Chapter 55
Surgical Robots:
System Development, Assessment, and Clearance

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ABSTRACT

Information technology and robotics have been integrated into interventional medicine for over 25 years. Their primary aim has always been to provide patient benefits through increased precision, safety, and minimal invasiveness. Nevertheless, robotic devices should allow for sophisticated treatment methods that are not possible by other means. Several hundreds of different surgical robot prototypes have been developed, while only a handful passed clearance procedures, and was released to the market. This is mostly due to the difficulties associated with medical device development and approval, especially in those cases when some form of manipulation and automation is involved. This chapter is intended to present major aspects of surgical robotic prototyping and current trends through the analysis of various international projects. It spans across the phases from system planning, to development, validation, and clearance.

INTRODUCTION

Prototyping a new device implies creating a system for the first time, dealing with all the challenges and unforeseen pitfalls. It has an especially important role in high-risk, high-value domains, such as interventional medicine. In the past decades, numerous different robotic surgery devices have been created, and only a few reached the market. The Medical Robotic Database (Pott, 2011) lists over 450 international surgical robotic projects, of which several dozen are with the potential to become commercially available. Parallel, the number of surgical robotics related publications has been steadily rising in the past years (O'Toole et al., 2010), making *Computer-Integrated Surgery* (CIS) one of the hottest areas within medical technology.

CIS refers to the entire field of technology-aided interventional medicine: theory and practical technology from image processing and augmented reality applications to automated tissue ablation. CIS means the combination of innovative algorithms, robotic devices, imaging systems, sensors and human–machine interfaces. These systems should work cooperatively with physicians in the planning and execution of surgical procedures, therefore the process involves continuous innovation and prototyping (Taylor & Kazanzides, 2008). A subfield of CIS is called *Image-Guided Surgery* (IGS), where the digital system is not necessarily involved in the physical part of the operation, but improves the quality of surgery by better visualization or guidance. IGS means the accurate registration (correlation and mapping) of the operative field to a pre-operative (typically *Magnetic Resonance Imaging*—MRI, or *Computer Tomography*—CT) imaging or intra-operative (*ultrasound*—US, fluoroscopy) data set of the patient, providing free-hand navigation, positioning accuracy of equipment, or guidance for a mechatronic system. IGS systems have been successfully prototyped and commercialized, and now being used in neurosurgery, radiotherapy, pediatrics, orthopedics and various other fields.

This chapter introduces the aims and means of surgical robot development, giving a better understanding of the difficulties the field is challenged with through examples taken from existing robots. Medical robots are mostly employed for the accuracy and reliability of their mechanics; however, it may still be hard to fully exploit their features, as surgical tasks are typically unique, involving the semi-autonomous manipulation of deformable objects in an organic, limited environment. Robot-assisted procedures offer remarkable advantages both for the patient and the surgeon. The ability to perform operations on a smaller scale makes microsurgery more accessible, and the stability of the devices.

Medical imaging gives the capability to navigate and position a surgical tool at the target

point. Furthermore, there is the option to introduce advanced digital signal processing to control or record the spatial point-of-interests and motions (Kazanzides et al., 2010). This can be useful for surgical simulation and risk-free training. Finally, robotized equipment can greatly add to the ergonomics of the procedures. The main advantages of robotic surgery systems, based on (Karas & Chiocca, 2007) and (Lirici et al., 1997), are the following:

- Superior 3D spatial accuracy provided by the robot,
- Specific design for maximum performance (including miniature robots),
- Stabilization of the instruments within the surgical field,
- Advanced ergonomics supporting long procedures,
- Stable performance,
- High fidelity information integration,
- Invulnerability to environmental hazards,
- Patient advantages (reduced blood loss, less trauma, shorter recovery time),
- Decreased costs (per treatment) due to shorter hospitalization and recovery,
- Possibility to provide better and more realistic training to physicians.

Further optional benefits:

- Improvement of manual dexterity, motion scaling,
- Physiological tremor filtering,
- Integrated 3D vision system with high definition (HD) resolution.

At the prototyping phase of a new system, not all of these benefits are apparent. The human–machine interface, ergonomics and economical features are typically developed in a later phase of product development.

Robots have been introduced to the operating room primarily to provide higher accuracy

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