Identification of Hazards in Invasive/Surgical Robotics

Péter Pausits, Gábor Szögi, Dénes Á. Nagy, Marsel Nallbani, Imre J. Rudas and Tamás Haidegger*
Antal Bejczy Center for Intelligent Robotics; Óbuda University Robotics Special College
Óbuda University, Budapest, Hungary
{peter.pausits, gabor.szogi, denes.nagy, marsel.nallbani, rudas, haidegger}@irob.uni-obuda.hu

Abstract—**Service robotics receives more and more attention in the developed world beside industrial applications. While industrial robotics conquered the factories, it was important that researches develop a number of principles and guidelines to help minimizing the risk of human accidents. Today's safety standards of industrial robotics almost completely exclude the possibility of physical interaction between the human operator and the robotic device. Just recently, a new paradigm, the divided workspace has prevailed, and as a consequence, a number of new and critical safety issues have emerged. Service robots have become even more complicated, as we cannot erect a fence around domestic robots, and in the case of medical robotics, the human–machine interaction is inevitable. The goal of this research was to explore and quantify human–machine interactions, and classify them based on their hazard level. The focus is on surgical robotic devices and their current applications, as this situation presents one of the most complex form of interaction. It is necessary to make service robots complying with safety standards, based on a unified and generally accepted methodology.**

Index Terms—invasive/surgical robots, human–machine interaction, hazards, medical device standard

I. Introduction

As a result of the continuous development and research, the field of medicine uses a great number of devices for diagnostics, surgery, treatment and rehabilitation [1-2]. The human body is so complex that every single procedure poses a different challenge to the inventors of medical devices and to the medical team. The growing autonomy of medical devices poses possible new hazards for their operators and the patients [3]. However, the recent development and targeted application of new medical devices greatly contributed to the recovery of patients and helps reducing the risks of complications. For hazard management and reduction of risks, a number of standardization bodies have been dealing with the safe operation of such devices. Due to their efforts, sophisticated standards exist in most fields, such as industrial robotics, nevertheless, the development of new applications keep requiring the revision of standards, as well as the creation of new ones.

In this work, the landscape of international standards (ISO and IEC) was explored, concerning single groups of devices and connections between the different overlapping fields were identified. Medical devices—including medical robots (robotic devices for medical use)—and numerous sub-domains within. Fig. 1 presents the various areas in which certain sub-domains are still hard to be defined accurately. Primarily, this study focuses on invasive/surgical robotic devices. While by the IEC definition of surgery refers to "procedures performed through a skin incision", practically, natural orifice access (NOTES) and minimally invasive procedures (MIS) are also considered in the same category. Today's surgical robots typically perform procedures in a master–slave (teleoperation) mode, based on image guidance, or in a cooperatively controlled way [1]. By examining the safety standards applied for these devices, shortcomings in the guidelines can be identified, especially regarding the autonomic functions of the robotic devices.
For this reason, the new IEC JWG35 standard focuses on the "Particular requirements for the basic safety and essential performance of medical robots for surgery". Most of the risks of these machines are very similar to those of industrial robots, which are included in the ISO 10218 (Robots and robotic devices – Safety requirements for industrial robots) international standard and the current FDIS ISO 15066 (Robots and robotic devices – Safety requirements for industrial robots – Collaborative operation). These standards served as a guideline when new sources of risk of invasive/surgical robots were explored.

II. Overview of Existing Standards

Due to the particularity of the field, one single safety standard for all medical devices is impossible. Some areas have seen new methods and proposals for safety validation [4], but no unified guiding standard has been proposed yet. Surgical robots (to some extent) are similar to industrial robots functioning in divided workspace, which have seen some recent improvement in standardizaton due to the ISO 13482:2014 (Robots and robotic devices – Safety requirements for personal care robots).

Certain domains, such as IGRT (image-guided radiotherapy) [5-6] and some other therapeutic procedures, including the application of CT (computed tomography) [7], MRI (magnetic resonance imaging) [8], US (ultrasound) [9] and X-ray [10] are already regulated via particular standards. Furthermore, single medical devices already exist for diagnostic measurement of the patient's state, for physiotherapy treatments, and for surgical procedures. Ultrasound is a widely used medical device, and its particular safety standards are the following: [9], [11-15]. The guidelines for the applications of laser devices in the medical field are also given.

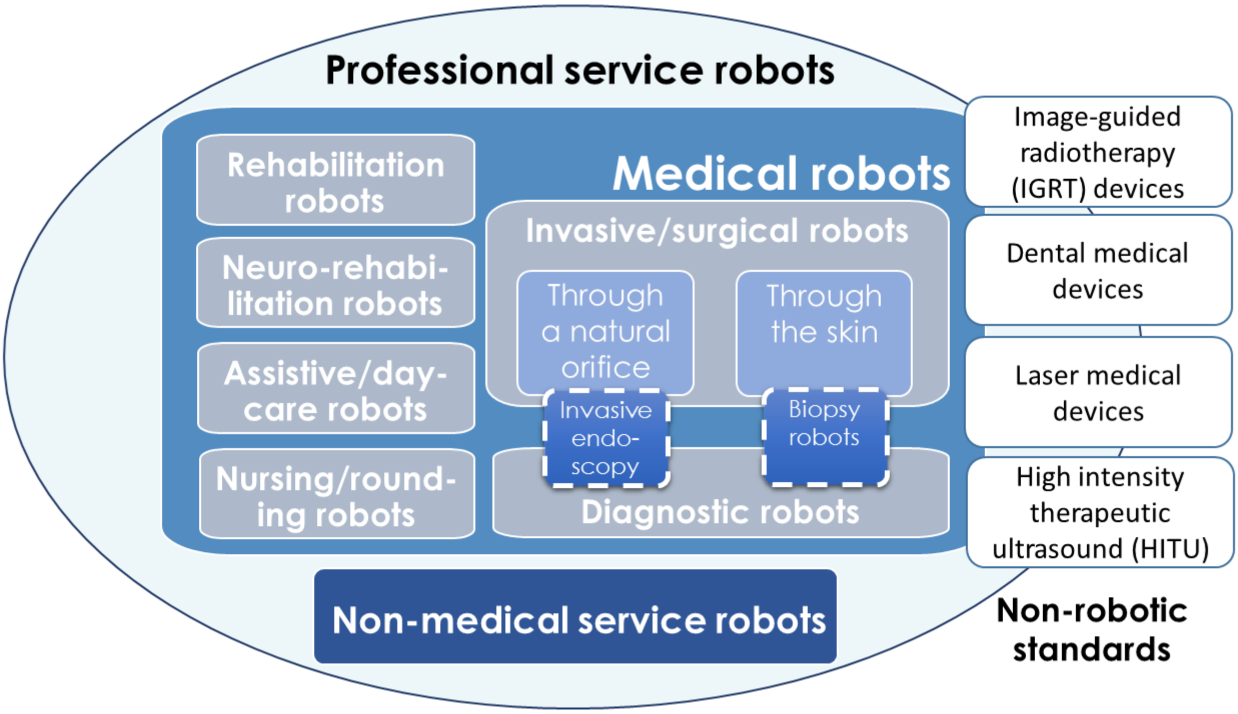

Figure 1. Various types of medical robotic devices fitting into the ISO 8373 and IEC 60601 context.

Medical devices used for intra-corporeal diagnostics are primarily endoscopes [16] and capsule endoscopes [17-18]. Endoscopy used in diagnostics contributes greatly to the success of surgical procedures and to the treatments [19] (IEC 60601-2-18). It is important to note that currently there is no safety standard for capsule endoscopy. Dental medical machines are a special field in which single diagnostic, surgical, rehabilitation devices and their safety standards have already been developed (IEC 60601-2-63, -65, -60).

III. ANALYSIS OF HAZARDS POSED BY INVASIVE/SURGICAL ROBOTS

Different ways of applications of invasive/surgical devices require further categorization. The two main groups of invasive/surgical robots are those that enter the body through a natural orifice and those that penetrate the skin. The two fields cannot be isolated completely, and the definition of surgery is still underway [20]. In this paper invasive surgical devices were also examined from the aspect of procedures executed by robots functioning in divided workspace. In this setup the safety technology of industrial robots have an important role in defining the threats posed by the robotic equipment.

Except for the end-effector, threats are similar in the case of all robots, so the starting point for analysis is the safety standards for industrial robots [21]. In Table I, the hazards of industrial robots are presented, whether they pose a threat in the case of surgical robots.

In the case of surgical robots, contact with the patient is necessary, thus we conducted further research to identify the hazards that can occur during single interactions. Automation of these functions may impose these hazards:

Lack of force feedback: Certain squeeze motions, incisions, drillings and all procedures that require adequate clamping force may not send feedback to the surgeon.

Failure of the force transmission device: In the case of wired force transmission, the wires or their mechanics can be damaged and result in unintended movement.

Blockage of the device in the body: Surgical devices that enter the body require continuous control and conduct due to the particularities of certain channels in the body. For this, they have intermittently placed joints [22] that can – in case of a failure – fix and get stuck.

Inflation of bodily cavities: Laparoscopic procedures require the inflation of the abdominal cavity, which can damage the patient's body if overpressure occurs [23], and may alter the function of the robotic device.

Unintended cessation of the power source: Both the procedure in process and the movements occurring during restart are in danger if a power outage happens during a procedure. In case of a restart, not adequately prescribed protocol movements and operations can pose significant threats.

Speed of signal transformation: If robots functioning in teleoperation mode are not adequately operated, the delay of visual and other feedbacks can be a hazard. If the time delay increases, a hazard of malfunctioning can occur [24].

Unintended movement from the operator: In the case of master–slave systems, movements of the operator that are opposite to the expected operation can pose a threat. A sneeze or a cough can provoke unintended movements of the hand that the robot might read as a command.

Application of high frequency: High frequency surgical procedures are primarily used when cutting soft tissues, and pose a number of new threats to the patient and the operator, unlike to the ones when traditional incisions are used [25].

Usage of materials damaging the living organism: Chemicals applied during the procedure can potentially be poisonous for the body.

Misplacement of the disconnected tissue: Disconnected tissue has to be continuously removed, as if they enter an

TABLE I

ROBOT HAZARDS BASED ON ISO 10218

Type of group	Hazard	Surgical robot
Mechanical hazards	movements (normal or unexpected) of any part of the robot arm (including back)	x
	movements (normal or unexpected) of external axis	x
	materials and products falling or ejection	
	manipulation of products and materials, including ejection	x
	impossibility to go out robot cell (via cell door) for a trapped operator in automatic mode	
	between fixtures (falling in); between shuttles, utilities	
Electrical hazards	process using high voltage or high frequency, i.e. electrostatic painting, inductive heating	x
	welding applications using high voltage	
Thermal hazards	cold surfaces or objects	x
	explosive atmosphere caused by the process, i.e., paint (atomized particles, powder painting), flammable solvents, grinding and milling dust	
	exposure to temperature extremes required to support the process	
Noise hazards	loss of balance, disorientation in working area of robot cell	
	inability of two persons assigned to a task to coordinate their actions through normal conversation	x
	long-term exposure to elevated noise levels	x
Vibration hazards	loosening of connections, fasteners, components resulting in unexpected stopping or expulsion of parts	x
Radiation hazards	EMF interference with proper operation of the robot system	
	exposed to process-related radiation, i.e. arc welding, laser	
Hazards associated with the environment	misidentification of real problem and compound problem by making incorrect or unnecessary actions	
Comb. of hazards	unexpected movements of robot or end-effectors or associated machine	x
	misinterpretation of collaborating robots or simultaneous motion	x
	high-speed rotational parts breaking or disengaging from part retention equipment	x
	contacted by process-related expulsion (i.e., spot welding)	
	part retention device fails	
	unrestrained robot or associated machine part (maintained in position by gravity) falls or overturns	x

undesired place they can cause complications during and after the procedure.

Collision of the robotic arms: Collision of the end-effectors is indispensable during a procedure, but as a consequence of a wrong command the arms can have an unintended contact, resulting in a negative effect.

Positioning of the end effector during its replacement: Repeated positioning of the end-effectors is necessary in the case of a laparoscopic procedure due to the restricted area of penetration. During the replacement of the equipment, the position can change leading to the damage of the tissue.

Unintended clamping force: Every soft and hard tissue has a different degree of tolerance regarding clamping force before they suffer permanent damage. Poorly chosen clamping force can be a threat to the tissue.

Unintended clamping time interval: Certain tissues can only be squeezed for only a certain amount of time with a certain amount of force before it potentially becomes damaged.

Speed of rotation: When drilling, the speed of rotation has to be well chosen to avoid a possible threat.

Unintended movement of the parts of the body: Soft and hard tissues have neurological particularities that can cause movement as a result of an unexpected effect. This is a potential hazard during surgical procedures.

Obviously, not every source of hazards appears in the case of a unique surgical robot; therefore, separate particular standards are necessary for invasive/surgical robots that enter through a natural orifice or through the skin. The threats included in the ISO 10218 standard provide the basis for the list of new threats in the case of surgical robots, as a special for of human–machine interaction. These hazards are presented in Table II. Tissue motions for example is a group of threats where adequate regulation of autonomous functions is required, however this issue only surfaced in the field of medical robotics and such was not present in the case of industrial applications. Further, when fixing tissue, taking the possible clamping forces and positions into consideration is necessary, as this also means a new threat to the success

TABLE II

NEW HAZARDS APPLYING TO INVASIVE/SURGICAL ROBOTS

Type of group	Hazard	Invasive/surgical robot	
		Natural orifice	Through skin
Mechanical hazards	Lack of force feedback	x	x
	Failure of the force transmission device	x	x
	Blockage of device in the body	x	x
	Pressure due to inflation	x	x
Electrical hazards	Unintended cessation of the power source	x	x
	Speed of signal transformation	x	x
Vibration hazards	Unintended movement from the part of the operator	x	x
Radiation hazards	Application of high frequency	x	x
Material/ substance hazards	Usage of materials damaging to the body	x	x
Hazards associated with the environment	Misplacement of the disconnected tissue	x	x
Comb. of hazards	Collision of the robotic arms		x
	Positioning of the end effector during its repl.	x	x
	Unintended clamping force	x	x
	Unintended clamping time interval	x	x
	Speed of rotation		x
Tissue motion hazards	Unintended movement of the parts of the body	x	x

of the operation and to the human body. An unexpected and unintended movement caused by the reflexes of the human body can also lead to serious injury. Consequently, adequate fixing also requires special attention.

IV. Conclusion

Medical robotics involves a special form of human–machine interaction, especially in the case of invasive applications. During our research, we concluded that as of today, there is no adequate standard for invasive/surgical robotic devices. Manufacturers and users have to apply certain related standards that do not completely address the risks of this field, especially in the case of autonomous operation. The creation and application of a safety standard is indispensable in the future, as the field of medical robotics is rapidly expanding, and complications during procedures can occur from previously unidentified sources. Furthermore, it can be concluded that current standards are obsolete and need an update due to the extensive pace of system development. This work has begun in the working groups of the major standardization bodies. In the future, definitions of invasive/surgical robots will be necessary with the further grouping along specific procedures that pose different threats to patients and operators.

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