Simple Tools for Surgeons

Design and Evaluation of Mechanical Alternatives for “Robotic” Instruments for Minimally Invasive Surgery

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Back: The PASSIST and the MIM in a (cardio)surgical setting
Computerpicture by Rogier van der Pol
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Simple Tools for Surgeons

Design and Evaluation of Mechanical Alternatives for “Robotic” Instruments for Minimally Invasive Surgery

PROEFSCHRIFT

ter verkrijging van de graad van doctor
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This research has been performed at the Medical Technological Development Department of the Academic Medical Centre in Amsterdam

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Voor Ruth, Mette, Tijmen en Bregje

CHAPTER 1

INTRODUCTION

1.1 Background

Conventional open surgery is based on the access to the tissue to be treated via one large incision of about 50-300mm. This large incision provides the surgeon and the assistant with direct view of the anatomy of the patient and allows introduction of their hands and instruments treating the tissue in the body. They can look down at their work with their head and neck in a neutral position[1]. The large incision allows the surgeon and the assistant to have their hands in direct contact with the tissue or to manipulate the tissue through simple surgical instruments such as knives, scissors, graspers and retractors. Surgeon are able to use both their hands working together right in front of their body, allowing natural hand-eye coordination *(see figure 1.1.)*. For delicate surgical actions it is even possible to support the wrists by leaning on the patient's body (thorax) or on a specially developed armrest.

Figure 1.1. Open surgery (Cardiac Bypass surgery): A big access wound for the patient, but straightforward and intuitive for the surgeon.

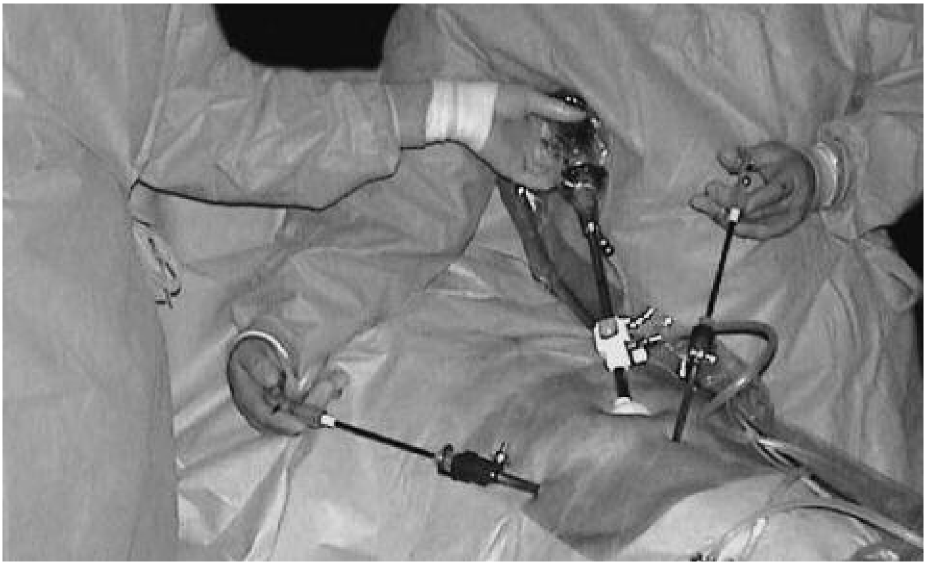

Figure 1.2. Endoscopic or Minimally Invasive surgery (MIS): small access wounds for the patient, but indirect and not intuitive for the surgeon·

Endoscopic surgery, or Minimally Invasive Surgery (MIS) is an operation technique based on the access to the tissue to be treated via several (3-5) small incisions of about 5-15mm in the patient's body. Through one of the incisions an endoscope, equipped with a small video camera, is inserted. The surgeon and the assistant look at a monitor on which the endoscopic images are presented. Through the other incisions, long, slender and rigid instruments are inserted to treat the internal tissue of the patient *(see figure 1.2.)*. To create a larger workspace inside the patient, the cavity is often insufflated with CO_2 gas. To prevent the gas from leaking out through the incisions and to protect the tissue near the incision, the endoscope and the instruments are inserted through trocars (plastic or metal cannulas) with an airtight sealing.

The advantages of these small incisions for the patient are the reduced post-operative pain, shorter hospital stay, improved cosmetics and reduced risk of wound infection[2]. MIS started around 1987[3], and currently most of the relative simple cholecystectomies and Nissen fundoplication procedures are performed laparoscopically [*table 1.1.*]. Technical advances and more than fifteen years of surgical experience stimulated surgeons to use minimally invasive techniques in more advanced surgical procedures, such as surgery of the colon, of blood vessels and even of the human heart[4-6].

Table 1.1. Surgical procedures and the percentage minimally invasive performed in 1999 in the US. [data: Medtech Insight, Mission Viejo, California]

	No. of Procedures	**Minimally Invasive, %**
General surgery		
Gallbladder	1.084.882	85
Nissen fundoplication	47.087	95
Adhesiolysis	215.760	72
Appendectomy	334.388	22
Colon resection	380 000	7
Hernia repair	820.191	14
Total	**2.882.308**	**47**
Gynecology		
Hysterectomy	582.000	15
Myomectomy	64.977	70
Pelvic floor reconstruction	160.000	40
Removal of adnexal structures	350.059	65
Total	**1.157.036**	**37**
Urology		
Nephrectomy	44.863	75
Cystocele/rectocele	158.144	45
Pediatric urology	25.000	80
Adrenalectomy	20.000	60
Total	**248.007**	**55**
Plastic surgery		
Breast reconstruction	182.000	15
Face and forehead lifts	80.000	25
Total	**262.000**	**18**
Thoracic surgery		
Luna biopsy	90.000	75
Luna resection	47.124	60
Total	**137.124**	**70**
Cardiothoracic surgery		
Coronary artery bypass surgery	330.000	17
Heart valve replacement	81.000	15
Congenital defect surgery	25.000	20
Total	**436.000**	**17**
Vascular interventional surgery		
Saphenous vein harvest	220.000	35
Peripheral vascular bypass	80.000	2
Aortoiliofemoral bypass	75.000	1
Abdominal aortic aneurysm	51.000	10
Total	**426.000**	**20**

These more complex surgical tasks require not only resectional tasks, like with cholecystectomy, but also require reconstruction tasks, such as suturing. However, with the present surgical equipment, despite their technical advances, MIS remains more difficult to perform than open surgery and requires more skills from the surgeon[7,8]. Therefore, most of these advanced endoscopic procedures are still in their experimental phase and are not spread widely [*table 1.1.*].

To increase the percentage of these advanced endoscopic procedures, new surgical techniques and instruments have to be developed and evaluated. To determine which instruments have to be developed it is important to get a good insight in the problems associated with endoscopic surgery.

1.2 Problems with endoscopic surgery

For the surgeon, endoscopic surgery complicates his or her way of working. One of the main difficulties is that the coupling between perception and manipulation, the hand-eye coordination, is disturbed. In open surgery, coordination of hand movements is based on direct view on the hands and tissue, which is straightforward and to which the brain is trained from childhood on.

A disturbing factor during MIS is that the direct 3-dimensional view is replaced by an indirect 2-dimensional view via an endoscope and a monitor. The endoscope with the attached video camera is manipulated by the assistant and is not coupled to the head or eye movements of the sur

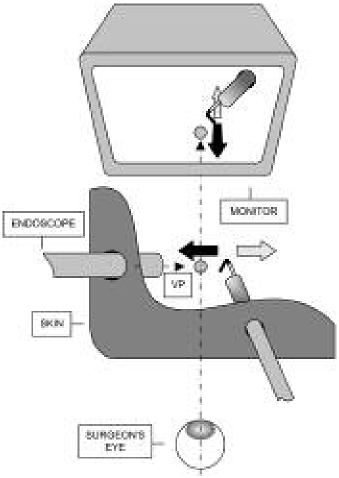

Figure 1.3. Disturbed hand-eye coordination due to misalignment of the natural viewpoint of the surgeon's eye and the view point (vp) of the endoscope. (*Picture by Mark Wentink*)

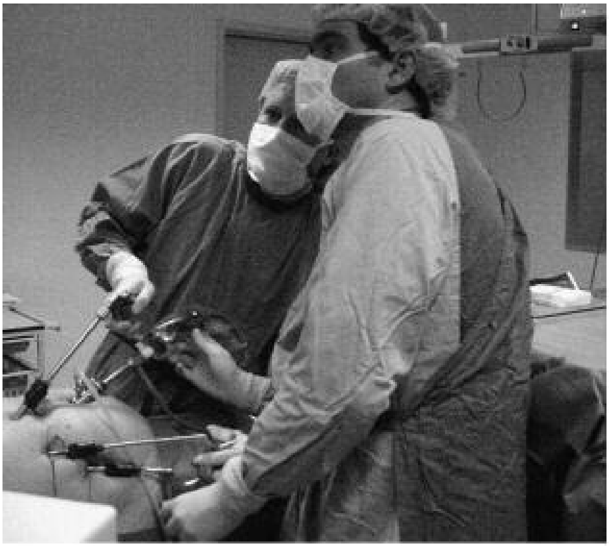

Figure 1.4. Disturbed hand-eye coordination due to misalignment of the natural viewpoint of the surgeon and the viewpoint on the monitor. The long and straight endoscopic instruments also force the surgeon and his assistant to work with a non-ergonomic posture for their hands, arms and body.

geon[9]. In addition, the endoscope usually has a line of sight different from the natural line of sight of the surgeon's eyes. The operation area and the instrument tips are viewed from this different direction. For example, if the camera is positioned perpendicularly (90°) to the surgeon's direction of view, then a movement of an instrument towards, or away from, the surgeon appears as a movement to the left or to the right on the monitor *(see figure 1.3.)*. In addition, the monitor on which the images are presented is usually not positioned in the surgeon's natural line of sight but on a trolley next to the patient, so that the surgeon has to look up and to the side to view the monitor *(see figure 1.4.)*.

A second complicating effect is that the incision acts as a pivoting point or point of rotation, the fulcrum effect[10]. Movements of the surgeon's hand about this incision are mirrored and scaled relative to the instrument tip *(see figure 1.5.)*. Furthermore, due to the fixed position of the incision, the freedom of positioning of the instruments is reduced from six degrees of freedom (DOFs) to four DOFs. For optimal tissue manipulation, the instruments are usually positioned at an angle of about 60°-90° relative to

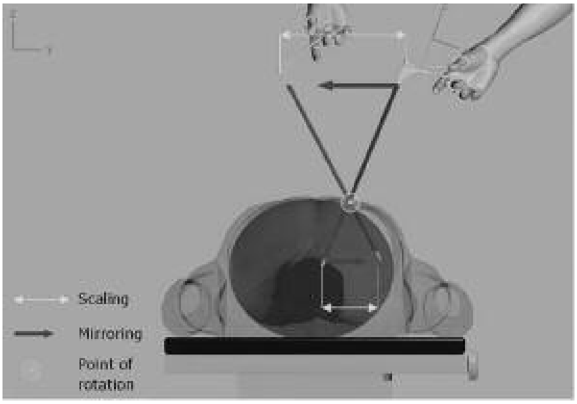

Figure 1.5. Disturbed hand-eye coordination because movements are mirrored and scaled due to the point of rotation in the patient's skin. (Picture by Rogier van de Pol)

each other. This orientation in combination with the length (approx. 40cm) of the straight instruments force surgeons to use their hands in an unsupported and unnatural posture with a large distance between the handles *(see figure 1.4.)*[1]. Because the hands are outside the human cavity, information about the position of hand and fingers does not directly support the manipulation of tissue (extended propriocepsis)[11]. In addition, tactile information of the tissue is lost because there is no contact between the hands and the tissue anymore.

Both the indirect observation as well as the indirect manipulation significantly disturb the hand-eye coordination and complicate the surgical technique. As a result, a long learning curve is required to adapt to endoscopic surgery[12]. Complex surgical tasks, like endoscopic sutured anastomosis, are very difficult with conventional endoscopic surgical instruments. MIS actually proved problematic for surgeons, notwithstanding its other benefits - longer procedure times, more difficult manipulation of instruments and more torturous ergonomics.

1.3 State of the art in endoscopic surgical techniques

The impact of technological innovations in routine surgical practice is low, due to a conservative surgical community and an adapting industry. It is not stimulating surgical innovation that residents learn their surgical techniques from Master surgeons, who have long experience in certain operation techniques and therefore are not motivated to adapt to new techniques. Developing new types of instruments by industry is expensive, time consuming and risk full. Therefore small changes on existing instruments are often introduced as *new* and *innovative*. Consequently, instruments for open surgery from the 2005-catalogue often look the same as those from the 1955, and even the endoscopic instruments of today often look similar to those from 1985, the early days of endoscopic surgery.

Some innovative instruments with a specific task for endoscopic surgery were developed over the last decade, such as the disposable stapling and clipping instruments for clipping vessels or closing and connecting bowels. Another recent innovative commercial available endoscopic instrument is an endoscopic needle holder and grasper with extra DOfs; the Radius manual manipulator[13]. This deflectable instrument was developed to improve ergonomics and manipulation, making endoscopic suturing and therewith more complex endoscopic surgery feasible.

Despite these few mechanical innovations, most new equipment in endoscopic surgery is based on electronical improvements. Endoscopic cameras are improving in image quality and size, flat monitors are introduced in the OR and even 3D imaging systems are developed recently. Other improvements are based on using high-frequency current to cut through tissue and seal small vessels. Ultrasonic technology is applied for the same reason.

None of these improvements have made endoscopic surgery as intuitive to use, or “easy” to learn as open surgery, due to the indirect way of camera control and instrument manipulation. The only instruments that return camera control to surgeons and provide them with an intuitive instrument manipulation are the “robotic” solutions.

“Robotic” solutions

To overcome some of the above-mentioned disadvantages of Minimally Invasive Surgery (MIS) and to stimulate the development of complex minimally invasive procedures, surgeons can be provided with technological solutions that help them to improve their surgical performance. Both for the indirect observation and the indirect manipulation in MIS, robotic solutions have been developed[14]. These devices are not real robots, because robots are supposed to perform their actions autonomously without direct interference of the operator. Although the surgical systems perform no part of the surgical procedure independently and are in fact remote controlled manipulators, they are referred to as “Robots” because the surgical community is used to this term for electromechanical equipment, so for any surgical equipment equipped with a motor.

Robotic camera holders

In a conventional endoscopic setting the surgeon is manipulating two endoscopic instruments with his or her hands and the assistant is controlling the endoscope with the camera and often an additional instrument for retracting. Depending on the experience of the assistant, the surgeon is giving instructions where to direct the camera. To avoid this indirect observation method, the surgeon should be able to adjust his or her own viewing direction. Hereto, an adjustable arm is needed to hold the camera. One of the solutions for this is a so-called "robotic" or remotely controlled arm, a motorized arm that can be activated by the surgeon using a specific human interface.

At this moment two robotic camera holders are commercially available: The EndoAssist (Armstrong Healthcare, Wycombe, United Kingdom), which uses head movements of the surgeon to activate the camera arm *(see figure 1.6.)*, and the LapMan (Medsys, Gembloux, Belgium), which uses control buttons in the surgeon's hand. A third robotic camera arm, the AESOP (Computer Motion, Coleta, California), which uses voice control as human interface, is no longer available. These systems are designed to rotate an endoscope about the incision in the human body in two DOFs and to move the endoscope in and out that incision, all in a motorized way.
The basic idea behind this approach is that the surgeon does not have to

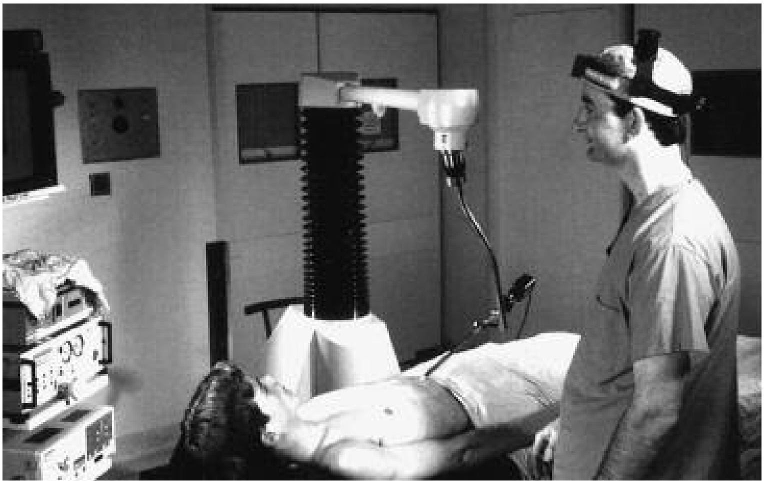

Figure 1.6. A "robotic" camera holder: the EndoAssist, controlled by head movements of the surgeon.

Figure 1.7. "Robotic" or Master-Slave telemanipulator (da Vinci®). On the left (behind the OR-table), the robotic arms (Slave) for controlling the endoscopic instruments and on the right the surgeon's console (Master).

interrupt the surgical process and that he or she does not have to release an instrument to reposition the camera.

Telemanipulators

As described in the background section (1.1), it is difficult to perform complex tasks in endoscopic surgery with conventional endoscopic instruments. To improve the manipulation capabilities of endoscopic instruments extra DOFs at the instrument tip, as well as a more ergonomic and intuitive control of these instruments are required.

Existing solutions to manipulate endoscopic instruments with extra DOFs in an ergonomic and intuitive way are the so-called Master-Slave robotic telemanipulators, like the *da Vinci®* system (Intuitive Surgical, Mountain View, CA, USA) *(see figure 1.7.)*[15]. This system was initially designed in cooperation with the US-military to translate the surgeon's hand movements to the tip of a surgical instrument in a remote operative field, like the battlefield or even space. When this so called Star Wars project was ended, Companies like Intuitive Surgical adopted this telemanipulation technology to develop Master-Slave manipulators for Minimally Invasive Surgery. These master-slave systems consist of three main components: a computer controller, a surgeon's interface device (master), and specially designed instruments, with extra degrees of freedom, attached to the robotic arms (slave). With these systems the surgeon can sit comfortably behind the master console looking at a 3D image of the surgical field.

Figure 1.8. Intuitive control of the endoscopic instruments with 7 DOFs of the da Vinci® robot; the surgeon's handles are always in the same orientation as the instrument's tips, like with open surgery.
(*Picture by UMC-Utrecht*)

The surgeon's fingers engage the master controls (joysticks) below the display. This way, the hands and wrists are in a natural position relative to the eyes, in line with the surgeon's point of view, and the surgeon is looking virtually at his own hands holding the instruments, like controlling instruments for open surgery *(see figure 1.8.)*. Contrary to the initial intention, in most hospitals the Master console is located in the same OR as the patient and the robotics arms (Slave) are located. With these robotic systems complex surgical tasks, like endoscopic sutured anastomosis, have shown to be feasible[16].

1.4 State of the art in comparable industrial instruments

To investigate what will be needed for camera holding or instrument handling in endoscopic surgery, it is instructive to see what is available for comparable devices in industry. Holders for (video)camera's are available in various configurations, ranging from simple tripods, manual controlled cranes (counterbalanced arms) to even remotely controlled electromechanical devices (robots)[17,18]. When we compare the industrial camera holders to the ones used for endoscopic surgery, it is remarkable that in industry the simple holders (tripods) are more frequently used than the robotic versions, but that in endoscopic surgery the focus is on robotic camera holders and the simple mechanical holders are rare and seldomly used.

Industrial instruments, which are comparable to instruments for endoscopic surgery (graspers, scissors, etc.), are rare. The best examples are instruments used in nuclear industry for handling radioactive material inside a bunker[19]. To protect the operator against radiation or nuclear contamination, radioactive material is placed in a bunker of lead and concrete and is visible through a thick layer of lead-glass. These materials are manipulated with remotely controlled instruments, with the user-handles outside and the instrument grippers inside the bunker. The manipulators are available in various configurations, ranging from simple mechanical devices to remotely controlled "robotic" versions. The simple versions have the handle at one side of a shaft, which crosses the concrete wall, and the gripper at the other side of the shaft (*see figure 1.9., left*). These instruments are comparable to conventional endoscopic instruments, having a mirroring and variable scaling effect. The mirroring and variable scaling make these devices very hard to use and therefore most instruments used in nuclear industry are mechanical manipulators, without a mirroring or scaling effect. These are counterbalanced mechanisms to which the user handle is connected outside the bunker and the gripper is connected inside the bunker (*see figure 1.9., middle*). Movements of the handle are translated with steel wires, bands and push bars, in 7 DOFs to the same movements of the gripper. Comparable instruments for endoscopic surgery do not exist, however.

Electromechanical Master-Slave telemanipulators (robots) are also available for the nuclear industry (*see figure 1.9., right*). These systems are used in situations (hazardous environment) where it is necessary that the human operator is on a remote location, so for real telemanipulation. With these systems there is an electronical or computer link connecting the Master with the Slave. A comparable instrument for endoscopic surgery is the da Vinci® telemanipulator as described in section 1.3.

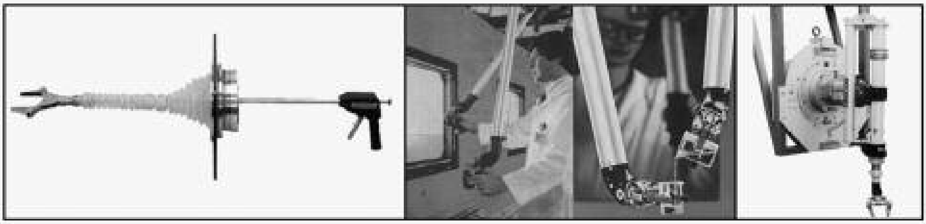

Figure 1.9. Three types of instruments used for handling nuclear material. Left: A relatively simple instrument with the gripper inside a bunker and the handle outside. Middle: Intuitive manipulation with a mechanical manipulator; The grippers inside the bunker (on the right) are mechanically connected with the operator's handles (on the left) outside, in 7DOFs. Right: An electro-mechanical arm (Slave). These arms can be manipulated from a remote location (Master), not shown her.

In summary: Devices (tripods for camera control and mechanical manipulators for instrument control), which are commonly in use in industry are not available for endoscopic surgery.

1.5 Objective of this thesis

With the limitations of the relatively primitive conventional endoscopic instruments and an assistant controlling the laparoscope, only the more simple endoscopic procedures are generally performed. Complex surgical procedures are enabled by the relatively complex "robotic" systems. These robotic systems, however, are expensive, not only to purchase (approx. 1.2 M €) but also in maintenance (approx. 100.000 € each year). They require specially trained personnel and a dedicated surgical team. Most hospitals cannot afford these systems and are forced to perform only the simple endoscopic procedures. Therefore complex surgical procedures, which can be robot-assisted performed or by a few specially trained surgeons only, are done with "open" surgery in the majority of patients, leading to non-optimal care. There are almost no instruments available that can fill the gap between conventional endoscopy and the robotic systems (*see figure 1.10.*). Their availability would increase the percentage of endoscopic procedures.

The main objective of this thesis is to provide simple surgical solutions, which are affordable for any surgeon and, which at least partly, fill the gap between conventional endoscopy and the highly technological robotic systems. To provide surgeons with instruments that are of real use to

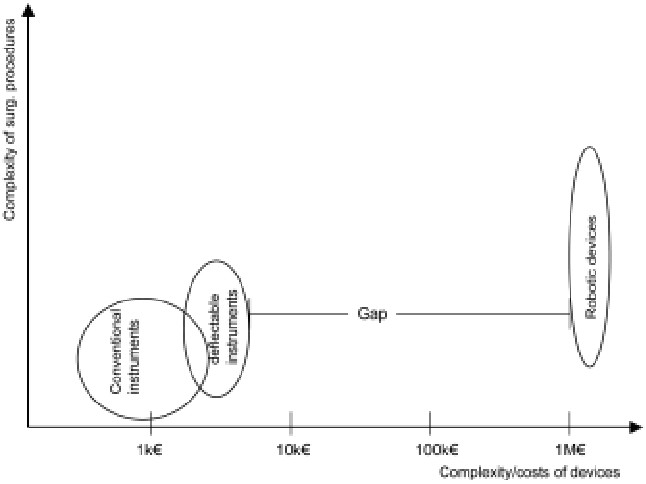

Figure 1.10. There is a big gap between conventional endoscopic instruments suitable for "simple" endoscopic surgery and the complex and expensive robotic devices suitable for complex endoscopic surgery. The available deflectable endoscopic instruments (Radius™ [13]) can only partly fill this gap.

them, it is important to involve surgeons in the developing process and have them evaluate prototypes in a early stage and if possible during surgery. This way, the surgeon's insight and experience will improve the instruments developed. We aim to develop and evaluate solutions, which provide direct, ergonomic and intuitive control of the endoscope and surgical instruments with extra degrees of freedom, relative to conventional endoscopic instruments. This main objective is divided into the following sub goals:

- To develop a mechanical camera holder and instrument holder for endoscopic surgery, which can be controlled by the surgeons themselves.
- To evaluate in a clinical study if these mechanical holders are of real use for the surgeons.
- To develop a mechanical manipulator for intuitive control of endoscopic instruments with extra degrees of freedom. A manipulator that provide surgeons with the same natural dexterity and full range of motion as the robotic devices, but for affordable costs.
- To evaluate if endoscopic surgery with the mechanical manipulator is feasible, by comparing the functionality of the manipulator to the functionality of conventional endoscopic instruments and robotic instruments.

To reach these goals it is important to investigate what is commercially available for camera and instrument holders and what are the available instruments for endoscopic instruments. From this investigation we can determine, not only the benefits and drawbacks of the available equipment, but also the essential requirements for developing new designs. In this thesis we describe this investigation, the developing process of the camera an instrument holder and the mechanical manipulator, the resulting prototypes of these devices and their evaluation.

1.6 Outline of this thesis

The thesis contains two main subjects: The mechanical holder for the endoscopic camera and instruments to assist the surgeon (*chapter 2 and 3*) and the mechanical manipulator to control the surgical instruments (*chapter 4 and 5*).

Chapter 2 describes a literature survey, which has been carried out to give an overview of the existing “robotic” and passive camera and instrument holders and their clinical value. The survey is based on about 70 papers and documents. The overview is organized in two sections, one section treating passive camera holders and the other section treating motorised camera holders with a diversity of interfaces for camera control. These different holders are compared as to their functionality, their ability as an instrument holder, operation times and the method of control.

Chapter 3 describes the development and clinical evaluation of the PASSIST, a passive assisting device for holding the endoscopic camera or an additional retracting instrument. The PASSIST is developed as a mechanical positioner, which can be manipulated by the surgeon himself using one hand. After building a few prototypes for pre-clinical experiments, a set of prototypes has been built for evaluation in clinical practice. Passive and robotic positioners are evaluated by comparing conventional laparoscopic cholecystectomies (gallbladder removal) performed with a surgical assistant and laparoscopic cholecystectomies performed using instrument positioners instead of an assistant.

Chapter 4 describes the development of a mechanical manipulator for minimally invasive surgery, from concept to a set of prototypes. This so called Minimally Invasive Manipulator (MIM) is designed as a purely mechanical alternative to robotic surgery. The purpose of the device is to translate the surgeon's wrist movements and grasping actions directly to the tip of the endoscopic instrument tip in 7 DOFs.

Chapter 5 describes a feasibility study with the MIM, by performing endoscopic tasks in a phantom model. Within this study the MIM device is compared to conventional endoscopic instruments by performing standardised tasks, such as needle manipulation and making surgical knots.

In ***chapter 6***, a discussion about the research that has been carried out is given. The functionality, benefits and drawbacks of the developed devices is discussed.

Finally in ***chapter 7***, a conclusion is presented and future research as well as utilisation of the developments of the PASSIST and the MIM will be discussed.

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CHAPTER 2

CAMERA AND INSTRUMENT HOLDERS AND THEIR CLINICAL VALUE IN MINIMALLY INVASIVE SURGERY

This chapter is a Published journal article:
Jaspers JEN, Breedveld P, Herder JL, Grimbergen CA.
Camera and instrument holders and their clinical value in minimally invasive surgery.

Surgical Laparoscopy, Endoscopy & Percutaneous Techniques.
14(3):145-152, June 2004.

Summary

Objective: *During minimally invasive procedures an assistant is controlling the laparoscope. Ideally, the surgeon should be able to manipulate all instruments including the camera him/herself, to avoid communication problems and disturbing camera movements. Camera holders return camera-control to the surgeon and stabilise the laparoscopic image. An additional holder can be used to stabilise an extra laparoscopic instrument for retracting.*

Methods: *A literature survey has been carried out giving an overview of the existing "robotic" and passive camera and instrument holders and, if available, results of their clinical value. Benefits and limitations were identified.*

Results: *Most studies showed that camera holders, passive and active, provide the surgeon with a more stable image and enables them to control their own view direction. Only the passive holders were suitable for holding instruments. Comparisons between different systems are reviewed.*

Conclusion: *Both active and passive camera and instrument holders are functional, and may be helpful to perform solo-surgery. The benefits of active holders are questionable in relation to the performance of the much simpler passive designs.*

2.1 Introduction

Minimally invasive surgery, or minimal access surgery, has great benefits for the patient as the injuries of the abdominal wall are much less compared to conventional open surgery. The potential advantage of fast recovery of the patient has led to an increase in interest in recent years and new applications are reported continuously[1,2]. Minimally invasive surgery, however, has important consequences for the functioning of the surgeon. There are severe disadvantages involved with the application of this complicated technique[3-6]. Important difficulties concern the indirect way of observing and manipulating. They complicate the surgeon's observation and manipulation activities and disorder the surgeon's eye-hand coordination *(see figure 2.1.)*.

It is common in laparoscopic operations that the surgeon is not directly in control of the endoscope as he needs both hands to perform the laparoscopic procedure. The visual information is collected by a camera assistant who controls the endoscope by following the surgeon's instructions and by using a set of empirical rules[7]. Examples of such rules are *'the tip of the moving instrument should remain in the middle of the picture'* and *'the abdominal wall should remain at the top of the picture'*. This indirect way of adjusting the viewpoint is not very intuitive[3]. It can lead to communication problems

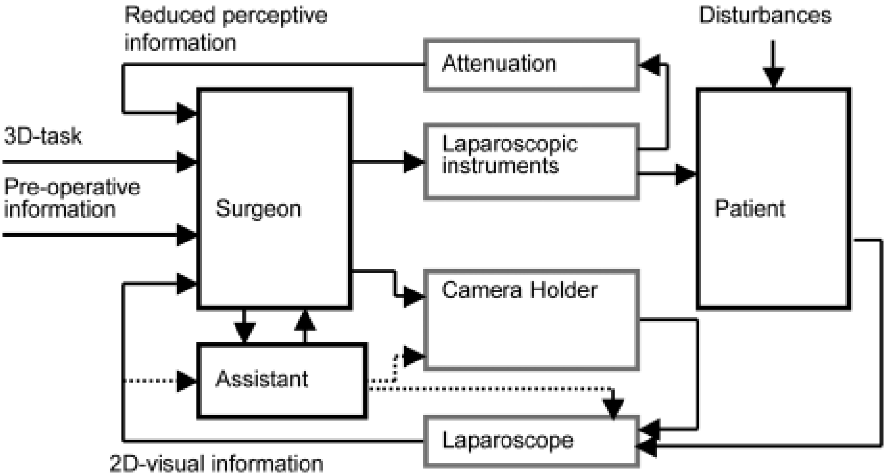

Figure 2.1. Block diagram of a minimally invasive procedure. The dominant and non-dominant hand of the surgeon both use laparoscopic instruments. The laparoscope is controlled by an assistant (dashed arrows), or by the surgeon him/herself using a camera holder.

between the surgeon and the assistant, and to an unsteady camera picture when the assistant has to stand still for a long time[8]. Mohrmann-Lendla and Fleischer[9] showed in an experiment that an unsteady camera picture decreases the performance of goal-directed hand movements. It is known from literature[10] that undesired movements of the camera by an assistant are disturbing. It is postulated that it is important for the surgeon to be in control over all his instruments including his own view by manipulating the camera himself. An experienced surgeon moving the camera will only make desired movements. In addition, these camera movements will provide him with extra depth perception and navigational information, due to movement parallax[10], because the movements are performed by the observer, the surgeon, himself.

A drawback of this way of working is that during the laparoscopic procedure the surgeon has to control the camera using a certain interface, which may interfere with the manipulating task. It is important that the camera has 'a locking mechanism' to allow the surgeon to continue his activities after repositioning the camera. Consequently, this way of working in which the surgeon controls the camera movements him/herself calls for supporting aids providing a locking mechanism for the camera position. If the surgeon uses a holder for the camera and he or she wants to do the operation without an assistant controlling an additional instrument (solo-surgery)[11,12] then the surgeon not only needs this provision for the camera, but also for this instrument.

A number of camera and instrument holders is presented in literature. Most of these studies focus on one type of holder, sometimes by addressing their clinical value, but studies, which compare the different types of holders, are rare.

The aim of this study is to compare the different studies on camera holders, to investigate their similarities and differences and to discuss which type of holder provides the best approach for clinical practice. In this study a survey of different holders is given. The solutions vary from passive (without a motor) mechanical holders to active (with a motor) electromechanical solutions (robot arms) with various user interfaces. The designs of the camera holders will be reviewed and an overview of existing camera holders will be presented. Literature assessing their clinical value will be treated, by comparing them as to their functionality, their ability as an instrument holder, operation times and the way they are controlled.

2.2 Materials and methods

An overview of camera holders will be presented focusing on technical research and developments, as well as clinical experience with camera holders in laparoscopic surgery. Going back to the year 1991, a number of relevant journals were scanned for useful information. Conference proceedings, books and web sites about laparoscopic surgery also were consulted. The survey resulted in about 70 papers and documents that have all been carefully read. In order to be certain no information was overlooked, the survey was completed with a thorough MEDLINE search. The overview is organized in two sections, one treating the manually controlled passive camera holders and the other treating motorised camera holders, with a diversity of interfaces for camera control. In table 2.1. an overview of the commercially available passive and active holders is given.

2.2.1 Subdivision of camera and instrument holders

Direct camera control and viewpoint adjustment can be realized by replacing the assistant by a passive camera holder that is manually controlled by the surgeon, or by an active camera holder that is driven by motors and controlled with a user interface. In both cases, there are two fundamental approaches in the mechanical construction used *(see figure 2.2.)*: designs

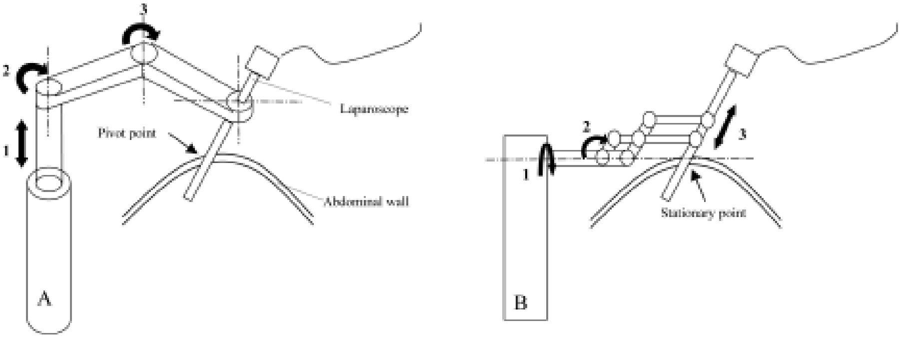

Figure 2.2. Two basic approaches for the mechanism of a camera holder. (A): SCARA-type, consisting of three motorised joints in combination with one passive (ball)joint. The incision in the abdominal wall is used as a passive joint, which results in reaction forces at the abdominal wall. The active three Degrees of Freedom (DOFs) are indirect translated to three different DOFs of the scope. (B): Parallelogram-type, consisting of three motorised joints that directly activate the three DOFs of the scope. The mechanism has a stationary point, which is positioned in the incision in the abdominal wall.

using the abdominal wall as a pivot point and designs with a mechanically invariant point (stationary point located at the incision in the abdominal wall). Most of the passive and active camera holders are using the incision as a pivot point. In these designs there is a considerable interaction with the abdominal wall that produces the pivoting forces[13-15]. In figure 2.2A a drawing of Selective Compliance Assembly Robot Arm; RRT electromechanical arm is given[16]. An alternative parallelogram design, which has a mechanically invariant point that can be positioned in the incision[17-20],

Table 2.1. Overview of 6 Passive and 5 active Camera holders

A	B	C	D	E	F	G	H
Passive holders							
PASSIST	*	*		1	Manual	*	+
Tiska	*			1	Manual, Foot		+/-
Martin arm		*	*	2	Manual	*	+/-
Unitrack		*	*	1	Manual, Finger		+/-
Ball trocar	*	*	*	1	Manual		+
Leonard arm		*	*	1	Manual, Finger	*	+/-
Active holders							
AESOP			*	0	Voice	*	-
EndoSista			*	0	Head	*	-
LapMan			*	1	Finger		-
Fips	*			1	Finger		+/-
Image track camera	*		*	1	Finger	*	+/-

A: Scope Holder, **B**: Stationary Point, **C**: Auto-clavable, **D**: Commer-cially Available, **E**: Nr. of Hands to Reposition, **F**: Release Break/Control Repositioning[1], **G**: Clinical Experience Published, **H**: Intuitive Use.

[1] Note that with passive holders only the braking system is controlled and repositioning is performed manually, whereas with active holders no break is present but repositioning is controlled.

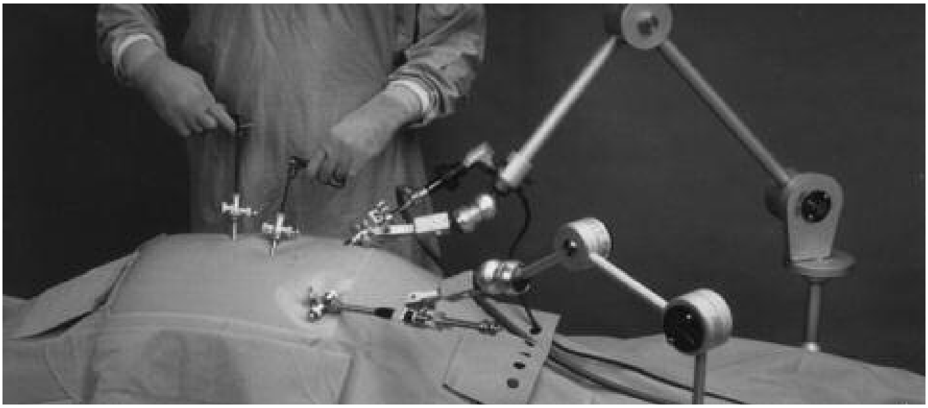

Figure 2.3. The First Assist (Leonard Medical Inc): one of the first passive SCARA type camera and instrument holders. The joints are pneumatically released

is given in figure 2.2B. This construction is based on the degrees of freedom as present inside the abdominal cavity and in this design the interaction forces with the abdominal wall are minimised and well defined.

Passive holders

A passive camera holder[7,12,15,17,18,20-29] consists of a number of bars connected with joints. Its base can be attached to the operating table rail, and its tip contains a clamp that holds the endoscope, or an additional instrument. The surgeon can move the holder by grasping it and moving it to the desired position. The friction in the joints or a brake system prevents the holder from moving when it is released, so that the endoscope remains in the desired position.

Active holders

An active camera holder is a motorised camera holder with joints that are driven by electric motors. There are many diverse user interfaces to control these electromechanical arms. They can be controlled by using a hand controller[13,20,30-32], or by grasping and moving like a passive camera holder[13,33-35]; in these cases one hand is needed for controlling the endoscope and the surgeon still has to release an instrument to move the endoscope. Releasing instruments can be prevented by using an instrument-mounted hand controller[11,12,34,36,37] a foot controller[13,30,38], voice control[1,33,39-41], by using the surgeon's head movements to control the robot[10,42-46], or by

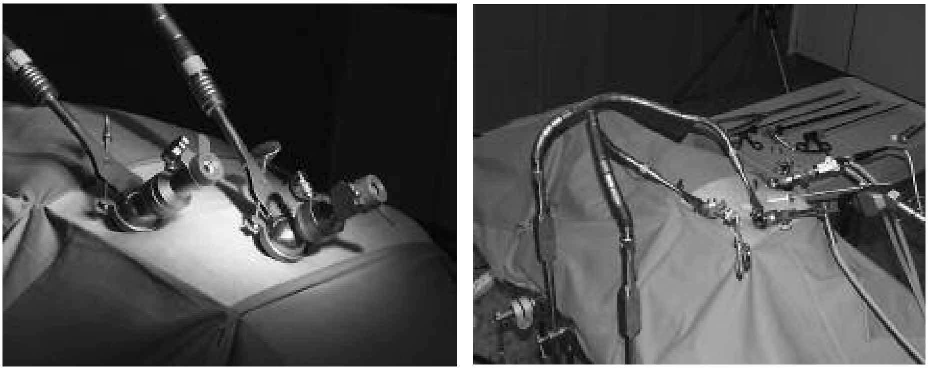

Figure 2.4. Passive camera and instrument holders: Ball trocar (BBraun/AESCULAP): a ball connected to a trocar shaft is clamped in a ring with adjustable friction. The ring is fixed to the operation table by an articulated clamp.

instrument tracking where de robot automatically keeps the tip of the dissecting instrument in the centre of the monitor[33,47,48].

2.3 Results

2.3.1 Overview of passive holders

The passive holders that were found in the literature differ in their construction - some with, others without a stationary point -, the way they are controlled and in the way braking is effected.

Commercially available

A number of commercially available passive camera holders has been constructed using a number of bars connected with ball-joints that are pneumatically controlled. Examples are: Unitrack (AESCULAP, Tuttlingen, Germany)[7,27], First Assist (Leonard Medical Inc., Huntingdon Valley, PA)[7,14,22,33] *(see figure 2.3.)*, SAM (Biomec, Cleveland, OH)[25] and Endoboy (Geyser-Endobloc s.a., Coudes, France)[15]. Although these holders do not have a parallelogram construction they can be repositioned with one hand, by pushing a button located near the endoscope clamp, leaving a certain amount of friction in the joints after unlocking. A passive trocar, holder stabilising a modified trocar with a ball-joint by adjustable friction, is the Ball trocar (AESCULAP, Tuttlingen, Germany)[28] *(see figure 2.4.)*. In this design there is a stationary point (centre of the ball-joint) that is roughly positioned just above the incision. This system allows single handed scope repositioning.

There are several passive holders with two bars and three linkages that are mechanically locked using a knob, like the Martin Arm (Karl Storz, Tuttlingen, Germany)[7,12,29] and the ASSISTO (GEOMED, Tuttlingen, Germany)[28]. To reposition the camera two hands are needed, one for releasing the brakes and one for repositioning the camera.

Proprietary prototypes

Besides the commercially available passive holders, a number of proprietary prototypes has been found in the literature. A passive holder with a stationary point and electromechanical brakes is the TISKA (Karlsruhe Research Center, Karlsruhe, Germany)[12,18,49]. It can be released using a foot controller, allowing single handed repositioning. This holder has a parallelogram mechanism with a stationary point. Another design what is based on a parallelogram mechanism with a stationary point is the PASSIST (Academic Medical Center, Amsterdam, NL.)[17,20,50]. It is a passive holder that is spring-balanced and uses adjustable friction. Without using brakes, the camera can be repositioned with one hand.
All these passive systems are also suitable as instrument holders[12,17,18,24, 49-51] and are fully autoclavable because of their simple design and the application of stainless steel.

2.3.2 Overview of active holders

The active holders differ in their construction and in the user interface allowing the surgeon to control the positioning. Because active camera holders are driven by electric motors, these holders are not fully auto-

Figure 2.5. Motorised or "Robotic" camera holders: Left: AESOP (Computer Motion): a SCARA type electromechanical arm activated by voice control. Right: EndoSista (Armstrong Healthcare): a SCARA type electromechanical arm activated by head movements.

clavable. They should therefore be covered by sterile drapes except for the autoclavable scope itself.

Commercially available

The most known active camera holder is the voice control AESOP (Computer Motion, Coletta, California)[12,13,30,31,38-41,50,52-60] (*Figure 2.5.*). It is a SCARA-type electromechanical arm fixed to the operation table rail.
Another SCARA-type electromechanical arm, which is activated by head movements, is the Endosista or Endo Assist (Armstrong Healthcare Ltd, High Wycombe, England)[12,42,44,45,60] *(see figure 2.5.)*. It is located on a trolley next to the operation table and. A third active camera holder of the SCARA type which is activated by a remote hand control unit (buttons) under the surgeon's glove is the LapMan (Medsys, Gembloux, Belgium)[32]. Like the Endosista, it is positioned on a trolley next to the operation table.
A different implementation of an active camera holder is the Image track camera (Olympus, Jap.)[34,35,61]. It is a visual field tracking camera having a zoom lens and a CCD chip on a motorised sliding mechanism built in the camera head. It is activated either by voice control or by a joystick. The camera is connected to the table rail with a counterweight-balanced passive manipulator. For small movements it can be considered as an active holder because of the motorised image tracking. For large movements, however, the camera is controlled by hand like a passive holder.

Proprietary prototypes

Besides the commercially available active endoscope positioners, a number of proprietary prototypes has been found in the literature.
An instrument-mounted handcontroller attached to a laparoscopic instrument is used with the FIPS (Karlsruhe Research Center, Karlsruhe, Germany)[11,12,36,49]. It is a lightweight arm fixed to the operation table rail. It has a C-arc mechanism connecting two axes in a stationary point. Also controlled by an instrument-mounted handcontroller is a parallelogram-type motorised camera holder developed by IBM-John Hopkins[19]. A modified voice controlled industrial arm called A460 CRS plus was developed at the department of surgery of the University of Montreal[62,63]. Instrument tracking, in which case the camera follows the instrument tip automatically, was applied to the camera holder based on the SCARA-type arm [SGRSS], developed at the Department of Surgery, Klinikum rechts der Isar München[47].
Voice control and instrument tracking were used in a SCARA-type motorised active camera holder FELIX, (Karlsruhe Research Center, Karlsruhe, Germany)[33]. A parallelogram-type motorised active camera holder (Simon

Fraser University in Burnaby, Canada) was applied with instrument tracking[48]. A camera holder with motorised optical zoom (faculty of Engineering of the University of Tokyo)[64] has been developed. It has a parallelogram mechanism and a zoom lens in the camera head, avoiding in/out movement of the laparoscope. Force control was applied in a motorised camera arm, called Roboscope (Academic Medical Centre, Amsterdam)[20]. It was intended for controlling a neurological scope and introducing active constraints, limiting the workspace. The Roboscope is located on a trolley next to the operation table and is a parallelogram mechanism with a stationary point. It is intuitively controlled by a sensor-ring around the scope. The last camera holder found in literature has a foot controlled motorised end-effector just for moving the scope in and out, ENDEX (UCLA school of Medicine, Los Angeles, CA)[65].

2.3.3 Clinical and laboratory experience with camera and instrument holders

In this paragraph (pre)clinical experience is given with camera holders by comparing them as to their functionality as a camera holder, their ability as an instrument holder, the way they are controlled, the resulting operation times and the appreciation by the surgeon.

Clinical experience with the manually controlled passive holders is reported of the First Assist[14,22,23] the Martin arm[29] and the PASSIST[17,50]. All systems are reported to function well and to produce stable images. Only with the PASSIST clinical experience is published using two systems holding a camera and an additional instrument for retracting the liver. When compared to human camera assistance in a clinical[29,50] or phantom[12] experiment, operation times with passive holders are not significantly different from those with human assistance. Only the set up and break down time is longer. Some studies show that with the holders there is a reduction in the number of lens cleaning actions.

Clinical experience with active holders is reported of the following types: The EASOP[30,31,40,41,50,52,53,55-59], the EndoSista[44-46], the A460 CRS plus[63], The Tokyo University manipulator[64], the Endex[65], the image track camera[34,35], the SGRCCS (47) and the A460[62]. All systems perform well, are safe, reduce the number of lens cleaning actions and produce stable images. Some studies compared laparoscopy with active camera holders, to conventional laparoscopy in clinical[30,31,34,35,41,45,46,50,57] or phantom[12,36,38,54] experiments. Although surgeons working with these systems indicate that they can concentrate better on their work being able to reposition the camera themselves, the operation time with these holders is at best equal to those with human assistance. The set-up and breakdown time of the systems is significantly longer, however.

Solo-surgery with these systems, passive and active, is possible. For some procedures an additional holder is needed for holding an instrument. In most studies a passive holder[12,17,21,50] is used for this task. In one study an active holder[30] is used, but only in the passive mode. Some studies indicate that the location of the holder at or near the operation table is important[12,30] as to avoid interference with the other instruments, especially when two holders are used. Changing the endoscope port during the procedure was found to be problematic when a camera holder was used[12].

Only four studies compared different camera and instrument holders, active and passive. Den Boer et al.[50] compared an active holder (AESOP) and a passive holder (PASSIST) to human assistance during clinical cholecystectomy. Both the active and the passive holder provided an accurate and stable image, and with approximately identical operation times. However, the number of camera repositioning actions decreased by more than half using a camera holder instead of human assistance. After the study, the co-operating surgeons indicated that they preferred the use of these holders over a surgical assistant, better concentrating on the dissecting task.

Arezzo et al.[12] compared in a laboratory setting (phantom cholecystectomy) three types of active camera holders (AESOP, Endosista and FIPS) and two passive holders (Tiska and Martin arm) for the camera. Another passive holder (Martin arm) was used for retracting. Procedures with human assistance were used as a control group. Human assistance leads to the shortest operation times, followed by the passive holders (Tiska and Martin arm). The active EASOP-arm was found to be the most comfortable holder followed by the passive Tiska. Arezzo et al. concluded that the combination of two Tiska endoarms, one for the scope and one for the instrument, is the optimal combination for cholecystectomy using solo surgery.

Allaf et al.[38] compared the voice controlled interface vs the foot controlled interface of an active camera holder (AESOP) in an experimental setting and reported that foot control was faster and had less operator-interface failures. Voice control, however, was more accurate in positioning.

Yavuz et al.[60] compared two active endoscope positioners (AESOP, Endosista) in an experimental setting and reported that the AESOP-arm is quicker and the positioning is more accurate than with the Endosista.

2.4 Discussion

In literature it is recognised that using a camera holder in laparoscopic surgery provides an optimal and stable image of the operation field compared to human assistance. The control of the endoscope by the surgeon him/herself is also generally considered to be superior to human assistance. There was no difference in these respects between the passive and active (robotic) camera holders.

When passive holders are used, the surgeon has to reposition the camera or instrument manually. The consequence is that the surgeon has to release one or two laparoscopic instruments to reposition the camera or instrument. This may be considered inconvenient, but studies show that operation times do not increase due to a strongly reduced number of camera movements[12,50] and a more stable image[29,50]. Surgeons indicate that using one hand (the dominant one) for repositioning the camera and therefore releasing one instrument is not an important limitation, because the surgeon is never dissecting when the camera should be moved. During the camera movement the surgeon, the observer, will obtain important depth and navigational information[10,43].

When active camera holders are used, many user interface solutions have been designed preventing the surgeon to release his instruments. Voice control, head movements, finger-activated and foot activated switches have been used. All these interface methods activates only one degree of freedom at the same time leading to non-efficient control[60]. In addition, the camera holder's movements are kept relatively slow for safety reasons making the interface very time consuming and awkward.

Foot controllers seem not optimal for controlling the endoscope as footswitches are already in use for other tasks in the operation room. The same goes for the finger activated control as the surgeon is already using both his hands in laparoscopy.

Head control could be intuitive but is still in an early stage of development. The ergonomics should be improved and positioning in more than one direction should be possible. Voice control is reported to lead to accurate control[12,54]. Voice control, however, is subject to operator-interface failures[54], is slow and less intuitive than manual repositioning. Hence, for controlling the camera a passive holder, which can be activated with one hand, is expected to be more efficient and economical.

A laparoscopic solo-surgery procedure can be realised introducing a holder for a retracting instrument in addition to the camera holder. Using active holders for the static task of retracting seems not efficient and retracting tissue using voice-, head- or foot-control seems unsafe. Hence,

for retracting a passive holder is expected to be more efficient and safe.
The voice controlled AESOP-arm is currently the most reported active camera holder. A few publications compare the performance of this holder to other systems. It is reported to be more accurate in positioning than the EndoSista[60] and faster than the other active holders reported with head-, foot- or finger-control[12].

The passive camera holders appear to function as good as or even better than the active camera holders[12,50]. The passive holders that can be repositioned with one hand are the most comfortable ones according to the surgeons[50]. Single-handed repositioning can be realised by using pneumatic or electromechanical brakes[7,14,18] or by balancing the camera holder e.g. using spring compensation and/or adjustable friction[17,28,29].

2.5 Conclusion

Both active and passive holders are functional, produce stable images and provide the surgeon with direct control of the camera and the instruments, as shown in figure 1. The positioning of the camera by the surgeon is intuitive and efficient leading to a reduced number of repositionings. The repositioning by the surgeon himself appears to lead to a number of actions and time use comparable to human assistance. Solo-surgery can by realised using a camera holder and an additional holder for the retracting instrument. A passive holder is indicated for the retracting instrument because of the static task of retracting and because of safety.

Passive camera holders appear to function as good as or even better than the currently available active camera holders. Therefore the benefits of active holders are questionable in relation to the much simpler, smaller and cheaper passive designs.

In conclusion, passive holders seem to be the most cost-efficient solution for controlling the camera and holding instruments. For efficient use in MIS they should allow repositioning with one hand, have a braking system or have a balanced construction with adjustable friction. More evaluation studies are needed to establish the merits of the different designs in clinical practice.

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CHAPTER 3

DESIGN AND EVALUATION OF ENDOSCOPE POSITIONERS

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And:
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Design and Feasibility of PASSIST, a Passive Instrument Positioner.
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Summary

Objective: *During minimally invasive procedures an assistant is controlling the camera and often a laparoscopic grasper. Ideally, the surgeon should be able to manipulate his own instruments because the indirect way of controlling complicates the surgeon's observation and manipulation actions and disturbs his eye-hand co-ordination. Reported solutions to replace the assistant are active positioners, "Robots", like the Aesop™ and the EndoAssist™. Because positioning the instruments is often a rather static task, the Academic Medical Center (AMC) has developed a passive assistant for instrument positioning (PASSIST) to allow solo-surgery. The PASSIST was designed to be a simple, fully autoclavable, slender and stiff positioner. The joints of the mechanism have an adjustable friction and have spring compensation for stabilising the instrument in a fixed position enabling intuitive single-hand repositioning. This chapter describes the design of the PASSIST and an evaluation study that uses time action analysis to evaluate objectively if Instrument positioners IPs can substitute a surgical assistant efficiently and safely.*

Methods: *78 Laparoscopic cholecystectomies (LC) were randomly performed with a surgical assistant or with an IP (either the voice-controlled AESOP or the manually controlled PASSIST) in four different hospitals, by 4 surgeons and 1 resident. Images from the laparoscope and two additional external cameras were recorded simultaneously. These recordings were analyzed with respect to the time, the number and type of actions performed, the positioning accuracy of the camera, and the peroperative complications. Additionally, the surgeons had to judge the difficulties for each operation, and the comfort of use of the IPs.*

Results: *The PASSIST and AESOP were able to replace the surgical assistant during LCs, both without significantly changing the mean total operation time ($p=0,18$) and actions performed ($p=0,86$). The laparoscope was repositioned significantly less frequently in the IP-group (49 times/LC) than in the assistant group (114 times/LC) ($p<0,001$). The positioning accuracy did not differ significantly between the two groups, nor did the peroperative complications. The results of the questionnaire showed that the surgeons preferred to operate with an IP instead of a surgical assistant.*

Conclusion: *This study showed that IPs enable surgeons to perform LC without a surgical assistant, with no significant change in operation time, number of actions needed. In addition, IPs reduced laparoscope repositioning without changing the positioning accuracy or the peroperative complications.*

3.1 Introduction

Various (supporting) instruments have been developed to facilitate laparoscopic surgery. *The development of supporting instruments took place in close conjunction with the increasing need for laparoscopic procedures like cholecystectomy.* An example of a supporting instrument is a camera positioner, which can help to hold a laparoscope, and yet allows for adjustment of the position[1]. Usually, during a laparoscopic procedure, a surgical assistant controls the laparoscope and, when needed, an additional grasper. Consequently, the surgeon has no direct control over his viewing direction and the laparoscopic image is often unstable, due to tremors and sudden movements of the surgical assistant. This indirect way of controlling the camera complicates the surgeon's observation and manipulation actions and disturbs the surgeon's eye-hand co-ordination[2-4]. It can also lead to communication problems between the surgeon and the assistant, to an unsteady image and to an inaccurate viewpoint when the assistant has to maintain a fixed pose for a long time. Furthermore, the positioning task is a relatively static and tiresome task for the surgical assistant.

The negative effects of the indirect positioning of the camera can be reduced by replacing the assistant by an instrument positioner. Positioners lack active unexpected or conflicting image movements, they do not get tired and provide a stable image[5,6]. For example, in laparoscopic cholecystectomy (LC) this could be advantageous in the dissection phase in which an accurate, central image is very important. Moreover, a second positioner could be used in LCs to hold the laparoscopic grasper that is used to stretch and to present the gallbladder. In this way, the surgeon would be able to perform the operation without an assistant, controlling the camera position himself and locking the camera in the desired position, resulting in a steady image and facilitating dissecting actions.

Commercially available remote controlled active positioners, in medical literature often called robots, will be described briefly in the next section. The subsequent section will describe the design, the development and the evaluation of an easy to handle, slender but stiff, passive laparoscopic positioner which allows the surgeon to perform laparoscopic procedures without a surgical resident.

3.2 Overview of instrument positioners

Instrument positioners can be divided into two main groups: passive positioners, which are manually repositioned by the surgeon, and active positioners, which are repositioned by a robotic device. Commercially available

Figure 3.1. The AESOP robotic arm (Computer Motion Inc.) (upper-left), Endo Assist (Armstrong Healthcare Inc.)(upper-right) and the Lapman (Medsys s.a.) (left).

remote controlled active positioners, are the *AESOP*™, the EndoAssist™ and the Lapman™ [1,7,8] *(see figure 3.1.)*. The active *AESOP* can position and lock the laparoscopic camera using voice control, without interruption of the operating actions of the surgeon. The EndoAssist is controlled by head movements. These active instrument positioners indeed provide a stable image and do not get 'tired'. In addition to the stabilizing task, the active positioners can be controlled by the surgeon without releasing the instruments and therefore without interrupting the actual manipulation actions. Although they function properly, these positioners are relatively slow due to the inherent time delays and safety reasons, need a lot of space, are expensive and not sterilizable and only control the camera. Furthermore, it is questionable whether the surgeon can effectively continue his manipulation tasks during controlling the positioner.

Figure 3.2. The Storz Holding system, a passive positioner.

Passive positioners are also available, like the Leonard Arm™, the Ball trocar™ and the Martin Arm™ or the similar Storz Holding system *(see figure 3.2.)*. Most of these positioners are mechanical arms with a series of mechanical linkages and instruments clips. In general, two hands are needed to reposition the instrument or the scope, or footswitches are needed to release electromagnetic or pneumatic brakes, which makes them relatively large and not easy to handle.

3.3 Design of the PASSIST

The passive instrument positioner described, called the PASSIST, is designed in a close collaboration between the Department of Medical Technological Development (MTO) and the surgical department of the AMC[9]. The MTO is an engineering department within the AMC Hospital, including a workshop for prototyping. This situation gives the opportunity to develop medical instruments in close collaboration with medical researchers. An experimental surgery department and the operating theatre of the academic centre makes it possible to test and to evaluate instruments in the same building where the devices are designed and built.

Multidisciplinary meetings resulted in the following design criteria:

- Slender mechanism, not interfering with the surgical actions of the operation team.
- Easy to connect to the table rail and easy fixation of the laparoscopic instrument.
- The device should be completely sterilizable.
- Intuitive and repositioning of the instrument single-handedly.
- Repositioning of the instrument without exerting tension, or initiating damage to the abdominal wall at the incision point.

In laparoscopy, the camera and the instruments have four degrees of freedom, three rotations around the incision point as well as one translation through the incision point. The positioner is based on a parallelogram mechanism that allows only movements in these four degrees of freedom *(see figure* 3.3.*)*. This stiff but slender mechanism has a stationary centre of motion. Because the centre of motion is in the incision point of the abdominal wall, all reaction forces are absorbed by the mechanism, resulting in minimal skin load near the incision point.
By manually adjusting using just one knob, the friction in all the joints can be varied, which gives the mechanism a variable resistance against movement, just enough to stabilize the instrument in a fixed position. To reposition the instruments the surgeon has to interrupt his surgical action to exert just a small force with only one hand to the positioner or the instrument itself. The instrument remains in the new position when the

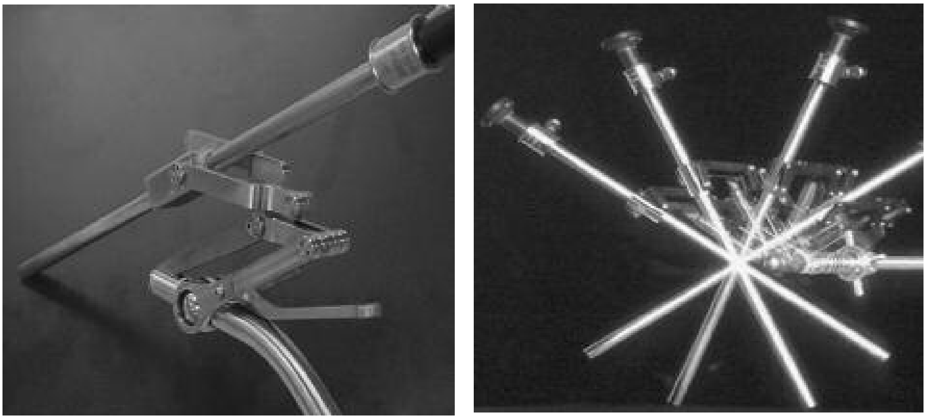

Figure 3.3. The PASSIST positioner designed with a parallelogram mechanism having a remote centre of motion.

surgeon releases the instrument. One of the axes of rotation is spring loaded to compensate for the weight of the scope including the video camera and wiring. This balancing allows a low level of friction in that joint, so repositioning of the scope is simple.

The whole device including the rail-clamp and connection bar is made out of stainless steel. It has an open structure, contains no electrical components and can be sterilized completely. The positioner can be connected to the table rail over the operation sheets at any location the surgeon prefers. Only a slender bar is present between the mechanism and the table rail, so the positioner hardly interferes with the other instruments.

3.4 First clinical results

The advantages and drawbacks of surgical procedures and new instruments are frequently analyzed by evaluating the complications in the postoperative follow-up period or by comparing total operating times in phantom or animal experiments[10-12] However, these evaluations do not provide any insight into the specific efficiency, functionality or limiting factors of the instrumentation used during the per-operative process. Therefore, analysis and critical evaluation of the technical equipment in a clinical setting are of great importance for minimally invasive procedures[13].

After testing our device successfully in a phantom experiment, it was applied in a few surgical procedures, namely Laparoscopic Cholecystectomy, Laparoscopic Assisted Vaginal Hysterectomy and Laparoscopic Spondylodesis in three hospitals with three different surgeons.

In standard LC the assistant has to stabilize the laparoscope and the grasper during the dissection phase of the operation. The new passive positioners were used to take over the stabilization of the camera and the grasper from the assistant *(see figure 3.4.)*. The results of an extended evaluation in a randomized trial are given in the next section.

In a standard Laparoscopic Assisted Vaginal Hysterectomy and the Laparoscopic Spondylodesis the assistant only has to stabilize the laparoscope, so in the experimental setting only one passive positioner was applied to take over the stabilization of the camera from the assistant.

In all these procedures the surgeon could perform the operation without an assistant. All surgeons indicated that the Passive Positioners are indeed small and slender and did not interfere with the surgical actions. The whole system is easy to use and can be fully sterilized even in a small autoclave. Single handed repositioning of the laparoscope is possible in any position when the mechanism is spring loaded to compensate for gravita-

Figure 3.4. LC with two passive positioners, one holding the camera (A) and one holding the laparoscopic retractor (B).

tional forces. In the Laparoscopic Spondylodesis the PASSIST positioner was advantageous because during that procedure a X-ray C-arm was needed, and there was simply no room left for the assistant near the table. Sometimes when the surgeon needed an extra hand, the scrub nurse could assist him, e.g. by repositioning the laparoscope. The surgeons had the impression that with the scope positioner the image was much more stable than with an assistant. Releasing an instrument in order to reposition the scope or the retractor was not found an important disadvantage. Although the positioners were only tested in these procedures, they are also useful in other minimally invasive procedures where a stable image is required or there is not much space for a camera assistant.

3.5 Evaluation of instrument positioners in a randomised clinical study

To analyze objectively if instrument positioners (PASSIST and *AESOP*) could substitute a surgical assistant efficiently and safely in a clinical situation, a randomized clinical study was performed[14]. Laparoscopic cholecystectomies with a surgical assistant and LCs with instrument positioners instead of an assistant were compared. The *AESOP* was considered representative for the commercially available active positioners. The procedure selected for investigation was the Laparoscopic Cholecystectomy because it is the most frequently performed laparoscopic procedure and it is carried out in accordance with a standard protocol. The advantages and limitations of the new instrument positioners in terms of reduction of number of actions and time in the assistance, and a more stable image of the operating area were evaluated. The study analyzed the efficiency of the procedure in terms of time and actions needed per phase, using time-action analysis, and it evaluated the safety in terms of the incidence of peroperative complications, the positioning accuracy of the image, and the judgment of the surgeons.

3.5.1 Methods

Patients and procedure

A multi-centre, randomized, prospective clinical trial was used to compare LCs performed with a surgical assistant (As-group) and without an assistant using instrument positioners (IP-group). Seventy-eight laparoscopic cholecystectomies were performed in 4 hospitals, by 4 surgeons who were experienced in performing LCs and by 1 resident. All surgeons randomly performed LCs in the As-group and in the IP-group as decided by drawing lots. An equal number of lots were distributed in the As-group as well as in the IP-group for each surgeon, to compensate for any variations caused by differences in individual surgical techniques and hospital policy. The study protocol was approved by the local Ethical Committees of the participating hospitals.

Instrument Positioners

In the IP-group, one surgeon used the active voice-controlled AESOP™, because he was already experienced in using the AESOP™ to position the laparoscope. The other surgeons used the PASSIST. None of the surgeons was experienced in solo-surgery, because residents used to assist LCs performed with or without instrument positioners as part of their surgical training.

Recording procedure

During the surgical procedures, the images from the laparoscope and the images from two additional external CCD-cameras were simultaneously recorded, using a 4-channel mixing device. The small CCD-cameras recorded one central overview of the surgical procedure, and a detailed image of the hands of the surgeon. In addition, an omni-directional microphone recorded the comments of the surgeon during the operation. The equipment was placed outside the range of motion of the operating team and the recorded procedures were analyzed outside the operating room to prevent interference with the peroperative procedure.

Data analysis

The efficiency and safety were determined for each procedure, using time-action method to analyze the peroperative process objectively[13,15,16]. The efficiency of the operation was analyzed by comparing the time and the number of actions, needed for each operation phase between the As-group and the IP-group. The type of actions was analyzed using a modified list of actions (*Table 3.1.*) as defined by Claus et.al.[15]. The outcomes of the As-group were used as the standardized reference for the IP-group. For the As-group, the total number of actions of the surgeon and the surgical assistant was scored. For the IP-group the total number of actions of the surgeon was scored. Additionally, the actions that the scrub-nurse took over from the surgical assistant were also scored in both procedures. For example, in the case the AESOP™ and 4 trocars were used, sometimes the scrub-nurse had to hold the gallbladder forceps because the AESOP™ only held the laparoscope. The efficiency was analysed in 3 phases (set-up, dissection and closure phase) as reported previously[13,16,17]. In short: The set-up phase was defined to start after the last sterile sheet was placed and to end with the first intra-abdominal dissection. The dissection phase was defined as the interval between the first intra-abdominal dissection and the removal of the gallbladder from the abdomen. The closure phase was defined as the interval between the removal of the gallbladder from the abdomen and the placing of the last suture.

The safety of the procedure was evaluated by determining the peroperative complications (e.g. arterial bleeding, gallbladder leakage, bowel injury), the positioning accuracy of the image, and by assessing difficulties during the operation by the surgeons. Signs of mild cholecystitis that became apparent during the operation, were also scored as a complicating factor because cholecystitis makes the dissection more difficult.

The positioning accuracy was defined as the accuracy with which the laparoscope showed each dissecting action in the centre of the image. Experienced surgeons were asked to indicate in which field of the monitor image the actions should be performed for safe task performance. Accordingly, the centre of the image was defined as a circle with a diameter of ⅔ of the height of the monitor *(see figure 3.5.)*. The position of the manipulating instrument's tip was determined in the image: Completely in the centre of the image, at the border of the image, or partly outside the monitor. For electro-surgical instruments, the tip was defined as the non-insulated part of the instrument. For other instruments, the tip was defined as the part between hinge and point. The position of the tip of the instrument was scored for each manipulating action of the experienced surgeons in the dissection phase. In addition, the number of times the laparoscope was repositioned (manually/or by verbal command) was analysed. Difficulties during the operation and the comfort of use of instrument posi-

Table 3.1. List of defined actions.

Surgical	Instrument	Others
Dissect	Insert instrument	Waiting for personnel
Stretch	Remove instrument	Waiting for instruction
Coagulate bleeding site	Reposition laparoscope	Waiting for tech. reason
Clip	Handle positioner	Command to reposition scope
Percussion/palpation	Reposition gallbladder forceps	Other verbal instruction
Irrigation/Suction	Clean instrument	Apply bandage
Suture	Set-up supporting-systems Use retrieval bag	

tioners were both evaluated using a questionnaire, which was completed after each procedure by the surgeon. The surgeons were asked to rate the answers on a scale ranging from 1-5 (1=not at all, 5=yes, absolutely). The average ratings of each answer were calculated to compare the As-group with the IP-group.

The resident's results were analysed separately from the results of the experienced surgeons because the operation times for the resident are significantly longer compared to those of an experienced surgeon. In addition, a sub-analysis was performed, analysing the outcomes of the AESOP™ and the PASSIST, separately.

The mean values and standard deviations were calculated for the time (in minutes) and number of actions, and for the positioning accuracy. The two-sided student t-test was used to compare the outcomes; $p<0.05$ was considered to be significant.

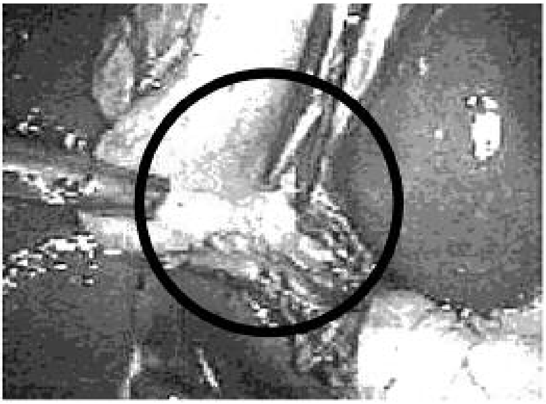

Figure 3.5. Positioning accuracy. The centre of the image is shown as a circle with a diameter ⅔ the height of the monitor image.

3.5.2 Results

There was no significant difference in patient characteristics (age, gender) or in the number of peroperative complications between the As-group and the IP-group (*Table 3.2.*), and no conversions to open cholecystectomy occurred in either group. Of the total of 78 LCs, the surgeons performed 30 LCs with a surgical assistant and 30 without, the resident performed 9 with and 9 without a surgical assistant. One surgeon used the AESOP™ instead of the PASSIST (5 LCs in each group).

Efficiency

The total operation time did not differ significantly for LCs performed with a surgical assistant (42±21 min.) compared to LCs performed with an IP (49±23 min., p=0.18)(Fig. 3.6). Moreover, the total number of actions did not differ either between the As-group (635±251 actions) and the IP-group (646±265 actions, p=0.86). The results per phase show that only the time for the set-up phase was increased significantly in the IP-group compared to the As-group. The number of actions did not differ between the 2 groups for any operation phase *(see figure 3.6.)*.

Positioning of laparoscope

The number of times the laparoscope was repositioned during an operation decreased significantly when an IP was used (49±27) instead of a surgical assistant (114±54, p<0.001). Nevertheless, the positioning accuracy of the laparoscope did not differ significantly between the groups: 43% of all dis-

Table 3.2. Patient's characteristics and peroperative complications.

	As-group *(n=39)*	**IP-group** *(n=39)*	**t-test ***
Males/Females	11 / 28	6 / 33	n.s.
Mean Age (yrs) (±SD)	51 (15.3)	51 (15.6)	n.s.
Cholecystitis	8	5	n.s.
Arterial bleeding	4	1	n.s.
Gallbladder perforation	18	15	n.s.
Endobag used	8	9	n.s.

* n.s. = not significant

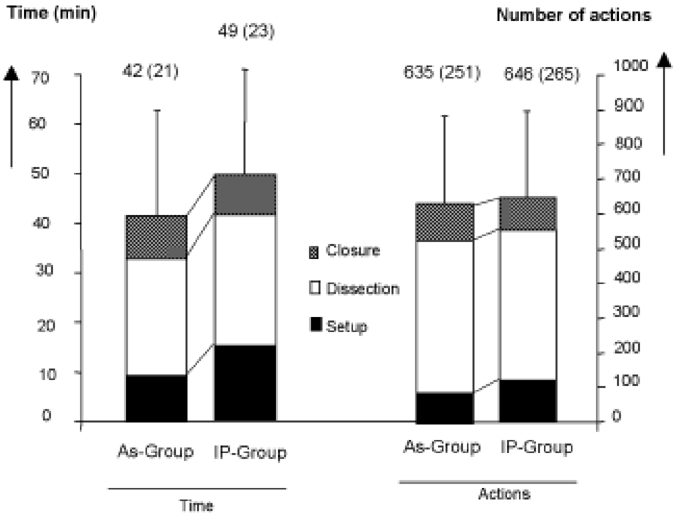

Figure 3.6. Time-action results. Average time and number of actions are shown per phase for the As-group and the IP-group of the experienced surgeons. Total time (± standard deviation) in minutes and number of actions are shown at the top.

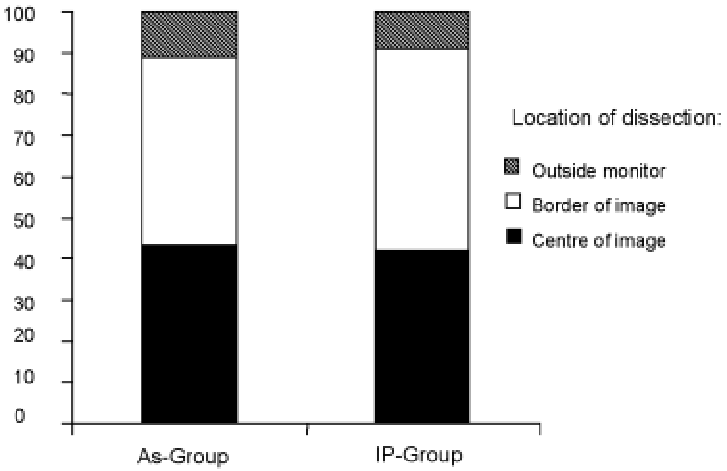

Figure 3.7. Positioning Accuracy. Percentage of actions performed inside the central circle, outside the circle, and totally outside the monitor are shown for the As-group as well as the IP-group of the experienced surgeons.

sections (80 manipulating actions ±45) was performed completely within the defined centre in the As-group; and 42% (86±50) in the IP-group (p=0.91) *(see figure 3.7.)*. Furthermore, 46% (72±29) of all dissecting actions was performed outside the defined centre in the As-group, and 11% (18±16) took place outside the monitor image. In the IP-group this was 49% (92±45) and 9% (13±13), respectively. The gallbladder forceps, held by the surgical assistant in the As-group and by the PASSIST in the IP-group, was repositioned on average 10 times per LC in the As-group, and 7 times in the IP-group (p=0.10).

Sub-analysis

Both the use of the AESOP™ and the PASSIST did not result in a significant difference in total operation time (33±7, 53±23 min, respectively) and the total number of actions needed (489±118, 678±275, respectively), compared to LCs performed with a surgical assistant (42±21 min., 635±251 actions). The number of times the laparoscope was repositioned reduced significantly using the AESOP or the PASSIST.

The results of the LCs performed by the resident did not differ significantly between the As-group and the IP-group (p=0.58). Naturally, the average total operation time (As-group 86 minutes, IP-group 90 minutes, p=0.69) and the total number of actions needed (As-group 1081±187, IP-group 1023±211, p=0.58) were higher for the LCs of the resident, compared to the results of the experienced surgeons.

Table 3.3. Difficulties and comfort questionnaire. Mean rating score, for each question per group, as expressed by the surgeons[†].

	Question	Assistant-group *(n=39)*	IP-group *(n=39)*
1.	The operation was difficult.	2.3	2.0
2.	The operation was efficient.	4.5	4.8
3.	The installation of the positioners was easy. *		3.8
4.	I was content with the laparoscope-positioner. *		4.5
5.	I was content with the forceps-positioner. *		3.2
6.	I can do this procedure without an assistant. *		4.9
7.	I would have preferred to operate with an assistant. *		1.8
8.	I was satisfied with the laparoscopic image.	3.9	4.2
9.	Overall the image centered correctly.	3.5	4.2
10.	The video-recording and persons involved bothered me.	1.0	1.0

[†] The answer had to be scored on a range from 1 to 5 : 1=No, not at all - 5 = Yes, absolutely.

* These questions were only asked in the IP-group

Questionnaire

The results of the questionnaire (*Table* 3.3.) showed that surgeons judged the operations as equally difficult and efficient for both groups. The surgeons indicated that instrument positioners could replace the surgical assistant. Furthermore, the surgeons indicated that they preferred the use of an IP to a surgical assistant, and finally they were more satisfied with the laparoscopic image if IPs were used to position the laparoscope.

3.6 Discussion

The slender laparoscopic positioner designed and built by the Medical Technological Development department of the AMC makes it possible for a surgeon to perform solo-surgery, if one or two of these are applied. The clinical trials indicate that this device is useful in all laparoscopic procedures except those where frequent camera movements are required. The positioners did their job well and the results provide us with data to further improve the device.

The evaluation in the randomized trial showed that there was no change in total operation time and the number of actions, using instrument positioners instead of a surgical assistant. In addition, the laparoscope was repositioned 60% less frequently when instrument positioners were used while retaining the positioning accurately of the image. Furthermore, the occurrence of peroperative complications (*Table 3.2.*) did not differ between the groups and the complications that occurred did not have any consequences for the operative use of instrument positioners or the outcome of the IP-group.

The total operation time did not change significantly, but the average set-up time did increase significantly with 6 minutes when instrument positioners were used. This increase was caused by the time needed for the installation. The surgeons often waited with installing the positioners until they were finished with their normal set-up procedure. In the future, set-up time will be reduced if the surgeons become experienced in using the positioners and in installing the positioners during the pneumoperitoneum. Furthermore, the design of the PASSIST could be further improved to reduce the time needed for installation.

The surgeons in this study were not experienced in solo-surgery, which might have resulted in a bias. The analysis results in this study revealed that the average set-up time was longer in the beginning and decreased during the 10 procedures performed with the PASSIST. The dissection and closing phases in the IP-group did not decrease during the ten procedures and were not longer than those phases in the As-group. Therefore, the inexperience of the surgeons might have caused an underestimation of the efficiency of the set-up phase of the IP-group, particularly for the surgeons using the PASSIST.

This study shows that instrument positioners can substitute a surgical assistant. This is especially relevant in the setting of a non-teaching hospital. In the teaching setting, residents frequently assist LCs as part of their surgical training program. Instrument positioners would deprive residents of this opportunity of learning laparoscopic skills. In fact, in our study a surgical assistant was often present during LCs with a positioner because of the educational aspect for residents. Sometimes, this resulted in the resident participating in a positioning task because he was at hand, although it was against the study protocol. In these cases, the actions of the assistant were added to the total number of actions of the IP-group. The surgeons indicated afterwards that they were fully convinced that those actions could have been done either by themselves or by the scrub-nurse. In other procedures when no resident was present, the surgeons indeed proved that they could operate fully without a surgical assistant. Of the total number of actions performed per LC, the surgeon himself performed on average 74% of the surgical actions in the As-group (471±193), and 88% in the IP-group (565±229, $p=0.10$). The number of actions performed by the resident did decrease significantly (23% in the As-group and 9% in the IP-group, $p<0.001$), without increasing the number of actions performed by the scrub-nurse (3% versus 3% $p=0.46$).

The positioning accuracy was assessed using a central circle. Experienced laparoscopic surgeons indicated that a safe diameter of the circle would be 2/3 of the height of the monitor. However, over 50% of the actions were performed outside the central circle. Apparently, in the clinical situation the surgeons often preferred a de-central view over an extra repositioning action. In our study, the actions performed outside the central circle did not lead to an increase in complications.

The questionnaire revealed that surgeons preferred to operate with an instrument positioner over a surgical assistant. The main reasons mentioned were: The stable image; the absence of misunderstandings of verbal commands between the surgeon and the assistant; and the reduced need to clean the lens of the laparoscope, which is also described in literature[18]. Furthermore, the surgeon was able to concentrate more on his dissection task, because less attention was required to position the laparoscope and the gallbladder forceps or to guide the assistant. In the case of the resident operating with the positioner, the supervising surgeon mentioned that he could focus better on the training aspect, e.g. by pointing out structures on the monitor, because he did not have to attend the laparoscope.

3.7 Conclusion

In this chapter the development and evaluation of a slender mechanical instrument positioner has been described. The evaluation study showed that:

- The developed instrument positioner enables surgeons to perform elective laparoscopic cholecystectomy without a surgical assistant.

- Replacing the surgical assistant with an instrument positioner does not result in a significant increase in time and in number of actions needed for LC.
- The use of instrument positioners reduces laparoscope repositioning without significantly changing positioning accuracy.
- Surgeons subjectively prefer to operate with an instrument positioner instead of a surgical assistant.

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CHAPTER 4

MECHANICAL MANIPULATOR FOR INTUITIVE CONTROL OF ENDOSCOPIC INSTRUMENTS WITH SEVEN DEGREES OF FREEDOM

Based on two publications:
J.E.N. Jaspers, M. Bentala, J.L. Herder, B.A.de Mol, C.A. Grimbergen. Mechanical manipulator for intuitive control of endoscopic instruments with seven degrees of freedom. Min Invas Ther and Allied Technol, 2004: 13 (3): 191-198.

And:
J.E.N. Jaspers, M. Shehata, F. Wijkhuizen, J.L. Herder, C.A. Grimbergen. Mechanical manipulator for intuitive control of endoscopic instruments with seven degrees of freedom. Proceedings ASME DECT 28th Biennial Mechanisms and Robotics Conference, Sept 28-Oct 2, 2004, Salt Lake City, Utah, paper number DECT04/MECH-57137.

Summary

Objective: *Performing complex tasks like endoscopic suturing in Minimally Invasive Surgery (MIS) is very demanding due to a disturbed hand-eye co-ordination, non-ergonomic instruments with limited degrees of freedom of motion (DOFs) and a lack of three-dimensional perception. Robotic tele-manipulator systems enhance surgical dexterity by providing up to 7 DOFs. This allows the surgeon to operate in an ergonomically favourable position with more intuitive manipulation of the instruments. Robotic systems, however, are very bulky, expensive and do not provide any force feedback. The aim of our study was to develop an alternative simple mechanical manipulator for MIS.*

Methods: *The Minimally Invasive Manipulator (MIM) is designed as a purely mechanical device, for intuitive manual control of surgical instruments in 7 DOFs. When manipulating the handle of the MIM, the instrument tip should follow the handle movements, without any scaling or mirroring effect.*

Results: *A prototype of the MIM has been built for the manipulation of 8 mm endoscopic instruments. It weights about 5kg, is balanced and can be connected to the operation table. The friction and stiffness of the MIM is roughly equal to that of a conventional endoscopic instrument and therefore provide some force feedback. First phantom experience indicates that the system functions properly and that complex manipulations like endoscopic suturing are feasible.*

Conclusion: *A set of MIMs seems to be an economical and small alternative for robotic systems. In addition to complete safety, it provides (limited) force feedback. It will offer more surgeons the capability to perform complex MIS.*

4.1 Introduction

The purpose of endoscopic surgery is to reduce surgical trauma to patients, resulting in less operative morbidity, faster recovery, and reduction in costs. In a variety of surgical disciplines endoscopic techniques are widely used for multiple surgical procedures. These procedures mainly consist of resectional tasks (such as cholecystectomy in general surgery), which do not demand a complex design of the endoscopic instruments. The design of these instruments was initially based on conventional surgical tools. The endoscopic instruments are long and have only four degrees of freedom (DOFs) in positioning, because these straight instruments have to pivot about a particular point of incision through the skin. Because of this design, the learning curves of MIS are longer than in open surgery. Therefore the minimally invasive approach of these techniques is not widely accepted, especially by senior surgeons. Furthermore, endoscopic instruments do not provide good ergonomics and sufficient dexterity to perform complex surgical tasks such as construction of a micro-anastomosis, while working on an unstable surgical field or in small areas. For these reasons the endoscopic surgical techniques until recently have had little impact on cardiac surgery. Over the past few years, minimally invasive direct coronary artery bypass grafting has been reintroduced into the arena of cardiac surgery and is rapidly gaining acceptance[1]. Improved techniques and instrumentation have led to encouraging short term-results[2-5]. However, endoscopically sutured anastomoses have not been possible because of the imprecision of the standard endoscopic instruments[6]. Recently introduced computer-assisted “robotic” systems have enabled endoscopically sutured micro-anastomoses in coronary artery bypass grafting[7-9]. These systems were designed to translate the surgeon’s hand movements to the tip of the endoscopic instrument in a remote operative field, using a computer system. Advantages of these systems are the 3D visualisation and the inclusion of a “wrist” at the end of the instruments, providing articulated motion in 7 DOFs: three translations, three rotations and the opening/closing action. However, these robotic systems still have considerable limitations. They are too large and too complex for easy use and they are expensive. Another limitation of these systems is the lack of force feedback. The feedback from the operation field consists of visual information only. Working with these instruments considerably lengthens the operation time and the learning curve. Lowering the costs and improving specifications are mandatory for these instruments to become a standard tool for endoscopic cardiac surgery.

In an attempt to overcome some of the above mentioned limitations we have developed a Minimally- Invasive Manipulator (MIM), which is designed as a small, economical and mechanical alternative for these computer-assisted "robotic" systems.

This study describes the design of a set of mechanical manipulators for minimally invasive surgery (MIS), focusing on cardiac surgery. Therefore, first a model of minimally invasive surgery will be introduced presenting the interrelation of the different manipulation aspects for the surgeon. From this model, the specific characteristics are derived which have to be taken into account in designing endoscopic instruments. Next, a number of strategies in mechanical design will be reviewed; these are of interest for the design of the mechanical manipulator with its particular demands. Some examples of available endoscopic instruments for cardiac surgery will be discussed to see if they cover these demands. Next the actual design criteria of the mechanical manipulator are defined, the design of the mechanical manipulator is presented and the different sub-solutions and innovative properties will be discussed. Finally, a technical evaluation of the prototype is presented. We will conclude discussing future developments in the field of endoscopic instruments.

4.2 Design criteria of endoscopic instruments

To analyse the limitations of minimally invasive surgery relative to conventional open surgery and to judge potential solutions by developing innovative endoscopic instruments, it is beneficial to model the human functioning involved in minimally invasive surgery *(see figure 4.1.)*. The model shows the surgeon manipulating the tissue of the patient using endoscopic instruments, guided by visual information from a laparoscope controlled by an assistant or by the surgeon himself. It can be observed that in the feedback loop, technology-related constraining mechanisms are in between the senses and hands of the surgeon and the tissue of the patient, hampering him to work as a craftsman[10].

The perception of the operating field is provided by the laparoscope giving a two-dimensional view of the operating field. The view on the operating field is mostly from a direction different from that of the eyes of the surgeon and the camera is manipulated by an assistant[11]. This disturbs the hand-eye co-ordination of the surgeon, so important for the delicacy of the operation actions[12,13]. Another disturbing factor is the force needed to position the relatively heavy instruments with the unsupported arm and hand.

The surgical treatment is performed by special, long endoscopic instruments of limited cross section with only four degrees of freedom in posi-

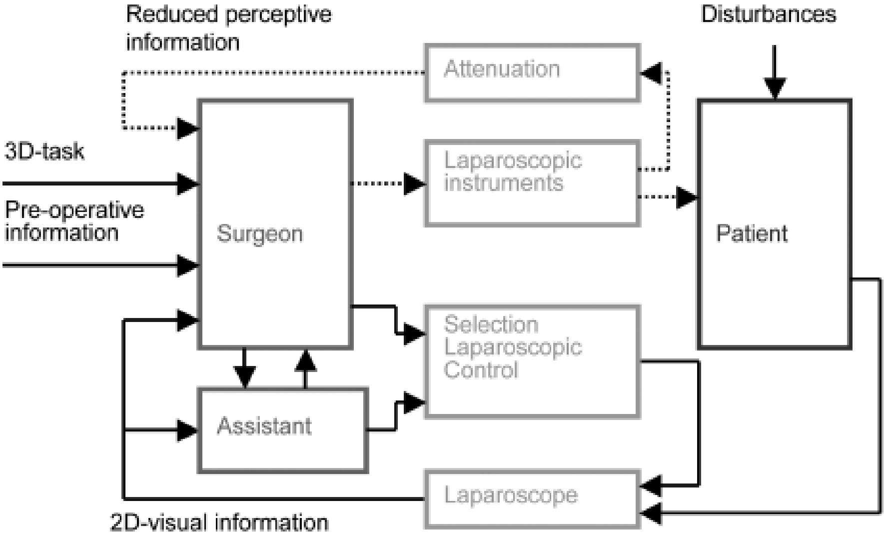

Figure 4.1. Block diagram of a minimally invasive procedure. The dominant and non-dominant hand of the surgeon both use laparoscopic instruments with low mechanical efficiency (dashed arrows). Visual information is limited by the laparoscope, which is often controlled by an assistant[2].

tioning *(see figure 4.2. left)*, because they have to pivot about a particular point of incision through the skin[12]. The design of conventional instruments for endoscopic surgery was initially based on mimicking the functions of conventional surgical tools. They look like scissors or graspers for open surgery but are longer to reach the tissue from outside the human body. This gives an important reduction in the manipulation capabilities relative to the human arm and hand with its redundant seven degrees of freedom in positioning[13]. In addition, the pivoting about the point of incision also introduces a mirroring and a variable scaling of the hand movements controlling the tip of the instrument, which should be compensated for by the surgeon (scaling and fulcrum effect)[14,15]. For example, complex surgical tasks like vascular anastomoses require hand movements with 6 or 7 DOFs. In open surgery the surgeon moves and rotates his arm and wrist simultaneously while holding the needle with a pair of tweezers in his hand. He is able to approach the tissue with the needle from the desired angle by using his wrist function, e.g. the tweezers in combination with the human hand have the full 7 DOFs. Furthermore, the surgeon is able to use both his hands working together in a natural and close relation to each other in a way the surgeon does not have to think about his hands movements. Together with the possibility of supporting his hands, this makes it possible to perform precise and complex surgical actions. With conventional endoscopic instruments with their limited number of DOFs in positioning makes it impossible to approach the tissue from different directions *(see figure 4.2. left)* and therefore almost impossible to perform precise and complex surgical actions. The handles of these long instruments force the surgeon to use his hands in an unsupported and unnatural posture with a larger distance to each other. The ergonomic quality of the laparoscopic instruments is relatively poor[16-20]. Due to the length and the orientation of the instruments the surgeon often has to work in an uncomfortable posture with extreme wrist positions.

Ideally medical instruments should be a natural extension of the human body[21,22]. Actions must be possible in an intuitive, comfortable and easy way, while feedback must be supplied such that forces and displacements containing feedback information are undisturbed and within the range of good sensitivity of the surgeon's hands. For intuitive control, actions of the surgeon must correspond to actions of the instrument (e.g. exerting force on a hand grip of a forceps should correspond to the pinching of the gripper, and movements of the surgeon's hands should correspond to identical movements of the gripper). As opposed to industrial applications, position servo control is undesirable due to hazardous force generation, and because it is unnatural for humans to interact with these servo systems. Force control is more appropriate and essentially more safe[23]. To maximize feedback, it is advantageous to make optimal use of the feedback present in the human body[22]. Therefore, body power is preferred over external force, such as electric or pneumatic power systems. As positive side effects, less complex and less heavy instruments result, without the burden of motors, sensors and electric wires. To use the feedback present, low friction mechanical solutions are required[10]. Alternatives for low friction designs are active friction (and inertia) compensation or teleoperation. These approaches allow adjustment of the transfer function, which may be useful for example in situations where operating forces are below the human sensory threshold, such as in microsurgery, and for filtering out tremor before the master's movement is transmitted to the slave unit. However, these master-slave systems are complex, there is a need for sensors that are suitable for sterilisation and are insensitive to disturbances and contact instability[24]. Mechanical design usually applies a kinematic perspective. Desired motion is taken as point of departure for the type and dimension synthesis of a linkage[25]. Awareness of forces seems to stimulate the design of simple and efficient mechanisms[25,26].

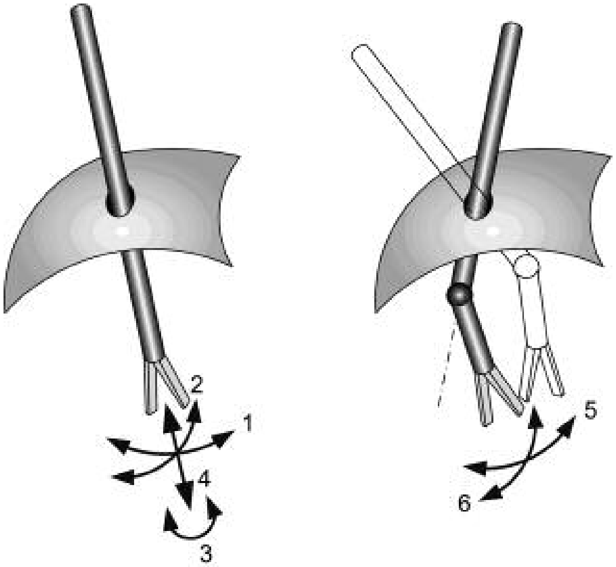

Figure 4.2. Conventional endoscopic instruments (left) have four degrees of freedom (DOFs); two rotations round the incision in the skin (DOF 1,2), the rotation of the instrument round its axis (DOF 3) and the in/out translation of the instrument (DOF 4). By adding two extra degrees of freedom (right), (DOF 5,6), the orientation of the instrument tip can be varied independently from the instrument shaft, enabling the surgeon to approach the tissue from different directions. The opening and closing of the instrument is the 7th DOF (picture by Mark Wentink).

4.3 Available instruments for M.I. cardiac surgery

A very complex and time-consuming action during surgery is the construction of a micro-anastomosis, e.g. in cardiac surgery or urology. To achieve this, movements in 6 or 7 DOFs are essential.

Endoscopic instruments with a full wrist function, or 7 DOFs, have been developed[27,28] with encouraging short term-results. These instruments enable the surgeon to approach the tissue from different directions *(see figure 4.2. right)* like instruments for open surgery. However, endoscopically sutured anastomoses, up till now, have not been feasible. The instruments of the recently introduced computer-assisted systems also enable the surgeon to approach the tissue from different directions. These "robotic" systems have enabled endoscopically sutured micro-anastomoses in coronary artery bypass grafting[6,7,8]. These systems were designed to translate the surgeon's hand movements in 6 or 7 DOFs to those of the endoscopic instruments tip maintaining the same spatial relation *(see figure 4.3.)*.

The wrist movements of the surgeon's hands are translated, in an intuitive way, to the movements of the instrument tip. These master-slave systems consist of three main components: a computer controller, a surgeons interface device (master), and specially designed instruments attached to the robotic arms (slave). Two robotic microsurgical systems that are currently being used clinically are the ZEUS® robotic surgical system (computer Motion Inc., Goleta, CA, USA), which is no longer available on the market, and the *da Vinci*® telemanipulation system (Intuitive Surgical, Inc., Mountain View, CA, USA) [4]. Both systems enable the surgeon to manipulate instruments in real-time on a remote operative field, linked by the computer system. The *da Vinci*® system has a high quality 3D visualisation, natural tremor is filtered and the instrument movements can be scaled in order to improve the surgeon's dexterity and ergonomics for micro-surgery. These systems, however, still have considerable limitations. They are too large for easy handling in a usual operating theatre and it takes a long time to set up the systems. The systems are intricate and require much tuning and maintenance. In addition they are expensive, both in purchase and in maintenance, and therefore most hospitals cannot afford these systems. Another limitation of these systems is the complete absence of force feedback, because the systems are position-controlled instead of force-controlled, the surgeon is not aware of the force that he is putting through the instrument tips at the tissues or the suturing materials. For safety reasons these position-controlled systems have limited forces and are therefore relatively slow. There is only visual information from the operation field.

In summary: The real benefits of these master-slave systems are the improved dexterity, because of the mechanical wrist function at the tip of the instrument, giving the system the full 7 DOFs. The combination with the intuitive and ergonomic handling of these devices, makes it possible to construct an endoscopic anastomosis. The benefits of the scaling possibilities, tremor filtering, and the telesurgery approach are not proven and in our opinion questionable. The complexity and the high costs of these systems seems a drawback for implementing these systems in routine surgery.

4.4 Design of the mechanical manipulator

Because of the complexity of the robotic devices and the less intuitive manipulation performance of the existing deflectable instruments, we decided to develop a mechanical manipulator for minimally invasive surgery (MIM), to fill the gap between normal endoscopic instruments and robotic manipulators.

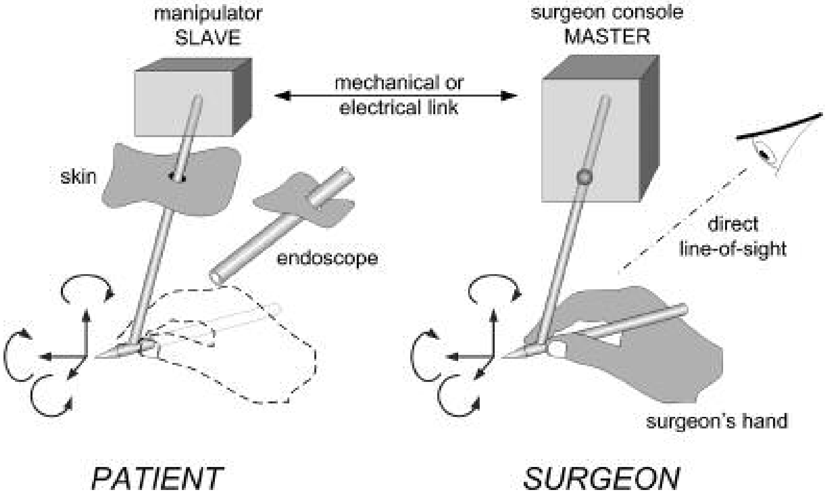

Figure 4.3. Schematic Master Slave system. The instrument tip as well as the surgeon's handle has six degrees-of-freedom in positioning. With a kinematic coupling between the handle and the tip, the instrument tip moves exactly in the same direction as the handle. This kinematic link can be implemented electronically (sensors, actuators, etc.) like in robotic devices, or mechanically (push bars, pulleys, etc.) like with a mechanical manipulator (*picture by Mark Wentink*).

4.4.1 Design criteria

In cardiac surgery suturing the anastomosis is the most complex surgical task and requires hand movements in 7 DOFs for both hands. To be able to construct minimally invasively an anastomosis with the manipulator, the system needs two endoscopic instruments with 7 DOFs at the tip *(see figure 4.2.)*. To reach the required 7 DOFs two extra joints are needed at or nearby the instrument tip. The kinematic requirements for the endoscopic instruments are adopted from literature[19] and from observations with M.I. (robotic) cardiac procedures. These requirements for the different DOFs are presented in table 4.1.

From literature[19,20] it is known that the forces needed at the instrument tip are about 5-10 Newton clamping force for grasping a needle and pulling and stretching tissue.

To provide an intuitive and ergonomic manipulation it is essential that the instrument is coupled by a mechanical link to the manipulator's handle in such a way that movement directions of the handle correspond to identical movement directions of the instrument tip in all DOFs *(see figure 4.3.)*.

Table 4.1. Manipulator workspace requirements.

DOF	reach
1 (rotation about incision)	± 90°
2 (rotation about incision)	± 90°
3 (rotation about instr. axis)	± 360°
4 (translation along instr. axis)	± 200 mm
5 (wrist deflection)	± 180°
6 (wrist deflection)	± 180°
7 (opening angle)	± 60°

In addition it is essential that the two handles of the devices have the same spatial orientation relative to each other as the instrument tips and that these handles can be placed outside the sterile area in a position that they can be manipulated in an ergonomic way by the surgeon.

Furthermore, to optimise the manipulation actions the surgeon should only have to activate the movements of the instrument without lifting its weight as well. Therefore the manipulators should be connected to the fixed world to lift its weight, and the activated movements of the devices should be balanced. To optimise force transmission and force feedback the devices should be lightweight to keep the inertia low, and the kinematical links should be stiff and with low friction. Finally the instruments of the device, which enter the patient's body, should be sterile and therefore it must be possible to decouple them from the manipulator for sterilization.

4.4.2 The mechanical manipulator

To copy the movements in 7 DOFs of the surgeon's hand to the corresponding movements at the instrument tip *(see figure 4.2. and 4.3.)* a connecting mechanism has been developed. For the copying of the movements of the first two DOFs a parallelogram mechanism has been chosen because of its slender and stiff design and the fact that it can copy two DOFs directly from the surgeons handle to the instrument tip *(figure 4.4.)*.

For the copying of the movements in the other 5 DOFs, steel pre-loaded wires (w) have been chosen because they can be easily guided through the parallelogram mechanism over its hinges, connecting the handle with the

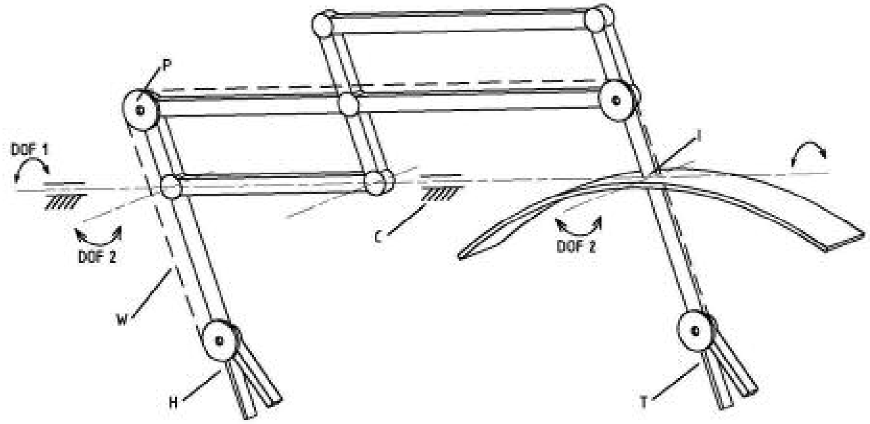

Figure 4.4. Schematic view of the Mechanical Manipulator. The movements of the handle (H) are transferred through the parallelogram to the movements of the instrument tip (T) round the incision (I) in the skin (DOF 1,2). The steel wires (W) for activating the other 5 DOFs are wrapped around pulleys (P) on the rotation axis of the mechanism in a way that the length of the wires is kept constant.

endoscopic instrument. These wires are wrapped around pulleys (p) positioned on the rotation axis of the parallelogram mechanism in such a way that, while moving the parallelogram mechanism, the length of the wires is kept constant and the movements in the other directions are not influenced. In total seven movement directions are copied. The next sections will first describe the different parts of the manipulator followed by how the movements of the 7 DOFs are activated.

Parallelogram

See figure 4.4. The manipulator consists of a parallelogram mechanism, which makes it possible to rotate an endoscopic instrument, coupled to this mechanism, about the incision (I) in the patient's body without a hinge located in the incision (DOF 2). The parallelogram mechanism itself can rotate about the main axis of the device (DOF 1), which passes through the incision in the abdominal wall. This main axis is coupled to the fixed world (C) (the operation table). On one side of the parallelogram mechanism the surgeon handle (H) is located, on the other side of the mechanism the endoscopic instrument is connected. By moving the handle in DOF 1 or DOF 2, the instrument tip (T) will follow these movements in identical movement directions.

Handle

See figure 4.5. The surgeon's handle is shaped like a pair of tweezers similar to the instruments used in open surgery. Because the handle-manipulator combination should allow movements in 7 DOFs, the handle itself should allow movements in 5 DOFs relative to the parallelogram mechanism. Therefore the handle consists of two handle parts (6h, 7h) that can individually rotate about the same axis (ah6,7), combining the deflection of the handle, when the two handle parts move in the same direction (DOF 6) with the opening/closing action of the handle, when the two handle parts move in the opposite direction (DOF 7). These two handle parts with their axis are coupled to a device (5h) that can rotate about an axis (ah5) (DOF 5), perpendicular to the axis where the handle parts rotate about (ah6,7). This combination is coupled to a shaft (3h), which can rotate about its own axis (DOF 3). Finally the complete handle combination is coupled with a linear bearing (4b) connected to the parallelogram mechanism, where it can move up and down (DOF 4).

Instrument

See figure 4.6. Like the surgeon's handle, the endoscopic instrument tip should also allow movements in 7 DOFs. Therefore the instrument grasper consists of two identical parts (6g, 7g) that can rotate individually about the same axis (ag6,7), combining the deflection, when the two grasper parts move in the same direction (DOF 6), with the opening or closing action of the instrument grasper, when the two grasper parts move in the opposite direction (DOF 7). To avoid a complex design of the instrument tip these grasper parts are coupled by a spring (s) pushing them in an open position. This way, only two steel wires (6w', 7w') are needed to activate the rotation or the closing of the grasper. These wires, which are guided over the rotation axis (ag5), connect the grasper parts (6g, 7g) to the two corresponding metal tubes (6t, 7t). By pulling on both tubes (6t, 7t) the grasper parts rotate in the opposite direction and the grasper will close (DOF 7). By pulling on one tube while releasing the other, the first part pushes the other part in the same direction, deflecting the instrument tip (DOF 6).
The grasper-spring combination can rotate about an axis (ag5), almost perpendicular to ag6,7. This deflection (DOF 5) is activated by a steel rod (5r), in combination with a lever (l), which deflects the tip by pushing the rod up and down. (*see figure 4.5.*)The instrument itself is coupled (3c) to one side of the parallelogram mechanism, where it can rotate about its own axis (DOF 3). Finally this instrument coupling-device (3c) is connected by a linear bearing (4b') to the parallelogram mechanism, where it can move up and down (DOF 4).

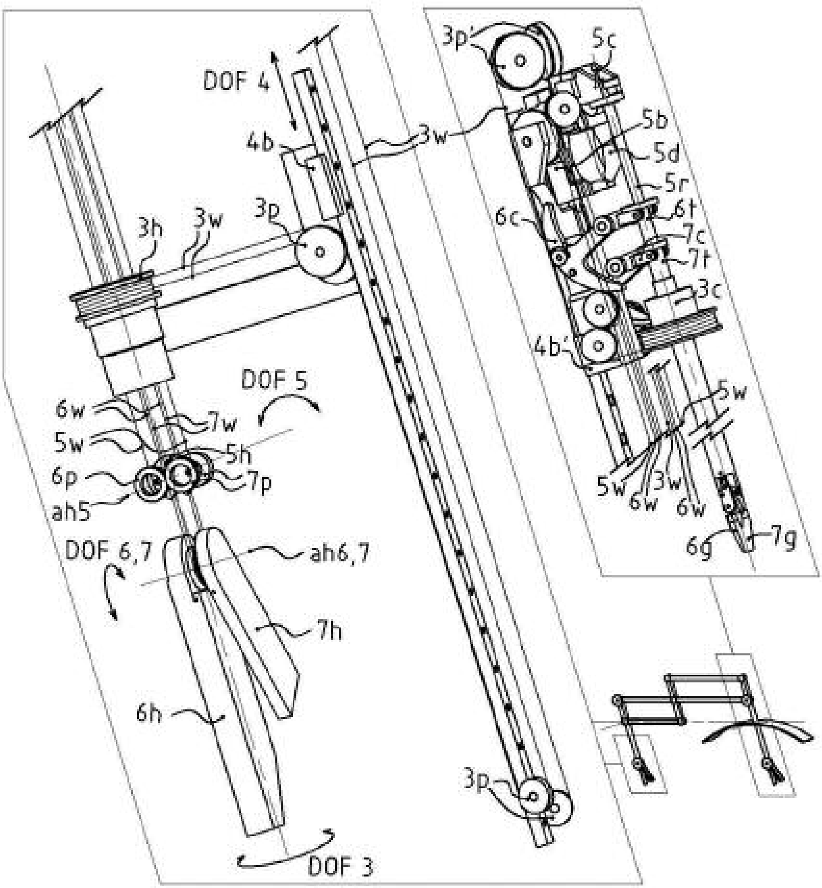

Figure 4.5. Schematic view of the handle and the instrument base of a manipulator showing the different movable parts and the way they are connected with wires. The abbreviation mark (1-7) of the different parts stands for the DOF in which they play a role. The abbreviation letter stands for the part they represent: h=handle, ah=handle axis, p=pulley w=wire, b=linear bearing, c=coupling device, d=disk, t=tube, r=rod and g=grasper part.

4.4.3 Mechanical transmission

Rotations about the incision (DOF 1,2)

See figure 4.4. The surgeon's handle (H) as well as the instrument is coupled to the parallelogram mechanism. Both the handle and the instrument tip (T) are at the same distance and in the same orientation to the rotation axis (DOF 1,2) of the device. So by moving the handle in these two DOFs, the instrument tip will move in the same direction.

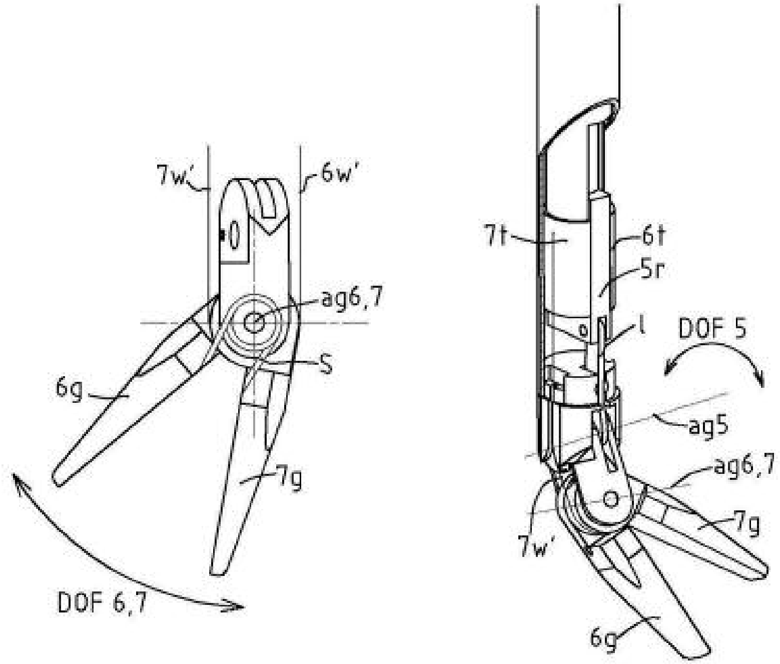

Figure 4.6. Detailed view of an instrument tip. The left picture shows how the deflection (DOF 6) and the opening and closing of the instrument tip (DOF 7) are combined, DOF 6 is when the grasper parts 6g and 7g move in the same direction and DOF 7 is when the grasper part move in he opposite direction. The right picture shows how these deflections (DOF 5-7) are activated. The abbreviation mark (5-7) of the different parts stands for the DOF in which they play a role. The abbreviation letter stands for the part they represent: ag=grasper axis, s=spring, l=lever, w'=wire, t=tube, r=rod and g=grasper part.

Rotation about the instrument axis (DOF 3)

See figure 4.5. A wire (3w) is wrapped around the handle's shaft (3h) and runs over a set of pulleys (3p) through the parallelogram to the coupling device (3c) of the endoscopic instrument where the wire is wrapped around again, to return to the handle's shaft (3h). By rotating the handle about its shaft, the wire forces the instrument to rotate about its axis too.

Translation along the instrument axis (DOF 4)

See figure 4.5. The handle is coupled to a linear bearing (4b) on which it can travel up and down. The rotation wire (3w) goes from the handles shaft down to the pulleys (3p) at the end of the linear bearing, then up again, through the parallelogram, then up to the pulleys (3p') at the end of the linear bearing (4b') on which the instrument is coupled and finally down to the coupling device (3c). By translating the handle upwards, the wire (3c) forces the instrument to translate in the same direction. The wires (5w-7w) go from the handle right up into and through the parallelogram to the coupling devices (5c-7c) on the linear bearing (4b'). By translating the handle downwards, the wires (5w-7w) force the instrument to translate in the same direction.

Deflection and opening or closing of the instrument tip (DOF 5,6,7)

See figures 4.5. and 4.6. For copying the movements of DOF 5, the handle part (5h) consists of a disk where wire (5w) is wrapped around. This wire goes through the mechanism to the coupling device (5c) on the linear bearing (4b'). This coupling device consists of a disk (5d) where wire (5w) is wrapped around. Another steel wire (5w') connects the disk with a small linear bearing (5b) which can be connected to the steel rod (5r) of the endoscopic instrument. The diameter ratio on the disk (5d) is chosen in a way that the rotation angle of the handle part (5h) is equal to the rotation angle of the instrument tip (5g). So by rotating the handle about axis (ah5) the wires force the instrument tip to rotate in the same direction about axis (ag5).

For copying the movements of the DOFs 6 and 7, the handle parts (6h, 7h) are connected to disks where the wires (6w, 7w) are wrapped around. Supporting pulleys (6p, 7p) lead these wires over the rotation axis (ah5) of the deflection of DOF 5 and through the mechanism to the corresponding coupling devices (6c, 7c) on the linear bearing (4b'). The coupling devices 6c and 7c consist of levers, which are on one side connected to the corresponding wire (6w, 7w) and on the other side can be coupled to the disks on the corresponding tube (6t, 7t) of the endoscopic instrument. The lever ratio is chosen in a way that the rotation angle of the handle part (6h, 7h) is equal to the rotation angle of the corresponding grasper part (6g, 7g). So by rotating the handle parts, the wires force the instrument graspers to rotate in the same direction about axis (ag6,7).

Balancing

For good manipulation capabilities and optimal force feedback it is essential that the surgeon only has to activate the movements of the endoscopic instrument without lifting the weight of the manipulator as well. For this reason the manipulator is coupled (C) to the operation table carrying its weight *(see figure 4.7.)*. For the same reason the movements of the

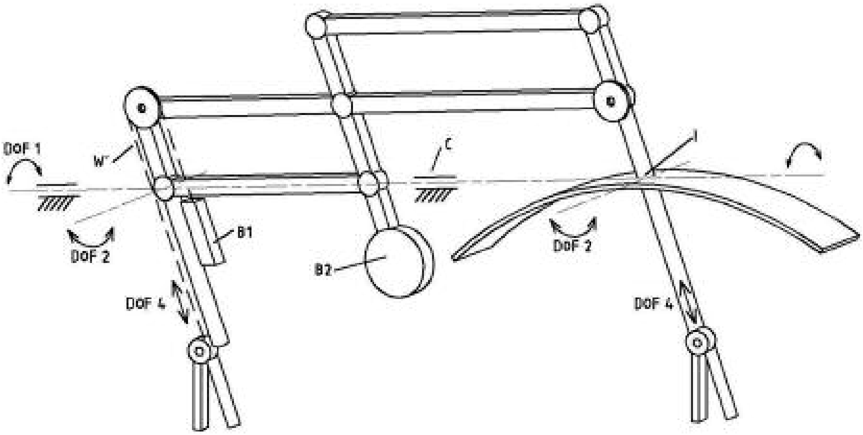

Figure 4.7. Schematic view of the way the manipulator is balanced. A counterweight (B1) is balancing the weight of the handle and the instrument of the manipulator, for the translation movements (DOF 4). The other counterweight (B2) is balancing the rotations about the incision (DOF 1,2).

parallelogram mechanism (DOF 1,2) and linear (up/down) movement of the device (DOF 4) are statically balanced. For balancing the weight of the handle and instrument for the linear movement (DOF 4), a counterweight (B1) is placed on an additional linear bearing close to the bearing (4b) on which the handle is coupled. This counterweight is connected with a wire (W2) to bearing (4b). By pushing the handle and the instrument up, the counterweight is forced down and vice versa. Due to this counterbalance the centre of mass is now at a fixed position and not dependent on the linear position of the handle and instrument (DOF 4). A second counterweight (B2), which is connected to one of the links of the parallelogram mechanism, positions the centre of mass exactly in the rotation axis of the manipulator, balancing the rotations (DOF 1,2) about the incision (I) in the patients' skin. The other movements (DOF 3,5,6,7) are not balanced, because these rotation movements are local and the handle and the instrument tip have a light weight.

Stiffness

The links of the manipulator are designed to be stiff and the joints are designed to have low friction, to optimise force transmission and force feedback. Hereto every hinge and pulley has a ball bearing. Special attention has

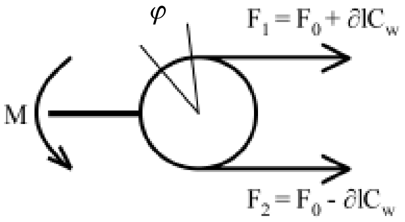

Figure 4.8. Schematic representation of a handle disk in combination with preloaded wires.

been given to the stiffness of the wire transmission, which activates DOFs 5, 6 and 7, the delicate movements of the instrument's tip. The wires are wrapped around disks located in the handle parts. The preloaded wires run from the handle disks through the manipulator to the levers connected to the instrument base and then return to the handle disks. The free ends of the wires are modelled as springs that have a stiffness k_w and are preloaded by a force F_0. The free ends are assumed fixed, in order to investigate the parasitic compliance in the transmission. If the wire is wrapped around a disk with a radius R, the torque on the disk required for a rotation φ of the disk *(see figure 4.8.)* is:

$$\mathbf{M = F_1R - F_2R = (F_0 + k_wu)R - (F_0 - k_wu)R} \quad (1)$$

where u is the cable travel, related to the rotation by $u = R\varphi$. As long as $F_0 - k_wu > 0$, the preload F_0 can be eliminated:.

$$\mathbf{M = 2k_wuR = 2k_w\varphi R^2} \qquad (2)$$

The rotation stiffness of the disk-wire combination becomes:

$$\mathbf{k_{rot} = M/\varphi = 2k_wR^2} \qquad (3)$$

This way, a double stiffness is obtained as long as the preload of the wires is larger than the activation forces. The diameter of the handle disks is 16mm, and the wires have a diameter of 0.7mm. Disks with a larger diameter should have made the handle bulky and wires with a larger diameter are too stiff to be guided smoothly over the supporting pulleys.

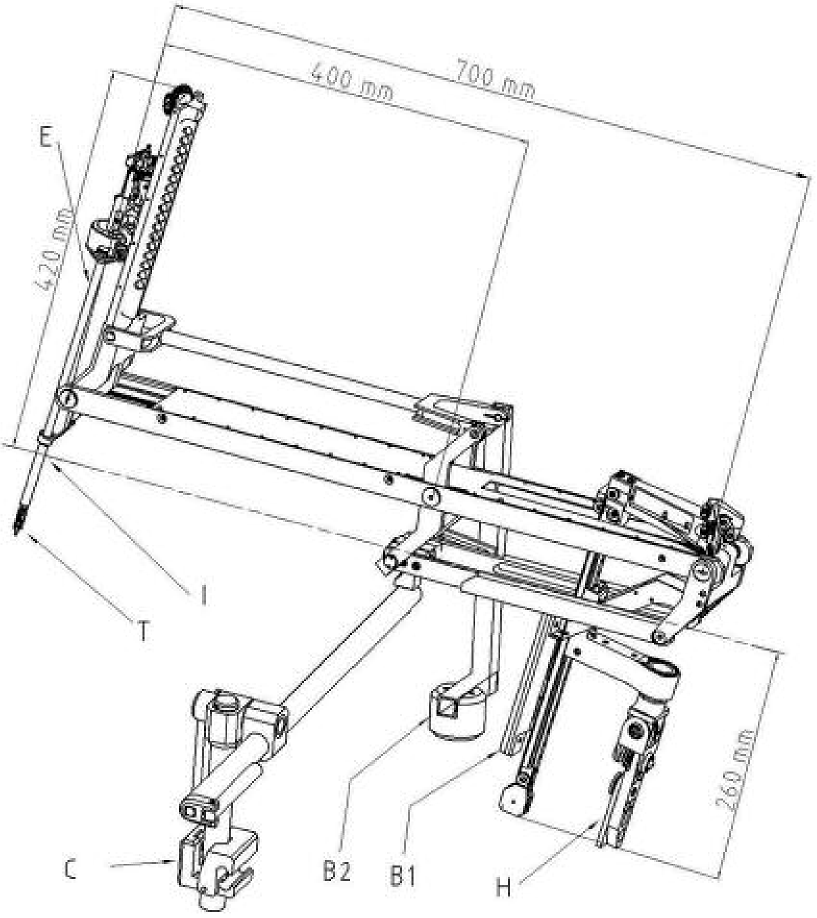

Figure 4.9 CAD drawing of the Mechanical Manipulator. The drawing shows the parallelogram mechanism with its main dimensions and the other essential part of the device: H=handle, E=endoscopic instrument, T=tip of instrument, I=incision in the patient's body where the instrument can rotate about (DOF 1,2), C=coupling to the operation table rail, B1=counterweight for balancing the translation movement (DOF 4) and B2=counterweight for balancing the rotations about the incision (DOF 1,2)

4.5 Results

A set of prototypes has been produced and functions properly; each of the seven DOFs can be copied from the handle to the instrument tip. A CAD drawing of one of the two prototypes of the manipulator is given in figure

Table 1. Manipulator test results

Conventional Endoscopic Instr.			**Mechanical Manipulator**		
DOF	Friction	Stiffness	DOF	Friction	Stiffness
1	-	0.2 N/mm	1	0.08 Nm/0.4 N	1.1 N/mm
2	-	0.2 N/mm	2	0.12 Nm/0.6 N	7.1 N/mm
3	0.007 Nm	2.6 Nm/rad	3	0.04 Nm	7.2 Nm/rad
4	1.2 N	200 N/mm	4	3.5 N	7.1 N/mm
			5	0.01 Nm	1.2 Nm/rad
			6	0.03 Nm	1.5 Nm/rad
5*	0.008 Nm	22 Nm/rad	7	0.04 Nm	1.8 Nm/rad

* The opening and closing of a conventional endoscopic instrument is the 5th DOF. It should be compared with the 7th DOF of the manipulator instrument.

4.9., with its main dimensions and the essential parts, which have been given the same marks as in the concept drawings of figures 4.4. and 4.7. Most parts of the manipulator are made of aluminium. One manipulator, including counterweights and endoscopic instrument, weights 5,5 kg. A conventional endoscopic instrument weights 100-250 grams.

The mechanical properties of a conventional 5mm endoscopic instrument as well as the properties of the first prototype are presented in table 4.1., where the technical results for the friction and stiffness are given for each DOF separately.

The measured force or torque needed at the handle to activate the movements of the instrument, without a reaction force on the instrument tip, gives an indication of the friction in the device. This friction is measured for each DOF by positioning small weights on the corresponding handle parts until the handle or the parallelogram mechanism starts moving.

The measured bending of the instrument handle under force while the tip is fixated, gives an indication of the stiffness of the device. This stiffness is measured for each DOF by positioning a weight on the corresponding handle part while measuring the deflection of the different handle parts or the parallelogram mechanism itself. Note that the

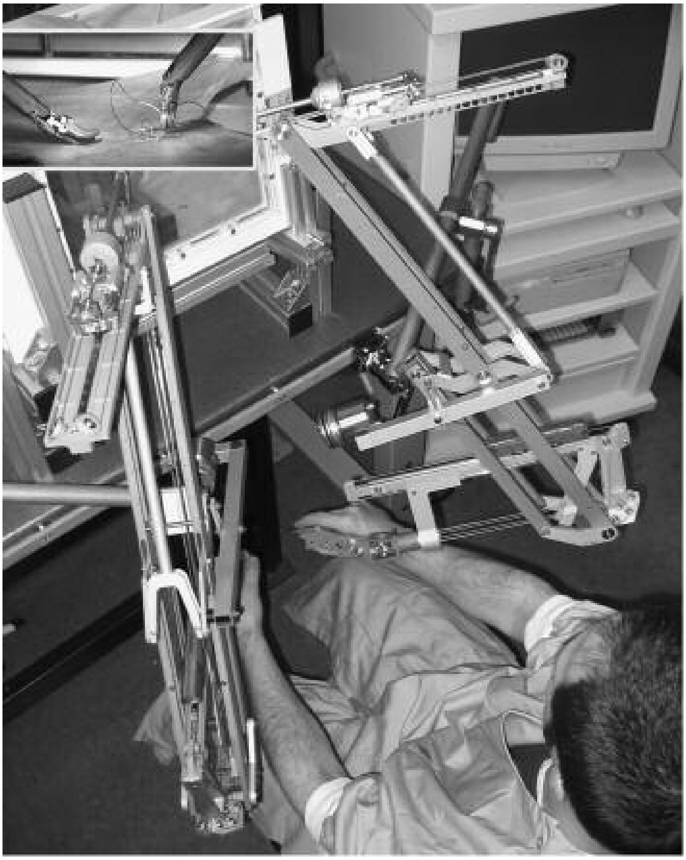

Figure 4.10. Prototype of the Mechanical Manipulator. The two manipulators are connected in an orientation to each other so that the surgeon can manipulate the handles of the device in an intuitive and ergonomic way. The inset shows the tips of the endoscopic instruments that are connected to the manipulator.

measurements of the conventional instrument are executed with a 5-mm instrument only and that the measurements of manipulator are executed with the whole device including the endoscopic instruments, which have a diameter of 8mm.

The specially developed endoscopic instruments can be coupled to the instrument base of the manipulator. In this way, instruments with different end-effectors can be applied.

4.5.1 Use of the device

Figure 4.10. shows a set of balanced manipulators in a phantom set-up coupled to an operation table rail with adjustable supporting arms. By positioning the devices in the proper orientation, the surgeon can have an ergonomic posture with his hands close to each other. It is even possible for him to sit on a chair. Although the device also has a pivot point in the incision, like other endoscopic instruments, the fact that the instrument as well as the handle can deflect, allows the surgeon to manipulate the device like an instrument for open surgery. The manipulator transfers the surgeon's hand movements mechanically to the instrument tip in a one-to-one ratio, allowing all 7 DOFs, without scaling and without mirroring effect, just as in the "robotic systems". This way, the handle and the instruments tip maintain the same spatial relation, e.g. handle and tip always remain parallel.

4.5.2 Phantom experiment

To test the devices, surgeons with and without endoscopic or robotic surgical experience were invited to perform some experiments. They performed pick-and-place experiments in a phantom set up under endoscopic conditions with the MIM and with conventional endoscopic instruments. The experiments were designed in such a way that the surgeons needed all 7 DOFs most of the time. This preliminary test showed that the system is functional. Most surgeons indicated that the manipulation with the device is intuitive. The friction for the translation movements was judged too high, however, and that they miss the 3D visualization, which was judged essential for delicate surgical tasks. Furthermore, positioning the instrument tip in maximal deflection and rotation leads to a non-ergonomic grip on the device's handle. Surgeons with experience in robotic surgery, used to work with instruments with additional DOFs, appreciated working with the manipulator more than surgeons with only experience in open or conventional endoscopic surgery.

4.5 Discussion

The Minimally Invasive Manipulator (MIM) is an example of a passive mechanical endoscopic instrument with the degrees of freedom of the human hand. With the MIM the surgeon does not have to stand up with his hands in a non ergonomic position, he does not have to manipulate long endoscopic instruments with only 4 DOFs in positioning and he does not have to adapt to the mirroring effect due to the incision in the patients

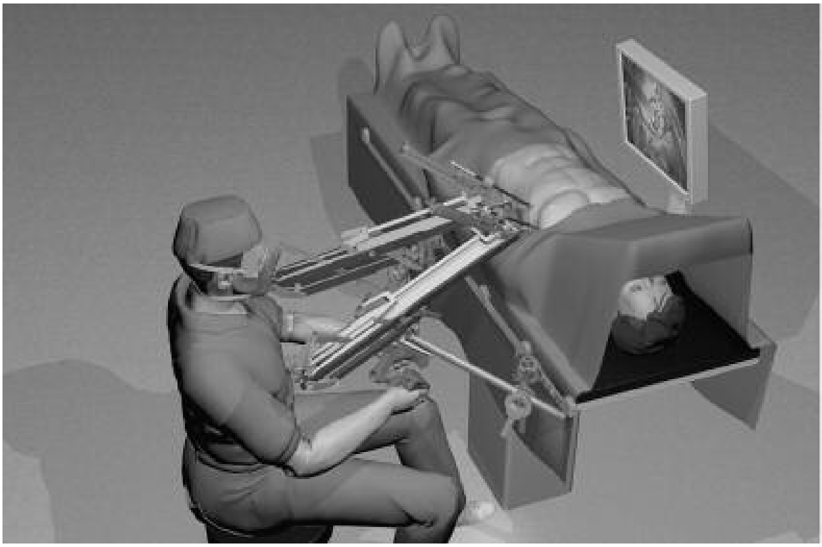

Figure 4.11. Concept of a set of Mechanical Manipulators in a clinical setting. The two manipulators are orientated relative to each other such that the surgeon can manipulate the handles of the device in an intuitive and ergonomic way, while sitting on a chair (A holder for the endoscopic camera is not drawn here)(*picture by Rogier v.d. Pol*).

body. The MIM improves the ergonomics for the surgeon. The surgeon can sit comfortably on a chair with supported hands and with his hands positioned in a natural orientation to each other *(see figure 4.11.)*. This provides him an improved eye-hand co-ordination, intuitive manipulation and an ergonomic posture[16,18]. Using for the endoscopic camera a passive holder[29,30], together with a properly placed monitor in line with his camera, the surgeon also will be able to manipulate his own viewing direction.

The test results show that the friction and elasticity for most DOFs are low enough when compared to a conventional endoscopic instrument. The friction for the translation movements (DOF 4) of the manipulator should be reduced, however. The stiffness of the wrist function and the grasping function (DOFs 5,6,7) should be increased. Although the manipulator is completely balanced, the total mass (5,5 kg) should be reduced to lower the inertia of the system and improve precise manipulation.

Using an actuated approach with force sensors and motors could have been chosen to reduce the inertia and the friction in the system. We believe, however, that an actuated solution would make the manipulator unnecessary complex and expensive. It should only be considered when mechanical solutions are not satisfactory. As surgical actions are executed in a precise and slow manner, the dynamic behaviour of the manipulator is of less importance.

Experiments with suturing tasks will be performed in the near future. Pick-and-place experiments in an experimental set up showed that the system is functioning well. The handles should be redesigned, however, to further improve the ergonomics in the extreme handle positions and the instrument tips should be reshaped for optimal needle handling. We believe that phantom, cadaver and animal experiments will show that complex surgical tasks like endoscopic suturing with the MIM are possible. Working with new instruments always implicates a learning curve in which the surgeon is getting familiar with an instrument and can adept to a new way of manipulation. Activating the manipulator is similar to activating a surgical robot, therefore, surgeons with experience in robotic surgery with quicker adept to working with the manipulator than surgeons with experience in open or conventional endoscopic surgery only.

In this study we focused only on the manipulation aspects of minimally invasive surgery and not on the visualization aspects. We used, for the first phantom experiments, a standard laparoscopic experimental setting with a 2D monitor. Experiments with other types of visualization, e.g. 3D monitors, projection screens or head-up-displays will be evaluated in the near future. Hopefully, the MIM will be an economical alternative for robotic manipulators, making a more general use feasible. Mechanical manipulators may improve the efficacy and efficiency of minimally invasive surgery. Avoiding disturbed eye-hand co-ordination may reduce learning curves and improve the acceptance of MIS.

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CHAPTER 5

THE MINIMALLY INVASIVE MANIPULATOR; AN INSTRUMENT IMPROVING THE PERFORMANCE IN STANDARDIZED TASKS FOR ENDOSCOPIC SURGERY.

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Diks J, Jaspers JEN, Wisselink W, Grimbergen CA.
The Minimally Invasive Manipulator; an instrument improving the performance in standardized tasks for endoscopic surgery.

Summary

Objective: *To evaluate the feasibility and efficacy of a mechanical minimal invasive manipulator (MIM) for endoscopic surgery. The MIM consists of two purely mechanical, hand-controlled endoscopic arms with joints, which allow 7 degrees of freedom (DOFs).*

Methods: *30 medical students performed 4 different tasks in a pelvic trainer box. with two conventional endoscopic needle holders or with a set of MIMs. The exercise consisted of 4 different tasks: repositioning coins, rope-passing, passing a suture through rings and tying a surgical knot. All experiments were recorded on videotape (S-VHS) and data was analysed afterwards by an independent observer using a quantitative time action analysis.*

Results: *A significant difference between numbers of total actions (including failures) was shown in most exercises in favour of the MIM-group. A significant difference in failures per task was shown in favour of the MIM-group as well. There was no significant difference shown in matter of total time per exercise.*

Conclusion: *These tasks clearly demonstrated the efficacy of the MIM, even though some technical flaws emerged during the experiments. Considering the fact that a first prototype of the MIM was tested, modifications are to be expected in a next model. These experiments show the potential of the MIM and it is expected to be a competitive and economical instrument for endoscopic surgery in the near future.*

5.1 Introduction

The purpose of endoscopic surgery is to reduce surgical trauma to patients, resulting in less operative morbidity, faster recovery, and reduction in costs[1,2].

Recently introduced robotic surgical systems have facilitated complex endoscopic surgery, such as micro-anastomoses in coronary artery bypass grafting[3,4] and aortic anastomosis[5,6]. These systems were designed to translate the surgeon's hand movements to the tip of the endoscopic instrument in a remote operative field, using a computer assisted Master-Slave system *(see figure 5.1.)*. Advantages of these systems are the 3D visualisation and the inclusion of a "wrist" at the end of the instruments, providing articulated motion in 7 degrees of freedom (DOFs): three translations, three rotations and the opening/closing action[7]. The wrist movements of the surgeon's hands are translated to the movements of the instrument tip, maintaining the same spatial relation.

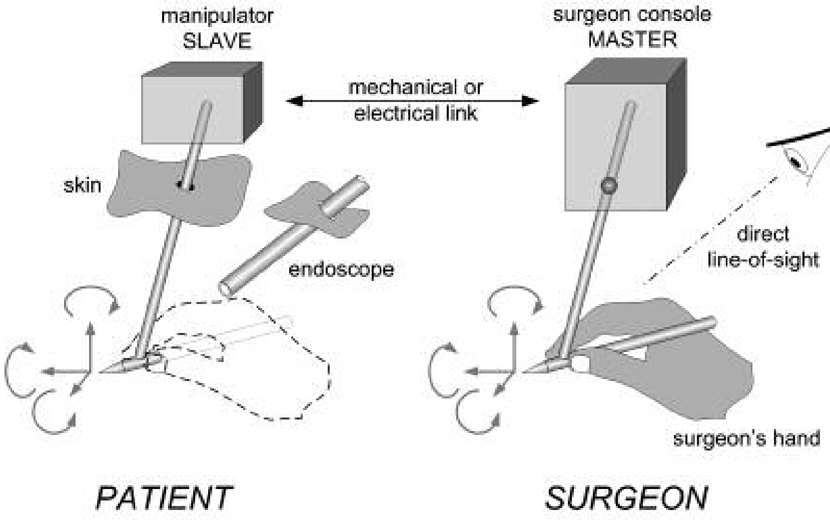

Figure 5.1. Schematic Master Slave system. The instrument tip as well as the surgeons handle has six degrees-of-freedom in positioning. With a kinematic coupling between the handle and the tip, the instrument tip moves exactly in the same direction as the handle. This kinematic link can be implemented electronically (sensors, actuators, etc.) like in robotic devices, or mechanically (push bars, pulleys, etc.) like with a mechanical manipulator (*picture by Mark Wentink*).

However, these robotic systems still have considerable limitations. They are large and bulky and they are expensive. Another limitation of these systems is the lack of force feedback[8,9,10]. The feedback from the operation field consists of visual information only. Lowering the costs and making the system more manageable are mandatory for these systems to become a standard tool for endoscopic surgery.

In an attempt to overcome some of the above mentioned limitations of robotic systems, a minimally- invasive manipulator (MIM) was developed. The MIM is a small, economical and mechanical alternative for robotic surgical systems. It consists of a balanced parallelogram mechanism on which a deflectable endoscopic instrument is attached at one end and at the other end a surgeon's handle. Instead of an electrical link, the instrument and handle are connected by a mechanical link *(see figure 5.1.)* in such a way that movement directions of the handle correspond to identical movement directions of the instrument tip in 7 DOFs. In addition, with a set of two of these devices, the two handles have the same spatial orientation relative to each other as the instrument tips and therefore can be manipulated by the surgeon in an intuitive and ergonomic way *(see figure 5.2.)*.

Figure 5.2. The Mechanical Manipulator in the experimental set-up. The picture shows two parallelogram mechanisms coupled to the table rail. The inset shows that movement directions of the handle correspond to identical movement directions of the instrument tip in all DOFs

First phantom experience indicated that the system functions properly and that suturing is feasible[11]. To test whether working with the MIM is indeed more intuitive and the extra DOFs are advantageous to working with conventional endoscopic instruments, it was necessary to define simple and reproducible manipulation experiments in which these extra functionalities would play a role. These experiments were subsequently used to compare manipulation with conventional endoscopic instruments to working with the MIM.

5.2 Methods and Materials

30 medical students, all without any surgical experience, performed four different experiments in a trainer box. Defined actions and failures per experiment are presented in table 5.1. The participants were randomized to perform the experiments either with two conventional endoscopic needle holders (Karl Storz, Tuttlingen, Germany) or with a set of MIMs. All experiments were performed with the instruments positioned in the same orientation to the target area for both groups. The endoscope was positioned in a holder (PASSIST)[12] in between the instruments, parallel to the surgeon's natural line of sight[13]. A 10mm 0° stereoscopic endoscope and 3-D camera (Carl Zeiss Ltd., Oberkochen, Germany) in combination with a Cardio View Head-Up-Display (HUD) (VISTA Medical Technologies, Inc., Carlsbad, CA, USA) *(see figure 5.2.)* was used in all experiments to provide the subjects with a stereoscopic image, which is claimed to be beneficial when using instruments with additional degrees of freedom[7]. Before starting each experiment, the participants had a one minute period to become familiarized with the setup.

Experiment 1: repositioning coins

This was a simple pick and place experiment. A 1-Eurocent coin had to be taken out of a receptacle with the left-hand instrument. The coin was to be presented to the right-hand instrument and subsequently the subject was to put the coin into a second receptacle. This sequence of picking up, passing over and dropping was repeated two times. Consequently, the same order of sequences was repeated, starting with the right-hand instrument. Unintentional or incorrect dropping of a coin was counted as a failure. The number of defined actions was counted and the total time was recorded from picking up the first coin to dropping the last coin into the last receptacle.

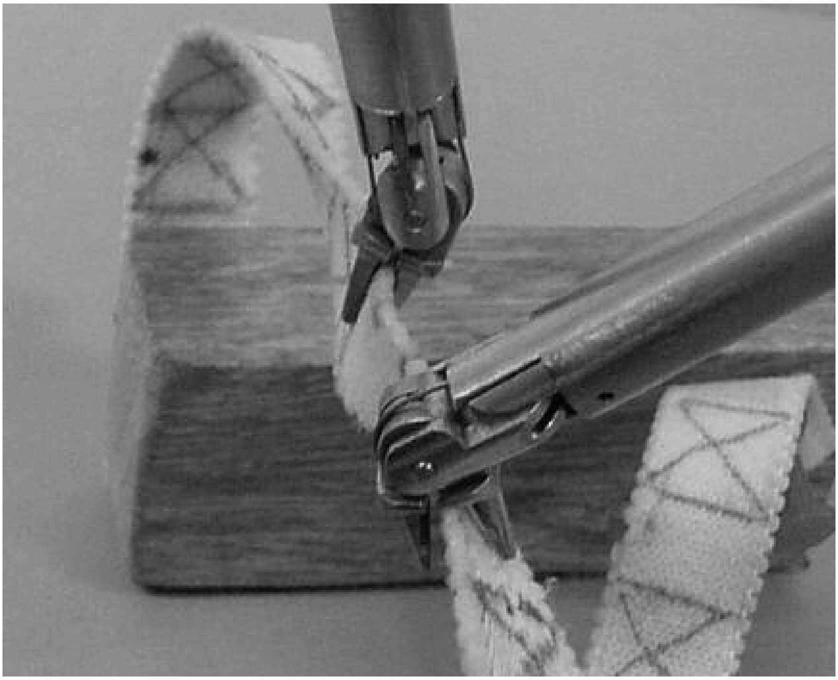

Figure 5.3. Experiment 2: rope-passing, manipulating a marked band with two instrument by grasping it at same side (MIM experiment)

Experiment 2: rope-passing

In this experiment the two instruments had to work together during manipulation. A marked rope (25x0.3cm) had to be alternately grasped with the left and the right instrument at indicated points, while keeping the rope above the floor of the training box. The rope was fastened at both ends and had 11 predetermined, marked grasping points. The rope had to be passed-through twice, once grasping the rope with both instruments on the same (left) side and once grasping the rope on both sides, on the right side with the right instrument and on the opposite (left) side with the left instrument. Grasping without touching the rope, grasping the printed lines in between the marked areas or dropping the rope was counted as a failure. Time from picking up the rope to total run-through was recorded and the number of defined actions was counted *(see figure 5.3.)*.

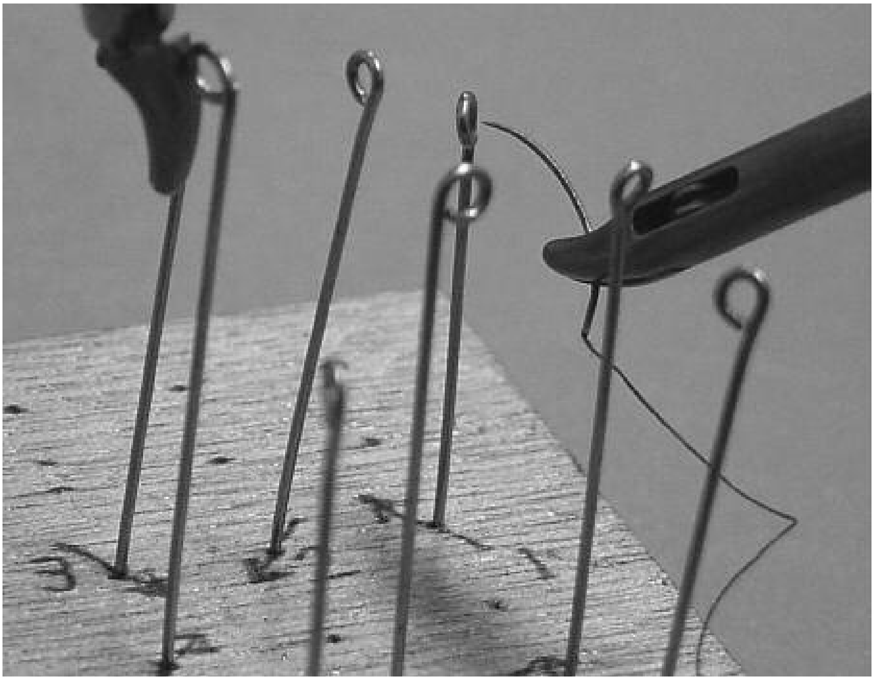

Figure 5.4. Experiment 3: passing a suture through rings, following a predefined path (Lap. Experiment)

Experiment 3: passing a suture through rings

The purpose of this task was to pass a surgical needle with a piece of suture (Prolene® 4-0) through eight rings, following a preindicated direction. Failures were determined as dropping the needle, 'floating' the needle in a ring without grasping it, grasping without touching the needle, not following the indicated direction, missing the ring with the needle-point and passing the ring only halfway. Total number of actions and the time from first grasping the needle to totally passing the last ring was recorded *(see figure 5.4.)*.

Experiment 4: tying a surgical knot

A suture (Vicryl® 3-0) was used to tie a surgical knot, consisting of one knot using two forward loops followed by one knot using a backward loop. The scored failures were 'mislooping' the suture, grasping without touching the suture and pulling the suture without passing the loop. Total number of actions as well as total time necessary to complete the task was recorded.

Analysis

All experiments were recorded on videotape (S-VHS) and data was analysed afterwards by an independent observer using a quantitative time action analysis to determine the efficacy, counting the actions and the time needed per task. Failures were counted as a measure for efficiency. A quantitative time-action analysis was performed through which a measure of efficiency in time and actions was determined. Table 5.1. shows the definitions for actions and failures per experiment.

Table 1. Definitions of actions and failures for all exercises

Actions/failures	**Definitions**
Coins:	
Grasping coin	Grasping a coin
Lifting coin	Elevate coin from receptacle
Transferring coin	Move coin towards next receptacle
Hand over coin the other	Hand over coin from one instrument to
Dropping coin	Dropping coin correctly into receptacle
Unintentional dropping coin	*Unintentional dropping coin during exercise*
Incorrect dropping coin	*Dropping coin outside receptacle or into wrong receptacle*
Rope:	
Grasping rope	Grasping the rope on correct place
Dropping rope	Dropping rope
Misgrasping rope (out place)	*Grasping rope, but on wrong place*
Misgrasping rope (no rope)	*Grasping without touching rope*

Table 1. Definitions of actions and failures for all exercises (continued)

Actions/failures	Definitions
Rings:	
Grasping needle	Each grasping of the needle or suture during exer cise
Passing ring	Passing a ring
Dropping needle	*Dropping the needle during exercise*
Floating needle	*Dropping needle while passing ring; needle doesn't fall, but hangs in the ring*
Misgrasping	*Grasping without touching the needle*
Wrong direction	*Passing a ring in wrong direction*
Missing ring	*Moving towards ring without passing it*
½ Passing	*Passing the ring halfway and subsequently taking the needle back from ring*
Knot:	
Making loop	Making a loop with the suture
Grasping suture	Grasping the suture
Pull through	Pulling the suture through the loop
Mislooping	*Making a loop without success*
Misgrasping	*Grasping without touching the suture*
Mispulling	*Pulling the suture without passing the loop*

Statistical analysis was performed using SPSS 12.0.1 for Windows ^{tm}. A Mann Whitney *U* test was used to compare differences between both methods. Data shows medians of time and actions with the according range. A p-value of $<0{,}05$ was considered statistically significant.

5.3 Results

All participants successfully completed the experiments, although there were problems with 6 participants in the MIM-group, doing the knot-tying experiment (see Discussion).

Tables 5.2.-5.3. show the results of the time-action analysis. Table 5.2. shows the median time and range needed per experiment to complete the task. There was no statistical significance shown in time needed to complete each exercise. In table 5.3., median actions and range needed per experiment are shown per action, as well as the median failures and range per experiment. Table 5.3. and figure 5.5. show the median total of actions (including failures) and range needed per experiment.

There were significantly less actions recorded in the MIM group for all exercises, except for the knot-tying experiment.

Subanalysis of the different exercises showed that grasping actions were significant less in the MIM-group in the Coins exercise (exp. 1) and Rings exercise (exp. 3): median 7, range 6-13 vs. median 10, range 6-18 ($p=0.01$) and median 30, range 25-45 vs. median 38, range 22-99 ($p=0.03$). Failures were shown to be significantly less in the MIM-group in the Coins exercise (exp. 1) and Rope exercise (exp. 2) median 1, range 0-8 vs. median 5, range 1-12 ($p<0.001$) and median 1, range 0-8 vs. median 10, range 3-29 ($p<0.001$). In the Rings and the Knot experiments, no significant difference in failures was shown, although a trend was shown in the Rings experiment in favour of the MIM-group; median 16, range 5-31 vs. median 21, range 10-101 ($p=0.068$).

Table 5.2. Time (s) per exercise necessary to complete exercise (median)

	Laparoscopy (n = 15)		**MIM** (n = 15)		
	time	*range*	*time*	*range*	*p-value*
Coins	301	126 – 622	339	151 – 600	NS
Rope	393	183 – 890	349	144 – 581	NS
Rings	704	407 – 1320	814	506 – 1529	NS
Knot	211	68 – 804	237 (n = 9)	128 – 1395	NS

NS: not significant

Table 5.3. Number of actions necessary to complete exercise (median)

	Laparoscopy (n = 15)		**MIM** (n = 15)		
	actions (n)	*range*	*actions (n)*	*range*	*p-value*
Coins:					
Grasping coin	10	6 - 18	7	6 – 13	0.01
Lifting coin	9	6 – 16	6	6 – 13	0.01
Transferring coin	8	6 – 16	6	6 – 13	0.03
Hand over coin	9	6 – 18	6	6 – 14	0.04
Dropping coin	6	6 – 6	6	6 – 6	NS
Failures	*5*	*1 – 12*	*1*	*0 – 8*	*< 0.001*
total (incl. failures)	48	32 – 86	32	30 – 67	< 0.001
Rope:					
Grasping rope	22	20 – 36	21	21 – 23	NS
Failures	*10*	*3 – 29*	*1*	*0 – 8*	*< 0.001*
total (incl. failures)	35	24 – 64	23	21 – 31	< 0.001
Rings:					
Grasping needle	38	22 – 99	30	25 – 45	0.03
Passing ring	8	8 – 8	8	8 – 8	NS
Failures	*21*	*10 – 101*	*16*	*5 – 31*	*NS (0.068)*
total (incl. failures)	67	44 – 208	55	40 – 82	0.02
Knot:			(n = 9)		
Making loop	6	3 – 10	6	3 – 21	NS
Grasping suture	2	2 – 6	2	1 – 15	NS
Pull through	2	2 – 2	2	0 – 3	NS
Failures	*6*	*0 – 20*	*3*	*0 – 3*	*NS*
total (incl. failures)	15	7 – 35	10	6 – 73	NS

NS: not significant

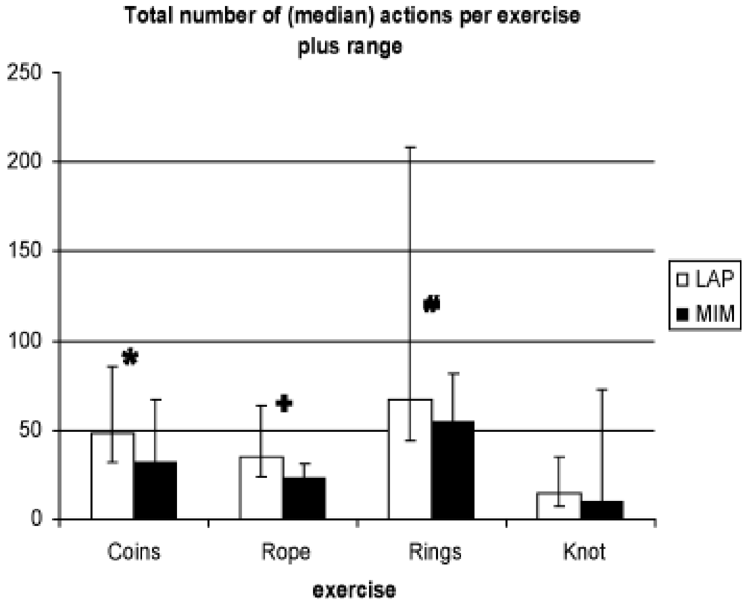

Figure 5.5. Total number of median actions (including failures) per exercise plus range *, + : $p < 0.001$, # : $p = 0.02$

5.4 Discussion

Endoscopic techniques are used for multiple surgical procedures, which mainly consist of resection tasks (such as cholecystectomy in general surgery). The design of endoscopic instruments was initially based on conventional surgical tools; they are long and have only four DOFs in positioning. These straight instruments have to pivot about a point of incision through the abdominal wall, which introduces a mirroring and a variable scaling of the hand movements controlling the tip of the instrument. This has to be compensated for by the surgeon (scaling and fulcrum effect)[14]. With conventional endoscopic instruments and their limited number of DOFs in positioning, it is impossible to approach the tissue from different directions and therefore it is almost impossible to perform delicate and complex surgical actions. The handles of these long instruments force the surgeon to use his hands in an unsupported and unnatural posture with a large distance to each other. The ergonomic quality of laparoscopic instruments is relatively poor[15,16]. Due to the length and the orientation of these instruments, the surgeon often has to operate in an uncomfortable posture with extreme wrist positions.

Furthermore, vision is two-dimensional; the image of an endoscopic camera is projected on a monitor. Largely due to these characteristics, the learning curves of MIS are long and steep[17,18] and especially in complex procedures its applicability has not yet been widely embraced.

In order to overcome various limitations in endoscopic surgery, robotic surgical systems have recently been introduced. These systems overcome problems such as difficult control, poor ergonomics, a poor view (2D) and limited DOFs in manipulation and other surgical tasks.

Although it seems these robotic surgical systems have their advantages and various series have been reported in which these systems have been successfully applied for clinical purposes[19,20], its disadvantages are not to be taken lightly. The systems are large and bulky, making them uncomfortable to move around in the operating room. Furthermore, the systems are expensive, both in purchase as in maintenance. These systems do not provide any force feedback, making the surgeon dependent of visual information only.

The MIM is a passive mechanical endoscopic instrument with the same DOFs as robotic systems, but with force feedback. When compared to conventional endoscopic instruments, the MIM improves the ergonomics for the surgeon, enabling him to position his hands in a natural orientation to each other, providing improved eye-hand coordination, intuitive manipulation and an ergonomic posture.

The conducted experiments were designed as simple tasks that can be executed in both groups, mainly due to the level of inexperience of our participants. They had to carry out the experiments with no surgical/endoscopic experience what so ever, to prevent a bias in the learning curve due to experience either in laparoscopy or robotic surgery. The experiments, however, were representative and resembled experiments used in the residents program for endoscopic surgery.

The set of MIMs was a first set of prototypes, and it was technically not yet perfected. During testing, technical flaws emerged, which will be corrected in a next prototype. The handles were noted not to be positioned quite favourably, which led to an additional amount of failures, such as dropping the needle in experiment 3. Furthermore, one of the MIMs showed excessive friction in one degree of freedom (in-out), which made it harder to manipulate in a small range, such as experiment 3.

In the knot tying experiment, another flaw of design was noted; 6 participants endured trouble in sliding a loop from one of the instruments. The joints at the tip of the instruments are not protected in the design, making it an easy trap for a piece of suture to get caught in. This happened in 6 of the 30 cases and it showed to be nearly impossible to get the suture out

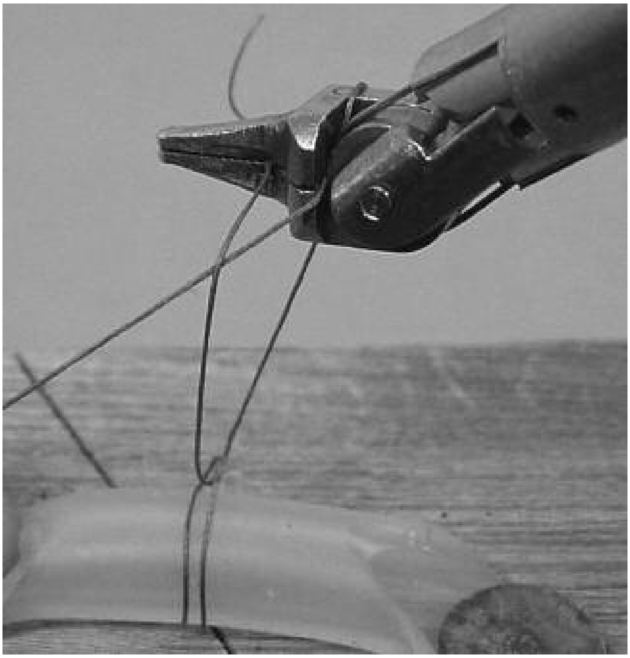

Figure 5.6. Experiment 4: knot-tying. A complication in this exercise is that with the MIM instruments, the suture is oftencaught in the grasper mechanism.

without damaging it *(see figure 5.6.)*. The above mentioned observations were very enlightening and will most certainly be considered in building a new set of prototypes.

Even with the above mentioned limitations of the MIM, it is shown that an additional number of DOFs in an endoscopic instrument is favourable. Although there was no difference in time in the experiments, there was a significant difference in the amount of actions and failures in the first 3 experiments. In the laparoscopy group, extra regrasping actions were needed to reposition the coin, rope or needle inside the grasper tips to be able to fulfil the exercises, leading to extra failures as well. The extra DOFs in the MIM group facilitated the exercises, because the coins, rope and rings were accessible from different angles. As a result, the participants needed fewer actions and had a smaller number of failures when compared to the laparoscopy group.

Considering the modifications that are to be expected in a next set of MIMs, it has been shown that the instrument has potential. By comparing the MIM with robotic devices in a experimental or clinical setting, it is expected to be a competitive and economical instrument for endoscopic surgery in the near future.

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CHAPTER 6

DISCUSSION

6.1 Introduction

Complex procedures in minimally invasive surgery (MIS) have evolved relatively slowly over the past years. Though the benefits of endoscopic surgery - shorter recovery times and less pain and trauma for the patient, lower costs and less time absence from work - are widely applicable across a range of procedures, realisation of those benefits beyond the relative simple gallbladder removal proved difficult. For more complex procedures, MIS actually proved problematic for surgeons, notwithstanding its benefits for the patient: longer procedure times, more difficult manipulation of instruments, more torturous ergonomics, the absence of a dedicated surgical team and a long learning curve. These drawbacks and the higher cost of these procedures (OR-time, endoscopic equipment and disposables) do not stimulate hospitals to invest in MIS. We believe that important advances in technology are required to obtain renewed interest in complex minimally invasive procedures for surgery. Fortunately, many of these advances are now being pursued by many companies, for example in surgical robotics, image guided surgery, electrosurgery and surgical instrument design.

The objective of this thesis was to provide surgeons with simple tools, which at least partly fill the gap between the conventional surgical instruments and the highly technological robotic systems. We have developed and evaluated a number of surgical instruments, which provide the surgeon with direct and intuitive control of the endoscope and of the surgical instruments providing extra degrees of freedom relative to conventional endoscopic instruments.

When we started our research, approximately 6 years ago, the surgical robotic systems just entered the clinical arena with the first promising clinical results. Because of their novelty, these robotic systems gained a lot of attention in scientific journals (966 hits on PubMed with “robotic surgery”) and also in the more popular media (1.150.000 Google hits with “robotic surgery”). Studies showed that performing robot-assisted surgery is feasible; with a robotic camera holder the assistant could be replaced and with a Master-Slave telemanipulator complex surgery like endoscopic sutured anastomosis, have shown to be feasible. Even telesurgery has been demonstrated with a robotic telemanipulator, by performing surgery on a patient in Strasbourg (France) while the surgeon was performing the procedure in New York City (USA)[1]. Because of their initial positive clinical results, the robotic systems aroused high expectations, and many surgeons were eager to obtain a robotic system.

Although Robot-assisted surgery showed promising results, there was never a breakthrough up till now. Clinical studies with robotic camera holders did not show benefits for the patients in terms of reduced operation times, hospital stay or complications. Clinical studies with Robotic Master-Slave systems showed the feasibility of these systems for a number of complex endoscopic procedures[2,3], but evaluation studies comparing surgery using these systems with conventional surgery are rare and the ones available do not show real benefits for the patient or for the hospital. Because of their costs and their complexity, these systems are only in use in some of the larger, mostly academic, hospitals. Consequently, most of the advanced robot-assisted surgical procedures are still in their experimental phase and not in general use.

Looking at the available robotic surgical systems, they are in fact not more than systems that copy actions directly from the surgeon's hands. The systems do not perform any actions by themselves, automatically and autonomously like industrial robots do. Because of their design, information about instrument positions, movements and actions is measured for control reasons, but this information is not recorded and used in the control of actions. Therefore, these systems do not provide the surgeon with additional feedback, like navigation or evaluation tools. Even the advanced possibility for telesurgery or teleconsulting is hardly ever used. The experience of the last five years showed that robotic surgery will not become an alternative technique for most endoscopic procedures in the near future. Therefore it seemed a fruitful approach searching for more simple, mechanical alternatives.

6.2 PASSIST, a passive camera holder

The evaluation study with the different active and passive camera and instrument holders showed that passive camera holders appear to function as good as or even better than active camera holders. Passive holders that can be repositioned with one hand are the most comfortable ones according to surgeons. They indicate that using one hand (the dominant hand) for repositioning the camera, and therefore releasing one instrument, is not an important limitation because the surgeon is never dissecting when the camera should be moved.

The PASSIST (Passive assistant), a slender laparoscopic positioner, was designed for single handed repositioning, using a compensation spring for balancing the scope against the gravitational force and adjustable friction for maintaining the scope in the desired position. The PASSIST makes it possible for surgeons to perform solo-surgery using one or two of these holders. Whether it is desirable to actually perform laparoscopic surgery without an assistant is not investigated. If a surgeon, for example, needs to convert to an open procedure, he might need an extra pair of hands. The clinical trials indicate that this device is useful in different laparoscopic procedures except in those where frequent camera movements are required, such as diagnostic laparoscopic procedures.

The evaluation of the randomized trial showed that there was no change in total operation time and in the number of actions, using instrument positioners instead of a surgical assistant. Therefore instrument positioners could substitute a surgical assistant in MIS. This is especially relevant in the setting of a non-teaching hospital. In the teaching setting, residents frequently assist laparoscopic cholecystectomies as part of their surgical training program. Instrument positioners would deprive residents of this opportunity of learning laparoscopic skills. On the other hand, if a resident is operating with the positioners, the supervising surgeon can focus better on the training aspect, e.g. by pointing out structures on the monitor, because he or she does not have to attend the laparoscope.

The surgeons who have experience with the positioners preferred to operate with an instrument positioner over having a surgical assistant. The surgeons were able to concentrate more on their dissection task, because less attention was required to position the laparoscope and the gallbladder forceps or to guide the assistant. Of course these are subjective arguments and they did not result in measurable shorter operation times or better outcome for the patients.

Although the clinical results with the passive positioners were satisfactory, it also provided us with data, which we used to further improve the PASSIST. The installation of the arms on the operation table was not intuitive and time consuming and the friction in some of the joints of the device were hard to adjust. Also the compensation spring, which was located outside the mechanism, was not optimal, it was hard to clean and it was only compensating in one direction. Therefore, an improved design[4] was made, which resulted in a prototype, that is stiffer, has a compensation spring inside the mechanism and provides the surgeon with more flexibility in positioning the holders to the operation table, compared to the holders used in the clinical study. This new design is used for a commercial version

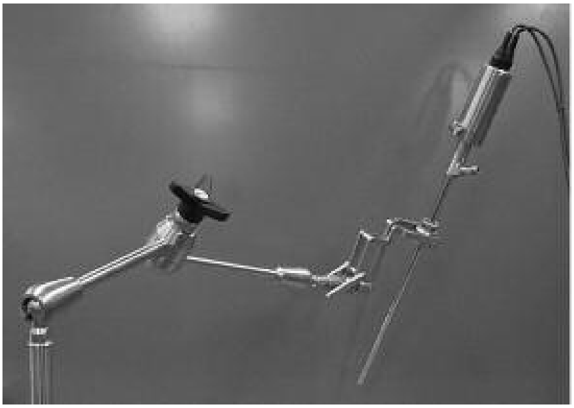

Figure 6.1. The commercial version of the PASSIST by Karl Storz, in combination with a Storz holding device (left).

of the PASSIST, which is planned to be brought out by Karl Storz in 2006 *(See figure 6.1.)*. Hopefully the number of PASSISTs sold within the next years will proof the benefits of this device.

6.3 MIM, a mechanical manipulator for MIS

Conventional endoscopic instruments have only four degrees of freedom (DOFs) in positioning and are not intuitive to manipulate because they have to pivot about the incision in the patient. Therefore, complex surgical tasks with these instruments are very hard to perform. The Minimally Invasive Manipulator (MIM) is an example of a passive mechanical instrument for MIS with the same DOFs (six) in positioning as those of the human wrist. The MIM improves the ergonomics for surgeons enabling them to sit comfortably on a chair with both their hands supported and in a natural orientation to each other. This way an improved eye-hand coordination, intuitive manipulation and an ergonomic posture is obtained. Although the MIM functions properly, there are still some shortcomings in the system which should be improved, such as the high friction in some DOFs and the ergonomics of the handle.

To give surgeons the impression manipulating instruments for open surgery, as was intended, it is important to have a system with low friction for every DOF. Because the friction for the translation movements (DOF 4) of the MIM is significantly larger (5-8 times) than, for example, the friction for the rotation movements about the incision (DOF 1,2), it is difficult to perform linear (orthogonal) movements with the manipulator. Therefore

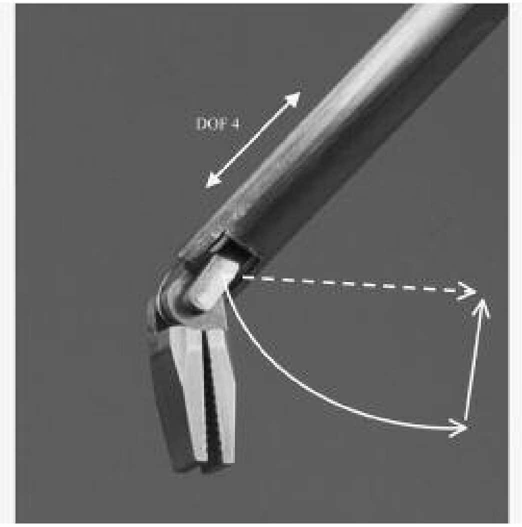

Figure 6.2. If there is too much friction in the linear movements of the manipulator (DOF 4); a linear (orthogonal) movement (dashed arrow) is performed by combining a rotational (polar) movement corrected by a linear movement (arrows). This will hamper activation of intuitive and precise movements.

most movements are more in a polar way about the incision corrected by separate activated linear movements in DOF 4 (*see figure 6.2.)*. The friction in all DOFs should be of the same level to make manipulation feel more like in open surgery and therewith improve the capability to perform complex manipulations. This can be achieved by reducing the friction in DOF 4 or by increasing the friction in the other DOFs.

In open surgery, surgeons hold their instruments (often a pair of tweezers) between their thumb and fingers, while making a suture. This way, they are able to rotate the pair of tweezers about its axis, not only by rotating their wrist, but also by rolling the instrument between the thumb and fingers. The current handle of the MIM-manipulator does not allow these rolling movements between thumb and fingers, hampering the surgeon in putting the needle through the tissue. Therefore a new handle has been designed, allowing the surgeon to roll the handle tip about its axis[5].

Experiments with manipulation tasks in a phantom set up showed that complex surgical tasks, like needle manipulation, are possible with the MIM. The study showed that fewer actions were needed and fewer failures were made to perform the experiments with the MIM than by performing the same experiments with conventional endoscopic instruments. The study was done with a stereo visual system (VISTA) including a Head-Mounted-Display to provide the surgeons with better depth information during their experimental tasks. Although not scientifically proven, surgeons who had experience in robotic assisted surgery (da Vinci® system) indicated that they needed 3D visual information to perform delicate 3D tasks[6]. A second advantage of a Head-Mounted-Display is that surgeons are able to hold their head in a neutral position like in open surgery, virtually looking at their hands, which improves hand-eye coordination. If a 3D endoscopic system is not available, the same situation can be reached with a flat (2D) panel display by positioning it in front of the surgeons' eyes roughly in between their head and their hands.

We did not show how the MIM performed in a cadaver, an animal or a clinical experiment. Therefore we are not sure yet if the present size and shape of the MIM is suitable to perform endoscopic procedures for a variety of disciplines, such as urology, cardiac surgery or general surgery. At present we have only developed needle holders for the MIM. To start (pre)clinical experiments with the MIM, also other types of instruments are needed, such as scissors, graspers and bipolar dissectors.

Although improved endoscopic instruments are essential to increase the percentage of endoscopic surgery, also economical and social factors are important. The new way of financing hospitals in the Netherlands, the DBC (Diagnose Behandel Combinatie) may stimulate hospitals to invest in new equipment and training facilities for endoscopic surgery. In the recent past a hospital was paid for the surgical procedure and separately for each day of the postoperative care. In fact it was financial beneficial for the hospital to perform the surgical procedure by open surgery, and to keep the patient in the hospital as long as possible. With the DBC-system a hospital is getting paid a fixed amount of money for the combination of diagnosis, surgical treatment and the postoperative care. This should stimulate the hospitals to make this combination as efficient as possible, e.g. an efficient surgical procedure in combination with a short hospital stay. The intended competition between hospitals, the publicity of the numbers and surgical outcome of the hospitals and more demanding patients, will force hospitals to invest in the best possible cure and care for the patients. This may also increase the percentage of endoscopic surgery, because endoscopic surgery has proven for many procedures to be advantageous for the patients.

Based on our findings and the social and economical stimulus, we believe that the PASSIST as well as the MIM may become an economical and user-friendly alternative for robotic devices, hopefully making more general use feasible. Mechanical manipulators may improve the efficacy and efficiency of minimally invasive surgery. By avoiding the need for compensating the mirroring effect and variable scaling of motion by the user, the length of learning curves may be reduced and the acceptance of endoscopic surgery could be improved substantially.

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CHAPTER 7

CONCLUSIONS, ONGOING AND FUTURE RESEARCH

7.1 Conclusions

The studies presented in this thesis aimed to develop and evaluate instruments for MIS that provide surgeons with simple tools, which are affordable and, which at least partly, fill the gap between conventional endoscopy and the highly technological robotic systems. This main objective is divided into the following sub goals, as mentioned in chapter 1:

1. To develop a mechanical camera holder and instrument holder for endoscopic surgery, which can be controlled by the surgeon him/herself.
2. To evaluate in a clinical study if these mechanical holders are of real use for the surgeons.
3. To develop a mechanical manipulator for intuitive control of endoscopic instruments with extra degrees of freedom. A manipulator that provide surgeons with the same natural dexterity and full range of motion as the robotic devices, but for an affordable price.
4. To evaluate if endoscopic surgery with the mechanical manipulator is feasible, by comparing the functionality of he manipulator to the functionality of conventional endoscopic instruments and robotic instruments.

1. The conclusion of chapter 2 of this thesis was that passive camera holders appear to function as good as or even better than the currently available active camera holders. Therefore the benefits of active holders are questionable in relation to the much simpler, smaller and cheaper passive designs. A passive holder is indicated as the retracting instrument because of the static task of retracting and because of safety. Therefore, passive holders seem to be the most cost-efficient solution for controlling the camera and holding instruments. For efficient use in MIS they should allow repositioning with one hand, have a braking system or have a balanced construction with adjustable friction.

   In the first part of chapter 3 the development and evaluation of a slender mechanical instrument and camera holder has been described. This resulted in a new prototype made out of stainless steel, which can be sterilized completely. One of the axes of rotation is spring loaded to compensate for the weight of the scope including the video camera and wiring. This balancing allows a low level of friction in the joints. With just one knob, the friction in all the joints can be varied, which gives the mechanism a variable resistance against movement, just enough to stabilize the instrument in a fixed position. To reposition the instruments the surgeon has to interrupt his surgical action to exert just a small force with only one hand to the positioner or the instrument itself. The instrument remains in the new position when the surgeon releases the instrument.

2. The evaluation study of the second part of chapter 3 of this thesis concluded that: the developed instrument positioner enables surgeons to perform laparoscopic cholecystectomy without a surgical assistant, replacing the surgical assistant with an instrument positioner does not result in a significant increase in time and in number of actions needed for laparoscopic cholecystectomy, the use of instrument positioners reduces laparoscope repositioning without significantly changing positioning accuracy and that surgeons subjectively prefer to operate with an instrument positioner instead of a surgical assistant.

3. In chapter 4 of this thesis we described the development of a manipulator that transfers the surgeon's hand movements mechanically to the instrument tip in a one-to-one ratio, allowing 7 DOFs, without scaling and without mirroring effect, just as in the "robotic systems". This development resulted in a prototype of which the handle and the instruments tip maintain the same spatial relation, e.g. handle and tip always remain parallel. By positioning the devices in the proper orientation, the surgeon can have an ergonomic posture with his hands close to each other. We developed and built a prototype of a manipulator of which the links between handle and instrument are designed to have high stiffness and the joints are designed to have low friction, to optimise force transmission and force feedback. Elasticity and friction measurements as well as a preliminary test showed that the system is functional, but that the friction for the translation movement was higher and the stiffness for the grasping movement was lower, compared to conventional endoscopic instruments. Because the prototype of the MIM was not developed according the Medical Device Directive (MDD) and it has still some shortcomings, it is not suitable for clinical evaluation yet.

4. In the preclinical study of chapter 4 of this thesis, 30 medical students with no surgical experience, performed 4 different manipulation tasks in a pelvic trainer box with two conventional endoscopic needle holders or with a set of MIMs. This resulted in a significant difference between numbers of total actions in most exercises in favour of the MIM-group. A significant difference in failures per task was shown in favour of the MIM-group as well. There was no significant difference shown as to total time per exercise. These tasks clearly demonstrated the efficacy of the MIM, even though some technical flaws emerged during the experiments. These experiments show the potential of the MIM and it is expected to become a competitive and economical instrument for endoscopic surgery in the near future.

Concluding, in this thesis two surgical devices for endoscopic surgery has been developed and tested by involving surgical expertise throughout the whole process. This thesis showed that "Simple Tools for Surgeons" can be an alternative for complex and expensive surgical solutions, like robotic devices. This resulted in one product (PASSIST) that is ready for commercialisation and one product that is under development aiming for commercialisation in the near future. Developing instruments together with clinicians in an academic medical centre leads to new products that are clinically driven, are interesting for industry and will be used in clinical practice.

7.2 Ongoing and future research

As mentioned in chapter 1, the most important advantage of Minimally Invasive Surgery (MIS) is the reduction of the trauma of access by making smaller wounds in the healthy tissue covering the target area. These smaller access ports cause directly the main drawbacks of MIS: The lack of direct manual and visual control of the tissue by the surgeon and the difficulties in creating sufficient working space. The PASSIST and the MIM deal with some of these drawbacks of MIS, by improving the visual control and by improving the manual control of endoscopic instruments. The PASSIST as well as the MIM was designed to work in the cavity in the patient's body, such as the abdominal or the thoracic cavity. To create sufficient working space, these cavities are insufflated with CO_2 gas. Some endoscopic procedures do not take place in these "natural" cavities, but in parts of the body where such cavities are not present, such as joints or in between skin and muscles. To create sufficient working space in these areas other techniques than CO_2 insufflation have to be implemented. Even if a working space can be created, this space will be much smaller than the

abdominal or thoracic cavity. Because conventional endoscopic instruments and also the PASSIST and the MIM are not suitable to be used in these "unnatural" cavities, new instruments have to be developed.
Endoscopic surgery will remain a complex surgical approach in the near future because of limitations of the imaging technology and of the endoscopic tools, which are in between the surgeon and the tissue of the patient to be treated. With technological innovations the percentage of endoscopic procedures could increase significantly. Therefore it will remain essential to invest in research to develop new, improved and user friendly instruments for endoscopic surgery. Recent and future research in innovations for endoscopic surgery, by the Academic Medical Centre and other institutes will illustrate this in the following paragraphs.

7.2.1 Future research with the PASSIST and the MIM

Prototypes of the PASSIST as well as well as the MIM have been built and evaluated, but both devices are not generally used in clinical practice. Therefore it will be of importance to stimulate research with both these devices to become standard equipment for the OR.

Future research with the PASSIST

A commercial version of the PASSIST is planned to be brought out in 2006. It will be interesting to provide a few surgeons with a set of these devices and design with them a large clinical trial performing Laparoscopic cholecystectomy to test if the stable image and the camera controlled by the surgeon, lead to a shorter operation time, less complications for the patient and possibly to solo-surgery without an assistant present. It also has to be determined which other endoscopic procedures can benefit from using these camera and instrument positioners.

Future research with the MIM

Thanks to a grant from the ministry of economic affairs (EZ), redesign of the MIM for clinical evaluation has been started in corporation with an Industrial design office. Shortcomings in the device, such as maintaining sterility, sterile changing of instruments, the absence of essential disposables and the high friction of the translation movement have to solved. Input from surgeons will be involved in the final design to guarantee that the clinical version will be suitable to perform their proposed procedures. When this next version is available, animal and clinical evaluations have to be organised and planned for different surgical disciplines, such as urology, cardiac surgery and general surgery. When the feasibility of a surgical procedure has been proven, large randomized clinical studies have to be developed to test the efficiency and (cost)effectiveness of surgery with this device as compared to conventional techniques or robotic surgery. Finally the MIM has to be commercialized to be able to supply surgeons all over the world with an ergonomic and affordable alternative to perform minimally invasive surgery.

7.2.2 Visualisation

Advanced visualisation and information technology will contribute to the renewed growth in endoscopic surgery by providing the surgeon with enhanced depth perception when performing complicated, physically intricate tasks. They also will provide the surgeon with the ability to view additional information in a picture-in-picture format, to facilitate real-time decision making during a procedure. We believe that conventional two-dimensional visualization systems compromise the ability of a surgeon to manoeuvre, especially in complex reconstructive surgery, and that three-dimensional vision will provide the surgeon with an advantage in these cases. Fortunately, in the imaging technology a lot of research has been done and is still going on by different research groups and companies around the world. Displays and flat panels are improving continuously, with better resolution, color, and reduced size and weight. Systems providing the surgeon with extra peroperative (image) data, digital recording,

Figure 7.1. A lightweight HUD, maybe useful for endoscopic surgery

distribution and storage of image data etc, are already on the market. Examples of these systems are the OR1™ (Karl Storz), the EndoALPHA™ (Olympus) and the EndoSuite™ (Stryker)[1-3]. New concepts of 3D displays have been developed[4,5]. Also the Head-Mounted-Displays are becoming lighter systems with better ergonomics and improved resolution *(see figure 7.1.)*. The interest from the industrial and the consumer market, like the fast growing market for computer games, is accelerating these developments even more.

7.2.3 Sensor technology

Much research has been done in sensor technology, by making sensors smaller and suitable to work in a clinical environment[6]. To provide surgeons with an improved feedback from the patient's tissue, sensors that measure force, temperature and eventually tactile information should be mounted inside the tip of endoscopic instrument[7]. Despite this research, suitable (force) sensors, which may function inside the human body, are rare.

To manipulate delicate tissue like bowel, it is of importance to provide the surgeon with force feedback of the clamping and pulling force on the tissue[8]. To provide force feedback in these directions in a conventional endoscopic instrument, frictionless transmission through the trocar and of the mechanism inside the instrument is the most promising approach[9,10]. To provide force feedback in an active system, such as surgical robotics, a frictionless mechanism is not needed. In surgical robotics force feedback can be achieved with servo technology in combination with force sensing in the instrument tip and the surgeon's handle[11,12], because the motors and electronics that activate the instruments already are present. The challenge is the design of a force sensor, which should be biocompatible, sterilizable and robust or cheap enough to be disposable and small enough to fit inside a grasper of a 5mm endoscopic instrument. Strain gauges are the standard method to measure force and have shown to be very successful. However, for applications in surgical instruments, the electric nature of these sensors is undesirable. With a temperature compensated strain gauge force measurement, four electrical wires come from the sensing point. These might be difficult to sterilise, subject to mechanical wear, limit miniaturisation, and the electrical sensing is potentially unsafe for use inside the patient's body and might interfere with other medical equipment. Furthermore, the strain gauge technique is very laborious to produce. Specialised know-how is required for the design and manufacturing of the deforming body to achieve the desired sensitivity and small cross-sensitivity.

Optical sensors could be an alternative option[13] because light is harm-

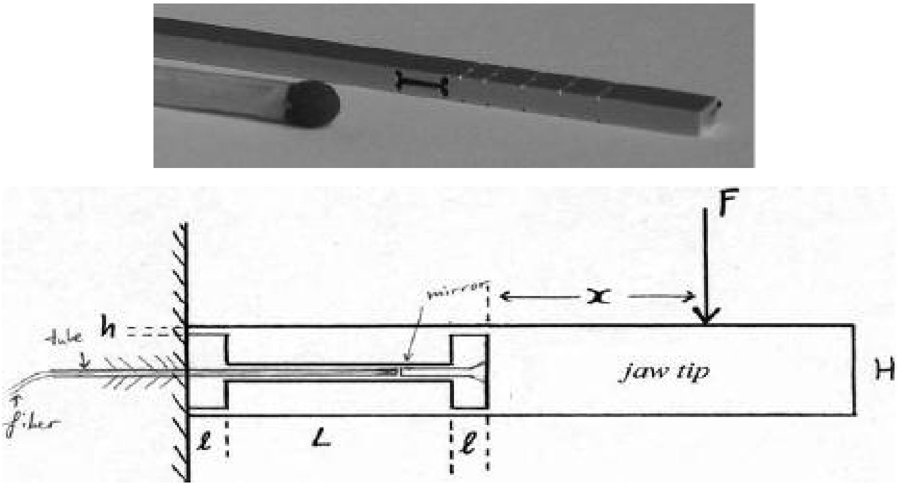

Figure 7.2. Test example of the optical force sensor, which reflect a part of a light bundle back into the fibre, dependently of the force (F) but independent of the point of application (x) of this force.

less for the patient, glass fiber is a very inert and strong material and optical sensors need only one glass fibre per sensor, which can have a sub-millimeter diameter and can easily be integrated in a grasper design.

Opto-Mechanical force sensor

We have developed an optical force sensor suitable to fit inside a grasper of a 5mm endoscopic instrument[14,15]. It consists of a deformable body inside the grasper parts, which, dependent on force, moves a small mirror up and down *(see figure 7.2.)*. An optic fiber is fed through the instrument to this deformable part. Through this 65 μm diameter optic fiber light is guided to the mirror and depending on the position of the mirror, a part of this light is reflected back into the same fiber and is guided back to a detector, which may be outside the body. This way, the intensity of the reflected light is a measure for the pinching force in the instrument grasper. Due to the position of the mirror inside the deformable part, the output signal is independent of the point of application of the force *(see figure 7.2.)*. A prototype of this grasper part with the optical sensor inside has been built and tested in a laboratory setting. The test results show that the detector signal is reproducible and almost a linear function of the amount of force (0-8 Newton) in the grasper part *(see figure 7.3.)*. With this prototype of an optic force sensor designed to fit inside the tip of an

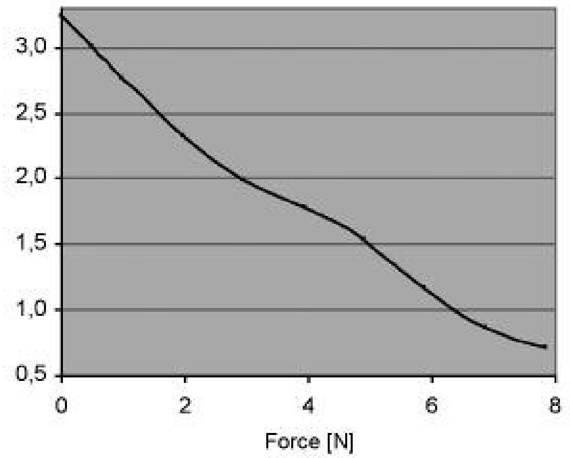

Figure 7.3. The output signal of the optical force sensor as function of the amount of force in the grasper.

endoscopic instrument it is possible to measure grasping forces without electrical wires in the sterile area.

In the near future an endoscopic instrument will be developed with two of these optical force sensors inside the grasper jaws, to measure the pinching force on the tissue. When the pinching force can be measured successfully, the endoscopic instrument will be further equipped with a force sensor inside the instrument's handle in combination with a motor drive. With this device it should be possible to compensate for the friction inside the instrument and even scale up the pinching force from the tissue to the reaction force on the handle, to improve force feedback in handling delicate tissues.

7.2.4 Instrument development

In our view the mechanics or mechanisms of instruments remain the biggest challenge for improving surgical instruments. Because most companies and institutions focus on electronics and computer hard- and software, there is little attention paid to research in the mechanical side of surgical instruments. To increase the percentage of endoscopic procedures in surgery it is essential to provide the surgeon with instruments with extra degrees of freedom at the tip, which can be controlled in an intuitive and ergonomic way. Only this way, more complex surgical tasks can be performed endoscopically. The MIM is an example of a device that controls instruments with these extra degrees of freedom. Although the MIM is a purely mechanical device, which is designed to be less complex and cheap

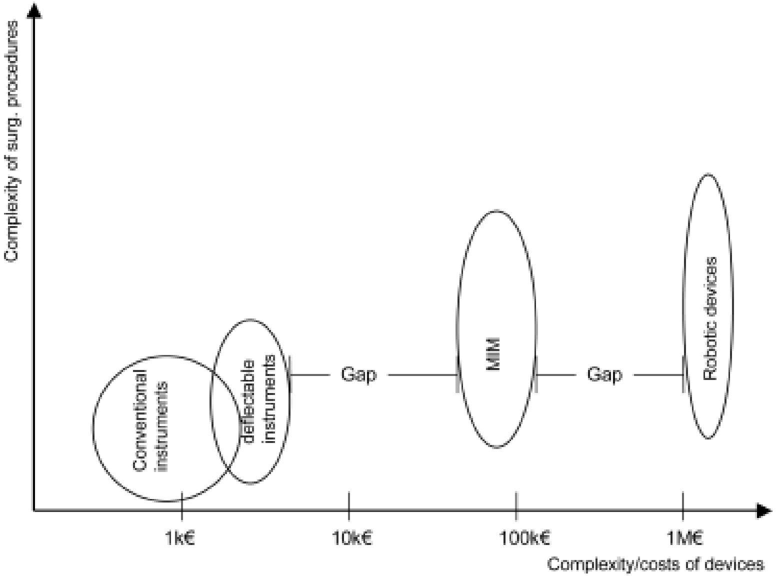

Figure 7.4. The MIM can be positioned between the deflectable (handheld) endoscopic instruments and the robotic device. This way more complex surgery can be achieved with a less complex and less expensive device. Even then there remains a gap between the MIM and the robotic devices and between the MIM and the conventional endoscopic instruments.

er than a Master-Slave "robotic" system, it is still larger and more expensive than a conventional endoscopic instrument and only suitable for procedures in the abdominal or thoracic cavity. Therefore we believe that there remains a gap between conventional endoscopic instruments and the MIM and also between the MIM and the robotic devices *(see figure 7.4.)*. Our ongoing and future research therefore should not only focus on further improving the MIM but should also focus on instruments specially developed to operate in small non-natural cavities (inside joint or in between muscles) and instruments with extra degrees of freedom, which may bridge these gaps. This paragraph describes some of our ongoing and future research on endoscopic instruments.

Hooked clip applier

For most Cardiac bypass surgery a vein originating from the patient's leg is used to bypass the stenoses in the arteries of the heart. Depending on the number of bypasses, a vein of about 30-50cm length is needed. In the standard procedure in the AMC an assistant harvests the vein, by making an incision in the patient's leg of about 30-50 centimeters, and cutting out the vein and clipping the side branches in that trajectory. Patients suffer from this large wound, which leaves a big scar, damages the muscles and gives a big infection risk. So there is a need for a less invasive approach. A cardiac surgeon from the AMC tried to harvest the vein, by making smaller (2-3cm) incisions every 10-12cm. He used a conventional clip applier and scissor to clip and cut the side branches under direct view, with promising results. To increase the distance between the incisions from 10cm to about 20-25cm the surgeon used a spoon-shaped dissector under video-endoscopic view. But conventional instruments or even existing endoscopic clipping and cutting instruments for this procedure were not satisfying because of their size and because the tip of an endoscopic clipper or cutter is obscured by its own shaft in a tunnel shaped working area. Therefore, a special hooked clip applier was developed to clip the side branches of the vein and to close the part of the vein, which remains inside the patients leg *(see figure 7.5.)*. This clip applier has a clip holder positioned perpendicularly to the end of the 5mm shaft. This way, the clip is always visible on the monitor even if the scope is in line with the in-

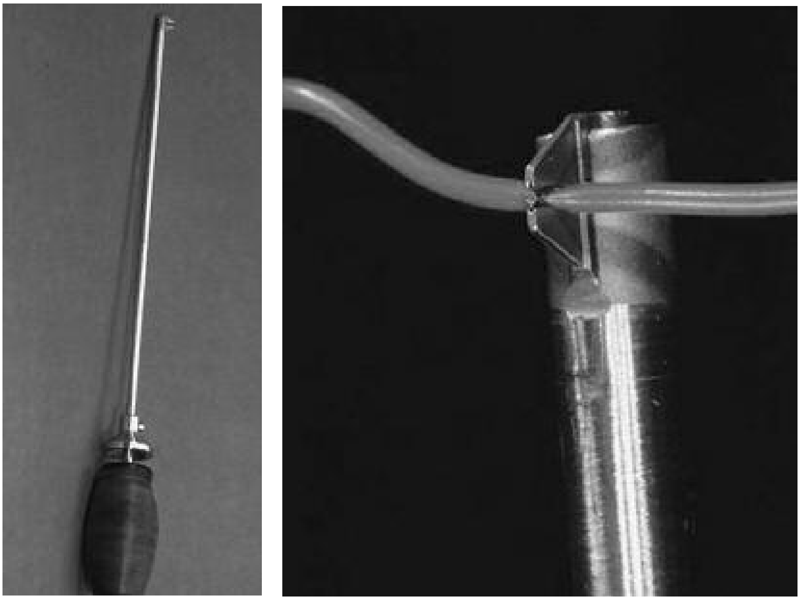

Figure 7.5. Hooked clip applier for clipping the side branches of a vein to be harvested from the patient's leg

Figure 7.6. Ankle retractor: A device to stretch the ankle to create sufficient working space inside the ankle to perform arthroscopic procedures

strument shaft, providing the surgeon with better control over his actions. Although the size of the hooked clip applier is larger than the shaft diameter, the fact that for this procedure no trocar is used makes this instrument suitable for minimally invasive vein harvesting.

Ankle retractor

In minimally invasive joint surgery, surgery is performed in between the bones of the joint. One of the disadvantages of the procedure is the lack of space between the different bones. To increase this space, it is possible to stretch the joint a little with an external retractor. The existing retractors consist of a strap around the ankle in combination with cables, pulleys and weights, which makes it complex and time consuming to install and to reposition for the different stretching directions during a procedure. Therefore, we developed, with the orthopedic department, a simple ankle retractor, which consists of an ankle strap that can be coupled to a surgeon's waist belt[16] *(see figure 7.6.)*. With this device the surgeon himself is able to stretch and control with his weight the patient's ankle to obtain the best access to the ankle joint. This way, the surgeon is able to stretch the patient's ankle, while having both his hands available for his instruments, just like a windsurfer using his trapeze. The device is inexpensive, gives reproducible results, is safe for the patient and is very easy to apply. This device is now successfully in use during standard arthroscopic procedures in the AMC and other hospitals around the world.

Blunt dissector

De Quervain's disease is a work related injury to the wrist, and is an example of RSI (Repetitive Strain Injury). There are several types of treatment possible for De Quervain's disease, varying from no treatment to surgical treatment, in the worst cases. The treatment can be quite cumbersome for patients because of resulting scars in a very visible spot. Even more important: complications like superficial radial nerve injury can be profound and permanent *(see figure 7.7.)*. Sharp injury, traction injury, or adhesions in the scar can cause neuritis in this high-contact area and greatly limit the hand and wrist function. This can be a very painful situation, even more painful than the original complaints associated with De Quervain's disease. An alternative approach to avoid al these disadvantages is endoscopic surgery. However, endoscopy of the wrist is not a standard procedure yet. This is the reason there are no instruments available presently specifically suited for endoscopy of this area of the body. We developed a blunt dissector[17] for endoscopic surgery in the upper extremities *(see figure 7.8.)*. With this new blunt dissector, with its specially designed dissecting tip, an incision is made 10-15cm away from the target area. Guiding a small 30° endoscope, it may be used to dissect, under sight, the skin from the underlying tissue, leaving the skin over this area intact. The scope can be moved to the front and backwards independently from the dissector to optimise the scope position for the dissecting

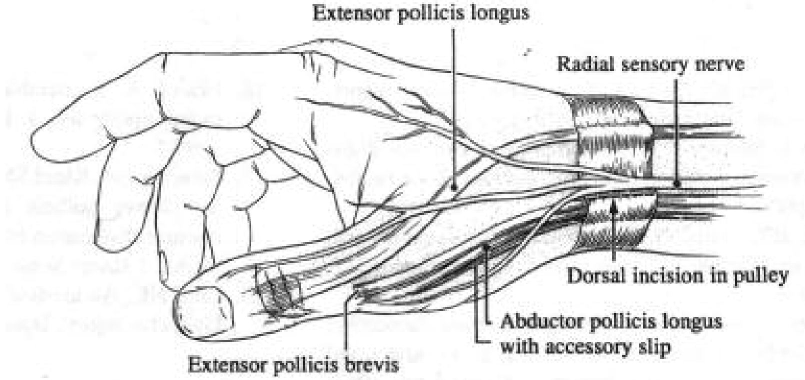

Figure 7.7. Regional anatomy indicating exposure required for the safe release of the ligament in de Quervain's disease. (*Drawn by P.Lynch, Medical Illustrator, Yale University.*) Hereto, an incision has to be made in the Pully, close to a nerve, with the risk of damaging it.

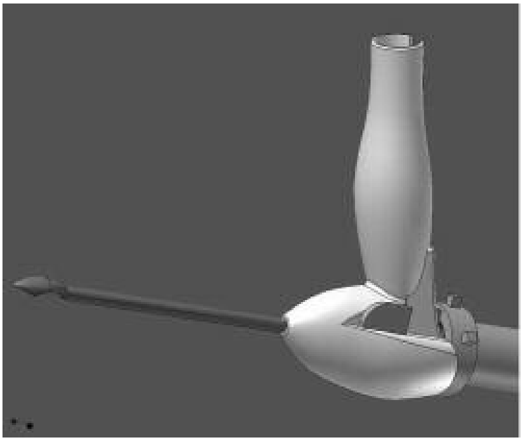

Figure 7.8. First prototype of the blunt dissector designed to create working space under endoscopic guidance and to perform the surgical procedure.

phase or the surgery phase. With the blunt dissector it is also be possible to insert sharp objects like scissors, which cut the dorsal carpal ligament, without the risk of damaging the surrounding tissue.

The first animal-tissue experiments with different dissecting tips show that endoscopic dissecting is possible. From these experimental results a prototype of the blunt dissector with a special designed handle is built and cadaver experiments will be executed within the near future.

Handheld instrument with extra degrees of freedom

At the MTO we have an endoscopic instrument under development with two extra degrees of freedom at the tip, based on the exchangeable instrument of the MIM-manipulator, but then with a handle directly coupled at the end of the shaft. With this instrument the movements of the surgeon's wrist are directly translated to the wrist movements at the instrument tip. Movements of the surgeon's hand about the incision in the patient are translated to mirrored and scaled movements of the instrument tip, however, like with conventional endoscopic instruments. With this instrument it should be possible to approach tissue from different directions, making more delicate manipulations possible. In view of the disturbed hand-eye coordination it has to be examined whether complex surgical actions with this instrument are possible.

Hybrid Manipulator with power steering

Although the MIM is designed as a device with low weight and low friction, some friction and mass inertia will always be present and will disturb the feedback in some way. If it is desirable to further decrease the weight or mass inertia, it can only been done in an active way, with motors and sensors. At the MTO we started research on this so-called hybrid approach. We developed a system, which in a laboratory setting represents the translation movement of the MIM (DOF 4)[18]. By moving the handle up and down, the tip of the instrument will move in the same direction *(see figure 7.7.)*. By adding force sensors at both the instrument tip and the handle, in combination with a motor attached to one of the wires connecting the handle and instrument, it was possible to compensate for the friction. This was done with only one small motor in combination with relatively simple electronics. By implementing this force controlled technology into the MIM, a hybrid or haptic system can be developed, which actively eliminates friction and can also scale forces up or down, which could be of importance in delicate procedures, for example in neurosurgery or microsurgery. With this hybrid manipulator it will be also possible to measure and record the

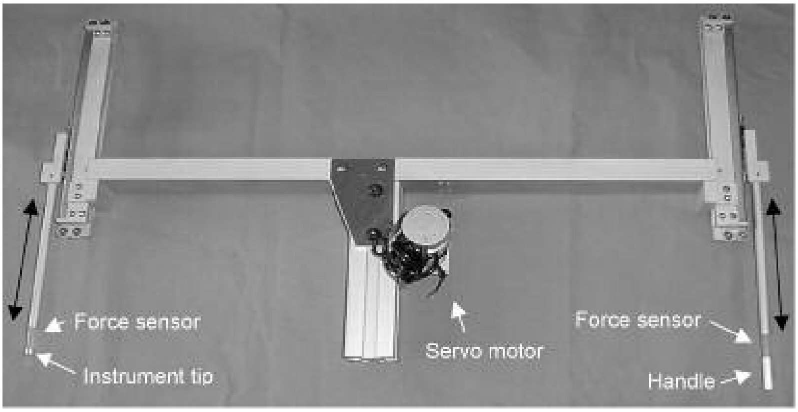

Figure 7.9. Demonstration model of a 1-DOF force controlled manipulator. The handle and the instrument, which can be manipulated in the direction of the black arrow, are equipped with a force sensor, measuring pulling and pushing force in that direction. The handle part and the instrument part are physically connected with a wire, like with the mechanical manipulator, but it is wrapped about a motor axis as well. This relatively small motor is able to eliminate the friction in the system or to scale up reaction forces from the instrument to the handle.

positions, movements and actions of the endoscopic instruments, for training, evaluation and navigation purposes. Because every DOF of the manipulator is connected to the fixed world (the OR-table), with a series of hinges, a simple positioning sensor at each hinge can measure the position of that DOF relative to the fixed world, and so the position of the instrument tip relative to the tissue can be calculated. This way a surgical procedure can be "recorded", making surgical evaluation possible. It may also be possible to use the manipulator preclinically in combination with training modalities in a Pelvi trainer or in virtual surgery. In combination with pre- and peroperative image data it will be then also possible to use the manipulator as a navigational tool or as a tool for preoperative planning or training.

We strongly believe that the "Simple Tools for Surgeons" developed during this project, the PASSIST and the MIM, have the potential to evoke a renewed growth in endoscopic surgery. Together with the approach described in this chapter and developments in hospital organisation, it will improve the acceptance for endoscopic surgery, because most of the drawbacks of endoscopic surgery can be overcome. Hopefully, contrary to the present situation, the endoscopic approach will become the standard in surgery and the open approach will become the exception within the next decade.

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SUMMARY

SIMPLE TOOLS FOR SURGEONS

Design and Evaluation of Mechanical alternatives for “robotic” instruments for Minimally Invasive Surgery

Performing complex tasks in Minimally Invasive Surgery (MIS) is demanding due to a disturbed hand-eye co-ordination, the application of non-ergonomic instruments with a limited number of degrees of freedom (DOFs) and due to the two-dimensional (2D) view controlled by the surgical assistance. Robotic camera holders and tele-manipulatory systems enhance surgical dexterity by providing the surgeon with 3D perception and instruments with up to 7 DOFs. They allow the surgeon to operate in an ergonomically favourable position with more intuitive manipulation of the instruments. Robotic systems, however, are very bulky, expensive and do not provide any force feedback from the tissue. Therefore routine MIS with these “robotic” systems is not common practice.

The main objective of my research project was to provide surgeons with simple tools, which at least partly fill the gap between conventional endoscopy and the highly technological robotic systems. To do so, we have developed and evaluated solutions, which provide the surgeon with direct and intuitive control of the endoscope and the endoscopic instruments.

The first device, which we have developed and evaluated, is a mechanical, spring-balanced camera and instrument holder as an alternative for the “robotic” electromechanical systems, to provide the surgeon with direct control of the camera and of instruments used for retracting. A clinical randomised study with this holder showed the benefits of this system over human camera and instrument control.

The other device, which we have developed and evaluated, is a mechanical manipulator for MIS. This device is designed as an economical alternative for the da Vinci® telemanipulator, providing the surgeon, just like the da Vinci®, with intuitive manipulation and 7 DOFs at the instrument tip, and in addition limited force feedback. A preclinical study with medical students with no surgical experience, compared the manipulator with conventional endoscopic instruments. This study showed that fewer actions were needed and fewer failures were made with the mechanical manipulator than with conventional endoscopic instruments.

The main conclusion of this thesis is that the developed relatively simple instruments can be an alternative for robotic systems.

SAMENVATTING

Tegenwoordig worden steeds meer operaties minimaal-invasief uitgevoerd. Deze aanpak wordt ook wel sleutelgatchirurgie genoemd. Bij minimaal-invasieve operaties worden er, in tegenstelling tot de standaard "open" techniek, geen grote incisies in het lichaam van de patiënt aangebracht, maar opereert men door toegangspoorten met een kleine diameter. Via deze toegangspoorten wordt een kijkbuis (scope) met videocamera en een aantal instrumenten in het lichaam gestoken waarmee de operatie wordt uitgevoerd. De reden dat er steeds meer vraag komt naar deze minimaal-invasieve manier van opereren is dat de patiënt dankzij de kleinere wonden sneller herstelt waardoor het aantal verpleegdagen afneemt en de patiënt sneller zijn dagelijkse activiteiten kan hervatten. Tevens is de kans op infecties bij dit soort operaties kleiner en is het cosmetische resultaat aanzienlijk verbeterd. Ten slotte zijn ook de totale verpleegkosten bij deze operaties over het algemeen lager dan bij de open chirurgie.

Voor de chirurg duurt het relatief lang om minimaal-invasieve operatietechnieken te leren en zijn deze moeilijker uit te voeren dan conventionele operatietechnieken, vanwege de volgende redenen:

- De directe visualisatie van het operatiegebied is verstoord. De chirurg kan niet direct op het weefsel kijken, maar kijkt naar een plat beeldscherm waarop een beeld van het operatiegebied wordt getoond dat gemaakt is door een kleine videocamera die gemonteerd is op de scope die in het lichaam van de patiënt is gebracht. De camera wordt bediend door een assistent, daarbij gestuurd door mondelinge instructies van de chirurg en dit kan leiden tot sub-optimale cameraposities, een onstabiel beeld vanwege trillende bewegingen van de assistent en tot communicatieproblemen. Een extra beperking hierbij is dat de scope, meestal niet in de natuurlijke kijkrichting van de chirurg kan worden geplaatst, maar vaak met een grote hoek ten opzichte van deze natuurlijke kijkrichting. Dit betekent dat hij zijn operatiegebied van opzij bekijkt ten opzichte van zijn instrumenten, waardoor bijvoorbeeld bewegingen van zijn handen op-en-neer worden gepresenteerd als bewegingen heen-en-weer op de monitor. Tenslotte staat de monitor meestal te hoog en opzij van de chirurg, waardoor de werkhouding slecht is en er rug- en nekklachten kunnen ontstaan
- De manipulatie met het endoscopisch instrumentarium is verstoord. Omdat met lange instrumenten wordt gewerkt om het te behandelen

orgaan van buiten het lichaam te kunnen bereiken, heeft de chirurg zijn handen ver van elkaar en vaak in een niet-ergonomische stand. Doordat de instrumenten via kleine sneetjes worden ingebracht, gaan er twee graden van bewegingsvrijheid verloren, zodat het niet meer mogelijk is weefsel van verschillende kanten te bereiken, hetgeen essentieel is voor het uitvoeren van complexe handelingen, zoals hechten van weefsel. Belangrijker nog is dat twee bewegingsgraden van vrijheid rond die sneetjes gespiegeld en geschaald worden doorgegeven. Dit betekent dat een beweging naar rechts van de hand van de chirurg resulteert in een beweging van de tip van het instrument naar links en dat, afhankelijk van het deel van het instrument dat zich in de patiënt bevindt, de uitslag van de tip groter of kleiner kan zijn dan die van de hand van de chirurg, het zogenaamde hefboomeffect.

Het volgende thuis-experiment vat de problematiek van de minimaal-invasieve operatietechniek samen:

Probeer eens je haren te kammen, niet in de spiegel, maar kijkend naar een televisie waarop je zelf te zien bent, gefilmd door een ander van opzij. De kam tape je vast aan een dikke breinaald of lange pollepel.

Het gevolg van dit alles is dat tot op heden alleen de “eenvoudige” operaties minimaal-invasief worden uitgevoerd (bijvoorbeeld het verwijderen van de galblaas) en dat de meer complexe operaties door de meeste chirurgen nog steeds open worden uitgevoerd, ondanks de potentiële voordelen van de minimaal-invasieve operaties.

Hoofdstuk 1 geeft een uitgebreide inleiding op de hiervoor beschreven problematiek en gaat in op de bestaande (robotica)oplossingen voor het visualisatie- en manipulatieprobleem.

Hoofdstuk 2 van dit proefschrift geeft een overzicht van de bestaande systemen om de camerabediening in “handen” te geven van de chirurg. Veel van dit soort systemen zijn elektromechanische “Robot”systemen, die op zich wel functioneren, maar complex, duur en vaak niet eenvoudig te bedienen zijn. De bestaande eenvoudige mechanische armen kunnen prima een camera of een instrument positioneren, alleen het re-positioneren van bijvoorbeeld de camera is hierbij lastig, omdat er twee handen nodig zijn om deze armen te “ontgrendelen” de camera te bewegen en weer vast te zetten. De chirurg heeft echter niet beide handen tot zijn beschikking tijdens de operatie, omdat hij ook het instrumentarium moet bedienen. Mechanische armen die met één hand te bedienen zijn, bleken het meest functioneel daar de chirurg hiermee in staat is zelf zijn camera te bedienen tijdens de operatie.

Hoofdstuk 3 behandelt vervolgens de ontwikkeling en de klinische evaluatie van de PASSIST (PASsive asSISTant), een passieve camera- en instrumentenhouder die ontwikkeld is door de Medisch- Technische Ontwikkelingsafdeling (MTO) van het AMC. Deze arm bestaat uit een parallellogrammemechanisme dat het mogelijk maakt een instrument te laten kantelen rond een incisie in de patiënt, zonder dat daar een scharnier nodig is en zonder reactiekrachten te genereren. Een veerbalans rond een van de assen zorgt ervoor dat het gewicht van de camera grotendeels wordt gebalanceerd. Een instelbare wrijving in de scharnieren van het mechanisme zorgt er voor dat de camera stabiel blijft staan in zijn ingestelde stand. Het positioneren vindt plaats door de camera vast te pakken met één hand en de houder, door de wrijving heen, naar zijn nieuwe positie te brengen.
Om te testen of dit principe werkt, is een klinische studie gedaan waarin het opereren met twee PASSIST-armen is vergelijken met het opereren met een assistent. Het resultaat hiervan was dat, hoewel de operatietijd met de PASSIST nauwelijks langer was, het aantal cameraverplaatsingen wel drastisch afnam. Met de PASSIST was het mogelijk voor de chirurg zijn instrumenten en de camera zelf te bedienen en de operatie zonder assistent uit te voeren, zonder tijdverlies (solochirurgie).

Hoofdstuk 4 beschrijft een oplossing voor de manipulatieproblematiek van het conventionele endoscopisch instrumentarium. Er is momenteel maar één instrument commercieel verkrijgbaar dat een oplossing biedt voor de geschetste problemen van de minimaal-invasieve chirurgie: de da Vinci® operatierobot (Intuitive Surgical Inc). Deze telemanipulator vertaalt de bewegingen van de hand van de chirurg computer-gestuurd naar die van de endoscopische instrumenten gekoppeld aan robotarmen. Dit systeem is echter zeer complex en duur. Als alternatief voor de robotchirurgie is door de MTO van het AMC een mechanische manipulator ontwikkeld voor het op een vergelijkbare intuïtieve manier bedienen van instrumenten voor de minimaal-invasieve chirurgie, de Minimaal-Invasieve Manipulator (MIM). Deze manipulator bestaat uit een relatief eenvoudig en mechanisch-gebalanceerd parallellogrammechanisme. Hieraan zijn zowel het handvat als het endoscopisch instrument gekoppeld, zodanig dat de tip van het instrument exact de bewegingen van het handvat volgt, zonder spiegeling of schaling. Een prototype van de MIM is gemaakt en in een testopstelling uitgetest.

Hoofdstuk 5 beschrijft een evaluatiestudie waarbij de MIM vergeleken is met conventioneel endoscopisch instrumentarium (de controlegroep). In deze studie werden gesimuleerde operatiehandelingen uitgevoerd door geneeskundestudenten zonder chirurgische ervaring, waarbij de experiment-tijden, -acties en -fouten werden gescoord. Het resultaat van deze studie was dat de experiment-tijden niet significant verschilden maar dat het aantal benodigde handelingen, voor het uitvoeren van de experimenten, en het aantal gemaakte fouten in de MIM groep beduidend lager waren dan in de controlegroep.

De belangrijkste conclusie van dit proefschrift is dat er met relatief eenvoudige instrumenten als alternatief voor de complexe "robotica" vergelijkbare, zo niet betere, resultaten kunnen worden geboekt binnen de minimaal-invasieve chirurgie. De verwachting is dan ook dat deze in-strumenten hun weg naar de chirurgische praktijk zullen vinden, waar ze een bijdrage kunnen leveren aan de opmars van de minimaal-invasieve chirurgie, die niet alleen beter is voor de patiënt maar ook beter is voor de chirurg.

Joris Jaspers, 2006

DANKWOORD

Mijn dagelijks werk speelt zich af op het grensvlak tussen de techniek en de geneeskunde, met ieder hun eigen taal en cultuur. Het samenwerken met deze verschillende groepen heeft er voor gezorgd dat ik mijn dagelijks werk in het AMC en in het bijzonder mijn onderzoek naar chirurgisch gereedschap met zoveel plezier heb uitgeoefend.

Toen ik in 1996 kwam werken als constructeur-ontwerper bij de Medisch-Technische Ontwikkelingsafdeling (MTO) van het AMC was de integratie van faculteit en ziekenhuis pas net gerealiseerd. Voor de MTO, die voornamelijk apparatuur ontwikkelde voor het facultaire preklinische onderzoek, was de kliniek een nog grotendeels onontgonnen terrein. Ik kreeg van Kees Grimbergen en Wim Schreurs de ruimte om de kliniek te gaan ontginnen en te onderzoeken of er daar voor de MTO interessant werk te doen was.

Een van de eerste projecten was een camerasteun voor de minimaal-invasieve chirurgie, waarvoor de MTO, in samenwerking met de toenmalige promovendus Wouter Sjoerdsma, een eerste prototype had gemaakt, maar die nog niet geschikt was voor klinische evaluatie. Een door mij ontworpen tweede prototype is vervolgens bij verschillende chirurgische ingrepen uitgetest, waarna ik dit ontwikkeltraject en de eerste klinische resultaten heb mogen presenteren op een congres over Medische Robotica in Pisa in 1999. Dit werd onbewust de start van mijn promotieonderzoek met als onderwerp: ontwikkeling en evaluatie van instrumenten voor de minimaal-invasieve chirurgie.

Ik wil dan ook als eerste mijn promotor bedanken. Kees, bedankt voor de ruimte die je mij hebt gegeven om, naast mijn dagelijkse werkzaamheden, mij bezig te kunnen houden met onderzoek. Jij bent altijd van mening geweest dat een ontwikkelingsafdeling niet alleen maar technische output (onderzoeksopstellingen, instrumenten e.d.) maar ook wetenschappelijke output (artikelen, congrespresentaties e.d.) moet leveren, om daarmee het bestaansrecht en de wetenschappelijke kant van ontwikkeling binnen een academisch ziekenhuis te benadrukken. Ik hoop dat onze artikelen en overige publicaties daar een bijdrage aan hebben kunnen leveren. Speciale dank ook voor het steeds weer redigeren van mijn “concepten” die je blauw van de veranderingen en verbeteringen aan mij teruggaf. Dit zorgde er wel voor dat mijn krakkemikkige engelse brouwsels steeds weer veranderde in goed leesbare artikelen en uiteindelijk dit proefschrift tot stand kwam. De congressen die we, vaak samen, bezochten, SMIT en EAES, heb ik niet

alleen als zeer leervol beschouwd, ze waren ook erg gezellig, mede gezien onze gezamenlijke voorkeur voor lekker eten.
Dit proefschrift gaat niet alleen over de ontwikkeling van instrumenten maar zeker ook over de (pre)klinische evaluatie daarvan. Dat vraagt om een tweede promotor vanuit de kliniek. Bas de Mol, bedankt voor jouw begeleiding, de boeiende gesprekken, maar vooral ook voor het feit dat jij het hebt aangedurfd om samen met de MTO te investeren in de ontwikkeling van de MIM, waarmee je het belang van nieuwe instrumenten voor de minimaal- invasieve (cardio)chirurgie hebt onderstreept.
Technisch onderzoek doen in een ziekenhuis is soms een wat eenzaam bestaan. Gelukkig liep parallel aan mijn onderzoek het MISIT (Minimally Invasive Surgery and Interventional Techniques) programma van de TU-Delft, waar vele onderzoekers en begeleiders 5 jaar hebben gewerkt aan technieken en instrumenten voor de minimaal-invasieve chirurgie. Later kwamen daar de onderzoekers van DBL (Delft Biorobotics Laboratory) bij. Mijn bezoeken aan de TU, de wetenschappelijke bijeenkomsten en uiteraard de “Hei-sessies” in het bos, waar op een ontspannen manier over medisch-technische onderwerpen werd gediscussieerd, waren erg waardevol, allen bedankt hiervoor. Just Herder, jou heb ik al leren kennen in het derde jaar van mijn studie werktuigbouwkunde, toen jij met warmtedraden cosmetische handschoenen aan het bewerken was en mij begeleidde bij mijn ontwerpopdracht. Jouw kennis van krachten en balanceren is verwerkt in de instrumenten die zijn beschreven in dit proefschrift en niet voor niets ben jij als “co-promotor” bij de promotiecommissie betrokken. Wij beiden zijn van de School van Cool. Professor Cool, de vele bijeenkomsten op uw kamer tijdens mijn afstuderen, waar menig conceptontwerp sneuvelde, hebben mijn denken over ontwerpen gevormd. Het potlood is nog steeds mijn belangrijkste ontwerpgereedschap. Jenny Dankelman, jij hebt mij in 1999 geattendeerd op dat eerste congres in Pisa. Bij de meeste congressen daarna was je er ook bij en dat was erg gezellig. Bedankt dat je in mijn promotiecommissie plaats hebt willen nemen. Mark Wentink, ook jij bezocht dezelfde congressen, maar vaker nog zag ik je op de TU waar we voor mij verhelderende gesprekken over hand-oog-coördinatie hadden. Bedankt voor jouw duidelijke figuren die ik heb mogen gebruiken voor mijn proefschrift. Paul Breedveld, discussiëren met jou houd je scherp en je moet van goede huize komen om jou van standpunt te laten veranderen. Bedankt voor de goede ideeën die uit deze discussies zijn geboren. Karen den Boer, jij was lange tijd de enige van de MISIT-groep die echt veel in het AMC was, zodat we elkaar regelmatig tegenkwamen. Bedankt dat je samen met Martijn Bruijn de klinische studie met de PASSIST hebt uitgevoerd.

De instrumenten beschreven in dit proefschrift waren er nooit gekomen zonder de inspanningen van mijn collega's van de MTO. Bij deze wil ik jullie allen dan ook hartelijk danken voor jullie bijdragen aan mijn promotieonderzoek. Ik wil een paar collega's persoonlijk bedanken: Morgan en Frank, bedankt voor het complexe 3D-ontwerpwerk dat jullie hebben uitgevoerd op de daarvoor eigenlijk te zwakke computers, zodat een crash regelmatig voor de nodige "afwisseling" zorgde. Bedankt ook voor het geduld en het doorzettingsvermogen om mijn soms onmogelijke wensen toch gerealiseerd te krijgen. Bertus, bedankt voor al die kleine maar ó zo nauwkeurige onderdeeltjes die je voor ons project gemaakt hebt. Tenslotte Wim, jij was het die me richting OK stuurde met de eerste versie van de PASSIST, en daarmee de aftrap hebt gegeven voor dit onderzoek. De discussies met jou over ontwerpen waren zeer motiverend, maar heel soms ook demotiverend als jij op driekwart van het ontwerptraject "piepend in de remmen ging hangen" omdat je vond dat het helemaal anders moest. Jouw creativiteit heeft de MTO groot gemaakt en het is terecht dat je daarvoor geridderd bent.

Behalve MTO-ers hebben ook vele stagiaires met hun afstudeeropdrachten een bijdrage geleverd aan mijn onderzoek: Volkert Bongers, Gerlof Krul, Vincent Hoveling, Susanne Harmse, Remco Berkhout, Kirsten Boscher, Frits Weening, Herman Kuis, Jornt Spijksma, Susanne Visch, Mattijs Hogeland, Gert Jan Griffioen, Tuan Dang en Rogier van de Pol. Allemaal hartelijk dank voor jullie bijdrage en inzet. Jullie aanwezigheid bij de MTO leverde niet alleen nieuwe ideeën op maar zorgde tevens voor een gezellige sfeer en hield ons allen jong. Rogier, jou wil ik tevens bedanken voor de prachtige computer animaties, die menig presentatie, artikel en de omslag van dit proefschrift hebben verhelderd. Studenten kunnen niet afstuderen zonder goede begeleiding vanuit "school". Deze begeleiders, waaronder Jan Gerritse, Jan Trentelman, Martine van Veelen, Richard Goossens en Prof. Snijders, wil ik daarvoor bedanken.

Een chirurgisch instrument wordt pas succesvol als het in samenspraak met chirurgen ontworpen is en door hen ook wordt uitgeprobeerd. Dirk Meijer, Laurens de Wit, Laurents Stassen, Willem Bemelman, Mohamed Bentala,Tom Jansen, Willem van Erp, Sjoerd de Blok, Jelle Ruurda, Ivo Broeders, en Paul Gründeman, bedankt dat jullie met mij hebben meegedacht en/of mijn prototypen hebben willen uitproberen op de OK. Jeroen Diks, bedankt voor het evalueren van de MIM en het verwerken van de uitkomsten, zodat met hoofdstuk 5 van dit proefschrift een evenwichtig boekje is ontstaan.

Een instrument wordt pas op grote schaal gebruikt als het ook wordt verkocht. Jan van Beurden, bedankt voor de inspanningen om de PASSIST onder de aandacht van de firma Karl Storz in Duitsland te brengen en mij daar te introduceren. Laten we hopen dat de PASSIST nog dit jaar te koop is. Met de MIM is het nog niet zo ver, die moet zich klinisch nog bewijzen. Jean Marc, jij stelde voor om een Biopartner-subsidie aan te vragen bij Economische Zaken, om hiermee de klinische en commerciële haalbaarheid van de MIM aan te tonen. De subsidie is binnen. Bedankt dat je samen met mij de stap wilt zetten om van het prototype van de MIM een succesvol product te maken.

Het omzetten van wetenschappelijke artikelen naar een eenduidig proefschrift doe je niet op een achternamiddag, terwijl dat wel de tijd was die ik daarvoor had gereserveerd. Rob Kreuger, bedankt voor de opmaak, vormgeving en omslag van dit proefschrift. Huybert, bedankt voor de prachtige foto op de omslag.

Tenslotte doe je promotieonderzoek (naast je werk) niet zonder de steun van familie en vrienden, zeker als je in het laatste jaar ook nog eens een huis wilt verbouwen. Rob en Klaas, zonder jullie hulp bij die verbouwing was mijn promotiedatum wéér verschoven. Het was een druk jaar. Het is dan ook heerlijk zo nu en dan tot rust te komen in “Casa Ria” bij mijn moeder in Portugal. Anna, bedankt voor de ruimte die je mij en mijn zussen, Stijntje en Maartje gaf om ons te kunnen ontplooien en voor de warmte op de Arenborg. Pas na ons gelijktijdige vertrek uit Venlo in 1989, besefte ik hoe belangrijk een thuis voor me was. Het was dan ook heerlijk dat ik daarna altijd welkom was (en ben) in “Hotel ’t Hanik” van mijn grootmoeder. Bommie, ik hoop u daar nog jaren te kunnen opzoeken. Ik weet hoe trots Bompa was bij de promotie van zijn zoon Pieter, mijn vader. Ik vind het dan ook heel jammer dat hij geen getuige heeft kunnen zijn van de promotie van zijn kleindochter (Klaartje) en geen getuige zal zijn van de promotie van zijn kleinzoon. Pieter, jij nam mij als kleine jongen mee naar de OK om me te laten zien hoe je, met beitel en zaag, een kunstheup plaatst. Machtig interessant was dat, waarna je vertelde ”Jongen ga nooit geneeskunde studeren, daar is straks geen droog brood meer mee te verdienen”. Braaf als ik was ben ik naar de TU gegaan om toch in de geneeskunde terecht te komen, ik denk dat dat achteraf een verstandige keuze is geweest. Als ingenieur uit een medisch nest voel ik me in het AMC als een vis in het water.

Tenslotte lieve Ruth, heel veel dank dat je bent blijven geloven in de goede afloop, ook al dacht ik jarenlang dat het nog maar enkele maanden zou duren.

CURRICULUM VITAE

04/06/1970	Born in Nijmegen, The Netherlands.
1983-1989	Atheneum-B at Marianum College in Venlo.
1989-1996	MSc-study Mechanical Engineering at Delft University Technology Graduated at the laboratory of Man-Machine Systems (Prof. Dr. ir. JC Cool). Title of MSc-thesis: Design of a force controlled mechanical hand prosthesis.
1999-2006	PhD-study at the Academic Medical Centre and the Delft University of Technology on the development and evaluation of mechanical alternatives for robotics in Minimally Invasive Surgery.
1996-1999	Product-Designer of Medical equipment at the Medical Technological Development Department of the AMC.
1999-2003	Project Manager medical devices at the Medical Technological Development Department of the AMC.
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2005-	Medical Devices Specialist at the Technology Transfer Office of the AMC.