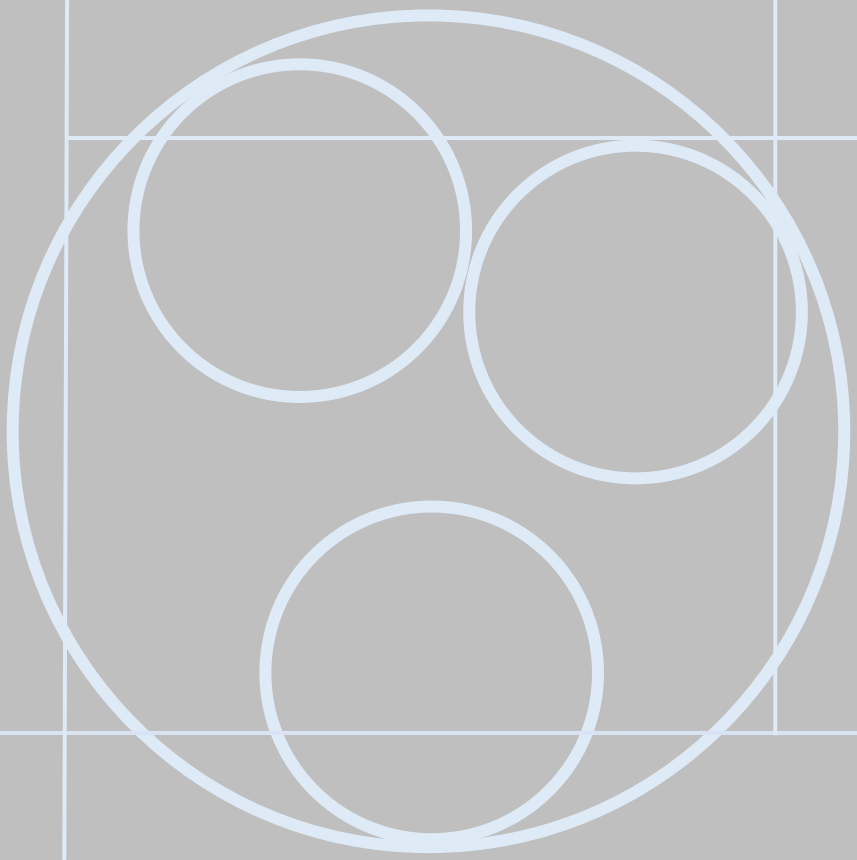

Developing an independently executable simulation training for ERCP

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ABSTRACT

Although simulators are widely recognized as being a valuable tool in ERCP training, the current use of simulation models in ERCP training program is still minimal due to the limited availability of instructors. This study aims to develop an independently executable training for the “ERCP Trainer”, a mechanical simulation model, that effectively and efficiently provides training in the most essential aspect of ERCP; selective cannulation. Several means are developed in which the instructor’s tasks of providing instructions, feedback and assessment are fulfilled by technological aids. All means together, form the independently executable training program. The effectivity of the program was tested by comparing the cannulation skills of a subject group that executed the developed training program with a control group. The difference in measured skill were rather small (*5.83/10.00* score vs. *5.59/10.00* score of control group) and due to the low sample size of the subject group, the results are not significant. While the test results are inconclusive, the developed training shows a lot of potential due to the advantages of the incorporated serious gaming elements and the relatively easy implementable proposed solutions for the found points of improvement.

CONTENTS

LIST OF ABBREVERATIONS

AI	Artificial Intelligence
AMC	Amsterdam Medical Center
ASGE	American Society for Gastrointestinal Endoscopy
BD	Bile Duct
CAI	Computer Assisted Instructions
CBD	Common Bile Duct
CBL	Computer Based Learning
CBT	Computer Based Training
EPBD	Endoscopic papillary balloon
ERCP	Endoscopic Retrograde Cholangiopancreatography
OR	Odds Ratio
OR	Operation Room
PD	Pancreatic Duct
PEP	Post ERCP Pancreatitis
PSP	Pancreatic Stone Protein
SOD	Sphincter of Oddi Disfunction
SOM	Sphincter of Oddi Manometry

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1 INTRODUCTION

1.1 General introduction

Because ERCP is, with an overall complication rate of approximately 9.8% (of which: PEP 5.4%, hemorrhage 2.0%, Cholangitis 1.0%, perforation 0.3%, cholecystitis 0.5%, other 1.1% [12]), one of the most risky and technically demanding procedures to perform by a gastroenterologist, a great deal of training is needed in order to achieve competency in performing this challenging procedure. The training is traditionally done according to the master-apprentice method, in which the trainees learn by performing on real patients, under supervision of an instructor. Trainees learn by "trial and error", which does not only put the patient's wellbeing at risk [13-16], but also contributes to longer OR times [17], resulting in increased costs [18]. On top of that, the frequency of training-opportunities that this risk-bearing method of training can provide is limited, since the amount depends on the number of incoming patients. Due to the randomly variating clinical indications and procedural difficulties of incoming patients, the number of suitable patients for trainee participation is even more limited.

As for multiple other medical disciplines, the focus should therefore increasingly be placed on simulation-based training, as an addition or alternative to traditional training. A simulator can facilitate a training environment that allows trainees to develop both technical and non-technical skills, with (for most simulators) the opportunity of unlimited repetition of specific tasks. In simulation-based training, trainees are allowed to make mistakes. Therefore, no (premature) interventions have to take place because of precautions. Trainees can proceed their performance also in difficult or awkward acts and learn from these experiences. The first phase of practical training, in which the beginner-trainees are highly unskilled and operate by means of trial and error, is the riskiest phase for the patient. Therefore, replacing the patient by a proper simulation model in the first phase of training would be a beneficial measure to decrease the risk for the patient, because only the more experienced (by means of simulation training) trainees will then participate during clinical practice. The experience of the trainee can, moreover, result in decreased OR times. But despite the fact that simulator training for ERCP has been possible for quite a while now, the actual use of simulators in ERCP training is all but standard [19-21]. The reasons for non-use may differ depending on both the type of simulator in question and target group (existing of the training provider and the trainee). The desired properties of a model for beginners vary from those of a model for more advanced practitioners, since the type of skills that need to be trained are from a different order. However, for now the focus should primarily be on developing a simulator for residents at the start of their program (meaning that there will be no prior ERCP experience), since trainees already showed to have great difficulties with mastering the most basic ERCP skills: a success rate of 80% for selectively cannulating the virgin papilla (the basis of ERCP) was found to be achieved after just 350-400 procedures [22]. Moreover, studies in other gastrointestinal or surgical disciplines showed that most errors occur in the beginning of training [23, 24], which points out the need for simulators that facilitate training from the beginning on.

Besides facilitating a training that focusses on the relevant skills for the selected target group, the model should also be affordable, ethically sound and relatively easy to use and implement in the training curriculum, in order to be of value (see *6.5 Remaining secondary objectives*). The type of simulator that suits these requirements best (in case of facilitating training to novels), is the mechanical simulator. Unlike ERCP simulators of a different type (e.g. computer-, anesthetizes animal-, ex-vivo animal tissue- and human cadaver models), mechanical simulators have already proven to be effective instruments for achieving basic ERCP skills that translate into clinical practice [20, 25, 26] while also being relatively cheap and easy in use. Computer simulators cost around 76.750$ -85.500$ for the most basic versions of the models [27], anesthetized animals suffer from severe ethical concerns and both ex-vivo animal tissue models and human cadaver models are rather impractical due to either availability issues or the high level of support that is needed to operate the model (Literature Study, J. Wesseling).

1.2 Independent practice

For all the listed reasons, mechanical simulators seem to be the ideal simulation models to provide ERCP training on to beginners. However, if training would shift from master-apprentice to simulator practice, additional time is required from the gastroenterologist (trainer), because simulator teaching sessions must be provided by him/her as a separate activity on top of his/her daily operating schedule. Finding sparse time in their busy schedule is often difficult, especially when it has to meet the schedule of the trainees as well. For this reason, simulator training is only provided twice a year to the trainees in the AMC (Amsterdam Medical Center).

It would therefore be attractive for both the trainer and trainee if training on the simulator could be carried out on a more independent basis. Not only will it save a lot of precious time of the expert (teaching) gastroenterologist, it will also take away the risk of instructor bias and will generate a more relaxed environment for the trainee to practice. The trainee can practice on any free moment without the stress of having his/her instructor judging him/her. Another option would be to replace the expert gastroenterologist instructor with another human assistant, but the amount of training that trainees receive is still subject to the availability of the instructor since trainees cannot train on any given moment because of need for an instructor to be present as well. Moreover, it is questionable whether or not the replacing human instructor is objective and sufficiently competent to properly execute the tasks of the expert instructor. To provide simulation training that is available to the trainee at any desired moment, the training needs to be independently executable by the trainee, without a human instructor. When the human instructor is excluded from the training, his/her tasks must be replaced by some technological means.

Some computer simulators already facilitate independently executable training exercises in which technology replaces some functions of the expert supervisor [28]. However, besides the listed drawbacks, computer simulators suffer from some additional downsides, which calls their suitability for the job into question: the haptic-feedback in computer simulators is anything but impressive and in most cases the models are purchased to facilitate training in multiple disciplines other than ERCP as well which makes the device less often available because it needs the be shared. Therefore, implementing the ideas of individualized practice into the favorable mechanical type of simulators will be investigated in this research study (in this case the "ERCP trainer", a mechanical simulator by Dr. Boškoski, Dr. Costamagna and Cook Medical [29]) in order to increase the use of simulators in ERCP training.

1.3 Study goal

The goal of this study is to:

> ***'Develop an independently executable training for the ERCP trainer that effectively and efficiently teaches beginners the most important ERCP skills.'***

1.4 Thesis outline

A systematic approach will be applied for this research, which is outlined in scheme below (figure …). In the first part of this research, all relevant information on the subject is set out in several theoretical chapters. In the second part, the requirements and conditions for the to-be-developed training will be declared, by defining the training objectives-, needs-, and the exploring the options for the means. Based on the design directions, concept(s) can be formulated in the third part. In the fourth part, the developed concept(s) will be tested. And in the final fifth part, the results of the tests and overall outcome of research will be evaluated.

Figure 1: Thesis outline

PART 1

THEORY

2 TECHNICAL ASPECTS OF THE ENDOSCOPE

In this chapter, first the history of ERCP will be shortly discussed, followed by the technical aspects of the endoscope and it's for ERCP intended variant "the duodenoscope". This will give a better insight in what ERCP is exactly and what the instruments are that an endoscopist is working with.

2.1 History

ERCP (Endoscopic Retrograde CholangioPancreatography) is an endoscopic technique that combines side viewing endoscopy with fluoroscopy, to diagnose and/or treat medical conditions in the bile ducts and main pancreatic duct. Fluoroscopy is an imaging technique in which X-rays are used to depict a real-time image of the body's interior. Endoscopy is a technique in which the interior of the body is examined and possibly operated, using a long flexible instrument with a camera incorporated at the tip, called an "endoscope". The first ERCP was done in 1968 [30] and was solely to analyze and diagnose (diagnostic ERCP), but with the introduction and incorporation of endoscopic sphincterotomy (the cutting of the biliary sphincter during endoscopy) in 1974 [31], also treatment became possible during the ERCP (therapeutic ERCP).

There are many different sorts of endoscopes, all with slightly different features that make the device optimal for a certain procedure or part of the body. The endoscope used in ERCP procedures is called a duodenoscope. The duodenoscope differs from a standard endoscope in its side positioned camera, offering the desired en-face view at the (major) duodenal papilla that most often needs to be cannulated. Additionally, a duodenoscope contains an elevator system that is incorporated at the tip. The elevator makes is possible to adjust the angle in which instruments enter the field of view when passed through the working channel and eventually exiting the head of the scope.

2.2 Components and mechanics of the scope

The standard endoscope consists of five basic components; 1) control body, 2) insertion tube, 3) bending section, 4) light guide connector, 5) light guide tube. The major systems that are incorporate in the scopes are; A mechanical system (the angulation system for rotating the tip of the scope and in case of a duodenoscope also the elevator system), a plumbing system (delivery of water and air to the target side or provide suction) and an illumination system (provide light and direct captured image from camera to monitor).

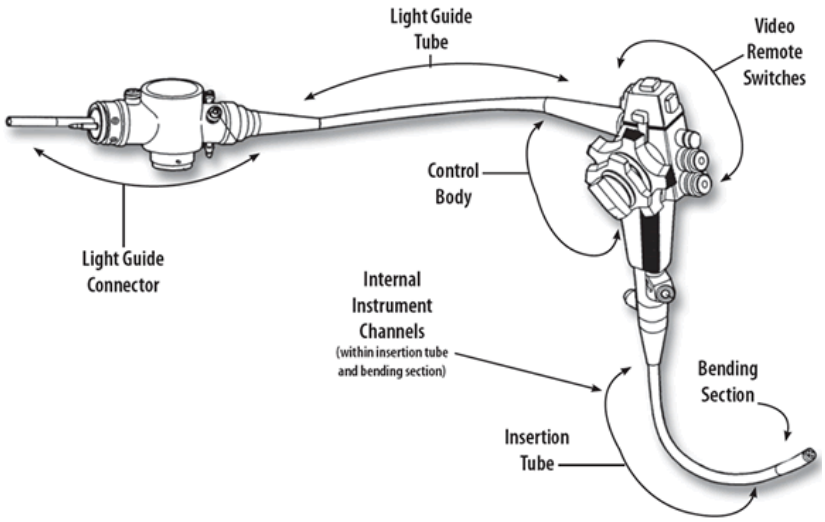


Figure 2: Parts of an endoscope [5].

2.2.1 Control body

The control body is the hand piece that functions as an input device for the operating gastroenterologist. In the control body, outlets of the plumbing system are located in order to control the supply of water, air and to the suction that is needed during surgery, by means of two valves on the control body: the suction valve and the air/water valve. The suction valve can be pressed if body fluids or gasses need to be drained away. If the air/water valve is pressed, a water spurt is released out nozzle at the distal tip, which can be used to remove tissue debris at the operation site or in case of a duodenoscope (with a side view camera) to clean the lens. If the air/water valve is covered (with a finger) but not pressed, air flows out of nozzle, in order to insufflate the organ or remove water from the lens.

Via a biopsy port in the control body, different instruments can be introduced to the target site in order to excise, coagulate, ablate, cut and remove tissue or take a biopsy. In duodenoscopes, the angle in which these instruments come out of the nozzle can be adjusted in order to cannulate with the proper angle. When the thumb control knob on the side of the control body is pressed in a counterclockwise direction, the elevator system in the tip of the scope rises and a more acute exit angle for the instruments arises. The movements of the distal tip of the scope are guided by an angulation system that can be controlled by two rotatable knobs, located on top of the elevator control knob on the control body. The smaller knob guides the right/left movements and the bigger knob controls the up and down movements. Both knobs can be locked to maintain a stable position. The rotation of the knobs is transmitted to angulation at the tip of the scope by means of a pully wire or a chain drive system in the control body that is connected to the tip by wires.

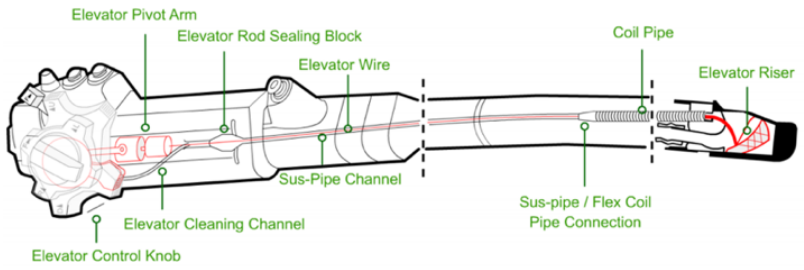


Figure 3: Duodenoscope Elevator Channel (ERCP Elevator Channel) [5].

2.2.2 Insertion tube

The insertion tube of a standard endoscope contains 1) electrical wires that couple the image sensor at the distal tip to a video processor, 2) glass fibers that transfer the light from the light source to the distal end of the scope, 3) a channel for suction and biopsy, 4) tubes for air, water and sometimes even an extra forward jet water tube, and 5) four wires for controlling the angulation of the distal tip. The duodenoscope has additional wires for controlling the elevator. While the content of the insertion tube does not vary much along different endoscopes, the length and thickness of the insertion tube as well as the mechanical construction of the sheath do vary for different endoscopes, depending on the procedure. For smooth insertion, endoscopes need to be able to transmit the (by the endoscopist) applied torques and movements from the most proximal part of the tube, to the most distal part, in the same proportion. Two spiral metal bends, running in opposite direction in the sheath, able the processing of these applied torques. The space in between the spiral rings, along with the stiffness of the metal make up the flexibility of the instrument. The flexibility of a scope used in the upper GI tract may be less flexible then a scope used in the colon, since the colon contains a lot of bends and curves. Besides flexibility, the insertion tube must contain the right elasticity in order to bend back in straight formation when pulled back, and also a proper column strength to prevent the tube from buckling.

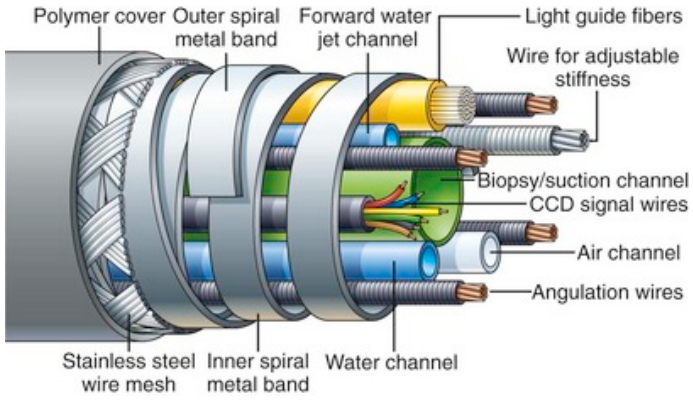


Figure 4: Internal components of an endoscope [6].

2.2.3 Bending section

The bending section incorporates the terminal ends of; the biopsy port, the air/water port, the electrical wires of the image sensor (covered by a lens) and the glass fibers of the illumination system (also covered by a lens). The air/water ports typically merge into one port in the last centimeters of the tip. In duodenoscope, the air/water ports end prior to the light and imaging

tubes, in order to clean the lenses. The imaging system uses a prism to deflect the 90 degrees angle of the side viewing duodenoscope. In duodenoscopes, the actual lift of the elevator system is also housed in the distal tip. Since the elevator is a mechanical moving system at the junction of the instrument and the body tissue, this system is very susceptible to contamination infection. In 2015 the Center for Disease Control released a statement about the outbreak of carbapenem-resistant Enterobacteriaceae, which turned out to be related to the elevator system of the duodenoscope [32]. Growing attention has since then been paid to the cleanability of this system. The bending section is constructed differently from the rest of the insertion tube, since the endoscopist needs to be able to execute movements of this particular part in four directions. Cross-orientated metal rings connected by pivot pins form the cylindrical structure of the bending section. A wire, with its endings attached to a (in most cases) chain mechanism, connects the pivots in longitudinal direction, which makes movement in two directions (up and down) possible when torque is applied to the chain mechanism. The same system is established for right-left movements but is rotated a quarter turn. This second system makes use of the same metal rings in the bending tip but connects other (the remaining) pivots in the longitudinal direction.

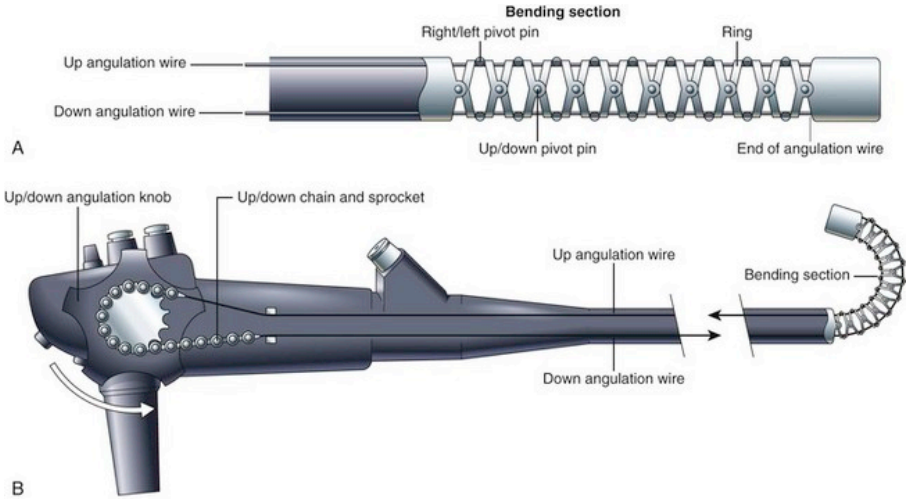


Figure 5: Mechanics of the bending section [3].

2.2.4 Light guide connector

The light guide connector is the most proximal (to the endoscopist) end of the scope and is basically the point of attachment for all the resources of the scope. The light guide connector plugs in to the processor that generates light to enter system and it connects the image capturing system of the scope to the monitor to display the captured images. An air pump is connected to this part of the scope to generate air flow towards the scope or the flow of water when the generated air is pressed in opposite direction on to the water bottle. The water from the bottle can enter the water tube of the scope via the light guide connector. The light guide connector also houses the reservoir of the suction channel, its ending and connects this ending to a device that generates the suction.

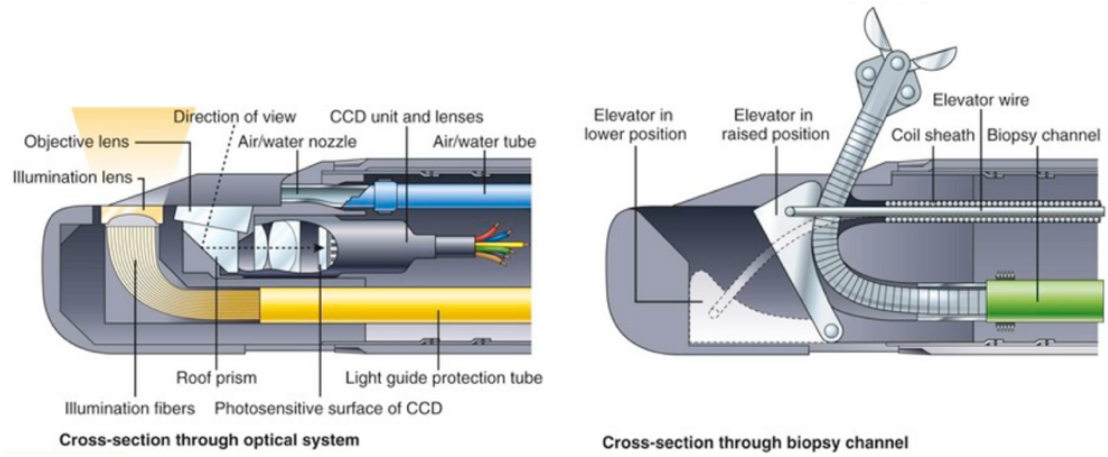


Figure 6: Duodenoscope distal tip assembly [6].

2.2.5 Light guide tube

The light guide tube connects the control body to the light guide connector and contains all the channels. The function of this tube is to enable space for the endoscopist to steer the control body. Technically, the control body could be assembled to the light guide connector directly since the control body functions as the input device that controls the generation of light guide connector. But when these parts are assembled directly onto each other, the endoscopist would not be able to displace the control body, which possibly induces an uncomfortable body position and could hinder his/her hand movements.

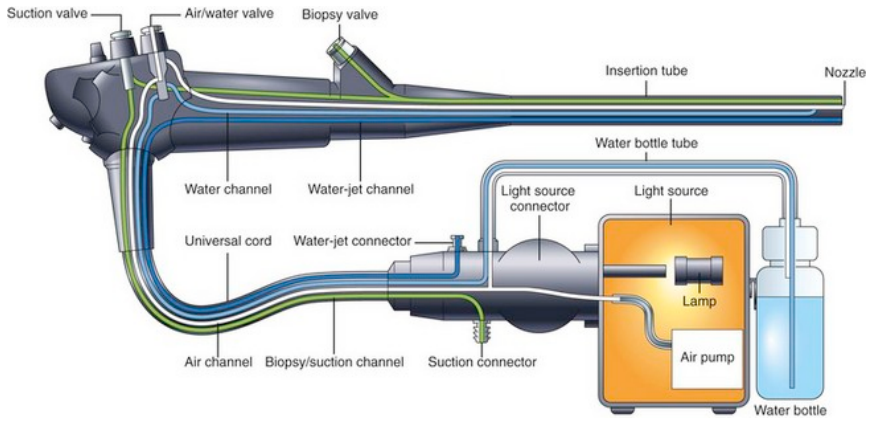


Figure 7: Configuration of Air, Water and Suction systems [6].

3 CLINICAL INDICATIONS FOR ERCP

In this chapter, the clinical indications for ERCP will be discussed. A clinical indication (for ERCP) is the observation or finding that leads to the belief that ERCP is needed for either diagnostic purpose or treatment. The observation or finding can be just a symptom of a certain disease or condition (then it is a suspicion of a certain condition), but also the condition or disease itself. Since ERCP is a complex and challenging procedure, it should only be conducted if there are very well substantiated clinical indications to do so. Therefore, knowledge of the different clinical indications and identifying them correctly is very important in minimizing patient risks. The performed procedure is thus often, but not always (in case of an incorrect indication), related to the clinical indication. The most common reason for legal allegation after ERCP treatment is performance without a good indication or incorrect indication [33]. The clinical indications for performing ERCP and the validity of it, is therefore crucial in the process. The most common clinical indications for ERCP will be discussed now.

3.1 Choledocholithiasis

If the patient suffers from choledocholithiasis, there are gallstones present in the common bile duct, that obstruct the outflow of the tract. The condition is a complication of cholelithiasis (gallstones in the gallbladder) that is seen in up to 15% of the patients suffering from cholelithiasis [34]. Cholelithiasis can cause jaundice and damage to the liver cell. The symptoms of the condition are those of cholelithiasis; pain in the right-upper quadrant of the abdomen, nausea and vomiting, especially after consuming fatty products. With an ultrasound, cholelithiasis can be diagnosed. Besides the presence of cholelithiasis, an elevation of bilirubin and serum transaminases in the blood could be indicators of choledocholithiasis. To confirm the diagnosis, magnetic resonance cholangiopancreatography can be executed. ERCP can be then performed to remove the gallstone with a balloon catheter or a Dormia basket (see *4.6 Balloon/basket stone extraction*). Choledocholithiasis is the most occurring indicating for performing ERCP.

3.2 Suspected stone

Gallstones can obstruct the common bile duct (choledocholithiasis), the gallbladder (cholelithiasis) or even the ampulla of Vater (impacted ampullary stone). If the ampulla of Vater is obstructed, the exocrine system of the pancreas gets impeded, which in turn can cause inflammation of the pancreas (pancreatitis). Since gallstones do not always result in a blockage, 80% of the people with gallstones even never show symptoms [35]. When the gallstone obstructs the bile duct, a biliary colic (known as a gallbladder attack) can cause cramps in the upper right part of the abdomen. Other complications of gallstones are pancreatitis, jaundice, cholangitis and cholecystitis (inflammation of the gallbladder). Gallstones can be divided into three types, based on their composition: pigment stones, cholesterol stones and mixed stones. As the name suggests, at least 80% of the weight percentage of cholesterol stones is cholesterol. The color variates from dark green/brown to light yellow or white and they have an oval form with a length of approximately 2 to 3 centimeters. Pigment stones are tinny, dark, and consist of primarily bilirubin, calcium and salts of the bile. Their weight percentage of cholesterol must be less then 20%. When present, there are often multiple of them. About 2% to 30% of the stones are pigment stones [35]. Mixed stones contain 20% to 80% cholesterol and other constituents as carbonate, palmitate phosphate and calcium. The calcium content often provides the visibility in radiography.

Besides gallstones, a pancreatic stone can also be an indication for ERCP. Pancreatic stones form due to decreased secretion of pancreatic stone protein (PSP), HCO_3 and citrate, that keep the pancreatic juice in its solution form. In patients with chronic pancreatitis, these factors appear to be present less, but also a decrease in PSP is often seen in patients with long-lasting alcohol abuse [36]. Pancreatic duct strictures can boost the formation of stones. Small pancreatic stones can be removed with ERCP.

3.3 Jaundice (thought secondary to biliary obstruction)

Jaundice is previously discussed as a symptom of certain indications/diseases, but in many studies jaundice is also an clinical indication for ERCP on itself. Jaundice is the condition in which the skin and the whites of the eye turn yellow due to high bilirubin levels in the blood. Normally the intensely yellow colored bilirubin is processed by the liver into bile juice, which ends up in de colon and gives the feces its brown color. When the bile flow, containing the bilirubin, is obstructed, the bilirubin will not be secreted but ends up in the blood. This obstruction can be caused by for instance Choledocholithiasis and Cholangitis and the treatment is as described previously for these indications. Jaundice can besides obstructions and stictions, which are called post-hepatic/cholestatic causes, also have a pre-hepatic/hemolytic and hepatic/hepatocellular cause. These pathologies occur prior to or within the liver and are therefore causes of jaundice that are not treatable with ERCP.

3.4 Sphincter of Oddi manometry (evaluation of pressure)

The sphincter of Oddi is the circular (sphincter) muscle that forms the passage from the common bile duct and the pancreatic ducts to the duodenum. It controls the flow of bile and pancreatic juice to the duodenum and prevents substances from the duodenum to enter the ducts. If a dysfunction of the sphincter of Oddi is suspected (abnormal contraction), a manometry (evaluation of pressure) can be performed. When the sphincter does not contract properly, the flow of pancreatic juice and bile can be obstructed, which causes an elevated pressure at the sphincter and results in pain, cholestasis and/or recurring

pancreatitis [37]. Sphincter of Oddi manometry (SOM) is considered the most reliable way of appointing sphincter of Oddi dysfunction [38], since it is the only technique that is able to measure the motor activity of the sphincter of Oddi directly [39]. SOM done intraoperative and percutaneously [40, 41], but usually it is performed by means of diagnostic ERCP. When abnormally high pressure is measured during the diagnostic ERCP, sequent therapeutic interventions (sphincterotomy, stent placement) could be necessary.

3.5 Cholangitis

Cholangitis is the inflammation of the bile ducts. It is caused by bacteria (or in some cases a virus) that can settle in the bile duct due to obstruction of bile flow. When no obstructions are present in the bile ducts, the constant flow of bile prevents bacteria to grow in the ducts. An obstruction can be caused by gallstones but constriction of the duct due to a tumor in the bile ducts, liver, pancreas or colon, can also prevent the flow. Typical symptoms of cholangitis are a fever, abdominal pain, jaundice (see *3.3 Jaundice (thought secondary to biliary obstruction)*), septic shock and mental confusion [42]. With medical imaging cholangitis can be confirmed when common bile duct dilation is visible. Cholangitis can be treated with ERCP; stone obstructions can be removed with a balloon or basket and constrictions can be treated by placing stents that enable the flow of bile.

3.6 Bile Leak

Bile leak arises when the bile ducts are damaged. The damage can either be caused by trauma or arise as a complication of surgery e.g.; cholecystectomy (gall bladder removal) or liver transplantation. Bile leaks through the perforations in the ducts into the abdominal cavity, which can cause pain, inflammation and infection in the abdominal cavity. Symptoms of bile leaks are; fever, nausea, abdominal pain and jaundice. Bile leaks can be treated with ERCP by placing a stent, performing naso-biliary drainage or with sphincterotomy. These treatments reduce the pressure gradient across the sphincter of Oddi, resulting in the preferred flow through the papilla and closing of the leak [43].

3.7 Pancreatitis (of unknown etiology, gallstone pancreatitis)

Pancreatitis includes acute pancreatitis and chronic pancreatitis. Both acute and chronic pancreatitis are inflammation of the pancreas and show symptoms of severe pain in the upper abdominal or left upper quadrant, nausea and vomiting. Chronic pancreatitis can develop as a result of an acute pancreatitis that does not recover. Acute pancreatitis is most often caused by gall stones in the common bile duct or the result of heavy alcohol use. Other causes are; direct trauma, medication, infections and tumors. Pancreatitis is treated with medication, antibiotics and painkillers, against the inflammation and the pain, but when caused by gall stones in the common bile duct or by strictures or stones in the pancreatic duct, ERCP is needed to place a pancreatic stent or remove the stone. ERCP is on itself a surgery with a relatively large risk of causing pancreatitis, because the cannulation of the ducts can be difficult which causes the pancreas to get irritated. Contrast injection and several therapeutic procedures can also encourage the emergence of pancreatitis.

3.8 Malignant structure

A tumor, also called a neoplasm, is an abnormal lump or growth of cells that can be either two malignant or benign. If the cells in the tumor are normal but just grew a bit too excessively till a certain extent, the tumor is called benign. But when the cells in the tumor are abnormal and the growth is uncontrollable the tumor is called malignant or a malignancy, because its cells are cancerous. In literature neoplasms and benign tumors are sometimes also reported as indications for ERCP. Benign tumors itself are not dangerous, but the lump can cause obstruction of certain ducts and therefore treatment is necessary in some cases. Malignancies can, just like benign tumors obstruct biliary or pancreatic ducts, but is on itself also dangerous since the malignancy can spread to other areas of the body or invade nearby tissue. The malignant biliary obstruction due to cancer in the head of the pancreas can be decompressed by stent placement during ERCP and proved to be successful in 90% of the cases [44].

3.9 Trends in clinical indications

Besides the overall occurrence rate of the indications, it is also important to identify trends in the numbers, if present. If a development of a certain indication is detected, this can be accounted for in determining important components of training. A population-based study by Moffat et al [45] plotted the indication rates over a period of 25 years, which provides a clear overview of the trends. Moffat et al examined the province Manitoba in Canada from 1984 to 2009. Manitoba is demographically comparable to the United States, in its mean income, mean age, present and division of different races, and in fertility [32]. The percentage for every indication fluctuates over the examined 25 years but in general some trends show; The percentage of Cholangitis and Bile Leak indications increases severely (approximately 19%), Pancreatic or Biliary Malignancy, Choledocholithiasis and Jaundice remain roughly stable, and Pancreatic disease and Abdominal Pain decrease with respectively 10% and 15%. These results do not immediately indicate a decline in pancreatic disease and an increase in cholangitis and bile leak. The results rather reflect the increase of therapeutic possibilities and procedures, and the decrease of diagnostic procedures. Jaundice and abdominal pain used to be indication for diagnostic ERCP to find out what was going on, but with the advent of safer methods, diagnostic ERCP is less often conducted for these reasons, which decrease the total amount.

4 ERCP PROCEDURES

In this chapter, the different type of ERCP procedures will be discussed. This will give an insight in how ERCP should be performed, step-by-step. First the basic steps of ERCP will be covered and thereafter the different types of treatments for certain indications will be explained.

4.1 Diagnostic vs therapeutic ERCP

ERCP is essential in identifying (in the old days) and primarily treating biliary and pancreatic diseases, but it is also one of the most challenging and highest-risk procedures to perform by a gastroenterologist [46], with the consequence that the rate of adverse events is relatively high [47]. The single best way of avoiding adverse patient outcome is therefore, ironically, avoiding ERCP for marginal indications, especially for higher risk patients [21]. With the advent of safer and less invasive diagnostic techniques (e.g. Magnetic Resonance Imaging, Endoscopic Ultrasound, Computer Tomography and Intraoperative Cholangiography), diagnostic ERCP is nowadays only performed in select situations, often when very precise clarity is needed in defining the anatomy and pathology of the ducts.

The number of diagnostic ERCP's performed per 100.000 population is the United States declined from 36.0 in 1998 to 8.6 in 2013, while the number of therapeutic ERCP's performed increased from 62.0 in 1998 to 83.9 in 2013 [48, 49]. This increase of therapeutic procedures has to do with the growing treatment possibilities. The total amount of ERCP's performed in the United States increased severely up until 1998, but since 1998 the rate of ERCPs performed declined. This can be explained by the fact that the increase in the rate of therapeutic ERCPs was less severe than the tremendous declining rate of the diagnostic ERCPs, due to the growing availability of new diagnostic techniques e.g. magnetic resonance cholangiopancreatography. Another explanation for the shown decrease in ERCPs is the fact that this research (and almost every other retrospective study containing patient statistics) only contained inpatient numbers, since the National Inpatient Sample was used as study population. Kozarek and Moffatt [45, 50] both state that ERCP is evolving into an primarily outpatient procedure and therefore the total amount of ERCPs performed is actually increased over the years, when outpatient ERCPs are taken into account.

4.2 Inserting the duodenoscope

Since the duodenoscope is side-viewing, the esophagus is intubated blindly. Intubation of the esophagus is most easily done by holding the scope horizontal and parallel to the examination table. The neck of the patient must be in slightly flexed position. By applying gentle forward pressure (without experiencing resistance) the duodenoscope may be passed down the esophagus until the cardia is reached. The cardia arises after 38-40 cm (from the teeth) and can be recognized by feeling a bit of resistance due to the sphincter. Again, gentle pressure may be applied to advance the tip into the stomach. When entering the stomach, the scope must be advanced along the lesser curvature and eventually rest on the greater curvature before entering the pyloric antrum. To keep the pylorus in view, slightly deflect the tip 'down' while sliding the shaft of the scope inwards along the greater curvature (Figure 9A). When the pyloric ring becomes close, the tip must be angled towards the neutral position until the pylorus is in 'setting sun' position (Figure 9B).

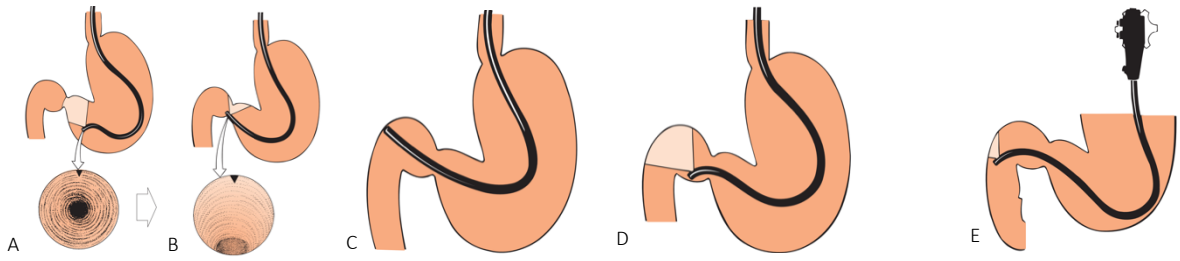


Figure 8: Steps of directing the scope trough the body (part 1) [2].

The scope can now be advanced forwards to pass the pylorus (Figure 9C). After passing the pylorus, the tip must be angled down and withdrawn slightly to virtually hook the tip beyond the pyloric ring (Figure 9D). For passing the superior duodenal angle into the descending duodenum, a corkscrew 'right twist and pull' manoevre needs to be done. The tip must be angled up towards neutral position and the scope must be advanced over the superior duodenal angle until the entry of the descending part of the duodenum is reached (Figure 9E). Thereafter, the instrument must be rotated 90° clockwise and the tip angled right and up, simultaneously (Figure 10A). To advance to tip further into the duodenum, the scope can be either pushed or straightened. Pushing is often used by beginners, since it avoids the risk of falling back into the stomach, but it results in a "long scope" which is unpleasant for the patient due to the loop in the stomach and control over the tip is reduced (Figure 10B). Straitening will result in the more pleasant "short scope" position, and is achieved by pulling while locking the tip of the scope beyond the superior duodenal angle (Figure 10C). Once the shaft of the scope is straight and withdrawn till no more that 70cm of instrument is inside the patient (Figure 10E), the knobs can be unlocked and the papilla should be in view in most cases or nearby (Figure 10D).

Correct en-face positioning in front of the papilla is crucial for successful cannulation [1, 51, 52], and since the papilla is often automatically in view on the display when the straightening maneuver is completed after the short route (short scope) [2], it could be hypothesized that performing intubation and executing route as described above, would contribute to quicker and better positioning in front of the papilla and with that greater cannulation success rates and less complications, since prolonged procedure time and increased cannulation attempts raise the risk at complications [53, 54]. However, no literature is found concerning the effect of intubation and the route taken on the cannulation rates and complications.

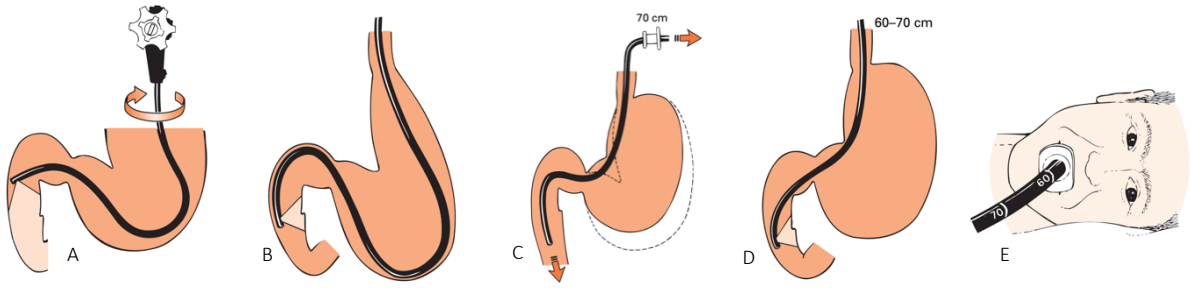
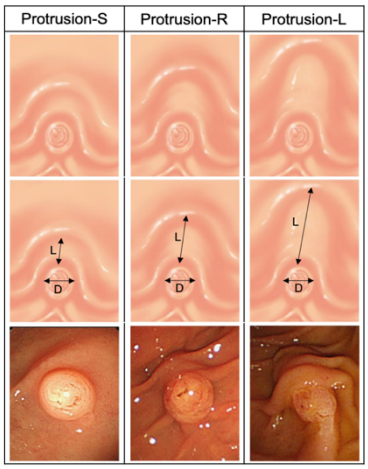


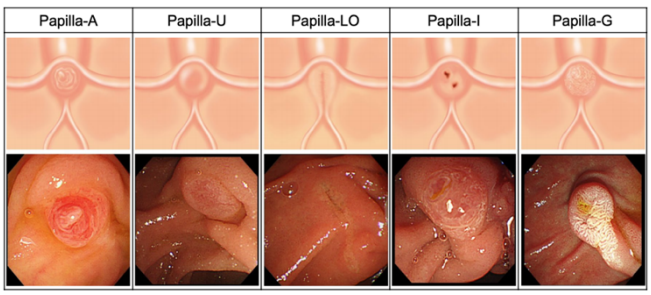
Figure 9: Steps of directing the scope trough the body (part 2) [2].

4.3 Locating and recognizing the papilla

In almost 80% of the patients [55], the major papilla is located on medial wall of the second part of the duodenum, at a mean distance of 10.56 ± 1.3 cm (min 7 cm, max 13 cm) from the pylorus [56]. However, the location may differ bit amongst patients; in 15.71% of the cases, the papilla is located at the posteromedial wall of the second part of the duodenum and at the posteromedial wall in the junction between the second and third part of the duodenum in 4.3% of the cases [55]. The color of the papilla slightly differs from the duodenum and the shape is cylindrical/cone shaped in 77.8% of the cases, hemispherical in 14.8% and flat in 8.2% [55]. The mean papillary protrusion is 7.7mm and a frenulum is present in 73.8% of the patients [55]. The papilla presents as a polypoid prominence with a length of 5-10 mm and width of 5 mm, and is often quite hidden by transverse, circular, duodenal folds [57]. Wantanabe et al [11] came up with a more detailed classification system for the papilla, which is depicted in Figure 10 and Table 1. The study of Wantanabe investigated the effect of the papilla shape and anatomy on the cannulation rates. For both the experienced and inexperienced endoscopists a large protrusion causes cannulation rates to be lower and the amount of attempts needed for cannulation to be higher. For inexperienced endoscopists, an isolated-, gyrus- and longitudinal type papilla leads to an increased amount of attempts needed for cannulation and for the longitudinal type also the eventual cannulation success rates decrease (Table 1 and Table 2).



Left: Oral protrusion types by Wantanabe et al [11]. Protrusion is the ratio of the length of the oral protrusion to the transverse diameter of the papilla



Right: Papilla pattern according to Wantanabe [11]. Papilla-A, comprising typical papilla with an annular shape; Papilla-U, unstructured without a clear orifice; Papilla-LO, comprising longitudinal grooves continuous with the orifice, with the length of the grooves being longer than the transverse diameter of the biliary duct axis of the papilla; Papilla-I, comprising two separate, isolated orifices of the biliary and pancreatic ducts, with the opening on the oral or left side being that of the biliary duct and that on the anal or right side being that of the pancreatic duct; and Papilla-G, with a gyrate structure

Figure 10: Papilla appearances [11].

Table 1: Prevalence rates of papilla types

From wantanabe et al	Prevalence rate, % (n)	Biliary duct cannulation rates			≥ 5 attempts needed for successful cannulation		
		All	*Inexperienced endoscopist*	*Experienced endoscopist*	*All*	*Inexperienced endoscopist*	*Experienced endoscopist*
Oral protrusion pattern	(n = 589)						
Small type (protrusion-S)	11.7 (69)	100 (69/69)	100 (37/37)	100 (32/32)	40.6 (28/69)	43.2 (16/37)	37.5 (12/32)
Regular type (protrusion-R)	77.9 (459)	97.6 (448/459)	97.5 (272/279)	97.8 (176/180)	39.0 (179/459)	45.9 (128/279)	28.3 (51/180)
Large type (protrusion-L)	10.4 (61)	95.1 (58/61)	95.3 (41/43)	94.4 (17/18)	63.9 (39/61)	67.4 (29/43)	55.6 (10/18)
Papilla pattern	(n = 589)						
Annular type (papilla-A)	67.1 (395)	98.0 (387/395)	98.3 (237/241)	97.4 (150/154)	41.5 (164/395)	46.1 (111/241)	34.4 (53/154)
Unconstructed type (papilla-U)	7.0 (41)	97.6 (40/41)	96.2 (25/26)	100 (15/15)	36.6 (15/41)	42.3 (11/26)	26.7 (4/15)
Longitudinal type (papilla-LO)	7.5 (44)	93.2 (41/44)	90.3 (28/31)	100 13/13)	40.9 (18/44)	51.6 (16/31)	15.4 (2/13)
Isolated type (papilla-I)	1.2 (7)	100 (7/7)	100 (4/4)	100 (3/3)	28.6 (2/7)	50.0 (2/4)	0
Gyrus type (papilla-G)	15.6 (92)	98.8 (91/92)	100 (52/52)	97.5 (39/40)	43.5 (40/92)	53.8 (28/52)	30.0 (12/40)
Unclassified	1.7 (10)	90.0 (9/10)	80.0 (4/5)	100 (5/5)			

The major duodenal papilla is surrounded by the sphincter of Oddi, that controls the flow of pancreatic juices and bile into the duodenum. The common bile duct and the pancreatic duct join together in a common channel before debouching into the major duodenal papilla, this junction is called the "Ampulla of Vater". Normally this common channel is short, but in alternate anatomy this channel can be longer or not even existing. Both the common bile duct (and its branches) and the pancreatic duct can be cannulated, but biliary cannulation is more common and less risky. For optimal cannulation rates of both ducts, the initial position of the endoscope is crucial [58]; a straight and short position, and the long axis of the papilla should be aligned with the 12 o'clock position. The pancreatic duct normally runs perpendicular, whereas the bile duct is parallel to the wall of the duodenum [52]. An experienced gastroenterologist performs successful selective cannulation in over 95% of the cases [22]. As mentioned before, in the past a minimum of 80% successful cannulation rate was used as measure for competency [59], nowadays a rate of 90% seems to be more appropriate [60].

Table 2: Difficulty of cannulating each papilla type

	No. of difficult biliary duct cannulations	Univariate analysis			Multivariate analysis		
		OR	*95% CI*	*p value**	*OR*	*95% CI*	*p value**
Oral protrusion pattern							
Protrusion-S (n = 32)	12	1.348	0.62–2.93	0.452			
Protrusion-R (n = 180)	51	0.503	0.264–0.96	0.037			
Protrusion-L (n = 18)	10	2.956	1.115–7.84	0.029	3.772	1.359–10.464	0.011
Papilla pattern							
Papilla-A (n = 154)	53	1.469	0.799–2.702	0.216			
Papilla-U (n = 15)	4	0.769	0.237–2.503	0.663			
Papilla-LO (n = 13)	2	0.374	0.081–1.732	0.208			
Papilla-I (n = 3)	0	n.c.					
Papilla-G (n = 40)	12	0.906	0.432–1.903	0.795			

4.4 Cannulation

The problem with cannulation is that the area beyond the orifice of the papilla is not visible, at least not directly, since only a catheter enters the papilla and the camera remains in the duodenum. After a short common channel, which even variates in length, the path will split up into two ducts. The catheter must be advanced into one of these specific ducts, but the fact that the endoscopist cannot see what he/she is doing, makes it rather difficult to direct the catheter in the desired duct. X-ray in combination with contrast or a detectable wire can be used for checking the location of the catheter, but the view provided on the x-ray images/video is vague and one dimensional. On top of that, the video or images come in retrospect, since for checking the location with X-ray, the catheter and/or wire must already be advanced into one of the ducts. The X-ray can only portray the location (or the wire) beyond the papilla when contrast is present or when the detectable wire is already there.

Since the endoscopist cannot rely on its sight in the area beyond the papilla, he/she must direct its course based on knowledge about the anatomy. The endoscopist must know the characteristics, construction and spatial design of the ductal and papillary area by heart, so that the cannulating instrument can be advanced following the desired path, blindly. In Figure 12 the anatomy of the biliary system is depicted, and in Figure 11 the spatial configurating of the papilla and its subsequent ductal system. Further elucidation on knowledge needed to perform selective cannulation is presented in *4.4 Cannulation.*

4.4.1 Confirming access to the right duct

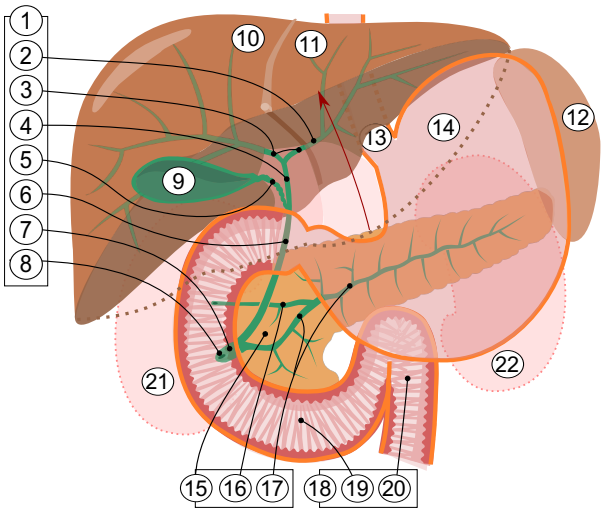


Figure 12: Anatomy of the biliary system [4].

*1. **Bile ducts**: 2. Intrahepatic bile ducts, 3. Left and right hepatic ducts, 4. Common hepatic duct, 5. Cystic duct, 6. Common bile duct, 7. Ampulla of Vater, 8. Major duodenal papilla 9. Gallbladder, 10–11. Right and left lobes of liver. 12. Spleen. 13. Esophagus. 14. Stomach. 15. **Pancreas**: 16. Accessory pancreatic duct, 17. Pancreatic duct. 18. **Small intestine**: 19. Duodenum, 20. Jejunum 21–22. Right and left kidneys. The front border of the liver has been lifted up (brown arrow).*

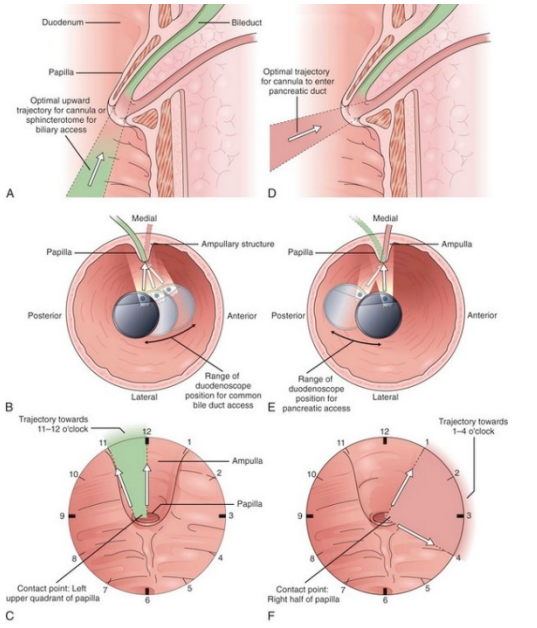
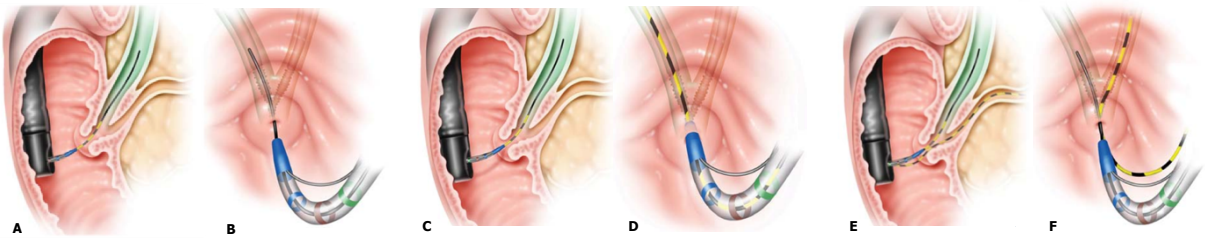


Figure 11: Spatial configurating of the papilla and its subsequent ductal system [8].

A–D, Optimal trajectories for cannulation of the bile duct (A, B, and C) and the pancreatic duct (D, E, and F) as projected in transverse (B and E), coronal (A and D) and sagittal (C and F) sections.

There are three conventional ways of confirming access to the right duct. 1) Cannulation can be done directly with a sphincterotome. This method if often first applied in case of biliary cannulation. 2) Contrast dye can be injected to visualize the duct with fluoroscopy. The amount of contrast must be minimized to avoid distension of the gallbladder or opacification of the pancreatic duct which may result in cholangitis or pancreatitis, the risk of post ERCP pancreatitis increases with the amount of contrast injections in the pancreatic duct and opacification [53, 61]. 3) The third technique is to first use a guidewire that is visible with fluoroscopy, to guide the cannulation of the desired duct. This eliminates the need for contrast dye and gentle passage of the wire into the pancreatic duct does not even increase the risk of pancreatitis significantly. There is also a combination of wire-guided and contrast guided cannulation possible.



***A&B** Technique 1: Sphincterotome outside the ampulla orifice, **A** Side view, **B** En-face view. **C&D** Technique 2: Sphincterotime advanced 1-2 mm inside ampulla orifice, **C** Side view, **D** En face view. **E&F** Technique 3: Double Wire Method, guidewire placed in PB (first) and CBD, **E** Side view, **F** En face view.*

Figure 13: Techniques for cannulation

There are three techniques for wire cannulation: the first technique may in some cases even facilitate an easier cannulation with catheter, since it first cannulates the papilla with the thinner hydrophilic guide wire only, and thereafter slides the catheter along the path of the guide wire. The second technique first engages the catheter into the common channel of the papilla and then advance the wire into the one of the desired ducts. The third technique is the double wire technique and is used for difficult biliary cannulations where the pancreatic ducts keeps on getting cannulated unintentionally. The wire is left in the pancreatic duct, locked, and the catheter is taken out and loaded with another wire. The wire in the pancreatic duct can now

be used to open up the papilla. By dropping the elevator a bit, the wire gets stretched and pushes on the wall of the papilla, creating a wider cannulation range for biliary cannulation with the second wire. Besides enabling visualization and providing assistance during cannulation, guidewires also function as a site for exchanging different assistance devices that are needed during ERCP. Guidewires are also required for stent placement, traversing and dilating strictures, and the sampling of cytologic tissue.

The risk at perforation of ducts or intramural dissection of the papilla is minimized by using soft wire tips. Two other less conventional ways to check whether the right duct is cannulated are by aspiration (bile is yellow, pancreatic juice is colorless) and by measuring the dept of the cannulation (deep duct cannulation is normally associated with bile duct cannulation, while intermediate duct cannulation relates to the pancreatic duct).

4.4.2 Bile duct cannulation

Biliary cannulation is the standard for ERCP, only in select cases the pancreatic duct is the duct of interest. For cannulating the bile duct with a standard catheter, the duodenoscope must be placed below the major duodenal papilla in straight and preferably short position, and the catheter should be positioned slightly below the papilla as well. The papilla needs to be located either in the lower left of the upper right quadrant of the display or the lower right of the upper left quadrant of the display (opinions variate [1, 62, 63]), while the long axis of the papilla should be in line with the 12 o'clock position and the papilla should be looked at en-face. When the scope is positioned as described and the orifice of the papilla is the center of the imaginary clock, the bile duct will normally be parallel to wall of the duodenum and in line of the 11 o'clock direction (exact line can variate between 10 o'clock and 1 o'clock). The goal is to advance the catheter trough the orifice of the papilla in the same horizontal and vertical axes as the duct of interest (in this case the bile duct). For biliary cannulation this means that the roof of the orifice should be entered, whereas for cannulation of the pancreatic duct the floor of the orifice should be entered. When the described course is followed (also see Figure 14 for illustration), the cannulating instrument should arrive in the bile duct. Achieving the correct position in front of the papilla and steering and advancing the catheter in the right direction is thus crucial for achieving successful biliary cannulation, minimizing the attempts and time needed, and with that, minimizing the risk at complications. There are of course situations in which the anatomy is slightly altered. Therefore, a slightly different technique is sometimes required, often making cannulation a bit more difficult. These techniques are described in *4.4.4 Difficult cannulation.*

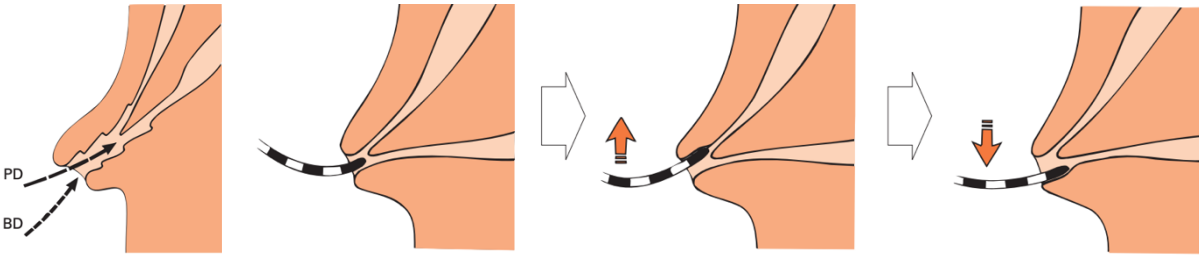


Fig. 6.30 The vertical axes for selective cannulation. BD, biliary duct; PD, pancreatic duct.

Fig. 6.31 (a) From the central catheter position . . .

(b) . . . lift up for the bile duct . . .

(c) . . . and drop down for the pancreatic duct.

Figure 14: Bile-, and pancreatic duct cannulation.

4.4.3 Pancreatic duct cannulation

Pancreatic duct cannulation is not the standard in ERCP. Most ERCPs desire bile duct cannulation where cannulation or even contact with the pancreatic duct should explicitly be avoided. In select cases (less then 10% of the performed procedures), however, pancreatic duct cannulation is the goal. For cannulation of the pancreatic duct, the duodenoscope should also be set in the en-face position and a bit to the left of the papilla. The pancreatic duct runs more perpendicular to the duodenal wall and advances towards the 2 o'clock (may variate between 1 o'clock and 3 o'clock) position from out the orifice. The catheter must therefore enter the floor of the orifice and then advance more to the right, to be in line with the horizontal and vertical axis of the pancreatic duct. To achieve a better overview of the position of the catheter, fluoroscopy can be used, but as mentioned before, the injected contrast increases the risk at post ERCP pancreatitis especially in the region of the pancreas.

4.4.4 Difficult cannulation

It must be mentioned that the above description of movements for cannulation is for normal papilla configuration, but an altered anatomy asks for another approach. In approximately 10 % of the cases, the term "difficult cannulation" applies. The papilla may be small, or buried in the diverticulum, or there may not even be an obvious cause. Based on literature, ≥10 minutes elapsed, ≥ 5 attempts and ≥ 4 pancreatic duct cannulations are reasonable parameters for difficult biliary cannulation [64]. The amount of attempts needed for cannulation, the elapsed time and the amount of pancreatic duct cannulations, are all factors that increase the risk at post ERCP pancreatitis [53, 54]. Bailey, Bourke and Kaffes showed that the risk at pancreatitis increases

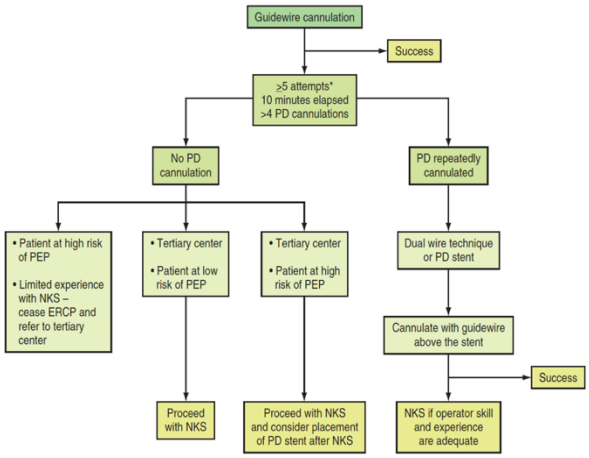
almost exponentially with the number of cannulation attempts [53]. When standard cannulation techniques turn out to be ineffective, it can be either decided to quit or to apply another technique. Cotton and Williams [2] described 8 tricks for difficult biliary cannulation:

What to do in case of a difficult bile duct: (Cotton and Williams [2]):

1. *Push in and angle up. Distorting the lateral duodenal wall may give a better view of the papilla.*
2. *Back off with the tip of the scope. The natural curl of the catheter can help achieve the upward axis if the papilla is approached from a greater distance.*
3. *Alternatively, get very close—the 'kissing technique':*
    a. *Have the catheter protruding minimally and the elevator lifted fully.*
    b. *Place the tip in the orifice using up angulation and scope withdrawal.*
    c. *Rotate the scope shaft sharply to the left to lift the tip of the catheter into the 11 o'clock position in the roof of the common channel and inject contrast.*
4. *Use a (double-lumen) sphincterotome. This makes it possible to change the angle of approach by bowing the tip. The stiffness of the instrument also facilitates the 'lifting' manoeuvre.*
5. *Try a tapered-tip catheter — carefully. Inadvertent submucosal injection can give alarming endoscopic and radiological appearances; usually it has no adverse clinical consequences but makes completion of the procedure more difficult, at least for several days.*
6. *Use a guidewire (preferably hydrophilic)—carefully. Sharp wires can be traumatic, but the technique is probably safer than repeated pancreatography:*
    a. *The assistant holds the accessories so that the guidewire protrudes about 6·mm from the catheter tip.*
    b. *Probe the roof of the common channel under fluoroscopy. If the pancreatic duct still contains contrast, the guidewire can be seen either to enter the pancreas (the duct moves on probing) or to advance easily in a different direction; then it must be in the bile duct;*
    c. *Advance the catheter into the duct over the wire, remove the wire, aspirate bile and then inject contrast.*
7. *Combine techniques 4 and 6 using a sphincterotome and a guidewire.*
8. *Pre-cutting (with a needle knife) is popular with some experts. However, there are risks involved; we recommend pre-cutting only for strong indications and not for diagnostic cholangiography alone.*

In case the procedure has been prolonged and/or the pancreatic duct has been injected with contrast or cannulated several times, it may be wise to abort ERCP because of the increasingly large risk at complications.

In advance of the procedure, the gastroenterologist should always have a strategy for coping with difficult biliary cannulation in the event that this will happen, because brainstorming during the procedure or unlimited trial and error would increase the risk of complications. There are several algorithms provided in literature to handle difficult cannulation [1, 52, 65, 66]. When the pancreatic duct is repeatedly cannulated unintentionally, biliary cannulation should be attempted with dual wire technique or pancreatic stent placement. Dual wire is the technique explained previously in which first a wire is placed in the pancreatic duct and thereafter the bile duct is cannulated with another wire. In pancreatic stent placement, a stent is placed in the pancreatic duct. The pancreatic stent functions as a tool to open up the papilla in another direction, just like the dual wire technique, but additionally the pancreatic stent reduces the risk of post ERCP pancreatitis due to its ability to decrease the pressure gradient across the pancreatic sphincter [67]. Since the risk at post ERCP pancreatitis is already quite large after multiple cannulation attempts, this is could be a valuable feature.



*The number of attempts will vary depending on patient risk for PEP and operator experience. Placement of PD stent preferred to double-wire technique.
NKS, Needle-knife sphincterotomy; *PD,* pancreatic duct; *PEP,* post-ERCP pancreatitis.

Figure 15: Algorithm for selective biliary cannulation during ERCP [1].

When cannulation is not achieved with catheters, sphincterotomes and guidewires, a final attempt can be done with needle-knife sphincterotomy (or pre-cut). The needle knife cuts the upper layers of the papilla (submucosa and mucosa) open to expose the biliary orifice and facilitate entry. Needle-knife sphincterotomy is often traditionally seen as a last resort only reserved for experienced gastroenterologist due to its risky character and high chance at pancreatitis, described in early studies [61]. More recent studies, however, showed that early use of needle-knife sphincterotomy did not increase the risk at pancreatitis, when performed by an experienced gastroenterologist, and even support early use of this cannulation method in selected cases [68, 69].

4.5 Instruments

Instruments for cannulation can be roughly divided into three categories: “basic catheters” with a possibly a flexible tip, containing one of two lumens for the passage of contrast or a wire, or “sphincterotomes”, containing an electrosurgical cutting wire at the distal end of the catheter to make incisions in the major (or minor) papilla. Although the main function of the cutting wire is sphincterotomy (cutting) for primarily stone extraction, the wire can also be used to deflect the tip in the proper axis for cannulation. The last category is “access (precut) papillotomy catheters”. These precut catheters make an incision in the papilla prior to cannulation and are used when standard methods for cannulation failed. The most commonly precut cannulation device is the needle-knife catheter, that uses a retractable electrosurgical cutting wire, but small scissors can also be incorporated in the catheter.

4.6 Balloon/basket stone extraction

The extraction of stones can be done using either a basket or a balloon, with sphincterotomy or biliary dilation (in case of bile stones). Either sphincterotomy or biliary dilation is needed, to make passage of the stones through the narrow duct and papilla possible. Biliary stones smaller then 10mm in diameter can be removed intact, while larger stones often require fragmentation [70, 71]. The bigger the stones get, the smaller the success rate of extraction becomes [71].

Smaller stones can be removed with Endoscopic papillary balloon dilation (EPBD), instead of sphincterotomy, which avoids cutting and damaging the sphincter. In EPDB a balloon catheter gradually inflates in the opening of the papilla. The balloon contains diluted contrast in order to visualize the position of the balloon and to observe the waist. When the waist disappears, no stricture should be expected, and further inflation can be maintained. The fully inflated balloon keeps its position for 20 to 45 seconds in order to widen the papilla and then deflates. This process can be repeated when necessary. EPDB was, however, nearly abandoned when studies showed an severe risk at EPDB related pancreatitis when used for large stones [72]. EPDB is now only used for small stones, where the risk at adverse events is lower and the success rate is comparable with sphincterotomy [73]. But since quite some gastroenterologist have concerns about the possible adverse events, sphincterotomy is the still the conventional way of enlarging the papilla. The sphincterotome cuts the papilla and sphincter open to enlarge the passage. The size of the incision should always be in proportion with the size of the stone, to both ensure easy passage of the stone and to avoid permanent damage to the sphincter. A combination of both balloon dilation and sphincterotomy seems very promising: similar percentages of stone clearance are achieved as for sphincterotomy alone, but the risk of adverse events and pancreatitis is lower [74].

4.6.1 Balloon

After selective cannulation with the balloon catheter and injecting contrast to visualize the stone, the balloon is first insufflated below the level of the stone (to measure the width of the passage) and then retracted (to check for blockages and avoid impaction of the stone). The extraction balloon can have a diameter of 8 to 20 mm and the air volume can be regulated with a two-way stop clock. Second, the uninflated balloon catheter is positioned above the stone by passing the stone with the thin catheter, whereupon the balloon is inflated, and the catheter is retracted, taking the stone with it. The stone is then gently pulled through the papilla into the duodenum and will be secreted out of the body in the natural way. An advantage of the balloon extraction is that it ensures complete clearance of the duct. Since the balloon covers the complete cross-section of the duct, residual small stones and debris get dragged along the way. Another advantage is that the balloon catheter can be inserted over a guide wire, making removal of intrahepatic stones also possible. Also, balloon extraction allows for clear occlusion cholangiograms. Finally, the balloon catheter cannot get stuck (impacted) in the duct due to its ability to shrink in volume. A severe disadvantage of balloon extraction is that the traction force is often not high enough to remove larger stones.

4.6.2 Basket

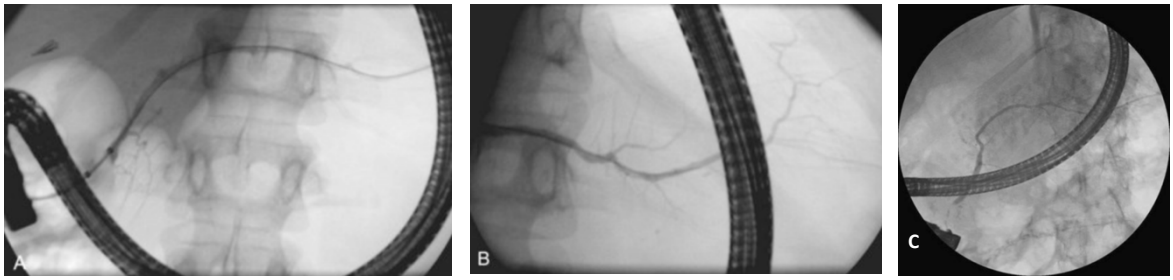
Another way of removing stones is with a basket. The baskets vary in sizes and configurations (e.g.; hexagonal, spiral, flower, helical). After cannulation and contrast injection for visualization, the wires of the basket maneuver along and around the stone by slowly pushing the catheter. The basket is then closed to firmly capture to stones in the basket. The basket can then be retracted all the way through the papilla and opened in the duodenum to release the stone there. The basket can be advanced over a guidewire or visualized by contrast. Baskets provide, overall, a better traction force, making it ideally suited for stones of medium size. Ozawa showed that quite some medium sized stones that could not be removed by the balloon catheter because no sufficient traction force could be applied, could be removed successfully by a basket catheter [75]. Small stones are, however, more difficult to capture by a basket then with a balloon catheter and another serious drawback of the basket is that it can get impacted in the lower bile duct or the papilla. The risk at basket impaction is the main reason for the United

States to prefer balloon catheters [76]. Lastly, an advantage of the basket is that large stones can be broken down by the strong wires of the basket itself, with mechanical lithotripsy (crushing the stones between the wires of the basket), balloon catheters must do this breakage in a separate act. Concluding: the preference for either balloon or basket extraction depends on the gastroenterologist and the situation, since both methods got some advantages and disadvantages relative to each other.

4.7 Pancreatogram

Conducting a cholangiogram (radiographic image of the biliary tree) is almost standard for therapeutic ERCP, since biliary therapy is more common and injecting contrast is less risky in this area. Pancreatography is more difficult and riskier. Therefore, it should be conducted only after sincere consideration. The shape, course, dimensions (although limited), volume and distribution of the main pancreatic duct are made visible during pancreatography for optimal guidance during therapy. Sometimes also the side branches can be visualized, but this is risky (even more prone to overfilling) and often irrelevant since the therapies are most commonly intended for and limited to the pancreatic duct. The reason why pancreatography is so risky, is that the injection of contrast in the pancreatic duct significantly increases the risk at pancreatitis [54]. Overfilling of the pancreatic duct can already occur with small amounts of contrast, making injection of the propriate amount a difficult and precise task. “Feathering” is a technique in which mild successive taps are applied on the syringe to provide a more controlled and subtle injection of the contrast. Overfilling can be identified on the pancreatogram as halos shaped in fuzzy structures, covering the pancreatic duct and its branches. This effect is called “acinarization” and is caused by the pressure and dense opacification of the tertiary, quaternary or smaller structure of the pancreatic duct. Segmental acinarization can also be caused by a stricture or stone that causes injection upstream of downstream, or when the catheter is impacted in a side branch of the duct.

Besides the guidance during therapy, pancreatography is also useful for diagnostic purpose. Different pathologies can be identified during pancreatography (e.g. ductal leaks, abnormalities in the duct or branches, filling defects or filled cystic spaces), each associated with a certain diagnosis.



***A** and **B**, Normal dorsal duct pancreatogram of head (**A**) and body and tail (**B**) regions. **C** Acinarization of the pancreatic body from overinjection of contrast material, [8]*

Figure 16: Pancreatogram images [8].

4.8 Stent placement (pancreatic and biliary)

Stents can either be made of plastic or metal, each comprising a variety of different sizes, lengths and shapes (straight or pigtail) for both pancreatic and biliary applications. The length is chosen as short as possible, extending from just above the obstruction to the duodenum (before the opposing wall). Plastic stents are made of Teflon, polyethylene or polyurethane and are cheap, easy insertable and effective for decreasing the pressure. Plastic stents need to be replaced approximately every three months, since the relatively small diameter (the diameter of the working channel of the scope at max) encourages the growth of bacterial biofilm and the accumulation of debris [77]. Self-expandable metal stents were introduced to reduce the reintervention frequency by extending the patency duration to six months. Since their post-expansion diameter can reach three times the diameter of plastic stents, occlusion/stenosis occur less quick, and therefore the patient has to come back less often for stent exchange. Bare metal stents however have severe limitations, making them (until recently) only suitable for biliary applications in patients with limited life expectancy. Metal stents integrate into the biliary wall and are therefore impossible to remove when blockage or patency requires to. For this reason, metal stents are traditionally only used in patients with limited life expectancy. Fully covered self-expendable stents have a silicon or PTFE coating that prevents ingrowth, enabling stent replacement. Therefore, the interest in using these stents for other applications then just the terminal patients is increasing. The coated metal stents, however, also have some drawbacks: possible migration of the stent, risk of cholecystic and high costs.

Biliary stents are used as an alternative to surgical bypass, for temporary or long-term drainage to treat and decompress (malignant or benign) obstructions/strictures for almost four decades [78]. Besides obstructions/strictures, stents can also be used for cannulation, leaks and some other purposes. Temporary drainage by stenting can be applied in case of postoperative obstructions, leaks, benign strictures, failed stone removal, or before surgical treatment as palliation. Benign biliary strictures

are the main reason for biliary stenting and can be cause by liver transplantation [79], primary sclerosing cholangitis [80], post operation injuries [81] and chronic pancreatitis [82]. Long term drainage (provided by stents) is provided for inoperable benign or malignant strictures of high-risk patients with larges stones. Long-term drainage indicates that the drainage provided by the stent should be permanent, but to be permanent the stent should be replaced periodically (except for terminal patients with a life expectancy less than the patency time. Occlusion is a common complication for biliary stents, caused by either the sludge in plastic stents or the tissue overgrowth in metal stents. Occlusion can lead to cholangitis or cholecystitis, but also migration can be the cause of inflammation. Migration of the stent is not rare but the effect that it causes varies. Quite often migration causes cholangitis or obstruction, but in rare cases perforation of the duodenal wall or obstruction of the bowel can take place [83].

Pancreatic stents are designed to minimize injury to the pancreatic duct, by being flexible and small of diameter. Therefore, pancreatic stents are almost always plastic. Pancreatic stents often contain multiple perforations to facilitate drainage from side branches. Pancreatic stents are used in the treatment of chronic pancreatitis (stricture dilation), pancreatic leaks, a pancreas divisum, pancreatic fluid collections, and sometimes for pancreatic malignancies that cause pancreatitis. Temporary pancreatic stents placement showed efficiency in the prevention of post ERCP pancreatitis, especially when the pancreatic duct is cannulated multiple times or in patients with higher risk [84]. Even for difficult biliary cannulations, pancreatic stents can be used to ease up biliary cannulation. There are, however, numerous complications associated with pancreatic stents, including: intensification or development of pancreatitis, duct disruption, quick occlusion (50% by six weeks and 100% by nine weeks [85]), stent migration (7.5% inward and 5.2% outward [86]), infection and stricture formation.

All stents are placed with a guidewire to guide along and a pusher tube to release the stent with. Larger stents also make use of an inner guiding catheter that enhances stability to facilitate the passage through tight strictures. The inner guiding tube passes over the guidewire and the stent and pusher tube subsequently pass over the guiding tube. Dilation or sphincterotomy is often not necessary, except when multiple stents are placed. Placing multiple stents proved to be useful for biliary benign strictures [87] because the greater stricture dilation can be achieved then with a single stent and multiple stents lower the chance at simultaneous occlusion of all stents; even if so, some bile can flow through the space between the stents.

4.9 Stent extraction (pancreatic and biliary)

Due to their limited patency, removal/exchange of stents is eventually always necessary (except for terminal patients). In some cases, e.g.; migration, accelerated occlusion or other adverse events, stents need to be removed prematurely. Plastic biliary stents are can almost always be removed quite easily, when accessible [88]. Migration can make the stents harder to access, especially the proximal migrated stents are more difficult to retrieve (removability of proximally migrated plastic stents ranges from 70% to 100% [88, 89]). Factors that complicate the extraction of proximal migrated stent include: impaction of the stent into the ductal wall, migration into the more peripheral branches or more upstream from a narrowed area. When extraction fails, a second stent can be placed to facilitate drainage, and removal of the first stent is attempted again during the upcoming extraction/replacement of the second stent [90]. Stents that migrated in distal direction often don't cause a problem, since they can pass through the intestine.

Fully covered self-expandable metal stents were introduced to be the removable version of metal stents, but still there are severe concerns about their extractability and the technique to do so, due to quite some cases of very difficult or even impossible removal [91, 92]. The mesh structure, with variating designs, may ask for another way of extraction then the smooth surface of plastic stents and the removability is hypothesized to be related to the mesh structure (zigzag or interlaced) [93].

Stents can be extracted with polypectomy snares, stone-extraction baskets and foreign-body retrieval forceps. The technique for extraction also variates, depending on the difficulty of the case. In easier cases the stent can just be grabbed with a snare (most commonly), forceps or a basket, and pulled into the biopsy portal. Indirect grasping is a technique used for proximally migrated stents. The lasso technique, using a guidewire the insert the lumen of the stent and a polypectomy snare to pass over it and grasp the stent. Some other techniques for stent retrieval are: Soehendra stent retriever technique, dilating balloon extraction, stent-in-stent and trimming of the self-expendable stent. Adverse events during or after the extraction of biliary stents arise in 0% to 9% of the cases [93, 94], and include: bleeding, pain, leakage, strictures and acute pancreatitis. Pancreatic stent extraction is advised to be conducted by an experienced endoscopist, since the risk at adverse events is 13%, including post ERCP pancreatitis, stent fragmentation, leakage and pancreatic duct disruption [95]. The techniques for pancreatic stent extraction are more or less the same as for biliary stent extraction.

4.10 Drainage

Drainage can be done endoscopically or percutaneously (not with ERCP) as a measure for decompression. Studies on comparing the success rate and complications/adverse for endoscopic and surgical drainage show variating outcomes [96-99], but since this literature study is about ERCP, only endoscopic drainage is going to be elaborated in this section. There are two types of endoscopic drainage: external (naso) and internal (stenting) drainage. Stent placement is already covered in *4.8 Stent placement (pancreatic and biliary)* and will therefore not be addressed here again. External drainage uses nasobiliary/nasopancreatic tubes, that are in essence very long stents, running all the way to the nose instead of debouching in the duodenum. The indications for placing nasobiliary/nasopancreatic tubes are also more or less the same as for biliary or

pancreatic stents. Although nasobiliary/nasopancreatic tubes are easy to remove (no endoscopy needed), allow for non-invasive cholangiograms or pancreatograms, and provide irrigation for mucus or debris, nasobiliary/nasopancreatic tubes are not the initial and/or conventional method of drainage, since it causes severe patient discomfort, risk for dislodgement and reposition the tube from the mouth to the nose is difficult. In select situations, for instance when very short-time drainage is needed in combination with incomplete stone clearance, nasobiliary/nasopancreatic tubes can offer a solution.

4.11 Manometry (pancreatic and biliary)

The sphincter of Oddi is a structure of smooth muscles that forms around the pancreatic duct, the common bile duct and the common channel (if present). When performing a manometry of the Sphincter of Oddi, often only the pressure of the biliary segment (of the sphincter) is measured to ease up the procedure and to minimize the risk at pancreatitis.
There are, however, concerns about the diagnostic abilities when measuring only one of the sphincters instead of both [100, 101]. Some diagnosis might be missed [102]. The rate of adverse events after performing SOM in patients with SOD is alarmingly high. Several studies, however, show that the risk is not related to the performance of the manometry [12, 103, 104]. The belief [105, 106] that manometry increases the risk at PEP is rather undifferentiated, since most studies that link manometry to PEP are done on patients suspected of SOD. SOD is on itself a severe risk factor PEP, no matter what kind of ERCP is performed [54].

A manometry catheter is used to perform the measurements in a SOM. The catheter is passed through the working channel of the duodenoscope, and advanced into the desired duct. Cannulation can be achieved with a guidewire or contrast. In the desired duct the pressure can be measured, whereafter the catheter can be withdrawn slowly, with repetitive small pulls. If desired, cannulation and manometry of the other duct can be performed, subsequently.

4.12 Sphincterotomy

Especially for large common bile duct stones, biliary sphincterotomy is often needed to retract the stones out of the narrow papilla (see stone extraction). Sphincterotomy is also used in difficult cannulations, by means of a pre-cut (see cannulation). An incision is made in the papilla and sphincter, facilitating easier access with the sphincterotome catheter. Sphincterotomy is also done in selective cases, prior to the placement of multiple large biliary stents, to create a wide enough passage to insert these. Lastly, sphincterotomy has become the preferred approach for treating patients with a type 2 SOD [107]. Because of the smaller papilla and narrow opening, typical for SOD patients, sphincterotomy is more difficult and riskier in SOD patients. Therefore, sphincterotomy should only be performed in these patients by very experienced gastroenterologist.

Although biliary sphincterotomy is more conventional, sometimes pancreatic sphincterotomy is performed as therapy as well. Most often pancreatic sphincterotomy is conducted as secondary therapy to facilitate another intervention. However, for some cases of SOD, chronic pancreatitis with papillary stricture/stenosis or a pancreatic divisum, pancreatic sphincterotomy is performed as primary therapy.

4.12.1 Developments

The constant development of new treatment possibilities is accompanied by greater technical demands. Gastroenterologist not only need to master a greater variety of tasks, but the innovative tasks often have a higher complexity as well. In the first years of ERCP, skills of the gastroenterologist existed of maneuvers or procedures that considered today as routine (e.g. cannulation of the ampulla) or the least complex interventions (e.g. standard sphincterotomy, extraction of small stones, stent placement) [108]. Over time, new complicated techniques were developed to treat the more complex cases (Billroth II anatomy) and other, until then untreatable, pancreaticobiliary diseases (removal of pancreatic stones). The relatively high-risk profile of ERCP, combined with its increasing complexity and diversity, makes ERCP a procedure which demands great competence. Competency of the gastroenterologist is essential for technical success of the procedure and minimizing the adverse events/complications and can only be achieved with sufficient knowledge of the different procedures and their technical aspects.

5 COMPLICATIONS OF ERCP

In this chapter, the possible complications will be discussed. It is important to get an insight in what the complications are and what the reason is for occurring. By identifying the risks and their source, the need for training will be exposed and, subsequentially, a proper training can be developed that focusses on training the core issues of ERCP.

5.1 Severity of the complications

ERCP is, as mentioned before, a challenging procedure and can therefore cause a wide variety of adverse events (also referred to as "complications"), ranging from minor and short-term, to severe, chronic and even death. Cotton et al. [109], developed a grading system for the major complications of ERCP and subdivided each complication into mild, moderate or severe.

Table 3: Consensus Definitions for the Major Adverse Events of ERCP, by Cotton et al [109]

	Mild	***Moderate***	***Severe***
Pancreatitis	Clinical pancreatitis, amylase at least three times normal more than 24 hours after the procedure, requiring admission or prolongation of planned admission to 2 to 3 days	Pancreatitis requiring hospitalization of 4 to 10 days	Hospitalization for more than 10 days, pseudocyst, or intervention (percutaneous drainage or surgery)
Bleeding	Clinical (i.e., not just endoscopic) evidence of bleeding, hemoglobin drop <3 g, no transfusion	Transfusion (4 units or fewer), no angiographic intervention or surgery	Transfusion (5 units or more), or intervention (angiographic or surgical)
Perforation	Possible, or only very slight leak of fluid or contrast, treatable by fluids and suction for ≤3 days	Any definite perforation treated medically for 4 to 10 days	Medical treatment for more than 10 days, or intervention (percutaneous or surgical)
Infection (cholangitis)	>38°C for 24 to 48 hours	Febrile or septic illness requiring more than 3 days of hospital treatment or percutaneous intervention	Septic shock or surgery

5.2 (Post ERCP) Pancreatitis

Pancreatitis is in nearly all studies the most common complication of ERCP. The rate varies quite much, but the average in the three most cited papers is around 3% [12, 110, 111]. Freeman et al [12] report in their study the highest PEP rate: 5.4% (127 in 2347 patients), of which 2,3% mild, 2.8% moderate and 0.4% severe. A mild pancreatitis goes accompanied by amylase levels that are three times higher than normal 24 hours after the procedure. Two to three extra hospital days are needed for treating this adverse event. A moderate pancreatitis requires four to ten extra hospital days. A severe pancreatitis demands more than 10 extra days, to for instance perform drainage of a pseudocyst or surgical intervention. Factors that increase the risk at PEP are: young age of patient (varies a bit between studies, either <60 years or <70 years), pre-cut, stone removal, difficult cannulation, combined percutaneous endoscopic procedure, suspected SOD, cirrhosis and a) small treatment center (Literature Study, J. Wesseling).

There are several techniques or methods to reduce the risk at PEP, but these are not applicable in every situation. Guidewire cannulation reduces the risk at PEP compared with contrast guided cannulation, since more than one contrast injection already enlarge the risk at PEP. Stent placement after biliary sphincterotomy for SOD [112], balloon dilation of the biliary sphincter [113], pancreatic sphincterotomy [114] and pre-cuts [115]. Some pharmacologic agents also proved their efficiency in reducing PEP [116], but availability and administering can be a problem.

5.3 Hemorrhage

A bit of bleeding, occurring quite often, is on itself not an adverse outcome towards the patient. When the blood loss gets clinically significant the term "hemorrhage" is used. The hemorrhage is mild if there is a clinical evidence of bleeding which is not just endoscopic, like for instance a hemoglobin drop to <3 g. Overall hemorrhage occurs approximately in 1,30% of the patients. Mild hemorrhage, occurring in 0.6% according to the study of Freeman et al [12], does not require a blood transfusion, but can be uncomfortable for the patient. Moderate hemorrhage, occurring in 0.9%, is characterized by a need for blood transfusion (≤ 4 units) but no surgical or angiographical intervention is needed in for this type of hemorrhage. Severe hemorrhage occurs in 0.5% and requires a blood transfusion of at least 5 units or surgical or angiographic intervention. Risk factors for hemorrhage are: Anticoagulation within three days after surgery (OR 5.11), coagulopathy before procedure (OR 3.32), small institution/center (OR 2.95), cholangitis before procedure (OR 2.59), obstructed papilla of Vater opening (OR 2.57), pre-cut (OR 2.45), mean case volume of endoscopist not more than one a week (OR 2.17), bleeding during procedure (OR 1.74) [12]. Hemorrhage can be minimized by replacing sphincterotomy by balloon dilation in patients with risk factors as coagulopathy. Also, the use of a blended current instead of a pure-cutting current [117] and the prophylactic injection of hypertonic saline-epinephrine proximal to the papilla [118] showed to reduce the risk at hemorrhage after sphincterotomy.

5.4 Perforation

Perforation can be done with the endoscope, but also with the catheter or the instruments (e.g. a stent or a guidewire). The perforation can occur in different sections of the body, endoscopic perforation for instance occurs within the bowel wall, while stents, guidewires or extended sphincterotomy can induce biliary or pancreatic duct perforations. What kind of perforation occurred is not always mentioned in literature, but the studies of Masci et al [111], Freeman et al [12] and Loperfido et al [110] report a (mean) perforation of the bowel wall with an endoscope in 0.32% of the patients and only Masci et al reports perforation during sphincterotomy (in 0.57% of the patients). Risk factors for duodenal perforation with an endoscope are: intramural injection of contrast medium (OR 12.35), Billroth II gastrectomy (OR 10.24) and pre-cut (OR 10.08) [110]. These high numbers highlight the need for careful consideration of the technique used during the operation. But it must be mentioned that due to the low occurrence perforations, its difficult to properly rate the risk factors. The numbers can therefore be a bit extreme.

Bowel wall perforations often need to be treated with surgical intervention. Duct perforations can often be treated (if not too severe) with endoscopic drainage [119]. Ways to avoid perforation also depend on the type of perforation. Sphincterotomy-caused perforations can be minimized by decreasing the length of the cutting wire that is in contact with the tissue. If perforation is suspected and thereafter detected by injection contrast, clipping can be performed to close the gap [120]. To prevent bile or pancreatic juices to leak into cavities, covered self-expendable metallic stent can be used for drainage [121]. If the perforation is not severe, solely suction can sometimes be enough.

5.5 Cholangitis

Cholangitis after ERCP occurs in about 0.81% of the patients. It is identified by a fever for 24 to 48 hours after the ERCP, with probably a biliary cause. The risk factors for Cholangitis after ERCP are jaundice (OR 4.77) and a small center (4.71) [110]. The best way to prevent cholangitis is by performing the ERCP by a specialized trained endoscopist in a large center. When jaundice is present, an alternative operation could also be considered to minimize the risk for infection.

5.6 Other complications

Other complication of ERCP are: Cholecystitis (0.35 %), basket trapping (0.12 %), cardiopulmonary events (0.20 %), drugs side effects (0.04 %) and death (0.12 %)[111]. These complications occur very seldom. None of the studies of Freeman et al [12], Loperfido et al [110] and Masci et al [111] have investigated the risk factors for these complications, probably due to their low occurrence rate.

5.7 Complications due to trainee performance or participation

For all different complications, factors are mentioned that increase the risk of occurring, but a factor that affects the success rate and increases the complication rate of ERCP in general, is the level of experience of the endoscopist and trainee participation. The fact that trainees or inexperienced performers form a greater risk to the patient might seem obvious, but it is important to highlight this, because despite its risks, master-apprentice training still seems to be the golden standard for ERCP training. The drastic need for simulation training becomes evident by pointing out the riskiness of trainee participation or inexperienced performers.

Cheng et al [13], Testoni [15], Cotton et al. [16], Rabenstein and Freeman [122, 123], all found that the risk at PEP increased when trainees where involved in the operation. Also, Williams showed that trainee involvement increases the risk at first time cannulation failure [124] and that the overall success rate of cannulation reduces to due to trainee participation [21]. Additionally, Voiosu et al [125] demonstrate an increase in cannulation success rates with the years of (performer) experience. The rate of procedure-related complications is 3% for experienced endoscopists versus 7% to 15% for inexperienced endoscopists [126].

The importance of sufficient practice becomes even more clear in the study by Jowell [127], which demonstrates that an “acceptable score”, a success rate of 65%, for deep biliary cannulation only occurs after performing 180 procedures. This issue is covered more extensively in *6.3 Defining objectives for the simulator*.

PART 2

DESIGN DIRECTIONS

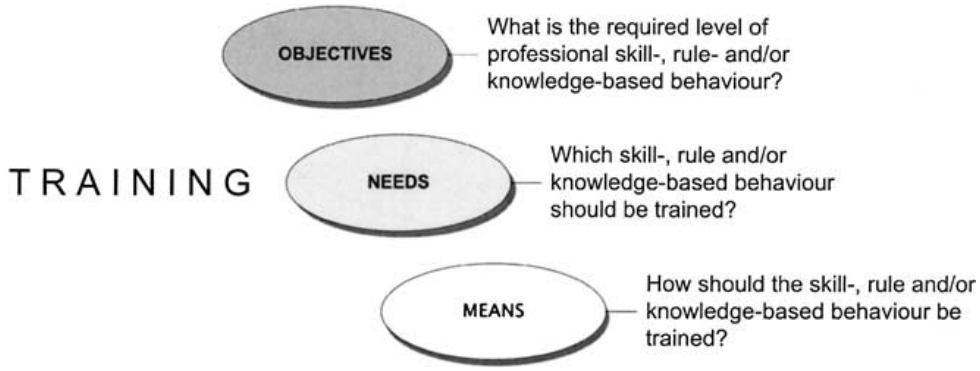


Figure 17: Training objectives, needs, means [7]

For developing the independently executable training for the ERCP trainer, the ideas of Wentink et al will be used (Figure 17). Wentink et al [7] state that for designing an effective and efficient training method for laparoscopic surgery, determining the training objectives, needs and means is crucial, since defining these three will provide an answer to the questions: What is the end goal of the training? (objectives), What should be trained? (needs), and How can we train it? (means).

6 TRAINING OBJECTIVES

The training objectives represent the level of competence that is expected of the trainee after completion of the designed training. The level of professional skill-, rule-, and knowledge-based behavior (described in 7 TRAINING NEEDS) that should be acquired by the trainee is determined by the set objectives. A training is effective when all training objectives are met. The overall goal of training for any kind of medical procedure, and thus also for ERCP, is to achieve competence. Therefore, the definition of competence for ERCP in general will first be discussed chapter. Till what extend competence should and could be achieved by training on the ERCP trainer (and its developed additions) will thereafter be discussed, which will result in formulating the objectives for the to-be-developed training. The goal of this chapter is to set the objectives for the individually executable training on the ERCP trainer.

6.1 Competence for ERCP in general

The definition of competence with regard to ERCP is rather inconsistent. In the ASGE credentialing guidelines, competence is defined as: "the minimal level of skill, knowledge, and/or expertise, derived through training and experience, required to safely and proficiently perform a task or procedure [128]". However, the core curriculum of the ASGE also explains that competence is difficult to define and quantify, and assessment is fairly subjective. The inconsistent definition may be due to the inequality of procedural cases for which the competency of performers is tested. One cannulation case might be considerably more difficult than another because of anatomical variations or numerous other reasons. Therefore, a rather general procedure as "cannulation" together with a certain minimum success rate or procedure volume, is a subjective and often unreliable measure for competence. More subdivision in procedures and variations in cases could make the definition and quantification of competence more clear (Literature Study, J. Wesseling), as well as more consistency and control over the assortment of procedural cases, which is possible with simulators.

Traditionally procedural volume is used as a benchmark for competence [128, 129] , but besides the fact that volume is a rather unreliable benchmark due to the highly variating skill acquisition rates amongst trainees, this benchmark does not provide any clarification on the types of skills that are needed for competence either (e.g. deep biliary cannulation, stone removal or pancreatic cannulation). Also, it remains unclear what the share of the trainee was during a procedure and how well the trainee performed, since every form of participation counts as a performed procedure. A success rate, of a variating amount (>80% [9, 22, 127, 130, 131], >85% [132, 133] and 90% [134, 135]) and for variating procedural acts (Pancreatic duct cannulation [127, 132], Selective duct cannulation [130, 131, 133-135] and Common bile duct cannulation [9, 22, 127, 132]), is increasingly used as a prerequisite for competence. This type of measurement accounts for the varying learning curves per procedure and per trainee. However, clarification still needs to be provided on when in the training process the measurement of the success rate should start, what the minimal amount of procedures is for defining the success rate and on how much assistance is allowed.

6.2 Competence on the simulator

Properly defining competence for ERCP in general is beyond the scope of this research (since it can be a thesis subject on its own due to all the different arguments and opinions formulated in literature), but it is, however, important to know what the trainee should be capable of at the end of their training period for the sake developing a proper simulator. To determine the set of skills that needs to be trained on the simulator, the objectives need to be identified. Because simulators are not intended to facilitate the full training program, the focus will only be on a selection of skills. Simulators can only be used for training till a certain extent, since trainees need to prove their skills in real practice at least a couple of times to their supervisor before full operating responsibility, and thus competence, can be ascertained. The general goal of training on a simulator is to significantly decrease the amount of clinical practice needed for achieving competence. To do so, the simulator must focus on training the main difficulties of ERCP; the ones that cost the trainees the most effort to get under control. These difficulties need to be identified and trained on. Objectives need to be formulated on when the goal of the simulator specific training is achieved, in other words: when simulator competence is achieved.

6.3 Defining objectives for the simulator

The frequency with which selective cannulation is used as a benchmark in literature already implies that cannulation can be a proper criteria for competency and with that a suited task to train on the simulator. This assumption is further strengthened by the fact that basically every ERCP procedure starts with cannulation and, moreover, in the study by Verma et al [22, 136], selective cannulation of the native papilla (in this case the common bile duct) showed to be even more difficult to achieve sufficient competence in then several sequential procedures as stone extraction, sphincterotomy and stent placement. The assumption that cannulation is the core element of ERCP and should therefore be the focus of the simulator training, was also confirmed by Dr. Voermans from the AMC. With practicing cannulation, the basic motor skills are taught. Acquiring these basic motor skills (e.g. controlling the side-viewing scope, hand-eye coordination from observing a display, scope positioning, precisely directing the catheter) seems to be the main challenge for trainees [58]. When cannulation skills are acquired and thus motor skills in controlling the scope and catheter are developed, achieving skills in the additional procedures will follow relatively quickly according to Dr. Voermans. Lastly, it is important to learn cannulation in the proper way to perform it with precision, since successful cannulation does not merely imply access of the duct of interest. It is also important to accomplish cannulation safe and efficiently in order to minimize complications.

For all these reasons listed above (its frequency of prevalence, its difficulty to get under control, its impact when not performed properly), cannulation will be the task to provide simulator training in. A certain success rate for selective cannulation on the simulator must therefore be set as the objective of the training for which simulator competence may be ascertained. To make sure that the set success rate criteria for competence is truly reliable, the circumstances and conditions need to be consequent for every training and measurement. Fortunately, the inconsistent and sometimes random factors (e.g. the amount of provided assistance or the difficulty level of the procedure) that distort the soundness of competence attribution in real clinical practice training, can often be controlled very well in simulation training due to the pre-programmability, which results in more legitimate competence accreditation. To preserve consistency, the exact difficulty level of the procedures for which the success rate is measured needs to be determined, the amount of procedures for which the success rate applies needs to be defined and equal for all trainees, and the moment at which the measurement starts in the training trajectory should be set and even as well for every trainee. This result in the following questions that must be answered in order to formulate a clear objective for the simulation training:

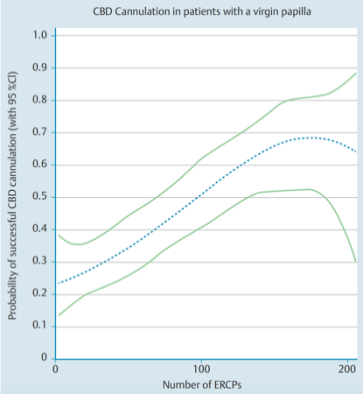
1. What should the exact minimum success rate of the trainee be for accrediting competence in selective cannulation on the ERCP trainer?

Procedures (in this case selective cannulation) on a simulator will always, to a certain extent, be slightly different from real clinical procedures. The act of selective cannulation may therefore be more difficult or easier on the simulator than in real clinical setting which can influence the choice for the set minimum success rate for competence on the simulator. The difficulty of selective cannulation on the simulator should therefore be compared with selective cannulation in real clinical practice. Expert Dr. Boškoski says that cannulation on the ERCP trainer is perceived as more difficult by many trainees since in this training model there is not opposing duodenal wall that facilitates backpressure and thus stabilization for the scope during cannulation. Combining the increased difficulty level with the finding that cannulation success rates variate between 80% and 90%, makes that the minimum selective cannulation success rate is for now set on 80%, but this can be adjusted based on try-outs. No distinction is made between deep, pancreatic or biliary cannulation, since the perceived difficulty for each of those two may variates per individual and eventually all of them need to be executable in any order for competence in selective cannulation.

2. What should the minimum amount of procedures be for determining the success rate?

The sample size (amount of procedures to base the success rate on) must meet a certain value in order for the success rate to be reliable. The minimum sample size also relies upon the moment at which the measurement starts, since the performance is likely to improve over time. When the first attempts are already incorporated in sample, quite a large sample size is needed in order for the average success rate to achieve 80%. It is therefore better to work with successive blocks. This if further explained in the answer on the next question.

3. At which moment in training should the measurement of competence (the success rate) start, and what should the minimum sample size be for determining the success rate?



Successive ERCP blocks	Trainees, n	Successful CBD cannulation, %	Range
1 to 20	12	26.7	0 % – 40.0 %
21 to 40	11	23.4	0 % – 50.0 %
41 to 60	11	30.0	0 % – 60.0 %
61 to 80	10	36.0	0 % – 60.0 %
81 to 100	8	52.6	0 % – 70.0 %
101 to 120	8	57.0	20.0 % – 80.0 %
121 to 140	4	56.5	25.0 % – 80.0 %
141 to 160	4	58.6	33.0 % – 86.0 %
161 to 180	2	60.7	50.0 % – 71.0 %
181 to 200	1	87.5	Not applicable

Figure 18: Cannulation success rates for increasing amount of performed procedures [9].

Left: Probability of a successful common bile duct (CBD) cannulation in patients with a virgin papilla, by trainees in endoscopic retrograde cholangiopancreatography. Right: Success of cannulation of the common bile duct (CBD) by trainees for successive groups of 20 procedures in patients with a virgin papilla (n=624 ERCP's)

There are several ways to measure the trainee's performance: periodically or constantly, immediately at the beginning of training or after some practice. Measuring from the very first instant on has the advantage that the learning curves can be observed very accurately since the measurement and thus the analysis of the performance occurs from the beginning till the end of the learning process. Immediate assessment, however, puts pressure on the trainee from the very first moment on. The

fact that the trainee is immediately observed while his/her performance may count for the final assessment (in case a large sample size is taken for the mean success rate), could cause stress and possibly creates an environment in which no mistakes can be made. Starting measurement after a period of unbound practice provides the freedom to make mistakes when getting familiar with the device and the task. The problem is, however, that it remains difficult to find an optimal moment for starting the measurement, and the learning curves cannot be observed from the beginning on.

The third option is to start measuring from the beginning on but to do consecutive measurements with a smaller sample size instead of one large sample for calculating the success rate. This way, the process is taken into account: poor performances from the beginning of training do not affect the measured success rate anymore when further in the training process. When measuring a mean success rate for a process for which the performance and thus the success rate increase over time (experience), a relatively small sample size is therefore preferred. However, for the success rate to be significant, the sample size should not be too small either. In an article which studied the learning curves of novices during ERCP training, Ekkelenkamp [9] measured the success rate successively for blocks of 20 ERCPs (see Figure 18). This type of measurement provides insight in the trainees complete learning process, while competence is measured adequately and the pressure on the trainee is reduced since for determining the success rate, only the latest 20 results are taken into account. Successive measurements of 20 ERCPs until the success rate of 80% is reached, will therefore also be used for this research project.

4. What should be the difficulty level(s) of the procedures for achieving competence on the simulator?

Competence should only be accredited when cannulation can be achieved for the more difficult cases as well. More difficult cannulation cases, as described in 4.4.4 Difficult cannulation, should therefore be facilitated in the model and be included in the blocks of competence measurement. What the different scenario's will be for the more difficult cases depends on the capabilities of the model. The ERCP trainer has the possibility to adjust the size of the papilla orifice, the configuration of the ducts (e.g. small or large common channel) and the orientation of the papilla, which provides numerous difficult, or at least different, cannulation cases. It is difficult to choose a percentage for the minimum of difficult cases to incorporate because the real perception of difficulty for each of the scenarios on the model will can only show from practical tests. The share of difficult cases for achieving competence is for now set on 50%, which means that 10 cases must be difficult in every block. This can, however, be adjusted later on based on the practical tests.

5. Till what extend will assistance allowed during the exercises?

The answer on this question is simple for an independently executable training; no assistance is allowed.

6.4 Defining objectives for the simulator, for the developmental phase.

The answers on the formulated questions offer clarification on when competence is achieved on the simulator and under which conditions is may be ascertained. A certain level of detail in defining competence is needed to create a more clear objective for the level of skills that is expected of the trainee after completing the training. Based on these set objectives, the training can be designed. The clarification of "competence in cannulation" was thus necessary to formulate the objective for the to-be-developed training, but it must be noted that in the developmental phase of training in which solutions must be found on how to make training on cannulation independently executable, the focus will not be on the precise benchmarks for the accreditation and assessment of competence just yet. First the workability, effectivity and efficiency of the developed solutions must be demonstrated before focusing on the details. The main training objective will therefore maybe shift a bit during the development of the training. In the beginning the main training objective will be rather general: facilitate independently executable cannulation training that shows to improve cannulation skills. Further on in the process the objective will get more specific: facilitating a cannulation training in which trainees efficiently achieve a simulator competence. Right now, the project is in its developmental phase, and therefore the training objective used for this thesis will be the first one: "facilitating independently executable cannulation training that shows to improve cannulation skills". When the developed means for properly training the skills that are required for cannulation are sufficiently developed and effective in training these skills, the focus can shift to implementing measures for accrediting overall competence. Due time limitations it is however not expected that this point (the shift in focus) will not be reached during this research project.

Because, in a later phase, the developed training must incorporate the function of determining the competence level of a trainee based on defined criteria such as those of *6.3 Defining objectives for the simulator*, the quantitative objectives as defined in *6.3 Defining objectives for the simulator* must still be kept in the back of the mind when designing the training program and the means. The developed mean for independent cannulation training must, in the end phase, perform certain quantitative measurements. Therefore, it might be useful to design the training mean(s) in a way that aspects as the statistic of the performance of an individual can, for instance, be saved.

6.5 Remaining secondary objectives

Besides the cannulation objective, there are several secondary objectives that the training should meet, which are focused on several different aspects of the device as well. In a prior conducted literature study (J. Wesseling) all models are ranked by how well significant features (of various impact levels) are represented in the model. This ranking is taken into account by means

of the secondary objectives; meaning that how well all the different features are presented in the ERCP trainer should remain the same or get better. When adjusting the ERCP trainer, important and positively present features (see Table 4) as the relatively low costs, no ethical concerns and patient safety should remain. Features as the pre-programmability, the documentation, time-limitation, part of routine training and objective assessment might be improved by the adjustments made for the main objective of individualizing practice.

Table 4: Features of the ERCP trainer rated (from Literature Study, J. Wesseling).

Feature	Pre-programmed	Demonstrates anatomy	Demonstrates motility (body dynamics)	Real scope/accessories	Papillotomy	Tactile sensation
Level of importance	1	2	1	2	2	3
Level of presence	Different papilla's, ducts and spacing possible	Simulated (crude)	x	Yes	No (bad artificial papilla)	Present

Feature	Coordination/ teamwork	Scoring of experience (compare overall results)	Clinical benefits (concurrent validation)	Anesthesia support needed	Animal technician support needed (installation)	Fluoroscopy
Level of importance	1	1	4	1	2	2
Level of presence	Yes	Good	Yes [26]	No	No	Real-time fluoroscopy image, not produced by performer

Feature	Estimated cost of model	Reusability	Special/ animal laboratory	Varying level of difficulties	Objective assessment	Documentation	Reproducibility
Level of importance	3	2	1	3	2	1	3
Level of presence	Relatively low	Unlimited	No	Yes	Yes	Manual	Yes

Feature	Part of routine training	Patient Safety	Ethical concerns	Assortment of procedures	real clinical setting	time limitation	Ease of use (portable/possible at very moment/set-up time)
Level of importance	3	4	3	3	1	2	2
Level of presence	Relatively easy	Safe	No	Moderate	No	No (limited supervision time of trainer)	Very good

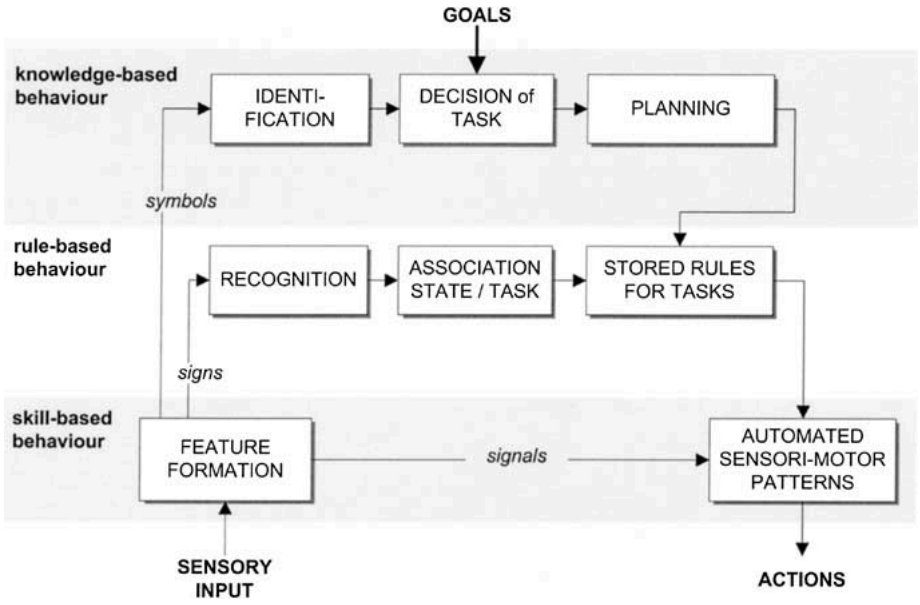
Level of importance: scale from 1 (least important) to 4 (most important)
Level of presence: red = bad/not represented, orange = medium represented, yellow = moderately represented, light green = well represented, dark green = very well represented.

7 TRAINING NEEDS

The training needs can be described as the difference between the initial level of competence of the trainees and the required level of competence (formulated in the training objectives). The amount and kind of training that is needed in skill-, rule-, knowledge-based behavior for meeting the set objectives is embodied in the training needs. The training needs specify what should be trained exactly in order to meet the set objective. To meet the objective, the training needs must be facilitated by some means. In this chapter the training needs for the training on the redesigned ERCP trainer will be defined.

7.1 Rasmussen's theory of human behavior

The act of cannulation consists of various different elements and steps that need to be combined or conducted consecutively in order to perform cannulation properly. In an effective and efficient training program, each of these elements thus needs to be covered and therefore all elements first need to be identified when designing the training on the ERCP trainer. Based on the human behavior theory of Rasmussen [137], the elements needed for performing the task of cannulation can be subdivided into three different categories: skill-based, rule-based and knowledge-based behavior.



Note that levels are not alternatives but interact in a way only rudimentarily represented in diagram.

Figure 19: Simplified illustration of three levels of performance of skilled human operators [137].

7.2 Skill-based behavior

Skills-based behavior is what takes place without conscious control. In endoscopy this behavior consists of the motor-skills (in some literature concerning ERCP also referred to as the technical skills) that are executed after an automated fast (and unconscious) selection of the suited muscles to do the job. For developing these skills from the level at which they may be perceived as challenging and execution is still very conscious, to the stage in which performance is automatic, unconscious and relatively easy, sufficient practical training is needed. Great parts of the ERCP performance can be seen as consecutive acts of skill-based behavior. During the automated skill-based behavior sensory information can additionally be perceived and direct the course of the skill-based behavior a bit. An example of this is visual information provided by the camera at the tip of the scope or the X-ray video/images during the procedure. The perceived sensory information is described by Rasmussen as a continuous signal. Skill-based behavior needed for the act of cannulation consist of the following elements:

1. **Controlling the scope** ***(Consists of:)***
   - Right/left rotating movements: by twisting left wrist (the hand holding the control section of the scope) or by applying torque to the insertion tube with right hand. By synchronizing both movements, torque can be applied to the scope even more efficiently.
   - Manipulate up/down angulation (or deflection) of the tip of the scope: Use first joint of thumb to control the up/down angulation knob (big knob). Down = clockwise, Up = counterclockwise.
   - To lock the position (up/down movement), the lever behind the large wheel should be pushed counterclockwise.
   - Manipulate right/left angulation of the tip of the scope: Use tip of thumb to control the right/left angulation know (smaller know). Right = clockwise, Left = counterclockwise.
   - To lock the left/right position, the lever on the small knob should be rotated counterclockwise

- To lift up the accessory (in cannulation case: catheter) coming out of the instrument channel, the elevator knob must be pushed forwards with the thumb of the left hand. The elevator in the distal tip should elevate in proportion to the distance the control knob is moved. The motion of the elevator and the knob should be smooth and easy without any "play" involved.

2. **Linking hand-eye coordination to the real-time images presented on the display (interact with the continuous signal)**

3. **Combine all movements to maneuver the scope to a position of interest, automated**

4. **Advancing a catheter through the biopsy port**

5. **Steering and guiding the catheter to a desired direction**

6. **Maintaining correct scope position while introducing and directing the catheter**

7.3 Rule-based behavior

Rule-based behavior is the behavior that is based upon imprinted information (the rules). A person reacts on a recognized situation in an orchestrated manner, according to the rules he/she learned for coping with that specific situation. Rule-based behavior is also typical for computer programming since it makes use of very clear rules: if <state X> then <action Y>. Rasmussen defines the perceived information at rule-based behavioral level as a discrete sign that can trigger a rule stored in the memory. For the recognition and the implementation of the corresponding action, moderate awareness is required. A clear example of rule-based behavior is hitting the brake when encountering a stop-sign in traffic. An example in ERCP is the algorithmic approach of coping with difficult cannulation, described in *4.4.4 Difficult cannulation*.

In literature on ERCP, rule-based behavior is not specifically mentioned. Often the somewhat more comprehensive term "cognitive skills" is used instead. While rule-based behavior is strictly speaking limited to decision making based on set rules, the cognitive skills include all theoretical knowledge needed for the act of cannulation: knowing what to do, how to do it and when, based upon imprinted knowledge and information. Instructions for how to perform certain act, for instance, fall under the cognitive skills. The instructions can also be interpreted as provided rules, but in this case there is no decision making involved since there is only one option. Instructions on how to perform an act can also be seen as rules, but then in the form of a protocol. Behavior based on these protocols is also important to learn and therefore some elements of the theoretical knowledge for cannulation should maybe be incorporated in the rule-based training needs as well. For developing the rule-based behavior or cognitive skills, sufficient study is needed in order to master all theoretical aspects of the task. This can be done by consulting literature, attending lectures, observing another's performance or watching informative videos. Technically, no practical training is needed for the development of the theoretical knowledge, although theory can also be learned in practice.

Composing the list of cognitive skills or rule-based behavior that should be covered in training on the simulator is less straightforward then the list of technical skills or skill-based behavior. Besides the directives for the act of cannulation specifically, there are numerous guidelines that apply for ERCP in general (e.g. knowing all clinical indications, contraindications, being aware of the limitation of ERCP, knowledge of the alternative options). Since this training is intended for beginners it could be argued that these general cognitive elements and protocol knowledge should be addressed in the training. In the United States the most common reason for legal allegation after ERCP is performing it without a good indication or based on wrong indications [33]. This is an important aspect for ERCP training, but it is not very well suited to implement into independent cannulation training on a simulator. The listed guidelines (knowing all clinical indications, contraindications, being aware of the limitation of ERCP, knowledge of the alternative options) can be categorized under the type of knowledge that can just as well be studied in books and thereafter tested by means of a written or oral exam. Some skills do not need the realistic environment of the OR to be effectively taught. Learning these aspects during practice may additionally also occur during the master-apprentice moments of training. A proper simulator can hopefully minimize the moments in which unskilled trainees practice on real patients and at least minimize the risk for the patient by taking on the first and most risky phase of training in which there is no control over the scope yet. But, although maybe till a lesser extent, master-apprentice teaching moments are still needed to acknowledge real clinical competence because simulators are not identical to the clinical situation yet. Written/oral exams and during practice teaching are a much simpler solution than implementing all these listed elements into practical independent simulator training. The focus of the rule-based needs that need to be implemented in the to-be-developed simulator training shall therefore be on the directives for cannulation specifically.

Although the rule-based behavior training needs are already limited to the cannulation related ones only, it remains debatable which exact rule-based needs should be implemented in the training. Especially in the first phase of training development, the training will be focused on facilitating practice in the cannulation essentials for beginners. Even within the subject "cannulation" the complexity of the procedure may vary due to anatomical variations, different papilla locations and alternative ductal and papillary orientations. For designing a basic cannulation training, it is therefore the question whether or not variations will be included and if yes, which ones. For determining if and which variations must be included in the training, the learning process

of beginners who practice independently on the ERCP trainer, first needs to be analyzed. Because the independent training on this simulator is completely new, there is no information about how difficult it is for a beginner to get a hold on even the most basic cannulation scenario. Based on analysis of the learning process, it can be determined if and which variations should be incorporated into the training. This analysis can take place by observing trainee's executing the (conceptual) version of the developed training. As for defining the main training objective, the set training needs in the beginning phase of training development will be more simple: "the cannulation rules for the most basic scenario" and might get more detailed and extensive in a later phase of the training development. The cognitive skills needed for cannulation consist of the following elements:

1. **Route to the papilla** *(consists of:)*
   - Being aware of and being able to cope with the effect of different patient positions
   - Knowing what maneuvers to make to pass the scope through the body up until the papilla

In literature the precise manner in which the scope is maneuvered through the mouth, esophagus, stomach and first part of the duodenum, is described as an important aspect of achieving the proper position in front of the papilla [2] (which is located on the duodenal wall of the second part of the duodenum). The whole route towards the papilla and all the acts needed to pass the route successfully, have been described in 4.2 Inserting the duodenoscope. According to Cotton et al [2] an incorrect way of advancing the scope to the papilla could result in patient discomfort because of redundant loops in the stomach and longer OR times. Moreover, practicing the route to the papilla already facilitates a way of gaining experience in directing the scope towards a position of interest.

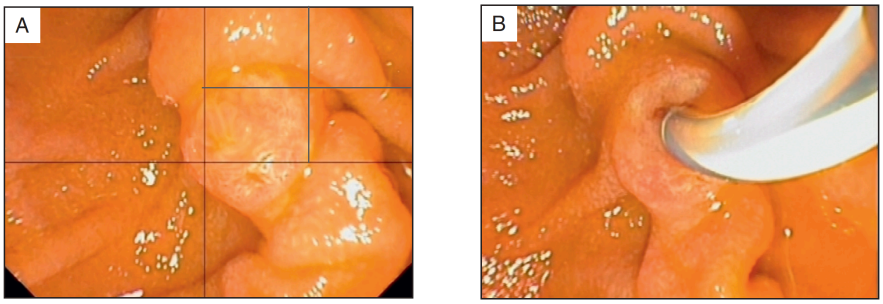
In the ERCP trainer of Boškoski and Costamagna the route is, however, scarcely represented: the scope is simply intubated via a tube of about 30cm's, which ends up in the area where the papilla is located. According to Boškoski, the route to the papilla indeed needs practice, but he argues that achieving competence in the route is relatively simple and may only take a couple of intubations. Moreover, skills in the route may develop quite automatically with gaining control over the scope in general. If the route to the papilla is, however, crucial for correct positioning, this should be implemented in the training. The first design concept should therefore facilitate a way of training the route to the papilla. It shall then be tested whether practicing the route has a positive influence on the overall process of achieving a proper position in front of the papilla with the end goal of successful cannulation.

2. **Anatomical knowledge** *(consists of:)*
   - Knowing the different possible locations of the papilla in the duodenum
   - Knowing the different possible appearances of the papilla
   - Knowing the different papilla orientations and the anatomical variances of the inside of the papilla and the ducts

In 4.3 Locating and recognizing the papilla the different possible papilla locations, appearances, orientations and anatomical variations have been described. The most prevalent ones of those need to be incorporated in training to teach anatomical knowledge on the spot and to prevent developing routine skills for just one scenario.

3. **Basic cannulation technique** *(consists of:)*
   - Knowing where to locate the papilla on the display
   - Knowing where to direct the catheter to for which duct

For successful cannulation, correct positioning in front of the papilla is crucial. As described in 4.4 Cannulation, The papilla should be located on the lower left corner of the upper right quadrant of the display. The papilla should be faced en-face, while the long axis of the papilla should be in line with the 12 o'clock position (Figure 20). When the proper position is achieved, the catheter may be advanced. For cannulation of the common bile duct, the catheter needs to be advanced towards the 11 o'clock direction when envisioning the en-face papilla as a clock, and for pancreatic cannulation the catheter should be directed towards 2 o'clock. To manipulating the angle in which the catheter approaches the papilla, the elevator systems should be used.



***A** The papilla orifice located in the left lower corner of the upper right quadrant. **B** Direct approach at 11 o'clock to enter the bile duct.*

Figure 20: Optimal monitor position of papilla for cannulation [1].

7.4 Knowledge-based behavior

Knowledge based behavior is the most complex type of behavior since it requires a combination of rule-based behavior and skill-based behavior in order to respond to new and unfamiliar situations. In these situations, the actions must be planned based on analytical observations and existing knowledge, requiring great consciousness and awareness [138]. The goal must the very clear during knowledge-based behavior and several plans needs to be developed to encounter the unfamiliar task and reach the goal. All plans need to be tested mentally against the goal to eventually select the most promising plan [7]. This type of behavior demands analytical skills and competence in strategic planning. Rasmussen describes the information that is perceived during knowledge-based behavior as symbols or chunks of conceptual information. These chunks of conceptional information are the foundation of planning and reasoning. Examples of knowledge-based behavior are identifying symptoms that do not apply to the known rules, dealing with unfamiliar anatomical variations and responding on complications occurs during the intervention.

Table 5. Amount of ERCPs needed to become competent [139].

Study	Competency marker	Competency results
Pancreatic duct cannulation		
Jowell et al [127]	80%	Achieved by 160 ERCPs
Watkins et al [132]	85%	Achieved by 70 ERCPs
Selective duct cannulation		
Schlup et al [134]	90%	Achieved by 120–150 ERCPs
Biau et al [135]	90%	Achieved by 79–300 ERCPs
Kowalski et al [130]	80%	Achieved by 180 ERCPs
Vitale et al [133]	85%	Achieved by 102 ERCPs
Waller et al [131]	80%*	Achieved by 100 ERCPs
Common bile duct cannulation		
Jowell et al [127]	80%	Not achieved by 200 ERCPs
Watkins et al [132]	85%	Not achieved by 100 ERCPs
Verma et al [22]	80%*	Achieved by 350 – 400 ERCPs
Ekkelenkamp et al [9]	80%	Achieved by 160 ERCPs

** Competency marker included native/intact papilla.*

Knowledge-based behavior is the most complex type of behavior, and therefore this type of behavior should not be the focus of the simulator training for beginners. Becoming proficient in the basic cases of cannulation, where no unexpected scenarios arise, requiring only rule-based and skill-based behavior, is already quite a job. An overview study by Shahidi et al [139], shown in Table 5, compares nine articles that studied the amount of ERCP's needed for a trainee to achieve competence in pancreatic duct cannulation, common bile duct cannulation and selective duct cannulation. Around 250 procedures (mean of Verma and Ekkelenkamp) are needed to achieve competence in common bile duct cannulation. Case difficulty was not mentioned in these studies. It must therefore be mentioned amongst these procedures there were probably also some cases in which unfamiliarity's arose and where thus knowledge-based behavior was required. But even when the share of cases with unfamiliarity's during cannulation is set to a unlikely high value of 50%, this means that still 125 ERCPs are needed to achieve competence, which illustrates how laborious training the basics of cannulation is.

7.5 Defining needs for the simulator

To meet the main objective of the training, eventually all the defined training needs must be represented the in the training by means of the training means. The terms "training means" will be elucidated in the next chapter "8 TRAINING MEANS". Translating all the training needs into means can be made substantially easier by summarizing all the needs into a couple of more general needs. This way, the (general) needs will be described as tasks that can be represented by the means in form of exercises that facilitate training in a task. The five summarized training needs are:

1. Controlling the scope
2. Route to the papilla
3. Positioning in front of the papilla
4. Guiding the catheter
5. Combining 3 and 4 for cannulation

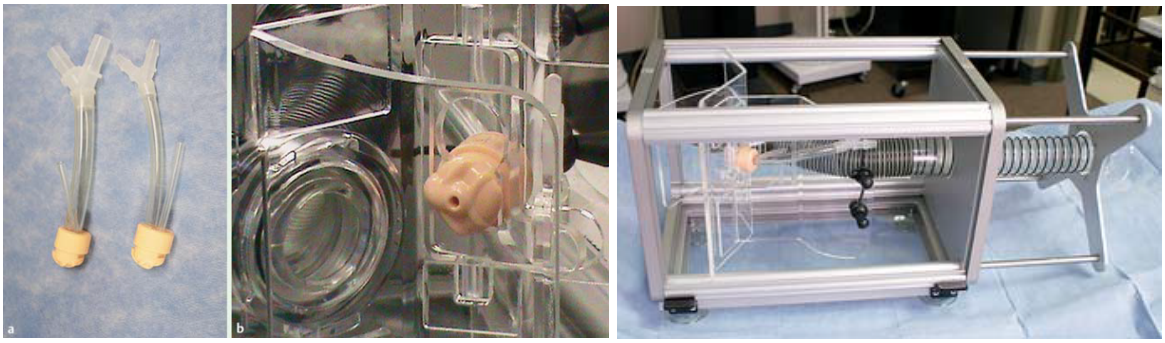
8 TRAINING MEANS

The training means are in essence a way of realizing or embodying the defined training needs, while adhering the main training objective of providing independently executable training in selective cannulation and the remaining secondary objectives. An effective and efficient way of training the listed needs on the simulation model without human assistance must be found, which will translate into the training mean(s). The ERCP trainer is the main model and thus core instrument to work with. Therefore, the properties of this model will first be discussed thoroughly in this chapter. To put this model into use and thus facilitate the training needs under the set conditions of the objectives, a complete program containing instructions and exercises must be developed which functions as a manual for using the simulator efficiently and effectively. It is, however, clear that the ERCP trainer cannot, as it is at the moment, facilitate and meet all the listed training needs and objectives. The substantial list of training needs in combination with the challenging objective of gaining simulator competence without human instructions and assessment makes that this model on its own is not enough to satisfy the demands. Therefore, some additional functions should possibly be added to the model. These additional extensions to the model will be the training means of this research project. For developing these means, the tasks of the instructor need to be defined clearly and subsequently literature must be consulted to come up with ways in which non-human means can overtake these tasks. This "ways and tricks to properly replace the instructor by means that do not involve direct human assistance" part of the mean(s) will be addressed in this chapter. In the next chapter 0

CONCEPT DEVELOPMENT AND SELECTION*, actual concepts for translating the training needs into independently executable exercises, will be formulated, making use of findings and theories that are described in this chapter.*

8.1 The ERCP trainer (by Boškoski and Costamagna)

The ERCP trainer is a mechanical training model designed by Dr. Costamagna and Dr. Boškoski. The model provides a mechanical representation of different ERCP procedures, with various anatomical variances. The esophagus and meanders of the stomach and first part of the duodenum are presented in the model as a tube, through which the scope must be advanced. At the end of the tube a space encaptured by two plastic walls will show, which represents the second part of the duodenum. The plastic walls, of which the papilla is located on one of them, portray the duodenal walls. The scope must be directed to the site of the papilla, where the process of positioning (correctly) in front of the papilla can begin. The papilla is constructed of a foam substance, which should mimic the tactile feedback of the human papilla. The orientation of the papilla can be adjusted by rotating the plastic plate on which the papilla is attached. The papilla can be detached easily, which makes it possible to use different papillae. The papillae are different in their orifice size and orientation of the ducts. The ducts are fixed to the papilla and consist of a common channel which branches out into a pancreatic duct and common bile duct. The size and length of the common channel, as well as the size of the pancreatic and common bile duct can variate, depending on the papilla that is mounted onto the model. All described components are implemented into a transparent box, which can be rotated to simulate the different patient orientations; prone, oblique or supine. Besides practicing overall scope control and selective cannulation with various levels of difficulty, also metal or plastic stent placement and stone extraction is possible in this model [10, 140]. A normal duodenoscope with its accompanied display for providing the camera view can be used for this model. X-ray images can be mimicked by mounting a black and white camera on top of the box.



A *The esophagus, stomach, and duodenal sweep are constructed from a plastic tube.* ***B*** *The pancreaticobiliary tree can be attached to the cage at various levels of difficulty [10].* ***C*** *The endoscopic retrograde cholangiopancreatography (ERCP) trainer consists of a metal cage, which serves to hold synthetic elements that comprise a model of the upper gastrointestinal and pancreaticobiliary tracts [10].*

Figure 21: ERCP trainer by Costamagna and Boškoski [10].

The great benefit of this model is that it provides haptic feedback to the user. The earlier conducted literature study showed that mechanical models, of which the ERCP trainer is one, are for many reasons (e.g. price, haptic feedback, no ethical concerns, large case-mix and unlimited repetition possibilities) the most attractive type of model to use for training. However, at the moment, there is no real program or philosophy for how the model should be used. The set-up of the training as well as the amount and quality of the provided feedback and instructions depend on the educator in question. Therefore, developing an actual training program for the model that is independently executable, would increase the model's usability tremendously.

8.2 Tasks of the instructor

Independently executable training has a lot of potential for both the trainee and the gastroenterologist functioning as teacher, but it will only work when the training is properly organized. In traditional practical ERCP training, the teacher has two functions: 1) providing instructions and directions during the performance of the trainee and 2) assessing the performance and providing feedback based on the performance. These tasks need to be covered by technology when eliminating the human instructor from the training. Additionally, documentation can be seen as a third task of the instructor, as it can be useful for observing the learning curves of the trainees. In independent training, documentation is more important than it is for traditional training because the teacher should be able to look back into the trainee's performances as the teacher will not be present to during the training itself. Especially for the first independent training concepts in which the computer-based assessment might not be as accurate as assessment by a human yet, the judgment of the computer should not be the only tool for evaluating the skills of a trainee. It should be possible for the teacher to look back into the whole recorded performance of a trainee and also into the various results during each training sessions, as assessed by the computer. These features must in independently executable training be covered by technology or others forms of communication that do not involve a human.

8.2.1 Instructions

There are generally two options for providing the instructions and directions: by interaction or by predefined non-interactive instructions (e.g. recorded instruction movies or instructions printed on a poster with elucidating drawings or pictures). Real-time interaction, with elements as adopting information, processing information and responding based upon that, requires a form of intelligence, and since human assistance is not an option in independent practice, real-time interaction can only be provided by artificial intelligence (AI). The technology required for AI is very complex and therefore it should only be used when a more simple solution would not suffice. For that reason, the other option "predefined non-interactive instructions" will be explored.

8.2.1.1 Education theory and education technology

The way in which the pre-defined instructions are constructed might affect the effectiveness of transmitting the information and the learning of the trainee. Therefore, for creating the predefined instructions, education theory and education technology and their various principles should be explored. In this section, the risks that predefined non-interactive instructions might bring will be outlined and solutions for minimizing the risks, and thereby improving the way of providing predefined instructions, will be sought by consulting numerous education principles such as "cognitive load theory", "e-learning", "computer assisted instructions (CAI)", "branching", "segmentation" and "multimedia learning" or "multimedia instruction". These principles can be used to optimize the independent learning. Because some of these educational terms are related to each other or have great overlap, the terms will be described in pairs.

8.2.1.1.1 E-learning and Computer-assisted instructions

Clarck et al [141], described e-learning as "instruction delivered on a digital device that is intended to support learning. The delivery hardware can range from desktop or laptop computers to tablets or smartphones, but the instructional goal is to support individual learning or organizational performance goals". E-learning is an education type that is very well suited for self-study, since in one of its forms, asynchronous e-learning, a live instructor is not needed. Asynchronous learning is a key component of flexible e-learning, since it does need the participant and instruction provider to be online at the same time or to interact directly [142]. The asynchronous type of e-learning is very similar to CAI. CAI is also called Computer Based Training (CBT) or Computer Based Learning (CBL). According to the International journal of education and development CAI is an instructional method that can be used online or offline and can enhance the learning process. CAI uses a computer and program to create the tool to teach the learner. Some advantages of CAI and CBT are that it allows the students to learn at their own pace, the privacy/individuality helps the slow and shy learners to learn, the learning is self-directed; students learn when they want to learn, there is more freedom to experiment and there is instantaneous response on their actions by the computer (when feedback is incorporated properly). On the other hand, the lack of personal interactive instructions in combination with a large chunk of provided information could lead to cognitive overload. Therefore, the way in which the information is presented and the way in which the teaching session is set-up must be constituted carefully, taking into account the learning principles.

8.2.1.1.2 Multimedia learning and Cognitive load theory

Multimedia learning is defined as "learning from words and pictures" and multimedia instructions as "presenting words and pictures that are intended to foster learning" [143]. Words can be either printed or spoken, pictures may be static or dynamic and both can be presented in digital form (e.g. on a screen or recorded sound) or non-digital (e.g. written or drawn out on paper). Multimedia learning is a result of the cognitive load theory of Sweller [144] and his ideas on how to prevent cognitive overload. The cognitive load can be described as the total amount of mental effort being used in the working memory. The working memory functions as a memory buffer, that we use for processing and manipulating task-relevant information. Because the storage is temporary and the capacity is limited, the working memory can become overloaded during learning when the amount of information or task presented at once is too much. Cognitive overload reduces the amount of information that can be processed and thereafter moved to the long-time memory.

According to Sweller, there are three types of cognitive load that contribute to the total cognitive load of a task. The intrinsic load can be described as the difficulty of a task for a particular learner. It is determined by the number of novel elements and the level of interactivity between the elements. Germane load refers to the amount of mental effort that is required to process the information of the task, understand it and thereafter access it or store it in the long-time memory. By providing examples and references during teaching to link new information to existing knowledge, automatic mental schemas are created that make new information easier to process. Extraneous load is the additional load imposed by unnecessary information in the instruction material. Things like background music, flashy images, too many provided details can causes some of the learner's capacity be spend dealing with the redundant information instead of the relevant information that contributes to the learning goal.

By changing the way in which information is delivered and presented (the instruction design), the cognitive load of a task can be decreased, and cognitive overload can be avoided. Multimedia learning is a key component of instruction design, acting as an instrument to reduce the cognitive load of a task with [144, 145]. The cognitive theory of multimedia learning developed by Mayer [146, 147], is in essence equal to the cognitive load theory of Sweller. The theory of Mayer, however, uses slightly different term (extraneous load = extraneous cognitive processing, intrinsic load = essential cognitive processing and germane

load = generative cognitive processing [148]), and Mayers theory is solely focused on the cognitive processes during multimedia learning. The three instructional goals as described by Mayer are also similar to the objectives of Swellers cognitive load theory: reduce extraneous cognitive processing, manage essential cognitive processing and foster generative cognitive processing. While the two theories are relatively similar, the theory of Mayer is best suited as guidance for the construction of the independently executable training program, due to its focus on multimedia learning and because of its clear formulation of principles that are associated with a certain type of cognitive processing. The principles can provide guidance in constructing the training and/or adjusting it. Mayer also provided an effect size for each principle when applied in case of an cognitive overload scenario [146, 147]. The effect size [d] represents the difference between two means divided by the standard deviation for the data and can have a value between 0.01 (very small) and 2 (huge).

Table 6. Effect size of every education principle (adapted from Mayer [146, 147]).

Category	Principle	Meaning	Effect size
Reducing extraneous processing	Coherence Principle	People learn better when extraneous words, pictures and sounds are excluded rather than included	0.86
	Signaling Principle	People learn better when cues that highlight the organization of the essential material are added	0.41
	Redundancy Principle	People learn better from graphics and narration than from graphics, narration and on-screen text	0.86
	Spatial Contiguity Principle	People learn better when corresponding words and pictures are presented near rather than far from each other on the page or screen.	1.10
	Temporal Contiguity Principle	People learn better when corresponding words and pictures are presented simultaneously rather than successively.	1.22
Managing essential processing	Segmenting Principle	People learn better from a multimedia lesson is presented in user-paced segments rather than as a continuous unit.	0.79
	Pre-training Principle	People learn better from a multimedia lesson when they know the names and characteristics of the main concepts.	0.75
	Modality Principle	People learn better from graphics and narrations than from animation and on-screen text.	0.76
Foster generative processing	Multimedia Principle	People learn better from words and pictures than from words alone.	0.79
	Personalization Principle	People learn better from multimedia lessons when words are in conversational style rather than formal style.	0.69
	Voice Principle	People learn better when the narration in multimedia lessons is spoken in a friendly human voice rather than a machine voice.	0.36
	Image Principle	People do not necessarily learn better from a multimedia lesson when the speaker's image is added to the screen.	0.20

8.2.1.1.3 Segmentation and Branching

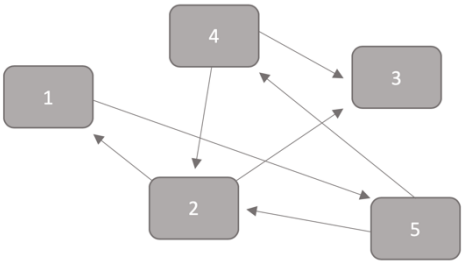
Learning without interaction brings along several risks. The precise content of the predefined instructions that shall be provided during the training, as well as the way in which they will be provided, is crucial for how effective and efficient learning will be. The content of the provided information is static, meaning that nothing more and nothing less than the provided information can be used during training. In interactive learning, an individual can ask questions when he/she requires further elucidation or additional instructions, but with predefined instructions this is not possible. It is therefore of utmost importance to incorporate all the information that any trainee might need for understanding the training and to learn. Also, the rate with which the difficulty of tasks or exercises increases must be doable for every trainee. It must be taken into account when setting up the program that for each individual, the learning rate can variate for different elements of the program. The provided information must therefore be very comprehensive in order to overcome missing information that might be crucial for one specific individual, and the buildup in difficulty of the tasks will be relatively slow also to be feasible for every trainee.

The fact that the program must be executable for every trainee almost automatically means that the program, when presented linear and identically to everyone, will not be optimal in terms of efficiency for most of the trainees. Individuals with a higher learning rate will have to go through the same comprehensive set of steps, as individuals with a lower learning rate where the comprehensive steps are actually intended for. To maintain both efficiency and effectiveness as much as possible for all trainees, the constitution of the program must be done very carefully in terms of what should be implemented in the program, what can be left out, and in which level of detail certain elements should be covered and examined in the program. Besides determining what information will be incorporated and what will be left out, the way in which the program is constructed can also contribute to efficiency. Creating options in the program to fast-forward parts, makes the program more adaptable to the learning process of an individual. This is an advantage of individual learning: because the trainee goes through the information and steps by itself, he/she can decide the tempo of scrolling through instructional slides or the tempo or the amount of replays of a video itself based on their own perceived experiences. Breaking down the content into smaller parts and implementing

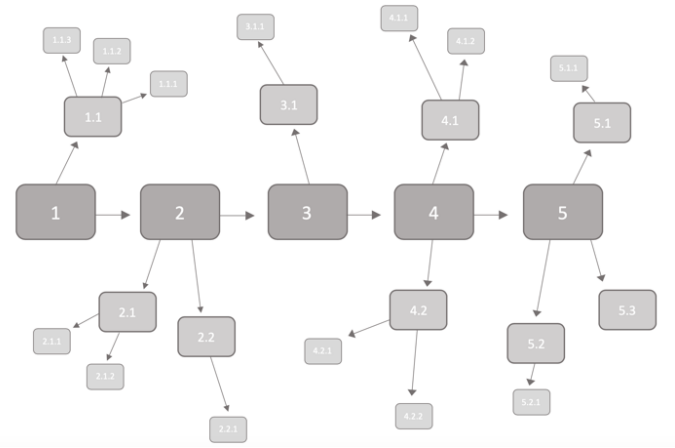
short pauses in between them that can be regulated by the trainee is often referred to as “segmentation”. Segmentation of presented information showed to decrease the risk at cognitive overload and improves the processing of information [149]. In practice, this means that tasks will be subdivided (segmented) into smaller tasks. This can be in terms of how information is presented in multimedia; spread out over multiple PowerPoint slides instead of presented onto one slide, but is can also be in subdividing a practical task; the act of cannulation will for instance be subdivided into the several smaller tasks (as defined in the five generalized training needs) to slowly build up the difficulty and thereby lower or spread the cognitive load. The segmentation of learning tasks, also called “part-task training”, showed to have an positive learning effect as long as the parts were performed sequentially in the whole task [150]. Since the five defined training needs are in essence five sequential steps for performing cannulation, practicing the needs separately in the correct order, should result in effective learning. This subject will be further discussed in *9.5.1 Part-task training.*

Besides segmentation, also “branching” can be used to respond to the individual. Branching is described by Hannafin [151] as a mean to de-linearize instructions with an external locus of control. Predefined non-interactive instructions are by nature more external, as instructions with an external locus of control are defined by Hannafin as “instruction in which all learners follow a predetermined path that is established by the designer without exercising individual judgement as to the appropriateness of the path” [151]. Internal locus of control, on the other hand, “is demonstrated in lessons where individuals control the path, pace, and/or contingencies of the instruction, typically by specifying choices among a range of designer-embedded options” [151]. Because in instructions with an external locus of control the learner has no direct control over the path of the presented information, the path seems linear (Figure 22A) instead of non-linear (Figure 22B). However, by implementing branched path options, the path gets non-linear, while the base of the path remains the same for everyone (Figure 22C). A learner who experiences no difficulties during a certain education program does not need to branch for further explanation or review, while another learner may struggle with the same program and therefore is in need for segmentation of the information by branching. Branching can in PowerPoint presentations for instance be done by implementing pop-ups.

A. Internal locus of control and linear



B. External locus of control and non-linear



C. Internal locus of control, non-linear and branched

Figure 22: linear and non-linear learning.

8.2.2 Feedback and assessment

Besides providing instructions and controlling the path, another crucial task of the instructor is to assess the performance of the trainee and provide feedback. Feedback is essential for the learning process of the student [152, 153], it provides direction, and it increases motivation and self-esteem [154-156]. It moreover helps students with rating their clinical practice more realistically [157]. Feedback can be provided by analyzing the overall or certain steps of the performance based on certain criteria. The correctness of (each step of the) performance is evaluated and a verdict is communicated back to the participant. When provided directly during the performance for separate steps or moves, feedback functions as guidance, and when provided afterwards it functions as an assessment of the overall performance. Providing feedback and assessment therefore requires a form of intelligence. Since there is no teacher present to provide the feedback in case of independent practice, the feedback must be delivered by technology, in the form of AI. As mentioned before, AI can become complex when used for comprehensive tasks. To minimize the complexity of the required AI technology, the tasks that require AI need to be separated and subdivided into smaller segments, and the use of AI needs to be narrowed down to the elements of training for which another simpler option does not suffice. This is in line with the learning principle of segmentation and the division of the training needs into five separate tasks.

The hand-eye coordination and basic scope handling is something that the trainee can and should develop on its own without feedback, but positioning in front of the papilla and guiding the catheter towards a point of interest are things that do require feedback, directly during the training process in the first learning stage and later on afterwards for grading the performance of the trainee. Direct feedback during the training of positioning makes the trainee feel and see when he/she is precisely in the correct position in front of the papilla and when not. Moreover, in the beginning of training it will make the trainee more aware of its own movements and hand-eye coordination since there is a focus point (position) for directing the scope to, which will be checked. The feedback by assessing the performance will function as a measurement of the competence in a certain skill. The combination of proper positioning and control over catheter advancement, should result in successful cannulation. Providing feedback during these acts separately and possibly also for the act of cannulation itself should therefore be incorporated in the model.

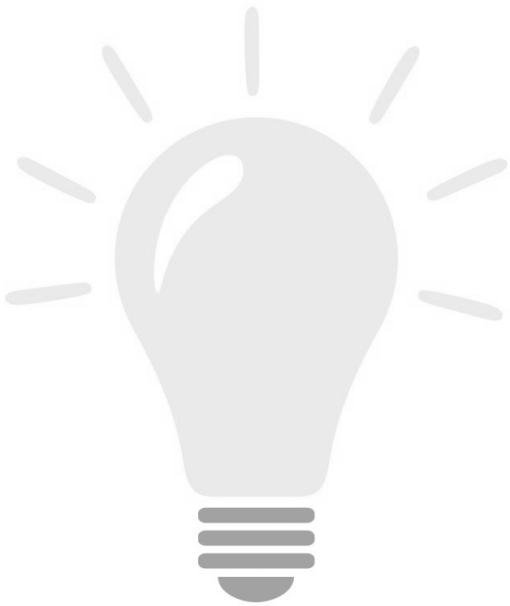
8.3 Serious gaming

Serious games are in contrast to traditional amusement games, designed with a different purpose than just entertainment. The main goal of serious games is learning. Bergeron [158] defined serous games as an: 'interactive computer application, with or without significant hardware component, that has a challenging goal, is fun to play and engaging, incorporates some scoring mechanism, and supplies the user with skills, knowledge or attitudes useful in reality'. Gaming is par excellence a tool that could very well be used for individual training on a simulator. According to Tennyson and Jorczak [159], simulation games are an effective instruction method since affective and cognitive processes are trained at the same time. In non-individual training, the goal that the teacher sets for the trainee and the fact that there is a form of performance assessment by the teacher and thereby competition between all the trainees, functions in a way as a non-computational game. When the teacher is taken away, elements such as the goal, the drive to perform, the motivation and the competition, disappear. Voluntary use of simulation labs results in minimal participation [160], because training without a goal, without control and without competition may lead to demotivation and boredom. A computational game that saves scores and reports scores back to the instructor can be the solution for this problem. The gaming element increases attention and visuospatial skills [161, 162] and the fact that performance is measured creates extrinsic motivation [163]. The concept of serious gaming may stimulate the voluntary training of skills [164].

Independent of the content, a game (for the simulation model) is expected to lead to better training results than voluntary use of a simulation model [163], because of the increased extrinsic motivation. However, the way that a game is setup and the actual content of the game may affect the true level of effectiveness of the training. Several studies state that it is important for educators and game designers to work together when designing and validating games for specific skills, in order for a game to be a true added value to the curriculum of a ERCP trainee [165-167]. Gaming may improve a training device compared to just fooling around with the device without a goal, but this does not necessarily say that the quality of that training (meaning, how well the adequate skills are developed by training on the model) is sufficient to be implemented into the curriculum. Attention must be paid to whether or not the correct skills and techniques are taught by playing the game. In the worst-case scenario, the trainee's level of competence can even decrease by playing a poorly designed serious game. When the game does not provide feedback or proper assessment of the performance, improper techniques and bad habits might develop by playing the game which are difficult to unlearn. This effect, in which previous learning obstructs or interferes with new learning, is called "negative transfer" [168].

PART 3

CONCEPT DEVELOPMENT & SELECTION



9 CONCEPT DEVELOPMENT AND SELECTION

For every of the main training needs, one or a couple of concepts will be developed and presented in this chapter. The concepts are based upon the findings in 8 TRAINING MEANS and aim to meet the set objectives. For some of the training needs the set objectives are very clear and the findings are binding, which will lead to one more obvious conceptual solution, while the objectives and findings for other training needs leave more options open, resulting in more than one concept. When there are several concepts for one training need, one concept will be selected based upon small tests and/or an informed consideration.

9.1 Introduction to ERCP and the duodenoscope

9.1.1 Instructions

The introduction to ERCP and the duodenoscope is rather straightforward. Because the human instructor is aimed to be avoided and AI is not needed for basic briefing, instructions will logically be provided by written text, images and videos. One concept is developed in which the basic principles of ERCP, the instructions on how to control the scope and the guidelines for catheter advancement into a duct of interest (the rule-based behavior parts of the "positioning" and "catheter guiding" training needs) are provided by means of a PowerPoint presentation. For the construction of the presentation, elements of learning theory and technology that were found in *8.2.1.1 Education theory and education technology*, are taken into account. For example: videos are not combined with (long) written texts and the combination with images is minimized (*modality principle/redundancy principle*), extraneous elements are limited (*coherence principle*), information is provided segmented (*segmentation principle*) and there is the option to skip or fast-forward parts/slides or request more information by means of pop-ups which accounts for different learning rates of the participants (*branching*). Additionally, the pre-training principle is also taken into account by designing a pre-training version of the PowerPoint presentation which the trainees can observe at home the day before practical training on the model. Naturally, the instruments are not available when practicing at home, but the important cognitive aspects of controlling the scope, passing the route and positioning or directing the scope for cannulation can already be reviewed once at home. During the practical part of the training, the same instructions are again provided at the beginning of the training. This time, the trainee may participate which the instructions on how to control the scope to get acquainted with the duodenoscope. True control over these skills will be established in the upcoming means.

9.1.2 Quick testing of the concept

The first concept of the PowerPoint presentation was sent to Dr. Voermans of the Amsterdam UMC, who is an experienced ERCP instructor. Voermans evaluated the presentation and concluded that the basic instructions on what ERCP is, what the indications and complications arc etc. (mostly adapted from an instructional video on YouTube [169]), were redundant because this information is well-known to trainees that begin with practical ERCP training, being in their 4th or 5th year of gastroenterology training. This part was therefore left out of the presentation. In Appendix A the PowerPoint presentation is shown of the instructions that the trainees must go through prior to the training at home.

9.2 Route to the papilla and controlling the scope

9.2.1 Instructions & exercises

After the instructions for controlling the scope, the route to the papilla will be covered. During practicing the route towards the papilla, the basics of controlling the scope will develop as well. For training the route to the papilla, three concepts are thought of but only one is developed, which will be further explained in the description of the concept. For all concepts the instructions will be provided in the same fashion: the instructions for passing the scope trough the body will be heavily segmented, since there are a lot of acts to perform during the route (adapted from *4.2 Inserting the duodenoscope*). The instructions and description of the tasks are shown in Appendix B. The trainee is asked to participate during the instructions with the duodenoscope on the appointed model to make the explained act more real to the participant. During the explanation of the route (the rule-based behavior), some exercises appear. The exercises facilitate training in the skill-based behavior (controlling and steering the scope) while the also the anatomy is explored during the route. Passing the route correctly can be seen as a combination of rule-based behavior and skill-based behavior. Multiple slides follow with the possibility to open pop-ups if more information is needed. After passing the route once, by participating during the instructional and "do it yourself" slides, the final exercise of this part is to pass the route within a certain time. If this time is met, the trainee is considered skilled enough at this part to move on. Of the main training needs, "controlling the scope" and "route to the papilla" are now covered. During this part of the presentation/program, no assessment or feedback is implemented in the training. The reason for this is that both the basic movements and the route are act that will develop relatively easily with a bit of practice. The "do it yourself" parts and the exercises can be executed on one of the models described in the concepts. The content of the exercises will be explained next, during the description of the concept.

9.2.2 Concept(s)

There are three options for facilitating training in the route to the papilla prior to the actual cannulation training on the ERCP trainer by Boškoski and Costamagna: 1) using a separate existing model, or 2) a newly developed entry model could be added to the training on which the route can be practiced, or 3) a representation of the route could be mounted onto the ERCP trainer

which replaces the tube. Because the practicing the route is just one part of the needs but a lot of work to develop a whole new model for and, moreover, added value of training the route is rather debatable, the more simple option: using an existing separate (inexpensive and simple) model to train the route upon, is used to test if training the route is actually needed. A plan was developed for practicing the route towards the papilla: The ERCP training model by KOKEN mpc (Figure 23) will be used, on which trainees shall carry out the exercises and the "do it yourself" sections of the "route to the papilla" part of the training program. In the KOKEN mpc model, the esophagus, stomach and first three parts of the duodenum, including the papilla and the pancreatic and common bile duct, are reconstructed out of thin silicon. The material is thus pliable, but by inflating the airtight model a bit, the walls of the stomach and duodenum get more rigid. The representation of the gastrointestinal area in manufactured into a plexiglass see-trough box. To maintain its shape the gastrointestinal track can be inflated.

***Left**: Koken model [170], **Right**: visualization of placed marker in stomach and duodenum.*

Figure 23: Model for representing the route to the papilla.

On the inside of the stomach and the duodenum several markers can be placed (Figure 23). The first exercise will be to navigate to these markers one by one. By navigating to different points on the model, the trainee will learn to control the scope and to guide it towards any direction. The fidelity of the model and the exact location of the markers is therefore not of great importance in this exercise. The exercise is completed successfully when all markers (in the indicated sequence) have been detected within a certain, to be determined, time. The real-time video images of the scope can be connected to the computer, and with MATLAB a certain program must be developed to recognize the markers, to time the performance and rate it.

9.2.3 Quick testing of the concept

On the 10th of April 2019, the Koken model with attached markers and the corresponding PowerPoint presentation with instructions and exercises was brought to the skills lab of the Erasmus MC in Rotterdam to connect it to a duodenoscope and discuss further development with an expert. The presentation was shown to endoscopist Dr. Koch of the Erasmus MC, after which he was requested to perform the exercises and thereafter provide feedback. According to Dr. Koch, training the route, especially on the Koken model, should be left out of the to-be-developed training program for multiple reasons. 1) the non-slip silicon made it almost impossible to slide the duodenoscope in, even after applying water or gel. The tactile and haptic feeling was described by Dr. Koch as something completely different from the real sensation. 2) Dr. Koch disapproved with the location of some of the markers because according to him these are places an endoscopist never has to reach and therefore it should not be incorporated in training. In defense of the model, however, it must be said that learning to control the scope rather than precise routine was the goal of this exercise. 3) the model is not on scale. The duodenum and stomach are too large, making the practice different than the real situation. 4) According to Dr. Koch the route is not really an issue for novels. In contrast to what literature Koch states, he claims that the papilla is reached by simple advancement of the scope and trainees can perform this act successfully after just two or three attempts. This was later on also confirmed by Dr. Boškoski. Both Dr. Boškoski and Dr. Koch state that the focus should not be on practicing the route since this is not an issue.

9.2.4 Concept selection

While some of the arguments of Dr. Koch can be argued, it was eventually decided to leave "practicing the route" out of the training program. The reason for this is that, indeed, the route is not the main focus of the training but facilitating proper training in it would require a lot of effort. There is no proper model available, so a model should then be developed. Due to time issues, the focus must be on the more important issue: cannulation. Basic scope control can be also be learned during the training of the elements of cannulation.

9.3 Positioning in front of the papilla

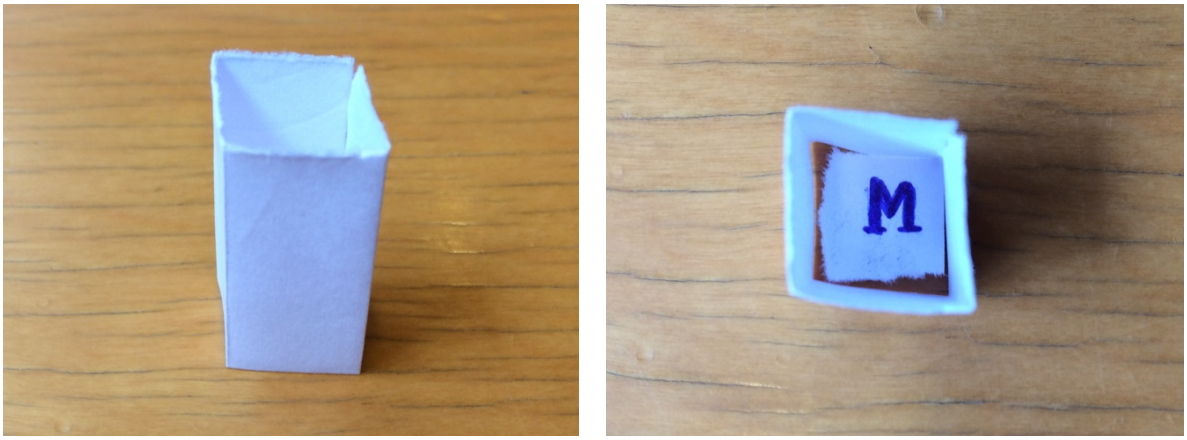
9.3.1 Instructions & exercises

The first part of cannulation is achieving the correct position in front of the papilla. Instructions on how to achieve this position (see *4.4 Cannulation*), primarily rule-based behavior, will be provided by means of images and written text, taken into account the findings of learning theory. The PowerPoint presentation for the instructions is depicted in Appendix A (and first part of Appendix C without the exercises). After going through the instructions, the exercise will follow. The goal of the exercise (exercise 1 of the program) is clear: achieve the correct position within a certain time. But how this will be checked and how feedback will be provided, that needs to be explored. Therefore, three concepts are developed. All concepts shall be add-ons for the base model: the ERCP trainer.

9.3.2 Concept(s)

Concept 1 – *boxes with letters*

A simple technique for training positioning is to replace the papillae with boxes that have high borders and an open upper surface. On the bottom of each box a letter is depicted, which will only be visible if the camera is positioned en-face, in front of the box. The advantage of this method is that no imaging is needed. The downside of this technique is that the assessment is not done by a computer. The trainee has to assess its own performance and the gastroenterologist can later on check it by reviewing the entire video recorded by the scope. Also, a way of ensuring the proper distance also needs to be developed (scope positioned not too close and not too far from the box) and a manner of checking whether the letter is in view from the correct point of view and not a rotated one in which the letter is viewed upside down for instance.



***Left picture**: incorrect scope angle, **right picture**: correct angle of the scope*

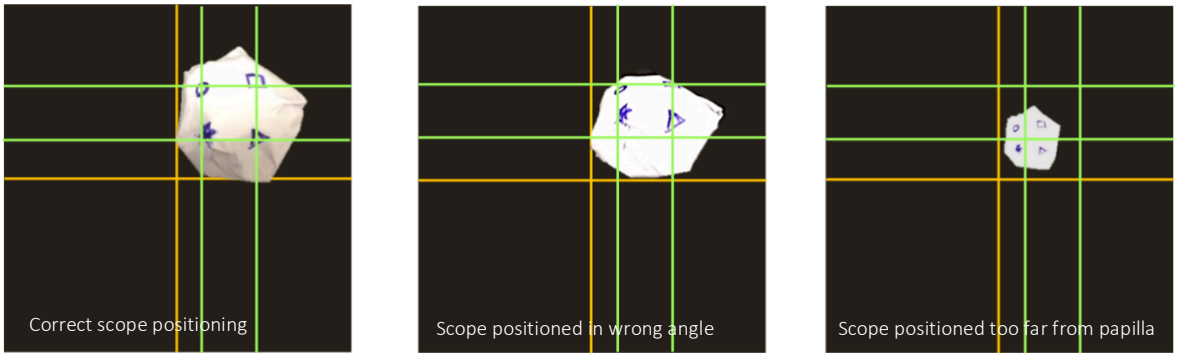
Figure 24: Simple prototype of concept 1.

Concept 2 – *Computer imaging with object recognition*

An artificial papilla with certain markers can be assembled onto the ERCP trainer. The video images of the scope can be used as an input for MATLAB. In MATLAB a script needs to be created which detects the markers and then decides whether they appear in the right position and size on the video image. The correct position needs to be programmed based on the findings in *4.4 Cannulation*. The time in which the correct position is achieved will be saved and shown to the participant after competition, which creates a competition and gaming element. The fact that all performances are saved creates the possibility for the instructor to observe the progress of each trainee. The assessment is thus done by the computer, since the game will stop and save the results when the correct position is achieved. The feedback during the performance is in a way already facilitated by the object detection function which shall provide a signal when one of the objects is close to the desired position (buzzer or light flash) and another signal when positioned correctly. Coaching by means of directly instructing the trainee which wheel to turn on the control handle or when to twist the insertion tube, is not possible in this concept. The expectation is, however, that the trainee can find out the correct acts out him/her-self without the need of instructions, as long as it is reported back to him/her when success is achieved. Figuring this out on your own is part of the learning process. It must be tested whether the type and amount of feedback incorporated in this concept is suited to facilitate the acquisition of correct positioning skills.

9.3.3 Quick testing of the concept(s)

Concept 1 suffered from too many drawbacks, therefore concepts 2 was attempted to develop. Multiple drafts of the object detection were developed and several scrips that were created in MATLAB. However, these all suffered from a lot of errors. Even with a blank background and when rather simplified objects were used, the objects were seldomly detected correctly.



The orange lines are just to illustrate the quadrants and may be omitted on the display if wanted. The four different marks must be in line with the intersection points of the green lines. To make it easier for the trainee, these lines could be depicted on the display. To make it more difficult for the trainee, these lines can be left out. Irrespective of whether the lines will be depicted on the display or not, the computer will use these same intersection points of the lines for verifying the position.

Figure 25: Papilla with detection marks, different scope positionings.

9.3.4 Concept selection

Based on the findings of the quick tests of the concepts for exercise 1, concept 2 was adjusted which resulted in the final and selected concept number 3. Instead of object detection by shape, now the detection is based on RGB colors. This method will now be discussed as the third and selected concept, and therefore the construction of this concept will be explained in more detail.

Concept 3 – *Computer imaging with color recognition*

material

The idea behind the exercise is the same as for concept 2, but instead of making the computer recognizing the shape of the markers, the computer will now detect the color of the marker. For developing the game of the first real exercise, MATLAB 2017 was used. In MATLAB, the computer vision system toolbox, the image processing toolbox and the image acquisition toolbox were used to retrieve some pre-programmed function from. The MATLAB Support Package for USB Webcams made it possible to use the build in webcam of the macOS device as a real-time video input and later on to use the video input of the duodenoscope. To use the video images of the scope, the Marshall Electronics HD-SDI to USB 3.0 converter was used. In MATLAB an additional function was created in which the user can choose to use the webcam as video input or the duodenoscope. The ERCP trainer and its associated papilla are used as a base model. For the markers, plain white paper is used on which the dots are drawn with felt-tip pens in the RGB colors red, green and blue. A circle, containing all three markers, can then be cut out and glued onto the papilla.

Detection of the markers

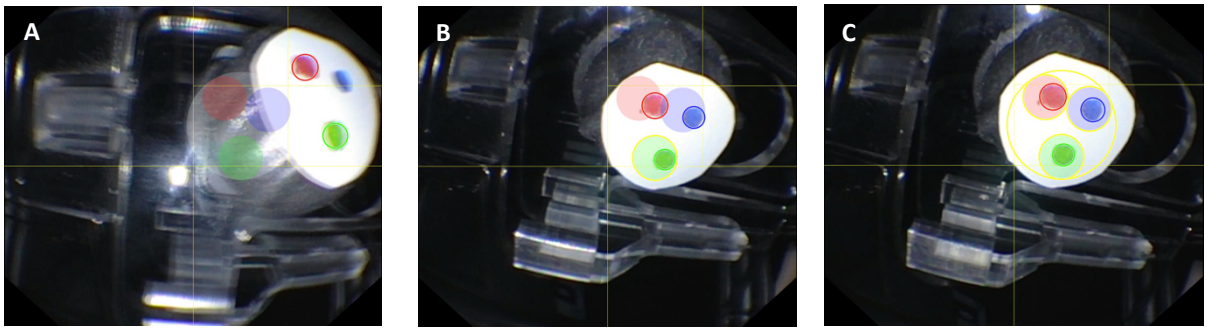
When running the developed script (see Appendix D) to start the game, a video object will be created from the video input. The returned color space of the video object will be RGB. The name of the participant will be requested and needs to be implemented in order to proceed running the game. The performance will be saved in a video which is assigned the name of the performer, the date and the current time. Then, a loop will start which acquires the real-time video images until either the set time limit is reached (implemented as number of frame rates) or all the markers are detected on the correct location. During the loop, every consecutive frame of the video object will be converted to a snapshot image in RGB. Depending on the input, which may be the webcam or a scope of different brands e.g. Pentax or Olympus, the image will be cropped and possibly mirrored to fit well on the computer display. Then the three layers of the image pixels (one which represents the red areas of the image in pixels, one green and one blue) are converted to grayscale in order to eventually convert the three layers of the image into a binary image. By converting to a binary image, all pixels with a luminance greater than a certain appointed level will be turned into white (value 1) and all others into black (value 0), instead of the different levels of grey. The level for each of the color layers was determined by trial and error, and must be adapted when another video input is used (or a different scope). For the Olympus duodenoscope the level for the binary conversion was set to 0.07 for the red layer, 0.08 for the green layer and 0.03 for the blue layer. A 2D median filter (medfilt2) for a 3x3 pixel neighborhood which was used to filter out some of the noise right before the binary conversion. After the binary conversion, the function “bwareopen” was used to filter out the small objects from the binary image. Thereafter, the function “bwlabel” was used to return the connected components of the image, in this case meaning the detected objects (regions) of the colors red, green and blue. By means of the “regionprops” function, certain properties (Area, Centroid, Major axis length, Minor axis length, Perimeter) of each labeled region are outlined. With the help of those properties of the detected objects, it can be verified whether or not each of the detected objects corresponds to the properties of the markers. The object will only be considered as the correct marker and thereby encircled with a red, green or blue circle on the display (as seen in Figure 26A, where the red and green markers are detected),

when it meets a list of criteria set in the function. The filters described above (RGB, bwareopen, bwlabel, etc) function as a pre-selection for the objects that are detected by "regionprops". After that, the final selection criteria are: **1)** the area of the object must be within a certain set maximum and minimum value (area of the object > 0.8*area of the target marker & < 3.0*area of the target marker). The "if" function used for this, sets criteria for both the location of the marker (on the display) and the size. **2)** the area of the object must be sufficiently circular (the object needs to have a circularity of greater than 0.7) The circularity of the object (value between 0 to 1) is determined by the following function:

$$C = \frac{4 * \pi * A}{P^2}$$

C = circularity, A = Area, P = Perimeter

Figure 26A depicts a screenshot of the game when the duodenoscope is in the ERCP trainer in front (but looking at it a bit sideways) of the papilla with the attached markers. The green and red markers are detected, while the blue marker is not because the shape is too oval and/or too small. Besides the requirements concerning the shape, the markers also need to appear on the right location on screen. The red marker will represent the point on the papilla (on the model) where the catheter needs the be advanced to for cannulation of the bile duct, the blue marker the point to advance the catheter to for pancreatic duct cannulation and the green marker is just a third referential point. If the marker appears on the right location in the display, in the corresponding target circles that are programmed onto the view on the display, the circle will light up yellow (Figure 26B). When all markers are located in their corresponding circles, the whole papilla will light up yellow (Figure 26C) and the exercise will stop. The time to achieve the correct position will be depicted and the video of the performance is saved.



Determining and programming the target area of the markers

Figure 26: screenshots of the color recognition during the exercise.

To depict on screen where to markers should appear (the target or goal area), some shapes were inserted into the video images that the participant will see on the computer. Figure 26A and Figure 28A better shows the shapes that are projected over the video input and therefore appear permanently on the same location on the display. Two diagonal yellow lines through the center, divide the screen up into four quadrants of which the right upper quadrant is again divided up into four quadrants. The papilla must be located in the lower left quadrant of the right upper quadrant. The papilla, as a whole, is depicted on the display as a white semi-transparent circle. The size of the in screen depicted white papilla is based on common sense and by using live ERCP video images as an input to check the correctness of the papilla location (visible in Figure 26A and Figure 28A). The radius of the papilla is set on 1/7 times the screen width. The red marker will depict the direction for the bile duct and the blue marker the direction of the pancreatic duct. On the real papilla the point of entrance (the orifice) is for both the bile duct and the pancreatic duct the same, but the angle in which the point of entrance is approached differs. In the exercise the blue and red makers will, however, be located a bit further from the center because overlapping markers cause errors and severely complicate the detection and control of position. Moreover, this exercise is just for positioning, so catheter advancement to the markers is no needed yet. It was deliberately chosen to make the target area's a bit larger than the dots, to create some allowed margin for the position of the dots. However, by making the areas larger than the dots, a much more rotated view onto the papilla would still be regarded as correct when there are only two dots and areas. By adding a third dot (the green dot), the allowed rotation of the scope is limited Figure 27.

When the third (green) reference point is not added, a more rotated view will be accepted while being an incorrect position in front of the papilla

Figure 27: Illustration of a rotated en-face position in in front of the papilla.

The center of the red target marker circle needs to be on the 11 o'clock line of the papilla and the center of the red target marker circle on the 2 o'clock line of the papilla. The exact location of the target markers is then determined by the criteria that the center of their circles need to be on the appointed lines and their areas are as large as possible while not overlapping each other and within the white papilla circle. The elaborative calculation of where the target markers will be located exactly can be found in the script (Appendix D), but in short the calculation of the location resulted in:

$$R_t = 3.7 * \frac{R_p}{9}$$

$$R_l = 5.3 * \frac{R_p}{9}$$

R_t = radius of the target marker [length presented in amount of pixels]
R_p = radius of the target (white) papilla [length presented in amount of pixels]
R_l = length from center of the papilla to center of the target marker [length presented in amount of pixels]

Figure 28C shows that the red target marker more or less corresponds to the point of biliary cannulation during real ERCP. This image was created with a prior version of the script in which the markers were still overlapping, but it shows that the position as it is requested in exercise 1 corresponds to the desired position in real clinical practice.

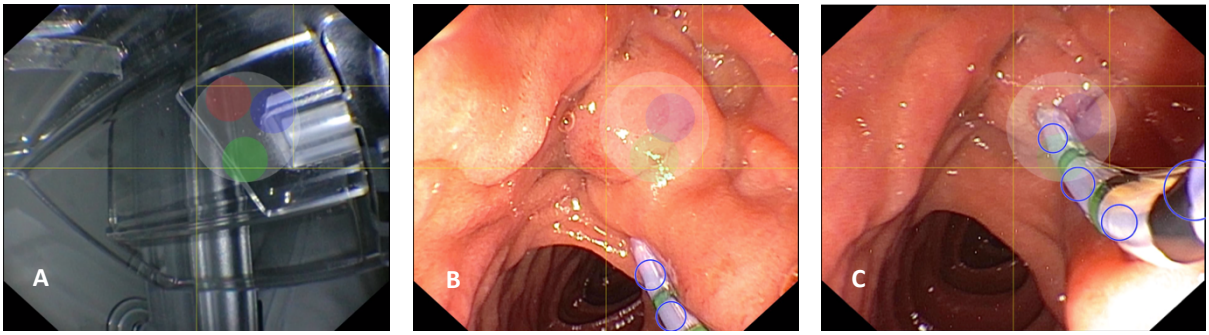


Figure 28: Screenshot in model (A) during real endoscopy (B & C).

To check whether the detected object is located within the target area the data of the video input which exists of pixels, needs to be matched to a standard xy-coordinate system. The xy-coordinate system is created as a mesh grid. The length and width of the video input are used for the length and width of the mesh grid, meaning that one pixel corresponds to 1x1 units on the mesh grid and the coordinate systems thus match.

The x and y coordinates of the circumference of the target marker can be calculated with the parametric (trigonometric) equation for the coordinates of all points on a circle's edge:

$$x = x_0 + r \cdot \cos(\varphi)$$

$$y = y_0 + r \cdot \sin(\varphi)$$

x_0 = the x-coordinate of the center of the target marker circle, r = the radius of the target marker circle and φ = polar coordinates of a circle (in this case every value from 0 to 2π, in steps of $\pi/50$)

The detected points are then placed on the mesh grid as a filled circle, using the standard equation of a circle. All points within the circle will have a value of 1 and all points outside the circle will have a value of zero.

$$A = (x_{grid} - x_0)^2 + (y_{grid} - y_0)^2 <= r^2$$

A = n x m matrix (n = length of video input data, m = width of video input data) with ones and zeros, x_{grid} = all x-coordinates of the grid, y_{grid} = all y-coordinates of the grid, r = the mean of the minor axis length and the major axis length of the object, x_0 = the x-coordinate of the center of the detected object (centroid) and y_0 = the y-coordinate of the center of the detected object.

To identify the x and y coordinates of all points of the object, the find function of MATLAB is used to provide all the coordinates of the points that have a value of 1. With the function "inpolygon" can then be checked whether or not all the coordinates of the object lie within a polygon formed by the retrieved x and y coordinates of the target area. If a point of the object lies within the polygon of the target area, the function will return a value of 1 for that point and a value of 0 when not within the polygon. Only if all returned values of the outcome of "inpolygon" are 1, then a yellow circle will appear on the display that surrounds

the target marker (Figure 26B). When all detected objects are within the appointed area (polygon) of their corresponding target marker, a great yellow circle will surround the entire papilla and the exercise will stop (Figure 26C). The whole script can be found in Appendix D.

9.4 Directing the catheter

9.4.1 Instructions & exercises

In the second exercise (exercise 2 of the whole program), guidance of the catheter will be trained. The goal of this exercise is thus to direct the catheter towards a requested position. Directing the catheter towards the proper direction consists of both skill-based behavior and rule-based behavior. The participant needs to know how to control the elevator knob that is needed for catheter advancement, and for selective cannulation the trainee also needs to know exactly where to direct the catheter to for each of the ducts. The instructions on how to control the elevator knob are provided by means of a short movie and written text on the PowerPoint presentation. The instructions on where to navigate the catheter to for which duct are already provided in the general instructional slides of the presentation and in the explanation of the first exercise. Originally one concept was developed for this exercise, since realizing the goal into an exercise results in one obvious solution.

9.4.2 Concept(s)

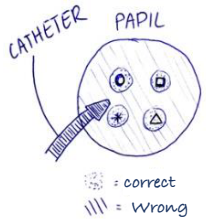


Figure 29: Sketch of papilla with markers

Realizing the goal of directing the catheter towards a specific target results in one obvious solution: create various markers to which the participant must direct to in a specific order, and apply touch sensors on the markers to assess the performance and the provide direct feedback to the participant of the correctness of his/her location. The original idea was to use 4 markers (as seen in Figure 29) for which a force that is applied too far away from the mark will be registered as incorrect and force that is applied in a certain radius (2-3 mm) as correct. Because for the first exercise eventually colored markers were chosen, the same colored markers were also used for the second exercise instead of the figure markers, meaning that there will be 3 markers instead of four. With the four randomly placed figure markers only the skill-based behavior of developing overall skills in catheter advancement is trained. But with the 3 colored markers, of which two of the markers are on the line towards the pancreatic duct and the common bile duct, also the specific directions for clinical practice are learned. This way the trainee not only develops the skill-based behavior for catheter advancement, but also remains aware of the rule-based behavior needed for real clinical deal.

The order for tapping the markers may be random sequences of “red”, “blue” and “green”. In-between sequences of colors, the scope must sometimes be retracted. The reason for these retractions is explained in *9.5.1 Part-task training*. In Figure 30 an example of an order that could be given to the trainees is depicted.

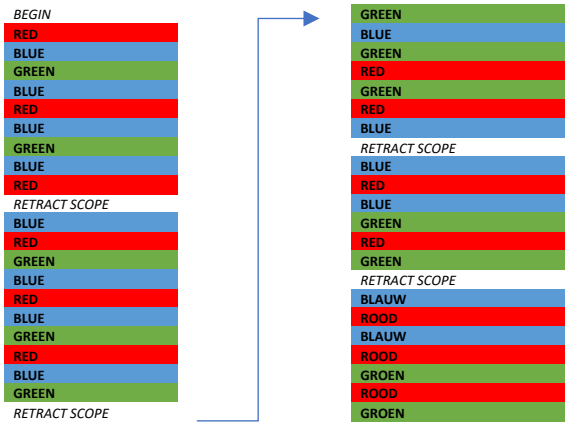


Figure 30: Example of color sequence during exercise

Material

The existing papilla of the ERCP trainer and the model itself are used for exercise 2. The sensor is modelled as a simple electric circuit, which closes as the catheter touches the marker. The markers and the tip of the catheter, therefore, need to be made of a conducting material and attached to the circuit. The markers are made from simple nails that puncture the papilla. The papilla is made out of rubber and with metal fibers and is thus a conductor. Sports tape is used for insulating the nails (from the conductive papilla) and for the attachment of the nails to the electric circuit. Jumper wires with female and male ends are used as wires for the electric circuit and a jumper wire with an alligator clip is used to attach the electric circuit to the catheter. The Huibregtse Triple Lumen Needle Knife of Cook Medical is used as the catheter. The ends of the nails are attached to jumper wires, which are connected to an Arduino Uno device. Both Arduino IDE and MATLAB are used for coding the exercise. In MATLAB, two support packages for Arduino were installed: “MATLAB Support Package for Arduino Hardware” and “Legacy Capacitive Sensor Add-On Library for Arduino”. By means of these packages, MATLAB can connect to the additional program Arduino IDE (programming application for Arduino) and implement the data of the Arduino to MATLAB. For the circuit, also a breadboard is used and three resistors of 1kOhm.

Sensing touch by voltage measurement

The sensor is modelled as a simple voltage meter. A microcontroller (Arduino Uno) in combination with MATLAB is used for measuring the voltage. Each of the markers on the papilla functions as a touch detection surface, as they will be connected, via jumper wires (electrical wire with a connector or pin at each end), to one of the analog input pins of the Arduino board and to one of the ground pins of the Arduino board. For the markers, nails of steel are used that puncture trough the papilla. The heads of the nails are the visible surfaces during the exercise and the tails of the nails, which will stick out of the backside of the papilla, will be attached to the jumper wires. Because the papilla is made of a conductive foamy material, body of the nail will be insulated with sports tape. As the Arduino is connected to the computer, the value of analog input pin can be read in MATLAB by using the function “readVoltage”. The function “readVoltage” measures the voltage applied to the analog pin relative to the ground pin. When the markers are not “touched” by an object connected to a power supply, the measured voltage will be zero because in this case there is no potential difference between the ground and the measured value of the pin. To detect the touch of the papillotome, the tip of the papillotome must therefore be loaded with a certain voltage. This voltage comes from one of the two power pins on the Arduino board. The Arduino, in turn, is powered by the USB cable coming from the computer. The two power pins on the Arduino have a regulated power supply of either 5V or 3.3V. An alligator clip jumper wire is with its male end plugged into the 5V power pin and with the other side clipped onto the Huibregtse Triple Lumen Needle Knife. In clinical practice, the needle knife is connected to the Electrosurgical Unit (the generator), but since this generator provides a relatively high current in combination with a severely high voltage, which could possibly be dangerous when not grounded properly, the power pin from the Arduino (generating a relatively low current in combination with a voltage so low that it is harmless) is connected to the needle knife instead. In the needle knife, a conductive wire runs all the way from the power supply attachment point at the grip handle, to the tip of the papillotome. At the tip of the papillotome the wire protrudes a little. When the tip touches one of the markers, the circuit will be closed and therefore the voltage can be measured.

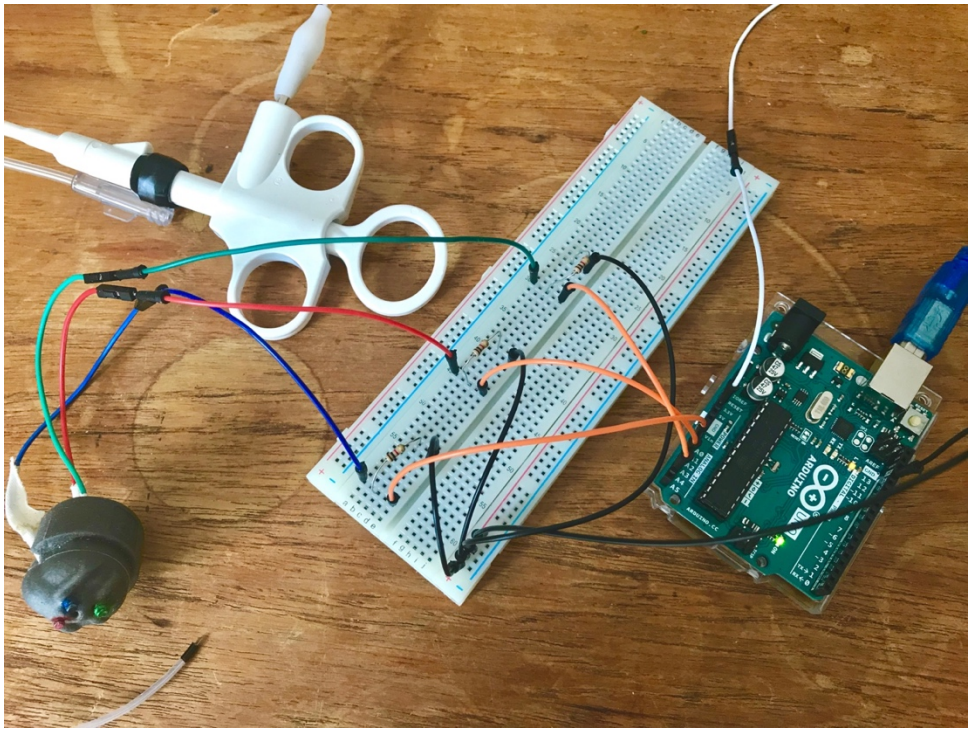
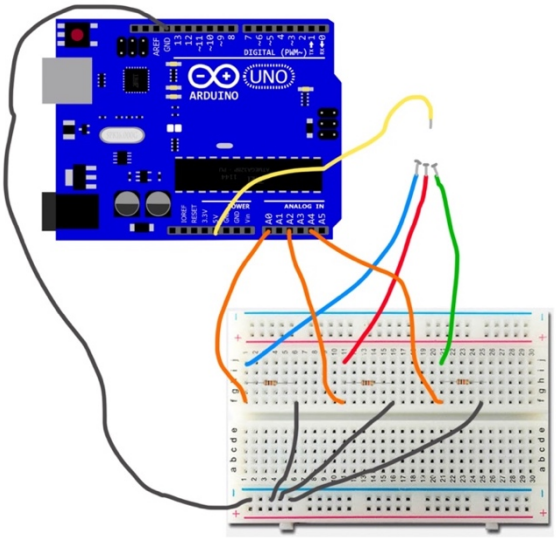


Figure 31: Picture of the set-up of the circuit

Figure 31 depicts the set-up of the circuit and Figure 32 represents a more schematic representation of the circuit. When the blue marker is touched, a current will flow through the blue wire and then trough the orange wire to analog in pin number A0. The voltage is then measured via the analog pin, with the existing MATLAB function from the Arduino add-on package "readVoltage". This function measures the voltage relative to the ground (0 Volt). The circuit is closed by connecting the wires to the ground pin (GND) in the Arduino. When envisioning the circuit as a battery powered circuit, the 5V pin of the Arduino can be seen as the positive side of a battery and the GND as the negative side of the battery to which the current will flow. Before going to GND a 1kOhm resistor is implemented in the circuit to prevent shorting the circuit. Ohms law explains that when there is no resistance (R), the current (I) will increase to infinity which would could damage the Arduino or the wires because a high current will cause an enormous heat (U = I*R).



The Arduino is powered via the USB cable that connects to the computer (cable left out of the figure). The yellow wires represent the circuit part from the 5V pin to the tip of the catheter (the catheter and it's attachment to the pin are left out of the figure). The papilla is not depicted in this figure for simplicity, but the touch surfaces at the end of the colored wires are still visible.

Figure 32: Schematic representation of the set-up of the circuit

It could be argued that digital pins are more suited for a binary measuring task as these, but when a force sensor (force sensing resistor) will be added onto the nails surface, a binary measurement will not be suited. Therefore, the analog pins were used for the construction. The voltage can be read from all the pins and plotted real-time in the same graph. The code can be found in Appendix E. This exercise can also be fully programmed in Arduino IDE instead of MATLAB, but because exercise 1 and 2 maybe need to be part of the same training program it is easier to use MATLAB for both.

9.4.3 Quick testing of the concept(s)

A simplified version of the concept was tested on its workability. In the test version, the wire coming out of the 5V pin is not attached to the catheter, whereby the end of the wire will touch the nail on the papilla instead of the catheter tip. For the test version, the ERCP trainer is also left out. The papilla is used as a separate object, not fixed onto the ERCP trainer. The test version shows that the circuit works and that the touches are plotted correctly in MATLAB.

9.5 Cannulation

In contrast to the other training needs, the concept for facilitating the last training need "cannulation" is very straightforward. Coming up with concepts for the instructions, the assessment and an overall exercise for independently practicing positioning and directing the catheter required some creative thinking, but what the exercise for practicing selective cannulation will be is evident: attempting selective cannulation on the ERCP trainer. Since all the instructions and skills needed for cannulation are already covered in the previous concept exercises, providing instructions or coaching is in theory (see *9.5.1 Part-task training*) not needed anymore when practicing actual selective cannulation on the Boškoski-Costamagna model. The trainee knows what to do and how to do it. The trainee just needs to combine the learned skills and practice this until an acceptable success rate is achieved. The only thing that needs to be added to the ERCP trainer to make "practicing cannulation" an exercises that is part of the developed training program, is a technological mean that checks whether or not the goal of the exercise (cannulating either the bile duct or the pancreatic duct) is accomplished. To do this, the technique of the catheter directing concept can be used. Conducting (touch) surfaces will be placed in each duct, so that a signal is given to the computer when the catheter tip ends up in a duct. Elements of the developed function for the positioning can be used to record the data of each trainee and eventually assess the competency level of the trainee based on the cannulation success rate.

Because of time limitations, the decision was made to not develop the technology for the last concept just yet. Testing the ability of the developed program, as a whole, to provide an effective independently executable cannulation training, is more urgent, and for the testing of the whole program, the technology for the cannulation exercise is not needed. The cannulation exercise can still be implemented in the program in the same way, only now the trainee needs to check the correctness of its cannulation (is the catheter located in the correct duct) him/herself by looking at the transparent ducts.

9.5.1 Part-task training

The trainee is competent in each of the core elements of selective cannulation (positioning and directing in the correct direction), which are trained in a sequential order, and therefore the trainee should (according to the article of Wightman and Lintern [150]) be qualified to execute the combined act, which results in cannulation, as well. However, the true effectivity of part-task training and its ability to transfer learned skills to real practice is called into question in some publications [171-174]. Van Merriënboer and Kester [174] describe part-task learning models as "Instructional models that apply an atomistic approach in which complex contents and tasks are reduced into increasingly simpler elements until reaching a level where the distinct elements can be taught to the learners" and whole-task models as "Instructional models that apply a holistic approach in which complex contents and tasks are analyzed in coherence and taught from their simplest, yet still meaningful, version toward increasingly more complex versions". By the way in which the act of cannulation is subdivided into five different tasks (the training needs), the developed program can thus be considered as a part-task training. De Croock at al [171] and van Merriënboer et al [172] both argue that part-task learning is ineffective. According to them, the fragmented instructions lead to the inability to integrate what is learned into new situations, which results in a rather poor transfer of the learned skills. Whole-task learning, on the other hand, helps learners to integrate the skills, attitudes and knowledge needed to effectively perform a complex task and thereby it enables them to transfer what is learned to daily life or work settings [173].

These statements call the effectivity of the developed training program, due to its part-task orientated set-up, into question. However, whole-task training would not be the appropriate set-up for this program either because of the high complexity of each of the tasks. The tasks "positioning" and "catheter directing" are even in their simples form already considerably difficult. Combining these two tasks together immediately at the beginning of training, would lead to cognitive overload. Van Merriënboer [172] acknowledges issue this by stating the following: *"if a very high level of automaticity of particular recurrent aspects is required, the learning tasks may provide insufficient repetition to provide the necessary amount of strengthening. Only then, it is necessary to include additional part-task practice for those selected recurrent aspects in the training program."* Since the training needs do require a high level of automation (being a combination of rule-based and skill-based behavior), part-task training is required in this case.

Although the use a part-task set-up for the training is now in a way justified, the risks of not transferring skills due to separate training of each of the tasks, still exists. To decrease this risk, aspects of whole-task training theory should be incorporated. This can be done as following: during every exercise the focus is still on one task, but during the consecutive exercise also the learned skill of the previous exercises needs to be consulted. This previously learned skill will only be a slight part of the consecutive exercises, the focus is more on the new skill. Because the previous skill is only in a small degree present in the upcoming exercise and moreover already practiced once, cognitive overload is avoided. In every consecutive exercise the amount of task that are represented in the exercise increases, but also the degree in which the task is present and the amount of cognitive load it requires decrease with every consecutive exercise. A schematic representation of this concept is provided in Figure 33. In the positioning exercise the controlling skills are consulted automatically. For the catheter directing exercise (exercise 2) the control skills will also be consulted automatically, but the positioning skills are not directly part of exercise 2. To make positioning part of this exercise, scope retraction moments are implemented into the tapping order, so that a proper position in front of the papilla to execute the tapping from must be established again. This way, the acts of positioning and catheter advancement will be merged. Another tool that is used to support the integration of the learned skills, is simply mentioning the overall goal of the training "cannulation" at each exercise and thereby explaining in each exercise that the main skill of that specific exercise is part of the overall requirements for proper cannulation.

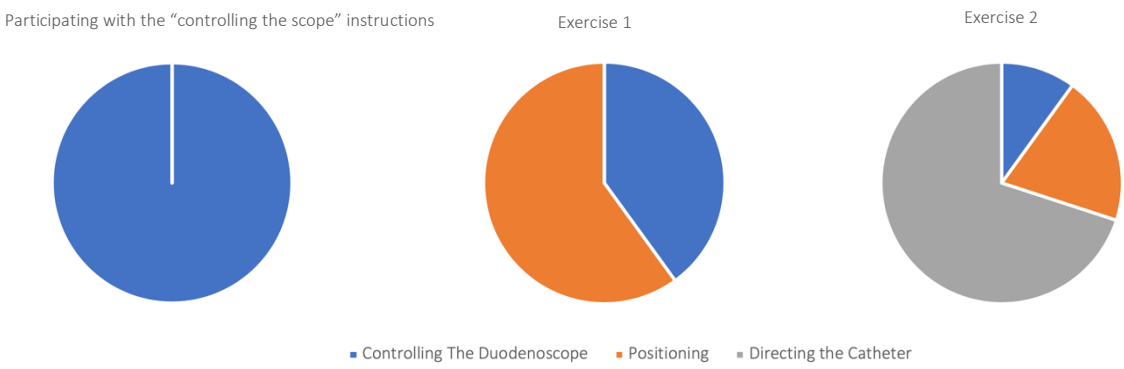


Figure 33: Amount of presence of a skill/task per exercise

PART 4

CONCEPT TESTING

10 CONCEPT TESTING

In this chapter the developed training program will be tested, in order to verify whether or not the objective of developing a training that results in increased cannulation skills has been met. The effectivity of the training as a whole will be tested, based on quantitative measurements. The method for conducting the experiment will first be discussed, thereafter the results will be outlined. During the execution of this experiment, the functioning of each separate element of the program (e.g. instructions, the exercises, the program set-up by means of difficulty increasement and cognitive overload) can, at the same time, be observed. Based on the results of the quantitative test, the on the scene observations and the afterwards feedback of the participants, the program as a whole can be evaluated and areas of improvement can be highlighted. The interpretation of the results and observations can be found in the discussion, which takes place in the next chapter..

10.1 Method

The effectiveness of the developed training program will be tested by comparing the skills of a subject group (Group 1) that has executed the developed training, with a subject group (Group 2) that did not execute the training. Regardless of the true effectiveness of the constituted training, the fact that trainees get some form of experience with the duodenoscope will lead to improvement of their skills. Therefore, Group 1 needs to be compared with a subject group that receives the same amount of exposure to the duodenoscope and the ERCP trainer, but without being guided by a training program.

Six trainees that are in their 4th of 5th year of the gastroenterology program in the Amsterdam UMC were selected for the experiment, as 4th and 5th year trainees do have some forward-viewing endoscopy experience, but no side-viewing endoscopy experience. Three trainees were randomly assigned to group 1 and the remaining three trainees were assigned to the control group 2. In fulfilment of the pre-training principle both groups received the same PowerPoint presentation that they needed to go through, two days prior to the experiment, which contained instructions for selective cannulation, on how to control the duodenoscope etc. (See Appendix A and first part of Appendix C). The same presentation was also shown to the trainees at the beginning of their first exercise, only now they were instructed to participate with the directions on how to control the duodenoscope. During the exercise, they receive five minutes to go through the presentation, before their first exercise really starts.

Table 7: Schedule of the experiment

			Room 1		Room 2	
Start	**End**	**Total time**	**Activity**	**Trainee**	**Activity**	**Trainee**
17:45	17:50	0:05	instructions	1A	instructions	2A
17:50	17:58	0:08	exercise 1	1A	exercise 1	2A
17:58	18:01	0:03	switch		switch	
18:01	18:06	0:05	instructions	1B	instructions	2B
18:06	18:14	0:08	exercise 1	1B	exercise 1	2B
18:14	18:17	0:03	switch		switch	
18:17	18:22	0:05	instructions	1C	instructions	2C
18:22	18:30	0:08	exercise 1	1C	exercise 1	2C
18:30	18:33	0:03	switch		switch	
18:33	18:38	0:05	exercise 2	1A	exercise 2	2A
18:38	18:41	0:03	switch		switch	
18:41	18:46	0:05	exercise 2	1B	exercise 2	2B
18:46	18:49	0:03	switch		switch	
18:49	18:54	0:05	exercise 2	1C	exercise 2	2C
18:54	18:57	0:03	switch		switch	
18:57	19:02	0:05	exercise 3	1A	exercise 3	2A
19:02	19:05	0:03	switch		switch	
19:05	19:10	0:05	exercise 3	1B	exercise 3	2B
19:10	19:13	0:03	switch		switch	
19:13	19:18	0:05	exercise 3	1C	exercise 3	2C
19:18	19:28	0:10	break		break	
19:28	19:33	0:05	exercise 4	2B		
19:33	19:37	0:04	switch			
19:37	19:42	0:05	exercise 4	1C		
19:42	19:46	0:04	switch			
19:46	19:51	0:05	exercise 4	1A		
19:51	19:55	0:04	switch			
19:55	20:00	0:05	exercise 4	2A		
20:00	20:04	0:04	switch			
20:04	20:09	0:05	exercise 4	1B		
20:09	20:13	0:04	switch			
20:13	20:18	0:05	exercise 4	2C		

The experiment consists of four exercises, of which the first three take place in two different rooms (see schedule in Table 7). During each exercise, only one trainee will be present in each room, together with a supervisor. The supervisor will not provide any instructions but is needed to assist with the catheter advancement (exercise 2 and 3) and to observe the proceedings for afterwards feedback. Catheter advancement can also be done without assistance, but to save time (time for conducting the experiment was limited), assistance was provided so that all time is spend on the task of interest and not on a side issue. Moreover, during real ERCP, an assistant helps with the catheter advancement trough the biopsy port. This task is therefore not part of the training needs. The trainees of group 1 do their first three exercises in room 1 in which the required elements for the developed training program are installed; the computer that runs the MATLAB script for the two games is connected to the duodenoscope tower, the adjusted papilla with the color markers is attached to the model (different papilla for exercise 1 and 2), and for the second exercise the Arduino set-up is attached. For group 1 the first exercise is equal to the first exercise of the developed training. During this exercise, the trainees have 8 minutes to complete the game (positioning the scope correctly in front of the papilla) as often as possible. After completion of every game, the scope must be retracted out of the model, to start over again. Prior to the game, the trainees have 5 minutes to go through the instructions on how to direct the scope. The instructions will finish with a slide that explains the exercise to the trainee. In the other room, trainees of group 2 receive the same prior instructions during exercise 1, but their last slide is different; their assignment is to play with the duodenoscope and model for 8 minutes. They are not allowed to use the catheter yet. They look at the normal monitor instead of the computer and a normal papilla without an opening (to avoid cannulation attempts) is attached to the model.

For the trainees of group 1, the second exercise is equal to the second exercise of the developed training. They have 5 minutes execute the exercise and cover as much of the provided sequence as possible. Group 2, again, is assigned to play with the scope and model for 5 minutes. The catheter can now be used by group 2, but cannulation of the papilla may not be attempted yet (papilla still has no opening). Exercise three is exactly the same for both groups; cannulation of the CBD may be attempted for 5 minutes and therefore a papilla with an opening ductal system attached to it, is fixed to model. The fourth exercise is also identical for both groups and takes places in the same room (room 2) for both groups. The trainees are asked to cannulate the CBD as often as possible within 5 minutes. The overview of all the whole training, including the exercises, can be found in Appendix C. During this exercise, an expert will assess the performance of each trainee (of both groups) based on some quantitative measurements and some subjective measurements that were retrieved from the OSATS form [175]:

Quantitative measurements:

I. Time needed to cannulate the CBD
II. Number of PD cannulations during each attempt
III. Number of pokes on the papilla during each attempt

Subjective measurements (score between 1 and 5):

I. Respect for tissue
II. Time and motion
III. Instrument handling

The expert appoints three grades with a value between 1 and 10 to every trainee, based on their performance during exercise 4. The average of those three grades results in an overall rate for the performance during exercise 4. The three grades are calculated as following:

$$Time\ Grade = 10 - ((A - 10) * 0.075)$$

$$Accuracy\ Grade = \frac{(N * 10 - (1.5 * TP) - (4 * PD))}{N}$$

$$Technique\ Grade = \frac{2 * (RT + TM + IH)}{3}$$

A *= average time of all CBD cannulation attempts,* ***N*** *= CBD cannulations,* ***TP*** *= total number of papilla touches during all successful attempts,* ***PD*** *= total number of PD cannulation during all successful attempt,* ***RT*** *= Respect for tissue score,* ***TM*** *= Time and Motion score,* ***IH*** *= Instrument handling score.*

The form that was handed to the expert to during the experiment is shown in Appendix I. To prevent biased judgement, the expert that performs the assessment will not know which trainee belongs to which group. Therefore, the sequence in which the trainees enter room 1 and perform exercise 4, is random. For the remaining three exercises the sequence of executing the exercises was assigned, so that the rest periods in-between exercises were equal for every trainee. Measuring the effectiveness of the independently executable training as a whole is not the only goal of the conducted experiment. The structure and set-up of the program will also be analyzed, by observing the behavior of Group 1 subjects during the whole training and by asking the subject for their feedback, afterwards. Based on these findings, an assessment can be made on how well the non-interactive instructions succeed in providing complete and qualitative instructions and on how well the tasks of the human educator have actually been replaced.

10.2 Results

Table 8 depicts an overview of the performance of each trainee during the 4th exercise. The overall grade for each trainee is determined and based on that an overall grade for each subject group can be defined. There are two overall grades for group 1: one that does incorporate the grade of trainee 1A and one that does not. The reason for this is that trainee 1A appeared to have some ERCP experience. Because of this experience, trainee 1A does not meet the criteria for the target group anymore. Including the score or this trainee could bias the outcome of comparison test.

Table 8: Results of the experiment

			Group 1			Group 2		
			Trainee 1A	Trainee 1B	Trainee 1C	Trainee 2A	Trainee 2B	Trainee 2C
Measurements	Attempt 1	Time	01:10	01:08	02:20	01:08	01:58	01:28
		PD cannulation	0	0	0	0	0	0
		Touch papilla	0	0	4	2	1	2
	Attempt 2	Time	01:09	00:48	00:50	01:12	01:59	01:18
		PD cannulation	1	0	0	0	0	0
		Touch papilla	2	0	1	1	2	0
	Attempt 3	Time	00:37	00:57	00:39	01:25		01:03
		PD cannulation	0	0	1	0		0
		Touch papilla	0	3	1	1		1
	Attempt 4	Time	00:36	00:51				00:59
		PD cannulation	0	0				0
		Touch papilla	1	2				0
	Attempt 5	Time	00:33	00:40				
		PD cannulation	0	0				
		Touch papilla	0	0				
	Attempt 6	Time		00:35				
		PD cannulation		0				
		Touch papilla		1				
	Mean time		00:49	00:49	01:16	01:15	01:58	01:12
Technique (observation by expert)	Respect for Tissue (RT)		3	3	2	2	2	3
	Time and Motion (TM)		2	2	2	2	2	2
	Instrument Handling (IH)		2	2	2	2	2	3
Grades	Grade 1 (Time)		7,1	7,1	5,1	5,1	1,9	5,4
	Grade 2 (Accuracy)		8,3	8,5	5,7	8,0	7,8	8,9
	Grade 3 (Technique)		4,7	4,7	4,0	4,0	4,0	5,3
	Overall grade individual		6,68	6,75	4,91	5,71	4,55	6,52
	Overall grade groups		***6,11***			***5,59***		
	Overall grade groups without Trainee 1A		***5,83***					

PART 5

EVALUATION

11 DISCUSSION AND RECOMMENDATIONS

In this chapter the results of the experiment will be analyzed and discussed. The quantifiable outcomes will be commented on in terms of what they can tell about the effectivity of the program, but the effectivity of the program as a whole and of every developed concept separately, will also be evaluated based upon the observations that took place during the experiment and the feedback provided by the participants. The potential of the developed program will be discussed, areas of improvement will be highlighted and based on that, recommendations on further research or developments will be provided.

11.1 Effectiveness of the training (based on the quantitative test results)

Although group 1 scored better at the last exercise, even without the incorporation of trainee 1A's score, the difference between the two groups is very small; a score of *5,83* for group 1 and *5,59* for group 2. Due to the very tiny difference and the small sample size of the subject groups, the results are not at all significant. Therefore, the developed program cannot be regarded as effective or as an added value just yet, when solely looking at the test results. Unfortunately, more subjects that meet the criteria could not be acquired at the time of testing, due to the limited resources of this student research project. To properly examine the effectiveness of the developed training, a similar test with larger subject groups should be conducted. However, even when a subsequent larger study demonstrates significant results, the question remains whether or not the acquired cannulation skills on the ERCP trainer will translate into improved cannulation skills during clinical practice. An additional test could be done to examine this question, but three studies that examined the translation of cannulation skills on the ERCP trainer and or another mechanical, model to clinical practice when training was provided by a human instructor, already showed positive results [20, 25] [26]. These studies were not for independently executed training, but when both the independently executable program and the simulator itself show to be effective, translation of cannulation skills acquired by the independently executable training on the ERCP training to clinical practice is more than likely.

Returning to the test results, there are some additional interesting findings. The fact that there is a gaming element involved, should automatically result in increased motivation and attention compared to random practice and voluntary use of the simulator [161-164]. This does, however, not show in the test result. The reasons for this are that the trainees of the control group did still feel some form of competition and arousal because of the experimental setting and the fact that they knew that their instructor was going to rate their skills at the end. In the normal non-experimental setting of random practice, this arousal and increased motivation will not be present. The arousal caused by the experimental setting may have led to biased results and therefore the assumption that gaming increases the motivation and thereby the learning is not rejected. Additionally, the fact that the time for each exercise was very short might have primarily affected the trainees of group 1 negatively, because the assignments that they were given required more time to understand than the assignments of group 2, that consisted of playing around. Not only did the understanding of the exercises presumably cost more time, but additionally the exercises, in which a certain skill needs to be developed, possibly didn't come into their own for such short practice times. Unfortunately, the time for conducting the experiment was limited, therefore observing and testing for longer periods was not possible. In a further research study, the effectivity should be measured over a longer period. By solely looking at the quantitative results of the experiment, no conclusions can be drawn regarding the effectivity of the developed training program in improving cannulation skills.

Passing conclusive judgement on the true effectivity and efficiency of the developed training program may not be possible just yet based on the test results, this however doesn't mean that using the program is not recommended. As mentioned, simulation training is urgently needed to reduce the risk for the patient and to expand training opportunities. Experts do not have the time to assist during simulation training and therefore trainees should practice on the simulator by themselves. Voluntary use however leads to demotivation since there is no goal to achieve, no check on the performance and no form of competition, and additionally it can also lead to training the wrong tasks and learning the wrong techniques. Implementing a gaming element by definition solves the motivation problem as mentioned before (*8.3 Serious gaming*), and potentially also the remaining two issues. Training the right tasks can be enforced by implementing exercises in the game of which the goal is to achieve competence in a (well considered) selected task. This is done in the developed program by facilitating exercises that cover the defined training needs. Using the right technique for performing the task can also be enforced to some extent, by using realistic and strict criteria for grading procedure success and providing sufficient instructions. In exercise 1 this is obtained by strict criteria for the size, the shape and the location of the marker. The criteria for the size make sure that the distance to the papilla is correct (too large area for example means that the scope is positioned to close to the papilla), the criteria for the shape ensures an en-face view at the papilla (when the area is too ovally shaped, the scope is enfacing the papilla too much from the side) and the location criteria makes sure that the papilla is located at the right location on the display (lower left corner of upper right quadrant) and not rotated so that the bile duct is still aligned with the 11 o'clock axis of the enfaced papilla. Without additional proof of the effectivity in numbers, the developed training can still be putted into practice, (hardly) without causing any negative effects as long as the game is properly designed. Then the only risk left that could be a result of independent training is careless use of the duodenoscope, but this can be minimized by facilitating one lesson in proper instrument handling. The set-up of the games and the training will be discussed in the next section.

11.2 Evaluation of the training based on observations and feedback

Examining the overall effectivity of the developed training based on quantitative measurements was not the only reason for conducting the experiment. The experiment was also carried out to evaluate the ability of the developed means to properly fulfill the essential tasks of the human instructor, and thereby to facilitate an independently executable training. This is done by observing the trainee's behavior during the experiment and asking for their feedback afterwards. By watching the subjects perform every step of the program, areas for improvement can easily be detected. This way the developed products/exercises can be evaluated on how well they perform as being a stand-alone mean that facilitates training in one of the defined training needs, but also on how well all developed means for the training needs together perform as being a complete program which results in increased cannulation skills.

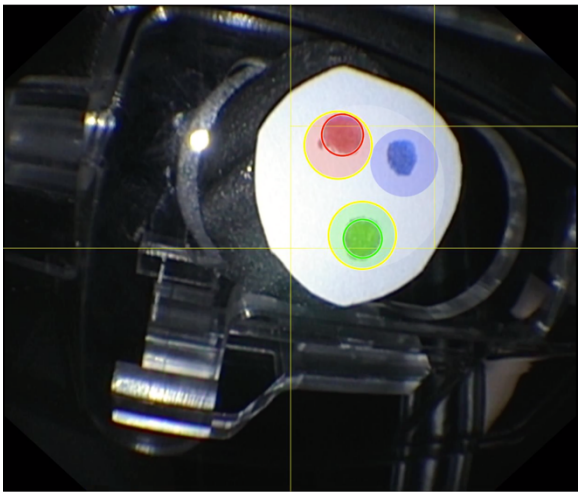
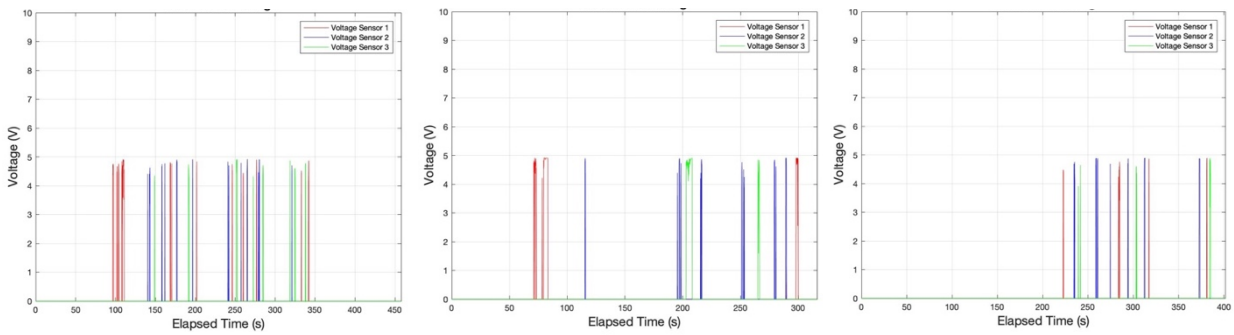


Figure 34: Screenshot of not detected blue marker

The instructions on how to control the scope did not seem to cause any issues. No struggle or cognitive overload was observed and therefore the provided information seems to properly match the level of the trainees. The first exercise did not seem to cause troubles either. The correct position was achieved numerous times within the set time for the exercise by every trainee. However, one of the trainees complained about the fact that the position was not recognized as correct while the three dots did appear in their target area's on screen (see Figure 34). There are three possible causes for this issue: 1) An error in the MATLAB script for recognizing the objects, 2) the dots are not depicted (drawn) correctly on the paper, 3) the angle of viewing at the papilla is incorrect. As the issue did not occur for other trainees and the papilla does appear to be faced a little sideways, an improper angle during the positioning seems the most likely cause. However, the blue dot does not appear fully round, therefore the drawing of the dots should be done with more precision.

During the second exercise, the trainees struggled with the first advancement of the catheter. It took them a while to perform the first tap on one of the dots (Figure 35). Yet, this does not necessary indicate improper or insufficient instructions. It can be expected that a new maneuver as such, with an unfamiliar control knob requires some time to get a hold on. During the exercise the trainees expressed their lack of understanding, but without providing additional instructions the trainees eventually all managed to figure it out.



Left graph represents the activities (over time) of trainee 1A, the middle graph represents trainee 1B, and the right graph represents trainee 1C.

Figure 35: Measurements during exercise 2

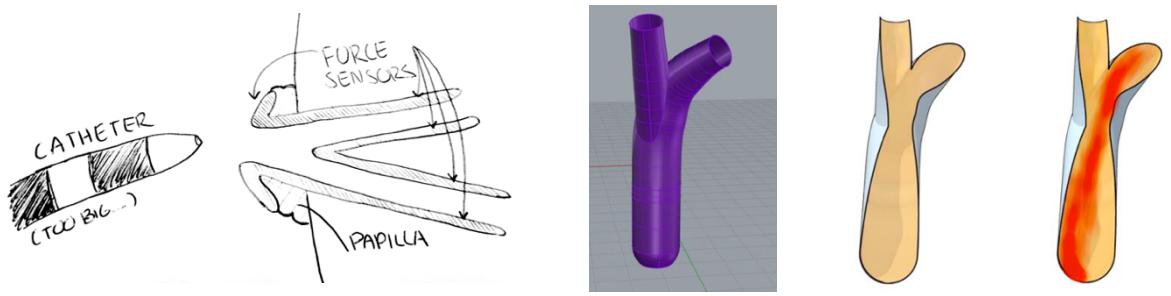
As mentioned before, the provided instructions appeared to be sufficient to successfully complete each exercise. The assessment performed by the means (the developed assessment technologies) served its function to direct the trainees towards the goal of the exercise and confirm correct outcomes. Each trainee was able to complete the program without experiencing difficulties with the execution of the exercises or understanding the provided information and instructions. However, while the separate exercises were executed properly according to the criteria of the assessment technology, not all trainees seemed to understand the real goal of the exercises. It was expected that the trainees would link the acts that they needed to perform in the exercises to the steps of cannulation, but in the second exercise, two of the trainees did not seem to consult the previously learned positioning rules and skills consistently during the catheter directing, and in the third exercise in which the whole act of cannulation was practiced, two of the trainees also did not seem to consult the previously learned positioning and catheter directing rules at all times. Apparently, the goals of exercise 1 and 2 were not linked to the overall goal "cannulation" properly. Although the need for a certain position to obtain successful cannulation as well as the need to guide in the proper direction for selective cannulation, was clearly denoted (by means of illustrations and written text) in the overall instructions and also in the description of each of the exercises, it appears that trainees might neglect that information for executing the second and third exercise. Not transferring the learned skills to the next exercise and not integrating every task into the overall and final task of cannulation, can be attributed to the part-task elements of the training program set-up. Section *9.5.1 Part-task training* already mentioned the risk of not integration skills when using part-task training, but this potential issue was expected to be avoided by implementing aspects of every previously learned skill into the consecutive exercise and by describing in the instructions of the exercise how the exercises relates to the overall goal of cannulation. These measures apparently were not enough to prevent the non-linkage and non-integration of the tasks.

If, or till what extend the developed training program actually leads to zero transfer or negative transfer, is not known. To uncover this, trainees should be tested after training for a longer time period. This whole examination can however be avoided by solving the non-linkage and non-integration issue of the program, and as a matter of fact, the solution for that is possibly rather simple: the assessment of the position (used for exercises 1) must also be implemented in exercise 2. Because the used measures did not sufficiently impose proper positioning in the second exercise, the act of positioning should be enforced by adding also the positioning criteria to the set requirements (for the assessment technology) for accrediting success. For practicing the combined act of cannulation in exercise 3, an assessment mean has not been developed just yet. Considering the neglection of the positioning rules when not assessed on, it is recommended to also implement the technique of object detection in this exercise. The location of the marker (dots) on the papilla need to be changed to make cannulation possible. Additionally, also warnings signs can be inserted into the exercises. Since the attention of some trainees cannot be caught during the instructions, signal needs to be given during the exercise. A warning signal containing a question such as "is your scope in the correct position in front of the papilla?", may be inserted during the exercise as a display confiscating message or audio/video message, and thereby pausing the exercise for a couple of seconds. During the cannulation exercise (exercise 3) these signs should also contain the question "did you direct the catheter towards the correct axis? (11 o'clock BD, 2 o'clock PD)", to make sure that the information of the previous scope direction exercises is consulted during the selective cannulation.

In *7.3 Rule-based behavior* it was questioned whether or not variations in difficulty must be incorporated in the training and, if so, which variations and at what point in training. In the experiment there were no variations in difficulty implemented because cannulation already appeared to be complex enough. It must be noted that during this experiment the amount of practice that the participants had was very little, considering the finding that the development of acceptable cannulation skills requires about 250 attempts (see *7.4 Knowledge-based behavior*). It is fair to say that implementing various difficulties into the training program at some point in training would improve the program, because the trainees then learn to apply learned skills in different scenarios. The outcomes of the experiment, however, do not provide new insights on what variations should be implemented in the training exactly and at what the point in training.

The view of experts and educators must be taken into account in the development of serious games [165-167]. Therefore, during the course of the investigation, two of decisions were made based on arguments put forward by the physicians and experts involved in the project: 1) choosing to leave the route to the papilla out of the program and 2) deciding to leave detailed explanation on what ERCP is, what the indication, the possible procedures, and the complications are, etc. out of the PowerPoint presentation. It could be argued that these decisions were to some extend in conflict with what literature advised on these topics, as in *4.2 Inserting the duodenoscope* it was hypothesized that the way in which the scope is passed through the body does affect the chances of cannulation success, and in *7.3 Rule-based behavior* it was stated that performing without proper indications is a common reason for legal allegations after ERCP. The evidence for the importance of the route is however scarce, and because other elements, as positioning for example, are systematically mentioned as being crucial for cannulation it was decided to focus on these elements. The arguments that dispute leaving out the protocol knowledge elements are more substantiated by literature. In *7.3 Rule-based behavior,* the section in which this issue is discussed, the need for training the more theoretical aspects was not dismissed, but the conclusion was that aspects can just as well be trained with more simple means (e.g. books, video's, written exams) and therefore this part is left out of the practical training. Protocol knowledge is however an undermined topic while thorough knowledge of this could significantly improve the effectiveness of learning during the practical training [176]. Therefore, it is recommended to add a pre-training to the developed program, that covers all the theoretical elements. An exam can be implemented at the end of this pre-training, so that the trainees are only allowed to start with the practical training simulation training when sufficient protocol knowledge is obtained.

Another point of discussion is the circuit set-up of the second exercises. It could be argued that digital pins are more suited for a binary measuring task as these. The reason for using the analog pins instead of digital pins was to keep the option of (variating) force sensors open. According to the expert (Dr. Voermans), learning to control the applied force during cannulation is however not part of the essentials for beginners. In the found literature on risk factors for developing post ERCP complications, applying larger forces during cannulation is indeed nowhere mentioned. The amount of contact with the papilla, however, is [53]. Responding to this risk factor, another recommendation for further development of the program is to implement touch sensors on the papilla surface and the whole inner lining of the ductal walls for assessing the performance of the trainee during the last cannulation exercise with more precision. When this is saved, the trainee can look into his/her performance afterwards by observing a 3D image of the papilla with the applied touches depicted onto its walls. The trainee can then observe whether his/her path was correct or not. The computer attached to the model can assess the performance by setting criteria for proper and incorrect performance. The more extensive feedback is very useful for the trainee to learn from his/her mistakes. It is also useful for the gastroenterologist teacher, who can now look back at the performance of the trainee at any time and see what he/her did wrong and at which moment of the procedure. When all performances of the trainee are saved, learning curves can be established for each trainee. Due to time limitations this idea could not be realized, but a sketch of the concept and computerized impressions is depicted in Figure 36.



Force sensors on ductal and papillary walls

3D images of papilla and ducts (on right image the applied forces are depicted)

Figure 36: Sketches and impressions of future additions to the cannulation exercise

12 CONCLUSION

Based on the quantitative results of the conducted experiment, unfortunately no statements can be made on the effectivity of the developed program. The low sample size in combination with the relatively small measured difference in cannulation skills between the two groups (*5.83/10.00* score vs. *5.59/10.00* score of control group) caused the results to be non-significant. This, however, does not necessarily mean that the goal of the research study "**providing an independently executable training that efficiently and effectively teaches beginners the most important ERCP skills"** is not achieved. Conducting the experiment and thereby observing the performance of the participants provided a good insight into the overall functioning of the training program.

The overall impression of the training's set-up and adequacy in meeting the objective and facilitating the needs while also properly replacing the essential tasks of the human instructor to remain effective and efficient, is predominantly positive. The pre-defined instructions showed to be effective in supplying all the required information for performing the exercises properly on an independent basis. No cognitive overload was observed during the testing of the program and all trainees were able to execute the whole program on their own without encountering any real problems. Training was facilitated in all the listed training needs by means of exercises and instructions. The developed technology for providing the required feedback, assessment and documentation during the exercises, also showed to function adequately.

Based on the observation during the experiment it can be concluded that the *controlling the scope* and *positioning* needs are, besides just being represented in the program, also represented in an acceptable and thus effective way. Positioning is learned in exercise 1 and scope control is shortly taught, by means of participation, during the instructional section at the start of the program, but scope control will also develop during the positioning exercise. The way in which the *catheter directing* and *combined act of cannulation* needs are represented in the program right now, is not sufficiently adequate just yet, because the learned positioning skills of exercise 1 did not seem to transfer to the consecutive catheter directing exercise (exercise 2) and cannulation exercise (exercise 3). It is however expected that this issue can be solved by simply adding aspects of exercise 1 and 2 to exercise 2 and 3: In the catheter directing exercise, consulting the positioning rules can be enforced by implementing assessment technology of exercise 1 and its criteria for a proper position into exercise 2. For exercise 3, no assessment technology was developed just yet, but the touch sensor technique of exercise 2 can be used to confirm access to the right duct. Additionally, also the assessment technology and criteria of exercise 1 can be used to enforce correct positioning in the third exercise.

Overall it can be concluded that although the effectiveness of the of the training relative to random simulator exposure could not be proven significantly in this research study, the developed program still looks very promising. The low costs of the developed program and the fact that the presence of an instructor is not required, are factors that positively contribute to the efficiency of the simulator. The incorporation of gaming elements into the program will lead to increased motivation compared to voluntary use, the careful delimitation of the tasks/exercises will result in a program that trains the right skills, and the incorporation of feedback and assessment will lead the improved skills and the use of proper techniques. The developed independently executable simulation training could, with some slight adjustments, be a solution to the urgent need for a save ERCP training that is available to the trainees at any time.

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APPENDICES

Appendix A

PowerPoint presentation to watch a day prior to the actual practical training.

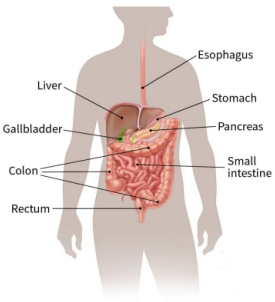
INTRODUCTION

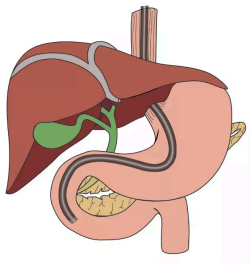
This training will start with an explanation of what ERCP is and for what it is mainly used. The basic principles will be explained by means of movies, images and written text. After clarifying the concept of ERCP, the focus will be on the core element of ERCP: cannulation. The requirements for successful cannulation will be described

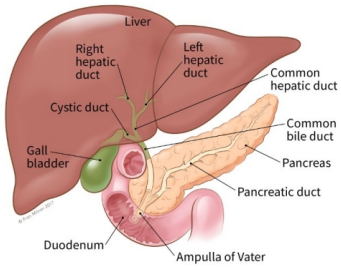
After the introduction, two parts "technical skills" and "theoretical knowledge" will follow that cover the requirements for performing cannulation. For the "technical skills" part is is recommended to participate and mimic the shown movements yourself with the duodedenoscope.

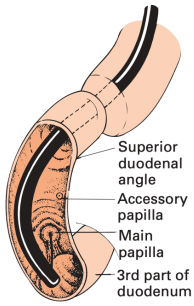
In the last part, the exercises will follow. These exercises need to be conducted on the model standing in front of you (the ERCP trainer).

Selective cannulation of the desired duct





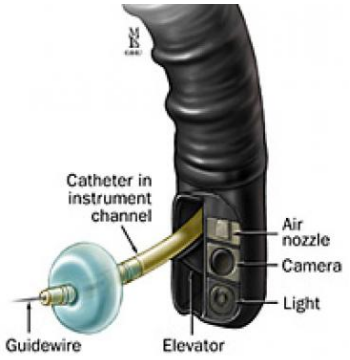




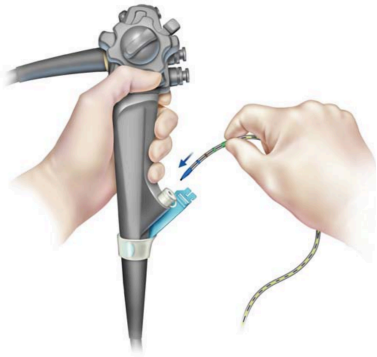
Landmarks in the duodenal loop.

After maneuvering the side-viewing endoscope (duodenoscope) through the mouth, esophagus and the stomach, the scope must be advanced to the combined entrance of the *pancreatic duct* and *common bile duct*: the **major duodenal papilla.** The papilla is located in the second part of the duodenum

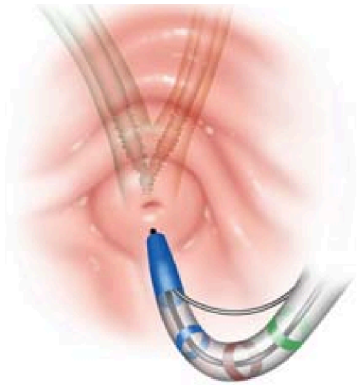
Selective cannulation of the desired duct



Tip of the duodenoscope



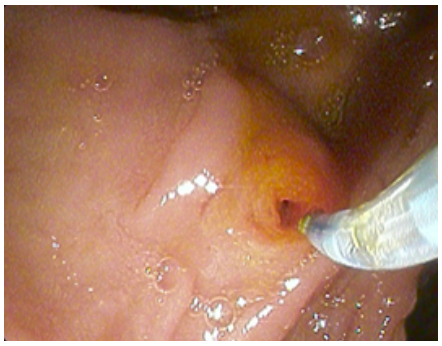
Advancing the catheter



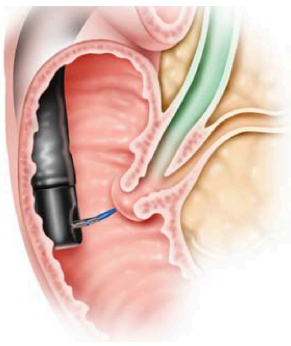
Papilla to be cannulated

Cannulation is done with a catheter (sometimes assisted by a guide-wire), coming out of the biopsy portal on the tip of the scope. The elevator system at the tip of the scope can lift the catheter up and down.

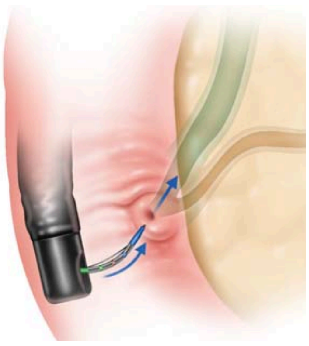
Selective cannulation of the desired duct

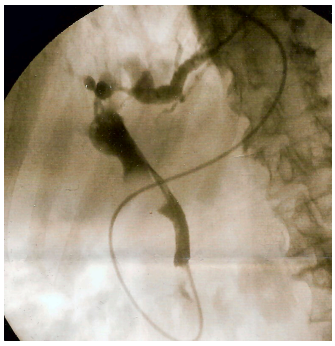


Cannulation of the papilla



Cannulation of the papilla





X-ray image of the cannulated papilla

Since the camera is attached to the scope, there is no sight of the area beyond the papilla orifice. Selective cannulation of either the bile duct or the pancreatic duct is therefore difficult.

Selective cannulation must be done based on the anatomical knowledge. When entered, the location of the guidewire and/or catheter (contrast) can be retrieved with fluoroscopy. The X-ray image is, however, from another perspective and vague

Required skills for selective cannulation

- Selective cannulation is the base of every ERCP procedure, but is (especially in the beginning of training) perceived as the most complex part of ERCP.
- The risk at complications (especially post ERCP pancreatitis) increases with the procedure time, the amount of failed attempts and needed and the level of contrast injections
- For achieving successful selective cannulation both **technical skills** and **theoretical knowledge** is needed.

<u>Technical skills:</u>

endoscopist needs to have ***complete control over the duodenoscope****. He/she must be able to maneuver and direct the scope into the desired position and to advance the catheter towards the point or direction of interest*

<u>Theoretical knowledge:</u>

the endoscopist needs to know ***how the scope should be orientated in front of the papilla*** *and link this to the images on the display, in which axes/direction the ducts run and where exactly to direct the catheter to in order to cannulate either the pancreatic or the bile duct.*

TRAIN TECHNICAL SKILLS

Controlling the duodenoscope

Feel free to participate when the slide is labeled with “do it yourself”.

EXPLANATORY

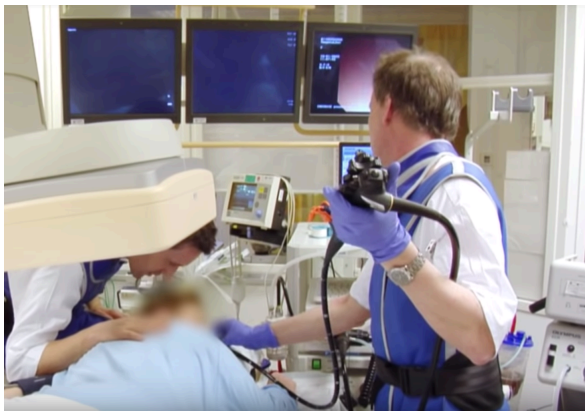
Hold the control handle with your left hand

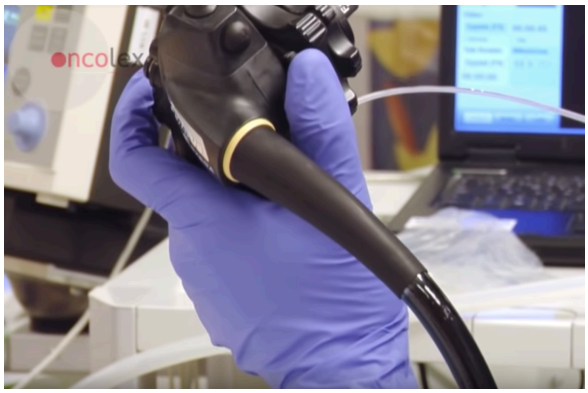
- The thumb must be in the position to control the two angulation knobs
- The index finger must be in position to control the air/water button.

Hold the insertion tube with your right hand

- hold the scope horizontal and parallel to the operation table
- The scope can be inserted into the mouth with your right hand

HOW TO HOLD THE SCOPE





DO IT YOURSELF

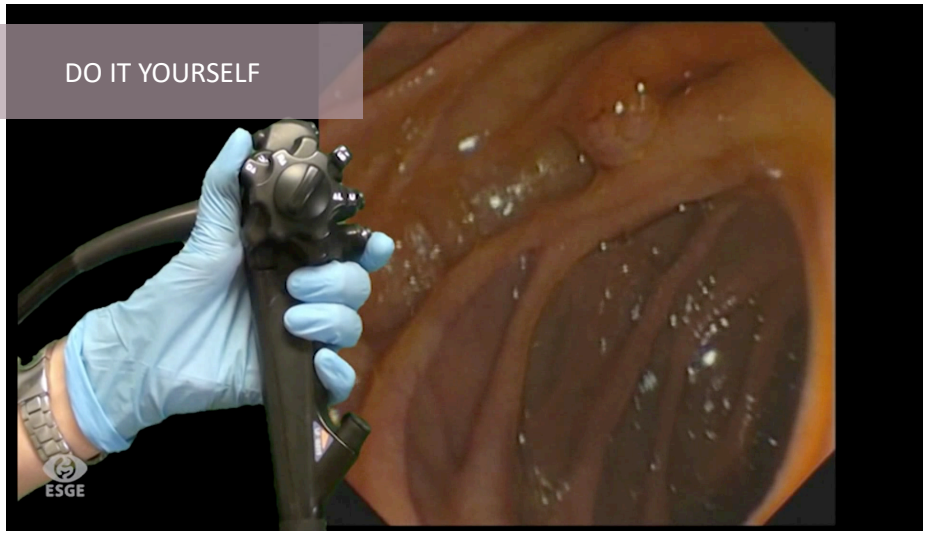
How to hold the scope

EXPLANATORY

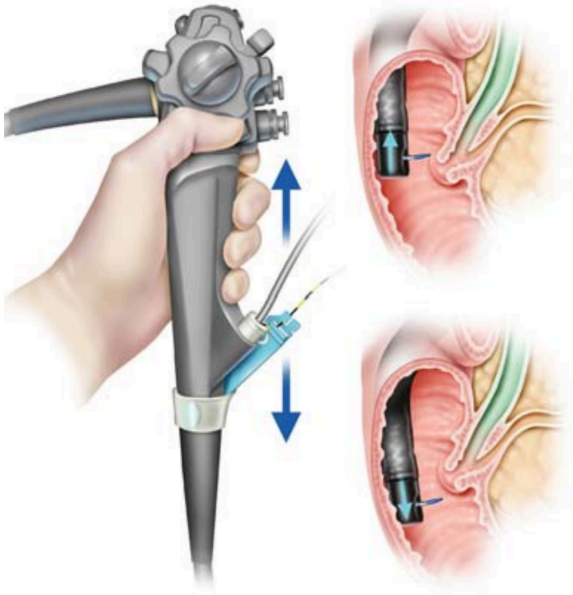
Basic movements

1. Push forward and pull back
2. Tip deflection: Up/Down and Right/Left.
3. Right and Left rotation (by applying torque)
4. Lifting up the catheter, coming out of the biopsy channel

DO IT YOURSELF

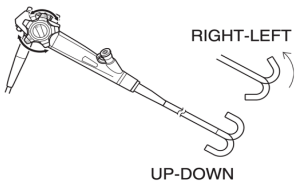


1. Push forward and pull back
(Move scope forwards and backwards)

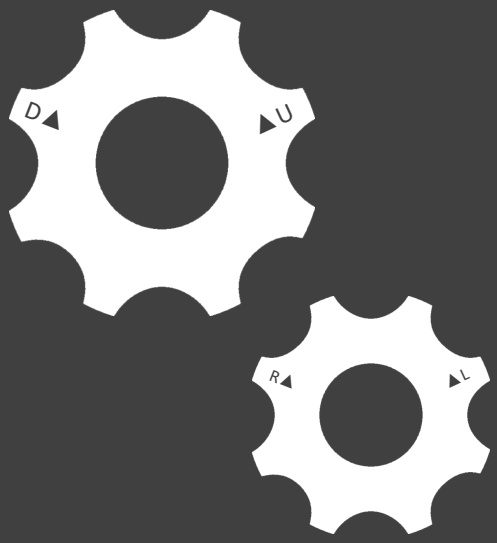


EXPLANATORY

2. Tip deflection up/down and left/right

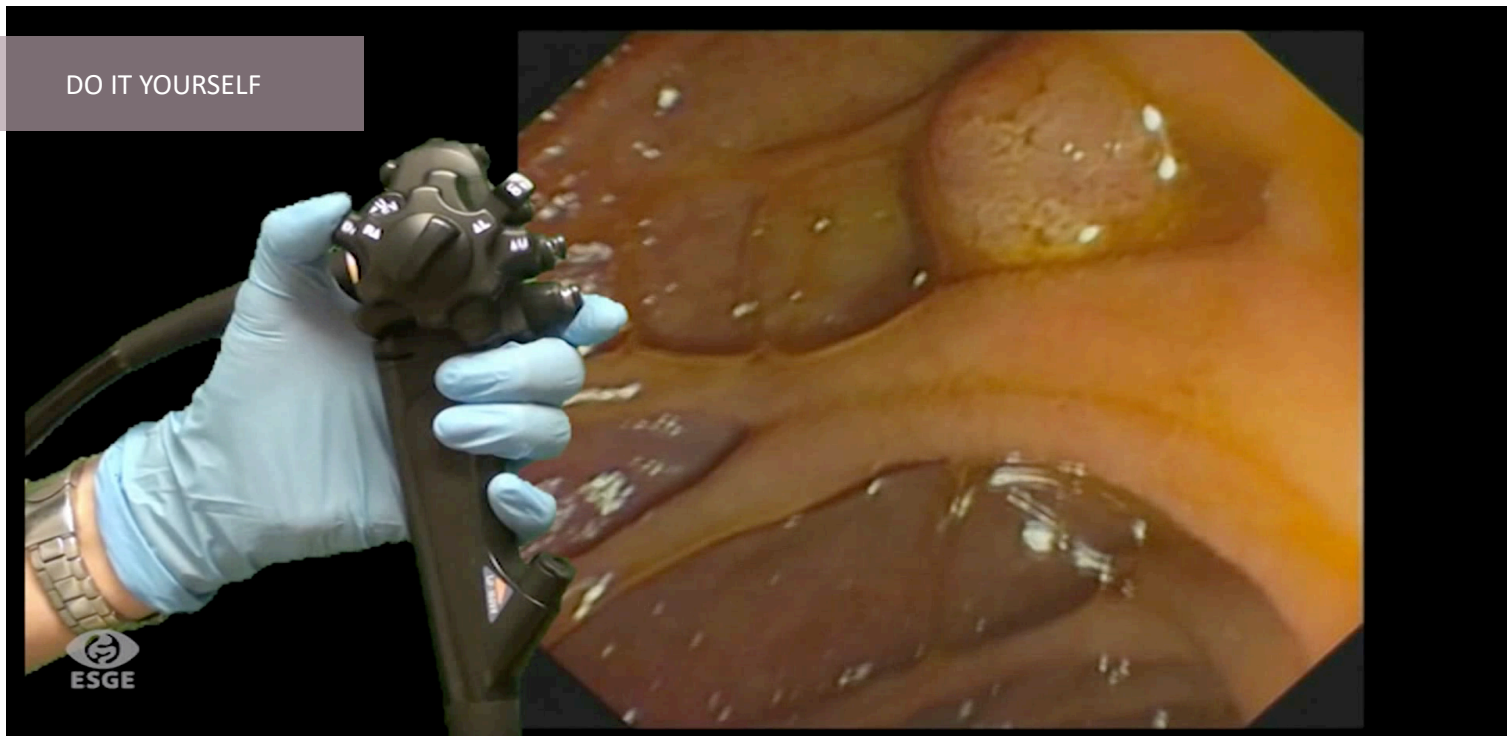


Use the first joint of your thumb to control the (big) up/down angulation knob



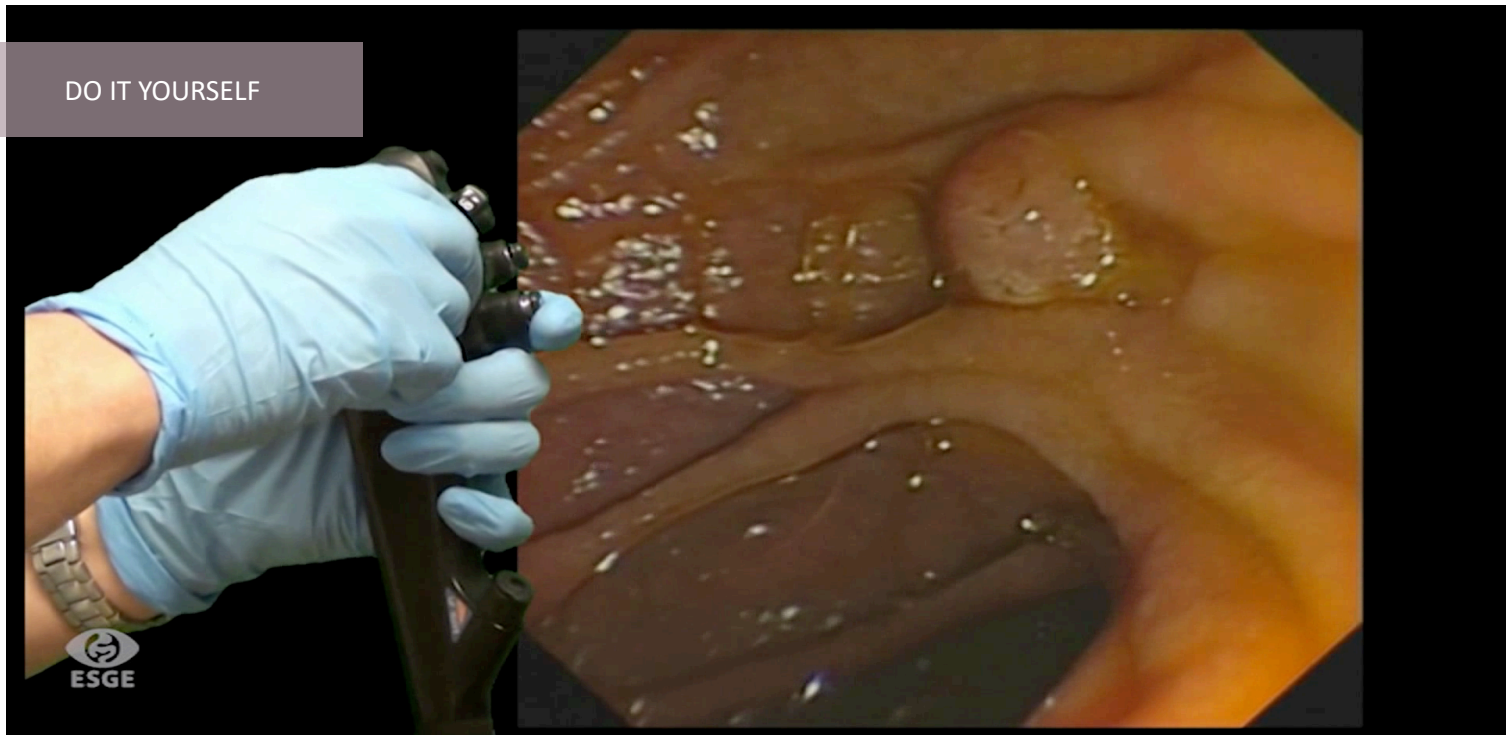
Use the tip of your thumb to control the (small) right/left angulation knob

DO IT YOURSELF



Tip deflection: up and down

DO IT YOURSELF

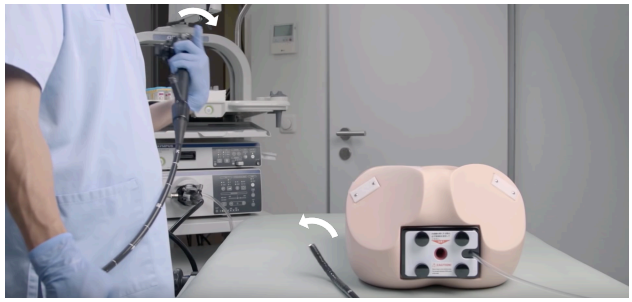


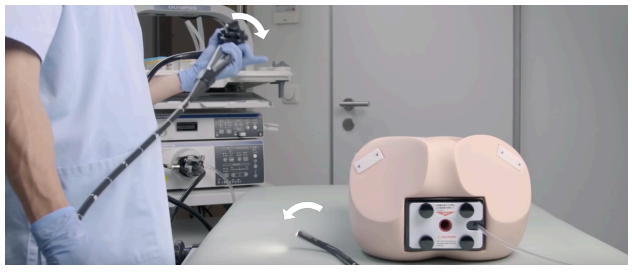
Tip deflection: left and right (Always perform with left thumb!! NOT with right hand as depicted in video!!)

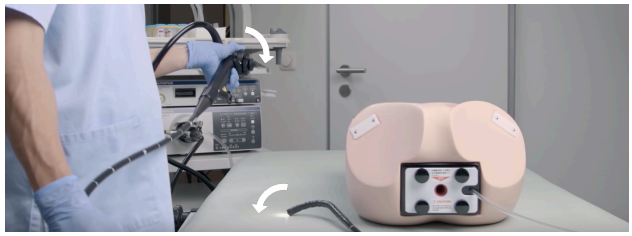
EXPLANATORY

Right and left rotation movements can by applied by:

- twisting left wrist (the hand holding the control section of the scope). *See pictures on the right*
- by applying torque to the insertion tube with right hand.
- By synchronizing both movements, torque can be applied to the scope even more efficiently





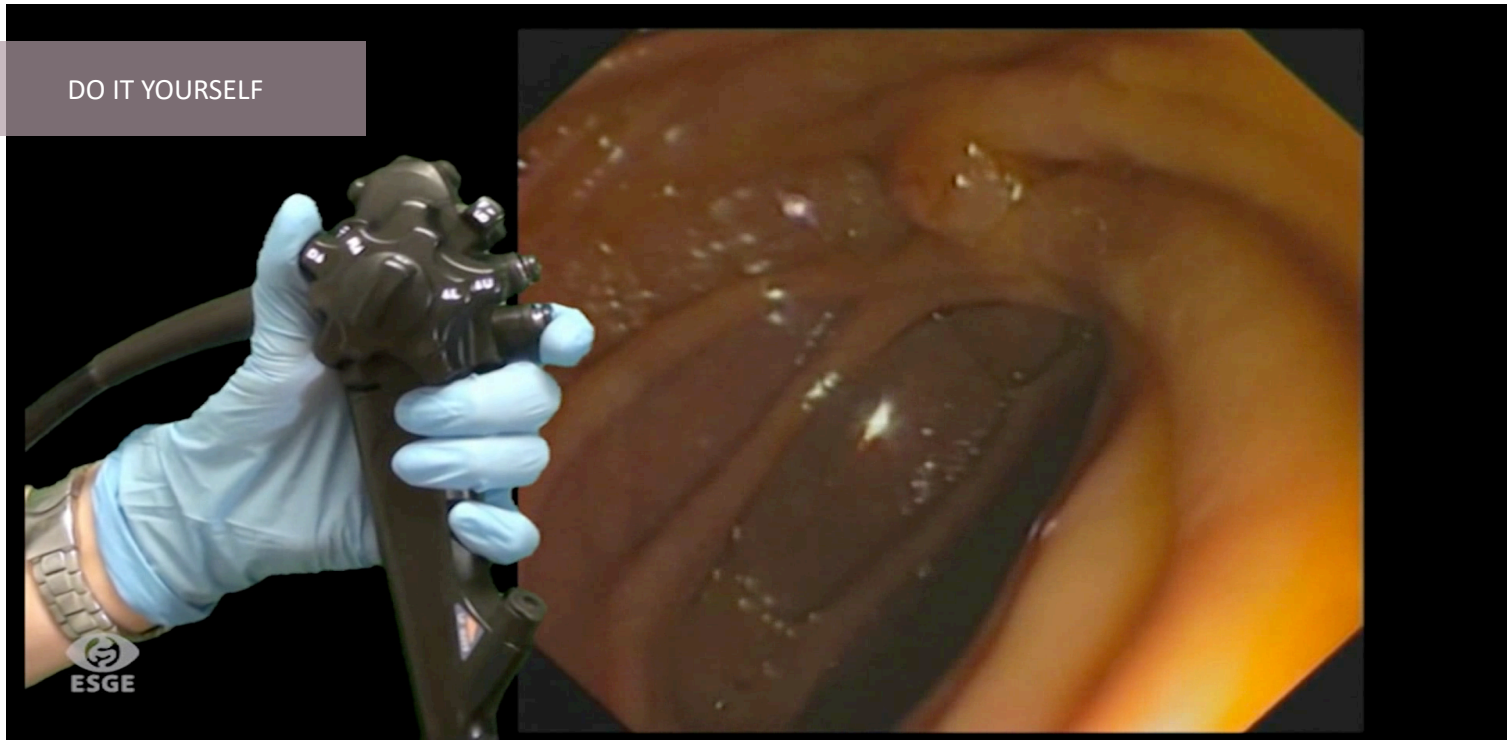


3. RIGHT AND LEFT ROTATION MOVEMENTS

EXPLANATORY

3. Right and left rotation movements

DO IT YOURSELF

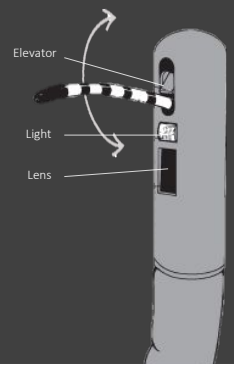


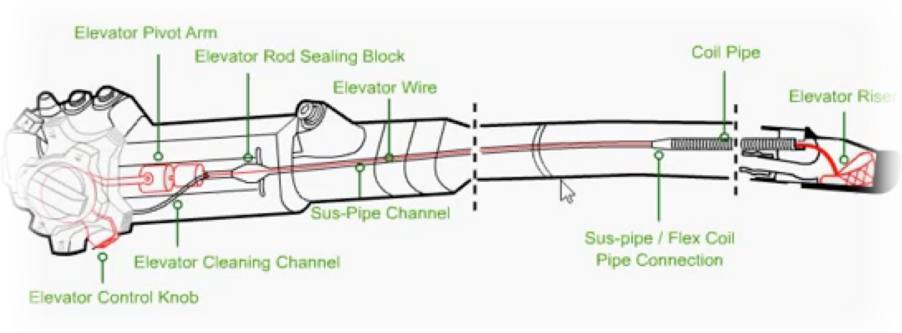
Right and left rotation (by applying torque)

EXPLANATORY

The elevator knob is used to lift up the instruments that are coming out of the biopsy channel of the side viewing endoscope.

In cannulation the elevator knob is used to direct the catheter into the duct of interest.



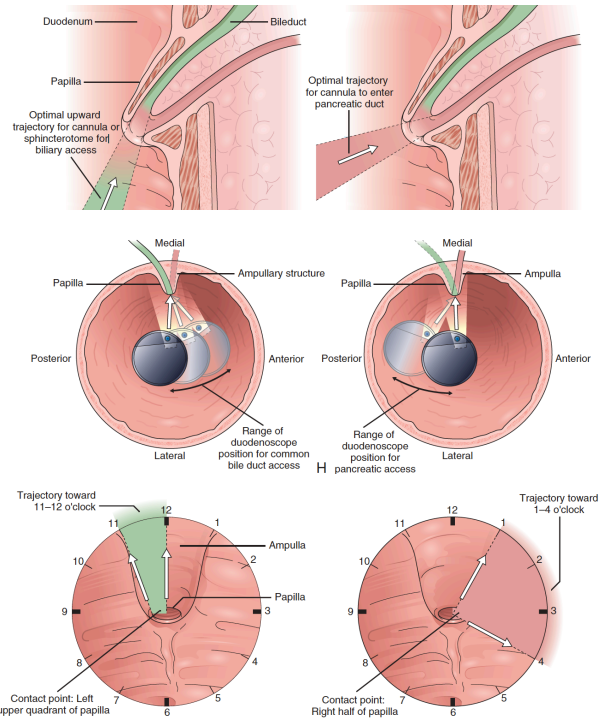


4. Lifting up the catheter, coming out of the biopsy portal

THEORETICAL KNOWLEDGE

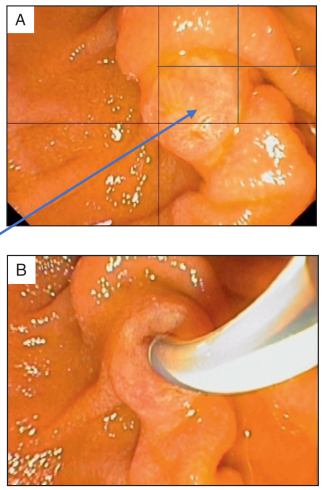
Instructions for successful selective cannulation

Precise positioning in front of the papilla



- For successful cannulation, the catheter must be advanced through the papillary orifice in the same horizontal and vertical axes as the desired duct system (**bile duct ± 11-12 o'clock** and **pancreatic duct ± 1-4 o'clock**)).

- When advancing the catheter, it must be noted that the catheter will emerge from the lower half of the right edge of the screen image. Therefore its best to achieve a monitor position in which the **papilla is located in the lower left corner of the upper right quadrant** (when dividing the display up into four quadrants).



Texts and drawings are partly adapted from:

Adler, D.G., B.T. Petersen, and T.H. Baron, *Cannulation of the major and minor papilla*, in *ERCP*. 2008, Elsevier Inc

Cotton, P. B., & Williams, C. (1996). ERCP: diagnostic technique. In *PB Cotton, C Williams: Practical gastrointestinal endoscopy* (pp. 105-138). Blackwell Science.

Canard, J. M., Lennon, A. M., Létard, J. C., Etienne, J., & Okolo, P. (2011). Endoscopic retrograde cholangiopancreatography. *Edinburgh. Elsevier Churchill livingstone*, 370-465

Gray, H. (1918). Anatomy of the human body, by Henry Gray. thoroughly rev. and re-edited by Warren H. *Lewis. Lea & Febiger, Philadelphia*.

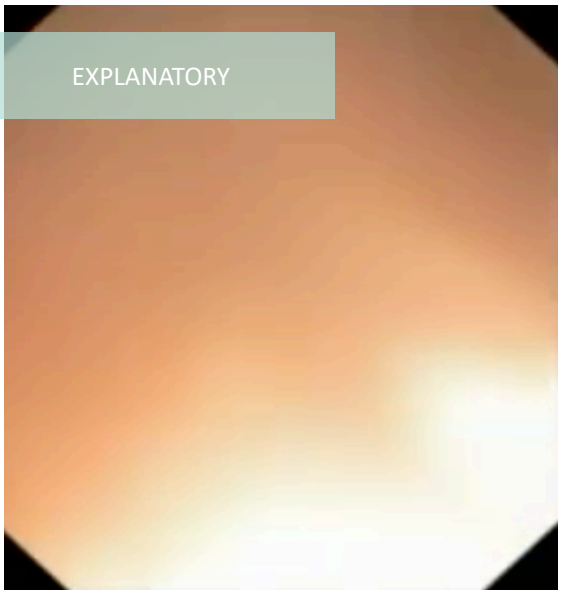
Appendix B

PowerPoint presentation with the instruction the route to the papilla and exercises

NAVIGATING THE SCOPE THROUGH THE BODY

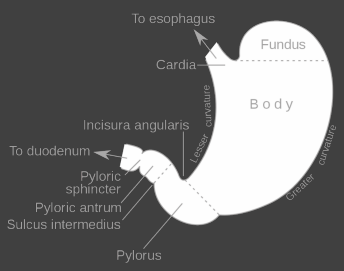
For successful cannulation of the biliary (or pancreatic) duct, proper positioning in front of the papilla is crucial. To achieve this position, the scope must be passed down through the body in the correct manner.

In this phase of training, the steps for manoeuvring the scope through the body properly, are explained in great detail. Each steps should be mimicked. At the end of this training part, the route will thus be, once, covered entirely. In between the steps, scope handling is trained during the interim exercises.



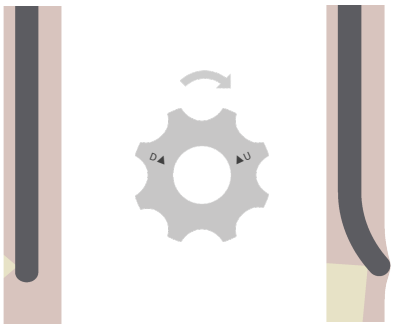
The video on the left depicts the view when descending down the esophagus.

- *Not much visible due to the side-view.*
- *At 10 seconds, the big knob is rotated down so that the tip is pushed into the wall with its backside, facilitating a better view.*



INTUBATION (UNTIL THE STOMACH)

EXPLANATORY

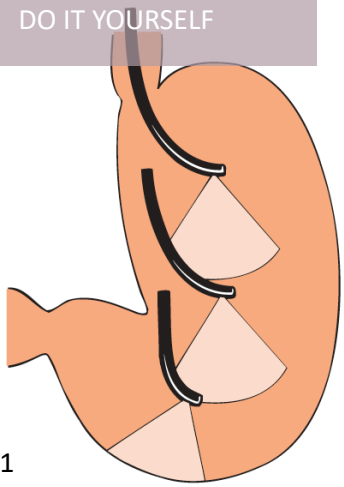


INTUBATION (UNTIL THE STOMACH)

1. Hold the instrument horizontally and parallel to the examination table with the patient's neck slightly flexed.
2. Use upward tip deflection combined with gentle advancement to pass through the hypopharynx to the level of the upper esophageal sphincter. (some right or left tip deflection can sometimes also be helpful)
3. Use gentle pressure combined with subtle tip deflection to pass the esophageal sphincter
4. After 38-40 cm (from the teeth) the cardia is reached, characterized by feeling of slight resistance due to the sphincter.
5. Use gentle pressure to advance the tip of the scope and enter the stomach.

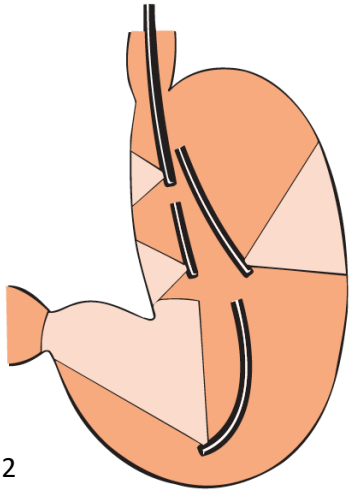
MODEL 1

DO IT YOURSELF



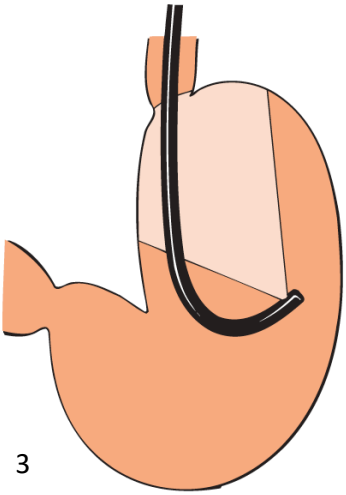
1

Advancing through the body of the stomach with the tip angled down provides axial views similar to forward-viewing instrument



2

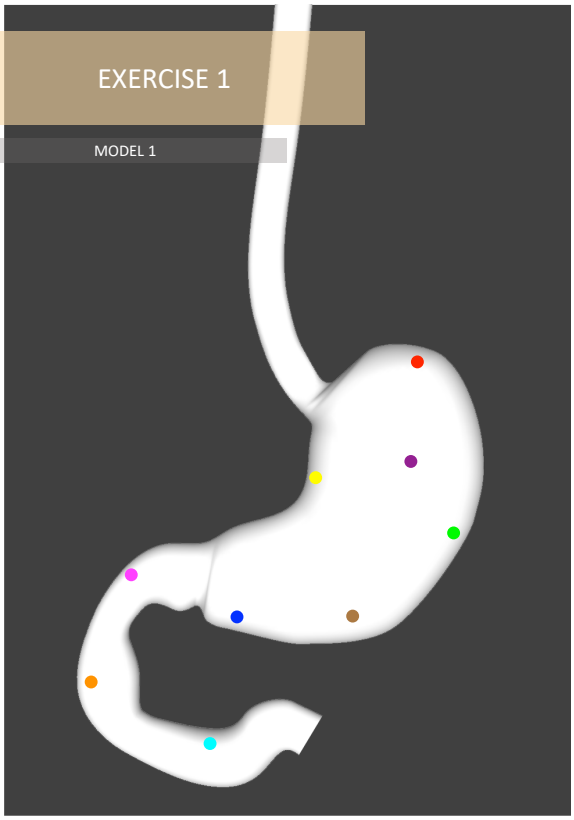
Rotate to obtain face-on views of all four wall of the proximal stomach



3

Pass the endoscope to the greater curvature and angle up to see the cardia

EXPLORING THE STOMACH



CONTROLLING THE SCOPE: DIRECTING THE SCOPE TOWARDS A POSITION OF INTEREST (1)

Direct the scope to the dots, one after one, in the following sequence:

1. Purple
2. Brown
3. Red
4. Blue
5. Orange
6. Green
7. Yellow
8. Magenta
9. Cyaan

The goal of the first exercise is get familiar with guiding the scope. The dots should be in clear shot, but no precision is yet asked concerning the orientation towards the dots or the exact distance from the dots. Not all dots are on locations that are realistic to navigate to in real life, but they are good targets for learning to steer the scope in a realistic environment.

When this task can be executed within (*) minutes, proceed to the next slide.

** Moet getest worden voor het model in kwestie hoe lang men er ongeveer over doet*

MODEL 1

EXERCISE 2

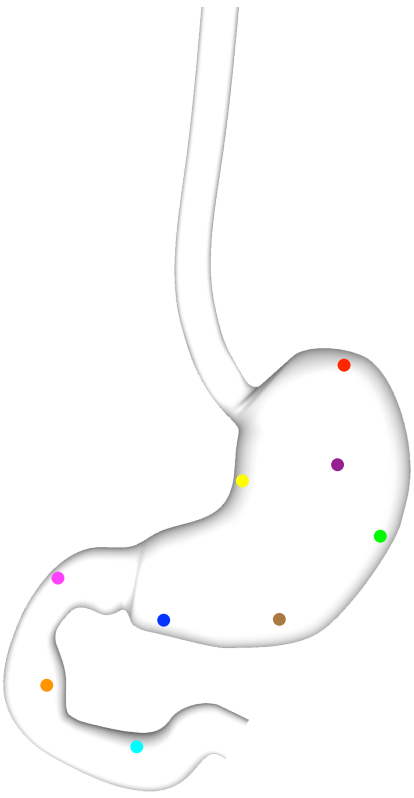
Direct the scope to the dots in the same sequence as in the previous exercise (1 Purple, 2 Brown, 3 Red, 4 Blue, 5 Orange, 6 Green, 7 Yellow, 8 Magenta, 9 Cyaan), but now use the catheter to gently tap on each dot of interest.

When advancing the catheter, it must be noted that the catheter will emerge from the lower half of the right edge of the screen image. Therefore its best to achieve a monitor position in which the dot is located in the lower left corner of the upper right quadrant or the upper left corner of the lower right quadrant (when dividing the display up into four quadrants).

When this task can be executed within (*) minutes, proceed to the next slide

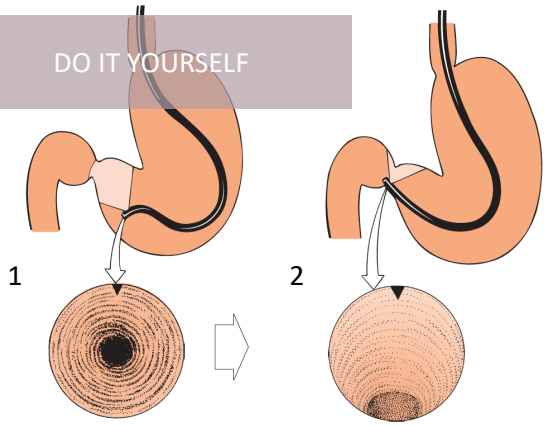
** Moet getest worden voor het model in kwestie hoe lang men er ongeveer over doet*

CONTROLLING THE SCOPE: DIRECTING THE SCOPE TOWARDS A POSITION OF INTEREST (2)



MODEL 1

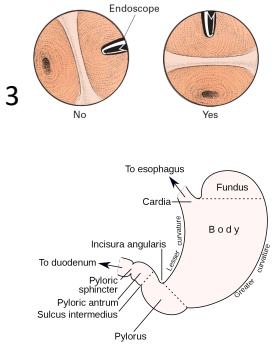
DO IT YOURSELF



Angle down to see the pylorus

then angle up to let the tip enter the pyloric canal with a 'setting sun' view

Use twist or the lateral control to square up the incisura angularis before passing into the pylorus



Click on images for more detailed instructions

1 Advance the tip through the pyloric antrum with a slight 'down' tip deflection to keep the pylorus in view (1), whilst sliding the shaft inwards and around the greater curvature of the stomach.

2 When close to the pyloric ring, angle the tip 'up' into the neutral position (or slightly beyond it) and advance (2). The ideal view of the pylorus during the maneuver is described as the 'setting sun' (2).

3 Sometimes it may be necessary to slide over the pylorus (i.e. lose the view of it), and then angle the instrument tip sharply downwards, so as to enter the duodenum blindly. Passage through the pyloric ring is felt rather than seen; success depends upon having the instrument in the central axis of the antrum. Check the orientation, if in difficulty, by withdrawing and angling the tip up. The incisura angularis should be seen square-on, not obliquely, so that further upward angulation would show the instrument shaft passing down the midline of the greater curvature of the gastric body (3). The lateral angling controls or shaft twist should be used to achieve the correct midline axis.

PASSAGE THROUGH THE PYLORUS

Cotton, P. B., & Williams, C. (1996). ERCP: diagnostic technique. In *PB Cotton, C Williams: Practical gastrointestinal endoscopy* (pp. 105-138). Blackwell Science.

DO IT YOURSELF

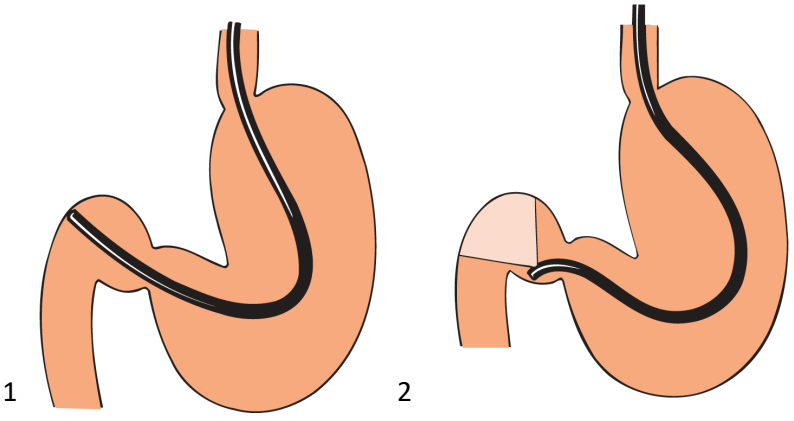
MODEL 1

Click on images for more detailed instructions

1 When the instrument passes the pylorus, the springiness of the redundant loop in the stomach propels the tip inward to the distal bulb (as with forward-viewing endoscopes) (1) and results in a 'red-out'.

2 Withdraw the instrument slightly, angling the tip sharply down and insufflating some air; the tip is then virtually hooked beyond the pyloric ring, and the view is similar to that obtained with a forward-viewing endoscope (2).

The roof of the bulb is seen face on, and lateral tip deflection and rotation provide views of the anterior and posterior walls. The inferior part or floor of the bulb is more difficult to survey; there is a tendency to fall back into the antrum during the necessary acute clockwise rotation.



after passing the pylorus the endoscope tip tends to impact the duodenal wall

Angle the tip down and withdraw into a hooked position to see the duodenum and cap

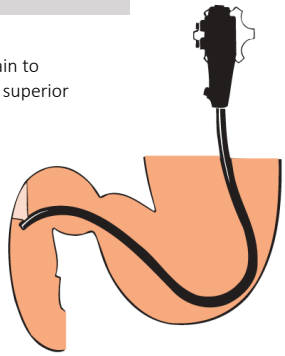
THROUGH THE STOMACH AND INTO THE DUODENUM

DO IT YOURSELF

MODEL 1

Click on images for more detailed instructions

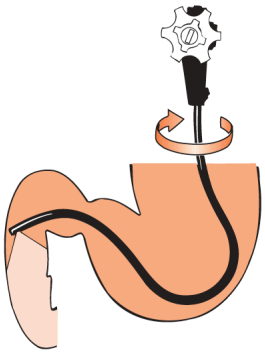
then angle up again to advance over the superior dudodenal angle



1

Passing the superior duodenal angle into the descending duodenum requires a corkscrew 'right twist and pull' maneuver as used with forward-viewing instruments. From the bulb-viewing position the tip is angled up towards the neutral position and advanced until it is over the superior duodenal angle at the entry of the descending duodenum (1).

and rotate 90° clockwise, whilst angling right and up, to view the descending duodenum.

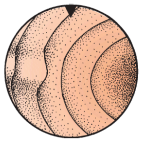


2

The tip is then angled acutely right and up at the same time as the instrument is rotated about 90° clockwise (2). .

A tunnel view of the papillary region from above.

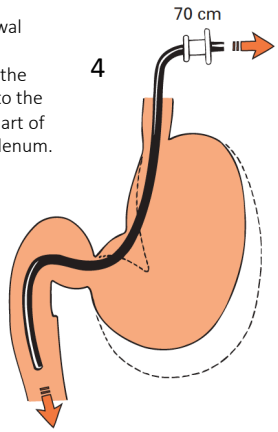
3



This corkscrew rotation produces a tunnel view of the upper part of the descending duodenum (3) and often of the telltale bulge of the pre-papillary fold.

Withdrawal helps to advance the scope into the second part of the duodenum.

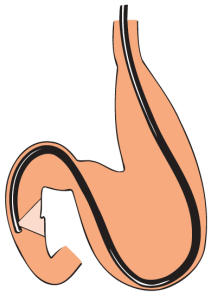
4



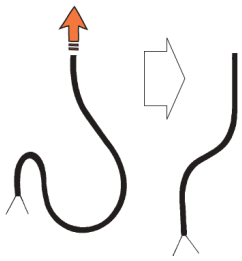
Further tip advance can be achieved simply by pushing, but—as with forward viewing scopes — this is much better achieved by pulling back, to shorten the loop in the stomach (4). When the shaft has been straightened (with less than 70·cm of instrument inside the patient), the tip will lie beyond the papilla of Vater. The descending duodenum is surveyed during gradual withdrawal, using tip manipulation and rotation.

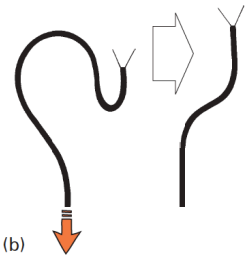
PASSING THE SUPERIOR DUODENAL ANGLE

EXPLANATORY



The long scope position, or "long route", is not the desired scope position due to redundant loop in stomach





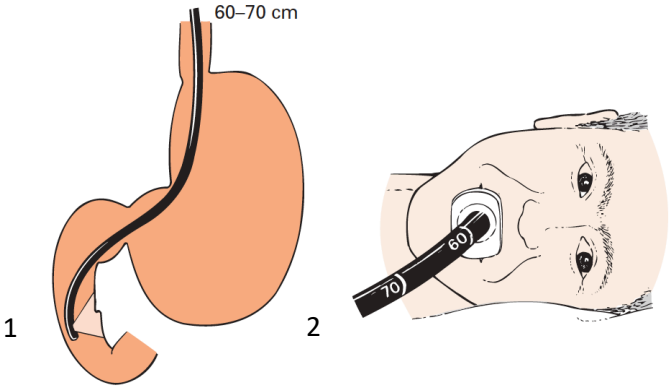
Performing a straightening maneouvre to achieve short scope positioning is preferred: in (a) the duodenum, and (b) the colon. The duodenum is the inverse of the colon. The short position is explained in the next slide

LONG SCOPE POSITION

DO IT YOURSELF

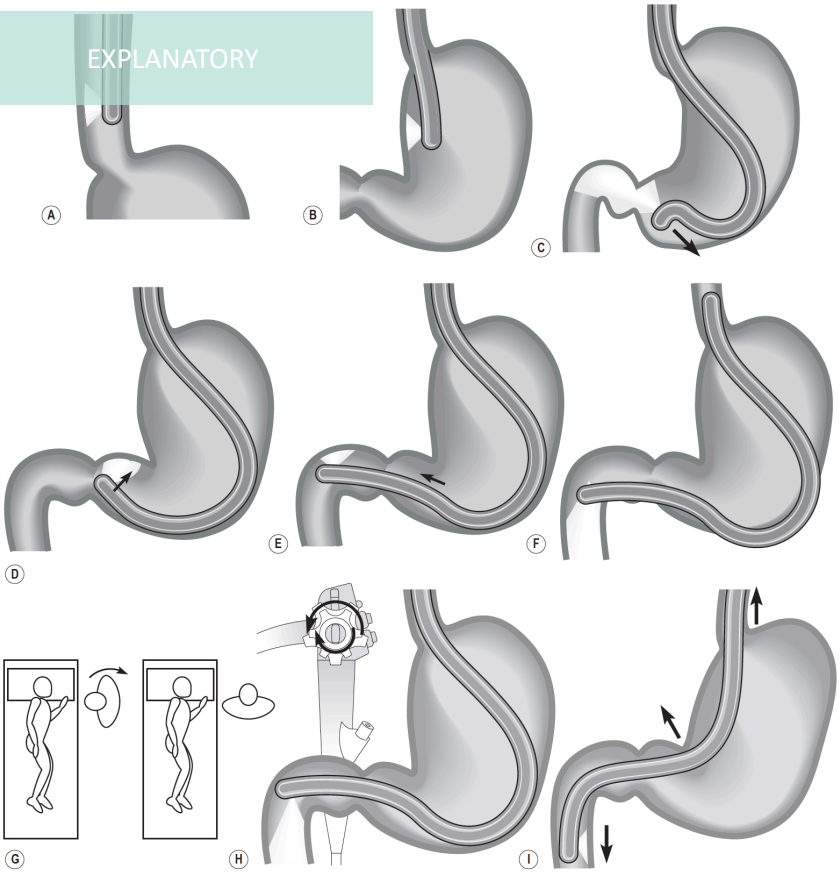
MODEL 1

1. Advance the tip to engage the superior duodenal angle.
2. Rotate yourself (and therefore the scope) to the right.
3. Angle the instrument tip fully to the right and fix it there (with the brake).
4. Angle the tip up, and withdraw the instrument slowly maintaining clockwise rotation. The instrument shaft will be straight in the 'short route' position (1) when the 60–70·cm mark is at the mouth (2).
5. Once the shaft is straight, the up/down and left/right control wheels can usually be released towards their neutral positions, and the patient rotated prone. The endoscopist can then turn back slightly to the left, so as to face more towards the patient. It should then be easy to find the papilla close by.



ACHIEVING SHORT SCOPE POSITION IN FRONT OF THE PAPILLA

EXPLANATORY



Inserting the duodenoscope and positioning over the papilla.

A. Duodenoscope advancing blind into the esophagus.
B. Advancing along the lesser curvature.
C. The endoscope rests on the greater curvature and faces the pylorus.
D. Deflection upwards, before advancing through the pylorus.
E. The apparatus advances to the superior flexure.
F. The endoscopist turns to his right through 90°.
G. The endoscopist has turned to his right through 90°.
H. Deflection upwards and to the right by turning the small wheel clockwise and the big wheel anti-clockwise.
I. Withdrawal of the endoscope to approximately 70 cm which removes the gastric loop.

OVERVIEW

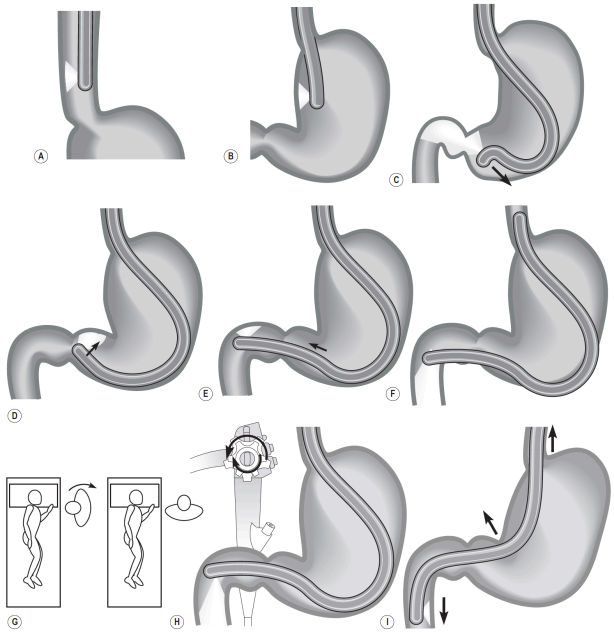
EXERCISE 3

MODEL 1

Perform the whole act of inserting the duodenoscope and positioning in front of the papilla (shown in the model as an orange dot), until it can be performed within (*) minutes.

** Moet getest worden voor het model in kwestie hoe lang men er ongeveer over doet*

INSERTING THE DUODENOSCOPE AND POSITIONING OVER THE PAPILLA.



A) Duodenoscope advancing blind into the esophagus. B) Advancing along the lesser curvature. C) The endoscope rests on the greater curvature and faces the pylorus. D) Deflection upwards, before advancing through the pylorus. E) The apparatus advances to the superior flexure. F) The endoscopist turns to his right through 90°. G) The endoscopist has turned to his right through 90°. H) Deflection upwards and to the right by turning the small wheel clockwise and the big wheel anti-clockwise. I) Withdrawal of the endoscope to approximately 70 cm which removes the gastric loop.

Texts and drawings are partly adapted from:

Adler, D.G., B.T. Petersen, and T.H. Baron, *Cannulation of the major and minor papilla*, in *ERCP*. 2008, Elsevier Inc

Cotton, P. B., & Williams, C. (1996). ERCP: diagnostic technique. In *PB Cotton, C Williams: Practical gastrointestinal endoscopy* (pp. 105-138). Blackwell Science.

Canard, J. M., Lennon, A. M., Létard, J. C., Etienne, J., & Okolo, P. (2011). Endoscopic retrograde cholangiopancreatography. *Edinburgh. Elsevier Churchill livingstone*, 370-465

Gray, H. (1918). Anatomy of the human body, by Henry Gray. thoroughly rev. and re-edited by Warren H. *Lewis. Lea & Febiger, Philadelphia*.

Appendix C

Complete training program as used for the experiment; containing the instructions first and thereafter the exercises.

TRAIN TECHNICAL SKILLS

Controlling the duodenoscope (5 minutes)

Feel free to participate when the slide is labeled with “do it yourself”.

EXPLANATORY

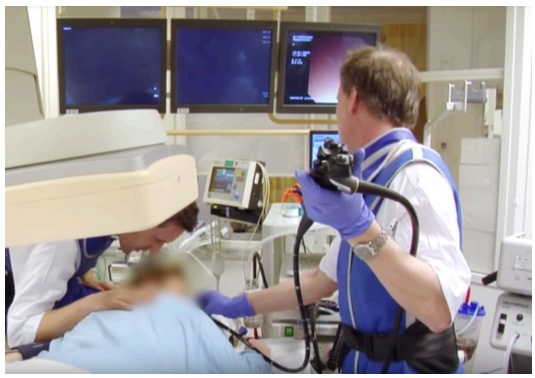
Hold the control handle with your left hand

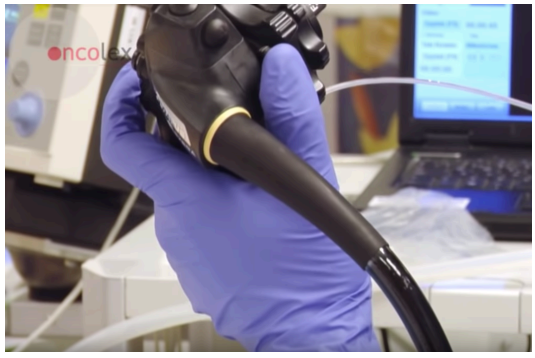
- The thumb must be in the position to control the two angulation knobs
- The index finger must be in position to control the air/water button.

Hold the insertion tube with your right hand

- hold the scope horizontal and parallel to the operation table
- The scope can be inserted into the mouth with your right hand

HOW TO HOLD THE SCOPE





DO IT YOURSELF

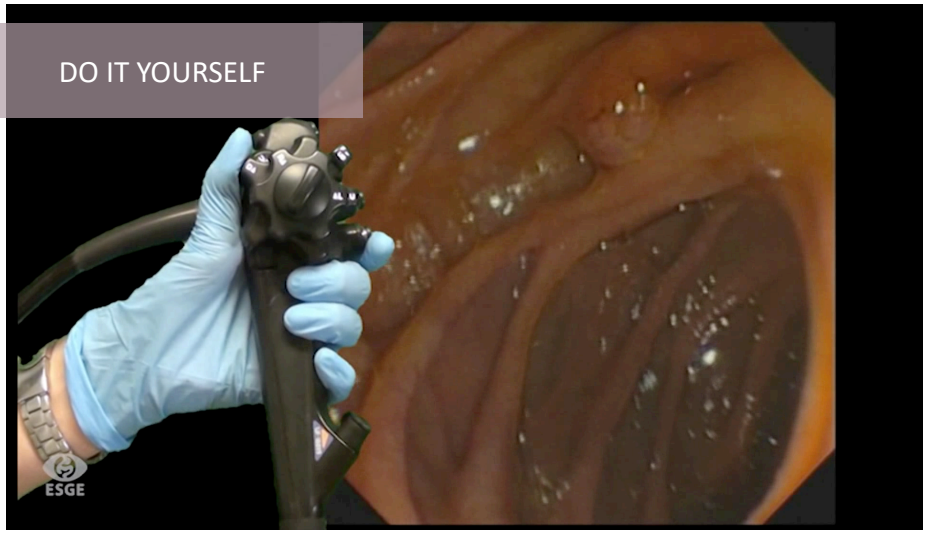
How to hold the scope

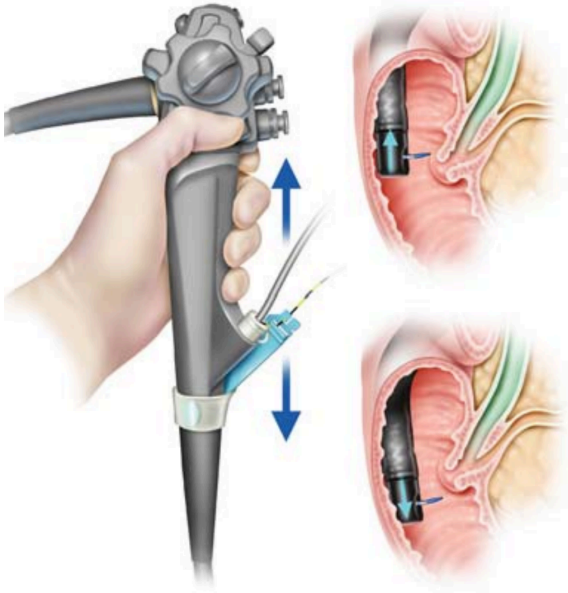
EXPLANATORY

Basic movements

1. Push forward and pull back
2. Tip deflection: Up/Down and Right/Left.
3. Right and Left rotation (by applying torque)
4. Lifting up the catheter, coming out of the biopsy channel

DO IT YOURSELF

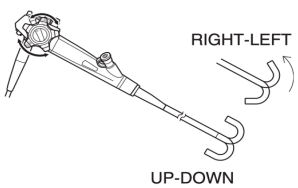




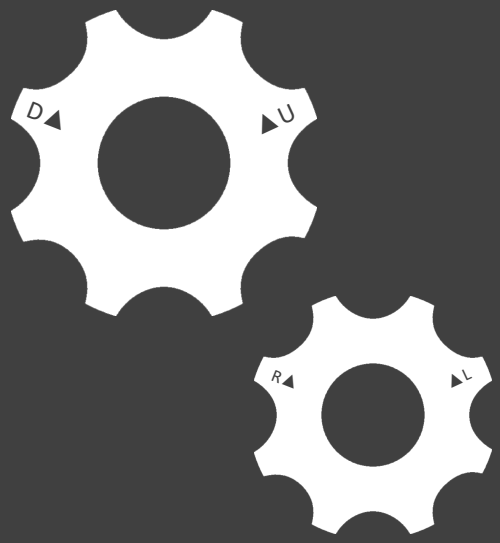
1. Push forward and pull back
(Move scope forwards and backwards)

EXPLANATORY

2. Tip deflection up/down and left/right

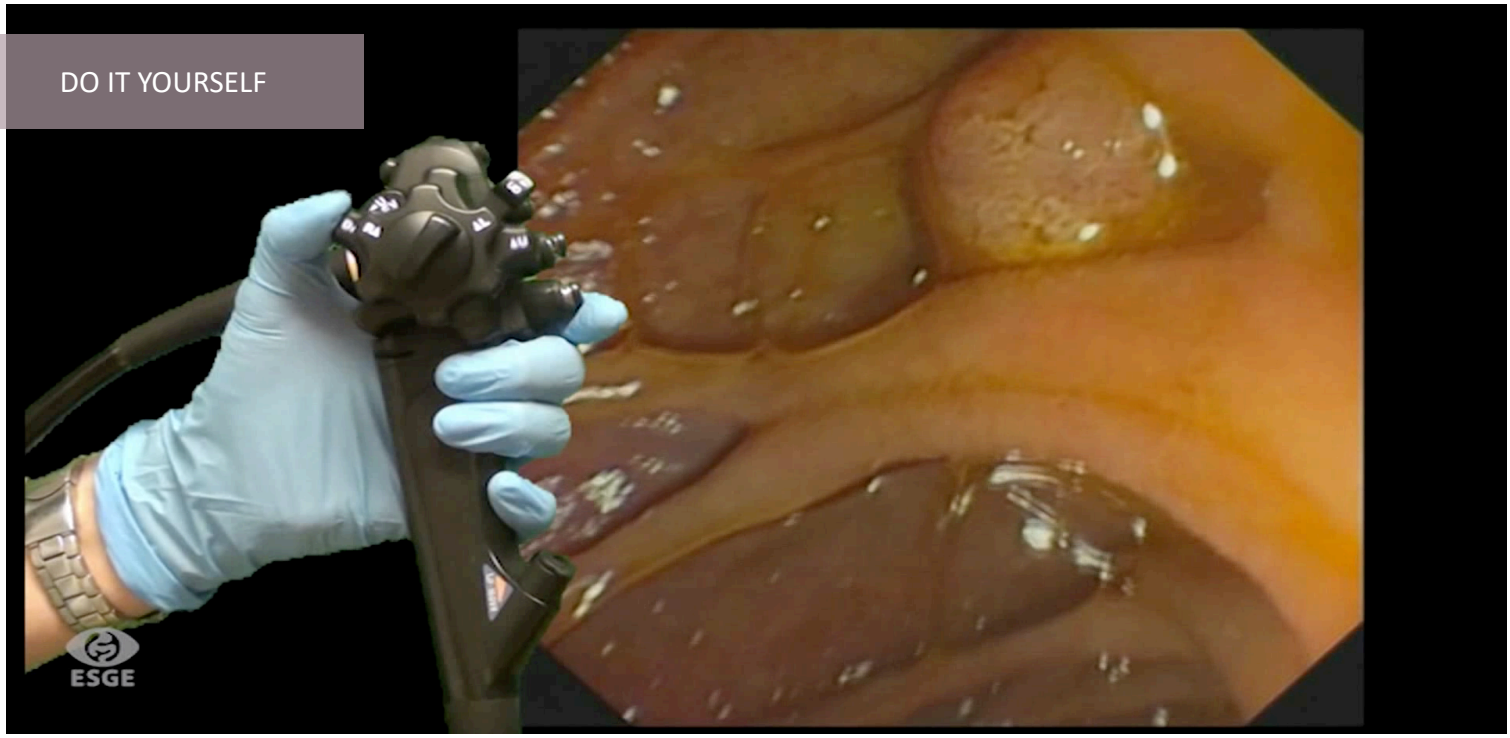


Use the first joint of your thumb to control the (big) up/down angulation knob



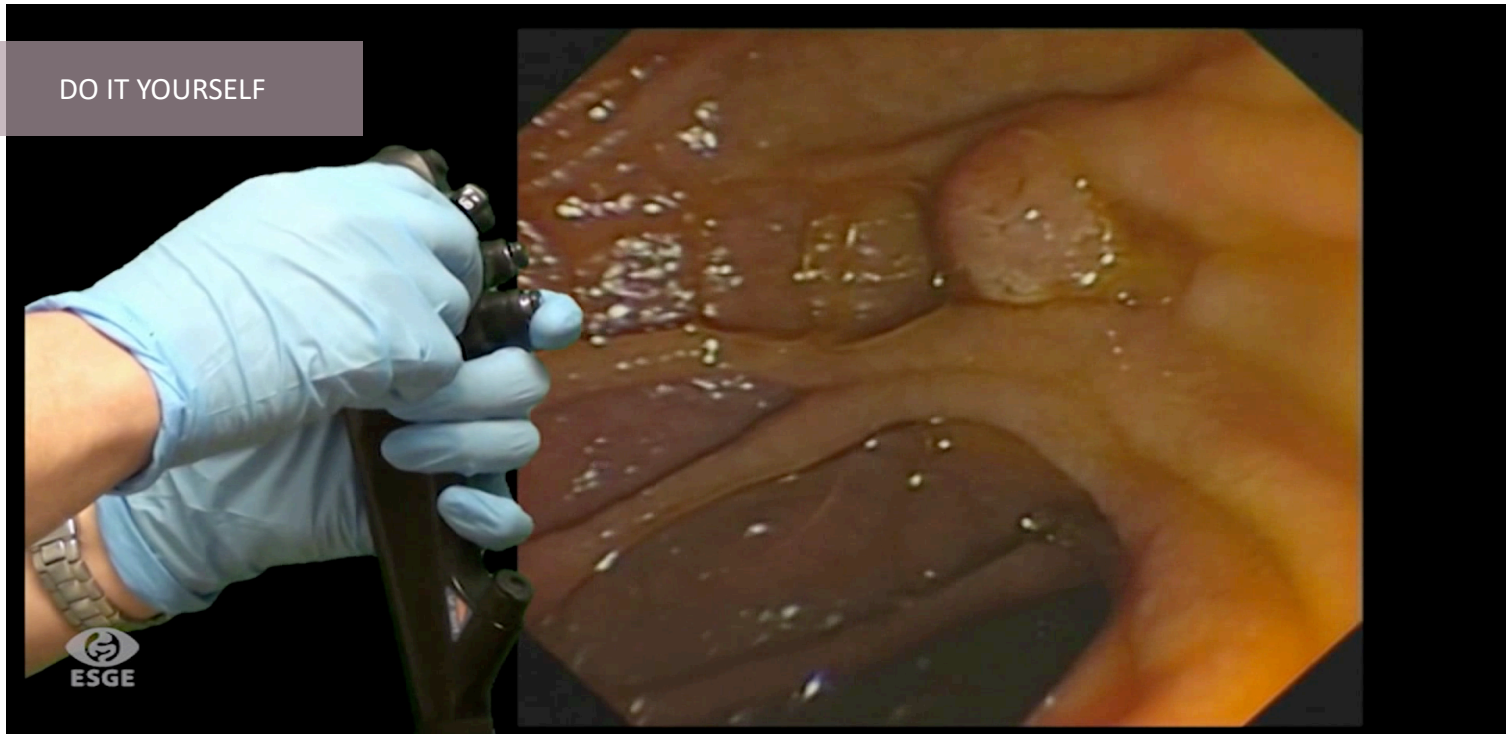
Use the tip of your thumb to control the (small) right/left angulation knob

DO IT YOURSELF



Tip deflection: up and down

DO IT YOURSELF

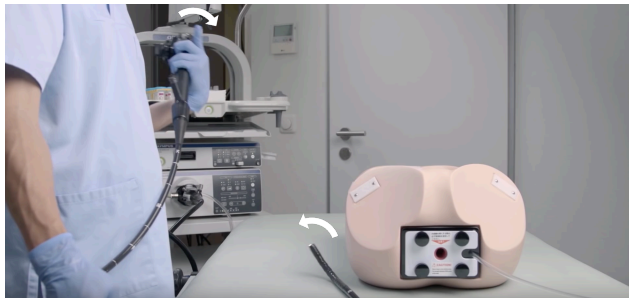


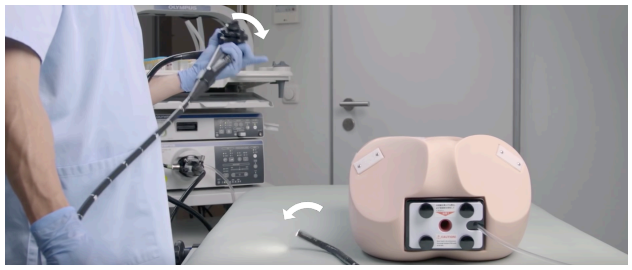
Tip deflection: left and right (Always perform with left thumb!! NOT with right hand as depicted in video!!)

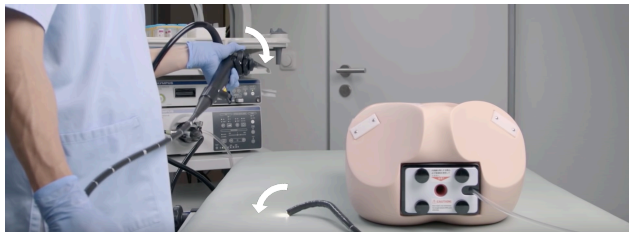
EXPLANATORY

Right and left rotation movements can by applied by:

- twisting left wrist (the hand holding the control section of the scope). *See pictures on the right*
- by applying torque to the insertion tube with right hand.
- By synchronizing both movements, torque can be applied to the scope even more efficiently





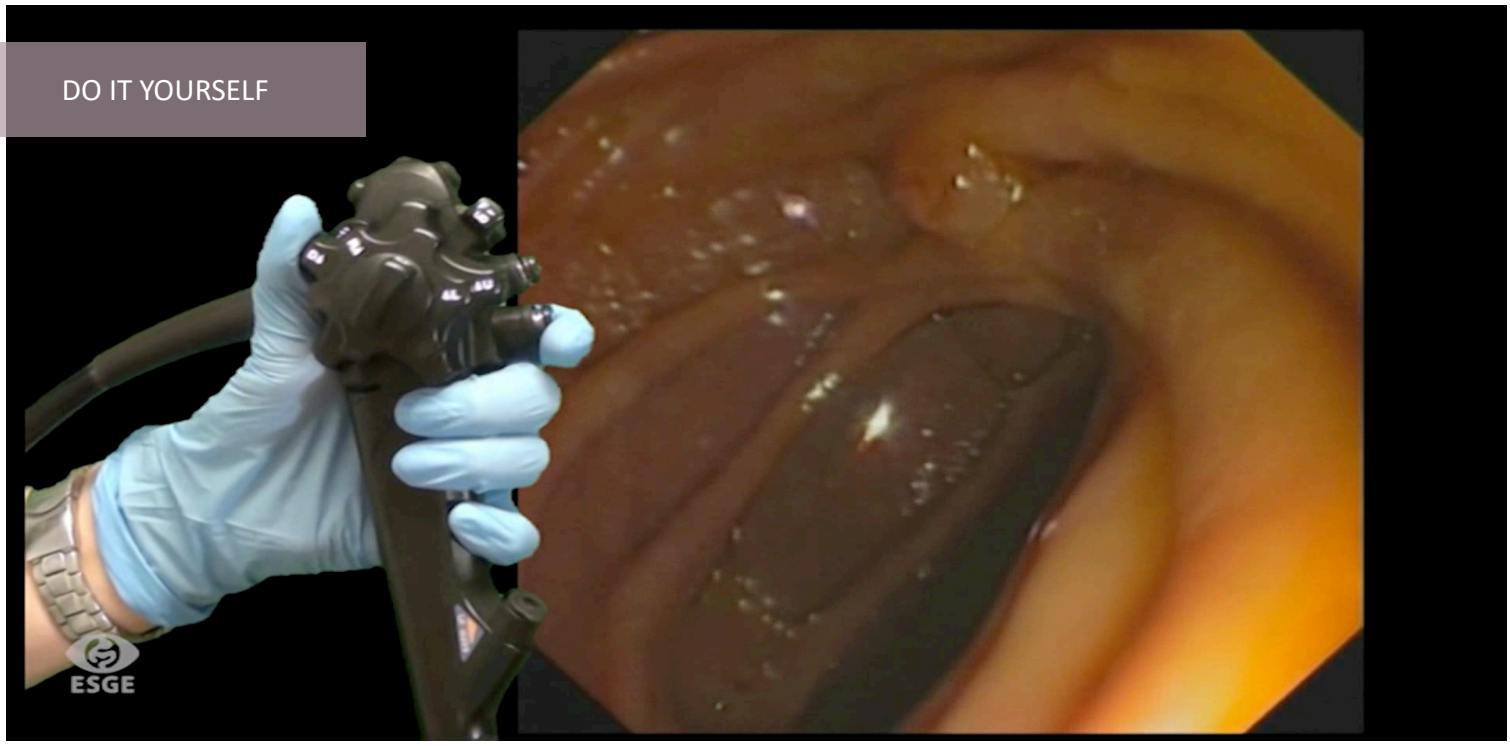


3. RIGHT AND LEFT ROTATION MOVEMENTS

EXPLANATORY

3. Right and left rotation movements

DO IT YOURSELF

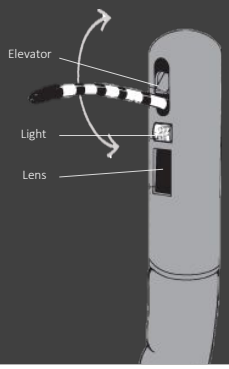


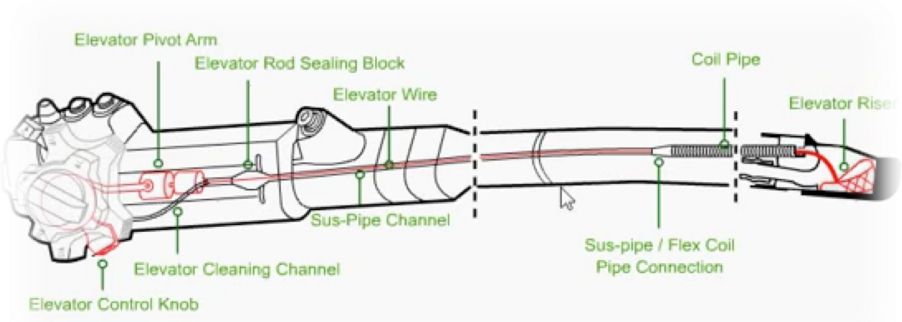
Right and left rotation (by applying torque)

EXPLANATORY

The elevator knob is used to lift up the instruments that are coming out of the biopsy channel of the side viewing endoscope.

In cannulation the elevator knob is used to direct the catheter into the duct of interest.



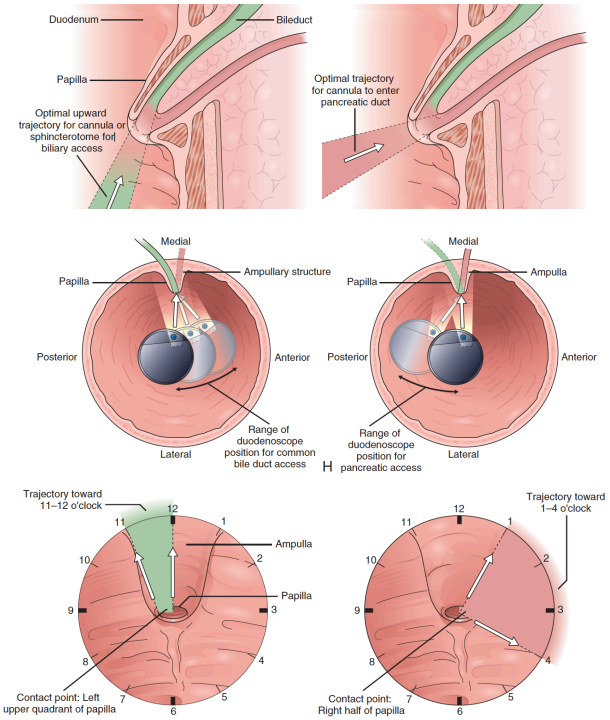


4. Lifting up the catheter, coming out of the biopsy portal

THEORETICAL KNOWLEDGE

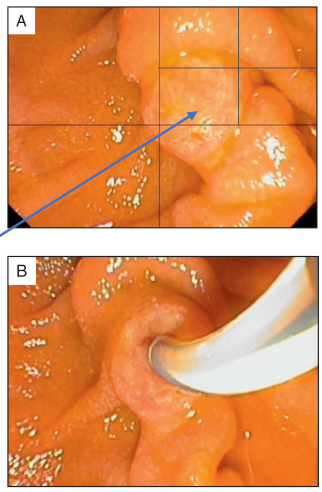
Instructions for successful selective cannulation

Precise positioning in front of the papilla



- For successful cannulation, the catheter must be advanced through the papillary orifice in the same horizontal and vertical axes as the desired duct system (**bile duct ± 11-12 o'clock** and **pancreatic duct ± 1-4 o'clock**)).

- When advancing the catheter, it must be noted that the catheter will emerge from the lower half of the right edge of the screen image. Therefore its best to achieve a monitor position in which the **papilla is located in the lower left corner of the upper right quadrant** (when dividing the display up into four quadrants).



EXERCISES

Read the instructions to perform the exercises within the appointed time

EXERCISE 1

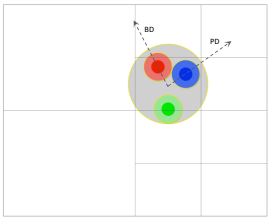
GROUP 2

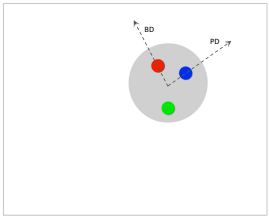
Getting familiar with the scope and linking executed movements to video images on the display.

Based on what was explained about: how to control the scope (slide 10-17) and how to position correctly in front of the papilla (slide 20), you can now try to get familiar with the scope and practice hand-eye coordination with the help of the computer, which is guiding you towards the correct position in front of the papilla.

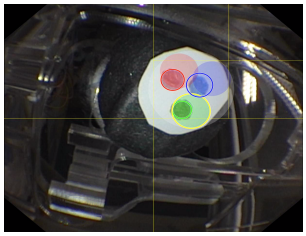
You have 10 minutes to practice with manoevering the scope into the correct position in front of the papilla. The dots on the papilla need to be positioned in the corresponding area on the computer screen. When camera/scope is positioned correctly in front of the papilla, and all three dots on the papilla thus are located in their corresponding area on the computer screen, the dots and the papilla will light up yellow and the exercise will stop. Withdraw the scope and repeat this exercise for 10 minutes.

TIME: 8 MINUTES



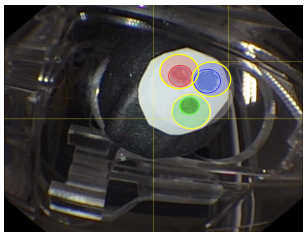


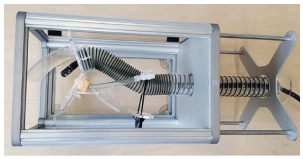
▲ Animation of correct scope positioning with guidance of the computer (left) and without (right). The papilla must be located in the lower left quadrant of the upper right quadrant of the display. The red dot is located on the axis of the common bile duct (11 o'clock) and the blue dot is located on the axis of the pancreatic duct (2 o'clock).



▲ Example of incorrect scope positioning on model

▼ Example of correct scope positioning on model





EXERCISE 1

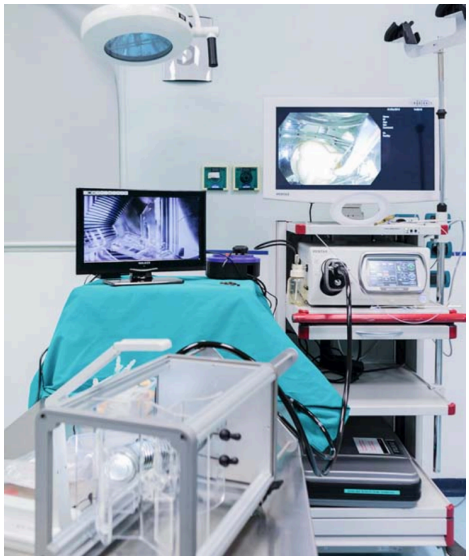
GROUP 1

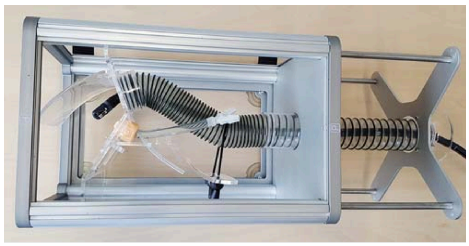
Getting familiar with the scope and linking executed movements to video images on the display.

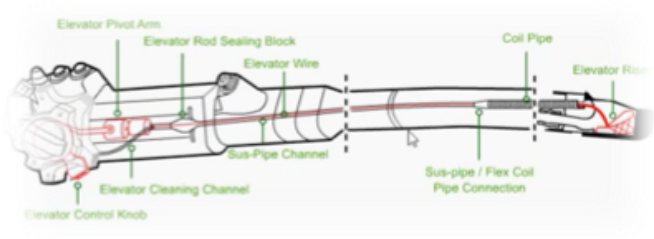
Based on what was explained about: how to control the scope (slide 10-17) and how to position correctly in front of the papilla (slide 20), you can now try to get familiar with the scope and practice hand-eye coordination.

You have 10 minutes to ”play” with the scope freely in the model to get used to it and to develop control over your movements with the scope. Cannulation is not possible yet, first try to get familiar with guiding the scope and positioning it in front of the papilla. Do not use the elevator function yet. Guiding the catheter is not part of this exercise.

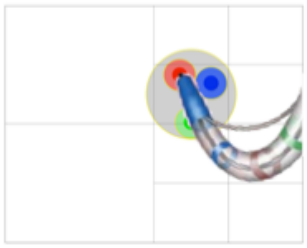
TIME: 8 MINUTES



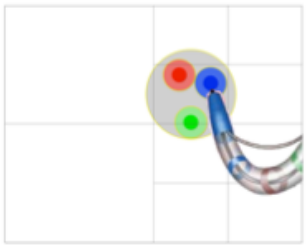




▼ Example of tapping the red marker



▼ Example of tapping the blue marker



GROUP 2

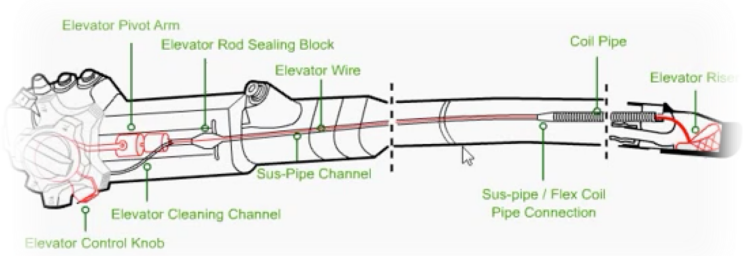
EXERCISE 2

Direct the catheter

Use the instructions on how to direct the elevator (slide 18), for practicing with guiding the catheter. In this exercise you must tap the by the computer requested marker (red, blue or green) with the catheter. When the marker is touched, a signal will appear. Withdraw the scope a little and then perform the exercise again for the next requested marker. Do this for 10 minutes

Have in mind that directing the catheter is needed for cannulation of the desired duct. The red marker is in the axis of the bile duct and the blue marker in the axis of the pancreatic duct. The common entry both ducts is, however, in real life in the center of the papilla. But for selectively cannulating the duct, different angles of entering the papilla are required. Those angles are represented correctly by the red and blue markers, but remember that for real cannulation the location of entry is more central than depicted in this exercise by the markers.

TIME: 8 MINUTES



GROUP 1

EXERCISE 2

Direct the catheter

Based on what was explained about how to control and direct the catheter (slide 18), now practice with the elevator and try to get control over the catheter.

You have 10 minutes to ”play” with the scope in the model and to get used to it.
Cannulation is not possible just yet, first try to get familiar with guiding the catheter towards planned positions.

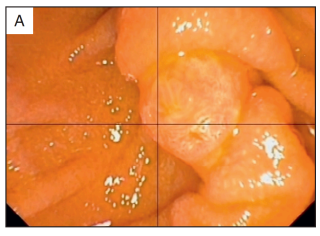
TIME: 8 MINUTES

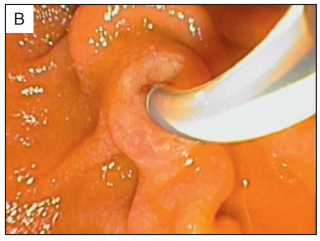
EXERCISE 3

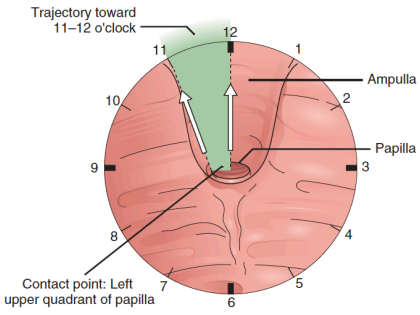
Selective cannulation

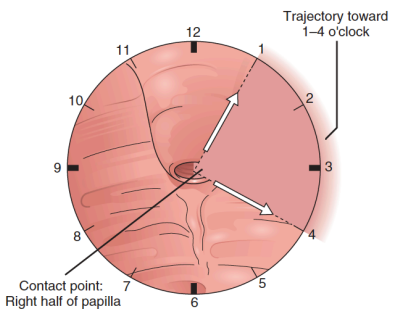
Now that the basic skills have been developed a bit, selective cannulation can be attempted. Practice cannulation repeatedly for 10 minutes . Mainly focus on cannulating the bile duct, but eventually you should also be able to cannulate the pancreatic duct when asked.

TIME: 8 MINUTES









GROUP 1 & 2

EXERCISE 4

Selective cannulation final test

Perform cannulation according to what the instructor says (either biliary or pancreatic cannulation). Achieve as many successful cannulations as you can in 10 minutes, but avoid cannulating the wrong duct. After each cannulation, the scope must be withdrawn. Your success rate, fail rate and time per cannulation will be measured.

GROUP 1 & 2

TIME: 8 MINUTES

Texts and drawings are partly adapted from:

Adler, D.G., B.T. Petersen, and T.H. Baron, *Cannulation of the major and minor papilla*, in *ERCP*. 2008, Elsevier Inc

Cotton, P. B., & Williams, C. (1996). ERCP: diagnostic technique. In *PB Cotton, C Williams: Practical gastrointestinal endoscopy* (pp. 105-138). Blackwell Science.

Canard, J. M., Lennon, A. M., Létard, J. C., Etienne, J., & Okolo, P. (2011). Endoscopic retrograde cholangiopancreatography. *Edinburgh. Elsevier Churchill livingstone*, 370-465

Gray, H. (1918). Anatomy of the human body, by Henry Gray. thoroughly rev. and re-edited by Warren H. *Lewis. Lea & Febiger, Philadelphia*.

Appendix D

MATLAB script for exercise 1: position training

```
%% Function for exercise 1 : Training Positioning
% To check camera inputs:
% imaqtool

% delete all previously saved data for new run
delete(imaqfind);
clear all;
close all;
clc;

% select video input
a = imaqhwinfo;
[Cam_Name, Cam_ID, Format] = Get_Info_Camera(a);
vid = videoinput(Cam_Name, Cam_ID, Format);

% Define properties of the video object
vid.FrameGrabInterval = 5;

% create movie for macOS - does not work for windows!
dt = datestr(datetime('now'));
gn = input('what is yout name?','s');
directory = uigetdir(pwd,'Choose result folder...') ;
v = VideoWriter([directory,sprintf('/%s:%s.avi',gn,dt)]);

% speed (framerate) of the video
v.FrameRate=5;

%% Start the loop for the exercise
% start the video aquisition
start(vid)

% Set a loop that stop after 200 frames of aquisition, amount of frames (run-time),
this can be adjusted
while(vid.FramesAcquired<=1000)

    % Get the snapshot of the current frame
    data1 = getsnapshot(vid); %original

    % Adjust the frame, resolution depends on selected video source
     data = data1; % for build in webcam
%    data = imcrop(data1,[280 0 1280 1080]); % for a PENTAX scope
%    data = imcrop(data1,[605 15 1240 1050]); % for an OLYMPUS scope
%    data = imcrop(data1,[494.16 50.36 1252.73 995.02]); % sqaure screen

    % Mirror the screen horizontally (needed for webcam input, NOT FOR MOST SCOPES)
    data = flipdim(data,2);

    % Convert the 3 RGB layers (red,blue,green) into grayscale
    % imshow(red) shows red layer in black and white color, white = red detected,
black = no red detected (per pixel)
```

```
    Diff_im_R = imsubtract(data(:,:,1), rgb2gray(data));
    Diff_im_G = imsubtract(data(:,:,2), rgb2gray(data));
    Diff_im_B = imsubtract(data(:,:,3), rgb2gray(data));

    % Use 2D median filter to filter out noise
    Diff_im_R = medfilt2(Diff_im_R, [3 3]);
    Diff_im_G = medfilt2(Diff_im_G, [3 3]);
    Diff_im_B = medfilt2(Diff_im_B, [3 3]);

    % Convert the filtered grayscale image to a binary image.
    % needs to be tuned (scale 0 to 1) again for every scope (by trial and error)
    Level_R = 0.07;
    Level_G = 0.08;
    Level_B = 0.03;

    % Convert to binary (black OR white) image
    Diff_im_R = im2bw(Diff_im_R,Level_R);
    Diff_im_G = im2bw(Diff_im_G,Level_G);
    Diff_im_B = im2bw(Diff_im_B,Level_B);

    % Remove all pixels less than 300px
    % bigger number detects only big objects, smaller number also detects smaller
objects
    Diff_im_R = bwareaopen(Diff_im_R,300);
    Diff_im_G = bwareaopen(Diff_im_G,300);
    Diff_im_B = bwareaopen(Diff_im_B,300);

    % Label all connected components (connected to next object on 8 sides) in the
binary image.
    bw_R = bwlabel(Diff_im_R, 8);
    bw_G = bwlabel(Diff_im_G, 8);
    bw_B = bwlabel(Diff_im_B, 8);

    % Provide the set of useful properties for each labeled region.
    stats_R =
regionprops(bw_R,'Centroid','MajorAxisLength','MinorAxisLength','Area','Perimeter')
;
    stats_G =
regionprops(bw_G,'Centroid','MajorAxisLength','MinorAxisLength','Area','Perimeter')
;
    stats_B =
regionprops(bw_B,'Centroid','MajorAxisLength','MinorAxisLength','Area','Perimeter')
;

    % Display grid
    % horizontal line in the middle of the screen:
    data = insertShape(data,'Line',[0 (length(data(:,1,1))/2) length(data(1,:,1))
(length(data(:,1,1))/2)],'Color','yellow','Opacity',0.2);
    % horizontal line, quarter of screen:
    data = insertShape(data,'Line',[(length(data(1,:,1))/2) (length(data(:,1,1))/4)
length(data(1,:,1)) (length(data(:,1,1))/4)],'Color','yellow','Opacity',0.2);
    % vertical line, middle of screen:
    data = insertShape(data,'Line',[(length(data(1,:,1))/2) 0
(length(data(1,:,1))/2) length(data(:,1,1))],'Color','yellow','Opacity',0.2);
    % vertical line, quarter of screen:
```

```
    data = insertShape(data,'Line',[((length(data(1,:,1))/4)*3) 0
((length(data(1,:,1))/4)*3)
(length(data(:,1,1))/2)],'Color','yellow','Opacity',0.2);

    % Radius of the papilla (white circle on screen)
    radiuss = (length(data(1,:,1))/7); % radius at 1/7 of screen width
%    radiuss = (length(data(1,:,1))/8); % radius at 1/8 of screen width

    % Plot whole papilla on display (as a transparant white circle)
    data = insertShape(data,'FilledCircle',[((length(data(1,:,1))/8)*5)
((length(data(:,1,1))/8)*3) radiuss],'Color','white','Opacity',0.2);

    % Center of papilla (white circle)
    x_cent = ((length(data(1,:,1))/8)*5); % In the center of the left lower
quadrant of the right upper quadrant of the screen
    y_cent = ((length(data(:,1,1))/8)*3);

    % Radius of the goal markers/dots, located on the papilla
    % optimal values for the both radia are retrieved from trial and error:
    % target markers are as large as possible, while they cannot overlap eachother
and cannot reach beyond the papilla area
    radius_dot       = radiuss/9*3.7; % radius of the markers/dots
    radius_dot_edge1 = (radiuss/9)*5.3; % position (part of radius) in the white
papilla

     % x & y coordinates of the markers/dots
     x_red   = x_cent-cos((pi/180)*60)*radius_dot_edge1;
     y_red   = y_cent-sin((pi/180)*60)*radius_dot_edge1;
     x_green = x_cent;
     y_green = y_cent+radius_dot_edge1; % green has larger radius because of lower
position
     x_blue  = x_cent+cos((pi/180)*30)*radius_dot_edge1;
     y_blue  = y_cent-sin((pi/180)*30)*radius_dot_edge1;

    % Display the markers on the display
    data = insertShape(data,'FilledCircle',[x_red y_red
radius_dot],'Color','red','Opacity',0.2);
    data = insertShape(data,'FilledCircle',[x_green y_green
radius_dot],'Color','green','Opacity',0.2);
    data = insertShape(data,'FilledCircle',[x_blue y_blue
radius_dot],'Color','blue','Opacity',0.2);

    % Display the image/video
    imshow(data)

    hold on

    % create a mesh grid for xy coordinates, instead of image data
    [xgrid, ygrid] = meshgrid(1:size(data,2), 1:size(data,1));

    % coordinates of circle
    th = 0:pi/50:2*pi;

    in_R = 0;
    in_G = 0;
```

```
    in_B = 0;

    % Encircle red objects that meet the set criteria
    for object_R = 1:length(stats_R)
        bc_R = stats_R(object_R).Centroid; % identify center of object
        ba_R = stats_R(object_R).Area; % identify area of object
        bd_R = (mean([stats_R(object_R).MajorAxisLength
stats_R(object_R).MinorAxisLength],2))/2; % mean length of object
        br_R = (4*pi*(stats_R(object_R).Area))/((stats_R(object_R).Perimeter)^2); %
determine roundness or circularity of object
        % only show cirles if object area is between 0.8 and 1.5 times the area of
the goal marker dot AND if circularity of above 0.7
            if ba_R <= 3.0*(((radius_dot/2)^2)*pi) & ba_R >=
0.8*(((radius_dot/2)^2)*pi) && br_R >0.7
                % plot the detected object
                circ_R = viscircles(bc_R,bd_R,'EdgeColor','r','LineWidth',2);
                % x&y coordinates of points on edge of goal circle
                values_x_R_goal = radius_dot * cos(th) + x_red;
                values_y_R_goal = radius_dot * sin(th) + y_red;
                % all points of the detected red object
                mask_R_real = ((xgrid-stats_R(object_R).Centroid(1)).^2 + (ygrid-
stats_R(object_R).Centroid(2)).^2) <= (bd_R).^2;
                [values_x_R_real values_y_R_real] = find(mask_R_real==1);
                % select all detected(real) points within the goal area
                in_R =
inpolygon(values_y_R_real,values_x_R_real,values_x_R_goal,values_y_R_goal);

                % show yellow circle when all pixels of the objects are within the
goal area
                if all(in_R) == 1
                    %plot(values_x_R_real,values_y_R_real,'c','Linewidth',2)

viscircles([x_red,y_red],radius_dot,'EdgeColor','y','LineWidth',2)
                end
            end
    end

    % Encircle green objects that meet the set criteria
    for object_G = 1:length(stats_G)
        bc_G = stats_G(object_G).Centroid;
        ba_G = stats_G(object_G).Area;
        bd_G = (mean([stats_G(object_G).MajorAxisLength
stats_G(object_G).MinorAxisLength],2))/2;
        br_G = (4*pi*(stats_G(object_G).Area))/((stats_G(object_G).Perimeter)^2);
             if ba_G <= 3.0*(((radius_dot/2)^2)*pi) & ba_G >=
0.8*(((radius_dot/2)^2)*pi) && br_G >0.7
                  circ_G = viscircles(bc_G,bd_G,'EdgeColor','g','LineWidth',2);
                % points on edge of goal circle
                values_x_G_goal = radius_dot * cos(th) + x_green;
                values_y_G_goal = radius_dot * sin(th) + y_green;
                % points within the detected object
                mask_G_real = ((xgrid-stats_G(object_G).Centroid(1)).^2 + (ygrid-
stats_G(object_G).Centroid(2)).^2) <= (bd_G).^2;
                [values_x_G_real values_y_G_real] = find(mask_G_real==1);
                % plot(values_x_G_goal,values_y_G_goal);
```

```
                in_G =
inpolygon(values_y_G_real,values_x_G_real,values_x_G_goal,values_y_G_goal);

                % show yellow circle when all pixels of the objects are within the
goal area
                if all(in_G) == 1
                    %plot(values_x_G_real,values_y_G_real,'c','Linewidth',2)

viscircles([x_green,y_green],radius_dot,'EdgeColor','y','LineWidth',2)
                end
            end
    end

    % Encircle blue objects that meet the set criteria
    for object_B = 1:length(stats_B)
        bc_B = stats_B(object_B).Centroid;
        ba_B = stats_B(object_B).Area;
        bd_B = (mean([stats_B(object_B).MajorAxisLength
stats_B(object_B).MinorAxisLength],2))/2;
        br_B = (4*pi*(stats_B(object_B).Area))/((stats_B(object_B).Perimeter)^2);
            if ba_B <= 3.0*(((radius_dot/2)^2)*pi) & ba_B >=
0.8*(((radius_dot/2)^2)*pi) && br_B >0.7
                circ_B = viscircles(bc_B,bd_B,'EdgeColor','b','LineWidth',2);
                % points on edge of goal circle
                values_x_B_goal = radius_dot * cos(th) + x_blue;
                values_y_B_goal = radius_dot * sin(th) + y_blue;
                % points within the detected circle
                mask_B_real = ((xgrid-stats_B(object_B).Centroid(1)).^2 + (ygrid-
stats_B(object_B).Centroid(2)).^2) <= (bd_B).^2;
                [values_x_B_real values_y_B_real] = find(mask_B_real==1);
                % in_B = inpolygon(values_y_B_real,length(data(:,1,1))-
values_x_B_real,values_x_B_goal,length(data(:,1,1))-values_y_B_goal);
                in_B =
inpolygon(values_y_B_real,values_x_B_real,values_x_B_goal,values_y_B_goal);
                if all(in_B) == 1
                    %plot(values_x_B_real,values_y_B_real,'c','Linewidth',2)

viscircles([x_blue,y_blue],radius_dot,'EdgeColor','y','LineWidth',2)
                end
            end
    end

  % show big yellow circle around papilla when all detected objects are within the
goal areas
  if all(in_R)==1 & all(in_G)==1 & all(in_B)==1

viscircles([((length(data(1,:,1))/8)*5),((length(data(:,1,1))/8)*3)],radiuss,'EdgeC
olor','y','LineWidth',2)

      open(v);
      frame = getframe(gcf);
      writeVideo(v,frame);
      break

  end
```

```
    hold off

    open(v);
    frame = getframe(gcf);
    writeVideo(v,frame);
end

% Both the loops end here.

if all(in_R)==1 & all(in_G)==1 & all(in_B)==1
    success = 'YES';
else
    success = 'NO';
end

Time = v.Duration; % time until succes
tn = num2str(Time);

close(v);

% Stop the video aquisition.
stop(vid);

% Flush all the image data stored in the memory buffer
flushdata(vid);

clc
% Clear all variables (except..._)
clearvars -except gn dt tn success

% print scoring results on screen
sprintf(' Participant: %s \n Completed successfully: %s \n Time to completion: %s
seconds \n Date: %s',gn,success,tn,dt)

% delete(imaqfind)
```

Appendix E

MATLAB script for exercise 2: catheter directing

```
%% Function for exercise 2 - Training direction the catheter

% For this code, a code found on mathworks was used as a reference:
% https://nl.mathworks.com/matlabcentral/answers/333946-how-to-plot-the-real-time-
data-from-arduino-in-matlab

% Arduino circuit construction:

% blue wire from papilla to breadboard, same row as orange wire (to A0) and
% resistor (gold, red, black, brown). At the other side of the resistor a
% black wire goes to GND

% red wire from papilla to breadboard, same row as orange wire (to A2) and
% resistor (gold, red, black, brown). At the other side of the resistor a
% black wire goes to GND

% green wire from papilla to breadboard, same row as orange wire (to A4) and
% resistor (gold, red, black, brown). At the other side of the resistor a
% black wire goes to GND

clear all
close all
clc

% This is a script that will plot Arduino analogRead values in real time
% Modified from http://billwaa.wordpress.com/2013/07/10/matlab-real-time-serial-
data-logger/
% The code from that site takes data from Serial

% User Defined Properties
a = arduino('/dev/cu.usbmodem14101','Uno')             % define the Arduino
Communication port
plotTitle = 'Arduino Data Log';  % plot title
xLabel = 'Elapsed Time (s)';     % x-axis label
yLabel = 'Voltage (V)';      % y-axis label
legend1 = 'Voltage Sensor 1'
legend2 = 'Voltage Sensor 2'
legend3 = 'Voltage Sensor 3'
yMax  = 10;                          %y Maximum Value
yMin  = 0;                       %y minimum Value
plotGrid = 'on';                 % 'off' to turn off grid
min = 0;                         % set y-min
max = 10;                        % set y-max
delay = .01;                     % make sure sample faster than resolution

% Define Function Variables
time = 0;
Red1 = 0;
Blue1 = 0;
Green1 = 0;
```

```
count = 0;


%Set up Plot
plotGraphRed = plot(time,Red1,'-r' )  % every AnalogRead needs to be on its own
Plotgraph
hold on                            %hold on makes sure all of the channels are
plotted
plotGraphBlue = plot(time,Blue1,'-b')
plotGraphGreen = plot(time, Green1,'-g' )
title(plotTitle,'FontSize',15);
xlabel(xLabel,'FontSize',15);
ylabel(yLabel,'FontSize',15);
legend(legend1,legend2,legend3)
axis([yMin yMax min max]);
grid(plotGrid);
tic

while ishandle(plotGraphRed) %Loop when Plot is Active will run until plot is
closed
         Red2 = readVoltage(a,'A2'); %Data from the arduino
         Blue2 = readVoltage(a,'A0');
         Green2 = readVoltage(a,'A4');
         count = count + 1;
         time(count) = toc;
         Red1(count) = Red2(1);
         Blue1(count) = Blue2(1)
         Green1(count) = Green2(1)
         %This is the magic code
         %Using plot will slow down the sampling time.. At times to over 20
         %seconds per sample!
         set(plotGraphRed,'XData',time,'YData',Red1);
         set(plotGraphBlue,'XData',time,'YData',Blue1);
         set(plotGraphGreen,'XData',time,'YData',Green1);
          axis([0 time(count) min max]);
          %Update the graph
          pause(delay);
end

delete(a);

disp('Plot Closed and arduino object has been deleted');
```

Appendix F

Time schedule of experiment (Dutch)

Tijd per game is later aangepast naar 5 min i.p.v. 8 min.

Tijdsplanning ERCP training test AMC						
van tevoren moeten de slides over wat ERCP is en hoe de scope werkt etc. doorgenomen worden (5min)						
het is niet de bedoeling dat observer 1 of observer 2 helpen tijdens de oefeningen, de trainees moeten het zelf doen met de gegeven instructies van de powerpoint						
17:30 - 17:40	inloop, uitleg, vragen, etc		*voor alle trainees in 1 kamer*			
17:40 - 17:45	klaarzetten					
		Kamer 1 (observer 1)			Kamer 2 (observer 2)	
		Groep 1 (trainee 1A, 1B, 1C)			Groep 2 (trainee 2A, 2B, 2C)	
17:45 - 17:58	13 min	oefening 1	1A		oefening 1	2A
17:58 - 18:01	3 min	wissel			wissel	
18:01 - 18:06	5 min	instructies			instructies	
18:06 - 18:14	8 min	oefening 1	1B		oefening 1	2B
18:14 - 18:17	3 min	wissel			wissel	
18:17 - 18:22	5 min	instructies			instructies	
18:22 - 18:30	8 min	oefening 1	1C		oefening 1	2C
18:30 - 18:33	3 min	wissel			wissel	
18:33 - 18:41	8 min	oefening 2	1A		oefening 2	2A
18:41 - 18:44	3 min	wissel			wissel	
18:44 - 19:52	8 min	oefening 2	1B		oefening 2	2B
18:52 - 18:55	3 min	wissel			wissel	
18:55 - 19:03	8 min	oefening 2	1C		oefening 2	2C
19:03 - 19:06	3 min	wissel			wissel	
19:06 - 19:14	8 min	oefening 3	1A		oefening 3	2A
19:14 - 19:17	3 min	wissel			wissel	
19:17 - 19:25	8 min	oefening 3	1B		oefening 3	2B
19:25 - 19:28	3 min	wissel			wissel	
19:28 - 19:36	8 min	oefening 3	1C		oefening 3	2C
19:36 - 19:39	3 min	wissel			wissel	
Hierna wisselen de kamers (of niet) en observer 1 en observer 2 ook mogelijk, zodat de expert niet weet welke groep/kamer welke vorm van training heeft gehad						
Laatste deel:						
		Kamer 1				
Kamer 1 of 2		Groep 1		Expert		
19:39 - 19:47	8 min	oefening 4	1A	19:43 - 19:47		
19:47 - 19:51	4 min	wissel				
19:51 - 19:59	8 min	oefening 4	1B	19:55 - 19:59		
19:59 - 20:03	4 min	wissel				
20:03 - 20:11	8 min	oefening 4	1C	20:07 - 20:11		
		Kamer 2				
Kamer 1 of 2		Groep 2		Expert		
19:44 - 19:52	8 min	oefening 4	2A	19:48 -19:52		
19:52 - 19:56	4 min	wissel				
19:56 - 20:04	8 min	oefening 4	2B	20:00 - 20:04		
20:04 - 20:08	4 min	wissel				
20:08 - 20:16	8 min	oefening 4	2C	20:12 - 20:16		
Schema Expert:						
19:43 - 19:47	kamer 1					
19:48 -19:52	kamer 2					
19:55 - 19:59	kamer 1					
20:00 - 20:04	kamer 2					
20:07 - 20:11	kamer 1					
20:12 - 20:16	kamer 2					

Tijdsplanning ERCP training test AMC						
van tevoren moeten de slides over wat ERCP is en hoe de scope werkt etc. doorgenomen worden (5min)						

het is niet de bedoeling dat Observer 1 of Observer 2 helpen tijdens de oefeningen, de trainees moeten het zelf doen met de gegeven instructies van de powerpoint						
17:30 - 17:40	inloop, uitleg, vragen, etc		*voor alle trainees in 1 kamer*			
17:40 - 17:45	klaarzetten					
		Kamer 1 (Observer 1)			Kamer 2 (Observer 2)	
		Groep 2 (trainee 1A, 1B, 1C)			Groep 2 (trainee 2A, 2B, 2C)	
17:45 - 17:58	13 min	oefening 1	1A		oefening 1	2A
17:58 - 18:01	3 min	wissel			wissel	
18:01 - 18:06	5 min	instructies			instructies	
18:06 - 18:14	8 min	oefening 1	1B		oefening 1	2B
18:14 - 18:17	3 min	wissel			wissel	
18:17 - 18:22	5 min	instructies			instructies	
18:22 - 18:30	8 min	oefening 1	1C		oefening 1	2C
18:30 - 18:33	3 min	wissel			wissel	
18:33 - 18:41	8 min	oefening 2	1A		oefening 2	2A
18:41 - 18:44	3 min	wissel			wissel	
18:44 - 19:52	8 min	oefening 2	1B		oefening 2	2B
18:52 - 18:55	3 min	wissel			wissel	
18:55 - 19:03	8 min	oefening 2	1C		oefening 2	2C
19:03 - 19:06	3 min	wissel			wissel	
19:06 - 19:14	8 min	oefening 3	1A		oefening 3	2A
19:14 - 19:17	3 min	wissel			wissel	
19:17 - 19:25	8 min	oefening 3	1B		oefening 3	2B
19:25 - 19:28	3 min	wissel			wissel	
19:28 - 19:36	8 min	oefening 3	1C		oefening 3	2C
19:36 - 19:39	3 min	wissel			wissel	
Laatste deel:						
		Observer 1				
Kamer 1		Groep 1		expert		
19:39 - 19:47	8 min	oefening 4	2A	19:43 - 19:47		
19:47 - 19:51	4 min	wissel				
19:51 - 19:59	8 min	oefening 4	2B	19:55 - 19:59		
19:59 - 20:03	4 min	wissel				
20:03 - 20:11	8 min	oefening 4	2C	20:07 - 20:11		
		Observer 2				
Kamer 2		Groep 2		expert		
19:44 - 19:52	8 min	oefening 4	2A	19:48 -19:52		
19:52 - 19:56	4 min	wissel				
19:56 - 20:04	8 min	oefening 4	2B	20:00 - 20:04		
20:04 - 20:08	4 min	wissel				
20:08 - 20:16	8 min	oefening 4	2C	20:12 - 20:16		
Schema expert:						
19:43 - 19:47	kamer 1					
19:48 -19:52	kamer 2					
19:55 - 19:59	kamer 1					
20:00 - 20:04	kamer 2					
20:07 - 20:11	kamer 1					
20:12 - 20:16	kamer 2					

Appendix G

Detailed report of the experiment

Exercise time : 5 minutes	
Papilla orientation : South	
Performance:	10 - 1.5*TP - 4*PD
Mean Technique:	2 * (TS + TM + HI) / 3
Grade 1 =	Mean Performance
Grade 2 =	Grade for mean time
Grade 3 =	Mean Technique

Group 1	1B					
Year : 5	*Finish time*	*Time*	*BD cannulation*	*PD cannulation (PD)*	*Touch papilla (TP)*	*Performance*
Attempt 1	01:08	01:08	yes	0	0	10
Attempt 2	01:56	00:48	yes	0	0	10
Attempt 3	02:53	00:57	yes	0	3	5,5
Attempt 4	03:44	00:51	yes	0	2	7
Attempt 5	04:24	00:40	yes	0	0	10
Attempt 6	04:59	00:35	yes	0	1	8,5
	Mean time	00:49			**Mean performance**	8,5
technique						
Tissue Sensitivity (TS)	3					
Time and Movement (TM)	2					
Handling the Instrument (HI)	2					
Mean technique	4,7					
Grade 1	8,5					
Grade 2	7,1					
Grade 3	4,7					
MEAN GRADE	**6,75**					

Group 1	1C					
Year : 5	*Finish time*	*Time*	*BD cannulation*	*PD cannulation (PD)*	*Touch papilla (TP)*	*Performance*
Attempt 1	02:20	02:20	yes	0	4	4
Attempt 2	03:10	00:50	yes	0	1	8,5
Attempt 3	03:49	00:39	yes	1	1	4,5
Attempt 4	05:00	01:11	NO	0	3	5,5
	Mean time	01:16			**Mean performance**	5,666666667
technique						
Tissue Sensitivity (TS)	2					
Time and Movement (TM)	2					
Handling the Instrument (HI)	2					
Mean technique	4					
Grade 1	5,7					
Grade 2	5,1					
Grade 3	4					
MEAN GRADE	**4,91**					

Group 1	1A					
Year : 5	*Finish time*	*Time*	*BD cannulation*	*PD cannulation (PD)*	*Touch papilla (TP)*	*Performance*
Attempt 1	01:10	01:10	yes	0	0	10
Attempt 2	02:19	01:09	yes	1	2	3
Attempt 3	02:56	00:37	yes	0	0	10
Attempt 4	03:32	00:36	yes	0	1	8,5
Attempt 5	04:05	00:33	yes	0	0	10
Attempt 6	05:00	00:55	NO	0	0	10
	Mean time	00:49			**Mean performance**	8,3
technique						
Tissue Sensitivity (TS)	3					
Time and Movement (TM)	2					
Handling the Instrument (HI)	2					
Mean technique	4,7					
Grade 1	8,3					
Grade 2	7,1					
Grade 3	4,7					
MEAN GRADE	**6,68**					
MEAN GROUP 1	**6,11**					
zonder 1A	**5,83**					

Group 2	2A					
Year : 4	*Finish time*	*Time*	*BD cannulation*	*PD cannulation (PD)*	*Touch papilla (TP)*	*Performance*
Attempt 1	01:08	01:08	yes	0	2	7

Attempt 2	02:20	01:12	yes	0	1	8,5
Attempt 3	03:45	01:25	yes	0	1	8,5
Attempt 4	05:00	01:15	NO	0	2	7
	Mean time	01:15			**Mean performance**	8
technique						
Tissue Sensitivity (TS)	2					
Time and Movement (TM)	2					
Handling the Instrument (HI)	2					
Mean technique	4					
Grade 1	8,0					
Grade 2	5,1					
Grade 3	4					
MEAN GRADE	**5,71**					

Group 2	2B					
Year : 5	*Finish time*	*Time*	*BD cannulation*	*PD cannulation (PD)*	*Touch papilla (TP)*	*Performance*
Attempt 1	01:58	01:58	ja	0	1	8,5
Attempt 2	03:57	01:59	ja	0	2	7
Attempt 3	05:00	01:03	Nee	0	1	8,5
	Mean time	01:58			**Mean performance**	7,75
technique						
Tissue Sensitivity (TS)	2					
Time and Movement (TM)	2					
Handling the Instrument (HI)	2					
Mean technique	4					
Grade 1	7,8					
Grade 2	1,9					
Grade 3	4,0					
MEAN GRADE	**4,55**					

Group 2	2C					
Year : 5	*Finish time*	*Time*	*BD cannulation*	*PD cannulation (PD)*	*Touch papilla (TP)*	*Performance*
Attempt 1	01:28	01:28	ja	0	2	7
Attempt 2	02:46	01:18	ja	0	0	10
Attempt 3	03:49	01:03	ja	0	1	8,5
Attempt 4	04:48	00:59	ja	0	0	10
Attempt 5	05:00	00:12	NEE	0	1	8,5
	Mean time	01:12			**Mean performance**	8,875
technique						
Tissue Sensitivity (TS)	3					
Time and Movement (TM)	2					
Handling the Instrument (HI)	3					
Mean technique	5,333333333					
Grade 1	8,9					
Grade 2	5,4					
Grade 3	5,3					
MEAN GRADE	**6,52**					
MEAN GROUP 2	**5,59**					

Appendix H

Concept for the experiment set-up (Dutch)

Benodigde materialen:

- ERCP trainer (Cook model)
- Oefenruimte
- Duodenoscope
- Onbewerkte papillen
- Papillen zonder opening
- Papillen met markers voor detectie en aanraking
- Computer applicatie (door Juliette)
- HD-SDI naar USB converter
- Catheter
- Expert voor beoordeling (Rogier)
- 2 groepen testpersonen: ERCP novices met endoscopie ervaring
- Laptop voor powerpoint presentatie (instructies etc)

Groep 1 is de controle groep
Groep 2 is de groep die gebruik maakt van de applicaties

Ven tevoren voor alle groepen:
Bekijken powerpoint presentatie waarin uitgelegd wordt wat ERCP is en dat cannulation uiteindelijk hetgeen is wat de trainees zullen gaan oefenen. In de presentatie wordt uitgelegd hoe de scope gecontroleerd kan worden en hoe men moet positioneren om de gewenste duct in te komen (10 min ongeveer?). Kan ook door de trainee van tevoren gekeken worden, dan kunnen ze alleen niet meebewegen met de scope.

Doel van de test:
Met behulp van het programmaatje en de instructie slides kan ERCP training mogelijk (tot op een zekere hoogte) zelfstandig worden. Ik wil uitzoeken of het opgestelde programma werkt. Zijn de instructies compleet genoeg of te uitgebreid (feedback van trainee is hiervoor nodig)?. Zorgt training met dit programma ook voor betere resultaten? Dit tweede kan uitgezocht worden door de skills van een groep die met de applicaties (de kleuren tracker en touch sensor) heeft geleerd te vergelijken met een controle groep die dat niet heeft gedaan. Omdat elke soort van ervaring wel iets doet, zal de controle groep dus evenveel scope tijd krijgen om gewoon “random” ervaring om te doen.

Ik twijfel nu nog een beetje of de controle groep doelgericht dezelfde dingen moet oefenen als de applicatie groep maar dan zonder de hulp van de applicaties, of dat ze gewoon random speel tijd krijgen met de scope. De applicatiegroep zal namelijk leren te cannuleren in stappen: eerste positioneren (bijvoorbeeld 10 min), dan richten met de katheter (10 min), dan pas echt cannuleren (10 min). Ze krijgen dan eigenlijk vrij weinig tijd om echt het cannuleren te oefenen. Als de controlegroep 30 minuten lang alleen maar cannuleren gaat oefenen weet ik niet of de uiteindelijke vergelijking van welke groep er meer cannulatie succes heeft nog wel eerlijk is? Uiteindelijk is cannuleren natuurlijk wel het doel dus zou dat beter moeten worden door de training, maar de oefentijd is relatief kort en misschien dus niet lang genoeg om het gefaseerde leertraject tot haar recht te laten komen hoewel het op langer termijn misschien wel beter kan werken.

De andere optie is dus om de controlegroep op een manier vergelijkbaar met de oefeningen van de applicatiegroep ervaring op te laten doen. Ze mogen dan bijvoorbeeld de eerste 10 minuten de catheter nog niet gebruiken en de tweede 10 minuten is het cannuleren van de papil nog niet mogelijk (verstop de opening van de papil). Hoe denk jij hierover rogier? Ik neig naar de tweede optie. Deze optie heb ik hieronder ook omschreven. Dit kan makkelijk omgezet worden naar 30min random oefentijd voor de controlegroep. Ik ben alleen wel bang dat ze dan misschien een beetje verveeld raken omdat er geen variatie in de oefening zit, waardoor de resultaten beïnvloed worden.

Testen

Bij test 1 en 2 wordt dus mogelijk een papil gebruikt waarbij er nog geen opening in zit, dit is om te voorkomen dat cannulatie al geprobeerd wordt. De opening kan simpelweg verstopt worden met een propje.

Test 1

Voor groep 1:
Trainee mag 10 minuten lang oefenen op het besturen van de scope en hand-oog-scherm-coördinatie. De trainee doet hier dus scopie ervaring op door een beetje te pielen. Cannuleren en überhaupt het besturen van de catheter wordt nog niet geoefend.

Voor groep 2:
Trainee mag 10 minuten lang oefenen op het besturen van de scope maar ditmaal helpt de applicatie bij het positioneren voor de papil.

Test 2

Voor groep 1:
Trainee mag 10 minuten lang random oefenen op het besturen van de catheter. Echt proberen te cannuleren is nog niet toegestaan, wel mag de trainee als hij/zij wil mikken op de papil.

Voor groep 2:
Trainee mag 10 minuten lang met behulp van de computer oefenen op het besturen van de catheter en de catheter in de juist richting bewegen. Ook hier kan nog niet gecannuleerd worden, maar wel wordt er geoefend op gericht voortbewegen van de catheter in de richting van de ducts.

Bij test 2 twijfel ik erover of ik bij groep 2 ook de opdracht moet geven om tijdens het sturen van de catheter in positie te blijven voor de papil (ook met behulp van het programma). Is dat op dat moment nog te veel gevraagd voor de trainees of is dat juist goed voor het leren cannuleren?

Test 3

Voor groep 1:
Trainee mag 10 minuten proberen selectief te cannuleren zonder behulp van computer of iets

Voor groep 2:
Trainee mag 10 minuten proberen selectief te cannuleren met behulp van computer die stuurt naar goede positionering voor de papil.

Test 4

Groep 1 & Groep 2 moeten proberen selectief te cannuleren voor 10 minuten en hun performance wordt beoordeeld op de volgende manier:

- Er wordt bijgehouden hoe lang ze erover doen en hoe vaak het lukt door de computer
- Er wordt ook door een expert gekeken hoe goed de cannulatie wordt uitgevoerd. De expert can beoordelen of het succes aan gelukt lag of dat er een goede techniek bij kwam kijken.

Ik twijfel eraan om bij test 4 de oriëntaties van de papil lichtelijk de veranderen, om zo te testen of de trainees de echte techniek wel beheersen of dat het meer een routine is die ze maar voor 1 configuratie kunnen uitvoeren. Maar misschien is dit nog te vroeg?

Later zijn tijden van de games en exercises aangepast naar 5 min.

Appendix I

Assessment form (Dutch)

ERCP training - beoordelingsformulier
Beoordelaar: _____ Datum: _____
A(n)ios: _____Opleidingsjaar: _____

Poging 1

Papil oriëntatie:

Tijd:
BD cannulatie gelukt:
Aantal PD cannulaties:
Aantal aanrakingen papil zonder cannulatie:

Poging 2

Papil oriëntatie:

Tijd:
BD cannulatie gelukt:
Aantal PD cannulaties:
Aantal aanrakingen papil zonder cannulatie:

Poging 3

Papil oriëntatie:

Tijd:
BD cannulatie gelukt:
Aantal PD cannulaties:
Aantal aanrakingen papil zonder cannulatie:

Poging 4

Papil oriëntatie:

Tijd:
BD cannulatie gelukt:
Aantal PD cannulaties:
Aantal aanrakingen papil zonder cannulatie:

Poging 5

Papil oriëntatie:

Tijd:
BD cannulatie gelukt:
Aantal PD cannulaties:
Aantal aanrakingen papil zonder cannulatie:

Poging 6

Papil oriëntatie:

Tijd:
BD cannulatie gelukt:
Aantal PD cannulaties:
Aantal aanrakingen papil zonder cannula

Weefselgevoel

1	2	3	4	5
Gebruikt frequent onnodige kracht of veroorzaakt weefselschade door onjuist gebruik instrumenten		Gaat zorgvuldig om met weefsel, incidenteel weefselschade		Consistente zorgvuldige behandeling weefsel met minimale weefselschade

---

Tijd en beweging

1	2	3	4	5
Frequent onnodige bewegingen		Redelijk efficiënte bewegingen, nog enkele onnodige bewegingen		Economische bewegingen, maximale efficiëntie

---

Hanteren van instrumenten

1	2	3	4	5
Maakt herhaaldelijk onzekere en/of onhandige bewegingen		Kundig gebruik van instrumenten, komt af en toe stijf of onhandig over		Vloeiende bewegingen, kundig

---