A Phantom Pig Abdomen as an Alternative for Testing Robotic Surgical Systems: Our Experience

Asko Ristolainen,[1] Gianluca Colucci[2] and Maarja Kruusmaa[1]

[1]Centre for Biorobotics, Faculty of Information Technology, Tallinn University of Technology, Tallinn, Estonia; [2]Worthing Hospital, Western Sussex Hospitals NHS Foundation Trust, Worthing, UK

Summary — The use of animals for testing and validating new medical devices and surgical techniques has raised ethical issues for a long time. Following the introduction of the Three Rs principle, significant efforts have been made to achieve a reduction in the numbers of animals used in testing. Nevertheless, the number of large animals used for testing purposes is still too high. This article describes a potential alternative to the use of large animals in the early phase of the development of surgical equipment — a high-definition phantom pig abdomen. The phantom pig abdomen was developed from computed tomography scans by using affordable materials, and it was used with two different robotic platforms. It permitted the testing of minimally-invasive robotic pancreatic enucleation, with or without intraoperative ultrasound guidance. The phantom pig abdomen has proven to be a realistic tool, with the potential to reduce the cost and time-frame of the experiments.

Key words: *alternative model, education, phantom, robotic surgery, Three Rs.*

Address for correspondence: *Asko Ristolainen, Centre for Biorobotics, Faculty of Information Technology, Tallinn University of Technology, Akadeemia tee 15A, 12618 Tallinn, Estonia.*
E-mail: *asko.ristolainen@ttu.ee*

Introduction

The number of new devices developed in medicine and veterinary science continues to increase every year. According to the Derwent World Patents Index® (DWPI SM), there was an increase of 12% in the number of device patents in the medical field between 2010 and 2011. The use of animals during the development and validation phase of new devices is still the established practice.

The use of animals for experimental purposes has raised ethical concerns since the beginning of the 18th century. In fact, Charles Darwin was one of the first scientists to condemn this practice (1). Since then, many countries have introduced specific laws and regulations on the use of animals for experimental purposes. A cornerstone was set by Russell and Burch in 1959, when they published *The Principles of Humane Experimental Technique* (2), which established the basis of the well-known Three Rs principles of *Refinement*, *Reduction* and *Replacement*. The idea behind this concept was to give scientists a specific framework when designing and conducting experiments, in order to enhance the well-being of the animals involved (*refinement*), to improve the quality of the data while using fewer animals (*reduction*), and to consider alternatives to animals for conducting the experiments (*replacement*). The European Community embraced these principles for the first time in *Directive 86/609/EEC* (3), and they were recently integrated and addressed in more detail in *Directive 2010/63/EU* (4). Now, the Three Rs principles constitute a prerequisite for good standards of practice in animal experimentation within the European Union.

Despite this new culture concerning the use of animals, the *Sixth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union* (3) showed that the total number of animals used for research and training purposes has only fallen from 12.1 million in 2005 to 12 million in 2008. Even if we take into account the different number of countries included (25 Member States in 2005 *versus* 27 Member States in 2008), the overall effect is somewhat disappointing. As we show in Table 1, the decrease in the use of some species has been compensated by a sharp increase in the use of mammals, especially large ones. This trend has been confirmed by the analysis of the use of animals for education and training, and for the research and development of products and devices for medicine, dentistry and veterinary science (excluding toxicology and other safety evaluation; Tables 2 and 3).

One way of reducing the numbers of animals used for training and for the development of surgical tools (which nowadays also includes robotic surgery systems) is to use animal organs received from abattoirs. Recently, Laird *et al.* (5) used the abdominal organs of calves, placed inside a standard laparoscopic abdominal trainer, to practice and demonstrate laparoscopic nephrectomy. Waseda

Table 1: A comparison of the use of different animal species, in the EU between 2005 and 2008

	Number of animals		
	2005[a]	2008[b]	Change (%)
Fish	1,749,178	1,087,155	–38
Mice	6,430,346	7,122,188	+11
Rats	2,336,032	2,121,727	–9
Pigs	66,305	92,813	+40
Goats	2146	3840	+80
Sheep	30,021	30,190	+0.5
Prosimians	677	1261	+86

[a]25 Member States; [b]27 Member States.

et al. (6) developed a box trainer that mimicked the human body with gas insufflation, and was filled with animal organs retrieved from an abattoir for various laparoscopic operations.

The problem with animal organs is that they can only be used for a limited amount of time. The unreliability of the equipment during the development phase is a major issue, as tests are often interrupted by equipment failures or malfunctions that affect the ability to readily carry out repeat tests in rapid sequence. In addition, the potential for significant variations in anatomical size and in structural relationships in the organs does not satisfy the need for a standard model.

In this article, we describe a method for the development of high-definition abdominal phantoms (a phantom is an artificial organ, or body parts, made from tissue-mimicking material). As an example, we describe the creation of a phantom pig abdomen that was developed and finalised within the SAFROS project (Patient Safety in Robotic Surgery — Seventh Framework Programme, European Community; 7). The phantom pig abdomen was created in order to test various devices, and to analyse the overall surgical workflow of pancreatic enucleation in minimally-invasive robotic surgery (MIRS). The goal of this phantom was to minimise experimental animal use within the SAFROS project, and to provide an affordable and efficient alternative to the use of animals, according to the Three Rs principles.

This article is organised as follows: in the *Materials and Methods* section we describe the design and fabrication of the phantom pig abdomen; in the *Results* section we provide examples of its use; and in the *Discussion* we consider the possible applications and advantages of the phantom pig abdomen.

Table 2: A comparison of the use of different species for education and training

	Number of animals		
	2005[a]	2008[b]	Change (%)
Fish	23,796	16,799	–29
Mice	86,597	82,606	–5
Rats	50,048	59,412	+19
Pigs	5854	8134	+40
Goats	317	422	+33
Sheep	956	1243	+30
Prosimians	0	0	—
Total (all species)	**198,994** (1.6% of all animals used)	**207,457** (1.7% of all animals used)	**+4**

[a]25 Member States; [b]27 Member States.

Table 3: A comparison of the use of different species in research and the development of products and devices for medicine, dentistry and veterinary science (excluding toxicology and other safety evaluations)

	Number of animals		
	2005[a]	2008[b]	Change (%)
Fish	933,278	83,525	–91
Mice	1,639,698	1,597,381	–3
Rats	920,875	840,909	–9
Pigs	15,159	22,799	+50
Goats	280	721	+157
Sheep	2721	4098	+51
Prosimians	0	0	—
Total (all species)	**3,746,028** (31% of all animals used)	**2,733,706** (22.8% of all animals used)	**–27**

[a]25 States; [b]27 states.

Materials and Methods

The development of the phantoms

Design and fabrication of the abdomen box

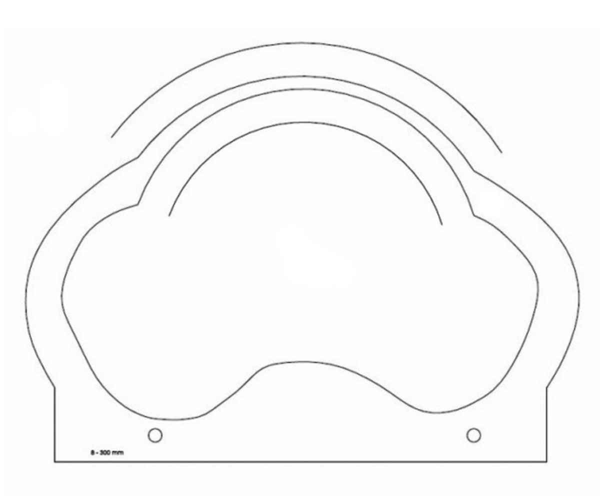
A simulation box was fabricated to mimic the structure of the intraoperative abdominal cavity of a pig during minimally-invasive surgery; it also included parameters for the simulation of an expanded volume within the cavity due to CO_2 insufflation (pneumoperitoneum). In the box, the skin, fat, bones and muscles were reproduced as a seamless layer.

The geometry of the simulation box was reconstructed by using a computed tomography (CT) scan of young pigs (retrieved from a previous study). The reconstructed models of the abdominal wall and organs were increased in size by a factor of 1.3, to emulate the abdomen of an adult pig weighing around 80 kilograms. From the CT scan, the abdominal cavity wall and all of the internal organs were segmented by using 3-D Slicer software (8). The segmentation results were then validated by a radiologist and a veterinarian. A 3-D abdominal cavity model was created, and the shape of the abdomen was altered, by using CAD software (see Figure 1), to simulate the induction of the pneumoperitoneum.

The virtual model of the box was divided into 40mm slices. A template drawing was then created for each of the slices, as shown in Figure 2, and the drawings were printed on paper on a 1:1 scale. The slices were cut out from the paper and glued (with two-component epoxy resin glue) as a template on 40mm-thick polystyrene foam sheets (Styrofoam 250 SL-A-N-40). Excess material was removed with a hot wire-cutter on the inside and around the template. In order to align the sections before glueing, holes were made in every slice, and a round 10mm wooden bar was used as a guide. By using different abrasive sandpapers, a smooth shape was given to the simulation box. Glass fibre was glued onto the smoothed outer layer, as well as onto the inner surfaces of the simulation box (see Figure 3).

The surfaces of the box were painted, and the openings were covered with transparent plastic sheets. Additional holes were created in the abdomen for the minimally-invasive surgical tools, according to the pre-operative plan for pancreatic

Figure 2: Template for the phantom pig abdomen box layer



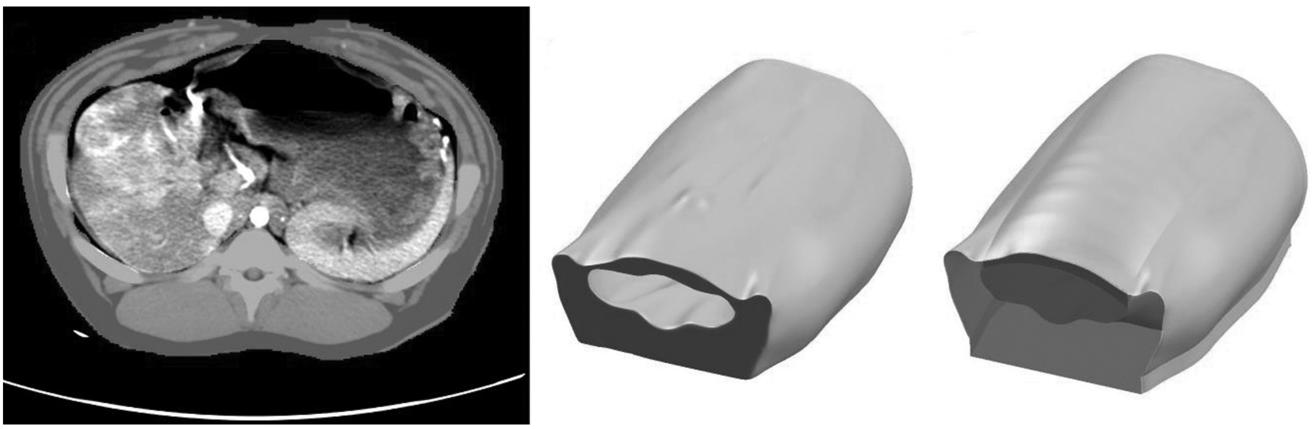
enucleation surgery. This was done in order to optimise the trajectory of the instruments, and to avoid any forbidden regions (e.g. ribs, nerves between the ribs). The holes were then covered with silicone pads, cast out of Dragon Skin® 10 Medium (Smooth-On, Inc.; Easton, PA, USA), to mimic the softness of the skin (see Figure 4).

Fabrication of the abdominal organs, intestines and blood vessels

The phantom pig abdominal organs were built by using the segmented organ models from the CT

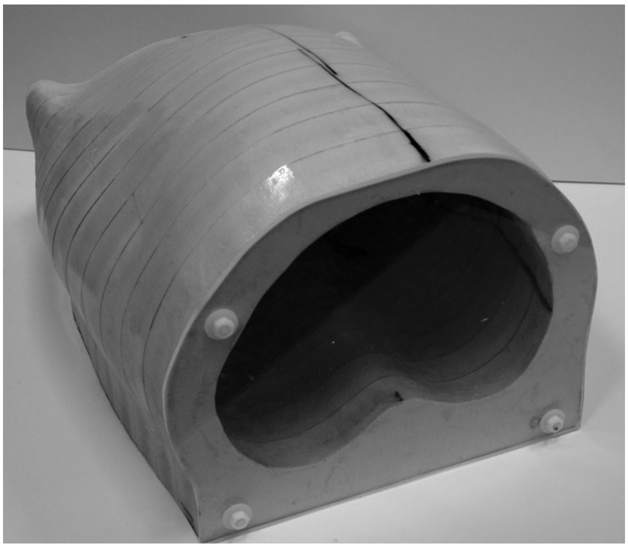
Figure 1: Reconstruction of the phantom pig abdomen box

a) b) c)



a) Shows the CT segmentation of the pig phantom box; b) shows the reconstructed abdominal cavity and walls of the pig; and c) shows the abdomen box model with the shape altered to simulate the induction of pneumoperitoneum.

Figure 3: Simulation box covered with glass fibre



scan. Negative moulds were initially created for the organs, and the actual moulds were produced by using a rapid prototyping 3-D printer (3DTouch 3D Printer; Bits from Bytes, Bristol, UK), as shown in Figure 5. The phantom organs (liver, stomach, spleen, kidneys and pancreas) were cast out of pigmented silicone (Dragon Skin® 10 Medium). The final models were then checked by a veterinarian, and compared to real pig organs obtained from an abattoir. The phantom organs were placed and fixed into the abdomen box, according to the original positioning of the organs on the CT scan, and in the virtual model of the phantom abdomen. The organs were fixed with rubber strings to allow them to move realistically (see Figure 6).

Figure 4: The assembled phantom pig abdomen

The same moulds can also be used to cast organs of other materials; for example, gelatine mixtures can be used to create organs with modifiable ultrasound and CT properties. The preparation of gelatine mixtures was described in our previous publication (9).

The intestines and blood vessels (abdominal aorta, portal vein and vena cava) were built from textiles that were fashioned into tubes and covered with a thin layer of silicone. The intestines were filled with sawdust, to give a realistic appearance and realistic CT properties. Before conducting tests on an assembled phantom abdomen, the overall fidelity of the model created was evaluated by one of the authors (Gianluca Colucci), who has had previous experience in laparoscopy with pigs.

The overall cost of the phantom pig abdomen (materials and moulds) was approximately 400€. The pancreas of the phantom pig abdomen is replaceable, and costs from 10€ to 15€ (when cast out of silicone rubber or gelatine mixture, respectively).

Test scenarios

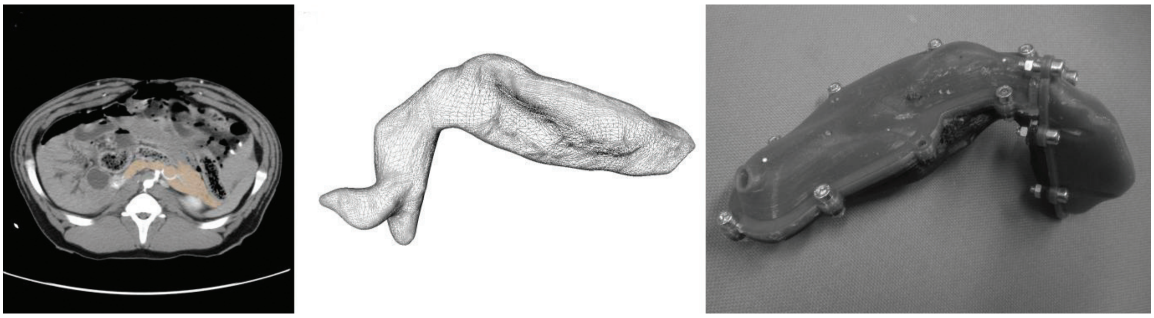
The phantom pig abdomen was prepared for two tests, in both of which pancreatic tumour enucleation was used as the surgical procedure.

The first test was conducted with a MIRO surgical platform (10). The goal of the first test was to use the platform to demonstrate and validate the pancreatic surgery scenario by using a robotic surgery system. For this test, the silicone pancreas was prepared with two tumours (20mm in diameter) and a Wirsung duct (4mm in diameter; see Figure 7, and Figure 6 for the highlighted tumour on the pancreas). The tumours were also made out of silicone (Dragon Skin® 10 Medium), but the elasticity of the pancreas phantom tissue was lower compared to the elasticity of the tumours. This reduced elasticity was achieved by using a silicone mixture with 33% silicone modifier (Slacker®; Smooth-On, Inc.) to cast the pancreas.

The second test was conducted to demonstrate an intraoperative scenario of pancreatic surgery, with a surgical system assembled by using two KUKA Lightweight robots (11). In order to demonstrate not only the enucleation of the tumour, but also the identification of the tumour, with ultrasound guidance, during surgery, the pancreas phantoms were cast from gelatine. This mimics the echogenic and CT properties of real tissue. This model had two cystic lesions (22mm and 18mm in diameter) and a Wirsung duct (4mm in diameter). The phantom pancreas was placed in a plastic box

Figure 5: Example of the organ preparation process

a) b) c)



a) Segmentation of the pig pancreas from the CT scan; b) reconstructed model; c) 3-D printed mould for phantom pancreas casting.

and surrounded with a clear gelatine medium, while ensuring that one side of the pancreas remained accessible for ultrasound acquisition. The pancreas within the plastic casing was fixed inside the phantom pig abdominal cavity (see Figure 8).

Results

The overall fidelity (i.e. reconstruction quality) of the phantom was evaluated in two ways: in comparison with the CT reconstruction, and after examination by a general surgeon with previous experience in laparoscopy with pigs (namely, Gianluca Colucci).

In our opinion, the manufactured phantoms offered a good replica of the anatomical features of the abdominal cavity of the pig. The position and spatial relationships of the organs were consistent with the CT reconstruction. The rigid abdominal wall offered robust protection for the internal structure during the simulations, while the silicone pads covering the insertion points reproduced

Figure 6: Internal image of the phantom showing the highlighted pancreas

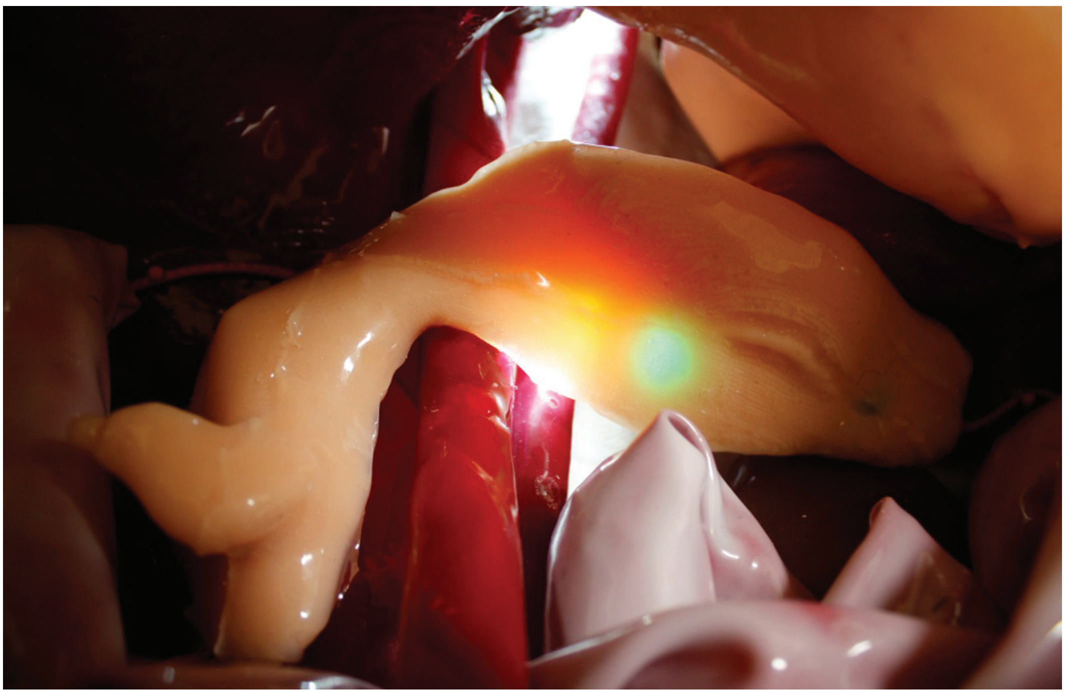


Figure 7: Model of the pancreas showing the placement of the tumours and duct

the stiffness of the trocar–skin interface. The outcome was a functional phantom with a high degree of realism in the overall appearance.

Since the organs were loosely attached to the posterior abdominal wall, their reactions to retraction (during the procedures) were smooth and natural. The organs, specifically the pancreas, showed comparable tactile feedback in the silicone form, and realistic ultrasound properties in the gelatine form, similar to the real tissue. The phantom is shown, with surgical robots during tests, in Figures 9 and 10.

It was not possible to obtain objective data with regard to the viscoelastic property of the pancreas. However, we asked several surgeons to compare the tactile feedback of the silicone model to that of real pancreatic parenchyma. Overall, the feedback indicated a satisfactory comparison between the silicone model and living tissue.

The gelatine model has the drawback of being inside a rigid box. Nevertheless, this did not cause extraneous movement or restrict access to the robotic instruments. The gelatine phantom demonstrated good ultrasound and CT properties, and the images obtained were comparable to the preliminary results experienced with living subjects, according to the subjective opinions of radiologists and surgeons. The Wirsung duct and the cystic lesions were clearly identifiable, allowing for the simulation of an intraoperative ultrasound-guided enucleation, with pre-operative localisation of the cysts and duct (see Figure 9 for the segmented ultrasound image and CT images of the phantom).

The phantom pig abdomen was found to be a good tool for validating the overall MIRS workflow in repeatable tests. The possibility of replacing organs (e.g. the pancreas) permitted the repeated testing of the surgical workflow of MIRS, in a phase where the robots would not have been sufficiently reliable to perform tests on living animals. During the project, our phantom was used not only to simulate the operation, but also to improve the safety of the interaction between the robot and the surrounding environment (assistant surgeon and patient).

Discussion

The high-definition phantom pig abdomen offered a realistic environment for testing when used with two robotic platforms. The features of the phantom in general, and of the two pancreatic models (silicone and gelatine), permitted testing of the overall robotic procedure and the intraoperative ultrasound guidance. These results set a robust basis for eliminating the need for animal experiments in the development phase of MIRS systems, where modifications to the system are usually necessary, before continuing with animal experiments in the final development stages. Animal experiments (usually involving pigs) are needed to test the performance of the finalised MIRS system in a real-life scenario, to prove that the system is sterile (i.e. does not cause any infections after the surgery) and acts safely with living tissue (i.e. does not cause any additional damage), before human trials are possible.

The phantom had two other major advantages. Firstly, the phantom offers consistent and more-standardised conditions. When creating the phantom, the anatomy and all of the anatomical variations can be controlled. It is also possible to introduce various pathological abnormalities (e.g. cysts, tumours), and to modify the relationships between the normal anatomical and the pathological structures. This eliminates the need to induce mutations for the creation of difficult models that

Figure 8: Gelatine pancreas placed in a plastic casing within the phantom pig abdomen

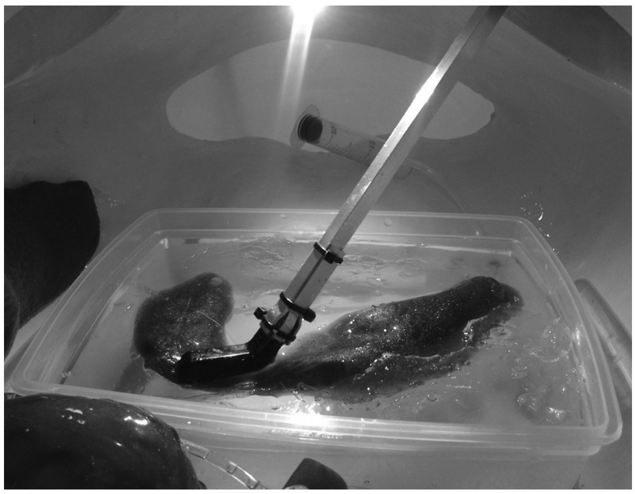


Figure 9: MIRO robot test runs with the phantom pig abdomen

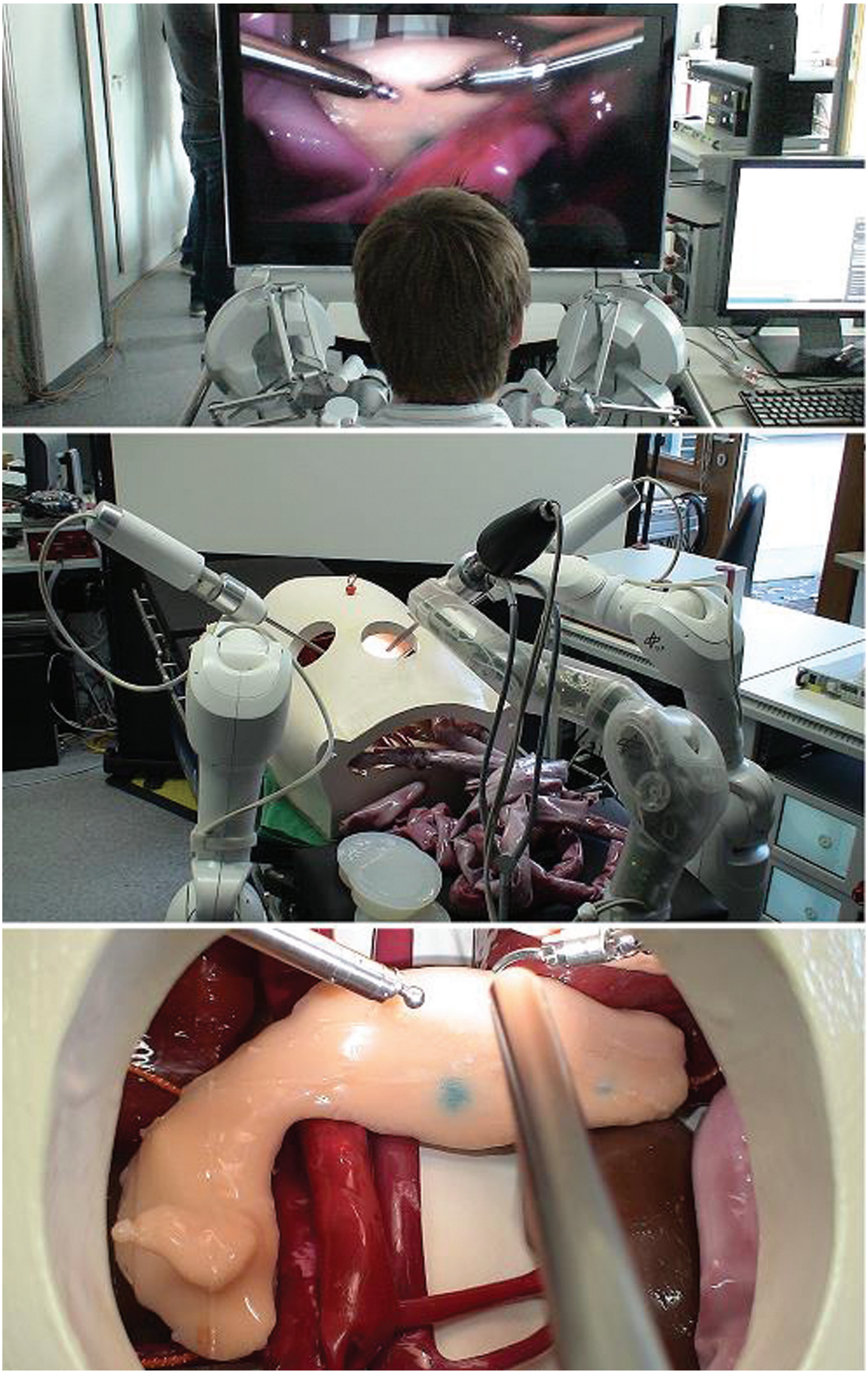
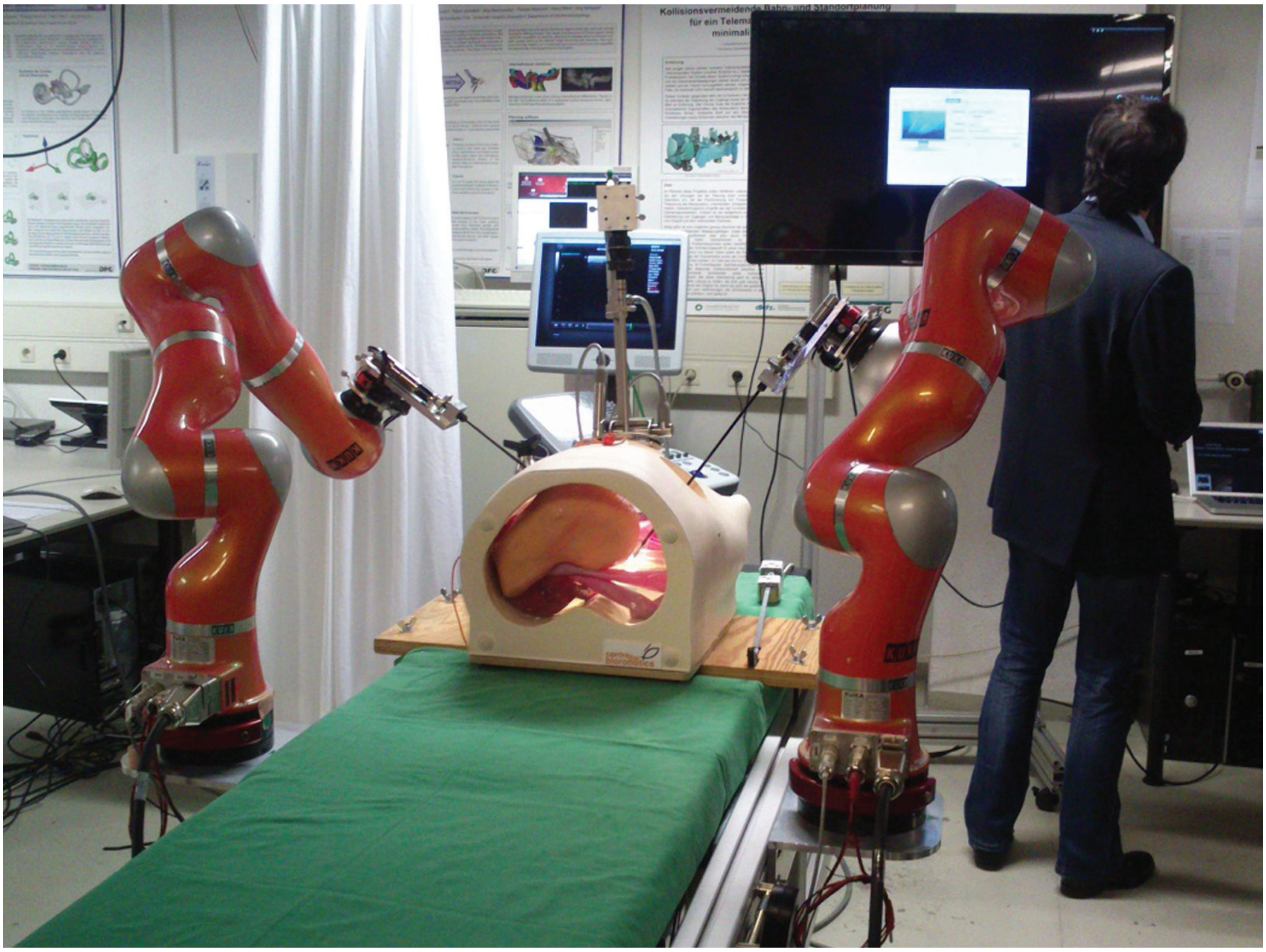


Figure 10: KUKA robots test runs with the phantom pig abdomen



mimic pathological conditions, for the testing of surgical procedures on live animals.

Secondly, the phantom permitted savings in terms of money and time. The use of animals has a high cost, as it requires not only the cost of purchase, but also the cost of maintaining a dedicated facility for housing and surgical procedures. In addition, there is the need for a specialised technician and a veterinarian to supervise the procedures, to ensure the well-being of the animals. Ethical approvals can also be time-consuming, and pose severe limitations on the experimental protocol. Moreover, in most cases and for various reasons, each animal can be used for only one procedure (e.g. when experimenting on particular organs, or due to ethical restrictions).

As the phantom has a modular design, it is possible to replace the damaged organ or structure within the abdomen between single tests, as required, making the whole process more efficient and less expensive.

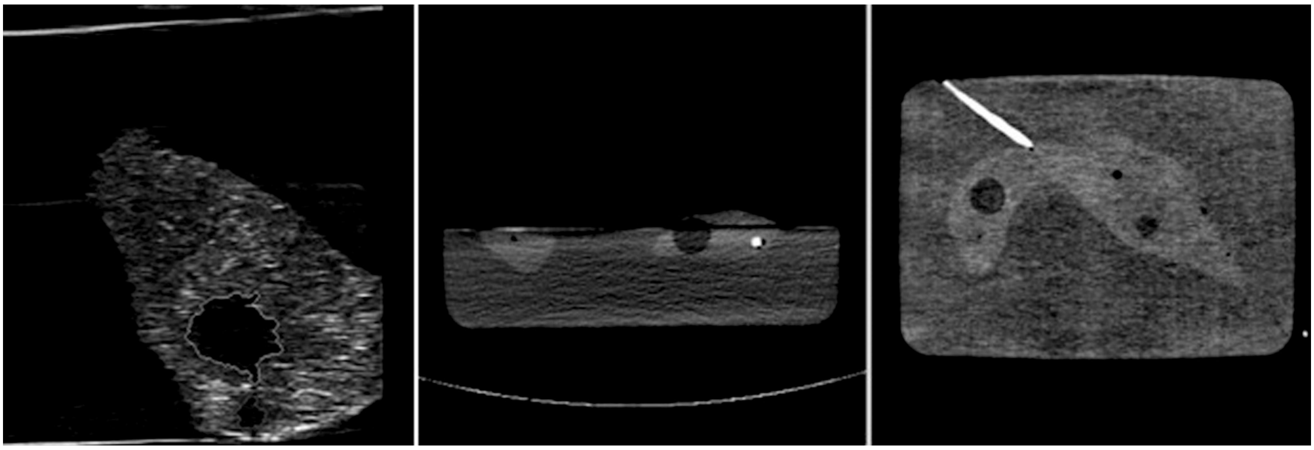
Conclusions

The creation of a high-definition phantom pig abdomen represents a good example of how to apply the Three Rs principles. During all of the preliminary phases of the SAFROS project, great care was taken to minimise the use of animals — for example, CT scans were obtained from another institution, where pigs had been used previously for a surgical procedure. We only used pig organs obtained from the abattoir, to check the fidelity of our organ models.

Overall, the phantom pig abdomen showed a good degree of fidelity, and offered a good alternative to animal testing throughout the project. The modular structure allowed organs inside the phantom to be changed easily, and tests to be performed in rapid sequence.

Beyond this project, the model can be used for other purposes. For example, phantoms have a role in training for both laparoscopic and robotic surgery. Even if there is an increasing use of virtual

Figure 11: Pancreas gelatine phantom with realistic segmented ultrasound (left image) and CT properties (centre and right images)



reality and simulators in robotic and laparoscopic surgery in general, we are far from having reliable simulators for complex operations. As further developments are made, high-definition phantoms will help to close this gap. For example, increased reality could be achieved through the fabrication of all internal organs with realistic ultrasound and CT properties.

In the future, the development of materials that will allow the use of energy sources (diathermy or ultrasonic devices), and the simulation of basic physiological features, such as blood circulation, will broaden the opportunities for the application of these phantoms.

Acknowledgments

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