Complementary routes towards precision urologic surgery: image guidance technologies and standardized training programmes

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CHAPTER 10

FUTURE PERSPECTIVES ON IMAGE-GUIDED SURGERY AND ROBOTIC TRAINING PROGRAMMES

Based on:
Precision Surgery: The role of intra-operative real-time image guidance - outcomes from a multidisciplinary European consensus conference
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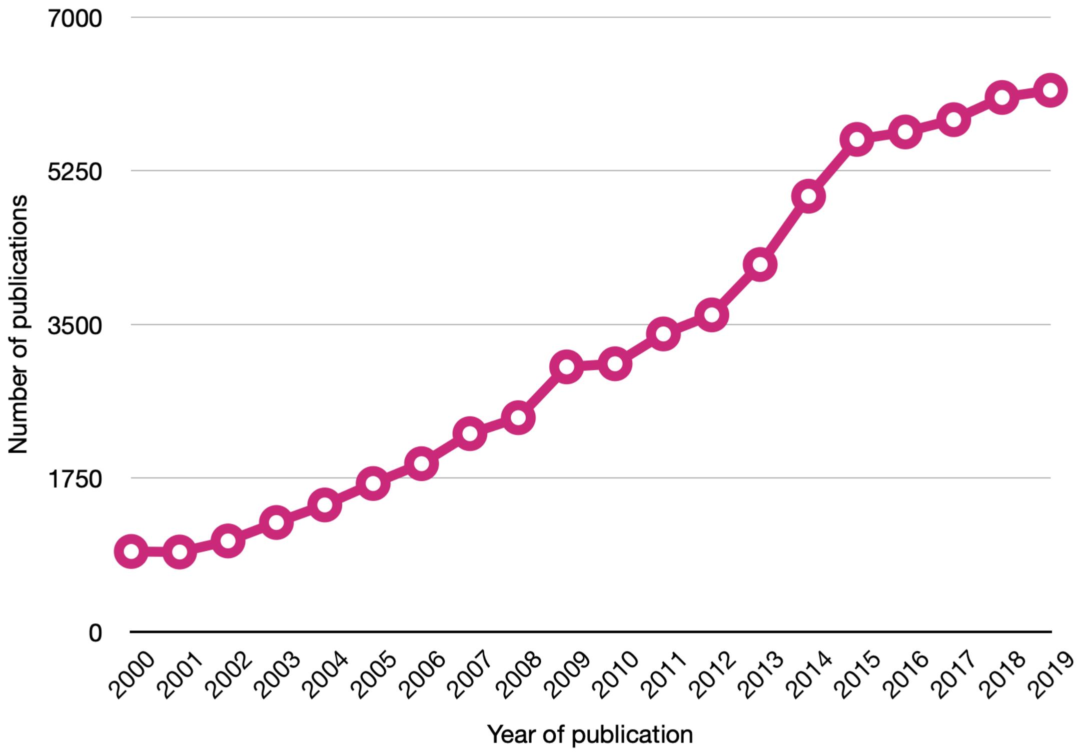
FUTURE PERSPECTIVES ON IMAGE-GUIDED SURGERY

Precision surgery has evolved considerably over the past century with the gradual introduction of minimally invasive techniques, particularly in surgical oncology. Here the aim is to achieve complete excision of the cancer, while optimising functional outcomes following the intervention. Key questions that swarm the surgeon's mind during the surgical procedure include: "Where is my precise anatomical target?", "How do I approach my target in an anatomically safe fashion?", "How can I ensure clear margins?", "Was the lesion excised completely?", "Is there residual disease that was not seen during surgery?" and "Did I remove or damage healthy tissue that could have been spared?". While traditionally pre-operative imaging has guided the planning of interventions, these critical issues in the management of cancer patients have led to major technological advances in intra-operative image-guided surgery over the past decades [1], with some becoming routine practice in several surgical disciplines (Figure 1) [1-6].

Figure 1: *Number of publications on image-guided surgery between 2000 and 2019 (Source: Pubmed; search strategy: "image-guided surgery").*



By using a combination of surgical planning information (i.e. road-maps such as the patient scans) and intraoperative imaging data (i.e. real time lesion identification), image-guided surgery aims to support localization and extension of the target(s) of interest with respect to the anatomical context, allowing patient-tailored precision surgery. Advances made in molecular imaging led to a technological growth in the field of image-guided surgery [7, 8]. However, while the technology is thriving with continuing innovations in optical imaging, identification of molecular targets and development of tissue-specific radioligands and fluorescence conjugated markers, there is a paucity of robust high-level evidence of effectiveness in improving outcomes for patients [3, 9].

We performed a multidisciplinary consensus meeting on image-guided surgery with the goal to establish definitions and gather considered opinions from expert medical, engineering and industry researchers, to obtain consensus on the current and future role of intra-operative image guidance, and define specific areas of research and development in the field, to stimulate further advances towards precision surgery.

During the two-day European congress on image-guided surgery and wet-lab training in fluorescence-guided surgery, held at ORSI Academy (Melle, Belgium) on 22nd-23rd November 2019 (https://www.igscongress.com), a one-day consensus meeting was conducted. Overall, 56 participants [20 researchers, 30 clinicians (12 urologists, 5 general surgeons, 6 nuclear medicine physicians, 3 radiologists, 2 oncologists, 1 dermatologist, 1 gynaecologist) and 6 representatives from Industry] formed the panel of experts and were selected according to their knowledge, their surgical experience, their research profile, the impact and number of their publications on image-guided surgery, and expertise in running surgical training courses. Moreover, as further counterproof of the high competency level, most of the experts participating to the consensus have or have had a main representative role within their respective scientific societies or industries. Using a Google Form (https://www.google.com/intl/it/forms/about/), a web-based survey concordant with the Delphi methodology was generated based on the available evidence and delivered one month before the beginning of the congress. This survey included fifteen statements on the clinical implementation of image-guided surgery that were set-up based on the existing literature. Consensus on a statement was defined as agreement of ≥80% between respondents. Statements over which consensus was not reached after the first

Delphi round were discussed during the one-day consensus-meeting during the aforementioned congress on image-guided surgery. Based on these discussions, four questions were deemed unclear and were rephrased. Respondents were then asked to answer these specific questions in a second Delphi round.

The response rate in the first and second Delphi rounds were, respectively, 100% and 61%. The level of agreement on the individual questions is reported in Table 1. With regard to the questions that covered the *conceptual potential* of image guidance, there was high-level agreement. Specifically, consensus was reached on the following: intra-operative, reliable image guidance 1) can improve surgical outcomes (Q1) [3, 9], 2) will have substantial impact on an increasing number of surgical procedures (Q2) by facilitating minimally invasive interventions (Q3), 3) can reduce positive surgical margins and optimise preservation of anatomical structures, which in turn will improve functional outcomes (Q4). The panel agreed that intra-operative image guidance should be developed further and integrated into surgical procedures which involve tissue excision, particularly relevant to cancer treatment (Q5). This will allow surgeons to perform complex procedures with increased accuracy and safety.

Greater variance was seen in the response on statements on the *actual clinical value* provided by image-guidance technologies because of lack of robust validation data. Despite popular statements such as “*seeing is believing*”, there was no consensus on specificity and sensitivity of the various technologies discussed (Q6). Intriguingly, specificity was not considered critical, while this is the only means to assure the right tissue is resected. Despite the limited availability of high-level evidence from randomized clinical trials, the panel expressed 80% confidence in the value of image-guidance (Q7), but there was a lack of consensus on its potential to influence intra-operative decision making (Q8). Overall, participants agreed that image-guided surgery can enhance but not replace routine pre-operative surgical imaging, such as CT or MRI scanning (Q9). Indeed, preoperative imaging provides the current benchmark for patient selection and planning of a surgical approach (Q10-11). Furthermore, the general consensus was that intraoperative imaging technologies should be able to facilitate determination of the depth of individual lesions (Q12).

***Table 1** – Key statements of the modified Delphi process to define the role of image guidance during surgery*

Item	Level of agreement
Conceptual potential of image-guided surgery	
1. Surgical outcomes could be improved by image guided surgery	95%
2. Image guidance will impact on an increasing number of surgeries	95%
3. Image guidance should help to promote minimally invasive surgery and to reduce potential overtreatment	95%
4. Imaging guidance can provide value (can tick multiple answers): - by improving target delineation in order to minimize positive surgical margins - by preserving delicate anatomic structures such as nerves	 95% 98%
5. Image guidance should be developed further and integrated in excising surgical procedures	86%
Actual clinical value of image-guided surgery	
6. Innovations in image guidance should focus on: - realizing a high specificity - realizing a high sensitivity, even when this negatively impacts the specificity	 55% 45%
7. Image guided surgery has already proven its value in patient care	80%
8. Today surgical procedures should be revised based on image guidance technologies: - Yes - No - Unable to answer	 55% 16% 29%
9. When added to existing surgical procedures, image-guided surgery methods should enhance and not replace routine surgical imaging	87%
10. For lesion targeted procedures to be effective, surgical guidance technologies should target exactly the same lesions as identified at preoperative imaging	95%
11. Image guidance should support identification of local metastases to at least the level provided by preoperative imaging levels	84%
12. Intraoperatively there is a demand for technologies that help identify superficially located (<1 cm beneath the surface) lesions and also deeper lying lesions	84%
13. Which kind of image-guided surgery should we use in daily clinical practice (multiple answers are possible)? - intraoperative ultrasound - radioguidance - fluorescence imaging - 3D printing models - 3D reconstruction - augmented reality	 82% 80% 87% 25% 50% 64%
14. Image guidance only has value when it provides directional guidance towards the target in vivo (i.e: tumour) or around the target in vivo (e.g.: nerves): - Yes - No - Unable to answer	 43% 54% 3%
15. Ex vivo back table tissue imaging (imaging of the tissue removed outside the patient) is considered image guided surgery when it influences the surgical procedure	95%

Moreover, intraoperative techniques should depict the same features as identified on preoperative planning, in addition to complementary features during surgery. This provides an important rationale for combining radioactive labelled markers (limited by spatial resolution) with fluorescence-guidance (limited by tissue penetration) to obtain a high level of intraoperative resolution [6, 7]. Ultrasound, radioguidance and fluorescence imaging were identified as modalities that are currently used for intraoperative guidance in different surgical specialties (Q13) [1-4, 6, 9]. However, despite the reliance on preoperative roadmaps (Q9-11), three dimensional (3D) reconstruction/planning approaches such as navigation and augmented reality display (i.e. the overlaying of 3D virtual models on the operative field in real time) were not unanimously considered as valuable modalities for routine intraoperative image-guided surgery (Q13). This is at odds with the extensive use of such technologies in neurosurgery and orthopaedics, which is especially based on their high potential in providing surgical guidance [1, 10]. An explanation for this discrepancy might lie in the fact that navigation and augmented reality displays are still mainly restricted to applications wherein bony structures can be used as a reference, while soft tissue applications are emerging, but are not yet as widely adopted [3, 6]. Moreover, in the latter tissue movement and deformation limit the current use of 3D preoperative models. Printing of 3D models was also not considered useful for providing intraoperative image guidance by the majority of the respondents, while their added value for patient counselling, surgical planning and education was acknowledge [5].

Consensus was also split on the value of image guidance in providing directional guidance towards the intraoperative target (e.g. the tumour) and the surrounding tissue (e.g. nerves; Q14), while the trend in surgery goes towards application of tissue sparing resections (such as nerve-sparing surgery) that focus on decreasing the level of surgical-induced side-effects. This, again, might be caused by the fast developments that are currently been made in tracer development and multicolour fluorescence/ hybrid approaches. Herein complementary tracers are used to highlight different anatomical features that can be discriminated during the same intervention, while these are still not widely available in the clinic. 95% of respondents stated that ex vivo assessment of surgical specimens (back-table tissue imaging) – similar to the principle of frozen section biopsy for histopathological evaluation of surgical resection margins [11] – is considered an intrinsic component of image-guided surgery when the imaging results could directly influence the surgical procedure (Q15).

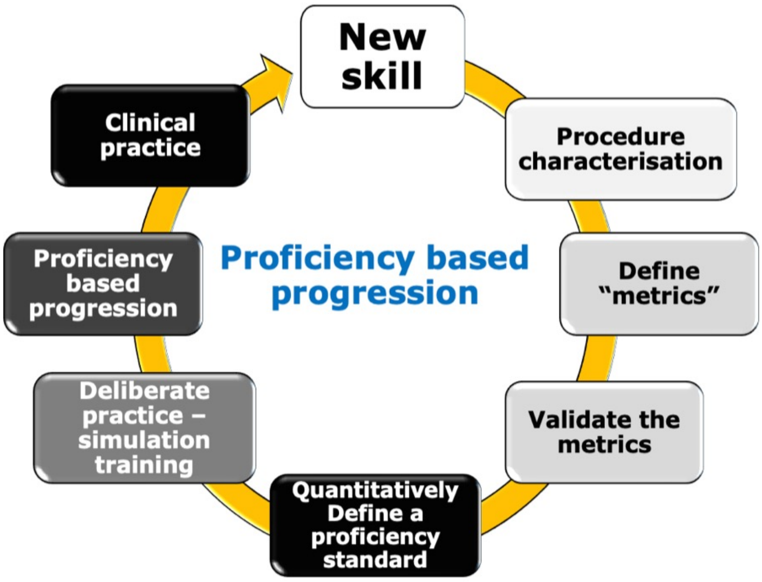
In summary, this international Delphi consensus conference represents, to our knowledge, the first multidisciplinary attempt to achieve consensus on the current role and the future directions of intraoperative image-guided surgery. This paper reports the multidisciplinary view of the different stakeholders who took part in the debate. As there is little that can be argued against the concept of advancing patient care via precision surgery, consensus was easily reached with regard to the potential improvements offered by image-guided surgery. When critical issues of sensitivity, specificity and outcomes were addressed, consensus became challenging, with some contradictory views. This highlighted the importance of developing technologies only in the context of addressing patient-centred unmet clinical needs, rather than innovations in search of sterile applications. Overall, the panel agreed that intraoperative imaging should complement the pre-operative roadmaps defined by radiological mapping. Modalities that digitally translate preoperative information into the surgical theatre, such as overlay technologies, were viewed less favourably compared to technologies that offer real-time imaging. At the same time ex vivo specimen imaging following surgical excision was considered of complementary value for precision surgery when decision-making during an intervention can be directly influenced.

The outcome of this Delphi consensus seems to be indicative to the need for further intensified research and development in this important and emerging field of technology. Something that can be enriched by the identification of reliable molecular targets. In particular, key issues of added value in improving clinical outcomes were highlighted and must be taken into consideration in the design of the next generation, as well as evaluation and validation in well-conducted clinical trials.

FUTURE PERSPECTIVES ON ROBOTIC TRAINING PROGRAMMES: PROFICIENCY-BASED PROGRESSION SIMULATION TRAINING

In 1993, Satava and colleagues [12] were the first to introduce the role of simulation-based training in the field of surgery. The Authors published the first prospective, randomized, and blinded clinical study demonstrating that trainees who underwent a virtual reality-based simulation training pathway performed significantly better than traditionally trained surgeons during laparoscopic cholecystectomy, thus achieving an optimal performance level before starting their clinical practice in the operating room [13]. In this study the authors introduced, for the first time ever, the “proficiency-based progression” (PBP) training methodology that differs significantly from traditional training pathways. Figure 2 depicts the key elements of this training method.

Figure 2: *Key elements of the proficiency-based progression training methodology*



Specifically, the operative procedure is characterized in detail to identify intraoperative objective performance metrics. The metrics are explicitly defined units of measurement that characterize elements of procedure/task performance that are scored in a binary fashion (i.e., occurred/did not occur). The metrics are quantitative assessments and are used for objective evaluations to track performance. This includes steps and performance errors. Error is defined as a ‘deviation from the optimal performance’. Steps are defined as component tasks of a specific procedure [14]. All performance metrics in a PBP approach are developed with experienced surgeons/clinicians and cumulative validation evidence derived from them (e.g., a Delphi consensus meeting, objective assessment of performance). These metrics are used to define a proficiency benchmark or proficiency level that trainees are required to demonstrate. The level of proficiency is based on the mean performance of the experienced practitioners performing the same training tasks [15].

After defining these objective metrics, trainees are required to continue training in a specific skill/task until the predefined benchmark is consistently met. Thereafter, the trainees will progress to the next level of difficulty. During this practice, trainees receive continuous formative feedback by very experienced surgeons and clinicians. The trainees never complete the medical procedure on a live patient until they have shown that they can adequately perform the task within a training context (PBP training is not complete until the trainee has demonstrated a level of proficiency-based on predefined benchmarks).

A recent systematic review and meta-analysis [16] analysed all published prospective, randomized and blinded clinical studies on PBP training to assess its benefit on learning clinical skills in comparison to the conventional training. Overall, 12 randomized clinical studies with a total of 239 participants were included in the analyses. The authors demonstrated that PBP training reduced the number of performance errors by 60% and reduced procedural time by 15% in comparison to non-PBP training. Moreover, trainees who completed PBP training performed more procedural steps (47%) than those who completed a standard training pathway. All these findings strongly confirm that PBP training improves trainees' performances when compared to high-quality simulation-based training programmes and overwhelmingly underline the need to fully implement PBP methodology in surgical and procedure-based medical treatment training pathways.

The application of this training model to robotic surgery (and urologic setting) might be crucial to reduce procedural errors with an additional potential effect on shortening the learning curve process for a specific procedure. Under this light, Mottrie and colleagues [17] developed and validated objective performance metrics for robot-assisted radical prostatectomy. Overall, these newly developed metrics reliably distinguished between the objectively assessed intraoperative RARP performance of very experienced surgeons and novice robotic surgeons. These metrics are imperative for effective and quality assured surgical training and lay the foundation to implement a simulation-based PBP training programme for modular RARP training.

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