TECHNOLOGY AROUND THE MINIMALLY INVASIVE SURGICAL APPROACHES OF THE LIVER AND PANCREAS AND THE IMPACT OF THE VIRTUAL REALITY SENSING

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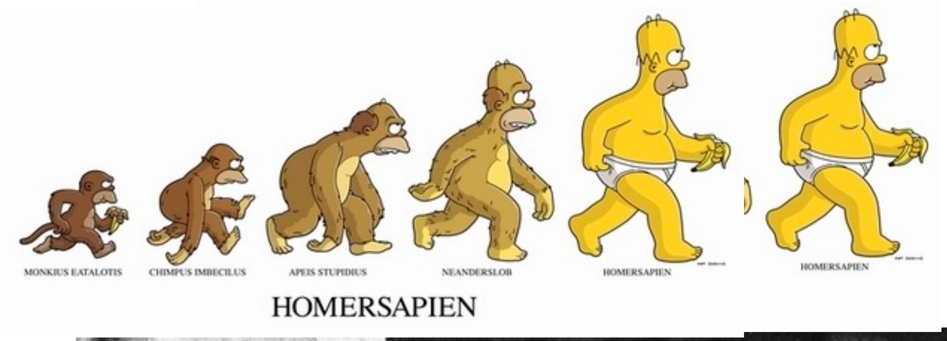
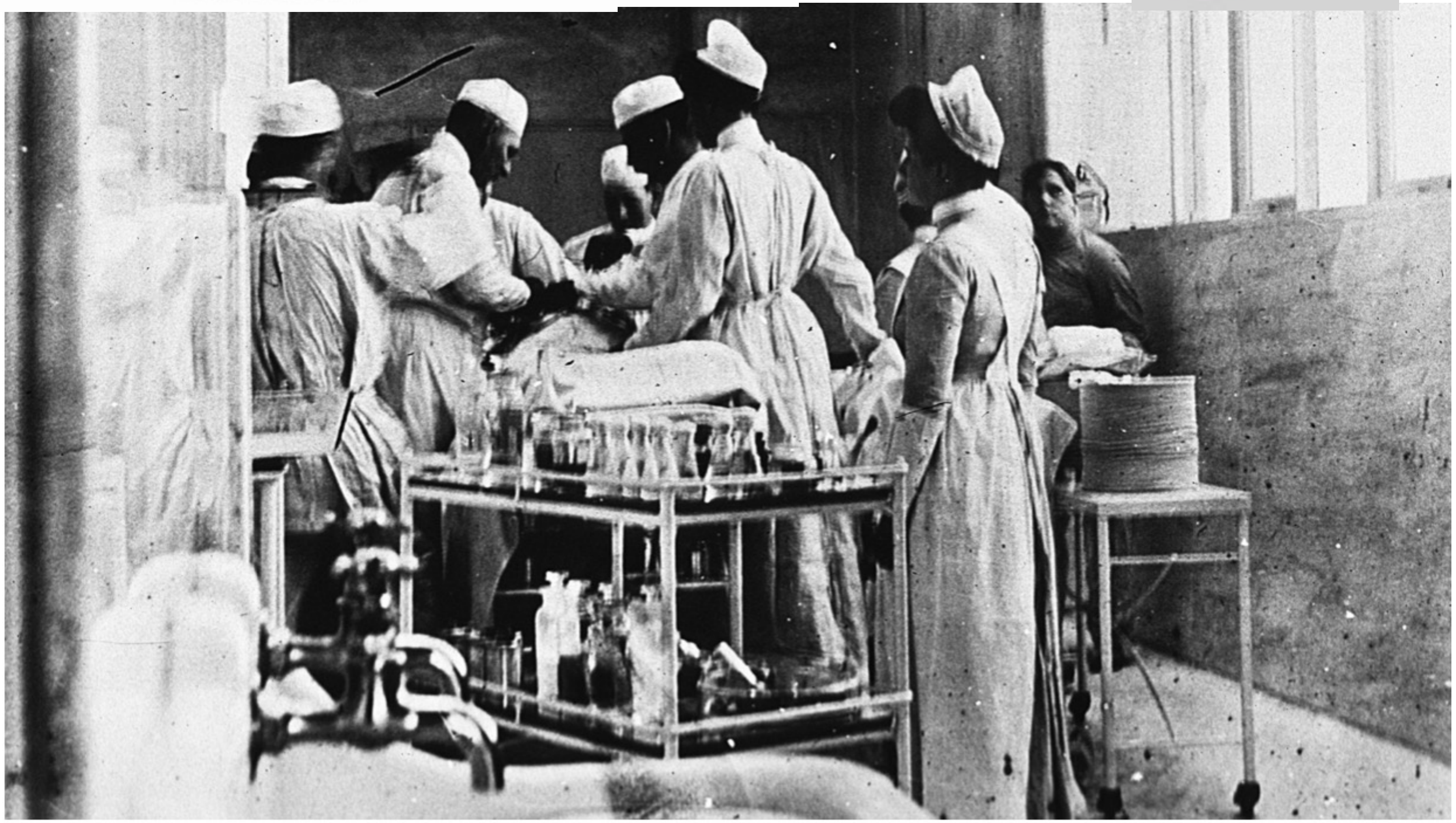
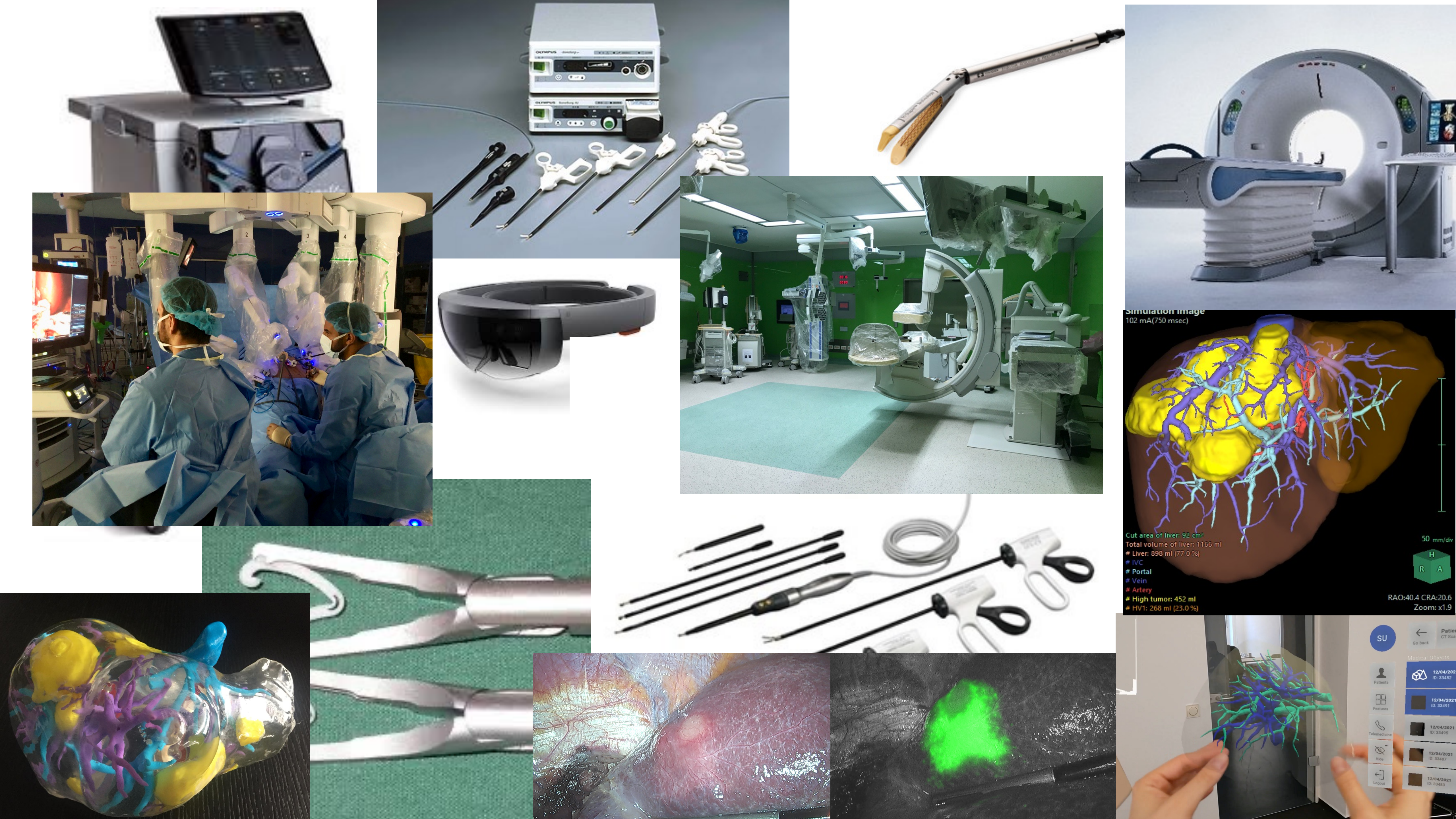
Università degli Studi del Sannio
International Ph.D. Excellence School
ITALO GORINI 2021
I. GO Ph.D. School ITALO GORINI

I HAVE NOTHING TO DISCLOSE





Surgery: The old fashion


Simulation image
102 mA(750 msec)
Cut area of liver: 92 cm²
Total volume of liver: 1166 ml
Liver: 898 ml (77.0 %)
IVC
Portal
Vein
Artery
High tumor: 452 ml
HV1: 268 ml (23.0 %)
50 mm/div
RAO:40.4 CRA:20.6
Zoom: x1.9
SU

SLIGHT PAIN!!!

LESS BLEEDING

SHORTER HOSP

FEW HOLES

SHORTER OR M

LITTLE MENTAL

RGICAL DISEASES

MOR REMOVAL

AUMA

Evolution of Laparoscopy

- Cystoscopes early 1800s (scopes into the bladder)
- Laparoscopy early 20th century (scopes into the abdomen)
- Laparoscope with video camera 1980s
- Early 80’s first laparoscopic removal of the gallbladder (Germany, France)

Minimally Invasive Surgery

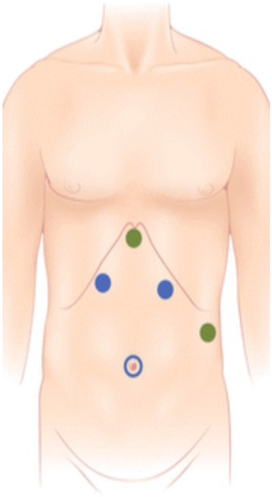
- Laparoscopy
- Thoracoscopy
- Arthroscopy
- Angioplasty
- Endoscopy
  - *Endoluminal
  - *Perivisceral
- Robotic surgery

LATEST AVAILABLE TECHNOLOGY IN SURGERY

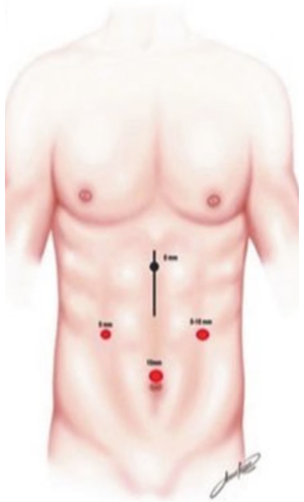
1. Robotic-Assisted Surgery
2. Near Infrared Fluoroscopy Guided Surgery
3. Virtual Reality applied to Robotics
4. Intraoperative 3D Hologram support (Mixed Reality)
5. 3-D Printing

Scars in Minimally Invasive Surgeries

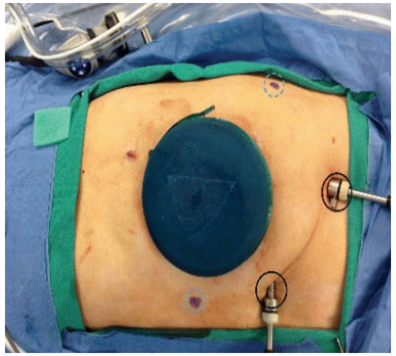
FULLY LAPAROSCOPIC



HYBRID

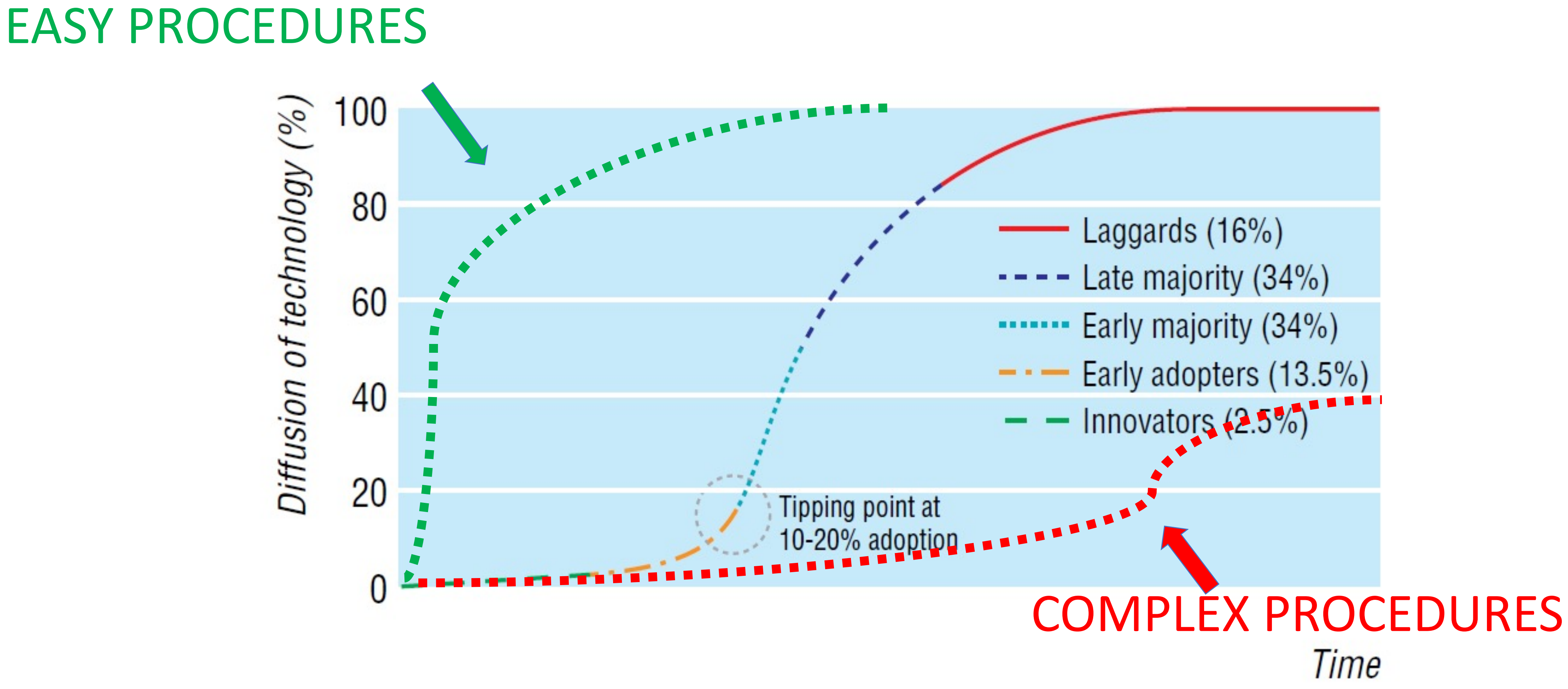


HAND-ASSISTED



ROBOTIC

The 5 Stages in Adoption of Innovations

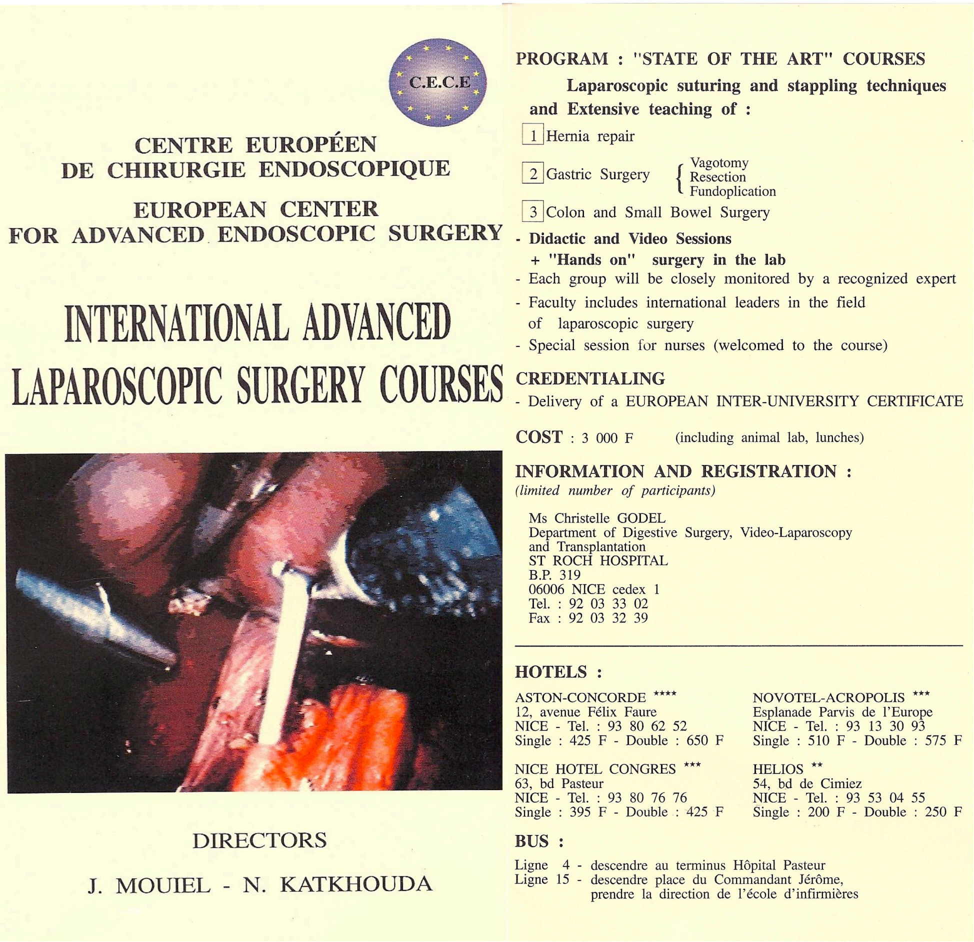


S-curve showing the five stages in adoption of innovations[2]

Wilson CB, *BMJ 2006*

ANNO DOMINI

1992...



C.E.C.E

CENTRE EUROPÉEN
DE CHIRURGIE ENDOSCOPIQUE

EUROPEAN CENTER
FOR ADVANCED ENDOSCOPIC SURGERY

INTERNATIONAL ADVANCED
LAPAROSCOPIC SURGERY COURSES

DIRECTORS

J. MOUIEL - N. KATKHOUDA

PROGRAM : "STATE OF THE ART" COURSES

Laparoscopic suturing and stappling techniques and Extensive teaching of :

1 Hernia repair

2 Gastric Surgery { Vagotomy, Resection, Fundoplication

3 Colon and Small Bowel Surgery

- Didactic and Video Sessions
  + "Hands on" surgery in the lab
- Each group will be closely monitored by a recognized expert
- Faculty includes international leaders in the field of laparoscopic surgery
- Special session for nurses (welcomed to the course)

CREDENTIALING

- Delivery of a EUROPEAN INTER-UNIVERSITY CERTIFICATE

COST : 3 000 F (including animal lab, lunches)

INFORMATION AND REGISTRATION :

(limited number of participants)

Ms Christelle GODEL
Department of Digestive Surgery, Video-Laparoscopy
and Transplantation
ST ROCH HOSPITAL
B.P. 319
06006 NICE cedex 1
Tel. : 92 03 33 02
Fax : 92 03 32 39

HOTELS :

ASTON-CONCORDE ****
12, avenue Félix Faure
NICE - Tel. : 93 80 62 52
Single : 425 F - Double : 650 F

NOVOTEL-ACROPOLIS ***
Esplanade Parvis de l'Europe
NICE - Tel. : 93 13 30 93
Single : 510 F - Double : 575 F

NICE HOTEL CONGRES ***
63, bd Pasteur
NICE - Tel. : 93 80 76 76
Single : 395 F - Double : 425 F

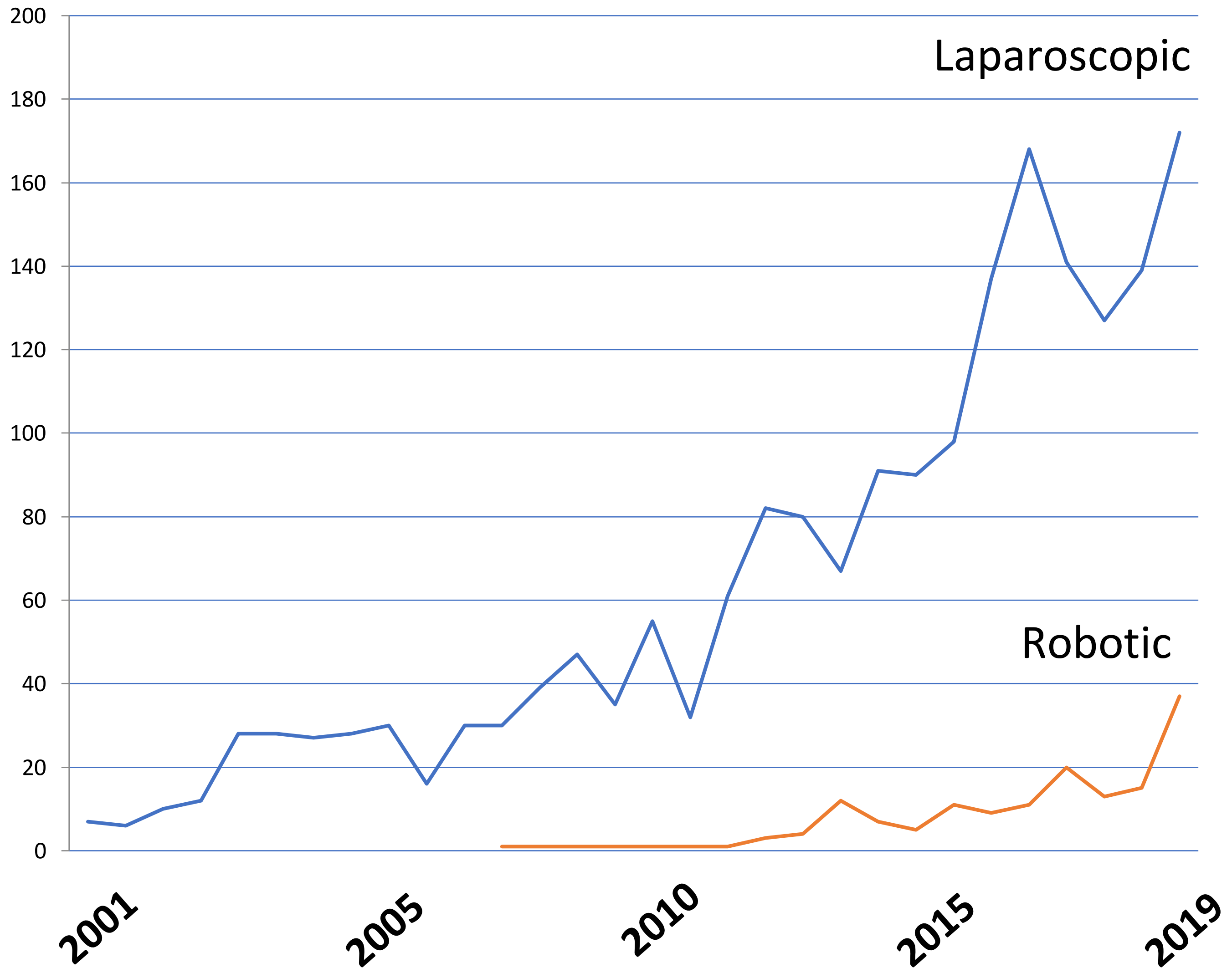
HELIOS **
54, bd de Cimiez
NICE - Tel. : 93 53 04 55
Single : 200 F - Double : 250 F

BUS :

Ligne 4 - descendre au terminus Hôpital Pasteur
Ligne 15 - descendre place du Commandant Jérôme, prendre la direction de l'école d'infirmières

Laparoscopic and Robotic Reports

(SCOPUS)



Consensus Conferences & Guidelines

The international position on laparoscopic liver surgery: The Louisville Statement, 2008.

2014

Recommendations for Laparoscopic Liver Resection

A Report From the Second International Consensus Conference Held in Morioka

2017

The Southampton Consensus Guidelines for Laparoscopic Liver Surgery

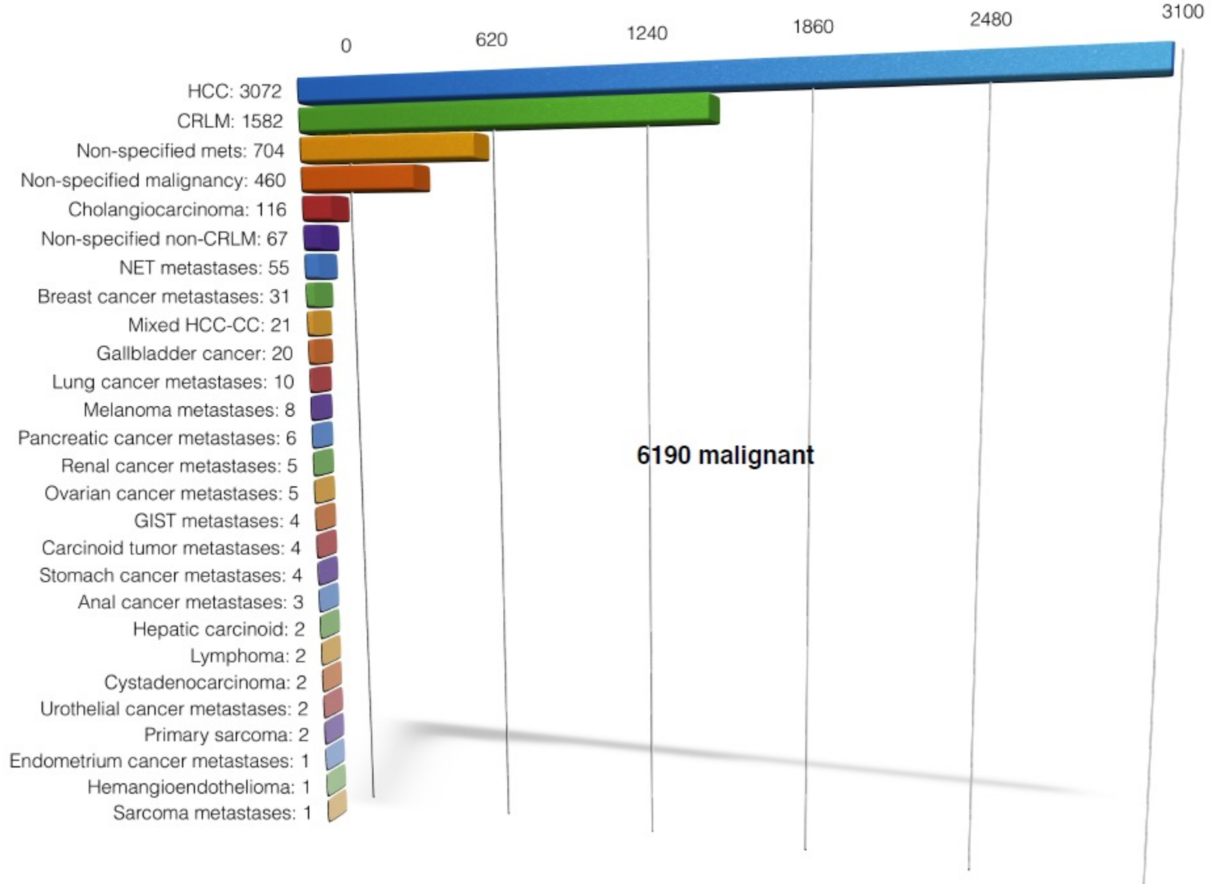
From Indication to Implementation

2019

EXPERT CONSENSUS AND GUIDELINES CONFERENCE ON MINIMALLY INVASIVE DONOR HEPATECTOMY

Comparative Short-term Benefits of Laparoscopic Liver Resection: 9000 Cases and Climbing

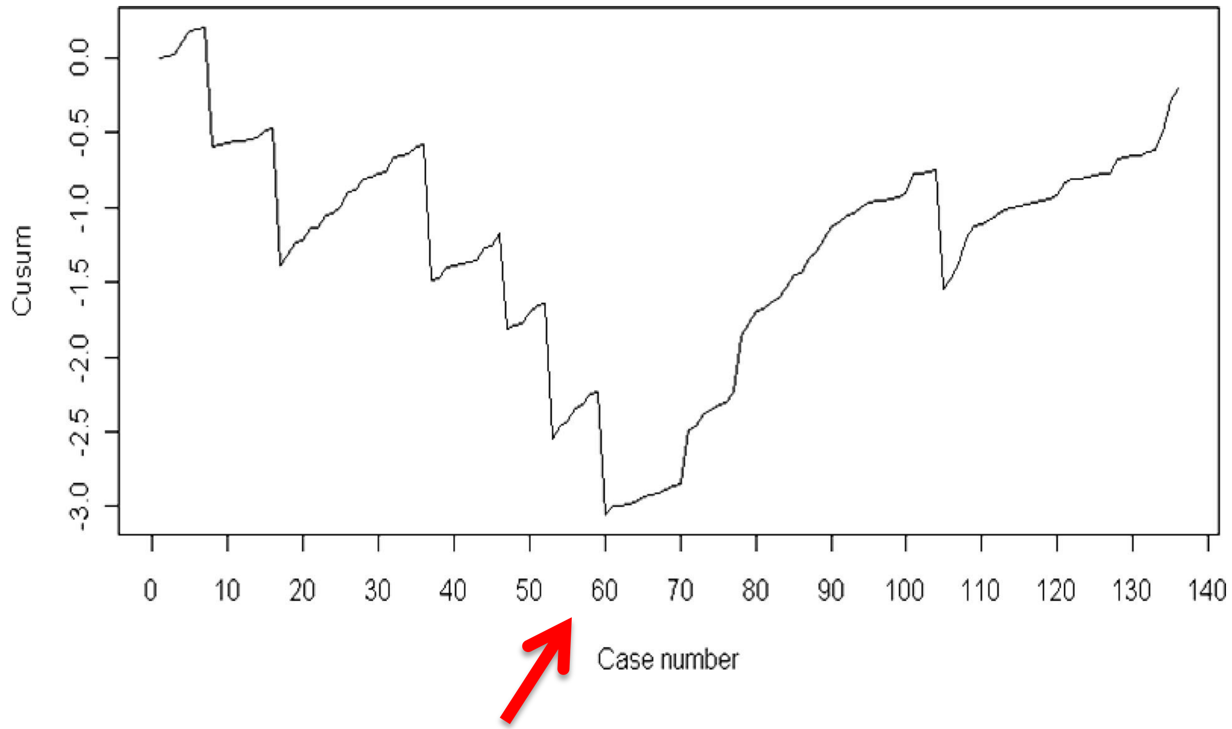
Ruben Ciria, MD, PhD,† Daniel Cherqui, MD,‡ David A. Geller, MD,§ Javier Briceno, MD, PhD,† and Go Wakabayashi, MD, PhD, FACS*||*



The Learning Curve in Laparoscopic Liver Resection

Improved Feasibility and Reproducibility

Luca Vigano, MD, Alexis Laurent, MD, PhD,* Claude Tayar, MD,* Mariano Tomatis, MD,† Antonio Ponti, MD,† and Daniel Cherqui, MD**



Vigano L, *Ann Surg* 2009

The single surgeon learning curve of laparoscopic liver resection

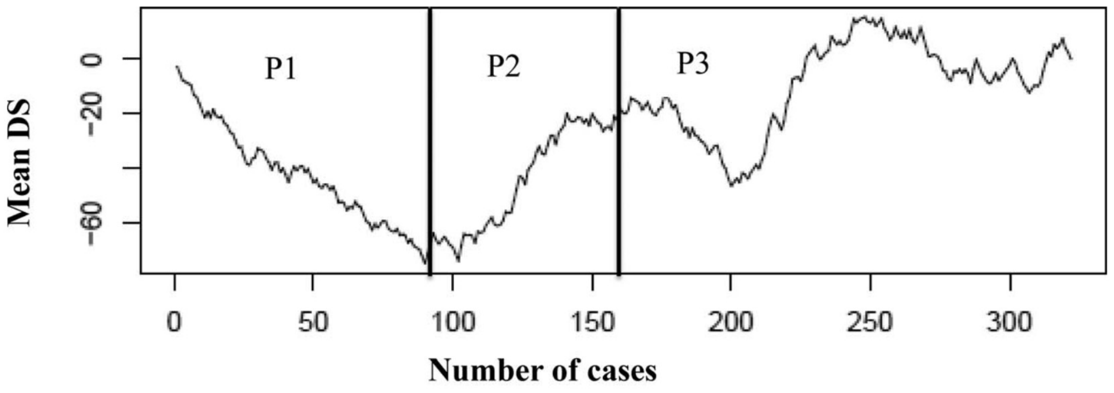
A continuous evolving process through stepwise difficulties

Federico Tomassini, MD[a], Vincenzo Scuderi, MD[a], Roos Colman, MD[b], Marco Vivarelli, MD[c],
Roberto Montalti, MD, PhD[c], Roberto Ivan Troisi, MD, PhD[a,*]

Grading the difficulty: the Difficulty Scale (DS).

Type of resection	Difficulty scale (DS)
Wedge S3, S4b	1
Left lateral sectionectomy (LLS)	2
Wedge S2, S5, S6	3
Mono (sub) segmentectomy S2-3-4b-5-6	4
Left hepatectomy	5
Wedge S4a-7-8; caudatectomy	6
Bisegmentectomy (excl. LLS)	7
Segmentectomy S4a, 7-8	8
Right hepatectomy; right trisectionectomy	9
Mesohepatectomy; left Trisectionectomy	10

DS = difficulty scale, LLR = laparoscopic liver resection.

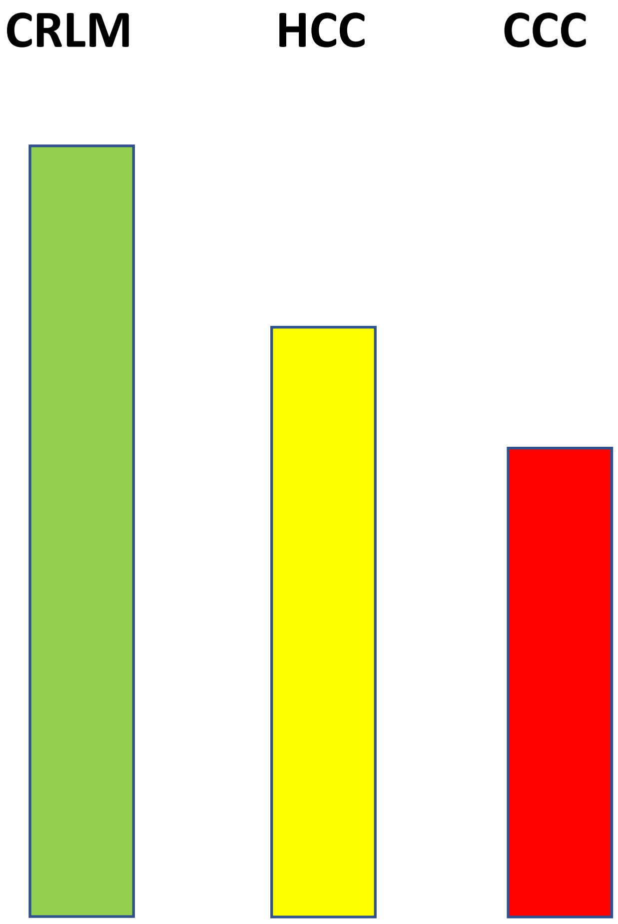


Overall DS	Period 1 (n=1-91) *Initial experience*	Period 2 (n=92-159) *Pushing the limits*	Period 3 (n=160-319) *Steady state*
4.6	3.8	5.3	4.7

Tomassini F, *Medicine* 2016

Level of Evidence MILS

Level	Example of Evidence
Level 1	Meta-analysis of Homogenous RCTs Randomized Control Trial
Level 2	Meta-analysis of Level 2 or Heterogenous Level 1 Evidence Prospective Comparative Study
Level 3	Review of Level 3 Evidence Case-control Study Retrospective Cohort Study
Level 4	Uncontrolled Cohort Studies Case Series
Level 5	Expert Opinion Case Report Personal Observation
Foundational Evidence	Animal Research *In Vitro* Research Ideas, Speculation

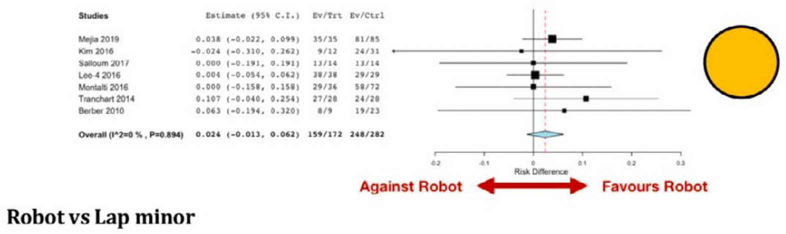


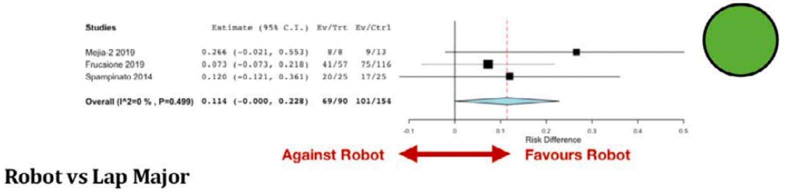
Challenges & Opportunities

- Level of Evidence
- Steep learning curve
- Indications (CRLM; HCC/ Cirrhosis; Cholangiocarcinoma's)
- Major hepatectomy / Lesions in the PS segments
- Parenchyma-saving approach of multifocality
- Living donor hepatectomy (Pediatric/Adult)
- Structured Educational Programs/ Proctorships
- Virtual Hepatectomy (3D); Augmented Reality….

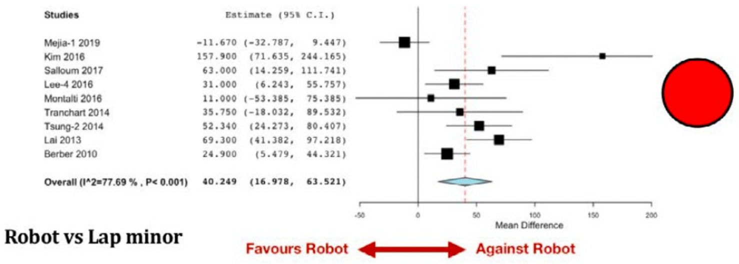
Robotic vs Laparoscopic Surgery

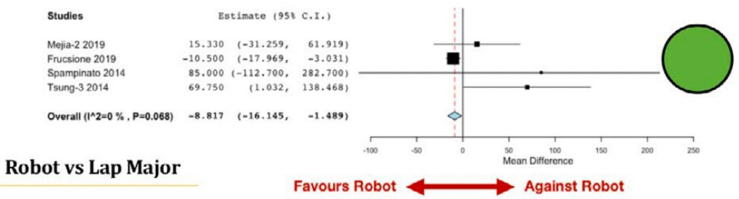
Complications



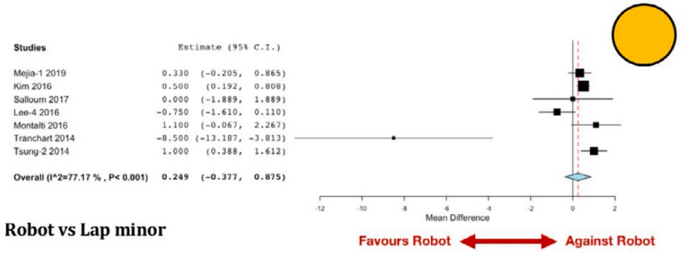


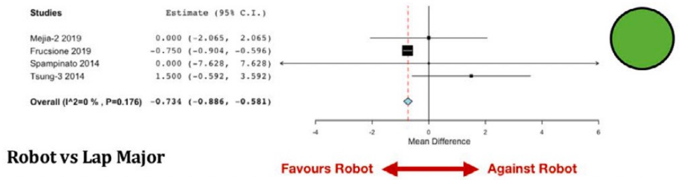
Op Time





Hospital Stay

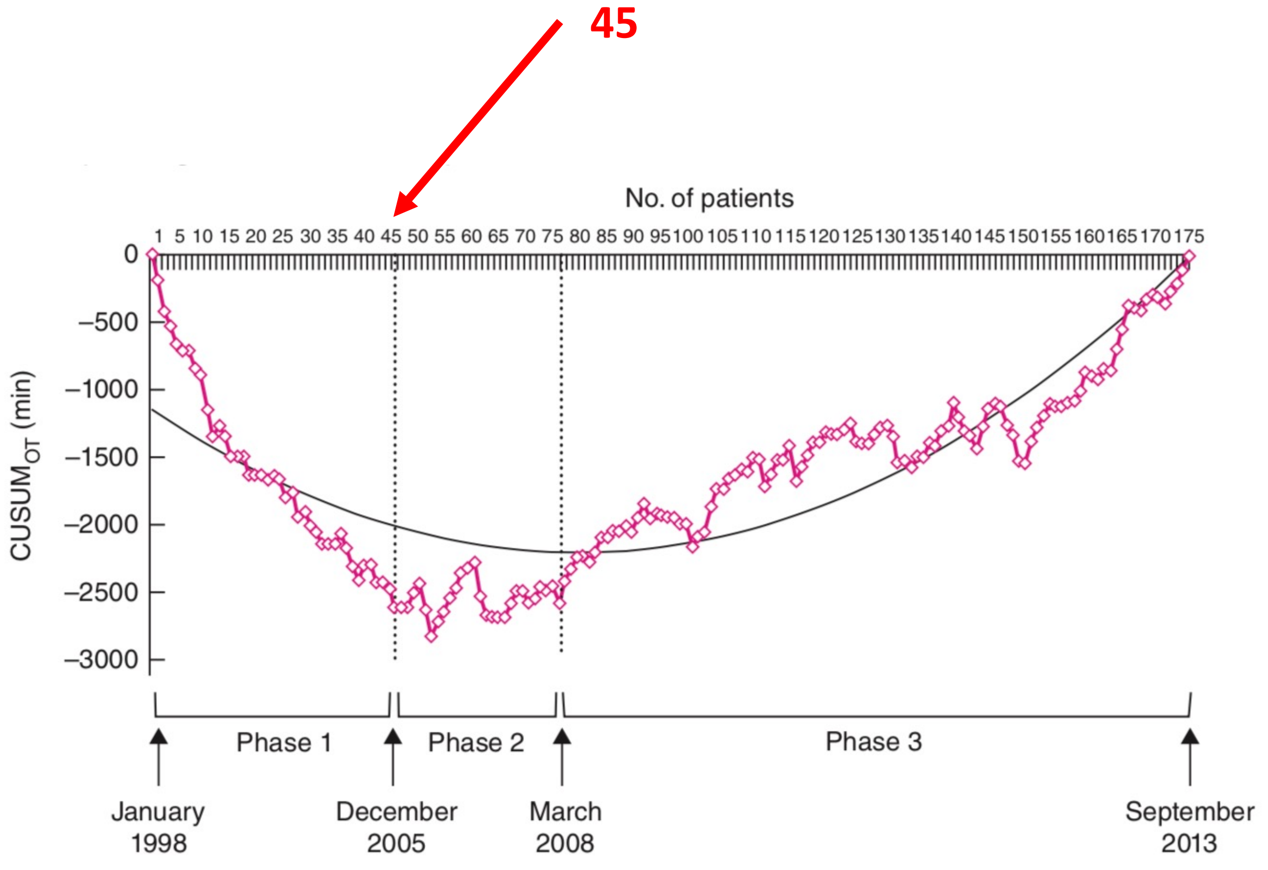




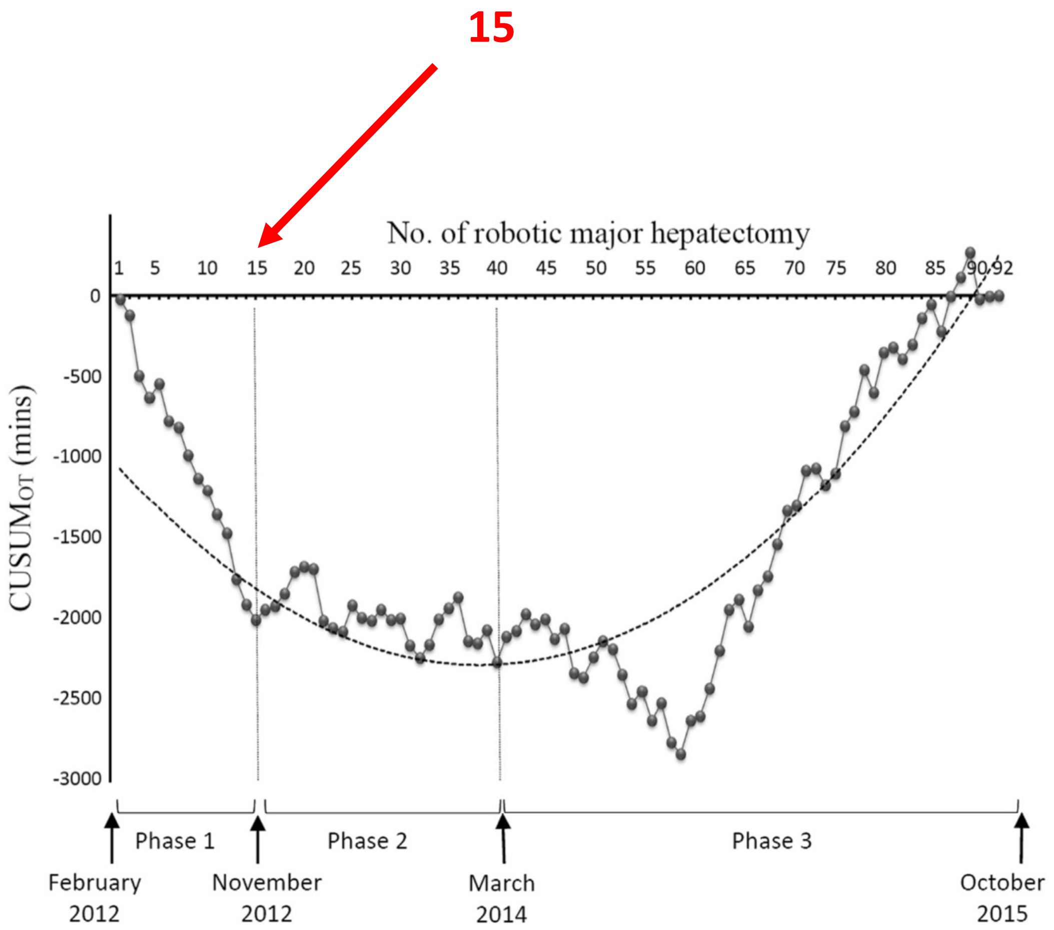
Robotic liver surgery may offer improved short-term outcomes compared to open procedures in most of the variables screened

Ciria R et Al. J Hepatobiliary Pancreat Sci. 2020

Learning curves of ROBOTICS in Major Hepatectomies



b CUSUM$_{OT}$ *versus* no. of patients

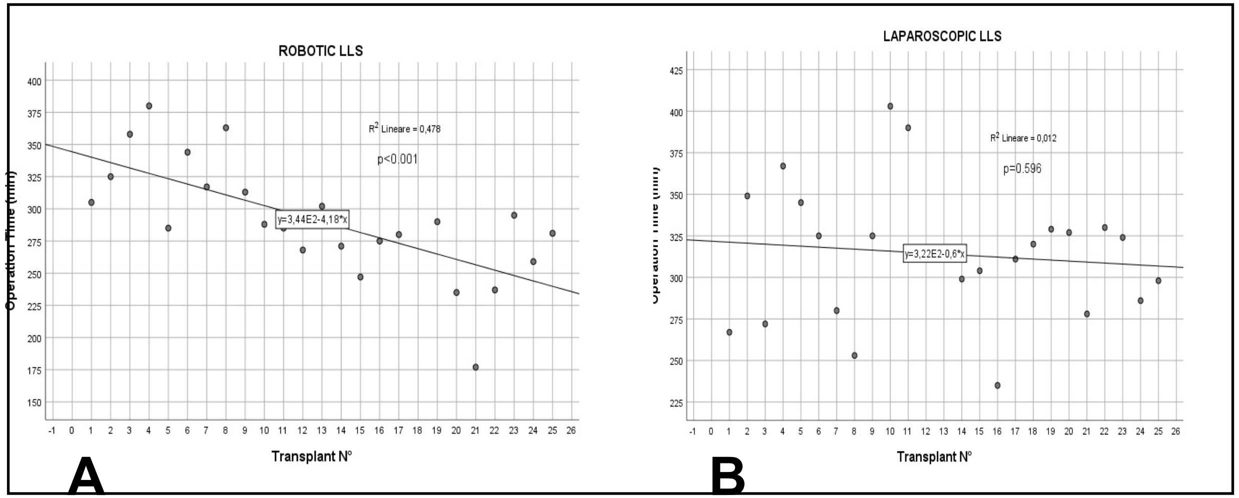


Gayet B et Al. BJS 2015

WU YM et Al. Surgery 2016

Learning curves of ROBOTICS in Living Donor Hepatectomy

Safety and Feasibility Report of Robotic-assisted Left Lateral Sectionectomy for Pediatric Living Donor Liver Transplantation: A Comparative Analysis of Learning Curves and Mastery Achieved With the Laparoscopic Approach



A: quickly reduced operating times thanks to the acceleration of the hilar dissection phase

Troisi RI et Al. Transplantation 2020

Robotic Versus Open Right Lobe Donor Hepatectomy for Adult Living Donor Liver Transplantation: A Propensity Score–Matched Analysis

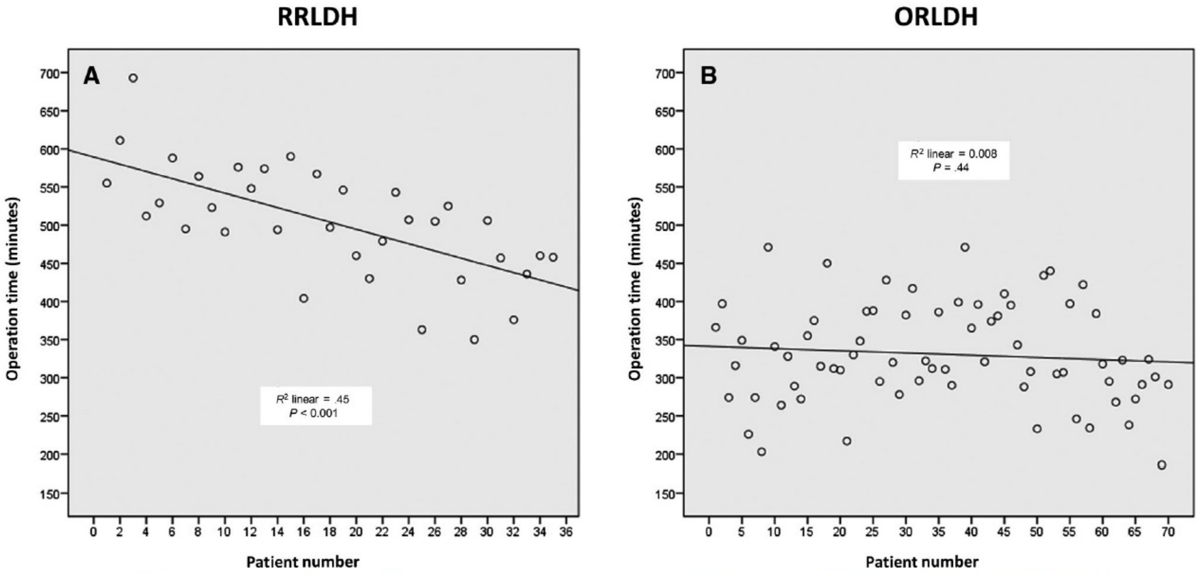


FIG. 4. Operative time evolution according to the patient number in the (A) RRLDH and (B) ORLDH groups.

Broering D & Troisi RI, Liver Transplantation 2020

Learning curves in minimally invasive hepatectomy: systematic review and meta-regression analysis

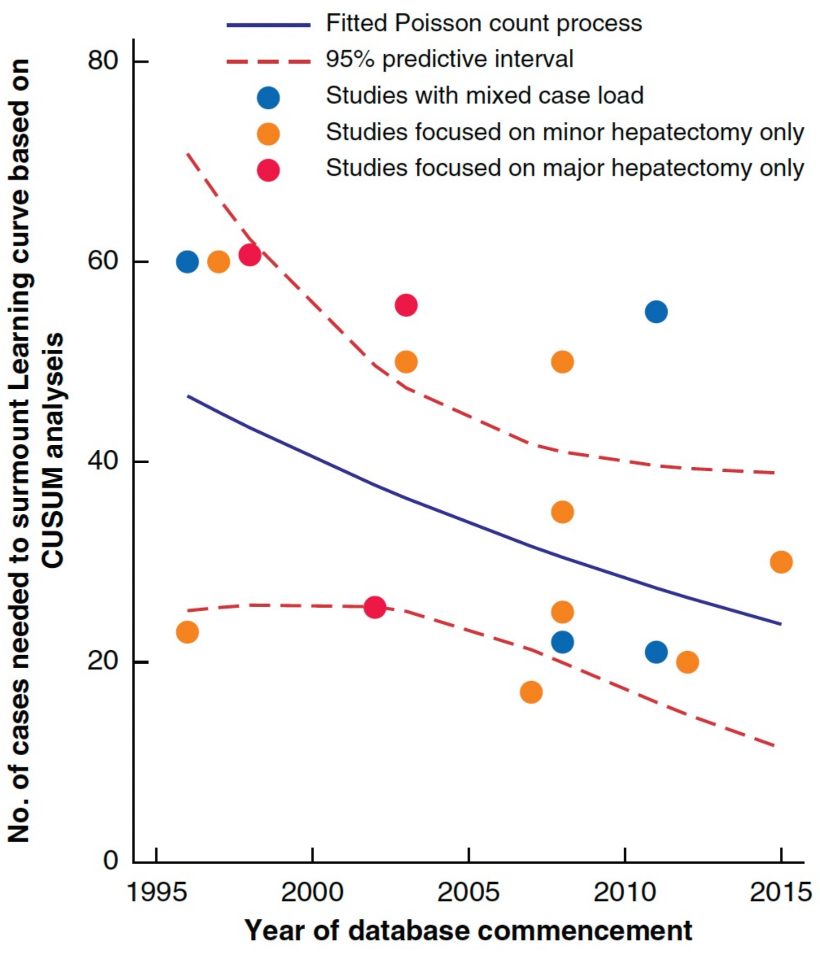


Fig. 2 Mixed-effects Poisson regression of the number of cases needed to surmount the learning curve *versus* year of study publication

- N° to surmount the LC appears greater for laparoscopy than for robotic:

➢ technical advantages;

➢ years of studies;

➢ experience with laparoscopy

Goh B et Al. BJS 2021

Laparoscopy vs Robotic Surgery

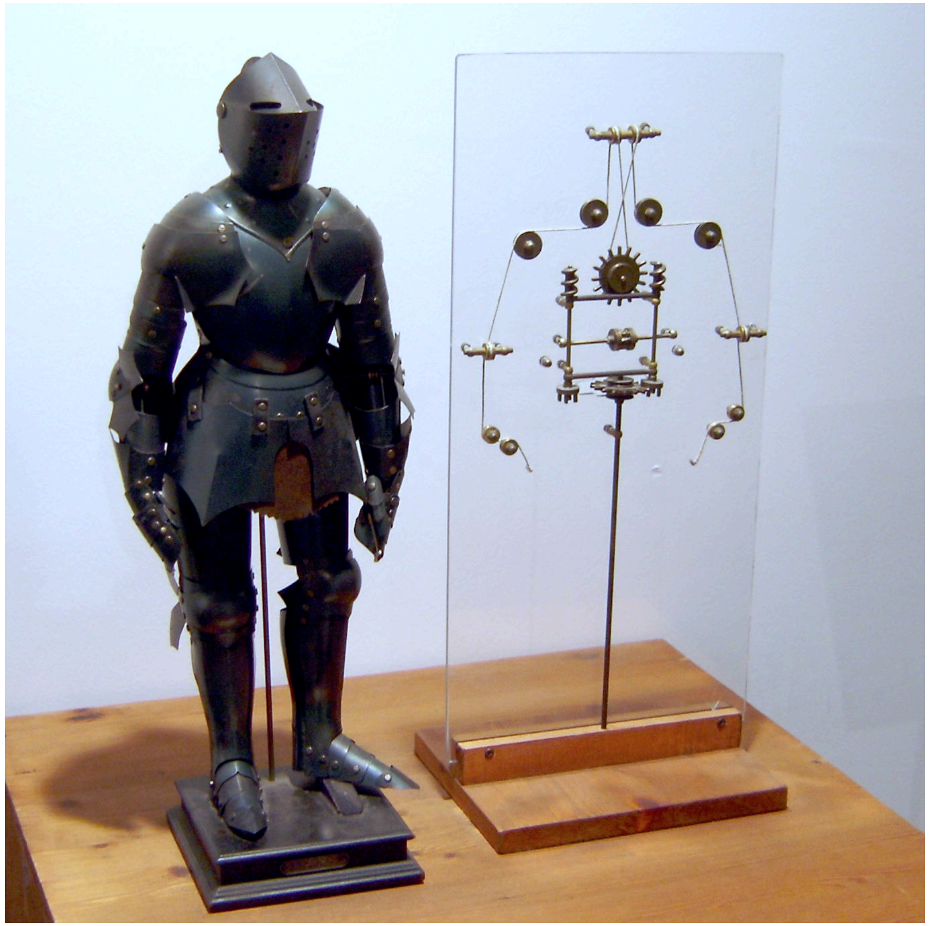
LAPAROSCOPIC SURGERY

- Preserved tactile feedback
- Wide range of instruments
- Easy instrument replacement
- Affordable costs

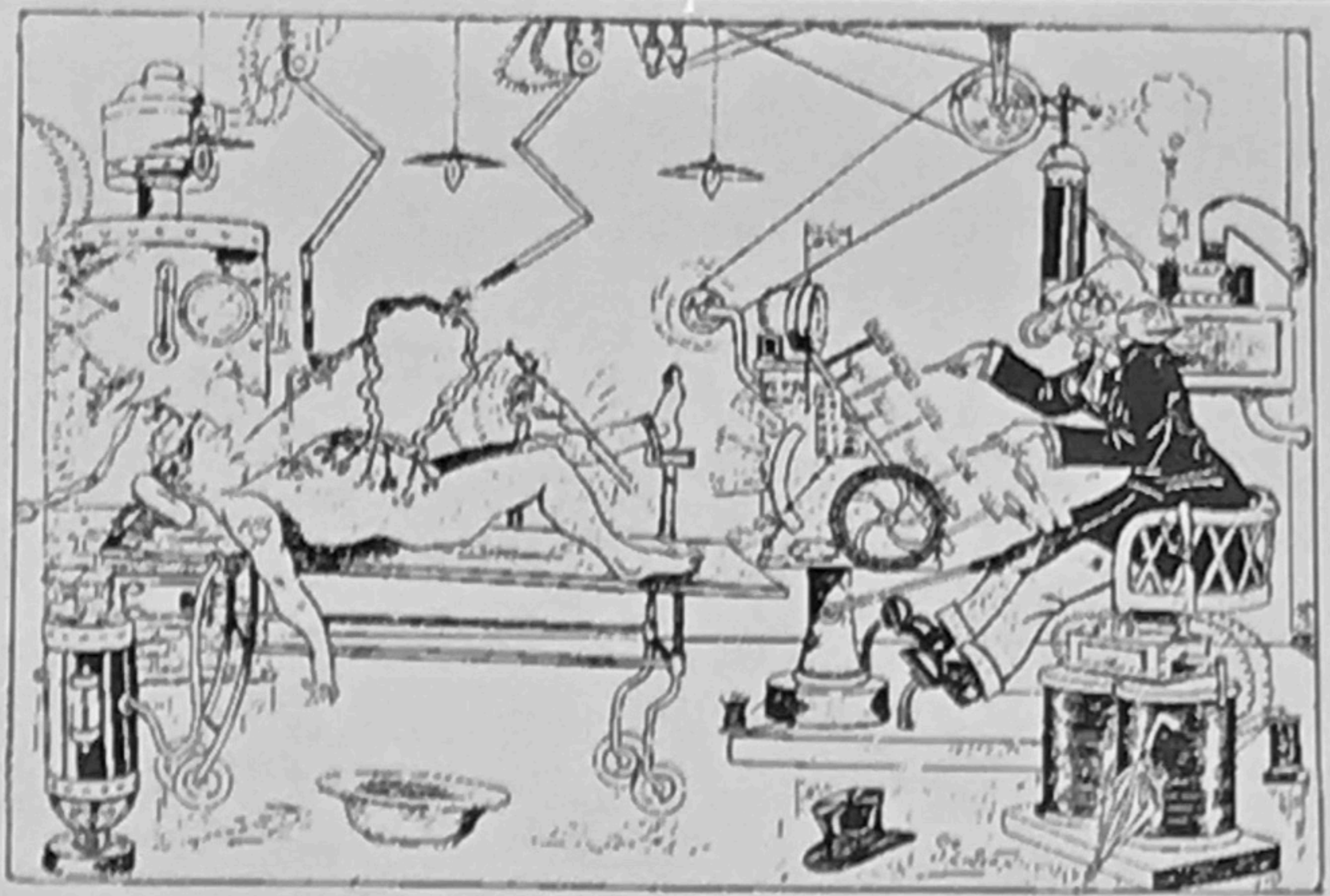
ROBOTIC SURGERY

- Stable and magnified view
- 7-degree of freedom
- Enhanced suturing
- Enhanced ergonomic
- *Master/Slave console for proctorship*
- *Digital Platform*

The dawn of robotic thinking



- *A mechanical knight able to sit up, wave its arms and move the head and jaw…(about 1495)*



UNE SALLE D'OPÉRATIONS EN L'AN 2000

A French comic drawing from 1914 showing how the artist envisioned the operating room of year 2000

Development of Surgical Robotics

- NASA (70'): provide surgical assistance for astronauts with remoted-control robots

- Military programs pushed up the further developments, basically the possibility to perform at a remote distance an operation

PUMA 560

CT-guided Brain Biopsy

1985

ROBODOC

Hip Replacement

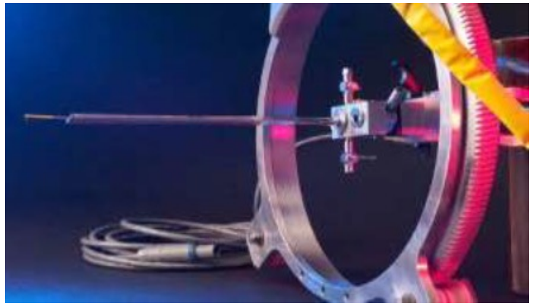
1992

ZEUS

1997-2000

1988

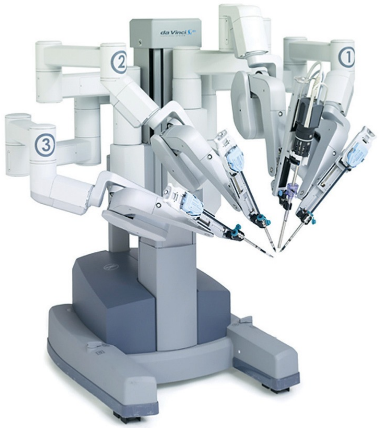
PROBOT



1994

AESOP

DA VINCI



[Shah J, Vyas A, Vyas D. **The History of Robotics in Surgical Specialties**. Am J Robot Surg. 2014;1(1):12–20. doi:10.1166/ajrs.2014.1006]

Robotic Surgery: What Does It Mean?

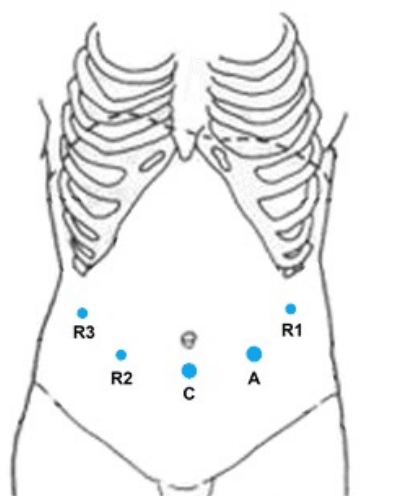
- Robotic surgery is performed by surgeons, not robots, by using joysticks and foot controls

The operation can be done from a distance

The robot that can translate the operator’s expertise in controlled maneuvers

The view of the surgical site is provided by a 3-D high

definition monitor



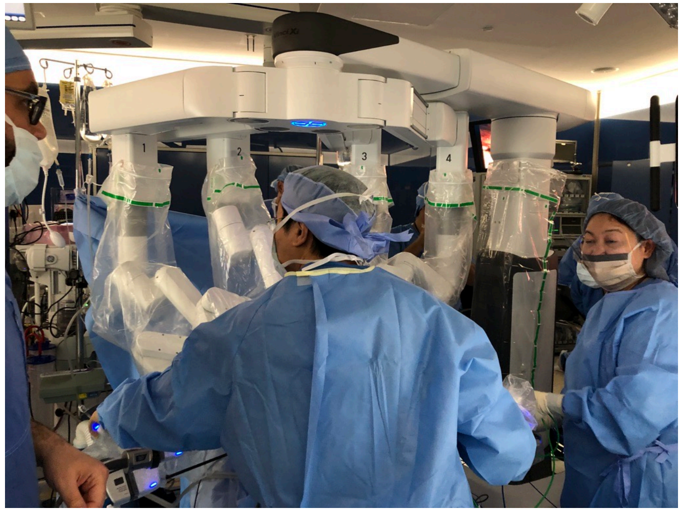
Trocar locations for robotic abdominal surgery

[Li J, Xi H et al., **Minimally invasive surgery as a treatment option for gastric cancer with liver metastasis: a comparison with open surgery**, Surg Endosc 2018, 32:1422–1433]

Da Vinci® Surgical System
How It Works

1

2



3

INTUITIVE SURGICAL®

Founded in 1995, allowed the first robotic surgery ever, as we know it.

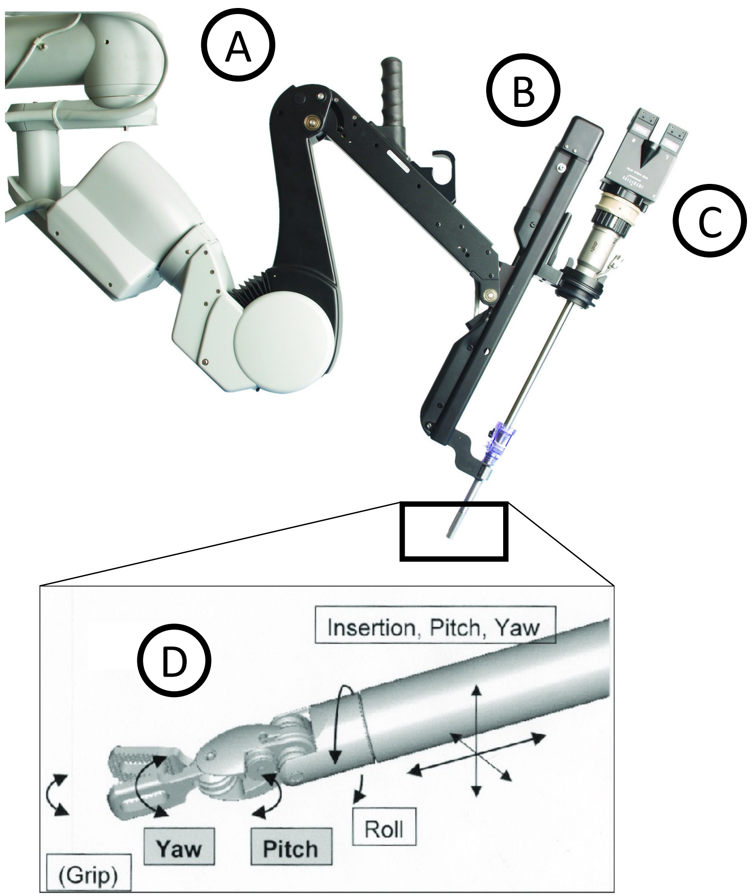
For years, *Intuitive* has been the only major market player in the industry: as for now it is still effectively a monopoly.

Price ranges **from $0.5 to $2.5 million**

[Peters BS, Armijo PR et al., **Review of emerging surgical robotic technology**, Surgical Endoscopy (2018) 32:1636–1655, doi: 10.1007/s00464-018-6079-2]

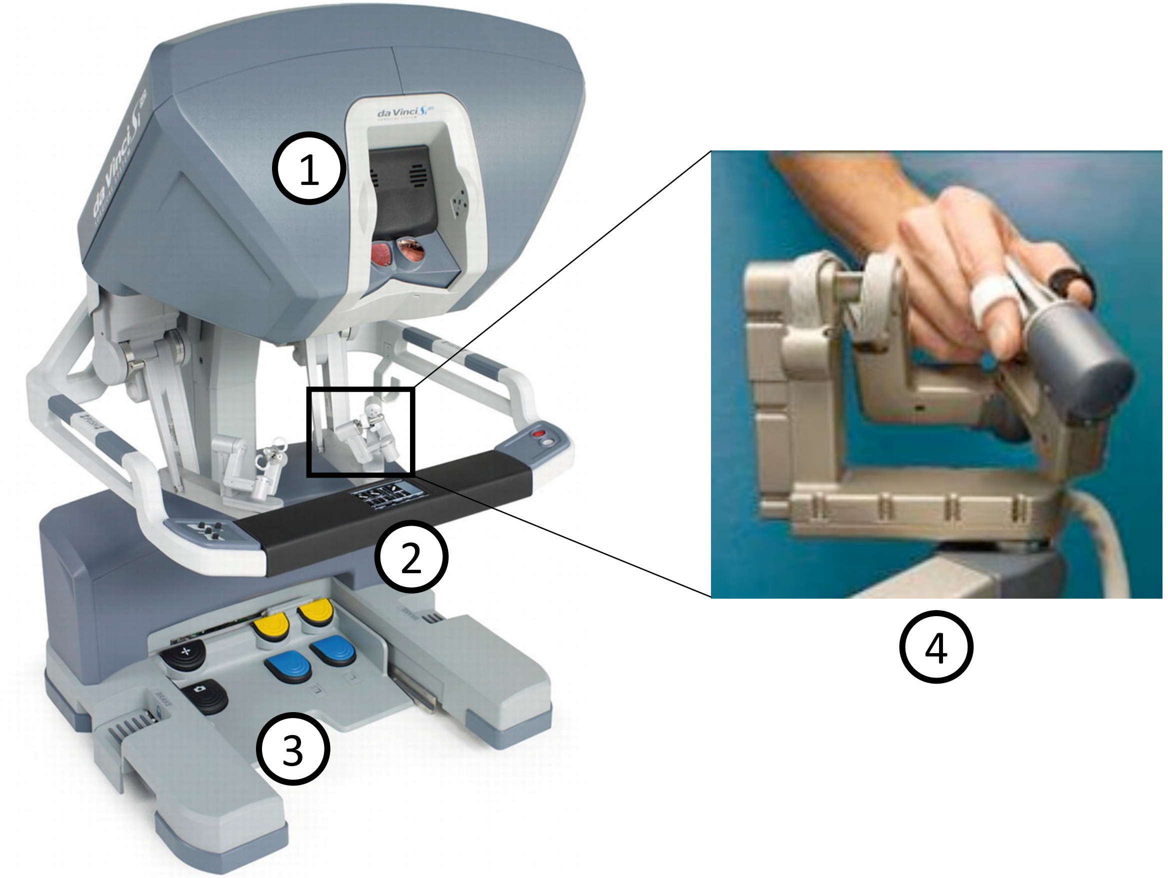
Da Vinci® Surgical System - How It Works

Robotic Arms



7 DOF (7 degrees of freedom)

The Console



Drawbacks

- Despite exponential growth, **costs** are often prohibitive for smaller health care systems and hospitals
- Need for easier and quicker docking/setup
- Lack of haptic feedback
- Stapling devices are not as handy as in open and LAP counterparts
- Lack of certain instruments, particularly energy devices (CUSA)
- Difficulties if a rapid conversion is needed
- Time consuming when not in experienced hands

[Troisi RI, Pegoraro F, Giglio MC et al., **Robotic approach to the liver: Open surgery in a closed abdomen or laparoscopic surgery with technical constraints?**, Surgical Oncology (2019), doi: https://doi.org/10.1016/ j.suronc.2019.10.012]

Robotics in General Surgery

- **First application**: urologic oncology for the treatment of prostate cancer, where laparoscopic surgery was rarely performed due to complexity and difficult maneuverability in the deep pelvis.

  shorter LOS (2.0 vs. 3.0 days)
  fewer blood transfusions (2.7% vs. 20.8%)

- In partial nephrectomies robot-assisted surgery increases the rates of success by 52% compared to open procedures
- In gynecology robotic-assisted hysterectomies are increasing thanks to the easier learning curve compared to laparoscopic procedures

  employed successfully in cases that would have otherwise required laparotomy

- In cardiosurgery, mitral valve repair has been one of the first and most successful application of the robotic surgical system
- Inguinal hernia repair, ventral hernia repair, and bariatric surgeries are growing indications with excellent results and a lower rate of recurrence/failure

[Chandra A, Snider JT, Wu Y, et al. **Robot-assisted surgery for kidney cancer increased access to a procedure that can reduce mortality and renal failure.** Health Aff (Millwood) 2015;34:220-8 - Oviedo Barrera RJ, **The Surgical Robot: Applications and Advantages in General Surgery**, Surgical Robotics (2018), doi: 10.5772/intechopen.68864]

The Robotic (R)Evolution

The Robotic (R)Evolution

- ***Senhance®***

By *TransEnterix*™*,* founded in 2006

Multi-port robotic system which provides 3D-HD vision, haptic feedback, and surgeon camera control via eye movements

The overall control of the *Senhance* system is similar to laparoscopy, as opposed to the master console interface of the *da Vinci* system.

Able to support ultrasonic devices

Price: $1.3 million, with reusable instruments with "unlimited" uses

[Peters BS, Armijo PR et al., **Review of emerging surgical robotic technology**, Surgical Endoscopy (2018) 32:1636–1655, doi: 10.1007/s00464-018-6079-2]

The Robotic (R)Evolution

- ***SPORT™ Surgical System***

By *Titan Medical Inc.*

Single Port Orifice Robotic Technology (SPORT) allows to insert a single instrument through a 25 mm incision

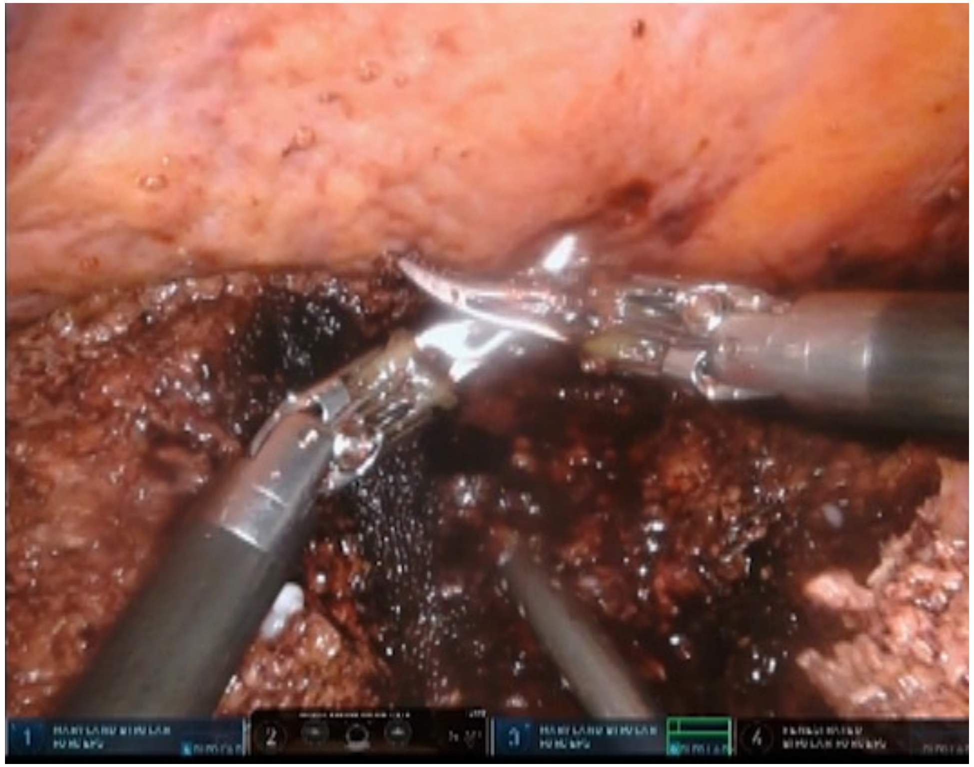
The device features multiple multi-articulated tools, with single-use replaceable tips

[SPORT™ Surgical System (2017) Titan Medical Inc. **http://www.titanmedicalinc.com/product**]

Robotics in HPB Surgery

- Da Vinci® Surgical System is currently the most used robotic device

- A big issue is the lack of a robotic version of CUSA®, one of the most effective devices for liver transection
- Easier reconstructions of vascular and biliary structures
- Enhanced suturing capacities



Robotics in Cardiac Surgery

Sensei X® Robotic Catheter System

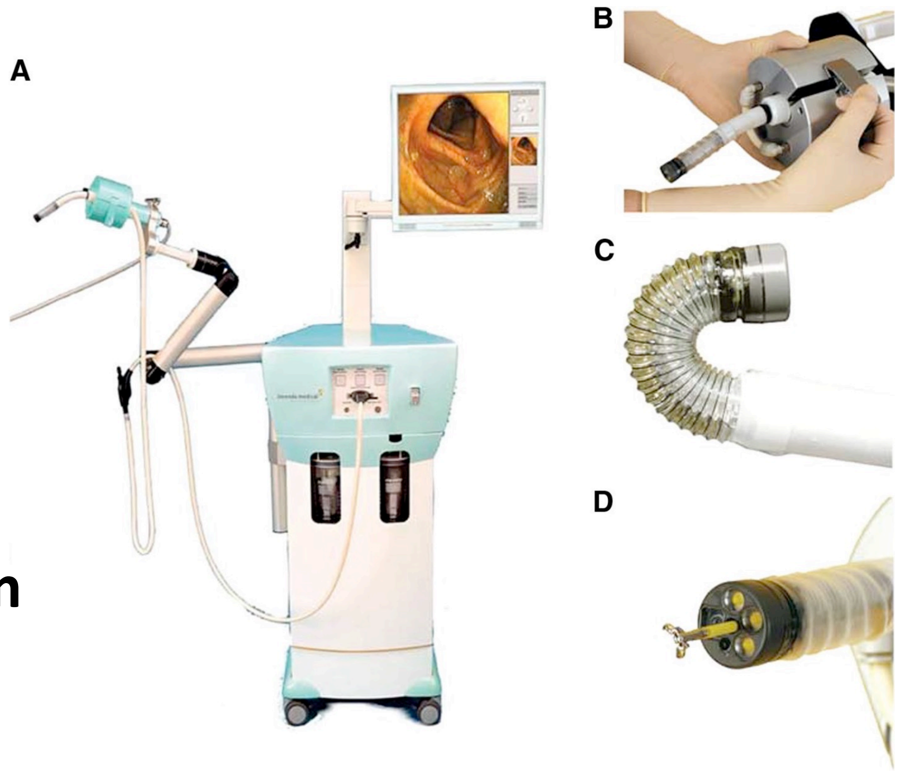
- For cardiac mapping, ablation, endovascular aneurism repair, cardiac catheter insertion
- The user's movement are transmitted to the catheter's tip via an external handle (located at a remote workstation), which can be moved in three dimensions from a remote controller
- A probe placed on the catheter's distal tip measures the bloodstream's haptic vibrations: these are then translated to the user via the controller
- The integrated robotic navigation system can trace a 3D mapping of the catheter's movements
- The workstation can visually display multiple information and functions simultaneously, such as imaging, 3D mapping, ICE, fluoroscopy, and EKG recordings

[Hansen Medical (2017). **http://www.hansenmedical.com/us/en/why-robotics** - Rafii-Tari H, Payne CJ, Yang GZ (2014) **Current and emerging robot-assisted endovascular catheterization technologies: a review**. Ann Biomed Eng 42:697–715. https ://doi.org/10.1007/s10439-013-0946-8]

Robotics in Endoscopic Surgery

Invendoscopy® E200

- Reusable handheld controller + single-use 170 cm sterile colonoscope
- Deflectable tip (180° in all directions), 35 mm bending radius
- User-friendly ergonomics
- All functions (tip deflection, insufflation, suction, image capture) can be operated single-handedly



NeoGuide® Endoscopy System

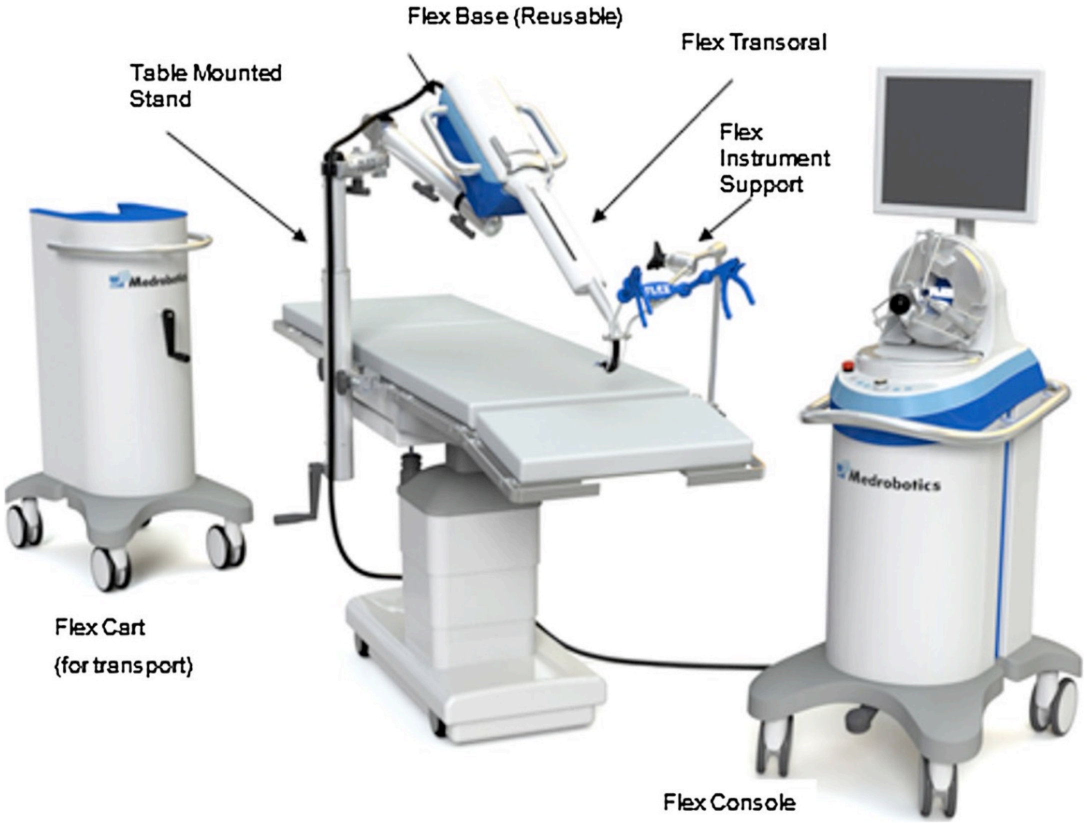
- Computer-aided colonoscope that utilizes Real-time 3D mapping
- less force applied to the walls of the organ
- As the scope is advanced the articulating segments take on the angle and shape of the distal tip as they “follow-the-leader” negotiating through colonic flexures

[Sterile single-use endoscopy; invendo medical GmbH (2017). **http://www.invendo-medical.com** - Eickhoff A, van Dam J, Jakobs R, Kudis V, Hartmann D, Damian U, Weickert U, Schilling D, Riemann JF (2007) **Computer-assisted colonoscopy (the NeoGuide Endoscopy System): results of the first human clinical trial (“PACE study”)**. Am J Gastroenterol 102:261–266]

Robotics in ORL Surgery

Flex® Robotic System

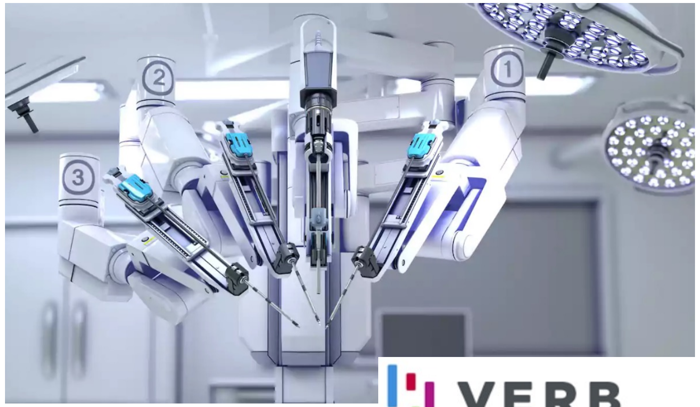
- Used to treat lesions of the oropharynx, hypopharynx, or supraglottic larynx
- Single-port operator-controlled surgery
- A joystick controller allows the movement of 3 mm articulating instruments
- Integrated 3D high-definition vision system
- Articulation of nearly 180°
- The endoscope has two lumens that provide a pathway for electrical connections or an irrigation tube, scissors, needle driver, grasper, and dissector.



[Medrobotics® Announces First Sale of Flex® Robotic System in Europe for Gastroenterology Applications. Medrobotics. October 5, 2018. Available online: **https://medrobotics.com/wp-content/uploads/2018/10/18-10-03_ Medrobotics-EU-GI-Launch.pdf**]

Systems in Development

- ***Versius®*** by *CMR Surgical™*. Made of a set of independent arms, each with their own base, which are meant to be smaller, more lightweight, and portable enough to move around the table during surgery or between ORs as needed



- ***Verb surgical®***, a joint venture between Johnson & Johnson and Google. The system is a digital surgery platform that combines robotics, advanced visualization, advanced instrumentation, data analytics, and multi-connectivity

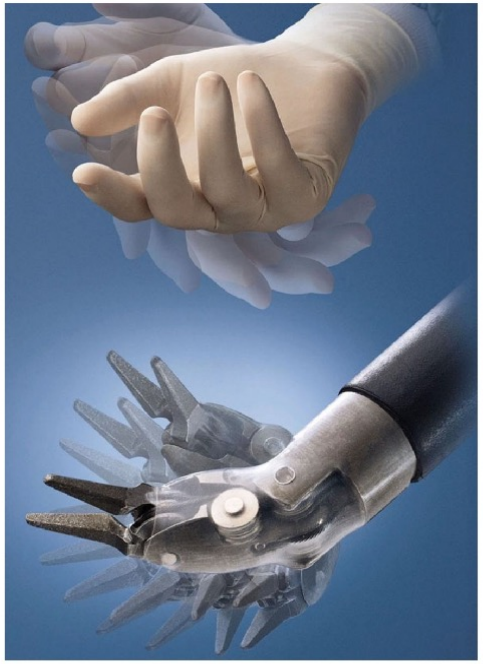
Thibault M (2016) Finally, details on Medtronic's robotics platform. Medical Device Business. **http://www.mddionline.com/blog/devicetalk/finally-details-medtronics-robotics-platform-06-08-16.** - Khateeb OM (2016) Democratizing Surgery Part 1: What Verb surgical is creating. Robotics Buisness Review. **https://www.linkedin.com/pulse/democratizing-surgery-how-verb-surgical-invented-new-category.**

Systems in Development or Ready to Clinical Application:
New directions

- Improve ergonomics
- Use of laparoscopic instruments (hybridization lap/rob)
- Reusable instruments
- Use separate arms which facilitate logistics and placement
- Improve the digital platform and interface with the surgeons
- Improve the teaching (proctorships) and training (simulators)
- Reproduce a force feedback (haptic feedback)
- Improve view, videos sharing and more…

Advantages

- Quicker patient recovery time
- Less blood loss
- Less pain (especially when compared to conventional open surgery)
- Effect on decreasing length of stay
- Effective proctorship (especially Da Vinci Xi)
- Better cosmetic result
- Immersive high-resolution 3D visualization
- Less fatigue for the surgeon
- Able to operate all four arms simultaneously
- Tremor filtration
- Fewer personnel in the OT
- **PROCTORING BY USING THE TEACHING CONSOLE**



[Troisi RI, Pegoraro F, Giglio MC et al., **Robotic approach to the liver: Open surgery in a closed abdomen or laparoscopic surgery with technical constraints?**, Surgical Oncology (2019), doi: https://doi.org/10.1016/ j.suronc.2019.10.012]

Cost Analysis

REVIEW

Robot-assisted laparoscopic liver resection: A review

C. Salloum, C. Lim, A. Malek, P. Compagnon, D. Azoulay*

Costs for robot-assisted laparoscopic hepatectomy

RALH remains extremely costly at the present time. Ji et al. [11], who studied the mean costs for RALH (material, broadened scope of activity, complications and duration of hospital stay), found that costs ($12,406) exceeded those for conventional laparoscopic hepatectomy ($7618). Conversely there did not seem to be any statistically significant difference between the two techniques concerning the cost of instruments. Packiam et al. [15], who compared conventional laparoscopic left lateral sectionectomy to robot-assisted laparoscopic left lateral sectionectomy, did not find any statistically significant difference in terms of costs of surgical material (instruments, stapling devices, and clips) ($4408 *vs.* $5130, respectively). However, when one considers the cost of purchasing and installing a robotic platform ($2,200,000) and the annual cost of maintenance ($150,000 per year), RALH is much more expensive than conventional laparoscopic hepatectomy. As there are no undeniable advantages of RALH over conventional laparoscopy, the use of the robotic platform for liver surgery should be reserved for the purposes of evaluation and only in expert centers.

Salloum C, *J Visc Surg* 2016

Are Robotic Surgeries Really Better?

Robot-assisted surgeries have only modest advantages over other approaches, a large analysis found.

The New York Times

August 16, 2021

Financial Impact of the Robotic Approach in Liver Surgery: A Comparative Study of Clinical Outcomes and Costs Between the Robotic and Open Technique in a Single Institution

Despoina Daskalaki, MD,[1] Raquel Gonzalez-Heredia, MD, PhD,[1] Marc Brown, CFA,[2]
Francesco M. Bianco, MD,[1] Ivo Tzvetanov, MD,[3] Myriam Davis, NP,[1]
Jihun Kim, MD,[1] Enrico Benedetti, MD,[3] and Pier C. Giulianotti[1]

J Laparoendosc Adv Surg Tech A 2017

TABLE 7. TOTAL COST OF OPEN AND ROBOTIC LIVER RESECTIONS IN HIGH- AND NON-HIGH-COST PATIENTS

Non-high-cost patients (<$100,000 total cost)				*High-cost patients (>$100,000 total cost)*			
	Cases (n)	*Total cost*	*Average cost*		*Cases (n)*	*Total cost*	*Average cost*
Including readmission							
Robotic	65	2,125,737	32,704	Robotic	3	425,475	141,825
Open	51	1,670,363	32,752	Open	4	636,775	159,194
Excluding readmission							
Robotic	65	2,107,567	32,424	Robotic	3	343,144	114,381
Open	51	1,616,172	31,690	Open	4	579,651	144,913

- Rob: less ICU days, LOS, morbidity = decreased average costs!

Robotics Value

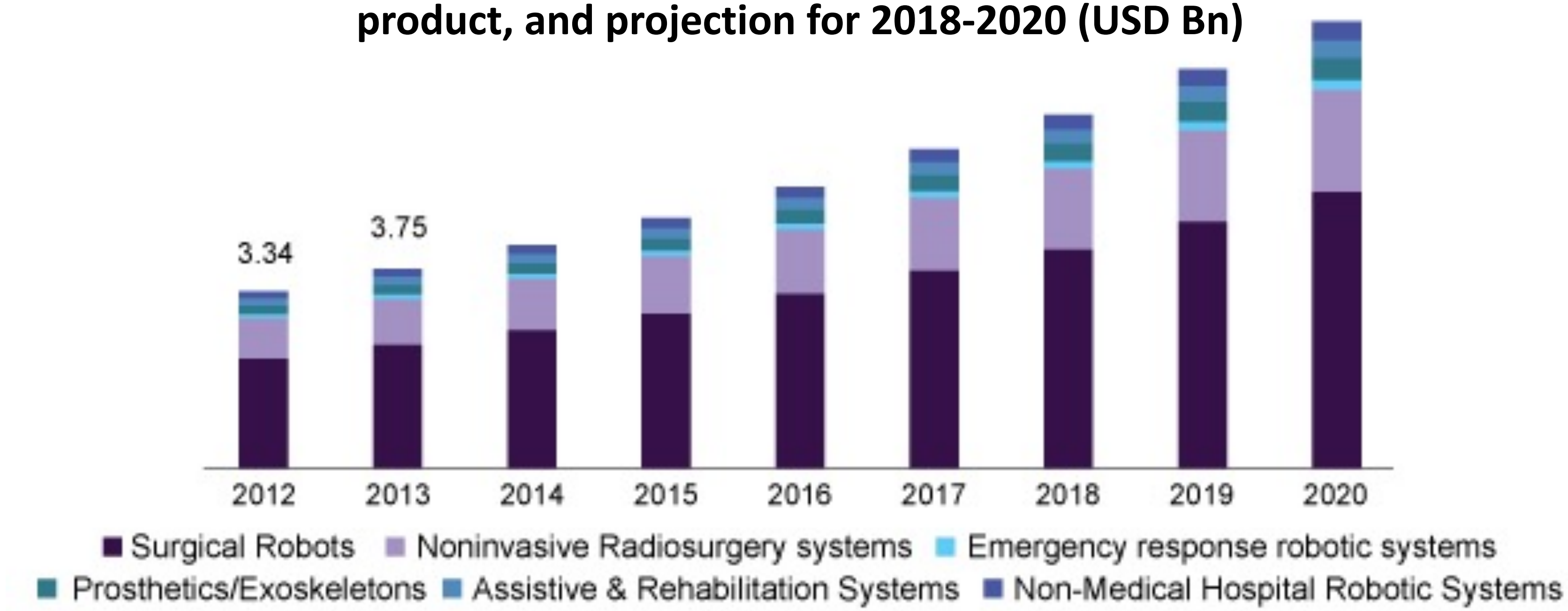
- Most investigations to date evaluated only the short-term value of robotic surgery, which is negatively impacted by the **demanding initial requirements**: the need of an adequate space and the significant additional equipment costs
- Considering the **long-term effects** of robotic assisted surgeries may add additional value:
  - ✓ quality improvements
  - ✓ better outcomes, that translate into costs savings due to less complications and reduced LOS
- "**The more cases, the better**" has shown to be the best strategy to further decrease the costs and increase robotic surgery value
- Usually, a limiting factor to surgery is the availability of inpatient beds; therefore, by decreasing LOS, **robotic surgery can potentially increase volume**, reducing its economic impact over time
- The introduction of **reusable instruments**, and the **increasing number of competitors** (all striving to improve certain critical aspects, such as haptic feedback and addition of a wider range of energy devices) are significantly lowering the overall financial burden of robotic surgery

[Perez RE, Schwaitzberg SD. **Robotic surgery: finding value in 2019 and beyond.** Ann Laparosc Endosc Surg 2019;4:51. doi: 10.21037/ales.2019.05.02]

The Robotic Revenue

- The estimated yearly number of procedures went from about 136,000 in 2008 to 877,000 in 2017
- Instruments and accessories make up the 52% of total revenues
- The estimated cost per procedure is around $3,568

North America medical robotic system market, by product, and projection for 2018-2020 (USD Bn)



[Schwitzer G, **New questions about the $3B/year robotic surgery business**, August 28, 2018. https://www.healthnewsreview.org
Medical Grand View Research, **Robotic Systems Market Size, Share & Trends Analysis Report By Product – 2018 Projection**, Report ID:978-1-68038-231-0]

Surgery enhanced by

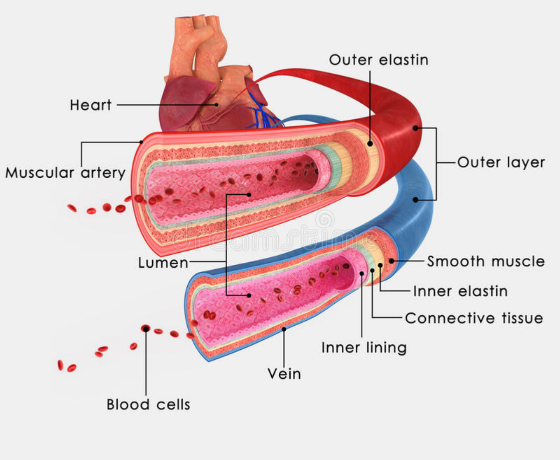
IndoCyanine Green (ICG)

Indocyanine Green is a tricarbocyanin developed by Kodak in 1955 for photographic studies and applied in medicine since the following year.

It’s very similar in his application to other contrast medium like methylene blue or sodium fluorescein but on the other side it offers some chemical-physical features:

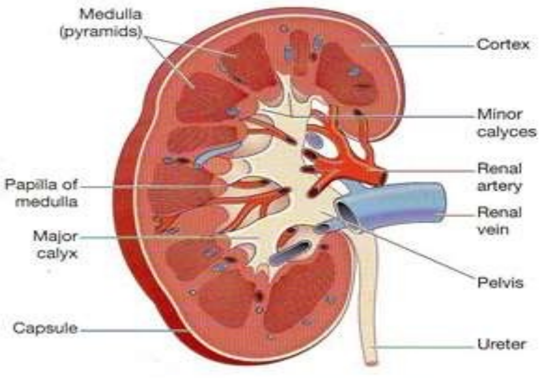
1. a stronger bond with plasmatic proteins
2. a short half-life that allows repeated and near injections
3. a lower toxicity

PHARMACOKINETIC

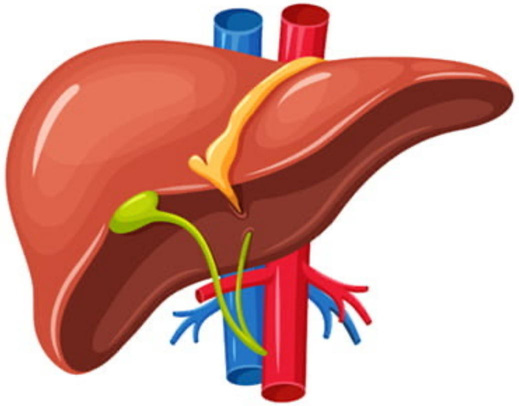


After 5-50'' from injection, ICG reaches veins and arteries

After 1 minute it arrives in kydneys where it remains for 20 minutes (wash-out time)



A longitudinal section of the right kidney.



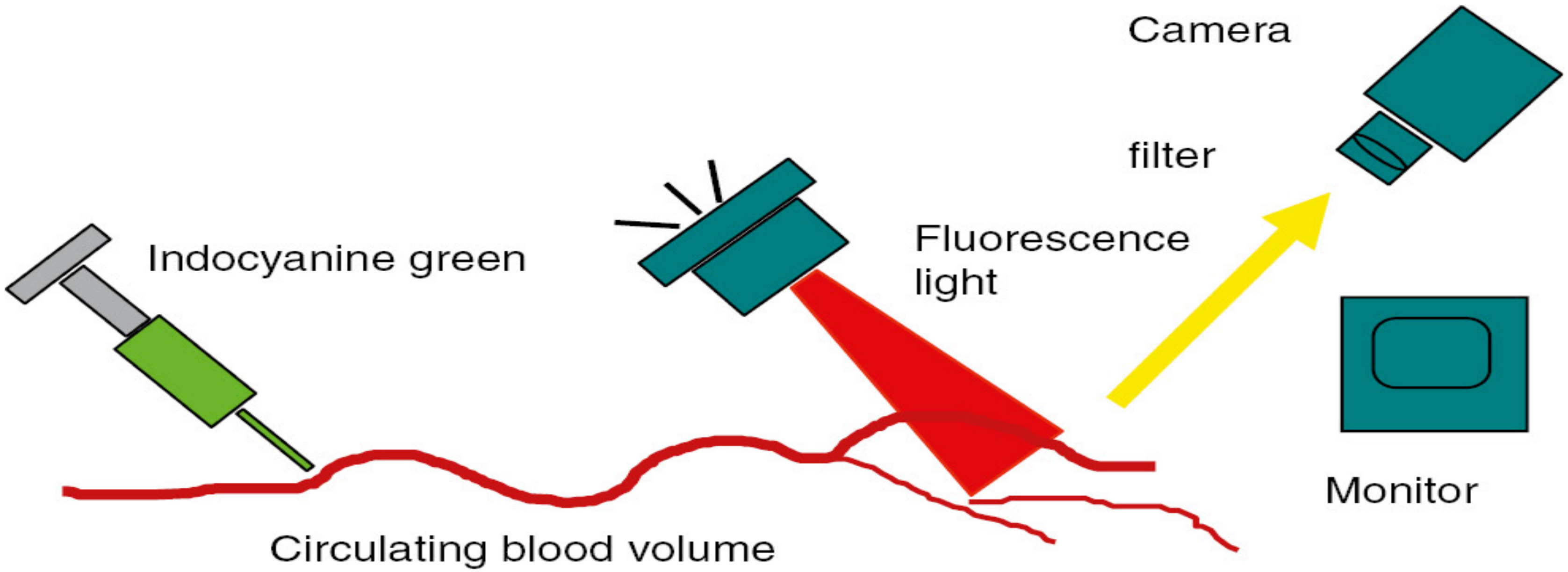
After 2 minutes, it reaches the liver and it's eliminated through bile without entero-hepatic recirculation

ICG-FLUORESCENCE IN HEPATOBILIOPANCREATIC SURGERY

After 24 hours from intravenous injection of ICG (0,5mg/kg), healty parenchyma has completed the elimination of the contrast, however it persists at intra- and perilesional level, allowing the identification of cholangiocarcinoma, hepatocarcinoma, colo-rectal or pancreatic liver metastasis.

Injected intraoperatively, ICG can provide a «road map» for hepatic surgery.

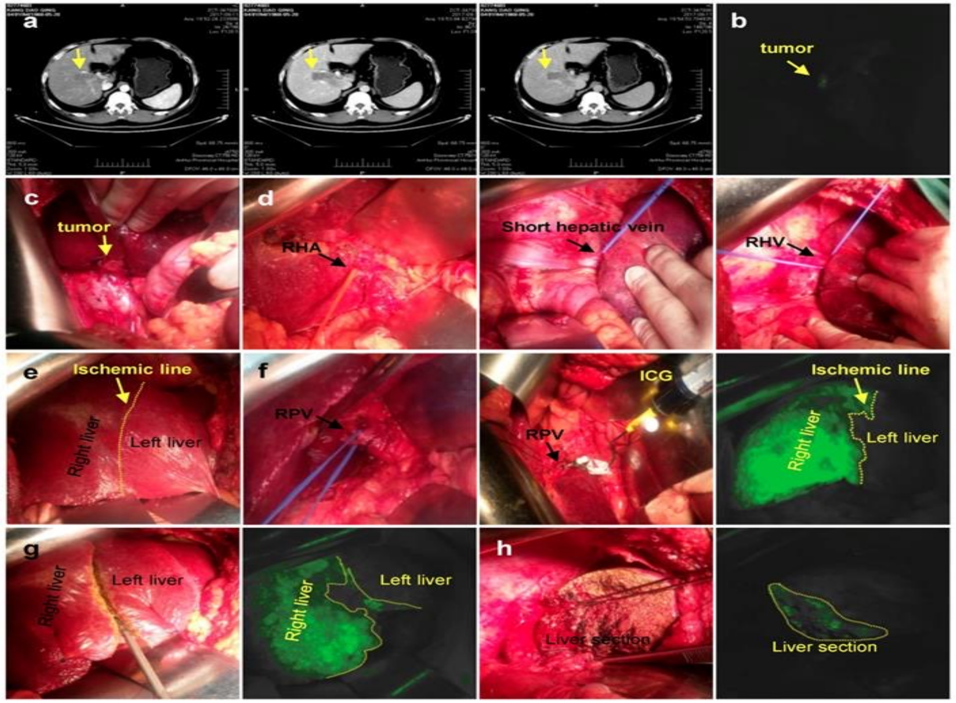
Another important use of ICG is the visualization of the anatomy of extra-hepatic biliary ducts.



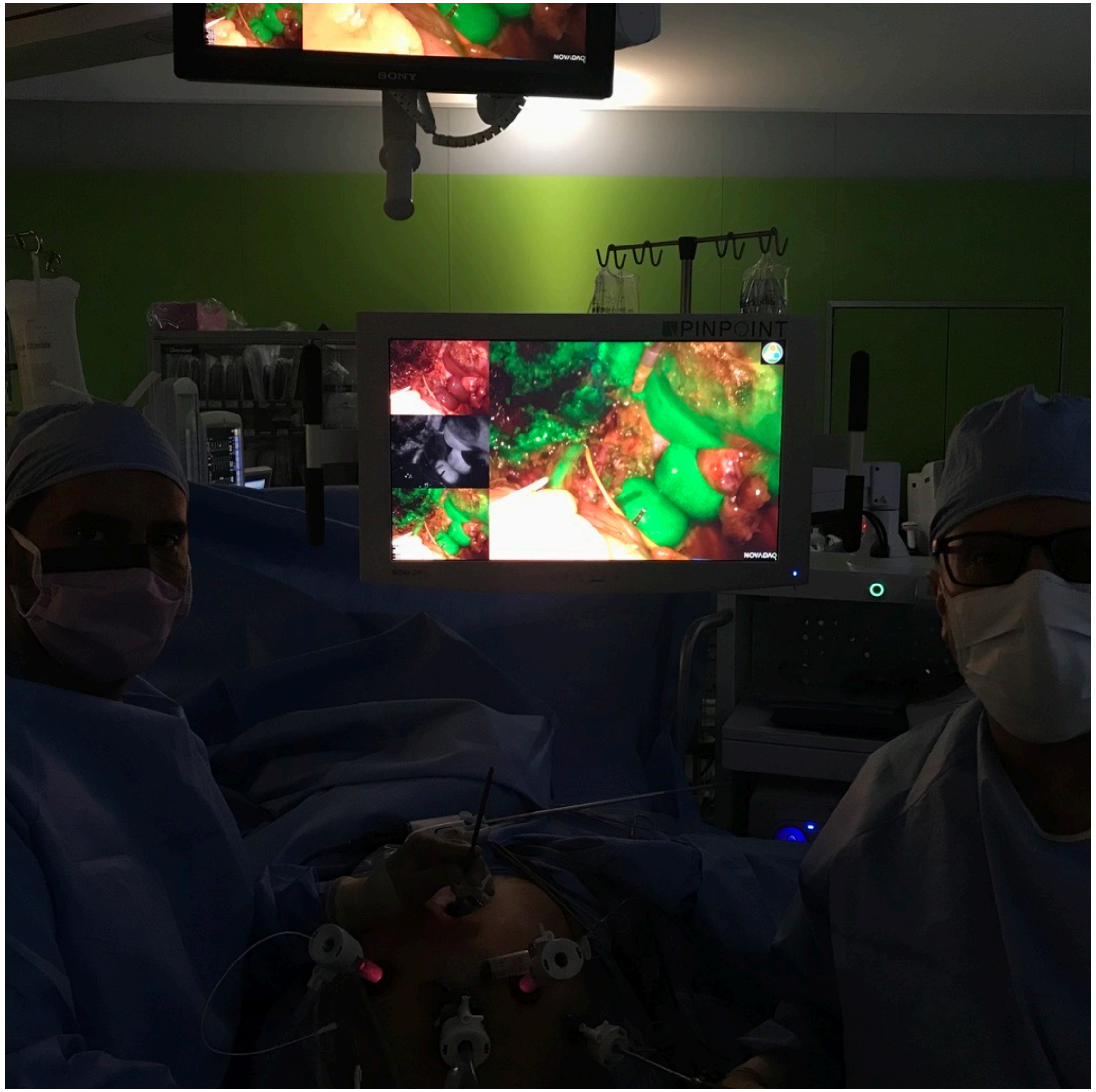
- **Hepatocellular carcinoma (HCC)** which obviously contains hepatocytes, ICG can be captured and retained by malignant cells; moreover, the secretion of ICG may be altered due to architectural disorders reducing the possibility of excretion
- Tumor formed by non-hepatocellular cells (i.e. metastases): ICG could be retained by a group of hepatocytes surrounding the nodule and compressed by the nodule itself
- Tumors containing predominantly epithelial cells that are normally part of the biliary ducts (cholangiocarcinoma): no dye absorption similar to metastases but with greater alterations in biliary delivery processes
- In clinical practice, currently no clearly defined timing for i.v. injection. Indeed, especially at an early stage, increased vascularization of the neoplasm could result in greater exposure to the dye, regardless of the type of cells contained therein.
- ICG contains iodine and consequentially it’s contraindicated in people with previous adverse reaction to iodinated contrasts or thyroid malfunctions.

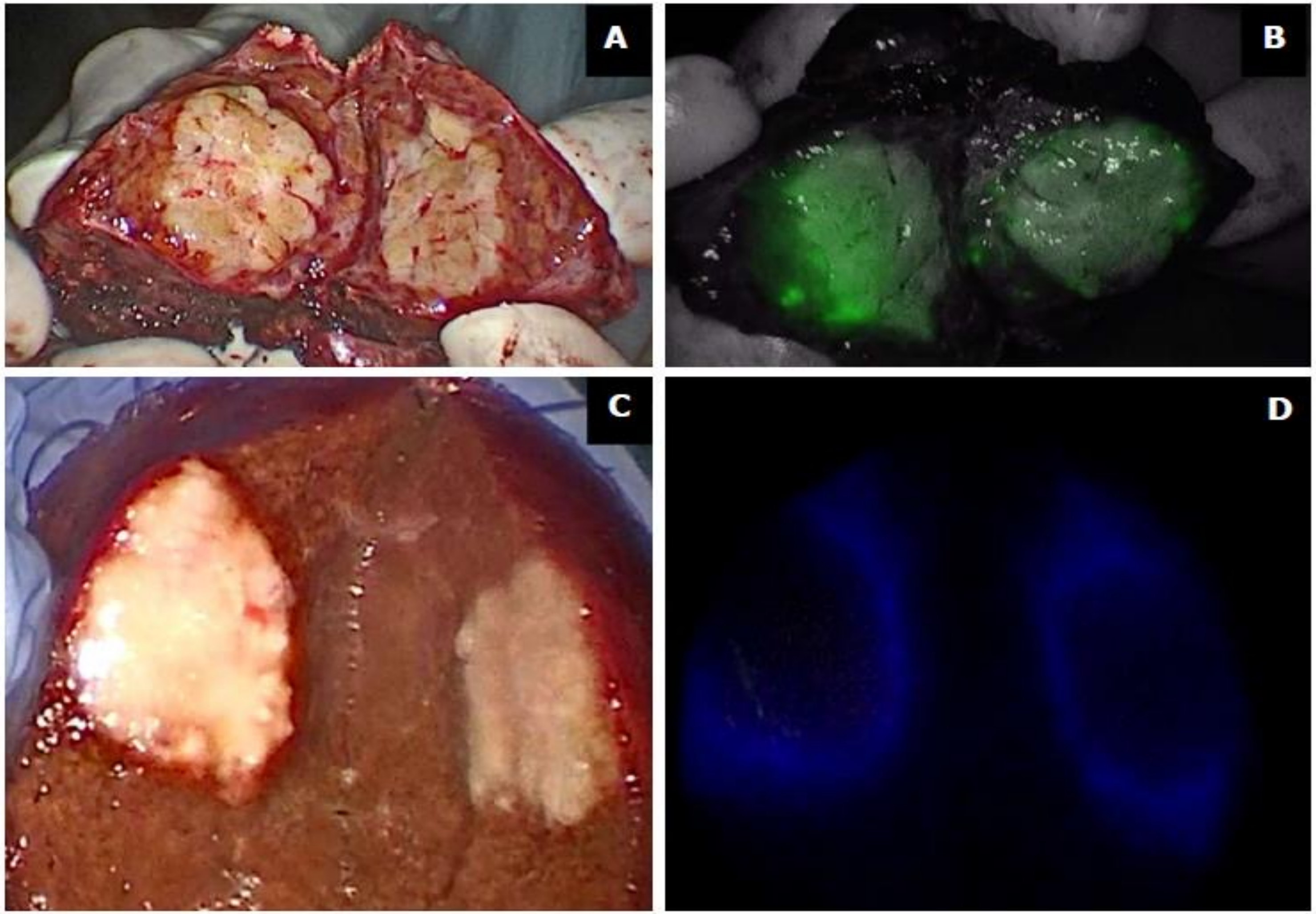
Nonetheless these important deficiencies, ICG-based fluorescence may be very helpful in HCC surgery in:

1. the detection of small superficial malignant nodules not detected in the preoperative study
2. excluding the malignant nature of small superficial nodules of uncertain contrast medium behavior (especially useful for HCC in cirrhotic liver tissue)
3. the execution of hepatic functional test (LiMon test)
4. The evaluation of the perfusion of the remnant liver after hepatic resections

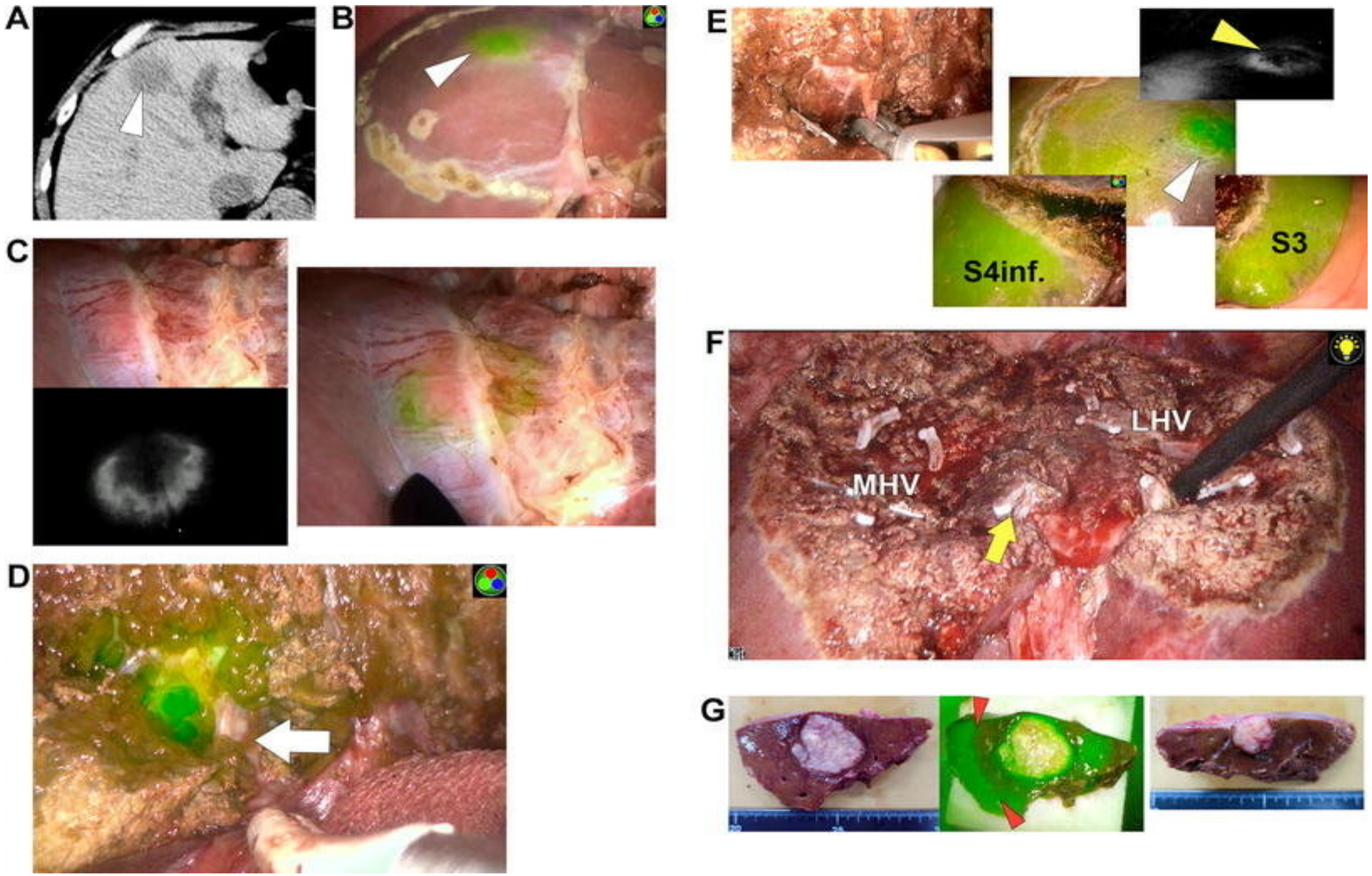


How it looks ICG Enhanced Laparoscopic Surgery



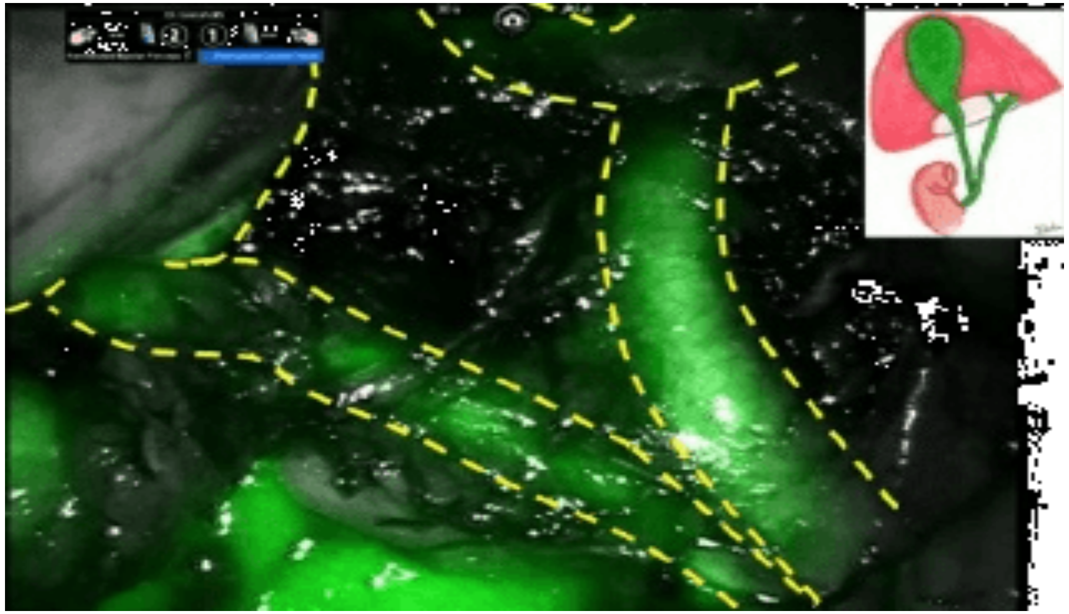


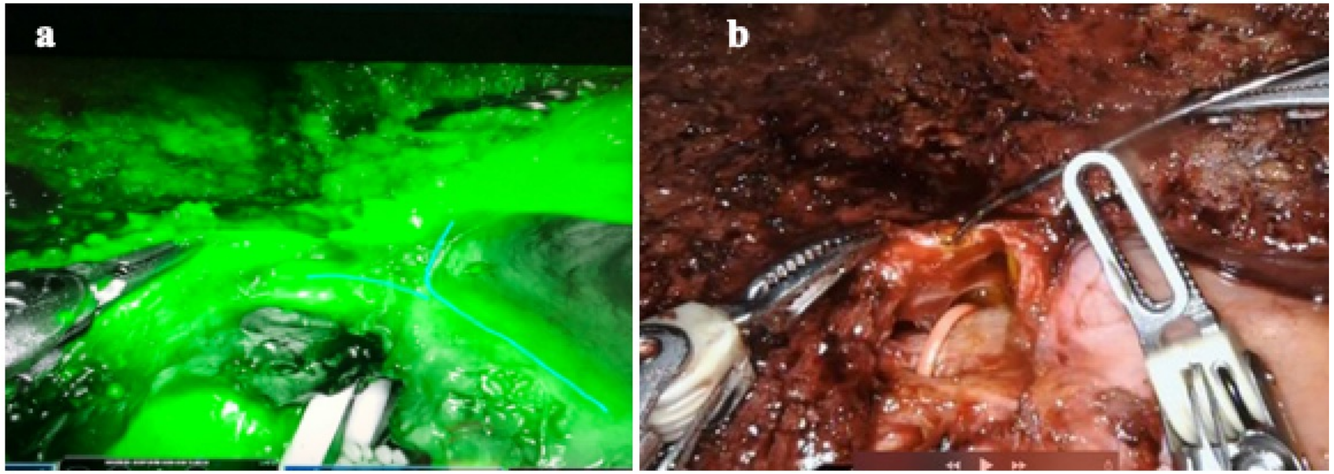
Indocyanine green in liver surgery. Primary liver tumors show intense and complete staining because their hepatocytes take up ICG but do not secrete it (A and B); liver metastases show a ring appearance because their cells do not take up ICG but hepatocytes surrounding the nodule are compressed (C and D). ICG: Indocyanine green.



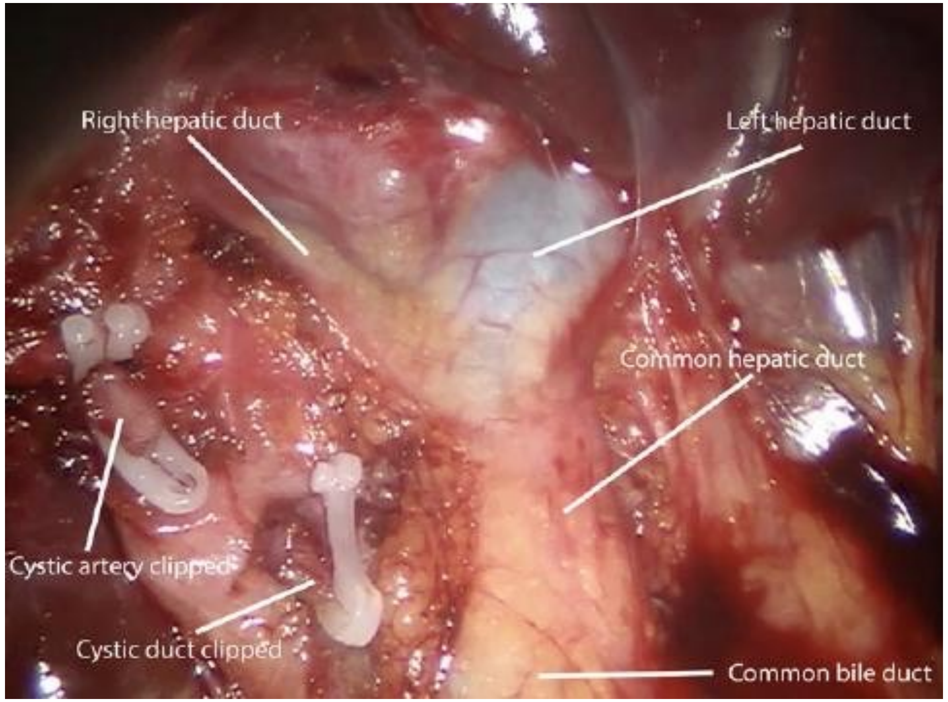
Laparoscopic hepatectomy using indocyanine green (ICG)-fluorescence imaging. A Preoperative computed tomography revealed a metastatic tumor (arrowhead) in the superior region of hepatic segment 4 (S4sup). B The hepatic transection line is set based on intraoperative ultrasound and fluorescence imaging of the main tumor, indicated on the liver surfaces as a green-pseudocolor (arrowhead). C Fluorescence imaging also identified a new lesion with rim fluorescence, consistent with a metastatic liver tumor, during dissection of the coronary ligament. The upper left, lower left, and right side images are the white-light color image, the monochromatic fluorescence image, and the fusion-fluorescence image, respectively. D ICG imaging during parenchymal transection shows the fluorescence signals that have accumulated around the main tumor adjacent to the root of the portal pedicle of S4sup (arrow), which allows confirmation of the surgical margin. E Following closure of the S4sup portal pedicle (upper left), ICG (1.25 mg) is injected intravenously and fluorescence images are obtained to confirm the blood supply to hepatic regions to be preserved (S2, S3, and S4inf). Both the main tumor (white arrowhead) and the newly detected tumor (yellow arrowhead) are located in ischemic region of the liver (S4sup). F The hepatic raw surface following resection of S4sup extended to S3. Arrow, MHV, and LHV indicate the stump of the S4sup portal pedicle, middle hepatic vein, and left hepatic vein, respectively. G Cut surfaces of the main tumor showing rim fluorescence (left) and the newly detected tumor (right). Red arrowheads indicate the boundaries between the parenchyma of S4inf with and S4sup without fluorescence.

ICG-FLUORESCENCE GUIDED CHOLANGIOGRAPHY

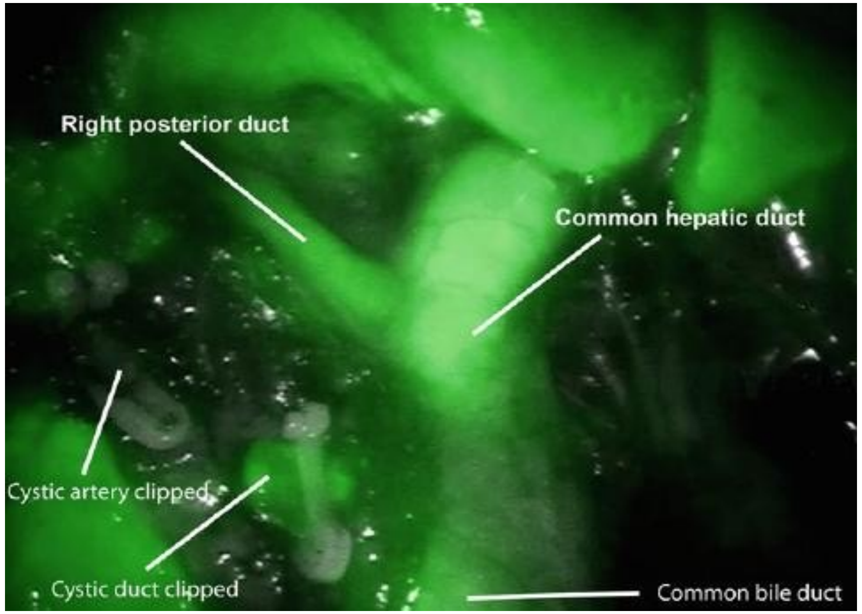




Troisi RI, Liver Transplantation 2020



Laparoscopic view without ICG after dissection



ICG-guided cholangiography after dissection

ICG-guided Pure Laparoscopic Right Donor Hepatectomy

Troisi RI, Rashidian N, El Sheikh Y

Department of Clinical Medicine and Surgery, Federico II University, Naples, Italy

Organ Transplant Center, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia

مستشفى الملك فيصل التخصصي ومركز الأبحاث
King Faisal Specialist Hospital & Research Centre
Gen. Org. مؤسسة عامة

LiMon Test

It's a non invasive way, ICG-guided, to monitor hepatic function before surgery.

Duration: 10 minutes

Continuous monitoring of HR and O2 saturation

It provides, through a transcutaneous densitometer, the following data:

1. Plasma Deletion Rate (PDR) (normal values >18-24% /min)
2. Retention rate at 15 minutes from injection (R15) (normal values <10%)

This test is very reliable but only in steady hemodynamic conditions & in presence of bilirubin level < 2,5 mg/dL.

As a matter of fact, elevate levels of bilirubin compete with indocyanine green for the bond with plasmatic proteins and this effects its pharmacokinetic

PDR and R15 effect post-operative morbidity and can give some data about maximum possible hepatic resection, even if these data must be confirmed and compared with those one obtained by hepatic volumetric reconstruction

R15 <10% -----------→ extended hepatic resection

10% < R15 <20% ----------→ not over bisegmentectomy

R15 >20% ------------→ not over segmentectomy

R15 > 30% -----------→ important increase of post-operative morbidity

(even if after a segmentectomy)

ICG-FLUORESCENCE IN COLO-RECTAL SURGERY

ICG-fluorescence has, also, a validated use in colo-rectal surgery and, above all, in prevention of anastomosis leakage (AL) that represent one of the most frequent complication (with a range between 3% and 28% considering all different types of anastomosis).

Among the different factors that can ease the appearance of ALs, those one, of more surgical importance, that can be expected and avoided are:

1. Inadequate tissue perfusion
2. Failed anastomosis control

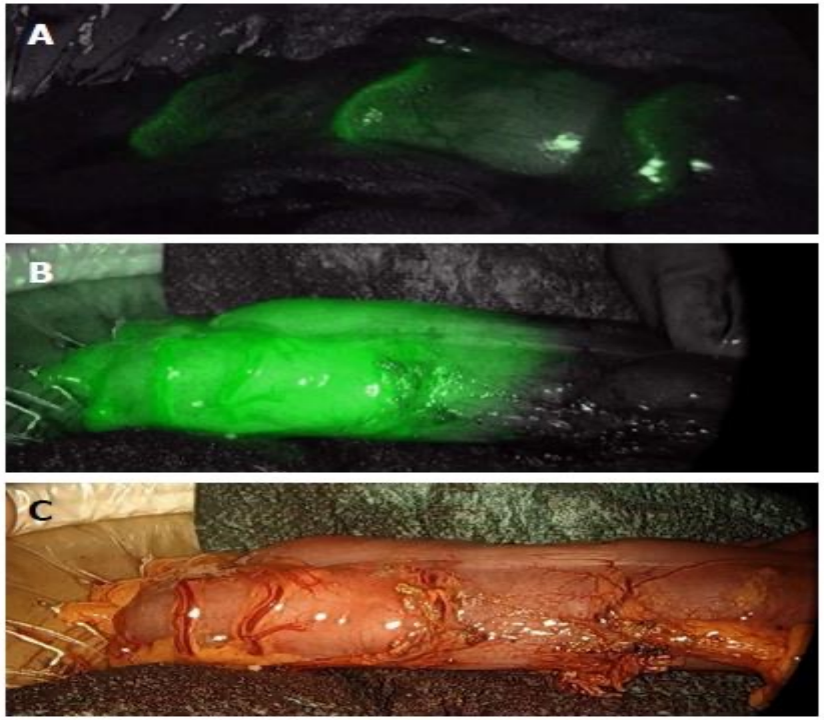


Figure 1 Colon perfusion before anastomosis during left colectomy. A few seconds after the i.v. injection of 0.3 mg/kg indocyanine green, bowel arteries clearly appear (A); thereafter, the bowel perfusion cut-off area becomes evident (B and C).

After the medium-lateral dissection necessary to release colon from descending to rectum and the intracorporeal division of proximal mesocolon, the surgeon comes to the section point, chosen in white light and marked with landmark.

At this point ICG is injected i.v. and after 50'' surgeon can observe the fluorescence of the descending colon and the perfusion of the section point and, if not convinced, change it. If necessary, it can be used another dose of ICG but generally the visualization is optimal.

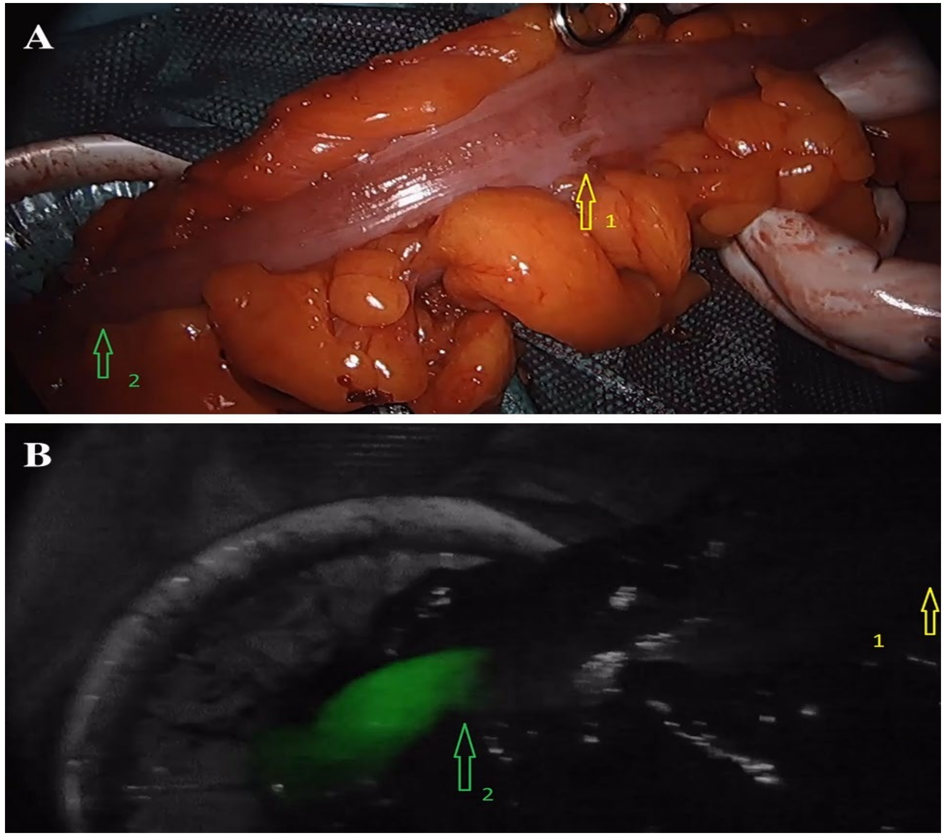
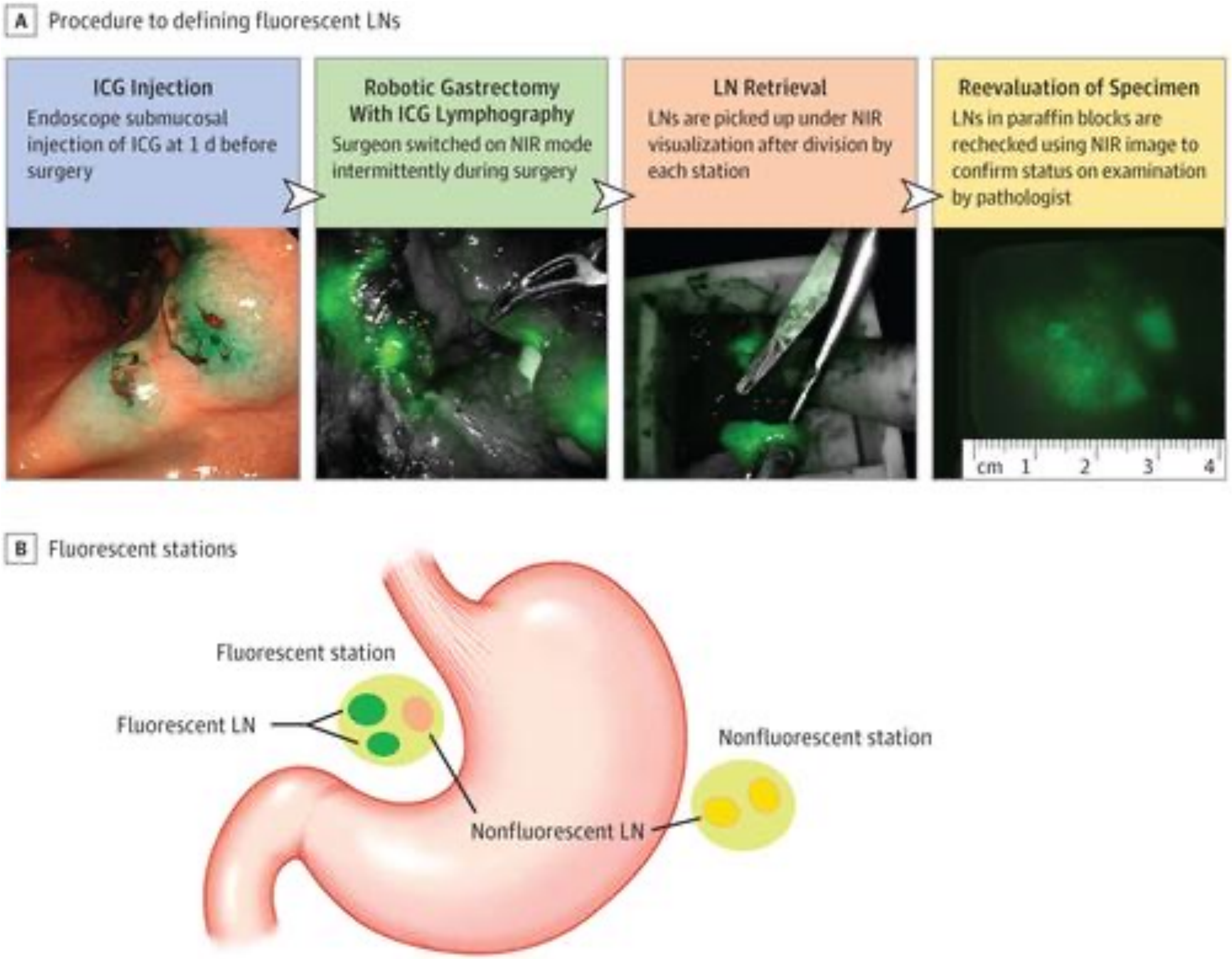


Fig. 1 Fluorescence evaluation during laparoscopic left hemicolectomy. **A** White light. **B** Near infra-red light. Arrow 1: site where the surgical team decided to mark as transection line due to the color and to the transection of the mesenterium. Arrow 2: site where the indo- cyanine green fluorescence angiography identifies the proper vascular supply of the colon

Preliminary results are suggesting that this technique is feasible and can help the surgeon to have a real-time visual reference of the lymph nodes during dissection along the main gastric vessels, thus adding a potentially valuable adjunct to perform a complete D2 lymphadenectomy.



SUMMARY ICG-GUIDED SURGERY (1)

- One of the most well-established use of fluorescence imaging is for checking anastomotic stump perfusion in visceral surgery. Some prospective uncontrolled series and retrospective controlled studies, mainly dealing with colorectal and esophageal surgery, have confirmed the usefulness of this technique
- The second field of application for which there is a unanimous consensus in the literature pertains to visualization of the biliary anatomy during cholecystectomy. A comparison with intraoperative cholangiography demonstrated the superiority of fluorescence in terms of simplicity, timing, and efficacy

SUMMARY ICG-GUIDED SURGERY (2)

- In liver surgery, multiple possible uses of fluorescence have been described (tumor visualization, especially in laparoscopic surgery, vascular segmentation, biliary leak identification).
- With regard to lymph node navigation in gastrointestinal tumors, most studies in the literature have focused on the sentinel node technique, whereas the use of fluorescence for complete lymphadenectomy has been described only by a few very experienced centers.

VIRTUAL REALITY

Digitalizing Hepatic Resections To Plan The Best Surgical Strategy

(3D rendering or modeling)

Why a 3D Rendering?

Visualization of anatomical and pathological structures

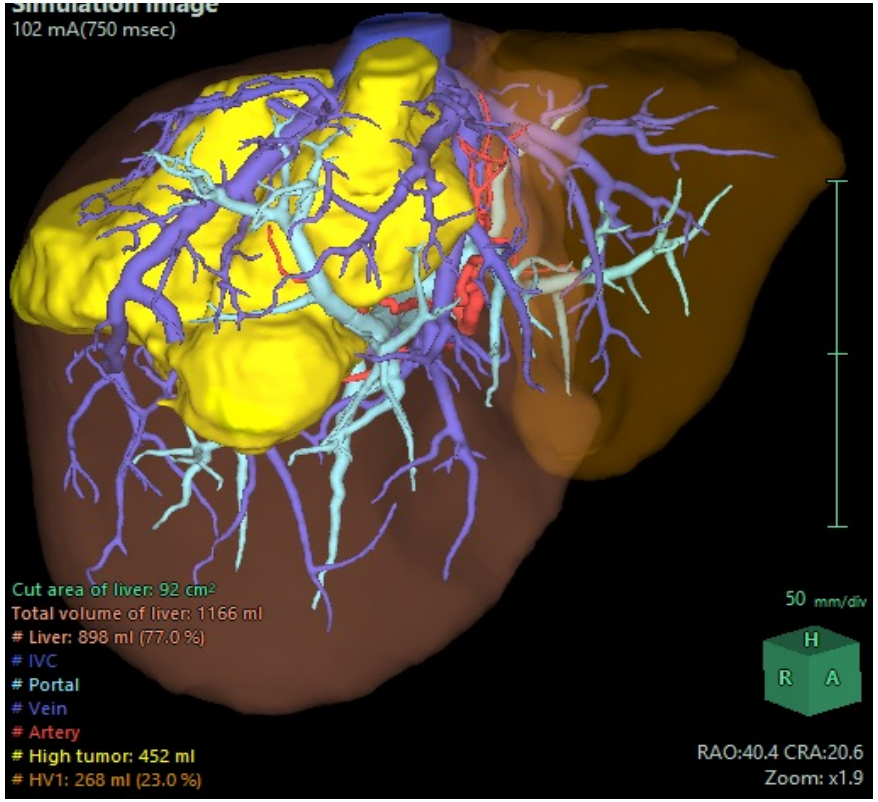
Evaluation of anatomical abnormalities

Particularly useful during minimally invasive surgery procedures:

1. Refine surgical planning(s)
2. Improved safety during transection
3. Potentially increasing surgical eligibility
4. Allowing parenchyma-sparing resection

How It Works: Step-by-Step

1) Triphasic CT-scan ⟶ slices thickness 1mm (0.6mm)



How It Works: Step-by-Step

2) Images loaded on local PACS and/or on the dedicated 3D Computer

- Dell® Precision 7820 – Intel® Xeon Silver 4114 CPU 2.20 GHz and 2.19 GHz Double Processor – 32 GB RAM – Windows 10 Pro

3) Contour-tracing of liver profile ⟶ automatic computation of liver volume

Software developed and optimized for **surgical use** and not for radiologic use.

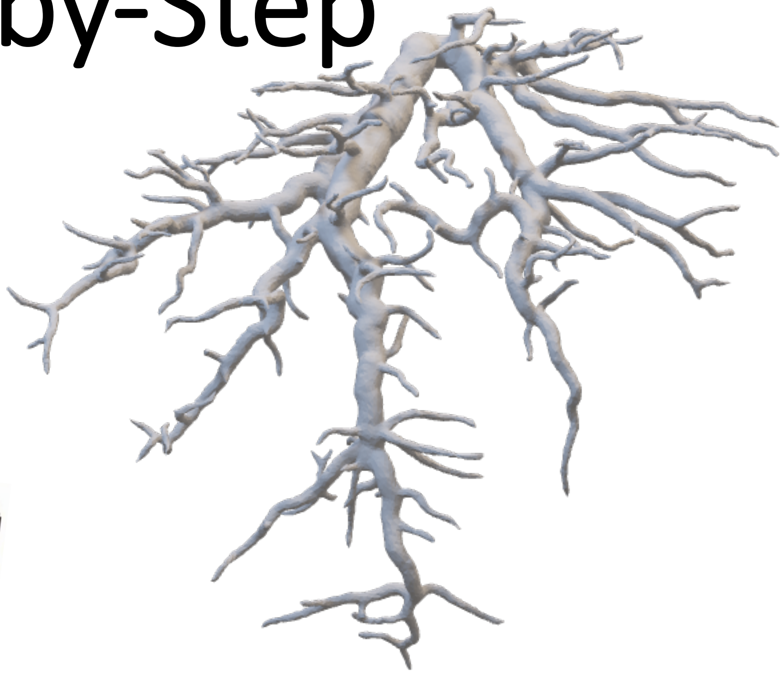
- **Semi-Automatic process** ⟶ automatic image density analysis coupled with shape analysis
- **Manual details** ⟶ manual corrections possible in case of failure or inaccuracy of the automatic process

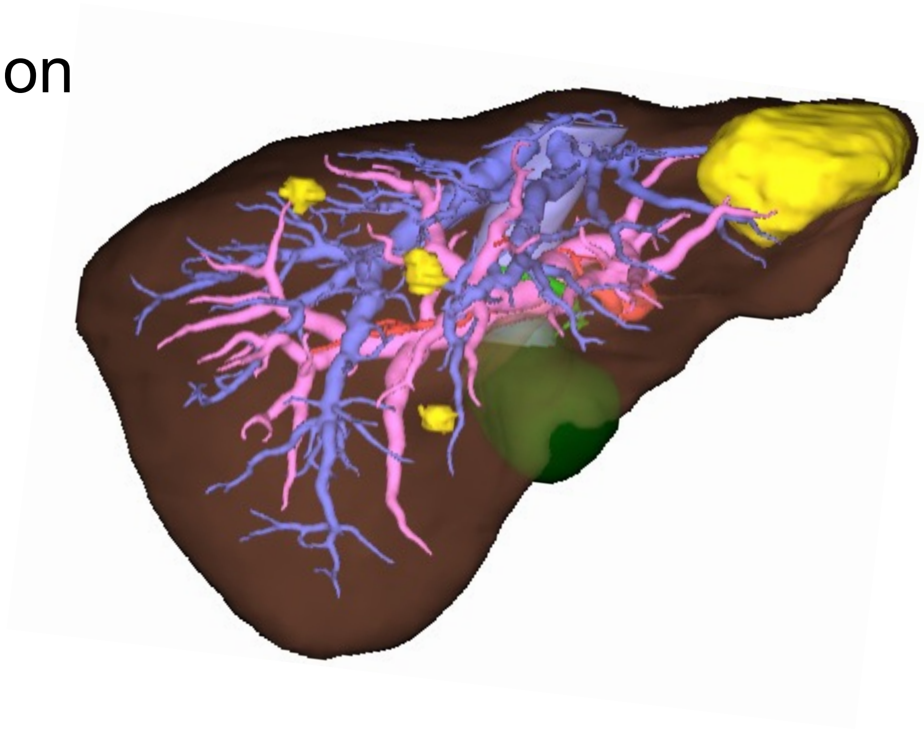
How It Works: Step-by-Step

4) Vascular profile

5) Lesion Extraction

6) 3D model

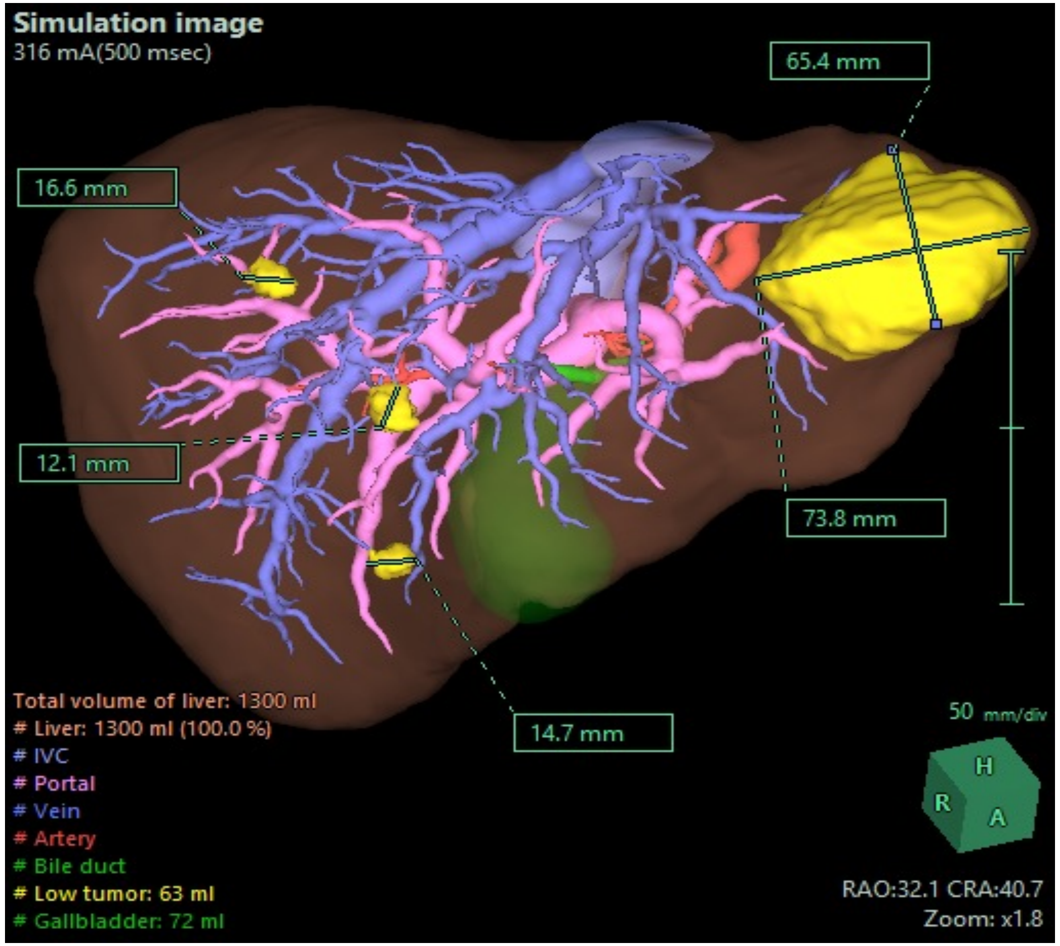




How It Works: Step-by-Step

7) Measurements

8) Volumetry



Operation: Operation1

Observation:

Result

Total liver volume	1281 ml
Remained liver volume	1126 ml (87.9 %)
Cut area of liver	112 cm^2

Region list

Name	**Volume**
Scoop1	6 ml (0.5 %)
Scoop2	21 ml (1.7 %)
Scoop3	10 ml (0.8 %)
Region1	118 ml (9.2 %)

How It Works: Step-by-Step

9) Resection Hypothesis

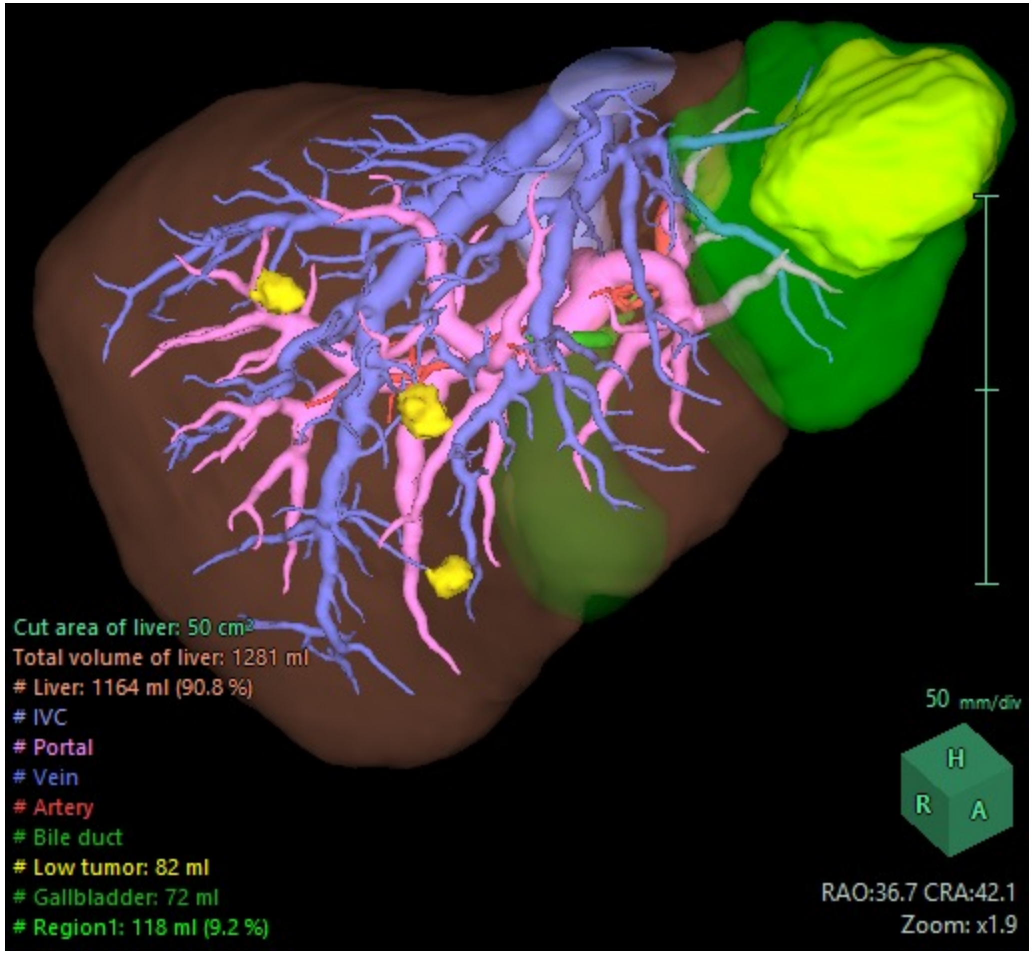
Operation: Operation1
Observation:

Result

Total liver volume	1281 ml
Remained liver volume	1164 ml (90.8 %)
Cut area of liver	50 cm^2

Region list

Name	Volume
Region1	118 ml (9.2 %)

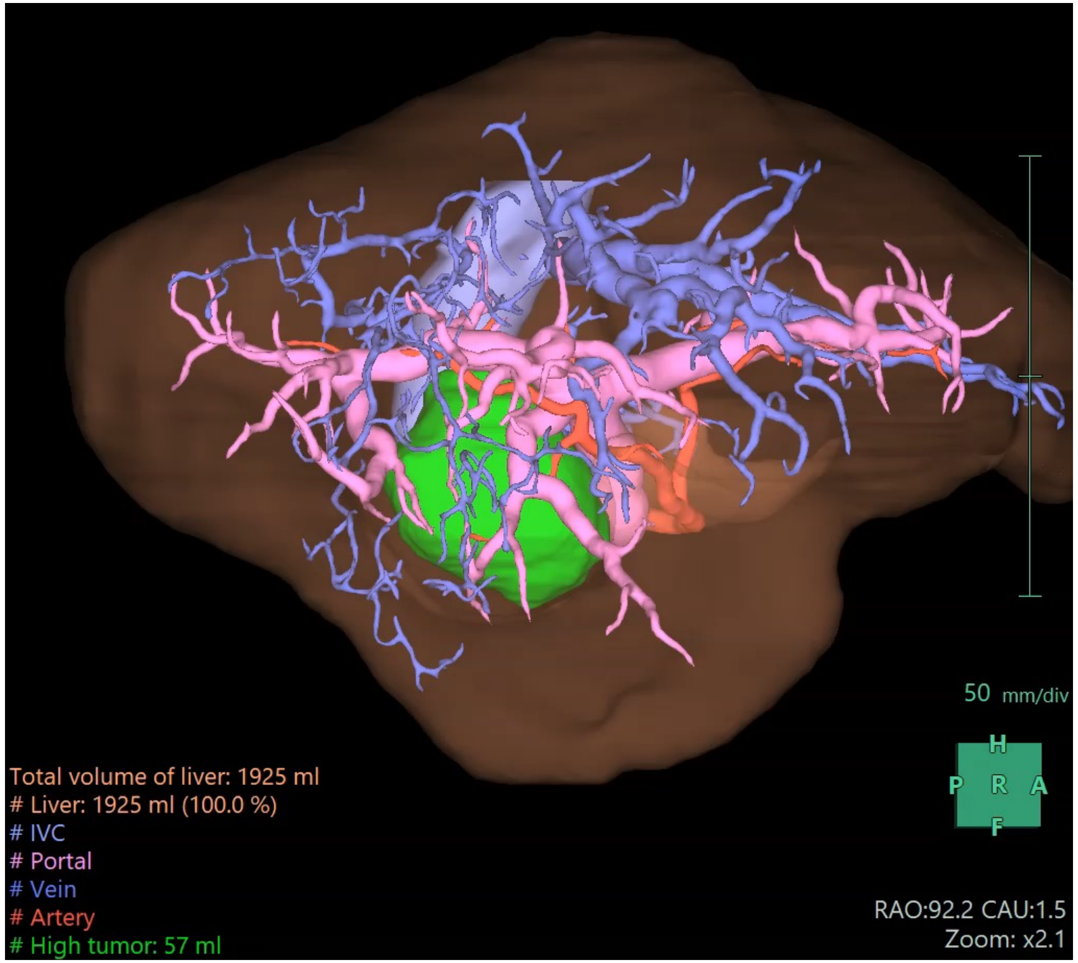


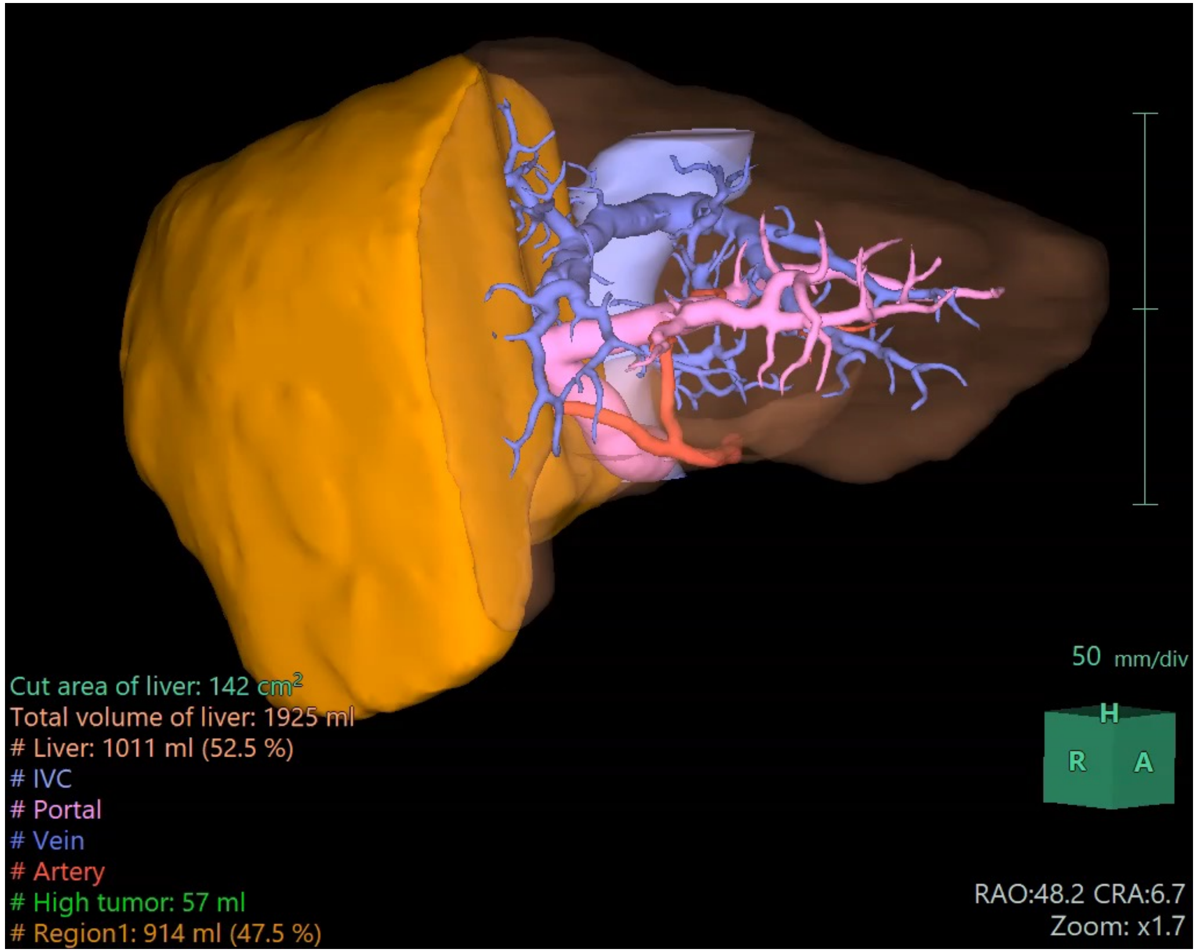
Parenchyma-Sparing Resections

P.M. – 80 y.o.

HCC Sg5-6 (4.5x4.7cm)
Adjacent to portal vein
and its right branch

AFP: 7.2 ng/mL





Operation: Hypot_Res

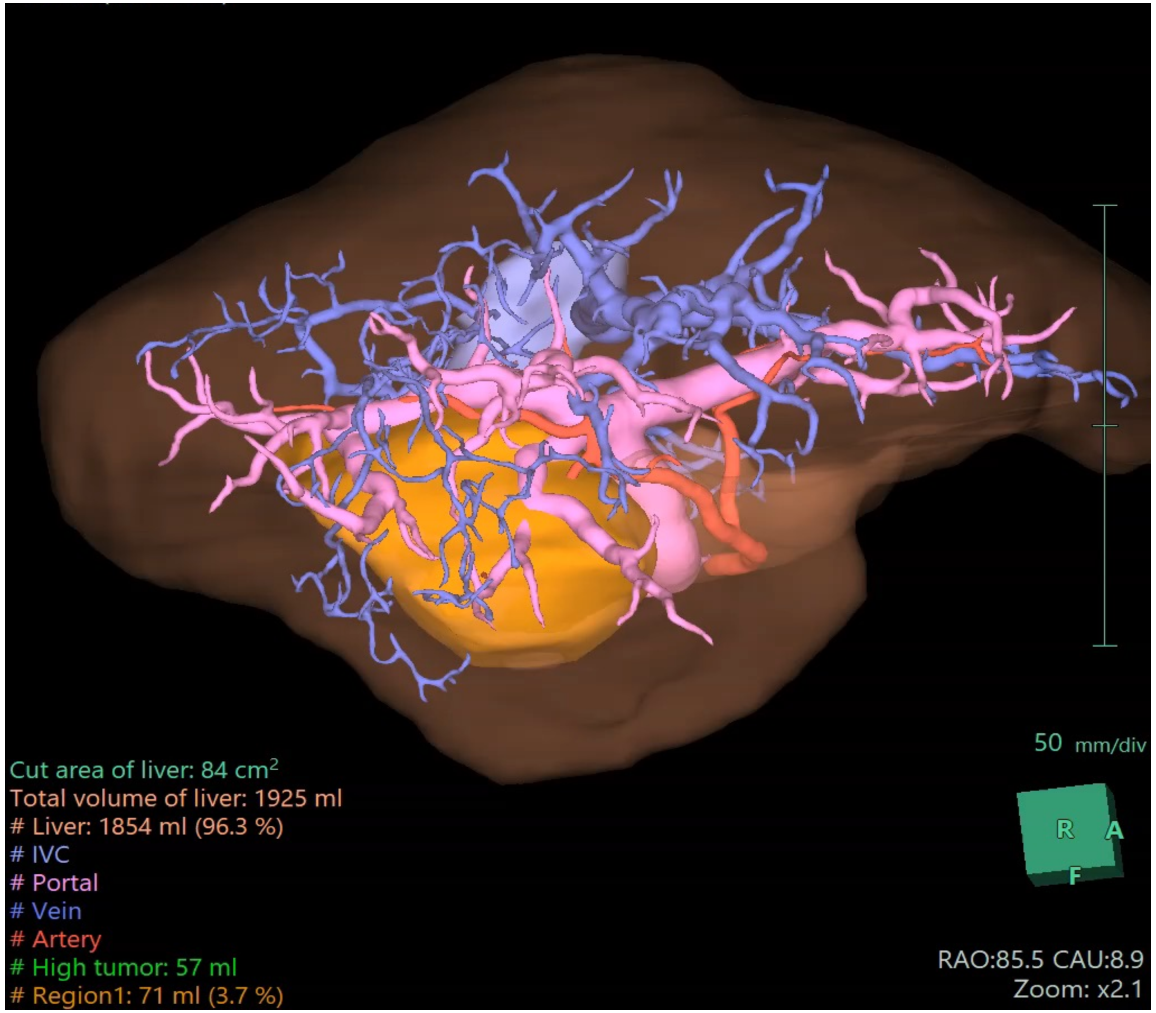
Observation:

Result

Total liver volume	1925 ml
Remained liver volume	1011 ml (52.5 %)
Cut area of liver	142 cm^2

Region list

Name	Volume
Region1	914 ml (47.5 %)



Operation: Operation1

Observation:

Result

Total liver volume	1925 ml
Remained liver volume	1854 ml (96.3 %)
Cut area of liver	84 cm^2

Region list

Name	Volume
Region1	71 ml (3.7 %)

Wedge resection Sg5-6 with dissection from right portal pedicle

- Macronodular cirrhosis
- No vascR1 (IOUS)

Drawbacks

- **Time-consuming procedure** (median reconstruction time: 2.5 hours [1.5-5.5 hours])
- **Organ displacements and deformations** during the surgical procedure
- **Biliary ducts rendered only if dilated**
- **Validated for CT-scans only**
- **No info on functional state** of remaining liver parenchyma ⟶ HB Scintigraphy, LiMON Test

Actually the 3D reconstruction is NOT replacing IOUS but its role is the SIMULATION of an operation!!

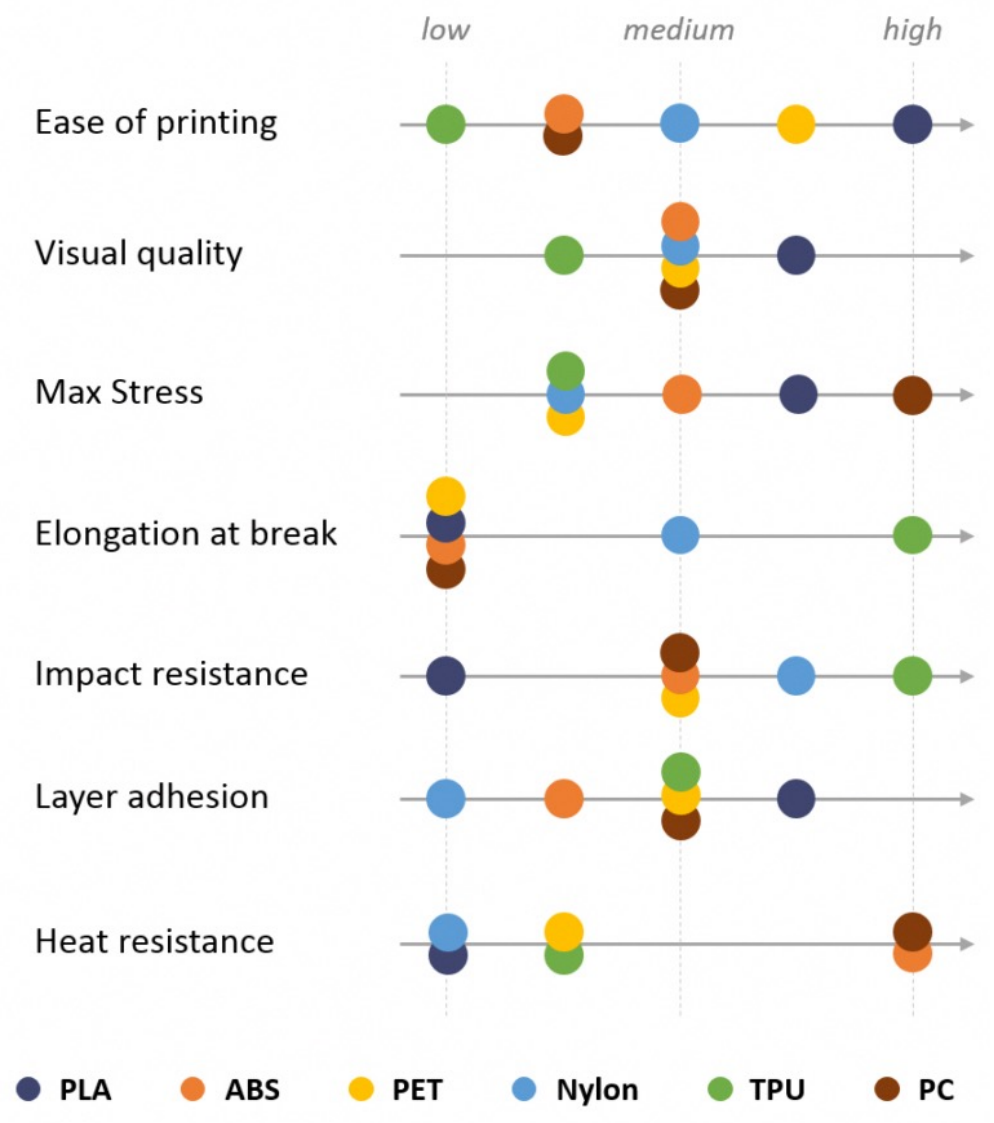
THE RISE OF 3D PRINTING

- **Early years: 1980 – 1999:** The first patent was found by Dr. H. Kodoma, in Japan, in 1980. During this period most of the technologies were being invented.

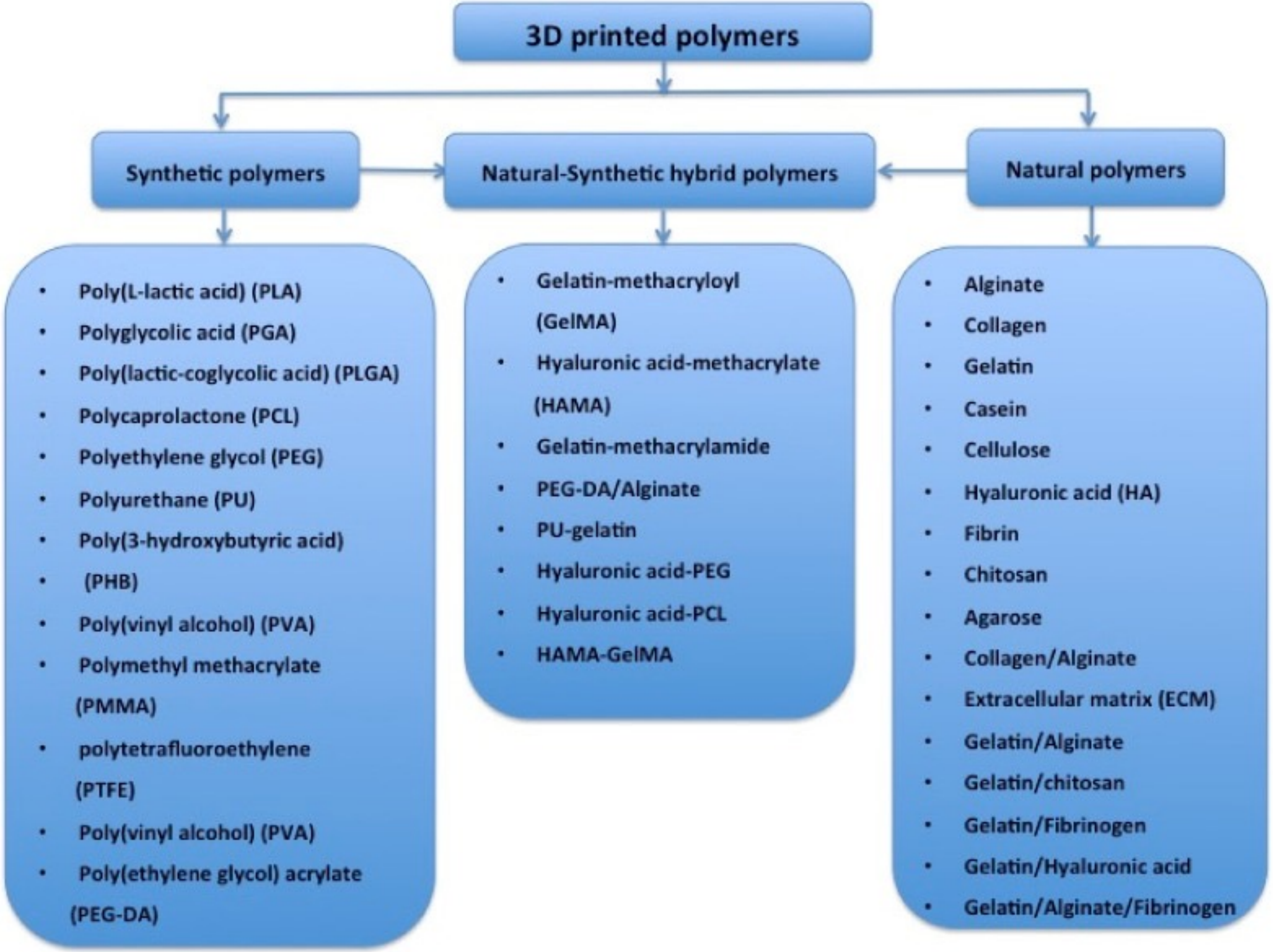
- **1999 to 2010:** 3D printing saw use in the fields of medicine and biology, aerospace, automotive and construction industries. Biggest breakthroughs in medical field happened when scientists at Wake Forest Institute for Regenerative Medicine successfully 3D printed a working human bladder. They printed a synthetic scaffold of the bladder and coated it with the host's cell.

- **2011 to the present day:** 3D printing technology has advanced at rapid rate over the last few years. The rapid increase in processing power and speed from improvements in chip technology has led to decreases in the overall cost of operation, increased accuracy of printers, and improved ease of operation.

MATERIALS IN 3D PRINTING



MATERIALS IN 3D BIOPRINTING



PURPOSE OF 3D PRINTING IN SURGERY

- **SURGICAL PLANNING**: To facilitate the planning of a given procedure by showing the anatomical details of the surgery site and anticipating technical problems; select most suitable surgical device and to define the management strategy

- **EDUCATION AND TRAINING**: To facilitate the comprehension of surgical procedure on the part for residents and young surgeons

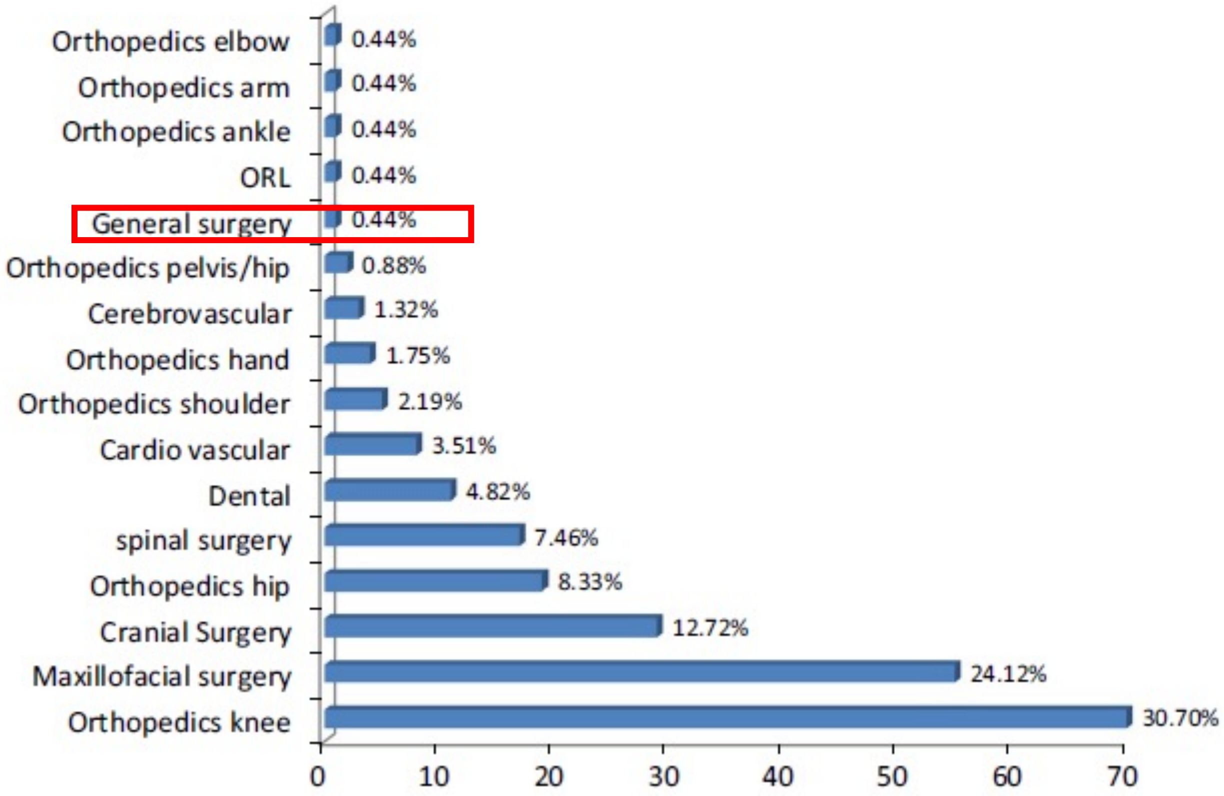
- **SIMULATION**: Thanks to the use of deformable materials that enable dissection, suturing and performance of anastomosis on patient specific platforms.

- **ANATOMICAL COMPREHENSION**: for better understanding od fine anatomical details which may influence the management of the underlying disease

- **PATIENT COUNSELING**: to enhance the patient's understanding of the planned intervention and his/her awareness of the expected outcomes and associated risk

- **SURGICAL TOOLS**: for the development of ad hoc 3D printed tools for experimental research in surgical technique and technologies

3D PRINTING IN SURGERY

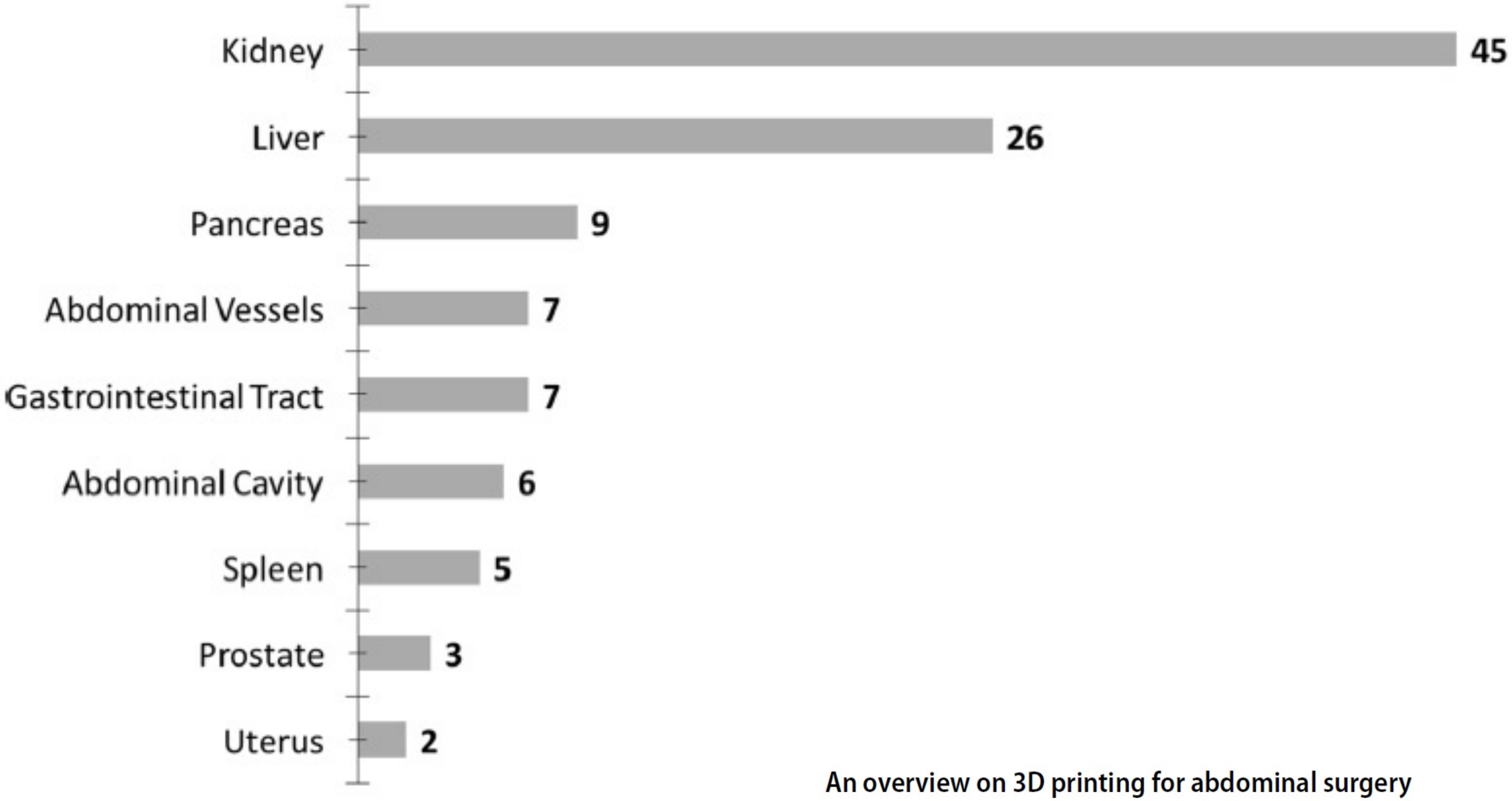


3D-printing techniques in a medical setting: a systematic literature review

Philip Tack[1*], Jan Victor[2], Paul Gemmel[3] and Lieven Annemans[1]

3D PRINTING IN ABDOMINAL SURGERY

Frequency of publication in relation to the anatomical district:

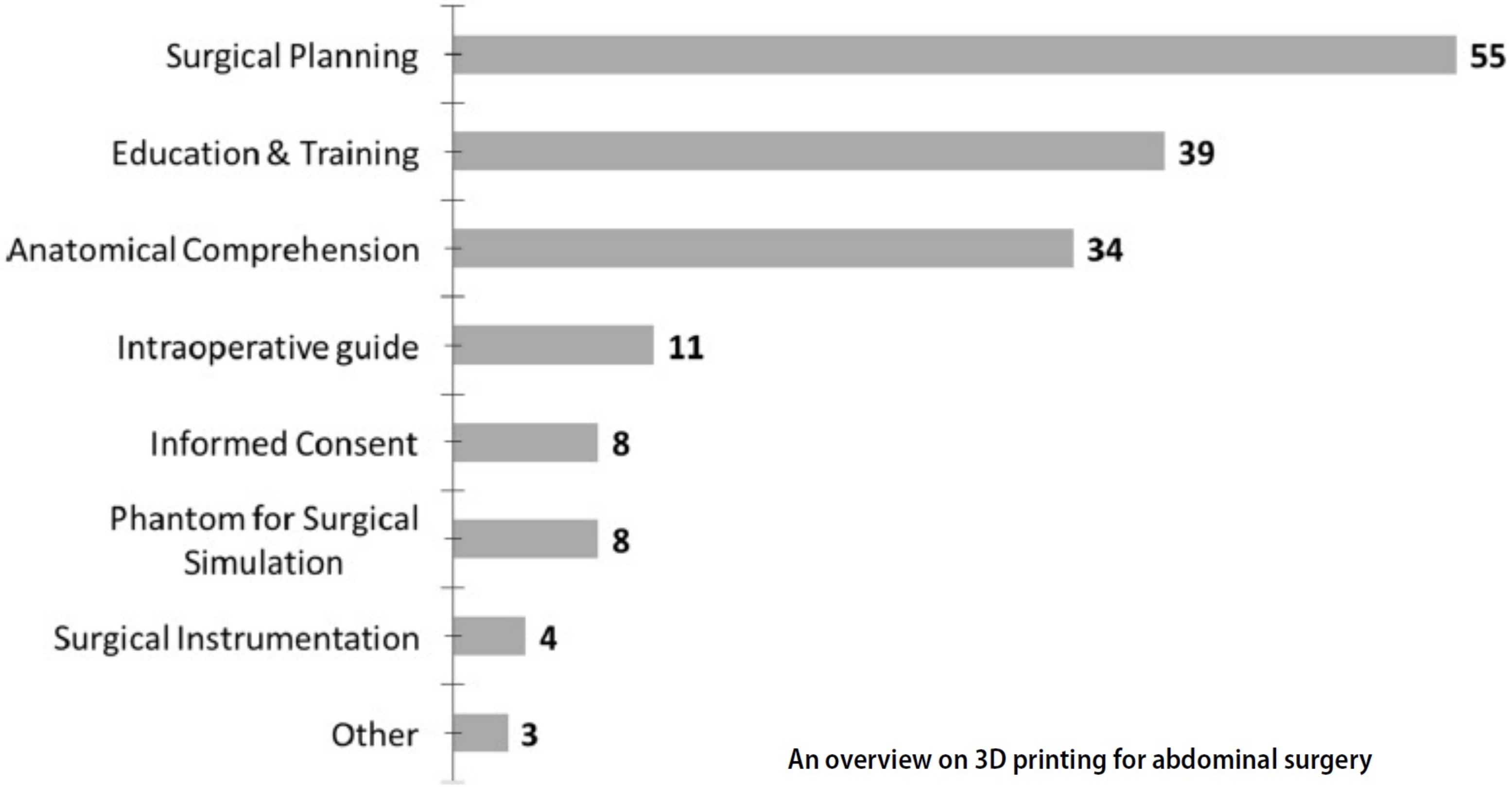


An overview on 3D printing for abdominal surgery

Andrea Pietrabissa[1,2] · Stefania Marconi[3] · Erika Negrello[1] · Valeria Mauri[1] · Andrea Peri[1] · Luigi Pugliese[1] · Enrico Maria Marone[1,2] · Ferdinando Auricchio[3]

3D PRINTING IN HPB SURGERY

Application:



An overview on 3D printing for abdominal surgery

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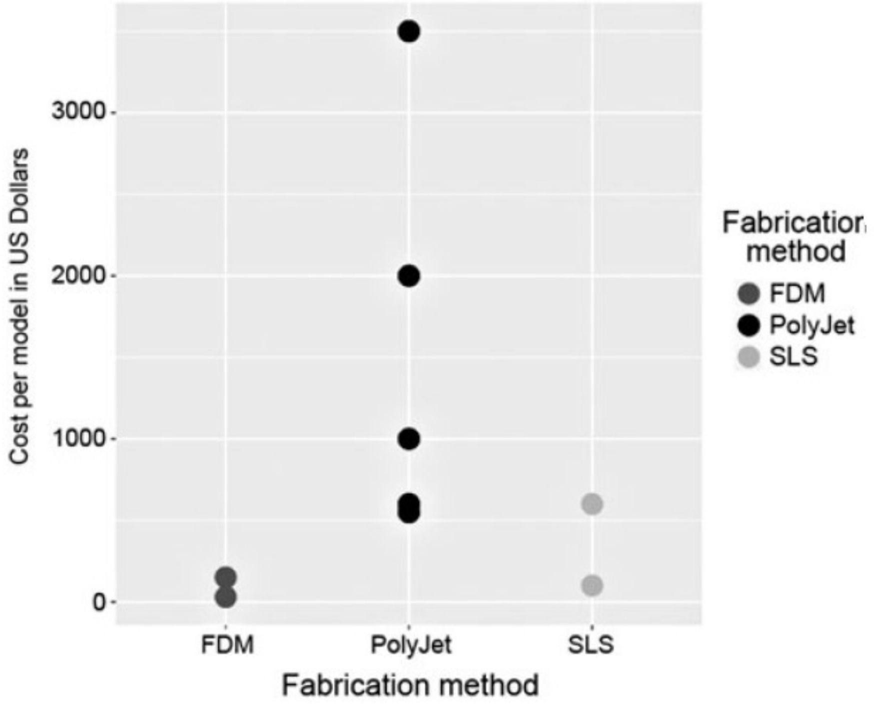
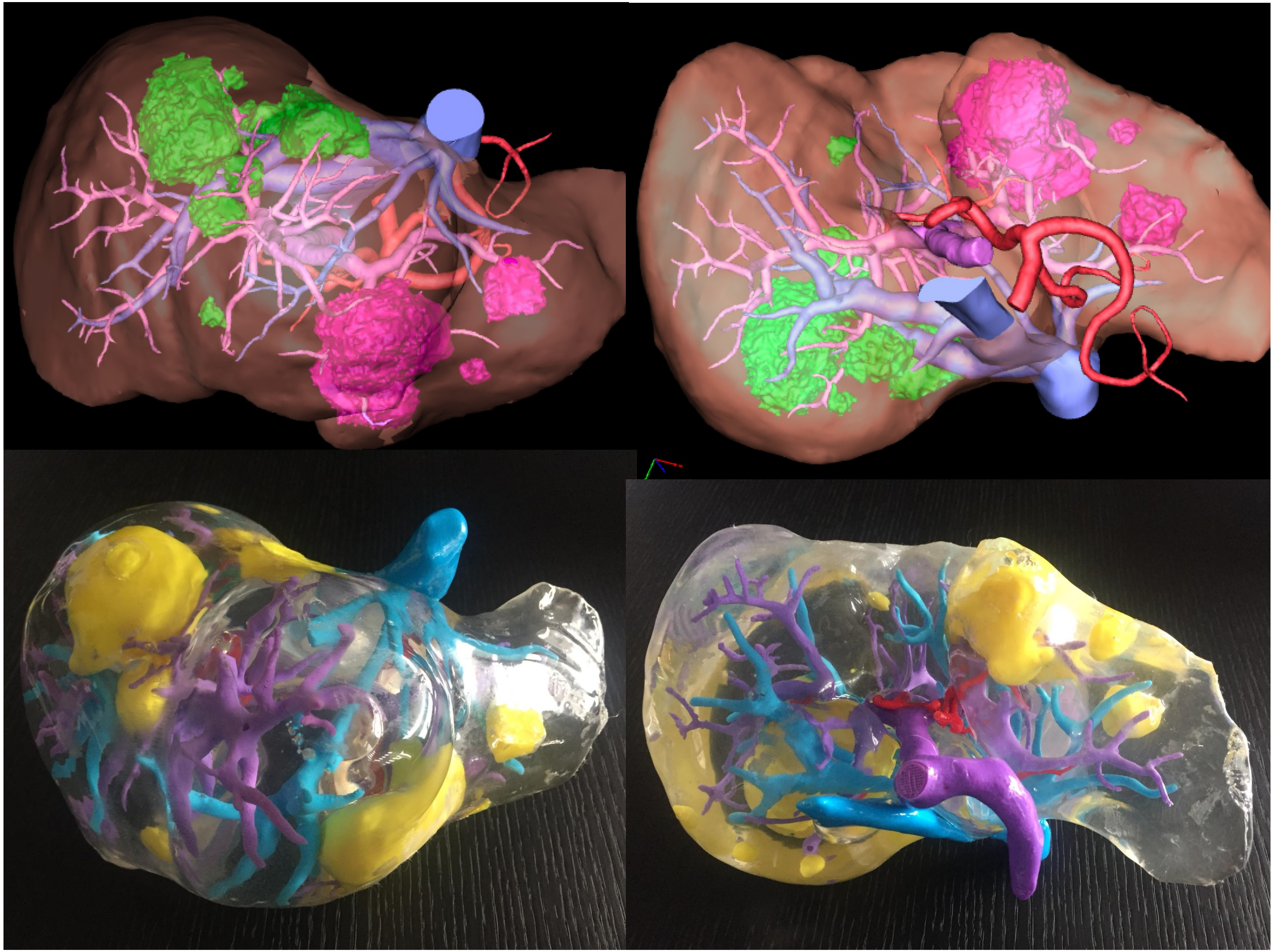
LIMITS OF 3D PRINTING

- **COSTS**: Depending by materials and kinds of 3D Printer (figure)
- **SPECIALIST**: Medical 3d printing requires basic knowledge and skills: anatomical structure segmentation, virtual modeling; preparation for 3D printing; printing process itself and post-processing
- **EXPOSURE TO IONIZING RADIATION**
- **TIMING**: Technologies with quick printing time/good models are more expensive and require several time not ever compatible with clinical and surgical timing. Complex models require different parts printing and then must be assembled



Jan Sylwester Witowski,[1] Jasamine Coles-Black, MD,[2] Tomasz Zbigniew Zuzak,[3] Michał Pędziwiatr, MD, PhD,[1] Jason Chuen, MBBS, FRACS, PGDipSurgAnat, MPH,[2] Piotr Major, MD, PhD,[1] and Andrzej Budzyński, MD, PhD[1]



Ghent University Hospital, Operating theatre, December 2017

CONCLUSIONS

- 3D printing is a useful tool for the preoperative study to highlight patient anatomical variation. Above all, it represents a useful teaching tool for students and young surgeons

- In the near future, bioartificial organs with tailored biological, biophysical, biochemical, and physiological properties can be 3D bio-printed through predesigned geometrical structures, biomaterial components, and processing parameters. Advanced polymer-based multidisciplinary efforts will reap much greater benefits in 3D organ bioprinting and will virtually replace failed/defective human organs.

Present Challenges

When coupling preoperative and intraoperative information, it is also possible to develop guidance software based on **Augmented Reality (AR)**.

The patient becomes virtually transparent in the surgeon's view so that he/she can locate vessels and tumors that are not directly visible and that he/she could previously only perceive through touching.

Image from: L. Soler, S. Nicolau, P. Pessaux, D. Mutter, J. Marescaux - «Real-time 3D image reconstruction guidance in liver resection surgery» - doi: 10.3978/j.issn.2304-3881.2014.02.03

MIXED REALITY
HOLOGRAMS AND HOLOLENSES!

Intraoperative 3D Hologram

- When the the physical world blends the digital one we are talking about MIXED REALITY

- During an operation, surgeons and assistants are performing operative steps imagining the preoperative simulation in their mind. Frequently the last steps are also checked just before starting the operation

- Some stress is observed in these moments of “last check”

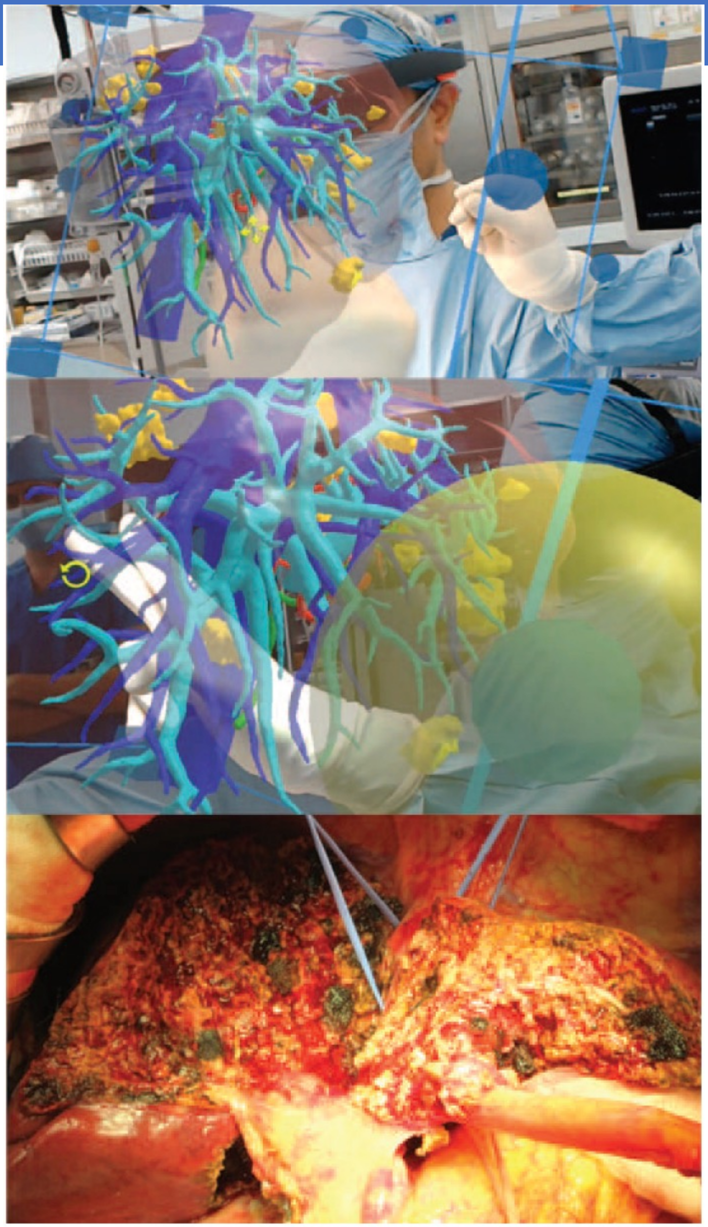
An example in Liver Surgery….*

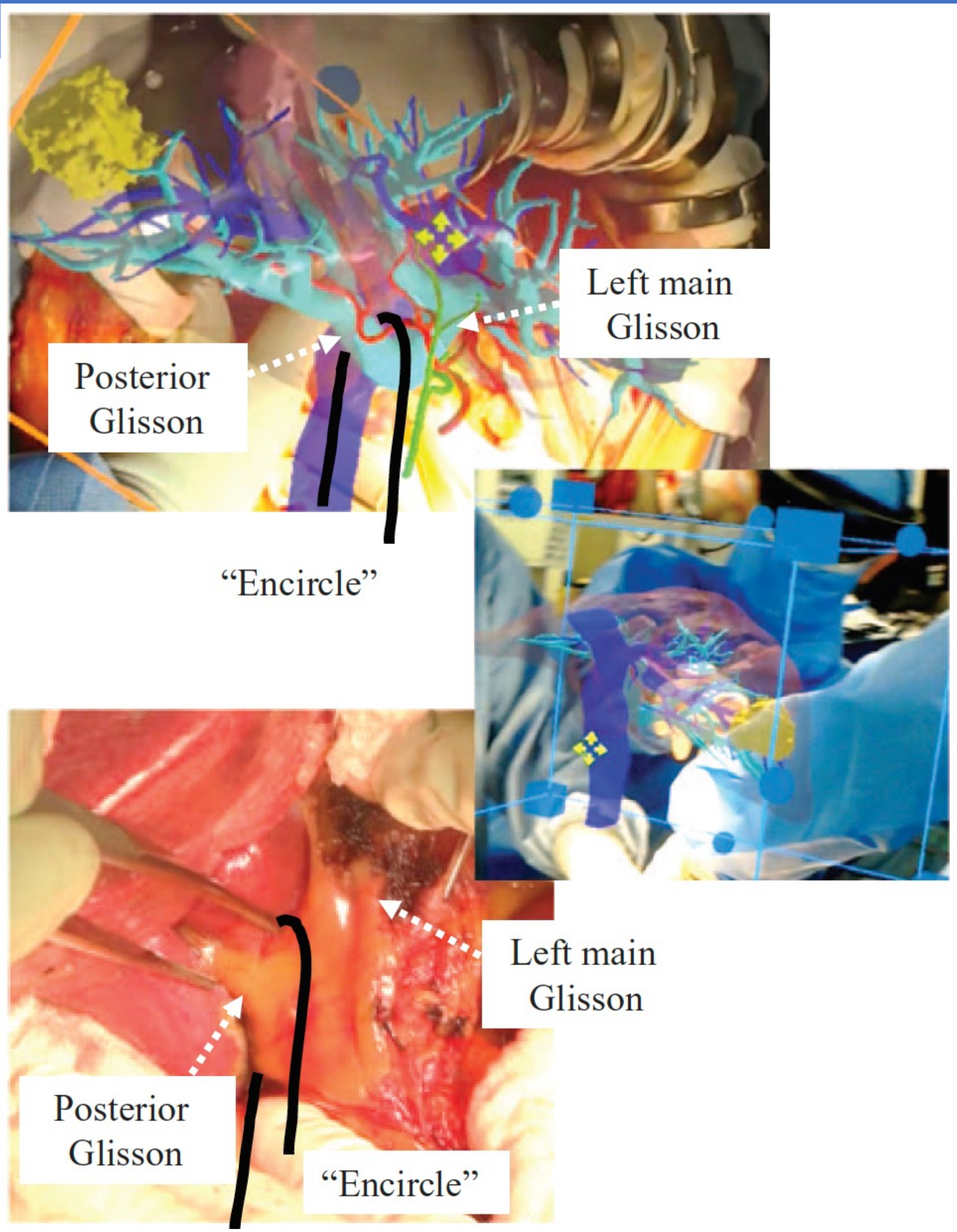
- Classical steps: liver mobilization, liver dissection, approach to the hilum (vessels) etc
- All the operators are “reviewing” such steps in their mind but without a clear and direct simultaneous coordination: is there a solution?

→ YES, the Mixed reality!

- *No need for sterilized monitors*
- *Much better spatial awareness*
- *3D pictures shared by ALL THE TEAM!*

* Solid organ with many structures inside and a variated anatomy from the standards in at lest 50% of the people

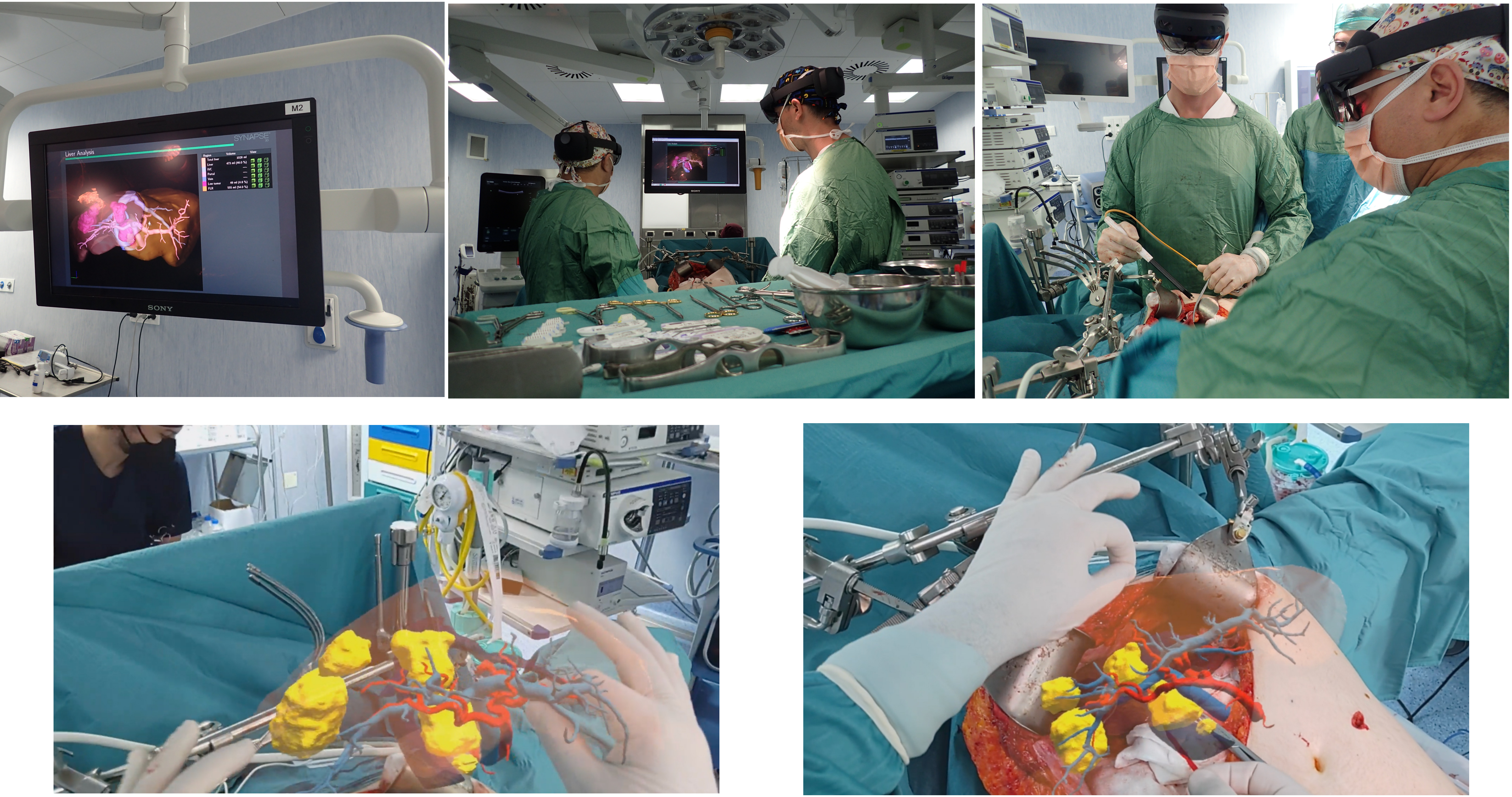




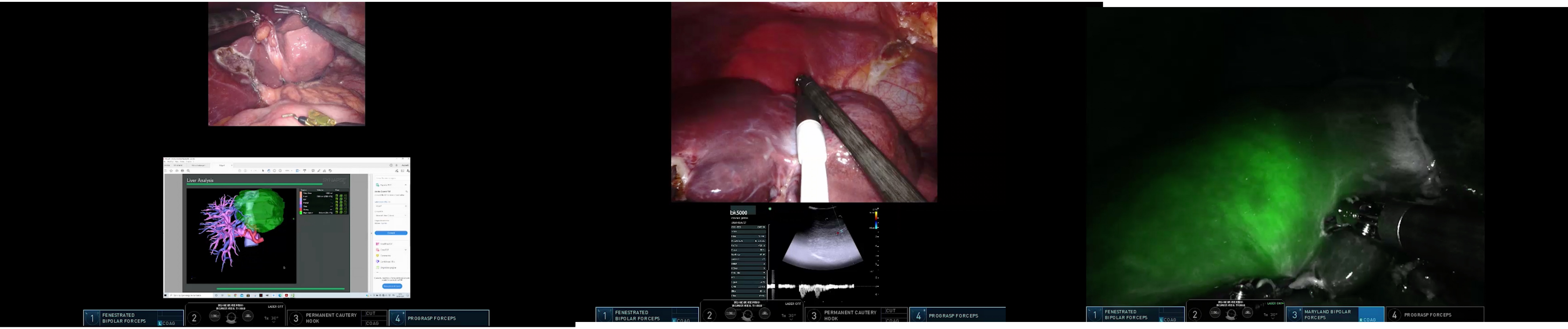
Head mounted displays intrinsically provide the user with an ***<u>egocentric viewpoint</u>*** and they allow the user to work hands free

In the Practice

- The surgeons are together reviewing all the last steps before but also during an operation
- This is possible in case of conventional procedures (open surgery) or minimally invasive (laparoscopic/ Robotic)
- The robotic approach can facilitate sharing the informations since the robot is a digital platform (ongoing trials)

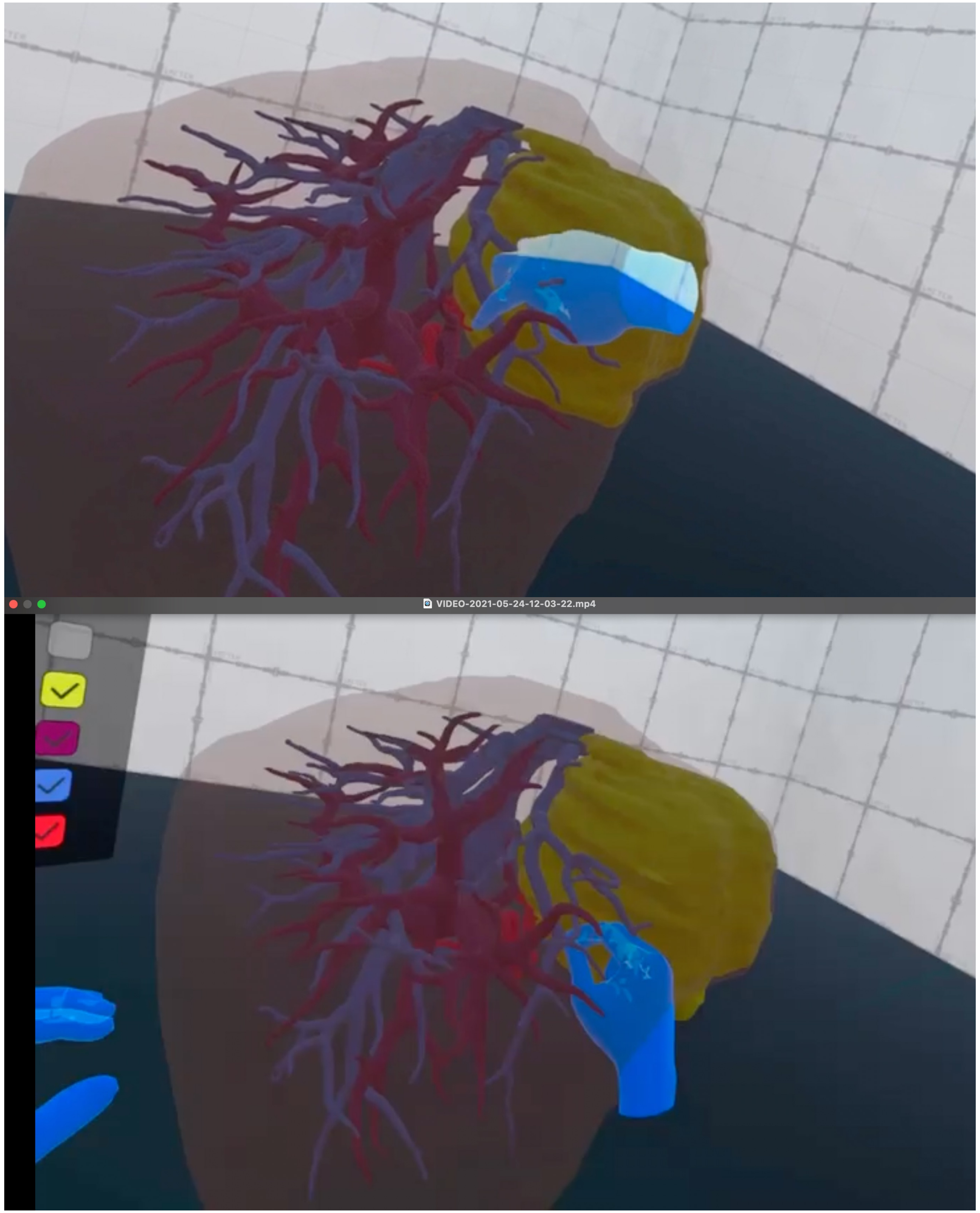

M2
SYNAPSE
Liver Analysis
SONY

TilePro & Firefly in Robotics



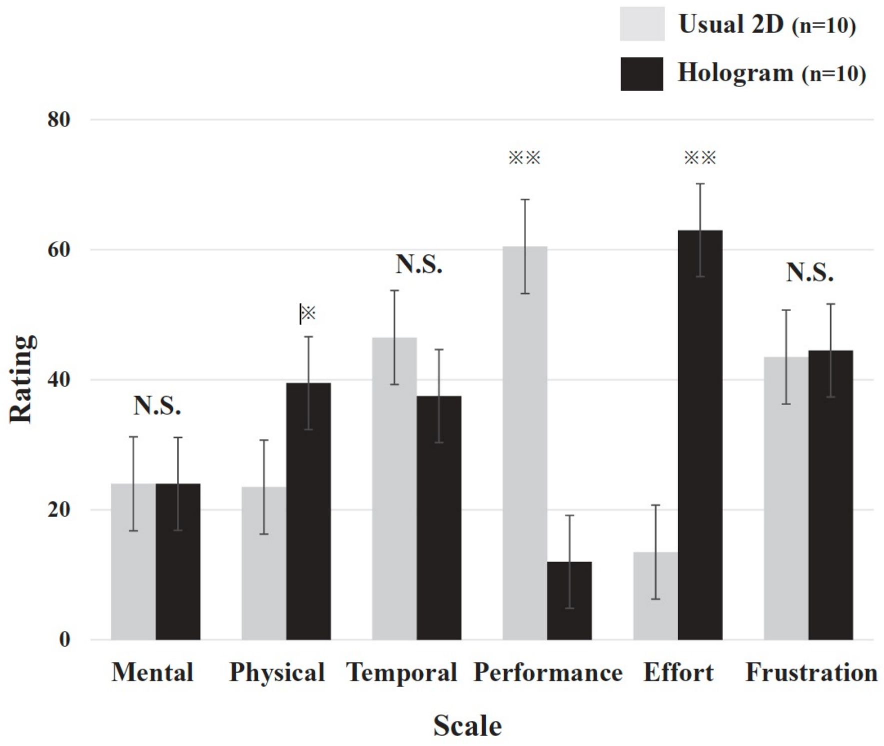
Visualize CT or Rendering or Ultrasound in real time, allow ICG enhanced view


da Vinci Xi
SURGICAL SYSTEM

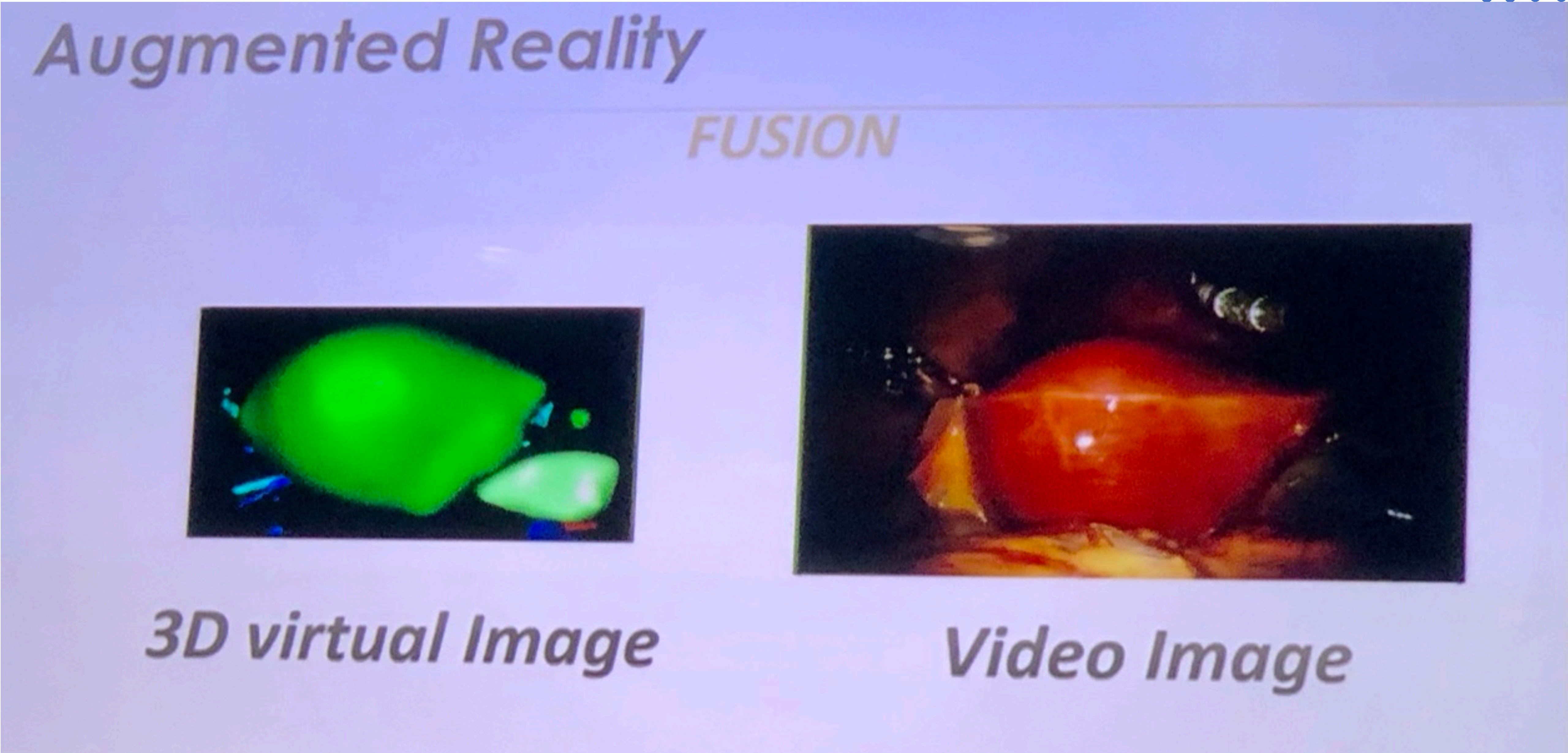

VIDEO-2021-05-24-12-03-22.mp4

Disadvantages

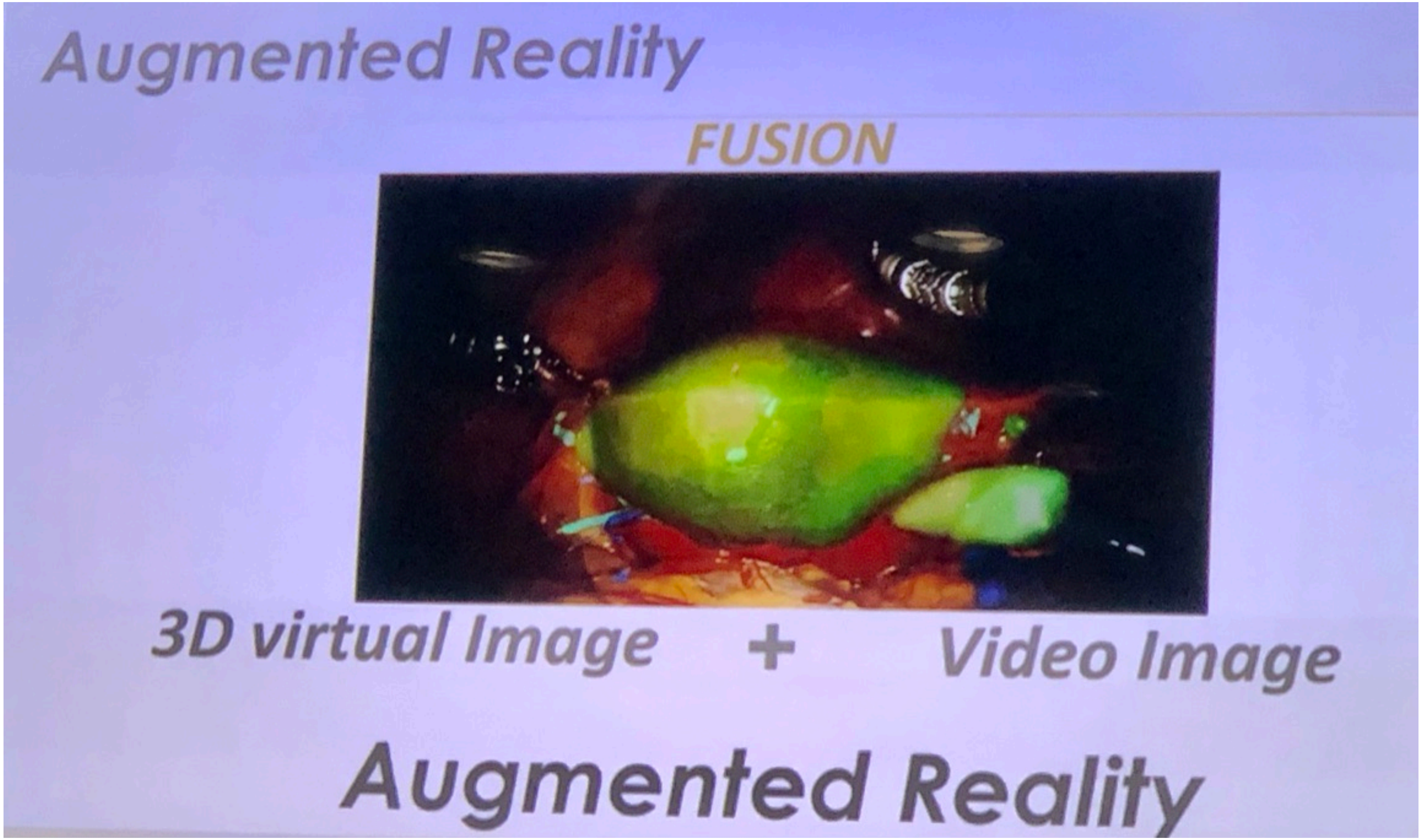
- Using a score system (NASA task load index) comparing 2D evaluation and Hololens in the OR this last scored higher for ***physical*** and ***efforts*** but lower for ***performances***: **indeed it took a while for the surgeons to get used with Hololens**



Near Future: from Mixed reality to Augmented Reality



Near Future: from Mixed reality to Augmented Reality



Conclusions (1)

- **Minimally Invasive Surgery: a continuous unstoppable evolution**
- Clear advantages for the patients. Surgery evolves towards miniaturization
- Robotic-assisted surgery: an approach to democratize MIS enhancing outcomes

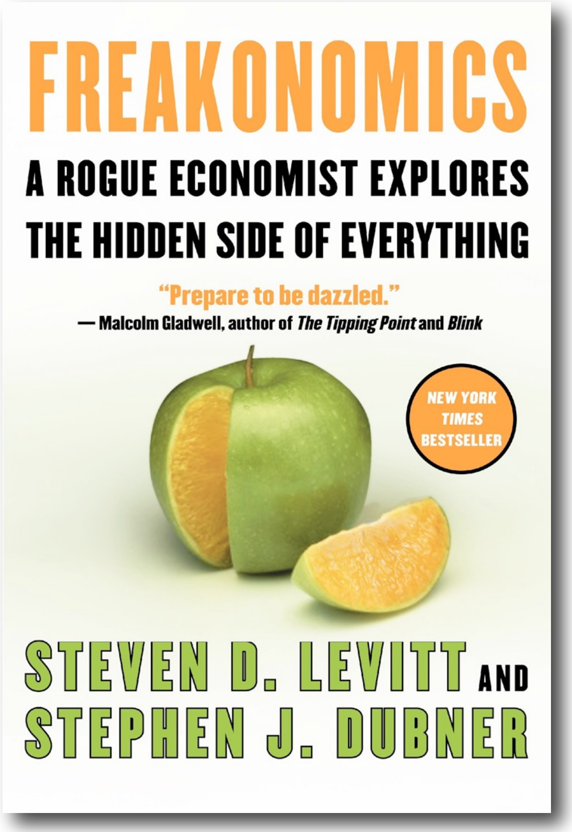
Use it for real-time navigation purposes and not only for simulation or “last check”

- **Difficulties to overcome: breathing artifacts; organ deformation by manipulation; position gap of the organ in open and laparoscopic surgery**

Conclusions (2)

- Smaller simple and easy to use holograms will facilitate the use in the OR> evolving to magnified glasses with built-in MR technology (**still in the early phase)**
- Use it for real-time navigation purposes and not only for simulation or “last check”
- Augmented reality: Difficult to adapt to a breathing body (breathing artifacts; organ deformation by manipulation; position gap of the organ in open and laparoscopic/robotic surgery)
- A big challenge would be to find measurable outcomes to justify cost-effectiveness of technology in surgery

Technology Evolution in Surgery



"Knowing what to measure and how to measure it makes a complicated world much less so."

Thank You!

UNIVERSITÀ DEGLI STUDI DI NAPOLI FEDERICO II

University Hospital

Historical Rectoral building

Apple Development Academy “Federico II”