol is detailed with the use of the husk. And a note (line 222) is added later.

Thank you, we have edited the manuscript to reflect the optional nature of the psyllium husk and the use of the material for the desired media.

6. Please refrain from using bullets or dashes in the protocol, and combine some of the shorter Protocol steps so that individual steps contain 2-3 actions and maximum of 4 sentences per step. Also maintain a single line spacing between successive steps.

This has been corrected.

- 7. Please ensure that all text in the protocol section is written in the imperative tense as if telling someone how to do the technique (e.g., "Do this," "Ensure that," etc.). The actions should be described in the imperative tense in complete sentences wherever possible. Avoid usage of phrases such as "could be," "should be," and "would be" throughout the Protocol. Any text that cannot be written in the imperative tense may be added as a "Note." E.g. lines 164-167,202-204, 237-238, etc. This has been done.
- 8. JoVE cannot publish manuscripts containing commercial language. This includes trademark symbols (™), registered symbols (®), and company names before an instrument or reagent. Please remove all

commercial language from your manuscript and use generic terms instead. All commercial products should be sufficiently referenced in the Table of Materials. E.g. AutoDesk Meshmixer, Fusion360, Prusa i3 MK3 etc.

We have corrected this.

9. Figure 3 legend has two entries labelled A. Please check and correct.

Thank you, this has been corrected.

10. Please sort the Materials Table alphabetically by the name of the material. Also, do not include the Table of Materials in the list of tables and figure and table legends. Please remove all formatting from the tables.

- 1 ·			
Inic	nac	naan	done.

Reviewers' comments:

Reviewer #1:

Manuscript Summary:

The MS outlines a procedure for creating a patient-specific digital model and micro-manufacturable phantom of the knee and proximal lower leg for use a task trainer for interosseous access.

The process relies largely on high quality and widely accessible open source software and hardware, with a couple of notable exceptions.

The methods are clearly described with an appropriate level of detail.

The illustrations are appropriate and thoughtfully designed.

Major Concerns:

None.

Minor Concerns:

The workflow described can be further optimized to increase speed, lower infrastructure requirements, make the technique more accessible, and extend the shelf life of the final product.

We would suggest the following modifications (or at least including a mention of them as potential alternatives in the MS):

Segmentation with 3D Slicer - no additions

Specific Comments:

- 1. Model editing with Autodesk Meshmixer: The following sequence of actions would significantly speed up and simplify the process. Unlikely to effect quality of results.
- Inspect + repair function: would automatically fix any inverted normals, remove floating/unconnected object and remove surface defects like holes. This would collapse points 2a, 2b, 2e into a single extremely fast and automatic operation

Thank you for your suggested change to the described process. Unfortunately, we were unable to replicate the steps in the way described in the reviewer's comments in a way that would produce a similar outcome. The Inspect + Repair process does not resolve the issues that each step as described in the manuscript complete.

- 2. Perform the triangle reduction at this point to reduce computational overhead of excess triangles. For this kind of geometry it can easily be reduced to around 10K without loss of clinically relevant detail.
- Plane-cuts.

The suggested modifications to the protocol are appreciated but the order is not optimized for our process. In order to import the model with the highest detail, we perform the reduction after the plane cut. We have added a comment regarding the reduction in computational overhead as suggested.

3. CAD: Authors used Autodesk Fusion 360. This software is quite expensive and not very accessible to many potential users but unfortunately available more accessible alternatives would involve the use of more software (e.g. Blender + openSCAD or FreeCAD) have significant learning curves, though once mastered, they would provide a wider range of capability than Fusion. Blender in particular has a more sophisticated boolean solver for mesh operation.

Thank you for your comments, and certainly it is not our goal to make the process not accessible. Fusion 360 was selected at the onset of the project by one of the authors for two reasons: 1. it was a no-cost option at the time due to educational licensing and 2. it was relatively straightforward to learn when compared to some of the other options described. As the authors were looking for an efficient and reproducible approach, it was the option selected. The authors fully appreciate the options and ability of the FOSS options but as this is the one utilized for this project, we described the process using F360 in the manuscript.

4. For slicing prior to print the authors used a proprietary non-free software Simplify3D. It's not clear what the benefit of this is over the highly sophisticated free and open-source Prusa Slicer that is customized for the printer used.

Having used both slicers for these prints it was our experience that the S3D software produced superior support material. Specifically, the ability of the support material to separate from the print when compared to the same print. As we understand that we are to indicate the software used, we are indicating as such. However, we recognize that given the ability to modify various parameters in other slicer software it would be possible to produce similar results outside S3D. This was not performed and therefore not represented in the manuscript.

5. Manufacturing: We would strongly recommend the use of ballistic gel (Clear Ballistics) instead of gelatin. It images well under ultrasound and x-ray/CT if that is required, can be stored indefinitely at room temperature, can be remelted and reused indefinitely and needle holes can be repaired with a heat gun. However due it's higher melting point, the 3D print would have to use a higher glass transition temperature to withstand the much higher temps of molten gel. Nylon (any of them, we use Bridge Nylon) would be a good choice. It would increase the cost of producing the model slightly

but would make a much more durable model.

Thank you for your comment, we to have some experience with the Clear Ballistics product, though your experience sounds more robust. Our limitations in the use of this product are mainly with the ability to produce sufficient numbers of our molds and bones with high-temp materials to withstand the warping. As well, once the bone is pierced a handful of times, the bone will leak and it requires the bone to be repaired as well. To this end, as well as the significant increase in cost, we elected at this time to utilize the gelatin mixture described. We appreciate the comments and are evaluating options for the creation of this models or similar versions with a more shelf-stable product.

Reviewer #2:

Manuscript Summary:

I commend the authors on this well-written manuscript which describes the use of additive manufacturing to create a part task trainer for simulation-based teaching of intraosseous line placement. The protocol utilizes CT imaging to generate 3D-printed patient-specific anatomic molds that are subsequently used to create the trainer using commercially available materials. The authors describe preliminary data from testing the trainer at their institution and conclude that the trainer was well-received by trainees. It offers several advantages to the traditional part-task trainers including patient-specificity, material modulation and recycling, high anatomic fidelity, and low cost.

Major Concerns:

Protocol:

1. Data and Segmentation (line 94-95, 117-119, 138-139). For potential users of this protocol that are unfamiliar with 3D printing techniques and may consider purchasing a printer to implement this protocol, it would be beneficial to elaborate on these limitations regarding size. What printer sizes would be expected to be acceptable for this protocol?

Thank you for the comment. We have added a remark in the manuscript reflecting the maximum print volume of the Prusa printer described at 250 x 210 x210 mm. It is conceivable that the reader may have a device that would meet their needs and comments have been added to the manuscript.

2. Related to the above comment, the protocol as written describes use of a specific printer (Prusa i3 MK3), which is a relatively high-quality commercial printer and is fairly expensive (~\$750 USD). For research or clinical groups who already own a printer or would like to purchase a different printer (e.g. for personal cost/size considerations), it would be helpful to explicitly outline how to this protocol could be adapted or utilized for other printers or filament types. Only minor changes/size considerations may be necessary but clearly addressing this issue would greatly improve the generalizability of the proposed technique.

Yes, the protocol is written for the specific printer but additions to the manuscript have been made as suggested. For the mold to separate, the mold is often designed to open along the long-axis of the model. As such, the long axis of the model is often the constraining factor. This has been added to the manuscript.

Minor Concerns:

3. Title: I would recommend removing "anatomically correct" from the title, as this is description non-specific. Terms like "high-fidelity" and "patient-specific" are more appropriate descriptors for this protocol. Additionally, if possible I would recommend including the term 3D printing in the title to clarify that this technology will be used.

Thank you for your suggested changes. The title and the description of the project has been edited to include the term "high-fidelity" in the place of "anatomically correct".

Protocol:

4. Line 132: "Eliminate unnecessary structures of the imported STL segments and refine the models to create the task trainer". Please define what structures would be considered unnecessary. Line 168-170: Please describe how/where to place the components to fix bones. What is an "appropriate space"?

This has been adjusted within the manuscript to better reflect our meaning.

5. Line 281: What aspects of the trainer are recyclable? Most 3D printed PLA materials cannot be recycled and new filaments will need to be purchased. Does this line refer only to the tissue media and simulated marrow? Please clarify; it would be important to know whether new materials (e.g. PLA or other filament) will need to be purchased for the creation of every anatomic mold.

Yes, the reviewer is correct that new materials are used in the 3D printing aspect. The intention of the statement regarding the ability to "reclaim" the tissue media is to permit a user to melt and pour a new model from existing tissue media. We apologize for the confusion. The bones, made of PLA, can be repaired using a 3D printing pen. Changes have been made to the manuscript.

Reviewer #3:

Manuscript Summary:

The authors present a cost-effective approach to a high-fidelity task-trainer for intra-osseous placement. The authors abide by the journal guidelines and present a brief, relevant introduction to the clinical importance of simulation, advantages and disadvantages to available simulation options. The authors then present their task trainer with sufficient detail in their protocol and mention a post-utilization survey by users. Overall, the task-trainer is found to be cost-efficient (by materials), high-fidelity with high relevance in the clinical setting.

Major Concerns:

The authors mention use amongst trainees but do not define specific training level or prior exposure to interosseus placement.

A comment regarding the training level of healthcare professionals who perform this procedure is now included. Thank you for the suggestion.

2. Familiarity with this procedure and tactile feedback is critical - experience (or lack there-of) could affect your survey results.

Yes, it is possible that level of experience could impact survey results. However, the evaluation of this model was done simultaneously with a training session for the performance of IO line placement. As those that evaluated the model were also given the opportunity to practice the IO placement on the currently available commercial "simulators" we believed this evaluation was indicative of the performance of the task trainer. At the conclusion of the training session, all individuals in attendance would be considered "trained" and could place IO lines clinically if necessary.

3. The authors present a cost-efficient task-trainer regarding materials, but do not disclose the costs of the software, 3-D printer and other durable equipment (refrigerator), and time that is part of this process.

Thank you for your comments regarding some of the other costs that are difficult to measure. The only software the authors purchased was a license for Simplify 3D for \$30 USD. The other software was either FOSS or it was available at no cost via academic licenses. The printer is a Prusa MK3 which can be purchased for ~\$900 USD plus an additional ~\$100 for shipping. While time is a significant factor for the production of all manufactured products, the actual amount of time to produce a final product is relatively little compared to the design and printing time. We recognize that these are difficult to quantify as the complexity of the printed model and the 3D modeling will play an important role in timing. As well, the experience of the individual with the process will greatly speed up the process.

4.Did the authors evaluate the actual haptic feedback by pressure sensors of this model to test for its fidelity? i.e tensile strength and viscosity compared to human/cadaveric tissue or was this measured by expert opinion?

No, tensile testing was not done. The similarities to the task trainer model and the performance of the procedure on a human was confirmed by individuals experienced in the placement of interosseous lines. As well, the standard training process is often focused entirely on the drilling portion of the procedure, and there is often no simulated tissue overlying the bone for simulation. This simulator takes advantage of a simulated soft tissue to allow the learner a chance to palpate landmarks as well as the simulated marrow and the ability to confirm placement by drawing "marrow" back prior to injection of fluids.

Minor Concerns:

5. The authors mention there is paucity of data on the effect of simulation on patient outcomes. There are several studies evaluating both adult and pediatric trauma populations, outcomes in mortality after implementation of simulation (Murphy et al. Injury, 2018; Jensen et al. Journal Trauma Acute Care Surgery, 2020). More discrete outcomes may less clear.

Thank you for your comment and the references are appreciated. To clarify our position, we are making the statement that simulation does not actually show evidence of improved task performance. In both articles mentioned in the reviewer's comments, the article discusses the merits of team training. We do not argue that point and we agree that team training and simulation to improve team performance appears to be one aspect of simulation that has demonstrated measurable results. Our position was more that the simulation of a procedure has not improved the actual performance of the procedure, which the article mentioned agree. The Jensen et al. Reference indicates that the overall survival characteristics are improved in high-simulation facilities, but the actual time to perform a critical

procedure was not improved. In Murphy et al. The authors also note improved outcomes and less time to operation but there is no evidence that simulation actually improved the skill of performing the operation, only the cognitive processes and team work.

6. I would recommend that the authors add references to their discussion on skill degradation (briefly mentioned in the conclusion).

Thank you, we have done so.