Workshop on Safety in Robotic Surgery

**Date:** Tuesday, 25th June 2013  
**Venue:** Room Number TBC, Sir Alexander Fleming Building, Imperial College London, SW7 2AZ  
**Location:** No 33 on the South Kensington Campus

**Workshop Aims:**

This workshop aims at summarizing the results and on going discussions within some of the EU-funded projects in robotic surgery, such as SAFROS, STIFF-FLOP, Active and micro-Ralp. Although patient safety in all types of surgery seems an obvious concept, the close examination of patient safety in the specific case of robotic surgery raises a number of concerns. The validity of these concerns is demonstrated by the steady growth of lawsuits brought against the manufacturer of surgical robots by patients injured during robot-assisted procedures. Safety in surgical procedures involving high technology devices is a system issue that cannot be solved by optimizing only one, or few, elements involved in the procedure. The optimal balance may be achieved by a combination of factors, including technology management, training, logistics, and concentration of robotic procedures into centers of excellence.

**Workshop Program:**

14.00-14.05 Paolo Fiorini, University of Verona, Italy  
**Introduction and Workshop Objectives**

14.05-14.20 Kaspar Althoefer, King's College London, UK  
**STIFF-FLOP - An inherently safe approach to MIS: Challenges and initial developments**  
The presentation will give an overview of the EU project STIFF-FLOP (STIFFness controllable Flexible and Learn-able manipulator for surgical OPerations) and report on developments until now. I will highlight the conceptual ideas driving the project and how these relate to safety considerations in the context of minimally invasive surgery. Challenges emerging when departing from traditionally rigid instruments and progressing towards flexible and even stiffness-controllable surgical tools will be discussed. Safety aspects have been investigated as part of the project and initial results will be presented.

14.20-14.35 Paolo Fiorini, University of Verona, Italy  
**The Safros Paradigm**  
Patient safety is a broad term, touching upon several areas spanning from medicine training to surgical procedures and engineering. Some of its key elements are:  
- **Recognition of organs** in ultrasound and CT imaging, to improve robot guidance.  
- Inexpensive **organ phantoms** that replicate the texture and other properties of real organs that would prove beneficial during low cost, ethical training.  
- **Virtual surgical simulation** based on physical realism.  
- An integrated **operating room monitoring system**, to provide a working environments where humans and robots can interact safely.
• Improvements on controlling surgical robots, to control algorithms able to limit the robot’s movements to improve its precision and reliability during unforeseen events.
• New telepresence interfaces.
• Standardized safety interface, i.e. a central system that collects data in the operating theatre and is able to prioritize it for the OR staff.
• Standardised training curricula for robotic surgery, based on sound educational paradigms applied and using virtual as well as physical simulations.

These areas were addressed during the project SAFROS, Patient Safety in Robotic Surgery, and will be described in this talk.

14.35-14.50 Prokar Dasgupta, King’s College London, UK
Safety aspects of modern approaches to robotic surgery
The lecture will highlight the translational aspects of robotic surgery such as image guidance and haptic maps to help the surgeon distinguish between healthy and diseased tissues. It will also discuss new robotic design to facilitate LESS and NOTES. Finally it will bring attendees up to date with the most important aspects of simulation for robotic training and patient safety.

14.50-15.05 Alberto Arezzo, University of Torino, Italy
Surgical robotics practice: the digestive surgeons perspective
Fifteen years after the introduction of robotics in general surgery practice, the exact role is still debated. Evidence-based and transparent methods failed to prove an advantage in terms of clinical results. Nevertheless there are at least three good reasons to insist in the development of robotic devices:

1. to do better, things already done by standard laparoscopy; but this was not the case when robotics where compared to standard laparoscopy in performing adrenalectomy, fundoplication for gastro-esophageal reflux disease, and more recently gastric by-pass as a treatment for obesity;
2. to do more often procedures in a laparoscopic way, that require lots of skills under standard condition, as they become easier; this might be the case of the treatment of rectal cancer, which is still done laparoscopically in less than 15% of cases in the western world, and which, in a recent well-known meta-analysis of published data, we could demonstrate that if approached laparoscopically, mortality might reduce of more than 50% compared to open surgery, with a statistically significant difference, as well as overall morbidity, could reduce of about 20% in a much more significant way; so that to expand this 15% of cases done laparoscopic might have tremendous effects; but the actual technology seems still not adequate to do this, as the opinion published on one of the most famous journals of Medicine, the N Engl J Med 363:8 19, 2010, concludes “To date, there have been no large-scale randomized trials of robot-assisted surgery, and the limited observational evidence fails to show that the long-term outcomes of robot-assisted surgery are superior to those of conventional procedures.”
3. to enable procedures of evident benefit for the patient which are not possible today with existing endoscopic technology, so that other possible applications and field of development are of course all the application of NOTES (Natural Orifices Translumenal Endoscopic Surgery), or the treatment of early cancers of the digestive tract, which survival is strictly related to the stage at diagnosis and removal.

We are in the phase at which Engineers should consult Clinicians to collaborate in the harmonization of procedures & instruments. We look forward to a robotic system which will be user friendly, would have flexibility in achieving remote areas of the abdominal cavity, force feedback and could allow miniaturization for NOTES applications.
15.05-15.20 Joerg Raczkowsky, Karlsruhe Institute of Technology, Germany

**Safety in robot assisted surgery by operating room monitoring**

The introduction of robot technology into the operating room aims to improve the therapy outcome. This also includes the topics basic safety and essential performance. In the frame of the EU FP7 project SAFROS a camera based monitoring system as an integral part of the operating room framework OP:Sense was developed. In order to make the first step towards situation awareness in the operating room all activities will be tracked by the system. It consists of different types of cameras: fiducial tracking, photonic mixing devices and Microsoft Kinect®. This sensor system delivers a huge amount of data of the surgical actions including patient, surgical personnel, robots, devices and tools. Partially, these objects are modelled as CAD models and could be identified by fiducials. Other objects have to be reconstructed based on 3D camera data. All information contributes to an online dynamic scene model for two different main purposes: (1) safety check depending on the actual state of the surgical workflow (2) sophisticated human machine interface by gesture interpretation. This research work is leading to future smart operating room.

15.20-15.35 Neil Abroug, CEA LIST DIASI, France

**Safety of operations of Robots in Healthcare**

This talk will present the architecture ensuring safety for application involving robots in healthcare. One of our first applications was a complete exoskeleton for quadriplegic people using invasive technologies. We will reuse this architecture in our surgical robotics platforms. We will describe how the solution proposed ensures machine safety, and the process to get the approval from the commissions in France allowing usage of a robot with patients.

15.35-15.50 Giancarlo Ferrigno, Politecnico di Milano, Italy

**Safety issues for robot in neurosurgery**

Safety is a primary issue in robotics. When cages cannot be used (typically in service robotics where machines and humans should cooperate), sensors and controls must be added to guarantee human protection against malfunctioning. In surgery the issue is still more complicated since the machine is working on a patient and this is particularly challenging in brain neurosurgery, given the size of operating volume that, if injured, can lead to severe permanent damages to the patient. Classical technique for increasing safety is the use of redundant sensors and hardware watch dogs. Safety is further challenged if the surgical robot is endowed with some autonomous behavior, since this may be unpredictable. The risk connected with autonomy can be tolerated if not allowing the autonomous behavior increases the threat to the patient. A typical example of this is the Cyberknife robotic system for radiotherapy that corrects, autonomously and without possible human intervention, the patient's movements during the dose delivery. In the ACTIVE FP7 project, the safety issue is tackled at several levels. The procedure is workflow driven with proper branches to safe state when hazard is detected. The OR is monitored by depth cameras detecting the actions of the staff and possible unwanted contacts or collisions. Active constraints are enforced for preventing adverse effects due to surgeon distractions or tiredness. Tool positions are monitored with more sensors (camera and encoders) in order to check for undetectable robot malfunctioning (broken encoders, registration errors etc.).

15.50-16.05 Timo Cuntz, Fraunhofer IPA, Germany

**Man-Machine-Team for Laparoscopic Interventions**

Our idea is that, surgeons and robots would be working together as a team at the operating table. The question whether to perform the surgery by hand or using robots does not arise as both methods are possible in parallel. Our new approach combines the capability of precise instrument guidance, even in hard to reach areas, through the use of a robot with the fast and flexible method of operating by hand. The implementation of our vision is not possible with the existing, bulky robotic systems used nowadays in the or-room. As the space around the operating table is very limited for our approach, smart, small robots
that have a large but secure moving range are necessary. Therefore we have developed a new parallel kinematic based manipulator consisting of two spherical kinematic chains. This system combines stiffness and accurate positioning with highly dynamic movements.

To realize this slim robot system with a large operating space, which is needed for the Man-Machine-Team, small and lightweight but nevertheless strong robotic instruments are also necessary. To realize these instruments we have developed progressive, compact yet still powerful instrument-drives. These hydraulic powered drives provide ten times the power density of electromagnetic motors with actuator diameters below 3mm.

Having set up the hardware, our future development will focus on a functional, easy to use input device to complete the Man-Machine-Team.

16.05-16.20 Rainer Konietzchke, DLR, Germany

**Contributions of Robotic System Modelling to Increase Safety in Surgical Robotics**

This talk presents methods for modelling and simulation of a surgical robotics system and their potential to increase safety in surgical procedures. First, potential use cases are sketched, namely planning and training, workflow design and validation, user interface and robot design, and monitoring. Then, different levels of modelling detail are proposed and related to the use cases. Methods for precise robot calibration are essential for good consistence between model and real system and are therefore addressed in detail for elastic-joint torque-controlled robots. In conclusion, several realized example use cases are shown such as simulation-based user studies, achieved sensitiveness in collision detection and a planning procedure based on online workspace maps.

16.20-16.35 Leonardo de Mattos, IIT, Italy

**The μRALP approach to safer vocal cord surgeries**

Operations on vocal cords are classified as microsurgeries due to the diminutive size of the operating site, which requires the use of a surgical microscope and special tools such as micromanipulators. They also require extremely high dexterity from the surgeon to minimize damage to healthy tissue and achieve good quality outcomes, which for the patient translates into successful treatment with fast recovery time and minimum impact on voice quality. This is not easily achieved with current surgical technologies, but may soon be facilitated with technologies being developed within the μRALP project. A main focus of this project is on safety, both for the patient and the surgeon. This is being pursued through the design of a new surgical endoscope incorporating MEMS actuators and real-time cancer visualization systems, and the creation of an ergonomic and intuitive control interface featuring several levels of surgical supervision. Together these systems will deeply impact the overall safety of phonosurgery, and likely also that of other microsurgical procedures.

16.35-16.50 Abdi Elahe, EPFL, Switzerland

**LIGRA: A LIfe Guard for Robotic surgery Assistance interface**

Global airline traffic systems have adapted standard and worldwide accepted rules and regulations to guarantee the safety of passengers and crews since many years ago [1]. Learning from safety procedures in this domain is hence a motivating way to make medical systems, e.g. surgical operations; safer [2].

We focused on surgery applications and our objective is to contribute in establishing unified and strict guidelines to improve patient safety and avoid damages and injuries due to factors such as negligence of the medical staff or lack of coherence in team work.

In this paper, we will present The LIGRA interface (LIfe Guard for Robotic surgery Assistance) [3]. We developed this application as a supervisory interface. It is a user friendly graphical interface visible to all the surgical staff. It centralizes all the information related to the surgical robot and other modules which may be useful for the surgical team such as the performance of the robot, the temperature of the surgery room, etc. The structure of the interface reflects the “belong-to / composed-by” relationship of technical components. The information displayed on the screen can
be updated in real-time depending on the flow of data from different modules. In case of undesirable situations, the system generates graphical and acoustic warnings and errors depending on the pertinence of the fault. Furthermore, the system is linked to a database on which all the gathered data during surgery are saved and is accessible later on. An interactive version of World Health Organization (WHO) Patient Safety Checklist [4] is integrated in the interface as a reminder of the essential checks and verifications to be made prior, during, and after the surgery. This interface has been developed during the European project SAFROS (Safety in Robotic Surgery) [5]. Nowadays there is no similar tool in operational robotics. 8 surgeons in Fondazione Centro San Raffaele have evaluated it by answering to some questionnaires. The results are quit promising and the interface is now integrated in the Mirosurge robot at DLR [6].

References

16.50-17.05 Evren Samur, Bogazici University, Turkey
Role of Haptics in Surgical Robotics:Safety Perspectives
Robotic surgery has been a domain of intense research activity in recent years. Despite the certain benefits such as providing high-definition visualization system and enhanced dexterity, the use of a teleoperated robotic system removes the direct contact of hands with tissues and thus, diminishes the sense of touch. All information about the patient is given to surgeons only through the visual sense. This imposes surgeons to exclusively rely on visual cues, compromising patient safety and telepresence. Up to now, the potential of haptic feedback in robotic surgery has not yet been fully exploited and thus, this application still represents a fascinating research field.
In this talk, I will discuss the role of haptic feedback in surgical robotics from the safety perspectives. An overview of available haptic technologies will be given and their limitations will be discussed.

17.05-17.30 Questions and Round table