Robotics and Autonomous Systems 62 (2014) 1342–1352

Contents lists available at ScienceDirect

Robotics and Autonomous Systems

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

A design framework for surgical robots: Example of the ARAKNES robot controller

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ARTICLE INFO

Article history:
Available online 9 May 2014

Keywords:
Surgical robot
Medical device
Design framework
Safety

ABSTRACT

It is a common preconception that developing and transferring a surgical device into the Operating Room (OR) represents a difficult enterprise. Indeed, after nearly three decades of surgical robotics research, many prototypes have been built, some have been technically validated, but just few found their way in the OR. Therefore, some causes that might influence the successful transfer of emerging surgical robotics technologies into hospitals and clinics are discussed in this work. On that account, a framework for the design of surgical robots that is well suited for research centers is also presented. Such framework provides a base approach for structuring surgical robotics developments in order to comply with European medical device regulations. Finally, an example case of a robot controller for a teleoperated surgical system is provided. The latter controller was successfully integrated during the ARAKNES project for Single Port Laparoscopy (SPL), carried out under the European Union's 7th Framework Program for Research and Technological Development.

1. Introduction

Originally, medical robots were inspired by the success of industrial robots. However, the specifics of medical applications led to research on better suited kinematics, actuation mechanisms and materials (i.e. biocompatibility and/or compatibility with medical imaging systems). In turn, the organizations in charge of medical device regulation (e.g. FDA, ISO/IEC) also updated, up to some extent, the standards defining the requirements for authorizing the use of any surgical device in the OR. Presently, almost three decades of research in the field have passed, and only few medical robot prototypes managed to reach the general public. Several factors might be at the origin of this situation, such as the challenge of carrying out research and operating on living organisms, which is not usually the case in industrial robotics, and also the difficulties of business creation in today's medical industry.

More particularly, if surgical robots being mainly developed at research centers are considered, another factor that might play a crucial role in their successful technological transfer is the availability of adequate design methodologies supporting the development process at all stages. Furthermore, due to the medical nature of surgical robotic developments, the selected methodologies should also comprise concise metrics for evaluating the true benefits of the technology being developed, together with strong safety considerations and additional studies which are usually dependent on socio-economic and market constraints of the targeted patient populations. Even though additional resources and development efforts would be certainly required in order to contemplate more than purely scientific design aspects, the short and long-term success rates of the proposed robotic solutions could be increased and, more importantly, the ethical commitment of offering better accessible medical technologies could be reinforced since an early development stage, such as the definition of the project feasibility. As a result, this work aims to provide such a methodological approach, which could be further appropriated and adapted according to the specifics of a selected surgical application.

In general, a surgical robot could be considered as a complex system consisting of:

- Articulated and motorized mechanical structures, sometimes inspired from conventional surgical instruments;
- Electronic components;
- Software controllers;
- Human machine interfaces (HMIs).

These components are developed by medical experts and engineers, and are used to perform interventions in constrained unstructured spaces, inside and/or outside of the patient's body, and

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http://dx.doi.org/10.1016/j.robot.2014.03.020
0921-8890/

in collaboration with the medical staff. Therefore, it might be easy to understand that a failure at any level can occur and it can be critical for the patient. Under such circumstances, it is desirable to dispose of methods for ensuring that each component is designed, implemented and integrated in order to achieve its intended function in optimal conditions.

The medical nature of surgical robotics also differs from many other disciplines that are not directly subject to ethical issues. For our purposes, the most immediate ethical concern is the requirement of experimental validations in humans. Thus, in order to achieve the ultimate objective of performing surgery and accelerating the technological transfer, the issue of complying with medical device regulations must be tackled since the first stages of every design.

A literature review on the design of safe surgical robots can confirm that up to now, previous works have mainly focused on two types of methods:

- Risk management,
- Risk reduction.

Regarding the former group of methods, several research works have been published, such as the fault tree analysis [1,2], the event tree analysis [1] and the fault tolerance algorithm [3]. These failsafe design methodologies, together with equivalent ones coming from the military and industrial sectors (e.g. *FMEA* and *HAZOP*), could be adapted and employed to identify undesirable events that could induce a failure at all stages of development of a system. The application of such methods in medical devices has been widely documented in the industry [4,5], since today these techniques are well-recognized risk management tools that are moreover required according to current regulations. Nonetheless, the final choice of a specific method from the set of options is still left to the designer. It can also be argued that the success of these risk management methodologies is highly dependent on the previous experience of the individuals in charge of certification, i.e. usually the quality and reliability experts.

Among the first works on the latter group of methods for risk reduction, the contributions of Davies [6], and Ng and Tan [7] can be mentioned. They recommended the use of:

- Simple reliable components, since a high degree of dependency in a system increases the chances of failure;
- Redundancy, for instance having backup power supplies, or using sensors at the level of the actuators and also at the output of the mechanical transmissions so that the system can continue to operate even if some components fail;
- Intrinsically safe components, which means preferring technologies whose construction and use imply a reduction of risks (e.g. brakes, clutches, dead-man-switches, mechanical fuses).

The first two recommendations should not be considered as contradictory, since redundancy should not search to increase *complex dependencies*, but to deliver independent and almost parallel-connected simple alternatives in case of failure. Confusions regarding these two guidelines often arise since guaranteeing the latter condition is not always an easy design task. For example, the circuitry that activates a redundant backup power supply so that the system can continue to operate should be a simple reliable component that operates in order to handle an exogenous (or even an endogenous) failure. The same reasoning should be applied to sensor redundancy, in which multiple sensors can be used while avoiding dependencies between them, i.e. allowing to measure the process even if one or more components fail. Schneider and Troccaz [8], Pierrot et al. [9] and Dombre et al. [10] have reported the use of these three guidelines in the robots *PADyC*, *HIPPOCRATE* and *SCALPP*, respectively.

Some previous works have focused on software risk reduction techniques. For instance, Lewis and Maciejewski [11] put forward a method to control a robotic manipulator in the presence of joint failures. Ikuta and Nokata [12] suggested the use of impact force and stress as a safety measure for human-care robots. Haddadin et al. [13] proposed reactive control strategies that can improve safety during human–robot interactions. Their approach consists of a collision detection method using joint torque sensor measurements and allowing to reduce contact forces below any level that is dangerous to the human operator.

Dependability principles also play an important role in current designs. These principles date from the 1830's [14] and some modern formulations were presented by Avižienis [15], Randell [16] and Laprie [17]. They were taken into account in the context of medical robots by Dowler [18], Dario et al. [19], Duchemin et al. [20], and were extended by Guiochet and Vilchis [21]. In general, a dependable system incorporates mechanisms to ensure its availability, reliability, safety, confidentiality, integrity and maintainability. Therefore, the majority of works cited herein can be considered as contributions to the design of dependable surgical robots.

Recently, Dombre et al. [22] published a framework for the design of medical robots. To the best knowledge of the authors, this is one of the first works that synthesizes the previously mentioned methodologies to conceive a safe medical robot. Even though they described the design process through three main initial steps, a complete design cycle was not formulated in their work. Therefore, the framework introduced in [22] is extended herein, in order to provide a base systematic approach that responds to the needs of research institutes and that can be further appropriated by the end-users depending on the specifics of the surgical application. The present work is also complementary to previous works by the authors on the software control architecture developed for the ARAKNES[1] project [23].

The paper is organized as follows. In Section 2 the base design process is thoroughly described, including some design recommendations and additional details regarding European directives for medical devices. In Section 3, an example case consisting of the robot controller software that was integrated in the ARAKNES project for SPL is then provided. Finally, Section 4 presents the final remarks and future works that are envisaged to improve the proposed design framework.

2. A design framework for surgical robots

A general overview of the proposed design cycle is shown in Fig. 1. The process starts with the definition of the specifications and ideally finishes a first iteration with experiments on human patients. In practice, however, the success of the ideal case will mainly depend on the available resources, the degree of development of the existing surgical platform and on the acquaintance of the designers with similar medical device developments. Alternatively, inexperienced researchers would be able to carry on with alternative non-human tests and more easily advance towards an eventual certification during a later iteration. The framework steps can be described as follows:

1. **Definition of the surgical system specifications**: the system specifications have to ensure that the developers (researchers) satisfy the requirements of the clients (the patients and the medical staff). Developers and clients must be able to interact at any point of the whole design process. Guidelines on surveying the customer needs can be found in the literature [4]. A requirements specification document will be produced at the end of this step. The following substeps should be considered:

[1] Array of Robots Augmenting the Kinematics of Endoluminal Surgery.