ALMA MATER STUDIORUM
UNIVERSITA' DI BOLOGNA

MASTER UNIVERSITARIO DI II LIVELLO

MINIMALLY INVASIVE AND ROBOTIC
PEDIATRIC SURGERY

Next frontiers in minimally invasive pediatric surgery: mechatronics, artificial intelligence and augmented reality

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The difficult path of innovation

Minimally invasive surgery grew up dramatically in the last 30 years. Now being a completely standardized surgical method, today it is almost impossible to exclude minimally invasive techniques for our patients: but the history was not so at the beginning. Starting with first pioneers acting in very hostile environments, every single step through a better way of making surgery had to overstep walls of mistrust and suspicion.

Kurt Karl Stephan Semm, a brilliant and far-sighted german gynecologist, performed first laparoscopic appendectomy in 1981; his studies started in early 1960s, with personal development of dedicated devices (manipulator, CO_2 insufflator) and invention of new techniques (intracorporeal knotting and suturing). Nevertheless, when he presented his first results about 10 years later, he was literally assaulted by contemporary surgeons, who considered operative laparoscopy unethical and really insane. [1] As industrial interest and economic involvement grew up, laparoscopy began to be widely accepted practice, and his pioneer got well deserved recognition.

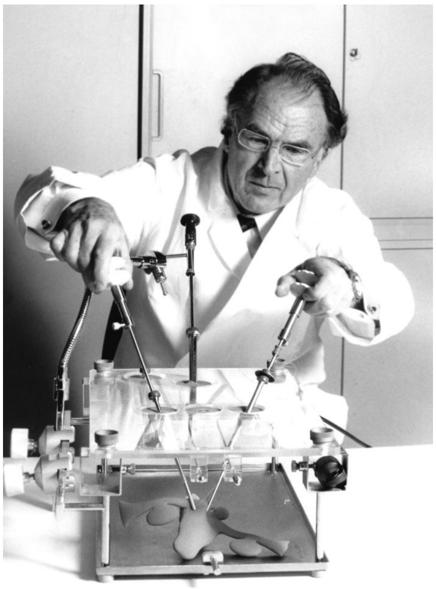


Fig. 1. Kurt Semm

As for these facts, innovation in minimally invasive surgery needs to be supported by many factors: clinical interest and needs, patient awareness, industrial and economic attractiveness. A lot of intellectual resistance is actually coming from the same people who, 20 or more years ago, were the main supporters of minimally invasive surgery: a novel surgical model, based upon latest technological advancements, represents a scary perspective for our long established points of view. Was it not the same for elder surgeon assaulting young Semm in that famous grand round? Fearing technical advancement was so, consciously or not, transformed into rejection due to ethical or economic issues: that is exactly what we always hear today in every single robotic surgery meeting (obviously from detractors' audience).

In this discussion, we will try to examine the state of the art of the surgical improvements three new pillars: robotics, artificial intelligence and augmented reality; moreover, to avoid dangerous drifts towards sterile self-satisfaction, we will explore all limitations and possible correctives to take a look into the real future of surgery.

State of art in robotic surgery

Standard MIS characteristics and limitations

The major advantages of MIS include reduced trauma, less pain, and shorter recovery times for the patient. The other side of MIS, unfortunately, is that, from the surgeon's point of view, it is minimal access surgery. Reduced access reduces dexterity, limits perception, increases strain and the likelihood of error, and lengthens procedure time. Micromechatronics has widely established the potential to improve accessibility in MIS.

Dexterity Enhancement

Although the human hand is amazing in its capabilities, there are procedures in microsurgery at or beyond the limits of its position resolution, especially when tremor is significant because of fatigue or stress. Reconstruction of vessels and nerves to repair an injured limb or digit is a slow process, requiring constant attention and fine motions. Fatigue could be reduced with teleoperated systems, in which the surgeon's motions are scaled down and the interaction forces at the micromanipulator tip are scaled up in force-reflecting teleoperation.

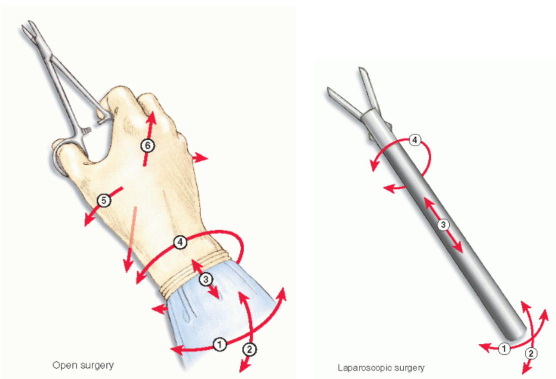


Fig. 2. Degrees of freedom: comparison between human hand and laparoscopic isntrument

Even when motion is on a relatively comfortable scale of several millimeters or centimeters, dexterity in MIS is often reduced by mechanical constraints. For example, in laparoscopic surgery, or MIS of the abdomen, long instruments inserted through 2–10-mm-diameter cannulas are constrained by the fulcrum where the cannula passes through the abdominal wall. [2] This reduces possible motions to 4 degrees of freedom (DOF), greatly increasing the difficulty of performing dexterous movements, as in suturing or knot tying. In flexible endoscopy of the colon or esophagus, flexion of the endoscope tip and manipulation are performed with an unintuitive array of knobs on the handle. In these situations, dexterity would be greatly improved with a teleoperated device with 6 DOF in the slave and intuitive control of the master. More enhanced platforms got up to 7 DOF (2011, DaVinci) and more efforts are made to extend this limit. Force, impedance, and hybrid force/position control problems are common in surgery, because of the compliance of tissue. When cutting, stiffness must be maintained normal to the cutting direction, while maintaining steady force in the cutting direction. Neurosurgeons placing clips on vessel malformations must control force on the clips while placing them. It is important to limit forces applied to tissue being retracted (held out of the way), even when it cannot be seen. While the parallel structure of the human hand and the wide range of cutaneous and kinesthetic sensors in the skin, muscle, and tendons allow it to elegantly perform many of these functions, the constraints of reduced access limit its ability. Some of this ability would be restored by teleoperated systems with transparent force feedback, but it would additionally be possible to aid the human with a system that passively, or actively through feedback control, maintained force or stiffness constraints in constant or reprogrammable directions.

Enhanced Perception

Much of the progress in MIS has occurred since the introduction of small charge-coupled device (CCD) cameras, making it convenient to obtain a video image from endoscopes with fiber optics or rigid lens trains. In fact, surgeons can now obtain close-up images of areas that could not even be seen directly before, because they were obscured from direct view in open surgery. The disadvantage of videoscopic surgery is that the image is usually two dimensional, has optical and perspective distortion, and has visual coordinates misaligned from the instrument coordinates. By controlling the relative orientation of the endoscope and slave manipulator, as well as the display and master, it is possible to maintain good display-control correspondence. Of course, even with vision, it is impossible to see tumors or other lesions embedded within tissue. Data from miniature ultrasound sensors could provide this information, especially if filtered, registered, and displayed with the visual scene. Surgeons detect hidden structures in conventional open surgery by feeling them. The pulse of an artery concealed in fat or the change in tissue consistency due to a lesion can be felt. The distribution of pressure when handling tissue gives clues to when the tissue might be damaged by excessive local stress. These sensations might be restored by a tactile sensor mounted on an instrument and a display giving a similar distribution to the surgeon's fingertips. In the same way, a catheter or endoscope with an array of pressure sensors might permit threading the catheter along a path of least resistance, reducing the possibility of damage to the vessel or tube walls. These are all examples of applications for tactile feedback that could be provided by a micromanipulator. [3]

Creating Access

Some regions of the body are currently inaccessible because of the limitations of passive devices. Current endoscopes cannot reach the middle 70% of the gastrointestinal tract, but a locomoting device might provide the flexibility to do so. Similarly, the forces required to insert catheters into long, tortuous, or branching vessels can cause damage, but, with appropriate sensors and active flexion, these could be made safer.

Actuators

Although many minimally invasive applications require micro-scale actuation, some allow larger remotely located actuators. For example, because the eye is easily accessible, relatively large manipulators can be used, even though the position resolution of these systems must be on the order of tens of micrometres or smaller. Hunter et al. developed a system for eye surgery using direct-drive electromagnetic actuators, while Jensen et al., Kozlowski et al., and Schenker et al. used dc motors to drive preloaded ball screw, cable, and hydraulic transmissions, respectively, without backlash. [4] Some groups have developed macro–micro-scale positioners, including Yan et al. with Lorentz magnetic levitation actuators and Mitsuishi et al. with stepper motors for angular position and hydraulic linear actuators for fine motion. [5] - [6] A major issue in the design of precise actuators and transmissions is backdriveability. While high reduction ratios and preloaded transmissions can improve positioning precision and eliminate backlash, they also create a high mechanical output impedance, which places greater demands on the force torque sensor and control algorithms, in order to accurately servo force or permit stable and transparent force feedback in teleoperation. Direct-drive actuation in a parallel kinematic arrangement maximizes backdriveability and reduces friction and backlash, but limits the manipulator workspace, especially in orientation. Hydraulic, pneumatic, and cable-driven systems allow high-power transmission from external actuators to small manipulators inside the patient. Hydraulic systems permit relatively large forces, but fluid incompressibility gives them a high (and nonlinear) output impedance. Pneumatics are more compliant, but the lower system pressure produces lower resultant forces in small devices. Cables allow compact transmission, but must be designed carefully to reduce unwanted compliance, friction, and backlash, and to avoid coupling between axes. Traditional systems for laparoscopic surgery provide an example of both external actuation and transmission to millimeter-scale mechanisms inside the patient. Dexterity in laparoscopic surgery is reduced, because only 4 DOF (three rotations plus in–out translation) are permitted through the fulcrum at the incision through which instruments are inserted. [7]

Fig. 3. A slave manipulator generation actuator (7 degrees of freedom)

The slave manipulator in robotic system adds 2 additional DOF inside, plus active grasping. Both cable- and hydraulically driven actuation have been implemented for the internal axes; the hydraulic version is shown in Fig. 3. The two systems are now being compared for performance and fidelity in the bilateral transmission of human and environment impedances. The 4 DOF possible through the fulcrum are controlled by external dc motors in a parallel arrangement. Different actuators become preferable at scales less than a few millimeters, for surgical applications, most notably shape-memory alloy (SMA) and polymer actuators. Both SMA and polymers permit fairly large strains, making them suitable for applications such as catheters, where bending is significant. SMA actuators are capable of very large stresses, making them ideal for microgrippers that must generate large forces. Unfortunately, both SMA and polymers have relatively slow response times; Hunter and Lafontaine estimate strain rates of 3 and 1 s , respectively. [8] Cooling of SMA is much more efficient at micro scales as the surface-to-volume ratio improves, however.

Recently, many authors have proposed a hybrid electromagnetic and tendon-driven actuator as an integral part of an MIS surgical instrument to achieve optimum angulation. [9] The design has used a tendon-driven structure to actuate the individual joints and an electromagnetic structure to lock the shape of the actuator. Prototypes of the proposed actuator are manufactured. Subsequently, the forward kinematics analysis of the developed system is carried out, and the performance of the new actuator has been effectively evaluated numerically and experimentally. The alignment of the joints could be adjusted based on the requirements of the MIS instruments. Here is presented an example in which each of the tendons passes through a sheathing channel located at 90° from the hinge of the swiveling component, which gives the MIS instrument an additional three DOFs movement in different directions.

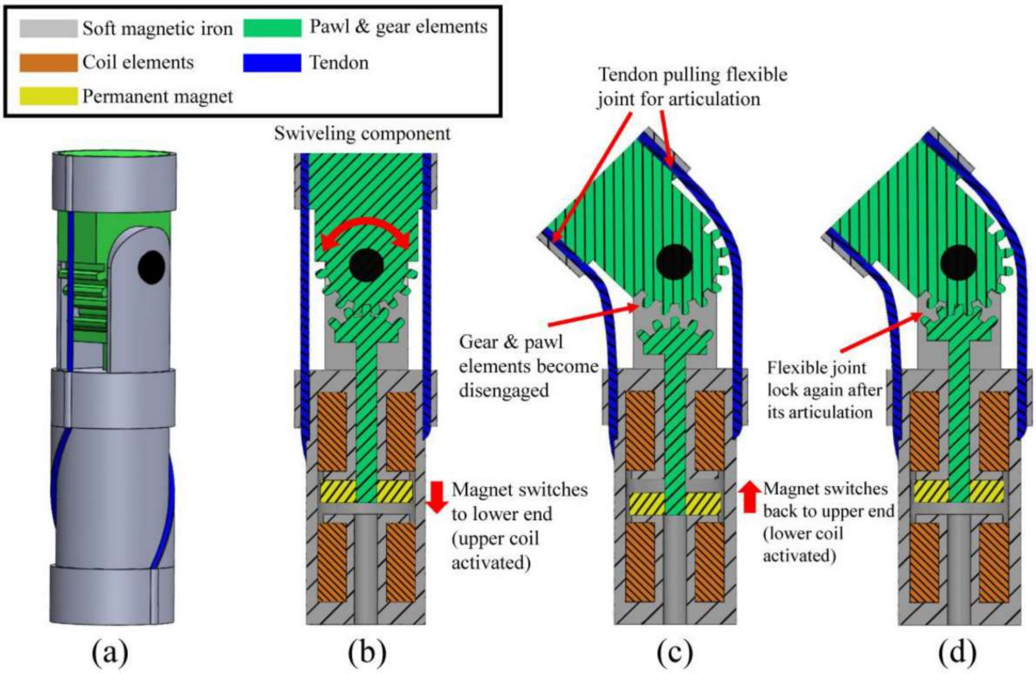


Fig. 4. New generation actuator with an hybrid electromagnetic and tendon-driven technology: 7 degrees of freedom in a reduced size tip

Sensing and display

Force and Taction

Force sensing is important to determine if a device has contacted the environment and to control or limit the contact force. Although, for a fully dextrous device, it is desirable to measure forces and torques on all six axes, for graspers and simpler manipulators, fewer will be adequate. The problems of displaying force to the surgeon are the same as actuation and control of force at the slave manipulator described above. It is also possible to use sensory substitution of visual or auditory feedback proportional to the sensed force. This does not permit the energy exchange between the surgeon's hand and tissue possible with bilateral force feedback, which allows the mechanical impedance of either side of the teleoperator to be felt at the other. The vast majority of haptic systems allow interaction only through a single net force, not through the spatially distributed set of forces measured by cutaneous mechanoreceptors. While a single net force provides clues as to the overall stiffness of the environment, it makes it quite difficult to find and distinguish local shape or hardness variations. Tactile sensation is extremely important in open surgery to allow the surgeon to feel structures embedded in tissue. Important vessels and ducts are usually shrouded in connective tissue; their presence must be felt, rather than seen, to avoid damage. A teletaction system comprised of a remote tactile sensor in the patient and a local tactile display transmits this information to the surgeon. At the University of California, Berkeley, technology has been developed for capacitive-based tactile sensing arrays in planar and cylindrical geometry. [10]

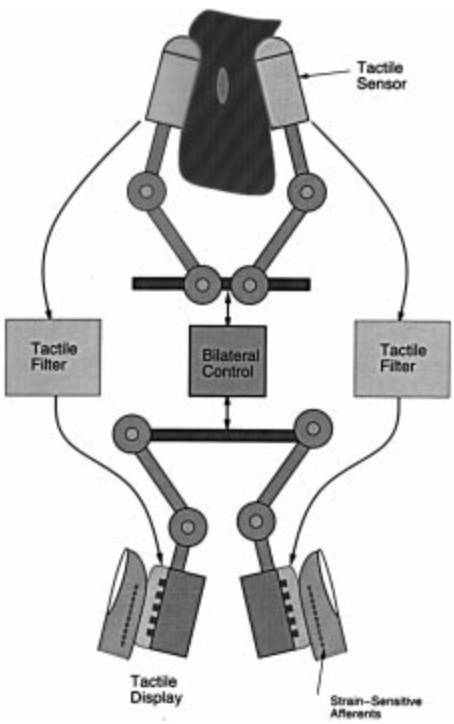


Fig. 5. Scheme of tactile feedback in robotic console

The normal strain-sensitive elements have a raw sensitivity (dependent on contact area) of less than 1000 Pa, bandwidth of 100 Hz, 7-b resolution, and, typically, an 8x8 array of elements on a 2.5-cm-diameter finger. Using silicon surface micromachining techniques, a tactile sensor for the end of a catheter, with 125 micron element spacing has also been developed. Capacitive tactile sensing technology is a mature technology with good linearity, good signal-to noise ratio, relatively low hysteresis, and flexible geometry. The main research issues to be resolved for the tactile sensor design are packaging to protect tissue and the sensor and cabling to bring signals out of the body without interfering with the range of motion of the mill manipulator. The mapping from the properties of embedded structures to surface pressures on contact is complex, however, and likely inexact. It is necessary to develop finite-element models of surface pressures resulting from a finger contacting tissue and present them using the tactile display. An important research goal is determining, based on human sensory processing capabilities, what needs to be presented at the fingertip to create a realistic, or at least plausible, representation of contact with a soft surface. [11]

Vision and Imaging

Visual data is relatively easy to obtain through fiber optics or endoscopes with rigid lens trains and CCD cameras. The primary difficulty is that the coordinates of the visual image may not correspond to manipulator axes. By controlling the relative orientations of the endoscope and slave manipulator, as well as the display and master, it is possible to maintain good display-control correspondence. This has been demonstrated by Hill et al. in an open surgical system by matching the (fixed) locations of these components as closely as possible to the normal eye–hand axes. It might be expected that using a stereoscopic imaging system would greatly improve performance, but this has not been the case with commercial laparoscopic systems to date. [12] It seems that this is because movements in three dimensions are initially open loop with closed-loop corrections. Geometric distortions are at least as significant as the loss of binocular disparity as a depth cue in planning the initial movement phase. Of course, even with vision, it is impossible to see tumors or other lesions embedded within tissue. Data from miniature ultrasound sensors could provide this information, especially if filtered, registered, and displayed with the visual scene. For rigid structures like bone, or for the brain, which is constrained by the skull, previously obtained CT or magnetic resonance (MR) images can be reconstructed in three dimensions and superimposed on visual images with registration using markers, feature matching, and/or robotic devices. When soft tissue is unconstrained, like the lung or liver, it will be much more difficult to estimate the location of lesions from previous images in deformed tissue. However, it is often possible to use fluoroscopic and CT imaging during a procedure, for example, to guide catheters in interventional radiology vascular techniques. Open-magnet MRI has been developed, allowing access to patients during imaging (please see in "Augmented reality" section).

Control and systems

Control

Some large-scale applications of robotics in surgery require the robot to act with a degree of autonomy. For example, in image-guided applications, such as machining the head of the femur to accept a prosthetic hip joint, the robot precisely follows a preplanned path, much as in computer aided machining processes. Micro-scale applications are more likely to act on soft tissues. Predicting the motion of soft tissues is beyond the current state of the art, however, so it is difficult in most situations for a robot to plan or use sensor guided actions autonomously. Consequently, most currently conceived micro mechatronic applications are telerobotic.
Although control algorithms for teleoperation with force feedback have existed since the 1950's and been refined for applications in space, undersea, and nuclear waste disposal, most research has emphasized issues of stability and transparency in contact between rigid manipulators and solid objects. Fidelity in transmitting interaction forces and the mechanical impedance of tissue is desirable, so that fragile tissue is not damaged and changes in tissue consistency can be felt. Recently, very promising work has been developed about a neural approach of tissue consistency robotic feeling, that can be successfully transmitted to surgeon console after robotic console itself estimated deformation of tissue. [13]

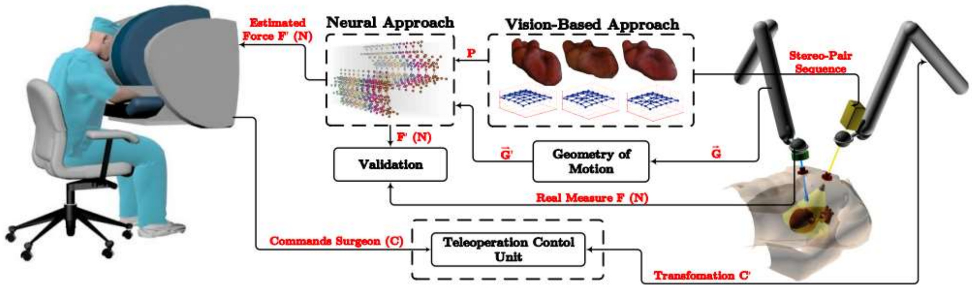


Fig. 6. Scheme of new generation, neural approach of tissue consistency sampling

Very little work has been done to measure tissue properties and changes in impedance with lesions, such as tumors, or to understand how humans use the wide array of cutaneous and kinesthetic sensing mechanisms to perceive these changes. Although force feedback algorithms may be optimized for accurate transmission of remote impedance, it may be desirable to provide enhancement or perhaps impedance amplification to maximize the user's perceptual capabilities. Time delay will be a significant factor in remote surgery, especially if satellite data transmission is necessary. Stability is a major problem in force feedback with time delay. Algorithms based on passivity that preserve stability have very poor fidelity with large delays. In some applications, supervisory control, in which the robot acts autonomously for periods under the supervision of the surgeon, could solve delay problems. [14] Unfortunately, as mentioned above, autonomy can imply the need for modeling, sensing, or prediction of tissue behavior for the robot to execute preplanned actions. Some straightforward behaviors, such as locomotion of an endoscopic manipulator, could be executed with the surgeon being able to stop or alter the robot's course when necessary, however.

Systems Aspects

Although some micromechatronic applications in surgery are in the early stages of conception and research, many are approaching development and application. As an idea comes closer to being a system in the operating room, understanding how it will be used becomes essential. In the era of cost reduction in medicine, the total cost of obtaining and using technology is of great importance to surgeons and the hospital administrators who buy the equipment. It is often extremely difficult to show that a new device performs better than an existing device, because outcomes must be measured in animal and human trials, where many confounding variables exist. Consequently, new technology often must be proven to be less expensive in order to compete. Since robotic devices may be more expensive to manufacture than passive instruments, savings must be demonstrated in total patient care, including efficiency in the operating room (which can also be extremely difficult to measure) and shorter hospital stays. It is also important to realize that technology is only a tool for the people responsible for a patient's health. If a device is too difficult to use or maintain, or if its improper use by untrained, fatigued, or harried staff can lead to complications, it is unlikely to be used. Sometimes, technology that seems like the obvious solution to a problem is not as effective as was hoped. For example, it would seem that stereoscopic endoscopes and displays would be more effective than monoscopic systems. [15] Despite some positive performance data from commercial stereo systems, several research groups have shown them to provide little performance benefit, and their greater expense and complexity have prevented their adoption by surgeons. Improving viewing geometry by proper placement of the video monitor in the operating room may provide a solution as effective as these systems.

Safety is, of course, a critical issue in surgical systems. Davies has reviewed many of the factors that should be considered to minimize risk to the patient (or the surgeon) and gives guidelines for the design of safe systems. System design practices include redundant sensors, hardware and software checks, and a simple user interface. As much as possible, the system should be designed to have passive constraints or limits that cannot be defeated by the failure of active components or software. These include kinematic constraints to restrict motion to a safe region and actuator force capabilities that do not exceed task requirements. A major difficulty in designing safe surgical systems is the lack of good data on soft tissue behavior. Without adequate mechanical models and experimental data, it is difficult to establish bounds on safe system performance. The needed data includes not only the immediate damage to tissue, but also trauma over time as the body responds to injury. [16] Understanding tissue behavior and the body's responses will be as important an engineering problem as the design of the surgical devices.

Robotic surgery enhancements

Efforts for a novel "EndoWrist"

Fig. 7. Actual setup of DaVinci Endowrist

A study in 2011 by Catherine et al. reviewed the various designs used to achieve distal active articulations for minimally invasive surgery. Included in the review is a table outlining actuation technology, diameter, length, bending angle, radius of curvature, number of DoFs and torque. [17] Only two devices had properties of <4 mm shaft diameter, <14 mm joint bending radius, and >=2 DoF. A device developed by Yamashita et al. is a 2-DoF bending manipulator with 3.5-mm shaft diameter. The manipulator uses rigid links with a unique combination of rolling and hinged joints for articulation and can achieve a relatively high bending torque of 27.9 N mm. The joint is fairly complex and requires 9 pieces to achieve one degree of freedom. Reducing the shaft diameter further is expected to be challenging due to the complexity of the joint. Additionally, the link offsets between the joints appear large reducing the compactness. The device also requires that the end-effector is passed down the lumen of the joint yet the joint has discrete bends which does not easily enable the use of end-effectors being passed down the lumen as their bending radii must be very small. The second device of interest has a 2.4 mm shaft diameter and was developed to deflect a laser fiber. The design uses a sliding curved joint type and is composed of alternating cylindrical and spherical pieces which slide with respect to each other. Four wires are used for actuating the joint and pass through holes in the wall of the cylindrical pieces. A hole through the spherical pieces provides an inner lumen for the laser fiber. The main limitation associated with the joint appears to be its relatively large bending radius of 12.7 mm. Introducing an end-effector to the end of this joint would likely push the compactness measurement beyond the desired 15 mm. To achieve 90° bending, the joint requires 25 components and is 19.9 mm long. For both of these devices, the joints are integrated at the tip of a hand-held instrument, driven by motors located at the handle. This complicates the control of all degrees of freedom of the instrument. From a second paper by Harada et al., they specifically reported that operators found it difficult to combine all movements to position the manipulator. [18] The teleoperation approach for controlling wristed instruments used by the da Vinci system solves this problem. Three other miniature instrument designs of note include concentric tube robots, the I-Flex and the Axsis robot. Concentric tube robots are composed of pre-curved super-elastic nitinol tubes arranged in a concentric fashion. The robot's overall shape, tip position, and orientation can be controlled by rotating and translating the individual tubes relative to one another. The key advantages of concentric tube robots include their small shaft diameter (<3 mm) and ease of fabrication. Their primary limitation for this application is their poor compactness. Since the solid curved tube must bend to a straight configuration without exceeding the material's elastic strain limit, the joint's bending radius must be relatively large. The I-Flex developed by the BioInspired Technology (BITE) Group at Delft University of Technology consists of a series of parallel cables positioned to form a ring with an external spring and an internal cable to constrain the cables. [19] The internal cable doubles as a method for actuating an end-effector. The diameter of the joint is 0.9 mm and can articulate up to 90 degrees in all directions with an approximated CM value of 10 mm. This instrument has most of the desired capabilities although joint stiffness is likely an issue as the backbone of the joint is merely seven small cables. Details of the device only exist on the BITE group's website and information on the instrument's joint stiffness or force transmission abilities are not provided.

The last miniature instrument of note is the Axsis system developed by Cambridge Consultants with a 1.8 mm shaft diameter which can articulate with two degrees of freedom. [20] The joint appears to consist of a series of rolling friction joints with cables passed through them for control. This design appears to be limited by its compactness as the maximum achievable angle for each rolling joint is minimal.

Fig. 8. Dimensional comparison between traditional EndoWrist and novel, nitinol-based instruments

Since the launch of DaVinci system, a lot of custom instruments have been developed for use with it. CIGITI was among the first to do this with the creation of a concentric tube instrument in 2015. [21] Other custom instruments for the dVRK include an instrument integrated with ultrasound and tactile sensing for better tumour localization and a 3.3 mm snake-like continuum manipulator. Two other custom instruments under development within CIGITI include a bone cutting device as well as an instrument specific for performing cleft palate surgery. From these custom instruments, three of them were developed specifically for miniaturization although not necessarily with the same criteria described for this research. The concentric tube instrument provides a small shaft diameter but with a large bending radius. The 3.3 mm snake-like continuum manipulator has a 0.7 mm endoscope channel and a 1.8 mm instrument channel. The instrument is restricted to planar bending and is not intended to replicate a "wrist". The instrument for cleft palate repair uses a pin jointed wrist at a 5 mm shaft diameter with potential to be reduced further but introduces the challenge of increased friction since the pulleys at the wrist are removed. None of these instruments have achieved a 3-DoF wrist below a 3 mm shaft diameter and a 15 mm compactness measurement.

To create a smaller instrument, the focus is placed on miniaturizing the wrist. The instrument's wrist requires intricate movement, high precision, and must be very small (2 mm diameter). In 2015, a review paper was published by Jelínek et al. on the "Classification of Joints Used in Steerable Instruments for Minimally Invasive Surgery". [22] The joint types included in the paper included rolling (using friction, teeth or belts), sliding (using curves or hinges), rolling sliding and bending flexure. As part of this review, the different joint types were qualitatively evaluated based on their performance relating to joint geometry and motion. The seven categories of performance were preventing axial split, preventing transverse split, preventing slip, torsional stiffness, space efficiency (size vs. DoF), providing inner lumen and overall design complexity. The performance is evaluated as either good (+), neutral (0), or weak (-). The total grades could range from -7 to +7. All of the joint categories were evaluated based on either planar (2D) or spatial (3D: perpendicular & revolved) implementations. The specific performance advantages of the bending flexure joint from the qualitative comparison include preventing axial and transverse splitting, torsional stiffness, providing an inner lumen as well as a low joint complexity. Considering the ultimate goal of achieving a 3-DoF wrist with an active end-effector, having an open lumen will enable the use of an off the shelf end-effector that can be actuated with a wire which passes through the tube's lumen. Alternatively, an open lumen could provide the possibility of integrating suction into the instrument in place of an end-effector. Likely the most important advantage of this joint type is the low complexity as they can be manufactured from a single piece of material. From a survey of continuum robots used for medical applications, Burgner et al. state that continuum joints can be constructed at smaller scales than those with discrete links due to the simplicity of their structures. [23] The most common form of bending flexure joint is a notched nitinol tube joint in which a section of a nitinol tube is cut away to allow for directional compliance in the tube. The joint can be actuated by applying tension to a cable fixed to the tube distally and in line with the cut. Tensioning the cable causes the joint to bend in the direction of the cut. So long as the flexing material remains within its elastic strain limit (6-10% for nitinol), releasing the cable tension allows the joint to return to its original, straight position.

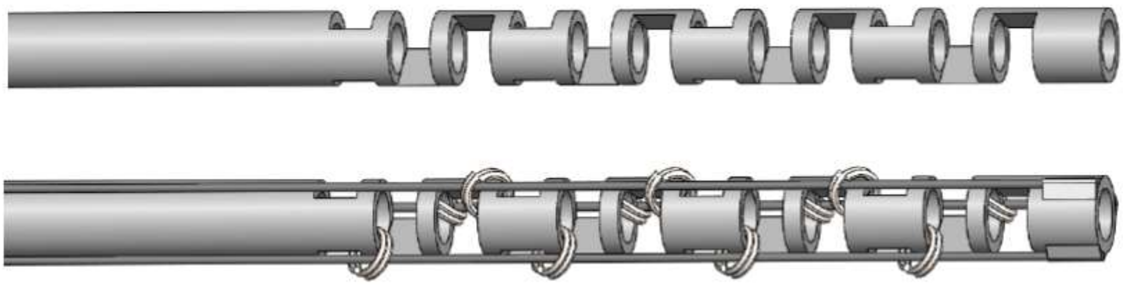


Fig. 9. Microstructure of nitinol tubes

These types of joints have been implemented for miniature dexterous medical instruments, including fiber-optic endoscopic cameras, articulated lasers, suction and irrigation probes, as well as wristed forceps, scissors and drills.

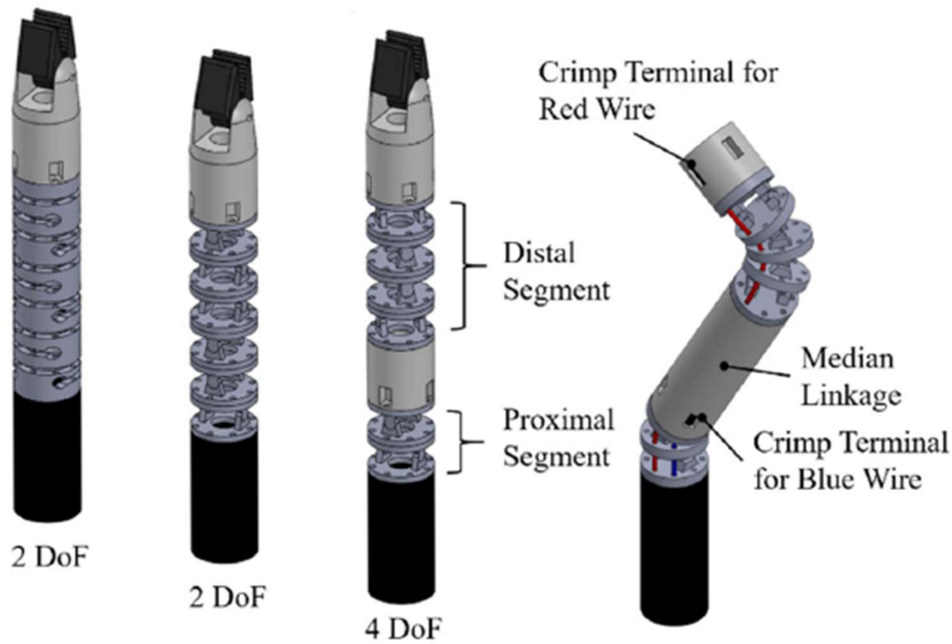


Fig. 10. Application of nitinol tubes for enhanced instrumentation

Various cutting patterns and shapes have been proposed to achieve directional compliance in the tube. The most basic of these designs involves cutting a square notch past the midline of the tube. To avoid buckling, a series of small notches are used to achieve the desired range of motion. This type of square notch joint has been made from a tube with an outer diameter as small as 0.46 mm. Therefore notched nitinol tube joints are a good candidate to achieve articulation of a wrist at the 2 mm scale.

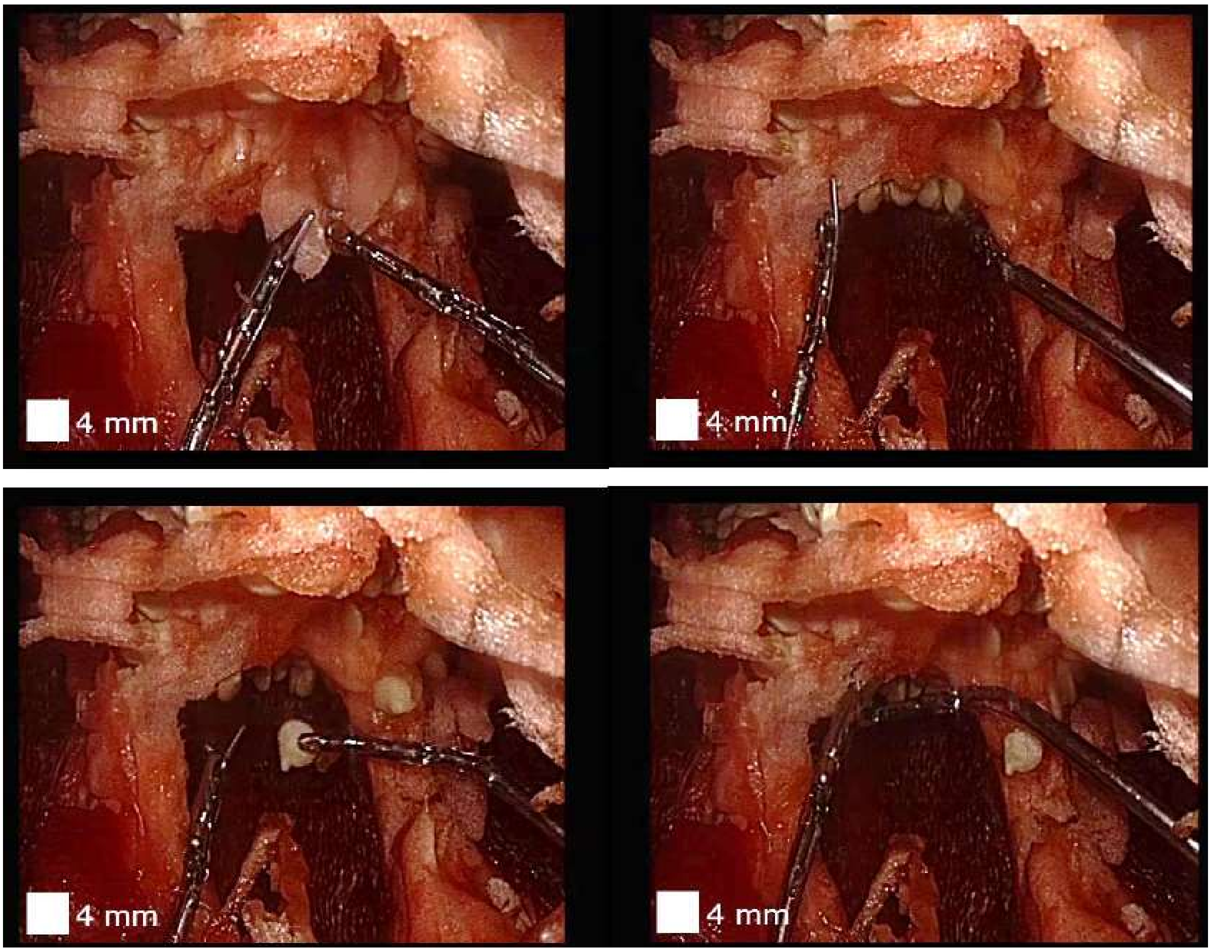


Fig. 11. Nitinol based instruments acting for dissection inside a bell pepper.

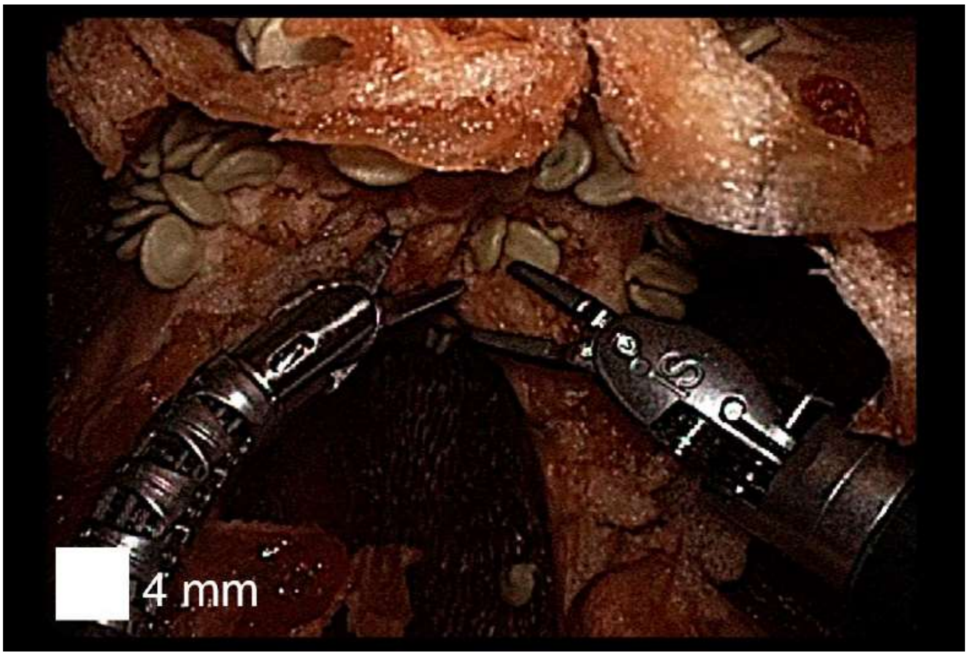


Fig. 12. Same situation of fig. 11, acting with a traditional EndoWrist.

Nitinol is a nickel-titanium alloy with unique superelastic properties along with relatively high stiffness. Nitinol can achieve approximately an order of magnitude more elastic strain than metals such as titanium and stainless steel and is an order of magnitude stiffer than plastics such as PTFE and polyurethane. It achieves superelasticity by storing mechanical energy in a solidsolid phase change instead of in dislocations as is the case in most metals. The most notable difference is the elastic strain limit.

Cooperation in development of robotic surgery: the Raven Project

Existing robotic surgical systems can be categorized into a spectrum based on the modality of interaction with the surgeon. These systems range from pure tele operated or master/slave systems that directly replicate the motions performed by the surgeon to supervisory or shared-control systems where the surgeon holds and remains in control of the medical instrument and the robot provides assistance, to purely autonomous systems where medical motions are planned off-line when detailed quantitative pre-operative plans of the surgical procedure can be laid out and executed autonomously without intraoperative modification. In addition, intelligent robotic assistants have also been proposed for rendering assistance in minimally invasive surgery. In this research, focus is pointed on autonomous execution of a tedious surgical sub-task known as surgical debridement, which involves removing damaged tissue from an affected area to allow the surrounding tissue to heal. [24] Note that prior work has addressed the problem of designing planning and control algorithms for autonomous execution of other surgical sub-tasks such as knot tying or suturing and tissue retraction during surgery. Recent advances in motion planning, control, and perception have enabled robotic systems to perform complex manipulation tasks in real world domains. These systems perform integrated task and motion planning by using state machines or task graphs for high-level task specification and motion planning algorithms for realization of low-level subtasks. Extensions have been proposed to consider uncertainty in task execution. This work uses a similar architecture for autonomy that integrates a high-level task specification in terms of a state machine with low-level planning. There is extensive prior work on calibration of kinematic parameters of robotic manipulators. Extensions have been proposed to simultaneously calibrate robot and sensor (e.g., camera) parameters. These methods do not account for errors resulting from material non-linearities such as cable stretch, prevalent in cost-effective cable-driven actuation mechanisms. In this model, surgical debridement is proposed as a sub-task of interest for experimental autonomous surgical robots. Surgical debridement is a tedious surgical sub-task in which dead or damaged tissue is removed from the body to allow the remaining healthy tissue to heal faster. It is tedious, so automating it has potential to reduce surgeon fatigue and there are contexts where increasing speed of debridement could speed healing. Surgical debridement involves detection, grasping, and motion planning components. Importantly, debridement can be considered at different levels of difficulty, allowing to start with a less complex environment as a first step toward more realistic environments. Thus far, it was considered an idealized environment in which fragments designated as damaged tissue are placed randomly on a planar work surface. The robot must find the damaged tissue fragments, grasp them, and move them to a receptacle. Future versions of the sub-task can include different types of fragments of varying sizes, more complex cavities with obstacles, and attaching the fragments to the work surface and requiring a cutting action for removal.

Nine failure modes for the robot system were set up:

Identification:

1) Fragment false negative: no detection of a fragment in the workspace.

2) Fragment false positive: detection of a fragment where none exists.

3) Pickup false negative: after successful grasping, no detection of a fragment in the gripper, causing an unnecessary regrasp.

4) Pickup false positive: after a pickup failure (see below), detection of a fragment in the gripper.

Grasping:

5) Grasp failure: the gripper is closed, but no part of the fragment is within the gripper.

6) Multiple grasp: the gripper unintentionally grasps multiple fragments. When targeting a single fragment for pickup, any other fragments grasped could possibly be healthy tissue, even if they happen not to be.

7) Pickup failure: the gripper has closed on some part of the fragment, but the fragment falls out of the gripper on lifting.

Movement:

8) Drop en route: after lifting, the fragment falls out during the move to the receptacle.

9) Dropoff failure: the fragment is dropped from the gripper upon arrival to the receptacle, but the fragment lands outside the receptacle.

A Raven surgical robot system was used. The Raven is an open-architecture surgical robot for laparoscopic surgery research with two cable-driven 7 DOF arms, intended to facilitate collaborative research on advances in surgical robotics. The primary difficulty in using the Raven for autonomous operation is state estimation. For surgical robots where space is limited and sterilization is essential, cable-driven actuators are often used and it is not feasible to install joint sensors at the distal ends of the devices. Such indirect control and sensing is inherently imprecise. As a result, even a small amount of slack or stretch in the cables can greatly increase the uncertainty in gripper pose. State estimation has previously been explored in simulation, but not in physical experiments. Since the kinematics introduce considerable uncertainty in the calculation of the gripper pose, a vision system was used to obtain direct measurements of the pose. The Raven presents challenges on this front as well. The size of the grippers is too small to use complex fiducial markers like those based on 2D bar codes. It was possible to place a fiducial marker on the wrist link of the robot, but the small size meant the cameras had trouble detecting the marker, and the measurement was highly noisy even when it was detected. A stereo vision system was used to estimate the pose using colored dots mounted on the gripper. The stereo vision system is also used to construct a static 3D point cloud from the disparity image, which is used to localize the fragments. Off-the-shelf stereo cameras are usually built for larger workspaces, and thus the camera pair would be too widely separated for our environment. A custom stereo camera was constructed using a pair of Prosilica GigE GC1290C cameras with 6 mm focal length lenses at a separation of 4.68 cm for this purpose. A Primesense Carmine sensor was used for obtaining point clouds of the environment. However, the Carmine relies on a projected texture, which does not work on specular reflective surfaces like the stainless steel the Raven tool is constructed from. Therefore, the Carmine cannot be used for detecting the gripper. The cameras must be registered to the robot frame to allow their detections to be used to direct the robot. However, the small size of the workspace prevents the camera field of view from including the robot base. To register the cameras, it was fabricated a removable bracket for a checkerboard that could be mounted to the robot base, putting the checkerboard in the camera field of view with a known pose relative to the base. This also allows calculation of the transform between bases of the individual arms, which are not precision mounted relative to each other, by using the camera as an intermediate frame.

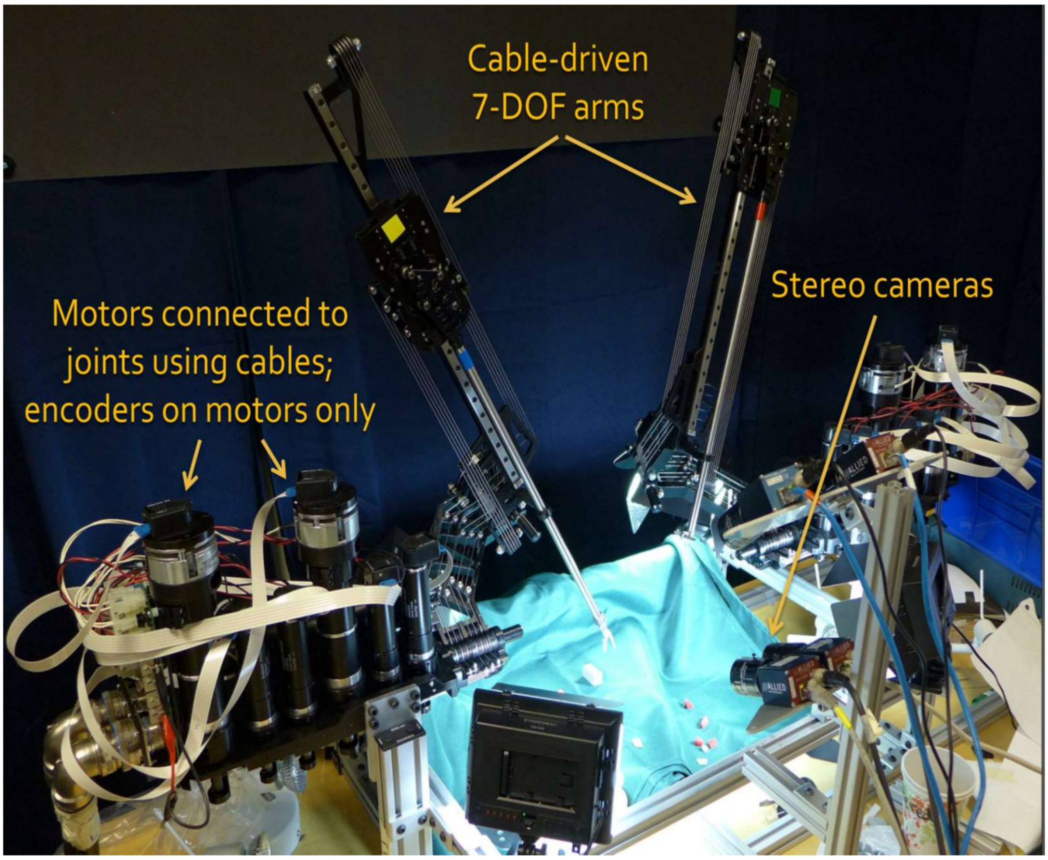


Fig. 13. The Raven surgical robot used in the explained experiment.

The experiment was performed with six foam rubber fragments in a random configuration. The receptacle, located at the front of the workspace, measured approximately 11×7 cm. For teleoperation, the human operator viewed the workspace through the stereo pair using a 3D monitor, and controlled the Raven using the Razer Hydra controller. As a baseline comparison, the task was performed in teleoperation by a third-year medical student with experience on a laparoscopic telesurgery simulator. The purpose is to provide the reader with a rough idea of the execution time for a human, rather than to perform a rigorous human-robot comparison experiment, especially since autonomous results shown here are far slower than the human. To simulate surgical conditions, the teleoperation was performed by viewing the workspace on an LG D2342 3D monitor (which uses polarized glasses-based technology) using the same cameras used by the autonomous system.

The autonomous system was executed ten times for each test, and the human operator executed the task five times. The autonomous system in two-arm operation took on average 2.1× longer than in teleoperation. However, the amount of time spent in motion for the two arm system was actually slightly less than for the overall teleoperation execution time. This was despite the fact that, in the autonomous operation, the robot moved slowly due to the need to obtain recent updates from the vision system. Although the teleoperator was permitted to use both arms simultaneously, we did not observe him using them in this manner. Each fragment was picked up sequentially. The autonomous system, however, was able to parallelize its arm movements. If the kinematics errors were reduced and the pose estimation improved, the camera updates could be less frequent and the speed of the robot higher. The planning and perception together took nearly 50% of the time. The perception code was coded in Python and was not optimized to take advantage of available GPU hardware, which indicates that significant speedups can be made.

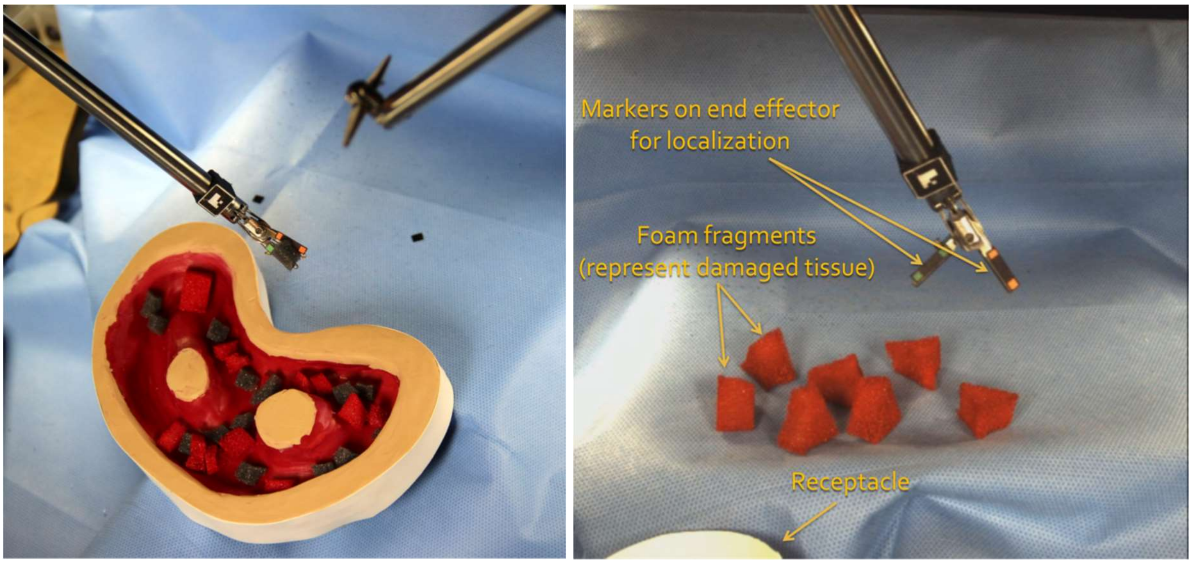


Fig. 14. Two levels of realism. On the right, two arms debridement with anatomical simulation. On the left, single arm without anatomical simulation.

The planning time was due in large part to the number of times the system must generate a new plan. Currently, the system must plan an average of 10.81 times during the move to, grasping, and dropoff of a single fragment. This is due to the 2.5 cm maximum distance that an arm is permitted to move before replanning. We found that increasing this distance caused the actual path to deviate too far from the planned path. Improved state estimation would reduce this deviation, allowing for longer distances between replanning. The short replanning distance allowed for a very small safety margin to be used, 1 mm. This allowed the two arms to pick up closely-packed fragments more quickly, as the arms could pick up adjacent fragments without penetrating the safety margin. The two-arm autonomous system was on average 1.5×faster than the one-arm system. This is less than a 2×speedup due in part to waiting time and to increased planning and perception times under the added complexity of two arms. Both autonomous and teleoperated systems were able to successfully complete all trials, recovering from grasp and motion failure modes. No false negatives were observed, though the vision system would occasionally lump two close fragments together as a single detection; once one of the fragments was picked up, the other would be correctly detected. The grasp failure rate was slightly higher for human teleoperation than for the autonomous system; probably this is due to the 3D camera not being spaced optimally for human viewing, which led to the human operator reporting a lack of sufficient depth perception.

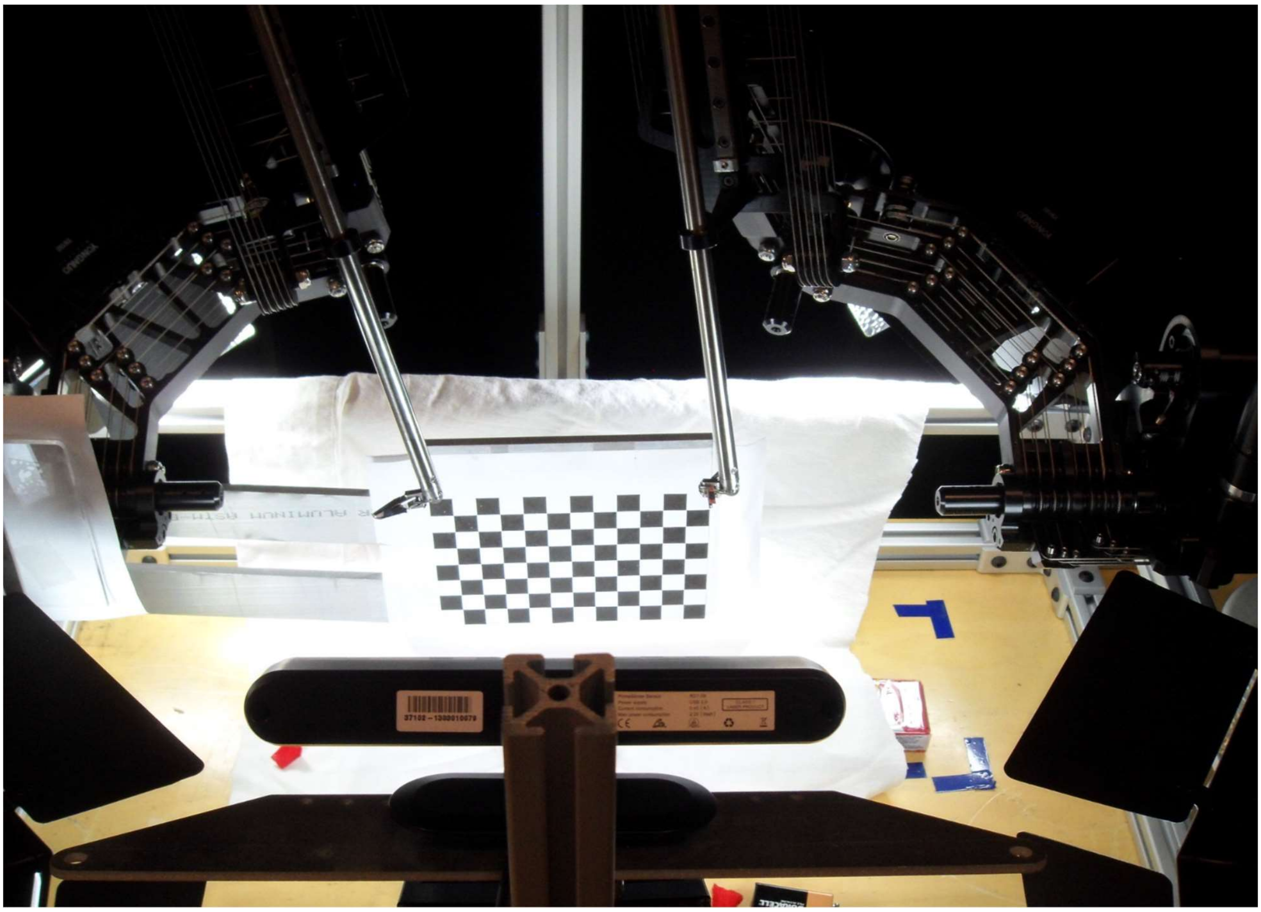


Fig. 15. Removable bracket for rigidly mounting a checkerboard in the workspace for registering the stereo cameras

Future focus will be on state estimation using empirical models of systematic and residual error and probabilistic models based on the Belief Space framework. Robot performance will be studied in more complex debridement scenarios, including a mix of fragment types (eg, healthy vs. diseased) and more complex body cavity models with obstacles. There is big interest in hybrid systems with both autonomous and human supervisory modes, as in a remote tele-surgery scenario, where a human supervisor is in the loop to periodically confirm a set of fragment detections and motion plans prior to execution. Furthermore, it will be explored the multilateral aspect of this task, including closer cooperation between arms (such as transferring fragments between arms as in the FLS training tasks), adding additional robots for more arms, and human robot collaboration in which one arm is autonomous and one arm is controlled by a human.

Next future of mechatronics

Electromagnetic actuators

Soft robotic systems are of increasing interest due to the promise they hold for ensuring safe human–robot interaction and highly robust and adaptable operation in complex, unstructured environments. They offer many advantages over conventional systems made of rigid elements. They can flexibly adapt to a great variety of configurations, and to different mechanical settings, can ensure safe cooperation with humans, and can facilitate the coordination of large numbers of degrees of freedom. Many types of stretchable and wearable sensors, soft actuators, soft energy harvesters, and storage devices have been developed, often motivated by applications in robotics, healthcare, and other domains. Mechanical systems based on soft actuators are also adaptable to systems of greatly varying length scales, ranging from miniature grippers, to mobile robots, wearable tactile displays, and biomedical devices. Methods of actuation for soft robotics include tendon-driven actuation, smart materials, such as shape memory polymers (SMPs), shape memory alloys (SMAs), pneumatic fiber braids, pneumatic polymers elastomers, hydrogels or electroactive polymers (EAPs). Despite their promise, all of these methods possess limitations in performance and controllability in comparison to systems based on electromagnetic motors. [25] There are several challenges that have prevented the development of high performance EMAs for soft robotics. Conventionally, such devices use rigid conductive wire inductors, such as copper wire coils, to generate time-varying magnetic fields via applied currents, and to exert forces on permanent magnet components. While wire electromagnetic inductors may be introduced into soft materials, their rigidity can greatly limit deformability, and can reduce the durability and longevity of the materials due to stress concentrations that develop at material boundaries.

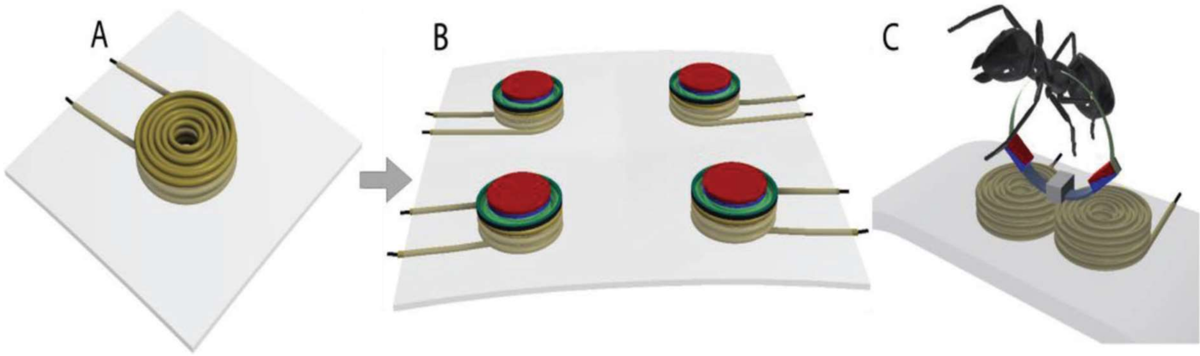


Fig. 16. Soft electromagnetic actuators for wearable tactile display and miniature robotics applications. A) Soft 3D helical coil adhered onto a soft silicone layer. B) An array of soft vibrotactile actuators, formed via the coupling of soft inductors with permanent magnets and flexible membrane suspensions; see Section 2. C) A miniature soft magnetic gripper, suited to micromanipulation tasks, formed from soft 3D helical coils and magnetic arms, shown with an ant.

A new process for the design and fabrication of 3D helical coils for use in soft electronics has been recently developed. [26] First, a liquid elastomer emulsion with high thermal conductivity is deposited in a thin layer (around 150 µm) on a flat surface using a stainless steel roller. A fine carbon fiber rod (200 µm) is slowly rolled onto the thin silicone composite, followed by heating with a hot plate. The cured silicone layer is peeled from the rod to form a hollow elastomer filament. The wall thickness of the hollow filament is ≈120 µm (see Figure S5, Supporting Information for more details). LM alloy is injected into the hollow fiber using a fine needle and syringe to form a long, stretchable, conductive hollow filament. Wire electrodes are inserted into the ends, forming electrical connections, and the hollow filaments are then sealed. The soft hollow filament is wrapped around a plastic cylinder to form a 3D helical coil, and, to maintain its shape, is integrated with a soft silicone substrate. To form actuators, the coils can be mechanically coupled to permanent magnets and flexible elastic membranes.

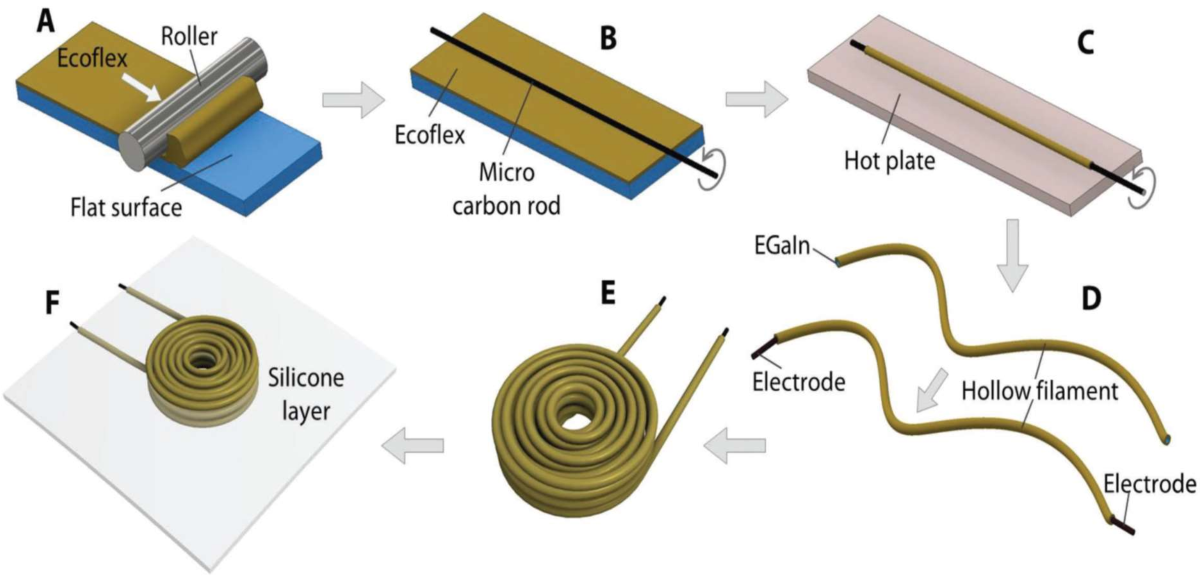


Fig. 17. Fabrication process for the soft, 3D helical coil inductor. A) A thin layer of liquid silicone elastomer (Ecoflex 0030) is laminated onto a flat surface using a stainless steel roller. B) A fine, carbon fiber rod is rolled onto the thin silicone layer. C) The laminated layer and rod are heated via hot plate. D) Liquid metal alloy (EGaIn) is injected into the hollow filament, and electrodes are inserted into the two ends. E) The hollow filament is wound to form a 3D helical coil. F) 3D helical coil is adhered to a soft silicone layer.

This technology could lead to construction of advanced miniature soft electromagnetic grippers that can flexibly grasp, hold, and release a specified object or tissue. The gripper is fabricated with the newly developed soft 3D helical coil and soft magnets, which are briefly described here. First, a permanent magnet (NdFeB, grade N52, K&J Magnetics, USA) is broken down into small magnetic particles using a hammer or planetary ball milling machine. Second, a liquid silicone (recommended by ratio 1:10 between the curing agent and elastomer, Sylgard 184 Silicone Elastomer, Dow Corning, USA) is homogenously mixed with the magnetic powder at a weight ratio of 1:9. After mixing, the solution is poured into a 3D printed mold, and aligned with an external permanent magnet. The orientation of the magnetic polarization of the arms of the gripper (angle α = 25°) is specified by curing in an external magnetic field imposed by a high strength permanent magnet. Curing is performed in an oven at 60 °C for 3 h. The magnetic arms are then mounted on a flexible beam (Ecoflex 0030, Smooth-On, Inc, Easton, PA, USA). After curing, the assembly is coupled to a pair of soft 3D helical coils, and the assembly is sealed via uncured Ecoflex 0030. Upon excitation of the coils, the arms of gripper may be independently controlled, opened, and closed magnetic fields produced by supplying current to the coils.

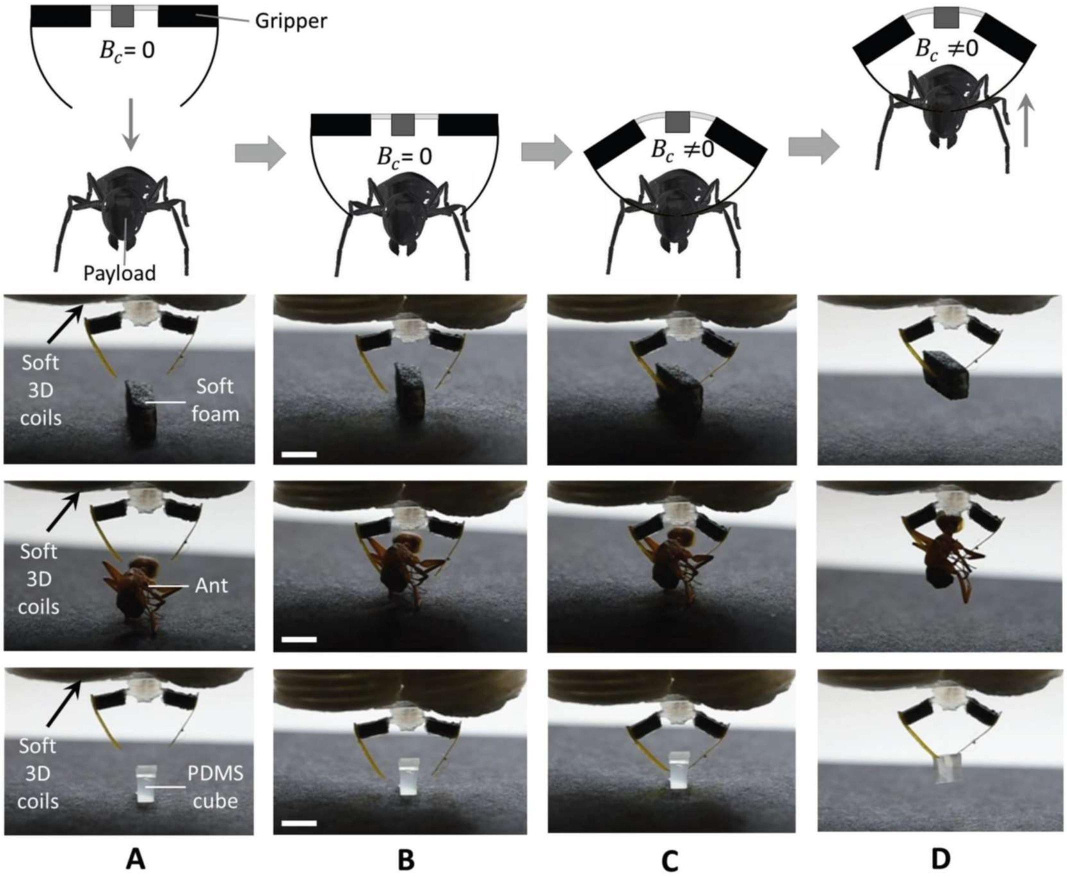


Fig. 18. Manipulation process steps and experimental validation for the miniature gripper with a soft foam cube, an ant, and a PDMS cube. A) Initial position of the gripper. B) The gripper approaches vertically from the top to the payload. C) The gripper holds and lifts the payload. D) The gripper moves back to its original position. The objects are ≈2 mm wide. Videos for real-time experiments are presented in the Supporting Information. Scale bar: 2 mm.

Research for an articulated joint structure robot platform

The da Vinci Si and Xi have wire-driven robotic arms for multiport surgery. Robot arms access the surgical target through multiple ports, but many studies have tried to reduce the number of ports. The da Vinci Si can perform single-port surgery using new curved instruments. Recently, the da Vinci SP was developed specifically for single-port surgery. Another type of wire-driven robot is the SPORT Surgical System (TITAN Medical, Canada), which has triple-segment robot arms with a slit structure and can carry out smooth motion in a single port. [27]

By a joint venture, Korean and USA engineers are actually developing a wire-driven surgical robot for single-port surgery. [28] Two major features of this robot are a joint structure to secure stiffness and double segments to fit the working volume in a single port. Most wire-driven robots are symmetrically controlled with rotating pulleys. In such robots, all wires can be controlled independently for precise movement and other features. The proximal joints and distal joints each have two degrees of freedom (DoFs), and the whole body is capable of rotational and translational motion. Consequentially, the end-effector can achieve a six-DoF motion.

There are two well-known structures of a snake-like surgical robot arm: the slit structure and the joint structure. The slit structure is a flexible pipe with slits in various patterns. The SPORT System is a representative example. [29] The slit structure can make a smoothly curved configuration, and the model is simplified to the curvature model. However, this structure does not have enough stiffness to perform some general surgical operations, including sutures.

An articulated robot arm with a joint structure consists of orthogonally stacked joints. One example is the da Vinci Si. A joint structure cannot be curved in a perfect curvature configuration, but it has stronger stiffness than a slit structure. The set of stacked joints that share the connected wires is called a segment. One segment with orthogonally stacked joints can bend with a two-DoF motion. In single-port surgery, dual robotic arms have to be able to maintain a triangular configuration like a crab's claw, and an articulated arm with multiple segments is essential to establish the working space.

The motion of the distal segments is affected by the motion of the proximal segments because the wires that control the distal segment pass through all stacked joints. The blue wire is connected to the median linkage with a wire crimp terminal and controls only the proximal segment. The red wire controls the distal segment and passes through all joints. This phenomenon is called the coupling problem, which must be solved to control robot arms with multiple segments.

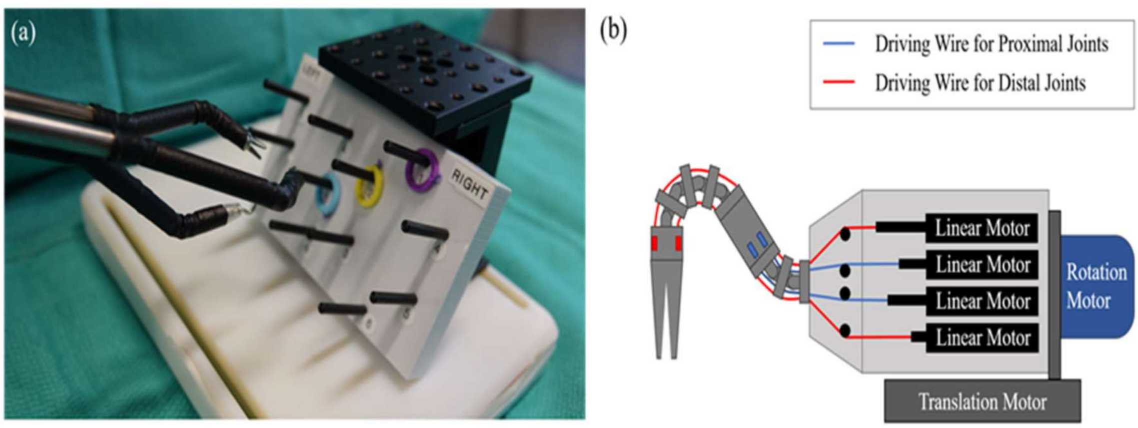


Fig. 19. Wire driven model. (a) Manipulating test prototype. (b) Conceptual diagram.

The accuracy of the robot model heavily influences the robot's performance. The robot arm has a tiny structure with a diameter of less than 6 mm. The robot arm operates inside the body, and it is hard to attach encoders or sensors to the arm to measure joint angles or trace the end-effector's position and orientation. This type of robot is usually controlled by open-loop control based on a mathematical model, unlike general industrial robot arms. The wire driving length has to be calculated from the robot model and a path generation algorithm according to an arbitrary input from the master device in real-time without any feedback from the joint configuration. Therefore, a comparison study about modeling approaches for tendon-actuated continuum robots was carried out.

Most snake-like robot arms have been analyzed with a constant-curvature model for convenience. Recently, a variable-curvature model was derived to improve the accuracy of the curvature model. The curvature model works well for a continuum body such as the slit structure, but it does not fit well with a joint structure. The driving wire length is calculated with modeling error, and wire slack behavior may occur between the joints, where the joints are not able to bend to the desired angle or maintain stiffness. In this research, a more accurate kinematic model was derived to fit an articulated robot arm with a joint structure, and effective path generation algorithms are proposed to solve the inverse kinematics.

One challenging problem is how to solve inverse kinematics from the task space to the wire-length space and generate an actuation path in real-time. A kinematic model of a wire-driven robot arm usually consists of three spaces called the task space, joint space, and wire-length space. The task space includes the position and orientation of the end-effector, which are given from the master device with the surgeon in real-time. The joint space deals with the joint configuration, which includes the joint angles, translation, and rotation of the robot arm. The wire-length space includes the wire-driving length from the motors.

This path generator was much faster and much more accurate than the optimization path generator. However, it could not restrict the actuation value to the mechanical limits. The experimental results showed performance improvement due to the accurate kinematic model and the validity of the path generators embedded in a surgical robot prototype. In future work, a path-regulation algorithm will be designed for a second path generator.

How to increase workspace: proposal of a spheric magnetical field driven robotic system

One of trends in robotic surgery is the procedure known as single-incision laparoscopic surgery (SILS), which is attracting a great deal of attention worldwide because of the benefits that this method can offer. In SILS, medical instruments and the laparoscope are operated through a single incision in the derma of the patient's abdominal cavity. Compared with traditional laparoscopic surgeries, SILS has several possible benefits including reduced operative complications, reduced postoperative pain, and better cosmetic results. In SILS, however, because the surgical instruments share a common incision, the interferences between the laparoscope and other medical instruments constrain the dexterity of surgical instruments and affect the field of views of the laparoscope. [30]

To solve these problems and take account clinical needs and technical requirements, fully inserted laparoscopes are designed. The interferences and visual affection can be alleviated by keeping the laparoscope away from the surgical incision. For a fully inserted laparoscope, the main challenge lies in the position and orientation control. Position and orientation here refer to the position and orientation of the robot relative to abdominal wall. In order to get clear and broader visual feedback in SILS, the position and orientation of the laparoscope should be controllable. [31]

Existing studies of the fully inserted laparoscope utilized in SILS have developed multiple methods of position control, including suturing, piercing, and attracting the laparoscope to the abdominal wall by an external permanent magnet (EPM). Hu et al. developed two types of stick-shaped laparoscopic robots, which adopt DC servo motors combined with worm gear mechanisms to enable the pan and tilt motion of the camera. [32] During the surgery, these two laparoscopic robots are fixed by being sutured on the abdominal wall. Castro et al. proposed a wireless miniature anchored laparoscopic robot, the pan and tilt motion of its camera is manipulated by two inner motors. By applying a needle to pierce through the patient's abdominal wall, the laparoscopic robot is fixed to the abdominal wall. However, both suturing or piercing methods have two significant shortcomings. One is the extra injures caused by suturing or piercing, the other is the limited reposition ability. Once these laparoscopic robots are fixed, it is difficult to reposition.

Different from the suturing and piercing methods, some research groups use EPMs to achieve the position control of the laparoscopic robot. Platt et al. proposed a fully-inserted modular wireless surgical robot. [33] By changing the payload in its cylindrical housing, the robot can achieve multiple functions. Through two magnetic caps at both ends of the robot, it can be magnetically attached to the inside of the abdominal wall and achieve pan motion by an EPM handle. Simi et al. designed a wireless laparoscopic camera system which embeds two internal permanent magnets (IPMs) in a capsule-shaped housing, two EPMs are adopted to achieve the pan and shift control of the laparoscopic robot, and the rotation of the camera along its axis is achieved by an inner motor. Compared with these methods of position control, the use of EMPs are more flexible. [34]

As for orientation control, most of the existing laparoscopic robots use micro motors and gear mechanisms to achieve the tilt motion of the inner camera, and adopt other mechanisms (suturing, piercing, EMP, etc.) to achieve the position control of the robot. However, the inner motor along with a relevant mechanism will complicate the structure, enlarge the dimension, and increase the energy consumption of the laparoscopic robot.

To address the above problems, a Chinese engineering study group proposed an innovative configuration of laparoscopic robot, which adopts external magnetic field to achieve position and orientation control of the laparoscopic robot. [35] Therefore, the inner motor-based motion mechanism can be removed, and the laparoscopic robot will have simpler structure, less energy consumption, and more room for other sensors. Inspired by the research of spherical motor, as well as the driving method of an intraocular micro robot OctoMag, a laparoscopic robot system is designed in this study. [36] Both OctoMag and the newly designed structure use multiply electromagnets to generate controllable magnetic field to control the position and of the robot. However, the OctoMag is designed for microrobots used in retinal procedures, therefore, gravity compensation of the robot is relatively easy to achieve due to the liquid work environment and the light weight of the robot. However, for the structure proposed in this paper, electromagnets need to provide enough force to compensate the gravity of the laparoscopic robot, which is the prerequisite for position and orientation control of the robot.

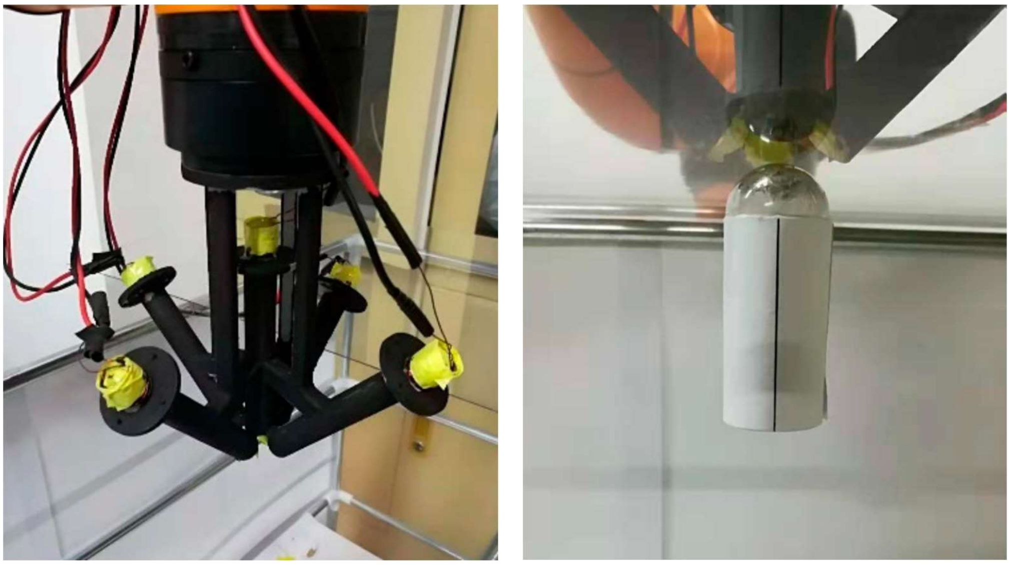


Fig. 20. The prototype of laparoscopic robot system: on the right, the driving device (the stator) which is consist of five electromagnets; on the left, the laparoscopic robot (the rotor).

The system consists of an external driving device (i.e., the stator) and an inner laparoscopic robot (i.e., the rotor). The stator consists of five electromagnets. The rotor is a capsule-shaped cylinder, whose hemispherical dome is installed with IPMs. Under the action of the external magnetic field, the stator can keep the rotor away from the incision and then make room for other surgical instruments in SILS. Thus, the interferences between rotor and other surgical instruments can be avoided. Additionally, the stator can provide position and orientation control of the rotor to achieve adjustable field of views. Since the driving system is separated from the laparoscopic robot, the laparoscopic robot has a simpler structure, less energy consumption, and smaller size.

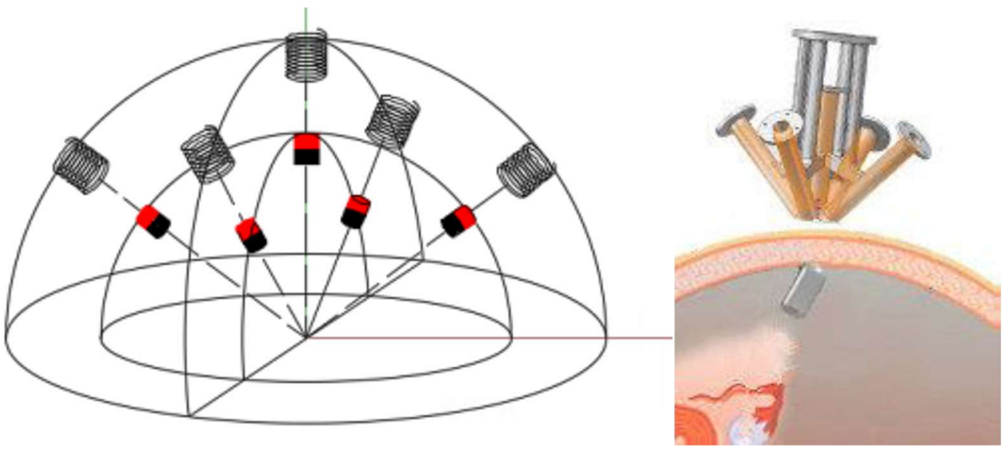


Fig. 21. On the right: distribution of electromagnets in the stator and the IPMs in the rotor; on the left: working principle diagram of laparoscopic robot

Actual applications

Simulation Platform for Pediatric Surgery

We have diffusely looked after several limitation of actual robotic surgery platforms in pediatric. The size of the surgical instrument is excessively large when this device is applied to newborns and infants. Moreover, it was highlighted that the following issues have a significant influence on the treatment outcome: the limitation of the surgical tool's operation, the obstruction of endoscopic vision and the position of trocars. [37] As one of the commercial examples, the Endo Wrist, which has a forceps diameter of 5 mm, was developed for the da Vinci Surgical System to solve these drawbacks as a surgical tool for pediatric surgery. However, many authors reported that the size of the surgical workspace slightly exceeded that of the workspace using surgical tools for adult surgery due to structural problems. [38]

In related works concerning robotic instruments, a forceps manipulator using a pneumatic soft actuator for a bending joint to solve wire-driven mechanism problem and magnetic resonance (MR)-compatible tools to maintain surgical accuracy and safety for pediatric bone biopsy were developed. Fujii et al. and Tagazawa et al. focused on developing surgical tools for pediatric surgery, and reported on the handling problem of a suturing needle. [39] In related works about surgical workspace creation, Sun et al. developed a da Vinci Surgical System simulator and used it to identify a suitable workspace based on the trocar point on the human body. [40] Using this system, they reported that a suitable position for the surgical robot can be calculated for individual patients, which includes pediatric surgery patients. Nouaille et al. studied the modeling and geometrical validation of surgical assistance tools and demonstrated that the configuration of surgical robots can be verified with respect to a mechanical structure. [41] Sun and Yeung considered that the placement of trocars is critical when creating a surgical workspace, and then conducted research to verify the optimal trocar position for the adult environment. In related works regarding the size of surgical instruments, those instruments with diameters of 3 to 8 mm have been verified for pediatric surgery. [42] From these results, it has been reported that the effectiveness varies depending on the case used.

To apply a surgery-assisted robot to pediatric surgery, two drawbacks must be solved, namely, the movement volume and the lack of vision field information. These drawbacks are factors that affect human operation. In the conventional development method for a robot, a scrap and build method is adopted, in which a prototype is produced and evaluated repeatedly. In the case of development using this method, the robot is manufactured as a real machine and then a human evaluation is carried out using the robot. It is difficult to manufacture a surgical assisted robot in the field of pediatric surgery using the conventional development method, taking into account the abovementioned limitations for the human evaluation carried out after developing the actual machine. Therefore, a design method was developed by Seno et al. to obtain a surgical assisted robot that could be applied to a narrow surgical workspace with a decreased burden on the surgeon during operation. [43] In that study, a human-in-the-loop type simulator was constructed to reproduce a virtual surgical workspace in which a surgeon could handle the designed robot in real time. In the surgical robot's development process, this simulator was proposed for use in the design stage. Using this simulator, the authors focused on the behavior of the tip of the forceps and measured the manipulability of each joint of the forceps manipulator to verify the ease of movement of the mechanism when used in virtual space. It was confirmed that the load applied to the forceps mechanism differs depending on the procedure. I was so verified the operational influence of the forceps manipulator from the perspective of differences in the tip mechanism on surgical procedures. Based on the results, it was confirmed that the difference in the mechanism resulted in a change in the forceps tips' trajectory. In addition, it was also confirmed that the distance between the joint for the bending movement and the next joint toward the tip had an influence on the accuracy of the needle handling and the workspace when carrying out a procedure involving needle insertion.

When carrying out the needle-hooking operation, the surgeon achieves needle handling using the movement of the wrist, given that the suture needle is curved. The wrist joint of the forceps manipulator plays an important role in the development of a master-slave control-type surgical assisted robot handled by a surgeon. Therefore, it was considered that an easy-to-use robot could be created by optimizing the mechanical design parameters based on the information related to the movement of this part by the surgeon. In the previous research studies, the needle-hooking motion used for esophageal anastomosis was examined during the application of a surgical assisted robot to an assumed congenital esophageal atresia procedure. The aim of this study [44] was to verify the influence on the needle-hooking motion in a procedure that imitated esophagus anastomosis in congenital esophageal atresia using the forceps manipulator, optimizing the mechanical parameters of the tip joint obtained in the previous research. Moreover, the effectiveness of the design optimization of the forceps manipulator based on the human operation was verified.

In a novel study by Kawamura et al., the virtual environment that assumed a congenital esophageal atresia procedure in pediatric surgery was constructed using the surgical workspace reproduction simulator developed in our previous works. [45] From a discussion with a pediatric surgeon, the authors learned that it was necessary to carry out treatment within a very narrow workspace of 40 × 40 × 50 mm for congenital esophageal atresia. In this experiment, the 40 × 40 × 50 mm workspace was reproduced by arranging the virtual wall on the left, right, and back side under the virtual environment.

The surgical procedure of congenital esophageal atresia, as targeted in this study, includes the suturing task of the upper esophagus and the lower esophagus, the ligation task, and the everting task of the esophagus for the placement of a needle on the back. Among these tasks, the suturing task in the upper esophagus and lower esophagus is considered difficult, and it is desirable to apply a surgical assisted robot. Therefore, in this experiment, the operation of the needle placement on the target point shown in the virtual environment was used as the procedure of this experiment. As shown in fig. 22, the target point was set as target point (A) when inserting the needle, and target point (B) when extracting the needle.

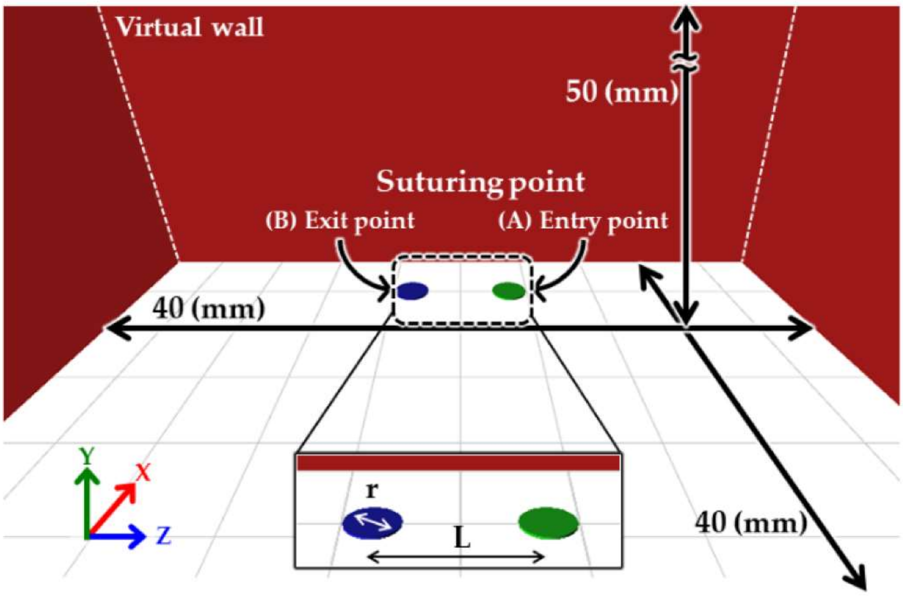


Fig. 22. Spatial setup

In congenital esophageal atresia, it is necessary to provide 8–12 sutures for the upper esophagus with diameters of approximately 10 mm, and for the lower esophagus with diameters of approximately 5 mm. Therefore, the radius r of the target point was set to 1 mm. The distance l between the target points was set as 8 mm, based on a discussion with a pediatric surgeon.

Moreover, Geomagic Touch™ (3D Systems, Rock Hill, SC, USA) was used as the operation input device, and force feedback was not provided in this experiment. Considering a task within a very narrow environment, the ratio of the operation input amount to the operation amount was set as 10:1.

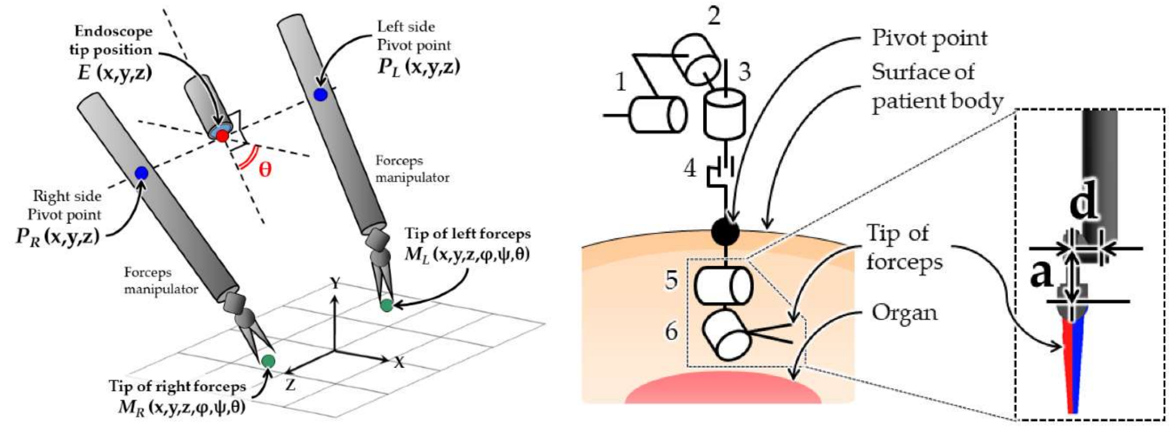


Fig. 23. Task execution

From the experimental results, it was confirmed that the needle handling accuracy could be improved when the needle-hooking task was carried out using the optimized conditions. Thus, the optimization of the mechanism with the invisible area rate of the tip of the forceps manipulator and the moving volume as variables was suggested.

The aim of this study was the verification of the optimization of the mechanical parameters based on human operation for needle-hooking operations in pediatric surgery. A needle-hooking task was carried out by four subjects with five types of mechanisms using the results of the Pareto optimal solution obtained in previous research. [46] In addition, the accuracy of the needle tip manipulation was verified.

When considering the actual surgical technique, there are other techniques to be considered, in addition to the technique that involves the cooperation of the left and right forceps manipulator. Given that the required motions differ between the left and right forceps manipulator, it is necessary to carry out the optimization for each mechanism of the manipulator based on the task required by each manipulator. Therefore, it was considered necessary to carry out optimization based on the cooperated operation and its evaluation index, to derive the mechanism of the surgical tool that is more suitable for pediatric surgery.

Actual needings

Introduction of robotic technology in the surgical field has offered objective and measurable advantages in comparison with traditional procedures. First advances in this area were limited to adapting industrial robots to the medical application without being optimized for the characteristics of specific surgical tasks. Consequently, in the last 15 years, numerous surgical groups worldwide have incorporated robotic technology to their daily practice.

However, despite years of research and the great potential of some systems, the field of surgical robotics is still only at the beginning of a very promising large-scale development. [47] The evolution experienced with the use of robotics in some medical procedures is expanding its area of application to more challenging scenarios, requiring further refinements in the proposed systems. In addition, the current surgical robotic systems are extremely expensive in acquisition, maintenance, disposable tools and training, representing much higher direct costs compared with open surgery and laparoscopic instrumentation. On the other hand, a legal framework that can accompany the development of these robotics systems is also fundamental, since neither the end-users at the experimental level nor the designers and manufacturers at the industrial level can properly appraise the risks nor duties entwined in their work until a clear analysis of the interplay between robotics and regulation has been made. [48]

Therefore, although a large number of robotic systems have been developed, several technical, logistic, economic and safety issues have not yet been addressed, limiting broader adoption of these systems by the majority of hospitals. It is then necessary to develop new surgical robots that satisfy the requirements of surgeons and to rectify the technical and economics aforementioned problems.

Clinical needs are established as prerequisites for any development programme of surgical robotic systems. They will ultimately define the goals and specification of the project. Nowadays, specific clinical needs in specific surgical procedures are demanding more customized robotic systems. [49] This differs from the approach of the da Vinci Surgical System, which in general, has been to find a clinical need for a multi-purpose technology, rather than to specifically design a technology for a targeted clinical application.

These clinical needs are:

Cost reduction. To gain acceptance, new robotic systems must demonstrate relative competitiveness versus a conventional alternative and achieve a favorable ratio of cost–benefit.

Effectiveness can be measured in different ways, e.g. by means of a better success rate, a reduced rate of complications, a reduced hospitalization time and/or a reduced blood loss. [50] Ultimately, the clinical effectiveness of a device with respect to a conventional surgical procedure, relative to its cost, will form the basis of its acceptability in any decision-making process performed by the medical authority. [51]

Time of intervention. Robotic surgery is associated with increased operation duration, which could have implications for patient safety. This extended duration is usually produced by the low speed to which robots are programmed to move during interventions and path planning strategies where robots often backtracked to areas previously treated. An increase in the speed, as well as the optimization of path planning could contribute to notably reduce the time of intervention. It has also been argued that longer operation time can be due to the lack of tactile feedback. This lack of tactile feedback could decrease the speed of surgeons' movements, who have to rely on visual information only.

Time and complexity for set-up. Future technical developments should contribute to reducing robotic system complexity and deployment time. Proper training and standardization of duties are also key points that could contribute to overcome the aforementioned difficulties. Teams that are well trained and quite familiarized with the equipment and the technology employed can notably reduce the set-up time. Standardized duties could contribute to improving coordination, accelerating the learning and execution of assigned tasks. Other strategies for reducing set-up time include enabling additional dedicated staffs that assist with setting up and clearing away the robot, or enabling a dedicated robotic operating theatre in such a way that the team does not need to move robots from/to another location before/after operation.

Reduced operating room (OR) footprint. Nowadays, surgical robots require a large footprint in the OR and use relatively cumbersome robotics arms with instruments that are still too rigid and straight. This is an important disadvantage in today's already crowded OR. The large footprints limit the assistant surgeon's access to the patient, as well as rapid access to the patient in case of emergency. Evolution of robotic assisted MIS requires lightweight flexible manipulators with minimum footprint and with the capacity of adaptation to areas that are more delicate, circuitous, and difficult to access. Extrinsic actuation often reduces the required manipulator diameter, increasing range of motion and accessibility to confined spaces. However, this comes at the potential price of large external footprint, increased friction and hysteresis, and introduction of elastic instabilities in the case of concentric-tube transmissions. On the other hand, direct intrinsic actuation may reduce footprint and friction while requiring larger manipulation diameters.

Data integration. Greater data integration could provide the surgeon with more patient information during surgery. This could help the surgeon to complete the procedure more safely and successfully, avoiding distractions and facilitating the access to preoperative studies. Data integration can include enhanced reality environments that would provide live feed from cameras, and additional information such as patient preoperative scans and 3D anatomical renderings. The interface can house such features as an image browser, ultrasonography, DICOM viewer for CT images, 3D image volume renderings and note-taking on images.

Improved decision-making. During an operation, decision-making is affected by variables such as tactile and visual perception, motor skill and instrument complexity, all of which are modified by robotic surgery, and may therefore, influence a surgeons' ability to use their experience in the decision-making process. Separation of the surgeon from the rest of the staff can also impact on the data acquisition that is used during the decision-making process. Future designs and developments should address tools that provide support and guidance in how to proceed effectively. The theory of distributed situation awareness puts forward the need for considering what aspects of the situation the surgeon needs to be aware of in order to support the decision-making process, while both distributed situation awareness and distributed cognition suggest reflecting on the role that other members of the operation theatre team can play in contributing to the surgeon's situation awareness.

Future fields of research

A crucial step in the design of new surgical robots is how to match the clinical needs to the technological possibilities. Technologies to be developed should aim not only to support current surgical procedures better, but also to open up new clinical opportunities.

Research on surgical robots should still provide response to various technical requirements, which we highlight below: [52]

Reduced size, shape and weight. Reduced access provided by new minimally access techniques imposes hard design constraints on the size, shape and weight of instruments and robotic modules conceived for these procedures. Surgical instruments should be sufficiently flexible and should have an ergonomic shape that eases their access, and a reduced size of between 3 and 6 mm that allows their simultaneous maneuverability. In the case of robotic modules, not only ergonomics and reduced size should be considered, but also weight, which can play an important role in the anchoring of the modules. For instance, in magnetic anchoring guidance systems, magnetic forces diminish logarithmically with increasing distances between internal and external modules, and with the weight of the internal device-magnet module. In the case of overweight patients, bigger and thus heavier external permanent magnets are required. On the one hand, this limits the available space for external actuations units and on the other, increases compression between the two magnetic components, which may damage the intervening tissue. Therefore, it is desirable to reduce the weight of internal modules below 35 g to limit the size and weight of external permanent magnets.

Greater number of degrees of freedom (DOF). A proper number of DOFs are required in order to achieve the desired mobility and surgery support. In MIS, surgical instruments must be manoeuvred around an entry point that restricts two of the instrument's DoF, leaving the surgeon in the best of cases, with 4 DOFs per instrument to work inside the patient (usually, yaw, pitch, roll and translation). This enables complicated tasks such as suturing. Instruments with multiple DOF (>4) are being proposed to address this problem. On the other hand, redundant kinematics with 7 or more DOFs for surgical robotic arms can allow for a more flexible OR setup, as well as collision avoidance with other robots or OR equipment.

Workspace. Workspace of tools will be constrained by the number of DOFs, the lengths of the links, the joint limits and possible collisions with its own links or other barriers such as anatomy. As robotic surgery implies performing technically complex procedures in small cavities, special attention should be paid to reduced workspaces. In reduced workspaces, the ports cannot maintain an adequate distance among the robotic arms to avoid external collision, especially when arms are actively working, which prevents optimal functioning. Many studies identified that the smallest workable volume with the da Vinci robot is 125 cm3, and encountered serious difficulties and higher complications rates with volumes smaller than 150 cm3. These limitations are particularly important in paediatric robotic surgeries.

Resolution. Resolution can be understood as the smallest incremental movement that the tool can make or measure. Resolution requirements are tied to surgical procedures; for instance, cholecystectomy requires a 2 mm resolution.

Platform stability. As stated in the first point, instruments should be sufficiently flexible to enable not only easy access, but also progressive propagation, and finally correct positioning. However, once the target location has been reached, fixation and stiffening of the instruments should be optimal to enable stable and precise operation.

Retraction. The high flexibility of the instruments can limit the effective transmission of forces to the tip tools. These forces are required to properly retract tissues, apply strong sutures or clips, or provide robust grasping.

Force feedback feeling. The loss of touch makes it difficult to feel when an instrument and an organ are in contact. Haptic feedback would provide the surgeon direct access to manipulation forces inside the patient and allow for more delicate manipulation of tissue, avoiding unintentional damage.

Suitable visualization and spatial orientation of the surgical field. In spite of the advances achieved with the inclusion of 3D high definition vision systems that provide an immersive view of the surgical field, surgeons still experience visual limitations in certain surgical scenarios. Colectomies, Nissen fundoplication, gastric bypass, coronary bypass procedures, mammary artery harvest procedures, are some representative examples of minimally invasive gastrointestinal and cardiac surgeries exhibiting visual problems. Paediatric surgical procedures also impose numerous restrictions. Solutions that help to increase the field of view (>70°) in occluded surgical regions, the depth perception along the line of sight, the resolution of tissue details at farther distances, or that allow visualization of the surgical field from different viewpoints during robotic surgery are highly required.

Wireless modules. On-board power supply and wireless controllers are desirable to provide independent deployment for robotic modules.

Triangulation. This is intended to replicate the experience of complex two-handed laparoscopic manipulations, which in turn are designed to imitate the technique used in open surgery. Therefore, it would be desirable to count with multi-channel instruments that can be moved independently, instead of inline instrumentation and optics.

Reduction of repetitive instrument exchange. The number of times that the instruments are exchanged varies depending on the different procedures. For instance, the need is higher in esofago-gastric junction surgery, splenic surgery and gastric surgery and lower in hepatic surgery and adrenal gland surgery. The average number of instrument exchanges during one procedure was calculated in 40, taking into account replacement of the instruments on two robotics arms and camera removal for cleaning, and summed up to 15 times (±4.5). The average time for instrument exchange was 6.8 s (±3.1) and the average time for cleaning the camera was

20 s (±4.3). Some instruments, such as the harmonic scalpel, need special adjustments to fit into the robotic arm. These average times can be increased if the assistant is not formally trained or not familiarized with the robotic equipment. In addition, although this is not usual, there is always a safety risk associated with the instrument exchange, especially if intra-corporal conditions can vary in the meanwhile. Therefore, for future developments, the removal and reinsertion of instruments should be reduced or avoided as far as possible.

Flexibility of rigid instruments. Surgical procedures involving complex anatomical pathways between the access route, entry point and operative sites can greatly benefit from flexible, articulated robotic instruments. Rigid-link devices with a higher degree of articulation enhance flexibility, but still exhibit several drawbacks such as the slow speed of forward motion, the limited radius of curvature and the large size of the external feeder.

Suctioning and irrigation capabilities. It is necessary to have available devices able to efficiently remove blood, blood clots and fluids from the surgical field.

Maneuverability. The tip of the surgical tools must have the ability to maneuver in all planes: vertical, horizontal and lateral.

Control requirements. From the standpoint of control, robotic surgery devices can be clustered into three major groups: (i) supervisory controlled robotic systems, in which the surgeon plans the operation off-line and the robot performs the specified motions autonomously under the supervision of the surgeon; (ii) robotic tele surgical systems, in which the robot is tele-operated or directly controlled by one or more surgeons using a master–slave methodology (e.g. the da Vinci Surgical System); and (iii) shared control systems, in which robotic devices are cooperatively controlled by a surgeon and a computer (the surgeon remains in control of the procedure and the robot provides steady-hand manipulation of the instrument). Haptic interfaces, virtual and augmented reality, natural control surfaces allowing for surgeon movement, purpose-built interfaces and contactless hand-tracking technology as surgical master, are some fundamental requirements that should be considered for improving current surgical control systems.

Ergonomics. The need for solving ergonomic problems is attracting a lot of attention in the last years, mainly due to the cumulative musculoskeletal injuries reported by surgeons while conducting MIS surgeries. Use of surgical robots requires that surgeons sit down for extended periods at a surgical console from which they control the robotic arms and view the surgical procedure through a high resolution viewer. This can lead to sustained trunk and neck flexion, resulting in discomfort in those regions. In addition, the motion scaling can force the surgeon to move his arms long distances at the console for certain man oeuvres (e.g. pulling on a thread), which, in contrast, are easily performed during laparoscopy. Similarly, the quality of the Metzenbaum scissors is not comparable with the laparoscopic counterpart, and there is no instrument comparable with a right-angle dissector). On the other hand, ergonomics for the assisting surgeon using a surgical robot are even worse than in standard laparoscopy. Interference of the robotic arms significantly reduces the dexterity of the assistant. There is no easy access to parameters of auxiliary devices (e.g. insufflator, diathermy) and communication with staff at the OR table might be disabled (e.g. noise of insufflator, respiratory device, patient warmer), causing significant mental stress. Thus, there is still room for further improving the ergonomic design of robots used in MIS, and the following factors are some of the considerations that should not go unnoticed:

Static bodily postures. New designs in the OR and instruments can significantly improve the position of surgeon, reducing fatigue and musculoskeletal stress.

Design of the instrumental grips. Adaptation of surgical instruments to the type of operation and the characteristics of surgeons could decrease overload on joints, ligaments and muscles of the upper extremities, avoiding forced postures and repetitive movements, and consequently, could improve the performance and effectiveness of the surgery.

Monitor Position. The monitor position is important because it influences decisively the posture adopted by the surgeon during surgery, which may cause discomfort and fatigue in the muscles of the back and neck due to a high inclination of the cervical spine.

Standardization of the trocar position. In this way, it would be possible to minimize collision of arms and disturbance of the assisting surgeon.

Training and credentials. The integration of robotic surgery into clinical practice still requires appropriate training.48 Hospitals are responsible for ensuring that surgeons are being trained, credentialed and monitored in an ethical manner to utilize robotic surgery.49 This issue is attracting increasing attention because there have been recent reports of litigation directed at hospitals resulting from insufficient training and insufficient credentialing for surgeons who are newly trained in robotic surgery. The American College of Obstetricians and Gynaecologists offers no specific recommendation, but comments that 'credentialing for robotic-assisted surgery within and across specialties is based on training, experience, and documented current competency'. There are certain tools, such as the global evaluative assessment of robotic skills

(GEARS), which permit objective assessment and can be used to grade performance during simulation exercises. This standardized assessment tool shows excellent consistency, reliability and validity. However, there is a lack of consensus on what the cut-offs for competency, proficiency and mastery should be. Further studies should evaluate its usefulness for surgical education and the establishment of competency in robotic surgery.[42-44] Therefore, there exists an urgent need for unifying the training and credentialing requirements to ensure patients' safety.

Legal and safety requirements

Several authors have already stated the need for metrics and regulatory standards for robotic surgery, since unlike industrial robots that operate in structured environments, surgical robots have a direct interaction with the human body. Consequently, several groups have been working in recent years with the aim of ensuring the safe use of surgical robots and computer assisted surgical systems for both patients and medical staff. [53] Worth mentioning are the efforts carried out by the Seventh Framework Programme Research Project SAFROS (FP7-ICT-2009.5.2), the USA National Institute of Standards and Technology (NIST), the Joint Working Groups JWG 9 and JWG 35 between the International Standardization Organization (ISO) and the International Electrotechnical Commission (IEC), as well as the Food and Drug Administration (FDA) through the 2015 robotically-assisted surgical devices (RASD) workshop.

SAFROS – patient safety in robotic surgery

One of the main objectives of this Seventh Framework Programme (FP7) Research Project was the definition of patient safety metrics for surgical procedures. The methodology implemented for the definition of this metrics involved three increasingly complex levels of analysis: product safety analysis, process safety analysis, and organizational safety analysis. This enabled evaluation of the safety of the proposed technologies considering them first individually, then analysing their impact when they are included in a surgical procedure, and finally, integrating them into a wider organizational context.

Thus, the product safety level assesses the technical features of the robotic surgery solutions, whereas the process safety analysis evaluates the effects of integrating the aforementioned products into the different stages of surgical procedures. The analysis of these levels provided, respectively, the set of technical and medical safety metrics that are summarized in Table 2.49 The product safety analysis was focused on virtual simulators for planning, pre-operative planning technologies and robotic simulators. Process safety analysis included factors such as the procedure-related risks, robotic-surgical procedure, patient related information and OR environment.

US National Institute of Standards and Technology (NIST)

NIST, in cooperation with members of the FDA, private industries, universities and other government agencies agreed to document and prioritize the measurement and measurement-related standards needs of a few categories of medical device. Five priorities were identified for surgical robots: [54]

Development of systems for measuring overall input/output motion performance of teleoperated surgical robots. The positional accuracy of a surgical robot is fundamental for preserving patient safety and achieving the best clinical results. Most of the procedures require sub-millimetre positioning accuracy and a few degrees angular orientation accuracy. However, position and orientation measurements are quite difficult to carry out routinely during an actual surgical procedure.

Development of performance metrics for evaluating the overall input/output motion of teleoperated surgical robots. For instance, it can involve the quantification of dead zones, dexterity, motion limits, dynamic behaviour and smoothness.

Identification of critical performance metrics for robotic surgical simulators. To be an effective training tool, the simulator should properly recreate the feel and performance of actual surgery. Thus, the challenge lies in understanding what aspects of the simulation are important and determining performance requirements and metrics for validation. Measurement devices are required to understand how faithful a surgical simulation is to actual surgery. Inadequate surgical simulator training can lead to safety hazards. Key parameters include measurement of real tissue deformation (bulk stiffness and local shape variations), contact interactions with instruments and realistic colouring and texturing of tissues. Measurement of actual robot or instrument motions is also required to validate the faithfulness of the simulation to the actual system performance.

Identification of critical performance metrics for force and haptic feedback. First, it is necessary to design and implement new sensors for measuring applied forces at the instrument tip, as well as systems for measuring overall input/output force feedback performance, before metrics to evaluate virtual constraints can be defined.

Development of communication and data standards to link surgical robots with medical imaging systems.

International Standardization Organization (ISO) and International Electrotechnical Commission (IEC)

Until recently, the ISO 10218 (Part 1 and Part 2) was the only international robotic standard devoted to safety. However, it just considered the isolated operation of industrial robots from humans, and prohibited human–robot collaboration. For this reason, in February 2014, the ISO 13482 was introduced in order to provide safety standards for applications involving close human–robot interaction. In addition, relevant standards are being prepared by ISO TC (Technical Committee) 184/SC 2 (subcommittee): robots and robotic devices.47 In the case of surgical robots, it is important to take into account that many medical device regulatory regimes, such as the European Commissions' Medical Device Directive, classify these robots as medical equipment or medical devices. In this sense, the SCs (Subcommittees) and WGs (Working Groups) of IEC TC 62: electrical equipment in medical practice, have been in charge of conducting the greater part of the medical equipment standardization work required to produce the IEC 60601 family of standards. These standards cover the safety requirements for medical electrical equipment and medical electrical systems that are actually utilized.56 This led to the conclusion that both the ISO TC 184/SC2 and IEC SC 62A play an important role in the medical robot standardization. As a first step, these organizations have decided to develop a horizontal medical robot standard, where the robotics and the medical electrical equipment converge. Then, further steps could be directed to develop vertical standards for different types of medical robots.

Under this perspective, the JWG 9 was established in April 2011. [55] The JWG 9 gathers together 69 experts from 19 countries with vast backgrounds in the fields of machine safety and medical device safety. The main objective of this group is to 'develop general requirements and guidance related to the safety of medical electrical equipment and systems that utilize robotic technology', covering invasive and non-invasive procedures. To attain this objective, JWG 9 has been analyzing the differences between the medical electric equipment as defined in IEC 60601–1 and the new medical robots, concluding that the key difference can be found in the definition of 'Degree of Autonomy', which in the ISO 8373 considers the robot operation without human intervention, and in the IEC 60601 family documents is not fully addressed. Some technical reports have already been presented, providing guidance on: defining Degree of Autonomy and how this can affect the risk assessment; methodologies for assessing the chance to the risk, and risk reduction suggestion; basic safety considerations in relation to IEC 60601–1.

Degree of Autonomy directly impacts risk assessment, although it has no direct correlation with risk. The following measures are recommended for reducing risks related to degree of autonomy: constraining the operational scenarios to reduce risk of harm due to incorrect actions; use of unique identifiers for safety related objects; the reliability of sensors and sensing algorithms should be increased to a level where no unacceptable risk occurs; identification algorithms should be designed in such a way that the probability of a certain decision being correct is calculated and can be monitored; validity checks should be implemented in decision which can lead to risky situations; decisions should be verified by diverse sensing principles.

In addition to working on formulating IEC/TR 60601–4-1,[40] the group has identified the need for particular standards for three kinds of medical robots: radiotherapy, surgery and rehabilitation robots. This has given rise to two additional joint working groups: JWG 35 – Medical robots for surgery and JWG 36 – Medical robots for rehabilitation. Of particular relevance to this article is the JWG 35, which was approved in 2015 to develop a particular standard for surgical robots. The new committee is composed of IEC/SC 62D and ISO/TC 184/SC 2, and about 10 meetings are planned before the completion of the standard by November 2018. The new standard for medical robots for surgery will be called, IEC 80601–2-77, Ed. 1.0: Medical Electrical Equipment – Part 2–77: particular requirements for the basic safety and essential performance of medical robots for surgery.

Food and Drug Administration (FDA)

On July 2015, the FDA carried out a public Workshop entitled 'Robotically-Assisted Surgical Devices (RASD): Challenges and Opportunities'. In this workshop, the FDA discussed topics related to the design, development, evaluation and regulation of RASD.[57]

From the system perspective, three factors were identified as fundamental for the successful application of RASD: (i) the understanding of the technological characteristics of RASD, so that changes to a device that could affect the performance of the RASD system can be easily detected; (ii) the understanding of the interdependence and interoperability of each component of the RASD system; and (iii) RASD training for the user and the OR team.

From a regulatory perspective, the FDA's CDRH (Center for Devices and Radiological Health)57 classifies all medical devices based on the risks the device poses to the patient and/or the user. Devices are classified into one of three categories: Class I – Low-risk devices; Class II – Moderate risk devices; Class III – Highest risk device.

The class to which a device is assigned determines, among other things, the type of premarketing submission or application required for FDA clearance to market. RASD are currently regulated as Class II 510(k) devices, under the 'Endoscope and accessories' regulation (21 CFR 876.1500). Thus, for a new or modified RASD to obtain FDA clearance, the new or modified device must be demonstrated to be 'substantially equivalent' to a 'predicate' (legally marketed) device. From this perspective, da Vinci Surgical System (Intuitive Surgical, Inc. Sunnyvale, CA) is the most cited robot for endoscopic surgery and it is the only RASD approved for use in the United States.

CE Marking

In Europe, robotic surgery devices require a CE-mark before they can be place onto the market. The CE mark signifies declaration by the responsible party that the robotic device is compliant with all appropriate European Union New Approach Directives, and more specifically, with the Council Directive 93/42/ECC, which is the Medical Device Directive (MDD). Thus, the CE mark must be obtained, certifying that the product complies with the essential requirements of the relevant EU health, safety and environmental protection legislation. The approval procedure is managed by independent Notified Bodies (NB), accredited by Brussels centrally. There are over 75 international, non-governmental NB for medical devices. Devices are divided into Classes I, IIa, IIb and III in accordance with Annex IX of MDD. The class is linked with the risk of the device and classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of body affected by the use of the device. This classification has an impact on the conformity assessment route that the manufacturer should follow in order to affix the CE marking on the robotic device. As a general rule, confirmation of conformity with the requirements must be based on clinical data. The following harmonized standards are considered as essential requirements: EN ISO 13485:2012, BS EN 62366:2008/IEC 62366–1:2015 Medical devices – Application of usability engineering to medical devices, IEC 62304: 2006 – Medical device software – Software life cycle processes, IEC 60601 family – Medical electrical equipment, EN ISO 14971:2012 Medical devices – Application of risk management to medical devices and ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice.

Artificial intelligence

Definition

While a number of definitions of artificial intelligence (AI) have surfaced over the last few decades, John McCarthy offers the following definition in a 2004 paper: " It is the science and engineering of making intelligent machines, especially intelligent computer programs. It is related to the similar task of using computers to understand human intelligence, but AI does not have to confine itself to methods that are biologically observable."

However, decades before this definition, the birth of the artificial intelligence conversation was denoted by Alan Turing's seminal work, "Computing Machinery and Intelligence", which was published in 1950. In this paper, Turing, often referred to as the "father of computer science", asks the following question, "Can machines think?" From there, he offers a test, now famously known as the "Turing Test", where a human interrogator would try to distinguish between a computer and human text response. While this test has undergone much scrutiny since its publish, it remains an important part of the history of AI as well as an ongoing concept within philosophy as it utilizes ideas around linguistics.
Stuart Russell and Peter Norvig then proceeded to publish: "Artificial Intelligence: A Modern Approach", becoming one of the leading textbooks in the study of AI. In it, they delve into four potential goals or definitions of AI, which differentiates computer systems on the basis of rationality and thinking vs. acting:

Human approach:

Systems that think like humans

Systems that act like humans

Ideal approach:

Systems that think rationally

Systems that act rationally

Deep learning vs. machine learning

Since deep learning and machine learning tend to be used interchangeably, it's worth noting the nuances between the two. As mentioned above, both deep learning and machine learning are sub-fields of artificial intelligence, and deep learning is actually a sub-field of machine learning.

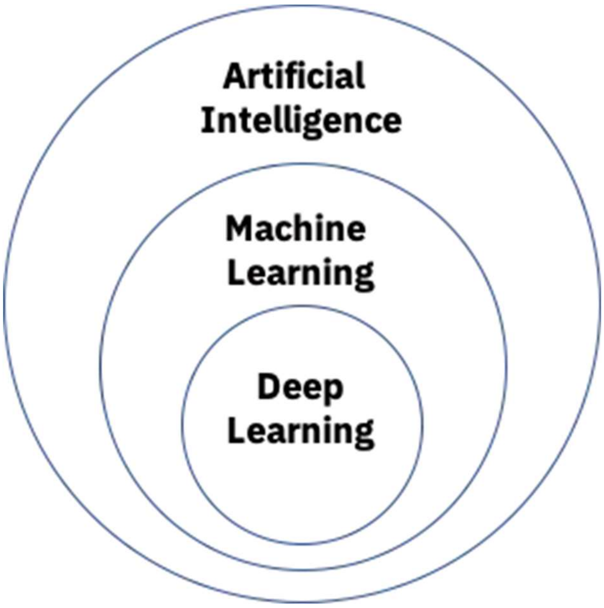


Fig. 24. Scheme of artificial intelligence

Deep learning is actually comprised of neural networks. "Deep" in deep learning refers to a neural network comprised of more than three layers—which would be inclusive of the inputs and the output—can be considered a deep learning algorithm. [56]

This is generally represented using the following diagram:

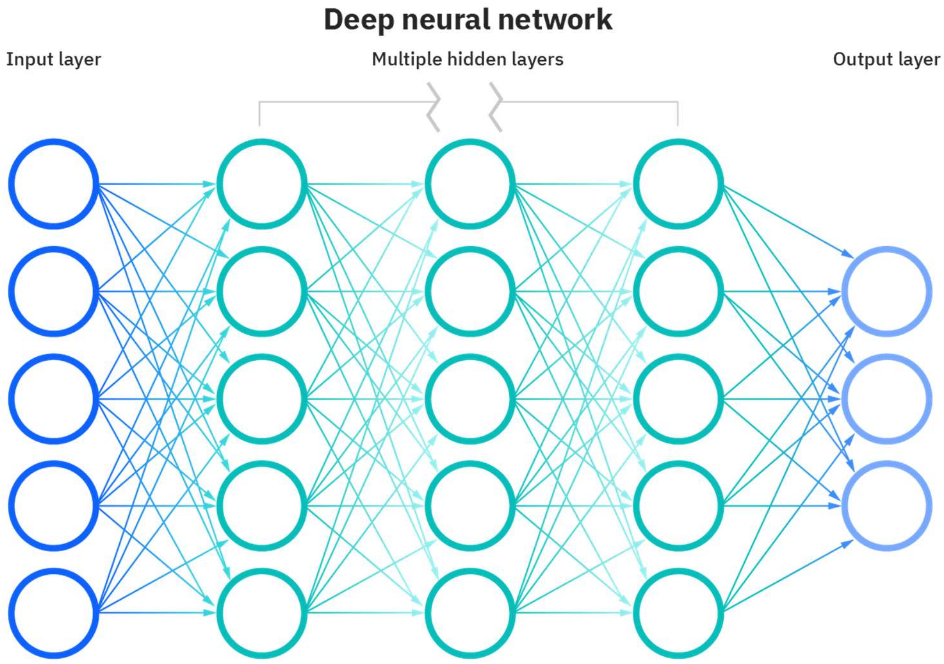


Fig. 25. Scheme of neural networks

The way in which deep learning and machine learning differ is in how each algorithm learns. Deep learning automates much of the feature extraction piece of the process, eliminating some of the manual human intervention required and enabling the use of larger data sets. You can think of deep learning as "scalable machine learning". Classical, or "non-deep", machine learning is more dependent on human intervention to learn. Human experts determine the hierarchy of features to understand the differences between data inputs, usually requiring more structured data to learn.

"Deep" machine learning can leverage labeled datasets, also known as supervised learning, to inform its algorithm, but it doesn't necessarily require a labeled dataset. [57]

It can ingest unstructured data in its raw form (e.g. text, images), and it can automatically determine the hierarchy of features which distinguish different categories of data from one another. Unlike machine learning, it doesn't require human intervention to process data, allowing us to scale machine learning in more interesting ways.

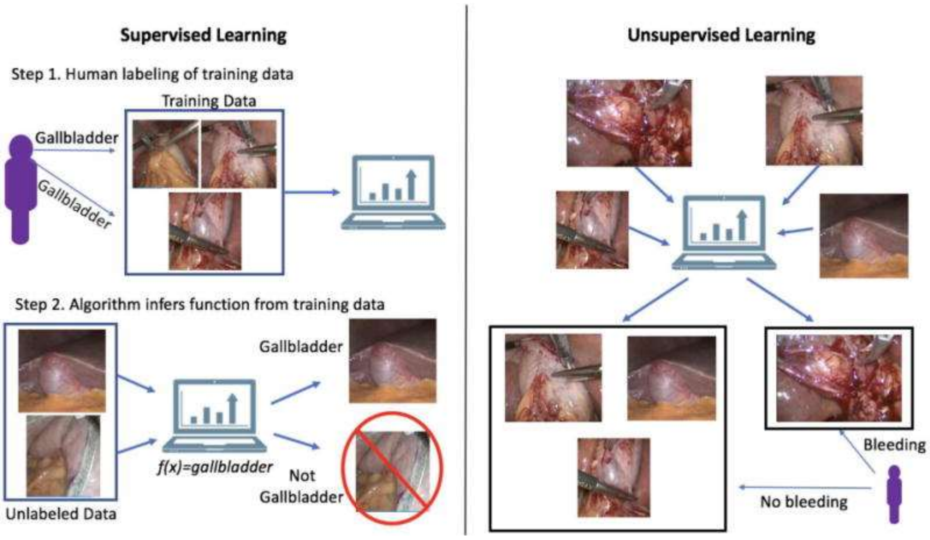


Fig. 26. Types of machine learning

A third category within machine learning is reinforcement learning, where a program attempts to accomplish a task (e.g. driving a car, inferring medical decisions) while learning from its own successes and mistakes. One can conceptualize reinforcement learning as the computer science equivalent of operant conditioning and is useful for automated tuning of predictions or actions, such as controlling an artificial pancreas system to fine tune the measurement and delivery of insulin to diabetic patients.

Natural Language Processing

Natural language processing (NLP) is a subfield that emphasizes building a computer's ability to understand human language and is crucial for large scale analyses of content such as electronic medical record (EMR) data, especially physicians' narrative documentation. [58] To achieve human-level understanding of language, successful NLP systems must expand beyond simple word recognition to incorporate semantics and syntax into their analyses.

Artificial Neural Networks

Artificial neural networks, a subfield of machine learning, are inspired by biological nervous systems and have become of paramount importance in many AI applications. Neural networks process signals in layers of simple computational units (neurons); connections between neurons are then parameterized via weights that change as the network learns different input-output maps corresponding to tasks such as pattern/image recognition and data classification. Deep learning networks are neural networks comprised of many layers and are able to learn more complex and subtle patterns than simple one or two-layer neural networks. [59] Clinically, these entities have significantly outperformed more traditional risk prediction approaches. For example, an ANN's sensitivity (89%) and specificity (96%) outperformed APACHE II sensitivity (80%) and specificity (85%) for prediction of pancreatitis severity six hours after admission. By using clinical variables such as patient history, medications, blood pressure, and length of stay, neural networks, in combination with other ML approaches, have yielded predictions of in-hospital mortality after open abdominal aortic aneurysm repair with sensitivity of 87%, specificity of 96.1%, and accuracy of 95.4%.

Computer Vision

Computer vision describes machine understanding of images and videos, and significant advances have resulted in machines achieving human-level capabilities in areas such as object and scene recognition. Important healthcare-related work in computer vision includes image acquisition and interpretation in axial imaging with applications including computer-aided diagnosis, image-guided surgery, and virtual colonoscopy. Initially influenced by statistical signal processing, the field has recently shifted significantly towards more data-intensive ML approaches, such as neural networks, with adaptation into new applications.

Utilizing ML approaches, current work in computer vision is focusing on higher level concepts such as image-based analysis of patient cohorts, longitudinal studies, and inference of more subtle conditions such as decision-making in surgery. For example, real-time analysis of laparoscopic video has yielded 92.8% accuracy in automated identification of the steps of a sleeve gastrectomy and noted missing or unexpected steps. [60] With one minute of high-definition surgical video estimated to contain 25 times the amount of data found in a high-resolution computed tomography image, video could contain a wealth of actionable data. Thus, while predictive video analysis is in its infancy, such work provides proof-of-concept that AI can be leveraged to process massive amounts of surgical data to identify or predict adverse events in real-time for intraoperative clinical decision support.

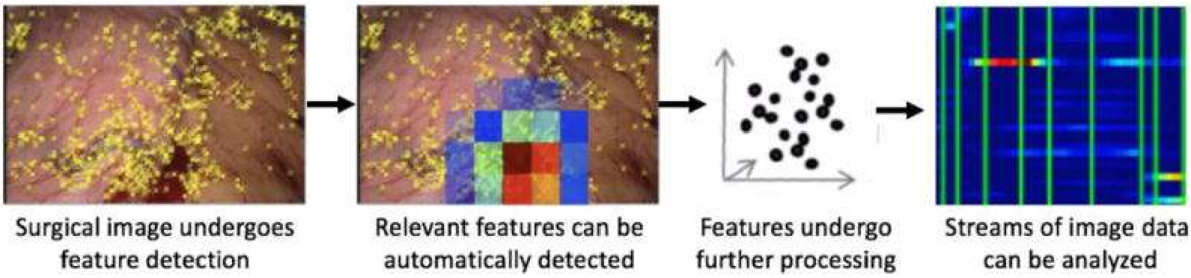


Fig. 27. Deep learning

Limitations of AI

As with any new technology, AI and each of its subfields are susceptible to unrealistic expectations from media hype that can lead to significant disappointment and disillusionment. AI is not a "magic bullet" that can yield answers to all questions. There are instances where traditional analytical methods can outperform ML or where the addition of ML does not improve on its results. As with any scientific endeavor, use of AI hinges on whether the correct scientific question is being asked and whether one has the appropriate data to answer that question. [61]

ML provides a powerful tool with which to uncover subtle patterns in data. It excels at detecting patterns and demonstrating correlations that may be missed by traditional methods, and these results can then be used by investigators to uncover new clinical questions or generate novel hypotheses about surgical diseases and management. However, there are both costs and risks to utilizing ML incorrectly.

The outputs of ML and other AI analyses are limited by the types and accuracy of available data. Systematic biases in clinical data collection can affect the type of patterns AI recognizes or the predictions it may make, and this can especially affect women and racial minorities due to long-standing under-representation in clinical trial and patient registry populations. Supervised learning is dependent on labeling of data (such as identification of variables currently used in surgery-specific patient registries) which can be expensive to gather, and poorly labeled data will yield poor results. A publically available National Institutes of Health (NIH) dataset of chest x-rays and reports has been utilized to generate AI capable of generating diagnoses of chest x-rays. NLP was used to mine radiology reports to generate labels for chest x-rays, and these labels were used to train a deep learning network to recognize pathology on images with particularly good accuracy in identifying a pneumothorax. However, an in-depth analysis of the dataset by Oakden-Rayner50 revealed that some of the results may have been from improperly labeled data. Most of the x-rays labeled as pneumothorax also had a chest tube present, raising concern that the network was identifying chest tubes rather than pneumothoraces as intended. [62]

An important concern regarding AI algorithms involves their interpretability, for techniques such as neural networks are based on a "black box" design. While the automated nature of neural networks allows for detection of patterns missed by humans, human scientists are left with little ability to assess how or why such patterns were discerned by the computer. Medicine has been quick to recognize that the accountability of algorithms, the safety/verifiability of automated analyses, and the implications of these analyses on human-machine interactions can impact the utility of AI in clinical practice. [63] Such concerns have hindered the use of AI algorithms in many applicative fields from medicine to autonomous driving and have pushed data scientists to improve the interpretability of AI analyses. However, many of these efforts remain in their infancy, and surgeon input early in the design of AI algorithms may be helpful in improving accountability and interpretability of big data analyses.

Furthermore, despite advances in causal inference, AI cannot yet determine causal relationships in data at a level necessary for clinical implementation nor can it provide an automated clinical interpretation of its analyses. While big data can be rich with variables, it is poor in providing the appropriate clinical context with which to interpret the data. Human physicians, therefore, must critically evaluate the predictions generated by AI and interpret the data in clinically meaningful ways.

AI in surgery

AI will have a primary role non only limited to surgical field. In the future, a surgeon will likely see AI analysis of population and patient-specific data augmenting each phase of care. Preoperatively, a patient undergoing evaluation for bariatric surgery may be tracking weight, glucose, meals, and activity through mobile applications and fitness trackers, with the data feeding into their electronic medical record (EMR). Automated analysis of all preoperative mobile and clinical data could provide a more patient-specific risk score for operative planning and yield valuable predictors for postoperative care. The surgeon could then augment their decision-making intraoperatively based on real-time analysis of intraoperative progress that integrates EMR data with operative video, vital signs, instrument/hand tracking, and electrosurgical energy usage. Intraoperative monitoring of such different types of data could lead to real-time prediction and avoidance of adverse events. Integration of pre-, intra-, and post-operative data could help to monitor recovery and predict complications. After discharge, post-operative data from personal devices could continue to be integrated with data from their hospitalization to maximize weight loss and resolution of obesity-related comorbidities.62 Such an example could be applied to any type of surgical care with the potential for truly patient-specific, patient-centered care.

Autonomy of AI in surgery

In 2016, Shademan et al reported complete in vivo, autonomous robotic anastomosis of porcine intestine using the Smart Tissue Autonomous Robot (STAR). [64] Although conducted in a highly controlled experimental setting, STAR quantitatively outperformed human surgeons in a series of ex vivo and in vivo surgical tasks. These trials demonstrated nascent clinical viability of an autonomous soft-tissue surgical robot for the first time. Unlike conventional surgical robots which are controlled in real-time by humans and which have become commonplace in particular subspecialties, STAR was controlled by artificial intelligence (AI) algorithms, and received input from an array of visual and haptic sensors. [65]

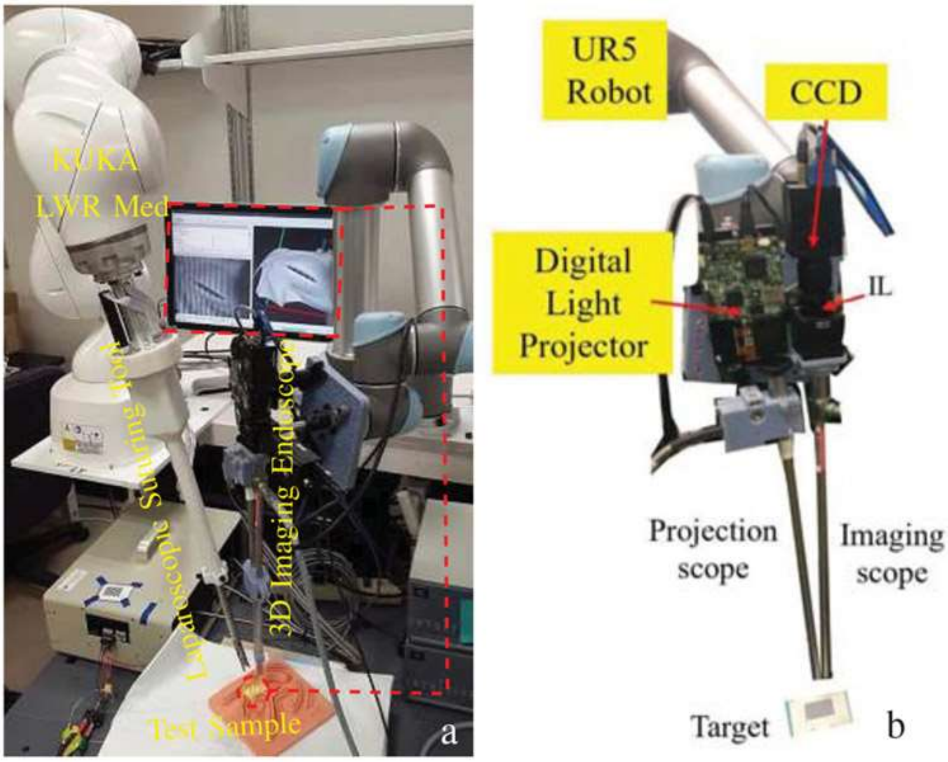
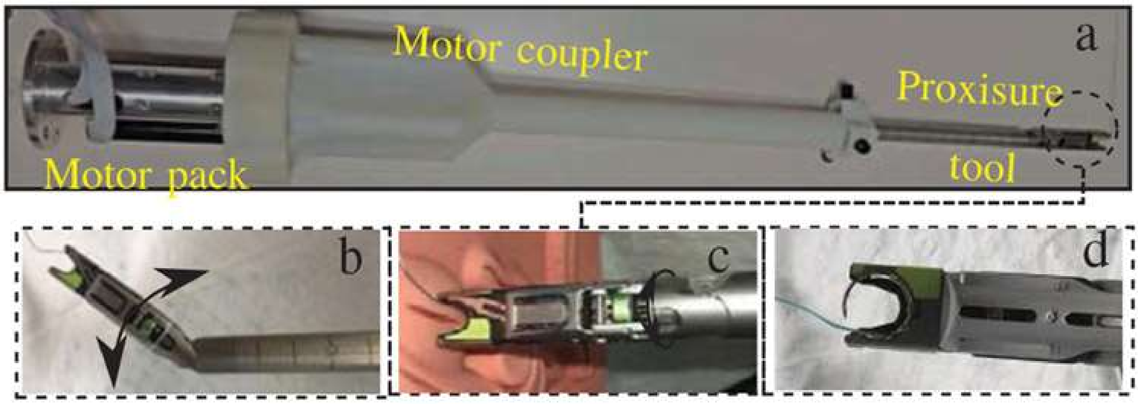


Fig. 28. a) Robotic laparoscopic suturing system, b) 3D imaging endoscope (IL: Imaging Lens).



a) Suturing tool, b) pitch actuation, c) roll actuation, d) needle drive.

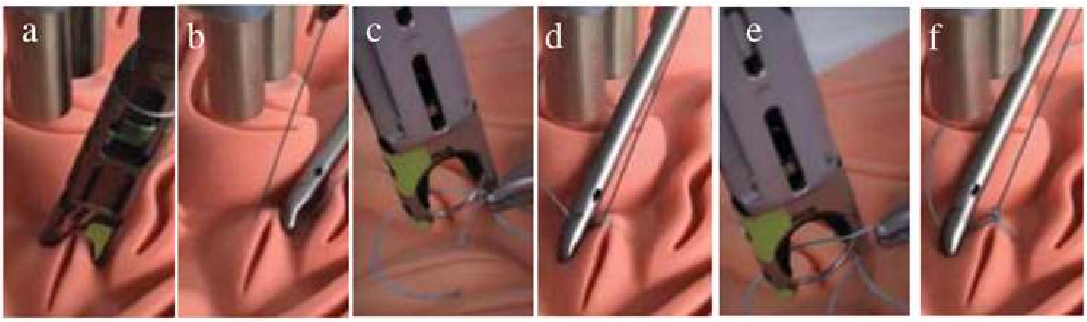


Fig. 29. Steps of executing a knot: a) bite, b) tensioning, c) first loop, d) tension of first loop, e) second loop, f) tension of second loop.

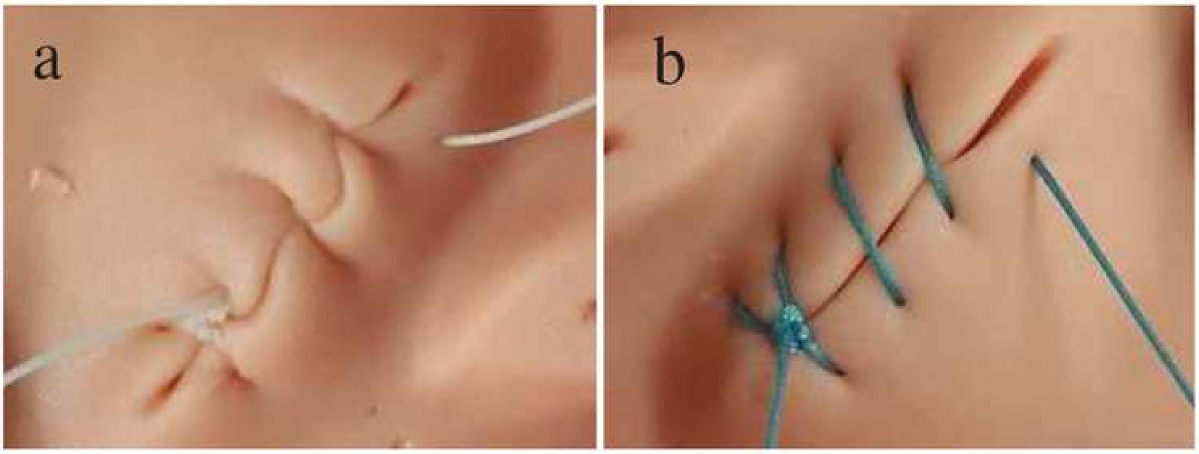


Fig. 30. Examples of suturing: a) manual, b) autonomous.

Autonomy: where are we really going?

The International Organization for Standardization (ISO 8373:2012) defines autonomy as "an ability to perform intended tasks based on current state and sensing without human intervention." [66] However, "autonomy" is not a singular state, but rather a scale in which the degree of human intervention is traded against full independence.

Future autonomous surgical robots will have ability to "see," "think," and "act" without active human intervention to achieve a predetermined surgical goal safely and effectively. Three parameters define the task of an autonomous surgical robot: mission complexity, environmental difficulty, and human independence. To enable this, the autonomous robot possesses visual and physical sensors that perceive the environment, a central processor that receives sensory input and calculates outputs, and mechanical actuators that permit physical task completion. Due to the highly deformable nature of soft tissue environments, the presence of hollow organs susceptible to rupture, and the delicacy of tissues, achieving a clinically viable, versatile autonomous surgical device will require considerable development and integration of control algorithms, robotics, computer vision, and smart sensor technology, in addition to extensive trial periods. [67]

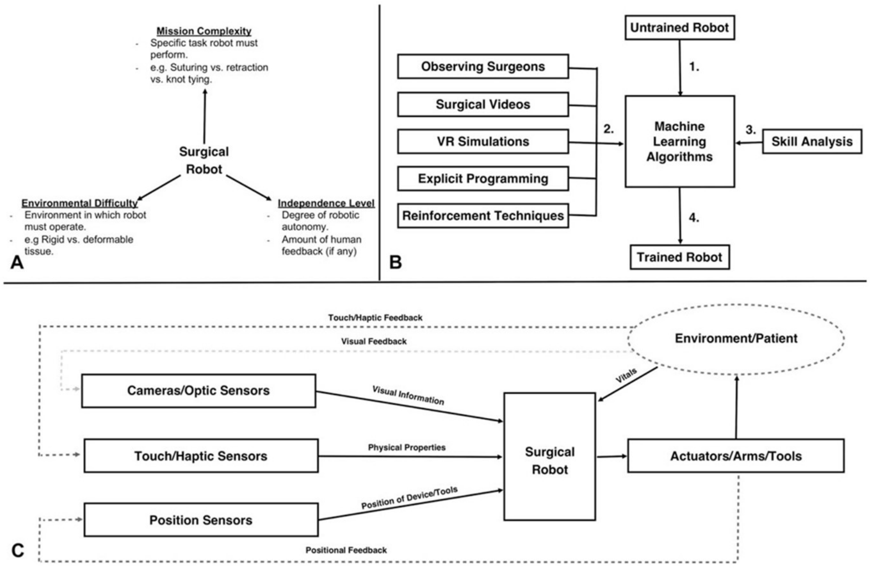


Fig. 31. Automomy flowchart

The robot must perform 2 intrinsic functions: first, the preprogrammed goal of the procedure it has been tasked with (its mission), and second, the ability to dynamically respond to the everchanging surgical environment. The robot's “surgical skill” consists of its ability to first map its perception (ie, sensory inputs) to an estimated environmental state, and then, map that estimate to a future action (ie, robotic outputs) in the most efficient way possible. Machine learning (ML), a form of AI, is the ability of a machine to learn from prior experiences, and has been proposed as a means to control the actions of autonomous devices.

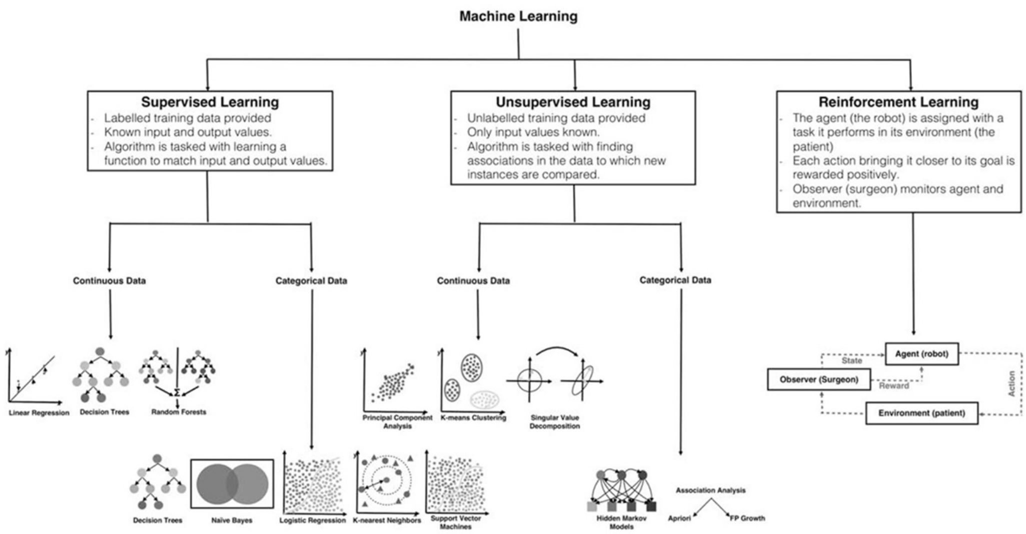


Fig. 32. Learning typologies

ML is most beneficial when applied to large, unwieldy datasets that are otherwise uninterpretable by humans. The robot's sensory apparatus produces a continuous stream of quantifiable data, to which ML algorithms will be applied in real time, so its processors can modify actions in synchrony with environmental changes and based upon its training. If the sensory stream is of comparable fidelity to human senses, such analytical algorithms will, at some point, demonstrate superiority over human perception. AI algorithms may therefore be able to delineate “occult” information in the sensory data that are otherwise imperceptible to humans, thereby predicting or detecting adverse events at a level exceeding human ability.

Augmented reality

AR (to augment, lat. augmentare: to improve, to supplement, to enhance) is the enrichment of the perceived reality by means of artificial virtual content. AR denotes a technique to combine a real world and virtual objects which are artificially generated digital content by a computer. AR can allow the user to see 3D virtual objects superimposed upon the real world. With the help of AR in medicine, a surgeon can see hidden organs inside a body and improve the perception of treatment procedure by interacting with the real world.

A complete AR system requires at least three components including a tracking component, a registration component, and a visualization component. A fourth component, a spatial model (i.e., a database) stores information about the real world and about the virtual world. [68] The real-world model is required to serve as a reference for the tracking component, which must determine the user's location in the real world. The virtual-world model consists of the content used for the augmentation. Both parts of the spatial model must be registered in the same coordinate system. AR uses a feedback loop between human user and computer system. The user observes the AR display and controls the viewpoint. The system tracks the user's viewpoint, registers the pose in the real world with the virtual content, and presents situated visualizations. AR combines real and digital elements in one of three ways including using a Head-Mounted Display, placing the visual information close in front of the user's point of view; using handheld devices, most commonly smartphones and tablets; and computer-generated overlay that is placed directly on real objects using projects or devices known as Spatial Displays. AR has been used to make inroads in the medical domain. For example, AR has been used to give surgeons information about the position of internal organs and the adjustments needed for needle biopsy. AR has the potential to impact on surgery in a number of novel ways, especially in the arena of surgical training in the virtual surgical environment. However, real-time enhancement of the surgical procedure remains a slightly tentative application. It is not yet validated that surgery can be enhanced with AR and in some instances, it could be distracting. Some features may be useful of systems like GG where with voice activation the operator could communicate beyond the theatre environment, retrieve images and test results without breaking scrub. Real-time updates regarding the progress of the trauma list would reduce unnecessary fasting of patients in the event of a delay in theatre.

Definitions from 2020 Strasbourg International Consensus Study group

In 2020, a large consensus about computer aided surgery has been reached by a Study Group coordinated in Strasbourg. [69] These statements are useful to focus on actual real clinical needing for surgery.

Image-Guided Surgery and Intervention

As expected, the first survey produced the largest amount of information by far. Analysis of the results showed that procedure, use, specific, technology, and planning were the words most often mentioned. After analyzing the results of the first survey, the researchers attempted to conceive of the field of image guidance as a discipline, a specialty, or maybe a new set of skills (radiology, surgery, endoscopy) or to view this field in terms of imaging methods (radiography, CT, MR, etc.); however, these attempts were not successful. The researchers ultimately decided to understand image guidance as the incorporation of imaging as an integral element of the minimally invasive procedure. The survey responses also indicated that collaboration between different disciplines and simultaneous convergence of technologies can disrupt this field. Consequently, the researchers proposed the following definition of image-guided surgery reflecting collaboration between professionals, convergence of disruptive technologies, and their integration at the center of image-guided minimally invasive techniques:

The synergy between interdisciplinary collaboration and convergence of multiple technologies (eg, guidance systems, immersive technologies), providing extensive visual information layers (eg, spectrum, resolution, transparency) and making them intuitive, upgrading existing surgical skills and forging new ones. Due to its comprehensive mindset (planning, guidance, control), a breakthrough transformation emerges to enforce state-of-the-art procedures and develop others, thereby achieving precision.

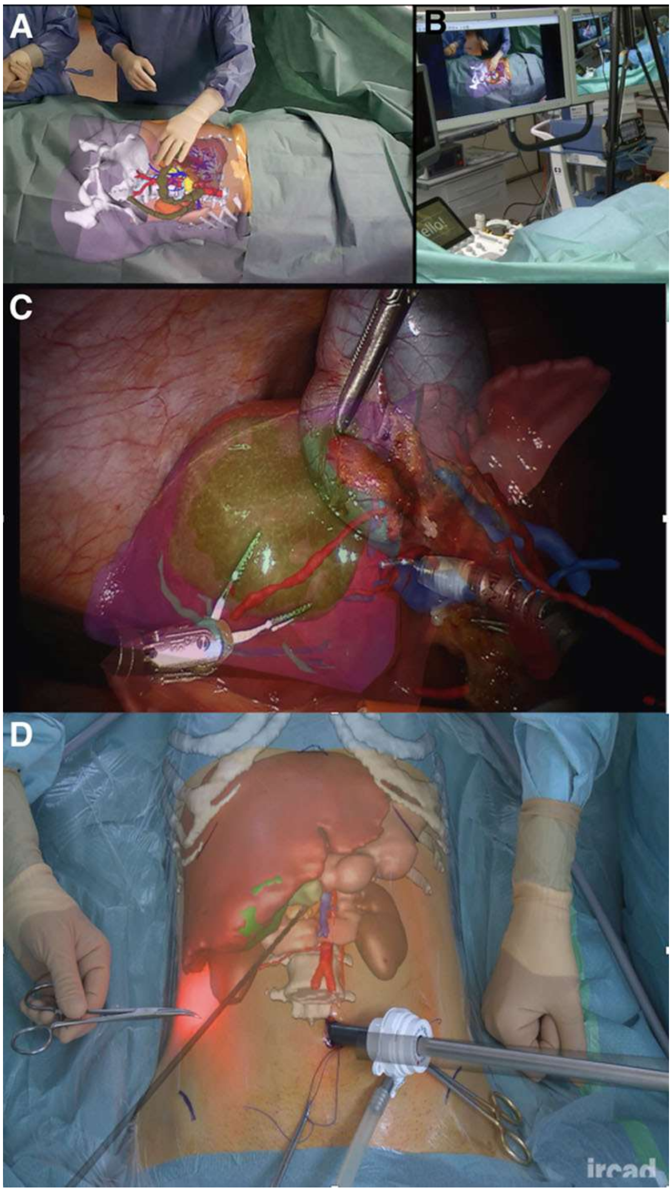


Fig. 33. Image-guided surgery and intervention. During the planning phase, a contrast-enhanced computed tomography scan acquisition is post-processed and segmented to obtain the 3-dimensional models employed to provide augmented reality. A and B, Show the use of the visual augmentation assisting the initial phase of a laparoscopic approach. C, Shows the same augmentation overlaid in the display used for laparoscopic vision, and (D) the possible switching from one to the other augmentations throughout the procedure.

Between the third and fourth surveys, the researchers changed the title of this item from "image-guided surgery" to "image-guided surgery and intervention," and as a result, the proportion of experts agreeing with the definition changed from 69% in the third round to 88% in the fourth round.

Both in responses to the online surveys and in face-to-face meetings, participants described image guidance as an evolution of other minimally invasive techniques, sharing common roots with interventional radiology, therapeutic endoscopy, and minimally invasive surgery. Likewise, the surveys showed that imaging methods relying on coordinate systems are used to guide procedures and provide a better understanding of anatomy to prevent damage to neighboring structures (by increasing situational awareness) but also increase exposure to ionizing radiation.

Computer-Assisted Surgery and Intervention

Because respondents to the first survey seemed to use computer assistance as a synonym for or as a part of image guidance, the researchers decided to dedicate a separate section on the second survey to computer assistance. Surprisingly, none of the responses to the second survey reinforced the idea that computer assistance is part of image guidance. Word cloud analysis showed that images and imaging were not among the top words associated with computer assistance and that the words most commonly associated with computer assistance were technology, planning, and procedures. After a detailed word-by-word discussion of the information collected from the first survey, the researchers proposed defining computer-assisted surgery as a way to enforce the skills of the physician but also to augment them, providing abilities that cannot be acquired without these tools:

Broad use of information technology frameworks to enhance physicians' skills and augment senses (eg, image-guided surgery), cognition (eg, deep learning, machine learning), and execution (eg, mechatronic, imaging and surgical robotics) with the aim to provide more precise and safer procedures.

This definition of computer assistance was widely agreed upon, by 90% of experts in the third survey and 91.5% in the fourth survey after minor modifications, the most important of which was the addition of and intervention in the title of the definition. One important contribution worth mention is the role of image post-processing (eg, 3-dimensional modeling) and immersive technologies (augmented, mixed, and virtual reality), providing user-friendly human-machine interfaces and making real-time information management easier and more intuitive. Even though these advanced tools can improve the operator's skills, a minimum required expertise in image reading should be mandatory before any procedure is started. Also related, a wide range of extra computer-assisted tools (3-dimensional modeling, simulations, etc.) can be integrated into training activities to help providers improve their abilities and learn new surgical skills before taking care of the patient.

Guidance Systems

In the first survey, the term navigation systems was used. After reviewing the results of that survey and conducting a deep dive into the field, and relying on solid concepts and definitions coming from different partners,18 the researchers proposed changing the broad term to guidance systems and conceptualizing navigation as a key feature of guidance systems. Ultimately, a definition was settled on in which guidance systems are conceptualized as having 3 core elements: guidance (assessing the vector from origin to target), navigation (information about the track from origin to target), and control (dynamic modification capabilities):

Any technology combining 3 core elements (guidance, navigation, and control), bringing location data and improving spatial orientation at any time during the procedure, making it possible to reach targets with increased precision and minimal disruption to surrounding tissues.

Among other evolving technologies, these systems need to grow associated in conjunction with visual data (eg, medical imaging), developing intuitive human-machine interfaces, and facilitating the planning strategy and tracking the position of instruments throughout the procedure. This definition was widely accepted, with 85% and 96% acceptance rates in the third and fourth surveys, respectively.

Hybrid Operating Room

After the systematic approach previously described, the rough idea of an advanced surgical and imaging facility was established, and the next step to complete the definition was related to imaging techniques and their role in the surgical/interventional setting. The following definition of a hybrid operating room was proposed:

Facility equipped with full surgical capabilities, including medical imaging based on coordinate systems (CT, MR, cone-beam CT) associated with other techniques (ultrasound, fluoroscopy) and/or *guidance systems. Through different types of human-machine interfaces, the planning, guidance, and control stages can be performed intraoperatively in a dynamic fashion.*

Fig.34. Ideal setup for hybrid operating room.

After the third and fourth online surveys, on which 95% and 96% of the respondents, respectively, agreed with the above definition, most of the experts expressed the need for a hybrid operating room classification. After the first 2 rounds, and after an initial attempt to classify hybrid operating rooms according to the number of imaging technologies was rejected, the classification detailed in Table Table22 was agreed upon. These suites were conceived of as the field where multiple types of information need to be put together in a comprehensive way, and an input-process-output approach was used to determine and separate different types of set-ups. This classification considers the facility input, its interfaces (processes), and usage essential levels (output) and stratifies their levels from 1 to 4 depending on task complexities.

Technical issues

Recent advances in portable computational units, optics, and photonics devices have enabled the scientific community to open many new fronts in biomedical research, with the development of innovative AR applications exploiting the potentialities offered by HMD technology. Such technology has reached the maturity to be translated into commercial products, and published works on HMDs provide glimpses of how AR will disrupt the surgical field, allowing for an ergonomic, intuitive, and 3-dimensional fruition of preoperative and intraoperative information.

Nowadays several commercial HMDs, such as Microsoft HoloLens, Meta or Magic Leap, integrate tracking and registration technology, and the deployment of software development kits has reduced technical complexity of custom application development, allowing for a wide range of users to easily create AR applications and attracting researchers to explore their potentialities for the implementation of surgical navigators.

The above-mentioned HMDs are designed following an optical see-through (OST) approach, which augments the natural view through the projection of virtual reality information on semitransparent displays in front of the user's eyes. The OST approach fits well in the surgical domain as it offers an instantaneous full-resolution view of the real world, allowing the natural synchronization of visual and proprioceptive information, and a complete situation awareness.

Ongoing research is aimed at the goal of providing a device conceived as a transparent interface between the user and the environment, a personal and mobile window that fully integrates real and virtual information. Commercial companies are rapidly improving HMD ergonomic aspects, for example, HoloLens 2 features an improved field of view (52° diagonal), which includes eye tracking, and offers more comfortable wearability.

However, maximizing surgical accuracy remains a challenge for manufacturers and researchers. Together with ergonomics, the achievement of precision objectives must be addressed to develop a visor suitable for guiding surgical operations, not to mention compliance with medical device regulations.

An increasing number of research studies propose the use of commercial HMDs to guide surgical interventions. To the best of our knowledge, these works are principally focused on the need to strengthen virtual/real patient registration (eg, use of an external localization system), improve virtual content stability, and solve calibration issues, and they underestimate the contribution of perceptual issues to the user accuracy.

One of the largest obstacles to obtain a perceptually correct augmentation is the inability to render proper focus cues in HMDs; indeed, the majority of systems offers the AR content at a fixed focal distance, failing to stimulate natural eye accommodation and retinal blur effects.

Recent works suggest to avoid the use of existing HMD-OST, which are not specifically designed for performing tasks in peripersonal space (<1 m), to guide manual tasks requiring a high level of precision, since perceptual issues, particularly "focal rivalry" (ie, inability to see simultaneously in focus the virtual and real content), can affect user performance.

Most commercial systems (HoloLens, Lumus, Meta, Ora2) indeed have a fixed focal plane at 2 m or more (often infinite). Thus, during manual tasks, virtual content is projected outside the user's eye depth of field, inducing a focal rivalry between real and virtual content and the well-known vergence-accommodation conflict. Nonobservance of manufacturer's guidelines (eg, Microsoft recommend against presenting AR content closer than 1.25 cm for the HoloLens 1) not only leads to visual fatigue but also to a proven reduction in user performance in completing a task, which requires keeping both the real and the virtual in focus simultaneously, for example, to connect points with a line, or to integrate virtual and real information for a reading task.

These issues highlight the need to develop tailored HMDs with a focal distance inside the peripersonal space, considering the tolerance offered by the human eye depth of field, so as to maximize user performance and minimize visual discomfort. Thus, the focal distance of HMDs specifically designed for surgery should be set at arm's length.

Alternatively, strategies allowing for the development of HMDs suitable for both near- and far-field applications could be considered. These include the following: multifocal plane displays, varifocal plane displays, computational multilayer displays, and integral imaging-based displays. Moreover, together with the demand for a proper focal distance, further technological effort is needed to meet the specifications of a large field of view, while satisfying at the same time the constraints for reduced and balanced weight (so that the head-down tilt position is sustainable for a prolonged time), and the compliance with medical regulations.

To conclude, our remarks are to underline the need to design ad hoc HMD for surgery in order to actually bring this technology in the clinical routine for surgical navigation.

The main limitation of AR systems is the registration technique employed. Actually, trending choice is represented by the registration and fusion are done between a 3D volume from the segmented magnetic resonance images of the patient and the real-time image that is recorded by a webcam placed over the patient in the operating theater, specifically above of the patient's abdomen. [70]

Some authors have developed techniques to improve and automate preoperative placement of trocars. Based on 3D information extracted from computed tomography (CT) images or MRI, the surgeons must remember this information once they are in the operating theatre.

In some options, an optimal access system with virtual endoscopic views is proposed, making the simulation with a phantom. [71]

Otherwise, the problem is addressed in image-guided surgery, and trocar placement is optimized from a robotic point of view. The validation is performed on animals.

More recently, the system requires the use of fiducials that have to be in the same position as when the CT was acquired. [72] In addition, the position and orientation of the patient have to be the same in the operating theater.

An enhancement is offered by a registration with fiducials MR-acquired, carried out to monitor the camera. These fiducials must be placed over the patient in the same positions in the operating theater and when the MR is acquired.

When MR images are acquired, the patient must lie on a stretcher with his/her back straight and centered on both sides to calculate the position and the orientation relative to an initial coordinate system.

A virtual model of the patient's organs is extracted from these images using techniques of digital image processing.

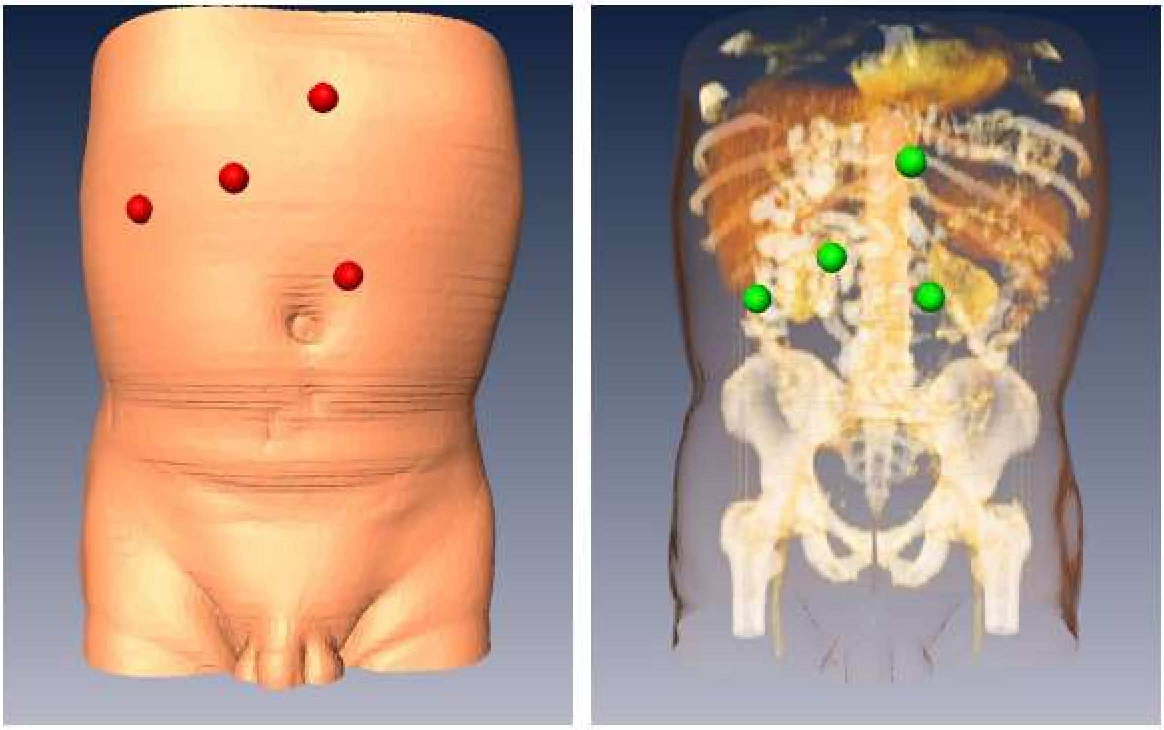


Fig. 35. Port placement in augmented reality.

The real-time images are recorded with a camera that shows the area of interest throughout the entire surgery. Initially, the intrinsic parameters of the camera are obtained to calibrate it. To do this, it is necessary to have different captures of planar checkerboard patterns, which should be different for each calibration image. Zhang's method is used for the calibration step, taking the correspondence between 2D image points and 3D scene points over a number of images.

Then, a hexadecimal mark is placed on the navel and centered and oriented. The next steps are the hexadecimal mark detection and the registration and fusion of the real image with the virtual model of the patient.

Initially, the experiments were to be performed through a segmentation of gadolinium contrast MR images. The use of this agent improves the image contrast and facilitates the segmentation of different organs to extract the patient's 3D model. Even though it is safe, there is always the possibility of small allergic reactions in the patient. For this reason and since this contrast agent is not commonly used for this type of pathology, the committee rejected its use in the MRI acquisition. This change caused more difficulties in the segmentation procedure of abdominal organs, but it did not affect the results or conclusions of the experiments.

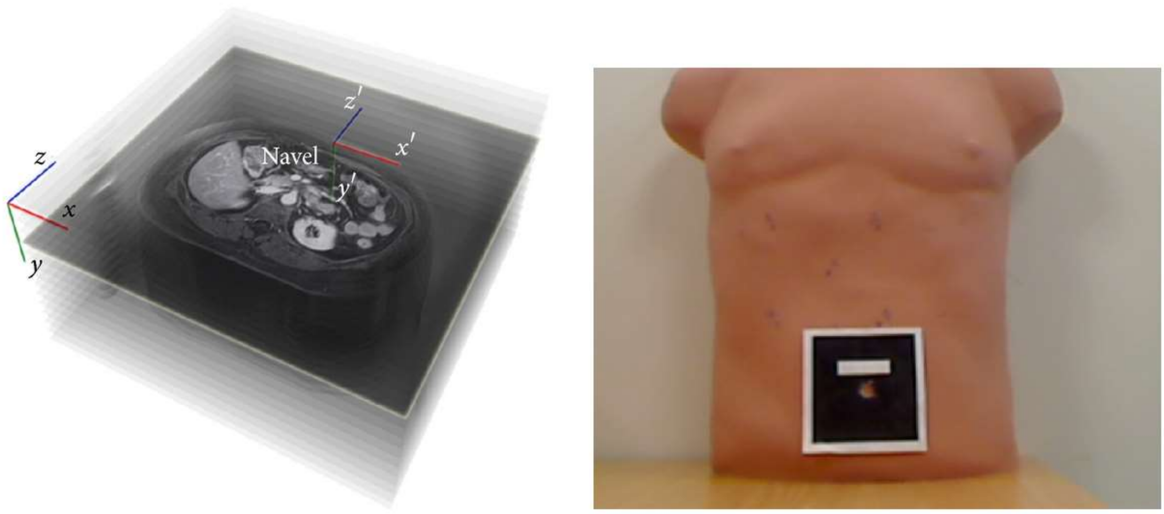


Fig. 36. MR segmentation and hexadecimal mark placement

The following protocol was used.

(i) Before the operation (the first time the surgeon visits the patient), the informed consent approved by the research ethics committee of the hospital and common information related to the MRI exam are given to the patient.

(ii) The day of the surgery, the patient goes to the presurgery room and then passes to the operating theater.

(iii) The surgeon performs the usual protocol until the operation ends. This protocol can be summarized as follows.

(1) First, with a biocompatible pen, the surgeon marks the points where he/she will make the four incisions through which trocars will be inserted.

(2) Second, the surgeon performs the four incisions based on his/her skill, experience, and traditional palpation techniques.

(3) When the four trocars are placed, the surgeon begins the operation according to the specific protocol for this type of surgery.

(4) Once the gallbladder has been extracted and the four incisions are sutured, the surgeon measures the four values or distances. These four distances measure the difference between the initial pen marks and the real incisions or, in other words, the correction that has to be made for the technique of pneumoperitoneum, the anatomical differences of patients, and the skill of the surgeon.

(5) Finally, the four incisions are bandaged.

(iv) The surgery ends, and the patient leaves the operating theatre and goes to the postoperation room where he/she wakes up and continues with the recovery protocol.

In the second experiment, the augmented reality system was used. The system hardware is composed of a display device and a camera. The goal of the camera is to capture the image in real-time in order to register and merge this sequence with the 3D virtual model of the patient. The display device is responsible for showing the fusion of the video and the virtual object. In this experiment, different display devices were evaluated. The stretcher with the patient was positioned between the stand and the surgeon. The actual image of the abdomen of the patient was captured by the camera which was positioned perpendicularly to the patient.

The sample selected for this experiment also consisted of 12 patients chosen randomly (seven men and five women). The protocol used was similar to the one used in previous experiment.

(i) Before the operation, the same informed consent as in the first experiment is given to the patient. Then, the MRI is acquired.

(ii) Thanks to different segmentation algorithms, a 3D model of the patient's organs is obtained with the MR images. Specifically, in all cases, the liver and kidneys were segmented; in some cases the gallbladder and aorta were extracted (for surgeon requirements). The tool to perform the segmentation was made ad hoc.

(iii) On the day of the surgery, all the steps were similar to the first experiment, with only one difference: when the surgeon marks with the pen, he/she used the AR system that registers and merges the 3D model with the real-time image. The result of this process is shown on the screen that is directly in front of the surgeon.

(iv) Once the 4 marks are drawn, the system is removed, and the surgeon continues the usual protocol until the surgery ends.

(v) Finally, the same four values or distances as in the first experiment are measured, and the patient goes to the postoperation room to wake up and continue the recovery protocol.

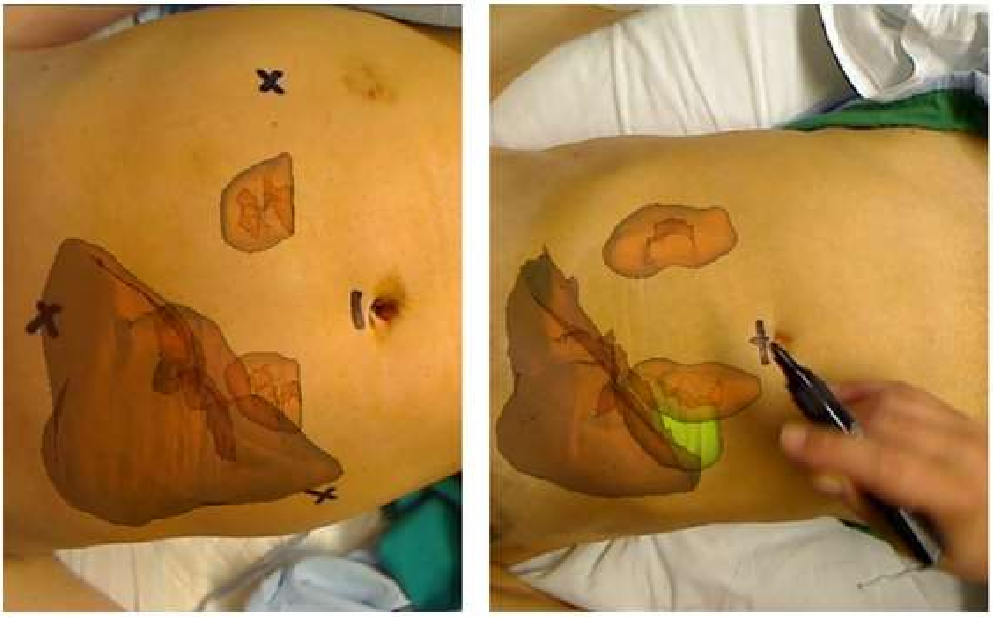


Fig. 37. Port placement with superimposed imaging.

The system improves the trocar placement accuracy by 33%, while variability was reduced by 65%. The use of an augmented reality system can be helpful in complex situations by providing additional information, where even the use of an internal camera view is not enough for the required accuracy. Another advantage of using the augmented reality system is its low cost and its applicability. When the surgeon has the internal information provided by the laparoscopic camera which has already been introduced into the patient, they have a finite and limited time to make the rest of the incisions. The longer the decision time, the higher the costs and the greater the risks for the patient. The augmented reality system is useful even in the hours before the operation (when the patient is awake and out of risk) making it possible to plan and reduce the time spent in the placement of the trocar in the operating theater. The augmented reality system also has direct application for automating and optimizing the trocar placement for guided surgery.

Conclusions

As widely detailed, the potential of computer and robotic aided surgery is huge. A lot of philosophy is often delivered beyond these technologies, but the main and bigger obstacle to their actual implementations is represented by the ignorance of real advantages and diffuse misperception of real impact on every-day surgical practice.

On one side, we have a lot of surgeons fully hyped by technological advancement, in good faith, but not really aware of consistency; they are not in contact with the multiform universe of engineering, and lacking of any chance to cooperate to new and more proficient surgical devices.

On the other side, a big audience of skeptic surgeons push to hinder any type of computer aided surgery, as it is perceived as dangerous interference with artistic and personalized face of surgical practice, up to doomsday scenarios of human replacement.

In real world, robotic and computer aided surgery is very far from a complete autonomization of theatre, that is (and will be for much more time!) specific human competence.

Technological advancement is actually a practical opportunity to enhance and improve quality of surgical care of our patients, and this is only way to decipher 21st century skyline of surgery.

This research is thus projected to deploy a more conscious vision of new technologies, in order to make a faster way to a real transition.

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