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# A Proficiency Based Stepwise Endovascular Curricular Training (PROSPECT) Program Enhances Operative Performance in Real Life: A Randomised Controlled Trial☆

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**WHAT THIS PAPER ADDS**

Fifty-eight endovascular procedures, performed by 32 surgical trainees, were included in a randomised controlled trial comparing three groups of trainees: the first group received e-learning and simulation training (PROSPECT), the second group only had access to e-learning, while the controls did not receive supplementary training. The trainees who completed PROSPECT were shown to have superior technical endovascular performance in real situations, with significantly fewer supervisor takeovers. Modern vascular curricula should include proficiency based training in a safe environment besides traditional clinical education to provide high quality vascular care.

**Objectives:** Healthcare evolution requires optimisation of surgical training to provide safe patient care. Operating room performance after completion of proficiency based training in vascular surgery has not been investigated.
**Design:** A randomised controlled trial evaluated the impact of a Proficiency based Stepwise Endovascular Curricular Training program (PROSPECT) on the acquisition of endovascular skills and the transferability of these skills to real life interventions.
**Materials:** All subjects performed two endovascular interventions treating patients with symptomatic iliac and/or superficial femoral artery stenosis under supervision. Primary outcomes were technical performances (Global Rating Scale [GRS]; Examiner Checklist), operative metrics, and patient outcomes, adjusted for case difficulty and trainee experience. Secondary outcomes included knowledge and technical performance after 6 weeks and 3 months.
**Methods:** Thirty-two general surgical trainees were randomised into three groups. Besides traditional training, the first group ($n = 11$) received e-learning and simulation training (PROSPECT), the second group ($n = 10$) only had access to e-learning, while controls ($n = 11$) did not receive supplementary training.
**Results:** Twenty-nine trainees (3 dropouts) performed 58 procedures. Trainees who completed PROSPECT showed superior technical performance (GRS 39.36 $\pm$ 2.05; Checklist 63.51 $\pm$ 3.18) in real life with significantly fewer supervisor takeovers compared with trainees receiving e-learning alone (GRS 28.42 $\pm$ 2.15; $p = .001$; Checklist 53.63 $\pm$ 3.34; $p = .027$) or traditional education (GRS 23.09 $\pm$ 2.18; $p = .001$; Checklist 38.72 $\pm$ 3.38; $p = .001$). Supervisors felt more confident in allowing PROSPECT trained physicians to perform basic ($p = .006$) and complex ($p = .003$) procedures. No differences were detected in procedural parameters (such as fluoroscopy time, DAP, procedure time, etc.) or complications. Proficiency levels were maintained up to 3 months.
**Conclusions:** A structured, stepwise, proficiency based endovascular curriculum including e-learning and simulation based training should be integrated early into training programs to enhance trainee performance.

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**Keywords:** Proficiency, Vascular training curriculum, Transferability, Endovascular skills, Simulation

## INTRODUCTION

Surgical education is challenged worldwide by the progressive healthcare demands to treat patients safely and to better prepare trainees prior to entering the operating room.[1–3] Over the past decade competency based surgical training and curricula standardisation have gained increasing interest, supported by growing evidence of clinical effectiveness.[3,4] Simulation based training has been shown to reduce operating time, decrease peri-operative errors, and enhance team

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performance leading to superior patient outcomes, for example in central line placement,[5,6] obstetric emergencies,[7,8] ophthalmological surgery,[9] laparoscopic surgery,[10,11] and crisis resource management.[12–16] Simulation based education can improve patient care and outcomes if part of a proficiency based curriculum,[17–19] allowing trainees to practice frequently until they master cognitive and technical skills.[20,21] Based on this evidence, the Fundamentals of Laparoscopic Surgery (FLS) and Fundamentals of Endoscopic Surgery (FES) have become mandatory to obtain the American Board of Surgery certification.[22,23]

Basic endovascular skills acquired during a proficiency based simulation training session in superficial femoral artery angioplasty have translated into improved operating performance.[24] To be of uniform and consistent value there is a need to implement this training method into a structured curriculum with evidence based learning goals,[25] such as the Proficiency based Stepwise Endovascular Curricular Training (PROSPECT) program that was recently developed.[26] This structured, stepwise, proficiency based validated endovascular program was designed to train cognitive, technical, and human factor skills during endovascular treatment of iliac and superficial femoral artery stenosis. It consists of online available e-learning modules and hands-on simulation modules on a VR simulator (Fig. 1).

The objective of this randomised controlled trial (RCT) was to evaluate the transferability of knowledge and technical skills acquired by this PROSPECT program to the operating room (OR), and to compare the OR performance of these PROSPECT trainees with those trainees who only had access to e-learning, or no additional training besides the conventional training. Evaluations were made of whether the proficiency based curriculum results in durable cognitive and technical skills, as measured by a multiple choice questionnaire and simulation exercise, up to 3 months after the real life procedures.

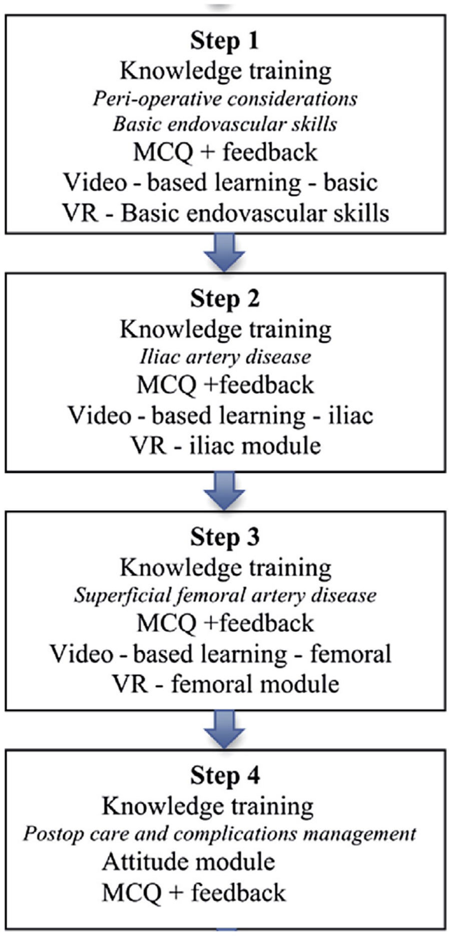


**Figure 1.** Steps of the PROSPECT program.

## MATERIALS AND METHODS

### *Study design*

A single-blinded RCT was conducted at an academic centre and nine general hospitals from October 2014 to February 2016 (Fig. 2).

The study followed a parallel group design with general surgery residents who were randomised to standard education combined with a simulation based proficiency based endovascular curriculum, to standard education combined with multimedia based training modules, or to standard education alone. Standard education refers to conventional training based on intra-operative learning and self study. The trial was registered at clinical trials.gov (NCT01965860).

### *Participants and randomisation*

All surgical trainees at Ghent University, irrespective of their postgraduate level (1–6), were invited to participate in this study. Thirty-two trainees agreed to participate (82% participation rate) and were randomised into three groups using the closed envelope technique: two intervention groups (PROSPECT group $N = 11$; e-learning group $N = 10$) and one control group ($N = 11$). Randomisation was stratified by postgraduate level. Assessors were blinded to the trainees' randomisation status.

Two endovascular interventions per participant were included in this RCT. Patients were eligible if they suffered from symptomatic (Rutherford classification 2–5) arterial disease of the lower limbs (stenosis TASC type A or B of iliac and/or femoral arteries). More complex TASC lesions were excluded as this program teaches basic endovascular skills and the VR simulator does not provide high quality TASC type C or D cases. Eligible patients were asked to participate by the supervising consultant and an informed consent form was signed by both the patients and the surgical trainees. The appropriate institutional review boards approved the study protocol.

### *Initial assessment*

After signing informed consent, cognitive and technical skill levels of each surgical trainee were evaluated to determine baseline experience in all groups. All participants completed a demographics and experience questionnaire, a multiple choice test (MCQ) to evaluate cognitive endovascular

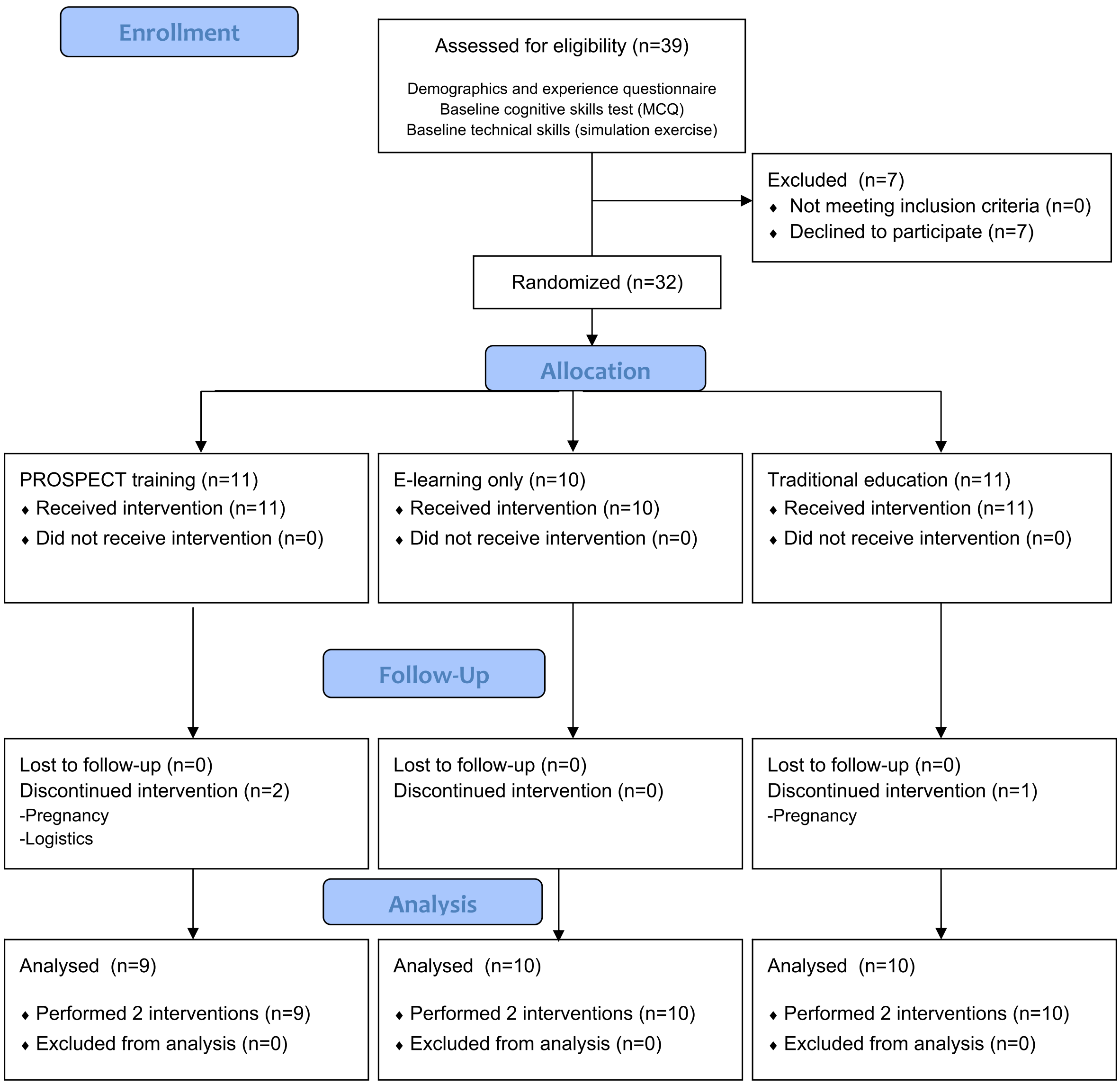

**Figure 2.** CONSORT diagram.

skills[26] and a simulation exercise treating bilateral iliac artery disease on the ANGIO Mentor Express System (Simbionix USA Corp., Cleveland, OH, USA) to assess technical skills. Each trainee was familiarised with the virtual reality (VR) simulator according to a standardised protocol prior to technical skills assessment.

### *Interventions*

Trainees randomised into the PROSPECT group completed a structured, stepwise proficiency based endovascular curriculum consisting of cognitive, technical, and non-technical skills training to explain the flow of the intervention and how to plan and execute an endovascular procedure.[26] This program consists of four modules, starting with basic endovascular skills principles. The second and third modules focus on iliac artery and superficial femoral artery disease treatment, and the fourth module explains post-operative complication management and attitude. These modules allow the trainee to learn endovascular procedures at their own pace in a structured stepwise fashion, away from clinical activities. Each module consists of an online e-learning part to obtain cognitive and non-technical skills and supervised hands-on simulation sessions to learn and practice technical endovascular skills.

Knowledge was tested after each module using a MCQ and technical performance was assessed during every simulation exercise using validated simulator metrics, a Global Rating Scale (GRS), and an Examiner Checklist.[26] Structured feedback was provided after each simulated procedure using the GRS and Examiner Checklist. Each trainee had to achieve cognitive (once) and technical proficiency (two separate occasions) at each level before proceeding to the next module. These benchmarks are based on the median score of experts in the field. A detailed description of the design and construct validity of this program has been published previously.[26]

Trainees in the e-learning group only received e-learning without access to hands-on simulation based training.

Subjects had to complete the MCQ test after each module. If benchmark levels were achieved, the subject could move on to the next e-learning module.

Trainees randomised into the control group received no additional training, but did receive weekly vascular papers to stimulate engagement in this RCT.

### Conventional training

All groups continued conventional clinical training. Participants were asked to keep a logbook of their endovascular experiences, self study, workshops, and conferences during the study. Individual self study was allowed. All groups had the opportunity to ask questions.

### Assessment

Within 6 weeks of completing the training program, every surgical trainee performed two endovascular procedures in the OR, being aware of the final assessment parameters of the study. As arterial puncture was not addressed in the curriculum, the sheath was inserted by the supervising vascular surgeon. After sheath placement, the trainee was in charge and performed the endovascular procedure with the supervising consultant scrubbed in. The consultant was blinded to the trainee's randomisation status. To ensure patient safety, final decisions about the endovascular approach and various tools used were proposed by the trainee but only executed if approved by the consultant. The supervising surgeons received standardised instructions to take over the procedure if patient safety was endangered, for example wrong selection or inappropriate use of endovascular tools, overlooking steps of the procedure, rough handling, etc.

All cases were videotaped. A single investigator, non-blinded to the randomisation status (HM) observed the entire procedure to oversee the video recordings and register operative metrics and number of consultant takeovers.

Technical performance was assessed by the blinded supervising consultant immediately post-intervention using the Examiner Checklist for diagnostic angiography, angioplasty and stenting (procedure specific rating scale) and the Global Rating Scale of endovascular performance (OSATS derived).[27] The supervising consultant was asked if he/she would allow the trainee to perform a simple or complex endovascular procedure. Additionally, one independent blinded vascular surgeon also scored the endovascular performance post-hoc by watching the videos of the fluoroscopy screen and hand movements to allow objective external rating. The inter-rater reliability of both technical skills' assessments was determined.

Surrogate measures of performance were operative metrics: total procedure time (between insertion and removal of the introducer sheath), fluoroscopy time, amount of contrast used, radiation dose, number of consultant takeovers, and peri-operative and post-operative complications. Intra-operative complications were recorded in the OR by the observer and supervising consultant. Post-operative complications were recorded at 30 days. The medical record of each patient was reviewed to gain information about age, sex, number and type of lesions, medical history, and drug use.

Additionally, cognitive as well as technical skills of all trainees were re-assessed after 6 weeks (pre-post-test). Furthermore, trainees randomised into the intervention groups were evaluated 3 months post-training to evaluate skills retention.

### Outcome measures

The primary outcome of this RCT was to measure the difference in technical performance during the real life procedures between the three groups, measured by OSATS derived rating scales.

Secondary outcomes included changes in knowledge (MCQ test) and technical skills (VR simulator) and skills retention after the training program. Additionally, all trainees in the intervention group completed a questionnaire on a Likert scale from 1 to 5 about their experience with the e-learning modules and simulation based training.

### Sample size calculation

Prior to the study a power analysis was performed to calculate the number of participants required in each of the three groups. Previous work comparing OSATS derived scores in endovascular interventions shows a Cohen D of two.[27] Using $\alpha$ of .05, a power of .80, and an expected dropout rate of 10%, the minimum number of surgical trainees required per group was seven.

### Statistical analysis

Statistical analysis was performed using SPSS 22.0 (SPSS Inc, Chicago, IL, USA). Descriptive statistics were calculated and expressed as the mean $\pm$ standard deviation. Parametric tests were used as variables were normally distributed as determined by the Shapiro Wilk test. To compare differences among the three groups, the ANOVA test with Tukey post hoc (continuous variables) and the Fisher's exact test (categorical variables) were used. A mixed linear regression with patient as random factor was performed to compare performances among the three groups taking into account both interventions. The supervising consultant scored the case complexity on a Likert scale (1—5). The analysis was adjusted for case difficulty and conventional clinical experiences of the trainees before and during the study period. Intra-class correlation coefficient (ICC) was calculated to evaluate inter-rater reliability between live assessment and post-hoc video based assessments. Difference on the pre-post-test was assessed by MCQ and a VR simulation exercise using the paired $t$ test. Level of significance was defined as $p$ value $< .05$.

## RESULTS

### Participant demographics and endovascular experience

Fifty-eight endovascular interventions on 56 patients were included in the study. Twenty-nine of the 32 surgical trainees completed the training program, resulting in a dropout rate of 9%. Two trainees withdrew because of pregnancy and one because of logistic problems in completing training while working in a district hospital (Fig. 1). Endovascular experience prior to the study among the participants was limited (Table 1).

### *Initial assessment*

The baseline MCQ test evaluating endovascular knowledge was similar at inclusion in the three groups (PROSPECT (mean 14.09 ± 3.11); e-learning (mean 14.90 ± 1.10); control (mean 14.36 ± 2.66); $p = .75$). Likewise, no significant differences among groups were noted in technical performance on the endovascular simulator (Table 2).

### *PROSPECT training*

Ten of 11 trainees in the PROSPECT group achieved the proficiency levels for cognitive and technical skills in each module of the stepwise endovascular training program (Fig. 1). It took the trainees a mean of 8.44 months (±2.46) to complete the PROSPECT program during their clinical training. Overall, the simulation and e-learning groups needed 8.52 (±2.93) hours to study the e-learning modules. Additionally, trainees required 4.76 (±2.79) hours of practice to achieve competency. This corresponds to a mean of 13 (±4.10) simulation sessions. Pre-post-test evaluation showed significant increase in knowledge and technical skills in both intervention groups for most parameters (Table 3).

### *Operative performance*

The quality of performance of trainees in real life in the PROSPECT group was scored significantly higher (GRS 39.36 ± 2.05; Checklist 63.51 ± 3.18) compared with surgical trainees receiving only e-learning (GRS 28.42 ± 2.15; $p = .001$; Checklist 53.63 ± 3.34; $p = .027$) or traditional education (GRS 23.09 ± 2.18; $p = .001$; Checklist 38.72 ± 3.38; $p = .001$). Five consultants supervised the cases, but the majority (71%) of the cases was supervised by one consultant. The live ratings were supported by post-hoc video assessment, showing good inter-rater reliability with the live scores (GRS ICC = .74; Examiner Checklist ICC = .78; Case Difficulty ICC = .71).

There were no significant differences between the first and second intervention in any group; however, general improvement in scores was noted: control (Checklist 5.10 ± 13.85; $p = .27$; GRS .2 ± 9.03; $p = .95$), e-learning (Checklist 6.60 ± 17.01; $p = .25$; GRS 5.10 ± 11.19; $p = .18$), PROSPECT (Checklist 4.22 ± 10.49; $p = .26$; GRS .56 ± 6.65; $p = .81$).

The blinded supervising consultant would allow seven PROSPECT trainees to perform a procedure independently, compared with four trainees in e-learning and three trainees in the control group ($p = .004$). Supervisors felt more confident in allowing simulation based trained participants to perform basic ($p = .006$) and more complex ($p = .003$) procedures. During the real life procedures, supervisor takeovers were seldom necessary in the PROSPECT group (.30 ± .50) compared with trainees of the e-learning (3.40 ± .53; $p = .001$) or traditional education groups (4.18 ± .54; $p = .001$).

In both intervention groups, trainees were highly satisfied with the e-learning modules (mean 4.59 ± .51). These have been rated as interactive and pleasant (mean 4.12 ± .70) with attractively presented content (mean 4.18 ± .64), resulting in more confidence to participate in endovascular procedures (mean 4.18 ± .95).

Similarly, simulation based training was regarded as a useful adjunct to clinical training (mean 4.63 ± .52) by increasing understanding (mean 4.63 ± .52) and confidence (mean 4.50 ± .54) during endovascular procedures. These trainees strongly agreed that simulation based training programs should be completed by every surgical trainee prior to treating real patients (mean 4.75 ± .46).

### *Patient outcomes*

No significant differences were observed in patient outcomes among the three groups (Table 4). Within 24 h of

**Table 1.** Demographics and experience of study participants.

| | PROSPECT intervention | e-learning intervention | Conventional control | Overall | *p* value |
|---|---|---|---|---|---|
| Postgraduate year | | | | | .68 |
| Level 1 | 2 | 3 | 4 | 9 | |
| Level 2 | 2 | 3 | 1 | 6 | |
| Level 3 | 4 | 1 | 3 | 8 | |
| Level 4 | 0 | 2 | 1 | 3 | |
| Level 5 | 1 | 1 | 1 | 3 | |
| Level 6 | 2 | 0 | 1 | 3 | |
| Sex | | | | | .75 |
| Male/Female | 6/5 | 4/6 | 6/5 | 16/16 | |
| No. endovascular cases assisted | | | | | .24 |
| 0–5 | 1 | 2 | 2 | 5 | |
| 5–10 | 2 | 1 | 1 | 4 | |
| 10–50 | 6 | 5 | 1 | 12 | |
| 50–100 | 1 | 1 | 5 | 7 | |
| 100–200 | 1 | 0 | 0 | 1 | |
| >200 | 0 | 1 | 2 | 3 | |

**Table 2.** Baseline assessment of technical endovascular skills on the simulator.

| | PROSPECT | e-learning | Control | *p* value |
|---|---|---|---|---|
| Global Rating Scale (max. score 55) | 20.64 (8.23) | 18.10 (5.72) | 18.55 (7.57) | .69 |
| Examiner Checklist (max. score 85) | 44.45 (17.18) | 40.10 (14.16) | 38.27 (13.45) | .62 |
| Total procedure time (min.) | 18.16 (7.92) | 22.79 (7.80) | 23.95 (9.06) | .24 |
| Total fluoroscopy time (min.) | 7.30 (4.50) | 11.08 (6.77) | 9.80 (4.30) | .26 |
| Roadmaps (no.) | 7.45 (2.98) | 9.10 (4.98) | 9.55 (7.97) | .67 |
| Completion of the case (% success rate) | 8 (73%) | 9 (90%) | 9 (82%) | .60 |

Baseline technical skills using previously validated rating scales and simulator metrics (mean, SD).

endovascular treatment, three minor (pseudo-aneurysm $n = 1$; wound infection $n = 1$; temporarily decreased renal function $n = 1$) and three major (unstable angina $n = 1$; amputation $n = 1$; bypass surgery $n = 1$) adverse events occurred.

At 30 days four minor adverse events noted: haematoma ($n = 1$), acute gout episode ($n = 1$), recurrent epistaxis ($n = 1$), and herpes zoster infection at the target leg ($n = 1$). There was only one patient presenting with a de novo lesion in the treated limb within 30 days.

## *Skills retention*

At 3 month follow-up the proficiency scores in the PROSPECT group for both cognitive and technical endovascular skills were maintained (Table 3). Similarly, the participants

**Table 3.** Achievement and maintenance of cognitive and technical endovascular skills (mean, SD).

| | | Knowledge (MCQ) | Global Rating Scale | Examiner checklist | Procedure time | Fluoroscopy time | Number of roadmaps |
|---|---|---|---|---|---|---|---|
| Prospect | Pretest | 14.00<br>3.39 | 19.78<br>7.24 | 43.56<br>15.76 | 20.12<br>6.90 | 8.22<br>4.37 | 8.11<br>2.80 |
| | Post-test 6wk | 18.11<br>1.36 | 49.56<br>3.78 | 83.22<br>1.99 | 15.76<br>5.18 | 8.48<br>3.38 | 8.33<br>3.00 |
| | Post-test 3mo | 18.25<br>1.98 | 51.13<br>3.44 | 82.25<br>1.75 | 13.44<br>2.67 | 6.30<br>2.57 | 6.25<br>1.83 |
| | *p* value pre-post | **.003** | **.001** | **.001** | .089 | .890 | .873 |
| | *p* value 6wk–3mo | .785 | .328 | .174 | **.045** | .072 | .170 |
| e-learning | Pretest | 14.88<br>1.13 | 16.25<br>4.10 | 35.63<br>11.38 | 24.76<br>6.88 | 11.97<br>7.09 | 10.13<br>5.06 |
| | Post-test 6wk | 17.88<br>.99 | 32.75<br>13.51 | 59.25<br>16.73 | 23.58<br>11.47 | 11.88<br>8.83 | 8.25<br>3.73 |
| | Post-test 3mo | 17.71<br>.75 | 24.14<br>6.65 | 51.71<br>16.31 | 16.30<br>3.60 | 8.72<br>7.21 | 6.43<br>7.19 |
| | *p* value pre-post | **.001** | **.008** | **.001** | .731 | .978 | **.008** |
| | *p* value 6wk–3mo | .838 | .076 | .086 | .128 | .424 | .486 |
| Control | Pretest | 14.00<br>2.49 | 18.00<br>7.75 | 37.60<br>13.98 | 24.72<br>9.17 | 10.12<br>4.39 | 10.10<br>8.17 |
| | Post-test 6wk | 15.20<br>2.70 | 21.20<br>7.48 | 42.80<br>15.39 | 23.95<br>7.19 | 11.65<br>4.10 | 9.90<br>3.18 |
| | Post-test 3mo | NA | NA | NA | NA | NA | NA |
| | *p* value pre-post | .288 | .164 | .190 | .720 | .344 | .932 |
| | *p* value 6wk–3mo | NA | NA | NA | NA | NA | NA |

Scores achieved during pre-post-test assessments 6 weeks and 3 months after completing the training program. Differences were assessed using the paired *t* test. Statistically significant values are in bold.
mo = months; wk = weeks.

**Table 4.** Assessment of operating room performances (mean, SD).

| | PROSPECT | e-learning | Control | *p* value General | PROSPECT vs. e-learning | e-learning vs. control | PROSPECT vs. control |
|---|---|---|---|---|---|---|---|
| Global Rating Scale | **39.36**<br>2.05 | **28.42**<br>2.15 | **23.09**<br>2.18 | **.001** | **.001** | .054 | **.001** |
| Examiner Checklist | **63.51**<br>3.18 | **53.63**<br>3.34 | **38.72**<br>3.38 | **.001** | **.027** | **.001** | **.001** |
| Supervisor takeovers | **.30**<br>.50 | **3.40**<br>.53 | **4.18**<br>.54 | **.001** | **.001** | .241 | **.001** |
| Procedure time (min) | 51.25<br>7.09 | 53.18<br>7.49 | 42.60<br>7.47 | .525 | .845 | .267 | .448 |
| Fluoroscopy time (min) | 11.97<br>1.43 | 14.35<br>1.51 | 11.38<br>1.52 | .238 | .240 | .131 | .798 |
| DAP | 44,071<br>3.80 | 61,306<br>.03 | 61,771<br>.37 | .609 | .347 | .979 | .408 |
| Number of angiograms | 9.04<br>3.27 | 15.01<br>3.43 | 10.86<br>3.46 | .362 | .197 | .345 | .730 |
| Contrast used (mL) | 65.14<br>9.16 | 78.77<br>9.61 | 71.37<br>9.73 | .205 | .077 | .543 | .302 |
| Peri-operative complications | 2/58<br>3.45% | 4/58<br>6.70% | 2/58<br>3.45% | .743 | .924 | .489 | .512 |
| In hospital minor AE | 2/58<br>3.45% | 1/58<br>1.72% | 0/58<br>0% | .769 | .975 | .483 | .593 |
| In hospital major AE | 1/58<br>1.72% | 1/58<br>1.72% | 1/58<br>1.72% | .941 | .790 | .893 | .735 |
| 30 days minor AE | 0/58<br>0% | 1/58<br>1.72% | 3/58<br>3.45% | .299 | .567 | .222 | .147 |
| 30 days major AE | 0/58<br>0% | 0/58<br>0% | 1/58<br>1.72% | .490 | .876 | .241 | .436 |

Performance assessments of the live cases by technical skill rating scales (LIVE), procedural parameters, and complication rates. A mixed linear regression was performed to take into account both interventions. Statistically significant values are in bold. AE = adverse event.

in the e-learning group retained the acquired knowledge skills 3 months post-training.

## DISCUSSION

This study has evaluated operative performances of surgical trainees in the hybrid angiosuite after completion of a stepwise proficiency based endovascular training program including simulation (PROSPECT). Trainees who completed PROSPECT demonstrated superior technical skills during real life endovascular treatments with fewer consultant takeovers, compared with the groups that received solely multimedia based learning or no additional training complementary to clinical education. These results demonstrate the transferability of simulator acquired endovascular skills to real life. E-learning without simulation sessions also significantly improved cognitive skills but technical proficiency levels were not achieved on the simulator or in real life. Therefore, it seems that e-learning cannot replace hands-on training but should be used as an adjunct to study cognitive skills prior to technical skills training. A general non-significant improvement in scores was noted between the first and second real life interventions in all groups, probably because of familiarisation with the hybrid angiosuite and flow of the intervention.

Despite enhanced endovascular performances in the PROSPECT group, operative metrics and patient outcomes were similar across the three groups (Table 4), which is in contrast to previous studies showing a decrease in operating time after simulation based training.[11,28] This may be explained by the takeovers of the supervising consultant, especially in the control group, to ensure patient safety,[29] which may have masked differences in operative metrics and complications if supervision had not been in place. Therefore, performance based assessment in the clinical environment evaluating transfer of acquired competencies into job behaviours (Kirkpatrick level 3 evidence) has been proven, but changes in patient outcomes (Kirkpatrick level 4) could not be determined.[30]

As the PROSPECT program offers basic endovascular skills training and improves trainees' performance, it should be integrated preferentially into the early phase of the learning process[31] and should become a prerequisite prior to treating real patients.[32,33] According to the Dreyfus model of skills acquisition, there are five phases in the learning process: novice, advanced beginner, competent, proficient, and expert.[34] The curriculum can train novices until proficiency levels are achieved (level 4 of the Dreyfus model), yet further real life endovascular experience in the angiosuite is crucial for trainees to master, improve, and obtain expert skills.

In this study, the acquired cognitive and technical endovascular proficiency levels by PROSPECT were retained 3 months after completing the program. Further skills retention will depend on clinical practice opportunities; however, refresher courses may be needed to retain proficiency.[35]

Although the results of this study demonstrate superior endovascular skills acquisition and skills transfer to the hybrid angiosuite by PROSPECT training, the main challenge is the implementation in surgical education.[36] In simulation based endovascular training tutors are still needed to provide structured feedback, which might pose a problem given the already limited staffing in surgical departments. Furthermore, these supervisors should be trained in providing constructive feedback and analysis to enrich the learning experience of surgical trainees.

Another barrier may be the limited time of trainees who have to learn various surgical skills in less time[37]; however, this study has shown that it is feasible to integrate PROSPECT into busy clinical training programs. If necessary, these training sessions can be organised during off-clinical time and after a night shift.[38,39] Moreover, as the curriculum improves OR performance and probably shortens the learning curve, fewer real life interventions may be needed to achieve endovascular proficiency.

Finally, integration of PROSPECT in surgical curricula will require funding for logistics and tutor availability.[40,41] Costs of logistics and faculty time supervising simulation sessions show a yearly cost in the range of 30,000€. The program can easily be initiated in other centres by setting up the simulator and providing the e-learning modules online; however, the main issue remains provision of an appropriate tutor during the simulation sessions at each centre. Additionally, a cost effectiveness analysis should be carried out to balance the educational costs and healthcare system benefits of this training curriculum.

### *Limitations*

The results of this trial may not be applicable to other countries. The PROSPECT program will be implemented in the training curricula at two other centres, one of which is in another country, to further evaluate the use and applicability of the program.

Trainees were explicitly told not to disclose the randomisation group to the supervising consultant but this may have occurred unintentionally and have influenced the scores of the supervising consultant. Also, cases within each of the three study groups were not evenly distributed among the supervising consultants, therefore, an independent blinded consultant vascular surgeon carried out post-hoc video ratings, showing strong agreement with the life ratings. There is a possibility of skills decay during the program as simulation practice was spread over a period of 8 months; however, this is of lesser importance because of the proficiency based design of the program.

In this study there was a dropout rate of 9%, which is within the expected range and is acceptable according to sample size calculations. Long-term skills retention was not assessed beyond 3 months post-training, which would provide more specific valuable information about need and timing of refresher courses.

As the procedures were closely supervised, operative metrics cannot be used to assess the operative performance of trainees in this study. The consultant took over and continued the intervention if the trainee was not able to do this safely, resulting in shorter procedure time and less use of contrast compared with a procedure entirely completed by a poorly performing trainee.

As the training program is not time based but proficiency based, there was a time difference between the trial groups. Trainees in the PROSPECT group had to obtain proficiency levels twice for each module and it was challenging to organise these simulation sessions within the schedules of both the trainee and supervisor. However, all endovascular cases performed and assisted throughout the program and during the follow-up period were registered by the trainee and the statistical analysis has taken this clinical experience into account.

This RCT suggests that simulation based training using a PROficiency based StePwise Endovascular Curricular Training is superior to traditional training or solely multimedia based training resulting in higher quality real life endovascular performances. These data should stimulate educational leaders to incorporate PROSPECT in postgraduate curricula to allow surgical trainees to learn and acquire basic endovascular skills in a risk free environment until proficiency, prior to performing real life procedures.[42]

## CONFLICT OF INTEREST

Isabelle Van Herzeele is consultant for Medtronic Academia (Tolochenaz, Swiss) and Silk Road Medical (Sunnyvale, CA); receives research grants of Medtronic Academia, (Tolochenaz, Swiss), Simbionix (Cleveland, Ohio, USA) and W.L. Gore & Associates (Flagstaff, USA). Rajesh Aggarwal is consultant for Applied Medical (Santa Margarita, CA). Frank Vermassen is consultant for Medtronic Academia (Tolochenaz, Swiss), W.L. Gore & Associates (Flagstaff, USA), Abbott Vascular (Illinois, CA) and Cordis Corporation (Fremont, CA). These relationships played no role in the design and conduct of the study, nor in the collection, management, analysis, and interpretation of data nor in the preparation of the manuscript. For the remaining authors, no conflicts of interest or financial ties are declared.

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COUP D'OEIL

# A Fishy Subclavian Artery Pseudoaneurysm

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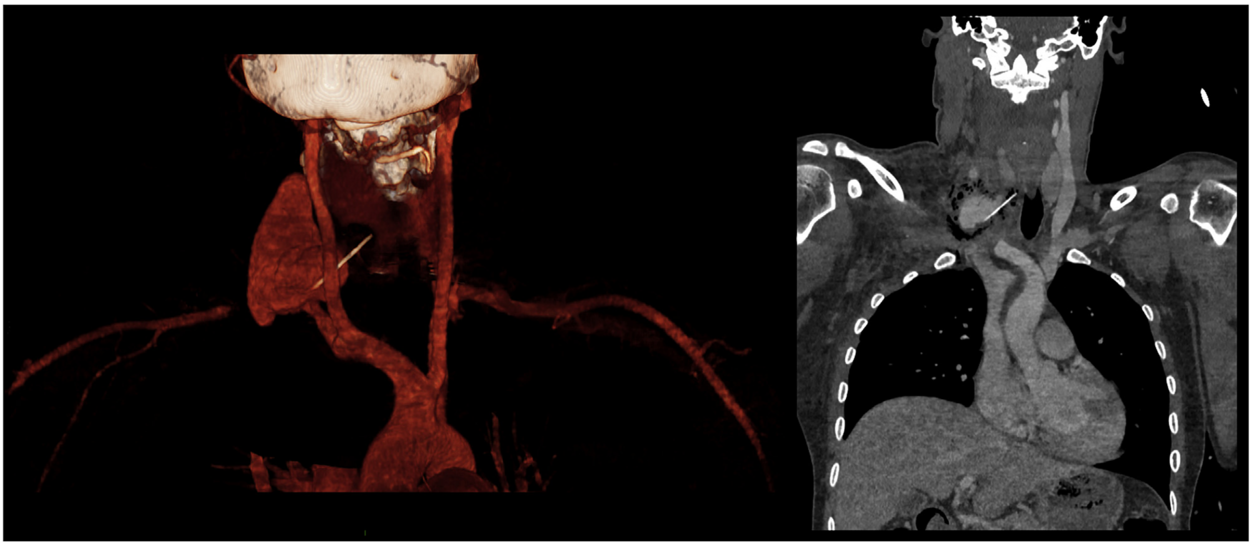

A 46 year old male was admitted with haematemesis and upper chest pain after eating fish. Computed tomography angiography (3D reconstruction on the left, coronal view on the right) showed cervical surgical emphysema and a right subclavian artery (RSA) pseudoaneurysm associated with a linear foreign body, explained by oesophageal perforation and continued migration of the sharp fish bone resulting in RSA injury and pseudoaneurysm. Surgical RSA repair and oesophagectomy were performed in an infected field, complicated by pseudoaneurysm recurrence and cervical abscess. Arterial ligature was ultimately necessary. Alas, no immediate revascularisation option was available for this right handed patient, resulting in incapacitating sequelae.

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