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Recent advances in robot-assisted surgical systems

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Abstract
In recent years there has been a steady growth in the number of new robotic devices developed for surgical intervention. The market has rapidly grown into a multibillion-dollar industry. A significant number of commercial robots have been developed for several surgical procedures. Considering the recent developments in surgical robotics and its significant market potential we have studied the existing commercially available robotic surgical systems. The purpose of this review is to understand the current trends and existing gaps in this field to provide the developers with proper insight about the future direction. We reviewed the systems based on their target anatomical location and summarized the working principle for each robot, including their regulatory status.
Keywords: Surgical robot, Minimally invasive surgery,Orthopedics, Neurosurgery, Microsurgery Medical robotics

1. Introduction

1.1. Robot-Assisted surgery

As the term implies, 'robot-assisted surgery' can be defined as a surgical procedure where a robotic system assists a surgeon in executing the complex, invasive surgical steps on a human body with increased control and flexibility enabling high accuracy and precision when compared to the traditional techniques . It is often associated with minimally invasive surgery (MIS), unless an open surgery, but fundamentally meaning that the robotic surgical procedure can be executed with small and minimum number of incisions, significantly benefitting the patient. It has the potential to reduce trauma and recovery period after the surgery when compared to the traditional surgery . The field of robot-assisted-surgery has greatly benefited with the improvement in computing power, associated technologies, and advent of imaging techniques such as ultrasound (US), computed tomography (CT) and magnetic resonance imaging (MRI). Termed as computer-integrated-surgery (CIS), it has revolutionized the way surgeries are planned and executed, taking advantage of patient specific information, pre-operative and intra-operative imaging, and state-of-the-art robotic-assisted surgical technologies]. One of the primary ways of classifying a robotic surgical system is categorizing them based on intended anatomical application, as also followed in this article. Before we discuss these systems in more detail in later sections based on target anatomy, it is also useful and important to understand their classification based on the technical approach taken towards system design viz. tele surgical robots, image guided robots and hand-on or cooperative surgical robots, as explained by Takácset al. Tele surgical robots take advantage of fundamental teleoperation mode where a master console is used to control the slave robot to control the end effector which in this case can be an endoscope or orthopedic tool or any other surgical tools. The advancements in haptic technologies, elimination of hand tremors etc. has made the tele surgical robotic surgeries increasingly more effective, although time delay is an area where much more research and development is required, particularly where distances between the master and slave site are large e.g., space or intercontinental applications. Another significant advantage is the capability of reducing the exposure to surgeons in case of radiation intensive environment. Image guided

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1.2. A brief history of robot-assisted surgical systems

The last four decades have seen a total transformation in robotics applied to the field of surgical treatments. In the year 1983 the world witnessed the development of the first robotic system in history for assistance during treatment on a human patient, called Arthrobot. It was used for the first time in 1984 at UBC Hospital in British Columbia followed by 60 arthroscopic procedures next year .Arthrobot assisted a surgeon in manipulation and positioning of patient's leg using voice command . The first robot that was used for direct surgical support on a patient dates to 1985 when an industrial Puma robot was used to perform biopsy on brain using CT . Later in 1988 another version of Puma robot was used to perform robotic transurethral resection . To simulate the prostate tissue for the resection, researchers used an acrylic box that contained a potato while the box was connected to an artificial penis. This robot had a specially designed cutting assembly. An axial cut was performed when the robot was in forward stroke while a diathermic cauterization was performed on return stroke . However, later, manufacturer of the Puma robot refused to allow its use in surgery citing that it is unsafe since it was originally intended to be used inside a barrier to avoid human contact . In 1991, Imperial College London developed ProBot, a robot for transurethral resection of the prostate]. In the same year, an orthopedic robot prototype ROBODOC was developed by IBM for high-speed milling and to assist with implant positioning by utilizing preoperative CT imaging . Five years later, in 1996, Automated Endoscopic System for Optimal Positioning (AESOP) was developed by Wang et al. for assisting surgeons to hold a camera. The camera was controlled by a foot pedal or a hand remote control . It was one of the first FDA approved robotic system for surgical applications . In that year, ZEUS robotic system was also introduced that comprised of AESOP system and two laparoscopic instruments with 6-Degrees of Freedom (DOF) . It received FDA approval in 2001 and in the same year the robot was used to perform the first transatlantic surgery from New York on a patient located in France . In the year 2000, Intuitive Surgical, which had been developing robotic surgical system for past few years, received FDA approval for its da Vinci surgical system which became the first FDA approved surgical robot for general laparoscopic surgery . These technological developments were the early days for surgical robotics. In the current era, the advancements in medical imaging, haptics, 3D vision, and miniaturization are helping engineers to build compact and more effective surgical robots. Improvements in sensory technologies have provided a more holistic view on the surgical approach and it is significantly contributing to the advancement of medical robotics. These sensors provide a better understanding of the interaction between the robotic tool and targeted organs. The percentage of general robotic surgeries performed in 2012 as a portion of total number of surgeries was as low as 1.8%. This number jumped to over 15 % by the year 2020 . The market size for robotic surgery is projected to be $19 billion by 2027

1.3. Purpose, scope, and arrangement of the article

Considering the recent developments and the significant potential surgical robotics market holds in the coming future we realized the need for a comprehensive review of the existing commercial surgical systems. To our knowledge, there has been no recent review article directed exclusively towards commercially available robot-assisted surgical systems that cover all anatomical regions. Therefore, our objective through this article is to review robotic systems that exist in the market. This will enable the developers and researchers including those just getting started in the field of surgical robotics to understand the current trends and identify the existing gaps and the requirements for the development of next generation of surgical robots. Since the focus of this review article is commercial robots our primary source of information were the websites of developing companies. Also, whenever required, peer reviewed articles have been included that were available through the search of the corresponding robot name in google scholar and PubMed. The scope of this article includes all robotic systems that are invasive, and we have excluded non-invasive therapeutic robotic devices. Systems that existed in the past but have been discontinued are not included in this study. Additionally, when available we have added brief information from relevant clinical studies or trials to get familiarized with the clinical results for a specific surgical system.

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The robotic systems reviewed in this article have been primarily classified based on the type of tissue the device operates on with subclassification based on anatomical region. A reader can also place them under several different categories as described by other methods of classification under Section 1, but for the purposes of this article we have followed the target tissue and anatomy as the basis. Section 2 "Robotic surgical systems for osseous tissue" discusses systems operating on bones, or those where instruments pass through the bones. Section 3 "Robotic surgical system for soft tissue" discusses systems that operate on soft tissues. The sub sections for each of these sections are based on specific anatomical region. Section 4"Robotic systems for microsurgery" discusses the robots developed and applied for microsurgery. Section 5 "Generic robotic surgical systems" discusses the systems that do not fall under any single specific surgical area rather have been designed to operate on multiple anatomical applications. In Section 6 "Discussion and Conclusion" we discuss our observation and current trends in the field of surgical robotics. We end the article with a table that acts as a quick reference for a reader to review the robot-assisted surgical systems discussed in this article.

2. Robotic surgical systems for osseous tissue

2.1. Hip and knee surgery

Stryker developed Mako , an Unites States food and drug administration (FDA), approved robotic system to assist surgeons in total hip replacement (THR), total knee replacement (TKR) and partial knee replacement (PKR) surgery. It also received conformiteeuropeenne (CE) mark for TKA, total hip arthroplasty (THA) and unicondylar knee replacement (UKR). The basic system consists of a robotic arm, a camera stand and a guidance module while the attachments including the cutting instruments vary as per specific application along with the software module. A surgeon uses a preoperative image of the patient's anatomy of interest and preplans the surgical procedure. Based on this preplanning the robotic arm creates a virtual boundary while operating on the patient using 84ubmillimet tools. The position of the patient and the robot during the operation is tracked using an optical tracker. This system has been widely used commercially. As of May 2021, it has been utilized for more than 500,000 procedures (THR, TKR & PKR) by surgeons across the world. One of the studies that compared 40 manual total knee arthroplasty (TKA) procedures with 40 Mako TKA procedures showed that robotic procedure led to decrease in post-operative pain, requirement of analgesics and physical therapy along with 26 % reduction in hospital stay .Tsolution One developed by THINK surgical is a CE marked and an FDA approved TKR or TKA surgical platform . It consists of two subsystems viz. TPLAN, a 3D preoperative planning workstation and TCAT, a computer-assisted tool. TPLAN enables a surgeon to plan positioning of the implants with respect to the 3D anatomy model of the patient. The other subsystem, TCAT, consists of an electromechanical arm and an arm base. The base consists of controller, monitor, software, pedant control and other tools . During surgery the surgeon registers the anatomical position with autonomous TCAT robotics system, and it performs the bone cutting actively under the supervision of the surgeon. As of early 2020, more than 550 TKA procedures had been performed globally using Tsolution One system . Think Surgical in partnership with Sagentia Innovation developed TMINI miniature robotic system, one of the most recent FDA approved 84ubmillimet systems for TKA surgery. It consists of TPLAN, Tnav, an optical tracking navigation control and Tmini, a handheld, wireless robotic device. TPLAN aids a surgeon in implantation of knee components by enabling creation of 3D models using CT images. The system automatically compensates the surgeon's hand movements for locating bone pins using optical tracking. Following this, the mechanical cutting guides are connected to pins mounted on bones allowing the resection of bones subsequently. Corin developed Omnibotics, an FDA approved, and CE marked robotic system for TKR or TKA procedure. It consists of a workstation, an OMNIBot cutting guide and a robotic ligament balancer called BalanceBotfig 1Before starting the surgical procedure, the surgeon checks the range of motion by attaching several sensors that are tracked by the tracker on the workstation. The BalanceBot enables the surgeon to measure tension in the soft tissue to better plan the implant placement. The system has imageless bone morphing

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technology that aids in building a 3D representation of the joint. Based on this information, the computer calculates the sizing and alignment of the implant. Once the plan is ready, based on this pre-operative plan bone resection is performed by surgeon using the robotic OMNIBot cutting guide which aligns itself automatically, post which tibia is reshaped. Once all bones are prepared, implants are positioned. After the procedure is completed, the surgeon uses the BalanaceBot again to measure the balance of the ligaments and check whether the joint is stable or not. The sensors are used again to check the range of motion. As of March 2020, 25,000 TKA procedures have been performed using OMNIBotics which includes 5000 cases where BalanceBot was used for ligament balancing . As per several 85submillimet studies performed in Europe for TKR, it was observed that Omnibotics group had higher Knee Society Scores (KSS) than manual arthroplasty. Significant improvements were also observed for WOMAC (Western Ontario and McMaster Universities Osteoarthritis) Pain, Stiffness, and Function and SF-12 (Short Form Survey) Physical Scores . Zimmer Biomet developed ROSA Knee system , an FDA approved robotic platform for resection of bones and to assist in positioning of implant during TKA. It consists of a robotic unit that has a robotic arm and an optical unit. Each unit consists of a touch screen. Surgeons use software to plan the positioning of an implant and its size. Both units are located on each side of the operating table. Based on the preoperative plan, robotic arms are positioned in a way to fix the location of a jig at the appropriate location and then pinned to the bone . Once it is fixed the surgeon performs the resection. Zimmer Biomet also developed a similar system ROSA Partial Knee system for partial knee arthroplasty (PKA) and ROSA Hip system for THA. As per multiple studies comparing ROSA knee TKA with manual procedure, it was shown that at six and twelve months interval group that underwent robotic procedure had higher Forgotten Knee and Oxford Knee scores along with less pain . Smith and Nephew developed Cori Surgical System , a handheld surgical robotic instrument for TKA and Unicompartmental Knee Arthroplasty (UKA). It does not require preoperative image rather an optically tracked tool paints over the anatomy to generate a real time 3D image of the bone. Optically tracked jigs are used to hold the anatomical site for accurate tracking. Once the anatomical area is mapped a surgeon can utilize Cori, an optically tracked burring tool (i.e., a precision milling tool) to remove bone from the target site. The burring tool tip has a retractable sleeve which protects the bone and comes out and covers the burring tool tip to avoid accidental damage to bones. Virtual boundary tracked by the optical tracker relative to the anatomical site facilitates this procedure. Navio , a handheld surgical system, similar to the Cori, is another CE marked and FDA approved robot developed by Smith and Nephew for TKA, patellofemoral arthroplasty (PFA) and UKR. A randomized controlled study by Adamska et al. Compared robotic TKA by CORI and NAVIO surgical system with manual TKA and concluded that both procedures reported satisfactory results, in turn implying that robotic method does not necessarily have compelling enough advantage compared to manual, particularly considering the cost incurred and the total surgical time. The 85submillimetr company of Johnson & Johnson, DePuy Synthes developed VELYS , an FDA approved robotic assisted solution for knee replacement surgery. It consists of a satellite station and a base station. Satellite station consists of a robotic assisted device, touch screen and a transfer mechanism. The base station consists of a camera, touchscreen, and footswitch and consoles that run various applications and drive the robotic device. The camera tracks the position of the bones, the robotic device, and instruments through optical markers. Prior to procedure the transfer mechanism holds the robotic device while during the surgery the robotic device is positioned along the operating table rail by the satellite station. The surgical robot aligns the cutting tool real time using optical markers mounted on anatomical site and the robot. Currently, for the VELYS system, a non-randomized clinical trial of 200 participants is underway in United States, results of which are expected by end of 2023 . In a separate study, Clatworthy presented data from a limited cohort for one-year results . The limited data showed high satisfaction by patients and 85submillime outcome scores. Monogram Orthopaedics developed a robotic system for aiding surgeons during knee replacement surgery. It consists of a 7-DOF robotic arm with a reach of 1.3 m. It enables the surgeon to perform complex tasks while using its flexible motion feature. The robot has integrated force and torque sensors for safety purposes and collision detection. The system comprises

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of a high efficiency rotary cutting system that can reach tiny areas. It can be tracked in real time due to its closed loop design. A navigation system, part of the overall robotic system offers real time imaging while following a pre-scanned analysis of the knee.

Fig. 1. OMNIBot robotic system includes a workstation, an OMNIBot cutting guide and a robotic ligament balancer BalanceBot. Figure reproduced with permission from Shatrov et al.

fig-1

2.2. Neurosurgery

Medtronic developed Mazor X Stealth Edition, an FDA approved robotic surgical guidance system for spine surgery (Fig 2). It consists of a workstation that includes a touchscreen control panel, system hardware components and a storage system for robotic guidance system. The guidance system is comprised of a table mounted arm, a control panel for the surgeon and a navigation system. A plan is prepared by the surgeon based on the prior CT scan or an O-arm scan during the surgery. The navigation system maps the operating field. Further, patient scan is performed, and each vertebral body is registered. The robotic arm moves according to the trajectory based on prior plan. Once position is fixed the required procedure is performed using the instruments. Stealth navigation, part of the system, allows real time visualization of implants and instruments. Several clinical studies performed using Mazor system showed high accuracy, increased reproducibility & predictability, significant reduction in time used between pedicle screw placements, and on an average 2.6 days shorter stay compared to open hand procedures . The Mazor X platform also received CE mark for the European market in 2017 .ExcelsiusGPS , by Globus Medical is an FDA approved and CE marked robotic system developed to assist with the spine surgery. The system utilizes preoperative & intraoperative CT and fluoroscopic images of the patients including a dynamic reference frame and camera for real time guidance of pedicle screw positioning. It consists of a foot pedal controlled robotic arm that is activated by the surgeon and positioned based on the pre-planned trajectory . Once the arm position is fixed, the screws are manually placed by the surgeon. The system optically tracks the robot and the patient position using optical trackers mounted on them. Vardiman et al. Reported the data from first 56 cases of pedicle screw placement using Excelsius GPS system and 97.7 % accuracy was observed. In these 56 cases, 348 screws were placed using this system, out of which only 9 had to be repositioned implying a success rate of 97.4 %. Excelsius GPS Cranial Solution also has an FDA approved robotic solution for cranial surgery. It can perform common and complex stereotactic procedures such as biopsies, stereo electroencephalography (SEEG). This system is broadly similar to the spine robot. One of the advantages with cranial solution is that preoperative MRI and CT are automatically merged for planning and navigation, unlike the spine robot which is based on CT. CUVIS-spine is an FDA and MFDS (Ministry of Food and Drug Safety), South Korea, approved, CE marked spine surgical robot system developed by CUREXO, a South Korean company. It consists of three parts viz. a robotic arm, a main console, and an optional staff console. The robotic system guides pedicle screw according to plan. Preoperative plan is generated based on pre surgical images for the target point, entry point and the route of the pedicle screw. A robotic arm acts as the positioning device for the pedicle screw insertion during the surgical procedure. An optical tracker tracks the patient and the surgical arm in real time for dynamic tracking. Both Excelsius GPS and CUVIS-spine have a force-controlled motion enabled controller to position the robotic arm and display the instrument position in real time . ROSA ONE Brain by Zimmer Biomet is an FDA approved surgical robot used for brain biopsy, SEEG, Deep Brain Stimulation (DBS) and endoscopy. The ROSA robotic arm acts as a gross positioning system and can be used for multiple minimally invasive brain interventions. The system uses a fixed fixture with the patient head and registers its

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position. Generally, the skull has a section removed so that surgeons can place electrodes in the brain, but ROSA burrs small holes for precise placement of instruments. It generates a 3D model of the patient's brain from multiple CT scans stacked together to create a preoperative plan. It uses another extension to support the patient's head with a stereotactic frame that has optical markers. The 6-dof robotic arm provides guidance, depth control, and speed control for the operating tool. ROSA is equipped with haptic feedback and will restrict placement of tools according to the preoperative plan. A standard master device communicates the preoperative plan through tele-manipulation; however, the robotic arm is equipped with force sensors to allow surgeons to adjust the arm manually. Several clinical studies have been performed and published using ROSA ONE Brain system since its introduction. One such study by Liu et al. evaluated the accuracy of lead placement in DBS between 2012 and 2016 for 144 patients. The methodology involved measurement of radial error (RE) and it was shown that no statistical difference was observed. It was shown that sub 87ubmillime accuracy was achieved for robot-assisted DBS . ROSA One Spine is Zimmer Biomet's FDA approved spine surgical assistive device, where the robotic arm facilitates the surgeons to perform thoracolumbar minimally invasive and complex spine procedure by utilizing the robotic arm as a positioning device for the surgical tools. Cheninetal. Evaluated the accuracy of pedicle screw placement using ROSA Spine under the guidance of fp CT and it was observed that out of 110 screws, 91.8 % were placed completely within the pedicle. Monteris developed Neuroblate , an FDA approved minimally invasive robotic system for Medical Resonance Imaging (MRI)-guided laser ablation for brain. The system primarily consists of laser probes, robotic probe driver, platform for attachment to MRI table, and a control workstation and is used with stereotaxic frames and systems for patient stabilization. It begins with a preoperative plan to determine the size and location of brain tissue that needs to be ablated. The stereotactic head frame is integrated with the patient carrier so that the patient can be transferred from the Operating Room (OR) to the MRI scan room. The NeuroBlate driver and probe are attached to the patient's skull and MRI scans provide intraoperative guidance of the laser probe during ablation. LAANTERN (Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System Trial) is one of the largest studies that has been sponsored by Monteris where up to 3000 patients were enrolled at multiple centers over five-year period, starting 2015 . One of the first studies published through this by Groot et al. Studied "efficacy of LITT (laser interstitial thermal therapy) for newly diagnosed and recurrent IDH wild-type glioblastoma" with final inclusion of 29 patients for new and 60 for recurrent. It was observed that in the newly diagnosed category median OS (Overall Survival) was similar to conventional surgical resection. It establishes viable solutions for patients who have tumor that either can't be operated upon or resected. Neuromate , an FDA approved robot by RENISHAW is used for DBS, SEEG, Neuro endoscopy, biopsy. Preoperative MRI and CT data is registered to the patient using the Neuromate registration module and intraoperative CT scan. Neuromate can perform stereotactic frame-based surgeries as well as frameless surgery. A laser tool is used to mark entry points on the patient's skull and once marking has been completed the laser tool can be replaced with the tool holder on the robotic arm. Drilling alignment is performed with Neuromate acting as a guide. Guide tubes and stylets can then be inserted, and perioperative scanning can confirm depth and location before moving onto electrode insertion. The robotic arm operates semi-autonomously while following a preoperative plan to mark entry points and aid surgeons in alignment of tools. Yasin et al. Reported their experience from 102 frameless stereotactic biopsies performed using Neuromate between March 2013 and April 2018. It was shown that Neuromate robot-assisted frameless stereotactic biopsies had a diagnostic yield similar to frame-based while encountering complications at comparable rates. Based on this data, the institution where these procedures were performed use Neuromate for all stereotactic neurosurgeries. AiM Medical Robotics developed a portable, MRI compatible, intraoperative robotic device for neurosurgery to address functional brain disorders such as Parkinson's, epilepsy and cancer. It can provide precise positioning of tools for neuro specific surgeries under MRI environment, letting surgeons take the advantage of imaging for targeting the site. Remebot is China's first home-grown minimally invasive neurosurgical robot approved by national medical products administration

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(NMPA), China, for deep brain surgery . It's a six-axis robotic arm that provides enhanced precision and flexibility of motion. It decreases the trauma caused due to brain surgeries, thereby faster recovery time for patients. The robot is equipped with MRI/CT compatible imaging system and is able to provide automatic positioning based on the imaging data. This feature helps surgeons to locate the diseased site. Through AI technology, the robot is capable of image identification, image processing, mapping accuracy and thereby provides an enhanced and optimized plan for surgery. Brain biopsy, implanting electrodes, operating for brain hematoma are examples of surgeries performed using Remebot. Li et al. Performed a retrospective study of 33 patients, divided into groups, and compared the safety, efficacy and accuracy of frameless brain tumor biopsy performed using Remobot with the frame-based procedures. No significant difference between diagnostic yield and complication rate was observed. It was concluded that both methods are safe and efficacious with Remobot having the advantage of shorter total time for procedures along with its wider application in young pediatric patients. Brainlab developed a 7-DOF robotic positioning arm Cirq to assist surgeons during Spinal and Cranial surgery. It is mounted on the OR table and controlled through a foot pedal. The arm can be manually moved as long as power is provided to the system. Buttons on the device can be used to freeze the position of the arm when holding and positioning tools are used for non-motorized instruments. Software such as Kick and Curve can be used for navigation with a tracking attachment module as well as Airo for intraoperative imaging. The foot pedal is a custom master device with alignment controlled by a small dial, and advancement and retraction of the end tool controlled by large buttons. It is an FDA approved and CE marked system. Chesney et al. Performed a retrospective study of 84 patients who underwent lumbar fusion surgery where placement of 714 transpedicular screws was performed using Cirq arm. The authors concluded that the Cirq robotic system demonstrated efficacy and safety for these procedures, but it still requires other comparative studies.

Fig. 2. Mazor X Stealth Edition Robot. Figure reproduced with permission from O'Connor .

fig-2

2.3. Dental surgery

Yomi by NEOCIS is an FDA approved robotic system for dental surgery. At the start of the procedure, Yomi constructs a preoperative plan from CT scans of the patient's mandible, maxilla, and teeth. Its software allows dynamic changes to the operation plan while Intra-operative tracking with an assistive robotic arm and real-time 3D graphics provides guidance for the surgery. The robotic arm also maintains alignment, position, and depth of operating drill. Yomi is equipped with haptic feedback to prevent deviation from the surgical plan and breaching the planned depth. Talib et al. Presented a report where they used and assessed the capabilities of Yomi by using the robotic system to position an implant in a 48-year-old woman who was missing maxillary left second premolar. The physicians were able to place the implant without any issues and observed quick healing. The patient also reported absence of any discomfort during the procedure demonstrating the advantage of haptic robotic procedure for placement of dental implants.

2.4. Generic osteotomy

CARLO by AOT is an autonomous robotic surgical device for Cold Ablation Robot-guided Laser Osteotomy (Fig 3). It is the world's first CE certified robotic surgical device that can cut bone with laser technology. The system includes an Er:YAG laser head with a tactile robotic arm (LBR Med from KUKA), a 3D navigation system and software for preoperative planning and intraoperative use. Carlo can perform cold ablation and cut bones in any desired shape. Due to the system's ability to use cold ablation method, the ablated bone structure stays porous and functional and as a result the

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tissue grows back and heals quicker . The laser head is mounted on the LBR med tactile medical grade robotic arm which ensures safe movement compatible for collaboratively working with human .Holzingeretal. Assessed CARLO for clinical application and reported the results from orthognathic procedure on 14 patients for midface osteotomy. Surgeons reported that they did not encounter any intraoperative complications. Also, all osteotomy procedures were within 0.80 mm average deviation with mean time of 4.6 min for robot setup at the start of procedure. Tinvai Medical technology, a China based medical company developed two robotic devices for trauma and spine surgeries – TiRobot andTiRobot-II . Both devices can operate on spine, pelvis, femoral neck, shoulder ankle and hand and have a robotic arm which acts as a gross positioning system for the 89ubmillimet tools for surgical procedure. The robotic arm can move precisely according to the pre-planned position for accurate positioning of the tool. An optical tracker tracks the robotic arm and tool for precise positioning. It has been approved by National Medical Products Administration (NMPA), China. As per Tinavi website, by September 2022, over 30,000 orthopedic procedures have been performed using TiRobot system distributed across 150+ medical institutions in China. It enables 89ubmillimetre precision for all spine and trauma related minimally invasive surgeries .

Fig. 3. Cold Ablation Robot-guided Laser Osteotome (CARLO) comprising of a laser head with robotic arm and navigation system. Figure reproduced with permission from Ureel .

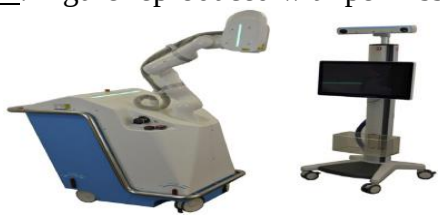

fig-3

3. Robotic surgical systems for soft tissue

3.1. Abdominal surgery

Avatera medical developed Avatera , a CE marked robotic system for minimally invasive surgery (MIS). It consists of two units: a surgical robot and a control unit. The surgical unit consists of four robotic arms that control instruments and endoscope. The control unit is comprised of flexible seat for the surgeon, an eyepiece, manual haptic input devices and footswitches. The eyepiece was designed so as to not obstruct the surgeon's mouth and ears to avoid any miscommunication between the surgeon and the team. The image displayed by the system exactly matches the human eye's natural field of view. In May 2022, Avatera medical reported the successful clinical application of the Avatera system in ten humans for removal of prostate and kidney tumors . These procedures were performed at the University of Leipzig Medical Center. As a result of this success, the system is being installed at more number of medical centers across Europe. Asensus surgical developed Senhance Surgical System, an FDA approved and CE marked robotic platform for laparoscopic procedures. It consists of independent robotic arms with a base platform for each arm and a control station equipped with a monitor screen to allow the surgeon to operate in a relaxed position. The system is active as long as the foot pedal switch is pressed, and the system freezes otherwise. It uses haptic feedback and a custom master device that allows independent control of the slave devices. Eye tracking technology is used for endoscopic control and an open console design allows staff to observe the surgeon's actions and communicate during the operation. Several number publications have reported clinical cases that used the Senhance surgical system. Few applications include colorectal, gynecology, pediatric etc. As latest as 2022, Holzer et al. Reported application of the system in pediatric robotic pyeloplasty on a year and half old girl. It was one of several examples of successful application of the Sehance robotic system. There was no recurrence of ureteropelvic junction obstruction after 6 months and normal growth was observed for the patient. Canady Surgical system developed by US medical

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innovation (USMI) is a laparoscopic surgical robot to assist with MIS. It has been designed such that it can also be used for open surgeries. The system is equipped with three robotic arms which act as a positioner for the laparoscopic tool and the endoscope and has a 'voice command' feature that frees up the surgeon and assistant to dedicate their resources towards surgical and other tasks. The company has also developed flexible laparoscopic tools such as FDA approved, Canady Flex RoboWrist for laparoscopic operation that can be utilized with this robot. Revo-i, developed by Meere company Inc., South Korea, is a surgical robot for laparoscopic procedures. It consists of a master console, operation cart and a vision cart. The master console consists of a 3D viewer, touch pad, control arm and foot pedal while the operation cart has of four arms where one of the arms is equipped with a 3D camera. The vision cart that has a touchscreen monitor enables visualization of the whole surgical procedure. The operating procedure is customizable due to several different end effector attachments. Revo-i has the benefit of haptic feedback. It has been approved by MFDS, South Korea. Lim et al.Studied the safety and efficacy of Revo-i for cholecystectomy through phase I clinical study performed on 15 patients. Intraoperative safety was the primary outcome evaluated while 30-day postoperative complication and patient satisfaction was the secondary outcome. The surgeons observed no intra or post-operative complications. Also, most patients reported satisfaction with the procedure performed using Revo-i. AutoLap developed by MST, is an FDA approved and CE marked system designed for holding and maneuvering laparoscopes or endoscopes during MIS. It consists of a processing unit consisting of all electronic components, a base unit, mounted on an OR bed, and a laparoscopic unit. The surgeon controls the laparoscope through a command unit. It consists of an autonomous endoscope that tracks the surgeon's standard laparoscopic tools and maintains endoscope in the field of surgeon's view. Titan medical developed a master-slave robotic system Enos that enables surgeons to perform the surgery through a single incision on the body. In the past it was referred to as Single Port Orifice Robotic Technology (SPORT) surgical system. The system consists of a surgeon workstation, an open console with a monitor, and a patient cart consisting of a single support boom holding a central unit (CU). During docking, a camera insertion tube (CIT) is connected to CU. CIT is made of 3D high-definition camera and a light source. The system has two multi-articulated instruments that are inserted through CIT. Micro Hands by Shandong Wego Surgical Robot Co. is a surgical robot developed by multiple universities in China in collaboration with their government. It is a master and slave type robot consisting of a surgeon console, a patient console, and other accessories. The surgeon console has several parts that include an image display device, left and right master arms, stand columns, armrest, and a control system. The control system processes the information received because of operation of the master console by the surgeon. The patient console has a suspension arm, lifting column, two slave arms, pedestal, and an electrical control system. The arms enable positioning of the laparoscopic tools and are inspired by origami folding style that require less space and have better dexterity. They are mounted on a single column movable base to consume less space. Yaoetal.Published the results for feasibility and safety of Micro Hand S from a Phase I clinical study where 81 patients underwent general surgery. Surgeons concluded that the system was reliable and safe for clinical applications, but the study had limitations such as small sample size, short follow up time etc. Considering these limitations, it was concluded that large, prospective, randomized controlled studies are required to further confirm the results from this study. Hugo RAS system is a CE marked, master-slave type, minimally invasive robotic assistive surgical system developed by Medtronic. A robotic arm equipped with custom end effector for laparoscopic tool manipulation is mounted on a single column on a cart with wheels underneath. The master can control up to four of these seven DOF arms and each arm can be equipped with a laparoscopic tool or an endoscope. The surgeons wear 3D glasses for the 3D view of the operation site and a tracker tracks 3D glass motion on the surgeon's head to track the video. Medtronic announced the first clinical trial in United States using Hugo RAS system in December of 2022. This is a part of ongoing clinical trials named Expand URO where 122 patients will be enrolled with the aim to study and evaluate the safety and performance of the Hugo RAS system for urological procedures .MIRA , a Robotic Assisted Surgical (RAS) device developed by Virtual Incision is a single port incision minimally

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invasive master and slave device. The slave device consists of two articulated miniaturized instrument arms and an integrated camera that can articulate to triangulate along with the arm. The master console has two monitors: one to view the surgical procedure and the other provides 3D visualization of MIRA. MIRA is going to be deployed in international space station (ISS) through a NASA funding to explore the possibility of utilizing such technologies in space. Virtual incision reported in May 2023 submission of its De Novo request to United States FDA. The purpose of this submission is to seek the authorization of MIRA surgical system for marketing for bowel resection procedures . The data from the first clinical trials performed for the purpose of investigational device exemption (IDE) were also reported in 2023 . The system was used to perform right or left colectomy on 10 patients consisting of 7 males and 3 females. No adverse events and intraoperative or postoperative complications were observed, and it was concluded that the system is safe and effective for the intended procedure .Vicarious Surgical Robot developed by Vicarious Surgical is a single port minimally invasive surgical robot which utilizes a single incision of 1.5 cm in the abdomen to perform laparoscopic surgery. The single port surgical device holds two human inspired arms and a camera. The arm has 9-DOF that is similar to DOF of upper body movement of a surgeon . For this master and slave type device the camera follows the surgeon's head for better visibility inside the abdomen and displays it on the master console. The advanced stereoscopic camera can rotate 360° in both directions for superior vison and 3D immersive experience. Vicarious Surgical also has a Virtual Reality (VR) headset for the surgeons which will be rolled out in the future version. The Anovo Surgical System byMomentis surgical is a master-slave system and FDA approved for Transvaginal Hysterectomy procedures. It is designed to replicate the motion of a surgeon's arms with wrist, elbow, and shoulder joints. The miniature robotic arms have human level dexterity, flexibility and 360° of articulation feature that provides optimal access, working angles and enables obstacle avoidance. It permits multiple instruments to be introduced to the body through a single port. Distalmotion developed an open platform robotic system, Dexter for robotic suturing and dissection tasks in a laparoscopic surgery. It consists of an open surgeon console and two patient carts positioned beside the operating table. Each cart is installed with an arm. The robot has a modular design and permits quick removal and repositioning of the two robotic arms. Its open architecture allows the surgeon to promptly switch between robotic approach for suturing and traditional laparoscopic approach for dissection. The standing laparoscopic mode can be used for stapling and vessel sealing tasks at the start and end of surgery. One of the major advantages of this system is the ability to leverage existing technologies within a hospital to perform the required surgery due to its open platform design. Dexter robotic system is CE marked. Thillouetal. Reported the experience from ten robot-assisted radical prostatectomy and lymph node dissection procedures performed using the Dexter system. Surgeons were comfortable using the system even for those without any experience of robotic surgery in the past. They attributed this to the adaptability of the system to existing setups. The device performed as intended without any incident of complication during the surgery. SOLOASSIST II byAKTORmed is an FDA approved and CE marked robotic endoscopic control system for MIS. It provides vibration free stable positioning within a unique range of movement and has manually adjustable axis on the distal arm that allows exceptional flexibility. Joystick feature of the system allows intuitive operation while voice control feature executes surgeon's commands with precision. It is compatible with most common operating tables and endoscopes. Another cost-effective version of the system by the same company is SOLOASSIST IIs , which is an entry level model especially suitable for unplanned emergency procedures. This system offers a set of sterile disposable components to enable immediate use of the system without any prior processing. SOLOASSIST IIs, a CE marked system, has voice control feature but does not have the intuitive joystick control feature. Ohmura et al. Studied the efficacy of joystick controlled SOLOASSIST system in laparoscopic surgery. Several factors such as operative time, setup time, number of participating surgeons etc. were investigated for laparoscopic cholecystectomy cases performed before and after introduction of the system. Overall, it was observed that the system is useful for both elective and emergency procedures. Further, shorter procedure times were recorded along with a smaller number of doctors that were

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required while no significant difference in blood loss and setup time was observed. Emaro developed by RIVERFIELD is the world's first pneumatic endoscopic manipulator developed in Japan. The manipulator moves the endoscope based on the head motion of the surgeon to map their field of view. An Inertial measuring unit (IMU) is mounted on the surgeon's head to detect its motion. The endoscope can also be operated with a foot pedal, manual switch and console .Riverfield also developed IvyA1 , a pneumatically operated robotic endoscope holder which can assist in laparoscopic surgical procedure. Yoshida et al. Reported their experience with EMARO during extraperitoneal inguinal hernia repair procedure on a 77-year-old man. Surgeons did not encounter any intraoperative complication and reported that the robotic procedure was comparable to the traditional manual surgery but has the advantage of enabling execution of solo surgery. Freehand developed two collaborative robots (cobots) – Vista and Panorama , each for specific type of surgeries. Vista has been designed for urological, upper gastrointestinal and bariatric surgeries while Panorama for gynecological, colorectal, and thoracic surgeries. They are CE marked and FDA approved cobots. The primary aim is to eliminate the requirement of an assistant for holding a camera during the surgery. The camera is held through a 3-joint modular design arm which is a part of robotic motion assembly providing steady platform. Further, it consists of Instinctive Motion Control (IMC) for reliable and error free interface for the surgeon. IMC is comprised of a headset to choose the direction of motion based on surgeon's motion. The direction of motion appears on an indicator unit. To activate the motion the surgeon presses a footswitch. The basic structure of both Vista and Panorama is same except that they have different range of motion due to specific surgical requirements. EndoMaster Pte Ltd, based in Singapore, developed EndoMaster EASE system, a robot-assisted surgical system that allows surgeons to perform incision-less surgeries for minimally invasive endoscopic surgery. As a feature of the system a surgeon can control two robotic arms that act as an extension of surgeon's arms to perform surgical procedures with maneuverability and precision. This robotic endoscope's design was inspired by the crab claw. One of the primary clinical applications of this system has been identified as treatment of gastrointestinal cancer using endoscopic submucosal dissection (ESD) due to its less invasive nature. Owing to its complex shape, executing ESD in colorectum is technically challenging due to the risk of colonic wall perforation. Endomaster EASE system simplifies it due to the feature of tissue retraction and superior visualization. As per early clinical studies performed on 6 patients, all had successful colorectal ESD, and no adverse event of perforation was observed. These early results have proven the suitability of system for ESD. This surgical instrument can remove early-stage stomach cancer without leaving scars . A Honk Kong based startup company, NISI, developed Novel Surgical Robotic System (NSRS) , a miniature surgical robot for natural orifice surgical procedure. This device can be inserted through natural orifice such as the rectum or the vagina to perform abdominal surgeries. It has two 10-DOF arms equipped with surgical tools folded inside its body, includes haptic feedback for the surgeon for precision sensing, and has a high definition 2D, 3D camera for precise workflow. It's a highly portable system that could also be mounted on a surgery table. The developers have defined surgeries related to abdominal and pelvic region as the target procedure for the NSRS system .Medicaroid, a Japan based company developed hinotori surgical robotic system for laparoscopic surgery. It has received the Japanese Ministry of Health, Labor and Welfare (MHLW) regulatory approval and is based on the concept of “co-existence of humans and robots”. The system consists of a surgeon cockpit, an operation unit, and a vision unit. Operation unit has several arms that have compact design, like human arms, with the objective of reducing interference between arms and an assistant or between the arms themselves. The surgeon unit has been designed ergonomically to maintain proper posture during surgeries and reduce the physical toll and stress taken by the surgeons. High-definition 3D images are available through the Vision unit on the stereoscopic viewer of the surgeon unit. Hinata et al. Reported the results from safety and efficacy study through preclinical and clinical evaluation performed using hinotori system. Preclinical studies were performed on porcine and cadavers. It was shown that complex procedures such as vesicourethral anastomosis in porcine and radical prostatectomy on cadavers took similar time as the daVinci

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system. Clinical studies were performed on 30 patients to evaluate the safety of the system through radical prostatectomy procedure. The system was shown to be safe as the adversarial events and device errors were below 15 %, a preset threshold value.

3.2. Bronchoscopy

Monarch platform is an FDA approved device by Ethicon, designed to perform therapeutic and diagnostic procedures for bronchoscopy. This teleoperated endoluminal robot can navigate inside the human body, take images, and treat without making any incision. It utilizes a custom controller allowing the surgeon to directly control the endoscope while they navigate the lungs. Visual feedback and image display is provided from the endoscope for navigation purposes. The feed rate and navigation can be controlled by the surgeon from the visual platform. Monarch platform has been used to treat more than 20,000 lung cancer patients by now. Recently, application of the platform to treat kidney issues due to stones is also being explored . University of California, Irvine reported the first successful clinical trial for robot-assisted electromagnetic guided percutaneous access and mini-percutaneous nephrolithotomy using the Monarch platform.

Ion endoluminal system by Intuitive is an FDA approved robot-assisted surgical platform for minimally invasive peripheral lung biopsy (Fig 4). Ion is flexible with the ability to articulate 180° in all directions allowing navigation far into the peripheral lung. This robotic bronchoscopy platform has an ultrathin and maneuverable catheter that provides precision by delivering accurate biopsy of hard-to-reach nodules even outside of the airways. With the use of fiber optic sensing technology, the system has unique sensing capability and stability. This technology allows maintaining the active robotic control of the catheter position also correcting the unwanted tip deflection. Simoffetal. Reported the results from a multicenter study performed using Ion endoluminal system to evaluate safety and procedural outcomes during robot-assisted bronchoscopy. 60 patients across multiple hospitals underwent biopsy and in total 67 nodules were targeted. 97 % biopsy completion was recorded with no incident of pneumothorax or airway bleeding. These favorable results showed that the system can be used to drive catheters safely in proximity to the target for biopsy.

Fig. 4. Ion Endoluminal System consisting of a cart and a controller. Figure reproduced with permission from Reisenauer .

fig-4

3.3. Cardiovascular surgery

Niobe and Vdrive , FDA approved systems developed by Stereotaxis, have been designed for performing cardiac ablation. These are a combination of Stereotaxis' products that work together to guide a catheter that ablates heart tissue which is causing arrhythmia. Niobe uses magnets on both sides of the body to navigate the Vdrive catheter up to the heart. The magnetic field controls the end of the catheter to precisely perform the ablation of the heart tissue. One of the advantages of the Stereotaxis system is that it reduces exposure of x-ray fluoroscopy to the patient and the staff compared to the manual ablation. Vdrive system consists of three different components viz. V-Sono for Intracardiac echocardiography (ICE) catheter manipulation, V-Loop Variable Loop Catheter Manipulator for circular mapping catheters (CMC) and V-CAS Catheter Advancement System for magnetic catheter body and fixed curve sheath manipulation. Nölker et al. Studied and compared clinical performance of V-Loop system for remote CMC manipulation during electrophysiology procedure with the conventional manual navigation. This study consisted of 120 patients who were

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supposed to undergo CMC study to be followed by pulmonary vein isolation (PVI). The patients were randomly allocated in 2:1 proportion representing remote:manual navigation. The effectiveness was compared based on successful navigation to the targeted PV and recordings of PV electrograms. It was shown that the robotic remote navigation performs similar as far as safety and effectiveness is concerned when compared to manual procedure. Vdrive has also received CE mark while Niobe has been approved by MHLW, Japan. CorpathGRX byCorindus, an FDA approved, and CE marked system operates on Percutaneous Coronary Intervention (PCI) and Pulmonary Vein Isolation (PVI). It uses robotic control for guide catheter, guide wire, and balloon stent catheter to treat heart arrhythmia. A surgeon operates the device from the radiation shielded cockpit inside the OR after manually starting the intervention from the groin. The OR staff will position Corpath attached to an extended reach arm so the surgeon can attach the manual set up at the patient's groin. Guide wire can be advanced, retracted, or rotated from the joystick on the control console through tele-manipulation. Smitson et al. Reported the safety and efficacy of the Corpath GRX system through a clinical study that enrolled 40 patients. These patients had shown obstructive coronary artery disease and indications for PCI. The study was evaluated based on clinical success and device technical success. Clinical success of 97.5 % along with 90.0 % of technical success was achieved. It was concluded that the Corpath GRX system is safe and effective for robotic PCI and enables high clinical and technical success rates. Corindus also developed Corpath GRX Neurovascular Robotic System for neurovascular interventions and is a CE marked system. Recently there has been a report from clinical trials performed at a global scale where 117 patients underwent robot-assisted neurovascular aneurysm embolization, claimed to be first such study in the world. It was performed using the Corpath GRX Neurovascular system where 94.0 % technical success and 95.7 % clinical success was achieved. This achievement has been noted as a transformative change in the field of neurovascular intervention . R-One , a CE marked robotic platform developed by Robocath has been designed for interventional cardiology to treat coronary artery disease through PCI. It includes a guide wire feeding system that is connected to a robotic arm to manually position it. The robotic arm is integrated on a table platform that the patient rests on. The cardiologists manually prepare the patient's entry point at the groin and load the guide wire into the system. The surgeon sits at a shielded control console and navigates using two monitors. Once the lesion has been identified, the stent can be loaded and progressed along the guide wire with the joystick. The future versions will be further developed to treat peripheral artery disease through PCI and stroke using the mechanical thrombectomy treatment. In May 2022, Robocath presented the results from clinical trials named R-Evolution study where safety and efficacy of R-One was studied during coronary angioplasty on 62 patients spread across several centers. 100 % clinical success was reported as there were no major complications reported at 30 day follow up. Further, more than 95.0 % technical success and 84.5 % reduction in radiation exposure was reported]. The Amigo Remote Catheter System (RCS) robotic system developed by Catheter Precision, has been designed for heart surgery. It is attached to the OR table and includes a catheter system that sits on a track above the patient. The catheter advancement and retraction are done by linear actuation towards or away from the patient. An interatrial trans-septal puncture is performed to insert the catheter and once inserted it can be rotated along with end deflection to stir the catheter to the site of operation. Amigo RCS received de novo approval from FDA in 2014 for right-sided radiofrequency catheter ablations. It was shown through clinical studies that success rates for high acute and chronic ablation were similar to manual procedures with similar duration of fluoroscopy and procedure time. There was a significant advantage in terms of decrease in radiation exposure while using the Amigo system.

3.4. Hair restoration

VENUSCONCEPT developed ARTAS iX , an FDA approved and CE marked intelligent robotic platform for hair restoration. It consists of a 7-axis KUKA robotic arm, a 44-micron high-definition multi-camera stereoscopic vision system, an advanced Artificial Intelligence (AI) system and a touch screen user interface (UI). The system intelligently selects the grafts from donor area and upon accurate identification and after developing the recipients site implants the grafts. The AI

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system continuously tracks the position, angle, size, and orientation of each hair follicle based on patient motion. A proprietary dissecting punch installed on the arm that has a muti-faceted tip removes sections of healthy hair follicles and grafts the hair by inserting the plugs in the transplant location. The UI enables the physicians to prepare a pre-operative 3D plan for customization and prescribing the recipient area. ArtasiX has also received CE mark and is claimed to be the world's first intelligent hair transplant platform .

3.5. Opthalmic surgery

Preceyes developed by Preceyes BV, a Dutch company is a CE marked micro surgical robotic device to assist with vitreoretinal surgery. It acts like a gross positioning device for the surgical tool and the tool can rotate along the remote center of motion. The device is a master slave device where the surgeon operates a 4-DOF instrument manipulator. It improves the precision of the surgeon's hand by downscaling movement and filtering hand tremors. The robotic instrument is locked in place when the surgeon releases their grip on the controller. Faridpooya et al. Studied the safety and feasibility of using Preceyes surgical system to perform epiretinal membrane (ERM) peeling surgery. 15 patients were enrolled and randomized in ratio of 2:1 proportion (robotic:manual). Surgeons did not record any clinically adverse event satisfying the primary objective. As secondary objectives, overall duration of surgery, best corrected visual acuity (BCVA), central retinal thickness (CRT) and distance travelled by forceps during peeling was measured. It was observed that duration of surgery was more than double in robot-assisted compared to manual, but distance covered by forceps was shorter while improvement in BCVA and CRT was same.

3.6. Otolaryngology

Flex robotic system by Novus assists with oropharynx, hypopharynx, and larynx surgery by accessing the body through the mouth i.e., transoral access (Fig-5). It was also developed for transanal surgery for conditions which require rectal lesion removal and was claimed to be the first miniaturized flexible endoscopic robot with features that allows maneuvering beyond areas that were unreachable through existing endoscopic microsurgery tools. The system consists of two units, viz. a control console and a cart and base along with a flexible robotic endoscope. The control unit has a joystick type haptic controller for precise 3D motion. The base is carried over the cart and enables stable operation of Flex Drive that is controlled through control unit. The Flex Drive robotic arm has a miniaturized, 3D, high definition, reusable digital camera at the end that enables image-based navigation. Flex navigates the body using a flexible robotic scope comprised of an inner and outer mechanism. The instruments are inserted into the robotic system to allow end effectors to treat sites inside the body usually inaccessible. This is a CE marked and FDA approved system. Morino et al. Performed a prospective study on 26 patients which underwent rectal lesion excision with full thickness excision on 14 patients and submucosal excision on 12 patients. Median operating time of 115 min was observed. For six patients the procedure had to be converted to transanal endoscopic operation. Other clinical results such as 30-day morbidity and positive resection margins were recorded including 12 months follow-up. Overall, it was concluded that it's a promising system that needs further technical refinements to improve the clinical results.

Fig. 5. Flex robotic system with (a) console and Flex Drive, (b) Flex Cart and Base, and (c) Flex Drive. Figure reproduced with permission from Morino et al.

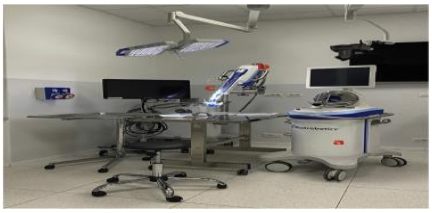

fig-5

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3.7. Urology

Procept BIOROBOTICS developed Aquabeam robotic system, an image guided surgical system for heat-free waterjet ablation of prostate tissue called Aquablation therapy. It is the first FDA approved robotic surgical system for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) by automatic resection of tissue. It uses a high velocity waterjet stream for ablation and tissue removal. The system consists of a console, robotic handpiece, and Conformal Planning Unit (CPU) . To start with, patient is positioned in dorsal lithotomy position following which a trans-rectal US transducer is inserted. The handpiece, a flexible scope is used for trans-urethral access of the bladder. Once the handpiece is registered treatment planning is performed. Post planning, treatment is initiated by pressing a foot pedal. Once the pedal is activated, a pump delivers high-velocity waterjet stream. The depth of penetration can be controlled by adjusting flow rates. Procept BIOROBOTICS reported extensive clinical data on safety, efficacy, and durability of Aquablation therapy using the Aquabeam system. The results were recorded from a multi-year follow up data from WATER (Waterjet Ablation Therapy for Endoscopic Resection), WATER II and OPEN WATER studies which evaluated safety and efficacy of resecting prostates 30–80 mL, 80–150 mL and 20–150 mL respectively. Both with regards to safety and efficacy, low rates with irreversible complications and durable results were observed across the whole range of prostate shapes and sizes . EDAP developed Focal One , an FDA approved, semi-robotic High Intensity Focused Ultrasound (HIFU) device for prostate ablation. It consists of computer hardware, image fusion software and trans-rectal US probe. Based on prior MRI and the US imaging and the fusion of both, target region is identified after which 3D model of the prostate is created. Once the treatment plan is created, probe is inserted trans-rectally and ablation is performed. Surgeons can constantly examine the ablation process and intervene to update the treatment plan. Hardenberg et al. Reported clinical data from a series of studies on patients that underwent focal HIFU therapy for targeted ablation using the Focal One system. A total of twenty-four patients were enrolled where nineteen were treated using focal and five using zonal HIFU. The follow up involved control MRI/TRUS fusion biopsy, change in Prostate-Specific Antigen (PSA), outcomes and complications reported by patients. 20 patients had biopsy at 12 months out of which 8 had positive biopsy within ablation region. No significant reduction in urinary continence was observed but potency had reduced. The study showed that focal HIFU enables local ablation but has limitations. Further studies are needed with strict follow-up procedures, as described in article, to judge the procedure described for prostate cancer therapy. EDAP also developed Ablatherm, an FDA approved, fully robotic HIFU device for non-invasive prostate treatment. The treatment starts with MRI and ultrasound fused imaging using the trans-rectal probe. Treatment is planned based on the imaging data after which target area is robotically ablated. It consists of a treatment, a control module and a probe that's designed for both imaging and treatment. The system has automatic safety features such as rectal cooling, detection of patient movement and real time monitoring of rectal wall. Chaussy et al. Reported the outcomes from transrectal HIFU therapy performed using the Ablatherm system that involved 65 patients with incidental prostate cancer at 70 years of age. Initial PSA of 4.9 ng/mL was recorded and after therapy, at 1.8 month follow up, lowest value of 0.07 ng/mL of PSA was observed. At mean follow up of 48 months a median PSA of 0.13 ng/mL was recorded. The intraoperative and postoperative side effects were minimum along with mild long-term effects. Overall, the HIFU therapy by Ablatherm has shown great potential after several years of investigation.

3.8. Multiple surgical applications

Intuitive Surgical developed da Vinci , an FDA approved robotic surgical system for MIS. It has three versions viz. da Vinci Xi Fig .6), da Vinci X and da Vinci SP, fundamentally consisting of a surgeon console, a patient cart, and a vision cart. A surgeon, seated at the console, controls instruments and camera that are installed on the patient cart through robotic arms. This console also provides a high-definition 3D view of the anatomy. The patient cart is located alongside the operation bed while the vision cart enables communication between all the components of the system. Clinical applications of the system include cardiac, colorectal, general, gynecology, head and neck, and thoracic surgeries

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while the da Vinci SP is specially designed for single port access surgery. Among the three versions, da Vinci Xi and da Vinci X have also received CE mark while da Vinci SP has received MHLW and MFDS approval. Since its FDA approval, being one of the first systems to do so, there are millions of procedures that have been performed using the da Vinci system. Perfint developed ROBIO EX , a CT and PET-CT guided system for robotically positioning the tools for tumor targeting, placement of tools for abdominal and thoracic interventions. These interventions include procedures like biopsy, Fine Needle Aspiration Cytology (FNAC), drainage and ablation of tumor. The procedure starts with treatment planning by exporting the CT images to the ROBIO EX workstation and determining the target and entry point. After confirmation by the radiologist, plan is forwarded to the 5-DOF axis ROBIO EX robotic arm that autonomously moves to the chosen coordinates. Following this, once the arm is stationary, a bush and bush holder is positioned at the end effector after which needle, or the appropriate tool is inserted . The system has a proprietary registration system called InstaReg that enables device registration within seconds using a simple push of a button. The system comes with several sterile disposables viz. guide adaptor, stabilizer, holder for the needle and a drape for the arm. Abdullah et al. reported their early experience from CT guided radiofrequency ablation (RFA) of liver using the ROBIO EX system performed on 11 patients with total of 17 lesions. The lesion at the farthest distance from skin was located 13.7 cm deep and the closest was at 6.2 cm. All lesions were successfully targeted, and no complications regarding the robotic system or the RFA procedure were reported. It was also observed that the number of needle adjustments needed were smaller and hence lesser procedural time owing to automated device. Overall, high accuracy was observed with a lesser number of adjustments needed. Perfint has also provided an extensive data from clinical studies in performed using ROBIO EX system. These case studies have been classified based either on type of procedure or the organ.

1.

Fig. 6. da Vinci Xi surgical system consisting of arms mounted on a rotating beam. Figure reproduced with permission from Hagen .

fig-6

4. Robotic systems for microsurgery

Medical Micro Instruments developed Symani surgical system, a CE marked robotic system for microsurgery. It's designed for performing open surgeries that need precision and motion scaling. It consists of a console and two robotic arms. The console is comprised of an ergonomic chair and manipulators that can be controlled by a surgeon and a footswitch. To address the complexities of microsurgeries, it has 7–20X motion scaling with tremor filtration features. The hand motion is scaled through the proprietary NanoWrist robotic micro instruments that have 3 mm wrists with 7-DOF. Some of the procedures that can be performed using Symani system include free flap reconstructions, lymphatic surgery, diabetic foot surgery, peripheral nerve repair, reconstruction for congenital malformations. Lindenblatt et al. Reported the first human clinical trials of the Symani system to perform lymphatic surgery on 5 patients that involved 10 robotic anastomosis procedures. The procedure was performed with 10X scaling with visualization either through a 3D system or an optical microscope. Although the first anastomoses procedure took more time, the duration decreased in later ones. The results confirmed the feasibility of the Symani robotic system and was observed to be safe for performing surgery on vessels that are smaller than 1 mm in size. Microsure developed MUSA, a CE marked tele manipulator microsurgery robotic platform. It consists of two master manipulators, robotic arms, a suspension ring, and foot pedals. Master manipulators are attached on both sides of the operating table controlled by surgeons who can be seated on each side. This enables a direct view

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of the operating site. Robotic arms are connected to the suspension ring. The robot has a feature of real time adjustment of motion scaling along with low acceleration and contact forces of the instruments during the surgery. van Mulken et al. Reported the first in-human trials of microsurgery using MUSA robotic platform and compared the data from 25 randomized females that either underwent robotic or manual lymphatico-venous anastomosis (LVA) procedure in breast cancer related lymphedema (BCRL). A total of 14 anastomoses were performed robotically and 26 manually. It was observed that the time taken in robotic procedure is higher but there was a steep reduction as the trials proceeded. Both robotic and manual procedures were done within 115 min. The Quality of Life (QoL) improved in both at 3 months follow up while there was slight improvement in Upper extremity lymphedema (UEL) for robot-assisted group. Overall, robot-assisted LVA in BCRL patients using MUSA system was shown to be feasible and safe.

5. Generic robotic surgical systems

EPIONE is an interventional robotic system developed for oncology by a French company named Quantum Surgical. The system is compatible with any imaging modality and the robot can be utilized with any ablation technology such as radiofrequency, microwave, cryoablation, irreversible electroporation to perform percutaneous ablation. It has a 6-DOF dexterous robotic arm to place the probe with a universal needle guide at the end effector and an optical tracker to track the arm. The robotic system is equipped with haptics and is capable of real time respiration tracking for synchronization for probe placement. The device is CE marked and FDA approved. Baère et al. Evaluated safety and feasibility of the EPIONE robotic system in CT guided percutaneous needle insertion procedure during thermal ablation of liver tumors. A total of 21 patients with 24 tumors were enrolled into the study. 22 lesions were adjudged proper for robotic needle positioning resulting in 95.7 % feasibility rate and among all lesions, needle adjustment was not required in 70.8 % tumors. With regards to safety, no adverse incidents were recorded, and no complications were observed after the procedures. LBR Med is a generic robot based on KUKA's LBR iiwa industrial robotic arm which has been adapted for medical use. It's a 7-axis robot equipped with dual channel joint torque sensors that allow collision detection to interact with patients, manual guidance by doctors through touch, and react to forces safely. As per KUKA, LBR Med robotic tool can be applied for several different applications that include Orthopedic surgery, diagnostic ultrasound, and MIS. It's suitable for orthopedics due to the stability it provides and high stiffness. The sensory technology and features such as safe human-robot collaboration enable ultrasound diagnostic applications while the advanced controllers make it suitable for MIS. The telemanipulation capability further adds to its attractive characteristics. XACT Robotics developed XACT ACE , an FDA approved, 5-DOF, hands free robotic system for supporting robotic insertion and steering instruments during percutaneous procedures. The image-based planning is combined with navigation capabilities for insertion and non-linear steering. It's designed for multiple applications (Lungs, liver, spine, kidney, lymph nodes, bone etc.) and multiple percutaneous procedures (ablation, biopsy, drug delivery, vertebroplasty, biomarkers, brachytherapy etc.). It can adapt to several body shape and positions. At the start robot moves to Entry Point Standby position and inserts and steers the instrument to first check point. The robot advances to the second checkpoint upon user confirmation. In case of any motion, a new trajectory is calculated, and target is confirmed through imaging. Based on this instrument is steered along new trajectory. XACT ACE has been successfully used in a large number of clinical scenarios that include liver dome, lymph node, lung, paraspinal, renal biopsies and other percutaneous procedures as listed in . One such case involved the procedure of prostate drainage where the patient had shown up with large prostate abscess . Even though the path to target was a long trajectory i.e., 128 mm, the XACT robot was able to reach the target within 11 min with 1 mm tip-to-target accuracy. Additionally, despite update in target location near procedure end, no patient repositioning was required. Galen Robotics Platform is a 5-DOF surgical tool positioning device to assist surgeons. The end effector of the device is mounted with a custom tool holder. A surgeon can attach a tool that they are already using without the need for any customization. It also responds to

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the surgeon's hand push to move to a desired position and orientation during the surgery with greater precision utilizing corporative control. The robotic device also features virtual boundary to assist a user. Galen robotics recently received de novo approval for a 'cooperative powered surgical assistant device for ENT surgery'. While the instrument is in the direct control of the surgeon this device assists them with precise and stable positioning. It may contain hardware components such as motors and software applications .Versius by CMR Surgical is a CE marked surgical robot designed for laparoscopic, gynecology, urology, colorectal and general surgery (Fig -7). Versius has light weight robotic arms with modular design that allows them to be positioned around the patient on individual carts. Up to 5 robot arms can work together. A 4-axis wrist joint at the end effector allows the use of surgical instruments to mimic a surgeon's wrist. The system relies on optical feedback from an endoscope camera attached to one of the arms. Kelkar et al. Performed an early clinical study to evaluate the performance and safety of the Versius robotic system for cholecystectomy. A total of 134 out of 143 patients i.e., 93.7 % underwent the robotic cholecystectomy while 9 patients were converted to other method, out of which 7 were attributed to the device owing to grasping failure. There were no intraoperative adverse events observed while 5.6 % of postoperative adverse events were recorded. The surgeons concluded that though the device is as safe as traditional laparoscopy but not suitable for cases with severe inflammation or thickening of gallbladder. A larger study at a wider scale over long term is required to further assess safety and efficacy aspects.

Fig. 7. Versius system with the surgeon console on the right. Figure reproduced with permission from Kayser.

fig-7

6. Discussion and conclusion

It has been over three decades since the first robot was introduced in surgery. In 2020, the surgical robot market in USA was little over a billion dollar, in 2022 it has almost doubled and is projected to grow at a compound annual growth rate of 17.9% till 2030. The projected growth rate in market size suggests a massive opportunity for the technology advancements and development of new surgical robotic systems. One of the most used robotic surgical systems across the world is the da Vinci system. Within its 22 years of FDA approval, it has been used to perform 10 million procedures and 6500 pieces have been sold in 67 countries for minimally invasive laparoscopic surgeries 55,000 surgeons around the globe have been trained on this system alone. This, along with the projected multibillion dollar market indicates that robotics is going to become an integral part of surgical procedures.

During our study on the commercially available robotic surgical devices, we observed that in case of orthopedics, the robotic surgical procedure has the advantage of utilizing pre-operative imaging and using optical markers to identify the target area during the intra operative procedure. Due to the rigid nature of the osseous tissue, the relative positioning of the markers does not change while in case of soft tissue, due to their complaint nature, the marker positions may change between the scans. These robotic devices take advantage of this rigid property also it facilitates the use of virtual boundary for orthopedic procedure with the utilization of optical tracking technology. Virtual boundary is useful in the absence of force feedback for hard tissues. Some systems are using optical trackers and eliminating the intraoperative imaging steps by tracking the surgical tools dynamically. Handheld robotic devices like Navio and Cori are leveraging this technology and implementing virtual boundary in real time. In orthopedic procedures we are observing the emergence of generic orthopedic surgical robotic devices which can perform customized bone resection. The generic nature of these

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robotic devices has the potential to enable the application of a single robotic device to multiple types of orthopedic surgeries e.g., the same system could be used for cranial, spine or knee surgery.

A vast number of robotic surgical systems are available for MIS and the majority among them have been developed for laparoscopic procedures for abdominal surgery. We observed a significant improvement in the ergonomic aspect of the robotic laparoscopic tools by incorporating more DOF for better dexterity. Some of these tools are motivated by biomimicry such as Vicarious Robots that was inspired by human arm structure while EndoMaster EASE system was inspired by crab claw. Traditionally laparoscopic surgeries faced the challenge of restricted access to certain areas of the body due to the limited dexterity of rigid instruments and inadequate reach of surgeon hands. Recent developments in robotics have enabled the deployment of multiple DOF arms in these restricted abdominal areas of the body. Features such as 360-degree articulation and foldable arms have opened a whole new approach to MIS. We also see development of robotic systems for single port surgeries that involve deployment of multiple instruments including endoscopic cameras through a single port. Most of the endoscopic vision systems developed earlier were limited due to the inherent disadvantage of 2D vision as far as depth perception is concerned. The recent developments in 3D vision systems have addressed these and have enabled the surgeon to have enhanced understanding of the spatial view of the surgical site. This superior vision system lets the surgeon operate and perform tasks such as suturing or dissection despite the lack of haptic feedback with greater confidence. Of late, some devices have started incorporating haptic feedback to provide surgeons with tactile feeling of the soft tissue during the surgery to provide greater control over the surgical instruments. Also, to reduce scars and expediate the recovery time in MIS there has been a trend towards decreasing the size of robotic laparoscopic tools. Vicarious Surgical Robot has reduced the incision size to as small as 1.5 cm . Some of the devices have been exclusively designed to hold and manipulate endoscopic cameras with greater precision to eliminate the need for extra assistance. This device also frees the surgeon's hand and lets them focus exclusively on the surgical tasks. The miniaturization of robotic assistive devices has opened opportunities to utilize the technology in long distance space exploration e.g., the robotic system, MIRA. This can be made possible since it is lightweight and has small footprint which contributes to less pay load.

For lung interventions, the reduction in size of catheters and their superior flexible design has extended the reach far into the peripheral lungs for biopsy during bronchoscopy. In the case of cardiac surgeries, the minimally invasive robotic catheter insertion devices have reduced the potential radiation exposure to the patient while at the same time achieving higher precision due to robotic control. Surgeons are not exposed to the radiation since the catheters can be tele operated from outside of the OR while being situated in a radiation shielded chamber.

Traditionally, the hair restoration has been performed manually by the surgeons. However recently the first robotic hair restoration robot has been developed. It uses the combination of image processing and robotic guidance. The image processing technology is now advanced enough to detect position of the hair follicles with high precision and speed. The precision control of the robotic arms enables the insertion of hair grafts at the preplanned locations.

Microsurgery where sub millimeter precision is required, robotic assistive surgery is playing an important role. The microsurgical devices filter the surgeons hand tremors, provide multiple fold motion scaling while at the same time providing enough DOF for high dexterity.

Robotic surgical systems developed for urological applications mostly include systems for prostate tissue ablation. Multiple approaches have been taken such as high velocity waterjet and HIFU for destroying the affected tissue. The recent advances in soft tissue imaging have enabled precise targeting of the affected area with the help of robotic control.

We also observed an increase in the number of generic surgical robotic assistive devices that can be utilized for positioning and manipulation of surgical instruments and are not limited to any specific surgical location or procedure. For instance, the Kuka robotic arm LRB Med is used for bone osteotomy as well as for hair restoration procedure. The Galen robotic platform is tool positioning device which can assist with any MIS surgical procedure. These general robotic systems are opening

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the opportunity to utilize them for multiple surgical applications therefore have the potential to reduce the overall robotic surgical cost by sharing the recourse among several surgical departments. This also minimizes the training time for the surgeons on each individual surgical device while optimizing the use of available resources.

The growth and expansion in surgical robotics will continue and further increase in the coming years due to rising demand for better surgical treatment. As more surgeons get trained and adopt robot-assisted surgery and the systems becomes more prevalent across medical institutions, we will see further innovation in this area and a greater number of new robotic surgical systems will be developed and available in the market. Although we have made a sincere effort to review the existing commercially available robotic systems and we believe it would enable a reader to get a comprehensive idea, but often we had limited amount of technical information from the company websites or the research articles due to proprietary information. This has been the limiting factor during the review process to include the technical details.

All the robotic systems reviewed in this article have been summarized in Table 1 that lists the name, approval status, country of origin and the target surgical procedure for each robotic system. We hope this will help a reader to quickly glance through the existing systems available in the market along with their details.

Table 1. Summary of robotic-assisted surgical systems along with their company, regulatory status, country of origin and their intended surgical procedure.

Robotic Surgical Platform	Company	Approval Agency	Country of Origin of the company	Surgical Procedure / Anatomical Region
Mako [26]	Stryker	FDA (510 K)	USA	THR (2012), TKR (2015), PKR (2015)
		CE		TKA (2008), THA (2010), UKR (2008)
TSolution One [29]	THINK Surgical	FDA 510 K (2019), CE (2017)	USA	TKA
TMINI [31]	THINK Surgical	FDA 510 K, 2023	USA	TKA
Omnibotics [33]	Corin	FDA (510 K, 2017), CE	UK	TKR
ROSA Knee system [37]	Zimmer Biomet	FDA (510 K, 2019), CE (2014)	USA	TKA
ROSA Partial Knee [39]		FDA (510 K, 2021)		PKR
ROSA Hip system [40]		FDA (510 K, 2021)		THA

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Surgical Robotic Platform	Company	Approval Agency	Country of Origin of the company	Surgical Procedure / Anatomical Region
Cori Surgical System [42]	Smith + Nephew	FDA (510 K, 2020)	UK	TKA, UKA
Navio [43]		FDA 510 K		UKR (2012), PFA (2014), TKA (2016)
		CE		UKR (2012)
VELYS [45]	Johnson & Johnson (J&J)	FDA 510 K (2020)	USA	TKA
Monogram [48]	Monogram Orthopaedics		USA	Knee Replacement
Mazor X Stealth Edition [49]	Medtronic	FDA 510 K (2018)	USA	Spine
Mazor X [52]		CE (2017)	USA	Spine
ExcelsiusGPS [53]	Globus Medical	FDA 510 K & CE (2017)	USA	Spine
ExcelsiusGPS Cranial Solution [55]		FDA 510 K (2020)		Brain
CUVIS-spine [56]	Curexo	FDA 510 K (2021), CE (2020), MFDS (2019)	South Korea	Spine
ROSA ONE Brain [58]	Zimmer Biomet	FDA 510 K (2019)	USA	Brain
ROSA One Spine [60]		FDA 510 K (2019)		Spine
Neuroblate [62]	Monteris	FDA 510 K (2013)	Canada	Brain
Neuromate [65]	Renishaw	FDA 510 K (2014), CE	UK	Brain
AiM Medical Robotics [67]	AiM Medical Robotics		USA	Brain
Remebot [68]	Remebot	NMPA (2018)	China	Brain
Cirq [31,71]	Brainlab	FDA 510 K (2019), CE (2020)	Germany	Spine, Cranial

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Surgical Platform	Robotic	Company	Approval Agency	Country of Origin of the company	Surgical Procedure / Anatomical Region
Yomi [73]		Neocis	FDA 510 K (2022)	USA	Dental
CARLO [75]		AOT	CE (2021)	Switzerland	Osteotomy
TiRobot [79] TiRobot-II [80]		Tinavi	NMPA (2016)	China	Orthopedic
Avatera [82]		Avatera Medical	CE (for urology and gynecology)	Germany	MIS
Senhance System [84]	Surgical	Asensus Surgical	FDA 510 K (2017), CE CE (2020)	USA	MIS Pediatric patients above 10kg
Canady RoboWrist [88]	Flex	USMI	FDA 510 K (2022)	USA	Laparoscopy
Revo-I [89]		Meerecompany	MFDS (2017)	South Korea	Laparoscopy
AutoLap [92]		MST	FDA 510 K (2013), CE	Israel	MIS
Enos [94]		TITAN Medical		Canada	Laparoscopy (Single port)
Micro Hand S [96]		Shandong Wego Surgical Robot Co	NMPA (2021)	China	Laparoscopy
Hugo RAS system [98]		Medtronic	CE (2021) urologic and gynecologic procedure	USA	Laparoscopy
MIRA [101]		Virtual Incision		USA	Laparoscopy (Single port)
Vicarious Robot [105]	Surgical	Vicarious Surgical		USA	Laparoscopy (Single port)
Anovo System [107]	Surgical	Momentis Surgical	FDA de novo (2021)	Israel	Hysterectomy (Natural Orifice)
Dexter [108]		Distalmotion	CE (2020)	Switzerland	Laparoscopy
SOLOASSIST II [110] SOLOASSIST IIs [111]		AKTORmed	FDA 510 K (2018), CE	Germany	Endoscopy
Emaro [113]		RIVERFIELD		Japan	Endoscopy
IvyA1 [115]					Endoscopy

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Vista [117]	Freehand	FDA, CE	UK	Laparoscopy
Panorama [117]				
EndoMaster EASE system [118]	EndoMaster Pte Ltd		Singapore	MIS Endoscopic
Novel Surgical Robotic System [121], [122], [123]	NISI		Hong Kong	Natural Orifice
Hinotori [124]	Medicaroid	MHLW	Japan	Laparoscopy
Monarch [179]	J&J	FDA 510 K	USA	Bronchoscopy (2021), Urology (2022)
Ion endoluminal system [128]	Intuitive Surgical	FDA 510 K (2019)	USA	Bronchoscopy
Vdrive [131]	Stereotaxis	FDA 510 K; V-SONO (2013), V-LOOP (2014), V-CAS (2015)	USA	Cardiac Ablation
		CE (2011)		
Niobe [131]		FDA 510 K (2003), MHLW (2013)		
Corpath GRX [133]	Corindus, Acquired by Siemens	FDA 510 K (2016), CE	Germany	Cardiac
Corpath GRX Neurovascular Robotic System [135]		CE (2019)		Brain
R-One [137]	Robocath	CE (2019)	France	Cardiac
The Amigo Remote Catheter System [180,140]		FDA de novo (2014)		Cardiac ablation
ARTAS iX [142]	VENUSCONCEPT	FDA 510 K (2018), CE (2019)	USA	Hair restoration
Preceyes [144]	Preceyes BV	CE (2019)	Netherlands	Vitreoretinal
Flex robotic system [146]	Novus	FDA 510 K (2017)	Turkey	Access to Oropharynx, Hypopharynx & Larynx; anus, rectum, distal colon

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Surgical Robotic Platform	Company	Approval Agency	Country of Origin of the company	Surgical Procedure / Anatomical Region
		CE (2014)		Otolaryngology
Aquabeam robotic system [147]	Procept BIOROBOTICS	FDA 510 K (2021)	USA	Prostate Ablation
Focal One [150]	EDAP	FDA 510 K (2018)	France	Prostate HIFU Ablation
Ablatherm [152]		FDA 510 K (2015)		
Da Vinci Xi [154]	Intuitive Surgical	FDA 510 K (2016), CE (2014)	USA	MIS
Da Vinci X [154]		FDA 510 K (2017), CE (2017)		MIS
Da Vinci SP [154]		FDA 510 K (2018), MFDS & MHLW (2022)		MIS (Single Port)
ROBIO EX [156]	Perfint Healthcare	CE	India	Abdominal, Thoracic
Symani surgical system [159]	Medical Micro Instruments	CE (2020)	Italy	Microsurgery
MUSA [161]	Microsure	CE (2019)	Netherlands	Microsurgery
EPIONE [166]	Quantum Surgical	FDA 510 K (2023), CE (2021)	France	Percutaneous Ablation
LBR Med [168]	KUKA		Germany	Multipurpose Robotic Arm
XACT ACE [169]	XACT Robotics	FDA 510 K (2022)	Israel	Instrument positioning during percutaneous procedure
XACT Robotics system [181]		CE (2018)		
Galen Robotics Platform [172]	Galen Robotics	FDA de novo (2023)	USA	ENT Surgery
Versius [174]	CMR Surgical	CE (2019)	UK	Laparoscopy, Gynecology, Urology, Colorectal, General

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