Grant Agreement number: 224565

Project acronym: ARAKNES

Project title: Array of Robots Augmenting the KiNematics of Endoluminal Surgery

Funding scheme: Large-scale integrating project (IP), FP7-ICT-Challenge 3: Components, systems and engineering/Micro/nano systems

Project website address: www.araknes.org

D10.5
Report on the Experimental Assessment

Due date of deliverable: [31/10/2012]
Actual submission date: [03/12/2012]

Start date of project: 01/05/2008 Duration: 54 months

Organisation name of lead contractor for this deliverable: NVN
Deliverable author: Sebastian Schostek, Marc Schurr

Version: Final

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
Dissemination Level		
PU	Public	**x**
PP	Restricted to other programme participants (including the Commission Service)	
RE	Restricted to a group specified by the consortium (including the Commission Service)	
CO	Confidential, only for members of the consortium (including the Commission Service)	

Document History

Version	Date	Author	Summary of Main Changes
1	28-11-2012	Marc Schurr, NVN	Main document
2	28-11-2012	Sebastian Schostek, NVN	Review and additions
3	28-11-2012	Martina Krautwald, NVN	Formatting and revision
4	30-11-2012	Selene Tognarelli and Arianna Menciassi (SSSA)	Formatting of the document following the ARAKNES template
4	03-12-2012	Paolo Dario (SSSA)	Approval of the document

Contents

Executive Summary 4

1 Assessment of the SPRINT robot 5

1.1 Animal trial of February 2012 5
1.1.1 General conditions 5
1.1.2 Procedure 6
1.1.3 Results and discussion 8

1.2 Animal trial of October 2012 9
1.2.1 General conditions 9
1.2.2 Procedure 10
1.2.3 Results 13

2 Assessment of the ARAKNES Research Platform 14

2.1 Animal trial of Feburary 2012 14
2.1.1 General conditions 14
2.1.2 Procedure 15
2.1.3 Results and discussion 17

2.2 Animal trial of October 2012 18
2.2.1 General conditions 18
2.2.2 Procedure 18
2.2.3 Results 21

3 Assessment of the perfusion sensor 22

3.1 Animal trial of June 2012 22

4 Assessment of the Scarlett magnetic assistive platform 23

4.1 Animal trial of June 2012 23

5 Conclusion & Discussion 25

Executive Summary

The surgical assessment of ARAKNES platform earlier prototypes and functional models was an effort that took place in a number of experimental sessions throughout the project, as reported in previous project deliverables.

The purpose of this deliverable is to report about the assessment of the mature stage devices and technologies.

This assessment was organized in three laboratory sessions from February 2012 until October 2012. Laboratory session means experiments lasting several days in each campaign. Each session consisted of a set-up of the respective technologies in an ex vivo setting as a rehearsal before in-vivo testing. This involved multiple partners for each session that took place at NVN's facilities or the animal OR in Tuebingen. This step-wise approach was necessary to ensure proper function of all systems and sub-systems and to train the respective experimenters (for medical doctors) in the use of the devices or the surgical experimental conditions (for engineers and other scientists).

The following laboratory sessions were conducted:

- January 30th – February 1st 2012
  Participants: SSSA, UB, KST, EPFL, OVE, NVN (20+ researchers)
  Focus on core surgical platforms
- June 4th & 5th 2012
  Participants: UB, KST, OVE, NVN (15 researchers)
  Focus on assistive platforms and devices
- October 23rd - 25th 2012
  Participants: SSSA, UB, KST, OVE, NVN (17 researchers)
  Focus on SPRINT robot and final Research Platform

All experiments were conducted as approved by the responsible regional government institution in accordance with the ARAKNES work program and the rules of the large animal research facility of Tuebingen University, Medical Faculty.

As described in the ARAKNES work program, the porcine animal model was used for all experiments, based on the generally good anatomical and size comparability of this animal model with the human. Experiments were carried out in a fully equipped OR which ensured a realistic setting for the trials.

1 Assessment of the SPRINT robot

1.1 Animal trial of February 2012

1.1.1 General conditions

- Date: 01.02.2012 / Single trial
- Trial-No.: ARAKNES/700-2/010212/007
- Request for authorization: C4/06
- Start time: 11:45 am
- End time: 2:30 pm

- Purpose of trial: Medical evaluation of performance characteristics for maneuvers; acquisition of video material for demonstrating the system and evaluation of instrument-tissue interaction

- Participants:

  Prof. Dr. med. Marc O. Schurr (MS)
  Prof. Dr. Arianna Menciassi
  Dr. Giancarlo Basili (GB)
  Dr. Sebastian Schostek
  Christian Graf
  Gianluigi Petroni
  Marta Niccolini
  Sebastiano Caccavaro
  Claudio Quaglia
  Verena König

- Animal data:

Species: Domestic Pig
Gender: Female
Weight: 57 kg
Animal-ID: 5895

- Anaesthesia:
  Anaesthesia: General anaesthesia
  Anaesthetist: Dr. Tim-Oliver Greiner (vet)

- Devices / Instruments:
  SPRINT (Single-Port lapaRoscopy bImaNual roboT) robot, Prototype, SSSA

1.1.2 Procedure

The procedure is carried out under general anaesthesia. The animal is in supine position.

A midline laparotomy is performed and the small bowel is exposed.

The SPRINT robot prototype is placed over the incision between the back legs of the animal (Figure 1). The SPRINT robot setup is firmly fixed to the OR table by two support arms, one on each side of the operating table. The robot comprises two robotic arms with 6 degrees of freedom plus an end effector for each arm. Both end effectors were general purpose graspers. Electro cautery was not implemented in this prototype. Furthermore, a stereoscopic HD camera was integrated. The SPRINT robot prototype is protected against liquids by latex sleeves; the electronic back-end is protected by a transparent housing.

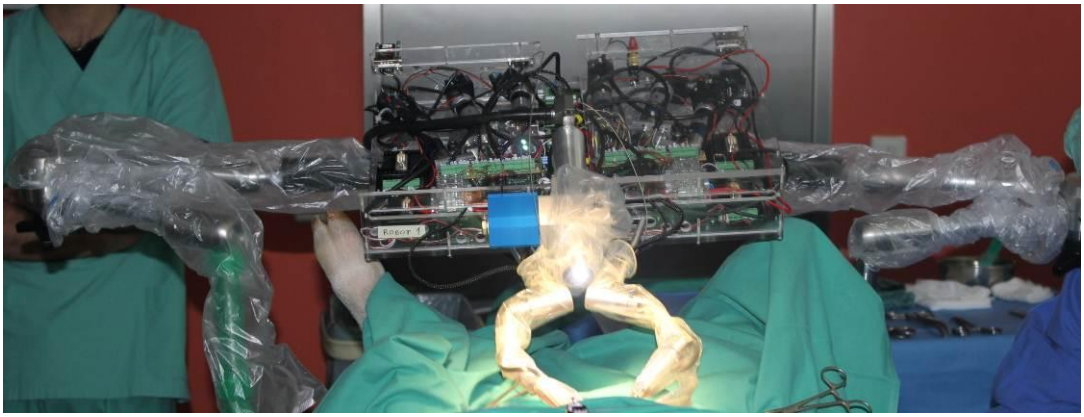

Figure 1: SPRINT robot fixed to the OR table.

The operator of the SPRINT robot prototype sits at the external user interface (master), see Figure 2. The external user interface consists of two modified phantom haptic interface devices and a 3D surgical monitor (polarization technique, provided by KST) displaying the images from the stereoscopic camera of the SPRINT robot prototype. In the actual setting of the in-vivo trial the operator had no direct visual contact to the surgical site, thus had to rely on the visual information from the stereoscopic camera and has to be supported by a local surgeon at the operating table, as it is common in robotic laparoscopic procedures.

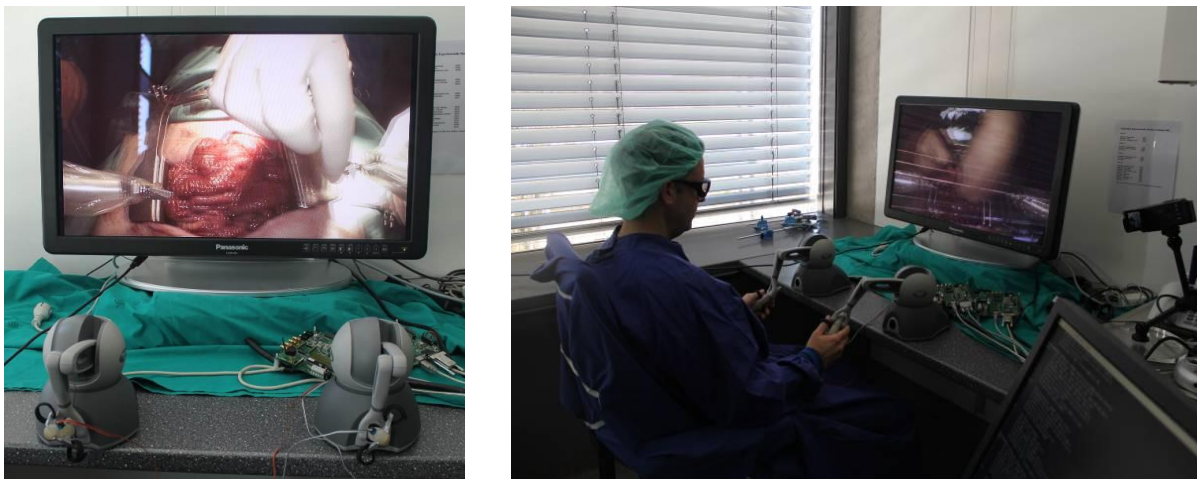

Figure 2: The external user interface with the haptic interface devices and a 3D-display.

Two procedures were carried out: First an enteral anastomosis has been performed by Dr. Gianluigi Basili assisted by Prof. Marc O. Schurr at the operating table for tissue exposure

and retraction. Second, a ligation of a bundle of mesenterial vessels at a small bowel segment has been performed by Prof. Dr. Marc O. Schurr, assisted locally by Dr. Sebastian Schostek in site the operating table.

- Small bowel entero-enterostomy

A bowel segment has been identified and, after creation of two holes, the small bowel has been sutured side-to-side by the SPRING robot prototype, see Figure 3. Supported by the assistant, both bowel segments have been incised. Assistance was mandatory as the preliminary SPRINT robot prototype was not yet provided with appropriate cutting means. Subsequently, the anastomosis has been performed by suturing the respective bowel segments together, creating an entero-enterostomy. Visual inspection revealed a successful anastomosis.

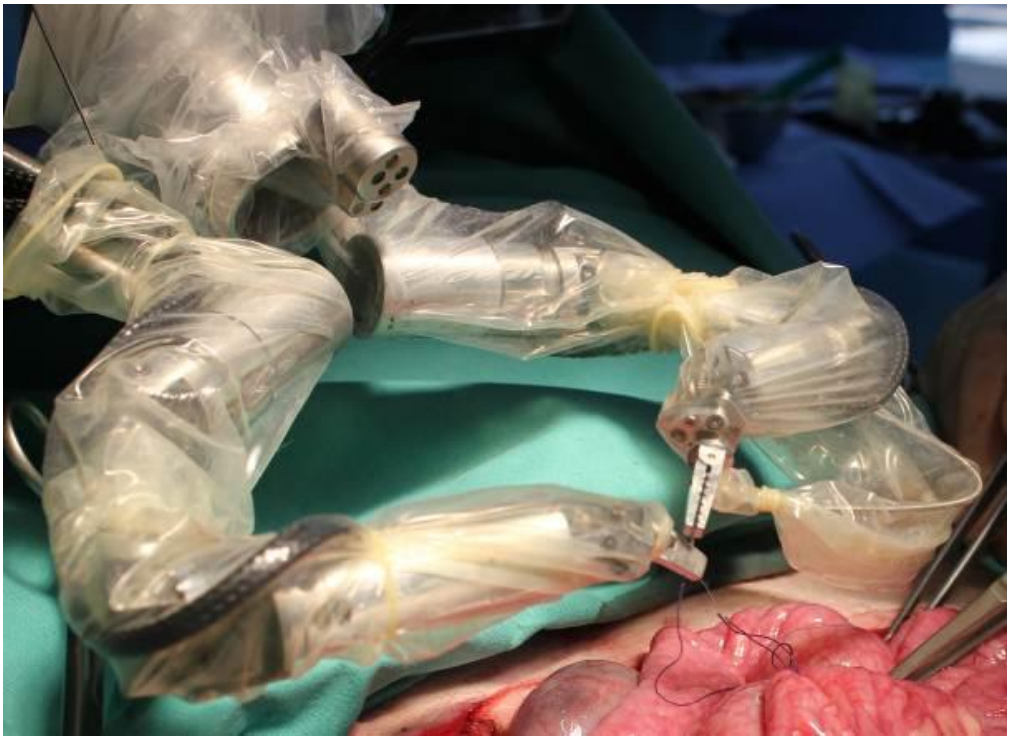

Figure 3: The operating SPRINT robot.

- Ligation of a mesenteric vessel bundle

A small bowel loop was lifted up to expose the mesentery. A mesenteric vessel bundle was then identified for ligation. First, a window has been created in the mesentery. This was supported by the assistant who retracted the bowel tissue for optimal display to the robot.

A second perforation of the mesentery has been generated on the other side of the vessel bundle, and a suture has been placed around the vessel bundle by the robot through both mesenteric perforations. The ligation has been finished and secured by a knot.

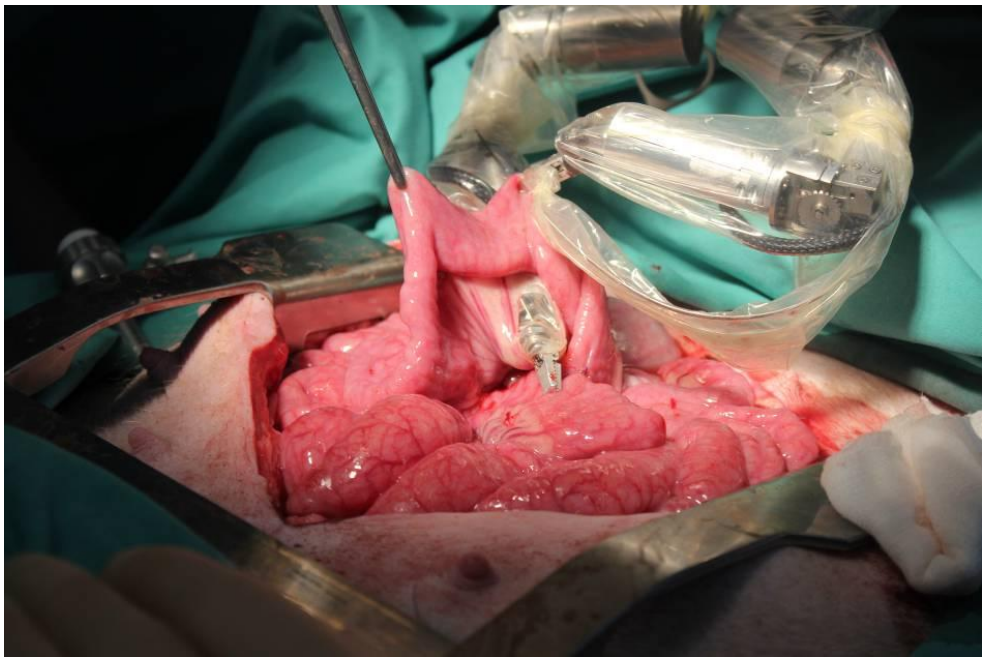

Figure 4: Preparation of a mesenteric artery for ligation

1.1.3 Results and discussion

The first live in vivo animal surgical assessment of the SPRINT robot was successful. The experiment has shown the fundamental applicability of the system in real surgery. Due to the technical constraints given by the current prototype, which cannot be used through a trocar, the procedure was carried out in an open fashion. In spite of the limitations of this approach, also the open procedure allows adequate testing of the basic functions of the system in handling tissue and surgical appliances, such as suture materials.

Two typical surgical manoeuvres were carried out with the SPRINT system, a continuous anastomotic suture and a vessel ligature. Both techniques proved feasible as reported in " A novel robotic system for single port laparoscopic surgery, Petroni, M. Niccolini, A. Menciassi, P. Dario, A. Cuschieri, Surgical Endoscopy.

During the suturing task, the needle had a tendency to rotate away between the jaws of the end-effector, when it was guided through the tissue. This is related to the geometry of the jaws of the instrument, which were not designed as a needle holder. This makes it difficult to judge, if the holding force provided by the closure of the grasper is fully sufficient, due to the jaw design bias. Thus it is recommended to replace the end-effector by a dedicated laparoscopic needle holder tip.

It was noted that the right instrument of the SPRINT manipulator system did not fully open its jaws. This was prototype related and was managed by supporting the opening of the tip manually. It was recommended to improve the reliability of the opening mechanism to allow a more fluent use of the instrument.

The overall positioning capability and precision of mechanical guidance of the SPRINT system was very adequate for a first prototype. However, further improvement is necessary to allow good guidance of the needle. In the current version, the manipulation of the needle led to a tear in the wall of the small bowel.

It has to be noted that the operation of the SPRINT system requires training. This becomes clear, when the performance between both persons (GB, MS) was compared. GB had received thorough training and has used SPRINT multiple times before in other tests. MS had not been exposed to the practical use of SPRINT before and had more difficulties in

using it. Especially the use of the re-indexing of the master arms requires training. The meaningful work space of the master arms is quite small and makes re-indexing necessary frequently.

In general, the suitability of the current master arms may require further considerations, since the use of the devices can appear "notchy" and counteract fluent and ergonomically relaxed use.

1.2 Animal trial of October 2012

1.2.1 General conditions

- Date: 25.10.2012 / Single trial
- Trial-No.: ARAKNES/700-2/251012
- Request for authorization: C5/11
- Start time: 10:15 am
- End time: 1:40 pm

- Purpose of trial: Training of both, engineers and medical doctors, in the use of the SPRINT-System. Evaluation of the SPRINT system.

- Participants:
  Prof. Dr. med. Marc O. Schurr
  Prof. Dr. med. Thomas Gottwald
  Prof. Dr. Arianna Menciassi
  Dr. Sebastian Schostek
  Dr. Marta Niccolini
  Martina Krautwald

- Animal data:
  Species: Domestic Pig
  Gender: Female
  Weight: 148,6 kg
  Animal-ID: 6469

- Anaesthesia:
  Anaesthesia: General anaesthesia
  Anaesthetist: Dr. Tim-Oliver Greiner (vet)

- Devices / Instruments:
  SPRINT (Single-Port lapaRoscopy bImaNual roboT) robot, Prototype, SSSA
  Tricam SL II Endoscopy Camera, KARL STORZ GmbH & Co. KG
  Xenon nova 175 light source, KARL STORZ GmbH & Co. KG
  Electronic insufflator, KARL STORZ GmbH & Co. KG

1.2.2 Procedure

The procedure was carried out under general anaesthesia and the animal was positioned in supine position on the operating table.

The size of the laboratory animal was chosen to compare with the adult human. The experiment was carried out under unsterile conditions as an acute procedure without the intention to survive the animal.

Following midline mini-laparotomy (approx. 4 cm) in the mid abdomen, the SPRINT system was inserted into the abdomen through the incision (Figure 5 and Figure 7). The ARAKNES flexible single port sleeve had already been pre-mounted on the shaft of the SPRINT robot and both parts, the single port device and the SPRINT-unit, were inserted together into the abdominal cavity. The manipulator arms of the slave had been covered by means of rubber sheaths to protect the kinematics from liquids and to protect the tissue from possible impingement between the joints. After placement of the SPRINT, the incision was sutured around the device to provide gas-tightness and the abdomen was insufflated up to levels of 14 mm Hg.

To facilitate insufflation and gas distension of the abdominal cavity, the SPRINT slave-unit had been covered with plastic draping. On one hand this draping provided protection of the housing of the unsterile slave-unit, as it is common in laparoscopy. On the other hand the plastic foil draping enabled effective gas distension by preventing gas loss from leaks of the slave mechanics.

During the experiment the SPRINT slave-unit was suspended by means of a mechanical arm mounted to the operating table. This connection of the system to the operating table offers the advantage that the system moves with the laboratory animal when the height of the table is changed. In addition any re-adjustment of the arm that may become necessary during the procedure can be carried out by the assistant at the operating table.

Then the surgeon was operating the SPRINT via the external user interface (Figure 6, Figure 8 and Figure 9), which is equipped with a 3D-display. A surgical assistant was positioned at the operating table for surveillance of the system and to provide technical help with re-positioning of the SPRINT, if needed.

The surgeons were instructed and trained by the engineers in operating the SPRINT, after having received proper technical introduction and after having carried out dry-training with the system under ex vivo conditions before the animal lab or, alternatively, aside the operating field at the same day.

Figure 5: Left: SPRINT-System; Right: SPRINT-System, air-tight sealing.

Figure 6: External user interface console in the animal operating theatre.

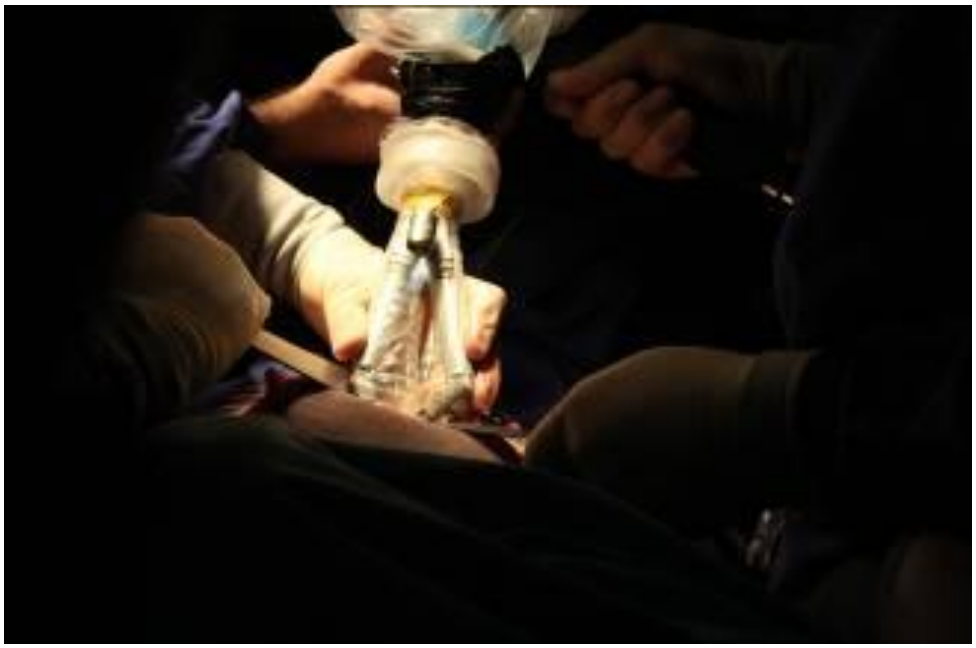

Figure 7: Insertion of the SPRINT via the mini-laparotomy.

Figure 8: Training in operating the SPRINT. The surgeon is using two master arms for guiding the SPRINT slave arms.

Figure 9: Training in operating the SPRINT: view point of the surgeon. A central video screen offers 3D vision, two lateral displays provide ancillary information about the system.

1.2.3 Results

First of all the compact size of the SPRINT robot in comparison to other laparoscopic robotic systems is a fundamental advantage from a surgical perspective. The system requires only little space at the operating table and can easily be positioned in the operating field. The weight of the slave-unit device (i.e. 3kg) is acceptable and does not cause difficulties in being fixed to the T-rail of the operating table.

Surgical insertion of the SPRINT slave was feasible; however, it was not possible to carry out the full intended insertion procedure with the arms and camera being introduced individually through the shaft. This was due to technical reasons and did not hamper the surgical evaluation of the system.

As described above, the system was entirely wrapped with protective gear, necessary to protect the delicate electronic and mechanical components. The plastic drapes did not disturb the surgical evaluation of the system. However, the covers of the internal arms were apparently punctured during the experiment or had not been sealed fully tight before the insertion. The penetration of body liquids into the covers of the arms led to damage of the slave unit with subsequent loss of function. First only one driver arm was affected, but during the course of the lab more drivers lost function. This caused a breakdown of the movement capabilities of the system.

The surgeons quickly learned how to operate the system. The master arms were found easy to use. The indexing function to re-align the position of the master-slave ratio into the ergonomic range of motion was found to be very useful and more intuitive than in the previous animal lab.

The optical system of SPRINT with its 3D capability is seen as an advantage in visualizing and controlling the manipulator unit.

In summary, the operation of the SPRINT is easy to learn. However, it needs a better air- and liquid-tight protective cover to be more resistant to surgical use conditions.

2 Assessment of the ARAKNES Research Platform

2.1 Animal trial of Feburary 2012

2.1.1 General conditions

- Date: 01.02.2012 / Single trial
- Trial-No.: ARAKNES/700-2/251012
- Request for authorization: C5/11
- Start time: 8:45 am
- End time: 11:45 am

- Purpose of trial: Medical evaluation of introduction and performance of ARAKNES Research Platform.

- Participants:
  Prof. Dr. med. Marc O. Schurr
  Prof. Dr. Arianna Menciassi
  Dr. Sebastian Schostek
  Dr. Giancarlo Basili
  Selene Tognarelli
  Marco Salerno
  Verena König

- Animal data:
  Species: Domestic pig
  Gender: Female
  Weight: 57 kg
  Animal-ID: 5895

- Anaesthesia:
  Anaesthesia: General anaesthesia
  Anaesthetist: Dr. Tim-Oliver Greiner (vet)

- Devices / Instruments:
  Flexible endoscope, EG-2970K, Pentax Europe GmbH
  SMA triangular frame with magnetic modules (ARAKNES Research Platform), Prototype, SSSA
  Tube Ø 16 cm, length 20 cm
  Laparoscopy tower, Karl Storz
  Laparoscopy forceps, Karl Storz

HF unit: VIO 300D, Erbe
Trocar, 5 mm and 10 mm
Verres-needle
Endoscpic snare
Endoscopic grasper
Endoscopic HF knife

2.1.2 Procedure

The procedure was carried out under general anaesthesia. The animal was in supine position. The flexible endoscope was introduced into the stomach. A laparoscopic access has been placed to visualize the intra-abdominal cavity and to be able to support manoeuvring of the endoscopic devices. A small incision is made with a scalpel and a Verres needle is slowly inserted into the incision. The Verres needle is then connected to the CO2 insufflation tubing and a pneumoperitoneum is obtained. The Verres needle is removed and a 10 mm trocar is positioned into the abdomen through the same incision. A 30° laparoscope is inserted through the trocar to obtain visualization of abdomen. A second 10 mm trocar was placed, as well as a 5 mm trocar.

A NOTES (natural orifice transluminal endoscopic surgery) access was placed using an HF knife. An overtube (prototyped by SSSA) was inserted through the oesophagus into the stomach. The overtube was placed in the gastrotomy with the flexible distal end, while the rigid proximal end remains accessible outside. Since no valve has been foreseen, the pneumoperitoneum could not be maintained. A valve has been added at the proximal end of the overtube, which allowed the establishment of a pneumoperitoneum.

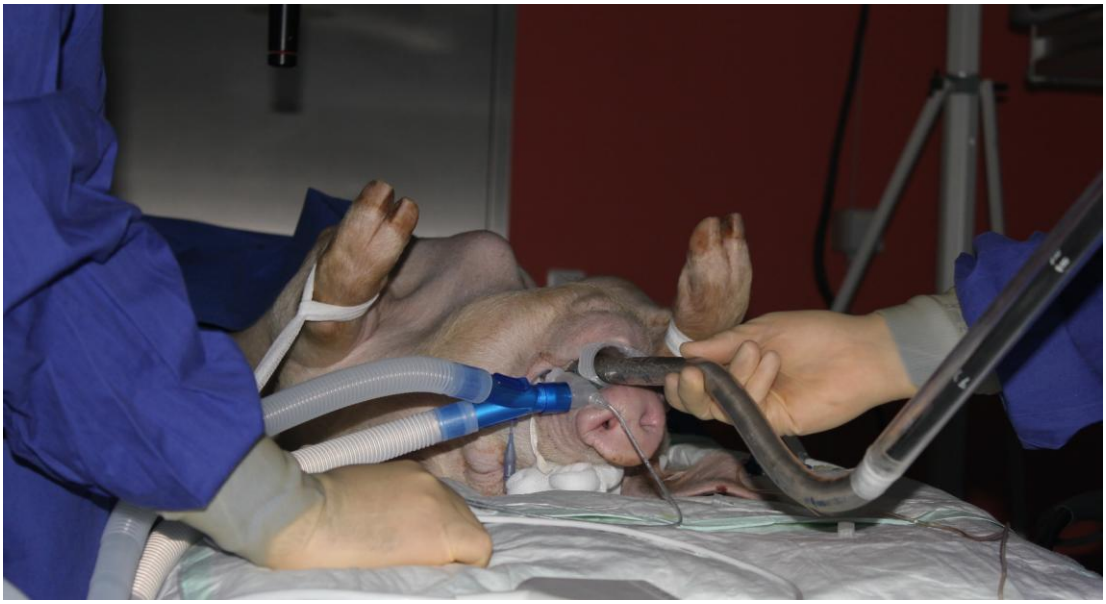

Figure 10: The overtube prototyped by SSSA.

The magnets frame (Figure 11) has three arms, which are connected with an elastic band and two joints. The frame is opened and pushed through the overtube. During the introduction, the frame got stuck inside the tube, most likely at the interface between the rigid and flexible parts of the overtube. The magnetic frame could be pushed out using a plastic tube. After introduction, the magnetic frame was lying inside the abdominal cavity.

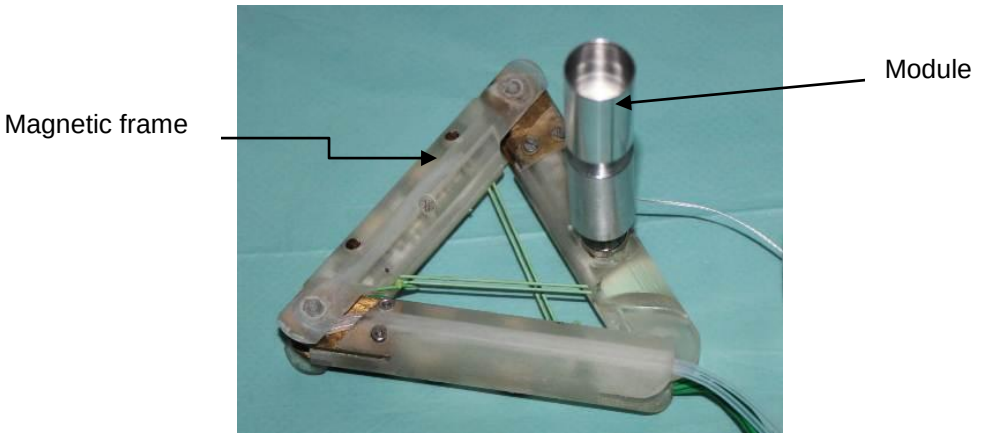

Figure 11: Magnet frame with the module.

A laparoscopic grasper is inserted into the 5 mm trocar to turn the module over. Then, the magnet frame is lifted up to the wall and moved around with the external magnet (Figure 12).

Figure 12: The position of the three trocars and the magnets.

The module (Figure 11) is pushed through the overtube. The module got stuck as well inside the overtube. A laparoscopic forceps is inserted through the trocar to pull the module from the distal end. The forceps could not reach it, thus a plastic tube is pushed through the overtube to push the module forward. Then the forceps grasped the module and pulled it out of the overtube.

The module should be placed into a socket of the magnetic frame. Numerous attempts to connect the module to the socket of the magnetic frame using the flexible endoscope failed. Both the module as well as the corresponding socket had active magnetic elements, which should help with the docking manoeuvre. During the various docking attempts, it turned out that the external magnet, which lifted the magnetic frame to the abdominal wall, interfered with the magnetic interaction between the module and the socket. Thus, the docking was strongly impeded and unsuccessful. The docking manoeuvre has been tried using endoscopic grasper grasping the module at various positions, magnetic interaction between the grasper forceps and the module magnet, as well as a snare. At different positions, the

manoeuvring was supported by a laparoscopic grasper. The time of these attempts was more the one hour.

Finally the docking manoeuvre succeeded, when the magnetic frame was not held by the external magnet, but was lying upside down on the intestines.

2.1.3 Results and discussion

The introduction of the devices into the abdominal cavity through a NOTES access was possible. However, the interface between the two sections of the overtube has to be improved to avoid the devices getting stuck inside.

A valve has to be added to the proximal end of the overtube to allow the pneumoperitoneum to be maintained. The length of the overtube limited the accessability of the abdominal cavity and restricted the manoeuvrability of the devices and instruments inserted.

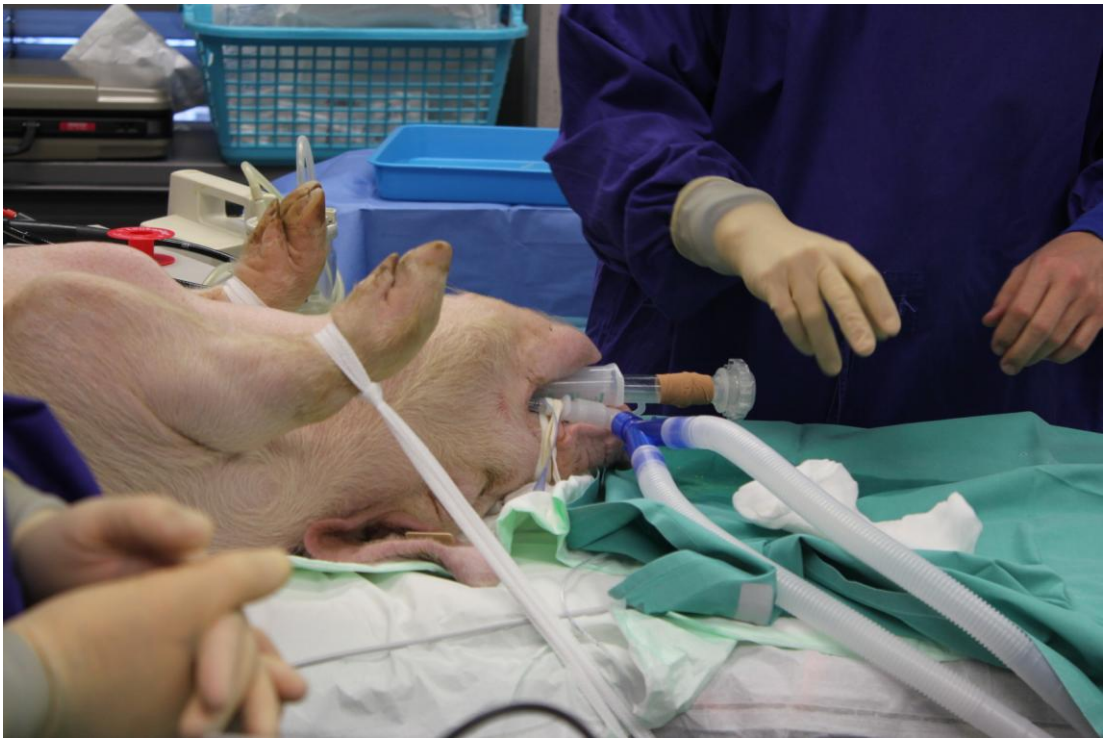

Figure 13: The valve added to the proximal end of the overtube for maintaining the pneumoperitoneum.

The docking manoeuvre using a magnetic socket was significantly impeded by the third external magnet.

The trial revealed general feasibility of the concept of the research platform. Both endoluminal introduction and assembly inside the abdominal cavity have been achieved. The NOTES access can be considered safe and effective, which is supported by current clinical state-of-the-art.

However, both the devices as well as the procedure have to be improved to come to a reliable and robust system setup. Especially a simplification of the docking procedure is required in order to allow a fast and reliable docking manoeuvre, even under difficult conditions. It is recommended to revise the general principle of magnetic docking, as the external magnetic field used to stabilize the platform counteracts the docking procedure.

2.2 Animal trial of October 2012

2.2.1 General conditions

- Date: 25.10.2012 / Single trial
- Trial-No.: ARAKNES/700-2/251012
- Request for authorization: C5/11
- Start time: 2:00 pm
- End time: 3:15 pm

- Purpose of trial: Test of the further improved Research Platform

- Participants:
  Prof. Dr. med. Marc O. Schurr
  Prof. Dr. med. Thomas Gottwald
  Prof. Dr. Arianna Menciassi
  Dr. Sebastian Schostek
  Dr. Marta Niccolini
  Martina Krautwald

- Animal data:
  Species: Domestic pig
  Gender: Female
  Weight: 148,6 kg
  Animal-ID: 6469

- Anaesthesia:
  Anaesthesia: General anaesthesia
  Anaesthetist: Dr. Tim-Oliver Greiner (vet)

- Devices / Instruments:
  Research Platform, Prototype, SSSA
  Overtube
  Tricam SL II Endoscopy Camera, KARL STORZ GmbH & Co. KG
  Xenon nova 175 Lichtquelle, KARL STORZ GmbH & Co. KG
  Electronic endoflator, KARL STORZ GmbH & Co. KG

2.2.2 Procedure

The procedure was carried out under general anaesthesia and the animal was placed in supine position.

Following mini-laparotomy in the mid abdomen, a flexible insertion tube was placed inside the abdomen through the incision. After placement of the tube, the incision was closed around it with a purse-string suture. Then the opened ARAKNES Research Platform was

inserted via the tube (Figure 15) and was closed by means of its shape memory actuators to form a triangle inside the abdomen (Figure 16).

Afterwards, the Research Platform was attached to the inner wall of the abdomen with a magnet on the outer side of the abdomen and it was moved along the inner side of the abdomen (Figure 17).

Figure 14: Closed Research Platform before insertion.

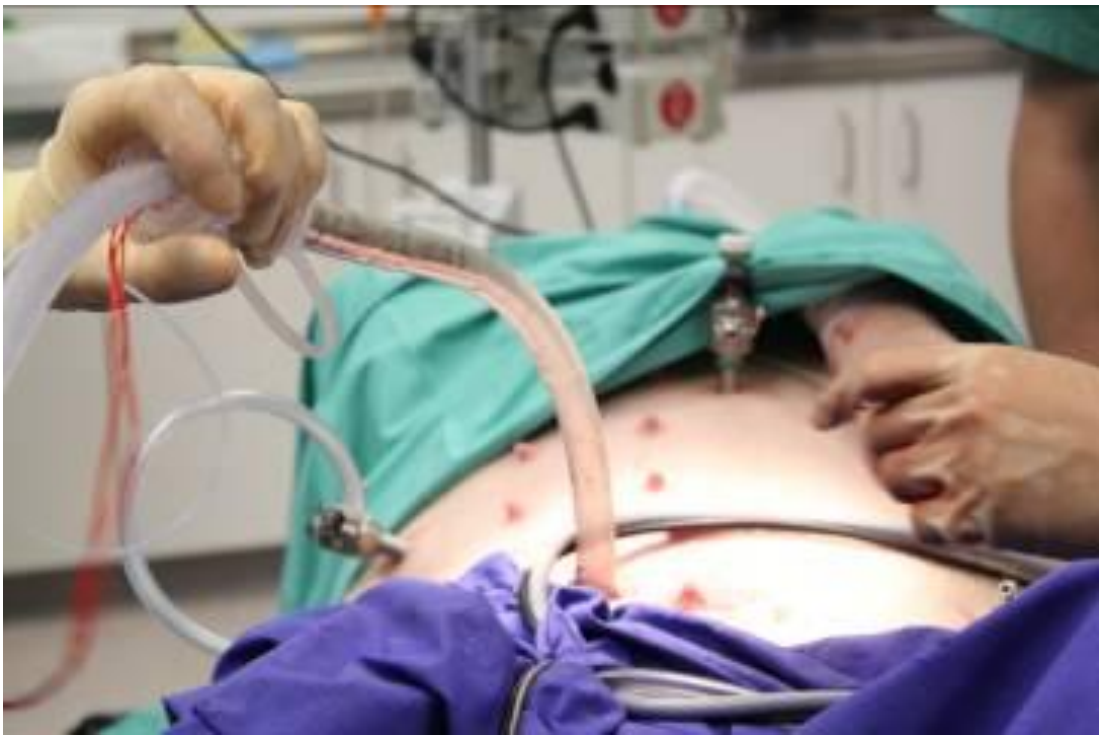

Figure 15: Insertion of the opened Research Platform via the access tube.

Figure 16: Closure of the Research Platform in the abdomen to its triangular shape.

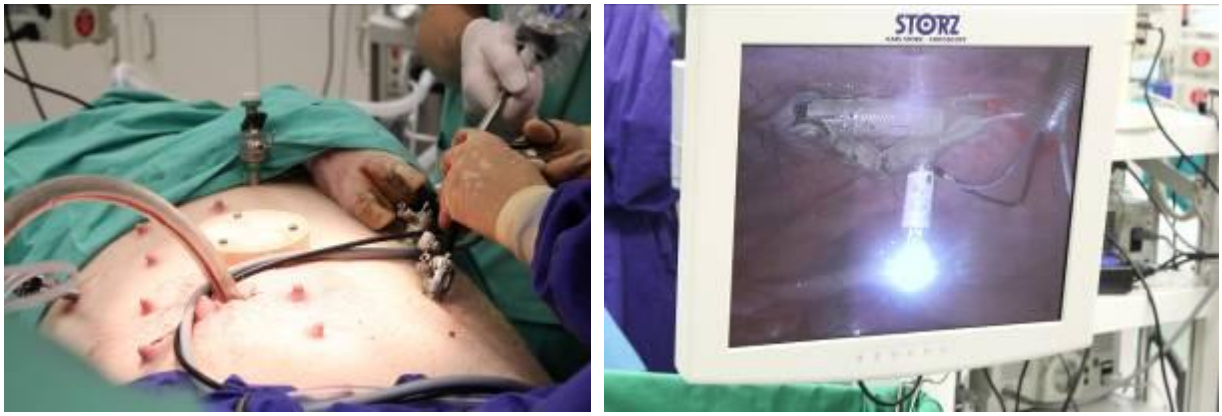

Figure 17: Left: Round magnet on the outside of the abdomen; Right: Research Platform attached to the inner wall of the abdomen by means of magnetic forces. The image shows the finally installed Research Platform with the camera attached.

As next step the tethered laparoscopic camera was inserted through the tube to enter the abdominal cavity. With the assistance of laparoscopic instrumentation the rear end of the camera unit was inserted into the connector part of the Research Platform (Figure 18). This maneuver was simple to perform. In a former version the connection of the camera and the Research Platform was done by means of magnetic forces. This caused magnetic conflict with the fixation of the Research Platform and with metal instruments. With the new connector realized in the recent version of the Research Platform these difficulties were overcome.

After proper fixation of the camera at the frame of the Research Platform, the camera system was used for inspection of the abdominal cavity (Figure 17). The camera has a

deflectable front-section that can be bent around 60 degrees to change the line of sight. The global position of the camera can be modified by moving the ARAKNES Research Platform using the magnetic fixation system at the abdominal wall.

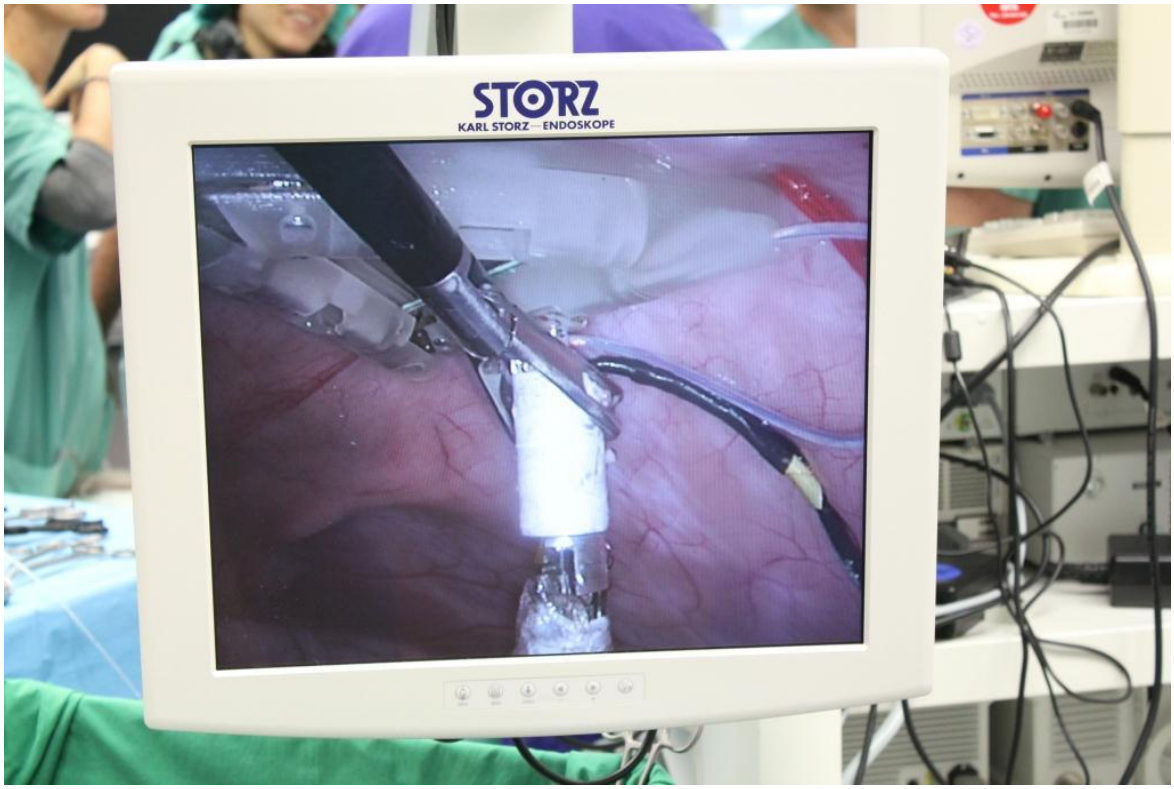

Figure 18: Insertion of the camera into the frame of the Research Platform.

2.2.3 Results

It was surgically feasible to position the Research Platform inside the abdomen and close it to a triangle without any problems. The attachment to the wall of the abdomen with the magnet went also well and the Research Platform could be easily moved along the wall of the abdomen using the magnet. Also attachment of the camera module to the platform went fast and without technical issues.

By combining these results with the feasibility of the NOTES procedure as assessed in the previous tests, we can conclude that the Research Platform, with its assembled modules, was successfully assessed for simple-trocar or NOTES procedures.

3 Assessment of the perfusion sensor

3.1 Animal trial of June 2012

This is a short summary of the experiment performed on 4-5 June. The experiment and the data generated are part of the report by UB and are not repeated in our report.

All procedures for testing the perfusion sensor (please see report by UB) were carried out under general anaesthesia with the laboratory animal in supine position. A midline laparotomy was performed; the small bowel and the stomach were displayed and opened for putting the sensor in direct contact with the mucosa surface of the respective organ.

The ischemia sensor is brought into direct contact with the tissue for baseline measurements. Then the perfusion of the respective area of the stomach or small bowel segment was interrupted by ligating or crossclamping vessels and organ wall.

The measurements were continued on the tissue restricted from perfusion. As the next step re-perfusion was allowed by removing the ligatures an opening of the clamps.

These maneuvers were repeated several times each (please see report by UB).

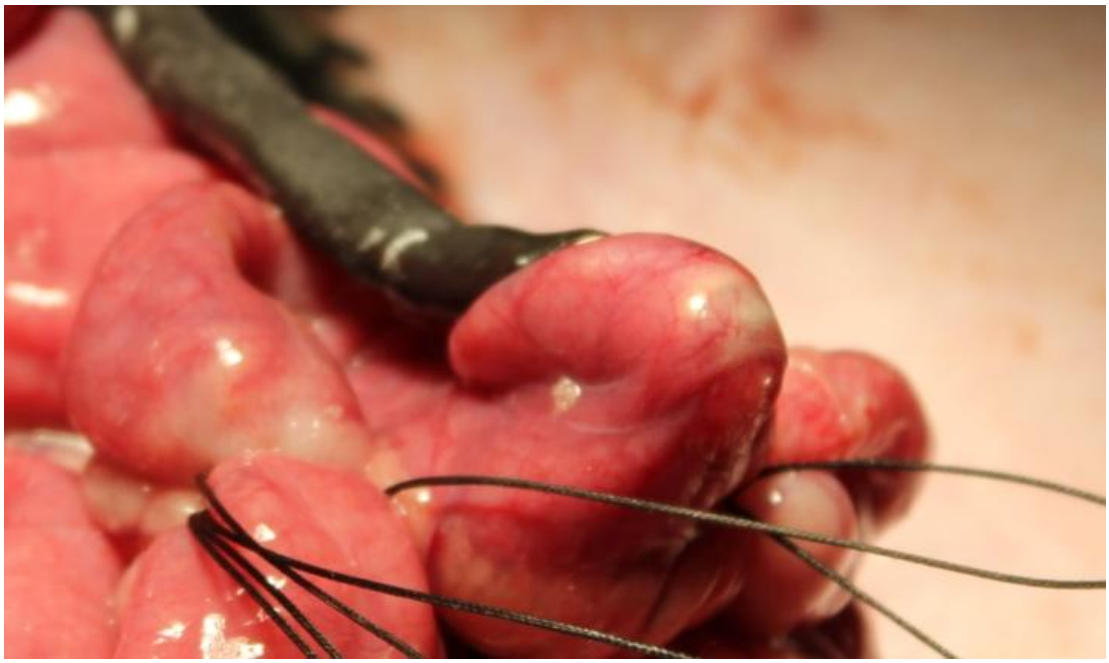

Figure 19: Sensor inserted into a small bowel loop, touching the mucosa. Ligatures for restricting perfusion.

4 Assessment of the Scarlett magnetic assistive platform

4.1 Animal trial of June 2012

The assessment of the Scarlett assistive platform was already reported in detail at the 2012 review meeting of the project. In this report we would like to give a summarizing overview of this test.

The purpose of the experiment was to study the use of laparoscopic instrumentation with multiple DOF (r2 CURVE, Tuebingen Scientific) in a single port approach, supported by assistive retraction of tissue independent from the single port access.

For this purpose the magneto-robotic unit Scarlett (OVE, NVN) was used to provide magnetic movement and traction to a magnetic grasper deployed and attached to the gallbladder. After the tip of the grasper has been placed and locked at the gallbladder, the tip was detached from the shaft of the instrument and left in place. A magnetic body has before been fixed to the detachable grasper tip, thus forming an object for magnetic attraction.

The magneto-robotic unit Scarlett is a mobile robot arm specifically developed for magnetic field application in surgery, to assist the ARAKNES core surgical platform with compatible surgical tools such as for trocar less retraction maneuvers and magnetic camera steering. The robot arm is a 5 DOF kinematics able to position and rotate a permanent magnet (4 kg) at the distal tip in all relevant directions. Special attention has been paid to the usability aspects as well as safety aspects of the robot arm that were implemented. The magneto-robotic unit has been realized on a laboratory model level.

By moving the Scarlett robot by means of a joy-pad, the surgeon was able to reposition the inner magnetic grasper, creating traction on the gallbladder tissue. This traction was used to support the exposure and dissection of the gallbladder by means of the multi-DOF instruments in single port technique.

The advantage of this approach was the independence of the assistive tissue traction from the movement of the single port instruments, allowing multi-directional dissection as it is common practice in conventional laparoscopic surgery.

This is seen as a relevant supportive means for complex single port procedures that are the target of the SPRINT robotic technology. Operation of the robotic arm proved to be subjectively easy and no conflicts arose with the surgical instrumentation or working space of the surgeons or assistive staff. The maneuverability in terms of speed, precision and stability was sufficient to perform key surgical tasks.

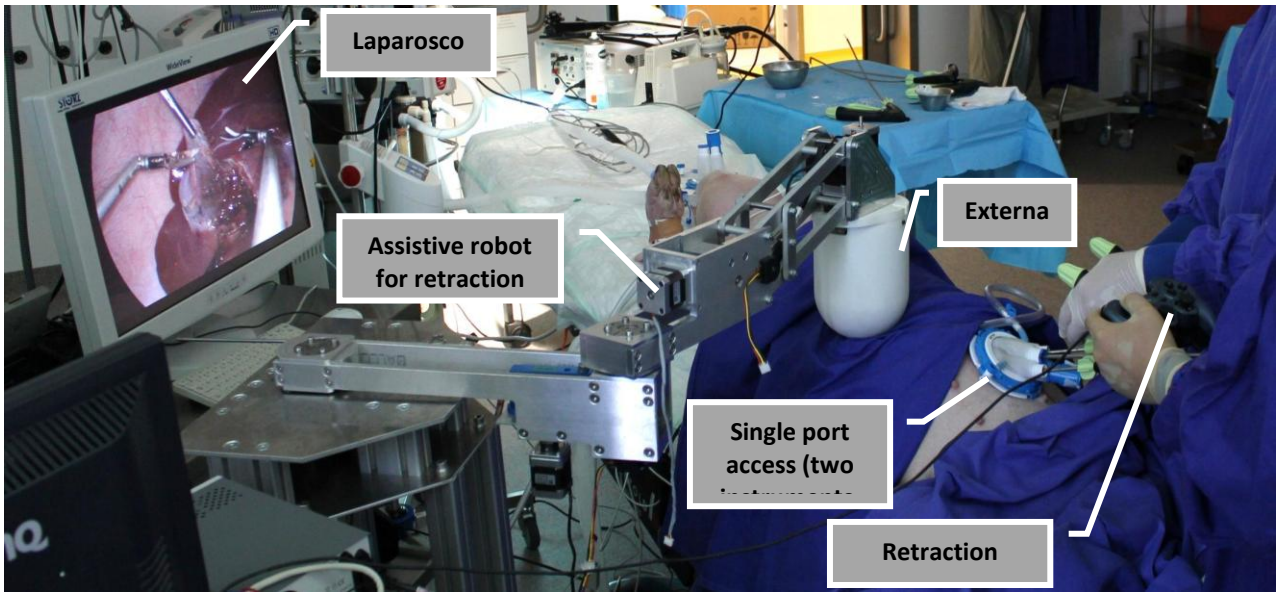

Figure 20: Setting at the OR table, see legends.

5 Conclusion & Discussion

The assessment of the ARAKNES platform has been an iterative process throughout the project to support the partners in defining medical application scenarios, drawing specifications derived from medical use conditions and to study the performance of functional device models and prototypes.

Thus, the results of the ex vivo and in vivo experiments have been part of the basis of the development of the ARAKNES technologies.

In more specific terms, the key development achievements in the area of single port robotics and allied technologies in the ARAKNES project have been subject to the surgical experiments. This concerns in particular the SPRINT system and the Research Platform.

For both systems the successful application according to their intended use as research prototypes in realistic surgical conditions could be demonstrated. The experiments had the character of fundamental feasibility studies and not of parametric evaluation in standardized settings. This is on one hand a limitation, on the other hand it can be understood from the breakthrough nature of the ARAKNES technologies. All devices studied in WP10 require full technical support by a highly qualified engineering team and cannot yet be used in more routine-like settings of experimental laparoscopic surgery. This is a common situation in the evaluation of entirely novel medical technology.

WP10 was able to establish the fundamental feasibility of the ARAKNES robotic technology concept and was able to verify the functionality of the key prototypes of the project.