Manual Control for Medical Instruments
in Minimally Invasive Surgery

Chunman Fan

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in Minimally Invasive Surgery

Proefschrift

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Preface

I would like to give my special thanks to all the volunteered students who participanted my experiments and David Jager who manufactured the Endo-PaC, this Ph.D thesis cannot be finished without their valuable contribution.

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Nobody has been more important to me in the pursuit of this ph.D project than the members of my family. No words is heavy enough for expressing my appreciation to my parents, whose infinitive love, support, trust, understanding and guidance are with me throughout the years in whatever I purse. At the end, I am grateful to my loving husband, Steven, who supports me and provides unending inspiration to my life and work. I wish we could extend our stories together while keep our curiosity towards exploring the world.

Chunman Fan,
Delft, March 2014.

Contents

Chapter 1

Introduction

”Now a surgeon should be youthful or at any rate nearer youth than age; with a strong and steady hand that never trembles, be ambidextrous, with vision sharp and clear and spirit undaunted...”

Book 7, De Medicina, A.Cornelius Celsus, 70 BC[105]

1.1 Background of Minimally Invasive Surgery

The term Minimally Invasive Surgery (MIS) was introduced by John Wickam [29] to describe the emerging therapeutic approach designed to minimise the traumatic insult to the patient by surgical and allied interventional procedures. In contrast with conventional open surgery, MIS is performed using long and slender instruments that are inserted into the patient's body through small incision(s) [4] or natural orifice(s) [130]. Visual feedback of the operating area is obtained via a small camera equipped on the tip of a medical instrument (i.e. endoscope), and presented on a monitor (Fig. 1.1). During such procedures, surgeons have to manoeuver the instruments outside the patient while looking at the monitor.

At first glance, MIS leads to less damage to the patient (e.g.: better cosmetic results) and shorter recovery time (e.g.: less hospitalisation) compared to conventional surgery. Surgeons, however, have to adapt their skills due to the absence of direct sight and touch, the restricted freedom of movement of the instruments and distorted eye-hand coordination[14] [144] [10] [28] [31]. Furthermore, as the surgeon's hands are outside of the patient, information about the position of the hand and fingers, does not directly support the tissue manipulation [122]. MIS thus requests changes in the way the surgeon observes the surgical space and approaches the tissue, resulting in difficulties in medical instrument manipulation and long learning curves,especially in complex medical procedures [133].

Based on a series of surgical applications, Cuschieri [4] divided MIS in five categorises: laparoscopic, thoracoscopic, perivisceral (or extraperitoneal), endoluminal and arthroscopic. In fact, if we look at the shape of the operative region, MIS can be subdivided

Figure 1.1: Minimally invasive cholecystectomy (galbladder removal). The surgeon (middle) is manipulating the grasping forceps(leftdown on the monitor screen) and the scissors (righdown on the monitor screen), while the assistant surgeon (left) is manipulating the endoscope.(Public Domain)

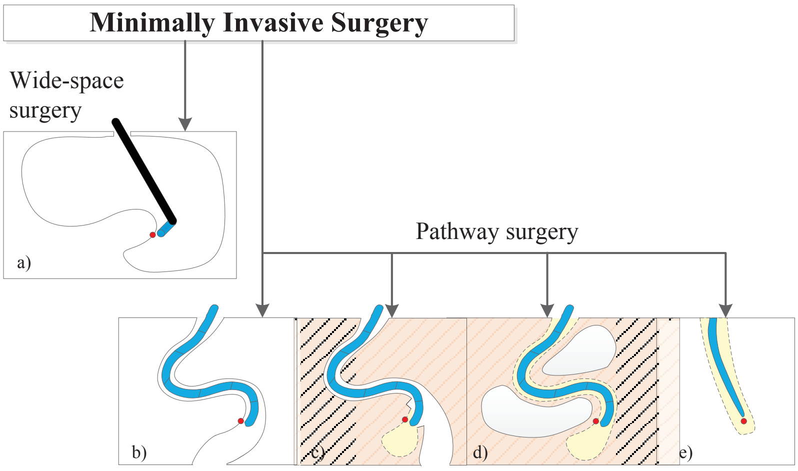

Figure 1.2: Illustration of surgical scenarios in minimally invasive surgery. a): wide-space surgery, such as laparoscopic or perivisceral surgery; b-e) pathway surgery, such as thoracoscopic, endoluminal and arthroscopic, in which surgery carried out along a 3-dimensional curved anatomic or instrument-created pathway.

into two categories, as i) surgery carried out in a relative wide hollow space (henceforth wide-space surgery, such as laparoscopic and perivisceral surgery), and ii) surgery carried out along a 3-dimensional curved pathway (henceforth pathway surgery, such as thoracoscopic, endoluminal and arthroscopic surgery) (Fig. 1.2). In wide-space surgery, due to the restrictions imposed by the small incision(s), the movements of instruments are mirrored and scaled allowing four degrees of freedoms (DoFs) [93] [76][4][14][31]], whereas in pathway surgery, the curvature of the path restricts the instrument movements within a narrow tunnel, further reducing the number of DoFs down to two [37] (Fig. 1.3).

1.2 Instrument manipulation difficulties in selected MIS applications

1.2.1 Laparosocpic surgery

Laparoscopic surgery is a form of wide-space surgery in which MIS is applied to the abdomen, such as laparoscopic cholecystectomy. It is commonly performed by a team of two surgeons: one surgeon manipulating the scissors and graspers while an assistant surgeon operating the endoscope (camera). The working space inside the abdominal cavity is created by insufflation with carbon dioxide gas. The design of nearly all laparoscopic instruments is based on mimicking the functions of conventional surgical tools. Long and rigid instruments with a small diameter (2-10 mm [29]) featured with a scissor or grasper as the end effector have been developed for tissue manipulation (Fig. 1.4).

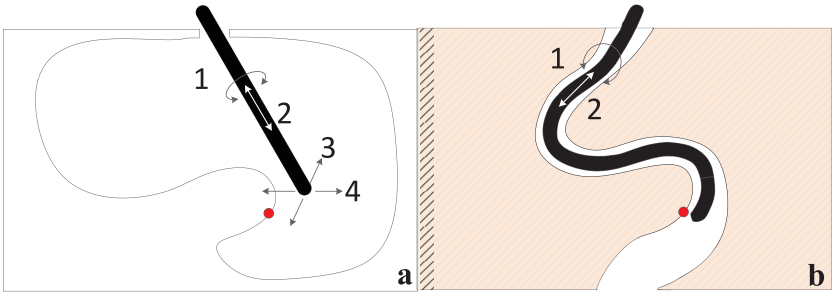

Figure 1.3: Illustration of instruments degree of freedoms (DoFs) in minimally invasive surgery. a) 4DoFs in wide-space surgery; b) 2DoFs in pathway surgery. The red dot indicates the surgical target.

Figure 1.4: Long and rigid instruments used in laparoscopic surgery[67].

Conventional rigid laparoscopic instruments do not have the same functionality as the human hand [14] [31], and cannot translate the actions of human hands as effectively in laparoscopic surgery as in open surgery. Due to the incision(s), rigid instruments can only move within a cone-shaped workspace around the incision point(s). With such instruments, surgeons are not able to reach targets outside of the cone-shaped workspace or to approach obstructed anatomic structures.

1.2.2 Natural Orifice Transluminal Endoscopic Surgery (NOTES)

With the help of flexible endoscopes [141] [7], Natural Orifice Transluminal Endoscopic Surgery (NOTES) was introduced in the early 1980s [41]. As a form of pathway surgery, NOTES is a collective name of procedures that utilize the natural orifices—such as mouth, nose or vagina—of the human body to gain access to surgery sites [102][119][64][125].

Instrument development for easy target approaching is considered as one of the fundamental problems [107].

Endo-Nasal Skull Base Surgery (ENSBS) is a NOTES-application performed when e.g. tumours are found at the skull base (Fig. 1.5) [64][125]. The success of creating an endonasal passage is essential for the success of this type of surgery, and often requires slow and meticulously precise instrument manoeuvring due to the very narrow nasal cavity and highly dedicated and complex vessels and nerves network around the skull base [66]. Currently, ENSBS is mostly carried out with rigid straight or pre-curved instruments that require long operation time due to lack of steerable instruments and easy-to-control interfaces [68][65].

1.2.3 Endovascular procedures

Endovascular procedures encompass a wealth of minimally invasive arterial procedures in which thin, long and flexible catheters/guide-wires are passed into and navigated through blood vessels, to treat several vascular lesions, such as Carotid stenosis, cerebral aneurysms, Arterio Venous Malformations (AVMs) and acute ischemic stroke [98][72](Fig. 1.6a). A standard endovascular procedure consists of advancing a guide-wire, sliding in a catheter along the guide-wire, retracting the guide-wire, and manoeuvring the catheter tip in order to reach the entrance of the branch arteries. Although procedures with catheters and guide-wires are often called interventions, in this thesis they will be characterised as pathway

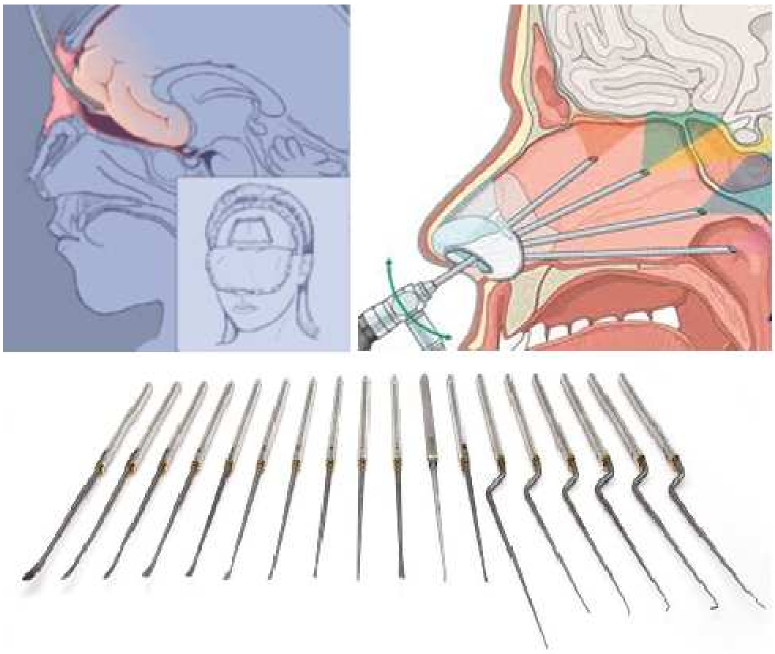

Figure 1.5: Top Left: traditional, open skull base operation, in which the forehead skill is removed and the skill is opened. Top right: Endo-nasal skull-base operation in which the brain base is approached via the nasal cavity. Bottom: surgical tools that used in Endo-nasal skull-base surgery

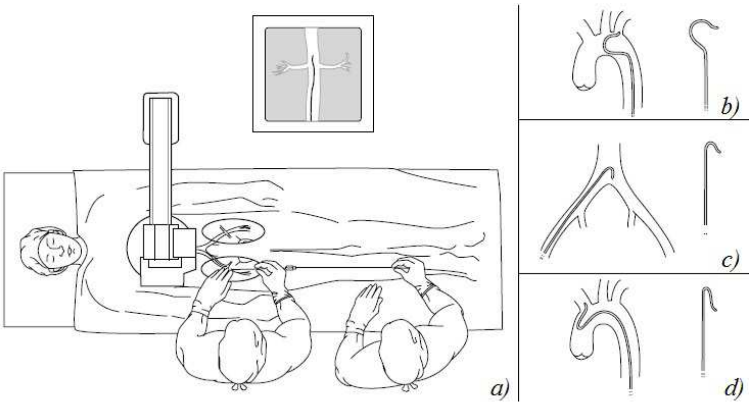

Figure 1.6: Schematic impression of Endovascular procedures and illustration of various selective catheters being manoeuvred during the procedures.(Adapted from [114])

surgery.

There are difficulties specific to the methodology and technology of endovascular procedures, among which the difficulty of catheter exchanging and manoeuvring is a common experience for interventionists. Conventional catheter/guide-wires have a straight tip shape and therefore lack flexibility [150] and are difficult to steer. To deviate into side branches, selective catheters featured with a pre-curved tip shape have been designed [98] (Fig. 1.6b-d). However, it has been estimated that endovascular interventionists perform on average 20 exchanges of catheters, guide-wires and sheaths, per procedure [6], leading to high risk of infection or embolization, long surgery time and larger radiation dose to the patient in case of using conventional X-ray fluoroscopy [98].

1.3 Current solutions to instrument manipulation and problem statement

The restriction in DoFs can be (partially) compensated by equipping conventional instruments with a steerable tip that bends in one or two DoFs. In literature, both robotic and mechanical solutions have been developed.

With the introduction of sensors and actuators, robotic systems provide the user an easy-to-control interface. Currently, the most common surgical robotic system on the market is the Da Vinci system [46][96][21], which consists of a master- and slave- consoles. The master console provides a 3-dimensional view of the surgical space, and the slave console contains a three or four-armed robotic system that is placed next to the operation table. During the surgical operation, the end-effectors of this robotic system are one-to-one controlled by the movements of the surgeon's hand and fingers, imitating these movements precisely. The disadvantages of using such robotic systems are the complexity of manufacture, high costs of execution and maintenance, lack of force feedback, time loss for pre-operative preparation and limitations of surgical applications [14][32].

As a more simple mechanical alternative for the Da Vinci, advanced steerable and manoeuvrable handheld instruments are being developed. In the field of wide-space surgery, *steerable instruments* (instruments with a distal steerable tip) are under development [11] [15][140][93][43][13], some of which are already commercially available [16] [126] [127] [129] [93]. In the field of pathway surgery, flexible instruments with a steerable segment on the tip and instruments with multiple segments along the shaft (henceforth *manoeuvrable instruments*) are being developed [60][97][33][58][71][79][101][103]. A few ones are commercially available on the market [60][97], but most development of manoeuvrable instruments are still in their experimental stage [33][58][71][79][101][103].

Problem statement

Handheld steerable and manoeuvrable instruments are mechanically much simpler than robotic systems but still have control issues in that manipulation is not as intuitive as the current robotic systems. This is one of the reasons why handheld steerable instruments are not yet fully implemented into clinical practise. In fact, many attempts of studies and developments for handheld steerable instruments have been made to create a surgical tool that is able to perform specific surgical functions. However, in most of the current handheld steerable tools the control interface is not optimised for dexterity for the surgeon. Especially for new and emerging surgical applications, such as endo-nasal skull base surgery, problems such as instrument interfacing and factors influencing the instrument manoeuvrability should be investigated and assessed as the first step of the entire instrument development process.

1.4 Goal of the thesis

The goal of this thesis is

- To describe and to categorize current developments of handheld steerable medical instruments;
- To assess commonly used control interfaces and the manoeuvrability of commercially available handheld steerable instruments by determining its influence on human performance;
- To determine potential solutions for manoeuvring difficulties for handheld manoeuvrable instruments used in pathway surgery;
- To build a simulator and carry out experiments to assess the proposed solutions in pathway surgery.

1.5 Thesis outline

This PhD thesis is based on published or submitted articles. Figure 1.7 shows a schematic view of the thesis structure and the mutual relations between the chapters.

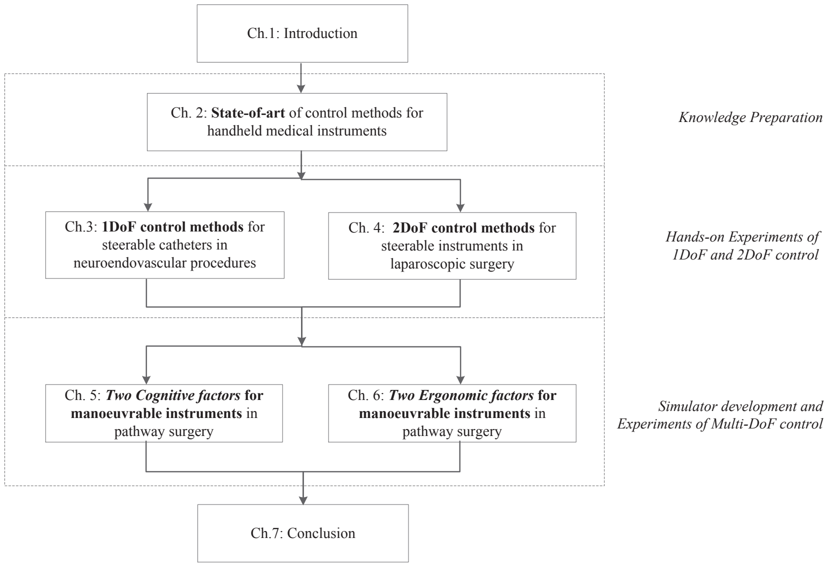

Figure 1.7: Thesis structure.

Followed by an overview of thesis outline and introduction that is given in Chapter 1, Chapter 2 presents the state-of-art in the development of manual control methods for handheld steerable instruments. In Chapter 3, an experiment that compared four 1DoF-control handles for steerable catheters in an simulated endovascular procedure was presented. In Chapter 4, an experiment that designed for comparing two 2DoF control interfaces (thumb control and wrist control) for steering in an orientation task is presented. Chapter 2-4 are considered as the preparation phase of getting known about the field of manual controlling for steerable medical instruments.

The results of Chapters 2-4 were triggers to the development of a simulator, the EndoPathController (Endo-PaC), as an investigation tool presented in the first part of Chapter 5. The second part of Chapter 5 as well as Chapter 6 contain a series of four experiments that were carried out with Endo-PaC concerning the investigation of several factors that influence manual control in pathway surgery. The experiments in Chapter 5 assess the influence of two cognitive factors, *control mapping* and *control display* on human performance; the experiments in Chapter 6 study the influence of two ergonomic factors, *control device* and *control mode* on human performance.

Finally, Chapter 7 summarizes the results of chapters 2-6, discusses the potential future development of Endo-PaC, and provides the recommendation for future steps to develop an intuitive manual control for instrument manipulation in MIS, specifically in pathway surgery.

Chapter 2

State-of-art in manual control methods for steerable MIS instruments

Chunman Fan, Dimitra Dodou,Paul Breedveld

Published in *Minimally Invasive Therapy & Allied Technologies, 22:127135, 2012*.
Under the title ”Review of manual control methods for handheld maneuverable instruments.”

2.1 Abstract

Background: By the introduction of new technologies, surgical procedures have been varying from free access in open surgery towards limited access in minimally invasive surgery. Improving access to difficult-to-reach anatomic sites (e.g. in neurosurgery or percutaneous interventions), needs advanced maneuverable instrumentation. Advances in maneuverable technology require the development of dedicated methods enabling surgeons to stay in direct, manual control of these complex instruments.

This study gives an overview of the state-of-art in the development of manual control methods for handheld maneuverable instruments. It categorizes the manual control methods in three levels: a) number of steerable segments, b) number of Degrees Of Freedom (DoF), and c) coupling between control motion of the handle and steering motion of the tip. The literature research was completed by using Web of Science, Scopus and PubMed.

The study shows that in controlling single steerable segments, direct as well as indirect control methods have been developed, whereas in controlling multiple steerable segments, a gradual shift can be noticed from parallel and serial control to integrated control. The development of multi-segmented maneuverable instruments is still in an early stage, and an intuitive and effective method to control them has to become a primary focus in the domain of minimally invasive surgery.

Keywords: Single Port Surgery, NOTES, Steerable Instruments, Flexible Instruments, Maneuverability

2.2 Introduction

Over the past decades, surgical procedures have evolved towards less invasive approaches by the introduction of new technologies [32]. Open surgery, as a traditional medical specialty, allows direct access to the surgical target but creates a large incision, leading to a sustained wound. The transfer from one large incision to one or more small incision(s) reduces damage to the patient and accelerates recovery time. Following a minimal access approach, key-hole surgery (Fig.2.1a), such as laparoscopic surgery [31], has become the preferred solution in many surgical procedures. Continuing the developments in the field of flexible endoscopy, (Fig.2.1b), new and experimental procedures such as NOTES [106] (Natural Orifice Transluminal Endoscopic Surgery, Fig. 2.1c), which is carried out through natural openings in the human body by following natural anatomical pathways, have been developed. It is expected that these developments will lead to future surgical procedures, in which surgery is carried out along a minimally-invasive 3D pathway through the tissue that is made artificially. Such procedures, called ”path-way” surgery throughout this study (Fig. 2.1d), are likely to be among future solutions in neurosurgery and percutaneous interventions with miniature maneuverable instruments and needles.

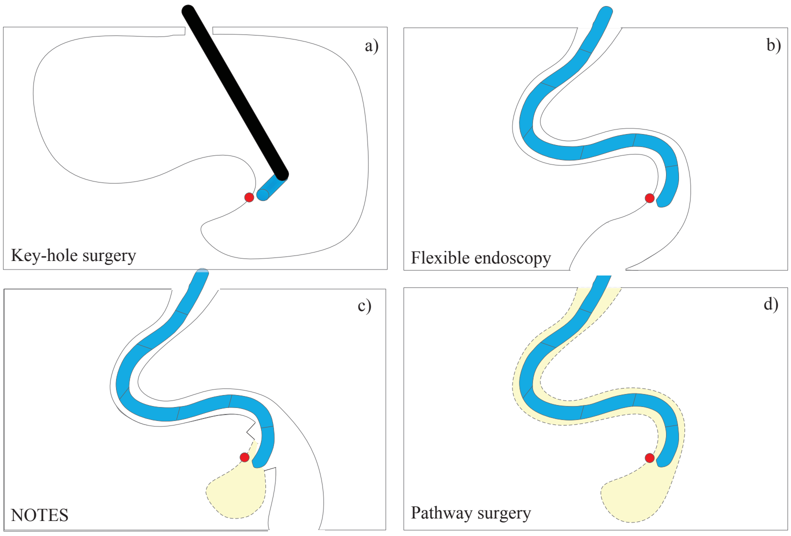

Figure 2.1: Surgical Scenarios. a) Key-hole surgery, e.g. laparoscopic surgery ; b) Flexible endoscopy, e.g. colonoscopy, gastroscopy, catheter interventions; c) Single Port Surgery or NOTES (Natural Orifice Transluminal Endoscopic Surgery); d) Path-way surgery in the future, potentially in neurosurgery and percutaneous interventions. In the figures, dash line and yellow-filled area indicate artificial cavity; Red dot indicates the surgical target; Blue color indicates steering segment(s) of the instrument and black color indicates rigid segment.

The evolution from open surgery towards path-way surgery requires special surgical skills as well as new surgical instruments. In open surgery, surgeons can access the surgical target from multiple directions via the large incision. Conventional surgical instruments can then be manipulated in open space in six Degrees Of Freedom (DoF). In key-hole surgery, accessing the target gets more difficult because conventional rigid instruments can only move within a cone-shaped workspace around the incision point(s), reducing the number of instrument DoF from six to four [14][29]. In path-way surgery, surgical targets cannot be accessed with conventional rigid instruments, since they do not allow to follow the curvature of the path. Thus, the less invasive surgery becomes, the more difficult the surgical target can be accessed and the higher the requirements on the instruments maneuverability.

As a solution for improving the accessibility of difficult-to-reach organs or anatomic structures, medical instruments with a maneuverable tip (a tip with one or multiple steering segments) are under development [32][11][15][43][93], some of which are already commercially available [115][16][91][129][60][92][126][127]. When inserted through a small incision, maneuverable (or steerable) instruments with a single 1- or 2-DoF steering segment at the tip allow a 6 DoF motion in space, and can access surgical targets that are outside of the cone-shaped workspace. However, such 2-DoF maneuverable instruments are not suitable for path-way surgery since they do not allow to follow a curved pathway. Maneuverable instruments with multiple steering segments that can be shaped to fit the curved pathway are therefore under investigation.

A number of studies on maneuverable instruments have been carried out [140][80][152][36]. Despite the availability of automated control approaches, handheld maneuverable instruments are preferred by surgeons due to the similarity to conventional instruments and the full control during surgical procedures allowing them to quickly and easily adapt to varying circumstances [11]. Developing intuitive and effective control methods for handheld maneuverable instruments is thus an important topic for engineers. The goal of this study is to review the state-of-art in the development of manual control methods for handheld maneuverable surgical instruments, and to investigate what would be the best-suited manual control method for future instruments for path-way surgery.

At Delft University of Technology, a literature search was carried out using Web of Science, Scopus and PubMed. To get a full overview of maneuverable approaches and their controls, each of the terms ”Catheter”, ”Endoscopic” and ”Surgical instrument” was combined with each of the terms ”articulation”, ”deflection”, ”angulation”, ”rotation”, ”deflectable”, ”DoF” and ”control” in a full-text search. Patent literature (www.espacenet.com) was searched for maneuverable surgical instruments as well with the same terms. A number of conference proceedings and books were consulted as well. This review study focuses on manual control methods applied in handheld maneuverable instruments. Studies on rigidity controlling, material stiffening and internal mechanisms of maneuverable instrument tips were not included. For more information on these topics the reader is referred to [11][77].

In this study, we categorized the manual control methods in three levels (Fig.2.2):

- number of steerable segments
- number of DoF
- coupling between the control motion of the handle and the steering motion of the tip

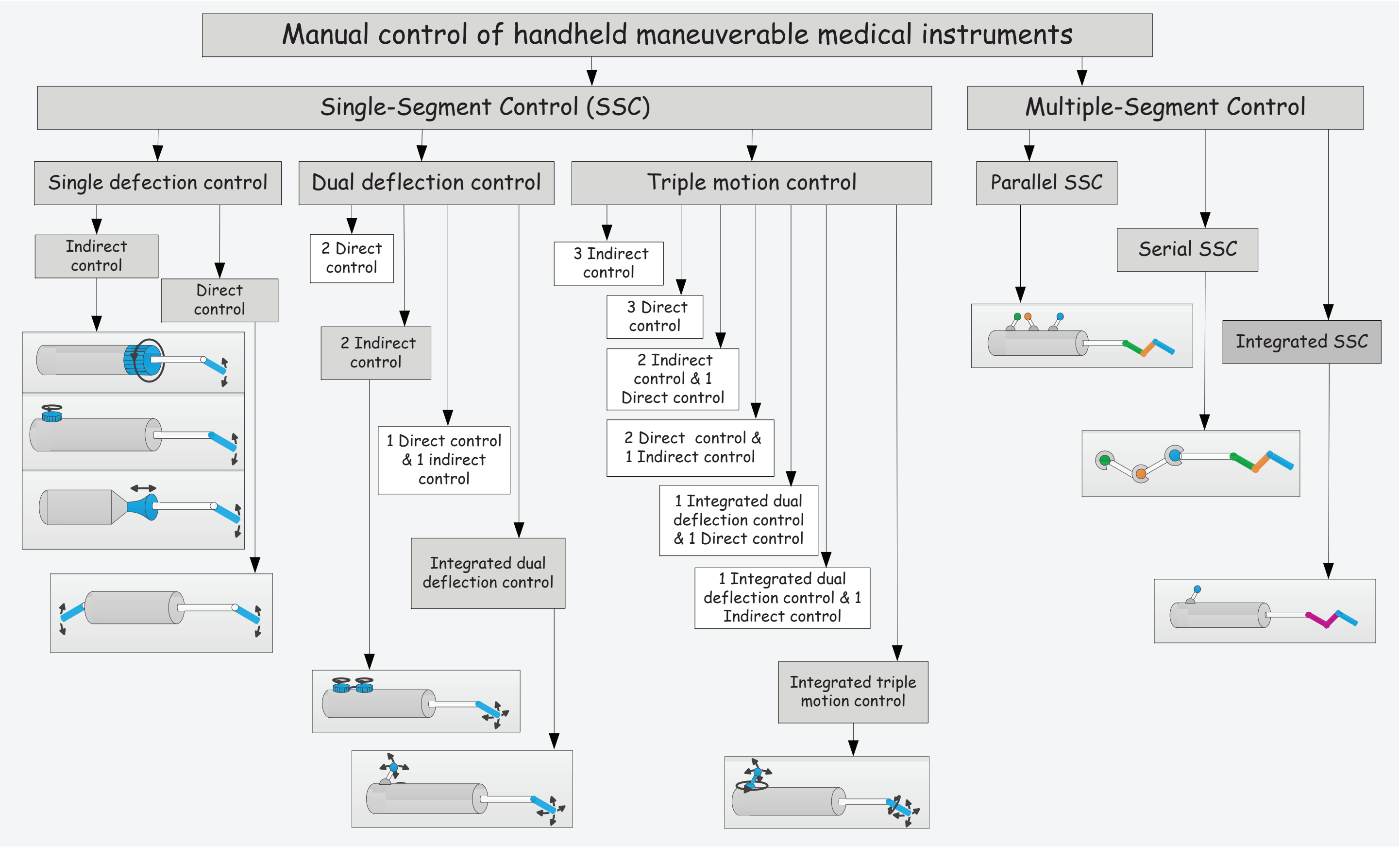

Figure 2.2: Scheme of manual control of handheld maneuverable medical instruments. Gray blocks indicate the session titles and reviewed developments/prototypes.

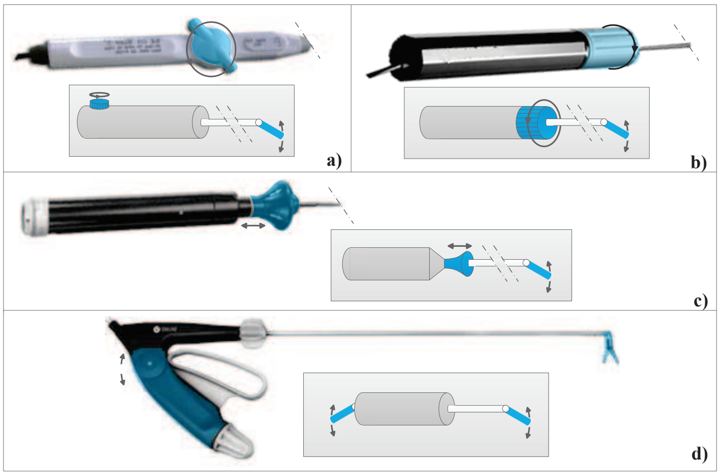

Figure 2.3: Indirect 1-DoF control and direct 1-DoF control. Top: Indirect 1-DoF control (a) Blazer platform (Courtesy of Boston Scientific, Natick, MA, USA) [115]; (b) Livewire TC ablation catheter handle (Courtesy of St. Jude Medical, St. Paul, MN, USA) [92]; (c) Ten-ten Duodecapolar diagnostic catheter handle (Courtesy of Boston Scientific, Natick, MA, USA) [116]. Bottom: Direct 1-DoF control: (d) Radius Surgical System (RSS, Courtesy of Tuebingen Scientific, Tuebingen, Germany) [140][38].

2.3 Single-segment control

As a maneuverable tip with one steering segment has maximally 3 DoFs (2 deflections and 1 rotation), three possibilities of single-segment control can be logically distinguished:*single deflection control (1 translational DoF: up/down or left/right), dual deflection control (2 translational DoFs: up/down and left/right) and triple motion control (2 translational DoFs and 1 rotational DoF).*

We further distinguish two sub-categories for single deflection control as direct control and indirect control. Direct control is for the case that the tip motion matches the surgeon's hand motion (wrist or finger deflection mapped to tip deflection and both deflections are in the same plane and same direction; wrist or finger rotation mapped to tip rotation and both rotations are in the same plane and the same direction). Indirect control is for the case that the tip motion differs from the surgeon's hand motion (wrist or finger deflection mapped to tip rotation; wrist or finger rotation mapped to tip deflection; wrist or finger deflection mapped to tip deflection and the directions are perpendicular to each other or are not in the same plane; wrist or finger rotation mapped to tip rotation and the rotations are not in the same direction or the same plane. Fig. 2.3).

2.3.1 Single Deflection Control

Indirect 1-DoF control

Indirect single deflection control has been applied in a variety of steerable catheters and guide wires in the form of a twisting-wheel, a rotating-collar and a sliding-piston or lever [115][91][92][126][116][117][33]. In the case that a finger rotation is mapped to a tip deflection, with the twisting-wheel and the rotating-collar, it is the circumduction of the surgeons finger that results in a tip deflection. The twisting-wheel controller is used in the Blazer catheter platform [115] (Fig. 2.3a, Boston Scientific, Natick, MA, USA) and the ComfortGrip handle [91] (St. Jude Medical, St. Paul, MN, USA), and the rotating-collar in the Livewire TC ablation catheter [92] (Fig. 2.3b, St. Jude Medical, St. Paul, MN, USA) and the Covidien roticulator [126] (Covidien Surgical, Mansfield, MA, USA). In all four products, the wheel and the collar are operated by the thumb and index finger while holding the handle in the palm of the hand. In the case of a sliding-piston or lever which moves forward/backward along the handgrip, the control motion (forward/backward) is perpendicular to the tip deflection (up/down). A sliding-piston, that is pulled and pushed by the thumb or index finger, can be found in the handle of the Polaris Dx steerable catheter [116] (Boston Scientific, Natick, MA, USA) and the Ten-Ten duodecapolar diagnostic catheter [117] (Fig. 2.3c, Boston Scientific, Natick, MA, USA), whereas in a computer-assisted arthroscope developed by Dario et al. [33], changes in the sliding-lever position are electronically encoded and transferred as driving signal for the up/down tip deflection.

Direct 1-DoF control

The only system found that applies direct 1-DoF control is the bendable handle of the Radius Surgical System [140][38] (Fig. 2.3d, RSS, Tuebingen Scientific, Tuebingen, Germany). The surgeon uses his wrist to bend the handle, which mechanically links to the tip and drives its deflection. The directions of handle bending and tip deflection are in one plane and mirrored with respect to each other (when the handle bends towards the shaft, so is the tip). Furthermore, the RSS is equipped with tip rotation, which is directly controlled by a rotating-knob on the handle.

2.3.2 Dual deflection control

By duplicating or combining the control methods for a single deflection mentioned in Section 2.1, three concepts can be logically derived for dual deflection control:*indirect 2x1-DoF control, direct 2x1-DoF control* and *indirect 1x1-DoF with direct 1x1-DoF control*, all three requiring two separate 1-DoF controllers. Additional to that, enabled by the natural dual deflection of the human wrist or thumb, a control concept with one integrated 2-DoF controller, direct 1x2-DoF control, is deduced. From these four concepts, only indirect 2x1-DoF and direct 1x2-DoF control methods were found in the literature.

Indirect 2x1-DoF control

For indirect 2x1-DoF control, two controllers are required, each of which deflects the tip in an individual direction. This control method has been broadly applied in the great majority of flexible endoscopes such as gastroscopes and colonscopes [60][77] (Fig. 2.4a) and has further been found in a bending forceps manipulator built by Yamashita et al. [148]. Gastroscopes and colonoscopes contain a maneuverable tip that bends in two directions (left/right and up/down), controlled by two twisting-wheels that are placed on top of each other and rotating in the same plane. Although the two twisting-wheels can theoretically be steered both at the same time, endoscopists are often using them individually and controlling only one motion at a time. Yamashitas forceps manipulator uses two dials that are located in a line on the handle. The rotation of the dials is encoded and corresponds to the horizontal and vertical bending angles of the tip.

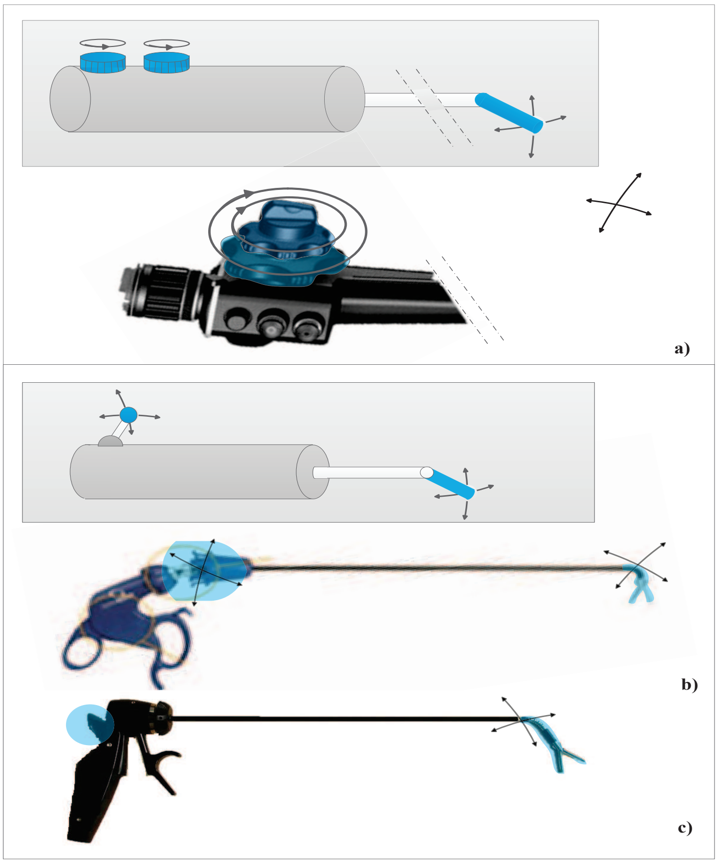

Figure 2.4: Indirect 2x1-DoF control and Direct 1x2-DoF control. Top:(a) Indirect 2x1-DoF control (Courtesy of Olympus colonoscope, Tokyo, Japan [60]). Bottom: Direct 1x2-DoF control: (b) RealHand (Courtesy of Novare Surgical system, Cupertino, CA, USA) [129], (c) Microflex (Courtesy of DEAM, Amsterdam, NL) [11].

Direct 1x2-DoF control

The ability of both the human wrist and thumb to move naturally in two perpendicular directions enables the surgeon to control 2 DoF simultaneously. In the case of wrist control, the handle of the instrument follows the surgeon's wrist movements and bends in two perpendicular directions, resulting in a dual deflection of the tip. A broad array of commercially available products and design prototypes have been found employing wrist control with varying handle forms. The RealHand (13) (Fig. 2.4b, Novare Surgical system, Cupertino, CA, USA) and the SILS Hand [127] (Covidien Surgical, Mansfield, MA, USA) both contain a conventional scissor-like handle, whereas the LaparoAngle [16] (CambridgeEndo, Framingham , MA, USA) has a sword-like handle shape. The Endo-Periscope [15] and I-Flex [12] (Delft University of Technology, Delft, NL) have a pencil-like handgrip and pincer grip respectively. In the case of thumb control, the tip deflects in the same direction as the thumb that operates a 2-DoF joystick. Thumb control is applied in the prototype of a handheld laparoscopic grasper [11] (Fig. 2.4c, DEAM, Amsterdam, NL), in which a thumb-controlled 2-DoF joystick provides the control input for the up/down and left/right tip deflection. The thumb-controlled grasper was strongly preferred with respect to wrist over wrist-controlled handgrip by novices in a tip orientation task due to the perceptive feeling in performance [36].

2.3.3 Triple motion control

Triple motion control can be considered as an extension of dual deflection control with a single rotation control. Two possibilities are hereby possible: *dual deflection with indirect rotation control* and *dual deflection with direct rotation control*, both requiring two or three controllers, depending on the type (i.e., indirect or direct) of the dual deflection control. An *integrated direct 1x3-DoF control* can be reasoned as well, in which one controller is sufficient. In fact, only the direct 1x3-DoF control was found in the literature.

Direct 1x3-DoF control

The EndoWrist (Fig. 2.5a), used in the Da Vinci surgical robot [5][69], incorporates the direct 1x3-DoF control, in which the two deflections and rotational motion of surgeon's hand are directly mapped to the deflections and rotation of the instrument tip. The Da Vinci robot is a master-slave system, in which the movements of the surgeon's wrist at the master unit are electronically recorded and transferred to the end-effector at the slave unit, resulting in a full motion mapping between surgeon's hand and instrument tip. Direct 1x3-DoF control has also been employed in the Minimally Invasive Manipulator [63] (Fig. 2.5b, MIM, Academic Medical Centre, Amsterdam, NL), which mechanically transfers the surgeons hand motion to the instrument tip in a one-to-one ratio by using parallelogram mechanisms driven by linkages or cable/pulley mechanisms.

2.4 Multiple-segment control

Methods for controlling multiple-segments can be systematically derived from the single-segment control methods mentioned in Section 2 according to the physical coupling be-

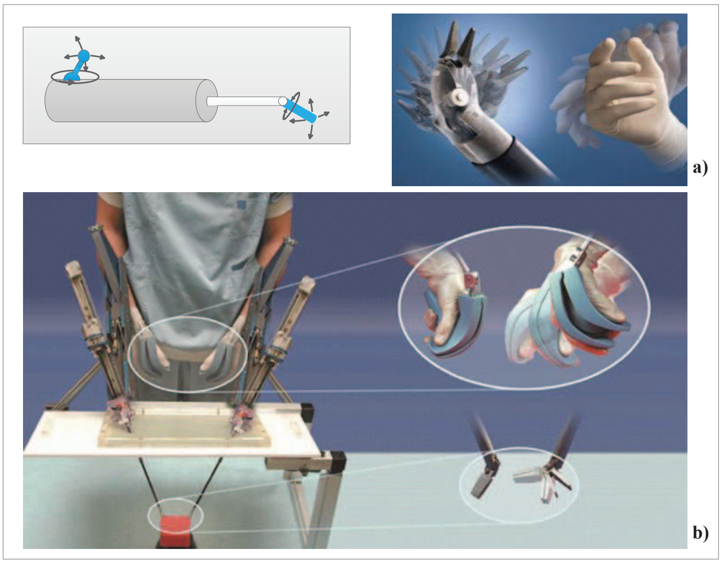

Figure 2.5: Direct 1x3-DoF control (a) EndoWrist (Courtesy of Intuitive Surgical, Sunnyvale, CA, USA) [5]; (b) Minimally Invasive Manipulator [63] (MIM, Courtesy of Academic Medical Centre, Amsterdam, NL)

tween the different controllers. In this study, we categorize various ways to control multiple segments into three main groups: *parallel single-segment control*, *serial single-segment control* and *integrated single-segment control* (Fig. 2.2). The first two concepts require as many controllers as segments, whereas the last one requires only one controller for any number of segments. As the development of instruments with multiple segments is still in its infancy, only a few examples of multiple-segment control have been found in the literature, mainly in patents [63][101].

2.4.1 Parallel single-segment control

In parallel single-segment control, each segment has its own controller, and each controller functions independently of the other controllers. The reported developments of parallel single-segment control vary in terms of construction and control method. The patented devices by Ostrovsky [101] and Martin et al. [79] (Fig. 2.6a) contain a number of links serially connected by means of cables. Sets with different number of links are grouped as one segment and steered by pulling/releasing the connection cables. The cables are controlled by three parallel twisting-wheels in the patent by Martin et al., and by two separated rotating-disks in the patent by Ostrovsky. Both patented devices are controlled indirectly since the control motion differs from the tip deflection motion. Another example of parallel single-segment control has been found in a patent by Imran [58], in which an elongated device equipped with two segments for insertion into a body cavity is described. The two segments contained temperature-activated shape-memory elements and are steered independently by

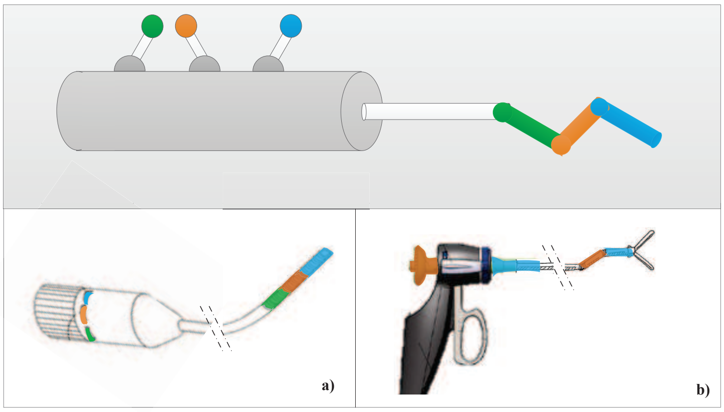

Figure 2.6: Sketch of parallel single-segment control and (a) patented maneuverable instrument with three parallel twisting-wheel controllers, adapted from [79]; (b) Duoflex, adapted from [137] .

a twisting-wheel and a sliding-lever. The Duoflex [137] (Fig. 2.6b, Delft University of Technology, Delft, NL) is a two-segmented cable-ring instrument that contains two separate direct control methods: a wrist-controlled handgrip to control the back tip segment and a thumb-controlled joystick to control the front tip segment. The two controllers can be individually locked to avoid fatigue of surgeons' hand. Among the parallel single-segment controlled instruments, only Duoflex and the patented devices by Martin et al. and Imran can be operated with a single hand.

2.4.2 Serial single-segment control

In serially connected controllers, the motion of each controller depends closely on the motion of the adjacent ones. One such example of control has been implemented in a multiple-segment instrument prototype called Multiflex [103] (Fig. 2.7, Delft University of Technology, Delft, NL). The maneuverable tip of the Multiflex contains five serially connected segments. Each segment is steered by selectively pulling and releasing one of four steering cables, which are fixed to a corresponding control-ring. Each control-ring functions as a joystick and can bend in all directions (2-DoF). The five control-rings are assembled serially on a stack and form the handgrip of device. The shape of the handgrip is altered by the bending position changes of all control-rings, and is then magnified and mirrored to the tip. Another example of serial single-segment control has been found in an articulating sheath by Danitz [34]. The tip segments and the controllers in the handle consist of pairs of orthogonal hinges that are serially connected with cables and each pair of hinges can be manipulated in 3 DoF (2 deflections and 1 rotation).

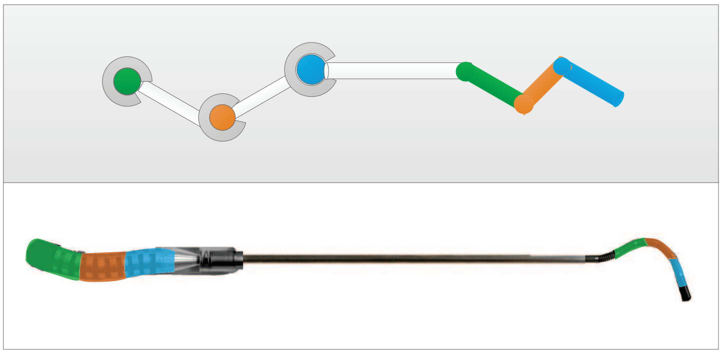

Figure 2.7: Sketch of serial single-segment control and Multiflex [103].

2.4.3 Integrated single-segment control

Integrated single-segment control refers to a control concept in which only the first segment of the instrument tip is actively steered, followed passively by the rest of the segments as the instrument moves forward. In this way, only one integrated 2-DoF controller is required for controlling an arbitrary number of segments. The EndoCarrier [71] and NeoGuide system [97] are two examples of integrated single-segment control that share similarities in control but differ in construction and motion transferring method. Both systems are steered by one integrated 2-DoF joystick whereas the leading motion is recorded and transferred electronically towards the preceding segments up to the tail. This results in a shape-memory locomotion similar to a snake that moves forward while memorizing the path of the head and sliding it backward along its body.

The EndoCarrier consists of serially connected identical cylindrical segments and is driven by motors at a constant forward speed, whereas the NeoGuide system consist of a leading section and a following section, and is operated manually at any desired speed. In the EndoCarrier, the recorded leading motion is transferred backwards after a fixed time delay regardless of the position of each segment, whereas in the NeoGuide, the recorded leading motion is only transferred backwards when the following section arrives at the same position as the leading section. Finally, as another example of integrated single-segment control, instead of hinges as in the previous two systems, the CardioArm (Fig. 2.8) [24][25] consists of multiple groups of cable-connected concentric tubes. The rigidity/limpness of the tubes is altered as a result of pulling/releasing the connecting cables in regular time intervals. The leading motion is then steered while the tubes are limp, whereas the leading direction is fixed when the tubes are rigid. The forward motion of the entire instrument and the pulling/releasing motions of the cables are controlled by motors. All three systems are equipped with an integrated 2-DoF joystick as a control interface for the leading segment.

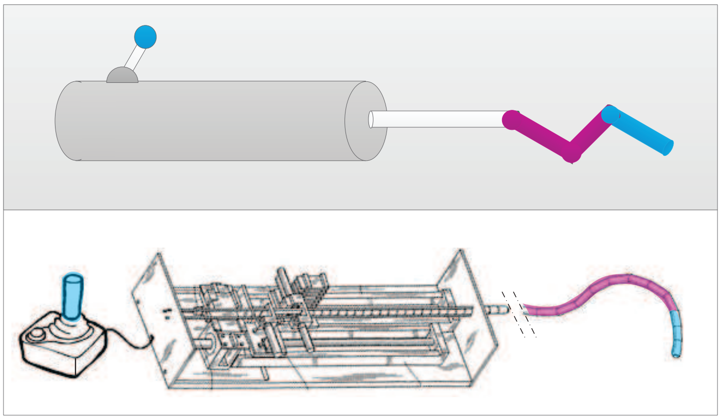

Figure 2.8: Sketch of integrated single-segment control and a concept sketch of CardioArm, adapted from [24][25].

2.5 Discussion

In the shift from open to path-way surgery, approaching the operation site becomes increasingly difficult due to the restricted maneuverability of the available instruments. Driven by the developments in NOTES, surgical instruments are being equipped with a maneuverable tip compensating for the limited freedom of motion, but introducing high-level control complexity to the surgeon.

In the case of controlling maneuverable (or steerable) instruments with a single steering segment at the tip, one controller is sufficient and the control motion is transferred to the tip either directly or indirectly. Direct 1-DoF control is more intuitive than indirect 1-DoF control due to the one-to-one mapping between the control motion and the tip motion, but the instruments featuring the latter control method are more commonly found in literature due to their mechanical simplicity, cheap manufacturing and suitability for disposable use (Fig. 2.3). For dual deflection and triple motion control, two categories of control methods can be distinguished: separated and integrated control. The former employs multiple 1-DoF controllers, whereas the latter requires only one integrated controller.

The categorizing concepts of separated and integrated control can be further applied in distinguishing control methods for maneuverable instruments (instruments with multiple steering segments at the tip). In order to maneuver multiple steering segments, separated control can be achieved either with parallel single-segment controllers or serial single-segment controllers, whereas integrated single-segment control uses only one integrated controller for the leading active segment and the following passive segments. Separated control features each segment of the maneuverable tip with one individual controller, meaning that each segment can be steered with full 2- or 3-DoF maneuverability. As a result, the maneuverable tip can be shaped into any arbitrary curvature, at the drawback that the control is very complex since the surgeon (or an entire team of surgeons) has to maneuver many controllers simultaneously. Integrated control allows less maneuverability as only 3D trajectories can be followed. As multi-segmented instruments are primarily being designed for this purpose, however, a limitation to shape memory locomotion is not considered as a drawback but as a strong benefit leading to easy control by just one surgeon with a smart instrument that precisely matches its surgical goal. Maneuverable instruments featured with integrated control would generate a user experience similar to conventional steerable instruments in aspects like eye-hand coordination, 3D-vision and surgical work flow, but with strongly extended functionality and maneuverability. Although easier to control, integrated control implies higher mechanical complexity and presents great design challenges to the engineers developing such instruments.

This review proposes a novel way of categorizing control methods for handheld maneuverable instruments based on physical coupling between the controllers, and the reviewed control methods are linked to future developments in path-way surgery. Although the current overview only contains control methods for instruments with a single tip (single-branched instruments), the information in this study can serve as a basis for research on manual control methods for multi-branched instruments, e.g. for Single Port Surgery (SPS) or NOTES.

This study shows that the development of multi-segmented maneuverable instruments is still in its infancy, and that their controls are still very basic and not very intuitive. The reviewed maneuverable instruments with multiple steering segments vary in size, control accuracy and medical application, and the respective control methods were developed solely for function but not for dexterity or versatility. The development of an intuitive and effective control method is a challenge to engineers and should become a primary focus in multiple-segmented instrument development within the domain of path-way surgery. Finding a solution for intuitive steering of single-branched systems is further essential for making the step to easy control of multi-branched systems, allowing complex surgical interventions through a single, small incision — the ultimate goal in minimally invasive surgery.

2.6 Summary

In this chapter we have an overview of the state-of-art in the development of manual control methods for handheld maneuverable instruments. The study shows that in controlling single steerable segments, direct as well as indirect control methods have been developed, whereas in controlling multiple steerable segments, a gradual shift can be noticed from parallel and serial control to integrated control. The development of multi-segmented maneuverable instruments is still in an early stage, and an intuitive and effective method to control them has to become a primary focus in the domain of minimally invasive surgery.

Chapter 3

1DoF control methods for steerable catheters in neuroendovascular procedures

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3.1 Abstract

Background: During neuroendovascular procedures, catheter manipulation is extremely time consuming due to careful movements and the difficulties for entering branch vessels. Steerable catheters providing adaptive tip shapes may result in a lower number of catheter exchanges and higher precision of catheter positioning, yet an intuitive and efficient control method for tip steering remains a challenge. A slider or knob featured on a handgrip is commonly implemented for controlling steerable catheters, but the effectiveness of the different control methods is unknown.

Method: A setup simulating an endovascular path was built for evaluating the effectiveness of four control handles as input device: Rotator-Top, Rotator-Front, Slider-Horizontal and Slider-Vertical. Sixteen participants were asked to advance a virtual catheter tip on the monitor towards a target as precise as possible. Each participant performed two trials of four experimental runs over four sessions. The performance was assessed in terms of task time, travel length of the tip, average distance to the centre of the vessel, and the number of collisions to the wall. Subjective evaluation was assessed using NASA Task Load Index.

Results and Conclusion: Significant differences between of the four handles were observed in terms of average distance (p=0.014 in the 1st trial and p=0.029 throughout the experiment) and the number of collisions (p=0.043 in the 2nd trial), showing that participants using Slider-Vertical exhibited best performance. Subjective preference was strongly given to Rotator controllers.

Key words: Neuroendovascular procedures, steerable catheters, control method

3.2 Introduction

Since the introduction of cerebral angiography, endovascular approaches for treating head and neck lesions were under investigation. Under image guidance, thin, long and flexible catheters/guide-wires can be navigated within blood vessels, to treat vascular lesions, such as Carotid stenosis, cerebral aneurysms, Arterio Venous Malformations (AVMs) and acute ischemic stroke [72]. Beside the benefits for the patient (e.g.: quicker recovery and less post-operative complications), neuroendovacular procedures are difficult to perform due to the visual-control misalignment and indirect manipulation of long medical instruments. A standard endovascular procedure contains 1) advancing a guidewire, 2) sliding a (pre-curved) catheter over the guide-wire, 3) retracting the guide-wire, and 4) manoeuvring the catheter tip to reach the entrance of the side vessel.

A number of pre-curved catheters are developed in order to fit various vessel curvatures [128] [90][104][87][94][118][35]. Due to the high precision requirements from neuroendovascular procedures [114], the catheter tip is carefully advanced while the interventionist slowly rotates the catheter shaft, which is extremely time consuming. As one of the solutions, catheters with a steerable tip (referred to hereinafter as steerable catheter) provide the adaptability of fitting different curvatures and lead to a smaller number of exchanges and higher precision of the catheter positioning.

Steerable catheters have been reported in the literature [150] and the developments are based on various properties of the steerable tip, such as 1) thermal sensitivity [131][134][39] [95]; 2) electrical sensitivity [154][47]; 3) pressure sensitivity [57][49]; 4) micro-motorization [151]; 5) cable-pull mechanism [1][54][23][9][75]. Among all the developments, a steerable catheter with a puller cable system is the easiest to manufacture and the safest to utilise. Commonly, one (or more) cable(s) is mounted between the tip and a control unit. The tip is mechanically deflected by sliding/rotating the control unit at the proximal end of the catheter [84][83][82].

Handgrips featured with a rotation knob or with a slider are the basic control modes of steerable catheters described in the literature [54][23][75][1]. The influence of each control mode on human performance, such as accuracy and intuitiveness, remains unexplored. The presented study implemented the two control modes into four handles according to the position of the control knob/slider and the direction of the control movements: 1) Sliding Horizontal (Sliding-H), 2) Sliding Vertical (Sliding-V), 3) Rotation Top (Rotation-T), and 4) Rotation Front (Rotation-F) (Fig. 3.1). A navigation task was developed in order to investigate the effects of the four different control methods on human performance.

3.3 Material and methods

3.3.1 Setup

A setup (Fig. 3.1) was built to simulate the endovascular procedures and to measure participants performance. The setup consists of 1) four various handles, 2) a catheter platform, and 3) visualization software simulating an endovascular path on the monitor.

Four handles (∅=20mm, L=150mm) were designed differing only in term of directions of the control motion, such as Sliding-H and Sliding-V, or in term of position of the knob.

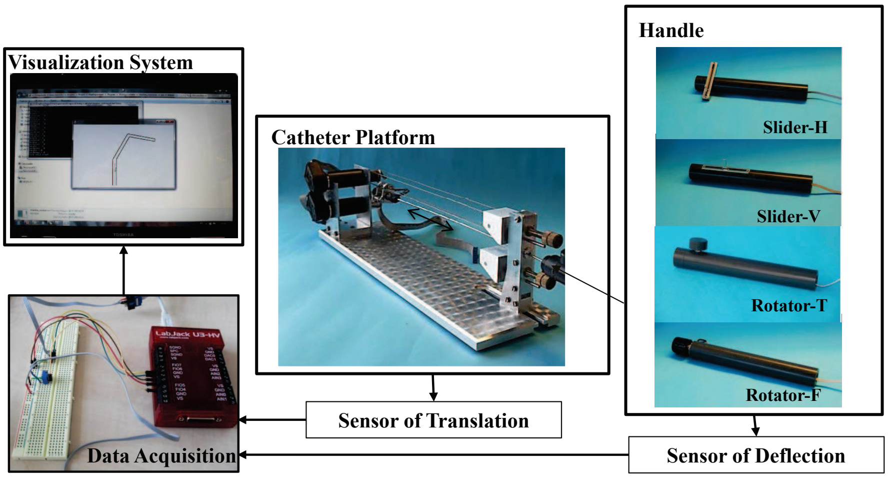


Figure 3.1: Experimental Setup: In one end of the catheter platform one handle is connected to the rod that mimics the catheter body. From that end the rod is pushed and pulled for translational movement. The rotator/slider on the handle can be manipulated for deflecting the virtual tip in the custom-designed software. Both translational and manipulating movements were detected by two sensors (one at the platform and one on the handle) that were read out from a data acquisition unit, that was electronically connected to a laptop.

Rotation-T is equipped with a rotation knob on top of the handgrip, whereas Rotation-F with a rotation knob in front of the handgrip, like a collar.

The catheter platform contains a rod with its distal end connected to a sliding wire. The forwarding movements of the rod were measured by an encoder mimicking the catheter translational movements. The proximal end of the rod was mounted with one of the four handles during the experiment.

The visualization software geometrically represents a path delineated by three consecutive blood vessels. The size and inclination angle are referred to the Common Carotid Artery(CCA), Internal Carotid Artery (ICA) and the branch vessels of its bifurcation - Middle Cerebral Artery (MCA) and Anterior Cerebral Artery (ACA) [44][112]. Two vessel sequences were considered: CCA-ICA-MCA and CCA-ICA-ACA and the angles were 30°, 50° and 120°, respectively (Fig. 3.2a-b). The ratio of the vessel size was 0.85 between CCA - ICA, 0.86 between ICA-MCA and 0.65 between ICA-ACA.

3.3.2 Task

Participants were asked to maneuver a virtual catheter tip (red section in Fig. 3.3) along a 2 dimensional path by using each of the four control handles. They were instructed to maintain the virtual tip inside the path, and advance the tip towards the end line (blue section in Fig. 3.3). They were further asked to avoid collisions and try to follow the centre line of the path as accurate as possible. Four paths representing two variations of sequences CCA-

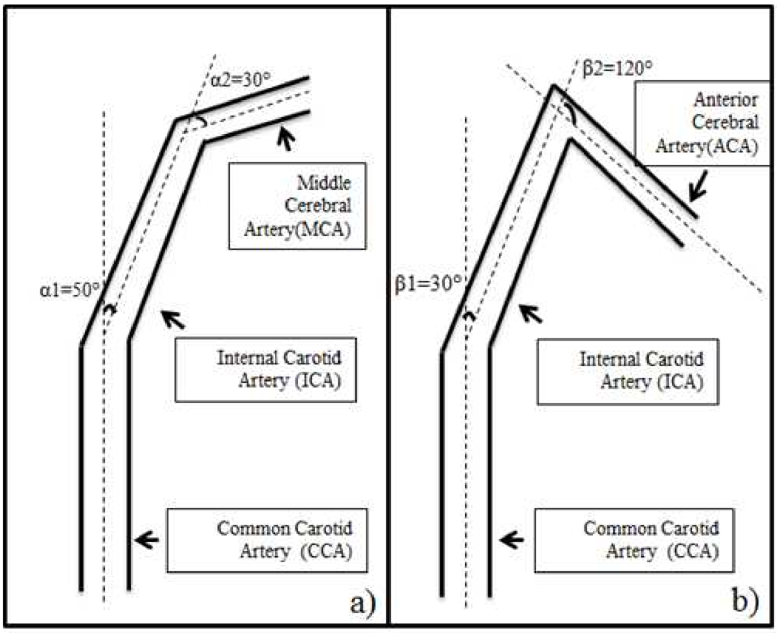


Figure 3.2: *The two simulated vessel models.*

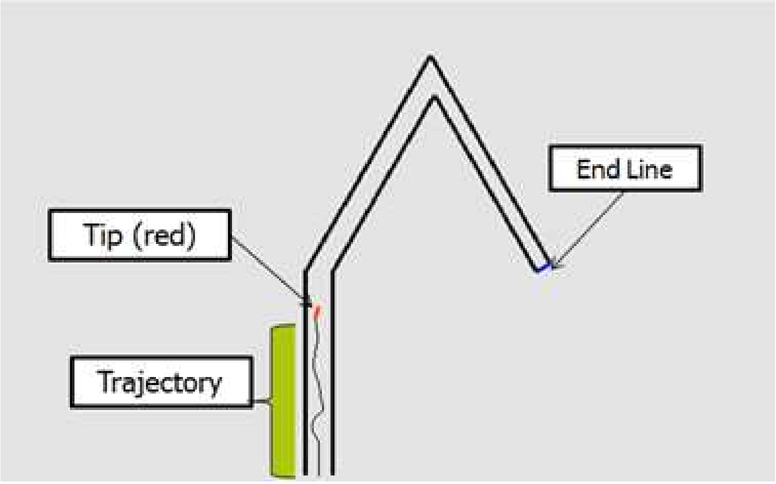


Figure 3.3: *Simulated endovascular navigation task: The catheter tip in red had to be manoeuvred within the path delineated by the black lines following the centre line of the path until it reaches the end line.*

ICA-MCA and CCA-ICA-ACA were presented (Fig. 3.4,panels c-f). Two geometrically similar paths were designed for practising purpose (Fig. 3.4a-b).

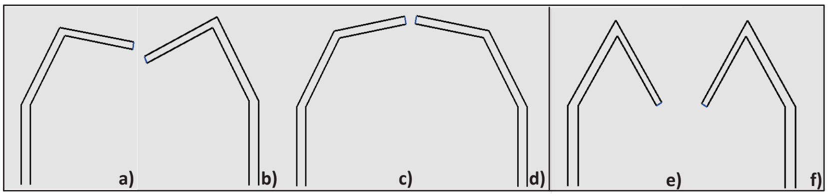


Figure 3.4: Screenshots of the simulation software. a) and b): two tasks used in the practice phase; c-d): four tasks used in the trial phase.

3.3.3 Participants

Sixteen participants (11 men and 5 women, aged between 20 and 35) from Delft University of Technology performed the experiment voluntarily. They were engineering students with no previous experience of neuroendovascular procedures or the experimental setup. All participants were right handed and did not have colour blindness.

3.3.4 Experiment

Each experiment started with a brief verbal introduction explaining the structure of the setup and the goal of the experiment. Participants were asked to perform the experiment with only the right hand under their most comfortable holding gesture. Next, the participant watched a short video demonstrating the experimental task and was asked to read a printed version of the experiment protocol (Fig. 3.5-top). Each experiment contained four sessions by using each of the four handles. The order of utilization of each handle was altered to eliminate the influence of the learning curve of the task. Each session included three phases: practice, trial, and a questionnaire during the break.

During the practice phase, the participants were asked to complete two practising runs in order to understand the experiment, and to find the most comfortable position for holding and manoeuvring the handle. Subsequently, during the trial phase, the participants were asked to perform two trials for each handle, and each trial contained four runs with various paths (Fig. 3.5-bottom). The trial phase was followed by a short break during which the participants were asked to grade the handle using NASA Task Load Index (TLX) for measuring subjective workload. At the end of the four sessions, additional questions were asked in the questionnaire, such as *what was your most preferred control handle*, *did you feel fatigue during the experiment*, *what was your personal strategy for completion of the experiment*, and *do you have suggestions or comments about the handles*.

3.3.5 Parameters and data analysis

The following parameters were used for assessing the task performance:

- *Task completion time (in seconds)*: time that each participant used in one trial;
- *Travel length of the tip (in arbitrary unit)*: length of the trajectory travelled by the tip distal end in one trial;

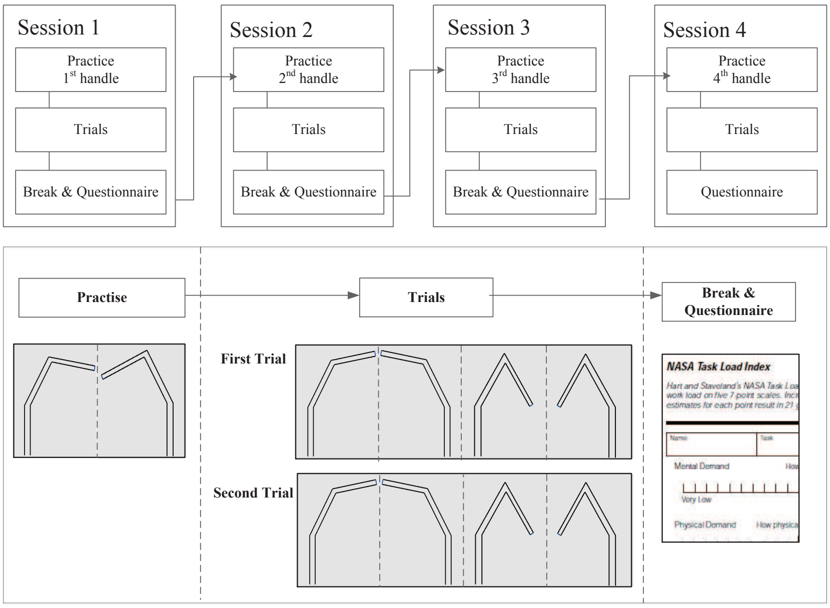


Figure 3.5: Experimental protocol.

- *Distance from the center line (in arbitrary unit)*: average distance to the center line in one trial. This measure indicates how accurate the tip trajectory fits the center line of the path;
- *Number of errors during the task*: number of times the tip passed over the black line delineating the vessel path throughout one trial;
- *TLX results*: including mental load, physical load, temporal load, performance load, effort load and frustration load with the use of each handle (Fig.4.9).

Recorded data were analyzed using SPSS20. One-way analysis of variance (ANOVA) with repeated measures and post-hoc Bonferroni test were conducted to investigate the differences between the four control handles in terms of task time, travel length and average distance over 1) first trial, 2) second trial, and 3) the two trials. For the dependent ordinal variables (number of errors and workload scores), Friedman test and Wilcoxon signed-rank test were used.

3.4 Result

3.4.1 Objective Measurements

Throughout the experiment, the results revealed significant difference of the four control handles in terms of average distance from center line (p=0.029) but not in terms of task time

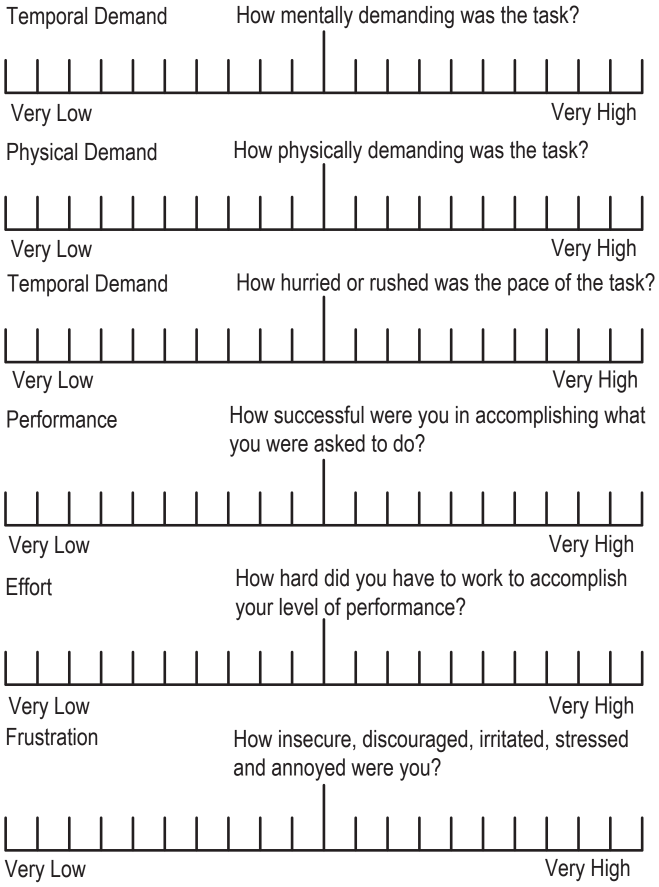


Figure 3.6: Image of the paper-and-pencil version of the NASA-TLX rating scale.

or travel length (Fig. 3.7). Post hoc tests indicated that Rotator-T led to shorter average distance to central line than Rotator-F (*p*=0.019). In the first trial, the four control handles did not differ significantly in terms of any of the investigated parameters, except for the average distance to the center line (*p*=0.014), whereas in the second trial, a difference was observed in number of errors (*p*=0.043). Post hoc tests revealed that in the first trial, participants using Rotator-T performed the experiment with a significantly shorter distance to center line than using Rotator-F (*p*=0.018). In the second trial, the results revealed that participants issued significantly lower number of errors using Slider-V compared to using Slider-H (*p*=0.003), using Rotator-T (*p*=0.021), and using Rotator-F (*p*=0.006, Fig. 3.8).

3.4.2 Subjective Evaluation

Statistical results of the subjective workload scores over the four handles are presented in Figure 3.9. Significant difference between the four handles was only observed in temporal demand ($\chi^2(3)=10.008$, *p*=0.019). The post hoc test revealed that participants using Slider-H or Slider-V experienced significantly higher temporal demand than using Rotation-F (Z= -2.371, *p*=0.018) and Rotation-T (Z=-2.125, *p*=0.034).

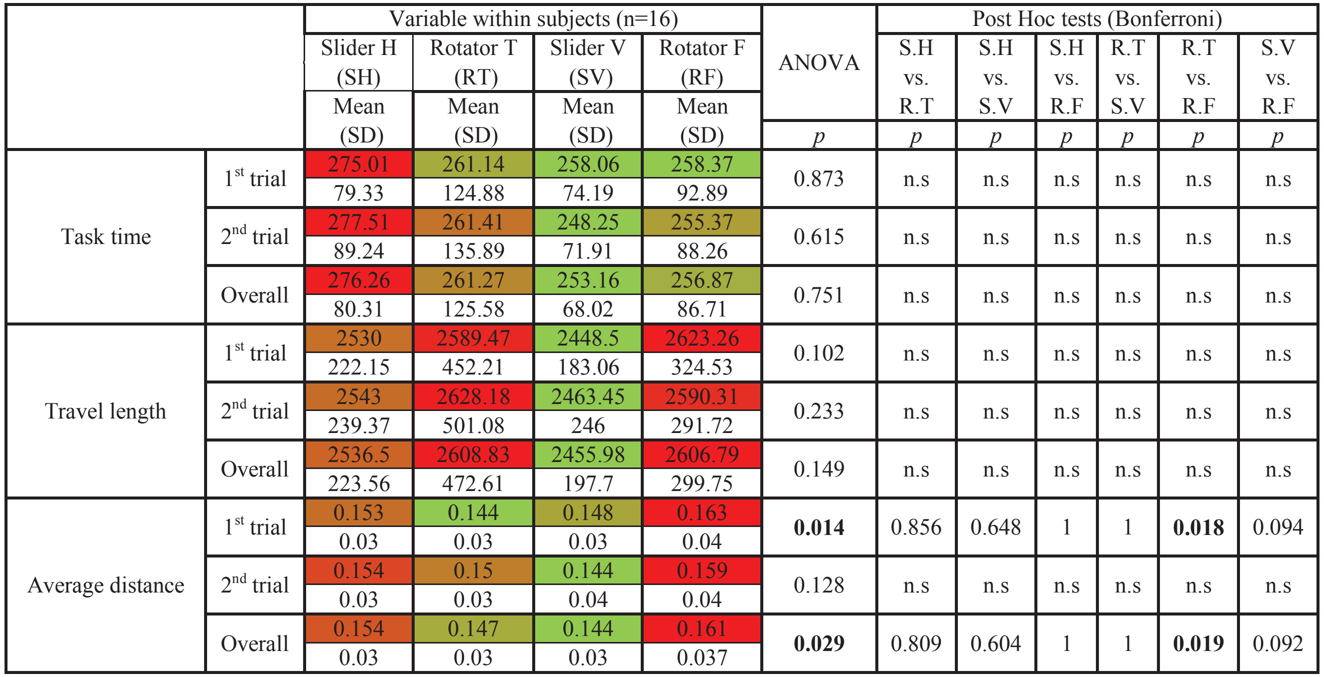
At the end of the experiment, Rotator-T and Rotator-F were preferred above Slide-H and Slide-V (Fig. 3.10). From the open comments, the two rotator-based handles were reported to be easier to control than sliders, since the holding gesture was more comfortable. Thirteen out of sixteen participants felt fatigue during of experiment, in which fatigue on the forearm was experienced most often (7 out of 13), four participants reported fatigue in their thumb and wrist, and two reported fatigue due to tired eyes.

3.5 Discussion

In this experiment sixteen participants used four handles to complete an experiment in which a virtual catheter had to be manoeuvred following the centre line of a delineated path on the screen. The participants using the vertical slider exhibited shorter time and travel length, closer to the central line, and specifically issued significantly lower number of errors during the second trial. It was observed that participants experienced higher temporal demand with this vertical slider than the other control handles. This outcome indicates that the vertical slider controller would facilitate novices' performance, but also gives high time-pressure (temporal load) to the participants.

We further noticed participants exhibited significantly shorter distance to central line using Rotator-T than using Rotator-F, whereas both rotator-handles were more preferred than slider-handles. From the open comments it became clear that participants felt more comfortable using rotator-handles. A likely explanation is that all participants used their thumb to do the control movements (Fig. 3.11, panels a-d), but rotating motion require smaller and less thumb movements compared with sliding motion.

A large percentage of the participants reported fatigue: some were received right after manipulation of Slider-H and Slider-V. One plausible reason would be that using thumb alone is perceived to be more difficult than the combination of thumb and index finger.



		Variable within subjects (n=16)				ANOVA	Post Hoc tests (Bonferroni)					
		Slider H (SH)	Rotator T (RT)	Slider V (SV)	Rotator F (RF)		S.H vs. R.T	S.H vs. S.V	S.H vs. R.F	R.T vs. S.V	R.T vs. R.F	S.V vs. R.F
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	*p*	*p*	*p*	*p*	*p*	*p*	*p*
Task time	1st trial	275.01	261.14	258.06	258.37	0.873	n.s	n.s	n.s	n.s	n.s	n.s
		79.33	124.88	74.19	92.89							
	2nd trial	277.51	261.41	248.25	255.37	0.615	n.s	n.s	n.s	n.s	n.s	n.s
		89.24	135.89	71.91	88.26							
	Overall	276.26	261.27	253.16	256.87	0.751	n.s	n.s	n.s	n.s	n.s	n.s
		80.31	125.58	68.02	86.71							
Travel length	1st trial	2530	2589.47	2448.5	2623.26	0.102	n.s	n.s	n.s	n.s	n.s	n.s
		222.15	452.21	183.06	324.53							
	2nd trial	2543	2628.18	2463.45	2590.31	0.233	n.s	n.s	n.s	n.s	n.s	n.s
		239.37	501.08	246	291.72							
	Overall	2536.5	2608.83	2455.98	2606.79	0.149	n.s	n.s	n.s	n.s	n.s	n.s
		223.56	472.61	197.7	299.75							
Average distance	1st trial	0.153	0.144	0.148	0.163	**0.014**	0.856	0.648	1	1	**0.018**	0.094
		0.03	0.03	0.03	0.04							
	2nd trial	0.154	0.15	0.144	0.159	0.128	n.s	n.s	n.s	n.s	n.s	n.s
		0.03	0.03	0.04	0.04							
	Overall	0.154	0.147	0.144	0.161	**0.029**	0.809	0.604	1	1	**0.019**	0.092
		0.03	0.03	0.03	0.037							

Figure 3.7: Results of objective and continuous measurements: Time, Travel Length and Average Distance. For each handle the mean and standard deviation (SD) of the dependent measure is reported, followed by the p value of each linear contrast. The value is presented with color scales, raising from green to red.

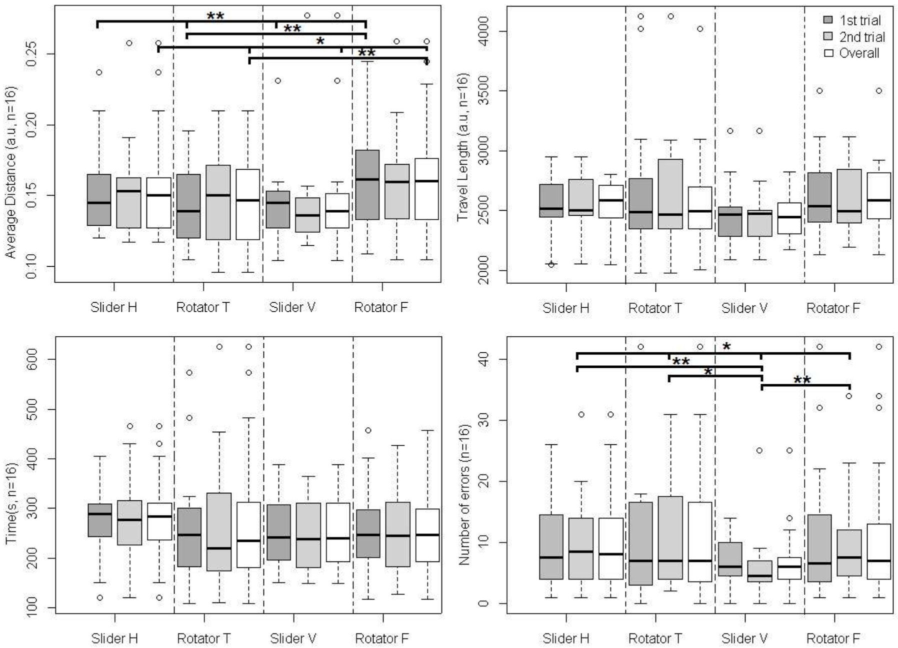
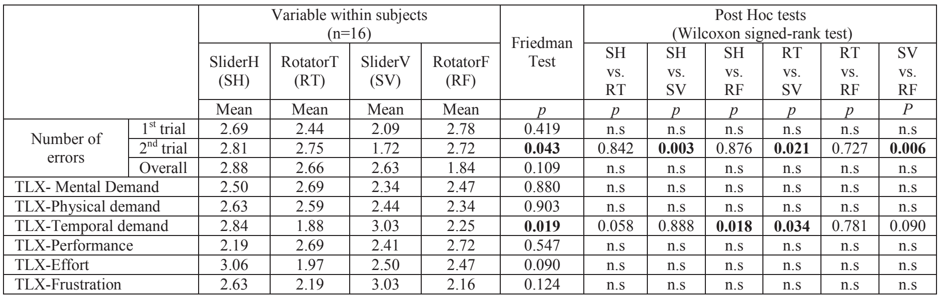


*Figure 3.8: Experiment results in 1st trial, 2nd trial and throughout two trials, including Task time, Travel length, Distance to the centre, and Number of errors. The results are presented as box plots, where every box has a line at the 25th quartile, median and 75th quartile. *p<0.05,**p<0.02.*



		Variable within subjects (n=16)				Friedman Test	Post Hoc tests (Wilcoxon signed-rank test)					
		SliderH (SH)	RotatorT (RT)	SliderV (SV)	RotatorF (RF)		SH vs. RT	SH vs. SV	SH vs. RF	RT vs. SV	RT vs. RF	SV vs. RF
		Mean	Mean	Mean	Mean	*p*	*p*	*p*	*p*	*p*	*p*	*P*
Number of errors	1st trial	2.69	2.44	2.09	2.78	0.419	n.s	n.s	n.s	n.s	n.s	n.s
	2nd trial	2.81	2.75	1.72	2.72	**0.043**	0.842	**0.003**	0.876	**0.021**	0.727	**0.006**
	Overall	2.88	2.66	2.63	1.84	0.109	n.s	n.s	n.s	n.s	n.s	n.s
TLX- Mental Demand		2.50	2.69	2.34	2.47	0.880	n.s	n.s	n.s	n.s	n.s	n.s
TLX-Physical demand		2.63	2.59	2.44	2.34	0.903	n.s	n.s	n.s	n.s	n.s	n.s
TLX-Temporal demand		2.84	1.88	3.03	2.25	**0.019**	0.058	0.888	**0.018**	**0.034**	0.781	0.090
TLX-Performance		2.19	2.69	2.41	2.72	0.547	n.s	n.s	n.s	n.s	n.s	n.s
TLX-Effort		3.06	1.97	2.50	2.47	0.090	n.s	n.s	n.s	n.s	n.s	n.s
TLX-Frustration		2.63	2.19	3.03	2.16	0.124	n.s	n.s	n.s	n.s	n.s	n.s

Figure 3.9: Results of number of errors and subjective workload. Results of Friedmans mean rank for each dependent measurement is presented, followed by the p-value for each linear contrast.

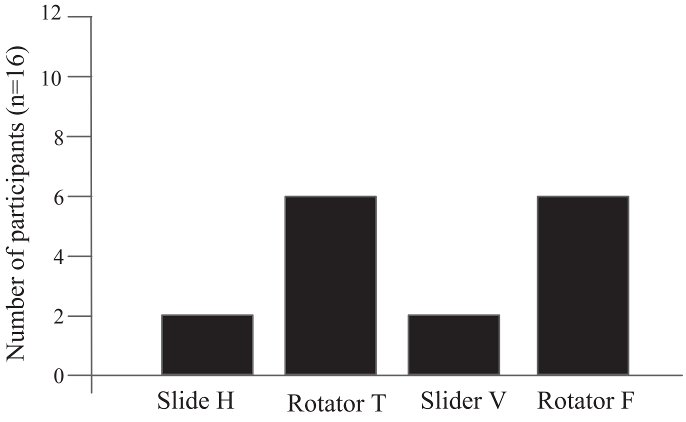


Figure 3.10: Subjective preference over the four handles at the end of the experiment

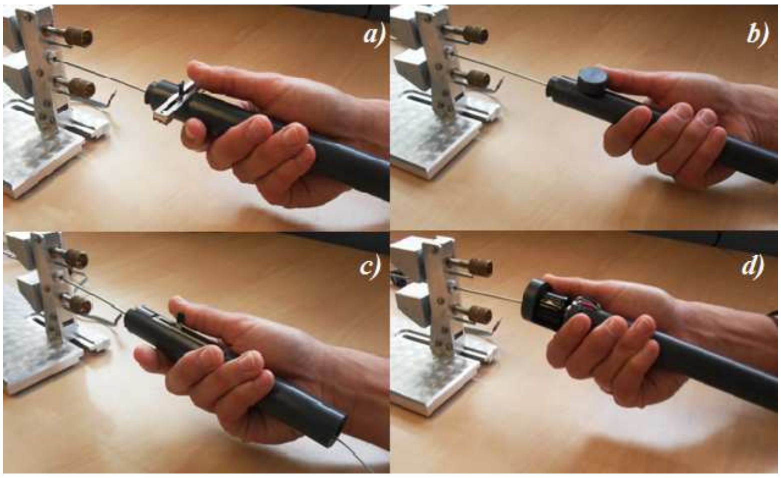


Figure 3.11: Common adopted holding gesture for each control method.

Both slider-handles and rotator-handles have been commonly applied in the development of steerable catheters [54][23][9][75] [1]. Our experiment revealed that Slider-Vertical controller would be the best choice for performing endovascular procedures by novices due to the general fast performance, shorter travel length and smaller deviation to to path central line. Results of this study also suggest that rotator-handles are strongly preferred. A knob featured on top the handle would lead to better performance with respect to a knob featured in front of the handle. Future studies should be carried out to assess the effect of other ergonomic related factors, such as relation between hand size and handle and knob size, on human performance.

3.6 Summary

This study assessed the effect of four control handles on human performance for manipulating steerable catheters in simulated neuroendovascular procedures. The best control handle was not revealed from the experimental and subjective results. Participants performed better performance using Slider-Vertical handle, but the Rotator-handles were strongly preferred by participants at the end of the experiment due to the easy manoeuvring movements. Other ergonomic factors, such as the hand size, handle and control-knob size, should be investigated in the future studies.

Chapter 4

2DoF control methods for steerable instruments in laparoscopic surgery

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Under the title ”Comparison of two control methods for minimally invasive surgical instruments.”

4.1 Abstract

Background: Laparoscopic surgery is performed with long and slender instruments through one or several incisions in the abdominal wall. Steerable instruments with flexible distal tips have been developed for improving the ease of access to anatomic structures. However, the development of an intuitive and efficient control method for such steerable instruments remains a challenge. To determine which interface is most intuitive and effective to control steerable instruments, the current study evaluates the performance of novices in orienting the tip of a steerable laparoscopic forceps using thumb control or wrist control.

Method: Using two steerable instruments, one controlled by the thumb and the other by the wrist, twenty-four novices were divided into two groups that had to carry out an experimental task in an EndoTrainer with one of the two instruments. The participants had to orient the tip of the instrument relative to five targets that were presented in a random order. After a break, the participants switched to a second measurement session with the other instrument, followed by a third measurement session with the first instrument. Each participant performed the task 240 times over the three measurement sessions. The performance was assessed by measuring the performance time, using a questionnaire and grading the work load.

Results: The performance time showed a significant learning curve for each control method. The shortest performance time was recorded during the third session with both control methods (42.7s for thumb control and 44.6s for wrist control). A significant difference in the performance time was observed in the second session ($p<0.02$) but not in the first and third session. The questionnaire showed that most participants had a preference for thumb control.

Conclusion: After a brief training period, thumb control and wrist control did not reveal significant differences in task performance. However, thumb control was strongly preferred by the participants due to the perceptive feeling in performance.

Key words: laparoscopic surgery, steerable instrument, control method, intuitiveness

4.2 Introduction

Laparoscopic surgery is performed with long and slender medical instruments through one or several small incisions on the abdominal wall. Despite having advantages in aspects of hospital stay and recovery time [31], the complexity of the surgeon's manipulation activities raises due to the limited Degrees of Freedom (DoF), the lack of direct visual contact and force feedback, etc. [29][123][14].

In laparoscopic surgery, the number of DoF of conventional rigid medical instruments is limited from six to four [14][29]. With such rigid instruments, surgeons are not able to reach obstructed anatomic structures. Therefore, instruments with a distal steerable tip are under development [11][15][140][93][43][13], some of which are already commercially available [16][129].

Robotic devices, such as the Da Vinci[5], can recapture the natural motion of the human hand with no fulcrum effect and high precision and stability. The surgeon's wrist/hand movements are transferred to the tip of the instruments intuitively using a computer system. Hand-held steerable instruments have strong advantages in terms of production costs and similarity to conventional rigid instrumentation [96]. Nevertheless, the ease of maneuvering hand-held steerable instruments is strongly affected by the method to control the steerable tip. In the case of *wrist control*, the surgeon's wrist motion is used to steer the distal tip by rotating the entire handgrip relative to the shaft. Wrist control has been used in a number of hand-held steerable instrument developments [140][96][63] and commercial products such as the Radius Surgical System [140], the Laparo-Angle (Fig. 4.1) [16] and the RealHand [129]. Alternatively, *thumb control* allows manipulation of the orientation of the distal steerable tip by moving a joystick mounted to the handgrip with the thumb. This method has been used for the prototype laparoscopic grasper Microflex (Fig. 4.2) [11] that has been designed by the Dutch company DEAM B.V.. Other control method, such as *single wheel control* [43] was also reported in the literature.

A number of previous studies have investigated whether surgical performance with steerable instruments is better than with conventional rigid instruments [140][80]. Waseda et al. [140] observed that the use of instruments with additional DoF improve the needle guiding accuracy compared to the use of conventional instruments. In the study of Martinec et al. [80], the use of steerable instruments slightly outperformed conventional instruments in two suturing tasks. Zahraee et al. [152] found that a joy-stick (a Wii Nunchuck controller) allowed more precise control than an articulated-handle (a wrist control interface modified from the handle of a conventional laparoscopic instrument) in a visual suturing task. However, it is yet unclear which control method for steerable instrument is most beneficial for dexterous performance.

This study compares wrist control with thumb control in a tip positioning and orientating task. Wrist control was applied with the Laparo-Angle whereas thumb control was applied with the Microflex. Both instruments were slightly modified to make them equivalent apart for the control method. In the study, twenty-four participants performed an experimental task in a trainer box to find out which control method is more efficient. Additionally, a work load questionnaire was used to investigate which control method is preferable.

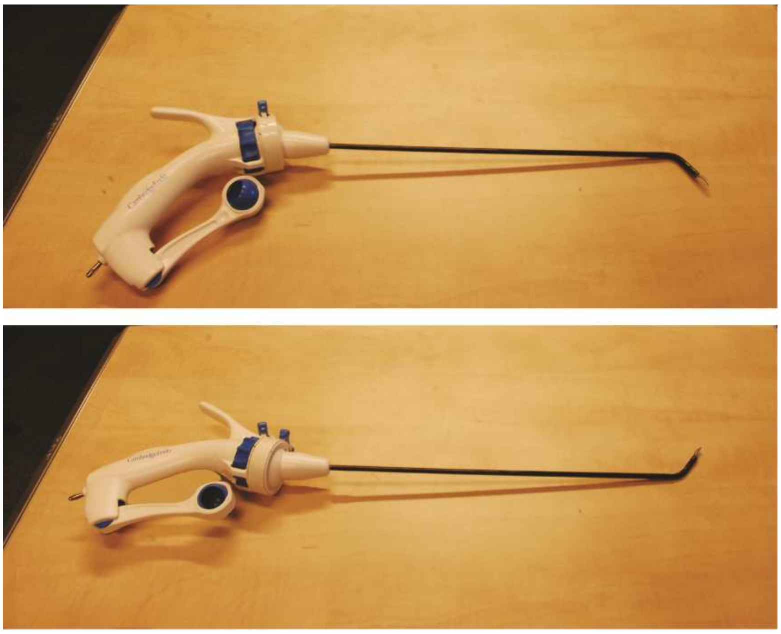


Figure 4.1: Wrist control instrument Laparo-Angle (Cambridge Endo, U.S.). Up: The handle and tip are at downward position. Down: The handle and tip are at upward position.

4.3 Material and methods

4.3.1 Instruments

Of the two instruments that we used, one was designed as a grasper (the Microflex) and the other one as a scissors (the Laparo-Angle). Since the goal of our study was to compare two control methods in positioning and orienting the tip, both instruments were slightly modified, so that the tips of the instruments were equal. The grasper and scissors were covered by a tightly fitting aluminum tube (L=50mm, ∅=6mm), locking the jaws in closed position and giving both tips the same length. During the experiment, the roticulators were also locked so that only left/right and up/down tip motions were allowed. As a result, the handgrip with the applied wrist/thumb control method was the only experimental variable (Fig. 4.3) that differed for the two instruments.

4.3.2 Participants

Twenty-four volunteers (nineteen male and five female) from Delft University of Technology participated in the experiment. They were divided into two groups with reversed order of instrument use. Group A started with the Microflex (thumb control) whereas group B started with the Laparo-Angle (wrist control). The participants were between 19-29 years old. All participants were right-handed and they had no prior experience with laparoscopic surgery.

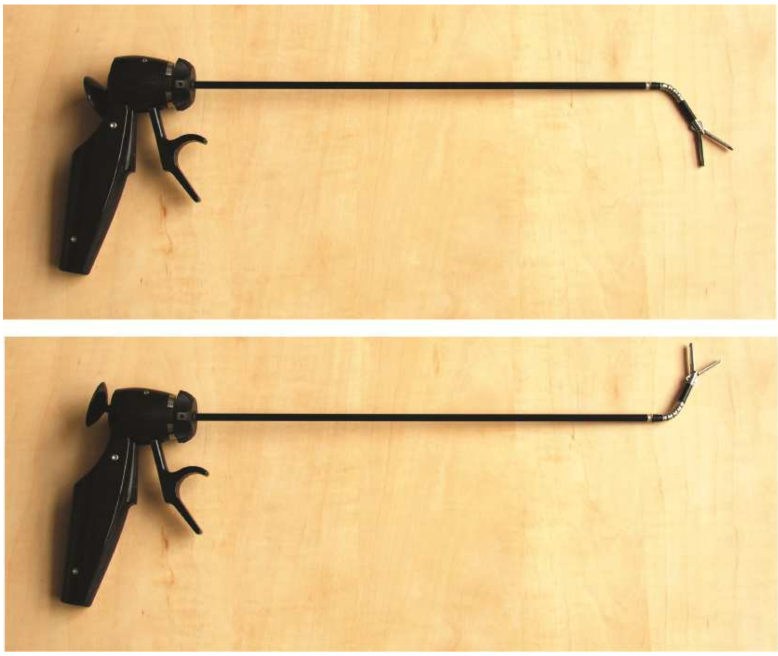


Figure 4.2: Thumb control instrument Microflex (DEAM, NL). Up: The ratchet and tip are at downward position. Down: The ratchet and tip are at upward position.

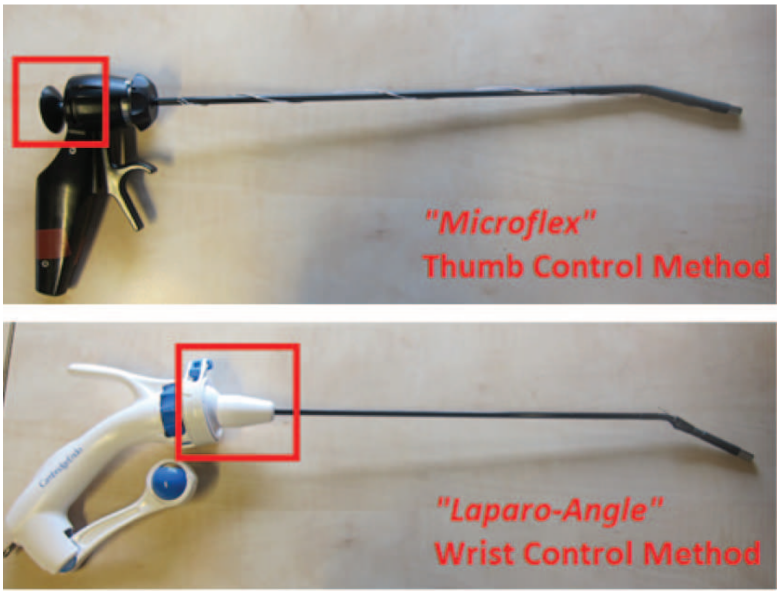


Figure 4.3: The two laparoscopic instruments (with modification) used in this study. In both instruments, the steerable tip has been covered by an aluminum tube locking the jaws in closed position and giving both tips the same length.

4.3.3 Setup

The setup is sketched in Fig. 4.4. The experiment was carried out in an EndoTrainer (Endo Innovations B.V, NL) consisting of a closed box with a camera positioned inside and a monitor placed at eye height. The box was covered by a surface with holes through which instruments can be inserted. Inside of the box, a round rubber plate (D=100mm) was placed. Five transparent plastic tubes with varying orientations (L=20mm, ∅=8mm) were fixed on top of the round plate. Each tube contained an electronic contact and a LED light. The electric contact was located 5mm deep from the tube entrance. The entrance of the tube was marked with a red circle. All electric contacts and LEDs were electronically connected to an USB controller (Labjack-U3, LabJack Corporation, U.S.A) which was controlled with a PC. The round plate and tubes occupied a space of approximately 100x100x20mm^3. The setup was positioned in front of the participants in order to avoid unnecessary distortions in eye-hand coordination [19]. Based on the difference in length between participants, the setup was lifted up or lowered to a comfortable height.

4.3.4 Task

A positioning and orienting task was used in this study as illustrated in Fig. 4.5. The participants were asked to move the steerable distal tip towards the target and insert it into the tube by using each of the two different control methods. The LED was lit to indicate which of the tubes was the target. When the tip was steered in nearly the same orientation as the target tube, the tip could move inside the target tube and touch the electric contact. A successful approach was then recorded and one of the subsequent other LEDs was lit. The total trajectory was designed to cover all possible pathways between the target tubes and consisted of 20 runs. The order of the runs was randomized on beforehand and equal for all participants. One trajectory was defined as one trial. Four trials were recorded as one session. Each participant performed three sessions (20x4x3=240 runs) using one of the two control methods.

4.3.5 Procedure

Figure 4.6 shows the procedure and the order of the control methods for each of the two participant groups. Instructions on how to perform the task were given to all participants via a video clip and a short demonstration. The participants practiced five runs at the beginning of each of the three sessions. For participants from group A, the experiment started with thumb control during the first session, followed by wrist control and thumb control in the second and third sessions. For participants from group B, the experiment sequence was wrist control - thumb control - wrist control. At the end of each session, the participants had a break and were asked to fill in a questionnaire and to use NASAs Task Load Index (TLX) [51] to assess their work load. TLX consists of a scale from 0 to 21 for six items, including Mental demand, Physical demand, Temporal demand, Performance, Effort and Frustration. A higher score means that a task is more demanding. Each participant needed about one hour to finish the experiment.

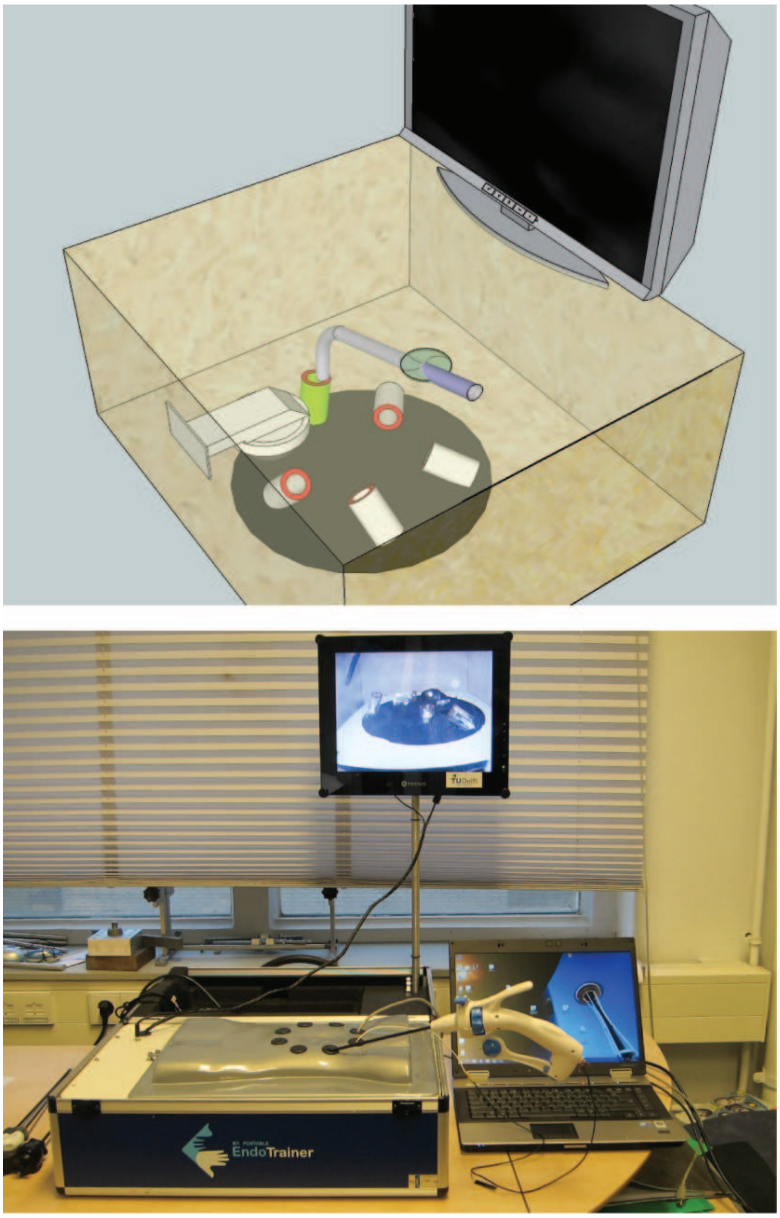


Figure 4.4: Sketch (top) and photo (bottom) of experiment setup

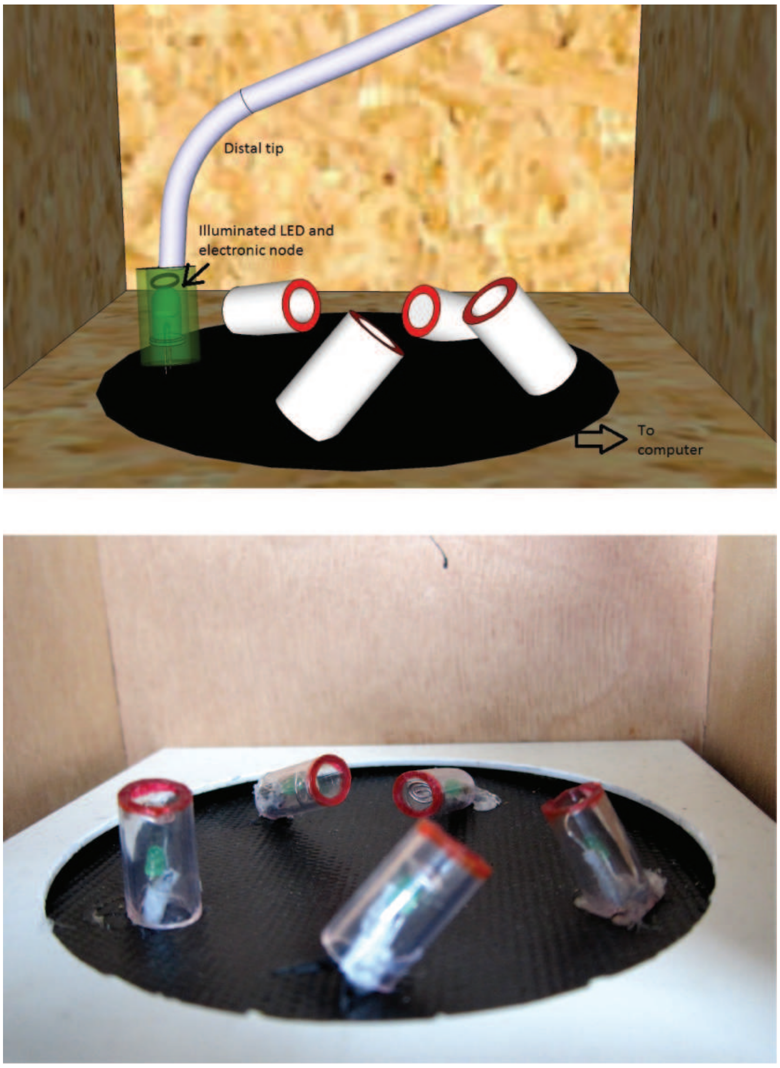


Figure 4.5: Sketch (top) and photo (bottom) of the transparent target tubes

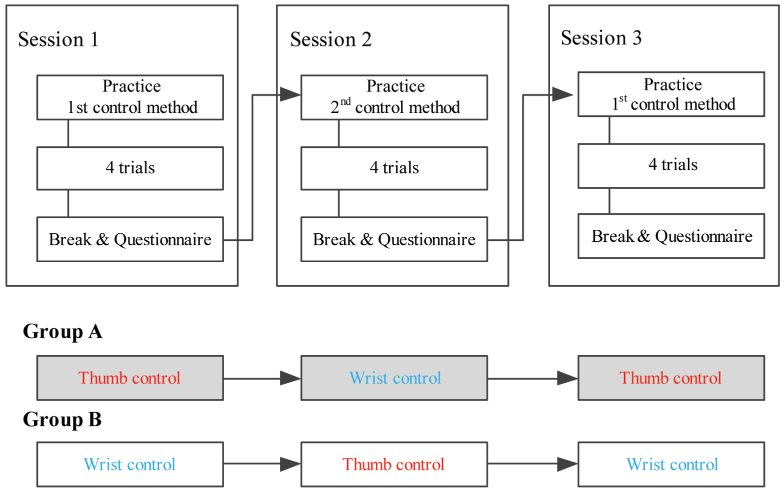


Figure 4.6: Flow chart of experiment procedure and order of the two control methods in the two groups

4.3.6 Statistics

The task performance time was recorded and statistically analyzed by using repeated measures ANOVA tests (analysis of variance). The effect of two control methods is considered to be significant in the case that the p value is smaller than 0.05.

4.4 Result

Figures 4.7 and 4.8 show the average task performance time and learning curves from each group (n=12, indicating there are 12 participants in each group) in the three sessions. The plot depicts the results as box and whisker, where the up/middle/bottom line of the boxes represent the upper quartile/median and/quartile values of the results. The ANOVA tests revealed no significant effect on the average task performance time of the two control methods for the first and third sessions but did show a significant difference for the second session ($p<0.02$). In the first session, the average task performance time was 127.4s and 124.2s, whereas in the second session, the average task performance time was 117.6s and 85.2s for group A and group B, respectively. In the third session, the average task performance time for these groups was 78.7s and 75.9s. The fastest performance was recorded during the third session for both control methods (42.7s for thumb control and 44.6s for wrist control).

The averaged TLX scores for the item Physical demand and Effort are shown in Fig. 4.9. During the second session, the Physical demand and Effort were significantly different between the two groups ($p<0.001$ and $p<0.02$). The average Physical demand score for group A during the second session was 15.5 and 7.0 for group B. The average Effort score for group A during the second session was 15.5 and 10.0 for group B. The results showed that, during the second session, participants from group A performed the experiment with more physical demand and effort. In the first and third session, no significant difference was found.

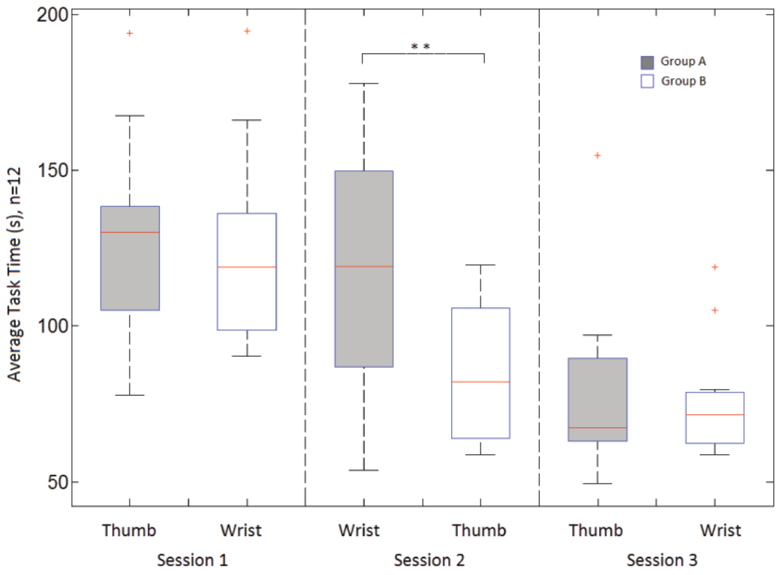


*Figure 4.7: Average task performance time in each session. The filled boxes indicate the results from group A, whereas the unfilled boxes indicate the results from group B. The results are presented as box and whisker plots, where every box has a line at quartile, median, and upper quartile values. **:p<0.02.*

Finally, the results of the questionnaire on the subjective preference revealed that 16 out of 24 participants chose thumb control as general preference (Fig. 4.10). 15 Participants rated thumb control to be easier in orientating and 16 participants rated thumb control to be faster in orientating. For the question of being precise to orientate, 13 votes were given to thumb control, 8 votes to wrist control and 3 votes to no difference.

4.5 Discussion

The current study investigated the performance in a positioning and orienting task in a portable laparoscopic trainer under standardized conditions with the method for controlling the orientation of the instrument tip as the independent experiment variable.

The difference of two control methods with respect to task performance time was not significant in the first and third sessions. This suggests that both thumb control and wrist control results in a similar performance during the learning phase and the experienced phase. However, for both task performance time and task load, significant differences were found in the second session. In this session, group A changed the control method from thumb control to wrist control while group B changed from wrist control to thumb control. Participants from group A experienced more physical demand and effort to finish the experiment and also needed more time to get used to the new way of controlling. This shows that it was more difficult to switch from thumb control to wrist control than opposite, indicating that thumb control is easier to get used to. It was also found that at the end of the experiment,

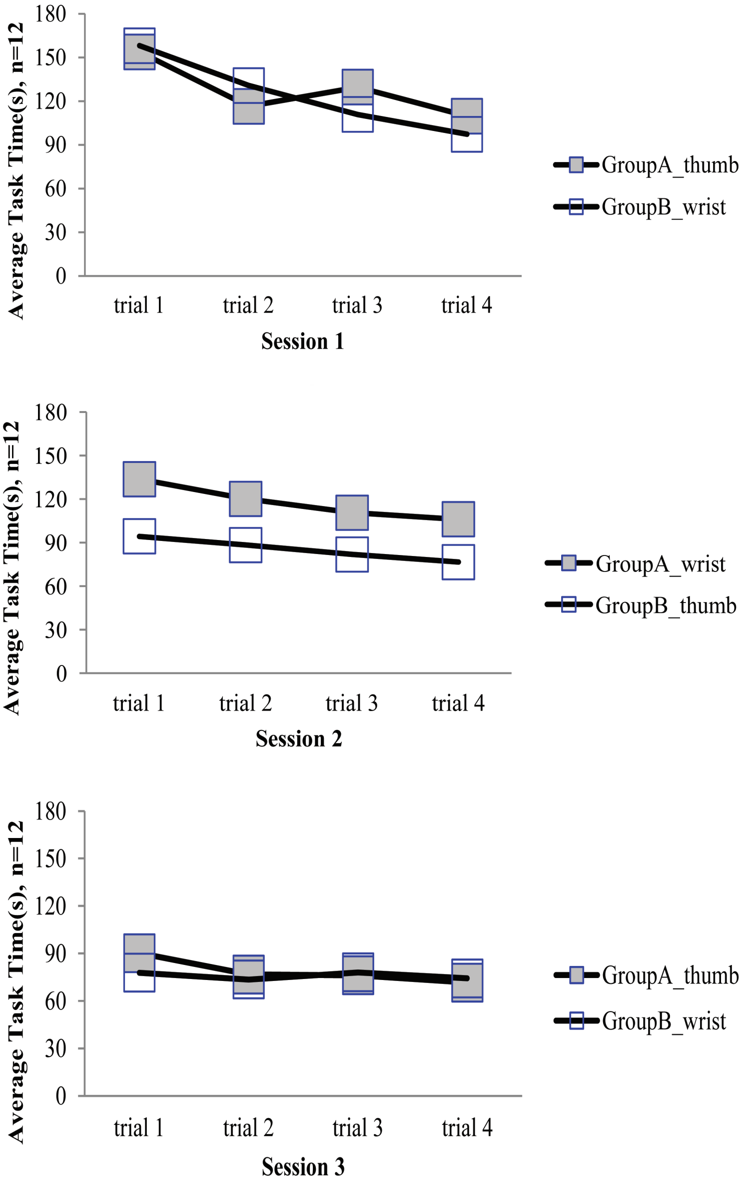


Figure 4.8: Average task performance time in each trial from three sessions. Filled marks indicate group A, whereas unfilled marks indicate group B.

thumb control was much preferred by the participants.

A likely explanation for these results is that all participants used their wrists to do common laparoscopic movements, such as to rotate the instrument around the shaft, to push/pull the instrument in and out of the trocar, the up/down and left/right movement at the incision

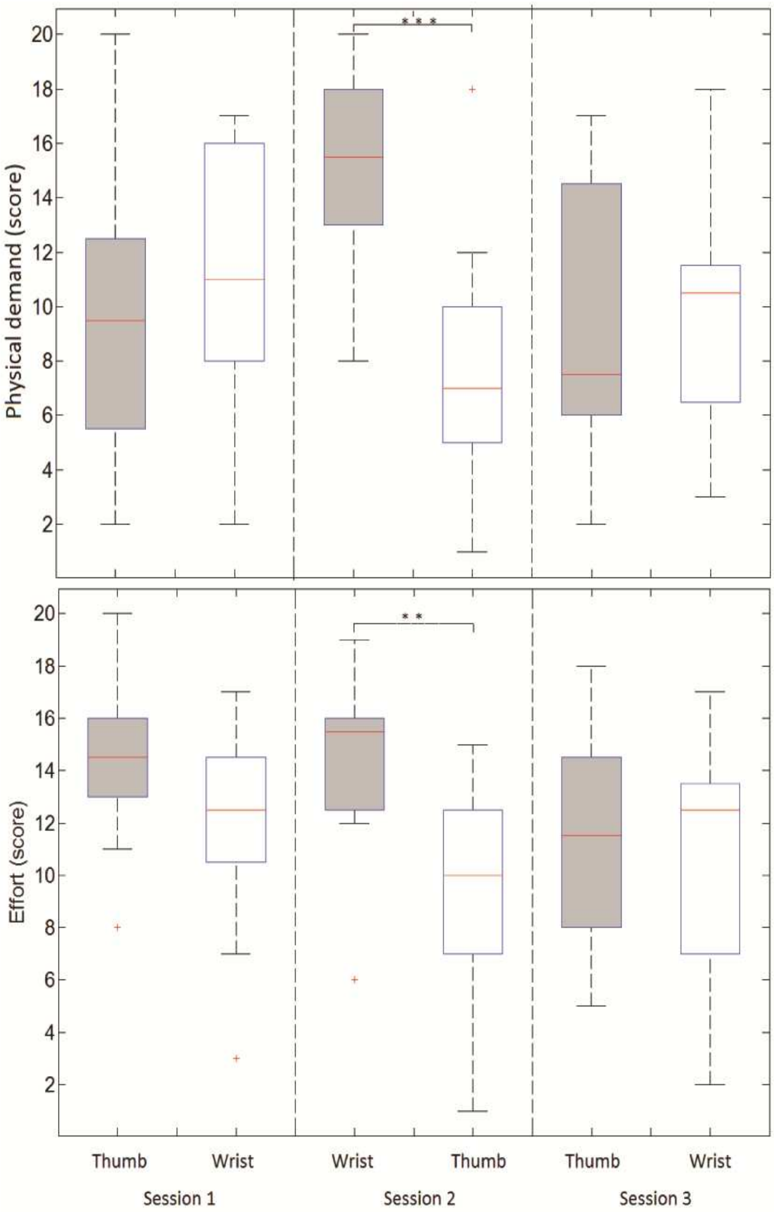


*Figure 4.9: Effect of different control methods on physical demand and effort in each session. The filled boxes indicate group A, whereas the unfilled boxes indicate group B. The results are presented as box and whisker plots, where every box has a line at quartile, median, and upper quartile values. **: $p<0.02$, ***: $p<0.001$.*

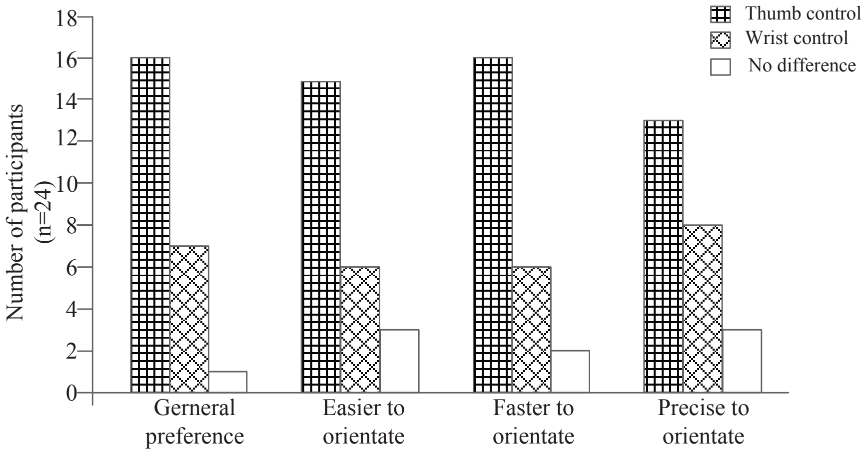


Figure 4.10: Questionnaire results for final preference

(4 DoF, Fig. 4.11-top). For steering the distal tip (2 extra DoF), the participants needed to do an extra steering maneuver with their hands. The extra steering maneuver was added to thumb in the case of thumb control(Fig. 4.11-middle) and to the wrist in the case of wrist control(Fig. 4.11-bottom). Thus, in order to control 6 DoF (2 DoF for distal tip steering and 4 DoF for the conventional laparoscopic movement), thumb control employs both thumb (2 DoF) and wrist (4 DoF) whereas wrist control employs only wrist (6 DoF).

When the participants from group A changed from thumb control to wrist control, they needed to get used to controlling 2 extra DoF with their wrist. Controlling and distinguishing 4 DoF with only one joint (the wrist) appears to be rather difficult to get used to. On the other hand, when the participants from group B changed from wrist control to thumb control, they had to control 2 DoF less with their wrist (which is easy) and get used to controlling these 2 DoF with their thumb (which not so difficult because thumb control is very common, e.g. for controlling joysticks in games, laptops or mobile phones). Nevertheless, in the end, all participants got experienced in both control methods. Hence, although in the third session, the control methods were changed again, no significant difference was observed anymore.

We should note here that the experimental task used in this experiment was relatively simple. In this study, the end-effector of each instrument was locked, whereas in practice, the opening/closing of end-effectors will result in increased complexity of the tasks. Hence, the manipulation of all DoFs will require more cooperation between fingers and wrist. Possibly the performance with the two control methods will differ in more complex tasks like manipulating tissue or suturing. Furthermore, the participants in this study had no previous experience with handling laparoscopic instruments while experience could also have an effect on the performance with steerable instruments.

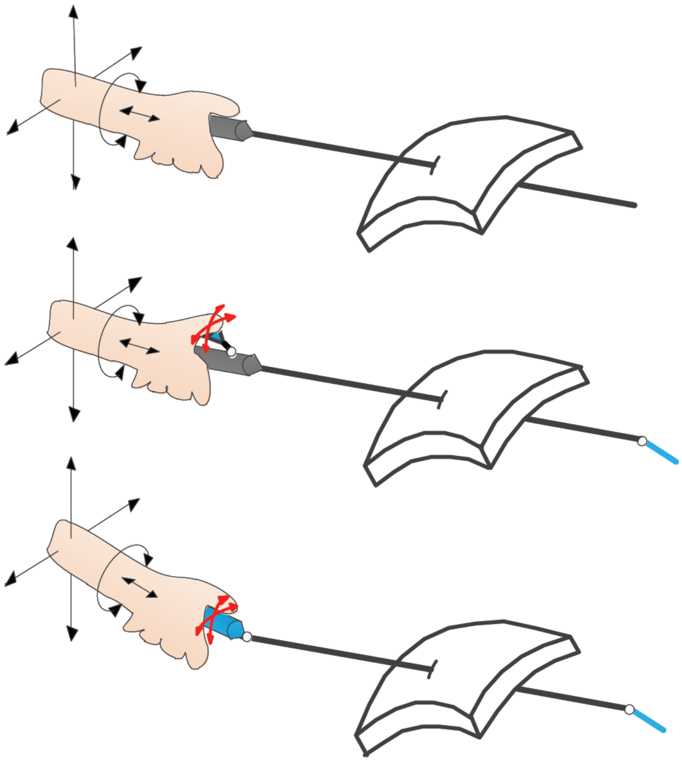


Figure 4.11: Illustration of control motions in this experiment. Top: Common control motions in laparoscopic procedure (four DoF), pull/push and rotation along the instrument shaft, up/ down, left/right at the incision. Middle: Thumb control motions (two DoF), left/right and up/down; Bottom: Wrist control motions (two DoF), left/right and up/down.

4.6 Summary

This study compared two control methods (*thumb control* and *wrist control*) which are used in the development of steerable medical instruments. The results show that for novices, thumb control method and wrist control method revealed no significant differences with respect to task time and task load. However, in the participant's personal opinions, thumb control was indicated as easier in use and strongly preferred.

4.7 Acknowledgement

The authors would like to thank all the participants for their contribution in this study.

Chapter 5

Two Cognitive factors for manoeuvrable instruments in pathway surgery

Chunman Fan, Dimitra Dodou, Paul Breedveld, Jenny Dankelman

Accepted by *Surgical Endoscopy*
Under the title ”Spatial orientation in pathway surgery”.

5.1 Abstract

Background: In the field of minimally invasive surgery, specifically in pathway surgery (i.e., minimal invasive procedures carried out transluminally or through instrument-created pathways), spatial disorientation is a common experience to endoscopists. In this article, two effects that may cause spatial disorientation in pathway surgery, ’control-display compatibility’ and ’local disorientation’, were studied.

Method: A custom-developed simulator Endo-PaC was developed and used for mimicking pathway surgical scenarios. In Study 1, two ways of control-display alignment, normal mapping and mirrored mapping were tested in combination with two control devices, thumb control and wrist control, in an orienting task using Endo-PaC. In Study 2, a tethered viewpoint was added to the virtual instrument tip, it was hypothesized that the visible tip would provide a cue of orientating direction in the reference frame during the instrument navigation. In both studies, novice participants were involved and their performance was evaluated with regard to task time, path length travelled by the virtual tip, time and number of warnings, and subjective workload and personal preference.

Results: In Study 1, normal-thumb and normal-wrist mapping yielded significantly lower means than mirrored-thumb and mirrored-wrist control for all investigated objective and subjective performance measurements. Out of 24 participants, 20 participants preferred normal control mapping. In Study 2, participants performed the task in shorter time and with shorter path length when the tip was visible tip on the monitor using a tethered viewpoint, but with a lower number and time of warnings without a visible tip.

Conclusion: The results of our studies show that eliminating the visual-display misalignment would greatly improve novice participants performance, reduce the training time and their cognitive workload. A visible tip on the monitor would provide strong direction cue and shorten the performance time, but might introduce collision errors to novices and therefore requires longer training time.

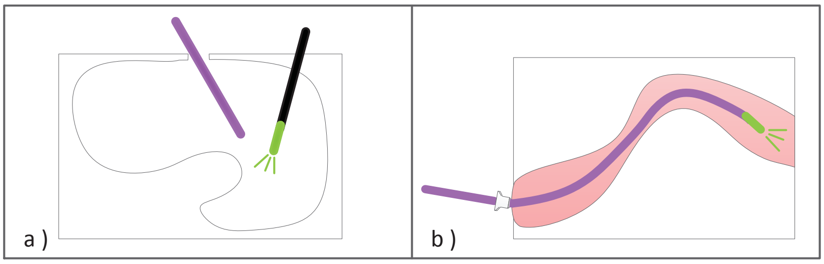


Figure 5.1: Illustration of camera and instrument position in two types of surgery. a): minimally invasive surgery, in which the camera is located over the surgical instrument and target; b) Natural Orifice Transluminal Endoscopic Surgery, in which camera is located on the tip of the surgical instrument. Black indicates an endoscope, green indicates the camera, and purple indicates the surgical instrument.

5.2 Introduction

In the field of Minimally Invasive Surgery (MIS), surgical instruments and endoscopic cameras are inserted through one or more small incisions inside the patient's body while the surgeon operates by looking at a monitor. The monitor is normally located over the patient and shows real time images taken from the operation area by means of an endoscopic camera. In laparoscopic surgery the camera is mounted at the tip of an endoscope and provides a view of the operating area over the surgical instrument (Fig. 5.1a), whereas in Natural Orifice Translumınal Endoscopic Surgery (referred to hereinafter as pathway surgery), an endoscopic camera is located at the tip of the surgical instrument itself. In the latter case, the camera is manipulated together with the instrument on multiple axes, making it difficult for the surgeon to maintain a sense of spatial orientation when navigating from one location in the anatomy to another. (Fig. 5.1b) [106][121]. In this article, we present two empirical studies investigating spatial disorientation in pathway surgery.

In the first study, the relationship between the control movements of the surgeon's hand and fingers and the display on the monitor, referred to as '*control-display compatibility*', and its effect on spatial disorientation and task performance will be investigated. Second, due to the fact that in pathway surgery the camera is positioned at the endoscope tip, the visual display provides an egocentric view, which compromises global situation awareness in such a way that during navigation surgeons may not know where the instrument is and where it is heading to in the next advancing step. Local disorientation is at play as well, because the movement of the distal flexible endoscope tip is controlled from the other end of the endoscope, which is proximal to the surgeon's hands [18]. As a result, the frame of reference differs for the surgeon's hands and the endoscope tip. In the second study, the effect of the frame of reference on task performance will be investigated.

Note: although the two studies are presented here together due to the similar cognitive aspects, they were performed separately and have distinct difference in aspects such as setup and instructions, inhibiting a direct comparison of the results between the two studies.

5.3 Study 1: Control-display compatibility

Control-display compatibility has been extensively studied in the field of teleoperation over the last 60 years. Worringham et al. [146] distinguished control-display compatibility as one of the three forms of compatibility between control and display movements, the other two being visual-motor compatibility and visual-trunk compatibility. Configurations with high control-display compatibility are associated with shorter reaction times and lower error rates as compared to settings with low control-display compatibility. Maximum compatibility is achieved if a vertical linear movement of the control, for example, corresponds to a vertical linear movement on the display. For overviews on control-display compatibility and other population stereotypes, see [22][53], including the compatibility of linear and circular displays with translator, rotary and thumbwheel controls. Many have compared a so-called ’normal’ control-display configuration, in which the movements displayed on the screen were in the same direction as the control movements, with other (e.g., mirrored, inversed, or reversed) control-display configurations and reported that the fastest performance was indeed achieved under the normal configuration [124][45][78][89]. Sometimes, however, physical constraints may inhibit maximum compatibility. In laparoscopy, for example, the insertion point of the surgical instruments acts as a pivot point, with as a result that the movements of the surgeon’s hands at one end of the instrument are mirrored at the other end of the instrument and therefore on the display—the so-called fulcrum effect [40][52].

In this study, we assessed the effects of control-display compatibility on human performance in a navigation pathway surgical task. Two ways of alignment, *normal mapping* (handle left->image left, handle up->image up) and *mirrored mapping* (handle left->image right, handle up->image down) were tested in combination with two control devices, thumb control and wrist control, in an orienting task during simulated scenarios of pathway surgery (Fig. 5.2). The two control devices are commonly used for manipulating catheters and steerable laparoscopic instruments [37], in which the deflection of the surgeon’s thumb/wrist operating the handle of the instrument is mapped to the deflection of the instrument tip. In line with the research listed above, we hypothesized that congruence between control movements and displayed movements would facilitate task performance.

5.3.1 Material and Methods

Setup: EndoPathController(Endo-PaC)

A simulator with a physical interface emulating the shaft and handle of a manoeuvrable instrument, Endo-PaC, was used (Fig. 5.3a). Endo-PaC features two alternative control methods on the handle, thumb and wrist control (Fig. 5.3b and Fig. 5.3c, respectively), both allowing 2-DoF steering motion (left/right and up/down, maximal range in both directions: 17.5 mm) and translational motion (forward/backward, maximal transitional range: 100 mm). Steering is tracked by two potentiometers, while translation is tracked by a position sensor.

Custom-designed software (developed in C++ using OpenGL library) visualizes a 3D curved tunnel (27 frames per second, Fig. 5.3d). The tunnel curvature, defined by its radius and period, is set to be within the maximal range of the steering motion (17.5 mm), and the tunnel length is configured such that the absolute distance between the incision plane and the target plane is equal to the maximal translation range of the Endo-PaC shaft (100 mm).

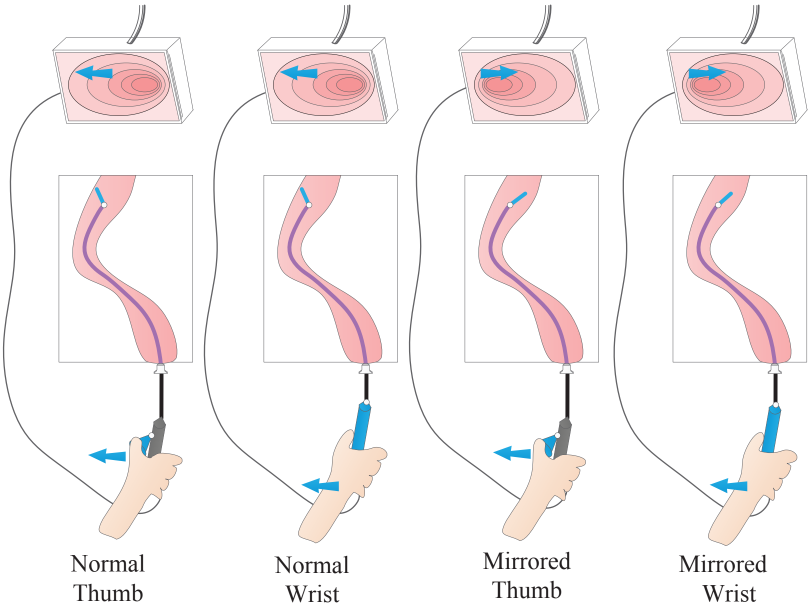


Figure 5.2: Illustration of four control modes in Study 1.

An endoscopic camera is featured at the tip of a virtual manoeuvrable instrument. The camera always points at the centre of the screen. The camera is steered by the control unit, and the camera movements are proportional to the steering movements with an amplification factor of 10. The simulation screen (400x300 pixels) is set to be identical to the camera's field of view. The resolution of steering motion is 0.12 mm and is defined by the resolution of the measurement unit (1 mV, LabJack Corporation, Lakewood, U.S.) and the settings of the simulation software (17.5x2 mm/300 pixels=0.12 mm/pixel). The resolution of translational motion is set at 1 mm.

The software checks the distance between the virtual camera tip and the tunnel central line at a frequency equal to the number of frames-per-second (27 Hz). A safe zone is preset by the software as an annulus with diameter equal to 0.7 of the diameter of the tunnel. When the tip moves outside the safe zone, the colour of the tunnel turns amber and a green arrow appears on the screen towards the central line, indicating the direction toward which the tip should be moved to prevent collision with the tunnel wall (Fig. 5.3e). The length of the arrow changes linearly and proportionally with the distance of the camera tip from the tunnel central line. If the tip collides with the wall, the tunnel turns red (Fig. 5.3f). When the task is completed successfully, the tunnel turns green (Fig. 5.3g).

Participants

Twenty-four undergraduate and PhD students (12 males and 8 females between 22 and 29 years old) from Delft University of Technology volunteered to participate in this study. All

Figure 5.3: Endo-PaC hardware and software units. a) the Endo-PaC setup, b) thumb control, c) wrist control, screenshots of the animation program in case of d) normal e) warning for near collision, f) collision, g) success. The green arrow appears only in the case of near collision or collision. The direction and length of green arrow is proportional to the position of the warning/collision and deviation to the tunnel central line.

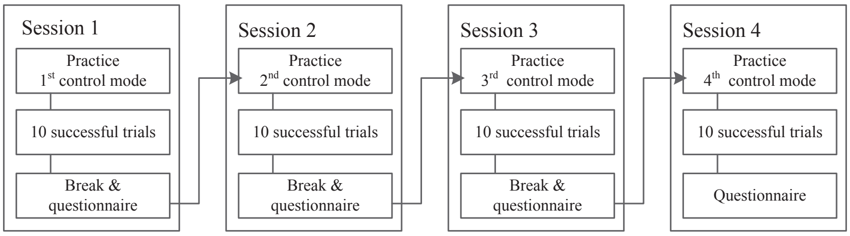


Figure 5.4: Experimental procedure of Study 1.

participants were right-handed and had no prior experience with minimally invasive surgery. None of the participants had used the Endo-PaC before. The study was approved by the Human Research Ethics Committee of Delft University of Technology.

Experimental procedures

All participants were tested in all four combinations of two control mappings (normal and mirrored) and two control devices (thumb and wrist), that is: Normal-Thumb (NT), Normal-Wrist (NW), Mirrored-Thumb (MT) and Mirrored-Wrist (MW) control. Each combination of control mapping and control device is called hereafter 'control mode'. The sequence of the four control modes was permuted to minimize order bias and learning effects.

Before starting the experiment, each participant was verbally informed that the goal of the experiment was to compare four control modes for manoeuvring surgical instruments and was introduced to minimally invasive surgery, steerable surgical instruments and the hardware (shaft, thumb control handle and wrist control handle) and software (virtual tunnel) components of Endo-PaC. Next, the participant watched a video demonstration explaining the colour changes of the virtual tunnel in cases of imminent collision to the tunnel wall, collision, and task completion. A second video demonstrated how to use the control unit with either control device (thumb control and wrist control) and explained the control-display correspondence in the cases of normal and mirrored mapping.

The experimental procedure was verbally explained by showing a printed version of the scheme in Fig. 5.4. The participants were informed that they would be asked to fill in a NASA-TLX questionnaire during the experiment, and a questionnaire with their preferences and comments at the end of the experiment. A printout of the NASA-TLX questionnaire was shown, and it was explained that each subscale should be answered by marking one of the ticks. Finally, a 2D schematic side view of three tunnels, one with on-centre and two with off-centre targets was shown, explaining that the target may not be always at the centre of the target plane, therefore, after arriving at the target plane, a steering manoeuvre may be needed in order to hit the target and complete the task. Next, each participant configured the steering unit to its central position so that the camera tip of the virtual instrument was placed at the centre of the screen. At that point the participant was instructed to guide Endo-PaC safely as fast as possible through a tunnel toward the spherical target located at the end of the tunnel and the experiment was started.

Each participant performed four tests with alternating usage of control modes. Each test consisted of a practice session, an experimental session and a break (Fig. 5.4). A practice session included three trials of reaching the target with one of the control modes. In the experimental session following a practice session, the participant used the control mode that he/she also used during the practice session. An experimental session was completed when the participant performed 10 successful trials, that is, reaching the target without any collision. If the virtual tip collided against the wall, the trial was discontinued and considered as unsuccessful. The 10 successful trials were realised in 10 tunnels of various curvatures.

The tunnels were constructed so that the absolute distance between the initial plane and the target plane were always 100 pixels and the target was always visible on the screen. The tunnel central line was calculated as a helix with $x(t) = a \times \cos(\alpha t)$; $y(t) = b \times \sin(\beta t)$; $z(t) = k \times t$; in which, a and b defined the width of the tunnel (held constant for all measurements) and were chosen based on the maximal range of the steering motion, α and β defined the period of the tunnel curve and were random numbers between -1 and 1 generated in MATLAB, and k (a constant) was chosen to fit the maximal motion range of the translational motion (17.5mm).

The order of the tunnels was randomly varied between the four sessions, to prevent the participants from adapting their manoeuvring strategy to the order of the tunnels. The order of tunnels per session was identical for all participants. That is, in the same session, all participants were tested with the same set of tunnels in the same order.

Each experimental session was followed by a short break, during which the participants were asked to fill out the NASA TLX questionnaire. At the end of the experiment, the participants filled out a questionnaire in which they were asked to give their preference between the four control modes and provide their impressions about the interface in general. The questions included were: *1. ”Which control method do you prefer? Please re-order them according to your preference (from most-prefer to least-prefer). Why?”; 2. ”Did you feel fatigued during the test? If yes, please explain in what way and at which time(s) during the test”; 3. ”Can you explain the strategy you followed to perform the test?”; 4. ”Do you have any suggestions for improving the control method?”; and 5. ”If you have any additional comments, suggestions, feelings, critics, etc., please add them here”*. The experiment lasted about 1.5 hour per participant. All questionnaires, videos, and oral instructions were in English.

Parameters and data analysis

The following parameters were chosen for assessing the task performance:

- *Task time (in seconds)*: the time taken to complete 10 successful trials in one experimental session (trials with collisions excluded);
- *Path length (in arbitrary units)*: the distance travelled by the virtual tip during the 10 successful trials in one experimental session;
- *Distance to the central line (in arbitrary unit)*: the average absolute distance between the travelled trajectory by the virtual tip at each point and the tunnel central line during the 10 successful trials in one experimental session;
- *Time of warnings (in seconds)*: the total time during which the virtual tip was outside of the safe-zone during 10 successful trials in one experimental session;

- *Number of warnings*: the total number of warnings issued during 10 successful trials in one experimental session;
- *Number of trials*: the total number of trials (i.e., both successful and unsuccessful) conducted to complete one experimental session;
- *TLX scores*: Subscales of the NASA-TLX questionnaire [51], the most widely used scales for measuring subjective workloads [59], contain 21-tick (20 equal intervals) bipolar scales to obtain rating for six items, including Mental demand, Physical demand, Temporal demand, Performance, Effort, and Frustration. Except from the performance subscale (rating from *’perfect’* =1 to *’failure’* =21), a higher score in a subscale means that a task is more demanding (rating from *’very low’* =1 to *’very high’* =21).

Recorded data were analysed using MatlabR2011b. A one-way repeated measures analysis of variance (ANOVA) with post-hoc test was conducted to investigate the differences between the four control modes over the four sessions. A one-way independent ANOVA with post-hoc test was conducted to investigate the differences between the four control modes in Session 1 (in which participants had no experience) and Session 4 (in which subject had gained some experience). An independent *t*-test was conducted to investigate the difference between normal mapping and mirrored mapping within Session 1 and Session 4. The effect was considered to be significant when the *p*-value was smaller than 0.05.

5.3.2 Results

Figure 5.5 shows that over the four sessions, the differences between control modes reached significance for all objective measurements. NT and NW yielded lower means than MT and MW for all investigated objective and subjective measures of task performance. Post hoc tests indicated that for both thumb and wrist control, normal mapping generally led to better task performance than mirrored mapping.

Specifically, in case of thumb control, participants exhibited shorter task time (p=0.014), shorter path length (p=0.001), shorter distance to central line (p=0.004), shorter time of warnings (p=0.009), and lower mental demand (p=0.007), less effort (p=0.009) and less frustration (p=0.010) when using normal than mirrored mapping. Similarly, in case of wrist control, using normal mapping led to shorter completion time (p=0.013), shorter path length (p=0.000), shorter distance to central line (p=0.000), shorter time of warnings (p=0.007), fewer warnings (p=0.005), lower mental demand (p=0.033), better subjective performance (p=0.039) and less effort (p=0.009) than using mirrored mapping.

Figure 5.6 shows that in Session 1 the four control modes did not differ significantly in terms of any of the investigated measures but participants using NT control exhibited the shortest path length (F=3.16, p=0.047) and participants using NW control experienced the least frustration (F=4.97, p=0.010). In Session 4, participants using NT control exhibited the shortest task time (F=3.74, p=0.027), path length (F=4.80, p=0.011), distance to central line (F=6.12, p=0.004), and time of warnings (F=7.30, p=0.002), least mental (F=6.65, p=0.030) and physical demand (F=4.87, p=0.011) and least effort (F=3.43, p=0.037). Post hoc tests revealed that 1) in case of thumb control, participants using normal mapping performed the experiment in shorter time, path length, distance to central line, and shorter time and number of warnings, and gave lower scores of mental demand, effort and worse performance than using mirrored mapping; and 2) in case of wrist control, participants using normal mapping gave lower scores of physical demand than using mirrored mapping. The results also revealed that 3) participants using NT exhibited shorter time and path length, and experienced less physical demand and effort than participants using MW; and 4) participants using NW exhibited shorter path length and time, and lower number of warnings, and gave lower scores of mental demand, physical demand and effort.

Figure 5.7 shows that in Session 4, using normal mapping led to shorter time (t=-2.87, p=0.009), path length (t=-3.38, p=0.003) and distance to central line (t=-2.80, p=0.010), and shorter time(t=-2.96, p=0.007) and lower number of warnings (t=-2.92, p=0.008) than using mirrored mapping. The TLX scores revealed that participants using normal mapping experienced lower mental demand (t=-3.14, p=0.005), physical demand (t=-3.91, p=0.000), and temporal demand (t=-2.60, p=0.016), better subjective performance (t=-2.42, p=0.024) and less effort (t=-3.32, p=0.031).

The results of subjective preference given by the participants at the end of the experiment (Fig. 5.8) showed that out of 24 participants, 20 participants preferred normal control mapping, among which 16 participants chose NT control and 4 chose NW control. Four participants chose mirrored control mapping, among which 3 chose MW control and 1 MT control.

5.3.3 Discussion

Four control modes, Normal-Thumb (NT), Normal-Wrist (NW), Mirrored-Thumb (MT), and Mirrored-Wrist (MW) control, were investigated in an orientating pathway-surgery task using a newly developed simulator. Throughout the four sessions of the experiment, participants performed better and self-reported lower mental workload when using normal than mirrored mapping. The difference between control mappings was the largest in Session 4, during which normal mapping clearly facilitated task performance, with participants exhibiting their best performance with NT control. These differences are supported by the subjective feedback given at the end of the experiment, with 20 out of 24 participants preferring normal over mirrored mapping. Our findings are in line with and expand previous empirical studies on control-display compatibility in other research fields (see section ’control-display compatibility’) by showing that normal mapping is preferred above mirrored mapping not only in terms of shorter task completion times, but also in terms of lower self-reported workload, measured by the NASA TLX, and higher accuracy, measured as a function of the lateral deviance from the central line.

Although both normal and mirrored mapping are utilized in steerable surgical instruments [37], it has been reported that most surgeons favour the normal mapping in which the steerable tip moves in identical direction with the control motion [11]. We found that the differences between the two control mappings were more pronounced when using thumb than wrist control. In other words, if a steerable endoscope is equipped with thumb control, participants experience lower workload and exhibit better performance when using normal mapping than mirrored mapping; if a steerable endoscope is equipped with wrist control, the differences between the two control mapping influence participants workload but not their performance.

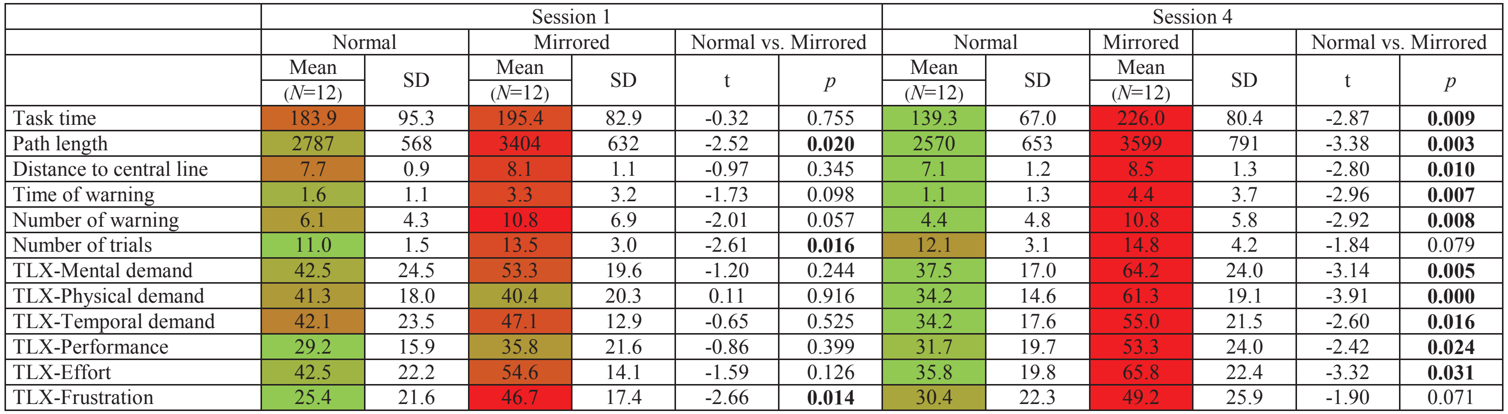
We further noticed that, participants could perform the experiment at a similar level in

	Normal Thumb		Normal Wrist		Mirrored Thumb		Mirrored Wrist		ANOVA		Post hoc					
											NT vs. NW	NT vs. MT	NT vs. MW	NW vs. MT	NW vs. MW	MT vs. MW
	Mean (N=24)	SD	Mean (N=24)	SD	Mean (N=24)	SD	Mean (N=24)	SD	F	p	p	p	p	p	p	p
Task time	163.0	80.7	156.6	68.7	213.5	76.7	207.5	88.9	9.54	**0.000**	1.000	**0.014**	**0.003**	**0.001**	**0.013**	1.000
Path length	2659	584	2825	561	3289	703	3645	691	26.34	**0.000**	0.258	**0.001**	**0.000**	**0.022**	**0.000**	0.117
Distance to central line	7.5	1.2	7.5	1.0	8.2	1.2	8.4	1.1	12.67	**0.000**	1.000	**0.004**	**0.005**	**0.007**	**0.000**	1.000
Time of warnings	1.7	1.8	1.4	2.0	3.8	3.4	3.4	2.6	10.18	**0.000**	1.000	**0.009**	**0.029**	**0.005**	**0.007**	1.000
Number of warning	6.1	4.8	5.3	3.9	10.1	6.6	11.0	6.7	8.26	**0.000**	1.000	0.071	**0.019**	**0.007**	**0.005**	1.000
Number of trials	11.4	2.2	11.8	3.8	14.1	4.4	14.3	4.3	4.89	**0.004**	1.000	0.080	**0.027**	0.066	0.219	1.000
TLX-Mental demand	39.2	19.4	44.0	20.4	60.0	27.3	61.0	23.6	9.02	**0.000**	1.000	**0.007**	**0.011**	**0.014**	**0.033**	1.000
TLX-Physical demand	33.6	16.2	44.0	18.3	50.8	27.6	58.6	22.1	5.93	**0.001**	0.373	0.092	**0.003**	1.000	0.120	1.000
TLX-Temporal demand	37.7	19.5	43.5	16.3	50.8	24.0	52.7	17.8	4.51	**0.006**	0.410	0.155	**0.039**	1.000	0.183	1.000
TLX-Performance	29.2	18.6	32.5	21.9	48.8	29.4	49.2	25.2	6.30	**0.001**	1.000	0.074	**0.032**	0.051	**0.042**	1.000
TLX-Effort	40.0	19.9	45.8	20.7	60.8	24.1	63.5	21.1	9.34	**0.000**	0.970	**0.009**	**0.003**	**0.039**	**0.037**	1.000
TLX-Frustration	26.3	18.5	28.8	21.8	45.0	22.0	47.1	24.7	7.92	**0.000**	1.000	**0.010**	**0.001**	**0.009**	0.074	1.000

Figure 5.5: Means and standard deviations (SD) of all dependent measures for four control modes over the four sessions in Study 1. F and p values of ANOVA and post hoc analysis are shown. p-values < 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).

	Session 1								ANOVA		Post hoc					
	Normal Thumb		Normal Wrist		Mirrored Thumb		Mirrored Wrist				NT vs. NW	NT vs. MT	NT vs. MW	NW vs. MT	NW vs. MW	MT vs. MW
	Mean (*N*=6)	SD	Mean (*N*=6)	SD	Mean (*N*=6)	SD	Mean (*N*=6)	SD	*F*	*p*	*p*	*p*	*p*	*p*	*p*	*p*
Task time	194.4	100.5	173.4	98.0	196.5	92.2	194.4	81.3	0.08	0.969	ns	ns	ns	ns	ns	ns
Path length	2742	668	2832	508	3118	449	3690	694	3.16	**0.047**	0.793	0.282	**0.011**	0.410	**0.020**	0.108
Distance to central line	8.0	1.2	7.5	0.6	8.1	1.2	8.1	1.0	0.43	0.733	ns	ns	ns	ns	ns	ns
Time of warnings	2.1	1.4	1.1	0.6	4.1	4.3	2.5	1.8	1.56	0.230	ns	ns	ns	ns	ns	ns
Number of warning	8.7	4.5	3.5	2.3	11.2	8.3	10.5	6.0	2.21	0.118	ns	ns	ns	ns	ns	ns
Number of trials	11.3	1.8	10.7	1.2	13.3	2.8	13.7	3.4	2.19	0.121	ns	ns	ns	ns	ns	ns
TLX-Mental demand	48.3	28.2	36.7	20.9	53.3	21.1	53.3	19.9	0.71	0.555	ns	ns	ns	ns	ns	ns
TLX-Physical demand	39.2	22.7	43.3	13.7	30.0	14.1	50.8	21.1	1.35	0.288	ns	ns	ns	ns	ns	ns
TLX-Temporal demand	40.0	25.5	44.2	23.5	51.7	15.1	42.5	9.4	0.40	0.755	ns	ns	ns	ns	ns	ns
TLX-Performance	30.8	13.9	27.5	18.9	35.0	26.3	36.7	18.3	0.26	0.853	ns	ns	ns	ns	ns	ns
TLX-Effort	52.5	24.2	32.5	16.0	56.7	12.5	52.5	16.4	2.24	0.116	ns	ns	ns	ns	ns	ns
TLX-Frustration	36.7	26.6	14.2	3.8	40.0	19.0	53.3	14.0	4.97	**0.010**	**0.041**	0.750	0.122	**0.021**	**0.001**	0.211
	Session 4								ANOVA		Post hoc					
	Normal Thumb		Normal Wrist		Mirrored Thumb		Mirrored Wrist				NT vs. NW	NT vs. MT	NT vs. MW	NW vs. MT	NW vs. MW	MT vs. MW
	Mean (*N*=6)	SD	Mean (*N*=6)	SD	Mean (*N*=6)	SD	Mean (*N*=6)	SD	*F*	*p*	*p*	*p*	*p*	*p*	*p*	*p*
Task time	110.3	35.1	168.3	81.4	245.0	93.1	207.0	68.6	3.74	**0.027**	0.183	**0.004**	**0.032**	0.083	0.368	0.377
Path length	2272	378	2922	736	3517	922	3680	71.5	4.80	**0.011**	0.131	**0.007**	**0.003**	0.165	0.081	0.697
Distance to central line	6.9	1.2	7.4	1.4	9.4	1.2	7.7	0.8	6.12	**0.004**	0.428	**0.001**	0.218	**0.004**	0.648	**0.012**
Time of warnings	0.7	0.7	1.5	1.7	6.5	3.9	2.3	1.9	7.30	**0.002**	0.532	**0.000**	0.240	**0.002**	0.572	**0.006**
Number of warning	2.7	2.7	6.2	6.1	13.5	4.9	8.0	5.5	4.97	0.100	0.237	**0.001**	0.078	**0.019**	0.530	0.070
Number of trials	12.7	3.7	11.5	2.5	16.7	4.5	13.0	3.2	2.39	0.099	ns	ns	ns	ns	ns	ns
TLX-Mental demand	35.0	15.5	40.0	19.5	80.8	27.3	57.5	20.4	6.65	**0.030**	0.686	**0.008**	0.080	**0.020**	0.166	0.287
TLX-Physical demand	32.5	15.1	35.8	15.3	58.3	27.3	64.2	5.9	4.87	**0.011**	0.747	**0.020**	**0.005**	**0.039**	**0.011**	0.573
TLX-Temporal demand	39.2	22.9	29.2	9.7	53.3	29.1	56.7	12.9	2.40	0.098	ns	ns	ns	ns	ns	ns
TLX-Performance	28.3	13.7	35.0	25.3	57.5	29.5	49.2	18.8	2.06	0.138	ns	ns	ns	ns	ns	ns
TLX-Effort	36.7	20.7	40.8	14.6	67.5	28.9	64.2	16.3	3.43	**0.037**	0.733	**0.019**	**0.034**	**0.039**	0.067	0.785
TLX-Frustration	24.2	19.6	36.7	24.8	52.5	33.1	45.8	18.8	1.47	0.252	ns	ns	ns	ns	ns	ns

Figure 5.6: Means and standard deviations (SD) of all dependent measures for four control modes in Session 1 and Session 4 of Study 1. F and p values of ANOVA and post hoc analysis are shown. p-values $<$ 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).



	Session 1						Session 4					
	Normal		Mirrored		Normal vs. Mirrored		Normal		Mirrored		Normal vs. Mirrored	
	Mean (*N*=12)	SD	Mean (*N*=12)	SD	t	*p*	Mean (*N*=12)	SD	Mean (*N*=12)	SD	t	*p*
Task time	183.9	95.3	195.4	82.9	-0.32	0.755	139.3	67.0	226.0	80.4	-2.87	**0.009**
Path length	2787	568	3404	632	-2.52	**0.020**	2570	653	3599	791	-3.38	**0.003**
Distance to central line	7.7	0.9	8.1	1.1	-0.97	0.345	7.1	1.2	8.5	1.3	-2.80	**0.010**
Time of warning	1.6	1.1	3.3	3.2	-1.73	0.098	1.1	1.3	4.4	3.7	-2.96	**0.007**
Number of warning	6.1	4.3	10.8	6.9	-2.01	0.057	4.4	4.8	10.8	5.8	-2.92	**0.008**
Number of trials	11.0	1.5	13.5	3.0	-2.61	**0.016**	12.1	3.1	14.8	4.2	-1.84	0.079
TLX-Mental demand	42.5	24.5	53.3	19.6	-1.20	0.244	37.5	17.0	64.2	24.0	-3.14	**0.005**
TLX-Physical demand	41.3	18.0	40.4	20.3	0.11	0.916	34.2	14.6	61.3	19.1	-3.91	**0.000**
TLX-Temporal demand	42.1	23.5	47.1	12.9	-0.65	0.525	34.2	17.6	55.0	21.5	-2.60	**0.016**
TLX-Performance	29.2	15.9	35.8	21.6	-0.86	0.399	31.7	19.7	53.3	24.0	-2.42	**0.024**
TLX-Effort	42.5	22.2	54.6	14.1	-1.59	0.126	35.8	19.8	65.8	22.4	-3.32	**0.031**
TLX-Frustration	25.4	21.6	46.7	17.4	-2.66	**0.014**	30.4	22.3	49.2	25.9	-1.90	0.071

Figure 5.7: Means and standard deviations (SD) of all dependent measures for normal and mirrored mapping in Session 1 and Session 4 of Study 1. t- and p-values for normal mapping versus mirrored mapping control are also shown. p-values $<$ 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).

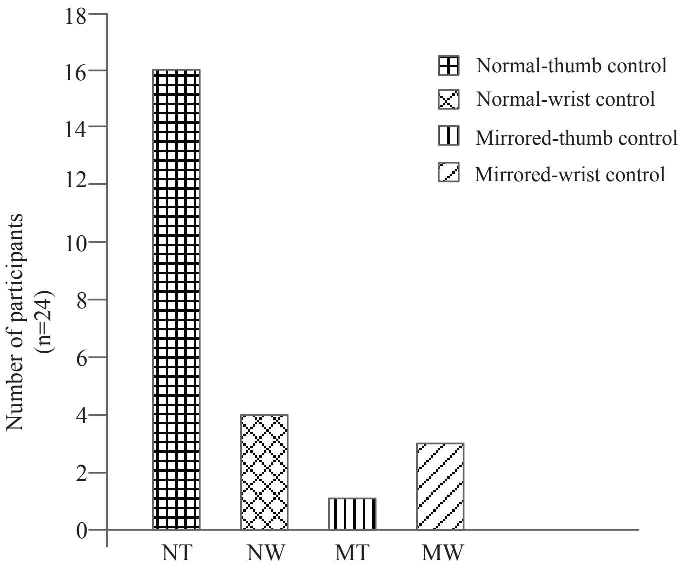


Figure 5.8: Subjective preference at the end of Study 1.

terms of objective measures using either NW or MT, but they experienced lower workload using NW resulting in fewer warnings and collisions than MT. On the contrary, comparing NT and MW, participants experienced similar level of workload using either NT or MW, but performed more accurate and faster using NT than using MW.

The present experiment is a first step assessing the effects of control-display compatibility on human performance in a navigation pathway surgical task. Future researches investigate questions as '*which is the dominant factor in the decision of control interfacing design: control device or control-display*' are needed. In the field of surgical instrument manoeuvring, previous research on control-display compatibility has almost exclusively concentrated on the 'fulcrum effect' in laparoscopic surgery. To our knowledge, this is the first analysis of control-display compatibility in 3D pathway surgical scenarios. The outcomes of our study provide guidelines for the most intuitive way to couple the control movements of surgeons with the display of the movements of a flexible endoscope.

5.4 Study 2: Frame of reference and local disorientation

Frame of reference is the coordinate system in which the location and movement of objects are defined [53][20]. An egocentric (immersive) frame of reference (i.e., the viewpoint of the operator) is considered as the most natural and has been associated with better navigational performance than allocentric frames of reference, as the former does not require any frame of reference transformations (see [20] for an overview). Allocentric (e.g., copla-

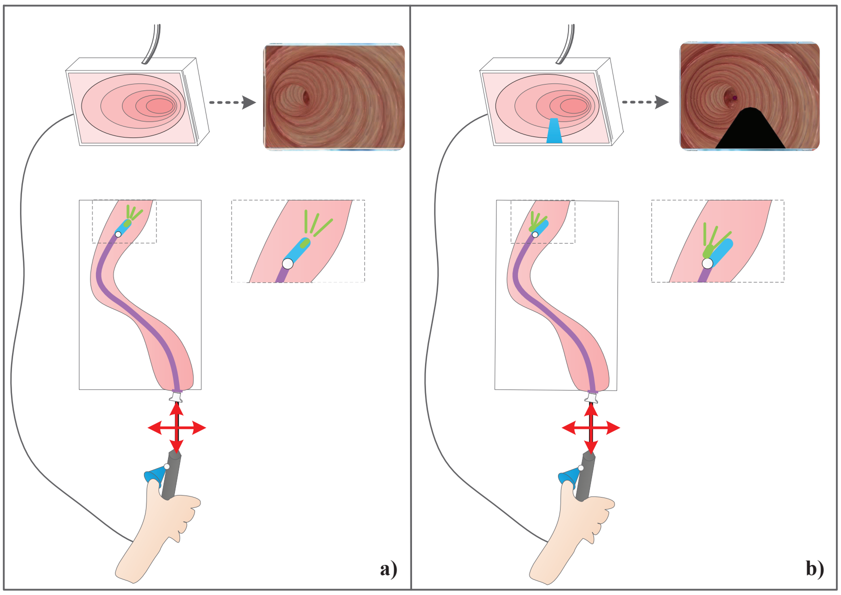


Figure 5.9: Illustration of two camera positions and corresponding screenshots of the simulation software in Study 2: a) invisible tip, in which the camera is on the tip of the instrument; b) visible tip, in which the camera is on the top of the instrument and behind the tip. Pink indicates the endoscope, blue indicates the steerable tip, green indicates the camera.

nar) frames of reference, on the other hand, bear the advantage that they provide a global viewpoint, thereby supporting situation awareness and the relative position and movement of objects [20] [143]. A third type of reference frame is called exocentric or tethered. In this case, a virtual tether attaches the viewpoint with the object that is manipulated (e.g., in the case of navigating an aircraft, imagine a display taken from a camera tethered at a fixed distance behind and above an aircraft). It has been suggested that a tethered viewpoint combines advantages of egocentric and allocentric frames of references, thereby providing better navigation performance than either of the latter two [88][138][139]. Specifically, similarly to an egocentric viewpoint, a tethered viewpoint supports local situation awareness and does not requires frame of reference transformations, while at the same time it provides a wide field of view, thereby supporting global situation awareness similar to how an allocentric viewpoint does.

In pathway surgery, the endoscopic camera is positioned at the tip of the instrument, providing an egocentric view, which compromises global situation awareness. Despite the egocentric view, local disorientation is at play as well, because the endoscope is flexible and the movement of the distal tip is controlled from the proximal end of the endoscope. As a result, the frame of reference differs for the surgeon's hands and the endoscope tip, and the surgeon should apply mental rotations in order to align his frame of reference with that of the endoscope tip. Adding to that, the endoscopic field of view is limited and landmarks vary between individuals (or even within the same individual due to dynamic movements of human organs), inhibiting global situation awareness even further, whereas the fact that the endoscope tip is not visible inhibits local situation awareness.

Golledge [42] defined navigation as ”the process of determining and following a path or route between an origin and a destination”. Knowing how to move along a particular path without getting lost is a challenge to novice endoscopists [18][27]. Much research effort has been devoted to providing navigational aids [26][17][81][113], in which a pre-modelled ’map’ of the navigated tunnel and shape information of the endoscope are presented. The tunnel map is obtained from preoperative images by means of fluoroscopy [26] or magnetic endoscope imaging [113], and sensors [17][81] are used for gathering shape information of the endoscope in real time (see [48] for an overview of such solutions). Such aids have been incorporated into training simulators, in which the reference frame differences between the surgeon and the instrument are also combined with an angled camera in visual reality [111].

Both robotic and mechanical solutions for improving endoscopes’ controllability have been developed [19] [147][153][62][135]. Besides the development of robotic endoscopes [19][147][153], simple mechanical solutions such as an oblique transparent hood [62][135] have been reported as well. In [62], for example, a transparent hood was attached to the tip of the endoscope, with the edge of the hood producing a circular ring on the monitor. It was expected that the transparent hood would maintain a clear visual field by keeping a distance between the scope and the anatomic structure, and the visible circular ring would enable easy anticipation of the advancing direction.

In study 2, the endoscope camera was set in the software to be behind of the instrument tip, and therefore the instrument tip was visible at the bottom on the monitor during half of the trials of the experiment (Fig. 5.9). We hypothesized that the visible tip would provide a cue of orientating direction in the reference frame during the instrument navigation, thereby reducing cognitive load and improving task performance.

5.4.1 Material and Methods

Setup: EndoPathController(Endo-PaC)

The same simulator with Study 1 was used here. The software settings were adjusted in order to show the visible tip at the bottom of the monitor, in which the endoscopic camera was featured on top of the instrument but 5 mm behind the tip.

Experimental procedures

Each participant was verbally informed that the goal was to compare two settings of the endoscopic camera: one in which the camera was set right on the instrument tip such that the tip is not visible on the monitor, and another in which the camera was set behind the instrument tip so that the tip is visible at the bottom of the monitor. All participants performed the study in six sessions first three sessions with an invisible tip and then three sessions with a visible tip (Fig. 5.10). The experimental protocol within each session, such as practice, experiment tasks, and questionnaire evaluation were identical to the protocol of Study 1.

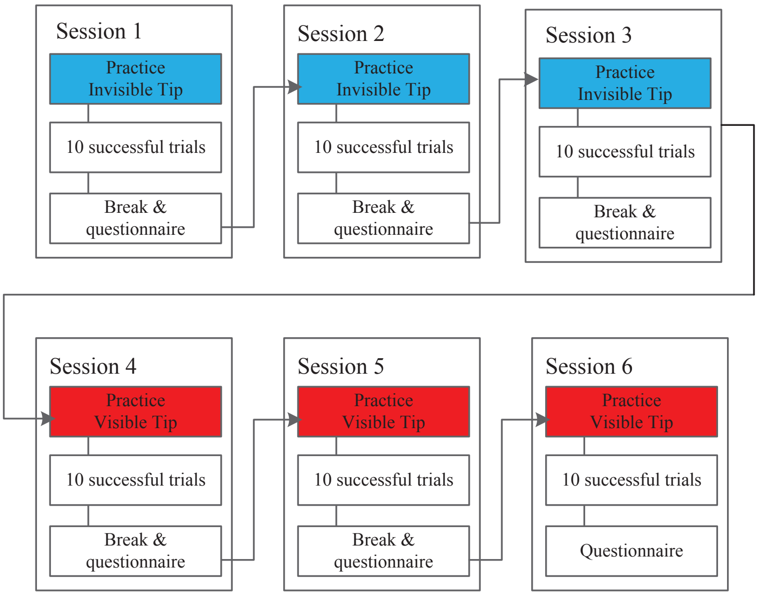


Figure 5.10: Experimental protocol of Study 2.

Participants

Twenty undergraduate and PhD students (14 males and 6 females between 20 and 31 years old) from Delft University of Technology volunteered to participate in this study. All participants were right-handed and had no prior experience with minimally invasive surgery. None of the participants had used the Endo-PaC before. The study was approved by the Human Research Ethics Committee of the Delft University of Technology. The experiment lasted about 1.5 hour per participant.

Parameters and Data analysis

The same parameters measured in Study 1 were used in this study. A paired t-test was conducted to test the difference of the two compared methods over and within sessions, respectively. The difference between the compared methods was considered to be significant when the p-value was smaller than 0.05. A negative effect size (t-value) was caused due to the direction of comparison. All analyses were conducted using MatlabR2011b.

5.4.2 Results

Figures 5.11 and 5.12 present the results of Study 2. Throughout the sessions, the participants exhibited shorter task time (t=3.68, p=0.000) and path length (t=6.18, p=0.000) under the condition with a visible tip, whereas they made shorter distance to the central line (*t*=-8.65, *p*=0.000), shorter time (*t*=-5.11, *p*=0.007) and fewer warnings (*t*=-3.92, *p*=0.006) under the condition with an invisible tip.

During Session 1 and Session 4, the participants performed the experiment with visible tip and invisible tip for the first time, respectively. The results showed that in these two sessions, participants exhibited shorter path length (*t*=6.25, *p*=0.000) but longer distance to central line (*t*=-4.32, *p*=0.017) than with invisible tip. In Session 3 and Session 6, the participants performed the experiment in shorter time (although no significance was observed) and shorter path length (*t*=5.43, *p*=0.000) with visible tip, but with distance to central line (*t*=-7.29, *p*=0.000), shorter time (*t*=-4.79, *p*=0.000) and fewer warning (*t*=-4.69, *p*=0.000) with invisible tip.

Figures 5.13 and 5.14 depict learning curves in terms of the evaluated parameters of participants in this study (n=20). The subjective preference given at the end of the study showed that out of 20 participants, 9 participants preferred visible tip, 8 chose invisible tip and 3 chose 'no difference' (Fig. 5.15). Open comments reported that 'with a visible tip it is easier to track the steering direction'.

5.4.3 Discussion

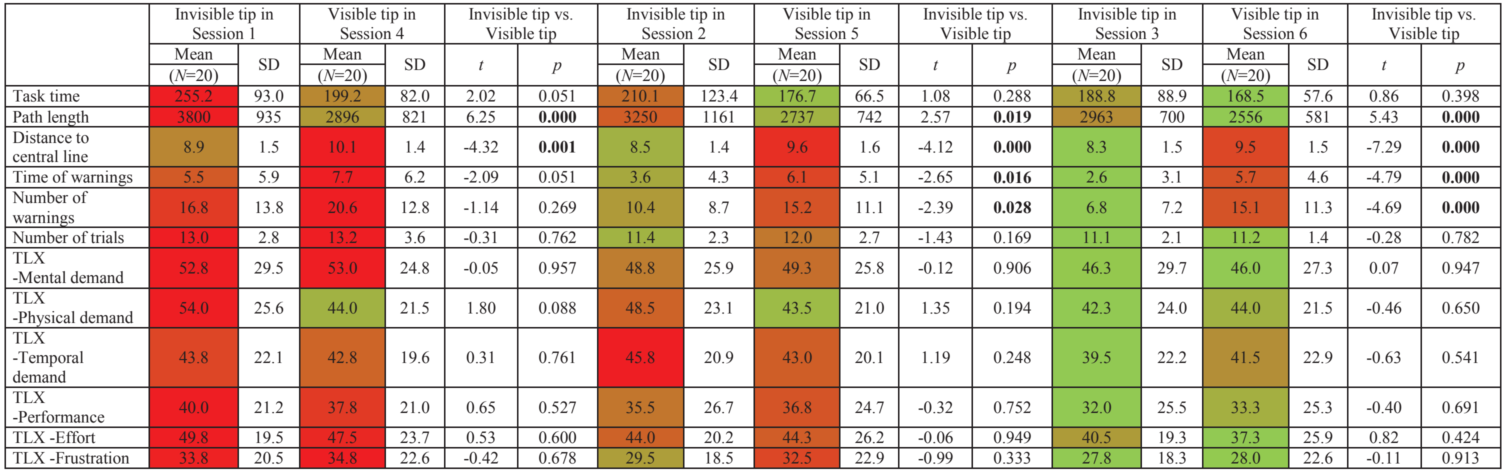
The results of Study 2 indicate that a visible tip greatly speeded up performance and reduced the path length in a navigation task. This finding supports our hypothesis that a visible tip serves as guidance, as it provides strong visual cues about the advancing direction. Although in Session 4, in which visual display was offered for the first time, participants experienced higher cognitive workload due to the new visual display initially, they quickly adapted in Sessions 5 and 6 and self-reported lower workload while making faster performance than in Session 4.

Despite the performance improvements in terms of time, path length and workload, it was observed that in the sessions in which the tip was visible, participants generated a large number of warnings and exhibited long distances to the central line. Apparently, the visible tip introduced difficulties in estimating the distance of the tip from the tunnel wall. Although after some time (in Sessions 5 and 6), participants adapted to the visible tip and performed the task with relatively fewer warnings than in Session 4, the results indicate that long-term learning with the visible tip might be needed.

There are several articles that reported the impact of a transparent hood during endoscopic navigation [135][30][70][149][136][74][132][86][50]. Among these studies, only two trials concluded that the use of a hood shortened the performance time and suggested that the outcome of using a hood might be influenced by the level of endoscopists expertise [135][50]; one reported decrease patient discomfort when using a hood [50]. As an alternative mechanical solution to local disorientation, our study provided the visual cue by locating the endoscopic camera behind the scope tip and assessed the navigation task in term of performance time as well as safety-related parameters, such as time/number of warning and distance to the central line of the tunnel. Our results corroborate previous findings that a visual cue providing direction information led to faster performance [62]. In an experiment in which twelve participants navigated an aircraft-like cursor through virtual tunnels using tethered displays with various tethered lengths, for example, Wang and Milgram [139] found that while global situation awareness increased with an increasing tether, a tether of intermediate length led to the highest local situational awareness. We further showed that

	Invisible tip in Sessions 1,2,3		Visible tip in Sessions 4,5,6		Invisible tip vs. Visible tip	
	Mean (*N*=60)	SD	Mean (*N*=60)	SD	*t*	*p*
Task time	218	104.9	181.5	69.5	3.68	**0.000**
Path length	3334	996	2612	608	6.18	**0.000**
Distance to central line	8.6	1.5	9.7	1.5	-8.65	**0.000**
Time of warnings	3.9	4.7	6.5	5.3	-5.11	**0.000**
Number of warnings	11.3	10.9	16.9	11.9	-3.92	**0.000**
Number of trials	11.8	2.5	12.1	2.8	-0.96	0.342
TLX-Mental demand	49.3	28.1	49.4	25.7	-0.07	0.944
TLX-Physical demand	48.3	24.3	43.8	21.5	1.70	0.094
TLX-Temporal demand	43.0	21.5	42.4	20.6	0.34	0.732
TLX-Performance	35.8	24.4	35.9	23.4	-0.04	0.967
TLX-Effort	44.8	19.7	43.0	25.2	0.76	0.448
TLX-Frustration	30.3	18.9	31.8	22.5	-0.97	0.338

Figure 5.11: Means and standard deviations (SD) of all dependent measures for invisible and visible tip over all sessions in Study 2. t- and p-values for invisible tip versus visible tip control are also shown. p-values < 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).



	Invisible tip in Session 1		Visible tip in Session 4		Invisible tip vs. Visible tip		Invisible tip in Session 2		Visible tip in Session 5		Invisible tip vs. Visible tip		Invisible tip in Session 3		Visible tip in Session 6		Invisible tip vs. Visible tip	
	Mean (*N*=20)	SD	Mean (*N*=20)	SD	*t*	*p*	Mean (*N*=20)	SD	Mean (*N*=20)	SD	*t*	*p*	Mean (*N*=20)	SD	Mean (*N*=20)	SD	*t*	*p*
Task time	255.2	93.0	199.2	82.0	2.02	0.051	210.1	123.4	176.7	66.5	1.08	0.288	188.8	88.9	168.5	57.6	0.86	0.398
Path length	3800	935	2896	821	6.25	**0.000**	3250	1161	2737	742	2.57	**0.019**	2963	700	2556	581	5.43	**0.000**
Distance to central line	8.9	1.5	10.1	1.4	-4.32	**0.001**	8.5	1.4	9.6	1.6	-4.12	**0.000**	8.3	1.5	9.5	1.5	-7.29	**0.000**
Time of warnings	5.5	5.9	7.7	6.2	-2.09	0.051	3.6	4.3	6.1	5.1	-2.65	**0.016**	2.6	3.1	5.7	4.6	-4.79	**0.000**
Number of warnings	16.8	13.8	20.6	12.8	-1.14	0.269	10.4	8.7	15.2	11.1	-2.39	**0.028**	6.8	7.2	15.1	11.3	-4.69	**0.000**
Number of trials	13.0	2.8	13.2	3.6	-0.31	0.762	11.4	2.3	12.0	2.7	-1.43	0.169	11.1	2.1	11.2	1.4	-0.28	0.782
TLX -Mental demand	52.8	29.5	53.0	24.8	-0.05	0.957	48.8	25.9	49.3	25.8	-0.12	0.906	46.3	29.7	46.0	27.3	0.07	0.947
TLX -Physical demand	54.0	25.6	44.0	21.5	1.80	0.088	48.5	23.1	43.5	21.0	1.35	0.194	42.3	24.0	44.0	21.5	-0.46	0.650
TLX -Temporal demand	43.8	22.1	42.8	19.6	0.31	0.761	45.8	20.9	43.0	20.1	1.19	0.248	39.5	22.2	41.5	22.9	-0.63	0.541
TLX -Performance	40.0	21.2	37.8	21.0	0.65	0.527	35.5	26.7	36.8	24.7	-0.32	0.752	32.0	25.5	33.3	25.3	-0.40	0.691
TLX -Effort	49.8	19.5	47.5	23.7	0.53	0.600	44.0	20.2	44.3	26.2	-0.06	0.949	40.5	19.3	37.3	25.9	0.82	0.424
TLX -Frustration	33.8	20.5	34.8	22.6	-0.42	0.678	29.5	18.5	32.5	22.9	-0.99	0.333	27.8	18.3	28.0	22.6	-0.11	0.913

Figure 5.12: Means and standard deviations (SD) of all dependent measures for invisible and visible tip in each session in Study 2. t- and p-values for invisible tip versus visible tip control are also shown. p-values $<$ 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).

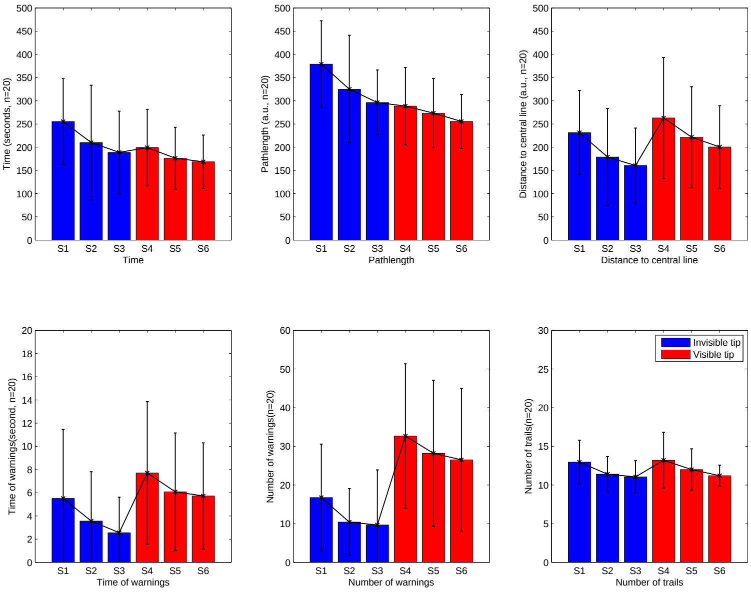


Figure 5.13: Plot of objective measurements from Study 2.

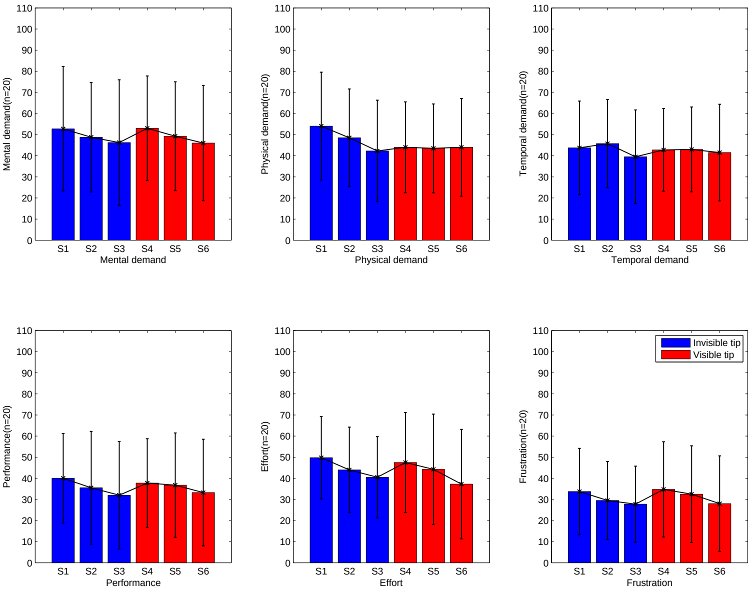


Figure 5.14: Plot of TLX subscales given in Study 2.

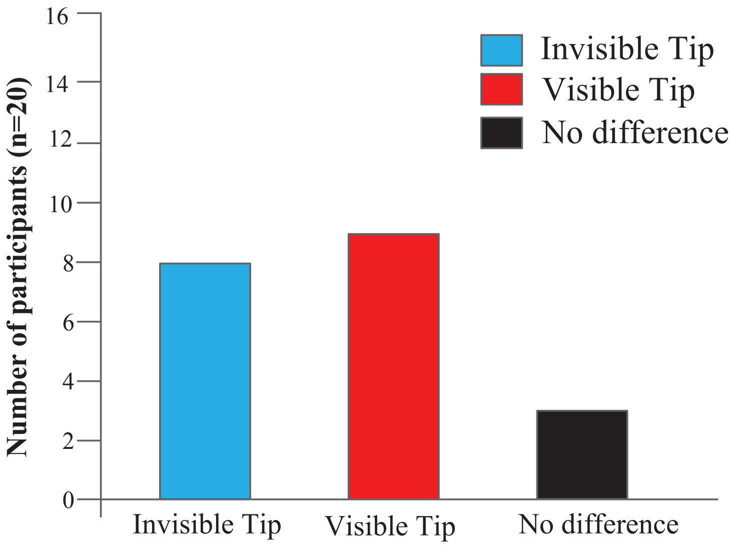


Figure 5.15: Subjective preference of Study 2.

for novices, the introduction of a visible tip may result to an increased number of collisions as compared to an invisible tip, possibly due to the visual obstruction caused by the tip itself and uncertain distance estimation between the camera, the scope tip and the surrounding anatomy.

One limitation of this study is that it was carried out using a simulator. Future studies could feature an endoscopic camera behind the tip in box trainer settings. Moreover, only novices were used. Repeating the experiment with residents and experienced surgeons may indicate different learning curves and adaptations to the visible tip than the present results. It would be further useful to change the scope tip into a transparent one, to prevent visual obstruction of the tip itself and the surrounding anatomy, and to compare the outcome with past experiments conducted using transparent hoods.

5.5 Summary

Many factors contribute to spatial disorientation during endoscopy, two of which being control-display incompatibility and local disorientation. Our studies showed that eliminating control-display misalignment, so that the controlled endoscope tip movements are in the same direction with the surgeon's hand movements, greatly improved novice task performance both in terms of task performance and workload. Our studies further revealed that a visible tip provides a strong direction cue and shortens task completion time, but at cost of an increased number of collision errors.

5.6 Acknowledgement

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Chapter 6

Two Ergonomic factors for manoeuvrable instruments in pathway surgery

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6.1 Abstract

Background: For pathway surgery, that is, minimal invasive procedures carried out transluminally or through instrument-created pathways, flexible instruments with a steerable tip (steerable instruments) and instruments with multiple steerable segments (manoeuvrable instruments) are being developed. As the accompanying control interfaces of handheld manoeuvrable instruments have not been optimized for intuitive manipulation, in the experiments described in this paper, we investigated the effect of control mode (1DoF or 2DoF), and control device (joystick or handgrip) on human performance in a navigation task.

Method: The experiments were conducted using the Endo-PaC (Endoscopic-Path Controller), a simulator that emulates the shaft and handle of a manoeuvrable instrument, combined with custom-developed software animating pathway surgical scenarios. Participants were asked to guide a virtual instrument without collisions towards a target located at the end of a virtual curved tunnel. The performance was compared with regard to task completion time, path length travelled by the virtual instrument, motion smoothness, collision metrics, subjective workload, and personal preference.

Results and Conclusion: The results indicate that 2DoF control leads to faster task completion and fewer collisions with the tunnel wall combined with a strong subjective preference compared with 1DoF control. Handgrip control appeared to be more intuitive to master than joystick control. However, the participants experienced greater physical demand and had longer path lengths with handgrip than joystick control.

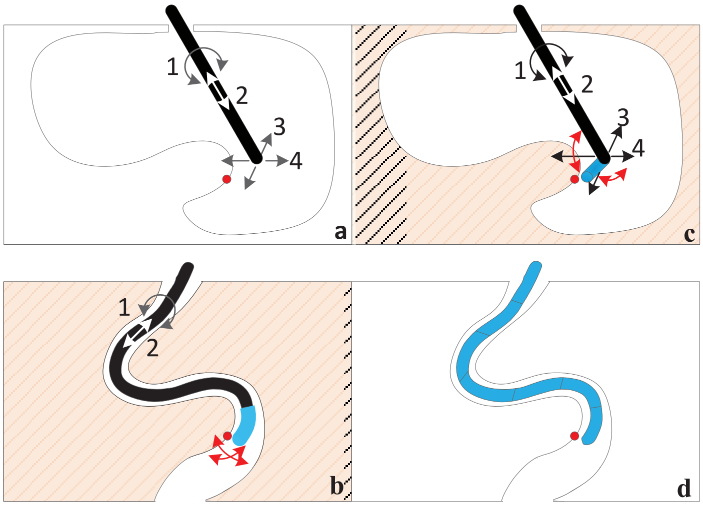


Figure 6.1: Illustration of instruments used in minimally invasive surgery. a) rigid instrument, b) flexible instrument, c) flexible instrument with one steerable segment on the tip, d) instrument with multiple steerable segments along the shaft.

6.2 Introduction

During the last decade, new types of minimally invasive procedures are being carried out through natural openings in the human body with an endoscope following transluminal or instrument-created pathways (e.g., Endo-Nasal Skull Base Surgery (ENSBS) [121]). In these types of procedures, called pathway surgery throughout this paper, instrument manipulation is constrained both by the incision point and by the curvature of the 3D path. Specifically, the incision point restricts the instrument motion within a cone-shaped workspace, reducing the number of degrees of freedom (DoF) from six to four (Fig. 6.1a), while the curvature of the path restricts the instrument motion within a narrow path, further reducing the number of DoF down to two: an axial translation along the shaft and an axial rotation of the shaft (Fig. 6.1b).

To facilitate manoeuvring through narrow curved paths, instruments with one or more steerable segments (featuring additional DoF on the tip or along the shaft) are being developed [11][93][15][43][99][16][71][37]. Rigid instruments with a single steerable segment at the tip, as those developed for single-port surgery [2-7], can access surgical targets that are outside the cone-shaped workspace but are not suitable for following a curved path. Flexible instruments with a steerable tip (henceforth steerable instruments, Fig. 6.1c) and instruments with multiple steerable segments along the shaft (henceforth manoeuvrable instruments, Fig. 6.1d) can be shaped into a 3D form, and are therefore suitable for following complex curved paths.

Handheld manoeuvrable instruments for pathway surgery are still in their infancy and vary in size and application area. In addition, the accompanying control interfaces have

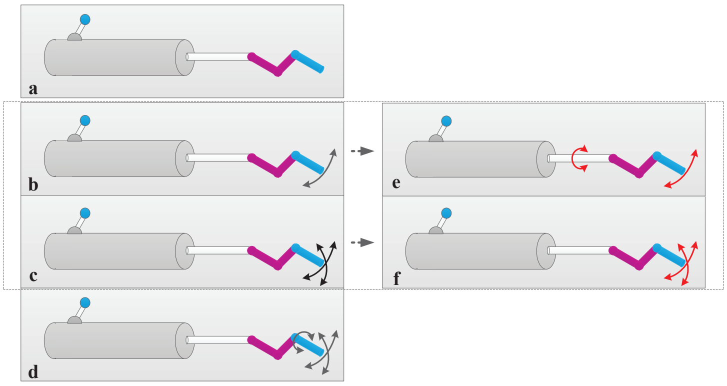


Figure 6.2: Sketch of Integrated Single Segment (ISS) control and illustrations of Deflection-Rotation control and Double-Deflection control (Adapted from [37]). a) ISS control, b) 1DoF ISS control, c) 2DoF ISS control, d) 3DoF ISS control, e) Deflection-Rotation control, f) Double-Deflection control.

in general not been optimized for intuitive manipulation such as dexterous steering along curves [37]. In a review of control interfaces for steerable instruments, Fan et al.[37] argued that, among all existing methods of controlling steerable instruments, Integrated Single Segment (ISS) manoeuvring (Fig. 6.2a) as an intuitive method to follow 3D trajectories in pathway surgery. ISS manoeuvring has been described in a 1979 patent about an instrument called the EndoCarrier [71] and has been further used in the NeoGuide system, a commercially available product used in colonoscopy [97]. With ISS manoeuvring, following 3D trajectories is achieved by actively steering the first segment only. The steering motion of the first segment is automatically transmitted backward along the manoeuvrable shaft and copied by the preceding segments as the instrument moves forward. Requiring only one manual control device for the tip, it can be expected that ISS manoeuvring leads to a user experience similar to conventional steerable instruments with respect to aspects such as eye-hand coordination and steering action. However, ISS manoeuvring has been rarely implemented in surgical settings and needs a lot of technical development and improvement for widespread use in pathway surgery.

6.2.1 Control mode

Fan et al. [37] made a subdivision of methods for ISS manoeuving based on the degrees of freedom of that tip (Fig. 6.2b-d). In the case of 1DoF deflection and 2DoF deflection control, the tip can deflect in one or two orthogonal planes, respectively. In the case of 3DoF control, the tip can also be rotated around its own axis independent of the rotation of the instrument shaft. 3DoF control is mechanically complex [2][63][5], whereas 1DoF control and 2DoF control are simpler and commonly implemented in handheld steerable instruments [16][15][127][99][115][91][92][126].

1DoF control has been applied in a variety of steerable catheters due to the requirement for miniaturization and its manufacturing simplicity [115][92][91][126]. By deflecting the catheter tip and by rotating the catheter shaft in a circumferential plane, 1DoF control facilitates manoeuvring through vascular structures and accessing side arteries [109][100]. 2DoF control has been incorporated in a number of flexible endoscopes, namely bi-directional gastroscopes and colonoscopies [60][61]. By twisting two knobs that are placed on top of each other in the handle, the tip can be steered in two orthogonal directions.

During pathway surgery, besides advancing the instrument, the surgeon needs to manoeuver the instrument in two orthogonal directions (up/down and left/right). In instruments employing 1DoF, a second DoF can be created indirectly, by rotating the instrument around its shaft. In this paper, we refer to 1DoF tip deflection + 1DoF shaft rotation control as *Deflection-Rotation control* or *DR control* (Fig. 6.2e). The mechanically more complex 2DoF tip deflection control will be called henceforth *Double Deflection control* or *DD control* (Fig. 6.2f).

6.2.2 Control device

The ability of both the human wrist and thumb to move naturally in two perpendicular directions enables the surgeon to control two DoF either one at a time or simultaneously. In the case of 1DoF deflection control, a 1DoF finger rotation or deflection is mapped to a 1DoF tip deflection, for example by using a rotation knob [127][115][92][91]. In the case of 2DoF deflection control, the 2DoF tip deflection follows the surgeons 2DoF wrist or thumb movements, for instance by using a joystick or handgrip (e.g., pencil-like or sword-like grasp) which articulates the instrument tip. 2DoF joystick control has been widely used in commercial gamepads and has been recently implemented in the prototype of a handheld laparoscopic grasper [11]. 2DoF handgrip control with a handle that can be articulated in two perpendicular directions relative to the shaft has been applied in a number of commercially available steerable surgical instruments for laparoscopic surgery [129][16][127].

6.2.3 Problem statement

When navigating in two directions (up/down and left/right) from one anatomic location to another along a curved path, DR control requires a mental transformation between the rotation of the instrument and the corresponding deflection of the tip, whereas DD control seems easier for the operator due to the one-to-one mapping between control motion and tip motion. On the other hand, DR control is technically easier to realize, potentially leading to lower production costs. The question is therefore whether the theoretical advantage of the one-to-one mapping in DD control as compared to DR control does translate into better task performance (e.g., in terms of task completion time, movement accuracy, and mental workload), which could justify opting for DD control despite its technical complexity and associated elevated production costs.

Besides the difference between DD and DR control, the effect of the design of the controller on surgical task performance deserves to be investigated as well. Fan et al. [23] compared 2DoF joystick with 2DoF handgrip control in a laparoscopic positioning task using a portable laparoscopic trainer and novice participants. These authors found that although the two controllers did not lead to significantly different task completion times, joystick control was preferred by the majority of the participants. However, as pathway surgery differs from laparoscopy in that in the former the surgeon has to manoeuver a flexible device along a curved 3D track rather than a rigid instrument around a pivot point, the results of our previous experiment are not readily applicable to a pathway surgical setting. This study provides a comparison of two control modes, DR and DD control, and two control devices, joystick and handgrip, with respect to task performance in a pathway surgical navigation task. Since the selected control mode has the largest impact on the mechanical complexity of the handle, we decided to start this study with an experiment comparing DR versus DD control followed by an experiment on joystick versus handgrip control.

6.3 Method

6.3.1 Experimental setup

Hardware

We designed an experimental setup, the Endo-PaC (Endoscopic-Path Controller), in which a virtual steerable endoscope is controlled using ISS manoeuvring in a simulated pathway surgical task. The Endo-PaC (Fig. 5.3a) is a plug-and-play simulator consisting of a mechanism that emulates the shaft and handle of a manoeuvrable instrument, enhanced with custom-developed software that simulates pathway surgical scenarios.

Endo-PaC uses four potentiometers (Contelec AG, Biel, Germany) and one position sensor (Waycon GmbH, Taufkirchen, Germany) to measure its shaft and handle motion in 5-DoF: a 2-DoF rotation at the base of the simulator measuring the motion of the virtual instrument around the incision, a 2-DoF rotation (left/right; up/down) at the handle measuring the deflection of the steering unit, and a 1-DoF translation along the shaft measuring the forward/backward motion of the virtual instrument.

The Endo-PaC can be connected to a laptop by a USB data acquisition unit LabJack-U3 (LabJack Corporation, U.S.A). The handle of the simulator (Figs 5.3a-c) is fabricated by means of additive manufacturing, allowing for variation in sizes and shapes of the handle and steering unit. The base of the simulator is equipped with a removable sideboard with an angle indicator (Figs 5.3b-c) so that the shaft can either be fixed at a desired angle or be moved freely when the sideboard is removed.

Software

Custom-made software (developed in C++ using OpenGL library) models a 3D curved tunnel with adjustable length, curvature and diameter, and reads the sensor measurements in real-time with standard communication protocols as used by Microsoft Windows (Fig. 5.3d). The tunnel is rendered to visually resemble the texture of a soft-tissue organ. The tunnel curvature was set to be within the maximal range of the steering unit (17.5 mm) and configured such that the normal (i.e., absolute) distance between the incision plane and the target plane was identical for all the trials and equal to the maximal translation range of Endo-PaC (100 mm).

An endoscopic camera is featured at the tip of a virtual manoeuvrable instrument and is steered by the steering unit of Endo-PaC, giving a perspective view of the tunnel. The simulation screen is set to be identical to the cameras field of view.

A safety-zone is pre-set by the software as an annulus with its outer diameter equal to the diameter of the tunnel and its inner diameter equal to 0.7 times the diameter of the tunnel. The software continuously checks the distance between the virtual tip and the centre line of the tunnel and gives a warning in case a collision is either imminent (when the distance is larger than the safety-zone inner diameter) or has occurred (when the distance is equal to the tunnel diameter). In clinical practice, surgeons commonly use texture and visible aspects of tissue deformation as a cue for estimating the instrument position during manoeuvring [108][120]. To introduce such a cue in a stylised way in our software, the colour of the tunnel turns into amber and a green arrow appears on the screen when the tip is out of the safety-zone (Fig. 5.3e), indicating the direction of a potential collision. The length of the arrow linearly increases/decreases with respect to the deviation from the tunnel central line. If the tip collides with the wall, the tunnel turns red (Fig. 5.3f), and the experiment is terminated. The tunnel turns green when the task has been completed successfully (Fig. 5.3g).

6.3.2 Task

Participants were asked to use Endo-PaC to guide a virtual manoeuvrable instrument towards a spherical target located at the end of the simulated 3D-curved tunnel as fast as possible and without collisions with the tunnel wall. First, each participant configured the steering unit to its neutral position by moving the virtual instrument tip with the camera to the centre of the image on the screen. A trial then started, and stopped when the target was reached or when a collision of the virtual tip against the tunnel wall occurred. Trials with a collision were excluded from the data analysis. Each participant was asked to perform four experimental sessions, each consisting of 10 successful trials (i.e., reaching the target without any collision). Ten 3D-tunnels with various curvatures were generated by using a randomizer in MATLAB (Version R2011b, The MathWorks, Inc., Natick, MA), and the order of these tunnels was varied randomly between the sessions to prevent that participants adapt their orientation strategy to a particular curvature or order of tunnels. The variation of tunnel curvatures and the order of tunnels in each session were identical to all participants. That is, in the same session, all participants received the same set of 3D tunnels in the same order.

6.4 Study 1: control mode - DR versus DD control

6.4.1 Participants

Twenty undergraduate and graduate students (15 men and 5 women aged between 25 and 32 years) from Delft University of Technology volunteered to participate and were assigned into two equally sized groups, Group A and Group B. All participants were right-handed and had no prior experience with minimally invasive surgery or Endo-PaC.

6.4.2 Procedure

Figure 6.3 shows the procedure and control mode order for the two groups. The control mode order in the four sessions was counterbalanced between the two groups: Group A

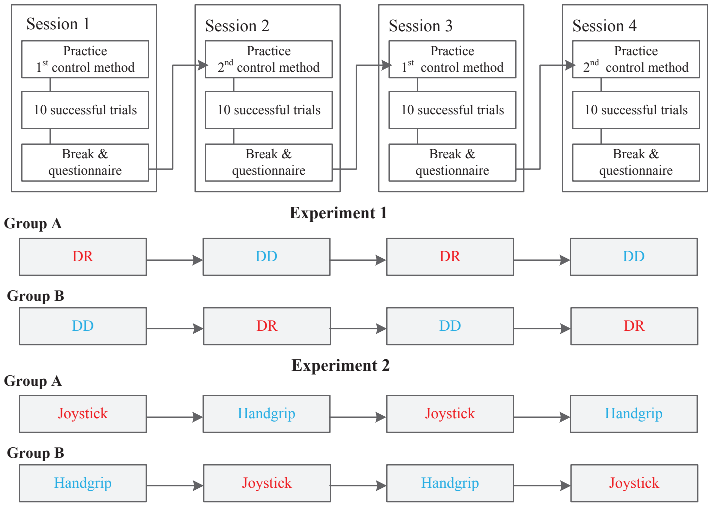


Figure 6.3: Flow chart of experiments' procedures. DR: Deflection-Rotation control; DD: Double-Deflection control.

started with DR control and then alternated between DD-DR-DD, and Group B started with DD control and alternated between DR-DD-DR. All sessions were conducted with a joystick controller.

Before starting the experiment, each participant was verbally informed about the goal of the experiment by one of the authors and watched a video demonstration about how to use the Endo-PaC with both control modes and what would happen on the screen in case of near-collision, collision and experiment completion. Each session started with a practice phase, followed by a testing phase and a break. The practice phase included three trials of reaching the target with the control mode used in that specific session. The testing phase was completed when the participant performed 10 successful trials (i.e., reaching the target without any collision). During the break at the end of the session, each participant was asked to fill in a questionnaire including NASA TLX subscales [51], the most widely used method for measuring subjective workload [59]. After completion of the experiment, all participants filled in an open questionnaire about their preference between the two control modes and their general impression about the interface. The experiment lasted about 1.5 hour per participant. The experiment was approved by the Human Research Ethics Committee of Delft University of Technology.

6.4.3 Parameters

The following parameters were chosen for assessing the task performance:

- *Task completion time (in seconds)*: the total time taken to complete 10 successful trials in one experimental session (trials with collisions were excluded);

- *Path length (in arbitrary unit)*: the total distance travelled by the virtual tip along the tunnel over the 10 successful trials in one experimental session;
- *Distance from the central line (in arbitrary unit)*: the averaged absolute distance between the travelled trajectory by the virtual tip at each point and the tunnel central line during the 10 successful trials in one experimental session;
- *Time of warnings (in seconds)*: the total time during which the virtual tip stayed outside of the safety zone during the 10 successful trials during one experimental session;
- *Number of warnings*: the total number of warnings issued during the 10 successful trials during one experimental session;
- *Number of trials*: the total number of trials conducted to complete 10 successful trials during one experimental session.
- *TLX scores*: TLX subscales are rated for six items within in a 100-points range with 5-point intervals, including Mental demand, Physical demand, Temporal demand, Performance, Effort and Frustration. Except for the performance (rating from 'perfect' to 'failure'), a higher score means that a task is more demanding (rating from 'very low' to 'very high').

6.4.4 Statistics

An independent *t*-test was conducted to compare control modes in each session. A paired *t*-test was used to compare control modes over a) the four sessions, b) sessions 1 and 2, and c) session 3 and 4. Differences between the two control modes were considered to be significant when the *p*-value was smaller than 0.05. A negative effect size (*t*-value) was caused due to the direction of comparison. All analyses were conducted using MATLAB R2011b.

6.4.5 Results of Study 1

Table 6.4 shows the means and standard deviations of all dependent measures for DR and DD controls in each session, as well as t-test comparisons between DR and DD controls in each session. The task completion time for DR control was longer than the task time for DD control by 52% (t=2.9, p=0.010) in Session 1 and by 57% (t=3.02, p=0.004) in Session 3. Moreover, in Session 3, the participants using DR control reported significantly higher physical demand than the participants using DD control (t=3.09, p=0.006).

During Sessions 2 and 4, the participants using DR control spent longer time outside the safety zone (Session 2: t=2.86, p=0.010; Session 4: t=2.40, p=0.028), conducted more trials (Session 2: t=4.47, p=0.000; Session 4: t=3.83, p=0.001), and self-reported more frustration (Session 2: t=3.60, p=0.002; Session 4: t=3.50, p=0.003), more effort (Session 2: t=3.95, p=0.001; Session 4: t=3.47, p=0.003) and better performance (Session 2: t=3.37, p=0.003; Session 4: t=3.52, p=0.002) than the participants using DD control. Additionally, in Session 4, participants using DR control experienced more physical demand (t=2.13, p=0.047) and more temporal demand (t=2.13, p=0.047) than the participants using DD control.

Table 6.5 shows the means and standard deviations of all dependent measures for DR and DD controls over the four sessions, as well as paired t-test comparisons between DR and DD controls over the four sessions. Over the four sessions, the participants conducted the task in longer time (t=5.46, p=0.000), longer distance from the central line (t=3.22, p=0.005), longer time of warnings (t=3.01, p=0.007), larger number of warnings (t=3.15, p=0.005), and more trials (t=5.84, p=0.000) using DR control than DD control. The results from the TLX scales showed that participants experienced significantly lower workload using DD control compared to DR control. Findings from the statistical analysis over Sessions 1 versus Session 2 and Sessions 3 versus Session 4 are consistent with the results over the four sessions, and the detailed data is provided in Table 2.

A total of 18 out of the 20 participants preferred DD control over DR control. In the open comments, 4 participants reported that ’there is no need for training with DD control’. Nearly all participants (17 out of 20) commented that they lost orientation after rotation using DR control and that this was highly annoying and resulted in a slow and bad performance.

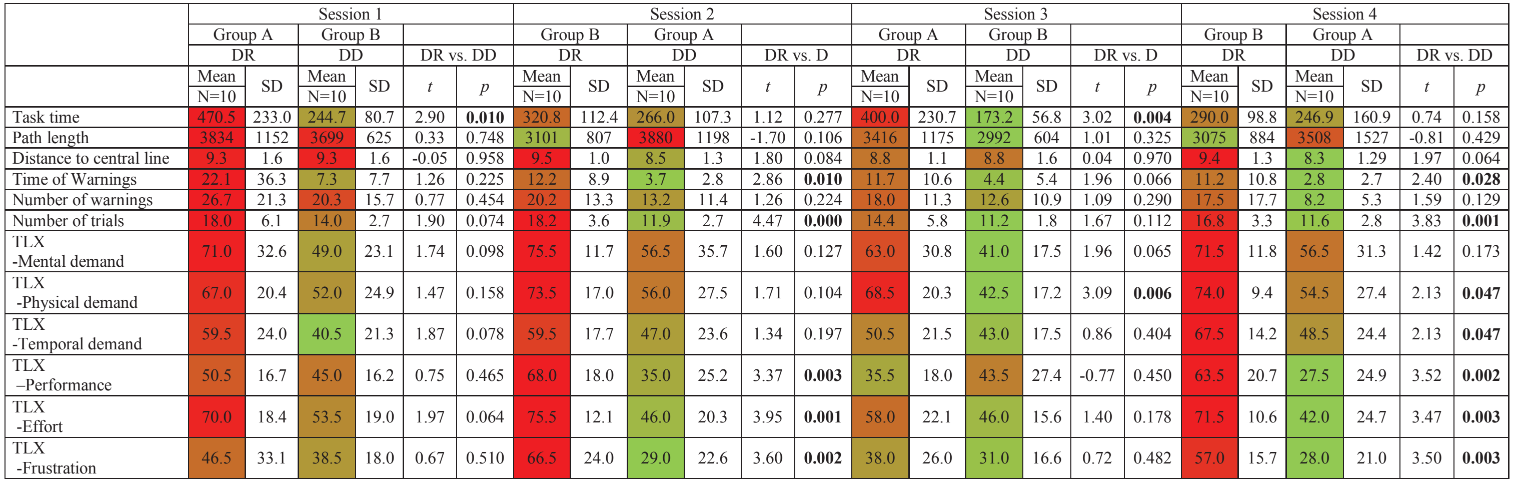
6.5 Study 2: Control device - Joystick control versus Handgrip control

6.5.1 Participants

The goal of Study 2 was to compare joystick and handgrip control in terms of human performance in a pathway surgical task. Twenty undergraduate and graduate students (16 men and 4 women between 20 and 29 years old) from Delft University of Technology joined in this experiment and were assigned into two equally sized groups (Group A and Group B). All participants were right-handed and had no prior experience with minimally invasive surgery or Endo-PaC. There was no overlap between the participants of Studies 1 and 2.

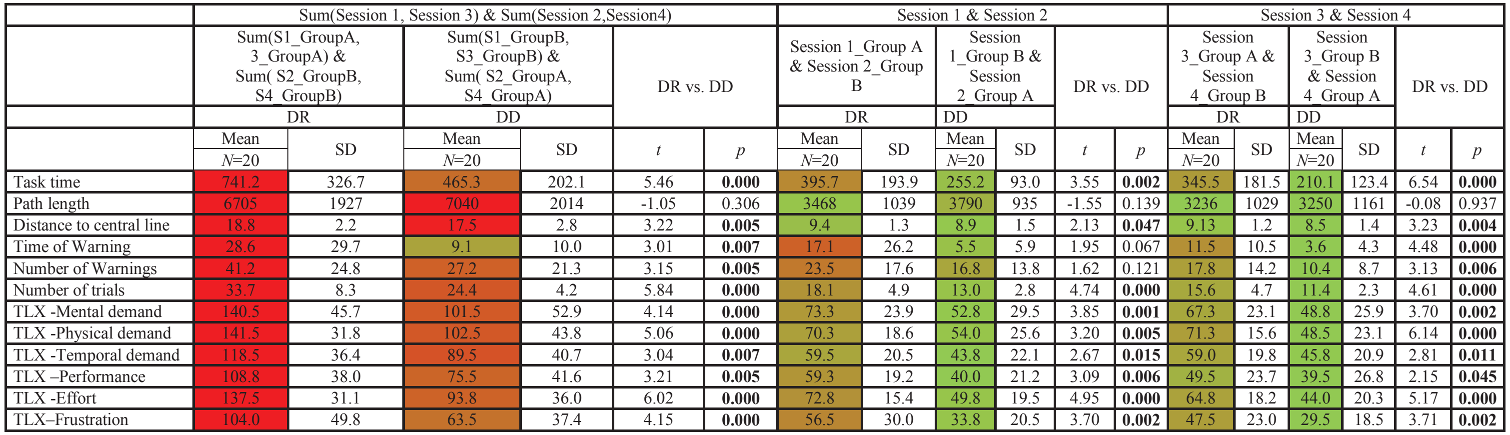
6.5.2 Procedure

Study 2 was carried out with the control mode that led to the best task performance in Study 1: DD control. The procedure and control device for the two groups are presented in Figure 6.3. The control device order in the four sessions was counterbalanced between the two groups, so that Group A started with joystick control and then alternated between handgrip-joystick-handgrip, and Group B started with handgrip control and then alternated between joystick-handgrip-joystick. Before the experiment started, the goal of the experiment was verbally explained to each participant and an instruction was given regarding the use of the two control devices and the screen output. The subsequent procedures, such as practice, experimental tasks and questionnaire evaluation, were identical to Study 1. The experiment lasted about 1 hour per participant. The experiment was approved by the Human Research Ethics Committee of Delft University of Technology.



	Session 1						Session 2						Session 3						Session 4					
	Group A		Group B				Group B		Group A				Group A		Group B				Group B		Group A			
	DR		DD		DR vs. DD		DR		DD		DR vs. D		DR		DD		DR vs. D		DR		DD		DR vs. DD	
	Mean N=10	SD	Mean N=10	SD	*t*	*p*	Mean N=10	SD	Mean N=10	SD	*t*	*p*	Mean N=10	SD	Mean N=10	SD	*t*	*p*	Mean N=10	SD	Mean N=10	SD	*t*	*p*
Task time	470.5	233.0	244.7	80.7	2.90	**0.010**	320.8	112.4	266.0	107.3	1.12	0.277	400.0	230.7	173.2	56.8	3.02	**0.004**	290.0	98.8	246.9	160.9	0.74	0.158
Path length	3834	1152	3699	625	0.33	0.748	3101	807	3880	1198	-1.70	0.106	3416	1175	2992	604	1.01	0.325	3075	884	3508	1527	-0.81	0.429
Distance to central line	9.3	1.6	9.3	1.6	-0.05	0.958	9.5	1.0	8.5	1.3	1.80	0.084	8.8	1.1	8.8	1.6	0.04	0.970	9.4	1.3	8.3	1.29	1.97	0.064
Time of Warnings	22.1	36.3	7.3	7.7	1.26	0.225	12.2	8.9	3.7	2.8	2.86	**0.010**	11.7	10.6	4.4	5.4	1.96	0.066	11.2	10.8	2.8	2.7	2.40	**0.028**
Number of warnings	26.7	21.3	20.3	15.7	0.77	0.454	20.2	13.3	13.2	11.4	1.26	0.224	18.0	11.3	12.6	10.9	1.09	0.290	17.5	17.7	8.2	5.3	1.59	0.129
Number of trials	18.0	6.1	14.0	2.7	1.90	0.074	18.2	3.6	11.9	2.7	4.47	**0.000**	14.4	5.8	11.2	1.8	1.67	0.112	16.8	3.3	11.6	2.8	3.83	**0.001**
TLX -Mental demand	71.0	32.6	49.0	23.1	1.74	0.098	75.5	11.7	56.5	35.7	1.60	0.127	63.0	30.8	41.0	17.5	1.96	0.065	71.5	11.8	56.5	31.3	1.42	0.173
TLX -Physical demand	67.0	20.4	52.0	24.9	1.47	0.158	73.5	17.0	56.0	27.5	1.71	0.104	68.5	20.3	42.5	17.2	3.09	**0.006**	74.0	9.4	54.5	27.4	2.13	**0.047**
TLX -Temporal demand	59.5	24.0	40.5	21.3	1.87	0.078	59.5	17.7	47.0	23.6	1.34	0.197	50.5	21.5	43.0	17.5	0.86	0.404	67.5	14.2	48.5	24.4	2.13	**0.047**
TLX –Performance	50.5	16.7	45.0	16.2	0.75	0.465	68.0	18.0	35.0	25.2	3.37	**0.003**	35.5	18.0	43.5	27.4	-0.77	0.450	63.5	20.7	27.5	24.9	3.52	**0.002**
TLX -Effort	70.0	18.4	53.5	19.0	1.97	0.064	75.5	12.1	46.0	20.3	3.95	**0.001**	58.0	22.1	46.0	15.6	1.40	0.178	71.5	10.6	42.0	24.7	3.47	**0.003**
TLX -Frustration	46.5	33.1	38.5	18.0	0.67	0.510	66.5	24.0	29.0	22.6	3.60	**0.002**	38.0	26.0	31.0	16.6	0.72	0.482	57.0	15.7	28.0	21.0	3.50	**0.003**

Figure 6.4: Means and standard deviations (SD) of all dependent measures for Deflection-Rotation (DR) and Double-Deflection (DD) control in each session of Study 1. t- and p-values for DR versus DD control per session are also shown. p-values < 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).



	Sum(Session 1, Session 3) & Sum(Session 2,Session4)						Session 1 & Session 2						Session 3 & Session 4					
	Sum(S1_GroupA, 3_GroupA) & Sum(S2_GroupB, S4_GroupB)		Sum(S1_GroupB, S3_GroupB) & Sum(S2_GroupA, S4_GroupA)		DR vs. DD		Session 1_Group A & Session 2_Group B		Session 1_Group B & Session 2_Group A		DR vs. DD		Session 3_Group A & Session 4_Group B		Session 3_Group B & Session 4_Group A		DR vs. DD	
	DR		DD				DR		DD				DR		DD			
	Mean *N*=20	SD	Mean *N*=20	SD	*t*	*p*	Mean *N*=20	SD	Mean *N*=20	SD	*t*	*p*	Mean *N*=20	SD	Mean *N*=20	SD	*t*	*p*
Task time	741.2	326.7	465.3	202.1	5.46	**0.000**	395.7	193.9	255.2	93.0	3.55	**0.002**	345.5	181.5	210.1	123.4	6.54	**0.000**
Path length	6705	1927	7040	2014	-1.05	0.306	3468	1039	3790	935	-1.55	0.139	3236	1029	3250	1161	-0.08	0.937
Distance to central line	18.8	2.2	17.5	2.8	3.22	**0.005**	9.4	1.3	8.9	1.5	2.13	**0.047**	9.13	1.2	8.5	1.4	3.23	**0.004**
Time of Warning	28.6	29.7	9.1	10.0	3.01	**0.007**	17.1	26.2	5.5	5.9	1.95	0.067	11.5	10.5	3.6	4.3	4.48	**0.000**
Number of Warnings	41.2	24.8	27.2	21.3	3.15	**0.005**	23.5	17.6	16.8	13.8	1.62	0.121	17.8	14.2	10.4	8.7	3.13	**0.006**
Number of trials	33.7	8.3	24.4	4.2	5.84	**0.000**	18.1	4.9	13.0	2.8	4.74	**0.000**	15.6	4.7	11.4	2.3	4.61	**0.000**
TLX -Mental demand	140.5	45.7	101.5	52.9	4.14	**0.000**	73.3	23.9	52.8	29.5	3.85	**0.001**	67.3	23.1	48.8	25.9	3.70	**0.002**
TLX -Physical demand	141.5	31.8	102.5	43.8	5.06	**0.000**	70.3	18.6	54.0	25.6	3.20	**0.005**	71.3	15.6	48.5	23.1	6.14	**0.000**
TLX -Temporal demand	118.5	36.4	89.5	40.7	3.04	**0.007**	59.5	20.5	43.8	22.1	2.67	**0.015**	59.0	19.8	45.8	20.9	2.81	**0.011**
TLX –Performance	108.8	38.0	75.5	41.6	3.21	**0.005**	59.3	19.2	40.0	21.2	3.09	**0.006**	49.5	23.7	39.5	26.8	2.15	**0.045**
TLX -Effort	137.5	31.1	93.8	36.0	6.02	**0.000**	72.8	15.4	49.8	19.5	4.95	**0.000**	64.8	18.2	44.0	20.3	5.17	**0.000**
TLX–Frustration	104.0	49.8	63.5	37.4	4.15	**0.000**	56.5	30.0	33.8	20.5	3.70	**0.002**	47.5	23.0	29.5	18.5	3.71	**0.002**

Figure 6.5: Means and standard deviations (SD) of all dependent measures for Deflection-Rotation (DR) and Double-Deflection (DD) control across sessions of Study 1. a) All four sessions, of which the results were summed for Sessions 1 and 3, and Sessions 2 and 4, respectively; b) Sessions 1 and 2; c) Sessions 3 and 4. p-values < 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).

6.5.3 Parameters

Beside the parameters that were measured in Study 1, such as time, path length and TLX subscales, also a kinematic parameter, the 1-dimensional (1D) motion smoothness along the control axis was analysed. This parameter, in $a.u./mm^3$ (a.u. = arbitrary unit), was calculated by the change in the acceleration (j) based on the third derivative of the position (h) of the virtual tip moving along its axis, defined as

$$j = \sqrt{\left(\frac{d^3h}{dt^3}\right)^2}$$

One- dimensional motion smoothness is then derived from the integrated squared jerk

$$J = \sqrt{\frac{1}{2}\int_0^T j^2 dt}$$

6.5.4 Statistics

An independent t-test was conducted to test the differences between the two control devices in each individual session. A paired t-test was used to compare control modes over a) the four sessions, b) sessions 1 and 2, and c) session 3 and 4. Differences between the two control modes were considered to be significant when the p-value was smaller than 0.05. All analyses were conducted using MATLAB R2011b.

6.5.5 Results of Study 2

Figure 6.8 show the average task completion time from each group. The fastest individual performances for completing an experimental session using both control devices occurred in Session 4 (49.06 s using joystick control and 59.53 s using handgrip control), during which session the average task times for 10 completed trials were 87.9 s and 88.1 s for joystick and handgrip control, respectively.

Figure 6.6 shows the means and standard deviations of all dependent measures for joystick and handgrip control in each sessions, as well as *t*-test comparisons between joystick and handgrip controls in each session. During Sessions 1 and 3, no significant differences between the two control devices were observed in terms of task time, path length and TLX scores. In Session 1, the 1D motion smoothness was significantly better for joystick than for handgrip control at both left/right and up/down directions (left/right direction: t=-2.19, p=0.042; up/down direction: t=-2.12, p=0.048). In Session 3, the two control devices did not differ in the 1D motion smoothness.

During Sessions 2 and 4, the path length was significantly shorter for joystick control than for handgrip control (Session 2: t=-2.64, p=0.017; Session 4: t=-2.84, p=0.011). Participants using handgrip control, on the other hand, self-reported significantly lower physical demand (Session 2: t=-3.63, p=0.002; Session 4: t=-3.37, p=0.003) than participants using joystick control. Participants using the joystick control self-reported a somewhat higher frustration than participants using handgrip control in all four sessions, but the difference did not reach significance.

Figure 6.7 shows the means and standard deviations of all dependent measures for joystick and handgrip control over the four sessions, as well as paired *t*-test comparisons between joystick and handgrip controls over the four sessions. The participants reported a lower physical demand (*t*=-3.81, *p*=0.001) and exhibited lower 1D motion smoothness using joystick control than using handgrip control (left/right direction: *t*=-7.87, *p*=0.000; up/down direction: *t*=-7.31, *p*=0.000). Also, the path length was significantly shorter for joystick control than for handgrip control (*t*=-3.90, *p*=0.000). No significant differences between the two control devices were observed in terms of task time or other items of the TLX subscales.

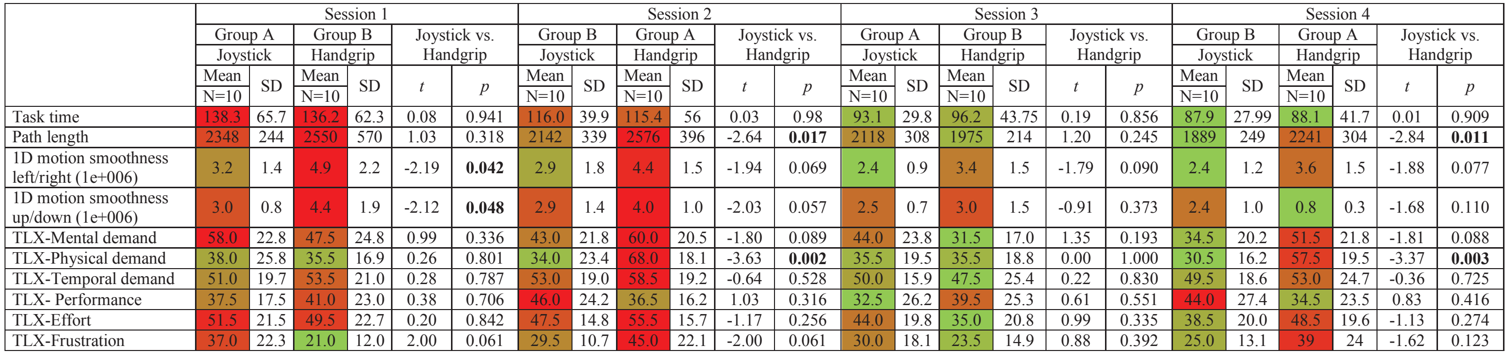
In the final questionnaire, 8 out of the 20 participants indicated a preference to joystick control, 10 participants preferred handgrip control, and 2 participants expressed no preference (Fig. 6.9). For the open question Did you feel fatigued during the test, 3 out of the 20 participants reported fatigue for joystick control (mainly around thumb and forearm), and 7 participants for handgrip control (mainly around wrist, forearm and shoulder).

6.6 Discussion

6.6.1 Control mode: DR control versus DD control

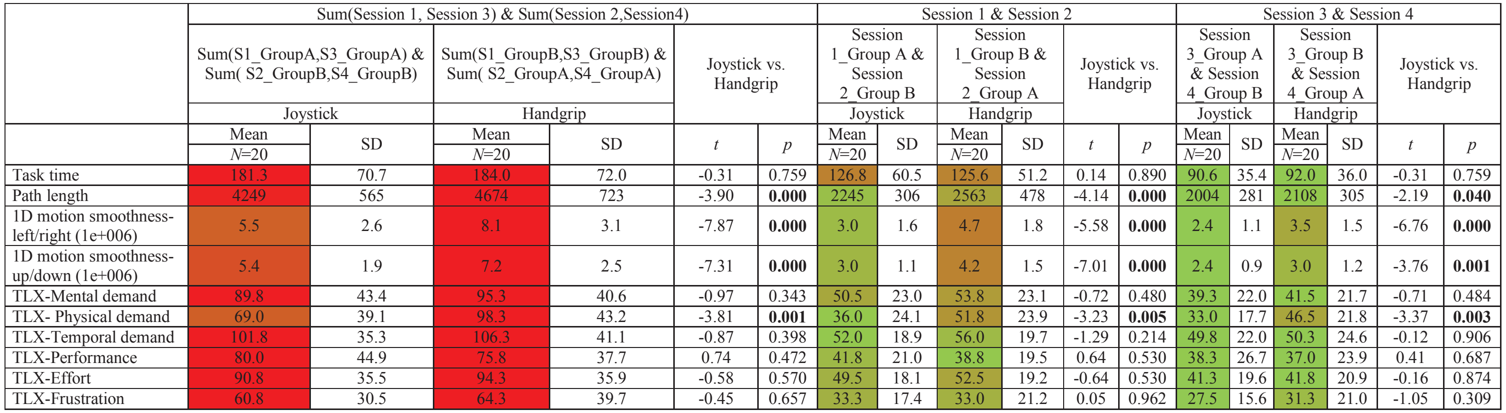
In Study 1, two control modes, Deflection-Rotation (DR) and Double-Deflection (DD) control, were compared in a navigation task. Using DD control led to shorter completion times, smaller distance from the centre line, shorter times of warnings and fewer number of warnings and trials than using DR control. No significant differences between the two control modes were observed in terms of path length. There are two likely explanations for these results: 1) using DR control needed more time to complete the experiment while taking trajectories similar to those taken with DD control; or 2) the trajectories created by DR control and DD control differed from each other: one was jagged due to small movements and the other was straight but detoured. In order to investigate which of these two explanations is more plausible, the trajectories travelled by the virtual tip using both control modes during Session 4 were plotted. Characteristic examples of these plots are presented in Figure 6.10, showing that 1) the trajectories using both control modes were jagged, 2) the trajectories with DR control were somewhat straighter than the DD control towards the end of the tunnel curve, but the distance from the central line during rotation in DR control was generally larger than the distance from the central line in DD control. Considering that the length of the tunnel's central line is always longer than the absolute distance between the start and target plane of the tunnel, it could be deduced that any advantages in path length gained by the straight trajectories under DD control toward the end of the tunnel curve are cancelled out by relatively large deviations from the central line during the rotation of the instrument, leading to comparable path lengths with DD control.

Open comments revealed that different participants followed two different strategies under DR control. When encountering a curved corner, one strategy was to first rotate, deflect the virtual tip to the opposite direction of the corner, and then forward the entire instrument while keeping this direction (Fig. 6.11-top). Other participants took the same steps of rotation and deflection, but then conducted a retro-rotation right after the deflection, before forwarding the entire instrument towards to the goal (Fig. 6.11-bottom). This observation



	Session 1						Session 2						Session 3						Session 4					
	Group A		Group B		Joystick vs. Handgrip		Group B		Group A		Joystick vs. Handgrip		Group A		Group B		Joystick vs. Handgrip		Group B		Group A		Joystick vs. Handgrip	
	Joystick		Handgrip				Joystick		Handgrip				Joystick		Handgrip				Joystick		Handgrip			
	Mean N=10	SD	Mean N=10	SD	*t*	*p*	Mean N=10	SD	Mean N=10	SD	*t*	*p*	Mean N=10	SD	Mean N=10	SD	*t*	*p*	Mean N=10	SD	Mean N=10	SD	*t*	*p*
Task time	138.3	65.7	136.2	62.3	0.08	0.941	116.0	39.9	115.4	56	0.03	0.98	93.1	29.8	96.2	43.75	0.19	0.856	87.9	27.99	88.1	41.7	0.01	0.909
Path length	2348	244	2550	570	1.03	0.318	2142	339	2576	396	-2.64	**0.017**	2118	308	1975	214	1.20	0.245	1889	249	2241	304	-2.84	**0.011**
1D motion smoothness left/right (1e+006)	3.2	1.4	4.9	2.2	-2.19	**0.042**	2.9	1.8	4.4	1.5	-1.94	0.069	2.4	0.9	3.4	1.5	-1.79	0.090	2.4	1.2	3.6	1.5	-1.88	0.077
1D motion smoothness up/down (1e+006)	3.0	0.8	4.4	1.9	-2.12	**0.048**	2.9	1.4	4.0	1.0	-2.03	0.057	2.5	0.7	3.0	1.5	-0.91	0.373	2.4	1.0	0.8	0.3	-1.68	0.110
TLX-Mental demand	58.0	22.8	47.5	24.8	0.99	0.336	43.0	21.8	60.0	20.5	-1.80	0.089	44.0	23.8	31.5	17.0	1.35	0.193	34.5	20.2	51.5	21.8	-1.81	0.088
TLX-Physical demand	38.0	25.8	35.5	16.9	0.26	0.801	34.0	23.4	68.0	18.1	-3.63	**0.002**	35.5	19.5	35.5	18.8	0.00	1.000	30.5	16.2	57.5	19.5	-3.37	**0.003**
TLX-Temporal demand	51.0	19.7	53.5	21.0	0.28	0.787	53.0	19.0	58.5	19.2	-0.64	0.528	50.0	15.9	47.5	25.4	0.22	0.830	49.5	18.6	53.0	24.7	-0.36	0.725
TLX- Performance	37.5	17.5	41.0	23.0	0.38	0.706	46.0	24.2	36.5	16.2	1.03	0.316	32.5	26.2	39.5	25.3	0.61	0.551	44.0	27.4	34.5	23.5	0.83	0.416
TLX-Effort	51.5	21.5	49.5	22.7	0.20	0.842	47.5	14.8	55.5	15.7	-1.17	0.256	44.0	19.8	35.0	20.8	0.99	0.335	38.5	20.0	48.5	19.6	-1.13	0.274
TLX-Frustration	37.0	22.3	21.0	12.0	2.00	0.061	29.5	10.7	45.0	22.1	-2.00	0.061	30.0	18.1	23.5	14.9	0.88	0.392	25.0	13.1	39	24	-1.62	0.123

Figure 6.6: Means and standard deviations (SD) of all dependent measures for joystick control and handgrip control in each session of Study 2. t- and p-values for DR versus DD control per sessions are also shown. p-values < 0.05 *are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).*



	Sum(Session 1, Session 3) & Sum(Session 2,Session4)						Session 1 & Session 2						Session 3 & Session 4					
	Sum(S1_GroupA,S3_GroupA) & Sum(S2_GroupB,S4_GroupB)		Sum(S1_GroupB,S3_GroupB) & Sum(S2_GroupA,S4_GroupA)		Joystick vs. Handgrip		Session 1_Group A & Session 2_Group B		Session 1_Group B & Session 2_Group A		Joystick vs. Handgrip		Session 3_Group A & Session 4_Group B		Session 3_Group B & Session 4_Group A		Joystick vs. Handgrip	
	Joystick		Handgrip				Joystick		Handgrip				Joystick		Handgrip			
	Mean *N*=20	SD	Mean *N*=20	SD	*t*	*p*	Mean *N*=20	SD	Mean *N*=20	SD	*t*	*p*	Mean *N*=20	SD	Mean *N*=20	SD	*t*	*p*
Task time	181.3	70.7	184.0	72.0	-0.31	0.759	126.8	60.5	125.6	51.2	0.14	0.890	90.6	35.4	92.0	36.0	-0.31	0.759
Path length	4249	565	4674	723	-3.90	**0.000**	2245	306	2563	478	-4.14	**0.000**	2004	281	2108	305	-2.19	**0.040**
1D motion smoothness-left/right (1e+006)	5.5	2.6	8.1	3.1	-7.87	**0.000**	3.0	1.6	4.7	1.8	-5.58	**0.000**	2.4	1.1	3.5	1.5	-6.76	**0.000**
1D motion smoothness-up/down (1e+006)	5.4	1.9	7.2	2.5	-7.31	**0.000**	3.0	1.1	4.2	1.5	-7.01	**0.000**	2.4	0.9	3.0	1.2	-3.76	**0.001**
TLX-Mental demand	89.8	43.4	95.3	40.6	-0.97	0.343	50.5	23.0	53.8	23.1	-0.72	0.480	39.3	22.0	41.5	21.7	-0.71	0.484
TLX- Physical demand	69.0	39.1	98.3	43.2	-3.81	**0.001**	36.0	24.1	51.8	23.9	-3.23	**0.005**	33.0	17.7	46.5	21.8	-3.37	**0.003**
TLX-Temporal demand	101.8	35.3	106.3	41.1	-0.87	0.398	52.0	18.9	56.0	19.7	-1.29	0.214	49.8	22.0	50.3	24.6	-0.12	0.906
TLX-Performance	80.0	44.9	75.8	37.7	0.74	0.472	41.8	21.0	38.8	19.5	0.64	0.530	38.3	26.7	37.0	23.9	0.41	0.687
TLX-Effort	90.8	35.5	94.3	35.9	-0.58	0.570	49.5	18.1	52.5	19.2	-0.64	0.530	41.3	19.6	41.8	20.9	-0.16	0.874
TLX-Frustration	60.8	30.5	64.3	39.7	-0.45	0.657	33.3	17.4	33.0	21.2	0.05	0.962	27.5	15.6	31.3	21.0	-1.05	0.309

Figure 6.7: Means and standard deviations (SD) of all dependent measures for joystick control and handgrip control across sessions of Study 2. a) All four sessions, of which the results were summed for sessions 1 and 3, and sessions 2 and 4, respectively; b) Sessions 1 and 2; c) Sessions 3 and 4. p-values < 0.05 are annotated in bold. Gradient scale visualizes the size of each dependent measure from green (the lowest value) to red (the highest value).

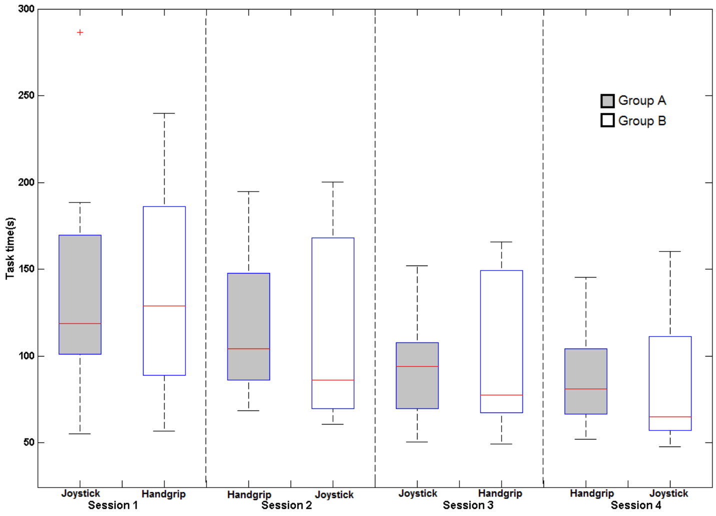


Figure 6.8: The recorded task time in each session (the time taken to complete 10 successful trials and trials with collisions excluded) of Study 2. The filled boxes indicate the results from Group A, whereas the unfilled boxes indicate the results from Group B.

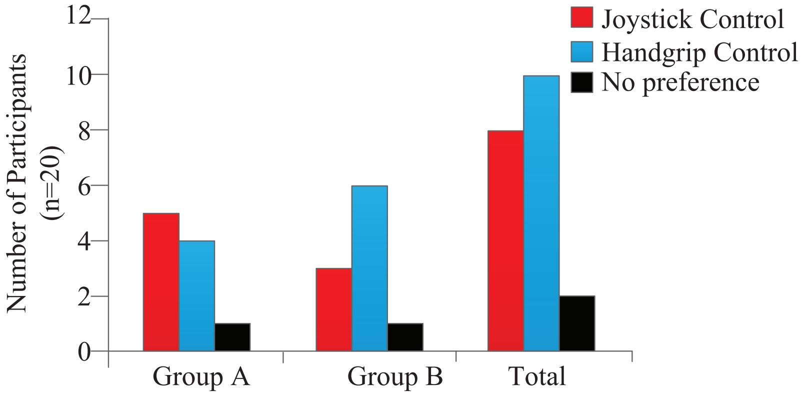


Figure 6.9: Subjective preference of two control devices in Study 2.

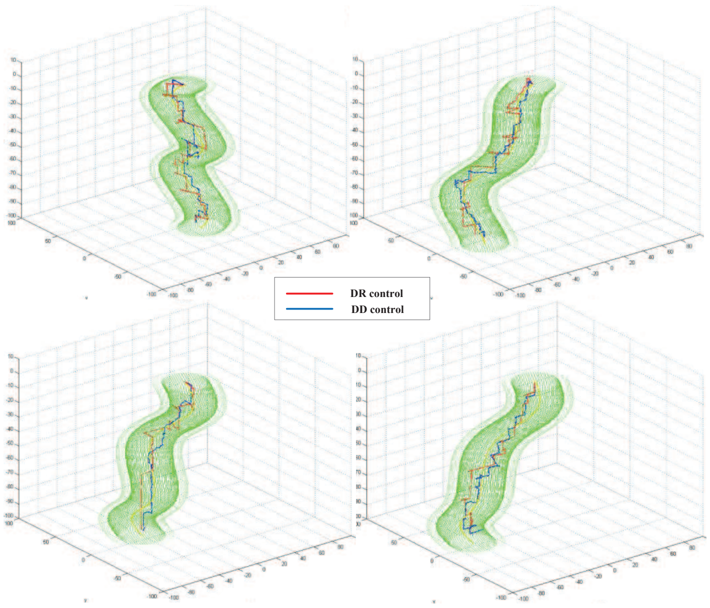


Figure 6.10: Characteristic examples of tip trajectories from DD control (blue) and DR control (red). Light green lines and strong green lines present tunnel wall and boundary of near-collision respectively, and the yellow line depicts the centre line of the tunnel.

raised our interest, because the participants using the first strategy reported loss of orientation after a few rotations, whereas the participants using the second strategy reported that they kept using a cartesian coordinate system throughout their performance, since they deliberately corrected their reference frame back to horizontal after each rotation.

As the virtual instrument tip was not visible in our experiment, participants could only imagine the instrument position based on their memory of the previous steps, and then think out the next step of manoeuvring. In the case of the first strategy using DR control, the virtual tip was steered in a polar coordinate system on the screen frame. Participants had great difficulty in keeping their orientation after some time and became blind of the position of the virtual tip. By randomly moving the instrument, they reconstructed a new cartesian system (for the tip location) and proceeded their manoeuvring. In clinical practise, 'getting lost' is a common experience for endoscopists who use DR control to control endoscope (e.g., a colonoscope [60][61]). It is possible that the second strategy observed from our experiment (including a retro-rotation step) could facilitate the endoscopist's spatial orientation during a navigation task. It was, however, noticed that the DD control was strongly preferred by the participants at the end of our experiment, strongly suggesting that DD control is more intuitive for novices.

6.6.2 Control device: Joystick control versus Handgrip control

Study 2 compared joystick and handgrip, two commonly used control devices for DD control. We noticed that throughout the experiment, participants travelled a shorter path using joystick control as compared to handgrip control, within comparable time periods, which means that participants generally performed the experiment with lower average speed when using joystick control than with handgrip control. In order to gain a better insight into this phenomenon, the trajectories travelled by the virtual tip using both control devices during Session 4 were plotted. Figure 6.12 shows a characteristic example of trajectories using handgrip control and joystick control. It can be seen that the trajectory using handgrip control was smooth and continuous, while the trajectory using joystick control was intermittent. The open comments in the questionnaire concur with these two distinct types of trajectory, with most participants reporting that they made a continuous snake-like movement (moving forward while steering) using handgrip control, and a stepwise movement (first moving forward, then steering) when using joystick control. They also reported that handgrip control was easy to master but led to difficult manoeuvring through the tunnel, whereas joystick control led to easy manoeuvring but took a while to master. In other words, handgrip control was more intuitive but requested greater effort for following the tunnel curvature, whereas joystick control facilitated the steering motion by allowing small adjustments but it was more difficult to get used to.

Pathway surgical procedures are frequently carried out by a team of two surgeons (cf., skull base surgery [64][125][121]): one being in charge of bringing the instrument to the target area through the pathway and the other conducting the operation on the target area. The outcome from our study suggests that handgrip control would offer better intuitiveness than joystick control in following the anatomical structure, while joystick control would be more suitable for tasks requiring targeting (or directing) motion. Note, however, that this study has been conducted with novices; further testing with expert surgeons is required to investigate whether different control devices are needed for different types of motion (i.e., joystick control for targeting vs. handgrip control for precise curvature following). For MIS instruments with multiple end effectors (such as single-port surgical platforms), it might be helpful to utilize a combined control device which allows handgrip control for dexterous steering and joystick control for directing.

No significant differences were observed between the two control devices regarding task completion time in any session. However, in Sessions 2 and 4, the greater path length, frustration and physical demand when using handgrip control as compared to joystick control suggest that it was more difficult to switch from joystick to handgrip control than the other way around. Interestingly, despite this difference, both groups achieved similar final performances in terms of task time in the last session. In the same line, in a study comparing joystick and handgrip control in a positioning and orientating task in a portable laparoscopic trainer, Fan et al. [36] found that it was easier for the participants to switch to joystick control than to handgrip control. In that study it was postulated that joystick control separates the steering motion (2DoF: left/right and up/down of the distal tip) from the common control motion of laparoscopic instruments (2DoF: translation and rotation of the instrument shaft), whereas handgrip control applies the 4DoF motion to only one joint (i.e., wrist). The frustration and physical demand NASA TLX scores of our current study confirm and expand this conclusion towards pathway surgical tasks.

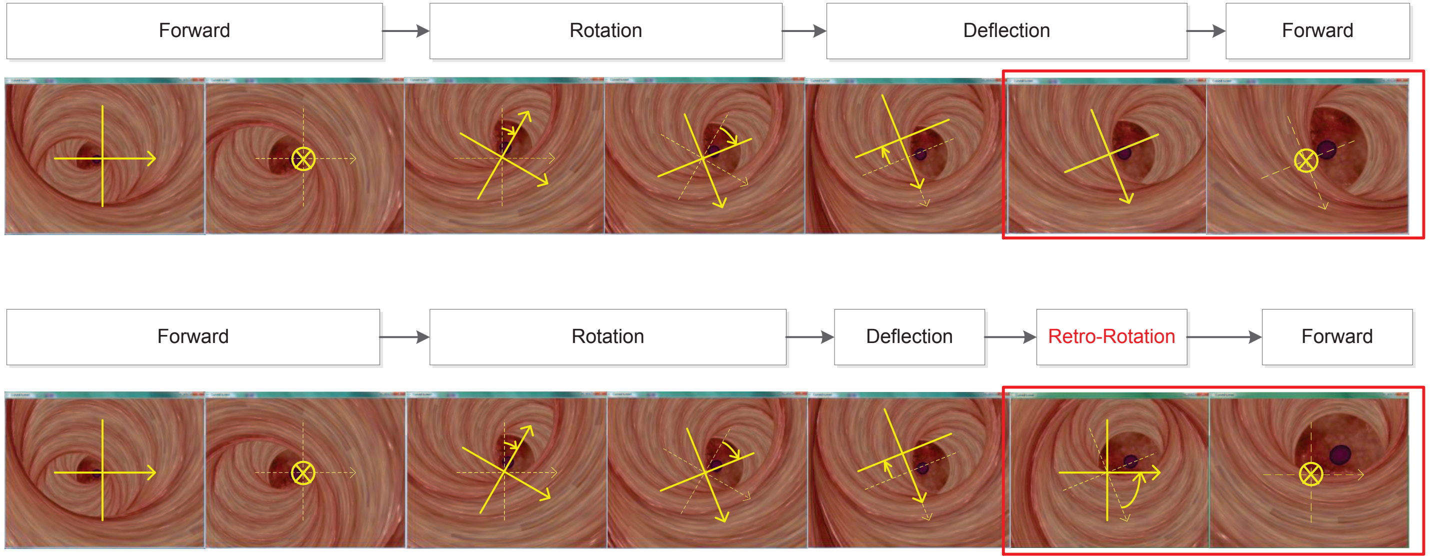


Figure 6.11: Screen shots of two strategies of manoeuvring using Deflection-Rotation (DR) control. The solid lines depict the current reference frame and the dashed lines depict to the reference frame of previous steering step. The long solid arrow refers to the steering axis, and the short solid arrows (both straight and curved) indicate participants' steering movements.

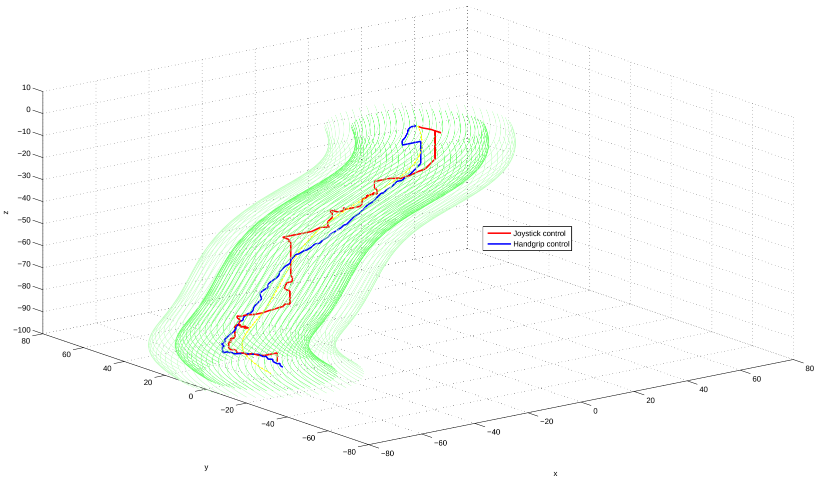


Figure 6.12: A characteristic example of tip trajectories from handgrip control (blue) and joystick control (red). Light green lines and strong green lines present tunnel wall and boundary of "near-collision" respectively, and the yellow line depicts the central line of the tunnel.

6.7 Summary

In this study, two control modes (DR and DD control), and two control devices (joystick and handgrip control) were compared in a navigation task using a newly developed pathway-surgery simulator. The experimental results show that compared to DR control, DD control led to faster and safer performance, and to a strong subjective preference. Joystick control resulted in slightly more precise targeting than handgrip control, whereas the latter appeared to be more intuitive to master dextrous steering. The two control devices featured similar overall task performance.

6.8 Acknowledgement

The research was funded by the Marie Curie Initial Training Network project IIIOS (Integrated Interventional Imaging Operation System, Project 238802) and carried out at the department BioMechanical Engineering of Delft University of Technology. The Author wants to thanks all the participants as well as thank Filip Jelínek and David Jager for designing and manufacturing the Endo-PaC.

Chapter 7

Conclusions and future research

7.1 Revision of the goal

During minimally invasive surgery, instrument movements are limited by the incisions and restricted by the anatomic structure. *Steerable instruments* (instrument with a single-segment steerable tip) and *manoeuvrable instruments* (instrument with multiple steerable segments) have been developed for compensating this restriction of DoFs, yet little attempt has been made concerning the intuitiveness of the control interface. The overall aim of this thesis is to investigate the manual controllability of new handheld steerable medical instruments used in various forms of minimally invasive surgery, such as, laparoscopic surgery, NOTES, and endovascular procedures. In order to achieve the objectives of the thesis, several experimental studies were performed and the results are presented in this thesis. The subgoals are given once more, since they provide the framework for the summary in following sessions.

- *To describe and to categorize current developments of handheld steerable medical instruments;*
- *To assess commonly used control interfaces and manoeuvrability of commercially available steerable instruments, and to determine their influence on human performance;*
- *To determine potential solutions concerning manoeuvring difficulties for handheld instruments used in pathway surgery;*
- *To build a simulator and carry out experiments for assessing the proposed solutions in pathway surgery.*

7.2 Summary of the performed experiments and the findings

7.2.1 On the current development of steerable and manoeuvrable medical instruments

A literature review of the state-of-art of manual control methods for handheld steerable instruments was conducted (Chapter 2). The review categorized the developed steerable instruments based on the physical coupling between the controllers and between the tip motion and the control motion. The literature study further revealed that

- the requirements on instrument manoeuvrability increase when the size of the surgical incision decreases;
- in the case of controlling multiple steerable segments, a gradual shift can be noticed from parallel and serial control to integrated control;
- as manoeuvrable instruments are primarily being designed for navigation along 3-dimensional curvatures, the concept of ISS (Integrated Single-Segmented control) resulting in a shape-memory locomotion could be a strong benefit for instrument navigation.

7.2.2 On the control of steerable instruments

1DoF control

It was noticed from the state-of-art (Chapter 2) that due to the mechanical simplicity and cheap manufacturing, two 1DoF control methods, rotating control and sliding control, have been applied in the design of commercial steerable catheters. An experiment was designed to investigate the difference between these two control methods and their influence on human performance (Chapter 3).

Catheters equipped with a steerable tip result in an adaptive tip shape and lead to higher precision of catheter positioning and less number of catheter changes. Sliders or knobs are widely applied as 1DoF controllers in the design of steerable catheters. However, the difference between these two control methods and their effectiveness is unknown. Based on the direction of the control movements, four handles were built (Rotator-Front, Rotator-Top, Slider-Vertical and Slider-Horizontal), and assessed in terms of accuracy, safety and subjective workload. The results revealed that slider-vertical handle provided generally faster and safer performance, whereas rotator handles were more preferred by participants at the end of the experiment (Chapter 3).

2DoF control

Subsequently, two 2DoF steerable instruments, the first one (a nearly market ready prototype) controlled by the thumb and the second one (commercially available product) controlled by the wrist, were compared in a positioning task using a portable laparoscopic trainer (Chapter 4).

In order to improve the ease of access to anatomic structure in laparoscopic surgery, steerable instruments are developed, in which handgrip using wrist control and joystick using thumb control have been implemented. Previous studies have investigated the differences of control methods between steerable instruments and conventional rigid instruments, whereas the difference between the two control methods for steerable instruments remains unclear. Our study evaluated the performance of novices in orientating a steerable tip using both aforementioned control methods. The results revealed that thumb control was easier to master and strongly preferred, although in terms of task time, no significant difference between the two control methods was observed. (Chapter 4).

7.2.3 On the control of manoeuvrable instruments

Multi-DoF control

Chapter 2 categorized the control methods for steering multiple segments (i.e., manoeuvrable instruments) into three main groups: parallel single-segment control, serial single-segment control and integrated single-segment control (ISS). ISS uses one controller to manoeuver the leading segment, followed passively by the rest of the segments as the instrument moves forward. The first two groups require as many controllers as the number of segments, whereas the last one requires only one controller. The ISS control concept results in a shape-memory locomotion similar to a snake motion and generates any arbitrary curvature, but does not have full controllability of each of the segments. Nonetheless, manoeuvrable instruments are primarily designed for navigation along 3-dimensional curvatures. The use of ISS may lead to easy and precise control due to the similarity to conventional steerable instruments (e.g., eye-hand coordination, 3-dimensional vision and surgical workflow).

The ISS concept and the other outcome from Chapter 2 triggered the development of an experimental simulator: Endo-PaC (EndoPathController). Endo-PaC mimics the shaft and handle of a manoeuvrable instrument with standard dimensions, and electronically measures the control motion of the user. Four experiments regarding two main factors, a cognitive factor and an ergonomic factor, were designed and conducted with novice participants using Endo-PaC (Chapter 5-6).

Cognitive factor-Control display

During pathway surgery, surgeons have to manoeuvre the instruments inside the patient while looking at the monitor. The information about the position of the hand and fingers (at the proximal end of the instrument) does not directly provide sufficient information of the tip movements (at the distal end of the instrument). The display on the monitor thus becomes crucial for providing visual feedback of the tip movements. In this thesis, two ways of control mapping, normal mapping (handle left->image left, handle up->image up) and mirrored mapping (handle left->image right, handle up->image down) were analysed in combination with two control devices (joystick control and handgrip control) in an orienting task with an endoscope during simulated scenarios of pathway surgery.

Throughout this experiment, participants performed better (shorter task completion time and higher accuracy) and experienced lower workload when using normal mapping with respect to mirrored mapping. It was further revealed that the differences between the two control mappings were more pronounced when using joystick than handgrip control. It implies that in the case of a joystick-controlled endoscope, participants experience lower workload and better performance when using normal mapping than using mirrored mapping; in the case of a handgrip controlled endoscope, differences between the two control mappings would highly influence participants workload but not their performance.

Cognitive factor-Local disorientation

Since the camera is usually positioned on the tip of the endoscope, during navigation, the visual display provides an egocentric view obtained from the camera. Surgeons do not know ”*where the instrument is*” and ”*where the instrument is heading for in the next advancing step*”. Therefore it is a common phenomenon that surgeons must rely on guesswork or randomly move the instrument for re-gaining the orientation information.

A number of studies [18] [17][81][113][26], have investigated this phenomenon, and solutions such as computer navigation aids, robotic endoscopes, and mechanical method implementing an oblique transparent hood were proposed. In this thesis, the endoscope camera was implemented in the software to be behind the instrument tip, and therefore the instrument tip was visible at the bottom on the monitor.

It was hypothesized that the visible tip would be helpful for instrument orientation in navigation [62][135][142]. The experiment results strengthen previous study [62] that ’*a visual cue providing direction information led to faster performance*’ but showing that for novices, the introduction of a visible tip might result in significant number of potential collisions due to the uncertain distance estimation between the camera, the scope tip and the surrounding anatomy.

Ergonomic factor-Control mode

During pathway surgery, besides advancing the instrument, the surgeon needs to manoeuver the instrument in two orthogonal directions (up/down and left/right). Since simple instruments employing 1DoF tip deflection cannot steer the second tip-DoF directly, the surgeon has to control this DoF indirectly by rotating the instrument around its shaft. In this thesis, we refer to this 1DoF tip deflection + 1DoF shaft rotation control as *DR-control* and the mechanically more complex 2DoF tip deflection control as *DD-control*.

From our experimental results, it was revealed that DR control and DD control significantly differ in terms of all objectively measured parameters and subjective workload, but not in path length. Further investigation revealed that the trajectories using DR control were straighter and further away from the central line of the simulated tunnel compared to those using DD control. This indicates that it is more difficult for novices to navigate along the tunnel curvature using DR control than using DD control.

It was further noticed that there were two strategies of keeping cognitive reference frame when using DR control. One strategy was to keep polar reference frame when rotating the instrument shaft; however, participants easily got lost and had to move the instrument randomly to regain their orientation. Another strategy was to keep a cartesian reference frame throughout the experiment, in which case participants deliberately corrected their reference frame after each rotation. It is plausible that the second strategy observed from this experiment could facilitate the spatial orientation during a navigation task.

Ergonomic factor-Control device

The ability of the human wrist and thumb to move naturally in two perpendicular directions enables the surgeon to control two DoFs individually or simultaneously. In the case of 2DoF deflection control, the 2DoF tip deflection follows the surgeon's 2DoF wrist or thumb movements, for instance by using a joystick or handgrip which articulates with the instrument tip.

The result of this experiment is in line with the outcome of Chapter 4, that is, it was easier for the novice participants to get used to joystick control than to handgrip control. Characteristic examples of trajectories using joystick control and handgrip control were found, in which the trajectory using handgrip control was smooth and continuous, and the trajectory using joystick control was intermittent. Participants' open comments revealed that in the case of handgrip control, the trajectory was continuous due to the snake-like steering movements (move forward while steering) and in the case of joystick control, the trajectory was intermittent due to the step-wise steering movements (move forward first then steering, then keep the orientation and move forward). It is therefore suggested that handgrip control offers better intuitiveness in approaching the target during the navigational task, whereas joystick control facilitates the participants' performance that requires only steering (or directing) motion.

The main findings of this thesis is illustrated in figure 7.1.

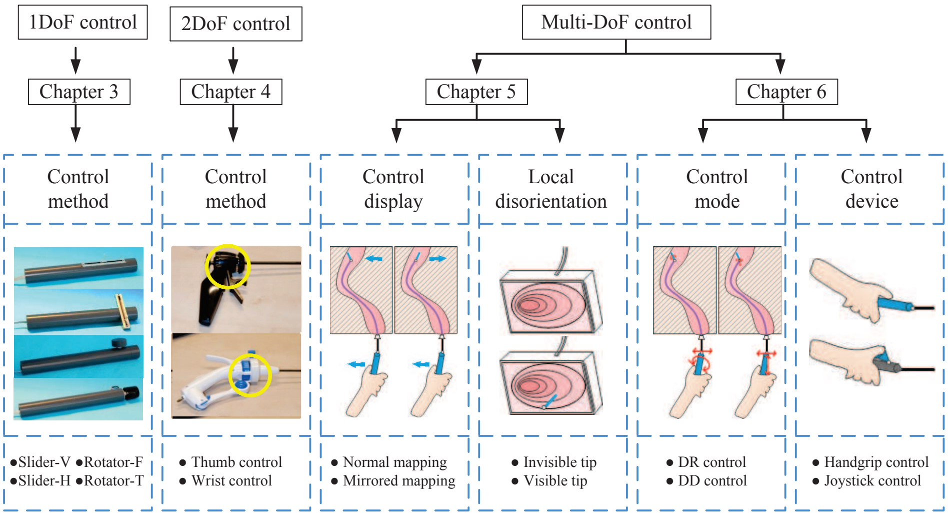


Figure 7.1: Studies conducted in this thesis

7.3 Research methodology and limitations in this Ph.D research

In this thesis, experiments with various research methods have been performed. Experiments in Chapter 4 were conducted in a portable laparoscopic box trainer; whereas experiments in Chapter 3 and Chapter 5-6 were conducted using custom-designed simulators.

In the catheter simulator setup of Chapter 3, the four handles to be compared were designed in order to feature control method as the only variable. The length and diameter of the handles are comparable to commercial products, and the range of sliding length and size of the knob are selected carefully from a range of commercially available components. The dimensions were therefore not optimized to e.g. the size of the hands of the subject. It is known that surgeons with small hands have difficulties using instruments with too large handles in Surgical Endoscopy[8][85][82].

In Chapter 4, the experimental setup only allowed us to record the task time. However, other parameters regarding the precise instrument positioning, such as the number of attempts to reach the targets and the distance travelled by the instrument tip, could be of great value. The following experiments presented in Chapter 5-6, were designed such that the full positioning parameters were recorded profoundly expanding the information gained.

Endo-PaC is a simulator designed for assessing vital factors of the ISS control concept. Therefore Endo-PaC is a simulator for investigating control interfacing rather than for validating surgical skills. Current software presents abstracted models that are geometrically similar to anatomic structures, such as a 3-dimensional curved tunnel and a 2-dimensional path. In the literature, modelling of a colon or endovascular tree has already been reported, therefore in the future more realistic models could be implemented into the simulator [110][3][73].

The present thesis considered only kinetic parameters, while measurements of the forces that participants applied to the pivot in Chapter 4 and to the control devices in Chapter 3, 5-6 were neglected. Extensive research regarding force feedback and its influence on surgical performance, are carried out by Chmarra et al. [145] and Horeman et al.[55][56]. The results presented in this thesis are a first step towards the investigation of the factors influencing the performance of ISS control in pathway surgery. Broader research into this topic including force measurement is needed as a next step. Last but not least, all the experiments in this thesis were conducted by novices: engineering students who had neither experience with the experiment setups nor knowledge of MIS instrument manipulation. Novices provide the advantage of out of the box thinking in combination with an unbiased perspective. Although experience-bias was considered as a disadvantage in this study, the involvement of skilled-surgeons or medical students could give valuable results as well.

7.4 Recommendation for the future research

The outcomes from this PhD study generated several recommendations for the future research:

- The experiments of this thesis were mainly conducted using a navigation task. In clinical practise, navigation inside the anatomic structure serves commonly the diagnosis purpose. Surgical procedures require not only navigational skills but also other specific tasks, such as positioning and needle-driving. It is therefore worth trying to create various tasks in the future development of the simulator, and to investigate the effect of various control device/mapping/strategy/display on human performance.
- This thesis made the first step in investigating an intuitive control method for multi-segmented instruments. Future research could expand the scenarios to specific clinical applications, such as Skull Base Surgery, and to objectively assess the influence of various control methods on human performance.
- Endo-PaC was designed for the assessment of vital factors for controlling multi-segment instruments. The outcome of this PhD thesis provides guidelines for the development of an ISS controller, such as the wrist control helps participants make a continuous trajectory and thumb control provides precise positioning. It is worthy to implement the suggested solution into an ISS controller design (Fig. 7.2).
- Although this thesis focuses on control methods for instruments with single or multiple segments (single-branch instrument), the information and results in this thesis can serve as a basis for research on manual control methods for multi-branch instruments, e.g. surgical platform for Single Port Surgery.
- An instrument design process is an iterative cycle starting with objectives to be attained. Based on these objectives, a feasibility analysis is performed resulting in an instrument concept which is then turned into a mechanical design. This thesis provides the feasibility analysis step of the first iteration of the intuitive manual control method for handheld steerable medical instruments. The outcomes should serve as input to the future mechanical development.

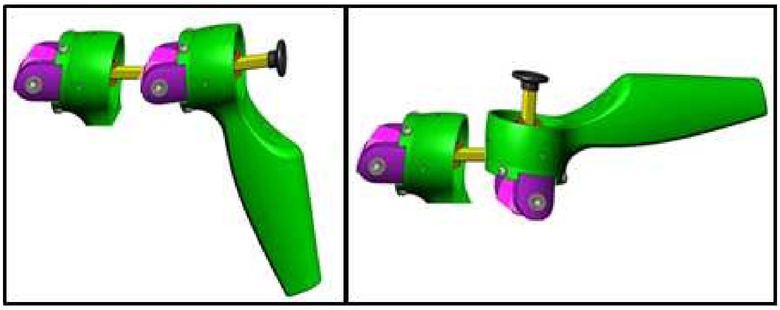


Figure 7.2: Illustration of two integrated joystick-handgrip controllers

7.5 Final remark

The purpose of this thesis project was to investigate the manual controllability of handheld steerable medical instruments used in minimally invasive applications. Literature study, hands on experiments using commercially available steerable instruments and new experiments using a self-developed simulator were carried out. The most important contribution of the presented project towards the research field consists of the first detailed investigation of key factors influencing the intuitiveness of manual control in minimally invasive applications, and more specifically, pathway surgery.

Appendix A

EndoPathController

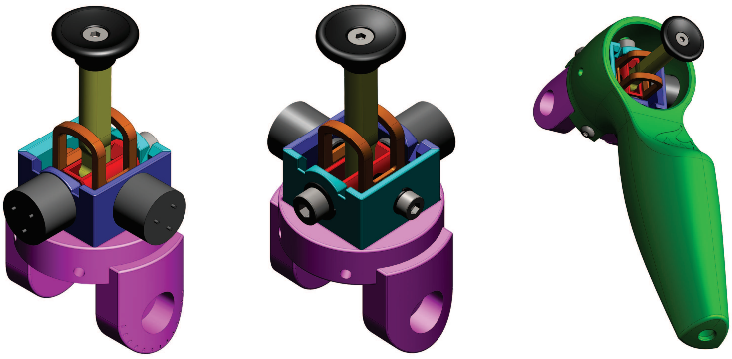


Figure A.1: Assembly view of the steering unit

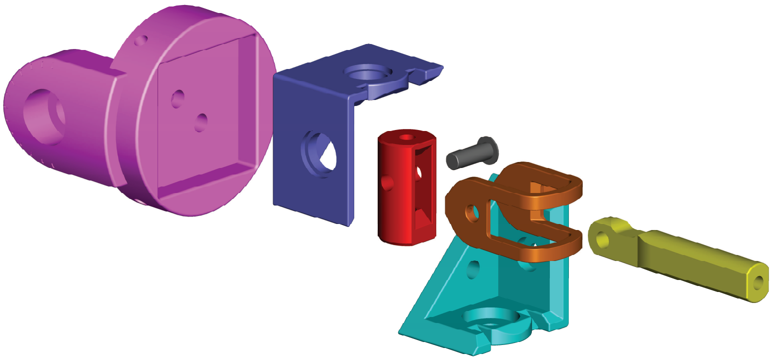


Figure A.2: Explored assembly view of the steering unit

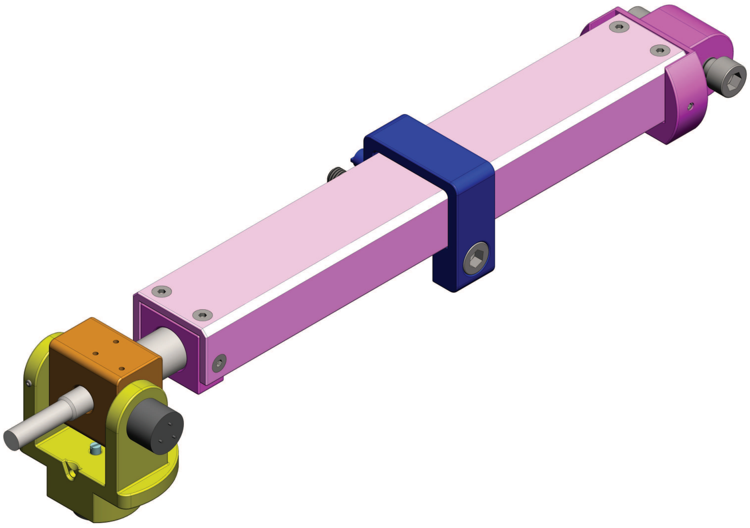


Figure A.3: Assembly view of the slider

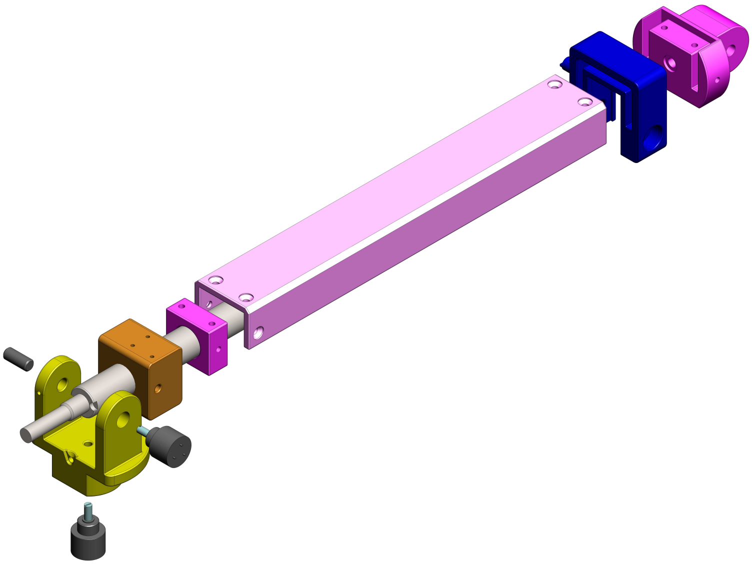


Figure A.4: Explored assembly view of the slider

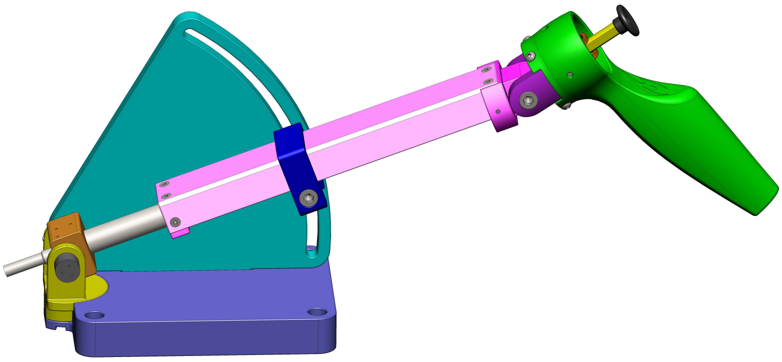


Figure A.5: Endo-PaC: FrontView

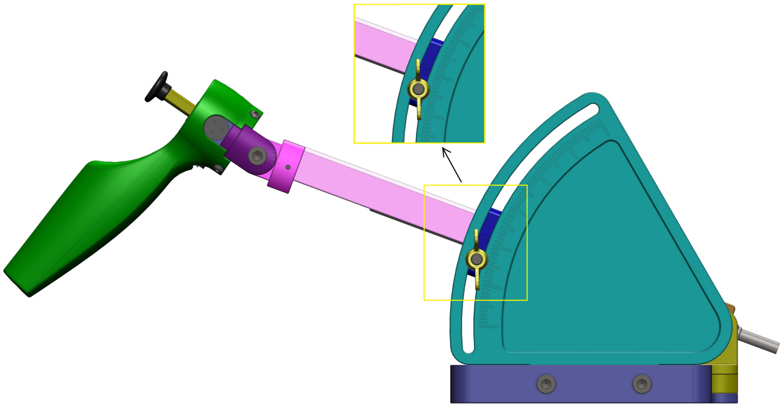


Figure A.6: Endo-PaC: SideView

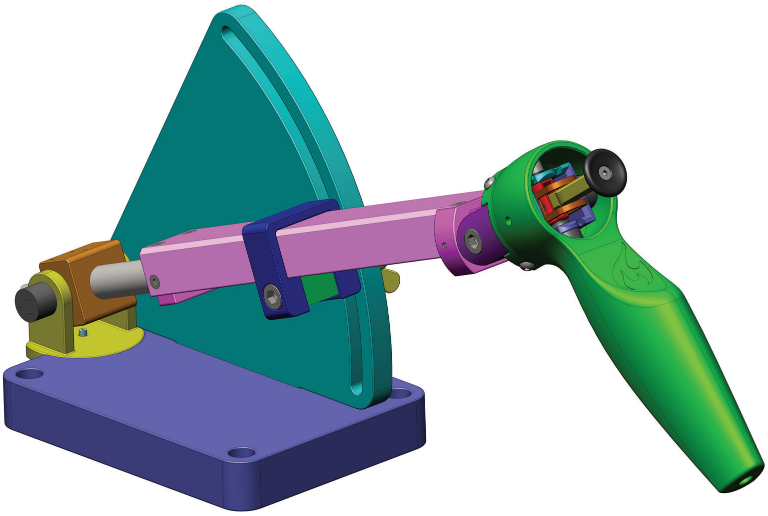


Figure A.7: Assembly view of Endo-PaC

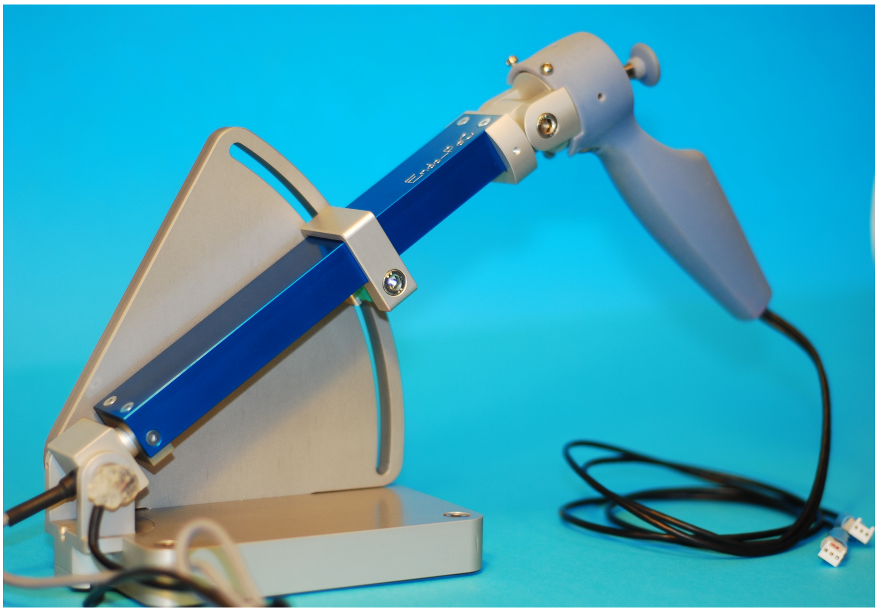


Figure A.8: Endo-PaC with a joystick control

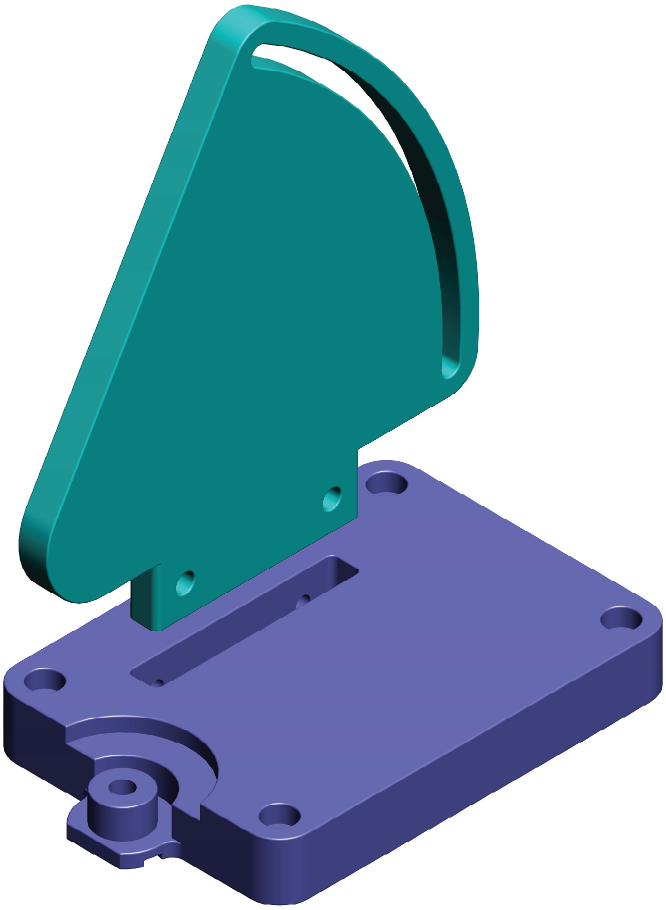


Figure A.9: Explored assembly view of the support board

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Summary

Manual control for Medical Instruments in Minimally Invasive Surgery

With the introduction of new technologies, surgical procedures have been varying from free access in open surgery towards limited access in minimal invasive surgery. During such procedures, surgeons have to manoeuver the instruments from outside the patient while looking at the monitor. Long and slender instruments are developed that can insert into the patients body through small incision(s) or natural orifice(s) with help of an endoscope following instrument created or transluminal pathways. In these types of procedures, called pathway surgery throughout this thesis, the incisions limit the instrument motion and reduce the number of degree of freedom (DoF) from six to four, while the curvature of the pathway restricts the instrument motion within a narrow tunnel, further reducing the number of DoF down to two.

After the establishment of conventional instruments, steerable instruments (instruments with one steerable segment on its tip) and manoeuvrable instruments (instruments with multiple steerable segments) are under development, yet the development of an intuitive and effective control interface for such instruments remains a challenge. The goal of this thesis is to assess the manoeuvrability of currently available commercial steerable instruments, and to find potential solutions to manoeuvring difficulties of medical instruments used in pathway surgery. To achieve this goal, we developed a simulator emulating the shaft and handle of a manoeuvrable instrument, and we conducted experiments that investigate the effects of various factors of manual manoeuvrability on human performance in a simulated surgical pathway task.

As many studies have reported new developments of steerable and manoeuvrable instruments, the first part of this thesis includes a survey of literature related with manual control methods for handheld steerable instruments, to investigate what would be the best-suited manual control method for future instruments for pathway surgery. A full overview of manoeuvrable approaches and their controls interfacing were provided, and a novel way of categorizing control methods for handheld manoeuvrable instruments based on physical coupling between the controllers was proposed. This study shows that in the case of controlling single steerable segment, direct- as well as indirect- control methods have been developed, whereas in the case of controlling multiple steerable segments, a gradual shift can be noticed from parallel and serial control to integrated control. The survey results are linked to future developments in pathway surgery, that is, instead of providing full manoeu-

vrability at each steerable segment, Integrated Single-Segment control (ISS, i.e. using one controller to manoeuvre the leading segment while the other steerable segments copy the leading motion) would generate a user experience similar to conventional steerable instruments in aspects like eye-hand coordination, 3-dimensional vision and surgical workflow.

The second part of this thesis provides two experiments that compare control methods for steerable instruments used in neuroendovascular surgery and laparoscopic surgery respectively. Firstly, an experiment was designed to investigate the effectiveness of two widely used 1DoF control methods, rotating control and sliding control, and their effects on human performance, such as accuracy, safety and intuitiveness. Based on directions of the control motions, four handles were built. The slider-vertical handle provided general faster and safer performance, whereas rotator handles were more preferred by participants at the end of the experiment. Subsequently, two 2DoF steerable instruments, one controlled by the thumb and the other by the wrist, were compared in a positioning task in a portable laparoscopic trainer. The experiment results showed that although the two compared control methods were not significantly different in terms of time, thumb control was strongly preferred by novices.

Currently the development of manoeuvrable instruments is still in its infancy, the ISS concept and the other outcome from the literature review was a trigger to develop a simulator, Endo-PaC (EndoPathController), allowing great possibility of investigating manual manoeuvrability for manoeuvrable medical instruments. Endo-PaC mimics the shaft and handle of a manoeuvrable instrument with standard dimensions, measures the control motion in 5DoF, and is electronically connected to a laptop computer. Custom-designed software visualizes circular tunnels, and participants were asked to guide the virtual steerable tip without collision towards a target that located at the end of the virtual curved tunnel as fast as possible.

The last part of this thesis presents four experiments using Endo-PaC for assessing two main aspects of manual controllability, cognitive aspect and ergonomic aspect, respectively. The first two experiments investigated two factors, *visual-display compatibility* and *local disorientation*, both of which contribute to spatial disorientation and yield a high cognitive load for surgeons in an endoscopic navigation task. The latter experiments assessed two methods of *control mode*, DR (Deflection Rotation) control and DD (Double Deflection) control, and two methods of *control device*, joystick control and handgrip control, for their effect on human performance with regard to task time, path length tracelled by the virtual tip, motion smoothness, subjective workload as well as personal preference.

It is concluded that manual controllability is key to the success ratio of using hand-held instruments in minimally invasive surgery. To new MIS procedures, such as pathway surgery, manoeuvrable instruments featuring ISS control allows less manoeuvrability but provide a strong benefit leading to easy control and high precision by just one clinician. Experiments with novice participants revealed that, in order to improve the manual controllability for ISS control during a navigation task, control interfacing featuring DD control leads to faster and safer performance compared with DR control, while handgrip control appeared to be more intuitive to master than joystick control. Furthermore, eliminating the visual-display misalignment, so that the controlled tip movements are in line with the surgeons hand movements, and providing a visible cue, so that the surgeon knows where the instruments heading for in the next advancing step, could greatly reduce the training time, facilitate performance and cause less cognitive load.

Samenvatting

Manual control for Medical Instruments in Minimally Invasive Surgery

Dankzij de introductie van nieuwe technologieën zijn chirurgische procedures geëvolueerd van volledige open chirurgie naar minimale invasieve technieken met beperkte toegang. Tijdens deze procedures moeten chirurgen instrumenten manipuleren die in het lichaam geschoven worden via een kleine insnede of via een natuurlijke opening. Met behulp van een endoscoop of via een doorlichtingstechniek wordt de weg die het instrument dient te volgen gevonden. Bij dit soort procedures die in deze thesis ’pathway sugery’ genoemd worden, wordt de bewegingsvrijheid van het instrument ernstig beperkt door de insnijding van zes vrijheidsgraden naar vier vrijheidsgraden, terwijl de weg die het instrument dient te volgen de bewegingsvrijdheid beperkt naar twee vrijheidsgraden in een smalle tunnel.

Nu conventionele instrumenten goed ingeburgerd zijn wordt de volgende stap in ontwikkeling gezet naar stuurbare instrumenten (instrumenten met n stuurbaar segment aan de tip) en manoevreerbare instrumenten (instrumenten met meerdere stuurbare elementen). Bij het ontwikkelen van deze instrumenten zit een grote uitdaging bij de besturingsmethode: deze dient tegelijk intuïtief en efficiënt te zijn. Het doel van deze thesis is in de eerste plaats om de besturingsmethode van instrumenten die tegenwoordig commerciëel beschikbaar zijn te onderzoeken en om vervolgens oplossingen te vinden voor de besturingsmethode van manoevreerbare medische instrumenten die gebruikt worden in ’pathway surgery’. Om dit doel te bereiken werd in het kader van dit ondrezoek een simulator ontwikkeld bestaande uit een verwisselbaar handvat van een manoevreerbaar instrument gekoppeld aan een computer. Met deze simulator werd experimenteel onderzoek verricht naar de invloed van verschillende factoren op de menselijke prestaties bij het volgen van een gesimuleerde route.

Omdat er tegenwoordig veel onderzoek gebeurt naar stuurbare en manoevreerbare instrumenten en er bijgevolg veel nieuwe publicaties verschijnen, bestaat het eerste deel van deze thesis uit literatuuronderzoek naar besturingsmethoden voor stuurbare chirurgische instrumenten. Er wordt verder in gegaan op de meest geschikte besturingsmethode voor instrumenten voor ’pathway surgery’. Er wordt een overzicht gepresenteerd van de verschillende benaderingen van manoevreerbare instrumenten en hun besturingsmethodes. Deze besturingsmethodes worden volgens de mechanische koppelig in categoriën ingedeeld. In het geval dat één element bestuurd wordt bestaan er zowel directe als indirecte besturingsmethoden terwijl in het geval dat er meerdre stuurbare elementen zijn er een evolutie is van parallelle en seriële besturing naar geïntegreerde besturing. De resultaten van deze studie wordten gekoppeld aan toekomstige ontwikkelingen in ’pathway surgery’, wat erop neer komt dat in plaats van alle elementen volledig bestuurbaar te maken er een gentegreerde besturing bestaat waarbij enkele het eerste element bestuurbaar is en de volgende elementen dit element volgen. Deze methode kan ervoor zorgen dat de gebruiker met het instrument kan omgaan als ware het een instrument met één stuurbaar element met betrekking tot oog-hand interactie, ruimtezicht en chirurgische procedure.

Het tweede deel van deze thesis bestaat uit twee experimenten die een vergelijking maken tussen twee specifieke besturingsmethodes voor stuurbare instrumenten gebruikt bij neuroëndovasculaire chirurgie en laparoscopische chirurgie. Het eerste experiment hheft als doel om onderzoek te doen naar de effectiviteit van twee veelgebruikte bestuursmethoden voor 1 vrijdheidsgraad: rotatiebesturing en translatiebesturing. Bij dit onderzoek werd vooral gekeken naar de effecten op de prestaties van de testpersonen, meerbepaald precisie, veiligheid en intuïtiviteit. Tijdens dit experiment werd gebruik gemaakt van vier verschillende handvaten die de verschillende besturingsmethodes implementeerden. De verticale translatiecontrole beleek hierbij over het algemeen de hoogste snelheid te geven terwijl de rotatiehandvaten de voorkeur van de deelnemers genoten. Bij een volgende experiment werd een vergelijking gemaakt tussen instrumenten met twee vrijheidsgraden waarbij het eerste wordt bestuurd met de duim en de tweede met een polsbeweging. Deze beide methoden worden vergeleken via een positioneringstaak in een labaroscopische trainer. Ondanks dat de onervaren deelnemers een voorkeur vertoonden voor duimbesturing bleek het verschil tussen beide methoden erg klein te zijn.

Op dit moment staan manoevreerbare instrumenten nog in hun kinderschoenen. De literatuurstudie is een aanzet om een simulator, Endo-PaC (EndoPathController) genaamd te ontwikkelen. Deze simulator emuleert het handvat en de schacht van een manoevreerbaar instrument met standaard afmetingen, meet de bewegingen in vijf vrijheidsgraden, is electronisch verbonden met een computer en laat gericht onderzoek naar de besturingsmethode van manoevreerbare medische instrumenten toe. Speciaal ontwikkelde software visualiseert de tunnels waardoor de deelnemers zo snel mogelijk een virtuele stuurbare tip naar een doel moeten sturen zonder te botsen met de wand.

Het laatste gedeelte van deze thesis beschrijft vier experiementen die met EndoPac uitgevoerd werden. De eerste experimenten behandelen twee hoofdaspecten van bestuurbaarheid: het cognitieve aspect en de ergonomie. De eerste twee experimenten vergelijken de rol van de visuele presentatie in de oog-hand coördinatie van de testpersoon en de locale oriëntatie. Bijgevolg speelt de visuele presentatie een vitale rol in de oriëntatie en de mentale belasting van de chirurg bij een navigatietaak. De laatste twee experimenten behandelen de verschillen tussen besturing met deflectie rotatie methode en besturing met de dubbele deflectie methode met behulp van twee handvaten: een joystick en een handgreep. Het doel van deze vergelijking is om te onderzoeken in welke zin deze verschillende besturingen invloed hebben op de interactie tussen de proefpersoon en het experiment. Hierbij werd vooral gekeken naar de benodigde tijd om de taak af te werken, de afgelegde afstand met de (virtuele) tip van het instrument, voltheid van de besturing, de subjetieve werkbelasting en de persoonlijke voorkeur.

Uit deze experimenten kan geconcludeerd worden dat de bestuurbaarheid een vitale factor is met betrekking tot het succesvolle gebruik van medische instrumenten in minimale invasieve chirurgie. Voor nieuwe procedures, zoals chirurgie in een smalle doorgang, biedt geïntegreerde besturing minder manoevreerbaarheid met betrekking tot volledige besturing, echter door de besturing te focussen op het voorste segment, kan een hogere precisie en een lagere werkbelasting verkregen worden. Uit experimenten met onervaren deenelemers werd afgeleid dat de manuele bestuurbaarheid voor geïntegreerde chirurgische methoden verbeterd kunnen worden door het van 1 vrijheidsgraad naar 2 vrijheidsgraden te gaan. Hierbij vervolledigde de proefpersoon de gegeven taken sneller en met hogere precisie. De handgreepbesturing werd ervaren als intuïtiever om aan te leren dan besturing met een joystick. In de ontwikkeling van manuele besturingsmethoden voor gentegreerde besturing is het vitaal om ervoor te zorgen dat de oriëntatie van de chirurg met betrekking tot wat op het scherm te zien is en wat in de pantint gebeurt optimaal verloopt. De linkt tussen beiden dient zo sterk mogelijk te zijn, bijvoorbeeld door het leveren van indicaties met betrekking tot de bewegingsrichting van het instrument. Op deze manier kan het instrument op een meer intuïtieve manier bestuurd worden en wordt de mentale belasting voor de chirurg minder.

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