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ORIGINAL ARTICLE

Transcarotid artery revascularization simulation using 3D printing and polymers

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Abstract

Background: Phantoms are often used to train new surgical technologies. Unfortunately, these products are expensive and typically have simplified anatomy, limiting access, and provide suboptimal training. This is a report of an in-house simulation using 3D printing and multilayer polymer hydrogels to train attending physicians on a new carotid stenting technology. **Methods:** TransCarotid Artery Revascularization (TCAR) is a novel procedure from Silk Road Medical for carotid stenting. To safely learn how to use this device, two attending surgeons performed a proctored simulation using a realistic, pulsatile, and bleeding human neck model. The simulation was created by 3D printing injection molds and casting anatomically correct polymer components. The following day, the TCAR procedure was performed on an 81-year-old man with symptomatic right carotid stenosis. **Results:** The TCAR procedure was successfully performed in the simulation model and in the live patient. The surgeons reported that the simulation allowed them to learn the procedure under risk-free but realistic operative conditions. The patient did not have any immediate or long-term adverse events. **Conclusions:** Replicating human anatomy using 3D printing and multilayer polymer hydrogels provides a cost-effective opportunity to practice using novel surgical technologies before attempting live cases.

Keywords: *carotid stenosis; novel device; endarterectomy*

Introduction

Surgical simulation can allow providers to acquire technical skills without risking injury to patients.[1] Carotid endarterectomy (CEA) is a procedure that has been scrutinized for requiring experienced surgeons to ensure optimal outcomes for patients.[2] CEA continues to be the primary surgery for carotid revascularization due to the increased stroke rate associated with carotid stenting. Transcarotid artery revascularization (TCAR) was developed as an alternative to CEA with the promise of maintaining a low intraoperative stroke rate and providing a treatment option for patients not suitable for CEA. This technology, recently approved by the US Food and Drug Administration, provides neuroprotection using blood flow reversal to prevent embolic events during carotid stenting. The technology resolves one of the primary causes of stroke in carotid artery stenting (CAS) by providing embolic protection intraoperatively. The overall stroke rate was 1.4% compared with the results of the CREST trial, which reported a stroke rate of 2.3% and 4.1% in CEA and CAS, respectively.[3,4] In addition, CAS has the notable benefit of a lower rate of myocardial infarction than CEA (1.1% and 2.3%, respectively). TCAR had a myocardial infarction rate of 0.7%, demonstrating comparable risk with CAS and significantly less risk of myocardial infarction compared with CEA.[3,4] Although TCAR has the potential to enhance the treatment of carotid artery stenosis, technical procedural nuances may be prohibit its timely acceptance by the surgical community. This is a report of an in-house surgical simulation using 3D printing and multilayer polymer hydrogels to train attending physicians on this new stenting technology before live surgery.

Surgical simulation has tremendous potential to improve patient safety through resident and physician training, however, currently available models have significant limitations. Current virtual reality systems lack the tactile realism of physical models and cannot be developed quickly to represent individual patient anatomy.[5] In addition, for this particular procedure, manipulating the physical components of the stent and testing the flow reversal system are vital in learning the technique. Partial task models, although appropriate for practicing specific skills, cannot be used to train physicians in full procedures or provide realistic experience of the operation as it would be with a live patient.[6] Cadaveric specimens are also limited in the realism of tissue properties, biohazard risk, and lack of blood flow.[7] Blood flow is of particular importance in the TCAR procedure, because blood flow reversal is a critical step during the surgery to prevent stroke.

The model described in this report was developed and validated using 3D printing and polyvinyl alcohol (PVA) to create a life-like whole-task simulation model that was used to familiarize staff members with all steps involved in this novel procedure.[8]

Methods

A 3D model of an idealized carotid artery was created using computer-aided design software (Meshmixer; 2015 version 11.0, San Rafael, CA). The model contained a common carotid artery segment (CCA), internal carotid artery with plaque embedded within the intimal layer, and external carotid artery. Anatomic structures also fabricated for the simulated neck included the skull with jaw, clavicles, facial and jugular veins, sternocleidomastoid muscles, vagus, and recurrent laryngeal and hypoglossal nerves. For the femoral sheath insertion site, the femoral vein, artery and nerve were created. The skin on both components included muscle, fat, and dermal and epidermal layers. Injection molds for each structure were printed and filled with color-appropriate PVA. Each anatomic structure underwent graded polymerization using freeze-thaw cycles to change the tactile quality accordingly. Bleeding was simulated in the skin and veins using pressure bags. A non-clinical ventricular assistive device was used to create pulsatile flow within a circuit for the carotid artery. Parallel circuits connected the common, external, and internal carotid arteries to create bidirectional flow. Bony landmarks including the skull, sternum, and clavicles were 3D printed and embedded in the PVA. The femoral vein was created within a slab of tissue meant to simulate a leg and was positioned at an appropriate anatomic distance from the neck.

The simulation was performed in a hybrid operating room equipped with angiography and ultrasonography under

Figure 1. Full simulation set-up before the operation, including neck (right) and femoral access sites (left). Musculature, bones, and pulsatile carotid within the neck are palpable. Ultrasonography was used to determine carotid and femoral anatomy before cut-down and percutaneous access.

Figure 2. (A) Neck cut-down to expose the common carotid artery and place the TCAR device. Two carotid surgeons unfamiliar with the device and approach are instructed through the procedure by a proctor. (B) Complete operative set-up during the simulation with vascular access sheaths in both the femoral vein and common carotid artery. The flow reversal circuit is also visualized with the flow controller set on low flow.

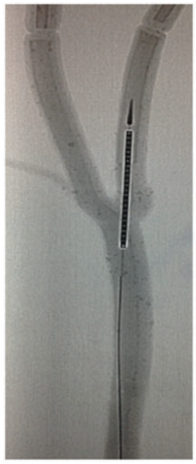

Figure 3. Fluoroscopy-guided placement of a carotid stent in the simulated vessel. The superior thyroid artery is visualized branching from the external carotid.

realistic operative conditions. The manufacturer provided a new TCAR device, and a standard set of carotid artery surgical instruments was used. The simulator and flow circuit were set up before the surgeons entered the room and were draped in typical fashion (Fig. 1).

To safely learn use of the TCAR before a live operation, two attending surgeons (one in the Department of Neurosurgery and one in the Division of Vascular Surgery) without previous experience on the TCAR device performed a proctored simulation using the simulated neck and femoral vein model as outlined in the Silk Road Video (Silk Road Medical, Sunnyvale, CA).[9] Each step of the procedure was performed, including ultrasonography and angiography (Figs. 2A and 3). The day after the simulation training, the TCAR procedure was performed on an 81-year-old man with symptomatic right carotid stenosis.

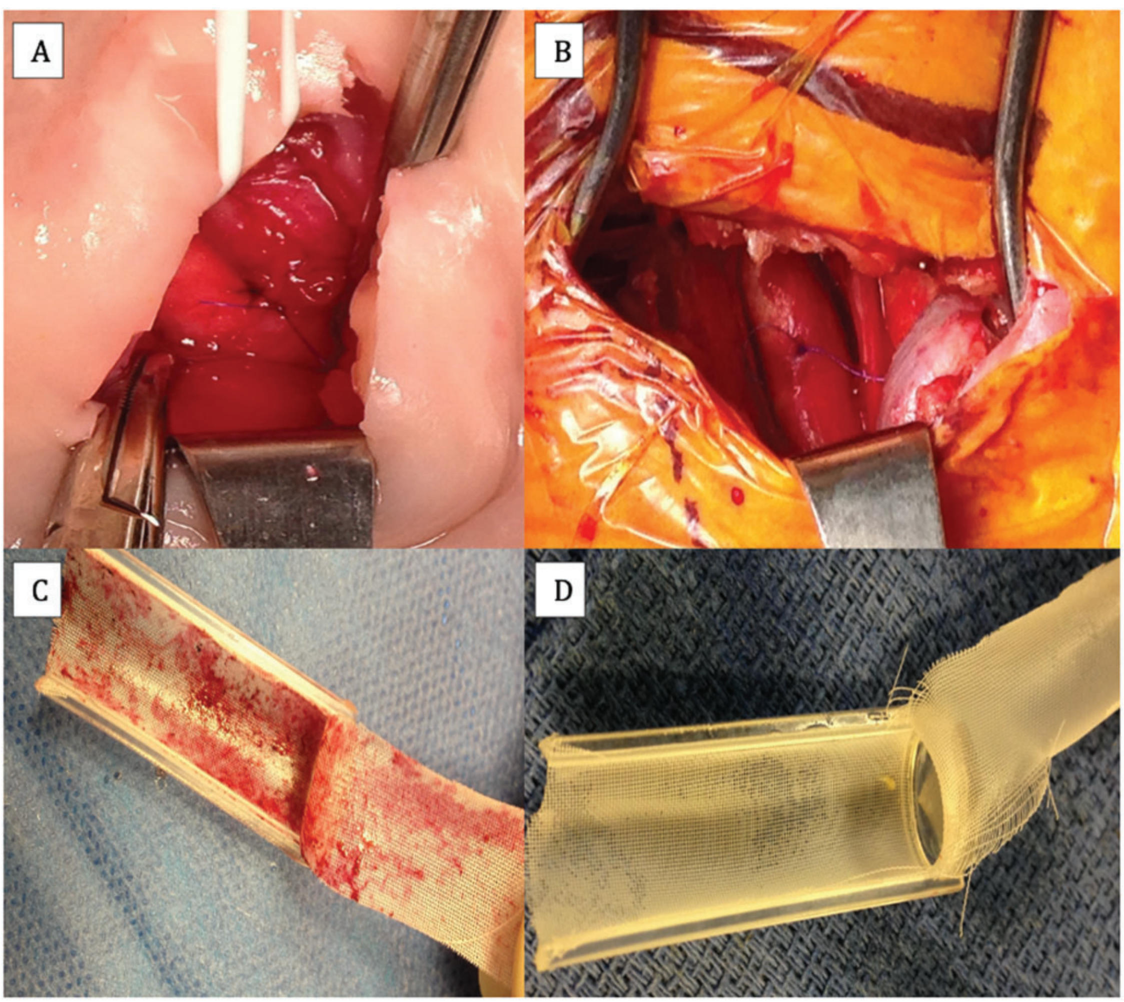

Figure 4. Upper: exposure of the common carotid artery and jugular vein in simulated (A) and live (B) procedures. A single prolene stich was used to close the TCAR access site. Lower: porous filtration device in place before blood entered back into the venous system shows debris collected during flow reversal during the simulation (C) and live procedure (D). Debris is seen within the simulated collection chamber, emphasizing the importance of flow reversal.

Figure 5. After the conclusion of the simulation, the model was dissected to expose the stent and gain a better understanding of how the TCAR device functions.

Results

The TCAR procedure was successfully performed in the simulation model and in the live patient. The surgeons reported that the simulation allowed them to learn the device under risk-free but realistic operative conditions. The life-like appearance of the simulated neck and pulsatile carotid (Fig. 4) encourage the vascular team to attempt a perfect practice run. Although the clinicians were first taught using a clear plastic tube, which is the company's standard practice, multiple questions arose during the polymer-based simulation. There were corrections made to the order of the procedural steps, use of the high-low flow button, and the correct maneuver to de-air the system. The surgeons were able to troubleshoot the TCAR and develop a hands-on understanding of its functionality. If these missteps and adjustments to technique were made with a live patient on the table, significant injury could have occurred. Interestingly, the device has a filter that can be inspected at the end of the procedure and after the simulation finished; friable plaque was present, demonstrating the benefit of flow reversal (Fig. 4). The full procedural nature of the simulation permitted interdisciplinary interaction and communication skills, such as requesting heparin administration and patient vital goals at appropriate times. The simulated TCAR took 87 min, comparable to the published mean procedure time of 73.6 min.[1] At the end of the simulation, the trainees and proctor performed a hands-on cadaveric-like dissection to further elucidate anatomic details (Fig. 5). This allowed the surgeons to appreciate how important the angle of needle entry into the carotid artery is to prevent dissection and how to avoid injury to the recurrent laryngeal nerve.

The TCAR on the patient the next day took 95 min. The patient did not have any immediate or long-term adverse events such as 30-day cranial nerve injury, stroke, myocardial infarction, and/or mortality.

Discussion

Replicating anatomy using 3D printing and multilayer polymer hydrogels provides an opportunity to practice using novel surgical technologies before attempting live cases. Surgical models that can replicate the operation in its entirety and give the surgeon a realistic experience with a new medical device can easily and safely replace the need for training on live patients. This surgical approach requires a carotid bifurcation length >5 cm to the clavicle and the absence of atherosclerotic burden in the CCA. These conditions are required for safe placement of the sheath and adequate clamping of the CCA during the procedure.[1] The model was made to meet these anatomic requirements for the TCAR procedure but can be made for simulation of all geometric patterns of carotid disease. Here, the model was fabricated using idealized anatomy for training on a new surgical technology, but it can be created from patient-specific imaging studies, giving surgeons the possibility to rehearse cases with particularly challenging anatomy. Future directions are focused on continuing training with this device at other institutions before human procedures. In addition, by measuring operative metrics during the simulation and comparing them with the outcomes of the live procedure, the simulation may be able to predict safe practitioners and serve as a certification tool.

Conflict of interest

The authors have no conflicts of interest to disclose.

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