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SHORT REPORT

Simulation Case Rehearsals for Carotid Artery Stenting☆

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Abstract A case series of 5 patients is presented assessing the utility of simulation case rehearsals of individual patients for carotid artery stenting on an endovascular simulator. Simulated and operative device dimensions were similar. Results of subjective surveys indicated that face and content validity were excellent. The simulations predicted difficulty with vessel cannulation, however had difficulty predicting post-stent changes in bifurcation angulation. Our experience suggests that it may be feasible to use patient-specific CTA-derived data in the creation of a realistic case rehearsal simulation. The overall utility of this concept, including cost-benefit analysis, has yet to be determined.

Introduction

It is increasingly emphasized that it is unethical to allow a junior trainee to ''practice'' on patients. Endovascular surgery is, in effect, simulated reality in that a two dimensional image of what is happening elsewhere is projected on a screen and the information depicted on the screen is used to make decisions regarding patient care. As a result, this area has lent itself well to simulation as it is relatively easy to replicate a two dimensional environment on a video screen.

The overall goal of simulation is to improve patient safety and outcomes through creation of a training environment which accurately mimics reality without jeopardizing patient care. Endovascular simulators have been used for generalized training and evaluation through the use of standardized anatomy and physiology.[1–4] One area of simulation that has proven to be difficult is the creation of a high fidelity process to accurately and reproducibly simulate an *individual* patient's anatomy. The transition from generalized to patient-specific simulation may have the potential to impact the outcome of the *individual* patient by permitting preoperative rehearsal, as well as allowing essentially perfect practice for junior trainees without patient risk.

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Table 1 Comparison of rehearsal and operative procedures

Significant anatomy	Patient 1		Patient 2		Patient 3		Patient 4		Patient 5		*P*
	Rehearsal	Operative	Rehearsal	Operative	Rehearsal	Operative	Rehearsal	Operative	Rehearsal	Operative	
	Bovine arch, difficult cannulation of CCA, unable to cannulate ECA	Bovine arch, CCA stenosis, difficult cannulation of CCA, unable to cannulate ECA	String sign, type II/III arch	String sign, type II/III arch	Bovine arch, left subclavian stenosis	Bovine arch, left subclavian stenosis	High grade, web-like synechial plaque	High grade, web-like synechial plaque	High grade	High grade	
Percent stenosis	70	70	90	90	80	80	80	80	90	90	
Contrast volume (mL)	70	119	55	57	57	175	52	126	66	110	.040
Total time (min)	42	87	23	57	20	75	19	83	27	108	.002
Fluoroscopy time (min)	12	15	14	7	11	14	10	13	14	12	
Fluoroscopy angle (degrees)	LAO 55	LAO 57	RAO 41	RAO 46	LAO 55	LAO 24	LAO 45	LAO 29	LAO 45	LAO 46	
Selective catheter	Bern, Vertebral, Simmons 1	Simmons 1	JB2, Vertebral, Simmons 1	Simmons 1	Simmons 2	Simmons 2	Vertebral	Vertebral	Vertebral	Vertebral	
Sheath (Fr)	6	5	6	6	6	6	6	6	6	6	
EPD (mm, diameter)	5.5	5.5	5.5	5.5	7	6.5	6	6.5	6	6	
Pre-stent dilation (mm, d × l)	None	None	None	None	None	5 × 20	4 × 30	3.5 × 30	3 × 30	3.5 × 30	
Stent dimensions (mm, d × l)	6 × 40	6 × 40	7 × 30	6—8 × 30	8 × 30	6—8 × 30	7 × 40	6-8 × 40	7 × 40	7 × 40	
Post-stent dilation (mm d × l)	5 × 30	5 × 20	6 × 30	6 × 30	6 × 30	6 × 30	5 × 30	5.5 × 30	6 × 40	5.5 × 40	
Residual stenosis (%)	50	50	10	20	0	0	0	0	0	0	
Post-stent vessel configuration	Similar		Similar		Similar		Dissimilar		Similar		

EPD, Embolic protection device.

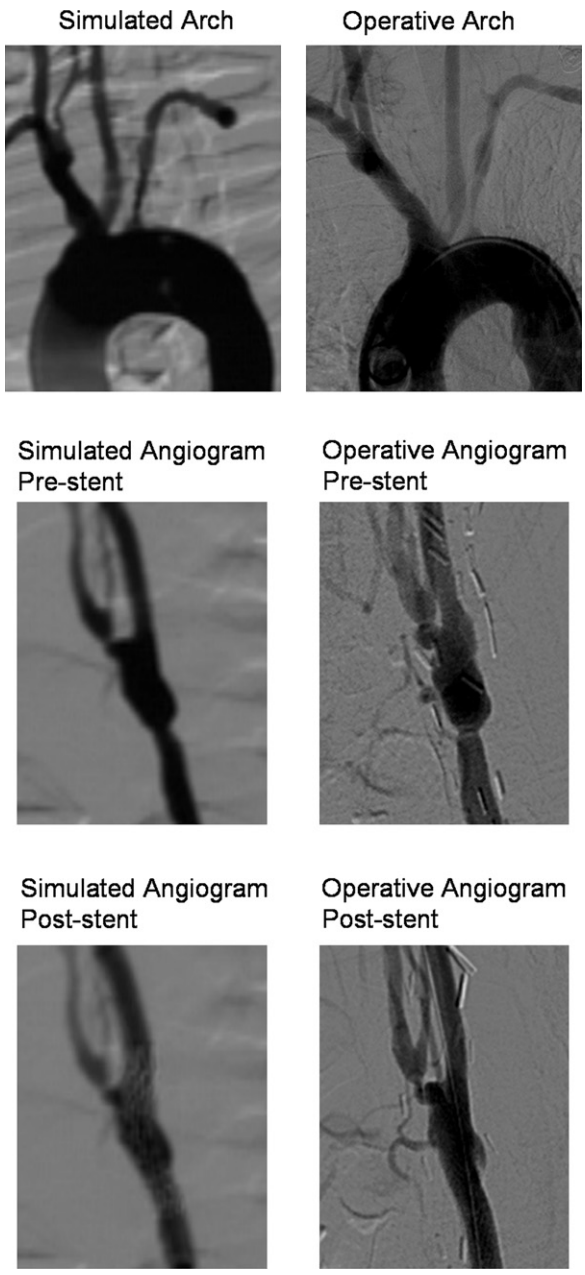

Figure 1 Patient 1.

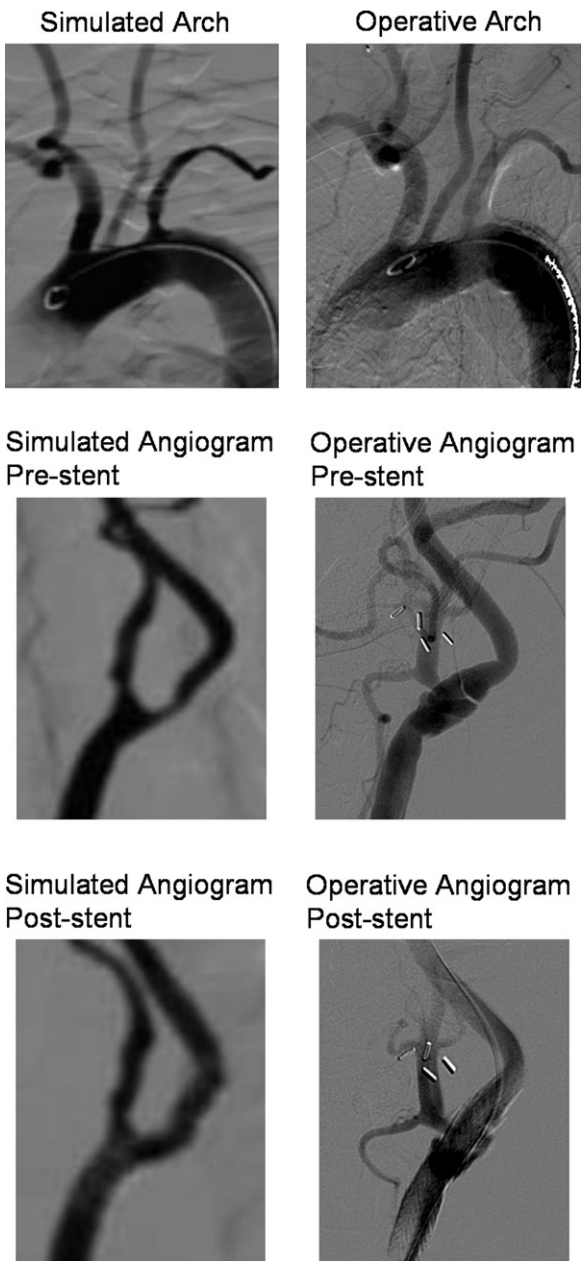

Figure 2 Patient 4.

Case report

The Angio Mentor simulator (Simbionix, Lod, Israel) is a haptics interface unit coupled to a computer. The haptics unit provides tactile feedback intended to replicate the feel of the target lesion. Real endovascular instruments are introduced into the haptics unit and displayed fluoroscopically within the vascular anatomy.

Formal institutional review board approval was obtained for this case series of five patients. Three attending surgeons performed the rehearsals (two surgeons performed two rehearsals each and one surgeon performed one rehearsal). Surgeons had previous carotid angioplasty/stent experience mean of 51 (range 13—80) with a mean of 16 (range 6—20) over the previous year. Patients were selected for intervention based upon standard indications for carotid artery angioplasty and stenting with high risk for surgery.[5] Anonymous computerized tomographic angiography (CTA) data sets were sent to Simbionix Corporation (Lod, Israel) and used as an anatomical scaffold by the PROcedure Rehearsal Studio to create simulation files. Turnover time was less than two weeks and no surgeries were delayed as a result of this study. The attending surgeon performed the simulated case in the 24 h prior to the procedure. Surveys (1—5, strongly disagree—strongly agree) were used to analyze subjective data assessing face validity (Does the simulator hardware look

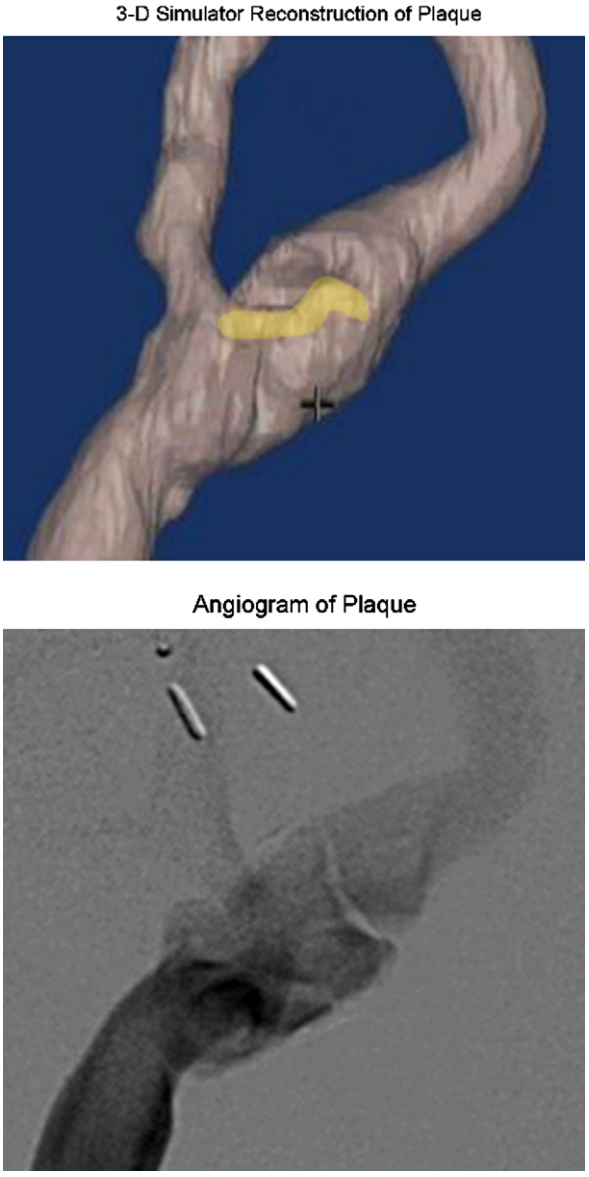

Figure 3 Patient 4.

real?) and content validity (Does the rehearsal mimic real life?). Descriptive analysis was performed for mean, median and standard deviation. Objective data were recorded for the simulation and the operative procedure. Data management and statistical analysis were performed using SPSS version 17 (SPSS Inc., Chicago, IL). Paired samples were analyzed using the paired samples *t*-test.

Simulated and operative embolic protection device (EPD), stent, and post-stent dilation balloon dimensions nearly matched. Predictors of operative outcomes included overall time and contrast volume (Table 1).

Arch anatomies were realistically replicated. Patient 1 had a bovine arch in which the simulation predicted cannulation to be more difficult than was expected by M2S (Lebanon, NH) reconstruction (Fig. 1). The simulation was accurate and multiple catheters were trialed with the selection of a catheter that allowed for successful although similarly difficult cannulation of the common carotid.

Inability to cannulate the external carotid artery was accurately predicted in patients 1 and 2. Simulation assisted in the decision not to make multiple attempts to force difficult cannulations.

The anatomy and tactile feedback of complex internal carotid lesions were realistically reproduced in patient 2 (string sign) and in patient 5 (high grade). The software accurately reproduced the tactile and 3-dimensional characteristics of the lesion in patient 4, however was unable to accurately depict it fluoroscopically (Figs. 2 and 3).

Rehearsal predictions of all post-stent vessel configurations were similar with the exception of patient 4. Two stents were used in the actual procedure due to distal migration of the first stent.

Preliminary subjective assessments of the simulator suggest that the simulator looks and performs realistically and that the PROcedure Rehearsal Studio software realistically replicates lesion characteristics and cannulation (Table 2). Subjective assessments also indicate that the rehearsals may positively impact overall patient outcomes.

Discussion

Modern methods of teaching endovascular skills focus on developing efficient training methods which lower operative risk for the patient.[1] However, these methods focus on general skill attainment and do not address the specific obstacles that individual patients present.

It has been technically challenging to develop a high fidelity process to accurately simulate an *individual* patient's anatomy and physiology. The clinical utility of this process, including overall cost: benefit ratios remain unclear as costs are prohibitive ($100,000 – $200,000, €70,000 – €140,000 for the simulator alone) and benefits have not been investigated. Most likely, case specific simulation will be most useful in the training of residents and fellows, essentially providing a ''perfect'' training environment with the goal of hastening the attainment and increasing the degree of proficiency, ultimately resulting in improved patient outcomes. It is probable that simulation rehearsals will not be necessary in routine cases, but that they may be helpful prior to the performance of difficult endovascular interventions.

Patient selection for endovascular interventions is based largely on static anatomy of the lesion and approach vessels. Rehearsals may assist in finding new approaches to these difficult cases and allow them to be safely performed endovascularly.

Results of this pilot study indicate that it is feasible to use patient-specific CTA-derived data in the creation of an endovascular simulation. Case rehearsals may be able to be performed with high face and content validity. However, they cannot be regarded as a completely accurate mission rehearsal as the simulation does not always predict post-stent vessel configuration. The overall utility of this concept will be best evaluated in a randomized trial.

Table 2 Surgeon evaluation of case rehearsal

Scale: 1 = strongly disagree; 2 = disagree; 3 = indeterminate; 4 = agree; 5 = strongly agree			
Face validity — Endovascular simulator hardware	Median	Mean	Std Dev
Imaging was realistic	5	5	0
Instruments were realistic	5	4.6	0.55
Tactile feedback was realistic	5	4.8	0.45
Physiologic feedback was realistic	5	4.8	0.45
Overall, the simulator was realistic	5	5	0
Easy to use	5	4.6	0.55
Worked well	4	4.2	0.45
Content validity — Endovascular simulator rehearsal software			
Realistically predicted patient anatomy	5	4.8	0.45
Realistically predicted anatomy of carotid bifurcation	5	5	0
Realistically predicted the internal carotid lesion	5	4.8	0.45
Realistically predicted other carotid lesions	5	4.4	0.89
Realistically predicted flow characteristics	5	4.8	0.45
Content validity — Preoperative rehearsal			
Helped with wire selection	4	4.2	0.84
Helped with catheter selection	5	4.8	0.45
Assisted with catheterization of the common carotid	5	4.8	0.45
Assisted with catheterization of the internal carotid	4	4.4	0.55
Assisted with catheterization of the external carotid	4	4.2	0.45
Increased overall efficiency of instrument use	5	5	0
Helped with stent selection	5	4.6	0.55
Predicted correct stent dimensions	5	4.8	0.45
Decreased OR time	5	5	0
Decreased fluoroscopy time	5	4.8	0.45
Decreased overall amount of contrast used	5	4	1.73
Decreased potential for damage to tissue	4	3.8	0.84
Helped with overall progression and flow of operation	5	5	0
Increased procedure safety for the patient	5	5	0
Outcome similar to that rehearsed on the simulator	5	4.8	0.45

Mean, median and standard deviation (std dev) of global rating scale surgeon evaluations of ANGIO Mentor Endovascular simulator, PROcedure Rehearsal Studio and preoperative rehearsal.

Conflict of Interest

None.

Appendix
Supplementary data

Supplementary data associated with this article can be found in the online version, at doi:10.1016/j.ejvs.2009.08.011.

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