Developments in Minimally Invasive Surgery and Interventional Techniques (MISIT)¹

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Abstract

To perform an operation in the classical way, an incision is made in the skin and the underlying tissues. An alternative for this way of operating is minimally invasive surgery. Here only small incisions are made in the skin and operations are performed by using special instruments. Visual feedback is obtained with a camera producing a 2D-display. Another important minimally invasive operating method is based on the use of catheters in arteries and venes.

This research project aims at decreasing the negative effects and limitations which accompany minimally invasive surgery and interventional techniques, so that these can be used more widely, thus bringing less damage to the patient and decreasing the costs for society.

Introduction

During the past decennia technical developments have initiated new methods for diagnostics and treatment in health care. Diagnostics concern noninvasive 3D-imaging methods like ultrasound echos, low dose röntgen for Computer Tomography (CT), and Magnetic Resonance Imaging (MRI). Other methods are based on the use of catheters with different types of sensors via blood vessels, bronchia, vagina, or the digestive tract. In some cases these channels can also be used for interventions, i.e. therapy using catheters.

To perform an operation in the classical way, an incision is made in the skin and the underlying tissues, so that the surgeon can reach the organ to be operated on with his hands. In this way the surgeon has an unrestricted view on the operating field. Moreover, he can feel whether the tissue handled is hard or soft. A disadvantage is that much damage is brought about to healthy tissue. Moreover, the risk of infections is proportional to the size of the skin cut.

An alternative for the classical way of operating is minimally invasive surgery. Here only small incisions are made in the skin. Operations are performed by using special

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instruments which are inserted via trocars, i.e. tubes which allow the surgeon to bring instruments or sensors into the body. Visual feedback is obtained by use of fibre optics, which transport the internal sensor images to a camera producing a 2D-display. Another way is the use of the natural openings in the human body to reach internal organs. In particular the use of catheters in arteries and venes is becoming more and more important. These interventional techniques are complex and require miniaturised tools. Advantages of these new types of intervention and surgery are the minimal damage to the patient leading to a shorter stay in the hospital, less pain, less morbidity and faster mobilisation, and thus to a smaller period of unproductivity.

A disadvantage is the increased amount of skills required from the surgeon. He has no good tactile feedback and his visual feedback is strongly limited. Moreover, his normal eye-hand coordination is no longer intact, due to the restricted tactile feedback and because the coordinate frame of the camera positioned by an assistent is different from that of the instruments the surgeon is working with.

In interventions a part of these issues are also present, but there the main limitation is the mechanical control of catheters and the diameter of the catheter obtainable.

This program aims at decreasing the negative effects and limitations which accompany minimally invasive surgery and interventional techniques, so that these can be used more widely, thus bringing less damage to the patient and decreasing the costs for society. As will be shown many problems can be seen as manual control topics

Disciplines involved

In order to solve the problem described, a number of very different disciplines is asked for. Generally, two different groups of disciplines can be distinguished viz. the technical disciplines needed to solve the many fundamental and technical design problems, and the medical disciplines which have to contribute in the formulation of the clinical problem as well as in the evaluation of technical solutions. Here it should be mentioned that in particular the high-tech contribution of knowledge of the technical disciplines is essential for a successfull program. The same applies for a number of medical disciplines, whereas the choice for a particular application field is more arbitrary. This choice is mainly dependent on the relevance for society and on the existing possibilities to collaborate with the medical university centers.

Motivation

The most important challenge of the MISIT-program is the integration of the medical and technical disciplines in order to come to a technical solution that will be accepted by the medical staff. The scientific challenge can be elucidated by the following five aspects.

Performance evaluation of the surgical team

A performance evaluation is necessary for two reasons. In the beginning of the project bottlenecks caused by the limitations of the available tools and methods have to be identified. In the course of the project, the evaluation has to be achieved on the positive and negative effects of prototype displays and tools and their effects on the performance

of the team as a feedback to the designers. An integral evaluation study in this area is new, and is rarely executed. A major problem is the fact that so many disciplines may be of importance for such a field study. The present situation in minimally invasive surgery is that the classical protocols are used with other, new and modern instruments. Hence the total result is far from optimal. New technology requires new protocols and integration of medical and technical aspects is essential. In such a way quality assurance of the medical technique can be obtained by a systematic evaluation of the procedures.

Improvement of eye-hand coordination, virtual reality techniques

As mentioned in the problem definition, in the present way of applying minimally invasive surgical techniques the eye-hand coordination is very poor, because viewpoint changes of images obtained by cameras via fibre optics are executed by verbal commands. In order to restore this coordination some coupling should be realised between the actions of the surgeon's hand and the viewpoint of the image of the operation field. Furthermore, the presentation of a 3D-image to the surgeon can be studied, which may lead to virtual reality techniques. Probably telemanipulators can be used, which directly can be controlled by the active surgeon. Both the approaches will be investigated.

Image processing

Different techniques have been developed to provide 3D information on the inside of the human body. These different techniques yield common features, but also provide different types of information. The common features, such as the position of bony structures provide a reference for integrating the information of the different sources, so that a more informative image can be presented to the surgeon. To integrate all pre- and peroperative information into one 3D data set requires a number of non-trivial transformations, because for instance the positions of the patients in the different scanning devices are not the same, so that relative positions of internal body structures will differ from each other but also from the positions in the operating theatre. This requires special real time transformation algorithms and presentation techniques.

Design of special tools

The present operating tools are far from optimal, due to friction which eliminates the possibility of force feedback, and restricted manipulation capabilities. Moreover, the ergonomics of the present surgical tools are very poor. The development of low-friction mechanisms may lead to better instruments. Additional movement modes, like bending of the tip of the instrument, may improve the dexterity of the task. Furthermore, tools have to be developed for activities like making anastomoses (connections between blood vessels) and orthopaedic surgery. Also here miniaturisation is critical. An important, closely related area is the design of well controllable catheters, that has many challenging problems, such as the choice of materials, the mechanical properties and again miniaturisation.

Miniaturisation of sensors

In order to monitor the internal state of the patient, but also for imaging purposes, sensors have to be developed which can be introduced by small diameter catheters. The

sensors to be developed will be used to measure physical quantities like temperatures, voltages, pressures, or ultrasound reflections, but also quantities like O_2 or CO_2 -content. This requires the investigation of different types of physical principles and their translation to devices and the development of a method to produce these devices. The interface techniques to be used are also important.

Projects

The program consists of the following six projects

1: Pre- and peroperative evaluation and task analysis of the surgical process

Minimally invasive surgery is a very young technique, Hence, the operation protocols and instruments are still in an early stage of development. The result is that the minimally invasive operation procedure is far from optimal. There are differences between surgeons, but also different patients are treated differently without precise reasons. To improve the surgical protocols, pre-operative knowledge of the patient (anatomy of the patient and e.g. location of a tumor) and peroperative knowledge of the operation should be used and integrated. This knowledge can be exploited to define modifications in the operating protocol.

To determine the efficiency of new instruments and protocols an evaluation study is also necessary. Such a field evaluation provides the data needed for the design and development of new surgical instruments, catheters and integrated display systems. The technique that is used to analyse the surgical process can be used for this evaluation. Furthermore, the reliability/safety of new instruments and protocols can be determined using the same technique.

Goals: Evaluating and improving surgical procedures during minimally invasive surgery. Better planning of the minimally invasive operation using pre-operative information. Improvement of the surgical process using task analysis of the process peroperatively. Evaluation of newly developed surgical instruments.

2: Eye-hand coordination and telemanipulation

In contrast with conventional surgery, minimally invasive surgery yields a complete lack of tactile/proprioceptive, 3D-perceptional and smell feedback. Therefore, three major problems have to be solved:

- o There is almost no feedback of position, velocity and force due to friction in surgical instruments.
- o Only a 2D-visual image is displayed, whereas a 3D-task has to be achieved.
- o In the operation theatre a surgical resident is specially involved in the positioning of the camera. So, due to the positioning of the trocars, the directions of view of the surgeon and the camera differ. Consequently, the surgeon has to make a mental transformation of the coordinate frame of the camera.

Goals: To study the eye-hand coordination in order to generate guidelines to design:

- o A telemanipulator to position the camera directly by the active surgeon,
- o A 3D-display from the data obtained from the camera (2D-information),
- o New surgical instruments for minimally invasive surgery.

Furthermore, it is intended to develop an assistive telemanipulator that can be controlled by the active surgeon. Moreover, a suitable 3D-presentation of the operation area should be designed.

3: Integration of physiological and anatomical information in minimally invasive procedures

In minimally invasive surgical procedures access to the body cavity is obtained by using a number of cylindrical cannulas with a limited diameter (2-10 mm). In interventional procedures the organ to be treated is approached by a catheter using natural pathways like the gastro-intestinal tract, airways or blood vessels. Steering of the surgical tools is performed by using an endoscopic camera and catheter which motion is monitored using X-ray or ultrasound. In addition to this real time image information, diagnostic image information (like MRI, SPECT, PET or CT) and diverse types of physiological signals may be available. It is very desirable to present all this information in an integrated way, and in the correct spatial context. Important implementations of this principle are:

Presentation of 3D-modality information about the tissue behind the surface of the organ in approaching an organ in minimally invasive surgery (virtual reality presentation) to make positional information available about critical structures like vessels, nerves and tumors.

Steering information may be provided directly in the X-ray image on the basis of physiological signals measured in catheterization procedures.

Multimodality image information may be integrated by image-fusion techniques, presenting the diagnostic information in their mutual spatial relation.

Goals: Design methods to integrate physiological and image information i.e. making the information available in the coordinate frame of the operating theater or catherization laboratory. Developing presentation methods for integrated 3D-image information.

4: Mechanical design of surgical instruments

The surgical instruments, presently available, are in general of a rather poor quality. Due to friction, about 70% of the applied manipulator force is lost, so the tactile and proprioceptive feedback, needed in order to achieve a good eye-hand coordination and thus a good performance of 3D-tasks, will not be realized. Important functions such as suturing, achieving an anastomosis (a connection between channels, for instance blood vessels), and gripping of soft tissue are very difficult to execute without damage of the organs and tissue. Connecting blood vessels on the beating heart during minimally invasive bypass surgery needs special attention, and thus special tools. Moreover,

hardly any instrument exists for minimally invasive orthopaedic surgery, such as operations in the shoulder joint and removing deep laying bone tumors.

Goals: The design of surgical instruments for minimally invasive surgery in general, for connecting blood vessels and for orthopaedics, in such a way that an optimal eye-hand coordination is achieved, so that 3D-tasks can be executed accurately and reliably.

5: Mechanical steering of catheters in minimally invasive interventions:

Minimally invasive interventions are performed with catheters which are introduced in the pathways available in the human body of which the blood vessel system is most important. The blood vessel system is a tree-like system with branches varying in diameter from centimeters (large arteries and veins) to tens of micrometers (arterioles and venules). An important limitation in the use of catheters is the degree in which locations in the vessel system can be reached determined by the diameter and steerability. The mechanical properties of catheters and the reduction of diameter, fundamental in the minimally invasive approach, should be a subject of study.

Up till now the steerability of catheters is based on varying the curvature of the tip by internal pulling wires. This principle is hampered by friction which increases in proportion to reduction of diameter.

The capability of developing catheter technology will enable the introduction of prototype catheters by investigating groups, which now are completely dependent on the commercially available products of the medical industries.

Goals: The improvement of the mechanical properties of catheters with steerability and reduction of diameter as most important aspects. The development of prototype catheters for new clinical procedures of which the clinical and economic value still has to be assessed.

6: Miniaturisation of sensors, actuators and interface-electronics used in catheters

Minimally invasive interventions are performed with catheters which are reaching the organ to be treated via pathways available in the human body (gastro-intestinal tract, airways and blood vessels). In these interventions therapy is performed, so the catheter has to contain at its tip a therapeutic mechanism containing an actuator which can be electric (electrodes), based on ultrasound (ultrasonic transducer), on mechanics (balloon, pump, gripper), or on light (glass fibers with external laser). In addition to a therapeutic mechanism the tip of the catheter may also be equipped with one or more sensing elements. These may be separate sensors (temperature, flow, pressure) but often the actuator method may also have a sensing capability (electrodes, ultrasonic transducer, glass fiber with external sensing element). The sensing of responses evoked by an actuator at the tip of the catheter may also provide valuable information.

An important parameter of catheters is the diameter, which should be as small as possible to extend the range of structures that can be treated. Reducing the diameter of the catheter has important implications for the design of the sensors and actuators at the catheter tip.

Goals: The design of actuators and sensors suitable to be used at catheter tips. Miniaturisation of actuator and sensor designs to enable reduction of catheter diameters.

Discussion

The central theme of the program is approached in six coherent projects which each treat one or more specific aspects. These projects therefore have a strong interrelationship (Table 1). The table shows that for instance project 1 provides information to the projects 2, 3, 4, 5 and 6, whereas project 4 contributes to projects 1,3 and 5.

Table 1: Direct interaction between the different projects.

Influencing projects	Influenced projects					
	1	2	3	4	5	6
1 Evaluation		*	*	*	*	*
2 Eye-hand coordination			*	*	*	
3 Physiological and anatomical info		*			*	
4 Surgical instruments	*		*		*	
5 Steering catheters	*		*	*		*
6 Miniaturisation of sensors/actuators				*	*	

The project on evaluation and task analysis of the surgical process provides a basis for the other projects in identifying and documenting the limitations of keyhole surgery and minimally invasive procedures. This method is also appropriate to evaluate alternative techniques as defined in the other projects. The project concerning eye-hand coordination and telemanipulation considers the lack and disturbance of sensory feedback, the most important intrinsic limitation of minimally invasive procedures, by an integrated system approach. The telemanipulation aspects provide a direct link with the projects involved with the design of surgical instruments and catheters. The project on integration of physiological and anatomical information in minimally invasive procedures deals with the presentation of the ever increasing amount of signals and image data. The data should be presented in relation to the region of interest and in relation to each other to enable the physician to perform his real time task interactively guided by the physiological information. The project devoted to the mechanical design of surgical instruments addresses the relatively poor quality and the limitations of endoscopic instruments. Miniaturization of surgical tools gives this project a strong link with the project directed towards the mechanical steering of catheters in minimally invasive interventions. The sensors and actuators to be placed on the catheters or surgical tools is the subject of the project on miniaturisation of sensors, actuators and interface-electronics. This project aims at new designs of sensor/actuator combinations enabling innovative interventional procedures.