Medical Image Analysis 33 (2016) 72–78

Contents lists available at ScienceDirect

Medical Image Analysis

journal homepage: www.elsevier.com/locate/media

Editorial

From computer-assisted intervention research to clinical impact: The need for a holistic approach

Sébastien Ourselin[a,*], Mark Emberton[b,c], Tom Vercauteren[a]

[a] Translational Imaging Group, Centre for Medical Image Computing, Dept. of Medical Physics & Biomedical Engineering, University College London, London, UK
[b] Division of Surgery & Interventional Science, University College London, London, UK
[c] University College Hospitals NHS Foundation Trust, London, UK

ARTICLE INFO

Article history:
Received 29 April 2016
Revised 9 June 2016
Accepted 13 June 2016
Available online 15 June 2016

Keywords:
Computer-assisted intervention
Valley of death
Medical devices
Health technology assessment

ABSTRACT

The early days of the field of medical image computing (MIC) and computer-assisted intervention (CAI), when publishing a strong self-contained methodological algorithm was enough to produce impact, are over. As a community, we now have substantial responsibility to translate our scientific progresses into improved patient care. In the field of computer-assisted interventions, the emphasis is also shifting from the mere use of well-known established imaging modalities and position trackers to the design and combination of innovative sensing, elaborate computational models and fine-grained clinical workflow analysis to create devices with unprecedented capabilities. The barriers to translating such devices in the complex and understandably heavily regulated surgical and interventional environment can seem daunting. Whether we leave the translation task mostly to our industrial partners or welcome, as researchers, an important share of it is up to us. We argue that embracing the complexity of surgical and interventional sciences is mandatory to the evolution of the field. Being able to do so requires large-scale infrastructure and a critical mass of expertise that very few research centres have. In this paper, we emphasise the need for a holistic approach to computer-assisted interventions where clinical, scientific, engineering and regulatory expertise are combined as a means of moving towards clinical impact. To ensure that the breadth of infrastructure and expertise required for translational computer-assisted intervention research does not lead to a situation where the field advances only thanks to a handful of exceptionally large research centres, we also advocate that solutions need to be designed to lower the barriers to entry. Inspired by fields such as particle physics and astronomy, we claim that centralised very large innovation centres with state of the art technology and health technology assessment capabilities backed by core support staff and open interoperability standards need to be accessible to the wider computer-assisted intervention research community.

1. The need for clinical impact in CAI research

Whether we like it or not, researchers, clinicians and funders are becoming very much impact driven. In the healthcare domain, articulating societal impact through a scientific and technology-focused research programme is challenging. However, making research matter by, showing a strong focus on a clinical area and, eventually demonstrating an improvement in patient care, is much easier. As such, we believe that the future of computer-assisted intervention (CAI) will be driven by the need for clinical impact. With this in mind, it is important to rely on efficient means of translating research into the clinic that also allow us to reach for scientific excellence.

1.1. The challenge of translation

The impact that CAI already had in clinical practice is undeniable. Surgical and interventional sciences (SIS) have historically been guided only by direct vision and touch. SIS have been and still are undergoing a paradigm shift as new technologies for data fusion, tool tracking, intra-operative imaging and sensing are introduced. Image-guided intervention (IGI) and computer-assisted intervention have already enabled greater surgical precision, resulting in reduced tissue trauma, co-morbidity and complications, in addition to shortened procedures and hospital stays.

However, far too little CAI research has reached the clinic, despite initial CAI systems appearing over 20 years ago. One major

* Corresponding author.
E-mail addresses: s.ourselin@ucl.ac.uk (S. Ourselin), m.emberton@ucl.ac.uk (M. Emberton), t.vercauteren@ucl.ac.uk (T. Vercauteren).

http://dx.doi.org/10.1016/j.media.2016.06.018
1361-8415/

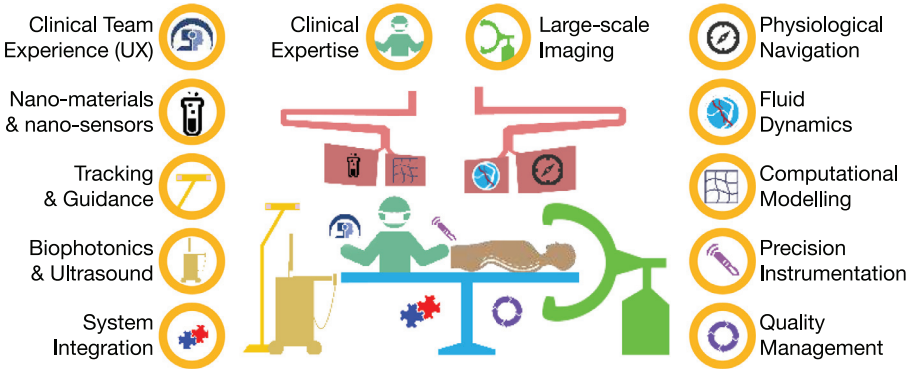

Fig. 1. Illustration of the expertise required to translate computer-assisted intervention research into clinical impact.

reason for this, is the substantial infrastructure and breadth of expertise required to design, implement and validate complete clinical-grade systems. Currently, many scientific and technological developments are being pursued across a disparate group of research laboratories highly specialised in a limited number of engineering and clinical areas. The barriers to translation arising from the heavily regulated clinical environment, the cost of the required infrastructure and the lack of open interfaces and interoperability standards among interventional devices are enormous. We believe that having a very broad set of relevant skills and know-how as illustrated in Fig. 1 (scientific expertise; clinical expertise; quality and regulatory affairs; good manufacturing practices; scalable engineering implementation; clinical trials; health economics; technology transfer) in large unified centres open to the broad research community will be key to go beyond these barriers and develop disruptive interventional systems that can be transferred to industry and become clinical standard of care.

1.2. Broadening the scope of the research field

Optimal clinical outcomes by contemporary CAI systems are hindered by predominant reliance on anatomical images, insufficient integration with innovative sensing, actuation and therapeutic devices as well as challenging demands in terms of skilful equipment handling and data interpretation. The potential to broaden the focus of CAI research and go beyond these limitations is there though. Existing CAI systems make suboptimal use of the large amount of data generated before and during interventions. Few, if any, clinically available systems effectively combine pre- and intra-operative imaging and information despite computational tools having the potential robustness and accuracy to carry out this task. Current surgical instruments and intra-operative imaging and sensing devices do not fully exploit physiologic and pathologic tissue responses and only a very limited subset have been integrated in CAI systems. There is also significant untapped potential to optimise the surgical environment by increasing the consideration and management of interactions between the multiple devices and software solutions present in the interventional suite.

It is our opinion that pathologically, anatomically and physiologically optimal surgery can be achieved by combining diagnostic-quality imaging and sensing with ergonomic smart instruments. Anatomical cues, which have been driving interventional therapies for centuries, will eventually be augmented by physiological and pathological insights.

2. Infrastructure to overcome the translation barriers

The paucity of translated CAI research can be explained by the existing gap between where the research typically ends and the level of development and validation that the industry requires to invest in the commercialisation of an innovative technology with a bearable risk. Waiting for the industry to fill the gap is certainly utopian. Furthermore, injecting more funding at a project level is probably not the most efficient and cost-effective means of crossing the proverbial MedTech's "Valley of Death".

Large-scale academic translational research platforms endowed with highly-trained, multidisciplinary teams could underpin several projects and act as a conduit to: demonstrate impact in clinical trials up to phase-III; improve translational success rate; shorten bench-to-bedside time; increase technology transfer through spin-off creation and licensing agreements.

To be successful, these translational platforms need to embrace the complexity of surgical and interventional sciences. The CAI community need to go beyond animal experiments and push for strong Health Technology Assessment (HTA) programmes that focus on evaluating the clinical impact of the developed technology. To this end, the translational platforms undoubtedly need to be associated with major teaching and research hospitals but also need to create international networks where technology developed in one centre can be clinically evaluated in another centre. System integration for CAI hardware and software devices need to be designed with modularity and interoperability in mind to ensure we capitalise on previous developments. Agile Quality Management Systems (QMS) need to be designed to take into account the specific needs of the CAI researchers but ensure the safety of the devices that are translated to the clinic and lower the barrier of technology transfer.

2.1. Stronger health technology assessment

Translational platforms will provide the required infrastructure to translate clinically effective and affordable innovation to the bedside. They will foster an ecosystem of projects focusing on key scientific, technological or clinical questions. The platform will raise the quality of the research deliverables to clinical standards which will allow for the evaluation of the clinical relevance of a proposed device.

With sufficient trust in the development process of the devices in the translational platform, each platform will be able to engage with other international centres to set up multi-institutional HTA projects and assess the clinical impact of the most promising innovative interventional systems.

Even with adequate resources, translating interventional devices into clinical applications and evaluating their potential patient benefit is a complex task given the regulations controlling introduction of novel devices into the operating theatre or interventional suite. To streamline the HTA ambition and initiate small and large clinical studies and trials, the platforms will need to leverage