Silicone-Shelled Phantoms

Affordable, reusable, silicone-shelled ballistic gel phantoms for ultrasound-guided procedural training designed using 3D printing

Benton Chuter, MS, Annie Kaufman, BA, Andrew Terajewicz, MS, Samuel Rodriguez, MD, Cynthia Khoo, MD, PhD
Department of Anesthesiology, Perioperative and Pain Medicine, Stanford University

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Introduction

- Performing ultrasound-guided regional anesthesia and vascular access procedures requires mental and physical dexterity, and high-quality training tools are needed to increase the accessibility of these techniques.

- Anesthesiologists practice these procedures on simulation phantoms, but existing solutions are often expensive or inadequate.

- We aimed to develop affordable, reusable, durable ballistic gel phantoms for regional anesthesia procedural training.

Direct Cast Method

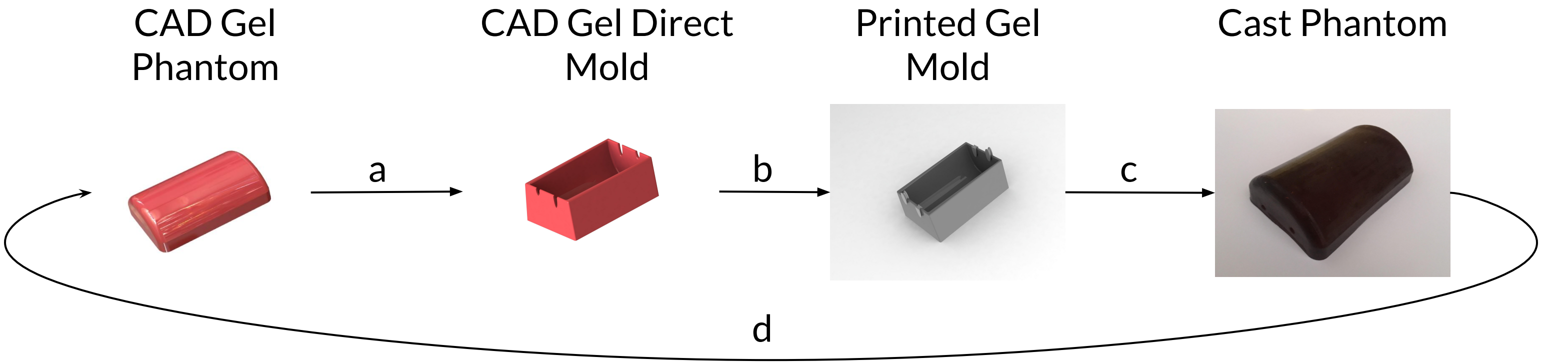


Figure 1: The direct cast method allows for rapid design iteration. It consists of the following steps:

a) Cavity Subtract

b) 3D Print

c) Prepare Mold & Cast Gel

d) Test and improve design

Silicone Shell Method

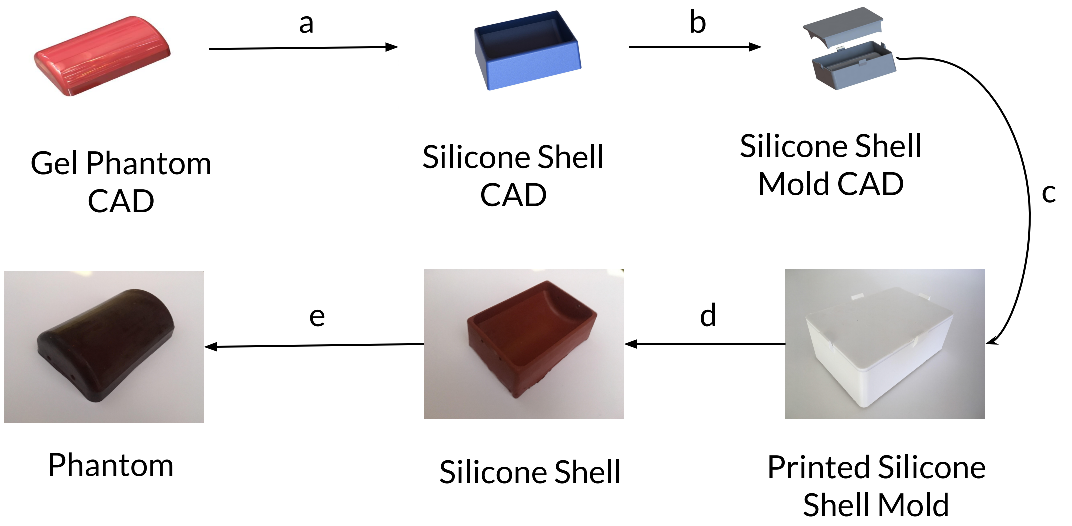


Figure 2: The silicone shell method creates the final product.

a) Cavity Subtract and Shell

b) Tooling Operation

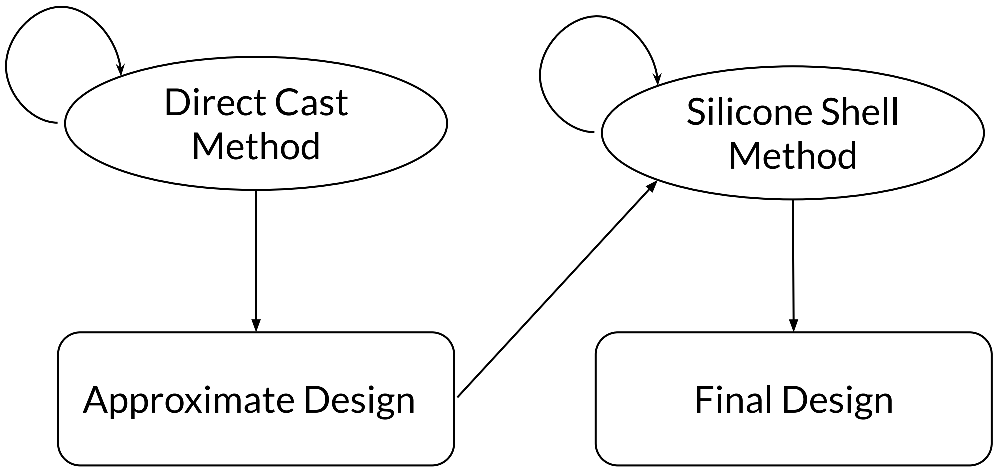
c) 3D Print

d) Demold and Cast Silicone

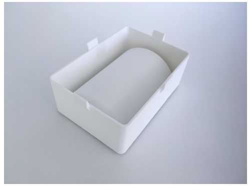
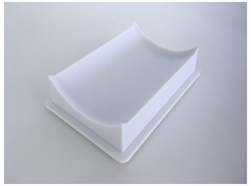
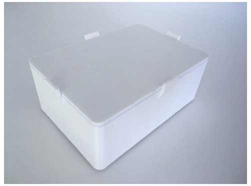
e) Prep Silicone Shell and Cast Gel

Steps d and e can be repeated to make many silicone-shelled phantoms.

Methods


Direct Cast Method
Silicone Shell Method
Approximate Design
Final Design

Silicone Molds

	Rectangular	Round	Vascular Access
			
Cast Silicone			
			

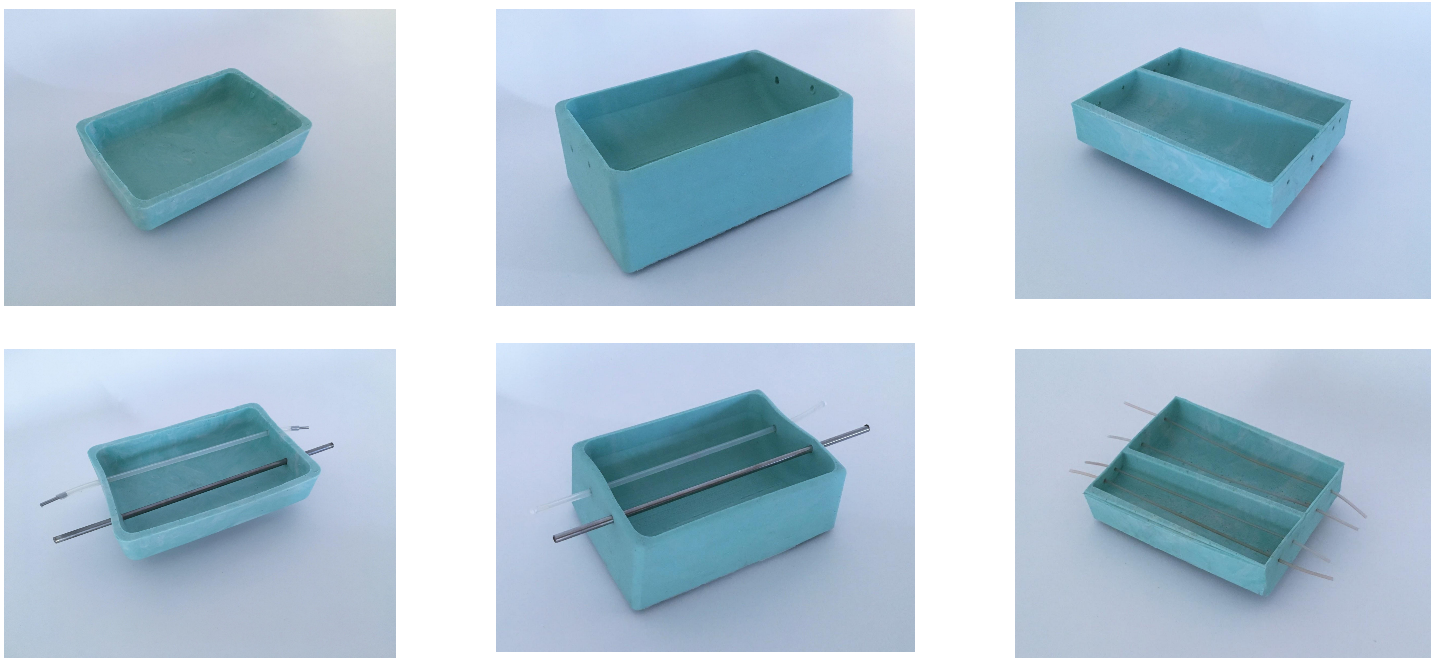
Two-part molds for casting silicone shells

Methods

Punch

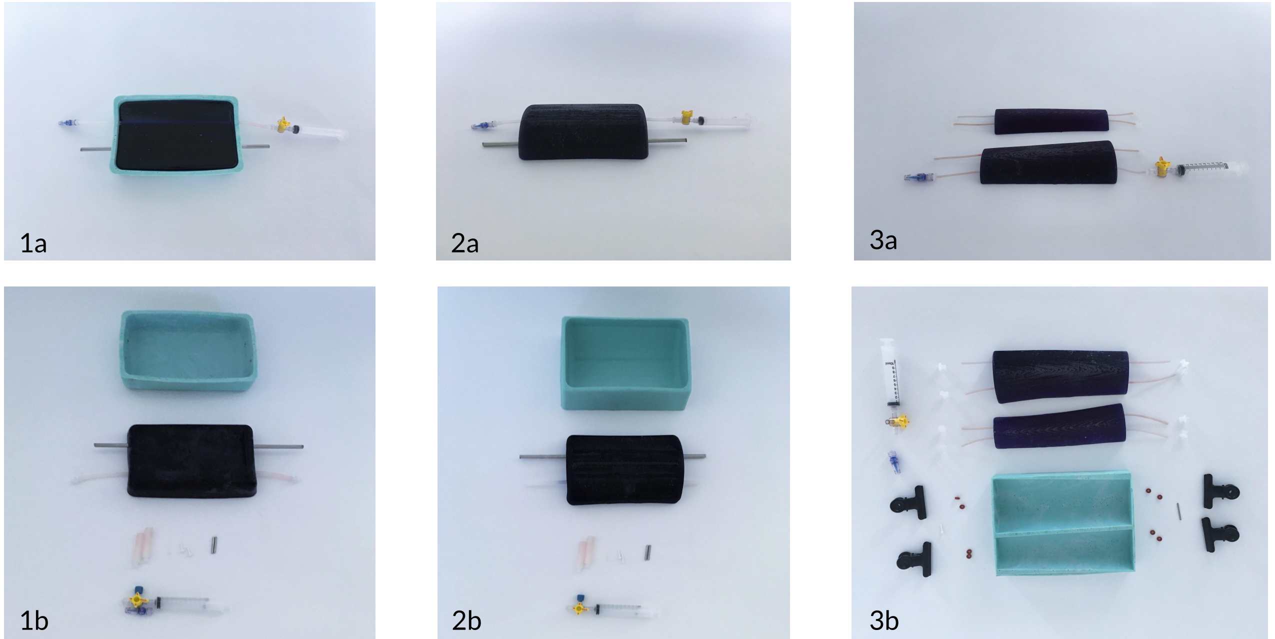
and

Line



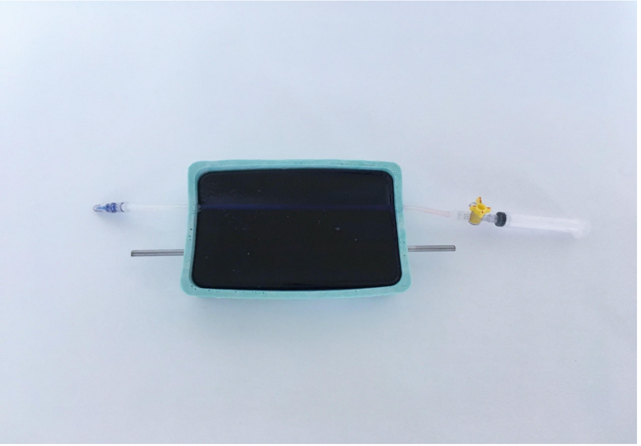
Silicone shells after removal from molds. Before and after punching, lining

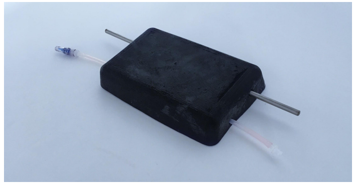
Results



Three model types customized for ultrasound-guided needling procedures: flat peripheral nerve block, curved peripheral nerve block, and vascular access. Shown prepared for use and exploded assembly. **1a)** Flat Peripheral Nerve Block. **1b)** Flat Peripheral Nerve Block in exploded assembly. **2a)** Curved Peripheral Nerve Block. **2b)** Curved Peripheral Nerve Block in exploded assembly. **3a)** Vascular Access. **3b)** Vascular Access in exploded assembly.

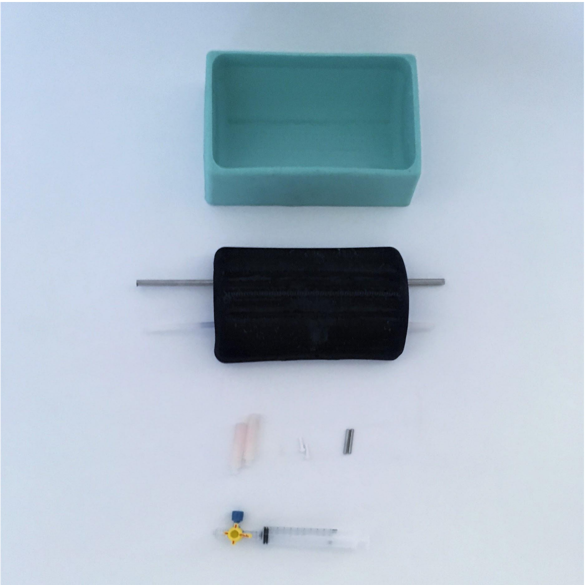
Results

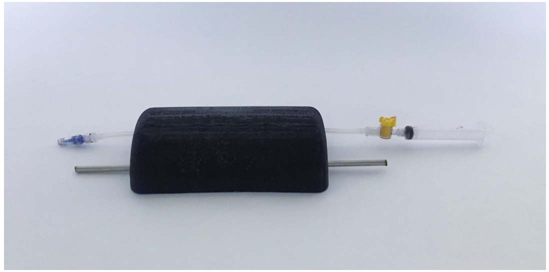


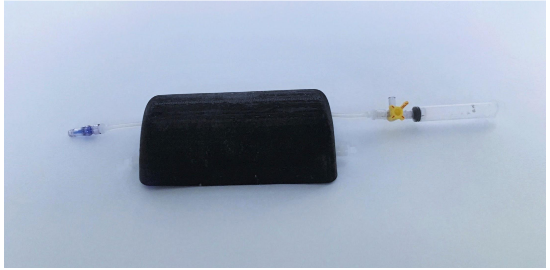


Rectangular phantom displayed for use

Results

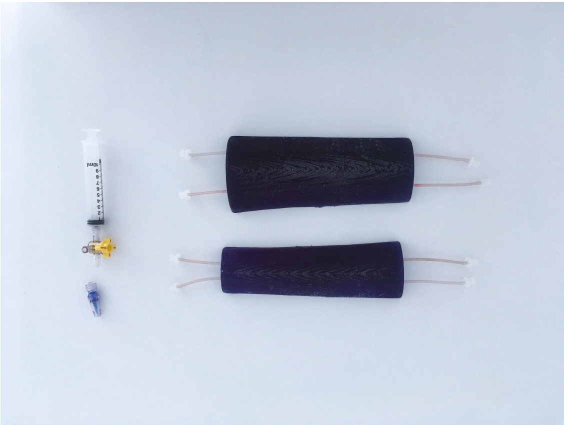


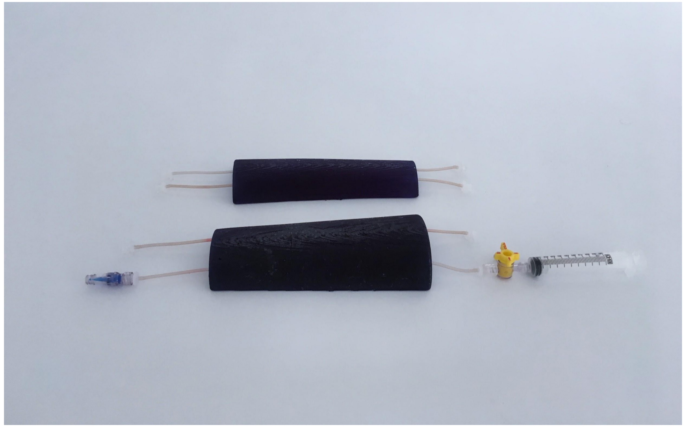




Round phantom displayed for use

Results





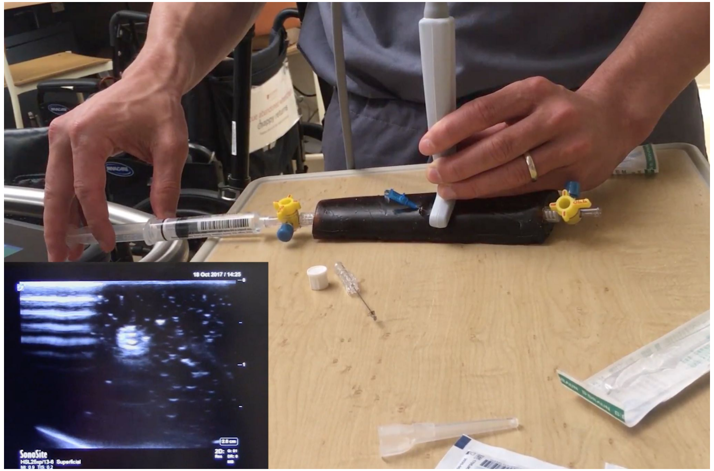
Vascular access phantoms displayed for use

Results

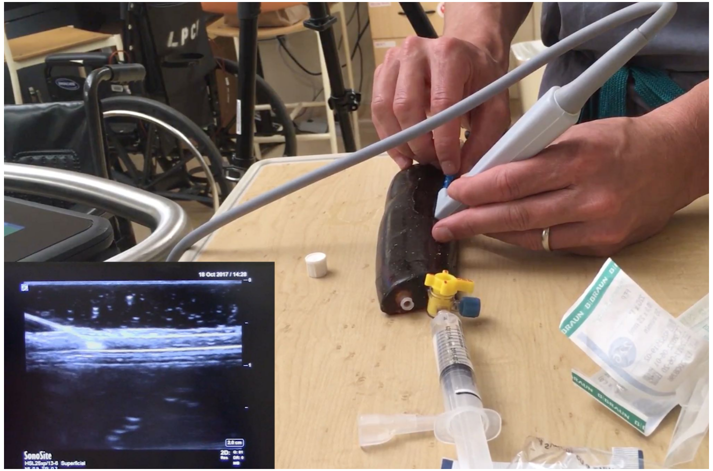
Nerve Block phantom cross-plane ultrasound of cavity

Nerve Block phantom cross-plane ultrasound of steel rod

Results

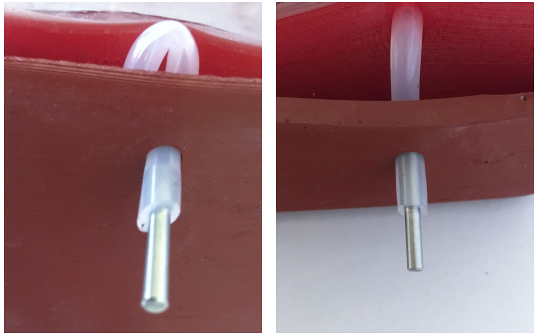


Cross-sectional view under ultrasound of an embedded, pressurized vessel

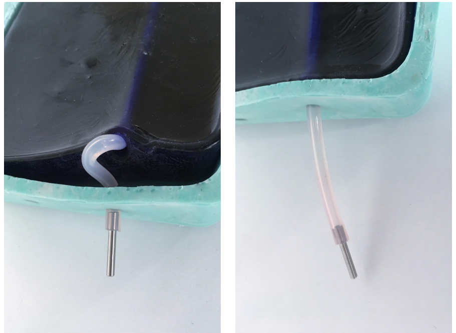


Longitudinal view under ultrasound of an embedded, pressurized vessel

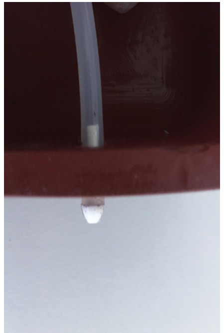
Maintenance



Round

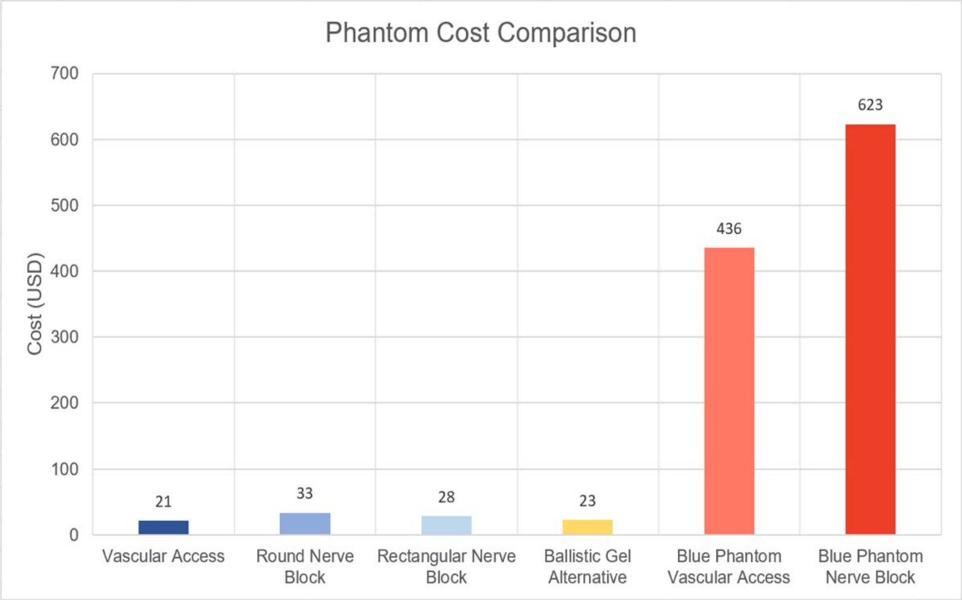


Rectangular



Vascular Access

Results



Phantom Cost Comparison
Cost (USD)
700
600
500
400
300
200
100
0
21
33
28
23
436
623
Vascular Access
Round Nerve Block
Rectangular Nerve Block
Ballistic Gel Alternative
Blue Phantom Vascular Access
Blue Phantom Nerve Block

Implementation

Ballistic gel phantom models in use teaching ultrasound guided peripheral IV placement at Stanford Hospital (left) and ultrasound guided regional anesthesia at the University of Rwanda Kigali (right)

Discussion

- Goals:
  - Improve access to high-quality ultrasound-guided procedural training
  - Alleviate health disparities
  - Improve health outcomes
- Innovative approaches:
  - 3D printing
  - Rapidly design and develop molds
  - Low cost
  - Durable
  - Reusable
- Applications:
  - Expand to a variety of low-resource settings
  - Advanced models for more complex nerve blocks
  - Improve technical skills and procedure success rates
  - Reduce patient discomfort, infection, injury, and other complications

References

1. Ruesch, S., Walder, B., & Tramèr, M. R. (2002). Complications of central venous catheters: internal jugular versus subclavian access—a systematic review. *Critical care medicine*, *30*(2), 454-460

2. O'Grady, N. P., Alexander, M., Burns, L. A., Dellinger, E. P., Garland, J., Heard, S. O., … the Healthcare Infection Control Practices Advisory Committee (HICPAC) (Appendix 1). (2011). Summary of Recommendations: Guidelines for the Prevention of Intravascular Catheter-related Infections. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *52*(9), 1087–1099.

3. Kornbau, C., Lee, K. C., Hughes, G. D., & Firstenberg, M. S. (2015). Central line complications. International Journal of Critical Illness and Injury Science, 5(3), 170–178.

4. Rosenthal, V. D. (2009). Central line-associated bloodstream infections in limited-resource countries: a review of the literature. Clinical infectious diseases, 49(12), 1899-1907.

5. Ahmed, O. M., Azher, I., Gallagher, A. G., Breslin, D. S., O'Donnell, B. D., & Shorten, G. D. (2018). Deliberate practice using validated metrics improves skill acquisition in performance of ultrasound-guided peripheral nerve block in a simulated setting. Journal of clinical anesthesia, 48, 22-27.

6. Morrow, D. S., & Broder, J. (2015). Cost-effective, reusable, leak-resistant ultrasound-guided vascular access trainer. The Journal of emergency medicine, 49(3), 313-317.

Questions?

Appendices

Introduction - Relevance

- Vascular access procedures are ubiquitous in the modern hospital. Central venous access alone is performed on approximately 8 percent of hospitalized patients[1], with 15 million patient-days of central vascular catheterization in US intensive care units (ICUs) each year[2].

- Effective line placement is not only an issue of patient comfort, but also important in decreasing the risk of infection, vascular injury, and other complications that can lead to increased morbidity and death along with greater health care costs[3]. The rate of catheter-associated infections in limited-resource countries varies from 1.6 to 44.6 cases for every 1000 patient-days in which ICU patients are subject to a central line[4].

- Current guidelines suggest comprehensive training in ultrasound guided techniques limit these complications[2], yet existing models are expensive and inadequate, especially for pediatric simulation.

Direct Cast Method

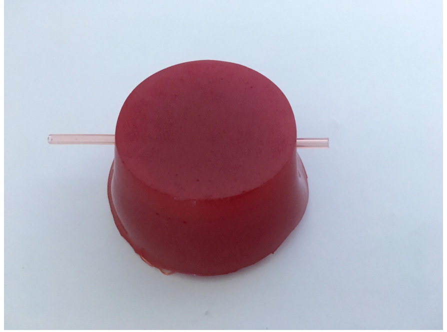
https://drive.google.com/open?id=1tj8zqhaEY0xB-P20ofBhz-qEXQIeRyjG

Commercial Silicone: Nerve Block Bread

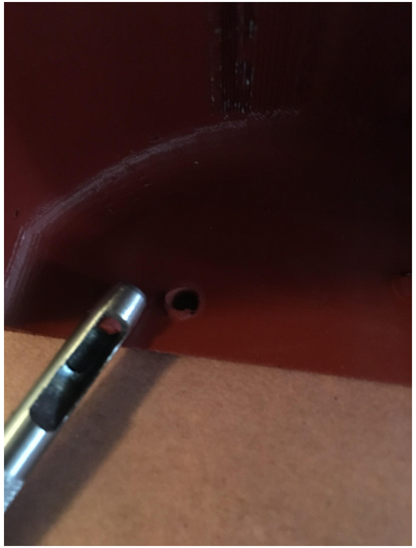
Commercial nerve block silicone bread plan
Similar to other nerve block designs, only with commercial bread pan and the advantages discussed above.

However, lacks the customizability of our prototyped phantom shells.

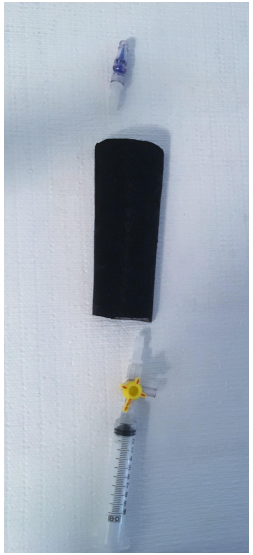
Commercial Silicone: VA Cupcake



Punching

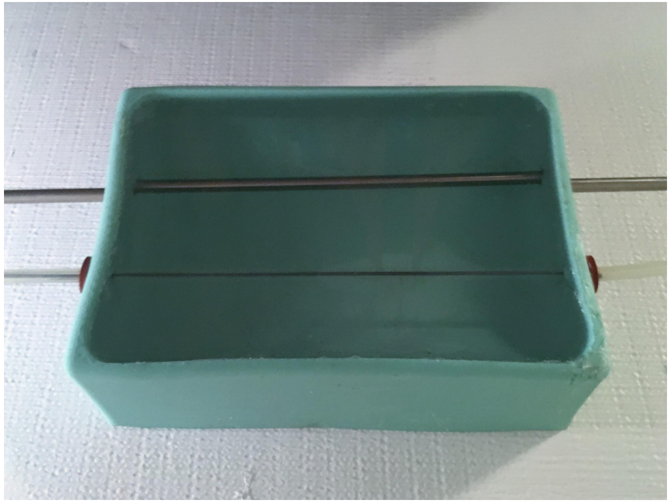


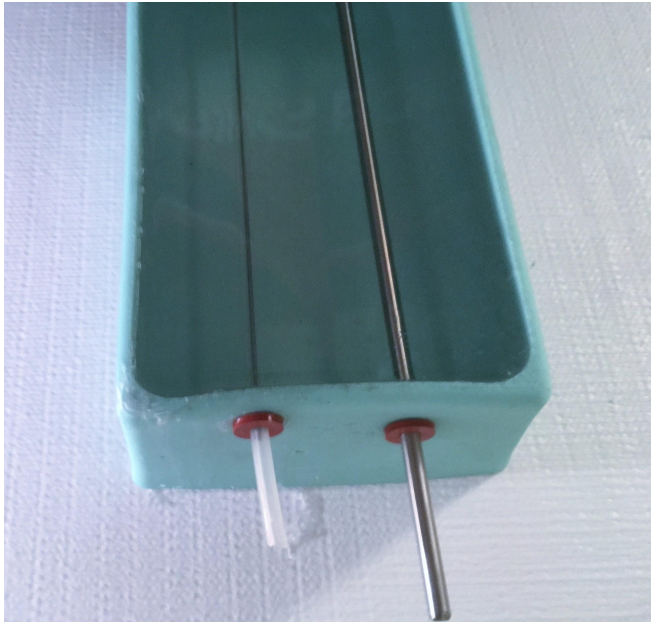
Post Cast Luer Adapters



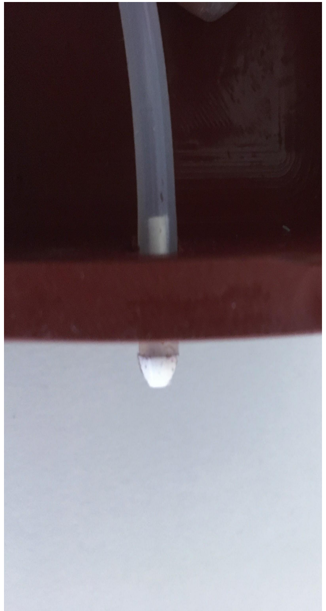
Video: https://photos.google.com/photo/AF1QipPR9oB6SheNrfoY4ZyDhaQ9g9xECXDZKUCm4pgu

Pre-Cast nerve block washers, straighteners



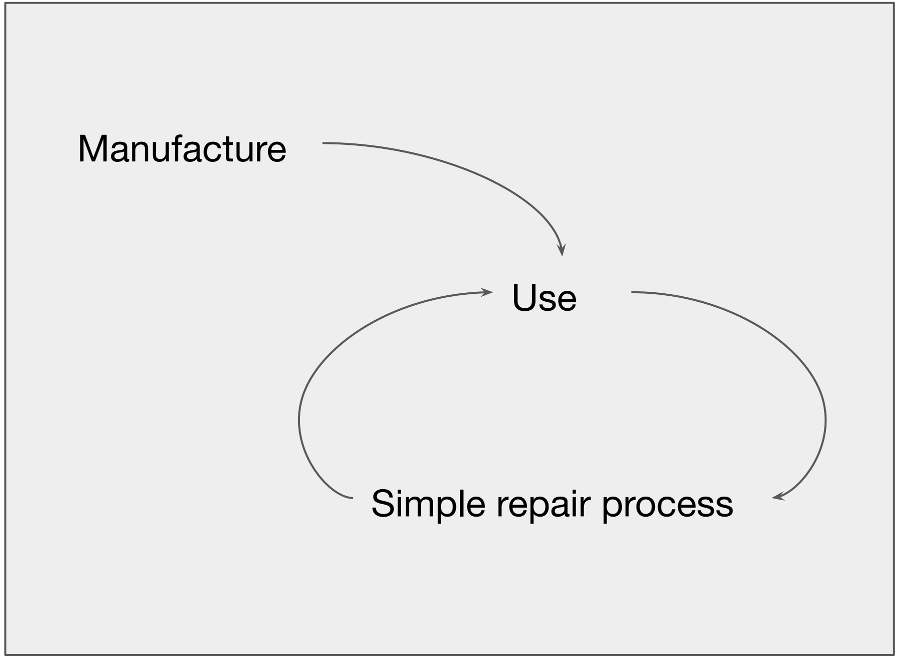


Threading/needling

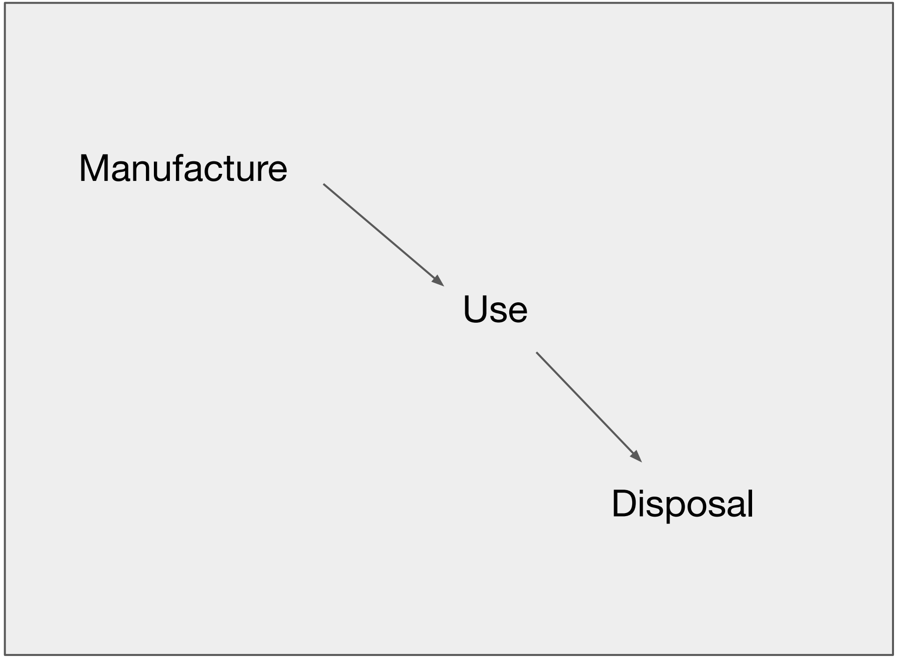


Lifecycle Comparison

Our Silicone-Shelled Ballistic Gel Phantom



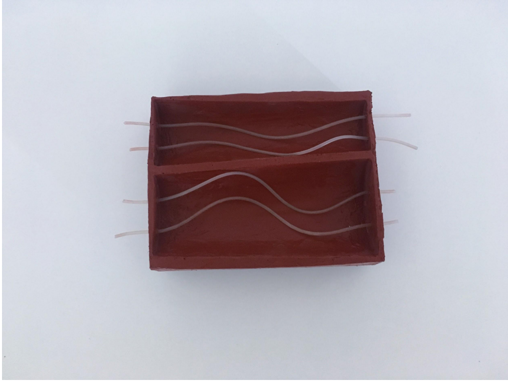
Standard Commercial/DIY phantoms

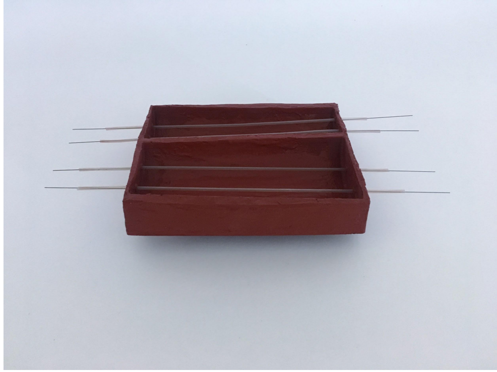


Threaded tubing post-cast

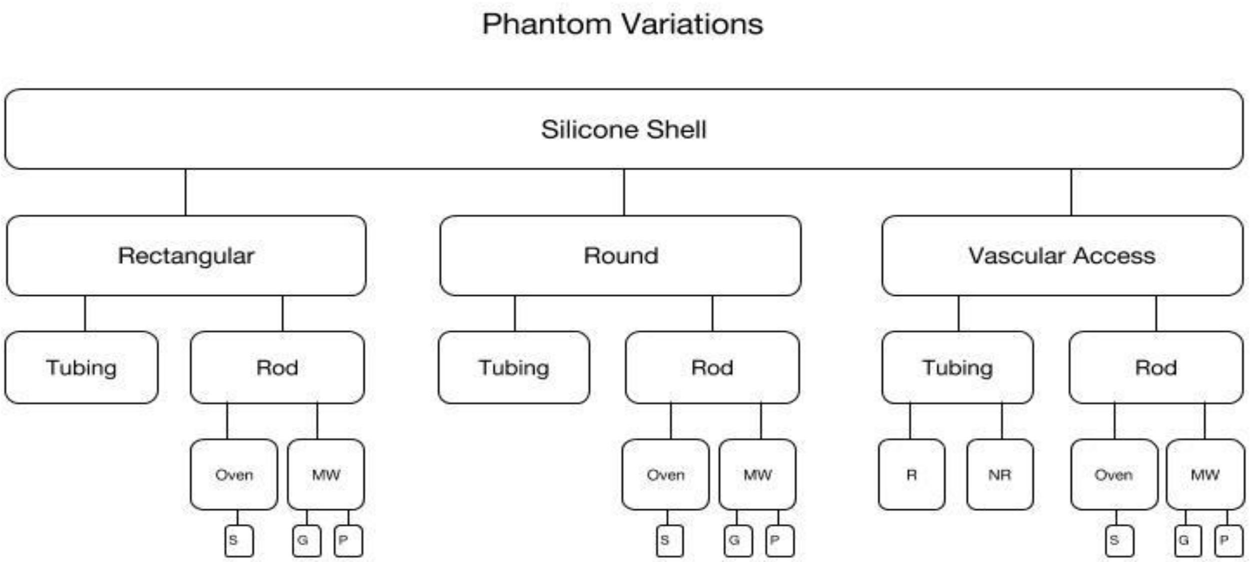
https://docs.google.com/file/d/1FMWgogYGS5RUGz0GN7hvNZ9TxWd3EhYdbw/preview
https://photos.google.com/photo/AF1QipPL5uQzcUHTsoC-G7ISC7Il9Ji_6U3ywMYdkFHF
https://photos.google.com/photo/AF1QipNwkyFnRo4KAIXfQcCy2iuTv1Jeh70M_jsvQvri

VA Tensioners, Straightening Lines





Variations


Phantom Variations
Silicone Shell
Rectangular
Round
Vascular Access
Tubing
Rod
Tubing
Rod
Tubing
Rod
Oven
MW
Oven
MW
R
NR
Oven
MW
S
G
P
S
G
P
S
G
P

Red vs Blue Silicone

- Durometer

- Platinum cure vs Tin Cure

Images from www.smooth-on.com

3D Printing: Equipment Considerations

- Most 3d printing vendors charge a 5-10x multiplier markup for their prints above material cost. If you intend to print more than $500 worth of prints I would recommend instead purchasing a 3d printer.

- Modestly capable and reliable 3d printers can be purchased at this price point. If you intend to only print PLA, the CR-10 can be a good choice at around US$400. The printer is cheap and can yield high quality prints. Although they have little official customer support, there is a large online community around this printer that is often willing to assist within hours.

- Qidi Tech produces great printers that in my experience are more robust and can produce high quality prints with a larger range of materials, although they have a smaller build volume. They also have excellent customer service, which is rare for most cheap Chinese 3d printers.

3D Printing: Equipment Considerations

- At the next price tier of US$2000-5000, Ultimakers are a solid choice with fantastic customer service, great printers, and a robust community.

- If printing TPU and other flexible filaments is a priority for you, you may look to upgrade the extruder system on these 3d printers or purchase a printer that was designed with this in mind. I have found that the Qidi tech can print TPU without modification fairly well. This can be further improved with extruder system upgrades such as the Flexion extruder. All molds used in this project were printed on a Qidi Tech One with the Flexion extruder system. The CR-10 often fails at TPU for longer prints. In general, direct drive extruders such as those in the Qidi Tech are better at printing flexible filament than bowden extruders, which are found in the CR-10 and UM3.

- Don't buy Makerbot. They're overpriced and overmarketed and yield generally inferior results.

3D Printing: Material Considerations

We have also experimented with different mold materials for casting the silicone shell.

TPU molds last longer and are easier to demold, PLA molds have the greatest dimensional accuracy but are the least robust and typically last only 1-3 casts.

ABS molds may last longer but will be require a more advanced printer to print without warping.

Polycarbonate molds are even more durable but suffer even more pronounced warping issues.

PLA, ABS and polycarbonate molds should be coated with a non-sulfured epoxy to smooth. All molds should be coated with silicone compatible mold release prior to the silicone pour.

In summary,
PLA molds are the easiest and cheapest to print but the least durable
ABS/Polycarbonate molds require an enclosed, heated bed/chamber but are more durable for direct casting
TPU molds print slower and may require extruder modifications but are more durable for silicone shell casting

3D Printing: Direct Cast Material Considerations

We experimented with several 3d printing materials to allow for recasting of the ballistic gel (describe TPU, PLA, ABS here) and found them to have limitations; therefore, developed a silicone mold. Main limitation is that their glass transition temperature often falls close to the the phantom gel melting point such that the gel phantoms cannot be recast whole inside them, but instead must be removed, cut, and repoured as with other gel phantoms.

3D Printing: Print Setting Considerations

As there are no overhang features on any of the molds supports are not necessary. In general err on the side of a higher infill percentage as this will limit warping during a direct cast and prolong mold life for silicone casting.

Since there are no intricate features I recommend using a nozzle diameter of at least 0.8mm instead of the standard 0.4mm. Doing so will lower print time and yield stronger molds.

These molds are large and require long prints. Standard 0.2mm layer height is recommended, although you can adjust this depending on your needs. Greater layer heights will print faster but will require more sanding to yield a smooth surface prior to epoxy coating.

More Detailed Direct Casting Method

Production Steps

1). Mold Creation:

Computer aided design (CAD) was used to create a 3d model of the desired gel phantom. We then used a cavity operation to create a single-part mold of gel phantom. We included slots for placing tubing and luer locks for vascular access or rods for nerve block phantoms as appropriate, then 3D-printed the mold using a 3D printer.

2). Casting the phantom:

We melted ballistic gel with food safe oil-soluble dye. Cornstarch can be used as an additive to create ultrasound artifact.

For vascular access phantoms, we prepared tubing and luer locks for the molds. The silicone was cut to be roughly 1cm shorter than the length of the mold to provide some tensile restoring force that will prevent the luer locks from being accidentally dislodged. The luer locks were inserted on each end of the mold and thin cyanoacrylate glue was used to secure them to the tubing. The cyanoacrylate glue can only be exposed to high temperatures for a short time; however, high temperature silicone glue can be used instead if temperatures remain high for any extended period. Luer latches were inserted to hold them in place.

For nerve block phantoms, rods were placed in the desired position before pouring gel into the molds.

The gel was melted (approximately 1 hour), de-bubbled, and dyed, then cast into the mold and allowed to cool and set for approximately 24 hours.

More Detailed Silicone Shell Casting Method

Step 1: Create CAD of silicone shell mold
Begin with the CAD for the desired gel phantom. Then create a negative of the gel form using the cavity operation. Finally, shell the negative and use the mold tooling operation to create a printable two part mold for the silicone shell.

Step 2: 3d-print two part silicone shell mold
We have experimented with different mold materials for casting the silicone shell. TPU molds last longer and are easier to demold, PLA molds have the greatest dimensional accuracy but are the least robust and typically last only 3-5 casts. ABS molds may last longer but will require a more advanced printer to print without warping. PLA and ABS molds should be coated with a non-sulfured epoxy to smooth. All molds should be coated with silicone compatible mold release prior to the silicone pour.

Step 3: Cast silicone shell
Mix and degas silicone. We used platinum cure Shore 60A silicone with a max operating temperature of 550 degrees Fahrenheit. Degassing is not strictly necessary but may improve surface finish and increase shell robustness. Then pour silicone mixture into 3D printed mold bottom. Press top mold slowly but firmly down against the bottom; the alignment features will stop the molds at the prescribed location. Ensure that the mold is completely full. Clamp mold halves together or place heavy item on top to ensure that the molds stay in place as the silicone sets. Once the silicone sets, remove silicone shell from 3D printed mold.

Step 4: Prepare silicone shell for gel casting
Use hollow punch to create hole that is approximately 75% the diameter of that of the tube, lock or rod that will interface with it. The undersizing forces the silicone to stretch around the tube, creating a tight seal that prevents the ballistic gel from leaking during recasting. For the current luer lock design, which has a ¼” diameter midsection, this practice suggests the use of a 3/16” hole punch. Cut silicone tubing slightly shorter than the length of the mold to create tension in tube. 90-95% of the total length is typically suitable. This will vary based on the stiffness of your chosen silicone shell and silicone tubing. Attach tubing to luer locks, sealing the connection with silicone sealant. If permanently residing in silicone shell, seal connection with silicone sealant. Allow silicone sealant to set. If creating a nerve block phantom, insert rods into holes so that they will extend through phantom.

Step 5: Cast ballistic gel
Melt ballistic gel with dye. Cornstarch can be used as an additive to create ultrasound artifact. Pour gel into silicone mold. Allow to cool and set undisturbed for 24 hours. After setting, the phantom is ready for use. The vascular access and round models can be removed to test their round contours, while the rectangular model can remain in the silicone indefinitely.

BOM

Per VA Phantom		
Total Cost	16.59	
Parts	Number per Assembly/Voume (in^3)	Cost per Assembly
Luer Locks	8.00	7.20
High-Temperature, Durometer 50A Silicone Tubing	4.00	1.76
Ballistic Gel (mix for 15%)	20.00	4.51
Dye	0.1 oz	0.25
Silicone Sealant	.1oz	0.16
Mann Release Technologies Ease	.10z	0.12
Shore 60A platinum cure silicone rubber (Smooth-Sil 960)	18.10 cubic inches (9 ounces/0.5625lb)	7.10
Mold		
Total Cost	24.82	
Parts	Number per Assembly/Voume (in^3)	Cost per Assembly
3D Printed Mold Top	36.36	14.54
3D Printed Mold Bottom	25.70	10.28

BOM

Per Rect Phantom with Silicone Shell		
Total Cost	28.41	
Parts	Number per Assembly/ Volume (in^3)	Cost per Assembly
304SS Rod	2.00	6.50
Ballistic Gel (mix for 15%)	51.12	11.54
Dye	0.1 oz	0.25
Silicone Sealant	.1oz	0.16
Mann Release Technologies Ease	.10z	0.12
Shore 60A platinum cure silicone rubber (Smooth-Sil 960)	22.51	9.84
Mold		
Total Cost	14.98	
Parts	Number per Assembly/ Volume (in^3)	Cost per Assembly
3D Printed Mold Top	18.58	7.43
3D Printed Mold Bottom	18.86	7.55

BOM

Per Round Phantom I		
Total Cost	33.41	
Parts	Number per Assembly/Volume (in^3)	Cost per Assembly
304SS Rod	2.00	6.50
Ballistic Gel (mix for 15%)	58.62	13.23
Dye	0.1 oz	0.25
Mann Release Technologies Ease	.10z	0.12
Shore 60A platinum cure silicone rubber (Smooth-Sil 960)	30.06	13.15
Mold		
Total Cost	54.02	
Parts	Number per Assembly/Volume (in^3)	Cost per Assembly
3D Printed Mold Top	44.25	17.70
3D Printed Mold Bottom	90.81	36.32

BOM

Other	
Manufacturing Equipment:	
	Temperature-Controlled Oven
	Cooking Thermometer
	Cooking Vessel (Breadpan or other)
	Silicone Mixing Vessels
	Silicone Mixing Tool / Spatula
	Scissors***
	Heatgun*
	Utility or X-Acto Knife**
Personal Protective Equipment	
	Goggles
	Oven Mitts
	Apron
	Close-toed shoes and non-flammable attire
*Optional. Does not affect performance but may be used to smooth the finished model for aesthetic purposes.	
**Also optional as it does not affect performance but may be used to trim the edges of the finished model for aesthetic purposes	
***A saw can also be used to cut large blocks of ballistic gel	

Commercial Silicone vs RTV Silicone

Commercial, professionally manufactured high-temp vulcanized silicone has several advantages:

1). Finish: Doesn't have bubbles found in prototyping room-temp vulcanizing silicone (which could be minimized in prototyping ones if I purchased and used $500 vacuum degassing chamber, but I don't have the funds for that). Aesthetically pleasing and improves finish of gel phantom. Also during recasting the smooth finish prevents bubbles of air from being trapped at bottom, which then need a lot of time to rise up and come out of the melted gel.

2). Durability: Can withstand much greater elongation before break. Generally longer-lasting and more tough.

3). Thickness: Doesn't need to be as thick. This:

A). Saves material

B). Allows for better recasting. Silicone is a thermal insulator. Thin layers allow gel to heat more quickly and more uniformly throughout. The current models can take 4 hours to totally remelt in oven and even then because of finish issues more time to get rid of these finish bubbles.

4). VA hole tension: Can punch smaller hole that the needle can still get through easily but holds tubing in place better so no washers, binder clips, wires, etc needed to prevent straying or leaking.

5). Cost and time: At scale it's cheaper per part and saves a lot of time. I'd gotten some quotes from a variety of manufacturers at some point regarding our specific phantoms if we would want them commercially made. Tooling would take ~$10,000 per mold if done in the US, ~$1500 per mold in China. After tooling the per part price is around $10 in quantities below 100.

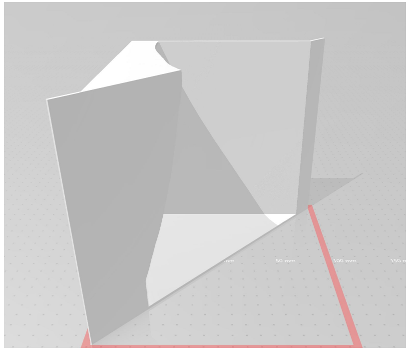
Ballistic Gel Dye

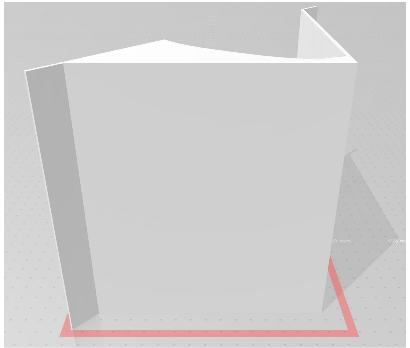
- Ever since the ClearBallistics stopped providing their normal dye and now only have specialized medical dye that quadruples the price of their gel I've been looking for alternatives. I'd thought that I'd found a good non-toxic dye but as I discovered when I last visited with the phantoms it bleeds and molds over time. Since then I've tested a variety of oil soluble dyes of several different classes: 2-napthol, iron oxide, mica, lake, etc.

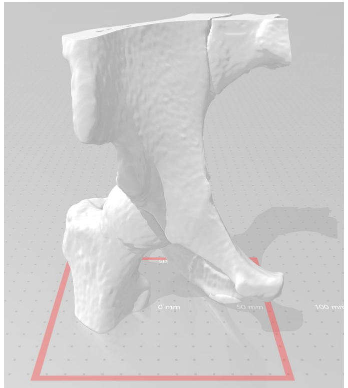
- Of these I think I've found another suitable non-toxic version but only time will tell if it molds or not. If this dye molds, bleeds, or fails for some other reason, I think it may be best just to pay the extra for the official ClearBallistics version even though it's way overpriced.

- To mitigate any chance of molding, I've put the phantoms in closed containers with desiccant packets in each. These packets come with colored indicator beads that will change color when they've expired.

Next Steps: Femoral







Recasting Tips

- I'd recommend recasting the phantoms in an oven with good temperature control; the small toaster oven and broiler that I have do not and as such are prone to burning the gel. A regular kitchen oven is ideal but it's a good idea to line the oven with aluminum foil beforehand and keep the phantoms in a baking tray just in case of an accident. If the gel spills into the oven whatever you can't clean out will burn.

- I'd also recommend allotting more time to recasting than you think you'll need. As discussed above, because the gel phantoms are thick to begin with, the bubbled texture and thick silicone shell mean that it can take a while for the phantoms to recast fully. Stopping halfway, with the bubbles halfway risen in the gel, will often leave them worse than when you started (unless you're using the commercial silicone, which doesn't suffer from the bubbling problem).

Global Need Example

- The need for effective training tools for ultrasound-guided vascular access procedures is especially pronounced in Rwanda.

- In Rwanda, the first international destination to which these models have been sent, there is a critical shortage of anesthesiologists. After the genocide, there remained only one certified anesthesiologist to serve a country of six million. While that number has since grown to nineteen, the population has also risen to almost twelve million.

- With this shortage of providers, vascular access training is not only a matter of mitigating risks and improving treatment outcomes but also of enabling vascular access and life-saving treatments that are dependent on it to be performed at all.

- Adequate training of fundamental skills such as vascular access is crucial for continued medical development.

631,579 : 1

The number of people for every fully trained anesthesiologist in Rwanda

Outcome Measures

- The training phantoms aim to improve placement success rates and reduce patient discomfort, while decreasing the chance of infection, vascular injury, and other complications that can lead to increased morbidity and death along with greater health care costs

- These outcomes can all be measured, and differences between groups using these training phantoms, other commercial phantoms, or control groups that have not received any additional training can be compared and analyzed.

- Measurements of mean time of access procedure, placement success rates, and reported patient discomfort levels provide immediate, quantifiable outcomes while larger studies on the long term morbidity and mortality rates of these groups can also be conducted.

Unique Value

- Existing models are either expensive or inadequate, especially for pediatric simulation. Commercial limb phantoms using proprietary gels typically cost several hundred US dollars, while other homemade ones comprising of synthetic or natural gelatin do not match clinically relevant anatomical structures and often consist of a basic rectangular contour. These models also face durability issues, with many phantoms that are marketed as self-healing failing after a few rounds of use.

- The grossly excessive cost of commercial models using proprietary gels and fundamental inaccuracies in the structure of homemade phantoms lead to limited, ineffective practice. The short lifespan of these products exacerbates these issues. Most homemade and commercial models also fail to accurately reflect smaller pediatric vasculature, which is inherently more challenging. Clinical outcomes are impaired as a result.

- This project addresses these major shortcomings as an affordable, reusable, physiologically-accurate pediatric phantom with tissue-comparable ultrasonic properties. By repurposing a readily available, affordable gel this product is able to match and improve upon commercial models while remaining below US$30 for combined parts and labor.

Comparable commercial model, priced US$570.96

Image from bluephantom.com

Other Citations (in paper)

Cozowicz, C., Poeran, J., & Memtsoudis, S. G. (2015). Epidemiology, trends, and disparities in regional anaesthesia for orthopaedic surgery. BJA: British Journal of Anaesthesia, 115(suppl_2), ii57-ii67.

Gabriel, R. A., & Ilfeld, B. M. (2018). Use of Regional Anesthesia for Outpatient Surgery Within the United States: A Prevalence Study Using a Nationwide Database. Anesthesia & Analgesia, 126(6), 2078-2084.

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