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# Image-Guided Interventional Robotics: Lost in Translation?

Gabor Fichtinger, *Fellow, IEEE*, Jocelyne Troccaz, *Fellow, IEEE* and Tamas Haidegger, *Senior Member, IEEE*

**Abstract**— Interventional robotic systems have been deployed with all existing imaging modalities, in an expansive portfolio of therapies and surgeries. Over the years, literature reviews have painted a comprehensive portrait of the translation of the underlying technology from research to practice. While many of these robots performed promisingly in pre-clinical settings, only a handful of them managed to evolve further, and break through the commercialization boundary, and even fewer reached a wide-scale adoption. Despite the undeniable success of service robotics in general, and particularly in some sophisticated medical applications, image-guided robotics’ impact remained modest compared to other surgical areas, especially laparoscopic minimally invasive surgery. This article aims to embrace the state-of-the-art on one hand, and to provide a comprehensive narrative to the situation described, to support future system developers and facilitating the translation from scientific research to applied clinical technology development.

**Index Terms**—Medical robots, Surgical robotics, Image-Guided Surgery, Robot-Assisted Surgery, Computer-Integrated Surgical Systems

## I. INTRODUCTION

SINCE the early 1990s, there has been an incessant growth in the research and development of image-guided interventional robotic systems, aspiring to address a wide spectrum of medical conditions and diseases. Numerous research reports and review articles have investigated the limitless potentials of these systems in a wide variety of clinical scenarios, charting out a tremendously exciting terrain of technology transfer [1–3].

In this article, we seek answers why scientifically excellent and technically sound systems have failed to make the critical breakthrough to wide-scale use. While robotics has evolved into a global megatrend [4], there have been no financially successful projects reported in this subdomain, which fact is worth some investigations. First, basic concepts and components of image-guided interventional robotic systems within the context of larger computer-integrated surgical and interventional systems are outlined, including pre-surgical planning, intraoperative execution and postoperative assessment with follow-up. While this high-level, model-

centered approach is instructive in multiple aspects, image-guided interventional robotic systems may also be classified in other ways: by mechanical design (e.g., kinematics, actuation), by level of autonomy (e.g., pre-programmed versus teleoperation versus constrained cooperative control), by operating environment (e.g., in-scanner, conventional operating room (OR)), by image guidance modality (e.g., Computed Tomography (CT), C-arm fluoroscopy, Magnetic Resonance Imaging (MRI), ultrasound (US)), by access technique (e.g., percutaneous, intra-cavity), by clinical application area (e.g., neuro, dental, cranial, prostate). In the consecutive sections, these dimensions will be parsed through to examine if and how clinical boundary conditions and design choices may affect translational success. The authors’ observations will be shared regarding some critical non-technological aspects of translation, such as regulatory affairs and financing. We will conclude with thoughts on future directions and prospects, both technical and non-technical terms.

As the confines of this article does not afford space for an exhaustive review, or even mention, of many of the consequential research and commercial systems, we direct the reader to a comprehensive list of advanced interventional robotic systems (Table 1) and to the extensive list of references.

## II. THE TRADITIONAL SURGICAL CAD/CAM PARADIGM

In this section, we discuss basic concepts of interventional robotic systems within the context of the wider Computer-Integrated Surgery (CIS) and interventional systems domain, also attempting to give a very brief historical and taxonomic perspective. “*CIS is the most commonly used term to cover the entire field of interventional medical technologies, from medical image guidance and augmented reality applications to automated tissue ablation*” [5].

A large family of CIS procedures can be represented by a model analogous to traditional industrial manufacturing systems. If the right pre-operative information is available, the intervention can be pre-planned ahead of time (offline, outside the OR), and executed in a reasonably predictable manner (involving some sort of intra-operative tracking for data registration and fusion).

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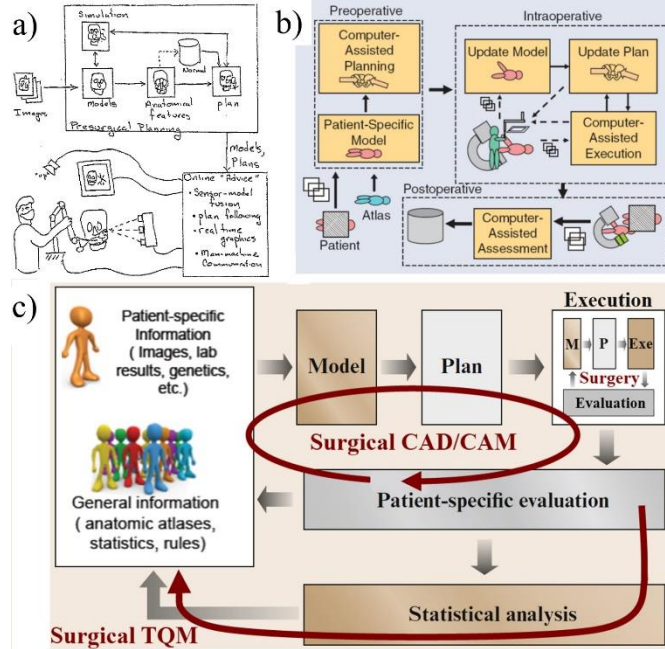
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Traditionally, these can be classified as surgical Computer-Aided Design (CAD) / Computer-Aided Manufacturing (CAM) systems (Fig. 1) [6]. In Surgical CAD, series of pre-operative medical images, statistical models, atlases, and other information are pre-operatively combined to model an individual patient; the computer then assists the physician in planning an appropriate intervention (this may happen to be built into a medical imaging system). In Surgical CAM, intra-operative medical images and additional sensor data are used in the OR to register the pre-operative plan to the actual patient. The model and the plan are updated throughout the procedure, while the physician performs the procedure using appropriate technology, such as optical guidance, perceptual guidance and, most interestingly for this paper, some robotic device. Post-operatively, the computer can play a crucially important role in reducing procedural errors (quality management), and in promoting consistent and improved delivery of the treatment (quality assurance). Procedural outcomes can be captured in statistical models, and fed back into the system for planning and optimizing subsequent procedures, which should foster evidence-based medicine in the context of human interventions.



**Fig. 1.** The traditional Surgical Computer-Aided Design / Computer-Aided Manufacturing (CAD/CAM) model, as **a)** first presented in 1993 [7]; **b)** then in digital in 2003 [8]; **c)** a more recent version, including the concept of Total Quality Management (TQM) in surgery in 2016, adapted from [9].

This “classic” Surgical CAD/CAM model was coined by Russell H. Taylor for describing CIS and interventional systems [7, 9]. The model has been a remarkably durable model throughout the three decades of evolution of the field. Numerous technological innovations have improved upon all underlying system components, yet the original model remains largely valid. Moreover, assuming very rapid control cycles, the Model→Plan→Execute→Model even fits teleoperation-type Robot-Assisted Minimally Invasive Surgery (RAMIS) systems like da Vinci [10].

It is well understood that the additional pre-operative or intra-operative information available, e.g., through imaging, may largely help to improve the spatial treatment accuracy, including the procedures performed as RAMIS. Prototype da Vinci setups have already demonstrated capabilities of patient-relative localization and other spatial navigation features [11].

One of the pioneering Surgical CAD/CAM systems was the neuromate (see Product Reference section at the end of this article), conceived in Grenoble by a group of pioneers who made seminal contributions to the field (Fig. 2) [12, 13].



**Fig. 2:** The current, commercially available version of the neuromate robot being set up for stereotactic brain biopsy. (Credit: Renishaw plc.)

While in industrial manufacturing, CAD/CAM suggest uniformly designed parts and perfectly streamlined processes, human patients exhibit huge variability to the point, where augmenting and guiding human tasks becomes extremely challenging technically and may affect the safety of the procedures involved. The Surgical CAD/CAM model does not aim to eliminate the human surgeon from the interventional process, nor it assumes a uniform patient, anatomy, or disease. The pre-operative planning is always specific to the patient, and usually involves some clinical judgement. Then, for many types of interventions, the rest of the procedure can be carried out with little or no human touch. The extreme example is stereotactic radiosurgery (performed with, e.g., the CyberKnife robotic system [14]), which can be fully automated, all the way, from target identification to delivery of the therapeutic dose.

In this article, we are primarily concerned with systems that employ “robotics” in executing the surgical plan, and we will specify the meaning of “robotic device” in this context. In the generic International Organization for Standardization (ISO) sense, industrial robots are pre-programmed, with multiple Degrees of Freedom (DoF), physically moving in their space and executing a task [15]. Early surgical CAD/CAM systems tended to employ retrofitted industrial robots to fulfill those criteria.

To a large extent, interventional robotic systems can be assessed by how they reconcile the pre-operative plan with the intraoperative reality, and if/how they cope with tissue motion and deformations during the procedure. Such capabilities assume a certain level of actuation and control of the robot, as well as a high-level interface or cooperation with the physician. Several taxonomies have been used to describe interventional

robots, most of them agreeing on a classification related to the level of interaction between the robot and the user when producing a movement. These taxonomy classes are active, passive, teleoperated and shared-actuation (or co-manipulated) robots. An active robot is able to move instruments in the operating room by its own (in a pre-programmed manner), whilst being supervised by an operator and requiring discrete actions from the operator (such as confirmation of critical steps). Passive arms (sometimes called passive robots) are most often unactuated mechanical arms, able to hold an instrument and to provide its position (see for instance radiotherapy applications [16]). Passive arms, where the user holds the instrument and provides the actuation, require continuous action from the human operator to carry out the intervention. Teleoperated robots are actuated systems, holding and moving instruments, but they are remotely controlled in real-time by a human operator, and are endowed with only very limited autonomous capabilities (such as tremor filtering) [5]. A prime example of RAMIS robots is the *da Vinci Surgical System*, discussed in depth by Haidegger et al. [10]

A variety of robots involve “shared actuation” scenario, where the human operator and the machine both hold the same instrument, and their intents are communicated to each another by applying and sensing force on the tool, a.k.a. force control. Teleoperated systems can further benefit from a priori anatomical information through the concept of cooperative control, where the surgeon is actually guiding the tool physically.

The robot may constrain the task kinematically through appropriate hardware design, such as enforcing linear, planar or conical motion, in a scenario typically referred to as “semi-active” [17]. Constraints may also be programmable and implemented using passive constraints [18] or active constraints [19] (a.k.a. virtual fixtures [20, 21, 22].) The systems with programmable constraints go by several names, they are often referred to as co-manipulated or hands-on or synergistic systems [23]. This means a hybrid control architecture, where the mechatronic system can impose physical, spatially defined Virtual Fixtures on the motion of the robot’s applied part, and allows for further safety and autonomous functions. This has been successfully implemented in retinal surgery with the Steady Hand system at Johns Hopkins [24], and with the *da Vinci* [25].

Active and co-manipulated robots require a planning phase to specify the task to be executed. Conversely, passive and standard teleoperated robots do not strictly involve explicit path planning (beyond what the traditional surgical plan means), since the operator always stays cognitively in the control loop. However, in the advent of surgical automation and subtask level autonomy, even for these types of systems, more sophisticated guidance may require such pre-operative planning [5]. A common issue to planning-based robots is the need to relate the intra-operative pose of the target to the pose of the robot, also known as “robot registration” issue. Often based on image registration and calibration approaches, it remains an obstacle to clinical translation. In the medical robotics vernacular, calibration is sometimes referred to as the “mother of all skills”, for its universal practical significance. Moreover, when the target moves due to the intervention itself or to physiological

activity (heart beating, breathing, etc.) more sophisticated approaches are required, such as visual servoing or model-based real-time re-planning [26, 27]. Such a high level of real-time automation, however, unavoidably raises safety issues [5].

Image guidance can also help with numerous other surgical domains, where the anatomy allows for more precise registration, such as in neurosurgery or ophthalmology [28–30]. Specific surgical setups that made it to Technology Readiness Level (TRL) 7+ are listed in Table I.

### III. PREVAILING MECHANICAL DESIGNS

The mechatronic design principles applied in an image-guided interventional robotic system, to a large extent, depend on the nature of the intended clinical application. For instance, a large and steadily growing family of image-guided interventions are performed percutaneously (minimally invasively through the skin, sometimes not even referred to as surgery) with needles or similar linear devices. These procedures have become the standard of care in biopsies, aspiration, tissue ablations, among much else. The classic unassisted freehand needle placement typically includes three decoupled tasks:

- 1) Touching down with the needle tip on the skin entry point, which can be achieved with 3D translational motion.
- 2) Orienting the needle by pivoting around the skin entry point, which can be achieved by two independent rotations around axes intersecting in the fulcrum point.
- 3) Inserting the needle into the body along a straight trajectory, which can be achieved by one-dimensional translation, possibly combined with some drilling and/or tapping action to reduce needle deflection while penetrating/passing through multiple tissue layers.

The final action is releasing the therapeutic payload (injection, deployment of implanted seeds or markers, heat, cold, etc.) or collecting biological material (aspirating fluids, cutting out tissue, etc.). Despite their apparent simplicity, percutaneous needle-based interventions can be complex mini-surgeries. Not surprisingly, robotic assistance has been proposed to aid in a wide variety of these procedures. Most robotic needle placement intervention systems mimic the corresponding freehand workflow, which explains why many of them employ decoupled mechatronic designs. Translation to the skin entry point can be achieved by Cartesian motion, and fulcrum motion can be conveniently performed by some compact parallelogram structure (e.g., as presented by Innomotion) or by some bi-plane “sandwich” structure (e.g., iSYS/Micromate) [20]. While decoupled mechatronics was an important safety feature for some time, its importance has faded since software control of serial manipulators has become highly reliable; meanwhile their physical structures also became sturdier. For example, decoupled Cartesian motion and remote center of motion is now firmware feature on the serial KUKA LBR Med robots that are used in several commercial and research systems (e.g., ARTAS, Epione, Monogram, ROBERT) [31, 32]. As a result, serial robots acquired from a variety of OEM sources can be found in nearly all specialties of interventional robotics.

### A. End-Effector Designs

Typically, intentional contact with the patient's body is only made by the end-effector of the robot, the "applied part". A great deal of research has been dedicated to developing steerable, bendable, or otherwise actuated and sensorized end-effectors. For an in-depth overview of a large family of such devices, we refer the reader to a companion paper in this special issue, on continuum robots by Dupont et al. [33]. For supporting needle placement interventions, motorized needle drivers have been tried in research [34] and significant work has been dedicated to steerable needles as well [35]. Despite such impressive research efforts, translational system designers tend to be extremely conservative when it comes to actuated end-effectors. As a first principle, direct transfer of energy (mechanical, thermal, radiation, etc.) to the patient's body is usually decoupled from the robotic system itself and is integrated as an OEM component, in order to reduce regulatory hurdles and to increase patient safety. Rare exceptions from this principle include the CyberKnife radiosurgery system with its controlled linear accelerator tool to deliver the radiation energy. Similar examples are the joint arthroplasty robots, such as ROBODOC and MAKRO, with their powered bone milling tools [36]. Another such example is the recently marketed HEARO, a cochlear implant navigation system featuring controlled power drilling and monitoring the drilling depth by virtual constraints and intraoperative sensing, such as monitoring facial nerve distance [37].

In most commercial needle placement robotic systems (e.g., Micromate and former Innomotion [38]), and orthopedic pedicle screw placement systems (e.g., Mazor X Stealth Edition or ExcelsiusGPS), the final tool insertion action is not actuated or motorized. The intention behind this design choice is to avoid the automated direct "energy transfer" into the patient's body, an aspect about which regulatory agencies are extremely strict, which involves costly and protracted regulatory processes. In these systems, the robot acts as an actuated or encoded arm to stabilize a simple guide sleeve, through which standard surgical tools (needles, trocars, etc.) can be manually inserted into the body. Therefore, physical contacts with the patient remain under the direct control (and liability) of the human surgeon or radiologist. If the robot joints are non-back-drivable, and have small backlash, their power can be turned off in order to prevent the robot from accidentally moving while the tool is inserted, which further promotes patient safety. These design choices allow the manufacturer to characterize the robotic intervention system as a naive tool holding device, thereby significantly easing its regulatory approval process. Moreover, all commercialized needle placement robotic systems employ standard commodity needles. Replacing these with custom-designed end pieces is a financially and logistically difficult proposition, and therefore usually avoided.

Table 1 provides a comprehensive list of commercial and advanced prototype image-guided interventional systems, spanning across various configurations, kinematic designs and surgical specialties.

## IV. PREVAILING IMAGE GUIDANCE MODALITIES IN INTERVENTIONAL ROBOTIC SYSTEMS

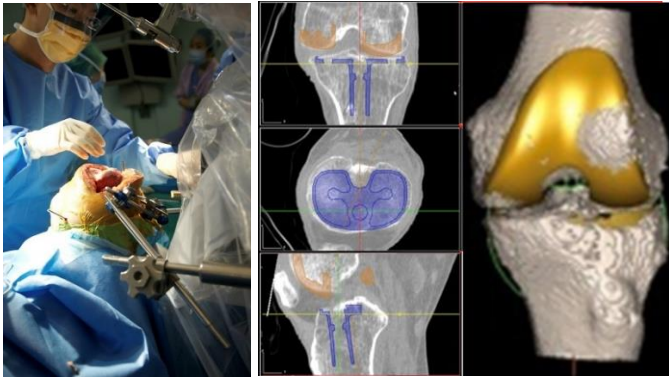
Interventional robotic systems have been deployed with all existing imaging modalities, in a wide variety of medical interventions. Existing literature provides a comprehensive portrait of the evolution of these systems [36, 39–41]. In the success or failure of an image-guided interventional robotic system, no factor is more important than the means of integration between the robot and imaging system, which fundamentally determines the usability. Ideally, the image modality is selected based on procedural constraints, e.g. what is the accepted modality and approach that has predicate regulatory approval, and acceptance by patients, providers, payers. In reality, however, interventional robotic system developers are often commissioned to develop a robotic system for an existing manual image-guided procedure and, alas, they seldom have freedom in selecting the optimal image guidance modality; the design process, in many aspects, is on a forced trajectory from the outset.

### A. Computed Tomography Guidance

CT appears to be the most frequently used imaging modality in robotic intervention systems, in part because it has been around for almost the longest time, and because there are numerous CT-guided manual interventions that robotic systems aspire to improve upon. The kind of interventions that had appeared historically first and seem to have been enjoying the longest success are the ones that use CT imaging only for pre-planning the procedure, in the so-called Surgical CAD phase, as we discussed earlier. In the operating room, surrogate markers are used to spatially register the planning CT with the patient and the surgical robot. There are many ways to achieve this registration. Most often, an intra-operative optical tracking device is used to localize anatomical landmarks or artificial markers (fiducials) placed on the patient prior to CT imaging and markers placed on the robot [42, 43]. Alternatively, electromagnetic tracking can also be used [44], mostly for catheter type robot application described a companion paper in this special issue by Kwok et al. [45] Optical tracking was applied in the historically first ROBODOC orthopedic hip and knee replacement surgery robot [46] and the more recently market-approved Stealth Autoguide robotic platform for providing trajectory guidance in intracranial surgeries [47]. A force-controlled cooperative robot-to-patient registration method was applied in the pioneering ROBODOC, using control to localize registration points with the robot's own end-effector (Fig. 3) [48].

A large variety of percutaneous (a.k.a. through-the-skin) interventions are performed with in-situ image guidance, on the CT scanner, such as injections, biopsies, aspirations, ablations. Percutaneous procedures tend to be reasonably easy to plan (requiring a skin entry point and a target point along a safe trajectory), quick to execute and convenient to verify by imaging. Owing to their general safety and straightforwardness, these procedures are performed in high volumes in outpatient settings. Not surprisingly, robotic systems appeared with the intent to increase the speed and accuracy of CT-guided needle placement procedures. Early research projects [49] were followed by commercial systems, such as the Innomotion [38].





**Fig. 3:** The ROBODOC (now called T-Solution one) Total Knee Arthroplasty (TKA) robot mounted for total knee replacement surgery (left). The surgical plan was created on preoperative CT imaging bases (right). [50]

On the whole, however, none of the commercialized in-scanner systems seem to have attained lasting popularity. One of the reasons is that CT imaging poses unforgiving conditions on robotic intervention systems. The overarching problem is that CT is based on X-ray imaging that exposes the patient and the staff to ionizing radiation. Regulatory agencies classify CT as a high-risk medical device. Integration with any sort (software or physical) with a CT scanner is exceedingly problematic because it would trigger lengthy and costly regulatory processes. As a result, interventional guidance systems (robotic and other) are not permitted to interact with a CT scanner in a direct manner. When an interventional system requires a CT scan, a human operator must manually set the desired scanning parameters (table/gantry positions, field of view, etc.) and trigger the acquisition on the scanner's console, and the robot may pull the resulting image from the hospital's Picture Archiving and Communication System (PACS). Under these circumstances, adaptations of the preconceived intervention plan and compensation for tissue motions and deformations are extremely problematic. Because any physical alteration of the CT scanner, both gantry and couch, is also prohibited, mounting the robot is still troublesome. Lightweight robots may be temporarily placed on the couch top together with the patient. But since couch profiles vary across scanner manufacturers and models, universally portable mounting solutions do not exist. Alas, each time the robot is mounted for an intervention, the spatial relationship between the robot and image coordinate frames must be recomputed in a calibration session, which also requires a CT scan (which requiring additional time and effort).

As robotic interventions are relatively rare compared to other routine imaging duties of a CT scanner, frequent mountings and dismountings of the robot aggregate to a major inconvenience. Although care facilities may try to schedule robotic interventions to be grouped together, this approach is still problematic because it is very hard to predict a priori which of the specific cases will require robotic assistance. Since freehand interventions would be impeded by the presence of the inactive robot, the device needs to be dismounted from the scanner when not in use. Finally, when the robot is dismounted, the entire system (robot, mount, computer, displays, trackers, cables, etc.) needs to be compactly packed for transportation and storage; a

seemingly innocuous issue that further dampens the enthusiasm of the technical and nursing staff for CT-guided interventional robotics. Altogether, technical and logistical complexities and associated costs hamper CT-guided interventional robotics, while simpler, smaller, and less expensive non-robotic assistive techniques [51] continue to present a stiff competition.

All said, CT-guided percutaneous interventions tend to be of relatively of low complexity, low cost, and high throughput. To put this in some perspective, a bilateral spinal nerve block with CT guidance, manually delivered, must be done in less than 15 minutes, including transporting the patient in and out of the scanner room, documentation, and the physician's dictation; a very high bar for a robotic system. And these procedures seem to have a non-intuitive arithmetic, in which compounding costs of setup and take down times seem to outweigh any procedural improvement. The equation would change instantly with proper integration between the robotic system and the diagnostic CT scanner, in which manufacturers do not seem to be interested.

### *B. Magnetic Resonance Imaging Guidance*

Magnetic Resonance Imaging (MRI) guidance has become prevalent in many minimally invasive procedures, including numerous needle placement procedures. MRI offers exquisite soft tissue contrast, as well as numerous options to monitor quantities pertinent to interventions, such as motion, deformation, strain, stiffness, temperature and more, to guide the delivery and to monitor the progress of interventions. In typical manual interventions, the patient is translated in and out of the magnet between image acquisition and intervention. In this classic manual approach, however, opportunities of controlling the surgical tool's trajectory to compensate for tissue motions and deformations are lost. Although the use of MRI guidance is highly desirable, physical limitations of conventional closed high-field MRI scanners present significant engineering obstacles by denying direct access to the patient.

Robotic assistance seems to be the only viable option to perform interventions inside long cylindrical MRI magnets. On the other hand, constructing robotic assistants for use inside a high-field MRI scanner is extremely challenging because the strong magnetic field excludes the use of most metals, electronic and electro-dynamic parts: just about everything that is used in conventional robots. MRI-guided robotic systems are discussed in-depth in a companion paper in this special issue, by Fischer et al. [52]. Nonetheless, a few important aspects of MRI guidance ought to be considered here. Most importantly, unlike CT or fluoroscopy, MRI is a safe imaging modality, as long as the operator is careful with the use of ferromagnetic metals inside the high-field bore. Fisher et al. explain how recent MR-safe and MR-compatible mechatronic and sensing technologies allow for safe and robust physical integration for robots inside high-field MRI scanners.

MRI, to some extent, has been open to designing custom imaging sequencing, which is only possible through limited and confidential research interfaces, hampering any translational effort. But the pertinent technical issues of translation from research to product do not seem to concern imaging per se. Capabilities of coupling imaging information with the robotic system are generally lacking because the scanner's control

interface is not accessible from within the robotic system. In some research systems, tracking and anatomical imaging sequences have been successfully interlaced to provide accurate real-time tracking of robots with the use of active tracking coils [53]. Active tracking technologies, however, have failed to translate out of the research setting because of their extensive dependencies on the given the MRI scanners for which they were developed. Active tracking requires mapping of the gradient field that is unique to each MRI scanner, custom hardware, custom MRI sequences, and dedicated imaging channels. It remains an open question whether scanner manufacturing companies will accommodate active tracking and opens the scanner's imaging control interface for full integration of interventional robots. This may happen only if manufacturers find sufficient financial incentive in MRI-guided interventional robotics. Although several MRI manufacturers have developed gantries with shorter and wider magnets, which support of performing manual interventions inside the bore, no apparent effort has been made to encourage in-scanner robotic interventions.

The advent of MR-based thermometry imaging has created considerable interest in MRI-guided Focused Ultrasound (MRgFUS) ablation treatments with robotic assistance inside the MRI bore. The appeal of this approach lays in that no physical contact needs to be made with the patient by a robotic manipulator to move a HIFU transducer extracorporeally over the target area, while the MRI scanner performs thermometry imaging of the target to monitor the progress of ablation.

The concept of MRgFUS originates from the pioneering work of Jolesz and Hynynen, implemented as an integrated image-guided robotic system [54], subsequently commercialized by Insightech. They used a 2-DOF Cartesian piezoelectric motor stage laid on the scanner couch, to move a HIFU energy transducer under the patient to create a predefined pattern of thermal lesions in the target. Insightec's ExAblate 2000 system was the first commercial MRgFUS that received U.S. Food and Drug Administration (FDA) approval in 2004 for the treatment of uterine fibroids. The ExAblate system is embedded in the couch of 1.5 Tesla or 3 Tesla General Electric MRI scanners, and as such, it is fully integrated with the host scanner. The Sonalleve MRgFUS system, developed by Philips Healthcare and now marketed worldwide, uses a 5-DOF robotic positioning system to move the HIFU transducer, fully integrated in the scanner's table. Another difference from the earlier mentioned ExAblate is in the thermal exposure protocol, by using a spiral trajectory for creating the thermal lesions. Besides being embedded in the couch, by interlacing anatomical and thermal imaging schemes, the reigning commercial MRgFUS systems are extremely tightly integrated with their host MRI scanner.

Still, challenging the status quo, several robotic manipulator systems have appeared over the past decade, with the intent to move the HIFU transducer in a more elaborate manner to allow for more complex thermal exposure geometries and intra-cavity and endoluminal accesses to hard-to-reach targets, such as transrectal and transurethral HIFU ablation of the prostate. For more details, we refer the reader to a review of robotic positioning devices for guiding MRgFUS systems in [55]. Among the more recent examples, Meltzer et al. repurposed a

commercially available passive transrectal manipulator for mounting a commercial HIFU unit for prostate cancer therapy [56]. Drake et al. mounted a commercial HIFU unit on an MRI-compatible in-house developed robotic arm for treating intraventricular hemorrhage in neonatal patients [57]. Damianou et al. proposed a similar concept for covering a relatively large treatment areas applications such as bone cancer ablation [58]. None of these research systems has been translated to commercial use thus far. One of the reasons for the measured pace of these projects is that the perennial issues of integration between the MRI scanner and the robot are extremely complicated, as controlling the robot and the HIFU unit are tied to anatomical and thermal imaging functions of the MRI scanner. At the same time, the ongoing development of larger extracorporeal transducer units, combined with more effective ultrasound energy targeting and focusing techniques, might somewhat reduce the urgency for inhouse developed robot-assisted HIFU systems.

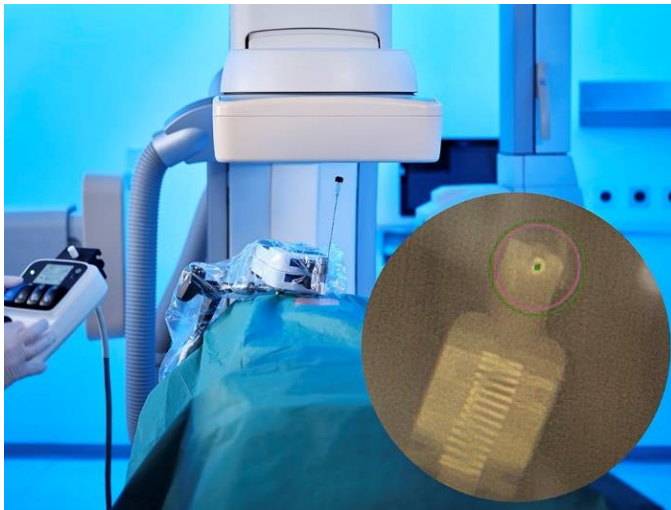
It is also worth mentioning General Electric's "Double Donut" open MRI scanner configuration, which originally aimed to offer a configuration suited for MRI-guided robotic interventions. Despite the apparent appeal of the general concept, technical complexities were unrelenting and, perhaps more importantly, it was unsuccessful commercially, forcing GE to end the product line before ultimately delivering on the promise. In the first two decades of MRI, low-field open MRI magnets dominated the market, as they were magnitudes less expensive to acquire and to maintain than high-field closed magnets. While the open magnets, despite their grainy low-quality image, were well-suited for interventional work, they were quickly pushed out by the rapidly growing diagnostic market. Nevertheless, it should also be noted that the complexity of integrating open magnets in the operating theater made it extremely hard to perform efficient surgeries and complicated interventions, such as the ones requiring full anesthesia. Still, one overarching logistical problem with the low-field open interventional MRI scanners is that they are bound to generate a financial loss, unless they are constantly doing interventions; so they must be constantly supplied not only with patients, but also with interventionalists, nurses and anesthesiologists. In the fee-for-service medical business climate, the pressure on intervention-only MRI facilities was irresistible and they rapidly repurposed their precious facilities for diagnostic MRI scanners, which, albeit not optimally, allow for a variety of simple percutaneous interventions, with shuttling patient in and out of the bore.

### C. Fluoroscopy Guidance

With the advent of distortion-free flat panel detectors and cone-beam image reconstruction, from the perspective of interventional robotics, fluoroscopy guidance offers just about all advantages of CT guidance, but with far fewer roadblocks and inconveniences for system developers. Studies have shown that the use of robotic assistance, for example, in fluoroscopy-guided spine surgery has led to a decreased overall radiation exposure for patients and surgeons alike, in addition to improved accuracy and consistency [59]. Still, a persistent lack of close integration of the fluoroscopy system and the robot stands in the way of a more rapid and wider-scale progress. Primarily, because intervention systems are not allowed to

control the fluoroscope to acquire X-ray images at will, which remains the main limitation. It is, however, a highly encouraging improvement that on some of the recent mobile C-arm devices, it is possible for the interventional system to rotate the imaging device to a desired position, although full control of the image acquisition, such as control over the tube current, is still out of reach. Such advanced features, dubbed as “task-driven source–detector trajectories”, are available for Siemens Zeego C-arms through a research Application Programming Interface (API). The current API offers even more, as the navigation application can also trigger the image acquisition at will [60, 61]. A forthcoming version of this API will allow the navigation application to modulate the tube voltage and current. The imaging pose and acquisition parameters of the C-arm can be optimized to provide the “best possible” visualization of the tool and/or the target anatomy, together or separately. Optimizations can seek to minimize the amount of dose to the patient, minimize the time of image acquisition, maximize the clarity of the image through model-based reduction of the artifacts caused by the robot. These objectives can be sought jointly or separately. Again, such functions are only available through confidential user interface and not yet cleared for use on humans.

On the positive side, most fluoroscopy tables come with standard side rails on which mounting of small robots is now a relatively straightforward task. Moreover, mobile C-arm fluoroscopy is extensively applied in needle placement interventions, and in many of these applications the interventional robot can be guided by visual servoing by the physician with joysticks to the optimal entry point and direction, without the need for calibration and computing trajectory control parameters for the robot. One such example is the recently marketed Micromate, a compact robot with visual servo control with 2D translation and 2D fulcrum rotation, carried by an unencoded adjustable positioning arm mounted on the table’s side rail (Fig. 4).



**Fig. 4:** The iSYS/Micromate/Stealth Autoguide robot mounted on the rail of an X-ray fluoroscopy table, set up for a needle placement intervention. The image insert shows a bull’s eye X-ray view of the robot’s end-effector. The surgeon is moving the

robot under joystick control, to align the needle with the X-ray fluoroscopy image. (Credit: iSYS Medizintechnik GmbH)

The manufacturer and users claim several advantages for the Micromate over the conventional freehand needle positioning technique, such as reduced dose to both physician and patient, steady aiming to reduce needle insertion attempts and adjustments. Here, one might rightfully lament on the vagaries of commercialization and why the first such product entered the marketplace nearly two decades after the demonstration of this powerful yet relatively straightforward concept [62]. The root causes might include slicker packaging of the robot, more effective marketing and financing, better clinical support, more favorable economic conditions, and better acceptance of the technology – probably all the above. And this logic applies more generally to disruptive technologies in this domain, not only to the robot itself.

A more tightly integrated system is the recently debuted eCential platform from the French company eCential Robotics, rings together intraoperative 2D/3D imaging, navigation and robotics, preventing pitfalls of coordinate frame registration [63].

For advanced computationally-guided robotic systems, such as steerable surgical manipulators [64], maintaining spatial registration between the C-arm image and the robot’s coordinate frame may remain a somewhat difficult task until the intervention system is granted more control over the fluoroscope. For example, the capability of interlacing low-dose robot tracking imaging sequences with intermittent higher-dose anatomical imaging is a promising feature for safer navigation of interventional tools. Unlike CT and MRI manufacturers that pursue most of their profits in the diagnostic imaging domain, fluoroscopy device manufacturers operate mainly in the interventional imaging domain. A closer, system-level coupling between the fluoroscopic imager and the interventional robotic system is a highly realistic expectation. All said, the prospects for translational success in fluoroscopy-guided interventional robotics is quite promising and has been steadily improving.

#### D. Ultrasound Guidance

Ultrasound is an inherently safe and relatively inexpensive imaging modality that has been spreading rapidly in interventional applications [65]. In many percutaneous procedures, US guidance has become the standard of care. At the same time, US imaging poses special challenges that have hampered US-guided interventional robotic systems in achieving sizable translational success. Perhaps the significant factor is that ultrasound imaging requires constant and well-controlled physical contact and acoustic coupling between the transducer and with the target tissue, while the transducer unavoidably displaces and deforms the target tissue and patient may also be moving. These circumstances usually require exquisite physical control over the US probe. Over the years, numerous robotic systems have emerged to assist in the task of US scanning; an in-depth review of these is available in a companion article in this special issue, on “robotic imaging” by Salcudean et al. [66], discussing robotic systems that carry a US probe. (In this article, we are concerned mostly with robots that carry out an intervention guided by US.)



An area of application where the acquisition of US images may be easier is transrectal US imaging. Not surprisingly, there are a few US-guided robotic systems on the market for transrectal prostate biopsy, such as the Artemis system [67] for transrectal needle placement approach (Fig. 5) and the Mona Lisa for transperineal needle placement approach [68]. Another promising device, albeit not yet in commercial use, is Veebot, a hand-held automated venipuncture device for rapidly drawing venous blood [69], using a system that works with either ultrasound or near-infrared imaging.



**Fig. 5:** The Eigen Artemis transrectal ultrasound-guided prostate biopsy robot cart. The image insert shows the locations of the planned and already executed biopsy locations. (Credit: Eigen)

Recently, US imaging has been going through an amazing development path; in the span of less than decade, bulky cart-size machines have shrunk to portable, and most recently, hand-held devices. At the same time, the imaging quality of these low-cost systems has been rapidly improving. In addition to a handful of historically successful large companies, such as Siemens, General Electric, the current US imaging scene includes a growing number of small, dynamic companies. More and more of them, such as Telemed (Vilnius, Lithuania) or Clarius (Barnaby, BC, Canada), support interventional applications through providing software interfaces for full control of the scanner's imaging parameters and to access raw radiofrequency image data. Unfettered access to the "guts" of the US machine has opened up truly exciting opportunities for interventional US image guidance. Combining these advanced functions with mechanical manipulation of the US transducer, it becomes possible to orient and press on the transducer to yield concurrently optimal images of the surgical tool and target tissues. Recent advances are reviewed in a companion paper in special issue by Salcudean et al. [66]. Recent AI approaches are fundamentally changing the way interventional robots can cope with tool tracking, tissue tracking and therapy monitoring in real-time. Another favorable trend for interventional robotics is the development of novel US transducers that are custom-

designed for interventional applications. All said, the future for US-guided interventional robotics is bright and its future has been arriving fast.

### E. Video (RGB) Image Guidance

Video image guided robot-assisted surgery, on the whole, has been the most successful thrust in the field of medical robotics. Since color video is readily outputted by laparoscopy, gastroscopy and colonoscopy devices, there is no systemic or safety barrier to integrate these imaging devices into robotic systems. The unprecedented success of the da Vinci has had an immensely positive impact on surgical robotics, and having been carried forward by this momentum, a variety of endoluminal interventional robot systems have also appeared. For an in-depth review of these systems, we refer the reader to two companion articles in this special issue, by Haidegger et al. [10] on da Vinci and related RAMIS systems and by Kwoh et al. [45] on endoluminal robotic systems.

## VI. ARTIFICIAL INTELLIGENCE IN INTERVENTIONAL ROBOTICS

As mentioned in Section II, medical robotics heavily relies on information acquisition and processing; before, during and after the intervention. A plan needs to be prepared to reach a defined target and perform suitable diagnostic or therapeutic actions. Very often, re-planning is necessary because soft biological tissues move and get deformed due to physiological conditions, patient position, and the surgical action itself [70]. From the beginning of the short history of surgical robotics, constant efforts have been made to extend the systems to address these moving and deformable, working environments. The sheer complexity of these highly dynamic environments in a safety-critical domain led developers to reducing the problem to somewhat simplified and more controllable scenarios.

In the first robotic systems for neurosurgery and orthopedics, physical fixation of the skull or bone eliminated target motion. Stereotactic neurosurgery involved keyhole access, allowing to ignore brain shift and tissue deformation. Later developments involved target tracking using fiducials or image-based localization to minimize invasiveness whilst adapting to target movements. The TMS-Robot, for trans-cranial magnetic stimulation, a non-invasive therapy for modulating neural pathways, updates the patient's head position using optical tracking of non-invasive markers pasted on the skin [71], while the ROSA neurosurgery robot [72] also provides head tracking using a laser-based surface sensor mounted on the robot arm. Other strategies included developing small robots mounted on the patient, allowing them to move with the anatomical structure of interest. This scenario was implemented in the OMNIBotics (earlier known as Praxiteles [73]) robot system for knee arthroplasty, where the robot is attached to the bone the surface of which is to be machined. However, when the structure of interest is a soft tissue, it may be necessary to acquire and process real-time information during the intervention and to account for the changes and re-plan the action. Currently, only very few commercial systems involve such a high-level of adaptation to continuously moving targets. One such notable example is the CyberKnife radiosurgery system (Fig 6.), which uses real-time chest tracking and biplane X-ray fluoroscopy imaging, combined with a statistical model

that correlates the motion of the chest and internal organs, to recompute the target position for the linear accelerator mounted on the robot arm.



**Fig. 6:** The CyberKnife M6 radiosurgery system. (Credit: Accuray)

Extensive research work has focused on visual servoing of robots, where the robot and imaging information are connected at a high or low level. Low-level connection has the potential to close the loop on intraoperative changes in real-time [74, 75]. For example, a recent paper surveys the specific issue of motion compensation in beating heart surgery [76]. These aspects raise questions about the autonomous capabilities of robots. Initially inspired by industrial automation, surgical robotics certainly generated expectations where the surgeon would be a humanoid robot making all decisions and conducting all actions regarding their patient. Yang et al. [77] proposed a 6-level scale ranging from systems, without any autonomy to systems where all strategic and tactical decisions would be made and executed by a machine, with the first 3 levels being:

- 1) No autonomy (e.g., a non-robotic tool),
- 2) Robot assistance (e.g., Mazor X),
- 3) Task-level autonomy (e.g., ROBODOC or maybe the more recent HEARO, which monitors the progress of the drill using multi-sensor information).

The human operator is in charge of planning and adaptation to the environment changes, whilst, in the last three levels (supervised autonomy, high-level autonomy, full autonomy), a machine is partly or totally in charge of these tasks. The clinical state-of-the-art is mostly confined to levels 1 to 3, while CyberKnife would be classified level 4. Yang's classification scheme was later refined and adjusted [5].

The recent rebirth of AI and machine learning certainly resuscitates these dreams [78]. However, up to now, the power of machine learning approaches has mostly been demonstrated in image processing: classification, detection and segmentation of organs or lesions and registration of images [79, 80]. One interesting feature of deep learning image registration lies in the fact that once trained, even a Deep Neural Network (DNN) can almost instantaneously produce a result, potentially usable for motion tracking or compensation. DNNs can also speed up biomechanical simulation for intraoperative re-planning of patient-specific tasks [81] or for robot control (during needle insertion for instance [82]).

AI has also generated highly promising results for surgical workflow analysis, segmentation, and recognition [83, 84].

Such methods aim to analyze surgical skills, not only allow for training and performance evaluation, but also for context-aware assistance to the surgeon to detect adverse events [85]. This also could be used to optimize the global surgical workflow and managing the operating room (such as signaling when the next patient can be prepped or transported toward the OR.) Finally, adequate modelling and assessment of the quality of surgical action is a prerequisite to achieving highly or fully autonomous robotic systems.

At the same time, AI raises new unsolved issues regarding safety, as transparency, accountability and trustworthiness of an AI-driven medical devices need to be proven. This adds several levels of complexity to the translation of research prototypes to certified clinical systems. To support product developers, this issue is being addressed by ethical guidelines and standards, such as the most recent *IEEE 7007 - Ontological Standard for Ethically Driven Robotics and Automation Systems* [86].

Finally, there has been recent over-emphasis in general on the prowess of AI as a “magic bullet” to solve all problems in image segmentation, registration, tracking, control, etc. In the pursuit of scientific and methodological novelty, there is now clear and present danger that the research community may prematurely bypass many of the worthy deterministic solutions, that, unlike most AI solutions (deep learning, etc.), can be validated and certified according to the highest norms and standards.

## VII. TRANSLATION FROM RESEARCH THROUGH PROTOTYPE TO PRODUCT

Today in all high-income countries, national healthcare systems are furnished with medical devices that are manufactured, maintained, and serviced by for-profit companies. The translation process from academic research to routine clinical practice leads through commercialization. In this setting, to achieve wide-scale clinical use is impossible without commercial success; these two, for all practical purposes, are synonymous. This is also in line with the requirements of any financial investor willing to provide funding for a new system's R&D period.

Academic researchers strive to develop novel technologies for solving pertinent clinical problems in the most practical and least expensive manner. Commercial devices, on the other hand, are designed to comply with regulations and to maximize profit for the manufacturer. In between the two lies the maze of reimbursement schemes, basically determining how much the healthcare providers (or the healthcare system) can pay for the purchase, operation and maintenance of the given medical device. When these colliding interests can be reconciled, the translation process might move forward but, more often, at the price of manifold design concessions. Not surprisingly many of the most technically advanced and forward-pointing features of novel research systems are severed from the final product; the history of interventional robotics is rife with casualties because of reduction to practice. For instance, Medtronic preferred the Mazor X Stealth, a rather conventional arm attached to the operating table, over the more innovative Mazor-Renaissance body-mounted robot [87, 88].

### A. Financial and business case considerations

Much of the current marketing efforts for surgical robots are

tightly focused on the United States sales, so the conditions and costs of entering that market (FDA 510(k)-based clearance, at least) must be incorporated into the costs of translation. In Europe, surgical robots are specifically prevalent in the BENELUX states, the UK, and Italy, albeit under widely varying local regulations. As different target countries present different prices and revenue perspectives, companies often enter with alternative business strategies (e.g., leasing to hospitals where legally permitted or renting) for the different countries. Companies appear to follow one of the two broad marketing trends: IP development or sales development. In both cases, the right business model is critical, i.e., how a CAPEX (capital expenditure) type robot cost can be monetized (through accessories, implants, maintenance, service costs, etc.).

As we saw earlier in the section on surveying image-guidance modalities, it is always critical how the robotic and imaging devices are coupled. A failure to achieve a mutually lucrative business agreement with the appropriate imaging device manufacturer is likely to put the robotic system's developer into a very difficult position. Moreover, these agreements may include an exclusivity clause that prevents the interventional system from being deployed on different brands of imaging scanners. It is why fluoroscopy-guided and ultrasound-guided interventional robotic systems may look forward to a brighter future than their CT-guided and MRI-guided counterparts.

In order an initially successful interventional system to survive and make it to the next level in technology transfer, it needs effective marketing, distribution, and support, which tend to be beyond the means of small and medium-size companies, particularly in the medical device domain. Consequently, more often, entry-level interventional robotic products are absorbed into well-established product portfolios of large manufacturers.

Two recent examples of this trend are how both the Mazor X Stealth and the Micromate robotic systems became absorbed by the Stealth surgical navigation product family of Medtronic. The lengthy development of the close connection between Mazor Robotic and Medtronic is especially instructive. Medtronic had invested initially \$20 million in 2016, and after lengthy preparations, Medtronic acquired a 15% stake in the company, in exchange for \$42 million (with a goodwill of \$280 million). Upon scheduling robot purchases, and technology and sales milestones, finally in 2018, they decided to buy the entire company, worth of \$1.64 billion. This fact is also significant because Medtronic's total backbone portfolio for the year was \$2.7 billion. Considering the approximate base price of \$850,000 and the additional \$1,500 per case of disposables, the direct payback on Mazor X seems to be a long way out in the future.

We can see similar trends elsewhere in the field of spine surgery. In 2014, Globus Medical acquired Excelsius, a key competency company, for roughly \$40 million. Their system received FDA approval and CE certification in 2017, and considering their robot's base price of \$1.5 million, it is unlikely that this investment has paid off for the company, even with the reported double-digit sales numbers. Nevertheless, according to Globus Medical's business reports, they are performing well in terms of revenue, growing 86% to \$15 million in 2020. Moreover, at the end of 2017, they acquired their CE-marked competitor, KB Medical, along with its IP

portfolio and the AQRate system. Because KB Medical had previously documented a capital investment of at least \$7.5 million, the value of the transaction could realistically have been around \$10–\$12 million.

Another example is Zimmer Biomet, which in 2016 acquired Medtech SA for at least \$132 million. Medtech had developed the Rosa Brain and Rosa Spine systems, which they sell for about \$700,000 each, meaning that an even with a generous 100 installations, return on the investment is yet to be realized.

All said, we have seen several smaller interventional robotics companies strategically swallowed up by their potential larger competitors, even if those initial investments are unlikely to generate sizable returns any time in the foreseeable future.

The large investments made by big players suggest that there is an appetite for robotic solutions, and that there are at least some areas that business believes in. Which begs the question if there is basis for optimism of growth for intra-scanner robotic procedures. The answer to this, at present at least, seems to be negative. Typically, in-scanner percutaneous interventions are relatively fast and of low cost. Historically, no big financial investment has ever gone into low-cost procedures because it seems to be extremely risky to expect healthy returns from procedures that would have to be performed in great numbers. Investors appear to be interested in expensive technologies for expensive surgeries.

### *B. Standardization and clearance*

International standardization of medical devices facilitates the market access for new medical products, helps overcome technical barriers to international trade, and supports market growth. While legislation and product safety regulations are the primary basis for creating specific product types that contribute to the creation of new markets, industry standards (international guidelines and recommendations) can help reduce safety risks for users (patients, doctors, and professionals) and reduce the risk of manufacturer liability [89].

For a long time, it was not clear whether medical robots should be considered robots at all, and some manufacturers were explicitly reluctant to refer to them as such. By doing so, they hope to stay clear of the relevant ISO technical standards and to avoid the FDA Pre-Market Approval (PMA) route and the European Machinery Directive 2006/42/EC, both being regulations that meant to prevent hazards introduced by robots into the operating room [90]. In its robotics standards, ISO consistently excludes medical devices, stating that they fall under other product classifications: the International Electrotechnical Commission's IEC-60601 family, describing the safety and performance requirements for Medical Electrical Equipment (MEE) and Medical Electrical Systems (MES). In 2015, the ISO Technical Committee 299 Robotics began work on a new standard, setting out basic safety and operational requirements for surgical robots [91].

In 2019, a new standard was published under the auspices of the IEC, IEC 80601-2-77, detailing requirements for the basic safety and essential performance of robotically assisted surgical devices. Despite being a relatively simple and of limited scope, this standard can inform bodies to establish the necessary link between the safety of MEE/MES and robotic systems. The U.S. FDA is also considering reviewing its own 510(k) procedures

to avoid placing high-risk systems on the market without proper certification process [92].

The most impactful change in recent decades in European medical legislation is the EU Medical Device Regulation MDR-745/2017 that came into full effect in May 2021. The new regulation significantly increased safety-related expectations and the requisite documentation for certifying medical devices, disproportionately affecting medical robots.

### VIII. DISCUSSION

It is a very difficult task to develop a new surgical robot system, and it is even more difficult to put it on the market. As this translation always involves significant simplification (i.e., reduction to practice), much of the research investment turns out to be futile (regarding the initial product).

Mammoth medical device companies active in the field have already taken very significant patenting and IP protection measures. Without a proper IP portfolio, it is unlikely that a new system will prevail in the Western markets. Technically, designing your own IP means developing completely new technical solutions instead of the currently best, most practical procedures, which make the R&D phase exceedingly costly and time-consuming.

To offset these costs, commercialization efforts tend to be aiming to simplify systems, at the cost of functionality. Instead of developing customized end-effectors, commercial system design efforts typically concentrate on alternative disposables, such as guide sleeves and other small accessories, that can generate a steady revenue stream for the manufacturer. By opting out of employing active tool manipulation, robotic systems give up the possibility of compensating for tissue deformation and motions occurring during tool-patient interaction. This might be of a lesser concern in procedures on rigid anatomical structures (e.g., in orthopedic and dental procedures), but it feels like a missed opportunity in many soft tissue interventions; an oversimplification that doubtless contributes to the reasons why percutaneous interventional robotics have failed to make major clinical breakthroughs. Still, despite all efforts to simplify and streamline systems, operating room time remains a critical issue, and traditionally, in the case of image-guided interventional systems, setting up a surgical robot takes a longer time than preparation for manual surgery, even if the actual procedure can be performed somewhat faster with the robot.

Aspects related to human–robot interaction seem crucially important to the translational success or failure of medical robot systems. In reviewing the literature, however, we found that the issue of how robotics and user interface technologies affect one another seems to have been severely under-researched, which was both surprising and somewhat alarming, given the significance of the problem. Only recently, Salcudean et al. [93] provided a critical review of human interfaces in medical robot systems. They survey recent surgical robots that have been used or tested in-vivo, focusing on the aspects of the human–robot interaction. They identified a variety of challenges that surgeons encounter in the operating room using robots, and they offer design requirements, in terms of clinical, technical, and human aspects, which should help developers to meet those

challenges. Their paper covers the full spectrum of medical robotics, but it would be a good starting point for investigations in the subject of human–robot interaction in interventional robotic systems. Conceivably, many projects have fallen by the wayside due to inadequate user interfaces, thus failing to make the translation from the research setting; this is a possibility that warrants scientific investigation.

Above all technical considerations, patient outcomes ought to decide if an interventional robot system is adopted to routine clinical practice. However, measuring improvements in patient reported outcomes is exceedingly hard, and data is only available for certain procedure types. Almost all current interventional robotic systems only perform procedures that have long been done with traditional techniques, quite reliably and efficaciously. Robotic systems may offer only slight, if any, technical improvements, and whether those translate to better clinical outcomes require lengthy and expensive clinical trials. Only a very few robotic systems have enjoyed large enough investments that could see them through such clinical trials. Not surprisingly, investors bank on expensive procedures that are done in large numbers, from which reasonable payback can be expected. Besides extensive trials with da Vinci [94], orthopedic procedures have yielded relatively solid data in hip and knee arthroplasty [95, 96, 97] and spinal pedicle screw fixation [98], and CyberKnife radiosurgery [14]. CyberKnife is optimized for highly precise treatment of smaller targets, which requires standard linear accelerators to deliver much of the prescribed radiation dose prior to the final radiosurgery “boost”. Despite well-documented clinical advantages of CyberKnife over conventional (3D–5D actuated) linear accelerators, only large treatment facilities can justify the costs and complexity involved with adding CyberKnife to their device park.

One should also ask if there is an obligation for researchers and industry to explore unmet needs that can be only addressed using robotic technologies, regardless to lack of commercial and financial incentives. For instance, in the global health context, there are many circumstances where remote delivery of procedures or interventions would make significant positive impact on the wellbeing of underserved communities where transportation and healthcare infrastructure are lacking. For example, in Canada, providing adequate healthcare for remote indigenous communities will never have the scale of economy to make these efforts profitable, yet the country cannot shrink from its responsibility to provide care for all citizens. The recent global pandemic also showed the need for more types of deployable medical robotics, and sped up prototype development in numerous areas [99].

Since the dawn of industrial modernization over 200 years ago, Western medicine held the belief self-evident that technology yields better patient care. In the relentless pursuit of scientific and technological modernity and novelty – which also drives science and academia – countless useful solutions have been bypassed and brushed aside for no reason other than “lacking novelty”. Some such technologies are now being brought back from oblivion under the banner of “frugal technologies” or “affordable technologies”. In interventional robotics, long-forgotten ideas, such as passive articulated arms, semi-automated or semi-manual segmentation and registration techniques, may as well see a renaissance, particularly in the



global health context, where they can enable low-cost solutions that can be widely deployed and robustly sustained. A singular advantage of low- and middle-income countries is that they do not have to overcome deeply entrenched commercial interests and calcified institutional habits, so they might even dash ahead in certain areas. A historical example to remember is how fully-wired North America was unexpectedly leapfrogged in mobile communication, and perhaps, we may see something similar in computer-assisted medical interventions and robotics.

It is worth lamenting on the recent report, sponsored by the World Health Organization, on reducing social inequalities in cancer [100], argues that “the ever-increasing research focus on expensive medicines for wealthy patients in wealthy countries and, in emerging economies, the displacement of domestic, affordable innovations by high-end expensive technology. Although commercial interests are driving many of the developments towards so-called precision medicine, the resultant inequalities can be exacerbated by allowing rights to be claimed as legal entitlements in overly individualistic contexts.” This seems to apply to the evolution of medical robotics in Western medicine. For this reason, the robotics community also started to pay attention to sustainability, even in the medical domain, which falls under the 4<sup>th</sup> UN Sustainable Development Goal (SDG) targeted for [101, 102].

## V. CONCLUSION

A primary goal of the myriad interventional robotics research projects currently under way in the world is to make surgical and interventional procedures more efficient and safer. Numerous concepts have been developed and prototyped in image-guided interventional systems, from the simplest needle biopsy guidance tool to the most sophisticated radiosurgery system with real-time compensation for physiological motions.

Despite countless new concepts and prototypes, only handful systems have reached commercial status, passing all hurdles of validation and certification. This article investigated the root causes of this discrepancy persisting, despite the perceived technological advantage of image-guided interventional robots.

As we saw, coupling between the imaging information and surgical decision making and action is a crucially ingredient of success. Yet, as we understand from numerous historical cases, superior technological solutions (mechanical design, control concept, etc.) do not necessarily lead to measurable clinical advantages. Improved patient outcome is the prevailing requirement, especially direct financial advantages, such as reducing costs, seldom, if ever, happens.

A closer look at the funding structure of a few successful companies showed most start-ups and innovation labs in the domain of our interest are severely underfunded, predestined to fail before reaching the human clinical status, let alone the commercial viability. For the better or worse, commercial success has become the sole measure of the practical usefulness of a medical device.

Arguably, the da Vinci robot became a commercial success primarily because aging wealthy men were willing to pay for milder side effects in prostate cancer surgery, and riding that wave, the system gained enough trust and momentum to prove its clinical utility in other domains as well. So much so that

during the past decade, the dominating procedure type with the da Vinci has become gynecology, where the robotic assistance has been empowering the human surgeons to perform many procedures with minimally invasive approaches. The ability to integrate imaging with telerobotic action took place in pricey interventions and with good financial returns to the investors. Libertarian proponents of the powers of free market may argue that this technology will eventually trickle down to improve outcomes for everybody, and they are putting their faith in that emerging competition will drive costs down. Sadly, this has not yet begun happening. And skeptics of free-market healthcare argue that it inevitably leads to unfair systems, with poorer individuals being unable to afford care, and that healthcare is an imperfect market and it is not in its nature to drive down costs; which seems an astute empirical observation.

All this, of course, does not mean that medical robotics research should stop, although we cannot directly measure the impact of prototypes on the field in general. Nevertheless, constituent technologies for calibration, registration, planning, tracking, guidance, etc., have been making their way, slowly though, into practice, and this trend must and will continue.

While developers need to maintain a pragmatic perspective, they should also be urged to critique strictly materialistic and financially-centered approaches to healthcare technology, in the interest of promoting equity and social justice. In order for interventional robotics to make true societal impact, it should cater to those who can the least afford it. This ideal, however, seems to be drifting ever further into the future.

## ABBREVIATIONS

AI	Artificial Intelligence
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
CAPEX	Capital Expenditure
CIS	Computer-Integrated Surgery
CE	Conformite Europeenne
CT	Computed Tomography
DNN	Deep Neural Network
DoF	Degree(s) of Freedom
FDA	U.S. Food and Drug Administration
HIFU	Highly Focused Ultrasound
IEC	International Electrotechnical Commission
ISO	International Standards Organization
IP	Intellectual Property
MDR	Medical Device Regulation
MEE	Medical Electrical Equipment
MES	Medical Electrical Systems
MIS	Minimally Invasive Surgery
MRI	Magnetic Resonance Imaging
MRgFUS	MRI-guided Focused Ultrasound
OEM	Original Equipment Manufacturer
OR	Operating Room
PACS	Picture Archiving and Communication System

## PROCEEDINGS OF THE IEEE – submission #

PMA	Pre-Market Approval
RAMIS	Robot-Assisted Minimally Invasive Surgery
R&D	Research and Development
SDG	Sustainable Development Goal
TKA	Total Knee Arthroplasty
TMS	Transcranial Magnetic Stimulation
TRL	Technology Readiness Level
US	Ultrasound

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ARTAS iX (Venus Concept Inc., Toronto, ON)  
 Artemis (Eigen, Grass Valley, CA, USA)  
 CyberKnife M6 (Accuray, Mountain View, CA, USA)  
 da Vinci Surgical System (Intuitive Inc., Sunnyvale, CA, USA)  
 Epione (Quantum Surgical, Montpellier, FR)  
 ExAblate 2000 (Insightech Ltd., Tirat Carmel, IL)  
 Innomotion (Innomedic GmbH, DE)  
 HEARO (CAscination AG, Bern, CH)  
 KUKA LBR Med (KUKA Roboter GmbH, Augsburg, DE)  
 MAKO (Stryker Co., Kalamazoo, MI, USA)  
 Mazor X Stealth Edition (Medtronic plc., Dublin, IE)  
 Mona Lisa (Bibot Surgical, SI)  
 Monogram (StartEngine Primary, LLC, Dover, DE, USA)  
 Micromate (iSYS Medizintechnik GmbH, Kitzbühel, AT)  
 Neuromate (Renishaw, Mississauga, Ontario, CA)  
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 Stealth Autoguide (Medtronic, Dublin, IE)  
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robotic paradigms and devices and image registration. Active in several clinical areas (urology, radiotherapy, cardiac surgery, orthopedics, etc.) in collaboration with Grenoble University Hospital and La Pitié Salpêtrière Paris Hospital. Thanks to industrial transfer, countless patients, worldwide, benefited from technology and systems she developed. Coordinating the

national excellence laboratory CAMI from 2016. IEEE Fellow, MICCAI Fellow. Dr. Troccaz has been an associate editor of the IEEE Transactions on Robotics and Automation" and of the IEEE Transactions on Robotics and is currently member of the steering committee of *IEEE Transactions on Medical Robotics and Bionics* and editorial board member of Medical Image Analysis. Member of the French Academy of Surgery. Recipient of several awards and medals: Award from the French Academy of Surgery in 2014; Silver Medal from CNRS in 2015; Chevalier de la Légion d'Honneur in 2016.



**Tamás Haidegger** (IEEE M'03, S'18) received his engineering degrees from the Budapest University of Technology and Economics MSEE and MSBME, then PhD in medical robotics. His main fields of research are medical technologies, control/teleoperation of surgical robots, image-guided therapy, and digital health technologies. Currently, he is associate professor at Óbuda University, the director of the

University Research and Innovation Center, and the technical lead of medical robotics research. Besides, he is a research area manager at the Austrian Center of Medical Innovation and Technology (ACMIT), working on surgical simulation and training. He is an active member of the IEEE Robotics and Automation Society (serving as an associate VP), IEEE SMC, IEEE EMBC, IEEE SA and euRobotics aisbl, holding leadership positions in the IEEE Hungary Section as well. He is co-Editor-in-Chief of Acta Polytechnica Hungarica and Associate Editor to the IEEE Trans. on Medical Robotics and Bionics, the IEEE Robotics & Automation Magazine. Dr. Haidegger is the author and co-author of over 250 scientific papers, books, articles across the various domains of biomedical engineering, with over 3,000 citations to his work. For his merits, he received the Gabor Dennis award, the MTA Bolyai Plaque and the NJSzT Kalmar award, among other recognitions. He has been running a professional blog on medical robotic technologies for over 15 years: <http://surgrob.blogspot.com>.

## APPENDIX

TABLE I

A COMPREHENSIVE LIST OF RECENT IMAGE-GUIDED INTERVENTIONAL SYSTEMS. ONLY TRL7 AND MORE ADVANCED RESEARCH PROTOTYPES ARE SHOWN. STATUS INDICATORS: R – RESEARCH, P – PRECLINICAL, C – COMMERCIAL OR D – DEFUNCT.

TKA: TOTAL KNEE ARTHROPLASTY, MRGFUS: MRI-GUIDED FOCUSED ULTRASOUND

#	System Name	Old name	Status	Manufacturer/Developer	HQ	Type	Target procedures	Reg. approval	Website	capital invested
1	AQRate		D	KBmedical, acquired by Globus	Ecublens, Switzerland			CE	<a href="http://www.kbmedical.com">http://www.kbmedical.com</a>	
2	AquaBeam		C	PROCEPT BioRobotics	Redwood, CA	Prostate ablation	Prostate ablation	FDA, CE	<a href="http://www.procept-biorobotics.com/technology.php">http://www.procept-biorobotics.com/technology.php</a>	\$173m; 2020: \$77m
3	ARTAS iX	ARTAS v3	C	Restoration Robotics Inc.	San Jose, USA	Aut. folliculi harvest and implantation	hair restoration	FDA, CE	<a href="http://www.restorationrobotics.com/">http://www.restorationrobotics.com/</a>	In 2016 \$4.82 m equity funding , Restoriation
4	Arthrobot		R	Jointech (Jianjia Robots)	Beijing? China	Arthroplasty				Series B \$14.72m, in 2020
5	ASRS	AVRA Surgical System, LISA	P	AVRA Surgical Robotics Inc. LG Mechatronic	New York, USA	IG robot with needle	Skin resurfacing		<a href="http://www.avrasurgicalrobotics.com/">http://www.avrasurgicalrobotics.com/</a>	
6	Automated Needle Targeting (ANT)		R	NDR Medical Technology Pte / MicroPort	Singapore	Needle guidance			<a href="https://www.biospectrumasia.com/news/27716329/singapore-s-surgical-robotic-firm-ndr-medical-closes-sgd8m-in-series-a-funding-round.html">https://www.biospectrumasia.com/news/27716329/singapore-s-surgical-robotic-firm-ndr-medical-closes-sgd8m-in-series-a-funding-round.html</a>	2020: \$5.75m
7	BEAR: Brescia Endoscope Assist		R	University of Brescia	IT	IGS	transnasal skull base surgery			
8	BioBot	iSR'obot Mona Lisa	C	Biobot Surgical PTE Ltd.	Singapore	IGS	Prostate biopsy	U.S. FDA 510(k) (2022)	<a href="http://www.biobotsurgical.com/product/NonCate/iSRobot-Mona-Lisa">http://www.biobotsurgical.com/product/NonCate/iSRobot-Mona-Lisa</a>	2011: \$4m
9	CASPAR		D	OrthoMaquet Rastatt	Rastatt, Germany					
10	CORI Surgical System		C	Smith + Nephew	London	IGS hand held	UKA and TKA		<a href="http://surgrab.blogspot.com/2020/07/cori-surgical-system-from-smithnephew.html">http://surgrab.blogspot.com/2020/07/cori-surgical-system-from-smithnephew.html</a>	
11	CUVIS-joint		P	Curexo		IGS	total knee arthroplasty		<a href="http://www.curexo.com/english/medical/sub01p03.php?PHPSESSID=f9d09f37ef54517e5efd5dabef7fe6e8">http://www.curexo.com/english/medical/sub01p03.php?PHPSESSID=f9d09f37ef54517e5efd5dabef7fe6e8</a>	
12	CUVIS-spine		P	Curexo		IGS	spine pedicle screw		<a href="http://www.curexo.com/english/medical/sub05.php?PHPSESSID=0779c9f63527a2a9828f59d8e6755c50">http://www.curexo.com/english/medical/sub05.php?PHPSESSID=0779c9f63527a2a9828f59d8e6755c50</a>	
13	Cyber Surgery		R	Cyber Surgery is a spin-off of Egile Corporation XXI.		IGS	spine surgery		<a href="https://cyber-surgery.com/">https://cyber-surgery.com/</a>	
14	DePuy Synthes	Orthotaxy	C	J&J		IGS	orthopaedic, TKA		<a href="https://www.jnjmedtech.com/en-US/companies/depuysynthes">https://www.jnjmedtech.com/en-US/companies/depuysynthes</a>	
15	eCential Robotics		R	Ecential Robotics SAS	Paris, FR	IGS	Spine		<a href="https://www.ecential-robotics.com/en/products">https://www.ecential-robotics.com/en/products</a>	In 2021.02: \$120m series B
16	EPICA		R	EPICA International		CT-guided			<a href="https://www.epicainternational.com/businesses/medical-robotics">https://www.epicainternational.com/businesses/medical-robotics</a>	
17	Epione		R	Quantum Surgical	Montpellier, FR	IG liver surgery	Liver biopsy	FDA 510(k), 2022	<a href="https://objectif-languedoc-roussillon.latribune.fr/innovation/innovation-medicale/2018-04-10/comment-quantum-surgical-innove-sur-le-traitement-du-cancer-du-foie-774841.html">https://objectif-languedoc-roussillon.latribune.fr/innovation/innovation-medicale/2018-04-10/comment-quantum-surgical-innove-sur-le-traitement-du-cancer-du-foie-774841.html</a>	\$50m in series A, June 2018
18	ExAblate 2000		C	Insightech Ltd.	Tirat Carmel, IL	MRgFUS		FDA	<a href="https://insightec.com/exablate-body/">https://insightec.com/exablate-body/</a>	\$632.9M in 10 series since 2010
19	Excelsius GPS		C	Globus Medical			IG pedicle screw placement			
20	Fraunhofer Needle placement robot		R	Fraunhofer IPA	Stuttgart, DE	KUKA iiwa and CT	needle placement		<a href="http://surgrab.blogspot.hu/2016/11/fraunhofer-ipas-new-needle-positioning.html">http://surgrab.blogspot.hu/2016/11/fraunhofer-ipas-new-needle-positioning.html</a>	
21	HEARO	ARTORG IGS robot	P	CAScination AG, together with MED-EL GmbH, University of Bern	Switzerland	IG drilling	Cochlear implant		<a href="http://surgrab.blogspot.hu/2017/03/artorg-image-guided-robot-for-cochlear.html">http://surgrab.blogspot.hu/2017/03/artorg-image-guided-robot-for-cochlear.html</a>	
22	HistoSonic		P	HistoSonic	Ann Arbor, Mich	IGS	non invasive heat therapy/HIFU		<a href="https://histosonics.com/">https://histosonics.com/</a>	\$54m in 2019 J&J partnership
23	HKU robot		R	University of Hong Kong	Hong Kong	MR safe neuosurgery	stereotaxis		first-intra-operative-mri-guided-robot-bilateral-stereotactic-neurosurgery	
24	HURWA		R	Beijing Hurwr Medical Technology	Beijing, CN	IGS	knee surgery		<a href="http://www.beijingetown.com.cn/2022-03/01/c_720866.htm">http://www.beijingetown.com.cn/2022-03/01/c_720866.htm</a>	



25	<b>IotaMotion</b>		R		Midwestern US	IGS	robotic cochlear implant system		IotaMotion	\$6.7 m+1.65 NIH grant
26	<b>Keranova</b>		R	Keranova	Lyon, FR	IGS	photoemulsification of cataractous lenses		<a href="https://www.keranova.fr">https://www.keranova.fr</a>	
27	<b>Kymero</b>		R	Koh Young Technology	Korea	IGS	Neuro		<a href="https://www.bioworld.com/articles/433640-Koh-young-aims-for-kymeros-global-expansion-after-netting-first-sale?v=preview">https://www.bioworld.com/articles/433640-Koh-young-aims-for-kymeros-global-expansion-after-netting-first-sale?v=preview</a>	\$17m
28	<b>Machnet</b>		R	Machnet Medical Robotics	Twente	IGS	IG neural			
29	<b>MAXIO</b>	PIGA	D	Perfint Healthcare Pvt. Ltd.	Tamil Nadu Chennai, India			FDA, CE	<a href="http://www.perfinthealthcare.com/MaxioOverview.asp">http://www.perfinthealthcare.com/MaxioOverview.asp</a>	\$33 m
30	<b>Mazor Renaissance</b>	SpineAssist	C	Mazor Robotics Ltd / acq by Medtronic	Orlando, Florida, USA / Dublin, IE				<a href="http://mazorrobotics.com/renaissance/">http://mazorrobotics.com/renaissance/</a>	\$72m investment from Medtronic 2016-2018; \$1.6bn buy option
31	<b>Mazor X / Mazor X Stelath Edition</b>		C	Medtronic		orthopaedic IGS robot	TKA		<a href="https://www.medtronic.com/us-en/healthcare-professionals/products/spinal-orthopaedic/spine-robotics/mazor-x-stealth-edition.html">https://www.medtronic.com/us-en/healthcare-professionals/products/spinal-orthopaedic/spine-robotics/mazor-x-stealth-edition.html</a>	
32	<b>Micromate</b>	B-Rob, iSYS	C	iSYS Medizintechnik GmbH / Partial acq by Medtronic	Kitzbühel, Austria			FDA, CE	<a href="http://www.isys.co.at/">http://www.isys.co.at/</a>	
33	<b>MIRIAM needle positioning robot</b>		R	DEMCON / U Twente		IG	Needle placement		<a href="https://www.demcon.nl/en/showcase/miriam/">https://www.demcon.nl/en/showcase/miriam/</a>	
34	<b>Monogram</b>		R	Monogram Orthopaedics		IGS	Joint replacement		<a href="https://www.kuka.com/en-hu/industries/loesungsdatenbank/2021/02/monogram-orthopaedics">https://www.kuka.com/en-hu/industries/loesungsdatenbank/2021/02/monogram-orthopaedics</a>	
35	<b>NaoTrac</b>		P	Brain Navi Biotechnology	Taiwan	IGS	neurosurgery	CE (2021)	<a href="https://jerrychen0.wixsite.com/brainnavi">https://jerrychen0.wixsite.com/brainnavi</a>	
36	<b>NavioPFS</b>	HipNav	C	Smith & Nephew	Plymouth, Minnesota, USA				<a href="http://bluebeltech.com/products/navio/partial-knee-replacement/">http://bluebeltech.com/products/navio/partial-knee-replacement/</a>	Acquired from Blue Belt Technologies Inc. in 2015 for \$275m
37	<b>Neuralink</b>		R	Neuralink		Electrode implant			<a href="https://gizmodo.com/elon-musks-neuralink-says-its-created-brain-reading-thr-1836435602">https://gizmodo.com/elon-musks-neuralink-says-its-created-brain-reading-thr-1836435602</a>	\$158m in 2017
38	<b>neuromate</b>	NeuroMate	C	Renishaw plc	Gloucestershire, United Kingdom				<a href="http://www.renishaw.com/en/neuromate-stereotactic-robot-10712">http://www.renishaw.com/en/neuromate-stereotactic-robot-10712</a>	
39	<b>Neurostar TMS Therapy System</b>		D	Neurostar	Tübingen, Germany				<a href="https://neurostar.com/what-is-neurostar-advanced-therapy">https://neurostar.com/what-is-neurostar-advanced-therapy</a>	
40	<b>Niobe</b>		C	Stereotaxis Inc.	St. Louis, Missouri, USA				<a href="http://www.stereotaxis.com/products/niobe/">http://www.stereotaxis.com/products/niobe/</a>	\$15m in 2020
41	<b>Omnibotics</b>	A.R.T.	C	OMNI Life Science Inc.	Massachusetts, USA	Surgical navigation/assistance			<a href="https://www.coringroup.com/healthcare-professionals/solutions/omnibotics/">https://www.coringroup.com/healthcare-professionals/solutions/omnibotics/</a>	
42	<b>OncoRobot</b>		R	Russian State Scientific Center for Robotics and Technical Cybernetics	RU	IG needle placement	Prostate brachy			
43	<b>Phecda</b>	Tianji	P	Beijing Tinavi	Beijing, China	IG surgery	spine surgery, pelvic and spinal fracture	CNDA	<a href="http://surgrob.blogspot.hu/2017/01/the-rise-of-medical-robotics-in-china.html">http://surgrob.blogspot.hu/2017/01/the-rise-of-medical-robotics-in-china.html</a>	
44	<b>Pulse</b>		C	Nuvasive		IGS	Spine		<a href="https://www.nuvasive.com/news/nuvasive-launches-pulse-the-first-integrated-technology-platform-to-enable-better-spine-surgery/">https://www.nuvasive.com/news/nuvasive-launches-pulse-the-first-integrated-technology-platform-to-enable-better-spine-surgery/</a>	
45	<b>RAFS</b>		R	MatOrtho, Bristol University	Bristol, UK	IG orthopaedic robot	fracture reduction		<a href="http://surgrob.blogspot.com/2018/07/uwe-bristols-rafs-fracture-reduction.html">surgrob.blogspot.com/2018/07/uwe-bristols-rafs-fracture-reduction.html</a>	
46	<b>Remebot</b>		C			IG surgery	frameless neursurgery	CNDA, CE	<a href="http://www.remebot.com.cn/">www.remebot.com.cn/</a>	Early: 19.8m 2020.12: \$66m in Series D
47	<b>RIO System</b>	MAKO	C	Stryker Inc. (formerly MAKO Surgical)	Florida, USA				<a href="http://www.makosurgical.com/">http://www.makosurgical.com/</a>	Acquired for \$1.65bn

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