A research review on clinical needs, technical requirements, and normativity in the design of surgical robots

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Abstract

Nowadays robots play an important role in society, mainly due to the significant benefits they provide when utilized for assisting human beings in the execution of dangerous or repetitive tasks. Medicine is one of the fields in which robots are gaining greater use and development, especially those employed in minimally invasive surgery (MIS). However, due to the particular conditions of the human body where robots have to act, the design of these systems is complex, not only from a technical point of view, but also because the clinical needs and the normativity aspects are important considerations that have to be taken into account in order to achieve better performances and more secure systems for patients and surgeons. Thus, this paper explores the clinical needs and the technical requirements that will trace the roadmap for the next scientific and technological advances in the field of robotic surgery, the metrics that should be defined for safe technology development and the standards that are being elaborated for boosting the industry and facilitating systems integration.

KEYWORDS

clinical needs, metrics, MIS, normativity, standards, surgical robots

1 | INTRODUCTION

Introduction of robotic technology in the surgical field has offered objective and measurable advantages in comparison with traditional procedures, including reduction of tissue traumatization, reduction of systemic inflammatory response, shorter hospitalization and rehabilitation time and reduced pain and discomfort. First advances in this area were limited to adapting industrial robots to the medical application without being optimized for the characteristics of specific surgical tasks. NeuroMate, Robodoc and CASPAR are some examples of adapted programmable industrial robots applied in the operating room with limited output and success. However, since the beginning of the 21st century, technological advances have enabled innovative robotic platforms able to perform complex interventions through minimal incisions (MIS) or natural orifices (NOTES). Consequently, in the last 15 years, numerous surgical groups worldwide have incorporated robotic technology to their daily practice. Figure 1 summarizes the main clinical applications where surgical robots have been adopted.

However, despite years of research and the great potential of some systems, the field of surgical robotics is still only at the beginning of a very promising large-scale development. The evolution experienced with the use of robotics in some medical procedures is expanding its area of application to more challenging scenarios, requiring further refinements in the proposed systems. In addition, the current surgical robotic systems are extremely expensive in acquisition, maintenance, disposable tools and training, representing much higher direct costs compared with open surgery and laparoscopic instrumentation. On the other hand, a legal framework that can accompany the development of these robotics systems is also fundamental, since neither the end-users at the experimental level nor the designers and manufacturers at the industrial level can properly appraise the risks nor duties entwined in their work until a clear analysis of the interplay between robotics and regulation has been made.

Therefore, although a large number of robotic systems have been developed, several technical, logistic, economic and safety issues have not yet been addressed, limiting broader adoption of these systems by the majority of hospitals. It is then necessary to develop new surgical robots that satisfy the requirements of surgeons and to rectify the technical and economics aforementioned problems. Based on this, the present article reviews the clinical needs, the technical requirements, and the normativity aspects that have to be taken into account in order to obtain designs with better performance and more secure systems for patients and surgeons.
Clinical needs are established as prerequisites for any development programme of surgical robotic systems. They will ultimately define the goals and specification of the project. Nowadays, specific clinical needs in specific surgical procedures are demanding more customized robotic systems. This differs from the approach of the da Vinci Surgical System, which in general, has been to find a clinical need for a multi-purpose technology, rather than to specifically design a technology for a targeted clinical application. Table 1 summarizes the main areas of improvement for surgical robots utilized in the clinical applications that were illustrated in Figure 1.

From Table 1 it is possible to extract the most urgent clinical needs that should be met in order to achieve greater acceptance and market penetration of surgical robots. These clinical needs are:

a. Cost reduction. To gain acceptance, new robotic systems must demonstrate relative competitiveness versus a conventional alternative and achieve a favourable ratio of cost–benefit. Effectiveness can be measured in different ways, e.g. by means of a better success rate, a reduced rate of complications, a reduced hospitalization time and/or a reduced blood loss. Ultimately, the clinical effectiveness of a device with respect to a conventional surgical procedure, relative to its cost, will form the basis of its acceptability in any decision-making process performed by the medical authority.

b. Time of intervention. Robotic surgery is associated with increased operation duration, which could have implications for patient safety. This extended duration is usually produced by the low speed to which robots are programmed to move during interventions and path planning strategies where robots often backtracked to areas previously treated. An increase in the speed, as well as the optimization of path planning could contribute to notably reduce the time of intervention. It has also been argued that longer operation time can be due to the lack of tactile feedback. This lack of tactile feedback could decrease the speed of surgeons' movements, who have to rely on visual information only.

c. Time and complexity for set-up. Future technical developments should contribute to reducing robotic system complexity and deployment time. Proper training and standardization of duties are also key points that could contribute to overcome the
aforementioned difficulties. Teams that are well trained and quite familiarized with the equipment and the technology employed can notably reduce the set-up time. Standardized duties could contribute to improving coordination, accelerating the learning and execution of assigned tasks. Other strategies for reducing set-up time include enabling additional dedicated staffs that assist with setting up and clearing away the robot, or enabling a dedicated robotic operating theatre in such a way that the team does not need to move robots from/to another location before/after operation.28

d. **Reduced operating room (OR) footprint.** Nowadays, surgical robots require a large footprint in the OR and use relatively cumbersome robotics arms with instruments that are still too rigid and straight. This is an important disadvantage in today's already crowded OR. The large footprints limit the assistant surgeon's access to the patient, as well as rapid access to the patient in case of emergency. Evolution of robotic assisted MIS requires lightweight flexible manipulators with minimum footprint and with the capacity of adaptation to areas that are more delicate, circuitous, and difficult to access. Extrinsic actuation often reduces the required manipulator diameter, increasing range of motion and accessibility to confined spaces. However, this comes at the potential price of large external footprint, increased friction and hysteresis, and introduction of elastic instabilities in the case of concentric-tube transmissions. On the other hand, direct intrinsic actuation may reduce footprint and friction while requiring larger manipulation diameters.29

e. **Data integration.** Greater data integration could provide the surgeon with more patient information during surgery. This could help the surgeon to complete the procedure more safely and successfully, avoiding distractions and facilitating the access to preoperative studies. Data integration can include enhanced reality environments that would provide live feed from cameras, and additional information such as patient preoperative scans and 3D anatomical renderings. The interface can house such features as an image browser, ultrasonography, DICOM viewer for CT images, 3D image volume renderings and note-taking on images.30

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**TABLE 1  Areas of improvement for surgical robots in different clinical applications**

<table>
<thead>
<tr>
<th>Medical area</th>
<th>Areas of improvement</th>
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<tbody>
<tr>
<td>Ophthalmology</td>
<td>• Poor decision-making/judgement&lt;br&gt;• Poor interpretation of qualitative data&lt;br&gt;• Expense and maintenance&lt;br&gt;• Availability&lt;br&gt;• Learning curve&lt;br&gt;• Possibility of malfunction&lt;br&gt;• Patient trust</td>
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<tr>
<td>General surgery</td>
<td>• Operating times and cost&lt;br&gt;• Cholecystectomy - found no clinical benefits to substantiate the use of such expensive technology&lt;br&gt;• Promising for pancreatic head resection and hepatectomy, but experience to date is limited&lt;br&gt;• In resections for neoplasm, robotic surgery may help to enhance the completeness of lymph node dissection</td>
</tr>
<tr>
<td>Cardiothoracic surgery</td>
<td>• Limitations with conventional laparoscopic instruments&lt;br&gt;• Operating in relatively narrow/confined thoracic cavities&lt;br&gt;• Triple and quadruple endoscopic coronary artery bypass graft (CABG) is currently in development&lt;br&gt;• High cost system and longer operative times</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>• Expensive&lt;br&gt;• There are insufficient studies to demonstrate the benefits of robotic surgery with respect to traditional methods&lt;br&gt;• Access option&lt;br&gt;• High cost&lt;br&gt;• Lack of tactile feedback and sensation&lt;br&gt;• Inability to reposition the patient&lt;br&gt;• Bulkiness of the current system</td>
</tr>
<tr>
<td>Urology</td>
<td>• Lack of tactile feedback&lt;br&gt;• Operating times and high costs</td>
</tr>
<tr>
<td>Otorhinolaryngology</td>
<td>• Challenges remain on using large size arms&lt;br&gt;• Current inability to use CO₂ laser via da Vinci, and significant thermal damage resulting from the use of monopolar electrocautery as the primary cutting and ablation instrument&lt;br&gt;• Expensive</td>
</tr>
<tr>
<td>Colorectal surgery</td>
<td>• No differences were found in duration of surgery, morbidity, length of hospital stay or oncological outcomes&lt;br&gt;• Expensive</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>• Expensive&lt;br&gt;• Existing technical solutions do not provide more accurate positioning in relation to the existing procedures that use stereotactic frames fixed to the patient’s head&lt;br&gt;• High degree of security and reliability is required, far higher than with other devices</td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>• Expensive&lt;br&gt;• High start-up cost&lt;br&gt;• Alignment of knee&lt;br&gt;• Tibial and femoral alignment</td>
</tr>
<tr>
<td>Paediatric surgery</td>
<td>• The major limitation is the size of the robotic instruments in relation to the pediatric patient&lt;br&gt;• High cost&lt;br&gt;• Robotics surgical procedures are difficult to be performed in many neonatal cases</td>
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f. Improved decision-making. During an operation, decision-making is affected by variables such as tactile and visual perception, motor skill and instrument complexity, all of which are modified by robotic surgery, and may therefore, influence surgeons’ ability to use their experience in the decision-making process. Separation of the surgeon from the rest of the staff can also impact on the data acquisition that is used during the decision-making process.\(^1\) Future designs and developments should address tools that provide support and guidance in how to proceed effectively. The theory of distributed situation awareness puts forward the need for considering what aspects of the situation the surgeon needs to be aware of in order to support the decision-making process, while both distributed situation awareness and distributed cognition suggest reflecting on the role that other members of the operation theatre team can play in contributing to the surgeon’s situation awareness.\(^3\)

A crucial step in the design of new surgical robots is how to match the clinical needs to the technological possibilities. Technologies to be developed should aim not only to support current surgical procedures better, but also to open up new clinical opportunities. Research on surgical robots should still provide response to various technical requirements, which we highlight below.\(^1\,2\,17\,\text{–}\,20\,23\,32\,37\):

a. Reduced size, shape and weight. Reduced access provided by new minimally access techniques imposes hard design constraints on the size, shape and weight of instruments and robotic modules conceived for these procedures. Surgical instruments should be sufficiently flexible and should have an ergonomic shape that eases their access, and a reduced size of between 3 and 6 mm that allows their simultaneous manoeuvrability. In the case of robotic modules, not only ergonomics and reduced size should be considered, but also weight, which can play an important role in the anchoring of the modules. For instance, in magnetic anchoring guidance systems, magnetic forces diminish logarithmically with increasing distances between internal and external modules, and with the weight of the internal device-magnet module. In the case of overweight patients, bigger and thus heavier external permanent magnets are required. On the one hand, this limits the available space for external actuation units and on the other, increases compression between the two magnetic components, which may damage the intervening tissue. Therefore, it is desirable to reduce the weight of internal modules below 35 g to limit the size and weight of external permanent magnets.

b. Greater number of degrees of freedom (DOF). A proper number of DOFs are required in order to achieve the desired mobility and surgery support. In MIS, surgical instruments must be manoeuvred around an entry point that restricts two of the instrument's DoF, leaving the surgeon in the best of cases, with 4 DOFs per instrument to work inside the patient (usually, yaw, pitch, roll and translation). This enables complicated tasks such as suturing. Instruments with multiple DOF (4) are being proposed to address this problem. On the other hand, redundant kinematics with 7 or more DOFs for surgical robotic arms can allow for a more flexible OR setup, as well as collision avoidance with other robots or OR equipment.

c. Workspace. Workspace of tools will be constrained by the number of DOFs, the lengths of the links, the joint limits and possible collisions with its own links or other barriers such as anatomy. As robotic surgery implies performing technically complex procedures in small cavities, special attention should be paid to reduced workspaces. In reduced workspaces, the ports cannot maintain an adequate distance among the robotic arms to avoid external collision, especially when arms are actively working, which prevents optimal functioning. The study presented in\(^38\) identified that the smallest workable volume with the da Vinci robot is 125 cm\(^3\), and encountered serious difficulties and higher complications rates with volumes smaller than 150 cm\(^3\). These limitations are particularly important in paediatric robotic surgeries.

d. Resolution. Resolution can be understood as the smallest incremental movement that the tool can make or measure. Resolution requirements are tied to surgical procedures; for instance, cholecystectomy requires a 2 mm resolution.

e. Platform stability. As stated in the first point, instruments should be sufficiently flexible to enable not only easy access, but also progressive propagation, and finally correct positioning. However, once the target location has been reached, fixation and stiffening of the instruments should be optimal to enable stable and precise operation.

f. Retraction. The high flexibility of the instruments can limit the effective transmission of forces to the tip tools. These forces are required to properly retract tissues, apply strong sutures or clips, or provide robust grasping.

g. Force feedback feeling. The loss of touch makes it difficult to feel when an instrument and an organ are in contact. Haptic feedback would provide the surgeon direct access to manipulation forces inside the patient and allow for more delicate manipulation of tissue, avoiding unintentional damage.

h. Suitable visualization and spatial orientation of the surgical field. In spite of the advances achieved with the inclusion of 3D high definition vision systems that provide an immersive view of the surgical field, surgeons still experience visual limitations in certain surgical scenarios. Colectomies, Nissen fundoplication, gastric bypass, coronary bypass procedures, mammary artery harvest procedures, are some representative examples of minimally invasive gastrointestinal and cardiac surgeries exhibiting visual problems. Paediatric surgical procedures also impose numerous restrictions. Solutions that help to increase the field of view (\(>70^\circ\)) in occluded surgical regions, the depth perception along the line of sight, the resolution of tissue details at farther distances, or that allow visualization of the surgical field from different viewpoints during robotic surgery are highly required.

i. Wireless modules. On-board power supply and wireless controllers are desirable to provide independent deployment for robotic modules.

j. Triangulation. This is intended to replicate the experience of complex two-handed laparoscopic manipulations, which in turn are designed to imitate the technique used in open surgery.
Therefore, it would be desirable to count with multi-channel instruments that can be moved independently, instead of inline instrumentation and optics.39

k. Reduction of repetitive instrument exchange. The number of times that the instruments are exchanged varies depending on the different procedures. For instance, the need is higher in esogastric junction surgery, splenic surgery and gastric surgery and lower in hepatic surgery and adrenal gland surgery. The average number of instrument exchanges during one procedure was calculated in30 taking into account replacement of the instruments on two robotics arms and camera removal for cleaning, and summed up to 15 times (±4.5). The average time for instrument exchange was 6.8 s (±3.1) and the average time for cleaning the camera was 20 s (±4.3). Some instruments, such as the harmonic scalpel, need special adjustments to fit into the robotic arm. These average times can be increased if the assistant is not formally trained or not familiarized with the robotic equipment. In addition, although this is not usual, there is always a safety risk associated with the instrument exchange, especially if intra-corporal conditions can vary in the meanwhile. Therefore, for future developments, the removal and reinsertion of instruments should be reduced or avoided as far as possible.

l. Flexibility of rigid instruments. Surgical procedures involving complex anatomical pathways between the access route, entry point and operative sites can greatly benefit from flexible, articulated robotic instruments. Rigid-link devices with a higher degree of articulation enhance flexibility, but still exhibit several drawbacks such as the slow speed of forward motion, the limited radius of curvature and the large size of the external feeder.31,42

m. Suctioning and irrigation capabilities. It is necessary to have available devices able to efficiently remove blood, blood clots and fluids from the surgical field.41,42

n. Manoeuvrability. The tip of the surgical tools must have the ability to manoeuvre in all planes: vertical, horizontal and lateral.

o. Control requirements. From the standpoint of control, robotic surgery devices can be clustered into three major groups: (i) supervisory controlled robotic systems, in which the surgeon plans the operation off-line and the robot performs the specified motions autonomously under the supervision of the surgeon; (ii) robotic telesurgical systems, in which the robot is tele-operated or directly controlled by one or more surgeons using a master–slave methodology (e.g. the da Vinci Surgical System); and (iii) shared control systems, in which robotic devices are cooperatively controlled by a surgeon and a computer (the surgeon remains in control of the procedure and the robot provides steady-hand manipulation of the instrument). Haptic interfaces, virtual and augmented reality, natural control surfaces allowing for surgeon movement, purpose-built interfaces and contactless hand-tracking technology as surgical master, are some fundamental requirements that should be considered for improving current surgical control systems.

p. Ergonomics. The need for solving ergonomic problems is attracting a lot of attention in the last years, mainly due to the cumulative musculoskeletal injuries reported by surgeons while conducting MIS surgeries. Use of surgical robots requires that surgeons sit down for extended periods at a surgical console from which they control the robotic arms and view the surgical procedure through a high resolution viewer. This can lead to sustained trunk and neck flexion, resulting in discomfort in those regions.43 In addition, the motion scaling can force the surgeon to move his arms long distances at the console for certain manoeuvres (e.g. pulling on a thread), which, in contrast, are easily performed during laparoscopy. Similarly, the quality of the Metzenbaum scissors is not comparable with the laparoscopic counterpart, and there is no instrument comparable with a right-angle dissector46.

q. Training and credentials. The integration of robotic surgery into clinical practice still requires appropriate training.46 Hospitals are responsible for ensuring that surgeons are being trained, credentialed and monitored in an ethical manner to utilize robotic surgery.49 This issue is attracting increasing attention because there have been recent reports of litigation directed at hospitals resulting from insufficient training and insufficient credentialing for surgeons who are newly trained in robotic surgery. The American College of Obstetricians and Gynaecologists offers no specific recommendation, but comments that ‘credentialing for robotic-assisted surgery within and across specialties is based on training, experience, and documented current competency’. Sood et al.50 state that the guidelines on credentialing for robotic competency are more opaque at this time and vary from institution to institution. There are certain tools, such as the global
evaluative assessment of robotic skills (GEARS), which permit objective assessment and can be used to grade performance during simulation exercises. This standardized assessment tool shows excellent consistency, reliability and validity. However, there is a lack of consensus on what the cut-offs for competency, proficiency and mastery should be. Further studies should evaluate its usefulness for surgical education and the establishment of competence in robotic surgery. Therefore, there exists an urgent need for unifying the training and credentialing requirements to ensure patients’ safety.

3 | NORMATIVITY FOR THE DESIGN OF SURGICAL ROBOTS

Several authors have already stated the need for metrics and regulatory standards for robotic surgery, since unlike industrial robots that operate in structured environments, surgical robots have a direct interaction with the human body. Consequently, several groups have been working in recent years with the aim of ensuring the safe use of surgical robots and computer assisted surgical systems for both patients and medical staff. Worth mentioning are the efforts carried out by the Seventh Framework Programme Research Project SAFROS (FP7-ICT-2009.5.2), the USA National Institute of Standards and Technology (NIST), the Joint Working Groups JWG 9 and JWG 35 of the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC), as well as the Food and Drug Administration (FDA) through the 2015 robotically-assisted surgical devices (RASD) workshop.

Next, a summary is made on the basis of these international working groups and regulatory organizations. A brief overview of the CE Marking of surgical robots is also included at the end of this section.

3.1 | SAFROS – patient safety in robotic surgery

One of the main objectives of this Seventh Framework Programme (FP7) Research Project was the definition of patient safety metrics for surgical procedures. The methodology implemented for the definition of this metrics involved three increasingly complex levels of analysis: product safety analysis, process safety analysis, and organizational safety analysis. This enabled evaluation of the safety of the proposed technologies considering them first individually, then analysing their impact when they are included in a surgical procedure, and finally, integrating them into a wider organizational context.

Thus, the product safety level assesses the technical features of the robotic surgery solutions, whereas the process safety analysis evaluates the effects of integrating the aforementioned products into the different stages of surgical procedures. The analysis of these levels provided, respectively, the set of technical and medical safety metrics that are summarized in Table 2. The product safety analysis was focused on virtual simulators for planning, pre-operative planning technologies and robotic simulators. Process safety analysis included factors such as the procedure-related risks, robotic-surgical procedure, patient related information and OR environment.

3.2 | US National Institute of Standards and Technology (NIST)

NIST, in cooperation with members of the FDA, private industries, universities and other government agencies agreed to document and prioritize the measurement and measurement-related standards needs of a few categories of medical device. Five priorities were identified for surgical robots:

a. Development of systems for measuring overall input/output motion performance of teleoperated surgical robots. The positional accuracy of a surgical robot is fundamental for preserving patient safety and achieving the best clinical results. Most of the procedures require sub-millimetre positioning accuracy and a few degrees angular orientation accuracy. However, position and orientation measurements are quite difficult to carry out routinely during an actual surgical procedure.

b. Development of performance metrics for evaluating the overall input/output motion of teleoperated surgical robots. For instance, it can involve the quantification of dead zones, dexterity, motion limits, dynamic behaviour and smoothness.
c. Identification of critical performance metrics for robotic surgical simulators. To be an effective training tool, the simulator should properly recreate the feel and performance of actual surgery. Thus, the challenge lies in understanding what aspects of the simulation are important and determining performance requirements and metrics for validation. Measurement devices are required to understand how faithful a surgical simulation is to actual surgery. Inadequate surgical simulator training can lead to safety hazards. Key parameters include measurement of real tissue deformation (bulk stiffness and local shape variations), contact interactions with instruments and realistic colouring and texturing of tissues. Measurement of actual robot or instrument motions is also required to validate the faithfulness of the simulation to the actual system performance.

d. Identification of critical performance metrics for force and haptic feedback. First, it is necessary to design and implement new sensors for measuring applied forces at the instrument tip, as well as systems for measuring overall input/output force feedback performance, before metrics to evaluate virtual constraints can be defined.

e. Development of communication and data standards to link surgical robots with medical imaging systems.

3.3 International Standardization Organization (ISO) and International Electrotechnical Commission (IEC)

Until recently, the ISO 10218 (Part 1 and Part 2) was the only international robotic standard devoted to safety. However, it just considered the isolated operation of industrial robots from humans, and prohibited human–robot collaboration. For this reason, in February 2014, the ISO 13482 was introduced in order to provide safety standards for applications involving close human–robot interaction. In addition, relevant standards are being prepared by ISO TC (Technical Committee) 184/SC 2 (subcommittee): robots and robotic devices. In the case of surgical robots, it is important to take into account that many medical device regulatory regimes, such as the European Commissions’ Medical Device Directive, classify these robots as medical equipment or medical devices. In this sense, the SCs (Subcommittees) and WGs (Working Groups) of IEC TC 62: electrical equipment in medical practice, have been in charge of conducting the greater part of the medical equipment standardization work required to produce the IEC 60601 family of standards. These standards cover the safety requirements for medical electrical equipment and medical electrical systems that are actually utilized. This led to the conclusion that both the ISO TC 184/SC2 and IEC SC 62A play an important role in the medical robot standardization. As a first step, these organizations have decided to develop a horizontal medical robot standard, where the robotics and the medical electrical equipment converge. Then, further steps could be directed to develop vertical standards for different types of medical robots.

Under this perspective, the JWG 9 was established in April 2011. The JWG 9 gathers together 69 experts from 19 countries with vast backgrounds in the fields of machine safety and medical device safety. The main objective of this group is to ‘develop general requirements and guidance related to the safety of medical electrical equipment and systems that utilize robotic technology’, covering invasive and non-invasive procedures. To attain this objective, JWG 9 has been analysing the differences between the medical electric equipment as defined in IEC 60601–1 and the new medical robots, concluding that the key difference can be found in the definition of ‘Degree of Autonomy’, which in the ISO 8373 considers the robot operation without human intervention, and in the IEC 60601 family documents is not fully addressed. Some technical reports have already been presented, providing guidance on:

a. defining Degree of Autonomy and how this can affect the risk assessment;

b. methodologies for assessing the chance to the risk, and risk reduction suggestion;

c. basic safety considerations in relation to IEC 60601–1.

Degree of Autonomy directly impacts risk assessment, although it has no direct correlation with risk. The following measures are recommended for reducing risks related to degree of autonomy:

a. constraining the operational scenarios to reduce risk of harm due to incorrect actions;

b. use of unique identifiers for safety related objects;

c. the reliability of sensors and sensing algorithms should be increased to a level where no unacceptable risk occurs;

d. identification algorithms should be designed in such a way that the probability of a certain decision being correct is calculated and can be monitored;

e. validity checks should be implemented in decision which can lead to risky situations;

f. decisions should be verified by diverse sensing principles.

In addition to working on formulating IEC/TR 60601–4–1, the group has identified the need for particular standards for three kinds of medical robots: radiotherapy, surgery and rehabilitation robots. This has given rise to two additional joint working groups: JWG 35 – Medical robots for surgery and JWG 36 – Medical robots for rehabilitation. Of particular relevance to this article is the JWG 35, which was approved in 2015 to develop a particular standard for surgical robots. The new committee is composed of IEC/SC 62D and ISO/TC 184/SC 2, and about 10 meetings are planned before the completion of the standard by November 2018. The new standard for medical robots for surgery will be called, IEC 80601–2–77, Ed. 1.0: Medical Electrical Equipment – Part 2–77: particular requirements for the basic safety and essential performance of medical robots for surgery.

3.4 Food and Drug Administration (FDA)

On July 2015, the FDA carried out a public Workshop entitled ‘Robotically-Assisted Surgical Devices (RASD): Challenges and Opportunities’. In this workshop, the FDA discussed topics related to the design, development, evaluation and regulation of RASD.
From the system perspective, three factors were identified as fundamental for the successful application of RASD: (i) the understanding of the technological characteristics of RASD, so that changes to a device that could affect the performance of the RASD system can be easily detected; (ii) the understanding of the interdependence and interoperability of each component of the RASD system; and (iii) RASD training for the user and the OR team.

From a regulatory perspective, the FDA’s CDRH (Center for Devices and Radiological Health) classifies all medical devices based on the risks the device poses to the patient and/or the user. Devices are classified into one of three categories: Class I – Low-risk devices; Class II – Moderate risk devices; Class III – Highest risk device.

The class to which a device is assigned determines, among other things, the type of premarketing submission or application required for FDA clearance to market. RASD are currently regulated as Class II 510(k) devices, under the ‘Endoscope and accessories’ regulation (21 CFR 876.1500). Thus, for a new or modified RASD to obtain FDA clearance, the new or modified device must be demonstrated to be ‘substantially equivalent’ to a ‘predicate’ (legally marketed) device. From this perspective, da Vinci Surgical System (Intuitive Surgical, Inc. Sunnyvale, CA) is the most cited robot for endoscopic surgery and it is the only RASD approved for use in the United States.

3.5 | CE Marking

In Europe, robotic surgery devices require a CE-mark before they can be placed onto the market. The CE mark signifies declaration by the responsible party that the robotic device is compliant with all appropriate European Union New Approach Directives, and more specifically, with the Council Directive 93/42/ECC, which is the Medical Device Directive (MDD). Thus, the CE mark must be obtained, certifying that the product complies with the essential requirements of the relevant EU health, safety and environmental protection legislation. The approval procedure is managed by independent Notified Bodies (NB), accredited by Brussels centrally. There are over 75 international, non-governmental NB for medical devices. Devices are divided into Classes I, Ila, Iib and III in accordance with Annex IX of MDD. The class is linked with the risk of the device and classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of body affected by the use of the device. This classification has an impact on the conformity assessment route that the manufacturer should follow in order to affix the CE marking on the robotic device. As a general rule, confirmation of conformity with the requirements must be based on clinical data. The following harmonized standards are considered as essential requirements: EN ISO 13485:2012, BS EN 62366:2008/IEC 62366–1:2015 Medical devices – Application of usability engineering to medical devices, IEC 62304: 2006 – Medical device software – Software life cycle processes, IEC 60601 family – Medical electrical equipment, EN ISO 14971:2012 Medical devices – Application of risk management to medical devices and ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice.

Finally, as a summary, Figure 2 gathers the main points described in this section.

4 | CONCLUSION

The research review carried out in this article shows up that in spite of the great progress achieved, robotic surgery should confront important
challenges in order to be successfully integrated into routine practice. Cost reduction, shorter time of intervention, reduced time and complexity for the set-up, reduced OR footprint, enhanced data integration and improved decision-making have been identified as the main clinical needs that have to be met in order to achieve greater acceptance and market penetration of surgical robots. Taking into account these clinical needs, the main technical requirements that should be addressed in the near future, and that consequently, will trace the roadmap for the next scientific and technological advances in the field of robotic surgery are: reduced size, shape and weight of the equipment, increased number of DOFs, increased resolution, improved platform stability, force feedback feeling, suitable visualization and spatial orientation of the surgical field, enhanced wireless modules, triangulation capabilities, reduction of repetitive instrument exchange, flexibility of rigid instruments, enhanced manoeuvrability, suction and irrigation capabilities, improved ergonomics and unified training and credentialing requirements.

In addition, the metrics that should be defined for safe and more efficient technology development and the regulatory standards that are being elaborated for boosting the industry and facilitating the systems integration have been presented. These metrics and regulatory standards for robotic surgery have been addressed from the perspective of the efforts carried out by the European FP7. Research Project SAFROS – Patient Safety in Robotic Surgery (FP7-ICT-2009.5.2), the Joint Working Groups JWG 9 and JWG 35 between the ISO and the IEC, as well as the FDA through the 2015 RASD workshop, and NIST. It is expected that in the coming decades, all surgery will be undertaken with at least some aspects of robotic surgery replacing or complementing open surgery. Global surgical markets, which were worth $3.2 billion in 2012, are anticipated to reach $19.96 billion by 2019. Therefore, it is possible to confirm that the field of surgical robotics is still only at the beginning of a very promising large-scale development.

REFERENCES


