

Award Number: W81XWH-04-2-0023

TITLE: Multi Institutional, Multi National Medical Simulator Validation Studies

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REPORT DATE: April 2008

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

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REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01-06-2007		2. REPORT TYPE Final		3. DATES COVERED (From - To) 1 JUN 2004 - 31 MAY 2007	
4. TITLE AND SUBTITLE Multi Institutional, Multi National Medical Simulator Validation Studies				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-04-2-0023	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Charles P. Steiner E-Mail: E-Mail: steinec@ccf.org				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Cleveland Clinic Foundation Cleveland, OH 44195				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The use of medical skills simulators for the training and assessment of clinicians is gaining support in the medical teaching facilities around the world. We propose the use and assessment of a medical simulator for the teaching of a set of urological procedures. Clinicians will be enrolled at multiple centers and complete a course of study which may involve the use of a medical simulation training system. At the end of the training the clinician's competency will be assessed and the impact of the use of a medical simulator will be evaluated across all of the centers participating.					
15. SUBJECT TERMS No subject terms provided.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
U	U	U	UU	14	USAMRMC

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Introduction

The primary goal of this research was to assess the role of a medical simulator in the teaching curriculum of clinicians enrolled in a urological training program. We proposed the enrolling of up to 50 clinicians with a range of experience from novice to board certified. The participants will be divided into equal groups and each provided an equivalent amount of baseline instruction in the use of the training simulator. Following instruction the enrollees were asked to complete 5 procedural tasks during which time they were assessed using 5 parameters of task competency.

Percutaneous Nephrostomy (PCN) involves the placement of a catheter in the renal collecting system for the purposes of collecting urine or relieving the volume or pressure of urine in the kidneys. The procedure is an interventional procedure usually performed under fluoroscopic or ultrasound guidance by interventional radiologists or urologists. The catheter is usually removed once the reason for the procedure has been satisfied. Training to perform this procedure is traditionally accomplished by the student first observing an accomplished clinician in the performance of this task followed by an opportunity to perform a PCN under supervision. The vernacular “see one, do one” is often cited as the traditional method of education. Competency in this procedure is usually not achieved until the clinician has completed 100 procedures and performance of 20 PCN procedures per year is required to maintain a level of certification.

Body

A medical simulator capable of training clinicians in basic endourological procedures and percutaneous nephrostomy was developed jointly by Simbionix, Ltd of Cleveland OH and Cleveland Clinic. The device was named PercMentor for Percutaneous Mentor or trainer.

A total of 48 clinicians volunteered to participate in the use of the PercMentor Simulator. Clinicians were classified as beginner, resident, fellow and certified. Each group had an equivalent number of participants. Beginner's had no specific PCN training and included medical students and operating room nurses. Residents were enrolled in a surgical residency program and were rotating through the urology service. Fellows had completed a surgical residency and were enrolled in a urology fellowship. Certified were board certified urologists and interventional radiologists specializing in urology.

The PercMentor was located in a training laboratory accessible 24 hours per day and adjacent the operating rooms. Each participant was free to visit the laboratory and complete their individualized training at their convenience. Prior to beginning the assessment tasks each participant completed an approximately 1 hour introduction to the training and the PercMentor simulator. This included instruction for logging into the system and an explanation of the data that was being collected on their performance. The anonymity of the participants was maintained by assigning each enrollee with a unique identifier which allowed for experience classification. The individual performance results were never shared with the participants or the participants supervisors. At the end of each training session the participant was able to determine their score but not the scores of other participants.

The tasks performed were the following:

- 1) Identify anatomy with fluoroscopy. This task involved the survey of the clinical workspace and the proper orientation of the virtual endoscope to signify the determination of the kidney and the spleen. The time in seconds for each identification was measured and reported.
- 2) Identify anatomy with ultrasound. This task was similar to task number 1 but with the use of virtual ultrasound imaging for visualization of the underlying anatomy. The same metrics were applied.
- 3) Identify the calices within the kidney. The virtual kidney was segmented into three regions, upper, middle and lower. The time in seconds to reach each region was measured and reported along with the total time.
- 4) Puncture balloons in a fixed period of time. Within the virtual bladder a series of random floating objects (balloons) were presented to the participant. Within a period of 5 minutes the number of balloons that were punctured using the virtual needle was recorded. In addition the amount of fluoroscopy used during the period was measured.
- 5) Free training of the simulator. A virtual clinical task was selected which was based on a typical clinical presentation of a patient presenting for nephrostomy. The time needed to complete the task of percutaneous nephrostomy was measured along with the amount of fluoroscopy used.

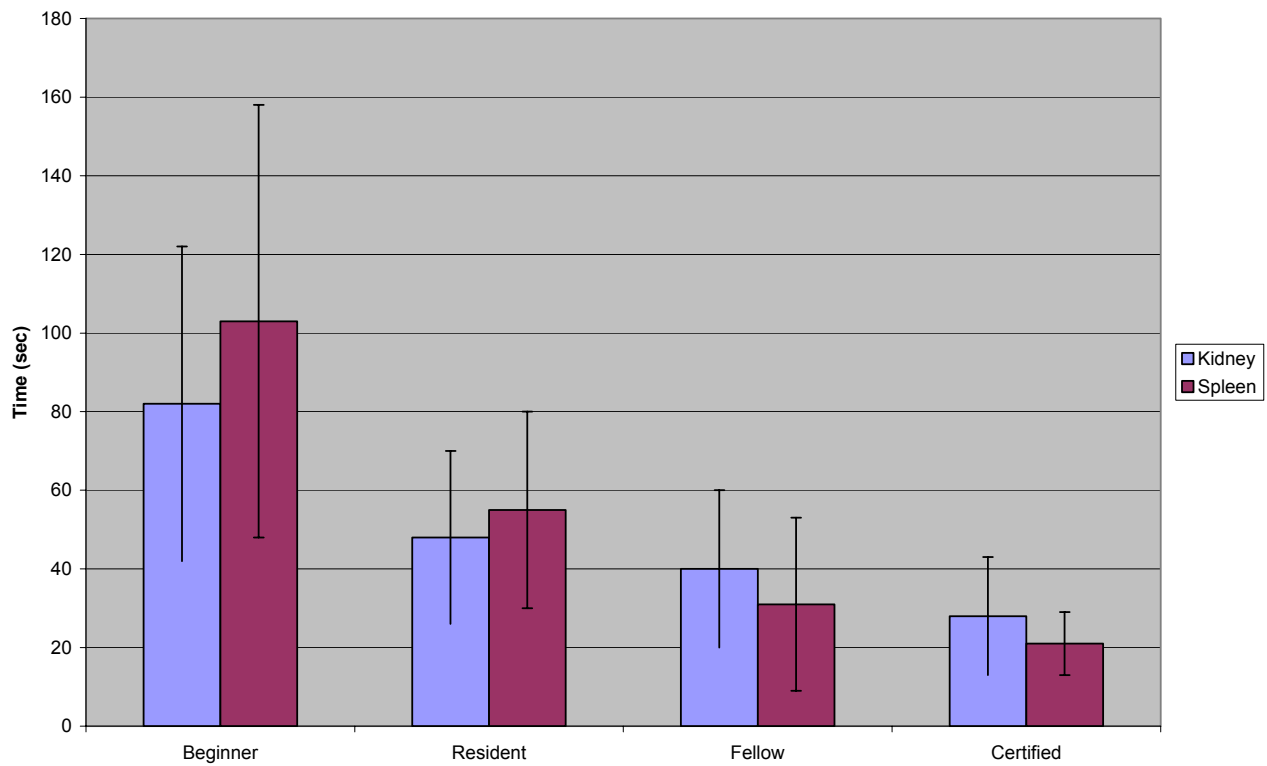
Key Research Accomplishments

- 1) Development of Percutaneous Nephrostomy Training Simulator (PercMentor)
- 2) Development of a training curriculum based on the PercMentor
- 3) Conduction of a training program utilizing the PercMentor
- 4) Evaluation of the training program using prospective methods
- 5) Reporting the results of the simulator evaluation

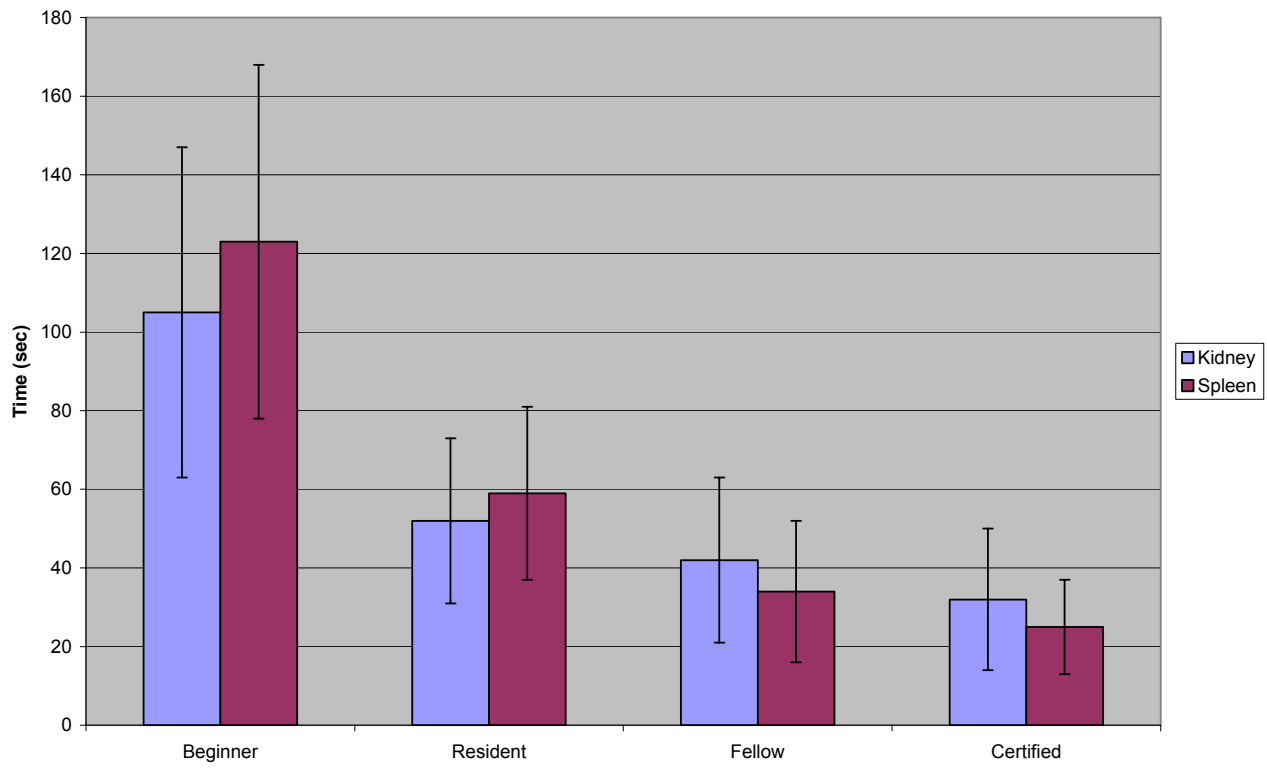
Reportable Outcomes

- 1) A fully functional Percutaneous Nephrostomy Training Simulator (PercMentor) was developed.
- 2) Training curricula were developed which utilized the PercMentor to evaluate the competence of clinicians in the performance of the PCN procedure.
- 3) The PercMentor training curricula developed can differentiate those individuals that have experience in the PCN procedure.
- 4) See Appendix for raw data – graphs shown below.

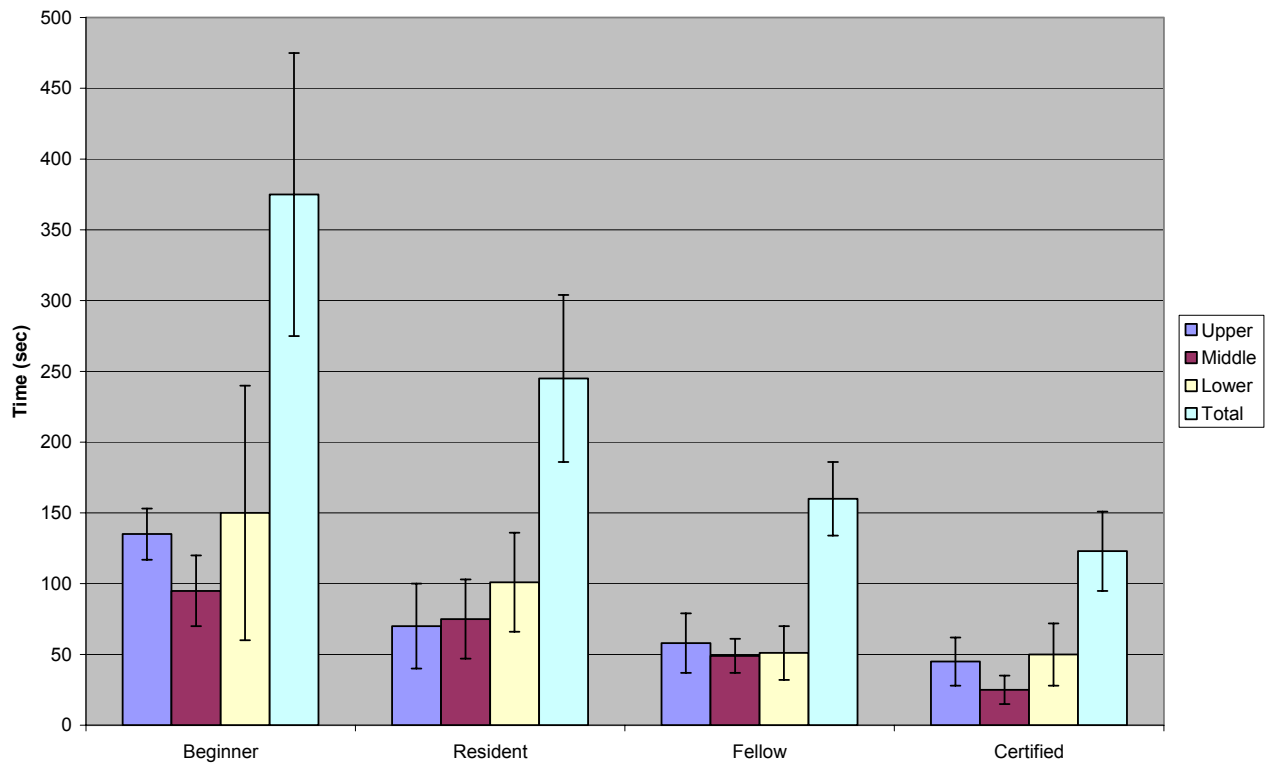
Task 1



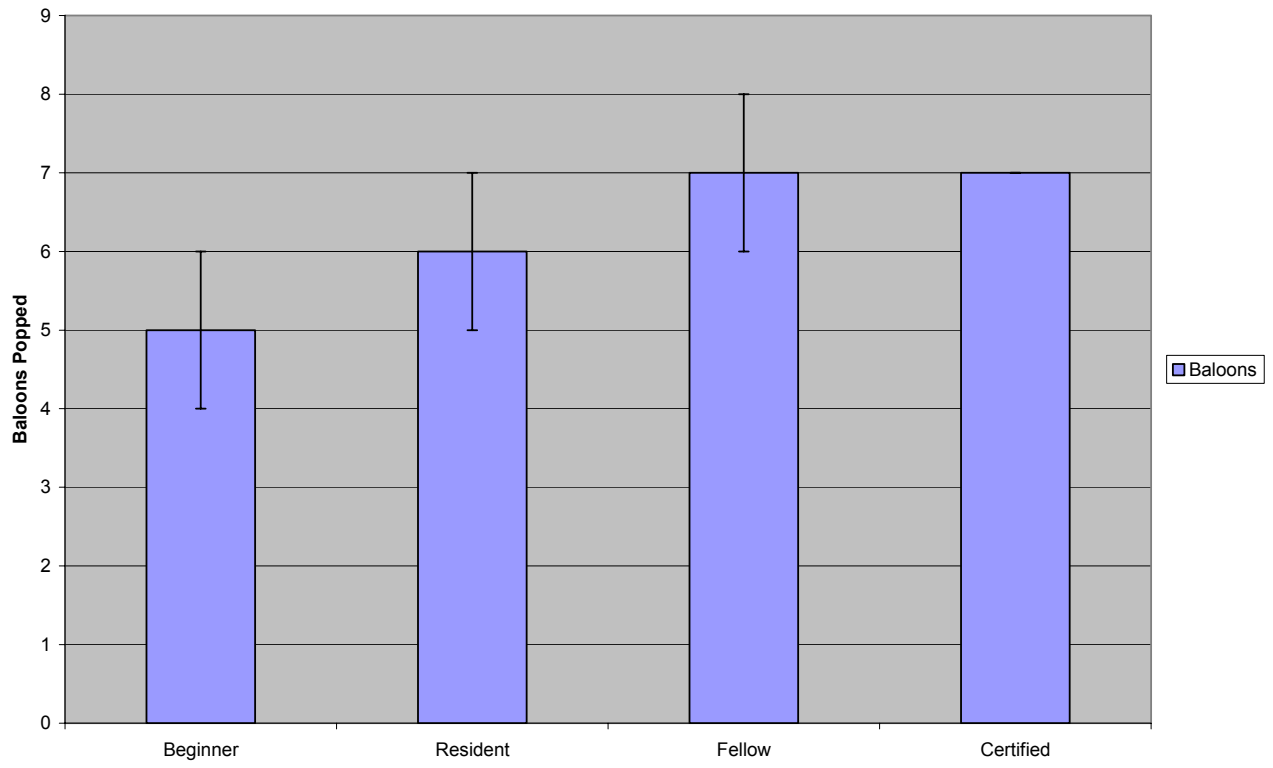
Task 2



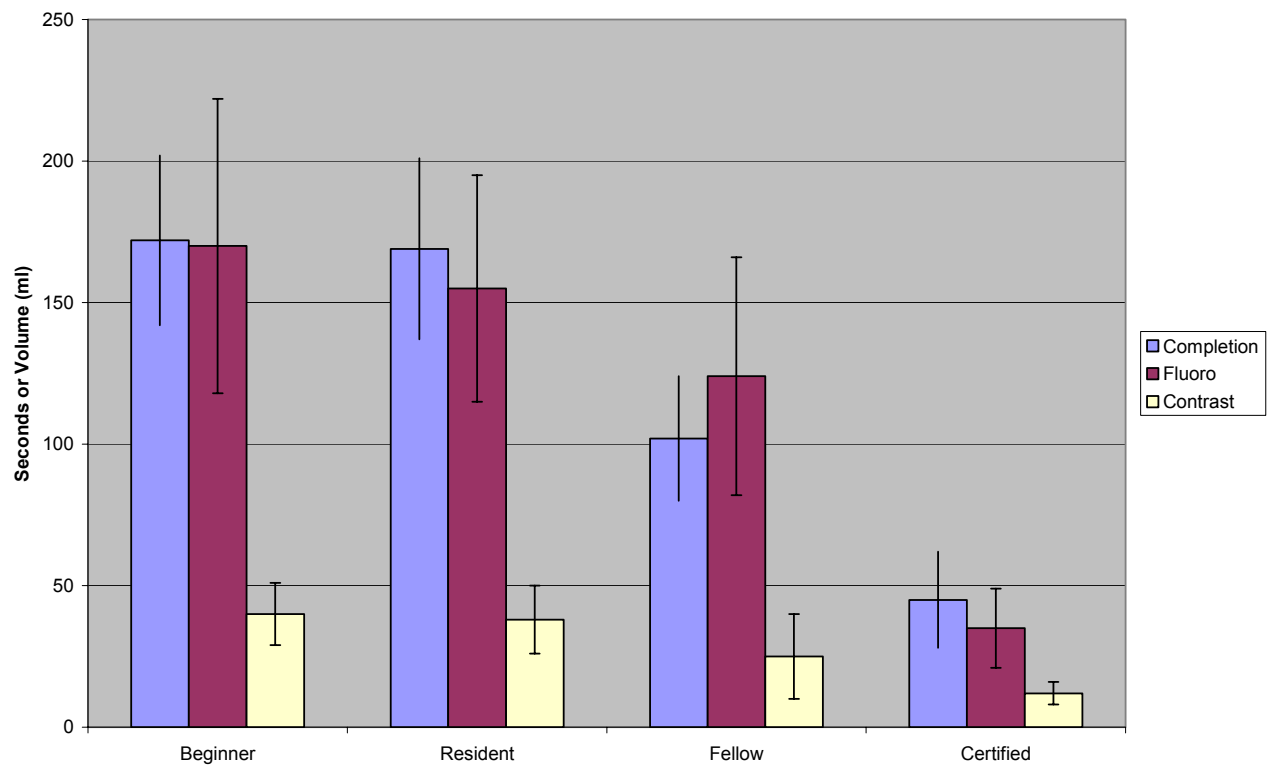
Task 3



Task 4 - Baloons



Task 5



Conclusions

The use of a virtual reality medical simulator for the percutaneous nephrostomy procedure can differentiate the level of competence among different clinicians. Integration of the PercMentor into a urological training program may improve the competence and provide for a measurement tool to assess the capabilities of graduates of the program.

Additional evaluation of this system is needed and the broader surgical assessment and credentialing community would benefit from the review and integration of this methodology into their training curricula.

References

1. Lee CL, Anderson JK, Monga M. Residency training in percutaneous renal access: Does it affect urological practice? *J Urol*. 2004 Feb;171(2 Pt 1):592-5.
2. Knudsen BE, Matsumoto ED, Chew BH, Johnson B, Margulis V, Cadeddu JA, Pearle MS, Pautler SE, Denstedt JD. Randomized, controlled, prospective study validating the acquisition of percutaneous renal collecting system access skills using a computer based hybrid virtual reality surgical simulator. *J Urol*. 2006 Nov;176(5):2173-8.

Appendices

Table 1 PCN Task 1: Identify Anatomy with Fluoroscopy

	# Participants	Kidney (sec)	Spleen (sec)
Beginner	12	82 ± 40	103 ± 55
Resident	12	48 ± 22	55 ± 25
Fellow	12	40 ± 20	31 ± 22
Certified	12	28 ± 15	21 ± 8

Table 2 PCN Task 2: Identify Anatomy with Ultrasound

	# Participants	Kidney (sec)	Spleen (sec)
Beginner	12	105 ± 42	123 ± 45
Resident	12	52 ± 21	59 ± 22
Fellow	12	42 ± 21	34 ± 18
Certified	12	32 ± 18	25 ± 12

Table 3 PCN Task 3: Calices Traversal Completion

	# Participants	Upper (sec)	Middle (sec)	Lower (sec)	Total (sec)
Beginner	12	135 ± 38	95 ± 25	150 ± 90	375 ± 100
Resident	12	70 ± 30	75 ± 28	101 ± 35	245 ± 59
Fellow	12	58 ± 21	49 ± 12	51 ± 19	160 ± 26
Certified	12	45 ± 17	25 ± 10	50 ± 22	123 ± 28

Table 4 PCN Task 4: Balloons Popped

	# Participants	# Balloons Popped	Flouro Time (sec)
Beginner	12	5 ± 1	280 ± 20
Resident	12	6 ± 1	255 ± 58
Fellow	12	7 ± 1	251 ± 55
Certified	12	7 ± 0	190 ± 30

Table 5 PCN Task 5: Free Training

	# Participants	Completion (sec)	Fluoro (sec)	Contrast Vol (ml)
Beginner	12	172 ± 30	170 ± 52	40 ± 11
Resident	12	169 ± 32	155 ± 40	38 ± 12
Fellow	12	102 ± 22	124 ± 42	25 ± 15
Certified	12	45 ± 17	35 ± 14	12 ± 4