#### **ORIGINAL CONTRIBUTIONS**





# Bariatric Surgical Simulation: Evaluation in a Pilot Study of SimLife, a New Dynamic Simulated Body Model

J. Danion<sup>1,2</sup> • G. Donatini<sup>1,2</sup> • C. Breque<sup>1</sup> • D. Oriot<sup>1</sup> • J. P. Richer<sup>1,2</sup> • J. P. Faure<sup>1,2</sup>

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#### Abstract

**Background** The demand for bariatric surgery is high and so is the need for training future bariatric surgeons. Bariatric surgery, as a technically demanding surgery, imposes a learning curve that may initially induce higher morbidity. In order to limit the clinical impact of this learning curve, a simulation preclinical training can be offered. The aim of the work was to assess the realism of a new cadaveric model for simulated bariatric surgery (sleeve and Roux in Y gastric bypass).

**Aim** A face validation study of SimLife, a new dynamic cadaveric model of simulated body for acquiring operative skills by simulation. The objectives of this study are first of all to measure the realism of this model, the satisfaction of learners, and finally the ability of this model to facilitate a learning process.

**Methods** SimLife technology is based on a fresh body (frozen/thawed) given to science associated to a patented technical module, which can provide pulsatile vascularization with simulated blood heated to  $37 \,^{\circ}$ C and ventilation.

**Results** Twenty-four residents and chief residents from 3 French University Digestive Surgery Departments were enrolled in this study. Based on their evaluation, the overall satisfaction of the cadaveric model was rated as 8.52, realism as 8.91, anatomic correspondence as 8.64, and the model's ability to be learning tool as 8.78.

**Conclusion** The use of the SimLife model allows proposing a very realistic surgical simulation model to realistically train and objectively evaluate the performance of young surgeons.

Keywords Bariatric surgery · Learning curve · Surgical simulation · SimLife

# Introduction

As obesity has become a worldwide public health concern, bariatric surgery has been also recognized as an appropriate and effective method to treat obesity and its related diseases [1-5]. The training needs for bariatric surgeons are therefore increasing in order to maintain a high quality of care for obese patients.

🖂 J. P. Faure

jean.pierre.faure@univ-poitiers.fr; j.p.faure@chu-poitiers.fr

J. Danion jerome.danion@chu-poitiers.fr

G. Donatini gianluca.donatini@chu-poitiers.fr

C. Breque cyril.breque@univ-poitiers.fr As reported in the literature [5], 3 major factors influence bariatric surgery care: hospital infrastructure and volume, surgical team volume, and surgical skills. While it may be difficult to change the first 2 factors that are not dependent on the surgeon, the third can be improved.

Surgical simulation provides the opportunity for supervised directed learning of trainees, allowing full mastering of technical skill and increasing performances before actual practice on patients [6–9].

D. Oriot denis.oriot@univ-poitiers.fr

J. P. Richer jean.pierre.richer@univ-poitiers.fr

- <sup>1</sup> ABS LAB, University Medical School of Poitiers, rue de la Milétrie, Bâtiment D1, TSA 51115 86073 Poitiers Cedex France
- <sup>2</sup> Departemant of Visceral, Digestif and Endocrine Surgery, University Hospital of Poitiers, 2 rue de la Miletrie BP 577 86021 Poitiers Cedex France

For this purpose, we developed the SimLife model, based on fresh human body given to science, dynamized by pulsatile vascularization with simulated blood, warmed to 37 °C and ventilation [10, 11].

The objectives of this study were to assess the realism of this model, the satisfaction of learners, and finally the ability of this model to facilitate the learning process.

# Method

The SimLife model consists of a donated human body, which is retrieved by the Body Donation Center of our university, prepared for surgical simulation [10]. Bodies arrived within 24 h after death, and a traceability number (anonymity) is established [10-12].

*Exclusion criteria* included all possible contaminations such as HIV, HBV, HCV, Creutzfeldt-Jacob, and tuberculosis, through analysis of a blood sample to perform serological tests; at the time of those simulations (2019) we were unaware of the risk of Coronavirus infection, but now we systematically tested all cadavers about the COVID status at their arrival at the Body Donation Center.

Each body was then prepared for surgical simulation (Fig. 1): cannulas were placed in both femoral arteries and left

Fig. 1 Schema of global vascular and aeric accesses of SimLife and the connections with the specific Pulse for Practice® device dedicated to re-vascularization and re-ventilation in a model of abdomino-pelvic and thoracic surgery common carotid artery (input) and both femoral veins and left internal jugular veins (output). The vascular axes of superior and inferior limbs may be excluded to target the trunk's vascularization [10-12]. A tracheotomy or orotracheal tube provided ventilation, and stomach emptying was obtained via a nasogastric tube.

Body's arterial tree was washed with water at low pressure (0.8 bar) and at a maximum temperature of 30 °C to eliminate whole blood and clots. Subsequent body cleaning and disinfection was performed and the body was frozen at -22 °C in a negative pressure cold room [7, 8].

When a SimLife simulation session was scheduled, before use and according to bodies' BMI, progressive body defrosting (at 16 °C) over several days (3 days minimum) was achieved. Finally, a testing procedure before starting on SimLife model was performed to check the physiological behavior of the model.

The specific technical module P4P (Pulse For Practice, patent number 1000318748 with international extension PCT/EP2016/075819 published on 2017/05/11, WO 2017/076717 A1) animated the body, which was perfused by blood-mimicking fluid (patent L18217) circulating in the arterial system in a pulsating manner, recoloring and warming internal organs to 37 °C, and restoring venous turgor. Output was guaranteed by venous output. Physiological



hemodynamic data were computer monitored continuously and adapted as needed, with heart rate, blood pressure, and respiratory rate, which could increase or decreased to mimic a hemorrhagic shock for example.

SimLife inner organs were re-vascularized, re-colored, and warmed by specific mimicking-blood liquid. Hemodynamic conditions were maintained and could be continuously modified by a computer-controlled device, ensuring identical physiological conditions of a real patient. For example, the pulsatile pump controlled by the computer automatically adjusted blood pressure according to possible iatrogenic accidents causing bleeding. Thus, a moderate bleeding induced an increase in flow up to a threshold where hemodynamic instability resulted in a complete loss of blood pressure and systemic circulation interruption [10–12].

The learning platform on cadaveric model was covered by previous approval of French Ministry of Health Ethics Committee (protocol number DC-2019-3704).

## **Study Design and Participants**

A total of 24 residents and chief residents (Table 1) consented to this study on a total of 4 occasions. The training days were hosted at the Medical school. Before performing each procedure, all participants were given a theoretical approach, which included lectures, videos, description of the technique, and an overview to the reperfused cadaver model. This was followed by hand-on training on SimLife models. We associated 2 trainees per station, with at least 1 supervising expert.

The theme of the first 2 sessions was the sleeve gastrectomy, and the 2 following sessions were the Roux-in-Y gastric bypass; this sequence allowed trainees to familiarize themselves with the SimLife model for a relatively simple procedure and then to move to a more technically demanding gastric by-pass.

 Table 1
 Numbers, status of trainees, and their previous experience in bariatric surgery

Status	Nu	mber	Mean and SD
Residents	20	Number of bariatric procedure achieved	0.88 (1.87)
		Number of bariatric procedure as assistant	9.82 (5.91)
		Number of bariatric procedure observed	15.84 (9.81)
Chief residents	4	Number of bariatric procedure achieved	7.83 (5.83)
		Number of bariatric procedure as assistant	30.83 (8.79)
		Number of bariatric procedure observed	50.94 (9.78)
Total	24	Number of bariatric procedure achieved	3.14 (5.97)
		Number of bariatric procedure as assistant	9.29 (7.82)
		Number of bariatric procedure observed	12.15 (10.72)

#### **Evaluation Survey**

At the end of each practical session, all surgical trainees completed an anonymous evaluation survey indicating their degree of satisfaction (feedback) on a Likert scale from 0 to 10 (0 = not at all to 10 = perfectly) on 4 items:

- 1. Ease of learning a specific surgical procedure using SimLife model,
- Accuracy of anatomic landmarks of SimLife model compared with clinical reality,
- 3. Degree of realism of SimLife model,
- 4. Overall satisfaction with the training model used.

## **Statistical Analysis**

Statistical analysis was performed by means of SAS 9.3 software. Values are reported as means and standard deviation (SD). Results are summarized in Table 1.

## Results

All participants completed and returned the evaluation survey corresponding to a response rate of 100% from the trainees. Participants included 20 residents and 4 chief residents from the French Nouvelle Aquitaine area including three university hospitals: Bordeaux, Limoges, and Poitiers. Their status and experience in bariatric surgery are summarized on Table 2.

The evaluation survey was carried out at the end of each session. Data were collected from the 4 training sessions. The 24 participants answered to the four survey questions. Based on these evaluations, the overall satisfaction of the cadaveric model had a mean score of 8.52 with SD of 0.83, realism had a mean score of 8.91 with SD of 0.94, anatomic correspondence had a mean score of 8.64 with SD of 0.96, and the model's ability to be learning tool had a mean score of 8.78 with SD of 0.85 (Table 2).

On the evaluation form given to each trainee the final question was as follows: would you advise a colleague to

 Table 2
 Trainees' responses to questionnaire (on a 0–10 Likert scale) about the quality of the model

Questions	<i>N</i> = 24	
Learning a procedure with this model	8.78 (0.85)	
Anatomic correspondence	8.64 (0.96)	
Realism	8.91 (0.94)	
Overall satisfaction	8.52 (0.83)	

participate in a training course using the SimLife model? One hundred percent of the trainees answered yes.

#### Discussion

Bariatric surgery requires, as well as other surgical subspecialties, acquisition of specific skills, which may be learnt throughout consistent practice. Corresponding at the Halstedian model of apprenticeship "learning on the job" creates the notion of a learning curve. The relationship between hospital volume and outcomes is well recognized; at least 100 cases annually per hospital are recommended as the minimal requirement to achieve a low risk for serious complications [13]. Moreover, a total experience of 500 cases was deemed necessary to diminish the risk for adverse outcomes and meet safety standards [13].

But an individual case report of 100 cases annually is not always feasible, and we focused on revisional bariatric surgery, as cited by Bonrath; in Germany an individual case volume of 300 procedures is referenced as a quality criterion [5].

The paradigm shift of training in surgery In experimental learning, Kolb showed that strategy of the initial used in learning process influences adequate skill acquisition [14]. Concerning bariatric surgery, the value of the classical surgical cursus, residency and fellowship training, is well documented [5, 9, 15–18]. But availability of fellowship in a high debit department of bariatric surgery is not the rule for all young surgeons. In Germany, as reported by Bonrath, over 80% of surgeons had none or little exposure to fellowship training [5]. While in North America a "Fellowship trained" is the rule to independently perform bariatric surgery. So designing fellowship training induced debate within the bariatric surgery societies without finding a worldwide agreement because the means available and the modalities of evaluation vary greatly from one country to another and sometimes from one university to another [8, 19–21].

Other solutions have been proposed, for example, the SAGES telementoring, which allows surgeons to reach the plateau of maximum performance more quickly by "correcting" intraoperative gestures, thanks to experts who can follow the procedure remotely. An evaluation is proposed via this device; unfortunately, it is only subjective since it is left to the expert's free appreciation [22] and always on a patient.

So in the last two decade, the surgical community stated that mentorship should not be the method of instruction that best prepares trainees to enter the modern world of surgery [6, 8, 17–21]. The milestone of the "new concept of training" should consist in exposing apprentices to features of real-life situations, without risks for living patients.

Surgical trainees may also benefit by activities performed far from operating theaters such as surgical simulation [23–25], coaching [26, 27], structured training programs [28], and many others [13].

In fact, the learning curve must shift from the operating theater to a "preclinical" model in simulation. This "natural" evolution of training also follows the incredible technological progress of surgery where the practitioner must master not only his surgical technique but also the tool he uses.

Which model for surgical simulation and evaluation?

Donald Kirkpatrick [29] in the late 1950s defined a training evaluation model based on four levels of evaluation. Each level is built from the information of the previous levels. In other words, a higher level is a finer and more rigorous assessment of the previous level: Level 1: Assessment of reactions, Level 2: Learning assessment, Level 3: Evaluation of transfer, and Level 4: Outcome Evaluation.

Level 1 with assessment of learners' reactions in front of the simulation model is fundamental. If we try to compare the simulation training of pilots and surgeons: a crucial element emerges. While computer models can perfectly simulate a long-distance flight with all possible anomalies, the same cannot be said for computerized surgical simulation. The root of surgical simulation should be the realism of the model to obtain the most immersive environment to the learners [30, 31].

A wide number of surgical simulators are available for the benefit of trainees [6, 7, 9, 10, 30, 32–41]. They can be divided into synthetic and organic simulators [7, 9]. Within the first group we have plastic, rubber, or latex-based simulator as well as virtual reality (VR) and computer-based simulation. Those simulators have the advantage to allow repetition of practice without any risk (no living being used), but these tools may sometimes present a lack of reality compared with human patients [7]. It is necessary to adapt simulation models to anatomical and/or physiological variations that cannot be perfectly programmed in a computerized scenario [42–44].

Organic type simulators provide high-fidelity environment and may be divided into animal-based and human-based. The first type is mainly represented by canine, baboons, or porcine model [7]. Nevertheless, some ethical restriction applied as living animal models are forbid in the UK and open discussion exist in some other European countries [7, 44].

The second organic model is represented by human cadaver, the historical model for practical training in surgery or interventional medicine [45, 46]. Indeed, fresh or embalmed human cadavers have been used for centuries as a learning tool in clinical anatomy [33, 34]. The major pitfall of human corpse is represented by the fact that this is a static model, which could not simulate actual condition of surgery like bleeding and hemodynamic instability, one of the most critical conditions that a surgeon may face, especially during laparoscopy [35–38].

To overcome this problem few teams introduced model of perfused cadaveric material, mainly in neurosurgery, reporting higher satisfaction of trainees and increased fidelity, similar to a living patient [6, 40–42]. These late reports



Fig. 2 Global view of laparoscopic sleeve gastrectomy during a bariatric SimLife session

particularly highlight the increased degree of reality represented by a perfused cadaveric model, which allowed training in hyper-realistic environment [39–41].

Furthermore, the use of cadavers is also a source of ethical reflection and emotional and psychological analysis for learners in their surgical behavioral training [47, 48].

Training on a cadaveric model (Figs. 2 and 3) seems to be the best compromise between learning in the operating room, the animal model, and/or virtual simulators [35].

Surgical apprenticeship on SimLife is performed safely and achieved a high satisfaction score among trainees, as shown previously. This last point is truly important as apprentice appreciation of simulators is the key to provide successful training as it allows gaining of confidence, increasing of experience, and mastering of surgical techniques, which may be lately translated into proficient medical practice [29, 41].

## Limitations of SimLife Model

First, the SimLife model revascularization by a bloodmimicking fluid-limited coagulation, platelet activation, and



Fig. 3 Intraopertive view after a slleve gastrectomy: the stomach after sleeve gastrectomy

thrombin-derived products could not be achieved as in a real standard patient. So the environment is closer to an extracorporeal circulation model.

Second, body availability and moreover overall mean cost per procedure limited the access to this model. This simulations' device cannot be reserved as initial training for junior residents, but it has to be implemented at the end of basic skills learning, which may be achieved on simpler models. Thus, SimLife should ideally be used for training in the last period of residency or during fellowship program to ensure skills mastering just before practicing on clinical theater. To also limit the cost, it is possible to set up SimLife training sessions with several specialties: on day one, orthopedic surgery; on day 2, bariatric and/or endocrine surgery (thyroidectomy with lymph node dissection for example, in this case it is necessary to adapt the body preparation without neck dissection: cannulas placement can be modified as required); and on day 3, cardiac surgery (heart valve surgery). To look further, this model can be implemented in other universities and countries.

# Conclusion

SimLife introduced a realistic bariatric surgery simulation model. It represents a relevant tool that can have a positive impact on the acquisition and mastery of advanced technical skills for young surgeons. The next step in this work will be the evaluation of performance acquisition over several sessions using specific evaluation scales.

## **Compliance with Ethical Standards**

**Conflict of Interest** C Breque, D Oriot, JP Richer, and JP Faure are patent co-owner of the P4P device permitting revascularization and reventilation.

All other authors declare that they have no conflict of interest.

**Statement of Human Rights** The learning platform on cadaveric model is covered by previous approval of French Ministry of Health Ethics Committee (protocol number DC-2019-3704).

**Informed Assent and Consent** Informed consent was obtained from all individual participants included in the study.

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