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Silicone models as basic training and research aid in endovascular neurointervention— a single-center experience and review of the literature

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Abstract The rapid development and wider use of neurointerventional procedures have increased the demand for a comprehensive training program for the trainees, in order to safely and efficiently perform these procedures. Artificial vascular models are one of the dynamic ways to train the new generation of neurointerventionists to acquire the basic skills of material handling, tool manipulation through the vasculature, and development of hand-eye coordination. Herein, the authors present their experience regarding a long-established training program and review the available literature on the advantages and disadvantages of vascular silicone model training. Additionally, they present the current research applications of silicone replicas in the neurointerventional arena.

Keywords Silicone models · Training · Research · Endovascular neurointervention

Introduction

Neurointervention procedures and their tools have rapidly evolved over the years after the introduction of the Guglielmi detachable coils (GDCs) [13, 14] to treat aneurysms and various other vascular and neoplastic diseases previously regarded as not treatable or managed by other means. This accelerated development and wider use of neurointerventional procedures have increased the demand for a comprehensive training program for the trainees [18, 21], in order to safely and efficiently perform these techniques. Artificial vascular models are one of the dynamic

ways to train the new generation to acquire the basic skills of equipment handling and material manipulation through the vasculature and development of hand-eye coordination. These basic abilities should be acquired in the lab prior to working on patients. Herein, the authors present their experience regarding a long-established training program and review the available literature on the advantages and disadvantages of vascular silicone model training. Additionally, they present the current research applications of silicone replicas in the neurointerventional arena.

Materials and methods

In vitro vascular model

The model used in our institution (Department of Neuroradiology, University Hospital of Zurich, Zurich, Switzerland) is a flow silicone vascular phantom model manufactured by Elastrat Sàrl (Geneva, Switzerland) (Fig. 1). It is made of soft, transparent silicone calibrated in shape and curvatures to mimic the human vasculature. The model incorporates the essential vasculature of the torso, neck, and cranium. Aneurysms at most common and ordinary locations are also included. The cranial part can be detached, and another model with variable configuration can be attached to avoid repetition. A pump is used to inject tap water mixed with a special liquid provided by the manufacturers in a ratio of 7:3 to reduce friction, as well as to make the circulating fluid similar in rheological properties to blood. These replicas are compatible with modern imaging modalities (subtraction angiography, computed tomography, magnetic resonance imaging, Doppler techniques). Moreover, their transparency to light makes them suitable for video and photographic monitoring.

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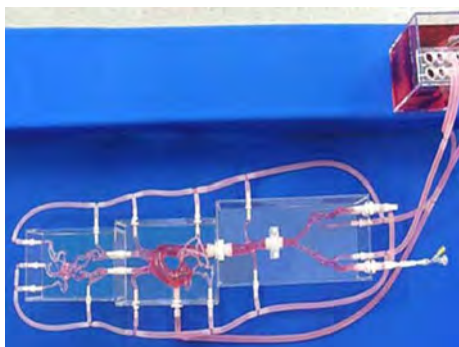


Fig. 1 The workstation provides a realistic environment for the simulation of endovascular procedures facilitating the learning experience (reproduced from the website: http://www.elastrat.ch/index.php?option=com_content&task=blogcategory&id=24&Itemid=83)

The endovascular environment

The endovascular environment is created based on a closed circulation circuit with the only opening being the port of vascular entry. This is big enough to allow 5, 6, and 7 F catheter insertion in the femoral artery. The fluid is pumped using an electric motor, and the flow is directed in such a way as to mimic the flow in the human body, with downward flow in the aorta and upward flow in the cervical and cranial vessels.

Training system

The training system is made as realistically as possible, in the context of a uniplane angiographic suite with capabilities of digital subtraction, road mapping, and video recording. The silicone model is positioned on the table instead of a patient. Fellows are taught to handle the tools and materials and improve their manipulation techniques. They are allowed to work on the model under supervision, strictly following the technical principles of interventional neuroradiology. Evaluation in real time can be done through the monitors that are located inside and outside the angio suite.

Results

In the time period 1996–2012, 178 fellows from 33 countries took part in the formal International Fellowship Program on Interventional Neuroradiology offered by our department.

Training on the dedicated neuroendovascular models takes place in the neuroangiographic laboratory for training, research, and development of our department. It is completed in three phases:

Phase 1:

1. Working in larger arteries, with 5 and 6 F catheters, learning to safely hook each of the major vessels and to do catheter exchange (Fig. 2).

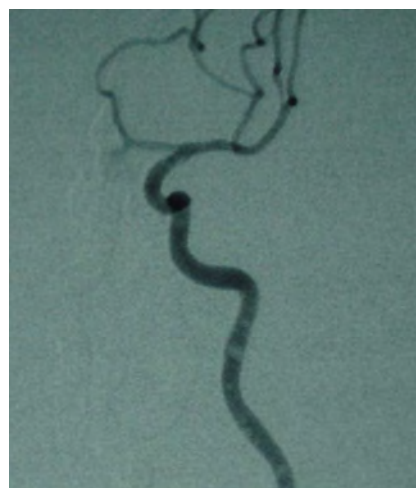


Fig. 2 Left internal carotid artery injection

2. Doing road map and navigating within the map.

Phase 2:

1. Handling and manipulating the microcatheters.
2. Shaping of microcatheters and guidewires.
3. Navigating through the cranial circulation with various vessel combinations.
4. Obtaining the working projection.

Phase 3:

1. Learning the selection, delivery, and detachment of the coils with adequate packing of the aneurysm.
2. Learning balloon- and stent-assisted coiling of wide-necked aneurysms, familiarizing with the double-microcatheter techniques, and getting accustomed to the use of nondetachable silicone balloons and stents (Fig. 3).

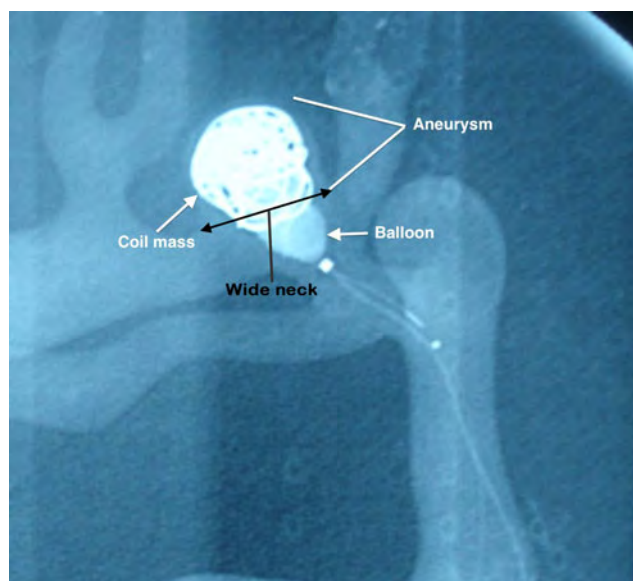


Fig. 3 Balloon remodeling technique application in a wide-necked aneurysm

As the training progresses, the trainees are periodically assessed as to the improvement in their performance for the following factors:

1. Manipulation of the angiographic machine and the table in a coordinated fashion.
2. Tool and material handling.
3. Hand-eye coordination.
4. Endovascular techniques.

In our institution, apart from training the beginners, the models are also used for testing newer devices such as new coils, stents, and thrombectomy devices, before being used in patients. In particular, their physical characteristics and their behavior are tested, and the technique of using the device is practiced. We found that this approach improves both the familiarity and the ease of handling the devices. During this process, some devices were evaluated as appropriate to use while others were not favored.

Discussion

The necessity of such programs

Neuroendovascular operations are among the complex and the highest-risk operations in medicine. The cerebral circulation is different from that of other organs not just by virtue of its complex anatomy and vascular pathology, but more importantly by virtue of the impact of inadvertent complications. The need for excellent technical training backed up by a thorough knowledge of the diseases of the neurovascular system is self-evident [23]. As the number of specialized centers around the world is increasing, there are relatively fewer cases in each center treated. So, acquisition of technical skills by the next generation of neurointerventionists is based mainly on alternative methods of learning, like animal models, silicone models, and computer-based simulation technology. Among the aforementioned training methodologies, silicone model training exhibits considerable advantages. These together with some unavoidable drawbacks are illustrated below.

Advantages of silicone models

To start with, learning to handle the endovascular tools and the angiographic machine properly (follow the catheter, road mapping technique, etc.) is of utmost importance. Most microwires and microcatheters are fine; they have to be handled meticulously to avoid damage before and during their usage. Learning the basic operative skills, like hooking of a vessel, guidewire manipulation, catheter exchange, shaping of microcatheters and guidewires, and coil placement, are all

learned in a stepwise manner effectively and as realistically as possible. Initially, the learning is voluntary with conscious orientation of hand-eye coordination. However, after repeated learning cycles, the manipulation becomes subconscious.

The models are also useful for testing new materials or devices [11, 20, 24, 26, 29, 33, 35]. Not only is the technique of their deployment learned, but also their physical behavior is controlled, before these are used in patients [22, 41]. The silicone models provide a fair sample of the real anatomy along with an opportunity to practice a number of technical and problem-solving skills [23, 36]. The anatomy may well be modified by introducing more challenging situations to refine techniques and to learn new tricks. The silicone models, apart from being compatible with angiographic studies [3, 22, 33], are transparent enough to allow direct visualization [13, 33, 36] to learn the three-dimensional (3D) behavior of coils during deployment [3, 17, 22]. Another distinct advantage is the sparing of expensive animal models [33]. Moreover, in animal models, extracranial vascular territories are used which are not a representative of the cerebrovascular system, whereas in silicone models, numerous solutions for modifying the perivascular environment exist (i.e., simulating the petrous canal with mold materials or simulating the brain with ballistic gel). The silicone models are good enough for basic training purposes as they provide artificial but realistic, safe, and reproducible test conditions [23, 33].

Disadvantages of silicone models

The training in silicone models is not without disadvantages. One of the major drawbacks encountered is the higher coefficient of friction and thus the higher resistance to catheters and guidewires during manipulation compared with real patients, especially when passing various devices through curved vessels [36]. To reduce the friction in our models, the circulating fluid is made slimier with the lubricating fluid supplied by the manufacturing company. Still friction remains a significant limiting factor. As stated by Cheuh et al. [5], models made of polyvinyl alcohol-hydrogel (PVA-H) are an alternative. PVA-H models demonstrate much lower friction, more elasticity, and allow pulsatile flow but have much shorter life than silicone models. To overcome the problem, the same authors have also suggested coating the inner layer of the silicone models with parylene or liquid silicone rubber (LSR) top coat [5]. An additional inherent drawback of silicone models is the need to remove devices from the replicas once deployed so that the models can be reused. This, although sometimes troublesome, can be done through the connection points of the models.

Admittedly, vascular models are few and fixed with limited variations [13, 36]. The trainees quickly learn the manipulation in few attempts in each of the models and, in this sense, the capability of the trainees is not fully tested. In the models,

the aneurysmal wall has the same thickness as the other parts of the models, lacking fragility [13]. Moreover, the feeling of controlled deployment is not attained while coiling such thick walled cavities, and percutaneous transluminal angioplasty (PTA) and stenting in cases of stenosis achieve much less dilation than expected or intended [36]. Training on vascular

models bears undoubtedly the inherent danger that the trainees develop a “wrong security” due to the evident absence of in vivo conditions like fragility of the vessels and lesions, spastic reaction of arteries, and occurrence of thromboembolic phenomena. It is therefore mandatory that the trainees are being continuously reminded by the supervisor about this

Table 1 Studies conducted with the aid of silicone models

Authors	Year	Scope	Model details
Chueh et al. [6]	2012	To quantify the flow restoration and characterization of the distal emboli pursuant to mechanical endovascular thrombectomy.	ICA/MCA with an ICA siphon
Majidi et al. [17]	2012	To evaluate the feasibility of aneurysm embolization by using detachable coils under intravascular ultrasonography guidance.	Lateral wall aneurysm
Mehra et al. [22]	2011	To investigate the impact of coil design on the distribution of the coil mass and to study the relationship between angiographic occlusion, packing density, and coil mass uniformity.	Lateral wall aneurysms
Chung et al. [7]	2010	To test whether embolus microspheres encountering the circle of Willis are carried proportionally to volume flow or express a preferred trajectory related to arterial morphology or embolus size.	Left and right VA and CCA inlets with pairs of outlets for the ECA, PCA, MCA, and ACA
Wakhloo et al. [40]	2008	To assess the technical feasibility of using a retrievable closed cell intracranial stent for safe removal of foreign bodies (coils) or clot.	Superior M2 division of the right MCA, and M1 segment of the right MCA
Bendok et al. [3]	2007	To investigate the effect of vascular reconstruction device (VRD)-assisted coiling (stent-assisted coiling) on packing density, effective neck coverage, angiographic outcome, and coil herniation into the parent vessel.	Lateral wall aneurysms
Schloesser et al. [30]	2007	To evaluate the effect of primary coil diameter choice (0.010 vs 0.018 in) upon complex framing coil stability.	Wide-necked silicone aneurysm
Watanabe et al. [41]	2007	To evaluate the packing efficacy of the HydroCoil Embolic System.	Ruptured lateral wall aneurysm
Du Mesnil de Rochemont et al. [8]	2006	To test the conformability of balloon-expandable stents to the carotid siphon.	Carotid siphon
Piotin et al. [28]	2004	To determine whether the use of platinum Soft and Ultra Soft Guglielmi detachable coils (GDCs) may improve the packing of aneurysms.	Lateral wall aneurysms
Tanaka et al. [37]	2004	To evaluate the conformity of self-expanding nitinol carotid stents with the course and endoluminal surface of silicone models of the normal human carotid artery.	Carotid bifurcation
Piotin et al. [27]	2003	To determine whether the use of complex-shaped platinum coils may be more effective than helical coils in packing of aneurysms.	Lateral wall aneurysms
Sugiu et al. [34]	2003	To compare the characteristics of J-shaped detachable platinum coils with those of spiral coils.	Lateral wall aneurysms
Tokunaga et al. [39]	2002	To evaluate the performance of long J-shaped coils and to define appropriate coil length and stiffness for large and giant aneurysms.	Lateral wall aneurysms
Martin et al. [19]	2001	To evaluate and quantify the benefit of the distal flow protection technique (balloon protection device) during the placement of stents in carotid stenoses.	Aortic arch to above the circle of Willis
Murphy et al. [25]	2000	To evaluate a mechanically detachable platinum coil system (introduction characteristics, ease of delivery and retrieval, detachability).	Models of dural AVF of the transverse sinus, carotid-cavernous fistula, and aneurysm of a vein of Galen
Standard et al. [32]	1994	To evaluate a dual-guidewire technique to retrieve fractured detachable coils.	Silicone catheterization model

MCA middle cerebral artery, *ICA* Internal carotid artery, *VA* Vertebral artery, *CCA* common carotid artery, *ECA* external Carotid Artery, *PCA* posterior cerebral artery, *ACA* anterior cerebral artery, *ACoA* anterior communicating artery, *AVF* arteriovenous fistula

central limitation during their training on models. Furthermore, it is essential that this training for the beginner in the field takes place in parallel with the observation of *in vivo* procedures.

In addition, the models include the major vessels of the brain but lack the distal cortical vasculature. As a result, manipulation of microwires and microcatheters in such small vasculature is not learned. Moreover, modeling of perforators is lacking; this is a consideration when training microwire navigation. Furthermore, there are no good arteriovenous malformation (AVM) models, not to mention that the flow dynamics of AVMs are extremely difficult to reproduce. Additionally, although flow-directed microcatheters can be used in these models, the lack of preferential flow renders their use and the overall training much limited. Finally, the technique of glue and/or particle injection cannot be learned from the silicone models, and the testing of biocompatibility is not possible due to the absence of biological conditions [33]. It is important to keep in mind that as we test new medical devices in such models, we are actually testing only their physical characteristics.

The fluoroscopic road-mapping simulation with a combination of silicone and animal-based models seems to be a more practical approach in addressing the issues raised above. Of major significance would also be the use individualized models instead of a standard model [36]. With this in mind, many studies have been conducted in the last 2 decades. The main objectives of this research are presented in the following section.

Research topics

The aforementioned advantages have drawn the attention of researchers to the application of silicone models in a great variety of research areas. Table 1 presents several studies conducted in the last years using silicone models with special interest in coils [3, 4, 12, 17, 19, 22, 25, 27–32, 34, 39, 41] and stents [2, 3, 8, 10, 19, 37, 38, 40].

Liquid embolic agents have also been tested. Imbesi et al. [15] evaluated the efficacy of such agents while studying the changes in the aneurysm flow dynamics after placing a non-detachable balloon in the parent vessel. Pötin et al. [29] determined the effectiveness of filling the cavity of aneurysms with detachable platinum coils and the combination of detachable platinum coils and a liquid embolic agent (tricellulose acetate polymer).

Other researchers focused on flow dynamics in aneurysms [1, 2, 4, 9, 10, 12, 15, 16, 31, 38]. For example, Acevedo et al. [1] used phase-contrast MRI computational fluid dynamics flow simulations. Barath et al. [2] evaluated hemodynamic changes induced by the implantation of a stent, and Fujimura et al. [10] quantified flow reduction in aneurysmal cavities produced by stent implants used for flow diversion. The intra-

aneurysmal flow characteristics before and after the placement of self-expanding stents were assessed by Tatshima et al. [38]. In addition, Cantón et al. [4] measured the changes in the intra-aneurysmal fluid pressure and parent vessel flow characteristics resulting from packing the aneurysmal sac with hydrogel-coated platinum coils, and the influence of flow dynamics in the parent vessel and of intra-aneurysmal coil embolization on flow pattern and pressure was investigated by Gobin et al. [12]. Furthermore, Sorteberg et al. [31] determined whether changes in pressure and flow observed after coiling are the result of the presence of coils plus thrombus (hemodynamic effect) or the result of the presence of the coils themselves (hydrodynamic effect). The complicated flow dynamics of internal carotid artery was studied by Kerber et al. [16]. Finally, the impact of the geometric configuration of parent artery in relation to the aneurysm on the 3D rotational angiography has also been assessed [9].

Moreover, new materials and devices have been tested in silicone models [20, 24, 26]. Oechtering et al. [26] tested intra-arterially administered magnetic microparticles for embolization of aneurysms with assistance from an external magnetic field. Matsubara et al. [20] developed a new sensor device to measure the coil insertion pressure via an optical system, and Müller-Hülsbeck et al. [24] evaluated the efficacy of filtration devices designed for cerebral protection during carotid angioplasty.

Stroke research has also been benefited from these models [6, 7]. For example Chung et al. studied the relationship among arterial topology, blood flow, and embolus trajectory and reported that embolus trajectory through the cerebral arteries is dependent on embolus size and strongly favors the middle cerebral artery for large emboli [7]. Chueh et al. assessed the effectiveness of mechanical endovascular thrombectomy in a model system of cerebrovascular occlusion [6]. The researchers found that the recanalization rate of the thrombectomy device was associated with the ability of the device to capture the clot during removal and the geometry of the cerebral vessels. In addition, the risk of embolic shower was influenced by the mechanism of action for the thrombectomy device [6].

Conclusion

Training with silicone models is a useful way to familiarize the younger generation of interventionists with the basic principles and techniques of interventional neuroradiology. The skills are acquired rapidly and safely in a phased manner from simple to complex tasks. In spite of certain disadvantages, the authors still feel that this training modality is good enough not only for learning the basic techniques, but also for assisting the scientific research and development.

Conflict of interest The authors have no personal financial interest in any of the materials or devices described in this article.

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Comments

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The article entitled “Silicone models as basic training and research aid in endovascular neurointervention—a single-center experience and review of the literature” by Srinivasan Paramasivam and colleagues describes the utility of silicone cerebrovascular replicas for training in endovascular techniques. Over the past decade, advances in 3D modeling and rapid prototyping have enabled a generation of anatomically accurate cerebrovascular models. This review is timely, as it emphasizes the need to develop solutions for comprehensive training as the dramatic increase in the availability of specialized interventional programs has subsequently decreased the volume available for endovascular training at academic medical centers [1]. The authors have trained an impressive 178 fellows in basic neurointerventional techniques using these silicone models. Moreover, the paper describes the necessity for advanced training of experienced interventionalists with new technology, namely, imaging systems and medical devices.

Numerous research studies that have advanced technology in neuroendovascular treatments using silicone vascular replicas are surveyed in this paper. The advantages of these models include reproducible engineering studies on hemodynamics and device characterization. Due to costs and societal sensitivities associated with animal experimentation, these models provide a viable alternative to address certain important questions in research of interventional neuroradiology. Researchers have seeded 3D vascular silicone models with endothelial cells [2], making a new generation of replicas that can serve as bioreactors. Yet other groups are working on new materials to generate vascular replicas that offer nearly identical tactile feedback with respect to the human cerebrovasculature. Advances in vascular replicas will continue to advance the discovery of improved technology for the treatment of cerebrovascular disease and offer enriching training programs for the foreseeable future.

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This is an important study stressing the role of silicone models as a training aid in endovascular neurointerventional fellowship training. Paramasivam et al provided their experience in using silicone models as training tools in their endovascular neurointerventional fellowship program. The authors have more than 15 years of experience in training fellows in the field of endovascular surgical neurology and have trained more than 170 fellows. According to their experience, using silicone models has had significant impact on expanding fellows’ skills in handling and manipulating and navigating microcatheter and guidewire and also performing procedures such as coil embolization with or without stent assistance. As the authors nicely outlined, silicone models can be also used as valuable research tools. For instance, we can design and execute complex experiments investigating the hemodynamic changes within the aneurysm following stent deployment or compare different clot-retrieving devices in a safe in vitro setting without risk of harming the patient. These sorts of experiments are essential components of the field considering the fact that not all the hemodynamic and biophysical aspects of the devices are fully understood.

Current guidelines recommend minimum procedural volume requirements in order to reach acceptable operator experience and proficiency in performing endovascular procedures [3, 4]. For example, this number is 30 procedures for aneurysm coil embolization. There are very few teaching institutions in the USA which meet minimum requirements for all the procedures needed to reach adequate operator experience [5]. Therefore, it is essential to use adjunct training modalities such as silicone models or computer simulators in order to help the trainees obtain and maintain adequate procedural skills. Computer simulators have been used as a valuable adjunct training modality for endovascular procedure training with proven impact on trainees’ skill improvement [6]. Similarly, Dr. Paramasivam’s study is a successful example of necessity and value of using silicone models in neurointerventional fellowship training.

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