ORIGINAL ARTICLE

Patient-specific simulation for endovascular procedures: qualitative evaluation of the development process

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Abstract

Background   Recent advancements in simulation permit patient-specific rehearsal of carotid artery stenting procedures. This study evaluates the feasibility of transferring patient-specific CT data into the simulator, creating a 3D reconstruction and performing a rehearsal. The face validity of the model was assessed.

Methods/Results   By thematic analysis of qualitative data, an algorithm was generated, focusing on simulation set-up, time of data transfer, software/compatibility issues and problem-solving strategies. The face validity of the simulated case was evaluated by 15 expert interventionalists: realism (median 4/5), training potential (median 4/5) and pre-procedure rehearsal potential for challenging CAS cases (median 4/5) were rated highly.

Conclusions   Setting up a procedure rehearsal is feasible and reproducible for different patients in different hospital settings without major software compatibility issues. The time to create a 3D reconstruction of patient-specific CT data is a major factor in the total time necessary to set up a rehearsal. The face validity is highly rated by experts. Copyright © 2010 John Wiley & Sons, Ltd.

Keywords   virtual reality; procedure rehearsal; endovascular; carotid artery stenting

Introduction

Rapid advances in simulator technology, combined with a demand for increased patient safety, have led to a growing interest in virtual reality (VR) simulation as a training tool to prepare physicians for complex procedures without harming the patient. A natural evolution in recent years has been the effort to scientifically validate these VR simulators as training tools. This research has shown that generic cases on the VR simulators are effective as both an assessment and a training tool (1–5). It provides novice interventionalists with new basic endovascular skills, can hone the existing skills of experienced interventionalists and enable them to learn new procedures, such as the carotid artery stenting procedure (CAS) (3).

   Within the past few years, the concept of 'rehearsal' has begun to appear in the medical literature as a novel way in which simulation might be used to improve operative performance and patient safety (6,7). Patient-specific procedure rehearsal is the opportunity to 'rehearse' the procedure in simulation, using the real patient's data, prior to performing the intervention on the

Figure 1. Stepwise process of the set-up of a patient-specific procedure rehearsal. VR, virtual reality; CAS, carotid artery stenting

patient (Figure 1). This new technological advancement signals a shift in the use of endovascular simulation, not only as a generic training tool for skills acquisition but also as a tool to allow tailored and patient-specific rehearsal.

Although the concept of rehearsing a specific task is new within the medical field, this is not the case in other high-stake industries. In the domains of music and sport, elite performers routinely rehearse specific upcoming events (8). In the military domain, rehearsal is even more standardized. The term 'mission rehearsal' refers to the practice of specific combat scenarios or military tasks before they are carried out on the battlefield. Apart from acting as an excellent tool to train the members of the team, it also has a planning component and provides the opportunity to assess the feasibility of certain strategic plans (9). The aviation and aerospace industries both have event-specific rehearsals (10).

Most surgeons spend much of their working time in 'performance' mode, i.e. in the equivalent of the concert or the competitive event. 'Training' (e.g. targeted development of specific skills) may occur as part of routine work, while 'rehearsal' (e.g. practice for a specific event) is largely not part of the culture of surgical work. Still, surgeons are expected to perform at the highest level on every occasion.

The use of VR simulation in the endovascular domain was given additional impetus after the US Food and Drug Administration (FDA) approved the CAS procedure for the treatment of carotid artery stenosis in 2004 (11). CAS involves the placement of a stent in a narrowed carotid artery to increase the blood flow to the brain and, more importantly, to scaffold friable plaque in the artery to prevent this from embolizing and causing a stroke. CAS is a high-risk complex procedure which ironically carries the risk of a peri-procedural stroke (exactly what it intends to prevent). Reported risk is 4–10%, depending on patient anatomy, demographics, symptom status and operator experience (12).

Numerous trials have established that there is a learning curve for CAS, with a decrease in procedural complications and improved operative performance with increased physician experience (13). As part of the approval of the CAS procedure, the FDA indicated that companies marketing CAS systems had to provide appropriate training for this complex procedure, and simulation was proposed as a tool to meet these demands (11). Simulation appears to have the potential to provide both the cognitive and technical training elements necessary to acquire the skills for the CAS procedure. As a next step, because of its complex and high-risk nature, it seemed logical that CAS became the first endovascular intervention for which patient-specific VR rehearsal was developed.

To date, incorporating individual patient data into simulators has required sophisticated technological support and was a time-consuming process (7). However, the PROcedure Rehearsal Studio™ (Simbionix USA Corp., Cleveland, OH, USA) software purports to allow the import of the CT data and the creation of subsequent endovascular simulations to be accomplished by clinicians themselves. This potentially makes the whole process more practical and faster.

The aim of this study was to explore the feasibility and accuracy of transferring patient-specific CT data of the carotid vessels onto VR software, and the feasibility of creating and performing a subsequent patient-specific rehearsal on the VR simulator with this new software. A secondary aim was to evaluate the face validity (realism) of the obtained 'real' patient VR simulation.

Materials and Methods

Evaluation of the process of setting up a procedure rehearsal

The research questions are suited to qualitative research. We used several methods to explore feasibility. There were two parts to the evaluation:

1. *Process of transferring CT data to the VR software and creating a patient-specific simulation.* During the development phase, (the transfer of CT data to VR software), field notes were recorded by the lead researcher (W.W.). Document analysis was used, with themes and steps extracted to develop an algorithm (W.W. and D.N.) (14,15). Although consideration was given to a range of variables, these were not predetermined, reflecting the grounded theory approach underpinning analysis. The process took place at three different hospital sites: St. Mary's Hospital, Imperial College Healthcare (ICL), London, UK; University Hospital Ghent (UZG), Ghent, Belgium; and the Sheffield Vascular Institute (SVI), Northern General Hospital, Sheffield, UK.

2. *Face validity of the CAS simulation.* Face validity was evaluated by experts' ratings. A purposive sample was selected. Inclusion criteria consisted of specific CAS expertise, defined according to a consensus document on CAS, as interventionalists who have performed a total of 50 or more CAS interventions (16). After performing the CAS case using VR simulation, experts completed a (semi-structured) questionnaire in which they used a five-point Likert scale on realism, training potential and procedure rehearsal promise (1 = poor to 5 = excellent). Data were entered to SPSS 17.0 and descriptive statistics computed.

Software and hardware systems

The Simbionix PROcedure™ rehearsal studio software was used to create the three-dimensional (3D) reconstructions, (Figure 2) and the AngioMentor™ Express (Simbionix) simulator was used to conduct the patient-specific simulations. The PROcedure rehearsal module of the Angiomentor™ Express simulator was used. The simulator is a part-task VR device, as arterial puncture and closure are not involved. The simulator comes as a single unit, which includes a haptics device, simulation computer, two LCD screens, controls for table movement, contrast medium injection, fluoroscopic C arm positioning, cine-loop recording, road mapping, balloon inflation and stent deployment (Figure 3). The haptics unit is designed to be the virtual patient with a simulated introducer in the groin, and allows the user to insert and manipulate guide wires, embolic protection devices (EPD), catheters, balloons and stents.

The lead researcher (W.W.) was introduced to the new PROcedure™ rehearsal studio software by a company representative. During a 45 min training session, the user interface of the segmentation software was explained and a manual provided. An example of data transfer was provided, with one dataset on an external hard disk.

CT data were used in the Digital Imaging and Communications in Medicine (DICOM) format. This represents a standard format for handling, storing, printing and transmitting information in medical imaging. The DICOM datasets were used for the 3D reconstructions. These datasets were generated by CT scanners with different slice capacities in the range of 16–64 slices. Older CT angiographies were also evaluated, created by a four-slice CT scanner. As DICOM data carriers, both CD-ROMs and external hard drives were used. DICOM data retrieval off the central hospital PACS server was carried out through the commercially available PACS client system in each of the three hospitals.
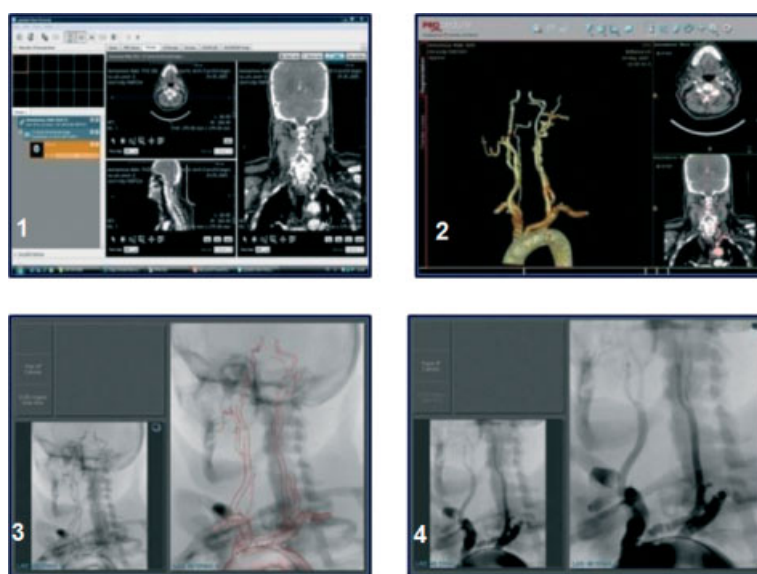

Figure 2. Process of 3D CT reconstruction: 1, original DICOM CT data; 2, 3D segmentation with the Simbionix PROcedure™ rehearsal studio software; 3, incorporation into the PROcedure rehearsal module of the Simbionix AngioMentor™ Express simulator; 4, virtual 2D angiography

Figure 3. Set-up of the Simbionix Angiomentor Express™ simulator in the angiosuite prior to performing a patient-specific procedure rehearsal. Components include: 1, video camera (for recording of hand movements); 2, fluoroscopy monitor; 3, laptop computer; 4, mechanical interface 'haptics' device; 5, sheath through which endovascular tools are inserted

Results

Process of transferring CT data to the VR software and creating a patient-specific simulation: the algorithm

Data retrieval

Over a 3 month period, approximately 100 h were spent on developing the process. The findings were recorded in field notes and the analysis resulted in an algorithm. A clinician (W.W.) uploaded 30 CT angiographies (CTAs) into the Simbionix PROcedure™ rehearsal studio software with the intent of creating patient-specific simulations. CTAs were gathered from the three different hospitals of the EVEResT research group. Twenty procedure rehearsals were set-up at ICL, five at SVI and five at UZG. At ICL the 16 most recent and available CTAs were gathered together with four randomly chosen older CTAs taken with a four-slice CT scanner. The scans included a variety of arch and carotid variations, including bovine arches, vessel tortuosities and varying degrees of vessel calcification and stenosis. Both SVI and UZG use magnetic resonance imaging (MRI) angiography in their standard protocol to evaluate carotid artery disease. Therefore, in each of these centres, five CTAs of the carotids and arch that could be readily found in retrospective records were chosen.

Although the CT-scan protocol for the arch and carotid vasculature differed somewhat in the three centres (pitch, rotation speed, contrast bolus injection, etc.), this was found to be insignificant and did not lead to difficulties in the eventual segmentation with the reconstruction software. A 16-slice CT scanner was necessary to produce DICOM imagery that resulted in a reconstruction and simulation of sufficient quality and realism. Four CTAs taken by an older four-slice CT scanner therefore did not lead to simulations that could be used.

Data transfer

Overall, the data (Figure 4) transfer of the source DICOM dataset was straightforward, fast (<5 min for each step) and occurred without major software compatibility issues. After five CT transfers, there was no further decrease in the time it took to transfer data to the simulator. The process was readily reproducible in the three hospital settings. The only variation was the specific PACS client software in each hospital, with its own user interface.
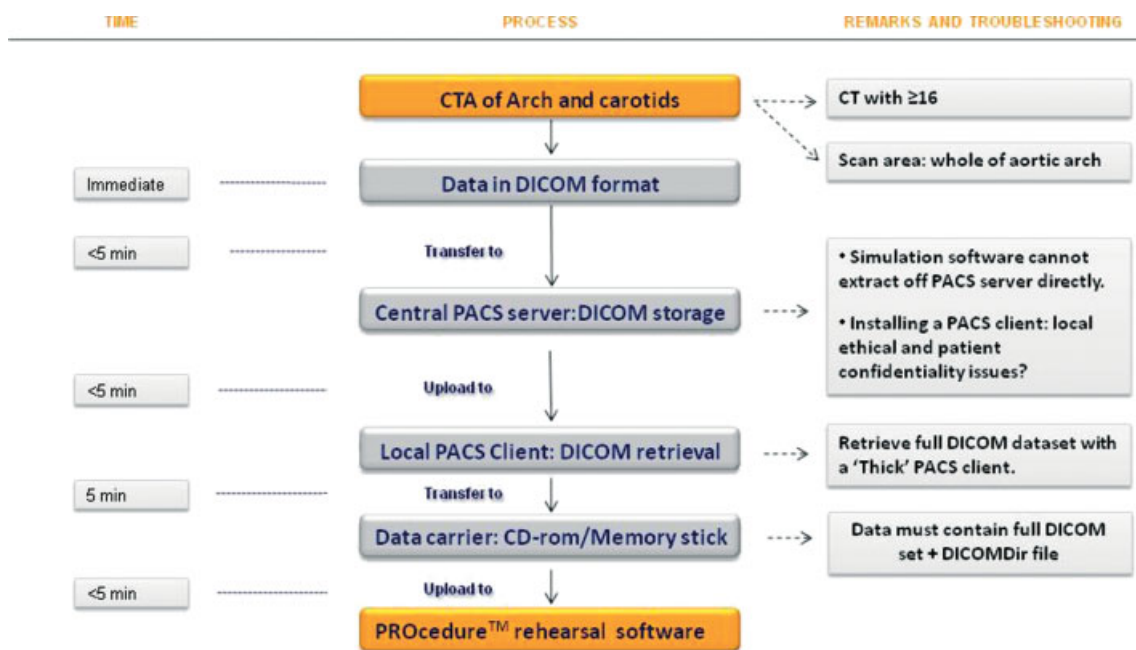

Figure 4. Algorithm describing the process of data transfer

Simulation software cannot extract the DICOM data of the PACS server itself, i.e. the software does not have a built in PACS client. Although it is technically possible to install a commercially available PACS client on the simulator laptop and connect this to the hospital PACS server, this can be associated with patient confidentiality and ethical issues. Nonetheless, both the extraction of the DICOM datasets of a 'thick' hospital PACS client onto an external data carrier and uploading this data into the simulation software works fast and without major software problems.

Data segmentation

The process of data segmentation is outlined in Figure 5. The reconstruction software uses an automated and manual level set method of segmentation to reconstruct the relevant vasculature. The software automatically

marks an initial mask: it amounts a set of voxels representing the anatomy of interest (i.e., the carotid and adjacent arteries). This mask can then be enhanced manually.

The degree of automated segmentation is heavily dependent on the quality of the initial DICOM dataset. Multiple factors can lead to an inadequate automated segmentation; these include patient motion artefacts, streaking artefacts, overriding bone and adjacent vascular structures (Figure 6). Two CT characteristics prevented an adequate segmentation and thus a patient-specific simulation:

1. Contrast filling defects (Figure 6) in the relevant vasculature, primarily seen in the more proximal part of the CCA and the result of local laminar flow in the vessels. This results in a defective centrelining and inability to start up a simulation.
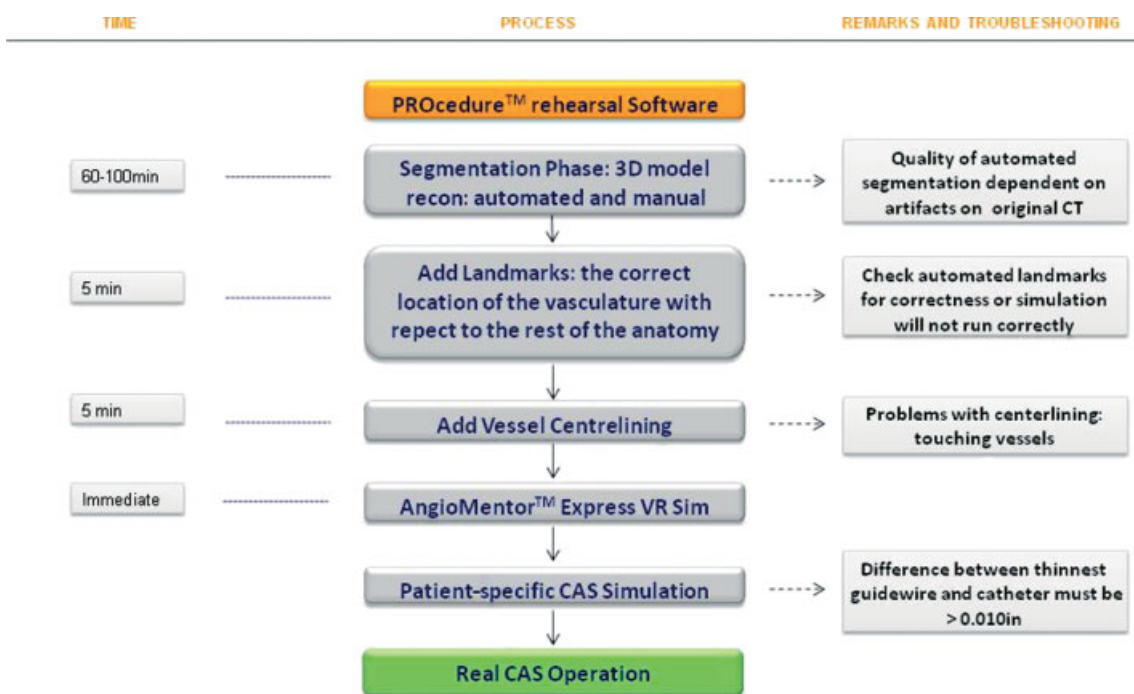

Figure 5. Algorithm describing the process of data segmentation and simulation
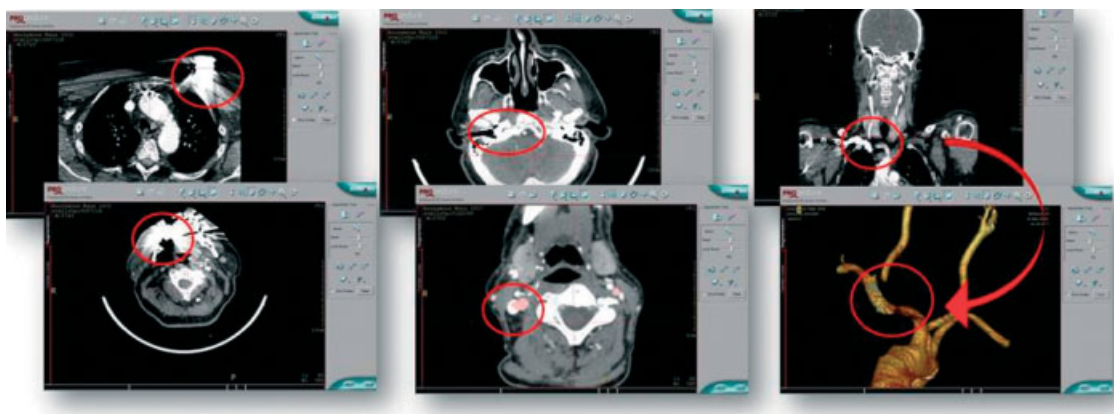

Figure 6. CT artifacts: (left) streaking artifacts; (middle) overriding bone and vessels; (right) contrast-filling defects
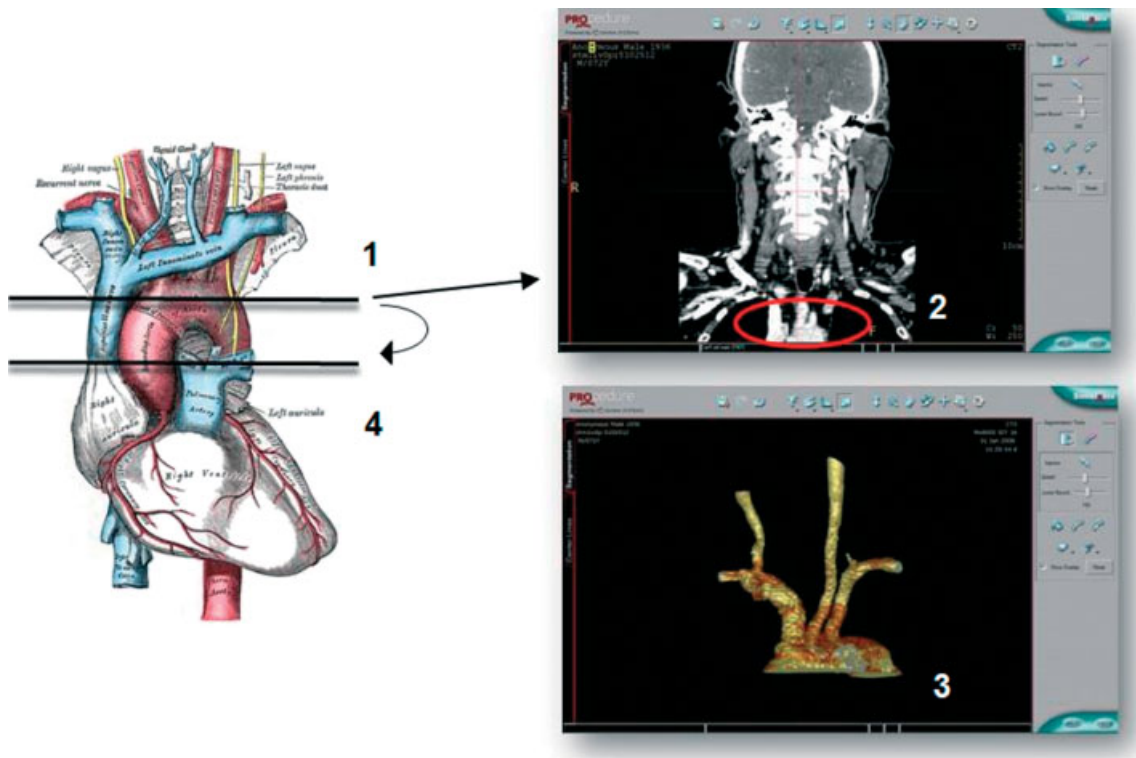
Figure 7. Incorrect and correct caudal levels of the CTA of the arch and carotids: 1, scan area too high on the aortic arch; 2, inadequate DICOM data of the arch; 3, 3D segmentation inadequate for a simulation set-up; 4, correct location of the caudal level of the CTA – ascending and descending aorta are separate entities on the same CT slice

2. A scan region that does not extend into the aortic arch (Figure 7). It was found that the most caudal CT slice had to visualize the ascending and descending aorta as two separate entities for the simulation software to be able to extrapolate the vasculature further down into the descending aorta and further up into the heart.

The next step consists of the assignment of five bony landmarks to the arterial reconstruction. These landmark points are designed to serve as anchors that indicate the correct location of the vasculature with respect to the rest of the anatomy. That way the simulator knows where to place the reconstruction in relation to the virtual fluoroscopy imagery of the skull and cervical spine. This process is not time consuming and is uncomplicated.

Vessel centrelining is an automated process and works very efficiently. This process only fails if there are touching vessels in the original segmentation which prevent the software from producing the correct lines (Figure 8). This occurs predominately between the side branches of the external carotid artery and is easily manually corrected by going back to the initial segmentation.

All the aforementioned artefacts limit the automated segmentation and necessitate additional manual segmentation. The degree of additional manual segmentation is the major factor in the total time necessary to set up a rehearsal. Aside from potential artefacts, the total time for the manual segmentation is also influenced by the extent to which the user wants to increase the realism by reconstructing all side branches and additional vessels. These

Figure 8. Example of inadequate centrelining due to touching vessels between the internal carotid artery and occipital artery (white ellipse)

include all the side branches of the ECA, all the contralateral vessels, the subclavian and vertebral arteries and the intracranial portions of these vessels. Overall,

a reconstruction can take anywhere between 60 and 100 min. In this study, confidence in adequate reconstruction was attained after approximately 10 reconstructions. After this it seems that it is not the learning effect but the quality of the CT scan that influences the time it takes to generate a 3D reconstruction.

Of the initial 30 CTAs, three could not be reconstructed adequately due to filling defects. Four CT scans were generated by a four-slice CT scanner and were of insufficient quality. A further three scans were not scanned low enough on the arch to allow for a reconstruction and subsequent simulation. This left 22 reconstructions that could be uploaded as a procedure rehearsal in the simulator device.

Data uploading and simulation

Uploading the 3D reconstruction into the Angiomentor simulator is also an automatic process and takes <1 min. The Angiomentor simulator itself accepts practically all commercially available catheters, balloons, EPD catheters, wires and sheaths commonly used in the CAS procedure. It was noted, however, that the difference in diameter between the thinnest (balloon) catheter and wire had to be >0.010 inch, so that the simulator could differentiate between the two instruments.

Subjective postprocedural questionnaire: face validity

Figure 9 reports 'expert' ratings of face validity. The realism was rated highly (median 4/5). Subjective comments made by the experts indicated that this score was not 5/5, as the tactile feedback the simulator provides is not fully realistic (median 3/5). Most notable are the conclusions by the 15 expert interventionalists that all physicians should train on such a model before embarking on CAS procedures on real patients (median 5/5), and that procedure rehearsal seems useful for practicing and evaluating the endovascular material before the real case (median 4/5). They indicated that they probably would not use it for every case (2/5) but certainly for the more challenging CAS procedures (4/5). The majority indicated time constraints in their daily medical practice as the reason for selectively using the technology for the more difficult cases only. Challenging cases were described as those with challenging access to either the common and/or internal carotid arteries.

Discussion

The results indicate that setting up a patient-specific endovascular VR procedure rehearsal is both feasible and practical in the clinical setting. The algorithm provides a stepwise approach to the set-up process. Sampling across three institutions suggests that the process is robust

and reproducible, without major software incompatibility issues. Expert ratings indicate strong face validity of the patient-specific VR rehearsal, with high ratings for training and preprocedural potential.

As a result of the above, procedure rehearsal has the potential to prepare the physician and interventional team for complex procedures and, in so doing, increasing patient safety. Preliminary results from follow-up studies confirm that procedure rehearsal provides the interventionalist and the team with an excellent opportunity to evaluate the tools, with an increased operative flow and teamwork as a result (17). These findings are confirmed by other research groups (6). It seems probable that the simulation technology and procedure rehearsal will progressively be incorporated into daily medical practice, much like in other high-stake industries. The drivers for this integration are well documented and critically include an ethical imperative to protect patients (18,19).

The 3D reconstruction of the relevant vasculature was identified as the most variable and time-consuming step in the whole process. Subsequently the quality of the CT DICOM data is of major influence for both the set-up time and the quality of the simulated rehearsal. However, the next generation of simulation software, which will allow manual overriding of these CT imperfections, combined with the additional knowledge this research has provided, should result in a decrease in CT scans inappropriate for VR simulation.

The present study represents the first scientific report on VR procedure rehearsal. Prior research has focused on validating the generic modules on endovascular VR simulators as an assessment and training tool (1–5). Training is defined as 'the process of bringing a person to an agreed standard of proficiency by practice and instruction'. The present paper differs from previous work, as its focus is on the act of rehearsal. Rehearsal is different from training, as it implies that a certain level of proficiency has already been achieved through prior practice. Rehearsal can be regarded as a final 'run-through' or a session of specific practice before a planned performance.

In medicine, one paper has outlined the principle of rehearsing a specific patient procedure (7). However, the simulation software used in that case did not allow the end-user to create the segmentations and simulations. Rather, it was performed by technicians from the simulator company. This is more time consuming, impractical and expensive. The paper illustrated that the angiography images and selection of tools during the simulated case show a high concordance with the real case.

However, there are many unanswered questions associated with the concept of VR procedure rehearsal. Further research will address these issues. If patient-specific simulation is to be useful as a preoperative rehearsal tool, the simulator should probably replicate the real operation in every aspect to the highest degree. This extreme level of fidelity might be difficult to achieve with the current generation of VR simulators. One can argue that this level of fidelity is of less importance when simulators are solely used as a generic tool to train

The model is realistic

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

The 3D angiographic images are realistic.

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

The simulator provides realistic tactile, "haptic" feedback: guide wire, balloon, stent, …

1	2	**③**	4	5
Definitely disagree		Unsure		Definitely agree

This model is useful for training physicians to perform carotid stenting.

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

All physicians should train on this model prior to performing carotid stenting on patients.

1	2	3	4	**⑤**
Definitely disagree		Unsure		Definitely agree

This model is useful for assessment of the skills required to perform a carotid stent.

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

The model is useful to evaluate the tools needed for the "real" case.

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

This model altered my preconceived choice of the endovascular material.

1	2	**③**	4	5
Definitely disagree		Unsure		Definitely agree

This simulation is useful to practice the "real" case prior to performing the real case on the patient.

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

I would consider performing a procedure rehearsal before every real CAS case.

1	**②**	3	4	5
Definitely disagree		Unsure		Definitely agree

I would consider performing a procedure rehearsal only for challenging cases.

1	2	3	**④**	5
Definitely disagree		Unsure		Definitely agree

Figure 9. Questionnaire: face validity and subjective evaluation. Median scores marked in red circles

novices or experienced interventionalists in the basic skills required for new procedures.

Another factor which may influence the effectiveness of the simulation is the accuracy of the 3D reconstruction. This is influenced by both user- and CT-dependent factors. As previously noted, a CT scan can contain a variety of artefacts, such as streaking artefacts, partial volume effects and filling defects, that can influence the accuracy of the reconstruction. Interfering factors on the CT scan, such as calcifications, ulcerations and adjacent vessels, can also distort the imagery and influence the accuracy of vessel stenosis quantitation.

Creating the correct 3D reconstruction is also a user-dependent process and interobserver differences may be seen. A radiologist may delineate the border of a (contrast-filled) vessel differently, according to the specific image windowing, and thus the vessel diameters and stenoses in the 3D reconstruction and simulation. The degree to which these (subtle) artefacts and imperfections have an influence on the usefulness of the actual simulation has to be seen.

Another point of discussion is who should create the 3D reconstructions for the simulation. As the user interface of the present simulator software is very intuitive to use, it is likely that any physician with knowledge of the relevant anatomy can make a 3D reconstruction. However, it will have to be scientifically demonstrated whether these reconstructions are as accurate as the gold

standard of a radiologist with the software on his/her workstation.

Further research will also have to look at how this technology should be used in daily medical practice. Which physicians should use procedure rehearsal before operating on their patients – everyone, or only the less experienced interventionalists? Should the full interventional team, including the scrub nurse, radiographer and circulating nurse, be involved in the simulation, and to what effect? Should it be offered to every patient or only those with a challenging anatomy? If this technology is implemented in clinical practice, one must also consider the medico-legal implications. Centres that do not have access to such technology could potentially be limited in their practice to perform specific high-risk procedures. What are the medico-legal consequences of adverse outcome and procedure rehearsal? Will a complication be scrutinized differently if no procedure rehearsal was performed although the technology was accessible? What are the consequences if a physician deviates from a technique that was successful on the simulator? Further, what are the implications for the simulation industry if procedures performed with a successful outcome on the simulator actually result in complications on the real patients?

In conclusion, this paper provides baseline information for what is likely to be a growth area in simulations for procedures. Many questions remain, but medical simulation is an evolving field and the development of procedure rehearsal applications in the coronary and endovascular abdominal aneurysm repair are already under way. Therefore, it seems likely that the use of this new technology will become more widespread and not confined to highly specialized research centres.

Further research should evaluate whether procedure rehearsal can indeed improve the interventionist's and team's preparation and lead to a reduction in the use of endovascular material, fluoroscopy time and contrast use. This may consequently result in an overall safer operation for the patient. This research may then lead to the implementation of such a device in the hospital environment, with a potential broadening of its application to different kinds of interventionalists and endovascular procedures.

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