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Residents and patients benefit from surgical simulation on a live porcine model, could we consider it as ethical?

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Abbreviations

AFUF: Association of Urologists-in-Training

EWTD: European Working Time Directive

IQR: InterQuartile Range

MIS: Minimally Invasive Surgery

OR: Operating Room

Introduction

In the modern era of surgical training, exposure of surgeons to patients in the operating room (OR) is limited. Surgical training on live animals is an important method of developing technical skills. Surgical training has been effective in advancing both technical and non-technical skills and emerged as a valuable adjunct to the traditional OR experience that many training systems have historically relied upon. The adoption of surgical simulation training in surgery has been greatly influenced by the field of aviation [1, 2], which relies heavily on intensive training in simulation before real world exposure and attributes the impressive safety record of the industry, at least in part, to this approach to training. Urology and general surgical education have changed considerably over the last ten years with the development of laparoscopic techniques. It incorporates greater amounts of simulation in their *curricula* to combat the structural changes that have resulted in limited patient exposure during surgical training [3-6].

Simulation has been particularly important in surgery because developing technical skills in the OR can be extremely challenging, especially using traditional (volume based) methods of surgical learning that are becoming less and less feasible in modern surgical settings [7]. This is due to a combination of legally enforced working time restrictions for trainees, pressure from hospitals for better operating room efficiency [8]. Furthermore, surgical training methods based solely in the OR also expose patients to potential damages, which can have lasting negative impacts for both the patients and training residents acquire specific technical skills prior to performing these skills in the operating on patients [9].

Although there is broad agreement on the importance of simulation, the models and simulators vary significantly, as do attitudes to the relative effectiveness of these different simulation models. In the case of, for example, the acquisition of laparoscopic technical skills, several studies have demonstrated the effectiveness of using live animal models, cadavers, as well as virtual reality or augmented reality simulators [10, 11]. But the cost, infrastructure, experience of faculty and fidelity are all factors that impact the adoption of these different approaches.

The live porcine model for surgery is well recognized for offering a high-fidelity model with major similarities to conventional human surgery and could be an extremely valuable model for surgical training [12]. However, surgical training on a live porcine model requires an infrastructure with the capacity to perform animal surgical procedures and raises ethical issues about the appropriateness of using animals for these purposes. Furthermore, animal models are costly and require the implementation of safeguards and procedures to ensure the 3Rs (reduction, replacement and refinement) which underpin animal work are respected.

The objective of this study was to assess the attitudes and feeling of French Urologists-in-training towards the technical skills development with the use of live animal models for surgical training.

Materials and methods

Surgical training sessions on live porcine models were designed, organized and delivered by French university centers and by the French Association of Urologists-in-Training (AFUF), focusing on both laparoscopic surgery and open laparotomy. These sessions are carried out 4 to 10 times a year, in a laboratory with the capacity and authorization to carry out surgical training sessions on a live porcine model. 6 to 8 urologists-in-training participated in the sessions, requiring 3 to 4 animals. All procedures were performed on animals under general anesthesia with appropriate analgesia in accordance with the best practices and the recommendations of the French laws on animal experimentation and ARRIVE guidelines.

1. Conduct of surgical training sessions on a live porcine model

Each surgical training session started with a 30-minute description of the surgical procedures to be performed. This theoretical first part was performed by faculty instructors, it allowed to define the objectives and the course of the session, and to explain the different surgical times. The urologists-in-training were divided into 4 teams by the training surgeon in order to associate urologists-in-training with similar levels of experience. The surgical procedures were performed under the supervision of an experimented surgeons. At the end of the training, emergency situations (vascular wounds, splenic wounds...) were created by the instructors and the urologists-in-training had to adapt to the types of emergency situations (conversion or not, approach in case of conversion, etc.). At the end of the surgical training session, a debriefing was carried out by the instructor in order to evaluate the difficulties encountered during the session, Figure 1 and 2.

2. Evaluation of the surgical training on a live porcine model

A computerized questionnaire GoogleForm © (Figure 3) was sent to all members (n=495) of the French Association of Urologists-in-Training (AFUF) (fellows and residents). The questionnaire was content validated by a panel of expert consisting of veterinary surgery, urology, general surgery and surgical education specialists. The questionnaire contained 15 key questions. This anonymous questionnaire allowed to obtain information about the population having participated in the surgical training sessions, the surgical procedures performed, the advantages of a live porcine model as well as its ethical limits.

Results

1. Studied population

A total of 198 questionnaires met the inclusion criteria. 36.4% (72/198) of the participants were fellows, 18.7% (37/198) 5-th year residents, 13.6% (27/198) 4-th year residents, 12.1% (24/198) 3-rd year residents, 14.1% (28/198) 2-nd year residents and 5.1% (10/198) 1-st year residents. The median (IQR) number of sessions conducted was 3 (2-5).

2. Surgical procedures performed and advantages of a live porcine model

Laparoscopic nephrectomy was the most frequently performed surgical procedure (79.3%) (157/198), then laparoscopic cystectomy (8.1%) (16/198), laparoscopic partial nephrectomy (6.6%) (13/198) and finally laparoscopic pyeloplasty (6.1%) (12/198), (Figure 4).

The main advantages of surgical training on a live porcine model were to be able to train for emergency situations (e.g. vena cava wound) (72.7%) (144/198), the similarity with conventional human surgery (65.7%) (130/198) and to be able to perform several surgical procedures on the same model (65.2%) (129/198). For the fellows (36.4%; 72/198 of the participants) and the residents (63.6%; 126/198 of the participants), the main advantages of surgical training on a live porcine model were to be able to train for emergency situations and (Fellows: 51/72, 70.9% and Residents: 93/126, 73.8%) and the similarity with conventional human surgery (Fellows: 38/72, 52.8% and Residents: 92/126, 73.0%), (Figure 5).

Thus, surgical training on a live porcine model was indispensable for 33.3% (66/198) of responders (Fellows: 18/72, 25.0% and Residents: 48/126, 38.1%), very useful for 56.6% (112/198) (Fellows: 39/72, 54.2% and Residents: 73/126, 57.9%) , little used for 9.1% (18/198) (Fellows: 13/72, 18.1% and Residents: 5/126, 4.0%) and useless for 1.0% (2/198) of responders (Fellows: 2/72, 2.8% and Residents: 0/126, 0%), (Figure 6).

For 79.8% (158/198) (Fellows: 52/72, 72.2% and Resident: 106/126, 84.1%) of the participants, surgical training on a live porcine model should be mandatory in the training of urologists-in-training.

3. Conduct of the surgical training sessions

Beginning the surgical training session with a first theoretical part and defining objectives for each session was useful for 89.9% (178/198) of the participants (Fellows: 66/72, 91.7% and Residents: 112/126, 88.9%). A debriefing at the end of the session on the difficulties encountered with the training surgeon was useful for 94.4% (187/198) of the participants (Fellows: 65/72, 90.3% and Residents: 122/126, 96.8%).

4. Types of advantages of a live porcine model and comparison with computer simulation models

According to the participants, the advantages of surgical training on a live porcine model were: technical progress in 87.4% (173/198) of the cases (Fellows: 54/72, 75.0% and Residents: 119/126, 94.4%), improved anticipation of the progress of a surgical procedure in 72.7% (144/198) of the cases (Fellows: 42/72, 58.3% and Residents: 102/126, 81.0%) and improved management of the surgical team (operating assistant and operating room nurse) in 51.5% (102/198) of the cases (Fellows: 31/72, 43.1% and Residents: 71/126, 56.3%), (Figure 7).

For 93.9% (186/198) of the respondents (Fellows: 67/72, 93.1% and Residents: 119/126, 94.4%), surgical training on a live porcine model was superior to computer simulation models in terms of similarity to conventional human surgery.

5. Ethical aspects of surgical simulation on a live porcine model

For 86.9% (172/198) of the participants (Fellows: 61/72, 84.7% and Residents: 111/126, 88.1%), it was ethical to perform the first surgical procedures on a live porcine model, rather than in a human; for the 13.1% (26/198) remaining respondents the use of live porcine model was considered as unethical. For 65.7% (130/198) of the participants (Fellows: 50/72, 69.4% and Residents: 80/126, 63.5%), there is currently no means of substituting the live porcine model for surgical training.

Discussion

For Urologist-in-training, surgical training on a live animal model is considered 'indispensable' or 'very useful'. Surgical skills improvement requires rigorous practical training in both open and minimally invasive surgery and the live porcine model enables trainees to effectively simulate both kinds of surgery [13-15].

Open surgery

The similarities in visceral and vascular anatomy between pigs and humans make them an ideal "candidate" for a high-fidelity model for simulation of open surgery. In this survey, according to the surgical trainees, training on a live porcine model makes it possible to make substantial technical progress in open surgery [16]. Historically, open surgery has been learned using the apprenticeship model, based on a learning system inspired by the Halstedian training method: "see one, do one, teach one", but this approach is outdated and inappropriate in this modern era of surgery [17]. Nevertheless, surgical training has not made learning in the OR obsolete. Indeed, training simulation sessions increase the confidence of the surgical trainers, who accompany the progress of the residents during the training. Thus, in the OR, the training surgeon and the trainees can focus on the specifics of the operation they are performing, knowing that the basic technical skills have been mastered. The training program in the OR must be balanced by the public's right to receive safe and effective surgical care, thus it is important ensure trainees have at least acquired core skills prior to attempting surgery on patients. The working time restrictions such as the European Working Time Directive (EWTD) has dramatically decreased the time spent by trainees in the OR, this has impacted the trainee's skills [18, 19].

The evolution of medical technology has had a major impact on the surgical management of urological diseases in particular the transition from open surgery to a mostly minimally invasive approach. As a result, open surgery is less common and trainees have few opportunities to acquire open surgical skills in the OR. The live porcine model could therefore offer trainees the opportunity to develop their open surgical skills which are not easily acquired by other modalities that lend themselves to laparoscopy and other novel techniques.

Minimally invasive surgery

Minimally invasive surgery (MIS) has increased in popularity in the field of urology due to its reduced risk of complications and shortened hospital stay while maintaining equivalent surgical outcomes to open surgery. The live porcine model is also a high-fidelity model for laparoscopic and robotic training, due to its high degree of anatomical similarity with human urinary organs [20-22]. This animal model also allows a laparoscopic 'force feedback' similar to conventional human surgery. Using laparoscopic surgical training models improves surgical resident's skills, accelerates the learning curve and reduces the time required for laparoscopic procedures [23]. The results of this survey are similar to those reported by Barussaud *et al.* [24] who evaluated the technical improvement of the residents, through specific exercises, during the different sessions. They reported a statistically significant decrease in time for all exercises during the different sessions. Of the participants, 92% were satisfied, 86% felt that the sessions had improved their technical skills, and 74% felt that the sessions had a positive impact on their clinical practice.

However, it seems to be unethical and inefficient to learn the first skills of laparoscopic surgery on live porcine model. The residents need to be confident with manipulation of surgical lap tools; previous repetitive training through workshops with a laparoscopic trainer is therefore critical to achieve before moving on to a live animal model for training. That said,

porcine laparoscopic nephrectomy has been shown to help Urologists inexperienced with laparoscopy to improve in all aspects of laparoscopic procedures, independent of additional training with a simulator [25], suggesting that a live porcine model may supersede any additional benefit derived from lower fidelity simulation.

Surgical emergencies

In recent years, the number of operations performed for urological trauma is decreasing with more conservative management of uro-trauma and an overall decreased incidence of trauma (in Europe). Trauma surgery, in contrast to planned/elective surgery, requires complex decision making under time pressure and therefore is typically not an ideal environment for training; it is often challenging for even experienced surgeons. As such, simulation is an essential component of trauma training, ranging from manikin based ATLS® training to live trauma surgery using a live porcine model, which have been shown to effectively improve technical and non-technical skills [26]. This survey showed that surgical training on a live porcine model to train for emergency situations and lifesaving surgery is considered by the participants as an effective and a valuable adjunct to real-world and lower fidelity simulation work.

Non-technical skills development

For responders, simulation on a live porcine model is a good way to improve non-surgical skills such situational awareness, communication and the management a surgical team during an emergency scenario. Non-technical skills [27, 28] are not usually the focus of surgical training but are critical in minimizing human error, which is known to contribute to the loss of about 98,000 lives per year [29, 30]. This animal model is therefore a potentially valuable way of integrating non-technical and technical skills during training.

Alternative surgical simulation models

Due to the clear ethical issues associated with the use of live animal models for skills training and rapid technological advancements in surgical education such as augmented and virtual reality, a multitude of alternative simulators have emerged. However, most of these simulators do not have dynamic 'force feedback' and their costs are prohibitive for many institutions. Furthermore, several studies have shown that the live porcine model is superior to virtual reality simulators and bench-top models in terms of improvement of resident skills [23, 31-33]. However, the Mimic da Vinci Trainer (MdVT, Mimic Technologies, Inc., Seattle, WA, USA), one of the most established virtual robotic surgical simulators, was shown to be as efficient as a live porcine model when learning robotic nephrectomy [34]. Another option is the use cadaveric porcine models, which may also be an efficient way to learn basic skills [35, 36]; Because it saves animal lives and the pain associated with surgical procedures, this option should be favored until the basic gestures are perfectly mastered by the learner.

Financial aspects

Rehman et al [37] compared the cost of using Da Vinci robotic console and surgical simulation on live porcine model, for a robot-assisted surgical training program. They reported that surgical simulation on Da Vinci robotic console was more economical than simulation live porcine model. Indeed, actually, the average cost of a surgical training session with 4 animals is between 3500 and 4000 euros [37]. These surgical training sessions are funded by universities, the French Association of Urologists-in-Training (AFUF) and by the laboratories private partners.

Ethical considerations

The high rate of participants (82.1%) who said that the use of live animals did not pose them any ethical problem is biased because the trainees knew before coming that their training would be done on live animals; it can be assumed that the surgeons opposed to this practice do not register for this type of training. It is even surprising that 13% of participants considered the practice as unethical.

In Europe, even if simulation techniques are widely developed in medicine, still 2% of animals used for scientific purposes are used for educational purposes (91% are rats or mice). The number of pigs used for surgical training is tiny compared to that intended for our food. The fact that these pigs are raised in excellent conditions of hygiene and well-being, much better than the millions of pigs intended for our food, does not constitute a justification: we do not legitimize an act because it is less cruel than another. Like most experiments involving animals, surgical training on living animals finds its legitimacy in an anthropocentric logic which advocate that a human life will always have more value than an animal life. An animal model allows the teacher and the learner to take their time, one to explain, the other to perform the act, without pressure and without loss of luck for a human patient; it also makes it possible to create complex situations in order to make the learner react. As long as they remain necessary, procedures enrolling animals must respect the 3R rule: Replace, Refine, Reduce. This presupposes that the learner has an excellent mastery of the theory and prior training on a corpse. The training must have the objective not of learning the gesture but of perfecting it.

Limitations

This study has limitations: the evaluation was conducted via a self-questionnaire by willing respondents, thus can be subject to selection bias. In fact, most participants responded stating they were satisfied, which may only mean that the participants enjoyed the course. The scope of the questionnaire was relatively narrow, focusing on satisfaction and the advantages/disadvantages of the sessions.

Conclusion

Surgical training on a live porcine model creates a high-fidelity environment at a relatively small cost to teach and assess technical and non-technical skills. The trainees confirmed that their surgical skills improved after participation in a porcine wet lab. Training with a live porcine model may represent one of the solutions to the challenges of safe and effective urology procedural training. For the respondents, the advantages of surgical simulation on a live porcine model provided also the ability to practice emergency situations and the similarity with conventional human surgery. It would also make it possible to progress technically, to improve situational awareness and the management of the surgical team during emergency scenarios. Trainees and patients could benefit from this risk-free mock surgical scenario. For these reasons, to date, the live porcine model remains one of the most effective surgical simulation models albeit ethically complex.

Disclosure of potential conflicts of interest

The authors declare to have no potential conflicts of interests.

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Figure Legends

Figure 1. Course of a surgical simulation session on a live porcine model

Figure 2. Laparoscopic intraperitoneal view of a live porcine model

Figure 3: GoogleForm © questionnaire for the evaluation of surgical simulation on a porcine model

Figure 4. Surgical procedures performed by the participants

Figure 5. Advantages of surgical training on live porcine model for the participants.

Figure 6. Interest of the surgical training sessions for the participants

Figure 7. Types of advantages of surgical training on live porcine model



Figure 1. Course of a surgical simulation session on a live porcine model

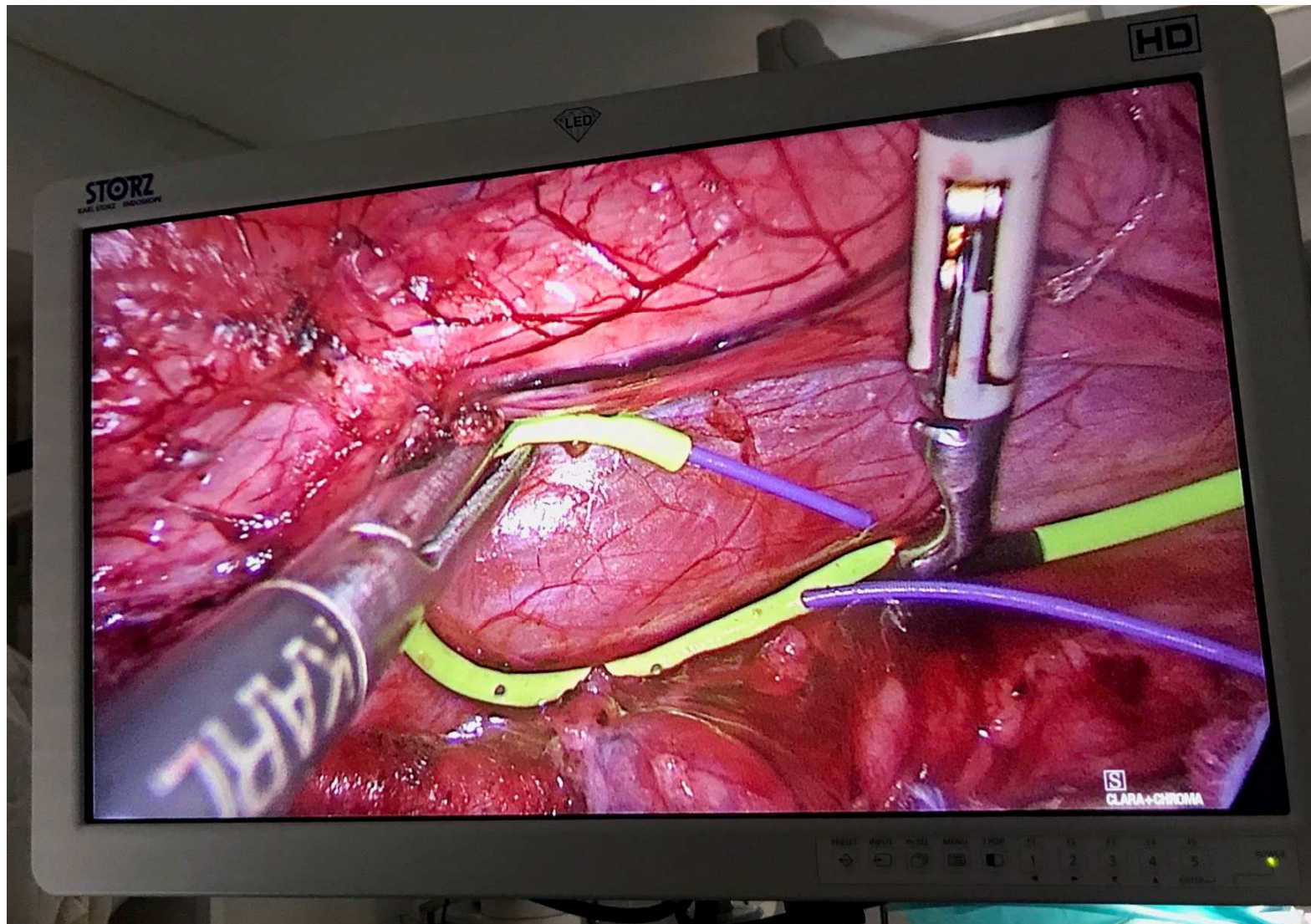


Figure 2. Laparoscopic intraperitoneal view of a live porcine model

Current situation:

- 1st year resident
- 2nd year resident
- 3rd year resident
- 4th year resident
- 5th year resident
- Fellow

How many porcine model simulation sessions have you done?

Which interventions have you performed most frequently?

- Laparoscopic Nephrectomy
- Laparoscopic Partial nephrectomy
- Laparoscopic pyeloplasty
- Laparoscopic cystectomy

Which advantages of the porcine model are the most important in your opinion?

- Similarity with conventional surgery
- To be able to train for emergencies (e.g. vascular wounds)
- To be able to carry out several interventions on the same model

Regarding your surgical training, do you think the porcine model simulation was:

- Indispensable
- Very useful
- Useful
- Useless

Do you think that simulation on porcine models should be mandatory in the training of residents?

- Yes
- No

Do you think that porcine model simulation is superior to a computer model?

- Yes
- No

Do you think that surgery on a porcine model has allowed you to make technical progress?

- Yes
- No

Do you think that surgery on a porcine model has helped you to improve your anticipation of the course of a procedure?

- Yes
- No

Do you think that surgery on a porcine model has allowed you to improve your management of the surgical team (operating assistant, operating room nurse)?

- Yes
- No

Do you find that a theoretical introduction (presentation of the material, the course of the session, presentation of the different surgical times, presentation of the risks and difficulties) to the session is useful?

- Yes
- No

Do you think a debriefing (difficulties encountered, questions) with the training surgeon would be useful?

-Yes

-No

Do you find it ethical to perform the first surgical techniques on a live porcine model?

-Yes

-No

Do you think there is a way to substitute the porcine model?

-Yes

-No

Figure 3. GoogleForm © questionnaire for the evaluation of surgical simulation on a porcine model

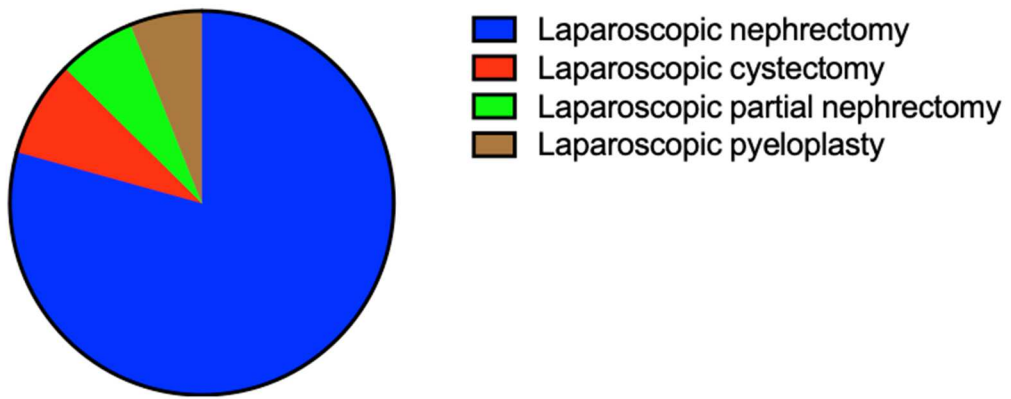


Figure 4. Surgical procedures performed by the participants

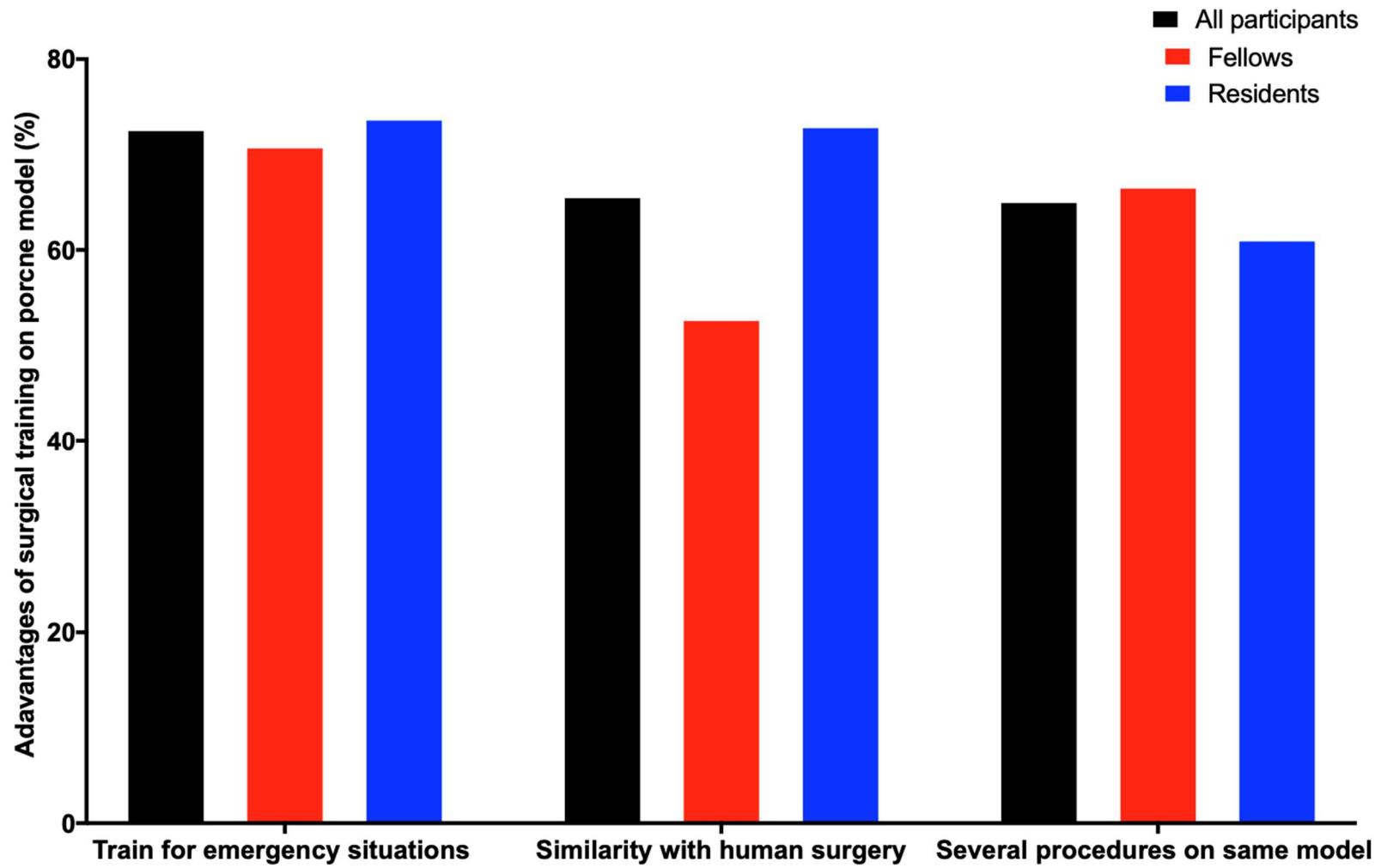
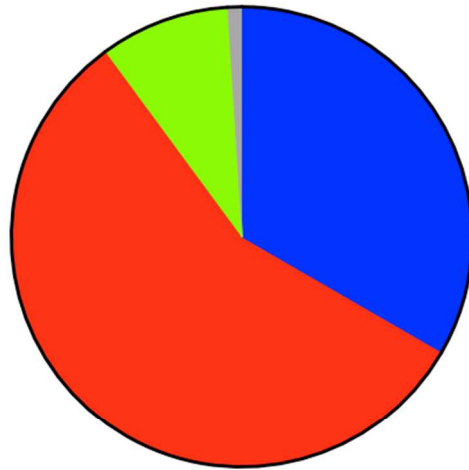
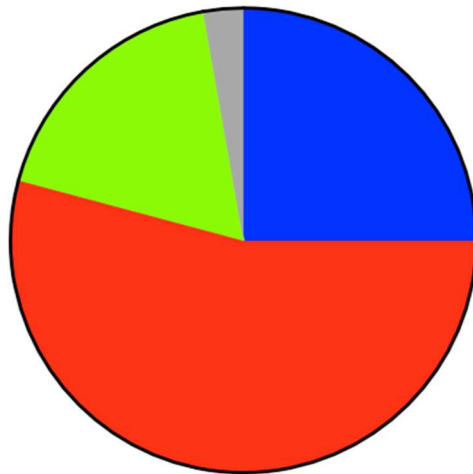


Figure 5. Advantages of surgical training on live porcine model for the participants.



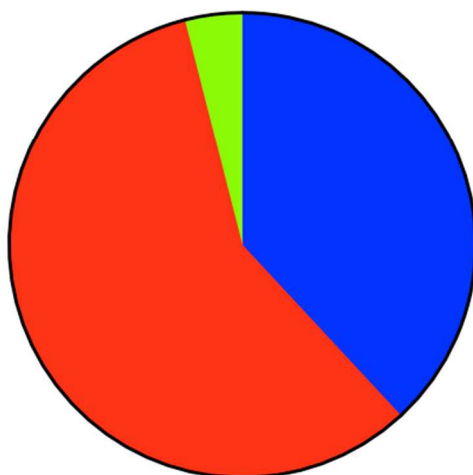
- Indispensable
- Very useful
- Little used
- Useless

All participants



- Indispensable
- Very useful
- Little used
- Useless

Fellows



- Indispensable
- Very useful
- Little used

Residents

Figure 6. Interest of the surgical training sessions for the participants

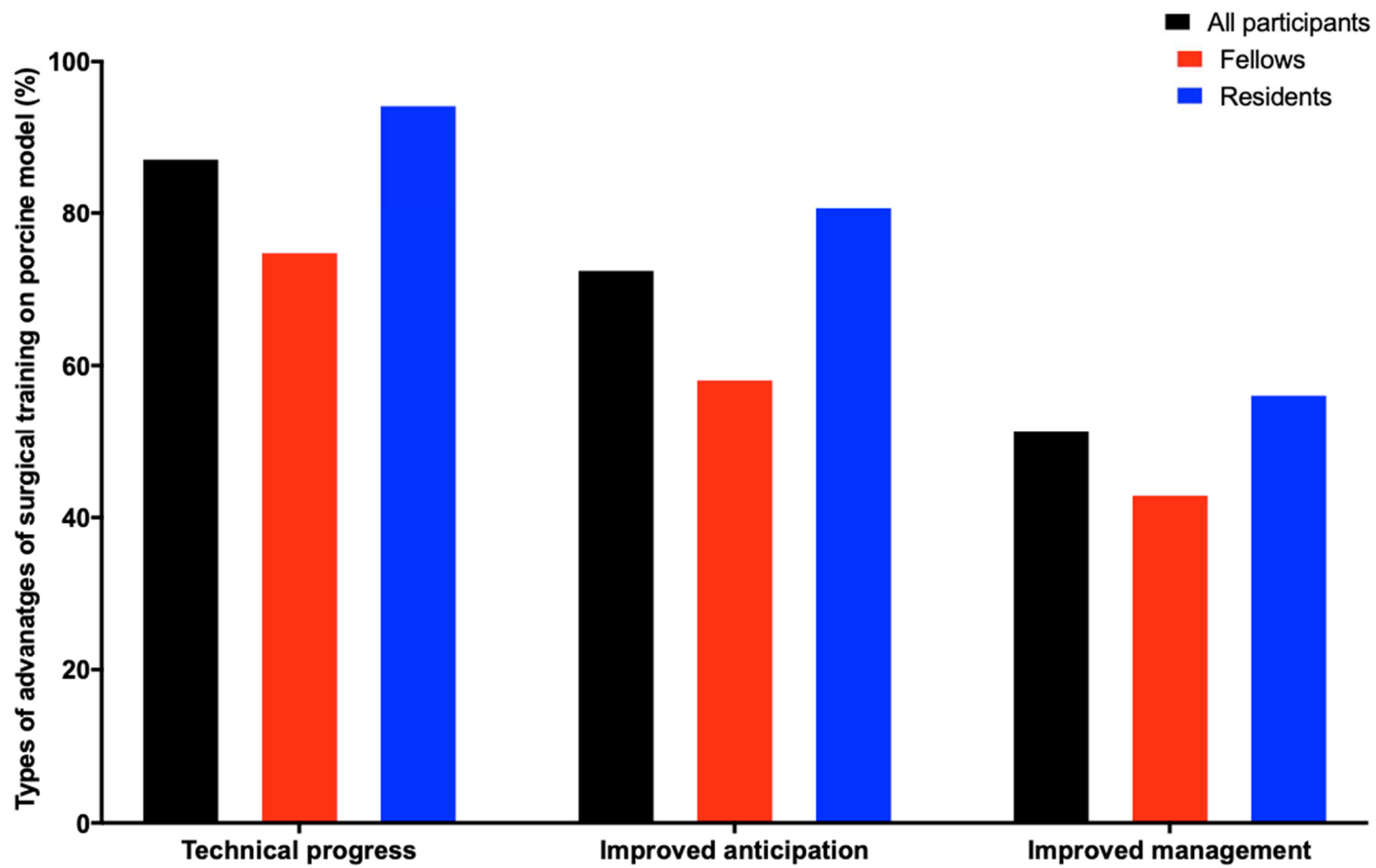


Figure 7. Types of advantages of surgical training on live porcine model