Future of Surgery

A response to the Royal College of Surgeons independent commission on the future of surgery open call for evidence

February 2018

Introduction

We welcome the opportunity to respond to the Royal College of Surgeons' independent commission on the future of surgery. This submission has been developed by the Royal Academy of Engineering on behalf of the UK Panel for Biomedical Engineering, hosted by the Academy.

The Panel is a special interest group hosted by the Academy with expert membership drawn from across the biomedical engineering landscape, including academia, industry, government agencies and funders. This response also draws on input from the Academy's Fellows with an interest in medical technologies. Together, the Panel and the Academy's Fellows include experts on a wide range of biomedical engineering fields that may impact the future of surgery.

This response outlines technological trends in biomedical engineering fields that could impact the future of surgery, many of which have been identified by the commission. This is not a comprehensive list and the Academy would be delighted to provide further engineering expertise to support the commission's work as required. In addition, opportunities for cross-sectoral learning between engineering and surgery that do not depend on new technologies have been highlighted, including learning from failures and the application of a systems approach.

Summary

There has been significant progress in many biomedical engineering fields in recent years that are likely to impact the future of surgery. These range from computer modelling for improved targeting of interventions, to new interventions like tissue engineering for currently untreatable indications. These technologies have the potential to significantly improve patient outcomes, through providing new or improved interventions, reducing side effects, or better resourcing surgeons for their work.

Scientific and technological barriers remain for bringing many of these technologies into routine practice. To accelerate this translation there is a need for increased collaboration between surgical teams, biomedical engineering researchers and SMEs. Improved collaboration will also help shape research and development towards meeting clinical needs.

Emerging technologies may impact surgery in a number of ways. Many will require surgeons to develop new skills. Some technologies, such as improving the quality of computer models, or the materials used in surgical procedures, will drive only incremental changes in surgical processes and high quality CPD may be sufficient to upskill surgeons. Other technologies may require more substantial changes to surgical training in certain fields, such as the use of robot-assisted surgery, or the development of novel interventions. However, engineering technology is also becoming an increasingly valuable tool to support the training of surgical teams, including the use of simulation centres both to develop technical skills and support human factors training.

Many of the innovations outlined below will require significant capital investment in equipment, such as imaging machines or cell therapy manufacturing facilities. It is therefore unlikely that they will be available at a large number of hospitals throughout the UK. Instead it is likely that the adoption of such technologies will further concentrate many surgical interventions at a small number of centres of excellence. This may have implications for patient choice and experience, care pathways, and capacity requirements for surgical teams, as well as associated medical teams.

It is also important to note that many of these technologies are interdependent and may therefore have complex and interdependent effects on surgical processes. For example computer modelling may also rely on the availability of improved imaging technologies, and implantable robotic technologies will depend upon the availability of new biomaterials.

Technological trends

Computer modelling and systems biology

Computer modelling already supports surgery in a variety of ways. Imaging data can be used to generate personalised anatomical models or 3D images that can inform surgical intervention, leading to improved individual outcomes. There is potential for the role of computer models in surgery to increase significantly in the coming years.

Systems biology uses experimental data to generate and validate increasingly sophisticated mathematical and computational models of biological systems. These can incorporate functional and biophysical as well as anatomical data. There is the potential for this technology to be used to develop more comprehensive personalised patient models to inform surgery. Such individualised models are likely to become increasingly valuable with demographic trends, such as an ageing population and increasing co-morbidities, leading to a more heterogeneous surgical patient population.

For example, Christ et al[1] outline the potential for systems biology models to be used to inform and guide liver resection surgery. Currently models can only incorporate anatomical data. However, anatomy does not correlate directly with function, particularly in individuals with liver disease or other co-morbidities. Systems biology models, combined with more in depth imaging data such as PET scans, could take into account function as well as anatomy. The authors argue that this could guide both interventions and post-surgery care plans, with benefits for patients.

There are a number of challenges to wider implementation of computer modelling to inform and guide surgery. Particularly, there is a need for further development of more multi-scale models, which will require access to high quality data.

Applying systems biology to surgery will also depend upon the clinical availability of high quality imaging technology. This may lead to complex surgery being increasingly concentrated at a limited number of centres where such technology is available. As surgeons already use computer models in some areas, there are unlikely to be large changes in training or working practices required. However, it will be important that computer interfaces are well designed and easy to use for clinical teams.

Biomaterials[2]

There have been significant advances in biomaterials research in recent years, including the development of materials that more closely reflect the properties of biological tissues, materials that can be used as carriers for drugs, cells or robotics, and materials whose properties can be modulated, for example by temperature. These advances have the potential to influence health and care, including surgery, in several ways.

Some materials applications, such as improved coatings on prosthetics or joint replacements, may have minimal impact on surgeons and surgical pathways but important improvements for patient outcomes. Other applications may have a more significant impact. For example, advances in scaffold materials for tissue engineering (see also the section on regenerative medicine), drug delivery routes, or bio-compatible materials that can facilitate the implantation of robotic systems for sensing or drug delivery, may expand the number of conditions that could be treated with surgical intervention and transplantation of tissues. This may have implications for patient choice, with the relative benefits and risks of such interventions compared to conventional treatment needing to be thoroughly evaluated and explained. It may also have implications for surgery capacity and surgical training for novel procedures.

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[1] Christ et al 2017. Computational modelling in liver surgery. Front. Physiol., 14 November 2017

[2] Information in this section has largely been drawn from: Biomaterials and tissue engineering in the UK. Biomedical Division of the Institute of Materials, Minerals and Mining. 2013.

For the potential of advances in biomaterials to be realised there is a need for increased engagement and collaboration between biomaterial research and clinical communities, to steer research to meet clinical needs and accelerate development.

Tissue engineering and regenerative medicine

A number of different technologies fall into the broad category of 'regenerative medicine'. Cell and gene therapy technology has been advancing particularly rapidly in recent years, supported by the activities of organisations such as the UK's Cell and Gene Therapy Catapult, and may have the greatest clinical impact in the near future. Some cell and gene therapies are nearing routine clinical use, particularly CAR-T cells which have shown excellent clinical promise for the treatment of cancer. The clinical success in this indication has provided confidence to accelerate innovation in others, including for neurological disorders like Parkinson's disease, and musculoskeletal disorders. Barriers remain to the translation of these technologies into routine practice, including a need for clear standards, for example for effective quality batch release and handover from manufacturing to clinical use.

The delivery of such treatments into routine clinical practice will likely require novel surgical approaches for cell delivery. It may also increase demand for surgical interventions as conditions that are not conventionally treated through surgery may require surgical delivery of cells. Additionally, many therapies under development are autologous or otherwise depend on patient-derived material. These require on-site processing and manufacturing centres. Even allogeneic products are likely to have a critical interface between delivery and surgery, with implications for the supply chain and surgical pathways[3]. This will necessarily limit surgical interventions to centres of excellence where manufacturing centres or other capabilities are located, which may be the new Advanced Therapy Treatment Centres funded by Innovate UK[4]. This centralisation of capabilities will have implications for surgery capacity and patient choice.

Large scale tissue engineering, with implications for wound treatment, orthopaedic indications or diabetes treatment, is moving more slowly than cell and gene therapies. Scientific barriers remain, including overcoming immunological challenges and establishing the correct sequencing of cell types to aid growth and repair. However, simple structures, for example for wound repair, are available demonstrating that progress is being made in the field[5]. Establishing effective regulatory regimes, particularly for new technologies such as bio-printing (using 3D printing technology to create biological tissues) is also a key challenge to widespread clinical implementation.

Biomechanics

Advances in biomechanics and engineering research, along with imaging and computer modelling approaches, are leading to improvements in surgical procedures, particularly orthopaedic procedures such as joint replacements. One example is the development of kinematically aligned joint replacement in place of traditional mechanically aligned replacement. This uses motion capture imaging and computer models to generate patient-specific surgical plans to align interventions to the patient's natural movement. Robot-assisted surgery can also play a role in delivering improved joint replacement surgery (see section below). There is evidence to suggest that such approaches show improved implant fit and alignment, as well as decreased loss of bone volume, compared to conventional manual surgery[6].

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[3] Hourd et al. 2014. Manufacturing models permitting roll out/scale out of clinically led autologous cell therapies: Regulatory and scientific challenges for comparability. Cytotherapy 16(8): 1033-47

[4] https://ct.catapult.org.uk/news-media/general-news/innovate-uk-announce-funding-establish-network-advanced-therapies-treatment

[5] E.g. Apligraf® http://www.apligraf.com/professional/what_is_apligraf/index.html

[6] Paul et al 1992. *Development of a surgical robot for cementless total hip arthroplasty.* Clin Orthop Relat Res 285:57-66

Such techniques require largely incremental changes to surgery, including increasing personalisation of intervention, and increasing use of imaging and computer assisted planning of interventions (as outlined above). Rather than radical changes in training, such advances will necessitate high quality ongoing CPD for surgeons. Additionally, and as outlined above for other technologies, this may lead to complex surgery being further concentrated at a limited number of centres where technology is available. Finally, the multiple steps involved in preparing and planning complex individualised surgery may require patients to attend additional appointments or extend the total length of procedures. This will have implications for centre capacity as well as patient choice and experience.

Another area for consideration is the potential increase in early surgical interventions to prevent the progression of arthritis and associated chronic diseases. This may include implants to replace smaller focal defects or rebalancing of the stabilising structures in the joint. Such early interventions would need to be one part of a complex package of care including drug therapy and patient self-care in the form of rehabilitation, diet, and movement monitoring through sensors and apps. Increased early surgical intervention will have implications for surgery and surgical teams. This will include increased working with a different, largely healthy, patient population, different anticipated patient outcomes, and therefore potentially different monitoring and post-surgery care regimes. It may also require further collaboration and integration of surgical teams with the broader healthcare pathway including community and preventative health.

Robotic systems

There is likely to be a significant increase in demand and availability of robotic systems as a part of surgical instrumentation in the coming years. These will range from simple hand-held systems with restricted applications through to 'master-slave' systems like the da Vinci® surgical system. Robot-assisted surgery can bring a number of benefits, notably high quality and consistent surgery even from relatively less experienced surgeons, and a reduction in stress for surgeons resulting from more structured workflow[7]. Hands-on robots are particularly beneficial due to the synergy in strengths between surgeons and robots.

Training in robot-assisted surgery, particularly for new applications and systems, will be essential for patient safety. Robots and virtual reality systems may themselves play a valuable role in supporting the training of surgeons where plastic phantom systems are insufficient. Well-equipped simulation centres, like the one at Imperial College London, can be used to train surgical teams, not only in technical skills but also in understanding human factors in surgery. Such simulation depends significantly on complex engineering design and implementation.

Further engineering developments are required to maximise the potential benefits of robotic systems in surgery. For example, advances in sensing technology and soft robotic systems will give robots an increased ability to interact with soft body tissues without causing harm. Similarly the application of 'big data' analytics, machine learning, and artificial intelligence (AI) will facilitate increased automation. AI technology must be applied with care. There will undoubtedly be benefits to the application of AI in imaging, planning, and simulating surgery, but its use within surgery may not be desirable due to the inability to fully understand or predict the actions of the robot on the patient. Further collaboration between engineers, device companies, and surgical teams will be important to facilitate research and steer the development of systems that most appropriately meets surgical and clinical needs.

There have been challenges in bringing robot-assisted surgery to routine practice, particularly complex regulatory barriers to clinical trials, and a lack of funding available to translate early potential through into scaled-up clinical practice. There have also been challenges for small UK

Nakamura et al 2010. *A comparison between robotic-assisted and manual implantation of cementless total hip arthroplasty.* Clin Orthop Relat Res 468: 1072-1081

Howell et al. *Kinematically aligned total knee arthroplasty,* Ch 160 in Insall & Scott Surgery of the Knee, Elsevier.

[7] Davies 2015. *Robotic surgery – a Personal view of past, present and future.* International Journal of Advanced Robotic Systems. 12(5)

companies to grow and scale up in the UK, instead being frequently bought out at an early stage by larger multinational companies[7]. Addressing these challenges would help accelerate the development of new robot-assisted systems in the UK.

It is possible that robotic systems may become increasingly specialised to meet the needs of different types of surgery, such as reconstructive surgery, orthopaedic surgery or neurosurgery. This will likely have resource implications for hospitals, and again may lead to complex surgery being concentrated at centres of excellence. However, it may also facilitate different hospitals taking lead roles for different types of surgery that require different state of the art equipment.

Nanomedicine[8]

The application of nanotechnology to medicine has a range of potential applications, from drug encapsulation and delivery to regenerative medicine. A number of these applications are relevant to, or may have implications for, surgery. For example, nanoribbons have been used to generate electric charge directly from the heart to power pacemakers, which if used routinely would incrementally change the surgical procedure for pacemaker implantation. Another potential application is the use of nanosensors to detect tiny numbers of cancer cells, enabling earlier treatment and a reduction in later stage invasive surgery. A number of barriers remain to routine implementation of nanotechnologies in medicine, particularly the need for a greater understanding of potential risks, as well as the concurrent development of appropriate regulation and governance.

Health technology assessment

Many of these advanced technologies associated with future surgical developments will require significant investment of NHS funds. Health technology assessment is therefore needed to assess the patient and system benefits associated with their use. Currently the National Institute of Health and Care Excellence's (NICE) Interventional Procedures programme[9] looks at the safety and efficacy of surgical procedures and produces guidance on about 30 procedures a year.

In the future a more multi-dimensional approach may be needed to fully evaluate the clinical-effectiveness and cost-effectiveness of these advanced technologies. For example, technical factors related to the design and ease of use of the technology may also need to be considered. This multi-dimensional approach to NICE guidance development could include active collaboration between stakeholders who consider aspects such as:

- Technical, scientific and engineering factors
- Human factors
- Ethical considerations
- Information governance
- Regulatory perspectives

NICE is aware of the need to develop new health technology assessment processes for innovative healthcare treatments and regularly reviews its guidance development processes and methods. NICE also produces medtech innovation briefings (MIBs) to provide information to people considering using new medical or diagnostic technologies, a number of which relate to innovations associated with surgical care[10].

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[8] The information in this section has been drawn from the following publication: Nanotechnology: the societal impact of the invisible. Institution of Mechanical Engineers. 2015.

[9] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance

[10] https://www.nice.org.uk/guidance/service-delivery--organisation-and-staffing/surgical-care

Non-technology based engineering trends

In addition to the technological changes outlined above, there are lessons that could be shared across the broader engineering sector and surgery.

Patient safety and learning from failures

In safety-critical, high-risk engineering sectors such as rail, marine, or aviation, high levels of safety have been generated through cultivating a system that learns from failures. This relies on a confidential (but not anonymous) reporting system to an independent body, followed by expert analysis that looks to understand the cause of failures rather than apportion blame. Findings from such analyses are published, allowing everyone to learn and update practices. Surgery is a similarly innovative and complex system where errors and failures are possible due to the failure of innovations or gaps in the system. The establishment of the Healthcare Safety Investigation Branch is an important step in improving learning from failures in healthcare. However, there could be practices that could be shared between engineering and surgical communities on the analysis of failure that could have further benefits for patient safety.

An engineering systems approach

The sheer size and complexity of the UK health and care system means that delivering change and improvement can be a significant challenge. Over the past two decades, there have been numerous calls to implement a more holistic systems approach to transform health and care to address the needs of a changing patient population. However, there has been no clear definition of what this might mean in practice. Engineers routinely use advanced systems thinking to address challenging problems in complex projects. Last year, the Academy worked with the Royal College of Physicians and the Academy of Medical Sciences to explore how an engineering systems approach can be applied in the health and care system. In summary, we found that more widespread application of a rigorous systems approach to health and care improvement, could have a transformative effect on health and care, with benefits for patients, service users, and providers[11].

The application of this approach to service delivery could have a significant impact on surgery, improving efficiency and patient flow through surgical pathways with benefits for patients and staff. Project partners are now exploring how this framework can be tested and applied in practice, ultimately for the benefit of patients and NHS staff, and we would welcome the opportunity to discuss potential opportunities with the commission or relevant colleagues.

[11] *Engineering better care*. 2017. Royal Academy of Engineering, Academy of Medical Sciences, Royal College of Physicians