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A ROBOTIC HELPING HAND TO THE DETECTION OF SMALL COLORECTAL TUMOURS IN LAPAROSCOPIC SURGERY

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Abstract: *The present paper proposes a systemic approach for developing medical robot-assisted systems: robotic small tumour(s) detection system used in colorectal laparoscopic surgery. This approach was proposed to guide the design process of robotic systems in laparoscopic colorectal surgery. The proposed design framework guides the engineers towards an equilibrium between surgical and clinical constrains, technical and technological possibilities in medical robotic development. A concept was developed based on the proposed framework. The developed concept was an Assisted Robotic Tumour Detection and Excision System (ARTES) - that is supposed to be capable to identify precisely the location of small colorectal tumours from a distance of at least 20 mm when biological tissues are interposed and assist the surgeon within the surgery. The ARTES system consist of three main components: 1) collaborative robotic system (that guide the sensing laparoscopic instrument through the colorectal area to identify the tumour labels – practically the tumour(s) location(s)); 2) laparoscopic sensing instrument (for scanning the colon or rectum area to identify the labelled tumours); 3) tumour(s) tags –intelligent labels with which the tumour(s) will be marked.*

Key words: *design framework, robot-assisted system, colorectal tumours, precise location, collaborative robot.*

1. INTRODUCTION

Robot-assisted surgery has expanded in macro-surgical specialties like urological, general, digestive, gynaecological, cardiovascular); however, the only two surgical robots that have proven their efficiency for human surgery are the Da Vinci Robotic Surgical System (Intuitive Surgical, Inc.) and the ARES Robot Auris Surgical Endoscopy System.

In addition, the cost of the two robotic systems might be prohibitive and the learning curves for surgeons are potentially steep. There are, nonetheless, potential advantages to the use of robot assisted laparoscopic system in digestive surgery, including increased precision and manoeuvrability of movements, scalability of motion, tremor filtration, better ergonomics, task automation, and surgical training [1, 2].

The colorectal cancer is the third most common cancer in the world [3] it's increasing dramatically in Romania in the last decade's consequent to changes in the alimentation habits. As access to diagnostic endoscopy became more available in Romania, an increasing number of tumours are detected in early stages when they have rather small sizes, up to 3 centimetres in diameter. Exactly these tumours are prone to a robot assisted laparoscopic identification and excision, the new high-tech approach which has changed the face of surgery [4].

An important issue for a robotic assisted laparoscopic system is to locate precisely these small colorectal tumours, simply because these surgical approaches do not offer the same amount of haptic feed-back as palpation does in open surgery. Therefore, if the tumour does not invade the serosa or has a soft texture, there is a high risk that the surgeon will not find it [5, 6].

Within this paper, we introduce a framework that guides the biomedical engineers towards an equilibrium between surgical constrains and technical possibilities of the moment in medical equipment development. Based on the proposed framework we developed a concept of the Assisted Robotic Tumour Detection and Excision System (ARTES) capable to identify precisely the location of colorectal tumours from a

distance of at least 20 mm when biological tissues are interposed.

2. RELATED WORK

An evidence-based critical analysis was conducted by focusing on the literature of the past 9 years regarding the two directions: "laparoscopic colon surgery" and "robotic-assisted colorectal surgery".

2.1 Laparoscopic colon surgery

Laparoscopic surgery was introduced during 1980s. Laparoscopic techniques rapidly gained popularity for simple surgical procedures but were slow to gain acceptance with more complicated surgical tasks due to the reduced dexterity of the laparoscopic instruments.

One of the problems faced by surgeons today is the inability to accurately identify the position of the small colorectal tumours (<2, 3 cm in diameter). Intraoperative identification of colorectal tumours that are not visible on the serosal side of the bowel is achieved today either by intraoperative endoscopy or by tattooing the tumour with certain biocompatible dyes (India Ink, charcoal particles or methylene blue) [7, 8]. The first method requires presence of the endoscopist and specific devices in the operative theatre and distends the bowel with air, which hampers further laparoscopic dissection. The tattoing method is not easy nor standardized. India Ink and charcoal particles, which last long in the bowel wall, [9,10] are not available in Romania while methylene blue has the major disadvantage that it is absorbed from the injection site after 6 hours [11, 12].

On the other hand, precise injection of the dye into the thin colorectal wall is challenging; the dye may be injected directly in the peritoneum which creates a new localisation issue, as it spreads on a large surface, but also an infectious issue, acute pain and distress to the patient due to subsequent peritonitis [12]. Presence of the tattoo in the tissue is also not free of risks, complications such as edema, necrosis and neutrophilic or eosinophilic infiltration, pericolic abscess, peritonitis or even bowel infarction [14] were identified.

To overcome some of the limitation of laparoscopic surgery the marriage of minimally invasive surgery with master-salve manipulators surgery was made during the '90s and the first robotic surgical systems were developed [15, 16].

2.2 Medical robotic surgical systems

Robotic surgical systems were designed to overcome the limitations of laparoscopic surgery by providing stable 3D views from a surgeon-controlled camera, angulated instruments with seven degrees of freedom, improved ergonomics and tremor filtering.

This has led to the increasing adoption of robotic surgery across many surgical specialities over the last 10 years and its increasing application in colorectal and rectal surgery [4] The effectiveness of robotic colorectal surgery is evident form the increasing number of research published on the subject every year [17].

At present the da Vinci surgical system designed by Intuitive Surgical is the only clinically applied platform for robotic surgery. However, this is likely to change soon, with several new robotic surgical platforms being introduced from 2017. The da Vinci surgical system consists of a surgeon console (master), a patient side cart (slave) with four interactive arms and a vision cart. The surgeon sits on the console, from which he has access to a stable 3D view of the anatomy and controls the side cart arms through the master controls. The patient side cart is 'docked' to the patient and three of the side cart arms attach to surgical instruments and one to the camera. The instruments have flexible wrists with seven degrees of freedom. The surgeon's assistant sits on the side of the patient and through a laparoscopic port can perform tasks such as suction/irrigation, vessel ligation and retraction.

3. THE PROBLEM

From the above arguments, one should be able to understand the complexity of the design process of a robotic-assisted system. Also, it has to be notice that there are some researches on robotic surgery systems, and also some robotic systems are on the market. But there is no robotic system on the market that facilitates the detection of small size colorectal tumours. Furthermore, the actual robotic surgery systems aren't so practical relevant because they are difficult to

use by surgeons, not ergonomic and very expensive for Romanian medical market.

4. METHODOLOGY

Due to the absence of technology specific regulation or national standards for designing medical robotics in Romania, a methodology for designing such systems was proposed hereinafter. For developing the current proposed methodology international standards, technical regulations and different design methods have been consulted. Particular attention was given to safety issues regarding collaboration between surgeon, robotic system and patient.

Figure 1 shows the overview of the proposed design methodology for medical cobots. The entire development consists of seven phases: Phase 1: Defining/Understanding the vision of the Assisted Robotic Tumour Detection System; Phase 2: Identify the Safety, Clinical and Technical Requirements Applicable to Medical Robotic Systems; Phase 3: Conceptual design of the Assisted Robotic Tumour Detection System; Phase 4: Robotic system risk assessment; Phase 5: Concept adjustments/ Generate the final solution/ Testing and validation. The proposed method is a top-down design method beginning with the vision of the medical robotic system, continuing with the detail mechanical and electrical design of the component parts, and reaching to the software interface development. Safety check and verification - validation approach was implemented at each phase.

Phase 1: ***Defining/Understanding the vision of the Assisted Robotic Tumour Detection System***

Assisted Robotic Tumour Detection System must allow surgeons to perform tumour labels identification tasks through tiny incisions using robotic technology and to maintain a fix and precise position and orientation. Robotic-assisted system have to be self-powered and computer-controlled to be programmed to bring into position and to be able to manipulate in a safe manner the tumour identification instruments. This relieves the surgeon of additional tasks and allows him to concentrate on the medical issues.

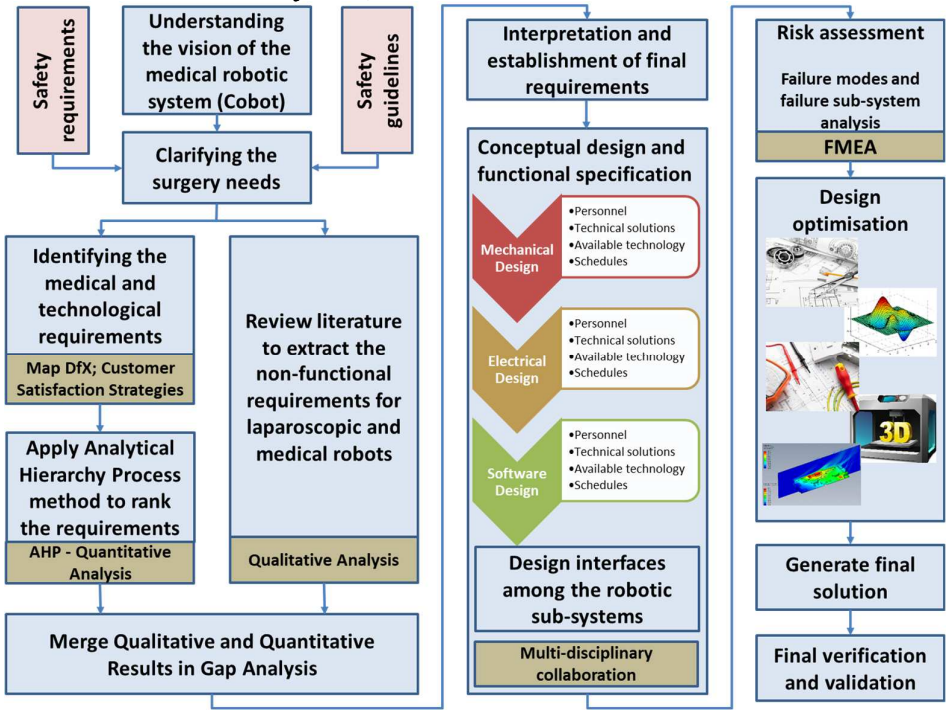

Figure 1. Design framework for Assisted Robotic Tumour Detection and Excision System (ARTES)

Phase 2: ***Identify the Safety, Clinical and Quality Requirements Applicable to Medical Robotic Systems***

The requirements identification means to determine the specific technical requirements with which a medical robotic device must comply. In general, these technical requirements fall under

one of the following three areas: 1) product safety; 2) clinical safety; and 3) quality systems compliance.

Product safety

Product safety is one of the key issues in designing a medical robotic system. Medical robots are used in medical settings for patients and concern human life. The safety issues of medical robots are more stringent, dedicated and critical than the other types of robots whatever they are. Depending on the specificity of the robotic system, three categories of product safety requirements are considered: a) Hardware safety (from the mechanical and electro- mechanical points of view), b) Software safety, c) Operational safety. Mechanical safety is the basic requirement for a robot, in general, but for medical robots in special. Possible approaches included redundancy sensors, impact force and stress sensors, mechanical constraints and fault detection [17]. Several design recommendations for electro-mechanical, software and operational issues of the robotic system are provided below.

Software safety issues [18, 19]

Design constrains	- HMI must be ergonomic and intuitive with unambiguous error messages - Incremental design of the controller (through functional blocks for instance) to facilitate the setup and validation phases - Avoid the use of non-deterministic modules
Intrinsically safe components	- To ensure predictability, a real-time compliant environment (defined by the timing requirements specs) must be used - Online modification of the robot workspace is recommended - Advanced sensory-based control schemes - Verification of the consistency of redundant information (position) is recommended - "Robust" processing algorithms of forces - "Graceful" (safe, predictable) shutdown in case of emergency must be implemented - Reversibility via a robot software that allows a quick release in case of emergency - - Monitoring of the current's loop (e.g. to detect a collision)

Electrical safety issues [18, 19]

Design constraints	- Actuator current and/or voltage should be limited - Compliance with electromagnetic compatibility (EMC) regulations - Separation of the power supply circuits for actuators, sensors and processing should be considered
Intrinsically safe components	- Emergency stop button should be accessible; - "Dead man" switches should be accessible (e.g. contact sensors, foot-pedals, etc.) - Hardware watchdogs should be employed
Redundancy	- Redundant safety systems should be considered - Multiple emergency stop buttons for easy access are recommended

Operational safety issues [20]

Intrinsically safe components	- Pre-operative planning modules to optimize the placement of the robot relative to the patient to meet accessibility constraints. - User manuals for all equipment; software and hardware components must be available and design documents should be well detailed - Pre-operative procedures should be well detailed, i.e. patient positioning, sterile draping, robot installation, setup and calibration routines, etc. - Software components should provide means of logging events for improved traceability - Intra-operative procedures should be intuitive and provide comprehensible "work-flows". - Training of surgeons and accompanying team should also be considered.

These upper guidelines must be supplemented with the specific requirements for each component in the system that will be issued from medical device standards.

To evaluate the product safety of a given medical robotic system someone should consider firstly the following international safety standards or regulations:

- IEC 60601-1 - Electrical and mechanical safety, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, defines the requirements regarding the electrical and mechanical safety of most types of medical electrical equipment, including medical robotic devices;
- IEC 60601-1-2 - Electromagnetic compatibility (EMC) - Protection against electromagnetic interference;

- IEC 60601-1-6 - Usability/human factors - Usability and human factors issues specific to medical devices;
- ISO 10993 series of standards - Biocompatibility - Requirements and testing to evaluate the effect of a device through contact with and within the body;
- ISO 14971 Risk management - is a recognized standard for the identification and mitigation of potential safety risks;
- ISO 13482 - Personal care safety - Whether or not deemed to be medical devices, robotic technologies intended to provide personal care.

Clinical Safety

The goal of the clinical safety evaluation process is to collect and continually analyse relevant data to help ensure that an equipment performs as intended under anticipated use conditions, and that the nature and probability of any risks are identified and determined to be acceptable when weighed against the benefits.

A clinical safety evaluation is not a discrete event but part of an ongoing process that is conducted throughout the entire lifecycle of a medical device, from prototype design and development, through regulatory review and approval process and, finally, during actual use after a medical equipment has been placed on the market. Specific issues addressed in a clinical safety evaluation of a medical robotic device could include [21, 22]:

- A review of similar medical equipment already on the market to be able to identify already known clinical safety risks;
- An assessment regarding the interoperability of a given medical robotic device with other devices;
- An evaluation of clinical investigations for compliance with the requirements of ISO 14155 to ensure their thoroughness and accuracy; and
- An assessment of robotic-specific functional safety requirements highlighted in the specific standards, standards mentioned in this article.

Technical or Quality Requirements

The third area of requirements applicable to medical robotic systems involves technical aspects that the system must fulfil, such as performance-related issues, reliability issues, and availability issues. This phase is known as generate the "technical specification document" for the robotic system [18].

Phase 3: ***Conceptual design of the Assisted Robotic Tumour Detection System***

The main objective of designing a medical robotic system is to keep it simple and functional. On the other hand, designing medical equipment isn't enough to guarantee that it is safe. Under these circumstances, standards can't hope to cover all risks. So, designers must make up for the areas standards don't cover by conducting a comprehensive risk analysis.

One of the factors that complicates the situation is that the safety system has its own reliability level. Designers must establish what this level is. One approach to make safety systems reliable is to either use two redundant safety systems or use one system that is tested periodically to see if it is still functioning. One possible approach would be to go through every component in the device and figure out what happens if it fails. Also, designers must anticipate what happens in the event of a second safety-system failure after a certain time. When the safety system fails silently it no longer protects the patient, but he must be safe!

Designers classically use both redundancy and diversity as safety features. Redundancy is simply duplicating the same feature while diversity is the use of two different methods to bring the same function.

Finally, the ergonomic component should not be neglected; medical equipment must be finally easy to use – ergonomic.

Phase 4: ***Robotic system risk assessment***

Once the general safety parameters have been identified, it is necessary to perform a Risk Assessment (also called Hazard Analysis). This is one step of an overall Risk Management process, as required by ISO 14971 (Application of risk management to medical devices). The requirements of ISO 14971:2007 are applicable to all stages of the life cycle of a medical device.

Designers must judge the severity of potential harm and the probability that the harm occurs. Once designers have identified the unacceptable risks, their next step is to define safety measures to mitigate them.

Here, the most common tool is a Failure Modes Effects Analysis (FMEA) or, better yet,

a Failure Modes Effects and Criticality Analysis (FMECA), both of which are covered by IEC 60812. Henceforth, the term FMEA will be used to refer to both methods.

The well-known risk models define three different levels of safety (Level A, Level B, Level C). Level A – equipment is nonharmful if it fails. Level C - equipment that fails can injure or kill someone. If equipment is neither A nor C, then it is level B by default. Categorizing equipment into one of the three levels helps determine how much testing is appropriate. Level A equipment just needs a system test. Level B tests must be detailed enough to check individual parts and/or modules. And as you might expect, most safety-medical equipment is at level C, which tests every component parts of the equipment.

Phase 5: ***Concept tests and adjustments/ Generate the final solution/ Final validation***

Concept testing must be done to gather information concerning how the developed concept could be improved as well as highlighting if any critical aspect has not been given enough attention during the concept development phase. The basic rule implemented during concept testing phase should be to listen more and talk less and take the feedback without arguing to create an open framework for discussion where criticism would not be refrained.

The testing and validation phase helps a product team ensure the design concept works as intended. With several potential concepts in hand, a suitable design now needs to be chosen that fulfils the product design specifications previously generated. This phase should serve as a basis for final design decisions. A multi skilled team should be involved here so that all angles of the chosen design can be evaluated. The concept that is closest in solving the problem identified and fulfils the most design requirements will now be developed in detail.

5. CONCEPT GENERATION

Based on the proposed methodology the concept of Assisted Robotic Tumour Detection and Excision System was generated (Figure 2). Concept generation was the most critical step in the design process. Starting with a set of customer needs and target specifications, the process concludes with an array of product alternatives from which a final design was selected (Figure 2).

Due to the space limitation of this article do not get into the details regarding implementation of the above highlighted framework, it will be pointed out only generated concept. In a future article, the whole process of implementing the framework and generating the concept will be detailed.

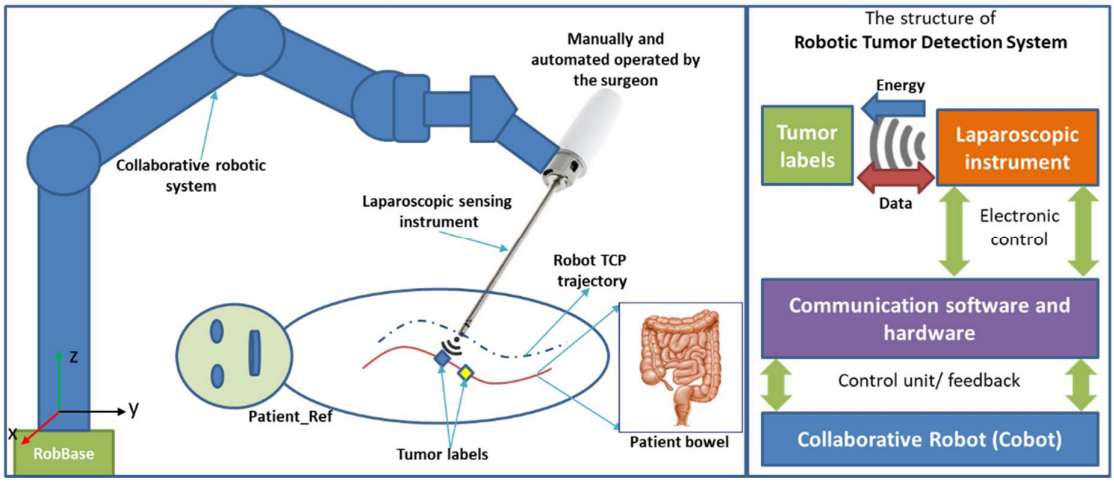

Figure 2. The overview of the Assisted Robotic Tumour Detection and Excision System (ARTES)

The identified requirements for the Assisted Robotic Tumour Detection and Excision System, were: a) allow being sterilized by standard methods (10%); b) addressing to laparoscopic surgery procedures (10%); c) allowing tumours' position identification extremely accurate (50%); d) automatic presentation of contextually-appropriate information (5%); e) easy to use

by a surgeon (5%); f) easy to set up (5%); g) graphical intuitive interface (5%); h) clear indication on the robot's display the logical/natural next step (10%).

The generated concept is presented in figure 2. The figure 2 presents a general view of the robotic system and the functioning principles of the Assisted Robotic Tumour Detection and Excision System components are presented.

6. CONCLUSIONS AND DISCUSSIONS

The future of surgical robotic systems, and especially the field of colorectal robotics surgery, is expanding rapidly and evolving intensely. Newly and innovative approaches are changing the original designs of large, multi-armed, robotic systems into more cost effective, smaller, and modular equipment.

These new technologies, like robotic detection of small and very small colorectal tumours in laparoscopic surgery will need to be borne out with rigorous investigational practical studies and cost must be reasonable to justify their use.

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SISTEM ROBOTIC SPECIALIZAT ÎN DETECȚIA TUMORILOR COLORECTALE DE MICI DIMENSIUNI FOLOSIT ÎN CHIRURGIA LAPAROSCOPICĂ

Rezumat:. Lucrarea de față propune o abordare sistemica pentru proiectarea și dezvoltarea sistemelor medicale robotice – sistem robotic de detectare a tumorilor colorectale de mici dimensiuni utilizat în chirurgia laparoscopică. Acest cadru a fost dezvoltat pentru a ghida procesul de proiectare a sistemelor robotizate în chirurgia laparoscopică colorectală a tumorilor mici și foarte mici. Abordarea propusă ghidează inginerii spre un echilibru între constrângerile chirurgicale și clinice, posibilitățile tehnice și tehnologice în dezvoltarea roboticii medicale. Aplicând abordarea propusă a fost dezvoltat un concept de robot capabil de detecția și excizia tumorilor colorectale de mici dimensiuni (ARTES) – sistemul este capabil să identifice cu precizie locația tumorilor colorectale mici și foarte mici de la o distanță de cel puțin 20 mm atunci când este interpus țesut biologic și să asiste chirurgul în cadrul intervenției chirurgicale. Sistemul ARTES constă din trei componente principale: 1) sistemul robotizat colaborativ (care ghidează instrumentul laparoscopic de detectare în zona colorectală pentru a identifica marcajele tumorale - practic, locația tumorii(lor); 2) instrument laparoscopic sensibil (pentru scanarea colonului sau rectului în vederea identificării tumorilor marcate); 3) marcaje tumorale - etichete „inteligente” cu care vor fi marcate tumorile.

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