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High-Fidelity Endovascular Simulation

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With the ongoing changes in graduate medical education, emphasis has been placed on simulation models to increase clinical exposure and optimize learning. In specific, high-fidelity simulation presents as a potential option for procedural-skill development in interventional radiology. With improved haptic, visual, and tactile dynamics, high-fidelity endovascular simulators have gained increasing support from trainees and certified interventionalists alike. The 2 most common high-fidelity endovascular simulators utilized today are the Procedicus VIST and ANGIO Mentor, which contain notable differences in technical features, case availability, and cost. From the perspective of a trainee, high-fidelity simulation allows for the ability to perform a greater volume of cases. Additionally, without the risk of potential harm to the patient, trainees can focus on repetition and improved performance in a stress-free environment. When errors are made, high-fidelity simulator metrics will generate instantaneous feedback and error notification, erasing ambiguity and thus facilitating learning. Furthermore, in an environment devoid of time and cost stressors, the supervising physician is afforded the opportunity to properly mentor and instruct the trainee throughout the case. For the experienced interventionalists, high-fidelity simulation allows for a decreased learning curve for new procedures or techniques, as well as the opportunity for procedure rehearsal for unusual or high-risk cases. Despite the limitations created by cost, high-fidelity endovascular simulation should continue to be increasingly utilized in the development of the interventional radiology curriculum.

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Introduction

Apprenticeship and graduated autonomy are the mainstays of traditional medical education.¹ Graduate medical education is changing; partially in response to extrinsic stressors, namely restrictions in residents' work hours—effectively shortening residency—and medical malpractice risks, contributing to decreased procedural autonomy calling into question preparedness of new graduates of procedure-based specialties.^{2,3} Over time, traditional methods will be less sustainable.^{2,3} Methods to enhance learning during residency are currently being explored, including simulation, which demonstrates effectiveness toward learning procedural skills.

While simulation is not new in medicine, recent emphasis on high-fidelity simulators to advance the skills in the workplace, already a mainstay in aviation, has begun. Like the preoperative and preflight checklist, simulators have been incorporated into the medical field and have been shown to result in improved confidence and performance.^{4,5} Simulation has the potential to increase patient safety, increase clinical exposure to more complex and rare cases, decrease long-term costs, and enable performance assessment, thus facilitating directed feedback.⁶

Simulation is commonly used in the minimally invasive procedures arena, as a digital option to involve working in a 3D field while viewing on a 2D monitor, specifically in laparoscopic techniques in general surgery, obstetrics and gynecology (OBGYN), and urology.⁷ The end goal of using high-fidelity simulation is to decrease the learning curve of any procedure and to achieve an adequate level of proficiency before it is practiced on the patient.

Open repair of vascular pathologies has largely been replaced by endovascular options, exemplified in the field of interventional radiology. However, because of the novelty and the changing nature of the many tools and treatment modalities,

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the result is a higher rate of error.⁸ Thus, potential for improved high-fidelity simulation has recently been explored, and the purpose of this review is to provide an overview of high-fidelity simulation as it pertains to endovascular techniques, commenting on its effectiveness, impact on patient care, and limitations.

What is High-Fidelity?

Fidelity is a term commonly used to describe how close a simulator is to mimicking the real-life experience, as well as the transferability of skills to the patient setting. Fidelity exists on a spectrum, listed as low, medium, or high fidelity. The recommended level of fidelity depends on the level or complexity of the skill that one hopes to obtain.⁹

Low-fidelity simulators are often immobile, are unable to mimic reality or situational context, and use materials that are different from the task being considered. Examples include meat products and mannequin body parts.¹⁰ Low-fidelity simulators have been shown to be useful in the training of basic tasks, such as advanced cardiovascular life support (ACLS), and are ideal for novices who may find more advanced features too overwhelming.¹¹

Medium fidelity simulators typically offer more realistic features than low-fidelity simulators, such as a pulse or a code mannequin. However, similarly to low-fidelity simulators, they are not serviceable for more advanced procedures such as surgery or endovascular procedures.

High-fidelity simulators use realistic and sophisticated materials to represent the actual setting and attempt to achieve a high degree of visual and auditory realism, tool interaction, and haptic feedback. Feedback, repetition, variation, range of difficulty, interactivity, and individualized learning—the pillars of simulation-based education—are all made possible with the use of high-fidelity simulators.^{12,13}

A high-fidelity simulator is also capable of simulating multiple pathologies or case scenarios. The concept of manipulating wires in a 3D field while viewing it on a 2D field can be modeled with a very realistic interface, thus making endovascular training ideal for high-fidelity simulation.¹⁴ All commercially available virtual reality (VR) endovascular procedure simulators are classified as high-fidelity because they are able to achieve these desired qualities.

It has been previously demonstrated that higher fidelity simulation may lead to more transferability of skills.¹⁵ Sidhu et al¹⁶ demonstrated that high-fidelity endovascular simulators resulted in a statistically significant increase in technical performance over lower-fidelity simulators. Another advantage of high-fidelity VR simulators is that they can provide an immediate performance assessment based on the set parameters.¹⁷ Finally, unlike other lower fidelity options, with high-fidelity simulation, curriculums can continually be modified to correlate to the ongoing developments in the field and can be tailored to a trainee's individual strengths and weaknesses.¹⁸

Validity

While evaluating a high-fidelity simulator, it is important to analyze its validity. Validation is used to determine if the

simulator will serve its purpose, and assesses transferability and maintenance of skills acquired from the simulator.¹⁹ The validity of the simulator is increased when 3 main components are met: face, content, and construct validity.

Face validity tests the simulator's ability to mimic reality. Content validity assesses the simulator's ability to do what it is intended to do, such as to teach and assess procedural knowledge. Construct validity assesses the simulator's ability to differentiate between different levels of expertise.

In the use of high-fidelity endovascular simulation, multiple studies have assessed its validity. Using the Procedicus VIST (Mentice, Gothenburg, Sweden) trainer as an example, Coates et al²⁰ demonstrated face, content, and construct validity, demonstrating its effectiveness as a high-fidelity simulator, with Dayal et al²¹ further establishing construct validity. These studies have proven the validity of high-fidelity endovascular simulators, thus demonstrating their effectiveness in the clinical setting.

Why Now?

When high-fidelity endovascular simulation was first introduced, the primary purpose was to introduce new devices on the market and new techniques to interventionalists. We speculate that the use of simulators for marketing rather than trainee education is a function of cost. When used for training, simulation was primarily used to practice mostly high-risk procedures as opposed to learning the fundamentals.²²

When simulation-based training programs were first implemented, their development was relatively unstructured, often relying on commercially available simulators or local interests, as opposed to a general needs assessment.²³ This unstructured setup often led to a lack of training on how to use the equipment, limited access outside normal working hours, and infrequent senior supervision, in turn leading to lack of engagement in the simulation product.²⁴ Now, trainees and educators have now begun to show more support for the integration of high-fidelity simulators into their training curriculum. Duran et al²⁵ showed that trainees do believe in the value of high-fidelity simulation training and would like to incorporate more of it into their curriculum.

Early high-fidelity simulators offered poor overall sensory feedback during the insertion and manipulation of guide-wires, making them of limited use. Improved haptics and tactile dynamics of these simulators have greatly improved and are now capable of accurately portraying a patient's physiology and improved manual feedback—an important part of any proceduralist's skill set. Furthermore, due to the emergence of endovascular procedures, a new variety of skills that were previously not utilized are now required.

With the limited time constraints, educators must now look for ways to optimize learning, thus lending way to the use of high-fidelity simulators.

Other Types of Simulators

Other lower-fidelity simulators most commonly used in practice are physical, animal, and human cadaver.

Physical

One of the benefits of physical simulators is that they are able to portray an authentic human anatomy. However, the friction associated with the insertion of endovascular devices into these physical vessels is very high, thus offering limited haptic feedback. Additionally, they are prone to damage after repetitive use and needle punctures. Furthermore, it is difficult to simulate pathologic conditions on these models, thus limiting their usefulness.²⁶

Animal

An animal simulator is capable of providing sufficient tactile and haptic feedback, but cannot simulate the human anatomy, and these simulators are not reusable. Similarly to physical simulators, animal simulators are also limited by the fact that they are often unable to simulate pathologic conditions. Furthermore, the use of animals may raise ethical concerns.²⁶

Human

Human cadavers are able to simulate the human anatomy with high realism, however similarly to animal simulators, the same procedure cannot be done in multiple attempts. Like both physical and animal simulators, it is difficult to simulate pathologic conditions.²⁶

High-Fidelity Simulators

VR endovascular simulators represent the high-fidelity simulators. These simulators allow for the insertion of a guidewire and catheter, as well as angioplasty, stenting, and other procedures for the cerebral, carotid, coronary, aortic, renal, and iliofemoral arteries in addition to more complex cases such as closure of the patent foramen ovale and caval filter deployment.^{17,27} Additionally, VR simulators can have visual, auditory, or tactile feedback depending on the specific simulator. They can also provide formative or summative feedback as well.

There are a number of available options, most notably the Procedicus VIST, ANGIO Mentor (3D Systems, Littleton, CO), and Simsuite Compass (Medical Simulation Corporation, Denver, CO). Of note, Simsuite is no longer available as of December 2017, as Medical Simulation Corporation has been taken over by Mentice, and hence is not included in the table for comparison.

Details in the Table 1 lies a comparison between the available modules, number of potential patient cases, special features, and average cost of purchase between the Procedicus VIST and ANGIO Mentor. Unfortunately, the comparison remains incomplete as some data were unable to be obtained.

The VIST offers a variety of special features. One of these is the degree of realism that is able to be achieved with this simulator. The VIST is the only simulator that uses real clinical devices up to 24 Fr, and remains the only full physics-based simulator allowing for system-generated objective assessment

of users, thus allowing its users to develop a deeper understanding of proper device selection. Furthermore, the VIST is the only simulator that is calibration free, thus allowing users to seamlessly switch between different devices and sizes.

Additional unique features to the VIST include its radiation safety incorporated software, which allows for live visualization of the radiation exposure to the patient and operator. Finally, the Mentice's "Case-it" functionality is a free add-on that allows for a real patient's anatomy to be incorporated into software, thus providing unlimited opportunities for building cases. Images of the Mentice Procedicus Vist system can be seen in Figures 1 and 2.

Utility of Simulation

In addition to responding to limitations upon trainee work hours and shortened residency, it has become even more important to optimize the learning process in an efficient manner in order to develop procedural proficiency.² Traditionally, the learning of basic skills in interventional radiology, such as catheter manipulation, can happen during routine diagnostic angiograms. However, due to the advancements made in imaging technology, the number of purely diagnostic angiograms has drastically decreased, limiting the opportunities to develop this crucial skill that serves as the foundation for endovascular procedures.²⁸⁻³⁰ Hence, high-fidelity simulation may have a potential role in learning these skills and has previously been shown to improve skills in surgical anastomoses.^{31,32}

Aside from the resultant decrease in radiation to the practitioner and not having to wear heavy protective gear, there are many benefits to high-fidelity VR simulations. Major benefits include the option to perform a greater volume of cases and the option for solidification of a skill set through repetition. Additional benefits include the opportunity in simulator systems to make and learn from mistakes.^{33,34}

Without potential harm to the patient, the trainee can continue to improve their performance and simulate the handling of procedure-related complications in a stress-free setting, which has been shown to be the optimal setting to maximize performance.³⁵⁻³⁸ Of note, this is also beneficial to the patient, as the risks to the patient are reduced by avoiding operators with lack of experience.

And because VR affords trainees the possibility to train in an environment free of the time and cost pressures of the operating room, they can be properly mentored by the expert throughout the case and stopped as necessary for further instruction or for critical teaching points.³⁹ Being able to break down the procedure into tasks and then analyze the individual components and provide a summative performance feedback serves as a signature purpose of VR simulation.⁴⁰ And when errors are made by the trainee, they will be detected in the metrics of the simulator and the trainer will be immediately notified. In the clinical setting, if a postoperative complication in the patient results from a procedural error caused by the trainee, it may be difficult to trace that complication back to the initial error. With the use of VR

Table 1. Comparison of Procedicus Vist (Mentice) and ANGIO Mentor (3D systems)

Endovascular Simulator	Modules	Number of Cases	Special Features	Average Cost
Procedicus VIST (Mentice)	Acute ischemic stroke intervention, aortic valve implantation, atrial septal defect and patent foramen ovale occlusion, below-the-knee intervention, cardiac rhythm management, carotid intervention, coronary angiography, coronary PRO, endovascular aortic repair, iliac/SFA intervention, left atrial appendage occlusion, neurovascular intervention, peripheral angiography, prostate artery embolization, renal denervation, renal intervention, thoracic endovascular aortic repair, transarterial chemoembolization, trans-septal puncture, uterine artery embolization, vascular trauma management	400+	-Realism -Calibration free -Radiation safety -Case-it functionality	\$200,000-\$300,000
ANGIO Mentor (3D systems)	<i>Basic skills:</i> endovascular, EP, Cardio <i>Peripheral interventions:</i> renal, iliac, SFA, atherectomy, lower extremities CTO, below the knee, peripheral embolization, trauma management <i>Electrophysiology:</i> Cardiac rhythm management, trans-septal puncture, AF ablation <i>Structural heart diseases:</i> TAVR, ASD/PFO closure, LAA closure <i>Aortic Interventions:</i> EVAR, TEVAR, Advanced TEVAR <i>Coronary interventions:</i> coronary, transradial coronary, coronary bifurcation, coronary CTO <i>Neurovascular interventions:</i> carotid, cerebral, acute ischemic stroke	150+	Unable to obtain information from company	Unable to obtain information from company

TAVR, transcatheter aortic valve replacement; ASD/PFO, atrial septal defect/patent foramen ovale; LAA, left atrial abnormality; CTO, chronic total occlusion; EVAR, endovascular aneurysm repair; TEVAR, thoracic endovascular aneurysm repair.

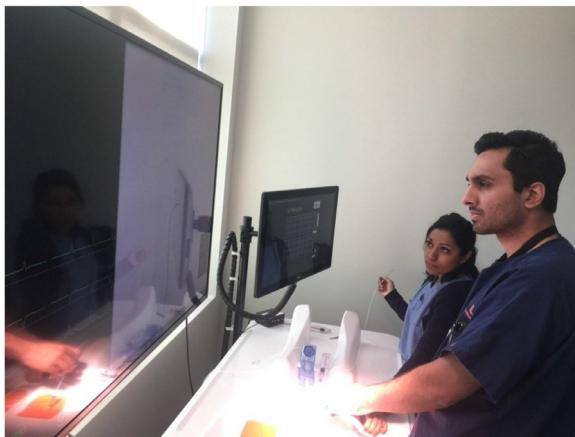


Figure 1. Mentice simulator in use real time.

simulators, which allow for instantaneous feedback and error notification, there is no ambiguity.^{41,42}

Additionally, VR simulators have been shown to be effective in enhancing the skills among all levels of expertise. VR has previously been demonstrated to improve residents' skills in peripheral angioplasty and stenting.⁴³ VR also has been shown to have a role for experienced interventionalists who can use it to learn new techniques or practice using new endovascular tools, as demonstrated by Van Herzele et al,⁴⁴ who documented improved performance among interventionalists in carotid artery stenting after using a high-fidelity simulator.

Simulation is also valuable to experienced interventionalists, allowing for cases that are not traditionally encountered during training. Procedures with a high-mortality rate and minimal room for error are quite rare in the clinical setting, and VR allows for a setting in which an interventional team can become skilled in such cases.

Another benefit of VR is that it allows for "rehearsals" prior to the actual procedure. Other studies have shown that these rehearsals can result in better decision making as well as a better understanding of the procedure itself.⁴³ Evidence has shown that a warm-up, already adopted in other high-performance industries such as sports,⁴⁵ can enhance performance and reduce errors by increased physical and mental preparedness.^{46,47} These rehearsals, which are made possible by VR simulators, lead to reduced operative and fluoroscopy times, as well as a reduction in time that endovascular tools are present in high-risk areas in the body.⁴⁸ Although other studies have advised against warm-ups as it may generate fatigue,⁴⁸ using high-fidelity simulation to address certain elements of the procedure as opposed to the entire procedure itself can be quite effective. In addition, representing the newest technology of endovascular simulation, some VR simulators have even made it possible to do patient-specific rehearsals by incorporating patient data and generating CT or magnetic resonance angiography (MRA) images with proprietary software.^{11,49}

Aside from the technical skills gained, these simulation centers have also been shown to improve interpersonal skills, such as communication, teamwork, and leadership, and cognitive skills, such as situational awareness, planning, decision making, and task management.⁵⁰

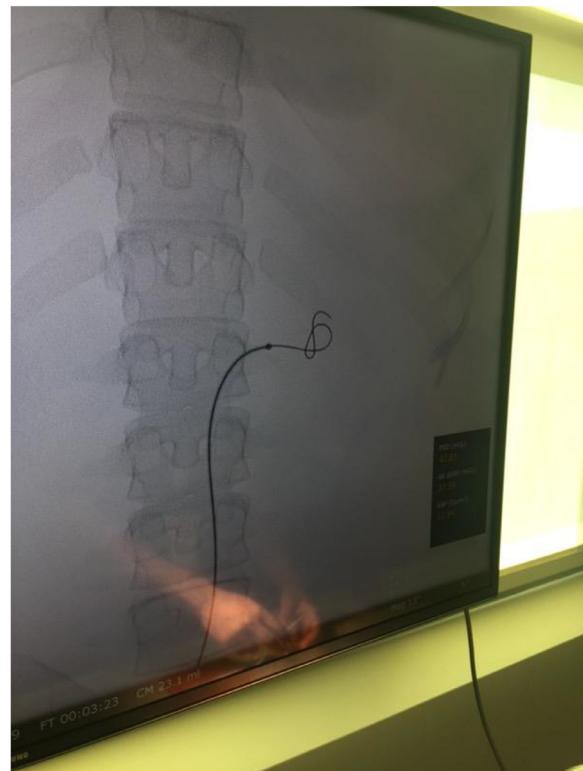


Figure 2. Mentice simulator on screen visualization.

Transferability

One of the first attempts at determining transferability was done by Aggarwal et al,⁵¹ who demonstrated decreased procedure time and contrast volume in renal artery procedures after using endovascular simulation. Since, few studies have been conducted that demonstrate the transferability of skills. Hseino et al⁵² conducted a trial on 10 trainees inexperienced in superficial femoral artery angioplasty, to determine transferability to the clinical setting, with half of the participants receiving training with the VIST simulator. Trainees were then assessed in their ability to perform a superficial femoral artery angioplasty on an actual patient, with the simulator trained trainees ultimately scoring significantly higher marks on the procedural-specific and global rating scales. Chaer et al⁵³ performed a similar study using iliofemoral angioplasty as the procedure of choice. With essentially the same setup as Hseino et al except with 20 trainees, this study also demonstrated that trainees who practiced on a high-fidelity simulator scored higher marks on procedural-specific and global rating scales.

See et al⁵⁴ conducted a systematic review that demonstrated that while endovascular simulation improved performance metrics, such as procedure time and fluoroscopy time, there are no level 1 studies that show that simulation can definitively improve patient outcome.

Limitations

A major and obvious limitation to a high-quality simulator is cost, which increases with the degree of fidelity. With the

need for quality graphics programming, sufficient computational power, and realistic visual, physical, and haptic interfaces.^{55,56} a VR simulator can cost in excess of \$200,000.²²

When weighed with cost of training, studies have demonstrated that a standard 4-year training in the operating theater costs approximately \$50,000 per resident, due to the increased operating times and decreased efficacy that are a result of a trainee's inexperience.⁵⁷ Simulation has the potential to increase efficiency, which should likely result in cost savings. Additionally, the potential reduction in adverse events that is likely to result from simulation training must be accounted.^{58,59} Other surgical fields have demonstrated that practice with high-fidelity simulation subsequently leads to greater efficiency and decreased errors.⁶⁰⁻⁶² Furthermore, VR simulators are a one-time investment and should get cheaper as the market expands and the range of simulations broaden, due to competition.¹⁸

Another way to offset costs to individual programs is to create regional simulation training centers that several institutions can share.⁶³ For institutions that have already made the investment in a high-fidelity simulator, objectives are to minimize cost per user. By offering training of this device externally, usage can be maximized or even profitable, with options to develop national training courses at specialized centers.⁴³

Another limitation to the implementation of these devices is the need for adequate space as well as staff to maintain the equipment. Due to the limitations in most facilities' abilities to constantly station an interventionalist at the simulator center, on hand staff may be necessary to regularly calibrate, update, and maintain the simulator. In addition, they may be needed to potentially troubleshoot problems that occur with the simulator. Although it would be ideal for this staff to also possess sufficient clinical knowledge (in addition to the technical knowledge already required) as pointed out by Dawson et al.,⁶³ this may not always be feasible. However, although it is agreed upon that the presence of an expert allows for optimal use, studies have also shown that training in the absence of expert feedback can also be very helpful.⁶⁴

Another criticism is the quality of the summative performance output that is provided by these simulators, such that many institutions do not even utilize these outputs.⁶⁵ Part of the challenge in this is that there is discrepancy on how various tasks (procedural, interpretive, etc.) should be assessed, as well as in regards to what should quantify as a passing score.¹⁸ Additionally, the surrogate measures that are used to assess for technical skill, such as time to completion, contrast use, fluoroscopy exposure time, and number of errors, may not accurately reflect overall skill level.¹¹

Going Forward

There are many ways in which we can further improve high-fidelity simulation as it becomes integrated into the curriculum. Increasing the variation and difficulty and tailoring the simulations to the weaknesses of the trainee seems to be the next line of focus. Other possible future uses for high-fidelity endovascular simulation are in the accreditation of interventionalists to continue practicing or in the graduating of

fellows. A review by Tsang et al⁶⁶ demonstrated a potential role for high-fidelity simulation in competency assessment.

Also, in order to accurately and definitively compare it to the real-world setting and assess transferability, there would need to be more studies that analyzed real-world performance in endovascular procedures before and after simulation, in order to assess for the transferability of technical and cognitive skills that were learned during simulation. VR training has already been proven to improve operative room performance and shorten learning curves in laparoscopic surgery,⁶⁷ as well as in colonoscopy and/or sigmoidoscopy,⁶⁸ so a similar trend is expected for high-fidelity endovascular simulator training.

In addition, no form of simulation has shown long-term benefit and efficacy in lowering complication rates and enhancing education.^{6,31} This may be due to the lack of simulator use, considering its expansion in the training has only recently begun. However, a study needs to determine this, and the Society of Interventional Radiology has called for validation of simulator training in relation to the improvement of real-world outcomes.²⁹

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