CUSTOM-DESIGNED
ENDOVASCULAR SIMULATION
MODELS

United Biologics Silicone Vasculature

United Biologics, Inc. designs and builds simulation models of a wide variety of arterial and venous anatomical configurations (Figure 4.17). These innovative, custom-designed and manufactured models can be either low- or high-fidelity simulation devices, according to use. The silicone rubber vessel models are rendered seamless, and the vessels can be filled with mildly lubricated fluid for SBT of endovascular procedures. Selective arterial catheter procedures are possible for the aorta, renal, hepatic, mesenteric, iliac, femoral, coronary, brachiocephalic, and intracranial internal carotid, vertebral, basilar, and proximal cerebral arteries. Intracranial vessel models have been designed to practice coiling of aneurysms in typical anatomical locations. A composite model, the Neuro System Model Plus™, was designed to include anomalous origins of brachiocephalic arteries. This device has a bovine carotid artery origin and a type III innominate artery. Simulation-based training with this device teaches proper catheter selection and manipulation through the anomalous arteries to reach the intracranial circulation for required interventional procedures.

With United Biologics simulated vasculature, SBT for endovascular clot removal in a simulated stroke model is possible. This high-fidelity simulation model allows realistic practice of microcatheter manipulation and clot extraction device placement without risk to an actual patient.

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DEVELOPMENT OF A
VASCULAR FLOW MODEL FOR
INTERVENTIONAL STROKE
THERAPY

Background

The increasing number of hospitals seeking certification as stroke centers of excellence by the Joint Commission has led to increasing interest in interventional stroke therapy, particularly on the part of hospitals interested in meeting the criteria for Comprehensive Stroke Centers.  This interest, in turn, has led to an increasing demand for physicians who are trained to provide intra-arterial thrombolysis and mechanical thrombectomy. The traditional pathway for training has been via an interventional neuroradiology (or endovascular surgical neuroradiology) fellowship. The number of fellowship-trained interventional neuroradiologists, however, is not sufficient to meet this increasing demand. As a result, interest has developed in providing specific training in stroke therapy—rather than the full range of interventional neuroradiology—to physicians from other backgrounds, such as interventional radiology and diagnostic neuroradiology.
Current Standards

The Society of Interventional Radiology (SIR) has developed training standards for interventional stroke therapy that outline the cognitive and technical skills necessary and how these skills may be required outside of an interventional neuroradiology fellowship. These standards are primarily intended for physicians who already possess catheter manipulation skills. These physicians do not typically have cognitive training in neurosciences or extensive experience with microcatheters in the cerebral circulation.

The SIR standards mandate specific cognitive qualifications. They also require training in neurospecific technical skills, as well as documentation of these skills. The skills include selective carotid and vertebral artery catheterization; experience with 3 French or smaller microcatheter/microwire systems; use of Y-connectors, tubing, catheter-flushing techniques; facility with air embolus prevention and guide catheter use.

Comprehensive Stroke Therapy Training

To facilitate acquisition of the necessary cognitive and technical skills, the SIR decided to develop a comprehensive stroke therapy training course. An integral part of the course is a hands-on workshop providing participants experience with the actual types of catheters, wires, flush systems, and techniques commonly used in intra-arterial thrombolysis. As this workshop was being developed, it became apparent that an anatomic flow model simulator that would serve this purpose was not commercially available.

The decision was made to develop a model that would allow selective catheterization of vessels in the setting of Type I–III aortic arches, exchange for a guide catheter, and microcatheter/microwire manipulation to select target vessels in the anterior and posterior intracranial circulation. The model also had to allow demonstration of proper connection, purging, and injection techniques to avoid air embolism. A model that did not require fluoroscopy but could be used with a video camera and monitor was considered essential.

Research into the designers and manufacturers of anatomic flow models utilized for training purposes by vendors of catheters, wires, and other devices designed for intracranial use led to United Biologics, Inc. (Tustin, California) as a potential source for creating the model. This company was willing to help develop a workable model, which they would then be able to market. The first prototype was an anatomic correct representation of the arterial system, extending from the common femoral arteries to the second- and third-order intracranial vessels. The model was made of silicone to simulate the elasticity of vessels and to allow visualization with a video camera system. Continuous, pressurized flow was provided using a proprietary solution designed to decrease friction. The prototype was evaluated using the catheters and wires planned for use in the comprehensive stroke therapy training workshop. All of the technical skills that the participants were expected to learn and demonstrate were test performed.

On the basis of this evaluation, several changes were made. A second camera and monitor were added to reproduce biplane imaging. A screen was designed to prevent the user from directly visualizing the intracranial circulation, thereby reproducing the actual patient situation. Modifications were made to the model at the time of the evaluation, and further modifications were recommended to simplify the intracranial portion of the model to allow for better visualization and to provide specific anatomic challenges.

Drawings of the proposed modifications were evaluated, and a revised model was produced. This model was again bench-tested. At this time, all of the skills were demonstrated and recorded for a training video. The final design was approved, and additional models were manufactured for the course. The comprehensive stroke therapy training workshop faculty members were shown the training video and were given the opportunity to practice the skills that they would be teaching. The faculty then worked one-on-one with the workshop participants. The participants were given the list of skills that would be tested and were given time to practice on their own. Each participant was then tested on the required skills, including setting up and purging the flush system, selective vessel catheterization, exchange for a guide catheter, and microcatheter selection of an intracranial target vessel. Feedback from the workshop faculty and participants was positive, and the models will continue to be used; some minor modifications were recommended (see Figures 4.18 and 4.19).

Simulation Equipment, Noncommercial

A fully equipped simulation laboratory requires highly technical, sophisticated, high-fidelity devices
only available through specialized commercial manufacturers. A definite need also exists for part-task, low-fidelity SBT at the novice trainee level. With the identification of a specific need, a variety of “home-made” inexpensive devices can be made “on site” in the laboratory workshop. Chapter 22 (Simulation in Breast Imaging) describes phantoms for SBT of image-guided breast biopsy using eggplant or layered meat segments with embedded almond “pseudolesions.” Turkey or chicken breast with embedded olives has also been used for simulated breast biopsy. The multilayered meat phantom was considered to have tactile sensation (i.e., haptics) similar to human breast tissue on biopsy. The simple phantoms allow SBT for biopsy localization by ultrasound, CT, and MRI.
An SBT device for vascular puncture and endovascular catheter insertion (i.e., Seldinger technique) can be simply constructed of wood and plastic tubing, obtained from a hardware store and of a diameter similar to that of an adult common femoral artery. The device shown in Figure 4.20 was constructed of oak side panels, with wooden clamps at both ends to fasten the tubing, and a plywood base. Sheet extruded polypropylene insulation material was placed beneath the tubing. The tubing was resistant to needle puncture, and it was necessary to use a small drill to make an entry site for the needle and the subsequent insertion of guidewire, vascular sheath, and catheter. Micropuncture arterial access can be well demonstrated with this device. The clear plastic tubing allows direct visualization of the procedure. An arterial stenosis can be simulated by application of a plastic or metal clamp, variably narrowing the tubing lumen. A trainee and instructor can work simultaneously on the device. Instruction in this SBT emphasizes the safe vascular insertion of the flexible tip guidewire to avoid potential injury and dissection of the artery wall. Simulation-based training with this simple part-task device is performed with novice trainees before participation in patient arteriography, with the goal of trainee early familiarity with equipment and techniques for safe catheter endovascular placement. This simulation device can also be used for SBT of puncture site closure devices.

**CONCLUSION**

A basic classification of medical SBT devices includes synthetic/physical models, animal models, human cadaver and virtual reality devices. Some examples of commercially available synthetic/physical and virtual reality devices were presented in this chapter. Other excellent similar devices are available. Examples of simple, low-fidelity part-task training simulation devices are noted that can be built in the workshop from readily available materials. The development and construction of a custom designed specific-use simulation device is noted.

Computer assisted simulation devices used alone have no more practical learning capability than a simple computer game. The development and use of medical simulation devices must be based on absolute, strict criteria. Complex educational, psychological, physiological, physics and engineering principles are used in the simulation device development and construction and in the fabrication of the training algorithm in which it is used.

The specific learning goal necessary from the simulation procedure must be fully verifiable through evidence based performance metrics. The computer based metrics system must reliably report the trainee simulated procedure technical and cognitive errors. Face validity (i.e., the system looks like what it represents), content validity (i.e., the system contains the material for necessary training), construct validity (i.e., critical factors are assessed that relate to the required skill(s) acquisition), and predictive validity (the learning performance on the system correlates with the actual clinical patient procedure performance) are vital factors in the simulation device development and its use in the simulation teaching algorithm.\(^5\)\(^-\)\(^8\)

**REFERENCES**


AQ1: Figure 4.17, 4.18 & 14.19 captions seems to be similar pls check.