UK-RAS White papers

ISSN-2398-4422
DOI: 10.31256/WP2021.2

UK-RAS NETWORK
ROBOTICS & AUTONOMOUS SYSTEMS

Surgical Robotics: Towards Measurable Patient Benefits and Widespread Adoption

www.ukras.org

UK-RAS NETWORK
ROBOTICS & AUTONOMOUS SYSTEMS

UKRAS.ORG

FOREWORD

SURGICAL ROBOTICS

Welcome to the UK-RAS White Paper Series on Robotics and Autonomous Systems (RAS). This is one of the core activities of UK-RAS Network, funded by the Engineering and Physical Sciences Research Council (EPSRC). By bringing together academic centres of excellence, industry, government, funding bodies and charities, the Network provides academic leadership, expands collaboration with industry while integrating and coordinating activities at EPSRC funded RAS capital facilities, Centres for Doctoral Training and partner universities.

The surgical robotics sector is currently undergoing a second renaissance, with a measurable increase in surgical robotics uptake by industry and in hospitals, and the UK is in a strong position to ride this wave of innovation, but challenges remain. In this paper, five years since the publication of the first UK-RAS White Paper on Surgical Robotics, we revisit the topic in light of significant changes in technology, regulatory processes, and adoption. This White Paper summarises the latest achievements in the sector and offers a measured view about the future of surgical robotics in the UK. It also identifies existing translational barriers and offers recommendations, which are hoped to influence government, industry, and healthcare providers in their future strategy.

The UK-RAS white papers are intended to serve as a basis for discussing the future technological roadmaps, engaging the wider community and stakeholders, as well as policy makers in assessing the potential social, economic and ethical/legal impact of RAS. It is our plan to provide future updates for these white papers so your feedback is essential - whether it be pointing out inadvertent omission of specific areas of development that need to be covered, or major future trends that deserve further debate and in-depth analysis.

Please direct all your feedback to info@ukras.org. We look forward to hearing from you!

Dr. Christos Bergeles | **Dr. Ana Cruz Ruiz** | **Prof. Ferdinando Rodriguez y Baena** | **Prof. Pietro Valdastri**

Acknowledgements and list of contributors:
The authors would like to thank the following members of the UK and international surgical robotics community for their valuable input, which was essential to identify our community's key capabilities, achievements, challenges, impact and future research directions.

- Kaspar Althoefer, Queen Mary University of London
- Martin Birchall, University College London
- James Chandler, University of Leeds
- Philip Chiu, The Chinese University of Hong Kong
- Dana Damian, University of Sheffield
- Brian Davies, Imperial College London
- Sanja Dogramadzi, University of Sheffield
- Stamatia Giannarou, Imperial College London
- Russell Harris, University of Leeds
- Ali K. Hoshiar, University of Essex
- Gernot Kronreif, ACMIT GmbH
- Yang Liu, University of Exeter
- Shan Luo, University of Liverpool
- Luigi Manfredi, University of Dundee
- Evangelos Mazomenos, University College London
- Shuhei Miyashita, University of Sheffield
- M. Ali Nasseri, Technische Universität München
- Subramanian Ramamoorthy, University of Edinburgh
- Agostino Stilli, University College London
- Danail Stoyanov, University College London
- Zion Tse, University of York
- Tom Vercauteren, King's College London
- Helge Wurdemann, University College London

EXECUTIVE SUMMARY

Five years since the publication of the first UK-RAS White Paper on Surgical Robotics, it is timely to revisit the topic in light of significant changes in technology, regulatory processes, and adoption. Despite several setbacks, driven by a move away from the Medical Devices Directive (MDD) to the more taxing Medical Devices Regulation (MDR), Brexit, and a global pandemic, the sector is now experiencing a second renaissance, with a measurable increase in surgical robotics uptake by industry and hospitals. This steep acceleration has been fuelled by notable large-scale acquisitions of prominent sector innovators, both nationally and internationally, which has helped to energise the community and encouraged disruptive innovations in science and engineering.

After a brief review of noteworthy highlights covering the past ten years, this White Paper summarises the latest achievements in the sector and offers a measured view about the future of surgical robotics in the UK. It also identifies existing translational barriers, followed by a detailed analysis of the country's Strengths, Weaknesses, Opportunities, and Threats (SWOT) in surgical robotics. Supported by a far-reaching consultation process with stakeholders from the UK-RAS Network, which began offline and concluded with a workshop focussed on defining a UK Surgical Robotics Roadmap on the 14th of May 2021, the White Paper closes with detailed recommendations related to funding of basic research, supporting translational endeavours, creating shared resources and clusters, attracting a skilled workforce from around the world and fostering international collaborations.

These recommendations aim at cementing the UK's position as a surgical robotics powerhouse and are hoped to influence government, industry, and healthcare providers in their future strategy.

"Despite several setbacks, driven by a move away from the Medical Devices Directive (MDD) to the more taxing Medical Devices Regulation (MDR), Brexit, and a global pandemic, the sector is now experiencing a second renaissance, with a measurable increase in surgical robotics uptake by industry and hospitals."

CONTENTS

"Advances in surgical robotics research will be driven by progresses in perception, manipulation and intelligent control, increased levels of computer assistance, innovative robotic architectures and personalised digital manufacturing.
All of these exciting research streams will be underpinned by fast-paced advances in artificial intelligence and the availability of large datasets to train machine learning algorithms."

1. A HISTORY OF SURGICAL ROBOTICS EXCELLENCE

The UK research community has a good international standing with regards to surgical robotics. Research in this field commenced in the UK in the 1990s, with early examples of first-in-human application [1] and commercialisation endeavours [2]. Activity on validation and commercialisation of mechatronics systems, however, has since slowed down with respect to global progress. Several novel concepts, such as the UK's pioneering research in soft robotics, have contributed to the state-of-the art, though the nation is best known for its research output, rather than its commercial successes.

The UK's approach to Robotics and Autonomous Systems changed in 2013, with the Government identifying the field as one of "Eight Great Technologies''[3] that would propel the UK economy in the future. This led to new funding opportunities and encouraged the establishment of academic posts in robotics, including surgical robotics. This investment has fuelled a growing UK-base of surgical robotics researchers, who, together with Renishaw (neurosurgery), Smith & Nephew (orthopaedics), and the "new kid on the block" CMR (laparoscopy), have contributed to the establishment of a thriving community with significant future potential.

Image based navigation [4] and **semantic interpretation** in the form of surgical tool tracking, 3D reconstruction in endoscopy [5], feature identification and tracking [6], as well as 4D surgical flows, have all seen strong research outputs. Such research excellence has led to the establishment of lasting relationships with international leaders in surgical robotics, such as Intuitive Surgical, and supported the scientific activities of Digital Surgery Ltd (now part of Medtronic Inc). **Surgical planning** and **post-operative skills assessment**, with a strong focus on neurosurgery [7] and cardiovascular surgery [8], has led Medtronic to work with UK researchers towards clinical trials of robotic electrode implantation. UK academics have also led EU-wide consortia on intelligent robotic orthopaedic surgery (**SmartSurg** [9]), with award-winning outputs on **surgical navigation** [10].

The community has been traditionally stronger in the domain of robot-assisted interventions, but notable research on system development has also taken place.

Prototype systems **Probot** [11], **Acrobot** [12], and components of **Micro-IGES** [13] were successfully deployed in first-in-human applications. Acrobot was commercialised with partial initial success, while **Micro-IGES** is under further development for commercialisation by **Precision Robotics**. Extensive research on design, modelling, engineering and autonomous control has been carried out on **neurosurgical robots** [14], **steerable needles** [15], [16], **concentric tube robots** and **magnetically actuated robots** [18], [19]. UK research was pioneering in the field of soft robotics (**STIFF-FLOP** [20]), discrete snake robots (**i-Snake** [21]) steerable needles (**EDEN2020** [22]) and magnetic flexible endoscopes (**MFE** [23]), many of which have been pre-clinically evaluated, and are moving towards first-in-human trials. Over the past decade, research has also intensified in the domain of **microrobotics**, **soft actuators** [24], and **implantable devices** [25]. Overall, UK academics are carrying out research across many scales, exemplifying the strong international position of our research portfolio.

Linking mechatronics with human agents through bespoke human/robot interaction mechanisms and novel sensing have also been explored. UK research led to the introduction of **active constraints** [26] as a shared control approach that is being deployed in commercial orthopaedic systems. **Perceptual docking** and intuitive **AR/VR** approaches [27] for superimposing multimodal information on surgical scenes have also seen extensive research and international recognition via awards and licensing.

2. UK SURGICAL ROBOTICS RESEARCH LANDSCAPE

Through the highs and lows of the last ten years, surgical robots have experienced a steady growth in both interest and uptake by the wider clinical community and industry. As shown in Fig. 1, surgical robots are now widely used in different areas of surgery, including urology, gynaecology and general abdominal surgery. The global surgical robots market was valued at about USD 4.5 billion in 2020 and is expected to pass USD 9.5 billion by 2026, registering a Compound Annual Growth Rate (CAGR) above 11% during the period of 2021-2026, as reported in Fig. 2. Importantly, as of the spring of 2021, the field has witnessed an unprecedented number of corporate acquisitions of leading surgical robotics manufacturers, such as Mazor (purchased by Medtronic), Mako (purchased by Stryker), Corindus (purchased by Siemens), Rosa (purchased by Zimmer Biomet), Bluebelt (purchased by Smith & Nephew), Omnilife (purchased by Corin), and Auris (purchased by Johnson & Johnson), a process that is fuelling an increase in demand never seen before. This surgical robotics “renaissance” is leading to what is likely the most fertile period in the field’s 40-year history.

Today, we can find examples of remarkable innovation in UK surgical robotics across all disciplines associated with this interdisciplinary field, ranging from new materials, structures, and manufacturing methods, to new sensors, sensing schemes, control approaches, and workflows.

Notable examples are in the field of **soft robotics**, with **new materials** (electroactive polymers [28], metamaterials [29] and hydrogels [30]), **new structures** (steerable needles [31], continuum robots [32], granular jamming [33], [34]), **new surgical phantoms** [35], [36], and **new sensors and sensing schemes** (Fibre-Bragg-Grating-based shape sensing [37], bioimpedance tomography [38], fibre-based Optical Coherence Tomography [39], Optical Doppler Flowmetry [40]), and **miniaturization**, a field that is still in its infancy, but that holds significant promise for the future of patient-specific, non-invasive medicine. As an example, research teams at the Hamlyn Center (Imperial College), supported by the EPSRC’s Microengineering Facility for Robotics, are developing a new class of tethered and untethered microscale (grippers [41], micro-tweezers [42], microbots [43]) and nanoscale [44] robots that enable autonomous and remote manipulation of cells and drugs. These new technologies are still in their infancy, but will eventually lead to localised treatment as well as targeted delivery of therapeutics for personalised and regenerative applications.

The growth in computational power and the advent of new imaging and visualisation technologies has also fuelled noteworthy advancements in **imaging** and **perception**, which are key elements of an immersive user experience in the operating theatre. New technologies

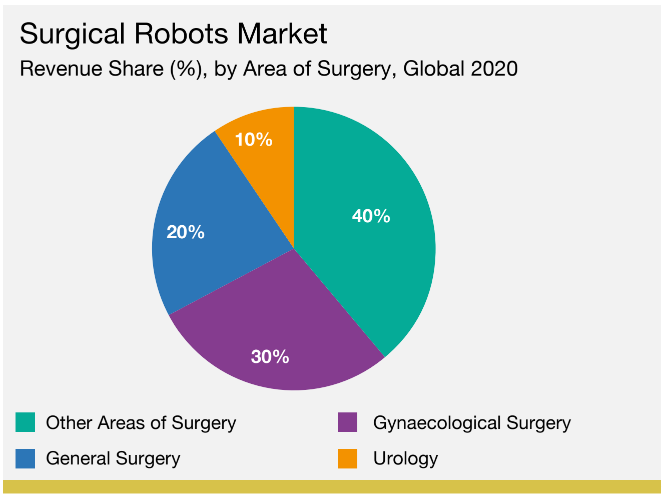


FIGURE 1.

Surgical Robots Market - segmentation by area of surgery. Source: Original data gathered from multiple market reports on robotic surgery.

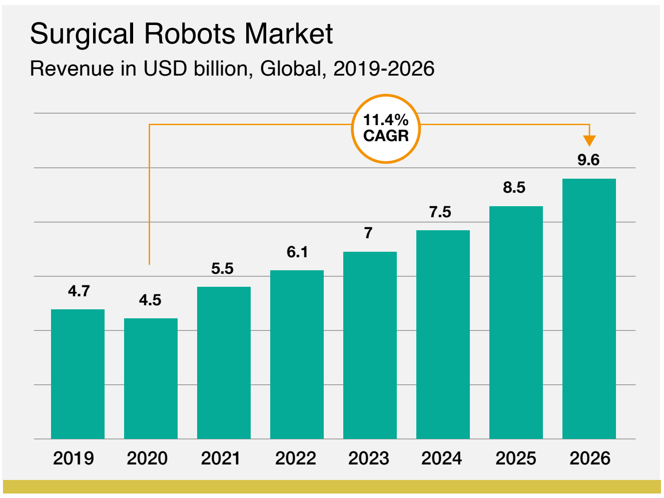


FIGURE 2.

Surgical Robots Market (2019 - 2026). Source: Original data gathered from multiple market reports on robotic surgery.

enable clinicians to **better interpret the physical world** (simultaneous localization and mapping of endovascular catheters [45], augmented reality of immersive and timely computer-assisted surgical guidance [46], depth imaging based automatic segmentation, registration and tracking for markerless computer assistance [47]), **process and review preoperative image data** (machine-learning based automatic image processing [48], and surgical planning [49]), and **better interpret and quantify surgical outcomes** (e.g. skills assessment [50], postoperative follow up [51]). Additionally, new hardware and algorithms help address the complex process of integrating a surgical robot in the cluttered Operating Room (OR), with a plethora of new **tracking sensors** (infrared, electromagnetic, structured light, time of flight, inertial measurement units) and **registration methods** that can now handle both hard and soft tissues within a cluttered environment (e.g. speckle imaging, deformable registration algorithms, occlusion handling).

A notable aspect of surgical robotics that has also seen unprecedented growth in recent years is **human-robot interaction**, which is the current focus for many leading research groups and companies. With the rise of collaborative robotics within and outside the (OR), multiple robotic companies now offer robotic arms purposely designed to work with a “human-in-the-loop”, e.g. Kuka, ABB, Stäubli, and Universal Robotics. Historically, safety in robotics has been addressed with isolation (caging), software (real-time controllers) and sensing (proximity sensors). Today’s robots are either designed to be inherently safe (e.g. Festo’s hybrid soft-hard robot [52]), or feature a new class of controllers and control strategies that can guarantee safety by bounding the response time of the system in case a collision is detected (e.g. Kuka’s LBR iiwa).

Human-robot interaction advances are also taking shape in the high level (often Cartesian) control space, with new algorithms and frameworks able to endow today’s state of the art robotic systems with a more natural and intuitive user experience. Notable examples are the extension of the classical cooperative control paradigm of **active constraints** (also known as virtual fixtures) to dynamic environments involving compliant tool-tissue interactions [53], or the concept of **natural motion for improved hands-on robotic control** [54], where the null space of redundant robot configurations is exploited to minimise the effect of mass, friction, and inertia at the tool point. Other notable examples include **adaptive**, **data driven approaches** to learn, support, or replace tedious manual tasks, such as suturing, camera holding/directing in laparoscopic surgery, and stent manufacturing [55], and **energy-based adaptive controllers** that ensure position accuracy without relying on high gains, thus taking full advantage of compliant manipulators [56].

Improvements in human-robot interaction are also exploiting the latest advancements in **sensor technology**, particularly in the context of gesture recognition and visualisation. The Leap Motion (Ultraleap Ltd., UK) hand tracking system, for instance, is being trialled as a user interface for robotic endonasal surgery; while the Hololens 1 and 2 (Microsoft Inc.) are finding new uses in the context of robotic surgery, to declutter the (OR), enable three dimensional visualisation of the patient anatomy, or even overlay accurate visual guidance cues directly onto the patient. Many of these new approaches have not yet reached maturity, but hold the promise for a truly seamless, markerless, and intuitive user experience for the surgeon in the not too distant future.

Finally, it must be noted that many of today’s advancements in robotic surgery have been made possible thanks to a **revolution in manufacturing**, which has eliminated many of the historical barriers hindering progress in hardware technology. This is significantly linked to the advent and exponential growth of **digitally-controlled freeform manufacturing processes**, such as 3D Printing, Hybrid Manufacturing, and Microfabrication. These are beginning to illustrate the new opportunities to produce intricate robotic devices with alternative materials, and even multi-material compositions. These can also be realised in a rapid and responsive manner, with viable economic production individually or in small batches. This is breathing new life into the slow growing field of mechanisms design, giving rise to **a plethora of novel devices and inventive new concepts**. Noteworthy examples are variable stiffness devices for soft tissue palpation [57], thermal drawing systems for the manufacture of next-generation dexterous catheters [58], pneumatic crawlers [59], MRI-compatible robotic positioners [60], dielectric elastomers as soft actuators [61], and swallowable capsules [62]. These are mostly systems at an early stage of research and development, but which provide a glimpse of what the future holds.

Interestingly, so far surgical robotics technologies have been most successfully translated from the research lab to the patients through a **start-up vehicle** that is later acquired by a larger company, with several examples provided at the beginning of this section. Start-ups, typically supported by venture capital funds, de-risk the innovative robotic platforms/technologies and take them through first-in-human trials. After this stage, they become appealing for large players in the field. Therefore, it is extremely important **to nurture the culture and the environment for surgical robotic start-ups to thrive**.

3. A PERSPECTIVE ON THE FUTURE OF SURGICAL ROBOTICS RESEARCH

In the future, surgical robotics has the potential to grow exponentially in a number of key areas of healthcare. This technological wave will be characterised by advances in perception, manipulation and intelligent control, increased levels of computer assistance, innovative robotic architectures and personalised digital manufacturing. All of these exciting research streams will be underpinned by fast-paced advances in artificial intelligence and the availability of large datasets to train machine learning algorithms.

Emerging real-time **tissue imaging techniques**, including optical coherence tomography, Raman spectroscopy, micro-ultrasound, tactile, photoacoustic, hyperspectral, and terahertz imaging, will complement advances in surgical vision to provide feedback for robotic control and increase the level of immersion for the surgeon. Higher levels of **autonomy**, where the most tedious and repetitive tasks are performed autonomously by the robot, will be enabled by the seamless integration of advanced perception modalities with quantitative models of clinical execution, based on the increasing amount of available data. It will be interesting to see where **clinical decision support systems** will have a concrete impact in the workflow of surgical robotic procedures, and to what extent they will be able to inform decisions related to autonomous planning and execution of surgical tasks. **Improved ergonomics** for the user interface, where only the pertinent information is displayed at the appropriate time in the most natural/least intrusive way, will eventually enable surgeons to take full advantage of the different technologies integrated in future robotic platforms. **Progress in telecommunications** (i.e. 5G and 6G) will enable telepresence in mentoring and training, as well as facilitate specialist surgeons to join remotely for specific elements of a surgical procedure where local expertise is not available. Finally, the automation of robotic intervention will also benefit from arising strengths in **model-based and AI techniques in biology** (e.g. cancer biology, from molecular to imaging).

In terms of design, **soft robotics** holds great promise in the surgical context thanks to the inherent safety provided by soft materials. One of the main challenges yet to be solved is the integration of **embodied intelligence** that would allow low-level functions to be executed autonomously, without the need for communicating local sensor readings to a central unit and then relaying the decision back to distal actuators. Wiring data signals along the length of soft robots creates a discontinuity in material properties, heavily degrading motion performance. Smart, responsive materials, combined with bio-inspired robot designs, may provide a solution to this open issue. Similarly, the ability to implement elements of a control algorithm within the design, for instance by means of fluidic logic, could increase the bandwidth of the system [63].

Another related challenge is **reliable manufacturing**. At the moment, soft robots are predominantly fabricated by manual techniques. This can result in inconsistencies across different batches and introduce unreliability and potential safety issues. The introduction of fabrication research, which is more conducive to upscaling and translation, will be key to facilitating effective and large-scale clinical deployment. Such digitally-controlled and automated manufacturing processes would enhance the opportunities for the creation of personalised robots and devices that are specific to patients and their treatments. Consequently, the introduction of advanced manufacturing processes to create robotic devices is foreseen as being critical to both increasing their capabilities in surgical applications, and to enabling their widespread adoption.

We expect **new architectures** for soft surgical robots to emerge from current research. For example, eversion soft robots, adapting their shape to the surrounding anatomy by growing into it, have great potential to enable diagnosis and treatment deeper inside the human body. While the basic principle has been already demonstrated for large hollow cavities (e.g. the large intestine), it is not clear yet how small we can go. Exciting opportunities to cure breast or pancreatic cancer may emerge if this new class of robots is able to navigate sub-mm lumens. Magnetic soft robots represent another viable option to navigate extremely narrow and convoluted anatomies, as they do not rely on on-board actuation structures like tendon or pneumatic chambers. New control paradigms aiming at controlling the entire shape of the robot, rather than just orienting the tip, may pave the way to safer interactions with the surrounding anatomy in a wide range of clinical applications, from cardiovascular interventions to brain surgery. The use of **biodegradable materials** represents another exciting opportunity for soft surgical robots. Once the desired target is reached and the intended functions are performed, the robot may be "digested" by the host organism, while releasing patient-specific drugs embedded in a biodegradable scaffold.

Given the level of maturity of soft surgical robots, we soon expect **first-in-human trials** to evaluate their safety and feasibility. If successful, these will certainly accelerate clinical uptake and translational efforts.

Untethered robots constitute another area that holds great potential for surgical applications at different dimensional scales, from the meso- (mm..cm) down to the micro- (μm..mm) and nano- (nm..μm) scale. At the **meso-scale**, medical capsule robots have been investigated to a great extent in the past decade, with magnetic actuation emerging as the most viable solution to control an endoscopic capsule inside the gastrointestinal tract. This strategy is now integrated into clinical platforms for upper gastrointestinal endoscopy and, in the future, may offer unprecedented diagnostic and therapeutic capabilities when combined with multimodal imaging (e.g. multi-spectral, autofluorescence, micro-ultrasound). Advances in energy storage, miniaturised electronics and wireless power transfer may however revive the alternative approach of "on-board actuation", where internal, miniature mechanisms are used to achieve specific functions, including active locomotion, biopsy sampling and drug delivery. At the **micro-/nano-scale**, the main open challenges are still related to energy transfer and biocompatibility. We expect pre-clinical and first-in-human trials to address these issues in the near future. Once these hurdles are cleared, micro- and nano-robots will offer an exciting opportunity to cure diseases at a cellular level ("single cell surgery"). Thus, reliable navigation strategies and real-time control techniques, combined with research into functionalized biocompatible materials, will play a crucial role in years to come. Successful demonstration of untethered robots at multiple scales may also lead to the exciting prospects of "multi-scale operation", where a pill-sized robot deploys an army of interventional micro-/nano-robots, or "multi-agent operation", where multiple untethered robots perform a collaborative task in hard-to-reach areas of the human body.

Beyond the fundamental research directions highlighted so far (and the many others that are not mentioned), we expect to see a new wave of **procedure-specific robotic platforms** emerging in the near future to address unmet clinical needs. An example is micro-surgery, where stability, precision, scaling and repeatability of motion provided by a robotic platform can alleviate the strong dependency between the experience of the surgeon and patient outcomes.

The design, fabrication and preliminary evaluation of a procedure-specific prototype is a crucial step in the translational pathway towards clinical deployment. This step is required to de-risk the technology and show safety and feasibility to potential investors/funding agencies before progressing to larger and more expensive trials. It also provides a first opportunity for a sanity check on the proposed health economic model, as only innovations with a cost-benefit ratio that improves on current standard of care have a chance of being adopted in the long term. Equally important, evaluation of new procedure-specific prototypes may highlight critical gaps in current knowledge and suggest new avenues of fundamental research.

Fully collaborative smart tools are also on the horizon, supported by hardware and software technologies that will soon reach maturity. ORs of the future may see one or multiple robots working in unison, seamlessly interacting with the surgeon, the patient and the environment. They will not require additional incisions for invasive tracked bodies, nor a complex setup phase to prepare the patient, register the scene and identify targets and obstacles. Instead, they will "just work", offering the surgeon a natural user experience, with the most appropriate level of assistance, ranging from gentle guidance for complex/delicate soft tissue interactions, to full automation, such as for suturing. Only relevant, well timed information will be offered to the surgeon without the need for explicit user input, precisely overlaid on the patient within an augmented scene, thus obviating the need for soon-to-be-outdated 2D displays.

In order to achieve substantial progress along these lines, specific **shared infrastructure** would be ideal. This includes joint data repositories (e.g. comprehensive case files, performance data, calibration/registration accuracy and robustness metrics on reference models, etc.), standardisation of data labelling and processing techniques, software tools to generate computer vision and other types of datasets for robotic surgery, clinically relevant experimental setups for autonomous surgical robots (e.g. dVRK, Raven, Kuka's LBR Med), and advanced equipment for robot fabrication and characterisation. We anticipate that academia/NHS collaboration will be the first step towards the establishment of such shared data infrastructure, e.g. following the example of Health Data Research (HDR) UK. Shared hardware infrastructure can entail use of common equipment, similar to the TERRINet initiative [64], or re-purposed clinical systems. Naturally, depending on the nature of the stakeholders, different Terms & Conditions for shared infrastructure usage may need to be in place.

4. TRANSLATIONAL BARRIERS

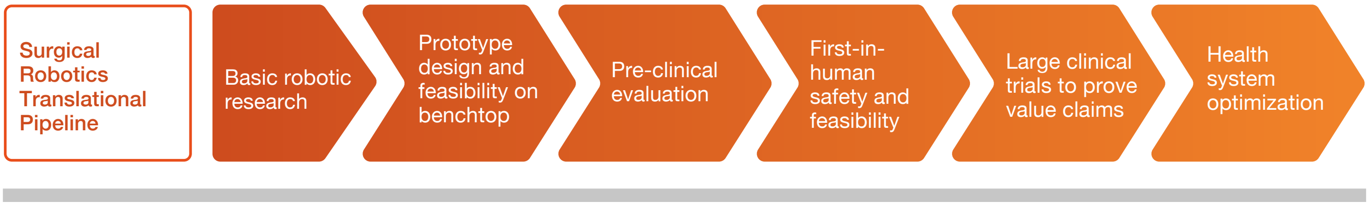


FIGURE 3.

Surgical robotics translational pipeline. Source: The authors.

For research excellence to lead to socioeconomic and patient benefits, a number of translational barriers must be overcome. Researchers should be aware of the ethical, regulatory, economic, and intellectual property barriers that need to be considered, and the funding mechanisms that are available in support of the translational journey, schematically represented in Fig. 3.

Ethical and acceptability barriers may include misinterpretation of robots by patients, e.g. thinking of humanoids rather than smart instruments, but also misunderstanding of the attribution of blame in case of malfunction or malpractice. As robot autonomy increases, digital security of robotic systems also comes into question. The community must engage in public/patient involvement activities to address such misunderstandings. Practitioners may consider robots as a threat to their work, therefore the concept of using robots as “smart tools” to empower, rather than replace, humans should be reinforced. Researchers must have a good understanding of the full spectrum of stakeholders, which includes not only end users and patients, but complete healthcare systems. The involvement of medical societies, such as the Royal College of Surgeons of England, and clinical trial units from the onset of research, can significantly help with acceptability and translational activities downstream. On this point, establishing stronger relationships with The National Institute for Health and Care Excellence (NICE), even in the form of introduction workshops for engineering researchers, can help academics better navigate the commercialisation and uptake landscape. Along these lines, a consortium of UK researchers is already helping to establish IDEAL guidelines [65] for robotic surgery, which supports iterative learning and incremental development and will serve as the blueprint for new technology development and evaluation. Further considerations should include the confidentiality of patient data, whether consent can be secured or retrospectively acquired in pursuit of commercial applications, as well as ultimate patient data ownership.

Regulatory and economic barriers: better education of academics in terms of healthcare regulations in the UK and worldwide is required. Naturally, regulations lag behind new technology. Therefore, academics should be in close contact with national and international certified bodies to ensure they are fully up to date with the requirements for clinical translation of their technology. Many institutions have started placing a greater emphasis on this, but further work is required to ensure that research does not disappear in the “valley of death” of medical devices. Post-Brexit UK may present opportunities in this domain, perhaps with a flexible set of regulations for advanced technologies. Contrary to carrying out research, the concept of manufacturing “at cost” should be reinforced, as it critically links with technology uptake. This interconnects with the health economics of surgical robots, wherein a generally expensive technology must showcase clear use cases within both centralised healthcare systems, such as the NHS, and decentralised ones, such as in the US. For example, academics are rarely acquainted with NHS cost recovery models, NICE quality-adjusted life year (QALY), or US-based reimbursement codes. Thorough health economics acts in support of solid business cases, which are key for raising capital for commercialisation. Finally, translational research requires strong support from universities’ business units, and the possibility of academic institutions to sustain the cost of IP protection over long periods of time. It may also be worth considering alternative marketing models, such as service-based models instead of direct purchase of expensive units - particularly in a healthcare system such as the NHS.

Intellectual property barriers: the importance of securing IP in support of commercialisation should be well understood by academics. It is costly for universities to maintain IP over long periods of time, and there is general rigidity in terms of IP ownership. For example, while internationally there may exist options for full ownership of IP by the creator, through own or grant funding, this is not the case in the UK. To recover some of the costs, UK universities still follow a fairly rigid approach when assigning IP for commercial exploitation, with spinout companies or licensees adversely affected in securing external investment as a result of a significant tethering to the academic institution. In particular, when compared to their US counterparts, British universities have yet to maximise the impact of their research output via commercialisation of arising technologies, and this is perhaps particularly exemplified in the surgical robotics sector. More often than not, the equity retained by UK institutions is prohibitively high for Venture Capitalists (VCs) to invest in. While the intention is to protect the investment of UK universities, the status quo can cause the opposite effect, perhaps making the alternative of establishing a company without the involvement of the university a preferable alternative.
A comparison of various models across Europe, Asia, and the US demonstrates that the "perfect way forward" has not yet been found, and it is imperative that more efforts are invested in pursuit of a better solution.

5. UK SURGICAL ROBOTICS STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Strengths

- NHS (England) is one of the largest single-payer healthcare systems in the world with generally well-connected patient records from hospitals to primary care
- Market and surgical innovation leadership
- Distributed research excellence across key enabling topics
- High quality clinical trial units
- Funding bodies across the translational spectrum
- Charities that fund medical research and involve patients
- International reputation for investment returns in UK Tech

S

Weaknesses

- Absence of an explicit innovation pipeline
- Limited availability of trained staff/researchers
- Affordability of robotic surgery is an issue in the NHS
- Risk-averse environment/mentality (Clinicians, Patients, NHS, Investors)
- Large NHS Trusts may be slow in adapting to new trends
- Marginal number of companies in the field
- Some fabrication methods currently used are not suited for industrial scale-up
- Global competition research-wise

W

T

Threats

- Global competition - Large markets with strong investment opportunities (China, USA)
- Brexit - Reduction in international research collaborations
- Brexit - Barrier to export/different regulations
- Restrictions in the ability to recruit top global talent at the early research career stages (PhD students)

O

Opportunities

- Collaborative robots that enhance surgical performance
- Development of innovative surgical robots from creation to pilot clinical trials in a single centre
- Ease the access and navigation through the MedTech innovation pathway
- Enhance surgical training in the NHS
- Ease the access to surgical robotic platforms
- Reduce the cost of public healthcare by using robotic approaches
- Brexit - Faster regulatory approval and joint certification for multiple markets (US, EU, China)
- Tackle global healthcare challenges
- Create new national industries for the engineering and manufacturing of innovative robots
- Better use of GP practices for patient care, enabled by technology

STRENGTHS

NHS (England) is one of the largest single-payer healthcare systems in the world with generally well-connected patient records from hospitals to primary care: Its digital systems and services (e.g., Summary Care Records (SCR) and National Record Locator (NRL)) help health professionals achieve the best outcomes for patients by locating patient records within the health system. The SCR system is currently used by 98% of GP practices, enabling them to automatically create digital records for all registered patients ("Summary Care Records (SCR) - NHS Digital" 2020).

Market and surgical innovation leadership: In 2019, the UK was ranked third globally in robotic surgery innovation [66]. As of 2020, it is also the second country with the largest revenue share (20%) in the European Robotic Endoscopy Devices Market (Fig. 4).

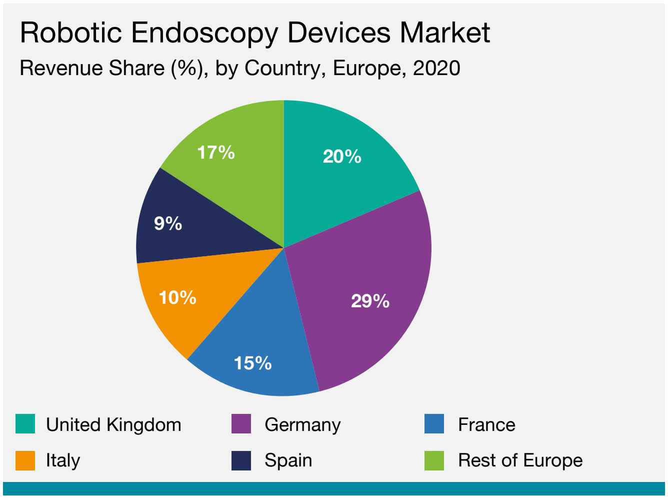


FIGURE 4.

Robotic Endoscopy Devices Market, Europe. Source: Original data gathered from multiple market reports on robotic endoscopy.

Distributed research excellence across key enabling topics: The UK counts on multiple internationally renowned institutions (universities, centres) undertaking or supporting research in surgical robotics.

High quality clinical trial units: The UK Clinical Research Collaboration (UKRC) infrastructure supports all aspects of clinical research through its Clinical Research Network (comprising 15 local networks distributed across England and 30 specialty therapy areas) and its Registered Clinical Trial Unit Network (composed of 53 units across the UK). Each unit in this network is evaluated by an International Review Committee of experts [67], [68].

Funding bodies across the translational spectrum: These range from funding bodies for basic and applied research (such as MRC, EPSRC, medical charities and EU projects), to funding bodies for translational development, such as Innovate UK and NIHR initiatives (e.g., Surgical MedTech Co-operative and the Invention for Innovation (i4i) Programme) [69].

Charities that fund medical research and involve patients: In 2019, AMRC medical research charities accounted for 51% of publicly funded medical research in the UK (AMRC 2019) [70]. Although a national strength, it is worth noting that most investments support research outside surgical robotics, with 61% of these funds invested in understanding health conditions (cause), 32% in treatment (cure), and 7% in prevention and management (care). Furthermore, Partnerships between charities and the NIHR resulted in 1,738 charity-funded studies supported through the NIHR's Clinical Research Network and 3,110 through its research infrastructure (CCF) [68].

International reputation for investment returns in UK Tech: In 2017, 205 incubators and 163 accelerators were identified in the UK; 14% of incubators focused on engineering and manufacturing (including robotics), 13% on health and wellbeing, and 29% on other digital technologies (such as virtual reality) [71]. In 2020, UK Tech VC investment was third worldwide, with MedTech being the second most funded sub-sector. The fact that 63% of total VC funding came from non-UK sources, denotes the international reputation for investment returns in UK Tech and the potential benefits of increasing domestic investment [72].

WEAKNESSES

Absence of an explicit innovation pipeline: While the sector has progressed and gained momentum in recent years, this has historically been through a technology push, rather than clinical pull. Clinical trial support, the evaluation of patient benefit, and wider clinical adoption have all been pursued in a fragmented way and ad hoc, with larger enterprises at a natural advantage compared to smaller companies (usually academic spinouts).

Limited availability of trained staff/researchers: There are no formal mandatory guidelines, pathways or curricula for the training of surgical robotics specialists in the UK or Europe. Numerous fellowships exist, however, training is often unstructured and acquired through mentorship or observation, learning "on the job" [73]. Consequently, it can be challenging to recruit for surgical robotics roles, whether in academia or industry, from the pool of graduates straight out of University.

Affordability of robotic surgery is an issue in the NHS: The feasibility of investment in robot-assisted Minimally Invasive Surgery (MIS) is dependent on the volume of cases that can be undertaken in a Trust, and thus the ability to recover the high upfront capital investment. Securing funding for operational costs (such as costly disposables) is also a limiting financial factor [74].

Risk-averse environment/mentality (Clinicians, Patients, NHS, Investors): Surgeons may be reluctant to use robots that have a large operating room footprint, a long setup time, lack haptic feedback, and risk malfunction or failure [74]. Recent surveys also show that UK patients were the least willing to undergo a minor or major robotic surgery [75]. On the other hand, some NHS Trusts require business cases to show a return on the proposed investment within 12 months [74], which leads to the perception that new robotics systems must first be trialled extensively in private hospitals to be proved beneficial and suitable for uptake by the NHS. Finally, the appetite for risk and investment horizon amongst UK investors is not conducive to large-scale investments in surgical robotics, which remain both high and long-term due to the slow clinical uptake, large capital and consumable costs, the need for extensive aftersales support, and generally longer procedure times, associated with current robotic technology.

Large NHS Trusts may be slow in adapting to new trends: Implementation may require large changes to the workforce (e.g., new ways of working, new roles) and new workflows that call for clinician buy-in, efficient leadership and adaptability [76].

Marginal number of companies in the field: The UK possesses only a few key players in the field, mainly CMR, Renishaw PLC, and Smith & Nephew PLC.

Some fabrication methods currently used are not suited for industrial scale-up: The critical relationship between advanced manufacturing processes and the expansion of robotics has been recognised by a cross-institutional collective of global researchers in robotics, who state that fabrication schemes are a core grand challenge which may provide major breakthroughs, significant research, and/or socioeconomic impact in robotics in the next 5 to 10 years [77].

Global competition research-wise: In 2019, the UK was ranked third globally in robotic surgery innovation [66], followed by four other EU countries (Netherlands, Spain, Germany, and France) and three from Asia (South Korea, China and India). However, in terms of research impact, the UK was only sixth, outranked by three other EU countries (Italy, Germany, and France).

OPPORTUNITIES

Collaborative robots that enhance surgical performance: Collaborative approaches that go beyond standard telemanipulation can establish a synergy between robot and surgeon and enable deeper and more meaningful interactions. These have the potential to improve surgical outcomes by ensuring safety in complex procedures, reducing the size of the surgical incision, shortening the learning curve for surgeons, reducing operating times, and eliminating outliers, while at the same time enhancing the user experience through a more intuitive and immersive user experience.

Development of innovative surgical robots from creation to pilot clinical trials in a single centre: Different centres in the UK already offer support for the development of innovative medical technologies, including the Wellcome/EPSRC Centre for Interventional and Surgical Sciences (WEISS), the Wellcome/EPSRC Centre for Medical Engineering (CME), the NIHR Incubator for Advanced Surgical Technology, the NIHR's Surgical MedTech Co-operative, and The Institute for Global Health Innovation (IGHI).

Ease the access and navigation through the MedTech innovation pathway: Knowledge and expertise drawn from existing centres that support MedTech development [78] (and other initiatives relevant to surgical robotics) could serve as the basis for a central national training and information facility for regulatory affairs and accelerate the process of proceeding from concept to clinical implementation for R&D groups.

Enhance surgical training in the NHS: Recent studies by NHS Foundation Trusts encourage the introduction of robotic surgery simulation in the core surgical training curriculum [79]. These platforms are more robust in terms of ensuring rapid surgical skills acquisition (through prompts, a structured approach, extensive practice before touching patients), a more standardised and unbiased assessment, and non-technical skills provision.

Ease the access to surgical robotic platforms: The nationalised structure of the UK's healthcare system could potentially allow for a well-orchestrated deployment, increased use, and effective organisation of individual (high-capital) robotic platforms. Early indications of this are initiatives such as the Robotic Surgery, Consumables and Related Services Framework [80], and the Robotic Medical Equipment, Associated Accessories and Consumables Framework [81].

Reduce the cost of public healthcare by using robotic approaches: If the fixed costs of robotic surgery (e.g., high fixed costs of equipment) can be spread across higher volumes, robotic surgery could potentially become cost effective [82] by reducing the length of hospital stays (as recently evidenced for robot-assisted radical prostatectomies [83]) and increasing the volume of inpatient surgeries.

Brexit - Faster regulatory approval and joint certification for multiple markets (US, EU, China): The responsibilities for the UK medical devices market are now governed by a single body: The Medicines and Healthcare products Regulatory Agency (MHRA). As of March 2021, the MHRA is working with the Health Research Authority (HRA) to pilot a new coordinated assessment pathway [84], which will streamline the review of clinical investigations involving medical devices.

Tackle global healthcare challenges: Full attainment of the UN's good health and wellbeing goals requires access to surgical services. Nevertheless, in low-income and lower-middle-income countries, nine of ten people do not have access to basic surgical care, and only a fifth of the world's specialist surgeons attend to the poorest half of the world's population [85]. Affordable technologies and digital learning tools could help bridge the surgical care division worldwide.

Create new national industries for the engineering and manufacturing of innovative robots: In 2018, the UK ranked 7th out of fifteen European countries in terms of medical devices exports based on manufacturers' revenues. It also incurred a negative medical devices trade balance, as imports were higher than exports (Medtech-Europe 2020) [86].

Better use of GP practices for patient care, enabled by technology: The Royal College of Surgeons of England recently highlighted the importance of tracking surgical outcomes (in the long-term) and redefining the notion of successful surgical procedures based on the patient's recovery and impact on their quality of life [87]. These long-term outcomes could be tracked by linking data from GP practices (post-surgery) to personalised care.

THREATS

Global competition - Large markets with strong investment opportunities (China, USA): The US holds almost half of the Surgical Robots market share globally, as reported in Fig. 5. Its position is strengthened by an increase in start-up funding, company acquisitions by medical device giants, and the support from both regulatory bodies and private companies. The EU and Asia Pacific follow with a marginal market share difference between them and an increase in investments, expansions, and regulatory approvals.

Brexit - Reduction in international research collaborations: The UK's primary collaboration partner and largest contributor to both research impact and innovation in surgical robotics is the EU. In the 2007–2013 period, the UK received €8.8 billion from the EU as part of Horizon 2020 and almost one in five academics in UK universities are from the EU. A potential loss in funding and human capital could undermine the UK's status as a global leader in science and innovation [66].

Brexit - Barrier to export/different regulations: From July 2023, new devices placed on the UK market will need to conform with UKCA marking requirements (or UKNI for Northern Ireland), while medical devices to be placed in the EU market must adhere to EU legislation, and obtain the CE mark to demonstrate compliance [88]. Exporters may also need a Certificate of Free Sale (CFS) to export medical devices [89].

Restrictions in the ability to recruit top global talent at the early research career stages (PhD students): UK institutions are moving towards a PhD research fee structure that makes international students largely ineligible for our scholarships. The ability to recruit internationally, and for those students to contribute to our research and IP generation, is crucial in a competitive global environment.

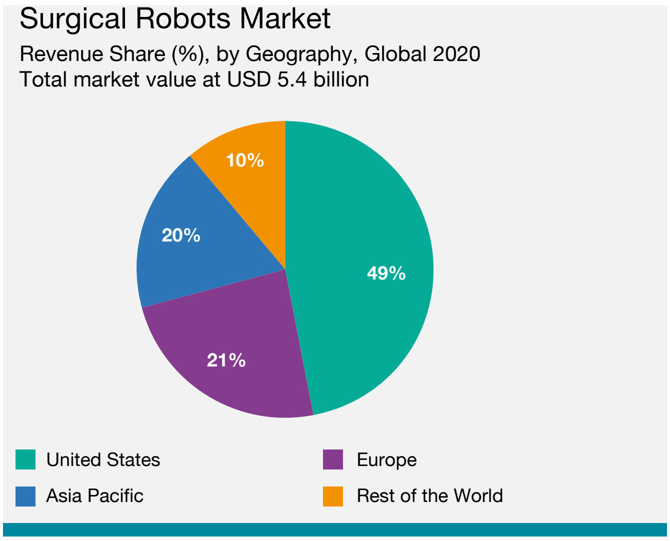


FIGURE 5.

Surgical Robots Market - geographical segmentation. Source: Original data gathered from multiple market reports on robotic surgery.

6. RECOMMENDATIONS

RECOMMENDATIONS TO ENHANCE UK RESEARCH AND IMPACT IN SURGICAL ROBOTICS

Considering national research excellence, recent institutional investments in surgical robotics, and the unique opportunities in post-Brexit UK, we set forth a set of recommendations to further support research activity in UK Surgical Robotics - with the aim to ultimately establish translational activities arising from academic research.

RECOMMENDATION A
DISCOVERY

Increase investment in Surgical Robotic Challenges. For the past 7 years (since 2015), the surgical robotic community has had the opportunity to participate in the Surgical Robotic Challenge, organised jointly by the Hamlyn Centre at Imperial College and the EPSRC UK RAS Network, on the occasion of the yearly Hamlyn Symposium on Medical Robotics. This is now a well-recognised annual event bringing together teams from all over the world. Starting from this world-leading position and leveraging substantial investment, we suggest the creation of transformative surgical robotics challenges to tackle urgent clinical needs and support the early discovery phase up to pre-clinical feasibility trials. These awards will build on our world-leading engineering and clinical base and accelerate innovation in surgical robotics.

RECOMMENDATION B
TRANSLATION

Consider improving the ecosystem for start-up companies in surgical robotics. The market for surgical robotics is growing fast and the UK has relevant and world-leading research in the field. However, at the moment, there is a marginal number of UK companies active in surgical robotics and some patient reluctance in adopting these new technologies. We suggest the Government consider directing specific InnovateUK calls towards the field of surgical robotics and UKRI funding to support the establishment of benchmarks, metrics and demonstrators of patient benefit via robotic surgery. This will fuel effective translation of innovations generated by UK-based researchers for the eventual benefit of patients and the NHS. At the same time, it will attract further international investment in UK-based high-tech companies.

RECOMMENDATION C
TRANSLATION

Consider how best to maximise the translational potential of academic research. Academic institutions should develop better mechanisms and metrics to quantify not just theirs, but society's overall benefit, as well as the effect that different translation models may have on the latter. One-size-fits-all approaches should be avoided in commercial translation. Flexible models should be favoured over rigid formulae, striking an appropriate balance of rights and responsibilities amongst stakeholders, which should be contingent on the skills, ambitions, makeup and degree of future involvement of the founding team. We suggest that UK universities review their current approaches and pursue a more comprehensive view about the return on the investments made in academic research.

RECOMMENDATION D
ASSET

Support the creation of anonymised annotated data repositories to facilitate research in surgical robotics. A clear direction of research in surgical robotics is towards autonomy. For a surgical robotic platform to be intelligent enough to make sensible decisions during a surgical procedure, a large amount of annotated and curated training data is crucial. In other countries (e.g., US), funding agencies are supporting the creation of dedicated repositories. In the UK, we have the unique opportunity offered by the NHS, the single largest healthcare provider in the world. We suggest the Government invest in the creation of a NHS-wide network of annotated/curated data repositories to train surgical robots.

RECOMMENDATION E
CLUSTER

Invest in Surgical Robotics Clusters. Surgical robotics is a multidisciplinary field and, as such, can greatly benefit from investment in bringing together engineers, scientists, manufacturing technologists, clinicians, nurses, patients, healthcare managers, clinical trialists, researchers in health economics, experts in technology transfer, and investors. This would facilitate the flow of discovery, capacity and activity, from basic investigations, through pre-clinical demonstrations, to fully certified commercial products. We suggest considering support for EPSRC/MRC/NIHR Joint Centres of Excellence in Surgical Robotics addressing different healthcare needs.

RECOMMENDATION F
SKILLS

To access the greatest global STEM talent in the surgical robotics workforce. Before Brexit, UK Universities and research centres were only able to attract postgraduate researchers from the EU due to PhD study fees being at vastly lower rates than for international students. This is about to be further exacerbated as these restrictions become UK-only. If no measures are taken, this will translate into a reduction in the quality and productivity of our research, with detrimental implications for current and future UK companies active in the field of surgical robotics. We suggest the Government and Universities to alter the eligibility requirements for Doctoral Training Partnerships (DTP) greatly beyond the current limit of 30% for non-UK nationals. This would enable UK research to attract the very best students from anywhere in the world and prepare a pipeline of first-class workforce adept to thriving in an industrial field that is expected to grow dramatically in the next decade. We also suggest for the Government to restore the ability for PhD studentships to be included in research grant proposals. This would allow principal investigators to better plan and resource their teams.

RECOMMENDATION G
SUPPORT

Facilitate collaboration among funding agencies with an interest in surgical robotics.
This field resides at the intersection of engineering, medicine, physics, manufacturing, public health and business development. As such, there are many funding agencies (EPSRC, MRC, NIHR, Innovate UK) and charities (CRUK, Wellcome Trust) with a strong interest in supporting activities in surgical robotics. While the creation of UKRI has certainly facilitated interactions, there is still room for improvement. We suggest considering the creation of a cross-cutting theme among multiple agencies with a specific focus on Surgical Robotics that distinctly encourages cross-disciplinary research collaboration.

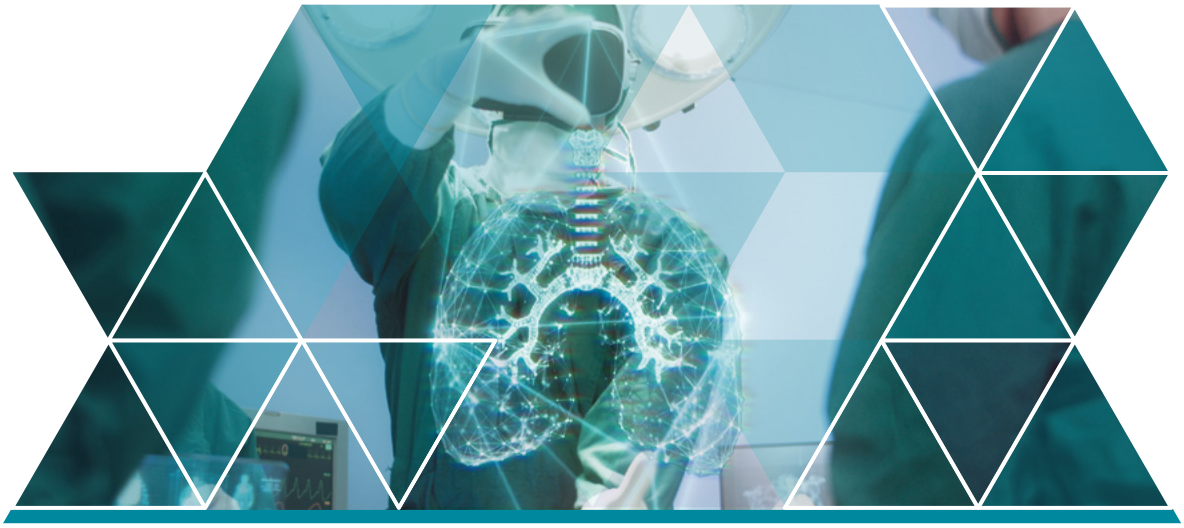
RECOMMENDATION H
SUPPORT

Facilitate further international collaborations in surgical robotics. Multiple mechanisms already exist to support international collaborations with research partners worldwide, including the EU, India, and the US. However, the existing agreement with the US (i.e. NSF-EPSRC Lead Agency Agreement) does not include the National Institutes of Health (NIH) and the NSF Division of “Information and Intelligent Systems” (IIS). These are the two funding bodies in the US that support the majority of research in surgical robotics. We suggest UKRI consider extending the current agreement to include the NIH and NSF-IIS, as well as pursuing new agreements with international funding bodies further afield. This would allow UK researchers in surgical robotics to join forces with their international colleagues to address open challenges in the field.

7. CONCLUSION

With numerous innovations taking place in the unexplored segments of early diagnosis and treatment, surgical robots will play a vital role in years to come. The UK is in a strong position to ride this wave of innovation, thanks to world-leading research and the presence of the largest single healthcare provider in the world. However, the country currently underperforms in translation and successful commercialisation of these technologies. The recommendations presented in this White Paper would ensure that we cement and capitalise on our competitive advantages despite very aggressive international competition from emerging economies (China, India) as well as from the more established players in the field (US and EU).

8. REFERENCES



[1] Harris SJ, Arambula-Cosio F, Mei Q, Hibberd RD, Davies BL, Wickham JE, Nathan MS, Kundu B. The Probot—an active robot for prostate resection. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 1997 Apr 1;211(4):317-25.

[2] https://www.medgadget.com/2006/02/the_acrobot_sur.html

[3] https://www.gov.uk/government/speeches/eight-great-technologies

[4] Lee SL, Lerotic M, Vitiello V, Giannarou S, Kwok KW, Visentini-Scarzanella M, Yang GZ. From medical images to minimally invasive intervention: Computer assistance for robotic surgery. Computerized Medical Imaging and Graphics. 2010 Jan 1;34(1):33-45.

[5] Maier-Hein, Lena, et al. "Optical techniques for 3D surface reconstruction in computer-assisted laparoscopic surgery." Medical image analysis 17.8 (2013): 974-996.

[6] Giannarou S, Visentini-Scarzanella M, Yang GZ. Probabilistic tracking of affine-invariant anisotropic regions. IEEE transactions on pattern analysis and machine intelligence. 2012 Apr 3;35(1):130-43.

[7] Sparks R, Vakharia V, Rodionov R, Vos SB, Diehl B, Wehner T, Miserocchi A, McEvoy AW, Duncan JS, Ourselin S. Anatomy-driven multiple trajectory planning (ADMTP) of intracranial electrodes for epilepsy surgery. International journal of computer assisted radiology and surgery. 2017 Aug;12(8):1245-55.

[8] Mazomenos EB, Chang PL, Rippel RA, Rolls A, Hawkes DJ, Bicknell CD, Desjardins A, Riga CV, Stoyanov D. Catheter manipulation analysis for objective performance and technical skills assessment in transcatheter aortic valve implantation. International journal of computer assisted radiology and surgery. 2016 Jun;11(6):1121-31.

[9] https://smartsurg-project.eu

[10] Cartucho J, Shapira D, Ashrafian H, Giannarou S. Multimodal mixed reality visualisation for intraoperative surgical guidance. International journal of computer assisted radiology and surgery. 2020 May;15(5):819-26.

[11] Mei Q, Harris SJ, Arambula-Cosio F, Nathan MS, Hibberd RD, Wickham JE, Davies BL. PROBOT—A computer integrated prostatectomy system. InInternational Conference on Visualization in Biomedical Computing 1996 Sep 22 (pp. 581-590). Springer, Berlin, Heidelberg.

[12] Davies B, Rodriguez F, Harris S, Jakopec M, Barrett A, Gomes P, Cobb J. An overview of the Acrobot® robotic surgical system for minimally invasive unicompartmental knee arthroplasty. Journal of Biomechanics. 2006(39):S211.

[13] Shang J, Leibrandt K, Giataganas P, Vitiello V, Seneci CA, Wisanuvej P, Liu J, Gras G, Clark J, Darzi A, Yang GZ. A single-port robotic system for transanal microsurgery—Design and validation. IEEE robotics and automation letters. 2017 Feb 13;2(3):1510-7.

[14] Deacon G, Harwood A, Holdback J, Maiwand D, Pearce M, Reid I, Street M, Taylor J. The Pathfinder image-guided surgical robot. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2010 May 1;224(5):691-713.

[15] Frasson L, Ko SY, Turner A, Parittotokkaporn T, Vincent JF, Rodriguez y Baena F. STING: a soft-tissue intervention and neurosurgical guide to access deep brain lesions through curved trajectories. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2010 Jun 1;224(6):775-88.

[16] Khadem M, Rossa C, Usmani N, Sloboda RS, Tavakoli M. Semi-automated needle steering in biological tissue using an ultrasound-based deflection predictor. Annals of biomedical engineering. 2017 Apr;45(4):924-38.

[17] Bergeles C, Gosline AH, Vasilyev NV, Codd PJ, Pedro J, Dupont PE. Concentric tube robot design and optimization based on task and anatomical constraints. IEEE Transactions on Robotics. 2015 Jan 23;31(1):67-84.

[18] Norton JC, Slawinski PR, Lay HS, Martin JW, Cox BF, Cummins G, Desmulliez MP, Clutton RE, Obstein KL, Cochran S, Valdastri P. Intelligent magnetic manipulation for gastrointestinal ultrasound. Science robotics. 2019 Jun 19;4(31).

[19] Miyashita S, Guitron S, Yoshida K, Li S, Damian DD, Rus D. Ingestible, controllable, and degradable origami robot for patching stomach wounds. In2016 IEEE international conference on robotics and automation (ICRA) 2016 May 16 (pp. 909-916). IEEE.

[20] Cianchetti M, Ranzani T, Gerboni G, De Falco I, Laschi C, Menciassi A. STIFF-FLOP surgical manipulator: Mechanical design and experimental characterization of the single module. In2013 IEEE/RSJ international conference on intelligent robots and systems 2013 Nov 3 (pp. 3576-3581). IEEE.

[21] Berthet-Rayne P, Gras G, Leibrandt K, Wisanuvej P, Schmitz A, Seneci CA, Yang GZ. The i 2 snake robotic platform for endoscopic surgery. Annals of biomedical engineering. 2018 Oct;46(10):1663-75.

[22] Riva M, Lopci E, Gay LG, Nibali MC, Rossi M, Sciortino T, Castellano A, Bello L. Advancing Imaging to Enhance Surgery: From Image to Information Guidance. Neurosurgery Clinics. 2021 Jan 1;32(1):31-46.

[23] Martin JW, Scaglioni B, Norton JC, Subramanian V, Arezzo A, Obstein KL, Valdastri P. Enabling the future of colonoscopy with intelligent and autonomous magnetic manipulation. Nature Machine Intelligence. 2020 Oct;2(10):595-606.

[24] Manfredi L, Capoccia E, Ciuti G, Cuschieri A. A Soft Pneumatic Inchworm Double balloon (SPID) for colonoscopy. Scientific reports. 2019 Jul 31;9(1):1-9.

[25] Atwya M, Kavak C, Alisse E, Liu Y, Damian D. Flexible and Expandable Robot for Tissue Therapies-Modeling and Design. IEEE Transactions on Biomedical Engineering. 2020 Jul 7.

[26] Bowyer SA, Davies BL, y Baena FR. Active constraints/virtual fixtures: A survey. IEEE Transactions on Robotics. 2013 Oct 16;30(1):138-57.

[27] Lerotic M, Chung AJ, Mylonas G, Yang GZ. Pq-space based non-photorealistic rendering for augmented reality. InInternational Conference on Medical Image Computing and Computer-Assisted Intervention 2007 Oct 29 (pp. 102-109). Springer, Berlin, Heidelberg.

[28] Guo J, Elgeneidy K, Xiang C, Lohse N, Justham L, Rossiter J. Soft pneumatic grippers embedded with stretchable electroadhesion. Smart Materials and Structures. 2018 Mar 27;27(5):055006.

[29] Ma J, Feng H, Chen Y, Hou D, You Z. Folding of tubular waterbomb. Research. 2020 Apr 10;2020.

[30] Forte AE, Galvan S, Manieri F, y Baena FR, Dini D. A composite hydrogel for brain tissue phantoms. Materials & Design. 2016 Dec 15;112:227-38.

[31] Frasson L, Ko SY, Turner A, Parittotokkaporn T, Vincent JF, Rodriguez y Baena F. STING: a soft-tissue intervention and neurosurgical guide to access deep brain lesions through curved trajectories. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2010 Jun 1;224(6):775-88.

[32] Mitros Z, Sadati S, Seneci C, Bloch E, Leibrandt K, Khadem M, da Cruz L, Bergeles C. Optic Nerve Sheath Fenestration with a Multi-Arm Continuum Robot. IEEE Robotics and Automation Letters. 2020 Jun 25;5(3):4874-81.

[33] Jiang A, Ranzani T, Gerboni G, Lekstutyte L, Althoefer K, Dasgupta P, Nanayakkara T. Robotic granular jamming: Does the membrane matter?. Soft Robotics. 2014 Sep 1;1(3):192-201.

[34] He L, Herzig N, de Lusignan S, Nanayakkara T. Granular jamming based controllable organ design for abdominal palpation. In2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC) 2018 Jul 18 (pp. 2154-2157). IEEE.

[35] Gallarello A, Palombi A, Annio G, Homer-Vanniasinkam S, De Momi E, Maritati G, Torii R, Burriesci G, Wurdemann HA. Patient-Specific Aortic Phantom With Tunable Compliance. Journal of Engineering and Science in Medical Diagnostics and Therapy. 2019 Nov 1;2(4).

[36] Herzig N, Maiolino P, Iida F, Nanayakkara T. A variable stiffness robotic probe for soft tissue palpation. IEEE Robotics and Automation Letters. 2018 Jan 15;3(2):1168-75.

[37] Khan F, Donder A, Galvan S, y Baena FR, Misra S. Pose Measurement of Flexible Medical Instruments Using Fiber Bragg Gratings in Multi-Core Fiber. IEEE Sensors Journal. 2020 May 8;20(18):10955-62.

[38] Hannan S, Aristovich K, Faulkner M, Avery J, Walker MC, Holder DS. Imaging slow brain activity during neocortical and hippocampal epileptiform events with electrical impedance tomography. Physiological Measurement. 2021 Feb 4;42(1):014001.

[39] Marques MJ, Hughes MR, Vyas K, Thrapp A, Zhang H, Bradu A, Gelikonov G, Giataganas P, Payne CJ, Yang GZ, Podoleanu A. En-face optical coherence tomography/ fluorescence endomicroscopy for minimally invasive imaging using a robotic scanner. Journal of biomedical optics. 2019 Jun;24(6):066006.

[40] Virdyawan V, y Baena FR. A long short-term memory network for vessel reconstruction based on laser doppler flowmetry via a steerable needle. IEEE Sensors Journal. 2019 Aug 8;19(23):11367-76.

[41] Power M, Thompson AJ, Anastasova S, Yang GZ. A monolithic force-sensitive 3D microgripper fabricated on the tip of an optical fiber using 2-photon polymerization. Small. 2018 Apr;14(16):1703964.

[42] Lee HT, Seichepine F, Yang GZ. Microtentacle Actuators Based on Shape Memory Alloy Smart Soft Composite. Advanced Functional Materials. 2020 Aug;30(34):2002510.

[43] Avci E, Grammatikopoulou M, Yang GZ. Laser-Printing and 3D Optical-Control of Untethered Microrobots. Advanced Optical Materials. 2017 Oct;5(19):1700031.

[44] Zhang D, Barbot A, Lo B, Yang GZ. Distributed Force Control for Microrobot Manipulation via Planar Multi-Spot Optical Tweezer. Advanced Optical Materials. 2020 Nov;8(21):2000543.

[45] Vasconcelos F, Mazomenos E, Kelly J, Stoyanov D. RCM-SLAM: Visual localisation and mapping under remote centre of motion constraints. In2019 International conference on robotics and automation (ICRA) 2019 May 20 (pp. 9278-9284). IEEE.

[46] Liu H, Auvinet E, Giles J, y Baena FR. Augmented reality based navigation for computer assisted hip resurfacing: a proof of concept study. Annals of biomedical engineering. 2018 Oct;46(10):1595-605.

[47] Liu H, Baena FR. Automatic markerless registration and 7tracking of the bone for computer-assisted orthopaedic surgery. IEEE Access. 2020 Feb 28;8:42010-20.

[48] Vercauteren T, Unberath M, Padoy N, Navab N. Cai4cai: the rise of contextual artificial intelligence in computer-assisted interventions. Proceedings of the IEEE. 2019 Oct 23;108(1):198-214.

[49] Granados A, Han Y, Lucena O, Vakharia V, Rodionov R, Vos SB, Miserocchi A, McEvoy AW, Duncan JS, Sparks R, Ourselin S. Patient-specific prediction of SEEG electrode bending for stereotactic neurosurgical planning. International journal of computer assisted radiology and surgery. 2021 May;16(5):789-98.

[50] Raza SJ, Froghi S, Chowriappa A, Ahmed K, Field E, Stegemann AP, Rehman S, Sharif M, Shi Y, Wilding GE, Kesavadas T. Construct validation of the key components of Fundamental Skills of Robotic Surgery (FSRS) curriculum—a multi-institution prospective study. Journal of surgical education. 2014 May 1;71(3):316-24.

[51] Durand-Hill M, Henckel J, Di Laura A, Hart AJ. Can custom 3D printed implants successfully reconstruct massive acetabular defects? A 3D-CT assessment. Journal of Orthopaedic Research®. 2020 Dec;38(12):2640-8.

[52] Stokes AA, Shepherd RF, Morin SA, Ilievski F, Whitesides GM. A hybrid combining hard and soft robots. Soft Robotics. 2014 Mar 1;1(1):70-4.

[53] Bowyer SA, y Baena FR. Dissipative control for physical human–robot interaction. IEEE Transactions on Robotics. 2015 Oct 8;31(6):1281-93.

[54] Petersen JG, y Baena FR. Mass and inertia optimization for natural motion in hands-on robotic surgery. In2014 IEEE/RSJ International Conference on Intelligent Robots and Systems 2014 Sep 14 (pp. 4284-4289). IEEE.

[55] Hu Y, Zhang L, Li W, Yang GZ. Robotic sewing and knot tying for personalized stent graft manufacturing. In2018 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS) 2018 Oct 1 (pp. 754-760). IEEE.

[56] Franco E, Garriga-Casanovas A, Tang J, y Baena FR, Astolfi A. Adaptive energy shaping control of a class of nonlinear soft continuum manipulators. IEEE/ASME Transactions on Mechatronics. 2021 Mar 2.

[57] Herzig N, He L, Maiolino P, Abad SA, Nanayakkara T. Conditioned haptic perception for 3D localization of nodules in soft tissue palpation with a variable stiffness probe. PloS one. 2020 Aug 11;15(8):e0237379.

[57] Gao A, Liu N, Shen M, EMK Abdelaziz M, Temelkuran B, Yang GZ. Laser-profiled continuum robot with integrated tension sensing for simultaneous shape and tip force estimation. Soft Robotics. 2020 Aug 1;7(4):421-43.

[59] Ataka A, Abrar T, Putzu F, Godaba H, Althoefer K. Model-based pose control of inflatable eversion robot with variable stiffness. IEEE Robotics and Automation Letters. 2020 Feb 26;5(2):3398-405.

[60] Squires A, Hovet S, Li R, Oshinski J, Ho Tse ZT. A body-mounted device for MRI-guided spinal therapy. The International Journal of Medical Robotics and Computer Assisted Surgery. 2021 Apr;17(2):e2235.

[61] Cao C, Diteesawat RS, Rossiter J, Conn AT. A reconfigurable crawling robot driven by electroactive artificial muscle. In2019 2nd IEEE International Conference on Soft Robotics (RoboSoft) 2019 Apr 14 (pp. 840-845). IEEE.

[62] Miyashita S, Guitron S, Yoshida K, Li S, Damian DD, Rus D. Ingestible, controllable, and degradable origami robot for patching stomach wounds. In2016 IEEE international conference on robotics and automation (ICRA) 2016 May 16 (pp. 909-916). IEEE.

[63] Nemitz MP, Abrahamsson CK, Wille L, Stokes AA, Preston DJ, Whitesides GM. Soft non-volatile memory for non-electronic information storage in soft robots. In 2020 3rd IEEE International Conference on Soft Robotics (RoboSoft) 2020 May 15 (pp. 7-12). IEEE.

[64] https://www.terrinet.eu/

[65] https://www.ideal-collaboration.net/

[66] Garas G, Cingolani I, Patel VM, Panzarasa P, Darzi A, Athanasiou T. Evaluating the implications of Brexit for research collaboration and policy: a network analysis and simulation study. BMJ open. 2019 Sep 1;9(9):e025025.

[67] https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm

[68] https://www.nihr.ac.uk/documents/about-us/our-contribution-to-research/research-performance/NIHR_Annual_Report_19_20.pdf

[69] https://epsrc.ukri.org/research/ourportfolio/themes/healthcaretechnologies/strategy/toolkit/landscape

[70] https://www.amrc.org.uk/making-a-difference-impact-report-2019

[71] Bone J, Allen O, Haley C. Business Incubators and accelerators: the national picture. BEIS Research paper; 2017.

[72] https://technation.io/report2021

[73] Dixon F, Keeler BD. Robotic surgery: training, competence assessment and credentialing. The Bulletin of the Royal College of Surgeons of England. 2020 Oct;102(7):302-6.

[74] Cole A, O'Neill P, Sampson C, Lorgelly P. Barriers to uptake of minimal access surgery in the united kingdom. OHE Consulting Report, London: Office of Health Economics. 2018 Mar 1.

[75] PWC. 2017. "Why AI and Robotics Will Define New Health." PricewaterhouseCoopers. https://www.pwc.com/gx/en/industries/healthcare/publications/ai-robotics-new-health/ai-robotics-new-health.pd

[76] Castle-Clarke, Sophie. 2018. "What Will New Technology Mean for the NHS and Its Patients?" The Health Foundation, the Institute for Fiscal Studies, The King's Fund and the Nuffield Trust. https://www.health.org.uk/sites/default/files/NHS-70-What-will-new-technology-mean-for-the-NHS.pdf.

[77] Yang GZ, Bellingham J, Dupont PE, Fischer P, Floridi L, Full R, Jacobstein N, Kumar V, McNutt M, Merrifield R, Nelson BJ. The grand challenges of Science Robotics. Science robotics. 2018 Jan 31;3(14):eaar7650.

[78] AHSN Network. n.d. "MedTech Landscape Review." Office for Life Sciences. Accessed May 22, 2021. https://www.ahsnnetwork.com/app/uploads/2019/02/MedTech-Landscape-Review-AHSN-Network.pdf.

[79] Bhakhri K, Harrison-Phipps K, Harling L, Routledge T. Should Robotic Surgery Simulation Be Introduced in the Core Surgical Training Curriculum?. Frontiers in Surgery. 2021 Mar 10;8:42.

[80] "Robotic Surgery, Consumables and Related Services." n.d. Accessed May 19, 2021. https://www.sbs.nhs.uk/fas-robotic-surgery.

[81] "Robotic Medical Equipment, Associated Accessories and Consumables." 2020. September 9, 2020. https://www.supplychain.nhs.uk/product-information/contract-launch-brief/robotic-medical-equipment/.

[82] Crew B. Worth the cost? A closer look at the da Vinci robot's impact on prostate cancer surgery. Nature. 2020 Apr 1;580(7804):S5-.

[83] Perez RE, Schwaitzberg SD. Robotic surgery: finding value in 2019 and beyond. Ann Laparosc Endosc Surg. 2019 May;4:51.

[84] MHRA 2021. "Notify the MHRA about a Clinical Investigation for a Medical Device." Medicines and Healthcare products Regulatory Agency. https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device.

[85] Meara JG, Leather AJ, Hagander L, Alkire BC, Alonso N, Ameh EA, Bickler SW, Conteh L, Dare AJ, Davies J, Mérisier ED. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. The lancet. 2015 Aug 8;386(9993):569-624.

[86] https://www.medtecheurope.org/resource-library/medtech-europes-facts-and-figures-2020/

[87] Royal College of Surgeons. 2018. "The Future of Surgery." Royal College of Surgeons. https://futureofsurgery.rcseng.ac.uk.

[88] MHRA. 2020. "Regulating Medical Devices in the UK." 2020. https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk.

[89] MHRA. 2021a. "Guidance Export Medical Devices." 2021. https://www.gov.uk/guidance/export-medical-devices-special-rules.

> "The commercial successes of the first generation clinical robotic systems have inspired an ever-increasing number of platforms from both commercial and research organisations, resulting in smaller, safer, and smarter devices that will underpin the future of precision surgery."

UK-RAS NETWORK
ROBOTICS & AUTONOMOUS SYSTEMS

www.ukras.org