Development of Simulator System Using Endovascular Evaluator for Catheter Intervention Training

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Objective: We formulated a simulator system for catheter intervention training by developing a sliding table and an electrically controlled camera-holding C-arm and combining them with the silicone vessel model EndoVascular Evaluator (EVE). We performed simulation of mechanical thrombectomy using this system and evaluated its usability for simulation training.

Methods: After three experts in neuroendovascular treatment were given instructions for the use of this system, they performed mechanical thrombectomy by a procedure as close as possible to that in clinical situations using an artificial thrombus model simulating left middle cerebral artery occlusion, and the procedural times and maneuvers were studied. The time required for guiding catheter placement in the cervical internal carotid artery (guiding time), time required for stent placement (stent placement time), and time required for retrieval of thrombus together with the stent (stent retrieval time) were measured, and the number of movements of the sliding table and C-arm during the procedure were counted.

Results: The intended procedure could be executed faithfully by all physicians. The mean guiding, stent placement, and stent retrieval times were 185 ± 18, 387 ± 33, and 616 ± 27 seconds, respectively. The mean numbers of table and C-arm movements during the procedure were 14 ± 1.7 and 8.3 ± 0.5, respectively.

Conclusion: This system allows operators to faithfully reproduce the mechanical thrombectomy procedure and is considered to have functions necessary for simulation training of catheter intervention and performance assessment.

Keywords: catheter intervention, simulation training, simulator system, fidelity, mechanical thrombectomy

Introduction
Recently, various medical training simulations are practiced. The objective of simulation training is to fill the clinical gap between knowledge and practice. As the training environment is closer to the clinical reality, training can be more effective. The simulator is important for securing the fidelity required for such training, and a practical simulator improves the quality of simulation training.1–5 In this study, we prepared a simulator system for training in neuroendovascular treatment and performed simulation of mechanical thrombectomy.

Subjects and Methods
Preparation of simulator system EndoVascular Evaluator (FAIN-Biomedical, Nagoya, Japan)
We prepared a catheter simulator system using the silicone artificial vessel model EndoVascular Evaluator (EVE: FAIN-Biomedical, Nagoya, Japan).5 EVE consists of the brain, trunk, heart, and peripheral extremity parts, through which channels of transparent silicone tubes mimicking the cardiovascular system including the heart and major arteries are arranged. A motor connected to the channels...
drives liquid into the heart in a pulsed manner and dynamically reproduces the systemic circulation of blood from the heart. Each part can be freely designed and replaced (Fig. 1A).

**Development of freely sliding table**

We developed a freely sliding table that can be moved horizontally on the basis of the beds of actual angiography systems. By mounting EVE on this table, it could be moved horizontally over a distance of 100 cm in the craniocaudal direction and 60 cm in the lateral direction. A screen can be fixed on the table to restrict the trainees’ direct view of the vessel model. In addition, the height of EVE could be changed by installing the table on a medical stretcher (Fig. 1B and 1C).

**Development of electrically controlled camera-holding C-arm**

We developed a camera holder that could be rotated in craniocaudal and lateral arcs by mimicking the C-arm of the angiography system. The movements of the camera holder were electrically controlled with button switches. For the safety of EVE itself and trainees, the rotation range in the craniocaudal direction was restricted to 90° (45° cranially and 45° caudally), and that in the lateral direction to 120° (60° to each side). A remote-controlled video camera with autofocusing and zooming functions, which was connected to a TV monitor, was mounted on the camera holder (Fig. 1D and 1E).

A simulator system that would support catheter treatment training was structured by combining EVE, a sliding table, a stretcher, a camera-holding arm, and a liquid crystal monitor (Fig. 1F).

**Simulation of mechanical thrombectomy**

To examine whether or not catheter treatment training is possible using this system, three experts of the Japanese Society for Neuroendovascular Therapy including authors (Y.H., T.S., and T.M.) carried out simulation of mechanical thrombectomy. First, they were given instructions about the use of this simulator system. Devices including an 8 Fr. OPTIMO temporary occlusion balloon (Tokai Medical Products, Aichi, Japan), 5 Fr. Excellent EN Catheter Hanafy Type (Hanako Medical, Saitama, Japan), 0.035-inch Radifocus Guidewire M Angle type (Terumo Corporation, Tokyo, Japan), Marksman microcatheter (Medtronic, Dublin, Ireland), 0.014-inch microwire Asahi Chikai (Asahi Intecc Co., Ltd, Aichi, Japan), and thrombectomy stent Trevo XP Provue Retriever 4 × 20 mm (Stryker, Kalamazoo, MI, USA) were prepared. In advance, the left middle cerebral artery was occluded with an artificial thrombus, a 9 Fr. sheath was inserted into the right femoral artery, and the artificial vascular channels of EVE were filled with 10 L of tap water dyed with BLOODACT (FAIN-Biomedical) Blue. To the water, 20 mL of Surfactant A and 100 mL of Surfactant B of BIOACT (FAIN-Biomedical) were added to facilitate sliding of the devices, and the channels were perfused with a pulsed flow. Information from the camera...
Simulator System for Catheter Intervention Training

The guiding time was 183, 163, and 209 seconds, stent placement time was 343, 397, and 423 seconds, and stent retrieval time was 652, 586, and 611 seconds. The number of table movements was 14, 18, and 15. The number of camera-holder arm movements was 9, 8, and 8 (Table 1).

Discussion

In the field of clinical medicine, surgery, in particular, the ability to eventually put knowledge into practice is of vital importance. The objective of simulation training is to fill this gap between knowledge and practice. In the field of neurosurgery, also, there have been reports on simulation training of neuroendoscopy, microscopic surgery, and catheter therapy. In conducting simulation training, it is important to create an environment that makes trainees feel as if they were in an actual clinical situation and allow them to concentrate on the training, and an excellent simulator is necessary to faithfully reproduce clinical settings in the training environment. Resusci Anne (Laerdal Medical Japan, Tokyo, Japan) and Sim Man (Laerdal) used in Basic Life Support and Advanced Life Support and LapVR (CAE Healthcare FL, USA) used for simulation training in endoscopic surgery have improved the quality of

Results

The three physicians could perform the entire procedure of mechanical thrombectomy using this simulator system. They all could complete the simulation by totally depending on the information displayed on the monitor screen without directly watching the vessel model even once during the simulation. The guiding time was 183, 163, and 209 seconds, stent placement time was 343, 397, and 423 seconds, and stent retrieval time was 652, 586, and 611 seconds. The number of table movements was 14, 18, and 15. The number of camera-holder arm movements was 9, 8, and 8 (Table 1).

was displayed on the monitor screen, and the angiography-guided intraprocedural environment was mimicked by placing the monitor between the operator and EVE to prevent direct observation of the artificial vascular channels (Fig. 2A). The operators performed thrombectomy by a procedure as close as possible to their usual clinical practice. The 8 Fr. OPTIMO was placed in the cervical internal carotid artery using a coaxial system via the aorta (Fig. 2B and 2C). Then, the TREVO XP was deployed at the thrombus using the Marksman (Fig. 2D), and the stent was retrieved after 5 minutes. On this simulation, the time from the insertion of the 8 Fr. OPTIMO into the sheath to its placement in the internal carotid artery (guiding time), time until the deployment of TREVO XP at the site of occlusion (stent placement time), and time until stent retrieval (stent retrieval time) were measured. In addition, the numbers of movements of the table and camera-holding arm during the procedure were recorded. The procedure times were measured by disregarding whether the thrombus could be retrieved or not.

Fig. 2 Perspective view of simulative mechanical thrombectomy (A). Monitor view during simulative mechanical thrombectomy (B–D). Anterior-posterior view of aortic arch and left common carotid artery cannulated with 8 French Fr. Optimo balloon guiding catheter (arrow) and preceding 6 French Fr. inner-catheter (arrow head) (B), left oblique view of cervical internal carotid artery cannulated with Optimo catheter (arrow head) and preceding inner-catheter (arrow head) (C) and magnified right oblique view of artificial embolus (arrow head) captured with TREVO XP stent retriever (arrow) in the left middle cerebral artery (D).
simulation training due to their excellent functions. In the field of neurosurgery, various simulators for training in bypass surgery and endoscopic surgery have been reported.8–11)

To make simulation training in neuroendovascular treatment more practical, it is necessary to make the training environment closer to clinical settings. Trainees are required not only to learn the procedure of catheter treatment and the usage of instruments, but also to experience comprehensive simulation including rinsing inside of the catheter, imaging, catheter and wire manipulation, and handling of various other devices. In the field of neuroendovascular treatment, a few simulators have been developed, and VIST (Mentice AB, Gothenburg, Sweden) is one of them.12) Since VIST is a digital system, various devices can be manipulated virtually, but they are limited to dedicated instruments, most of the devices that are actually used in clinical settings including catheters cannot be used. On the other hand, the silicone vessel model EVE can be perfused with a liquid through the artificial vascular channels and is superior as a simulator in that various maneuvers that are performed in actual treatment, such as rinsing and imaging, can be simulated and that most catheter-related devices in clinical use can be used. However, in actual training using EVE, time was needed for moving the manually manipulated camera, and it often became necessary to directly observe the artificial vessels, distracting trainees from simulation. We, therefore, developed a simulator system that would prepare an environment more faithful to the clinical settings by combining a sliding table and an electrically controlled camera-holding arm with EVE.

In this study, simulation of mechanical thrombectomy was performed among neuroendovascular procedures because it includes many important technical elements of catheter treatment. As this procedure requires trainees to manipulate the microcatheter and microwire and eventually deploy stents in intracranial vessels in addition to the placement of a guiding catheter, perfusion, and imaging, they can learn basic techniques of endovascular treatment. In addition, mechanical thrombectomy has been reported to be effective as a treatment for acute-phase cerebral infarction,13–16) and shortening of the time until recanalization is a condition for improving the outcome. Therefore, simulation training in thrombectomy is considered to contribute to improvements in the clinical effectiveness and safety of catheter treatment.

The simulator system that we have developed cannot reproduce all aspects of clinical practice. In clinical situations, patients may not be sufficiently sedated, and the surgeon is placed under psychological stress. The fidelity of simulation training has four aspects, that is, physical, technical, environmental, and psychological, but the fidelity pursued by the present system is limited to the technical aspect.17) The three neuroendovascular surgeons completed the entire procedure of mechanical thrombectomy in about 20 minutes, which is considered shorter than the time required for actual treatment. In addition, as the sliding table and C-arm were operated under monitoring with a high-resolution camera, the numbers of their movements were fewer. These are the results of simulation performed by neuroendovascular surgeons under specific conditions and cannot be directly compared with actual clinical data. Therefore, the results of this study are expected to serve as reference data for the assessment of the achievement level in future simulation training.

This study disclosed some points that need to be evaluated or improved in this system. Dyeing the water in the channel improves the visibility of blood vessels monitored with a video camera, but devices in the vessels were occasionally difficult to observe due to refraction of light by the silicone vascular wall. However, this refraction is expected to be reduced considerably by modifying the lighting method. It must also be noted that, in this system not using radiation, the position of a device inserted into a catheter cannot be confirmed until it is pushed out of the catheter unlike actual clinical practice. Moreover, the vessel models of EVE used in this system had standard shapes, but the degree of meandering and furcation angles of actual blood vessels vary among patients. Therefore, simulation training can be made more practical by preparing a wide variety of vessel models and making them alterable.

<table>
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<th>Interventionists</th>
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<th>B</th>
<th>C</th>
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<tr>
<td>Time required for guiding catheter placement (sec)</td>
<td>183</td>
<td>163</td>
<td>209</td>
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<tr>
<td>Time required for stent placement (sec)</td>
<td>343</td>
<td>397</td>
<td>423</td>
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<tr>
<td>Time required for stent retrieval (sec)</td>
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<tr>
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<tr>
<td>Number of moving camera</td>
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Conclusion

We developed a sliding table and an electrically controlled camera-holding C-arm and formulated a simulation system for catheter treatment training by combining them with the silicone vessel model EVE. Three experts in neuroendovascular treatment attempted simulation of mechanical thrombectomy using this simulator and could complete the entire procedure. This system is considered to have basic functions necessary for simulation training in catheter treatment.

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Disclosure Statement

Neither the first author nor any of the coauthors have any conflicts of interest.

References