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## **OR Black Box and Surgical Control Tower: recording and streaming data and analytics to improve surgical care**

Pietro Mascagni<sup>1,2</sup>, Nicolas Padoy<sup>1</sup>

1. ICube, University of Strasbourg, CNRS, IHU Strasbourg, France
2. Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy

### **Corresponding author:**

Nicolas Padoy, Ph.D.

ICube, c/o IHU-Strasbourg,

1 Place de L Hôpital,

67000 Strasbourg, France

Email: npadoy@unistra.fr

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**Running title:** Surgical Data Science for Surgical Safety

**Highlights**

- Modern surgery is a highly effective yet error-prone sociotechnical process performed on more than 300 million people yearly
- Surgical Data Science is a novel discipline using surgical digital data and advanced analytical methods to improve surgical care
- Operating room (OR) black boxes record data from multiple sources to study factors affecting surgical safety, while surgical control towers analyze live surgical data to provide real-time assistance during surgical procedures
- Early works on the topic have shown the occurrence of an average of 20 errors per procedure, have developed algorithms capable of recognizing the workflow of surgery with over 80% of accuracy and have designed advanced visualization methods for radiation safety during X-ray based procedures
- Surgical data and artificial intelligence will contribute to a fourth surgical revolution characterized by smart assistance in perceptual, cognitive and physical tasks

## **Summary**

Effective and safe surgery results from a complex sociotechnical process prone to human error. Acquiring large amount of data on surgical care and modelling the process of surgery with artificial intelligence's computational methods could shed lights on system strengths and limitations and enable computer-based smart assistance. With this vision in mind, surgeons and computer scientists have joined forces in a novel discipline called Surgical Data Science. In this regard, operating room (OR) black boxes and surgical control towers are being developed to systematically capture comprehensive data on surgical procedures and to oversee and assist during operating rooms activities, respectively. Most of the early Surgical Data Science works have focused on understanding risks and resilience factors affecting surgical safety, the context and workflow of procedures, and team behaviors. These pioneering efforts in sensing and analyzing surgical activities, together with the advent of precise robotic actuators, bring surgery on the verge of a fourth revolution characterized by smart assistance in perceptual, cognitive and physical tasks. Barriers to implement this vision exist, but the surgical-technical partnerships set by ambitious efforts such as the OR black box and the surgical control tower are working to overcome these roadblocks and translate the vision and early works described in the manuscript into value for patients, surgeons and health systems.

**Key words:** Surgical Control Tower, OR Black Box, Surgical Safety, Surgical Data Science

## Introduction

The effectiveness and volume of surgery has dramatically increased in the last decades, with more than 300 million procedures performed in 2012[1]. However, surgery is still not the safe place we would like it to be, as surgical adverse events represent a great part of medical mistakes[2], the third leading cause of death in the United States[3]. Furthermore, the large volume of procedures performed turn even low incidence safety treats into major global health issues, making surgical safety a research priority.

When performing an operation, surgeons need to communicate with a team of highly specialized collaborators, capture and interpret multiple signals coming from high-tech devices, recall and project surgical principles into the present case, anticipate consequences of decisions and, finally, act in a timely manner for the benefit of patients. The success and coordination of all events of this highly complex sociotechnical process result in effective care. However, this process demands a high physical and cognitive effort and any flaw in it can translate into harms for patients.

Modelling the surgical process with data and analytics could offer tremendous insights to optimize surgical care. Data-driven approaches in surgery have so far allowed to create high-fidelity simulators used to guarantee that competence is acquired in a safe setting[4] and to design cognitive aids such as checklists and time-outs[5] to make sure that the right information is recalled at the appropriate moment and is delivered to the right team member.

Surgery has learned to implement these solutions from other high-stake, team-based, technology intensive sectors as aviation and Formula One[6,7]. The reliance on operating room (OR) black boxes[8] and surgical control towers[9] could be the next lesson learned to improve surgical efficacy and safety. OR black boxes, similarly to flight recorders, are designed to systematically capture OR data from multiple sources in order to allow post-

operative (offline) analysis of error and near misses while surgical control towers, similarly to air traffic control towers, are being developed for real-time (online) data streaming and analysis, as a means to oversee, coordinate and feedback operators on OR activities.

The present paper will introduce the key elements enabling the vision of data-driven solutions in surgery, describe insights from early works related to OR black boxes and surgical control towers, illustrate a future scenario in which advanced analytics are used to promote safety in laparoscopic cholecystectomy, and conclude with a perspective on the road ahead.

### **Big Data and Artificial Intelligence for Surgical Data Science**

The growing uptake of image-guided interventions, such as minimally invasive surgery, interventional radiology and surgical endoscopy, is not only revolutionizing how we care for patients but also how we study surgery[10]. Indeed, the images guiding these procedures, whether radiological or endoscopic, are a natural source of direct, unbiased and rich information on intraoperative events. These digital images are much more informative and reliable than operator dictated post-operative reports and, if properly analyzed and quantified, could shed light on OR events and inform on strategies to improve safety. In addition, these visual information on surgical procedures can be enriched with other data generated in the OR - such as anesthesia monitors, OR devices usage, additional intraoperative imaging[11], environmental cameras and microphones - and during perioperative care - such as patients' clinical history and outcomes stored in electronic medical records and imaging studies in picture archiving and communication system (PACS). The offline analysis of these surgical big data[12] could elucidate strengths and weaknesses of the surgical process to address with a system approach while the online processing of these

digital information could provide operators with timely and highly specific feedbacks to ameliorate patients care.

Machine and deep learning are needed to draw meaning out of surgical big data as these, by definition, are too large and complex to analyze with classical statistical methods[13]. These advanced computational methods automatically find complex patterns in data, learn to make predictions without being explicitly programmed and improve their performances with increasing amounts of data. These characteristics paired with state-of-the-art performances in computer vision and natural language processing tasks, such as guiding an autonomous vehicle or naturally answering questions, made deep learning in particular one of the main analytical techniques powering the recent surge in artificial intelligence (AI).

The availability of surgical big data and the growing accessibility of powerful AI techniques could allow to accumulate detailed knowledge on the surgical process through offline analysis and to extract timely and actionable insights to feedback to surgical staff through online processing (Figure 1). This is the vision of Surgical Data Science, a novel discipline using data and advanced analytics to improve the quality and safety of interventional healthcare[14].

### **OR Black Box, Surgical Control Tower and Related Works**

To fully exploit the large amount of digital surgical data, comprehensive information needs to be recorded in a standardized, synchronized and systematic manner. This has always been difficult in the OR, one of the most siloed part of the surgical cycle of care. Many have proposed to deploy audio-visual recorders[15,16], however this idea was only recently scaled by Teodor Grantcharov's group with the OR Black Box<sup>®</sup> (Surgical Safety Technologies Inc., Toronto, ON, Canada). Their multiport recording device captures synchronized audiovisual, physiological and environmental data from the OR[8]. So far, the comprehensive data

collected by the OR Black Box<sup>®</sup> were analyzed by specifically trained surgeons and served to shed light on system factors that characterize surgical safety. For instance, they identified most common distractions and counted a median of 20 errors per case[17], found out that coaching and proactive team management are the most frequent resilience supports in the OR[18,19] and that performance reports facilitate team debriefing[20].

These pioneering works demonstrate the tremendous potential of systematically acquiring and thoroughly analyzing comprehensive and direct observations of surgical events. However, up to now these offline analyses have been mostly performed manually. Manual analysis is a costly and labor-intensive process involving highly trained professionals prone to fatigue and errors. Analytical methods to automatically process and extract valuable information from large amounts of surgical data are needed to scale this approach. In addition, while humans often synthesize information qualitatively, analytical models such as deep learning algorithms “see” the information contained in images and audio files as matrices of bits and translate those into quantitative and reproducible information that could be used to precisely measure and predict outcomes of surgical value.

Such deep learning models would first need to understand the context[21] and workflow[22] of surgery to then be able to speak the “language of surgery”, i.e. gain information of higher semantic value. For instance, deep learning models were developed to recognize surgical instruments in 80 publicly available laparoscopic cholecystectomy videos (Cholec80)[23] with an average area under the receiver operator characteristic (ROC) curve above 0.99[24] while reliable tool localization[25] and tracking[26] (Figure 2a) were achieved on the same dataset deploying methods requiring very few human inputs. Such tool-tissue interactions information have indeed been used to gain insights of higher surgical value, such as estimating surgical technical skills[27] and detecting bleeding events[28]. Deep learning models were also trained to recognize phases of common procedures, as

surgeons do when learning a procedure. Automatic recognition of laparoscopic cholecystectomies[23] (Figure2b), laparoscopic sleeve gastrectomy[29] and colorectal surgeries[30] phases was achieved with above 80% of accuracy and could be used offline to quickly browse videos for coaching surgical trainees and to quantify statistical characteristic of surgical workflows for correlation with patient's clinical presentation and outcomes. In addition, phase recognition and tool detection predictions together could be used to localize critical moments in surgical videos and produce selective, condensed video for documentation and performance assessment[31]. Deep learning is also being used to study ORs' environment through videos acquired by ceiling-mounted cameras. In this setting, deep learning models were trained to detect[32] and estimate body pose of OR staff, also using videos recorded at low-resolution to preserve OR staff privacy[33] (Figure 2c). The information provided by the analysis of ceiling-mounted cameras videos, together with simulation and augmented reality visualization of X-ray radiation, have been harnessed by the Computational Analysis and Modeling of Medical Activities (CAMMA) research group (University of Strasbourg, France) to build a radiation awareness systems to quantify and visualize patients and clinician's radiation exposures during training for X-ray based procedures[34]. Furthermore, people detection and pose estimation algorithms, together with analysis of physiological signals reflecting operator's cognitive workload, are starting to be used to study OR team dynamics in order to devise cognitive engineering strategies[35] to improve non-technical skill impacting surgical safety.

Thanks to today's accessibility to powerful computational resources and advances in algorithms efficiency, the type of analyses so far described could be performed in real-time, online, to feedback surgeons during procedures. This would allow us to move from "counting", accumulating knowledge to devise system policies, to "acting", intervening during procedures with case-specific feedbacks. Online, surgical phase recognition and tool

detection models could, for instance, be used to efficiently coordinate OR staff and inform on ORs status. Furthermore, by comparing the current surgical workflow versus data of past cases, these models could trigger smart notifications warning surgeons of unexpected, risky scenarios before an adverse event occurs, as an air traffic control tower would notify two airplanes in a collision trajectory. CONDOR (Connected Optimized Network & Data in Operating Rooms)[36] is a French multi institutional project aimed at turning the vision of a surgical control tower into reality. Fundamental requisites to enable surgical control towers are that data can be streamed in and out of ORs in real time and can be synchronized with metadata, i.e. extra information on the data, such as the results of analysis to feedback in the OR. CONDOR contributed to these aspects by proposing a standard and interoperable format to store surgical imaging data and metadata in a synchronized fashion, namely DICOM-RTV (Digital Imaging and Communications in Medicine Real Time Video), and the development of an over IP (Internet Protocol) system to stream OR data in a matter of milliseconds[37].

### **Surgical Data Science for Laparoscopic Cholecystectomy**

Here we would like to motivate the use of the kind of approaches outlined above to promote safety in a common and highly standardized abdominal surgical procedure and depict a future scenario were the analytical models being developed today by CAMMA and other Surgical Data Science groups are used to support surgical care.

Laparoscopic cholecystectomy (LC) is one of the most common abdominal surgical procedures, with almost 1 million cases performed per year in the United States alone[38]. LC is a generally safe, often outpatient, procedure mostly indicated to treat benign diseases of the gallbladder[39]. The procedure is so common and well standardized[40] that is often among the first operations performed by general surgery residents. However, LC can also be extremely complex, requiring advanced technical and cognitive skills and at times resulting

in conversion to open surgery and/or adverse events[41]. The most feared adverse events of LC are bile duct injuries (BDIs), in 97% of the cases caused by the visual perceptual illusion of dividing the cystic duct while actually cutting the common bile duct[42]. Patients experiencing bile duct injuries have a threefold increase in mortality at 1 year[43], often sue (and win) their surgeons[44] and were estimated to cost about 1 billion per year in the United States[45]. A number of strategies have been devised to prevent BDI, including: preoperative patients stratification[41], identifying anatomical landmarks to safely start the dissection of the hepatocystic triangle[46], achieving a critical view of safety[47,48] or using additional imaging[49,50] to conclusively identify the cystic duct, and bailing-out to other procedures in case of anatomical doubts[51]. Despite the proved value of these approaches and the effort surgical societies are placing in decreasing the rates of BDI[52], scarce implementation of strategies for safe LC was reported[53,54] and this feared complication is still experienced by up to 2/3 of surgeons in their career[55].

In the future, Surgical Data Science solutions could foster the implementation of the safety strategies presented above by aggregating and processing data and automatically providing timely support to surgical staff.

In this future scenario, a machine learning algorithm detects a LC case in the surgical waiting list, pulls out of the electronic medical record the data necessary to predict the case complexity, and presents it to a surgeon identified as having the right expertise and technical skills (Figure 3a). Next, an appropriate OR slot is automatically reserved for the patient. Once in the OR, a virtual assistant informs the OR staff about the case peculiarities, expected events and guides the WHO Surgical Safety Checklist time out before skin incision[56] (Figure 3b). Intraoperatively, a deep learning model confirms or adapts the complexity expectations analyzing the first few minutes of the laparoscopic video. When the surgeon is about to start the dissection of the hepatocystic triangle, a deep learning model is triggered to

detect anatomical landmarks[57] and indicated whether the surgeon is incising the peritoneal reflection at the right high or is entering a “no go” zone[58] (Figure 3c). Before dividing the cystic duct, the hepatocystic anatomical structures are highlighted and the critical view of safety is automatically assessed[59] (Figure 3d). Based on the feedback, the surgeon is either given the green light to proceed with clipping and cutting, prompted to dissect further or bail-out. Throughout the whole procedures, the remaining surgical duration[60] and the needed instruments are displayed to the entire OR staff to increase situational awareness and readiness. Furthermore, OR data are continuously streamed to an external surgical control room from which senior surgeons are able to remotely proctor multiple cases and administrators can monitor OR status (Figure 3e). Last, following the procedure a complete report is automatically generated, and critical sequences of videos are stored for documentation, education and auditing purposes (Figure 3f).

### **The Road Ahead**

Recent surgical history has seen three major paradigm shifts, namely the introduction of general anesthesia, the implementation of asepsis and the uptake of minimally invasive procedures. The dramatic increase in the number and type of sensors deployed in surgical environments, the development of powerful algorithms capable to model complex data and learn from experience and the expanding armamentarium of precise and robotic actuators place surgery on the verge of a fourth revolution[14]. This fourth surgical revolution will be characterized by smart assistance in perceptual, cognitive and physical tasks[61] to augment[62] rather than replace surgeons[63].

Despite its potential impact, the fourth revolution is likely to be a gradual one. This is not surprising, as surgery, given its high-stake and complexity, is a tightly regulated field that has to scrutinize innovation[64]. The introduction of smart analytics, assistance and

autonomy in surgery will likely follow a course similar to the one being experienced by the automotive industry in their quest for safer and more effective transportation. The car manufacturer first introduced sensors and analytics in their vehicles to automatically warn drivers about engine problems and scheduled revisions, informing without intervening, a task that OR black boxes and surgical control tower could help implement in surgery in the near future. Then, they equipped higher-end models with smart driving supports in the form of lane-keeping and parking assistants, aiding the driver but leaving humans in full physical and legal control; highly standardized surgical procedures like cholecystectomy are likely to experience the kind of smart assistance depicted in Figure 3 in the next decade. Finally comes autonomous driving with its immense technical, legal and moral implications; Surgical Data Science and robotics together could someday lead to various levels of surgical autonomy[65], but this is still an uncharted territory.

It is now important to channel the energy resulting from the general enthusiasm surrounding AI in surgery to fulfill expectation with evidence of value. A number of challenges need to be faced in order to translate the fundamental Surgical Data Science works here described from the research domain to surgical practices.

First, AI models will have to show consistent performances across different settings, surgeons' preferences and patients' populations. Surgical data coming from multiple institutions and annotated by various surgeons in a standardized and shared manner should be stored in a public database available to research group and industries for benchmarking purposes.

Second, AI solutions will have to work within the technical constraints of ORs, namely limited computational power and data streaming capabilities. Recent developments in lightweight and efficient AI algorithms[66,67] and OR data transmissions frameworks like the one developed within the CONDOR project will help to find a middle ground.

Third, regulatory bodies will need to adapt their requirements for safety and efficacy evidence to make sure that this kind of innovation is neither fast-tracked by the hype surrounding it nor penalized by its novelty. In 2013, a working group formed by the International Medical Device Regulators Forum (IMDRF) and chaired by the U.S. Food and Drug Administration (FDA) defined these stand-alone medical software as “Software as a Medical Device” (SaMDs) and outlined characteristics, risk categorization, quality management and evidence requirements for SaMDs[68].

Finally, the more legal, economical and sociological implications of introducing smart devices in a highly sensitive field like surgery will need to be explored. The establishment of a permanent forum of stakeholders could facilitate the debate around open issues such as liability and moral implications of computer-aided decisions, reimbursement strategies, patients and physicians’ acceptance of various level of autonomy, the education necessary to effectively manage solutions at the intersections of technical and health sciences and, not less important, how to democratize worldwide access to innovation improving surgical safety.

Ambitious projects like the OR black box and surgical control tower formalize and disseminate the vision of improving surgical care with data analytics, promote surgical-technical partnerships to identify pressing needs and develop efficient solutions, and lay the technical foundations to deploy Surgical Data Science solutions for the benefit of patients.

**Conflicts of interest:**

- P.M. declares that he has no competing interest.
- N.P. declares that he has no competing interest.

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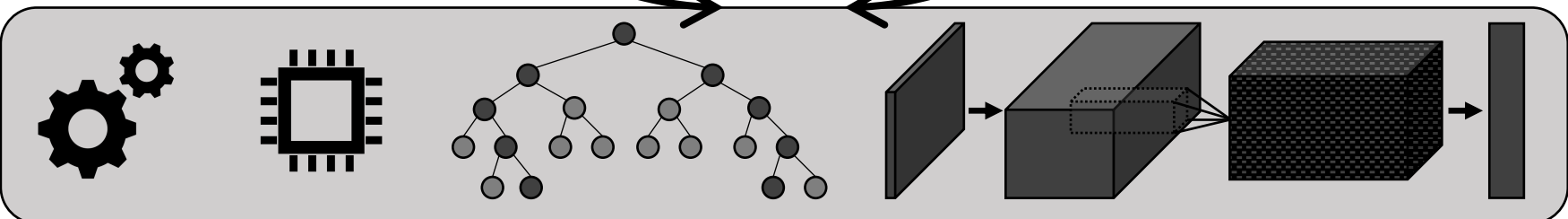
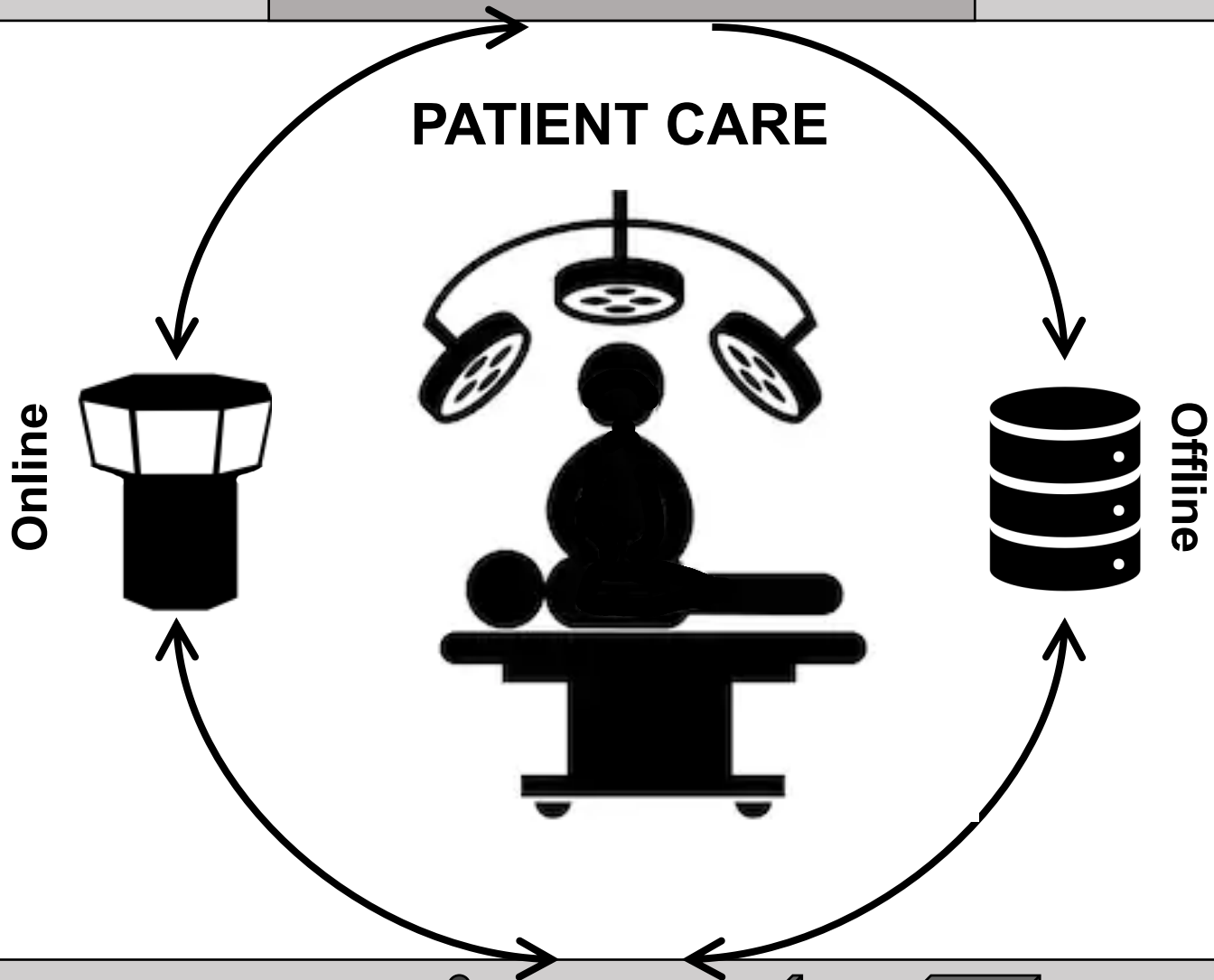
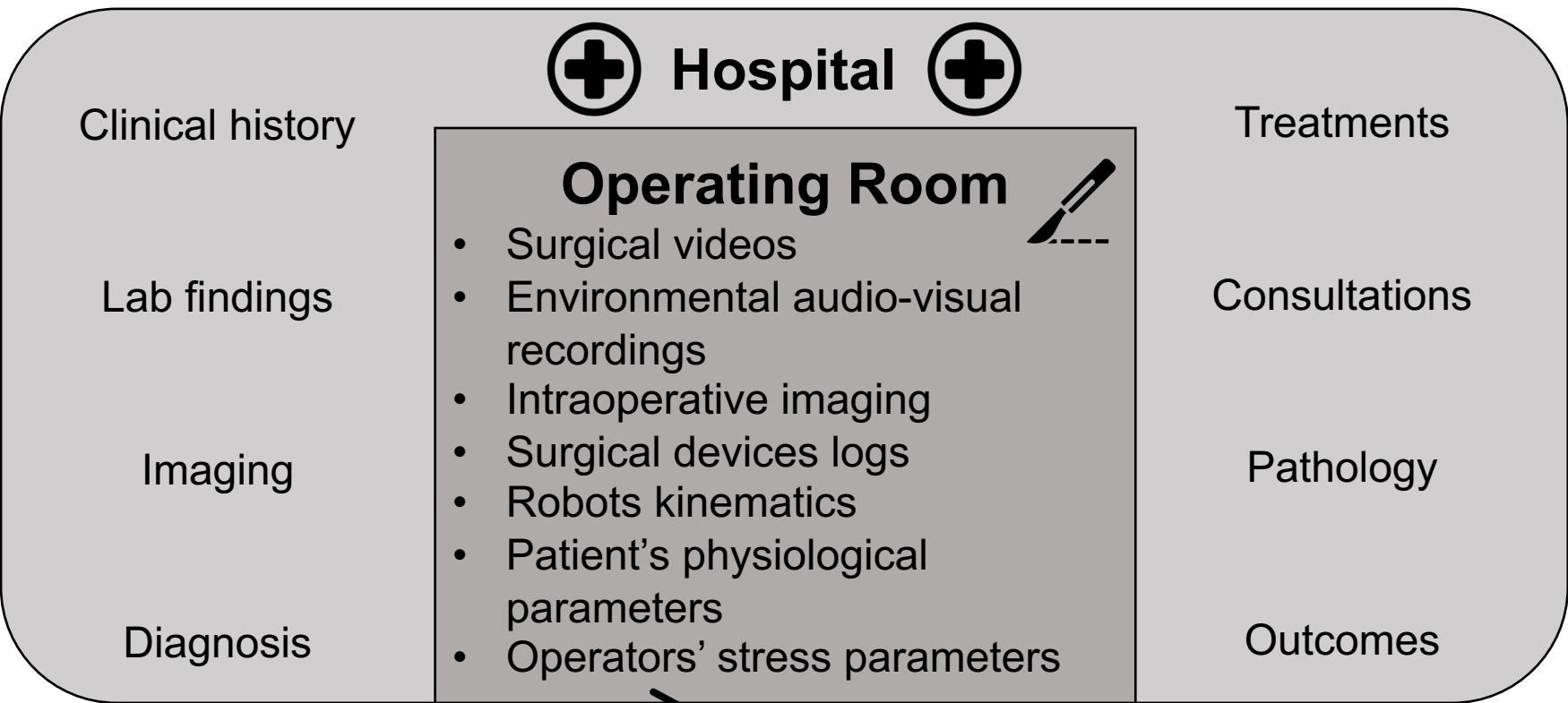
## Figures

**Figure 1.** Schematic representation of the Surgical Data Science framework. The large amount of data produced in the surgical cycle of care are systematically aggregated, analyzed offline for knowledge generation and online to generate actionable outputs, with the overall goal to enhance surgical care.

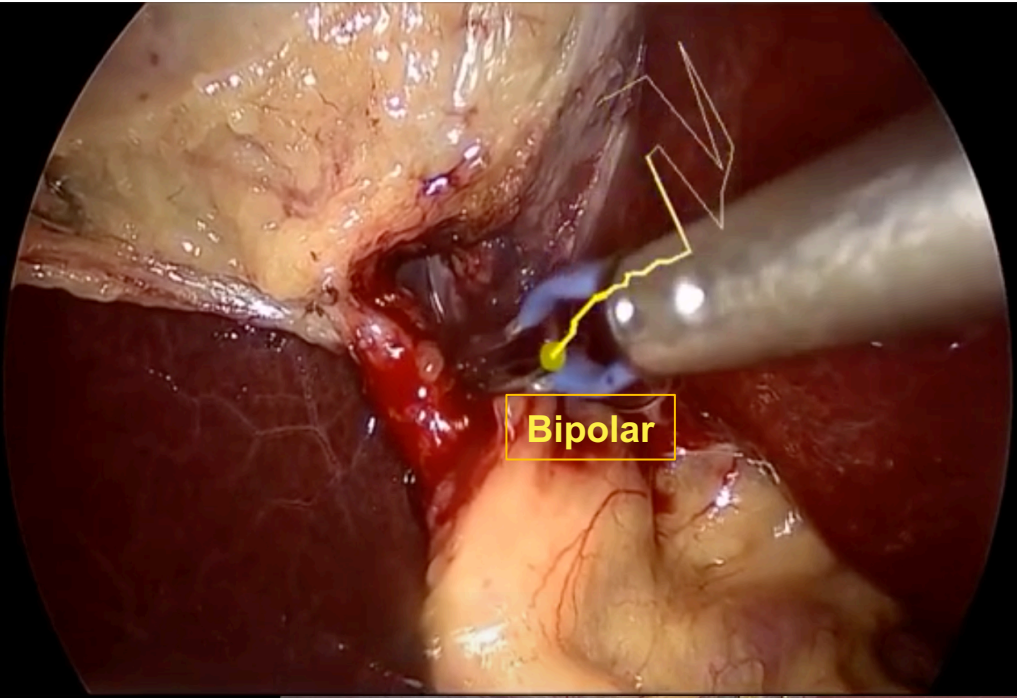
**Figure 2.** Illustration of tool tracking (a), phase prediction in laparoscopic cholecystectomy (b) and OR staff pose estimation (c). Videos showcasing qualitative results of CAMMA research are available here: <http://camma.u-strasbg.fr/videos>

**Figure 3.** Storyboard depicting of a future scenario in which various Surgical Data Science solutions are deployed along the cycle of care to promote safety in LC. EMR: electronic medical record; RSD: remaining surgical duration.

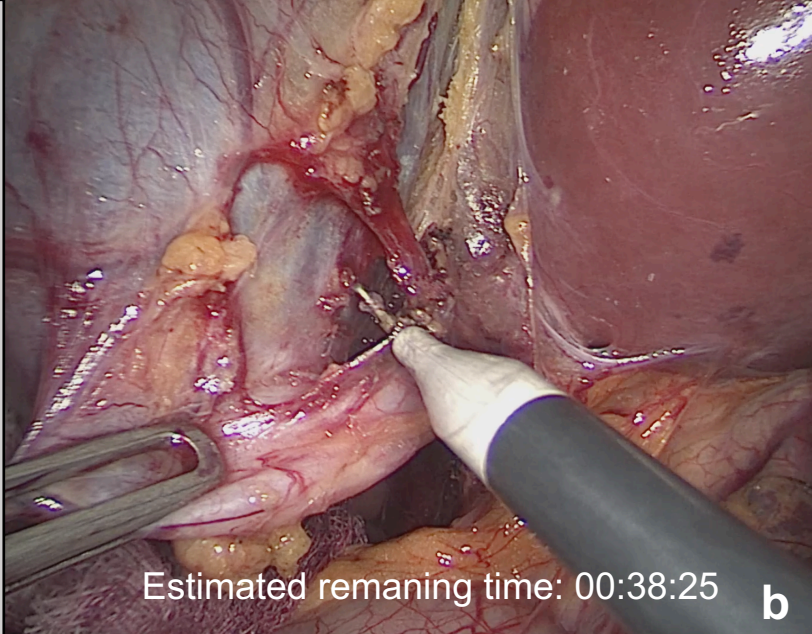
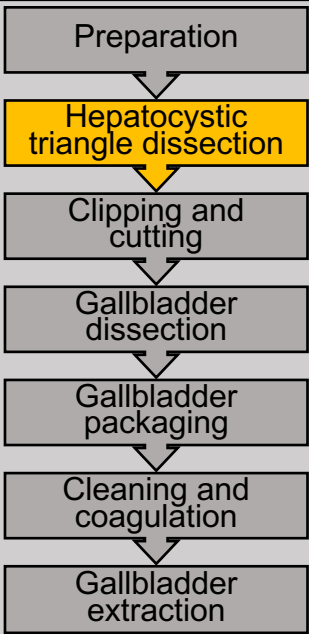
# SURGICAL BIG DATA



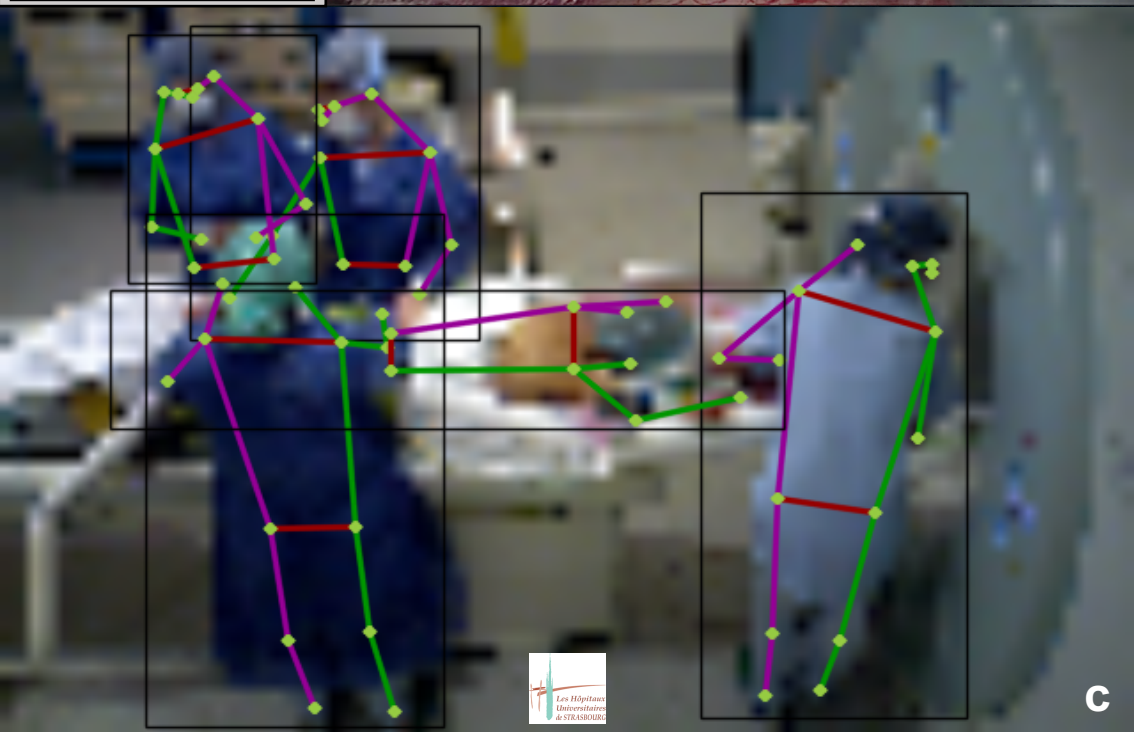
# ARTIFICIAL INTELLIGENCE



**a**



**b**



**c**

EMR



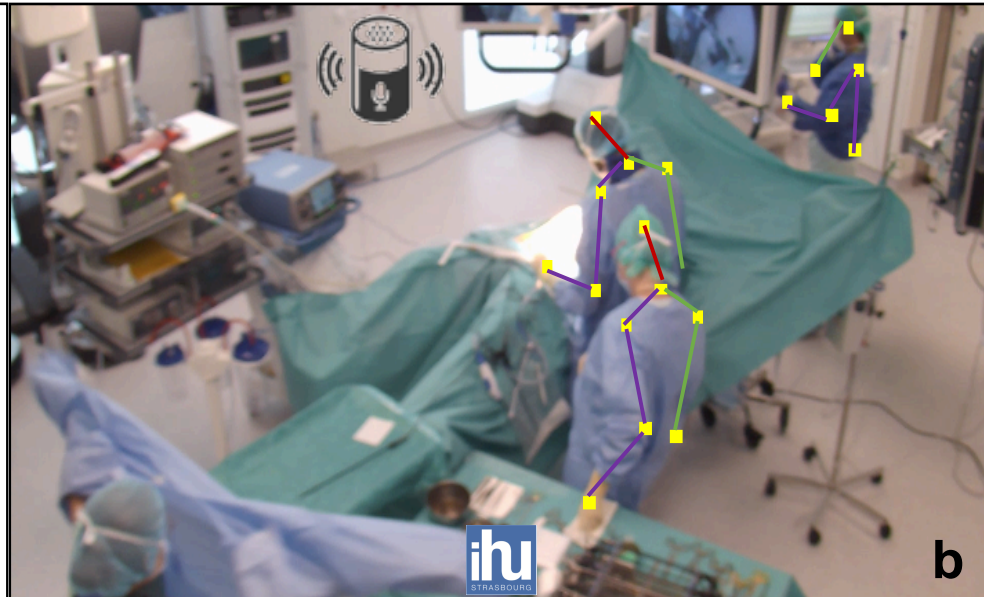
Preoperative  
imaging



Historical  
database



a



b

PHASE

Hepatocystic  
triangle  
dissection

PREPARE

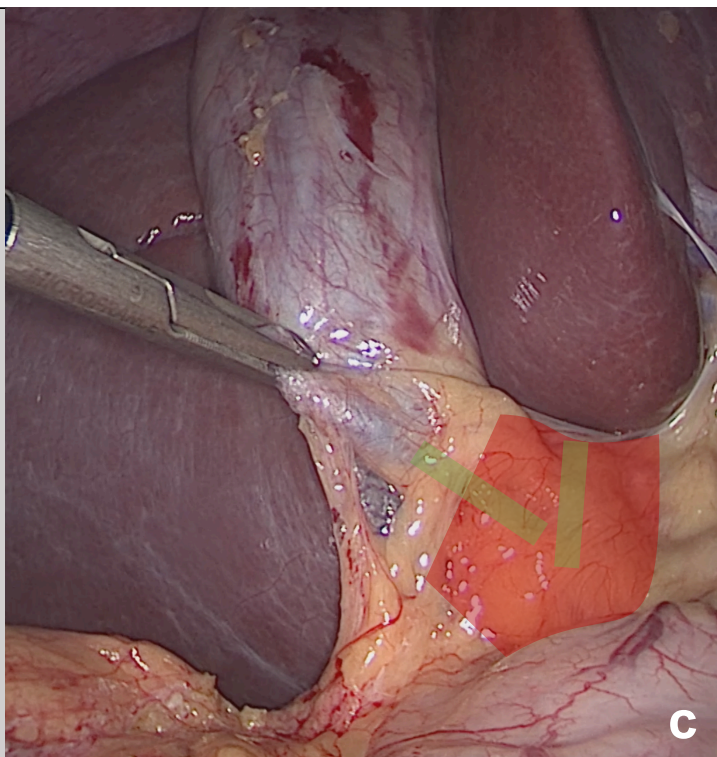
Hook

RSD

00:26:12

Smart  
assistance

ON



c

PHASE

CVS time out  
✓ Two  
structures  
✓ Hepatocystic  
triangle  
✓ Cystic plate

PREPARE

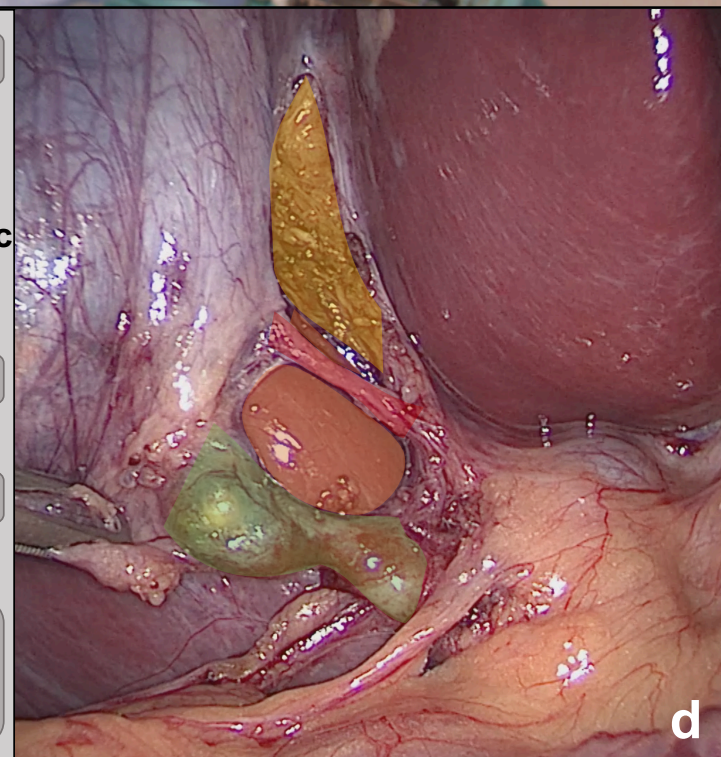
Clipper

RSD

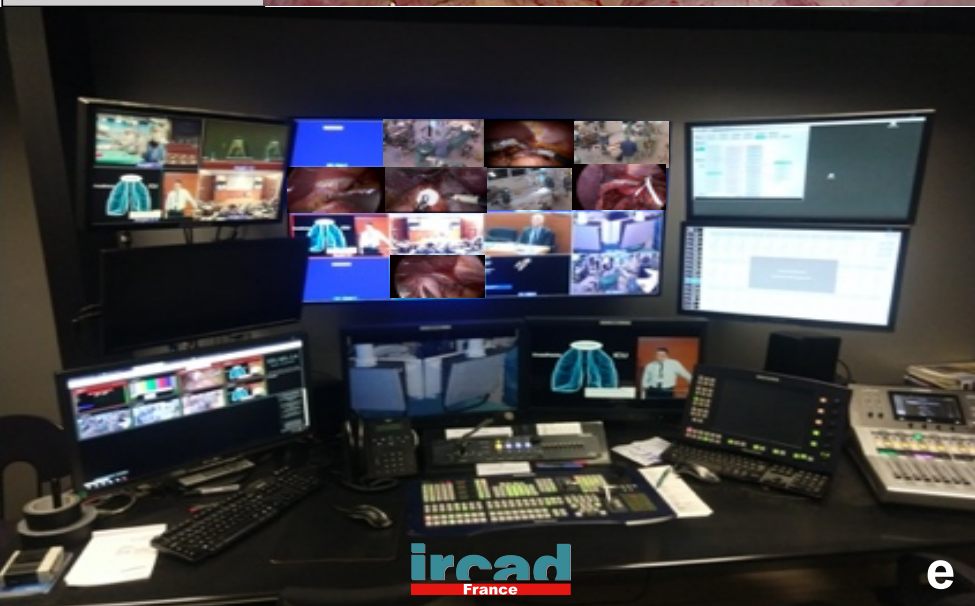
00:15:34

Smart  
assistance

ON



d

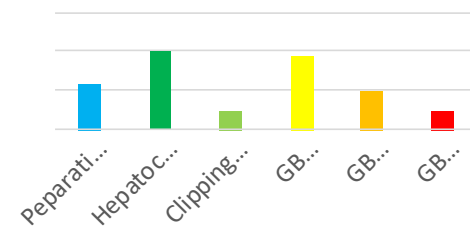


e

Report

Lorem ipsum dolor sit  
amet, consectetur  
adipiscing elit. Fusce vitae  
lacus eget leo ultrices  
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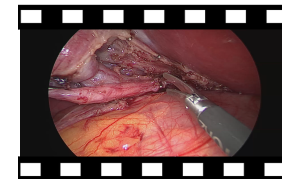
Phases



Events

GB perforation: 0  
Minor bleedings: 1  
Major bleedings: 0

Video



f